Blood Gas Systems

OPTI® CCA-TS2 Analyzer

Operator's Manual

OPTIMedical

OPERATOR'S MANUAL REVISION LOG

(Please record any changes made to this manual)

Revision	Release Date	Approved by	Description
A	March 2013		per PCR120183
B	July 2013		per PCR130109
C	August 2013		per PCR130137
D	May 2016		CO1745
E	March 2017		CO1838
F	02APR18		CO2129
G	16JUL18		CO2397
H	23MAR21		CO2955
I	TBD		CO3843

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CE

Rx ONLY

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PD7301 REV I

Important Information! Important Information!

This Operator´s Manual contains important warnings and safety information to be observed by the user.

This instrument is only intended for one area of application which is described in the instructions. The most important prerequisites for application, operation and safety are explained to ensure smooth operation. No warranty or liability claims will be covered if the instrument is applied in areas other than those described or if the necessary prerequisites and safety measures are not observed.

The instrument is only to be operated by qualified personnel capable of observing these prerequisites.

Only accessories and supplies either delivered by or approved by OPTI Medical Systems are to be used with the instrument.

Due to this instrument's operating principle, analytical accuracy not only depends on correct operation and function, but also upon a variety of external influences beyond the manufacturer's control. Therefore, the test results from this instrument must be carefully examined by an expert, before further measures are taken based on the analytical results.

Treatment should never be administered based on results that are flagged on the printout.

Instrument adjustment and maintenance with removed covers and connected power mains are to be performed only by a qualified technician who is aware of the dangers involved.

Instrument repairs are to be performed only by the manufacturer or qualified service personnel.

Important Information! Important Information!

Operating Safety Information

- Overvoltage Category II when connected to a branch circuit.
- This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules.

Caution:

- The instrument is designed as a conventional device (closed, not waterproof type).
- Do not operate the instrument in an explosive environment or in the vicinity of explosive anesthetic mixtures containing oxygen or nitrous oxide.
- This instrument is suitable for continuous operation.
- The power plug is to be plugged into a ground socket only. When using an extension cord, make sure that it is of the proper size and is properly grounded.
- Mains supply cord should meet the following minimum standards: grounded 3 prong, shielded, 18 AWG, 300V.
- Any breakage of the ground lead inside or outside the instrument or a loose ground connection can cause a hazardous condition when operating the instrument. Intentional disconnection of the grounding is not permitted.
- When replacing the fuses, make sure that they are of the same type and rating as the original fuses. Never use repaired fuses or short-circuit the fuse holders.

This device is a Class 1 Laser product according to the requirements of IEC 60825-1.
The LEDs have been certified as an EXEMPT RISK GROUP in compliance with IEC 62471.

The maximum energy output is as follows:

670 nm (LED): 40 Microwatts max. for 400ms
780 nm (Laser): 40 Microwatts max. for 400ms
850 nm (Laser): 40 Microwatts max. for 400ms

Caution: Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.

Conditions of Acceptability:

Coin cell battery on main board:

- Overcharging, short circuiting, reverse charging, mutilation or incineration of the cells must be avoided to prevent one or more of the following occurrences: release of toxic materials, release of hydrogen and/or oxygen gas, rise in surface temperature.
- If a cell has leaked or vented, it should be replaced immediately using protective gloves.
- If and when necessary, these cells must be replaced with identical new ones from the same manufacturer. If a cell to be replaced is connected with other cells in series, it is recommended that the other cells be replaced with new ones at the same time.
- Reverse polarity installation of the cell in the end product must be avoided.

Operating Safety Information

Operating Safety Information

Recommendations for Usage and Storage of Lithium Ion Battery Pack:

a) Do not dismantle, open or shred secondary cells or batteries.

b) Do not expose cells or batteries to heat or fire. Avoid storage in direct sunlight.

c) Do not short-circuit a cell or a battery. Do not store cells or batteries haphazardly in a box or drawer where they may short-circuit each other or be short-circuited by other metal objects.

d) Do not remove a cell or battery from its original packaging until required for use.

e) Do not subject cells or batteries to mechanical shock.

f) In the event of cell leaking, do not allow the liquid to come in contact with skin or eyes. If contact has been made, wash the affected area with copious amounts of water and seek medical advice.

g) Do not use any charger other than that specifically provided for use with the equipment.

h) Observe the plus (+) and minus (-) marks on the cell, battery and equipment and ensure correct use.

i) Do not use any cell or battery which is not designed for use with the equipment.

j) Do not mix cells of different manufacture, capacity, size or type within a device.

k) Keep cells and batteries out of reach of children.

l) Seek medical advice immediately if a cell or a battery has been swallowed.

m) Always purchase the correct cell or battery for the equipment.

n) Keep cells and batteries clean and dry.

o) Wipe the cell or battery terminals with a clean dry cloth if they become dirty.

p) Secondary cells and batteries need to be charged before use. Always use the correct charger and refer to the manufacturer's instructions or equipment manual for proper charging instructions.

q) Do not leave a battery on prolonged charge when not in use.

r) After extended periods of storage, it may be necessary to charge and discharge the cells or batteries several times to obtain maximum performance.

s) Secondary cells and batteries give their best performance when they are operated at normal room temperature (20 °C ± 5 °C).

t) Retain the original product literature for future reference.

u) Use cell and battery only in the application for which it was intended.

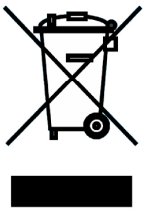
v) When possible, remove the battery from the equipment when not in use.

w) Dispose of cells and batteries properly.

Operating Safety Information

Symbol Definitions

The symbols described below are used on the packaging of OPTI® CCA-TS2 related products.

Symbol	Explanation
	Attention Symbol – Refer to the Operator's Manual or Service Manual for further instructions. This symbol is located on the inside of the instruments and product packaging.
EXP 	Expiration / Use By Symbol – Product to be used by the expiration date indicated to the right of this symbol. This symbol is located on all consumables, which are controlled via an expiration or use by date.
LOT	Batch Code Symbol – Manufacturing lot number is located to the right of this symbol. This symbol is located on all products, which are controlled via a lot number.
	Do Not Re-use Symbol – Identifies products which are <u>not</u> to be used for more than the specified period of time as defined in the product instructions. This symbol is located on all applicable product packaging.
	Recycle Plastic Symbol - Identifies the clear plastic material (polyethylene terephthalate glycol) used in the packaging of the product. Containers identified with this symbol can be considered recyclable. This symbol is located on all applicable product packaging.
	WEEE-Symbol - This product complies with WEEE Directive 2002/96/EC which mandates the treatment, recovery and recycling of electric and electronic equipment.

Symbol	Explanation
	Biohazard Symbol – Products and/or components containing this symbol should be handled as biohazardous material after use.
	Temperature Limit Symbol – Products and/or components which contain this symbol must be stored within the specified temperature range.
IVD	For in-vitro diagnostic use
CE	This product fulfills the requirements of Directive 98/79/EC on in-vitro diagnostic medical devices.
REF	Catalog number
	Please read pack insert. / Follow the instrument's instructions for use!
	Manufactured by
EC REP	Authorized European Community Representative
Rx ONLY	Prescription use only

PREFACE

Welcome

Your OPTI® CCA-TS2 Analyzer is a powerful tool designed to help you quickly, accurately and efficiently conduct basic testing of pH, carbon dioxide partial pressure (PCO_2), oxygen partial pressure (PO_2), sodium (Na^+), potassium (K^+), ionized calcium (Ca^{++}), chloride (Cl^-), glucose (Glu), blood urea nitrogen (BUN), lactate (Lac), total hemoglobin concentration (tHb) and hemoglobin oxygen saturation (SO_2), depending on the cassette configuration, in the convenience of your own laboratory.

This manual will help guide you through setting up your analyzer and will help you start analyzing samples. As you become familiar with the operation of the unit, you should use the manual as a reference for day-to-day routines and as a guide for maintenance and troubleshooting.

How to use this manual

If you have an analyzer that is not yet set up, you should begin by reading Chapters 1 and 2.
For programming and quality control functions, read Chapters 3 and 4.
Information on analyzer operation and data management is contained in Chapters 5 and 6.
Detailed maintenance and service information can be found in Chapters 7 and 8.
Operating principles are described in Chapter 9.

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1 INTRODUCTION

1.1 Intended Use

The OPTI® CCA-TS2 Critical Care Analyzer is intended to be used for the measurement of pH, carbon dioxide partial pressure (PCO_2), oxygen partial pressure (PO_2), sodium (Na^+), potassium (K^+), ionized calcium (Ca^{++}), chloride (Cl^-), glucose (Glu), blood urea nitrogen (BUN/urea), lactate (Lac), total hemoglobin concentration (tHb) and hemoglobin oxygen saturation (SO_2) in samples of whole blood, and pH, sodium, potassium, ionized calcium, chloride, glucose and BUN (urea) in serum and plasma, in either a traditional blood gas, clinical laboratory setting or point-of-care locations by personnel minimally qualified to perform and report these results.
The table below provides important information regarding supported sample types, available reporting units and analyzer measurement ranges for each parameter.

For customers located in the United States, the B-Lac cassette (BP7561) has not yet been cleared for Point of Care (POC) use in the United States.

	Sample Type			Available Units		Measurement Range	Display Resolution
Parameter	**Whole blood**	**Plasma**	**Serum**	**Default**	**Other**	**Default Units**	**Lo/Hi**
pH	x	x	x	pH units		6.6 - 7.8	0.01/0.001
PCO_2	x			mmHg	kPa	10 - 200	1/0.1
PO_2	x			mmHg	kPa	10 - 700	1/0.1
Na^+	x	x	x	mmol/L		100 - 180	1/0.1
K^+	x	x	x	mmol/L		0.8 - 9.99	0.1/0.01
Ca^{++}	x	x	x	mmol/L	mg/dL	0.2 - 3.0	0.01
Cl^-	x	x	x	mmol/L		50 - 160	1/0.1
Glu	x	x	x	mg/dL	mmol/L	30 - 400 / 1.7 - 22.2	0.1
BUN/urea	x	x	x	mg/dL	mmol/L	2.8 - 112.0 / 1 - 40	0.1/0.01
tHb	x			g/dL	mmol/L, g/L	5 - 25 / 3.1 - 15.5	0.1
SO_2	x			%		60 - 100	1/0.1

B-Lac Cassette

	Available Units		Range of Indication*	Measurement Range	Display Resolution
Parameter	**Default**	**Other**	**Default/Other Units**	**Default/Other Units**	**Lo/Hi**
pH	pH units		6.6 - 7.8	6.818 - 7.8	0.01/0.001
PCO_2	mmHg	kPa	10 - 200	10 - 200 / 1.33 - 26.66	1/0.1
PO_2	mmHg	kPa	10 - 700	10 - 700 / 1.33 - 93.31	1/0.1
Lactate	mmol/L	g/dL	0.4 - 17.5 / 3.6 - 157.7	0.4 - 17.5 / 3.6 - 157.7	0.1/0.01
tHb	g/dL	mmol/L	5 - 25 / 3.1 - 15.5	5 - 24 / 3.1 - 14.9	0.1
SO_2	%		60 - 100	60 - 100	1/0.1

* The Range of Indication is the range the analyzer is capable of measuring and may include values outside the Measurement Range. The performance of the analyzer outside the Measurement Range specified in the table has not been validated. Only results within the Measurement Range should be reported.

1.2 Principles of Operation

The OPTI CCA-TS2 is a microprocessor-controlled medical instrument measuring optical fluorescence from discrete sensors called optical electrodes (optodes).

A disposable, single-use cassette contains all of the elements needed for calibration, sample measurement and waste containment. Specific calibration information from the cassette is scanned into the analyzer by holding the cassette package in front of the bar code scanner. The cassette is then placed into the measurement chamber.

The analyzer warms the cassette to 37.0 ± 0.1 °C (98.6 ± 0.1 °F), and performs a calibration verification on the sensors for PCO_2 and PO_2 by passing a precision calibration gas mixture across the optode sensors. The pH and electrolyte channels are calibrated with precision buffer solution contained in the cassette. The tHb and SO_2 channels are factory-calibrated.

When calibration is verified, the analyzer aspirates the blood sample into the cassette and across the optode sensors. Fluorescence emission is then measured after equilibrating with the blood sample. After a single measurement, the cassette, containing the blood sample, is removed from the analyzer and discarded. The analyzer contains no reagents, blood or waste.

1.3 Contents

Before you begin installing your OPTI CCA-TS2 Analyzer, take a moment to look over the contents to ensure you have the following:

- Power supply with power cord
- Battery (Optional)
- 1 Multi-level Standard Reference Cassette (SRC) (Levels 1, 2 and 3)
- Thermal printer paper
- tHB calibration cassette

You will also need the following consumables prior to setup:

- OPTI sensor cassettes
- Gas bottle
- Quality Control Material - OPTI CHECK or OPTI CHECK PLUS (with glucose or BUN cassettes)

1.4 Analyzer Components

Before setting up the OPTI CCA-TS2 Analyzer, it is important to familiarize yourself with the analyzer's components:

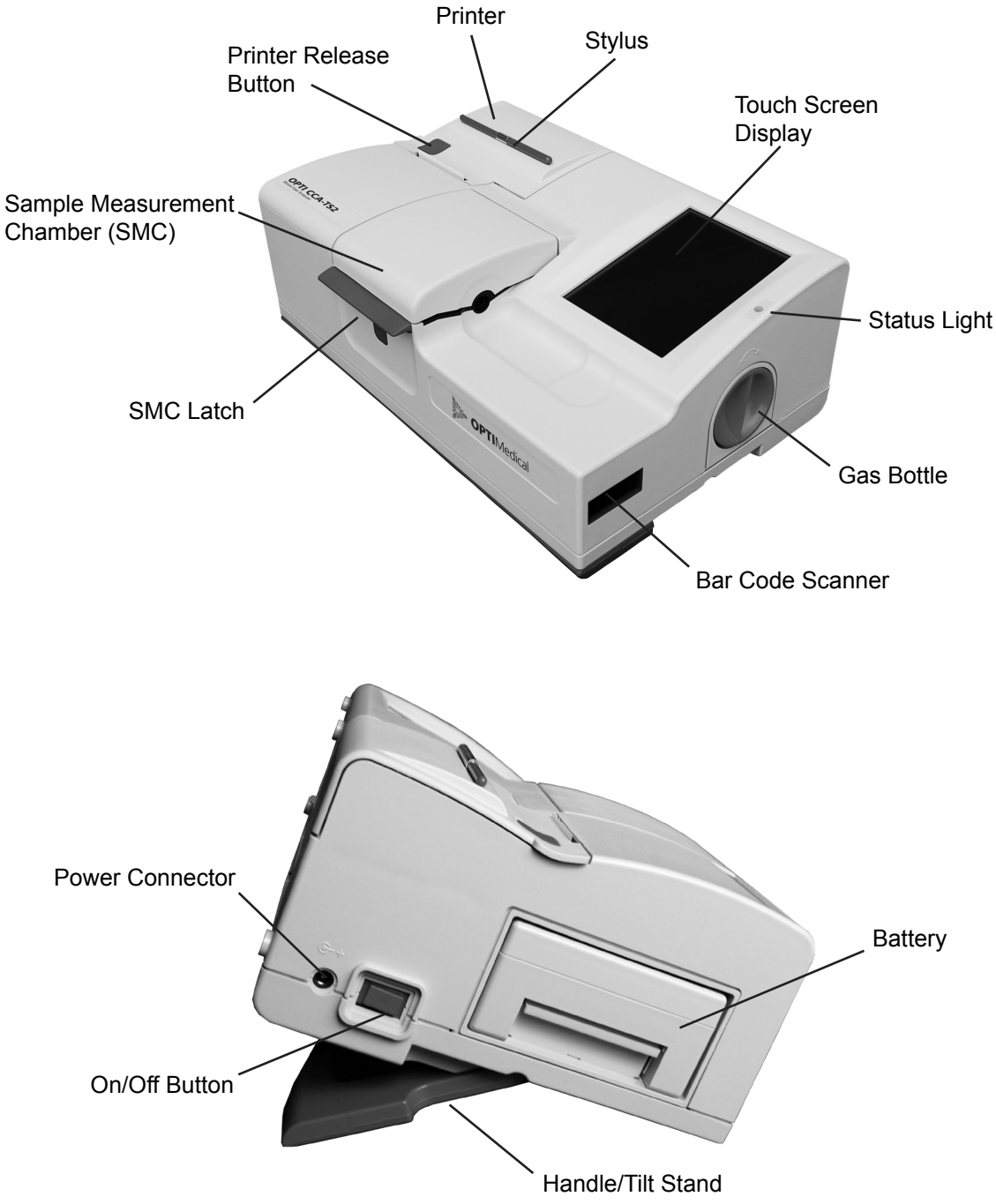


Fig. 1-1 OPTI CCA-TS2 Major Components

Touch Screen

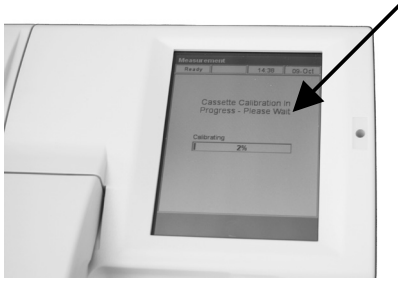


Fig. 1-2 Touch Screen

The analyzer activities are communicated to you through a backlit **Touch screen** (Fig. 1-2), displaying the activities of the analyzer, sample results and other relevant information.

You communicate with the analyzer through a graphical user interface which is used to perform all analyzer functions.

Status Light

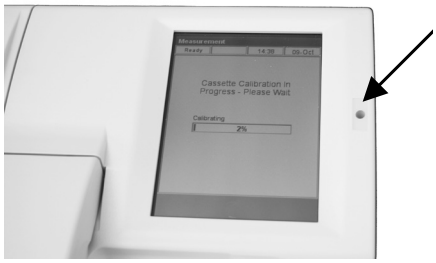


Fig. 1-3 Status Light

To the right of the display is a two-color **status light** (Fig. 1-3). During operation you will see one of the following:

- **Green Light**: The system is running a measurement and waiting for user action.
- **Blinking Green Light**: System is in process of calibration or measurement. Do not open the cover.
- **Red Light**: A red status light indicates an error that will terminate the process.
- **Blinking Red Light**: System has encountered a problem and needs operator interaction before it will proceed.

Sample Measurement Chamber (SMC)

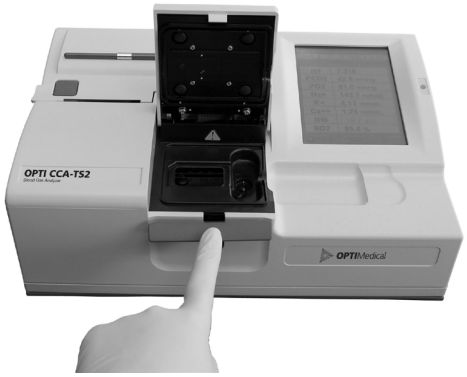


Fig. 1-4 Open SMC Cover

Inside the top of the unit is the **Sample Measurement Chamber** (SMC) for the OPTI Cassette. To open the cover, press down on the red SMC latch, and the cover will pop up (Fig. 1-4).

Several LEDs and two infrared lasers are located inside the sample measuring chamber.

Bar Code Scanner

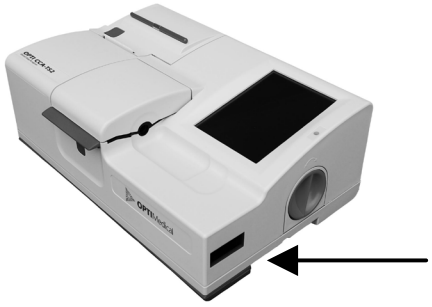


Fig. 1-5 Bar Code Scanner

The **bar code scanner** on the right side of the instrument reads lot, expiration information, and QC ranges if applicable from cassettes, controls, SRCs and gas bottles, as well as user-input bar codes for operator and patient IDs (Fig. 1-5).

Thermal Printer

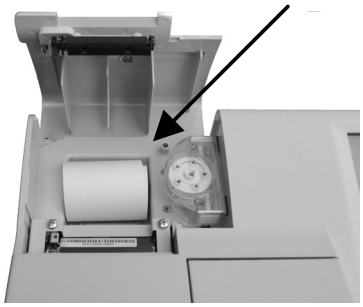


Fig. 1-6 Thermal Printer

The **thermal printer** is accessed by pressing the red printer release button on the door (Fig. 1-6).
The printer uses heat-sensitive paper to print measured values, quality control values, calibration values, as well as patient and diagnostic information.

Peristaltic Pump

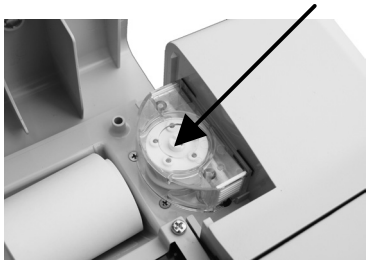


Fig. 1-7 Peristaltic Pump

Contained within the same compartment is a **peristaltic pump** cartridge which is used to transport liquids and gases (Fig. 1-7).
All liquids are contained within the OPTI Cassette and do not enter the instrument.

NOTE: The peristaltic pump cartridge is a replaceable item (See Maintenance Section 7.4.1).

Model and Serial Numbers

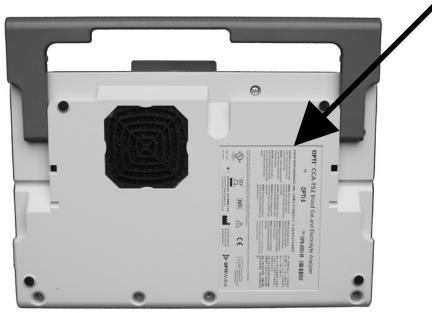


Fig. 1-8 Model and Serial Numbers

The **model and serial number** identifiers are located on an identification plate on the bottom panel of the unit (Fig. 1-8).

Back of Analyzer

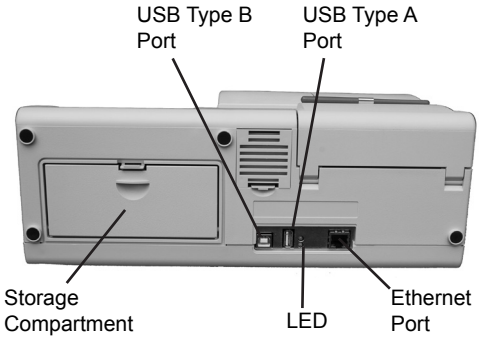


Fig. 1-9 Back of the OPTI CCA-TS2

On the rear of the unit is (Fig. 1-9):

- An **Ethernet port** for exporting data and connecting to a network.
- An **LED** which indicates the charging status of the battery.
- A **USB Type A port** to quickly load software and import/export data using a standard USB mass storage device.
- A **USB Type B port** for exporting serial data to a computer.
- A **storage compartment** that can hold an extra paper roll, the SRC, other supplies or accessories (Fig. 1-9).

Battery Pack (Optional)

Fig. 1-10 Battery Pack

On the left side of the unit is the rechargeable **battery pack**. It is removed by squeezing the handle and sliding it out (Fig. 1-10). The battery allows you to operate the OPTI CCA-TS2 without having to plug the unit into an electrical outlet.
The battery is charged automatically whenever the analyzer's external power supply is plugged into an electrical outlet.

Power Connector and Power Button

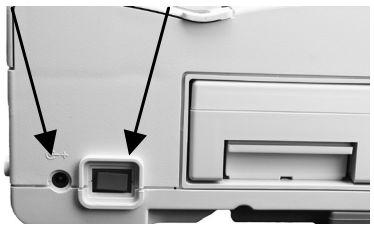


Fig. 1-11 Power Connector and Power Button

Next to the battery pack is the **power connector** where you can connect the OPTI CCA-TS2 to an external power supply (Fig. 1-11).
The **power button** is located on the left side of the unit next to the power connector (Fig. 1-11).

NOTE: To power down the system, hold the power button in for 2 seconds.

Carrying Handle

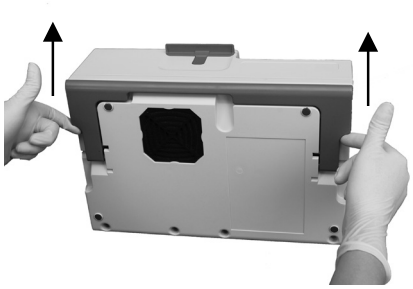


Fig. 1-12 Carrying Handle

The OPTI CCA-TS2 is equipped with a carrying handle for easy transport, which can also be used as a tilt stand to place the instrument at a convenient viewing angle for the user.

- To extend the handle to carrying position, place the analyzer on its back and position your fingers in the cutouts on each side of the handle. Push up until the handle is fully extended (Fig. 1-12).
- To use the handle as a tilt stand, pull down the handle (Fig. 1-13) and lock it in the lower position (Fig. 1-14). Turn analyzer back to original position (Fig. 1-15).

Fig. 1-13 Pull down handle

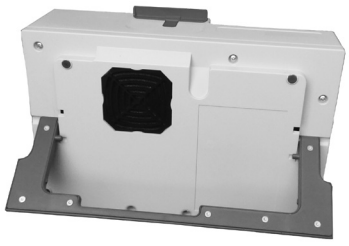


Fig. 1-14 Tilt stand

Fig. 1-15 Tilt stand

1.5 Consumables

OPTI Sensor Cassette

Fig. 1-16 OPTI Sensor Cassette

The self-contained **OPTI Sensor Cassette** has an integral valve with a reservoir. The valve seals away the sample after measurement, allowing safe, clean sample disposal (Fig. 1-16).

Sample Fillport and Syringe Adapter

Fig. 1-17 Sample Fillport and Syringe Adapter

The **sample fillport** is contained in the OPTI Cassette and projects from the chamber for easy, automatic sampling. It includes a removable syringe adapter for sampling with a syringe.
For sampling with a capillary, simply remove the adapter (Fig. 1-17).

NOTE: The syringe adapter may be removed while the cassette is inside the SMC.

NOTE: ***DO NOT INJECT*** *the sample. It will be aspirated automatically.*

Sample Aspiration Tube (E-Lyte CCA Cassette)

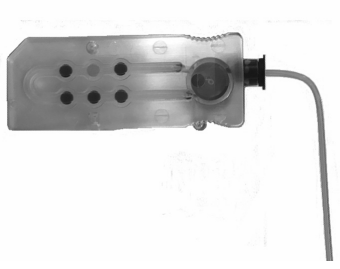


Fig. 1-18 Sample Aspiration Tube

The **sample aspiration tube** (Fig. 1-18) is to be used to aspirate a patient sample from a sample tube on the E-Lyte CCA cassette.

NOTE: When the sample aspiration tube is used for a whole blood sample, electrolyte and pH results will be available, but there will be no pCO_2 derived results.

Standard Reference Cassette (SRC)

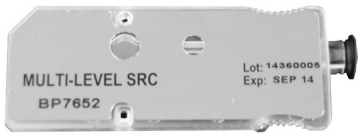


Fig. 1-19 Standard Reference Cassette

The **Standard Reference Cassette (SRC)** (Fig. 1-19) is a reusable sensor cassette used for daily quality control testing. The multi-level SRC can be found in the storage compartment of your analyzer. Each new analyzer comes with one multi-level SRC that can test at 3 levels. The SRC should be kept in its pouch when not in use (see section 4.5.1 for instructions).

tHb Calibration Cassette

Fig. 1-20 tHb Calibration Cassette

The reusable **tHb Calibration Cassette** (Fig. 1-20) is used for the quarterly calibration of the OPTI CCA-TS2 Analyzer (See Section **7.3 Quarterly Maintenance - Performing tHb Calibration**).

Gas Bottle

Fig. 1-21 Gas Bottle

During calibration, the OPTI CCA-TS2 uses a **precision gas** which is completely self-contained in a disposable low-pressure bottle. The bottle is inserted on the right side of the unit after scanning the bar code (Fig. 1-21).
The TS2 will only work with gas bottles with a red base (BP7162).

Congratulations!

You have just learned the basic components of the analyzer and are now ready to install your system.

2 SETUP

2.1 Important Safety Instructions

Before you begin installing your OPTI® CCA-TS2 Analyzer, carefully read the overview information in this chapter.

For your own safety and the proper operation of your equipment, always follow these precautions when working with your OPTI CCA-TS2:

- Keep the analyzer away from all sources of liquids such as sinks and wash basins.
- Keep the analyzer away from explosive gases or vapors.
- Always handle blood samples and collection devices with care.
- Use approved protective gloves to avoid direct contact with sample.
- Dispose of OPTI Cassette according to local regulations.

2.2 Choosing a Location

Location is important for trouble-free operation of your analyzer. Before you begin setup, choose a site that is convenient for your sampling needs and meets the following physical requirements of the unit:

- Grounded electrical outlet.
- Away from direct sunlight.
- Room temperature within 10 - 30° C (50 - 86° F).
- Relative humidity of 5% - 95% (non-condensing).
- Ample room to allow air to circulate around the unit.
- Away from strong electromagnetic fields, such as those created by electric motors and X-ray equipment.
- Away from explosive gases or vapors.
- Placed on flat surface with ample room between air vents on bottom of unit and surface to prevent unit overheating.

NOTE: Above requirements also apply when the OPTI CCA-TS2 operates on battery power outside a laboratory setting.

2.3 Setting up the OPTI CCA-TS2 Analyzer

You are now ready to prepare your OPTI CCA-TS2 Analyzer for operation.

Begin by placing the analyzer on a secure table top that allows plenty of working space and is convenient to a power connection.

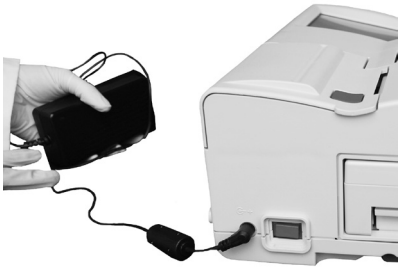


Fig. 2-1 Power Cord Connection

1. Plug in the Power Supply

- Plug the power supply into the receptacle on the left side of the unit (Fig. 2-1).
- Plug the power cord into the power supply.
- Plug the cord into a grounded electrical outlet.

NOTE: To protect your OPTI CCA-TS2 and other electronic devices from damage caused by electrical power spikes, OPTI Medical recommends the use of a surge protector.

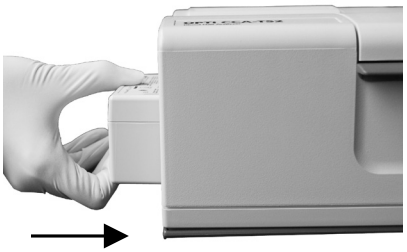


Fig. 2-2 Insert Battery Pack

2. Install the Battery Pack in its Housing

- Push the battery pack into the opening on the left hand side of the OPTI CCA-TS2 (Fig. 2-2).

NOTE: The battery will need to be charged for at least 2.5 hours prior to using the OPTI CCA-TS2 on battery power. It will be charged automatically whenever the analyzer's external power supply is plugged into an electrical outlet.

The lower LED on the back of the analyzer turns green while the battery is being charged.
The top LED turns green when charging is complete.

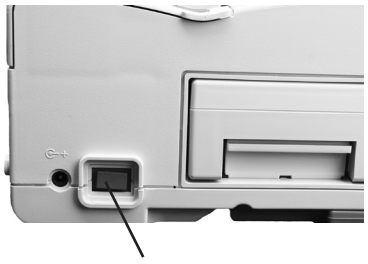


Fig. 2-3 Power Button

3. Turn on the Power

- Locate the power button on the left side of the unit and push down to turn the power on (Fig. 2-3).

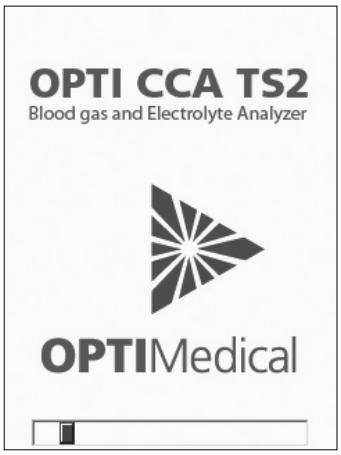


Fig. 2-4 Startup screen

- This is the first screen that will appear after the power is turned on (Fig. 2-4).

Fig. 2-5 Select New Gas Bottle

Fig. 2-6 Scan Barcode

4. Installing a New Gas Bottle

This screen will appear after initial power-up sequence, when no gas bottle is present (Fig. 2-5).

- Press **<New Gas Bottle>**.
- Open the gas bottle by unscrewing the cap.
- When prompted (Fig. 2-6), scan the new gas bottle bar code on the insert sheet by holding it 2-3 inches (5-8 cm) from the bar code scanner located on the bottom right-hand corner of the analyzer.
- The red line from the bar code scanner should cover the entire bar code.
- The analyzer will beep when the bar code is accepted.
- If the bar code is not recognized by the scanner the first time, try scanning the barcode again.
- Record the date of installation on the gas bottle for later reference.

NOTE: If the insert sheet is misplaced, you can enter the lot number on the gas bottle label manually. Press <Manual> *in the Scan Bar Code Screen and enter the number using the numeric keypad.*

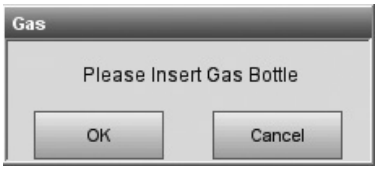


Fig. 2-7 Insert Gas Bottle

- When prompted (Fig. 2-7), insert the gas bottle in its housing and turn clockwise until fingertight (Fig. 2-8). Press OK.

NOTE: The gas bottle expires 6 months after installation or after exceeding the labeled expiration date, whichever comes first.

NOTE: The bar code contains expiration information. Two weeks prior to expiration of the gas bottle, the OPTI CCA-TS2 will alert the operator once, as a reminder to order a replacement gas bottle.

Fig. 2-8 Insert Gas Bottle

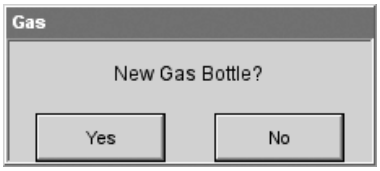


Fig. 2-9 New Gas Bottle

- When this display appears (Fig. 2-9), press Yes to install a new gas bottle.

NOTE: If after the initial installation you need to remove a gas bottle and reinstall the same bottle, respond No *to the* <New Gas Bottle?> *prompt. The next screen will prompt you to enter the number of weeks in service using the numeric keypad (See section 7.5.1). Here you may refer back to the installation date, which was recorded on the gas bottle.*

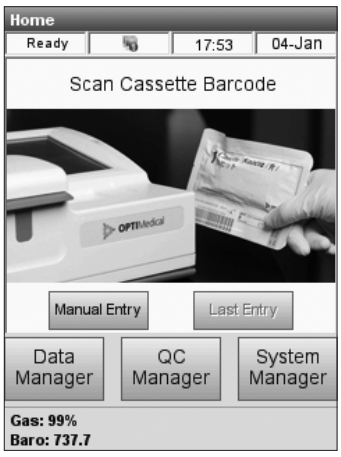


Fig. 2-10 Ready screen

The OPTI CCA-TS2 will now begin to warm up and perform a gas purge, which will be indicated by a progress bar displayed on the screen.

Once the warm-up is complete, the **<Ready>** display appears (Fig. 2-10).

5. Installing the Printer Paper

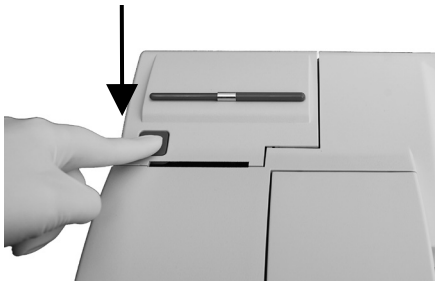


Fig. 2-11 Open Printer Cover

- Press the red printer release button on the printer cover to access the printer (Fig. 2-11).

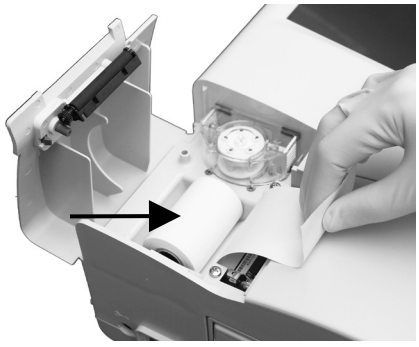


Fig. 2-12 Install Printer Paper

- Place the roll of printer paper into the paper tray.
- Pull the end of the paper upward and slightly out of the paper tray (Fig. 2-12).

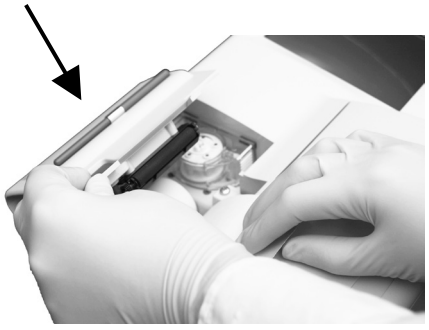


Fig. 2-13 Close Printer Cover

- Hold the paper and close the printer cover (Fig. 2-13).
- The paper will automatically feed through as the printer starts printing.

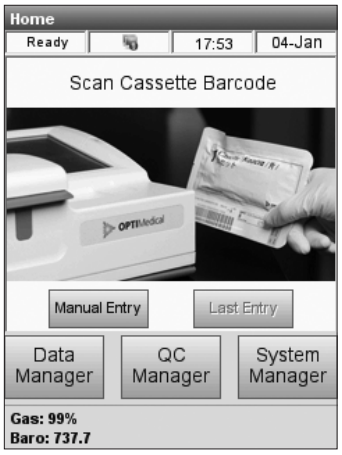


Fig. 2-14 Scan Bar Code

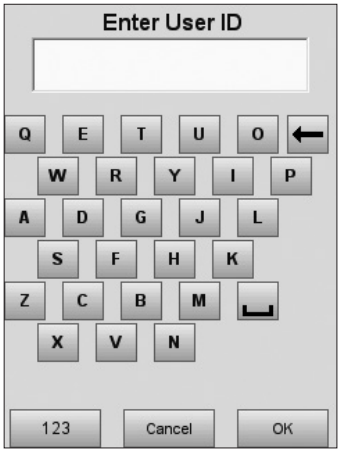


Fig. 2-15 Enter User ID

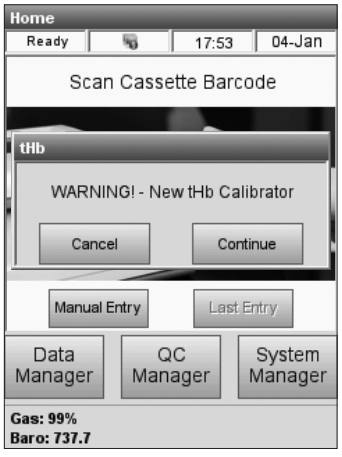


Fig. 2-16 New Calibrator

6. Performing tHb Calibration

The tHb Calibrator Cassette should be run prior to patient testing when first setting up your analyzer. The tHb calibrator should then be run every three months. Your OPTI CCA-TS2 will remind you when the tHb calibration is due. The tHb Calibrator Cassette can be found in the storage compartment in the back of your analyzer.

- In the **<Ready>** display, scan the bottom bar code on the calibrator cassette package by holding it 2-3 inches (5-8 cm) from the bar code scanner located on the bottom right-hand corner of the analyzer (Fig. 2-14).

NOTE: A tHb calibration can also be run from the QC menu by pressing <QC Manager>QC>tHb Calibrator> *instead of scanning the barcode in the* <Ready> *screen.*

- The red line from the bar code scanner should cover the entire bar code.
- A beep and a green status light indicates a valid bar code.

- If **<Non Secure User ID Entry>** is enabled in the security settings (see Section 3.2.3), you will be asked to enter the user ID (Fig. 2-15). Depending on security settings, user access to running Hb calibrators may be restricted.

NOTE: Bar-coded user IDs may be entered from this screen using the bar code scanner.

- A warning will be displayed the first time a new tHb Calibrator lot is used (Fig. 2-16). Press **<Continue>**.

Fig. 2-17 Clean Optics

- Gently clean the optics window and the inside top cover of the sample chamber with a soft lint free cloth (Fig. 2-17).
  Press OK.

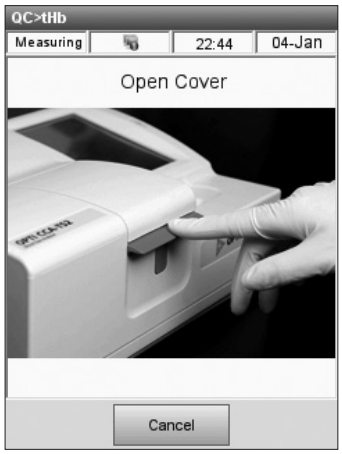


Fig. 2-18 Open Cover

- Open the SMC cover by pressing down on the center of the red latch (Fig. 2-18).

Fig. 2-19 Wipe and Insert Cassette

- Gently wipe both sides of the Calibrator Cassette with a clean dry cloth and examine it to ensure it is clean. Insert it into the chamber and press down to properly seat the cassette (Fig. 2-19).

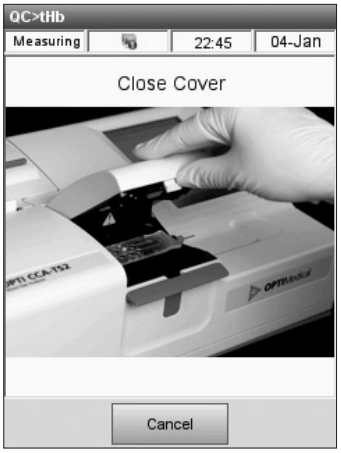


Fig. 2-20 Close Cover

- Close the sample chamber cover (Fig. 2-20).

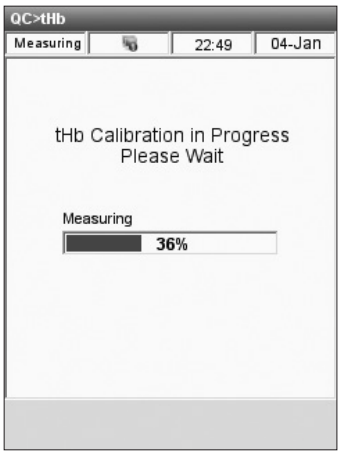


Fig. 2-21 tHb Calibration

- After the cover has been closed, the instrument will automatically detect the presence of the calibrator cassette and begin calibration (Fig. 2-21).

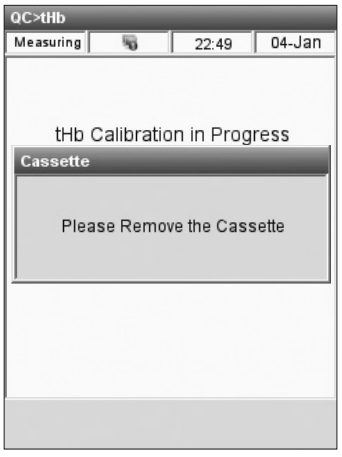
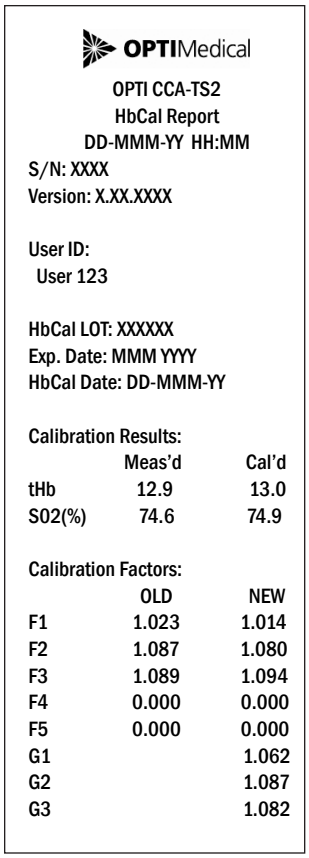


Fig. 2-22 Remove Calibrator

- After the calibration is complete, you will be prompted to open the sample chamber cover and remove the cassette (Fig. 2-22).
- Place the calibrator cassette back into its pouch immediately after removal from the instrument.

NOTE: Make sure to keep the calibrator cassette with the instrument at all times.



OPTIMedical

OPTI CCA-TS2
HbCal Report
DD-MMM-YY HH:MM
S/N: XXXX
Version: X.XX.XXXX

User ID:
User 123

HbCal LOT: XXXXXX
Exp. Date: MMM YYYY
HbCal Date: DD-MMM-YY

Calibration Results:

	Meas'd	Cal'd
tHb	12.9	13.0
SO2(%)	74.6	74.9

Calibration Factors:

	OLD	NEW
F1	1.023	1.014
F2	1.087	1.080
F3	1.089	1.094
F4	0.000	0.000
F5	0.000	0.000
G1		1.062
G2		1.087
G3		1.082

Fig. 2-23 HbCal Report

- The unit will now begin printing the Hb Calibration Report showing calibration results and calibration factors (Fig. 2-23).

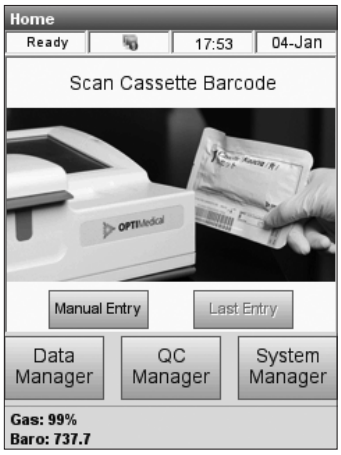


Fig. 2-24 Ready Screen

- Once the Hb Calibration is complete, the **<Ready>** display will appear (Fig. 2-24) and the analyzer is ready for operation.

- OPTI Medical recommends that you run controls prior to running patient samples on a new analyzer. You must set up your OPTI Check control lot information in your new analyzer prior to running them. SRCs do not require setup and can be found in the storage compartment in the back of your analyzer.
- Refer to section 3.2.1 of this manual for the QC Setup procedure. Refer to section 4.5 of this manual for QC recommendations and instructions for running QC measurements.

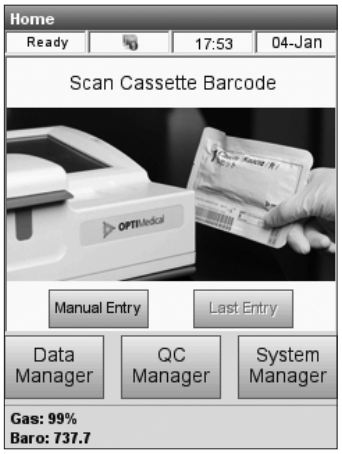


Fig. 2-25 Ready Screen

7. The Ready Display

The **<Ready>** display (Fig. 2-25) appears when the analyzer is ready for operation and also displays important status information such as:

- **<Gas>** - Displays the percentage of gas remaining.
- **<Baro>** - Displays the current barometric pressure.

The **<Ready>** display also provides access to the following system functions:

- **<Data Manager>** – This menu allows you to print out patient, control and diagnostic information. It also provides you with the ability to import/export data.
  For more information on printing and importing/exporting data, see **Chapter 6. Data Management**.
- **<QC Manager>** – This menu allows you to perform control measurements.
  For more information, see **Chapter 4. Calibration and Quality Control**.
- **<System Manager>** - This menu contains the following settings and functions:
  - Time and Date (Chapter 3.1)
  - Setup (Chapter 3.2)
  - Maintenance (Chapter 3.2.5 and 7.1)
  - Diagnostics (Chapter 8.2)

3 CUSTOMIZATION

Your OPTI® CCA-TS2 analyzer is shipped preset to easily perform sampling operations. Through the touch screen you can enter patient data and initiate printing of patient, QC and diagnostics reports, as well as enter additional information to tailor the instrument's performance to match the particular needs of your lab.

For safety and security the OPTI CCA-TS2 customization can be protected by configuring security to allow only authorized users to make changes (see security section 3.2.3).

All system setup selections entered will reside in the instrument memory even after the system power is turned off.

3.1 Setting Time and Date

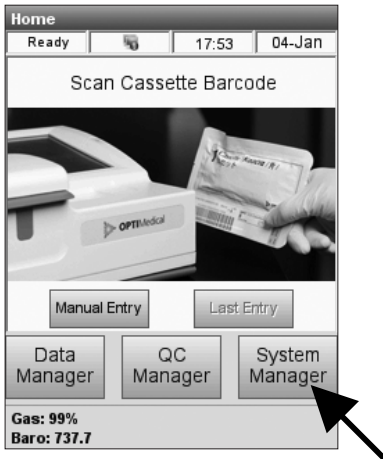


Fig. 3-1 Select System Manager

1. To set the time and date, press **<System Manager>** in the main menu (Fig. 3-1).

2. Press **<Time and Date>** in the **<System>** menu (Fig. 3-2).

3. Enter the User ID and password (factory setting **ADMIN/ADMIN**) when prompted (Fig. 3-3) to access the **<Time and Date>** screen.

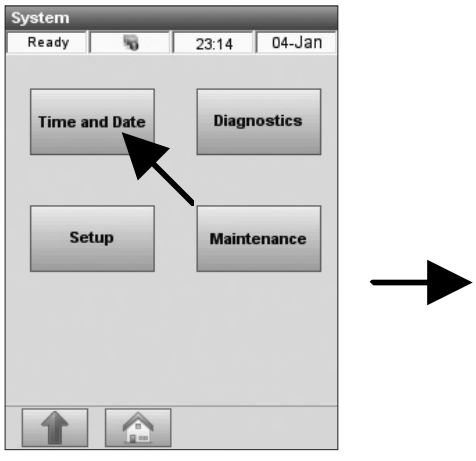


Fig. 3-2 Select Time and Date

Fig. 3-3 Login

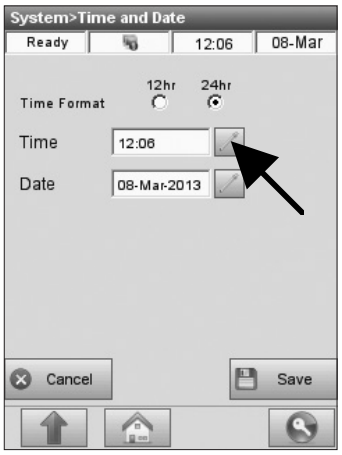


Fig. 3-4 Time and Date

4. In the **<System > Time and Date>** screen (Fig. 3-4), press to leave the default time and date setting unchanged, or press the button to call up a numeric keypad that can be used to change the time and date setting.
5. To change the **<Time Format>** from **<12-hour>** time units to **<24-hour>** time units, press the respective radio button.
6. Press Save to accept the changes.
7. To log off after making the changes, press the **<Log Off>** button in the bottom right corner of the screen.
8. Press to return to the **<System>** screen or to return to the main menu.

3.2 Setup

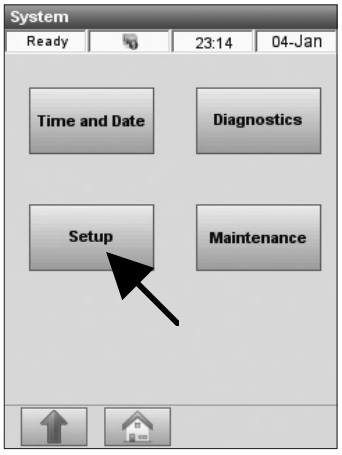


Fig. 3-5 Setup

Setup menus let you set up quality control materials, program the setup of the printed reports, set up system security and customize several other system features.

The **<Setup>** menu consists of three screens, **<Patient/QC>**, **<Security>** and **<System>**.

1. In the main screen, press **<System Manager>** to access the **<System>** menu.
2. Press **<Setup>** to select this function (Fig. 3-5).

3.2.1 QC Setup

3.2.1.1 Setting up the Quality Control Material

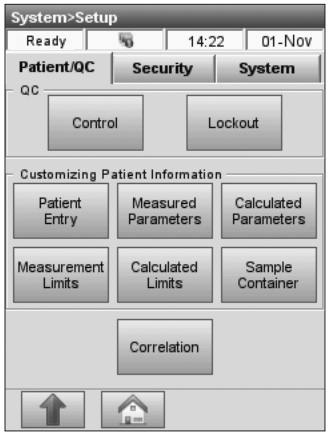


Fig. 3-6 Select Control

Fig. 3-7 Scan Bar Code

When you open a new box of OPTI CHECK or OPTI CHECK PLUS, the lot number should be entered into the analyzer, along with the target ranges. Each QC level of control has its own unique lot number printed on the information sheet contained in the control box.

NOTE: OPTI CHECK and OPTI CHECK PLUS Quality Control materials are designed for your OPTI CCA-TS2 and have assigned assay ranges for each measured parameter.

NOTE: The procedure for programming QC ranges as described below is identical for all levels.

NOTE: The OPTI CCA-TS2 can save information for one lot of OPTI CHECK and one lot of OPTI CHECK PLUS concurrently for each level.

1. In the main menu, select **<System Manager>** and **<Setup>**.
2. Enter security information if enabled (see Section 3.2.3.1).
3. On the **<Patient/QC>** tab, select **<Control>** (Fig. 3-6).
4. Take the bar code sheet out of the OPTI CHECK box and scan **Barcode A** for the applicable level of OPTI CHECK or OPTI CHECK PLUS (Fig. 3-7).
   - Hold the bar code 2-3 inches (5-8 cm) from the bar code scanner located on the bottom right-hand corner of the analyzer.
   - The red line from the bar code scanner should cover the entire bar code.
   - A beep and a green status light indicates a valid bar code.

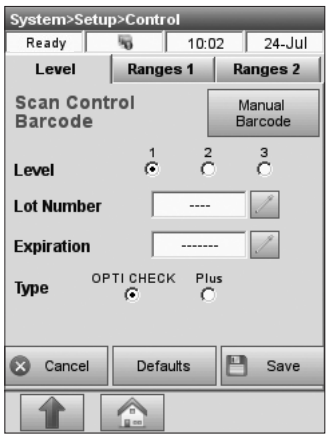


Fig. 3-8 Confirm Lot Information

5. Scan **Barcode B** when prompted. These two bar codes contain all necessary lot information for each level, and may be confirmed in the subsequent screens.
6. When using OPTI CHECK PLUS, scan **Barcode C** for the applicable level.
7. Confirm lot number, expiration date and control type on the package insert supplied with the control material (Fig. 3-8). If the bar code is unavailable, press **<Manual Barcode>** and enter the control information manually. Users should not enter control limits manually prior to scanning or manually entering the control barcode information.

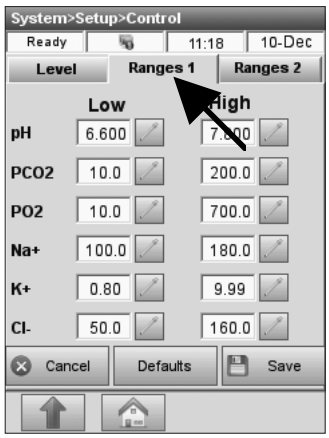


Fig. 3-9 Confirm Assay Ranges

8. Press the **<Ranges 1>** tab to confirm the assay ranges on the package insert supplied with the control material (Fig. 3-9).
   If the bar code is unavailable, press the button and enter the numbers using the keypad.

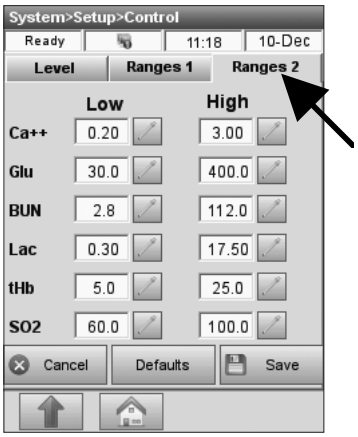


Fig. 3-10 Confirm Assay Ranges

9. Press **<Ranges 2>** to go to the next display to enter the ranges for all other measured parameters available with this control material (Fig. 3-10).
   - You will find the assay ranges printed on the data sheet in the box of control material. Alternately you may develop your own assay ranges from multiple measurements according to your hospital's procedures.
   - Although it is recommended you review all analyte assay ranges, you may press Save at any time after the bar code is scanned, and the ranges will be accepted from the bar code.

To continue quality control programming, repeat the above procedure for QC Level 2 and QC Level 3.

3.2.1.2 Selecting QC Lockout

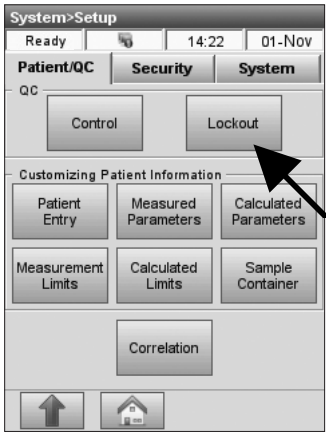


Fig. 3-11 QC Lockout

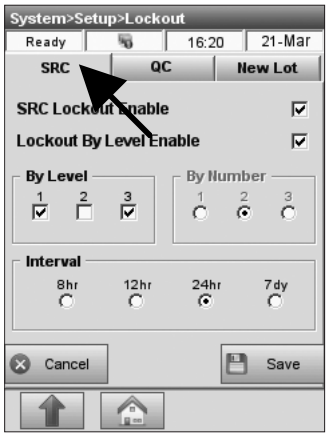


Fig. 3-12 SRC Lockout

This menu can be used to 'lock out' operators unless some form of QC is peformed. OPTI Medical recommends using each option described below. Each facility should develop their own policies on the frequency and type of QC based on the regulatory requirements. The instrument is factory-set with lockout options turned off. To change these settings, follow the steps below:

- In the main menu, select **<System Manager>** and **<Setup>**. Select **<Lockout>** in the **<Patient/QC>** tab (Fig. 3-11).
- The **<Lockout>** menu contains 3 screens: **<SRC>**, **<QC>** and **<New Lot>**.

Option 1:

<SRC Lockout Enable> (Fig. 3-12).
When this option is enabled, SRC measurements must be performed at specified intervals for patient measurements to be allowed.

1. To specify the number of SRC measurements to be performed, make sure **<Lockout By Level Enable>** is not selected and select 1, 2 or 3 in the **<By Number>** option.
2. To specify the levels to run, select **<Lockout By Level Enable>** and the levels to run in the **<By Level>** option.
3. Define the time interval during which SRC measurements must be run. Options are 8, 12, 24 hours and 7 days.
4. The SRC lockouts are disabled by default.
5. Press Save to accept the changes.

NOTE: The selected time interval starts with the time this feature is activated.

Fig. 3-13 QC Lockout

Option 2:

<QC Lockout Enable> (Fig. 3-13).
When this option is enabled, external QC measurements must be performed at specified intervals for patient measurements to be allowed.

1. To specify the number of QC measurements to be performed, make sure **<Lockout By Level Enable>** is not selected and select 1, 2 or 3 in the **<By Number>** option.
2. To specify the levels to run, select **<Lockout By Level Enable>** and the levels to run in the **<By Level>** option.
3. Define the time interval during which QC measurements must be run. Options are 8, 12, 24 hours,7 days and 1 month.
4. By default, QC Lockout is disabled.
5. Press Save to accept the changes.

NOTE: The selected time interval starts with the time this feature is activated.

NOTE: More than one option can be selected. For instance, laboratories can require that a combination of SRCs and liquid QC is run on a daily basis. This should be based on hospital policy.

NOTE: Control lockouts are based on data stored in the Controls database (see Section 4). This database may include data measured with any cassette lot or cassette type.

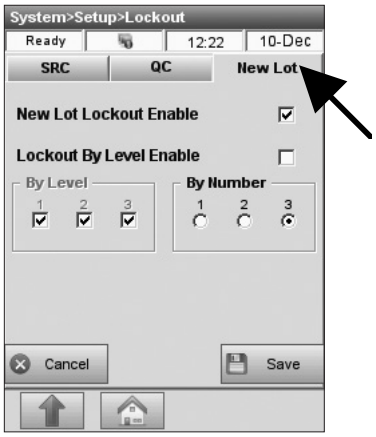


Fig. 3-14 New Lot Lockout

Option 3:

<New Lot Lockout Enable> (Fig. 3-14). When this option is enabled, controls must be run with every new lot of cassettes for patient measurements to be allowed.

1. To specify the number of QC measurements to be performed, make sure **<Lockout By Level Enable>** is not selected and select 1, 2 or 3 in the **<By Number>** option.
2. To specify the levels to run, select **<Lockout By Level Enable>** and the levels to run in the **<By Level>** option.
3. By default, this option is disabled.
4. Press Save to accept the changes.
5. Press  to return to the **<Setup>** screen or  to return to the main menu.

3.2.2 Customizing Patient Information

3.2.2.1 Setting up Patient Information

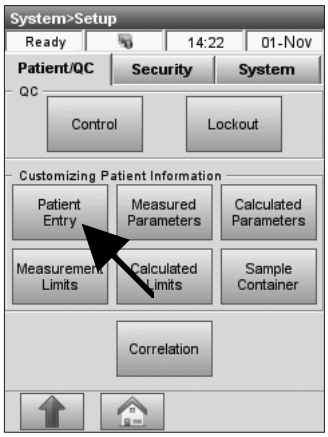


Fig. 3-15 Select Patient Entry

In this function you can define which patient information is required during, as well as printed after, each measurement.

- In the main menu, select **<System Manager>** and **<Setup>**.
- On the **<Patient/QC>** tab, press **<Patient Entry>** (Fig. 3-15).

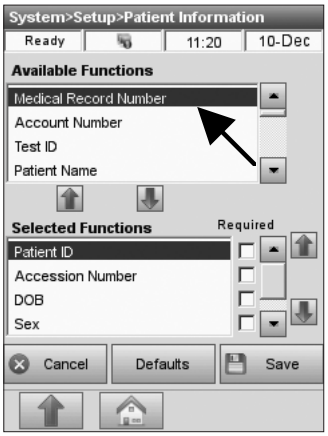


Fig. 3-16 Patient Information

In the **<Patient Information>** screen, you can customize the list of patient information (Fig. 3-16).

The top half of the screen displays all available options, the bottom half shows the selected options.

1. To add patient entry options to your list, select the desired option in the **<Available Functions>** field in the top half of the screen. (Fig. 3-16). Press the blue **<Down>** arrow to move this option to your list in the **<Selected Functions>** field on the bottom.
2. To remove options from your list, press the **<Up>** arrow.

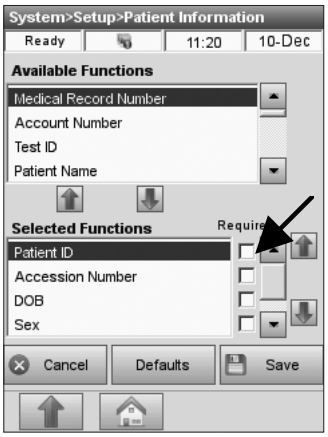


Fig. 3-17 Patient Information

3. Press **<Required>** (Fig. 3-17) to make a patient entry option a required entry.

   The default options for patient information are:

   - Patient ID (25 alphanumeric characters)
   - Accession No. (25 numeric characters)
   - Date of Birth (DOB) (Month, DD, YYYY)
   - Sex (unknown, male or female)
   - Temperature (default value 37.0 °C)

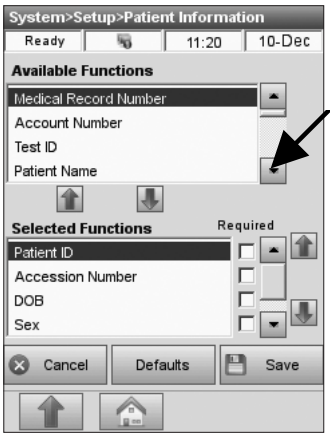


Fig. 3-18 Patient Information

4. Scroll down for the following additional options (Fig. 3-18).

   - Medical Record Number (25 numeric characters)
   - Account No. (25 numeric characters)
   - Test ID (25 alphanumeric characters)
   - Patient First Name (25 alpha characters)
   - Patient Last Name (25 alpha characters)
   - Age (0-150)
   - Attending Physician (25 alpha characters)
   - Patient Location (25 alpha characters)
   - Sample Collection Time (Month, DD, YYYY, HH:MM)
   - Sample Type: (Art/Ven/MixVen/Cap/Cord/CPB), where:
     Art = Arterial
     Ven = Venous
     MixVen = Mixed Venous
     Cap = Capillary
     Cord = Cord
     CPB = Cardio Pulmonary Bypass
   - Puncture Site (LR/RR/LB/RB/LF/RF/Cord/Scalp), where:

LR = Left Radial	RR = Right Radial
LB = Left Brachial	RB = Right Brachial
LF = Left Femoral	RF = Right Femoral
Cord = Cord	Scalp = Scalp

   - Allen's Test (unknown, positive or negative)
   - tHb Type (adult or fetal, default is adult)
   - Bypass (pump off or on)
   - O2 Mode (Rm Air/Mask/T-P/NC/Vent/Bag/Hood/Other), where:
     RmAir = Room Air
     Mask = Mask
     T-P = T-Piece
     NC = Nasal Canula
     Vent = Vent
     Bag = Bag (Manual Resuscitation)
     Hood = Hood
     Other = Other

- Vent Mode (No/SIMV/PSV/PCV/CMV-AC/CPAP/PCIVR/BIPAP), where:

  No = None
  SIMV = Synchronized Intermittent Mandatory Ventilation
  PSV = Pressure Supported Ventilation
  PCV = Pressure Control Ventilation
  CMV/AC = Controlled Mechanical Ventilation / Assist Control
  CPAP = Continuous Positive Airway Pressure
  PCIVR = Pressure Control Inverse Ratio
  BIPAP = Bi-Level Positive Airway Pressure

- Pplat (default value 0)
- Mvol (VE) (default value 0 L)
- PIP (default value 0)
- Liter Flow (default value 000.00 Lpm)
- Tvol (VT) (default value 0 mL)
- PS (default value 0)
- PEEP (default value 0)
- Rate (f) (default value 0 bpm)
- CPAP (default value 0)
- tHb (default value 15.0 g/dL)
- FIO_2 (default value 0.21)
- MCHC (default value 33.3%)
- RQ (default value 0.84)
- P_{50} (default value 26.7 mmHg)
- Bilevel Pressure (default value 0.00/0.00)
- I/E Ratio (default value 0)
- Comment field (50 alphanumeric characters)

5. The options will be shown in the patient entry form during a patient measurement in the order they are listed in the lower box. The order can be changed by selecting the desired option in the lower box and pressing the **<Up>** or **<Down>** arrow buttons to the right of the selection box (Fig. 3-19) to move the option up or down in the list.

6. Press Save to accept the changes.

7. Press to return to the **<Setup>** screen or to return to the main menu.

NOTE: Input parameters that are not selected will not be printed or exported. If a parameter must be exported then it should be selected.

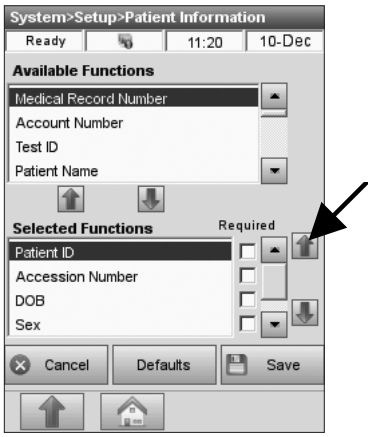


Fig. 3-19 Patient Information

3.2.2.2 Setting up Measured Parameters

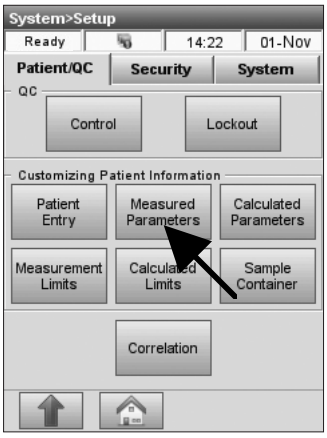


Fig. 3-20 Measured Parameters

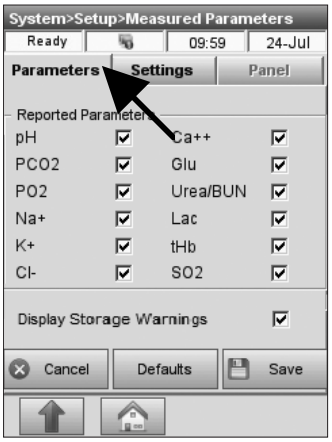


Fig. 3-21 Parameters

The **<Measured Parameters>** menu contains three submenus, **<Parameters>**, **<Settings>** and **<Panel>**, with various parameter setup functions.

- In the main menu, select **<System Manager>** and **<Setup>**.
- On the **<Patient/QC>** tab, press **<Measured Parameters>** (Fig. 3-20).

The **<Parameters>** tab contains the following options (Fig. 3-21):

- **<Reported Parameters>** - With this function you can suppress results for certain parameters. The results for these parameters will not appear in the stored patient results or on the printout.

  1. To permanently suppress results for all patient and control measurements for all cassette styles, deselect the specific parameters in the parameter list.
     By default, all parameters are activated.
  2. Press Save to save your selection.

- **<Display Storage Warnings>** -
  This function enables display of warning messages for out-of-storage conditions for B-Lac and E-BUN cassettes during patient and QC measurements. By default, this function is enabled.

  1. To disable this function, press the check box to remove the check mark.
  2. Press Save to save your selection.

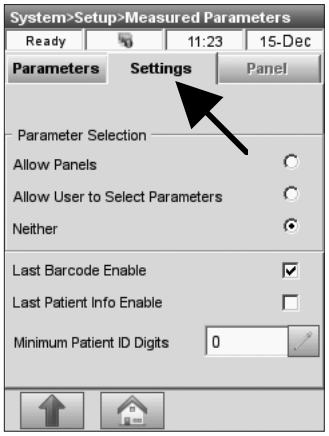


Fig. 3-22 Settings

The **<Settings>** screen contains the following options (Fig. 3-22):

- **<Allow Panels>** allows users to set up customized panels of sensors (see section 3.2.2.7 for more detail).
- If **<Allow User to Select Parameters>** is selected, the user will be prompted to select which parameters to measure after initiating a patient measurement.
- **<Neither>** is selected by default.
- **<Last Barcode Enable>** enables the **<Last Entry>** button on the main screen so that the previous barcode scanned can be used for the current patient measurement. By default, this option is disabled.
- **<Last Patient Info Enable>** enables the **<Last Patient Info>** button shown during the measurement so that the patient information from the previous measurement can be used as the default for the current measurement. By default, this option is disabled.
- **<Minimum Patient ID Digits>** lets you set a minimum number of required digits for the Patient ID.
- Press Save to save the settings.

3.2.2.3 Setting up Test Panels

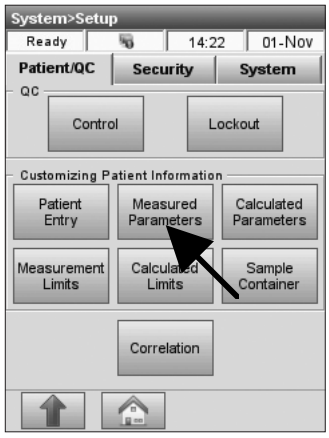


Fig. 3-23 Measured Parameters

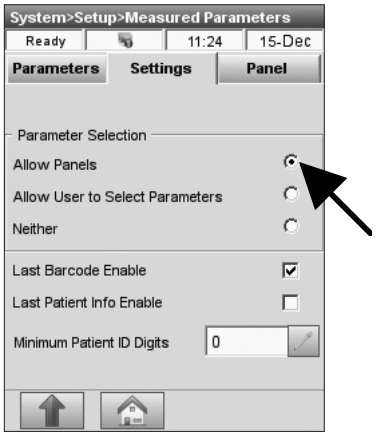


Fig. 3-24 Allow Panels

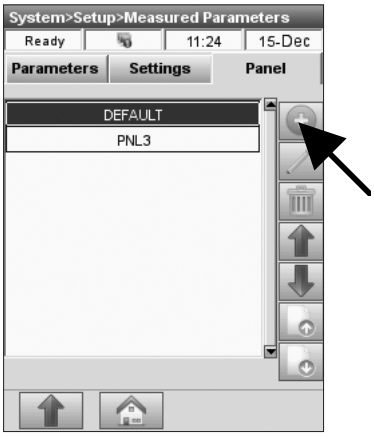


Fig. 3-25 Add Panel

This menu allows you to set up and maintain customized analyzer test panels.

Customized test panels eliminate the need for device operators to repeatedly select test parameters for given situations. For example, your institution may require one sequence of tests for use in the emergency room, and a different sequence of tests for the operating room. You can set up and name test panel configurations using tests available on a cassette for these specific situations.

1. In the main menu, select **<System Manager>** and **<Setup>**.
2. On the **<Patient/QC>** tab, press **<Measured Parameters>**.(Fig. 3-23),
3. On the **<Settings>** tab (Fig. 3-24), press **<Allow Panels>**. By default, this option is disabled.
   - When this option is enabled, a pop-up screen will appear when a cassette is scanned showing available panels. The cassette default is always available if no measured parameters are disabled that are on the cassette.
   - Only panels with parameters that are available on the cassette will be displayed. E.g., if you set up a panel with Na^+, K^+ and Ca^{++}, this option will only be displayed, if you scan a cassette that measures these parameters.
4. In the **<Measured Parameters>** menu (Fig. 3-25), select the **<Panel>** tab.
5. Press  to add a new test panel.

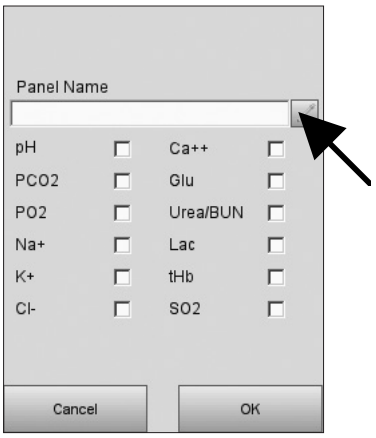


Fig. 3-26 Select Parameters

6. In the subsequent screen (Fig. 3-26), press and enter a name for the test panel. Select the parameters to be included in the panel.
7. Press OK to accept the settings.

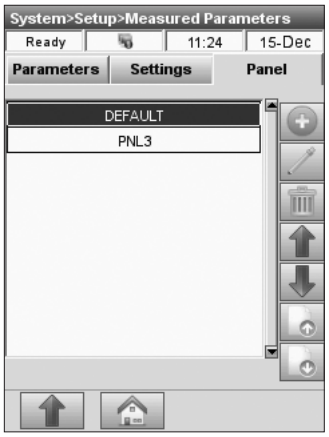


Fig. 3-27 Panels

8. To edit an existing panel, select the panel (Fig. 3-27) and press .
9. Press to delete an existing panel.
   The default panel cannot be edited or deleted.
10. Use the **<Up>** and **<Down>** arrows to reorder the panels in the list.
11. Use the **<Previous>** and **<Next>** buttons to display the previous or next page of panel configurations.
12. Press to return to the **<Setup>** screen or to return to the main menu.

3.2.2.4 Setting up Calculated Parameters

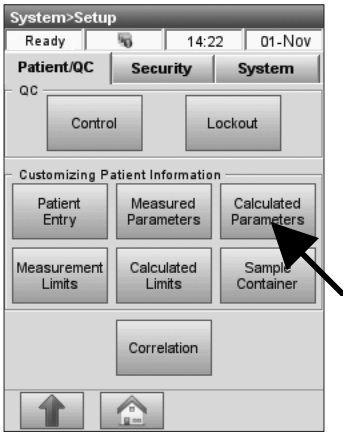


Fig. 3-28 Calculated Parameters

With this menu you can select the calculated parameters for each cassette style to be printed on the patient report. The printout order is fixed; however, calculated parameters may be selected for inclusion in or exclusion from the printout.

NOTE: The display will always let you view all available calculated parameters.

1. In the main menu, select **<System Manager>** and **<Setup>**.
2. On the **<Patient/QC>** tab, press **<Calculated Parameters>** (Fig. 3-28).

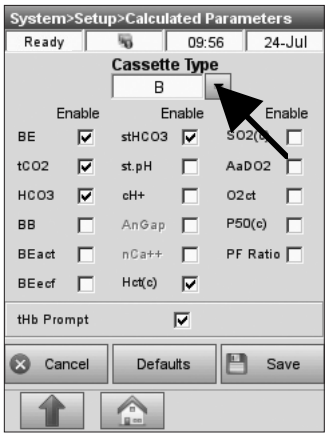


Fig. 3-29 Select Parameters

3. Select the cassette type (Fig. 3-29).
4. Select the parameters to be printed.
5. Press Save to accept the changes.
6. Press ↑ to return to the **<Setup>** screen or ⌂ to return to the main menu.

3.2.2.5 tHb Prompt

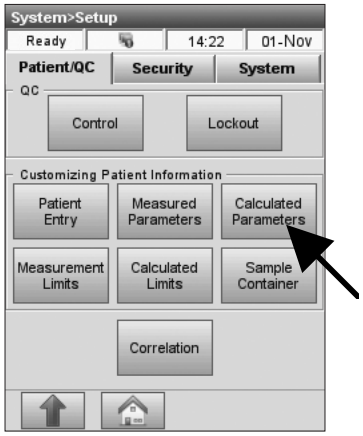


Fig. 3-30 Calculated Parameters

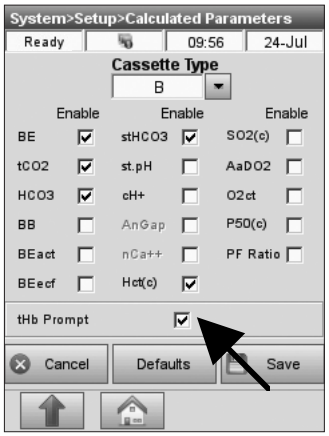


Fig. 3-31 tHb Prompt

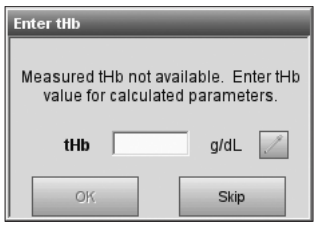


Fig. 3-32 Enter tHb Value

This menu enables you to enter the tHb value from another source to receive the calculated parameters listed below when tHb has been suppressed.

- Base excess (BE)
- Buffer bases (BB)
- Base excess actual (BEact)
- Standard pH (st.pH)
- Standard bicarbonate (st.HCO_3^-)
- Oxygen content (O_2ct)

1. From the main menu, select **<System Manager>** and **<Setup>**.
2. On the **<Patient/QC>** tab, press **<Calculated Parameters>** (Fig. 3-30).
   - By default the prompt is turned on (Fig. 3-31). When the prompt is turned off, the analyzer uses a default value for the following calculated parameters: BE (Base Excess), BEact (Base excess actual), st.pH (standard pH) and st. HCO_3^- (standard bicarbonate).
   - If tHb is suppressed and the prompt to enter tHb is turned off, then BB and O_2ct will be suppressed if a tHb value has not been entered.
   - To enter a tHb value, press the **<Patient Information>** button when displayed during calibration or sample measurement, and go to page 2 to enter the value (Fig. 3-32).

NOTE to B-60 cassette users: BB and O2ct require a valid tHb value to be accurate. Because tHb is not measured on the B-60 cassette, these calculated parameters are not available when running B-60 cassettes.

3.2.2.6 Setting up Limits for Measurement Parameters

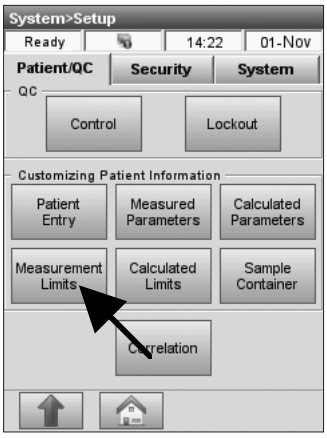


Fig. 3-33 Measurement Limits

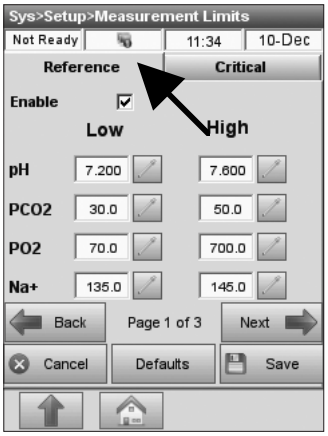


Fig. 3-34 Reference Limits

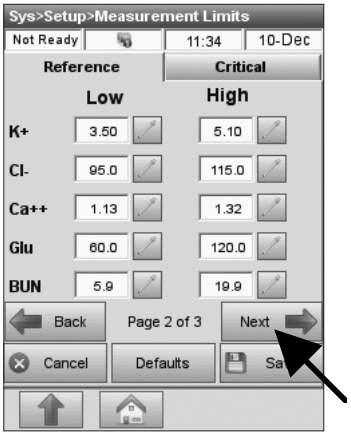


Fig. 3-35 Enter Limits 2

This menu allows you to set up reference and critical measurement limits for all measured parameters.

A result that is outside the limits you define here will be flagged with a single up-arrow if above the high reference limit, or a single down-arrow if below the low reference limit. Results above or below the critical limits will be flagged with a double up-/or down-arrow. A message is included on the printout explaining each arrow.

NOTE: When the patient temperature has been changed, both the uncorrected and corrected parameters will be checked against the limit values programmed here and flagged accordingly.

1. In the main menu, select **<System Manager>** and **<Setup>**.
2. On the **<Patient/QC>** tab, press **<Measurement Limits>** (Fig. 3-33).
3. On the **<Reference>** tab (Fig. 3-34), select the parameter you want to change and press  to enter the new limit value. By default, reference ranges are enabled.
4. Press  to access pages 2 and 3 with the remaining parameters (Fig. 3-35).
5. Press  to accept the new limit value.

The instrument is preset to the following reference ranges:

pH:	7.200 - 7.600
PCO_2:	30.0 - 50.0 mmHg
PO_2:	70.0 - 700.0 mmHg
Na^+:	135.0 - 145.0 mmol/L
K^+:	3.50 - 5.10 mmol/L
Cl^-:	95.0 - 115.0 mmol/L
Ca^{++}:	1.13 - 1.32 mmol/L
Glu:	60.0 - 120.0 mg/dL
Glu:	3.3 - 6.7 mmol/L
BUN:	5.9 - 19.9 mg/dL
Urea:	2.1 - 7.1 mmol/L
Lac:	0.90 - 1.70 mmol/L
tHb:	12.0 - 17.0 g/dL
SO_2:	90.0 - 100.0 %

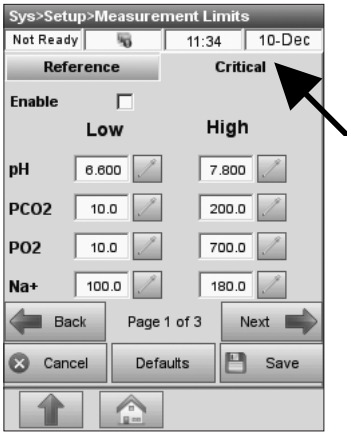


Fig. 3-36 Enter Critical Limits

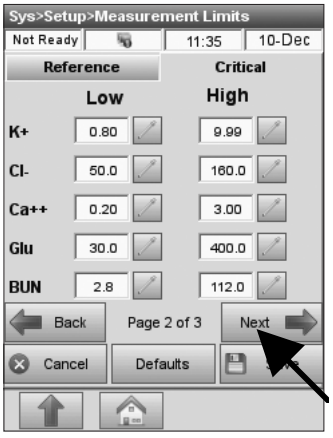


Fig. 3-37 Critical Limits 2

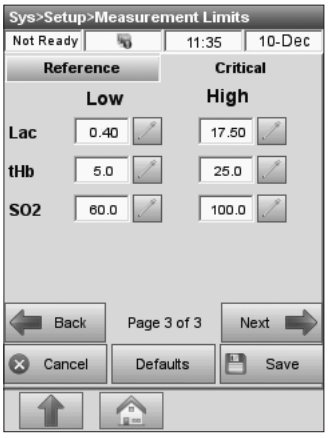


Fig. 3-38 Critical Limits 3

- For information on how to change units of measure, see section 3.2.4.2.

NOTE: Each facility should establish its own reference ranges. The preset analyzer ranges are for reference only and are derived from "Tietz, Burtis C, et al (Eds.), Textbook of Clinical Chemistry and Molecular Diagnostics, 4th Ed., (Elsevier Saunders, 2006) pps. 2252-2302".

6. Select the **<Critical>** tab (Fig. 3-36). By default, critical ranges are disabled. Press **<Enable>** to enter critical limit values.
7. Select the parameter you want to change and press to enter the new limit value.
8. Press Next to access pages 2 and 3 with the remaining parameters (Fig. 3-37 and Fig. 3-38).
9. Press Save to accept the new limit values.

The instrument is preset to the measurement ranges of the OPTI CCA-TS2:

pH:	6.600 - 7.800
PCO_2:	10.0 - 200.0 mmHg
PO_2:	10.0 - 700.0 mmHg
Na^+:	100.0 - 180.0 mmol/L
K^+:	0.80 - 9.99 mmol/L
Cl^-:	50.0 - 160.0 mmol/L
Ca^{++}:	0.20 - 3.00 mmol/L
Glu:	30.0 - 400.0 mg/dL
Glu:	1.7 - 22.2 mmol/L
BUN:	2.8 - 112.0 mg/dL
Urea:	1.0 - 40.0 mmol/L
Lac:	0.40 - 17.50 mmol/L
tHb:	5.0 - 25.0 g/dL
SO_2:	60.0 - 100.0 %

- In all data input screens, if values outside the acceptable input range are entered, the system automatically flags the error and displays the valid range.

10. Press to return to the **<Setup>** screen or to return to the main menu.

3.2.2.7 Setting up Limits for Calculated Parameters

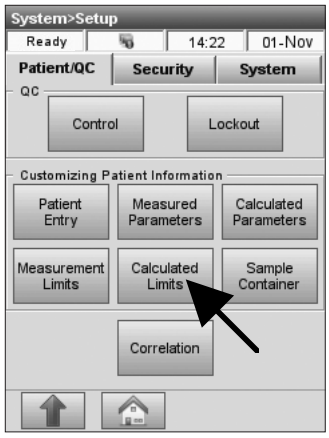


Fig. 3-39 Calculated Limits

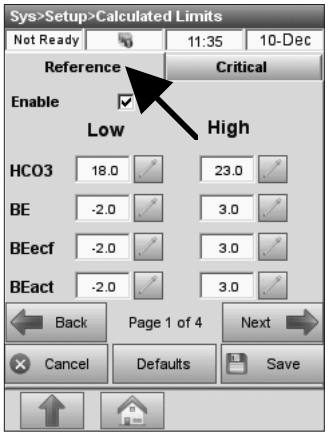


Fig. 3-40 Reference Limits

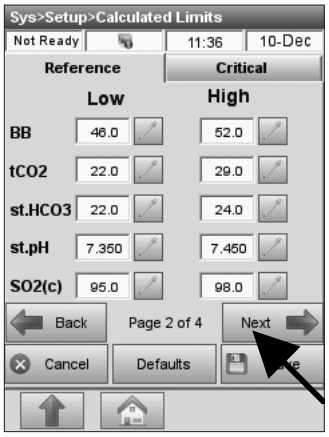


Fig. 3-41 Enter Limits 2

This menu allows you to set up reference and critical measurement limits for all calculated parameters. A result that is outside the limits you define here will be flagged with a single up-arrow if above the high reference limit, or a single down-arrow if below the low reference limit. Results above or below the critical limits will be flagged with a double up-/or down-arrow. A message is included on the printout explaining each arrow.

NOTE: When the patient temperature has been changed, both the uncorrected and corrected parameters will be checked against the limit values programmed here and flagged accordingly.

1. In the main menu, select **<System Manager>** and **<Setup>**. Press **<Calculated Limits>** on the **<Patient/QC>** tab (Fig. 3-39).
2. On the **<Reference>** tab (Fig. 3-40), select the parameter you want to change and press  to enter the new limit value. By default, reference ranges are enabled.
3. Press  to access Pages 2, 3 and 4 with the remaining parameters (Fig. 3-41).
4. Press  to accept the new limit value.

The instrument is preset to the following reference ranges:

HCO_3^-:	18.0 - 23.0 mmol/L
BE:	-2.0 - 3.0 mmol/L
BE_{ecf}:	-2.0 - 3.0 mmol/L
BE_{act}:	-2.0 - 3.0 mmol/L
BB:	46.0 - 52.0 mmol/L
tCO_2:	22.0 - 29.0 mmol/L
st.HCO_3^-:	22.0 - 24.0 mmol/L
st.pH:	7.350 - 7.450
SO_2(c):	95.0 - 98.0 %
O_2ct:	15.0 - 23.0 mL/dL
Hct(c):	34.0 - 51.0 %
cH^+:	36.0 - 44.0 nmol/L
$AaDO_2$:	5.0 - 20.0 mmHg
AnGap:	10.0 - 20.0 mmol/L
P_{50}:	25.0 - 29.0 mmHg
nCa^{++}:	0.10 - 3.00 mmol/L
P/F Ratio:	400 - 500 mmHg

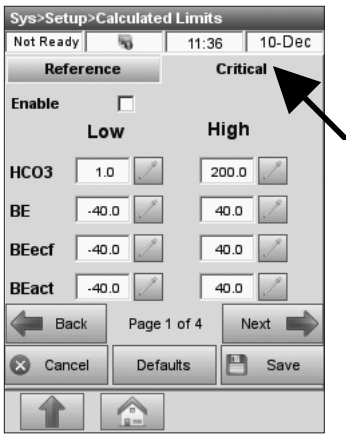


Fig. 3-42 Enter Critical Limits

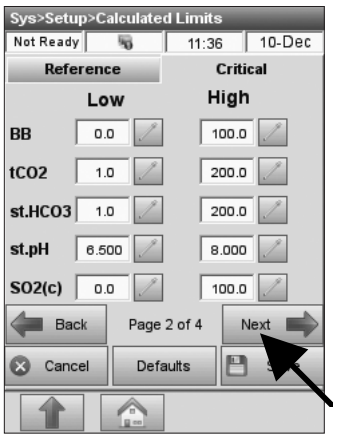


Fig. 3-43 Critical Limits 2

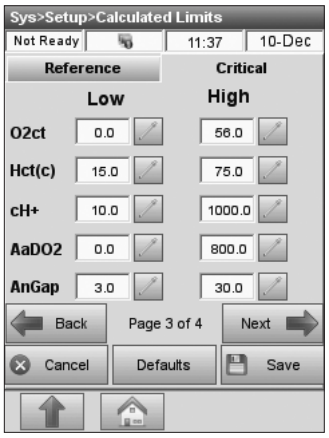


Fig. 3-44 Critical Limits 3

- To change units of measure, see section 3.2.4.2.

NOTE: Each facility should establish its own reference ranges. The preset analyzer ranges are for reference only and are derived from "Tietz, Burtis C, et al (Eds.), Textbook of Clinical Chemistry and Molecular Diagnostics, 4th Ed., (Elsevier Saunders, 2006) pps. 2252-2302".

5. Select the **<Critical>** tab (Fig. 3-42). By default, critical ranges are disabled. Press **<Enable>** to enter critical limit values.
6. Select the parameter you want to change and press to enter the new value.
7. Press Next to access pages 2, 3 and 4 with the remaining parameters (Figs. 3-43 and 3-44) and press Save to accept the new values.

The instrument is preset to the measurement ranges of the TS2:

HCO_3^-:	1.0 - 200.0 mmol/L
BE:	-40.0 - +40.0 mmol/L
BE_{ecf}:	-40.0 - +40.0 mmol/L
BE_{act}:	-40.0 - +40.0 mmol/L
BB:	0.0 - 100.0 mmol/L
tCO_2:	1.0 - 200.0 mmol/L
st.HCO_3^-:	1.0 - 200.0 mmol/L
st.pH:	6.500 - 8.000
SO_2(c):	0.0 - 100.0 %
O_2ct:	0.0 - 56.0 mL/dL
Hct(c):	15.0 - 75.0 %
cH^+:	10.0 - 1000.0 nmol/L
$AaDO_2$:	0.0 - 800.0 mmHg
AnGap:	3.0 - 30.0 mmol/L
P_{50}:	15.0 - 35.0 mmHg
nCa^{++}:	0.10 - 3.00 mmol/L
P/F Ratio:	10 - 800 mmHg

- In all data input screens, if values outside the acceptable input range are entered, the system automatically flags the error and displays the valid range.

8. Press to return to the **<Setup>** screen or to return to the main menu.

3.2.2.8 Sample Container Menu

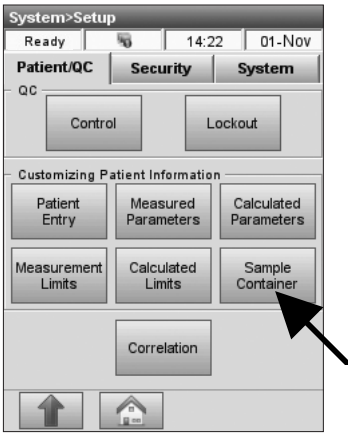


Fig. 3-45 Sample Container

This menu allows you to select a sample container when using the E-Lyte CCA cassette only.

1. In the main menu, select **<System Manager>** and **<Setup>**.
2. In the **<System Setup>** menu, press **<Sample Container>** on the **<Patient/QC>** tab (Fig. 3-45).

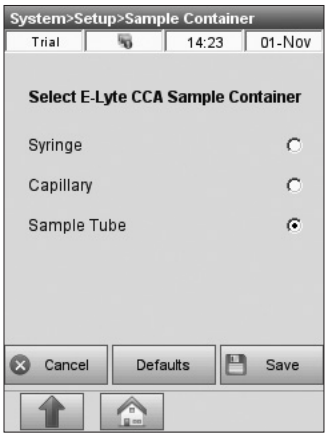


Fig. 3-46 Select Sample Container

3. Select your sample container (Fig. 3-46).
4. Press Save to accept the changes.

   You will also have the option to select a sample container during calibration.

5. Press  to return to the **<Setup>** screen or  to return to the main menu.

3.2.2.9 Setting up Correlation Factors

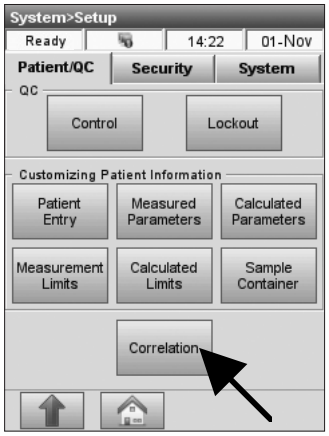


Fig. 3-47 Select Correlation

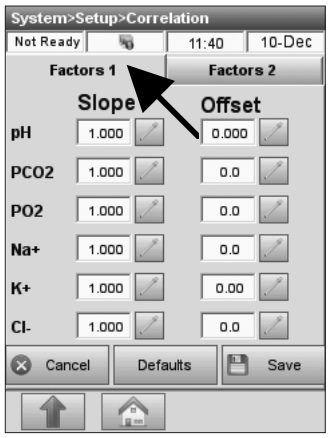


Fig. 3-48 Correlation Factors 1

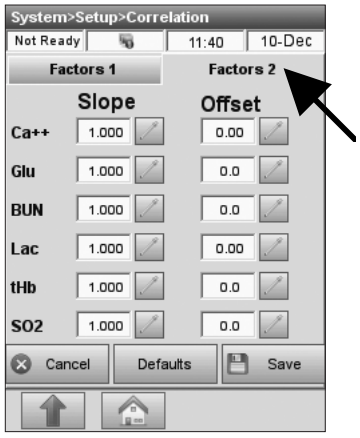


Fig. 3-49 Correlation Factors 2

Correlation factors let you correlate results from your OPTI CCA-TS2 to other analyzers. Correlation factors are available for all measured parameters.

NOTE: Slope is a multiplicative factor and Offset is an additive factor, using the following formula:
*Correlated value = Raw value * slope + offset.*

1. In the main menu, select **<System Manager>** and **<Setup>**.
2. On the **<Patient/QC>** tab, press **<Correlation>** (Fig. 3-47).
3. Select the numbers you want to change by pressing (Fig. 3-48). Enter the new numbers.
4. Press **<Factors 2>** to go to the next screen (Fig. 3-49).
5. When entering the actual offset value, select whether it is an additive or subtractive value using the +/- keys.

NOTE: The factory setting is 1.000 for all slopes and 0.0(00) for the offsets. This deactivates the correlation factors.

6. Continue through the other parameters, setting their correlation factors as above.
7. Press Save to accept the changes.
8. Press to return to the **<Setup>** screen or to return to the main menu.

CAUTION: *Since altering the correlation factors will alter your measurement results, be very careful to enter the correct values and confirm the settings by running at least 10 comparison measurements between the OPTI CCA-TS2 and the instrument to which it is to be correlated.*

3.2.3 Setting up Security

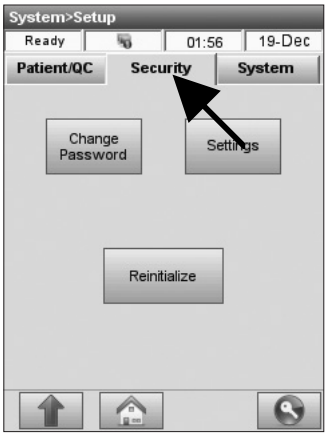


Fig. 3-50 Security

The OPTI CCA-TS2 has three types of security options (Fig. 3-50):

- **<Settings>** - Use this option to set up various security settings including User IDs and User Groups (See section 3.2.3.1).
- **<Change Password>** - Use this option to change your password while you are logged on (See section 3.2.3.2).
- **<Reinitialize>** - Use this option to delete the database and return to the system default settings (See section 3.2.3.3).

1. To access this menu, select **<System Manager>** and **<Setup>** in the main menu.
2. In the **<System Setup>** screen, press the **<Security>** tab (Fig. 3-50).

3.2.3.1 Selecting Security Settings

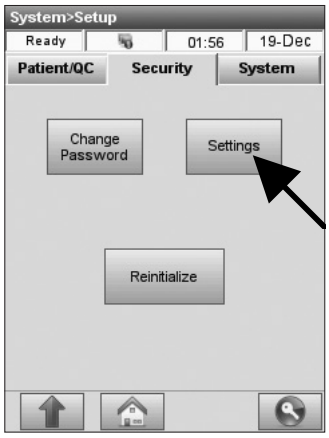


Fig. 3-51 Settings

The **<Settings>** menu contains three screens:

- **<Settings>** with various security options.
- **<Users>** to set up User IDs.
- **<Groups>** to set up User Groups.

1. Select **<System Manager>** and **<Setup>** in the main menu.
2. On the **<Security>** tab in the **<Setup>** menu, press **<Settings>** (Fig. 3-51) to access the **<Settings>** menu.

Fig. 3-52 Login

3. You will be asked to enter User ID and Password (factory setting ADMIN/ADMIN) (Fig. 3-52).

3.2.3.1.1 Security Settings

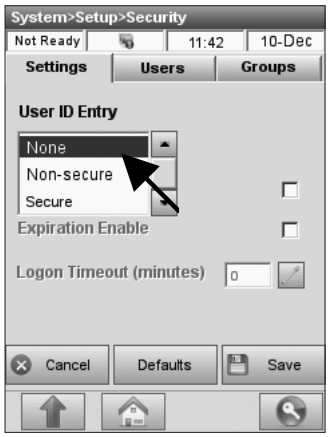


Fig. 3-53 Security Settings

Fig. 3-54 Non-secure User ID

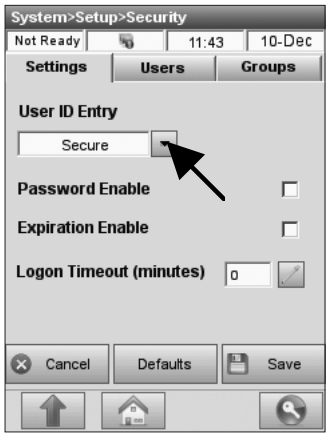


Fig. 3-55 Secure User ID

The **<Security Settings>** menu has various security options.

1. To disable all security options, select **<None>** in the **<User ID Entry>** drop-down box (Fig. 3-53). With all security disabled, the only menus that require user ID and password entry are the Fset (Factory Settings), Time/Date and Security Setup menus. Time/Date and Security Setup menus use the defaults **ADMIN/ADMIN**. FSet requires a different User ID and password.
2. The default security setting is **<Non-secure User ID Entry>** (Fig. 3-54). In this mode, the analyzer will request a user ID before patient testing, QC testing, maintenance activities and running an Hb calibrator. This mode will not verify a user ID and does not require programming of user IDs or groups. In this mode, some activities will still be protected by the **ADMIN** password, such as changing the time and date and the security setup menu.
3. **<Secure User ID Entry>** (Fig. 3-55) will enable the option to set up secure user IDs and create groups of users with certain privileges. This option must be selected to enable passwords and user ID expiration.

   When this option is enabled, users will be asked to log in to the OPTI before they can perform any operations. The OPTI will verify the login and only allow the user to perform duties assigned to that user. Logins can be by user ID only.

   The user ID can be entered by bar code scanner for easy access. Once logged in, the OPTI will enter the user ID for all activities performed by the user automatically.

   - For added security, you can enable passwords by selecting **<Password Enable>**. When users first log in to the OPTI, they will be asked to enter a password (system default PASSWORD). For future login, they will be required to enter user ID and password.

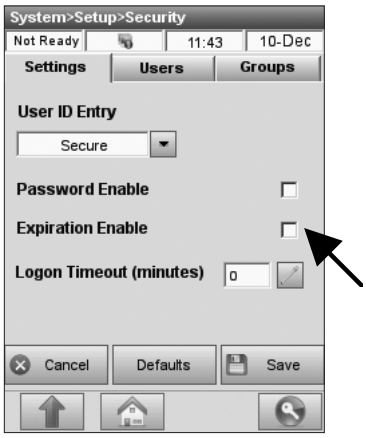


Fig. 3-56 Expiration

- **<Expiration Enable>** (Fig. 3-56) allows an administrator to set an expiration date for each user ID.
- **<Logon Timeout>** (Fig. 3-56). When security is enabled, users must log in to the analyzer. When they are finished, they must either log off using the **<Log Off>** button  in the bottom right corner, or the analyzer can be set to log off automatically after a set number of minutes of idle time. Set the **<Logon Timeout>** to 0 to disable it.

3.2.3.1.2 Setting up User IDs

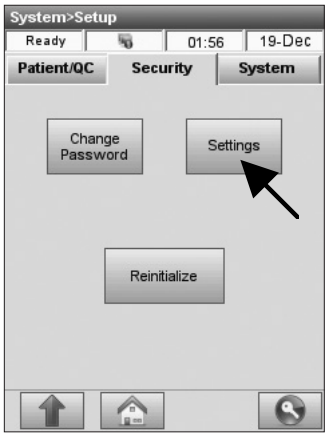


Fig. 3-57 Settings

The **<Users>** menu is used to set up user Identifications.

1. To access this menu, select **<System Manager>Setup>Security>** from the main menu.
2. On the **<Security>** tab, press **<Settings>** (Fig. 3-57).

Fig. 3-58 Users

3. Select the **<Users>** tab (Fig. 3-58).

   The default user ID is **ADMIN**. The **ADMIN** user ID cannot be deleted, changed and cannot expire. The default password for the **ADMIN** user ID is **ADMIN**. To change this password, log in as **ADMIN** and go to **<Change Password>** in the security tab (see Section 3.2.3.2).

NOTE: You can create another user ID with ADMIN rights, if you do not wish to use ADMIN as your user ID.

4. Press  (Fig. 3-58) to enter a new user to be added to the list of authorized users.
   The analyzer can store up to 300 user IDs.

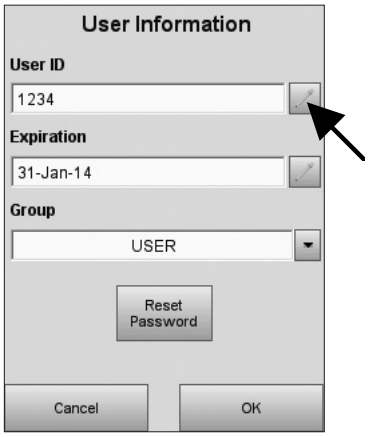


Fig. 3-59 User Information

5. In the **<User Information>** screen (Fig. 3-59), press to enter the user ID (up to 25 characters).
6. If **<Expiration>** is selected in the setup menu, enter an expiration date for the user ID.
7. You can add the user to pre-configured **<Groups>** at this time, or you can do this later, once custom groups have been created (see Section 3.2.3.1.3)

   The first time users log in to the OPTI, they will be asked to create a password.

Fig. 3-60 Users

8. To edit an existing user, select the user (Fig. 3-60) and press to make the changes. Press **<Reset Password>** (Fig. 3-59) to reset the user's password.
9. To delete a user from the list of valid users currently stored in memory, select the user and press the button.
10. Press to select all entries.
11. Press the button to print the list of all users currently stored in memory.
12. Use the **<Previous>** and **<Next>** buttons to display the previous or next page of user IDs.

3.2.3.1.3 Setting up User Groups

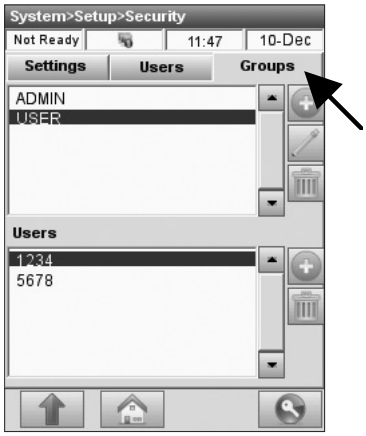


Fig. 3-61 Groups

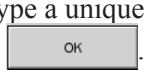
The **<Groups>** menu is used to set up user groups and assign group permissions to perform specific functions on the analyzer.

1. Select the **<Groups>** tab in the **<System> Setup>Security>** menu (Fig. 3-61).

   There are 2 system default user groups:

   - The **ADMIN** group has access to all functions except FSet in the analyzer. This user group cannot be changed or deleted, however, other users may be added to the **ADMIN** group.
   - A **User** group has also been set as a default. This group may be edited or deleted.

2. To add a new user group, press  in the top section of the screen (Fig. 3-61).

3. In the subsequent screen (Fig. 3-62), press  and type a unique name for the user group. Press  .

4. To assign group functions to a user group, press **<Functions>** (Fig. 3-62).

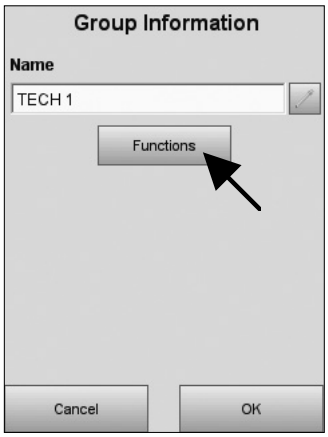


Fig. 3-62 Enter Group Name

- The top half of the **<Select Group Functions>** screen (Fig. 3-63) displays all available options, the bottom half shows the selected options.

5. To add group functions, select the desired option from the top menu and press the blue **<Down>** arrow  to move this option to your list in the selection field on the bottom.

   The default options for user group functions are:

   Patient Measurement
   Control Measurement
   SRC Measurement
   tHb Calibrator
   Perform Maintenance
   Control Setup

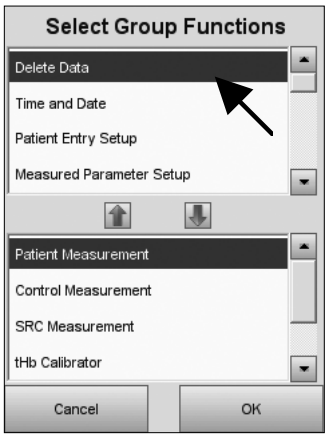


Fig. 3-63 Group Functions

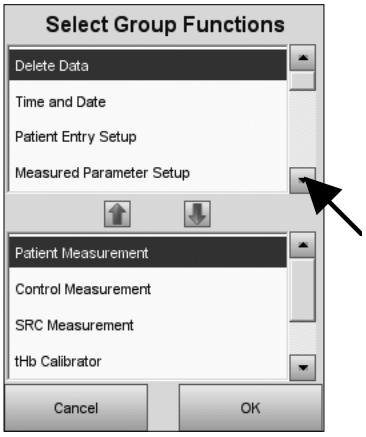


Fig. 3-64 Select Group Functions

6. Scroll down for the following additional options (Fig. 3-64):

   Delete Data
   Time and Date
   Patient Entry Setup
   Measured Parameter Setup
   Calculated Parameter Setup
   Measurement Limits Setup
   Calculated Parameter Limits Setup
   Correlation Factor Setup
   Units Setup
   Hardware Setup
   Ethernet Setup
   Communications Setup
   Lockout Setup
   Language Setup
   Printer Setup
   Maintenance Setup
   Security Setup
   B-Lac Setup

7. To remove options from your list, select the option and press the **<Up>** arrow.
8. Press OK to accept the changes.

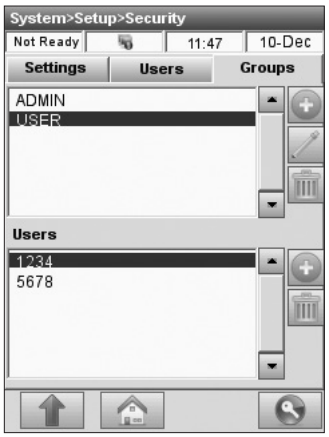


Fig. 3-65 User Groups

9. To add users to this group, press in the **<Users>** section in the bottom half of the screen (Fig. 3-65).
10. To delete a user from a user group, select the user and press the button.
11. To edit an existing user group, select the group in the **<Group>** section in the top half of the screen, and press to make the changes.
12. To delete a user group from the list, select the group and press the button.
13. Press to return to the **<Setup>** screen or to return to the main screen.

3.2.3.2 Setting up a Password

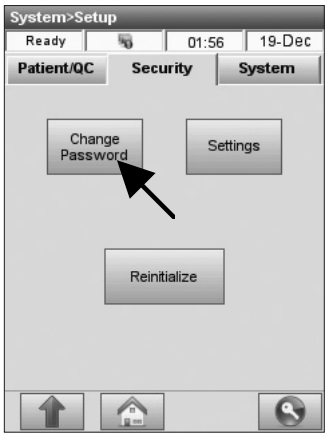


Fig. 3-66 Change Password

Fig. 3-67 Enter Password

The OPTI CCA-TS2 has a password function which, when activated, will require entry of a valid password to log in.

The factory default user ID and password is **ADMIN**. The factory-set password can be changed to any number/letter combination (up to 25 alphanumeric characters).

1. In the main menu, select **<System Manager>** and **<Setup>**.
2. On the **<Security>** tab, press **<Change Password>** (Fig. 3-66).

NOTE: This function is only active if security and password are enabled, and the user is logged in.

3. Press  to enter the new password (Fig. 3-67).
4. Retype the password and press  to accept the changes.

CAUTION: *Make sure the password is kept confidential and in a safe place. Passwords can not be retrieved!*

5. Press  to return to the **<Setup>** screen or  to return to the main screen.

3.2.3.3 System Reinitialization

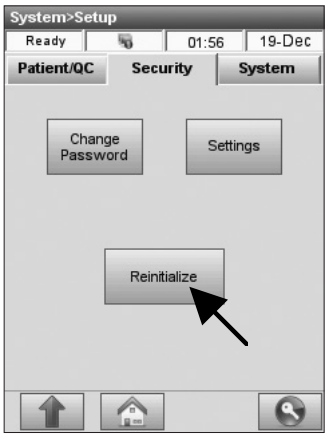


Fig. 3-68 Reinitialize

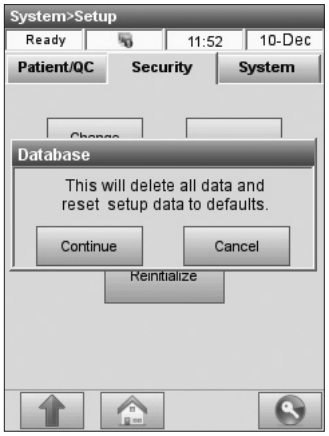


Fig. 3-69 Reinitialize

Reinitializing the system returns all programmed options to their factory-set (default) values and deletes all patient and QC values. Please make sure that all valuable data has been backed up before reinitialization. The OPTI analyzer configuration may be downloaded and then reloaded after reinitialization to restore user IDs, groups and other setup options. See section 6.4.2 for instructions.

1. In the main menu, select **<System Manager>** and **<Setup>**.
2. In the **<System Setup -> Security>** menu, press **<Reinitialize>** (Fig. 3-68).
3. Enter **ADMIN** user ID and password.
4. A message will be displayed asking you to confirm your choice (Fig. 3-69).
5. Press  to return to the **<Setup>** screen or  to return to the main screen.

3.2.4 Miscellaneous System Settings

3.2.4.1 Setting the Printer

Fig. 3-70 Select Printer

The **<Printer>** menu allows you to program the printing functions of your analyzer.

It contains three submenus: **<Settings>**, **<Header>** and **<Configuration>**.

1. In the main menu, select **<System Manager>** and **<Setup>**.
2. In the **<System Setup>** menu, press the **<System>** tab and then **<Printer>** (Fig. 3-70).

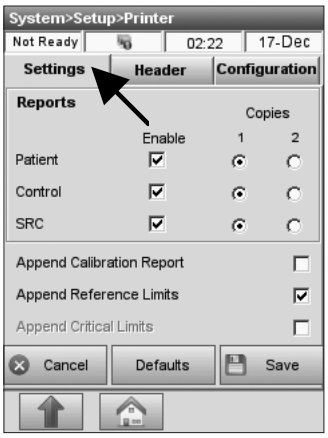


Fig. 3-71 Printer Settings

In the **<Settings>** tab (Fig. 3-71), you can enable printing of a patient, control or SRC report after each measurement. In the default settings, these options are activated.

You can also select to add a calibration report and reference and critical limits to each patient report.

1. Select the options to be enabled.
2. Press Save to accept the changes.
3. Press to return to the **<Setup>** screen or to return to the main menu.

NOTE: Reference and Critical limits must be enabled in <Measurement Limit> setup in order to be able to configure printing of these limits.

Fig. 3-72 Header

In the **<Header>** menu (Fig. 3-72), you can add custom headers to your printed reports.

1. Select **<Custom Header Enable>**, press and enter the custom header.
2. Press Save to accept the changes.
3. Press to return to the **<Setup>** screen or to return to the main menu.

Fig. 3-73 Printer Configuration

The OPTI CCA-TS2 can be connected to an external networked printer. In the **<Configuration>** tab (Fig. 3-73), you can select the printer configuration.

1. Select **<External Printer>** or **<Both Printers>**.
2. Enter the **<Printer Port>**. Ask your network administrator if you are unsure of the value.
3. Enter the **<Printer IP Address>**. Ask your network administrator if you are unsure of the value.
4. Press Save to accept the changes.
5. Press to return to the **<Setup>** screen or to return to the main menu.

3.2.4.2 External Serial Printer

Fig. 3-74 Printer Setting Japanese

This feature is only supported when Japanese language is selected and when using the Epson TM-U295 printer.

1. In the main menu, select **<System Manager>** and **<Setup>**.
2. In the **<System Setup>** menu, press the **<System>** tab and then **<Printer>** (Fig. 3-74).

Fig. 3-75 External Printer

3. On the **<Configuration>** tab (Fig. 3-75), select **<External Printer>**.
4. Insert the USB end of an approved USB-to-Serial adapter into the OPTI Type A USB port.
5. Connect the serial end of the USB-to-Serial adapter to the Epson printer cable.
6. Follow the printer instructions for connecting the Epson printer cable to printer and power.
7. On the bottom of the Epson TM-U295 printer there is a set of dip switches. All switches should be in the **OFF** position except for 1 and 3. These should be **ON**. Refer to the printer manual for details.
8. The External Epson Serial Printer is now ready for use.

3.2.4.3 Defining Units

Fig. 3-76 Select Units

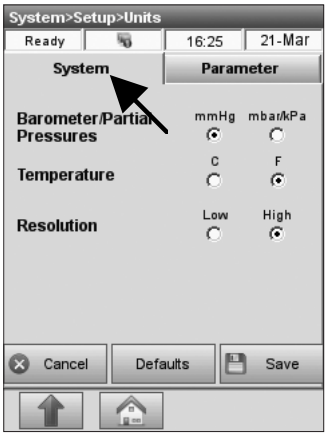


Fig. 3-77 System

This menu lets you change the units of measure for pressure, temperature, output resolution, total hemoglobin, Ca^{++}, Glu, BUN (urea) and Lac.

1. In the main menu, select **<System Manager>** and **<Setup>**.
2. In the **<System Setup>** menu, press the **<System>** tab, then press **<Units>** (Fig. 3-76).
3. In the **<System>** screen, select the units for the displayed parameters (Fig. 3-77).
4. The selection for **<Resolution>** on this menu determines the number of digits displayed and printed past the decimal point, for all measured parameters.

NOTE: The selection applies to patient sample results only. By default, the resolution for patient samples is high.
Resolution is always high for Control and SRC results.

Resolution examples are shown in the following table:

	Low	**High**
•	pH 7.34	pH 7.341
•	PCO_2 43 mmHg	PCO_2 43.2 mmHg
•	PO_2 87 mmHg	PO_2 86.8 mmHg
•	Na^+ 143 mmol/L	Na^+ 143.3 mmol/L
•	K^+ 4.6 mmol/L	K^+ 4.57 mmol/L
•	Cl^- 103 mmol/L	Cl^- 103.1 mmol/L
•	Ca^{++} 1.21 mmol/L	Ca^{++} 1.21 mmol/L
•	Glu 100.5 mg/dL	Glu 100.5 mg/dL
•	BUN 18.5 mg/dL	BUN 18.5 mg/dL
•	Lac 14.51 mmol/L	Lac 14.51 mmol/L
•	tHb 14.6 g/dL	tHb 14.6 g/dL
•	SO_2 99 %	SO_2 99.8 %

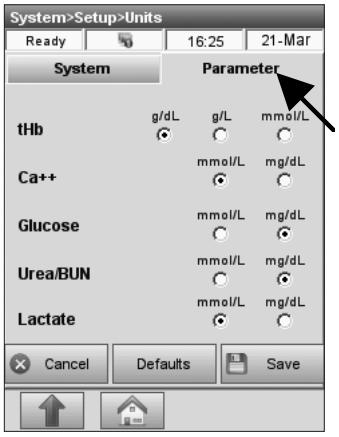


Fig. 3-78 Parameters

5. Press the **<Parameter>** tab to go to the next screen (Fig. 3-78), and select the units for the remaining parameters.

Your OPTI CCA-TS2 has been factory preset to the following units:

- Baro/Partial Pressure mmHg
- Temperature °C
- Resolution High
- tHb g/dL
- Ca^{++} mmol/L
- Glucose mg/dL
- Urea/BUN mg/dL
- Lactate mmol/L

6. Press Save to accept the changes.
7. Press  to return to the **<Setup>** screen or  to return to the main menu.

3.2.4.4 Selecting a Language

Fig. 3-79 Select Language

This menu lets you choose the language you want the OPTI CCA-TS2 to use for displays and printouts.

1. In the main menu, select **<System Manager>** and **<Setup>**.
2. In the **<System Setup>** menu, press the **<System>** tab and then **<Language>** (Fig. 3-79).

Fig. 3-80 Select Language

3. Select the desired language (Fig. 3-80).
4. Press Save to accept the changes.
5. Press to return to the **<Setup>** screen or to return to the main menu.

3.2.4.5 Hardware Settings

The **<Hardware>** menu is used to adjust the local barometric pressure, the audible alarm, and standby mode.

3.2.4.5.1 Entering the Barometric Pressure

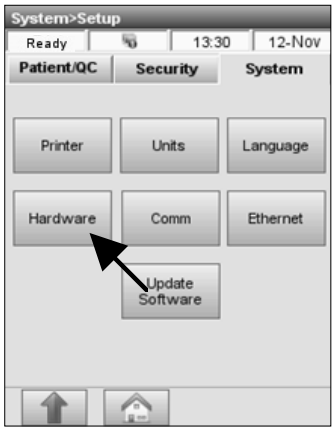


Fig. 3-81 Select Hardware

To adjust the tracking barometer within the OPTI CCA-TS2, follow the instructions below:

1. In the main menu, select**<System Manager>** and **<Setup>**.
2. In the **<System Setup>** menu, press the **<System>** tab and then **<Hardware>** to select this function (Fig. 3-81).

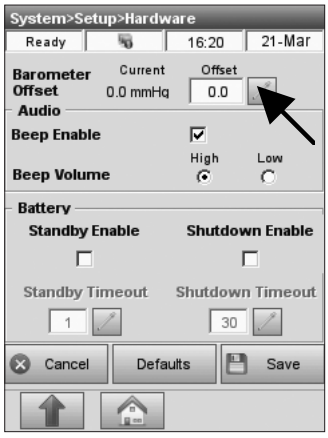


Fig. 3-82 Barometric pressure

3. Press  to enter an offset from the true barometric pressure (Fig. 3-82).
4. Type in the new numbers and press 

to accept the changes.
5. Press  to return to the **<Setup>** screen or  to return to the main menu.

CAUTION: *Use the absolute barometric pressure and not the altitude-corrected pressure (check with your local weather service or airport).*

NOTE: You may change barometric pressure units from mmHg to mbar (See section 3.2.4.2).

NOTE: You should check the barometric pressure periodically.

3.2.4.5.2 Beep Adjustment

Fig. 3-83 Enable Beep

This option lets you adjust the volume of the audible alarm (Beep).

1. In the main menu, select **<System Manager>** and **<Setup>**.
2. In the **<System Setup>** menu, press the **<System>** tab and then **<Hardware>**.
3. Select **<Beep Enable>** (Fig. 3-83).
4. Select **<High>** or **<Low>** for **<Beep Volume>**.
5. Press Save to accept the changes.
6. Press to return to the **<Setup>** screen or to return to the main menu.

3.2.4.5.3 Standby

Fig. 3-84 Standby

This menu allows you to select options that will help conserve power to extend battery life. These options are only active if the analyzer is operated from the battery.

1. In the main menu, select **<System Manager>** and **<Setup>**.
2. In the **<System Setup>** menu, press the **<System>** tab and then press **<Hardware>**.
3. In the **<Hardware>** screen, select the following options (Fig. 3-84):
   - **<Standby Enable>** - If this mode is enabled, the system will automatically go into Standby after a certain time of analyzer inactivity. When you enable this option you can select the number of minutes before the OPTI will go into standby mode.

     NOTE: The screen will appear dark when the analyzer is in standby mode. Press the touch screen to exit standby mode and resume normal operation.
   - **<Shutdown Enable>** will shut down the instrument after a certain time period of analyzer inactivity to conserve power. When you enable this option you can select the number of minutes before the OPTI will shut down. To restart, push the power button.
4. Press 

to accept the changes.
5. Press  to return to the **<Setup>** screen or  to return to the main menu.

3.2.4.6 Setting up Communications

Fig. 3-85 Communications

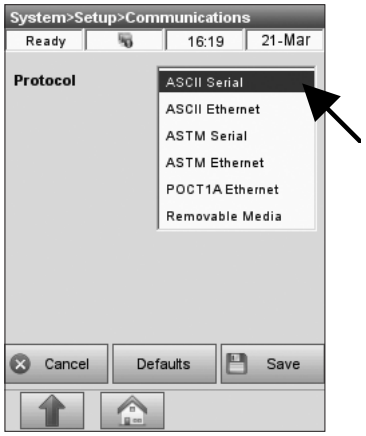


Fig. 3-86 Select Protocol

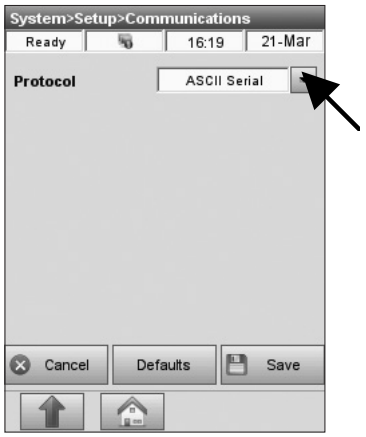


Fig. 3-87 ASCII Serial

The OPTI CCA-TS2 has a USB Type B port for serial communications and an Ethernet port that may be used to communicate with a remote computer. These ports may be selected to transmit data in ASCII, ASTM or POCT1 format.

A USB Type A port may be selected for exporting data to a removable mass storage device.

CYBER SECURITY NOTE:
When exporting data, patient information could be exposed to unauthorized users. Consult your IT security, before selecting a communication protocol.

1. In the main menu, select **<System Manager>** and **<Setup>**.
2. In the **<System Setup>** menu, press the **<System>** tab and then **<Comm>** (Fig. 3-85).

In the **<System->Setup->Communications>** screen (Fig. 3-86), you can select the communications **<Protocol>**:

- **<ASCII Serial>**
- **<ASCII Ethernet>**
- **<ASTM Serial>**
- **<ASTM Ethernet>**
- **<POCT1AEthernet>**
- **<Removable Media>**.

NOTE: ASCII will only work for languages that use a Latin based character set.

<ASCII Serial> (Fig. 3-87) - Data in easy to read OPTI Medical custom format. The OPTI CCA-TS2 exports data string identical to the internal printer output.

- Press Save to accept the changes.

NOTE: Only Latin-based characters are supported. Some characters may be different from the printout depending on the language selected.

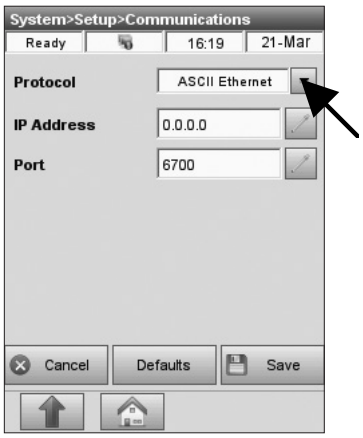


Fig. 3-88 ASCII Ethernet

<ASCII Ethernet> (Fig. 3-88) - Data in easy to read OPTI Medical custom format. The OPTI CCA-TS2 exports data string identical to the internal printer output.

- Enter IP address of the host computer and port.
- Press Save to accept the changes.

NOTE: Only Latin-based characters are supported. Some characters may be different from the printout depending on the language selected.

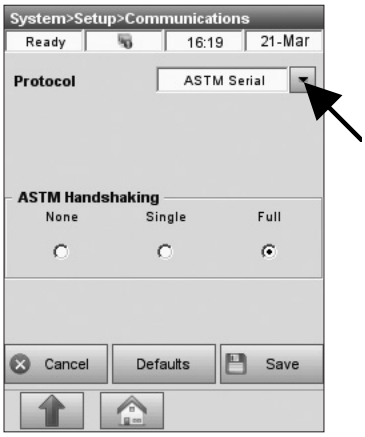


Fig. 3-89 ASTM Serial

<ASTM Serial> (Fig. 3-89) - Complies with ASTM standard. Please refer to OPTI CCA-TS2 interface specifications for more information.

- Select **<ASTM Handshaking>**.

  <None> – all data is sent without an acknowledgement.

  <Single> – communication is established and all data is sent in a single message with acknowledgment.

  <Full> – communication is established and each record is sent separately with an acknowledgement.

- Press Save to accept the changes.

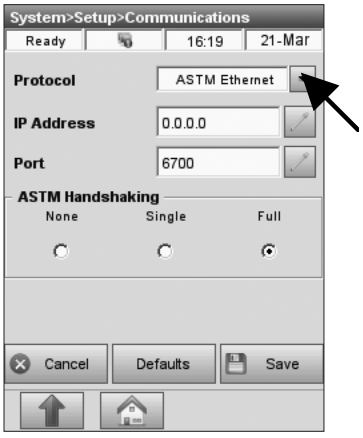


Fig. 3-90 ASTM Ethernet

<ASTM Ethernet> (Fig. 3-90) - Complies with ASTM standard. Please refer to OPTI CCA-TS2 interface specifications for more information.

- Enter IP address of the host computer and port.
- Select **<ASTM Handshaking>**.

  <None> – all data is sent without an acknowledgement.

  <Single> – communication is established and all data is sent in a single message with acknowledgment.

  <Full> – communication is established and each record is sent separately with an acknowledgement.

- Press Save to accept the changes.

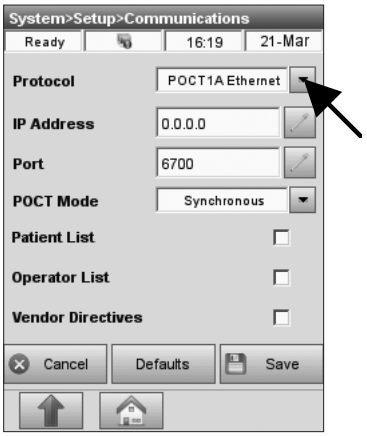


Fig. 3-91 POCT1AEthernet

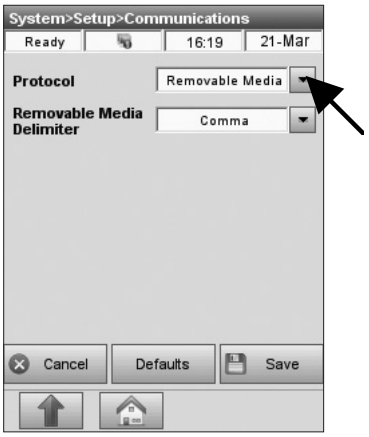


Fig. 3-92 Removable Media

<POCT1AEthernet> (Fig. 3-91) - Make the following selections:

<IP Address> – IP address of host computer

<Port> – Communication port number.

<POCT Mode> – Continuous or Synchronous

<Patient List> – If enabled, the patient list is sent from remote computer.

<Operator List> – If enabled, the Operator IDs are sent from remote computer.

<Vendor Directives> – If enabled, vendor directives are supported.

- Press Save to accept the changes.

<Removable Media> (Fig. 3-92) -
Use this option to export data using a USB mass storage device.

- Select **<Comma>** or **<Semicolon>** for your CSV file delimiter in MS Excel.
- Press Save to accept the changes.
- Press to return to the **<Setup>** screen or to return to the main menu.

3.2.4.7 Configuring Ethernet Settings

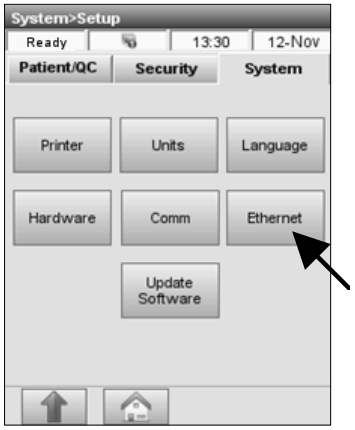


Fig. 3-93 Ethernet

The **<Ethernet>** screen is used to configure Ethernet settings required for discovery and set the IP address if static.

1. In the main menu, select **<System Manager>** and **<Setup>**.
2. In the **<System Setup>** menu, press the **<System>** tab and then **<Ethernet>** (Fig. 3-93).

Fig. 3-94 Ethernet Settings

3. The **<System>Setup>Ethernet>** menu will appear (Fig. 3-94).

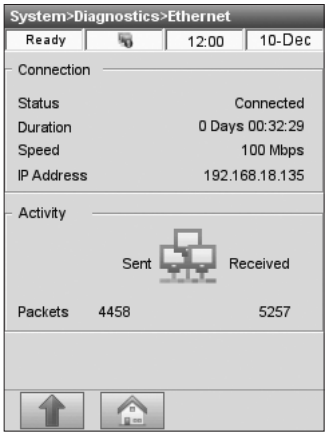


Fig. 3-95 Ethernet Test

To set up Ethernet communication:

1. Connect the instrument to an active network.
2. In the main menu, select **<System Manager> Diagnostics>Tests>Ethernet>**.
3. Verify that the test status is **<Connected>** and that the displayed instrument IP address is valid (not all zeros) (Fig. 3-95).

Fig. 3-96 Ethernet Settings

4. Go back to the **<System>Setup>Ethernet>** screen (Fig. 3-96) and fill in the following fields as needed:

   <IP Type> – choose static or dynamic IP Type.

   <IP Address> – static IP address of the instrument. Enter the IP address, if IP type is set to static. Ask your network administrator if you are unsure of the value.

   <Subnet Mask> – Enter the subnet mask, if IP type is set to static. The subnet mask is specific to your network. Ask your network administrator if you are unsure of the value.

   <Gateway> – Enter the gateway address, if IP type is set to static. The gateway address is network specific. Ask your network administrator if you are unsure of the value.

   <Discovery Port> – is used for instrument discovery. Use for static and dynamic IP types. The discovery port is set to 6703 by default, but can be changed if needed.

NOTE: If static IP type is selected, the instrument IP address and Gateway need to be on the same network to communicate.

5. Press Save to accept the changes.
6. Press  to return to the **<Setup>** screen or  to return to the main menu.

When network connection is enabled, the status bar displays the network icon  (Fig. 3-96).

3.2.4.8 Software Update Instructions

Fig. 3-97 Update Software

Fig. 3-98 Login

Fig. 3-99 Software Update

Software Version 1.11 and later

1. Insert the USB stick included with the upgrade kit into the type A USB port in the back of the instrument.
2. In the main menu, select **<System Manager>** and **<Setup>**.
3. In the **<System Setup>** menu, press the **<System>** tab and then **<Update Software>** (Fig. 3-97).

4. If you are not already logged in as administrator, the following login form will be displayed. Log in with administrator credentials and press OK (Fig. 3-98).

5. The following message box (Fig. 3-99) will be displayed while the software is being updated, which can take several minutes.

   Once the software is updated, the system will reboot.

6. After the system reboots, navigate to the **<Sensors>** tab on the **<System>Diagnostics>** menu and verify that the new software version is installed.

NOTE: Once software version 1.11 or later is installed, it is not recommended to downgrade to a version prior to release 1.11.

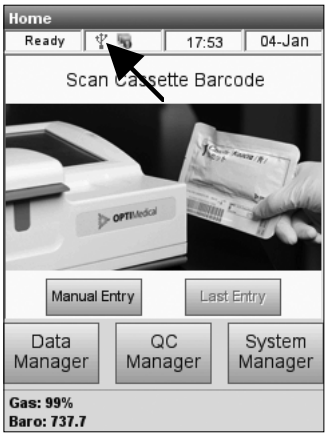


Fig. 3-100 Remove USB stick

Software Versions 1.10 and below

1. Insert the USB stick included with the upgrade kit into the type A USB port in the back of the instrument.
2. Cycle the power on the TS2.
3. Once the ready screen is displayed, press the USB icon on the status bar to safely remove the USB memory stick (Fig. 3-100).

3.2.5 Maintenance Setup

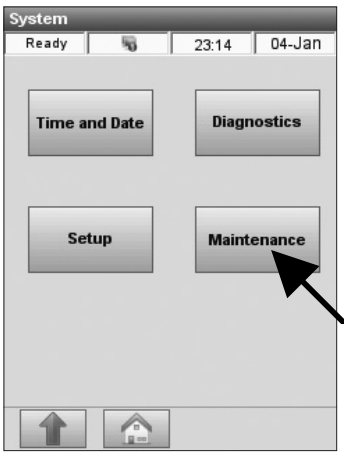


Fig. 3-101 Select Maintenance

This menu allows you to select maintenance reminder options for your analyzer.

Any maintenance actions that you perform through the maintenance reminders will be captured in the maintenance log of the analyzer.

1. From the **<Ready>** display, select **<System Manager>** and **<Maintenance>** (Fig. 3-101).
2. Enter User ID if enabled.

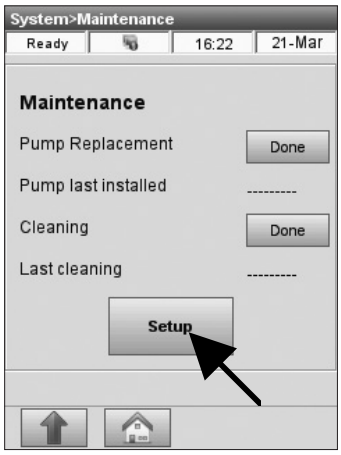


Fig. 3-102 Maintenance Setup

3. In the **<Maintenance>** menu (Fig. 3-102), press **<Setup>**.

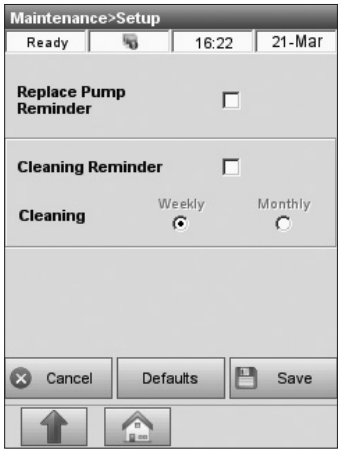


Fig. 3-103 Reminder Options

4. In the **<Setup>** screen (Fig. 3-103), you can select **<Replace Pump Reminder>** to alert you when the peristaltic pump needs replacement.
5. If you enable the option **<Cleaning Reminder>**, the system will alert you when weekly or monthly cleaning is due.

   Select **<Monthly>** cleaning if the analyzer is not used weekly.

   Refer to Chapter 7 for maintenance procedures.

4 CALIBRATION AND QUALITY CONTROL

4.1 Calibration

Each lot of OPTI cassettes is calibrated during the manufacturing process. The calibration is performed using high precision standard solutions and gravimetrically-prepared gas mixtures to determine the cassette's measurement characteristics at multiple points within the analyte's measurable range. Every cassette package is then labeled with a bar code containing this calibration information, as well as its lot number and expiration date.

Prior to running a sample, the cassette bar code is either entered manually or scanned into the analyzer by holding the cassette package in front of a conveniently located bar code scanner. The cassette is then installed and a calibration verification is performed according to the method described in Section 9.3 for each cassette style. In addition, an optical zero-point calibration of all optical channels is performed.

During the calibration and measurement processes, diagnostic tests are automatically performed to assure correct operation of the instrument and measurement of the cassette. These tests include automatic checks of the cassette for packaging integrity, temperature control, fluidic control during calibration, proper equilibrium behavior of the sensors during calibration and measurement, automatic detection of bubbles and short sample during aspiration, and automatic detection of low gas, low battery, dirty optics, or worn pump conditions.

Calibration of the tHb channel is required every 3 months. This calibration is performed using the tHb Calibration Cassette in a manner similar to other instruments that measure tHb and/or hemoglobin derivatives optically. The tHb calibration verifies the measurement optics and electronics and corrects any potential drift.

For more information, including detailed instructions, on the tHb calibration, see Section 7.3 "Quarterly Maintenance" in this manual.

4.2 QC Overview

The intent of a Quality Control program is to assure reliable patient values over the clinically significant ranges for all the measured parameters. The program should involve the total process of specimen collection, preparation and results analysis, reporting and interpretation, and the training of personnel involved in all of these processes.

A Quality Control program for blood gas analysis includes the analysis of materials with known values or ranges of expected values and the comparisons of the results from the analyzer with these values. This program allows the analytic performance of a laboratory to be evaluated and documented.

An effective Quality Control program should include:

- evaluation of precision over the entire analytical range
- an assessment of failure modes and their effects and means of management, throughout the process
- simple statistical calculations which provide a means of assessing precision
- control charts or graphs which contain warning limits to assist the technical staff in the evaluation of results
- a clear set of guidelines to assist the staff in determining if patient results are acceptable
- a clear set of corrective actions to be taken in "out-of-control" situations

4.3 Proficiency Testing

Proficiency testing complements the above Quality Control program and has become an integral part of a complete laboratory Quality Assurance program. The analysis of unknown samples demonstrates that your results are unbiased by previous experience and these samples more closely reflect the testing of patient samples. Proficiency testing may also serve to expand your Quality Control testing by providing samples with different levels of analytes than those measured in the daily testing program.

The relative testing performance of each laboratory participating in the proficiency survey is determined by comparing test results obtained from a significantly large group of laboratories using the same or similar instrumentation.

CAUTION: *Use proficiency material that is clear.*
Do not use material that contains dyes or emulsions.

The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) has published a protocol for establishing a quality assurance program. The Health Care Financing Administration (HCFA) and the Clinical and Laboratory Standards Institute (CLSI formerly NCCLS) have published standards for quality assurance in medical laboratories.

4.4 Calibration Verification

Calibration verification allows for the validation of the blood gas analyzer's ability to recover known values at various points within the reportable range of all parameters and may be required by various regulatory agencies.

The OPTI CCA-TS2 Analyte Section, included in the back section of this manual, provides precision and recovery data for all the measured parameters in the ranges that are usually encountered in the diagnostic testing of patients.

A calibration verification kit is available from OPTI Medical for all parameters except tHb and SO_2. For calibration verification of tHb and SO_2, OPTI Medical recommends testing whole blood against a reference analyzer.

4.5 QC Recommendations

The multi-level Standard Reference Cassette (SRC) should be used as a control for the OPTI CCA-TS2 analyzer. The SRC contains a stable optical sensor simulator which is measured by the device in exactly the same manner as any other cassette and provides assurance that all parameters measured by the analyzer are consistent. The OPTI will subject the SRC sensors to different levels of light to simulate low, normal and high patient measurements. Level 1 and level 3 represent high and low samples and are the system default settings based on the OPTI Medical QC recommendations. The results obtained should fall within limits contained in the SRC barcode.

NOTE: Hospitals should develop their own policy and procedures on the number of QC samples to be run on a daily basis as mandated by the regulatory agency under which they operate.

After receipt of a shipment of cassettes and at monthly intervals thereafter, validation should be performed by analysis of OPTI CHECK or OPTI CHECK PLUS Blood Gas Controls. These materials should provide target values for all measured parameters over a range of measurement values typically seen in each testing site laboratory. The results obtained should fall within limits defined by the day-to-day variability as measured in the user's laboratory facility.

OPTI Medical recommends the following as a minimum testing frequency of QC materials:

Control	**Frequency**
SRC levels 1 and 3	At least 1x per day in operation
OPTI Check or OPTI Check Plus Liquid Controls	1 month intervals and with each new shipment of cassettes.

4.5.1 Running an SRC Measurement

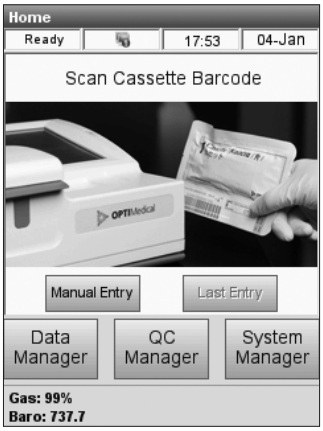


Fig. 4-1 Scan Barcode

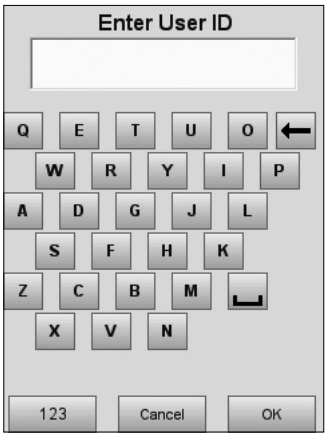


Fig. 4-2 Enter User ID

Fig. 4-3 New SRC Lot

OPTI Medical Systems recommends running levels 1 and 3 (high and low values) of the Standard Reference Cassette (SRC) as a daily quality control for the OPTI CCA-TS2 analyzer.

1. In the main menu, scan the bottom bar code on the SRC package by holding it 2-3 inches (5-8 cm) from the bar code scanner located on the bottom right-hand corner of the analyzer (Fig. 4-1).

NOTE: Instead of scanning the barcode in the main menu, SRC measurements can also be run from the QC menu by pressing <QC Manager>QC>SRC>.

- The red line from the bar code scanner should cover the entire bar code.
- A beep indicates a valid bar code.
- A red status light indicates an invalid bar code (e.g. SRC expired).

NOTE: If the bar code is damaged or unreadable, press <Manual Entry> *and enter the bar code digits using the keypad.*

2. If **<Non Secure User ID Entry>** is enabled in the security settings (see Section 3.2.3), you will be asked to enter the user ID (Fig. 4-2).

NOTE: Bar-coded user IDs may be entered from this screen using the bar code scanner.

3. A warning will be displayed when a new SRC lot is used (Fig. 4-3). Press **<Continue>**.

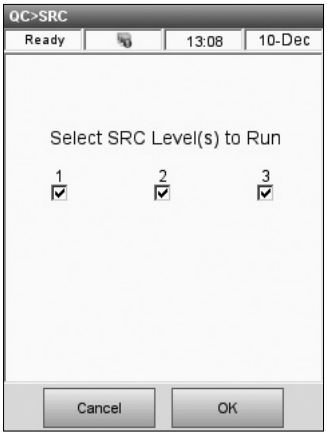


Fig. 4-4 Select Level

4. Select the desired levels (Fig. 4-4) and press OK.

Fig. 4-5 Open Cover

5. Open the sample chamber cover by pressing down on the center of the red latch (Fig. 4-5).

Fig. 4-6 Insert SRC

6. Examine the SRC to ensure it is clean and insert it into the chamber. Press down to properly seat the SRC (Fig. 4-6).

Fig. 4-7 Close Cover

7. Close the sample chamber cover (Fig. 4-7).

Fig. 4-8 SRC Measurement

- After the cover has been closed, the instrument begins the measurement process which is indicated on the display screen (Fig. 4-8). During this time (about 60 seconds per level), a progress bar is displayed.

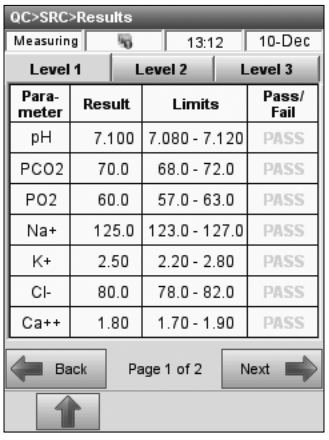


Fig. 4-9 SRC Results (1)

- When the measurement is complete, the unit displays the results (Fig. 4-9).

8. Press Next to display additional results (Fig. 4-10).

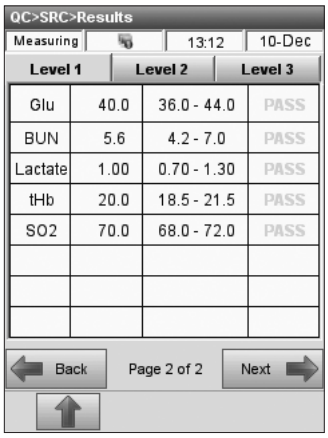


Fig. 4-10 SRC Results (2)

Fig. 4-11 Remove the cassette

9. Press the **<Level 2>** and **<Level 3>** tabs to display the results for the respective levels.

NOTE: If SRC measurements are completed prior to running cassettes with liquid controls, all analytes will be displayed. To reduce the displayed analytes, run liquid controls on the desired cassette styles

- The unit automatically checks the results against the ranges and stores the results in its internal database.
- For parameters within range, **<Pass>** will be displayed and printed.
- For parameters out of range, or if an internal drift is detected, **<Fail>** will be displayed.

NOTE: The printout will start automatically when the first results are displayed. This feature may be turned off in setup (See Section 3.2.4.1). Additional information on printing reports can be found in Chapter 6, Data Management.

10. Press  (Fig. 4-10) to exit the results screen.
11. You will then be prompted to open the sample chamber cover and remove the SRC (Fig. 4-11).
12. Place the SRC back into its pouch immediately after removal from the instrument.
13. Close the sample chamber cover.
    - If the SRC test failed, gently clean the SRC, the optics window, and the inside cover of the SMC with alcohol and a lint-free cloth and repeat this process. If it fails again, refer to the troubleshooting section in Chapter 8 of this manual.

NOTE: For application of QC Lockout, please refer to section 3.2.1.2.

NOTE: Verify with your particular regulatory agency and your internal policy regarding number of levels and frequency of SRCs to be run.

4.5.2 Running a QC Sample

Policies regarding the measurement of QC samples are at the discretion of the individual hospital. OPTI Medical Systems recommends that QC solutions be run, as a minimum, with each new lot number of cassettes and at monthly intervals thereafter.

You should only use the manufacturer recommended controls OPTI CHECK and OPTI CHECK PLUS which do **NOT** contain dye or other colored material. Whenever a new lot of controls is opened, be sure to enter the lot number information into the analyzer as described in Chapter 3 "Customization".

NOTE: Store controls at temperature recommended by the manufacturer

NOTE: The target value of PO_2 is very sensitive to storage conditions and barometric pressure. High altitude environments may see recovery outside the target range.

The control material should provide target values for all measured parameters over a range of measurement values typically seen in a laboratory. The results obtained should fall within limits established by the user's laboratory.

4.5.2.1 Running Controls (OPTI CHECK, OPTI CHECK PLUS)

Fig. 4-12 Select QC-Manager

1. To run controls, press **<QC Manager>** in the main menu (Fig. 4-12), and select **<Control>** in the **<QC>** menu.

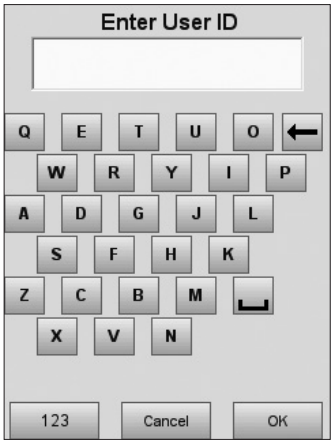


Fig. 4-13 Enter User ID

2. If **<Non Secure User ID Entry>** is enabled in the security settings (see Section 3.2.3), you will be asked to enter the user ID (Fig. 4-13).

NOTE: Bar-coded user IDs may be entered from this screen using the bar code scanner.

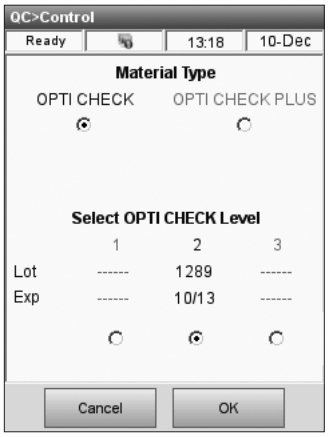


Fig. 4-14 Select QC Level

3. Select the desired level (Fig. 4-14) and press OK.

NOTE: If a new lot number of QC material is used, make sure the ranges have been entered into the system prior to running a sample. (See Section 3.2.1.1).

4. Scan the bar-coded strip on the OPTI Cassette package by holding it 2-3 inches (5-8 cm) from the bar code scanner located on the bottom right-hand corner of the analyzer to automatically record the lot and calibration information for the specific cassette (Fig. 4-15).

   - The red line from the barcode scanner should cover the entire bar code.
   - The unit will beep and the status light will turn green to confirm a valid bar code.
   - In case of an expired cassette, the light will turn red.

Fig. 4-15 Scan Bar Code

NOTE: If the bar code is damaged or unreadable, press <Manual Entry> *and enter the bar code digits printed on the bar code label using the numeric keypad.*

NOTE: A control measurement may be made using any cassette lot or cassette type.

Fig. 4-16 Open Cover

5. Open the sample chamber cover by pressing down on the center of the red latch (Fig. 4-16).

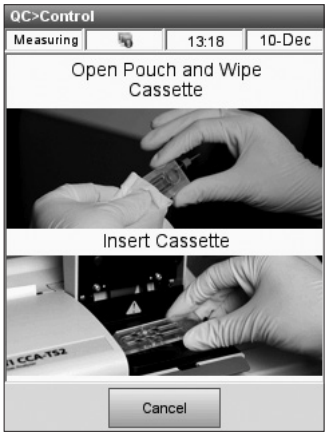


Fig. 4-17 Insert Cassette

6. Tear open the cassette pouch and remove the cassette. Wipe any excess moisture from the cassette with a clean dry cloth.

NOTE: If the QC sample is to be introduced with a capillary tube, remove the syringe adapter before placing the cassette into the chamber.

7. Insert the cassette into the chamber. Press down to ensure that the cassette is seated properly (Fig. 4-17).

NOTE: Run cassettes immediately after opening pouch. Do not run, if cassette has been out of pouch for more than 15 minutes (2 minutes for B-Lac cassettes).

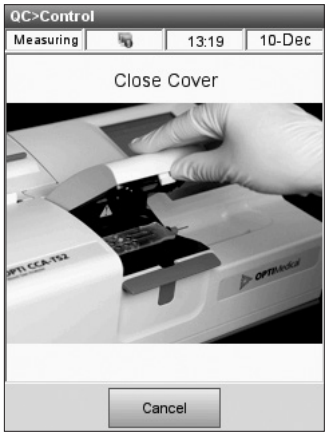


Fig. 4-18 Close Cover

8. Close the SMC cover (Fig. 4-18).

Fig. 4-19 B-Lac Open Cover

Fig. 4-20 B-Lac Open Pouch

Fig. 4-21 B-Lac Close Cover

B-Lac Cassettes

- Open the sample chamber cover by pressing down on the center of the red latch (Fig. 4-19).

NOTE: For B-Lac cassettes, out-of-storage warnings will be displayed (Figs. 4-19 - 4-21). This function is enabled by default and can be disabled in the System>Setup menu (see Section 3.2.2.2.)

- The contents of the cassette package are stable when stored at 2-8°C (35-46°F) until the expiration date printed on the label. Allow cassettes to equilibrate at room temperature for 1 hour prior to use.
- Cassettes that are in use may be left at room temperature (18-30°C or 64-86°F) for 4 weeks; however, cassettes should not be refrigerated again after they have been left at room temperature for 1 hour or more.
- Tear open the cassette pouch and remove the cassette (Fig. 4-20).

NOTE: If the QC sample is to be introduced with a capillary tube, remove the syringe adapter before placing the cassette into the chamber.

- Insert the cassette into the chamber. Press down to ensure that the cassette is seated properly (Fig. 4-20).

NOTE: Run B-Lac cassettes immediately after opening pouch. Do not run, if cassette has been out of pouch for more than 2 minutes.

- Close the SMC cover (Fig. 4-21).

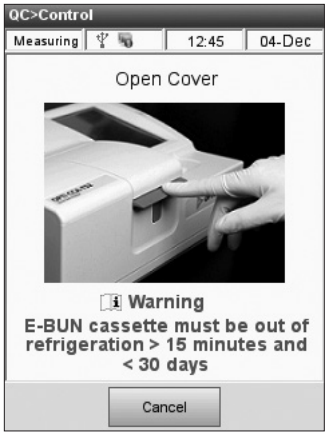


Fig. 4-22 E-BUN Open Cover

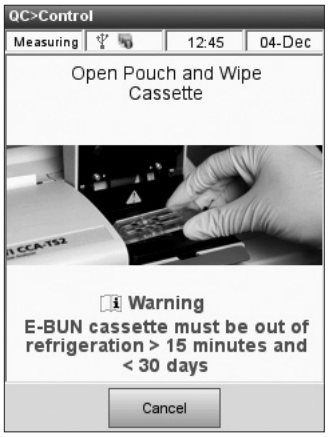


Fig. 4-23 E-BUN Open Pouch

Fig. 4-24 E-BUN Close Cover

E-BUN Cassettes

- Open the sample chamber cover by pressing down on the center of the red latch (Fig. 4-22).

NOTE: For E-BUN cassettes, out-of-storage warnings will be displayed (Figs. 4-22 - 4-24). This function is enabled by default and can be disabled in the System>Setup menu (see Section 3.2.2.2.)

- The contents of the cassette package are stable when stored at 2-8°C (35-46°F) until the expiration date printed on the label. Allow cassettes to equilibrate at room temperature for 15 minutes prior to use.
- Cassettes that are in use may be left at room temperature (18-30°C or 64-86°F) for 30 days; however, cassettes should not be refrigerated again after they have been left at room temperature for 15 minutes or more.
- Tear open the cassette pouch and remove the cassette (Fig. 4-23). Wipe any excess moisture from the cassette with a clean dry cloth.

NOTE: If the QC sample is to be introduced with a capillary tube, remove the syringe adapter before placing the cassette into the chamber.

- Insert the cassette into the chamber. Press down to ensure that the cassette is seated properly (Fig. 4-23).

NOTE: Run E-BUN cassettes immediately after opening pouch. Do not run, if cassette has been out of pouch for more than 15 minutes.

- Close the SMC cover (Fig. 4-24).

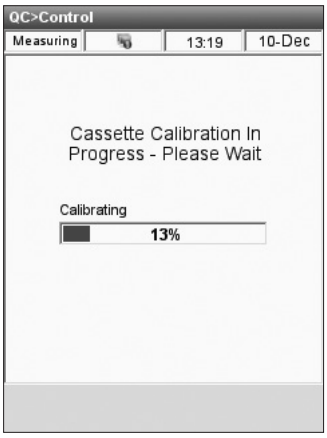


Fig. 4-25 Control Calibration

Fig. 4-26 Place Control

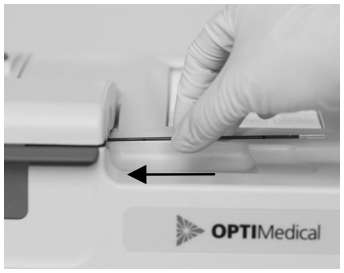


Fig. 4-27 Attach Capillary Tube

9. The system starts to calibrate (Fig. 4-25). The green status light is now lit, indicating that a measurement is occurring and that the sample chamber cover should not be opened.

NOTE: If the sample measurement chamber cover is opened while the green status light is blinking, the cassette calibration will be cancelled and the cassette must be discarded.

10. Calibration is complete and it is time to place a sample (Fig. 4-26).
11. Remove an ampoule from the box of controls and invert gently to resuspend the scattering particles, being careful not to heat it with your hands.

NOTE: Do not shake ampoule vigorously. Excessive bubble formation may affect results.

12. Gently tap the head of the ampoule with your fingernail to remove any liquid.
13. Carefully open the ampoule by breaking off the top.

NOTE: Protect your fingers by using gloves or tissue while breaking ampoule.

14. Either aspirate directly from the ampoule or use a capillary to withdraw a small amount of control material from the ampoule for aspiration.
15. Hold the ampoule at a 45° angle during aspiration (Fig. 4-26). Use a new ampoule for each sample.
16. When using capillary tubes, push the tube firmly into the fillport (Fig. 4-27).

*NOTE: OPTI recommends to aspirate directly from ampoule and use one ampoule per measurement. However, if you wish to use capillary tubes, please use **unheparinized** capillary tubes for control measurement.*

17. Press OK (Fig. 4-26).

Fig. 4-28 QC Measurement

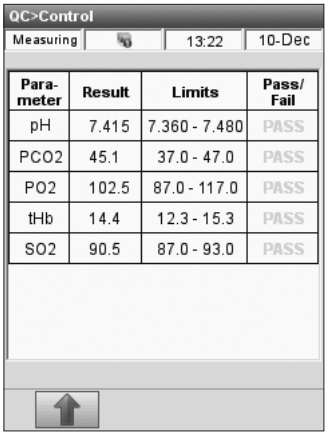


Fig. 4-29 QC Results

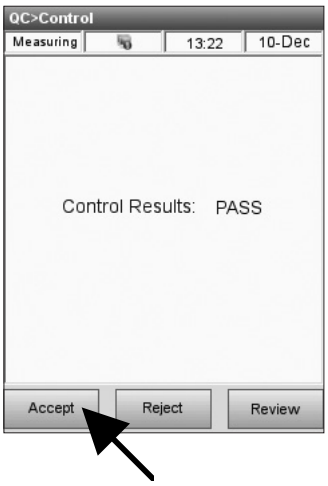


Fig. 4-30 Accept QC Results

- The QC sample is aspirated into the cassette, and then measurement starts (Fig. 4-28). At this time the status light begins flashing green indicating that the cover should not be opened.
- Upon completion of the measurement, the results are displayed (Fig. 4-29).
- The OPTI CCA-TS2 Analyzer will indicate whether the values are within or outside the programmed ranges with a <Pass/Fail> display next to the parameter label.
- Results obtained are applicable to the sensor cassette type being used for patient sample (B Type shown for reference).

18. Press  (Fig. 4-29) to accept or reject results.
    - In the subsequent screen (Fig. 4-30), you can press **<Accept>** if results are acceptable, and the results will be stored in the Control Database.
    - Select **<Reject>** to reject the results. Rejected results will not be stored in the Control Database.
    - Select **<Review>** to view the results again.

NOTE: In either case, the results will be printed. Please follow the regulatory guidelines of your hospital for documenting corrective action, if results are rejected.

NOTE: Data will be exported using the configured export method (see Section 3.2.4.5) when the results are printed.

NOTE: The automatic printout feature may be turned off in setup (See Section 3.2.4.1). Additional information on printing reports and exporting data can be found in Chapter 6, Data Manager.

- For troubleshooting, refer to Chapter 8.

19. When prompted, open the sample chamber cover and remove the cassette.
    - If other levels of controls are to be run, repeat the procedure.

5 SAMPLE HANDLING AND PATIENT TESTING

The OPTI® CCA-TS2 Analyzer provides fast and convenient measurement of pH, PCO_2, PO_2, Na^+, K^+, Ca^{++}, Cl^-, Glucose, BUN (urea), Lactate, tHb and SO_2 in whole blood, and pH, Na^+, K^+, Ca^{++}, Cl^-, Glu and BUN (urea) in serum and plasma.

The analyzer will accept specimens directly from most syringes, capillary tubes and the OPTI Medical ComfortSampler™ through the fillport on the OPTI Cassette.

NOTE: Always follow proper safety procedures when handling biological samples.

5.1 Specimen Collection and Handling

5.1.1 Safety

Universal precautions must be observed when collecting blood specimens. It is recommended that all blood specimens be handled as if capable of transmitting human immunodeficiency virus (HIV), hepatitis B virus (HBV), or other bloodborne pathogens. Proper blood collection techniques must be followed in order to minimize risk to the laboratory staff, and gloves should be worn. Please refer to CLSI document M29-A3, Protection of Laboratory Workers from Occupationally Acquired Infections, Approved Guideline - Third Edition; March 2005, for further information on safe handling of these specimens.

5.1.2 Sample Requirements

Refer to CLSI document H11-A4, Procedures for the Collection of Arterial Blood Specimens; Approved Standard - Fourth Edition; September 2004, for detailed information on sample collection, storage and handling.

Blood sampling for analysis must be performed under proper medical supervision with details of collection, including sampling devices, site selection, sample handling documentation and specific procedures used approved by the personnel responsible.

5.1.3 Anticoagulants and Sample Collection Devices

Lithium heparin is the only acceptable anticoagulant for blood gas and electrolyte analysis. Lithium heparin, sodium heparin or balanced heparin salts are the only acceptable anticoagulants for blood gas analysis. Other anticoagulants such as EDTA, citrate, oxylate and fluoride have a significant effect on blood pH and electrolyte levels and should not be used. Lithium heparin should not be used for samples taken also for analysis of lithium.

5.1.4 Syringes

If liquid heparin is used as an anticoagulant, collection devices should be no larger than the amount of blood required to minimize the effects of dilution of the blood by the anticoagulant solution. Although plastic syringes are commonly used for collection of blood specimens for blood gas analysis, there have been reports in literature regarding the use of plastic syringes when PO_2 values higher than normal are expected.
Particular attention should be paid to cooling blood samples in ice water, because of the CO_2 and oxygen solubility in some plastics. If blood specimens are expected to have very high PO_2 values, care should be taken to analyze the specimen as quickly as possible following collection to avoid the need for cooling.

NOTE: `Attention should be paid to thorough mixing of whole blood samples prior to analysis, since sedimentation of blood cells affects the measurement of total hemoglobin.

5.1.5 Capillary Tubes

Capillary blood specimens should be collected using capillary tubes which have a minimum volume, filled, of 125 µL. The OPTI Medical capillary tubes (MC0024) are ideally suited with a minimum volume, filled, of 200 µL. The capillary tubes for pH, blood gas, and electrolyte analysis should not be used for samples taken for the analysis of lithium. OPTI Medical has only validated the use of capillaries MC0024 for performing blood gas measurements on the OPTI CCA analyzers (GD7046, GD7013 and GD7045). The capillaries are not validated for use with blood gas analyzers from other manufacturers

Samples may be collected in capillary tubes after warming the area or otherwise stimulating it to promote arterial circulation before the puncture. The puncture should be made deeply enough to ensure a free and rapid flow of blood.

Do not use clay-capped capillary tubes as the rough, broken edge left when the capillary is cut may cause damage to the OPTI cassette fill port. Use only capillary tubes with fire-polished ends to prevent damage to the cassette. If a mixing flea is used, as required in some capillary tubes, take care to remove the flea prior to sample introduction to avoid damage to the cassette.

Specimens collected in capillary tubes are stable at room temperature for up to 30 minutes after collection because of the rapid cooling of the sample accomplished during filling.

Cooled samples provide relevant glucose values for up to 30 minutes, uncooled samples for up to 10 minutes. Serum must be separated within these time limits.

5.1.6 OPTI Medical ComfortSamplers®

Blood may be collected for analysis on the OPTI CCA-TS2 with the OPTI Medical ComfortSampler to provide a filled shielded capillary tube.

After collection, the ComfortSampler should be capped and transported in a horizontal position to the instrument for analysis within 30 minutes, as with all specimens collected in capillary tubes.

Cooled samples provide relevant glucose values for up to 30 minutes, uncooled samples for up to 10 minutes. Serum must be separated within these time limits.

5.1.7 Sample Collection Tubes

Collect blood in a sample collection tube, aspirating the sample with a sample aspiration tube (BP7183).

NOTE: Whole blood samples should be analyzed as soon as possible, ideally within 5 minutes after collecting the sample. For brief storage of up to one hour, the sample should be iced.

NOTE: When the sample aspiration tube is used for a whole blood sample, electrolyte and pH results will be available, but there will be no pCO_2 derived results.

5.1.8 Handling and Storage of Samples

Please refer to CLSI Document H18-A3, Procedures for the Handling and Processing of Blood Specimens; Approved Guideline - Third Edition, November 2004, for a detailed discussion of guidelines for the collection of acceptable specimens, instrument calibration, and quality control in pH and blood gas analysis; including details of many potential sources of error which may cause inaccurate results.

Whole blood samples should be collected in a heparinized syringe, ComfortSampler or capillary and analyzed as soon as possible after collection. Immediately after collection, check the syringe or other device for air bubbles and carefully expel any trapped bubbles, following the manufacturer's recommended procedure. Extreme caution should be used to avoid needle stick injury. If collected in a syringe or vacuum tube, mix the specimen thoroughly with anticoagulant by gentle inversion or by rolling the syringe between both hands. Properly identify the specimen, following usual procedures for such documentation. Place the syringe containing the specimen in an ice slurry. Blood gases, pH and glucose content will change if the specimen remains at room temperature in a syringe for more than 5 minutes due to cellular metabolism.

PO_2 changes due to oxygen consumption may be influenced by several factors, including: white blood cell count, reticulocyte count, storage temperature and initial PO_2 value. At storage temperatures of 1 to 5 °C, the results obtained from the specimen are valid up to 2 hours. Samples expected to have high white blood cell count, reticulocyte count, or high PO_2 values should be analyzed as soon as possible after collection.

Erythrocyte aggregation and sedimentaton may occur very quickly in syringes containing pathologic blood samples and may adversely affect the measurement of ctHb in any analyzer. To prevent such errors, first insert the OPTI CCA-TS2 cassette into the analyzer to initiate calibration. Next, mix the syringe sample well by rolling the syringe for at least 60 seconds, after expelling any trapped bubbles, then immediately measure in the OPTI CCA-TS2.

The OPTI CCA-TS2 system aspirates blood in the same manner from syringes, capillaries or ComfortSampler. No changes are made to the aspiration rate, volume or timing. Therefore, there are no biases or imprecision dependent upon the sample introduction method. Sufficient volume must, however, be present in syringes (0.25 mL in a 1 mL syringe) to prevent mechanical interference between the syringe plunger and the syringe adapter.

Errors in blood analysis on properly collected samples may result from improper mixing of the sample after collection and before measurement; contamination with room air resulting from failure to expel any trapped bubbles after collection; and from metabolic changes in the sample.

Serum samples should be obtained by collecting blood in an untreated blood collecting tube. The sample should stand for 30 minutes to allow the clot to form prior to centrifugation. After centrifugation, remove the serum from the clot, and cap or seal the sample tube. If storage is required, the sample should be tightly capped, refrigerated at 4 to 8 °C for no longer than 48 hours, and allowed to return to room temperature, 15 to 30 °C, prior to analysis. Each laboratory should determine the acceptability of its own blood collection syringes, capillaries and tubes and the serum or plasma separation products. Variations in these products exist between manufacturers, and at times, from lot to lot.

NOTE: Serum is an unsuitable sample material for accurate glucose analysis, because the retention time of the erythrocytes in the sample is too long.
The process of glycolysis may lead to decreased glucose values in serum samples.

5.1.9 Handling and Storage of Sensor Cassettes

The OPTI Sensor Cassettes are stable when stored at 4-30°C (39-86°F) until the expiration date printed on the label.

B-Lac and E-BUN Cassettes are stable when stored at 2-8°C (35-46°F) until the expiration date printed on the label. Allow cassettes to equilibrate at room temperature for **1 hour (B-Lac)** or **15 minutes (E-BUN)** prior to use.

B-Lac and E-BUN Cassettes that are in use may be left at room temperature (18-30°C or 64-86°F) for **4 weeks (B-Lac)** and **30 days (E-BUN)**. However, cassettes should not be refrigerated again after they have been left at room temperature for **1 hour (B-Lac)** or **15 minutes (E-BUN)** or more.

The OPTI CCA-TS2 has a function that will display warning messages for out-of-storage conditions for B-Lac and E-BUN cassettes during patient and QC measurements.

This function is enabled by default and can be disabled in System Setup. See Section 3.2.2.2 Setting up Measured Parameters.

CAUTION: *Do not expose cassettes to temperatures above 46°C (115°F).*
OPTI Medical cannot guarantee the performance of the cassette when stored at temperatures outside the recommended range.

5.1.10 Test Conditions

Sample Size:	a minimum of 125 µL (60µL for B60 cassette)
Sample Type:	heparinized whole blood, serum, plasma
Sample Application:	syringe, capillary, ComfortSampler or sample collection tube with sample aspiration tube (E-Lyte CCA Cassette only)
Ambient Temperature:	10 - 30 ºC (50 – 86 ºF)
Relative Humidity:	5% to 95% (non-condensing)
Type of Measurement:	optical fluorescence (pH, PO_2, PCO_2, Na^+, K^+, Ca^{++}, Cl^-, Glucose, BUN (urea), Lactate), and reflectance (tHb, SO_2)

5.2 Sample Preparation

5.2.1 Whole Blood Samples

Collect blood in a heparinized syringe, a capillary tube, ComfortSampler or sample collection tube with sample aspiration tube (E-Lyte CCA Cassette only).
Whole blood samples should be analyzed as soon as possible, ideally within 5 minutes after collecting the sample. For brief storage of up to one hour, the sample should be iced.

CAUTION: *Whole blood samples require the proper amount of anticoagulant to prevent the sample from clotting. DO NOT use anticoagulants such as EDTA, citrate, oxalate, etc. Use only heparin salts as anticoagulants.*

CAUTION: *Sedimentation of red cells may occur rapidly in whole heparinized blood. This may affect your tHb results. Make sure your sample is free of trapped gas bubbles and completely mixed, by rolling the syringe between the palms of your hands and inverting end over end for at least one minute, just prior to sample introduction.*

5.3 Running A Patient Sample

(Whole Blood, Serum and Plasma)

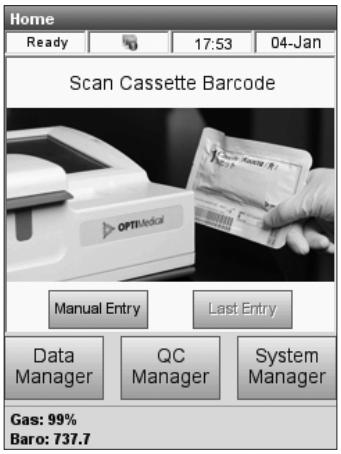


Fig. 5-1 Scan Bar Code

Fig. 5-2 Login

The OPTI CCA-TS2 Analyzer is fast and easy to operate. Whenever the **<Ready>** screen appears, the unit is ready for sample measurement.

1. Turn on the OPTI CCA-TS2 and wait until this display appears (Fig. 5-1).
2. If security is enabled (see Section 3.2.3), log in to the OPTI using your user ID and password (Fig. 5-2).
   - The user ID you use to log in will appear in the user ID fields on printouts and logs for all activities you perform until you log off.
3. Scan the bar code on the OPTI cassette package by holding it 2-3 inches (5-8 cm) from the bar code scanner located on the bottom right-hand corner of the analyzer (Fig. 5-1).
   - The red line from the bar code scanner should cover the entire bar code.
   - A beep and a green status light indicates a valid bar code.
   - A red status light and error message indicates an invalid bar code (e.g. cassette expired) (See Chapter 8, Troubleshooting).

NOTE: If the bar code is damaged or unreadable, press <Manual Entry> *and enter the bar code digits using the numeric keypad.*

- If you are using the same lot number of cassettes as for the previous patient sample and the **<Last Barcode Enable>** option is enabled in setup (Section 3.2.2.2), you do not have to scan the cassette barcode. You can press the **<Last Entry>** button (Fig. 5-1) instead and the cassette information will be recalled. The analyzer will identify the lot number, and prompt you to open the cover, wipe and insert the cassette and close the cover.

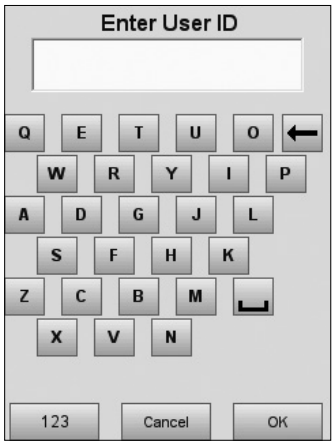


Fig. 5-3 Enter User ID

- During warm-up, the OPTI CCA-TS2 checks the gas pressure. Once it reaches 5% or less, the value will be displayed in red. If the pressure is too low, a warning will appear asking you to install a new gas bottle (see Section 7.5.1). If a gas bottle has not been properly installed, the gas pressure value will also be displayed in red.

4. If **<Non Secure User ID Entry>** is enabled in the security settings (see Section 3.2.3), you will be asked to enter the user ID (Fig. 5-3).

NOTE: Bar-coded user IDs may be entered from this screen using the bar code scanner.

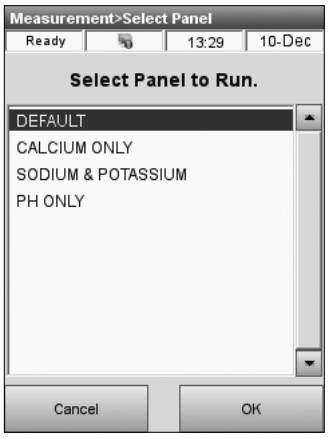


Fig. 5-4 Select Panel

- If customized test panels have been set up in **<Setup>** (see Section 3.2.2.6), the **<Select Panel>** screen (Fig. 5-4) will appear and display a list of available panels.
- Select the desired panel and press OK.

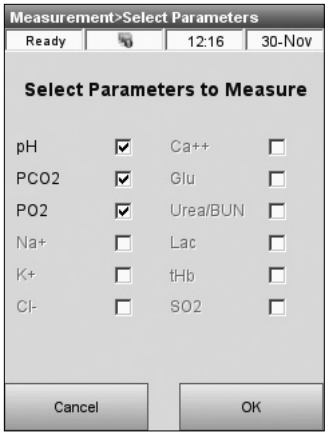


Fig. 5-5 Select Parameters

- If <**Allow User to Select Parameters>** has been enabled in **<Setup>** (see Section 3.2.2.2), the **<Select Parameters to Measure>** screen (Fig. 5-5) will be displayed and give you the option to select the results for certain parameters for the current measurement.
- Select the desired parameters and press OK.

Fig. 5-6 Open SMC Cover

5. Press down on the center of the red latch to open the Sample Measurement Chamber (SMC) (Fig. 5-6).

6. Insert the cassette as follows:

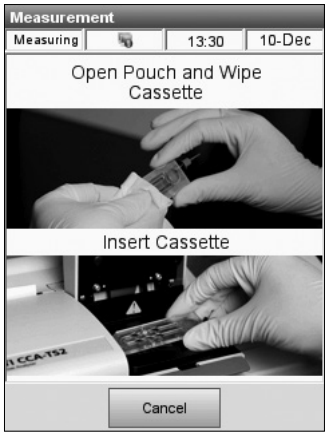


Fig. 5-7 Insert Cassette

- Open the OPTI Sensor Cassette pouch and remove the cassette (Fig. 5-7). After opening the pouch, proceed with the following steps immediately.

NOTE: Run cassettes immediately after opening pouch. Do not run, if cassette has been out of pouch for more than 15 minutes (2 minutes for B-Lac cassettes).

NOTE: For sample introduction with a capillary tube, sample aspiration tube or a ComfortSampler, remove the syringe adapter before placing the cassette into the chamber.

- Gently wipe both sides of the cassette with a clean dry cloth to remove excess moisture.
- Insert the cassette in the chamber. Press down to ensure the cassette is properly seated (Fig. 5-7).

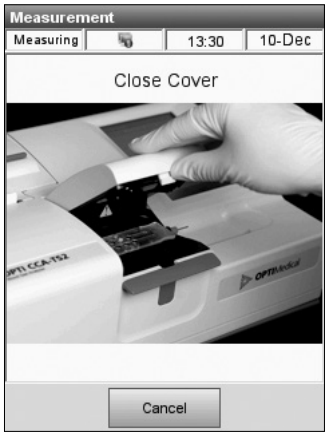


Fig. 5-8 Close Cover

- Close the SMC cover by pressing it down firmly (Fig. 5-8).
- The green status light starts to blink indicating that the SMC cover should not be opened during this time.

NOTE: If the SMC cover is opened while the green status light is blinking, the cassette calibration will be cancelled and the cassette must be discarded.

Fig. 5-9 B-Lac Open Cover

Fig. 5-10 B-Lac Open Pouch

Fig. 5-11 B-Lac Close Cover

B-Lac Cassettes

- Open the sample chamber cover by pressing down on the center of the red latch (Fig. 5-9).

NOTE: For B-Lac cassettes, out-of-storage warnings will be displayed (Figs. 5-9 - 5-11). This function is enabled by default and can be disabled in the System>Setup menu (see Section 3.2.2.2.)

- The contents of the cassette package are stable when stored at 2-8°C (35-46°F) until the expiration date printed on the label. Allow cassettes to equilibrate at room temperature for 1 hour prior to use.
- Cassettes that are in use may be left at room temperature (18-30°C or 64-86°F) for 4 weeks; however, cassettes should not be refrigerated again after they have been left at room temperature for 1 hour or more.
- Open the OPTI Sensor Cassette pouch and remove the cassette (Fig. 5-10). After opening the pouch, proceed with the following steps immediately.

NOTE: Run B-Lac cassettes immediately after opening pouch. Do not run, if cassette has been out of pouch for more than 2 minutes.

NOTE: For sample introduction with a capillary tube, sample aspiration tube or a ComfortSampler, remove the syringe adapter before placing the cassette into the chamber.

- Insert the cassette into the chamber. Press down to ensure that the cassette is seated properly (Fig. 5-10).

- Close the SMC cover (Fig. 5-11).
- The green status light starts to blink indicating that the SMC cover should not be opened during this time.

NOTE: If the SMC cover is opened while the green status light is blinking, the cassette calibration will be cancelled and the cassette must be discarded.

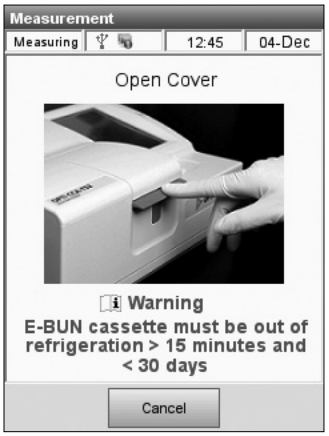


Fig. 5-12 E-BUN Open Cover

Fig. 5-13 E-BUN Open Pouch

Fig. 5-14 E-BUN Close Cover

E-BUN Cassettes

- Open the sample chamber cover by pressing down on the center of the red latch (Fig. 5-12).

NOTE: For E-BUN cassettes, out-of-storage warnings will be displayed (Figs. 5-12 - 5-14). This function is enabled by default and can be disabled in the System>Setup menu (see Section 3.2.2.2.)

- The contents of the cassette package are stable when stored at 2-8°C (35-46°F) until the expiration date printed on the label.
  Allow cassettes to equilibrate at room temperature for 15 minutes prior to use.
- Cassettes that are in use may be left at room temperature (18-30°C or 64-86°F) for 30 days; however, cassettes should not be refrigerated again after they have been left at room temperature for 15 minutes or more.
- Open the OPTI Sensor Cassette pouch and remove the cassette (Fig. 5-13). After opening the pouch, proceed with the following steps immediately.

NOTE: Run E-BUN cassettes immediately after opening pouch. Do not run, if cassette has been out of pouch for more than 15 minutes.

NOTE: For sample introduction with a capillary tube, sample aspiration tube or a ComfortSampler, remove the syringe adapter before placing the cassette into the chamber.

- Gently wipe both sides of the cassette with a clean dry cloth to remove excess moisture.
- Insert the cassette into the chamber.
  Press down to ensure that the cassette is seated properly (Fig. 5-13).
- Close the SMC cover (Fig. 5-14).
- The green status light starts to blink indicating that the SMC cover should not be opened during this time.

NOTE: If the SMC cover is opened while the green status light is blinking, the cassette calibration will be cancelled and the cassette must be discarded.

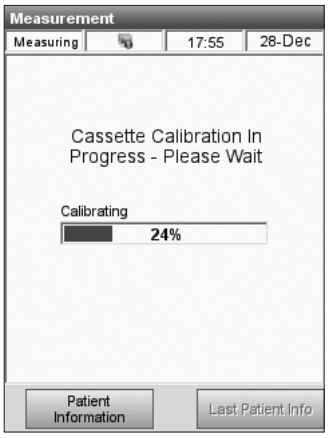


Fig. 5-15 Cassette Calibration

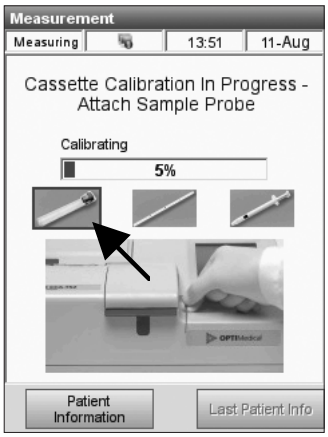


Fig. 5-16 E-Lyte CCA Cassette - Sample Tube selected

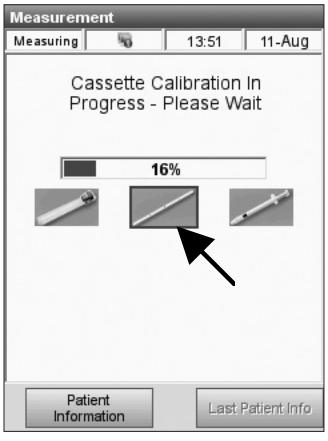


Fig. 5-17 E-Lyte CCA Cassette - Capillary selected

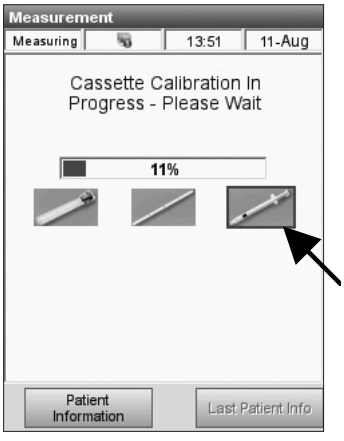


Fig. 5-18 E-Lyte CCA Cassette - Syringe selected

7. The system will now check the integrity of the cassette and then calibrate (Fig. 5-15). For more information about calibration, please refer to Chapter 4 “Calibration and Quality Control”.

NOTE: The OPTI CCA-TS2 will hold calibration for 10 minutes for all cassette types except B-Lac. B-Lac cassettes will hold calibration for 2 minutes. The OPTI CCA-TS2 will beep, warning you when only 1 minute remains on the calibration. After this time elapses, a message will be displayed to discard the cassette.

NOTE: If tHb/SO_2 has been disabled (see Section 3.2.2.2), you may attach the sample at any time during calibration and press OK *. The sample will then be automatically aspirated after calibration and the measurement will begin.*

- When an E-Lyte CCA Cassette is inserted, the calibration screen will display the default selection for the sample container (Fig. 5-16) as selected in the **<Sample Container Menu>** (see Section 3.2.2.8). If necessary, you may change the sample container during calibration by selecting a different icon (Fig. 5-17 and Fig. 5-18).

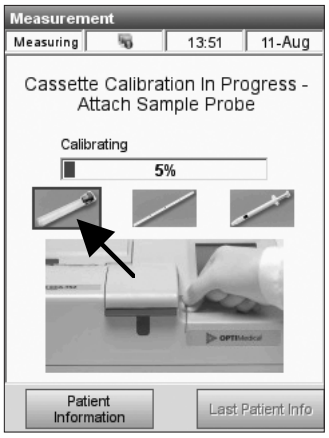


Fig. 5-19 Sample Tube

8. When the **<Sample Tube>** option is selected on the E-Lyte CCA cassette, you will be asked to attach the sample aspiration tube (Fig. 5-19).

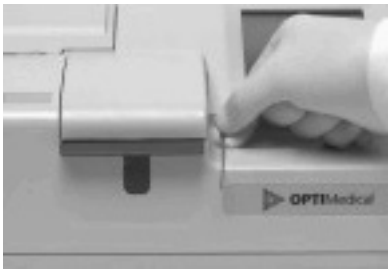


Fig. 5-20 Attach Sample Aspiration Tube

9. Remove the red syringe adapter from the cassette and firmly insert the shorter end of the sample aspiration tube into the cassette fill port (Fig. 5-20). The sample aspiration tube should be facing downward.

Fig. 5-21 Place Sample Collection Tube

10. After the successful calibration, the status light will stop blinking, and the display will prompt you to place the sample collection tube (Fig. 5-21).

Fig. 5-22 Place Sample Tube

Fig. 5-23 Remove Sample

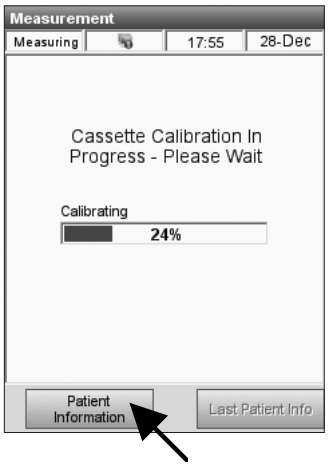


Fig. 5-24 Patient Information

- Place the sample aspiration tube in the sample container (Fig. 5-22) and press OK. The sample is then aspirated.

11. Once the sample has been aspirated to the first cassette sensor, a display will appear asking the operator to remove the sample from the sample aspiration tube (Fig. 5-23).

- Remove the sample and press OK.
- If the user removes the sample and selects OK, the analyzer will move the sample from the sample aspiration tube into the cassette for measurement.
- If the user does not select OK, the system will wait 20 seconds and then beep every 2 seconds for the next 10 seconds to remind the user to acknowledge removal of the sample.
- The instrument will automatically continue with the measurement process after the 30 seconds elapse.

12. You can enter patient information while calibration is in progress by pressing **<Patient Information>** button (Fig. 5-24).

- Press the **<Last Patient Info>** button to use the last patient info as the default for the current patient information, if this option is enabled in **<Setup>** (see Section 3.2.2.2).
- This option will populate all patient info fields with the last patient data.
  If user ID security is enabled, the user ID field will contain the user ID of the user currently logged in. All patient information used as the default can be edited.
- Verify that patient ID and all other input parameters are correct for every patient sample measurement.
- Press the **<Patient Info>** button to enter new patient information or to not use the last patient info as the default.

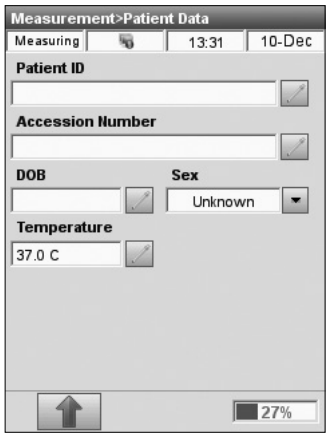


Fig. 5-25 Edit Patient Data

13. The **<Patient Data>** entry screen (Fig. 5-25) contains the information that was configured in **<Setup>** (Section 3.2.2.1).

    The following options are set by default:

    - Patient ID (25 alphanumeric characters)
    - Accession No. (25 numeric characters)
    - Date of Birth (DOB)
    - Temperature (default value 37.0 °C)
    - Sex (unknown, male or female)

14. To enter patient data, press  (Fig. 5-25). Use the alphanumeric keypad to type in the desired information or scan a barcode for Patient IDs and Accession Nos.

15. Pressing  will access subsequent patient data entry screens, if configured in **<Setup>** (Section 3.2.2.1).

NOTE: If patient data parameters have been set up as <Required>*, you will not be able to exit the Results screen until that information has been entered.*

16. Press  when you are finished editing patient info.

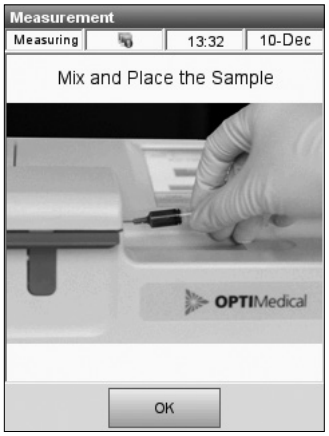
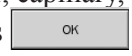


Fig. 5-26 Mix and place sample

17. For any cassette type or sample container other than the E-Lyte CCA sample tube option, the following display will appear after successful calibration (Fig. 5-26). The status light will stop blinking, and you will be asked to mix and place the sample.

    - When using syringe samples, mix the sample well by rolling it between the palms of your hands and inverting end over end.
    - Sedimentation of blood cells causes alteration of tHb values. Therefore mix the sample well just prior to analysis.

18. Attach the sample to the cassette fillport using a syringe and adapter, capillary, or ComfortSampler, and press  (Fig. 5-26).

    - When using a syringe, make sure the red syringe adapter is not touching the syringe plunger.

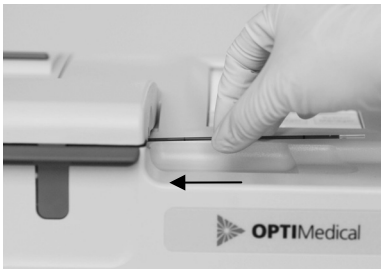


Fig. 5-27 Attach Capillary

WARNING: *Do not inject the sample!*
It will be aspirated automatically.

- When using capillary tubes, remove the red syringe adapter and push the tube firmly into the fillport (Fig. 5-27).

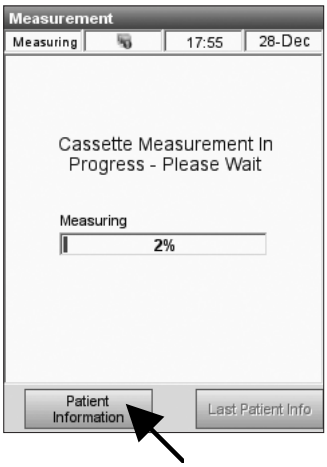


Fig. 5-28 Patient Information

- The sample will then be aspirated and measured (Fig. 5-28).

  During the measurement, the status light is blinking and a progress bar is displayed.

- Do not open the cover of the sample measurement chamber during the measurement. If you do, the cassette and the sample must be discarded.

19. You can again enter patient information while measurement is in progress by pressing **<Patient Information>** (Fig. 5-28). Please follow the steps for patient data entry described under calibration step 12 on p. 5-13.

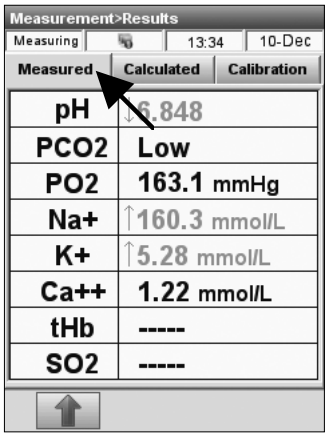


Fig. 5-29 Measurement results

When the analysis is completed, the status light stops blinking and the instrument alerts you that the measurement has been completed with a "beep".

At this time you may continue entering or editing the patient information for up to three (3) minutes.

After the three (3) minutes have elapsed, the **<Measurement Results>** will automatically be displayed (Fig. 5-29).

NOTE: The printout will start automatically when the first results are displayed. This feature may be turned off in setup (See Section 3.2.4.1).

NOTE: If ASTM, POCT1, or removable media is enabled, the results will not be printed until the user exits the measurement process. The data will also be exported when it is printed. Additional information on printing reports and exporting data can be found in Chapter 6, Data Management.

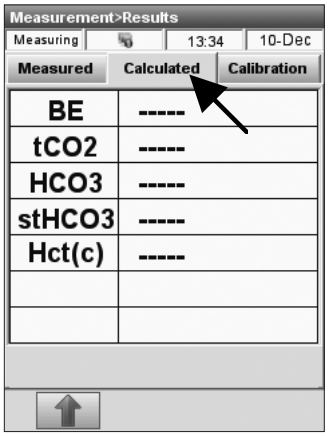


Fig. 5-30 Calculated results

The second tab displays the **<Calculated Results>** (Fig. 5-30).

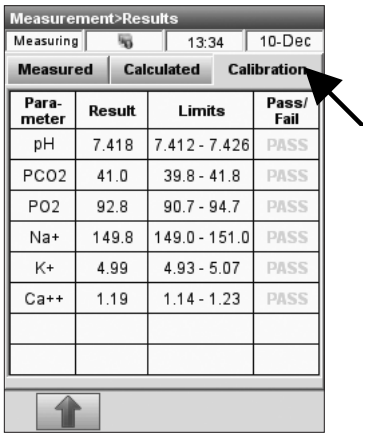


Fig. 5-31 Calibration results

The third tab displays **<Calibration Results>** from the gas calibration preceding the measurement (Fig. 5-31).

20. Open the cover and remove the cassette.

CAUTION: *When used, the OPTI Cassette contains human body fluids and must be treated as medical waste. Handle with appropriate care and dispose of in accordance with local regulations.*

- If patient temperature was entered, the blood gas values and affected calculated parameters displayed are temperature corrected.

- The display will show results according to the type of sensor cassette used (See Chapter 10.2, Sensor Cassettes).
- The resolution of the measured parameters may be configured “HIGH” (Na^+ = 156.4 mmol/L) or “LOW”(Na^+ = 156 mmol/L) in the setup menu (See section 3.2.4.2).
- The OPTI CCA-TS2 Analyzer indicates when values are above or below the programmed ranges with 1 UP ↑ or DOWN ↓ arrow, if they are outside the reference ranges or 2 arrows ↑↑, ↓↓, if they are outside the critical ranges. Values outside the reference ranges appear amber and values outside the critical ranges appear red on the display. If values are outside the measurable range, a ‘HIGH’ or ‘LOW’ will be displayed.
- When a value for any measured parameter can not be determined, the display will show a series of dashes “----” and the printout will contain an error message stating that the result was suppressed.
- When a possible measurement error occurs, the OPTI will flag patient results with a “?” on the display and printout and a blinking result on the screen. Repeat the measurement if possible.

WARNING: Treatment should never be administered based on results that are flagged on the printout.

6 DATA MANAGEMENT

The **<Data Manager>** menu allows you to print out Measurement, Diagnostics and Statistics Reports. It also provides you with the ability to import and export information to a connected computer or by using a USB mass storage device.

6.1 Printing Measurement and Statistics Reports

6.1.1 Patient Measurement Reports

Fig. 6-1 Data Manager

The **<Data Manager>** menu allows you to print out patient measurement reports.

You can print out individual measurement results, groups of measurement results, or all the results in memory.

In the default setting, patient reports are set to print automatically after each measurement.

Information on how to change these settings can be found in Section 3.2.4.1.

1. To print a patient report, select **<Data Manager>** in the main menu (Fig. 6-1).

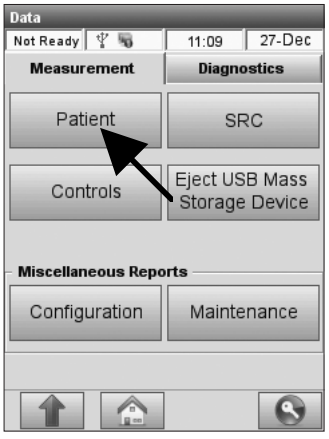


Fig. 6-2 Select Patient Report

2. On the **<Measurement>** tab, select **<Patient>** (Fig. 6-2).

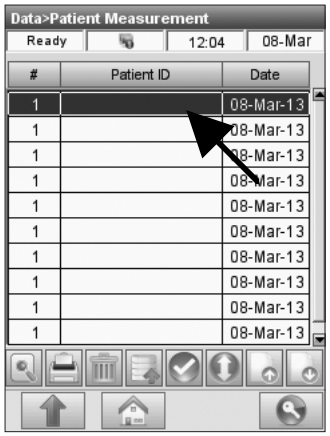


Fig. 6-3 Patient Measurements

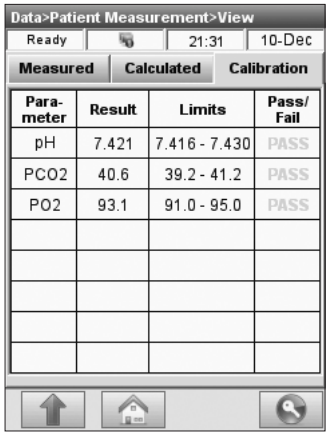


Fig. 6-4 Measurement Results

3. In the **<Data - Patient Measurement>** screen (Fig. 6-3), select a measurement and press the **<View>** button to display the measurement results (Fig. 6-4).
4. Use the **<Previous>** and **<Next>** buttons to display the previous or next page of measurements.
5. To print individual results, highlight the desired measurement (Fig. 6-3).
6. To print groups of results, highlight the first measurement to be printed, press **<Mark>** and select the last measurement to be printed. All the measurements in between will be selected.
7. Press **<All>** to select all results stored in the instrument.
8. Press **<Print>** to print your selection.
9. Records can be deleted from the database by marking them and pressing **<Delete>**.

NOTE: If you do not have permission to delete records, the button will not be active.

10. Press to return to the **<Data>** screen or to return to the main menu.

6.1.2 SRC Measurement Reports

Fig. 6-5 Select SRC

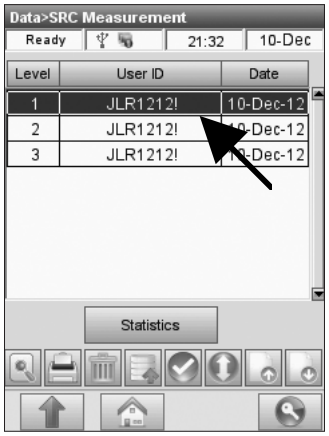


Fig. 6-6 SRC Measurements

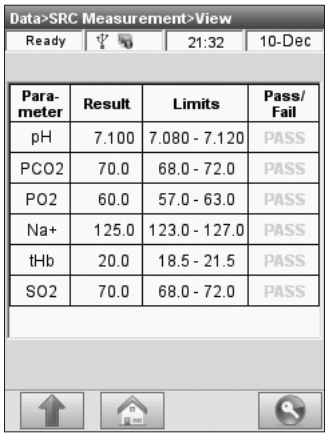


Fig. 6-7 View SRC Results

The **<Data Manager>** menu allows you to print out SRC reports and statistical information.

You can print out individual SRC results, groups of SRC results, or all the results in memory.

In the default setting, SRC reports are set to print automatically after each measurement.

Information on how to change these settings can be found in Section 3.2.4.1.

1. To print an SRC report, select **<Data Manager>** in the main menu.
2. On the **<Measurement>** tab, select **<SRC>** (Fig. 6-5).
3. In the **<Data - SRC Measurement>** screen (Fig. 6-6), select a measurement and press the **<View>** button to display the measurement results (Fig. 6-7).
4. Use the **<Previous>** and **<Next>** buttons to display the previous or next page of measurements.
5. To print individual results, highlight the desired measurement (Fig. 6-6).
6. To print groups of results, highlight the first measurement to be printed, press **<Mark>** and select the last measurement to be printed. All the measurements in between will be selected.
7. Press **<All>** to select all results all results stored in the instrument.
8. Press **<Print>** to print your selection.
9. Records can be deleted from the database by marking them and pressing **<Delete>**.

NOTE: If you do not have permission to delete records, the button will not be active.

6.1.3 SRC Statistics Reports

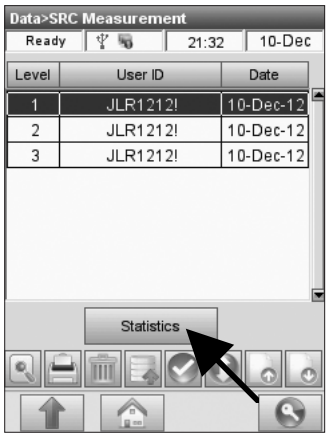


Fig. 6-8 SRC Statistics

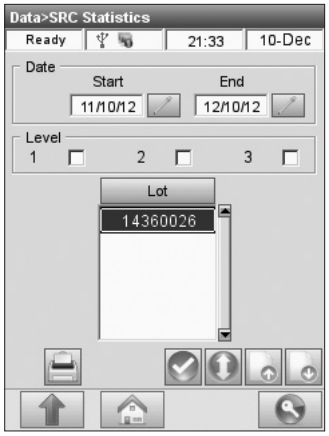


Fig. 6-9 SRC Statistics

The OPTI CCA-TS2 allows you to print out the statistics for SRC measurements.

1. In the main menu, select **<Data Manager>** **<SRC>**.
2. In the **<Data - SRC Measurement>** screen, press the **<Statistics>** button (Fig. 6-8).

NOTE: A minimum of two records is required to print a statistics report for each lot per level.

3. In the **<Data>SRC Statistics>** screen (Fig. 6-9), press to select a **<Start>** date and **<End>** date for the statistics report to be printed.
4. Select **<Level>** and **<Lot>**.
5. Use the **<Previous>** and **<Next>** buttons to display the previous or next page of measurements.
6. To print results for individual lots, highlight the desired lot (Fig. 6-9).
7. To print groups of results, highlight the first lot to be printed, press **<Mark>**, then select the last lot to be printed. All the lot numbers in between will be selected.
8. Press **<All>** to select all results all results stored in the instrument.
9. Press **<Print>** to print your selection.
10. Press to return to the **<Data>** screen or to return to the main menu.

6.1.4 Control Measurement Reports

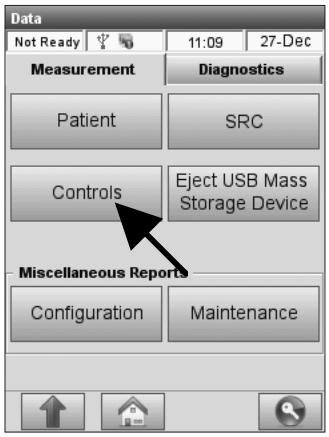


Fig. 6-10 Select Controls

Fig. 6-11 Controls Measurement

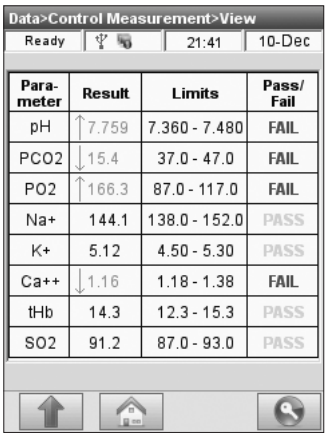


Fig. 6-12 View Control Results

The **<Data Manager>** menu allows you to print control measurement reports and statistical information.

You can print out individual control results, groups of control results, or all the results in memory.

In the default setting, control reports are set to print automatically after each measurement.

Information on how to change these settings can be found in Section 3.2.4.1

1. In the main menu, select **<Data Manager>**.
2. On the **<Measurement>** tab, select **<Controls>** (Fig. 6-10).
3. In the **<Data - Control Measurement>** screen (Fig. 6-11), select a measurement and press the **<View>** button to display the measurement results (Fig. 6-12).
4. Use the **<Previous>** and **<Next>** buttons to display the previous or next page of measurements.
5. To print individual results, highlight the desired measurement (Fig. 6-11).
6. To print groups of results, highlight the first measurement to be printed, press **<Mark>** and select the last measurement to be printed. All the measurements in between will be selected.
7. Press **<All>** to select all results all results stored in the instrument.
8. Press **<Print>** to print your selection.
9. Records can be deleted from the database by marking them and pressing **<Delete>**.

NOTE: If you do not have permission to delete records, the button will not be active.

6.1.5 Control Statistics Reports

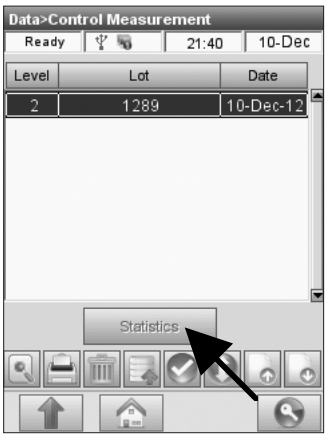


Fig. 6-13 Controls Statistics

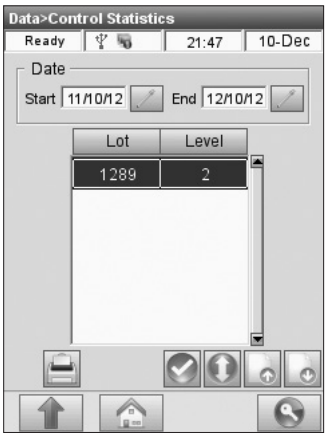


Fig. 6-14 Controls Statistics

The OPTI CCA-TS2 allows you to print out statistics for control measurements.

1. In the main menu, select **<Data Manager>** **<Control>**.
2. In the **<Data - Control Measurement>** screen, press the **<Statistics>** button (Fig. 6-13).

NOTE: A minimum of two records is required to print a statistics report for each lot per level.

3. In the **<Data>Control Statistics>** screen (Fig. 6-14), press to select a **<Start>** date and **<End>** date for the statistics report to be printed.
4. Select **<Level>** and **<Lot>**.
5. Use the **<Previous>** and **<Next>** buttons to display the previous or next page of measurements.
6. To print results for individual lots, highlight the desired lot and level (Fig. 6-14).
7. To print groups of results, highlight the first lot to be printed, press **<Mark>**, then select the last lot to be printed. All the lot numbers in between will be selected.
8. Press **<All>** to select all results all results stored in the instrument.
9. Press **<Print>** to print your selection.
10. Press to return to the **<Data>** screen or to return to the main menu.

6.2 Printing Diagnostics Reports

6.2.1 Patient Diagnostics Reports

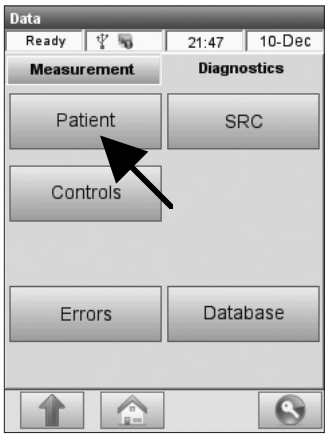


Fig. 6-15 Diagnostics

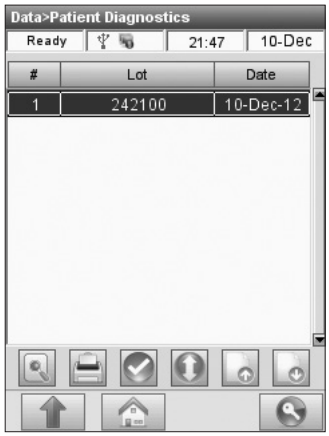


Fig. 6-16 Select Measurement

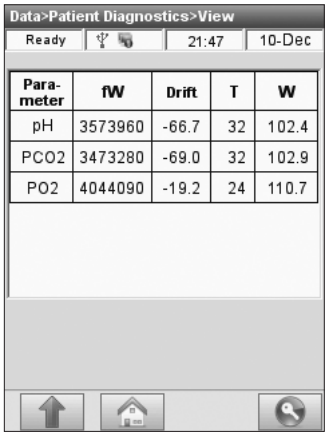


Fig. 6-17 Patient Diagnostics

The **<Patient Diagnostics Report>** contains information about the measured signal in femtowatts and drifts observed during measurement.

You can print out reports of individual patient measurements, groups of patient measurements, or all the measurements in memory.

1. To print a patient diagnostics report, select **<Data Manager>** in the main menu.
2. In the **<Data>** screen, press the **<Diagnostics>** tab and select **<Patient>** (Fig. 6-15).
3. In the **<Data - Patient Diagnostics>** screen (Fig. 6-16), select the desired measurement and press the **<View>** button to display the measurement results (Fig. 6-17).
4. Use the **<Previous>** and **<Next>** buttons to display the previous or next page of measurements.
5. To print individual results, highlight the desired measurement (Fig. 6-16).
6. To print groups of results, highlight the first measurement to be printed, press **<Mark>** and select the last measurement to be printed. All the measurements in between will be selected.
7. Press **<All>** to select all results all results stored in the instrument.
8. Press **<Print>** to print your selection.
9. Press to return to the **<Data>** screen or to return to the main menu.

6.2.2 SRC Diagnostics Reports

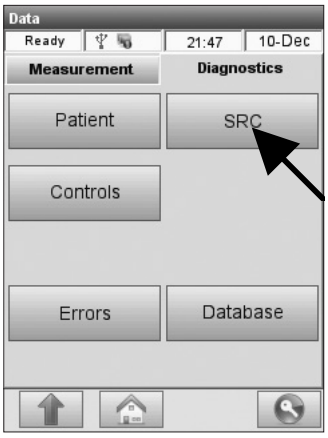


Fig. 6-18 Select SRC

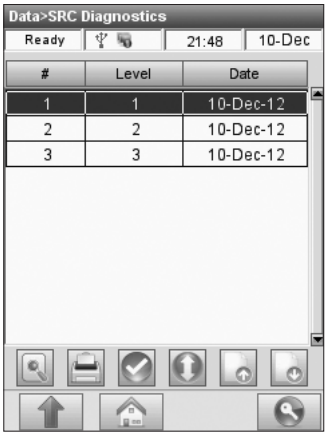


Fig. 6-19 Select Measurement

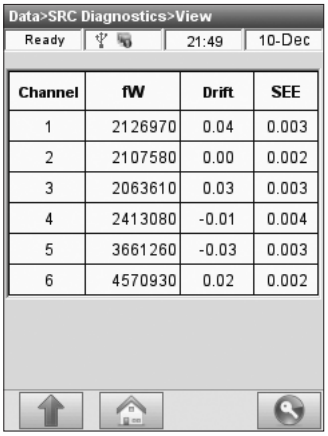


Fig. 6-20 SRC Diagnostics

The **<SRC Diagnostics Report>** contains information about the measured signal in femtowatts and drifts observed during measurement.

You can print out reports of individual SRC measurements, groups of SRC measurements, or all the measurements in memory.

1. To print an SRC Diagnostics Report, select **<Data Manager>** in the main menu.
2. In the **<Data>** screen, press the **<Diagnostics>** tab and select **<SRC>** (Fig. 6-18).
3. In the **<Data - SRC Diagnostics>** screen (Fig. 6-19), select the desired measurement and press the **<View>** button to display the measurement results (Fig. 6-20).
4. Use the **<Previous>** and **<Next>** buttons to display the previous or next page of measurements.
5. To print individual results, highlight the desired measurement (Fig. 6-19).
6. To print groups of results, highlight the first measurement to be printed, press **<Mark>** and select the last measurement to be printed. All the measurements in between will be selected.
7. Press **<All>** to select all results all results stored in the instrument.
8. Press **<Print>** to print your selection.
9. Press to return to the **<Data>** screen or to return to the main menu.

6.2.3 Controls Diagnostics Reports

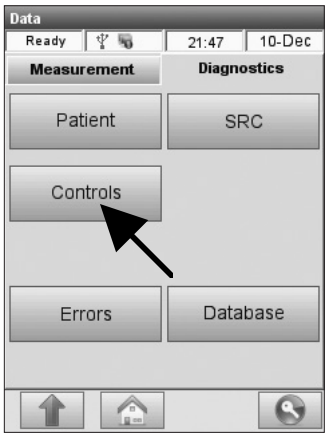


Fig. 6-21 Select Control

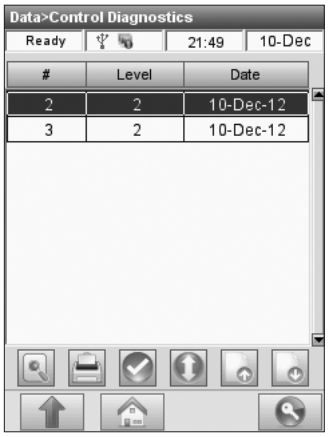


Fig. 6-22 Select Measurement

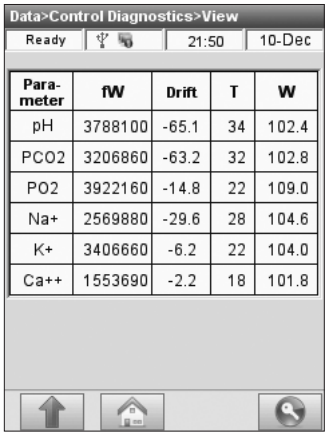


Fig. 6-23 Control Diagnostics

The **<Controls Diagnostics Report>** contains information about the measured signal in femtowatts and drifts observed during measurement.

You can print out reports of individual control measurements, groups of control measurements, or all the measurements in memory.

1. To print a Controls Diagnostics Report, select **<Data Manager>** in the main menu.
2. In the **<Data>** screen, press the **<Diagnostics>** tab and select **<Controls>** (Fig. 6-21).
3. In the **<Data - Control Diagnostics>** screen (Fig. 6-22), select the desired measurement and press the **<View>** button to display the measurement results (Fig. 6-23).
4. Use the **<Previous>** and **<Next>** buttons to display the previous or next page of measurements.
5. To print individual results, highlight the desired measurement (Fig. 6-22).
6. To print groups of results, highlight the first measurement to be printed, press **<Mark>** and select the last measurement to be printed. All the measurements in between will be selected.
7. Press **<All>** to select all results all results stored in the instrument.
8. Press **<Print>** to print your selection.
9. Press to return to the **<Data>** screen or to return to the main menu.

6.2.4 Error Report

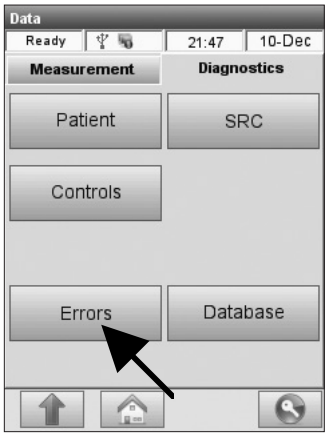


Fig. 6-24 Select Errors

This printout reports all errors logged in the database.

1. To print an error report, select **<Data Manager>** in the main menu.
2. In the **<Data>** screen, press the **<Diagnostics>** tab and select **<Errors>** (Fig. 6-24).

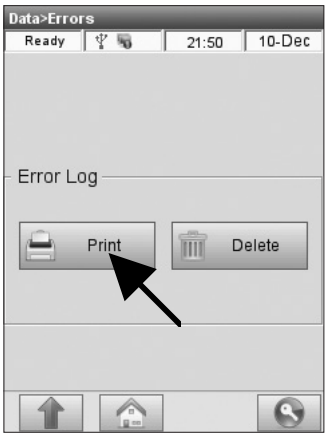


Fig. 6-25 Print or Delete Error Log

3. Press Print to print the error report (Fig. 6-25).
4. Press Delete to delete the error database.

NOTE: If you do not have permission to delete records, the Delete *button will not be active.*

Fig. 6-26 Delete Error Log

5. Confirm your choice by pressing Yes in the **<Delete the Error Log?>** screen (Fig. 6-26).
6. Press to return to the **<Data>** screen or to return to the main menu.

6.3 Miscellaneous Reports

6.3.1 Maintenance Report

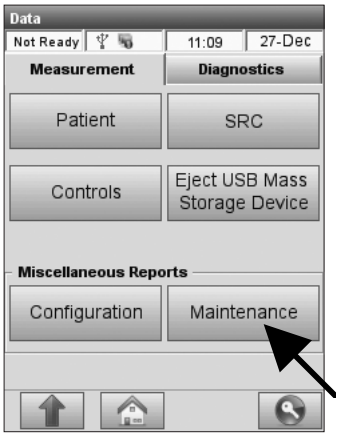


Fig. 6-27 Maintenance

This printout reports all maintenance events that were logged in the **<Maintenance>** menu (see Sections 7.2, 7.3 and 7.4.1).

1. To print a maintenance report, select **<Data Manager>** in the main menu.
2. In the **<Data>** screen on the **<Measurement>** tab, select **<Maintenance>** (Fig. 6-27).

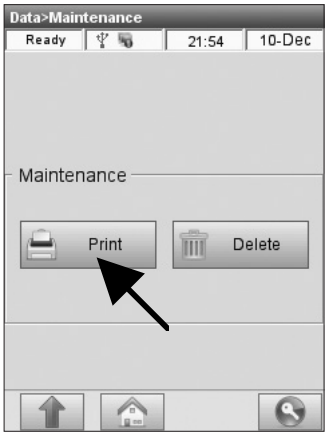


Fig. 6-28 Maintenance Report

3. Press Print to print the maintenance report (Fig. 6-28).
4. Press Delete to delete the maintenance database.

NOTE: If you do not have permission to delete records, the Delete *button will not be active.*

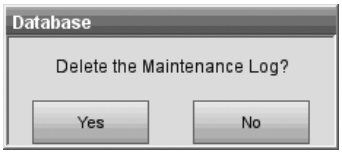


Fig. 6-29 Delete Maintenance Log

5. Confirm your choice by pressing Yes in the **<Delete the Maintenance Log?>** screen (Fig. 6-29).
6. Press to return to the **<Data>** screen or to return to the main menu.

6.4 Importing/Exporting Data

The OPTI CCA-TS2 provides you with the ability to export Patient and QC information to a connected computer or HIS/LIS.

Prior to sending data to a computer, the OPTI CCA-TS2 communication port must be configured in **<Communications Setup>** (see Section 3.2.4.6) and a physical connection to the receiving computer must be made.

CYBER SECURITY NOTE: When exporting data, patient information could be exposed to unauthorized users. Consult your IT security, before selecting a communication protocol.

6.4.1 Exporting Measurement Data

Fig. 6-30 Select Data

1. To export measurement results, select **<Data Manager>** in the main menu.
2. On the **<Measurement>** tab, select **<Patient>**, **<SRC>** or **<Controls>** (Fig. 6-30).

NOTE: Data will be exported using the setting selected in the Communications Setup (see Section 3.2.4.6)

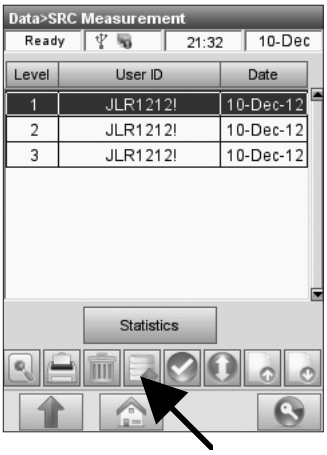


Fig. 6-31 Export Data

3. Select the data to be exported and press **<Export>** to start the data transfer (Fig. 6-31).

Fig. 6-32 Export Selected Data

4. A message will be displayed asking you to confirm your choice (Fig. 6-32).

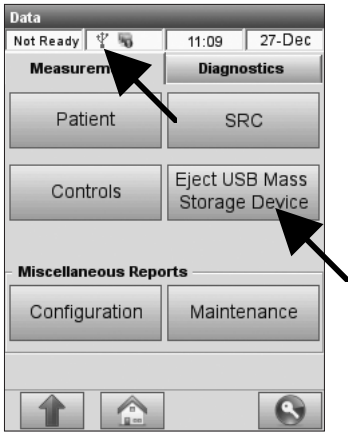


Fig. 6-33 Eject USB device

5. After exporting to a USB device, touch the USB icon in the status bar at the top of the screen or the button **<Eject USB Mass Storage Device>** to remove the USB device safely (Fig. 6-33).
6. You will be asked to eject the USB device safely (Fig. 6-34).
7. Select Yes to remove the device. An acknowledgement screen will be displayed when it is safe to remove the device.
8. Press to return to the **<Data>** screen or to return to the main menu.

Fig. 6-34 Eject USB device

Whenever a record is being exported, an export status icon will appear in the status area (Fig. 6-35). Touching the export status icon will display the **<Export Status>** menu (6-36).

The **<Export Status>** menu can also be accessed through the **<Systems>Diagnostics>** menu.

For more information, see Section 8.2.22 Export Status.

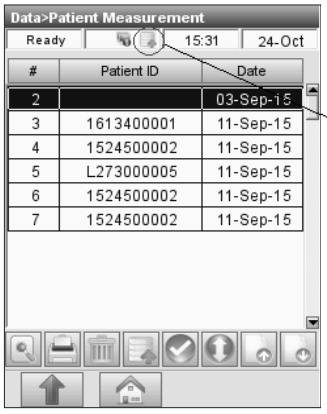


Fig. 6-35 Export Status

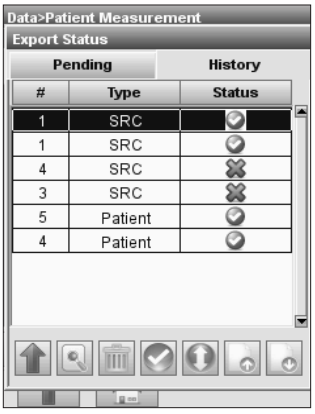


Fig. 6-36 Export Status

6.4.2 Importing/Exporting Configuration Data

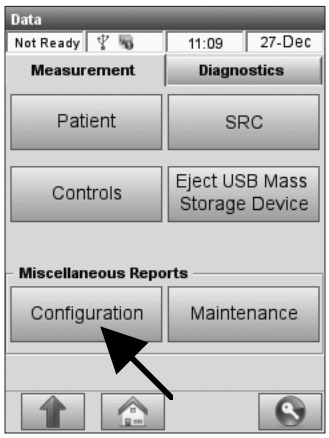


Fig. 6-37 Configuration

Fig. 6-38 Insert USB device

Fig. 6-39 Eject USB device

You can use this function to import or export configuration data to an XML file. It includes all setup information which can be imported into any instrument.

1. To import or export configuration data, select **<Data Manager>** in the main menu.
2. On the **<Measurement>** tab, select **<Configuration>** (Fig. 6-37).

NOTE: The factory settings (FSet) cannot be imported; they can only exported.

3. Insert a USB device and select **<Export>** or **<Import>** as desired (Fig. 6-38).

NOTE: The <Export> and <Import> buttons are grayed out unless a USB device is inserted.

4. To remove the USB device safely, touch the USB icon in the status bar at the top of the screen or the button **<Eject USB Mass Storage Device>** (Fig. 6-37).

5. You will be asked to eject the USB device safely (Fig. 6-39).
6. Select Yes to remove the device. An acknowledgement screen will be displayed when it is safe to remove the device.
7. Press to return to the **<Data>** screen or to return to the main menu.

6.4.3 Exporting the Database

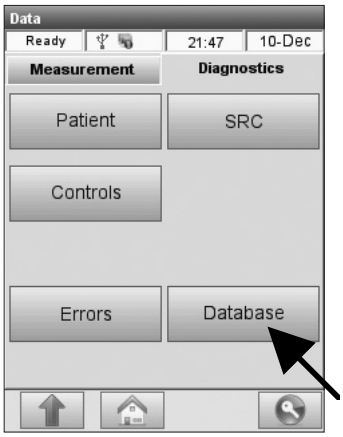


Fig. 6-40 Select Database

The database option will export the database to removable media when selected.

1. To export the database, select **<Data Manager>** in the main menu.
2. Press the **<Diagnostics>** tab and select **<Database>** (Fig. 6-40).

Fig. 6-41 Insert USB device

3. Insert a USB device and select **<Export>** (Fig. 6-41).

NOTE: This can take several minutes depending on the size of the database.

4. To remove the USB device safely, touch the USB icon in the status bar at the top of the screen (Fig. 6-40).

Fig. 6-42 Eject USB device

5. You will be asked to eject the USB device safely (Fig. 6-42).
6. Select Yes to remove the device. An acknowledgement screen will be displayed when it is safe to remove the device.
7. Press to return to the **<Data>** screen or to return to the main menu.

7 MAINTENANCE

7.1 Daily Maintenance

No daily maintenance is required for the OPTI® CCA-TS2 system.

7.2 Weekly Maintenance

Once a week, the Sample Measurement Chamber (SMC) must be cleaned. Open the top cover and clean the optics surface as well as the underside of the SMC cover with a lint-free cloth, dampened with a dilute alcohol or dilute bleach cleaner as needed. Be sure to remove all blood residue with a 10:1 diluted bleach solution. A cotton swab may be used for cleaning the smaller parts of the SMC.

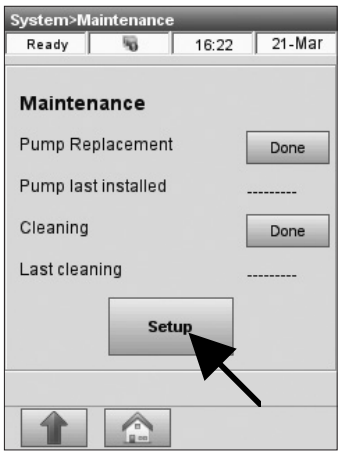


Fig. 7-1 Maintenance Setup

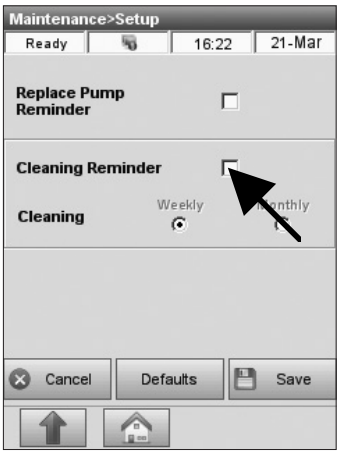


Fig. 7-2 Select Cleaning

The OPTI CCA-TS2 has a function that allows you to select maintenance reminder options which will alert you when analyzer cleaning is due.

Any maintenance actions that you perform through the maintenance reminders will be captured in the maintenance log of the analyzer.

1. From the **<Ready>** display, select **<System Manager>** and **<Maintenance>**.
2. Enter User ID if enabled.
3. In the **<Maintenance>** menu (Fig. 7-1), press **<Setup>**.
4. In the **<Setup>** screen (Fig. 7-2), you can select the option **<Cleaning Reminder>**.

   Select **<Weekly>** for weekly maintenance and **<Monthly>** cleaning if the analyzer is not used on a weekly basis.

   The analyzer will then remind you when the next analyzer cleaning is due.
5. After you perform the analyzer cleaning procedure, go to the **<Maintenance>** screen (Fig. 7-1) and press Done next to **<Cleaning>**.

   The date of the last cleaning will be displayed for future reference.

7.3 Quarterly Maintenance – Performing tHb Calibration

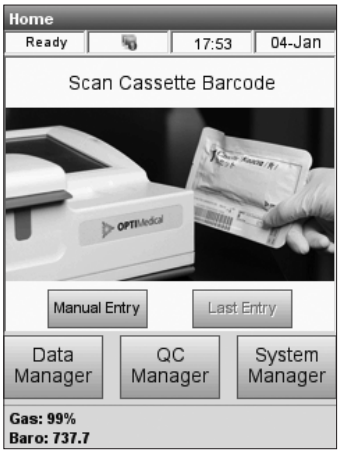


Fig. 7-3 Scan Bar Code

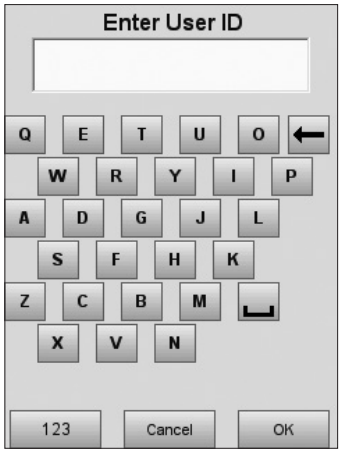


Fig. 7-4 Enter User ID

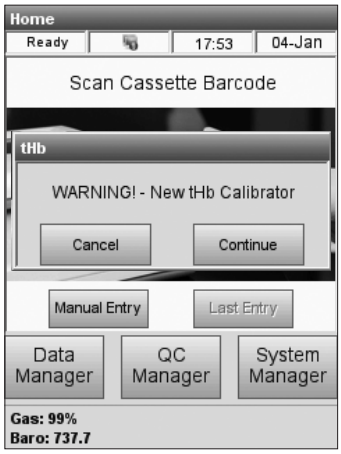


Fig. 7-5 New Calibrator

Calibration of the tHb channel is required every 3 months. This calibration is performed using the tHb Calibrator Cassette and verifies the measurement optics and electronics and corrects any potential drift. The tHb Calibrator Cassette can be found in the storage compartment in the back of your analyzer.

1. In the main screen, scan the bottom bar code on the calibrator cassette package by holding it 2-3 inches (5-8 cm) from the bar code scanner located on the bottom right-hand corner of the analyzer (Fig. 7-3).

NOTE: A tHb calibration can also be run from the QC menu by pressing <QC Manager>QC>tHb Calibrator> *instead of scanning the barcode in the* <Ready> *screen.*

- The red line from the bar code scanner should cover the entire bar code.
- A beep and a green status light indicates a valid bar code.

2. If **<Non Secure User ID Entry>** is enabled in the security settings (see Section 3.2.3), you will be asked to enter the user ID (Fig. 7-4). Depending on security settings, user access to running Hb calibrators may be restricted.

NOTE: Bar-coded user IDs may be entered from this screen using the bar code scanner.

3. A warning will be displayed the first time a new tHb Calibrator lot is used (Fig. 7-5). Press **<Continue>**.

Fig. 7-6 Clean Optics

4. Gently clean the optics window and the inside top cover of the sample chamber with a soft lint free cloth. Press OK (Fig. 7-6).

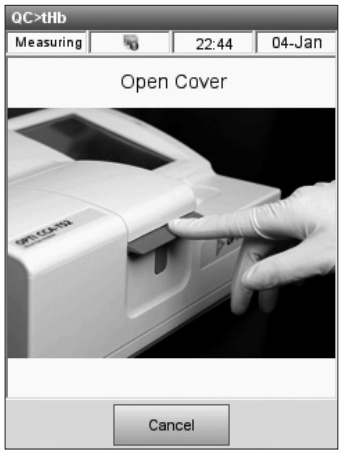


Fig. 7-7 Open Cover

5. At the prompt, open the SMC cover by pressing down on the center of the red latch (Fig. 7-7).

Fig. 7-8 Wipe and Insert Cassette

6. Gently wipe both sides of the tHb-Calibrator Cassette with a clean dry cloth and examine it to ensure it is clean. Insert it into the chamber and press down to properly seat the cassette (Fig. 7-8).

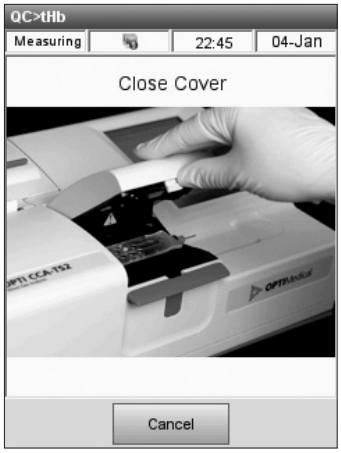


Fig. 7-9 Close Cover

7. Close the sample chamber cover (Fig. 7-9).

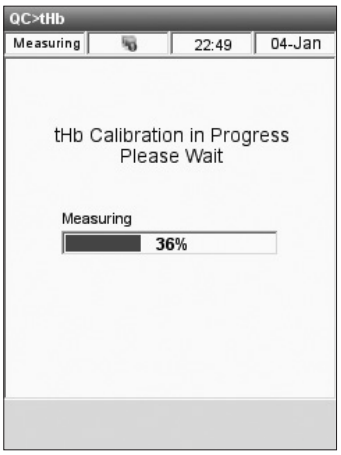


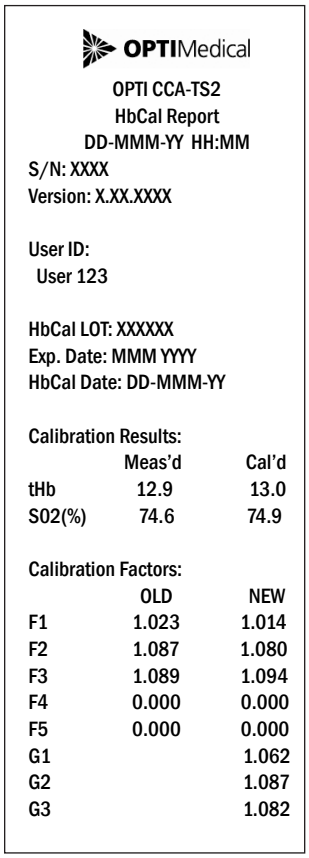
Fig. 7-10 tHb Calibration

- After the cover has been closed, the instrument will automatically detect the presence of the calibrator cassette and begin calibration (Fig. 7-10).

Fig. 7-11 Remove Calibrator

8. After the calibration is complete you will be prompted to open the sample chamber cover and remove the cassette (Fig. 7-11).
9. Place the calibrator cassette back into its pouch immediately after removal from the instrument.

NOTE: Make sure to keep the calibrator cassette with the instrument at all times.



OPTIMedical

OPTI CCA-TS2
HbCal Report
DD-MMM-YY HH:MM
S/N: XXXX
Version: X.XX.XXXX

User ID:
User 123

HbCal LOT: XXXXXX
Exp. Date: MMM YYYY
HbCal Date: DD-MMM-YY

Calibration Results:

	Meas'd	Cal'd
tHb	12.9	13.0
S02(%)	74.6	74.9

Calibration Factors:

	OLD	NEW
F1	1.023	1.014
F2	1.087	1.080
F3	1.089	1.094
F4	0.000	0.000
F5	0.000	0.000
G1		1.062
G2		1.087
G3		1.082

Fig. 7-12 HbCal Report

- The unit will now begin printing the tHb Calibration Report showing both the old and new calibration results and calibration factors (Fig. 7-12).

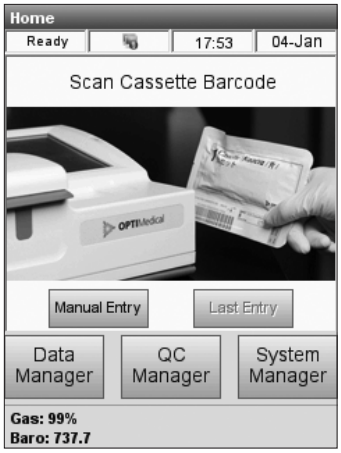


Fig. 7-13 Ready Screen

- Once the Hb Calibration is complete, the **<Ready>** display will appear (Fig. 7-13).

7.4 Annual Maintenance

Once a year, the peristaltic pump cartridge and gas I/O port must be replaced to assure that your analyzer operates at peak performance.

7.4.1 Replacing Peri Pump Cartridge

To change the cartridge:

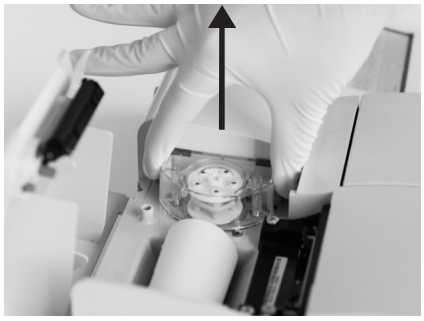


Fig. 7-14 Remove Pump Cartridge

1. Open the printer cover door by pressing the red printer release button. The peri pump is located to the right of the printer. Remove the pump by firmly grasping the ends of the housing and pulling upward (Fig. 7-14).

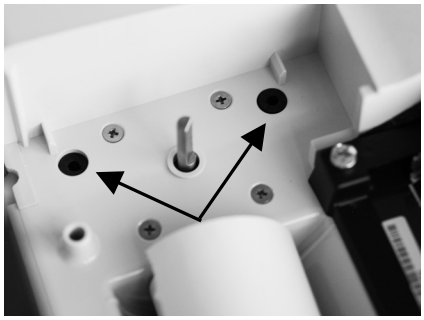


Fig. 7-15 Pump Seals

2. Replace the pump seals (Fig. 7-15) only if they are damaged or clogged. Remove the old pump seals with a pair of hemostats or tweezers. Carefully grasp the seal and pull it out.

CAUTION: *When removing the seals, take extra care to avoid damaging the nipples located at the bottom of the seal recess.*

3. Press the new pump seals into the seal recess with the large side facing up.

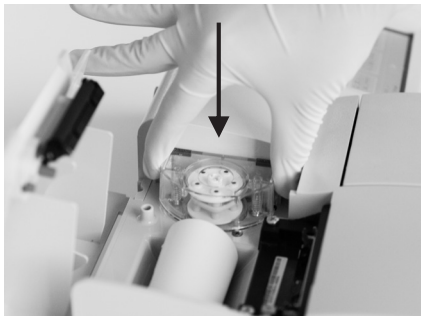


Fig. 7-16 Install New Cartridge

4. Install the new pump cartridge by first rotating the flat surface on the pump motor shaft to align with the flat surface of hole (keyway) in the pump cartridge roller. Press the cartridge firmly down until it is fully seated on the housing of the instrument (Fig. 7-16).

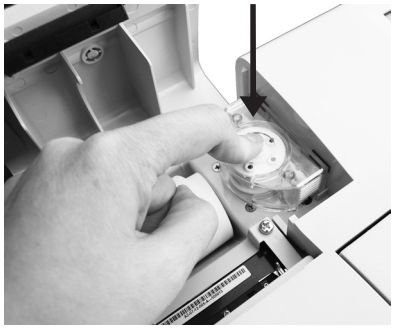


Fig. 7-17 Push on Pump Roller

5. Press the pump cartridge roller down until it firmly sits on the shaft of the pump motor (Fig. 7-17).
6. Perform a **<Pump Test>** (see section 8.2.16) to ensure correct operation. Make sure the pump rotates smoothly without excessive noise. In addition, run one sample in control mode. Make sure the control measurement passes without errors.

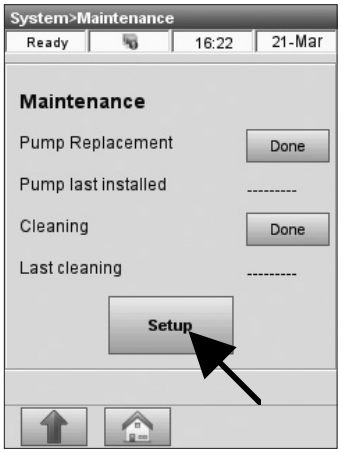


Fig. 7-18 Maintenance Setup

The OPTI CCA-TS2 has a function that allows you to select maintenance reminder options which will alert you when the next pump replacement is due.

Any maintenance actions that you perform through the maintenance reminders will be captured in the maintenance log of the analyzer.

1. From the **<Ready>** display, select **<System Manager>** and **<Maintenance>**.
2. Enter User ID if enabled
3. In the **<Maintenance>** menu (Fig. 7-18), press **<Setup>**.

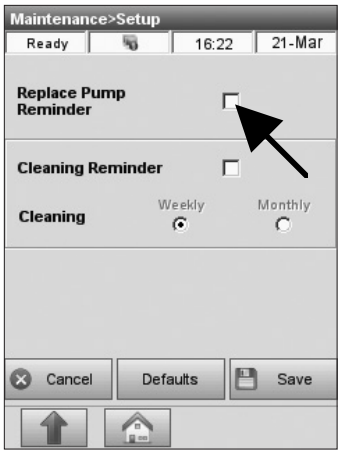


Fig. 7-19 Replace Pump

4. In the **<Setup>** screen (Fig. 7-19), you can select the option **<Replace Pump Reminder>**.

   The analyzer will then remind you when the next pump replacement is due.
5. After you replace the peristaltic pump, go to the **<Maintenance>** screen (Fig. 7-18) and press Done next to **<Pump Replacement>**.

   You will be prompted to enter the Date of Manufacture (DOM)

   The date of the last pump replacement will be displayed for future reference.

7.4.2 Replacing Gas I/O Port

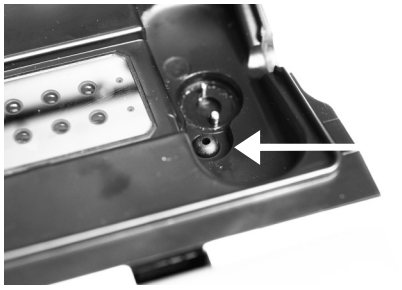


Fig. 7-20 Gas I/O Port

To change the gas I/O port:

1. Open the SMC cover. Remove the black I/O port by grasping it with a hemostat or tweezers and firmly pulling upward (Fig. 7-20). Discard the old part.
2. Install the new gas I/O port with the rounded surface pointing up and press it into the recess. When fully seated, the I/O port is approximately 1/8 inch (3mm) above the surrounding surface.
3. Perform a **<Pump Test>** (see section 8.2.16) to ensure correct operation. Make sure the pump rotates smoothly without excessive noise. In addition, run one sample in control mode. Make sure the control measurement passes without errors.

7.5 As Needed Maintenance

7.5.1 Changing the Gas Bottle

Fig. 7-21 Select New Gas Bottle

Fig. 7-22 Scan Bar Code

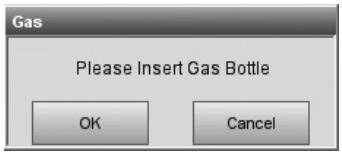


Fig. 7-23 Insert Gas Bottle

Fig. 7-24 Gas Bottle

The calibration gas bottle is designed to provide approximately 80 sampling operations (45 for B-Lac). The following message will alert the operator that the gas bottle needs to be changed (Fig. 7-21).

To change the gas bottle:

1. Press **<New Gas Bottle>**.
2. Unscrew the gas bottle by turning the knob on the bottom counterclockwise.
3. Take a new gas bottle and remove its cap.
4. When prompted (Fig. 7-22), scan the new gas bottle bar code on the insert sheet by holding it 2-3 inches (5-8 cm) from the bar code scanner on the bottom right-hand corner of the analyzer.
   - The red line from the barcode scanner should cover the entire barcode.
   - The analyzer will beep when the barcode is accepted.
   - Record the date of installation on the gas bottle for later reference.

NOTE: If the insert sheet is misplaced, you can enter the lot number on the gas bottle label manually. Press <Manual> *(Fig. 7-22) and enter the number using the numeric keypad.*

NOTE: The bar code contains expiration information. The OPTI CCA-TS2 will alert the operator two weeks before the gas bottle expires.

NOTE: The gas bottle should always be stored with the cap on.

5. When prompted (Fig. 7-23), install the new gas bottle.
6. Insert the bottle into its housing and turn it clockwise until finger-tight (Fig. 7-24). Press OK (Fig. 7-23).

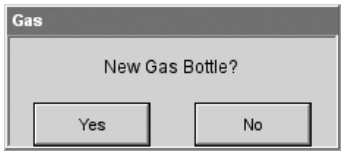


Fig. 7-25 New Gas Bottle

7. When this display appears (Fig. 7-25), press Yes to install a new gas bottle.

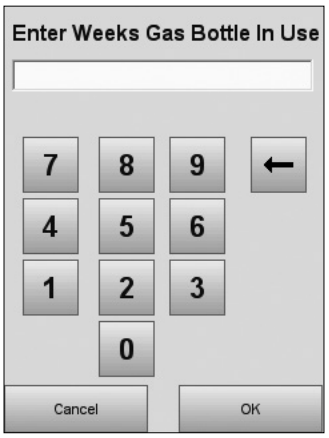


Fig. 7-26 Number of Weeks in use

NOTE: If you are reinstalling a used bottle, respond No *to the* <New Gas Bottle?> *prompt. You will then be asked to enter the number of weeks in service using the numeric keypad (Fig. 7-26). Here you may refer back to the installation date, which was recorded on the gas bottle.*

NOTE: The gas bottle in-use expiration is 6 months from installation or the shelf life of the gas bottle, whichever comes first.

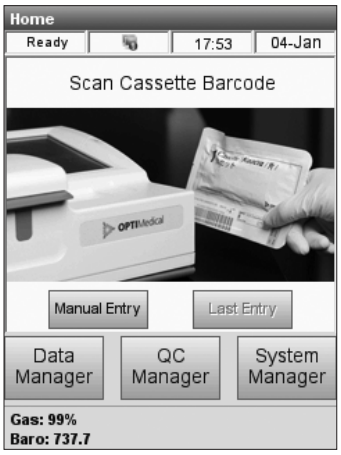


Fig. 7-27 Ready screen

- The analyzer will initiate a purge of the system, which will be indicated by a progress bar displayed on the screen, and will then return to the main screen (Fig. 7-27).

7.5.2 Changing the Printer Paper

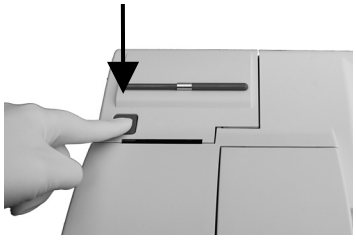


Fig. 7-28 Open Printer Cover

The thermal printer paper supplied by OPTI Medical contains an indicator strip to alert you when the paper roll should be changed.

To change the roll:

1. Press the red printer release button on the printer cover to acces the printer (Fig. 7-28).

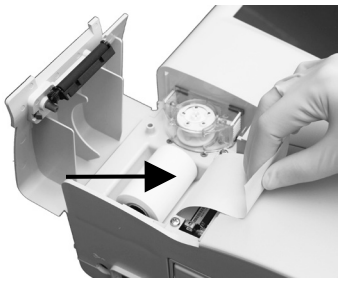


Fig. 7-29 Install Printer Paper

2. Place the roll of printer paper into the paper tray.
3. Pull the end of the paper upward and slightly out of the paper tray (Fig. 7-29).

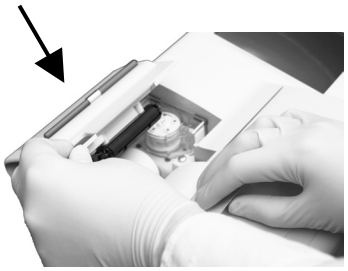


Fig. 7-30 Close Printer Cover

4. Hold the paper and close the printer cover (Fig. 7-30).
   - The paper will automatically feed through as the printer starts printing.

7.5.3 Performing Routine Cleaning

The OPTI CCA-TS2 Analyzer is designed to require very little maintenance. Routine cleaning consists of wiping the exterior analyzer surfaces including touch screen with a soft, damp cloth.

NOTE: Do not use cleaners with ammonia, abrasives, or greater than 10% bleach on the OPTI CCA-TS2 analyzer.

NOTE: Do not spray cleaning spray directly onto the screen.

8 DIAGNOSTICS AND TROUBLESHOOTING

Your OPTI® CCA-TS2 Analyzer is designed to provide trouble-free service.
However, any measuring device may occasionally malfunction requiring you to identify the cause of the problem and initiate corrective action.

This chapter describes OPTI CCA-TS2 specific system messages and recommends steps that should return your analyzer to operation. System errors are stored in memory and an error report can be printed (see Section 6.2.4).

If your OPTI CCA-TS2 does not perform correctly after conducting the basic steps outlined in this chapter, you should contact OPTI Medical Systems for technical assistance.

8.1 System Error and Warning Messages

The OPTI CCA-TS2 displays the following types of system status messages:

<SYSTEM WARNING MESSAGES>

- System warning messages notify the operator of conditions requiring operator intervention to complete the current measurement.

<SYSTEM ERROR MESSAGES>

- These errors occur during sample analysis and are specific to the current sample being analyzed. Error alarms indicate the status of the current measurement or additional required operator entry.

<SYSTEM STOP MESSAGES>

- These alarms indicate system conditions that must be resolved before system operation can be continued.

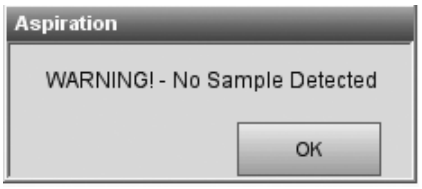
<NOT READY MESSAGES>

- These alarms indicate system conditions that must be resolved before system operation can resume.

<FATAL ERROR MESSAGES>

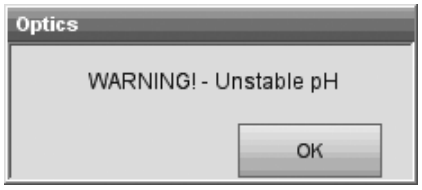
- These errors indicate conditions that halt system operation and may require instrument repair. Contact Technical Support for assistance.

8.1.1 System Warning Messages



<WARNING! - No Sample Detected>
The sensors did not detect any sample.

- Make sure the sample is properly attached and not clotted and does not contain air bubbles.
- Wait for the system to recalibrate.
- Remix the sample carefully.
- If the system does not detect the sample after retrying, press OK to notify the system that the sample is reattached and reaspirate sample.



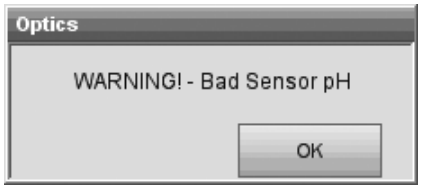
<WARNING! - Unstable pH>
The displayed measured parameter is unstable.

NOTE: This message is a warning. The analyzer will, however, display a result for the parameter concerned.

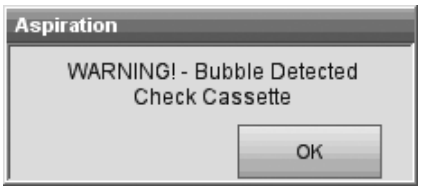
- For lactate cassettes, you have the option of continuing the measurement by pressing Continue or stopping by pressing Reject.
- For all other cassettes, press OK to continue.
- Once the measurement is complete, remove cassette and check for aspirated bubbles.
- If bubbles are present over a sensor, do not report that parameter.

<WARNING! - Bad Sensor pH>
The displayed sensor is defective.

- For lactate cassettes, you have the option of continuing the measurement by pressing Continue or stopping by pressing Reject. If you continue, no results will be provided for the defective sensor or any calculated result, which utilizes this measurement in its calculation.



- For all other cassettes, press OK to continue. The results for the defective sensor will not be provided.



<WARNING! - Bubble Detected>
A bubble was detected at the light gates.

- Remove the cassette.
- Press OK to continue.
- Examine the cassette and look for bubbles. If bubbles are present over a sensor, rerun the patient or QC sample.

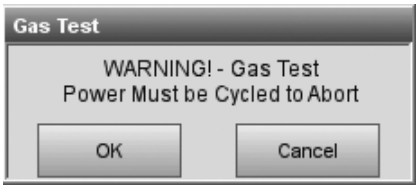
<WARNING! - Dirty Optics>
The optics or cassette are dirty.

- Remove the cassette. Inspect the cassette and optics on bottom and top plate. Clean, if necessary.
- Reinsert the cassette and press OK to rerun the test.

<WARNING! - Gas expires soon!>
The gas bottle dating will expire in two weeks.

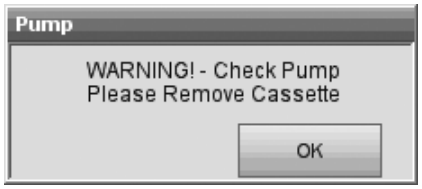
- Press OK to continue. Make sure you have another gas bottle on hand or ordered.

NOTE: The gas bottle expires 6 months after installation or after exceeding the labeled expiration date, whichever comes first.



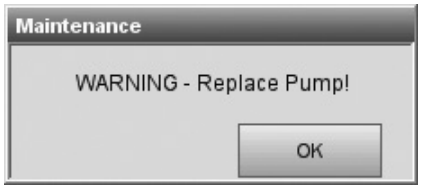
<WARNING! - Gas Test!>
The **<Gas Test>** is designed exclusively for use by authorized OPTI Medical personnel to check for leaks in the gas system. This test will last 2 hours and can only be interrupted by switching the analyzer off.

- Press Cancel to cancel this test.



<WARNING! - Check Pump>
The peristaltic pump is getting worn.

- Remove the cassette.
- Retry with a new cassette.
- Change the peristaltic pump cartridge (See Section 7.4.1).



<WARNING! – Replace Pump>

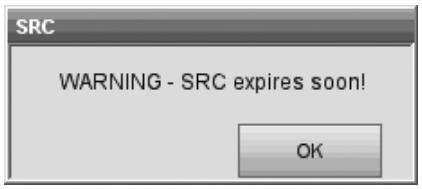
The peristaltic pump is due to be replaced.

- If maintenance reminders are enabled, the replace pump reminder will appear once when due during cassette installation.
- Afterwards, a reminder message will be appended to the end of every patient and QC measurement report, until the pump is replaced and the **<Done>** button is selected on the system maintenance menu. See section 7.4.1 for instructions.

<WARNING! – OPTI Requires Cleaning>

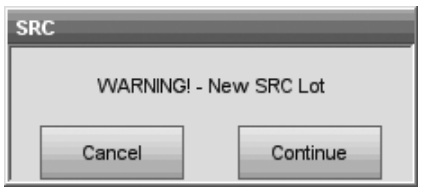
The Sample Measurement Chamber (SMC) is due to be cleaned.

- If maintenance reminders are enabled, the cleaning reminder will appear once when due during cassette installation.
- Afterwards, a reminder message will be appended to the end of every patient and QC measurement report until the instrument is cleaned and the **<Done>** button is selected on the system maintenance menu. See section 7.2 for instructions



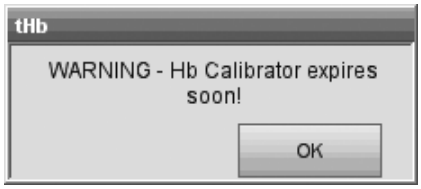
<WARNING! - SRC expires soon!>
The SRC will expire in two weeks.

- Press OK to continue. Make sure you have more SRCs on hand or ordered.



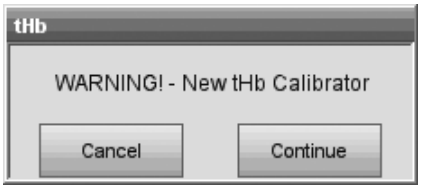
<WARNING! - New SRC Lot>
This message is displayed to alert the user that a new SRC lot is being used.

- Press [Continue] to continue measurement with the new SRC.



<WARNING! - Hb Calibrator expires soon!>
The Hb Calibrator cassette will expire in two weeks.

- Press [OK] to continue. Make sure you have another Calibrator Cassette on hand or ordered.



<WARNING! - New tHb Calibrator>
This message is displayed to alert the user that a new tHb calibrator is being used.

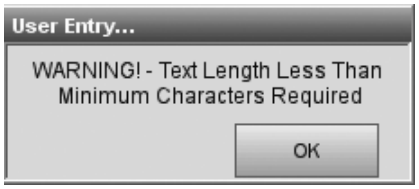
- Press [Continue] to continue measurement with the new tHb calibrator.

<WARNING! - Control Failed!>
A control measurement has failed during B-Lac Setup.

- Press [OK] to rerun the measurement.

<WARNING! - Required Fields - Missing Data>
If patient data options have been set up as **<Required>** in the **<Setup>** menu (Section 3.2.2), the required information will have to be entered before the user can exit this screen.

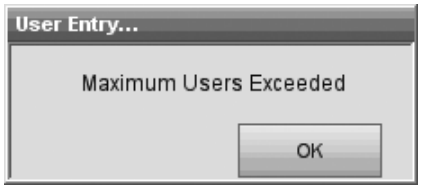
- Press [OK] and enter the required information.



<WARNING! - Text Length Less Than Minimum Characters Required>
If a minimum number of characters has been set up for patient ID entry (Section 3.2.2.2), the patient ID entered must meet the required minimum.

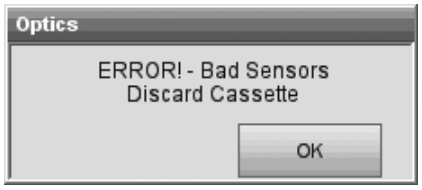
- Press [OK] and enter a patient ID with the required number of characters.

8.1.2 System Error Messages



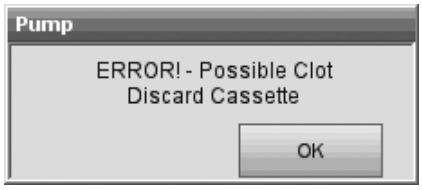
<Maximum Users Exceeded>
The number of user IDs stored in memory has reached 300.

- Press OK to continue.
- Delete unused user IDs from memory (See Section 3.2.3.1.2).



<ERROR! - Bad Sensors>
Two or more measured parameter sensors are bad.

- Press OK, discard the cassette and repeat the test with a new cassette.



<ERROR! - Possible Clot>
A sample error has occurred. This may be due to a clot or blockage preventing sample aspiration.

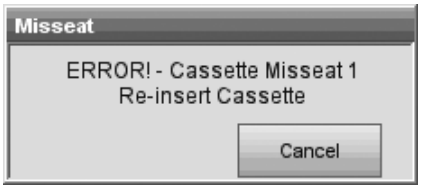
- Press OK and discard cassette.

<ERROR! - B-Lac Setup failed>
This error message appears when the reproducibility of the OPTI Check controls during the lactate setup procedure is out of range.

- Repeat lactate setup procedure. Make sure to aspirate the OPTI Check directly from the ampoule.
- Repeat the lactate setup using a different lactate cassette lot.
- Call Technical Support.

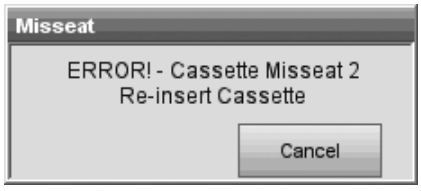
<ERROR! - Wrong/Different Lot>
An incorrect cassette type or lot was scanned in during B-Lac setup.

- All cassettes used during lactate setup must be the same lot number.
- Make sure the cassette type is B-Lac.



<ERROR! - Cassette Misseat 1>
The cassette was not properly placed into the chamber or it was previously used.

- Open the SMC cover.
- Reinsert the cassette and verify proper seating.



<ERROR! - Cassette Misseat 2>
The cassette was not properly placed into the chamber or it was previously used.

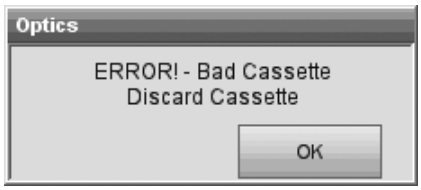
- Open the SMC cover, remove and reinsert the cassette and close the cover. Optionally, tap the cassette firmly on the tabletop to dislodge bubbles.

OR

- Press Cancel to use a different cassette. Make sure to wipe the new cassette dry before inserting it into the SMC.
- Check pump and I/O port.

<ERROR! - Cassette Misseat 2>
The cassette was not properly placed into the chamber or it was previously used.

- Press OK, discard the cassette and repeat test with a new cassette.
- If the message still appears with a different cassette, turn the power off and back on and retry.

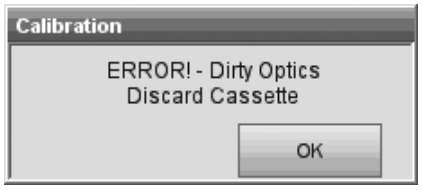


<ERROR! - Bad Cassette>
The cassette or its packaging is defective.

- Press OK, discard the cassette and repeat test with a new cassette. Make sure to wipe the new cassette dry before inserting it into the SMC.
- If the message still appears with a different cassette, turn the power off and back on and retry.

<ERROR! - Bad Calibration>
The instrument did not calibrate due to problems with the cassette or instrument.

- Press OK, discard the cassette and repeat the test with a new cassette.
- If the message still appears with a different cassette, turn the power off and back on and retry.



<ERROR! - Dirty Optics>
The analyzer is unable to calibrate the sample light gates due to dirty optics or cassette.

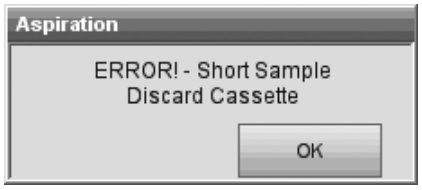
- Remove and discard the cassette. Inspect and clean the optics glass and inside the sample measurement chamber top cover.
- Press OK to continue.
- Check the LEDs (See Section 8.2.4).

<ERROR! - Calibration Expired>
The cassette has been holding the calibration for more than 10 minutes without a sample being attached. This error can also be triggered if any sample is detected on the front light gate that does not meet the required sample volume (smaller than short sample).

- Press OK and discard the cassette.

<ERROR! - Unstable Sensors>
A sample error has occurred. This may be due to a clot or large air bubble if two or more sensors are unstable.

- Press OK and discard the cassette.
- Check the sample and rerun with a new cassette.



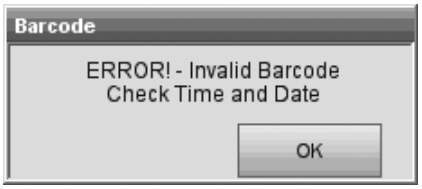
<ERROR! - Short Sample> The system was not able to aspirate enough contiguous sample fluid to cover the optode sensors after multiple aspiration attempts. If a bubble was detected, the system attempted to restart the aspiration and was not able to aspirate enough sample.

- Press OK and discard the cassette.

<ERROR! - Invalid Barcode>

The bar code was invalid. The OPTI CCA-TS2 either misread the bar code label or it is an invalid bar code for the OPTI CCA-TS2.

- Press OK to retry.
- If the error message appears again, check the product package for intended use.
- Check the bar code scanner (see Sections 8.2.11 or 8.3.2).
- Clean the bar code scanner. Using a lint-free cloth dampened with a dilute alcohol, gently wipe the face of the scanner clean.
- Retry the bar code.



<ERROR! - Invalid Barcode - Check Time and Date>

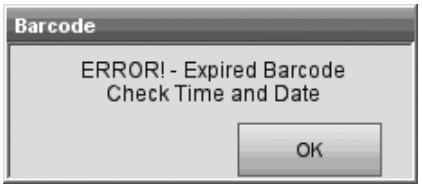
The bar code was invalid. The OPTI CCA-TS2 either misread the bar code or the product (i.e. gas bottle, cassette or SRC) has expired.

- Press OK to retry.
- If the error message appears again, check the date in **<System ->Time and Date>**.
- Verify the product expiration date.

<ERROR! - Invalid Barcode - Different QC Lot>

The bar code was invalid.

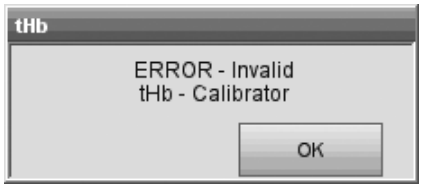
- Verify that **<Barcode A>** and **<Barcode B>** of the QC material is from the same level and lot number.
- Press OK to continue.



<ERROR! - Expired Barcode>

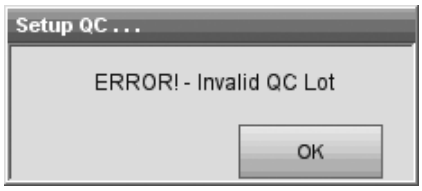
The cassette expiration date has been reached.

- Press OK to retry.
- If the error message appears again, check the date in **<System ->Time and Date>**.
- Verify the product expiration date.



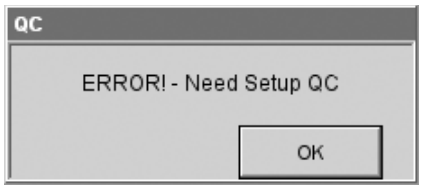
<ERROR! - Invalid tHb Calibrator>
The cassette placed in the SMC is invalid.

- Verify that the cassette placed in the SMC is a valid Hb calibrator.
- Press OK to continue.



<ERROR! - Invalid QC Lot>
The QC lot is invalid.

- Press OK to continue.
- Configure the control material under **<Setup>** and retry.

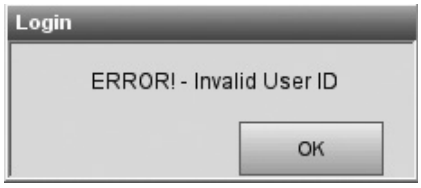


<ERROR! - Need Setup QC>
A measurement of QC materials was attempted prior to setting up.

- Press OK to continue.
- Configure the QC material under **<Setup>** and retry.

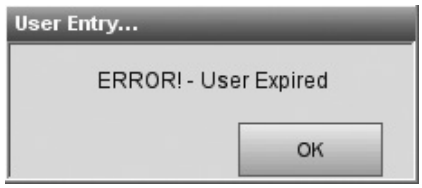
<ERROR! - User ID Already Exists>
The selected user ID already exists in the database.

- Press OK to continue.
- Enter a unique user ID.



<ERROR! - Invalid User ID>
The user ID does not exist in current user database.

- Press OK to continue.
- Retry with a valid user ID.

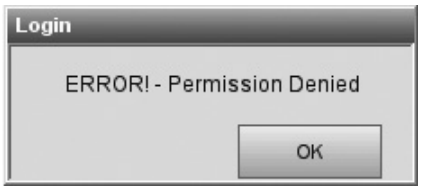


<ERROR! - User Expired>
The user ID expired.

- Press OK to continue.
- Update the user information.

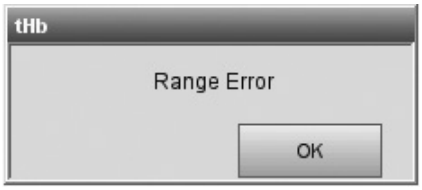
<ERROR! - Passwords Don't Match>
The password entered was incorrect.

- Press OK to continue.
- Enter the correct password.



<ERROR! - Permission Denied>
Permission denied since user does not have access privileges for the selected function.

- Press OK to continue. Information on setting up user permissions can be found in Section 3.2.3.1.3.



<Range Error>
This error may occur during Hb calibration.
The error is triggered, when the correction is greater than 10%.

- Press OK and replace the Hb calibrator.

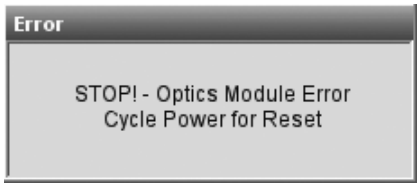
<ERROR! - Not enough records in Level 1/2/3>
There are not enough records in the database to generate a statistics report. A minimum of two records is required for each lot per level.

- Press OK to continue.

<ERROR! - Group Name Already Exists>
The selected group name already exists in the database.

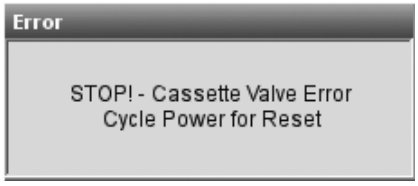
- Press OK to continue.
- Enter a unique group name.

8.1.3 System Stop Messages



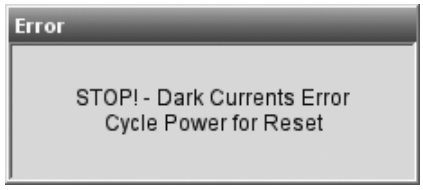
<STOP! - Optics Module Error>
Optics Module Error detected when reading optics data.

- Shut down the system and restart to attempt to clear the error.



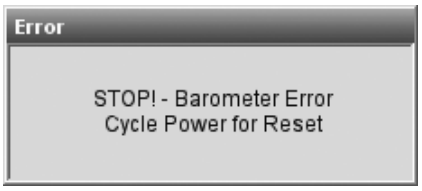
<STOP! - Cassette Valve Error>
The cassette valve failed to find the home position.

- Shut down the system and restart to attempt to clear the error.



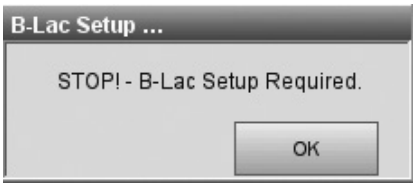
<STOP! - Dark Currents Error>
Dark currents exceed allowable limits.

- Shut down the system and restart to attempt to clear the error.



<STOP! - Barometer Error>
The barometer reading is outside the measurement range.

- Shut down the system and restart to attempt to clear the error.



<STOP! - B-Lac Setup Required>
This error message will appear if you try to run lactate cassettes and the lactate parameter has not been set up on your analyzer.

- Refer to section 8.2.20 for instructions to set up the lactate parameter.

<STOP! - Temperature Out of Range>
The temperature is out of range during any kind of measurement.

- Press OK and continue.
- If the error message appears again, check the temperature under **<System - Diagnostics>**.

8.1.4 Not Ready Messages

<Not Ready: Gas Not Installed>
The gas bottle is empty or has not been installed properly. If you remove a gas bottle that is still valid, you will have to reinstall the same gas bottle.

- Press **<New Gas Bottle>** and reinstall the gas bottle (See Section 7.5.1).

<Not Ready: Gas Expired>
The in-use (6 months) or labeled shelf-life of the gas bottle has expired.

- Press **<New Gas Bottle>** and replace the gas bottle (see Section 7.5.1).

<Not Ready: Low Battery>
The battery voltage is low.

- Operate the analyzer on AC power and/or recharge the battery.

<Not Ready: Battery Critical>
The battery is discharged and the instrument will not perform any measurements.

- Install a freshly charged battery or recharge for up to 2.5 hours before the next sample is run, or operate the analyzer on AC power.

<Not Ready: Temperature Out Of Range>
The temperature is out of range.

- Wait for the analyzer to reach the correct temperature.
- Cycle the power if the analyzer does not go to **<Ready>** within a few minutes.
- If the analyzer does not become **<Ready>** within a reasonable time, check the temperature under **<System - Diagnostics>**.
  Check that ambient temperature is within operating specifications on page 2-1.

<Not Ready: Temperature Error>
The SMC temperature exceeds 39 °C for more than 20 seconds.

- Press **<Data Manager>** or **<System Manager>** to exit this screen.
- Contact Technical Support for assistance.

<Not Ready: SRC Lockout>
If **<SRC Lockout>** has been activated in **<Setup>** (see Section 3.2.1.2), this message will be displayed if SRCs have not been run within the specified time.

- Press **<Run SRC>** and run SRCs (see Section 4.5.1).

<Not Ready: QC Lockout>
If **<QC Lockout>** has been activated in **<Setup>** (see Section 3.2.1.2), this message will be displayed if controls have not been run within the specified time.

- Press **<Run QC>** and run control materials (see Section 4.5.2,1).

<Not Ready: Remote Lockout>
The instrument has been locked remotely and cannot be used.

- Press **<Data Manager>**, **<QC Manager>** or **<System Manager>** to exit this screen.

<Not Ready: FSet Error>

The factory settings have been corrupted and are not valid.

- Shut down the system and restart to attempt to clear the error.
- If the error cannot be cleared by cycling the power, contact Technical Support for assistance.

<Measurement Access Prohibited>
The user does not have privileges to run a patient measurement as defined by the security settings (Section 3.2.3).

- Press **<Data Manager>**, **<QC Manager>** or **<System Manager>** to exit this screen.

8.1.5 Fatal Error Messages

<Fatal Error: Barometer Out Of Range>
Barometer failure. The barometer reading is outside measurement range.

- Shut down the system and restart to attempt to clear the error.
- If the error cannot be cleared by cycling the power, contact Technical Support for assistance.

<Fatal Error: Cassette Valve>
The cassette valve failed to find the home position.

- Shut down the system and restart to attempt to clear the error.
- If the error cannot be cleared by cycling the power, contact Technical Support for assistance.

<Fatal Error: Dark Currents>

Dark currents exceed allowable limits.

- Shut down the system and restart to attempt to clear the error.
- If the error cannot be cleared by cycling the power, contact Technical Support for assistance.

<Fatal Error: Optics>

Failure detected in optics system.

- Shut down the system and restart to attempt to clear the error.
- If the error cannot be cleared by cycling the power, contact Technical Support for assistance.

<Fatal Error: Database>

Error detected in database.

- Shut down the system and restart to attempt to clear the error.
- If the error cannot be cleared by cycling the power, contact Technical Support for assistance.

<Exception!>

Processor exception occurred.

- Press OK to exit the screen and contact Technical Support for assistance.

NOTE: Please capture the information on the screen for technical support.

For Technical Support inside the USA:

Please contact OPTI Medical at +1-770-510-4444, toll free at +1-800-490-6784 option 1 or technicalsupport@optimedical.com.

Outside the USA:

Please contact your authorized OPTI Medical distributor.

8.2 Diagnostics

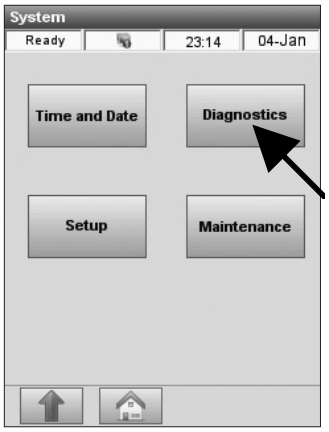


Fig. 8-1 Diagnostics

Your OPTI CCA-TS2 has a number of useful diagnostic programs.

In the main menu, press **<System Manager-> Diagnostics>** (Fig. 8-1).

The **<Diagnostics>** screen contains three tabs with various diagnostic functions: **<Sensors>**, **<Hardware>** and **<Tests>**.

8.2.1 Checking Versions

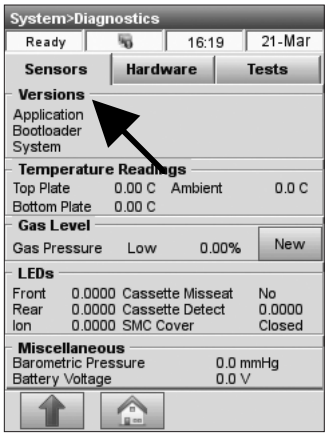


Fig. 8-2 Versions

In the main menu, press **<System Manager -> Diagnostics>**.

The first option on the **<Sensors>** screen, **<Versions>** (Fig. 8-2), allows you to check the system versions.

- Press  to return to the **<System>** screen or  to return to the main menu.

8.2.2 Checking System Temperatures

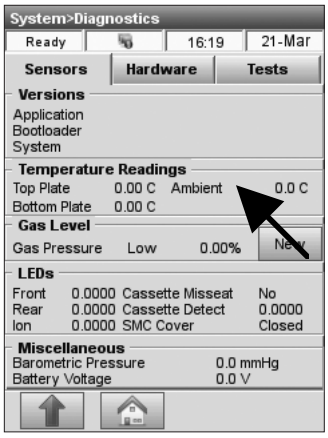


Fig. 8-3 Temperature

In the main menu, press **<System Manager -> Diagnostics>**.

The **<Temperature Readings>** option lets you check the various system temperatures: **<Top Plate>**, **<Bottom Plate>** and **<Ambient>** (Fig. 8-3).

NOTE: If top or bottom plate temperatures are out of range, the temperature display will change to red.

- Press  to return to the **<System>** screen or  to return to the main menu.

8.2.3 Checking Gas Pressure

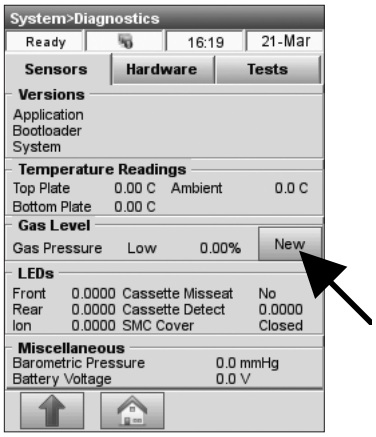


Fig. 8-4 Gas Pressure

The **<Gas Level>** option allows you to check the percent remaining of the gas bottle (Fig. 8-4).

With a new gas bottle in place, the pressure should be approx. 99%, with the bottle removed, the pressure should be 00%.

In the main menu, press **<System Manager>** and **<Diagnostics>**.

- To install a new gas bottle, press  .
- Scan the gas bottle bar code located on the insert sheet to install a new gas bottle (see Section 7.5.1 “Changing Gas Bottle”) .
- Press  to return to the **<System>** screen or  to return to the main menu.

8.2.4 Checking the LEDs

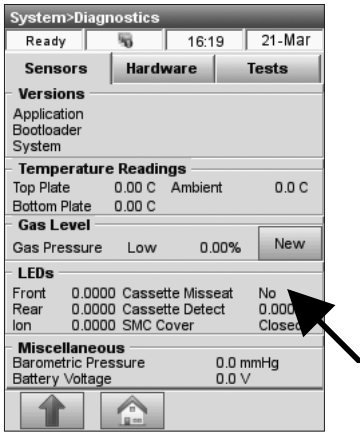


Fig. 8-5 LEDs

This menu can be used to check proper functioning of the LEDs and is designed for use by trained service personnel only.

In the main menu, press **<System Manager -> Diagnostics>**.

The following information is displayed in the **<LEDs>** section (Fig. 8-5):

- **<Front>**, **<Rear>**, **<Ion>** - fluid light gates.
- **<Cassette Misseat>** detector (located in cover)
- **<Cassette Detect>** sensor
- **<SMC Cover>** - this function indicates whether the SMC cover is closed or open.
- Press  to return to the **<System>** screen or  to return to the main menu.

8.2.5 Verifying Barometric Pressure

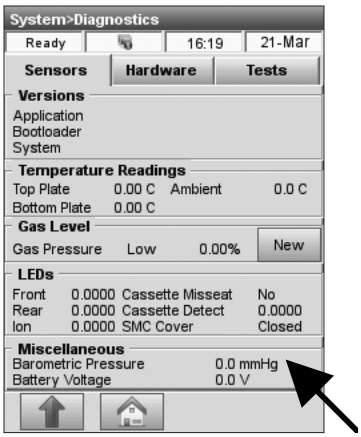


Fig. 8-6 Barometric Pressure

This menu displays the current barometric pressure.

In the main menu, press **<System Manager -> Diagnostics>**.

- The **<Miscellaneous>** section will show the current barometric pressure (Fig. 8-6).
- If the barometric pressure requires adjustment, refer to Setup, Section 3.2.4.4.1 “Entering the Barometric Pressure” for setting the barometer.
- Press  to return to the **<System>** screen or  to return to the main menu.

8.2.6 Checking the Battery Voltage

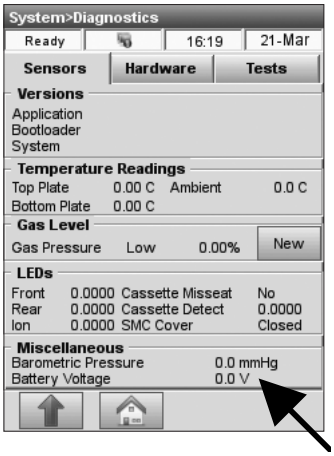


Fig. 8-7 Battery Voltage

This selection lets you check the battery voltage.

In the main menu, press **<System Manager -> Diagnostics>**.

- The second display in the **<Miscellaneous>** section shows the battery voltage (Fig. 8-7).
- If the voltage is below 9.0V, the battery needs to be recharged or may need replacement.
- Press  to return to the **<System>** screen or  to return to the main menu.

8.2.7 Checking the Cooling Fan

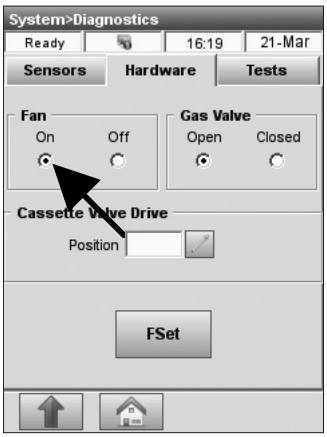


Fig. 8-8 Cooling Fan

The purpose of this test is to check for proper functioning of the cooling fan.

In the main menu, press **<System Manager -> Diagnostics>**.

- Select the **<Hardware>** tab.
- Press the **<On>** button under **<Fan>** to start the test (Fig. 8-8).
- You should feel the draft of the fan by placing your hand over the fan at the back side of the analyzer.
- Press  to return to the **<System>** screen or  to return to the main menu.

8.2.8 Checking the Gas Valve

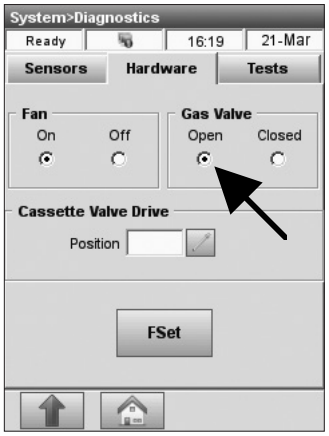


Fig. 8-9 Gas Valve

The purpose of this test is to check for proper function of the gas valve.

In the main menu, press **<System Manager -> Diagnostics>**.

- Select the **<Hardware>** tab.
- Press the **<Open>** button under **<Gas Valve>** to start the test (Fig. 8-9).
- A faint hissing sound may be heard with the pump cartridge removed and the gas valve open.
- Press  to return to the **<System>** screen or  to return to the main menu.

8.2.9 Checking the Valve Drive

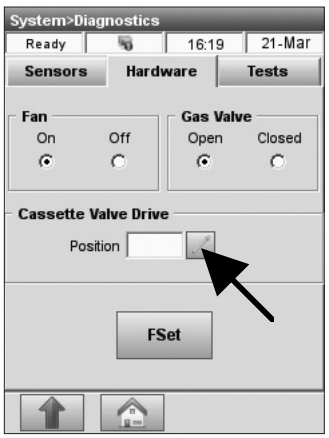


Fig. 8-10 Valve Drive

This diagnostic checks the proper operation of the cassette valve drive mechanism.

In the main menu, press **<System Manager -> Diagnostics>**.

- Select the **<Hardware>** tab.
- Press  (Fig. 8-10) and enter the various positions (allowed positions are 1 - 12) to verify the valve drive moves smoothly and precisely.
- Press  to return to the **<System>** screen or  to return to the main menu.

8.2.10 Checking the Factory Settings (FSet)

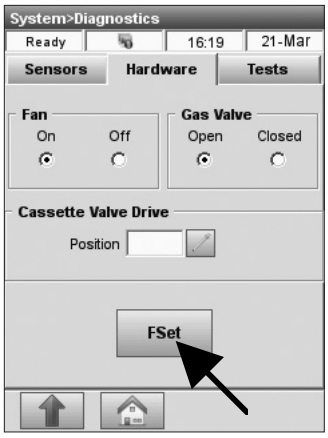


Fig. 8-11 Factory Settings

The **<FSet>** function (Fig. 8-11) is designed exclusively for use by authorized OPTI Medical personnel and requires a special User ID and password.

- Press  to return to the **<System>** screen or  to return to the main menu.

8.2.11 Checking the Bar Code Scanner

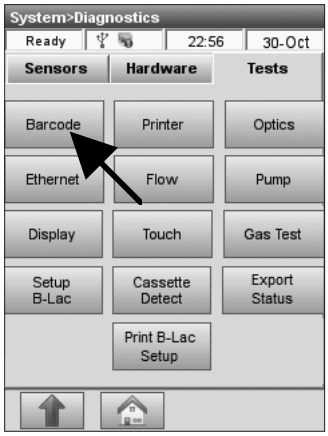


Fig. 8-12 Barcode Test

Fig. 8-13 Scan Barcode

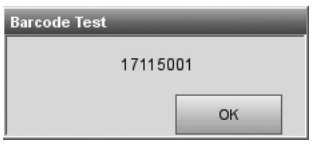


Fig. 8-14 Barcode Test

This option allows you to check the function of the bar code scanner.

In the main menu, press **<System Manager -> Diagnostics>**.

- Select the **<Tests>** tab.
- Press **<Barcode>** to start the test (Fig. 8-12).

- To test the bar code scanner, scan a bar code label of e.g. a sensor cassette (Fig. 8-13).
- The display will show a sequence of numbers (Fig. 8-14). Compare the numbers with those printed on the cassette bar code label. Matching information confirms the proper function of the bar code scanner.
- Press  to return to the **<Tests>** screen.
- Press  to return to the **<System>** screen or  to return to the main menu.

8.2.12 Checking the Printer

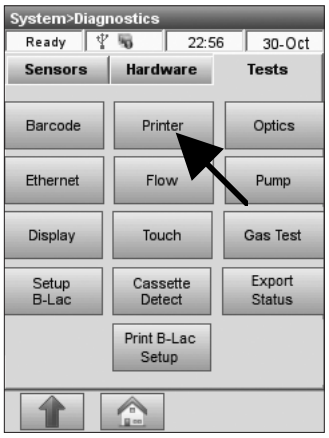


Fig. 8-15 Printer Test

This diagnostic function lets you check for the proper functioning of the built-in thermal printer. To activate:

In the main menu, press **<System Manager -> Diagnostics>**.

- Select the **<Tests>** tab.
- Press **<Printer>** to start the test (Fig. 8-15).
- The printer will output a test print.
- Check if the alphanumeric printout is legible and all the characters are properly printed.
  If the printout is deficient, your printer may need replacement.

To replace the printer, follow the steps below.

- Turn the OPTI CCA-TS2 off.
- Remove the paper roll and pump cartridge.
- Unscrew the two thumbscrews holding the printer in place.
- Pull printer up and out towards the paper tray.
- Disconnect the cable from the receptacle.
- Install the new printer in reverse order.
- Press  to return to the **<System>** screen or  to return to the main menu.

8.2.13 Checking the Optics

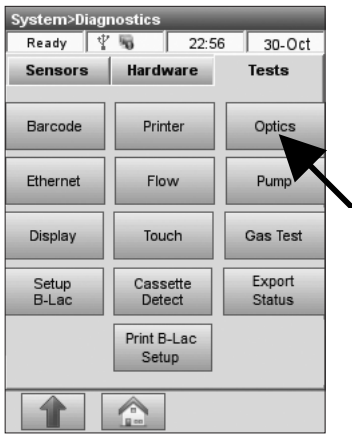


Fig. 8-16 Optics Test

This option checks the output of the six optics channels. This test is designed for trained service personnel.

In the main menu, press **<System Manager -> Diagnostics>**.

- Select the **<Tests>** tab.
- Press **<Optics>** to start the test (Fig. 8-16).

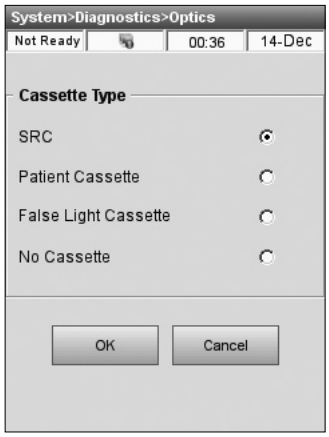


Fig. 8-17 Cassette Type

- Select the Cassette type and press 

(Fig. 8-17).

Fig. 8-18 Insert Cassette

- Insert the cassette and close the cover (Fig. 8-18).
- An optics tests will be performed to verify operation of the optical system.

Fig. 8-19 Remove Cassette

- At the completion of the test, the results will be printed and you will be asked to remove the cassette (Fig. 8-19).

8.2.14 Checking the Ethernet Interface

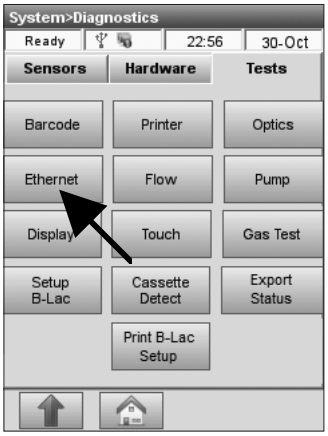


Fig. 8-20 Ethernet Test

The purpose of this test is to check for proper functioning of the Ethernet interface.

In the main menu, press **<System Manager -> Diagnostics>**.

- Select the **<Tests>** tab.
- Press **<Ethernet>** to start the test (Fig. 8-20).

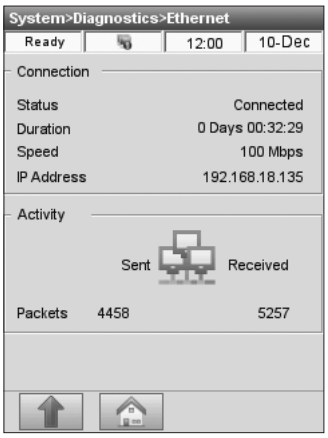


Fig. 8-21 Ethernet Test

- The system will send out data and check if they are received (Fig. 8-21).
- Press  to return to the **<System>** screen or  to return to the main menu

8.2.15 Checking the Pump Flow

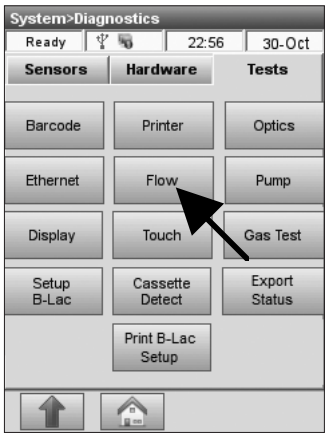


Fig. 8-22 Flow Test

This option is designed to test the pump cartridge.

In the main menu, press **<System Manager -> Diagnostics>**.

- Select the **<Tests>** tab.
- Press **<Flow>** to start the test (Fig. 8-22).

Fig. 8-23 Insert Cassette

- Insert a new cassette (Fig 8-23).
- Close the SMC cover.

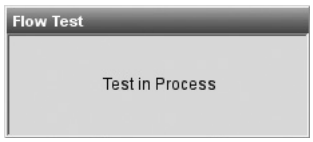


Fig. 8-24 Flow Test in Process

- Wait for test results (Fig. 8-24).

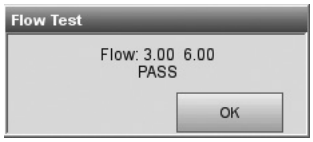


Fig. 8-25 Flow Test Pass

- The two numbers indicate the actual flow rates clockwise and counter clockwise (Fig. 8-25). If one of the two or both rates are out of range, the test fails.
- Repeat test or replace the pump cartridge, if the test fails. See replacement instructions in Chapter 7.4.1.

NOTE: It is possible that the test fails the first time, even if the pump cartridge is working correctly.

Fig. 8-26 Remove Cassette

- Remove the cassette (Fig. 8-26).

8.2.16 Checking the Pump Motor

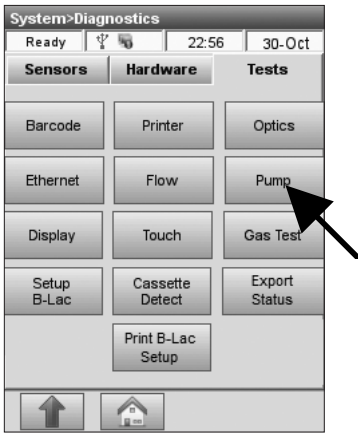


Fig. 8-27 Pump Motor Test

The purpose of this test is to check the proper functioning of the peristaltic pump motor.

In the main menu, press **<System Manager -> Diagnostics>**.

- Select the **<Tests>** tab.
- Press **<Pump>** to start the test (Fig. 8-27).

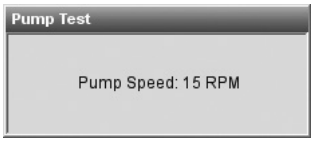


Fig. 8-28 Pump Speed

- The pump will automatically step through all the speeds used during normal operation (7.5 to 120 rpm (revolutions per minute)) (Fig. 8-28) and return to the **<Tests>** screen.

8.2.17 Checking the Display

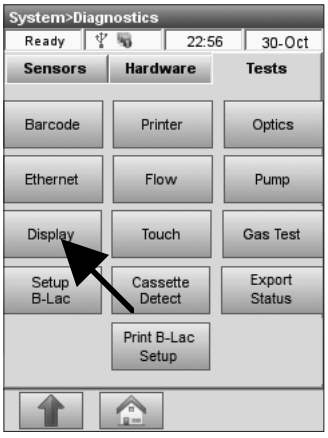


Fig. 8-29 Display Test

The purpose of this test is to check the proper operation of the display.

In the main menu, press **<System Manager -> Diagnostics>**.

- Select the **<Tests>** tab.
- Press **<Display>** to start the test (Fig. 8-29).
- The display will turn red, green and blue.
  If this is not the case, your display is defective and needs to be replaced.
- Press  to return to the **<System>** screen or  to return to the main menu.

8.2.18 Checking the Touch Screen

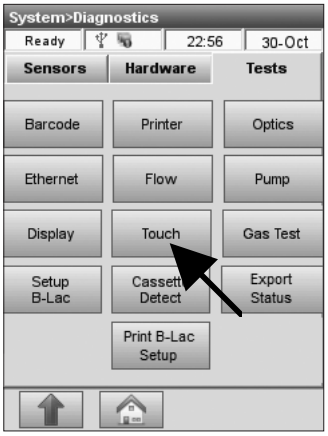


Fig. 8-30 Select Touch Test

The purpose of this test is to check the proper operation of the touch screen.

In the main menu, press **<System Manager -> Diagnostics>**.

- Select the **<Tests>** tab.
- Press **<Touch>** to start the test (Fig. 8-30).

Fig. 8-31 Perform Touch Test

- Touch the screen and a dot should appear under the touched location (Fig. 8-31).
- If not, press **<Calibrate>** to perform a touch calibration.

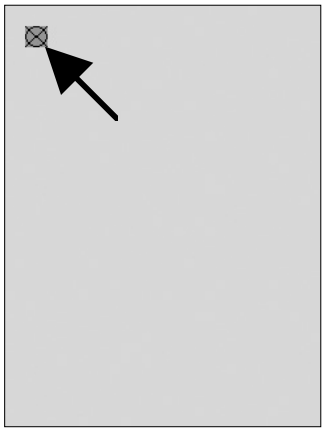


Fig. 8-32 Touch Calibration

- Using a finger, stylus or pointed object (e.g. syringe adapter), touch the center of the calibration mark as it moves around the screen (Fig. 8-32).

NOTE: Do not use sharp objects, since they may damage the screen.

- When finished press 

.
- Press  to return to the **<System>** screen or  to return to the main menu.

8.2.19 Gas Test

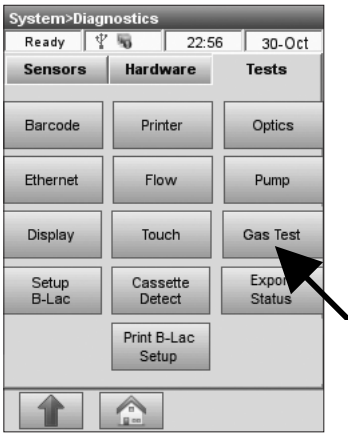


Fig. 8-33 Gas Test

The **<Gas Test>** (Fig. 8-33) is designed exclusively for use by authorized OPTI Medical personnel to check for leaks in the gas system.

NOTE: This test will last 2 hours. It can only be interrupted by switching the analyzer off.

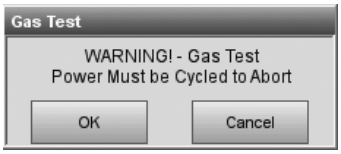


Fig. 8-34 Gas Test

- Press Cancel to cancel this test (Fig. 8-34).

8.2.20 Setting up the B-Lac Cassette

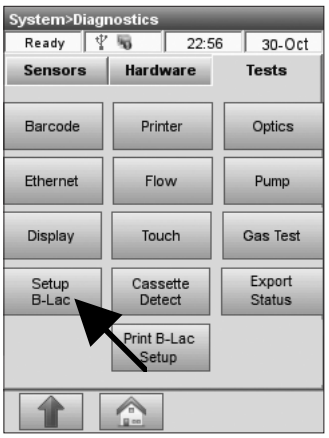


Fig. 8-35 B-Lac Setup

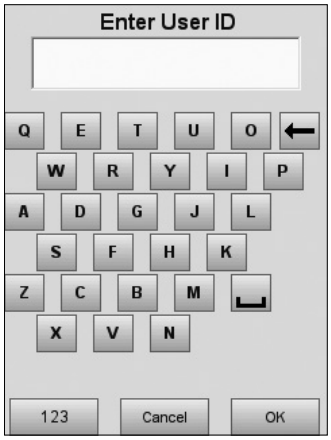


Fig. 8-36 Enter User ID

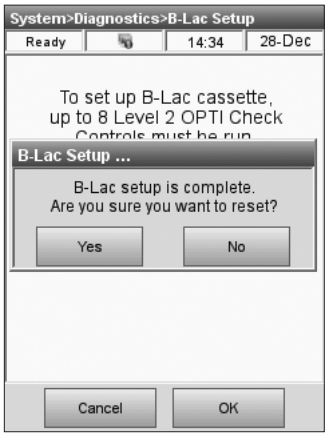


Fig. 8-37 B-Lac Setup

The **<B-Lac Setup>** menu is used to enable the running of lactate cassettes. The B-Lac setup procedure only has to be performed once on your analyzer. The setup will permanently enable B-Lac cassettes on your analyzer. The setup is not cleared by power loss, software upgrades, reset, or otherwise clearing the analyzer's database.

Contact Customer Service to order a B-Lac Setup Kit, BP7657, free of charge.

This is not a troubleshooting procedure. Call Technical Support for further assistance.

In the main menu, press **<System Manager -> Diagnostics>**.

- Select the **<Tests>** tab.
- Press **<Setup B-Lac>** (Fig. 8-35).

- Enter the security information if enabled (Fig. 8-36). Information on security functions can be found in Section 3.2.3.

NOTE: Bar-coded user IDs may be entered from this screen using the bar code scanner.

This message (Fig. 8-37) is displayed if lactate is already set up.

- Press [No] to keep the current settings and cancel the setup process.
- Press [Yes] to start the setup process.

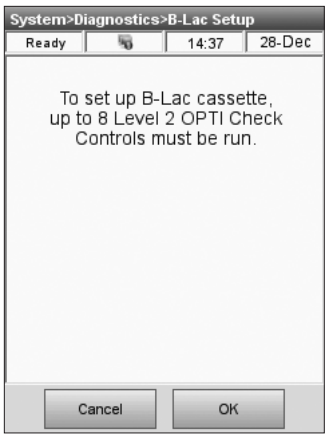


Fig. 8-38 Run Controls

To set up the B-Lac cassettes, you have to run up to 8 ampoules of OPTI Check level 2 (Fig. 8-38). Please make sure you have at least 8 ampoules of the same lot of OPTI Check and 8 B-Lac cassettes of the same lot on hand before starting setup.

- Press OK to run the first sample. Refer to section 4.5.2.1 for instructions on running controls.

Fig. 8-39 Run Controls

- After each level of OPTI Check is run, you will return to this screen (Fig. 8-39). You will not receive a results screen or printout until the setup procedure is complete. Continue to run the OPTI check with the same lot of cassettes and OPTI check until prompted. You may run from 5 to 8 OPTI checks.

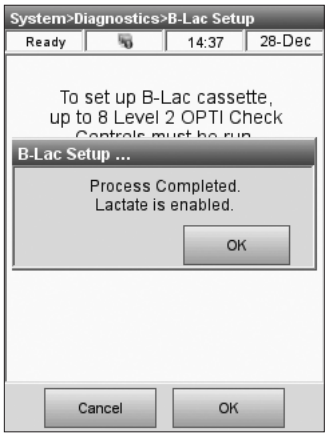


Fig. 8-40 B-Lac enabled

- After running the required number of samples, the lactate parameter is enabled (Fig. 8-40).
- Press OK to exit the menu.

  You will receive a B-Lac setup report once complete.

NOTE: The B-Lac Setup report can also be printed from the System>Diagnostics>Test screen. See Section 8.2.23.

After completing this procedure, OPTI Medical recommends that you run two levels of OPTI Check using B-Lac cassettes to verify performance.

Storage and Handling:

The contents of the package are stable when stored at 2-8°C (35-46°F) until the expiration date printed on the label. Allow cassettes to equilibrate at room temperature for 1 hour prior to use.

Cassettes that are in use may be left at room temperature (18-30°C or 64-86°F) for 4 weeks; however, cassettes should not be refrigerated again after they have been left at room temperature for 1 hour or more.

CAUTION: *Do not expose cassettes to temperatures above 46°C (115°F). OPTI Medical cannot guarantee the performance of the cassette when stored at temperatures outside the recommended range.*

Fig. 8-41 Out-of-storage warning

The OPTI CCA-TS2 has a function that will display warning messages for out-of-storage conditions for B-Lac and E-BUN cassettes during patient and QC measurements (Fig. 8-41).

This function is enabled by default and can be disabled in System Setup. See Section 3.2.2.2 Setting up Measured Parameters.

8.2.21 Cassette Detect

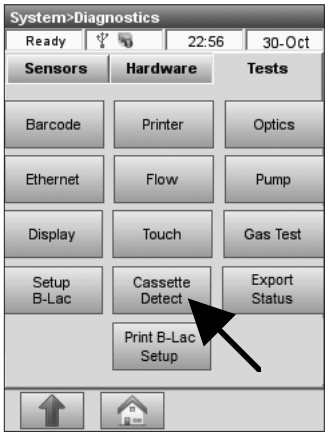


Fig. 8-42 Cassette Detect

The purpose of this test is to calibrate the Cassette Detect function when instruments stop detecting the cassettes. The message **<Open Cover>** will be displayed, and cassette calibration will not be started.

In the main menu, press **<System Manager -> Diagnostics>**.

- Select the **<Tests>** tab.
- Press **<Cassette Detect>** to start the calibration (Fig. 8-42).

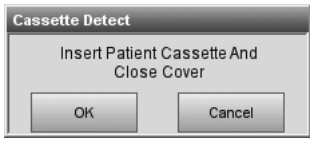


Fig. 8-43 Insert Cassette

- Insert a patient cassette (Fig. 8-43).

Fig. 8-44 Remove Cassette

- Remove the cassette and leave the cover open (Fig. 8-44).

Fig. 8-45 Close Cover

- Close the SMC cover (Fig. 8-45).

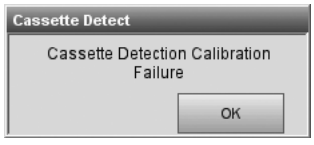


Fig. 8-46 Calibration

- The system performs a Cassette Detection Calibration (Fig. 8-46).

8.2.22 Export Status

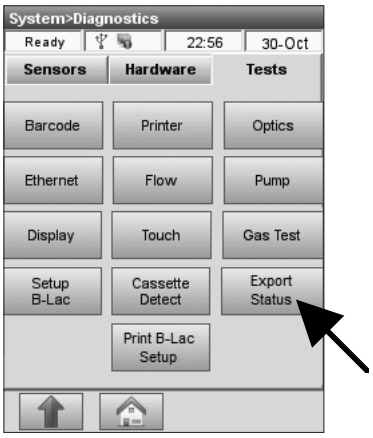


Fig. 8-47 Export Status

The **<Export Status>** menu allows you to check the status of exported records.

In the main menu, press **<System Manager -> Diagnostics>**.

- Select the **<Tests>** tab.
- Press **<Export Status>** (Fig. 8-47).

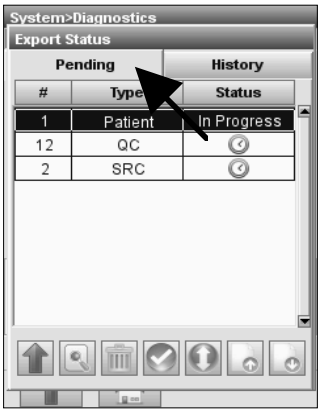


Fig. 8-48 Pending

The **<Export Status>** menu consists of two tabs, a **<Pending>** tab and a **<History>** tab.

The **<Pending>** tab lists records that are either in the process of being exported or are waiting to be exported (Fig. 8-48).

Records are moved from the **<Pending>** list to the **<History>** list when they are exported.

- The **<Record #>** column contains the record or sample number for each record.
- The **<Type>** column shows the record type as either Patient, QC, or SRC.
- The **<Status>** column shows the record export status with the text **<In Progress>** if the export is in progress, or with a clock icon if it is pending export.

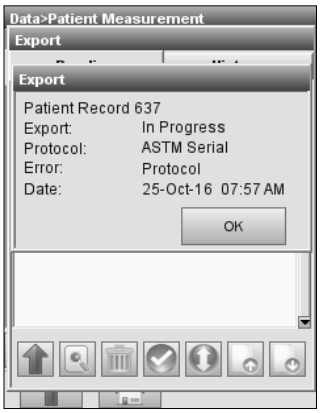


Fig. 8-49 Export Status

Fig. 8-50 Delete Data

The **<Pending>** tab includes the following buttons:

- The **<Up>** button is always active. Touching it closes the **<Export Status>** menu to return to the previous menu.
- The **<View>** button is active, if there is at least one record in the list. Selecting a record and pressing displays the following details for the selected record (Fig. 8-49):

  <Record Type/Number>
  <Export Status> (in progress or pending)
  <Protocol> (ASCII Serial, ASCII Ethernet, ASTM Serial, ASTM Ethernet, POCT1A Ethernet, or Removable Media)
  <Error> (Unknown, Establish, or Protocol)
  <Date/Time> record was selected for export.
- The **<Delete>** button is active, if there is at least one record in the list. Selecting a record or multiple records and then pressing , displays an acknowledgement dialog (Fig. 8-50).

  Press Yes to delete the records or No to cancel.
- The **<Select>** button is active, if there is at least one record in the list. Touching it selects the currently highlighted record. A subsequent touch of another record in the list will select that record as well as any records between it and the selected record.
- **<Select All>** is active, if there is at least one record in the list. It selects and highlights all records in the list.
- **<Page Up>** is active, if there is more than one page of records. Touching it displays the previous page of records in the list.
- **<Page Down>** is active, if there is more than one page of records. Touching it displays the next page of records in the list.

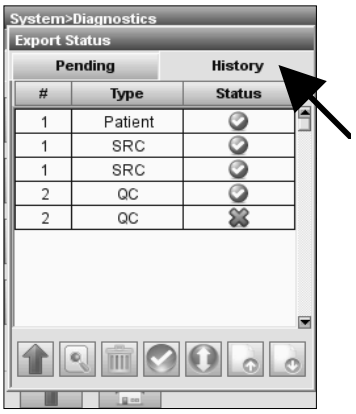


Fig. 8-51 History

The **<History>** tab lists the last 100 records that have been either successfully exported or failed to export (Fig. 8-51).

Records are removed and inserted using FIFO (First In First Out) order.

The **<History>** list has the same headings as the **<Pending>** list.

- The **<Record #>** column contains the record or sample number for each record.
- The **<Type>** column shows the record type as either Patient, QC, or SRC.
- The **<Status>** column shows the record export status as a checkmark , if the export was successful, or an , if the export failed.

The **<History>** tab contains the same buttons as the **<Pending>** tab with the same functionality (see previous page).

8.2.23 Print B-Lac Setup Report

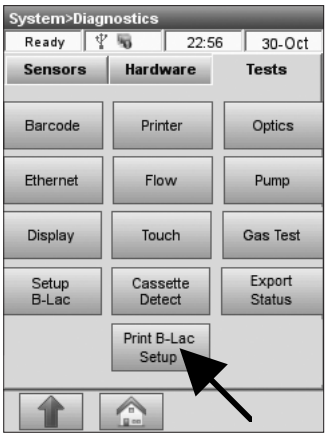


Fig. 8-52 B-Lac Setup Report

The B-Lac Setup Report prints automatically after successful completion of the B-Lac Cassette Setup.

The **<Print B-Lac Setup>** function can be used to print additional copies of the report.

In the main menu, press **<System Manager -> Diagnostics>**.

- Select the **<Tests>** tab.
- Press **<Print B-Lac Setup>** to start the printout (Fig. 8-52).
- The system will start printing the B-Lac Setup Report.

8.3 Troubleshooting

8.3.1 Troubleshooting Procedure for tHb/SO_2

If your OPTI fails an Hb calibration or QC measurement for tHb or SO_2, OPTI Medical recommends that you clean the SMC cover of your analyzer and then repeat the measurement. The two small optical channels pictured below are responsible for the tHb and SO_2 measurements. These channels may get clogged or dirty, causing the tHb and SO_2 to fail calibration or OPTI Check controls.
The simple cleaning procedure below can be used for OPTI CCA-TS2 analyzers and may correct tHb and SO_2 failures.

1. Open the SMC cover and locate the two small optical channels pictured below (Fig. 8-53).

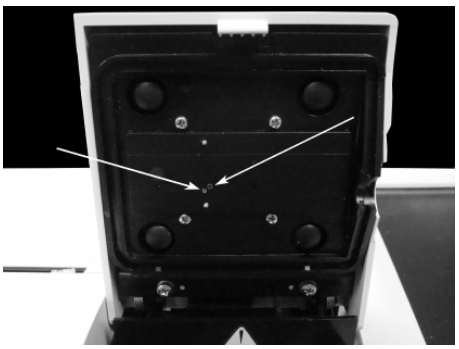
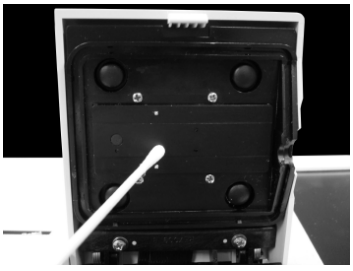


Fig. 8-53 Locate Optical Channels

2. Clean the optical channels using a cotton swab or lint-free cloth dipped in alcohol (Fig. 8-54).



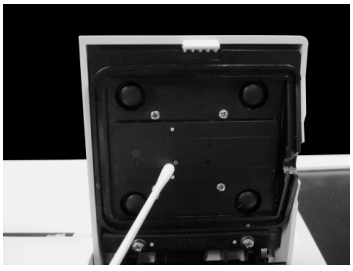


Fig. 8-54 Clean Optical Channels

Please contact OPTI Medical Technical Support for any additional questions or information regarding this procedure.

8.3.2 Troubleshooting Procedure for Bar Code Scanner

If you experience difficulty scanning bar codes, clean the bar code scanner window with alcohol and a lint-free cloth.

If difficulty continues, check the bar code scanner window for scratches.

Call OPTI Medical Technical Support for a replacement bar code scanner window.

9 OPERATING PRINCIPLES

9.1 Intended Use

The OPTI® CCA-TS2 Critical Care Analyzer is intended to be used for the measurement of pH, carbon dioxide partial pressure (PCO_2), oxygen partial pressure (PO_2), sodium (Na^+), potassium (K^+), ionized calcium (Ca^{++}), chloride (Cl^-), glucose (Glu), blood urea nitrogen (BUN/urea), lactate (Lac), total hemoglobin concentration (tHb) and hemoglobin oxygen saturation (SO_2) in samples of whole blood, and pH, sodium, potassium, ionized calcium, chloride, glucose and BUN (urea) in serum and plasma, in either a traditional blood gas, clinical laboratory setting or point-of-care locations by personnel minimally qualified to perform and report these results.

For customers located in the United States, the B-Lac cassette (BP7561) has not yet been cleared for Point of Care (POC) use in the United States.

9.2 Principles of Procedure

Luminescence is the emission of light energy resulting from excited molecules returning to a resting state. When luminescence is initiated by light, it is commonly referred to as fluorescence. When a fluorescent chemical is exposed to light energy of an appropriate color, electrons in the molecules of the fluorescent chemical are excited. A very short time later, the electrons return to a resting state and in this process sometimes emit a small amount of light energy. This energy is less than the excitation energy and so has a different color. That is, the emitted light (fluorescence emission), is red-shifted from the excitation light, and is much less intense.[1]

Fluorescent optodes (from **opt**ical electr**odes**) measure the intensity of light emitted from fluorescent dyes exposed to a specific analyte. The emitted light is distinguished from excitation light by means of optical filters. Because the excitation light energy is kept constant, the small amount of light that results is changed only by the concentration of the analyte. The concentration of the analyte is determined by the calculation of the difference in fluorescence measured at a known calibration point and that measured with the unknown concentration of analyte. For a description of the measurement principles of the individual analytes, please refer to the analyte section of the OPTI CCA-TS2 Operator's Manual.

[1] Guilbault GG, Ed., Practical Fluorescence, 2nd Ed., Marcel Dekker, 1990.

9.3 Operation

The OPTI CCA-TS2 is a microprocessor-based instrument measuring optical fluorescence.

A disposable, single-use cassette contains all the elements needed for calibration, sample measurement and waste containment. After scanning the calibration information specific to a cassette into the instrument by holding the cassette package in front of a convenient bar code scanner, the cassette is placed into the measurement chamber. The analyzer warms the cassette to 37.0 ± 0.1 °C, and performs a calibration verification on the sensors for PCO_2 and PO_2 by passing a precision calibration gas mixture across the optode sensors. The pH and electrolyte channels are calibrated with precision buffer solution contained in the cassette. The tHb and SO_2 channels are factory-calibrated. When calibration is verified, the analyzer aspirates the blood sample into the cassette and across the optode sensors. Fluorescence emission is then measured after equilibrating with the blood sample. After a single measurement, the cassette, containing the blood sample, is removed from the analyzer and discarded. The analyzer contains no reagents, blood or waste.

During each measurement, light originating from lamps in the analyzer is passed through optical filters so that photons of a specific color are transmitted to the sensors, causing them to emit fluorescence.

The intensity of this emitted light depends upon the partial pressure of oxygen (PO_2), carbon dioxide (PCO_2), hydrogen ion concentration (pH), electrolyte concentration (Na^+, K^+, Ca^{++}, Cl^-) or metabolite concentration (glucose, BUN (urea), lactate) of the blood in direct contact with the sensors, as described above. The light emitted by the fluorescent sensors is measured by the analyzer after passing through lenses and additional optical components. A filter is used to isolate specific colors of interest from this returning light for measurement by a light detector.

For tHb and SO_2, red and infrared light from one LED and two laser diodes is directed via dichroic beamsplitters and optical waveguides onto and through an optically polished window to the blood in the cassette over the O_2 sensor. This light is partially absorbed and reflected by the erythrocytes and sensor overcoat then reflected back up into the instrument, traveling via an optical waveguide to a photodiode. The intensity of light reflected back at each wavelength varies in a well-defined way with the blood ctHb and SO_2, and is used in their measurement.

The output signal of the detectors is converted by the microprocessor to a numeric readout in conventional units of measure and displayed on the front of the device. Other values commonly used for the assessment of oxygen and acid-base status are calculated from these measured values.

9.4 Specimen Collection and Handling

9.4.1 Safety

Universal precautions must be observed when collecting blood specimens. It is recommended that all blood specimens be handled as if capable of transmitting human immunodeficiency virus (HIV), hepatitis B virus (HBV), or other bloodborne pathogens. Proper blood collection techniques must be followed in order to minimize risk to the laboratory staff, and gloves should be worn. Please refer to CLSI document M29-A3, *Protection of Laboratory Workers from Occupationally Acquired Infections, Approved Guideline - Third Edition;* March 2005, for further information on safe handling of these specimens.

9.4.2 Sample Requirements

Refer to CLSI document H11-A4, *Procedures for the Collection of Arterial Blood Specimens; Approved Standard - Fourth Edition*; September 2004, for detailed information on sample collection, storage and handling.

Blood sampling for analysis must be performed under proper medical supervision with details of collection, including sampling devices, site selection, sample handling documentation and specific procedures used approved by the personnel responsible.

9.4.3 Anticoagulants and Sample Collection Devices

Lithium heparin is the only acceptable anticoagulant for blood gas and electrolyte analysis. Lithium heparin, sodium heparin or balanced heparin salts are the only acceptable anticoagulants for blood gas analysis. Other anticoagulants such as EDTA, citrate, oxylate and fluoride have a significant effect on blood pH and electrolyte levels and should not be used. Lithium heparin should not be used for samples taken also for analysis of lithium.

9.4.4 Syringes

If liquid heparin is used as an anticoagulant, collection devices should be no larger than the amount of blood required to minimize the effects of dilution of the blood by the anticoagulant solution. Although plastic syringes are commonly used for collection of blood specimens for blood gas analysis, there have been reports in literature regarding the use of plastic syringes when PO_2 values higher than normal are expected. Particular attention should be paid to cooling blood samples in ice water, because of the CO_2 and oxygen solubility in some plastics. If blood specimens are expected to have very high PO_2 values, care should be taken to analyze the specimen as quickly as possible following collection to avoid the need for cooling. *Attention should be paid to thorough mixing of whole blood samples prior to analysis, since sedimentation of blood cells affects the measurement of total hemoglobin.*

9.4.5 Capillary Tubes

Capillary blood specimens should be collected using capillary tubes which have a minimum volume, filled, of 125 µL. The OPTI Medical capillary tubes (MC0024) are ideally suited with a minimum volume, filled, of 200 µL. The capillary tubes for pH, blood gas, and electrolyte analysis should not be used for samples taken for the analysis of lithium. OPTIMedical has only validated the use of capillaries MC0024 for performing blood gas measurements on the OPTI CCA analyzers (GD7046, GD7013 and GD7045). The capillaries are not validated for use with blood gas analyzers from other manufacturers.

Samples may be collected in capillary tubes after warming the area or otherwise stimulating it to promote arterial circulation before the puncture. The puncture should be made deeply enough to ensure a free and rapid flow of blood.

Do not use clay-capped capillary tubes as the rough, broken edge left when the capillary is cut may cause damage to the OPTI cassette fill port. Use only capillary tubes with fire-polished ends to prevent damage to the cassette. If a mixing flea is used, as required in some capillary tubes, take care to remove the flea prior to sample introduction to avoid damage to the cassette.

Specimens collected in capillary tubes are stable at room temperature for up to 30 minutes after collection because of the rapid cooling of the sample accomplished during filling.

Cooled samples provide relevant glucose values for up to 30 minutes, uncooled samples for up to 10 minutes. Serum must be separated within these time limits.

9.4.6 OPTI Medical ComfortSamplers®

Blood may be collected for analysis on the OPTI CCA-TS2 with the OPTI Medical ComfortSampler to provide a filled shielded capillary tube.

After collection, the ComfortSampler should be capped and transported in a horizontal position to the instrument for analysis within 30 minutes, as with all specimens collected in capillary tubes.

Cooled samples provide relevant glucose values for up to 30 minutes, uncooled samples for up to 10 minutes. Serum must be separated within these time limits.

9.4.7 Sample Collection Tubes

Collect blood in a sample collection tube, aspirating the sample with a sample aspiration tube (BP7183).

NOTE: Whole blood samples should be analyzed as soon as possible, ideally within 5 minutes after collecting the sample. For brief storage of up to one hour, the sample should be iced.

NOTE: When the sample aspiration tube is used for a whole blood sample, electrolyte and pH results will be available, but there will be no pCO_2 derived results.

9.4.8 Handling and Storage of Samples

Please refer to CLSI Document H18-A3, *Procedures for the Handling and Processing of Blood Specimens*; Approved Guideline - Third Edition, November 2004, for a detailed discussion of guidelines for the collection of acceptable specimens, instrument calibration, and quality control in pH and blood gas analysis; including details of many potential sources of error which may cause inaccurate results.

Whole blood samples should be collected in a heparinized syringe, ComfortSampler or capillary and analyzed as soon as possible after collection. Immediately after collection, check the syringe or other device for air bubbles and carefully expel any trapped bubbles, following the manufacturer's recommended procedure. Extreme caution should be used to avoid needle stick injury. If collected in a syringe or vacuum tube, mix the specimen thoroughly with anticoagulant by gentle inversion or by rolling the syringe between both hands. Properly identify the specimen, following usual procedures for such documentation. Place the syringe containing the specimen in an ice slurry. Blood gases and pH content will change if the specimen remains at room temperature in a syringe for more than 5 minutes due to cellular metabolism.

PO_2 changes due to oxygen consumption may be influenced by several factors, including: white blood cell count, reticulocyte count, storage temperature and initial PO_2 value. At storage temperatures of 1 to 5 °C, the results obtained from the specimen are valid up to 2 hours. Samples expected to have high white blood cell count, reticulocyte count, or high PO_2 values should be analyzed as soon as possible after collection.

Erythrocyte aggregation and sedimentaton may occur very quickly in syringes containing pathologic blood samples and may adversely affect the measurement of ctHb in any analyzer. To prevent such errors, first insert the OPTI CCA-TS2 cassette into the analyzer to initiate calibration. Next, mix the syringe sample well by rolling the syringe for at least 60 seconds, after expelling any trapped bubbles, then immediately measure in the OPTI CCA-TS2.

The OPTI CCA-TS2 system aspirates blood in the same manner from syringes, capillaries or ComfortSampler.

No changes are made to the aspiration rate, volume or timing. Therefore, there are no biases or imprecision dependent upon the sample introduction method. Sufficient volume must, however, be present in syringes (0.25 mL in a 1 mL syringe) to prevent mechanical interference between the syringe plunger and the syringe adapter.

Errors in blood analysis on properly collected samples may result from improper mixing of the sample after collection and before measurement; contamination with room air resulting from failure to expel any trapped bubbles after collection; and from metabolic changes in the sample.

Serum samples should be obtained by collecting blood in an untreated blood collecting tube. The sample should stand for 30 minutes to allow the clot to form prior to centrifugation. After centrifugation, remove the serum from the clot, and cap or seal the sample tube. If storage is required, the sample should be tightly capped, refrigerated at 4 to 8 °C for no longer than 48 hours, and allowed to return to room temperature, 15 to 30 °C, prior to analysis. Each laboratory should determine the acceptability of its own blood collection syringes, capillaries and tubes and the serum or plasma separation products. Variations in these products exist between manufacturers, and at times, from lot to lot.

NOTE: Serum is an unsuitable sample material for accurate glucose analysis, because the retention time of the erythrocytes in the sample is too long. The process of glycolysis may lead to decreased glucose values in serum samples.

9.4.9 Handling and Storage of Sensor Cassettes

The OPTI Sensor Cassettes are stable when stored at 4-30°C (39-86°F) until the expiration date printed on the label.

B-Lac and E-BUN Cassettes are stable when stored at 2-8°C (35-46°F) until the expiration date printed on the label. Allow cassettes to equilibrate at room temperature for **1 hour (B-Lac)** or **15 minutes (E-BUN)** prior to use. **B-Lac and E-BUN Cassettes** that are in use may be left at room temperature (18-30°C or 64-86°F) for **4 weeks (B-Lac)** and **30 days (E-BUN)**. However, cassettes should not be refrigerated again after they have been left at room temperature for **1 hour (B-Lac)** or **15 minutes (E-BUN)** or more.

The OPTI CCA-TS2 has a function that will display warning messages for out-of-storage conditions for B-Lac and E-BUN cassettes during patient and QC measurements.

This function is enabled by default and can be disabled in System Setup. See Section 3.2.2.2 Setting up Measured Parameters.

CAUTION: *Do not expose cassettes to temperatures above 46°C (115°F). OPTI Medical cannot guarantee the performance of the cassette when stored at temperatures outside the recommended range.*

9.5 Procedure

9.5.1 Materials Needed

Description	Part Number
Sensor Cassettes in various analyte configurations	see Chapter 10, Supplies
Multi-Level Standard Reference Cassette	BP7652
Calibration Gas Bottle	BP7162
Hb Calibrator Cassette	BP7653
Printer Paper	HP0070

The OPTI CCA-TS2 automatically processes the sample through the necessary steps, then displays and prints the results. For details of this operation, please refer to Chapter 5 of the Operator's Manual.

9.5.2 Test Conditions

Sample Size:	a minimum of 125 µL (60µL for B60 cassette)
Sample Type:	heparinized whole blood, serum and plasma
Sample Application:	syringe, capillary, ComfortSampler or sample collection tube with sample aspiration tube (E-Lyte CCA Cassette only)
Ambient Temperature:	10 - 30 ºC (50 – 86 ºF)
Relative Humidity:	5% to 95% (non-condensing)
Type of Measurement:	optical fluorescence (pH, PO_2, PCO_2, Na^+, K^+, Ca^{++}) Cl^-, Glu, BUN (urea), Lac) and reflectance (tHb, SO_2)

9.5.3 Input Values

Parameter	Ranges/Options	Default
Patient ID	25 alphanumeric characters	Blank
Accession Number	25 numeric characters	Blank
Date of Birth	Month, DD, YYYY	
Patient Sex	Male, female or unknown	unknown
Patient temperature, T	14.0 to 44.0 °C 57.2 to 111.2 °F	37.0 °C 98.6 °F
Medical Record Number	25 numeric characters	Blank
Account Number	25 numeric characters	Blank
Test ID	25 alphanumeric characters	Blank
Patient Name		
First Name	25 alpha characters	Blank
Last Name	25 alpha characters	Blank
Age	1-150	0
Attending Physician	25 alpha characters	Blank
Patient Location	25 alpha characters	Blank
Sample Collection Time	Month, DD, YY, HH:MM	Blank
Sample Type	Art, Ven, MixVen, Cap, Cord, CPB, where: Art = Arterial Ven = Venous MixVen = Mixed Venous Cap = Capillary Cord = Cord CPB = Cardio-Pulmonary Bypass	Art
Puncture Site	LR/RR/LB/RB/LF/RF/ Cord/Scalp, where: LR = Left Radial RR = Right Radial LB = Left Brachial RB = Right Brachial LF = Left Femoral RF = Right Femoral Cord = Cord Scalp = Scalp	LR

Parameter	Ranges/Options	Default
Allen's Test	Unknown, positive or negative	Unknown
Hemoglobin type	Adult or fetal	Adult
Bypass	Off Pump / On Pump	Off Pump
O2 Mode	Rm Air, Mask, T-P, NC, Vent, Bag, Hood or Other, where: Rm Air = Room Air Mask = Mask T-P = T-Piece NC = Nasal Cannula Vent = Ventilator Bag = Bag (manual resuscitation) Hood = Hood Other = Other	Rm Air
Ventilator Mode	No, SIMV, PSV, PCV, CMV/AC, CPAP, PCIVR, or BIPAP, where: No = None SIMV = Synchronized Intermittent Mandatory Ventilation PSV = Pressure Support Ventilation PCV = Pressure Control Ventilation CMV / AC = Controlled Mechanical Ventilation / Assist Control CPAP = Continuous Positive Airway Pressure PCIVR = Pressure Control Inverse Ratio BIPAP = Bi-Level Positive Airway Pressure	No
Plateau Pressure (Pplat)	0.0 to 100.0	0.0
Minute Volume (VE)	0 to 120	0
Peak Inspiratory Pressure (PIP)	0 to 140	0
Flow Rate (Liter Flow) (FR)	0.00 to 300.00	0.00
Tidal Volume (VT)	0 to 4000	0
Pressure Support Value (PS)	0.0 to 99.9	0.0
Positive End Expiratory Pressure (PEEP)	0 to 50	0

Parameter	Ranges/Options	Default
Rate (f)	0 to 155 bpm	0
Continuous Positive Airway Pressure (CPAP)	0 to 50	0
Total hemoglobin, tHb	1.0 to 26.0 g/dL 0.62 to 16.14 mmol/L 1 to 260 g/L	15.0 g/dL 9.31 mmol/L 150 g/L
FIO_2	0.21 to 1.0	0.21
Mean corpuscular hemoglobin concentration, MCHC%	29.0 to 37.0 %	33.3 %
Respiratory quotient, RQ	0.70 to 2.00	0.84
P_{50}	15.0 to 40.0 mmHg 2.0 to 5.33 kPa	26.7 mmHg 3.56 kPa
Bi-Level Pressure Numerator	0.2 - 9.9	1.0
Bi-Level Pressure Denominator	0.2 - 9.9	1.0
I/E Ratio Numerator	0.2 - 9.9	1.0
I/E Ratio Denominator	0.2 - 9.9	1.0
Comment Field	50 alphanumeric characters	Blank

9.5.4 Calculated Values

Parameter	Range	Display Resolution	Units
Actual bicarbonate, HCO_3^-	1 to 200	0.1	mmol/L
Base excess, BE	-40 to +40	0.1	mmol/L
Base excess ecf, BE_{ecf}	-40 to +40	0.1	mmol/L
Base excess actual, BE_{act}	-40 to +40	0.1	mmol/L
Buffer base, BB	0 to 100	0.1	mmol/L
Total CO_2, tCO_2	1 to 200	0.1	mmol/L
Standard bicarbonate, $st.HCO_3^-$	1 to 200	0.1	mmol/L
Standard pH, st.pH	6.5 to 8.0	0.001	pH units
Oxygen saturation, SO_2 (c)	0 to 100	0.1	%
Oxygen content, O_2ct	0 to 56	0.1	mL/dL
Hematocrit, Hct(c)	15 to 75	1	%
Hydrogen ion concentration, cH^+	1000 to 10	0.1	nmol/L
Alveolar-arterial oxygen difference $AaDO_2$	0 to 800	0.1	mmHg
Anion Gap, AG	3 to 50	1	mmol/L
P_{50}	15 to 35	0.1	mmHg
nCa^{++}	0.1 to 3.0	0.1	mmol/L
P/F Ratio	10 to 800	1	mmHg

9.5.5 Calibration

Each lot of OPTI cassettes is calibrated during the manufacturing process. The process utilizes high precision standard solutions spanning the operating range for pH and ions. For O_2, CO_2, tHb and SO_2 the calibration parameters are determined using specially targeted calibration standards focusing on the clinically critical ranges. Every cassette package has a bar code label containing this calibration information as well as its lot number and expiration date.

Prior to running a sample, the cassette's bar code is scanned into the analyzer by holding the cassette package in front of a conveniently located bar code scanner. The cassette is then installed and a calibration is performed using the precision buffer within the cassette and a precision gas mixture. In addition, an optical zero point calibration of all six channels is performed.

During the calibration and measurement processes, diagnostic tests are automatically performed to assure correct operation of the instrument and measurement of the cassette. These tests include automatic checks of the cassette for packaging integrity, proper cassette temperature control, fluidic control during calibration, proper equilibration behavior of the sensors during calibration and measurement, automatic detection of bubbles and short sample during aspiration, and automatic detection of low gas or low battery, dirty optics, or worn pump conditions.

9.5.6 Quality Control

On initial use of each shipment of cassettes, and at 1 month intervals thereafter, validation of the lot should be performed by analysis of OPTI Medical blood gas, electrolyte, metabolite, tHb and SO_2 controls (OPTI CHECK or OPTI CHECK PLUS). This material should provide target values for all measured parameters over a range of measurement values typically seen in each laboratory.

The results obtained should fall within limits defined by the day-to-day variability as measured in the user's laboratory.

It is recommended to aspirate Quality Control and Proficiency testing material directly from the ampoule. This procedure helps to minimize sensitivity to pre-analytic and other errors associated with the use of aqueous controls (see Limitations Section).

The multi-level Standard Reference Cassettes (SRCs) should be used as a control for measurement and proper analyzer operation. These cassettes can test at 3 levels and OPTI Medical Systems recommends that SRC measurements should be performed for levels 1 and 3 (high and low values) once each day of OPTI CCA-TS2 operation. The test cassettes contain a stable optical sensor simulator which is measured by the device in exactly the same manner as any other cassette and provides assurance that measurement of all analytes by the device is consistent. The results obtained should fall within limits supplied with the SRCs. For SRC limit values, see analyte section of this manual.

All specific performance specifications reported in this summary are determined from the above, minimal recommendations for quality control verification.

The Standard Reference Cassettes are a complemetary method in quality control testing. In traditional blood gas analyzers, liquid quality control (QC) material is run several times a day to verify the system measurement, including reagents, used for patient testing. On these systems, multiple patient samples are run using the same reagent system. On the OPTI CCA-TS2, all reagents needed to run a single patient measurement are pre-packaged in a single disposable cassette. Each cassette is an individual reagent and sensor system.

The traditional method of running a liquid QC material several times each day does not check these individual reagent and sensor systems. Therefore, manufacturers have developed complementary QC methods to ensure all elements of the system are monitored. OPTI Medical Systems has a two-step approach. First the SRC, the OPTI CCA-TS2's electronic/optical simulator, checks the electronics, optics, thermostats, etc. of the system. Second, when a sample cassette is inserted, it performs an extensive quality check prior to patient sampling to ensure, among other things, that the reagent system contained within the cassette is within pre-defined limits. If it is not, an error message occurs and the cassette is discarded. In addition, automatic checks are performed of packaging integrity, temperature control, proper fluidic control, bubble detection, etc. This approach provides a quality control check of the system similar to traditional liquid QC without incurring additional costs to the laboratory.

Every hospital is required to develop its own policies and procedures for quality control checks. Minimum guidelines are defined by a variety of regulatory agencies. Many agencies have updated their regulations to incorporate complementary QC methods such as the SRC. Some, however, have not.

For agencies requiring a liquid QC material and for institutions requiring additional QC checks, OPTI CHECK and OPTI CHECK PLUS are available. These controls are specially formulated aqueous liquid control materials that contain all analytes measurable by the OPTI CCA-TS2. They contain a stable suspension of polystyrene micro beads which reflect and partially absorb red and infrared light similarly to erythrocytes, allowing true measurement of tHb and SO_2. The three control levels contain three different concentrations of micro beads to simulate low, medium, and high hemoglobin blood samples.

9.5.7 Reference Intervals[2]

Reference intervals are useful in describing typical results found in a defined population of apparently healthy people. Reference intervals should not, however, be used as absolute indicators of health and disease due to variability among methods, laboratories, locations and other considerations. Individual laboratories should generate their own set of reference intervals. Guidelines for defining and determining reference intervals are published in the 2000 NCCLS C28-A2 guideline: "How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline – Second Edition".

The analyzer is preset to adult reference intervals derived from "Tietz, Burtis C, et al (Eds.), Textbook of Clinical Chemistry and Molecular Diagnostics, 4th Ed., (Elsevier Saunders, 2006) pps. 2252-2302". The preset intervals and procedures for adjusting the intervals to those derived for the individual laboratory are described in section 3.2.2.4 of this manual.

9.5.8 Specific Performance Characteristics

All performance data in this section was generated on OPTI CCA-TS2 systems with the SRC run daily to check QC. Quality control material was run with each new lot of cassettes.

9.5.9 Limitations

The OPTI CCA-TS2 system is designed to measure whole blood, serum, or plasma, to be controlled with Standard Reference Cassettes on a daily basis, and with aqueous solutions for each new lot of cassettes. Aqueous controls are portable and quite convenient to use with the OPTI CCA-TS2 system, however, their low oxygen carrying capacity and temperature sensitivity is well known. Measurements of such materials are more prone to pre-analytic error as well as analyzer-specific errors, compared to similar measurements of whole blood. The OPTI CCA-TS2 system is no exception to this, and demonstrates somewhat poorer PO_2 precision with aqueous controls than with whole blood, due to the large amount of plastic material comprising its disposable measurement chamber.

The OPTI CCA-TS2's tHb measurement is sensitive to pathologically rapid sedimentation rates of the erythrocytes, often induced by excessive rate and amounts of rouleaux formation[3]. This is observable as rapid sedimentation and clarification due to erythrocyte aggregates falling to the bottom of the syringe within minutes of mixing. The OPTI CCA-TS2 breaks up most of the rouleaux and other aggregates by rapidly aspirating the whole blood sample with high shear rate, however in rare pathologic cases the rouleaux aggregates persist or reform during the aspiration and cause a positive tHb offset of up to 3 g/dL, typically within the range 7-12 g/dL.

Any measurement outside the Measurement Range will be indicated on the display as ' LOW ' for values lower than the range and ' HIGH ' for values above the range. However, the printed report will show out-of-range values with reference to the end value of the measurement range; for example, the printed report will show a PCO_2 value of 220 mmHg as:

PCO_2 > 200 mmHg (Meas.Lim)

For measurement ranges of the individual analytes, see Analyte Section of this Operator's Manual.

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[2] Tietz; Burtis C, et al (Eds.), Textbook of Clinical Chemistry and Molecular Diagnostics, 4th Ed., (Elsevier Saunders, 2006) pps. 2252-2302.

[3] J.B.Henry, Clinical Diagnosis and Management by Laboratory Methods, 19th Ed., 1996, p.590,777

9.5.10 Interferences

Selected substances endogenous and exogenous to human blood were tested for interference in accord with CLSI EP7-A2[4]. These substances were selected on the basis of their optical absorbance or fluorescence properties likely to affect the optical signal measured by the OPTI CCA-TS2, or the optical properties of the sensor measured by the analyzer. To cause interference to the optical sensors, the substances must be highly mobile (low molecular weight) and highly colored, in order to penetrate the optode membrane barriers quickly (within the 90 sec. measurement interval), and then strongly absorb light or emit light of the proper color. To cause interference to the tHb and SO_2 reflectance measurements, the substances must strongly absorb or scatter red or infrared light, relative to normal whole blood.

The following substances were tested in whole blood at the CLSI-recommended test level or higher, and showed no interference to any measured analyte, including blood gas, electrolytes, and tHb/SO_2:

Bile Acids (30 µmol/dL)

Bilirubin (40 mg/dL)

Beta-Carotene (3.0 mg/dL)

Hemolysis (10%) During hemolysis K^+ is released from the blood cells thereby increasing the measured K^+. In the same manner, protein released from the cells binds ionized Ca^{++} and decreases the concentration. While an accurate value is reported, it will reflect the actual changes caused by hemolysis.

Lipemia (equivalent to 3000 mg/dL triglycerides)

Elevated white blood cell count (30,000 WBC/µL)

The following substances were tested in plasma at the CLSI-recommended test level or higher, and showed no interference to blood gas and electrolyte analytes:

Coumadin (Warfarin) (12 mg/dL)

Dicumarol (Dicoumarin) (11 mg/dL)

Procain (Novacaine) (13 mg/dL)

Acetaminophen (Paracetamol) (20 mg/dL)

The OPTI CCA-TS2 system was evaluated for the interference of sample temperature on measurement (iced samples). No measurable sensitivity to sample temperature was found.

For more detailed information on interferences, see analyte section of this Operator's Manual.

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[4] Clinical and Laboratory Standards Institute (CLSI). Interference Testing in Clinical Chemistry; Approved Guideline - 2nd Edition. CLSI document EP7-A2. CLSI, Wayne, PA, 2005

9.5.11 Accessories

OPTI Sensor Cassettes

Type "B", BP7562 (pH, PCO_2, PO_2, tHb, SO_2)

Type "E", BP7587 (pH, PCO_2, PO_2, Na^+, K^+, tHb, SO_2)

Type "E-Ca", BP7560 (pH, PCO_2, PO_2, Na^+, K^+, Ca^{++}, tHb, SO_2)

Type "E-Cl", BP7559 (pH, PCO_2, PO_2, Na^+, K^+, Cl^-, tHb, SO_2)

Type "E-Glu", BP7564 (pH, PCO_2, PO_2, Na^+, K^+, Glu, tHb, SO_2)

Type "E-BUN (urea)", BP7588 (pH, PCO_2, PO_2, Na^+, K^+, BUN (urea), tHb, SO_2)

Type "B-Lac", BP7561 (pH, PCO_2, PO_2, Lac, tHb, SO_2)

Type "B60", BP7586 (pH, PCO_2, PO_2)

Type "E-Lyte CCA", BP7667 (pH, Na^+, Ca^{++}, K^+, Cl^-)

Use: For measurement of various analytes with the OPTI CCA-TS2 Analyzer.
Contents: Box contains 25 individually packaged cassettes. Each disposable plastic cassette contains buffer and optical sensors.
Composition: Aqueous HEPES-bicarbonate buffer solution 0.2 mL with biocides.
Storage: Refer to package labeling.
Stability: Expiration date and lot number are printed on each cassette container label.

Multi-Level Standard Reference Cassettes (SRCs) BP7652

Use: For diagnostic and daily QC check of the OPTI CCA-TS2
Contents: Each package contains one reusable SRC Cassette.
Composition: Stabilized optode sensors with assay values:

	Level 1	*Level 2*	*Level 3*	
pH	7.080 - 7.120	7.380 - 7.420	7.580 -7.620	pH units
PCO_2	68.0 - 72.0	38.0 - 42.0	18.0 - 22.0	mmHg
PO_2	57.0 - 63.0	97.0 - 103.0	167.0 - 173.0	mmHg
Na^+	123.0 - 127.0	143.0 - 147.0	163.0 - 167.0	mmol/L
K^+	2.2 - 2.8	4.2 - 4.8	6.7 - 7.3	mmol/L
Ca^{++}	1.7 - 1.9	1.0 - 1.2	0.6 - 0.8	mmol/L
Cl^-	78.0 - 82.0	103.0 - 107.0	128.0 - 132.0	mmol/L
Glu	36.0 - 44.0	106.0 - 114.0	296.0 - 304.0	mg/dL
Glu	2.00 - 2.44	5.88 - 6.33	16.43 - 16.87	mmol/L
BUN	4.2 - 7.0	26.6 - 29.4	68.6 - 71.4	mg/dL
Urea	1.5 - 2.5	9.5 - 10.5	24.5 - 25.5	mmol/L
Lac	0.70 - 1.30	2.00 - 3.00	4.50 - 5.50	mmol/L
Lac	6.3 - 11.7	18.0 - 27.0	40.5 - 49.5	mg/dL
tHb	18.5 - 21.5	12.5 - 15.5	6.5 - 9.5	g/dL
SO_2	68.0 - 72.0	88.0 - 92.0	96.0 - 100.0	%

Storage: Refer to package labeling.
Stability: Expiration date and lot number are printed on each package label and encoded on the attached bar code label.

Calibration Gas, BP7162

Use:	For calibration of pH, PCO_2 and PO_2 in the OPTI CCA-TS2 Analyzer.	
Contents:	Each disposable, low-pressure cylinder contains 0.35 liters of gas at 28 psi at 21 °C.	
Composition:	Oxygen	14.0 ± 0.02%
	Carbon Dioxide	6.0 ± 0.02%
	Nitrogen	balance
Storage:	Refer to package labeling.	

Hb Calibrator Cassette, BP7653

Use:	For quarterly calibration of the OPTI CCA-TS2 Analyzer.
Contents:	Each package contains one reusable calibrator cassette.
Composition:	Stabilized optode sensors
Storage:	Refer to package labeling.
Stability:	Expiration date and lot number are printed on each package label and encoded on the attached bar code label.

Precautions

Use of calibration solutions, calibration gas, sample aspiration tubes or optodes not manufactured by OPTI Medical Systems could void the warranty.

Once used, the sample cassette holds human body fluids which may be potentially infectious; handle with appropriate care to avoid skin contact or ingestion.

For *in-vitro* diagnostic use.

For professional use only.

Bibliography

1. Guilbault GG, Ed., *Practical Fluorescence*, 2nd Edition, Marcel Dekker, 1990
2. Tietz; Burtis C, et al (Eds.), *Textbook of Clinical Chemistry and Molecular Diagnostics*, 4th Ed., (Elsevier Saunders, 2006) pps. 2252-2302.
3. J.B.Henry, *Clinical Diagnosis and Management by Laboratory Methods*, 19th Ed., 1996, p.590,777
4. Clinical and Laboratory Standards Institute (CLSI). *Interference Testing in Clinical Chemistry; Approved Guideline - 2nd Edition*. CLSI document EP7-A2. CLSI, Wayne, PA, 2005

10 SUPPLIES

Each OPTI® CCA-TS2 is shipped with maintenance supplies and other accessories. Below is a listing of all necessary supplies and accessories. To order replacement supplies and accessories, contact your local authorized OPTI Medical Distributor or, in the U.S., call the OPTI Medical Order Entry Department at 1-800-490-6784 (OPTI) Monday through Friday, 8 AM to 5 PM eastern time. Our Order Entry representatives will gladly provide any assistance you may require.

Description	Part Number
10.1 Analyzer	
OPTI CCA-TS2 Analyzer with Accessory Kit	GD7046
OPTI CCA-TS2, Rilibak Analyzer with Accessory Kit	GD7046D
10.2 Cassettes	
OPTI Cassette ‘B’ (25 per box)	BP7562
OPTI Cassette ‘E’ (25 per box)	BP7587
OPTI Cassette ‘E-Ca’ (25 per box)	BP7560
OPTI Cassette ‘E-Cl’ (25 per box)	BP7559
OPTI Cassette ‘E-Glu’ (25 per box)	BP7564
OPTI Cassette ‘E-BUN(urea)’ (25 per box)	BP7588
OPTI Cassette ‘B-Lac’ (25 per box)	BP7561
OPTI Cassette ‘B60’ (25 per box)	BP7586
OPTI Cassette ‘E-Lyte CCA’ (25 per box)	BP7667
10.3 Controls/Calibrators	
Multi-level Standard Reference Cassette (SRC)	BP7652
OPTI CHECK, Trilevel	HC7008
OPTI CHECK PLUS, Trilevel	HC7009
tHb-Calibrator Cassette	BP7653

Description	Part Number
10.4 Consumable Items	
Printer Paper (1 roll)	HP0070
Calibration Gas Bottle	BP7162
Capillary Tubes (250 pcs)	MC0024
ComfortSampler with Accessories	BP0600
ComfortSampler Basic Kit	BP0610
ComfortSampler Bulk, w/o Needle	BP0630
ComfortSampler Bulk, Needle w/Protector	BP0640
Sample Aspiration Tube, E-Lyte CCA Cassette (26 pcs)	BP7183
10.5 Accessories	
Paper, Roll, Printer	HP0070
Power Supply	EI7020
Assembly, Wand, Touch Screen	BP7245
Quick Setup Guide, English	AT7301
10.6 Manuals	
Operator's Manual	PD7301
10.7 Spare Parts	
Battery Assembly	EI7019
Peripump Cartridge Kit	BP7012
Power Cord	EX0197
Power Cord, Europe	EX0173
Seal SMC Gas I/O Port	RE7030

NOTE: Please refer to OPTI CCA-TS2 service manual for other spare parts.

10.8 Technical Assistance

Most often, problems with your OPTI CCA-TS2 can be resolved over the telephone, getting the analyzer back in service within minutes. Our technicians have the training and experience necessary to provide dependable technical assistance.

The OPTI Medical Service Hotline (U.S. market only) is staffed to provide prompt troubleshooting assistance seven (7) days per week, twenty-four (24) hours per day. Should you need troubleshooting assistance or application information regarding your OPTI Medical analyzer just contact the OPTI Medical Service Hotline for assistance.

In the U.S., call **1-800-490-6784 (OPTI)** to request technical assistance from OPTI Medical Systems, Inc.

Should you require additional service support, our OPTI Medical Service Hotline can provide complete details on all available service options and ensure that any instrument downtime is minimized.

10.9 Warranty Registration (U.S. Market Only)

After successful completion of the installation of your new OPTI CCA-TS2, complete the enclosed *Installation and Instrument Warranty Report* form. Return the completed form to OPTI Medical Systems, Inc. to ensure warranty support if you ever need warranty assistance. The model and serial numbers of your OPTI CCA-TS2 are on the bottom panel of the unit.

Please read the Instrument Warranty Terms and Conditions and become familiar with this agreement.

Each new analyzer purchased has a one year warranty from the date the analyzer is placed into service.

Contact the OPTI Medical Service Hotline for any assistance regarding warranty or support.

ANALYTES

pH

Clinical Significance[1]

The pH value of the blood, serum or plasma may be the single most valuable factor in the evaluation of the acid-base status of a patient. The pH value is an indicator of the balance between the buffer (blood), renal (kidney) and respiratory (lung) systems, and one of the most tightly controlled parameters in the body. The causes of abnormal blood pH values are generally classified as:

a) primary bicarbonate deficit - metabolic acidosis

b) primary bicarbonate excess - metabolic alkalosis

c) primary hypoventilation - respiratory acidosis

d) primary hyperventilation - respiratory alkalosis

An increase in blood, serum or plasma pH (alkalemia) may be due to increased plasma bicarbonate, or a feature of respiratory alkalosis due to an increased elimination of CO_2, due to hyperventilation.

A decreased pH value (acidemia) in blood, serum or plasma may occur due to an increased formation of organic acids, an increased excretion of H^+ ions in certain renal disorders, an increased acid intake such as in salicylate poisoning or loss of alkaline body fluids. Respiratory acidosis is the result of a decreased alveolar ventilation and may be acute; as the result of pulmonary edema, airway obstruction or medication, or may be chronic; as the result of obstructive or restrictive respiratory diseases.

Measurement Principle

The pH optode measurement principle is based upon pH-dependent changes of the luminescence of a dye molecule immobilized in the optode. Such pH indicator dyes have been used by chemists for many years to perform acid-base titration in turbid media.

The relationship of luminescence to pH is quantified by a variant of the Mass-Action Law of chemistry,

$$I_0 / I = 1 + 10^{pKa-pH}$$

which describes how the fluorescence emission intensity increases as the blood pH is increased above the dye's characteristic pKa[2]. pH optodes do not need a reference electrode to measure pH, however, they exhibit a small sensitivity to the ionic strength of the sample being measured[3].

Measurement Range

Range	Resolution (Low/High)	Units
6.6 to 7.8	0.01/0.001	pH units

Standard Reference Cassette (SRC) Limit Values

LOW	NORMAL	HIGH	Units
7.100 ± 0.02	7.400 ± 0.02	7.600 ± 0.02	pH units

Interferences

Optode pH measurements have a known sensitivity to the blood ionic strength[3], which is determined primarily by variation in serum levels of sodium. The OPTI CCA-TS2 utilizes an internal Na^+ sensor to actively compensate and correct for this sensitivity. That is, the OPTI CCA's reported pH has no measurable interference from hyponatremic or hypernatremic samples, nor for ionic strength variations within the physiologic limits of 100 to 190 mmol/L.

Heparin salts are the only acceptable anticoagulants. Other anticoagulants such as citrate, EDTA, oxalate, and fluoride cause significant interferences to the pH sensor.

The following exogenous interferents were quantified in tonometered plasma, showing interferences to dyes which typically have short half-lives within the body before being metabolized by the liver. This testing was done on the OPTI CCA platform, with a standard OPTI style pH sensor. No changes were made to the sensor or the measurement principle, so the interference of the OPTI CCA-TS2 is equivalent to the OPTI CCA.

Substance	Amount	pH change
Sodium fluorescein	26 mg/dL	unstable
Cardio (indocyanine) green	0.5 mg/dL	-0.04
Methylene blue	25 mg/dL	-0.16

Only clear, uncolored quality control materials, such as OPTI CHECK or OPTI CHECK PLUS brand aqueous controls should be used with the OPTI CCA-TS2 system. Colored materials, including proficiency testing materials, may interfere with the pH measurement, or fail to be properly aspirated.

Reproducibility

Controls

Within run precision (S_{wr}) and Total Precision (S_T), were determined from 2 runs per day with 2 replicates per run over a period of 20 days following the CLSI guideline EP5-A2. Typical results for 3 different control levels are shown below.

pH	OPTI Check Level 1	OPTI Check Level 2	OPTI Check Level 3
Days Run	20	20	20
Total Average	7.151	7.415	7.624
Within Run St. Dev. (S_{wr})	0.003	0.006	0.005
Within Run % CV	0.0%	0.1%	0.1%
Total Precision St. Dev. (S_T)	0.005	0.007	0.007
Total % CV	0.1%	0.1%	0.1%

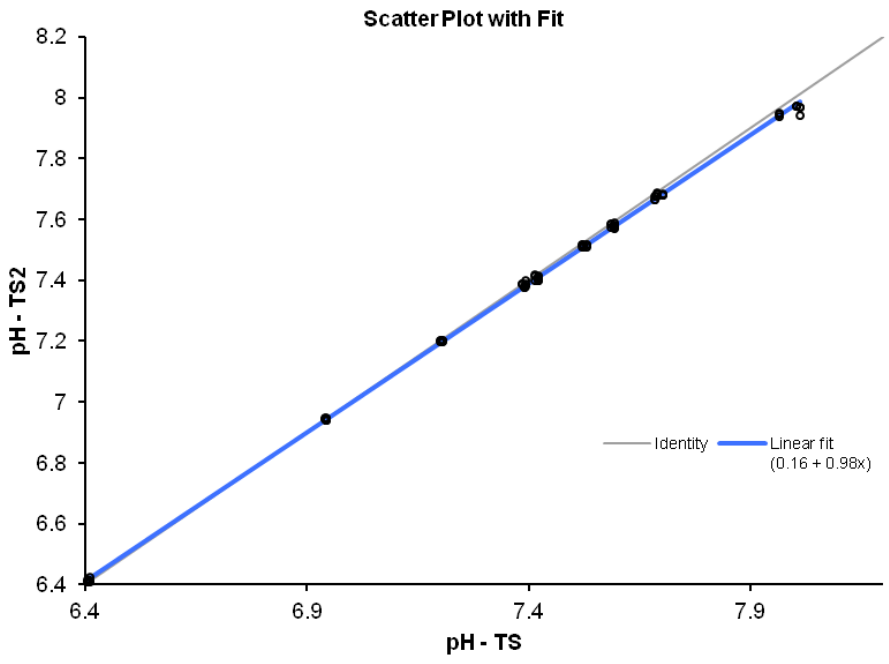
Whole Blood

Within-run precision in whole blood samples was evaluated at 3 different concentrations on one OPTI CCA-TS2. The table below shows the Averages, Standard Deviations and % CV calculated from 10 samples for each level.

pH	Whole Blood		
	Level 1	Level 2	Level 3
Average	7.134	7.341	7.518
St. Dev	0.004	0.006	0.009
%CV	0.05%	0.08%	0.13%
n	10	10	10

Linearity

Wherever possible, linearity for the OPTI CCA-TS2 measurement has been established against reference materials or methods. The linearity of the pH sensor on the OPTI CCA-TS2 has been established versus the same sensor on the OPTI CCA-TS using whole blood samples tonometered with different $\%CO_2$ gas mixtures to establish the correlation.



Parameter and Specification	Value
Number of Samples	81
Slope	0.98
Offset	0.16
R^2	1.000
Sy|x	0.009

Correlation to Other Methods[4]

OPTI CCA vs other pH Instruments on whole blood in a typical setting

Excess blood aliquots from specimens collected for blood gas analyses were analyzed by both traditional and non-traditional operators of blood gas equipment in hospital laboratories. The blood was analyzed on the OPTI CCA after obtaining the requisite results from existing instrumentation used for these analyses and operated and controlled following their established procedures.

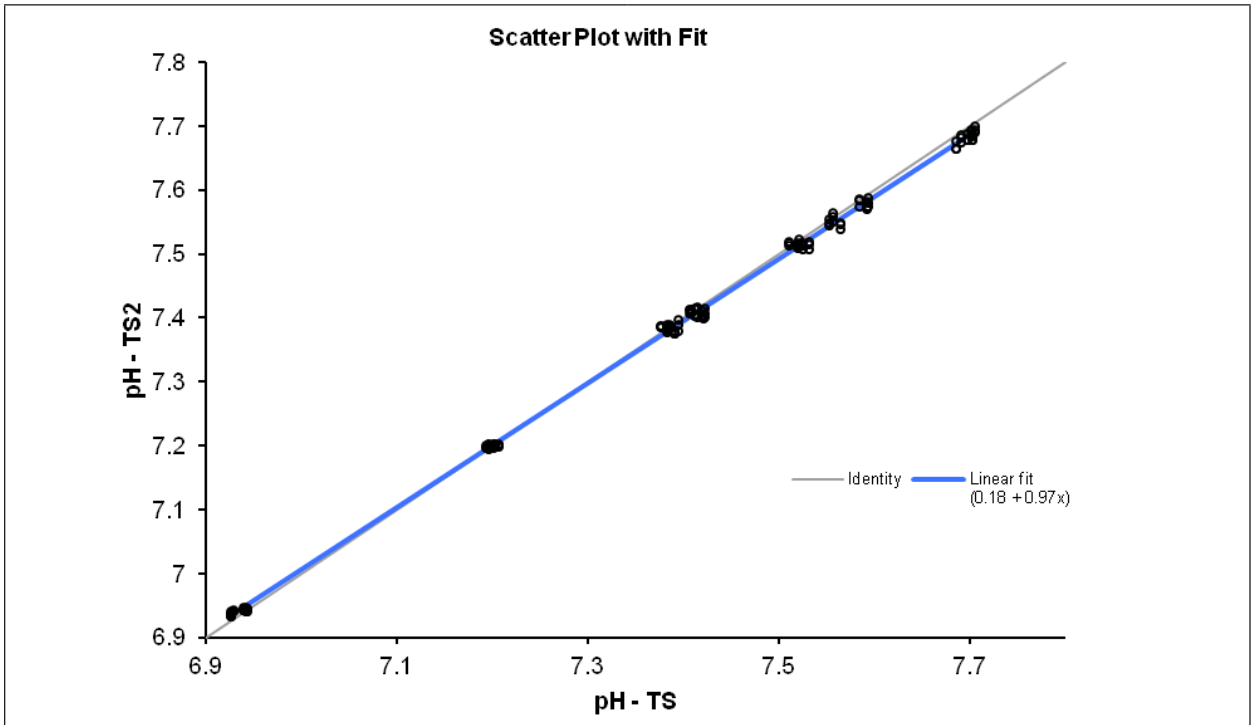
Correlation

Comparative Method*	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
Analyzer A (whole blood)	0.9269	0.534	0.9789	0.013	7.19 to 7.56	103
Analyzer B (whole blood)	1.0800	-0.579	0.9954	0.009	7.01 to 7.55	173
Analyzer C (whole blood)	1.126 ± 0.018	-0.946 ± 0.134	0.9868	0.018	7.09 to 7.58	105
Analyzer D (whole blood)	1.003 ± 0.008	-0.032 ± 0.058	0.9947	0.014	6.86 to 7.63	174
Analyzer E (whole blood)	1.104 ± 0.010	-0.739 ± 0.077	0.9919	0.014	6.80 to 7.60	183

* For more information on specific analyzers used, please contact OPTI Medical Technical Support.

OPTI CCA-TS2 vs OPTI CCA-TS on whole blood in a typical setting

In Method Comparisons carried out following the experimental protocol recommended in the CLSI guideline EP9-A2, Volume 15, Number 19 using whole blood samples on the OPTI CCA-TS2 versus the OPTI CCA-TS.



Parameter and Specification	Value
Number of Samples	126
Range	6.927 to 7.705
Slope	0.97
Offset	0.18
R^2	0.998
Sy|x	0.008

References

1. Tietz, Norbert W., Ed., *Clinical Guide to Laboratory Tests,* 2nd Ed., (Philadelphia: W.B.Saunders, Co., 1990) p. 436.
2. Peterson JI, et.al., *A Fiber Optic pH Probe for Physiological Use*, Anal.Chem. 53,p.864, 1980.
3. Wolfbeis OS, Offenbacher H, *Fluorescence Sensor for Monitoring Ionic Strength and Physiological pH Values*, Sensors and Actuators 9, p.85, 1986.
4. OPTI Medical. Model equation for regression statistics is: [results of OPTI Analyzer] = slope(m) [comparative method results] + intercept(b).

pH (Dry Sensor - B-Lac Cassette)

Clinical Significance[1]

The pH value of the blood, serum or plasma may be the single most valuable factor in the evaluation of the acid-base status of a patient. The pH value is an indicator of the balance between the buffer (blood), renal (kidney) and respiratory (lung) systems, and one of the most tightly controlled parameters in the body. The causes of abnormal blood pH values are generally classified as:

a) primary bicarbonate deficit - metabolic acidosis

b) primary bicarbonate excess - metabolic alkalosis

c) primary hypoventilation - respiratory acidosis

d) primary hyperventilation - respiratory alkalosis

An increase in blood, serum or plasma pH (alkalemia) may be due to increased plasma bicarbonate, or a feature of respiratory alkalosis due to an increased elimination of CO_2, due to hyperventilation.

A decreased pH value (acidemia) in blood, serum or plasma may occur due to an increased formation of organic acids, an increased excretion of H^+ ions in certain renal disorders, an increased acid intake such as in salicylate poisoning or loss of alkaline body fluids. Respiratory acidosis is the result of a decreased alveolar ventilation and may be acute; as the result of pulmonary edema, airway obstruction or medication, or may be chronic; as the result of obstructive or restrictive respiratory diseases.

Measurement Principle

The pH optode measurement principle is based upon pH-dependent changes of the luminescence of a dye molecule immobilized in the optode. Such pH indicator dyes have been used by chemists for many years to perform acid-base titration in turbid media.

The relationship of luminescence to pH is quantified by a variant of the Mass-Action Law of chemistry, which describes how the fluorescence emission intensity of the dry pH sensor decreases as the blood pH is increased above the dye's characteristic pKa.

$$\frac{I_0}{I} = \frac{1 - 10^{\,pH-pKa}}{R - 10^{\,pH-pKa}}$$

R is the ratio of minimum fluorescent intensity (pH >> pKa) to maximum fluorescent intensity (pH << pKa). pH optodes do not need a reference electrode to measure pH, however, they exhibit a small sensitivity to the ionic strength of the sample being measured[2].

Measurement Range

Range	Resolution (Low/High)	Units
6.6 to 7.8	0.01/0.001	pH units

B-Lac Cassette Measurement Range

Range of Indication*	Measurement Range	Resolution (Low/High)	Units
6.6 to 7.8	6.818 to 7.8	0.01/0.001	pH units

* The Range of Indication is the range the analyzer is capable of measuring and includes values outside the Measurement Range. The performance of the analyzer outside the Measurement Range specified in the table has not been validated. Only results within the Measurement Range should be reported.

Standard Reference Cassette (SRC) Limit Values

LOW	NORMAL	HIGH	Units
7.100 ± 0.02	7.400 ± 0.02	7.600 ± 0.02	pH units

Interferences

The following exogenous interferents were quantified in tonometered whole blood samples spiked with a number of endogenous and exogenous chemicals and tested for interference following the CLSI guideline EP7-A2, showing interferences to dyes which typically have short half-lives within the body before being metabolized by the liver. This testing was done on the OPTI CCA-TS2 platform, with a standard OPTI style pH sensor.

Chemical	Interferent Concentration	pH Level	Interference
Acetaminophen	1.66 mM	7.17	NO
		7.52	NO
Ascorbic acid	0.23 mM	7.17	NO
		7.52	NO
B-Hydroxybutyric acid, Na salt	16.03 mM	7.17	NO
		7.52	NO
Bilirubin	0.26 mM	7.17	NO
		7.52	NO
Cardiogreen	0.0065 mM	7.17	NO
		7.52	NO
Ethanol	86.8 mM	7.17	NO
		7.52	NO
Evans blue	0.0104 mM	7.17	NO
		7.52	NO
Halothane	0.759 mM	7.17	NO
		7.52	NO
Intralipid	1%	7.17	NO
		7.52	NO

Chemical	Interferent Concentration	pH Level	Interference
Methylene Blue	0.125 mM	7.17	NO
		7.52	NO
Sodium Chloride	20 mM	7.17	NO
		7.52	NO
Fluorescein	1.064 mM	7.17	N/A*
		7.52	N/A*

* At the interferent concentration tested (1.064 mM), the pH will be suppressed. However, for lower concentrations, the pH may show a bias.

Reproducibility

Controls

Within-run precision (S_{wr}) and Total Precision (S_T), were determined from 2 runs per day with 2 replicates per run over a period of 20 days following the CLSI guideline EP5-A3. Typical results for 3 different control levels are shown below:

Dry pH	OPTI Check Level 1	OPTI Check Level 2	OPTI Check Level 3
Days Run	20	20	20
Total Average	7.118	7.393	7.590
Within Run St. Dev. (S_{wr})	0.004	0.004	0.005
Within Run % CV	0.14%	0.09%	0.12%
Total Precision St. Dev. (S_T)	0.004	0.005	0.006
Total % CV	0.014%	0.09%	0.14%

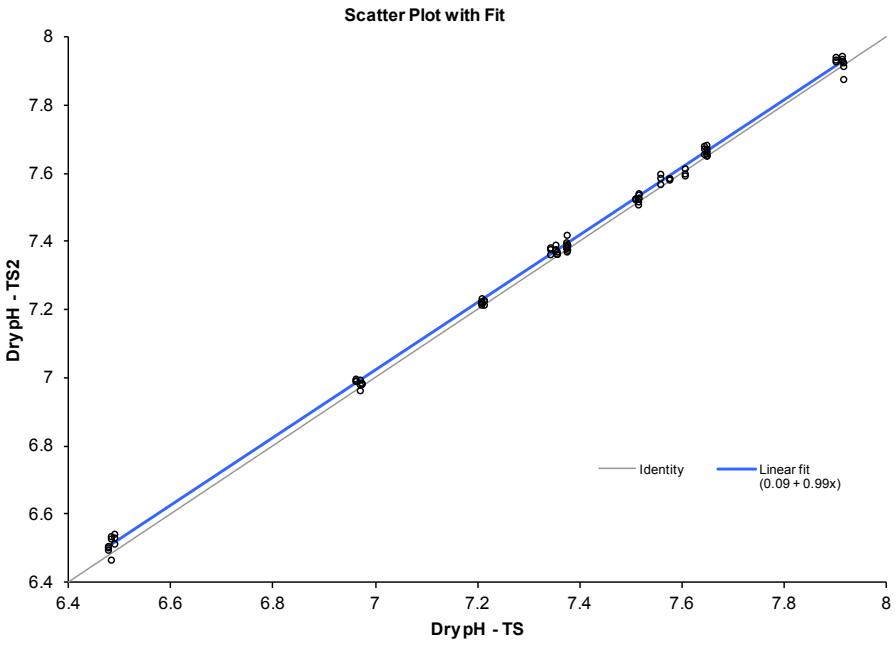
Whole Blood

Within-run precision in whole blood samples was evaluated at 3 different concentrations on the OPTI CCA-TS2. The table below shows the Averages, Standard Deviations and % CV calculated from 10 samples for each level.

Dry pH	Whole Blood		
	Level 1	Level 2	Level 3
Average	7.144	7.305	7.534
St. Dev	0.006	0.010	0.016
%CV	0.09%	0.13%	0.22%
n	10	10	10

Linearity

Wherever possible, linearity for the OPTI CCA-TS2 measurement has been established against reference materials or methods. The linearity of the pH sensor on the OPTI CCA-TS2 has been established versus the same sensor on the OPTI CCA-TS using whole blood samples tonometered with different $\%CO_2$ gas mixtures to establish the correlation.



Parameter and Specification	Value
Number of Samples	81
Slope	0.99
Offset	0.09
R^2	0.998
Sy|x	0.015

Correlation to Other Methods[3]

OPTI CCA-TS2 vs other pH Instruments on whole blood in a typical setting

Excess blood aliquots from specimens collected for blood gas analyses were analyzed by both traditional and non-traditional operators of blood gas equipment in hospital laboratories. The blood was analyzed on the OPTI CCA-TS after obtaining the requisite results from existing instrumentation used for these analyses and operated and controlled following their established procedures.

Correlation

Comparative Method*	Slope	Intercept	R^2	Sy.x	Range	n
OPTI R	0.96	0.27	0.984	0.019	6.78 to 7.54	147
Analyzer A	1.03	-0.20	0.968	0.015	7.091 to 7.538	111

* For more information on specific analyzers used, please contact OPTI Medical Technical Support.

OPTI CCA-TS2 with B-Lac Cassette vs other pH Instruments on whole blood (in-house testing)

Whole blood samples from multiple donors were tonometered with different $\%CO_2$ gas mixtures to generate a wide range of pH values. The blood samples were analyzed in parallel on the B-Lac cassette and other laboratory instruments.

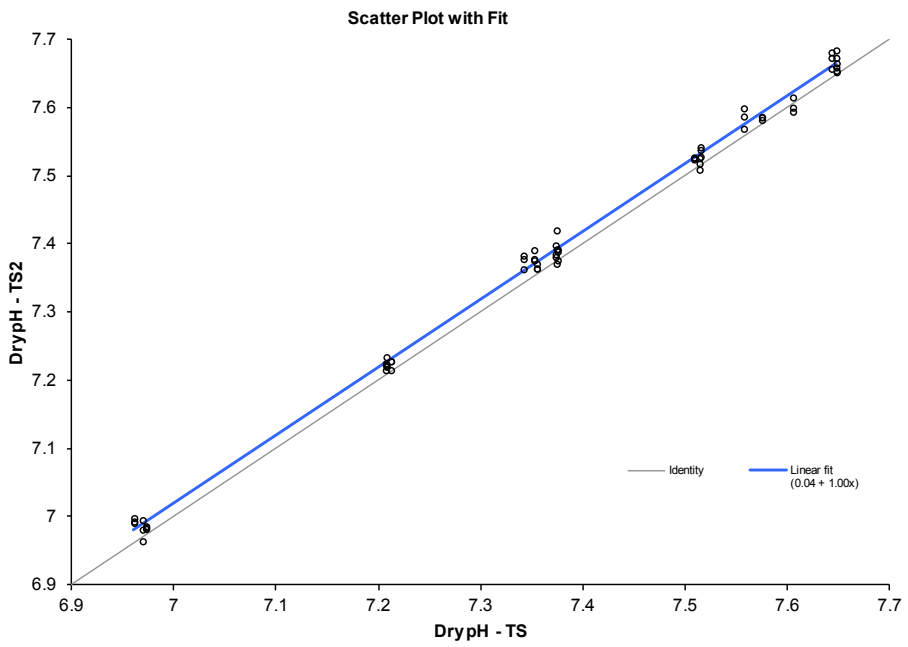
Correlation

Comparative Method*	Slope	Intercept	R^2	Sy.x	Range	n
Analyzer B	1.03	-0.21	0.996	0.016	6.578 to 7.611	174
Analyzer C	1.03	-0.19	0.996	0.015	6.582 to 7.701	174
Analyzer D	1.008	-0.062	0.990	0.027	6.873 to 7.840	60

* For more information on specific analyzers used, please contact OPTI Medical Technical Support.

OPTI CCA-TS2 vs OPTI CCA-TS on whole blood in a typical setting

In Method Comparisons carried out following the experimental protocol recommended in the CLSI guideline EP9-A2, Volume 15, Number 19 using whole blood samples on the OPTI CCA-TS2 versus the OPTI CCA-TS.



Parameter and Specification	Value
Number of Samples	63
Range	6.961 to 7.648
Slope	1.00
Offset	0.04
R^2	0.997
Sy|x	0.013

References

1. Tietz, Norbert W., Ed., *Clinical Guide to Laboratory Tests,* 2nd Ed., (Philadelphia: W.B.Saunders, Co., 1990) p. 436.
2. Wolfbeis OS, Offenbacher H, *Fluorescence Sensor for Monitoring Ionic Strength and Physiological pH Values*, Sensors and Actuators 9, p.85, 1986.
3. OPTI Medical. Model equation for regression statistics is: [results of OPTI Analyzer] = slope(m) [comparative method results] + intercept(b).

PCO_2

Clinical Significance[1]

The PCO_2 value of arterial blood is used to assess how well the body eliminates carbon dioxide, a by-product of metabolism. A PCO_2 value below the normal range is termed respiratory alkalosis and indicates *hypocapnia*, a condition caused by increased alveolar ventilation such as hyperventilation. An arterial PCO_2 above the normal range is termed respiratory acidosis and indicates *hypercapnia*, a sign of ventilatory hypoventilation and failure, resulting from cardiac arrest, chronic obstructive lung disease, drug overdose, or chronic metabolic acid-base disturbances.

Measurement Principle

The PCO_2 optode measurement principle is based upon placing a pH optode behind an ion-impermeable membrane[2], just as conventional PCO_2 blood gas electrodes employ the Severinghaus CO_2 electrode construction. As such, PCO_2 optodes may suffer interference from volatile acids and bases in blood, just as conventional PCO_2 electrodes.

The PCO_2 partial pressure is influenced by the local barometric pressure, as dictated by Dalton's law. The OPTI CCA-TS2 incorporates a pressure transducer, which accurately tracks the local barometric pressure and automatically compensates for it. The OPTI CCA-TS2 has been factory-calibrated to the absolute barometric pressure.

Measurement Range

Range	Resolution (Low/High)	Units
10 to 200	1/0.1	mmHg
1.33 to 26.66	0.1/0.01	kPa

Standard Reference Cassette (SRC) Limit Values

LOW	NORMAL	HIGH	Units
70.0 ± 2.0	40.0 ± 2.0	20.0 ± 2.0	mmHg
9.33 ± 0.27	5.33 ± 0.27	2.67 ± 0.27	kPa

Interferences

Interference testing was done on the OPTI CCA platform, with a standard OPTI style pCO_2 sensor. No changes were made to the sensor or the measurement principle, so the interference of the OPTI CCA-TS2 is equivalent to the OPTI CCA.

Only clear, uncolored quality control materials, such as OPTI CHECK or OPTI CHECK PLUS brand aqueous controls should be used with the OPTI CCA-TS2 system. Colored materials, including proficiency testing materials, may interfere with the pCO_2 measurement, or fail to be properly aspirated.

Reproducibility

Controls

Within-run precision (S_{wr}) and Total Precision (S_T), were determined from 2 runs per day with 2 replicates per run over a period of 20 days following the CLSI guideline EP5-A2. Typical results for 3 different control levels are shown below:

PCO_2 (mmHg)	OPTI Check Level 1	OPTI Check Level 2	OPTI Check Level 3
Days Run	20	20	20
Total Average	74.5	45.0	24.8
Within Run St. Dev. (S_{wr})	0.8	0.3	0.3
Within Run % CV	1.1%	0.7%	1.1%
Total Precision St. Dev. (S_T)	0.9	0.5	0.4
Total % CV	1.3%	1.0%	1.5%

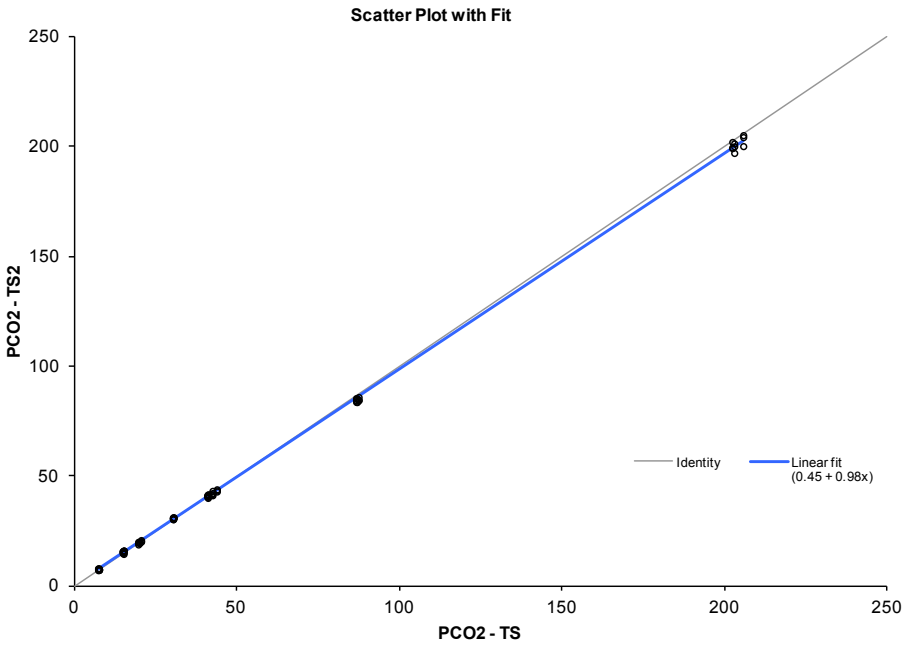
Whole Blood

Within-run precision in whole blood samples was evaluated at 3 different concentrations on the OPTI CCA-TS2. The table below shows the Averages, Standard Deviations and % CV calculated from 10 samples for each level.

PCO_2 (mmHg)	Whole Blood		
	Level 1	Level 2	Level 3
Average	21.4	46.2	91.6
St. Dev	0.3	0.4	1.7
%CV	1.60%	0.90%	1.82%
n	10	10	10

Linearity

Wherever possible, linearity for the OPTI CCA-TS2 measurement has been established against reference materials or methods. The linearity of the pCO_2 sensor on the OPTI CCA-TS2 has been established versus the same sensor on the OPTI CCA-TS using whole blood samples tonometered with different $\%CO_2$ gas mixtures to establish the correlation.



Parameter and Specification	Value
Number of Samples	72
Slope	0.98
Offset	0.45
R^2	0.999
Sy|x	0.975

Correlation to Other Methods[3]

OPTI CCA vs other Blood Gas Instruments on whole blood in a typical setting

Excess blood aliquots from specimens collected for blood gas analyses were analyzed by both traditional and non-traditional operators of blood gas equipment in hospital laboratories. The blood was analyzed on the OPTI CCA after obtaining the requisite results from existing instrumentation used for these analyses and operated and controlled following their established procedures.

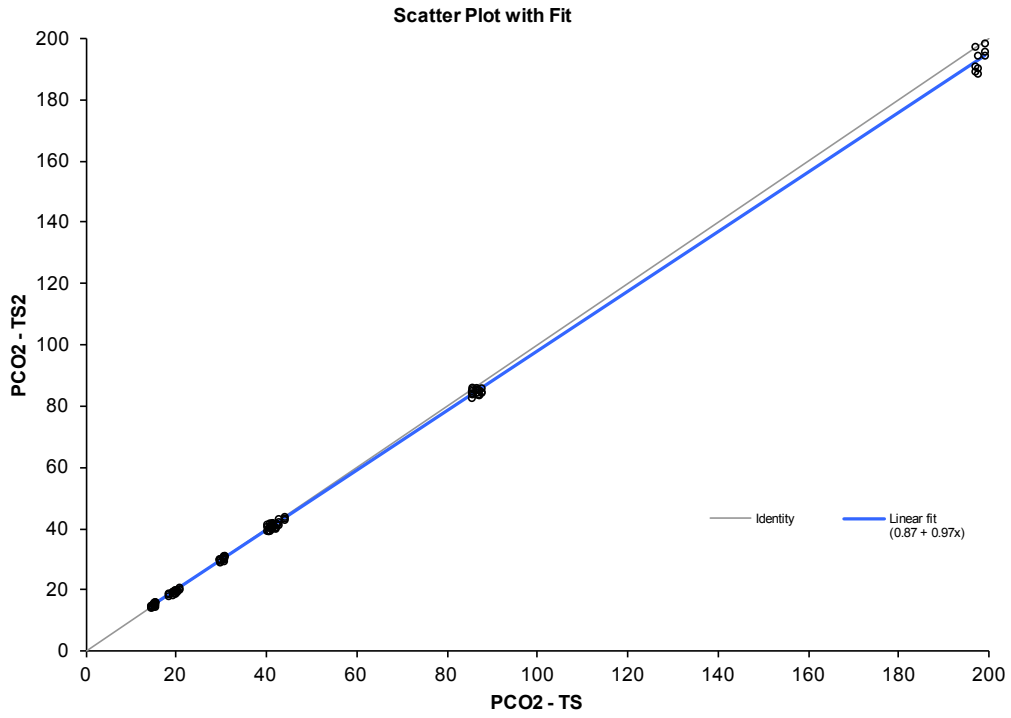
Correlation

Comparative Method*	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
Analyzer A (whole blood)	0.9751	1.623	0.9871	1.16	28 to 72	103
Analyzer B (whole blood)	0.9740	2.66	0.9937	1.12	24 to 92	173
Analyzer C (whole blood)	0.988 ± 0.022	0.807± 1.015	0.9750	2.584	23 to 81	105
Analyzer D (whole blood)	1.073 ± 0.011	-2.785 ± 0.521	0.9910	2.050	17 to 122	174
Analyzer E (whole blood)	1.067 ± 0.009	-4.41 ± 0.468	0.9936	1.817	22 to 120	183

* For more information on specific analyzers used, please contact OPTI Medical Technical Support.

OPTI CCA-TS2 vs OPTI CCA-TS on whole blood in a typical setting

In Method Comparisons carried out following the experimental protocol recommended in the CLSI guideline EP9-A2, Volume 15, Number 19 using whole blood samples on the OPTI CCA-TS2 versus the OPTI CCA-TS.



Parameter and Specification	Value
Number of Samples	117
Range	14.3 to 198.9
Slope	0.97
Offset	0.87
R^2	0.999
Sy|x	1.114

References

1. Tietz, Norbert W., Ed., *Clinical Guide to Laboratory Tests*, 2nd Ed., (Philadelphia: W.B.Saunders, Co., 1990) p. 436.
2. Vurek GG, Feustel PJ, Severinghaus JW, *A Fiber Optic PCO_2 Sensor*, Ann.Biomed.Eng. 11, p.499, 1983.
3. OPTI Medical. Model equation for regression statistics is: [results of OPTI Analyzer] = slope(m) [comparative method results] + intercept(b).

PCO_2 (Dry Sensor - B-Lac Cassette)

This section has been updated with data for the redesigned PCO_2 sensor for the B-Lac cassette that was submitted in a new 510(k).

Clinical Significance[1]

The PCO_2 value of arterial blood is used to assess how well the body eliminates carbon dioxide, a by-product of metabolism. A PCO_2 value below the normal range is termed respiratory alkalosis and indicates *hypocapnia*, a condition caused by increased alveolar ventilation such as hyperventilation. An arterial PCO_2 above the normal range is termed respiratory acidosis and indicates *hypercapnia*, a sign of ventilatory hypoventilation and failure, resulting from cardiac arrest, chronic obstructive lung disease, drug overdose, or chronic metabolic acid-base disturbances.

Measurement Principle

The PCO_2 sensor measurement principle is based upon placing a pH optode behind a gas-permeable membrane to measure a hydrogen concentration change in the internal solution when CO_2 permeates through the gas permeable membrane. The reaction sequence is outlined below.

$$CO_2 + H_2O \rightarrow H_2CO_3 \rightarrow H^+ + HCO_3^-$$

The hydrogen concentration change is measured by an optical pH sensor. The change in the hydrogen ion concentration is proportional to the carbon dioxide partial pressure in the specimen.

Measurement Range

Range of Indication/ Measurement Range	Resolution (Low/High)	Units
10 to 200	1/0.1	mmHg
1.33 to 26.66	0.1/0.01	kPa

Standard Reference Cassette (SRC) Limit Values

LOW	NORMAL	HIGH	Units
70.0 ± 2.0	40.0 ± 2.0	20.0 ± 2.0	mmHg
9.33 ± 0.27	5.33 ± 0.27	2.67 ± 0.27	kPa

Interferences

The following exogenous interferents were quantified in tonometered whole blood samples spiked with a number of endogenous and exogenous chemicals and tested for interference following the CLSI guideline EP7-A2, showing interferences to dyes which typically have short half-lives within the body before being metabolized by the liver. This testing was done on the OPTI CCA-TS2 platform, with the redesigned pCO_2 sensor.

Chemical	Interferent Concentration	PCO_2 Level	Interference
Acetaminophen	1.66 mM	83 mmHg	NO
		17 mmHg	NO
Acetylsalicylic acid	3.33 mM	83 mmHg	NO
		17 mmHg	NO
Ascorbic acid	0.23 mM	83 mmHg	NO
		17 mmHg	NO
B-Hydroxybutyric acid, Na salt	16.03 mM	83 mmHg	NO
		17 mmHg	NO
Bilirubin	0.26 mM	83 mmHg	NO
		17 mmHg	NO
Cardiogreen	0.0065 mM	83 mmHg	NO
		17 mmHg	NO
Cysteine (hydrochloride hydrate)	6.41 mM	83 mmHg	NO
		17 mmHg	NO
Ethanol	86.8 mM	83 mmHg	NO
		17 mmHg	NO
Evans blue	0.0104 mM	83 mmHg	NO
		17 mmHg	NO
Glycolic acid	10 mM	83 mmHg	NO
		17 mmHg	NO
Halothane	0.759 mM	83 mmHg	NO
		17 mmHg	NO
Ibuprofen	2.43 mM	83 mmHg	NO
		17 mmHg	NO
Intralipid	1%	83 mmHg	NO
		17 mmHg	NO
Methylene Blue	0.125 mM	83 mmHg	NO
		17 mmHg	NO
Sodium Chloride	20 mM	83 mmHg	NO
		17 mmHg	NO
Fluorescein	1.064 mM	83 mmHg	NO
		17 mmHg	NO

Reproducibility

Controls

Within-run precision (S_{wr}) and Total Precision (S_T), were determined from 2 runs per day with 2 replicates per run over a period of 20 days following the CLSI guideline EP5-A3. Typical results for 3 different control levels are shown below:

Dry PCO_2 (mmHg)	OPTI Check Level 1	OPTI Check Level 2	OPTI Check Level 3
Days Run	20	20	20
Total Average	71.906	42.168	25.199
Within Run St. Dev. (S_{wr})	1.608	0.326	0.337
Within Run % CV	2.2%	0.8%	1.3%
Total Precision St. Dev. (S_T)	1.727	0.385	0.371
Total % CV	2.4%	0.9%	1.5%

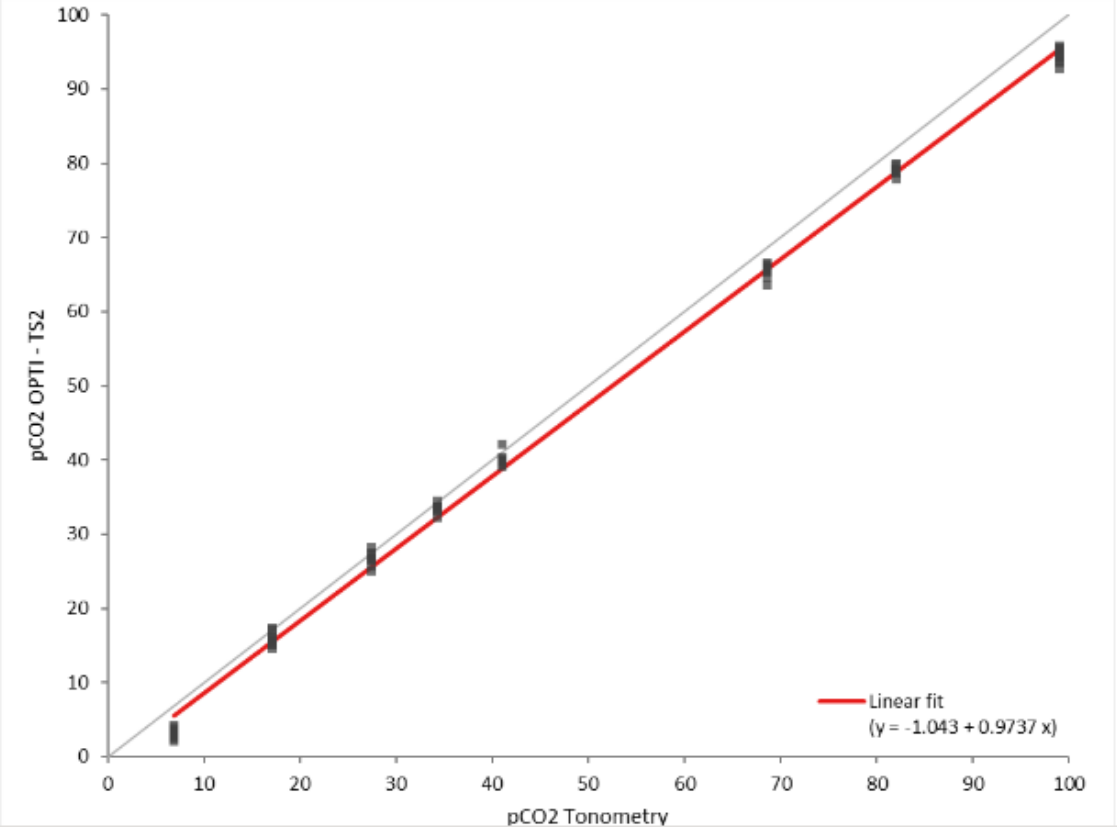
Whole Blood

Within-run precision in whole blood samples was evaluated at 3 different concentrations on the OPTI CCA-TS2. The table below shows the Averages, Standard Deviations and % CV calculated from 10 samples for each level.

Dry PCO_2 (mmHg)	Whole Blood		
	Level 1	Level 2	Level 3
Average	78.8	40.2	15.7
St. Dev	0.4	0.3	0.6
%CV	0.55%	0.84%	3.58%
n	10	10	10

Linearity

Wherever possible, linearity for the OPTI CCA-TS2 measurement has been established against reference materials or methods. The linearity of the pCO_2 sensor on the OPTI CCA-TS2 has been established versus gravimetric targets using whole blood samples tonometered with different $\%CO_2$ gas mixtures to establish the correlation.



Parameter and Specification	Value
Number of Samples	71
Slope	0.9737
Offset	-1.043
R^2	0.998
Sy|x	1.43

Correlation to Other Methods[2]

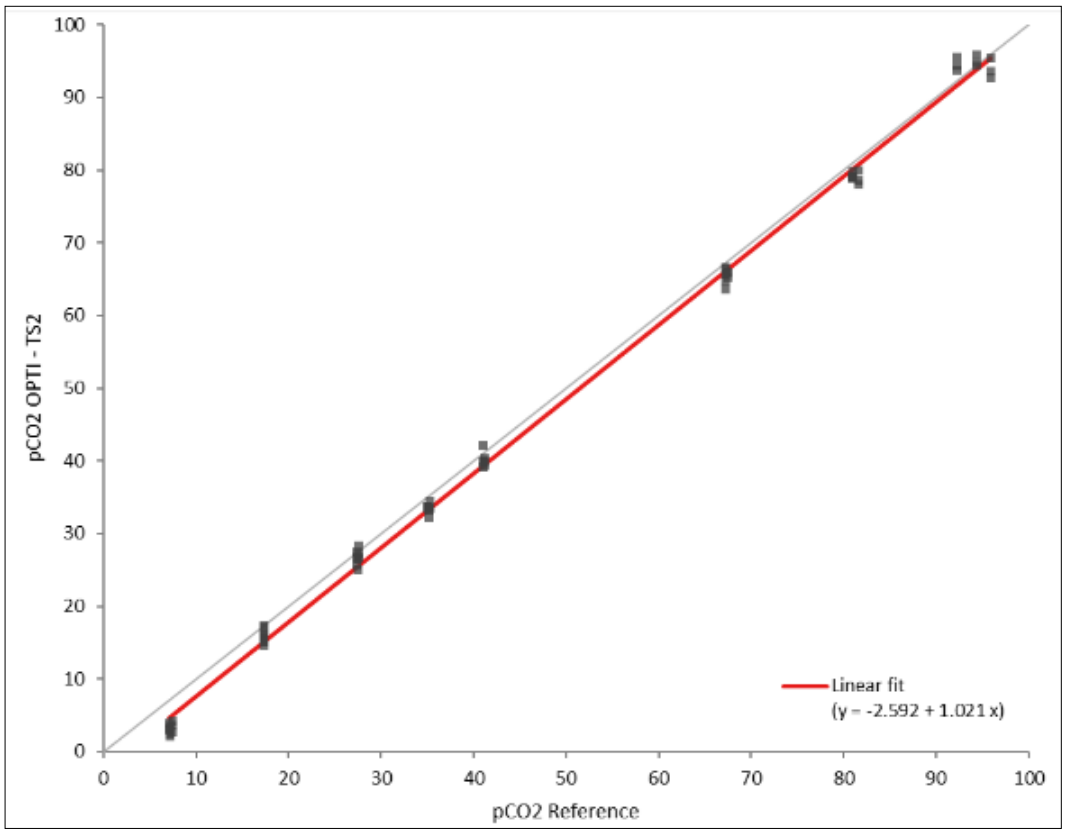
OPTI CCA-TS2 with B-Lac Cassette vs other Blood Gas Instruments on whole blood (in-house testing)

Whole blood samples from multiple donors were tonometered with different $\%CO_2$ gas mixtures to generate a wide range of pCO_2 values. The blood samples were analyzed in parallel on the B-Lac cassette and other laboratory instruments.

Correlation

Comparative Method*	Slope	Intercept	R^2	Sy.x	Range	n
Analyzer A	1.021	-2.592	0.998	1.43	2.03 to 95.86	52

* For more information on specific analyzers used, please contact OPTI Medical Technical Support.



References

1. Tietz, Norbert W., Ed., *Clinical Guide to Laboratory Tests*, 2nd Ed., (Philadelphia: W.B.Saunders, Co., 1990) p. 436.
2. OPTI Medical. Model equation for regression statistics is: [results of OPTI Analyzer] = slope(m) [comparative method results] + intercept(b).

PO_2

Clinical Significance[1]

The PO_2 value of arterial blood is used to assess how well the body is able to absorb oxygen in the lungs. Values below the normal arterial PO_2 (*arterial hypoxemia*) are usually caused by pulmonary, circulatory, or respiratory abnormalities (e.g. bronchial obstruction, vascular problems, decrease in cardiac output, increased oxygen demand, anatomical heart defect, low inspired O_2 content). Generally, O_2 levels above 100 mmHg do not contribute significantly to the oxygen content since, with normal hemoglobin concentrations, 80 - 100 mmHg, PO_2 provides a 97% saturation level, and a level greater than 100% cannot be achieved.

Measurement Principle

The PO_2 optode measurement principle is based upon luminescence quenching, first documented in the 1930's[2], and commercially utilized to measure blood PO_2 in 1983[3]. The relationship of luminescence to PO_2 is quantified by the Stern-Volmer equation,

$$I_0 / I = 1 + kP$$

which describes how the fluorescence emission intensity "I" is reduced as the PO_2 "P", is increased. Unlike conventional electrochemical "Clark" PO_2 electrodes, the oxygen optode does not consume oxygen molecules during the measurement.

The PO_2 partial pressure is influenced by the local barometric pressure, as dictated by Dalton's law. The OPTI CCA-TS2 incorporates a pressure transducer, which accurately tracks the local barometric pressure and automatically compensates for it. The OPTI CCA-TS2 has been factory-calibrated to the absolute barometric pressure.

Measurement Range

Range	Resolution (Low/High)	Units
10 to 700	1/0.1	mmHg
1.33 to 93.31	0.1/0.01	kPa

Standard Reference Cassette (SRC) Limit Values

LOW	NORMAL	HIGH	Units
60.0 ± 3.0	100.0 ± 3.0	170.0 ± 3.0	mmHg
8.00 ± 0.40	13.33 ± 0.40	22.66 ± 0.40	kPa

Interferences

Interference testing was done on the OPTI CCA platform, with a standard OPTI style pO_2 sensor. No changes were made to the sensor or the measurement principle, so the interference of the OPTI CCA-TS2 is equivalent to the OPTI CCA.

Only clear, uncolored quality control materials, such as OPTI CHECK or OPTI CHECK PLUS brand aqueous controls should be used with the OPTI CCA-TS2 system. Colored materials, including proficiency testing materials, may interfere with the pO_2 measurement, or fail to be properly aspirated.

Reproducibility

Controls

Within-run precision (S_{wr}) and Total Precision (S_T), were determined from 2 runs per day with 2 replicates per run over a period of 20 days following the CLSI guideline EP5-A2. Typical results for 3 different control levels are shown below.

PO_2 (mmHg)	OPTI Check Level 1	OPTI Check Level 2	OPTI Check Level 3
Days Run	20	20	20
Total Average	71.6	100.0	137.7
Within Run St. Dev. (S_{wr})	1.3	1.4	1.4
Within Run % CV	1.8%	1.4%	1.0%
Total Precision St. Dev. (S_T)	1.5	1.7	1.8
Total % CV	2.1%	1.7%	1.3%

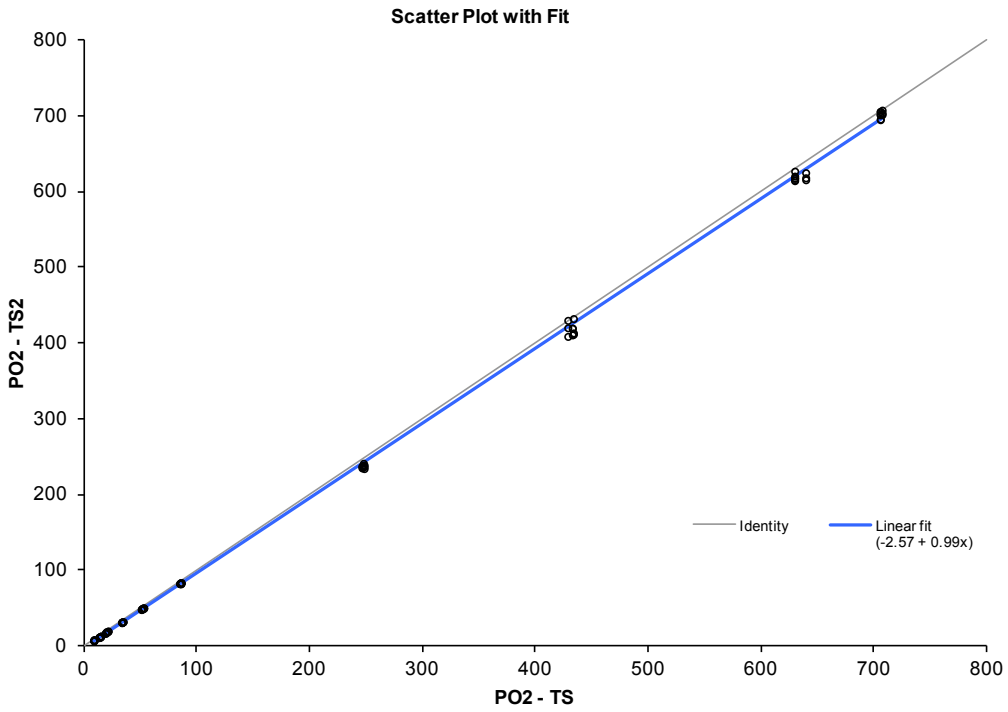
Whole Blood

Within-run precision in whole blood samples was evaluated at 3 different concentrations on the OPTI CCA-TS2. The table below shows the Averages, Standard Deviations and % CV calculated from 10 samples for each level.

PO_2 (mmHg)	Whole Blood		
	Level 1	Level 2	Level 3
Average	54.8	90.3	434.5
St. Dev	0.5	0.5	5.1
%CV	0.97%	0.52%	1.18%
n	10	10	10

Linearity

Wherever possible, linearity for the OPTI CCA-TS2 measurement has been established against reference materials or methods. The linearity of the pO_2 sensor on the OPTI CCA-TS2 has been established versus the same sensor on the OPTI CCA-TS using whole blood samples tonometered with different $\%O_2$ gas mixtures to establish the correlation.



Parameter and Specification	Value
Number of Samples	90
Slope	0.99
Offset	-2.57
R^2	0.999
Sy|x	4.938

Correlation to Other Methods[4]

OPTI CCA vs other Blood Gas Instruments on whole blood in a typical setting

Excess blood aliquots from specimens collected for blood gas analyses were analyzed by both traditional and non-traditional operators of blood gas equipment in hospital laboratories. The blood was analyzed on the OPTI CCA after obtaining the requisite results from existing instrumentation used for these analyses and operated and controlled following their established procedures.

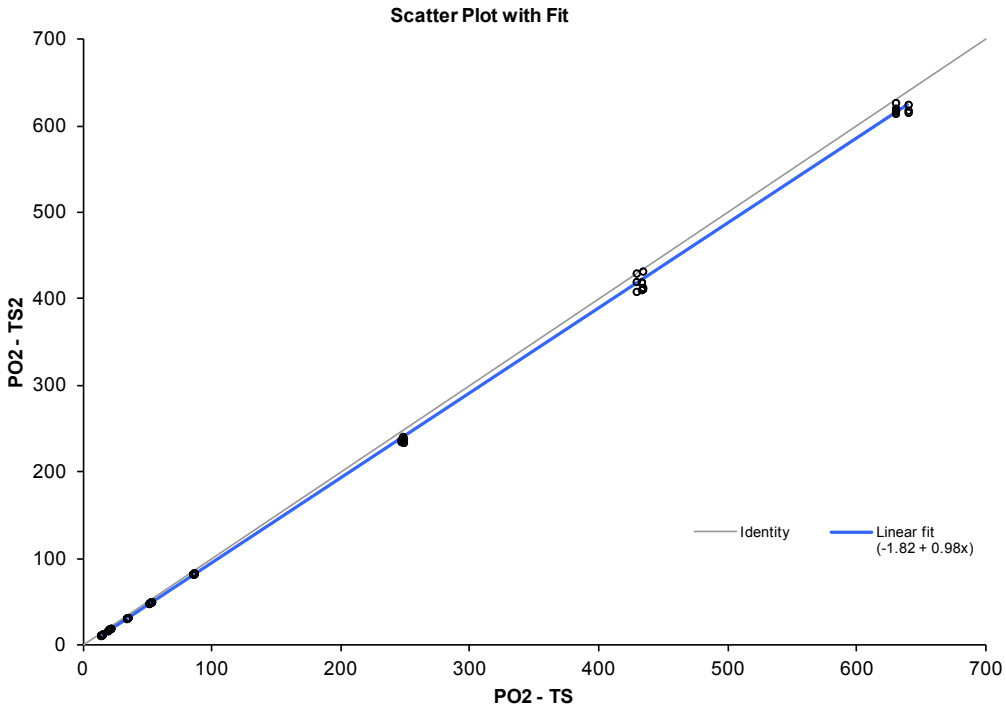
Correlation

Comparative Method*	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
Analyzer A (whole blood)	0.9419	3.28	0.9875	18.27	36 to 563	103
Analyzer B (whole blood)	1.0192	-4.13	0.9969	4.10	34 to 291	173
Analyzer C (whole blood)	0.918 ± 0.087	8.083 ± 1.402	0.9954	8.032	29 to 407	105
Analyzer D (whole blood)	1.041 ± 0.006	-6.244 ± 0.931	0.9969	6.379	37 to 598	174
Analyzer E (whole blood)	0.993 ± 0.009	1.646 ± 0.893	0.9925	4.458	34 to 321	183

* For more information on specific analyzers used, please contact OPTI Medical Technical Support.

OPTI CCA-TS2 vs OPTI CCA-TS on whole blood in a typical setting

In Method Comparisons carried out following the experimental protocol recommended in the CLSI guideline EP9-A2, Volume 15, Number 19 using whole blood samples on the OPTI CCA-TS2 versus the OPTI CCA-TS.



Parameter and Specification	Value
Number of Samples	144
Range	13.5 to 639.3
Slope	0.98
Offset	-1.82
R^2	1.000
Sy|x	3.931

References

1. Tietz, Norbert W., Ed., *Clinical Guide to Laboratory Tests*, 2nd Ed., (Philadelphia: W.B.Saunders, Co., 1990) p. 436.
2. Kautsky H, *Quenching of Luminescence by Oxygen*, Transactions Faraday Society 35, p.216, 1939
3. CDI, *3M Healthcare System 200 Extracorporeal Blood Gas Monitor*. See, for example, Lubbers DW, Gehrich J, Opitz N, *Fiber Optics Coupled Flourescence Sensors for Continuous Monitoring of Blood Gases in the Extracorporeal Circuit*, Life Supports Systems 4, p.94, 1986.
4. OPTI Medical. Model equation for regression statistics is: [results of OPTI Analyzer] = slope(m) [comparative method results] + intercept(b).

PO_2 (Dry Sensor - B-Lac Cassette)

Clinical Significance[1]

The PO_2 value of arterial blood is used to assess how well the body is able to absorb oxygen in the lungs. Values below the normal arterial PO_2 (*arterial hypoxemia*) are usually caused by pulmonary, circulatory, or respiratory abnormalities (e.g. bronchial obstruction, vascular problems, decrease in cardiac output, increased oxygen demand, anatomical heart defect, low inspired O_2 content). Generally, O_2 levels above 100 mmHg do not contribute significantly to the oxygen content since, with normal hemoglobin concentrations, 80 - 100 mmHg, PO_2 provides a 97% saturation level, and a level greater than 100% cannot be achieved.

Measurement Principle

The PO_2 optode measurement principle is based upon luminescence quenching, first documented in the 1930's[2], and commercially utilized to measure blood PO_2 in 1983[3]. The relationship of luminescence to PO_2 is quantified by the Stern-Volmer equation,

$$I_0 / I = 1 + kP$$

which describes how the fluorescence emission intensity "I" is reduced as the PO_2 "P", is increased. Unlike conventional electrochemical "Clark" PO_2 electrodes, the oxygen optode does not consume oxygen molecules during the measurement.

The PO_2 partial pressure is influenced by the local barometric pressure, as dictated by Dalton's law. The OPTI CCA-TS2 incorporates a pressure transducer, which accurately tracks the local barometric pressure and automatically compensates for it. The OPTI CCA-TS2 has been factory-calibrated to the absolute barometric pressure.

Measurement Range

Range of Indication/ Measurement Range	Resolution (Low/High)	Units
10 to 700	1/0.1	mmHg
1.33 to 93.31	0.1/0.01	kPa

Standard Reference Cassette (SRC) Limit Values

LOW	NORMAL	HIGH	Units
60.0 ± 3.0	100.0 ± 3.0	170.0 ± 3.0	mmHg
8.00 ± 0.40	13.33 ± 0.40	22.66 ± 0.40	kPa

Interferences

The following exogenous interferents were quantified in tonometered whole blood samples spiked with a number of endogenous and exogenous chemicals and tested for interference following the CLSI guideline EP7-A2, showing interferences to dyes which typically have short half-lives within the body before being metabolized by the liver. This testing was done on the OPTI CCA-TS2 platform, with a standard OPTI style pO_2 sensor.

Chemical	Interferent Concentration	Tonometry Level/mmHg	Interference
Acetaminophen	1.66 mM	48 mmHg	NO
		416 mmHg	NO
Acetylsalicylic acid	3.33 mM	48 mmHg	NO
		416 mmHg	NO
Ascorbic acid	0.23 mM	48 mmHg	NO
		416 mmHg	NO
B-Hydroxybutyric acid, Na salt	16.03 mM	48 mmHg	NO
		416 mmHg	NO
Bilirubin	0.26 mM	48 mmHg	NO
		416 mmHg	NO
Cardiogreen	0.0065 mM	48 mmHg	NO
		416 mmHg	NO
Cysteine (hydrochloride hydrate)	6.41 mM	48 mmHg	NO
		416 mmHg	NO
Ethanol	86.8 mM	48 mmHg	NO
		416 mmHg	NO
Evans blue	0.0104 mM	48 mmHg	31.2 mmHg
		416 mmHg	NO
Glycolic acid	10 mM	48 mmHg	NO
		416 mmHg	NO
Halothane	0.759 mM	48 mmHg	NO
		416 mmHg	NO
Ibuprofen	2.43 mM	48 mmHg	NO
		416 mmHg	NO
Intralipid	1%	48 mmHg	NO
		416 mmHg	NO
Methylene Blue	0.125 mM	48 mmHg	NO
		416 mmHg	-46.5 mmHg
Sodium Chloride	20 mM	48 mmHg	NO
		416 mmHg	NO
Fluorescein	1.064 mM	48 mmHg	NO
		416 mmHg	NO

Reproducibility

Controls

Within-run precision (S_{wr}) and Total Precision (S_T), were determined from 2 runs per day with 2 replicates per run over a period of 20 days following the CLSI guideline EP5-A3. Typical results for 3 different control levels are shown below.

Dry PO_2 (mmHg)	OPTI Check Level 1	OPTI Check Level 2	OPTI Check Level 3
Days Run	20	20	20
Total Average	72.087	98.772	137.496
Within Run St. Dev. (S_{wr})	1.037	1.008	1.505
Within Run % CV	1.44%	1.02%	1.09%
Total Precision St. Dev. (S_T)	1.174	1.181	2.172
Total % CV	1.63%	1.20%	1.58%

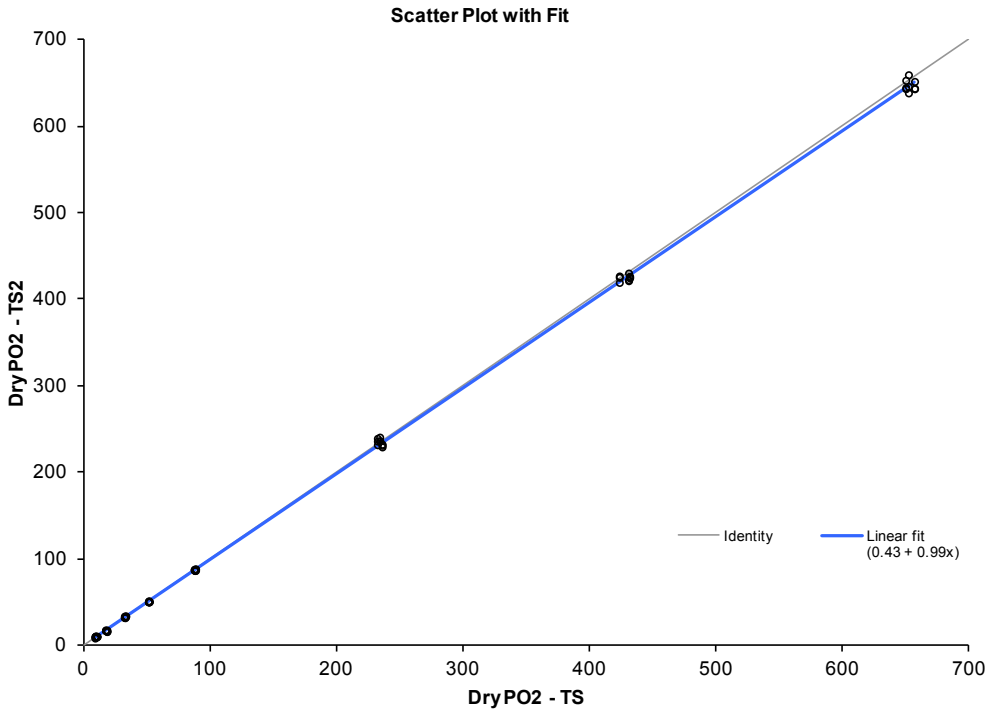
Whole Blood

Within-run precision in whole blood samples was evaluated at 3 different concentrations on the OPTI CCA-TS2. The table below shows the Averages, Standard Deviations and % CV calculated from 10 samples for each level.

Dry PO_2 (mmHg)	Whole Blood		
	Level 1	Level 2	Level 3
Average	46.0	81.4	423.9
St. Dev	0.5	1.0	3.5
%CV	1.13%	1.22%	0.83%
n	10	10	10

Linearity

Wherever possible, linearity for the OPTI CCA-TS2 measurement has been established against reference materials or methods. The linearity of the pO_2 sensor on the OPTI CCA-TS2 has been established versus the same sensor on the OPTI CCA-TS using whole blood samples tonometered with different $\%O_2$ gas mixtures to establish the correlation.



Parameter and Specification	Value
Number of Samples	72
Slope	0.99
Offset	0.43
R^2	0.999
Sy|x	3.528

Correlation to Other Methods[4]

OPTI CCA-TS2 vs other Blood Gas Instruments on whole blood in a typical setting

Excess blood aliquots from specimens collected for blood gas analyses were analyzed by both traditional and non-traditional operators of blood gas equipment in hospital laboratories. The blood was analyzed on the OPTI CCA-TS2 after obtaining the requisite results from existing instrumentation used for these analyses and operated and controlled following their established procedures.

Correlation

Comparative Method*	Slope	Intercept	R^2	Sy.x	Range	n
OPTI R	1.04	-2.76	0.968	8.72	27 to 288	148
Analyzer A	0.97	3.73	0.992	5.24	27.0 to 423.8	110

* For more information on specific analyzers used, please contact OPTI Medical Technical Support.

OPTI CCA-TS2 with B-Lac Cassette vs other Blood Gas Instruments on whole blood (in-house testing)

Whole blood samples from multiple donors were tonometered with different $\%O_2$ gas mixtures to generate a wide range of pO_2 values. The blood samples were analyzed in parallel on the B-Lac cassette and other laboratory instruments.

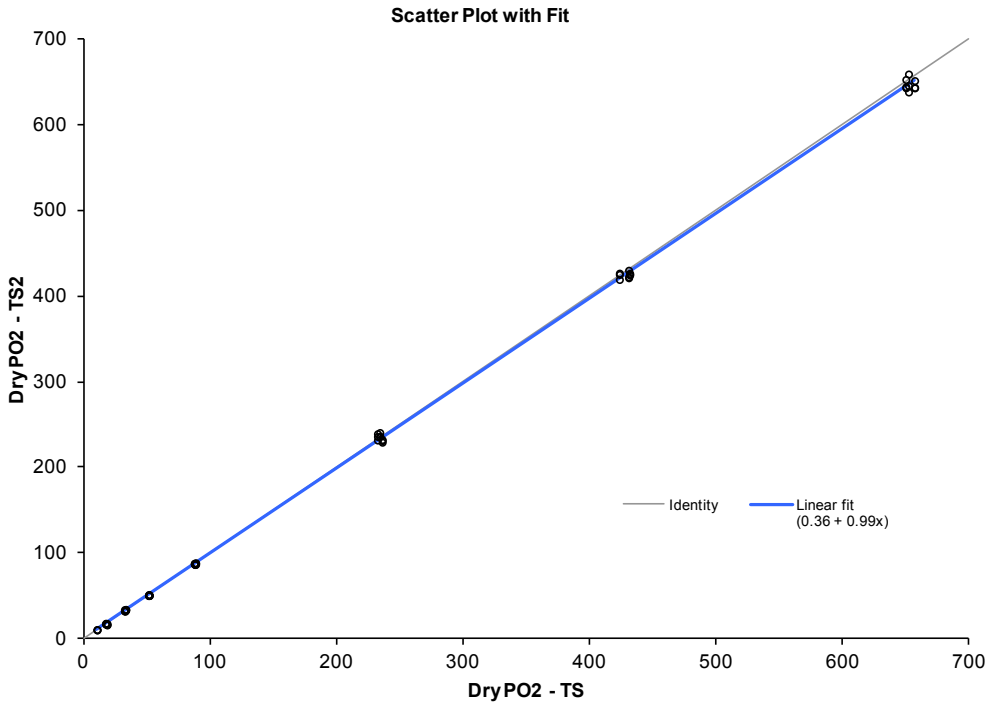
Correlation

Comparative Method*	Slope	Intercept	R^2	Sy.x	Range	n
OPTI CCA	0.94	4.84	0.998	9.77	19.9 to 642.8	161
Analyzer B	0.95	6.32	0.992	18.25	17.0 to 635.7	161
Analyzer C	1.007	-1.14	0.998	12.83	6.03 to 699.59	98

* For more information on specific analyzers used, please contact OPTI Medical Technical Support.

OPTI CCA-TS2 vs OPTI CCA-TS on whole blood in a typical setting

In Method Comparisons carried out following the experimental protocol recommended in the CLSI guideline EP9-A2, Volume 15, Number 19 using whole blood samples on the OPTI CCA-TS2 versus the OPTI CCA-TS.



Parameter and Specification	Value
Number of Samples	66
Range	10.7 to 656.6
Slope	0.99
Offset	0.36
R^2	0.999
Sy|x	3.680

References

1. Tietz, Norbert W., Ed., *Clinical Guide to Laboratory Tests*, 2nd Ed., (Philadelphia: W.B.Saunders, Co., 1990) p. 436.
2. Kautsky H, *Quenching of Luminescence by Oxygen*, Transactions Faraday Society 35, p.216, 1939
3. CDI, *3M Healthcare System 200 Extracorporeal Blood Gas Monitor*. See, for example, Lubbers DW, Gehrich J, Opitz N, *Fiber Optics Coupled Flourescence Sensors for Continuous Monitoring of Blood Gases in the Extracorporeal Circuit,* Life Supports Systems 4, p.94, 1986.
4. OPTI Medical. Model equation for regression statistics is: [results of OPTI Analyzer] = slope(m) [comparative method results] + intercept(b).

Sodium (Na^+)

Clinical Significance[1]

Sodium is the major cation of extracellular fluid. Its primary functions in the body are to chemically maintain osmotic pressure and acid-base balance and to transmit nerve impulses. Sodium functions at the cell membrane level by creating an electrical potential between different cell membranes causing the transmission of nerve impulses and neuromuscular excitability to be maintained. Sodium is involved in some enzyme catalyzed reactions as a cofactor. The body has a strong tendency to maintain a total base content, and only slight changes are found even under pathologic conditions.

Low sodium values, *hyponatremia*, usually reflect a relative excess of body water rather than a low total body sodium. Reduced sodium levels may be associated with: low sodium intake; sodium losses due to vomiting or diarrhea with adequate water and inadequate salt replacement, diuretics abuse, or salt-losing nephropathy; osmotic diuresis, metabolic acidosis; adrenocortical insufficiency; congenital adrenal hyperplasia; dilution type due to edema, cardiac failure, hepatic failure; and hypothyroidism.

Elevated sodium values, *hypernatremia*, are associated with conditions with water loss in excess of salt loss through profuse sweating, prolonged hyperpnea, severe vomiting or diarrhea, diabetes insipidus or diabetic acidosis; increased renal sodium conservation in hyperaldosteronism, Cushing's syndrome; inadequate water intake because of coma or hypothalamic diseases; dehydration; or excessive saline therapy.

The sodium value obtained may be used in the diagnosis or monitoring of all disturbances of the water balance, infusion therapies, vomiting, diarrhea, burns, heart and kidney insufficiencies, central or renal diabetes insipidus, endocrine disturbances and primary or secondary cortex insufficiency of the adrenal gland or other diseases involving electrolyte imbalance.

Measurement Principle

The Na^+ ion optodes are closely related to the more familiar Ion Selective Electrodes (ISEs). The optodes use ion selective recognition elements (ionophores) similar to those used in ISEs, however the ionophores are linked to fluorescent dyes instead of electrodes. These types of dyes have been used since the 1970's to visualize and quantify cellular ion levels in fluorescence microscopy and cell counters[2]. As the ion concentration increases, these ionophores bind larger amounts of ions and cause the fluorescence intensity to increase or decrease, depending on the particular ion. Like the pH optode, the ion optodes do not need a reference electrode, however, several of them do exhibit a small pH sensitivity which is automatically compensated in the OPTI CCA-TS2 using the measured pH.

Measurement Range

Range	Resolution (Low/High)	Units
100 to 180	1/0.1	mmol/L

Standard Reference Cassette (SRC) Limit Values

LOW	NORMAL	HIGH	Units
125.0 ± 2.0	145.0 ± 2.0	165.0 ± 2.0	mmol/L

Interferences

The OPTI CCA Na^+ sensor has no measurable interference from K^+ variation within the range 0.8-10 mmol/L.

The OPTI CCA Na^+ sensor does exhibit a small interference from Li^+. Li^+ levels of 1.0, 2.5, and 6.4 mmol/L will cause a positive Na^+ bias of 0.9, 1.2, and 1.3 mmol/L, respectively. A syringe sample anticoagulated with typical amounts of lithium heparin has 1-4 mmol/L of lithium, which offsets the measured Na^+ by less than 1%.

To minimize the interference from lithium, use syringes containing the lowest acceptable heparin level. Carefully follow the syringe manufacturer's recommendation regarding proper filling of the syringe.

A partially filled syringe results in excessive lithium concentration.

The OPTI CCA Na^+ results include an appropriate correction for pH at all values of pH.

This correction may introduce an extra source of variability at the extreme values.

Heparin salts are the only acceptable anticoagulants. Other anticoagulants such as citrate, EDTA, oxalate, and fluoride cause significant interferences to the electrolyte sensors.

The following exogenous interferents were quantified in tonometered plasma, showing interferences to dyes which typically have short half-lives within the body before being metabolized by the liver. This testing was done on the OPTI CCA platform, with a standard OPTI style Sodium sensor. No changes were made to the sensor or the measurement principle, so the interference of the OPTI CCA-TS2 is equivalent to the OPTI CCA.

Substance	Amount	Na^+ change (mmol/L)
Sodium fluorescein	26 mg/dL	unstable
Cardio (indocyanine) green	0.5 mg/dL	-18.0
Methylene blue	25 mg/dL	-2.0

Only clear, uncolored quality control materials, such as OPTI CHECK or OPTI CHECK PLUS brand aqueous controls should be used with the OPTI CCA-TS2 system. Colored materials, including proficiency testing materials, may interfere with the sodium measurement, or fail to be properly aspirated.

Reproducibility

Controls

Within run precision (S_{wr}) and Total Precision (S_T), were determined from 2 runs per day with 2 replicates per run over a period of 20 days following the CLSI guideline EP5-A2. Typical results for 3 different control levels are shown below:

Na^+ (mmol/L)	OPTI Check Level 1	OPTI Check Level 2	OPTI Check Level 3
Days Run	20	20	20
Total Average	126.1	143.7	156.5
Within Run St. Dev. (S_{wr})	0.6	0.7	0.4
Within Run % CV	0.4%	0.5%	0.3%
Total Precision St. Dev. (S_T)	0.7	0.7	0.6
Total % CV	0.6%	0.5%	0.4%

Whole Blood

Within-run precision in whole blood samples was evaluated at 3 different concentrations on the OPTI CCA-TS2. The table below shows the Averages, Standard Deviations and % CV calculated from 10 samples for each level.

Na^+ (mmol/L)	Whole Blood		
	Level 1	Level 2	Level 3
Average	136.5	167.4	112.7
St. Dev	0.4	0.2	0.4
%CV	0.26%	0.13%	0.33%
n	10	10	10

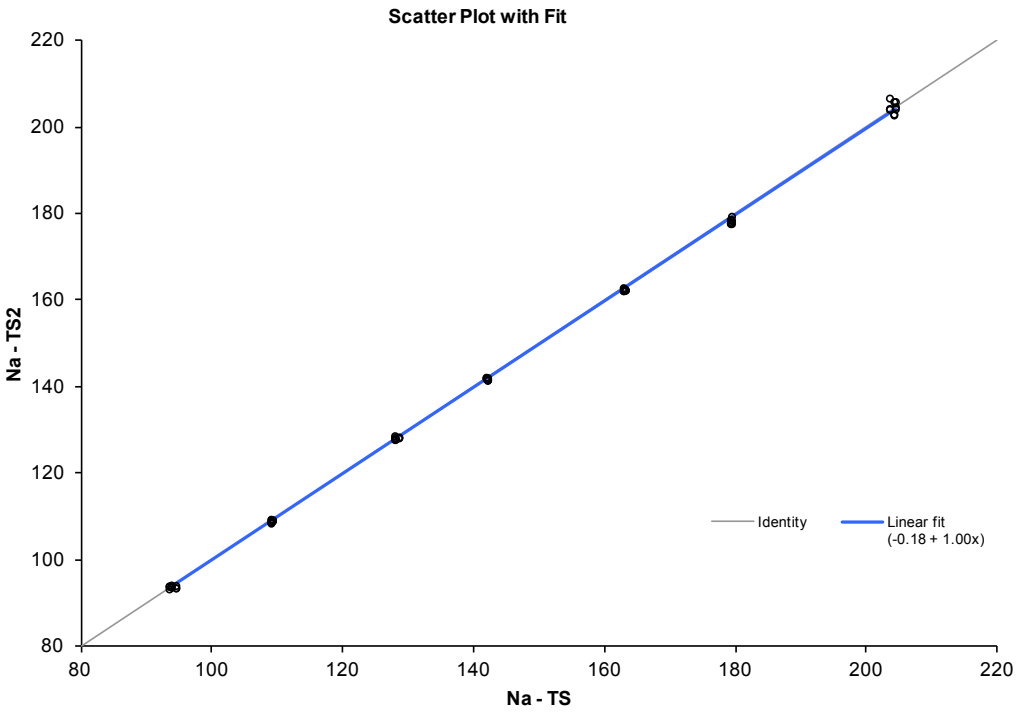
Linearity

Wherever possible, linearity for the OPTI CCA measurement has been established against reference materials or methods. Sodium linearity is established by measurement of gravimetrically prepared, N.I.S.T. traceable aqueous standard solutions (Sodium $_{ST}$) and by measurement of N.I.S.T. Standard Reference Material956a Electrolytes in Human Serum (Sodium $_{NIST}$). No changes were made to the sensor or the measurement principle, so the traceability of the OPTI CCA-TS2 is equivalent to the OPTI CCA.

Correlation

	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
$Sodium_{ST}$	0.9788	2.456	0.99911	1.32	104 to 188	30
$Sodium_{NIST}$	1.0172	3.244	0.99957	0.55	121 to 161	18

Direct linearity for the OPTI CCA-TS2 measurement has been established against reference materials or methods. The linearity of the Sodium sensor on the OPTI CCA-TS2 has been established versus the same sensor on the OPTI CCA-TS using whole blood samples tonometered with mid level mixtures and spiked or diluted to establish the correlation.



Parameter and Specification	Value
Number of Samples	63
Slope	1.00
Offset	-0.18
R^2	0.999
Sy|x	0.781

Correlation to Other Methods[3]

OPTI CCA vs other Electrolyte Instruments on Whole Blood and Serum in a typical setting

Excess blood aliquots from specimens collected for blood gas analyses were analyzed by both traditional and non-traditional operators of measurement equipment in hospital laboratories. The sample was analyzed on the OPTI CCA after obtaining the requisite results from existing instrumentation used for these analyses and operated and controlled following their established procedures.

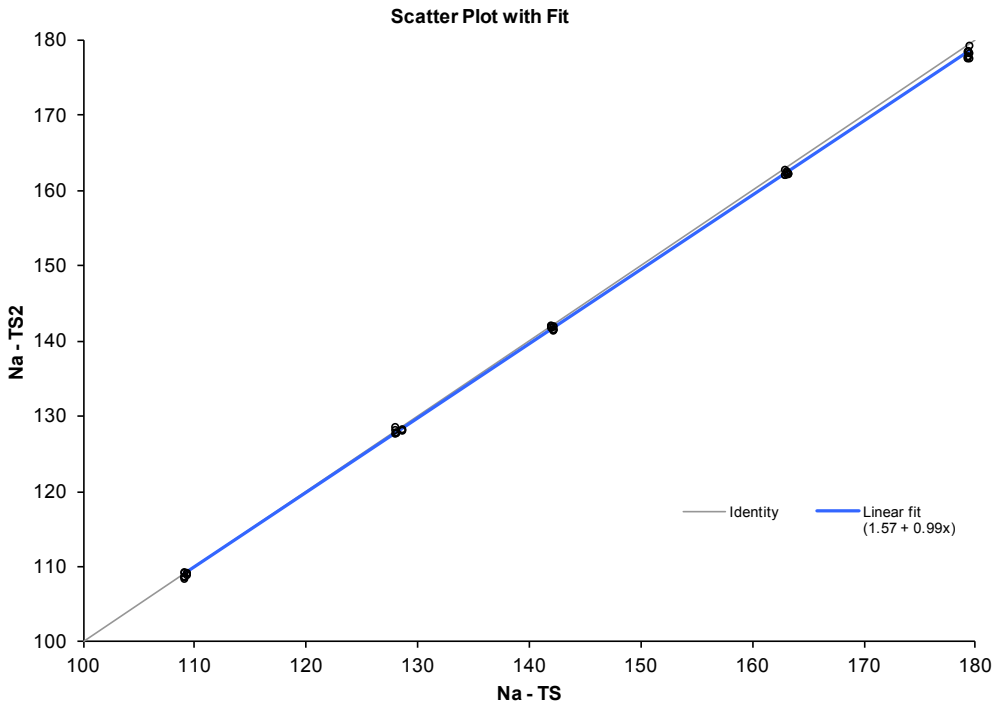
Correlation

Comparative Method*	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
Analyzer A (whole blood)	0.6500	50.15	0.7564	2.21	126 to 149	103
Analyzer B (whole blood)	0.9313	9.34	0.9180	1.95	129 to 156	173
Analyzer C (whole Blood)	1.084 ± 0.226	-14.929 ± 3.176	0.9784	1.826	128 to 174	105
Analyzer D (whole blood)	1.080 ± 0.021	-6.382 ± 2.855	0.9678	2.007	117 to 163	174
Analyzer E (serum)	0.873	15.49	0.8911	1.77	128 to 149	68
Analyzer F (serum)	1.025	-4.57	0.9376	1.57	127 to 148	102

* For more information on specific analyzers used, please contact OPTI Medical Technical Support.

OPTI CCA-TS2 vs OPTI CCA-TS on whole blood in a typical setting

In Method Comparisons carried out following the experimental protocol recommended in the CLSI guideline EP9-A2, Volume 15, Number 19 using whole blood samples on the OPTI CCA-TS2 versus the OPTI CCA-TS.



Parameter and Specification	Value
Number of Samples	45
Range	109.0 to 179.4
Slope	0.99
Offset	1.57
R^2	0.999
Sy|x	0.390

References

1. Tietz, Norbert W., Ed., *Clinical Guide to Laboratory Tests*, 2nd Ed., (Philadelphia: W.B.Saunders, Co., 1990) p. 436.
2. Tsien R, *New Calcium Indicators and Buffers with High Selectivity Against Magnesium and Protons*, Biochemistry 19, p.2396-2404, 1980.
3. OPTI Medical. Model equation for regression statistics is: [results of OPTI Analyzer] = slope(m) [comparative method results] + intercept(b).

Potassium (K^+)

Clinical Significance[1]

Potassium is the major cation in the intracellular fluid and functions as the primary buffer within the cell itself. Ninety percent of potassium is concentrated within the cell, and damaged cells release potassium into the blood. Potassium plays an important role in nerve conduction, muscle function, and helps maintain acid-base balance and osmotic pressure.

Elevated potassium levels, *hyperkalemia*, can be found in oligouria, anemia, urinary obstruction, renal failure due to nephritis or shock, metabolic or respiratory acidosis, renal tubular acidosis with the K^+/H^+ exchange and hemolysis of the blood. Low potassium levels, *hypokalemia*, can be found in excessive loss of potassium through diarrhea or vomiting, inadequate intake of potassium, malabsorption, severe burns and increased secretion of aldosterone. High or low potassium levels may cause changes in muscle irritability, respiration and myocardial function.

The potassium value obtained may be used to monitor electrolyte imbalance in the diagnosis and treatment of infusion therapies, shock, heart or circulatory insufficiency, acid-base imbalance, therapy with diuretics, all kinds of kidney problems, diarrhea, hyper- and hypo-function of adrenal cortex and other diseases involving electrolyte imbalance.

Measurement Principle

The K^+ ion optodes are closely related to the more familiar Ion Selective Electrodes (ISEs).
The optodes use ion selective recognition elements (ionophores) similar to those used in ISEs, however the ionophores are linked to fluorescent dyes instead of electrodes. These types of dyes have been used since the 1970's to visualize and quantify cellular ion levels in fluorescence microscopy and cell counters[2]. As the ion concentration increases, these ionophores bind larger amounts of ions and cause the fluorescence intensity to increase or decrease, depending on the particular ion. Like the pH optode, the ion optodes do not need a reference electrode, however, several of them do exhibit a small pH sensitivity which is automatically compensated in the OPTI CCA-TS2 using the measured pH.

Measurement Range

Range	Resolution (Low/High)	Units
0.8 to 9.99	0.1/0.01	mmol/L

Standard Reference Cassette (SRC) Limit Values

LOW	NORMAL	HIGH	Units
2.5 ± 0.3	4.5 ± 0.3	7.0 ± 0.3	mmol/L

Interferences

The OPTI CCA K^+ sensor has no measurable interference from Na^+ variation within the range 100-190 mmol/L.

The OPTI CCA K^+ results include an appropriate correction for pH at all values of pH. This correction may introduce an extra source of variability at the extreme values.

The OPTI CCA K^+ sensor has no interference from ammonia or ammonium ion present at normal physiologic levels (below 100 μmol/L). At hyperammonemia (plasma levels of 300 μmol/L), the OPTI CCA K^+ sensor will show a potassium offset of +0.4 mmol/L, and at extreme hyperammonemia (plasma levels of 3000 μmol/L), the OPTI CCA K^+ sensor will show a potassium offset of +4.4 mmol/L.

Heparin salts are the only acceptable anticoagulants. Other anticoagulants such as citrate, EDTA, oxalate, and fluoride cause significant interferences to the electrolyte sensors.

The following exogenous interferents were quantified in tonometered plasma, showing interferences to dyes which typically have short half-lives within the body before being metabolized by the liver. This testing was done on the OPTI CCA platform, with a standard OPTI style Potassium sensor. No changes were made to the sensor or the measurement principle, so the interference of the OPTI CCA-TS2 is equivalent to the OPTI CCA.

Substance	Amount	K^+ change (mmol/L)
Sodium fluorescein	26 mg/dL	-0.7
Cardio (indocyanine) green	0.5 mg/dL	-0.4
Methylene blue	25 mg/dL	+2.4

Only clear, uncolored quality control materials, such as OPTI CHECK or OPTI CHECK PLUS brand aqueous controls should be used with the OPTI CCA-TS2 system. Colored materials, including proficiency testing materials, may interfere with the potassium measurement, or fail to be properly aspirated.

Reproducibility

Controls

Within run precision (S_{wr}) and Total Precision (S_T), were determined from 2 runs per day with 2 replicates per run over a period of 20 days following the CLSI guideline EP5-A2. Typical results for 3 different control levels are shown below.

K^+ (mmol/L)	OPTI Check Level 1	OPTI Check Level 2	OPTI Check Level 3
Days Run	20	20	20
Total Average	2.92	4.86	5.92
Within Run St. Dev. (S_{wr})	0.03	0.03	0.03
Within Run % CV	0.9%	0.6%	0.5%
Total Precision St. Dev. (S_T)	0.03	0.03	0.04
Total % CV	1.0%	0.6%	0.6%

Whole Blood

Within-run precision in whole blood samples was evaluated at 3 different concentrations on the OPTI CCA-TS2. The table below shows the Averages, Standard Deviations and % CV calculated from 10 samples for each level.

K^+ (mmol/L)	Whole Blood		
	Level 1	Level 2	Level 3
Average	3.65	8.15	2.07
St. Dev	0.01	0.02	0.05
%CV	0.38%	0.26%	2.49%
n	10	10	10

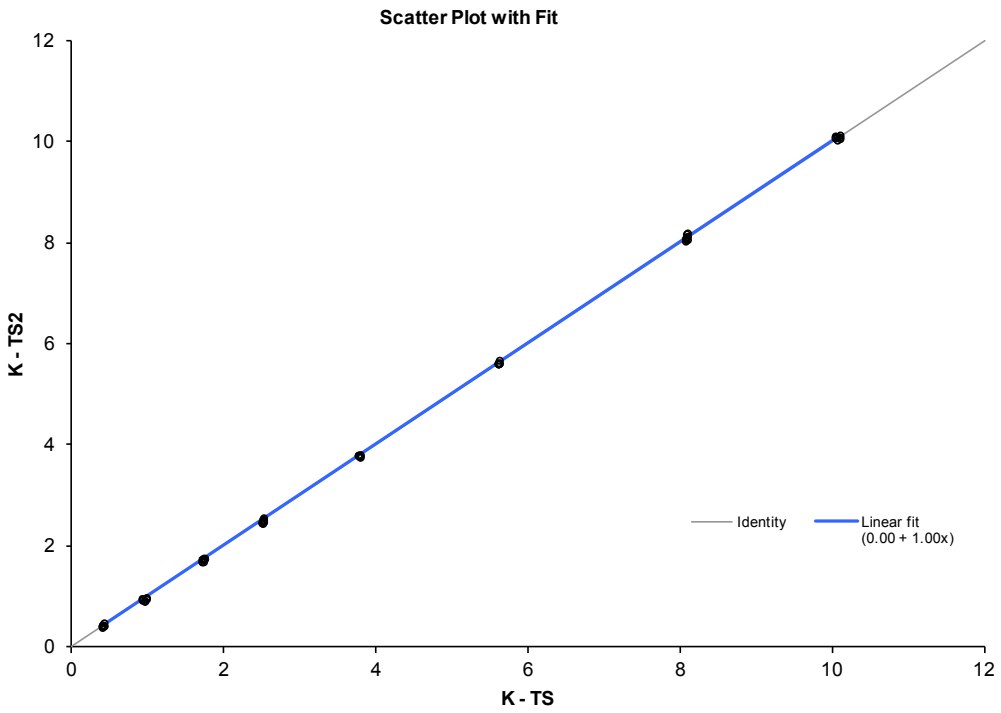
Linearity

Wherever possible, linearity for the OPTI CCA measurement has been established against reference materials or methods. Potassium linearity is established by measurement of gravimetrically prepared, N.I.S.T. traceable aqueous standard solutions (Potassium $_{ST}$) and by measurement of N.I.S.T. Standard Reference Material 956a Electrolytes in Human Serum (Potassium $_{NIST}$). No changes were made to the Potassium sensor or the measurement principle, so the traceability of the OPTI CCA-TS2 is equivalent to the OPTI CCA.

Correlation

	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
$Potassium_{ST}$	0.9964	0.116	0.99893	0.14	1.0 to 9.0	30
$Potassium_{NIST}$	0.9723	0.135	0.99956	0.05	2.0 to 6.0	18

Direct linearity for the OPTI CCA-TS2 measurement has been established against reference materials or methods. The linearity of the Potassium sensor on the OPTI CCA-TS2 has been established versus the same sensor on the OPTI CCA-TS using whole blood samples tonometered with mid level mixtures and spiked or diluted to establish the correlation.



Parameter and Specification	Value
Number of Samples	72
Slope	1.00
Offset	0.00
R^2	1.000
Sy|x	0.032

Correlation to Other Methods[3]

OPTI CCA vs other Electrolyte Instruments on Whole Blood and Serum in a typical setting

Excess blood aliquots from specimens collected for blood gas analyses were analyzed by both traditional and non-traditional operators of measurement equipment in hospital laboratories. The sample was analyzed on the OPTI CCA after obtaining the requisite results from existing instrumentation used for these analyses and operated and controlled following their established procedures.

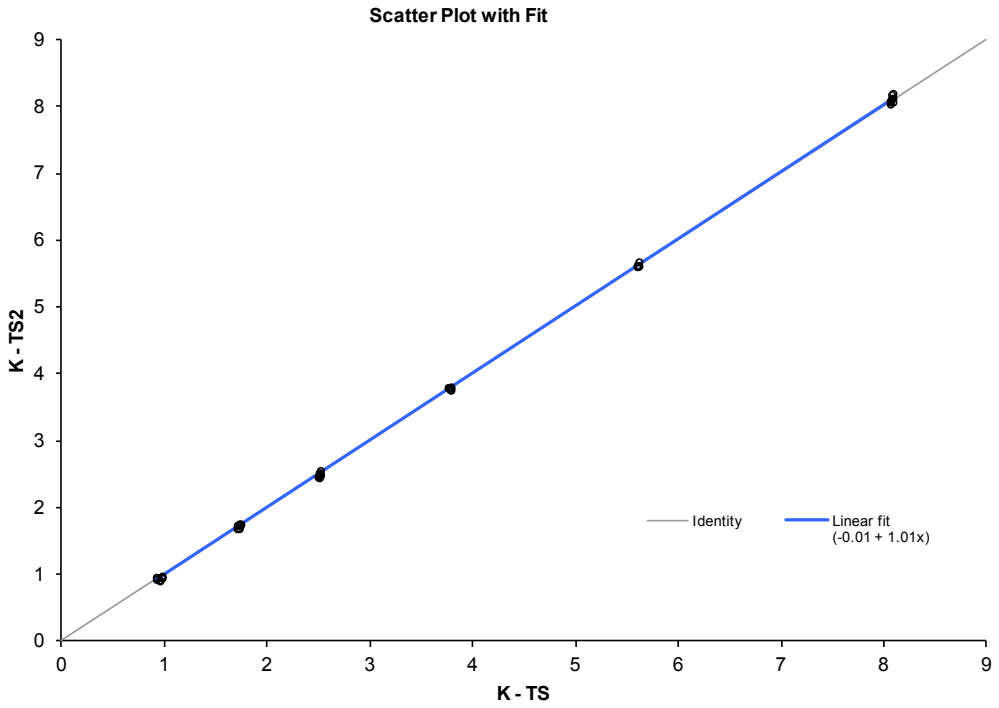
Correlation

Comparative Method*	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
Analyzer A (whole blood)	1.0816	-0.138	0.9857	0.13	2.1 to 6.4	103
Analyzer B (whole blood)	1.0225	-0.008	0.9673	0.15	2.5 to 6.0	173
Analyzer C (whole blood)	1.021 ± 0.019	-0.087 ± 0.077	0.9830	0.197	2.3 to 9.4	105
Analyzer D (whole blood)	1.050 ± 0.126	0.062 ± 0.055	0.9879	0.18	2.2 to 9.4	174
Analyzer E (serum)	1.084	-0.315	0.9855	0.181	2.9 to 7.5	68
Analyzer F (serum)	1.126	-0.397	0.9784	0.108	3.0 to 5.4	102

* For more information on specific analyzers used, please contact OPTI Medical Technical Support.

OPTI CCA-TS2 vs OPTI CCA-TS on whole blood in a typical setting

In Method Comparisons carried out following the experimental protocol recommended in the CLSI guideline EP9-A2, Volume 15, Number 19 using whole blood samples on the OPTI CCA-TS2 versus the OPTI CCA-TS.



Parameter and Specification	Value
Number of Samples	54
Range	0.9 to 8.1
Slope	1.01
Offset	-0.01
R^2	0.999
Sy|x	0.031

References

1. Tietz, Norbert W., Ed., *Clinical Guide to Laboratory Tests*, 2nd Ed., (Philadelphia: W.B.Saunders, Co., 1990) p. 436.
2. Tsien R, *New Calcium Indicators and Buffers with High Selectivity Against Magnesium and Protons*, Biochemistry 19, p.2396-2404, 1980.
3. OPTI Medical. Model equation for regression statistics is: [results of OPTI Analyzer] = slope(m) [comparative method results] + intercept(b).

Ionized Calcium (Ca^{++})

Clinical Significance[1]

Calcium in blood is distributed as free calcium ions (50%); bound to protein, mostly albumin (40%); and 10% bound to anions such as bicarbonate, citrate, phosphate and lactate. However, only ionized calcium can be used by the body in such vital processes as muscular contraction, cardiac function, transmission of nerve impulses and blood clotting. The OPTI CCA-TS2 measures the ionized portion of the total calcium. In certain disorders such as pancreatitis and hyperparathyroidism, ionized calcium is a better indicator for diagnosis than total calcium.

Elevated calcium, *hypercalcemia*, may be present in various types of malignancy, and calcium measurements may serve as biochemical markers. In general, while ionized calcium may be slightly more sensitive, either ionized or total calcium measurements have about equal utility in the detection of occult malignancy. Hypercalcemia occurs commonly in critically ill patients with abnormalities in acid-base regulation and losses of protein and albumin, which gives a clear advantage to monitoring calcium status by ionized calcium measurements.

Decreased calcium, hypocalcemia, is found in patients with decreased intestinal absorption, increased renal elimination, increased deposition of calcium in the bones, increased binding to proteins when the pH increases or binding to citrate, and hypoparathyroidism.

Patients with renal disease caused by glomerular failure often have altered concentrations of calcium, phosphate, albumin, magnesium and pH. Since these conditions tend to change ionized calcium independently of total calcium, ionized calcium is the preferred method of accurately monitoring calcium status in renal disease[2].

Ionized calcium is important for diagnosis or monitoring of: hypertension management, parathyroidism, renal diseases, malnutrition, kidney stones, multiple myeloma and diabetes mellitus.

Ionized calcium may be reported either as the actual ionized calcium, referred to actual pH of the patients, or as normalized ionized calcium, to a standard pH at pH 7.40. The binding of calcium by protein and small anions is influenced by pH and because of this relationship specimens should be analyzed at the pH of the patient's blood.

Measurement Principle

The Ca^{++} ion optodes are closely related to the more familiar Ion Selective Electrodes (ISEs). The optodes use ion selective recognition elements (ionophores) similar to those used in ISEs, however the ionophores are linked to fluorescent dyes instead of electrodes. These types of dyes have been used since the 1970's to visualize and quantify cellular ion levels in fluorescence microscopy and cell counters[3]. As the ion concentration increases, these ionophores bind larger amounts of ions and cause the fluorescence intensity to increase or decrease, depending on the particular ion. Like the pH optode, the ion optodes do not need a reference electrode, however, several of them do exhibit a small pH sensitivity which is automatically compensated in the OPTI CCA-TS2 using the measured pH.

Measurement Range

Range	Resolution (Low/High)	Units
0.2 to 3.0	0.01	mmol/L

Standard Reference Cassette (SRC) Limit Values

LOW	NORMAL	HIGH	Units
1.8 ± 0.1	1.1 ± 0.1	0.7 ± 0.1	mmol/L

Interferences

The OPTI CCA Ca^{++} sensor does exhibit an interference from bisulfate and phenylacetic acid.

Heparin salts are the only acceptable anticoagulants. Other anticoagulants such as citrate, EDTA, oxalate, and fluoride cause significant interferences to the electrolyte sensors.

The following exogenous interferents were quantified in tonometered plasma, showing interferences to dyes which typically have short half-lives within the body before being metabolized by the liver. This testing was done on the OPTI CCA platform, with a standard OPTI style Ionized Calcium sensor. No changes were made to the sensor or the measurement principle, so the interference of the OPTI CCA-TS2 is equivalent to the OPTI CCA.

Substance	Amount	Ca^{++} change (mmol/L)
Sodium fluorescein	26 mg/dL	unstable
Cardio (indocyanine) green	0.5 mg/dL	+0.1
Methylene blue	25 mg/dL	unstable

Only clear, uncolored quality control materials, such as OPTI CHECK or OPTI CHECK PLUS brand aqueous controls should be used with the OPTI CCA-TS2 system. Colored materials, including proficiency testing materials, may interfere with the ionized calcium measurement, or fail to be properly aspirated.

Reproducibility

Controls

Within run precision (S_{wr}) and Total Precision (S_T), were determined from 2 runs per day with 2 replicates per run over a period of 20 days following the CLSI guideline EP5-A2. Typical results for 3 different control levels are shown below:

Ca^{++} (mmol/L)	OPTI Check Level 1	OPTI Check Level 2	OPTI Check Level 3
Days Run	20	20	20
Total Average	1.57	1.27	0.79
Within Run St. Dev. (S_{wr})	0.01	0.01	0.01
Within Run % CV	0.9%	0.7%	0.9%
Total Precision St. Dev. (S_T)	0.02	0.01	0.01
Total % CV	1.5%	1.0%	1.5%

Whole Blood

Within-run precision in whole blood samples was evaluated at 3 different concentrations on the OPTI CCA-TS2. The table below shows the Averages, Standard Deviations and % CV calculated from 10 samples for each level.

Ca^{++} (mmol/L)	Whole Blood		
	Level 1	Level 2	Level 3
Average	1.21	2.58	0.82
St. Dev	0.004	0.010	0.005
%CV	0.35%	0.40%	0.59%
n	10	10	10

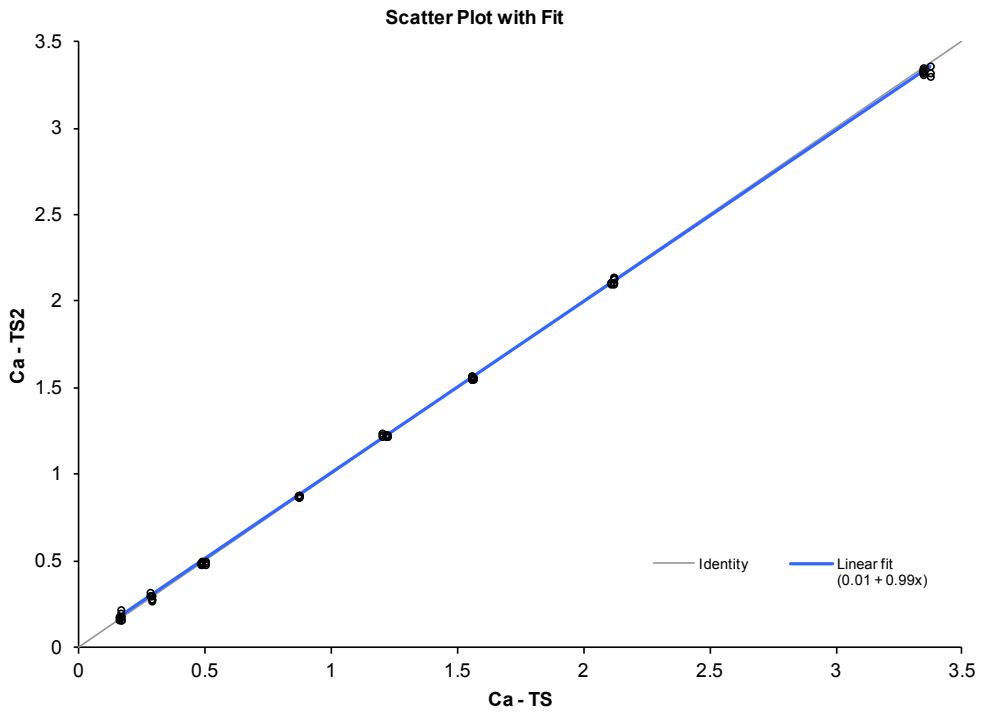
Linearity

Wherever possible, linearity for the OPTI CCA measurement has been established against reference materials or methods. Ionized Calcium linearity is established by measurement of gravimetrically prepared, N.I.S.T. traceable aqueous standard solutions (Ionized Calcium $_{ST}$) and by measurement of N.I.S.T. Standard Reference Material 956a Electrolytes in Human Serum (Ionized Calcium $_{NIST}$).
No changes were made to the Ionized Calcium sensor or the measurement principle, so the traceability of the OPTI CCA-TS2 is equivalent to the OPTI CCA.

Correlation

	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
ionized Calcium$_{ST}$	1.0022	-0.0025	0.99983	0.017	0.2 to 3.0	24
ionized Calcium$_{NIST}$	0.9938	0.0081	0.99843	0.016	1.07 to 1.71	12

Direct linearity for the OPTI CCA-TS2 measurement has been established against reference materials or methods. The linearity of the Ionized Calcium sensor on the OPTI CCA-TS2 has been established versus the same sensor on the OPTI CCA-TS using whole blood samples tonometered with mid level mixtures and spiked or diluted to establish the correlation.



Parameter and Specification	Value
Number of Samples	72
Slope	0.99
Offset	0.01
R^2	0.999
Sy|x	0.017

Correlation to Other Methods[4]

OPTI CCA vs other Electrolyte Instruments on whole blood in a typical setting

Excess blood aliquots from specimens collected for electrolyte analyses were analyzed by both traditional and non-traditional operators of measurement equipment in hospital laboratories. The sample was analyzed on the OPTI CCA after obtaining the requisite results from existing instrumentation used for these analyses and operated and controlled following their established procedures.

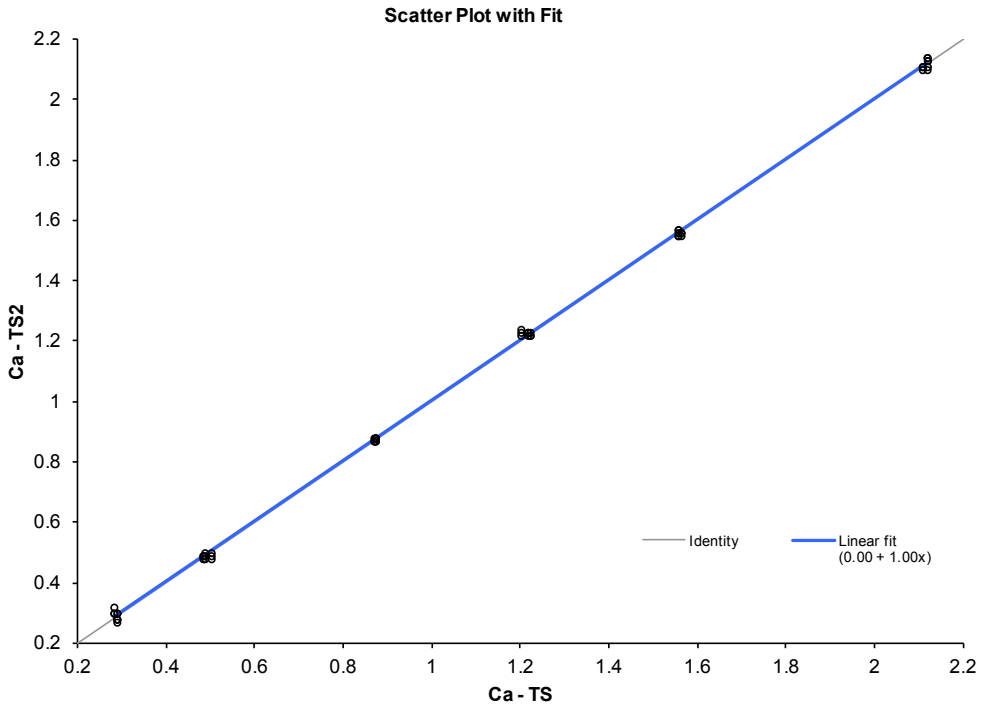
Correlation

Comparative Method*	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
Analyzer A (whole blood)	0.8732	-0.064	0.8392	0.07	0.68 to 1.34	103
Analyzer B (whole blood)	0.9548	-0.024	0.9453	0.04	0.94 to 1.67	101

* For more information on specific analyzers used, please contact OPTI Medical Technical Support.

OPTI CCA-TS2 vs OPTI CCA-TS on whole blood in a typical setting

In Method Comparisons carried out following the experimental protocol recommended in the CLSI guideline EP9-A2, Volume 15, Number 19 using whole blood samples on the OPTI CCA-TS2 versus the OPTI CCA-TS.



Parameter and Specification	Value
Number of Samples	54
Range	0.28 to 2.12
Slope	1.00
Offset	0.00
R^2	0.999
Sy|x	0.013

References

1. Tietz, Norbert W., Ed., *Clinical Guide to Laboratory Tests*, 2nd Ed., (Philadelphia: W.B.Saunders, Co., 1990) p. 436.
2. Burritt MF, Pierides AM, Offord KP: *Comparative studies of total and ionized serum calcium values in normal subjects and in patients with renal disorders.* Mayo Clinic proc. 55:606, 1980.
3. Tsien R, *New Calcium Indicators and Buffers with High Selectivity Against Magnesium and Protons*, Biochemistry 19, p.2396-2404, 1980.
4. OPTI Medical. Model equation for regression statistics is: [results of OPTI Analyzer] = slope(m) [comparative method results] + intercept(b).

Chloride (Cl^-)

Clinical Significance[1]

Chloride is an anion that exists predomininantly in extracellular spaces. It maintains cellular integrity through its influence on osmotic pressure. It is also significant in monitoring acid-base balance and water balance. In metabolic acidosis, there is a reciprocal rise in chloride concentration when the bicarbonate concentration drops.

Decreased levels are found in severe vomiting, severe diarrhea, ulcerative colitis, pyloric obstruction, severe burns, heat exhaustion, diabetic acidosis, Addison's disease, fever and acute infections such as pneumonia.

Increased levels are found in dehydration, Cushing's syndrome, hyperventilation, eclampsia, anemia and cardiac decompensation.

Measurement Principle

The Cl^- ion optodes are closely related to the more familiar Ion Selective Electrodes (ISEs).
The optodes use ion selective recognition elements (ionophores) similar to those used in ISEs, however the ionophores are linked to fluorescent dyes instead of electrodes. These types of dyes have been used since the 1970's to visualize and quantify cellular ion levels in fluorescence microscopy and cell counters[2]. As the ion concentration increases, these ionophores bind larger amounts of ions and cause the fluorescence intensity to increase or decrease, depending on the particular ion. Like the pH optode, the ion optodes do not need a reference electrode, however, several of them do exhibit a small pH sensitivity which is automatically compensated in the OPTI CCA-TS2 using the measured pH.

Measurement Range

Range	Resolution (Low/High)	Units
50 to 160	1/0.1	mmol/L

Standard Reference Cassette (SRC) Limit Values

LOW	NORMAL	HIGH	Units
80.0 ± 2	105.0 ± 2	130.0 ± 2	mmol/L

Interferences

The OPTI CCA Cl^- sensor does exhibit a significant (greater than 2:1) positive interference from bromide, iodide, interlipid and nitrite. Minor interference is observed from phenylacetic acid salicyate and thiocynate. This testing was done on the OPTI CCA platform, with a standard OPTI style Chloride sensor. No changes were made to the sensor or the measurement principle, so the interference of the OPTI CCA-TS2 is equivalent to the OPTI CCA.

Heparin salts are the only acceptable anticoagulants. Other anticoagulants such as citrate, EDTA, oxalate, and fluoride cause significant interferences to the electrolyte sensors.

Only clear, uncolored quality control materials, such as OPTI CHECK or OPTI CHECK PLUS brand aqueous controls should be used with the OPTI CCA-TS2 system. Colored materials, including proficiency testing materials, may interfere with the chloride measurement, or fail to be properly aspirated.

Reproducibility

Controls

Within run precision (S_{wr}) and Total Precision (S_T), were determined from 2 runs per day with 2 replicates per run over a period of 10 days following the CLSI guideline EP5-A2. Typical results for 3 different control levels are shown below.

Cl^- (mmol/L)	OPTI Check Level 1	OPTI Check Level 2	OPTI Check Level 3
Days Run	10	10	10
Total Average	95.3	107.1	115.6
Within Run St. Dev. (S_{wr})	0.6	1.4	0.5
Within Run % CV	0.7%	1.3%	0.4%
Total Precision St. Dev. (S_T)	0.7	1.4	0.6
Total % CV	0.8%	1.3%	0.5%

Whole Blood

Within-run precision in whole blood samples was evaluated at 3 different concentrations on the OPTI CCA-TS2. The table below shows the Averages, Standard Deviations and % CV calculated from 10 samples for each level.

Cl^- (mmol/L)	Whole Blood		
	Level 1	Level 2	Level 3
Average	104.1	141.3	57.5
St. Dev	0.3	1.0	0.3
%CV	0.28%	0.73%	0.51%
n	10	10	10

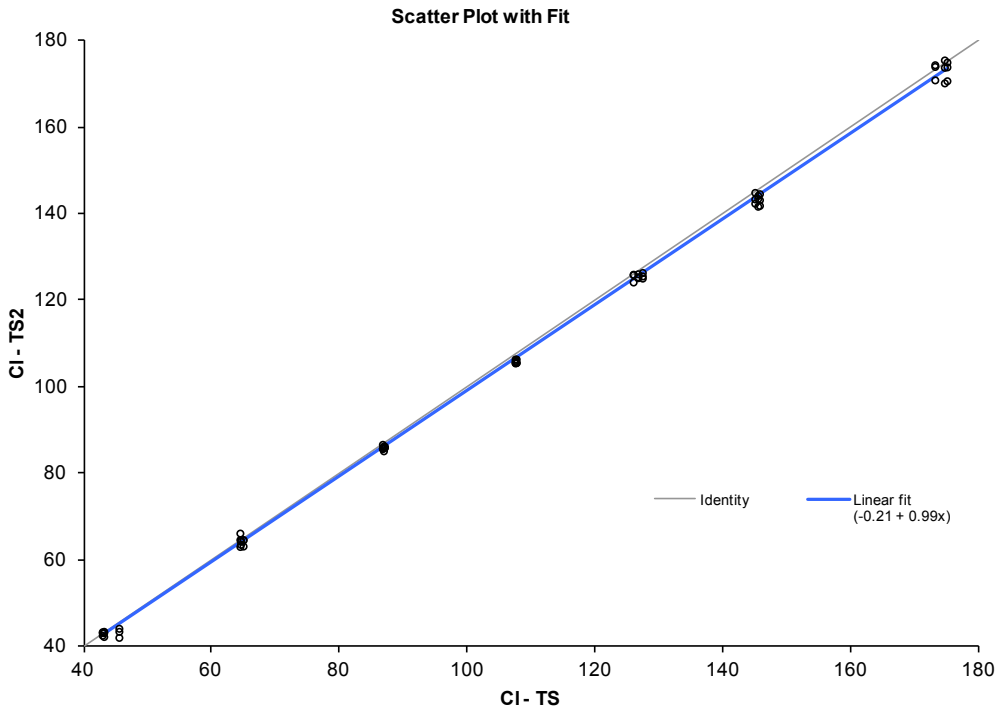
Linearity

Wherever possible, linearity for the OPTI CCA measurement has been established against reference materials or methods. Chloride linearity is established by measurement of gravimetrically prepared, N.I.S.T. traceable aqueous standard solutions (Chloride $_{ST}$). Chloride linearity in serum is established against Chloridometry (Chloride $_{CL}$). No changes were made to the Chloride sensor or the measurement principle, so the traceability of the OPTI CCA-TS2 is equivalent to the OPTI CCA.

Correlation

	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
$Chloride_{ST}$	1.0076	-0.56	0.99984	0.68	58 to 160	15
$Chloride_{CL}$	1.0064	-2.44	0.99823	1.66	74 to 142	16

Direct linearity for the OPTI CCA-TS2 measurement has been established against reference materials or methods. The linearity of the Chloride sensor on the OPTI CCA-TS2 has been established versus the same sensor on the OPTI CCA-TS using whole blood samples tonometered with mid level mixtures and spiked or diluted to establish the correlation.



Parameter and Specification	Value
Number of Samples	63
Slope	0.99
Offset	-0.21
R^2	0.999
Sy|x	1.218

Correlation to Other Methods[3]

OPTI CCA vs other Electrolyte Instruments on whole blood in a typical setting

Excess blood aliquots from specimens collected for electrolyte analyses were analyzed by both traditional and non-traditional operators of measurement equipment in hospital laboratories. The sample was analyzed on the OPTI CCA after obtaining the requisite results from existing instrumentation used for these analyses and operated and controlled following their established procedures.

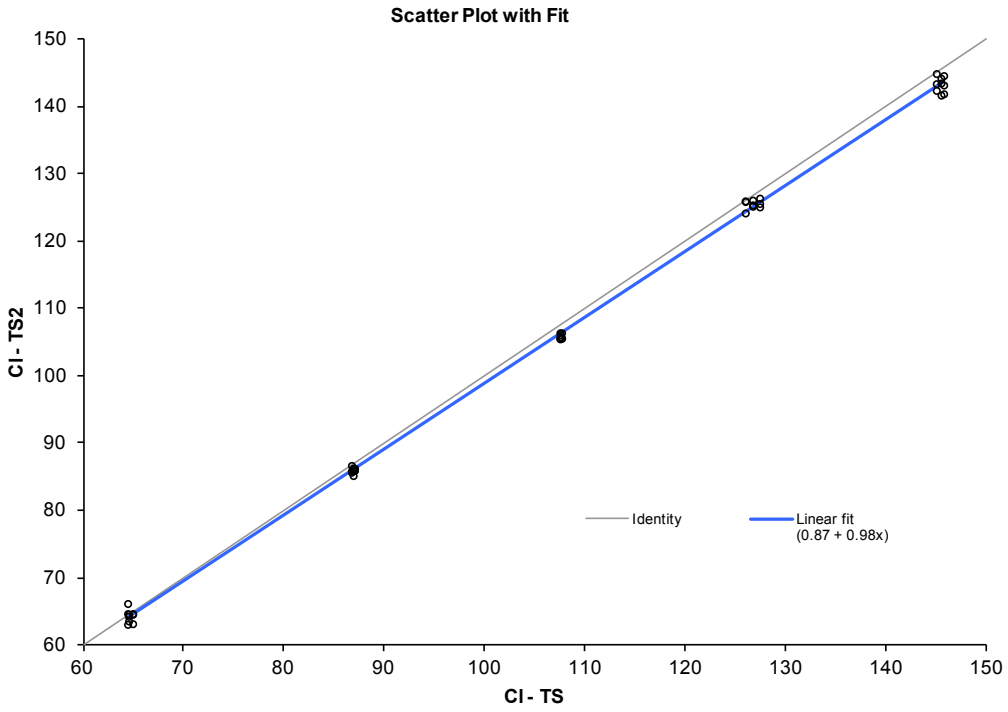
Correlation

Comparative Method*	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
Analyzer A (whole blood)	0.9965	0.95	0.9246	1.96	92 to 117	173

* For more information on specific analyzers used, please contact OPTI Medical Technical Support.

OPTI CCA-TS2 vs OPTI CCA-TS on whole blood in a typical setting

In Method Comparisons carried out following the experimental protocol recommended in the CLSI guideline EP9-A2, Volume 15, Number 19 using whole blood samples on the OPTI CCA-TS2 versus the OPTI CCA-TS.



Parameter and Specification	Value
Number of Samples	45
Range	64.4 to 145.7
Slope	0.98
Offset	0.87
R^2	0.999
Sy|x	0.863

References

1. Tietz, Norbert W., Ed., *Clinical Guide to Laboratory Tests*, 2nd Ed., (Philadelphia: W.B.Saunders, Co., 1990) p. 436.
2. Tsien R, *New Calcium Indicators and Buffers with High Selectivity Against Magnesium and Protons,* Biochemistry 19, p.2396-2404, 1980.
3. OPTI Medical. Model equation for regression statistics is: [results of OPTI Analyzer] = slope(m) [comparative method results] + intercept(b).

Glucose (Glu)

Clinical Significance[1]

Glucose is the primary energy source of the body with the brain and erythrocytes being totally dependent upon glucose for their energy requirements. Therefore the blood glucose concentration plays a central role in energy metabolism and its maintenance is essential for survival. The concentration of glucose in the blood is determined by a balance between the utilization of glucose and its intake from the diet or from synthesis within the body. Alterations in this balance may produce either hyperglycaemia (elevated blood glucose levels) or hypoglycaemia (low blood glucose levels). Both of these conditions have serious consequences for health and require treatment, which explains why measurement of blood glucose is one of the most frequently requested laboratory tests. In addition the treatment for hyperglycaemia has the potential to make the patient hypoglycaemic if the patient is not carefully monitored.

Abnormal Levels

Hyperglycaemia can be due to a number of causes, which can be subdivided into those due to *diabetes mellitus* or those due to non-diabetic causes. Diabetes mellitus is a syndrome of chronic hyperglycaemia, which is due to either absolute insulin deficiency, or reduced tissue response to insulin, or both. It is a common condition, which is diagnosed according to strict criteria that rely upon measurement of the blood glucose level. Nondiabetic causes of hyperglycaemia include *postprandial* (occurs immediately after a carbohydrate-containing meal), *factitious* (blood taken from an arm where glucose is being infused), *drugs* (produce a tissue insensitivity to insulin), *non-pancreatic endocrine disease* (excessive production of anti-insulin hormones), *pancreatic disorders* (secondary diabetes mellitus, and *stress* (physical and psychogenic types causing excess secretion of cortisol and catecholamines).

Hypoglycaemia is an acute medical condition with a number of characteristic signs and symptoms which are accompanied by biochemical hypoglycaemia and which are relieved by the administration of glucose. The causes of hypoglycaemia can be divided into three groups: medication/toxins, reactive hypoglycaemia and fasting hypoglycaemia. Hypoglycaemia due to excessive amounts of certain *medications or toxins* include insulin (insulin overdose is the most common cause of hypoglycaemia), oral hypoglycaemic or sulphonylureas, ethanol and other drugs such as salicylate and propanalol. *Reactive Hypoglycaemia* occurs, within 5-hours of a carbohydrate meal in otherwise normal patients, in patients with early adult onset diabetes mellitus and in patients who have had gastric surgery. *Fasting Hypoglycaemia* can be due to insulinomas, non-pancreatic tumors, endocrine disorders, liver failure, sepsis, renal failure or autoimmune disorders.

Measurement Principle

The glucose optode measurement is based on the enzymatic oxidation of glucose.

$$\text{Glucose} + O_2 \xrightarrow[\text{glucose oxidase}]{} \text{gluconic acid} + H_2O_2$$

The sensor is constructed of an enzyme layer over an oxygen sensor. As a sample containing glucose contacts the sensor, the oxidation of the glucose consumes the oxygen locally present in the sensor.

This decrease in oxygen is detected in the same manner (luminescence quenching) as described for the PO_2 optode. The amount of glucose is determined to be proportional to the rate at which the oxygen is consumed.

Measurement Range

Range	Resolution (Low/High)	Units
30 to 400 (70 to 400 mg/dL for samples with pO_2 levels from 401-700 mmHg)	0.1/0.1	mg/dL
1.7 to 22.2	0.01/0.01	mmol/L

Standard Reference Cassette (SRC) Limit Values

LOW	NORMAL	HIGH	Units
40.0 ± 4.0	110.0 ± 4.0	300.0 ± 4.0	mg/dL
2.2 ± 0.22	6.1 ± 0.22	16.65 ±0.22	mmol/L

Interferences

The OPTI CCA Glucose sensor does exhibit interference from PO_2 levels that exceed 700 mmHg. The Glucose sensor corrects for PO_2 values up to 700 mmHg. Glucose values are suppressed when PO_2 values are > 700 mmHg. This testing was done on the OPTI CCA platform, with a standard OPTI style Glucose sensor. No changes were made to the sensor or the measurement principle, so the interference of the OPTI CCA-TS2 is equivalent to the OPTI CCA.

Heparin salts are the only acceptable anticoagulants. Other anticoagulants such as citrate, EDTA, oxalate, and fluoride cause significant interferences to the Glucose sensor.

Only clear, uncolored quality control materials, such as OPTI CHECK PLUS brand aqueous controls should be used with the OPTI CCA-TS2 system. Colored materials, including proficiency testing materials, may interfere with the Glucose measurement, or fail to be properly aspirated.

Reproducibility

Controls

Within run precision (S_{wr}) and Total Precision (S_T), were determined from 2 runs per day with 2 replicates per run over a period of 10 days following the CLSI guideline EP5-A2. Typical results for 3 different control levels are shown below:

Glucose (mg/dL)	OPTI Check Level 1	OPTI Check Level 2	OPTI Check Level 3
Days Run	10	10	10
Total Average	40.5	95.7	316.2
Within Run St. Dev. (S_{wr})	1.6	3.5	7.5
Within Run % CV	3.9%	3.6%	2.4%
Total Precision St. Dev. (S_T)	2.4	4.4	9.4
Total % CV	5.9%	4.6%	3.0%

Whole Blood

Within-run precision in whole blood samples was evaluated at 3 different concentrations on the OPTI CCA-TS2. The table below shows the Averages, Standard Deviations and % CV calculated from 10 samples for each level.

Glucose (mg/dL)	Whole Blood		
	Level 1	Level 2	Level 3
Average	82.7	166.1	34.6
St. Dev	3.8	8.2	2.4
%CV	4.65%	4.91%	6.94%
n	10	10	10

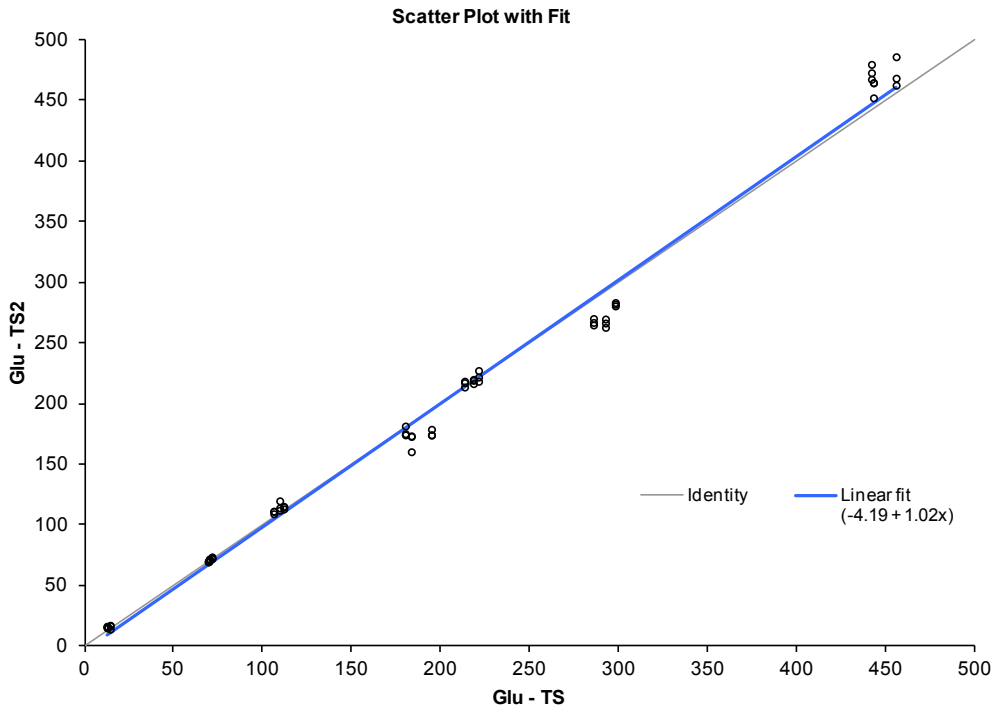
Linearity

Wherever possible, linearity for the OPTI CCA measurement has been established against reference materials or methods. Glucose linearity is established by measurement of gravimetrically prepared, N.I.S.T. traceable aqueous standard solutions (Glucose $_{ST}$). Glucose linearity in serum is by measurement of N.I.S.T. Standard Reference Material 965 Glucose in Frozen Human Serum (Glucose $_{NIST}$).
No changes were made to the Glucose sensor or the measurement principle, so the traceability of the OPTI CCA-TS2 is equivalent to the OPTI CCA.

Correlation

	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
Glucose $_{ST}$ (mg/dL)	0.9874	3.26	0.9959	7.57	30 to 400	126
Glucose $_{ST}$ (mmol/L)	0.9874	0.181	0.9959	0.420	1.6 to 23.0	126
Glucose $_{NIST}$ (mg/dL)	1.0256	-7.79	0.9912	8.13	97 to 306	36
Glucose $_{NIST}$ (mmol/L)	1.0256	-0.432	0.9912	0.451	5.4 to 17.0	36

Direct linearity for the OPTI CCA-TS2 measurement has been established against reference materials or methods. The linearity of the Glucose sensor on the OPTI CCA-TS2 has been established versus the same sensor on the OPTI CCA-TS using whole blood samples tonometered with mid level mixtures and spiked or diluted to establish the correlation.



Parameter and Specification	Value
Number of Samples	63
Slope	1.02
Offset	-4.19
R^2	0.991
Sy|x	13.362

Correlation to Other Methods[2]

OPTI CCA vs other Glucose Instruments on Whole Blood, Plasma and Serum in a typical setting

Excess sample aliquots from specimens collected for metabolyte analyses were analyzed by both traditional and non-traditional operators of measurement equipment in hospital laboratories. The sample was analyzed on the OPTI CCA after obtaining the requisite results from existing instrumentation used for these analyses and operated and controlled following their established procedures.

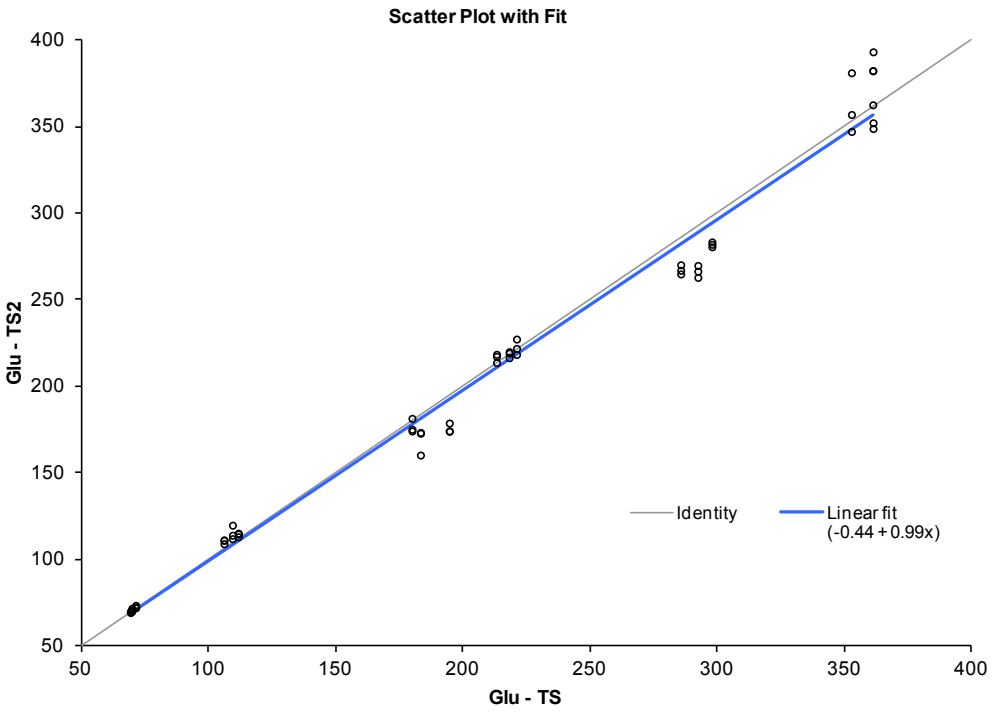
Correlation

Comparative Method*		Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
Analyzer A (whole blood)	mg/dL	1.0081	5.16	0.9735	11.81	27 to 328	106
Analyzer B (plasma)	mg/dL	0.9986	-2.34	0.9933	8.500	49 to 398	167
OPTI CCA (whole blood vs. plasma)	mg/dL mmol/L	1.058 1.058	2.36 0.13	0.9700 0.9700	21.600 1.200	37 to 395 2.1 to 21.9	103 103
Analyzer C (serum)	mg/dL	0.9500	5.73	0.9784	10.51	78 to 294	68
Analyzer D (serum)	mg/dL	0.9910	3.99	0.9772	10.74	36 to 344	102
Analyzer E (whole blood)	mg/dL	0.9776	-1.29	0.9864	9.74	86 to 340	85

* For more information on specific analyzers used, please contact OPTI Medical Technical Support.

OPTI CCA-TS2 vs OPTI CCA-TS on whole blood in a typical setting

In Method Comparisons carried out following the experimental protocol recommended in the CLSI guideline EP9-A2, Volume 15, Number 19 using whole blood samples on the OPTI CCA-TS2 versus the OPTI CCA-TS.



Parameter and Specification	Value
Number of Samples	54
Range	69.4 to 361.3
Slope	0.99
Offset	-0.44
R^2	0.983
Sy|x	12.849

References

1. Tietz, Norbert W., Ed., *Clinical Guide to Laboratory Tests*, 2nd Ed., (Philadelphia: W.B.Saunders, Co., 1990) p. 436.
2. OPTI Medical. Model equation for regression statistics is: [results of OPTI Analyzer] = slope(m) [comparative method results] + intercept(b).

BUN (Urea)

Clinical Significance[1]

Urea is produced in the liver as a by-product from the breakdown of amino acids. These are transaminated and deaminated to ammonia, which is a toxin. Detoxification of ammonia occurs in the urea cycle where two molecules of ammonia are joined to a molecule of carbon dioxide to form urea.
On an average protein diet, urinary excretion expressed as urea nitrogen is 12 to 20 g/day.[2]

Abnormal Levels

The blood urea reflects the balance between production and excretion.

Causes of high blood urea levels (> 7.1 mmol/L urea, 20 mg/dl BUN).

These may result from increased production or decreased excretion. Causes of increased production include a high protein intake, gastrointestinal bleeding with absorption of amino acids and peptides, or increased tissue breakdown which may be due to serious illness, trauma or certain drugs such as tetracyclines and glucocorticoids. Decreased excretion is associated with a low glomerular filtration rate (GFR). This can be due to a number of reasons, which can be classified as pre-renal uraemia due to dehydration, renal uraemia due to intrinsic failure in the kidney or postrenal uraemia due to an obstruction to urine outflow.

Causes of low blood urea levels (< 2.1 mmol/L urea, 6 mg/dL BUN).

These are less common than high levels and can be due to decreased production or increased excretion. Decreased production can be due to ingestion of a low protein diet, very severe liver failure and, in infants only, inborn errors of the urea cycle. Increased secretion is due to an increased GFR. This can be due to over-enthusiastic infusion of intravenous fluids, inappropriate ADH secretion or pregnancy.

Measurement Principle

The BUN (urea) optode measurement is based on the enzymatic hydrolysis of urea by the enzyme urease.

$$\text{Urea} + H_2O + 2H^+ \xrightarrow[\text{Urease}]{} 2\,NH_4^+ + CO_2$$

The ammonium ions are measured by an ammonium-selective fluorescence-based optical sensor (optode). The amount of urea present is proportional to the ammonium concentration detected.

Measurement Range

Range	Resolution (Low/High)	Units
2.8 to 112.0	0.1/0.1	mg/dL
1 to 40	0.01/0.01	mmol/L

Standard Reference Cassette (SRC) Limit Values

LOW	NORMAL	HIGH	Units
5.6 ± 1.4	28.0 ± 1.4	70.0 ± 1.4	mg/dL
2.0 ± 0.5	10.0 ± 0.5	25.0 ± 0.5	mmol/L

Interferences

The OPTI CCA BUN(urea) sensor has no interference from ammonia or ammonium ion present at normal physiologic levels (below 100 µmol/L) nor at hyperammonemia (plasma levels of 300 µmol/L).
At extreme hyperammonemia (plasma levels of 3000µmol/L), the OPTI CCA BUN(urea) sensor will show an offset of +4.8 mg/dL BUN (1.7 mmol/L urea). This testing was done on the OPTI CCA platform, with a standard OPTI style BUN(urea) sensor. No changes were made to the sensor or the measurement principle, so the interference of the OPTI CCA-TS2 is equivalent to the OPTI CCA.

Heparin salts are the only acceptable anticoagulants. Other anticoagulants such as citrate, EDTA, oxalate, and fluoride cause significant interferences to the BUN(urea) sensor.

Only clear, uncolored quality control materials, such as OPTI CHECK PLUS brand aqueous controls should be used with the OPTI CCA-TS2 system. Colored materials, including proficiency testing materials, may interfere with the BUN(urea) measurement, or fail to be properly aspirated.

Reproducibility

Controls

Within run precision (S_{wr}) and Total Precision (S_T), were determined from 2 runs per day with 2 replicates per run over a period of 10 days following the CLSI guideline EP5-A2. Typical results for 3 different control levels are shown below.

BUN (mg/dL)	OPTI Check Level 1	OPTI Check Level 2	OPTI Check Level 3
Days Run	10	10	10
Total Average	74.1	19.3	5.9
Within Run St. Dev. (S_{wr})	3.0	0.6	0.1
Within Run % CV	4.0%	3.2%	1.9%
Total Precision St. Dev. (S_T)	3.5	0.7	0.2
Total % CV	4.7%	3.7%	3.2%

Whole Blood

Within-run precision in whole blood samples was evaluated at 3 different concentrations on the OPTI CCA-TS2. The table below shows the Averages, Standard Deviations and % CV calculated from 10 samples for each level.

BUN (mg/dL)	Whole Blood		
	Level 1	Level 2	Level 3
Average	6.03	26.61	85.59
St. Dev	0.03	0.25	0.97
%CV	0.53%	0.93%	1.13%
n	10	10	10

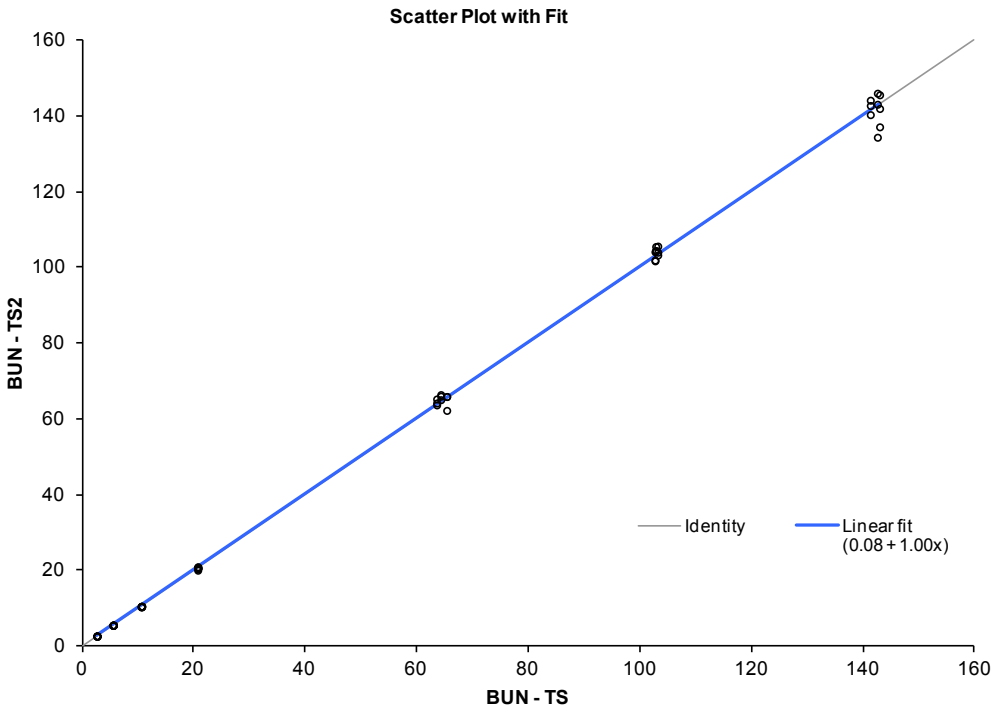
Linearity

Wherever possible, linearity for the OPTI CCA measurement has been established against reference materials or methods. BUN(urea) linearity in serum is by measurement of N.I.S.T. Standard Reference Material 909b in Frozen Human Serum (BUN_{NIST}). No changes were made to the BUN(urea) sensor or the measurement principle, so the traceability of the OPTI CCA-TS2 is equivalent to the OPTI CCA.

Correlation

	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
BUN_{NIST}	1.0046	1.58	0.991	1.75	16 to 86	6

Direct linearity for the OPTI CCA-TS2 measurement has been established against reference materials or methods. The linearity of the BUN (urea) sensor on the OPTI CCA-TS2 has been established versus the same sensor on the OPTI CCA-TS using whole blood samples tonometered with mid level mixtures and spiked or diluted to establish the correlation.



Parameter and Specification	Value
Number of Samples	63
Slope	1.00
Offset	0.08
R^2	0.998
Sy|x	1.703

Correlation to Other Methods[3]

OPTI CCA-TS vs other BUN (urea) Instruments on Plasma and Serum in a typical setting

Excess sample aliquots from specimens collected for metabolyte analyses were analyzed by both traditional and non-traditional operators of measurement equipment in hospital laboratories. The sample was analyzed on the OPTI CCA-TS after obtaining the requisite results from existing instrumentation used for these analyses and operated and controlled following their established procedures.

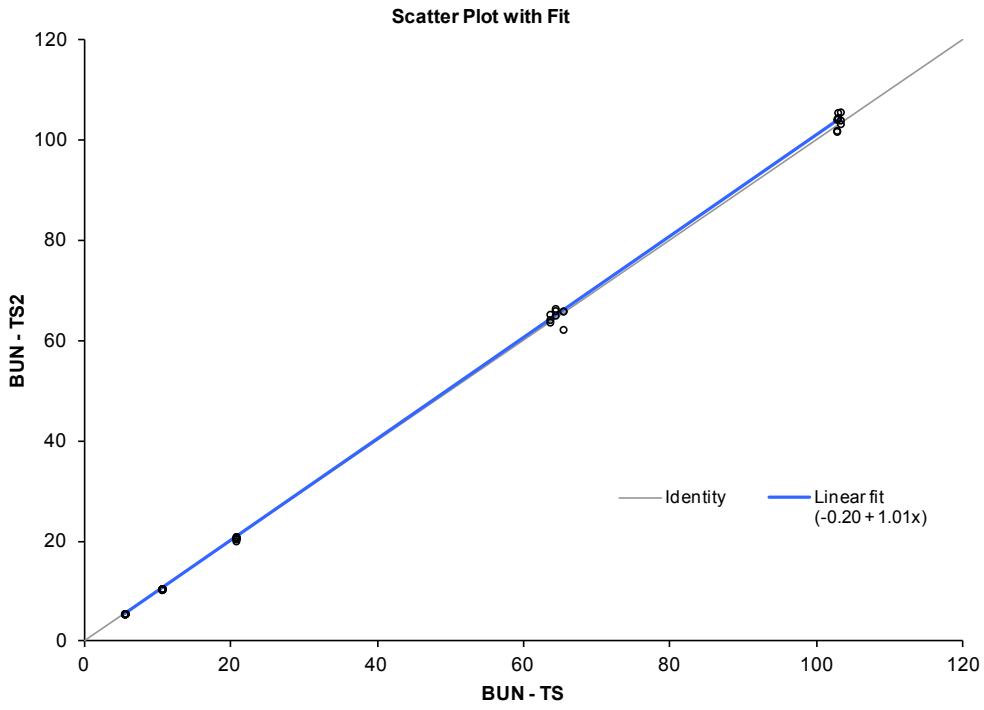
Correlation

Comparative Method*	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
Analyzer A (plasma) mg/dL	0.940	2.97	0.9975	1.046	8 to 89	68
Analyzer B (plasma) mg/dL	1.058	-3.04	0.9988	1.12	4 to 106	102
Analyzer C (serum) mg/dL	0.993	0.44	0.9953	1.00	6 to 65	47
Analyzer D (serum) mg/dL	0.971	-0.27	0.9822	0.98	5 to 42	50
Analyzer E (whole blood) mg/dL	1.069	-0.62	0.9928	1.04	3.1 to 48	113

* For more information on specific analyzers used, please contact OPTI Medical Technical Support.

OPTI CCA-TS2 vs OPTI CCA-TS on whole blood in a typical setting

In Method Comparisons carried out following the experimental protocol recommended in the CLSI guideline EP9-A2, Volume 15, Number 19 using whole blood samples on the OPTI CCA-TS2 versus the OPTI CCA-TS.



Parameter and Specification	Value
Number of Samples	45
Range	5.5 to 103.2
Slope	1.01
Offset	-0.20
R^2	0.999
Sy|x	0.883

References

1. Tietz, Norbert W., Ed., *Clinical Guide to Laboratory Tests*, 2nd Ed., (Philadelphia: W.B.Saunders, Co., 1990) p. 436.
2. Tietz, Burtis C.(Ed.), *Textbook of Clinical Chemistry and Molecular Diagnostics*, 4th Ed., (Elsevier Saunders, 2006), p. 802.
3. OPTI Medical. Model equation for regression statistics is: [results of OPTI Analyzer] = slope(m) [comparative method results] + intercept(b).

Lactate (B-Lac Cassette)

This section includes data based on the redesigned Lactate sensor that has been included in a new 510(k) submission.

Clinical Significance[1]

Lactic Acid is produced as an intermediate in carbohydrate metabolism. The blood lactate concentration is primarily related to the rate of lactate production in white skeletal muscle, the brain, renal medulla and erythrocytes and the rate of lactate metabolism of the liver and kidneys. High lactate levels, coupled with a pH of less than 7.25 may indicate Lactic Acidosis.

Lactic Acidosis has two clinically significant types: 1) hypoxic which is associated with lowered availability of oxygen to the body tissues and 2) metabolic which is associated with disease, drugs/toxins or inborn metabolic issues.

Hypoxia is the most common cause of the lactic acidosis and may indicate sepsis, shock, hypovolemia, hypo-perfusion and left ventricular failure. Types of hypoxia include:

- **Anemic Hypoxia**: Hypoxia due to lowered oxygen-carrying capacity of the blood; this may be either from a decrease in total hemoglobin or a change in components of the hemoglobin.
- **Stagnant Hypoxia**: A type seen when not enough oxygen is transported by the blood because blood flow is reduced, such as with heart failure.
- **Histotoxic Hypoxia**: Hypoxia that is due to impaired use of oxygen by tissues
- **Hypoxic Hypoxia**: Hypoxia that is due to insufficient oxygen reaching the blood.
- **Ischemic Hypoxia**: Hypoxia that occurs when blood flow to tissue is low.

Measurement Principle[1]

The OPTI Medical lactate biosensor contains the enzyme lactate oxidase to selectively catalyze the reaction between lactate and oxygen, as outlined in the reaction sequence.

$$\text{L-Lactate} + O_2 \rightarrow (\text{Lactate Oxidase}) \rightarrow \text{Pyruvate} + H_2O_2$$

The oxygen consumption is measured photochemically by an optical sensor. The rate of oxygen consumption is proportional to the concentration of lactate in the specimen.

Measurement Range

Range of Indication/ Measurement Range	Resolution (Low/High)	Units
0.4 to 17.5	0.01/0.01	mmol/L
3.6 to 157.7	0.1/0.1	mg/dL

Standard Reference Cassette (SRC) Limit Values

LOW	NORMAL	HIGH	Units
1.00 ± 0.30	2.50 ± 0.50	5.00 ± 0.50	mmol/L
9.0 ± 2.7	22.5 ± 4.5	45.0 ± 4.5	mg/dL

Interferences

The Lactate sensor response in whole blood is affected by the amount of hemoglobin present in the sample. The algorithm used to analyze the fluorescence data from the Lactate sensor applies a correction based on the measured total hemoglobin (tHb) value to compensate. Thus the reported lactate value for the B-Lac cassette has no significant interference from tHb in the range 5 g/dL to 20 g/dL. For samples with tHb values greater than 20 mg/dL the Lactate value is not reported.

The following exogenous interferents were quantified in tonometered whole blood samples spiked with a number of endogenous and exogenous chemicals and tested for interference following the CLSI guideline EP7-A2, showing interferences to dyes which typically have short half-lives within the body before being metabolized by the liver. This testing was done on the OPTI CCA-TS platform, with a standard OPTI style Lactate sensor. No changes were made to the sensor or the measurement principle, so the interference of the OPTI CCA-TS2 is equivalent to the OPTI CCA-TS.

Chemical	Test level Concentration	Lactate Level mM	Interference
Acetaminophen	1.66 mM	~ 2 mM	NO
		~ 5 mM	NO
Acetylsalicylic acid	3.33 mM	~ 2 mM	NO
		~ 5 mM	NO
Ascorbic acid	0.23 mM	~ 2 mM	NO
		~ 5 mM	NO
B-Hydroxybutyric acid, Na salt	16.03 mM	~ 2 mM	NO
		~ 5 mM	NO
Bilirubin	0.26 mM	~ 2 mM	NO
		~ 5 mM	NO
Cardiogreen	0.0065 mM	~ 2 mM	0.93 mM
		~ 5 mM	5.16 mM
Cysteine (hydrochloride hydrate)	6.41 mM	~ 2 mM	NO
		~ 5 mM	NO
Ethanol	86.8 mM	~ 2 mM	NO
		~ 5 mM	NO
Evans blue	0.0104 mM	~ 2 mM	0.35 mM
		~ 5 mM	NO
Glycolic acid	10 mM	~ 2 mM	3.10 mM
		~ 5 mM	3.13 mM

Chemical	Test level Concentration	Lactate Level mM	Interference
Halothane	0.759 mM	~ 2 mM	NO
		~ 5 mM	NO
Ibuprofen	2.43 mM	~ 2 mM	NO
		~ 5 mM	NO
Intralipid	1%	~ 2 mM	NO
		~ 5 mM	NO
Methylene Blue	0.125 mM	~ 2 mM	NO
		~ 5 mM	NO
Sodium Chloride	20 mM	~ 2 mM	NO
		~ 5 mM	NO
Flourescein	1.064 mM	~ 2 mM	NO
		~ 5 mM	NO
Glucose	22.22 mM	~ 2 mM	NO
		~ 5 mM	NO
Hydroxyurea	0.5 mM	~ 2 mM	NO
		~ 5 mM	NO
Pyruvic Acid	0.24 mM	~ 2 mM	NO
		~ 5 mM	NO

Reproducibility

Controls

Within-run precision (S_{wr}) and Total Precision (S_T), were determined from 2 runs per day with 2 replicates per run over a period of 20 days following the CLSI guideline EP5-A3. Typical results for 3 different control levels are shown below:

Lactate (mmol/L)	OPTI Check Level 1	OPTI Check Level 2	OPTI Check Level 3
Days Run	20	20	20
Total Average	0.95	2.331	4.637
Within Run St. Dev. (S_{wr})	0.052	0.079	0.144
Within Run % CV	5.47%	3.39%	3.11%
Total Precision St. Dev. (S_T)	0.059	0.088	0.163
Total % CV	6.21%	3.78%	3.52%

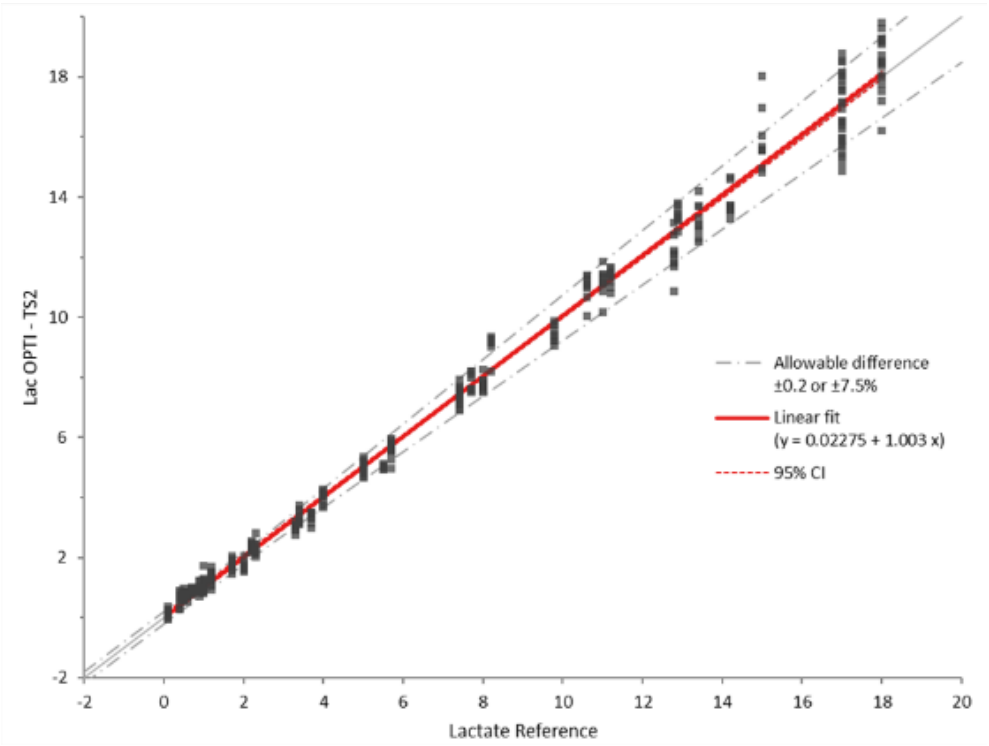
Whole Blood

Within-run precision in whole blood samples was evaluated at 3 different concentrations on the OPTI CCA-TS2. One repeat was run on 10 different analyzers in parallel due to the rapid change of lactate in whole blood. The table below shows the Averages, the Standard Deviations and the %CV calculated from 10 samples for each level.

Lactate (mmol/L)	Whole Blood		
	Level 1	Level 2	Level 3
Average	3.20	5.38	2.09
St. Dev	0.16	0.25	0.08
%CV	4.98%	4.67%	3.65%
n	10	10	10

Linearity

Direct linearity for the OPTI CCA-TS2 measurement has been established against reference materials or methods. The linearity of the Lactate sensor on the OPTI CCA-TS2 has been established versus a reference device using whole blood samples that had been spiked or diluted as needed to cover the measurement range.

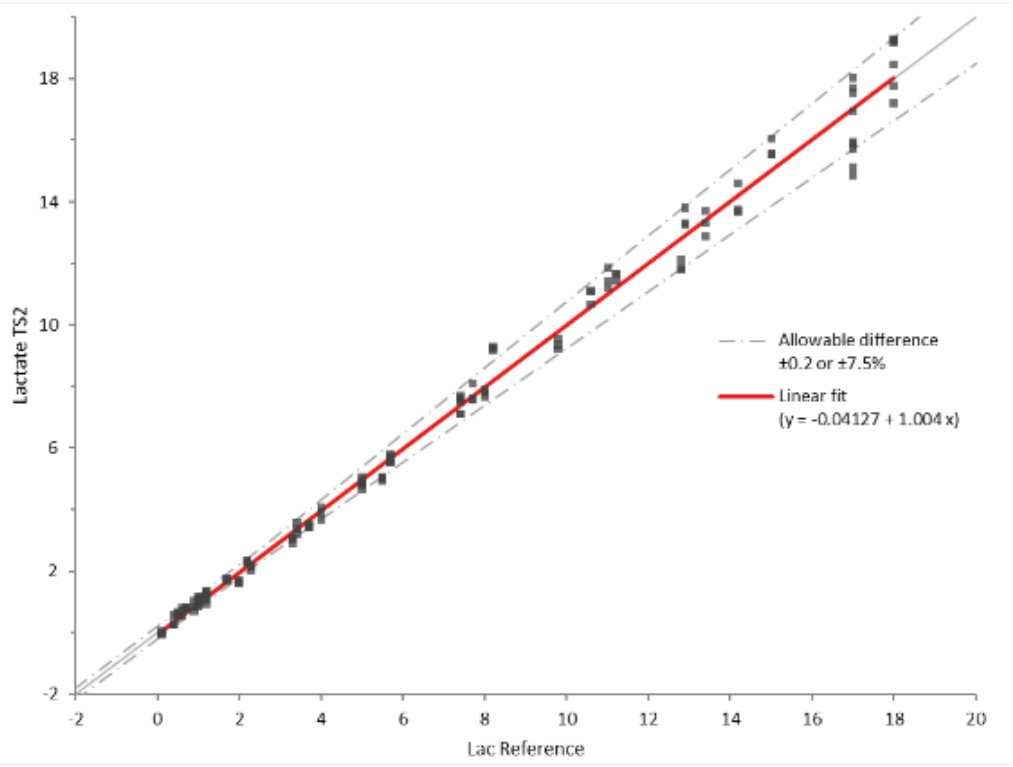


Parameter and Specification	Value
Number of Samples	378
Slope	1.003
Offset	0.02275
R^2	0.990
Sy|x	0.5586

Correlation to Other Methods[2]

OPTI CCA-TS2 vs Reference Analyzer on whole blood (in-house testing)

In Method Comparisons carried out following the experimental protocol recommended in the CLSI guideline EP9-A2, Volume 22, Number 19 using whole blood samples on the OPTI CCA-TS2 versus the Reference Analyzer.



Parameter and Specification	Value
Number of Samples	126
Slope	1.004
Offset	-0.04127
R^2	0.996
Sy|x	0.5286

References

1. Tietz. (2006). *Clinical Chemistry and Molecular Diagnostics* (4th Edition ed.). (C. A. Burtis, E. R. Ashwood, & D. E. Burns, Eds.) St. Louis, Missouri: Elsevier Saunders.
2. OPTI Medical. Model equation for regression statistics is: [results of OPTI Analyzer] = slope(m) [comparative method results] + intercept(b).

Total Hemoglobin Concentration (ctHb) and Hemoglobin Oxygen Saturation (SO_2%)

Clinical Significance[1]

total Hemoglobin concentration (ctHb)

The hemoglobin is the main component of erythrocytes. It serves as the vehicle for transportation of oxygen within the bloodstream and each gram of hemoglobin can carry 1.39 mL of oxygen. The oxygen combining capacity of the blood is directly proportional to the hemoglobin concentration rather than to the number of red blood cells (RBC), because some red cells contain more hemoglobin than others.

Although oxygen transport is the main function of hemoglobin, it also serves as an important buffer in the extracellular fluid. Decreases in the amount of hemoglobin can come about as a result of a decreased concentration of hemoglobin in the erythrocytes, or a decreased number of erythrocytes that contain a normal concentration of hemoglobin.

Decreased levels are found in anemia states, hyperthyroidism, severe hemorrhage and hemolytic reactions due to transfusions of incompatible blood, reaction to chemical, infectious and physical agents as well as various systemic diseases. Increased levels are found in hemoconcentration of the blood, chronic obstructive pulmonary disease and congestive heart failure.

*c*tHb gives valuable information in an emergency situation if interpreted not in an isolated fashion but in conjunction with other pertinent laboratory data.

*c*tHb is used to screen for disease associated with anemia, to determine the severity of anemia, to follow the response to treatment for anemia and to evaluate polycythemia.

Hemoglobin Oxygen Saturation (SO_2%)

When each heme group of the hemoglobin molecule is associated with one molecule of oxygen, the hemoglobin is referred to as oxyhemoglobin (O_2Hb). The amount of oxyhemoglobin, expressed as a fraction of the total functional hemoglobin (able to bind oxygen), is termed hemoglobin oxygen saturation (SO_2%). The largest portion (about 98%) of blood oxygen content is the oxygen bound to hemoglobin. The reference interval for arterial blood from healthy adults is typically 94 to 98%[2]. Decrease in SO_2 below the critical level necessary for tissue oxygen saturation is a grave clinical situation. Low oxygen saturation may be caused by many of the same factors responsible for arterial *hypoxemia*. Low fractional oxyhemoglobin (FO_2Hb), defined as a fraction of total available hemoglobin, may also be caused by unusually large amounts of non-functional hemoglobins, high concentrations of deoxyhemoglobin, chemically altered hemoglobin or factors affecting the affinity of hemoglobin for oxygen, including: temperature, pH, PCO_2, 2,3-DPG concentration and type of hemoglobin.[3]

Measurement Principle

The measurement of total Hemoglobin (ctHb) and oxygen saturation (SO_2) uses the well-established principle of optical reflectance. Red and infrared light at three wavelengths is directed at whole, non-hemolyzed blood within a precisely-defined part of the cassette over the O_2 optode. The photons are partially absorbed and reflected by erythrocytes in a manner proportional to hemoglobin level; at low hemoglobin levels the unabsorbed photons strike the O_2 optode's pink overcoat and are reflected back up through the blood a second time. A portion of the reflected light exits the top of the cassette and is measured by a detector in the instrument. The infrared wavelengths are selected for the hemoglobin measurement because they are largely independent of SO_2, that is, the predominate forms of adult and fetal hemoglobin absorb similarly within the 750-850 nm wavelength range. The red wavelength is utilized for the SO_2 measurement because it is much more strongly absorbed by deoxyhemoglobin than all other hemoglobins, and it is picked close to the isosbestic point for oxy- and carboxyhemoglobin. Sensitivity to erythrocyte aggregation (rouleaux formation) is minimized by maintaining high shear force just prior to measurement (see Interferences below).

Measurement Range

	Range of Indication/ Measurement Range	Resolution (Low/High)	Units
tHb	5 to 25	0.1	g/dL
SO_2	60 to 100	1/0.1	%

B-Lac Cassette Measurement Range - tHb

Range of Indication*	Measurement Range	Resolution (Low/High)	Units
5 to 25	5 to 24	0.1/0.01	g/dL

*The Range of Indication is the range the analyzer is capable of measuring and includes values outside the Measurement Range. The performance of the analyzer outside the Measurement Range specified in the table has not been validated. Only results within the Measurement Range should be reported.

Standard Reference Cassette (SRC) Limit Values

	LOW	NORMAL	HIGH	Units
tHb	20.0 ± 1.5	14.0 ± 1.5	8.0 ± 1.5	g/dL
SO_2	70.0 ± 2.0	90.0 ± 2.0	98.0 ± 2.0	%

Interferences

The following exogenous interferents were quantified in tonometered whole blood, showing interferences to dyes which typically have short half-lives within the body before being metabolized by the liver. This testing was done on the OPTI CCA platform, with a standard OPTI style cassette. No changes were made to the sensor or the measurement principle for the tHb and SO_2 measurement, so the interference of the OPTI CCA-TS2 is equivalent to the OPTI CCA.

EXOGENOUS

Substance	Test Level Concentration	Test Level - tHb	tHb change (g/dL)
B-Hydroxybutyric acid, Na salt	16.03 mM	<10 g/dL	-0.72 g/dL
Cardiogreen	0.0065 mM	<10g/dL	4.93g/dL
		12-18g/dL	4.59g/dL
Intralipid	1%	14.0g/dl	0.82g/dl
Methylene Blue	0.125 mM	<10g/dL	1.15g/dL
		12-18g/dL	0.99g/dL
Sodium Chloride	20 mM	<10g/dL	-0.75g/dL

Substance	Test Level Concentration	Test Level - SO_2	SO_2 change (g/dL)
Cardiogreen	0.0065 mM	70.9%	13.0%
Evans Blue	0.0104 mM	70.9%	22.1%
Methylene Blue	0.125 mM	70.9%	-14.4%

ENDOGENOUS

Substance	Amount	tHb change (g/dL)	SO_2 change (%)
Carboxyhemoglobin	10%	-2.0	<2%
Carboxyhemoglobin	20%	-3.3	<2%
Methemoglobin	13%	+1.7	-7%

Rapidly sedimenting blood samples should be mixed thoroughly and immediately aspirated into the OPTI cassette, as described in Section 5.1.7 “Handling and Storage of Samples”, to ensure accurate tHb measurements. If allowed to sediment, the blood sample’s reported tHb may be falsely high or low.

Fetal hemoglobin taken from cord blood extracts was tested and showed no interference to the tHb and SO_2 measurement.

Only clear, uncolored quality control materials, such as OPTI CHECK or OPTI CHECK PLUS brand aqueous controls should be used with the OPTI CCA-TS2 system. Colored materials, including proficiency testing materials, may interfere with the tHb and SO_2 measurement, or fail to be properly aspirated.

Reproducibility

Controls

Within-run precision (S_{wr}) and Total Precision (S_T), were determined from 2 runs per day with 2 replicates per run over a period of 20 days following the CLSI guideline EP5-A3. Typical results for 3 different control levels are shown below:

tHb (g/dL)	OPTI Check Level 1	OPTI Check Level 2	OPTI Check Level 3
Days Run	20	20	20
Total Average	20.311	14.049	8.705
Within Run St. Dev. (S_{wr})	0.066	0.317	0.105
Within Run % CV	0.32%	2.26%	1.21%
Total Precision St. Dev. (S_T)	0.082	0.326	0.114
Total % CV	0.40%	2.32%	1.31%

SO_2 (%)	OPTI Check Level 1	OPTI Check Level 2	OPTI Check Level 3
Days Run	20	20	20
Total Average	82.298	89.841	97.628
Within Run St. Dev. (S_{wr})	0.069	0.135	0.174
Within Run % CV	0.08%	0.15%	0.18%
Total Precision St. Dev. (S_T)	0.078	0.153	0.198
Total % CV	0.09%	0.17%	0.20%

Whole Blood

Within-run precision in whole blood samples was evaluated at 3 different concentrations on the OPTI CCA-TS2. The table below shows the Averages, Standard Deviations and % CV calculated from 10 samples for each level.

tHb (g/dL)	Whole Blood		
	Level 1	**Level 2**	**Level 3**
Average	8.9	15.5	18.9
St. Dev	0.2	0.1	0.1
%CV	2.15%	0.82%	0.44%
n	10	10	10

SO_2 (%)	Whole Blood		
	Level 1	**Level 2**	**Level 3**
Average	73.6	94.4	99.9
St. Dev	0.3	0.3	0.0
%CV	0.39%	0.28%	0.00%
n	10	10	10

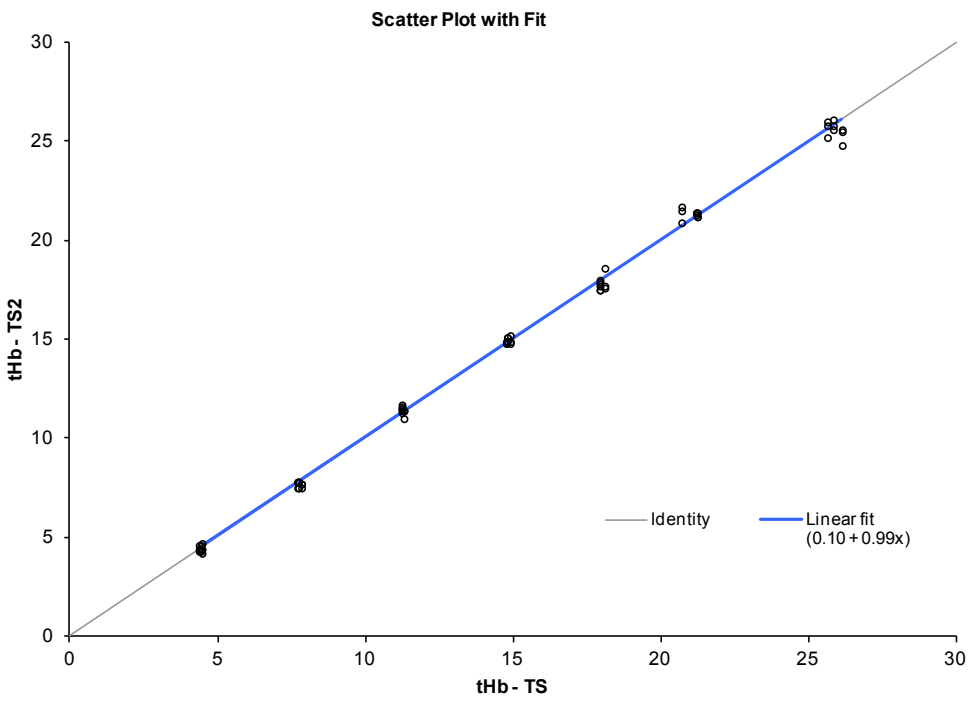
Linearity

Wherever possible, linearity for the OPTI CCA-TS measurement has been established against reference materials or methods. Total hemoglobin content linearity is established by the photometric determination of cyanmethemoglobin[5]. No standard method exists for the measurement of oxygen saturation. No changes were made to the tHb measurement principle, so the linearity of the OPTI CCA-TS2 is equivalent to the OPTI CCA-TS.

Correlation

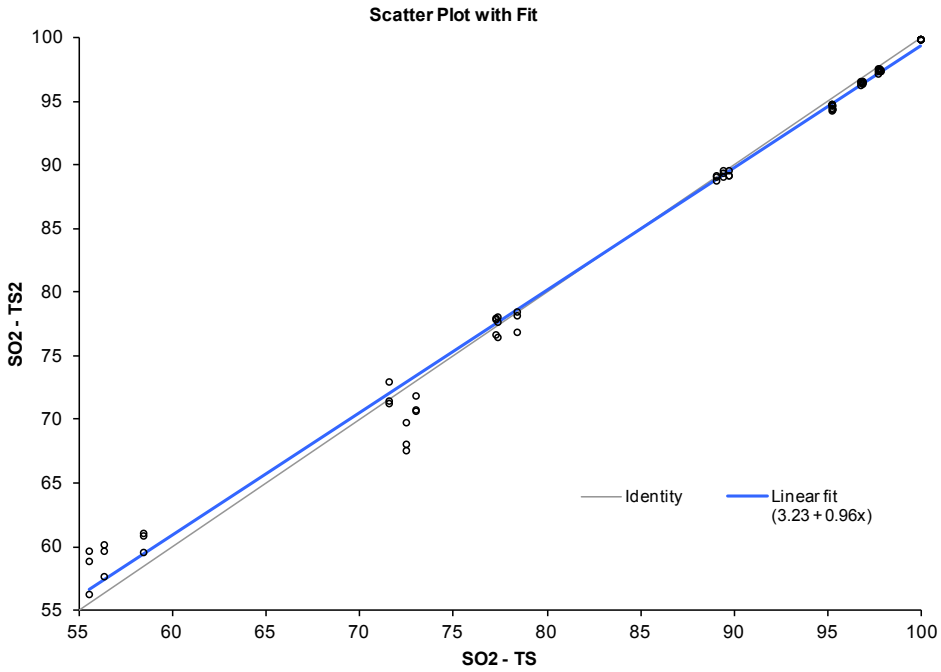
	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
tHb (g/dL)	0.984	0.165	0.995	0.59	5.2 to 22.0	84

Wherever possible, linearity for the OPTI CCA-TS2 measurement has been established against reference materials or methods. The linearity of the tHb measurement on the OPTI CCA-TS2 has been established versus the OPTI CCA-TS using whole blood samples that were prepared with different amounts of red blood cells and tonometered with a mid level $\%O_2/\%CO_2$ gas to establish the correlation.



Parameter and Specification	Value
Number of Samples	63
Slope	0.99
Offset	0.10
R^2	0.997
Sy|x	0.343

The linearity of the SO_2 % measurement on the OPTI CCA-TS2 has been established versus the same sensor on the OPTI CCA-TS using whole blood samples tonometered with different $\%O_2$ gas mixtures to establish the correlation.



Parameter and Specification	Value
Number of Samples	72
Slope	0.96
Offset	3.23
R^2	0.991
Sy|x	1.325

Correlation to Other Methods[4]

OPTI CCA-TS2 vs other pH/Blood Gas Instruments on whole blood in a typical setting

Excess blood aliquots from specimens collected for blood gas analyses were analyzed by both traditional and non-traditional operators of blood gas equipment in hospital laboratories. The blood was analyzed on the OPTI CCA-TS2 after obtaining the requisite results from existing instrumentation used for these analyses and operated and controlled following their established procedures.

Correlation tHb

Comparative Method*	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
Analyzer A (whole blood)	1.0284	-0.375	0.9778	0.47	6.0 to 16.1	103
Analyzer B (whole blood)	0.9877	0.14	0.9715	0.37	6.9 to 14.8	173
Analyzer C (whole blood)	1.077 ± 0.020	-0.284 ± 0.227	0.9650	0.74	5.4 to 17.4	215
Analyzer D (whole blood)	1.018	0.166	0.992	0.58	4.6 to 27.1	48

Correlation SO_2

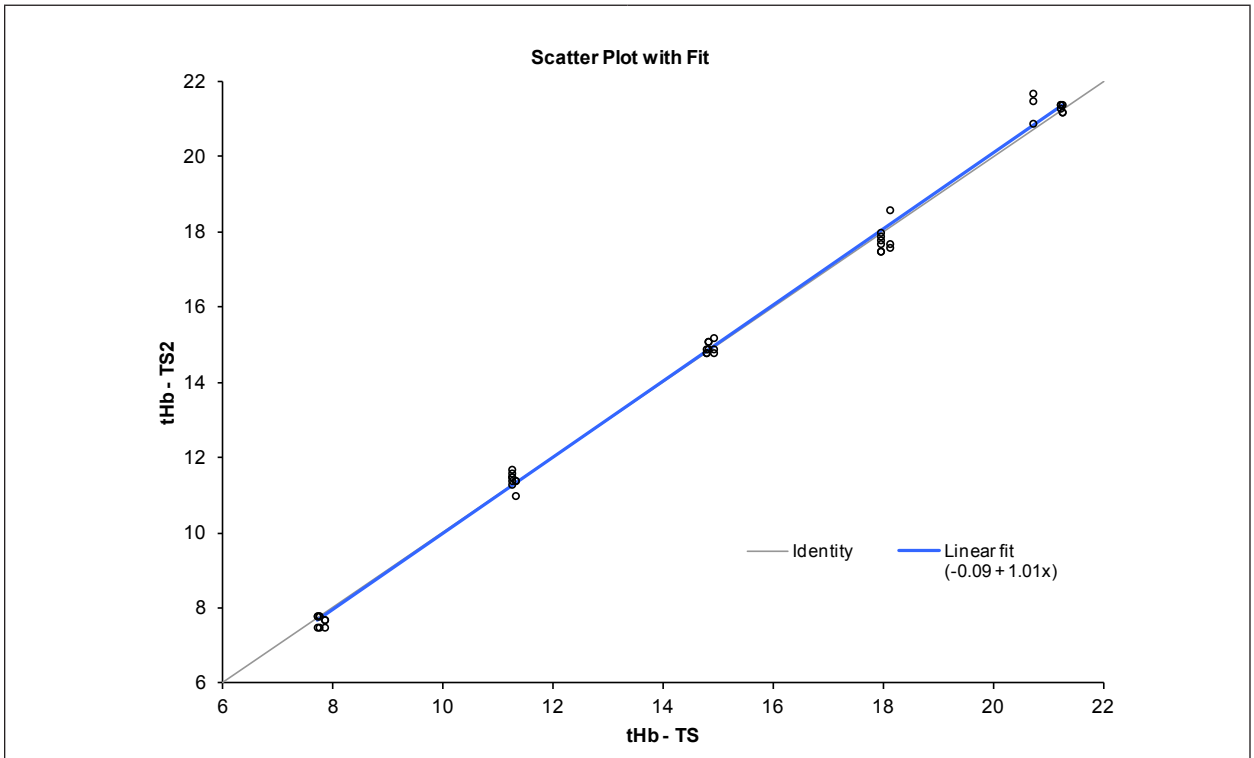
Comparative Method*	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
Analyzer A (whole blood)	0.8678	12.99	0.9738	0.73	73 to 100	103
Analyzer B (whole blood)	0.7972	18.81	0.9064	1.81	64 to 100	173
Analyzer C (whole blood)	1.021 ± 0.016	-2.920 ± 1.522	0.9752	1.47	62 to 100	215
Analyzer D (whole blood)	0.9040	8.929	0.988	1.33	66.3 to 99.9	54

* For more information on specific analyzers used, please contact OPTI Medical Technical Support.

OPTI CCA-TS2 vs OPTI CCA-TS on whole blood in a typical setting

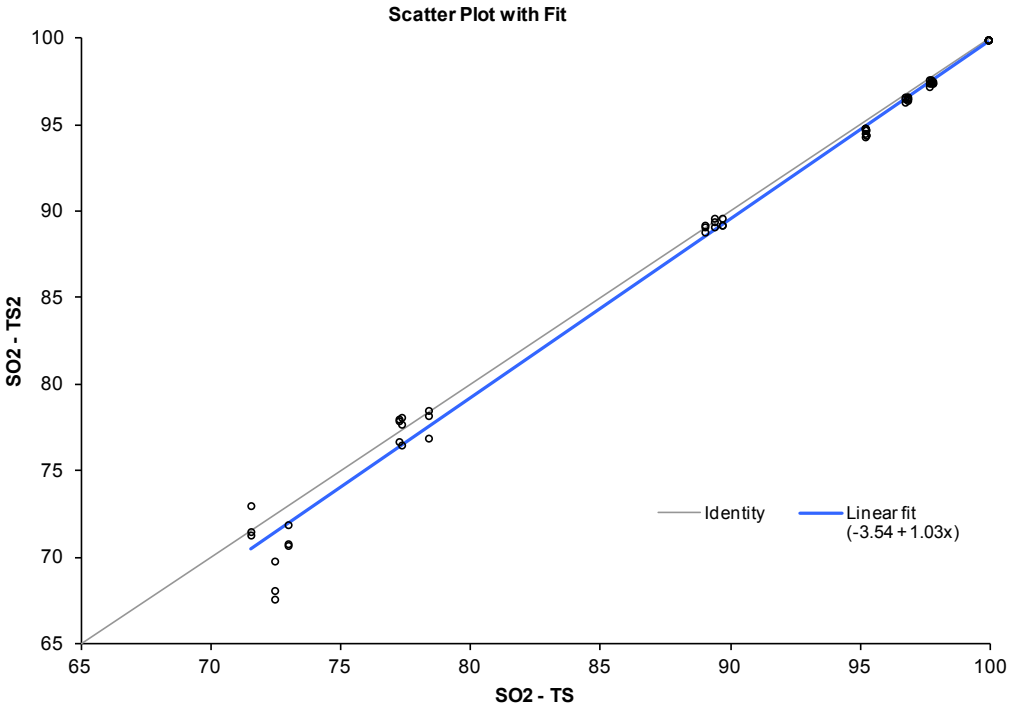
In Method Comparisons carried out following the experimental protocol recommended in the CLSI guideline EP9-A2, Volume 15, Number 19 using whole blood samples on the OPTI CCA-TS2 versus the OPTI CCA-TS.

tHb



Parameter and Specification	Value
Number of Samples	45
Range	7.7 to 21.2
Slope	1.01
Offset	-0.09
R^2	0.996
Sy|x	0.298

SO_2



Parameter and Specification	Value
Number of Samples	63
Range	71.5 to 99.9
Slope	1.03
Offset	-3.54
R^2	0.992
Sy|x	0.939

References

1. Tietz, Norbert W., Ed., *Clinical Guide to Laboratory Tests*, 2nd Ed., (Philadelphia: W.B.Saunders, Co., 1990) p. 436.
2. Tietz; Burtis C, et al (Eds.), *Textbook of Clinical Chemistry and Molecular Diagnostics*, 4th Ed., (Elsevier Saunders, 2006) pps. 2252-2302.
3. Tietz; Burtis C, et al (Eds.), *Textbook of Clinical Chemistry and Molecular Diagnostics*, 4th Ed., (Elsevier Saunders, 2006) p. 1004.
4. OPTI Medical. Model equation for regression statistics is: [results of OPTI Analyzer] = slope(m) [comparative method results] + intercept(b).
5. NCCLS. *Reference and Selected Procedures for the Quantitative Determination of Hemoglobin in Blood; – Approved Standard 3rd Edition*; NCCLS document H15-A3. NCCLS, Wayne, PA, 2000.

APPENDIX A - TECHNICAL SPECIFICATIONS

Measurement Range

Parameter	Measurement Range	Display Resolution (Lo/Hi)	Units
pH	6.6 - 7.8	0.01/0.001	pH units
PCO_2	10 - 200	1/0.1	mmHg
PO_2	10 - 700	1/0.1	mmHg
Na^+	100 - 180	1/0.1	mmol/L
K^+	0.8 - 9.99	0.1/0.01	mmol/L
Ca^{++}	0.2 - 3.0	0.01	mmol/L
Cl^-	50 - 160	1/0.1	mmol/L
Glu	30 - 400 (70 - 400 for samples with PCO_2 levels between 401 and 700 mmHg)	0.1	mg/dL
Glu	1.7 - 22.20	0.01	mmol/L
BUN	2.8 - 112.0	0.1	mg/dL
Urea	1 - 40	0.01	mmol/L
tHb	5 - 25	0.1	g/dL
SO_2	60 - 100	1/0.1	%

B-Lac Cassette Measurement Range

Parameter	Range of Indication*	Measurement Range	Display Resolution (Lo/Hi)	Units
pH	6.6 - 7.8	6.818 - 7.8	0.01/0.001	pH units
PCO_2	10 - 200	10 - 200	1/0.1	mmHg
PO_2	10 - 700	10 - 700	1/0.1	mmHg
Lactate	0.4 - 17.5	0.4 - 17.5	0.1/0.01	mmol/L
tHb	5 - 25	5 - 24	0.1	g/dL
SO_2	60 - 100	60 - 100	1/0.1	%

* The Range of Indication is the range the analyzer is capable of measuring and may include values outside the Measurement Range. The performance of the analyzer outside the Measurement Range specified in the table has not been validated. Only results within the Measurement Range should be reported.

Barometric Pressure

300 to 800 mmHg

Operating Altitude

Up to 3048m (10,000ft)

Pollution Degree

Degree 2, normal indoor laboratory environment. Air contains only non-conductive pollutants with occasional condensation.

Operating Parameters

Minimum Sample Size	125µL (60µL for B60 cassette)
Sample Type	heparinized whole blood, plasma or serum
Sample Application	syringe, capillary or ComfortSampler
Sample Input	automatic aspiration
Analysis Time	< 2 minutes, typically approx. 1 minute to result
Ambient Temperature Range	10 °C - 30 °C (50 °F - 86 °F)
Storage/Shipping Temperature Range	-20 °C - 50 °C (-4 °F - 122 °F)
Relative Humidity Range	5% - 95% (non-condensing)
Type of Measurement	optical fluorescence, for tHb/SO_2 optical absorbance/reflectance

Input Values

Patient ID	25 alphanumeric characters
Accession Number	25 numeric characters
Date of birth	Month, DD, YYYY
Patient Sex	Male, female or unknown
Patient Temperature	14.0 – 44.0° C (57.2 - 111.2°F)
Medical Record Number	25 numeric characters
Account Number	25 numeric characters
Test ID	25 alphanumeric characters
Patient Name	
First Name	25 alpha characters
Last Name	25 alpha characters
Age	1-150
Attending Physician	25 alpha characters

Patient Location	25 alpha characters
Sample Collection Time	Month, DD, YYYY, HH:MM
Sample Type	Art/Ven/MixVen/Cap/Cord/CPB, where: Art = Arterial Ven = Venous MixVen = Mixed Venous Cap = Capillary Cord = Cord CPB = Cardio-Pulmonary Bypass
Puncture Site	LR/RR/LB/RB/LF/RF/Cord/Scalp, where: LR/RR = Left Radial/Right Radial LB/RB = Left Brachial/Right Brachial LF/RF = Left Femoral/Right Femoral Cord = Cord Scalp = Scalp
Allen's Test	Unknown, positive, negative
Hemoglobin Type	adult or fetal
Bypass	Off Pump / On Pump
O_2 Mode	RmAir/Mask/T-P/NC/Vent/Bag/Hood/Other Where: RmAir = Room Air Mask = Mask T-P = T-Piece NC = Nasal Cannula Vent = Ventilator Bag = Bag (manual resuscitation) Hood = Hood Other = Other
Vent Mode	No/SIMV/PSV/PCV/CMV-AC/CPAP PCIVR/BIPAP, where: No = None SIMV = Synchronized Intermittent Mandatory Ventilation PSV = Pressure Support Ventilation PCV = Pressure Control Ventilation CMV-AC = Controlled Mechanical Ventilation / Assist Control CPAP = Continuous Positive Airway Pressure PCIVR = Pressure Control Inverse Ratio BIPAP = Bi-Level Positive Airway Pressure
Plateau Pressure, Pplat	0.0 – 100.0
Minute Volume, MVOL (VE)	0 – 120

Peak Inspiratory Pressure, PIP	0 – 140
Flow Rate, Liter Flow (FR)	0.00 – 300.00
Tidal Volume, TVol (VT)	0 – 4000
Pressure Support Value, PS	0.0 – 99.9
Positive End Expiratory Pressure, PEEP	0 – 50
Rate (f)	0 – 155
Continuous Positive Airway Pressure, CPAP	0 – 50
Total Hemoglobin, tHb	1.0 - 26.0 g/dL 0.62 – 16.14 mmol/L 1 – 260 g/L
FIO_2	0.21 – 1.00
Mean corpuscular hemoglobin concentration, MCHC%	29.0 – 37.0 %
Respiratory quotient, RQ	0.70 – 2.00
P50	15.0 – 40.0 mmHg
BiLevel Pressure Numerator	0.2 - 9.9
BiLevel Pressure Denominator	0.2 - 9.9
I/E Ratio Numerator	0.2 – 9.9
I/E Ratio Denominator	0.2 – 9.9
Comments Field	50 alphanumeric characters

Temperature Corrected Values

Parameter	Range	Display Resolution (Lo/Hi)	Units
pH^t	6.6 - 7.8	0.01/0.001	pH units
PCO_2^t	10 - 200	1/0.1	mmHg
PO_2^t	10 - 700	1/0.1	mmHg

Calculated Parameters

Parameter	Units	Measurement Range	Reference Range	Reference Source
Actual bicarbonate (HCO_3^-)	mmol/L	1.0 to 200.0	18 to 23	Tietz[1], p. 2179
Base excess (BE)	mmol/L	-40 to +40	-2 to +3	Tietz[1], p. 2179
Base excess ecf (BE_{ecf})	mmol/L	-40 to +40	-2 to +3	Tietz[1], p. 2179
Base excess actual (BE_{act})	mmol/L	-40 to +40	-2 to +3	Tietz[1], p. 2179
Buffer bases (BB)	mmol/L	0.0 to 100.0	46 to 52	Henry[2], p. 152
Total CO_2 (tCO_2)	mmol/L	1.0 to 200.0	22 to 29	Tietz[1], p. 2181
Standard bicarbonate (st. HCO_3^-)	mmol/L	1.0 to 200.0	22 to 24	Shapiro[3], p. 175
Standard pH (st.pH)	pH units	6.500 to 8.000	7.35 to 7.45	Tietz[1], p. 2201
Oxygen saturation (SO_2(c))	%	0.0 to 100	95.0 to 98.0	Henry[2], p. 1453
Oxygen content (O_2ct)	vol %	0.0 to 56.0	15.0 to 23.0	Tietz[1], p. 2200
Hematocrit (Hct(c))	%	15 to 75	34 to 51	Tietz[1], p. 2192
Hydrogen ion concentration (cH^+)	nmol/L	10.0 to 1000.0	36 to 44	Tietz[1], p. 2201
Alveolar-arterial oxygen partial pressure difference ($AaDO_2$)	mmHg	0.0 to 800.0	5 to 20	Henry[2], p. 157
Anion Gap (AG)	mmol/L	3 to 30	10 to 20	Tietz[1], p. 2178
P50	mmHg	15.0 to 35.0	25 to 29	Tietz[1], p. 1392
Normalized ionized calcium (nCa^{++})	mmol/L	0.1 to 3.0	Should be determined by individual facility	N/A
P/F Ratio	mmHg	10 to 800	Should be determined by individual facility	N/A

The calculated parameters in the OPTI CCA-TS2 are based on the CLSI Standard C12-A, when available.

[1] Tietz, Norbert.W., “Reference Intervals”, pp 2175-2217, Tietz Textbook of Clinical Chemistry, 2nd Edition, Philadelphia, W.B. Saunders Co., 1994.

[2] Henry JB, “Clinical Diagnosis and Management by Laboratory Methods”, 19th Edition, Philadelphia, W.B. Saunders Co., 1996

[3] Shapiro BA, Peruzzi WT, Kozelowski-Templin R. “Clinical Application of Blood Gases”, 5th Ed.,(Chicago: Mosby, 1994)

Data Management

Printout	Built-in thermoprinter
Communication	1 x USB Type A port, 1 x USB Type B port, 1 x Ethernet port
Format	ASCII, ASTM, POCT1 and CSV.
Storage	Data storage on the OPTI CCA-TS2 is dynamic. Storage capacity: up to 500 patient records up to 70 QC records per level up to 105 SRC records per level

Mains Supply for External Power Supply

100 ± 10% VAC to 240 ± 10% VAC, 50/60 Hz, 1.8A ± 10%

DC Supply for Instrument

16V ± 10%, 3.75A ± 10%

Overvoltage Category

Category II when connected to a branch circuit

Dimensions and Weight

Height	4.7 in.	12.0 cm
Width	14.2 in.	36.2 cm
Depth	9.1 in.	23.0 cm
Weight		
Instrument	8.65 lbs	3.9 kg
Battery	0.94 lbs	0.42 kg

Classifications

Approvals:	UL 61010-1, IEC 61010-2, IEC 61010-2-101, CAN/CSA C22.2 NO.61010-1, CE, FCC Class B
LED Classification:	IEC 62471 Exempt Risk Group
Mode of Operation:	Continuous Operation
Laser Classification:	This device is a Class 1 laser device according to IEC 60825-1
Explosion Protection:	This device is not designed for operation in explosive environments

Temperature[4]

$$T\left[°F\right] = \frac{9}{5} \cdot T\left[°C\right] + 32$$

$$T\left[°C\right] = \frac{5}{9} \cdot \left(T\left[°F\right] - 32\right)$$

Units Used in Measured and Input Parameters for Calculations

pH.....pH-unit
PCO_2.....mmHg
PO_2.....mmHg
Na.....mmol/L
K .....mmol/L
Ca..... mmol/L
Cl..... .mmol/L
Glu.....mg/dL
BUN ..... mg/dL
Lac .....mmol/L
tHb .....g/dL
SO_2.....%

[4] Burtis AB, Ashwood ER, "Tietz Textbook of Clinical Chemistry" 2nd Ed. (Philadelphia, W.B. Saunders 1994), p. 2165

Conversion Table for Units[5]

ctO_2, O_2ct, tCO_2	1 vol% = 1 ml/dl = 0.4464 mmol/l
tHb	1 g/dl = 10 g/l = 0.6206 mmol/l
barometric pressure, PCO_2, PO_2	1 mmHg = 1.3333 mbar = 0.1333 kPa
ionized Calcium (Ca^{++})	1 mmol/L = 4.008 mg/dL = 2mEq/L
glucose	1 mmol/L = 18.02 mg/dL
	1 mg/dL = 0.0555 mmol/L
BUN(urea)	1 mmol/L urea = 2.801 mg/dL BUN
Lactate	1 mmol/L = 9.01 mg/dL
	1 mg/dL = 0.111 mmol/L

Equations[6]

cH+

Concentration (activity) of hydrogen ions in plasma.

$$cH^+ = 10^{(9-pH)}$$ [nmol/L] [6]

st.pH

Standard pH of the blood is defined as the pH value of a blood sample which has been equilibrated at 37 ºC with a gas mixture having a PCO_2 = 40 mmHg.

$$st.pH = (0.8262 - 0.01296 \cdot tHb + 0.006942 \cdot BE) \cdot lg \cdot (0.025 \cdot PCO_2) + pH$$ [pH-unit] [6]

HCO_3^-

Bicarbonate concentration in plasma.

$$HCO_3^- = 0.0307 \cdot PCO_2 \cdot 10^{(pH-6.105)}$$ [mmol/L] [1]

[5] Burtis AB, Ashwood ER, "Tietz Textbook of Clinical Chemistry" 2nd Ed. (Philadelphia, W.B. Saunders 1994), p. 46.

[6] Marsoner HJ, "Quantities and Algorithms Related to Blood Gas and Acid Base Analysis", AVL Medizintechnik Graz, 1995.

st.HCO_3^-

Standard bicarbonate of the blood, defined as the plasma bicarbonate concentration in blood which has been equilibrated at 37 ºC with a gas mixture having a PCO_2 = 40 mmHg.

$$\mathrm{st.HCO_3^-} = 10^{(\mathrm{st.pH}-6.022)} \quad \text{[mmol/L]}$$ [6]

tCO_2

Total concentration of CO_2 in plasma, the sum of dissolved CO_2 and bicarbonate.

$$\mathrm{tCO_2} = \mathrm{HCO_3^-} + (0.0307 \cdot PCO_2) \quad \text{[mmol/L]}$$ [7]

BE

The base excess of the blood results from a calculation to determine the titratable base of the blood, which in principle is measured by titration of the blood with a strong acid or base to a pH of 7.4 with PCO_2 = 40 mmHg at 37 ºC.

$$\mathrm{BE} = (1 - 0.014 \cdot \mathrm{tHb}) \cdot \left[(1.43 \cdot \mathrm{tHb} + 7.7) \cdot (\mathrm{pH} - 7.4) - 24.8 + \mathrm{HCO_3^-}\right] \quad \text{[mmol/L]}$$ [7]

BE_{ecf}

The base excess of extracellular fluid is a quantity that reflects only the non-respiratory components of acid-base balance (tHb = 5 g/dL).

$$\mathrm{BE_{ecf}} = 16.2 \cdot (\mathrm{pH} - 7.4) - 24.8 + \mathrm{HCO_3^-} \quad \text{[mmol/L]}$$ [7]

$BE_{(act)}$

Base excess at actual oxygen saturation.

$$\mathrm{BE_{(act)}} = (1 - 0.0143 \cdot \mathrm{tHb}) \cdot \left[(1.63 \cdot \mathrm{tHb} + 9.5) \cdot (\mathrm{pH} - 7.4) - 24.26 + \mathrm{HCO_3^-}\right] - 0.2 \cdot \mathrm{tHb} \cdot \left(1 - \frac{SO_2}{100}\right) \quad \text{[mmol/L]}$$ [8]

---

[7] CLSI. *Blood Gas and pH Analysis and Related Measurements; Approved Guideline.* NCCLS document C46-A, 2001.

[8] Zander R., Die korrekte Bestimmung des Base Excess (BE mmol/l) im Blut. Anesthesiol. Intensivmed. Notfallmed. Schmerzther.

BB

The buffer base is the concentration of buffering anions which is available in whole blood to buffer strong acids and consists mainly of protein anions and bicarbonate. Of the protein anions, hemoglobin is the most significant.

$$BB = BE + 41.7 + 0.42 \cdot tHb$$ [mmol/L] [6]

$SO_2(c)$

The oxygen-hemoglobin dissociation curve theoretically allows that oxygen saturation of available hemoglobin can be calculated, provided the form of the curve is known. Factors which are known to affect this curve include: hemoglobin species, pH, PCO_2, temperature and 2,3 diphosphoglycerate (2,3 DPG) content. Although it is possible to calculate this value, the assumptions which are made in the calculation can cause significant errors in the resulting value for those patients who are in the most critical clinical state. The OPTI CCA-TS2 has the capability to provide a measured SO_2 from the blood sample. It is recommended that this measured value, if available, should be used in preference to the calculated SO_2.

If not available from measurement, and if calculation is selected:

$$SO_2\% = \frac{Q}{Q+1} \cdot 100\%$$

Adult :

$$lgQ = 2.9 \cdot lgPO_2^{\,k} + 1.661 \cdot 10^{-0.074 \cdot PO_2^{\,k}} - 4.172$$

$$lgPO_2^{k} = lgPO_2 + 0.48 \cdot (pH - 7.4) - lg(\frac{26.7}{26.7}) + 0.0013 \cdot BE$$

$$P_{50} = 26.7$$

Fetal :

$$lgQ = 2.9 \cdot lg\,PO_2^{\,k} + 1.3632 \cdot 10^{-0.0533 \cdot PO_2^{\,k}} - 4.113$$ (7)

$$lgPO_2^{\,k} = lgPO_2 + 0.48 \cdot (pH - 7.4) - lg(\frac{21.5}{26.7}) + 0.0013 \cdot BE$$ (6)

$$P_{50} = 21.5$$

ctO_2

Oxygen content is the sum of oxygen bound to hemoglobin as O_2Hb and the amount of oxygen dissolved in the plasma. This value is calculated from the measured O_2Hb and tHb if available and is estimated from the calculated SO_2 if the measured O_2Hb is not available and if the calculation of oxygen saturation is selected.

If measured O_2Hb and tHb are available:

$$ctO_2 = 1.39 \cdot \frac{O_2Hb}{100} \cdot tHb + 0.00314 \cdot PO_2$$ [vol%] [7]

NOTE: *If PO_2 is not available, ctO_2 is calculated with PO_2 = 90 mmHg.*

If measured O_2Hb and tHb are not available and calculated SO_2 is enabled:

$$tO_2 = 1.39 \cdot \frac{SO_2}{100} \cdot \mathrm{tHb} + 0.00314 \cdot PO_2$$

[vol%] [7]

***NOTE**: If PO_2 is not available, ctO_2 is calculated with PO_2 = 90 mmHg.*

P50

The oxygen partial pressure at half saturation, $P50$, is defined as the PO_2 value for a given blood sample at which 50% of the hemoglobin is saturated with oxygen. While the actual $P50$ value can only be determined by interpolation after measurement of oxygen saturation of a blood specimen tonometered to levels of oxygen to provide an oxyhemoglobin slightly greater than and slightly less than 50% with pH and PO_2 held constant at 7.4 and 40 mmHg respectively, the OPTI CCA-TS2 allows for the estimation of $P50$ from measured SO_2% , PO_2 and pH. If a measured SO_2% is not available, the $P50$ value may be input via keypad.

For Adult hemoglobin:

$$P_{50} = 26.7 \cdot 10^{\left(\lg PO_2 - \lg PO_2{}^{k}\right)}$$

where:

$$\lg PO_2{}^{k} = \frac{(\lg Q + 4.172)}{2.9}$$

$$Q = \frac{SO_2}{100\% - SO_2}$$

[mmHg] [6]

For Fetal hemoglobin:

$$P_{50} = 25.0 \cdot 10^{\left(\lg PO_2 - \lg PO_2{}^{k}\right)}$$

where:

$$\lg PO_2{}^{k} = \frac{(\lg Q + 4.113)}{2.9}$$

$$Q = \frac{SO_2}{100\% - SO_2}$$

[mmHg] [6]

$AaDO_2$

The alveolar to arterial oxygen tension gradient (PAO_2 - PaO_2) is the difference between the alveolar oxygen tension, estimated above, and the measured oxygen tension of arterial blood.

$PAO_2 = (P_{total} - 47)\ FIO_2 - PACO_2\ [FIO_2 + (1 - FIO_2)/R]$ [mmHg][7]

$PACO_2 = PaCO_2$ (alveolar PCO_2)

Apply above equation for $PAO_2 \geq PO_2$*, otherwise* $PAO_2 = PO_2$

pH^t

pH corrected to patient temperature other than 37 ºC.

$$pH^t = pH - [0.0147 + 0.0065 \cdot (pH - 7.4)] \cdot (t - 37)$$ [pH-unit] [7]

cH^{+t}

Concentration of hydrogen ions corrected to patient temperature other than 37 ºC.

$$cH^t = 10^{(9 - pH^t)}$$ [nmol/L] [6]

PCO_2^t

PCO_2 value corrected to patient temperature other than 37 ºC.

$$PCO_2^t = PCO_2 \cdot 10^{0.019 \cdot (t - 37)}$$ [mmHg] [7]

PO_2^t

PO_2 value corrected to patient temperature other than 37 ºC.

$$PO_2^t = PO_2 \cdot 10^{\left[\frac{5.49 \cdot 10^{-11} \cdot PO_2^{3.88} + 0.071}{9.72 \cdot 10^{-9} \cdot PO_2^{3.88} + 2.30}\right] \cdot (t - 37)}$$ [mmHg] [6]

$AaDO_2^t$

Alveolar to arterial oxygen tension difference corrected to patient temperature other than 37 ºC.

$$AaDO_2^t = PAO_2^t - PaO_2^t$$ [mmHg] [7]

where:

$PAO_2^t = (P_{total} - PH_2O^t)\ FIO_2 - PACO_2^t\ [FIO_2 + (1 - FIO_2)/R]$

with $PH_2O^t = 47 * 10^{[0.0237 - 0.0001\ (t-37)]\ (t-37)}$

and $PACO_2 = PaCO_2$ (alveolar PCO_2 = arterial PCO_2)

Apply above equation for $PAO_2^t \geq PO_2^t$*, otherwise* $PAO_2^t = PO_2^t$

Hct(c)

Hct(c) as a function of tHb.

$$\text{Hct(c)} = \text{tHb}\left[\text{g} / \text{dl}\right] / (\text{MCHC\%} / 100) \quad [\%]$$ [9]

Where MCHC% is the Mean Cell Hemoglobin Concentration, representing the average concentration by weight of hemoglobin inside the average red cell.

Default value of MCHC% = 33.3% (input range: 29.0% to 37.0%)

AG

The anion gap is a calculated parameter used to express the difference in concentrations of major cations and anions in the blood specimen.

$$AG = Na^{+} + K^{+} - Cl^{-} - HCO_3^{-} \quad [\text{mmol/L}]$$

nCa^{++}

The ionized calcium value normalized to pH = 7.40.

For blood:

$$nCa^{++}\ (pH = 7.4) = Ca^{++} * 10^{\,0.22*(pH-7.4)} \quad [\text{mmol/L}]$$

For plasma or serum:

$$nCa^{++}\ (pH = 7.4) = Ca^{++} * 10^{\,0.24*(pH-7.4)} \quad [\text{mmol/L}]$$

P/F Ratio

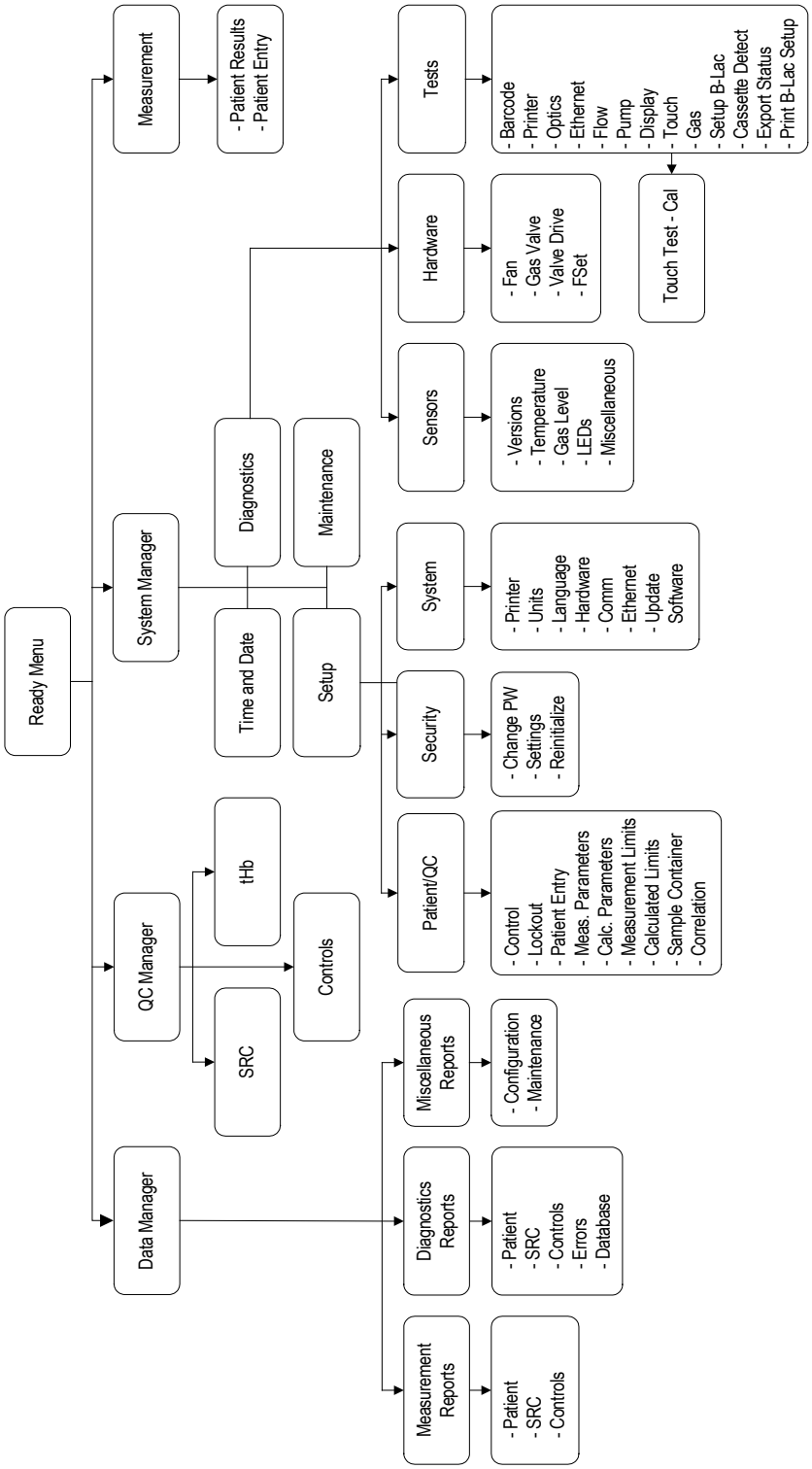
$$\text{P/F Ratio} = PaO_2 / FiO_2 \quad [\text{mmHg}]$$

where

PaO_2 = partial pressure of arterial O_2
FiO_2 = fraction of inspired O_2

[9] Simmons A, ed. Hematology, “A Combined Theoretical & Technical Approach”, pp. 28-29 (Philadelphia, W.B. Saunders, 1989)

APPENDIX B - MENU STRUCTURE



APPENDIX C - MAINTENANCE LOG

Month: _____ Year: _____

WEEKLY:	Week: 1		Week: 2		Week: 3		Week: 4	
	Date	Initial	Date	Initial	Date	Initial	Date	Initial
Clean Sample Measurement Chamber								

QUARTERLY:								
	Date	Initial	Date	Initial	Date	Initial	Date	Initial
Perform tHb Calibration								

ANNUALLY:								
	Date	Initial	Date	Initial	Date	Initial	Date	Initial
Replace peristaltic pump cartridge								

AS NEEDED:								
	Date	Initial	Date	Initial	Date	Initial	Date	Initial
Clean analyzer surfaces								
Change gas bottle								
Change printer paper								

APPENDIX D - REPORT FORMATS

Basic Patient Report

(ABG example)

OPTIMedical

OPTI CCA-TS2
Patient Report
DD-MMM-YY HH:MM

PATIENT INFORMATION
Patient ID
FG34567
Accession Number
5678912
Medical Record Number
00541698
Test ID
BLOOD-GAS
DOB: 25-Jan-1985
Sex: Male
Temperature: 37.0 C
Patient First Name
JOHN
Patient Last Name
SMITH
Attending Physician:
DR. JOHNSON
Patient Location:
ER
Sample Collection Time:
12-Feb-13 11:26
Age: 28
Sample Type: Art
PuncSite: LR
Allen's Test: Negative
tHb Type: Adult
Bypass: off-pump
O2 Mode: RmAir
Vent Mode: No

Sample No.: 291

ACID/BASE

pH	↓	7.143	
PCO2	↑	76.0	mmHg
PO2		74.5	mmHg
BE	↓	- 6.0	mmol/L
tCO2		27.3	mmol/L
HCO3	↑	24.9	mmol/L

HEMOGLOBIN/OXYGEN STATUS

tHb	-------	g/dL
SO2	-------	%
Hct[c]	-------	%

ENTERED PARAMETERS

Pplat:	62.0	
Mvol (VE):	50	L
PIP:	6	
Liter Flow:	165.00	Lpm
Tvol (VT):	50	mL
PS:	49.0	
PEEP:	19	
Rate(f):	60	bpm
CPAP:	61	
tHb:	15.0	g/dL
FIO2	0.21	
MCHC:	33.3	%
RQ	0.84	
P50	26.7	mmHg
BiLevel	1.0 / 1.0	
I/E	1.0 / 1.0	

Barometer: 739.6 mmHg
Operator ID: 123456789012

Lot: 250100
S/N: 0
Version: 1.000037

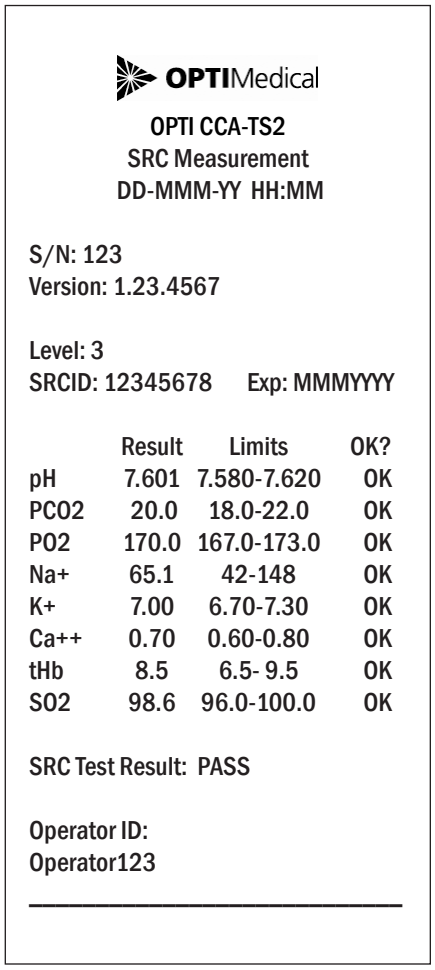
REFERENCE RANGES

pH	7.200 - 7.600	
PCO2	30.0 - 50.0	mmHg
PO2	70.0 - 700.0	mmHg
tHb	12.0 - 17.0	g/dL
SO2	90.0 - 100.0	%

MESSAGES
pH under 7.200 (Ref.Lim)
PCO2 over 50.0 (Ref.Lim)
tHb Result suppressed.
SO2 Result suppressed.

SRC Measurement Report

(E-Ca example)



OPTIMedical

OPTI CCA-TS2
SRC Measurement
DD-MMM-YY HH:MM

S/N: 123
Version: 1.23.4567

Level: 3
SRCID: 12345678 Exp: MMMYYYY

	Result	Limits	OK?
pH	7.601	7.580-7.620	OK
PCO2	20.0	18.0-22.0	OK
PO2	170.0	167.0-173.0	OK
Na+	65.1	42-148	OK
K+	7.00	6.70-7.30	OK
Ca++	0.70	0.60-0.80	OK
tHb	8.5	6.5- 9.5	OK
SO2	98.6	96.0-100.0	OK

SRC Test Result: PASS

Operator ID:
Operator123

SRC Statistics Report

OPTIMedical

OPTI CCA-TS2
SRC Statistics Report
DD-MMM-YY HH:MM

S/N: 123
Version: 1.00.0037

Level 1
SRCID: 12345678 Exp: MMMYYYY

Number run: 6
Number ok : 6

ABG LIMITS:

pH	7.080 - 7.120	
PCO2	68.0 - 72.0	mmHg
PO2	57.0 - 63.0	mmHg

Date	pH	PCO2	PO2	OK?
Feb4	7.120	67.8	59.3	OK
Feb4	7.120	72.2	59.7	OK
Feb4	7.110	69.8	58.7	OK
Feb4	7.100	69.2	58.6	OK
Feb7	7.070	67.8	58.8	OK
Feb7	7.080	67.3	57.3	OK
Mean:	7.107	70.0	56.6	
SD:	0.015	1.9	1.7	
CV%:	0.210	2.8	3.0	

ELECTROLYTE LIMITS

Na+	123.0 - 127.0	mmol/L
K+	2.20 - 2.80	mmol/L
Cl-	78.0 - 82.0	mmHg

Date	Na+	K+	Cl-	OK?
Feb4	125.0	2.50		OK
Feb4	125.0	2.50		OK
Feb4	125.0	2.50		OK
Feb4	125.0	2.50		OK
Feb7	125.0	2.50		OK
Feb7	125.0	2.50	79.8	OK
Mean:	125.0	2.50	0.0	
SD:	000.0	0.00	0.0	
CV%:	000.0	0.00	0.0	

HEMOGLOBIN LIMITS

tHb	18.5 - 21.5	g/dL
SO2	68.0 - 72.8	%

Date	tHb	SO2	OK?
Feb4	20.0	70.0	OK
Feb4	19.9	69.9	OK
Feb4	19.9	69.9	OK
Feb4	20.0	70.0	OK
Feb7	20.0	70.0	OK
Feb7	19.9	70.0	OK
Mean:	19.9	69.9	
SD:	0.1	0.1	
CV%:	0.3	0.3	

ADDITIONAL LIMITS

Ca++	1.70 - 1.90	mmol/L

Date	Ca++	OK?
Feb4	1.80	OK
Feb4	1.80	OK
Feb4	1.80	OK
Feb4	1.80	OK
Feb7	1.80	OK
Feb7	1.80	OK
Mean:	1.80	
SD:	0.00	
CV%:	0.00	

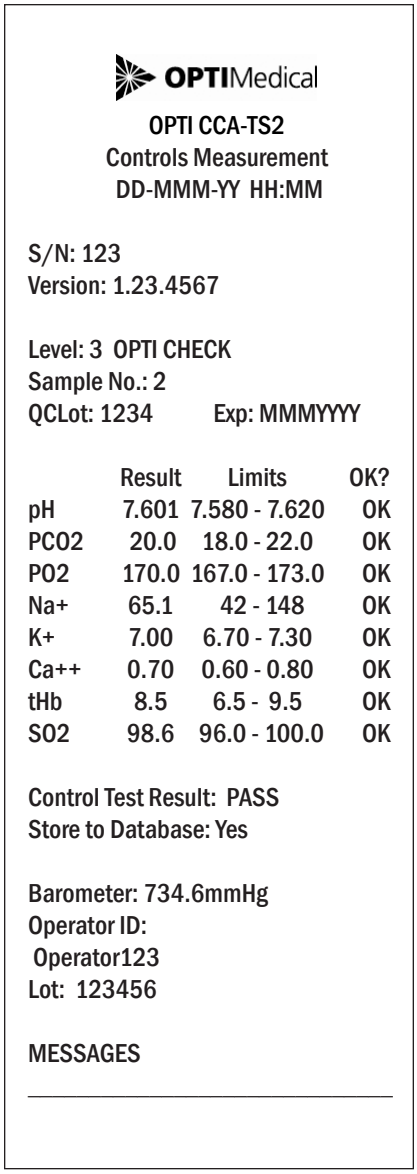
METABOLITES:

Glu	36.0 - 44.0	mg/dL
BUN	4.2 - 7.0	mg/dL
Lactate	0.70 - 1.30	mmol/L

Date	Glu	BUN	Lactate	OK?
Feb4			1.00	OK
Feb4			1.00	OK
Feb4		5.6	1.00	OK
Feb4	40.0	5.6	1.00	OK
Feb7	40.0	5.6	1.00	OK
Feb7	40.0	5.6	1.00	OK
Mean:	40.0	5.6	1.00	
SD:	0.2	0.0	0.00	
CV%:	0.4	0.9	0.00	

Controls Measurement Report

(E-Ca example)



OPTIMedical

OPTI CCA-TS2
Controls Measurement
DD-MMM-YY HH:MM

S/N: 123
Version: 1.23.4567

Level: 3 OPTI CHECK
Sample No.: 2
QCLot: 1234 Exp: MMMYYYY

	Result	Limits	OK?
pH	7.601	7.580 - 7.620	OK
PCO2	20.0	18.0 - 22.0	OK
PO2	170.0	167.0 - 173.0	OK
Na+	65.1	42 - 148	OK
K+	7.00	6.70 - 7.30	OK
Ca++	0.70	0.60 - 0.80	OK
tHb	8.5	6.5 - 9.5	OK
SO2	98.6	96.0 - 100.0	OK

Control Test Result: PASS
Store to Database: Yes

Barometer: 734.6mmHg
Operator ID:
Operator123
Lot: 123456

MESSAGES

Controls Statistics Report

OPTIMedical

OPTI CCA-TS2
Control Statistics Report
DD-MMM-YY HH:MM

S/N: 123
Version: 1.00.0037

Level 1
QCLot: 1278 Exp: MMMYYYY
CassLot: 250100
251402
Number run: 6
Number ok : 2

ABG LIMITS:

pH	7.370 - 7.490	
PCO2	35.0 - 45.0	mmHg
PO2	88.0 - 118.0	mmHg

Date	pH	PCO2	PO2	OK?
Feb4	High	↓12.3	↑153.1	N
Feb4	High	↓10.8	↑154.7	N
Feb4	High	↓16.1	↑148.4	N
Feb4	High	↓14.7	↑151.3	N
Feb7	7.450	43.9	96.3	OK
Feb7	7.431	44.3	102.6	OK
Mean:	7.441	23.7	134.1	
SD:	0.013	15.9	27.0	
CV%:	0.181	67.2	20.2	

ELECTROLYTE LIMITS

Na+	136.0 - 150.0	mmol/L
K+	4.50 - 5.30	mmol/L

Date	Na+	K+	OK?
Feb4			OK
Feb4			OK
Feb4	----	5.03	N
Feb4			OK
Feb7			OK
Feb7	142.9	4.88	OK
Mean:	----	4.96	
SD:	----	0.11	
CV%:	----	2.14	

HEMOGLOBIN LIMITS

tHb	12.2 - 15.2	g/dL
SO2	87.0 - 93.8	%

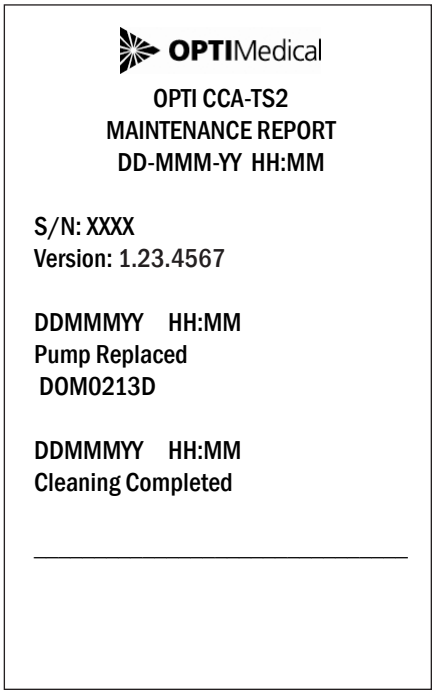
Date	tHb	SO2	OK?
Feb4	14.2	88.6	OK
Feb4	14.3	88.8	OK
Feb4	14.0	88.5	OK
Feb4	14.2	88.6	OK
Feb7	14.2	88.6	OK
Feb7	14.2	88.9	OK
Mean:	14.2	88.7	
SD:	0.1	0.2	
CV%:	0.7	0.2	

ADDITIONAL LIMITS

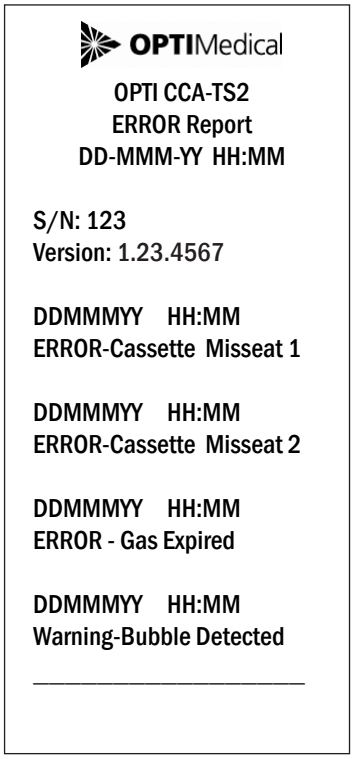
Ca++	1.10 - 1.30	mmol/L

Date	Ca++	OK?
Feb4		OK
Feb4		OK
Feb4	1.15	OK
Feb4		OK
Feb7		OK
Feb7	1.24	OK
Mean:	1.19	
SD:	0.06	
CV%:	5.33	

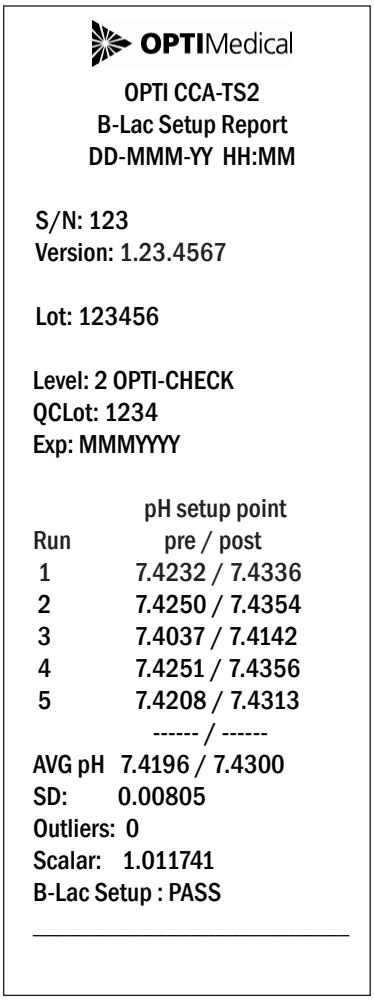
Maintenance Report



Error Report



B-Lac Setup Report



OPTIMedical

OPTI CCA-TS2
B-Lac Setup Report
DD-MMM-YY HH:MM

S/N: 123
Version: 1.23.4567

Lot: 123456

Level: 2 OPTI-CHECK
QCLot: 1234
Exp: MMMYYYY

Run	pH setup point pre / post
1	7.4232 / 7.4336
2	7.4250 / 7.4354
3	7.4037 / 7.4142
4	7.4251 / 7.4356
5	7.4208 / 7.4313
	------ / ------
AVG pH	7.4196 / 7.4300
SD:	0.00805
Outliers:	0
Scalar:	1.011741

B-Lac Setup : PASS

INDEX

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