

OPTI™ CCA-TS Analyzer

Operator's Manual



OPERATOR'S MANUAL REVISION LOG
(Please record any changes made to this manual)

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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 A 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.
- 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 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.

Operating Safety Information

Symbol Definitions

The symbols described below are used on the packaging of OPTI™ CCA-TS 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.



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.



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 not 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.



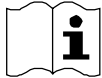
For in-vitro diagnostic use



This product fulfils 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



Authorized European Community Representative

PREFACE

Welcome

Your OPTI™ CCA-TS Analyzer is a powerful tool designed to help you quickly, accurately and efficiently conduct basic testing of hydrogen ion concentration (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 maintenance is contained in Chapters 5 and 6. Detailed service information and operating principles can be found in Chapters 7 and 8.

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PO ₂	PO2-1
PO ₂ (Dry Sensor - B-Lac Cassette)	PO2-B-1
Sodium (Na ⁺)	Na-1
Potassium (K ⁺).....	K-1
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1 INTRODUCTION

1.1 Intended Use

The OPTI™ CCA-TS Critical Care Analyzer is intended to be used for the measurement of hydrogen ion concentration (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.

Parameter	Sample Type			Available Units		Measurement Range (Default Units)	Display Resolution (Lo/Hi)
	Whole blood	Plasma	Serum	Default	Other		
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	mg/dL	100 - 180	1/0.1
K^+	x	x	x	mmol/L	mg/dL	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	mg/dL	50 - 160	1/0.1
Glu	x	x	x	mg/dL	mmol/L	30-400 / 1.7-22	1/0.1
BUN/urea	x	x	x	mg/dL	mmol/L	2.8-112.0 / 1-40	0.1/0.01
Lac	x			mmol/L	mg/dL	0.3 - 17.5	0.01/0.01
tHb	x			g/dL	mmol/L, g/L	5 - 25	0.1
SO_2	x			%		60 - 100	1/0.1

1.2 Principles of Operation

The OPTI CCA-TS 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-TS Analyzer, take a moment to look over the contents to ensure you have the following:

- Power supply with power cord
- Battery
- 2 Standard Reference Cassettes (SRC) (Level 1 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-TS Analyzer, it is important to familiarize yourself with the analyzer's components:

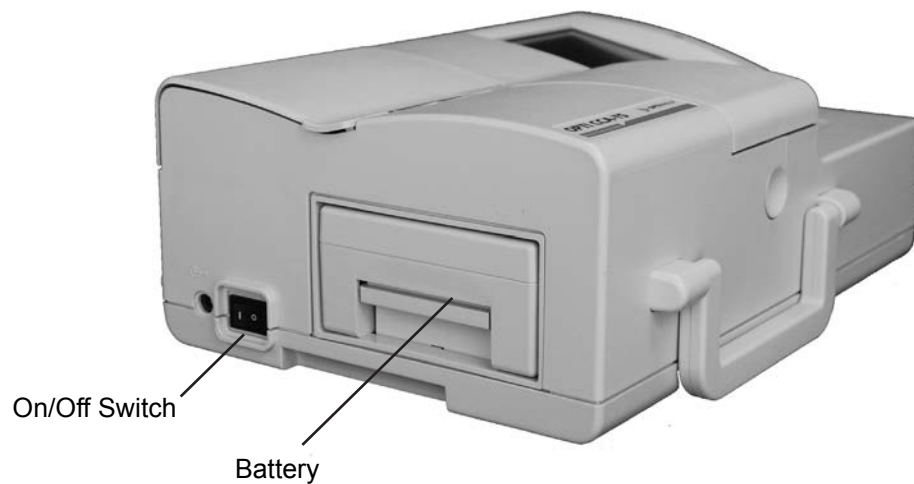
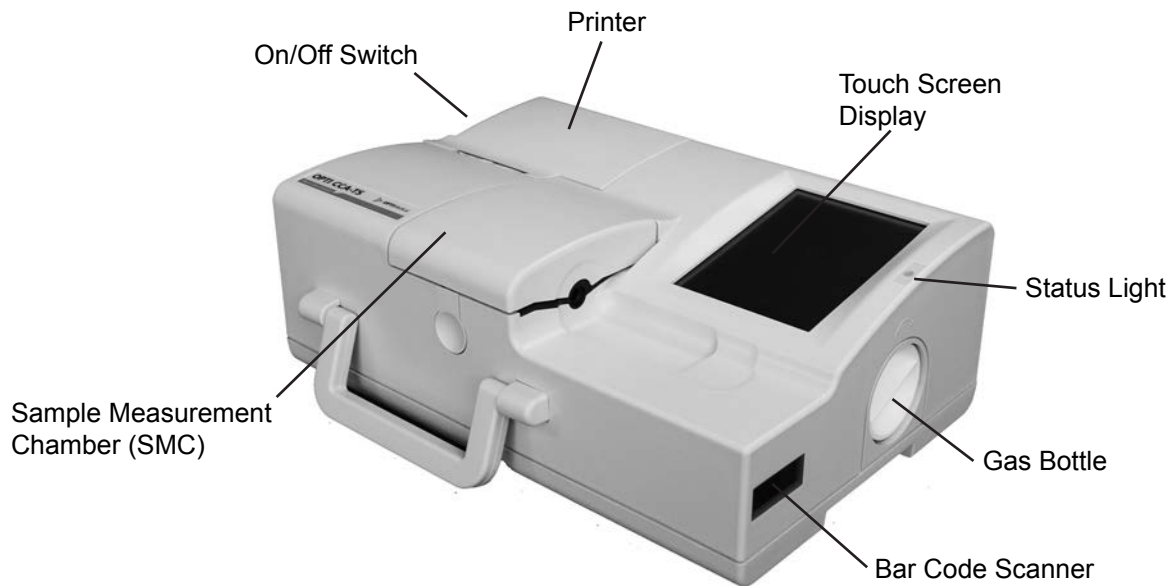


Fig. 1-1 OPTI CCA-TS Major Components

Touch Screen



Fig. 1-2 Touch Screen

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

You communicate with the analyzer through a graphical user interface. The graphic interface is a **touch screen** used to perform all analyzer functions. (Fig. 1-2).

Status Light

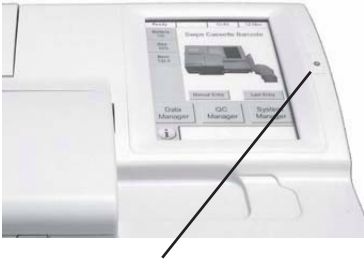


Fig. 1-3 Status Light

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:** System is ready for measurement.
- **Blinking Green Light:** System is in process of calibration or measurement. Do not open the cover.
- **Red Light:** Major error has occurred, system has stopped.
- **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, depress the button, 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

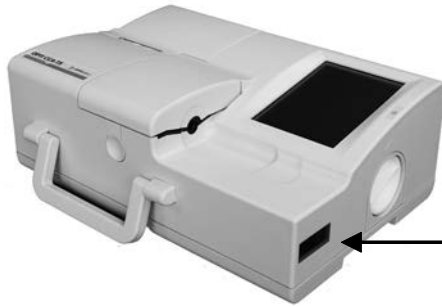


Fig. 1-5 Bar Code Scanner

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

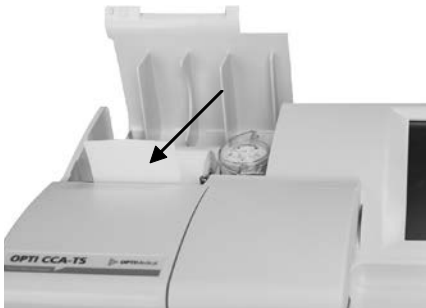


Fig. 1-6 Thermal Printer

The **thermal printer** is accessed by raising the door on the top of the unit (Fig. 1-6). The printer uses heat-sensitive paper to output information in 27 columns. The analyzer can print measured values, quality control values, calibration values, as well as patient and diagnostic information.

Peristaltic Pump

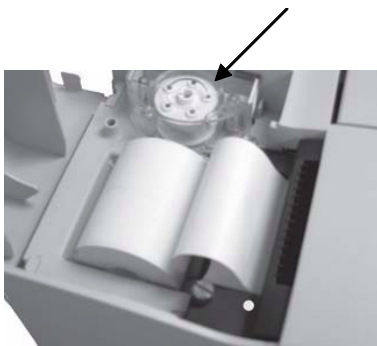


Fig. 1-7 Peristaltic Pump

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 6.4.1).

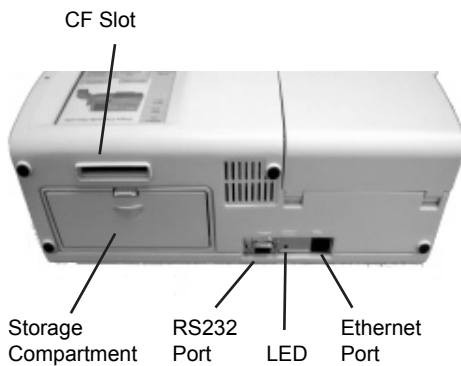
Model and Serial Numbers



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

Fig. 1-8 Model and Serial Numbers

Back of Analyzer

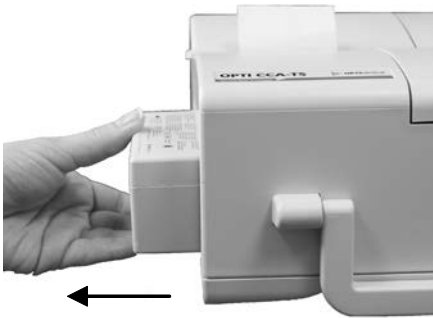


On the rear of the unit is (Fig. 1-9):

- An **RS232 interface port**
- An **Ethernet port**
- An **LED** which indicates the charging status of the battery.
- A **storage compartment** that can hold an extra paper roll, the SRCs, other supplies or accessories (Fig. 1-9).
- A **Compact Flash Card slot (CF Slot)** for software updates and data archiving.

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

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-TS without having to plug the unit into an electrical outlet.

The battery may either be charged in the OPTI CCA-TS unit or independently in the optional Battery Charger - Part number BP7036.

Fig. 1-10 Battery Pack

Power Connector and On/Off Switch



Fig. 1-11 Power Connector and On/Off Switch

Next to the battery pack is the **power connector** where you can connect the OPTI CCA-TS to an external power supply (Fig. 1-11).

The **On/Off** switch is located on the left side of the unit next to the power connector (Fig. 1-11).

NOTE: Allow a 30 second delay when switching the power ON/OFF.

1.5 Consumables

OPTI Sensor Cassette



Fig. 1-12 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. 1-12).

Sample Fillport and Syringe Adapter



Fig. 1-13 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. 1-13).

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.*

Standard Reference Cassettes (SRCs)



Fig. 1-14 Standard Reference Cassette

Standard Reference Cassettes (SRCs) (Fig. 1-14) are reusable sensor cassettes used for daily quality control testing. SRCs can be found in the storage compartment of your analyzer. Each new analyzer comes with a level 1 and a level 3 SRC. Level 2 SRCs are available if desired. SRCs should be kept in their pouches when not in use (see section 4.5 for instructions).

tHb Calibration Cassette



Fig. 1-15 tHb Calibration Cassette

The reusable **tHb Calibration Cassette** (Fig. 1-15) is used for the quarterly calibration of the OPTI CCA-TS Analyzer (See Section 6.3 **Quarterly Maintenance - Performing tHb Calibration**).

Gas Bottle



Fig. 1-16 Gas Bottle

During calibration, the OPTI CCA-TS 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. 1-16).

Congratulations!

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

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2 SETUP

2.1 Important Safety Instructions

Before you begin installing your OPTI™ CCA-TS 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-TS:

- 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 - 32° C (50 - 90° F).
- Maximum relative humidity of 95%.
- 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-TS operates on battery power outside a laboratory setting.

2.3 Setting up the OPTI CCA-TS Analyzer

You are now ready to prepare your OPTI CCA-TS 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-TS and other electronic devices from damage caused by electrical power spikes, OPTI Medical recommends the use of a surge protector.

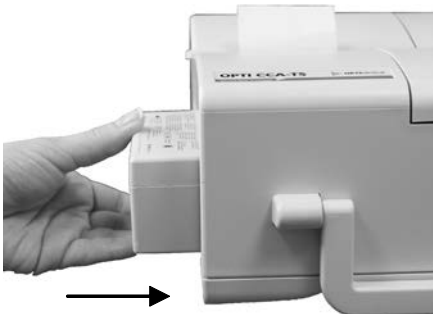


Fig. 2-2 Insert Battery Pack

2. Install the Battery Pack in its Housing

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

NOTE: The battery will need to be charged for at least 6 hours prior to using the OPTI CCA-TS on battery power. It will be charged automatically whenever the analyzer's external power supply is plugged into an electrical outlet.

The status LED on the rear of the instrument is always on while the battery is being charged. The LED blinks rapidly (four times per second) when the battery is fully charged. It blinks slowly (once every 1.5 seconds) when charging a depleted battery.



Fig. 2-3 Power Switch

3. Turn on the Power

- Locate the power switch on the left side of the unit and switch to 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).
- Press .

4. Setting the Time and Date



Fig. 2-5 Enter Time

- The system will now prompt you to enter the current time using the numeric keypad (Fig. 2-5).
- Enter hour and minutes and press .



Fig. 2-6 Select Month

- You will then be asked to enter the month (Fig. 2-6).
- Select the month from the keypad and press .



Fig. 2-7 Enter Date

- In the next screen, you may enter the current day (Fig. 2-7).
- Press and enter the 4-digit year.
- After entering the current time and date press to save your settings.

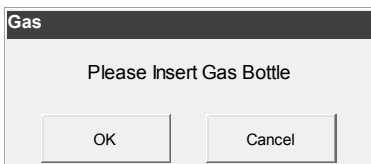
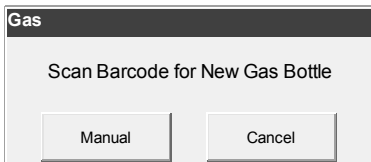
5. Installing a New Gas Bottle



Fig. 2-8 Select New Gas Bottle

- This screen will appear after initial power-up sequence, when no gas bottle is present (Fig. 2-8).
- Press **<New Gas Bottle>**.
- Open the gas bottle by unscrewing the cap.
- Scan the new gas bottle bar code 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.
- The bar code can be found on the gas bottle instructional insert.
- Record the date of installation on the gas bottle for later reference.

*NOTE: To enter the bar code manually, press **<Manual>** and enter the bar code using the numeric keypad.*



- Press when prompted to insert the gas bottle.



Fig. 2-9 Gas Bottle

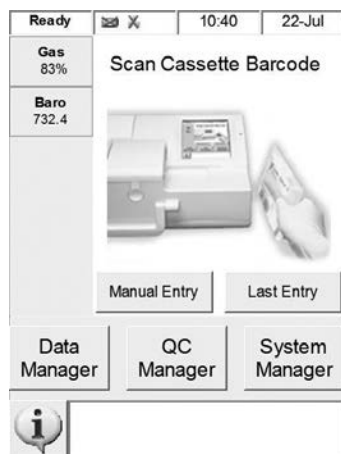
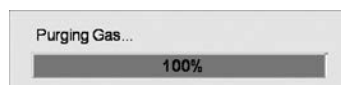
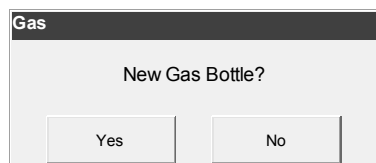


Fig. 2-10 Ready screen

- Insert the gas bottle in its housing and turn clockwise until fingertight (Fig. 2-9).

NOTE: The gas bottle expires 9 months after installation or after exceeding the labeled expiration date, whichever comes first.

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

- When this display appears, press 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 to the prompt <New Gas Bottle?>. The next screen will prompt you to enter the number of weeks in service using the numeric keypad (See section 6.5.3). Here you may refer back to the installation date, which was recorded on the gas bottle.

The OPTI CCA-TS will now begin to warm up and perform a gas purge, which will be indicated on the status bar at the bottom of the screen.

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

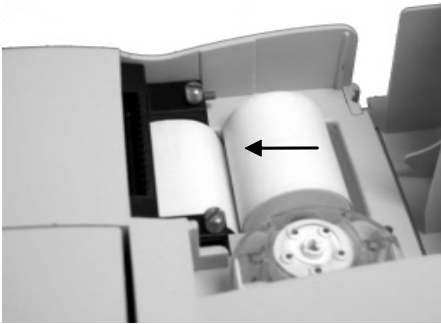


Fig. 2-11 Inserting Printer Paper

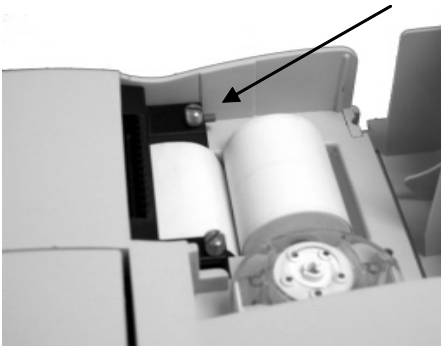


Fig. 2-12 Paper Advance Button

6. Installing the Printer Paper

- Place paper into the paper tray.
- With the OPTI CCA-TS switched on, thread the paper into the feeder slot, as shown in the diagram, on the analyzer (Fig. 2-11).
- As soon as the printer detects the paper, it will automatically feed the paper completely through the printer. The paper advance button should only be used if paper is present.

- To advance paper after the initial installation, press the red paper advance button located on the left side of the printer (Fig. 2-12).

NOTE: The red paper advance button is only active when the printer detects paper in the printer.

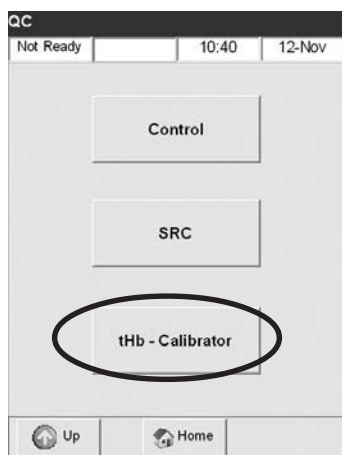


Fig. 2-13 Select tHb-Calibrator

7. 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 quarterly. Your OPTI CCA-TS 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, select **<QC Manager>**.
- In the **<QC Manager>** menu, select **<tHb-Calibrator>** (Fig. 2-13).

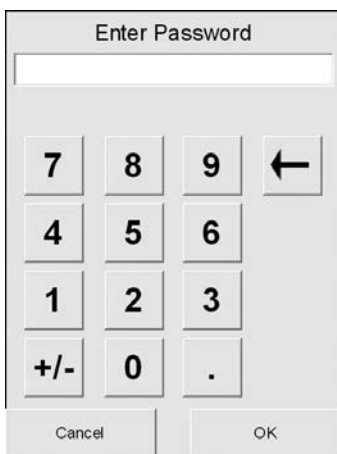


Fig. 2-14 Enter Password

- Use the numeric keypad to enter the password (factory default 404) (Fig. 2-14).



Fig. 2-15 Enter Operator ID

- Use the alphanumeric keypad to enter the Operator ID or press **OK** to bypass this function (Fig. 2-15).
- If Secure Op. IDs is activated under Setup (see Section 3.3.2.4.3) your 4-digit PIN # will be required in place of your Operator ID.

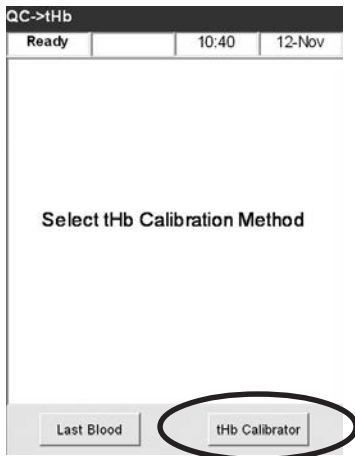


Fig. 2-16 Select tHb Calibrator

- Select **<tHb Calibrator>** (Fig. 2-16).

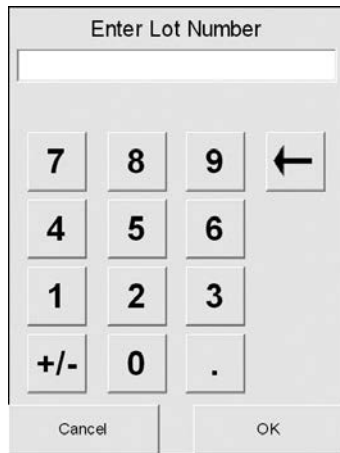


Fig. 2-17 Enter Lot Number

- Enter the lot number of the Calibrator cassette located on the top surface of the cassette and press **OK** (Fig. 2-17).



Fig. 2-18 Open Cover

- At the prompt open the SMC cover by pressing the button (Fig. 2-18).

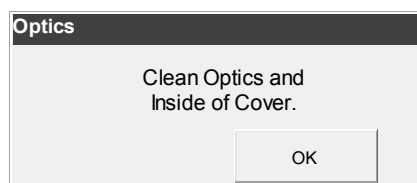


Fig. 2-19 Clean Optics and Inside of Cover

- Gently clean the optics window and the inside top cover of the sample chamber with a soft lint free cloth (Fig. 2-19).

Press .

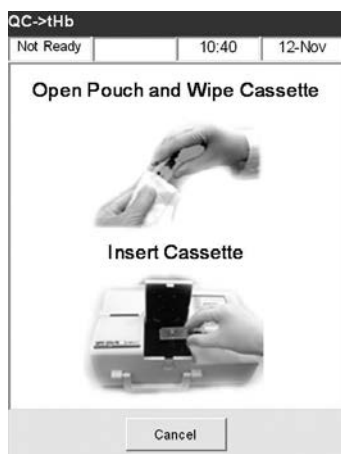


Fig. 2-20 Wipe and Insert Cassette

- 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. 2-20).



Fig. 2-21 Close Cover

- Close the sample chamber cover (Fig. 2-21).

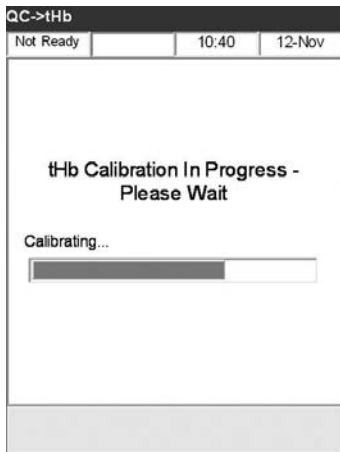


Fig. 2-22 tHb Calibration

After the cover has been closed, the instrument will automatically detect the presence of the calibrator cassette and begin calibration (Fig. 2-22).

- After the calibration is complete you will be prompted to open the sample chamber cover and remove the cassette.
- 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.

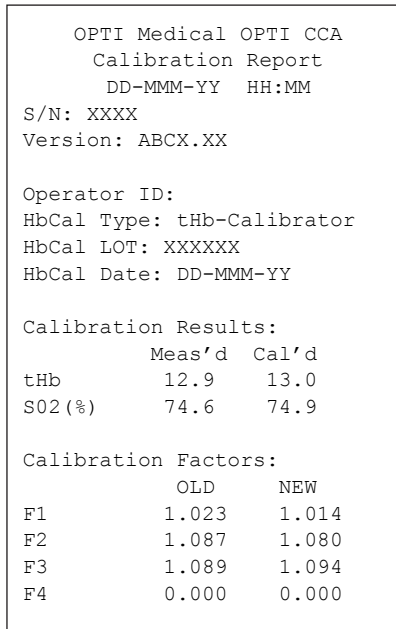


Fig. 2-23 HbCal Report

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

OPTI Medical recommends that you run controls prior to running patient samples on a new analyzer. You must set up your SRCs and OPTI Check control lot information in your new analyzer prior to running them. The SRCs can be found in the storage compartment in the back of your analyzer.

Refer to section 3.3.1 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.

Congratulations! Your OPTI CCA-TS analyzer is now ready for operation.

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3 CUSTOMIZATION

Your OPTI™ CCA-TS 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 calibration 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-TS customization can be protected by a security code. The analyzer's programming or existing parameters can then be changed only by entering the correct security code.

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

3.1 Data Manager

This menu allows you to print out Measurement/Diagnostics Reports and Statistics. It also provides you with the ability to export information if connected to a computer. You can find procedures for printing information in Chapter 4 "Calibration and Quality Control" and Chapter 5 "Patient Testing".

3.2 Setting Time and Date

1. In the main menu, press **<System Manager>** (Fig. 3-1) to access the **<System>** menu.
- Press **<Time and Date>** (Fig. 3-2).
 - Enter the password (factory setting 404) when prompted to access the **<Time and Date>** screen (Fig. 3-3).

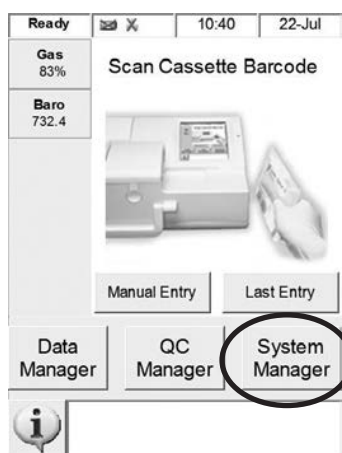


Fig. 3-1 Select System Manager



Fig. 3-2 Select Time and Date

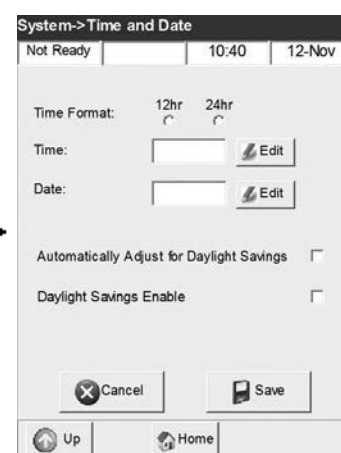


Fig. 3-3 Time and Date

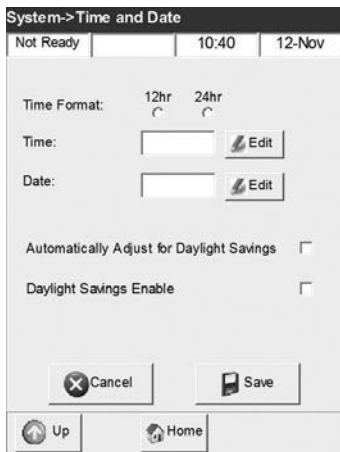







Fig. 3-4 Time and Date

2. 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.
3. To change the **<Time Format>** from **<12-hour>** time units to **<24-hour>** time units, press the respective radio button.
4. Select **<Automatically Adjust for Daylight Savings>** if you want the system clock to change to Daylight Savings Time automatically.
5. To change from Standard Time to Daylight Savings Time manually, select the option **<Daylight Savings Enable>**.
6. Press  to accept the changes.
7. Press  to return to the **<System>** screen or  to return to **<Ready>**.

3.3 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.

1. From the **<Ready>** display, press **<System Manager>** to access the **<System>** menu.
2. Press **<Setup>** to select this function (Fig. 3-5).
3. Enter the password **404** to access the setup functions.

NOTE: You may not be prompted to enter a password if the password was previously disabled (see Section 3.3.3.4.1).

NOTE: If the factory-set password was changed, enter the currently valid password.

3.3.1 QC Setup

3.3.1.1 Setting Up the Standard Reference Cassette (SRC)

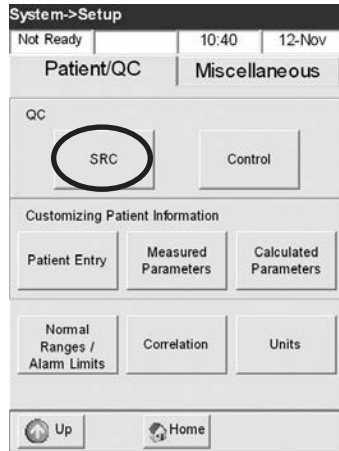


Fig. 3-6 Select SRC



Fig. 3-7 Scan Bar code

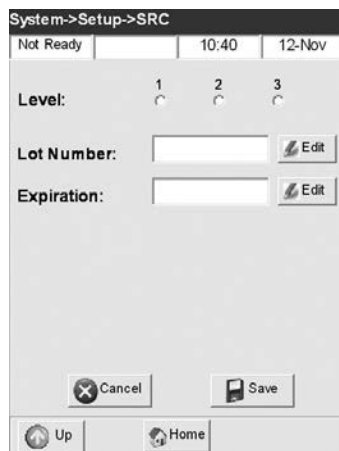
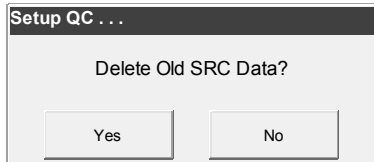
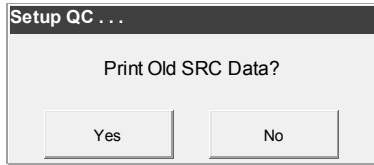


Fig. 3-8 Confirm SRC Information

When you open a new SRC, the lot number should be entered into the analyzer, along with the expiration date. Each SRC level of control has its own unique lot number printed on the pouch.

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

1. From the **<Ready>** display, select **<System Manager>** and **<Setup>**.
 2. Enter the password if this security function has been activated under **<Setup>**.
 3. In the **<System Setup>** menu, press **<SRC>** (Fig. 3-6).
 4. Take an SRC pouch and scan the bar code 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. 3-7).
 - 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, enter the bar code digits using the keypad.*
5. If the level, lot number and expiration date are correct, press **Save** to accept (Fig. 3-8).



NOTE: If previous SRC data exists, the unit will prompt the user to either print and/or delete this data from the database.

NOTE: If no previous QC data exists in the database, the print and delete display screens will be bypassed.

6. Press to obtain a printout of the old SRC database.
7. Press to delete the old SRC database.

To continue quality control (SRC) programming, repeat the above procedure for all levels of SRCs.

3.3.1.2 Setting up the Quality Control Material Lot and Level

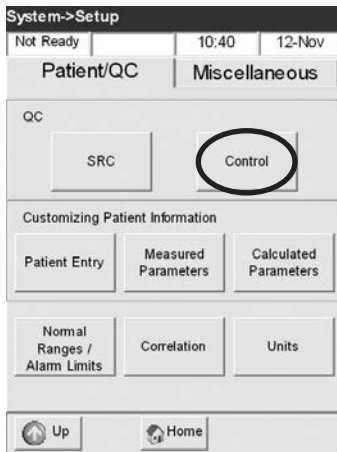


Fig. 3-9 Select Control

1. From the **<Ready>** display, select **<System Manager>** and **<Setup>**.
2. Enter the password if this security function has been activated under **<Setup>**.
3. Select **<Control>** (Fig. 3-9).
4. Scan the 36-digit bar code marked **SCAN A** for the applicable level supplied with OPTI CHECK or OPTI CHECK PLUS.
5. Scan the second 36-digit bar code marked **SCAN B** supplied with the same OPTI CHECK or OPTI CHECK PLUS control lot. 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 the third 36-digit bar code marked **SCAN C** for the applicable level.

NOTE: If bar code is not available, press <Manual Entry> on the <Scan Barcode> screen and manually enter control data.

3.3.1.2.1 Entering Control Expiration Date, Type, and Assay Ranges

Fig. 3-10 Confirm Lot Information

When you open a new box of OPTI CHECK, OPTI CHECK PLUS or another recommended product, 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-TS and have assigned assay ranges for each measured parameter. Do not use a control material that contains dyes, fluoro-carbons or silicones as these constituents will affect the results reported.

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

1. From the previous bar code scans, confirm lot number, expiration date and control type on the package insert supplied with the control material (Fig. 3-10). If the bar code is unavailable, press **<Manual Entry>** on the **<Scan Barcode>** screen and enter the control information manually.
2. Press **Save** to accept.

NOTE: If previous QC data exists, the unit will prompt the user to either print and/or delete this data from the database.

NOTE: If no previous QC data exists in the database, the print and delete display screens will be bypassed.

3. Press **Yes** to obtain a printout of the old database.
4. Press **Yes** to delete the old database.

*NOTE: If you do not want to change the current lot information, but want to verify current programmed QC ranges, press **<NO>** for both of the above options.*

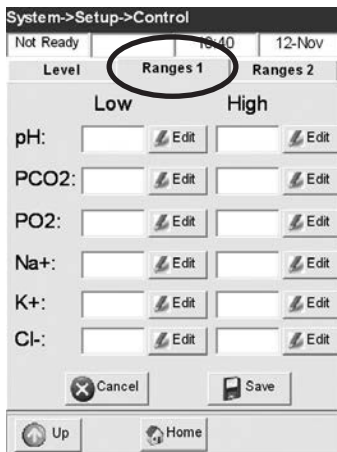



Fig. 3-11 Confirm Assay Ranges

5. Press the **<Ranges 1>** tab to confirm the assay ranges on the package insert supplied with the control material (Fig. 3-11).

If the bar code is unavailable, press the  button and enter the numbers using the keypad.

6. Press  to accept.

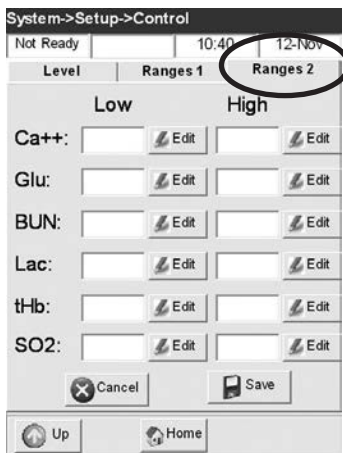



Fig. 3-12 Confirm Assay Ranges

7. Press **<Ranges 2>** to go to the next display to enter the ranges for all other measured parameters available with this control material (Fig. 3-12). Enter 0.0 for unassayed parameters.

- 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  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.

3.3.2 Customizing Patient Information

3.3.2.1 Selecting Which Patient Information is Requested and Printed

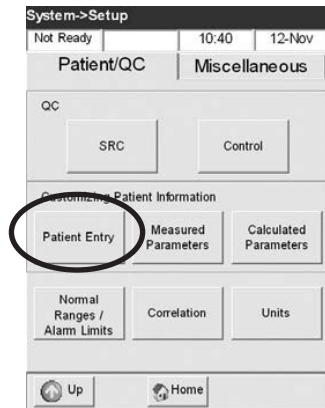


Fig. 3-13 Select Patient Entry

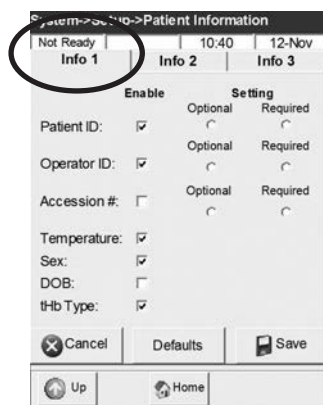


Fig. 3-14 Patient Info 1

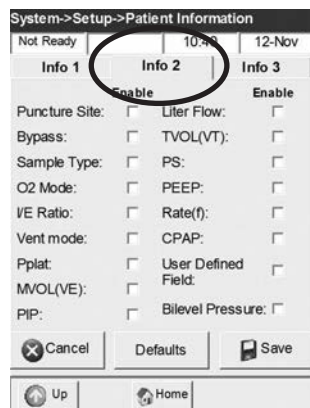


Fig. 3-15 Patient Info 2

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

- From the **<Ready>** display, select **<System Manager>** and **<Setup>**.
- In the **<System Setup>** menu, press **<Patient Entry>** (Fig. 3-13).
- In the **<Info 1>** screen, select the options to be enabled (Fig. 3-14).
- Select **<Optional>** or **<Required>** for:
 - Patient ID
 - Operator ID
 - Accession Number
- Other options to be selected are:
 - Temperature
 - Sex
 - DOB
 - tHb Type
- Press the **<Info 2>** tab to access and enable the following parameters (Fig. 3-15).

Puncture Site	Liter Flow
Bypass	TVOL(VT)
Sample Type	PS
O ₂ Mode	PEEP
I/E Ratio	Rate (f)
Vent Mode	CPAP
Pplat	User defined field
MVOL(VE)	Bilevel Pressure
PIP	

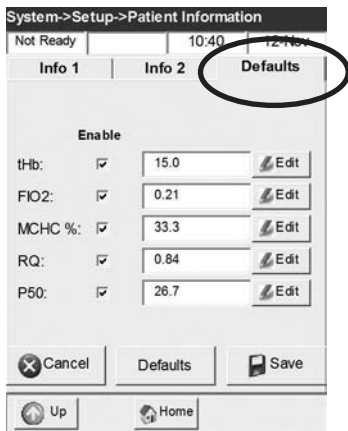


Fig. 3-16 Defaults

The **<Defaults>** screen (Fig. 3-16) allows you to program the default values for patient input parameters with the exception of patient temperature.

The instrument comes with factory programmed default values, which represent typical values. The programmed default values will be printed and used for the calculated parameters, unless they are changed by the operator during a measurement. You can change the default values only if the parameter has been enabled. After each measurement, the value will be reset to the default value, even after the system has been turned off. Exceptions are the Hb type and P50, which remain at the selected value until the system is powered off.

The first parameter is tHb (Fig. 3-16). This is the tHb value used in calculations of various parameters if measured tHb is not available.

- Press **<Enable>** to display the default value for this parameter (15.0 g/dL). Press **Edit** to change this value using the numeric keypad.

NOTE : Units for the tHb and P50 may be changed per instructions found in Section 3.3.2.3.

The remaining default parameters are:

MCHC%:	33.3 %
FIO ₂ :	0.21
RQ:	0.84
P50:	26.7 mmHg

NOTE: The default values indicated above are the original factory settings. If out-of-range values are entered, the system automatically flags the error and shows the valid range.

- Press **Save** to accept the changes.
- Press **Up** to return to the **<Setup>** screen or **Home** to return to **<Ready>**.

3.3.2.2 Selecting Which Parameters Are Blanked/Disabled

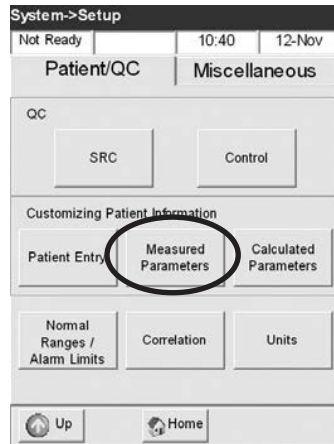


Fig. 3-17 Measured Parameters

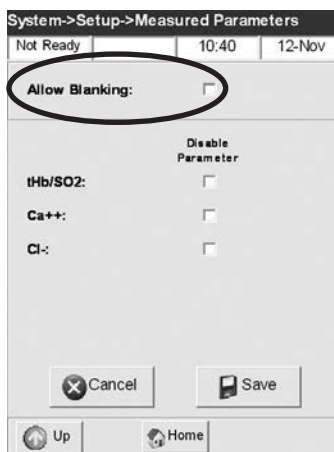


Fig. 3-18 Select Allow Blanking

In the **<Measured Parameters>** menu you can enable parameter blanking and disable certain parameters from being reported on the analyzer.

1. From the **<Ready>** display, select **<System Manager>** and **<Setup>**.
2. In the **<System Setup>** menu, press **<Measured Parameters>** (Fig. 3-17).

3. Press **<Allow Blanking>** to allow parameter blanking (Fig. 3-18).

If blanking is enabled, the user is prompted to choose which measured parameter will be disabled or removed from the record after each patient sample measurement. If for example, Ca⁺⁺ is disabled, this result will not appear in the stored patient results or on the printout.

4. Select the parameters to be disabled.
5. Press **Save** to save the settings.
6. Press **Up** to return to the **<Setup>** screen or **Home** to return to **<Ready>**.

3.3.2.3 Selecting Which Calculated Parameters Are Printed

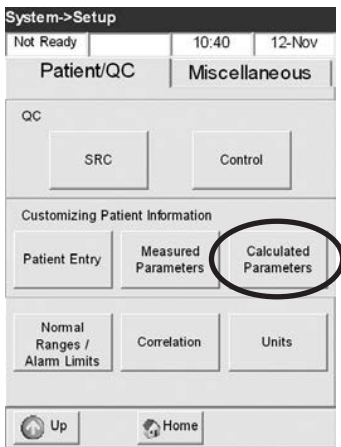


Fig. 3-19 Select Calculated Parameters

With this menu you can select the calculated parameters 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. From the **<Ready>** display, select **<System Manager>** and **<Setup>**.
2. In the **<System Setup>** menu, press **<Calculated Parameters>** (Fig. 3-19).

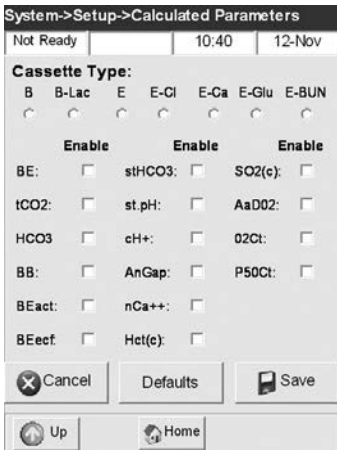





Fig. 3-20 Select Parameters

3. Select the cassette type (Fig. 3-20).
4. Select the parameters to be printed.
5. Press  to accept the changes.
6. Press  to return to the **<Setup>** screen or  to return to **<Ready>**.

3.3.2.4 Setting Normal Ranges or Alarm Limits

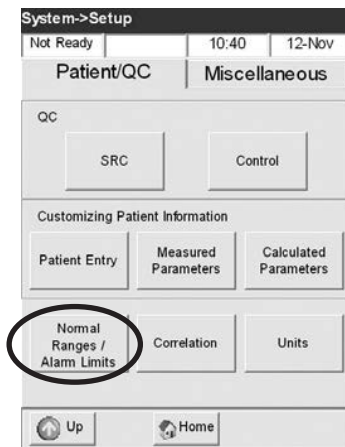


Fig. 3-21 Select Normal Ranges

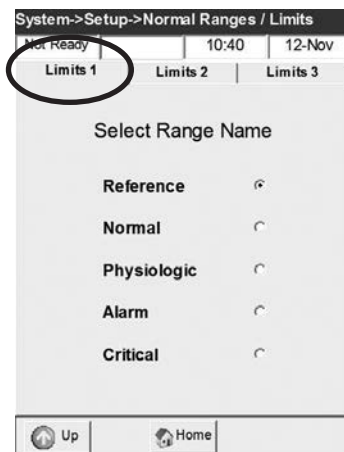


Fig. 3-22 Select Limits Name

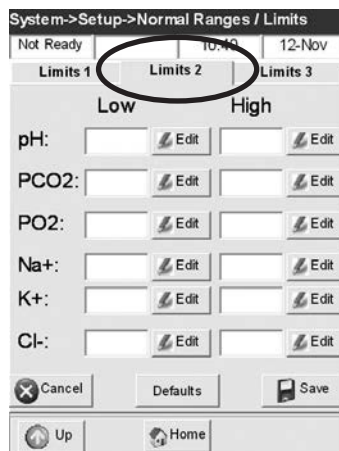


Fig. 3-23 Enter Limits 2

This menu enables you to change both the limits “name” as it appears on the printout and the limit values themselves, for pH, PCO_2 , and all other measured parameters. These limit names can be based on your hospital policy and may be selected from the following - “Reference”, “Normal”, “Physiologic”, “Alarm” or “Critical”.

A result that is outside the limits you define here will be flagged with an up-arrow if high, or down-arrow if low. A message is included on the printout explaining each arrow, using the name selected here.

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. From the **<Ready>** display, select **<System Manager>** and **<Setup>**.
2. In the **<System Setup>** menu, press **<Normal Ranges/Alarm Limits>** (Fig. 3-21).
3. On the **<Limits 1>** tab, select the limits range name you wish to use (Fig. 3-22):
 - Reference
 - Normal
 - Physiologic
 - Alarm
 - Critical
4. Press **<Limits 2>** to advance to the next screen (Fig. 3-23).
5. Select the parameter you want to change and press **Edit** to enter the new limit value.
6. Press **Save** to accept the new limit value.

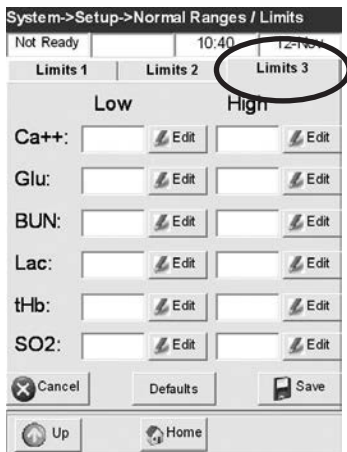




Fig. 3-24 Enter Limits 3

7. Press **<Limits 3>** to advance to the next screen (Fig. 3-24) with the remaining parameters.

The instrument is preset to the following ranges of limit values:

pH:	7.2 - 7.6
PCO ₂ :	30 - 50 mmHg
PO ₂ :	70 - 700 mmHg
Na ⁺ :	135 - 145 mmol/L
K ⁺ :	3.5 - 5.1 mmol/L
Cl ⁻ :	95 - 115 mmol/L
Ca ⁺⁺ :	1.12 - 1.32 mmol/L
Glu:	60.0 - 120.0 mg/dL
Glu:	3.3 - 6.6 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 - 17 g/dL
SO ₂ :	90 - 100 %

- Units may be changed (See section 3.3.2.6).
- In all data input screens, if unreasonable numbers are entered, the system automatically flags the error and displays the valid range.
- If you wish to turn off limits flagging, enter the system ranges for each parameter. For instance, for pH, the low is 6.600 and the high is 7.800 (See Analytes Section for specifications of the reportable ranges for each parameter measured).
- The limits entered here will reside in the instrument memory even after system power is turned off.

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

3.3.2.5 Setting up Correlation Factors

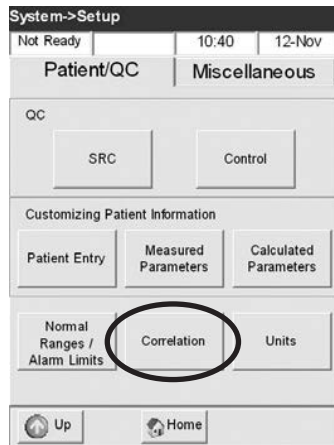


Fig. 3-25 Select Correlation

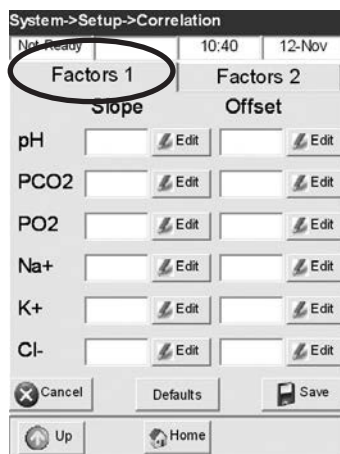


Fig. 3-26 Correlation Factors 1



Fig. 3-27 Correlation Factors 2

Correlation factors let you correlate results from your OPTI CCA-TS to other Blood Analyzers. Correlation factors are available for pH, PCO_2 , PO_2 , Na^+ , K^+ , Ca^{++} , Cl^- , Glu, BUN (urea), Lac, tHb, and SO_2 .

NOTE: Slope is a multiplicative factor and Offset is an additive factor, using the following formula:

$$\text{Correlated value} = \text{Raw value} * \text{slope} + \text{offset.}$$

1. From the **<Ready>** display, select **<System Manager>** and **<Setup>**.
 2. In the **<System Setup>** menu, press **<Correlation>** (Fig. 3-25).
 3. Select the numbers you want to change by pressing **Edit** (Fig. 3-26). Enter the new numbers.
 4. Press **<Factors 2>** to go to the next screen (Fig. 3-27).
 5. When entering the actual offset value, select whether it is an additive or subtractive value using the +/- keys.
- NOTE: The factory setting is 1.0(00) 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 **Up** to return to the **<Setup>** screen or **Home** to return to **<Ready>**.

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-TS and the instrument to which it is to be correlated.*

3.3.2.6 Defining Units

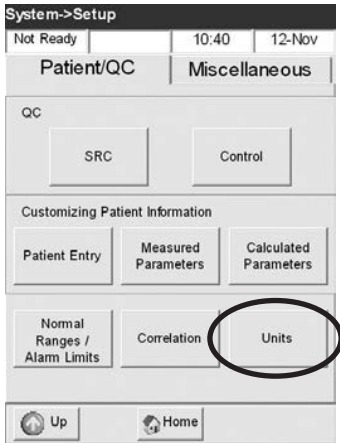


Fig. 3-28 Select Units

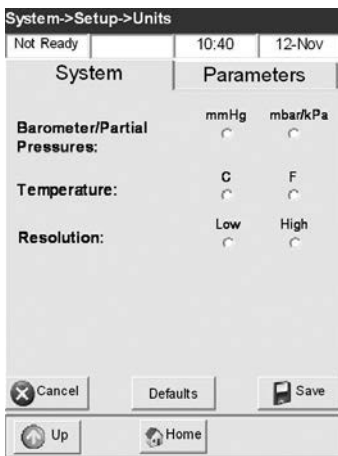


Fig. 3-29 Select Units

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

1. From the **<Ready>** display, select **<System Manager>** and **<Setup>**.
2. In the **<System Setup>** menu, press **<Units>** (Fig. 3-28).
3. In the **<Units>** screen, select the units for the displayed parameters (Fig. 3-29).
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 sample results only. 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 5.71 mmol/L	Glu 5.71 mmol/L
• BUN 18.5 mg/dL	BUN 18.5 mg/dL
• Lac 14.5 mmol/L	Lac 14.5 mmol/L
• tHb 14.6 g/dL	tHb 14.6 g/dL
• SO ₂ 90 %	SO ₂ 89.8 %

NOTE: PO₂ and PCO₂ values above 100 mmHg are always displayed to the nearest whole number.

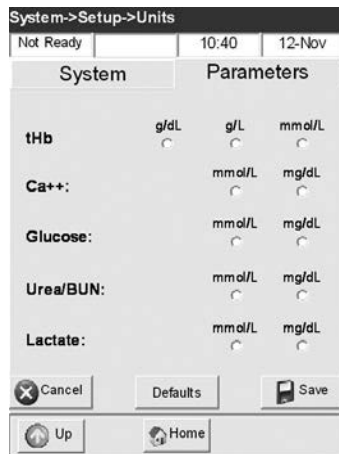





Fig. 3-30 Select Units

5. Press the **<Parameters>** tab to go to the next screen (Fig. 3-30), and select the units for the remaining parameters.

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

- Baro/Partial Pressure mmHg
- Temperature °C
- Resolution Low
- tHb g/dL
- Electrolytes mmol/L
- Glucose mmol/L
- BUN mg/dL
- Lac mmol/L

NOTE: The OPTI CCA-TS automatically recalculates the units stored in the database to the changed unit value.

6. Press  to accept the changes.
7. Press  to return to the **<Setup>** screen or  to return to **<Ready>**.

3.3.3 Miscellaneous

3.3.3.1 Setting up Security

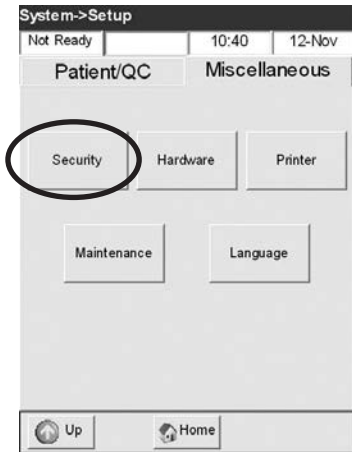


Fig. 3-31 Select Security

The OPTI CCA-TS has three types of security:

1. A **Password Function** to limit access to various system functions (See section 3.3.3.1.1).
 2. **QC Lockouts** to help hospitals meet their QC policies (See section 3.3.3.1.2).
 3. A **Secure Operator ID** function to limit access to analyzer to properly trained, authorized users (See section 3.3.3.1.3).
- From the **<Ready>** display, select **<System Manager>** and **<Setup>**.
 - In the **<System Setup>** menu, press the **<Miscellaneous>** tab, and select **<Security>** (Fig. 3-31).

3.3.3.1.1 Setting Up a Password



Fig. 3-32 Enter Password

The OPTI CCA-TS has a password function which, when activated, will deny access to the setup menus and certain database functions. The correct password will have to be entered to grant access to these menus and functions. The password is especially useful to ensure that only authorized operators can alter customized settings. The factory default password is **404**. The factory-set password can be changed to any number between 0 and 9999 (up to 4 digits).

1. Select **<Password Enable>** in the **<Security>** menu (Fig. 3-32). You will then be able to enter a number (1-4 digits) in the **<Setup PW>** field.

2. Press **Edit** to enter the numbers and press **Save** to accept the changes.

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

3. Press **Up** to return to the **<Setup>** screen or **Home** to return to **<Ready>**.

3.3.3.1.2 Selecting QC Lockout

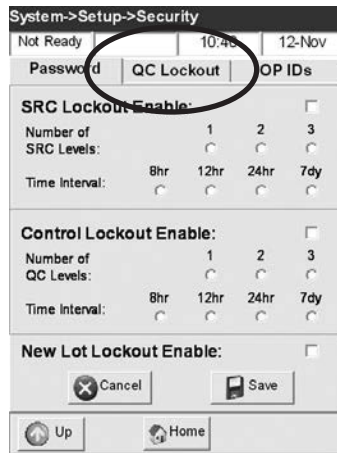


Fig. 3-33 Select QC Lockout

This menu allows the facility to ‘lock out’ operators unless some form of QC has been run. OPTI Medical recommends option 1 and option 3 as 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 lock-out options turned off.




To activate these options:

- Select **<QC Lockout>** in the **<Security>** menu (Fig. 3-33).

Option 1:

<SRC Lockout Enable> - Under this option you can require that one, two or three levels of SRCs must be run at regular intervals. If the selected number of SRCs is not run, patient measurements will not be allowed.

- <8hr>** - Requires SRCs to be run every 8 hours.
- <12hr>** - Requires SRCs to be run every 12 hours.
- <24hr>** - Requires SRCs to be run every 24 hours.
- <7dy>** - Requires SRCs to be run every 7 days.

1. Select the desired option.
2. Press  to accept the changes.
3. Press  to return to the **<Setup>** screen or  to return to **<Ready>**.




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

Option 2:

<Control Lockout Enable> - Under this option you can require that one, two or three levels of liquid controls must be run at regular intervals.

If the selected number of controls is not run, patient measurements will not be allowed.

- <8hr>** - Requires controls to be run every 8 hours.
- <12hr>** - Requires controls to be run every 12 hours.
- <24hr>** - Requires controls to be run every 24 hours.
- <7dy>** - Requires controls to be run every 7 days.

1. Select the desired option.
2. Press  to accept the changes.
3. Press  to return to the **<Setup>** screen or  to return to **<Ready>**.




*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. The system default is QC lockout disabled.*

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. Patient measurements will not be allowed unless all analytes on that cassette have satisfied the lockout requirements for number of control levels and required time period.

Option 3:

<New Lot Lockout Enable> – Controls must be run with every new lot of cassettes. At least one level must have passed within the previous 60 days. If this is not done, the system will not allow patient samples to be run.

*NOTE: More than one option can be selected.
For instance, laboratories can require that a combination of SRCs and controls are run on a daily basis. This should be based on hospital policy. The system default is QC lockout disabled.*

1. Select the desired option.
2. Press  to accept the changes.
3. Press  to return to the **<Setup>** screen or  to return to **<Ready>**.

3.3.3.1.3 Setting up Secure Operator IDs

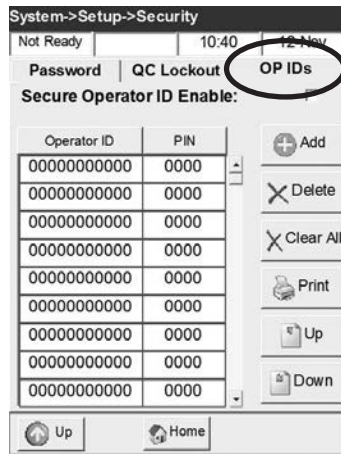


Fig. 3-34 Select OP IDs

The **<OP IDs>** menu is used to enter Operator identification IDs and password (PIN). With this feature enabled, the system will “lock out” unauthorized users from operating the analyzer.

- Select **<OP IDs>** in the **<Security>** menu (Fig. 3-34).
- Select **<Secure Operator ID Enable>**.

NOTE: If you do not select this option, the <Secure Op IDs> feature is turned off, and operators will not be required to enter their PIN numbers to operate the analyzer.

1. Press **+ Add** to enter the Operator ID number (up to 11 digits) and a unique 4-digit personal identification number (PIN) to be added to the list of authorized users.

The analyzer can store up to 300 Operator IDs and associated PINs.

NOTE: The 4-digit PIN must be unique and will be required by the operator to access analyzer functions. The Operator ID number will be printed on all reports associated with their PIN.

OR

2. Select an Operator ID number to be deleted from the list of valid users currently stored in memory, and press the **X Delete** button to remove the operator ID from memory.

OR

3. Press the **Print** button to print the list of all operator IDs, along with their associated PINs, as currently stored in memory.
4. Press **Home** to return to **<Ready>**.

3.3.3.2 Entering the Barometric Pressure

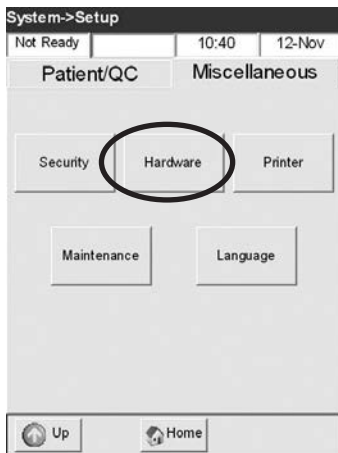


Fig. 3-35 Select Hardware

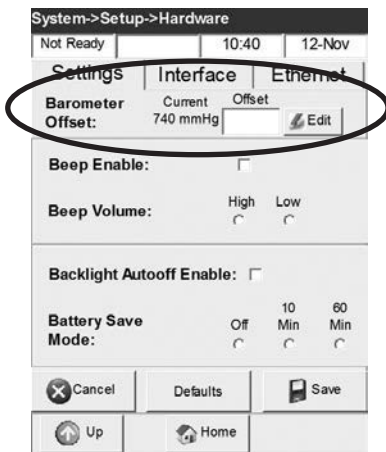


Fig. 3-36 Enter barometric pressure

The **<Hardware>** menu consists of three screens, **<Settings>**, **<Interface>** and **<Ethernet>**.

The **<Settings>** screen is used to adjust your local barometric pressure, the audible alarm, and battery save mode.

The **<Interface>** and **<Ethernet>** screens can be used to configure communication settings.

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

1. From the **<Ready>** display, select **<System Manager>** and **<Setup>**.
2. In the **<System Setup>** menu, press the **<Miscellaneous>** tab and then **<Hardware>** to select this function (Fig. 3-35).
3. In the **<Settings>** menu, press **Edit** to enter an offset from the true barometric pressure (Fig. 3-36).
4. Type in the new numbers and press **Save** to accept the value.
5. Press **Up** to return to the **<Setup>** screen or **Home** to return to **<Ready>**.

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 3.3.2.6).

3.3.3.3 Beep Adjustment

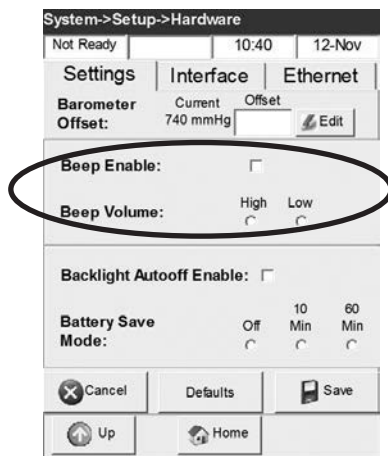





Fig. 3-37 Enable Beep

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

1. From the **<Ready>** display, select **<System Manager>** and **<Setup>**.
2. In the **<System Setup>** menu, press the **<Miscellaneous>** tab and then **<Hardware>**.
3. In the **<Settings>** screen, select **<Beep Enable>** (Fig. 3-37).
4. Select **<High>** or **<Low>** for **<Beep Volume>**.
5. Press  to accept the changes.
6. Press  to return to the **<Setup>** screen or  to return to **<Ready>**.

3.3.3.4 Battery Saver

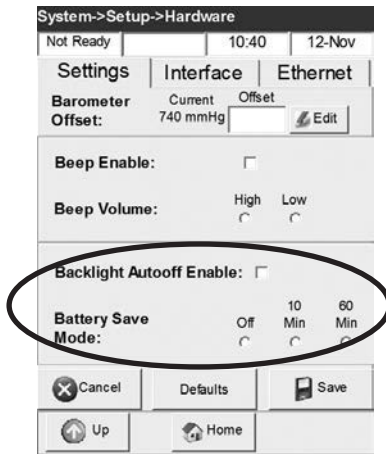


Fig. 3-38 Backlight Auto-Off




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

1. From the **<Ready>** display, select **<System Manager>** and **<Setup>**.
2. In the **<System Setup>** menu, press the **<Miscellaneous>** tab and then **<Hardware>**.
3. In the **<Hardware>** screen, select the following options (Fig. 3-38):

- **<Backlight AutoOff Enable>**- If battery save mode is also enabled, the backlight of the display will turn off automatically after the selected duration.

NOTE: The screen will appear dark when the analyzer is in standby mode and Backlight Auto Off is enabled. Press the touch screen to exit standby mode and resume normal operation.

- **<Battery Save Mode>** will put the instrument into standby mode which turns off the sample measurement chamber heaters to conserve the battery. Battery save mode has the following options:
 - **<Off>** - The system will always stay on in the **<Ready>** mode until the operator turns the system off.
 - **<10 Min>** - The system will go to standby mode after 10 minutes of inactivity.
 - **<60 Min>** - The system will go to standby mode after 60 minutes of inactivity.

4. Press  to accept the changes.
5. Press  to return to the **<Setup>** screen or  to return to **<Ready>**.

3.3.3.5 Setting Up Communications

Your OPTI CCA-TS has an RS232 standard serial interface with a baud rate fixed at 9600 and an Ethernet port. These ports may be configured for ASCII and ASTM output.

3.3.3.5.1 Configuring the Communication Format



Fig. 3-39 Interface

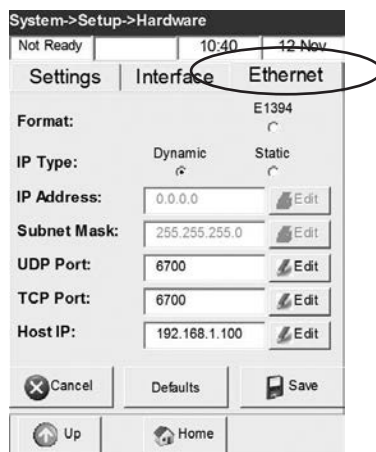


Fig. 3-40 Ethernet Settings

1. From the **<Ready>** display, select **<System Manager>** and **<Setup>**.
2. In the **<System Setup>** menu, press the **<Miscellaneous>** tab and then **<Hardware>**.
3. In the **<Interface>** screen (Fig. 3-39), you can select **<External Barcode Enable>**.
4. Select the communication **<Format>**: **<ASCII>**, **<ASTM>**, or **<CF>**.
 - **<ASCII>** - Data in easy to read OPTI Medical custom format. The OPTI CCA-TS exports data string identical to the internal printer output.
 - **<ASTM>** - Complies with ASTM standard. Please refer to OPTI CCA-TS interface specifications for more information.
 - **<CF>** - Compact Flash is used for archiving data to a Compact Flash Card. An Export Kit is available (BP7140) with a properly formatted card, instructions and card reader. The database can be exported to the Compact Flash card in CSV format and then read by a PC. Select **<Comma>** or **<Semicolon>** for your CSV file delimiter in MS Excel.
 - **<Link>** - Select **<Serial>** or **<Ethernet>**.
5. The **<Ethernet>** screen (Fig. 3-40) is used to configure Ethernet settings: **<Format>**, **<IP Type>**, **<IP Address>**, **<Subnet Mask>**, **<UDP Port>**, **<TCP Port>**, and **<Host IP>**.

NOTE: The analyzer must be connected to an active network to activate this menu.



Fig. 3-41 Ethernet Test

To set up Ethernet communication:

- Connect instrument to an active network.
- Go to **<System -> Diagnostics -> Tests -> Ethernet>**.
- Verify that the test status is **<Connected>** and you have a valid IP address (not all zeroes) (Fig. 3-41).



Fig. 3-42 Interface

- Go back to menu **<System -> Setup -> Hardware -> Interface>** (Fig. 3-42).
- Choose communication format **<ASCII>** or **<ASTM>**.
- Change communication link from **<Serial>** to **<Ethernet>**.

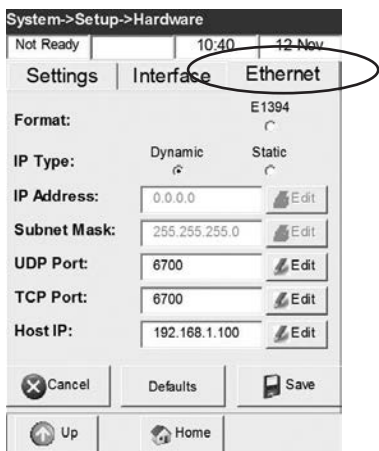


Fig. 3-43 Ethernet

- Choose the **<Ethernet>** tab (Fig. 3-43).
 - Set **<TCP Port>** to what your data manager specifies is your instrument port. Each analyzer type may have a different port specified.
 - Enter your computer's host IP address into the **<Host IP>** field.
 - Press **Save**.
 - **<Format>** (E1394), **<IP Type>** (Dynamic), and **<UDP Port>** fields should remain at default.
6. Press **Up** to return to the **<Setup>** screen or **Home** to return to **<Ready>**.

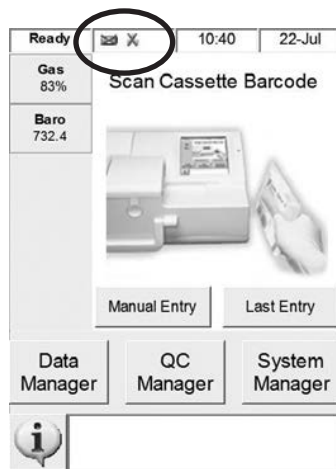






Fig. 3-44 Ready Display

The **<Ready>** screen displays whether Compact Flash Card and network connection are enabled (Fig. 3-44) using the following icons:

-  - The compact flash card is writable.
-  - The compact flash card is not writable.
-  - The network is connected.
-  - The network is not connected.

3.3.3.6 Setting the Printer

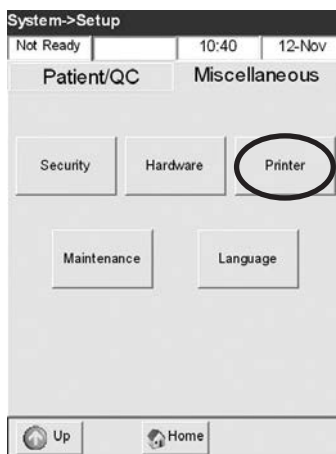


Fig. 3-45 Select Printer

This menu allows you to program the printing functions of your analyzer.

1. From the **<Ready>** display, select **<System Manager>** and **<Setup>**.
2. In the **<System Setup>** menu, press the **<Miscellaneous>** tab and then **<Printer>** (Fig. 3-45).

In the **<Settings>** menu (Fig. 3-46), you can select to have a patient report printed at the end of each measurement. The second option lets you add a calibration report to each patient report. The next option lets you add reference ranges to each patient report. The last option lets you select how many copies will be printed.

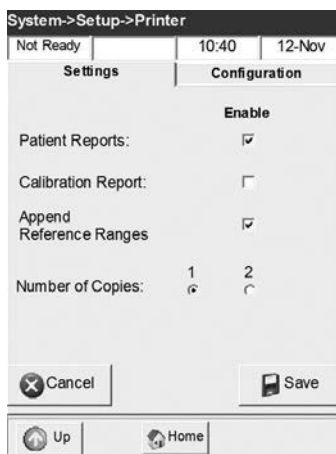





Fig. 3-46 Printer Settings

3. Select the options to be enabled.
4. Press  to accept the changes.
5. Press  to return to the **<Setup>** screen or  to return to **<Ready>**.

NOTE: This setting affects the patient report only. All other print functions are still active, even if the patient report is not activated.

3.3.3.7 Maintenance

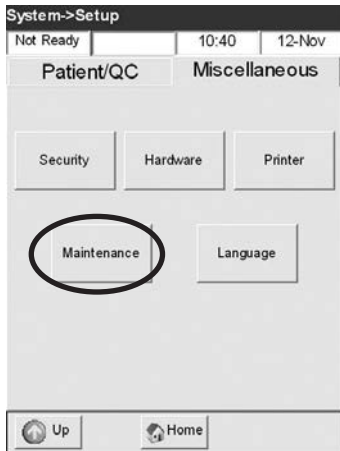


Fig. 3-47 Select Maintenance

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 **<Setup>**.
2. In the **<System Setup>** menu, press the **<Miscellaneous>** tab and then **<Maintenance>** (Fig. 3-47).

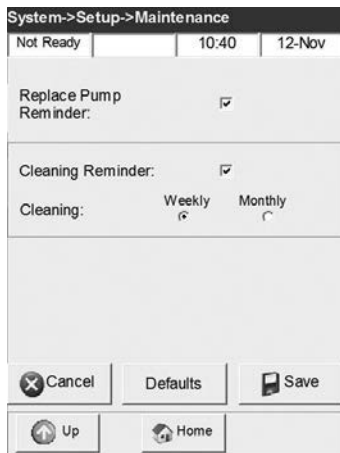


Fig. 3-48 Maintenance Options

In the **<Maintenance>** menu (Fig. 3-48), you can select **<Replace Pump Reminder>** to alert you when the peristaltic pump needs replacement.

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 6 for maintenance procedures.

3.3.3.8 Selecting a Language

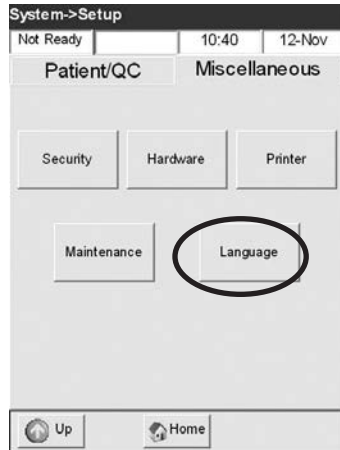


Fig. 3-49 Select Language

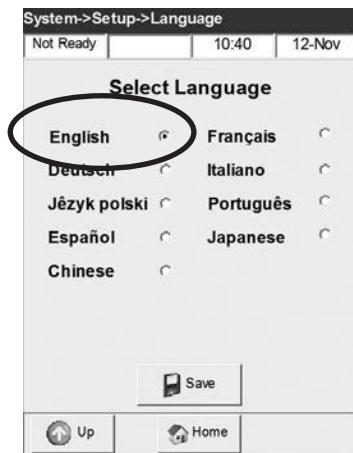





Fig. 3-50 Select Language

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

1. From the **<Ready>** display, select **<System Manager>** and **<Setup>**.
2. In the **<System Setup>** menu, press the **<Miscellaneous>** tab and then **<Language>** (Fig. 3-49).

3. Select the desired language (Fig. 3-50).
4. Press  to accept the changes.
5. Press  to return to the **<Setup>** screen or  to return to **<Ready>**.

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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'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 verification is performed using a precision gas mixture and the cassette's internal storage buffer, in a manner similar to other combined blood gas / ion analyzers. 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. A second HbCal option is available on the OPTI™ CCA-TS. The HbCal – Last Blood option allows the OPTI CCA-TS to be correlated to another tHb measurement method. When the Last Blood is run, the OPTI CCA-TS will compensate for any measurement bias, allowing any future measured samples to match the alternate device.

For more information, including detailed instructions, on the HbCal options, see Section 6.3 “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-TS 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 SO₂. For calibration verification of tHb and SO₂, OPTI Medical recommends testing whole blood against a reference analyzer.

Should a laboratory wish to perform a calibration verification for measurement values outside the broad range, OPTI Medical Systems suggests tonometry of whole blood for PO_2 and PCO_2 , correlation against flame photometry for electrolytes, correlation against cyanmethemoglobin method for tHb, and blood pH correlation with conventional blood gas analyzers.

For calibration verification of glucose, OPTI Medical Systems recommends the hexokinase procedure as proposed by the FDA, “Federal Register” 39, No. 126, 24136-24147.

In the case of BUN (urea), OPTI Medical Systems recommends correlation against the end-point coupled enzyme method described by Sampson and Baird, et.al., in Clinical Chemistry 26: 816-826, 1980.

4.5 QC Recommendations

Two standard Reference Cassettes (SRC) should be used as a control for the OPTI CCA-TS analyzer. The level 1 and level 3 SRCs represent high and low samples. The SRCs 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 all measured parameters by the analyzer are consistent. 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 or other equivalent material as recommended by OPTI Medical Systems. These materials should provide target values for pH, PCO_2 , and all other 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 level 1	At least 1x per day in operation
SRC level 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

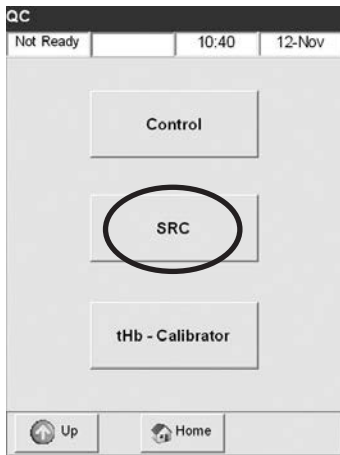



Fig. 4-1 Select SRC

1. From the **<Ready>** display, select **<QC Manager>**.
2. Select **<SRC>** (Fig. 4-1).



Fig. 4-2 Enter Operator ID

3. Enter your Operator ID, or 4-digit PIN using the alphanumeric keypad (Fig. 4-2).
To bypass this function, press .

NOTE: If Operator ID is configured as “required” in Setup, you cannot go to the next step unless a valid Op. ID is entered.

NOTE: If Secure Op. IDs is activated under Setup, you will be prompted for your 4-digit PIN # instead of your Op. ID.

NOTE: Bar-coded Operator IDs may be entered using the bar code scanner.

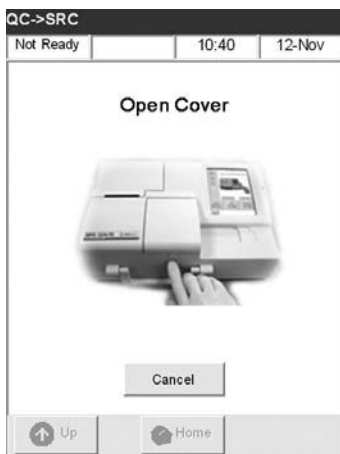


Fig. 4-3 Open Cover

4. Open the sample chamber cover by pressing the button (Fig. 4-3).

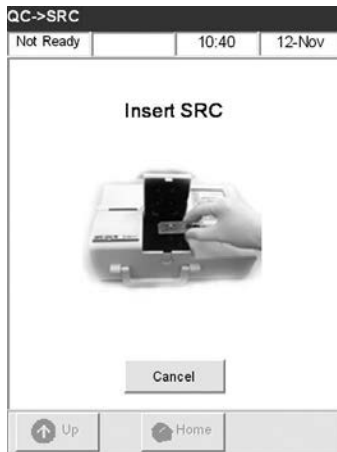


Fig. 4-4 Insert SRC

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



Fig. 4-5 Close Cover

6. Close the sample chamber cover (Fig. 4-5).

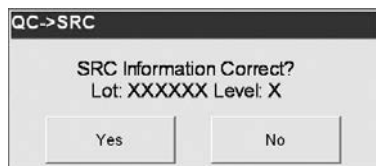


Fig. 4-6 Confirm SRC Information

After the cover has been closed, the instrument will automatically detect which level of SRC has been inserted and prompt you to verify the lot number and level (Fig. 4-6). This information can be found on both the SRC cassette itself and its storage pouch.

If the information shown on the display is correct, press to continue.

If this information is incorrect, press to interrupt this sequence and return to **<QC Manager>**. (See Section 3.3.1.1, "Setting up the Standard Reference Cassette (SRC)").

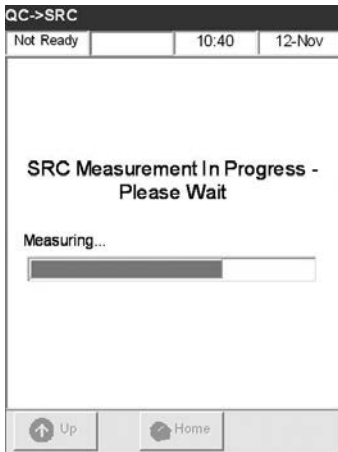


Fig. 4-7 SRC Measurement

QC->SRC->Results			
Ready		10:40	12-Nov
Para-meter	Result	Limits	Pass / Fail
pH	7.42	7.417 - 7.431	PASS
PCO2	40.1	39.1 - 41.1	PASS
PO2	89.7	88.6 - 92.6	PASS
Na+	149.3	148.5 - 150.5	PASS
K+	5.01	4.93 - 5.07	PASS
Ca++	1.21	1.17 - 1.25	PASS
Cl-	5.01	4.93 - 5.07	PASS
Glu	1.21	1.17 - 1.25	PASS

Navigation buttons: Back, Page 1 of 2, Next, Up, Home.

Fig. 4-8 SRC Results (1)

QC->SRC->Results			
Ready		10:40	12-Nov
Para-meter	Result	Limits	Pass / Fail
BUN	6.0	4.2 - 7.0	PASS
Lac	2.3	2.0 - 3.0	PASS
tHb	11.2	6.00 - 10.0	FAIL
SO2	81.0	82.0 - 91.0	FAIL

Navigation buttons: Back, Page 2 of 2, Next, Up, Home.

Fig. 4-9 SRC Results (2)

After you have verified that the SRC information is correct, the instrument begins the measurement process which is indicated on the display screen (Fig. 4-7). During this time (about 60 seconds), a progress bar is displayed.

- When the measurement is complete, the unit displays the results (Fig. 4-8 and Fig. 4-9).

NOTE: Results obtained are applicable to the sensor cassette type being used for patient sample.

- 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.
- Open the sample chamber cover and remove the SRC.
 - Place the SRC back into its pouch immediately after removal from the instrument.
 - 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 of this manual.
 - Perform the second SRC measurement with another SRC Level in the same manner. If both SRC tests passed, the unit is ready to perform measurements.

NOTE: For application of QC Lockout, please refer to section 3.3.3.1.2.

NOTE: Verify with your particular regulatory agency and your internal policy regarding number of levels and frequency of SRCs to be run. A third level (normal range) of SRC is available as an option (Part Number BP7554).

4.5.2 Printing SRC Results

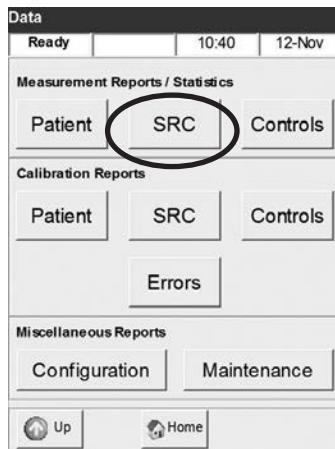


Fig. 4-10 Select SRC



Fig. 4-11 SRC Measurements

The screenshot shows the 'Data->SRC Measurement->View' screen with the following table:

Para-meter	Result	Limits	Pass / Fail
pH	7.42	7.417 - 7.431	PASS
PCO2	40.1	39.1 - 41.1	PASS
PO2	89.7	88.6 - 92.6	PASS
tHb	8.1	6.00 - 6.10	FAIL
SO2	20	13.1 - 13.5	FAIL
Na+	149.3	148.5 - 150.5	PASS
K+	5.01	4.93 - 5.07	PASS
Ca++	1.21	1.17 - 1.25	PASS

Up | Home

Fig. 4-12 View SRC Results

This menu allows you to print out SRC reports or SRC statistical information.

1. From the **<Ready>** display, select **<Data Manager>**.
2. Select **<SRC>** (Fig. 4-10).
3. In the **<Data - SRC Measurement>** screen (Fig. 4-11), press the **View** button to display the SRC results (Fig. 4-12). Use the **Up** and **Down** buttons to display the previous or next page of results.
4. To print individual results, highlight the desired measurement (Fig. 4-11). To print groups of results, highlight the first measurement to be printed, press **Mark**, then select the last measurement to be printed. All the measurements in between will be selected. Press **All** to select all results.
5. Press **Print** to print your selection.
6. Press the **<Statistics>** button to print out the statistics from the most recent 30 days of SRC measurements for all levels.
7. After printout, the database can be deleted by pressing **Delete**.
8. If a password has been activated under **<Setup>**, you must enter it at this time before the data is deleted.

The unit will now delete all SRC data from the internal database.

9. Press **Home** to return to the **<Ready>** display.

4.5.3 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 use only manufacturer recommended controls such as 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 PO₂ 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.

4.5.3.1 Running Controls (OPTI CHECK, OPTI CHECK PLUS)

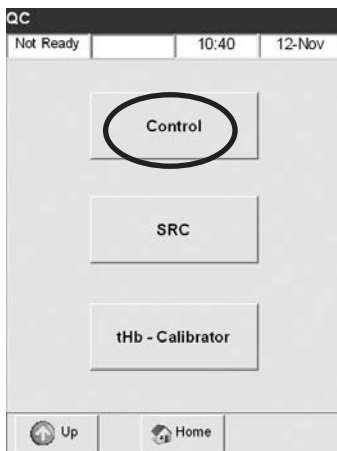


Fig. 4-13 Select Control

1. In the **<Ready>** display, press **<QC Manager>**.
2. Select **<Control>** (Fig. 4-13).



Fig. 4-14 Enter Operator ID

3. Enter your Operator ID, or 4-digit PIN using the alphanumeric keypad (Fig. 4-14).

To bypass this function, press .

NOTE: If Operator ID is configured as "required" in Setup, you cannot go to the next step until a number is entered.

NOTE: If Secure Op. IDs is activated under Setup, you will be prompted for your 4-digit PIN # instead of your Op. ID.

NOTE: Bar-coded Operator IDs may be entered using the bar code scanner.

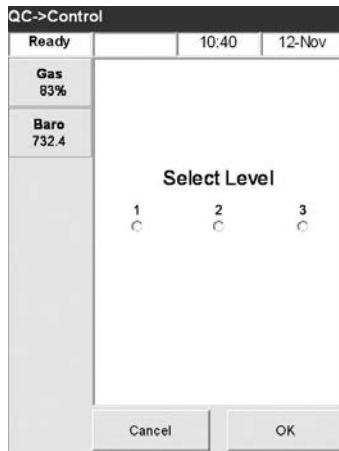


Fig. 4-15 Select QC Level

4. Select the desired level (Fig. 4-15) and press

.

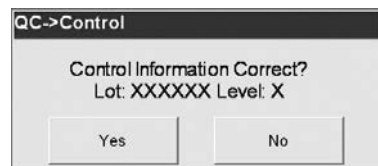


Fig. 4-16 Confirm Lot Number

5. Press if the lot number is correct (Fig. 4-16).

NOTE: If a new lot number of QC material is entered, make sure the ranges have been entered into the system prior to running a sample. (See Chapter 3, Customization). If the password function is enabled, you will be asked for it before deleting the database for the old lot number.

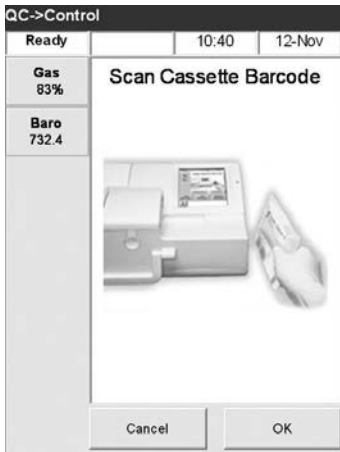


Fig. 4-17 Scan Bar Code

6. 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. 4-17).

- 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.

NOTE: Refer to special handling instructions inside the cassette box for refrigerated cassettes.

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. 4-18 Open Cover

7. Open the sample chamber cover by pressing the release button (Fig. 4-18).
8. Tear open the cassette pouch being careful not to tear the bar code. Remove the cassette and 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.



Fig. 4-19 Insert Cassette

9. Insert the cassette into the chamber. Press down to ensure that the cassette is seated properly (Fig. 4-19).

NOTE: Run cassettes immediately after opening pouch, if possible, but no later than 15 minutes after opening the pouch.

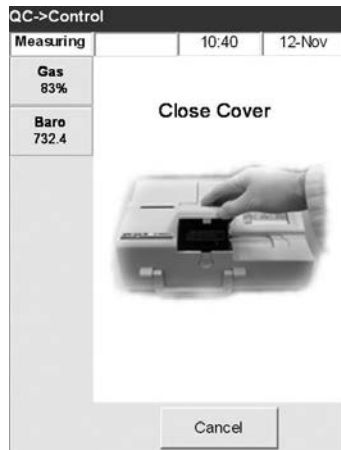


Fig. 4-20 Close Cover

10. Close the SMC cover (Fig. 4-20).

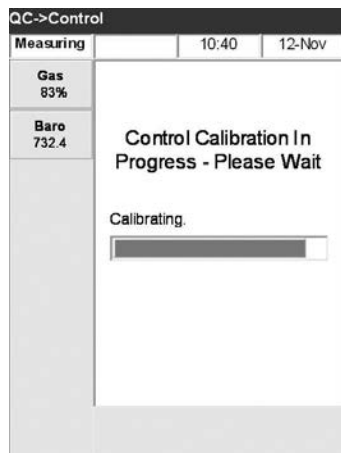


Fig. 4-21 Control Calibration

11. The system starts to calibrate (Fig. 4-21).
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.

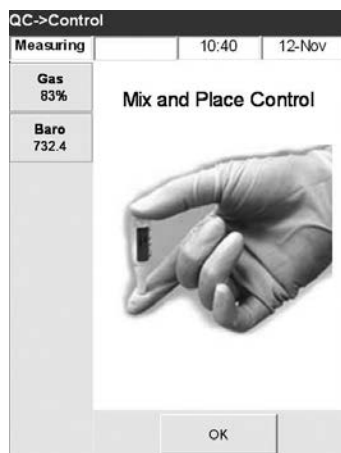


Fig. 4-22 Place Control

12. Calibration is complete and it is time to place a sample (Fig. 4-22).

- 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.

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

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

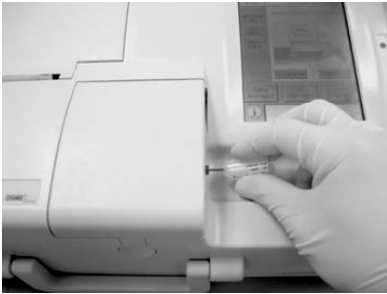


Fig. 4-23 Direct Aspiration

- Either aspirate directly from the ampoule or use a capillary to withdraw a small amount of control material from the ampoule for aspiration.

13. Hold the ampoule at a 45° angle during aspiration (Fig. 4-23). Use a new ampoule for each sample.



Fig. 4-24 Attach Capillary Tube

14. If using capillary tubes, push the tube firmly into the fillport (see Fig. 4-24).

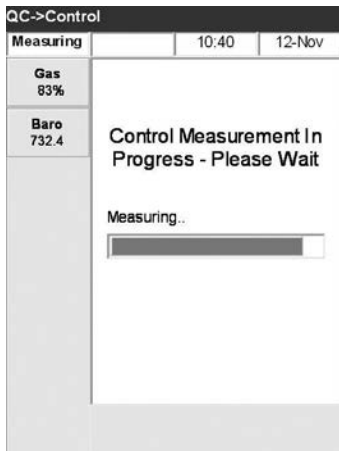


Fig. 4-25 QC Measurement

15. Press . The QC sample is aspirated into the cassette and the measurement starts (Fig. 4-25). At this time the status light begins flashing green indicating that the cover should not be opened.

QC->Control->Results			
Ready		10:40	12-Nov
Parameter	Result	Limits	Pass / Fail
pH	7.42	7.417 - 7.431	PASS
PCO2	40.1	39.1 - 41.1	PASS
PO2	89.7	88.6 - 92.6	PASS
tHb	8.1	6.00 - 6.10	FAIL
SO2	20	13.1 - 13.5	FAIL
Na+	149.3	148.5 - 150.5	PASS
K+	5.01	4.93 - 5.07	PASS
Ca++	1.21	1.17 - 1.25	PASS

Fig. 4-26 QC Results

Upon completion of the measurement, the results are displayed (Fig. 4-26).

- The OPTI CCA-TS 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 (E-Ca Type shown for reference).

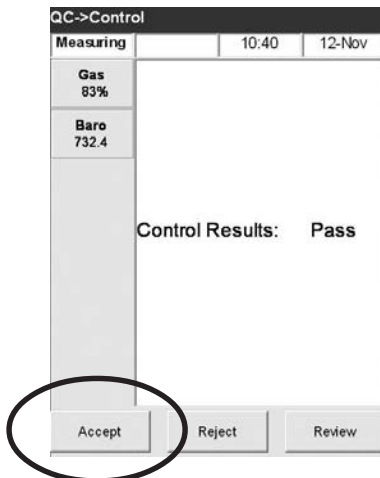



Fig. 4-27 Accept QC Results

16. Press  to accept or reject results.

- Press <Accept> if results are acceptable (Fig. 4-27), 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.

In either case, the results will be printed when the data input is complete. Please follow the regulatory guidelines of your hospital for documenting corrective action, if results are rejected.

If any of the results are outside of the OPTI CCA-TS's measurement range, giving a 'LOW' or 'HIGH', the results cannot be accepted to the controls database.

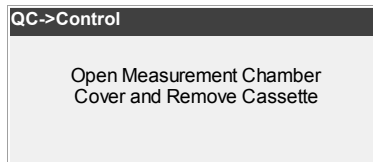


Fig. 4-28 Open SMC Cover and Remove Cassette

17. Open the sample chamber cover and remove the cassette (Fig. 4-28).

- If other levels of controls are to be run, repeat the procedure.

4.5.4 Printing Control Reports

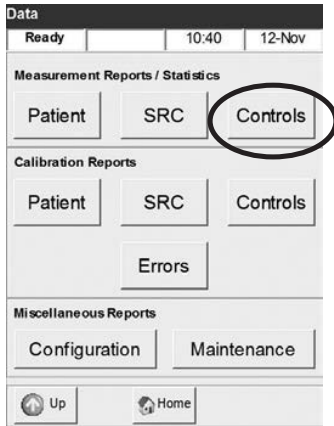


Fig. 4-29 Select Controls

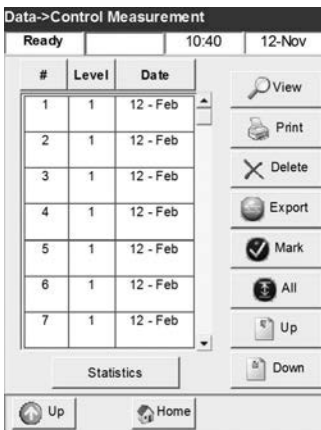


Fig. 4-30 Controls Measurement

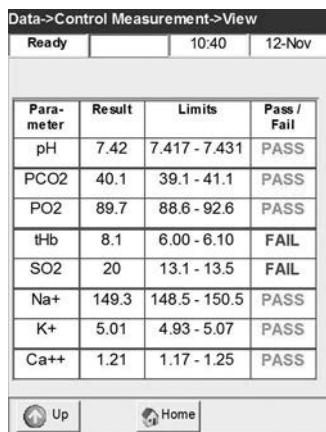


Fig. 4-31 View Control Results

Your OPTI CCA-TS can print control measurement reports and statistical information.

1. In the **<Ready>** display, select **<Data Manager>**.
2. Press **<Controls>** (Fig. 4-29).
3. In the **<Data - Control Measurement>** screen (Fig. 4-30), press the **View** button to display the Control results (Fig. 4-31). Use the **Up** and **Down** buttons to display the previous or next page of results.
4. To print individual results, highlight the desired measurement (Fig. 4-30). To print groups of results, highlight the first measurement to be printed, press **Mark**, then select the last measurement to be printed. All the measurements in between will be selected. Press **All** to select all results.
5. Press **Print** to print your selection.
6. Press the **<Statistics>** button to print a statistical report of the last 30 control measurements or more, if available in database.
8. After printout, the database can be deleted by pressing **Delete**.
9. Before the database is deleted, enter the password to initiate the procedure, if a password has been activated under **<Setup>**.
10. Press **Home** to return to the **<Ready>** display.

4.5.5 Sending Data to a Computer

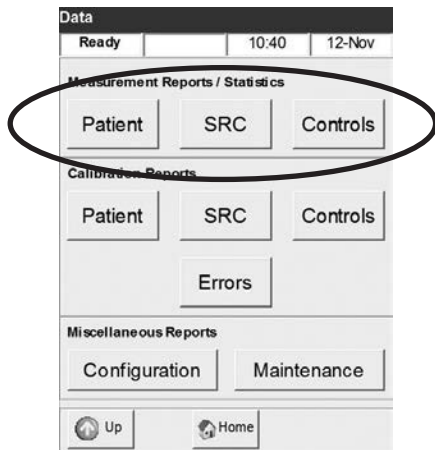


Fig. 4-32 Select Data

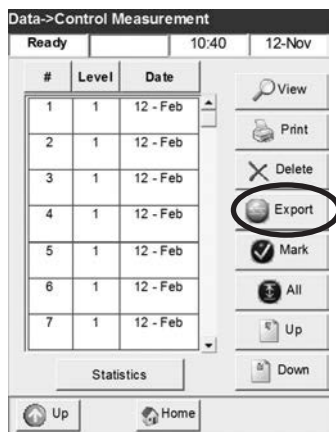


Fig. 4-33 Export Data

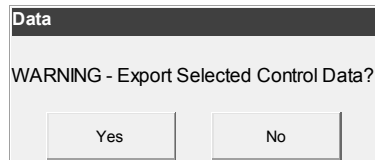



Fig. 4-34 Export Selected Data

The OPTI CCA-TS 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-TS communication port must be configured (See section 3.3.3.5) and a physical connection to the receiving computer must be made.

Before exporting to the Compact Flash (CF) Card (included in CF Export Kit BP7140), make sure that the Compact Flash card is properly inserted in the CF port.

1. In the **<Ready>** display, select **<Data Manager>**.
2. Select **<Patient>**, **<SRC>** or **<Controls>** (Fig. 4-32).
3. Select the data to be exported and press  to start the data transfer (Fig. 4-33).

A warning will be displayed asking you to confirm your choice (Fig. 4-34).

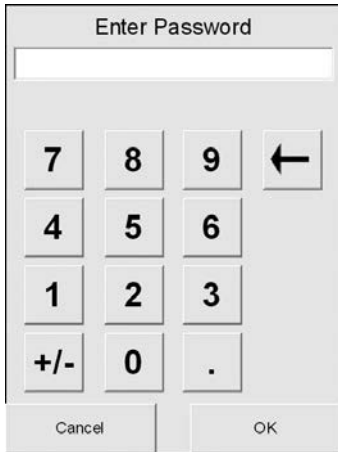


Fig. 4-35 Enter Password

If the password has been activated under **<Setup>**, you will be asked to enter the password to initiate the procedure.

4. Use the numeric keypad to enter the password (Fig. 4-35).

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5 SAMPLE HANDLING AND PATIENT TESTING

The OPTI™ CCA-TS Analyzer provides fast and convenient measurement of pH, PCO_2 , PO_2 , Na^+ , K^+ , Ca^{++} , Cl^- , Glu, BUN (urea), Lac, 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 $\bar{P}O_2$ 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.

5.1.5 Capillary Tubes

Capillary blood specimens should be collected using capillary tubes which have a minimum volume, filled, of 125 μ L. The OPTI Medical capillary tubes (MC0024) are ideally suited with a minimum volume, filled, of 200 μ L. The capillary tubes for pH, blood gas, and electrolyte analysis should not be used for samples taken for the analysis of lithium.

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-TS 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 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 sedimentation 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-TS 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-TS.

The OPTI CCA-TS 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.

5.1.8 Test Conditions

Sample Size:	a minimum of 125 μ L (60 μ L for B60 cassette)
Sample Type:	heparinized whole blood, serum, plasma
Sample Application:	syringe, capillary or ComfortSampler
Ambient Temperature:	10 - 32 °C (50 – 90 °F)
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)

5.2 Sample Preparation

5.2.1 Whole Blood Samples

Collect blood in a heparinized syringe, a capillary tube or a ComfortSampler. 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.

WARNING: *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.*

WARNING: *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)

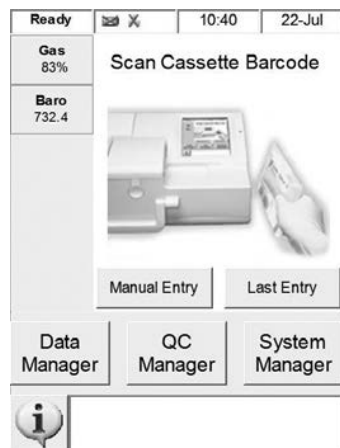


Fig. 5-1 Ready Display

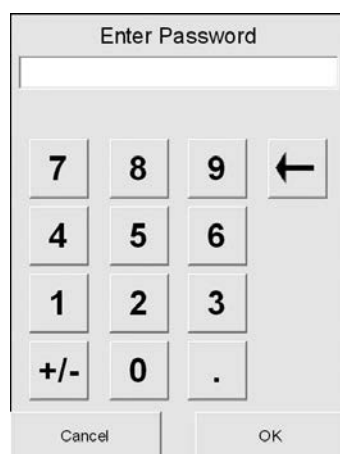


Fig. 5-2 Enter Password



Fig. 5-3 Scan Bar Code

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

1. Turn on the OPTI CCA-TS and wait until this display appears (Fig. 5-1).

2. Enter the password if requested (Fig. 5-2).

NOTE: During warm-up, the OPTI CCA-TS checks the gas pressure. Once the gas bottle pressure reaches 10% or less, the value will be displayed in red. If the pressure is too low, a warning will appear alerting you to low gas or no gas. If no gas remains refer to section 6.5.1 of this manual to remove and install a new gas bottle.

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. 5-3).
 - 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 indicates an invalid bar code (e.g. cassette expired).
Read the message on the analyzer display for detailed information (See Chapter 7, Troubleshooting).

NOTE: Refer to special handling instructions inside the cassette box for refrigerated cassettes.

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



Fig. 5-4 Open SMC Cover



Fig. 5.5 Open Cassette Packet and Insert Cassette



Fig. 5-6 Close Cover

- Press the cover release button to open the Sample Measurement Chamber (SMC) (Fig. 5-4).

NOTE: If using the same lot number of cassette as the previous patient sample, the cassette information may be recalled by pressing the <Last Entry> button in the <Ready> screen. The analyzer will then identify the lot number, and prompt you to open the cover, wipe and insert the cassette and close the cover.

- Enter your Operator ID or four (4) digit PIN # if requested.

4. Insert the cassette as follows:

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

NOTE: The cassette should be run immediately after opening the pouch, but no later than 15 minutes after opening.

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

NOTE: If possible avoid tearing the bar code when opening the cassette pouch.

- 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. 5-5).
- Close the SMC cover by pressing it down firmly (Fig 5-6).
- 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.

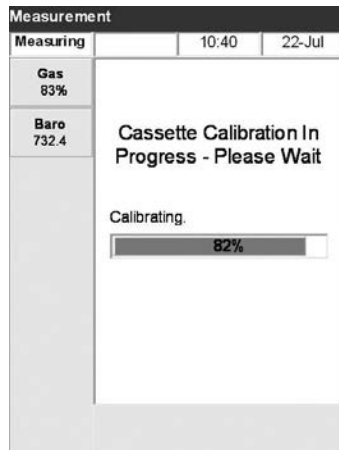


Fig. 5-7 Cassette Calibration

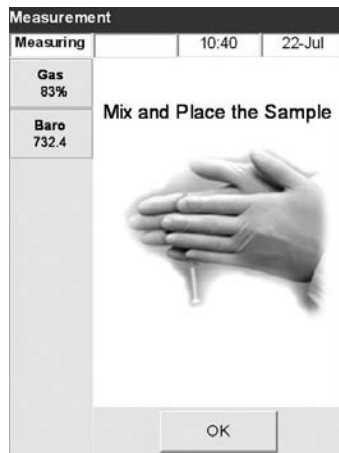


Fig. 5-8 Mix and place sample

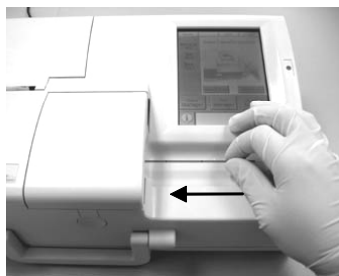


Fig. 5-9 Attach Capillary

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

NOTE: The OPTI CCA-TS 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-TS 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/SO₂ has been disabled (see Section 3.3.2.2), you may attach the sample at any time during calibration and press . The sample will then be automatically aspirated after calibration and the measurement will begin.

- After the successful calibration the status light will stop blinking, and the display will prompt you to mix and place the sample (Fig. 5-8). Mix the syringe 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.

- Using a capillary, a syringe and adapter, or ComfortSampler, attach the sample to the cassette fillport (Fig. 5-9 and Fig. 5-10), and press .

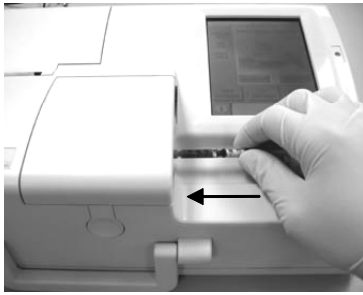


Fig. 5-10 Attach Syringe Sample

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

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

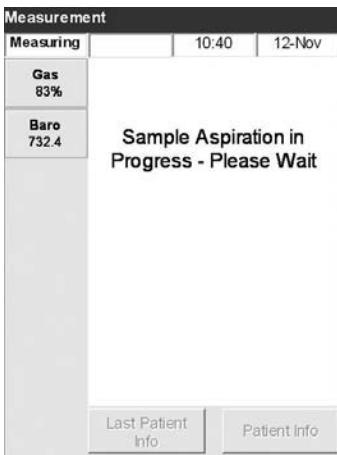


Fig. 5-11 Sample Aspiration

- The sample will then be aspirated (Fig. 5-11).

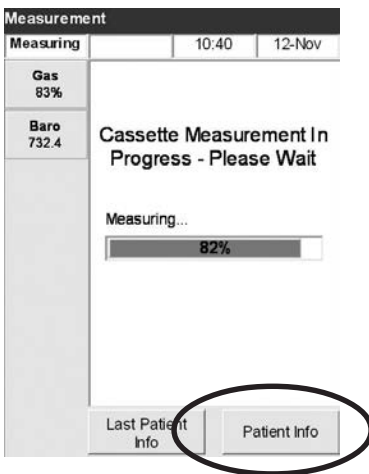


Fig. 5-12 Sample Measurement

- Next the sample is measured. During the measurement the status light is blinking and a progress bar is displayed (Fig. 5-12).
Do not open the cover of the sample measurement chamber during the measurement. If you do, the cassette and the sample must be discarded.
8. To enter patient information while measurement is in progress, press **<Patient Info>** (Fig. 5-12).

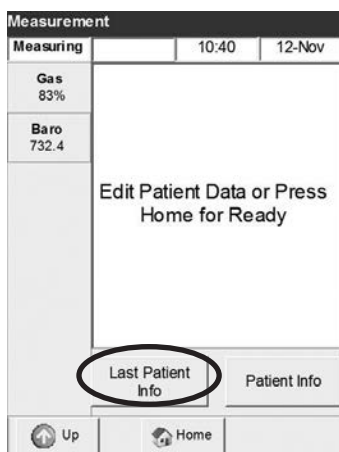


Fig. 5-13 Edit Patient Data

The screenshot shows the 'Measurement->Patient Data' screen, labeled 'Page 1 of 7'. It features a status bar with 'Measuring', '10:40', and '12-Nov'. The main area contains several input fields with 'Edit' buttons: 'Operator ID', 'Patient ID', 'DOB', 'Accession #', and 'Temperature'. Below these is a 'Sex' section with radio buttons for '?', 'Male', and 'Female'. At the bottom, there are 'Back', 'Next', 'Finish', and 'Home' buttons, along with a '15%' indicator.

Fig. 5-14 Edit patient data (1)

The screenshot shows the 'Measurement->Patient Data' screen, labeled 'Page 2 of 7'. It features a status bar with 'Measuring', '10:40', and '12-Nov'. The main area contains several input fields with 'Edit' buttons: 'tHb', 'FIO₂', 'MCHC %', 'RQ', and 'P₅₀'. At the bottom, there are 'Back', 'Next', 'Finish', and 'Home' buttons, along with a '30%' indicator.

Fig. 5-15 Edit patient data (2)

- Press the **<Last Patient Info>** button (Fig. 5-13) to use the last patient info as the default for the current patient info.
 - This option will populate all patient info fields with the last patient data including patient ID and operator ID numbers. If operator ID security is enabled, the operator ID field will display the operator ID of the last patient sample. All patient information used as the default can be edited.
 - Verify that patient ID, operator ID, and all other input parameters are correct for every patient sample measurement.
 - Press the **<Patient Info>** button to enter new patient info or to not use the last patient info as the default.
9. The first patient data entry screen contains the following information (Fig. 5-14):
- Operator ID (11 alphanumeric characters)
 - Patient ID (15 alphanumeric characters)
 - Accession No. (12 alphanumeric characters)
 - Date of Birth (DOB)
 - Temperature (default value 37.0 °C)
 - Sex (unknown, male or female)

NOTE: Patient and Operator IDs and Accession Nos. may be entered using the bar code scanner.

10. To enter patient data, press **Edit**. Use the alphanumeric keypad to type in the desired information. Press **OK** to save the information entered.
11. Pressing **Next** will access subsequent patient data entry screens (Fig. 5-15):
- tHb (default value 15.0 g/dL)
 - FIO₂ (default value 0.21)
 - MCHC (default value 33.3%)
 - RQ (default value 0.84)
 - P₅₀ (default value 26.7 mmHg)

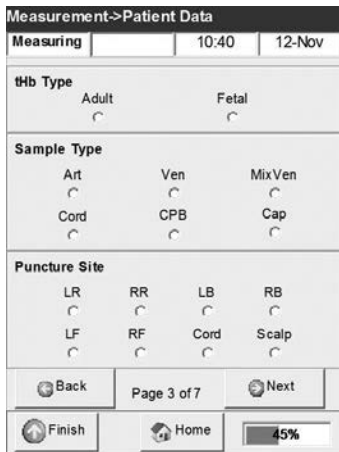


Fig. 5-16 Edit patient data (3)

12. Press **Next** again and the following patient information is displayed (Fig. 5-16):

- Hb Type (adult or fetal, default is adult)
- Patient 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

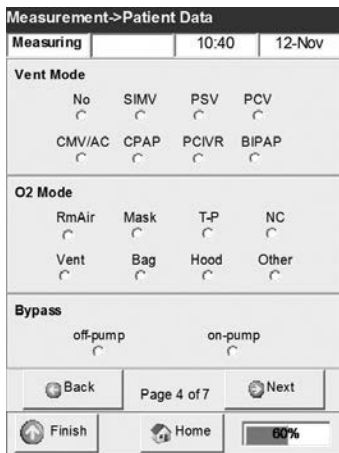


Fig. 5-17 Edit patient data (4)

13. Press **Next** for the following information (Fig. 5-17):

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

PRVC = Pressure-Regulated Volume Control

- 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

- Bypass (Off-pump or on-pump)

Measurement->Patient Data			
Measuring		10:40	12-Nov
PEEP	<input type="text"/>	<input type="button" value="Edit"/>	
CPAP	<input type="text"/>	<input type="button" value="Edit"/>	
Rate (f)	<input type="text"/>	<input type="button" value="Edit"/>	
Liter Flow	<input type="text"/>	<input type="button" value="Edit"/>	
TVol (VT)	<input type="text"/>	<input type="button" value="Edit"/>	
MVol (VE)	<input type="text"/>	<input type="button" value="Edit"/>	
PIP	<input type="text"/>	<input type="button" value="Edit"/>	
Pplat	<input type="text"/>	<input type="button" value="Edit"/>	
PS	<input type="text"/>	<input type="button" value="Edit"/>	
<input type="button" value="Back"/> Page 5 of 7 <input type="button" value="Next"/>			
<input type="button" value="Finish"/> <input type="button" value="Home"/> <input type="button" value="75%"/>			

Fig. 5-18 Edit patient data (5)

14. The next set of patient data contains the following information (Fig. 5-18):
- PEEP (default value 0)
 - CPAP (default value 0)
 - Rate (f) (default value 0 bpm)
 - Liter Flow (default value 000.00 Lpm)
 - TVol (VT) (default value 0 mL)
 - MVol (VE) (default value 0 L)
 - PIP (default value 0)
 - Pplat (default value 0)
 - PS (default value 0)

Measurement->Patient Data			
Measuring		10:40	12-Nov
Bilevel Pressure			
<input type="text"/>	<input type="button" value="Edit"/>		
<input type="text"/>	<input type="button" value="Edit"/>		
I/E Ratio			
<input type="text"/>	<input type="button" value="Edit"/>		
<input type="text"/>	<input type="button" value="Edit"/>		
<input type="button" value="Back"/> Page 6 of 7 <input type="button" value="Next"/>			
<input type="button" value="Finish"/> <input type="button" value="Home"/> <input type="button" value="90%"/>			

Fig. 5-19 Edit patient data (6)

15. Press again and select the following (Fig. 5-19):
- BiLevel Pressure (default value 0.00/0.00)
 - I/E Ratio (default value 0)

Measurement->Patient Data			
Measuring		10:40	12-Nov
User Field 1	QQQQQQQQQ	<input type="button" value="Edit"/>	
User Field 2	QQQQQQQQQ	<input type="button" value="Edit"/>	
User Field 3	QQQQQQQQQ	<input type="button" value="Edit"/>	
Blanking			
pH:	<input type="checkbox"/>	Cl-:	<input type="checkbox"/>
PCO2:	<input type="checkbox"/>	Ca++:	<input type="checkbox"/>
PO2:	<input type="checkbox"/>	Glu:	<input type="checkbox"/>
Na+:	<input type="checkbox"/>	Urea/BUN:	<input type="checkbox"/>
K+:	<input type="checkbox"/>	Lac:	<input type="checkbox"/>
		tHb/SO2:	<input type="checkbox"/>
<input type="button" value="Back"/> Page 7 of 7 <input type="button" value="Next"/>			
<input type="button" value="Finish"/> <input type="button" value="Home"/> <input type="button" value="100%"/>			

Fig. 5-20 Edit patient data (7)

16. The last set of patient data contains the following information (Fig. 5-20):
- User Field 1 (9 alphanumeric characters)
 - User Field 2 (9 alphanumeric characters)
 - User Field 3 (9 alphanumeric characters)
 - Blanking

NOTE: Parameter blanking will omit a parameter from the printout. (See Section 3.3.2.2 for detailed description).

17. If no value is entered, a default value will be used and printed.


Measurement->Results	
Measuring	10:40 12-Nov
Measured	Calculated
pH	7.188
PCO2	70.6 mmHg
PO2	70.5 mmHg
tHb	8.1 g/dL
SO2	20 %
Na+	126.0 mmol/L
K+	3.01 mmol/L
Ca++	1.55 mmol/L

Fig. 5-21 Measurement results

Measurement->Results	
Measuring	10:40 12-Nov
Measured	Calculated
BE	-3.8 mmol/L
tCO2	28.4 mmol/L
HCO3	26.2 mmol/L
BB	44.2 mmol/L
BEact	-4.5 mmol/L
BEecf	-2.0 mmol/L
stHCO3	20.7 mmol/L


Fig. 5-22 Calculated 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 until you have completed it or display the results immediately by pressing  Up at any time.

If the screen has not been touched for approximately three (3) minutes the results will automatically be displayed (Fig. 5-21).

The second tab displays the calculated parameters (Fig. 5-22).

18. Press  Up to move directly to the next sample display.

- If patient temperature was input, it will be displayed in place of a calculated parameter. In this case, the blood gas values displayed are temperature corrected.
- The display will show results according to the type of sensor cassette used (See Chapter 9.2, 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 3.3.2.6).
- The OPTI CCA-TS Analyzer “flags” values that are above or below the programmed ranges with an up or down arrow. If the value is outside the measurable range, a ‘HIGH’ or ‘LOW’ will be displayed and a > or < with a range printed out in the message section on the patient report.
- 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.

Measurement->Results			
Measuring		10:40	12-Nov
Measured	Calculated	Calibration	
Parameter	Result	Limits	Pass / Fail
pH	7.42	7.417 - 7.431	PASS
PCO2	40.1	39.1 - 41.1	PASS
PO2	89.7	88.6 - 92.6	PASS
tHb	8.1	6.00 - 6.10	FAIL
SO2	20	13.1 - 13.5	FAIL
Na+	149.3	148.5 - 150.5	PASS
K+	5.01	4.93 - 5.07	PASS
Ca++	1.21	1.17 - 1.25	PASS

Up Home

Fig. 5-23 Calibration results

The third tab displays calibration data from the gas calibration preceding the measurement (Fig. 5-23).

19. Open the cover and remove the cassette and press  Home to go to the next sample.

To edit the patient data, press **<Patient Data>**.

NOTE: The printout will automatically start when the first results are displayed. This feature may be turned off in setup (See Section 3.3.3.6).

5.4 Printing Patient Reports

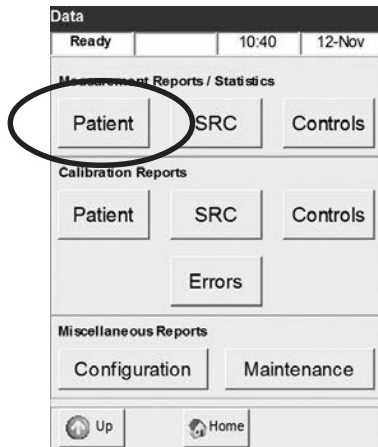


Fig. 5-24 Select Patient Report

 A screenshot of the 'Data->Patient Measurement' screen. At the top, it shows 'Ready', '10:40', and '12-Nov'. Below this is a table with the following data:

#	Patient ID	Date
7001	422556776	21-Jun-2010
6553	793824543	27-May-2010
6347	987432647	25-May-2010
5923	787356987	15-Apr-2010

 To the right of the table are several icons: a magnifying glass (View), a printer (Print), a checkmark (Mark), a trash can (Delete), and a globe (All). At the bottom are 'Up' and 'Home' navigation buttons.

Fig. 5-25 Measurement Results

This menu lets you print out patient reports. You can print out individual patient results, groups of patient results, or all the results in memory.

1. From the **<Ready>** display, select **<Data Manager>**.
2. Press **<Patient>** (Fig. 5-24).
3. In the **<Patient Measurement>** screen (Fig. 5-25), press the **View** button to display the measurement results. The sorting order within the individual columns may be changed from ascending to descending by pressing the column header.
4. To print individual results, highlight the desired measurement. To print groups of results, highlight the first measurement to be printed, press **Mark**, then select the last measurement to be printed. All the measurements in between will be selected. Press **All** to select all results.
5. Press **Print** to print your selection.
6. After printing, patient data may be deleted by pressing **Delete**.
 - After data has been deleted, the system will return to the **<Data Manager>**.
7. Press **Home** to return to the **<Ready>** screen.
 - If a password has been selected under the setup menu, it must be entered prior to deleting data from the database.

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6 MAINTENANCE

6.1 Daily Maintenance

No daily maintenance is required for the OPTI™ CCA-TS system.

6.2 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 ammonia-based cleaner as needed. Be sure to remove all blood residue. A cotton swab may be used for cleaning the smaller parts of the SMC.

6.3 Quarterly Maintenance – Performing tHb Calibration

6.3.1 Performing HbCal - tHb-Calibrator

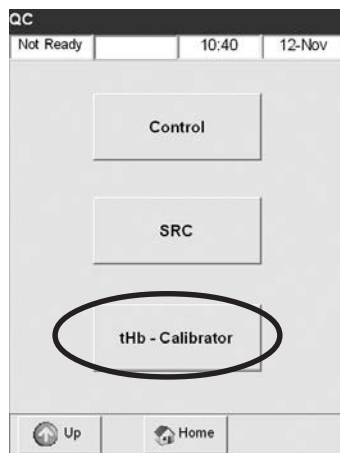


Fig. 6-1 Select tHb-Calibrator

1. In the <Ready> display, select <QC Manager>.
2. In the <QC Manager> menu, select <tHb-Calibrator> (Fig. 6-1).



Fig. 6-2 Enter Password

- 3. Use the numeric keypad to enter the password (factory default 404) (Fig. 6-2).



Fig. 6-3 Enter Operator ID

- 4. Use the alphanumeric keypad to enter the Operator ID or press **OK** to bypass this function (Fig. 6-3).

NOTE: If Operator ID is configured as “required” in Setup, you cannot go to the next step unless a valid Op. ID is entered.

NOTE: If Secure Op. IDs is activated under Setup, you will be prompted for your 4-digit PIN # instead of your Op. ID.

NOTE: Bar-coded Operator IDs may be entered using the bar code scanner.

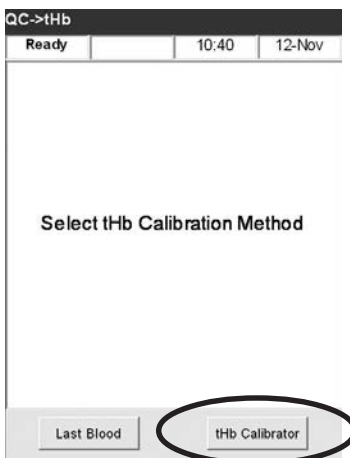


Fig. 6-4 Select tHb Calibrator

- 5. Select **<tHb Calibrator>** (Fig. 6-4).

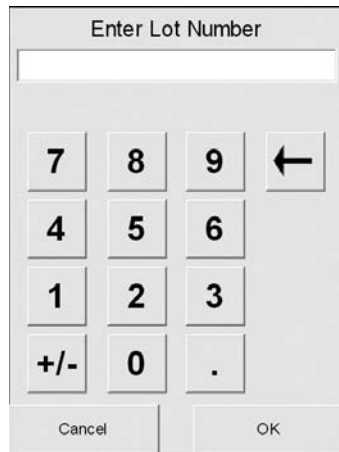


Fig. 6-5 Enter Lot Number

6. Enter the lot number of the tHb-Calibrator cassette located on the top surface of the cassette and press (Fig. 6-5).



Fig. 6-6 Open Cover

7. At the prompt open the SMC cover by pressing the button (Fig. 6-6).



Fig. 6-7 Clean Optics and Inside of Cover

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

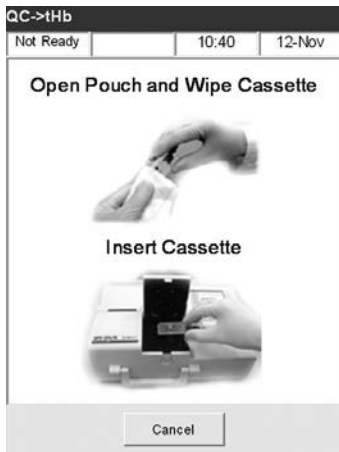


Fig. 6-8 Wipe and Insert Cassette

9. 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. 6-8).



Fig. 6-9 Close Cover

10. Close the sample chamber cover (Fig. 6-9).

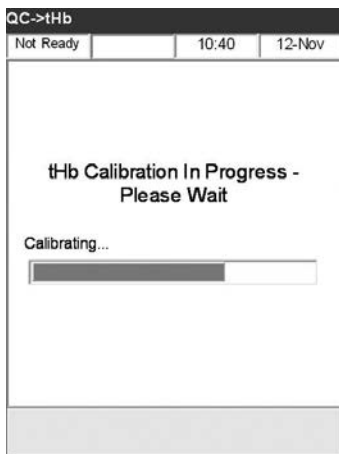


Fig. 6-10 tHb Calibration

After the cover has been closed, the instrument will automatically detect the presence of the calibrator cassette and begin calibration (Fig. 6-10).

11. After the calibration is complete you will be prompted to open the sample chamber cover and remove the cassette.
12. 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.

```

OPTI Medical OPTI CCA
  Calibration Report
    DD-MMM-YY  HH:MM
S/N: XXXX
Version: ABCX.XX

Operator ID:
HbCal Type: tHb-Calibrator
HbCal LOT: XXXXXX
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

```

The unit will now begin printing the tHb Calibration Report showing both the old and new calibration results and calibration factors (Fig. 6-11).

Fig. 6-11 HbCal Report

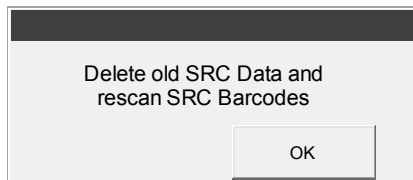


Fig. 6-12 Delete and rescan SRC data

13. After completion of Hb Calibration, it is necessary to delete and reload the current SRC data for each level. (Refer to section 3.3.1.1 Setting up the Standard Reference Cassette).
14. Press (Fig. 6-12) to proceed to the **<SRC Setup>** menu.
15. Verify performance by now running SRC measurements and 3 levels of OPTI Check.

6.3.2 Performing HbCal – Last Blood

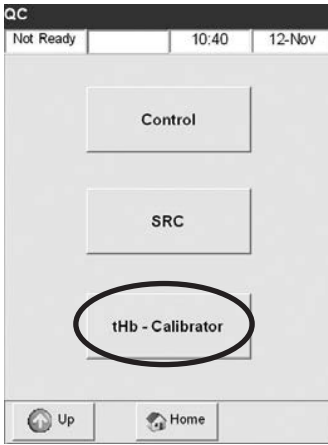


Fig. 6-13 Select tHb-Calibrator

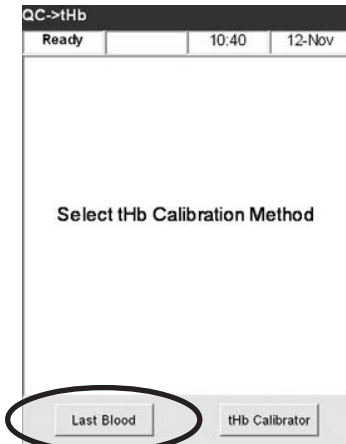


Fig. 6-14 Select Last Blood



Fig. 6-15 Enter tHb Value

1. Perform a tHb Calibration using the tHb-Calibrator Cassette (per Section 6.3.1) prior to beginning HbCal-Last Blood.
2. Perform a normal sample analysis using a sample previously measured on an alternate analyzer. Ensure the sample is well mixed prior to measurement.
3. From the **<Ready>** display, select **<QC Manager>**.
4. Press **<tHb-Calibrator>** (Fig. 6-13).
5. Select **<Last Blood>** (Fig. 6-14).
6. Use the numeric keypad to enter the tHb value (Fig. 6-15). Press to save the value.

NOTE: If an HbCal has been performed with the tHb-Calibrator, the last measured blood tHb and SO₂ will not be available and a new blood measurement must be made to perform an HbCal with blood. OPTI Medical Systems recommends use of the tHb-Calibrator and not blood for calibration of tHb and SO₂.

NOTE: A maximum of ± 3g/dL tHb correction and ± 3% SO₂ correction is allowed due to constraints within the instrument.

NOTE: The instrument will not allow a value to be entered that is outside the instrument's range for adjustment or measurement.

7. Use the numeric keypad to enter the SO₂ value. Press to save the value.
8. Press to return to the **<Ready>** screen.

6.4 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.

6.4.1 Replacing Peri Pump Cartridge

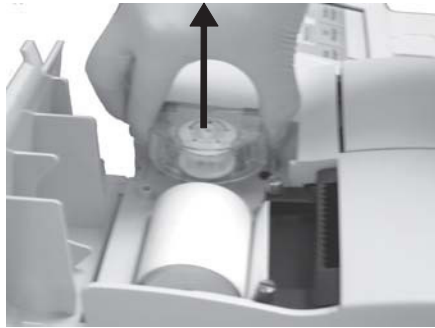


Fig. 6-16 Remove Pump Cartridge



Fig. 6-17 Pump Seals

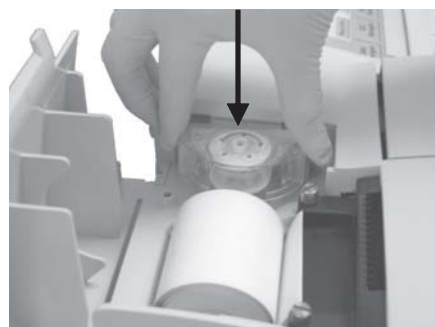


Fig. 6-18 Install New Cartridge

To change the cartridge:

1. Open the printer cover door. 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. 6-16).

2. Replace the pump seals only as needed. Remove the old pump seals with a pair of hemostats or tweezers (Fig. 6-17). 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.
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. 6-18).



Fig. 6-19 Push on Pump Roller

5. Press the pump cartridge roller down until it firmly seats on the shaft of the pump motor (Fig. 6-19).
6. Perform a **<Pump Test>** (see section 7.2.16) 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.

6.4.2 Replacing Gas I/O Port



Fig. 6-20 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. 6-20). Discard the old part.
2. Install the new gas I/O port with the rounded surface pointing up and press them 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 7.2.16) 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.

6.5 As Needed Maintenance

6.5.1 Changing the Gas Bottle



Fig. 6-21 Select New Gas Bottle

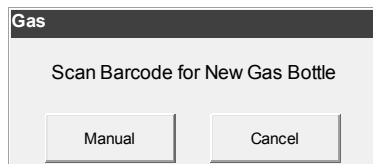


Fig. 6-22 Scan Bar Code

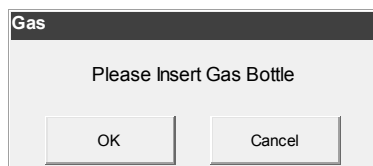


Fig. 6-23 Insert Gas Bottle



Fig. 6-24 Gas Bottle

The calibration gas bottle is designed to provide approximately 100 sampling operations, depending on the mode of use. The following message will alert the operator that the gas bottle needs to be changed (Fig. 6-21).

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. 6-22), scan the new gas bottle bar code 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 barcode scanner should cover the entire barcode.
 - The analyzer will beep when the barcode is accepted.
 - The barcode can be found on the gas bottle instructional insert.
 - Record the date of installation on the gas bottle for later reference.

NOTE: To enter the bar code manually, press **<Manual>** and enter the bar code using the numeric keypad.

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

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

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

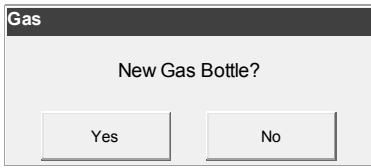


Fig. 6-25 New Gas Bottle

- In the **<New Gas Bottle?>** screen (Fig. 6-25), press **Yes** to confirm the installation of a new gas bottle.

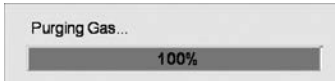


Fig. 6-26 Purging Gas

The analyzer will initiate a purge of the system, which will be indicated on the status bar on the bottom of the screen (Fig. 6-26).

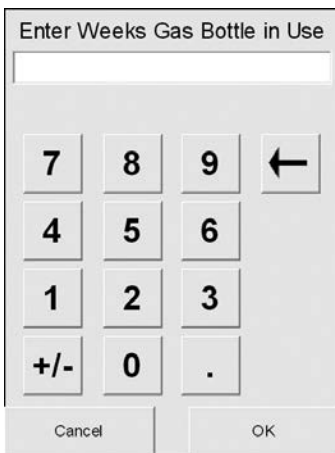


Fig. 6-27 Enter Number of Weeks in use

*NOTE: If you need to remove the gas bottle and reinstall it, respond **No** at the prompt **<New Gas Bottle?>**. You will then be prompted to enter the number of weeks in service using the numeric keypad (Fig. 6-27). Here you may refer back to the installation date, which was recorded on the gas bottle.*

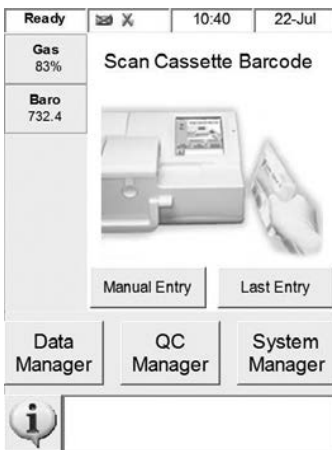


Fig. 6-28 Ready screen

- The unit will then return to the **<Ready>** screen (Fig. 6-28).

6.5.2 Changing the Printer Paper

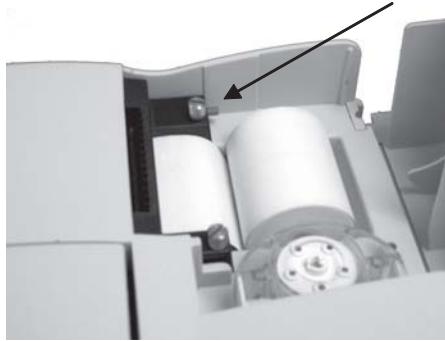


Fig. 6-29 Paper Advance Button

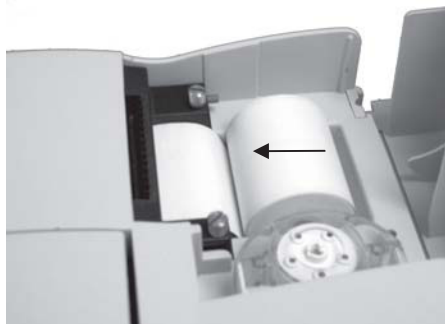


Fig. 6-30 Insert New Roll

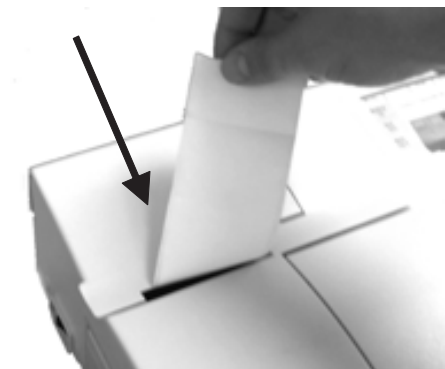


Fig. 6-31 Tear Off Excess Paper

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. Open the cover on the top of the analyzer.
2. Press the paper advance button to eject any remaining paper (Fig. 6-29).
3. Remove the old roll.
4. With the OPTI CCA-TS powered on, place a new roll of paper in the chamber and thread it into the feeder. Use the diagram in the paper well to make sure the paper is inserted correctly (Fig. 6-30).
5. As soon as the printer detects the paper, it will automatically feed the paper completely through the printer. The paper advance button should only be used if the paper is present.
6. To advance paper after the initial installation, press the red paper advance button located on the left side of the printer (See Fig. 6-29).
7. Close the top cover of the analyzer and tear off any excess paper (Fig. 6-31).

6.5.3 Performing Routine Cleaning

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

NOTE: Never use strong or abrasive cleaners on the OPTI CCA-TS Analyzer.

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7 DIAGNOSTICS AND TROUBLESHOOTING

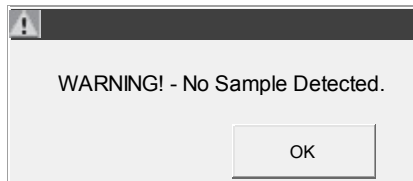
Your OPTI™ CCA-TS Analyzer is designed to provide trouble-free service.

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-TS specific error messages and recommends steps that should return your OPTI CCA-TS to operation.

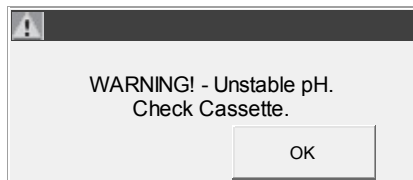
If your OPTI CCA-TS does not perform correctly after conducting the basic steps outlined in this chapter, you should contact OPTI Medical Systems for technical assistance.

7.1 Error Displays



The sensors did not see any sample. Make sure sample is properly attached and not clotted and does not contain air bubbles. Wait for the system to recalibrate.

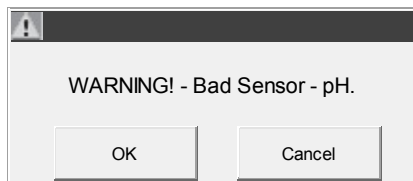
- Remix sample carefully.
- Press to notify the system that the sample is reattached and reaspirate sample.



The displayed measured parameter is unstable.

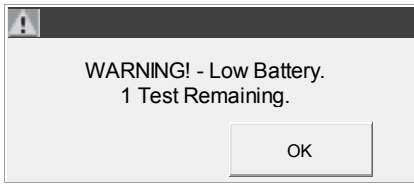
NOTE: This message is a warning. The analyzer will, however, display a result for the parameter concerned.

- Remove cassette and check for aspirated bubbles.
- If bubbles are present over a sensor, do not report that parameter.



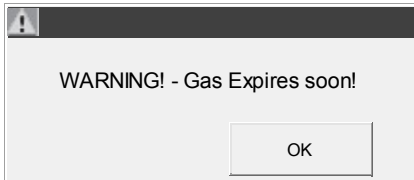
The displayed sensor is bad.

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



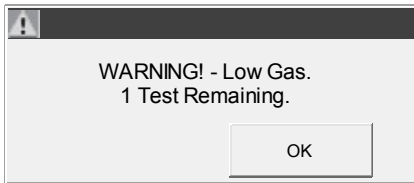
The battery voltage is low.

- Complete the current test by pressing .
- Replace the battery or recharge it by plugging the unit into the main power supply as soon as possible.



The gas bottle will expire in two weeks.

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

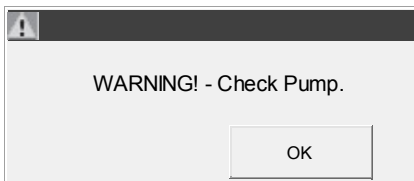


If the percentage in the gas bottle reaches 4 %, this message will be displayed.

- Complete the current test by pressing .
- Replace the gas bottle at the completion of the test. (See Section 6.5.1).

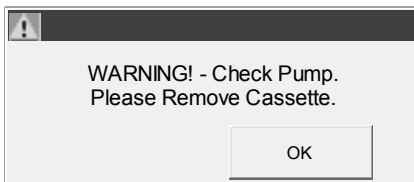
NOTE: Replace the gas bottle at the next warning, and the OPTI CCA-TS will automatically perform the necessary 1 minute gas purge. Otherwise use the diagnostic routine to perform the purge. (See Section 6.5.1).

NOTE: The gas bottle expires 9 months after installation or after exceeding the labeled expiration date, whichever comes first.



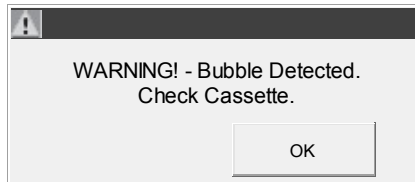
The peristaltic pump is getting worn.

- Press to continue measurement. Perform pump diagnostic (see Section 7.2.16), if this warning persists.
- If the pump diagnostic fails, replace the pump cartridge (see section 6.4).



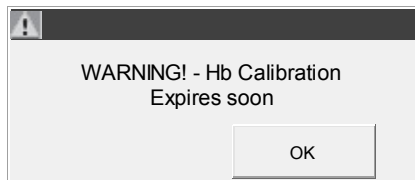
The peristaltic pump is getting worn.

- Remove the cassette.
- Retry with a new cassette.
- Change the peristaltic pump cartridge.



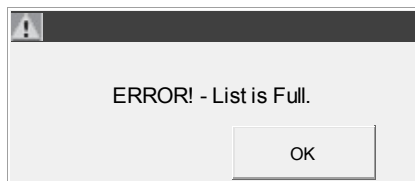
A bubble was detected at the light gates.

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



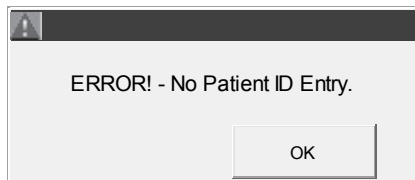
This display only appears once prior to the three month expiration of the tHb Calibration and acts as a reminder to run the tHb Calibrator.

- Press to continue.



The number of secure users (operator IDs) stored in memory equals 300.

- Press to continue.
- Delete unused Operator IDs from memory (See Section 3.3.3.1.3).



If Patient ID, Operator ID and/or Accession No. is required and not entered, this error will be displayed.

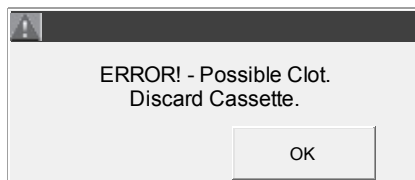
- Press to edit the patient data and add the required information. A new printout will be given with the required information.

NOTE: If the required information is not entered, results will be displayed and printed out, however, the system will not return to <Ready>.



Two or more measured parameter sensors are bad.

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



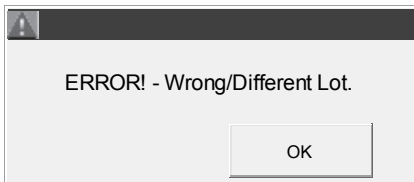
A sample error has occurred. This may be due to a clot or blockage preventing sample aspiration.

- Press and discard cassette.



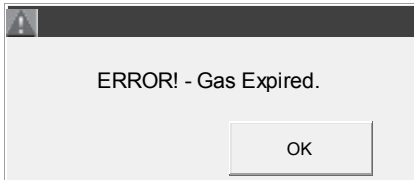
This error message appears when the reproducibility of the OPTI Check controls during the lactate setup procedure is out of range.

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



An incorrect cassette type or lot was scanned in during lactate setup.

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



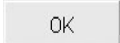
The gas bottle has expired or you have used an invalid bar code.

NOTE: The gas bottle expires 9 months after installation or after exceeding the labeled expiration date, whichever comes first.

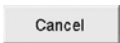
- Check the gas bottle label. Make sure it is for this particular gas bottle and the expiration date has not been exceeded. If expired, insert a new gas bottle.
- Check proper date setting in **<System ->Time and Date>**.



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.
- Press  to continue.

OR

- Press  to return to the **<Ready>** display and retry after installing a new cassette.



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.

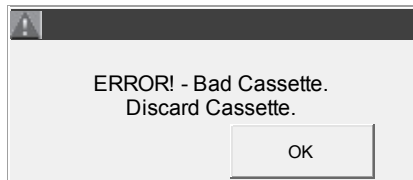
OR

- Press to use a different 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 wait 30 seconds. Then turn the power back on and retry.



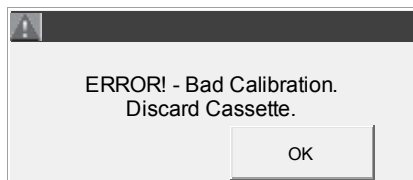
The cassette was not properly placed into the chamber or it was previously used.

- Press , discard the cassette and repeat test with a new cassette.
- If the message still appears with a different cassette, turn the power off and wait 30 seconds. Then turn the power back on and retry.



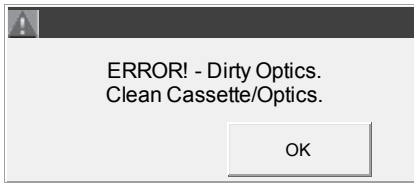
The cassette or its packaging is defective.

- Press , 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 wait 30 seconds. Then then turn power back on and retry.



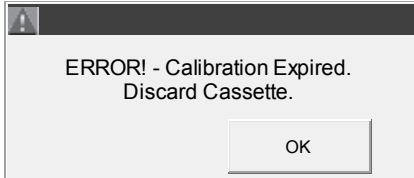
The instrument did not calibrate due to problems with the cassette or instrument.

- Press , 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 wait 30 seconds. Then turn the power back on and retry.



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 to rerun the test.



The cassette has been holding the calibration for more than 10 minutes without a sample being attached.

- Press and discard the cassette.



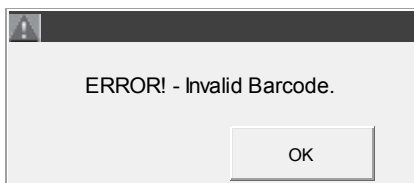
A sample error has occurred. This may be due to a clot or large air bubble if two or more sensors are unstable.

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



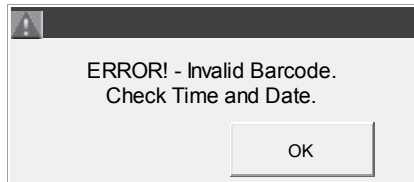
The system was not able to aspirate enough contiguous sample fluid to cover the optode sensors after multiple aspiration attempts. If a bubble was detected, the system attempted to restart the aspiration and was not able to aspirate enough sample.

- Press , and discard the cassette.



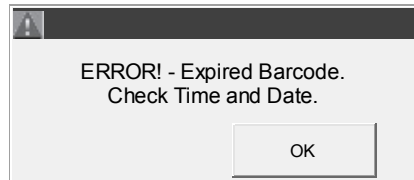
The bar code was invalid. The OPTI CCA-TS either misread the bar code label or it is an invalid bar code for the OPTI CCA-TS.

- Press to retry.
- If the error message appears again, check the product package for intended use.
- Check the bar code scanner (see Section 7.2.11).
- Clean the bar code scanner. Using a lint-free cloth dampened with a dilute alcohol or ammonia-based cleaner, gently wipe the face of the scanner clean.
- Retry the bar code.



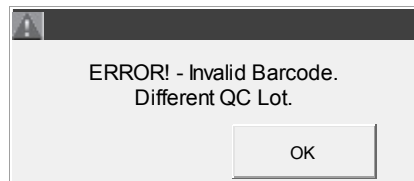
The bar code was invalid. The OPTI CCA-TS either misread the bar code or the product (i.e. gas bottle, cassette or SRC) has expired.

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



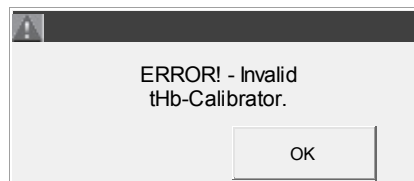
The cassette expiration date has been reached.

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



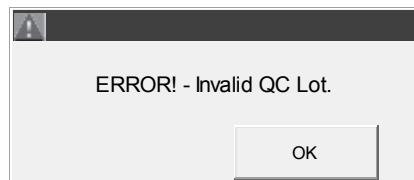
The bar code was invalid.

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



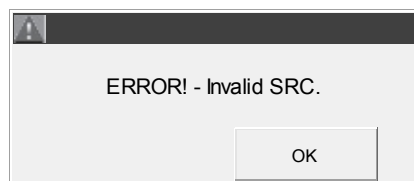
The cassette placed in the SMC is invalid.

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



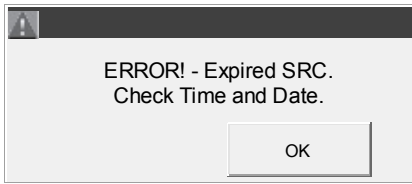
The QC lot is invalid.

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



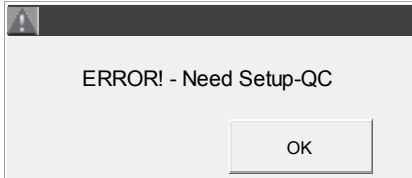
The SRC type is invalid.

- Press to continue.
- Remove the SRC.
- Configure the SRC data in **<Setup>** and retry.



The SRC expiration date has been reached.

- Press and remove the SRC.
- If the error message appears again, check the date in **<System ->Time and Date>**.
- Configure a new SRC under **<Setup>** and retry.



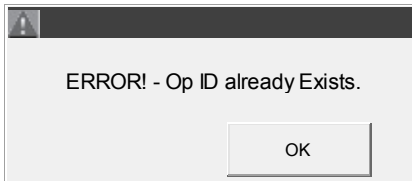
A measurement of QC materials, either liquid or SRCs, was attempted prior to setting up.

- Press to continue.
- Configure the SRCs and/or liquid QC material under **<Setup>** and retry.



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 to continue.
- Check the LEDs (See Section 7.2.4).



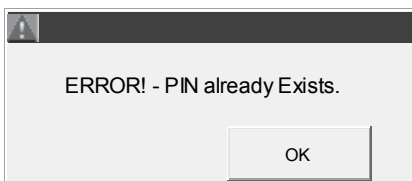
The Operator ID already exists in the database.

- Press to continue.
- Enter a unique Operator ID.



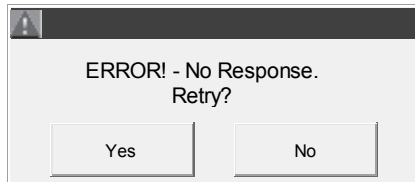
The PIN number does not exist in current Secure Op. ID database.

- Press to continue.
- Retry with a valid PIN number.



The PIN number already exists in database.

- Press to continue.
- Enter a unique PIN number.



The OPTI CCA-TS received no response from the host computer.

- Press to retry.

If the problem persists:

- Check connection between the OPTI CCA-TS and the host computer.
- Check the OPTI CCA-TS's communication configuration under **<System -> Hardware>**.
- Check the host computer.

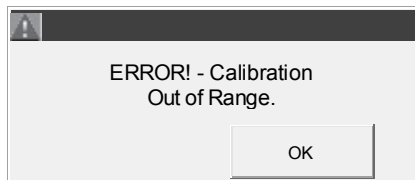


The OPTI CCA-TS received a negative (NAK) response from the host computer.

- Press to retry.

If the problem persists:

- Check the host computer or contact the facility IT manager.

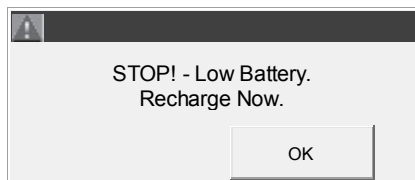


This error may occur during Hb calibration.

The error is triggered, when the correction is greater than 10%.

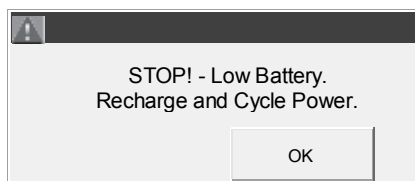
To retry:

- Replace the Hb calibrator.
- Perform a **<Last Blood>** calibration instead.



The battery is low.

- Install a freshly charged battery or recharge for up to 6 hours before the next sample is run, or operate the analyzer on AC power.



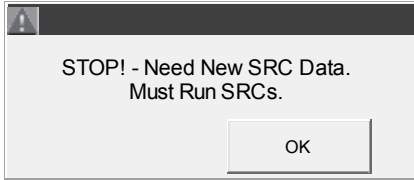
The battery is low.

- Install a freshly charged battery or recharge for up to 6 hours before the next sample is run, or operate the analyzer on AC power.
- Turn the power off, wait 30 seconds and then turn the power back on.



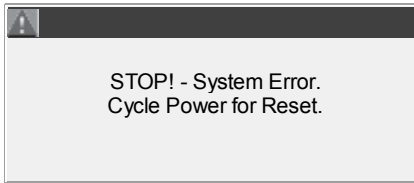
The gas cylinder is empty.

- Replace the gas cylinder and press .



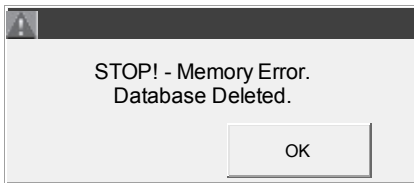
If SRC QC lockout has been activated in **<Setup>**, this message will be displayed if SRCs have not been run within the specified time.

- Press and run SRCs.



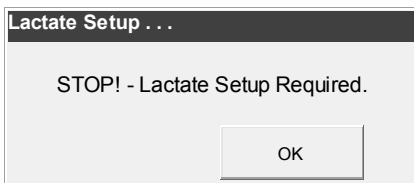
The instrument has detected an internal error.

- Discard the cassette.
- Turn the power off, wait 30 seconds and then turn the power back on.



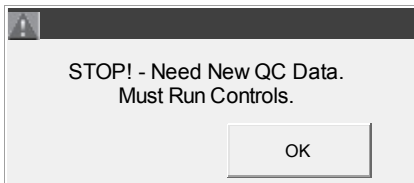
Patient, QC and other databases were deleted.

- Press and the instrument will reinitialize.



This error message will appear if you try to run lactate cassettes if the lactate parameter has not been set up on your analyzer.

- Refer to section 7.2.20 for instructions to set up the lactate parameter.



If QC lockout has been activated in **<Setup>** this message will be displayed if controls have not been run within the specified time.

- Press and run control materials.



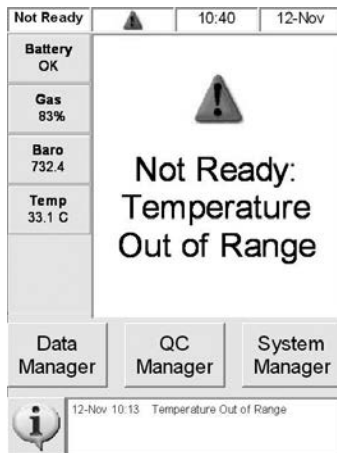
The temperature is out of range during any kind of measurement.

- Press and continue.
- If the error message appears again, check the temperature under **<System - Diagnostics>**.



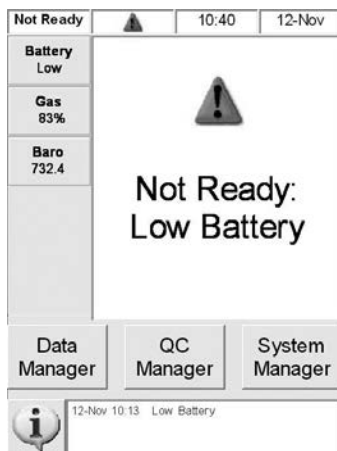
The gas pressure is low.

- Replace the gas bottle (See Section 6.5.1).



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.



The battery voltage is low.

- Operate the analyzer on AC power and/or recharge the battery.

7.2 Diagnostics



Fig. 7-1 Diagnostics

Your OPTI CCA-TS has a number of useful diagnostic programs.

From the **<Ready>** display, press **<System Manager-> Diagnostics>** (Fig. 7-1).

The **<Diagnostics>** screen contains three tabs with various diagnostic functions: **<Sensors>**, **<Control>** and **<Tests>**.

7.2.1 Checking Versions

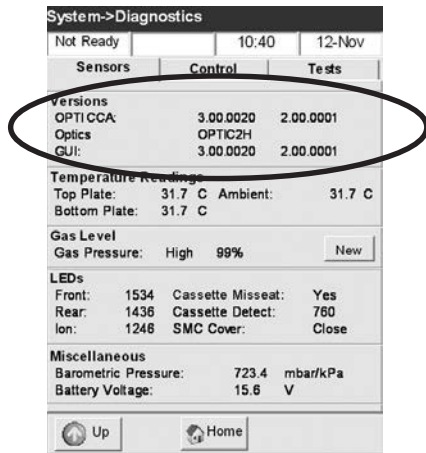


Fig. 7-2 Versions

From the **<Ready>** display, press **<System Manager -> Diagnostics>**.

The first option on the **<Sensors>** screen, **<Versions>** (Fig. 7-2), allows you to check the software version, version of the optical module, as well as the GUI version.

7.2.2 Checking System Temperatures

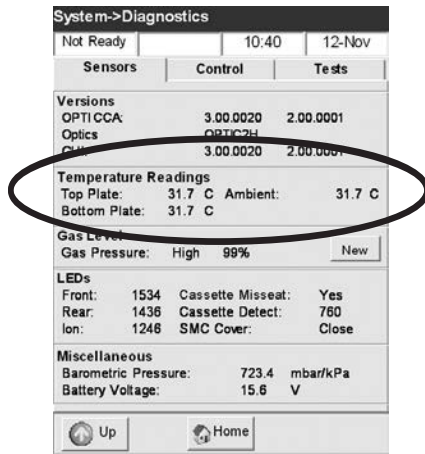


Fig. 7-3 Temperature

From the **<Ready>** display, press **<System Manager -> Diagnostics>**.

The **<Temperature>** option lets you check the various system temperatures: **<Top Plate>**, **<Bottom Plate>** and **<Ambient>** (Fig. 7-3).

NOTE: If top or bottom plate temperatures are out of range, the temperature display will change to red.

7.2.3 Checking Gas Pressure

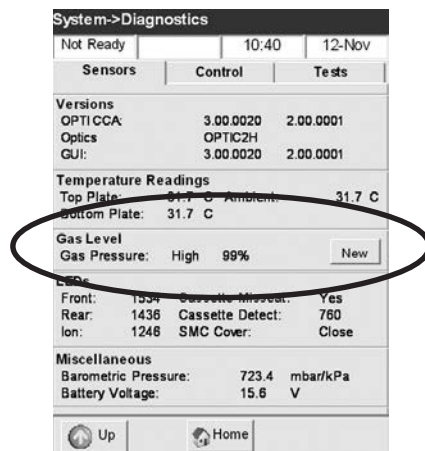


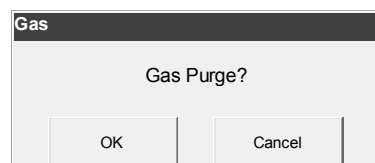
Fig. 7-4 Gas Pressure

The **<Gas Level>** option allows you to check the percent remaining of the gas bottle (Fig. 7-4).

With a new gas bottle in place, the pressure should be approx. 99%, with the bottle removed, the pressure should be 00%.

From the **<Ready>** display, press **<System Manager>** and **<Diagnostics>**.

- To install a new gas bottle, press **New**.
- Scan the bar code located on the side of the gas bottle to install a new gas bottle (see Section 6.5.1 “Changing Gas Bottle”).



- Press **OK** to initiate a gas purge or press **Cancel** to cancel this function and return to the **<Diagnostics>** screen.

7.2.4 Checking the LEDs

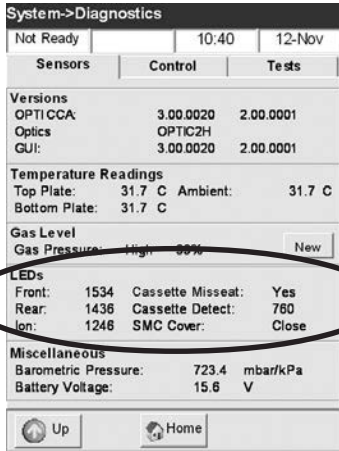



Fig. 7-5 LEDs

The purpose of this test is to check proper functioning of the LEDs. This test should be performed only by trained service personnel.

From the **<Ready>** display, press **<System Manager -> Diagnostics>**.

The following information is displayed in the **<LEDs>** section (Fig. 7-5):

- **<Front>**, **<Rear>**, **<Ion>** - fluid light gates.
- **<Cassette Misseat>** detector (located in cover)
- **<Cassette Detect>** sensor
- **<SMC Cover>** - this test function indicates whether the SMC cover is closed or open.
- Press  to return to the **<System>** screen.

7.2.5 Verifying Barometric Pressure

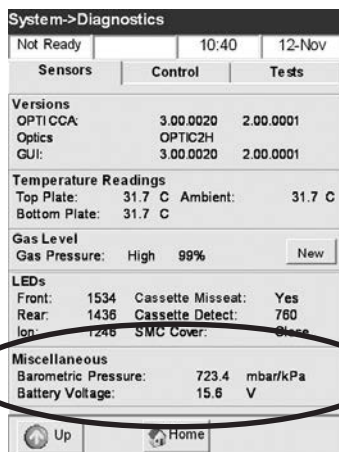


Fig. 7-6 Barometric Pressure

This menu displays the current barometric pressure.

From the **<Ready>** display, press **<System Manager -> Diagnostics>**.

- The **<Miscellaneous>** section will show the current barometric pressure (Fig. 7-6).
- If the barometric pressure requires adjustment, refer to Setup, Section 3.3.3.2 “Entering the Barometric Pressure” for setting the barometer.

7.2.6 Checking the Battery Voltage

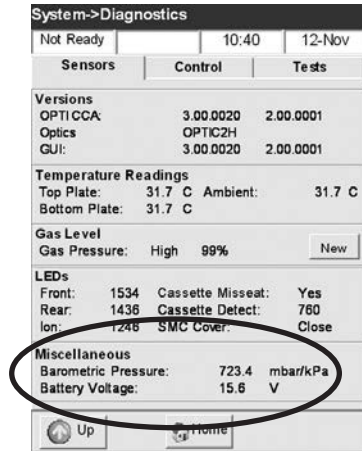


Fig. 7-7 Battery Voltage

This selection lets you check the battery voltage.

From the **<Ready>** display, press **<System Manager>** and **<Diagnostics>**.

- The second display in the **<Miscellaneous>** section shows the battery voltage (Fig. 7-7).
- If the voltage is below 11.8V, the battery needs to be recharged or may need replacement.

7.2.7 Checking the Cooling Fan

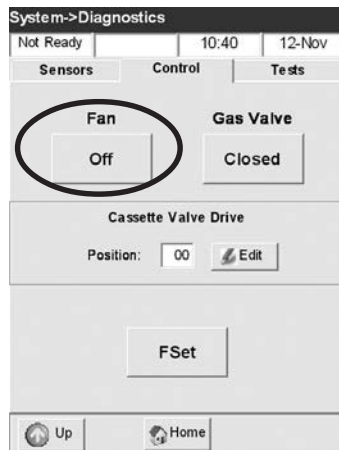



Fig. 7-8 Cooling Fan

The purpose of this test is to check for proper functioning of the cooling fan.

From the **<Ready>** display, press **<System Manager>** and **<Diagnostics>**.

- Select the **<Control>** tab.
- Press the **<On/Off>** button under **<Fan>** to start the test (Fig. 7-8).
- When **<On>** is selected, 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.

7.2.8 Checking the Gas Valve

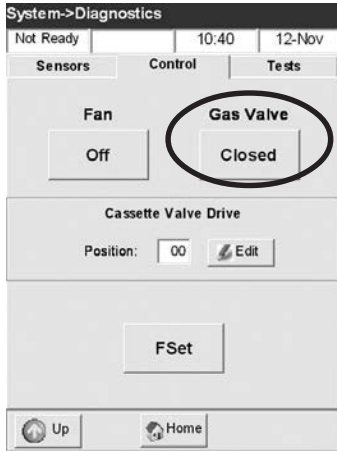



Fig. 7-9 Gas Valve

The purpose of this test is to check for proper function of the gas valve.

From the **<Ready>** display, press **<System Manager>** and **<Diagnostics>**.

- Select the **<Control>** tab.
- Press the **<Open/Closed>** button under **<Gas Valve>** to start the test (Fig. 7-9).
- A faint hissing sound may be heard with the pump cartridge removed and the gas valve open.
- Press  to return to the **<System>** screen.

7.2.9 Checking the Valve Drive

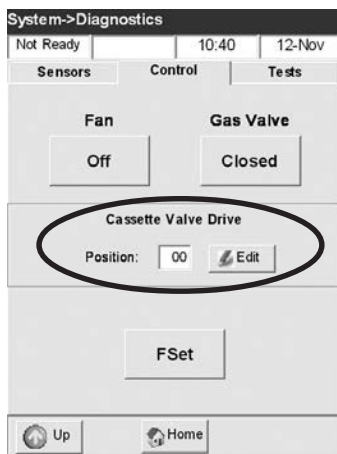




Fig. 7-10 Valve Drive

This diagnostic checks the proper operation of the cassette valve drive mechanism.

From the **<Ready>** display, press **<System Manager>** and **<Diagnostics>**.

- Select the **<Control>** tab.
- Press  to start the test (Fig. 7-10).
- Enter the various positions (allowed positions are 1 - 6) and verify the valve drive moves smoothly and precisely.
- Press  to return to the **<System>** screen.

7.2.10 Checking the Factory Settings

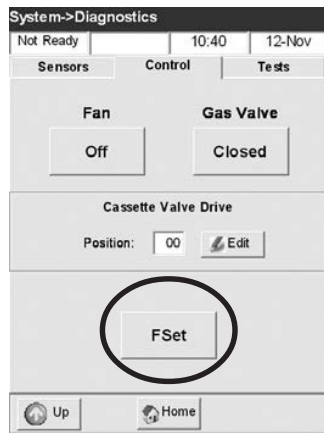


Fig. 7-11 Factory Settings

This **<Fset>** function (Fig. 7-11) is designed exclusively for use by authorized OPTI Medical personnel.

7.2.11 Checking the Bar Code Scanner

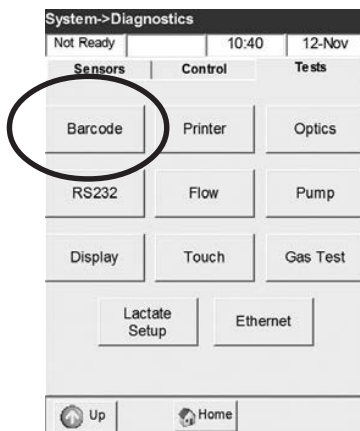


Fig. 7-12 Barcode Test

This option allows you to check the function of the bar code scanner.

From the **<Ready>** display, press **<System Manager>** and **<Diagnostics>**.

- Select the **<Tests>** tab.
- Press **<Barcode>** to start the test (Fig. 7-12).

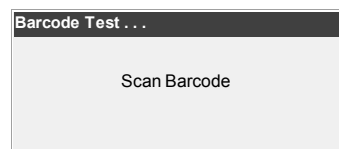




Fig. 7-13 Scan Barcode



Fig. 7-14 Barcode Test

- To test the bar code scanner, scan a bar code label of e.g. a sensor cassette (Fig. 7-13).
- The display will show a sequence of numbers (Fig. 7-14). 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.

7.2.12 Checking the Printer

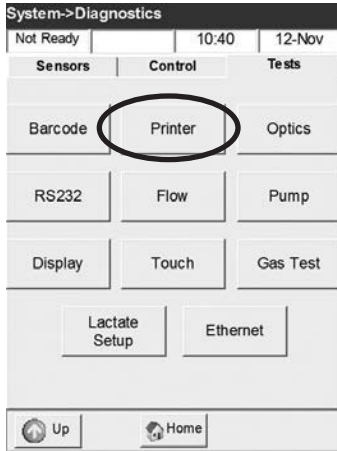


Fig. 7-15 Printer Test

This diagnostic function lets you check for the proper functioning of the built-in thermal printer. To activate:

From the **<Ready>** display, press **<System Manager>** and **<Diagnostics>**.

- Select the **<Tests>** tab.
- Press **<Printer>** to start the test (Fig. 7-15).
- 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-TS 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.

7.2.13 Checking the Optics

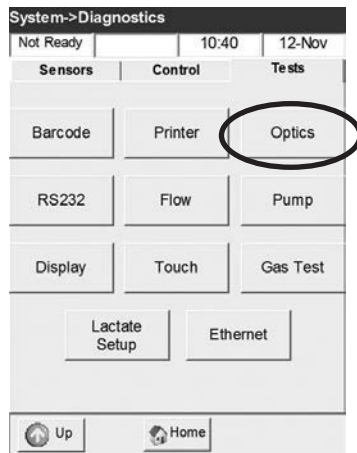


Fig. 7-16 Optics Test

This option checks the output of the six optics channels. This test is designed for trained service personnel.

From the **<Ready>** display, press **<System Manager>** and **<Diagnostics>**.

- Select the **<Tests>** tab.
- Press **<Optics>** to start the test (Fig. 7-16).



Fig. 7-17 Insert SRC

- Insert an SRC and press (Fig. 7-17).

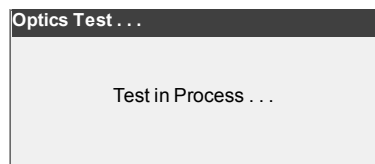


Fig. 7-18 Optics Test

- The system will now check the optics (Fig. 7-18).

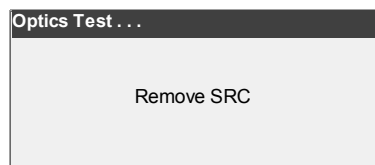


Fig. 7-19 Remove SRC

- At the completion of the test, a printout of the results will be printed and the **<Remove SRC>** message will be displayed (Fig. 7-19).

7.2.14 Checking the RS232 Interface

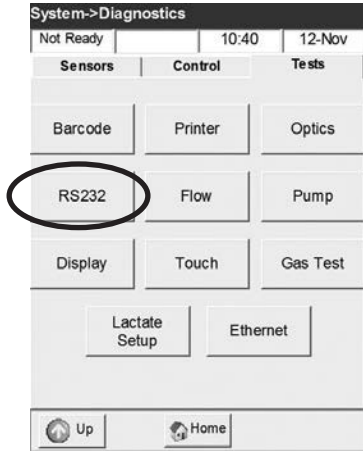


Fig. 7-20 RS232 Interface

The purpose of this test is to check for proper functioning of the serial interface.

From the **<Ready>** display, press **<System Manager -> Diagnostics>**.

- Select the **<Tests>** tab.
- Press **<RS232>** to start the test (Fig. 7-20).

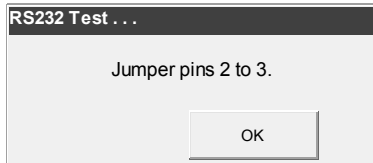


Fig. 7-21 Jumper Pins 2 to 3

- It is important to have pins 2 and 3 (send and receive - see Appendix A, p. A-6) shorted together (Fig. 7-21).
- Press and the system will send out a test string and check if it can be received.

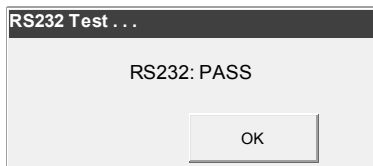


Fig. 7-22 Interface Test Pass

- The instrument will display a **<Pass>** or **<Fail>** message (Fig. 7-22).
- Press to return to the **<Tests>** screen.

7.2.15 Checking the Pump Flow

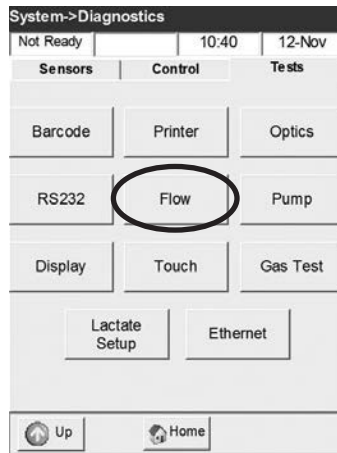


Fig. 7-23 Flow Test

This option is designed to test the pump cartridge.

From the **<Ready>** display, press **<System Manager>** and **<Diagnostics>**.

- Select the **<Tests>** tab.
- Press **<Flow>** to start the test (Fig. 7-23).

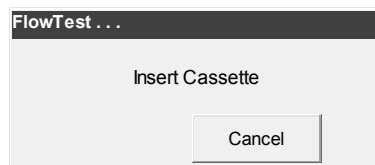


Fig. 7-24 Insert Cassette

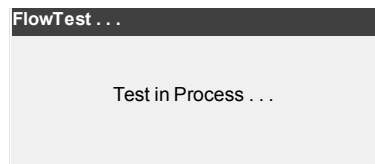


Fig. 7-25 Flow Test in Process

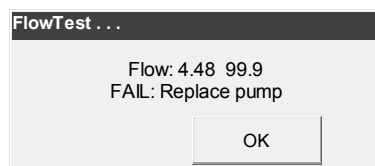


Fig. 7-26 Flow Test Fail

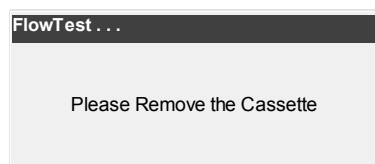


Fig. 7-27 Remove Cassette

- Insert a new cassette (Fig 7-24).
- Close the SMC cover.

- Wait for test results (Fig. 7-25).

- The two numbers indicate the actual flow rates clockwise and counter clockwise (Fig. 7-26). 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 6.

NOTE: It is possible that the test fails the first time, even if the pump cartridge is working correctly.

- Remove the cassette (Fig. 7-27).

7.2.16 Checking the Pump Motor

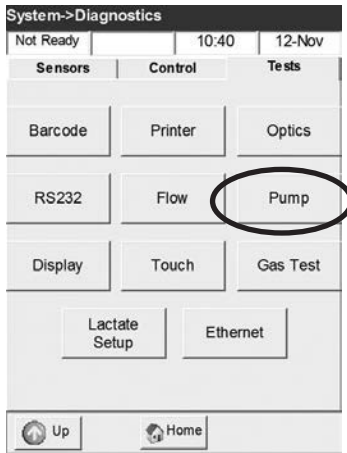


Fig. 7-28 Pump Motor Test

The purpose of this test is to check the proper functioning of the peristaltic pump motor.

From the **<Ready>** display, press **<System Manager -> Diagnostics>**.

- Select the **<Tests>** tab.
- Press **<Pump>** to start the test (Fig. 7-28).

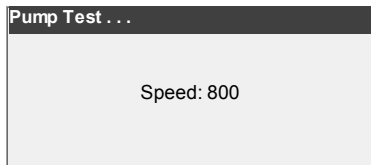


Fig. 7-29 Pump Speed

- The pump will automatically step through all the speeds used during normal operation (50 to 800 pps (pulses per second)) (Fig. 7-29) and return to the **<Tests>** screen.

7.2.17 Checking the Display

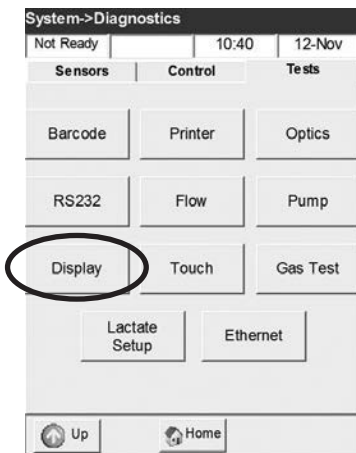



Fig. 7-30 Display Test

The purpose of this test is to check the proper operation of the display.

From the **<Ready>** display, press **<System Manager -> Diagnostics>**.

- Select the **<Tests>** tab.
- Press **<Display>** to start the test (Fig. 7-30).
- The display will turn red, green and blue. If this is not the case, your display is defective and needs to be replaced.
- Press  **Up** to return to the **<System>** screen.

7.2.18 Checking the Touch Screen

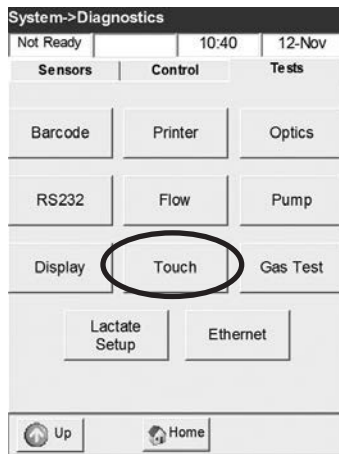


Fig. 7-31 Select Touch Test



Fig. 7-32 Perform Touch Test




Fig. 7-33 Perform Touch Calibration

The purpose of this test is to check the proper operation of the touch screen.

From the **<Ready>** display, press **<System Manager -> Diagnostics>**.

- Select the **<Tests>** tab.
- Press **<Touch>** to start the test (Fig. 7-31).

- Touch the screen and a dot should appear under the touched location (Fig. 7-32).
- If not, press **<Calibrate>** to perform a touch calibration.
- Press  to return to the **<System>** screen.

- 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. 7-33).

NOTE: Do not use sharp objects, since they may damage the screen.

- When finished press .

7.2.19 Gas Test

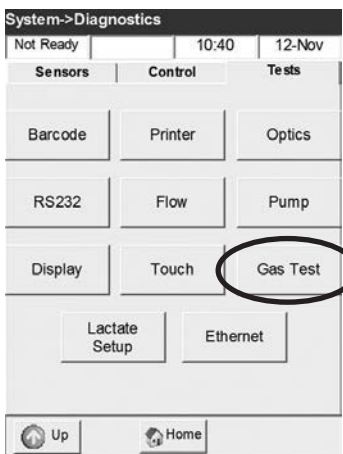


Fig. 7-34 Gas Test

The **<Gas Test>** (Fig. 7-34) 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.

7.2.20 Lactate Setup

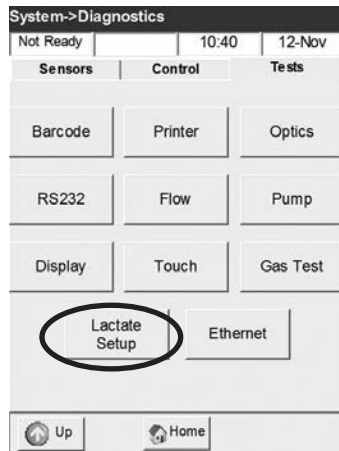


Fig. 7-35 Lactate Setup



Fig. 7-36 Enter Operator ID



Fig. 7-37 Lactate Setup

The **<Lactate Setup>** menu is used to enable the running of lactate cassettes. New analyzers from OPTI Medical are already set up for the lactate parameter and do not require this step. Only follow this procedure if you wish to set up B-Lac cassettes.

The lactate 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.

This is not a troubleshooting procedure. Call Technical Support for further assistance.

From the **<Ready>** display, press **<System Manager -> Diagnostics>**.

- Select the **<Tests>** tab.
- Press **<Lactate Setup>** (Fig. 7-35).
- Enter the setup password **404** to access the setup functions. If the factory-set password was changed, enter the currently valid password.
- Enter the Operator ID or press **OK** to bypass this function (Fig. 7-36).

If Operator ID is configured as “required” in Setup, you cannot go to the next step unless a valid Op. ID is entered.

If Secure Op. IDs is activated under Setup, you will be prompted for your 4-digit PIN # instead of your Op. ID.

This message (Fig. 7-37) 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.

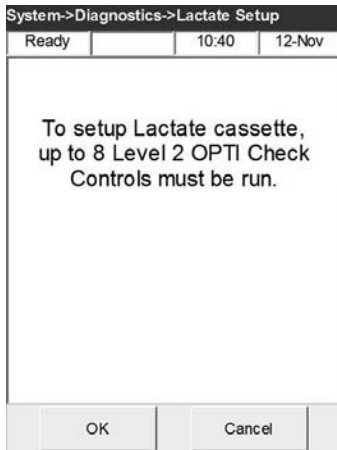


Fig. 7-38 Run Controls

To set up lactate, you have to run up to 8 ampoules of OPTI Check level 2 (Fig. 7-38). Please make sure you have at least 8 ampoules of the same lot of OPTI Check and 8 lactate cassettes of the same lot on hand before starting setup.

- Press to run the first sample. Refer to section 4.5.3.1 for instructions on running controls.

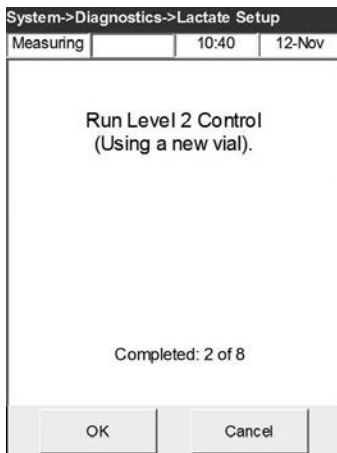


Fig. 7-39 Run Controls

- After each level of OPTI Check is run, you will return to this screen (Fig. 7-39). 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. 7-40 Lactate enabled

- After running the required number of samples, the lactate parameter is enabled (Fig. 7-40).
- Press to exit the menu. You will receive a lactate setup report once complete.

After completing this procedure, OPTI Medical recommends that you run two levels of OPTI Check using B-Lac cassettes to verify performance.

7.2.21 Checking the Ethernet Interface

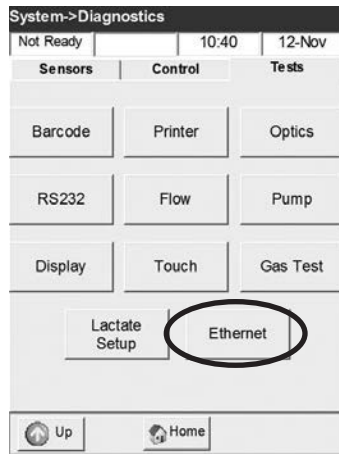


Fig. 7-41 Ethernet

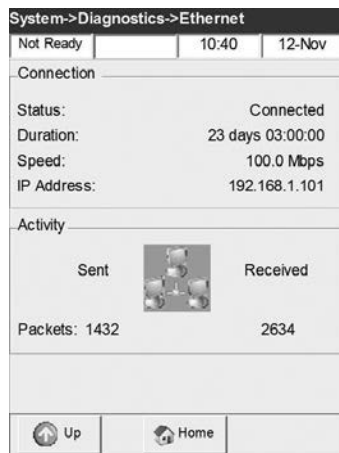



Fig. 7-42 Ethernet Test

The purpose of this test is to check for proper functioning of the Ethernet interface.

From the **<Ready>** display, press **<System Manager -> <Diagnostics>**.

- Select the **<Tests>** tab.
- Press **<Ethernet>** to start the test (Fig. 7-41).

- The system will send out data and check if they are received (Fig. 7-42).
- Press  to return to the **<Tests>** screen.

7.2.22 Calibration Reports

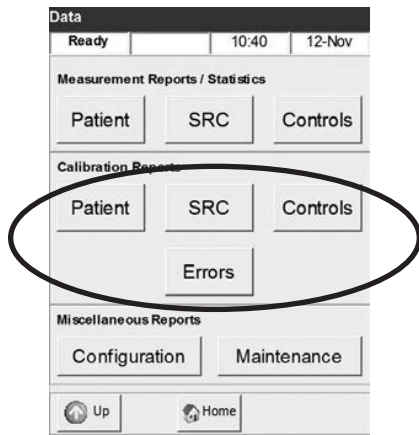


Fig. 7-43 Data Manager

This option allows you to print calibration reports.

From the **<Ready>** display, press **<Data Manager>** to access the **<Data>** screen (Fig. 7-43).

The section **<Calibration Reports>** contains the following reports:

<Patient>, **<SRC>**, **<Controls>** and **<Errors>**.

7.2.22.1 Patient Calibration Report

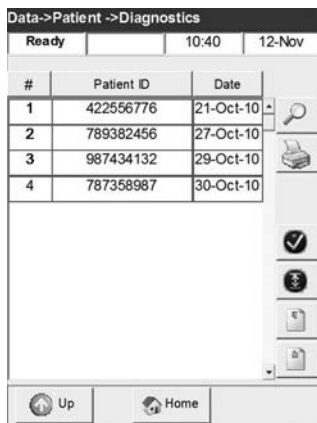


Fig. 7-44 Select Measurement

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

- To print a patient calibration report, select **<Calibration Reports -> Patient>** in the **<Data>** screen (Fig. 7-43).
- In the **<Data - Patient Diagnostics>** screen (Fig. 7-44), select the desired measurement and press the **View** button to display the results (Fig. 7-45). Use the **Up** and **Down** buttons to display the previous or next page of results.
- To print individual results, highlight the desired measurement (Fig. 7-44). To print groups of results, highlight the first measurement to be printed, press **Mark**, then select the last measurement to be printed. All the measurements in between will be selected. Press **All** to select all results.
- Press **Print** to print your selection.
- Press **Up** to return to the **<Data>** screen.

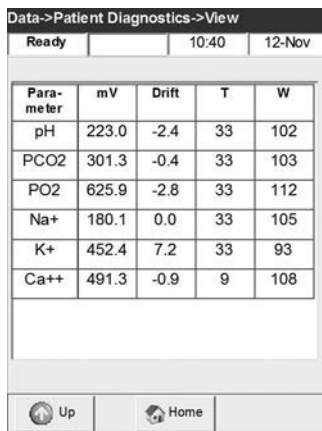


Fig. 7-45 Patient Diagnostics

7.2.22.2 SRC Calibration Report

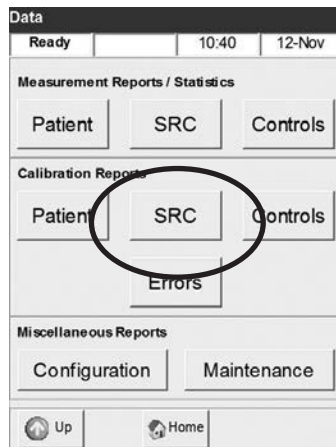


Fig. 7-46 Select SRC



Fig. 7-47 Select Measurement

The screenshot shows the 'Data->SRC Diagnostic->View' screen with a status bar at the top indicating 'Ready', '10:40', and '12-Nov'. Below this is a table with columns for 'Sensor', 'mV', '% Drift', and '% SEE'. The table contains 6 rows of data. At the bottom are navigation buttons for 'Up' and 'Home'.

Sensor	mV	% Drift	% SEE
1	31.1	-0.09	0.03
2	49.4	-0.08	0.01
3	35.7	-0.09	0.02
4	35.0	-0.03	0.00
5	92.8	-0.04	0.00
6	94.9	-0.02	0.00

Fig. 7-48 SRC Diagnostics

The **<SRC Calibration Report>** shows details of measured signals in millivolts as well as drifts observed during the measurement.

- To print an SRC report, select **<Calibration Reports -> SRC>** in the **<Data>** screen (Fig. 7-46).
- In the **<Data - SRC Diagnostics>** screen (Fig. 7-47), select the desired measurement and press the **View** button to display the SRC results (Fig. 7-48). Use the **Up** and **Down** buttons to display the previous or next page of results.
- To print individual results, highlight the desired measurement (Fig. 7-47). To print groups of results, highlight the first measurement to be printed, press **Mark**, then select the last measurement to be printed. All the measurements in between will be selected. Press **All** to select all results.
- Press **Print** to print your selection.
- Press **Up** to return to the **<Data>** screen.

7.2.22.3 Control Calibration Report

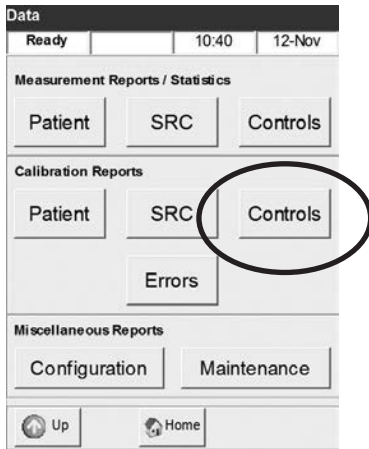


Fig. 7-49 Select Control

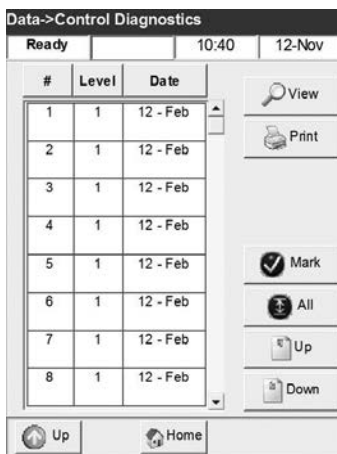


Fig. 7-50 Select Measurement

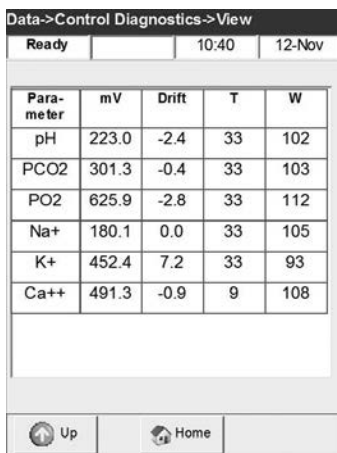


Fig. 7-51 Control Diagnostics

The **<Control Calibration Report>** shows details of measured signals in millivolts as well as drifts observed during measurement.

- To print a controls report, select **<Calibration Reports ->Controls>** in the **<Data>** screen (Fig. 7-49).
- In the **<Data - Control Diagnostics>** screen (Fig. 7-50), select the desired measurement and press the **View** button to display the control results (Fig. 7-51). Use the **Up** and **Down** buttons to display the previous or next page of results.
- To print individual results, highlight the desired measurement (Fig. 7-50). To print groups of results, highlight the first measurement to be printed, press **Mark**, then select the last measurement to be printed. All the measurements in between will be selected. Press **All** to select all results.
- Press **Print** to print your selection.
- Press **Up** to return to the **<Data>** screen.

7.2.22.4 Error Log

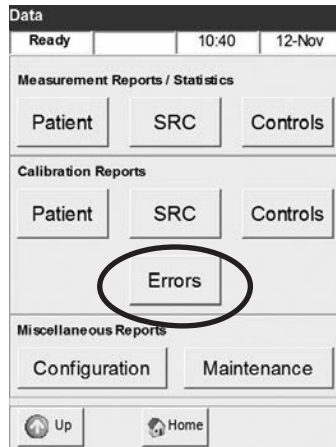


Fig. 7-52 Select Errors

This menu gives you the option to print or delete the error log from the database.

- To print an error log, select **<Calibration Reports -> Errors>** in the **<Data>** screen (Fig. 7-52).

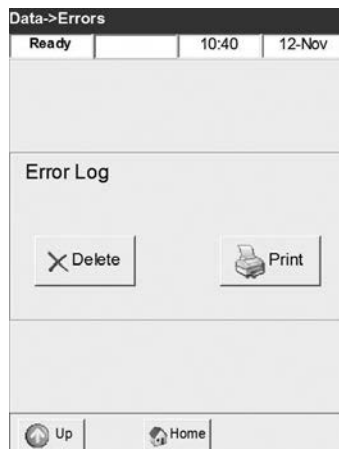




Fig. 7-53 Print or Delete Error Log

- Press  **Print** to print the error log (Fig. 7-53).
- Press  **Delete** to delete the error database.

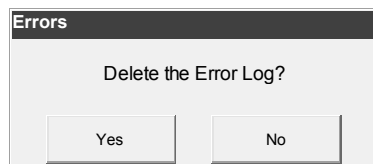




Fig. 7-54 Delete Error Log

- Confirm your choice by pressing  **Yes** in the **<Delete the Error Log?>** screen (Fig. 7-54).
- Press  **Up** to return to the **<Data>** screen.

7.2.22.5 Configuration Report

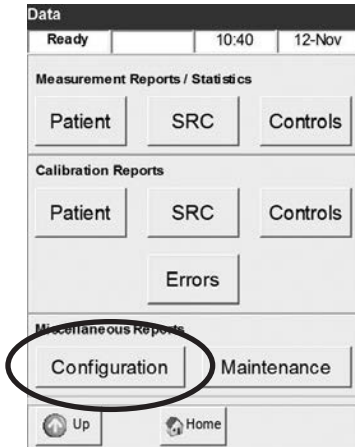


Fig. 7-55 Configuration Report

This printout reports all settings such as QC ranges, reference limits, correlation factors, patient information, printout settings etc.

- To print a configuration report, select **<Configuration>** in the **<Data>** screen (Fig. 7-55).
- Press to return to the **<Data>** screen.

NOTE: After initial setup, a configuration report should be printed and kept in a safe place for later reference.

7.2.22.6 Maintenance Log

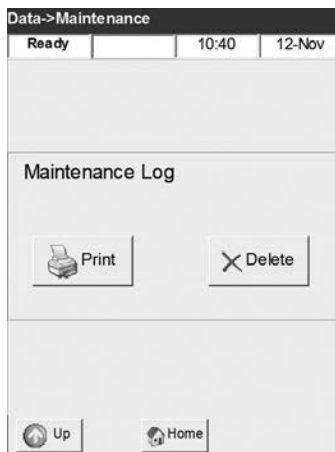


Fig. 7-56 Maintenance Log

This printout reports all logged maintenance events.

- To print a maintenance log, select **<Maintenance>** in the **<Data>** screen (Fig. 7-55).
- Press to print the maintenance log (Fig. 7-56).
- Press to delete the maintenance database.

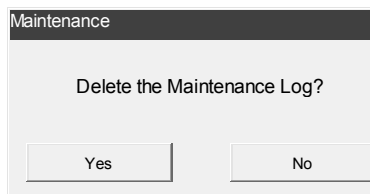


Fig. 7-57 Delete Maintenance Log

- Confirm your choice by pressing in the **<Delete the Maintenance Log?>** screen (Fig. 7-57).
- Press to return to the **<Data>** screen.

7.3 Troubleshooting Procedure for tHb/SO₂

If your OPTI fails an Hb calibration or QC measurement for tHb or SO₂, 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 SO₂ measurements. These channels may get clogged or dirty, causing the tHb and SO₂ to fail calibration or OPTI Check controls. The simple cleaning procedure below can be used for OPTI CCA, OPTI CCA-TS, or OPTI R analyzers and may correct tHb and SO₂ failures.

1. Open the SMC cover and locate the two small optical channels pictured below (Fig. 7-58).

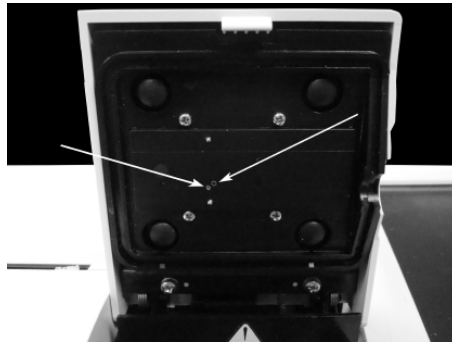


Fig. 7-58 Locate Optical Channels

2. Clean the optical channels using a cotton swab or lint-free cloth dipped in alcohol or ammonia-based cleaner (Fig. 7-59).



Fig. 7-59 Clean Optical Channels

Please contact OPTI Medical at +1 770.510.4444, or 800.490.OPTI (6784) or technicalsupport@optimedical.com for any additional questions or information regarding this procedure.

7.4 *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.

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8 OPERATING PRINCIPLES

8.1 Intended Use

The OPTI™ CCA-TS Critical Care Analyzer is intended to be used for the measurement of hydrogen ion concentration (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.

8.2 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 **optical electrodes**) 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-TS Operator's Manual.

¹ Guilbault GG, Ed., Practical Fluorescence, 2nd Ed., Marcel Dekker, 1990.

8.3 Operation

The OPTI CCA-TS 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.

8.4 Specimen Collection and Handling

8.4.1 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.

8.4.2 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.

8.4.3 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.

8.4.4 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.*

8.4.5 Capillary Tubes

Capillary blood specimens should be collected using capillary tubes which have a minimum volume, filled, of 125 μ L. The OPTI Medical capillary tubes (MC0024) are ideally suited with a minimum volume, filled, of 200 μ L. The capillary tubes for pH, blood gas, and electrolyte analysis should not be used for samples taken for the analysis of lithium.

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.

8.4.6 OPTI Medical ComfortSamplers™

Blood may be collected for analysis on the OPTI CCA-TS 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.

8.4.7 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 sedimentation 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-TS 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-TS.

The OPTI CCA-TS 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.

8.5 Procedure

8.5.1 Materials Needed

Description	Part Number
Sensor Cassettes in various analyte configurations	see Chapter 9, Supplies
Standard Reference Cassette Level 1	BP7536
Standard Reference Cassette Level 3	BP7543
Calibration Gas Bottle	BP7001
Printer Paper	HP0070

The OPTI CCA-TS 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.

8.5.2 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 or ComfortSampler
Ambient Temperature:	10 - 32 °C (50 – 90 °F)
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)

8.5.3 Input Values

Parameter	Range	Default	Display Resolution	Units
Patient ID	15 alphanumeric characters	Blank		
Operator ID	11 alphanumeric characters	Blank		
Accession Number	12 alphanumeric characters	Blank		
Patient temperature, T	14 to 44	37.0	0.1	°C
	58 to 111		0.1	°F
Patient Sex	Male, female or ?	?		
Hemoglobin type	adult or fetal	adult		
DOB	MMM-DD-YYYY			
Puncture Site	LR/RR/LB/RB/LF/RF/ Cord/Scalp, where:	LR		
	LR = Left Radial RR = Right Radial LB = Left Brachial RB = Right Brachial LF = Left Femoral RF = Right Femoral Cord = Cord Scalp = Scalp			
Bypass	Off Pump / On Pump	Off Pump		

Parameter	Range	Default	Display Resolution	Units
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		
Total hemoglobin, tHb	1 to 26 1 to 260 1 to 16	15.0	0.1 1 0.01	g/dL mg/dL mmol/L
Mean corpuscular hemoglobin concentration, MCHC%	29.0 to 37.0	33.3	0.1	%
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		
FIO ₂	0.21 to 1.0	0.21	0.01	
respiratory quotient, RQ	0.70 to 2.00	0.84	0.10	
P ₅₀	15 to 40	26.7	0.1	mmHg
Vent Mode	No, SIMV, PSV, PCV, CMV/AC, CPAP, PCIVR, or BIPAP, where: No = None SIMV = Synchronized Intermittent Mandatory Ventilation PSV = Pressure Support Ventilation	No		

Parameter	Range	Default	Display Resolution	Units
	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			
Tidal Volume (VT)	0 to 4000	0	1	mL
Minute Volume (VE)	0 to 120	0	1	L
Peak Inspiratory Pressure (PIP)	0 to 140	0	1	
Plateau Pressure (Pplat)	0 to 100	0	0.1	
Pressure Support Value (PS)	0 to 99.9	0	0.1	
Positive End Expiratory Pressure (PEEP)	0 to 50	0	1	
Continuous Positive Airway Pressure (CPAP)	0 to 50	0	1	
Rate (f)	0 to 155	0	1	bpm
Flow Rate (Liter Flow) (FR)	0 to 300	0	1	LPM
Inspiratory/Expiratory Ratio (I/E Ratio)	0.2 - 9.9 / 0.2 - 9.9	0 / 0	0.1	
Bi-Level Pressure	0.2 - 9.9 / 0.2 - 9.9	0 / 0	0.1	
User Field 1, 2, 3	9 alphanumeric characters	Blank		

8.5.4 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

8.5.5 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 similar to that used by conventional blood analyzers. 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.

8.5.6 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 SO₂ controls (OPTI CHECK or OPTI CHECK PLUS) or other equivalent material which has been recommended by OPTI Medical Systems. 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).

A minimum of two Standard Reference Cassettes (SRCs), of different levels, should be used as a control for measurement and proper analyzer operation. OPTI Medical Systems recommends that the SRC measurement be confirmed within acceptance ranges on both levels once each day of OPTI CCA-TS operation. These special 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. Level 1 and level 3 SRCs are supplied with the analyzer producing low and high values for all measured parameters. An optional, normal range SRC (Level 2) is available from OPTI Medical Systems.

All specific performance specifications reported in this summary are determined from the above, minimal recommendations for quality control verification.

The OPTI CCA-TS's equivalent QC method, Standard Reference Cassette (SRC), is a relatively new concept 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. The OPTI CCA-TS is one of a new generation of systems where 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. For SRC limit values, see analyte section of this manual.

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 equivalent 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-TS'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 equivalent 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.

OPTI CHECK and OPTI CHECK PLUS are specially formulated aqueous liquid control materials that contain all analytes measurable by the OPTI CCA-TS. 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 SO₂. The three control levels contain three different concentrations of micro beads to simulate low, medium, and high hemoglobin blood samples.

OPTI CHECK and OPTI CHECK PLUS provide a method of performing daily QC checks for laboratories selecting to measure liquid QC material.

8.5.7 Reference Intervals²

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 3.3.2.4 of this manual.

8.5.8 Specific Performance Characteristics

All performance data in this section was generated on OPTI CCA-TS systems with the SRC run daily to check QC. Quality control material was run with each new lot of cassettes.

² Tietz; Burtis C, et al (Eds.), Textbook of Clinical Chemistry and Molecular Diagnostics, 4th Ed., (Elsevier Saunders, 2006) pps. 2252-2302.

8.5.9 Limitations

The performance characteristics are affected by the following sample considerations:

The preferred test liquid is whole human blood for all parameters. It is necessary to tonometer blood to obtain values to evaluate accuracy of PO_2 and PCO_2 because patient samples must be considered to be unknown. Tonometry of blood introduces potential errors unrelated to the blood gas system being evaluated. Accuracy of the gas values used, temperature control and thermostating of the tonometer, humidification of the tonometry gases, duration of tonometry and transfer of the sample from the tonometer to the instrument for analysis are examples of potential pre-analytical error.

pH of blood cannot be predicted in tonometry. All tonometered samples analyzed in these studies were analyzed in duplicate on an AVL 995 to establish correlation. Precision of PCO_2 and PO_2 measurement, as well as pH was evaluated over a 20 day period using two OPTI CCA-TS systems with two replicates per run using a commercially available solution of reduced bovine hemoglobin which has been demonstrated to be comparable to tonometered whole blood.³

The OPTI CCA-TS 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-TS 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-TS 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-TS's tHb measurement is sensitive to pathologically rapid sedimentation rates of the erythrocytes, often induced by excessive rate and amounts of rouleaux formation⁴. 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-TS 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:

$$PCO_2 > 200 \text{ mmHg (Meas.Lim)}$$

For measurement ranges of the individual analytes, see Analyte Section of this Operator's Manual.

³ Mahoney JJ, Wong RJ, Van Kessel AL, Reduced Bovine Hemoglobin Solution Evaluated for Use as a Blood Gas Quality Control Material. Clin.Chem.39/5,874-79 (1993)

⁴ J.B.Henry, Clinical Diagnosis and Management by Laboratory Methods, 19th Ed., 1996, p.590,777

8.5.10 Interferences

Selected substances endogenous and exogenous to human blood were tested for interference in accord with CLSI EP7-A2⁵. 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-TS, 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 SO₂ 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/SO₂:

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-TS 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.

⁵ Clinical and Laboratory Standards Institute (CLSI). Interference Testing in Clinical Chemistry; Approved Guideline - 2nd Edition. CLSI document EP7-A2. CLSI, Wayne, PA, 2005

8.5.11 Accessories

OPTI Sensor Cassettes

Type "B", BP7562 (pH, PCO₂, PO₂, tHb, SO₂)

Type "E", BP7587 (pH, PCO₂, PO₂, Na⁺, K⁺, tHb, SO₂)

Type "E-Ca", BP7560 (pH, PCO₂, PO₂, Na⁺, K⁺, Ca⁺⁺, tHb, SO₂)

Type "E-Cl", BP7559 (pH, PCO₂, PO₂, Na⁺, K⁺, Cl⁻, tHb, SO₂)

Type "E-Glu", BP7564 (pH, PCO₂, PO₂, Na⁺, K⁺, Glu, tHb, SO₂)

Type "E-BUN (urea)", BP7588 (pH, PCO₂, PO₂, Na⁺, K⁺, BUN (urea), tHb, SO₂)

Type "B-Lac", BP7561 (pH, PCO₂, PO₂, Lac, tHb, SO₂)

Type "B60", BP7586 (pH, PCO₂, PO₂)

Use:	For measurement of various analytes with the OPTI CCA-TS 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.

Standard Reference Cassettes (SRCs)

Use:	For diagnostic and daily QC check of the OPTI CCA-TS
Contents:	Each package contains one reusable SRC Cassette.
Composition:	Stabilized optode sensors with assay values:

	Level 1 BP7536	Level 2 (Optional) BP7554	Level 3 BP7543	
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	36.0 - 54.0	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, BP7001

Use:	For calibration of pH, PCO_2 and PO_2 in the OPTI CCA-TS Analyzer.	
Contents:	Each disposable, low pressure cylinder contains approximately 2 liters of gas (at less than 145 psi at 21 °C)	
Composition:	Oxygen	14.0 ± 0.02%
	Carbon Dioxide	6.0 ± 0.02%
	Nitrogen	balance
Storage:	Refer to package labeling.	

Battery Charger (Optional), BP7036

Use:	For fast charging of extra battery pack for the OPTI CCA-TS.
Contents:	Each charger contains a power supply with circuitry.
Input voltage:	100-240 VAC, 50-60 Hz
Storage:	Refer to package labeling.

Precautions

Use of calibration solutions, calibration gas, 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. Mahoney JJ, Wong RJ, Van Kessel AL, *Reduced Bovine Hemoglobin Solution Evaluated for Use as a Blood Gas Quality Control Material*. Clin.Chem.39/5,874-79 (1993)
4. J.B.Henry, *Clinical Diagnosis and Management by Laboratory Methods*, 19th Ed., 1996, p.590,777
5. Clinical and Laboratory Standards Institute (CLSI). *Interference Testing in Clinical Chemistry; Approved Guideline - 2nd Edition*. CLSI document EP7-A2. CLSI, Wayne, PA, 2005

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9 SUPPLIES

Each OPTI™ CCA-TS 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
<p>9.1 Analyzer</p> <p>OPTI CCA-TS Analyzer with Accessory Kit</p>	GD7013
<p>9.2 Cassettes</p> <p>OPTI Cassette 'B' (25 per box)</p> <p>OPTI Cassette 'E' (25 per box)</p> <p>OPTI Cassette 'E-Ca' (25 per box)</p> <p>OPTI Cassette 'E-Cl' (25 per box)</p> <p>OPTI Cassette 'E-Glu' (25 per box)</p> <p>OPTI Cassette 'E-BUN(urea)' (25 per box)</p> <p>OPTI Cassette 'B-Lac' (25 per box)</p> <p>OPTI Cassette 'B60' (25 per box)</p>	<p>BP7562</p> <p>BP7587</p> <p>BP7560</p> <p>BP7559</p> <p>BP7564</p> <p>BP7588</p> <p>BP7561</p> <p>BP7586</p>
<p>9.3 Controls/Calibrators</p> <p>Standard Reference Cassette (SRC) - Level 1</p> <p>Standard Reference Cassette (SRC) - Level 2</p> <p>Standard Reference Cassette (SRC) - Level 3</p> <p>OPTI CHECK, Trilevel</p> <p>OPTI CHECK PLUS, Trilevel</p> <p>tHb-Calibrator Cassette</p>	<p>BP7536</p> <p>BP7554</p> <p>BP7543</p> <p>HC7008</p> <p>HC7009</p> <p>BP7542</p>

Description	Part Number
<p>9.4 Consumable Items</p> <p>Printer Paper (1 roll)</p> <p>Calibration Gas Bottle (1 pc)</p> <p>Capillary Tubes (250 pcs)</p> <p>Syringe Adapters (250 pcs/box)</p> <p>ComfortSampler with Accessories</p> <p>ComfortSampler Basic Kit</p> <p>ComfortSampler Bulk, w/Needle</p> <p>ComfortSampler Bulk, w/o Needle</p> <p>ComfortSampler Bulk, Needle w/Protector</p>	<p>HP0070</p> <p>BP7001</p> <p>MC0024</p> <p>BP7600</p> <p>BP0600</p> <p>BP0610</p> <p>BP0620</p> <p>BP0630</p> <p>BP0640</p>
<p>9.5 Accessories</p> <p>Battery Charger</p> <p>Battery Assembly</p> <p>CF Export Kit</p> <p>Case, Carrying</p>	<p>BP7036</p> <p>BP7007</p> <p>BP7140</p> <p>YB7025</p>
<p>9.6 Manuals</p> <p>Operator's Manual</p> <p>CD, Operator's Manual</p> <p>Service Manual</p>	<p>PD7040</p> <p>PD7066</p> <p>PD7041</p>

Description	Part Number
9.7 Spare Parts	
Peripump Cartridge Kit	BP7012
Power Supply	EI7007
Power Cord	EX0197
Power Cord, Schuko	EX0173
Printer Assembly	BP7090
Seal SMC Gas I/O Port	RE7030

9.8 Technical Assistance

Most often, problems with your OPTI CCA-TS 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.

9.9 Warranty Registration (U.S. Market Only)

After successful completion of the installation of your new OPTI CCA-TS, 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-TS 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	pH-1
pH (Dry Sensor - B-Lac Cassette).....	pH-B-1
PCO ₂	PCO2-1
PCO ₂ (Dry Sensor - B-Lac Cassette)	PCO2-B-1
PO ₂	PO2-1
PO ₂ (Dry Sensor - B-Lac Cassette)	PO2-B-1
Sodium (Na ⁺)	Na-1
Potassium (K ⁺)	K-1
Ionized Calcium (Ca ⁺⁺)	Ca-1
Chloride (Cl ⁻)	Cl-1
Glucose (Glu)	Glu-1
BUN (Urea).....	BUN-1
Lactate (B-Lac Cassette).....	Lac-1
Total Hemoglobin Concentration (ctHb) and Hemoglobin Oxygen Saturation (SO ₂ %).....	THB/SO2-1

pH

Clinical Significance¹

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 CO₂, 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,

$$I_0 / I = 1 + 10^{pK_a - pH}$$

which describes how the fluorescence emission intensity increases as the blood pH is increased above the dye's characteristic pK_a². 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 measured³.

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 strength³, which is determined primarily by variation in serum levels of sodium. The OPTI CCA-TS utilizes an internal Na⁺ sensor to actively compensate and correct for this sensitivity. That is, the OPTI CCA-TS'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 interferences were quantified in tonometered plasma, showing interferences to dyes which typically have short half-lives within the body before being metabolized by the liver.

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-TS system. Colored materials, including proficiency testing materials, may interfere with the pH measurement, or fail to be properly aspirated.

Reproducibility

Typical Within-Run (Swr), Between-Day (Sdd) and Total (ST) Precision is determined from 1 run per day with 2 replicates per run for 20 days on each of two OPTI CCA-TS instruments. pH is expressed in pH units.

Material	mean	Swr (CV%)	Sdd (CV%)	ST (CV%)
OPTI CHECK PLUS (aqueous control solution)				
Level 1	7.166	0.003 (—)	0.003 (—)	0.003 (—)
Level 2	7.414	0.0003 (—)	0.002 (—)	0.002 (—)
Level 3	7.620	0.0005 (—)	0.003 (—)	0.006 (—)
Serum	7.524	0.001 (—)	0.003 (—)	0.003 (—)
Reduced Bovine Hemoglobin Solution	7.44	0.0005 (—)	0.002 (—)	0.003 (—)

All specific performance characteristics tests were run with default instrument calibration and after normal recommended equipment quality control checks were performed (see Operator's Manual).

Specimens at each level were analyzed in replicates of two for 20 days. The within-run and between-day standard deviations were calculated by the analysis of variance method.

Linearity⁴

Wherever possible, linearity for the OPTI CCA-TS measurement has been established against reference materials or methods. Linearity for pH of whole blood is established by measurement of blood specimens which were tonometered to various CO₂ values, and measured on an AVL 995 pH/Blood Gas Analyzer standardized to N.I.S.T. traceable pH buffers, and on three OPTI CCA-TS systems.

Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
1.0174	-0.1099	0.99972	0.006	6.85 – 7.67	81

Correlation to Other Methods⁴

OPTI CCA-TS 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-TS after obtaining the requisite results from existing instrumentation used for these analyses and operated and controlled following their established procedures.

Comparative Method*	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
Analyzer A (whole blood)	0.9269	0.534	0.9789	0.013	7.17 – 7.52	103
Analyzer B (whole blood)	1.0800	-0.579	0.9954	0.009	7.01 – 7.55	173
Analyzer C (whole blood)	1.126 ± 0.018	-0.946 ± 0.134	0.9868	0.018	7.09 – 7.58	105
Analyzer D (whole blood)	1.003 ± 0.008	-0.032 ± 0.058	0.9947	0.014	6.86 – 7.63	174
Analyzer E (whole blood)	1.104 ± 0.010	-0.739 ± 0.077	0.9919	0.014	6.81 – 7.62	183

* 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. 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 Significance¹

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 CO₂, 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.

$$\frac{I_0}{I} = \frac{1 - 10^{\text{pH}-\text{pKa}}}{R - 10^{\text{pH}-\text{pKa}}}$$

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 measured².

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

Tonometered whole blood samples were spiked with a number of endogenous and exogenous chemicals and tested for interference following the CLSI guideline EP7-A2:

Chemical	Interferent Concentration	pH Level	Interference
Acetaminophen	1.66 mM	7.170	NO
		7.520	NO
Acetylsalicylic acid	3.33 mM	7.170	NO
		7.520	NO
Ascorbic acid	0.23 mM	7.170	NO
		7.520	NO
B-Hydroxybutyric acid	16.03 mM	7.170	NO
		7.520	NO
Bilirubin	0.26 mM	7.170	NO
		7.520	NO
Cardiogreen	0.0065 mM	7.170	NO
		7.520	NO
Cystein	6.41 mM	7.170	NO
		7.520	NO
Ethanol	86.8 mM	7.170	NO
		7.520	NO
Evans blue	0.0104 mM	7.170	0.140
		7.520	NO
Glycolic acid	10 mM	7.170	NO
		7.520	NO
Halothane	0.759 mM	7.170	NO
		7.520	NO
Ibuprofen	2.43 mM	7.170	NO
		7.520	NO
Intralipid	1%	7.170	NO
		7.520	NO
Methylene Blue	0.125 mM	7.170	NO
		7.520	0.033
Sodium Chloride	20 mM	7.170	NO
		7.520	NO

The following samples were identified as interfering with the dry pH sensor in the interference study performed for the OPTI LION 510(k) submission.

Interferent	Test Level	Change
Sodium Bisulphate	11.5mM	-0.16
Phenylacetic Acid	10.0mM	-0.12
Methylene Blue	25mg/dL	Unstable
Fluorescein	25mg/dL	Unstable

Reproducibility

Controls

Within-Run (Swr) and Total (ST) Precision 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 three different lots of B-Lac cassettes are shown below.

Material	mean	Lot 1		Lot 2		Lot 3	
		Swr	ST	Swr	ST	Swr	ST
OPTI CHECK (aqueous control solution)							
Level 1	7.17	0.011	0.014	0.008	0.007	0.005	0.006
Level 2	7.44	0.010	0.010	0.010	0.010	0.004	0.005
Level 3	7.65	0.011	0.011	0.007	0.007	0.004	0.006

Whole Blood

Within-Run precision in whole blood samples was evaluated at three different pH concentrations using multiple instruments and multiple cassette lots.

	pH in Whole Blood		
	Level 1	Level 2	Level 3
Average	7.170	7.306	7.610
St. Dev	0.008	0.007	0.011
%CV	0.12%	0.10%	0.14%
n	18	18	18

Linearity³

Wherever possible, linearity for the OPTI CCA-TS measurement has been established against reference materials or methods. The linearity of the dry pH sensor has been established versus the standard pH sensor which is already approved for use on the OPTI CCA-TS system. Whole blood samples tonometered with different %CO₂ gas mixtures were used to establish the correlation.

Linearity of Whole Blood Samples

Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
0.99	0.09	0.996	0.016	6.59-7.86	189

Correlation to Other Methods³

OPTI CCA-TS vs other pH Instruments on whole blood in a typical setting

pH analysis of heparinized whole blood samples was performed at multiple clinical sites. Samples were analyzed on the OPTI CCA-TS in parallel with laboratory instrumentation operated by hospital personnel and controlled following the hospital's established procedures.

Comparative Method*	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
OPTI R Analyzer A	0.96	0.27	0.984	0.019	6.78 – 7.54	147
	1.03	0.20	0.968	0.015	7.091 – 7.538	111

* For more information on specific analyzers used, please contact OPTI Medical Technical Support.

OPTI CCA-TS with B-Lac Cassette vs other pH Instruments on whole blood (in-house testing)

Whole blood samples from multiple donors were tonometered with different %CO₂ 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.

Comparative Method*	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
Analyzer B	1.03	-0.21	0.996	0.016	6.578 - 7.766	174
Analyzer C	1.03	-0.19	0.996	0.015	6.582 - 7.701	174

* 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. 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).*

PCO₂**Clinical Significance¹**

The PCO₂ value of arterial blood is used to assess how well the body eliminates carbon dioxide, a by-product of metabolism. A PCO₂ value below the normal range is termed respiratory alkalosis and indicates *hypocapnia*, a condition caused by increased alveolar ventilation such as hyperventilation. An arterial PCO₂ 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 PCO₂ optode measurement principle is based upon placing a pH optode behind an ion-impermeable membrane², just as conventional PCO₂ blood gas electrodes employ the Severinghaus CO₂ electrode construction. As such, PCO₂ optodes may suffer interference from volatile acids and bases in blood, just as conventional PCO₂ electrodes.

The PCO₂ partial pressure is influenced by the local barometric pressure, as dictated by Dalton's law. The OPTI CCA-TS incorporates a pressure transducer, which accurately tracks the local barometric pressure and automatically compensates for it. The OPTI CCA-TS has been factory-calibrated to the absolute barometric pressure.

Measurement Range

Range	Resolution (Low/High)	Units
10 to 200	1/0.1	mmHg

Standard Reference Cassette (SRC) Limit Values

LOW	NORMAL	HIGH	Units
70.0 ± 2	40.0 ± 2	20.0 ± 2	mmHg

Reproducibility

Typical Within-Run (Swr), Between-Day (Sdd) and Total (ST) Precision is determined from 1 run per day with 2 replicates per run for 20 days on each of two OPTI CCA-TS instruments. PCO₂ is expressed in mmHg.

Material	mean	Swr (CV%)	Sdd (CV%)	ST (CV%)
OPTI CHECK PLUS (aqueous control solution)				
Level 1	74.2	0.07 (0.1)	0.70 (1.0)	0.71 (1.0)
Level 2	45.5	0.05 (0.1)	0.27 (0.6)	0.28 (0.6)
Level 3	22.8	0.04 (0.2)	0.21 (0.9)	0.22 (1.0)
Serum	40.9	0.09 (0.2)	0.47 (1.2)	0.48 (1.2)
Reduced Bovine Hemoglobin Solution	43.6	0.09 (0.2)	0.44 (1.0)	0.45 (1.0)

All specific performance characteristics tests were run with default instrument calibration and after normal recommended equipment quality control checks were performed (see Operator's Manual).

Specimens at each level were analyzed in replicates of two for 20 days. The within-run and between-day standard deviations were calculated by the analysis of variance method.

Precision and Recovery on Whole Blood

Whole blood was tonometered at 37 °C to various levels of gravimetrically prepared gases with CO₂ concentrations certified to 0.03% absolute by the manufacturer. For each tonometered level, 3 replicates were run on each of three OPTI CCA-TS systems. All values are in mmHg.

Expected	n	Observed	Swr	bias	%Recovery
10.4	9	10.9	0.28	0.5	105 %
27.6	9	29.3	0.36	1.7	106 %
27.8	9	29.1	0.41	1.3	105 %
45.0	9	44.2	0.33	-0.8	98 %
60.6	9	60.3	0.55	-0.3	100 %
69.2	9	69.4	0.55	0.2	100 %
80.1	9	81.2	0.68	1.1	101 %
100.8	9	102.4	1.15	1.6	102 %
201.3	9	195.5	1.21	-5.8	97 %

Linearity³

Wherever possible, linearity for the OPTI CCA-TS measurement has been established against reference materials or methods. PCO₂ linearity is established against values determined on whole blood tonometered to gravimetrically prepared gases with CO₂ concentrations certified to 0.03% absolute by the manufacturer, and measured on three OPTI CCA-TS systems.

Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
0.9681	2.148	0.99967	1.53	11 - 201	81

Correlation to Other Methods³

OPTI CCA-TS 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-TS after obtaining the requisite results from existing instrumentation used for these analyses and operated and controlled following their established procedures.

Comparative Method*	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
Analyzer A (whole blood)	0.9751	1.623	0.9871	1.16	28 – 72	103
Analyzer B (whole blood)	0.9740	2.66	0.9937	1.12	24 – 92	173
Analyzer C (whole blood)	0.988 ± 0.022	0.807 ± 1.015	0.9750	2.584	23 – 81	105
Analyzer D (whole blood)	1.073 ± 0.011	-2.785 ± 0.521	0.9910	2.050	17 – 122	174
Analyzer E (whole blood)	1.067 ± 0.009	-4.41 ± 0.468	0.9936	1.817	22 – 120	183

* 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. Vurek GG, Feustel PJ, Severinghaus JW, *A Fiber Optic PCO₂ 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).*

PCO₂ (Dry Sensor - B-Lac Cassette)

Clinical Significance¹

The PCO₂ value of arterial blood is used to assess how well the body eliminates carbon dioxide, a by-product of metabolism. A PCO₂ value below the normal range is termed respiratory alkalosis and indicates *hypocapnia*, a condition caused by increased alveolar ventilation such as hyperventilation. An arterial PCO₂ 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 PCO₂ 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 CO₂ permeates through the gas permeable membrane. The reaction sequence is outlined below.



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	Resolution (Low/High)	Units
10 to 200	1/0.1	mmHg
1.30 to 26.66	0.1/0.01	kPa

Standard Reference Cassette (SRC) Limit Values

LOW	NORMAL	HIGH	Units
70.0 ± 2	40.0 ± 2	20.0 ± 2	mmHg
9.33 ± 0.27	5.33 ± 0.27	2.67 ± 0.27	kPa

Interferences

Tonometered whole blood samples were spiked with a number of endogenous and exogenous chemicals and tested for interference following the CLSI guideline EP7-A2:

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	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
Cystein	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	-24.68 mmHg
		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

Reproducibility

Controls

Within-Run (Swr) and Total (ST) Precision 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 three different lots of B-Lac cassettes are shown below.

Material	mean	Lot 1		Lot 2		Lot 3	
		Swr	ST	Swr	ST	Swr	ST
OPTI CHECK (aqueous control solution)							
Level 1	68	1.73	1.73	2.49	2.87	1.02	1.23
Level 2	42	0.44	0.51	1.11	1.20	0.45	0.59
Level 3	23	0.91	0.93	2.08	2.36	0.91	0.92

Whole Blood

Within-Run precision in whole blood samples was evaluated at three different PCO₂ concentrations using multiple instruments and multiple cassette lots.

	PCO ₂ in Whole Blood		
	Level 1	Level 2	Level 3
Average	78.6	39.3	17.0
St. Dev	1.8	1.7	1.8
%CV	2.3%	4.4%	10.6%
n	18	18	18

Linearity²

The linearity of the dry PCO₂ sensor was established using whole blood samples tonometered with different gas mixtures of known gravimetric composition. The reference PCO₂ values of the tonometered blood samples were calculated from the gas composition using the following equation:

$$PCO_2 = (\text{Barometric Pressure} - 47) * \%CO_2$$

Linearity of Whole Blood Samples

Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
0.97	2.26	0.992	3.82	7 - 205	177

Correlation to Other Methods²

OPTI CCA-TS vs other PCO₂ Instruments on whole blood in a typical setting

PCO₂ analysis of heparinized whole blood samples was performed at multiple clinical sites. Samples were analyzed on the OPTI CCA-TS in parallel with laboratory instrumentation operated by hospital personnel and controlled following the hospital's established procedures.

Comparative Method*	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
OPTI R Analyzer A	0.99	4.15	0.984	3.53	21 – 184	146
	0.94	1.88	0.982	1.62	22.7 – 93.2	112

* For more information on specific analyzers used, please contact OPTI Medical Technical Support.

OPTI CCA-TS with B-Lac Cassette vs other PCO₂ Instruments on whole blood (in-house testing)

Whole blood samples from multiple donors were tonometered with different %CO₂ gas mixtures to generate a wide range of PCO₂ values. The blood samples were analyzed in parallel on the B-Lac cassette and other laboratory instruments.

Comparative Method*	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
OPTI CCA (std PCO ₂ sensor) Analyzer B	1.00	2.12	0.994	3.52	13 - 196	162
	0.96	1.75	0.986	3.34	13 - 104	153
Analyzer C	1.01	-0.47	0.994	3.74	15 - 199	162

* 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).*

PO₂**Clinical Significance¹**

The PO₂ 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 PO₂ (*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 O₂ content). Generally, O₂ levels above 100 mmHg do not contribute significantly to the oxygen content since, with normal hemoglobin concentrations, 80 - 100 mmHg, PO₂ provides a 97% saturation level, and a level greater than 100% cannot be achieved.

Measurement Principle

The PO₂ optode measurement principle is based upon luminescence quenching, first documented in the 1930's², and commercially utilized to measure blood PO₂ in 1983³. The relationship of luminescence to PO₂ is quantified by the Stern-Volmer equation,

$$I_0 / I = 1 + kP$$

which describes how the fluorescence emission intensity "I" is reduced as the PO₂ "P", is increased. Unlike conventional electrochemical "Clark" PO₂ electrodes, the oxygen optode does not consume oxygen molecules during the measurement.

The PO₂ partial pressure is influenced by the local barometric pressure, as dictated by Dalton's law. The OPTI CCA-TS incorporates a pressure transducer, which accurately tracks the local barometric pressure and automatically compensates for it. The OPTI CCA-TS has been factory-calibrated to the absolute barometric pressure.

Measurement Range

Range	Resolution (Low/High)	Units
10 to 700	1/0.1	mmHg

Standard Reference Cassette (SRC) Limit Values

LOW	NORMAL	HIGH	Units
60.0 ± 3	100.0 ± 3	170.0 ± 3	mmHg

Reproducibility

Typical Within-Run (Swr), Between-Day (Sdd) and Total (ST) Precision is determined from 1 run per day with 2 replicates per run for 20 days on each of two OPTI CCA-TS instruments. PO₂ is expressed in mmHg.

Material	mean	Swr (CV%)	Sdd (CV%)	ST (CV%)
OPTI CHECK PLUS (aqueous control solution)				
Level 1	68.9	0.13 (0.2)	0.59 (0.9)	0.61 (0.9)
Level 2	100.6	0.09 (0.1)	0.87 (0.9)	0.87 (0.9)
Level 3	142.7	0.13 (0.1)	1.37 (1.0)	1.38 (1.0)
Serum	92.2	0.08 (0.1)	0.72 (0.8)	0.73 (0.8)
Reduced Bovine Hemoglobin Solution	83.1	0.15 (0.2)	0.61 (0.7)	0.63 (0.8)

All specific performance characteristics tests were run with default instrument calibration and after normal recommended equipment quality control checks were performed (see Operator's Manual). Specimens at each level were analyzed in replicates of two for 20 days. The within-run and between-day standard deviations were calculated by the analysis of variance method.

Precision and Recovery on Whole Blood

Whole blood was tonometered at 37 °C to various levels of gravimetrically prepared gases with O₂ concentrations certified to 0.03% absolute by the manufacturer. For each tonometered level, 3 replicates were run on each of three OPTI CCA-TS systems. All values are in mmHg.

Expected	n	Observed	Swr	bias	%Recovery
20.8	7	21.2	0.97	0.4	102 %
41.5	7	39.9	1.03	-1.6	96 %
48.6	7	50.0	0.84	1.4	103 %
75.4	7	75.1	1.04	-0.3	100 %
120.4	9	121.2	2.06	0.8	101 %
201.3	8	206.3	2.67	5.0	102 %
300.5	9	296.8	4.91	-3.7	99 %
489.4	7	489.5	12.92	0.1	100 %
499.5	7	485.9	16.22	-13.6	97 %

Linearity⁴

Wherever possible, linearity for the OPTI CCA-TS measurement has been established against reference materials or methods. PO₂ linearity is established against values determined on whole blood tonometered to gravimetrically prepared gases with O₂ concentrations certified to 0.03% absolute by the manufacturer, and measured on three OPTI CCA-TS systems.

Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
0.9844	1.864	0.99974	4.52	21 – 500	68

Correlation to Other Methods⁴

OPTI CCA-TS 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-TS after obtaining the requisite results from existing instrumentation used for these analyses and operated and controlled following their established procedures.

Comparative Method*	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
Analyzer A (whole blood)	0.9419	3.28	0.9976	18.27	36 - 563	103
Analyzer B (whole blood)	1.0192	-4.13	0.9969	4.10	34 - 291	173
Analyzer C (whole blood)	0.918 ± 0.087	8.083 ± 1.402	0.9954	8.032	29 – 407	105
Analyzer D (whole blood)	1.041 ± 0.006	-6.244 ± 0.931	0.9969	6.379	37 – 598	174
Analyzer E (whole blood)	0.993 ± 0.009	1.646 ± 0.893	0.9925	4.458	34 – 322	183

* 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. 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 Fluorescence 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).*

PO₂ (Dry Sensor - B-Lac Cassette)

Clinical Significance¹

The PO₂ 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 PO₂ (*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 O₂ content). Generally, O₂ levels above 100 mmHg do not contribute significantly to the oxygen content since, with normal hemoglobin concentrations, 80 - 100 mmHg, PO₂ provides a 97% saturation level, and a level greater than 100% cannot be achieved.

Measurement Principle

The PO₂ optode measurement principle is based upon luminescence quenching, first documented in the 1930's², and commercially utilized to measure blood PO₂ in 1983³. The relationship of luminescence to PO₂ is quantified by the Stern-Volmer equation,

$$I_0 / I = 1 + kP$$

which describes how the fluorescence emission intensity "I" is reduced as the PO₂ "P", is increased. Unlike conventional electrochemical "Clark" PO₂ electrodes, the oxygen optode does not consume oxygen molecules during the measurement.

The PO₂ partial pressure is influenced by the local barometric pressure, as dictated by Dalton's law. The OPTI CCA-TS incorporates a pressure transducer, which accurately tracks the local barometric pressure and automatically compensates for it. The OPTI CCA-TS has been factory-calibrated to the absolute barometric pressure.

Measurement Range

Range	Resolution (Low/High)	Units
10 to 700	1/0.1	mmHg
1.30 - 93.31	0.1/0.01	kPa

Standard Reference Cassette (SRC) Limit Values

LOW	NORMAL	HIGH	Units
60.0 ± 3	100.0 ± 3	170.0 ± 3	mmHg
8.00 ± 0.40	13.33 ± 0.40	22.66 ± 0.40	kPa

Interferences

Tonometered whole blood samples were spiked with a number of endogenous and exogenous chemicals and tested for interference following the CLSI guideline EP7-A2:

Chemical	Interferent Concentration	PO ₂ Level	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	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
Cystein	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	31.16 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	-27.62 mmHg
Sodium Chloride	20 mM	48 mmHg	NO
		416 mmHg	NO

Reproducibility

Controls

Within-Run (Swr) and Total (ST) Precision 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 three different lots of B-Lac cassettes are shown below.

Material	mean	Lot 1		Lot 2		Lot 3	
		Swr	ST	Swr	ST	Swr	ST
OPTI CHECK (aqueous control solution)							
Level 1	72	1.25	1.38	1.07	1.10	0.69	0.75
Level 2	109	1.73	1.97	1.77	2.04	1.36	1.63
Level 3	155	1.48	1.89	1.76	2.19	1.31	1.69

Whole Blood

Within-Run precision in whole blood samples was evaluated at three different PO₂ concentrations using multiple instruments and multiple cassette lots.

	PO ₂ in Whole Blood		
	Level 1	Level 2	Level 3
Average	48.4	83.3	398.8
St. Dev	1.5	2.7	13.6
%CV	3.1%	6.0%	3.4%
n	18	18	18

Linearity⁴

The linearity of the dry PO₂ sensor was established using whole blood samples tonometered with different gas mixtures of known gravimetric composition. The reference PO₂ values of the tonometered blood samples were calculated from the gas composition using the following equation:

$$PO_2 = (\text{Barometric Pressure} - 47) * \%O_2$$

Linearity of Whole Blood Samples

Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
0.98	4.00	0.998	8.05	7 - 701	191

Correlation to Other Methods⁴

OPTI CCA-TS vs other PO₂ Instruments on whole blood in a typical setting

PO₂ analysis of heparinized whole blood samples was performed at multiple clinical sites. Samples were analyzed on the OPTI CCA-TS in parallel with laboratory instrumentation operated by hospital personnel and controlled following the hospital's established procedures.

Comparative Method*	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
OPTI R Analyzer A	1.04	-2.76	0.968	8.72	27 - 288	148
	0.97	3.73	0.992	5.24	27.0 - 423.8	110

* For more information on specific analyzers used, please contact OPTI Medical Technical Support.

OPTI CCA-TS with B-Lac Cassette vs other PO₂ Instruments on whole blood (in-house testing)

Whole blood samples from multiple donors were tonometered with different %O₂ gas mixtures to generate a wide range of PO₂ values. The blood samples were analyzed in parallel on the B-Lac cassette and other laboratory instruments.

Comparative Method*	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
OPTI CCA (Std. PO ₂ sensor)	0.94	4.84	0.998	9.77	19.9 - 642.8	161
Analyzer B	0.95	6.32	0.992	18.25	17.0 - 635.7	161

* 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. 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 Fluorescence 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 Significance¹

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 counters². 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-TS 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	145.0 ± 2	165.0 ± 2	mmol/L

Interferences

The OPTI CCA-TS Na⁺ sensor has no measurable interference from K⁺ variation within the range 0.8-10 mmol/L.

The OPTI CCA-TS 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-TS 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.

Substance	amount	Na ⁺ change (mmol/L)
Sodium fluorescein	26 mg/dL	unstable
Cardio (indocyanine) green	0.5 mg/dL	-18
Methylene blue	25 mg/dL	-2

Only clear, uncolored quality control materials, such as OPTI CHECK or OPTI CHECK PLUS brand aqueous controls should be used with the OPTI CCA-TS system. Colored materials, including proficiency testing materials, may interfere with the ion measurement, or fail to be properly aspirated.

Reproducibility

Typical Within-Run (Swr), Between-Day (Sdd) and Total (ST) Precision is determined from 1 run per day with 2 replicates per run for 20 days on each of two OPTI CCA-TS instruments. Sodium values are expressed in mmol/L.

Material	mean	Swr (CV%)	Sdd (CV%)	ST (CV%)
OPTI CHECK PLUS (aqueous control solution)				
Level 1	117.3	0.10 (0.1)	0.49 (0.4)	0.50 (0.4)
Level 2	142.3	0.11 (0.1)	0.50 (0.4)	0.51 (0.4)
Level 3	158.6	0.11 (0.1)	0.70 (0.4)	0.72 (0.5)
Serum	151.9	0.08 (0.1)	0.92 (0.6)	0.92 (0.6)
Reduced Bovine Hemoglobin Solution	122.3	0.09 (0.1)	0.64 (0.5)	0.65 (0.5)

All specific performance characteristics tests were run with default instrument calibration and after normal recommended equipment quality control checks were performed (see Operator's Manual). Specimens at each level were analyzed in replicates of two for 20 days. The within-run and between-day standard deviations were calculated by the analysis of variance method.

Linearity³

Wherever possible, linearity for the OPTI CCA-TS 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 Material 956a Electrolytes in Human Serum (Sodium_{NIST})

	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
Sodium _{ST}	0.9788	2.456	0.99911	1.32	104 – 188	30
Sodium _{NIST}	1.0172	3.244	0.99957	0.55	121 – 161	18

Correlation to Other Methods³

OPTI CCA-TS 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-TS after obtaining the requisite results from existing instrumentation used for these analyses and operated and controlled following their established procedures.

Comparative Method*	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
Analyzer A (whole blood)	0.6500	50.15	0.5721	2.21	126 – 149	103
Analyzer B (whole blood)	0.9313	9.34	0.9180	1.95	129 – 156	173
Analyzer C (whole blood)	1.084 ± 0.226	-14.929 ± 3.176	0.9784	1.826	128 – 174	105
Analyzer D (whole blood)	1.080 ± 0.021	-6.382 ± 2.855	0.9678	2.007	117 – 163	174
Analyzer E (serum)	0.873	15.49	0.8911	1.77	128 – 149	68
Analyzer F (serum)	1.025	-4.57	0.9376	1.57	127 – 148	102

* 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. 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 Significance¹

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 counters². 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-TS using the measured pH.

Measurement Range

Range	Resolution (Low/High)	Units
0.8 to 10	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-TS K⁺ sensor has no measurable interference from Na⁺ variation within the range 100-190 mmol/L.

The OPTI CCA-TS 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-TS 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-TS 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-TS 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.

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-TS system. Colored materials, including proficiency testing materials, may interfere with the ion measurement, or fail to be properly aspirated.

Reproducibility

Typical Within-Run (Swr), Between-Day (Sdd) and Total (ST) Precision is determined from 1 run per day with 2 replicates per run for 20 days on each of two OPTI CCA-TS instruments. Potassium values are expressed in mmol/L.

Material	mean	Swr (CV%)	Sdd (CV%)	ST (CV%)
OPTI CHECK PLUS (aqueous control solution)				
Level 1	2.61	0.004 (0.2)	0.026 (1.0)	0.026 (1.0)
Level 2	4.50	0.005 (0.1)	0.030 (0.7)	0.030 (0.7)
Level 3	5.58	0.006 (0.1)	0.048 (0.9)	0.47 (0.4)
Serum	7.11	0.010 (0.1)	0.08 (1.1)	0.08 (1.1)
Reduced Bovine Hemoglobin Solution	2.92	0.004 (0.1)	0.02 (0.8)	0.02 (0.8)

All specific performance characteristics tests were run with default instrument calibration and after normal recommended equipment quality control checks were performed (see Operator's Manual). Specimens at each level were analyzed in replicates of two for 20 days. The within-run and between-day standard deviations were calculated by the analysis of variance method.

Linearity³

Wherever possible, linearity for the OPTI CCA-TS 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})

	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
Potassium _{ST}	0.9964	0.116	0.99893	0.14	1.0 – 9.0	30
Potassium _{NIST}	0.9723	0.135	0.99956	0.05	2.0 – 6.0	18

Correlation to Other Methods³

OPTI CCA-TS 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-TS after obtaining the requisite results from existing instrumentation used for these analyses and operated and controlled following their established procedures.

Comparative Method*	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
Analyzer A (whole blood)	1.0816	-0.138	0.9857	0.13	2.1 – 6.4	103
Analyzer B (whole blood)	1.0225	-0.008	0.9673	0.15	2.4 – 6.0	173
Analyzer C (whole blood)	1.021 ± 0.019	-0.087 ± 0.077	0.9830	0.197	2.3 – 9.4	105
Analyzer D (whole blood)	1.050 ± 0.126	0.062 ± 0.055	0.9879	0.055	2.2 – 9.4	174
Analyzser E (serum)	1.084	-0.315	0.9855	0.181	2.9 – 7.5	68
Analyzser F (serum)	1.126	-0.397	0.9784	0.108	3.0 – 5.4	102

* 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. 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 Significance¹

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-TS 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.

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 disease².

Ionized calcium is important for diagnosis or monitoring of: hypertension management, parathyroidism, renal diseases, malnutrition, kidney stones, multiple myeloma and diabetes mellitus.

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 counters³. 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-TS 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-TS 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.

<u>Substance</u>	<u>amount</u>	<u>Ca⁺⁺ change mmol/L</u>
Sodium fluorescein	26 mg/dL	unstable
Cardio (indocyanine) green	0.5 mg/dL	+0.01
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-TS system. Colored materials, including proficiency testing materials, may interfere with the ion measurement, or fail to be properly aspirated.

Reproducibility

Typical Within-Run (Swr), Between-Day (Sdd) and Total (ST) Precision is determined from 1 run per day with 2 replicates per run for 20 days on each of two OPTI CCA-TS instruments. Ionized calcium values are expressed in mmol/L.

<u>Material</u>	<u>mean</u>	<u>Swr (CV%)</u>	<u>Sdd (CV%)</u>	<u>ST (CV%)</u>
OPTI CHECK PLUS (aqueous control solution)				
Level 1	1.26	0.001 (0.1)	0.007 (0.6)	0.007 (0.6)
Level 2	1.16	0.002 (0.2)	0.010 (0.9)	0.011 (0.9)
Level 3	0.79	0.001 (0.1)	0.005 (0.7)	0.005 (0.7)
Serum	0.64	0.001 (0.1)	0.01 (1.8)	0.01 (1.8)
Reduced Bovine Hemoglobin Solution	0.81	0.001 (0.2)	0.007 (0.9)	0.007 (0.9)

All specific performance characteristics tests were run with default instrument calibration and after normal recommended equipment quality control checks were performed (see Operator's Manual). Specimens at each level were analyzed in replicates of two for 20 days. The within-run and between-day standard deviations were calculated by the analysis of variance method.

Linearity⁴

Wherever possible, linearity for the OPTI CCA-TS 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})

	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
ionized Calcium _{ST}	1.0022	-0.0025	0.99983	0.017	0.2 - 3.0	24
ionized Calcium _{NIST}	0.9938	0.0081	0.99843	0.016	1.07 - 1.71	12

Correlation to Other Methods⁴

OPTI CCA-TS 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-TS after obtaining the requisite results from existing instrumentation used for these analyses and operated and controlled following their established procedures.

Comparative Method*	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
Analyzer A (whole blood)	0.8732	-0.064	0.8392	0.07	0.7 - 1.3	103

* 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. 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 Significance¹

Chloride is an anion that exists predominantly 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 counters². 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-TS using the measured pH.

Measurement Range

Range	Resolution (Low/High)	Units
50 to 160 mmol/L	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-TS 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 thiocyanate.

Only clear, uncolored quality control materials, such as OPTI CHECK or OPTI CHECK PLUS brand aqueous controls should be used with the OPTI CCA-TS system. Colored materials, including proficiency testing materials, may interfere with the ion measurement, or fail to be properly aspirated.

Heparin salts are the only acceptable anticoagulants. Other anticoagulants such as citrate, EDTA, oxalate, and fluoride cause significant interferences to the electrolyte sensors.

Reproducibility

Typical Within-Run (Swr), Between-Day (Sdd) and Total (ST) Precision is determined from 1 run per day with 2 replicates per run for 20 days on each of two OPTI CCA-TS instruments. Chloride values are expressed in mmol/L.

Material	mean	Swr (CV%)	Sdd (CV%)	ST (CV%)
OPTI CHECK PLUS (aqueous control solution)				
Level 1	76.8	0.12 (0.2)	0.51 (0.7)	0.53 (0.7)
Level 2	100.2	0.10 (0.1)	0.74 (0.7)	0.75 (0.8)
Level 3	116.8	0.11 (0.1)	0.45 (0.4)	0.47 (0.4)
Serum	97.6	0.06 (0.1)	1.03 (1.1)	1.03 (1.1)
Reduced Bovine Hemoglobin Solution	79.2	0.07 (0.1)	0.78 (1.0)	0.80 (1.0)

All specific performance characteristics tests were run with default instrument calibration and after normal recommended equipment quality control checks were performed (see Operator's Manual). Specimens at each level were analyzed in replicates of two for 20 days. The within-run and between-day standard deviations were calculated by the analysis of variance method.

Linearity³

Wherever possible, linearity for the OPTI CCA-TS 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})

	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
Chloride _{ST}	1.0076	-0.56	0.99984	0.68	58 - 160	15
Chloride _{CL}	1.0064	-2.44	0.99823	1.66	74 - 142	16

Correlation to Other Methods³

OPTI CCA-TS 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-TS after obtaining the requisite results from existing instrumentation used for these analyses and operated and controlled following their established procedures.

Comparative Method*	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
Analyzer A (whole blood)	0.9965	0.95	0.9246	1.96	92 - 117	173

* 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. 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 Significance¹

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.

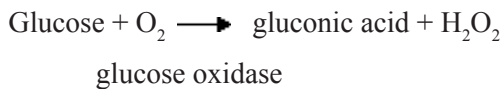
Abnormal Levels

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 propranolol. *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.



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 between 401-700 mmHg)	0.1	mg/dL
1.7 to 22	0.01	mmol/L

Standard Reference Cassette (SRC) Limit Values

LOW	NORMAL	HIGH	Units
40.0 ± 4	110.0 ± 4	300.0 ± 4	mg/dL
2.2 ± 0.22	6.1 ± 0.22	16.65 ± 0.22	mmol/L

Interferences

The OPTI CCA-TS Glu sensor does exhibit an interference from oxalate and EDTA at the levels used for anticoagulants. Heparin salts are therefore the only acceptable anticoagulants. The OPTI CCA-TS Glu sensor does exhibit an interference from PO_2 levels that exceed 700 mmHg. The Glu sensor corrects for PO_2 values up to 700 mmHg. Glucose values are suppressed when PO_2 values are > 700 mmHg.

Reproducibility

Typical Within-Run (Swr), Between-Day (Sdd) and Total (ST) Precision is determined from 1 run per day with 2 replicates per run for 20 days on each of two OPTI CCA-TS instruments. Glucose values are expressed in mg/dL and mmol/L.

Material		mean	Swr (CV%)	Sdd (CV%)	ST (CV%)
OPTI CHECK PLUS Level 1 (aqueous control solution)	(mg/dL)	44.9	0.28 (0.6)	1.38 (3.1)	1.42 (3.2)
	(mmol/L)	2.49	0.02 (0.6)	0.08 (3.1)	0.08 (3.2)
OPTI CHECK PLUS Level 2 (aqueous control solution)	(mg/dL)	102.8	0.38 (0.4)	2.87 (2.8)	2.90 (2.8)
	(mmol/L)	5.70	0.02 (0.4)	0.16 (2.8)	0.16 (2.8)
OPTI CHECK PLUS Level 3 (aqueous control solution)	(mg/dL)	252.4	1.7 (0.7)	12.4 (4.9)	12.5 (5.0)
	(mmol/L)	14.01	0.09 (0.7)	0.69 (4.9)	0.69 (5.0)
Serum (mg/dL)		71.9	0.3 (0.4)	1.7 (2.4)	1.8 (2.5)
	(mmol/L)	3.94	0.02 (0.4)	0.09 (2.4)	0.10 (2.5)

All specific performance characteristics tests were run with default instrument calibration and after normal recommended equipment quality control checks were performed (see Operator's Manual). Specimens at each level were analyzed in replicates of two for 20 days. The within-run and between-day standard deviations were calculated by the analysis of variance method.

Linearity²

Wherever possible, linearity for the OPTI CCA-TS 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}).

	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
Glucose _{ST} mg/dL	0.9874	3.26	0.9959	7.57	30 - 400	126
Glucose _{ST} mmol/L	0.9874	0.181	0.9959	0.420	1.6 - 23.0	126
Glucose _{NIST} mg/dL	1.0256	-7.79	0.9912	8.13	97 - 306	36
Glucose _{NIST} mmol/L	1.0256	-0.432	0.9912	0.451	5.4 - 17	36

Correlation to Other Methods²

OPTI CCA-TS 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-TS after obtaining the requisite results from existing instrumentation used for these analyses and operated and controlled following their established procedures.

Comparative Method*		Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
Analyzer A (whole blood)	(mg/dL)	1.0079	-0.7539	0.9932	6.509	30 – 400	138
	(mmol/L)	1.0079	-0.04	0.9932	0.36	1.7 – 22.2	138
Analyzer B (plasma)	(mg/dL)	0.9986	-2.34	0.9866	8.5	44 – 398	167
	(mmol/L)	0.9986	0.13	0.9866	0.47	2.4 – 22.1	167
OPTI CCA (whole blood vs. plasma)	(mg/dL)	1.058	2.36	0.97	21.6	37 – 395	103
	(mmol/L)	1.058	0.13	0.97	1.20	2.1 – 21.9	103
Analyzer C (serum)		0.950	5.73	0.9784	10.51	78 - 294	68
Analyzer D (serum)		0.991	3.99	0.9772	10.74	36 – 344	102

* 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).*

BUN (Urea)

Clinical Significance¹

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).

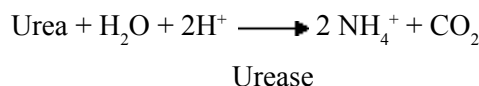
These may result from increased production or decreased excretion. Causes of increased production include a high protein intake, gastrointestinal bleeding with absorption of amino acids and peptides, or increased tissue breakdown which may be due to serious illness, trauma or certain drugs such as tetracyclines 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.



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
BUN	2.8 to 112.0	0.1	mg/dL
Urea	1 to 40	0.01	mmol/L

Standard Reference Cassette (SRC) Limit Values

	LOW	NORMAL	HIGH	Units
BUN	5.6 ± 1.4	28.0 ± 1.4	70.0 ± 1.4	mg/dL
Urea	2 ± 0.5	10 ± 0.5	25 ± 0.5	mmol/L

Interferences

The OPTI CCA-TS 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-TS BUN(urea) sensor will show an offset of +4.8 mg/dL BUN (1.7 mmol/L urea).

Reproducibility

Typical Within-Run (Swr), Between-Day (Sdd) and Total (ST) Precision is determined from 1 run per day with 2 replicates per run for 20 days on each of two OPTI CCA-TS instruments. BUN(urea) values are expressed in mg/dL and mmol/L, respectively.

Material	mean	Swr (CV%)	Sdd (CV%)	ST (CV%)
OPTI CHECK PLUS Level 1 (BUN mg/dL)	60.5	0.07 (0.1)	0.42 (0.7)	0.43 (0.7)
(aqueous control solution) (Urea mmol/L)	21.6	0.02 (0.1)	0.15 (0.7)	0.15 (0.7)
OPTI CHECK PLUS Level 2 (BUN mg/dL)	20.3	0.02 (0.1)	0.12 (0.6)	0.12 (0.6)
(aqueous control solution) (Urea mmol/L)	7.2	0.01 (0.1)	0.04 (0.6)	0.04 (0.6)
OPTI CHECK PLUS Level 3 (BUN mg/dL)	4.4	0.01 (0.2)	0.10 (2.2)	0.10 (2.2)
(aqueous control solution) (Urea mmol/L)	1.57	0.003 (0.2)	0.035 (2.2)	0.035 (2.2)
Serum (BUN mg/dL)	11.2	0.01 (0.1)	0.1 (0.8)	0.1 (0.8)
(Urea mmol/L)	4.0	0.004 (0.1)	0.04 (0.8)	0.04 (0.8)

All specific performance characteristics tests were run with default instrument calibration and after normal recommended equipment quality control checks were performed (see Operator's Manual). Specimens at each level were analyzed in replicates of two for 20 days. The within-run and between-day standard deviations were calculated by the analysis of variance method.

Linearity³

Wherever possible, linearity for the OPTI CCA-TS measurement has been established against reference materials or methods. BUN(urea) linearity is established with N.I.S.T SRM 909b Human Serum.

Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
1.0046	1.58	0.99919	1.75	16 - 86	6

Correlation to Other Methods³

OPTI CCA-TS 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-TS after obtaining the requisite results from existing instrumentation used for these analyses and operated and controlled following their established procedures.

Comparative Method*	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
Analyzer A (serum)	0.940	2.97	0.9975	1.05	8 – 89	68
Analyzer B (serum)	1.058	-3.04	0.9988	1.12	4 – 106	102
Analyzer C (plasma)	0.993	0.44	0.9953	1.00	6 – 65	47
Analyzer D (plasma)	0.971	-0.27	0.9822	0.98	5 – 42	50

* 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. 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)

Clinical Significance¹

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 Principle¹

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.



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	Resolution (Low/High)	Units
0.3 – 17.5	0.01 / 0.01	mmol/L
2.7 – 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 ± 9.0	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 20mg/dL the Lactate value is not reported.

The following substances were tested following the CLSI guideline EP7-A2:

Chemical	Test level Concentration	d max	Lactate Level mM	Interference
Acetaminophen	1.66 mM	0.2mM	2	NO
			5	NO
Acetylsalicylic acid	3.33 mM	0.2mM	2	NO
			5	NO
Ascorbic acid	0.23 mM	0.2mM	2	NO
			5	NO
B-Hydroxybutyric acid	16.03 mM	0.2mM	2	NO
			5	NO
Bilirubin	0.26 mM	0.2mM	2	NO
			5	NO
Cardiogreen	0.0065 mM	0.2mM	2	0.4 mM
			5	1.1 mM
Cystein	6.41 mM	0.2mM	2	NO
			5	NO
Ethanol	86.8 mM	0.2mM	2	NO
			5	NO
Evans blue	0.0104 mM	0.2mM	2	NO
			5	NO
Glycolic acid	10 mM	0.2mM	2	1.4 mM
			5	1.0 mM
Halothane	0.759 mM	0.2mM	2	NO
			5	NO
Ibuprofen	2.43 mM	0.2mM	2	NO
			5	NO

Chemical	Test level Concentration	d max	Lactate Level mM	Interference
Intralipid	1%	0.2mM	2	NO
			5	NO
Methylene Blue	0.125 mM	0.2mM	2	0.6 mM
			5	1.1 mM
Sodium Chloride	20 mM	0.2mM	2	NO
			5	NO

Additional interferences were found with the use of Sodium Fluoride (NaF) collection tubes. Heparin salts are the only recommended anti-coagulants acceptable for use on the B-Lac cassette.

Reproducibility

Controls

Within-Run (Swr) and Total (ST) Precision 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 three different lots of B-Lac cassettes are shown below. (Lactate values in mmol/L).

Material	mean	Lot 1		Lot 2		Lot 3	
		Swr	ST	Swr	ST	Swr	ST
OPTI CHECK (aqueous control solution)							
Level 1	0.89	0.12	0.14	0.09	0.1	0.06	0.09
Level 2	2.39	0.17	0.19	0.16	0.18	0.09	0.13
Level 3	4.20	0.28	0.31	0.17	0.22	0.22	0.26

Whole Blood

Within-Run precision in whole blood samples was evaluated at three different lactate concentrations using multiple instruments and multiple cassette lots.

	Lactate in Whole Blood		
	Level 1	Level 2	Level 3
Average	2.81	4.03	5.44
St. Dev	0.16	0.18	0.32
%CV	5.6%	4.6%	5.9%
n	12	12	12

Linearity²

Wherever possible, linearity for the OPTI CCA-TS measurement has been established against reference materials or methods. Linearity for the measurement of Lactate has been established versus the gravimetric concentration of lactate in a dilution sequence of aqueous buffers following CLSI guideline EP6-A.

Slope	Intercept	Correlation Coefficient (R ²)	Sy.x	Range	n
0.93	-0.08	0.993	0.47	0.3 – 17.5	107

Linearity was also established versus the I-STAT analyzer using whole blood samples that had been spiked with lactic acid to cover the measurement range.

Slope	Intercept	Correlation Coefficient (R ²)	Sy.x	Range	n
1.00	0.00	0.978	0.67	1.06 - 16.91	405

Correlation to Other Methods²

OPTI CCA-TS vs other Lactate Instruments on whole blood in a typical setting

Lactate analysis of heparinized whole blood samples was performed at multiple clinical sites. Samples were analyzed on the OPTI CCA-TS in parallel with laboratory instrumentation operated by hospital personnel and controlled following the hospital's established procedures.

Comparative Method*	Slope	Intercept	Correlation Coefficient (R ²)	Sy.x	Range	n
Analyzer A	0.96	-0.01	0.944	0.64	0.78 - 13.96	175
Analyzer B	1.18	-0.54	0.953	0.55	0.40 - 11.3	49

* For more information on specific analyzers used, please contact OPTI Medical Technical Support.

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 (SO₂%)

Clinical Significance¹

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.

ctHb gives valuable information in an emergency situation if interpreted not in an isolated fashion but in conjunction with other pertinent laboratory data.

ctHb 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 (SO₂%)

When each heme group of the hemoglobin molecule is associated with one molecule of oxygen, the hemoglobin is referred to as oxyhemoglobin (O₂Hb). The amount of oxyhemoglobin, expressed as a fraction of the total functional hemoglobin (able to bind oxygen), is termed hemoglobin oxygen saturation (SO₂%). 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 SO₂ 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 (FO₂Hb), 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, PCO₂, 2,3-DPG concentration and type of hemoglobin.³

Measurement Principle

The measurement of total Hemoglobin (ctHb) and oxygen saturation (SO₂) 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 O₂ 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 O₂ 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 SO₂, 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 SO₂ measurement because it is much more strongly absorbed by deoxyhemoglobin than all other hemoglobins, and it is picked close to the isobestic 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	Resolution (Low/High)	Units
tHb	5 to 25	0.1	g/dL
SO ₂	60 to 100	1/0.1	%

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	90.0 ± 2	98.0 ± 2	%

Interferences

The following interferents were quantified in whole blood, showing sensitivity to dyes similar to most CO-oximeters:

Substance	amount	ctHb change (g/dL)	SO ₂ change (%)
EXOGENOUS			
Cardio (Indocyanine) Green	0.5 mg/dL	+4.7	+4%
Evan's Blue	5.0 mg/dL	< 1	-17%
Methylene Blue	25 mg/dL	+3.0	-37%
ENDOGENOUS			
Carboxyhemoglobin	10%	-2.0	< 2%
Carboxyhemoglobin	20%	-3.3	< 2%
Methemoglobin	13%	+1.9	-7%

Rapidly sedimenting blood samples should be mixed thoroughly and immediately aspirated into the OPTI cassette, as described above in “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 SO₂ measurement.

Reproducibility

Typical Within-Run (Swr), Between-Day (Sdd) and Total (ST) Precision is determined from 1 run per day with 2 replicates per run for 20 days on each of two OPTI CCA-TS instruments. ctHb is expressed in g/dL and SO₂ in %.

Material		mean	Swr (CV%)	Sdd (CV%)	ST (CV%)
OPTI CHECK PLUS Level 1 (aqueous control solution)	(ctHb)	19.7	0.009 (0.1)	0.049 (0.3)	0.05 (0.3)
	(SO ₂ %)	77.8	0.03 (0.03)	0.13 (0.2)	0.13 (0.2)
OPTI CHECK PLUS Level 2 (aqueous control solution)	(ctHb)	14.2	0.02 (0.1)	0.07 (0.5)	0.08 (0.5)
	(SO ₂ %)	86.8	0.03 (0.1)	0.11 (0.1)	0.11 (0.1)
OPTI CHECK PLUS Level 3 (aqueous control solution)	(ctHb)	8.84	0.009 (0.1)	0.05 (0.5)	0.05 (0.6)
	(SO ₂ %)	95.4	0.02 (0.1)	0.14 (0.1)	0.14 (0.2)

All specific performance characteristics tests were run with default instrument calibration and after normal recommended equipment quality control checks were performed (see Operator’s Manual). Specimens at each level were analyzed in replicates of two for 20 days. The within-run and between-day standard deviations were calculated by the analysis of variance method.

Linearity⁴

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.

	Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
Total Hemoglobin	0.9839	0.165	0.99483	0.59	5.2 – 22.0	84

Correlation to Other Methods⁴

OPTI CCA-TS 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-TS after obtaining the requisite results from existing instrumentation used for these analyses and operated and controlled following their established procedures.

Comparative Method*		Slope	Intercept	Correlation Coefficient	Sy.x	Range	n
Analyzer A (whole blood)	(ctHb)	1.0285	-0.375	0.9778	0.47	6.0 – 16.1	103
	(SO ₂ %)	0.8678	12.99	0.9738	0.73	73 – 100	103
Analyzer B (whole blood)	(ctHb)	0.9866	0.14	0.9715	0.37	6.9 – 14.8	173
	(SO ₂ %)	0.7972	18.80	0.9064	1.81	64 – 100	173
Analyzer C (whole blood)	(ctHb)	1.077 ± 0.020	-0.284 ± 0.227	0.9650	0.739	5.4 – 17.4	215
	(SO ₂ %)	1.021 ± 0.016	-2.920 ± 1.522	0.9752	1.470	62 – 100	215

* 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. 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.

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APPENDIX A - TECHNICAL SPECIFICATIONS

Measurement Range

Parameter	Range	Display Resolution (Lo/Hi)	Units
pH	6.6 to 7.8	0.01/0.001	pH units
PCO ₂	10 to 200	1/0.1	mmHg
PO ₂	10 to 700	1/0.1	mmHg
Na ⁺	100 to 180	1/0.1	mmol/L
K ⁺	0.8 to 10	0.1/0.01	mmol/L
Ca ⁺⁺	0.2 to 3.0	0.01	mmol/L
Cl ⁻	50 to 160	1/0.1	mmol/L
Glu	30 to 400	0.1	mg/dL
	(70 to 400 for samples with PO ₂ levels between 401-700 mmHg)		
Glu	1.7 to 22	0.01	mmol/L
BUN	2.8 to 112	0.1	mg/dL
Urea	1 to 40	0.01	mmol/L
Lac	0.3 to 17.5	0.01	mmol/L
tHb	5 to 25	0.1	g/dL
SO ₂	60 to 100	1/0.1	%

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 - 32 °C (50 °F - 90 °F)
Relative Humidity Range	5% - 95% (non-condensing)
Type of Measurement	optical fluorescence, for tHb/SO ₂ optical absorbance/reflectance

Input Values

Patient ID	15 alphanumeric characters
Operator ID	11 alphanumeric characters
Accession Number	12 alphanumeric characters
Patient Temperature	14 – 44° C (58 - 111°F)
Patient Sex	male, female or ?
Date of birth	MMM-DD-YYYY
Hemoglobin Type	adult or fetal
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
Bypass	Off Pump / On Pump
Sample Type	Art/Ven/MixVen/Cap/Cord/CPB, where: Art = Arterial Ven = Venous MixVen = Mixed Venous Cap = Capillary Cord = Cord CPB = Cardio-Pulmonary Bypass
Total Hemoglobin, tHb	1 - 26 g/dL / 10 – 260 mg/dL / 0.6 – 16.1 mmol/L
Mean corpuscular hemoglobin concentration, MCHC%	29.0 – 37.0 %

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
FIO ₂	0.21 – 1.0
Respiratory quotient, RQ	0.70 – 2.00
P50	15 – 40
Vent Mode	No/SIMV/PSV/PCV/CMV-AC/CPAP PCIVR/BIPAP/PRVC, 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 PRVC = Pressure-Regulated Volume Control
Tidal Volume, TVol (VT)	0 – 4000
Minute Volume, MVOL (VE)	0 – 120
Peak Inspiratory Pressure, PIP	0 – 140
Plateau Pressure, Pplat	0 – 100
Pressure Support Value, PS	0 – 99.9
Positive End Expiratory Pressure, PEEP	0 – 50
Continuous Positive Airway Pressure, CPAP	0 – 50
Rate (f)	0 – 155
Flow Rate, Liter Flow (FR)	000.00 – 300.00
Inspiratory / Expiratory Ratio, I/E Ratio	0.2 – 9.9 / 0.2 – 9.9
BiLevel Pressure	0.2 - 9.9 / 0.2 - 9.9
User Field 1, 2 and 3	9 alphanumeric characters

Calculated Values

Actual bicarbonate (HCO_3^-)	1.0 - 200.0 mmol/L
Base excess (BE)	-40 - +40 mmol/L
Base excess ecf (BE_{ecf})	-40 - +40 mmol/L
Base excess actual (BE_{act})	-40 - +40 mmol/L
Buffer bases (BB)	0.0 - 100.0 mmol/L
Total CO_2 (tCO_2)	1.0 - 200.0 mmol/L
Standard bicarbonate (st.HCO_3^-)	1.0 - 200.0 mmol/L
Standard pH (st.pH)	6.500 - 8.000
Oxygen saturation (SO_2)	0.0 - 100.0%
Oxygen content (O_2ct)	0.0 - 56.0 mL/dL
Hematocrit (Hct(c))	15 - 75%
Hydrogen ion concentration (cH^+)	10.0 - 1000.0 nmol/L
Alveolar-arterial oxygen partial pressure difference (AaDO_2)	0.0 - 800.0 mmHg
Anion Gap (AG)	3 - 30 mmol/L
P50	15.0 - 35.0 mmHg
nCa ⁺⁺	0.1 - 3.0 mmol/L

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

Reference Ranges

Parameter	Units	Range	Reference Source
Actual bicarbonate (HCO ₃ ⁻)	mmol/L	18 to 23	Tietz ¹ , page 2179
Base excess (BE)	mmol/L	-2 to +3	Tietz ¹ , page 2179
Base excess ecf (BE _{ecf})	mmol/L	-2 to +3	Tietz ¹ , page 2179
Base excess actual (BE _{act})	mmol/L	-2 to +3	Tietz ¹ , page 2179
Buffer bases (BB)	mmol/L	46 to 52	Henry ² , page 152
Total CO ₂ (tCO ₂)	mmol/L	22 to 29	Tietz ¹ , page 2181
Standard bicarbonate (st.HCO ₃ ⁻)	mmol/L	22 to 24	Shapiro ³ , page 175
Standard pH (st.pH)	pH units	7.35 to 7.45	Tietz ¹ , page 2201
Oxygen saturation (SO ₂ (c))	%	95.0 to 98.0	Henry ² , page 1453
Oxygen content (O ₂ ct)	vol %	15.0 to 23.0	Tietz ¹ , page 2200
Hematocrit (Hct(c))	%	34 to 51	Tietz ¹ , page 2192
Hydrogen ion concentration (cH ⁺)	nmol/L	36 to 44	Tietz ¹ , page 2201
Alveolar-arterial oxygen partial pressure difference (AaDO ₂)	mmHg	5 to 20	Henry ² , page 157
Anion Gap (AG)	mmol/L	10 to 20	Tietz ¹ , page 2178
P50	mmHg	25 to 29	Tietz ¹ , page 1392
Normalized ionized calcium (nCa ⁺⁺)	mmol/L	0.1 to 3.0	

¹ Tietz, Norbert.W., "Reference Intervals", pp 2175-2217, Tietz Textbook of Clinical Chemistry, 2nd Edition, Philadelphia, W.B. Saunders Co., 1994.

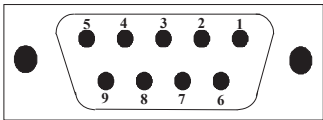
² Henry JB, "Clinical Diagnosis and Management by Laboratory Methods", 19th Edition, Philadelphia, W.B. Saunders Co., 1996

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 RS232C, 1 x CF slot, 1 x Ethernet port
Format	ASCII and ASTM
Storage	Data storage on the OPTI CCA-TS is dynamic. Typical storage capacity is >150 patient records. QC data for 1 month at 3 levels SRC data for 1 month at 3 levels

RS232C – Pin Configuration



REAR VIEW OF OPTI CCA-TS

- Pin 1 = No Connection
- Pin 2 = RxD
- Pin 3 = TxD
- Pin 4 = DTR
- Pin 5 = GND
- Pin 6 = DSR
- Pin 7 = No Connection
- Pin 8 = CTS
- Pin 9 = No Connection

Mains Supply for External Power Supply

100 ± 10% VAC to 240 ± 10% VAC, 50/60 Hz

Overvoltage Category

Category II when connected to a branch circuit

Dimensions and Weight

Height	4.7 ²	12.0 cm
Width	14.2 ²	36.2 cm
Depth	9.1 ²	23.0 cm
Weight		
w/o Battery	10 lbs	4.5 kg
with Battery	12 lbs	5.5 kg

Classifications

Approvals:	UL3101-1, CAN/CSA C22.2 NO.1010.1, CE, FCC Class A
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

Calculated Parameters

The calculated parameters in the OPTI CCA-TS are based on the CLSI Standard C12-A, when available.

Temperature⁴

$$T[{}^{\circ}F] = \frac{9}{5} \cdot T[{}^{\circ}C] + 32$$

$$T[{}^{\circ}C] = \frac{5}{9} \cdot (T[{}^{\circ}F] - 32)$$

⁴ Burtis AB, Ashwood ER, "Tietz Textbook of Clinical Chemistry" 2nd Ed. (Philadelphia, W.B. Saunders 1994), p. 2165

Units Used in Measured and Input Parameters for Calculations

pH.....pH-unit	Cl..... mmol/L
PCO ₂mmHg	Glu.....mmol/L
PO ₂mmHg	BUN mg/dL
Na.....mmol/L	Lacmmol/L
Kmmol/L	tHbg/dL
Ca..... mmol/L	SO ₂%

Conversion Table for Units⁵

ctO ₂ , O ₂ ct, 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

Equations⁶

cH⁺

Concentration (activity) of hydrogen ions in plasma.

$$cH^+ = 10^{(9-pH)} \quad [\text{nmol/L}]^6$$

st.pH

Standard pH of the blood is defined as the pH value of a blood sample which has been equilibrated at 37 °C with a gas mixture having a PCO₂ = 40 mmHg.

$$\text{st.pH} = (0.8262 - 0.01296 \cdot \text{tHb} + 0.006942 \cdot \text{BE}) \cdot \lg \cdot (0.025 \cdot \text{PCO}_2) + \text{pH} \quad [\text{pH-unit}]^6$$

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.

HCO₃⁻

Bicarbonate concentration in plasma.

$$\text{HCO}_3^- = 0.0307 \cdot \text{PCO}_2 \cdot 10^{(\text{pH}-6.105)} \quad [\text{mmol/L}]^1$$

st.HCO₃⁻

Standard bicarbonate of the blood, defined as the plasma bicarbonate concentration in blood which has been equilibrated at 37 °C with a gas mixture having a $\text{PCO}_2 = 40$ mmHg.

$$\text{st.HCO}_3^- = 10^{(\text{st.pH}-6.022)} \quad [\text{mmol/L}]^6$$

tCO₂

Total concentration of CO₂ in plasma, the sum of dissolved CO₂ and bicarbonate.

$$\text{tCO}_2 = \text{HCO}_3^- + (0.0307 \cdot \text{PCO}_2) \quad [\text{mmol/L}]^7$$

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 $\text{PCO}_2 = 40$ mmHg at 37 °C.

$$\text{BE} = (1 - 0.014 \cdot \text{tHb}) \cdot [(1.43 \cdot \text{tHb} + 7.7)(\text{pH} - 7.4) - 24.8 + \text{HCO}_3^-] \quad [\text{mmol/L}]^7$$

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).

$$\text{BE}_{\text{ecf}} = 16.2 \cdot (\text{pH} - 7.4) - 24.8 + \text{HCO}_3^- \quad [\text{mmol/L}]^7$$

⁷ CLSI. *Blood Gas and pH Analysis and Related Measurements; Approved Guideline*. NCCLS document C46-A, 2001.

BE_(act)

Base excess at actual oxygen saturation.

$$BE_{(act)} = (1 - 0.0143 \cdot tHb) \cdot [(1.63 \cdot tHb + 9.5) \cdot (pH - 7.4) - 24.26 + HCO_3^-] - 0.2 \cdot tHb \cdot \left(1 - \frac{SO_2}{100}\right) \quad [mmol/L]^8$$

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.

$$BB = BE + 41.7 + 0.42 \cdot tHb \quad [mmol/L]^6$$

SO₂(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, *PCO₂*, 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-TS has the capability to provide a measured *SO₂* from the blood sample. It is recommended that this measured value, if available, should be used in preference to the calculated *SO₂*.

If not available from measurement, and if calculation is selected:

$$SO_2 \% = \frac{Q}{Q+1} \cdot 100\% \quad (7)$$

Adult :

$$\lg Q = 2.9 \cdot \lg PO_2^k + 1.661 \cdot 10^{-0.074 \cdot PO_2^k} - 4.172$$

$$\lg PO_2^k = \lg PO_2 + 0.48 \cdot (pH - 7.4) - \lg\left(\frac{26.7}{26.7}\right) + 0.0013 \cdot BE$$

$$P_{50} = 26.7$$

Fetal :

$$\lg Q = 2.9 \cdot \lg PO_2^k + 1.3632 \cdot 10^{-0.0533 \cdot PO_2^k} - 4.113$$

$$\lg PO_2^k = \lg PO_2 + 0.48 \cdot (pH - 7.4) - \lg\left(\frac{21.5}{26.7}\right) + 0.0013 \cdot BE$$

$$P_{50} = 21.5$$

⁸ Zander R., Die korrekte Bestimmung des Base Excess (BE mmol/l) im Blut. Anesthesiol. Intensivmed. Notfallmed. Schmerzther.

ctO₂

Oxygen content is the sum of oxygen bound to hemoglobin as O₂Hb and the amount of oxygen dissolved in the plasma. This value is calculated from the measured O₂Hb and tHb if available and is estimated from the calculated SO₂ if the measured O₂Hb is not available and if the calculation of oxygen saturation is selected.

If measured O₂Hb and tHb are available:

$$ctO_2 = 1.39 \cdot \frac{O_2Hb}{100} \cdot tHb + 0.00314 \cdot PO_2 \quad [\text{vol}\%]^9$$

NOTE: If PO₂ is not available, ctO₂ is calculated with PO₂ = 90 mmHg.

If measured O₂Hb and tHb are not available and calculated SO₂ is enabled:

$$tO_2 = 1.39 \cdot \frac{SO_2}{100} \cdot tHb + 0.00314 \cdot PO_2 \quad [\text{vol}\%]^9$$

NOTE: If PO₂ is not available, ctO₂ is calculated with PO₂ = 90 mmHg.

P50

The oxygen partial pressure at half saturation, P₅₀, is defined as the PO₂ 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 PO₂ held constant at 7.4 and 40 mmHg respectively, the OPTI CCA-TS allows for the estimation of P₅₀ from measured SO₂%, PO₂ and pH. If a measured SO₂% is not available, the P₅₀ value may be input via keypad.

For Adult hemoglobin:

$$P_{50} = 26.7 \cdot 10^{(\lg PO_2 - \lg PO_2^k)}$$

where:

$$\lg PO_2^k = \frac{(\lg Q + 4.172)}{2.9}$$

$$Q = \frac{SO_2}{100\% - SO_2}$$

[mmHg]⁶

⁹ CLSI. *Blood Gas and pH Analysis and Related Measurements; Approved Guideline*. NCCLS document C46-A, 2001.

For Fetal hemoglobin:

$$P_{50} = 25.0 \cdot 10^{(\lg PO_2 - \lg PO_2^k)}$$

where:

$$\lg PO_2^k = \frac{(\lg Q + 4.113)}{2.9}$$

$$Q = \frac{SO_2}{100\% - SO_2} \quad [\text{mmHg}]^6$$

AaDO₂

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.

$$PAO_2 = (P_{\text{total}} - 47) FIO_2 - PACO_2 [FIO_2 + (1 - FIO_2)/R] \quad [\text{mmHg}]^7$$

$$PACO_2 = PaCO_2 \text{ (alveolar } PCO_2)$$

Apply above equation for $PAO_2 \geq PO_2$, otherwise $PAO_2 = PO_2$

pH^t

pH corrected to patient temperature other than 37 °C.

$$pH^t = pH - [0.0147 + 0.0065 \cdot (pH - 7.4)] \cdot (t - 37) \quad [\text{pH-unit}]^7$$

cH^{tt}

Concentration of hydrogen ions corrected to patient temperature other than 37 °C.

$$cH^t = 10^{(9 - pH^t)} \quad [\text{nmol/L}]^6$$

PCO₂^t

PCO₂ value corrected to patient temperature other than 37 °C.

$$PCO_2^t = PCO_2 \cdot 10^{0.019(t-37)} \quad [\text{mmHg}]^7$$

PO₂^t

PO₂ value corrected to patient temperature other than 37 °C.

$$PO_2^t = PO_2 \cdot 10^{\left[\frac{5.49 \cdot 10^{-11} \cdot PO_2^{3.88} + 0.071}{9.72 \cdot 10^{-9} \cdot PO_2^{3.88} + 2.30} \right] (t-37)} \quad [\text{mmHg}]^6$$

AaDO₂^t

Alveolar to arterial oxygen tension difference corrected to patient temperature other than 37 °C.

$$\text{AaDO}_2^t = \text{PAO}_2^t - \text{PaO}_2^t \quad [\text{mmHg}]^7$$

where:

$$\text{PAO}_2^t = (\text{P}_{\text{total}} - \text{PH}_2\text{O}^t) \text{FIO}_2 - \text{PACO}_2^t [\text{FIO}_2 + (1 - \text{FIO}_2)/\text{R}]$$

$$\text{with } \text{PH}_2\text{O}^t = 47 * 10^{[0.0237 - 0.0001(t-37)](t-37)}$$

$$\text{and } \text{PACO}_2 = \text{PaCO}_2 \text{ (alveolar } \text{PCO}_2 = \text{arterial } \text{PCO}_2)$$

Apply above equation for $\text{PAO}_2^t \geq \text{PO}_2^t$,

otherwise $\text{PAO}_2^t = \text{PO}_2^t$

Hct(c)

Hct(c) as a function of tHb.

$$\text{Hct(c)} = \text{tHb}[\text{g} / \text{dl}] / (\text{MCHC}\% / 100) \quad [\%]^{10}$$

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.

$$\text{AG} = \text{Na}^+ + \text{K}^+ - \text{Cl}^- - \text{HCO}_3^- \quad [\text{mmol/L}]$$

nCa⁺⁺

The ionized calcium value normalized to pH = 7.40.

For blood:

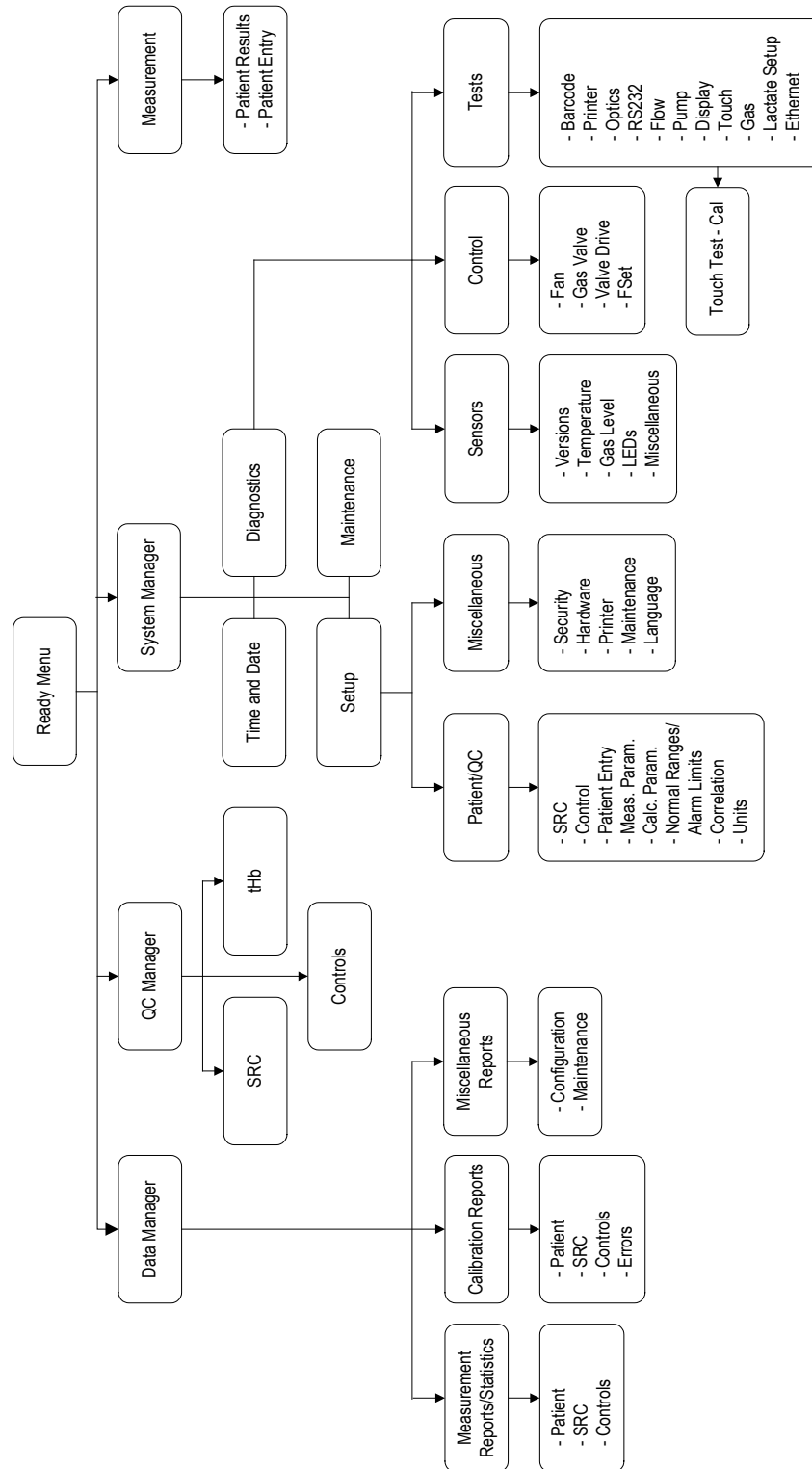
$$\text{nCa}^{++} (\text{pH} = 7.4) = \text{Ca}^{++} * 10^{0.22 * (\text{pH} - 7.4)} \quad [\text{mmol/L}]$$

For plasma or serum:

$$\text{nCa}^{++} (\text{pH} = 7.4) = \text{Ca}^{++} * 10^{0.24 * (\text{pH} - 7.4)} \quad [\text{mmol/L}]$$

¹⁰ 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

(E-Glu example)

OPTI Medical OPTI CCA-TS Patient Report DD-YYY-MM HH:MM	P50 26.7 mmHg
Pat. ID: 123456789012345	VntMode N/A
Access. No.:123456789012	TVol 0 mL
Sample No.: 2345	MVol 0 L
ACID/BASE 37.0°C 38.5°C	PIP 0
pH 7.343 7.322	Pplat 0.0
PCO2 41.0 43.8mmHg	PS 68
PO2 84.9 93.5mmHg	PEEP 0
BE - 3.7 mmol/L	CPAP 0
tCO2 23.0 mmol/L	Rate(f) 0 bpm
HCO3 21.0 mmol/L	L.Flow 0 Lpm
ELECTROLYTES	I/E 1: 1.0
Na+ 140.2 mmol/L	BiLevel 0.0/ 0.0
K+ 3.67 mmol/L	PuncSite LR
HEMOGLOBIN/OXYGEN STATUS	Bypass On-Pump
tHb 14.4 g/dL	Barometer 739.6 mmHg
SO2 95.7 %	Operator ID:123456789012
Hct[c] 43.2 %	S/N:123456 LOT:123456
METABOLITES	(Ref.Lim)
Glu 62.1 mg/dL	pH 7.20 - 7.60
ENTERED PARAMETERS	PCO2 30 - 50 mmHg
Temp 38.5 °C	PO2 70 - 700 mmHg
Sex Male	Na+ 135 - 145 mmol/L
Hb Type Adult	K+ 3.5 - 5.1 mmol/L
SamType Art	Cl- 95 - 115 mmol/L
MCHC 33.3 %	Ca++ 1.12 - 1.32 mmol/L
O2 Mode Room Air	Glu 60.0 - 120.0 mg/dL
FIO2 0.21	tHb 12.0 - 17.0 g/dL
RQ 0.84	SO2 90 - 100 %
	MESSAGES
	Reminder:Run SRCs today

SRC Measurement Report
(E-Ca example)

```
-----  
OPTI Medical OPTI CCA-TS  
SRC Measurement  
DD-MMM-YY HH:MM  
  
Level: 3  
SRC ID:XXXXX Exp: MMY  
  
      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+   165.1    142-148      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:123456789012  
S/N:123456  
-----
```

SRC Statistics Report**(ABG example)**

```

OPTI Medical OPTI CCA-TS
  SRC Statistics
  DD-MMM-YY  HH:MM
Level 1
SRCID:XXXXXXXX Exp:DDMMYY
S/N: XXXXX
Number run: 26
Number ok : 26
ABG LIMITS:
pH      7.100-7.150
PCO2    68.0- 72.0 mmHg
PO2     57.0- 63.0 mmHg
Date    pH      PCO2   PO2    OK?
08Aug   7.13    67.8   59.3   OK
09Aug   7.12    72.2   59.7   OK
10Aug   7.11    69.8   58.7   OK
11Aug   7.10    69.2   58.6   OK
12Aug   7.07    67.8   58.8   OK
13Aug   7.08    67.3   57.3   OK
14Aug   7.09    67.4   57.4   OK
15Aug   7.11    71.5   56.8   OK
16Aug   7.09    68.0   56.3   OK
17Aug   7.08    68.0   57.1   OK
19Aug   7.10    68.0   56.2   OK
20Aug   7.11    68.1   55.4   OK
21Aug   7.12    68.8   55.6   OK
22Aug   7.13    69.3   55.5   OK
23Aug   7.12    70.1   54.5   OK
24Aug   7.11    70.2   54.5   OK
25Aug   7.10    70.5   53.7   OK
26Aug   7.10    71.5   53.7   OK
27Aug   7.11    68.0   54.1   OK
28Aug   7.11    71.8   54.2   OK
29Aug   7.12    72.7   55.3   OK
30Aug   7.13    72.7   55.4   OK
31Aug   7.13    72.5   56.9   OK
01Sep   7.11    71.1   57.0   OK
02Sep   7.12    72.1   58.0   OK
03Sep   7.11    72.1   57.0   OK
-----
Mean:   7.107  70.0  56.6
SD:     0.015  1.9   1.7
CV%:    0.21%  2.8%  3.0

```

Controls Measurement Report

(E-Ca example)

```
-----  
OPTI Medical OPTI CCA-TS  
Controls Measurement  
DD-MMM-YY HH:MM  
  
Level: 2 OPTI-check  
Sample No.:2345  
QCLot:1234 Exp:MMYYYY  
  
      RESULT   LIMITS   OK?  
pH    7.551    7.48-7.56  OK  
PCO2  69.8      65-75      OK  
PO2   99.8      96-105     OK  
Na+   144.2     142-148    OK  
K+    4.46      4.0-4.8    OK  
Ca++  1.10      1.0-1.2    OK  
tHb   14.7      14.0-15.3  OK  
SO2   98.3      96-99      OK  
  
Control Test Result:  PASS  
Store to Database:    YES  
  
Barometer: 744.5 mmHg  
Operator ID:12345678901  
S/N:1234 Lot:123456  
-----
```

Controls Statistics Report**(ABG Cassette example)**

OPTI Medical OPTI CCA-TS
 Controls Statistics
 DD MMM YY HH:MM

Level: 1 OPTI-check
 QCLOT:XXXX Exp: MMYYY
 CassLot: XXXXXX
 S/N: XXXX
 Number run: 26
 Number ok: 26

ABG LIMITS:

pH 7.070-7.130
 PCO2 63.0- 77.0 mmHg
 PO2 60.0- 80.0 mmHg

Date	pH	PCO2	PO2	OK?
08Aug	7.123	71.5	73.6	OK
09Aug	7.113	73.6	74.5	OK
10Aug	7.090	76.2	73.7	OK
11Aug	7.101	70.3	75.2	OK
12Aug	7.123	67.8	68.0	OK
13Aug	7.101	69.7	66.8	OK
14Aug	7.076	67.9	75.9	OK
15Aug	7.080	73.7	78.5	OK
16Aug	7.093	72.5	66.3	OK
17Aug	7.099	71.5	69.0	OK
18Aug	7.105	73.5	68.1	OK
19Aug	7.119	76.7	70.7	OK
20Aug	7.104	69.3	77.6	OK
21Aug	7.098	67.0	65.9	OK
22Aug	7.079	66.9	77.0	OK
23Aug	7.084	70.5	62.9	OK
24Aug	7.123	70.2	77.7	OK
25Aug	7.078	73.9	68.9	OK
26Aug	7.129	71.9	67.0	OK
27Aug	7.109	71.5	62.8	OK
28Aug	7.103	64.8	78.6	OK
29Aug	7.113	69.9	70.2	OK
30Aug	7.107	71.9	79.0	OK
31Aug	7.093	67.8	67.6	OK
01Sep	7.079	75.2	78.0	OK
02Sep	7.083	74.2	78.9	OK

 Mean: 7.123 69.7 73.6
 SD: 0.017 1.6 1.2
 CV%: 0.23% 0.3% 0.4%

Configuration Report (Part 1)

NOTE: The values and settings shown are for example purposes only. Please refer to your particular analyzer's configuration report for its correct values and settings.

<p>OPTI Medical OPTI CCA-TS For Research Use Only Not for use in diagnostic procedures Configuration Report DD-MMM-YY HH:MM S/N: XXXX Version: ABCX.XX</p> <p>Baro. Factor : 0.0 mmHg</p> <p>Patient Info - Pat.ID : ON / Opt. Oper.ID : ON / Opt. AccNum. : ON / Opt. DOB : ON Temp. : ON Sex : ON Hb Type : ON Sample Type: ON tHb : ON MCHC : ON O2 Mode : OFF FIO2 : ON RQ : ON P50 : ON Vent Mode : ON TVol : ON MVol : ON PIP : ON Pplat : ON PS : ON PEEP : ON CPAP : ON Rate : ON Liter Flow : ON I/E Ratio : ON BiLevel : ON User Def. : ON User Def.2 : ON User Def.3 : ON Puncture Site : ON Bypass : ON Def. tHb : 15.0 g/dL Def. MCHC : 33.3% Def. FIO2 : 0.21 Def. RQ : 0.84 Def. P50 : 26.7 mmHg</p>	<p>Reference Limits - pH 7.200-7.600 PCO2 30.0- 50.0 mmHg PO2 70.0-700.0 mmHg Na+ 135.0-145.0 mmol/L K+ 3.50- 5.10 mmol/L Cl- 95-115.0 mmol/L Ca++ 1.12- 1.32 mmol/L Glu 60.0-120.0 mg/dL BUN 5.9- 19.9 mg/dL Lac 0.90- 1.70 mmol/L tHb 12.0- 17.0 g/dL SO2 90.0-100.0 %</p> <p>Controls Info - Lev. 1 LimMin LimMax pH 7.120-7.240 PCO2 60.0- 76.0 mmHg PO2 62.0- 86.0 mmHg Na+ 121.0-131.0 mmol/L K+ 2.60- 3.40 mmol/L Cl- 84.0- 94.0 mmol/L Ca++ 1.44- 1.74 mmol/L Glu 30.0-400.0 mg/dL BUN 2.8-112.0 mg/dL Lac 0.70- 1.10 mmol/L tHb 18.2- 22.2 g/dL SO2 76.0-82.0 % QCLOT: 9169 Exp: Mar2012 Lev. 2 LimMin LimMax pH 7.360-7.480 PCO2 37.0- 45.0 mmHg PO2 90.0-114.0 mmHg Na+ 137.0-151.0 mmol/L K+ 4.40- 5.20 mmol/L Cl- 102.0-112.0 mmol/L Ca++ 1.14- 1.34 mmol/L Glu 30.0-400.0 mg/dL BUN 2.8-112.0 mg/dL Lac 1.90- 3.30 mmol/L tHb 12.8- 15.8 g/dL SO2 87.0- 93.0 % QCLOT: 9269 Exp: Mar2012 Lev. 3 LimMin LimMax pH 7.580-7.680 PCO2 17.0-27.0 mmHg PO2 131.0-155.0 mmHg Na+ 151.0-165.0 mmol/L K+ 5.30- 6.30 mmol/L Cl- 118.0-128.0 mmol/L</p>	<p>Ca++ 0.66- 0.90 mmol/L Glu 30.0-400.0 mg/dL BUN 2.8-112.0 mg/dL Lac 3.60- 5.40 mmol/L tHb 8.1- 11.1 g/dL SO2 94.0- 99.0 % QCLOT: 9369 Exp: Mar2012 Printouts - Patient : ON, copies 1 Calib. : OFF Ref. Rng : ON</p> <p>Dest. : Both Connect. : Ethernet IP Port : 9100 IP Addr. : 192.168.13.211 Security - Password : ENABLED QC Lockout - SRC Levels : 0 QC Levels : 0 New Lot : OFF</p> <p>Miscellaneous Units - Units : Conventional Temp : Celcius Time : 24-hour tHb : g/dL Ca++ : mmol/L Glu : mg/dL BUN : mg/dL Lac : mmol/L Resolution : High Correlation Factors - Normal Cassettes</p> <table border="1"> <thead> <tr> <th></th> <th>Slope</th> <th>Offset</th> </tr> </thead> <tbody> <tr><td>pH</td><td>1.000</td><td>0.000</td></tr> <tr><td>PCO2</td><td>1.000</td><td>0.0</td></tr> <tr><td>PO2</td><td>1.000</td><td>0.0</td></tr> <tr><td>Na+</td><td>1.000</td><td>0.0</td></tr> <tr><td>K+</td><td>1.000</td><td>0.00</td></tr> <tr><td>Cl-</td><td>1.000</td><td>0.0</td></tr> <tr><td>Ca++</td><td>1.000</td><td>0.00</td></tr> <tr><td>Glu</td><td>1.000</td><td>0.0</td></tr> <tr><td>BUN</td><td>1.000</td><td>0.0</td></tr> <tr><td>Lac</td><td>1.000</td><td>0.0</td></tr> <tr><td>tHb</td><td>1.000</td><td>0.0</td></tr> <tr><td>SO2</td><td>1.000</td><td>0.0</td></tr> </tbody> </table> <p>Hardware - Ext. Barcode : OFF CF Delimiter :</p>		Slope	Offset	pH	1.000	0.000	PCO2	1.000	0.0	PO2	1.000	0.0	Na+	1.000	0.0	K+	1.000	0.00	Cl-	1.000	0.0	Ca++	1.000	0.00	Glu	1.000	0.0	BUN	1.000	0.0	Lac	1.000	0.0	tHb	1.000	0.0	SO2	1.000	0.0
	Slope	Offset																																							
pH	1.000	0.000																																							
PCO2	1.000	0.0																																							
PO2	1.000	0.0																																							
Na+	1.000	0.0																																							
K+	1.000	0.00																																							
Cl-	1.000	0.0																																							
Ca++	1.000	0.00																																							
Glu	1.000	0.0																																							
BUN	1.000	0.0																																							
Lac	1.000	0.0																																							
tHb	1.000	0.0																																							
SO2	1.000	0.0																																							

Configuration Report (Part 2)

```

Communications -
  Baud      : 9600
  Format    : RS232- ASCII
  Link     : RS232
  Language : English
  Battery Saver -
    AutoOff : Always On
    Display : Always On
  Measured Parameters -
    Blanking : OFF
  B
    pH      PCO2   PO2   tHb
    SO2
  B-Lac
    pH      PCO2   PO2   Lac
    tHb     SO2
  B-60
    pH      PCO2   PO2
  E
    pH      PCO2   PO2   Na+
    K+      tHb    SO2
  E-Cl
    pH      PCO2   PO2   Na+
    K+      Cl-    tHb   SO2
  E-Ca
    pH      PCO2   PO2   Na+
    K+      Ca++   tHb   SO2
  E-Glu
    pH      PCO2   PO2   Na+
    K+      Glu    tHb   SO2
  E-BUN
    pH      PCO2   PO2   Na+
    K+      BUN    tHb   SO2

Calculated Parameters -
  B
    BE      tCO2   HCO3
    st.HCO3 Hct(c)
  B-Lac
    BE      tCO2   HCO3
    st.HCO3 Hct(c)
  B-60
    BE      tCO2   HCO3
    st.HCO3
  E
    BE      tCO2   HCO3
    st.HCO3 Hct(c)
  E-Cl
    BE      tCO2   HCO3
    st.HCO3 AnGap
  E-Ca
    BE      tCO2   HCO3
    st.HCO3 Hct(c)

```

```

E-Glu
  BE      tCO2   HCO3
  st.HCO3 Hct(c)
E-BUN
  BE      tCO2   HCO3
  st.HCO3 Hct(c)

FSET Values -
System Version: 3.00.0037
GUI App.: 3.00.0037
CCA App.: 3.00.0037
GUI Boot: 3.00.0000
CCA Boot: 3.00.0001
  IDAC1: 1464
  IDAC2: 2024
  IDAC3: 708
S/N: XXXX
  pH False: 583
  O2 False: 2116
  CO2 False: 663
  Ca False: 1855
  K False: 9151
  Na False: 2335
  Low Limit: 278
  Up Limit: 1985
  Low offset: 500.000
  Up factor: 0.800
  Home offset: 240
  PHR Correction: 160
  PCR Correction: 75
  GAS 0psi :441
  GAS 140psi :3611
  pH Dry Scalar : 0.000000
  Printer Fix: No
  Laser Parameters:
  HbCal Life: 3
  WQC_SETTLE: 0.1000
  WQC_NUM : 75
  SAM_SETTLE: 0.1000
  SAM_NUM : 75
  K1: 3.5711 F1: 0.9717
  K2: 3.2248 F2: 1.0010
  K3: 0.8407 F3: 0.9825
  K4: -9.2500 F4: 0.0000
  K5: 17.5040 F5: 0.0000
  K6: 5.0090 F6: 7.9000
  K7: 12.3660 F7: 44.7000
  K8: 121.3850 F8: 11.4000
  K9: 0.1321 F9: 41.4000
  K10: 0.1428 F10: 15.8000
  K11: 0.0040 F11: 2.0000
  K12: 1.2586 F12: 48.5000

```

Maintenance Report

```
-----  
OPTI Medical OPTI CCA-TS  
MAINTENANCE REPORT  
  DD-MMM-YY  HH:MM  
S/N: XXXX  
Version: ABCX.XX  
  
DDMMYY      HH:MM  
Pump Replaced  
  DOM0213D  
DDMMYY      HH:MM  
Cleaning Completed  
  
-----
```

Error Report

```
-----  
OPTI Medical OPTI CCA-TS  
  ERROR Report  
  DD-MMM-YY  HH:MM  
S/N: XXXX  
Version: ABCX.XX  
  
  DDMMYY      HH:MM  
ERROR-Cassette Misseat 1  
  DDMMYY      HH:MM  
ERROR-Cassette Misseat 2  
  DDMMYY      HH:MM  
ERROR - Gas Expired  
  DDMMYY      HH:MM  
Warning-Bubble Detected  
  DDMMYY      HH:MM  
Stop - Low Gas  
  
-----
```

Lactate Setup Report

```
-----  
OPTI Medical OPTI CCA-TS  
Lactate Setup Report  
DD-MMM-YY HH:MM
```

```
Level: 2 OPTI-check  
QCLot:XXXX Exp: MMYYY
```

```
          pH setup point  
Run      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
```

```
Scalar Setup : PASS
```

```
S/N:2999 LOT:020651
```

```
-----
```

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