Blood Gas Systems

OPTI™ R Analyzer

Operator's Manual

OPTIMedical

OPERATOR'S MANUAL REVISION LOG

(Please record any changes made to this manual)

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PD7032 REV K

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™ R related products.

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

Symbol	Explanation
	Biohazard Symbol – Products and/or components containing this symbol should be handled as biohazardous material after use.
	Temperature Limit Symbol – Products and/or components which contain this symbol must be stored within the specified temperature range.
IVD	For in-vitro diagnostic use
CE	This product 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
EC REP	Authorized European Community Representative

PREFACE

Welcome

Your OPTI™ R 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^{++}), total hemoglobin concentration (tHb) and hemoglobin oxygen saturation (SO_2) 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.

Table of Contents

1 INTRODUCTION

1.1 Overview

The OPTI™ R Analyzer is a blood gas and electrolyte analyzer for use in whole blood, serum or plasma.

The OPTI R Analyzer is designed to provide rapid results for pH, carbon dioxide partial pressure (PCO_2), oxygen partial pressure (PO_2), sodium (Na^+), potassium (K^+), ionized calcium (Ca^{++}), total hemoglobin concentration (tHb), and hemoglobin oxygen saturation (SO_2).
The table below provides important information regarding supported sample types, available reporting units and analyzer measurement ranges for each parameter.

	Sample Type			Available Units		Measurement Range	Display Resolution
Parameter	**Whole blood**	**Plasma**	**Serum**	**Default**	**Other**	**(Default Units)**	**(Lo/Hi)**
pH	x	x	x	pH units		6.8 - 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
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 R Analyzer is a microprocessor-controlled medical instrument measuring optical fluorescence from discrete sensors called optical electrodes (optodes).

A multi-use cassette contains the sensors, storage buffer and a valve to control fluid flow. After reading the calibration information specific to a cassette into the instrument by holding the cassette package in front of a convenient bar code reader, 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 channel is calibrated with the wash buffer contained in the Fluid Pack which is tonometered with the gas from the gas bottle. The electrolyte channels are calibrated using the wash buffer solution contained in the Fluid Pack. The tHb and SO_2 channels are factory-calibrated. When calibration is verified, the analyzer is ready for sampling. Up to 50 blood samples can be analyzed on one cassette. At the start of an analysis, 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 completion of the measurement, the ananlyzer will wash the cassette and perform a gas calibration. The Fluid Pack contains the wash solution and a waste pouch.

1.3 Contents

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

- Power supply with power cord
- Shutdown pack, shutdown cassette and 2 shutdown bottles
- Syringe and stylette for troubleshooting
- Gas bottle
- Thermal printer paper
- Calibrator cassette (Cal)

NOTE: The Cal Cassette is located inside the door for the thermal printer.

You will also need the following consumables prior to setup:

- OPTI R cassette
- OPTI R Fluid Pack
- OPTI Check Quality Control Material

1.4 Analyzer Components

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

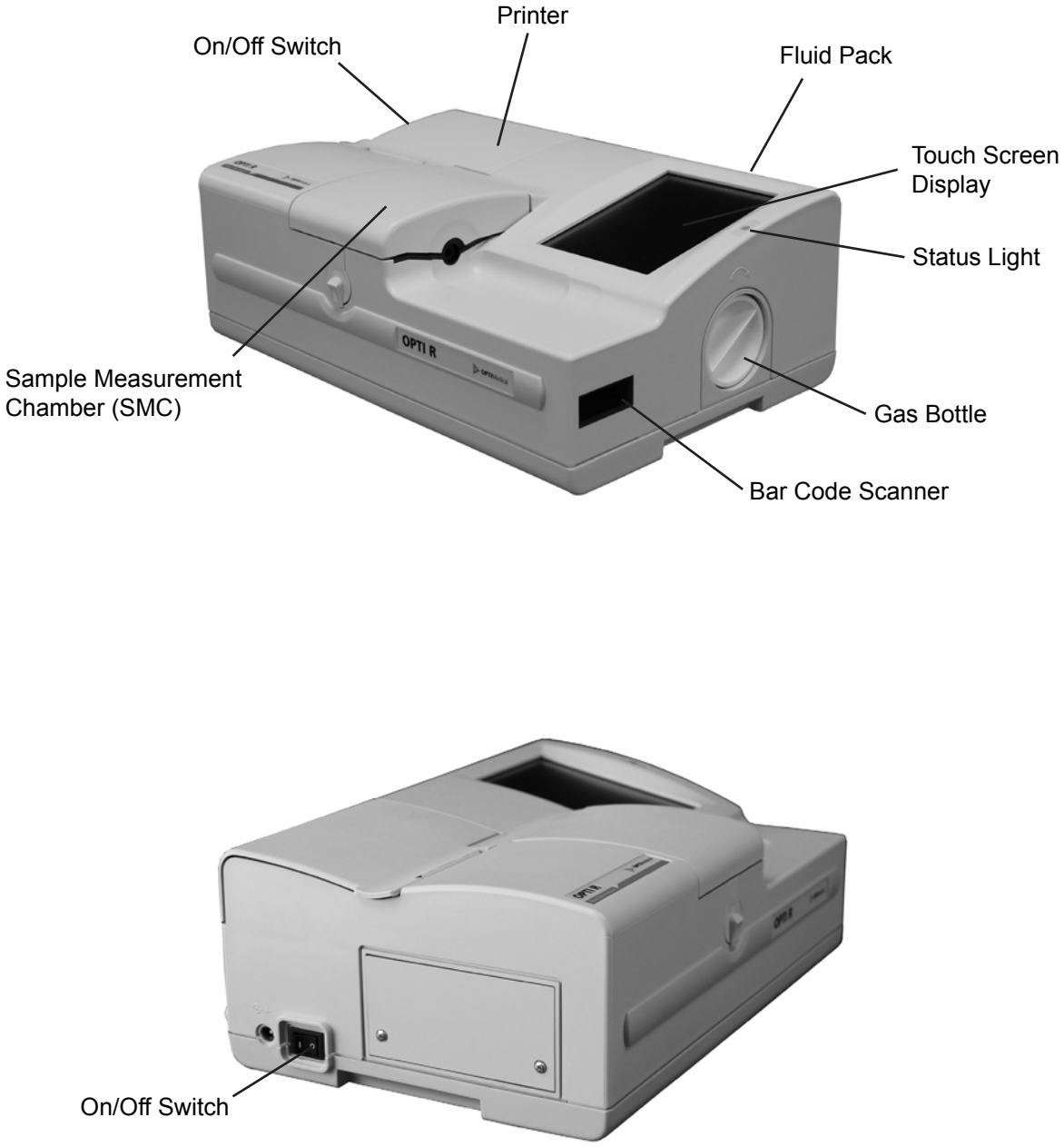


Fig. 1-1 OPTI R Major Components

Touch Screen

Fig. 1-2 VGA and Touch Screen

The analyzer activities are communicated to you through a backlit **VGA 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

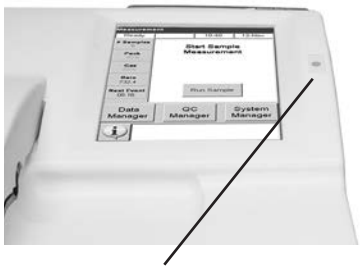


Fig. 1-3 Status Light

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)

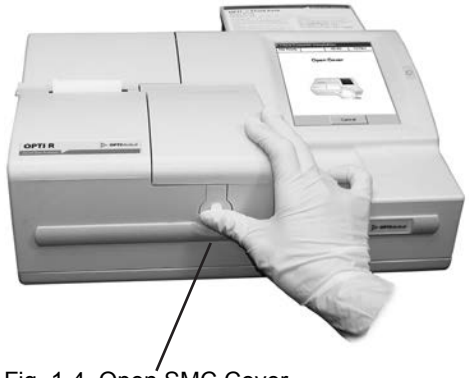
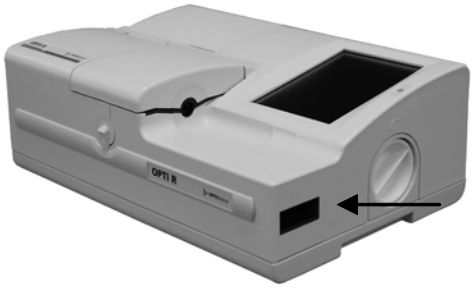


Fig. 1-4 Open SMC Cover

Inside the top of the unit is the **Sample Measurement Chamber** (SMC) for the OPTI R Cassette. To open the cover, slide the latch up and press the release button. The cover will then pop up (Fig. 1-4).

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

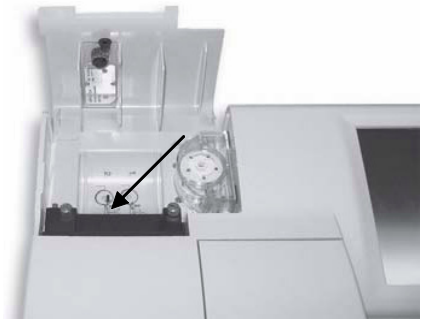
Bar Code Scanner



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

Fig. 1-5 Bar Code Scanner

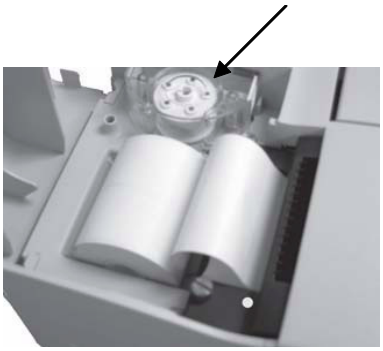
Thermal Printer



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.

Fig. 1-6 Thermal Printer

Peristaltic Pump



Contained within the same compartment is a **peristaltic pump** cartridge which is used to transport liquids and gases (Fig. 1-7).

NOTE: The peristaltic pump cartridge is a replaceable item (See Maintenance Section 6.4.1).

Fig. 1-7 Peristaltic Pump

Model and Serial Numbers

Fig. 1-8 Model and Serial Numbers

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

Back of Analyzer

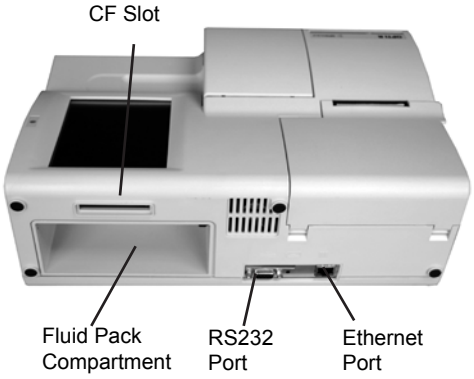


Fig. 1-9 Back of the OPTI R

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

- An **RS232 interface port**
- An **Ethernet interface port**.
- An **OPTI R Fluid Pack Compartment** which incorporates a sensor that detects the presence of a Fluid Pack.
- A **Compact Flash Card slot (CF Slot)** for software updates or storage of patient and QC data in a .CSV file.

Power Connector and On/Off Switch

Fig. 1-10 Power Connector and On/Off Switch

On the left side of the unit is the **power connector** where you can connect the OPTI R to an external power supply (Fig. 1-10).

The **On/Off** switch is located on the left side of the unit next to the power connector (Fig. 1-10).

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

Shutdown Pack

Fig. 1-11 Shutdown Pack

The OPTI R Analyzer comes with a **Shutdown Pack** (Fig. 1-11), which is used to perform a complete shutdown of the analyzer.

- Once the analyzer is in use, do not turn the power off for an extended period of time (>72 Hours) without performing a complete shutdown procedure (see Maintenance Section 6.6.3.2)
- If the analyzer is not being used for less than 72 hours, it is recommended to perform a powerdown instead of a shutdown (see Section 6.6.3.1).

1.5 Consumables

OPTI R Cassette

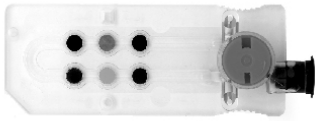


Fig. 1-12 OPTI R Cassette

The reusable **OPTI R Cassette** has an integral valve to control the fluid flow (Fig. 1-12).

Sample Fillport and Syringe Adapter

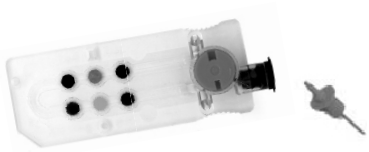


Fig. 1-13 Sample Fillport and Syringe Adapter

The **sample fillport** is contained in the OPTI R Cassette and projects from the chamber for easy, automatic sampling (Fig. 1-13). For sampling with a syringe, use the optional syringe adapter (BP7600).

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

OPTI R Fluid Pack

Fig. 1-14 Fluid Pack

The self-contained **OPTI R Fluid Pack** uses a unique design to prevent waste spillage. The waste is converted into a gel as it enters the fluid pack to eliminate the possibility of waste spillage during pack disposal. The OPTI R Fluid Pack is connected to the rear of the analyzer (Fig. 1-14).

Gas Bottle

Fig. 1-15 Gas Bottle

During the master calibration, the OPTI R 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. 1-15).

Calibrator Cassette

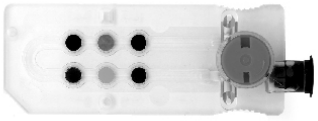


Fig. 1-16 Calibrator Cassette

The reusable **Calibrator Cassette** (Fig. 1-16) is used for the quarterly calibration of the OPTI R Analyzer (See Section **6.3 Quarterly Maintenance - Running the Calibrator**).

Congratulations!

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

2 SETUP

2.1 Important Safety Instructions

Before you begin installing your OPTI™ R 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 R:

- 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 R Cassette and Fluid Pack according to local regulations.

2.2 Choosing a Location

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

- Grounded electrical outlet.
- Away from direct sunlight.
- Room temperature within 10 - 30° C (50 - 86° F).
- 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.

2.3 Setting up the OPTI R Analyzer

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

Fig. 2-2 Power Switch

2. Turn on the Power

- Locate the power switch on the left side of the unit and switch to ON (Fig 2-2).

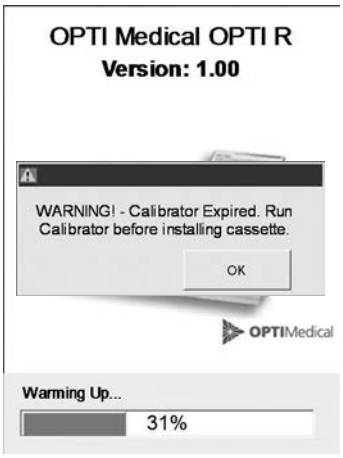


Fig. 2-3 Start-up screen

- This is the first screen that will appear after the power is turned on (Fig. 2-3)
- Press OK.

Fig. 2-4 Enter Time

3. Setting the Time and Date

- The system will now prompt you to enter the current time using the numeric keypad (Fig. 2-4).
- Enter hour and minutes and press OK.

Fig. 2-5 Select Month

- You will then be asked to enter the month (Fig. 2-5).
- Select the month from the keypad and press OK.

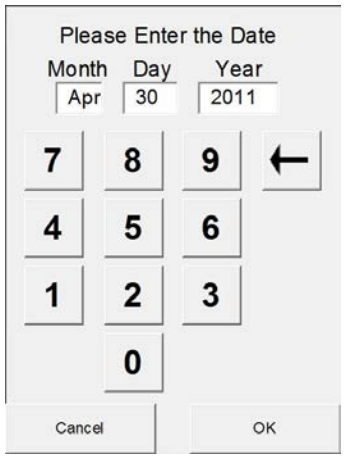


Fig. 2-6 Enter Date

- In the next screen, you may enter the current day (Fig. 2-6).
- Press OK and enter the 4-digit year.
- After entering the current time and date press OK to save your settings.

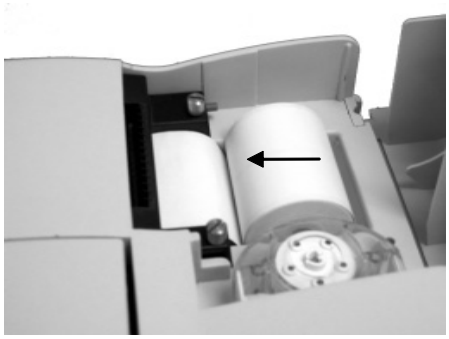


Fig. 2-7 Inserting Printer Paper

4. Installing the Printer Paper

- Place paper into the paper tray.
- With the OPTI R switched on, thread the paper into the feeder slot, as shown in the diagram, on the analyzer (Fig. 2-7).
- 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.

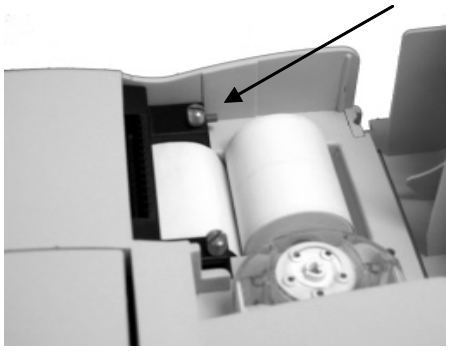


Fig. 2-8 Paper Advance Button

- To advance paper after the initial installation, press the red paper advance button located on the left side of the printer (Fig. 2-8).

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

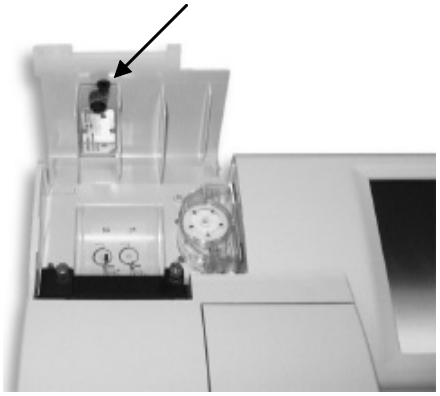


Fig. 2-9 Calibrator Cassette

5. Run the Calibrator Cassette

Run the calibrator cassette (Fig. 2-9) on a new OPTI R before installation of the Fluid Pack and sensor cassette.

Refer to section **6.3 Quarterly Maintenance** for instructions.

Fig. 2-10 Select New Fluid Pack

6. Installing a New Fluid Pack

Begin installation with the OPTI R Fluid Pack.

- Press **<New Fluid Pack>** (Fig. 2-10).

NOTE: Gloves should be worn when handling the Fluid Pack.

Fig. 2-11 Insert OPTI R Fluid Pack

- Record the installation date on the label of the pack.
- Remove the protective strip and insert the new OPTI R Fluid Pack in the compartment on the rear of the analyzer (Fig. 2-11).
- Insert the guide on the left side of the pack into the slot of the pack receptacle.
- Rotate the fluid pack until it snaps into place to complete the installation.

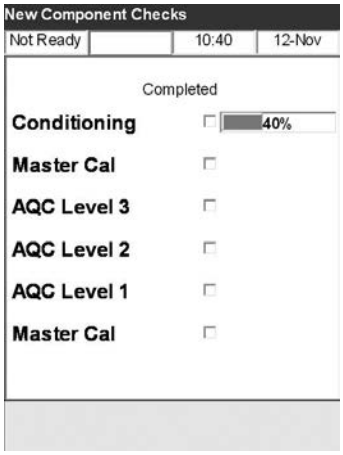


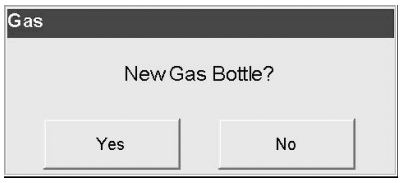
Fig. 2-12 New Component Check

- As soon as the Fluid Pack is inserted, the system will detect the presence of the Fluid Pack and retrieve the pack information from the integrated transponder.
  All of the information will be stored in the analyzer's database.

  The system will then perform an integrity check of the Fluid Pack (Fig. 2-12).
- If you wish to change the Fluid Pack QC ranges, this step must be done now. See Chapter 4 for instructions.

Fig. 2-13 Scan Gas Bar Code

Fig. 2-14 Insert Gas Bottle



7. Installing a New Gas Bottle

After installation of the OPTI R Fluid Pack, you will be asked to install the 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. (Fig. 2-13).
  The bar code can be found on the gas bottle instructional insert.
- The red line from the bar code scanner should cover the entire bar code.
- The analyzer will beep when the bar code is accepted.
- 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.*

- When prompted (Fig. 2-14), insert the gas bottle in its housing and turn clockwise until fingertight.
- Press OK.

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 R 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 Yes to install a new gas bottle.

NOTE: If after the initial installation you need to remove a gas bottle and reinstall the same bottle, respond No *to the 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.*

Fig. 2-15 Installing new cassette

Fig. 2-16 Scan cassette bar code

Fig. 2-17 Open SMC Cover

8. Installing the Sensor Cassette

After installation of the OPTI R gas bottle is complete, this display appears (Fig. 2-15).

- Press **<Install Cassette>**.
- 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 until the bar code labeled **Scan A** is recognized (Fig. 2-16).
- The red line from the bar code scanner should cover the entire bar code.
- A beep and a green status light indicate 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).
- Next, turn the cassette pouch over and hold in front of the scanner until bar code **Scan B** is read appropriately.
- A beep and a green status light indicate a valid bar code.

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

- Slide the latch up and press the release button to open the Sample Measurement Chamber (SMC) (Fig. 2-17).

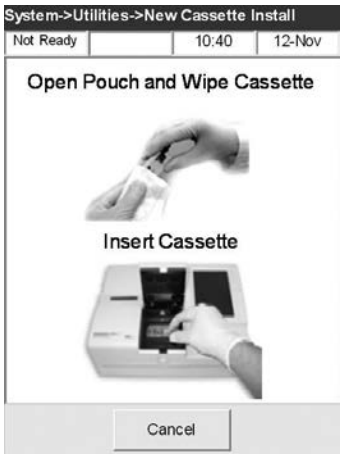


Fig. 2-18 Open Packet and Insert Cassette

- Insert the cassette as follows:
- Open the OPTI R Sensor Cassette packet and remove the cassette from the pouch (Fig. 2-18).

NOTE: If possible avoid tearing the two bar codes 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. 2-18).

Fig. 2-19 Close Cover

- Close the SMC cover by pressing the SMC cover down firmly (Fig. 2-19).

NOTE: The user should not remove the cassette unless prompted to do so. Removal of the cassette without being prompted will cause premature expiration of the sensor cassette.

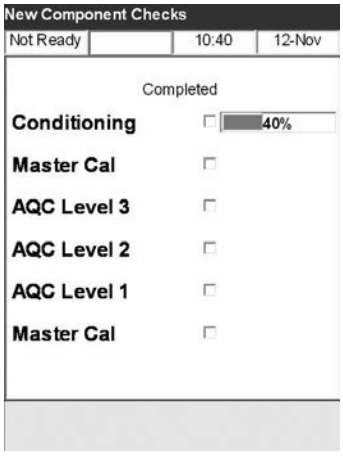


Fig. 2-20 New Component Checks

8.1 New Component Checks

After a new fluid pack or cassette is installed, the system will check the integrity of the fluid pack and cassette and calibrate. The instrument will display the status of the five major steps during installation. Preconditioning stabilizes the cassette sensors. The Master Calibration is performed using the calibration buffer and the gas bottle. This is followed by a measurement of all three AQC levels. Finally, a second calibration is performed. This calibration maximizes the number of samples that can be run once the analyzer is in ready mode. (Fig. 2-20).

Fig. 2-21 STAT Sample Option

8.2 STAT Sample Option during Cassette Installation

If the **<STAT Sample>** option is enabled in the Auto QC menu (see Section 4.5.1.1 Setting up Auto QC), the analyzer will allow you to run STAT Samples during a cassette or fluid pack installation.

The analyzer will perform a cassette calibration and then allow you to run one STAT sample after calibration and between each Auto QC sample, for a total of 4 samples. STAT samples can be run approximately 10 minutes into the installation.

The option to run a STAT sample will time out after 3 minutes, after which the OPTI R will go on to the next operation in the installation. Using this option will add additional time to the installation process.

Press No to skip the STAT sample option (Fig. 2-21) and continue with the installation. By default the STAT sample option is disabled.

NOTE: During the measurement of the STAT sample, the cassette calibration has been verified, but Auto QC verification of the cassette is still pending. Wait for completion of Auto QC verification to verify accuracy of the STAT sample results.

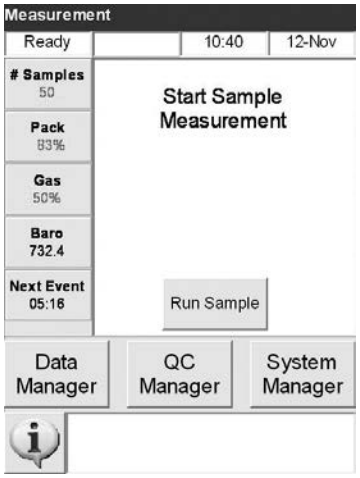


Fig. 2-22 Ready Display

9. The Ready Display

Once calibration and 3 levels of AutoQC measurements are completed, the **<Ready>** display will appear (Fig. 2-22).

The **<Ready>** display informs the user of important status information such as:

- **<# of Samples>** - Number of patient samples remaining on the cassette currently installed in the analyzer.
- **<Pack>** – Percent remaining in the OPTI R Fluid Pack.
- **<Gas>** - Displays the percentage of gas remaining.
- **<Baro>** - Displays the current barometric pressure.
- **<Next Event>** - Displays the time remaining to the next calibration/AutoQC measurement.

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

- **<Data Manager>** – This menu allows you to print out patient and control information. It also provides you with the ability to export information if the OPTI R is connected to a computer.
  For more information on printing information, see **Chapter 4. Calibration and Quality Control** and **Chapter 5. Patient Testing**.
- **<QC Manager>** – This menu allows you to set up and perform AutoQC and manual control measurements.
  For more information, see **Chapter 4. Calibration and Quality Control**.
- **<System Manager>** - This menu contains the following settings and functions:
  - Time and Date (see Chapter 3.2)
  - Diagnostics (see Chapter 7.2)
  - Setup (see Chapter 3.3)
  - Utilities (see Chapter 6.6)

3 CUSTOMIZATION

Your OPTI™ R 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 R 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 **<System->Time and Date>** screen (Fig. 3-3).

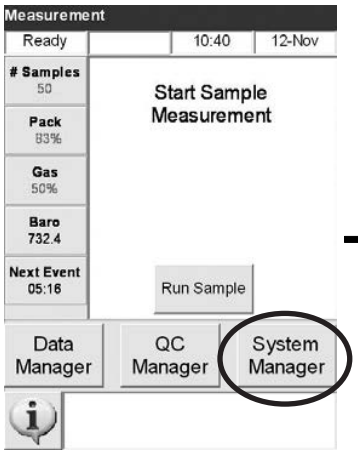


Fig. 3-1 Select System Manager

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 Up to leave the default time and date setting unchanged, or press the Edit 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. To change from Standard Time to Daylight Savings Time, select the option **<Daylight Savings Enable>**.
5. Press Save to accept the changes.
6. Press Up to return to the **<System>** screen or Home to return to **<Ready>**.

3.3 Setup

Fig. 3-5 Setup

Setup menus let you 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** (if enabled) to access the setup functions.

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

3.3.1 Customizing Patient Information

3.3.1.1 Selecting Which Patient Information is Requested and Printed

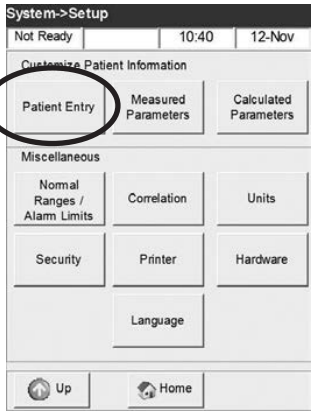


Fig. 3-6 Select Patient Entry

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

1. From the **<Ready>** display, select **<System Manager>** and **<Setup>**.
2. In the **<System Setup>** menu, press **<Patient Entry>** (Fig. 3-6).

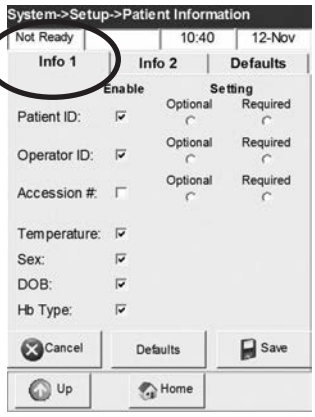


Fig. 3-7 Patient Info 1

3. In the **<Info 1>** screen, select the options to be enabled (Fig. 3-7).
4. Select **<Optional>** or **<Required>** for:

   Patient ID
   Operator ID
   Accession Number

5. Other options to be selected are:

   Temperature
   Sex
   Date of Birth (DOB)
   Hb Type

Fig. 3-8 Patient Info 2

6. Press the **<Info 2>** tab to access and enable the following parameters (Fig. 3-8).

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	

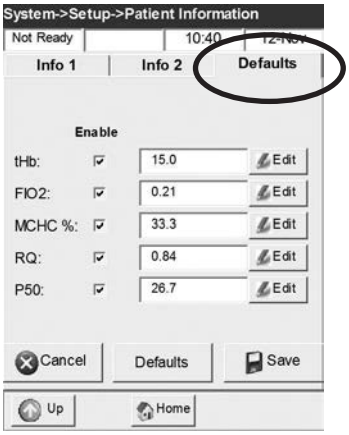


Fig. 3-9 Defaults

The **<Defaults>** screen (Fig. 3-9) 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. 3-9). 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 P_{50} 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
P_{50}:	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>**.

3.3.1.2 Selecting Which Parameters Are Blanked/Disabled

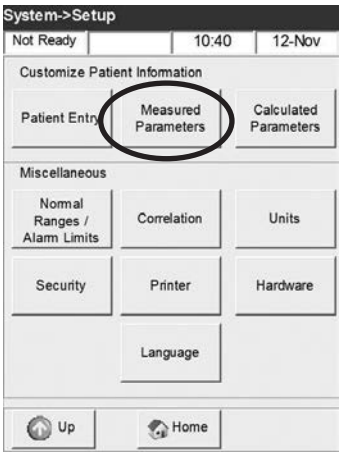


Fig. 3-10 Measured Parameters

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. 3-10).

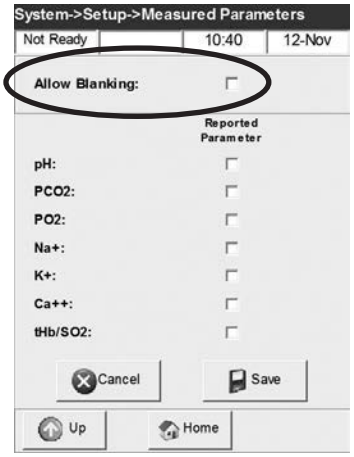


Fig. 3-11 Select Allow Blanking

3. Press **<Allow Blanking>** to allow parameter blanking (Fig. 3-11).

   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. The next option, **<Reported Parameters>**, allows you to permanently disable the selected parameters from all patient measurements.
5. Press Save to save the settings.
6. Press Up to return to the **<Setup>** screen or Home to return to **<Ready>**.

3.3.1.3 Selecting Which Calculated Parameters Are Printed

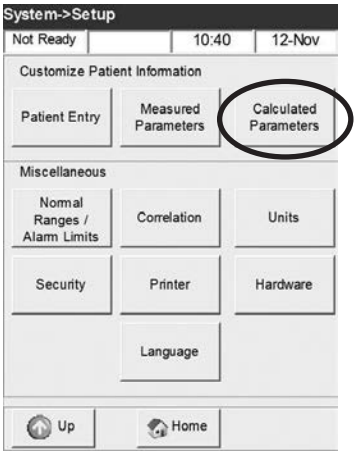


Fig. 3-12 Select Calculated Parameters

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. 3-12).

Fig. 3-13 Select Parameters

3. Select the cassette type (Fig. 3-13).
4. Select the parameters to be printed.
5. Press Save to accept the changes.
6. Press Up to return to the **<Setup>** screen or Home to return to **<Ready>**.

3.3.2 Miscellaneous

3.3.2.1 Setting Normal Ranges or Alarm Limits

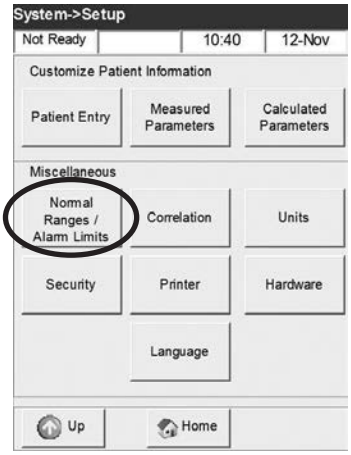


Fig. 3-14 Select Normal Ranges/ Alarm Limits

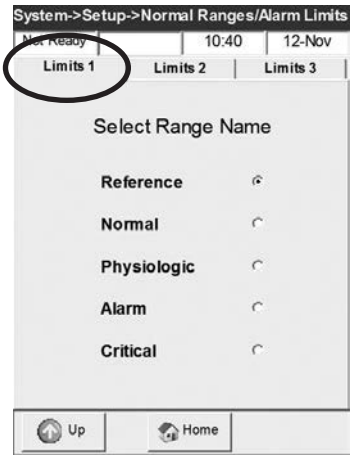


Fig. 3-15 Select Limits Name

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, in the **<Miscellaneous>** section, press **<Normal Ranges/Alarm Limits>** (Fig. 3-14).
3. On the **<Limits 1>** tab, select the limits range name you wish to use (Fig. 3-15):

   Reference
   Normal
   Physiologic
   Alarm
   Critical

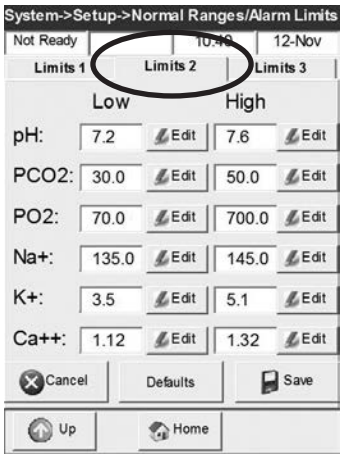


Fig. 3-16 Enter Limits 2

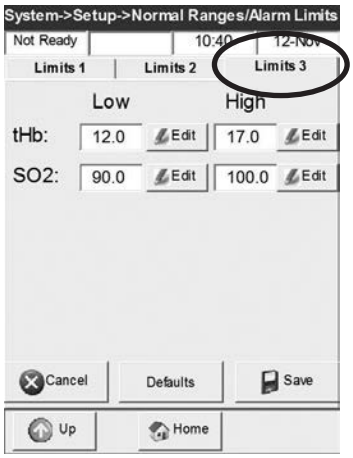


Fig. 3-17 Enter Limits 3

4. Press **<Limits 2>** to advance to the next screen (Fig. 3-16).
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.
7. Press **<Limits 3>** to advance to the next screen (Fig. 3-17) 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
Ca^{++}:	1.12 - 1.32 mmol/L
tHb:	12 - 17 g/dL
SO_2:	90 - 100 %

- Units may be changed (See section 3.3.3.3).
- 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 Up to return to the **<Setup>** screen or Home to return to **<Ready>**.

3.3.2.2 Setting up Correlation Factors

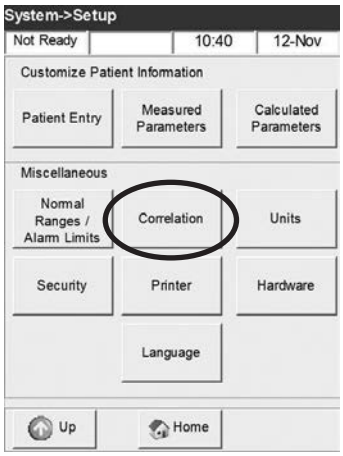


Fig. 3-18 Select Correlation

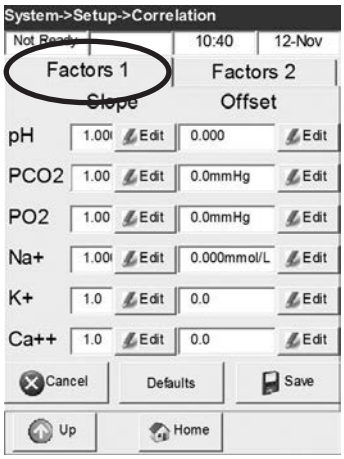


Fig. 3-19 Correlation Factors 1

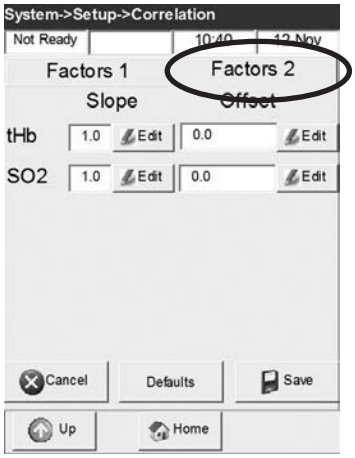


Fig. 3-20 Correlation Factors 2

Correlation factors let you correlate results from your OPTI R to other Blood Analyzers. Correlation factors are available for pH, PCO_2, PO_2, Na^+, K^+, Ca^{++}, tHb, and SO_2.

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

1. From the **<Ready>** display, select **<System Manager>** and **<Setup>**.
2. In the **<System Setup>** menu, press **<Correlation>** (Fig. 3-18).
3. Select the numbers you want to change by pressing Edit (Fig. 3-19). Enter the new numbers.
4. Press **<Factors 2>** to go to the next screen (Fig. 3-20).
5. When entering the actual offset value, select whether it is an additive or subtractive value using the +/- keys.

NOTE: The factory setting is 1.000 for all slopes and 0.000 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 R and the instrument to which it is to be correlated.*

3.3.2.3 Defining Units

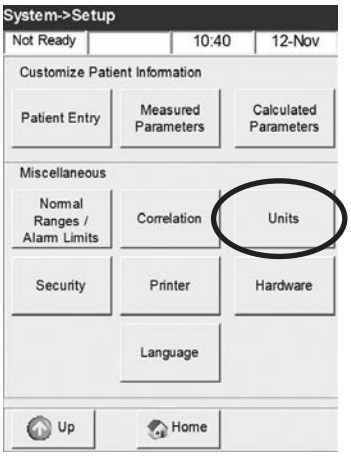


Fig. 3-21 Select Units

Fig. 3-22 Select Units

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

1. From the **<Ready>** display, select **<System Manager>** and **<Setup>**.
2. In the **<System Setup>** menu, press **<Units>** (Fig. 3-21).
3. In the **<Units>** screen, select the units for the displayed parameters (Fig. 3-22).
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 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
•	Ca^{++} 1.21 mmol/L	Ca^{++} 1.21 mmol/L
•	tHb 14.6 g/dL	tHb 14.6 g/dL
•	SO_2 90 %	SO_2 89.8 %

**PO_2 and PCO_2 above 100 mmHg are always displayed to the nearest whole number.*

Your OPTI R has been factory preset to the following units:

- Baro/Partial Pressure: mmHg
- Temperature: °C
- tHb: g/dL
- Electrolytes mmol/L
- Resolution Low

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

3.3.2.4 Setting up Security

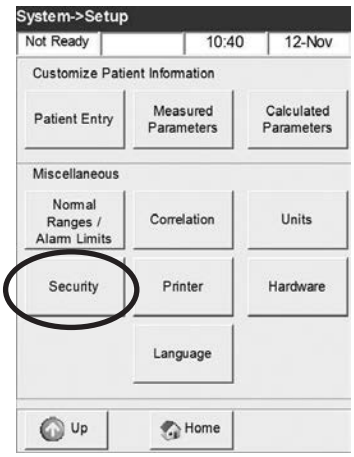


Fig. 3-23 Select Security

The OPTI R has three types of security:

1. A **Password Function** to limit access to various system functions (See section 3.3.2.4.1).
2. **QC Lockouts** to help hospitals meet their QC policies (See section 3.3.2.4.2).
3. A **Secure Operator ID** function to limit access to analyzer to properly trained, authorized users (See section 3.3.2.4.3).

- From the **<Ready>** display, select **<System Manager>** and **<Setup>**.
- In the **<System Setup>** menu, press **<Security>** (Fig. 3-23).

3.3.2.4.1 Setting Up a Password

Fig. 3-24 Enter Password

The OPTI R 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. 3-24). 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>**.

3.3.2.4.2 Selecting QC Lockout

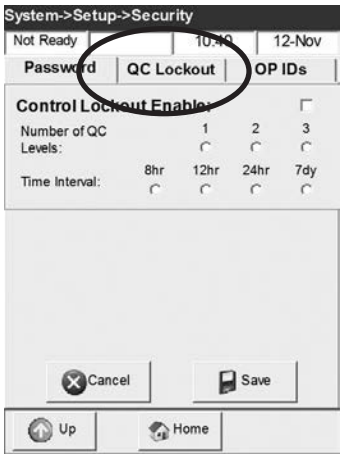


Fig. 3-25 Select QC Lockout

This menu allows the hospital to 'lock out' operators unless some form of QC has been run. QC Lockouts do not apply to Auto QC settings. When activating QC lockouts, you will be required to perform external OPTI CHECK measurements before a patient measurement can be performed.
Each facility should develop their own policies on the frequency and type of QC based on the regulatory requirements. The instrument is factory-set with lockout options turned off.

To activate these options:

- Select **<QC Lockout>** in the **<Security>** menu (Fig. 3-25).

<Control Lockout Enable> - With 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 Save to accept the changes.
3. Press Up to return to the **<Setup>** screen or Home to return to **<Ready>**.

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.

3.3.2.4.3 Setting up Secure Operator IDs

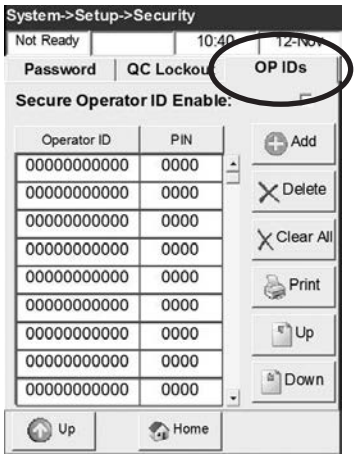


Fig. 3-26 Select OP IDs

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. 3-26).
- 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 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>**.

3.3.2.5 Setting the Printer

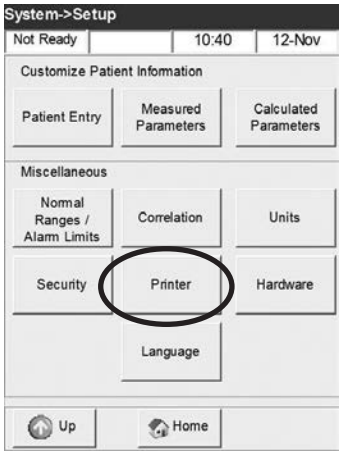


Fig. 3-27 Select Printer

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

- From the **<Ready>** display, select **<System Manager>** and **<Setup>**.
- In the **<System Setup>** menu, press **<Printer>** (Fig. 3-27).

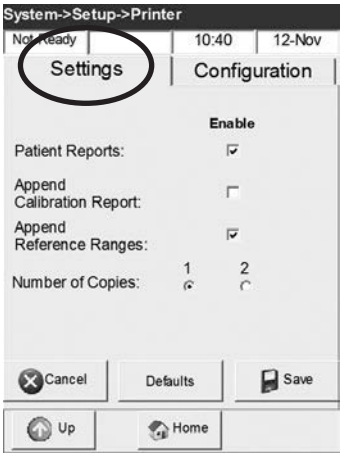


Fig. 3-28 Select Print Options

In the **<Settings>** menu (Fig. 3-28), 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.

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

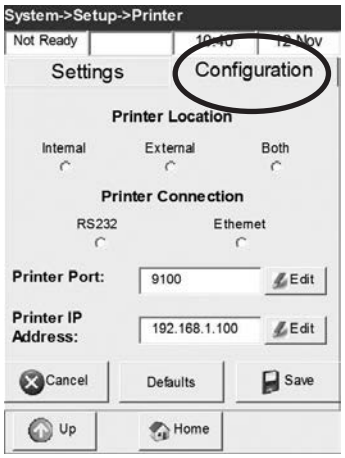


Fig. 3-29 Select Printer Configuration

In the **<Configuration>** menu (Fig. 3-29), you can select printer location, printer connection, printer port and printer IP address.

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

3.3.2.6 Entering the Barometric Pressure

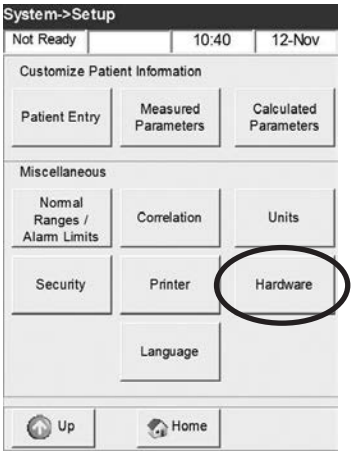


Fig. 3-30 Select Hardware

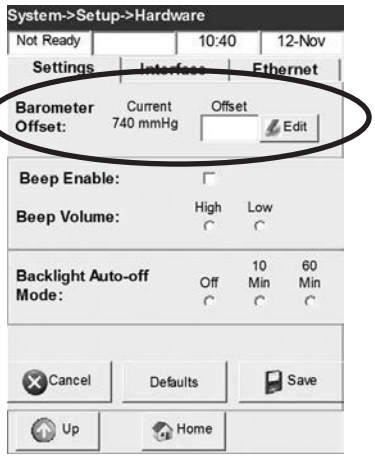


Fig. 3-31 Enter barometric pressure

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 automatic backlight function.

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

To adjust the tracking barometer within the OPTI R, follow the instructions below:

1. From the **<Ready>** display, select **<System Manager>** and **<Setup>**.
2. In the **<System Setup>** menu, press **<Hardware>** to select this function (Fig. 3-30).
3. In the **<Settings>** menu, press Edit to enter an offset from the true barometric pressure (Fig. 3-31).
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).*

3.3.2.7 Beep Adjustment

Fig. 3-32 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 **<Hardware>**.
3. In the **<Settings>** screen, select **<Beep Enable>** (Fig. 3-32).
4. Select **<High>** or **<Low>** for **<Beep Volume>**.
5. Press Save to accept the changes.
6. Press Up to return to the **<Setup>** screen or Home to return to **<Ready>**.

3.3.2.8 Automatic Backlight Function

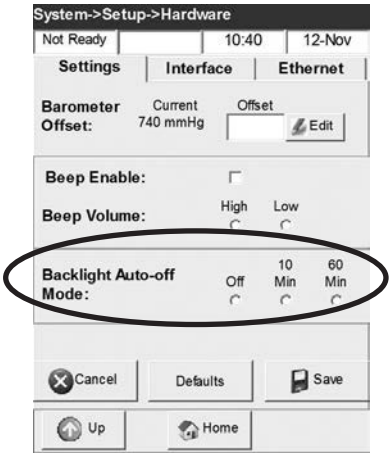


Fig. 3-33 Backlight Auto-Off

In this menu you can enable the automatic backlight function. When this function is enabled, the backlight of the display will turn off automatically at the selected time interval.

1. From the **<Ready>** display, select **<System Manager>** and **<Setup>**.
2. In the **<System Setup>** menu, press **<Hardware>**.
3. In the **<Settings>** screen, select **<OFF>**, **<10 Min>** or **<60 Min>** time intervals for the backlight auto off feature (Fig. 3-33).
4. Press Save to accept the changes.
5. Press Up to return to the **<Setup>** screen or Home to return to **<Ready>**.

3.3.2.9 Setting Up Communications

Your OPTI R 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.

3.3.2.9.1 Configuring the Communication Format

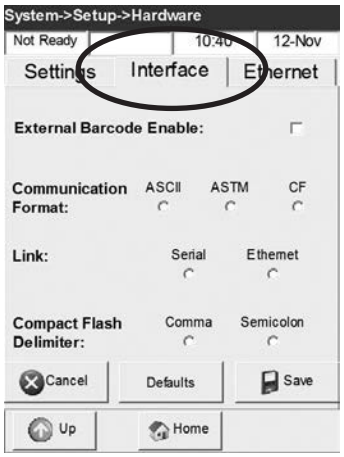


Fig. 3-34 Communication Format

1. From the **<Ready>** display, select **<System Manager>** and **<Setup>** .
2. In the **<System Setup>** menu, press **<Hardware-> Interface>**.
3. The **<Interface>** screen contains the following options (Fig. 3-34):

- **<External Barcode Enable>**.
- **<Format>**: **<ASCII>**, **<ASTM>**, or **<CF>**.
- **<ASCII Format>** - Data in easy to read OPTI Medical custom format. The OPTI R exports data string identical to the internal printer output.
- **<ASTM Format>** - Complies with ASTM standard with handshaking and data formatting.
- **<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. By selecting **<Comma>** or **<Semicolon>**, data can be easily exported into a PC.
- **<Link>** - Select **<Serial>** or **<Ethernet>**.

4. The **<Ethernet>** screen (Fig. 3-35) is used to configure Ethernet settings: **<Format>**, **<IP Type>**, **<IP Address>**, **<Subnet Mask>**, **<UDP Port>**, **<TCP Port>**, and **<Host IP>**.

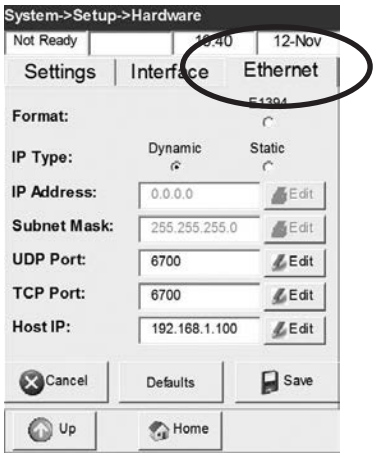


Fig. 3-35 Ethernet Settings

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

3.3.2.10 Selecting a Language

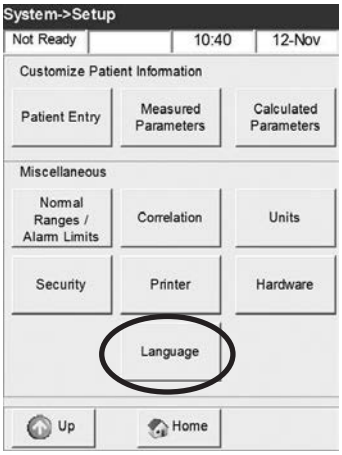


Fig. 3-36 Select Language

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

1. From the **<Ready>** display, select **<System Manager>** and **<Setup>**.
2. In the **<System Setup>** menu, press **<Language>** (Fig. 3-36).

Fig. 3-37 Select Language

3. Select the desired language (Fig. 3-37).
4. Press Save to accept the changes.
5. Press Up to return to the **<Setup>** screen or Home to return to **<Ready>**.

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 two bar codes containing this calibration information, as well as its lot number and expiration date.

For each new cassette the cassette's bar code is read 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 wash buffer from the fluid pack, in a manner similar to other combined blood gas / ion analyzers.
In addition, an optical zero point calibration of all optical channels is performed.

After the cassette has passed the initial calibration the OPTI R utilizes a unique calibration matrix. The calibration verification is performed every 30 minutes to verify the stability of the sensor cassette. The next item in the calibration matrix is performed after each patient measurement. After the measurement the cassette is washed and the calibration is verified with fresh buffer. The final item in the calibration matrix is a master calibration that uses the buffer in the fluid pack combined with the precision gas bottle.

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, temperature control, fluidic control during calibration, proper equilibrium behavior of the sensors during calibration and measurement, automatic detection of bubbles and short sample detection and automatic detection of low gas, dirty optics, or worn pump conditions.

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

For more information, including detailed instructions, 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 R Analyte Section included in 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.

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.

4.5 QC Recommendations

Policies regarding the measurement of QC samples are established by the individual hospital. The OPTI R is factory preset to perform an automatic QC measurement in the AutoQC mode every 8 hours. It is also possible to perform external QC measurements using controls such as OPTI CHECK which do **NOT** contain dye or other colored material. Whenever a new lot of control is opened, be sure to enter the lot information into the analyzer as described below. 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 Systems recommends the use of **a noncolored pH/blood gas/electrolyte control** containing scattering particles for tHb control for routine evaluation of imprecision as a part of an effective quality control program.

4.5.1 QC Setup

4.5.1.1 Setting up Auto QC

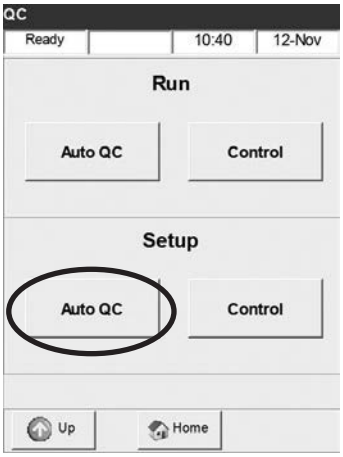


Fig. 4-1 Select Auto QC

Fig. 4-2 Select Auto QC Time and Level

The OPTI R Analyzer is factory preset to perform an automatic QC measurement in the Auto QC mode every 8 hours. To change the Auto QC settings:

1. Select **<QC Manager>** in the **<Ready>** display.
2. Select **<Auto QC>** under **<SETUP>** (Fig. 4-1).

Auto QC Scheduler

1. In the **<Setup -> Auto QC>** screen (Fig. 4-2), select a time slot and enter the time at which you want the analyzer to perform the control measurements.
2. Select the levels to be measured.
3. Select the days of the week to run Auto QC.
4. Press Save to save the changes or press Next to move to page 2 of Auto QC setup.

NOTE: The OPTI R will automatically run AQC level 1 and level 3 once a day to check the integrity of the cassette. These two levels will be run, even if Auto QC is disabled.

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

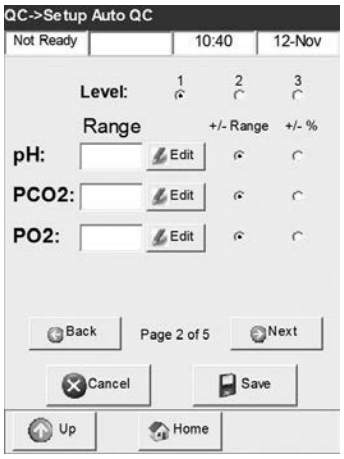


Fig. 4-3 Adjust Auto QC Ranges

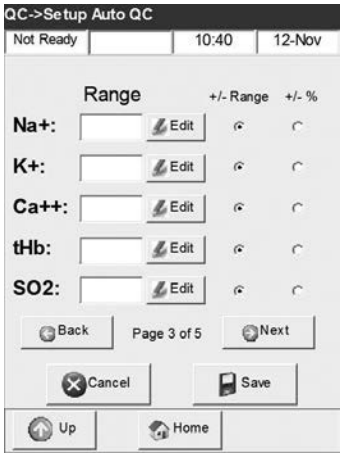


Fig. 4-4 Adjust Auto QC Ranges

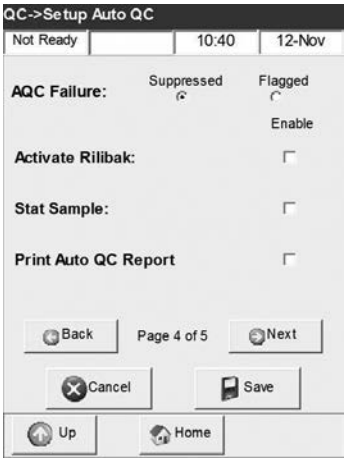


Fig. 4-5 Select Auto QC Options

Adjust Auto QC ranges

This menu allows you to change the Auto QC limits either by a +/- range or percent from the target value programmed in the fluid pack. The ranges can only be tightened from the target value and the target value can not be changed.

1. Select the Auto QC level (Fig. 4-3).
2. Select **<+/- Range>** or **<+/- %>** for each parameter that you would like to change.
3. Press the Edit button and enter the desired +/- value for the range.
4. Press Next to access page 3 of the Auto QC setup and edit the Na^+, K^+, Ca^{++}, tHb, and SO_2 ranges (Fig. 4-4). Or press Save to save the changes.
5. Adjust ranges for electrolytes and tHb and SO_2.
6. Press Save to save the changes.
7. Go to the previous screen to change the next level of Auto QC.
8. Press Next to access page 4 of the Auto QC setup for more **Auto QC Options** (Fig. 4-5).

Miscellaneous Auto QC Options

- If an **<AutoQC failure>** occurs and **<Suppressed>** is selected (Fig. 4-5), the patient results for the failing QC parameter will not be reported. If **<Flagged>** is chosen, the analyzer will print an error message on each printout for the failing QC parameter.
- Press **<Enable>** to enable **<Rilibak>** mode. This mode requires use of a Type 2 Fluid Pack and is only available in software version 3.04 and higher. Once activated, the OPTI R will calculate the Auto QC ranges for levels 2 and 3 and the square mean in conformance with Rilibak regulations. Press this button before installing a new pack to activate. In this mode Auto QC level 1 is not available. Level 1 will be used as part of a slope check only.
- Press **<Enable>** to enable the **<Stat Sample>** option to run a STAT sample during cassette or fluid pack installation. This feature must be enabled prior to installation.

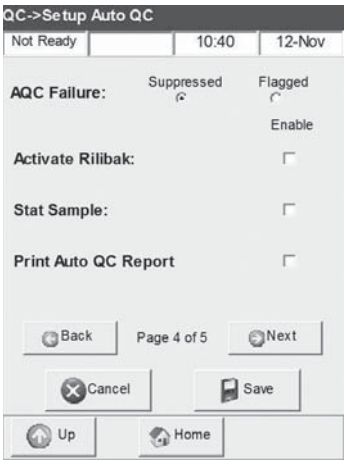


Fig. 4-6 Select Auto QC Options

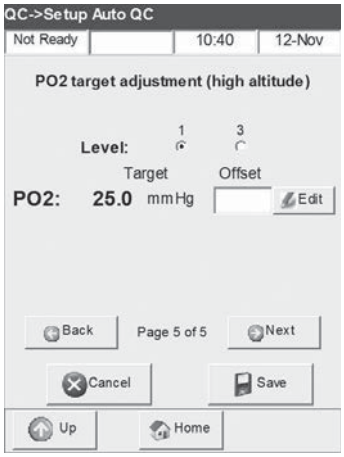


Fig. 4-7 Adjust AutoQC Oxygen Target

Fig. 4-8 Select Date Range

Once enabled, the OPTI R will ask if you would like to run a Stat sample after calibration and after each level of Auto QC during pack and cassette installation. The OPTI R will allow a 3 minute window to run a Stat sample before moving on to the next operation.

- If **<Print Auto QC Report>** is enabled (Fig. 4-6), the Auto QC results will be printed after completion of each Auto QC measurement.

Press Save to save changes or press Next to move on to page 5 of Auto QC setup.

Adjust Auto QC Oxygen Target for High or Low Altitudes

This menu allows you to change the PO_2 Auto QC target by entering an offset value. The target may have to be changed at very high and low altitudes. An offset value can be entered for levels 1 and 3 only. The user should establish the offset value.

1. Select the level of Auto QC to be adjusted (level 1 or level 3) (Fig. 4-7).
2. Press Edit to enter the offset.
3. To lower the target, enter a negative value and to raise the target, enter a positive value.
4. Press Save to save changes.

Select Date Range for Auto QC Statistics Report

This menu allows you to specify the date range for statistical analysis of Auto QC data (Fig. 4-8).

1. Select the level of Auto QC to be analyzed or select **<All>** to analyze all 3 levels.
2. Press Edit to enter the start and end date.
3. Press OK to generate statistics report.

4.5.1.2 Setting up the External Control Material Lot and Level

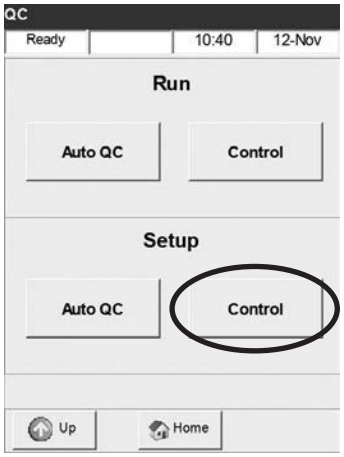


Fig. 4-9 Select Control

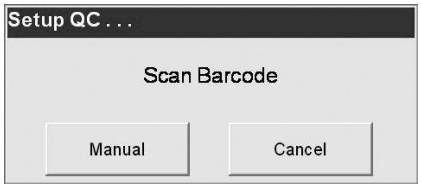


Fig. 4-10 Scan Bar Code

1. From the **<Ready>** display, select **<QC Manager>**.
2. Select **<Control>** under **<SETUP>** (Fig. 4-9).
3. Scan the 36-digit bar code marked **Scan A** for the applicable level supplied with OPTI CHECK (Fig. 4-10).
4. Scan the second 36-digit bar code marked **Scan B** supplied with the same OPTI CHECK control lot. These two bar codes contain all necessary lot information for each level, and may be confirmed in the subsequent screens.
5. If bar code is not available, press **<Manual>** on the **<Scan Barcode>** screen and manually enter control data.

4.5.1.2.1 Entering Control Expiration Date, Type, and Assay Ranges

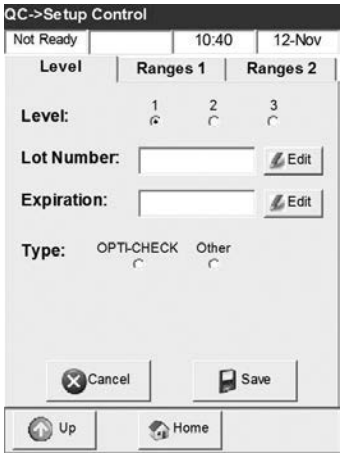


Fig. 4-11 Confirm Lot Information

When you open a new box of OPTI CHECK, 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.

CAUTION: *Do not use a control material that contains dyes, fluoro-carbons or silicones as these constituents will affect the results reported.*

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. 4-11).
   If the bar code is unavailable, press **<Manual>** on the **<Scan Barcode>** screen and enter the control information manually.
2. Press Save to accept.

3. Press Yes to obtain a printout of the old database.
4. Press Yes to delete the old database.
   - If no previous QC data exists in the database, the print and delete display screens will be bypassed.
   - 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.

NOTE: If <NO> *is selected here, the new information is not saved.*

5. Press the **<Ranges 1>** tab to confirm the assay ranges on the package insert supplied with the control material (Fig. 4-12).
   If the bar code is unavailable, press the Edit button and enter the numbers using the keypad.
6. Press Save to accept.

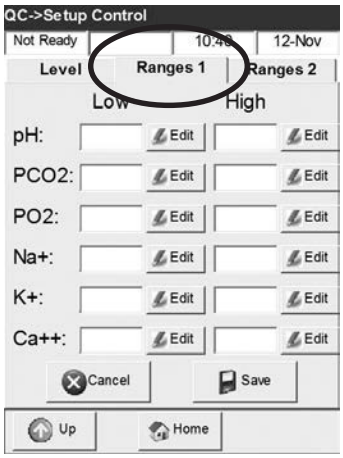


Fig. 4-12 Confirm Assay Ranges 1

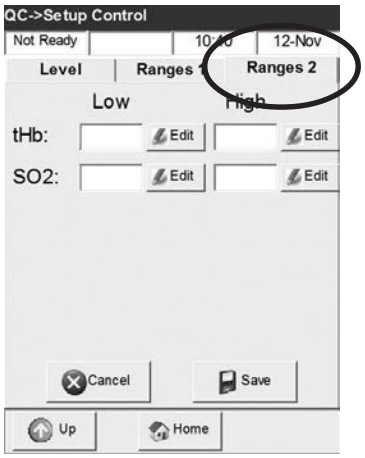


Fig. 4-13 Confirm Assay Ranges 2

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. 4-13). Enter 0.0 for unassayed parameters.
8. Alternately you may develop your own assay ranges from multiple measurements according to your hospital's procedures.
9. It is recommended you review all analyte assay ranges. You may press Save at any time after the bar code is scanned, and the ranges will be accepted from the bar code.

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

4.5.2 Performing QC Measurements

4.5.2.1 Running Auto QC Measurements

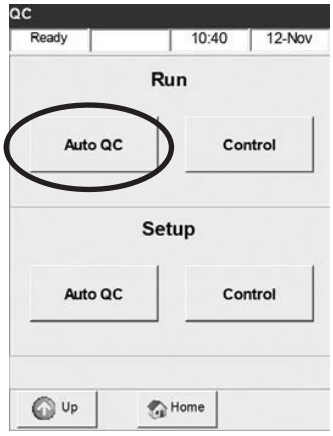


Fig. 4-14 Select Auto QC

1. In the **<Ready>** display, press **<QC Manager>**.
2. Select **<Auto QC>** in the **<RUN>** menu (Fig. 4-14).

Fig. 4-15 Enter Operator ID

3. Enter your Operator ID, or 4-digit PIN using the alphanumeric keypad (Fig. 4-15).
   To bypass this function, press OK.

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.

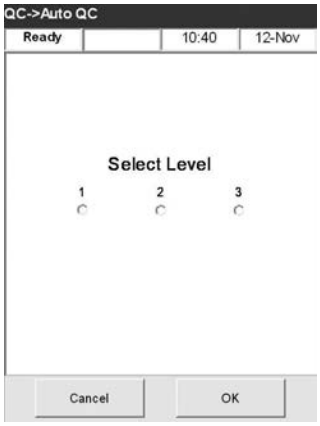
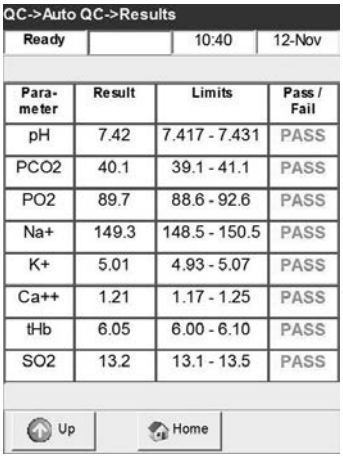


Fig. 4-16 Select Auto QC Level

4. Select the desired level (Fig. 4-16) and press OK.

Fig. 4-17 Auto QC measurement

5. The QC sample is aspirated into the cassette and the measurement starts (Fig. 4-17).



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
tHb	6.05	6.00 - 6.10	PASS
SO2	13.2	13.1 - 13.5	PASS

Fig. 4-18 Auto QC results

Upon completion of the measurement, the results are displayed and printed (Fig. 4-18).

6. The OPTI R Analyzer will indicate whether the values are within or outside the programmed ranges with a **<Pass/Fail>** display next to the parameter label.
7. Press Up to return to **<QC Manager>**.

4.5.2.2 Running an External QC Sample (OPTI CHECK)

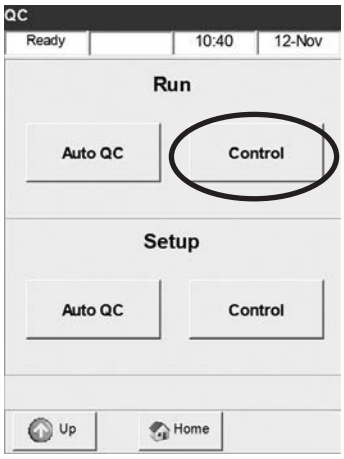


Fig. 4-19 Select Control

Fig. 4-20 Enter Operator ID

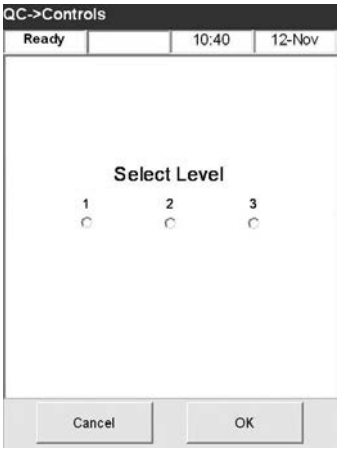


Fig. 4-21 Select QC Level

The OPTI R is factory preset to perform an automatic QC measurement in the AutoQC mode every 8 hours. It is also possible to perform external QC measurements using controls such as OPTI CHECK which do **NOT** contain dye or other colored material. Store controls at temperature recommended by the manufacturer.

The target value of PO_2 is very sensitive to storage conditions and barometric pressure.

High altitude environments may see recovery outside the target range.

1. In the **<Ready>** display, press **<QC Manager>**.
2. Select **<Control>** in the **<RUN>** menu (Fig. 4-19).
3. Enter your Operator ID, or 4-digit PIN using the alphanumeric keypad (Fig. 4-20).
   To bypass this function, press OK.

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.

4. Select the desired level (Fig. 4-21) and press OK.

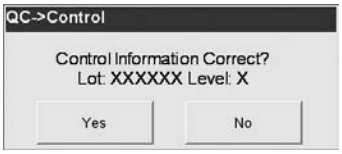


Fig. 4-22 Confirm Lot Number

Fig. 4-23 Place Control

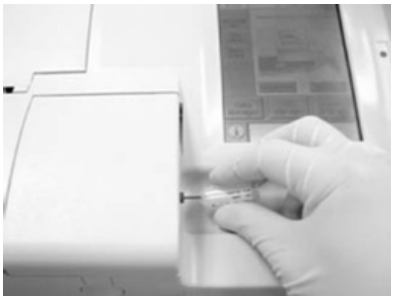


Fig. 4-24 Direct Aspiration

Fig. 4-25 Attach Capillary Tube

5. Press Yes if the lot number is correct (Fig. 4-22).

   - 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 Section 4.5.1.2).
     If the password function is enabled, you will be asked for it before deleting the database for the old lot number.

6. It is time to place a sample (Fig. 4-23).

   - Remove an ampoule from the box of controls and shake 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.

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

   - Aspirate directly from the ampoule or use a capillary or syringe to withdraw a small amount of control material from the ampoule for aspiration.
   - Best results are obtained from direct aspiration from the ampoule via the syringe adapter. To accomplish this, insert the syringe adapter in the cassette fillport and hold the ampoule at a 45^{o} angle, making sure fluid is always in contact with the syringe adapter during aspiration (Fig. 4-24).
   - It is recommended to utilize a new ampoule of control material for each analyzer.

7. Push the capillary tube or syringe firmly into the fillport or syringe adapter, respectively (Fig. 4-25 and Fig. 4-26).

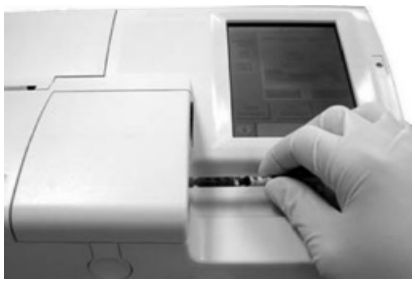


Fig. 4-26 Attach Syringe

CAUTION: *When using a syringe, withdraw the ampoule contents slowly to minimize agitation and do not allow bubbles to move through the syringe.*

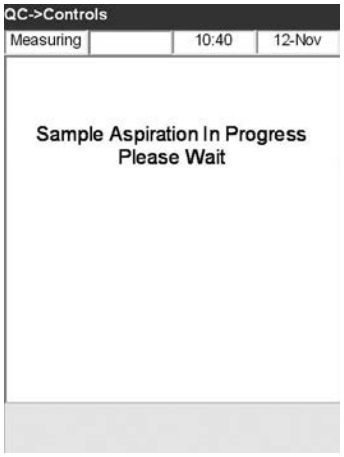


Fig. 4-27 Sample Aspiration

8. Press OK. The QC sample is aspirated into the cassette (Fig. 4-27).

Fig. 4-28 Remove Sample

9. Once the sample is drawn into the analyzer, you will be prompted to remove the sample and press OK (Fig. 4-28).

Fig. 4-29 QC Measurement

Then the measurement starts (Fig. 4-29).
At this time the status light begins flashing green indicating that the cover should not be opened.

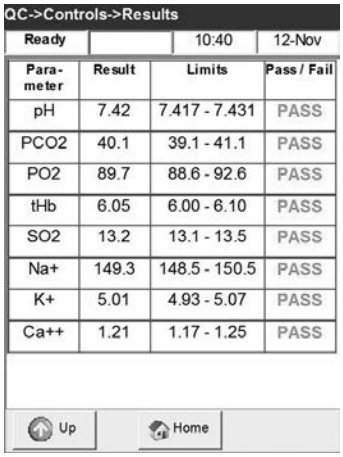


Fig. 4-30 QC Results

Upon completion of the measurement, the results are displayed (Fig. 4-30).

- The OPTI R Analyzer will indicate whether the values are within or outside the programmed ranges with a **<Pass/Fail>** display next to the parameter label.

10. Press Up to go to the next screen which gives you the option to accept or reject the results.

    - Press **<Accept>** if results are acceptable (Fig. 4-31), and the results will be stored in the Control Database.

    - Select **<Reject>** to reject the results. Rejected results will not be stored in the Control Database.

    - Select **<Review>** to view the results again.

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

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

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

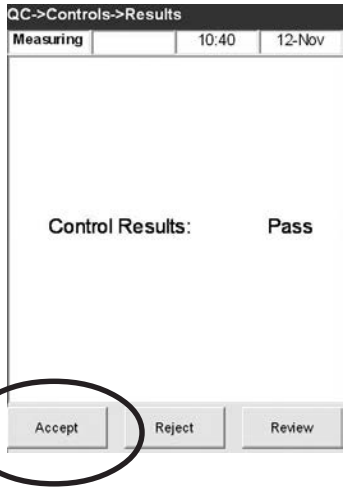


Fig. 4-31 Accept QC Results

4.5.3 Printing QC Reports

4.5.3.1 Printing Auto QC Reports

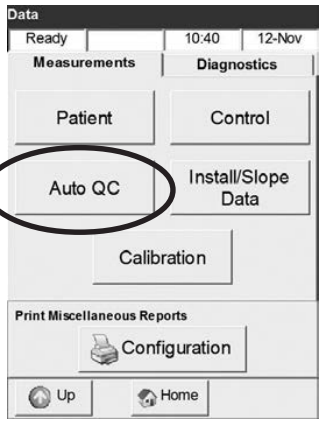


Fig. 4-32 Select Auto QC

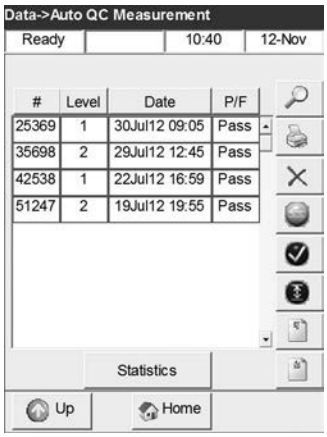


Fig. 4-33 Auto QC Measurement

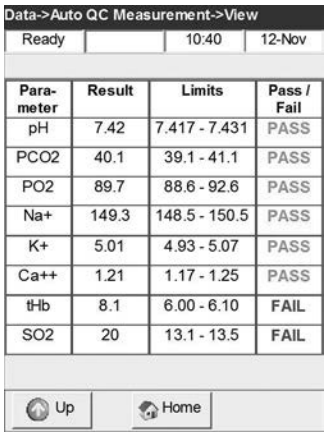


Fig. 4-34 Auto QC Results

Your OPTI R can print reports containing information on the mean, Standard Deviation (SD) and Coefficient of Variation (CV) of stored Auto QC data.

1. In the **<Ready>** display, select **<Data Manager>**.
2. Press **<Auto QC>** (Fig. 4-32).
3. In the **<Data - Auto QC Measurement>** screen (Fig. 4-33), press the View button to display the Control results (Fig. 4-34). 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. 4-33). 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 and select the levels for which statistics are to be printed.
7. After printout, the database can be deleted by pressing Delete.
8. Before the database is deleted, enter the password to initiate the procedure, if a password has been activated under **<Setup>**.
9. Press Home to return to the **<Ready>** display.
10. Press **<Install/Slope Data>** (Fig. 4-32) to view data from pack and cassette installations. The installation data will apply the pack limits set by OPTI Medical. The **<Install/Slope Data>** menu will also allow you to view the slope check data obtained.

4.5.3.2 Printing External Control Reports

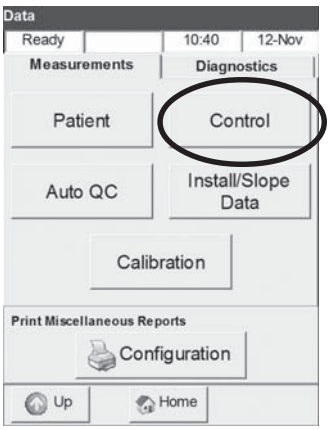


Fig. 4-35 Select Controls

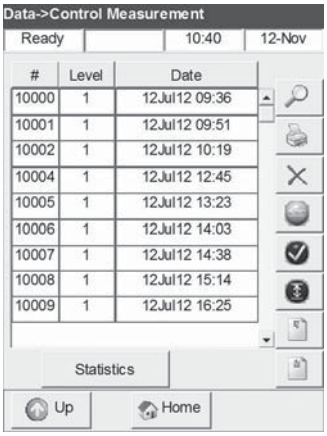


Fig. 4-36 Control Measurement

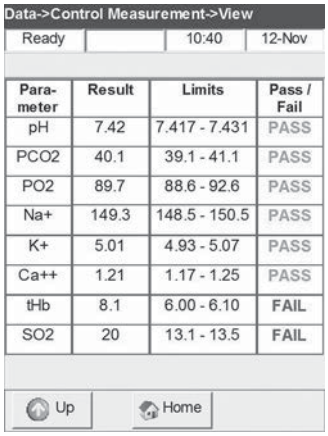


Fig. 4-37 View Control Results

Your OPTI R can print reports containing information on the mean, Standard Deviation (SD) and Coeff cient of Variation (CV) of stored QC data.

1. In the **<Ready>** display, select **<Data Manager>**.
2. Press **<Control>** (Fig. 4-35).
3. In the **<Data - Control Measurement>** screen (Fig. 4-36), press the View button to display the Control results (Fig. 4-37). 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. 4-36). To print groups of results, highlight the f rst 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 and select the levels for which statistics are to be printed.
7. After printout, the database can be deleted by pressing Delete.
8. Before the database is deleted, enter the password to initiate the procedure, if a password has been activated under **<Setup>**.
9. Press Home to return to the **<Ready>** display.

4.5.4 Sending Data to a Computer

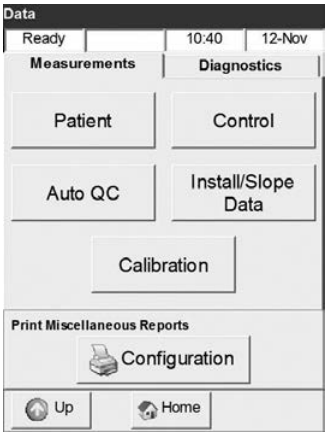


Fig. 4-38 Select Data

The OPTI R 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 R communication port must be configured (See section 3.3.2.8) 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.

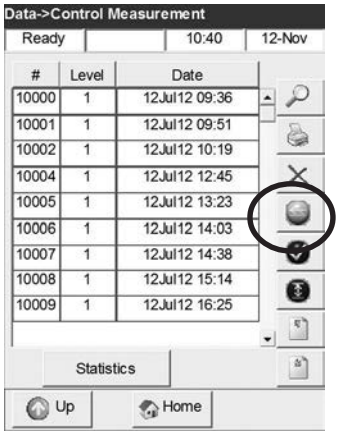


Fig. 4-39 Export Data

1. In the **<Ready>** display, select **<Data Manager>**.
2. Select **<Patient>**, **<AutoQC>**, **<Controls>** or **<Calibration>** (Fig. 4-38).
3. Select the data to be exported and press Export to start the data transfer (Fig. 4-39).

Fig. 4-40 Export Selected Data

4. A warning will be displayed asking you to confirm your choice (Fig. 4-40).

4.6 Calibration

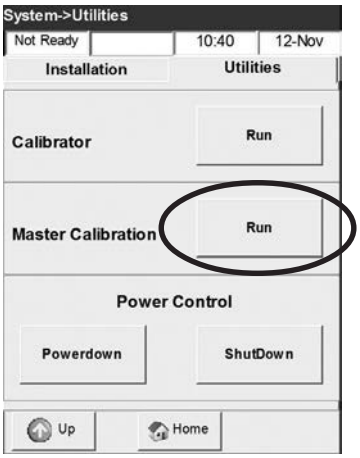


Fig. 4-41 Master Calibration

The analyzer will perform a calibration verification every 30 minutes and after each measurement. You may, however, perform a master calibration at any time by selecting **<Master Calibration - Run>** from the **<System Manager -> Utilities>** menu (Fig. 4-41).

After completing the calibration successfully, the analyzer will return to the **<Ready>** display.

5 SAMPLE HANDLING AND PATIENT TESTING

The OPTI™ R Analyzer provides fast and convenient measurement of pH, PCO_2, PO_2, Na^+, K^+, Ca^{++}, tHb and SO_2 in whole blood, and pH, Na^+, K^+ and Ca^{++}, 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 R 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 NCCLS document H11-A4, Procedures for the Collection of Arterial Blood Specimens; Approved Standard - Fourth Edition; September 2004, for detailed information on sample collection, storage and handling.

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

5.1.3 Anticoagulants and Sample Collection Devices

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

5.1.4 Syringes

If liquid heparin is used as an anticoagulant, collection devices should be no larger than the amount of blood required to minimize the effects of dilution of the blood by the anticoagulant solution. Although plastic syringes are commonly used for collection of blood specimens for blood gas analysis, there have been reports in literature regarding the use of plastic syringes when PO_2 values higher than normal are expected.

Particular attention should be paid to cooling blood samples in ice water, because of the CO_2 and oxygen solubility in some plastics. If blood specimens are expected to have very high PO_2 values, care should be taken to analyze the specimen as quickly as possible following collection to avoid the need for cooling.
Attention should be paid to thorough mixing of whole blood samples prior to analysis, since sedimentation of blood cells affects the measurement of total hemoglobin.

5.1.5 Capillary Tubes

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

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.

5.1.6 OPTI Medical ComfortSamplers™

Blood may be collected for analysis on the OPTI R 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.

5.1.7 Handling and Storage of Samples

Please refer to NCCLS 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, 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 R.

The OPTI R 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.

5.1.8 Test Conditions

Sample Size:	a minimum of 125 µL
Sample Type:	heparinized whole blood, serum and plasma
Sample Application:	syringe, capillary or ComfortSampler
Ambient Temperature:	10 - 30 ºC (50 – 86 ºF)
Relative Humidity:	5% to 95% (non-condensing)
Type of Measurement:	optical fluorescence (pH, PO_2, PCO_2, Na^+, K^+, Ca^{++}) 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)

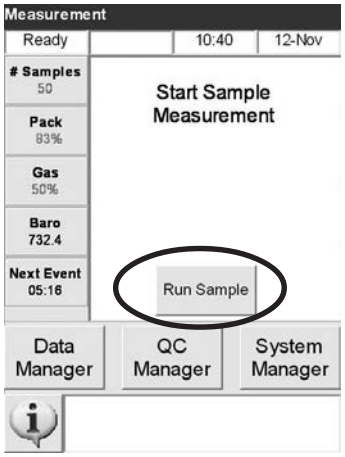


Fig. 5-1 Ready Display

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

1. In the **<Ready>** display, press **<Run Sample>** to start the measurement (Fig. 5-1).

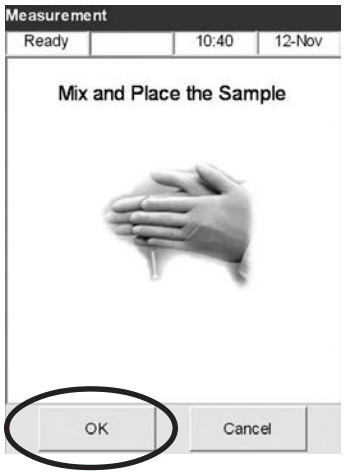


Fig. 5-2 Mix and place sample

2. The display will then prompt you to mix and place the sample (Fig. 5-2). Mix the syringe sample well by rolling it between the palms of your hands and inverting end over end. When placing a syringe sample, attach a new syringe adapter.
   - Sedimentation of blood cells causes alteration of tHb values. Therefore mix the sample well just prior to analysis.

Fig. 5-3 Attach Capillary Sample

3. Using a capillary, a syringe and adapter, or ComfortSampler, attach the sample to the cassette fillport (Fig. 5-3 and Fig. 5-4), and press OK to start the sample measurement. The sample is then aspirated.

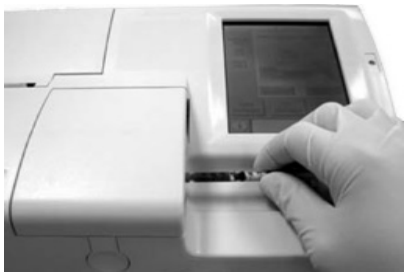


Fig. 5-4 Attach Syringe Sample

- 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. 5-5 Remove Sample

4. After the sample has been aspirated, remove the sample and confirm by pressing OK (Fig. 5-5).

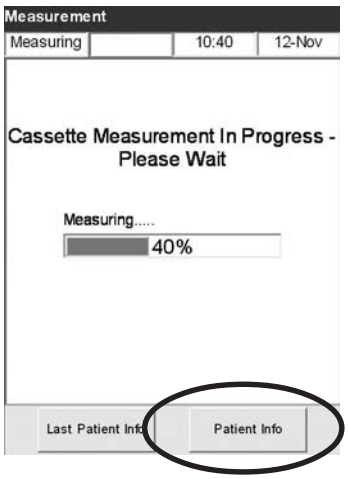


Fig. 5-6 Sample Measurement

Next the sample is measured. During the measurement the status light is blinking and a progress bar is displayed (Fig. 5-6).

5. To enter patient information while measurement is in progress, press **<Patient Info>** (Fig. 5-6).

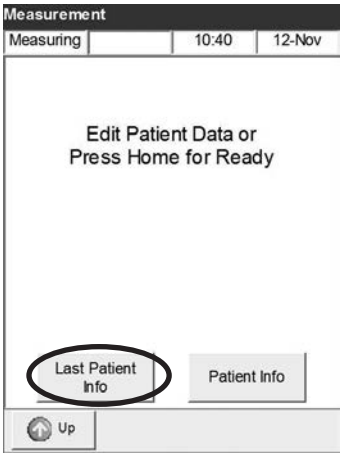


Fig. 5-7 Edit Patient Data

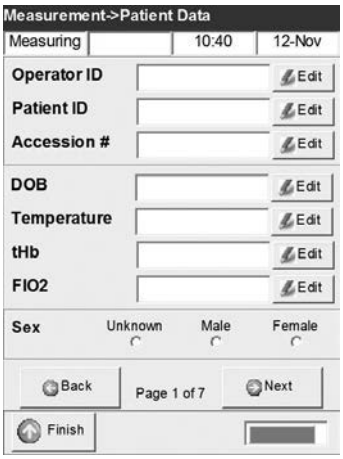


Fig. 5-8 Edit patient data (1)

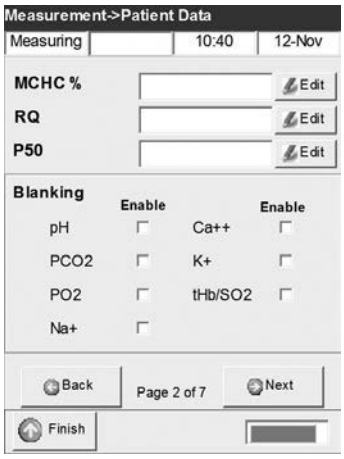


Fig. 5-9 Edit patient data (2)

- Press the **<Last Patient Info>** button (Fig. 5-7) 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.

6. The first patient data entry screen contains the following information (Fig. 5-8):
   - 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)
   - tHb (default value is 15.0 g/dL)
   - FIO_2 (default value 0.21)
   - Sex (unknown, male or female)

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

7. To enter patient data, press Edit. Use the alphanumeric keypad to type in the desired information. Press OK to save the information entered.
8. Pressing Next will access subsequent patient data entry screens (Fig. 5-9):
   - MCHC (default value 33.3%)
   - RQ (default value 0.84)
   - P_{50} (default value 26.7 mmHg)
   - Blanking

NOTE: Parameter blanking will omit a parameter from the printout. (See Section 3.3.1.2 for detailed description).

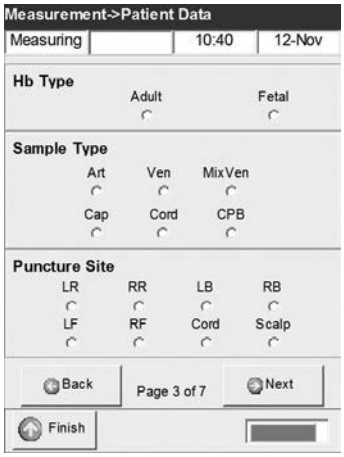


Fig. 5-10 Edit patient data (3)

9. Press Next again and the following patient information is displayed (Fig. 5-10):
   - 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. 5-11 Edit patient data (4)

10. Press Next for the following information (Fig. 5-11):
    - 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)

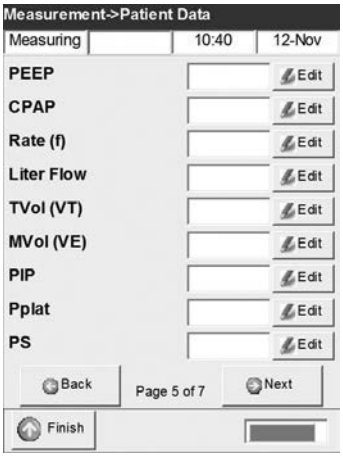


Fig. 5-12 Edit patient data (5)

11. The next set of patient data contains the following information (Fig. 5-12):
    - 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)

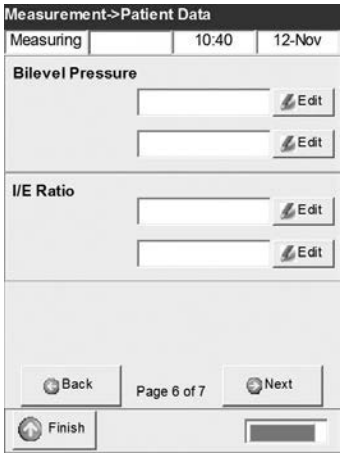


Fig. 5-13 Edit patient data (6)

12. Press Next again and select the following (Fig. 5-13):
    - BiLevel Pressure (default value 0.00/0.00)
    - I/E Ratio (default value 0)

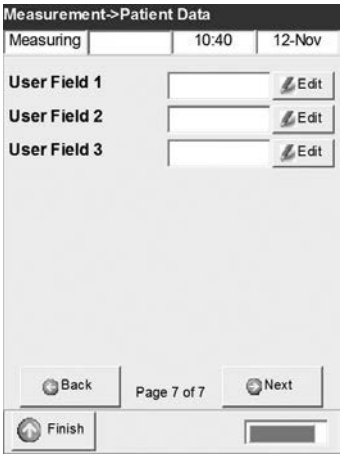


Fig. 5-14 Edit patient data (7)

13. The last set of patient data contains the following information (Fig. 5-14):
    - User Field 1 (9 alphanumeric characters)
    - User Field 2 (9 alphanumeric characters)
    - User Field 3 (9 alphanumeric characters)

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

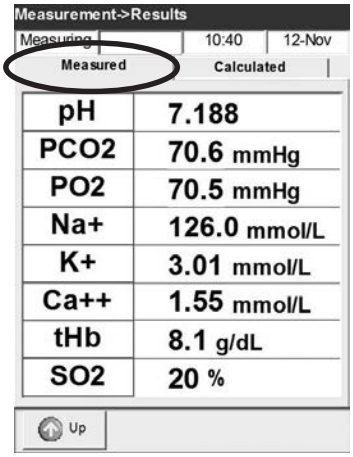


Fig. 5-15 Measurement results

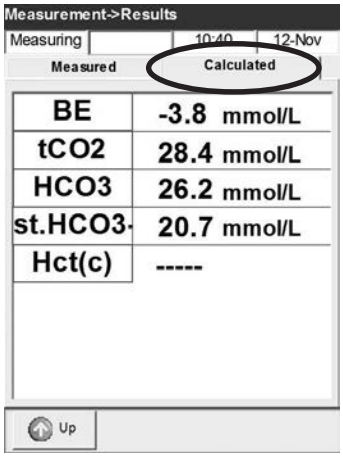


Fig. 5-16 Calculated parameters

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. 5-15).

The second tab displays the calculated parameters (Fig. 5-16).

15. 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 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 3.3.2.3).
    - The OPTI R 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 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.

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

5.4 Printing Patient Reports

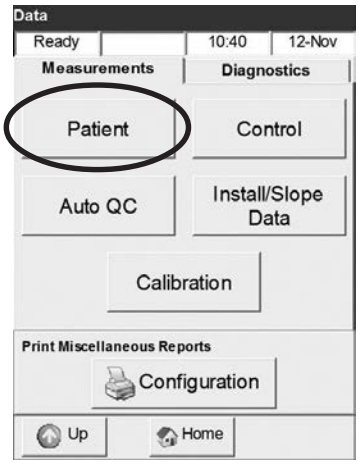


Fig. 5-17 Select Patient Report

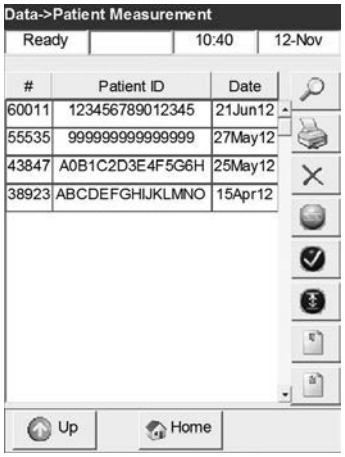


Fig. 5-18 Measurement Results

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. 5-17).
3. In the **<Patient Measurement>** screen (Fig. 5-18), 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.

6 MAINTENANCE

6.1 Daily Maintenance

No daily maintenance is required for the OPTI™ R analyzer.

6.2 Weekly Maintenance

Once a week, the Sample Measurement Chamber (SMC) must be cleaned. It is recommended that cleaning should be performed when changing the cassette, since it will result in premature expiration of the sensor cassette. 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 – Running the Calibrator

Fig. 6-1 Select Utilities

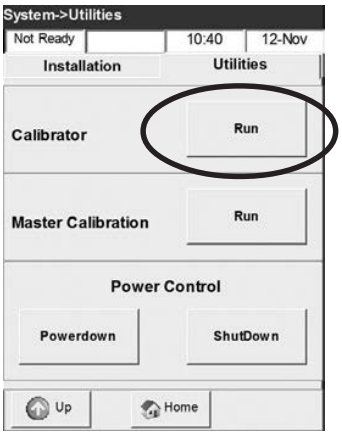


Fig. 6-2 Select Calibrator - Run

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

The calibrator measurement should be performed when changing the cassette, since it will result in premature expiration of the sensor cassette.

1. In the **<Ready>** display, select **<System Manager>**.
2. In the **<System>** menu, select **<Utilities>** (Fig. 6-1).
3. In the **<Utilities>** menu, select **<Calibrator - Run>** (Fig. 6-2).

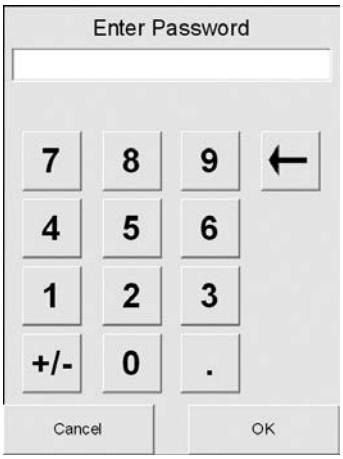


Fig. 6-3 Enter Password

4. Use the numeric keypad to enter the password (Fig. 6-3).

Fig. 6-4 Enter Operator ID

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

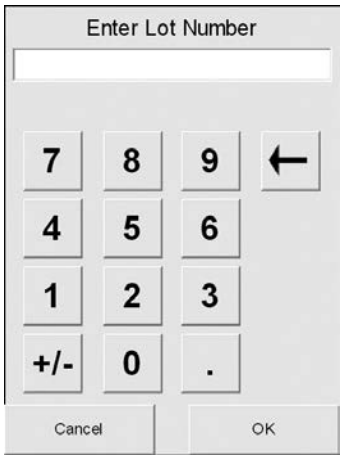


Fig. 6-5 Enter Lot Number

6. Enter the lot number of the Calibrator cassette located on the top surface of the cassette and press OK (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 OK.

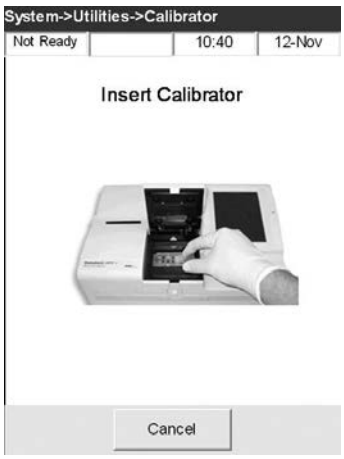


Fig. 6-8 Wipe and Insert Cassette

9. 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. 6-8).

Fig. 6-9 Close Cover

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

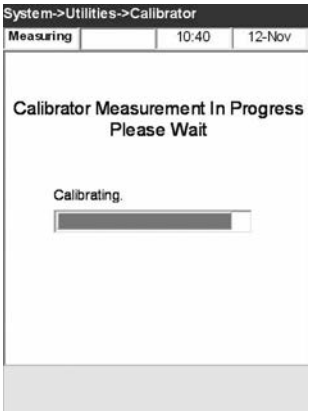


Fig. 6-10 Calibration in Progress

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 the clip inside of the printer door immediately after removal from the instrument.

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

```
     OPTI Medical OPTI R
      Calibrator Report
       DD-MMM-YY  HH:MM
S/N: XXXX
Version: ABCX.XX

Operator ID:
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
```

Fig. 6-11 Calibrator Report

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

6.4 Semiannual Maintenance

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

6.4.1 Replacing Peri Pump Cartridge

WARNING: *It is recommended that this maintenance procedure should be performed when changing the sensor cassette, since it will result in premature expiration of the sensor cassette currently installed in the analyzer.*

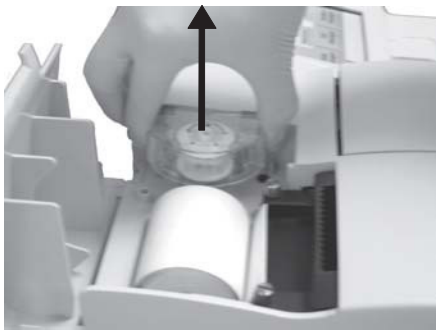


Fig. 6-12 Remove Pump Cartridge

Fig. 6-13 Pump Seals

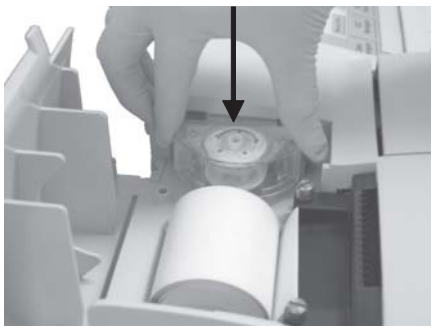


Fig. 6-14 Install New Cartridge

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. 6-12).

CAUTION: *When used, the pump contains human body fluids. Dispose of the pump according to local regulations.*

2. Replace the pump seals only as needed. Remove the old pump seals with a pair of hemostats or tweezers (Fig. 6-13). 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. 6-14).

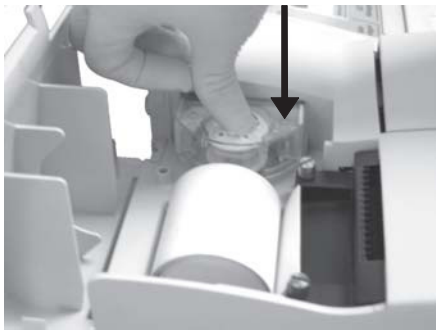


Fig. 6-15 Push on Pump Roller

5. Press the pump cartridge roller down until it firmly seats on the shaft of the pump motor (Fig. 6-15).
6. Perform a **<Master Calibration>** to ensure correct operation. Make sure the pump rotates smoothly without excessive noise.

6.4.2 Replacing SMC I/O Ports

Fig. 6-16 SMC I/O Ports

To change the SMC I/O ports:

1. Open the SMC cover. Remove the black I/O ports by grasping them with a hemostat or tweezers and firmly pulling upward (Fig. 6-16). Discard the old parts.
2. Install the new SMC I/O ports with the rounded surface pointing up and press them into the recess. When fully seated, the I/O ports are approximately 1/8 inch (3mm) above the surrounding surface.
3. Perform a **<Master Calibration>** to ensure correct operation. Make sure the pump rotates smoothly without excessive noise.

6.5 As Needed Maintenance

6.5.1 Changing the Sensor Cassette

Fig. 6-17 Installing new cassette

When no cassette is present in the sample measurement chamber or the current cassette has reached the maximum number of samples (50 patient or 45 QC measurements) or its in-use expiration (7 days), this display appears (Fig. 6-17).

1. In case the cassette is expired, press **<Install Cassette>** to install a new cassette.

Fig. 6-18 Installing new cassette

2. Otherwise, go to **<System Manager-> Utilities->** and press **<Cassette>** on the **<Installation>** tab (Fig. 6-18).
3. Remove old cassette.

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

Fig. 6-19 Scan cassette bar code

4. 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 until the bar code labeled **Scan A** is recognized (Fig. 6-19).
5. The red line from the bar code scanner should cover the entire bar code.
6. A beep and a green status light indicate a valid bar code.
7. 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).

Fig. 6-20 Scan second bar code

8. Next, turn the cassette pouch over and scan the bar code labeled **Scan B** (Fig. 6-20).
9. A beep and a green status light indicate a valid bar code.

Fig. 6-21 Open SMC Cover

10. Slide the latch up and press the release button to open the Sample Measurement Chamber (SMC) (Fig. 6-21).

Fig. 6-22 Insert Cassette

11. Insert the cassette as follows:
12. Open the OPTI R Sensor Cassette packet and remove the cassette from the pouch (Fig. 6-22).

CAUTION: *Do not tear the two bar codes when opening the cassette pouch.*

13. Gently wipe both sides of the cassette with a clean dry cloth to remove excess moisture.
14. Insert the cassette in the chamber and press down to ensure it is properly seated (Fig. 6-22).

Fig. 6-23 Close Cover

15. Close the SMC cover by pressing it down firmly (Fig. 6-23).

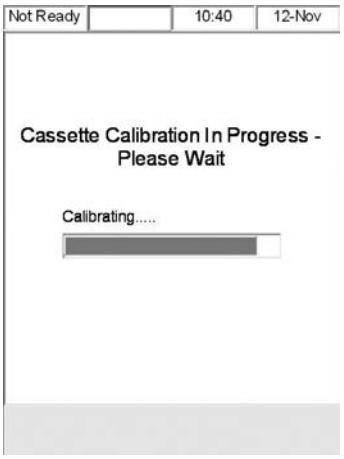


Fig. 6-24 Cassette Calibration

The system will now check the integrity of the cassette and then calibrate (Fig. 6-24)
For more information about calibration, please refer to Chapter 4 “Calibration and Quality Control”.

WARNING: *Do not remove the sensor cassette until the applicable number of patient samples or expiration date has been reached. Removal of the cassette without being prompted to do so, will result in premature expiration of the sensor cassette currently installed in the analyzer.*

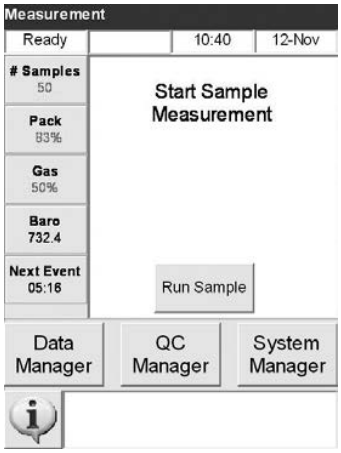


Fig. 6-25 Ready Display

Once the calibration is complete, the **<Ready>** display appears, identifying the number of samples available on the new cassette (Fig. 6-25).

6.5.2 Changing the Fluid Pack

Fig. 6-26 Select New Fluid Pack

The OPTI R Fluid Pack is designed for 100 - 150 measurements. When this display appears (Fig. 6-26), the Fluid Pack is empty and needs replacement.

1. In case the Fluid Pack is low, press **<New Fluid Pack>**.

Fig. 6-27 Installing new Fluid Pack

2. Otherwise, go to **<System Manager-> Utilities->** and press **<Fluid Pack>** on the **<Installation>** tab (Fig. 6-27).
3. Remove the old Fluid Pack from the fluid pack compartment on the rear of the analyzer and install the red protective connector strip.
4. Record the installation date on the label of the new pack.

Fig. 6-28 Insert OPTI R Fluid Pack

5. Remove the protective strip and insert the new OPTI R Fluid Pack in the compartment on the rear of the analyzer (Fig. 6-28).

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

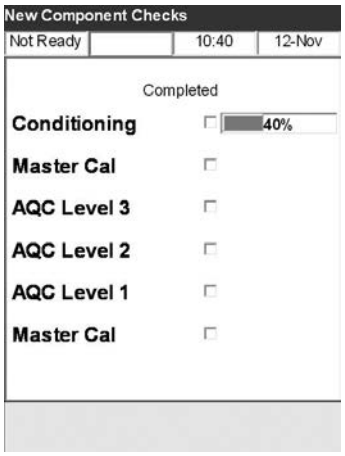


Fig. 6-29 New Component Check

- As soon as the Fluid Pack is inserted, the system will detect the presence of the Fluid Pack and retrieve the pack information.

  The system will now perform an integrity check of the Fluid Pack (Fig. 6-29).

6.5.3 Changing the Gas Bottle

Fig. 6-30 Changing Gas Bottle

The gas bottle is designed for 80 - 120 measurements. When this display appears (Fig. 6-30), the gas bottle is empty and needs replacement.

1. In case of an empty gas bottle, press **<New Gas Bottle>**.

Fig. 6-31 Installing new gas bottle

2. Otherwise, go to **<System Manager-> Utilities->** and press **<Gas Bottle>** on the **<Installation>** tab (Fig. 6-31).

Fig. 6-32 Remove Gas Bottle

3. Unscrew the old gas bottle by turning the knob on the bottom counterclockwise (Fig. 6.32).

Fig. 6-33 Scan Bar Code

Fig. 6-34 Insert Gas Bottle

Fig. 6-35 New Gas Bottle

4. Take a new gas bottle and remove its cap.
5. When prompted (Fig. 6-33), 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 R will alert the operator two weeks before the gas bottle expires.

6. Insert the bottle into its housing and turn it clockwise until finger-tight (Fig. 6-34).
7. Press OK

8. In the **<New Gas Bottle?>** screen (Fig. 6-35), press Yes to confirm the installation of a new gas bottle.

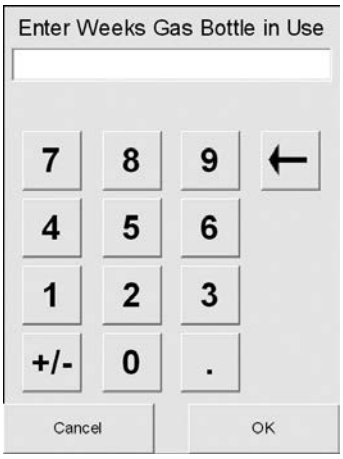


Fig. 6-36 Enter Number of Weeks in use

- If you 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. 6-36). Here you may refer back to the installation date, which was recorded on the gas bottle.

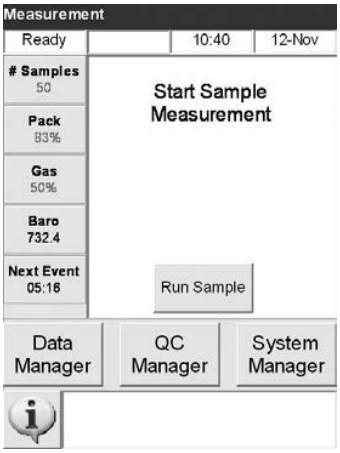


Fig. 6-37 Ready screen

9. The **<Ready>** display will now be reset to reflect the status of the new gas bottle, identifying the percentage remaining (Fig. 6-37).

6.5.4 Changing the Printer Paper

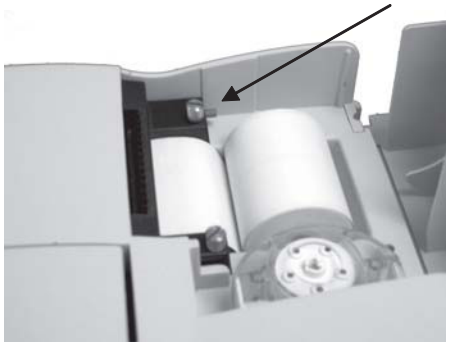


Fig. 6-38 Paper Advance Button

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. 6-38).
3. Remove the old roll.

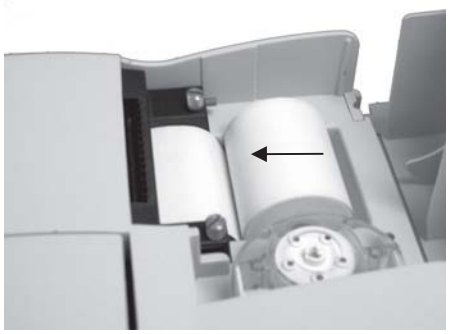


Fig. 6-39 Insert New Roll

4. With the OPTI R 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. 6-39).
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. 6-38).

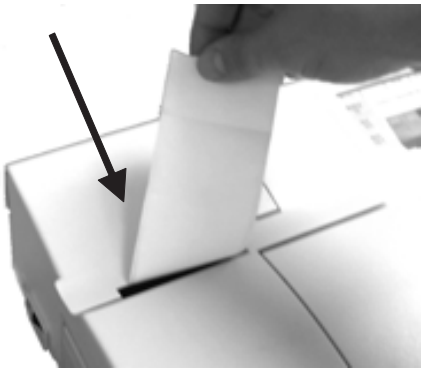


Fig. 6-40 Tear Off Excess Paper

7. Close the top cover of the analyzer and tear off any excess paper (Fig. 6-40).

6.5.5 Performing Routine Cleaning

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

WARNING: *Never use strong or abrasive cleaners on the OPTI R Analyzer.*

6.6 System Utilities

The **<Utilities>** menu contains the following functions: **<Calibrator>**, **<Master Calibration>**, **<Powerdown>** and **<Shutdown>** procedures.

- In the main menu, press **<System Manager>** (Fig. 6-41) to access the **<System>** menu. Press **<Utilities>** (Fig. 6-42) and the **<System -> Utilities>** screen will appear (Fig. 6-43).

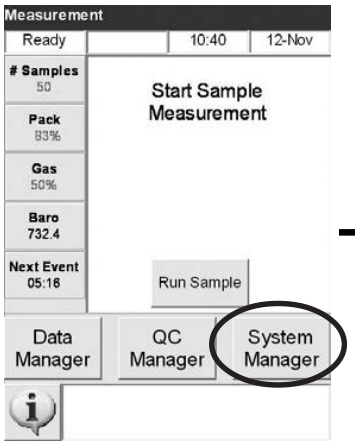


Fig. 6-41 System Manager

Fig. 6-42 Select Utilities

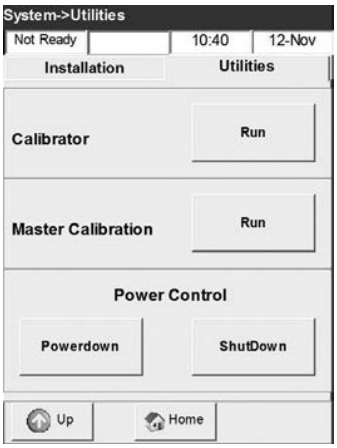


Fig. 6-43 System Utilities

6.6.1 Calibrator

(see 6.3.1 - Quarterly Maintenance)

6.6.2 Master Calibration

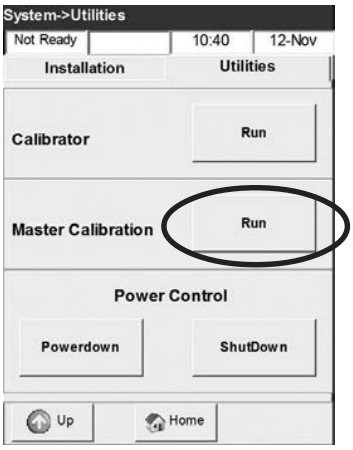


Fig. 6-44 Select Run

The analyzer will perform a calibration verification every 30 minutes. You may, however, perform a master calibration at any time by selecting **<Master Calibration-> Run>** from the **<System Manager -> Utilities>** menu (Fig. 6-44).

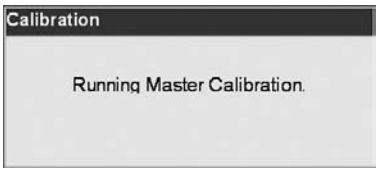


Fig. 6-45 Master Calibration

After completing the calibration successfully, the analyzer will return to the **<Ready>** display.

6.6.3 Taking out of Operation

6.6.3.1 Powerdown Procedure

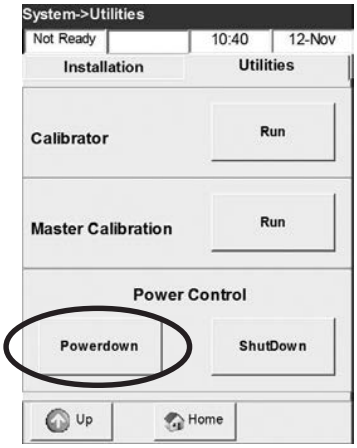


Fig. 6-46 Select Powerdown

For extended periods of inactivity of up to 72 hours, the system can be powered down.

- Select **<System Manager -> Utilities>** from the **<Ready>** menu.
- In the **<Utilities>** menu, select **<Powerdown>** to start this procedure (Fig. 6-46).

Fig. 6-47 Confirm Powerdown

- In the following display (Fig. 6-47), press
  Yes to initiate the powerdown or
  No to return to the **<Utilities>** menu.

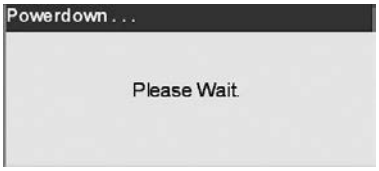


Fig. 6-48 Powering down

- The system will then power down (Fig. 6-48).

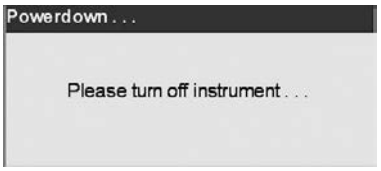


Fig. 6-49 Turn off instrument

- Turn the instrument off when prompted (Fig. 6-49).

6.6.3.2 Shutdown Procedure

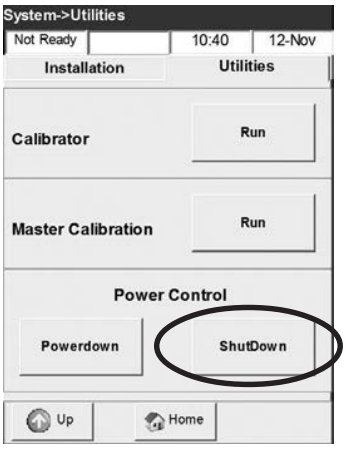


Fig. 6-50 Select Shutdown

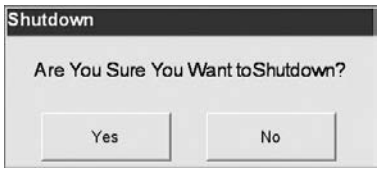


Fig. 6-51 Confirm Shutdown

Fig. 6-52 Remove Fluid Pack

This routine assists you in performing a complete shutdown of the analyzer. A complete shutdown may be initiated to prepare the analyzer for shipping or in case the analyzer is not being used for an extended period of time (exceeding 72 hours).

- Never attempt to turn off the power for an extended period of time (>72 hours) without performing a complete shutdown of the analyzer.
- If the analyzer is <u>not</u> being used for less than 72 hours, it is recommended to perform a power down instead of a shutdown (See Section 6.6.3.1).

To perform the shutdown, you will need the following items:

- Two containers, one filled with at least 50 mL of water, the other one empty.
- One shutdown pack (supplied with the accessory kit)
- One shutdown cassette (part number BP7111) (supplied with the accessory kit)

1. Select **<System Manager -> Utilities>** from the **<Ready>** menu.
2. In the **<Utilities>** menu, select **<Shutdown>** to start this procedure (Fig. 6-50).
3. In the following display (Fig. 6-51), press Yes to start the shutdown procedure.
4. When prompted (Fig. 6-52) remove the Fluid Pack and push the protective strip supplied with the accessory kit firmly onto the Fluid Pack connector.

Fig. 6-53 Insert Shutdown Pack

5. Next, insert the shutdown pack carefully in the fluid pack receptacle (Fig. 6-53).

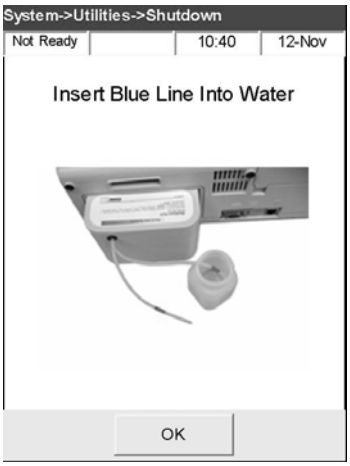


Fig. 6-54 Insert blue line

6. Then place the line with the blue band into the disposable container filled with water (Fig. 6-54). Press OK.

Fig. 6-55 Insert red line

7. The line with the red band is placed into the empty container (Fig. 6-55). Press OK.

Fig. 6-56 Open Cover

8. Open the cover of the sample measurement chamber (Fig. 6-56).

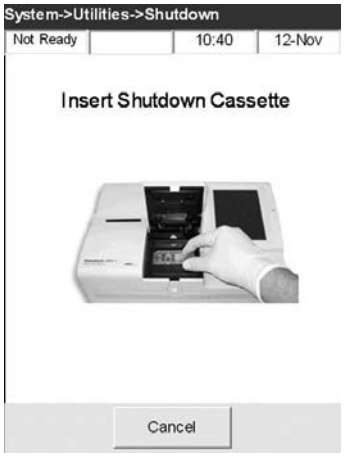


Fig. 6-57 Insert Shutdown Cassette

9. Insert the shutdown cassette (Fig. 6-57).

Fig. 6-58 Close Cover

10. Close the SMC cover (Fig. 6-58).

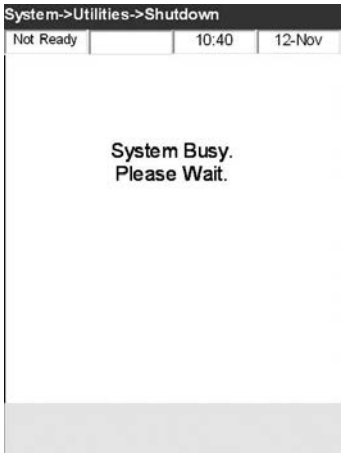


Fig. 6-59 Shutdown procedure

The analyzer will flush all lines with water for approximately one minute (Fig. 6-59).

Fig. 6-60 Remove blue line

11. Upon completion, remove the line with the blue band from the water container and place it on a cloth, making sure not to obstruct the line. The line with the red band remains in its container (Fig. 6-60). Press OK.

During this cycle, all lines are purged of air.

Fig. 6-61 Remove red line and Shutdown Pack

12. Upon completion, you will be prompted to remove the red line and the shutdown pack (Fig. 6-61).

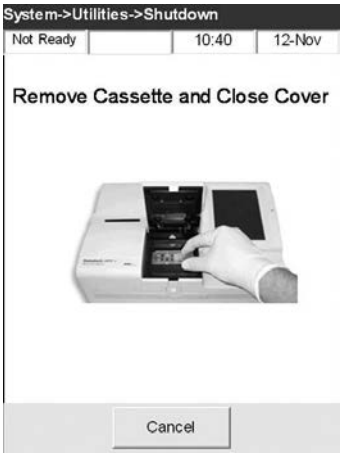


Fig. 6-62 Remove Cassette

13. Open the SMC cover, remove the shutdown cassette and close the cover (Fig. 6-62).

Fig. 6-63 Remove gas bottle

After the cassette has been removed, you will be asked to remove the gas bottle (Fig. 6-63).

14. Unscrew the gas bottle by turning the knob on the bottom counterclockwise.

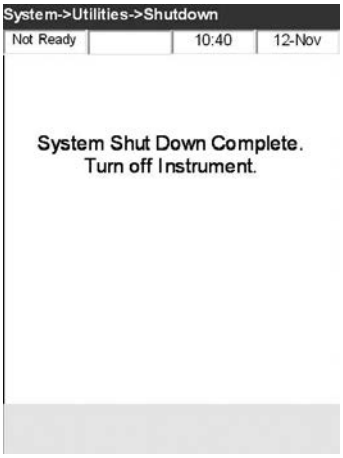


Fig. 6-64 Turn off instrument

15. When the shutdown is complete (Fig. 6-64), turn the system power off.

7 DIAGNOSTICS AND TROUBLESHOOTING

Your OPTI™ R 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.

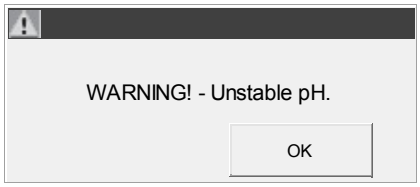
This chapter describes OPTI R specific error messages and recommends steps that should return your OPTI R to operation.

If your OPTI R 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

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 OK to notify the system that the sample is reattached and reaspirate sample.



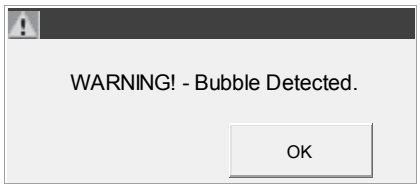
Unstable pH (PCO_2 or PO_2 or other measured parameter).

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

- Repeat sample measurement.

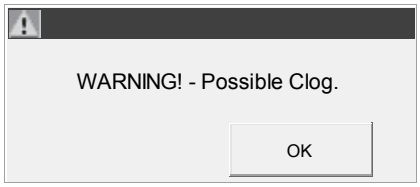
The pH (PCO_2 or other measured parameter) sensor is bad.

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



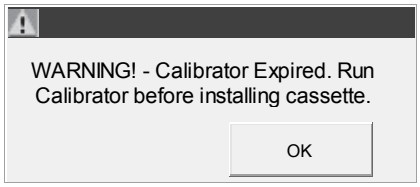
A bubble was detected at the light gates.

- Confirm the message by pressing OK and let the instrument clear the error through automatic cassette wash.
- Remix sample and rerun.
- Make sure a minimum sample volume of 125 µL is used.
- Remove any bubbles in the sample.



Sample was detected at the front light gate but did not reach the rear light gate.

- Confirm the message by pressing OK and let the instrument clear the error through automatic cassette wash.
- Replace the cassette.
- If error persists, call OPTI Medical Technical Support.

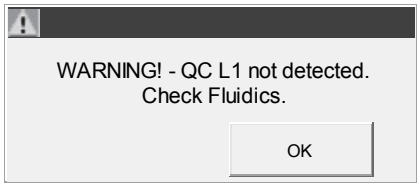


This display only appears once prior to the expiration of the 3-month calibration and acts as a reminder to run the Calibrator.

- Press OK to continue.
- Go to **<System Manager -> Utilities>** and run calibrator.

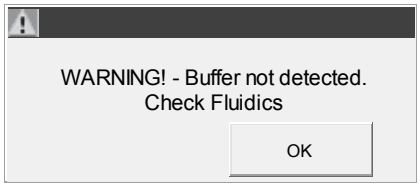
The number of secure users (operator IDs) stored in memory equals 300.

- Press OK to continue.
- Delete unused Operator IDs from memory (See Section 3.3.2.4.3).



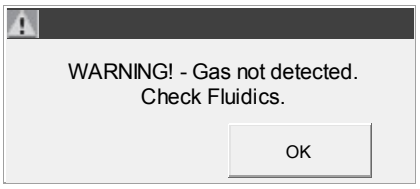
During Auto-QC measurement, the Auto-QC solution could not be detected.

- Check fluid pack level and replace if level is below 20%.
- Perform fluidics trouble shooting procedure (See Section 7.3.1).



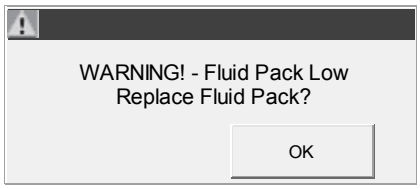
The instrument could not successfully aspirate wash buffer and the pack level is greater than 10%.

- Press OK and go to **<System Manager -> Utilities->** to perform a **<Master Calibration>**.



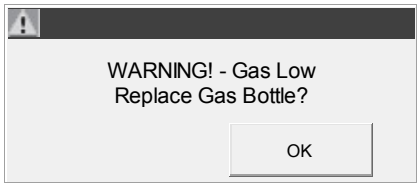
During a Master calibration, the calibration gas was not detected.

- Check the gas bottle level and replace if below 20%.
- Perform fluidics trouble shooting procedure (See Section 7.3.1).



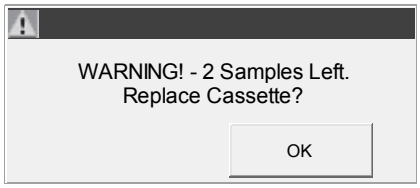
The fluid pack level is less than 10%.

- It is recommended to replace the fluid pack at this time.



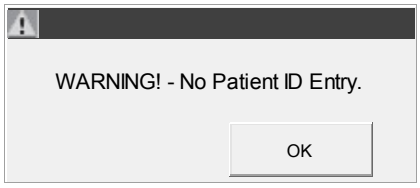
The gas bottle level is less than 10%.

- It is recommended to replace the gas bottle at this time.



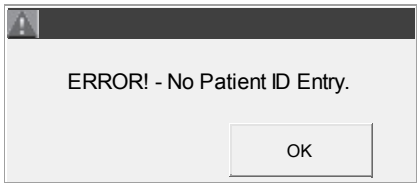
Once the number of available samples reaches 2, this warning is displayed.

- Make sure you have new cassettes on hand.
- Leave cassette in place to run the 2 samples left.
- Replace cassette now, if it is inconvenient to replace the cassette after 2 samples (it will take approx. 25 minutes of calibration time after installing a new cassette).



If Patient ID (Operator ID and/or Accession Number) is required and no patient data was input or patient data was previously edited without adding the required information, this warning will be displayed.

- Press OK to continue and edit the patient data.

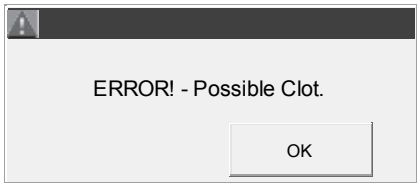


If Patient ID (Operator ID and/or Accession No.) is required and still not entered, this error will be displayed.

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

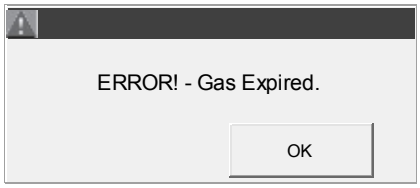
Two or more measured parameter sensors are bad.

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



The instrument could not clear the buffer from the cassette.

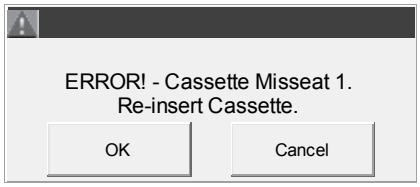
- Press OK and go to **<System Manager -> Utilities->** to perform a **<Master Calibration>**.



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>**.

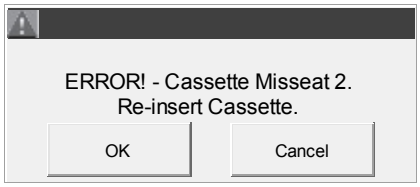


The cassette was not properly placed into the chamber.

- Open the SMC cover.
- Reinsert the cassette and verify proper seating.
- Press OK to continue.

  OR

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



The cassette was not properly placed into the chamber.

- Open the SMC cover, remove and reinsert the cassette and close the cover.

  OR

- Press Cancel to abort.

The cassette was not properly placed into the chamber.

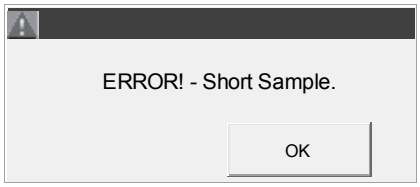
- Press OK, discard the cassette and repeat test with a new cassette.

The cassette or its packaging is defective.

- Press OK, discard the cassette and repeat test with a new cassette. Make sure to wipe the new cassette dry before inserting it into the SMC.

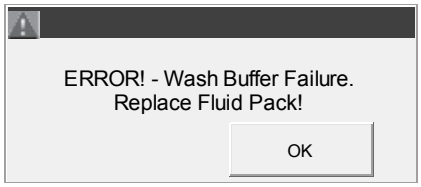
A sample error has occurred. This may be due to a clot or large air bubble if two or more sensors are unstable.

- Press OK, and let instrument clear the error through automatic cassette wash.
- Check the sample for contaminants.
- Rerun the sample.



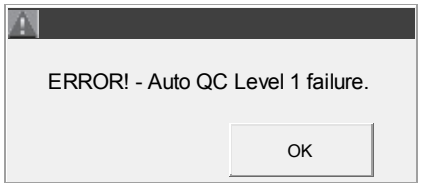
The system was not able to aspirate enough contiguous sample fluid to cover the optode sensors after multiple aspiration attempts.

- Press OK, and let instrument clear the error through automatic cassette wash.
- Check sample for sufficient volume and air bubbles.
- Rerun the sample.



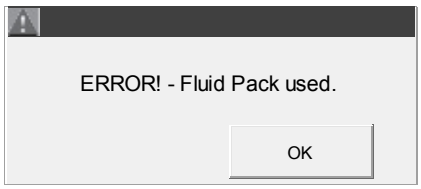
During Fluid Pack installation, the wash buffer was found to be contaminated due to a damaged pouch.

- Press OK and replace the fluid pack



During Fluid Pack installation, the AQC L1 was outside the limits.

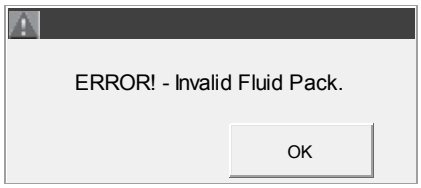
- Press OK and rerun AQC L1 once prompted.



This message indicates that the Fluid Pack inserted has a fill level of less than 90%.

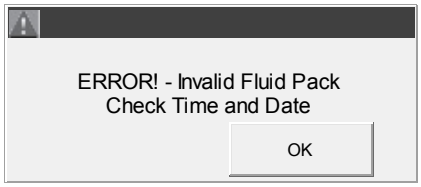
- Press OK to replace the Fluid Pack.

NOTE: A used pack can only be reinstalled in the same instrument from which it was removed.



This error appears, when a newly installed pack is defective and fails calibration verification.

- Press OK, discard the defective pack and install a new fluid pack.

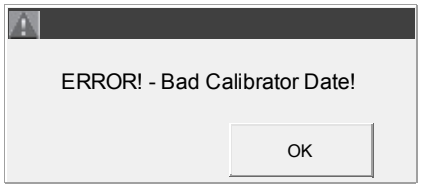


The current time/date is invalid as compared to the fluid pack manufacturing date.

- Please check the date of the instrument in the Time/Date setting menu. In particular, make sure the year is entered correctly.

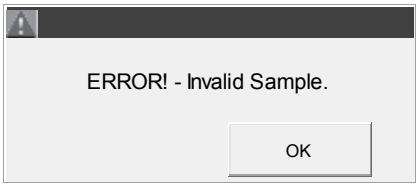
The waste sensor is unable to detect fluid movement.

- Cycle power and check if error recurs.
- Replace cassette.



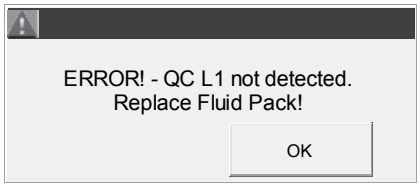
The expiration date of the calibrator cassette is invalid.

- Check Time/Date of instrument.
- Re-enter lot number of calibrator cassette.
- Replace calibrator cassette.



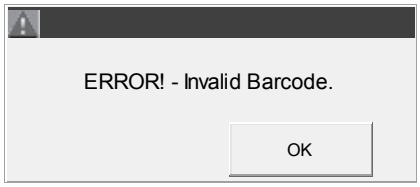
The sample cannot be analyzed, because one or more sensors do not yield a valid optics signal.

- Re-run sample – make sure the sample does not have extreme high or low analyte levels.



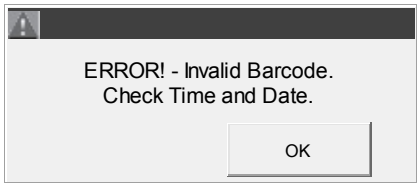
During Auto-QC measurement, the Auto-QC solution could not be detected

- Check fluid pack level and replace if level is below 20%
- Initiate AutoQC measurement manually (QC manager).
- Perform fluidics trouble shooting procedure (See Section 7.3.1)



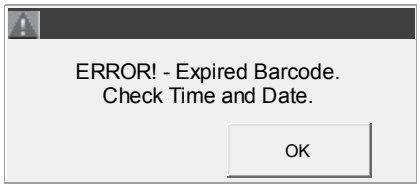
The bar code was invalid (the OPTI R either misread the bar code label or it is an invalid bar code for the OPTI R).

- Press OK to retry.
- If the error message appears again, check the product package for intended use.
- Check the bar code scanner (see Section 7.2.10).
- 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.



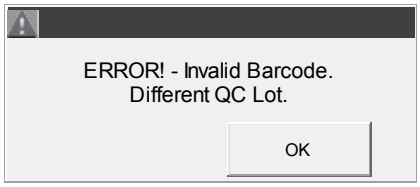
The bar code was invalid (the OPTI R either misread the bar code or the product (i.e. gas bottle, cassette or Fluid Pack) has expired).

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



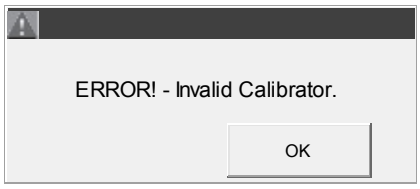
The cassette expiration date has been reached.

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



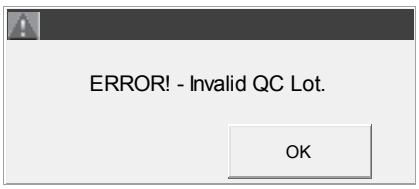
The bar code was invalid.

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



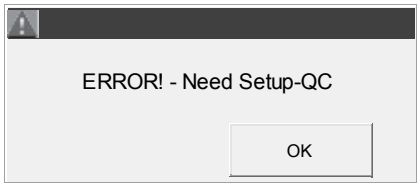
The cassette placed in the SMC is invalid.

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



The QC lot is invalid.

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



A measurement of QC materials was attempted prior to setting up.

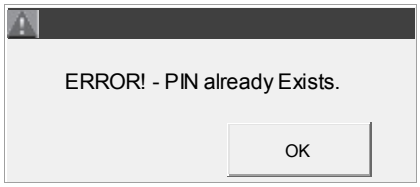
- Press OK to continue.
- Configure the new QC material under **<QC Setup>** and retry.

The Operator ID already exists in the database.

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

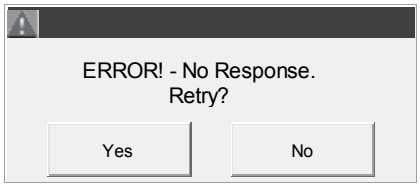
The PIN number does not exist in current Secure Op. ID database.

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



The PIN number already exists in database.

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

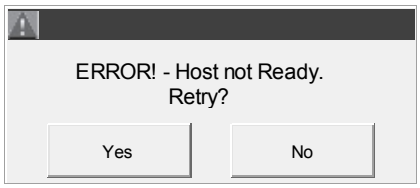


The OPTI R received no response from the host computer.

- Press Yes to retry.

If the problem persists:

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

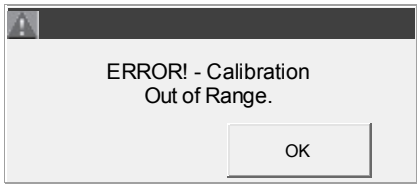


The OPTI R received a negative (NAK) response from the host computer.

- Press Yes to retry.

If the problem persists:

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

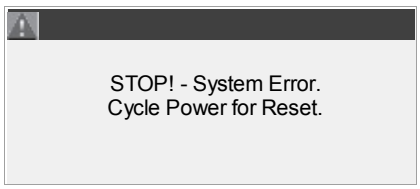


This error may occur during the 3-month calibration. The error is triggered, when the correction is greater than 30%.

- Replace the calibrator.

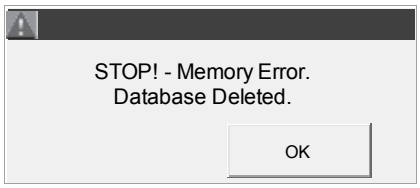
The gas cylinder is empty.

- Replace the gas cylinder and press OK.



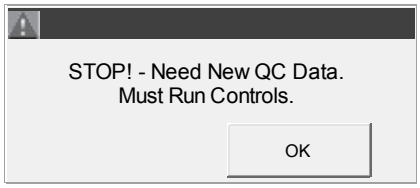
The instrument has detected an internal error.

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



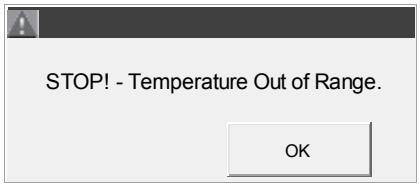
Patient, QC and other databases were deleted.

- Press OK and the instrument will reinitialize.



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

- Press OK and run control materials.



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

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

This prompt indicates that no fluid pack is present or that the fluid pack is invalid. A fluid pack is only valid if it passes all the installation checks.

- Follow the prompts to install a new fluid pack (see Section 6.5.2).

The Fluid Pack has a fill level of 0% in one or more fluid pouches.

- Press **<New Pack>** to install a new Fluid Pack. (see Section 6.5.2).

During the pack installation, the wash buffer or one of the QC levels was outside the installation limits

- Install a new Fluid Pack (see Section 6.5.2).

The Fluid Pack has either reached the shelf-life expiry date or the 4 weeks in-use expiry.

- Remove the expired fluid pack, and follow the prompts to install the new fluid pack (see Section 6.5.2).

The gas pressure is low.

- Replace the gas bottle (see Section 6.5.3).

The in-use (9 months) or labeled shelf-life of the gas bottle has expired.

- Replace the gas bottle (see Section 6.5.3).

The gas bottle is rejected if the gas concentration is outside the specifications.

- Replace the gas bottle (see Section 6.5.3).
  If error persists, perform “Fluidics Trouble-shooting” section 7.3.

This prompt indicates that no cassette is present or that the current cassette is invalid.
The cassette may be invalid because it expired or it was rejected.

- Install a new sensor cassette (see Section 6.5.1).

The cassette has reached the maximum of 50 patient samples or its in-use limit of 7 days.

- Replace the cassette (see Section 6.5.1).

The cassette has reached the maximum of 42 QC samples.

- Replace the cassette (see Section 6.5.1).

The cassette failed one of the installation checks (pouch integrity check, excessive bubbles in buffer or end-point error).

- Replace the cassette (see Section 6.5.1).

The temperature is out of range.

- Wait for the analyzer to reach the correct temperature.
- If the analyzer does not become **<Ready>** within a reasonable time, check the temperature under **<System Manager -> Diagnostics>**.

Wash solutions and/or AQC L2 could not be detected, although fluid levels of all solutions are greater than 10%.

- Press OK to go to **<System Manager -> Utilities>** to perform a **<Master Calibration>**.

Analyzer is unable to detect AQC L1, L2, or L3.

- Press **<Rerun AQC>** to repeat AQC measurement.
- If error persists, go to fluidics troubleshooting section 7.3.1.

During the wash, the fillport could not be cleared of sample fluid.

- Remove the sample if still attached and press OK to clear the error.
- If problem persists, go to **<System Manager -> Utilities>** and initiate a **<Master Calibration>**.

The waste sensor is unable to detect fluid movement.

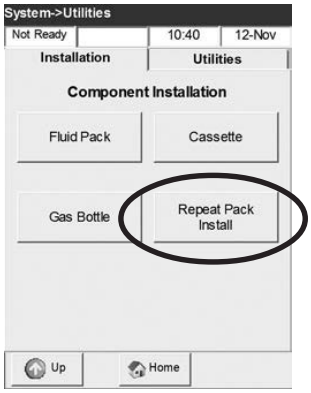
- Cycle power and check if error recurs.
- Replace cassette (see Section 6.5.1).

The analyzer was unable to detect the wash buffer.

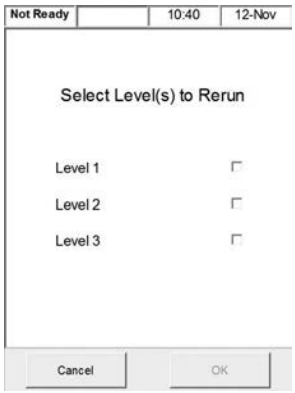
- Replace the fluid pack. If the error persists, perform “Fluidics Troubleshooting” section 7.3.

This message is displayed, if any of the parameters of any of the AQC levels failed the range.
To determine which AQC level and which parameter failed, go to **<Data Manager - Auto QC>**.
Select the failed level and view the results, or print the Auto QC report.

- Rerun the failed AQC level.
- If the problem persists, repeat pack installation with the currently installed pack and cassette. The cassette and pack do not need to be removed.



- Go to the **<System Manager - Utilities - Installation>** tab, and press **<Repeat Pack Install>**.



- Select the failing AQC level(s) and repeat measurement.
- If the problem persists, replace cassette and/or fluid pack.

7.2 Diagnostics

Fig. 7-1 Diagnostics

Your OPTI R has a number of useful diagnostic programs.

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

The **<Diagnostics>** screen contains five menus with various diagnostic functions: **<Sensors>**, **<Consumable Status>**, **<Control>**, **<Cassette Valve Drive>** and **<Tests>**.

7.2.1 Checking Versions

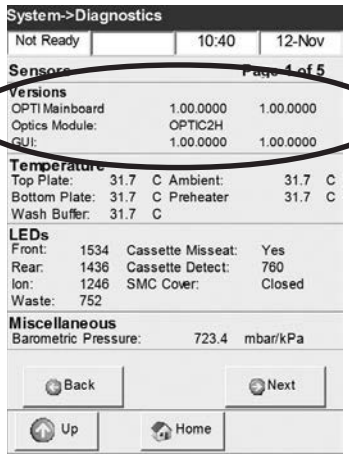


Fig. 7-2 Versions

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

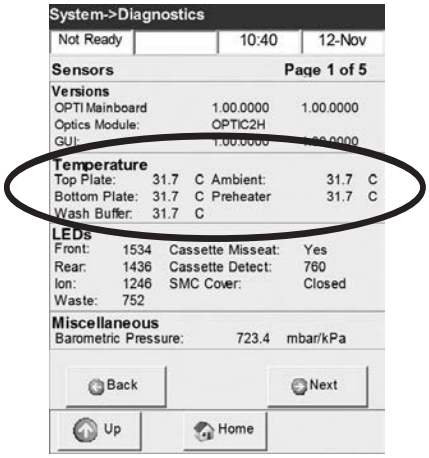


Fig. 7-3 Temperature

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

The **<Temperature>** option lets you check the various system temperatures: **<Top Plate>**, **<Bottom Plate>**, **<Wash Buffer>**, **<Ambient>** and **<Preheater>** (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 the LEDs

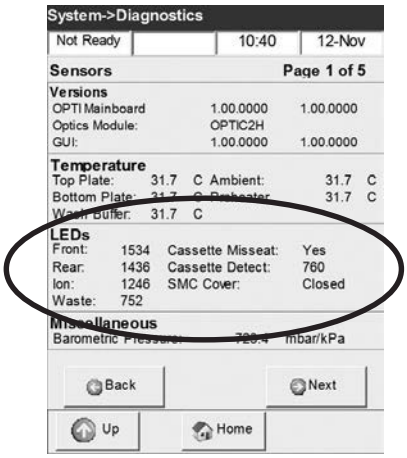


Fig. 7-4 LEDs

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. 7-4):

- **<Front>**, **<Rear>**, **<Ion>**, **<Waste>** - 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 Up to return to the **<System>** screen.

7.2.4 Verifying Barometric Pressure

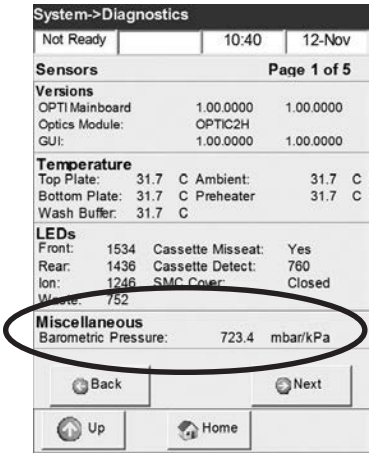


Fig. 7-5 Barometric Pressure

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. 7-5).
- If the barometric pressure requires adjustment, refer to Setup, Section 3.3.2.6 “Entering the Barometric Pressure” for setting the barometer.

7.2.5 Checking Consumable Levels

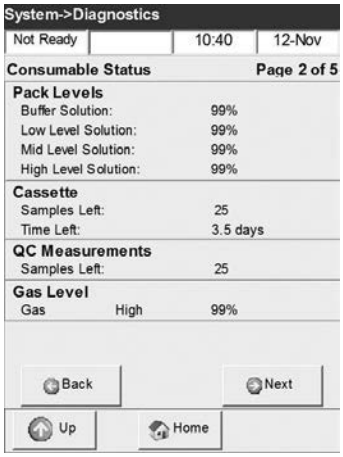


Fig. 7-6 Reagent Levels

The **<Consumable Status>** screen (Fig. 7-6) allows you to check the fluid levels remaining in the Fluid Pack, the number of samples and usage time left on the sensor cassette, number of QC measurements left and gas pressure remaining in the gas bottle.

From the **<Ready>** display, press **<System Manager -> Diagnostics>**.
In the **<Diagnostics - Sensors>** screen, press Next to access **<Consumable Status>**.

With a new Fluid Pack/Gas Bottle in place, the level should be approx. 99%, with Fluid Pack/Gas Bottle removed, it should be 00%.

- For instructions on installing a new Fluid Pack, gas bottle and sensor cassette, see Section 6 “Maintenance”.

7.2.6 Checking the Cooling Fan

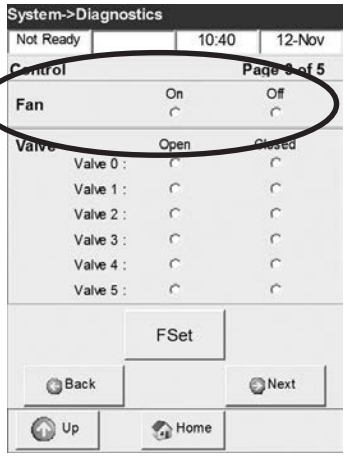


Fig. 7-7 Cooling Fan

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

From the **<Ready>** display, press **<System Manager -> Diagnostics>**. In the **<Diagnostics - Sensors>** screen, press Next to access **<Consumable Status>**, then press Next again to access the **<Control>** screen.

- Select **<On>** or **<Off>** next to **<Fan>** to start the test (Fig. 7-7).
- 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 Up to return to the **<System>** screen.

7.2.7 Checking Valves

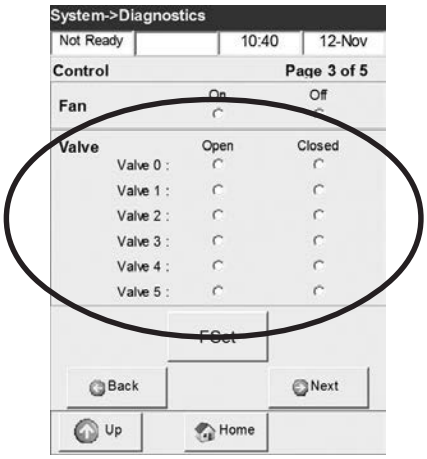


Fig. 7-8 Valves

The purpose of this test is to check for proper function of the gas and buffer valves.

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

In the **<Diagnostics - Sensors>** screen, press Next to access **<Consumable Status>**, then press Next again to access the **<Control>** screen.

- Select **<Open>** or **<Closed>** for the following valves (Fig. 7-8):
  0 = Wash buffer, 1 = Gas valve, 2 = QC Solution L1, 3 = QC Solution L2, 4 = QC Solution L3, 5 = Gas select valve.
- A faint hissing sound may be heard if valve 1 and valve 5 are opened at the same time and no cassette is present.

CAUTION: This will cause the gas bottle to drain quickly.

- Press Up to return to the **<System>** screen.

7.2.8 Checking the Factory Settings

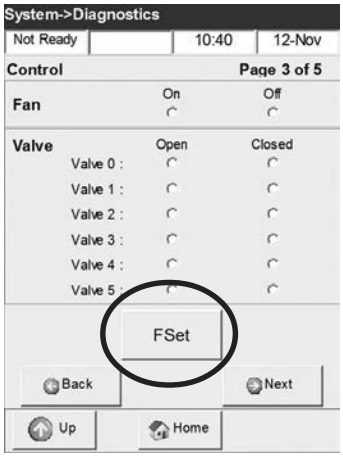


Fig. 7-9 Factory Settings

This **<Fset>** function (Fig. 7-9) is designed exclusively for use by authorized OPTI Medical personnel.

7.2.9 Checking the Valve Drive

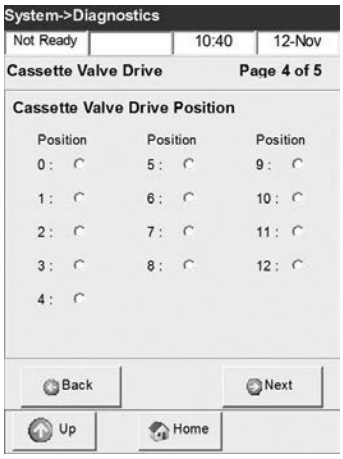


Fig. 7-10 Valve Drive

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

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

In the **<Diagnostics - Sensors>** screen, press Next repeatedly to access the **<Cassette Valve Drive>** screen (Page 4 of 5).

- Select position 1 and then position 0.
- Observe and verify that a 360 degree rotation of the valve drive occurs smoothly and precisely (Fig. 7-10).

NOTE: The valve drive is located in the SMC.

- Press Up to return to the **<System>** screen.

7.2.10 Checking the Bar Code Scanner

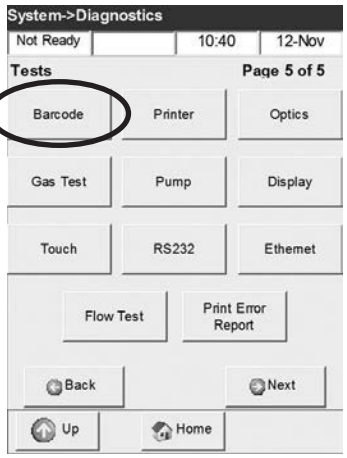


Fig. 7-11 Barcode Test

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

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

In the **<Diagnostics - Sensors>** screen, press Next repeatedly to access the **<Tests>** screen (Page 5 of 5).

- Press **<Barcode>** to start the test (Fig. 7-11).

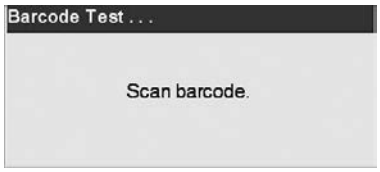


Fig. 7-12 Scan Barcode

- To test the bar code scanner, scan a bar code label of e.g. a sensor cassette (Fig. 7-12).

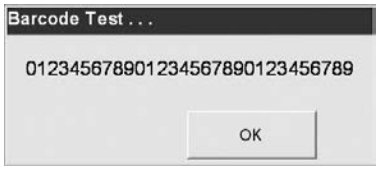


Fig. 7-13 Barcode Test

- The display will show a sequence of numbers (Fig. 7-13). Compare the numbers with those printed on the cassette bar code label. Matching information confirms the proper function of the bar code scanner.
- Press OK to return to the **<Tests>** screen.
- Press Up to return to the **<System>** screen.

7.2.11 Checking the Printer

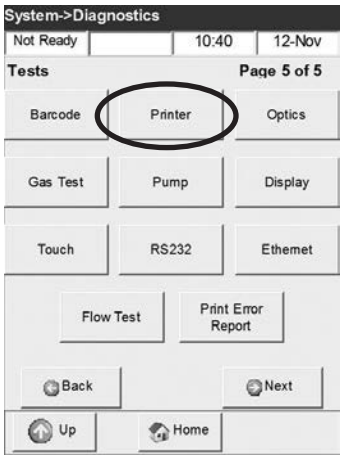


Fig. 7-14 Printer Test

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 -> Diagnostics>**.

In the **<Diagnostics - Sensors>** screen, press Next repeatedly to access the **<Tests>** screen (Page 5 of 5).

- Press **<Printer>** to start the test (Fig. 7-14).
- 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 R 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.

7.2.12 Checking the Optics

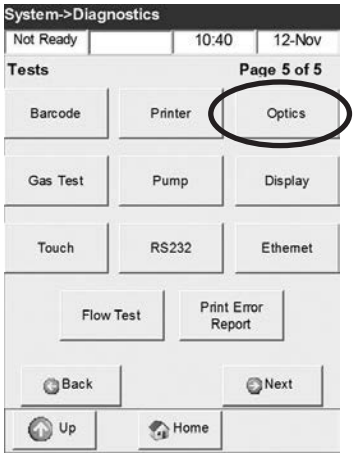


Fig. 7-15 Optics Test

This option checks the optics and electronics for drift and instability. This test is designed for trained service personnel. Running this test will invalidate the cassette.

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

In the **<Diagnostics - Sensors>** screen, press Next repeatedly to access the **<Tests>** screen (Page 5 of 5).

- Press **<Optics>** to start the test (Fig. 7-15).

Fig. 7-16 Insert Calibrator

- Insert a calibrator cassette and press OK (Fig. 7-16).

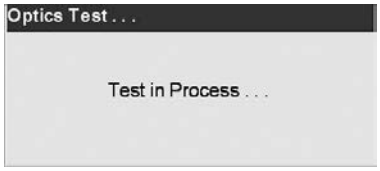


Fig. 7-17 Optics Test

- The system will now check the optics (Fig. 7-17).

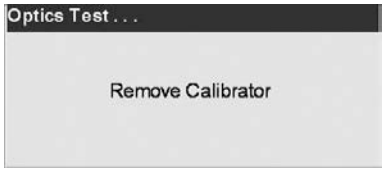


Fig. 7-18 Remove Calibrator

- At the completion of the test, a printout of the results will be printed and the **<Remove Calibrator>** message will be displayed (Fig. 7-18).

7.2.13 Gas Test

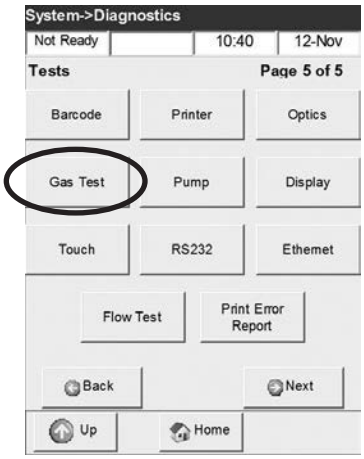


Fig. 7-19 Gas Test

The **<Gas Test>** (Fig. 7-19) is designed exclusively for use by authorized OPTI Medical personnel to check for leaks in the gas system.

NOTE: This test will last for 2 hours. It can only be interrupted by switching the analyzer off.

7.2.14 Checking the Pump Motor

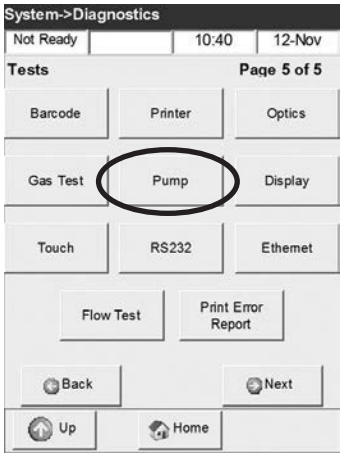


Fig. 7-20 Pump Motor Test

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

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

In the **<Diagnostics - Sensors>** screen, press Next repeatedly to access the **<Tests>** screen (Page 5 of 5).

- Press **<Pump>** to start the test (Fig. 7-20).

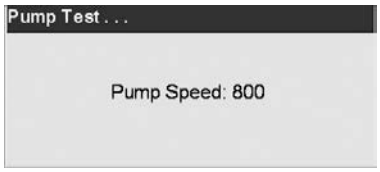


Fig. 7-21 Pump Speed

- The pump will automatically step through all the speeds used during normal operation (50 to 800 pps (pulses per second)) (Fig. 7-21) and return to the **<Tests>** screen.

7.2.15 Checking the Display

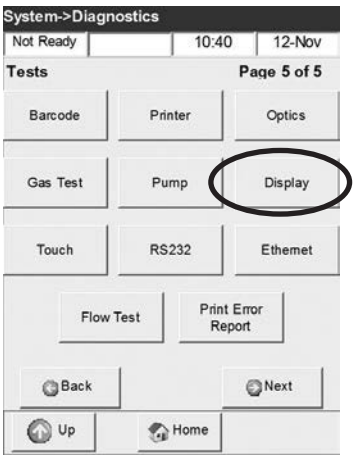


Fig. 7-22 Display Test

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

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

In the **<Diagnostics - Sensors>** screen, press Next repeatedly to access the **<Tests>** screen (Page 5 of 5).

- Press **<Display>** to start the test (Fig. 7-22).
- 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.

7.2.16 Checking the Touch Screen

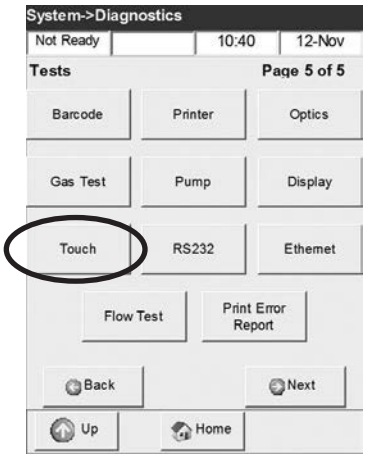


Fig. 7-23 Select Touch Test

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

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

In the **<Diagnostics - Sensors>** screen, press Next repeatedly to access the **<Tests>** screen (Page 5 of 5).

- Press **<Touch>** to start the test (Fig. 7-23).

Fig. 7-24 Perform Touch Test

- Touch the screen and a dot should appear under the touched location (Fig. 7-24).
- If not, press **<Calibrate>** to perform a touch calibration (Fig. 7-25).
- Press Up to return to the **<System>** screen.

Fig. 7-25 Perform Touch Calibration

- Using a finger, stylus or pointed object (e.g. syringe adapter), touch the center of the calibration mark as it moves around the screen (Fig. 7-25).

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

- When finished press Save.

7.2.17 Checking the RS232 Interface

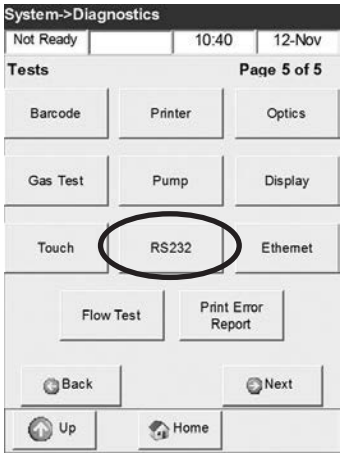


Fig. 7-26 RS232 Interface

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

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

In the **<Diagnostics - Sensors>** screen, press Next repeatedly to access the **<Tests>** screen (Page 5 of 5).

- Press **<RS232>** to start the test (Fig. 7-26).

Fig. 7-27 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. 7-27).
- Press OK and the system will send out a test string and check if it can be received.

Fig. 7-28 Interface Test Pass

- The instrument will display a **<Pass>** or **<Fail>** message (Fig. 7-28).
- Press OK to return to the **<Tests>** screen.

7.2.18 Checking the Ethernet Interface

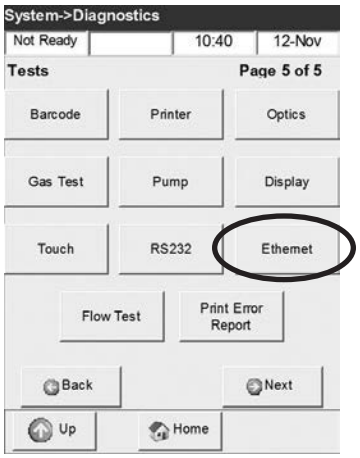


Fig. 7-29 Ethernet

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

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

In the **<Diagnostics - Sensors>** screen, press Next repeatedly to access the **<Tests>** screen (Page 5 of 5).

- Press **<Ethernet>** to start the test (Fig. 7-29).

Fig. 7-30 Connect Network Cable

- It is important to have the network cable connected (Fig. 7-30).

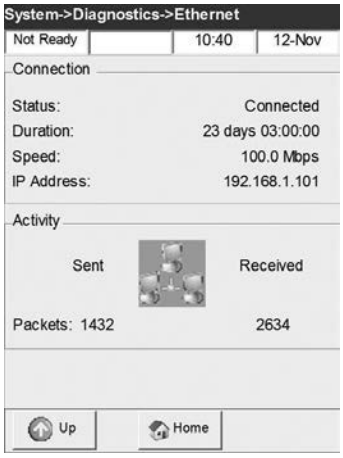


Fig. 7-31 Ethernet Test

- Press OK and the system will send out data and check if they are received (Fig. 7-31).
- Press Up to return to the **<Tests>** screen.

7.2.19 Checking the Pump Flow

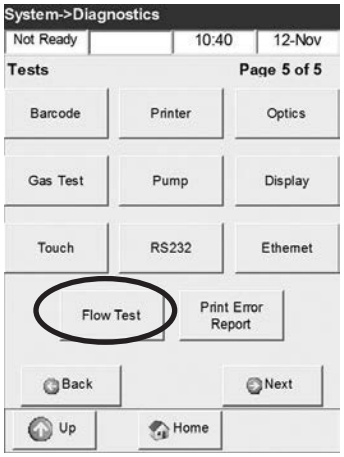


Fig. 7-32 Flow Test

This option is designed to test the OPTI R fluidics.

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

In the **<Diagnostics - Sensors>** screen, press Next repeatedly to access the **<Tests>** screen (Page 5 of 5).

- Press **<Flow Test>** to start the test (Fig. 7-32).

Fig. 7-33 Insert Cassette

- Leave the current cassette in place or insert either a new cassette or the shut-down cassette. (Fig 7-33).

NOTE: This test can be performed at any time and will not invalidate a cassette.

- Close the SMC cover.

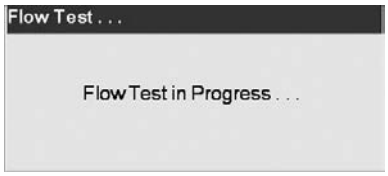


Fig. 7-34 Flow Test

- Wait for test results (Fig. 7-34).

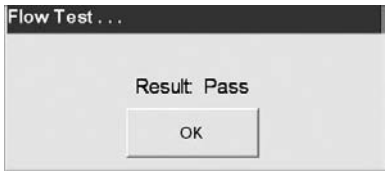


Fig. 7-35 Flow Test - Pass

- The test result indicates if buffer or air was detected at the front and ion light gate. For the test to PASS, both light gates need to detect buffer (Fig. 7-35).

Fig. 7-36 Flow Test - Fail

- If either one or both light gates detect air, the test fails. (Fig. 7-36)
- Repeat test. If the test continues to fail, test the fluidics as outlined in Chapter 7.3.1.

7.2.20 Printing Error Report

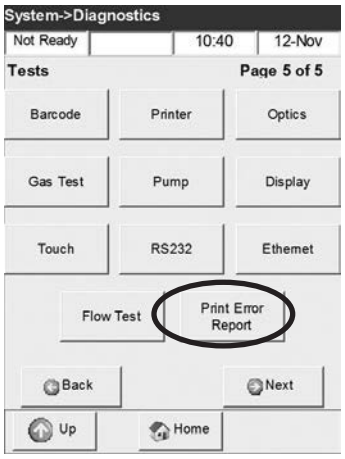


Fig. 7-37 Print Error Report

This menu gives you the option to print out the last 100 error occurrences.

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

In the **<Diagnostics - Sensors>** screen, press Next repeatedly to access the **<Tests>** screen (Page 5 of 5).

- Press **<Print Error Report>** (Fig. 7-37) to print out the error report.

7.2.21 Diagnostic Reports

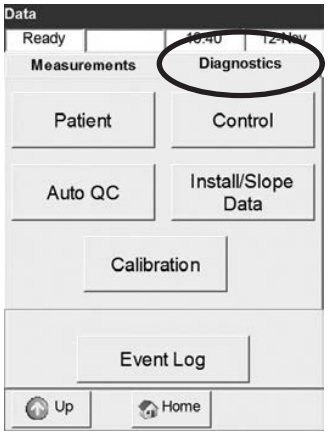


Fig. 7-38 Data Manager

This option allows you to print diagnostic reports.

From the **<Ready>** display, press **<Data Manager>** to access the **<Data>** screen (Fig. 7-38).

The **<Diagnostics>** tab contains the following reports:

<Patient>, **<Control>**, **<Auto QC>**, **<Install/ Slope Data>**, **<Calibration>** and **<Event Log>**.

7.2.21.1 Patient Diagnostic Report

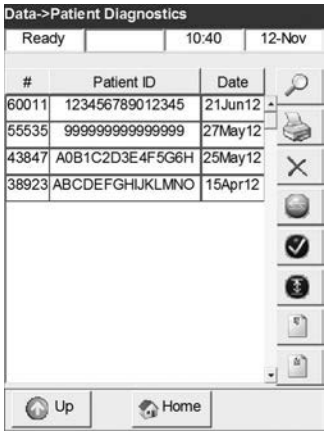


Fig. 7-39 Select Measurement

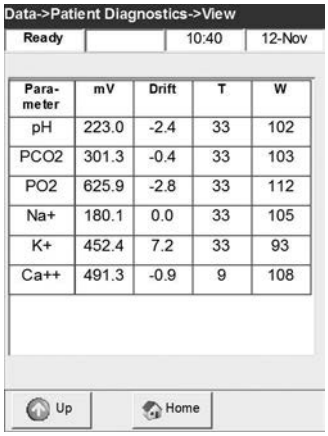


Fig. 7-40 Patient Diagnostics

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

- To print a patient diagnostics report, select **<Diagnostics -> Patient>** in the **<Data>** screen (Fig. 7-38).
- In the **<Data - Patient Diagnostics>** screen (Fig. 7-39), select the desired measurement and press the View button to display the results (Fig. 7-40). Use the Up and Down buttons to display the previous or next page of results.
- To print individual results, highlight the desired measurement (Fig. 4-39). 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.

7.2.21.2 Auto QC Diagnostic Report

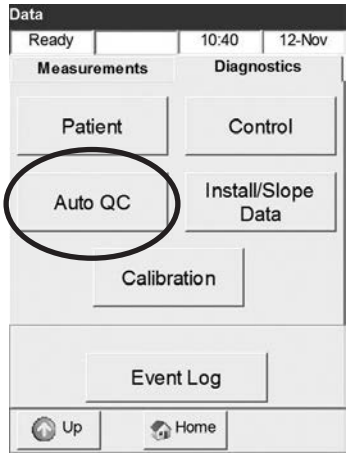


Fig. 7-41 Select Auto QC

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

- To print an Auto QC report, select **<Diagnostics -> Auto QC>** in the **<Data>** screen (Fig. 7-41).

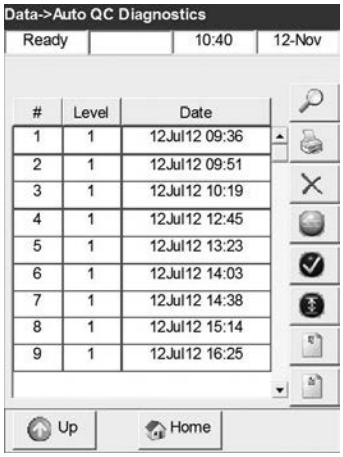


Fig. 7-42 Select Measurement

- In the **<Data - Auto QC Diagnostics>** screen (Fig. 7-42), select the desired measurement and press the View button to display the Auto QC results (Fig. 7-43). Use the Up and Down buttons to display the previous or next page of results.
- To print individual results, highlight the desired measurement (Fig. 7-42). 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.

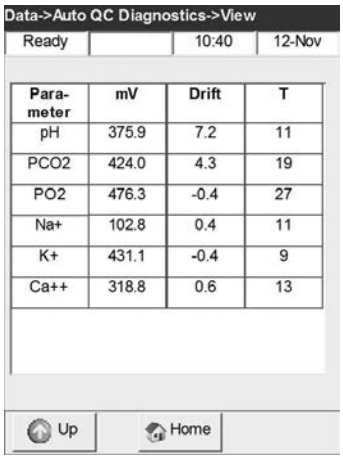


Fig. 7-43 Auto QC Diagnostics

- Press **<Install/Slope Data>** (Fig. 7-41) to view data from pack/installations and slope check.

7.2.21.3 Control Diagnostic Report

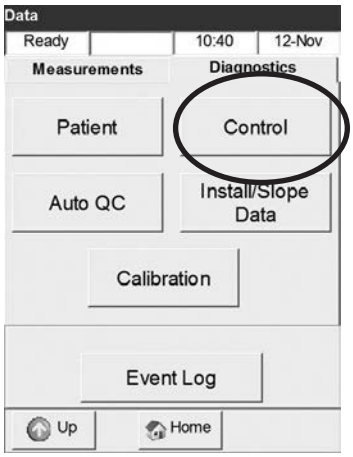


Fig. 7-44 Select Control

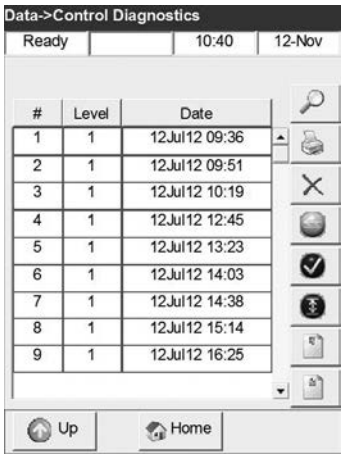


Fig. 7-45 Select Measurement

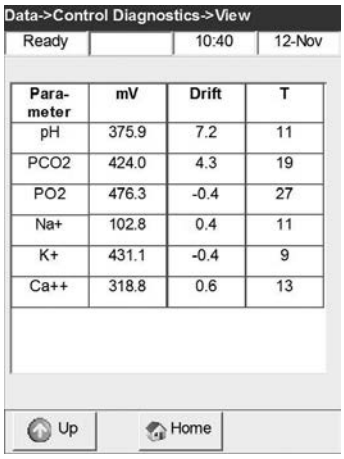


Fig. 7-46 Control Diagnostics

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

- To print a controls report, select **<Diagnostics ->Controls>** in the **<Data>** screen (Fig. 7-44).

- In the **<Data - Control Diagnostics>** screen (Fig. 7-45), select the desired measurement and press the View button to display the control results (Fig. 7-46). Use the Up and Down buttons to display the previous or next page of results.
- To print individual results, highlight the desired measurement (Fig. 7-45). 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.

7.2.21.4 Calibration Diagnostic Report

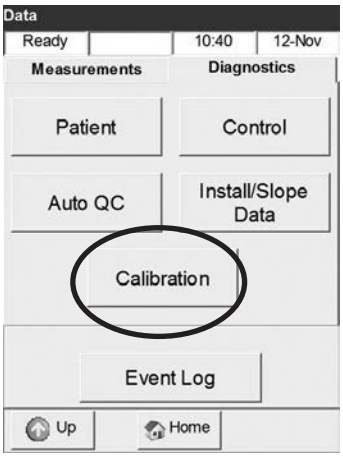


Fig. 7-47 Select Calibration

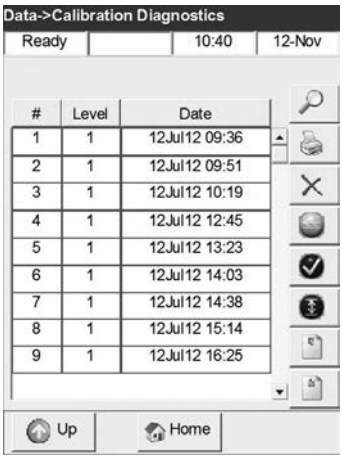


Fig. 7-48 Select Calibration

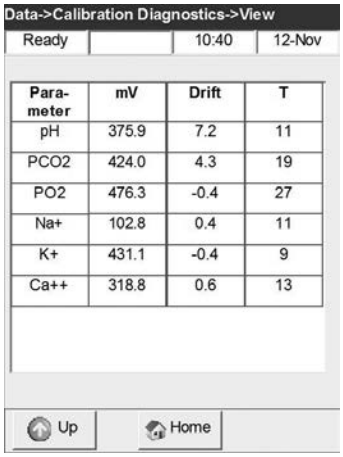


Fig. 7-49 Calibration Diagnostics

The **<Calibration Diagnostic Report>** is available with the results after each measurement detailing the measured signal in millivolts and drifts.

- To print a calibration diagnostics report, select **<Diagnostics -> Calibration>** in the **<Data>** screen (Fig. 7-47).

- In the **<Data - Calibration Diagnostics>** screen (Fig. 7-48), select the desired calibration and press the View button to display the results (Fig. 7-49). Use the Up and Down buttons to display the previous or next page of results.
- To print individual results, highlight the desired measurement (Fig. 7-48). 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.

7.2.21.5 Event Log

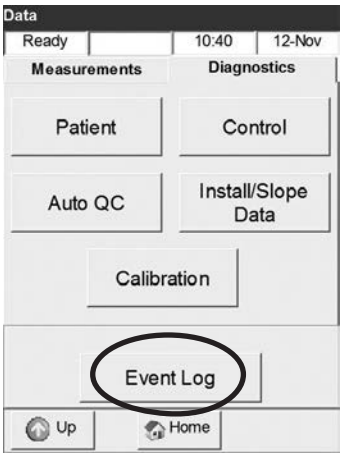


Fig. 7-50 Select Event Log

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

- To print an event log, select **<Diagnostics -> Event Log>** in the **<Data>** screen (Fig. 7-50).

Fig. 7-51 Print or Delete Event Log

- Press Print to print the event log (Fig. 7-51).
- Press Delete to delete the event log. Confirm your choice by pressing Yes in the **<Delete the Event Log?>** screen (Fig. 7-52).
- Press Up to return to the **<Data>** screen.

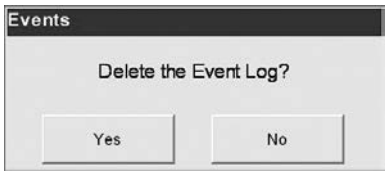


Fig. 7-52 Delete Confirmation

7.2.21.6 Configuration Report

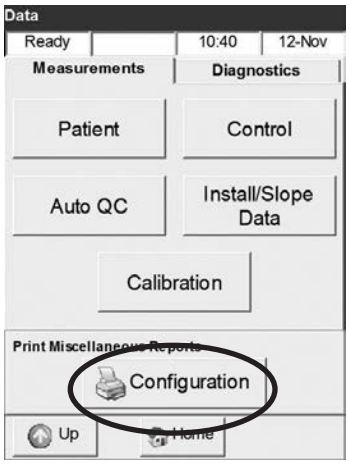


Fig. 7-53 Configuration Report

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. 7-53).
- Press Up 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.

7.3 Troubleshooting

7.3.1 Fluidics Troubleshooting

This section describes a complete check of the OPTI R fluidics system. It identifies leaks and/or blockages.

WARNING: During step 1 through 14 always aspirate the solutions, never inject, as this could lead to permanent damage to the analyzer and/or fluid pack.

1. Install a new pack fluid pack, open the SMC and remove the cassette.
2. Go to **<Diagnostics – Control>** and open valve 0.
3. Attach service syringe to the rear SMC port and gently pull (Fig. 7-54). Clear buffer should be aspirated, with little or no bubbles. If the line is blocked, follow the blockage removal procedure (7.3.2).

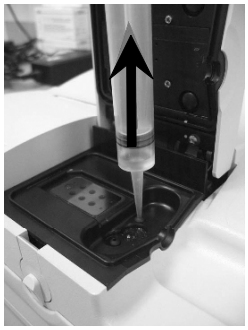


Fig. 7-54 Aspirate from rear SMC Port

4. Close valve 0 and open valve 2.
5. Attach service syringe to the rear SMC port and gently pull. Cloudy buffer should be aspirated, with little or no bubbles. If the line is blocked, follow the blockage removal procedure (7.3.2).
6. Close valve 2 and open valve 3.
7. Attach service syringe to the rear SMC port and gently pull. Clear buffer should be aspirated, with little or no bubbles. If the line is blocked, follow the blockage removal procedure (7.3.2).
8. Close valve 3 and open valve 4.
9. Attach service syringe to the rear SMC port and gently pull. White colored buffer should be aspirated, with little or no bubbles. If the line is blocked, follow the blockage removal procedure (7.3.2).

10. Close valve 4 and open valve 5.
11. Attach service syringe to the rear SMC port and gently pull. After some buffer residue, air should be aspirated from the vent port.
12. With gas bottle in place, leave valve 5 open then cycle valve 1 open then closed.
13. Gas should come out the rear SMC port.
14. Close valve 5.

WARNING: The following steps are to be performed using biohazard protection.

15. Connect the syringe to the front SMC port and apply light pressure. The port should be blocked.

Fig. 7-55 Apply Pressure to Front SMC Port

16. Remove the pump cartridge, place a paper towel over the front pump receptacle and repeat above step – the fluid path should be open to the front pump receptacle (Fig. 7-55).
17. Remove the fluid pack and connect the syringe to the rear pump receptacle. While holding a paper towel over the fluid pack receptacle, slowly depress the syringe. The fluid path should be open to the fluid pack receptacle.

18. Remove the paper towel and block the top port of the fluid pack receptacle with the gloved finger. Slightly pressurize the syringe and check for the tube to be blocked (Fig. 7-56).

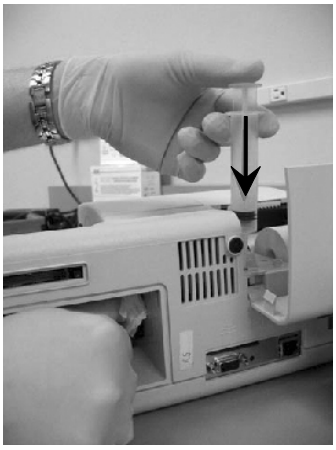


Fig. 7-56 Apply pressure to rear pump port.

7.3.2 Clog Removal

In case the above checks yielded a blocked fluid line, proceed as follows:

1. Remove the fluid pack and the valve cartridge.
2. Once the valve cartridge is removed, the 4 fluid ports indicated need to be checked/cleared with the stylette (Fig. 7-57).
3. Gently insert the stylette into each of the ports.

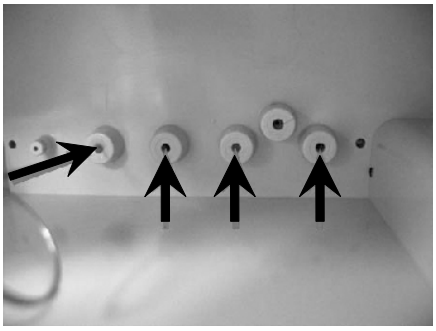


Fig. 7-57 Insert stylette into the valve cartridge ports.

4. Remove the fluid pack receptacle. Insert the stylette into the bottom four ports (Fig. 7-58).

Caution: Do not insert stylette into the top port, since this may cause a puncture of the internal waste line.

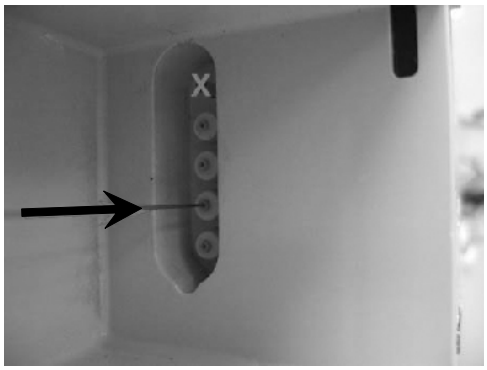


Fig. 7-58 Insert stylette into the fluid pack ports.

5. Attach the service syringe to the four fluid ports referenced in step 2. Check for the lines to be clear, otherwise repate step 3 and 4.

7.3.3 Repair Verification

After blockage removal, repeat the respective troubleshooting section to make sure the blockage has been cleared. For example, if QC level 2 solution (valve #3) could not be aspirated, clear the line with the stylette, then repeat step 6 and 7 of the troubleshooting procedure. If the blockage removal was successful, but QC solutions cannot be aspirated, replace the valve cartridge.

7.3.4 Troubleshooting Procedure for tHb/SO_2

If your OPTI fails an Hb calibration or QC measurement for tHb or SO_2, OPTI Medical recommends that you clean the SMC cover of your analyzer and then repeat the measurement. The two small optical channels pictured below are responsible for the tHb and SO_2 measurements. These channels may get clogged or dirty, causing the tHb and SO_2 to fail calibration or OPTI Check controls. The simple cleaning procedure below can be used for OPTI CCA, OPTI CCA-TS, or OPTI R analyzers and may correct tHb and SO_2 failures.

1. Open the SMC cover and locate the two small optical channels pictured below (Fig. 7-59).

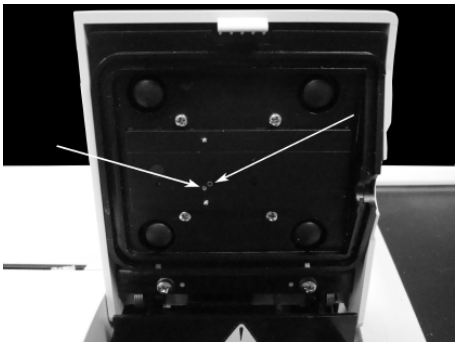
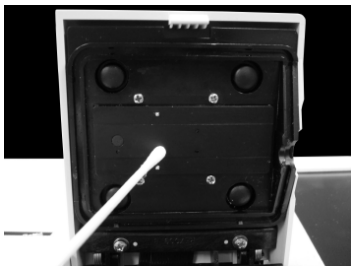


Fig. 7-59 Locate Optical Channels

2. Clean the optical channels using a cotton swab or lint-free cloth dipped in alcohol or ammonia-based cleaner (Fig. 7-60).



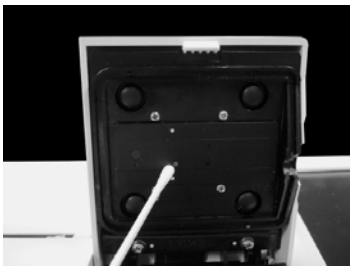


Fig. 7-60 Clean Optical Channels

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.

8 OPERATING PRINCIPLES

8.1 Intended Use

The OPTI™ R 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^{++}), total hemoglobin concentration (tHb) and hemoglobin oxygen saturation (SO_2) in samples of whole blood, and pH, sodium, potassium, and ionized calcium 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 **opt**ical electr**odes**) measure the intensity of light emitted from fluorescent dyes exposed to a specific analyte. The emitted light is distinguished from excitation light by means of optical filters. Because the excitation light energy is kept constant, the small amount of light that results is changed only by the concentration of the analyte. The concentration of the analyte is determined by the calculation of the difference in fluorescence measured at a known calibration point and that measured with the unknown concentration of analyte. For a description of the measurement principles of the individual analytes, please refer to the analyte section of the OPTI R Operator's Manual.

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

8.3 Operation

The OPTI R is a microprocessor-based instrument measuring optical fluorescence.

A cassette contains the sensors, storage buffer and a valve to control fluid flow. After reading 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 channel is calibrated with the wash buffer contained in the fluid pack which is tonometered with the gas from the gas bottle.
The electrolyte channels are calibrated using the wash buffer solution contained in the Fluid Pack.
The tHb and SO_2 channels are factory-calibrated. When calibration is verified, the analyzer is ready for sampling. Up to 50 blood samples can be analyzed on one cassette. At the start of an analysis, 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 completion of the measurement, the analyzer will wash the cassette and perform a gas calibration. The Fluid Pack contains the wash solution and a waste pouch.

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) or electrolyte concentration (Na^+, K^+, Ca^{++}) 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 *c*tHb 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 NCCLS 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 µL. The OPTI Medical capillary tubes (MC0024) are ideally suited with a minimum volume, filled, of 200 µL. The capillary tubes for pH, blood gas, and electrolyte analysis should not be used for samples taken for the analysis of lithium.

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.

8.4.6 OPTI Medical ComfortSamplers™

Blood may be collected for analysis on the OPTI R 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.

8.4.7 Handling and Storage of Samples

Please refer to NCCLS 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 *c*tHb in any analyzer. To prevent such errors, 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 R.

The OPTI R 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.

8.5 Procedure

8.5.1 Materials Needed

Description	Part Number
Sensor Cassette, Type “E-Ca-50”	BP7601
Syringe Adapters (250 per box)	BP7600
OPTI R Fluid Pack	BP7092
Calibration Gas Bottle	BP7001
Printer Paper	HP0070
Calibration Cassette	BP7535

The OPTI R automatically processes the sample through the necessary steps, then displays and prints the results. For details of this operation, please refer to the remainder of the Operator’s Manual.

8.5.2 Test Conditions

Sample Size:	a minimum of 125 µL
Sample Type:	heparinized whole blood, serum and plasma
Sample Application:	syringe, capillary or ComfortSampler
Ambient Temperature:	10 - 30 ºC (50 – 86 ºF)
Relative Humidity:	5% to 95% (non-condensing)
Type of Measurement:	optical fluorescence (pH, PO_2, PCO_2, Na^+, K^+, Ca^{++}) 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 58 to 111	37.0	0.1 0.1	°C °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 = Left Radial RR = Right Radial LB = Left Brachial RB = Right Brachial LF = Left Femoral RF = Right Femoral Cord = Cord Scalp = Scalp	LR		
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 0.6 to 16.1	15.0	0.1 1 0.1	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
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 R 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 the first 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, the buffer contained in the Fluid Pack 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, 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, dirty optics, or worn pump conditions. Once the cassette is calibrated, it is ready for use.

8.5.6 Quality Control

The OPTI R utilizes three independent solutions contained in the fluid pack for performing automatic quality control. These solutions are completely independent from calibrating solutions and provide three unique levels of analyte concentration. The Auto QC function can be programmed to run up to five times per day and perform as many as three levels per run. Details on programming Auto QC can be found in Chapter 3, Customization, of this manual.

On initial use of a new cassette, validation is performed by analysis of each of the three Auto QC solutions. It is recommended to run one level of control every shift or at a minimum two levels every 24 hours.

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

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. For agencies requiring a liquid QC material, OPTI CHECK is available.

OPTI CHECK is a specially formulated aqueous liquid control material that contains all analytes measurable by the OPTI R. It contains a stable suspension of polystyrene micro beads which reflect and partially absorb red and infrared light similarly to erythrocytes, allowing true measurement of tHb and SO_2. The three control levels contain three different concentrations of micro beads to simulate low, medium, and high hemoglobin blood samples. OPTI CHECK provides a method of performing daily QC checks for laboratories selecting to measure liquid QC material.

8.5.7 Reference Intervals[2]

Reference intervals are useful in describing typical results found in a defined population of apparently healthy people. Reference intervals should not, however, be used as absolute indicators of health and disease due to variability among methods, laboratories, locations and other considerations. Individual laboratories should generate their own set of reference intervals. Guidelines for defining and determining reference intervals are published in the 2000 NCCLS C28-A2 guideline: “How to Define and Determine Reference Intervals in the Clinical Laboratory; Approved Guideline – Second Edition”.

The analyzer is preset to adult reference intervals derived from “Tietz, Burtis C, et al (Eds.), Textbook of Clinical Chemistry and Molecular Diagnostics, 4th Ed., (Elsevier Saunders, 2006) pps. 2252-2302”. The preset intervals and procedures for adjusting the intervals to those derived for the individual laboratory are described in section 3.3.2.1 of this manual.

8.5.8 Specific Performance Characteristics

All performance data in this section was generated on OPTI R systems with OPTI CHECK Controls run daily to check QC.

[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 thermostatting 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 R 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 R system is designed to measure whole blood, serum, or plasma, to be controlled with aqueous solutions. Aqueous controls are portable and quite convenient to use with the OPTI R 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 R 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 R's tHb measurement is sensitive to pathologically rapid sedimentation rates of the erythrocytes, often induced by excessive rate and amounts of rouleaux formation[4]. 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 R breaks up most of the rouleaux and other aggregates by rapidly aspirating the whole blood sample with high shear rate, however in rare pathologic cases the rouleaux aggregates persist or reform during the aspiration and cause a positive tHb offset of up to 3 g/dL, typically within the range 7-12 g/dL.

Any measurement outside the Measurement Range will be indicated on the display as ' LOW ' for values lower than the range and ' HIGH ' for values above the range. However, the printed report will show out-of-range values with reference to the end value of the measurement range; for example, the printed report will show a PCO_2 value of 220 mmHg as:

$PCO_2 > 200$ mmHg (Meas.Lim)

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

[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-A2[5]. These substances were selected on the basis of their optical absorbance or fluorescence properties likely to affect the optical signal measured by the OPTI R, or the optical properties of the sensor measured by the analyzer. To cause interference to the optical sensors, the substances must be highly mobile (low molecular weight) and highly colored, in order to penetrate the optode membrane barriers quickly (within the 90 sec. measurement interval), and then strongly absorb light or emit light of the proper color. To cause interference to the tHb and SO_2 reflectance measurements, the substances must strongly absorb or scatter red or infrared light, relative to normal whole blood.

The following substances were tested in whole blood at the CLSI-recommended test level or higher, and showed no interference to any measured analyte, including blood gas, electrolytes, and tHb/SO_2:

Bile Acids (30 µmol/dL)

Bilirubin (40 mg/dL)

Beta-Carotene (3.0 mg/dL)

Hemolysis (10%) During hemolysis K^+ is released from the blood cells thereby increasing the measured K^+. In the same manner, protein released from the cells binds ionized Ca^{++} and decreases the concentration. While an accurate value is reported, it will reflect the actual changes caused by hemolysis.

Lipemia (equivalent to 3000 mg/dL triglycerides)

Elevated white blood cell count (30,000 WBC/µL)

The following substances were tested in plasma at the CLSI-recommended test level or higher, and showed no interference to blood gas and electrolyte analytes:

Coumadin (Warfarin) (12 mg/dL)

Dicumarol (Dicoumarin) (11 mg/dL)

Procain (Novacaine) (13 mg/dL)

Acetaminophen (Paracetamol) (20 mg/dL)

The OPTI R 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 R Sensor Cassette, Type "E-Ca-50", BP7601

Use:	For measurement of pH, PCO_2, PO_2, Na^+, K^+, Ca^{++}, tHb, and SO_2 with the OPTI R Analyzer. Each reusable cassette is good for 50 patient samples or 7 days of in-use operation.
Contents:	Each assembly contains 4 individually packaged cassettes. Each 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.

Syringe Adapter, Box (250 pcs.), BP7600

Use:	For use with the OPTI R cassettes when sampling from syringes.
Contents:	Each package contains 250 syringe adapters and a package insert.
Composition:	Not Applicable
Storage:	Not Applicable
Stability:	Not Applicable

Calibrator Cassette, BP7535

Use:	For quarterly calibration of the OPTI R Analyzer.
Contents:	Each package contains one reusable calibrator cassette.
Composition:	Stabilized optode sensors
Storage:	Refer to package labeling.
Stability:	Expiration date and lot number are printed on each package label and encoded on the attached bar code label.

Calibration Gas, BP7001

Use:	For calibration of pH, PCO_2 and PO_2 in the OPTI R 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.	

OPTI R Fluid Pack, BP7092

Use:	For automatic Quality Control, cassette calibration/wash and waste containment for the OPTI R.
Contents:	Buffered solutions
Composition:	Aqueous HEPES-bicarbonate buffer solution with biocides
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 and fluid pack hold 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

9 LINEARITY AND CORRELATIONS

9.1 Instrument Setup and Preparation

1. Verify that the **<Time and Date>** settings under the OPTI R analyzer **<Setup>** options match those of the facility's reference instrument. (Section 2-1 of Operator's Manual)
2. Open the printer cover and load the thermal paper into the analyzer by pressing the red paper advance button. Then run the calibrator cassette as shown in Section 6-3 of the Operator's Manual.
3. If no OPTI R Fluid Pack has been previously loaded into the analyzer, the message on the display screen will be **<Not Ready: No Fluid Pack>** (Fig. 2-10 of Operator's Manual). Follow the step by step instructions in the operator's manual for correct installation of fluid pack and gas canister. If a new sensor cassette has not yet been installed into the OPTI R analyzer, please follow the instructions with the guidance of your representative.
4. The OPTI R Analyzer will now begin calibration of the sensor cassette and will display **<Ready>** when this activity has been completed (approximately 20 minutes).
5. The **<Ready>** display will then inform you that installation was successful and 2 levels of OPTI Check must be run. Press **<Continue>** and follow the instructions that appear on your display as described in the Operator's Manual.

NOTE: The OPTI Check controls must be set up prior to using this feature or running controls. Refer to Chapter 4 of the Operator's Manual for further instructions.

6. Run Quality Control Testing in accordance with the reference manufacturer's recommendations. Verify that all QC testing results are well within the recommended limit level ranges.
7. Customize all OPTI R patient and sample information entries to match those of your reference instrument, as required by your testing facility (Chapter 3 of the OPTI R Operator's Manual).

9.2 Aqueous Quality Control Testing

Chapter 4 of the OPTI R Operator's Manual explains the process of setting up and running Auto QC as well as external controls if deemed necessary by your facility. Please refer closely to this section in order to set up automatic testing according to your facility's preferences.

9.3 Performing a Patient Analysis

1. From the **<Ready>** display, press **<Run Sample>**.

NOTE: Prior to analysis, the sample must be mixed thoroughly to achieve a uniform distribution of red blood cells and plasma. Improperly mixed blood may produce variable results for all analytes. The specimen should be gently rotated for a minimum of one minute prior to analysis and then introduced into the analyzer immediately. Any delay in the introduction of the sample into the predicate device and the OPTI R analyzer could cause extreme differences in the measurement results. Please follow the CLSI correlation and precision guidelines.

2. Using the sample collected in the heparinized syringe, run the patient sample on the reference device. Remove air from the syringe, place a red syringe adapter onto the end of the syringe, attach the patient sample (with syringe adapter) to the cassette fillport, and press **<OK>**. The OPTI R will then display **<Sample Aspiration In Progress - Please Wait>**. Once the sample has been completely aspirated from the syringe, remove the syringe from the analyzer when prompted and press **<OK>**.
3. Press **<Patient Info>** to edit/enter patient and sample information during the OPTI R Analyzer measurement cycle. See Chapter 5 of the Operator's Manual for more detailed information.
4. Upon completion of both analyses, record the results displayed on the reference analyzer and the OPTI R Analyzer. Run the number of predetermined patient sample comparisons in accordance with your evaluation protocol.

9.4 Recording and Evaluating the Data

1. Please use the enclosed data sheets for all records.
2. Results should be reviewed and approved (by signature) by the Laboratory Director or Medical Director overseeing laboratory testing in your facility.

Helpful Hints

Verify that the OPTI R Analyzer wash/calibration process is completed and that the OPTI R **<Ready>** screen is displayed. This ensures that the time between analysis of the sample performed by the reference device and the OPTI R Analyzer is minimal.

Patient Sample Data Sheet

Hospital/Facility:	Date:
Ref. Instrument (x) and S/N:	OPTI (y) S/N:
Evaluator:	

Predicate Device

Date	pH (x)	pCO_2 (x)	pO_2 (x)	tHb meas. (x)	SO2 meas. (x)	Na^+ (x)	K^+ (x)	iCa (x)	Cl^- (x)	Glu (x)	BUN (x)	Lac (x)

OPTI-TS or OPTI R ANALYZER (circle)

Date	pH (y)	pCO_2 (y)	pO_2 (y)	tHb meas. (y)	SO2 meas. (y)	Na^+ (y)	K^+ (y)	iCa (y)	Cl^- (y)	Glu (y)	BUN (y)	Lac (y)

Data Reviewed By: Title/Department:	Date:

10 SUPPLIES

Each OPTI™ R is shipped with maintenance supplies and other accessories. Below is a listing of all necessary supplies and accessories. To order replacement supplies and accessories, contact your local authorized OPTI Medical Distributor or, in the U.S., call the OPTI Medical Order Entry Department at 1-800-490-6784 (OPTI) Monday through Friday, 8 AM to 5 PM eastern time. Our Order Entry representatives will gladly provide any assistance you may require.

Description	Part Number
10.1 Analyzer	
OPTI R Analyzer with Accessory Kit	GD7031
10.2 Cassettes	
OPTI R Cassette 'E-Ca 50' (4 pcs)	BP7601
10.3 Controls/Calibrators	
OPTI CHECK, Trilevel	HC7008
Calibrator Cassette	BP7535

Description	Part Number
10.4 Consumable Items	
Printer Paper (1 roll)	HP0070
Calibration Gas Bottle (1 pc)	BP7001
Fluid Pack (1 pc)	BP7092
Capillary Tubes (250 pcs)	MC0024
Syringe Adapters (250 pcs/box)	BP7600
ComfortSampler with Accessories	BP0600
ComfortSampler Basic Kit	BP0610
ComfortSampler Bulk, w/Needle	BP0620
ComfortSampler Bulk, w/o Needle	BP0630
ComfortSampler Bulk, Needle w/Protector	BP0640
10.5 Accessories	
CF Export Kit	BP7140
10.6 Manuals	
Operator's Manual	PD7032
Service Manual	PD7039

Description	Part Number
10.7 Spare Parts	
Peripump Cartridge Kit	BP7118
Power Supply	EI7007
Power Cord	EX0197
Power Cord, Schuko	EX0173
Printer Assembly	BP7090
Cassette - Shutdown	BP7111
Pack - Shutdown	BP7110
Bottle - Shutdown	MK0056

10.8 Technical Assistance

Most often, problems with your OPTI R can be resolved over the telephone, getting the analyzer back in service within minutes. Our technicians have the training and experience necessary to provide dependable technical assistance.

The OPTI Medical Service Hotline (U.S. market only) is staffed to provide prompt troubleshooting assistance seven (7) days per week, twenty-four (24) hours per day. Should you need troubleshooting assistance or application information regarding your OPTI Medical analyzer just contact the OPTI Medical Service Hotline for assistance.

In the U.S., call **1-800-490-6784 (OPTI)** to request technical assistance from OPTI Medical Systems, Inc.

Should you require additional service support, our OPTI Medical Service Hotline can provide complete details on all available service options and ensure that any instrument downtime is minimized.

10.9 Warranty Registration (U.S. Market Only)

After successful completion of the installation of your new OPTI R, 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 R are on the bottom panel of the unit.

Please read the Instrument Warranty Terms and Conditions and become familiar with this agreement.

Each new analyzer purchased has a one year warranty from the date the analyzer is placed into service.

Contact the OPTI Medical Service Hotline for any assistance regarding warranty or support.

ANALYTES

pH

Clinical Significance[1]

The pH value of the blood, serum or plasma may be the single most valuable factor in the evaluation of the acid-base status of a patient. The pH value is an indicator of the balance between the buffer (blood), renal (kidney) and respiratory (lung) systems, and one of the most tightly controlled parameters in the body. The causes of abnormal blood pH values are generally classified as:

a) primary bicarbonate deficit - metabolic acidosis

b) primary bicarbonate excess - metabolic alkalosis

c) primary hypoventilation - respiratory acidosis

d) primary hyperventilation - respiratory alkalosis

An increase in blood, serum or plasma pH (alkalemia) may be due to increased plasma bicarbonate, or a feature of respiratory alkalosis due to an increased elimination of CO_2, due to hyperventilation.

A decreased pH value (acidemia) in blood, serum or plasma may occur due to an increased formation of organic acids, an increased excretion of H^+ ions in certain renal disorders, an increased acid intake such as in salicylate poisoning or loss of alkaline body fluids. Respiratory acidosis is the result of a decreased alveolar ventilation and may be acute; as the result of pulmonary edema, airway obstruction or medication, or may be chronic; as the result of obstructive or restrictive respiratory diseases.

Measurement Principle

The pH optode measurement principle is based upon pH-dependent changes of the luminescence of a dye molecule immobilized in the optode. Such pH indicator dyes have been used by chemists for many years to perform acid-base titration in turbid media.

The relationship of luminescence to pH is quantified by a variant of the Mass-Action Law of chemistry,

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

which describes how the fluorescence emission intensity increases as the blood pH is increased above the dye's characteristic pKa[2]. pH optodes do not need a reference electrode to measure pH, however, they exhibit a small sensitivity to the ionic strength of the sample being measured[3].

Measurement Range

Range	Resolution (Low/High)	Units
6.6 to 7.8	0.01/0.001	pH units

Reference Intervals[4]

Each laboratory should establish its own reference interval for pH as performed on the OPTI R as factors such as altitude can affect such measurements.

Sample type	Range
Whole blood, arterial	
Premature newborn, 48 hr	7.35-7.50
Full term, birth	7.11-7.36
Full term, 1 day	7.29-7.45
Children, adults	7.35-7.45

Interferences

Optode pH measurements have a known sensitivity to the blood ionic strength[5], which is determined primarily by variation in serum levels of sodium. The OPTI R utilizes an internal Na^+ sensor to actively compensate and correct for this sensitivity. That is, the OPTI R's reported pH has no measurable interference from hyponatremic or hypernatremic samples, nor for ionic strength variations within the physiologic limits of 100 to 190 mmol/L.

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

The following exogenous interferents were quantified in tonometered plasma, showing interferences to dyes which typically have short half-lives within the body before being metabolized by the liver.

Substance	amount	pH change
Sodium fluorescein	25 mg/dL	unstable
Cardio (indocyanine) green	0.5 mg/dL	0.02
Methylene blue	25 mg/dL	unstable

Only clear, uncolored quality control materials, such as OPTI CHECK brand aqueous controls should be used with the OPTI R 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 R instruments. pH is expressed in pH units.

Material	**mean**	**S_{wr} (CV%)**	**S_{dd} (CV%)**	**S_T (CV%)**
OPTI CHECK (aqueous control solution)				
Level 1	7.188	0.002 (—)	0.005 (—)	0.006 (—)
Level 2	7.414	0.003 (—)	0.009 (—)	0.010 (—)
Level 3	7.579	0.010 (—)	0.014 (—)	0.018 (—)
Serum	7.227	0.008 (—)	0.010 (—)	0.013 (—)
Reduced Bovine Hemoglobin Solution	7.428	0.008 (—)	0.008 (—)	0.011 (—)

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.

Linearity

Wherever possible, linearity for the OPTI R 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 CO_2 values, and measured on an AVL 995 pH/Blood Gas Analyzer standardized to N.I.S.T. traceable pH buffers, and on three OPTI R systems.

Slope[6]	Intercept	Correlation Coefficient	Sy*x	Range	n
0.9724	0.219	0.99714	0.013	7.17 – 7.55	29

Correlation to Other Methods

OPTI R 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 R 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
Chiron (whole blood)	0.9806	0.139	0.9723	0.016	7.13 – 7.59	95
Roche OMNI (whole blood)	1.0416	-0.304	0.9961	0.011	6.8 – 7.53	314

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. Tietz; Burtis C, et al (Eds.), Textbook of Clinical Chemistry and Molecular Diagnostics, 4th Ed., (Elsevier Saunders, 2006) pps. 2252-2302.
5. Wolfbeis OS, Offenbacher H, Fluorescence Sensor for Monitoring Ionic Strength and Physiological pH Values, Sensors and Actuators 9, p.85, 1986
6. Model equation for regression statistics is: [results of OPTI Analyzer] = slope(m) [comparative method results] + intercept(b).

PCO_2

Clinical Significance[1]

The PCO_2 value of arterial blood is used to assess how well the body eliminates carbon dioxide, a by-product of metabolism. A PCO_2 value below the normal range is termed respiratory alkalosis and indicates *hypocapnia*, a condition caused by increased alveolar ventilation such as hyperventilation.
An arterial PCO_2 above the normal range is termed respiratory acidosis and indicates *hypercapnia*, a sign of ventilatory hypoventilation and failure, resulting from cardiac arrest, chronic obstructive lung disease, drug overdose, or chronic metabolic acid-base disturbances.

Measurement Principle

The PCO_2 optode measurement principle is based upon placing a pH optode behind an ion-impermeable membrane[2], just as conventional PCO_2 blood gas electrodes employ the Severinghaus CO_2 electrode construction. As such, PCO_2 optodes may suffer interference from volatile acids and bases in blood, just as conventional PCO_2 electrodes.

Measurement Range

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

Reference Intervals[3]

Each laboratory should establish its own reference interval for PCO_2 as performed on the OPTI R as factors such as altitude can affect such measurements.

Sample type	Range, mmHg
Whole blood, arterial	
Newborn	27-40
Infant	27-41
Adult male	35-48
Adult female	32-45

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 R instruments. PCO_2 is expressed in mmHg.

Material	mean	S_{wr} (CV%)	S_{dd} (CV%)	S_T (CV%)
OPTI CHECK (aqueous control solution)				
Level 1	69.4	1.17 (1.7)	0.39 (0.6)	1.69 (2.4)
Level 2	43.2	0.91 (1.2)	0.48 (1.1)	1.51 (3.5)
Level 3	23.5	0.50 (2.1)	0.94 (4.0)	1.45 (6.2)
Serum	40.4	0.93 (2.3)	0.22 (0.5)	1.15 (2.8)
Reduced Bovine Hemoglobin Sol.	43.7	0.88 (2.0)	0.71 (1.6)	0.87 (2.0)

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 CO_2 concentrations certified to 0.03% absolute by the manufacturer. For each tonometered level, 2 replicates were run on each of three OPTI R systems. All values are in mmHg.

Expected	n	Observed	Swr	bias	%Recovery
17.1	6	18.8	1.47	1.7	110 %
27.4	6	27.2	0.60	-0.2	99 %
40.7	6	42.8	1.40	2.1	105 %
74.5	6	74.5	2.86	-0.1	100 %
82.1	4	80.5	1.10	-1.6	96 %

Linearity

Wherever possible, linearity for the OPTI R measurement has been established against reference materials or methods. PCO_2 linearity is established against values determined on whole blood tonometered to gravimetrically prepared gases with CO_2 concentrations certified to 0.03% absolute by the manufacturer, and measured on three OPTI R systems.

Slope[4]	Intercept	Correlation Coefficient	Sy*x	Range	n
0.9636	2.143	0.99860	1.47	17 - 82	27

Correlation to Other Methods

OPTI R 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 R 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
Chiron (whole blood)	0.9510	-0.828	0.9684	1.80	11 – 65	94
Roche OMNI (whole blood)	1.0615	-3.44	0.9923	2.22	19 – 140	314

References

1. Tietz, Norbert W., Ed., Clinical Guide to Laboratory Tests, 2nd Ed., (Philadelphia: W.B.Saunders, Co., 1990) p. 436.
2. Vurek GG, Feustel PJ, Severinghaus JW, A Fiber Optic PCO_2 Sensor, Ann.Biomed.Eng. 11, p.499, 1983.
3. Tietz; Burtis C, et al (Eds.), Textbook of Clinical Chemistry and Molecular Diagnostics, 4th Ed., (Elsevier Saunders, 2006) pps. 2252-2302.
4. Model equation for regression statistics is: [results of OPTI Analyzer] = slope(m) [comparative method results] + intercept(b).

PO_2

Clinical Significance[1]

The PO_2 value of arterial blood is used to assess how well the body is able to absorb oxygen in the lungs. Values below the normal arterial PO_2 (*arterial hypoxemia*) are usually caused by pulmonary, circulatory, or respiratory abnormalities (e.g. bronchial obstruction, vascular problems, decrease in cardiac output, increased oxygen demand, anatomical heart defect, low inspired O_2 content). Generally, O_2 levels above 100 mmHg do not contribute significantly to the oxygen content since, with normal hemoglobin concentrations, 80 - 100 mmHg, PO_2 provides a 97% saturation level, and a level greater than 100% cannot be achieved.

Measurement Principle

The PO_2 optode measurement principle is based upon luminescence quenching, first documented in the 1930's[2], and commercially utilized to measure blood PO_2 in 1983[3]. The relationship of luminescence to PO_2 is quantified by the Stern-Volmer equation,

$$I_0 / I = 1 + kP$$

which describes how the fluorescence emission intensity "I" is reduced as the PO_2 "P", is increased. Unlike conventional electrochemical "Clark" PO_2 electrodes, the oxygen optode does not consume oxygen molecules during the measurement.

Measurement Range

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

Reference Intervals[4]

Arterial oxygen tension, PO_2 is dependent upon the inspired oxygen tension, as well as various physiologic variables, and the administration of oxygen is common in the treatment of patients in need of blood gas analysis. Hypoxemia is defined as an arterial PO_2 below an acceptable range while breathing room air, with about 21% oxygen, at sea level. Increasing altitudes above sea level will produce lower inspired oxygen tensions and therefore, lower arterial PO_2 values.
Below are listed acceptable arterial oxygen tensions at sea level, while breathing room air:

Sample type	Range, mmHg
Whole blood, arterial	
Birth	8-24
1 day	54-95
2 days - 60 yr	83-108
>60 yr	>80
>70 yr	>70
>80 yr	>60
>90 yr	>50

Each laboratory should establish its own reference interval for PO_2 as performed on the OPTI R as factors such as altitude can affect such measurements.

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 R instruments. PO_2 is expressed in mmHg.

Material	mean	S_{wr} (CV%)	S_{dd} (CV%)	S_T (CV%)
OPTI CHECK (aqueous control solution)				
Level 1	71.4	4.84 (6.8)	1.07 (1.5)	2.27 (3.2)
Level 2	99.3	2.27 (2.3)	1.44 (1.5)	3.42 (3.4)
Level 3	139.3	2.88 (2.1)	1.53 (1.1)	5.46 (3.9)
Serum	100.9	2.00 (2.0)	1.05 (1.0)	2.99 (3.0)
Reduced Bovine Hemoglobin Solution	95.6	2.16 (2.2)	0.95 (1.0)	2.24 (2.3)

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 O_2 concentrations certified to 0.03% absolute by the manufacturer. For each tonometered level, 2 replicates were run on each of three OPTI R systems. All values are in mmHg.

Expected	n	Observed	Swr	bias	%Recovery
34.2	5	35.6	0.32	1.4	104 %
47.9	6	48.2	0.99	0.4	101 %
81.4	6	83.5	2.47	2.1	103 %
142.9	6	139.4	1.83	-3.5	98 %
413.7	4	410.8	7.71	-2.9	99 %

Linearity

Wherever possible, linearity for the OPTI R measurement has been established against reference materials or methods. PO_2 linearity is established against values determined on whole blood tonometered to gravimetrically prepared gases with O_2 concentrations certified to 0.03% absolute by the manufacturer, and measured on three OPTI R systems.

Slope[5]	Intercept	Correlation Coefficient	Sy*x	Range	n
0.9914	0.928	0.99989	2.26	34 – 414	27

Correlation to Other Methods

OPTI R 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 R 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
Chiron (whole blood)	0.9362	10.32	0.9947	13.21	19 - 575	92
Roche OMNI (whole blood)	1.0640	-6.58	0.9910	5.48	21 - 279	314

References

1. Tietz, Norbert W., Ed., Clinical Guide to Laboratory Tests, 2nd Ed., (Philadelphia: W.B.Saunders, Co., 1990) p. 436.
2. Kautsky H, Quenching of Luminescence by Oxygen, Transactions Faraday Society 35, p.216, 1939
3. CDI, 3M Healthcare System 200 Extracorporeal Blood Gas Monitor. See, for example, Lubbers DW, Gehrich J, Opitz N, Fiber Optics Coupled Flourescence Sensors for Continuous Monitoring of Blood Gases in the Extracorporeal Circuit, Life Supports Systems 4, p.94, 1986.
4. Tietz; Burtis C, et al (Eds.), Textbook of Clinical Chemistry and Molecular Diagnostics, 4th Ed., (Elsevier Saunders, 2006) pps. 2252-2302.
5. Model equation for regression statistics is: [results of OPTI Analyzer] = slope(m) [comparative method results] + intercept(b).

Sodium (Na^+)

Clinical Significance[1]

Sodium is the major cation of extracellular fluid. Its primary functions in the body are to chemically maintain osmotic pressure and acid-base balance and to transmit nerve impulses. Sodium functions at the cell membrane level by creating an electrical potential between different cell membranes causing the transmission of nerve impulses and neuromuscular excitability to be maintained. Sodium is involved in some enzyme catalyzed reactions as a cofactor. The body has a strong tendency to maintain a total base content, and only slight changes are found even under pathologic conditions.

Low sodium values, *hyponatremia*, usually reflect a relative excess of body water rather than a low total body sodium. Reduced sodium levels may be associated with: low sodium intake; sodium losses due to vomiting or diarrhea with adequate water and inadequate salt replacement, diuretics abuse, or salt-losing nephropathy; osmotic diuresis, metabolic acidosis; adrenocortical insufficiency; congenital adrenal hyperplasia; dilution type due to edema, cardiac failure, hepatic failure; and hypothyroidism.

Elevated sodium values, *hypernatremia*, are associated with conditions with water loss in excess of salt loss through profuse sweating, prolonged hyperpnea, severe vomiting or diarrhea, diabetes insipidus or diabetic acidosis; increased renal sodium conservation in hyperaldosteronism, Cushing's syndrome; inadequate water intake because of coma or hypothalamic diseases; dehydration; or excessive saline therapy.

The sodium value obtained may be used in the diagnosis or monitoring of all disturbances of the water balance, infusion therapies, vomiting, diarrhea, burns, heart and kidney insufficiencies, central or renal diabetes insipidus, endocrine disturbances and primary or secondary cortex insufficiency of the adrenal gland or other diseases involving electrolyte imbalance.

Measurement Principle

The Na^+ ion optodes are closely related to the more familiar Ion Selective Electrodes (ISEs). The optodes use ion selective recognition elements (ionophores) similar to those used in ISEs, however the ionophores are linked to fluorescent dyes instead of electrodes. These types of dyes have been used since the 1970's to visualize and quantify cellular ion levels in fluorescence microscopy and cell counters[2]. As the ion concentration increases, these ionophores bind larger amounts of ions and cause the fluorescence intensity to increase or decrease, depending on the particular ion. Like the pH optode, the ion optodes do not need a reference electrode, however, several of them do exhibit a small pH sensitivity which is automatically compensated in the OPTI R using the measured pH.

Measurement Range

Range	Resolution (Low/High)	Units
100 to 180	1/0.1	mmol/L

Reference Intervals[3]

Sample type	Range, mmol/L
Whole blood, serum and plasma	
Premature, 48 hr	128-148
Newborn	133-146
Infant	139-146
Child	138-145
Adult	136-145
>90 yr	132-146

Interferences

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

The OPTI R 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 R 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	25 mg/dL	unstable
Cardio (indocyanine) green	0.5 mg/dL	-15
Methylene blue	25 mg/dL	unstable

Only clear, uncolored quality control materials, such as OPTI CHECK brand aqueous controls should be used with the OPTI R 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 R instruments. Sodium values are expressed in mmol/L.

Material	mean	S_{wr} (CV%)	S_{dd} (CV%)	S_T (CV%)
OPTI CHECK (aqueous control solution)				
Level 1	127.1	0.42 (0.3)	1.09 (0.9)	1.31 (1.0)
Level 2	146.3	0.46 (0.3)	1.31 (0.9)	1.44 (1.0)
Level 3	160.2	0.28 (0.2)	1.39 (0.9)	1.51 (0.9)
Serum	141.0	0.53 (0.4)	1.15 (0.8)	1.43 (1.0)
Reduced Bovine Hemoglobin Solution	141.7	0.51 (0.4)	1.78 (1.3)	2.16 (1.5)

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.

Linearity

Wherever possible, linearity for the OPTI R 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[4]	Intercept	Correlation Coefficient	Sy*x	Range	n
$Sodium_{ST}$	1.0554	-5.760	0.99979	0.75	93 – 179	30
$Sodium_{NIST}$	0.9898	2.611	0.99875	1.015	123 – 164	14

Correlation to Other Methods

OPTI R 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 R 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
Chiron (whole blood)	0.9121	13.16	0.8923	1.99	123 – 146	95
Roche OMNI (whole blood)	1.0087	-2.24	0.8996	2.30	126 – 158	314
AVL 9181 (whole blood)	0.8824	16.39	0.8966	2.34	123 – 158	314

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. Tietz; Burtis C, et al (Eds.), Textbook of Clinical Chemistry and Molecular Diagnostics, 4th Ed., (Elsevier Saunders, 2006) pps. 2252-2302.
4. Model equation for regression statistics is: [results of OPTI Analyzer] = slope(m) [comparative method results] + intercept(b).

Potassium (K^+)

Clinical Significance[1]

Potassium is the major cation in the intracellular fluid and functions as the primary buffer within the cell itself. Ninety percent of potassium is concentrated within the cell, and damaged cells release potassium into the blood. Potassium plays an important role in nerve conduction, muscle function, and helps maintain acid-base balance and osmotic pressure.

Elevated potassium levels, *hyperkalemia*, can be found in oligouria, anemia, urinary obstruction, renal failure due to nephritis or shock, metabolic or respiratory acidosis, renal tubular acidosis with the K^+/H^+ exchange and hemolysis of the blood. Low potassium levels, *hypokalemia*, can be found in excessive loss of potassium through diarrhea or vomiting, inadequate intake of potassium, malabsorption, severe burns and increased secretion of aldosterone. High or low potassium levels may cause changes in muscle irritability, respiration and myocardial function.

The potassium value obtained may be used to monitor electrolyte imbalance in the diagnosis and treatment of infusion therapies, shock, heart or circulatory insufficiency, acid-base imbalance, therapy with diuretics, all kinds of kidney problems, diarrhea, hyper- and hypo-function of adrenal cortex and other diseases involving electrolyte imbalance.

Measurement Principle

The K^+ ion optodes are closely related to the more familiar Ion Selective Electrodes (ISEs). The optodes use ion selective recognition elements (ionophores) similar to those used in ISEs, however the ionophores are linked to fluorescent dyes instead of electrodes. These types of dyes have been used since the 1970's to visualize and quantify cellular ion levels in fluorescence microscopy and cell counters[2]. As the ion concentration increases, these ionophores bind larger amounts of ions and cause the fluorescence intensity to increase or decrease, depending on the particular ion. Like the pH optode, the ion optodes do not need a reference electrode, however, several of them do exhibit a small pH sensitivity which is automatically compensated in the OPTI R using the measured pH.

Measurement Range

Range	Resolution (Low/High)	Units
0.8 to 10	0.1/0.01	mmol/L

Reference Intervals[3]

Sample type	Range, mmol/L
Serum	
Premature, 48 hr	3.0-6.0
Newborn	3.7-5.9
Infant	4.1-5.3
Child	3.4-4.7
Adults	3.5-5.1
Plasma	
Male	3.5-4.5
Female	3.4-4.4

Interferences

The OPTI R K^+ sensor has no measurable interference from Na^+ variation within the range 100-190 mmol/L.

The OPTI R 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 R 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 R K^+ sensor will show a potassium offset of +0.4 mmol/L, and at extreme hyperammonemia (plasma levels of 3000 μmol/L), the OPTI R 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	25 mg/dL	-0.8
Cardio (indocyanine) green	0.5 mg/dL	-0.4
Methylene blue	25 mg/dL	unstable

Only clear, uncolored quality control materials, such as OPTI CHECK brand aqueous controls should be used with the OPTI R 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 R instruments. Potassium values are expressed in mmol/L.

Material	mean	S_{wr} (CV%)	S_{dd} (CV%)	S_T (CV%)
OPTI CHECK (aqueous control solution)				
Level 1	2.93	0.029 (1.0)	0.019 (0.6)	0.043 (1.5)
Level 2	4.89	0.012 (0.2)	0.029 (0.6)	0.034 (0.7)
Level 3	5.94	0.018 (0.3)	0.038 (0.6)	0.045 (0.8)
Serum	7.39	0.047 (0.6)	0.076 (1.0)	0.150 (2.0)
Reduced Bovine Hemoglobin Solution	5.34	0.025 (0.5)	0.063 (1.2)	0.072 (1.3)

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.

Linearity

Wherever possible, linearity for the OPTI R 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[4]	Intercept	Correlation Coefficient	Sy*x	Range	n
$Potassium_{ST}$	0.9725	0.108	0.99996	0.03	0.6 – 8.5	30
$Potassium_{NIST}$	1.0416	-0.023	0.99990	0.030	2.0 – 6.0	14

Correlation to Other Methods

OPTI R 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 R 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
Chiron (whole blood)	0.9614	-0.025	0.9922	0.074	2.9 – 5.7	97
Roche OMNI (whole blood)	0.9764	-0.04	0.9839	0.12	2.8 – 9.4	314
AVL 9181 (whole blood)	0.9897	-0.084	0.9865	0.11	2.8 – 9.6	314

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. Tietz; Burtis C, et al (Eds.), Textbook of Clinical Chemistry and Molecular Diagnostics, 4th Ed., (Elsevier Saunders, 2006) pps. 2252-2302.
4. Model equation for regression statistics is: [results of OPTI Analyzer] = slope(m) [comparative method results] + intercept(b).

Ionized Calcium (Ca^{++})

Clinical Significance[1]

Calcium in blood is distributed as free calcium ions (50%); bound to protein, mostly albumin (40%); and 10% bound to anions such as bicarbonate, citrate, phosphate and lactate. However, only ionized calcium can be used by the body in such vital processes as muscular contraction, cardiac function, transmission of nerve impulses and blood clotting. The OPTI R 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 disease[2].

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 counters[3]. As the ion concentration increases, these ionophores bind larger amounts of ions and cause the fluorescence intensity to increase or decrease, depending on the particular ion. Like the pH optode, the ion optodes do not need a reference electrode, however, several of them do exhibit a small pH sensitivity which is automatically compensated in the OPTI R using the measured pH.

Measurement Range

Range	Resolution (Low/High)	Units
0.2 to 3.0	0.01	mmol/L

Reference Intervals[4]

Sample type	Range, mmol/L
Serum and plasma	
Adults	1.15-1.33

Interferences

The OPTI R 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.

Substance	amount	Ca^{++} change mmol/L
Sodium fluorescein	25 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 brand aqueous controls should be used with the OPTI R system. Colored materials, including proficiency testing materials, may interfere with the pH or 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 R instruments. Ionized calcium values are expressed in mmol/L.

Material	**mean**	**S_{wr} (CV%)**	**S_{dd} (CV%)**	**S_T (CV%)**
OPTI CHECK (aqueous control solution)				
Level 1	1.526	0.034 (2.2)	0.022 (1.4)	0.039 (2.6)
Level 2	1.196	0.015 (1.3)	0.009 (0.8)	0.017 (1.4)
Level 3	0.808	0.021 (2.6)	0.006 (0.7)	0.025 (3.1)
Serum	0.43	0.022 (5.1)	0.008 (1.9)	0.029 (6.7)
Reduced Bovine Hemoglobin Solution	1.11	0.010 (0.9)	0.020 (1.8)	0.022 (2.0)

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.

Linearity

Wherever possible, linearity for the OPTI R 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[5]	Intercept	Correlation Coefficient	Sy*x	Range	n
ionized Calcium$_{ST}$	1.0213	-0.039	0.99940	0.027	0.47 – 2.6	30
ionized Calcium$_{NIST}$	1.0373	-0.057	0.98509	0.058	1.07 - 1.71	14

Correlation to Other Methods

OPTI R 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 R 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
Chiron (whole blood)	0.8371	0.246	0.9641	0.040	0.3 - 1.4	92
Roche OMNI (whole blood)	0.8151	0.20	0.9564	0.03	0.85 – 2.19	314
AVL 9181 (whole blood)	0.9628	0.096	0.9550	0.03	0.86 – 2.0	314

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. Tietz; Burtis C, et al (Eds.), Textbook of Clinical Chemistry and Molecular Diagnostics, 4th Ed., (Elsevier Saunders, 2006) pps. 2252-2302.
5. Model equation for regression statistics is: [results of OPTI Analyzer] = slope(m) [comparative method results] + intercept(b).

Total Hemoglobin Concentration (ctHb) and Hemoglobin Oxygen Saturation (SO_2%)

Clinical Significance[1]

total Hemoglobin concentration (ctHb)

The hemoglobin is the main component of erythrocytes. It serves as the vehicle for transportation of oxygen within the bloodstream and each gram of hemoglobin can carry 1.39 mL of oxygen. The oxygen combining capacity of the blood is directly proportional to the hemoglobin concentration rather than to the number of red blood cells (RBC), because some red cells contain more hemoglobin than others.

Although oxygen transport is the main function of hemoglobin, it also serves as an important buffer in the extracellular fluid. Decreases in the amount of hemoglobin can come about as a result of a decreased concentration of hemoglobin in the erythrocytes, or a decreased number of erythrocytes that contain a normal concentration of hemoglobin.

Decreased levels are found in anemia states, hyperthyroidism, severe hemorrhage and hemolytic reactions due to transfusions of incompatible blood, reaction to chemical, infectious and physical agents as well as various systemic diseases. Increased levels are found in hemoconcentration of the blood, chronic obstructive pulmonary disease and congestive heart failure.

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

*c*tHb is used to screen for disease associated with anemia, to determine the severity of anemia, to follow the response to treatment for anemia and to evaluate polycythemia.

Hemoglobin Oxygen Saturation (SO_2%)

When each heme group of the hemoglobin molecule is associated with one molecule of oxygen, the hemoglobin is referred to as oxyhemoglobin (O_2Hb). The amount of oxyhemoglobin, expressed as a fraction of the total functional hemoglobin (able to bind oxygen), is termed hemoglobin oxygen saturation (SO_2%). The largest portion (about 98%) of blood oxygen content is the oxygen bound to hemoglobin. The reference interval for arterial blood from healthy adults is typically 94 to 98%[2]. Decrease in SO_2 below the critical level necessary for tissue oxygen saturation is a grave clinical situation. Low oxygen saturation may be caused by many of the same factors responsible for arterial *hypoxemia*. Low fractional oxyhemoglobin (FO_2Hb), defined as a fraction of total available hemoglobin, may also be caused by unusually large amounts of non-functional hemoglobins, high concentrations of deoxyhemoglobin, chemically altered hemoglobin or factors affecting the affinity of hemoglobin for oxygen, including: temperature, pH, PCO_2, 2,3-DPG concentration and type of hemoglobin.[3]

Measurement Principle

The measurement of total Hemoglobin (*c*tHb) and oxygen saturation (SO_2) uses the well-established principle of optical reflectance. Red and infrared light at three wavelengths is directed at whole, non-hemolyzed blood within a precisely-defined part of the cassette over the O_2 optode. The photons are partially absorbed and reflected by erythrocytes in a manner proportional to hemoglobin level; at low hemoglobin levels the unabsorbed photons strike the O_2 optode's pink overcoat and are reflected back up through the blood a second time. A portion of the reflected light exits the top of the cassette and is measured by a detector in the instrument. The infrared wavelengths are selected for the hemoglobin measurement because they are largely independent of SO_2, that is, the predominate forms of adult and fetal hemoglobin absorb similarly within the 750-850 nm wavelength range. The red wavelength is utilized for the SO_2 measurement because it is much more strongly absorbed by deoxyhemoglobin than all other hemoglobins, and it is picked close to the isosbestic point for oxy- and carboxyhemoglobin. Sensitivity to erythrocyte aggregation (rouleaux formation) is minimized by maintaining high shear force just prior to measurement (see Interferences below).

Measurement Range

	Range	Resolution (Low/High)	Units
tHb	5 to 25	0.1	g/dL
SO_2	60 to 100	1/0.1	%

Reference Intervals[4]

Oxygen Saturation

Sample type	Range, %
Whole blood, arterial	
Newborn	40-90
thereafter	94-98

Total hemoglobin[5]

Sample type	Range, g/dL
Whole blood	
Adult male	13.9-16.3
Adult female	12.0-15.0

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	+5.0	+3.5%
Evan's Blue	5.0 mg/dL	< 1	-17%
Methylene Blue	25 mg/dL	+3.4	Low
ENDOGENOUS			
Carboxyhemoglobin	10%	-2.2	< 2%
Carboxyhemoglobin	20%	-3.3	< 2%
Methemoglobin	20%	+4.5	-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 SO_2 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 R instruments. *c*tHb is expressed in g/dL and SO_2 in %.

Material		**mean**	**S_{wr} (CV%)**	**S_{dd} (CV%)**	**S_T (CV%)**
OPTI CHECK Level 1	(ctHb)	20.0	0.34 (1.7)	0.06 (0.3)	0.43 (2.1)
(aqueous control solution)	(SO_2%)	78.9	0.47 (0.6)	0.10 (0.1)	0.47 (0.6)
OPTI CHECK Level 2	(ctHb)	14.1	0.20 (1.4)	0.18 (1.3)	0.44 (3.1)
(aqueous control solution)	(SO_2%)	84.4	0.62 (0.7)	0.50 (0.6)	1.02 (1.2)
OPTI CHECK Level 3	(ctHb)	9.3	0.15 (1.6)	0.13 (1.4)	0.29 (3.1)
(aqueous control solution)	(SO_2%)	91.2	0.73 (0.8)	0.81 (0.9)	1.22 (1.3)

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.

Linearity

Wherever possible, linearity for the OPTI R measurement has been established against reference materials or methods. Total hemoglobin content linearity is established by the photometric determination of cyanmethemoglobin.[6]

No standard method exists for the measurement of oxygen saturation. For the purpose of evaluation, SO_2 linearity is evaluated against a target oxygen saturation in a normal human blood sample.

	Slope[7]	Intercept	Correlation Coefficient	Sy*x	Range	n
Total Hemoglobin	0.9850	0.334	0.98901	1.107	5.5 -23.5	40
SO_2	0.9573	3.43	0.99898	0.879	40 - 100	40

Correlation to Other Methods

OPTI R 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 R 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
Chiron 865 (whole blood)	(ctHb)	0.9886	-0.067	0.9737	0.56	3.7 – 16.1	93
	(SO_2%)	0.8350	16.19	0.9772	1.11	59 – 100	90
Roche OMNI (whole blood)	(ctHb)	0.9365	0.27	0.9691	0.45	7.3 – 15.9	314
	(SO_2%)	0.9115	7.07	0.9759	1.97	33 – 99.8	314

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. Tietz; Burtis C, et al (Eds.), Textbook of Clinical Chemistry and Molecular Diagnostics, 4th Ed., (Elsevier Saunders, 2006) pps. 2252-2302.
5. Kaplan LA, Pesce AJ. Clinical Chemistry: Theory, Analysis, Correlation, 3rd Ed. (Mosby-Year Book, 1996) p. 729.
6. 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.
7. Model equation for regression statistics is: [results of OPTI Analyzer] = slope(m) [comparative method results] + intercept(b).

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 9.99	0.1/0.01	mmol/L
Ca^{++}	0.2 to 3.0	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
Sample Type	heparinized whole blood, plasma or serum
Sample Application	syringe, capillary or ComfortSampler
Sample Input	automatic aspiration
Analysis Time	< 2 minutes, typically approx. 1 minute to result
Ambient Temperature Range	10 °C - 30 °C (50 °F - 86 °F)
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
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 (HCO3-)	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_2ct)	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
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.

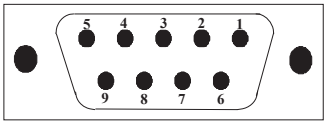
[2] Henry JB, “Clinical Diagnosis and Management by Laboratory Methods”, 19th Edition, Philadelphia, W.B. Saunders Co., 1996

[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 R is dynamic. Storage capacity is >300 patient records. QC data for 2 months at 3 levels

RS232C – Pin Configuration



REAR VIEW OF OPTI R

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″	12.0 cm
Width	14.2″	36.2 cm
Depth		
w/o Fluid Pack	9.1″	23.0 cm
with Fluid Pack	15.1″	38.0 cm
Weight		
w/o Fluid Pack	10 lbs	4.5 kg
with Fluid Pack	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 R are based on the NCCLS Standard C12-A, when available.

Temperature[4]

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

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

[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	K.....mmol/L
PCO_2.....mmHg	Ca .....mmol/L
PO_2.....mmHg	Hb.....g/dL
Na..... mmol/L	SO_2.....%

Conversion Table for Units[5]

ctO_2, O_2ct, tCO_2	1 vol% = 1 ml/dl = 0.4464 mmol/l
tHb	1 g/dl = 10 g/l = 0.6206 mmol/l
barometric pressure, PCO_2, PO_2	1 mmHg = 1.3333 mbar = 0.1333 kPa
ionized Calcium (Ca^{++})	1 mmol/L = 4.008 mg/dL = 2mEq/L

Equations[6]

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 ºC with a gas mixture having a PCO_2 = 40 mmHg.

$$st.pH = (0.8262 - 0.01296 \cdot tHb + 0.006942 \cdot BE) \cdot lg \cdot (0.025 \cdot PCO_2) + pH \quad \text{[pH-unit]}\ ^{6}$$

[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.

HCO_3^-

Bicarbonate concentration in plasma.

$$HCO_3^- = 0.0307 \cdot PCO_2 \cdot 10^{(pH-6.105)}$$ [mmol/L] [1]

$st.HCO_3^-$

Standard bicarbonate of the blood, defined as the plasma bicarbonate concentration in blood which has been equilibrated at 37 ºC with a gas mixture having a PCO_2 = 40 mmHg.

$$st.HCO_3^- = 10^{(st.pH-6.022)}$$ [mmol/L] [6]

tCO_2

Total concentration of CO_2 in plasma, the sum of dissolved CO_2 and bicarbonate.

$$tCO_2 = HCO_3^- + (0.0307 \cdot PCO_2)$$ [mmol/L] [7]

BE

The base excess of the blood results from a calculation to determine the titratable base of the blood, which in principle is measured by titration of the blood with a strong acid or base to a pH of 7.4 with PCO_2 = 40 mmHg at 37 ºC.

$$BE = (1 - 0.014 \cdot tHb) \cdot \left[(1.43 \cdot tHb + 7.7) \cdot (pH - 7.4) - 24.8 + HCO_3^-\right]$$ [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).

$$BE_{ecf} = 16.2 \cdot (pH - 7.4) - 24.8 + HCO_3^-$$ [mmol/L] [7]

[7] NCCLS. *Blood Gas and pH Analysis and Related Measurements; Approved Guideline.* NCCLS document C46-A, 2001.

$BE_{(act)}$

Base excess at actual oxygen saturation.

$$BE_{(act)} = (1 - 0.0143 \cdot tHb) \cdot [(1.63 \cdot tHb + 9.5) \cdot (pH - 7.4) - 24.26 + HCO_3^-] - 0.2 \cdot tHb \cdot \left(1 - \frac{SO_2}{100}\right)$$

[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.

$$BB = BE + 41.7 + 0.42 \cdot tHb$$

[mmol/L] [6]

$SO_2(c)$

The oxygen-hemoglobin dissociation curve theoretically allows that oxygen saturation of available hemoglobin can be calculated, provided the form of the curve is known. Factors which are known to affect this curve include: hemoglobin species, pH, PCO_2, temperature and 2,3 diphosphoglycerate (2,3 DPG) content. Although it is possible to calculate this value, the assumptions which are made in the calculation can cause significant errors in the resulting value for those patients who are in the most critical clinical state. The OPTI R has the capability to provide a measured SO_2 from the blood sample. It is recommended that this measured value, if available, should be used in preference to the calculated SO_2.

If not available from measurement, and if calculation is selected:

$$SO_2\% = \frac{Q}{Q+1} \cdot 100\% \quad (7)$$

(6)

Adult :

$$lgQ = 2.9 \cdot lgPO_2^{\,k} + 1.661 \cdot 10^{-0.074 \cdot PO_2^{\,k}} - 4.172$$

$$lgPO_2^k = lgPO_2 + 0.48 \cdot (pH - 7.4) - lg(\frac{26.7}{26.7}) + 0.0013 \cdot BE$$

$$P_{50} = 26.7$$

Fetal :

$$lgQ = 2.9 \cdot lg\,PO_2^{\,k} + 1.3632 \cdot 10^{-0.0533 \cdot PO_2^{\,k}} - 4.113$$

$$lgPO_2^{\,k} = lgPO_2 + 0.48 \cdot (pH - 7.4) - lg(\frac{21.5}{26.7}) + 0.0013 \cdot BE$$

$$P_{50} = 21.5$$

[8] Zander R., Die korrekte Bestimmung des Base Excess (BE mmol/l) im Blut. Anesthesiol. Intensivmed. Notfallmed. Schmerzther.

ctO_2

Oxygen content is the sum of oxygen bound to hemoglobin as O_2Hb and the amount of oxygen dissolved in the plasma. This value is calculated from the measured O_2Hb and tHb if available and is estimated from the calculated SO_2 if the measured O_2Hb is not available and if the calculation of oxygen saturation is selected.

If measured O_2Hb and tHb are available:

$$ctO_2 = 1.39 \cdot \frac{O_2Hb}{100} \cdot tHb + 0.00314 \cdot PO_2$$

[vol%] [9]

NOTE: *If PO_2 is not available, ctO_2 is calculated with PO_2 = 90 mmHg.*

If measured O_2Hb and tHb are not available and calculated SO_2 is enabled:

$$tO_2 = 1.39 \cdot \frac{SO_2}{100} \cdot tHb + 0.00314 \cdot PO_2$$

[vol%] [9]

NOTE*: If PO_2 is not available, ctO_2 is calculated with PO_2 = 90 mmHg.*

P50

The oxygen partial pressure at half saturation, *P*50, is defined as the PO_2 value for a given blood sample at which 50% of the hemoglobin is saturated with oxygen. While the actual *P*50 value can only be determined by interpolation after measurement of oxygen saturation of a blood specimen tonometered to levels of oxygen to provide an oxyhemoglobin slightly greater than and slightly less than 50% with pH and PO_2 held constant at 7.4 and 40 mmHg respectively, the OPTI R allows for the estimation of *P*50 from measured SO_2% , PO_2 and pH. If a measured SO_2% is not available, the *P*50 value may be input via keypad.

For Adult hemoglobin:

$$P_{50} = 26.7 \cdot 10^{\left(\lg PO_2 - \lg PO_2{}^{k}\right)}$$

where:

$$\lg PO_2{}^{k} = \frac{(\lg Q + 4.172)}{2.9}$$

$$Q = \frac{SO_2}{100\% - SO_2}$$

[mmHg] [6]

[9] NCCLS. *Blood Gas and pH Analysis and Related Measurements; Approved Guideline.* NCCLS document C46-A, 2001.

For Fetal hemoglobin:

$$P_{50} = 25.0 \cdot 10^{\left(\lg PO_2 - \lg PO_2{}^{k}\right)}$$

where:

$$\lg PO_2{}^{k} = \frac{(\lg Q + 4.113)}{2.9}$$

$$Q = \frac{SO_2}{100\% - SO_2}$$

[mmHg] [6]

$AaDO_2$

The alveolar to arterial oxygen tension gradient (PAO_2 - PaO_2) is the difference between the alveolar oxygen tension, estimated above, and the measured oxygen tension of arterial blood.

$PAO_2 = (P_{total} - 47)\ FIO_2 - PACO_2\ [FIO_2 + (1 - FIO_2)/R]$ [mmHg][7]

$PACO_2 = PaCO_2$ (alveolar PCO_2)

Apply above equation for $PAO_2 \geq PO_2$*, otherwise* $PAO_2 = PO_2$

pH^t

pH corrected to patient temperature other than 37 ºC.

$$pH^t = pH - [0.0147 + 0.0065 \cdot (pH - 7.4)] \cdot (t - 37)$$

[pH-unit] [7]

cH^{+t}

Concentration of hydrogen ions corrected to patient temperature other than 37 ºC.

$$cH^t = 10^{(9 - pH^t)}$$

[nmol/L] [6]

$PCO_2{}^t$

PCO_2 value corrected to patient temperature other than 37 ºC.

$$PCO_2{}^t = PCO_2 \cdot 10^{0.019 \cdot (t - 37)}$$

[mmHg] [7]

$PO_2{}^t$

PO_2 value corrected to patient temperature other than 37 ºC.

$$PO_2{}^t = PO_2 \cdot 10^{\left[\frac{5.49 \cdot 10^{-11} \cdot PO_2{}^{3.88} + 0.071}{9.72 \cdot 10^{-9} \cdot PO_2{}^{3.88} + 2.30}\right] \cdot (t - 37)}$$

[mmHg] [6]

$AaDO_2^t$

Alveolar to arterial oxygen tension difference corrected to patient temperature other than 37 ºC.

$$AaDO_2^t = PAO_2^t - PaO_2^t \quad [mmHg]\ ^{7}$$

where:

$$PAO_2^t = (P_{total} - PH_2O^t)\ FIO_2 - PACO_2^t\ [FIO_2 + (1 - FIO_2)/R]$$

with $PH_2O^t = 47 * 10^{[0.0237 - 0.0001\ (t-37)]\ (t-37)}$
and $PACO_2 = PaCO_2$ (alveolar PCO_2 = arterial PCO_2)

Apply above equation for $PAO_2^t \geq PO_2^t$,
otherwise $PAO_2^t = PO_2^t$

Hct(c)

Hct(c) as a function of tHb.

$$Hct(c) = tHb\left[g / dl\right] / (MCHC\% / 100) \quad [\%]\ ^{10}$$

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%)

nCa^{++}

The ionized calcium value normalized to pH = 7.40.

For blood:

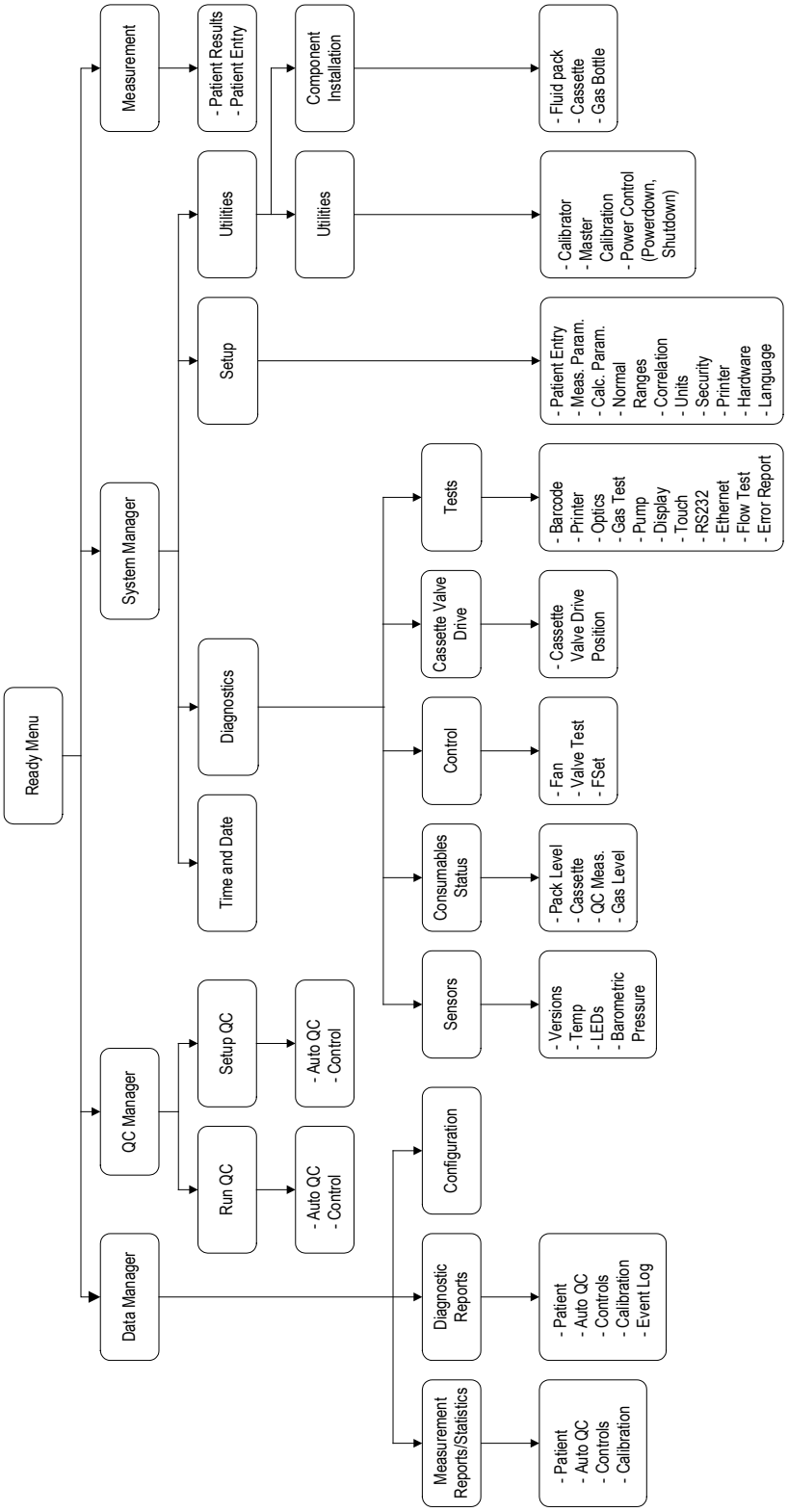
$$nCa^{++}\ (pH = 7.4) = Ca^{++} * 10^{\ 0.22*(pH-7.4)} \quad [mmol/L]$$

For plasma or serum:

$$nCa^{++}\ (pH = 7.4) = Ca^{++} * 10^{\ 0.24*(pH-7.4)} \quad [mmol/L]$$

[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
Run Calibrator								

SEMIANNUALLY:								
	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 cassette								
Change fluid pack								
Change printer paper								

APPENDIX D - REPORT FORMATS

Basic Patient Report

```
 OPTI Medical OPTI R
    Patient Report
  DD-MMM-YY  HH:MM

Pat. ID: 123456789012345
Access. No.:123456789012
Sample No.: 2345

ACID/BASE @37°C
 pH       7.343
 PCO2     41.0   mmHg
 PO2      84.9   mmHg
 BE     - 3.7    mmol/L
 tCO2     23.0   mmol/L
 HCO3     21.0   mmol/L

ELECTROLYTES
 Na+    140.2    mmol/L
 K+       3.67   mmol/L
 Ca++     1.47   mmol/L
 nCa++    0.97   mmol/L

HEMOGLOBIN/OXYGEN STATUS
 tHb      14.4   g/dL
 SO2      95.7   %
 Hct[c]   43.2   %

ENTERED PARAMETERS
 Temp     38.5   °C
 Sex      Male
 Hb Type Adult
 SamType Art
 MCHC     33.3   %
 O2 Mode Room Air
 FIO2     0.21
 RQ       0.84
```

```
P50         26.7   mmHg
VntMode   N/A
TVol          0    mL
MVol          0    L
PIP           0
Pplat       0.0
PS           68
PEEP          0
CPAP          0
Rate(f)       0    bpm
L.Flow        0    Lpm
I/E  1:   1.0
BiLevel 0.0/ 0.0
PuncSite   LR
Bypass    On-Pump


Barometer     739.6 mmHg
Operator ID:12345678901
S/N:1234      LOT:123456

REFERENCE RANGES
pH    7.20 -   7.60
PCO2    30 -     50 mmHg
PO2     70 -    700 mmHg
Na+    135 -    145 mmol/L
K+     3.5 -    5.1 mmol/L
Ca++ 1.12 -   1.32 mmol/L
tHb   12.0 -   17.0 g/dL
SO2     90 -    100 %

MESSAGES
```

Auto QC Measurement Report

```
----------------------------
     OPTI Medical OPTI R
    Controls Measurement
      DD-MMM-YY  HH:MM


Level: 2
Sample No.:2345
PackLot:123456  Exp:MMMYYYY

      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

Barometer: 744.5 mmHg
Operator ID:12345678901
S/N:1234  Lot:123456

----------------------------
```

Auto QC Statistics Report

```
    OPTI Medical OPTI R
    Controls Statistics
      DD-MMM-YY  HH:MM

Level: 2 OPTI-check
QCLot:XXXX Exp: MMMYY
CassLot: XXXXXX
S/N: XXXX
Number run: 3
Number ok:  3

ABG LIMITS:
pH   7.390 - 7.470
PCO2  40.0 - 48.0   mmHg
PO2   86.0 - 110.0  mmHg

Date    pH  PCO2 PO2 OK?
04May 7.412 43.9 95.3 OK
04May 7.410 43.5 95.8 OK
05May 7.410 43.6 98.3 OK
------------------------
Mean  :7.411  43.6  96.4
SD    :0.002   1.1   1.4
CV%   :0.033   2.6   1.4

Electrolyte Limits:
Na+  139.0 - 149.0 mmol/L
K+    4.40 - 5.20  mmol/L

Date  Na+    K+  OK?
04May 143.9 4.76 OK
04May 143.6 4.74 OK
05May 143.8 4.77 OK
------------------------
Mean  :143.5  4.80
SD    :  0.3  0.04
CV%   :  0.2  0.90
```

```
HEMOGLOBIN LIMITS:
tHb   12.8 - 15.8 g/dL
SO2   87.0 - 93.0   %

Date    tHb  SO2  OK?
04May  14.3 89.3  OK
04May  13.4 89.1  OK
05May  13.9 88.9  OK
------------------------
Mean  :13.9  89.1
SD    : 0.3  2.2
CV%   : 1.8  2.5

ADDITIONAL LIMITS:
Ca++  1.14 - 1.35  mmol/L

Date  Ca++            OK?
04May 1.24            OK
04May 1.20            OK
05May 1.22            OK
------------------------
Mean  :1.22
SD    :0.3
CV%   :2.28
```

AQC Install/Slope Measurement Report

```
 ---------------------------
      OPTI Medical OPTI R
AQC Install/Slope Measurement
       DD-MMM-YY  HH:MM


 Level: 2
 Sample No.:2345
 PackLot:123456  Exp:MMMYYYY

       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

 Barometer: 744.5 mmHg
 Operator ID:12345678901
 S/N:1234  Lot:123456

 ---------------------------
```

Controls Measurement Report

```
----------------------------
     OPTI Medical OPTI R
    Controls Measurement
      DD-MMM-YY  HH:MM


Level: 2   OPTI-check
Sample No.:2345
QCLot:1234  Exp:MMMYYYY

      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

```
    OPTI Medical OPTI R
    Controls Statistics
      DD-MMM-YY  HH:MM

Level: 2 OPTI-check
QCLot:XXXX Exp: MMMYY
CassLot: XXXXXX
S/N: XXXX
Number run: 3
Number ok:  3

ABG LIMITS:
pH   7.390 - 7.470
PCO2  40.0 - 48.0   mmHg
PO2   86.0 - 110.0  mmHg

Date    pH  PCO2 PO2 OK?
04May 7.412 43.9 95.3 OK
04May 7.410 43.5 95.8 OK
05May 7.410 43.6 98.3 OK
------------------------
Mean  :7.411  43.6  96.4
SD    :0.002   1.1   1.4
CV%   :0.033   2.6   1.4

Electrolyte Limits:
Na+  139.0 - 149.0 mmol/L
K+    4.40 - 5.20  mmol/L

Date  Na+    K+  OK?
04May 143.9 4.76 OK
04May 143.6 4.74 OK
05May 143.8 4.77 OK
------------------------
Mean  :143.5  4.80
SD    :  0.3  0.04
CV%   :  0.2  0.90
```

```
HEMOGLOBIN LIMITS:
tHb   12.8 - 15.8 g/dL
SO2   87.0 - 93.0   %

Date    tHb  SO2  OK?
04May  14.3 89.3  OK
04May  13.4 89.1  OK
05May  13.9 88.9  OK
-------------------------
Mean  :13.9  89.1
SD    : 0.3  2.2
CV%   : 1.8  2.5

ADDITIONAL LIMITS:
Ca++  1.14 - 1.35  mmol/L

Date  Ca++            OK?
04May 1.24            OK
04May 1.20            OK
05May 1.22            OK
-------------------------
Mean  :1.22
SD    :0.3
CV%   :2.28
```

Patient Measurement Calibration Report

```
----------------------------
   OPTI Medical OPTI R
    Calibration Report
      DD-MMM-YY  HH:MM


      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

Barometer: 744.5 mmHg
S/N:1234  Lot:123456

----------------------------
```

Patient Diagnostics Calibration Report

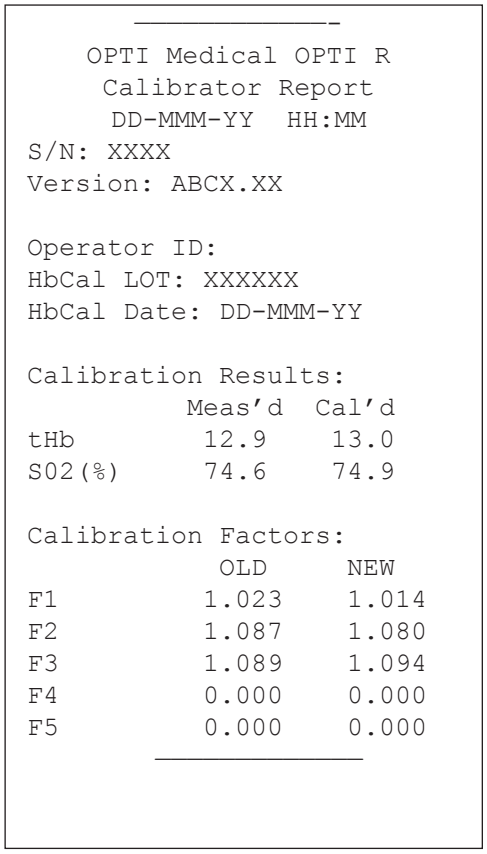
```
      ______________

     OPTI Medical OPTI R
     Calibration Reports
       DD-MMM-YY  16:08
S/N: XXXX
Version ABCX.XX

DDMMMYY 15:56
CassLot:XXXXXX
PackLot:XXXXXX
        mV   Drift  T
pH    116.7   1.7   37
pCO2  101.8   0.7   19
pO2   295.1  -0.4   15
Na+   116.9   0.6   17
K+    269.0  -0.7   19
Ca++  437.5  -2.0   19

 -------------------------
```

Calibrator Report



```
      ______________-
    OPTI Medical OPTI R
     Calibrator Report
      DD-MMM-YY  HH:MM
S/N: XXXX
Version: ABCX.XX

Operator ID:
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
F5         0.000    0.000
       ______________
```

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.

```
 OPTI Medical OPTI R
 Configuration Report
   DD-MMM-YY  HH:MM
S/N: XXXX
Version: ABCX.XX

Baro. Offset : 0.000
Patient Info -
  Pat.ID        : ON/Opt.
  Oper.ID       : ON/Opt.
  Acc. Num.     : 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 Def2     : ON
  User Def3     : ON
  Puncture Site : ON
  Bypass        : ON

Patient Info Defaults -
  tHb   : 15.0 g/dL
  MCHC  : 33.3%
  FIO2  : 0.21
  RQ    : 0.84
  P50   : 26.7 mmHg

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
  Ca++ 1.12-1.32 mmol/L
  tHb  12.0-17.0 g/dL
  SO2  90.0-100.0
```

```
Controls Info -
Lev. 1 LimMin  LimMax
  pH    7.120-7.220
  PCO2  64.0-78.0 mmHg
  PO2   57.0-81.0 mmHg
  Na+   118.0-128.0mmol/L
  K+    2.20-3.20 mmol/L
  Ca++  1.44-1.74 mmol/L
  tHb   17.9-21.9 g/dL
  SO2   76.0-82.0 %
  QCLot: 9169 Exp: Jan2010
Lev. 2 LimMin  LimMax
  pH    7.380-7.460
  PCO2  40.0-48.0 mmHg
  PO2   88.0-112.0 mmHg
  Na+   140.0-150.0 mmol/L
  K+    4.00-4.80 mmol/L
  Ca++  0.20-3.00 mmol/L
  tHb   12.8-15.8 g/dL
  SO2   86.0-92.0 %
  QCLot: 9269 Exp: Jan2010
Level 3 LimMin  LimMax
  pH    7.550-7.650
  PCO2  18.0-26.0  mmHg
  PO2   132.0-156.0 mmHg
  Na+   156.0-166.0 mmol/L
  K+    4.80-6.00 mmol/L
  Ca++  0.20-3.00 mmol/L
  tHb   8.1-11.1   g/dL
  SO2   93.0-99.0  %
  QCLot: 9369 Exp: Jan2010
Fluid Pack Info -
Level 1 LimMin  LimMax
  pH    7.060-7.180
  PCO2  67.0-83.0 mmHg
  PO2   18.0-42.0 mmHg
  Na+   122.0-132.0 mmol/L
  K+    2.50-3.30 mmol/L
  Ca++  1.71-2.01 mmol/L
  tHb   11.8-15.8 g/dL
  SO2   85.0-92.0 %
  Volume: 42088 uL
  Pack Lot: 123456
  Exp: Jan-31-2010
Level 2 LimMin  LimMax
  pH   7.300-7.420
  PCO2  39.0-47.0 mmHg
  PO2   88.0-112.0 mmHg
  Na+  136.0-150.0 mmol/L
  K+    4.60- 5.40 mmol/L
  Ca++  1.15- 1.35 mmol/L
  tHb   18.5- 21.5 g/dL
  SO2   75.0- 81.0 %
  Volume: 28508 uL
  Pack Lot: 123456
  Exp: Jan-31-2010
```

Configuration Report (Part 2)

```
Level 3 LimMin  LimMax
  pH    7.610-7.710
  PCO2  16.0-26.0  mmHg
  PO2   138.0-168.0 mmHg
  Na+   150.0-164.0 mmol/L
  K+    5.30-6.30 mmol/L
  Ca++  0.60-0.84 mmol/L
  tHb   8.0-11.0 g/dL
  SO2   92.0-98.0  %
  Volume: 29150 uL
  Pack Lot: 123456
  Exp: Jan-31-2010
Buffer LimMin  LimMax
  pH    7.280-7.410
  PCO2  40.0-48.0  mmHg
  PO2   159.0-183.0 mmHg
  Na+   137.0-151.0 mmol/L
  K+    4.90-5.70 mmol/L
  Ca++  1.20-1.40 mmol/L
  tHb   18.5-21.5  g/dL
  SO2   76.0-82.0  %
  Volume: 10179 uL
  Pack Lot: 123456
  Exp: Jan-31-2010
Printouts -
  Patient  : ON, copies 1
  Calib.   : OFF
 Security -
  Password : ENABLED
  QC Lockout -
    QC Levels   :0
Miscellaneous
 Units -
  Units : Conventional
  Temp  : Celcius
  Time  : 24-hour
  tHb   : g/dL
  Ca++  : mmol/L
  Resolution : High
Correlation Factors -
    Normal Cassettes
             Slope  Offset
    pH       1.000  0.000
    PCO2       1.0    0.0
    PO2        1.0    0.0
    Na+        1.0    0.0
    K+        1.00   0.00
    Ca++      1.00   0.00
    tHb        1.0    0.0
    SO2        1.0    0.0
Communications -
 Baud   : 9600
 Format  : RS232/ASCII
 Language: English
 Backlight Auto-Off -
           60 minutes
```

```
FSET Values -
 Version: ABCX.XX
 IDAC1: 1464
 IDAC2: 2024
 IDAC3: 708
 S/N: XXXX
 MAC:00:50:C2:3D:B7:24
 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
 Printer Fix: Yes
 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
 Pump Rate: 10.0000
 Waste Det: 75
 LED1: 40: 1.0000
 LED2: 62: 1.0000
 LED3: 50: 1.0000
 LED4: 50: 1.0000
 LED5: 42: 1.0000
 LED6: 38: 1.0000
 LED1CAL:     0.0
 LED2CAL:     0.0
 LED3CAL:     0.0
 LED4CAL:     0.0
 LED5CAL:     0.0
 LED6CAL:     0.0
```

Error Report

```
-------------------------
  OPTI Medical OPTI R
      ERROR Report
   DD-MMM-YY  HH:MM
S/N: XXXX
Version: ABCX.XX


 DDMMMYY     HH:MM
ERROR-Cassette  Misseat 1
 DDMMMYY     HH:MM
ERROR-Cassette  Misseat 2
 DDMMMYY     HH:MM
ERROR - Gas Expired
 DDMMMYY     HH:MM
Warning-Bubble Detected
 DDMMMYY     HH:MM
Stop - Low Gas

-------------------------
```

Optics Test Report

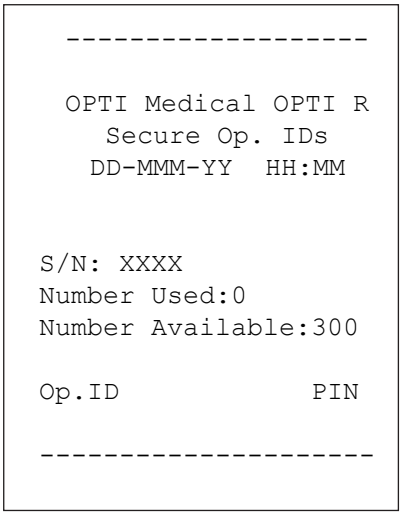
```
OPTI R Optics Test
DD-MMM-YY  13:25
S/N: XXXX

       pH     PCO2   PO2
AVG  :   461    441   1014
%DR  :-0.49   1.40   0.30
%CV  : 0.38   0.35   0.14
%SEE : 0.36   0.27   0.13
DARK :  117    158     84

       Na      K     Cl/Ca
AVG  :   875    577    965
%DR  : 0.54  -0.19  -0.55
%CV  : 0.14   0.41   0.22
%SEE : 0.11   0.40   0.20
DARK :   25     36    104

       tHb6   tHb7   tHb8
sig  :  438    644    605
ref  : 1621   2986   1886
ratio: 0.27   0.22   0.32
```

Operator ID Report



```
  --------------------

  OPTI Medical OPTI R
     Secure Op. IDs
    DD-MMM-YY  HH:MM


S/N: XXXX
Number Used:0
Number Available:300

Op.ID            PIN

----------------------
```

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