

EDAN

i15

Blood Gas and Chemistry Analysis System

Version 1.1

CE

About this Manual

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Statement

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Terms Used in this Manual

This guide is designed to give key concepts on safety precautions.

WARNING

A **WARNING** label advises against certain actions or situations that could result in personal injury or death.

CAUTION

A **CAUTION** label advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.

NOTE

A **NOTE** provides useful information regarding a function or a procedure.

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Chapter 1 Safety Guide

1.1 Intended Use

i15 Blood Gas and Chemistry Analysis System (including Blood Gas and Chemistry Analyzer, Calibrant Fluid Pack, Test Cartridge) is a portable, automated system that measures blood gases, blood chemistries, and hematocrit in whole blood samples. The system is intended for use only by trained technologists, nurses, physicians and therapists. It is intended for use in a laboratory environment, near patient or point-of-care settings. By timely providing test results, the system helps the medical professionals make faster decisions about patient treatment, and thus improves the quality of patient care.

1.2 Warnings and Cautions

In order to use the system safely and effectively, and avoid possible dangers caused by improper operation, please read through the user manual and be sure to be familiar with all functions of the system and proper operation procedures before use. Always keep this manual with the analyzer. Please pay attention to the following warning and caution information.

1.2.1 Safety Warnings

NOTE:

The reliability of the analyzer and the safety of operators are considered during product design and production. The following safety and preventive measures should be carried out:

WARNING


Safety Warnings

1. The analyzer is not intended for treatment.
 2. The analyzer is not intended for home use.
 3. Do not use the analyzer if it is damaged or defective.
 4. The analyzer should be installed by a qualified service engineer. Do not try to access the interior of the analyzer. Only authorized service personnel could remove the analyzer enclosure.
 5. To avoid electrical shock, never modify the analyzer's AC power circuits.
-
-


WARNING

6. The analyzer is intended for use only by trained technologists, nurses, physicians and therapists. Operators should be familiar with the contents of this user manual before operation.
 7. The results given by the system should be examined based on the overall clinical condition of the patient, and should not be a substitute for regular checking.
 8. To ensure grounding reliability, only connect the system to a hospital-grade power receptacle.
 9. Connect the analyzer to a grounded socket and make certain that the mains supply meets the requirements specified in the user manual.
 10. Do not exceed the maximum permitted load when using multiple portable socket-outlets to supply the system.
 11. **SHOCK HAZARD** - Do not attempt to connect or disconnect a power cord with wet hands. Make certain that your hands are clean and dry before touching a power cord.
 12. If you have any questions about the power adaptor or the power cord, use the battery but not the AC power supply. Prior to using AC power supply, inspection of the power adaptor and the power cord is recommended. If it is necessary, consult EDAN or its authorized distributors for service.
 13. The analyzer is not waterproof. Do not use it in locations where water or any liquid leakage may occur.
 14. Do not cast any fluid onto the system surface, as fluid seepage into the electrical circuitry may cause excessive leakage current or system failure.
 15. Do not spray cleaning fluids on the system, as this may force cleaning fluid into the system and damage electronic components. It is also possible for solvent fumes to build up and form flammable gases or damage internal components.
 16. To avoid the possibility of electrostatic shock and damage to the system, avoid using aerosol spray cleansers on the analyzer screen.
 17. **EXPLOSION HAZARD** – The analyzer is not suitable for use in the presence of a flammable anesthetic mixture with oxygen or other flammable compounds.
-
-

WARNING

18. To avoid electrical shock, never use the system in altitude exceeding 3,000 meters above sea level.
 19. Periodically have the safety of the system checked by a qualified service engineer.
 20. Only accessories supplied or recommended by the manufacturer should be used. Otherwise, performance and electric shock protection can not be guaranteed.
 21. Blood samples should be collected according to proper medical guidelines which contains collection details, such as site selection, collection procedures, sample handling, etc. Sterile techniques should be followed to prevent the site from being contaminated.
 22. Handle blood samples and collection devices with care, and wear approved protective gloves to avoid direct contact with samples.
 23. To avoid electrical shock and damage to the system, turn off the analyzer and disconnect the analyzer from the AC power source before cleaning and disinfecting.
 24. To avoid the airinlet and airoutlet of the fan being blocked by foreign matters, check them regularly.
 25. To avoid being injured, never touch the stitch of a calibrant fluid pack.
 26. To avoid being hurt, never look into the scanner beam light.
 27. The system is for in vitro diagnostic use only.
 28. Perform quality control (QC) tests regularly to make certain that the system works smoothly.
 29. The disposable test cartridges should only be used a single time.
 30. Never replace a calibrant fluid pack when the analyzer is off.
 31. A calibrant fluid pack is intended for single use only. If a calibrant fluid pack is removed from the system, it can not be inserted into the system again.
 32.  Test cartridges are biohazardous waste after use. They should be disposed of according to local regulatory guidelines.
-

WARNING

33.  Never use an external electronic simulator under electromagnetic environment, and never touch it by hand during an external simulator test.
34. Do not use the analyzer after its life cycle, and it should be disposed of according to local regulations after its life cycle.

Battery Care

35. Improper operation may cause the lithium battery (hereinafter called battery) to be hot, ignited or explode, and it may lead to the declination of the battery capacity. It is necessary to read the user manual carefully and pay attention to warning messages.
36. The battery of the same model and specifications provided by the manufacturer should be used.
37. **Danger of explosion** - Do not reverse the anode and the cathode when installing the battery.
38. Do not heat or splash the battery or throw it into fire or water.
39. When there is leakage or a foul smell, stop using the battery immediately. If your skin or clothes come into contact with the leakage liquid, cleanse it with clean water at once. If the leakage liquid splashes into your eyes, do not wipe them. Irrigate them with clean water first and seek medical assistance immediately.
40. The analyzer and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal. Batteries are hazardous waste. Do not dispose of them together with house-hold garbage. At the end of their lives hand the batteries over to the applicable collection points for the recycling of waste batteries. For more detailed information about recycling of this product or the battery, please contact your local Civic Office, or the shop where you purchased the product.
41. Remove the battery from the analyzer when the analyzer is not used for a long time.
42. If the battery is stored alone and not used for a long time, we recommend that the battery should be charged at least once every 6 months to prevent overdischarge.
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







1.2.2 Safety Cautions


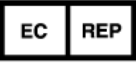










CAUTION

1. Do not use the analyzer in a dusty environment with bad ventilation or in the presence of corrosives.
2. To avoid misdiagnosis, make sure that the time and date of the system are correct.
3. The system is only intended to analyze whole blood samples. Never use it to analyze serum or plasma.
4. If there are clots or bubbles in the blood sample, discard it and collect samples again.
5. Perform the sample test immediately after its collection to get the most accurate results. Measure samples for blood gases and Ca^{++} within 10 minutes, and measure samples for other analytes within 30 minutes.
6. Transport, store and use the analyzer, test cartridges, calibrant fluid packs and controls according to the user manual.
7. Only those accessories (such as test cartridges, calibrant fluid packs, controls, etc) supplied by EDAN or its authorized distributors should be used.
8. Connect the analyzer with those peripherals recommended by EDAN.
9. Maintain the system as described in the user manual to avoid potential damage.
10. Do not clean the analyzer and accessories with abrasive fabric.
11. Do not immerse the analyzer into liquid under any circumstances.
12. Make sure that there is no intense electromagnetic interference source around the analyzer, such as radio transmitters, mobile phones etc. Attention: large medical electrical equipment such as electrosurgical equipment, radiological equipment and magnetic resonance imaging equipment is likely to bring electromagnetic interference.
13. Extreme humidity may affect test results. A relative humidity greater than 80% may cause inaccurate results.
14. Use this system at a temperature between 10°C and 31°C. Outside this range, the system may produce inaccurate results.

1.3 Symbols and Definitions

The following symbols will appear on the packaging of the system:

Symbol	Description
	Caution!
	Consult instructions for use
	Biological risks
	Static electricity sensitive
	Recycle
	The symbol indicates that the device complies with the European Council Directive 98/79/EEC concerning medical devices.
	On/Off button
	Network port
	Serial port
	USB (Universal Serial Bus) connection
	Trademark
	Test cartridge insert direction
	Calibrant fluid pack chamber door is closed.
	Calibrant fluid pack chamber door is open.
	In vitro diagnostic device

	Indicates that the device should be sent to special agencies according to local regulations for separate collection after its useful life.
	Authorized representative in the European Community
	Manufacturer
	Date of manufacture
	Temperature limitations
	Do not reuse
	Use by
	Contains sufficient for (n) tests
	Control
	Serial number
	Catalog number
	Batch code

Chapter 2 System Overview

NOTE:

The pictures and interfaces in this manual are for reference only.

2.1 Introduction

The system is for in-vitro analysis of whole blood, designed to deliver quantitative results for a panel of tests. The product consists of an analyzer incorporating a user interface with a large color touch screen interfacing to the electronic analyzer. The user interface module contains the analyzer CPU and all of the required electronic interfaces for external communication and data storage. The product consists of a single-use cartridge into which the sample is introduced. The cartridge contains electrochemical sensors which generate signals related to concentration levels in the blood. These concentration levels are displayed on the screen of the analyzer, stored in memory, and can be transmitted by communication link or Wi-Fi to the Data Management System (DMS).

The following tables list the parameters that can be determined by the system:

Measured Parameters:

Symbol	Description
pH	Negative logarithm of the hydrogen ion concentration
$p\text{CO}_2$	Partial pressure of carbon dioxide
$p\text{O}_2$	Partial pressure of oxygen
K^+	Potassium ion concentration
Na^+	Sodium ion concentration
Cl^-	Chloride ion concentration
Ca^{++}	Concentration of ionized calcium
Hct	Hematocrit: the volume occupied by red blood cells in a given volume of whole blood.

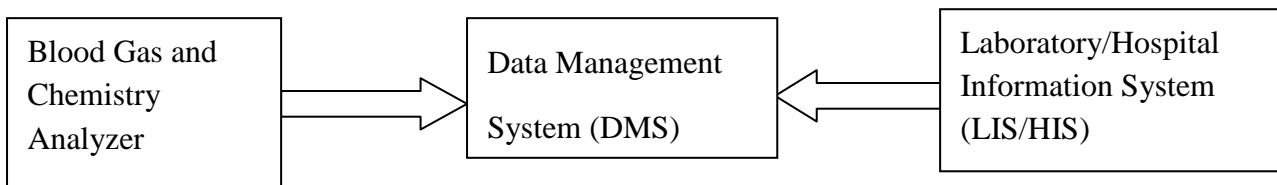
Calculated Parameters:

Symbol	Description
cH^+	Hydrogen ion concentration
$cH^+ (T)$	Hydrogen ion concentration corrected for entered patient temperature
pH (T)	pH value corrected for entered patient temperature
$pCO_2 (T)$	pCO_2 corrected for entered patient temperature
$pO_2 (T)$	pO_2 corrected for entered patient temperature
$HCO_3^- \text{act}$	Bicarbonate ion concentration
$HCO_3^- \text{std}$	Bicarbonate ion concentration normalized to a pCO_2 of 40mmHg
BB (B)	Buffer base
BE (B)	Base excess (B)
BE (ecf)	Base excess (ecf)
ct CO_2	Total carbon dioxide
$Ca^{++} (7.4)$	The ionized calcium concentration of blood normalized to pH 7.4
AnGap	An approximation of the difference between measured cations and measured anions in the sample
tHb (est)	An estimation of the hemoglobin contained in the sample
sO_2 (est)	An estimation of hemoglobin oxygen saturation: a ratio of the amount of hemoglobin bound to oxygen to the total amount of hemoglobin able to bind oxygen
$pO_2 (A-a)$	Alveolar-arterial oxygen tension difference
$pO_2 (A-a) (T)$	Alveolar-arterial oxygen tension difference corrected for entered patient temperature
$pO_2 (a/A)$	Arterial-alveolar oxygen tension ratio
$pO_2 (a/A) (T)$	Arterial-alveolar oxygen tension ratio corrected for entered patient temperature

RI	Respiratory index: the ratio of the alveolar-arterial blood oxygen-pressure difference to arterial pO_2
RI (T)	Respiratory index: the ratio of the alveolar-arterial blood oxygen-pressure difference to arterial pO_2 when both values are corrected for patient temperature
pO_2/FIO_2	The ratio of arterial pO_2 to the fraction of inspired oxygen
$pO_2(T)/FIO_2$	The ratio of arterial pO_2 to the fraction of inspired oxygen corrected for the entered patient temperature

Configuration: main unit, printer, scanner, and simulator.

2.2 System Frame



◆ Blood Gas and Chemistry Analyzer

The Blood Gas and Chemistry Analyzer is an electronic instrument which is used to analyze whole blood samples (measuring blood gases, electrolytes, metabolites, and hematocrit). The analyzer can:

- Scan bar codes of test cartridges, calibrant fluid packs, controls, patient and operator ID, etc.
- Identify the types of test cartridges.
- Control the flow of fluids.
- Maintain sample temperature at 37°C.
- Measure the ambient barometric pressure and ambient temperature.
- Measure electrical signals generated by chemical sensors and biosensors.
- Analyze and display the concentrations of analytes in whole blood samples.
- Transmit test results to the Data Management System (DMS).

- Store all kinds of test results and data, such as patient sample results, control test results, proficiency test results, simulator test results, etc.
- Animatedly demonstrate the operating process.

◆ Data Management System (DMS)

DMS refers to a computer which is loaded with the data management software. With the DMS, you can:

- Enter test application data.
- Edit patient information, view, check and print test results.
- View, check and print quality control (QC) test results.
- Search for patient test results by patient name, patient ID, date and time, department, etc.
- Calculate the amount of work of a physician, the results for a parameter of a patient during a period, the test times and the fee of a parameter, and print the statistics results.
- Set the following items: operator, department, sample status, printing, bar code, etc.
- Backup and restore data, view logs.
- View data for instrument diagnosis.
- Import patient information from LIS/HIS.
- Manage up to 20 analyzers simultaneously, storing test results transmitted by analyzers.

NOTE:

Sample ID should be different on analyzers connecting to the same DMS.

◆ HIS/LIS

HIS/LIS transmits patient information to the DMS.

2.3 Analyzer Appearance



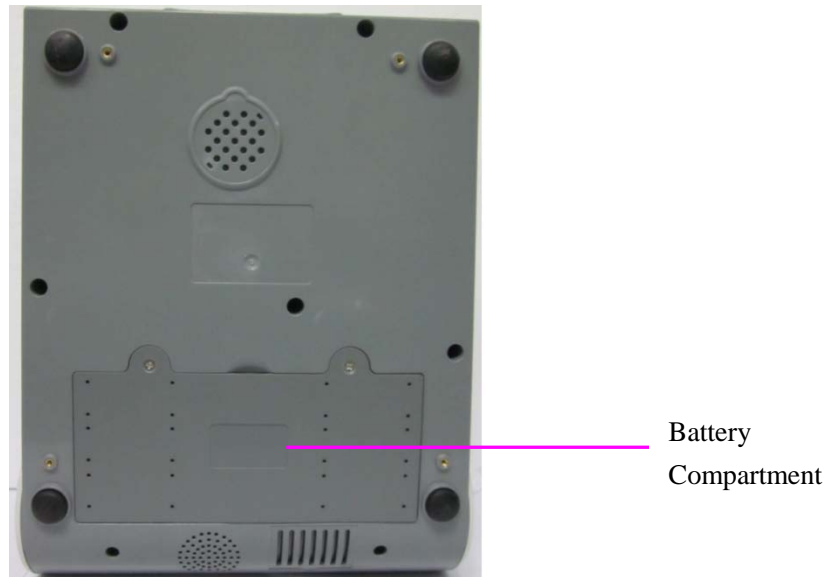


Figure 2-1 Analyzer Major Components

2.4 System Parts

2.4.1 Thermal Printer

The thermal printer is located at the upper left top of the analyzer. It can print patient sample test results, quality control test results, calibration results, etc.

2.4.2 Test Cartridge

Next to the thermal printer is the test cartridge port. A test cartridge is inserted into the analyzer through the test cartridge port. An indicator is located inside the test cartridge port. If the test cartridge is inserted properly, the indicator will turn green. If not, the indicator will turn red, and the system will prompt you. If you want to perform an external electronic simulator test, you also need to insert the simulator into the test cartridge port.

The unit-use test cartridge is intended to be used together with the analyzer. The fluidic chamber on the test cartridge is used to hold used calibrants and sample fluids. The sensors on the test cartridge can generate electrical signals that can be measured by the analyzer. The sample fillport is used to connect the syringe/capillary tube for automatically aspirating samples. Test cartridges are available in different configurations concerning the type of parameters reported by them. For details, please refer to the table below.

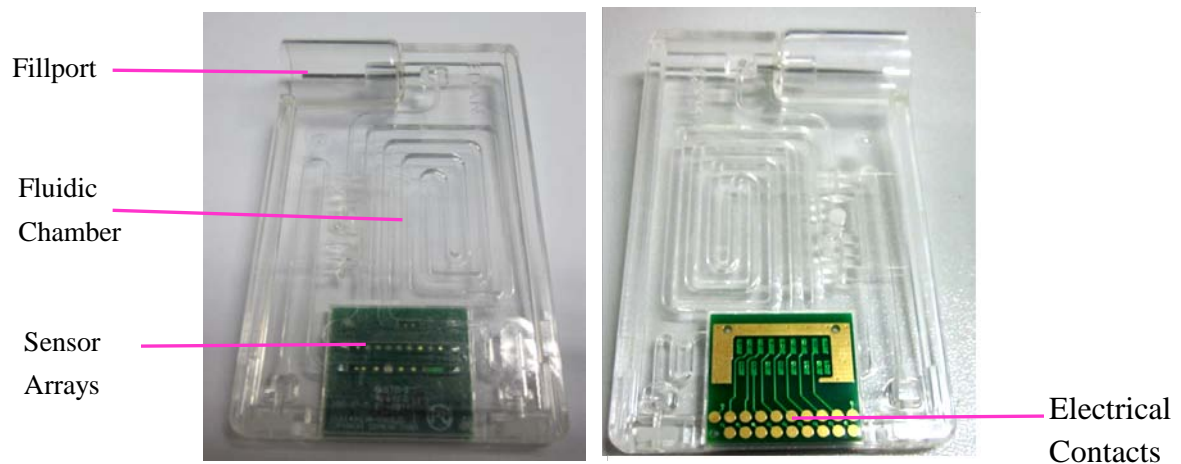


Figure 2-2 Test Cartridge

Table 2-1 Test Cartridge Types

Cartridge Type	Measured Parameters	Calculated Parameters
BG8	pH, $p\text{CO}_2$, $p\text{O}_2$, Na^+ , K^+ , Cl^- , Ca^{++} , Hct	cH^+ , HCO_3^- act, HCO_3^- std, BE (ecf), BE (B), BB (B), ct CO_2 , $s\text{O}_2$ (est), Ca^{++} (7.4), AnGap, tHb (est), $p\text{O}_2$ (A-a), $p\text{O}_2$ (a/A), RI, $p\text{O}_2/\text{FIO}_2$, cH^+ (T), pH (T), $p\text{CO}_2$ (T), $p\text{O}_2$ (T), $p\text{O}_2$ (A-a) (T), $p\text{O}_2$ (a/A) (T), RI (T), $p\text{O}_2$ (T)/ FIO_2
BG3	pH, $p\text{CO}_2$, $p\text{O}_2$	cH^+ , HCO_3^- act, HCO_3^- std, BE (ecf), BE (B), BB (B), ct CO_2 , $s\text{O}_2$ (est), $p\text{O}_2$ (A-a), $p\text{O}_2$ (a/A), RI, $p\text{O}_2/\text{FIO}_2$, cH^+ (T), pH (T), $p\text{CO}_2$ (T), $p\text{O}_2$ (T), $p\text{O}_2$ (A-a) (T), $p\text{O}_2$ (a/A) (T), RI (T), $p\text{O}_2$ (T)/ FIO_2

Packaging

1. The type of the cartridge is labeled on the test cartridge.
2. Each test cartridge is sealed in a foil pouch containing a strip of desiccant.
3. The bar code on the foil pouch contains information such as the cartridge type, lot number and expiration date, etc.
4. 25 test cartridges are packaged per box, and 4 boxes are packaged into a shipping carton.

Storage and Usage

Test cartridges should be stored at 4 - 30°C, and should be used at 10 - 31°C with the relative humidity of 25% - 80% (non-condensing).

Disposal



The sample is contained in the test cartridge, so test cartridges should be disposed of as biohazardous waste, complying with local regulatory guidelines.

NOTE:

- ✓ If the pouch has been damaged, the test cartridge should not be used.
- ✓ Only test cartridges provided by EDAN or its authorized distributors should be used.
- ✓ Only test cartridges properly stored should be used.
- ✓ Never reuse test cartridges.
- ✓ Never touch the fillport or electrical contacts of a test cartridge.
- ✓ Use test cartridges before their expiration date as labeled on the package, and use them immediately after removing them from their pouches.
- ✓ Test cartridges should be kept out of direct sunlight and heat.
- ✓ The analyzer, test cartridges and the testing environment should be at the same temperature prior to a test.
- ✓ Test cartridges should not be dropped or stressed.

2.4.3 Power Indicator

The power indicator is on the lower left bottom of the analyzer. During the operation you can see one of the following:

- Green Light: The analyzer is on and the power supply is normal. The analyzer can be powered either by the rechargeable lithium battery or AC power. Or the system is off and has been connected to AC power.
- Blinking Yellow Light: The power is supplied by the rechargeable lithium battery and the battery is low.
- Yellow Light: The rechargeable lithium battery is being charged.

2.4.4 LCD Screen and Touch Screen

The activities of the analyzer are communicated to you through the LCD screen, displaying the analyzer activities, test results, database information, prompts, etc. You communicate with the analyzer through the touch screen which allows you to perform tests, make selections, enter data, and view information, etc.

2.4.5 I/O Ports

On the left side of the analyzer are I/O ports:




USB Interfaces (4): allow you to connect your analyzer with peripherals such as scanners, printers, etc.

Serial Port: allows engineers from the factory to perform debugging.

Network Port: allows network connection to the DMS.

2.4.6 On/Off Button

The **On/Off** button  is on the left side of the analyzer.

2.4.7 Calibrant Fluid Pack

The calibrant fluid pack chamber is on the right side of the analyzer. You can install the calibrant fluid pack in it for sensor calibration. The calibrant fluid pack ejector beside the door is used to open the chamber door. On the calibrant fluid pack ejector is a calibrant fluid pack chamber lock to help users close the calibrant fluid chamber door securely.

A calibrant fluid pack containing calibrant solutions is intended to be used together with the analyzer to perform one-point sensor calibration. Calibrant fluid packs are available for 100 and 200 sampling operations. Contact EDAN or its authorized distributors to order calibrant fluid packs for your system.



Figure 2-3 Calibrant Fluid Pack

Packaging

1. The calibrant fluid pack is sealed in a foil pouch filled with protective gases.
2. The bar code on the foil pouch contains information such as the lot number and expiration date.
3. Each calibrant fluid pack is packaged into a box, and 6 boxes are packaged into a shipping carton.

Storage and Usage

Calibrant fluid packs should be stored at 2 - 8°C (avoid freezing) with the ambient pressure of 65 - 106.6kPa, and should be used at 10 - 31°C with the relative humidity of 25% - 80% (non-condensing). The calibrant fluid pack expires 30 days after its installation or after exceeding the labeled expiration date, whichever comes first. The remaining days and usages are displayed on the status bar at the bottom of the screen.


NOTE:

- ✓ If the pouch has been damaged or there is any leakage, the calibrant fluid pack should not be used.
- ✓ Only those calibrant fluid packs provided by EDAN or its authorized distributors should be used.
- ✓ Use calibrant fluid packs before their expiration date as labeled on the package.
- ✓ A calibrant fluid pack is intended for single use only. If a calibrant fluid pack is removed from the system, it cannot be inserted into the system again.

2.4.8 Bar Code Scanner

On the same side as the calibrant fluid pack chamber is the built-in scanner for scanning bar codes on test cartridges, calibrant fluid packs, controls, operator ID, patient ID, sample ID, etc. The analyzer can also be connected to external scanners as mentioned in 2.4.11.

Follow the steps below to scan a bar code:

1. Press **Scan Barcode** or  to activate the bar code scanner, and the scanner will emit a red beam.
2. Align the bar code with the red beam so that the red beam covers the whole bar code.

NOTE:

The distance between the analyzer and the bar code should be 6 - 15cm.

3. If the bar code is scanned successfully, the analyzer will beep and automatically turn off the scanner.
4. If the scanned data is valid, the system will display the screen for the next procedure. If the scanned data is invalid, a message will pop up to prompt you.

CAUTION

1. In order to avoid injury, never look into the red beam.
 2. To avoid damage, never scratch the protective glasses of the scanner with hard objects.
 3. To avoid damage and injury, never strike the protective glasses of the scanner.
 4. To avoid unsuccessful scanning, clean the scanner with a lint-free cloth when there is visible dirt.
-
-

2.4.9 Exhaust Fan

The exhaust fan is located at the rear of the analyzer to prevent the analyzer from overheating. When the analyzer temperature is over preset threshold, the fan will be automatically turned on.

NOTE:

- ✓ Make sure that the vents of the analyzer are not obstructed to ensure good ventilation.
- ✓ If the exhaust fan does not run properly, please contact EDAN or its authorized distributors for assistance.

2.4.10 Electronic Simulator

Electronic simulators are quality control devices for checking the analyzer's ability to take accurate measurements of voltage, current and conductivity from test cartridges.

Internal Electronic Simulator

Internal electronic simulator is self-contained in the analyzer for automatically conducting simulator tests at the preset frequency.

External Electronic Simulator

Users can run the external electronic simulator test according to their own needs, and EDAN recommends that users run it every 24 hours. Each external electronic simulator is packaged separately. When you have doubt about the reliability of test results, you can run the external electronic simulator test to help troubleshoot.

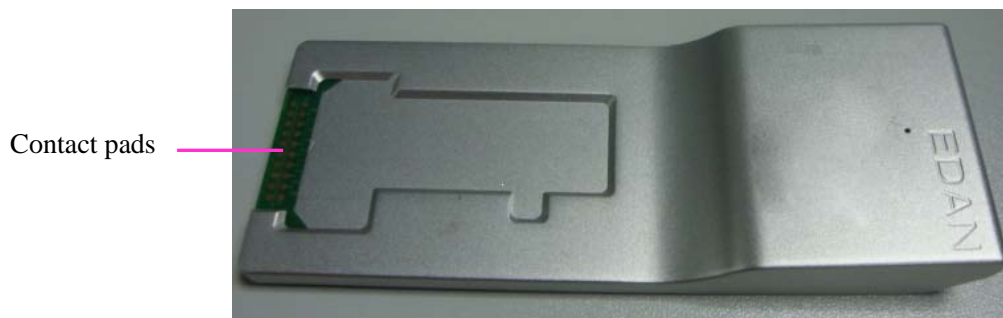


Figure 2-4 External Electronic Simulator

If the contact pads have been contaminated, please clean the external electronic simulator.

Follow the steps below to clean the external electronic simulator:

1. Moisten a lint-free cloth with 100% alcohol;
2. Wipe the external electronic simulator with the lint-free cloth.

NOTE:

- ✓ Never immerse the simulator into any liquids.
- ✓ The cloth should be wet but not dripping.

2.4.11 Peripherals

Only the following external scanners should be connected to the analyzer through USB ports: Honeywell 1900.

Only the following external printers should be connected to the analyzer through USB ports: HP LaserJet P401DN, and HP LaserJet P1606DN.

NOTE:

- ✓ Only peripherals recommended by EDAN should be connected to the analyzer.
- ✓ When connecting a Honeywell 1900 scanner to the analyzer, the scanner should be set.

2.5 Configuration

2.5.1 Standard Configuration

- ◆ i15 analyzer
- ◆ 1 power cable
- ◆ 1 power adaptor
- ◆ 4 printer paper
- ◆ 1 rechargeable lithium battery
- ◆ 1 user manual
- ◆ 1 warranty card
- ◆ 2 packing lists

2.5.2 Options

- ◆ Test cartridges
- ◆ Calibrant fluid pack
- ◆ External electronic simulator
- ◆ Capillary adaptor
- ◆ Controls
- ◆ Data management system software
- ◆ Honeywell 1900 scanner

Chapter 3 Installation Guide

3.1 Unpacking Inspection

Visually examine the package prior to unpacking. If there are any signs of mishandling or damage, contact the carrier to claim for damage. After unpacking the device, customers should follow the PACKING LIST to check the product carefully and to make sure no damage occurred during transportation. Then, install the device according to the installation requirements and procedures. If there is any problem, contact the manufacturer or its authorized distributors immediately.

WARNING

DO NOT use the analyzer if it is damaged or defective.

NOTE:

Keep the package for future transportation or for storage.

3.2 Installation Requirements

3.2.1 Environmental Requirements

Location is of great importance for the smooth running of your analyzer. Prior to installing the analyzer, choose a site that meets the following requirements:

- Convenient for the analyzer to be connected to a grounded electrical receptacle in case it is powered by AC power.
- Keep the analyzer away from direct exposure to strong sunlight.
- Ambient Temperature between 10°C and 31°C.
- Relative Humidity of 25% - 80% (non-condensing).
- Ambient Pressure within 70 - 106.6kP (525 - 800mmHg).
- Placed onto a clean and flat surface with good ventilation.
- Keep the analyzer away from equipment with strong electric field and strong magnetic field.
- Keep the analyzer away from explosive gases or vapors.

NOTE:

The requirements above also apply when your analyzer is powered by a rechargeable lithium battery.

3.2.2 Power Requirements

The analyzer needs to be connected to a grounded electrical outlet with the voltage between $100\pm 10\%$ VAC - $240\pm 10\%$ VAC and the frequency of 50/60Hz.

3.3 Setting Up

Now you can prepare your analyzer for operation.

First, please place the analyzer on a secure table surface with environments that meet the requirements as described in section 3.2.

3.3.1 Connecting to AC Power

1. Insert the power adaptor into the power connector on the analyzer.
2. Plug the power cord into the power adaptor.
3. Plug the power cord into a grounded electrical outlet.

NOTE:

- ✓ Make sure the power requirements as described in 3.2.2 are met.
- ✓ To avoid the analyzer and other electronic devices being damaged by electrical power spikes, a surge protector is recommended.

3.3.2 Installing the Battery

WARNING

Switch off the analyzer and unplug it before installing or removing the battery.

If the analyzer is powered by a rechargeable lithium battery, please install the battery first.

◆ Battery Installation

Follow the steps below to install the battery:

1. Turn off the analyzer, disconnect the power supply, and remove the power adaptor and other connecting cables.
2. Place the analyzer upside down on a flat surface covered with cloth or another type of protecting pad.
3. Remove the screws of the battery compartment using a cross-head screw driver, and then

remove the battery compartment cover.



4. Take the battery out from its package and put it into the compartment. Make sure the battery connector is on the right and the battery label faces down. Install the battery into the compartment.



WARNING

Do not touch the battery connector with fingers or metallic materials, to avoid the hazards posed by the short-circuit to you and the battery.

5. Arrange the battery flat in the compartment, and push the strip at the end of the battery into the gap.



6. Shut the battery compartment cover and secure it with the screws.

◆ Battery Removal

Remove the battery in reverse order. You can pull the strip at the end to take the battery out from the compartment.

NOTE:

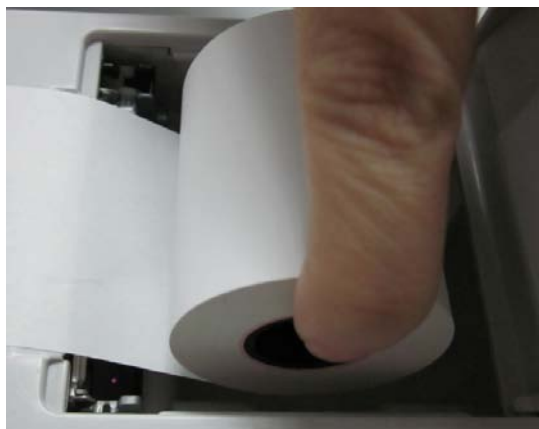
- ✓ The battery needs to be charged prior to using it.
- ✓ Only those batteries supplied by EDAN or its authorized distributors should be used with the analyzer.
- ✓ When the analyzer is powered by the battery and the battery is low, the system will prompt you to connect the analyzer to an external power outlet. At the same time, the battery indicator icon on the status bar at the bottom of the screen will also blink.
- ✓ The battery will automatically be charged whenever the analyzer is connected to an electrical outlet.

3.3.3 Installing the Printer Paper

The analyzer utilizes rolled thermal paper with the width of 50mm. When the printer paper runs out during the printing or is not loaded, the warning message “*Paper?*” will appear on the screen. Then you should load or replace the printer paper immediately.

◆ Procedures for Loading Rolled Thermal Paper

1. Open the casing.
2. Gently place the paper in the paper tray with the outside of the paper facing the thermal print head.



3. Pull about 2 cm of paper out and shut the printer casing.

◆ Procedures for Replacing Rolled Thermal Paper

The procedures for replacing rolled thermal paper is almost the same as loading rolled thermal paper, except that you need to remove the remained rolled thermal paper prior to step 2.

CAUTION

1. Only use the printer paper provided by EDAN or its authorized distributors, otherwise the printer may be damaged. This kind of damage is not covered by warranty.
2. Do not touch the thermosensitive print head or the paper sensor by hand, in case they are damaged by static electricity.

NOTE:


Unless when replacing paper or troubleshooting, do not leave the printer casing open.

3.3.4 Turning On/Off the Analyzer


NOTE:

Make sure that all the cables are securely connected before you turn on the analyzer.

◆ Turn On the Analyzer

Press the **On/Off** button  on the left side of the analyzer to turn it on.

◆ Turn Off the Analyzer

1. Press  on the bottom left of the screen, the following message will pop up:

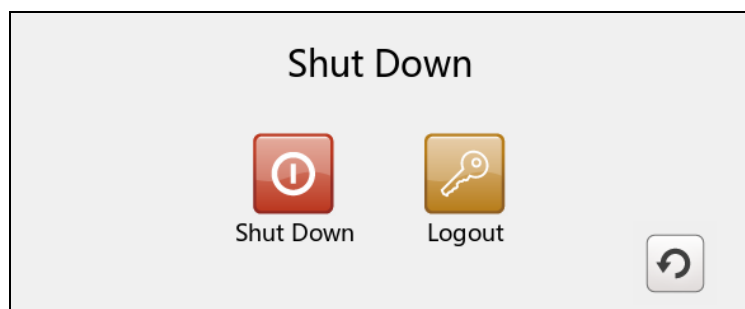


Figure 3-1 Turn Off Analyzer


2. Press , and press **OK** in the pop up dialog box.


NOTE:

Never turn off the system when it is performing tests or printing data.

3.3.5 User Login and Logout

◆ User Login

1. Press the **On/Off** button on the left hand side of the analyzer to turn it on.
2. Enter the user name and password manually, and press .

To enter the user name with the bar code scanner, press  first, and then scan the user name bar code.

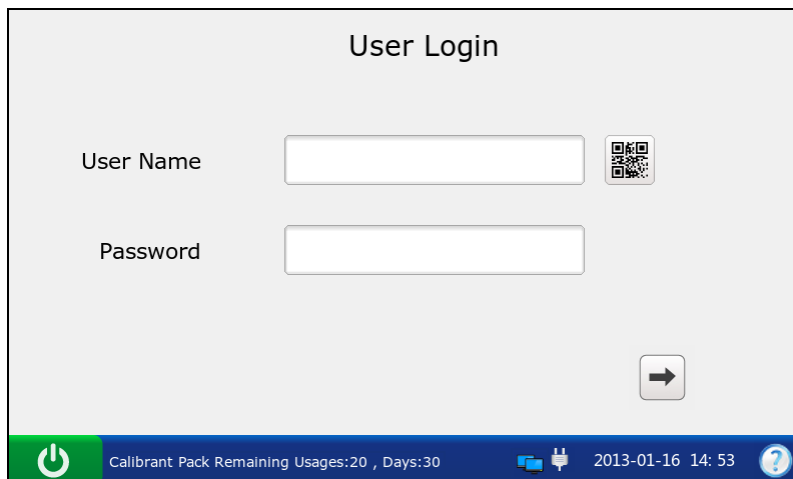



Figure 3-2 Enter User Name and Password

◆ User Logout

1. Press  on the bottom left of the screen, the following message will pop up:

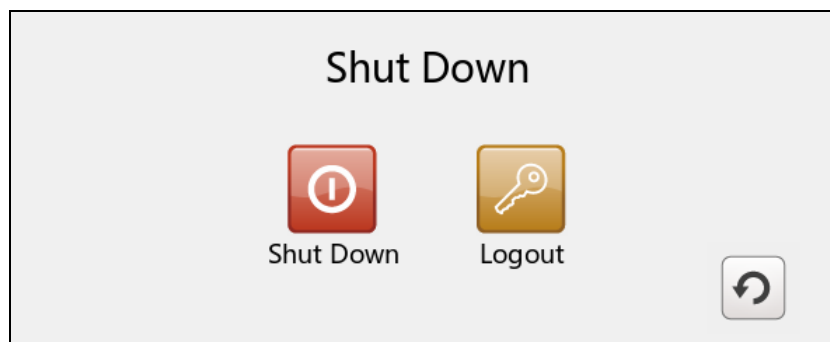





Figure 3-3 User Logout

2. Press , and press **OK** in the pop up dialog box. The system will go to the User Login screen. Enter a user name and password to change users.

NOTE:

Never log out of the system when it is performing tests or printing data.

3.3.6 Setting the Date and Time

1. On the Main screen, press  to access the System Setup screen.
2. Press  to access the Date & Language Setup screen.
3. Select the desired date and time, and press **OK** in the pop up dialogue box.
4. Press **OK** to accept the changes.
5. Press **Return** to return to the Main screen.


CAUTION

1. Make sure the current date and time of the system are correct, or it may cause misdiagnosis.
2. Changing date and time directly affects date and time saved with each test data.

3.4.7 Viewing Training Videos

The system has training videos for guiding your operations.

Follow the steps below to view training videos:

1. Press  on the bottom right of the screen to access the Help screen.

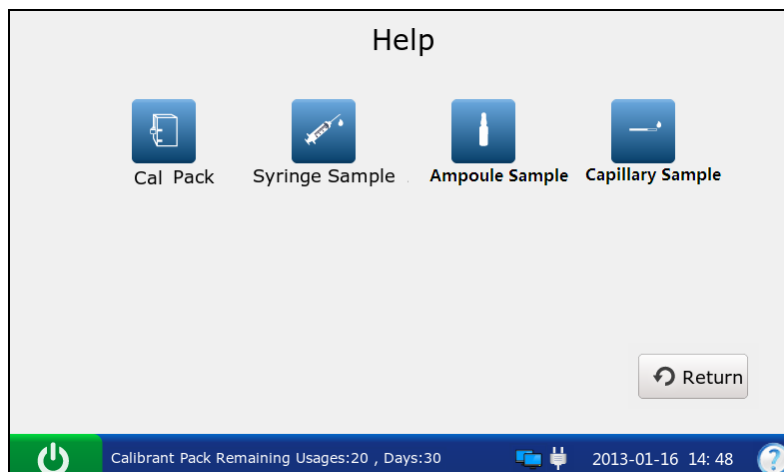






Figure 3-4 Help Screen

2. Press  to view the video for replacing a calibrant fluid pack.
3. Press  to view the video for analyzing syringe samples.
4. Press  to view the video for analyzing ampoule samples.



5. Press  to view the video for analyzing capillary samples.
6. Press **Return** to go back to the Main screen.

3.4.8 Replacing a Calibrant Fluid Pack

WARNING

1. The replacement of a calibrant fluid pack should be performed only when the analyzer is on.
2. A calibrant fluid pack is intended for single use only. If a calibrant fluid pack is removed from the system, it can not be inserted into the system again.

Follow the steps below to replace a calibrant fluid pack:

1. Examine the expiration date on the package of a calibrant fluid pack to ensure it has not expired.
2. Remove the calibrant fluid pack from its package, and equilibrate it to room temperature. The calibrant fluid pack needs to stand at room temperature for at least 24 hours.
3. Wipe any moisture from the foil pouch with a dry clean cloth.
4. On the Main screen, press  to go to the System Setup screen.
5. Press . The system will go to the screen below:

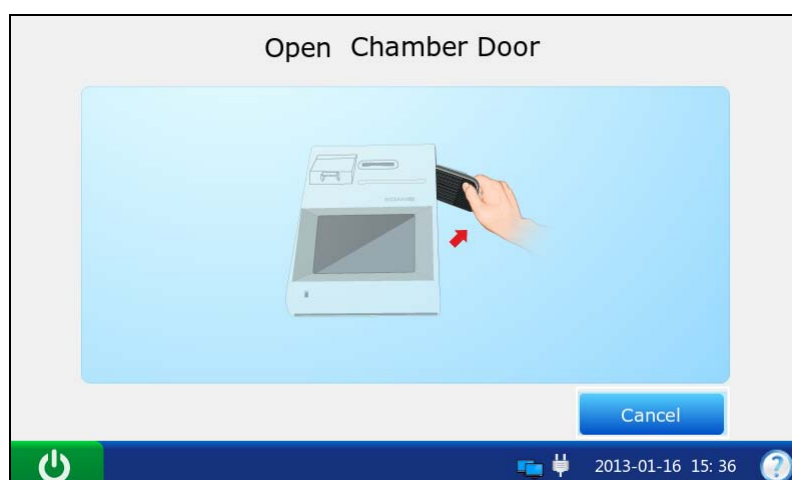


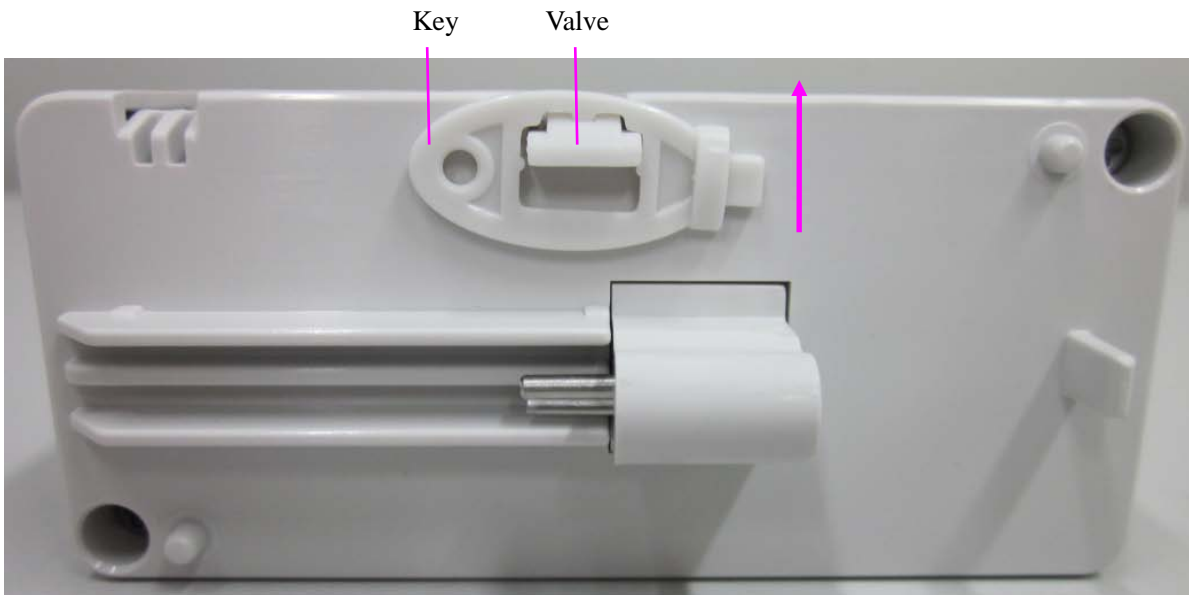
Figure 3-5 Open Chamber Door

6. Open the foil pouch, and remove the calibrant fluid pack from it.

NOTE:

Avoid tearing the bar code on the foil pouch.

7. Remove the calibrant fluid pack cap, and remove the key by pushing it with your finger in the direction as shown by the arrow in the picture below.

**NOTE:**

Avoid pushing the valve when removing the key.

8. Unlock the calibrant fluid pack chamber lock with the key, and then pull the calibrant fluid pack ejector to open the calibrant fluid pack chamber door.
9. Remove the used calibrant fluid pack from the system. The system will go to the screen for the next procedure, and the scanner will be turned on automatically.

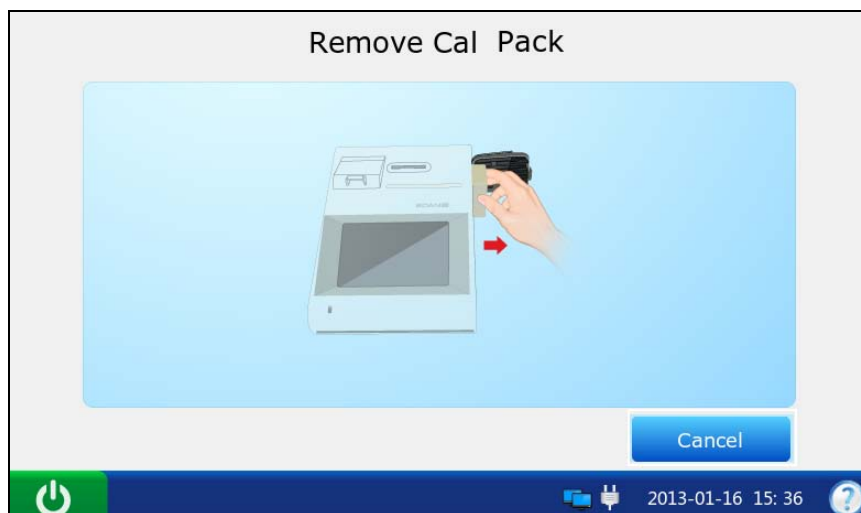



Figure 3-6 Remove Old Calibrant Fluid Pack

10. Scan the bar code on the new calibrant fluid pack foil pouch with the bar code scanner.

If the bar code is scanned successfully, the system will beep and the scanner will be turned off automatically. If the scanned data is valid, the system will display the screen for the next procedure. If the scanned data is invalid, a message will pop up to prompt you.

If the scanner is turned off automatically, press  first, and then scan the bar code.

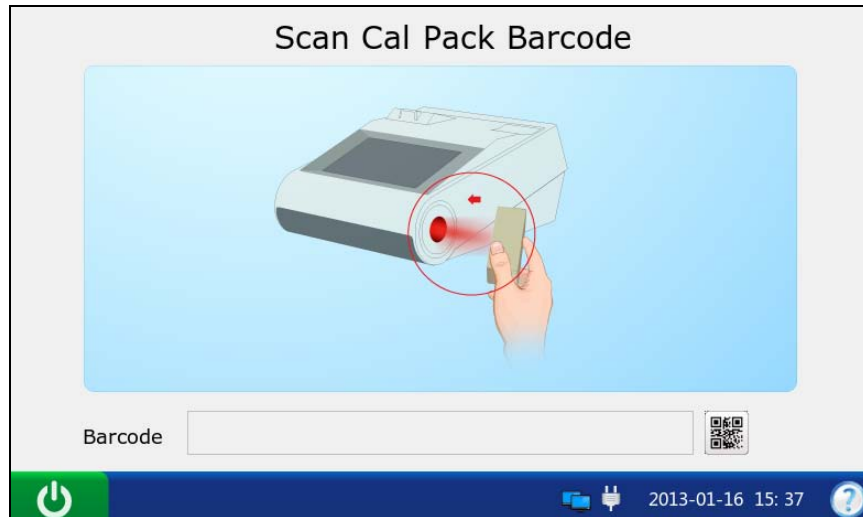


Figure 3-7 Scan Bar Code

11. Insert the new calibrant fluid pack into its chamber, and push it gently to make sure that it clicks into place. The system will go to the screen for the next procedure.

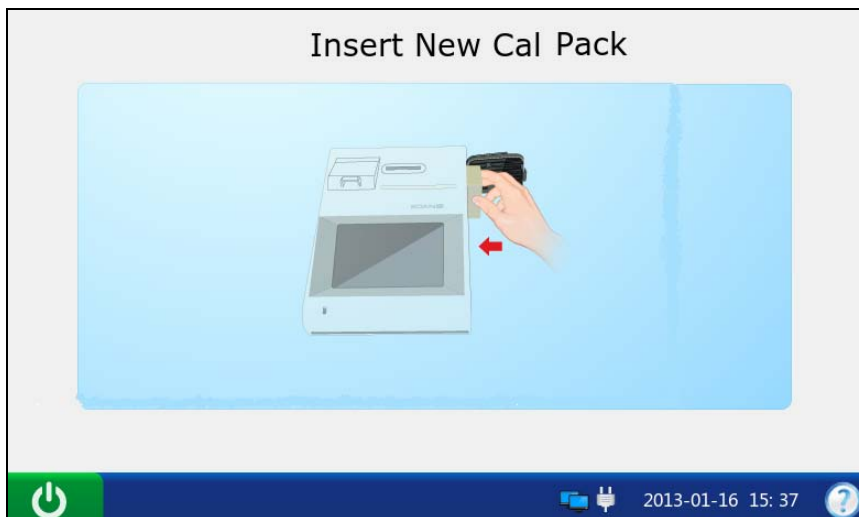


Figure 3-8 Install Calibrant Fluid Pack

12. Close the chamber door.



Figure 3-9 Close Chamber Door

13. Lock the calibrant fluid pack chamber lock to close the chamber door securely.

14. Press **OK** in the pop up message. The system will then go to the Main screen.

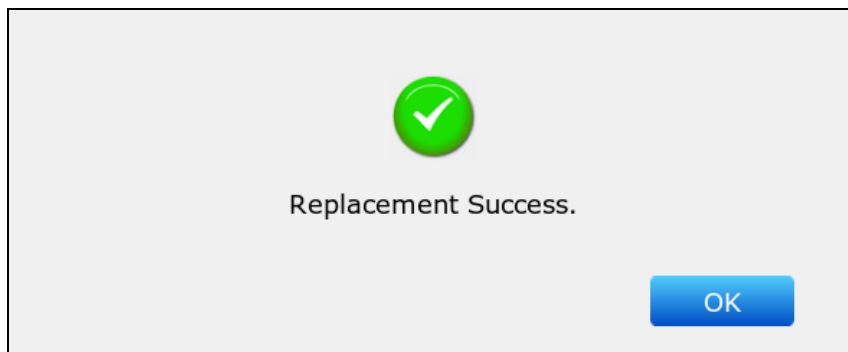


Figure 3-10 Replacement Success

NOTE:

- ✓ Always follow the proper procedures to replace a calibrant fluid pack, or else the system will not run smoothly, and the following message will pop up:

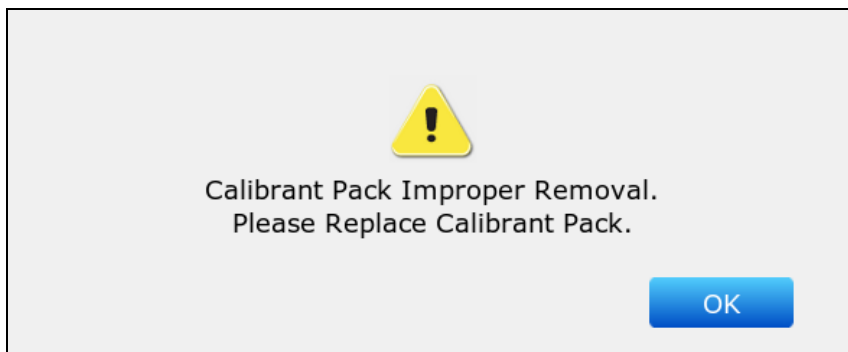


Figure 3-11 Calibrant Fluid Pack Improper Removal

- ✓ If the bar code is not that of a calibrant fluid pack, the following message will pop up:

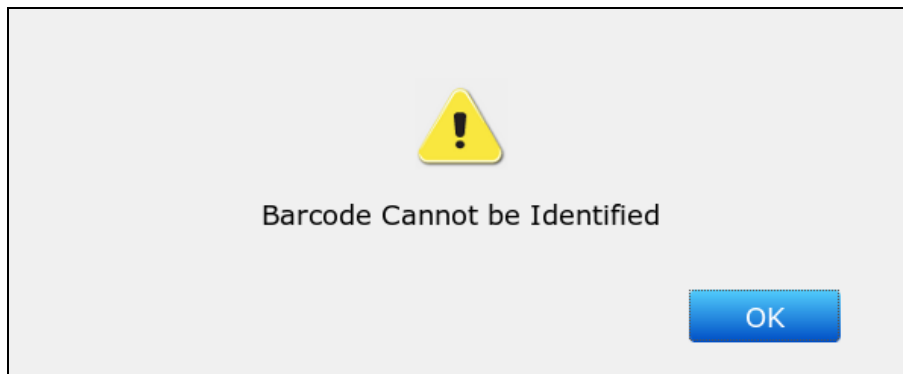


Figure 3-12 Unidentified Bar Code


- ✓ If the bar code is that of a used calibrant fluid pack or that of an expired calibrant fluid pack, the following message will pop up:



Figure 3-13 Calibrant Fluid Pack Can Not be Used

3.3.9 DEMO Test

The system can demonstrate the sample testing processes through animation. Follow the steps below to perform a DEMO test:

1. Logout of the system. The system will access the User Login screen.
2. Enter demo in both the user name and password fields, and then press . The system will go to the following screen:

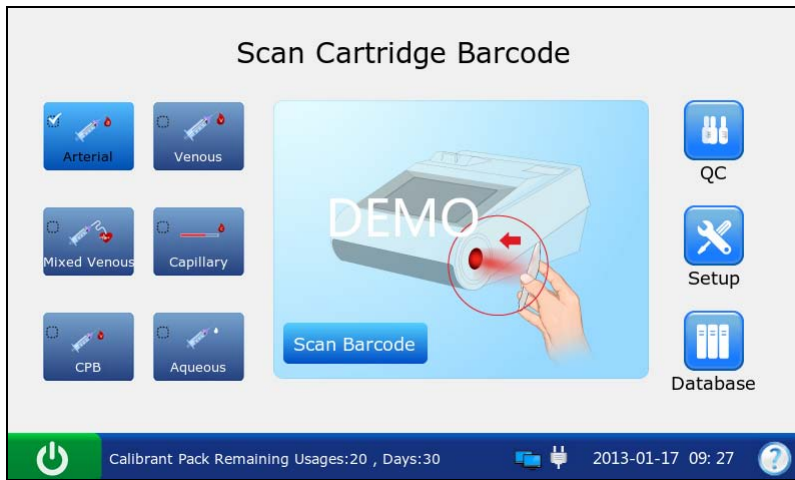


Figure 3-14 DEMO Test Screen 1

3. Press **Scan Barcode**.

4. Press **Next**.

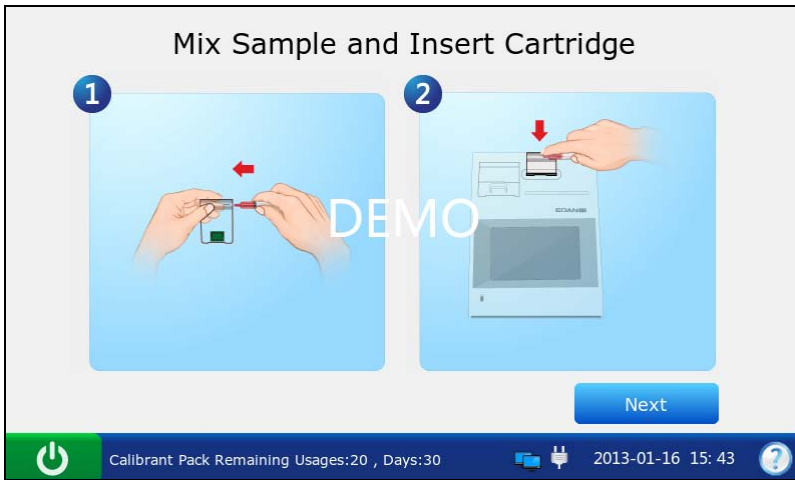


Figure 3-15 DEMO Test Screen 2

5. The system simulates aspirating calibrant.

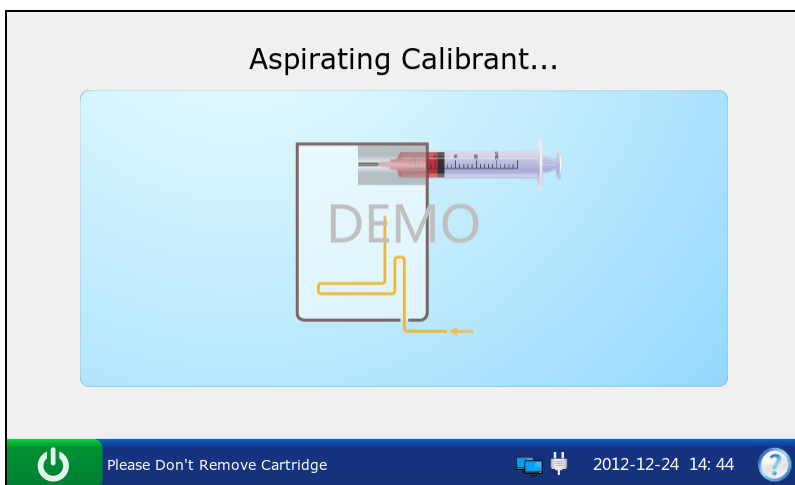


Figure 3-16 DEMO Test Screen 3

6. The system simulates calibration.

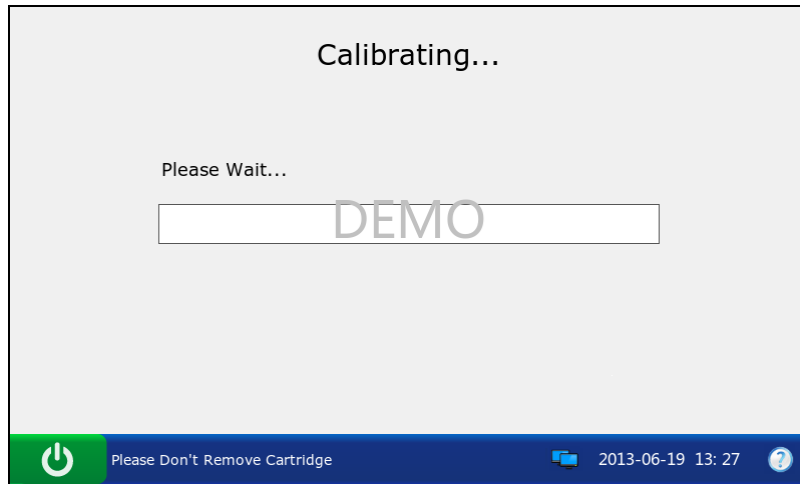


Figure 3-17 DEMO Test Screen 4

7. The system simulates sampling.

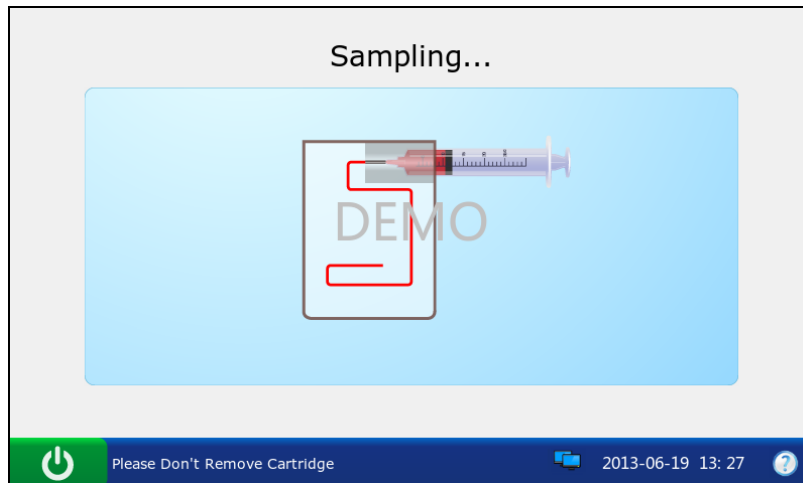


Figure 3-18 DEMO Test Screen 5

8. The system simulates testing.

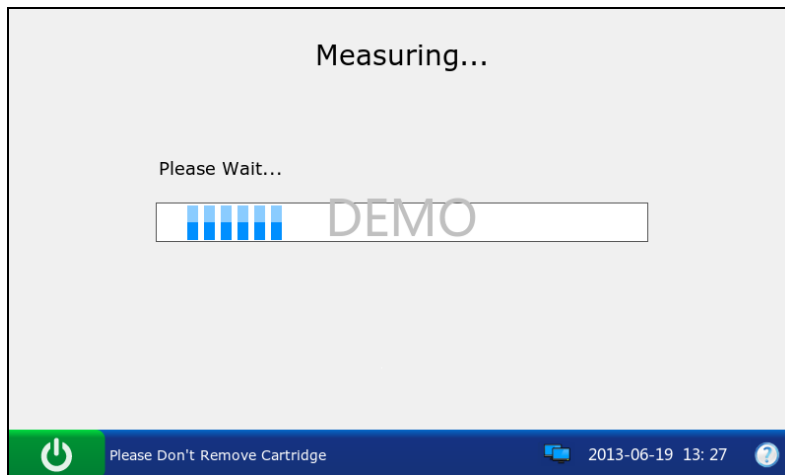
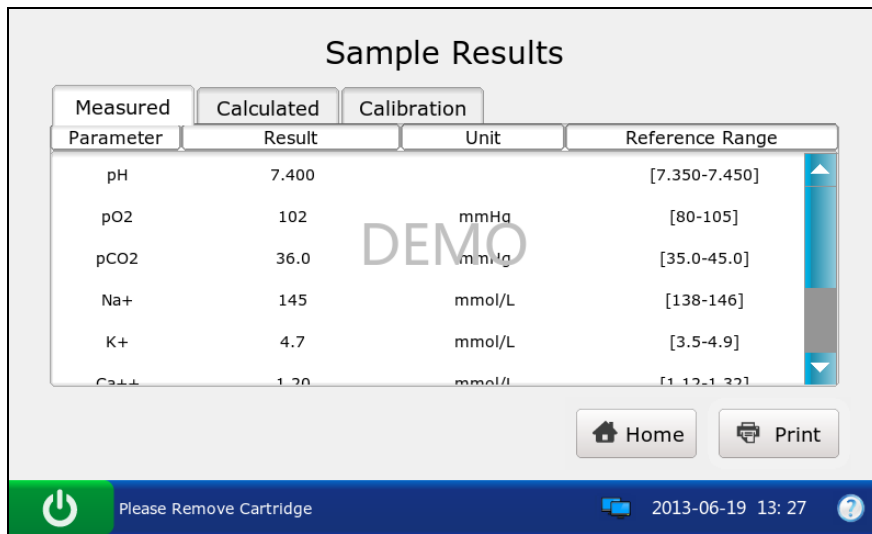


Figure 3-19 DEMO Test Screen 6

9. The system simulates displaying test results.



The screenshot shows a 'Sample Results' screen with a table of test results. The table has columns for 'Parameter', 'Result', 'Unit', and 'Reference Range'. The results are as follows:

Parameter	Result	Unit	Reference Range
pH	7.400		[7.350-7.450]
pO2	102	mmHg	[80-105]
pCO2	36.0	mmHg	[35.0-45.0]
Na+	145	mmol/L	[138-146]
K+	4.7	mmol/L	[3.5-4.9]
Ca++	1.20	mmol/L	[1.12-1.32]

Below the table are 'Home' and 'Print' buttons. At the bottom, there is a status bar with a power icon, the text 'Please Remove Cartridge', the date and time '2013-06-19 13:27', and a help icon. A large 'DEMO' watermark is overlaid on the table.

Figure 3-20 DEMO Test Screen 7

10. Press **Home** to return.

11. Follow the steps as described in 3.3.5 to logout of the system.

3.3.10 Connecting Peripherals

Connect peripherals with the system through USB ports, and make sure that the system meets the requirements in IEC60601-1-1.

NOTE:

- ✓ Only peripherals recommended by EDAN should be connected.
- ✓ Make sure that the whole system meets the requirements in IEC60601-1-1.

Follow the steps below to set a Honeywell 1900 scanner:

1. Connect a Honeywell 1900 scanner to the analyzer through a USB port.
2. Hold the scanner with your right hand, and trigger the scanner with your forefinger.
3. Scan the following bar codes in sequence.



1 DEFOVR.
Remove Custom Defaults



2 DEFAULT.
Activate Defaults



3 TERMID130.
USB Serial



4 232BAD9.
115,200



5 VSUFQR.
**Add CR Suffix
All Symbologies**

4. Use the scanner to scan a bar code of a test cartridge. If the bar code is successfully scanned, the scanner is successfully set.

Chapter 4 Setup


The system can be configured according to your clinical needs. The setup can only be done by authorized operators. You can perform the following setup with the Setup menu:

- Printer Setup
- Network Setup
- Date & Language Setup
- Backlight & Volume Setup
- QC Lockout Setup
- Patient Information Setup
- Reference Ranges Setup
- Units Setup
- Correlation Factors Setup
- Hct Setup

NOTE:

- ✓ Only administrators, service engineers and engineers from the manufacturer can get access to this function.
- ✓ The system will remember all the changes in setup even after the system is turned off.

4.1 Getting into the Setup Screen

1. Press the **On/Off** button on the left hand side of the analyzer to turn it on.
2. Enter the user name and password manually, and press .




To enter the user name with the bar code scanner, press  first, and then scan the user name bar code.



Figure 4-1 Enter User Name and Password

3. Press  on the Main screen, and the system will go to the Setup screen.

4.2 System Setup

The system displays the System Setup screen after pressing  on the Main screen by default. If you are now on the Test Setup screen, press **System Setup** to get to the System Setup screen.

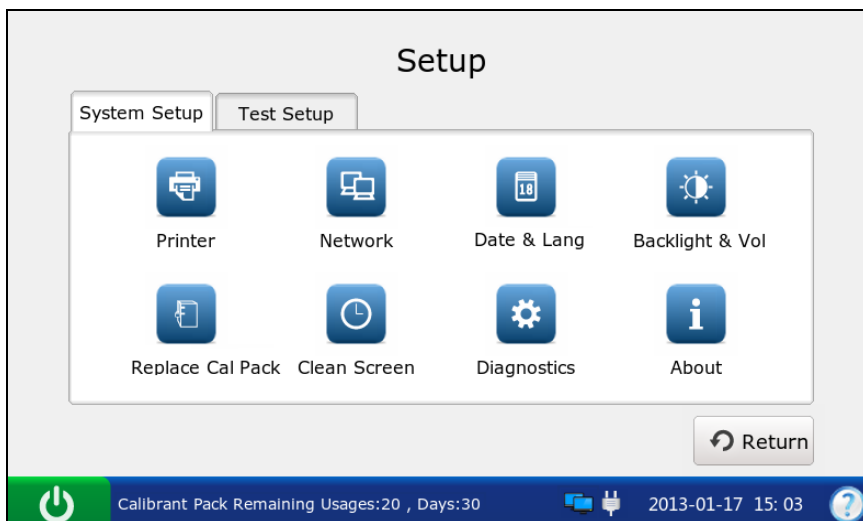



Figure 4-2 Setup-System Setup Screen

You can perform the following actions:

4.2.1 Printer Setup

This menu lets you configure the printer that the system uses, what are printed in reports, and the number of copies it prints.

Follow the steps below to set the printer:

1. Press  to access the Printer Setup screen.

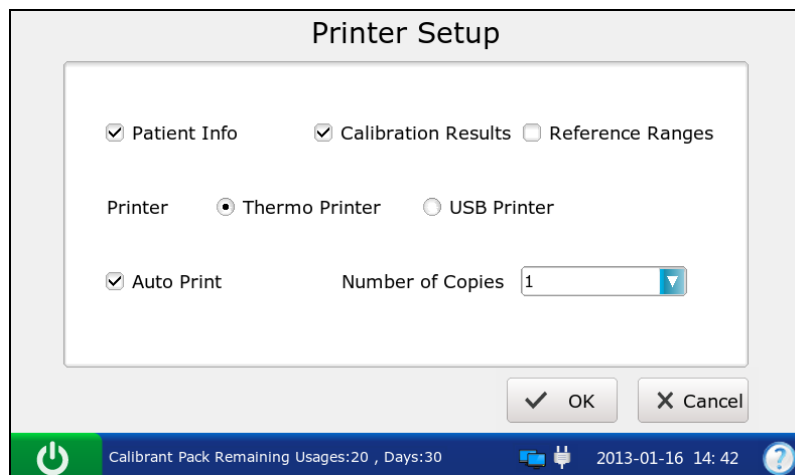



Figure 4-3 Printer Setup Screen

2. On the Printer Setup screen, you can:
 - Select whether to print patient information. The mark ✓ will appear if Patient Info is selected, and the default is to print patient information.
 - Select whether to print calibration results. The mark ✓ will appear if Calibration Results is selected, and the default is to print them.
 - Select whether to print reference ranges. The mark ✓ will appear if Reference Ranges is selected, and the default is to not print them. If Reference Ranges is selected, the reference ranges will be contained in the patient sample report, and the acceptable ranges will be contained in the control test report.
 - Select the printer to be used. There are two options: Thermo Printer and USB Printer. The default is Thermo Printer.
 - Select whether to turn on Auto Print. The mark ✓ will appear if Auto Print is turned on, and the default is to turn on Auto Print.
 - Select the number of copies. There are two options: 1 and 2. The default is 1.
3. Press **OK** to accept the changes, and the system will return to the System Setup screen.

4.2.2 Network Setup

This menu allows you to configure the communication methods, transmitting methods, and the manner that the analyzer is connected to the network.

Follow the directions below to configure the network:

1. Press  to access the Network Setup screen.
2. There are three tabs: Communication, Network, and WIFI.

◆ Network Setup

- 1) Press **Communication** to go to the Communication Setup screen.

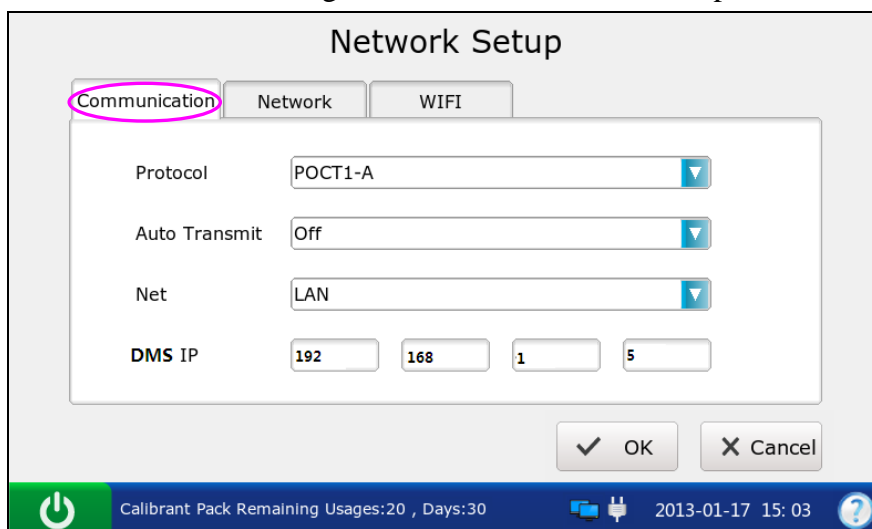


Figure 4-4 Network – Communication Setup Screen

- 2) On the Communication Setup screen, you can:
 - Select the communication protocols. There is only one option: POCT 1-A.
 - Select whether to transmit patient sample results automatically. There are two options: On and Off. If your selection is On, patient sample results will be transmitted automatically after each measurement. The default is On.
 - Select the communication methods. There are two options: Network and WIFI. The default is Network.
 - Enter the IP address of the DMS to which your analyzer is connected.
- 3) Press **OK** to accept the changes, and the system will return to the System Setup screen.

◆ Network Setup

- 1) Press **Network** to access the Network-Network Setup screen.

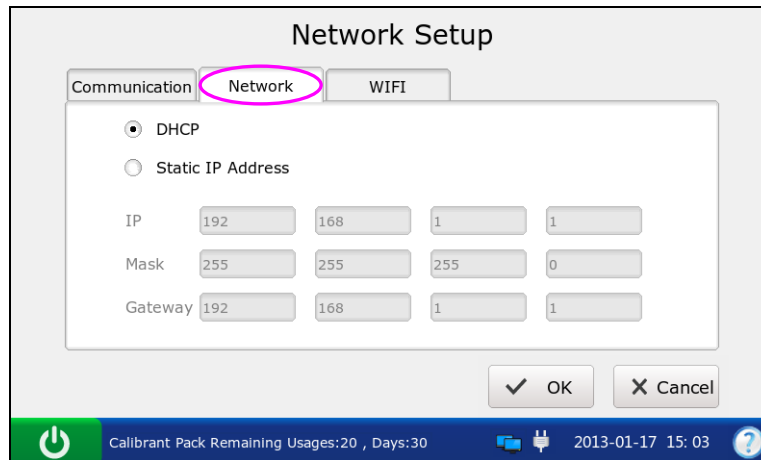


Figure 4-5 Network – Network Setup Screen

- 2) Select the way that the analyzer is connected to the network. There are two options: DHCP (dynamic host configuration protocol) and Static IP addresses. The Default is DHCP. If the latter one is selected, the following information should be entered: IP address, the default gateway, and the network mask.

NOTE:

- ✓ The static IP address should be in the same area network with the IP address of the DMS.
- ✓ IP addresses for analyzers connected to the same DMS should be different.
- ✓ Only when both the DMS and the analyzer have been connected to network successfully can the analyzer transmit data to the DMS.

- 3) Press **OK** to accept the changes, and the system will return to the System Setup screen.

◆ WIFI Connection

- 1) Press **WIFI** to access the WIFI Setup screen.



Figure 4-6 Network - WIFI Setup Screen

- 2) Press **Search WIFI**, the system will automatically search networks and display them. If the system displays Lock for the network password, it is necessary to enter its password to connect the system to it.
- 3) Press the network you want to connect, and press **Connect WIFI**.

NOTE:

The selected network should be in the same area network with that of the DMS.

- 4) Press **Return**, and the system will return to the System Setup screen.

4.2.3 Date & Language Setup

With this menu you can set the time and date, the date format, and the language the analyzer uses for displays and printouts.

Follow the instructions below to set the date and language:

1. Press  to go to the Date & Language Setup screen.

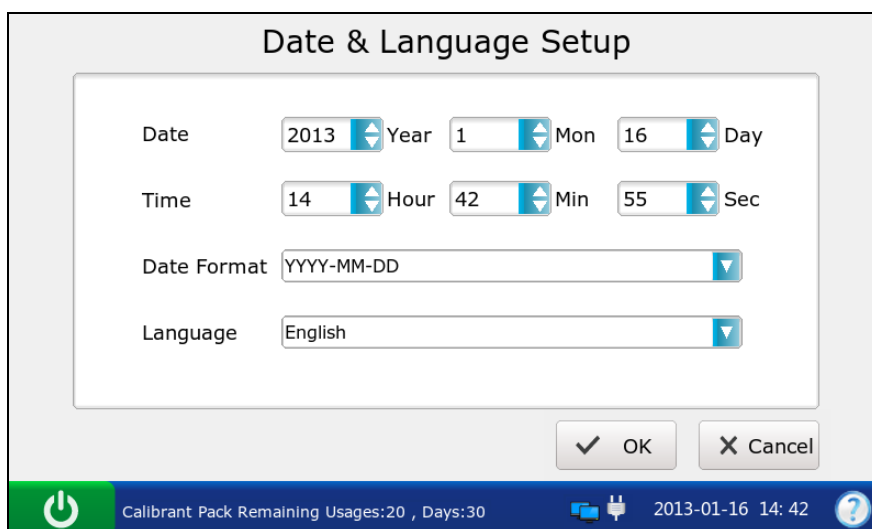


Figure 4-7 Date & Language Setup Screen

2. On the Date & Language Setup screen, you can:
 - Change the time and date of the system.
 - Select the date format. There are three formats: MM-DD-YYYY, YYYY-MM-DD and DD-MM-YYYY. The default is YYYY-MM-DD.
 - Select the language for displays and printouts. The options are: Simplified Chinese and English. The default language is English.
3. Press **OK** to accept the changes, and the system will return to the System Setup screen.

4.2.4 Backlight & Volume Setup

This menu allows you to define the idle time after which the backlight will be automatically turned off, the brightness of the backlight, the key tones and the volume.

1. Press  to go to the Backlight & Volume Setup screen.

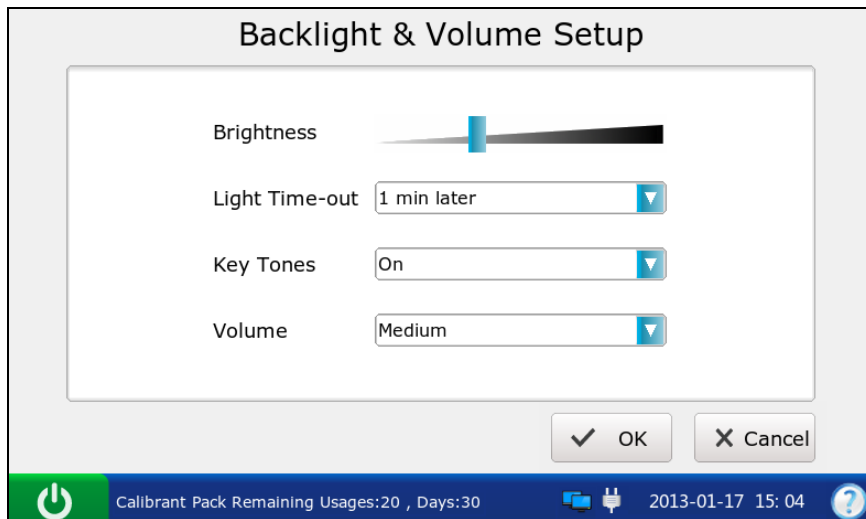


Figure 4-8 Backlight & Volume Setup Screen

2. On the Backlight Setup screen, you can:
 - Adjust the brightness of the backlight with the slider.
 - Select the idle time after which the backlight will be automatically turned off. The options are: never, 10 seconds, 1 minute, 3 minutes and 5 minutes. The default setting is 1 minute.

NOTE:

The system will enter standby mode after the backlight is turned off. Press the LCD screen to resume normal operation mode.

- Set the key tones. There are two options: On and Off. If On is selected, and the volume is not mute, the system will beep after each effective press.
 - Select the volume of the system. There are four options: High, Medium, Low and Mute. The default is Medium.
3. Press **OK** to accept the changes, and the system will return to the System Setup screen.

4.2.5 Diagnostics


This menu lets you diagnose some modules of the analyzer to check its operation. It helps to troubleshoot.

NOTE:

Only service engineers and engineers from the manufacturer can perform this action.

4.2.6 About the Analyzer

The system contains information about your analyzer which makes it convenient for you to know more about your analyzer and call for technical assistance if necessary.

1. Press  to go to the About screen.

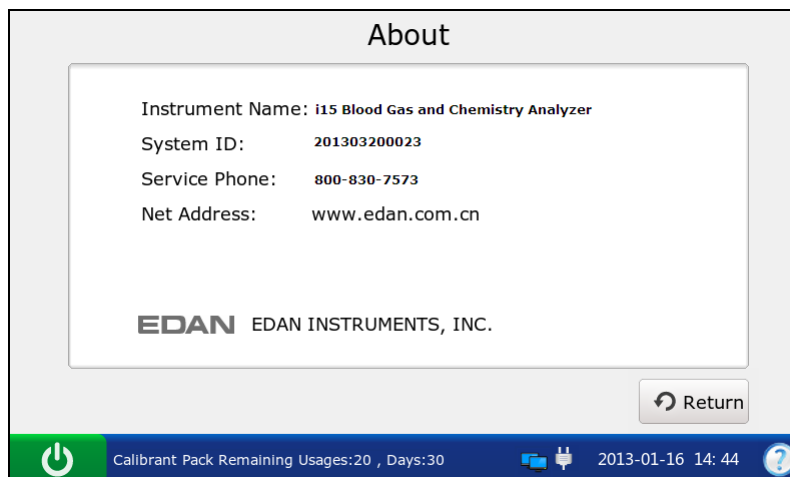


Figure 4-9 About Screen

2. View the information on the screen.
3. Press **Return** to get access to the System Setup screen.

4.3 Test Setup

Press **Test Setup** on the Setup screen to access the Test Setup screen, and then you can perform the following operations:

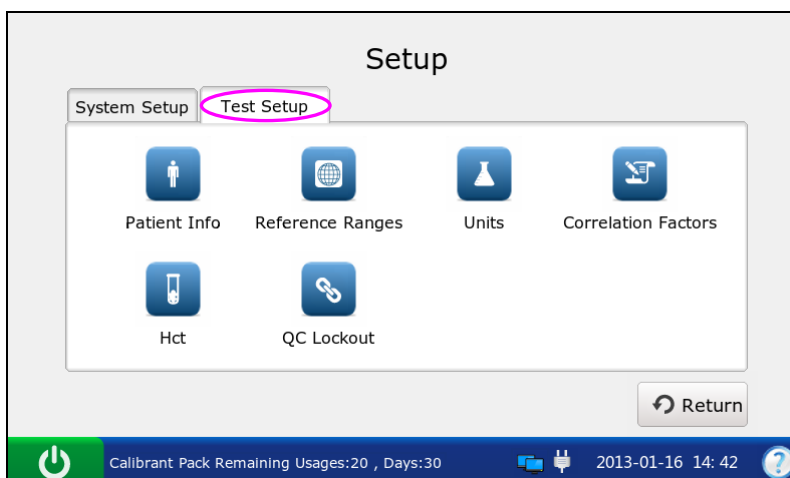



Figure 4-10 Setup – Test Setup Screen

4.3.1 QC Lockout Setup

This menu allows you to configure QC lockout. If QC lockout function is enabled, the system will not report test results for those parameters that have failed quality control tests, and the results for these parameters will be flagged with xxx. If QC lockout function is disabled, the system will report test results for those parameters that have failed quality control tests, and the test results for these parameters will be flagged with ***. The default setting is enabling QC Lockout function.

Follow the procedures below to set QC Lockout:

1. Press  to go to the QC Lockout Setup screen.

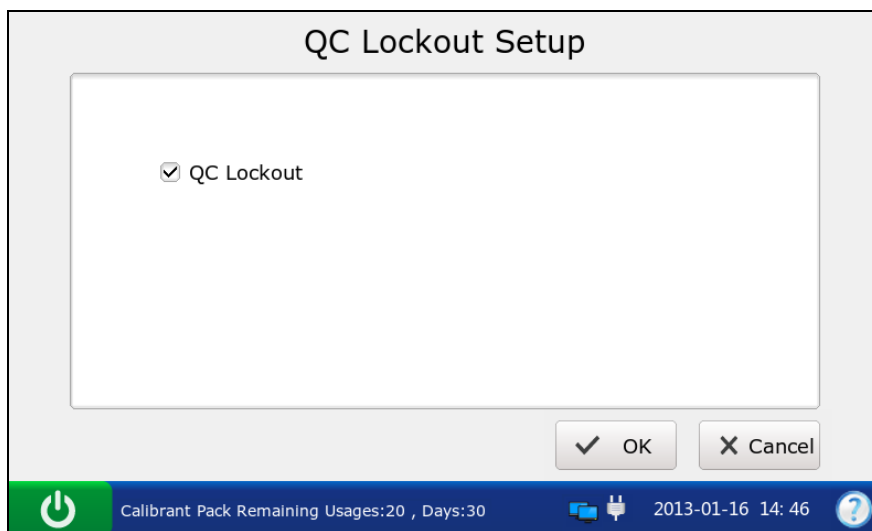


Figure 4-11 QC Lockout Setup Screen

2. Select whether to enable QC Lockout function. will appear if QC Lockout function is enabled.
3. Press **OK** to accept the changes, and the system will return to the Test Setup screen.

4.3.2 Patient Information Setup

This menu allows you to select which parameters will be displayed on the Edit Patient Information screen during each patient sample test. The default displayed parameters are patient ID, temperature, FIO₂ and operator ID. The table below lists the parameters for patient information.

Table 4-1 Patient Information


Parameter	Range	Resolution	Unit
Patient ID	1 - 16 digits	N/A	N/A
Operator ID	1 - 16 digits	N/A	N/A
Sample ID	1 - 16 digits	N/A	N/A
Temperature	14.0 – 44.0	0.1	°C
	57.2 – 111.2	0.1	°F
Sex	Male, Female, /	N/A	N/A
tHb (Total hemoglobin)	1.0 – 26.0	0.1	g/dL
	10 - 260	1	mg/dL
	0.6 – 16.1	0.1	mmol/L
FIO ₂	0.21 - 1.00	0.01	x.xx
	21 - 100	1	%
MCHC (Mean corpuscular hemoglobin concentration)	29.0 - 37.0	0.1	g/dL
	290 - 370	1	g/L
RQ (respiratory quotient)	0.70 - 2.00	0.01	x.xx
Hemoglobin type	Adult, Children, Newborn	N/A	N/A
Puncture site	LR/RR/LB/RB/LF/RF/Cord/Scalp/LHF/ RHF/LH/RH/AIC, PA Catheter, CPB or Other, where: LR=Left Radial RR= Right Radial LB= Left Brachial RB= Right Brachial LF= Left Femoral RF= Right Femoral LHF= Left Hand Finger RHF= Right Hand Finger LH= Left Heel RH= Right Heel AIC= Arterial Indwelling Catheter CPB= Cardiopulmonary Bypass PA Catheter= PA Catheter Other= Other	N/A	N/A
Bypass	Pump Off / Pump On	N/A	N/A
O ₂ mode	Rm air, Mask, T-P, NC, Vent, Bag, Hood or Other, where: Rm Air=Room Air	N/A	N/A

	Mask= Mask T-P= T-Piece NC= Nasal Cannula Vent= Ventilator Bag= Bag (manual resuscitation) Hood= Hood Other= Other		
I/E Ratio	0.2 - 9.9/0.2 - 9.9	0.1	x.xx
Vent mode	No, SIMV, PSV, PCV, CMV/AC, CPAP, PCIVR, or BIPAP, where: No= None SIMV= Synchronized Intermittent Mandatory Ventilation PSV= Pressure Support Ventilation PCV= Pressure Control Ventilation CMV/AC= Controlled Mechanical Ventilation/ Assist Control CPAP= Continuous Positive Airway Pressure PCIVR= Pressure Control Inverse Ratio BIPAP= Bi-Level Positive Airway Pressure	N/A	N/A
Pplat (Plateau Pressure)	0 - 100	1	cmH ₂ O
MVol (Minute Volume)	0 - 120	1	Lpm
PIP (Peak Inspiratory Pressure)	0 - 140	1	cmH ₂ O
Liter Flow	0 - 300	1	Lpm
TVol (Tidal Volume)	0 - 4000	1	mL/kg
PS (Pressure Support)	0 - 99.9	0.1	cmH ₂ O
PEEP (Positive End Expiratory Pressure)	0 - 50	1	cmH ₂ O
Rate	0 - 155	1	Bpm
CPAP (Continuous Positive Airway Pressure)	0 - 50	1	cmH ₂ O
Bi-Level Pressure	0.2 - 9.9/0.2 - 9.9	0.1	x.xx

NOTE:

- ✓ There is no barometric pressure item in patient information. If the barometric pressure sensor malfunctions, the system will not report results for the parameters related to oxygen.
- ✓ The selected items will be printed out in patient sample reports if Patient Info is selected in section 4.2.1 Printer Setup.

Follow the instructions below to select which patient information is required:

1. Press  to get access to the Patient Information Setup screen.
2. Press **Patient Info 1**, and select the desired parameters. ✓ indicates the parameter is selected.

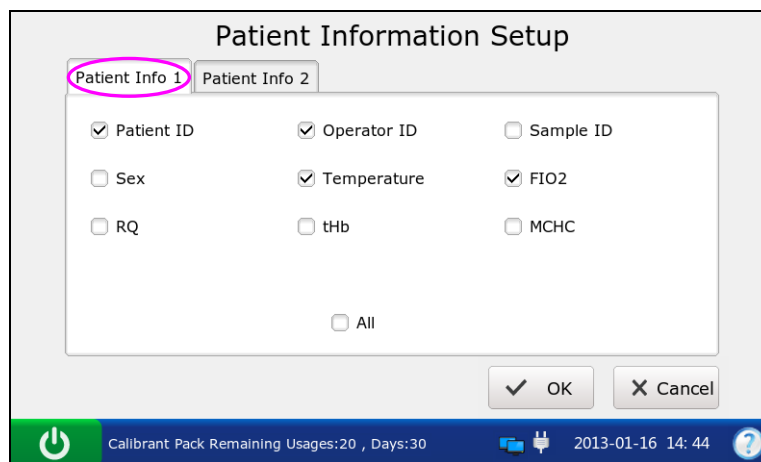


Figure 4-12 Patient Information 1 Screen

3. Press **Patient Info 2**, and select the desired parameters. ✓ indicates the parameter is selected.

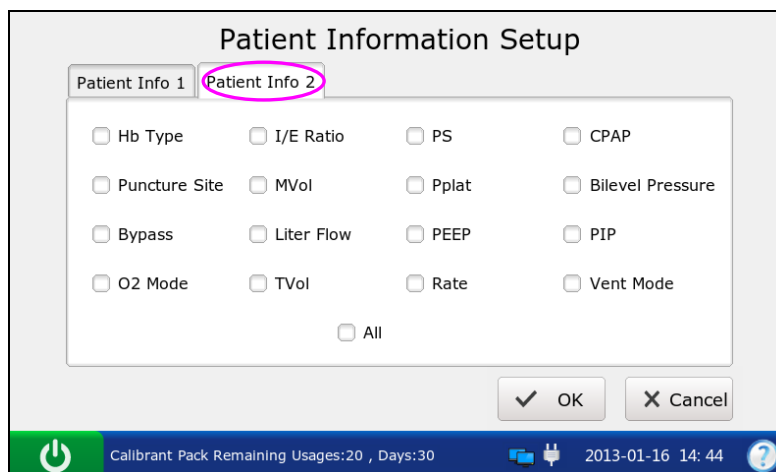


Figure 4-13 Patient Information 2 Screen

NOTE:

Select **All** to select all the parameters at each screen.

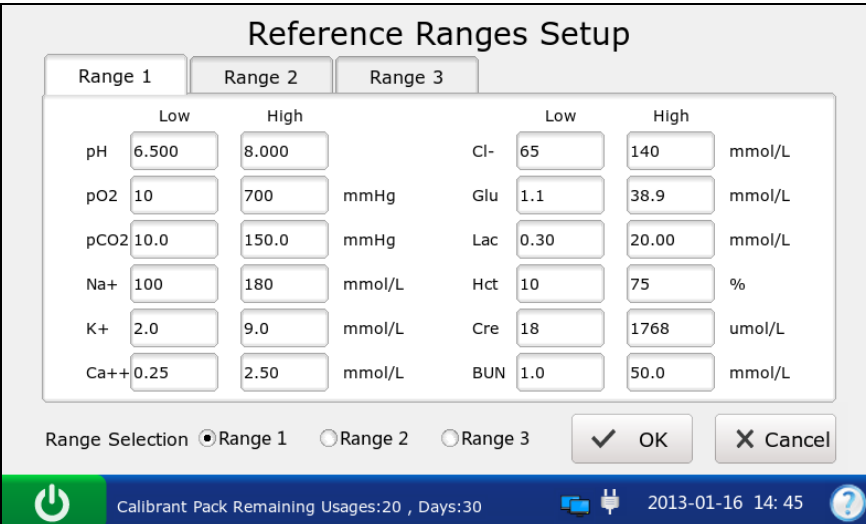
4. Press **OK** to accept the changes, and the system will return to the Test Setup screen.

4.3.3 Reference Ranges Setup

With this menu you can set the reference range for each measured parameter. There are three options: Reference Range 1, Reference Range 2, and Reference Range 3. The default is Reference Range 1. A result that is out of the reference range will be flagged with an up/down arrow. Reference ranges are factory set to be the measurement ranges for each measured parameter. Values outside reference ranges are not flagged with an up/down arrow. Therefore reference ranges must be set according to internal procedures at your individual institution. Because reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that reference ranges be set according to the population being tested.

Follow the instructions below to set the reference ranges:

1. Press  to access the Reference Ranges Setup screen.



	Low	High		Low	High	
pH	6.500	8.000		Cl-	65	140 mmol/L
pO ₂	10	700	mmHg	Glu	1.1	38.9 mmol/L
pCO ₂	10.0	150.0	mmHg	Lac	0.30	20.00 mmol/L
Na ⁺	100	180	mmol/L	Hct	10	75 %
K ⁺	2.0	9.0	mmol/L	Cre	18	1768 umol/L
Ca ⁺⁺	0.25	2.50	mmol/L	BUN	1.0	50.0 mmol/L

Range Selection Range 1 Range 2 Range 3

Calibrant Pack Remaining Usages:20 , Days:30 2013-01-16 14: 45

Figure 4-14 Reference Ranges Setup Screen

2. Select the desired reference range, and edit the limits for those parameters you want to change.
3. Press **OK** to accept the changes, and the system will return to the Test Setup screen.

NOTE:

- ✓ If unacceptable values are entered, the system will display the correct range.
- ✓ The limits entered will be saved in the system even after the system is shut down.


4.3.4 Units Setup

This function allows you to select the units for measured parameters, calculated parameters and parameters of patient information.

Table 4-2 Units for Parameters

Parameter	Default Unit	Alternate Units
Ca ⁺⁺	mmol/L	mg/dL
pCO ₂	mmHg	kPa
pO ₂	mmHg	kPa
Glu	mmol/L	mg/dL
Lac	mmol/L	mg/dL
Hct	%	x.xx
Cre	μmol/L	mg/dL
BUN	mmol/L	mg/dL
tHb(est)	g/dL	g/L, mmol/L
sO ₂ (est)	%	x.xx
pO ₂ (A-a)	mmHg	kPa
pO ₂ (a/A)	x.xx	%
RI	x.xx	%
pO ₂ /FIO ₂	mmHg	mmHg/%, kPa, kPa/%
Ca ⁺⁺ (7.4)	mmol/L	mg/dL
pCO ₂ (T)	mmHg	kPa
pO ₂ (T)	mmHg	kPa
pO ₂ (A-a)(T)	mmHg	kPa
pO ₂ (a/A)(T)	x.xx	%
RI(T)	x.xx	%
pO ₂ (T)/FIO ₂	mmHg	mmHg/%, kPa, kPa/%
Temperature	°C	°F
FIO ₂	x.xx	%
tHb	g/dL	g/L, mmol/L
MCHC	g/dL	g/L
Baro/Partial Pressure	mmHg	kPa

Follow the directions below to select the desired units for the parameters:

1. Press  to get access to the Units Setup screen.
2. Press **Units 1**, and select the desired units for the parameters whose units you want to change.

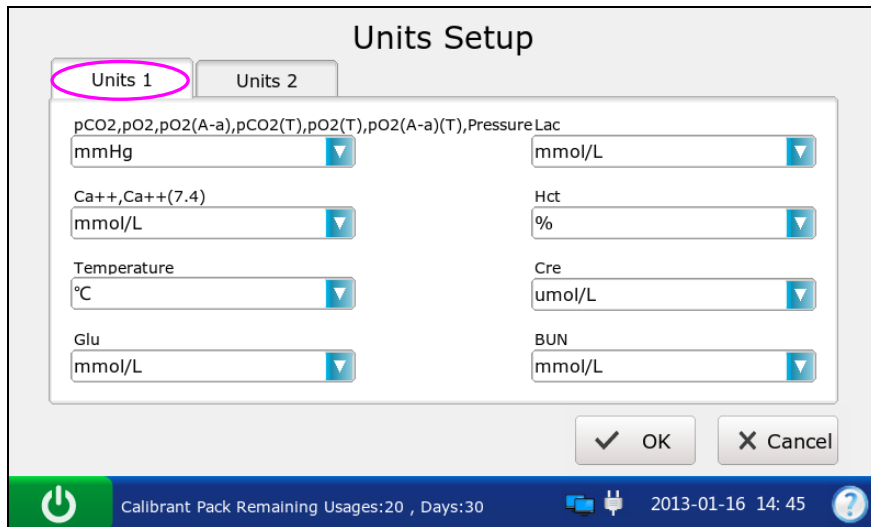


Figure 4-15 Units Setup 1 Screen

3. Press **Units 2**, and select the desired units for the parameters whose units you want to change.

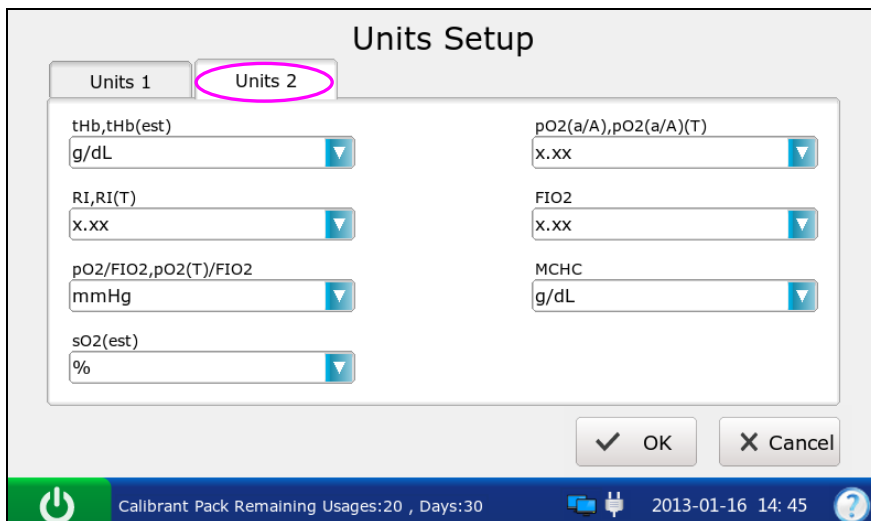


Figure 4-16 Units Setup 2 Screen

4. Press **OK** to accept the changes, and the system will return to the Test Setup screen.

NOTE:


The results stored in the system are automatically converted to match new units.

4.3.5 Correlation Factors Setup

Correlation factors allow you to correlate results obtained from the system to results obtained from another system. The ranges for the slope and offset of each parameter are listed in table 4-3.

Table.4-3 Correlation Factors

Parameter	Slope Range	Offset Range
pH	1.200 – 0.800	+/- 1.000
pCO ₂	1.200 – 0.800	+/- 10.0 mmHg +/- 1.33 kPa
pO ₂	1.200 – 0.800	+/- 40 mmHg +/- 5.33 kPa
Na ⁺	1.200 – 0.800	+/-30.0 mmol/L
K ⁺	1.200 – 0.800	+/- 1.00 mmol/L
Cl ⁻	1.200 – 0.800	+/- 20.0 mmol/L
Ca ⁺⁺	1.200 – 0.800	+/- 0.500 mmol/L
Glu	1.200 – 0.800	+/- 50.0 mg/dL +/- 2.78 mmol/L
Lac	1.200 – 0.800	+/- 4.00 mmol/L +/- 36.0 mg/dL
Cre	1.200 – 0.800	+/- 30 umol/L
BUN	1.200 – 0.800	+/- 1.8 mmol/L
Hct	1.200 – 0.800	+/- 20 % PCV

1. Press  to get access to the Correlation Factors Setup screen.

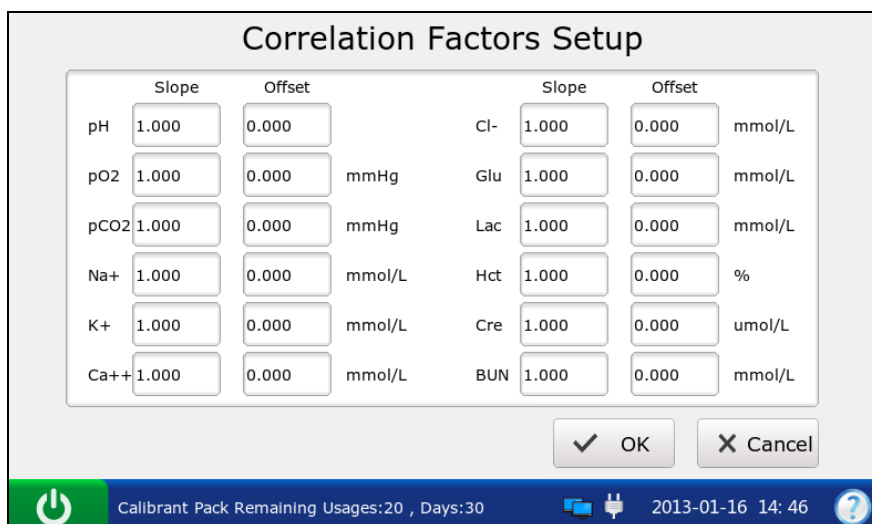


Figure 4-17 Correlation Factors Setup Screen

2. Edit the values of the slopes and offsets for the parameters whose correlation factors you want to change.
3. Press **OK** to accept the changes, and the system will return to the Test Setup screen.

NOTE:

- ✓ The default value is 1.0 for all slopes and 0.0 for all offsets.
- ✓ Changing correlation factors affects future test results, but does not affect past, stored test results.

4.3.6 Hct Setup

When only Hct levels are measured for whole blood samples, this menu allows you to select the anticoagulants.

1. Press  to get access to the Hct Setup screen.

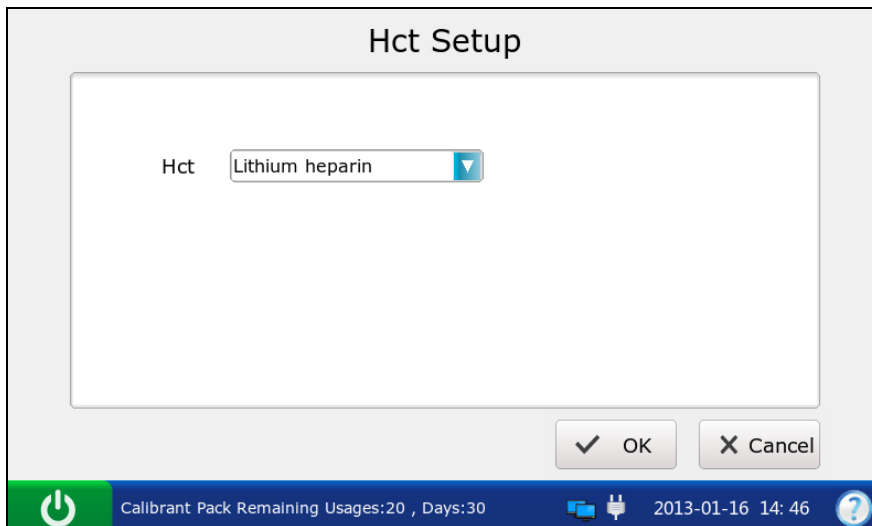


Figure 4-18 Hct Setup Screen

2. Select the desired anticoagulant. There are three options: K₂EDTA, K₃EDTA, lithium heparin. The default is lithium heparin.
3. Press **OK** to accept the changes, and the system will return to the Test Setup screen.

Chapter 5 Patient Analyzing

NOTE:

Take safety measures when working with biological samples, such as wearing approved gloves, etc.

5.1 Sample Collection and Preparation

5.1.1 Sample Collection

Blood samples should be collected according to proper medical guidelines containing collection details, such as site selection, collection procedures, sampling devices, sample handling, etc. Sterile techniques should be followed to prevent the site from being contaminated.

WARNING

Handle blood samples and collection devices with care, and wear approved protective gloves to avoid direct contact with samples.

NOTE:

- ✓ Only fresh whole blood samples are recommended for use.
- ✓ When taken for electrolyte analysis, venous samples should not be collected from a central venous catheter containing silver sulfadiazine or chlorhexidine, because they have a great influence on sodium levels.
- ✓ Samples should be collected by trained professionals.
- ✓ For mixed venous samples, the system reports only pO_2 result.

5.1.2 Anticoagulants

Only those sample devices containing the proper amount of calcium-titrated (balanced) heparin or lithium heparin as the anticoagulant should be used to collect whole blood samples. If calcium-titrated (balanced) heparin is used as an anticoagulant, the minimum heparin-to-blood ratio should be 2.3 units of heparin per 1.0mL of blood sample. If a sample is analyzed for ionized calcium, the maximum heparin-to-blood ratio should be 15 units of heparin per 1.0mL of blood sample; if not, the maximum heparin-to-blood ratio should be 50 units of heparin per 1.0mL of blood sample.

CAUTION

If there are clots in the blood sample, discard it and collect samples again.

NOTE:

Don't use the following anticoagulants: EDTA, citrate, and oxalate, because they have a great influence on test results for pH and electrolytes.

5.1.3 Collection Devices and Volume

Samples can be introduced into the system with the following devices: syringes and capillary tubes. It is recommended that VITREX[®] Blood Gas Capillary Tubes with a minimum volume, filled of 175 μ L (Article Number: 182413) should be used.

NOTE:

- ✓ The system uses 110 μ L samples for analysis, and make sure it can aspirate enough sample.
- ✓ The minimum fill volume for a 1mL syringe is 200 μ L.
- ✓ The minimum fill volume for a 2mL syringe is 800 μ L.
- ✓ The minimum fill volume for a 5mL syringe is 1.5mL.
- ✓ Dislodge bubbles from the syringe, and cover it as soon as the sample is collected. Cork should never be used to cover the syringe.
- ✓ A capillary tube should be filled to capacity and covered securely. Cork or clay should never be used to cover the capillary tube.

5.1.4 Notes

Follow the **notes** below to ensure that test results are accurate:


1. Cover the sample device immediately after collection to prevent it from being contaminated by air.
2. Mix blood samples thoroughly prior to sample introduction.
3. Make sure there are no clots in blood samples, or else the results will be inaccurate.
4. Perform the sample test immediately after its collection to get the most accurate results. Measure samples for blood gases and Ca⁺⁺ within 10 minutes, and measure samples for other analytes within 30 minutes.
5. Used sample devices are biohazardous waste, and should be handled abiding by local regulatory guidelines.


5.2 Patient Analyzing

NOTE:

Ensure that the displayed date and time are correct before each sample test, because they are part of the patient sample data. Contact the administrator if the date and/or time are incorrect.

5.2.1 Procedures for Patient Analyzing

1. Press the **On/Off** button on the left hand side of the analyzer to turn it on.
2. Enter the user name and password manually, and then press .

To enter the user name with the bar code scanner, press  first, and then scan the user name bar code.

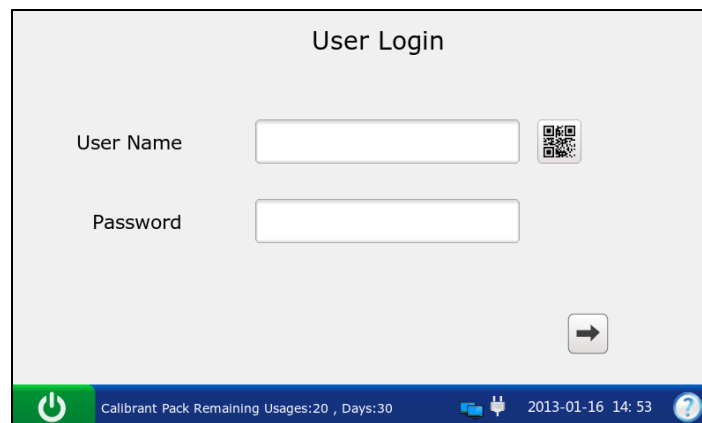


Figure 5-1 Enter User Name and Password

3. Press the button for the blood sample type on the Main screen. \checkmark will appear if the button is selected. The default type is **Arterial**.

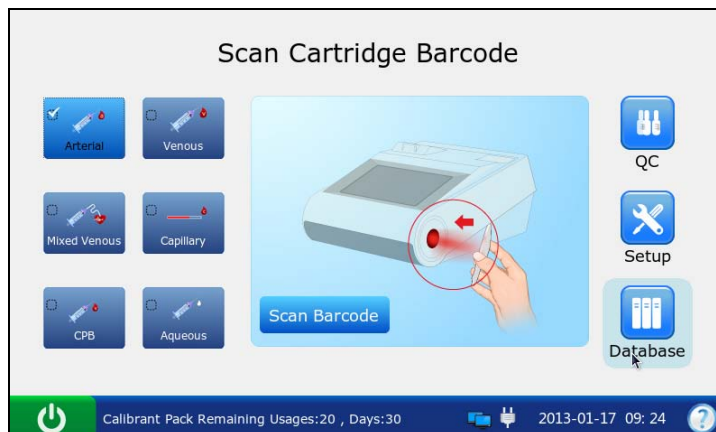


Figure 5-2 the Main Screen

CAUTION

Make sure that the selected sample type button is consistent with the blood sample, or the result may be inaccurate.

4. Press **Scan Barcode**, and scan the bar code on a new cartridge foil pouch.

If the bar code is scanned successfully, the system will beep and the scanner will be automatically turned off. If the scanned data is valid, the system will display the screen for the next procedure. If the scanned data is invalid, a message will pop up to prompt you.

5. Open the foil pouch and remove the cartridge from it.

NOTE:

- ✓ Avoid tearing the bar code on the foil pouch.
 - ✓ For sample introduction with a capillary tube, insert a capillary adaptor into the fillport after removing the cartridge.
6. Roll the syringe or capillary tube between palms and gently invert it end over end for several times to mix the sample completely.

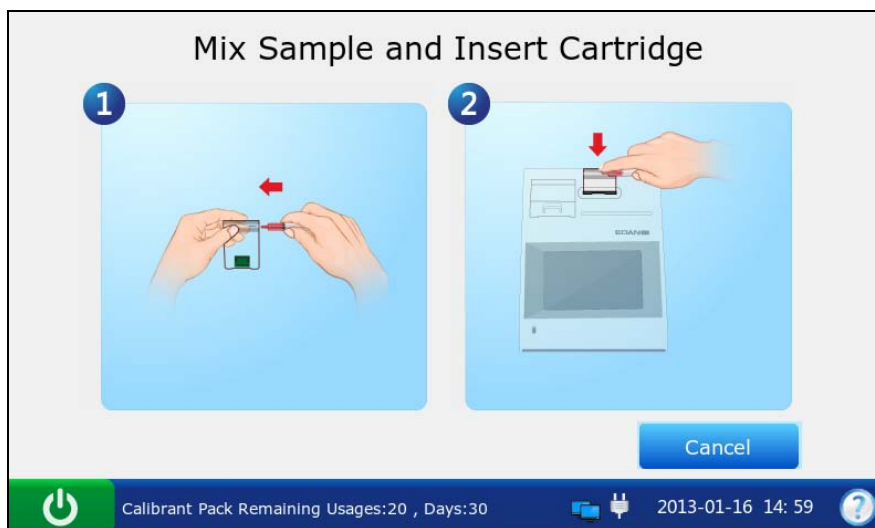


Figure 5-3 Mix Sample and Insert Cartridge

NOTE:

- ✓ To avoid inaccurate test results, mix the sample thoroughly prior to sample introduction.
- ✓ To avoid inaccurate test results, make sure there are no trapped bubbles or clots in the sample.

7. Insert the syringe or capillary tube into the fillport of the cartridge.

NOTE:

- ✓ When using a syringe, discard the first 2 drops of blood sample first, then remove the needle from it, and finally insert it into the fillport.
 - ✓ When using a capillary tube, insert the capillary tube into the adaptor till the tube reaches the interface between the adaptor and the cartridge.
8. Gently insert the cartridge into the cartridge port, and carefully press down to ensure it clicks into place.

For a valid cartridge, the indicator in the cartridge port will turn green, and the system will automatically aspirate calibrant. For an invalid cartridge, the indicator will turn red, the cartridge will be ejected and a message will pop up to prompt you.

NOTE:

- ✓ Never inject the sample. It will be aspirated automatically.
 - ✓ The cartridge can not be removed from the analyzer until the measurement is complete.
9. Enter patient information. The screen displayed depends on the selection in section 4.3.2 Patient Information Setup. The screen for the default patient information setup is shown below:

The screenshot shows a software interface titled "Enter Patient Information". It features a "Patient Info1" tab and several input fields: "Patient ID" (with a QR code icon), "Temperature" (with a "°C" label), "Operator ID" (pre-filled with "admin"), and "FIO2". An "OK" button is positioned at the bottom right of the input area. Below the input area is a "Calibrating..." progress bar with several blue bars. The bottom status bar includes a power icon, the text "Please Don't Remove Cartridge", a USB icon, the date and time "2013-01-16 15: 01", and a help icon.

Figure 5-4 Enter Patient Data

NOTE:

- ✓ It is not necessary to enter all the above parameters. You can press **OK** at any time.
- ✓ If no parameters are selected in section 4.3.2 Patient Information Setup, the system will go to the Aspirating Calibrant screen when the test cartridge is properly inserted.
- ✓ The system can not go back to the screen for entering patient information after you press **OK**, and patient information has to be edited in the patient sample database.

10. Press **OK**. The system will go to the following screens:

- a). If the system is aspirating calibrant, the system will go to the following screen:

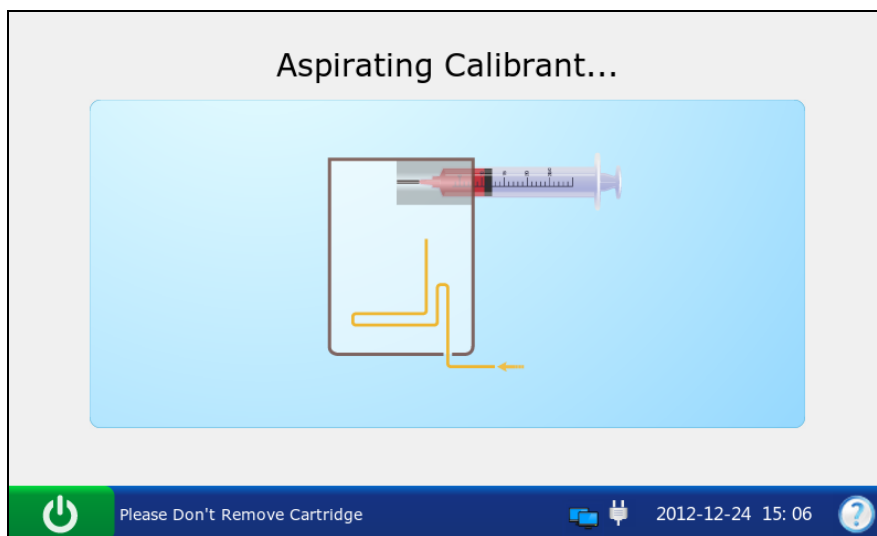


Figure 5-5 Aspirating Calibrant...

- b). If the system is calibrating sensors, the system will go to the screen below:

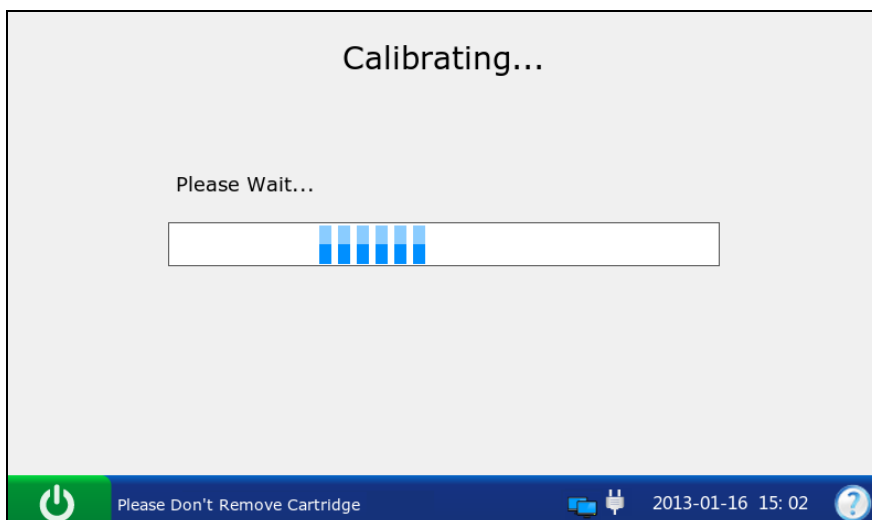


Figure 5-6 Calibration in Progress

c). If the system is sampling, the system will go to the screen below:

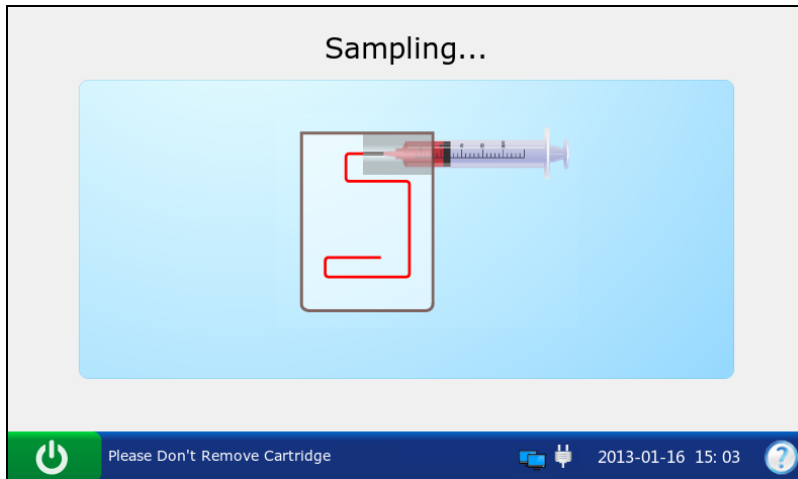


Figure 5-7 Sampling...

d). If the system is analyzing patient samples, the system will go to the screen below:

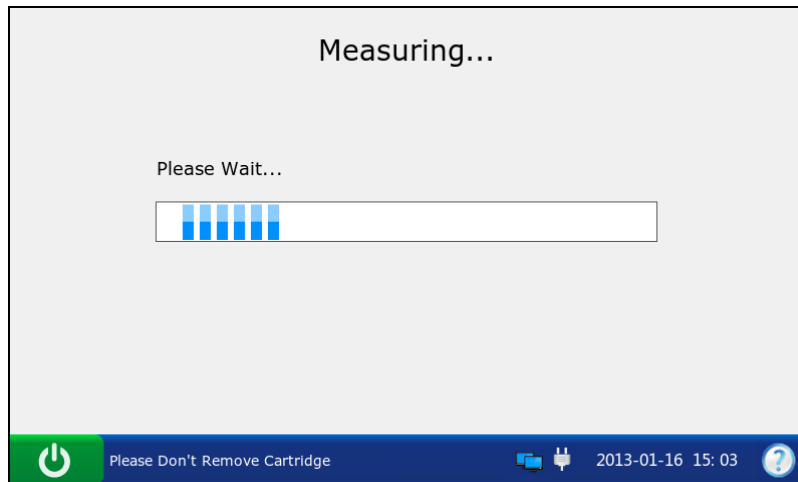


Figure 5-8 Measurement in Progress

e). If the test is complete, the system will go to the screen below:

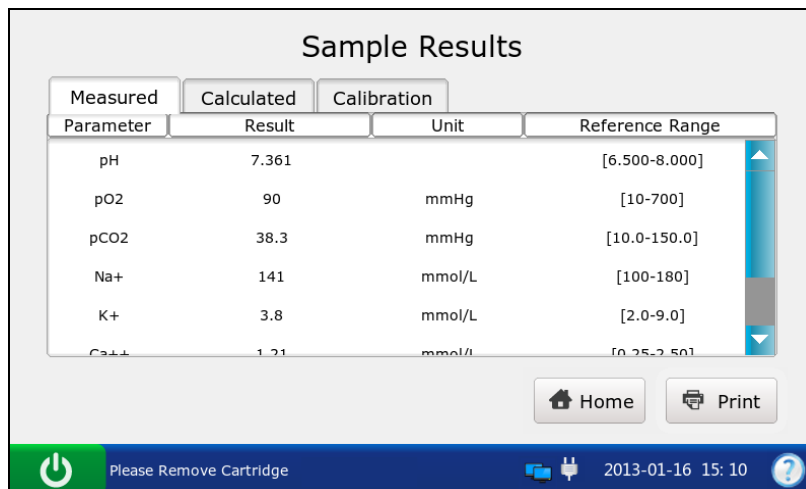
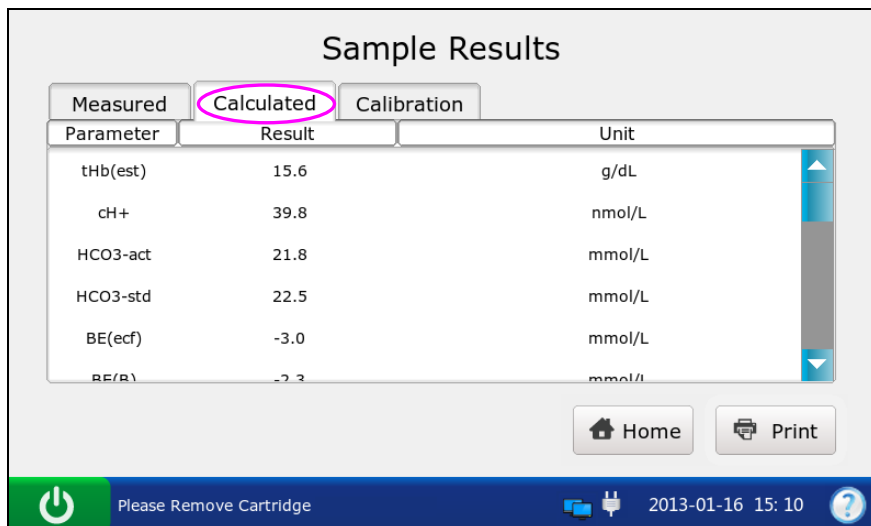


Figure 5-9 Sample Results

NOTE:

- ✓ Upon the completion of the test, the indicator in the cartridge port will be off, the message “Please Remove Cartridge” will be displayed on the status bar at the bottom of the screen, and the cartridge will be ejected.
 - ✓ If the screen has not been touched for 10 seconds after the test is complete, the test results will be displayed automatically even if you do not press **OK**.
 - ✓ If patient temperature is entered, the test results will be displayed both at 37°C and at the patient’s temperature.
 - ✓ If Auto Transmit is turned on in section 4.2.2 Network Setup, patient sample results will be transmitted to the DMS automatically.
 - ✓ If Auto Print is selected in section 4.2.1 Printer Setup, patient sample results will be printed automatically. If it is not selected, press **Print** to print the test results.
11. View the test results. The system displays the results for measured parameters by default.

Press **Calculated** to view the results for calculated parameters.



Measured	Calculated	Calibration
Parameter	Result	Unit
tHb(est)	15.6	g/dL
cH+	39.8	nmol/L
HCO3-act	21.8	mmol/L
HCO3-std	22.5	mmol/L
BE(ecf)	-3.0	mmol/L
BE(B)	-2.3	mmol/L

Home Print

Please Remove Cartridge 2013-01-16 15:10

Figure 5-10 Calculated Parameters

Press **Calibration** to view the calibration results.

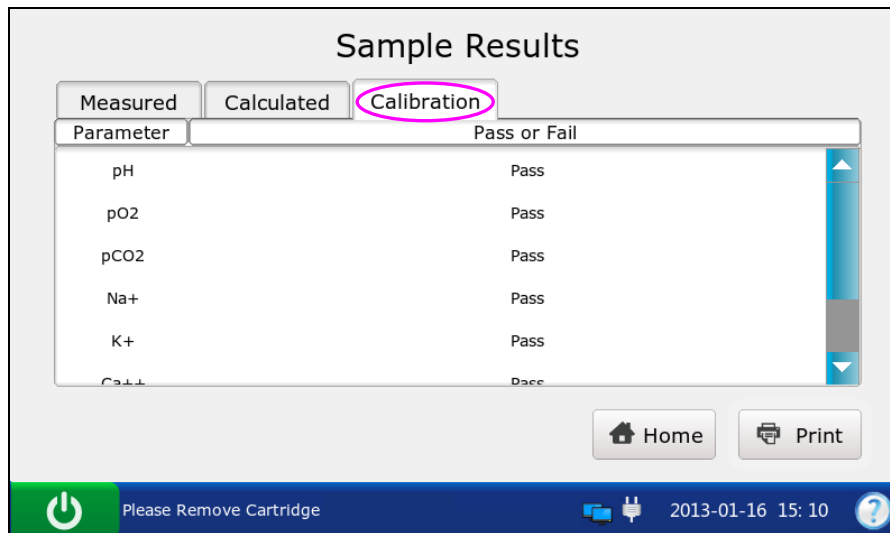


Figure 5-11 Calibration Parameters

Symbols such as > may appear on the Results screen, refer to section 5.2.2 Understanding Result Symbols to understand their meanings.

WARNING

Never make treatment decisions according to test results containing symbols as described in section 5.2.2 Understanding Result Symbols.

12. Remove the test cartridge from the system.
13. Press **Home** to return to the Main screen.

The contents of a patient sample report depend on the type of the test cartridge you have used, the options selected in section 4.2.1 Printer Setup and section 4.3.2 Patient Information Setup, and the errors and alarms the system detects during the measurement. The table below is an example of a patient sample report:

EDAN i15	
System ID	201303200023
Report Type	Patient Sample Report
Sample Type	Arterial
Print Time	2012-03-20 15:20:00
Test Time	2012-03-20 15:10:00
Patient ID	88888
Operator ID	55555
Patinet Information	

Temperature	37	°C
Sex	Female	
tHb	30	g/dL
FIO ₂	20	
MCHC		g/dL
RQ		
Hb type	Adult	
Puncture site	LR (Left Radial)	
Bypass	Pump Off	
O ₂ mode		
I/E Ratio	0/0	
Vent mode	None	

.....

Calibration Results

pH	Fail
pCO ₂	Pass
pO ₂	Pass
Na ⁺	Pass
K ⁺	Pass
Ca ⁺⁺	Pass
Cl ⁻	Pass
Glu	Pass
Lac	Pass
Hct	Pass
Cre	Pass
BUN	Pass

Results for Measured Parameters

pH	---		
pCO ₂	xxx		mmHg
pO ₂	70		mmHg
Na ⁺	???		mmol/L
K ⁺	1.0	↓	mmol/L
Ca ⁺⁺	200	↑	mmol/L
Cl ⁻	>		mmol/L
Glu	<		mmol/L
Lac	5	***	mmol/L

...

Results for Calculated Parameters

cH ⁺	1	nmol/L
pH(T)	1	

$p\text{CO}_2(\text{T})$	1	***
$p\text{O}_2(\text{T})$	1	>
$\text{HCO}_3^- \text{act}$	1	<
$\text{HCO}_3^- \text{std}$	1	
BE (ecf)	1	
$\text{Ca}^{++}(7.4)$	1	
...		
Reference Ranges		
pH	[7.35 - 7.45]	
$p\text{CO}_2$	[35.0 - 45.0]	mmHg
$p\text{O}_2$	[80.0 - 100.0]	mmHg
Na^+	[138.0 - 146.0]	mmol/L
K^+	[3.50 - 4.90]	mmol/L
Ca^{++}	[1.12 - 1.32]	mmol/L
Cl^-	[98 - 109]	mmol/L
Glu	[3.9 - 5.8]	mmol/L
Lac	[0.36 - 1.7]	mmol/L
Hct	[35 - 51]	%
Cre	[0.6 - 1.3]	mg/dL
BUN		

5.2.2 Understanding Result Symbols

The following table shows the symbols that may appear on the screen:

Symbol	Description
> or <	The result is above or below the measurement range.
↑ or ↓	The result is above or below the reference range.
---	The measured parameter fails calibration.
xxx	The measured parameter fails quality control (QC) tests, and QC lockout function is enabled in Setup.
***	The measured parameter fails quality control (QC) tests, and QC lockout function is disabled in Setup.
	The result for the calculated parameter is valid, but the measured parameter used to determine this calculated parameter fails quality control (QC) tests, and QC lockout function is disabled in Setup.
???	The result for the measured parameter is invalid.

NOTE:


- ✓ Invalid test result for a calculated parameter will not be displayed on the screen.
- ✓ Valid test result for a calculated parameter will not be displayed on the screen, if the measured parameter used to determine the result fails quality control (QC) tests, and QC lockout function is enabled in Setup.

5.3 Patient Sample Database

The patient sample database displays patient sample data for the most recent month by default, and it can store up to 10000 data entries. The system displays 50 pieces of data on every page. Press **Prev.** and **Next** to page through the screens of the displayed data entries. When 80% of the space is occupied, the system will prompt you to export the stored data to a removable disk (such as a USB drive). If data is not exported, the system will continue to save new data. When the database is full, the system will always prompt you to export data. If data is still not exported, the system will automatically delete the oldest one to accommodate a new one. The following operations can be performed in the patient sample database: transmitting patient sample data to the Data Management System (DMS) through WIFI or the network, exporting patient sample data to a removable disk (such as a USB drive), viewing the details of patient sample data, editing patient information, searching for and printing patient sample data, etc.

NOTE:

- ✓ Only patient information data can be edited.
- ✓ Test results for calculated parameters may be changed due to the alteration of patient information data.

On the Database screen, press  to access the Patient Sample Database screen.

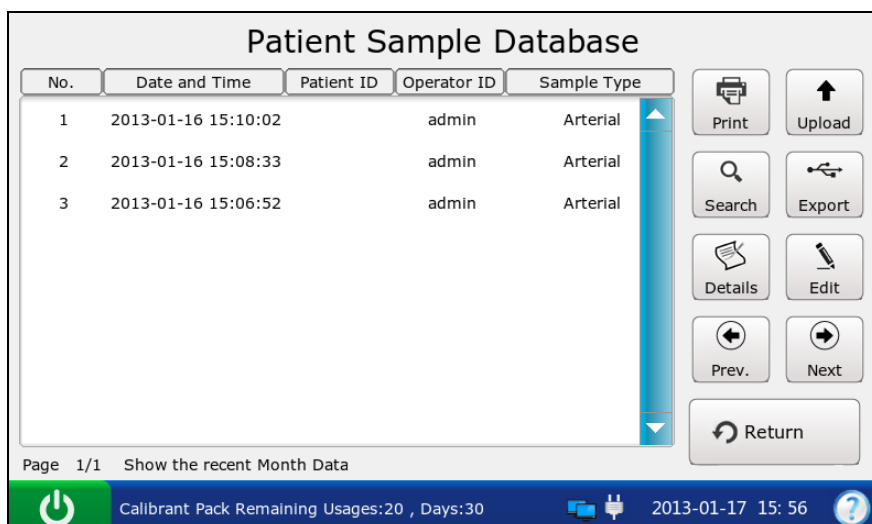


Figure 5-12 Patient Sample Database Screen

5.3.1 Searching for Patient Sample Data

1. On the Patient Sample Database screen, press **Search**.
2. Enter the search conditions, and press **OK**.

Patient Sample Search

Patient ID

Operator ID

Start Time 2013 Year 1 Mon 17 Day

End Time 2013 Year 1 Mon 17 Day

✓ OK ✕ Cancel

Calibrant Pack Remaining Usages:20 , Days:30 2013-01-17 16:03

Figure 5-13 Enter Search Conditions

3. The system automatically begins the search and displays the results.

Patient Sample Search Results

No.	Date and Time	Patient ID	Operator ID	Sample Type
1	2013-01-16 15:10:02	admin	admin	Arterial
2	2013-01-16 15:08:33	admin	admin	Arterial
3	2013-01-16 15:06:52	admin	admin	Arterial

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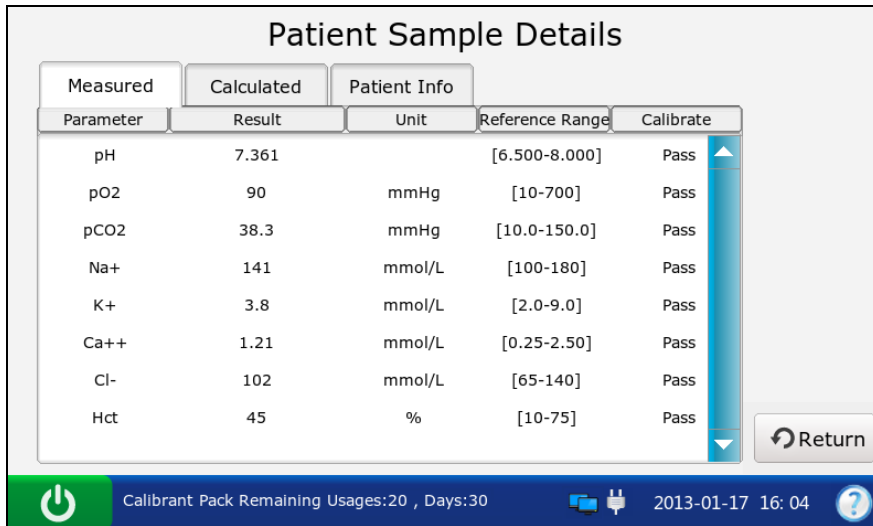
Calibrant Pack Remaining Usages:20 , Days:30 2013-01-17 16:03

Figure 5-14 Search Results

4. Press **Return** to go back to the Patient Sample Database screen.

5.3.2 Viewing Details of Patient Sample Data

1. Press the patient sample data you want to view.
2. Press **Details**. The system displays the details of measured parameters by default.



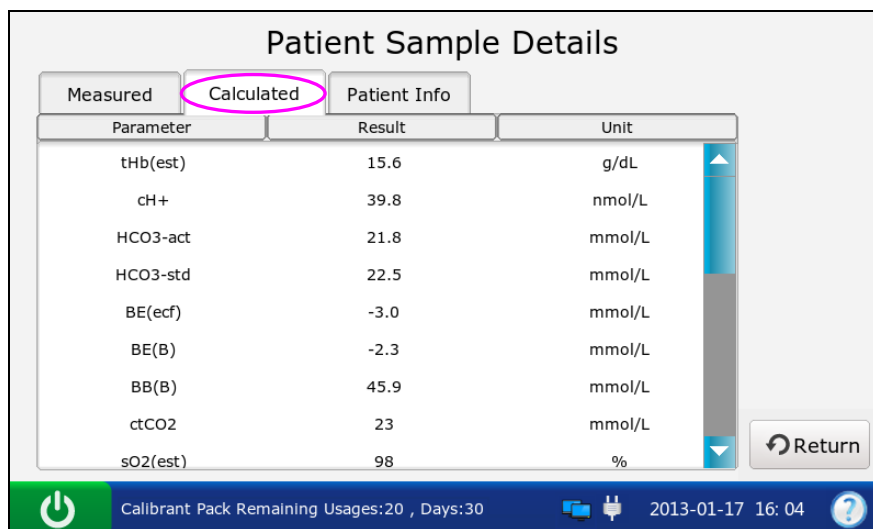
The screenshot shows the 'Patient Sample Details' screen with the 'Measured' tab selected. The table below displays the measured parameters, their results, units, reference ranges, and calibration status.

Parameter	Result	Unit	Reference Range	Calibrate
pH	7.361		[6.500-8.000]	Pass
pO2	90	mmHg	[10-700]	Pass
pCO2	38.3	mmHg	[10.0-150.0]	Pass
Na+	141	mmol/L	[100-180]	Pass
K+	3.8	mmol/L	[2.0-9.0]	Pass
Ca++	1.21	mmol/L	[0.25-2.50]	Pass
Cl-	102	mmol/L	[65-140]	Pass
Hct	45	%	[10-75]	Pass

At the bottom of the screen, there is a status bar showing 'Calibrant Pack Remaining Usages:20 , Days:30', the date and time '2013-01-17 16:04', and a 'Return' button.

Figure 5-15 Details of Measured Parameters

3. Press **Calculated** to view the details of calculated parameters.



The screenshot shows the 'Patient Sample Details' screen with the 'Calculated' tab selected. The table below displays the calculated parameters, their results, and units.

Parameter	Result	Unit
tHb(est)	15.6	g/dL
cH+	39.8	nmol/L
HCO3-act	21.8	mmol/L
HCO3-std	22.5	mmol/L
BE(ecf)	-3.0	mmol/L
BE(B)	-2.3	mmol/L
BB(B)	45.9	mmol/L
ctCO2	23	mmol/L
so2(est)	98	%

The 'Calculated' tab is highlighted with a pink circle. At the bottom of the screen, there is a status bar showing 'Calibrant Pack Remaining Usages:20 , Days:30', the date and time '2013-01-17 16:04', and a 'Return' button.

Figure 5-16 Details of Calculated Parameters

4. Press **Patient Info** to view the details of patient information.

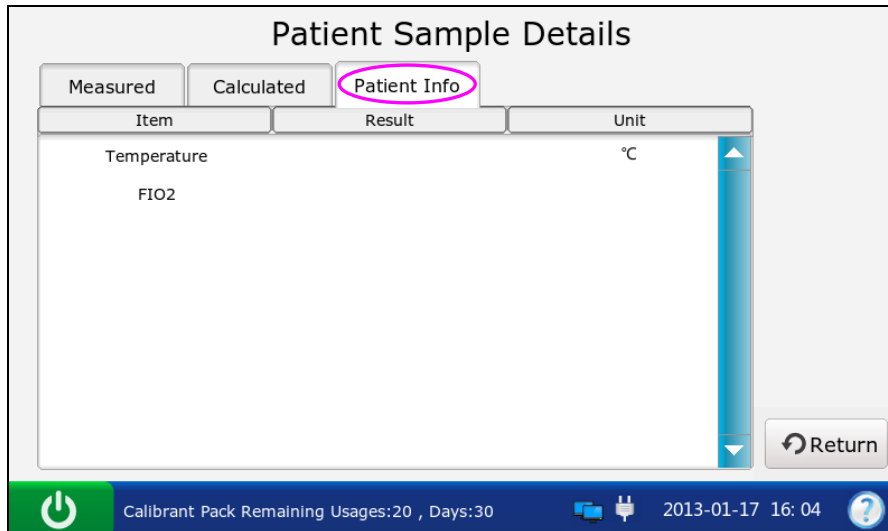


Figure 5-17 Details of Patient Information

5. Press **Return** to go back to the Patient Sample Database screen.

5.3.3 Editing Patient Information Data

1. Select the desired patient sample data, and then press **Edit**.
2. Edit the patient information data. The following screen will be displayed for the default patient information setup:

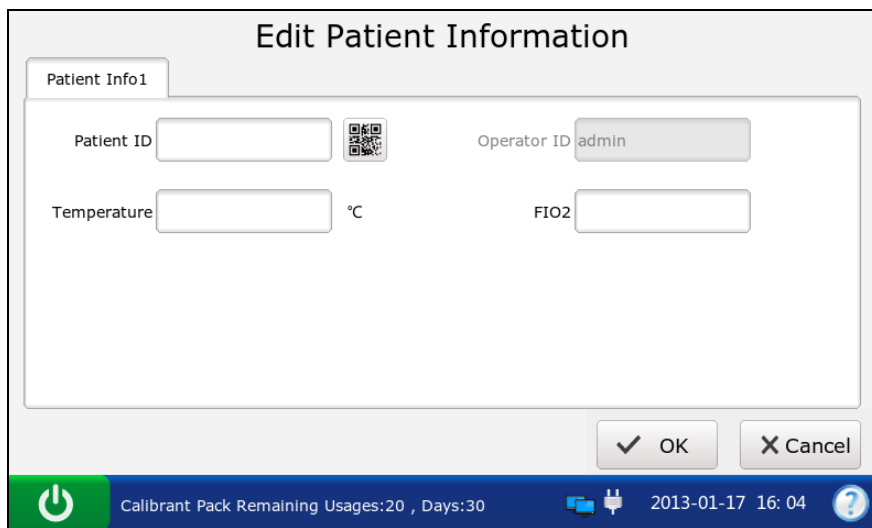


Figure 5-18 Edit Patient Data

NOTE:

The screen displayed depends on the selection in section 4.3.2 Patient Information Setup.

3. Press **OK** to save the changes, and the system will return to the Patient Sample Database screen.

5.3.4 Exporting/Uploading/Printing Patient Sample Data

1. Open the patient sample database.
2. Select the desired patient sample data.

To	Do this
Export	Insert a removable disk into the analyzer, and then press Export .
Upload	Press Upload .
Print	Press Print .

NOTE:

If no patient sample data is selected before pressing **Export/Upload/Print**, all of the data stored in the patient sample database will be exported/uploaded/printed.

Chapter 6 Quality Control (QC) Tests

Quality Control (QC) tests could ensure the normal operation of the system and the reliability of test results. Policies related to the measurement of QC samples are at the discretion of your individual institution. It is recommended to perform QC tests in the following situations:

- You are using the system for the first time.
- You wish to verify the performance of newly received test cartridges.
- You wish to verify the storage condition of test cartridges.
- You wish to verify the performance of the system.
- You doubt test results.

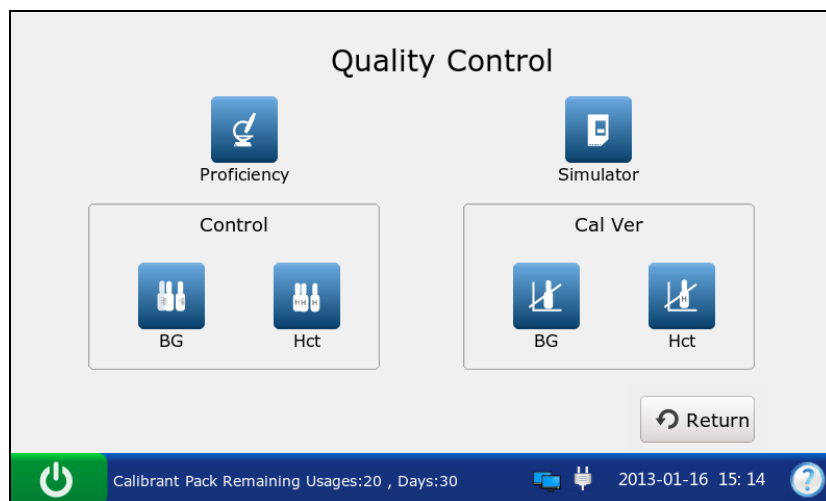


Figure 6-1 Quality Control Screen

6.1 Control Test

Control tests are intended to verify the efficient performance of the system. To verify the performance of each lot of newly received test cartridges, analyze at least two levels of controls in duplicate using a verified analyzer.

6.1.1 Controls

Controls are intended for use to monitor test cartridge performance at multiple points within the clinical range. Controls used are RNA Medical[®] QC823 Blood Gas•Electrolyte•Metabolite•BUN controls and RNA Medical[®] QC900 Hematocrit controls. The concentrations of reactive ingredients in various levels of controls are known. Controls do not contain human serum or serum products, but do contain buffers and preservatives. Acceptable

ranges for controls specific to the i15 Blood Gas and Chemistry Analysis System are programmed in the bar code on the user manual for controls provided by EDAN.

Packaging

1. RNA Medical[®] QC823 Blood Gas•Electrolyte•Metabolite•BUN controls are contained in 2.5mL glass ampoules, and RNA Medical[®] QC900 Hematocrit controls are contained in 1.7mL glass ampoules.
2. The controls package contains information such as the control name, level, lot number and expiration date, etc.

Storage and Usage

Controls should be stored at 2 - 8°C (avoid freezing) with the relative humidity of 25% - 93% (non-condensing).

Controls should be used at 10 - 31°C with the relative humidity of 25% - 80% (non-condensing).

Before Use

Controls should be equilibrated to room temperature before use. If oxygen is to be measured, the ampoule needs to stand at room temperature for 4 hours. If not, the ampoule needs to stand at room temperature for only about 30 minutes.

Immediately before use, mix controls completely by shaking the ampoule gently, and always hold an ampoule at tip and at bottom with forefinger and thumb to minimize increasing controls temperature. Tap the tip of the ampoule carefully with your fingernail to remove any solution.

NOTE:


- ✓ Store and use controls according to the user manual, and use them before the expiration date as labeled on the package.
- ✓ Only controls provided by EDAN or its authorized distributors should be used.
- ✓ For test cartridges with pH, $p\text{CO}_2$, $p\text{O}_2$, Ca^{++} sensors, a new ampoule and syringe or capillary tube should be used for each test. For test cartridges without pH, $p\text{CO}_2$, $p\text{O}_2$, Ca^{++} sensors, the remaining solution can still be used if the ampoule is opened within 10 minutes.
- ✓ The test results should fall within the acceptable ranges programmed in the bar code on the user manual for controls provided by EDAN.

6.1.2 Procedures for Control Test

Follow the steps below to perform a control test:

1. Examine the package label of controls to ensure they have not expired.
2. Remove an ampoule from the box of controls and equilibrate it to room temperature.

If oxygen is to be measured, the ampoule needs to stand at room temperature for 4 hours. If not, the ampoule needs to stand at room temperature for only about 30 minutes.

3. Press the **On/Off** button on the left hand side of the analyzer to turn it on.
4. Enter the user name and password manually, and then press .





To enter the user name with the bar code scanner, press  first, and then scan the user name bar code.



Figure 6-2 Enter User Name and Password

5. On the Main screen, press  to go to the Quality Control screen.
6. Select the desired control type.

Press  to perform a control test for blood gases and electrolytes.

Press  to perform a control test for Hct.

7. Press **Scan Barcode**, and scan the bar code on a new cartridge foil pouch.

If the bar code is scanned successfully, the system will beep and the scanner will be automatically turned off. If the scanned data is valid, the system will display the screen for the next procedure. If the scanned data is invalid, a message will pop up to prompt you.



Figure 6-3 Scan Bar Code

8. Open the foil pouch and remove the cartridge from it.

NOTE:

- ✓ Avoid tearing the bar code on the foil pouch.
- ✓ For sample introduction with a capillary tube or an ampoule, insert a capillary adaptor/ampoule adaptor into the fillport after removing the cartridge.
- ✓ When inserting an ampoule adaptor into the fillport of a test cartridge, make sure the indent of the adaptor is on the upside as shown in the picture below:



9. Press **Scan Barcode**, and scan the bar code on the controls user manual.

If the bar code is scanned successfully, the system will beep and the scanner will be automatically turned off. If the scanned data is valid, the system will display the screen for the next procedure. If the scanned data is invalid, a message will pop up to prompt you.



Figure 6-4 Scan Bar Code

NOTE:

Keep the controls user manual for a future control test use.

10. Mix the controls completely by shaking the ampoule gently, and then tap the tip of the ampoule carefully with your fingernail to remove any solution.

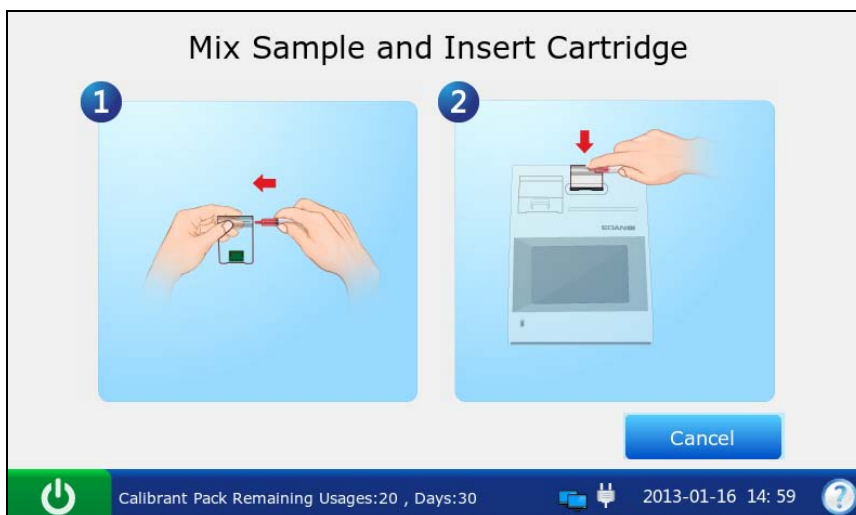


Figure 6-5 Mix Controls and Insert Cartridge

NOTE:

Avoid heating the ampoule with your hands when shaking the ampoule.

11. Open the ampoule by snapping off the top and immediately transfer control solution by slowly drawing an appropriate amount of solution with a syringe or capillary tube from the bottom of the ampoule.

NOTE:

- ✓ When using an ampoule for sample introduction, you need not transfer control solution. Insert the ampoule into the adaptor after opening it, and directly go to step 13.
- ✓ Take protective measures when opening the ampoule, such as using gloves, tissue, etc.

12. Insert the syringe or capillary tube into the fillport of the cartridge.

NOTE:

- ✓ When using a syringe, discard the first 2 drops of solution first, then remove the needle from it, and finally insert it into the fillport.
- ✓ When using a capillary tube, directly insert the capillary tube into the adaptor till the tube reaches the interface between the adaptor and the cartridge.
- ✓ To avoid inaccurate test results, make sure there are no bubbles in the sample. If bubbles continually exist, use a new ampoule and syringe or capillary tube to collect samples again.

13. Gently insert the cartridge into the cartridge port, and carefully press down to ensure that it clicks into place.

For a valid cartridge, the indicator in the cartridge port will turn green, and the system will automatically aspirate calibrant. For an invalid cartridge, the indicator will turn red, the cartridge will be ejected and a message will pop up to prompt you.

NOTE:

- ✓ The cartridge can not be removed from the analyzer until the measurement is complete.
- ✓ Never inject the sample. It will be aspirated automatically.

14. The system automatically aspirates calibrant.

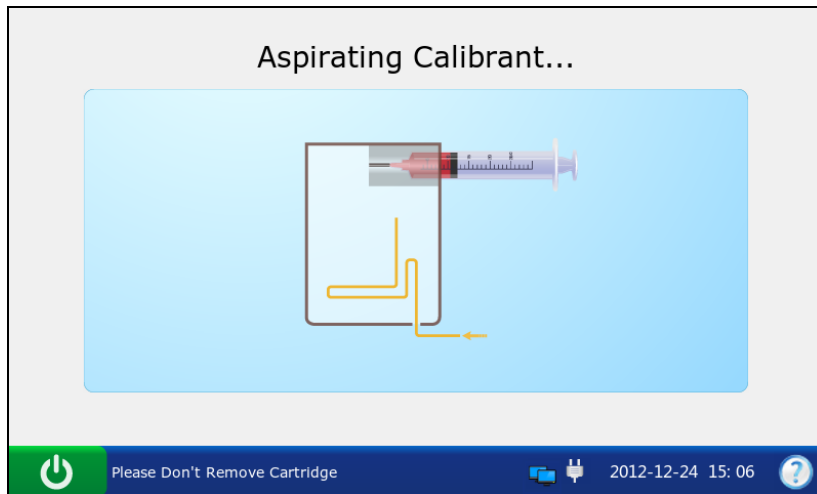


Figure 6-6 Aspirating Calibrant...

15. The system automatically performs calibration.

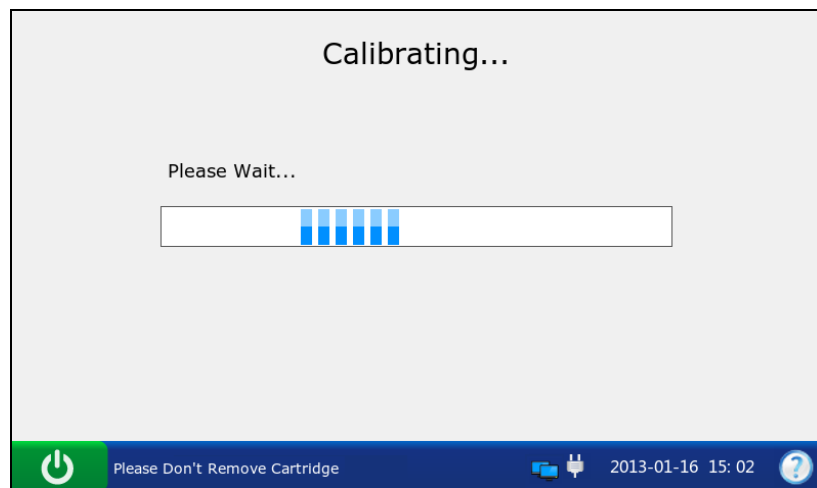


Figure 6-7 Calibration in Progress

16. The system automatically aspirates samples when calibration is complete.

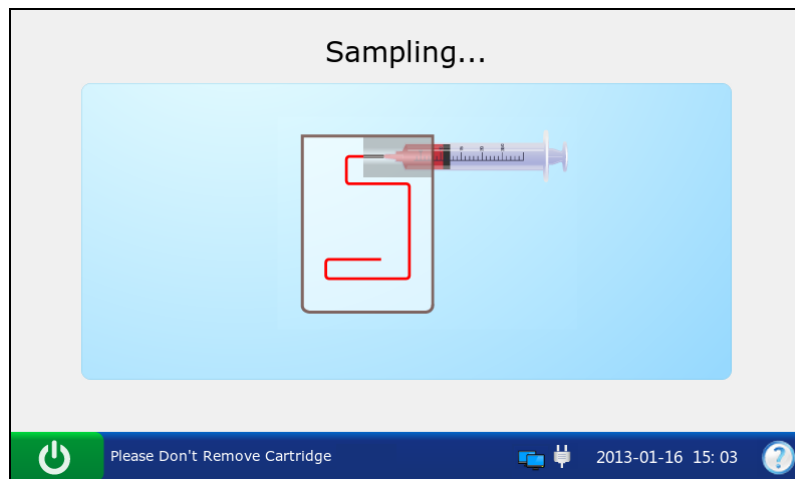


Figure 6-8 Sampling...

17. The system automatically analyzes the sample upon the completion of sampling.

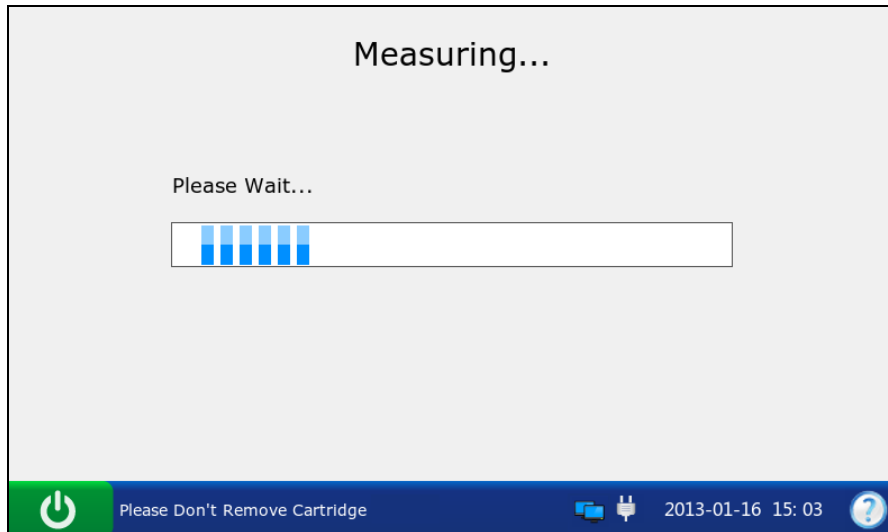


Figure 6-9 Measurement in Progress

18. The system automatically displays the test results upon the completion of the test.

Parameter	Result	Unit	Range	QC Status
pH	7.400		[7.100-7.700]	Under Control
pO2	102	mmHg	[94-110]	Under Control
pCO2	42.0	mmHg	[39.0-45.0]	Under Control
Na+	134	mmol/L	[130-138]	Under Control
K+	4.4	mmol/L	[4.0-4.8]	Under Control
Ca++	1.10	mmol/L	[1.00-1.20]	Under Control

Figure 6-10 Control Test Results

19. View the results.

NOTE:

- ✓ The system will indicate whether the results are within or outside the acceptable ranges with **Under Control/Out of Control**.
- ✓ If a parameter fails calibration, the system will not be able to determine whether it is under control, and will display **Calibration Failure** to prompt you.

- ✓ The system will not report the result for a parameter failing the control test in the patient sample analysis, if QC Lockout function is enabled in Setup. To report the result for the parameter, repeat the control test till the parameter passes it.
- ✓ If the results are outside the acceptable ranges, check the following items first, and then perform another test.
 - Refer to the user manual to confirm that the test procedures are correct.
 - Test cartridges and controls are stored properly and have not expired.
 - The system passes the electronic simulator test.

If all the above items are verified, but the results are still outside the acceptable ranges, please stop using the system and contact EDAN or its authorized distributors for assistance.

20. Remove the test cartridge from the system.

21. Press **Print** to print the results.

22. Press **Home** to return to the Main screen.

The contents of a control test report depend on the type of controls you have used, the type of the test cartridge you have used, the options selected in section 4.2.1 Printer Setup and the errors and alarms the system detects during the analysis. Here is an example of a control test report.

Control Test Report

EDAN i15	
System ID	201303200023
Report Type	Control Test Report
Print Time	2012-03-20 15:20:00
Test Time	2012-03-20 15:00:00
Operator ID	55555
Lot Number	21209
Calibration Results	
pH	Pass
pCO ₂	Fail
pO ₂	Pass
...	

Control Test Results

pH 7.5
 $p\text{CO}_2$ --- mmHg
 $p\text{O}_2$ 70 mmHg
 Na^+
 K^+
 Ca^{++}
 Cl^-
 Glu
 Lac
 Hct
 Cre
 BUN

pH Under Control
 $p\text{CO}_2$ Calibration Failure
 $p\text{O}_2$ Under Control
 Na^+ Under Control
 K^+ Under Control
 Ca^{++} Under Control
 Cl^- Under Control
 Glu Under Control
 Lac Under Control
 Hct Under Control
 Cre Under Control
 BUN Under Control

Control Ranges

pH [7.35 - 7.45]
 $p\text{CO}_2$ [35.0 - 45.0] mmHg
 $p\text{O}_2$ [80.0 - 100.0] mmHg
 Na^+ [138.0 - 146.0] mmol/L
 K^+ [3.50 - 4.90] mmol/L
 Ca^{++} [1.12 - 1.32] mmol/L
 Cl^- [98 - 109] mmol/L
 Glu [3.9 - 5.8] mmol/L
 Lac [0.36 - 1.7] mmol/L
 Hct [35 - 51] %
 Cre [0.6 - 1.3] mg/dL
 BUN

6.1.3 Control Database

The control database displays control test data for the most recent month by default, and it can hold up to 1000 data entries. The system displays 50 data entries on every page. Press **Prev.** and **Next** to page through the screens of the displayed data entries. When 80% of the space is occupied, the system will prompt you to export the stored data to a removable disk (such as a USB drive). If data is not exported, the system will continue to save new data. When the database is full, the system will always prompt you to export the stored data. If data is still not exported, the system will automatically delete the oldest one to accommodate a new one. The following operations can be performed in the control database: transmitting control test data to the Data Management System (DMS) through WIFI or the network, exporting control test data to a removable disk (such as a USB drive), viewing the details of control test data, searching for and printing control test data, etc.

On the Database screen, press  to get to the Control Database screen.

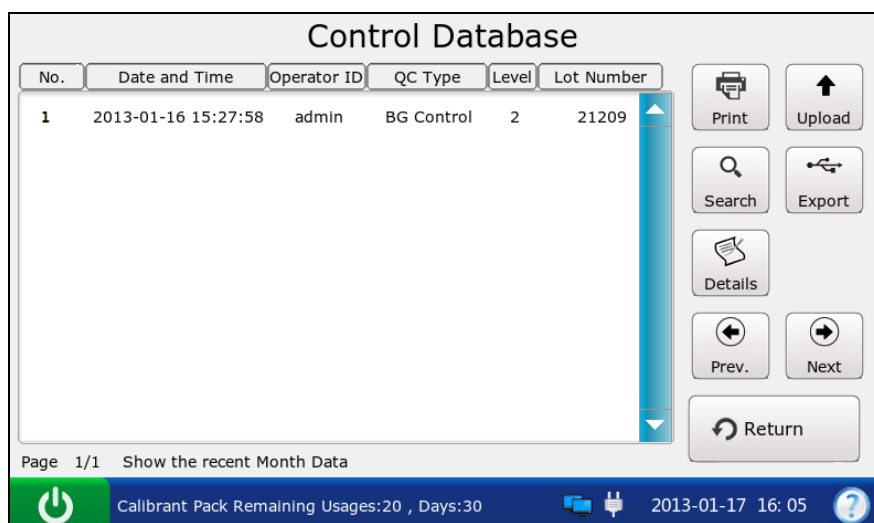


Figure 6-11 Control Database Screen

6.1.3.1 Searching for Control Test Data

1. On the Control Database screen, press **Search**.
2. Enter the search conditions, and press **OK**.

Control Search

Operator ID

QC Level

Start Time Year Mon Day

End Time Year Mon Day

✓ OK ✕ Cancel

Calibrant Pack Remaining Usages:20 , Days:30 2013-01-17 16:05

Figure 6-12 Enter Search Conditions

- The system automatically begins the search and displays the results.

Control Search Results

No.	Date and Time	Operator ID	QC Type	Level	Lot Number
1	2013-01-16 15:27:58	admin	BG Control	2	21209

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Calibrant Pack Remaining Usages:20 , Days:30 2013-01-17 16:05

Figure 6-13 Search Results

- Press **Return** to go back to the Control Database screen.

6.1.3.2 Viewing Details of Control Test Data

- Press the control test data you want to view.
- Press **Details**. The system displays the details:

Parameter	QC Status	Result	Unit	Reference Range
pH	Under Control	7.400		[7.100-7.700]
pO ₂	Under Control	102	mmHg	[94-110]
pCO ₂	Under Control	42.0	mmHg	[39.0-45.0]
Na ⁺	Under Control	134	mmol/L	[130-138]
K ⁺	Under Control	4.4	mmol/L	[4.0-4.8]
Ca ⁺⁺	Under Control	1.10	mmol/L	[1.00-1.20]
Cl ⁻	Under Control	101	mmol/L	[97-105]

Calibrant Pack Remaining Usages:20 , Days:30 2013-01-17 16: 06

Figure 6-14 Details of Control Test Results

3. View the details.
4. Press **Return** to go back to the Control Database screen.

6.1.3.3 Exporting/Uploading/Printing Control Test Data

1. Open the control database.
2. Select the desired control test data.

To	Do this
Export	Insert a removable disk into the analyzer, and then press Export .
Upload	Press Upload .
Print	Press Print .

NOTE:

If no control test data is selected before pressing **Export/Upload/Print**, all of the data stored in the control database will be exported/uploaded/printed.

6.2 Proficiency Test

Proficiency tests are also called external quality control tests. In proficiency tests, the analysis of unknown samples from external quality control providers can reflect the accuracy of the system.

6.2.1 Procedures for Proficiency Test

Follow the directions below to perform a proficiency test:

1. Examine the package label of proficiency samples to ensure they have not expired.
2. Remove an ampoule from the box and equilibrate it to room temperature.

If oxygen is to be measured, the ampoule needs to stand at room temperature for 4 hours. If not, the ampoule needs to stand at room temperature for only about 30 minutes.

3. Press the **On/Off** button on the left hand side of the analyzer to turn it on.

4. Enter the user name and password manually, and then press .




To enter the user name with the bar code scanner, press  first, and then scan the user name bar code.



Figure 6-15 Enter User Name and Password

5. On the Main screen, press  to go to the Quality Control screen, and then press .

6. Press **Scan Barcode**, and scan the bar code on a new cartridge foil pouch.

If the bar code is scanned successfully, the system will beep and the scanner will be automatically turned off. If the scanned data is valid, the system will display the screen for the next procedure. If the scanned data is invalid, a message will pop up to prompt you.



Figure 6-16 Scan Bar Code


7. Open the foil pouch and remove the cartridge from it.

NOTE:

- ✓ Avoid tearing the bar code on the foil pouch.
- ✓ For sample introduction with a capillary tube or an ampoule, please insert a capillary adaptor/ampoule adaptor into the fillport after removing the cartridge.
- ✓ When inserting an ampoule adaptor into the fillport of a test cartridge, make sure the indent of the adaptor is on the upside as shown in the picture below:



- Enter the lot number of the proficiency sample, and then press **Enter**.

To enter the lot number information with the bar code scanner, press  first, and then scan the bar code.

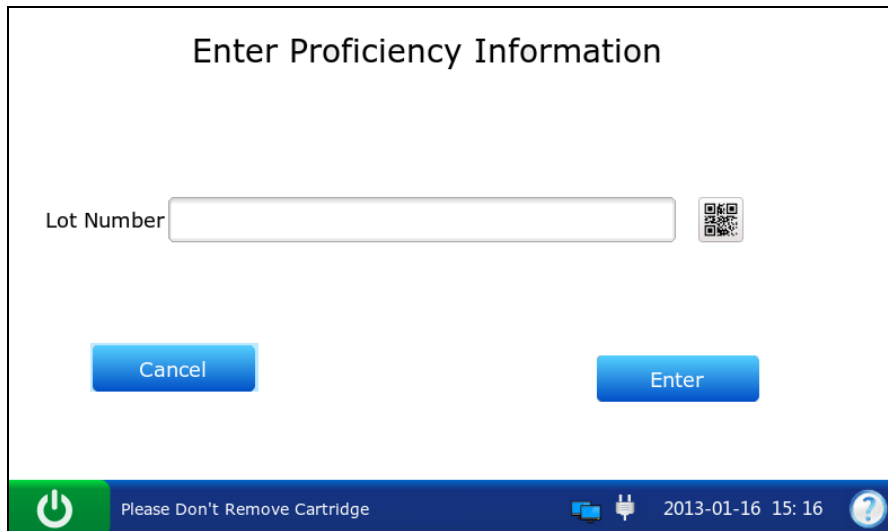


Figure 6-17 Enter Information

NOTE:

Only lot number information within 1-16 digits is acceptable.

- Mix the proficiency sample completely by shaking the ampoule gently, and then tap the tip of the ampoule carefully with your fingernail to remove any solution.

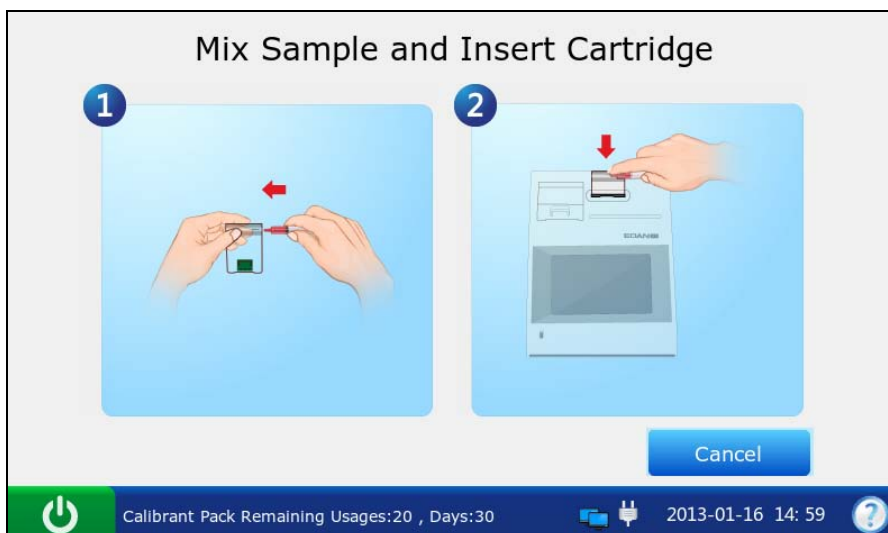


Figure 6-18 Mix Proficiency Sample and Insert Cartridge

NOTE:

Avoid heating the ampoule with your hands when shaking the ampoule.

10. Open the ampoule by snapping off the top and immediately transfer proficiency solution by slowly drawing an appropriate amount of solution with a syringe or capillary tube from the bottom of the ampoule.

NOTE:

- ✓ When using an ampoule, you need not transfer the proficiency solution. Insert the ampoule into the adaptor after opening it, and directly go to step 12.
 - ✓ Take protective measures when opening the ampoule, such as using gloves, tissue, etc.
11. Insert the syringe or capillary tube into the fillport of the cartridge.

NOTE:

- ✓ When using a syringe, discard the first 2 drops of solution first, then remove the needle from it, and finally insert it into the fillport.
 - ✓ When using a capillary tube, directly insert the capillary tube into the adaptor till the tube reaches the interface between the adaptor and the cartridge.
 - ✓ To avoid inaccurate test results, make sure there are no bubbles in the sample. If bubbles continually exist, use a new ampoule and syringe or capillary tube to collect samples again.
12. Gently insert the cartridge into the cartridge port, and carefully press down to ensure that it clicks into place.

For a valid cartridge, the indicator in the cartridge port will turn green, and the system will automatically aspirate calibrant. For an invalid cartridge, the indicator will turn red, the cartridge will be ejected and a message will pop up to prompt you.

NOTE:

- ✓ The cartridge can not be removed from the analyzer until the measurement is complete.
- ✓ Never inject the sample. It will be aspirated automatically.

13. The system automatically aspirates calibrant.

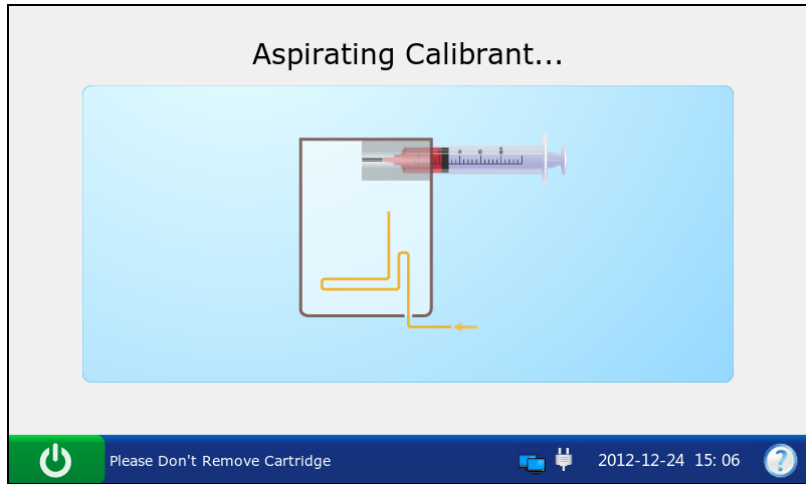


Figure 6-19 Aspirating Calibrant...

14. The system automatically performs calibration.

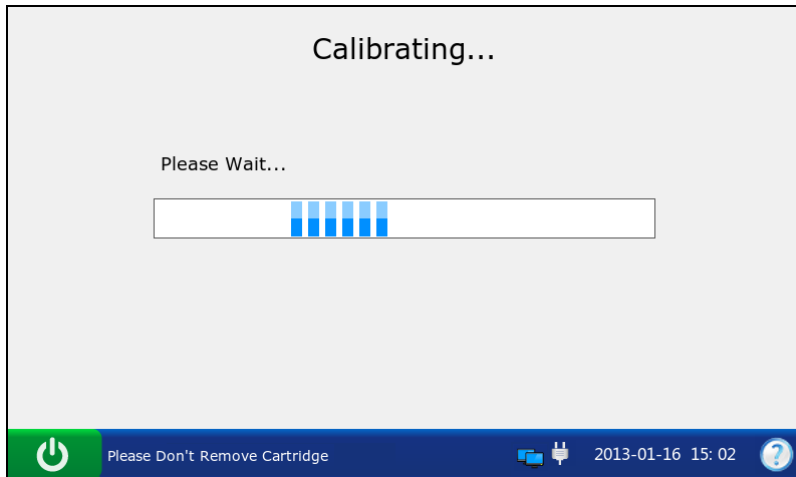


Figure 6-20 Calibration in Progress

15. The system automatically aspirates samples when calibration is complete.

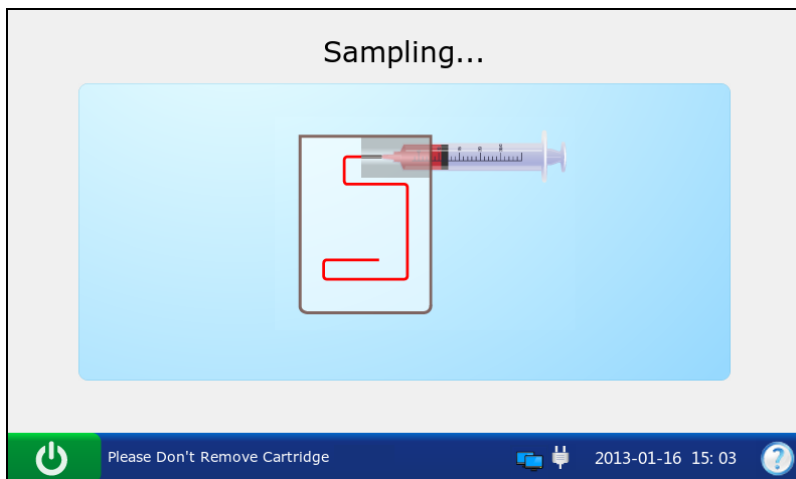


Figure 6-21 Sampling...

16. The system automatically analyzes the sample upon the completion of sampling.

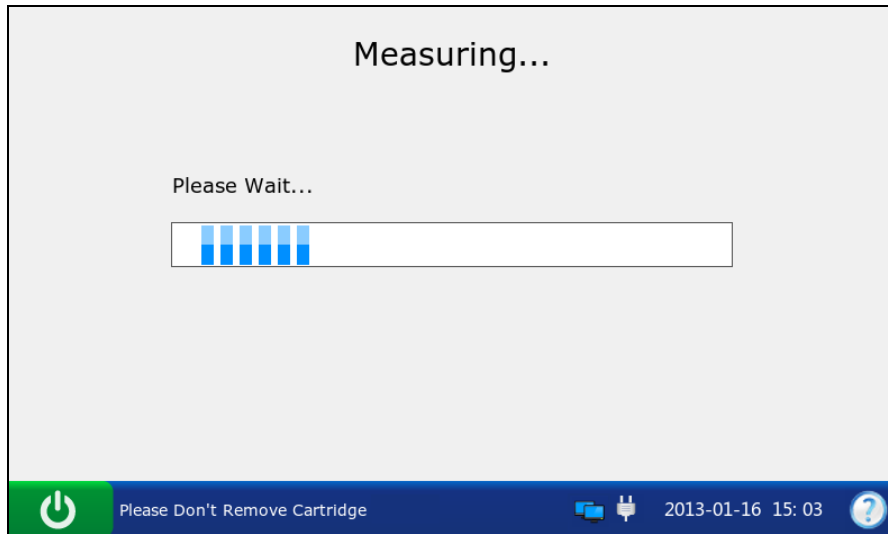


Figure 6-22 Measurement in Progress

17. The system automatically displays the test results upon the completion of the test.

Parameter	Result	Unit	Calibration Result
pH	7.400		Pass
pO2	102	mmHg	Pass
pCO2	42.0	mmHg	Pass
Na+	134	mmol/L	Pass
K+	4.4	mmol/L	Pass
Ca++	1.10	mmol/L	Pass

Figure 6-23 Proficiency Test Results

18. View the results.

19. Remove the test cartridge from the system.

20. Press **Print** to print the results.

21. Press **Home** to return to the Main screen.


Here is an example of a proficiency test report.

Proficiency Test Report

EDAN i15		
System ID	201303200023	
Report Type	Proficiency Test Report	
Print Time	2012-03-20 15:20:00	
Test Time	2012-03-20 15:10:00	
Operator ID	55555	
Lot Number	21209	
Calibration Results		
pH	Pass	
pCO ₂	Pass	
pO ₂	Pass	
...		
Proficiency Test Results		
pH	7.4	
pCO ₂	40	mmHg
pO ₂	90	mmHg
Na ⁺	140	mmol/L
K ⁺	4.0	mmol/L
Ca ⁺⁺	1.2	mmol/L
Cl ⁻	101	mmol/L
Glu	4.1	mmol/L
Lac	0.8	mmol/L
Hct	40	%
Cre	0.7	mg/dL
BUN	23	mmol/L

6.2.2 Proficiency Database

The proficiency database displays all the proficiency test data by default, and it can store up to 1000 data entries. The system displays 50 data entries on every page. Press **Prev.** and **Next** to page through the screens of the displayed data entries. The following operations can be performed in the proficiency database: transmitting proficiency test data to the Data Management System (DMS) through WIFI or the network, exporting proficiency test data to a removable disk (such as a USB drive), viewing the details of proficiency test data, searching for and printing proficiency test data, etc.

On the Database screen, press  to get access to the Proficiency Database screen.

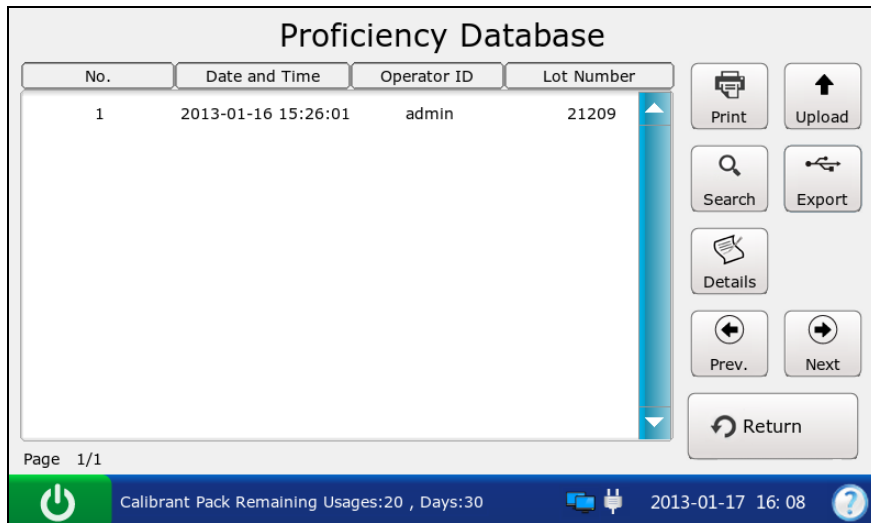


Figure 6-24 Proficiency Database Screen

6.2.2.1 Searching for Proficiency Test Data

1. On the Proficiency Database screen, press **Search**.
2. Enter the search conditions, and press **OK**.

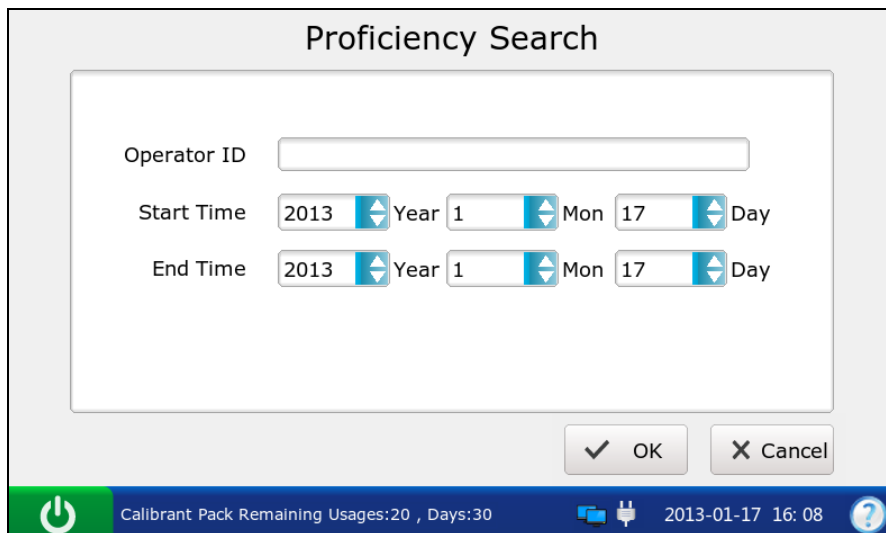


Figure 6-25 Enter Search Conditions

3. The system automatically begins the search and displays the results.

Proficiency Search Results			
No.	Date and Time	Operator ID	Lot Number
1	2013-01-16 15:26:01	admin	21209

Page 1/1

Callibrant Pack Remaining Usages:20 , Days:30

2013-01-17 16: 08

Figure 6-26 Search Results

4. Press **Return** to go back to the Proficiency Database screen.

6.2.2.2 Viewing Details of Proficiency Test Data

1. Press the proficiency test data you want to view.
2. Press **Details**. The system displays the details:

Proficiency Details			
Parameter	Result	Unit	Calibration Result
pH	7.400		Pass
pO2	102	mmHg	Pass
pCO2	42.0	mmHg	Pass
Na+	134	mmol/L	Pass
K+	4.4	mmol/L	Pass
Ca++	1.10	mmol/L	Pass
Cl-	101	mmol/L	Pass
Hct	32	%	Pass

Callibrant Pack Remaining Usages:20 , Days:30

2013-01-17 16: 20

Figure 6-27 Details of Proficiency Test Results

3. View the details.
4. Press **Return** to go back to the Proficiency Database screen.

6.2.2.3 Exporting/Uploading/Printing Proficiency Test Data

1. Open the proficiency database.
2. Select the desired proficiency test data.

To	Do this
Export	Insert a removable disk into the analyzer, and then press Export .
Upload	Press Upload .
Print	Press Print .


NOTE:


If no proficiency test data is selected before pressing **Export/Upload/Print**, all of the data stored in the proficiency database will be exported/uploaded/printed.

6.3 Simulator Test

6.3.1 Procedures for External Simulator Test

Follow the procedures below to perform an external simulator test:

1. Press the **On/Off** button on the left hand side of the analyzer to turn it on.
2. Enter the user name and password manually, and then press .

To scan the bar code of the user name, press  first, and then scan the bar code.

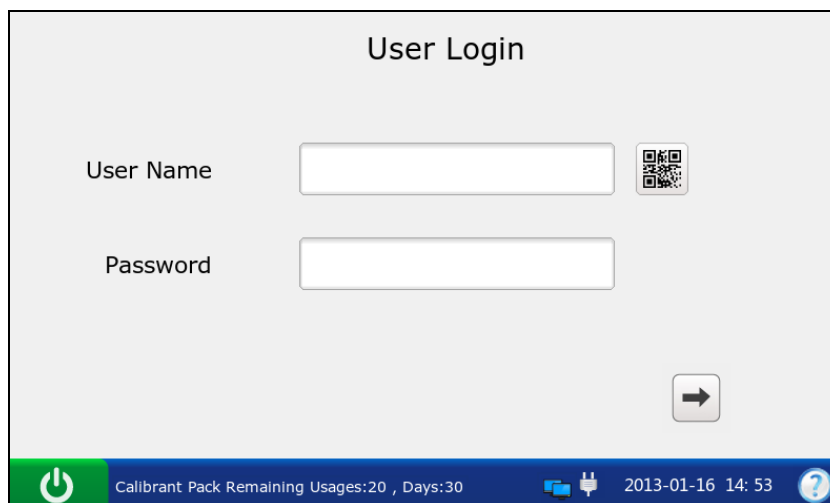


Figure 6-28 Enter User Name and Password



3. On the Main screen, press  to go to the Quality Control screen, and then press .
4. Gently insert the external electronic simulator into the cartridge port, and press down to ensure it clicks into place. If the electronic simulator is inserted properly, the system will automatically perform a simulator test.



Figure 6-29 Insert External Simulator

NOTE:

- ✓ Avoid touching the contact pads.
 - ✓ Never touch the simulator after inserting it into the system.
5. The system automatically starts to perform an external simulator test.

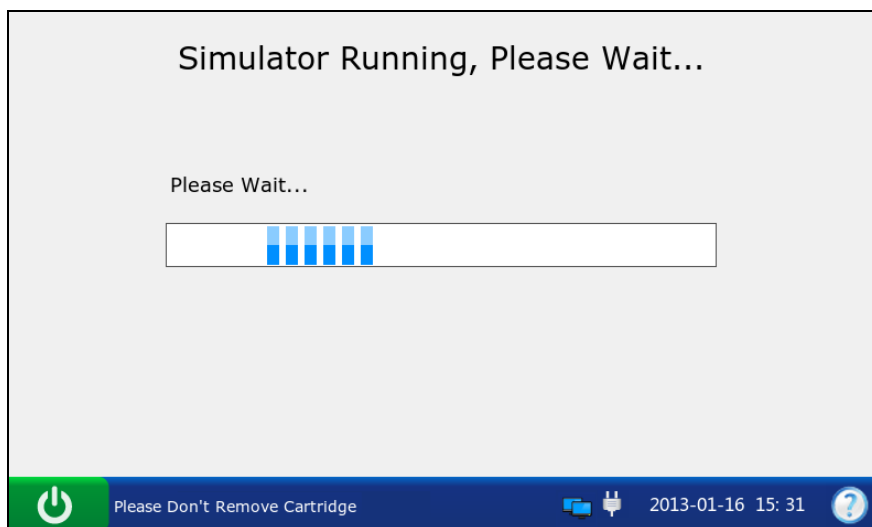


Figure 6-30 Measurement in Progress

- The system automatically displays the test result upon the completion of the test.

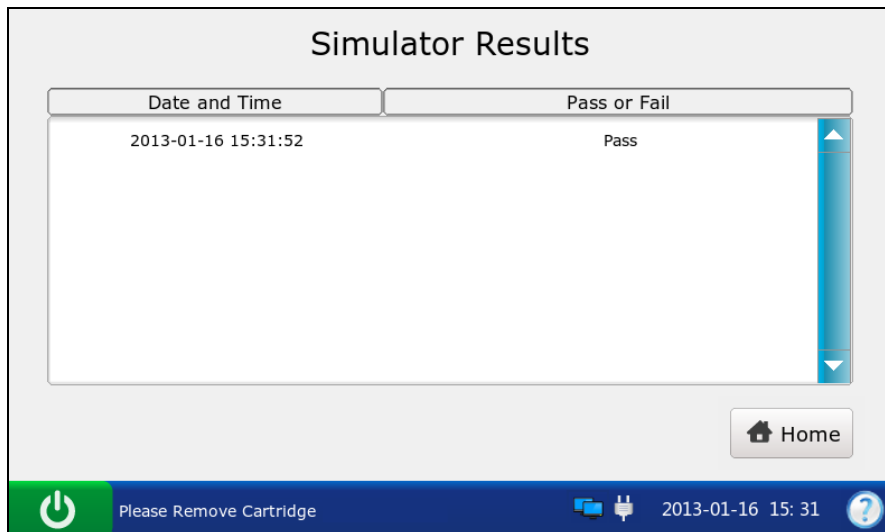


Figure 6-31 External Simulator Test Result

- View the result.

NOTE:

- ✓ Upon the completion of the test, the message “Please Remove Cartridge” will be displayed on the status bar at the bottom of the screen, and the simulator will be ejected.
- ✓ If the system passes the external simulator test, it can be used to analyze samples.
- ✓ If the system fails the external simulator test, perform the test again or try another simulator. If it passes the test, it can be used to analyze samples. If it fails again, contact EDAN or its authorized distributors for assistance.

- Press **Home** to go to the Main screen.

- Remove the external simulator from the system, and put it back.


NOTE:

Never remove the external simulator until the test is complete.

6.3.2 Simulator Database

The simulator database displays all of the simulator test data by default, and it can store up to 2000 data entries. The system displays 50 data entries on every page. Press **Prev.** and **Next** to page through the screens of the displayed data entries. When 80% of the space is occupied, the

system will prompt you to export the stored data to a removable disk (such as a USB drive). If data is not exported, the system will continue to save new data. When the database is full, the system will always prompt you to export data. If data is still not exported, the system will automatically delete the oldest one to accommodate a new one. The following operations can be performed in the simulator database: transmitting simulator test data to the Data Management System (DMS) through WIFI or the network, exporting simulator test data to a removable disk (such as a USB drive), searching for and printing simulator test data, etc.

On the Database screen, press  to get access to the Simulator Database screen.

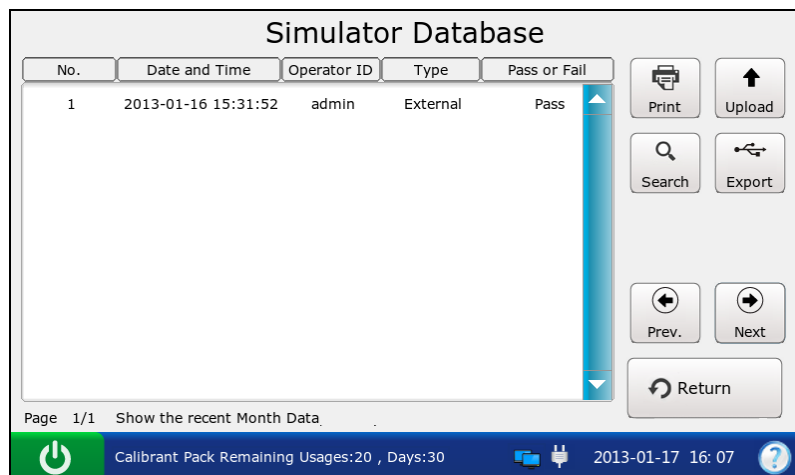


Figure 6-32 Simulator Database Screen

6.3.2.1 Searching for Simulator Test Data

1. On the Simulator Database screen, press **Search**.
2. Enter the search conditions, and press **OK**.

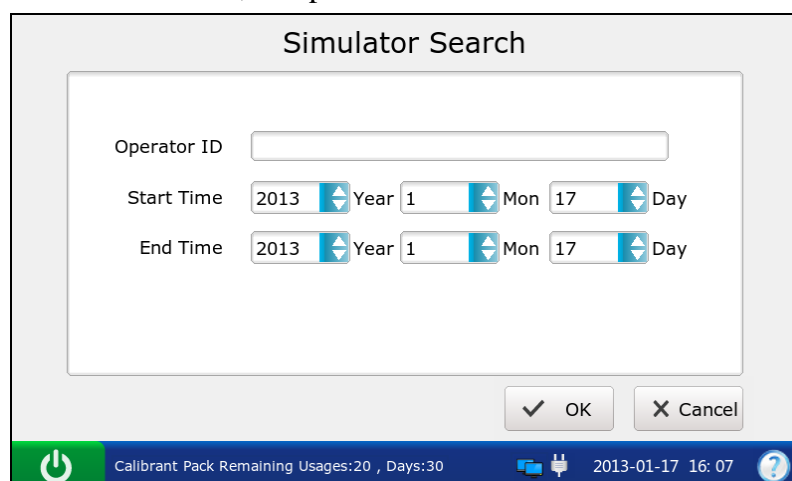


Figure 6-33 Enter Search Conditions

- The system automatically begins the search and displays the results.

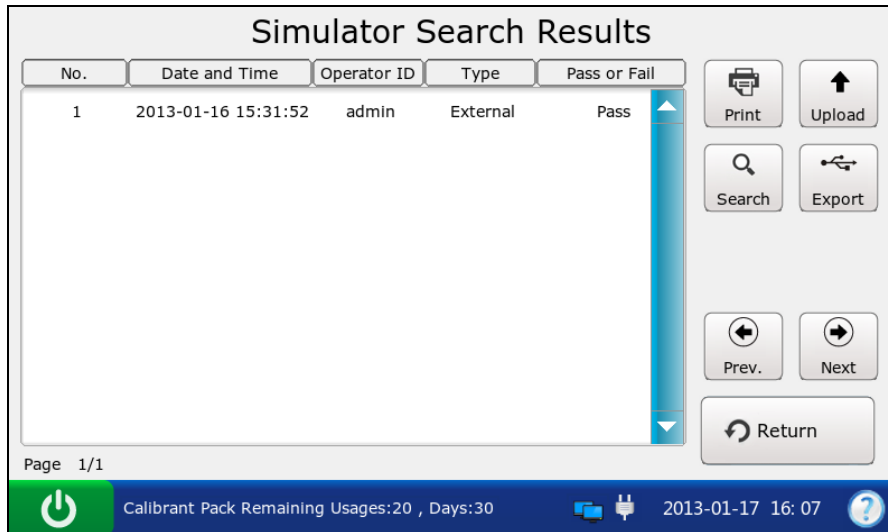


Figure 6-34 Search Results

- Press **Return** to go back to the Simulator Database screen.

6.3.2.2 Exporting/Uploading/Printing Simulator Test Data

- Open the simulator test database.
- Select the desired simulator test data.

To	Do this
Export	Insert a removable disk into the analyzer, and then press Export .
Upload	Press Upload .
Print	Press Print .

NOTE:

If no simulator test data is selected before pressing **Export/Upload/Print**, all of the data stored in the simulator database will be exported/uploaded/printed.

Here are examples of simulator test reports:

External Simulator Test Report

EDAN i15	
System ID	201303200023
Report Type	External Simulator Test Report
Print Time	2012-03-20 15:20:00
Test Time	2012-03-20 15:20:00
Operator ID	admin
Result	Pass

Internal Simulator Test Report

EDAN i15	
System ID	201303200023
Report Type	Internal Simulator Test Report
Print Time	2012-03-20 15:20:00
Test Time	2012-03-20 15:20:00
Operator ID	admin
Result	Pass

Chapter 7 Data Management

7.1 Introduction


The system has powerful data management ability. It can logically manage the results for different tests and transmit them to the DMS.

There are two ways of transmitting data:

- With a removable disk such as a USB drive
- Through LAN/WLAN

NOTE:

The transmitted data can only be opened by the DMS.

On the Main screen, press  to get access to the Database screen.

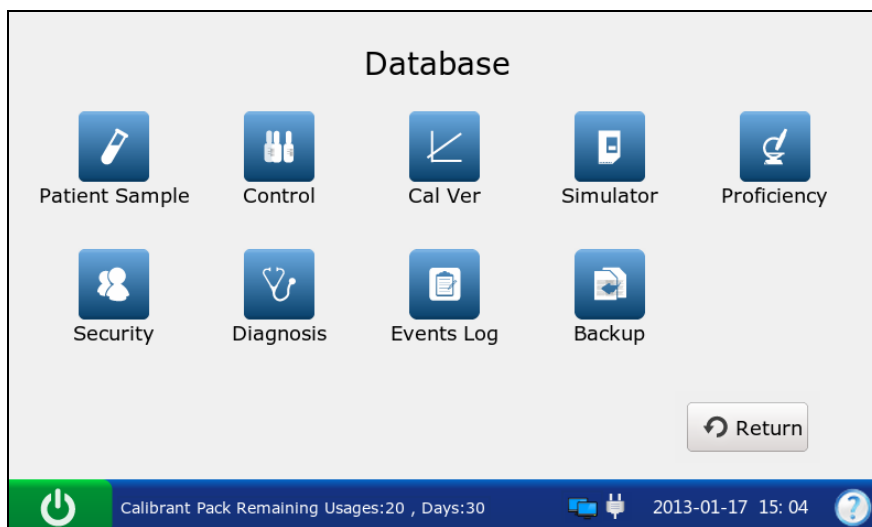


Figure 7-1 Database Screen

7.2 Databases


The following databases have been described in the previous chapters: Patient Sample Database, Control Database, Proficiency Database, Simulator Database. In this part, the databases below will be described: Security Database, Diagnosis Database, Events Log Database and Backup.

7.2.1 Security Database

NOTE:

Only administrators can get access to the security database.

The security database displays all the security data by default, and it can store up to 100 data entries. The system displays 50 data entries on every page. Press **Prev.** and **Next** to page through the screens of the displayed data entries. The following operations can be performed in the security database: deleting security data, searching for operators, adding and editing security data, etc.

On the Database screen, press  to get access to the Security Database screen.

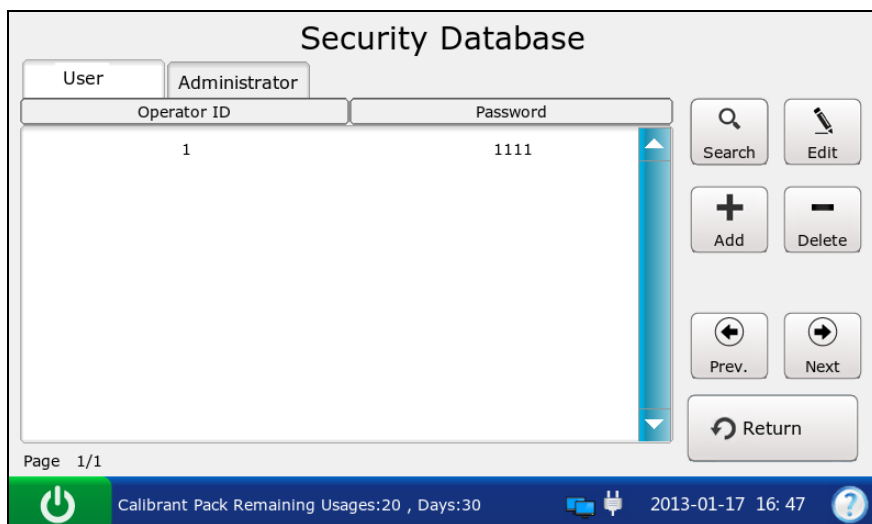


Figure 7-2 Security Database Screen

Operators are divided into four levels according to their access rights: operators, administrators, service engineers and engineers from the manufacturer. If an operator cannot access a function, the following message will appear:

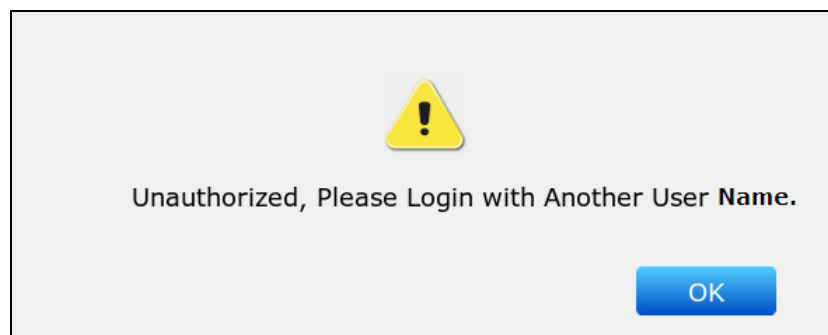


Figure 7-3 No Access Rights

7.2.1.1 Searching for an Operator

1. On the Security Database screen, press **Search**.
2. Enter the operator ID, and press **OK**.

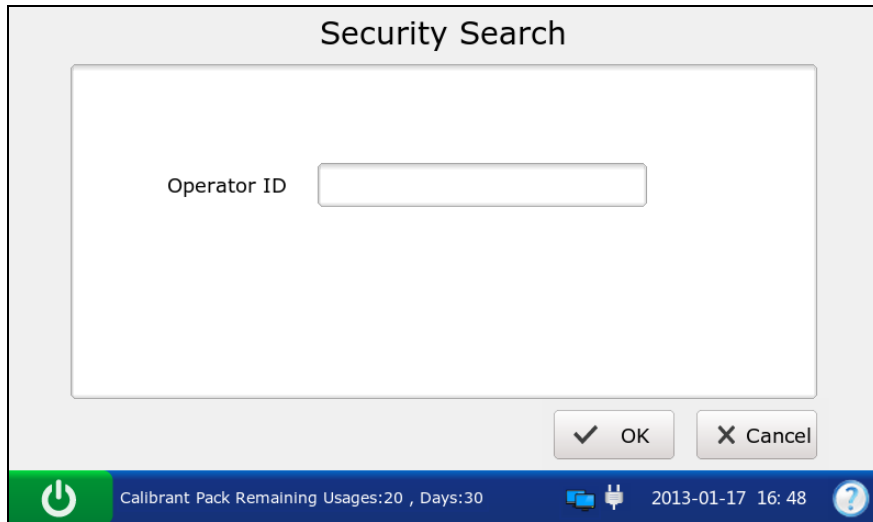


Figure 7-4 Enter Search Conditions

3. The system automatically begins the search and displays the results.

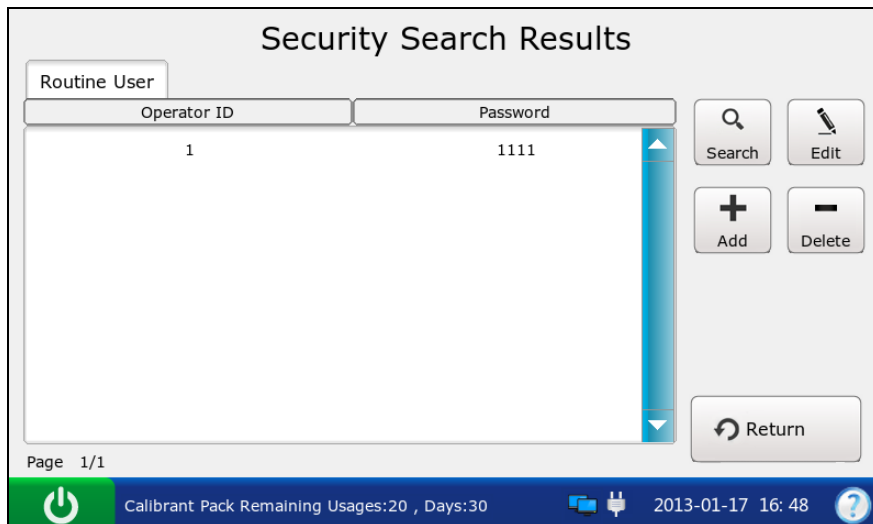
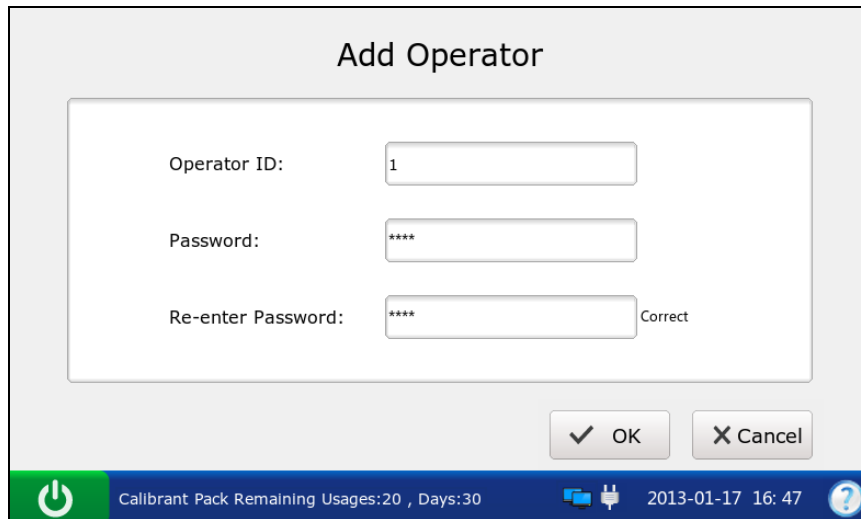


Figure 7-5 Search Results

4. Press **Return** to go back to the Security Database screen.

7.2.1.2 Adding an Operator

1. On the Security Database screen, press **Add**.
2. Enter the operator ID, password and re-enter the same password.



The screenshot shows a dialog box titled "Add Operator". It contains three input fields: "Operator ID" with the value "1", "Password" with "****", and "Re-enter Password" with "****". A "Correct" label is positioned to the right of the re-enter password field. At the bottom right of the dialog are "OK" and "Cancel" buttons. The system status bar at the bottom of the screen displays a power icon, the text "Calibrant Pack Remaining Usages:20 , Days:30", a USB icon, the date and time "2013-01-17 16:47", and a help icon.

Figure 7-6 Add Operator

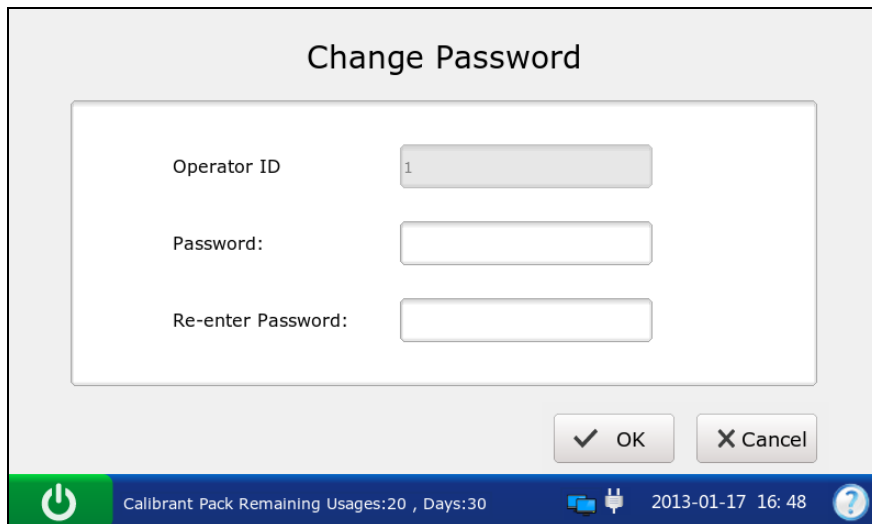
3. Press **OK** to save the changes, and press **OK** in the pop up dialog box. The system will go to the Security Database screen.

NOTE:

- ✓ The operator ID is case sensitive, and should be 1 - 16 characters long (including both letters and numbers). "admin/demo/service/edan", or upper and lower case combinations of these words are not permitted.
- ✓ The password is case sensitive, and should be 4 - 16 characters long (including both letters and numbers).

7.2.1.3 Changing Operator Password

1. Select the operator data you want to edit.
2. Press **Edit**.
3. Enter the password, and re-enter the same password.



Change Password

Operator ID

Password:

Re-enter Password:

✓ OK ✕ Cancel

Calibrant Pack Remaining Usages:20 , Days:30 2013-01-17 16:48

Figure 7-7 Change Operator Password

4. Press **OK** to save the changes, and press **OK** in the pop up dialog box. The system will go to the Security Database screen.

NOTE:

The password is case sensitive, and should be 4 - 16 characters long (including both letters and numbers).

7.2.1.4 Deleting Security Data

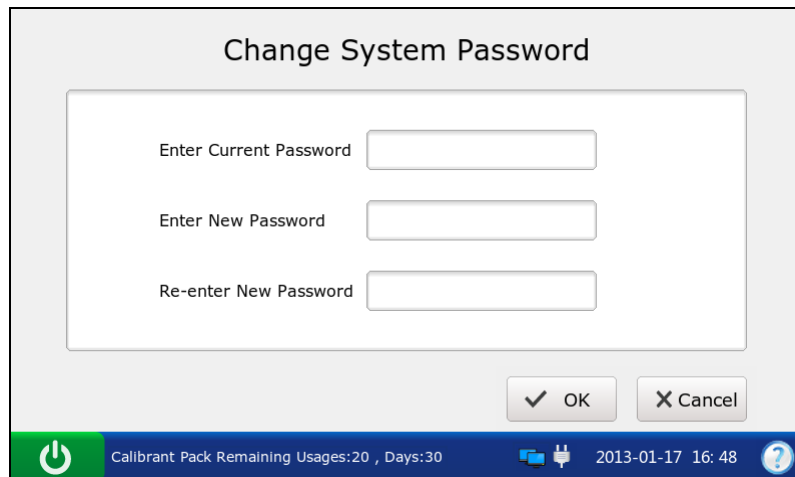
1. Select the desired security data.
2. Press **Delete**, and press **OK** in the pop up message.

NOTE:

If no security data is selected before pressing **Delete**, all of the data stored in the security database will be deleted.

7.2.1.5 Changing System Password

1. Press **Administrator** on the Security Database screen.
2. Press **Edit**.
3. Enter the current system password, enter the new system password and re-enter the same password.



Change System Password

Enter Current Password

Enter New Password

Re-enter New Password

✓ OK ✕ Cancel

Calibrant Pack Remaining Usages:20 , Days:30 2013-01-17 16:48

Figure 7-8 Change System Password

4. Press **OK** to accept the changes, and press **OK** in the pop up dialog box. The system will go to the User Login screen.

NOTE:

- ✓ The default factory system password is 123456.
- ✓ Only administrators can change the system password (Even engineers from the manufacturer can not change it, although they can retrieve the password to the default factory setting).

7.2.2 Diagnosis Database


The diagnosis database displays diagnosis data for the most recent month by default, and it can store up to 10000 data entries. The following operations can be performed in the diagnosis database: exporting diagnosis data to a removable disk (such as a USB drive), viewing the details of diagnosis data, searching for and printing diagnosis data, etc.

NOTE:

Only service engineers and engineers from the manufacturer can get access to the diagnosis database.

7.2.3 Events Log Database

The events log database records the following information: User Login and Logout, changing time and date, changing slopes and offsets, changing patient information, deleting data stored in databases, replacing a calibrant fluid pack. It can store up to 10000 data entries. The system displays 50 data entries on every page. Press **Prev.** and **Next** to page through the screens of the displayed data entries. You can export, search for and print the events with the events log database.

On the Database screen, press  to get access to the Events Log Database screen.

No.	Date and Time	Operator ID	Operation
1	2013-01-16 16:02:37	edan	Login
2	2013-01-16 15:54:26	edan	Login
3	2013-01-16 15:42:49	demo	Login
4	2013-01-16 15:41:24	admin	Login
5	2013-01-16 15:37:48	admin	Login
6	2013-01-16 15:37:22	admin	Login
7	2013-01-16 15:36:47	admin	Login
8	2013-01-16 15:36:26	admin	Login

Page 1/1 Show the recent Month Data

Calibrant Pack Remaining Usages:20 , Days:30 2013-01-17 16: 25

Figure 7-9 Events Log Database Screen

7.2.3.1 Searching for Events Data

1. On the Events Log Database screen, press **Search**.
2. Enter the search conditions, and press **OK**.

Operator ID	<input type="text"/>
Start Time	2013 Year 1 Mon 17 Day
End Time	2013 Year 1 Mon 17 Day
<input type="button" value="OK"/> <input type="button" value="Cancel"/>	

Calibrant Pack Remaining Usages:20 , Days:30 2013-01-17 16: 25

Figure 7-10 Enter Search Conditions

- The system automatically begins the search and displays the results.

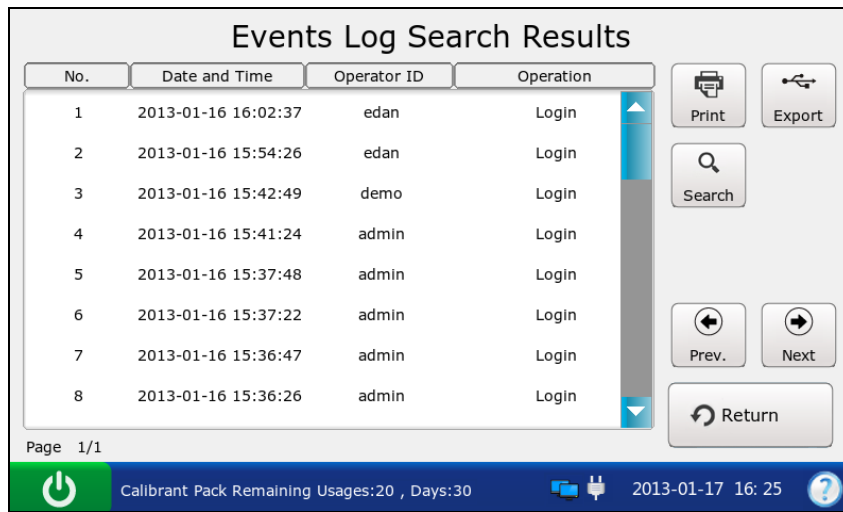


Figure 7-11 Search Results

- Press **Return** to go back to the Events Log Database screen.

7.2.3.2 Exporting/Printing Events Data

- Open the events log database.
- Select the desired event data.

To	Do this
Export	Insert a removable disk into the analyzer, and then press Export .
Print	Press Print .

NOTE:

If no event data is selected before pressing **Export/Print**, all of the data stored in the events log database will be exported/printed.

Here is an example of an event log report:

EDAN i15	
System ID	201303200023
Print Time	2012-03-20 15:20:00
Log Time	2012-03-20 15:20:00
Report Type	Events Log Report
Operator ID	1111
Operation	Change date and time

7.2.4 Backup

With this function, all of the stored data in the following databases can be backed up: Patient Sample Database, Control Database, Proficiency Database and Simulator Database.

Follow the steps below to backup data:

1. On the Database screen, press  to access the Backup screen.

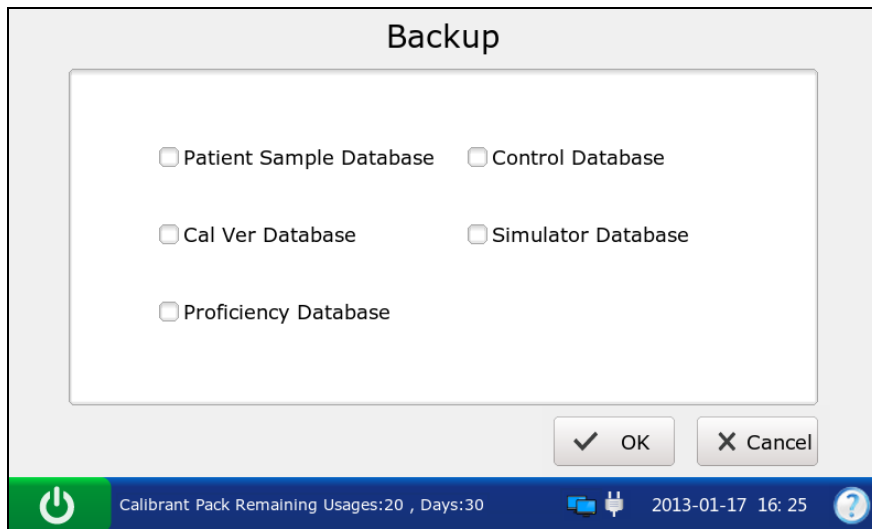


Figure 7-12 Backup Screen

2. Select the database you want to backup. \checkmark indicates the database is selected.
3. Press **OK**, and press **OK** in the pop up dialog box, the system will backup all of the data stored in the database.
4. Press **OK** in the pop up dialog box to delete all of the data in the backup database.

CAUTION

Deleting data in the backup database is permanent. Deleted data can not be recovered after deletion.

Chapter 8 Online Update

8.1 Introduction

- Online update refers to analog board software update.
- The system can download the latest version of the update program from the network and automatically install it.
- Only engineers from the manufacturer can perform this action.

8.2 Procedures for Online Update

NOTE:

Avoid interruption of the power supply during the update process.

1. Press **Setup** → **Diagnostics** → **Analog Update**.
2. The system will automatically download the latest version of the update program and perform updating.
3. Press **OK** when the update is complete. If the update fails, the system will prompt you.

Chapter 9 Troubleshooting

The following table lists some problems you may encounter to assist in troubleshooting.

Table 9-1 Troubleshooting Examples

Item	Problem	Solution
1	A test cartridge will not be ejected automatically when a test is complete.	If the system is running smoothly, remove the test cartridge ejector cap, pull the middle hole with a pointed object, and remove the test cartridge from the system.
2	A test cartridge is inserted into the system prior to a test.	Remove the test cartridge ejector cap, pull the middle hole with a pointed object, and remove the test cartridge from the system.
3	A simulator will not be ejected automatically when a simulator test is complete.	Remove the test cartridge ejector cap, pull the middle hole with a pointed object, and remove the simulator from the system.
4	A test cartridge can not be removed because of power interruption during operation.	Connect the system to AC power, and turn on the system. After about 1 minute, the test cartridge will be ejected automatically. If it is not ejected automatically, remove the test cartridge ejector cap, pull the middle hole with a pointed object, and remove the test cartridge from the system.
5	A test cartridge can not be ejected because the system malfunctions, for example, the system is dead.	Reboot the system. After about 1 minute, the test cartridge will be ejected automatically. If it is not ejected automatically, remove the test cartridge ejector cap, pull the middle hole with a pointed object, and remove the test cartridge from the system.
6	The prompt “Cartridge is not Qualified” appears.	Perform an electronic simulator test to confirm that the system is working smoothly. If the system passes the simulator test, perform sample tests with new test cartridges. If the problem continues after several attempts, please contact EDAN or its authorized distributors for assistance.
7	The prompt “POGO_PIN does Not Contact	Perform the test again with a new test cartridge. If the prompt appears again,

	Well” appears.	please contact EDAN or its authorized distributors for assistance.
8	The prompt “Cartridge Expired” appears.	Verify that the current date is correct. If the prompt appears again, check that the test cartridge has not expired. If it has expired, use a new test cartridge that has not expired.
9	The prompt “Calibrant is Not Aspirated Properly” appears.	Perform the test again with a new test cartridge. If the prompt appears again, please contact EDAN or its authorized distributors for assistance.
10	The prompt “Air is Not Aspirated Properly” appears.	Perform the test again with a new test cartridge. If the prompt appears again, please contact EDAN or its authorized distributors for assistance.
11	The prompt “Sample Error. Maybe Clots are Detected in Sample” appears.	Check that there are no clots in the blood sample. If there are clots, discard it and collect samples again.
12	The prompt “Insertion Error” appears.	Verify that a simulator is inserted during a simulator test and a test cartridge is inserted during a sample test.
13	The prompt “Calibrant Pack Expired, Confirm Date Setup and Calibrant Pack’s Expiration Date” appears.	Verify that the current date is correct. If the prompt appears again, check that the calibrant fluid pack has not expired. If it has expired, replace the calibrant fluid pack following the user manual instructions.
14	The prompt “Remaining Days: 0” appears.	The calibrant fluid pack has expired. Replace the calibrant fluid pack following the user manual instructions.
15	The prompt “Calibrant Pack Depleted” appears.	The calibrant fluid pack has been depleted. Replace the calibrant fluid pack following the user manual instructions.
16	The prompt “Current Date Error” appears.	The date is earlier than the manufacture date of the calibrant fluid pack. Ensure that the current date is correct.
17	The prompt “Calibrant Pack Improper Removal. Please Replace Calibrant Pack” appears.	The calibrant fluid pack is removed from the system improperly. Replace the calibrant fluid pack following the user manual instructions.

18	The prompt “Barcode Cannot be Identified” appears.	Ensure that the bar code is that of a calibrant fluid pack.
19	The prompt “Calibrant Pack Can’t be Used, Please Scan Again” appears.	Ensure that the bar code is that of a new calibrant fluid pack and that the new calibrant fluid pack has not expired.
20	The calibrant fluid pack chamber door can not be opened.	Ensure that the calibrant fluid pack chamber lock has been unlocked before opening the door.
21	The system fails to scan the calibrant fluid pack or test cartridge bar code.	Check that the calibrant fluid pack or test cartridge bar code is not destroyed, and scan it again.
22	Paper does not run from the paper tray.	Open the printer casing, adjust the paper position carefully, and close the printer casing. Press Print to print a record.
23	Paper-jam appears.	If a jam occurs for the first time, it might be caused by an inappropriate placement of the paper. In this case, open the paper casing, remove the paper from the paper tray, remove the paper with rumples, put the paper in the paper tray again, adjust the position of the paper carefully and close the casing. If the problem continues, please contact EDAN or its authorized distributors for assistance.
24	The prompt “Paper?” appears.	Check whether there is paper in the printer tray. If it has been depleted, load paper again, and shut the printer casing. If the problem continues, please contact EDAN or its authorized distributors for assistance.
25	There is no sound after you successfully press the touch screen.	Check the volume setup.
26	The system can not be connected to a network through WIFI.	Ensure that the intensity of the network signal is strong and that the network setup is correct.
27	The system can not communicate with the DMS.	Ensure that the network or WIFI is successfully connected, and that the IP address of the DMS is correct.

28	Fluids have been spilled on the screen.	Clean and disinfect the screen following the user manual instructions.
29	The USB scanner does not work smoothly.	Check the scanner type. If it is the type recommended by EDAN, remove the scanner from the system, and insert it again. Set the scanner, and scan a bar code again.
30	Forget the user name or password.	For an operator, contact the administrator for assistance. For an administrator, contact EDAN or its authorized distributors for assistance.
31	The lithium battery can not be charged.	Install the lithium battery following the user manual instructions. Connect the system to AC power. The system will be charged automatically. If it still can not be charged, please contact EDAN or its authorized distributors for assistance.
32	There are fluids flowing from the bottom of the analyzer.	Move the analyzer horizontally, and clear the fluids. Remove the calibrant fluid pack from the analyzer and check whether it is damaged. If it is not damaged, perform a simulator test and a control test to ensure the proper performance of the system.
33	The prompt “Ambient Temperature Out of Range” appears.	Check that the ambient temperature is within 10 - 31°C, and that the air vents are not obstructed. Reboot the system. If the problem continues, please contact EDAN or its authorized distributors for assistance.
34	The prompt “Heating Abnormally” appears.	Please contact EDAN or its authorized distributors for assistance.
35	The prompt “Abnormal Cam Location” appears.	Please contact EDAN or its authorized distributors for assistance.
36	The date setup can not be saved after you shut down the system.	Please contact EDAN or its authorized distributors for assistance.
37	The system makes abnormal sounds.	Please contact EDAN or its authorized distributors for assistance.

Chapter 10 Cleaning, Care and Maintenance

The system needs little care and maintenance. Clean and maintain it periodically to ensure its optimum performance.

10.1 Cleaning and Disinfecting the Analyzer



Follow proper safety procedures and take protective measures such as wearing approved gloves when cleaning and disinfecting the system.

NOTE:

- ✓ Follow the instructions in this manual when cleaning and disinfecting the system.
- ✓ Inside the test cartridge port should never be cleaned.
- ✓ A test cartridge and a calibrant fluid pack should never be cleaned.

10.1.1 Cleaning and Disinfecting the Exterior Surfaces

Clean and disinfect the exterior surfaces to remove dust, splatters, blood, etc. Policies regarding the cleaning and disinfecting intervals are at the discretion of your individual institution.

Following the procedures below to clean and disinfect the exterior surfaces:

1. Turn off the analyzer.
2. Disconnect the power cord and the power adaptor.
Disconnect the connecting cables if the system is connected to other pieces of equipment.
3. Dampen a lint-free cloth with 0.5% sodium hypochlorite solution.

NOTE:

The cloth should be wet but not dripping.

4. Clean the exterior surfaces with the wet cloth.
5. Clean the surfaces with the wet cloth to disinfect them after the surfaces are completely dry.

NOTE:

- ✓ Clean the surfaces prior to disinfecting them.
 - ✓ Make sure the surfaces are thoroughly dry before disinfecting them.
6. When the surfaces are thoroughly dry, reconnect the power cord, power adaptor and other connecting cables.



10.1.2 Cleaning and Disinfecting the Screen

Clean and disinfect the screen to remove dust, splatters, blood, etc. Policies regarding the cleaning and disinfecting intervals are at the discretion of your individual institution. Follow the steps below to clean and disinfect the screen:

1. Dampen a lint-free cloth with 0.5% sodium hypochlorite solution.

NOTE:

The cloth should be wet but not dripping.

2. On the Main screen, press  to go to the Setup screen.
3. Press  on the System Setup screen.
4. Select the desired time period during which the system will have no response when you touch the screen. There are four options: 30 seconds, 1 minute, 2 minutes and 5 minutes. The default is 30 seconds.

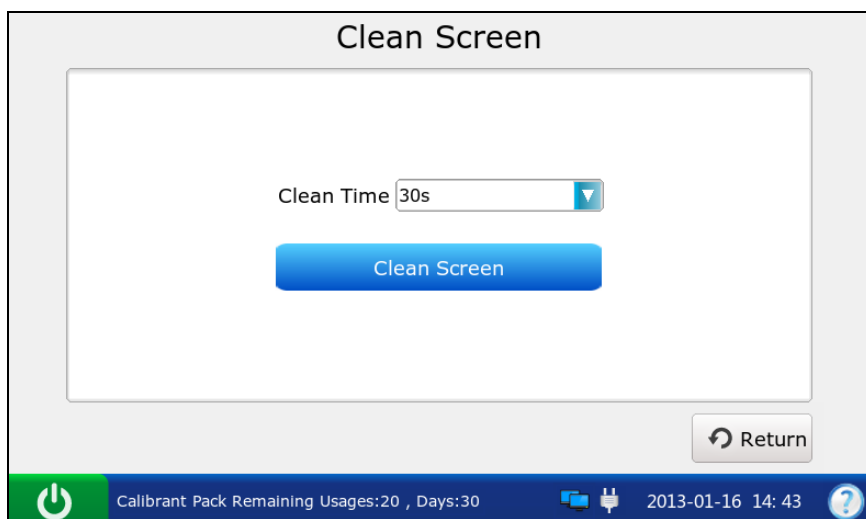


Figure 10-1 Select Clean Time

5. Press **Clean Screen**. The system will display the screen below:

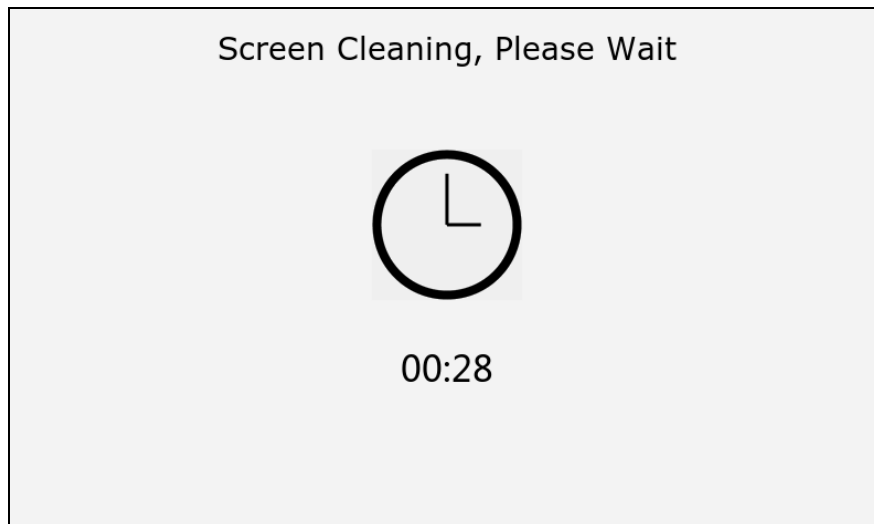


Figure 10-2 Remaining Time

6. Clean the screen with the lint-free cloth.
7. Repeat steps 4-6 to disinfect the screen with the lint-free cloth after the screen is thoroughly dry.

NOTE:

- ✓ Clean the screen prior to disinfecting it.
 - ✓ Make sure that the screen is thoroughly dry before disinfecting it.
8. Press **Return** twice to return to the Main screen.

10.1.3 Cleaning the Printer Head

Dirty and soiled thermal printer heads will decrease the printing definition, so printer heads should be cleaned at least once a month.

Open the printer casing and remove the printer paper. Clean the printer head gently with a clean soft cloth dampened in 75% alcohol. For stubborn stains, soak the stain with a little alcohol first and wipe it off with a clean soft cloth. After air drying, load the printer paper and shut the printer casing.

CAUTION


1. Prevent the detergent from seeping into the system while cleaning. Do not immerse the analyzer in liquid under any circumstances.
 2. Do not clean the system with abrasive fabric.
-


10.2 Care and Maintenance

10.2.1 Recharging and Replacement of Battery

◆ Capacity Identification


Current capacity of the rechargeable battery can be identified according to the battery symbol on the status bar at the bottom of the LCD screen:

 : Full capacity.



 : Capacity is not full.

 : Capacity is limited, and recharging should be taken into account.

 : Capacity is low, the battery should be recharged soon.

 : Capacity is empty. The battery should be recharged immediately.

NOTE:

- ✓ If the system is powered only by AC power, the symbol for the adaptor  will appear on the status bar at the bottom of the screen.
- ✓ If the analyzer is powered only by the battery, one of the symbols above will appear on the status bar at the bottom of the screen.
- ✓ If the analyzer is powered by both the battery and AC power, and the battery is not being charged, the symbol  will appear on the status bar at the bottom of the screen.

◆ Recharging

The analyzer is equipped with a recharge control circuit together with a rechargeable lithium battery. When the analyzer is connected to the mains supply, the battery will be recharged automatically. Because of the capacity consumption during storage and transport, the battery capacity will not be full when it is used for the first time. Battery recharging should be considered before the first use.

NOTE:

If the battery has not been used for more than two months, it should be recharged before use.

◆ Replacement

When the useful life of the battery is over, or there is a foul smell or leakage, please contact EDAN or its authorized distributors for replacement.

WARNING

1. Only the battery of the same model and specifications provided by EDAN should be used.
 2. Danger of explosion - Do not reverse the anode and the cathode when installing the battery.
 3. Remove the battery from the system if it is not used for a long time.
 4. If the battery is stored alone and not used for a long time, it is recommended that the battery should be charged at least once every 6 months to prevent overdischarge.
 5. When the battery's useful life is over, contact EDAN or the local distributor for disposal or dispose of the battery according to local regulations.
-
-

10.2.2 Printer Paper

CAUTION

Only use the printer paper provided by EDAN or its authorized distributors, otherwise the printer may be damaged. This kind of damage is not covered by warranty.

Storage Requirements:

- Do not put the printer paper under fluorescence for a long time.
- Printer paper should be stored in a dry, dark and cool area, avoiding excessive temperature, humidity and sunshine.
- Make sure there is no polyvinyl chloride or other chemicals in the storage environment, which will lead to color change of the paper.

10.2.3 Maintenance of the Analyzer

The following safety checks should be performed at least once every 24 months by a qualified person who has adequate training, knowledge, and practical experience to perform these tests.

- a) Inspect the analyzer and accessories for mechanical and functional damage.
- b) Inspect the safety related labels for legibility.
- c) Verify the analyzer functions properly as described in the instructions for use.

If the analyzer is not functioning properly or fails any of the above tests, it has to be repaired.

WARNING

Failure on the part of the responsible individual institution employing this equipment to implement a satisfactory maintenance schedule may cause undue equipment failures.

Analyzer:

- Avoid excessive temperatures, sunshine, humidity or dirt.
- Avoid shaking the analyzer violently when moving it to another place.
- Prevent any liquid from seeping into the analyzer.

Chapter 11 Theory

The system utilizes the electrochemical method to determine the concentrations of blood gases and blood chemistries, and utilizes the conductivity method to determine the concentration of Hct. Many parameters can also be calculated such as cH^+ , HCO_3^- act, HCO_3^- std, BE(ecf), BE(B), BB(B), and so on.

11.1 Measurement Method

Methods

Measurements are performed on undiluted specimens. Undiluted methods are also called direct methods, whereas methods that dilute the sample are called indirect methods.

For electrolytes, direct methods measure the free ion concentration of analyte (apparent or free ion activity) per unit volume of plasma water, and indirect methods measure the concentration of analyte per unit volume of plasma. It is known that the direct method gives the clinically significant result for electrolytes. When there is disagreement between the methods, such as when the patient has abnormal total protein or lipid levels, it results from interference on the indirect method. At normal levels of protein and lipids the systematic offset between methods is often corrected for in commercial direct measuring instruments so that the normal ranges for all instruments are in agreement. Sensors have been calibrated in the manufacture so that normal ranges are in agreement with indirect reference methods at normal levels of total protein and lipids.

Direct measurement of hematocrit by the conductometric technique gives a result related to the non-conducting excluded volume fraction of the sample. Red blood cell volume is the predominant component of the nonconducting volume, but proteins, lipids, and white blood cells also contribute. Elevated hematocrit readings are expected at abnormally elevated levels of these components. Decreased hematocrit readings are expected at abnormally low levels of protein, such as found in hemodiluted samples taken from cardiopulmonary bypass. Osmotic imbalance causes a discrepancy between direct (conductometric, spun) and indirect (Coulter) measurements because of variation in the meancell volume.

Sensors

Sensor refers to the electrode embedded in test cartridges. There are three different types of sensors:

- Potentiometric Sensor
- Amperometric Sensor
- Conductometric Sensor

Potentiometry: A potential is recorded using a voltmeter, which relates to the concentration of the sample. A reference electrode is used to provide a stable, fixed potential against which other potential differences can be measured. This measurement technique is used for pH, $p\text{CO}_2$ and electrolytes.

Amperometry: The magnitude of an electrical flow of current is proportional to the concentration of the substance being oxidized or reduced at an electrode. This measurement technique is used for $p\text{O}_2$, glucose and lactic acid.

Conductivity: The specific impedance of a sample as measured by two conducting electrodes held at a constant voltage is directly proportional to the conductive properties of the sample. This technique is used for Hct.

11.2 Determination of Test Results

11.2.1 Determination of the Analyte Concentration

The concentration of the analyte is determined with the potentiometric and amperometric sensors. For both sensors, the analyte concentration is calculated using:

- 1) The known analyte concentration of calibrant solution;
- 2) The measured voltage or current of the calibrant solution.
- 3) The measured voltage or current of the sample.

For potentiometric sensors, the analyte activity in the sample is calculated from the Nerst equation:

$$E_{\text{sample}} - E_{\text{calibrant}} = S \log (\alpha_{\text{sample}}/\alpha_{\text{calibrant}})$$

Where E denotes the potential, α denotes the activity of an ion, and S denotes the slope of the sensor.

11.2.2 Determination of Cell Concentration

Hct

In whole blood, the cellular constituents, red and white blood cells and platelets do not conduct electricity, while plasma does. For a sample whose electrolyte concentration is given, the more cells, the less conductivity. The total cell concentration of the whole blood is determined from:

- 1) The known value of the electrolyte concentration in the calibrant.
- 2) The measured electrolyte concentration of the sample.
- 3) The measured conductivity signal generated by the calibrant.
- 4) The measured conductivity signal generated by the sample.

CPB

When samples with abnormally low protein levels are tested, the system need to use the CPB compensation algorithm. The CPB compensation algorithm is specially intended for use when samples are taken from patients on cardiopulmonary bypass. It also applies to the adult whose protein levels are abnormally low.

11.3 Equations for Calculated Parameters

cH^+

Hydrogen ion concentration

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

$HCO_3^-_{act}$

Bicarbonate ion concentration

$$HCO_3^-_{act} = 0.0307 \times pCO_2 \times 10^{(pH - 6.105)} \text{ [mmol/L]}$$

$HCO_3^-_{std}$

Bicarbonate ion concentration normalized to a pCO_2 40mmHg

$$HCO_3^-_{std} = 24.5 + 0.9 \times A + [(A - 2.9)^2 \times (2.65 + 0.31 \times tHb (est))] / 1000 \text{ [mmol/L]}$$

Where $A = BE (B) - [0.2 \times tHb (est) \times (100 - sO_2 (est))] / 100$, $tHb (est)$ can be entered by users, and the default value for $tHb (est)$ is 15g/dL.

BE (ecf)

Base excess (ecf)

$$\text{BE (ecf)} = \text{HCO}_3^- \text{act} - 24.8 + (16.2 \times (\text{pH} - 7.40)) \text{ [mmol/L]}$$

BE (B)

Base excess (B)

$$\text{BE (B)} = (1 - 0.014 \times \text{tHb (est)}) \times [\text{HCO}_3^- \text{act} - 24.8 + (1.43 \times \text{tHb (est)} + 7.7) \times (\text{pH} - 7.40)] \text{ [mmol/L]}$$

Where tHb (est) can be entered by users, and the default value for tHb (est) is 15g/dL.

BB (B)

Buffer Base

$$\text{BB (B)} = \text{BE (B)} + 41.7 + 0.42 \times \text{tHb (est)} \text{ [mmol/L]}$$

Where tHb (est) can be entered by users, and the default value for tHb (est) is 15g/dL.

ctCO₂

Total carbon dioxide

$$\text{ctCO}_2 = \text{HCO}_3^- \text{act} + 0.0307 \times p\text{CO}_2 \text{ [mmol/L]}$$

Ca⁺⁺ (7.4)

The ionized calcium concentration of blood normalized to pH 7.4

$$\text{Ca}^{++} (7.4) = \text{Ca}^{++} \times 10^{[0.178 \times (\text{pH} - 7.40)]} \text{ [mmol/L]}$$

AnGap

An approximation of the difference between measured cations and measured anions in the sample

$$\text{AnGap} = (\text{Na}^+ + \text{K}^+) - (\text{Cl}^- + \text{HCO}_3^- \text{act}) \text{ [mmol/L]}$$

tHb (est)

An estimation of the hemoglobin contained in the sample

$$\text{tHb (est)} = \text{MCHC} \times \text{Hct} / 100 \text{ [g/dL]}$$

Where MCHC is the mean corpuscular hemoglobin concentration, and can be entered by users.

The default value for MCHC is 34g/dL. The unit for Hct is %PCV.

sO₂ (est)

An estimation of hemoglobin oxygen saturation: a ratio of hemoglobin bound to oxygen to the total amount of hemoglobin able to bind oxygen

$$sO_2(est) = \frac{pO_2^{*3} + \alpha \times pO_2^*}{pO_2^{*3} + \alpha \times pO_2^* + \beta} \times 100 \quad [\%]$$

pO₂ (A-a)

Alveolar-arterial oxygen tension difference

$$pO_2(A-a) = pO_2(A) - pO_2(a) \text{ [mmHg]}$$

pO₂ (a/A)

Arterial-alveolar oxygen tension ratio

$$pO_2(a/A) = pO_2(a) / pO_2(A) \text{ [mmHg]}$$

RI

Respiratory index: the ratio of the alveolar-arterial blood oxygen-pressure difference to arterial pO₂

$$RI = pO_2(A-a) / pO_2(a)$$

pO₂ / FIO₂

The ratio of arterial pO₂ to the fraction of inspired oxygen

$$pO_2 / FIO_2 = pO_2 / FIO_2 \text{ [mmHg]}$$

pH (T)

pH value corrected for entered patient temperature

$$pH(T) = pH - [0.0147 + 0.0065 \times (pH - 7.4)] (T - 37)$$

cH⁺ (T)

Hydrogen ion concentration corrected for entered patient temperature

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

$p\text{CO}_2(\text{T})$

$p\text{CO}_2$ corrected for entered patient temperature

$$p\text{CO}_2(\text{T}) = p\text{CO}_2 \times 10^{0.019(\text{T}-37)} \text{ [mmHg]}$$

 $p\text{O}_2(\text{T})$

$p\text{O}_2$ corrected for entered patient temperature

$$p\text{O}_2(\text{T}) = p\text{O}_2 \times 10^{\frac{5.49 \times 10^{-11} p\text{O}_2^{3.88} + 0.071}{9.71 \times 10^{-9} p\text{O}_2^{3.88} + 2.30} (\text{T}-37)} \text{ [mmHg]}$$

 $p\text{O}_2(\text{A-a})(\text{T})$

Alveolar-arterial oxygen tension difference corrected for entered patient temperature

$$p\text{O}_2(\text{A-a})(\text{T}) = p\text{O}_2(\text{A})(\text{T}) - p\text{O}_2(\text{a})(\text{T}) \text{ [mmHg]}$$

 $p\text{O}_2(\text{a/A})(\text{T})$

Arterial-alveolar oxygen tension ratio corrected for entered patient temperature

$$p\text{O}_2(\text{a/A})(\text{T}) = p\text{O}_2(\text{a})(\text{T}) / p\text{O}_2(\text{A})(\text{T}) \text{ [mmHg]}$$

RI (T)

Respiratory index: the ratio of the alveolar-arterial blood oxygen-pressure difference to arterial $p\text{O}_2$ when both values are corrected for patient temperature

$$\text{RI}(\text{T}) = p\text{O}_2(\text{A-a})(\text{T}) / p\text{O}_2(\text{a})(\text{T})$$

 $p\text{O}_2(\text{T})/\text{FIO}_2$

The ratio of arterial $p\text{O}_2$ to the fraction of inspired oxygen corrected for the entered patient temperature

$$p\text{O}_2(\text{T}) / \text{FIO}_2 = p\text{O}_2(\text{T}) / \text{FIO}_2 \text{ [mmHg]}$$

Chapter 12 Parameters

12.1 pH

pH reflecting the acid-base status of a patient is the negative logarithm of the hydrogen ion concentration.

pH is measured by potentiometry with a pH selective membrane electrode. The concentration of hydrogen ions is determined by the measured potential through the Nernst equation.

If test results are inconsistent with the clinical assessment, the sample should be analyzed again with a new test cartridge.

12.1.1 Intended Use

The pH test is intended for the quantification of pH in arterial, venous, or capillary whole blood samples.

pH is an important clinical indicator to assess the acid-base imbalance caused by pathologic conditions, such as ventilatory dysfunction and renal inadequency. The reasons for abnormal blood pH values are:

- primary bicarbonate deficit - metabolic acidosis
- primary bicarbonate excess - metabolic alkalosis
- primary hypoventilation - respiratory acidosis
- primary hyperventilation - respiratory alkalosis

12.1.2 Traceability

pH values assigned to calibrant and controls are traceable to NIST standards.

12.1.3 Temperature Correction

pH is a temperature dependent quantity which is measured at 37°C on the system. The pH value can be corrected to the patient's temperature other than 37°C. Patient temperature can be entered on the Enter Patient Information screen during each patient sample test.

The pH at the patient's temperature is calculated as follows:

$$\text{pH}(T) = \text{pH} - [0.0147 + 0.0065(\text{pH} - 7.4)](T - 37)$$

12.1.4 Performance Characteristics

Experiments are designed according to the following CLSI guidelines: CLSI EP6-A for linearity studies, CLSI EP9-A2 for method comparison studies, and CLSI EP7-A2 for interference studies. Typical performance data presented below were obtained by technologists, nurses, physicians and therapists trained in the use of the system and the comparative method.

Repeatability on RNA Medical[®] QC823 Blood Gas●Electrolyte●Metabolite●BUN controls was estimated using one lot of test cartridges, and 20 replicates of each control level were successively analyzed on one i15 Blood Gas and Chemistry Analysis System. RNA Medical[®] QC823 Blood Gas●Electrolyte●Metabolite●BUN controls are traceable to NIST standards.

In the following repeatability data table below, SD refers to the standard deviation.

Controls	Mean	SD
Level 1	7.161	0.0061
Level 2	7.401	0.0104
Level 3	7.565	0.0074

Precision and recovery on whole blood samples was estimated using multiple whole blood samples with pH values spanning the measurement range.

Parameter	N	Expected	Observed	Swr	bias	%Recovery
pH	9	7.085	7.110	0.021	0.025	100.4%
	9	7.325	7.357	0.020	0.032	100.4%
	9	7.581	7.559	0.011	-0.022	99.7%
	9	7.656	7.673	0.010	0.017	100.2%

Linearity was estimated using reference materials and reference methods. Three replicates of each level of materials were analyzed in parallel on the i15 Blood Gas and Chemistry Analysis System and the Rapidpoint 400 system. Reference materials used were RNA Medical[®] CVC123 Calibration Verification Controls, and they were traceable to NIST standards. In the table below, Sy.x refers to the standard error of estimate.

Parameter	N	Slope	Intercept	Correlation Coefficient	Sy.x	Range
pH	15	0.98	0.12	0.99996	0.00397	6.715 – 7.768

In the comparison study, samples were analyzed in parallel on the i15 Blood Gas and Chemistry Analysis System and the Rapidpoint 400 system. Two replicates of each sample were analyzed on each system.

Parameter	N	Slope	Intercept	Correlation Coefficient	Sy.x	Range
pH	215	1.0259	-0.1934	0.9919	0.0126	7.137 – 7.720

12.1.5 Interfering Substances

Aqueous sample was spiked by addition of a potentially interfering substance to the following test concentration to test for interferences. Twelve replicates of both the spiked sample and the unspiked sample were tested on two i15 Blood Gas and Chemistry Analysis Systems with one lot of test cartridges. The interference was computed using the difference between the mean of the spiked sample and the unspiked sample.

The following substances were tested and found not to be clinically significant for the pH measurement: 24mmol/L Hydroxyurea, 1.0mmol/L Magnesium, 20mmol/L Lactate, 4.00mmol/L Salicyte, 37.5mmol/L Bromide, and 20mmol/L β -hydroxybutyrate.

NOTE:

It is possible that there are other substances interfering with the pH measurement.

12.2 $p\text{CO}_2$

$p\text{CO}_2$, the partial pressure of carbon dioxide, is measured by potentiometry. $p\text{CO}_2$ is determined by the measured potential through the Nernst equation.

If test results are inconsistent with the clinical assessment, the sample should be analyzed again with a new test cartridge.

12.2.1 Intended Use

The $p\text{CO}_2$ test is intended for the quantification of $p\text{CO}_2$ in arterial, venous, or capillary whole blood samples.

$p\text{CO}_2$ is an important indicator to reflect respiratory acid-base balance. If $p\text{CO}_2$ is above the normal range, it is termed respiratory acidosis. If $p\text{CO}_2$ is below the normal range, it is termed respiratory alkalosis. Metabolic factors can also cause $p\text{CO}_2$ increase/decrease: metabolic acidosis leads to decreased $p\text{CO}_2$, and metabolic alkalosis leads to increased $p\text{CO}_2$. $p\text{CO}_2$ along with pH is a more persuasive tool to assess acid-base balance.

12.2.2 Traceability

$p\text{CO}_2$ values assigned to calibrant and controls are traceable to NIST standards.

12.2.3 Temperature Correction

$p\text{CO}_2$ is a temperature dependent quantity which is measured at 37°C on the system. The $p\text{CO}_2$ value can be corrected to the patient's temperature other than 37°C. Patient temperature can be entered on the Enter Patient Information screen during each patient sample test.

The $p\text{CO}_2$ at the patient's temperature is calculated as follows:

$$p\text{CO}_2(T) = p\text{CO}_2 \times 10^{0.019(T - 37)}$$

12.2.4 Performance Characteristics

Experiments are designed according to the following CLSI guidelines: CLSI EP6-A for linearity studies, CLSI EP9-A2 for method comparison studies, and CLSI EP7-A2 for interference studies. Typical performance data presented below were obtained by technologists, nurses, physicians and therapists trained in the use of the system and the comparative method.

Repeatability on RNA Medical[®] QC823 Blood Gas•Electrolyte•Metabolite•BUN controls was estimated using one lot of test cartridges, and 20 replicates of each level were successively analyzed on one i15 Blood Gas and Chemistry Analysis System. RNA Medical[®] QC823 Blood Gas•Electrolyte•Metabolite•BUN controls are traceable to NIST standards.

In the following repeatability data table below, SD refers to the standard deviation.

Controls	Mean	SD
Level 1	68.63	2.650
Level 2	43.97	1.368
Level 3	24.41	1.910

Precision and recovery on whole blood samples was estimated using multiple whole blood

samples with $p\text{CO}_2$ values spanning the measurement range.

Parameter	N	Expected	Observed	Swr	bias	%Recovery
$p\text{CO}_2$	9	123.2	124.9	4.5	1.7	101.4%
	9	42.8	42.5	1.2	-0.3	99.3%
	9	21.3	20.1	1.5	-1.2	94.4%
	9	10.6	10.0	1.1	-0.6	94.3%

Linearity was estimated using reference materials and reference methods. Three replicates of each level of materials were analyzed in parallel on the i15 Blood Gas and Chemistry Analysis System and the Rapidpoint 400 system. Reference materials used were RNA Medical® CVC123 Calibration Verification Controls, and they were traceable to NIST standards. In the table below, $S_{y.x}$ refers to the standard error of estimate.

Parameter	N	Slope	Intercept	Correlation Coefficient	$S_{y.x}$	Range
$p\text{CO}_2$	15	1.00	0.22	0.99998	0.215	17.8 – 84.0

In the comparison study, samples were analyzed in parallel on the i15 Blood Gas and Chemistry Analysis System and the Rapidpoint 400 system. Two replicates of each sample were analyzed on each system.

Parameter	N	Slope	Intercept	Correlation Coefficient	$S_{y.x}$	Range
$p\text{CO}_2$	215	0.9394	1.4498	0.9868	1.5950	11.5 – 73.8

12.2.5 Interfering Substances

Aqueous sample was spiked by addition of a potentially interfering substance to the following test concentration to test for interferences. Twelve replicates of both the spiked sample and the unspiked sample were tested on two i15 Blood Gas and Chemistry Analysis Systems with one lot of test cartridges. The interference was computed using the difference between the mean of the spiked sample and the unspiked sample.

The following substances were tested and found not to be clinically significant for the $p\text{CO}_2$ measurement: 24mmol/L hydroxyurea, 1.0mmol/L magnesium, 20mmol/L lactate, 4.00mmol/L

salicyte, 37.5mmol/L bromide, and 20mmol/L β -hydroxybutyrate.

NOTE:

It is possible that there are other substances interfering with the $p\text{CO}_2$ measurement.

12.3 $p\text{O}_2$

$p\text{O}_2$, the partial pressure of oxygen, is measured by amperometry. The oxygen reduction current is proportional to the dissolved oxygen concentration.

If test results are inconsistent with the clinical assessment, the sample should be analyzed again with a new test cartridge.

12.3.1 Intended Use

The $p\text{O}_2$ test is intended for the quantification of $p\text{O}_2$ in arterial, venous, or capillary whole blood samples.

The $p\text{O}_2$ value of arterial blood is important in assessing the efficiency of pulmonary gas exchange.

12.3.2 Traceability

$p\text{O}_2$ values assigned to calibrant and controls are traceable to NIST standards.

12.3.3 Temperature Correction

$p\text{O}_2$ is a temperature dependent quantity which is measured at 37°C on the system. The $p\text{O}_2$ value can be corrected to the patient's temperature other than 37°C. Patient temperature can be entered on the Enter Patient Information screen during each patient sample test.

The $p\text{O}_2$ at the patient's temperature is calculated as follows:

$$p\text{O}_2(T) = p\text{O}_2 \times 10^{\frac{5.49 \times 10^{-11} p\text{O}_2^{3.88} + 0.071}{9.71 \times 10^{-9} p\text{O}_2^{3.88} + 2.30} (T-37)}$$

12.3.4 Performance Characteristics

Experiments are designed according to the following CLSI guidelines: CLSI EP6-A for linearity studies, CLSI EP9-A2 for method comparison studies, and CLSI EP7-A2 for interference studies. Typical performance data presented below were obtained by technologists, nurses, physicians and

therapists trained in the use of the system and the comparative method.

Repeatability on RNA Medical[®] QC823 Blood Gas●Electrolyte●Metabolite●BUN controls was estimated using one lot of test cartridges, and 20 replicates of each level were successively analyzed on one i15 Blood Gas and Chemistry Analysis System. RNA Medical[®] QC823 Blood Gas●Electrolyte●Metabolite●BUN controls are traceable to NIST standards.

In the following repeatability data table below, SD refers to the standard deviation.

Controls	Mean	SD
Level 1	65.3	2.95
Level 2	103.0	3.02
Level 3	150.8	4.65

Precision and recovery on whole blood samples was estimated using multiple whole blood samples with pO_2 values spanning the measurement range.

Parameter	N	Expected	Observed	Swr	bias	%Recovery
pO_2	9	21.4	21.7	1.3	0.3	101.4%
	9	149.7	151.6	3.7	1.9	101.3%
	9	271.8	270.8	8.0	-1.0	99.6%
	9	422.2	421.7	18.7	-0.5	99.9%

Linearity was estimated using reference materials and reference methods. Three replicates of each level of materials were analyzed in parallel on the i15 Blood Gas and Chemistry Analysis System and the Rapidpoint 400 system. Reference materials used were RNA Medical[®] CVC123 Calibration Verification Controls, and they were traceable to NIST standards. In the table below, $Sy.x$ refers to the standard error of estimate.

Parameter	N	Slope	Intercept	Correlation Coefficient	$Sy.x$	Range
pO_2	15	0.92	4.51	0.99989	2.58604	39.6 – 448.2

In the comparison study, samples were analyzed in parallel on the i15 Blood Gas and Chemistry Analysis System and the Rapidpoint 400 system. Two replicates of each sample were analyzed on each system.

Parameter	N	Slope	Intercept	Correlation Coefficient	Sy.x	Range
pO_2	215	0.9811	1.3173	0.9986	2.0303	20.4 – 191.0

12.3.5 Interfering Substances

Aqueous sample was spiked by addition of a potentially interfering substance to the following test concentration to test for interferences. Twelve replicates of both the spiked sample and the unspiked sample were tested on two i15 Blood Gas and Chemistry Analysis Systems with one lot of test cartridges. The interference was computed using the difference between the mean of the spiked sample and the unspiked sample.

The following substances were tested and found not to be clinically significant for the pO_2 measurement: 24mmol/L hydroxyurea, 1.0mmol/L magnesium, 20mmol/L lactate, 4.00mmol/L salicyte, 37.5mmol/L bromide, and 20mmol/L β -hydroxybutyrate.

NOTE:

It is possible that there are other substances interfering with the pO_2 measurement.

12.4 Sodium (Na^+)

Sodium is measured by potentiometry with an ion-selective electrode. The concentration of sodium ions is determined by the measured potential through the Nernst equation. The system uses a direct (undiluted) method to measure sodium and the obtained values may differ from those obtained by an indirect (diluted) method.

If test results are inconsistent with the clinical assessment, the sample should be analyzed again with a new test cartridge.

12.4.1 Intended Use

The sodium test is intended for the quantification of sodium in arterial, venous, or capillary whole blood samples.

Sodium is the major cation in the extracellular space in the body. It plays an important part in maintaining osmotic pressure and acid-base balance.

Monitoring blood sodium level is important in the diagnosis or monitoring of diseases involving electrolyte imbalance and all disturbances of the water balance, heart and kidney insufficiencies,

and so on.

12.4.2 Traceability

Sodium ion concentration values assigned to calibrant and controls are traceable to NIST standards.

12.4.3 Performance Characteristics

Experiments are designed according to the following CLSI guidelines: CLSI EP6-A for linearity studies, CLSI EP9-A2 for method comparison studies, and CLSI EP7-A2 for interference studies. Typical performance data presented below were obtained by technologists, nurses, physicians and therapists trained in the use of the system and the comparative method.

Repeatability on RNA Medical[®] QC823 Blood Gas•Electrolyte•Metabolite•BUN controls was estimated using one lot of test cartridges, and 20 replicates of each level were successively analyzed on one i15 Blood Gas and Chemistry Analysis System. RNA Medical[®] QC823 Blood Gas•Electrolyte•Metabolite•BUN controls are traceable to NIST standards.

In the following repeatability data table below, SD refers to the standard deviation.

Controls	Mean	SD
Level 1	114.6	0.83
Level 2	140.1	0.83
Level 3	168.7	0.92

Precision and recovery on whole blood samples was estimated using multiple whole blood samples with Na⁺ values spanning the measurement range.

Parameter	N	Expected	Observed	Swr	bias	%Recovery
Na ⁺	9	111.2	111.7	0.7	0.5	100.4%
	9	140.5	140.8	1.6	0.3	100.2%
	9	166.0	167.3	3.1	1.3	100.8%

Linearity was estimated using reference materials and reference methods. Three replicates of each level of materials were analyzed in parallel on the i15 Blood Gas and Chemistry Analysis System and the Rapidpoint 400 system. Reference materials used were RNA Medical[®] CVC123 Calibration Verification Controls, and they were traceable to NIST standards. In the table below, Sy.x

refers to the standard error of estimate.

Parameter	N	Slope	Intercept	Correlation Coefficient	Sy.x	Range
Na ⁺	15	0.98	1.30	0.99999	0.1924	102.6 – 180.3

In the comparison study, samples were analyzed in parallel on the i15 Blood Gas and Chemistry Analysis System and the Rapidpoint 400 system. Two replicates of each sample were analyzed on each system.

Parameter	N	Slope	Intercept	Correlation Coefficient	Sy.x	Range
Na ⁺	215	0.9813	2.3952	0.9961	1.1661	102.3 – 164.9

12.4.4 Interfering Substances

Aqueous sample was spiked by addition of a potentially interfering substance to the following test concentration to test for interferences. Twelve replicates of both the spiked sample and the unspiked sample were tested on two i15 Blood Gas and Chemistry Analysis Systems with one lot of test cartridges. The interference was computed using the difference between the mean of the spiked sample and the unspiked sample.

The substances that interfere with the Na⁺ measurement are listed below:

37.5mmol/L bromide will increase Na⁺ results by 5.5mmol/L.

The following substances were tested and found not to be clinically significant for the Na⁺ measurement: 24mmol/L hydroxyurea, 1.0mmol/L magnesium, 20mmol/L lactate, 4.00mmol/L salicyte, 12.5mmol/L bromide, and 20mmol/L β -hydroxybutyrate.

NOTE:

It is possible that there are other substances interfering with the Na⁺ measurement.

12.5 Potassium (K⁺)

Potassium is measured by potentiometry with an ion-selective electrode. The concentration of potassium ions is determined by the measured potential through the Nernst equation. The system uses a direct (undiluted) method to measure potassium and the obtained values may differ from those obtained by an indirect (diluted) method.

If test results are inconsistent with the clinical assessment, the sample should be analyzed again with a new test cartridge.

12.5.1 Intended Use

The Potassium test is intended for the quantification of potassium in arterial, venous, or capillary whole blood samples.

Potassium is the most abundant cation in the intracellular fluid, and plays an important role in nerve conduction and muscle function. It also helps maintain acid-base balance and osmotic pressure.

Potassium value is important for patients who are undergoing infusion therapies, who are experiencing heart insufficiency, and so on.

12.5.2 Traceability

Potassium ion concentration values assigned to calibrant and controls are traceable to NIST standards.

12.5.3 Performance Characteristics

Experiments are designed according to the following CLSI guidelines: CLSI EP6-A for linearity studies, CLSI EP9-A2 for method comparison studies, and CLSI EP7-A2 for interference studies. Typical performance data presented below were obtained by technologists, nurses, physicians and therapists trained in the use of the system and the comparative method.

Repeatability on RNA Medical[®] QC823 Blood Gas•Electrolyte•Metabolite•BUN controls was estimated using one lot of test cartridges, and 20 replicates of each level were successively analyzed on one i15 Blood Gas and Chemistry Analysis System. RNA Medical[®] QC823 Blood Gas•Electrolyte•Metabolite•BUN controls are traceable to NIST standards.

In the following repeatability data table below, SD refers to the standard deviation.

Controls	Mean	SD
Level 1	1.92	0.014
Level 2	4.51	0.041
Level 3	6.70	0.047

Precision and recovery on whole blood samples was estimated using multiple whole blood

samples with K^+ values spanning the measurement range.

Parameter	N	Expected	Observed	Swr	bias	%Recovery
K^+	9	3.40	3.35	0.04	-0.05	98.5%
	9	4.00	4.01	0.03	0.01	100.3%
	9	9.37	9.36	0.20	-0.01	99.9%

Linearity was estimated using reference materials and reference methods. Three replicates of each level of materials were analyzed in parallel on the i15 Blood Gas and Chemistry Analysis System and the Rapidpoint 400 system. Reference materials used were RNA Medical® CVC123 Calibration Verification Controls, and they were traceable to NIST standards. In the table below, $Sy.x$ refers to the standard error of estimate.

Parameter	N	Slope	Intercept	Correlation Coefficient	$Sy.x$	Range
K^+	15	1.0	-0.04	0.99997	0.03787	1.82 – 12.09

In the comparison study, samples were analyzed in parallel on the i15 Blood Gas and Chemistry Analysis System and the Rapidpoint 400 system. Two replicates of each sample were analyzed on each system.

Parameter	N	Slope	Intercept	Correlation Coefficient	$Sy.x$	Range
K^+	215	1.0068	-0.0409	0.9983	0.0594	2.55 – 6.70

12.5.4 Interfering Substances

Aqueous sample was spiked by addition of a potentially interfering substance to the following test concentration to test for interferences. Twelve replicates of both the spiked sample and the unspiked sample were tested on two i15 Blood Gas and Chemistry Analysis Systems with one lot of test cartridges. The interference was computed using the difference between the mean of the spiked sample and the unspiked sample.

The following substances were tested and found not to be clinically significant for the K^+ measurement: 24mmol/L hydroxyurea, 1.0mmol/L magnesium, 20mmol/L lactate, 4.00mmol/L salicyte, 37.5mmol/L bromide, and 20mmol/L β -hydroxybutyrate.

NOTE:

It is possible that there are other substances interfering with the K^+ measurement.

12.6 Ionized Calcium (Ca^{++})

Ionized calcium (Ca^{++}) is measured by potentiometry with an ion-selective electrode. The concentration of ionized calcium is determined by the measured potential through the Nernst equation.

If test results are inconsistent with the clinical assessment, the sample should be analyzed again with a new test cartridge.

12.6.1 Intended Use

The ionized calcium test is intended for the quantification of ionized calcium in arterial, venous, or capillary whole blood samples.

Ca^{++} , the physiologically active form of calcium, plays an important role in muscle contraction, transmission of nerve impulses, and cardiac functions.

For patients who are in critical care situations, especially those who need to receive large amounts of blood, the Ca^{++} level should be monitored closely.

12.6.2 Traceability

Ionized calcium concentration values assigned to calibrant and controls are traceable to NIST standards.

12.6.3 Performance Characteristics

Experiments are designed according to the following CLSI guidelines: CLSI EP6-A for linearity studies, CLSI EP9-A2 for method comparison studies, and CLSI EP7-A2 for interference studies. Typical performance data presented below were obtained by technologists, nurses, physicians and therapists trained in the use of the system and the comparative method.

Repeatability on RNA Medical[®] QC823 Blood Gas•Electrolyte•Metabolite•BUN controls was estimated using one lot of test cartridges, and 20 replicates of each level were successively analyzed on one i15 Blood Gas and Chemistry Analysis System. RNA Medical[®] QC823 Blood Gas•Electrolyte•Metabolite•BUN controls are traceable to NIST standards.

In the following repeatability data table below, SD refers to the standard deviation.

Controls	Mean	SD
Level 1	1.47	0.029
Level 2	1.16	0.026
Level 3	0.46	0.019

Precision and recovery on whole blood samples was estimated using multiple whole blood samples with Ca^{++} values spanning the measurement range.

Parameter	N	Expected	Observed	Swr	bias	%Recovery
Ca^{++}	9	1.05	1.05	0.03	0.00	100.0%
	9	1.21	1.20	0.01	-0.01	99.2%
	9	2.68	2.68	0.07	0.00	100.0%

Linearity was estimated using reference materials and reference methods. Three replicates of each level of materials were analyzed in parallel on the i15 Blood Gas and Chemistry Analysis System and the Rapidpoint 400 system. Reference materials used were RNA Medical[®] CVC123 Calibration Verification Controls, and they were traceable to NIST standards. In the table below, Sy.x refers to the standard error of estimate.

Parameter	N	Slope	Intercept	Correlation Coefficient	Sy.x	Range
Ca^{++}	15	0.98	0.37	0.99998	0.00972	0.15 – 3.74

In the comparison study, samples were analyzed in parallel on the i15 Blood Gas and Chemistry Analysis System and the Rapidpoint 400 system. Two replicates of each sample were analyzed on each system.

Parameter	N	Slope	Intercept	Correlation Coefficient	Sy.x	Range
Ca^{++}	215	0.9987	0.0019	0.9910	0.0265	0.61 – 1.73

12.6.4 Interfering Substances

Aqueous sample was spiked by addition of a potentially interfering substance to the following test concentration to test for interferences. Twelve replicates of both the spiked sample and the

unspiked sample were tested on two i15 Blood Gas and Chemistry Analysis Systems with one lot of test cartridges. The interference was computed using the difference between the mean of the spiked sample and the unspiked sample.

The substances that interfere with the Ca^{++} measurement are listed below:

- 12.5mmol/L bromide will increase Ca^{++} results by 0.07mmol/L.
- 37.5mmol/L bromide will increase Ca^{++} results by 0.17mmol/L.

The following substances were tested and found not to be clinically significant for the Ca^{++} measurement: 24mmol/L hydroxyurea, 1.0mmol/L magnesium, 20mmol/L lactate, 4.00mmol/L salicyte, and 20mmol/L β -hydroxybutyrate.

NOTE:

It is possible that there are other substances interfering with the Ca^{++} measurement.

12.7 Chloride (Cl^-)

Chloride is measured by potentiometry with an ion-selective electrode. The concentration of chloride ions is determined by the measured potential through the Nernst equation. The system uses a direct (undiluted) method to measure chloride, and the obtained values may differ from those obtained by an indirect (diluted) method.

If test results are inconsistent with the clinical assessment, the sample should be analyzed again with a new test cartridge.

12.7.1 Intended Use

The chloride test is intended for the quantification of chloride in arterial, venous, or capillary whole blood samples.

Cl^- , the major anion in the extracellular space in the body, plays a role in the regulation of the acid-base balance, and regulates osmotic pressure together with Na^+ .

Monitoring Cl^- value is vital for patients who suffer from hypertension, cardiac distress, etc.

12.7.2 Traceability

Chloride ion concentration values assigned to calibrant and controls are traceable to NIST standards.

12.7.3 Performance Characteristics

Experiments are designed according to the following CLSI guidelines: CLSI EP6-A for linearity studies, CLSI EP9-A2 for method comparison studies, and CLSI EP7-A2 for interference studies. Typical performance data presented below were obtained by technologists, nurses, physicians and therapists trained in the use of the system and the comparative method.

Repeatability on RNA Medical[®] QC823 Blood Gas●Electrolyte●Metabolite●BUN controls was estimated using one lot of test cartridges, and 20 replicates of each level were successively analyzed on one i15 Blood Gas and Chemistry Analysis System. RNA Medical[®] QC823 Blood Gas●Electrolyte●Metabolite●BUN controls are traceable to NIST standards.

In the following repeatability data table below, SD refers to the standard deviation.

Controls	Mean	SD
Level 1	78.8	0.62
Level 2	96.7	0.84
Level 3	127.1	0.76

Precision and recovery on whole blood samples was estimated using multiple whole blood samples with Cl⁻ values spanning the measurement range.

Parameter	N	Expected	Observed	Swr	bias	%Recovery
Cl ⁻	9	80.0	80.0	0.3	0.0	100.0%
	9	106.5	106.6	1.3	0.1	100.1%
	9	133.0	133.0	1.8	0.0	100.0%

Linearity was estimated using reference materials and reference methods. Three replicates of each level of materials were analyzed in parallel on the i15 Blood Gas and Chemistry Analysis System and the Rapidpoint 400 system. Reference materials used were RNA Medical[®] CVC123 Calibration Verification Controls, and they were traceable to NIST standards. In the table below, Sy.x refers to the standard error of estimate.

Parameter	N	Slope	Intercept	Correlation Coefficient	Sy.x	Range
Cl ⁻	15	0.98	0.37	0.99998	0.2404	72 - 146

In the comparison study, samples were analyzed in parallel on the i15 Blood Gas and Chemistry Analysis System and the Rapidpoint 400 system. Two replicates of each sample were analyzed on each system.

Parameter	N	Slope	Intercept	Correlation Coefficient	Sy.x	Range
Cl ⁻	215	0.9955	0.2967	0.9961	0.9802	77 - 132

12.7.4 Interfering Substances

Aqueous sample was spiked by addition of a potentially interfering substance to the following test concentration to test for interferences. Twelve replicates of both the spiked sample and the unspiked sample were tested on two i15 Blood Gas and Chemistry Analysis Systems with one lot of test cartridges. The interference was computed using the difference between the mean of the spiked sample and the unspiked sample.

The substances interfering with the Cl⁻ measurement are listed below:

- 12.5mmol/L bromide will increase Cl⁻ results by 15.5mmol/L.
- 4.00mmol/L salicyte will increase Cl⁻ results by 15.0mmol/L.

The following substances were tested and found not to be clinically significant for the Cl⁻ measurement: 24mmol/L hydroxyurea, 1.0mmol/L magnesium, 20mmol/L lactate, and 20mmol/L β -hydroxybutyrate.

NOTE:

It is possible that there are other substances interfering with the Cl⁻ measurement.

12.8 Hematocrit (Hct)

Hematocrit is a measurement of the volume occupied by red blood cells in whole blood samples. Hematocrit is determined by conductometry with two gold electrodes. The conductance of the blood sample is inversely related to the hematocrit value.

If test results are inconsistent with the clinical assessment, the sample should be analyzed again with a new test cartridge.

12.8.1 Intended Use

The hematocrit test is intended for the quantification of hematocrit in arterial, venous, or capillary whole blood samples.

Hematocrit is a useful indicator for assessing states of blood volume, such as anemia and erythrocytosis.

12.8.2 Traceability

Hematocrit values assigned to calibrant and controls are traceable to NIST standards.

12.8.3 Performance Characteristics

Experiments are designed according to the following CLSI guidelines: CLSI EP6-A for linearity studies, CLSI EP9-A2 for method comparison studies, and CLSI EP7-A2 for interference studies. Typical performance data presented below were obtained by technologists, nurses, physicians and therapists trained in the use of the system and the comparative method.

Repeatability on RNA Medical[®] QC900 Hematocrit controls was estimated using one lot of test cartridges, and 20 replicates of each level were successively analyzed on one i15 Blood Gas and Chemistry Analysis System. RNA Medical[®] QC900 Hematocrit controls are traceable to NIST standards.

In the following repeatability data table below, SD refers to the standard deviation.

Controls	Mean	SD
Low	20.3	0.93
High	49.7	0.47

Precision and recovery on whole blood samples was estimated using multiple whole blood samples with Hct values spanning the measurement range.

Parameter	N	Expected	Observed	Swr	bias	%Recovery
Hct	9	25.5	26.2	0.5	0.7	102.7%
	9	44.0	44.6	0.9	0.6	101.4%
	9	64.0	62.5	1.5	-1.5	97.7%

Linearity was estimated using reference materials and reference methods. Three replicates of

each level of materials were analyzed in parallel on the i15 Blood Gas and Chemistry Analysis System and the Rapidpoint 400 system. Reference materials used were RNA Medical® CVC 9005 Hematocrit Calibration Verification Controls, and they were traceable to NIST standards. In the table below, $Sy.x$ refers to the standard error of estimate.

Parameter	N	Slope	Intercept	Correlation Coefficient	$Sy.x$	Range
Hct	15	0.99	0.56	0.99988	0.34811	15.0 – 62.0

In the comparison study, samples were analyzed in parallel on the i15 Blood Gas and Chemistry Analysis System and the Rapidpoint 400 system. Two replicates of each sample were analyzed on each system.

Parameter	N	Slope	Intercept	Correlation Coefficient	$Sy.x$	Range
Hct	215	0.9729	1.0199	0.9932	0.7518	23 - 53

12.8.4 Interfering Substances

The substances interfering with the hematocrit measurement are listed below:

- A significant increase in white blood cell count may increase the hematocrit results.
- Total protein level will increase the hematocrit results.
- Abnormally high lipids may increase the hematocrit results.
- Factors interfering with sodium results will also interfering with hematocrit results.

NOTE:

It is possible that there are other substances interfering with the hematocrit measurement.

Chapter 13 Warranty and Service

13.1 Warranty

EDAN warrants that EDAN's products meet the labeled specifications of the products and will be free from defects in materials and workmanship that occur within the warranty period.

The warranty is void in cases of:

- a) Damage caused by mishandling during shipping.
- b) Subsequent damage caused by improper use or maintenance.
- c) Damage caused by alteration or repair by anyone not authorized by EDAN.
- d) Damage caused by accidents.
- e) Replacement or removal of serial number label and manufacture label.

If a product covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period, EDAN will, at its discretion, repair or replace the defective part(s) free of charge. EDAN will not provide a substitute product for use when the defective product is being repaired.

13.2 Contact Information

If you have any question about maintenance, technical specifications or malfunctions of devices, contact your local distributor.

Alternatively, you can send an email to EDAN service department at: support@edan.com.cn.

Appendix 1 Specifications

A1.1 Environment Requirements

Analyzer	Usage	Temperature	10 - 31°C
		Humidity	25% - 80% (non-condensing)
		Ambient Pressure	70 - 106.6kPa (525 - 800mmHg)
	Transport and Storage	Temperature	-20 - 60°C
		Humidity	25% - 93% (non-condensing)
		Ambient Pressure	40 - 106.6kPa (300 - 800mmHg)
Test Cartridge	Usage	Temperature	10 - 31°C
		Humidity	25% - 80% (non-condensing)
		Ambient Pressure	70 - 106.6kPa (525 - 800mmHg)
	Transport	Temperature	4 - 37°C
		Humidity	≤ 93% (non-condensing)
		Ambient Pressure	40 - 106.6kPa (300 - 800mmHg)
	Storage	Temperature	4 - 30°C
		Humidity	≤ 93% (non-condensing)
		Ambient Pressure	40 - 106.6kPa (300 - 800mmHg)
Calibrant Fluid Pack	Usage	Temperature	10 - 31°C
		Humidity	25% - 80% (non-condensing)
		Ambient Pressure	70 - 106.6kPa (525 - 800mmHg)
	Transport and Storage	Temperature	2 - 8°C (avoid freezing)
		Humidity	≤ 93% (non-condensing)
		Ambient Pressure	65 - 106.6kPa (489 - 800mmHg)
Controls	Usage	Temperature	10 - 31°C

		Humidity	25% - 80% (non-condensing)
		Ambient Pressure	70 - 106.6kPa (525 - 800mmHg)
		Temperature	2 - 30°C
	Transport	Humidity	25% - 93% (non-condensing)
		Ambient Pressure	40 - 106.6kPa (300 - 800mmHg)
		Temperature	2 - 8°C (avoid freezing)
	Storage	Humidity	25% - 93% (non-condensing)
		Ambient Pressure	40 - 106.6kPa (300 - 800mmHg)
		Temperature	2 - 8°C (avoid freezing)

A1.2 Analyzer Specifications

Size	315*238*153mm (length ×width ×height)	
Weight	3.8Kg (rechargeable battery included, adaptor not included)	
LCD Screen	7 inch, 800*480, Color TFT	
Power	Voltage	100V - 240V~
	Input Current	1.2A - 0.5A
	Frequency	50Hz/60Hz
	Rechargeable Battery	14.8VDC/4200mAh
USB Interface	4 USB Interfaces	
Serial Port	DB9	
Bar Code Scanner	embedded	

A1.3 Performance Specifications

Sample Volume	110uL
Test Time	It takes no more than 70s from sampling to display of test results.

A1.4 Printer

Printer	Built-in thermal printer, thermal printer paper
Paper Width	48mm

A1.5 Rechargeable Battery

Type	Rechargeable lithium battery
Working Time	When the battery is fully charged, the system can analyze and print 50 samples.
Necessary Charge time	No more than 8 hours
Rated Capacity	4200mAh
Rated voltage	14.8V
Charge Mode	Constant voltage/current
Charge Current (standard)	0.2C ₅ A
Charge Temperature	0°C - +50°C (+32°F - +122°F)
Operating Temperature	-20°C - +60°C (-4°F - +140°F)
Storage	Short Term (within 1 month): -20°C - +60°C (-4°F - +140°F) Middle Term (within 3 months): -20°C - +45°C (-4°F - +113°F) Long Term (within 1 year): -20°C - +20°C (-4°F - +68°F) During storage, recharge the battery at least every six months.
Cycle Life	≥300 times

A1.6 Safety Specifications

Comply with	EN 61010-1: 2001, EN 61010-2-101: 2002, EN 61326-1: 2006, EN 61326-2-6: 2006
Degree of protection against harmful ingress of water	Ordinary equipment (Sealed equipment without water proof)
Degree of safety in presence of flammable gases	Equipment not suitable for use in presence of flammable gases
EMC	CISPR 11 Group 1, Class A
Electric shock	Class I
Mode of operation	Continuous

Appendix 2 Measurement Ranges

A2.1 Measurement Ranges for Measured Parameters

Parameter	Measurement Range
pH	6.500 - 8.000
pO_2	10 - 700mmHg
pCO_2	10 - 150mmHg
K^+	2.0 - 9.0mmol/L
Na^+	100 - 180mmol/L
Cl^-	65 - 140mmol/L
Ca^{++}	0.25 - 2.50mmol/L
Hct	10 - 75 %PCV

A2.2 Measurement Ranges for Calculated Parameters

Parameter	Measurement Range
cH^+	10.0 - 316.2nmol/L
$cH^+(T)$	10.0 - 316.2nmol/L
pH(T)	6.500 - 8.000
$pCO_2(T)$	10.0 - 150.0mmHg
$pO_2(T)$	10 - 700mmHg
HCO_3^- act	1.0 - 99.9mmol/L
HCO_3^- std	1.0 - 99.9mmol/L
BB(B)	13.1 - 82.4mmol/L
BE(B)	(-30.0) - (+30.0)mmol/L
BE(ecf)	(-30.0) - (+30.0)mmol/L
ct CO_2	1 - 100mmol/L
$Ca^{++}(7.4)$	0.23 - 2.70mmol/L
sO_2 (est)	1% - 100%
AnGap	(-10) - (+99)mmol/L
tHb(est)	3.4 - 25.5g/dL
$pO_2(A-a)$	0 - 733mmHg
$pO_2(A-a)(T)$	0 - 733mmHg
$pO_2(a/A)$	0.00 - 1.00
$pO_2(a/A)(T)$	0.00 - 1.00
RI	0.00 - 20.00
RI(T)	0.00 - 20.00
pO_2/FIO_2	250 - 700mmHg
$pO_2(T)/FIO_2$	250 - 700mmHg

Appendix 3 Reference Ranges

NOTE:

Because reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that the individual institutions should establish their own reference ranges according to the population being tested. The following reference ranges are for reference only.

Parameter	Reference Range	
	Arterial	Venous
pH	7.35 - 7.45	7.31 - 7.41
pO_2 (mmHg)	80 - 105	35 - 40
pCO_2 (mmHg)	35 - 45	41 - 51
Na^+ (mmol/L)	138 - 146	138 - 146
K^+ (mmol/L)	3.5 - 4.9	3.5 - 4.9
Cl^- (mmol/L)	98 - 109	98 - 109
Ca^{++} (mmol/L)	1.12 - 1.32	1.12 - 1.32
Hct (%)	38 - 51	38 - 51

Appendix 4 EMC Information

Guidance and manufacture's declaration - electromagnetic emissions- for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic emission		
The system is intended for use in the electromagnetic environment specified below. The user of the system should ensure that it is used in such an environment.		
Emission test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The system uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference to nearby electronic equipment.
RF emissions CISPR 11	Class A	The system is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	


Guidance and manufacture's declaration - electromagnetic immunity - for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity			
The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.			
Immunity test	IEC 61326-1&61326-2-6 test level	Compliance level	Electromagnetic environment -guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±4kV contact ±8kV air	±4kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floor is covered with synthetic material, the relative humidity should be at least 30%.

Electrical fast transient/burst IEC 61000-4-4	±1kV for power supply lines	±1kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1kV line to line ±2kV line to ground	±1kV line to line ±2kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50Hz/60Hz) magnetic field IEC 61000-4-8	3A/m	3A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 1 cycle 40% UT (60% dip in UT) for 5/6 cycles 70% UT (30% dip in UT) for 25/30 cycles <5% UT (>95% dip in UT) for 250/300 cycles	<5% UT (>95% dip in UT) for 1 cycle 40% UT (60% dip in UT) for 5/6 cycles 70% UT (30% dip in UT) for 25/30 cycles <5% UT (>95% dip in UT) for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the system requires continuous operation during power mains interruptions, it is recommended that the system be powered from an uninterruptible power supply or a battery.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

**Guidance and manufacturer's declaration – electromagnetic immunity –
for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING**

Guidance and manufacture's declaration – electromagnetic immunity			
The system is intended for use in the electromagnetic environment specified below. The customer or the user of the system should ensure that it is used in such an environment.			
Immunity test	IEC 60601 & 61326 test level	Compliance level	Electromagnetic environment -guidance

<p>Conducted RF IEC 61000-4-6</p>	<p>3Vrms 150kHz to 80MHz</p>	<p>3Vrms</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3.5}{E_1} \right] \sqrt{P} \quad 80\text{MHz to } 800\text{MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800\text{MHz to } 2.7\text{GHz}$ <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>Radiated RF IEC 61000-4-3</p>	<p>3V/m 80MHz to 2.7GHz</p>	<p>3V/m</p>	

NOTE 1: At 80MHz and 800MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast can not be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the system is used exceeds the applicable RF compliance level above, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the system.

^b Over the frequency range 150kHz to 80MHz, field strengths should be less than 3V/m.

**Recommended separation distances between portable and mobile
RF communication equipment and the EQUIPMENT or SYSTEM-
For EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING**

Recommended separation distances between portable and mobile RF communications equipment and the system			
The system is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the system can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the system as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.7 GHz
	$d = \left[\frac{3.5}{V_1} \right] \sqrt{P}$	$d = \left[\frac{3.5}{E_1} \right] \sqrt{P}$	$d = \left[\frac{7}{E_1} \right] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.			
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.			
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Appendix 5 FCC Information

A5.1 FCC Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- ◆ Reorient or relocate the receiving antenna.
- ◆ Increase the separation between the equipment and receiver.
- ◆ Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- ◆ Consult the dealer or an experienced radio/TV technician for help.

This device complies with Part 15 of FCC Rules.

Operation is subject to the following two conditions:

This device may not cause harmful interference, and this device must accept any interference received, including interference that may cause undesired operation.

NOTE:

The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment. Such modifications could void the user's authority to operate this equipment.

A5.2 FCC RF Radiation Exposure Statement

This equipment complies with FCC RF radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with a minimum distance of 20 centimeters between the radiator and your body.

Appendix 6 Order List

WARNING

Only accessories supplied or recommended by EDAN should be used. Otherwise, the performance and electric shock protection can not be guaranteed.

The following accessories are recommended to be used on the analyzer.

Part Name	Part Number
Power Adaptor	21.21.064186
Printer Paper	01.57.471304-10
Rechargeable Lithium-ion Battery	01.21.064143
Power Cable (American)	21.13.036384-10
Power Cable (European)	01.13.36014
Test Cartridges (BG8)	02.04.240995
Test Cartridges (BG3)	02.04.240996
Calibrant Fluid Pack (100 sampling)	02.04.240997
Calibrant Fluid Pack (200 sampling)	02.04.240998
External Electronic Simulator	03.41.341001
Capillary Adaptor	01.51.410690
Data Management System Software	02.05.250435-10
RNA Medical [®] QC823 Blood Gas ●Electrolyte ●Metabolite●BUN Control (Level 1)	01.26.074008
RNA Medical [®] QC823 Blood Gas●Electrolyte ●Metabolite●BUN Control (Level 2)	01.26.074009
RNA Medical [®] QC823 Blood Gas ●Electrolyte●Metabolite●BUN Control (Level 3)	01.26.074010
RNA Medical [®] QC900 Hematocrit Control (Low)	01.26.074014
RNA Medical [®] QC900 Hematocrit Control (High)	01.26.074015
Honeywell 1900 scanner	21.18.052311

P/N: 01.54.455691-11

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