i15/i15A

Blood Gas and Chemistry Analysis System

Version 3.1

User Manual

CE

EDAN

About this Manual

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Statement

This manual will help you to better understand the operation and maintenance of the product. It is reminded that the product should be used strictly in compliance with this manual. User operation failing to comply with this manual may result in malfunction or accident for which EDAN INSTRUMENTS, INC. (hereinafter called EDAN) cannot be held liable.

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EDAN holds the rights to modify, update, and ultimately explain this manual.

Regulatory Approval Remarks

- The following features are not available in the USA at the time of release of this user manual:
  - Lac measurement
  - Glu measurement
- The following kinds of test cartridges are not available in the USA at the time of release of this user manual:
  - BG10/MicroSample-BG10/Micro-BG10 Test Cartridge
  - BG9/ MicroSample-BG9/Micro-BG9 Test Cartridge
  - BG4/ MicroSample-BG4/Micro-BG4 Test Cartridge
  - BG5/ MicroSample-BG5/Micro-BG5 Test Cartridge
  - BC6/ MicroSample-BC6/Micro-BC6 Test Cartridge
  - BG9-Lac/ MicroSample- BG9-Lac/Micro- BG9-Lac Test Cartridge
  - MicroSample-BG8/Micro-BG8 Test Cartridge
  - MicroSample-BG3/Micro-BG3 Test Cartridge
  - MicroSample-BC4/Micro-BC4 Test Cartridge

- The following kind of test cartridge is not available in the USA and CE areas at the time of release of this user manual:
  - MicroSample-SC4

Responsibility of the Manufacturer

EDAN only considers itself responsible for any effect on safety, reliability and performance of the equipment if:

Assembly operations, extensions, adjustments, modifications or repairs are carried out by persons authorized by EDAN, and

The electrical installation of the relevant environment complies with national standards, and

The instrument is used in accordance with the instructions for use.

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.

A Table of Contents

Chapter 1 Safety Guide

1.1 Intended Use/ Indications for Use

The i15/i15A Blood Gas and Chemistry Analysis System (including Blood Gas and Chemistry Analyzer, Calibrant Fluid Pack, Test Cartridge and Controls) is a portable, automated system that measures pH and blood gases (pCO_2, pO_2), metabolites (Glu, Lac), electrolytes (Na^+, K^+, Ca^{++}, Cl^-) and hematocrit in arterial and venous whole blood samples with lithium heparin or calcium balanced heparin, and measures electrolytes (Na^+, K^+, Ca^{++}, Cl^-) in serum samples. The system is intended for in-vitro diagnostic use only by trained health care professionals in a laboratory environment, near patient or point-of-care settings.

pH, pCO_2, pO_2: Whole blood measurement of certain gases in whole blood, or pH of whole blood, is used in the diagnosis and treatment of life‐threatening acid‐base and/or oxygenation disturbances.

Hct: Whole blood measurements of the packed cell volume of a blood sample are used to distinguish normal from abnormal states, such as anemia and erythrocytosis (an increase in the number of red blood cells)

Na^+: Sodium measurement is used in the diagnosis and treatment of aldosteronism, diabetes insipidus, adrenal hypertension, Addison's disease, dehydration, or diseases involving electrolyte imbalance.

K^+: Potassium measurement is used to monitor electrolyte balance in the diagnosis and treatment of disease conditions characterized by low or high potassium levels

Cl^-: Chloride measurement is used in the diagnosis and treatment of electrolyte and metabolic disorders such as cystic fibrosis and diabetic acidosis.

Ca^{++}: Calcium measurements are used in the diagnosis and treatment of parathyroid disease, a variety of bone diseases, chronic renal disease and tetany (intermittent muscular contractions or spasms).

Glu: Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, idiopathic hypoglycemia and of pancreatic islet cell tumors.

Lac: Lactate (lactic acid) measurement is used to evaluate the acid-base status of patients suspected of having lactic acidosis.

NOTE: The measurement of metabolites (Glu and Lac) by the i15/i15A Blood Gas and Chemistry Analysis System is **NOT** available in the USA at the time of release of this user manual.

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.

⚠ **For Rx Only**

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.
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. Do not position the analyzer so that it is difficult to disconnect the AC plug.
10. **Connect the analyzer to a grounded socket and make certain that the mains supply meets the requirements specified in the user manual.**

WARNING

11. Do not exceed the maximum permitted load when using multiple portable socket-outlets to supply the system.
12. 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.
13. 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.
14. The analyzer is not waterproof. Do not use it in locations where water or any liquid leakage may occur.
15. Do not spill any fluid onto the system surfaces, as fluid seepage into the electrical circuitry may cause excessive leakage current or system failure.
16. 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.
17. To avoid the possibility of electrostatic shock and damage to the system, avoid using aerosol spray cleansers on the analyzer screen.
18. **EXPLOSION HAZARD –** The analyzer is not suitable for use in the presence of a flammable anesthetic mixture with oxygen or other flammable compounds.
19. To avoid electrical shock, never use the system in altitude exceeding 4500 meters above sea level.
20. **LASER RADIATION –** The bar code scanner is a Class 1M laser product. Do not view directly with optical instruments.
21. Periodically have the safety of the system checked by a qualified service engineer.
22. Only accessories supplied or recommended by the manufacturer should be used. Otherwise, performance and electric shock protection cannot be guaranteed.
23. Blood samples should be collected according to proper medical guidelines which contain collection details, such as site selection, collection procedures, sample handling, etc. Sterile techniques should be followed to prevent the site from being contaminated.
24. Handle blood samples and collection devices with care, and wear approved protective gloves to avoid direct contact with samples.
25. 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.

WARNING

26. To avoid the air inlet and air outlet of the fan being blocked by foreign matter, check them regularly. Keep the exhaust opening away from the wall or similar items that can block it. Always use the system in a room with good ventilation.
27. To avoid being injured, never touch the needle of a Calibrant Fluid Pack.
28. To avoid being hurt, never look into the scanner beam light.
29. The system is for in vitro diagnostic use only.
30. Perform quality control (QC) tests regularly to make certain that the system works smoothly.
31. The disposable test cartridges should only be used a single time.
32. Never replace a Calibrant Fluid Pack when the analyzer is off.
33. 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.
34.  The sample is contained in the test cartridge, so test cartridges should be disposed of as biohazardous waste, complying with local regulatory guidelines.
35.  Never use an external electronic simulator under electromagnetic environment, and never touch it by hand during an external simulator test.
36. Do not use the analyzer after its life cycle, and it should be disposed of according to local regulations after its life cycle.
37. Any serious incident that has occurred in relation to the device shall be reported to the manufacturer and the competent authority of the Member State in which the user and/or the patient is established.
38. Before using the product, it should be checked. Replacement should be taken if there is any evident defect or signs of aging which may impair the safety or performance.

Battery Care

39. 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.
40. The battery of the same model and specifications provided by the manufacturer should be used.
41. **Danger of explosion** - Do not reverse the anode and the cathode when installing the battery.
42. Do not heat or splash the battery or throw it into fire or water.
43. Do not crack or pick the battery.

44. WARNING

45. 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.
46. 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.
47. Remove the battery from the analyzer when the analyzer is not used for a long time.
48. 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.

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 errors in sample identification, 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. The sample should be kept at room temperature and tested within 30 minutes of collection. Blood collected for special studies, e.g., A-a O2 gradient, or “shunt” studies should be analyzed within five minutes of collection [1].
6. Transport, store and use the analyzer, test cartridges, calibrant fluid packs and quality control (QC) materials according to the user manual.
7. Never perform any forceful operation, such as forcefully inserting/removing test cartridges/Calibrant Fluid Packs.
8. Only those accessories (such as test cartridges, Calibrant Fluid Packs, quality control (QC) materials, etc) supplied by EDAN or its authorized distributors should be used.

CAUTION

9. Connect the analyzer with those peripherals recommended by EDAN.
10. Maintain the system as described in the user manual to avoid potential damage.
11. Do not clean the analyzer and accessories with an abrasive cloth.
12. Do not immerse the analyzer into liquid under any circumstances.
13. 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.
14. Extreme humidity may affect test results. A relative humidity greater than 80% may cause inaccurate results.
15. Use this system at a temperature between 10 °C and 31 °C (50 °F and 88 °F). Outside this range, the system may produce inaccurate results.

References:

[1] CLSI C46-A2 Blood Gas and pH Analysis and Related Measurements; Approved Guideline 2nd Edition.

1.3 Symbols and Definitions

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

No.	Symbol	Description
1.		Caution
2.		Consult instructions for use
3.		Warning, biological hazard (Background colour-yellow; symbol and outline-black)
4.		Static electricity sensitive
5.		Recycle
6.		CE mark

7.	FCC ID： SMQ9113EDAN	This device complies with Part 15 of the FCC Rules. Operation conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
8.		Conforms to UL Std. 61010-1, IEC Std. 61010-2-010, 61010-2-081, 61010-2-101 Certified to CSA Std. 61010-1, IEC Std. 61010-2-010, 61010-2-081, 61010-2-101
9.		On/Off button
10.		Network port
11.		Serial port
12.		USB (Universal Serial Bus) connection
13.		Trademark
14.		Test cartridge insert direction
15.		Calibrant Fluid Pack chamber door is closed.
16.		Calibrant Fluid Pack chamber door is open.
17.		In vitro diagnostic medical device
18.		Disposal Method
19.		Authorized representative in the European Community
20.		Manufacturer

21.		Date of manufacture
22.		Temperature limit
23.		Do not reuse
24.		Use-by Date
25.		Contains sufficient for <n> tests
26.		Control
27.		Serial number
28.		Batch code
29.		Caution: Federal (U.S.) Law restricts this device to sale by or on the order of a physician.
30.		This way up
31.		Fragile, handle with care
32.		Keep dry
33.		Stacking limit by number
34.		Handle with care
35.		Do not step on

36.		Front
37.		Battery check

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 and serum, 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 Software (DMS) or HIS/LIS. The following tables list the parameters that can be determined by the system:

Measured Parameters:

NOTE: The measured parameters (Glu and Lac) are NOT available in the USA at the time of release of this user manual.

Symbol	Description
pH	Negative logarithm of the hydrogen ion concentration
pCO_2	Partial pressure of carbon dioxide
pO_2	Partial pressure of oxygen
K^+	Potassium ion concentration
Na^+	Sodium ion concentration
Cl^-	Chloride ion concentration
Ca^{++}	ionized Calcium concentration
Hct	Hematocrit: the volume occupied by red blood cells in a given volume of whole blood.
Glu	Glucose concentration
Lac	Lactate concentration

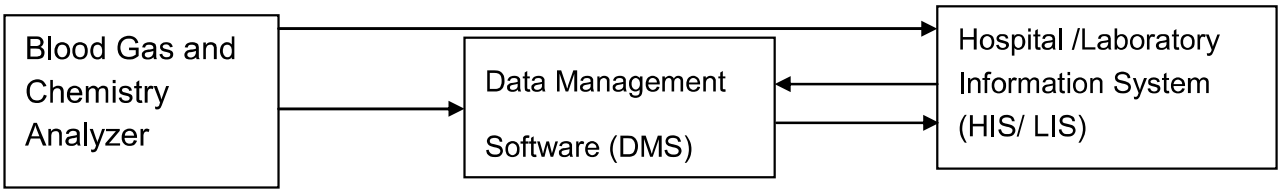
Calculated Parameters:

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^-act	Bicarbonate ion concentration
HCO_3^-std	Bicarbonate ion concentration normalized to a pCO_2 of 40 mmHg
BB (B)	Buffer base
BE (B)	Base excess (B)
BE (ecf)	Base excess (ecf)
$ctCO_2$	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
mOsm	Milliosmole

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:

1) Scan bar codes of test cartridges, Calibrant Fluid Packs, controls, calibration verification controls, patient and operator ID, etc.
2) Identify the types of test cartridges.
3) Control the flow of fluids.
4) Maintain sample temperature at 37°C (98.6°F).
5) Measure the ambient barometric pressure and ambient temperature.
6) Measure electrical signals generated by chemical sensors and biosensors.
7) Analyze and display the concentrations of analytes in whole blood samples.
8) Transmit test results to the Data Management Software (DMS) or HIS/LIS.
9) Store all kinds of test results and data, such as patient sample results, control test results, proficiency test results, calibration verification test results, simulator test results, etc.
10) Demonstrate the operating process with videos.

◆ **Data Management Software (DMS)**

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

1) Enter patient information under Test Application Screen.

2) Edit patient information, view, check, print, and export patient test results.
3) View, check, print, and export quality control (QC) test results, calibration verification test results, proficiency test results and simulator test results.
4) Print or search for patient results by patient name, patient ID, date and time, department, etc.
5) Calculate the amount of work, Diagnostic results and items under Statistics Screen. The statistics results can be printed and exported.
6) Perform Data Dictionary Setup, Printing Setup, System Setup and i15 Setting under Setup screen. Backup and restore data, view logs under Data Maintenance Screen.
7) Upload data from analyzers or USB Disk for viewing.
8) Import patient information from LIS/HIS.
9) Simultaneously connect 10 analyzers via wire or wireless network. Send data to LIS/HIS under HL7 Protocol and receive data from other analyzers provided by a third party under ASTM Protocol.
10) The DMS can only receive non-private patient information from LIS/HIS under HL7 Protocol.

NOTE: Sample ID on analyzers connected to the same DMS should be different.

◆ **HIS/LIS**

HIS/LIS transmits patient information to the DMS, and receives data from both the analyzer and the DMS.

2.3 Analyzer Appearance

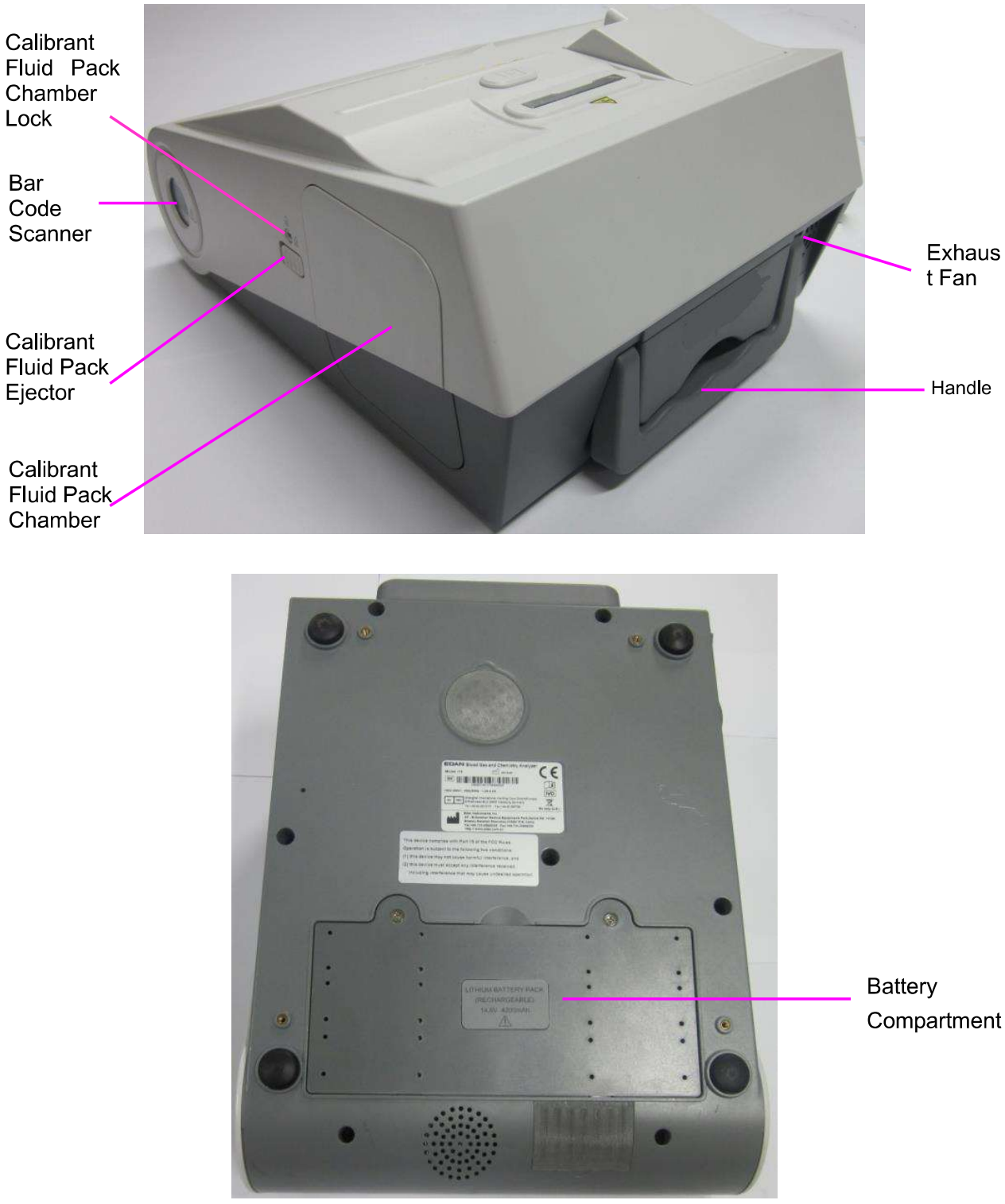


Figure 2-1 Analyzer Major Components

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 (QC) test results, calibration results, etc.

2.4.2 Test Cartridge

The Test Cartridge, sold separately, contains the sample fillport, the complete sample pathway, sensors, measuring chamber and all waste. The measured values available are determined by the type of Test Cartridge. Please see Table 2-1 on the following page for a listing of Test Cartridge types, order numbers, and the measured and calculated values available with each type. In use, a test cartridge is inserted into the analyzer through the test cartridge port, located next to the thermal printer. An indicator is located inside the test cartridge port. If the test cartridge is inserted properly, the indicator will turn green, illuminating the Test Cartridge. 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 single-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.

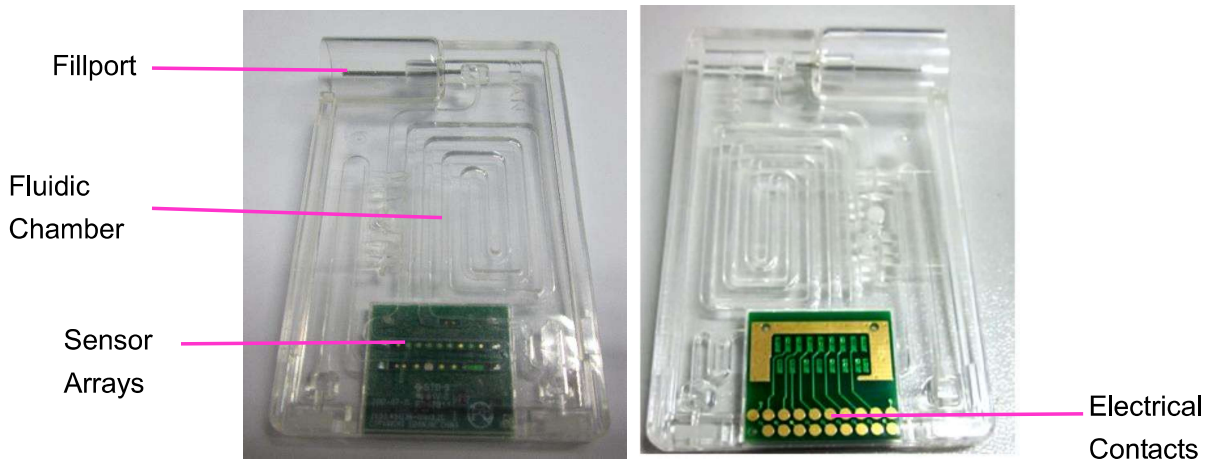


Figure 2-2 Test Cartridge

Table 2-1 Test Cartridge Types

Test Cartridge Type	Measured Parameters	Calculated Parameters	NOTE
BG8; MicroSample-BG8; Micro-BG8	pH, pCO_2, pO_2, Na^+, K^+, Cl^-, Ca^{++}, Hct	cH^+, HCO_3-act, HCO_3-std, BE(ecf), BE(B), BB(B), $ctCO_2$, $sO2$(est), Ca^{++}(7.4), AnGap, tHb(est), pO_2(A-a), pO_2(a/A), RI, pO_2/FIO_2, cH^+(T), pH(T), pCO_2(T), pO_2(T), pO_2(A-a)(T), pO_2(a/A)(T), RI(T), pO_2(T)/FIO_2, mOsm	MicroSample-BG8 and Micro-BG8 are **NOT** available in the USA at the release of this user manual

BG3; MicroSample-BG3; Micro-BG3	pH, pCO_2, pO_2	cH^+, HCO_3-act, HCO_3-std, BE(ecf), BE(B), BB(B), $ctCO_2$, sO_2(est), pO_2(A-a), pO_2(a/A), RI, pO_2/FIO_2, cH^+(T), pH(T), pCO_2(T), pO_2(T), pO_2(A-a)(T), pO_2(a/A)(T), RI(T), pO_2(T)/FIO_2	MicroSample-BG3 and Micro-BG3 are **NOT** available in the USA at the release of this user manual
BC4; MicroSample-BC4; Micro-BC4	Na^+, K^+, Cl^-, Ca^{++}, Hct	tHb(est), mOsm	MicroSample-BC4 and Micro-BC4 are **NOT** available in the USA at the release of this user manual
BG10; MicroSample-BG10; Micro-BG10	pH, pCO_2, pO_2, Na^+, K^+, Cl^-, Ca^{++}, Glu, Lac, Hct	cH^+, HCO_3-act, HCO_3-std, BE(ecf), BE(B), BB(B), $ctCO_2$, sO_2(est), Ca^{++}(7.4), AnGap, tHb(est), pO_2(A-a), pO_2(a/A), RI, pO_2/FIO_2, cH^+(T), pH(T), pCO_2(T), pO_2(T), pO_2(A-a)(T), pO_2(a/A)(T), RI(T), pO_2(T)/FIO_2 , mOsm	**NOT** available in the USA at the release of this user manual
BG9; MicroSample-BG9; Micro-BG9	pH, pCO_2, pO_2, Na^+, K^+, Cl^-, Ca^{++}, Glu, Hct	cH^+, HCO_3-act, HCO_3-std, BE(ecf), BE(B), BB(B), $ctCO_2$, sO_2(est), Ca^{++}(7.4), AnGap, tHb(est), pO_2(A-a), pO_2(a/A), RI, pO_2/FIO_2, cH^+(T), pH(T), pCO_2(T), pO_2(T), pO_2(A-a)(T), pO_2(a/A)(T), RI(T), pO_2(T)/FIO_2 , mOsm	**NOT** available in the USA at the release of this user manual
BG4; MicroSample-BG4; Micro-BG4	pH, pCO_2, pO_2, Lac	cH^+, HCO_3-act, HCO_3-std, BE(ecf), BE(B), BB(B), $ctCO_2$, sO_2(est), pO_2(A-a), pO_2(a/A), RI, pO_2/FIO_2, cH^+(T), pH(T), pCO_2(T), pO_2(T), pO_2(A-a)(T), pO_2(a/A)(T), RI(T), pO_2(T)/FIO_2	**NOT** available in the USA at the release of this user manual
BG5; MicroSample-BG5; Micro-BG5	pH, pCO_2, pO_2, Glu, Lac	cH^+, HCO_3-act, HCO_3-std, BE(ecf), BE(B), BB(B), $ctCO_2$, sO_2(est), pO_2(A-a), pO_2(a/A), RI, pO_2/FIO_2, cH^+(T), pH(T), pCO_2(T), pO_2(T), pO_2(A-a)(T), pO_2(a/A)(T), RI(T), pO_2(T)/FIO_2	**NOT** available in the USA at the release of this user manual

BC6; MicroSample-BC6; Micro-BC5	Na^+, K^+, Cl^-, Ca^{++}, Glu, Lac, Hct	tHb(est)，mOsm	**NOT** available in the USA at the release of this user manual
BG9-Lac; MicroSample-BG9-Lac; Micro- BG9-Lac	pH，pCO_2，pO_2，Na^+，K^+，Cl^-，Ca^{++}，Lac，Hct	cH^+，HCO_3-act，HCO_3-std，BE(ecf)，BE(B)，BB(B)，$ctCO_2$，sO_2(est)，Ca^{++}(7.4)，AnGap，tHb(est)，pO_2(A-a)，pO_2(a/A)，RI，pO_2/FIO_2，cH^+(T)，pH(T)，pCO_2(T)，pO_2(T)，pO_2(A-a)(T)，pO_2(a/A)(T)，RI(T)，pO_2(T)/FIO_2，mOsm	**NOT** available in the USA at the release of this user manual
MicroSample-SC4	Na^+, K^+, Cl^-, Ca^{++}	mOsm	**NOT** available in the USA and CE areas at the release of this user manual

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.

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:

1) Never use test cartridges failing control tests.
2) If the pouch has been damaged, the Test Cartridge should not be used.
3) Only Test Cartridges provided by EDAN or its authorized distributors should be used.
4) Only Test Cartridges properly stored should be used.
5) Never reuse Test Cartridges.
6) Never touch the fillport or electrical contacts of a Test Cartridge.
7) Use Test Cartridges before the expiration date as labeled on the package, and use them immediately after removing them from their pouches.
8) Test Cartridges should be kept out of direct sunlight and heat.
9) The analyzer, Test Cartridges and the testing environment should be at the same

temperature prior to a test.

10) Test Cartridges should not be dropped or stressed.
11) Please refer to its user manual for its storage conditions and shelf life and other detailed information.

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:

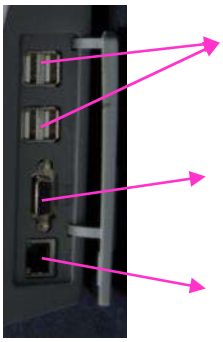
1) Green Light: The analyzer is on and the power supply is normal. The analyzer can be powered either by the rechargeable lithium battery or AC power. Or the system is off and has been connected to AC power.
2) Blinking Yellow Light: The power is supplied by the rechargeable lithium battery and the battery is low.
3) 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 or HIS/LIS.

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 solution is intended to be used together with

the analyzer to perform one-point sensor calibration. Calibrant Fluid Packs are available for 50 and 100 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.

Before Use

Calibrant Fluid Packs should be brought to room temperature before use. Allow at least 30 minutes for a Calibrant Fluid Pack to equilibrate to room temperature.

NOTE:

1) If the pouch has been damaged or there is any leakage, the Calibrant Fluid Pack should not be used.
2) Only those Calibrant Fluid Packs provided by EDAN or its authorized distributors should be used.
3) Use a Calibrant Fluid Pack before the expiration date as labeled on the package.
4) 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.
5) Never use Calibrant Fluid Packs failing control tests.
6) Please refer to its user manual for its storage conditions and shelf life and other detailed information.

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, calibration verification controls, operator ID, patient ID, sample ID, etc. The analyzer can also be connected to external scanners as mentioned in Section 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 – 15 cm (2.36-5.9 in).
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:

✓ Moisten a dust-free and lint-free cloth with Ethanol (75%) or Isopropanol (70%);

✓ Wipe the external electronic simulator with the dust-free and 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-up according the instruction in 3.3.10 Connecting Peripherals.

2.5 Configuration

2.5.1 Materials Provided

1) 1 i15/i15A Analyzer
2) 1 power cable
3) 1 power adaptor
4) 12 thermal printer paper
5) 1 rechargeable lithium battery
6) 1 screwdriver
7) 1 user manual

8) 1 quick reference card
9) 1 certificate of approval
10) 1 packing list

2.5.2 Materials Needed but Not Included

1) Test Cartridges
2) Calibrant Fluid Pack
3) External Electronic Simulator
4) Capillary Adaptor
5) Ampoule Adaptor
6) Controls

2.5.3 Options

1) Calibration Verification Controls
2) Data Management Software
3) Honeywell 1900 scanner

2.6 Configurations of Different Models

Configurations	i15	i15A
Touch Screen	X	X
Built-in Scanner	X	X
External Scanner	•	•
Built-in Printer	X	X
External Printer	•	•
Internal Simulator	X	X
External Simulator	•	•
Lithium Battery	X	•
NOTE: **X** = Standard; • = Optional;		

2.7 Network Security

2.7.1 Operating Environment

Hardware Configuration

- CPU module: AT9G45
- Peripheral device: USB Disk
- I/O interface: USB port, serial port and network port

Software Operating Environment

- Development system environment: Linux
- Integrated development environment: Eclipse
- Programming language: C/C++

Network Configuration

- Network interface: 10/100M
- Network type: LAN
- Network architecture: CS

2.7.2 Security Software

- None

2.7.3 Data and Device interface

1) Serial port
2) USB interface
3) Network interface
4) Wireless network card
5) Transmission protocol: the communication between the product and HIS/LIS system is achieved via HL7 protocol.
6) Storage format: text format, compressed package format and picture format

2.7.4 Access Control

Unauthorized users can’t access into the analyzer’s software.

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:

1) Convenient for the analyzer to be connected to a grounded electrical receptacle in case it is powered by AC power.
2) Keep the analyzer away from direct exposure to strong sunlight.
3) Ambient Temperature between 10 °C and 31 °C (50°F and 88°F).
4) Relative Humidity of 25% - 80% (non-condensing).
5) Ambient Pressure within 57 - 106.6 kPa (428 – 800 mmHg).
6) Placed onto a clean and flat surface with good ventilation.
7) Keep the analyzer away from equipment with strong electric field and strong magnetic field.
8) 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±10% VAC - 240±10% VAC and the frequency of 50/60 Hz.

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 a 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 by popping out a window as the following screenshot displays. At the same time, the battery indicator icon on the status bar at the bottom of the screen will also blink.

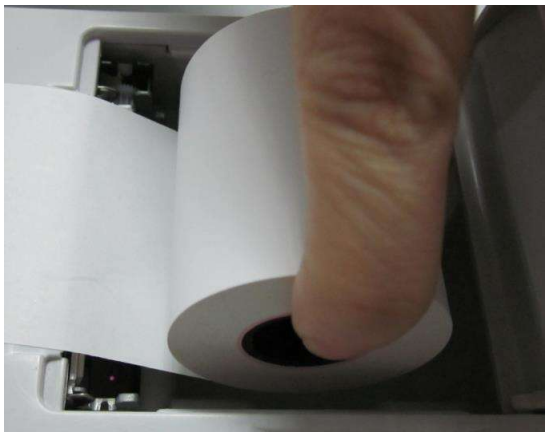
✓ The battery will automatically be charged whenever the analyzer is connected to an electrical outlet.

3.3.3 Installing and Replacing the Printer Paper

The analyzer utilizes rolled thermal paper with a width of 50 mm. When the printer paper runs out during the printing or is not loaded, the warning message "*No Paper in Printer*" 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 a little 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  .

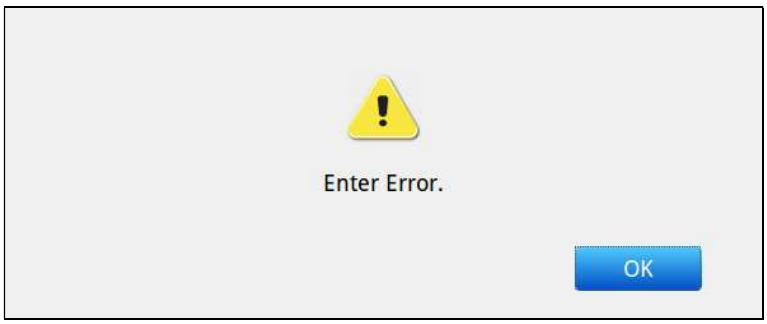
   To enter the user name with the bar code scanner, press  first, and then scan the user name bar code.

Figure 3-2 Enter User Name and Password

When logging in for the first time, use the user name **admin** and password **123456**. After entering the system, you can edit your password and add more users by using the procedures introduced in 7.2.1.5 Changing System Password and 7.2.1.2 Adding an Operator.

If any entered information is wrong, the system will prompt users by popping out a

window as the following screenshot displays when the user presses Login.



◆ **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.

3. Press will cancel the Figure 3-3.

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.

3.3.7 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.

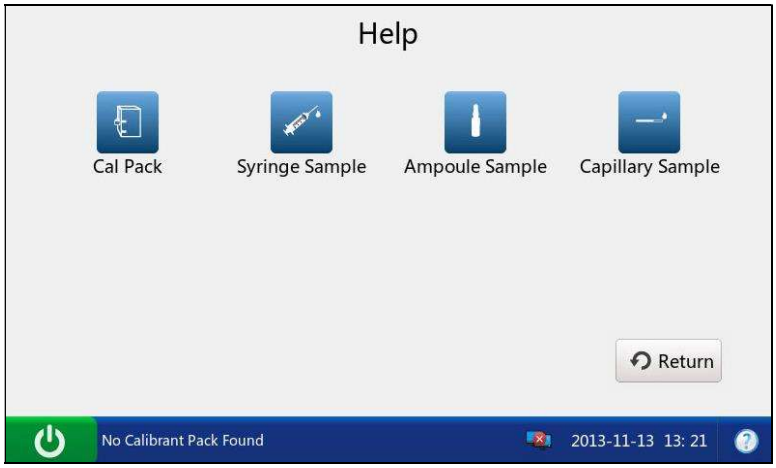


Figure 3-4 Help Screen

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.

3.3.8 Replacing a Calibrant Fluid Pack

WARNING

1. Never replace a Calibrant Fluid Pack when the analyzer is off.
2. 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.

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 30 minutes.
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:

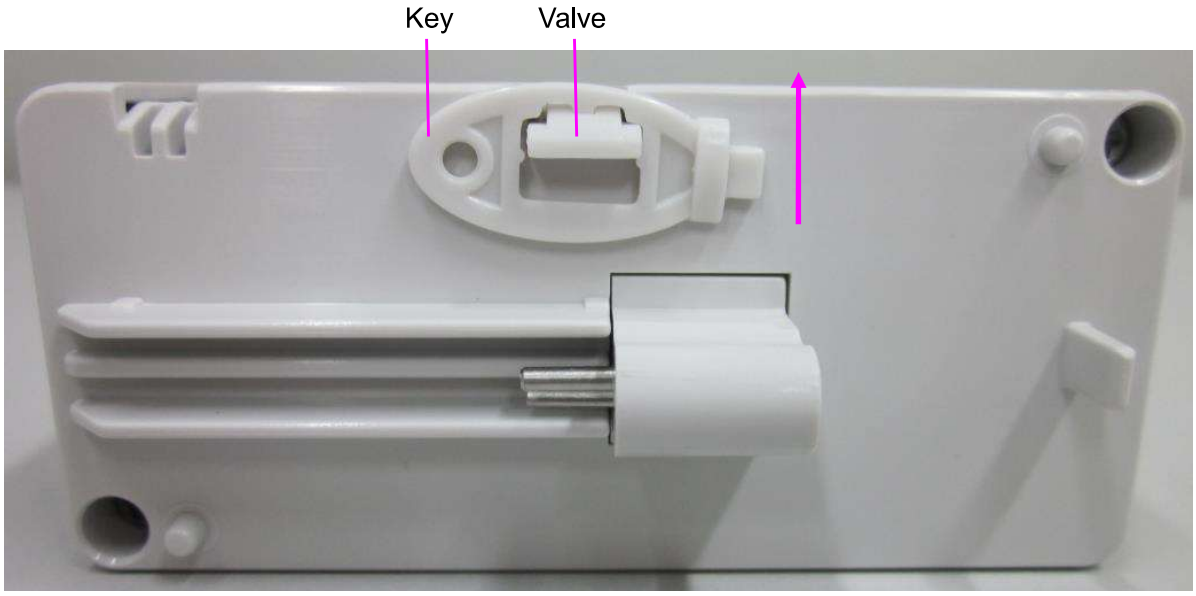
Figure 3-5 Open Chamber Door

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 on the right side of the analyzer.
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.

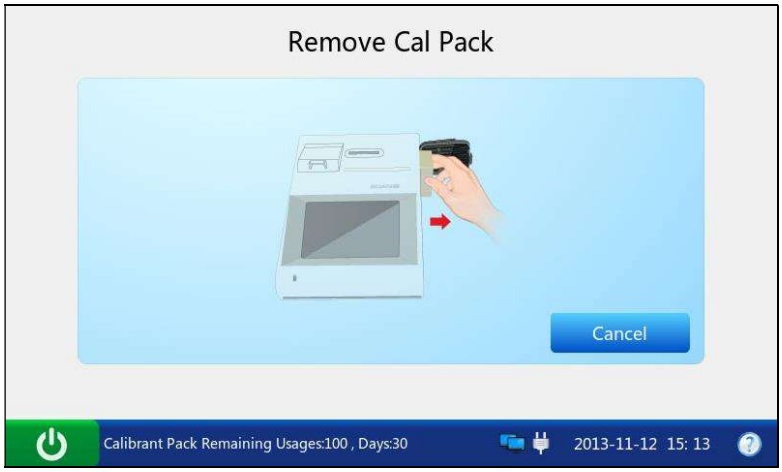


Figure 3-6 Remove Old Calibrant Fluid Pack

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.

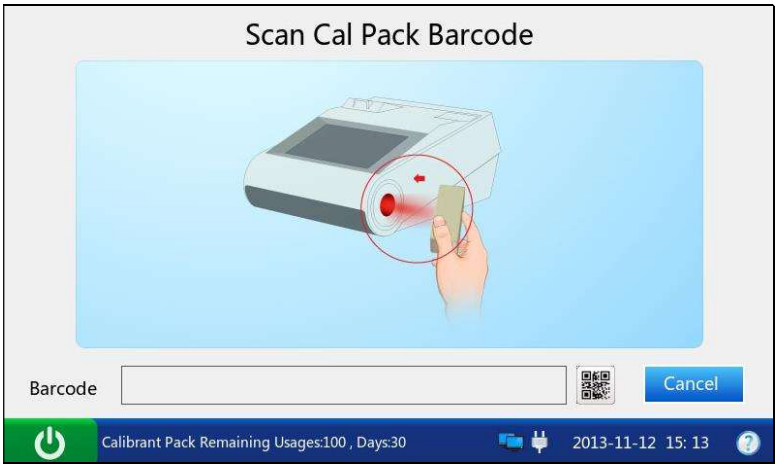


Figure 3-7 Scan Bar Code

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 that of a used Calibrant Fluid Pack, the following message will pop up:

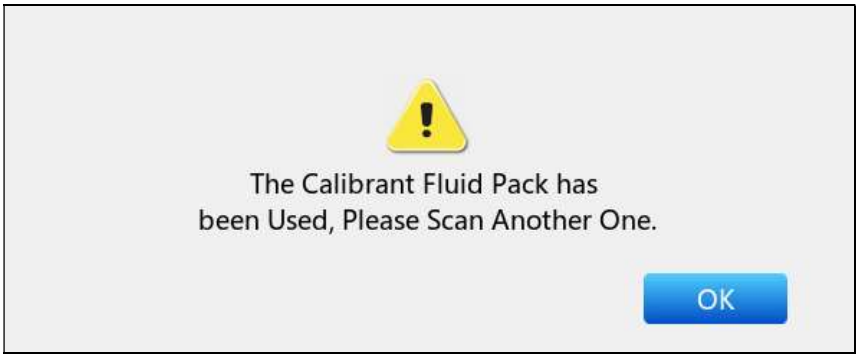
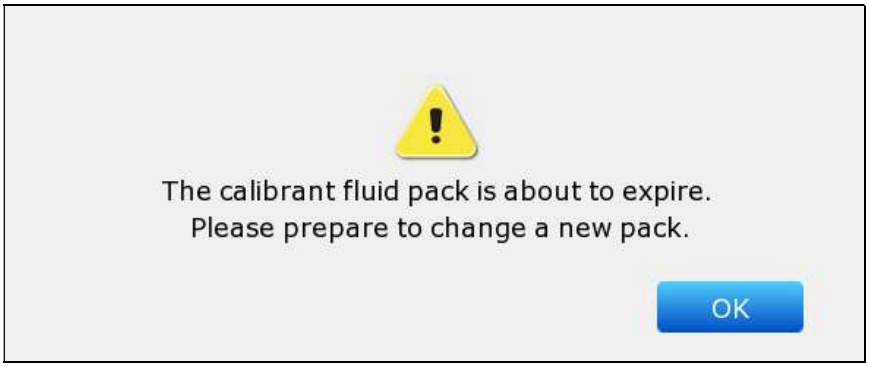


Figure 3-12 Calibrant Fluid Pack was Used

✓ If the bar code is that of an expired Calibrant Fluid Pack, the following message will pop up:

Figure 3-13 Calibrant Fluid Pack Expired

✓ If the Calibrant Fluid Pack is about to expire after 24 hours, the system will pop up a message on the screen to remind users to replace it.



3.3.9 DEMO Test

The system can demonstrate the sample testing process and the Calibrant Fluid Pack replacing process through animation.

3.3.9.1 DEMO Sample Tests

◆ In Test Mode 1, follow the steps below to perform a DEMO sample 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 Login. The system will go to the following screen:

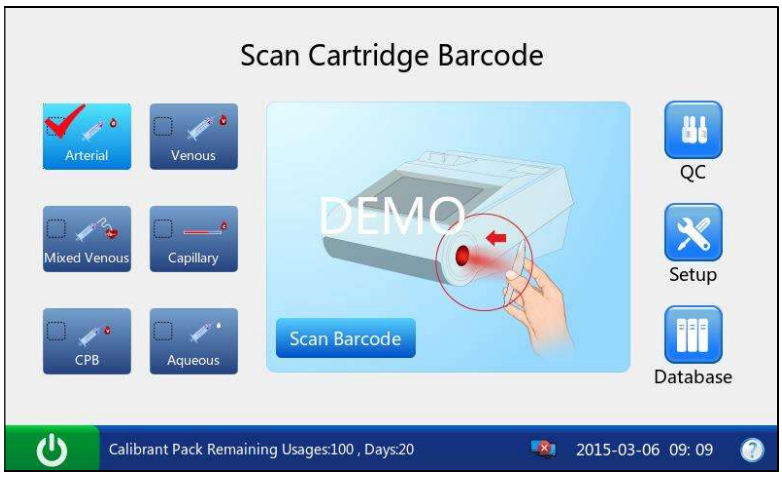


Figure 3-14 DEMO Sample Test Screen 1

3. Press **Scan Barcode** to scan the barcode of test cartridge and the system will pop out the following Screen.

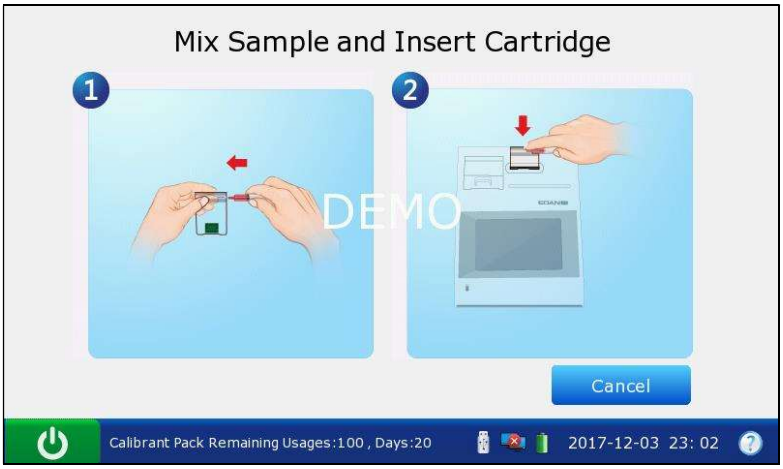


Figure 3-15 DEMO Sample Test Screen 2

4. Insert Test cartridge and the system will enter into the following screen.

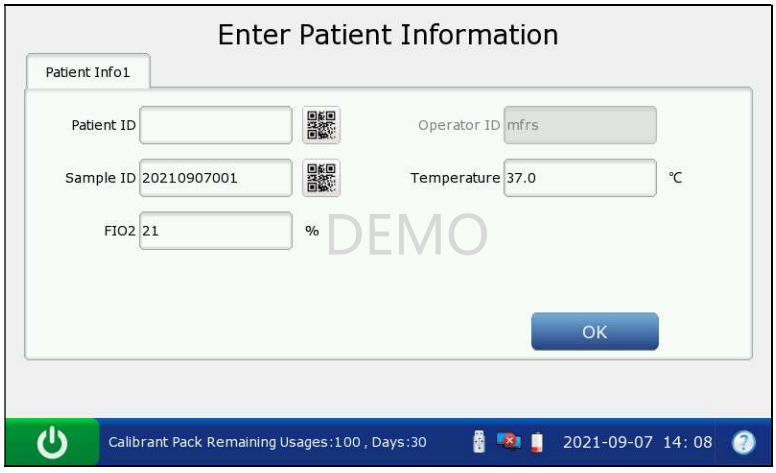


Figure 3-16 DEMO Sample Test Screen 3

5. Press **OK** and the system begins to simulate calibrating.

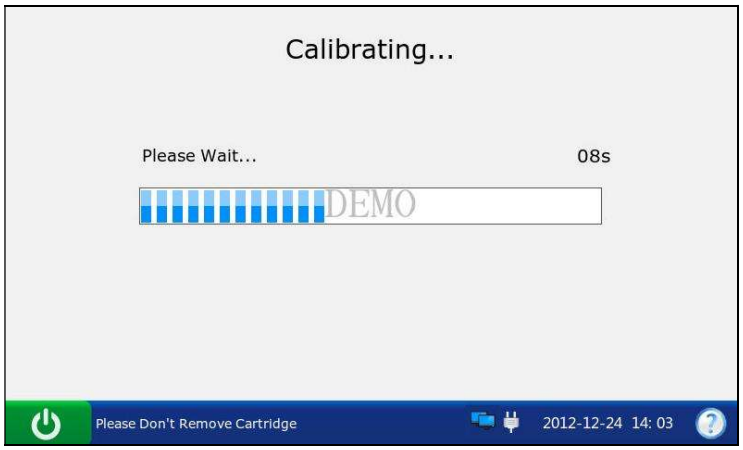


Figure 3-17 DEMO Sample Test Screen 4

6. The system simulates sampling.

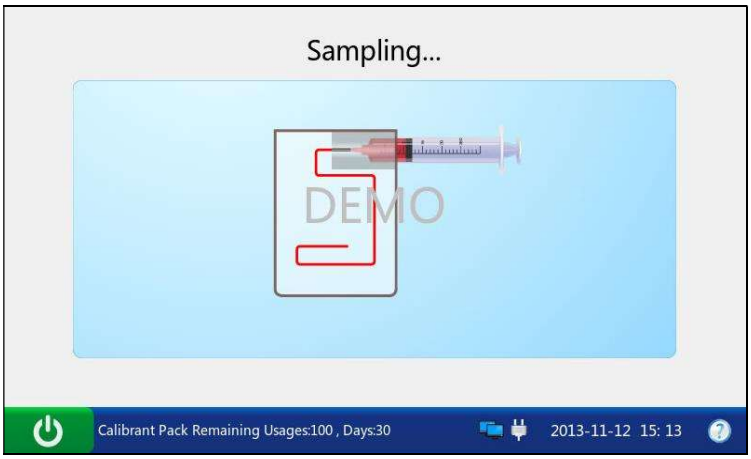


Figure 3-18 DEMO Sample Test Screen 5

7. The system simulates testing.

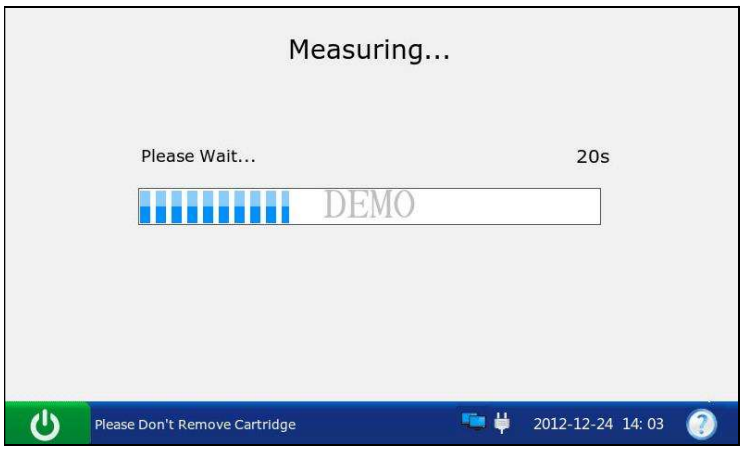


Figure 3-19 DEMO Sample Test Screen 6

8. The system simulates displaying test results.

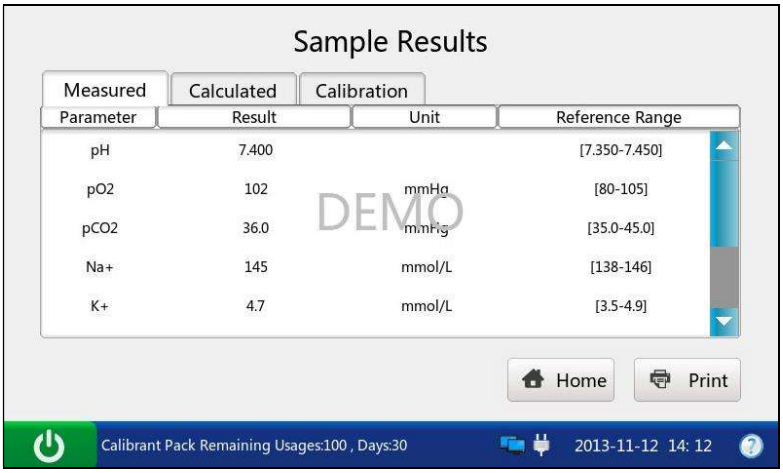


Figure 3-20 DEMO Sample Test Screen 7

9. Press **Home** to return.
10. Follow the steps as described in 3.3.5 to logout of the system.

◆ In Test Mode 2, follow the steps below to perform a DEMO sample 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 Login. The system will go to the following screen:

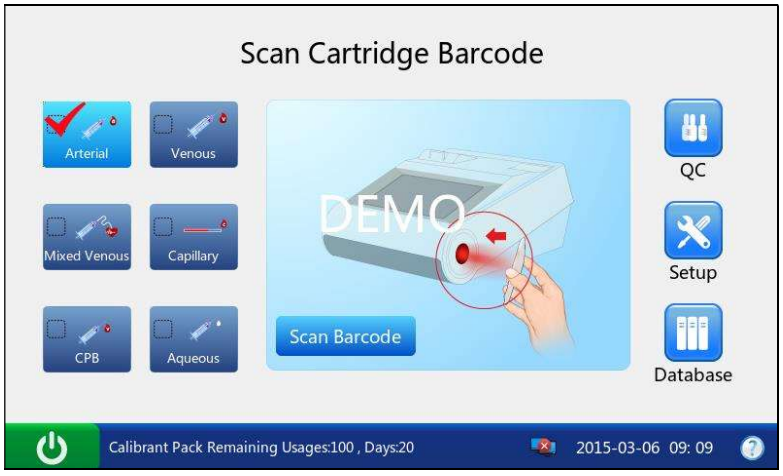


Figure 3-21 DEMO Sample Test Screen 1

3. Press **Scan Barcode** to scan the barcode of test cartridge and the system will pop out the following Screen.

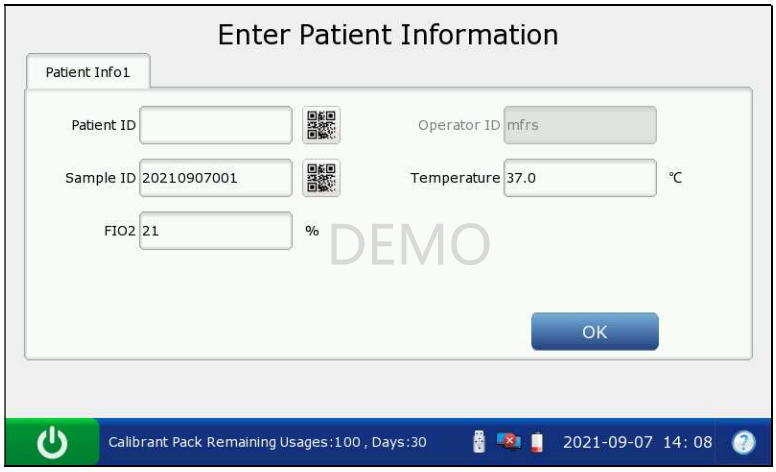


Figure 3-22 DEMO Sample Test Screen 2

4. Press **OK** and insert Test cartridge.

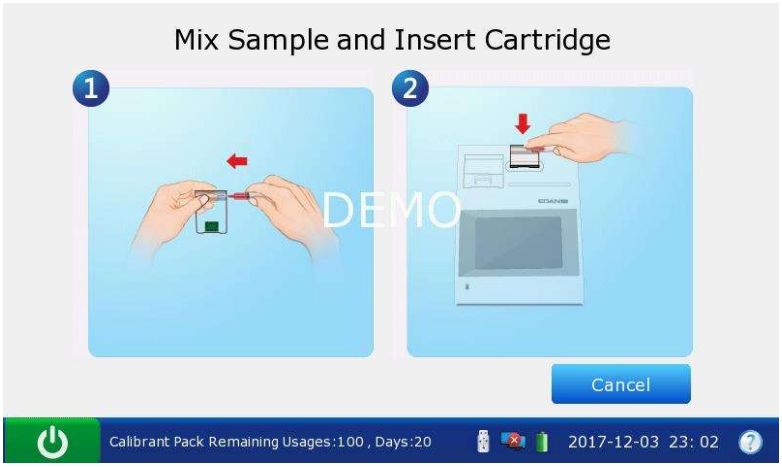


Figure 3-23 DEMO Sample Test Screen 3

5. The system begins to simulate calibrating.

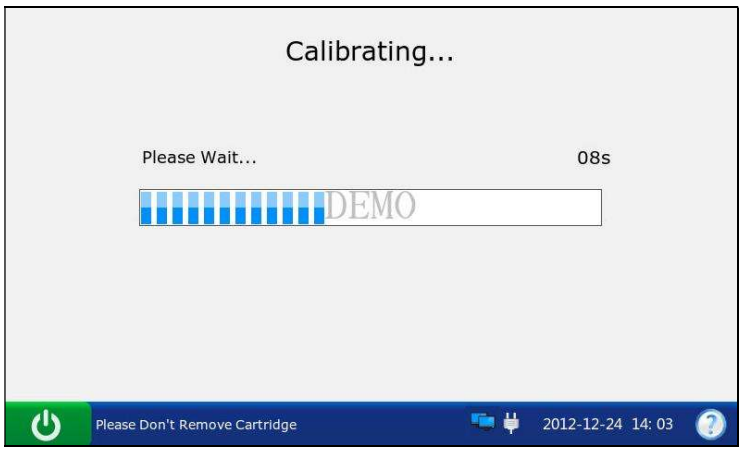


Figure 3-24 DEMO Sample Test Screen 4

6. The system simulates sampling.

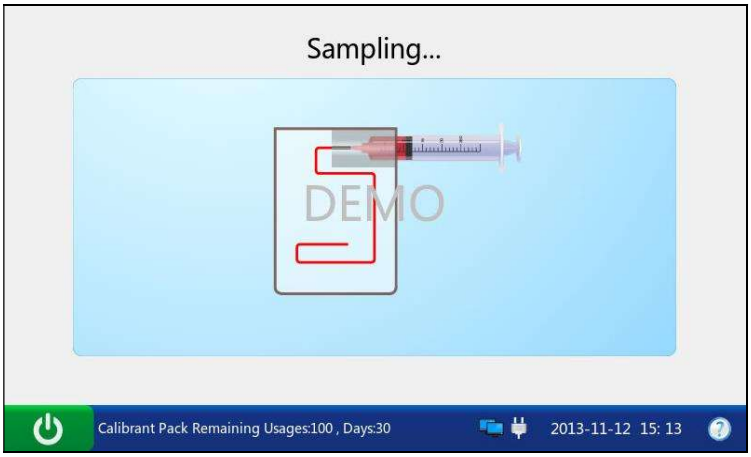


Figure 3-25 DEMO Sample Test Screen 5

7. The system simulates testing.

Figure 3-26 DEMO Sample Test Screen 6

8. The system simulates displaying test results.

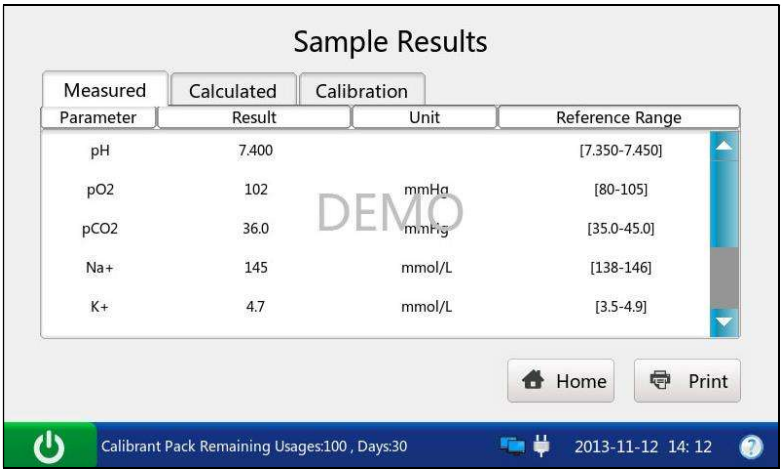


Figure 3-27 DEMO Sample Test Screen 7

9. Press **Home** to return.
10. Follow the steps as described in 3.3.5 to logout of the system.

3.3.9.2 DEMO Calibrant Fluid Pack Replacing

Follow the steps as described in 3.3.8 to perform a Calibrant Fluid Pack replacing process.

3.3.10 Connecting Peripherals

NOTE: Only peripherals recommended by EDAN should be connected to the system.

Follow the steps below to setup 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.

Remove Custom Defaults

Activate Defaults

USB Serial

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
- Internal Simulator Setup
- Calibration Setup
- Test Mode 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 Login.

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

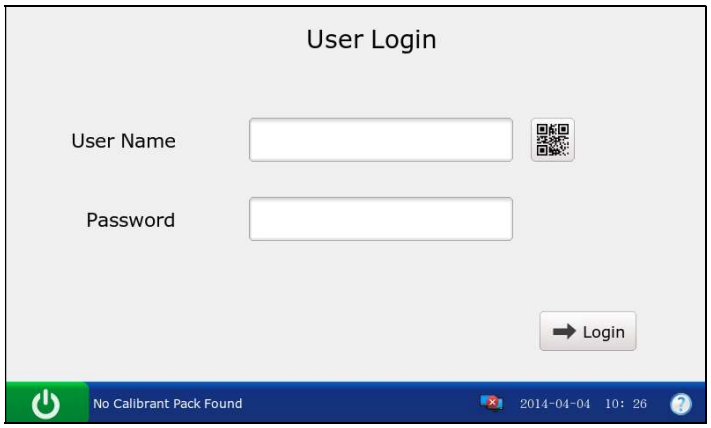


Figure 4-1 Enter User Name and Password

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.

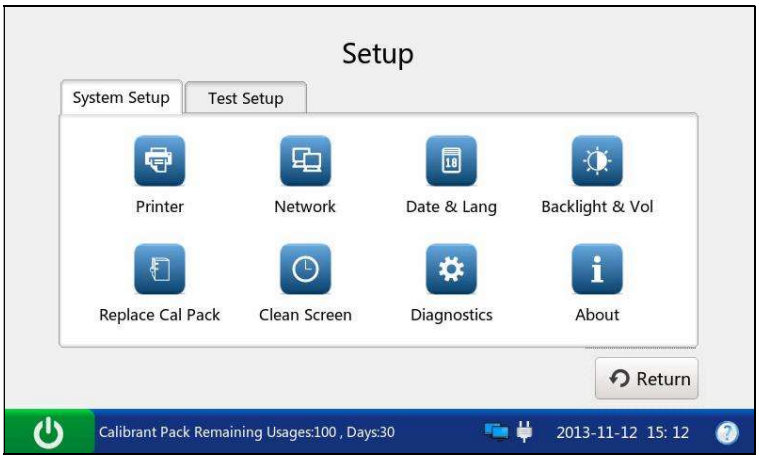


Figure 4-2 Setup-System Setup Screen

You can perform the following actions:

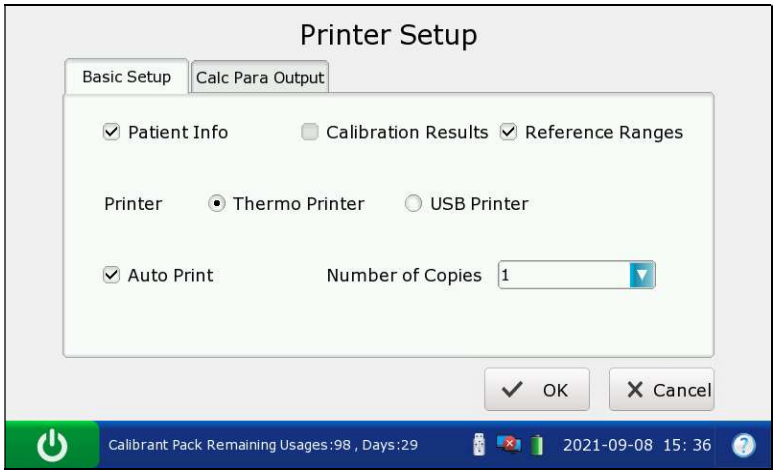
4.2.1 Printer Setup

This menu lets you configure the printer that the system uses, what are printed in reports, the number of copies it prints, and the calculated parameters to be printed on the patient report.

NOTE:

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

1. Press to access the Printer Setup screen.
2. There are two tabs: Basic and Calculated Parameter Output.
   - ◆ Basic Setup
   1) Press **Basic Setup** to go to the Basic Setup Screen.



2) On the Basic 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 reference ranges. The mark √ will appear if Reference Ranges is selected, and the default is to 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 quality control (QC) 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.

     NOTE:

     If Auto Print is turned on, control test results, proficiency test results, calibration verification test results and simulator test results will be automatically printed out.
   - Select the number of copies. There are two options: 1 and 2. The default is 1.

     NOTE:

     Calibration Results can't be selected and the default is not to print them.
3) Press **OK** to accept the changes, and the system will return to the System Setup screen.

◆ Calculated Parameter Output Setup

1) Press **Calc Para Output** to access the Calculated Parameter Output Setup screen.

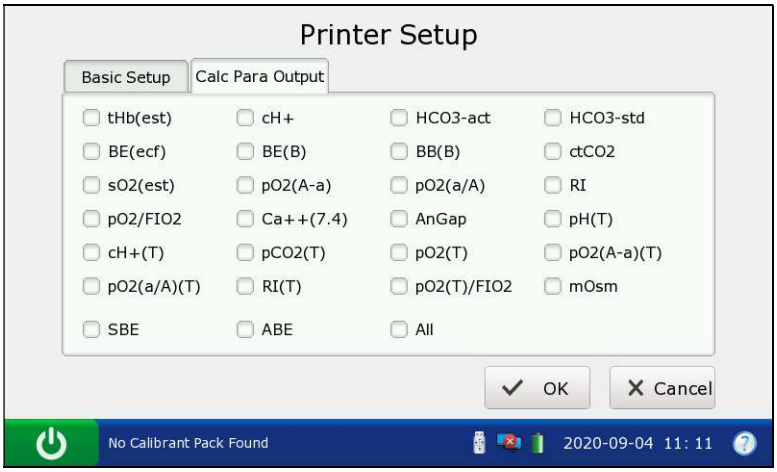


Figure 4-4 Printer – Calculated Parameter Output Setup Screen

2) Select the desired parameters. √ indicates the parameter is selected.

NOTE:

- ✓ Select **All** to select all the parameters on the screen.
- ✓ For calculated parameters not available on the test cartridge, the system will not print out them, even though they are selected.

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 four tabs: Communication, Local IP, WIFI and Properties.

◆ **Network Setup**

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

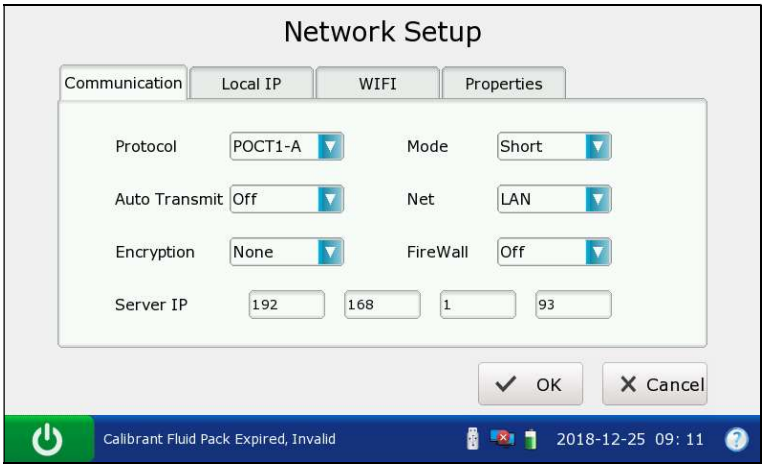
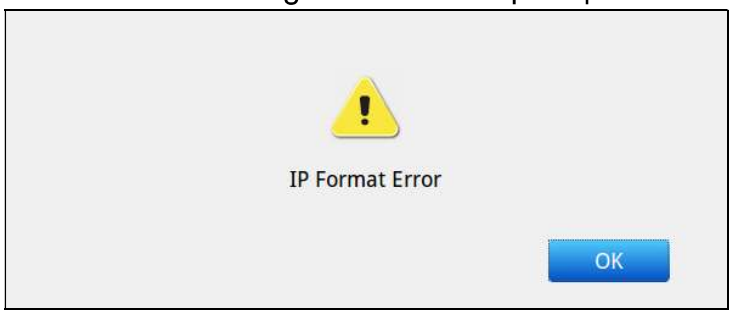


Figure 4-5 Network – Communication Setup Screen

2) On the Communication Setup screen, you can:

- ➢ Select the communication protocols. There are two options: POCT 1-A and HL7v2.4. The default is 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 Off.
- ➢ Select the mode. There are two options: Long and Short. The default is Short.
- ➢ Select the Net. There are two options: LAN and WIFI. The default is LAN.
- ➢ Select the encryption mode. There are two options: None and TLS. The default is None. If TLS is selected, the transmission under communication protocols will be encrypted.

- Select whether to open the firewall. There are two options: On and Off. If your selection is On, the analyzer can prevent cyber attacks.
- Enter the IP address of the DMS or HIS/LIS to which your analyzer is connected. If the entered IP address is wrong, the system will pop out a window as the following screenshot to prompt users.



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

◆ **Local IP Setup**

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

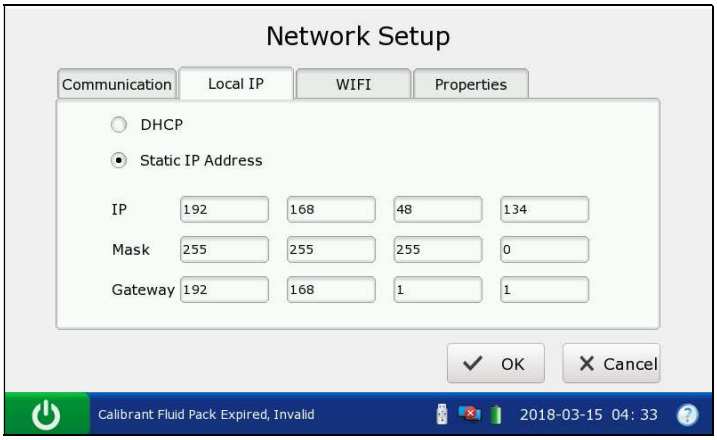
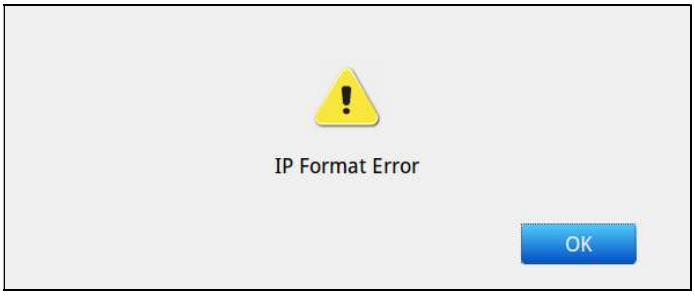


Figure 4-6 Network – Local IP Setup Screen

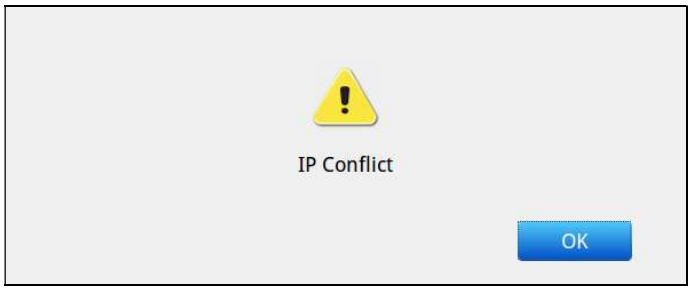
- Select the way that the analyzer is connected to the network. There are two options: DHCP (dynamic host configuration protocol) and Static IP addresses. The Default is DHCP. If the latter one is selected, the following information should be entered: IP, gateway and mask.

When set Static IP addresses:

If the entered IP, gateway or mask is wrong, the system will pop out a window as the following screenshot displays to prompt users.



If the entered IP is the other instrument's IP, the system will pop out a window as the following screenshot displays to prompt users.



NOTE:

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

2) 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.

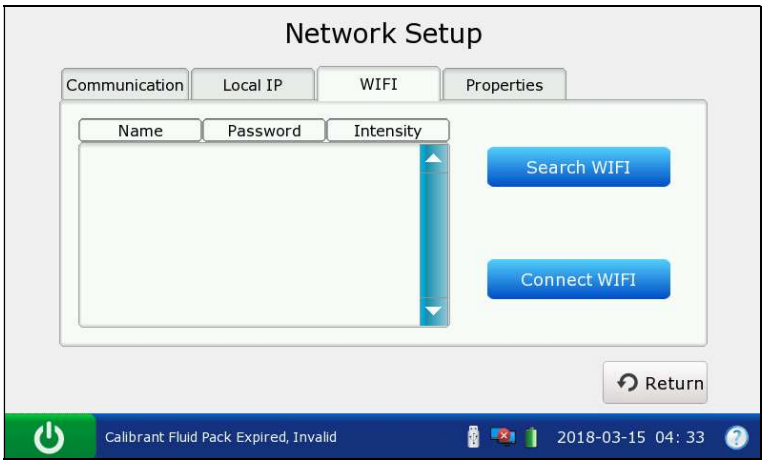
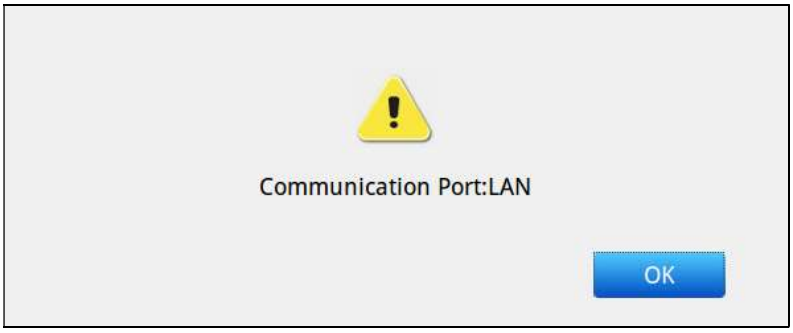


Figure 4-7 Network - WIFI Setup Screen

2) Press **Search WIFI**, the system will automatically search WIFI and display them. If the system fails to search **WIFI,** the system will pop out a window as the following screenshot displays to prompt users.

3) Select the network you want to connect, and press **Connect WIFI**.

If users select LAN for Net in the Network – Communication Setup Screen, the system will pop out a window as the following screenshot displays to prompt users to re-select WIFI for Net in the Network – Communication Setup Screen.



If the selected WIFI needs a password, the system will pop out a window as the following screenshot displays to require users to enter password.

If the selected WIFI needs a password and users don't enter the password or enter a wrong password, the system will pop out a window as the following screenshot displays to prompt users the analyzer fails to connect WIFI.

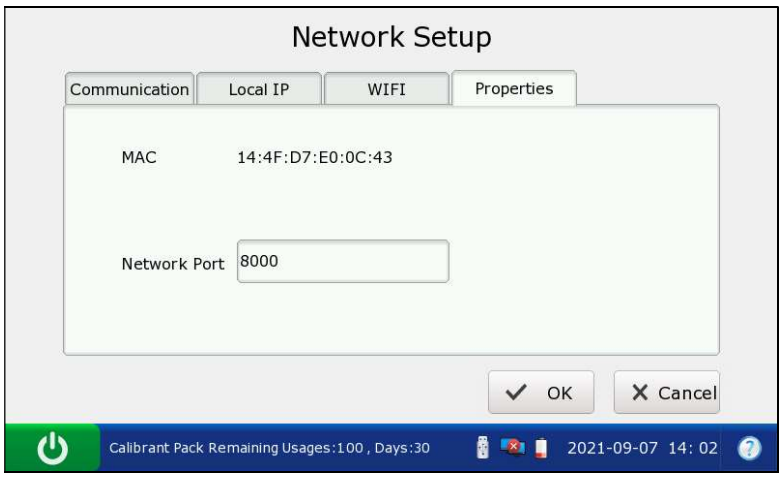
If the selected WIFI doesn't need a password, the system will directly connect the WIFI.

NOTE: The selected network should be in the same area network with that of the DMS or HIS/LIS.

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

◆ **Check Properties**

1) Press **Properties** to access to the Properties Screen to check MAC address and network port. Please note that the Network Port can be changed.



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.

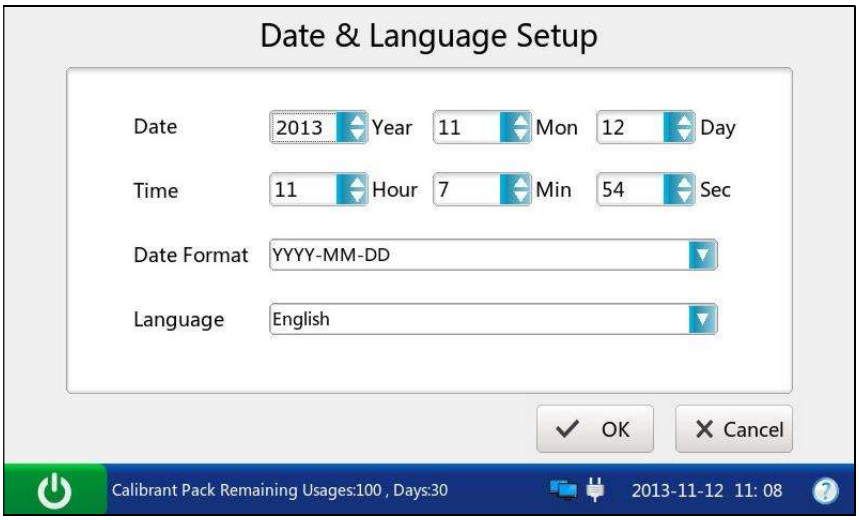


Figure 4-8 Date & Language Setup Screen

2. On the Date & Language Setup screen, you can:

- Change the time and date of the system.

  NOTE:

  If the changed date or time is inconsistent with the actual date or time, the system will prompt users by popping out a window as the following screenshot displays after pressing **OK** to save the changes.

- 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 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 protection mode, the key tones and the volume.

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

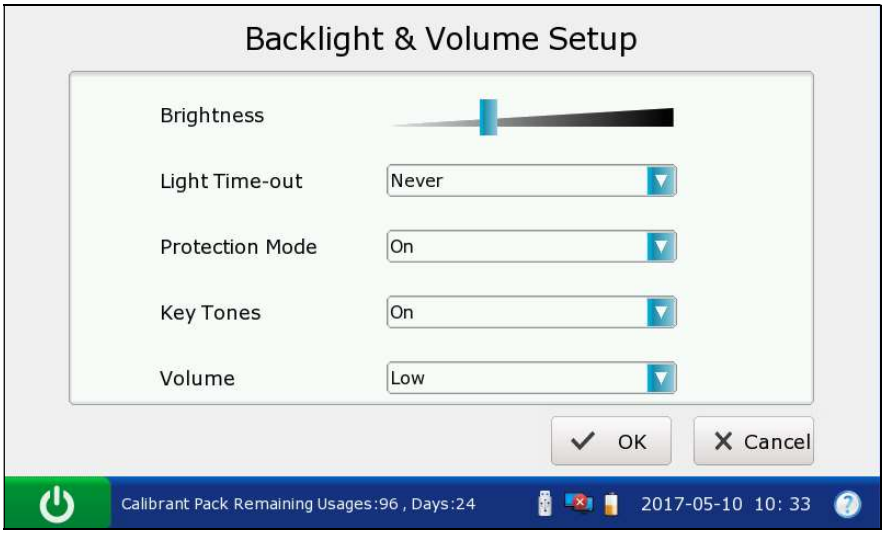


Figure 4-9 Backlight & Volume Setup Screen

2. On the Backlight Setup screen, you can:

- Brightness: Adjust the brightness of the backlight with the slider.
- Light Time-out: 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 never.

  NOTE:

  The backlight can be activated by directly touching the screen or pushing On/Off switch.
- Set the protection mode. There are two options: On and Off. If On is selected, the system will automatically go back to the Login Screen after reaching the idle time set by users. If Off is selected, the backlight will not go back to the Login Screen after reaching the idle time set by users.
- 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 service engineers diagnose some modules of the analyzer to check its operation. It helps to troubleshoot. Only service engineers and engineers from the manufacturer can perform this action. If the operator who doesn't log in with the service account, the system will pop out the following window when pressing  (**Diagnostics**).

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. View the information on the screen. Press **Return** to get access to the System Setup screen.
2. If the software needs to be updated, press 

and the system will pop out a

window as the following screenshot displays.

3. Press **OK** and the system will pop out a window as the following screenshot displays to require users to insert a USB Drive which should have the software package.

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:

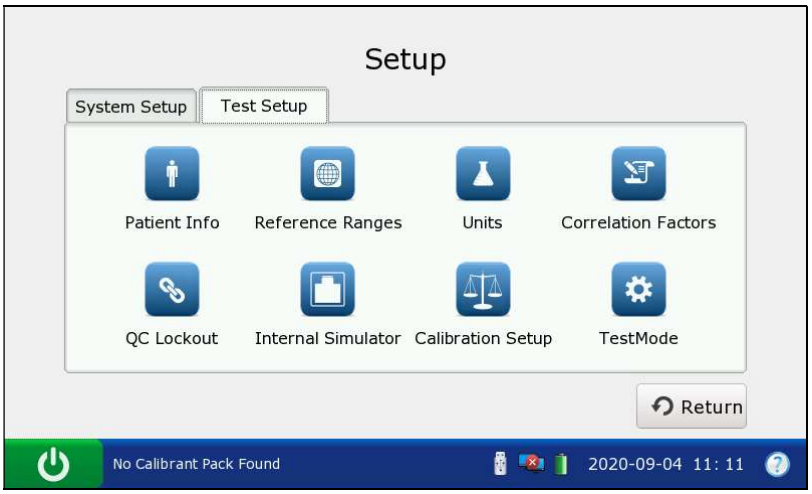


Figure 4-10 Setup – Test Setup Screen

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 (QC) 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 (QC) 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.

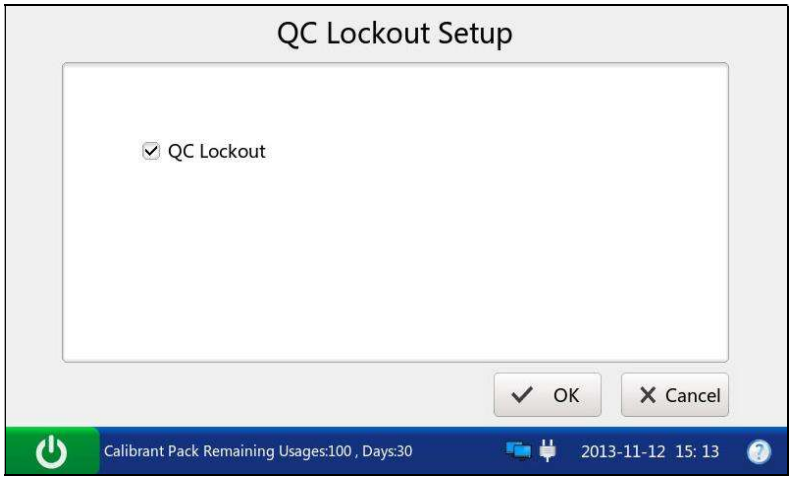


Figure 4-11 QC Lockout Setup Screen

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, FIO_2 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
Gender	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	0.15 ~ 1.00	0.01	x.xx
	15 - 100	1	%
RQ (respiratory	0.70 - 2.00	0.01	x.xx

quotient)			
Date of Birth	8 digits	N/A	N/A
Hospital	1-16 digits	N/A	N/A
MCHC	29 g/dL ~ 37 g/dL	0.1	g/dL
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 Mask= Mask T-P= T-Piece NC= Nasal Cannula Vent= Ventilator Bag= Bag (manual resuscitation) Hood= Hood Other= Other	N/A	N/A
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	N/A	N/A

Vent mode	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_2O
MVol (Minute Volume)	0 - 120	1	Lpm
PIP (Peak Inspiratory Pressure)	0 - 140	1	cmH_2O
Liter Flow	0 - 300	1	Lpm
TVol (Tidal Volume)	0 - 4000	1	mL/kg
PS (Pressure Support)	0 - 99.9	0.1	cmH_2O
PEEP (Positive End Expiratory Pressure)	0 - 50	1	cmH_2O
Rate	0 - 155	1	Bpm
CPAP (Continuous Positive Airway Pressure)	0 - 50	1	cmH_2O
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.

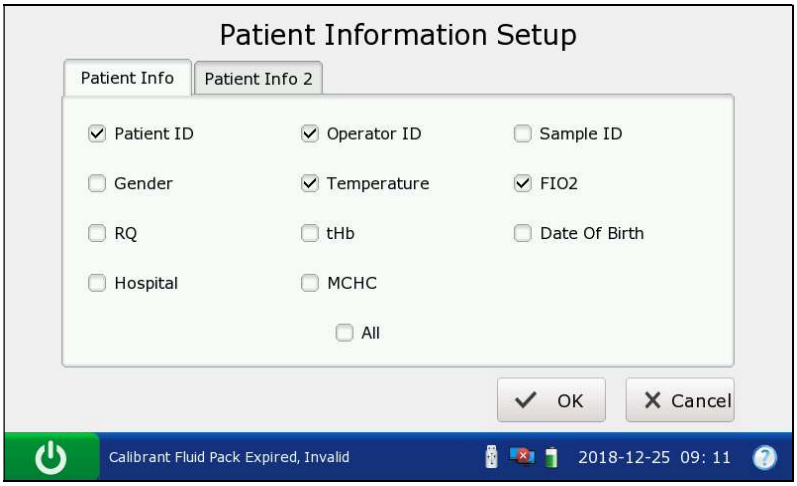


Figure 4-12 Patient Information 1 Screen

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

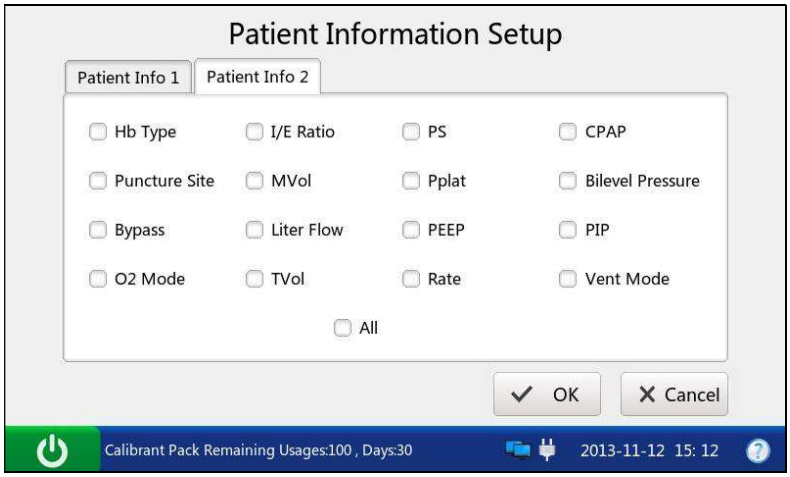


Figure 4-13 Patient Information 2 Screen

NOTE:

✓ Select **All** to select all the parameters on 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 six options: Arterial, Venous, Mixed Venous, Capillary, CPB and Aqueous. The default is Arterial. A result that is out of the reference range will be flagged with an up/down arrow. The reference ranges may vary with demographic factors such as age, gender and heritage, it is recommended that the default reference ranges be reset according to the population being tested or the internal procedures at your individual institution.

Follow the instructions below to set the reference ranges:

1. Press  to access the Reference Ranges Setup screen.

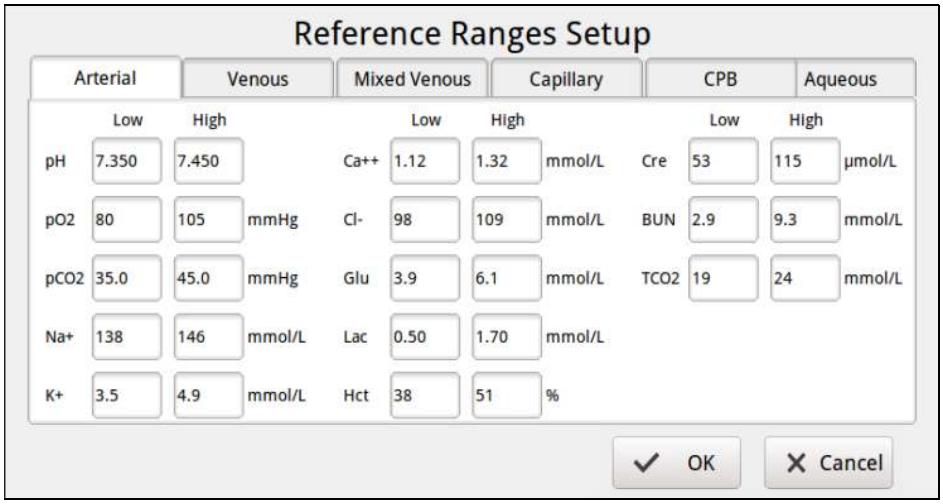


Figure 4-14 Reference Ranges Setup Screen

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.
- ✓ The reference ranges as in Figure 4-14 will be automatically displayed in accordance with the selected type of blood sample.
- ✓ The default reference range of Mixed Venous, Capillary, CPB and Aqueous is identical with the arterial's reference range. The default reference range can be reset according to the population being tested or the internal procedures at your individual institution.

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, mEq/L
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

Parameter	Default Unit	Alternate Units
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, mEq/L
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
K^+	mmol/L	mEq/L
Na^+	mmol/L	mEq/L
Cl^-	mmol/L	mEq/L

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.

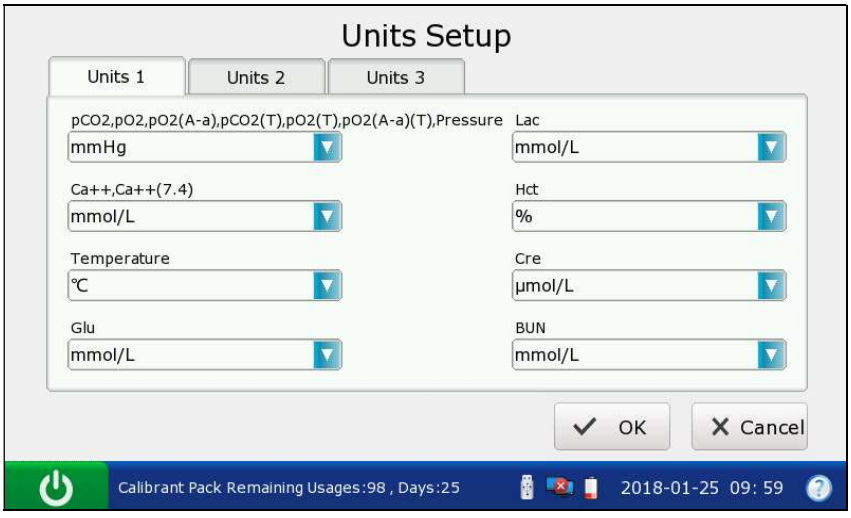


Figure 4-15 Units Setup 1 Screen

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

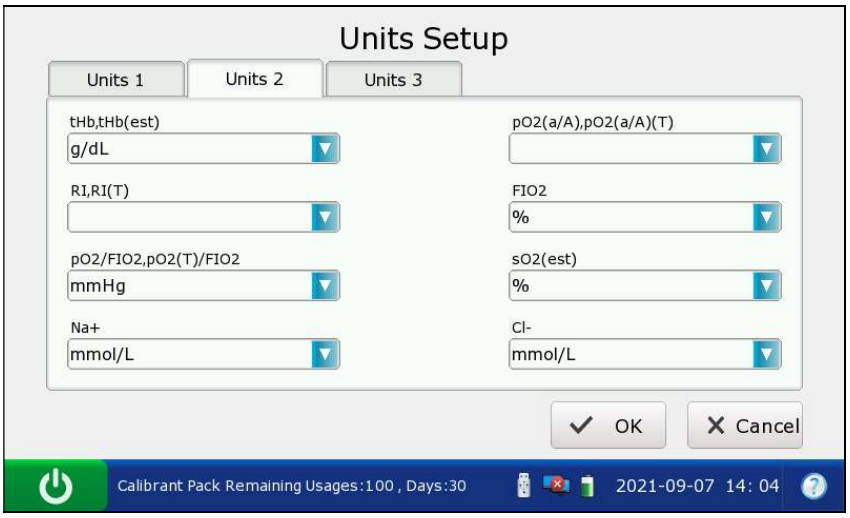


Figure 4-16 Units Setup 2 Screen

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

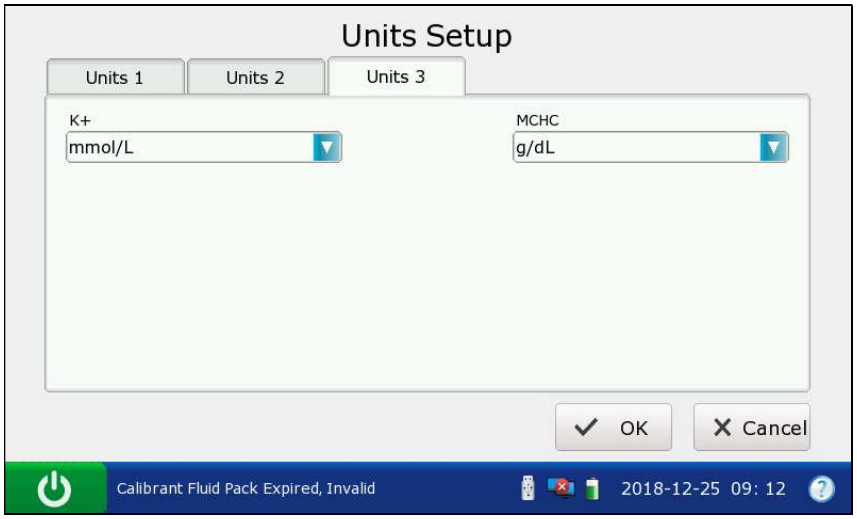


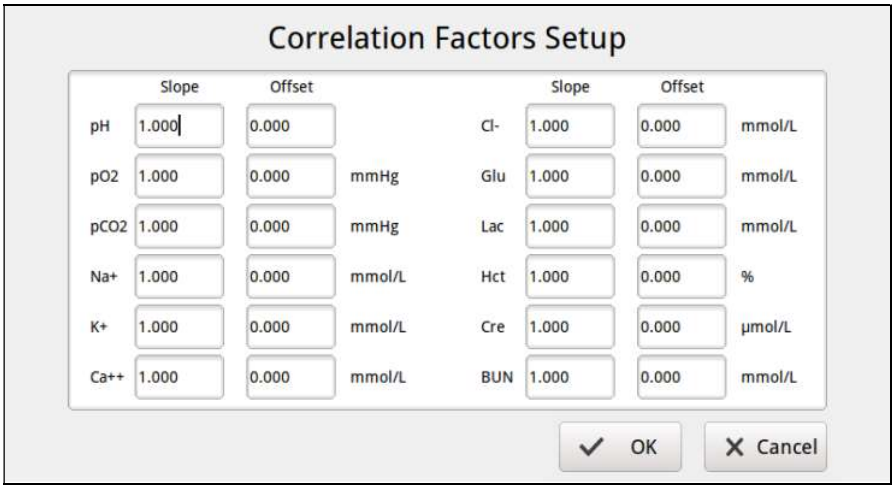
Figure 4-17 Units Setup 3 Screen

5. 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

Only service engineers and engineers from the manufacturer can change correlation factors.



4.3.6 Internal Simulator Setup

This menu allows you to set whether to run the internal simulator test, and set the time at which the system performs the test every day.

1. Press  to access the Internal Simulator Setup screen.

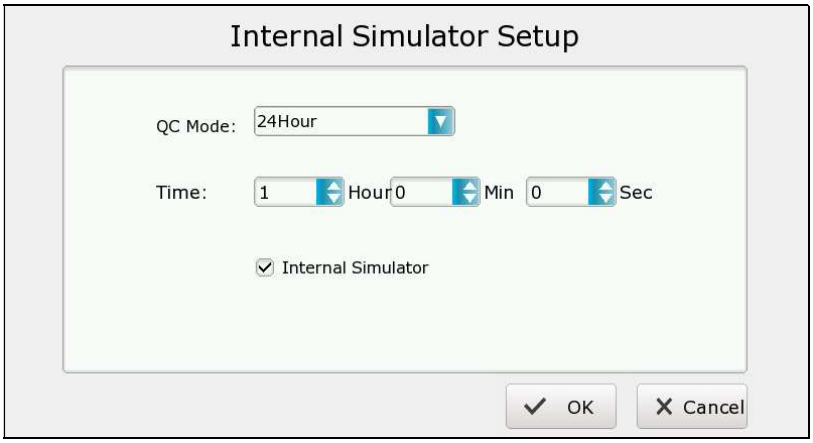


Figure 4-18 Internal Simulator Setup Screen

2. Select whether to run the internal simulator test. The mark √ will appear if Internal Simulator is selected, and the default is to select it.
3. If the Internal Simulator is selected, select QC Mode (24 Hour or 8 Hour) and set time (the default is 01:00:00). If 24 Hour is selected and the time is set as 1 Hour 0 Min 0 Sec, the system will automatically perform internal simulator test 24 hours later from 01:00:00.
4. Press **OK** to accept the changes, and the system will return to the Test Setup screen.

4.3.7 Calibration Setup

NOTE: If one or more of the selected parameters fail calibration tests, the test will halt.

1. Press  to go to the Calibration Setup screen.

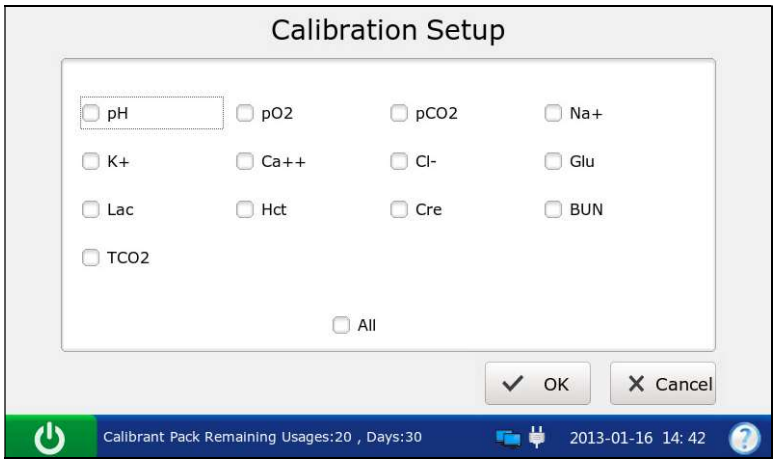


Figure 4-19 Calibration Setup Screen

2. pH, pO_2, pCO_2, K^+, Glu, Lac and Hct are selected in default by the system. Select the desired parameters. √ indicates the parameter is selected. Select **All** if you want to select all the parameters on the screen.
3. Press **OK** to accept the changes, and the system will return to the Test Setup screen.

4.3.8 Test Mode Setup

1. Press  to go to the Test Mode Setup screen.

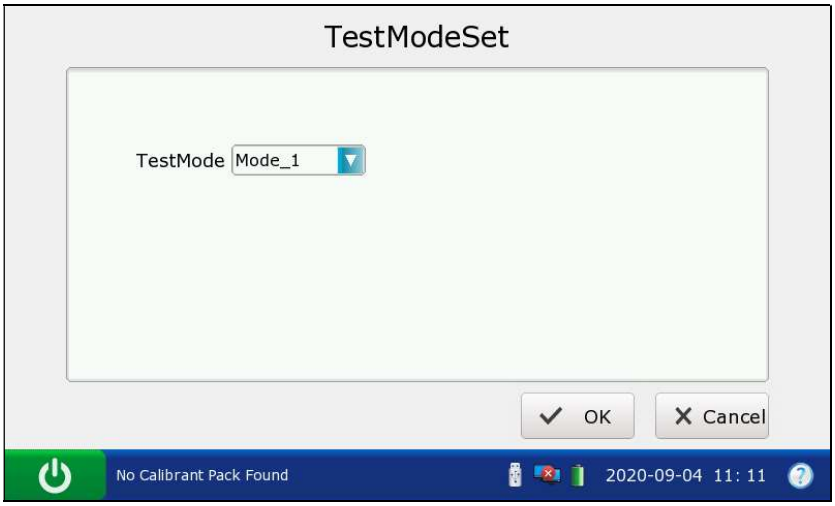


Figure 4-20 Test Mode Setup Screen

2. On the Test Mode Setup screen, you can select the desired test mode. There are two options: Mode 1 and Mode 2. If your selection is Mode 1, the sample test is to be performed by first scanning cartridge barcode, next inserting the cartridge and then entering the patient information; if your selection is Mode 2, the sample test is to be performed by first scanning cartridge barcode, next entering the patient information and then inserting the cartridge. The default is Mode 1.
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

The serum sample can be obtained from the whole blood which doesn't contain anticoagulant by centrifugation.

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.
- ✓ 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. Liquid heparin, when present in excess, may cause errors by dilution for pH, pCO_2, pO_2, electrolyte and hematocrit measurements.

CAUTION

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

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

5.1.3 Collection Devices and Volume

Blood Samples may be collected in 1mL, 3 mL or 5mL syringes, capillary tubes or vacuum blood collection tubes with lithium or balanced heparin. Vacuum or other blood collection tubes are not recommended for collection of samples for blood gas analysis.

Serum samples can be obtained from the whole blood which doesn't contain anticoagulant by centrifugation.

Samples may be introduced into the system with the following devices: syringes and capillary tubes. It is recommended that VITREX® Blood Gas Capillary Tubes which can hold up to 175µl or RNA Medical® Brand Safe-Wrap Blood Collection Tubes which can hold up to 220 µL should be used.

Sample Collection Device	Test Cartridge Type	Minimum fill volume after discarding bubbles and the first 2 drops of blood
Syringe (1mL)	BG8, BG3, BC4, BG10, BG9, BG4, BG5, BC6, BG9-Lac	500µL
	All test cartridges excluding BG8, BG3, BC4, BG10, BG9, BG4, BG5, BC6, BG9-Lac	300µL
Syringe (3mL)	BG8, BG3, BC4, BG10, BG9, BG4, BG5, BC6, BG9-Lac	800µL
	All test cartridges excluding BG8, BG3, BC4, BG10, BG9, BG4, BG5, BC6, BG9-Lac	600µL
Syringe (5mL)	BG8, BG3, BC4, BG10, BG9, BG4, BG5, BC6, BG9-Lac	1.5mL
	All test cartridges excluding BG8, BG3, BC4, BG10, BG9, BG4, BG5, BC6, BG9-Lac	1.4mL
Capillary Tube	BG8, BG3, BC4, BG10, BG9, BG4, BG5, BC6, BG9-Lac	140µL
	All test cartridges excluding BG8, BG3, BC4, BG10, BG9, BG4, BG5, BC6, BG9-Lac	80µL
Microcollection Device	BG8, BG3, BC4, BG10, BG9, BG4, BG5, BC6, BG9-Lac	140µL
	All test cartridges excluding BG8, BG3, BC4, BG10, BG9, BG4, BG5, BC6, BG9-Lac	80µL

5.1.4 Notes

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

1. When sampling from a catheter, CLSI recommends[1] to discard 6 times the dead space of the catheter before taking a blood sample.
2. Visually inspect the blood sample for air bubbles. Right after sampling and before mixing, tap the syringe to move any bubbles to the top of the sampler and expel.

[1] CLSI. Procedures for the collection of arterial blood specimens; Approved Standard – 4th edition. CLSI document H11-A4. Wayne, Pennsylvania, USA 2004.

Cover the sample device immediately after collection to prevent it from being contaminated by air.

3. Mix blood samples thoroughly prior to sample introduction. Small diameter collection devices, (1 mL syringes or capillary tubes) may be difficult to remix, so samples from these containers should be sampled as soon as possible.
4. Make sure there are no clots in blood samples, or else the results will be inaccurate.
5. Perform the sample test immediately after its collection to get the most accurate results. The sample should be kept at room temperature and tested within 30 minutes of collection. Blood collected for special studies, e.g., A-a O2 gradient, or “shunt” studies should be analyzed within five minutes of collection.
6. Used sample devices are biohazardous waste, and should be handled according to local regulatory guidelines.

5.2 Sample Test

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.

✓ The sample test in this user manual is described in accordance with Test Mode 1.

5.2.1 Procedures for Blood Sample 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 Login.

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

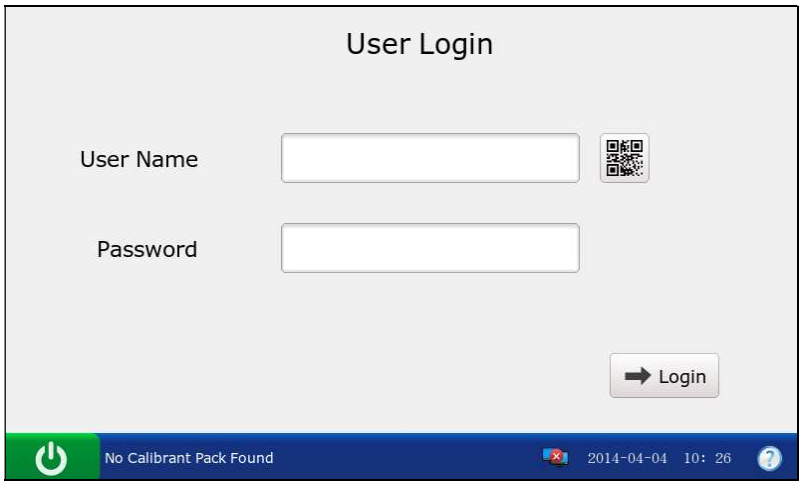


Figure 5-1 Enter User Name and Password

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

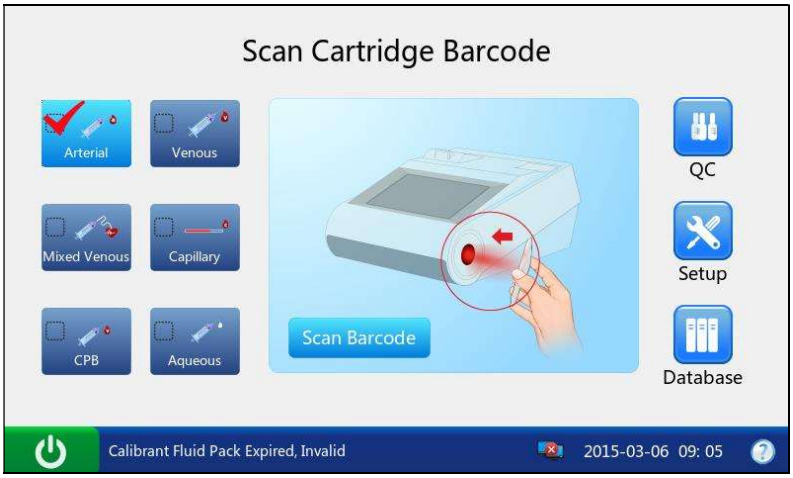


Figure 5-2 the Main Screen

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.

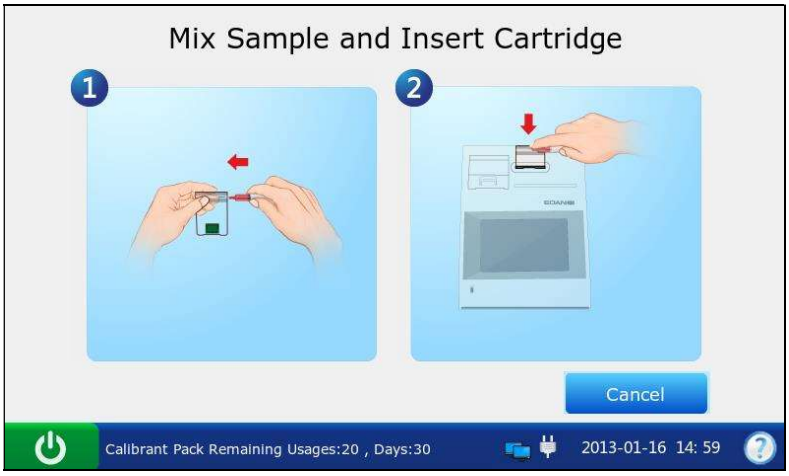


Figure 5-3 Mix Sample and Insert Cartridge

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. Make sure that the fillport is not blocked by the syringe's piston.
- ✓ 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 cannot 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.

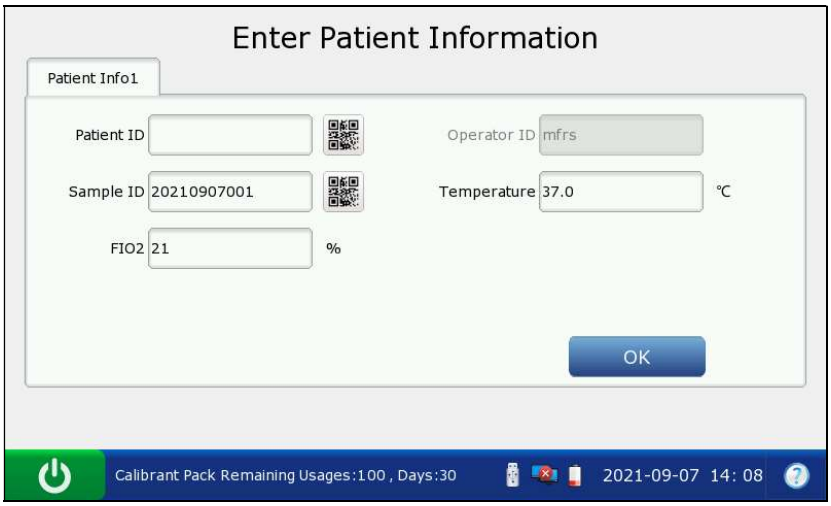


Figure 5-4 Enter Patient Data

NOTE:

- ✓ It is not necessary to enter all the above parameters. You can press **OK** at any time. The system will provide default values for temperature and FIO_2 as the

Figure 5-4 shows. The operator can change the default values in accordance with actual needs.

- ✓ 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 cannot 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:

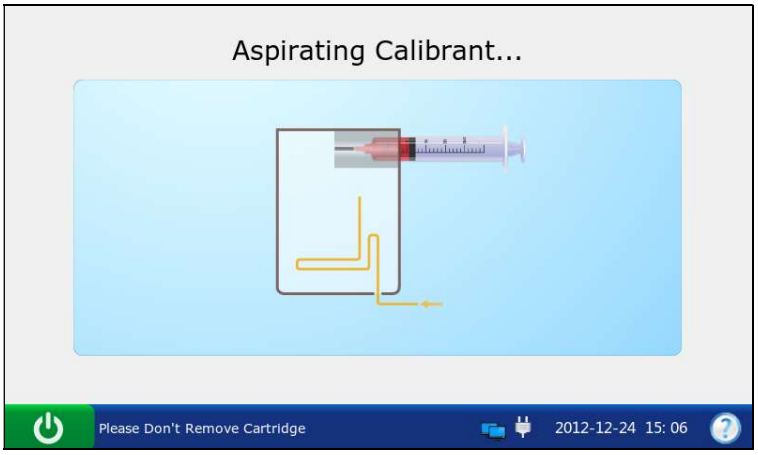


Figure 5-5 Aspirating Calibrant…

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

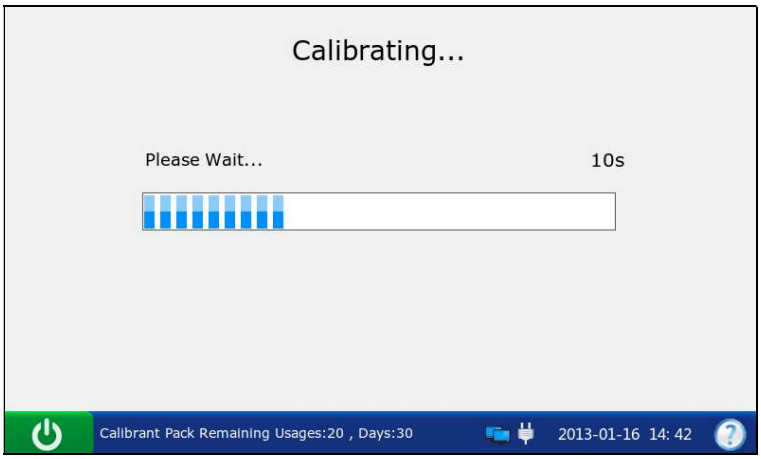


Figure 5-6 Calibration in Progress

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

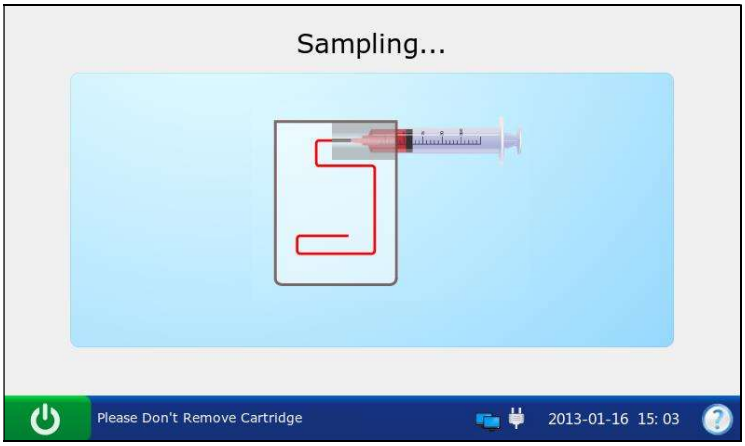


Figure 5-7 Sampling

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

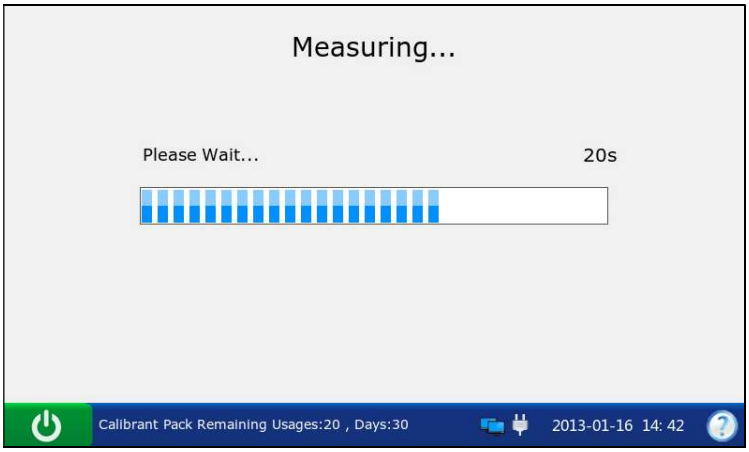


Figure 5-8 Measurement in Progress

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

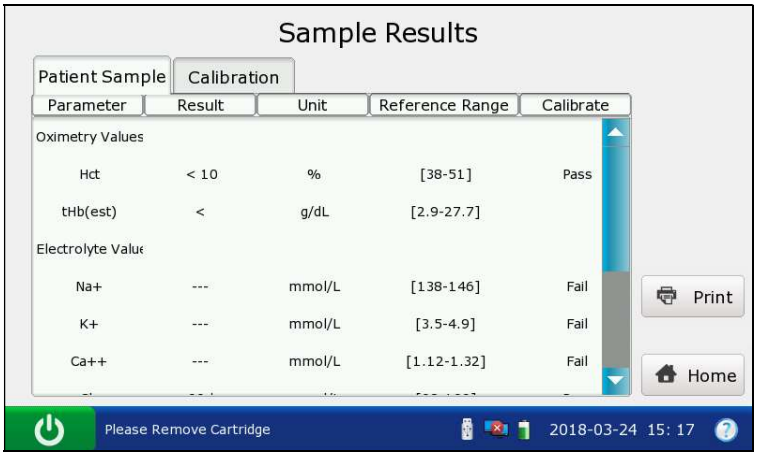


Figure 5-9 Sample Results

NOTE:

✓ If pH<7.2 or pH>7.6, the value of Ca^{++} (7.4) will not be displayed.

✓ 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 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 patient sample results by default.

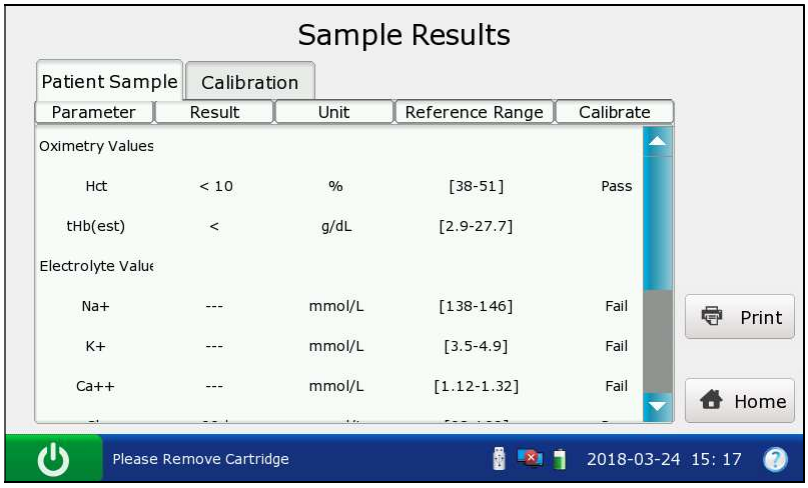


Figure 5-10 Calculated Parameters

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

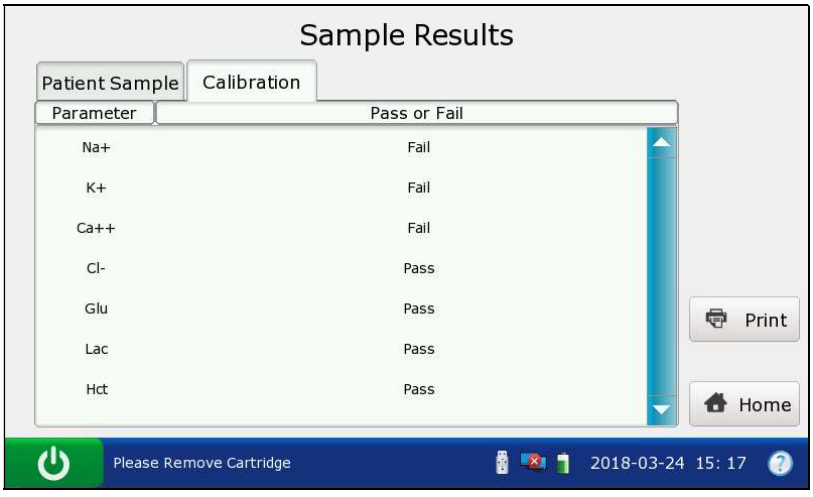


Figure 5-11 Calibration Parameters

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. After test is finished, the system will beep and prompt you to remove the test cartridge from the system immediately.
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:

System ID	M13704860027	
Report Type	Patient Sample	
Sample Type	Arterial	
Print Time	2016-01-21 17:26:36	
Test Time	2016-11-03 00:02:13	
Patient ID		
Cart. Lot		
Operator ID edan		
Patient Information		
Sample ID		
Temperature	37.00	℃
Gender		
tHb	30.00	g/dL
FIO_2	xxx	%
RQ	xxx	
Hb type		
Puncture site		
Bypass		
O_2 mode		
I/E Ratio		
Vent mode		
.....		
Blood Gas Values		
pH	>	8.000

pCO_2	<	10.0	mmHg
pO_2	145		mmHg
Oximetry Values			
Hct	15		%
sO_2(est),r	100	***	%
tHb(est),r	5.3		g/dL
Electrolyte Values			
Na^+	160	***	mmol/L
K^+	4.7	***	mmol/L
Ca^{++}	1.35	***	mmol/L
Ca^{++}(7.4),r	……		mmol/L
Cl^-	100	***	mmol/L
Acid-Base Status			
HCO_3-act,r	30.6	***	mmol/L
HCO_3-std,r	40	***	mmol/L
BE(ecf),r	18.5	***	mmol/L
BE(B),r	16.4	***	mmol/L
BB(B),r	60.3	***	mmol/L
$ctCO_2$,r	31	***	mmol/L
AnGap,r	34	***	mmol/L
cH^+,r	<	***	mmol/L
mOsm,r	315.4	***	mmol/L
pO_2/FIO_2,r	……		mmHg
RI,r	0.00	***	
pO_2(A-a),r	0	***	mmHg
pO_2(a/A),r	1.00	***	
Reference Ranges			
pH	7.35	7.45	
pCO_2	35	45	mmHg
pO_2	80	105	mmHg
Na^+	138	146	mmol/L
K^+	3.5	4.9	mmol/L
Ca^{++}	1.12	1.32	mmol/L
Cl^-	98	109	mmol/L
Glu	3.9	6.1	mmol/L
Lac	0.5	1.7	mmol/L
Hct	41	53	%

Notes	
,r	calculated values
*******	out control/unlock
.....	invalid values
>	>measured range
<	<measured range
Ca^{++}(7.4),r	unavailable

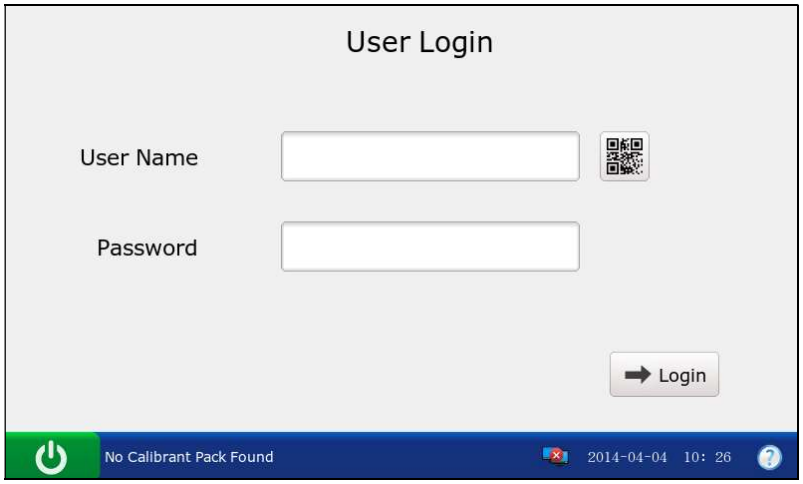
NOTE:

- ✓ If pH<7.2 or pH>7.6, the value of Ca^{++} (7.4) will not be displayed.
- ✓ The reference range provided in the example of a patient sample report is the arterial blood's reference range. In addition, the reference range of Hct is the male's reference range.
- ✓ The printed-out reference ranges are identical with the reference ranges set in Section 4.3.3. The default reference ranges in section 4.3.3 can be reset in accordance with the population being tested or the internal procedures at your individual institution. If the reference ranges in Section 4.3.3 are changed, the printed-out reference ranges in the patient sample report will change.

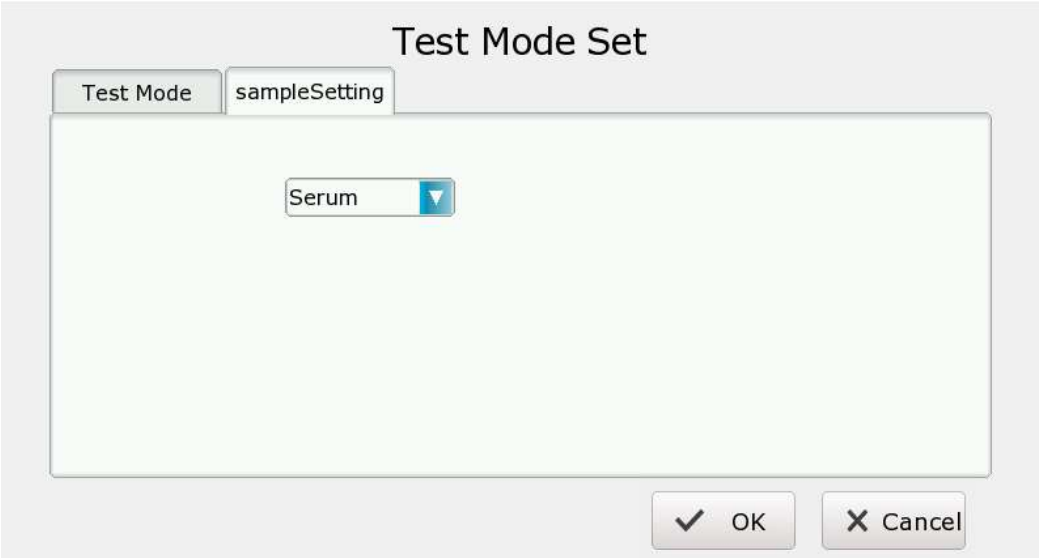
5.2.2 Procedures for Serum Sample Test

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 Login.

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



3. Press **Setup→Test Setup→Sample Setting** to enter into the sample setting screen, and select **Serum** in the screen, and then press **OK**.



4. Select Serum sample type on the Main screen. √ will appear if the button is selected.

Figure 5-2 the Main Screen

CAUTION

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

5. Press **Scan Barcode**, and scan the bar code on a new MicroSample-SC4 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.

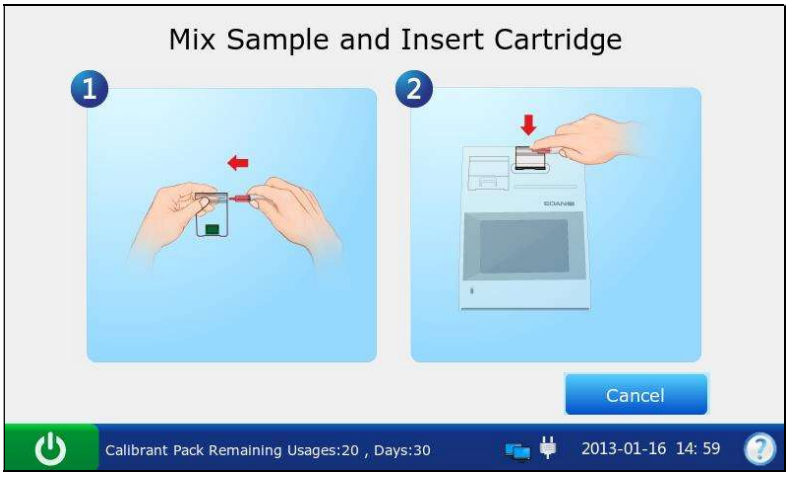
6. Open the foil pouch and remove the MicroSample-SC4 cartridge from it.

   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.

7. Roll the syringe or capillary tube between palms and gently invert it end over end for several times to mix the sample completely.



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

   NOTE:

   ✓ When using a syringe, make sure that the fillport is not blocked by the syringe's piston.

   ✓ When using a capillary tube, insert the capillary tube into the adaptor till the tube reaches the interface between the adaptor and the cartridge.

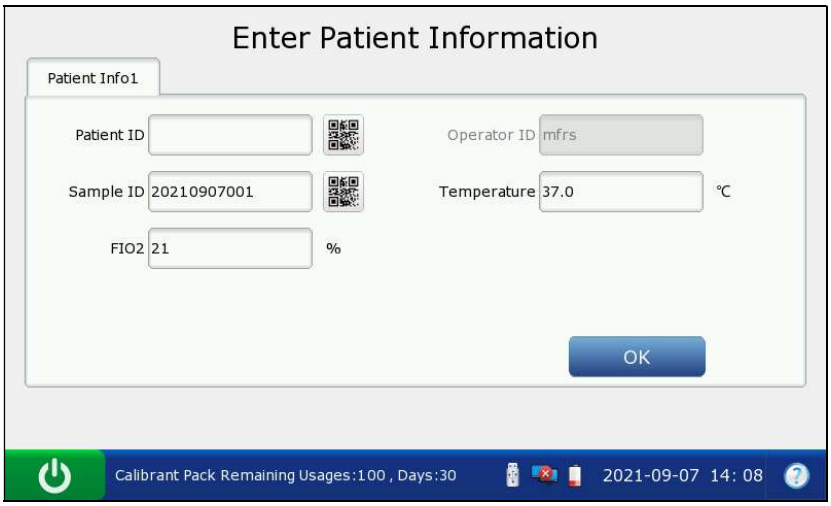
9. Gently insert the cartridge into the cartridge port, and carefully press down to ensure it clicks into place. For a valid cartridge, the indicator in the cartridge port will turn green, and the system will automatically aspirate calibrant. For an invalid cartridge, the indicator will turn red, the 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 cannot be removed from the analyzer until the measurement is complete.

10. Enter patient information. The screen displayed depends on the selection in section 4.3.2 Patient Information Setup.

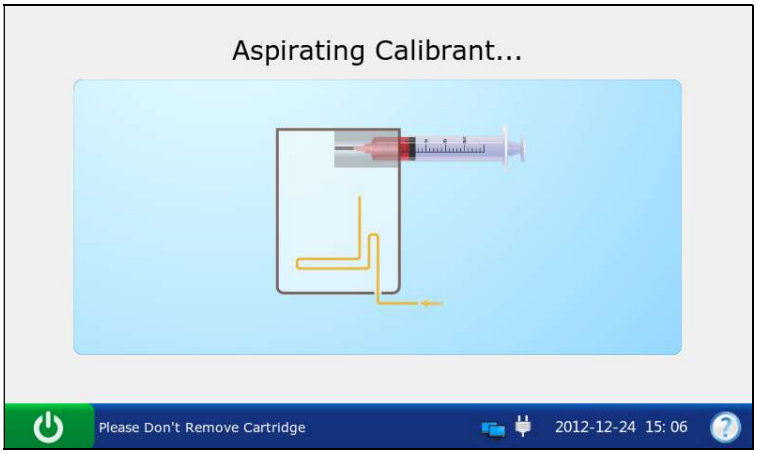


NOTE:

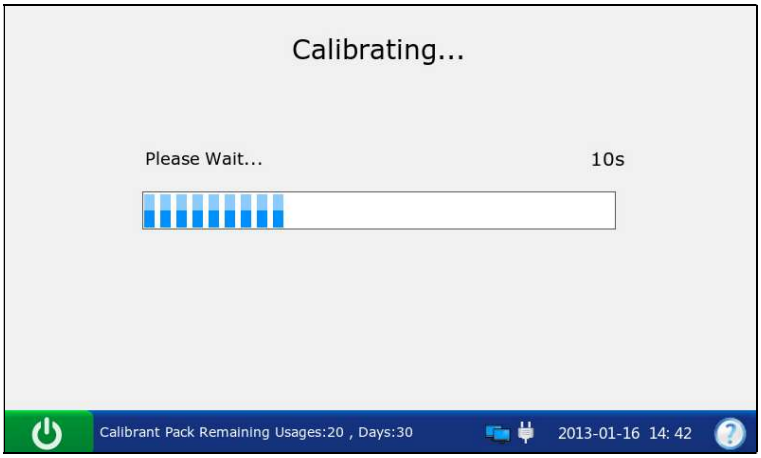
- ✓ It is not necessary to enter all the above parameters. You can press **OK** at any time. The system will provide default values for temperature and FIO_2 as the Figure 5-4 shows. The operator can change the default values in accordance with actual needs.
- ✓ If no parameters are selected in section 4.3.2 Patient Information Setup, the system will go to the Aspirating Calibrant screen when the test cartridge is properly inserted.
- ✓ The system cannot 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.

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

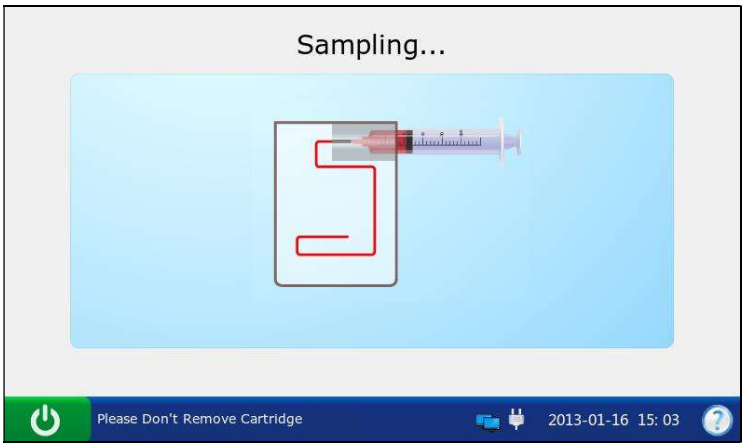
If the system is aspirating calibrant, the system will go to the following screen:



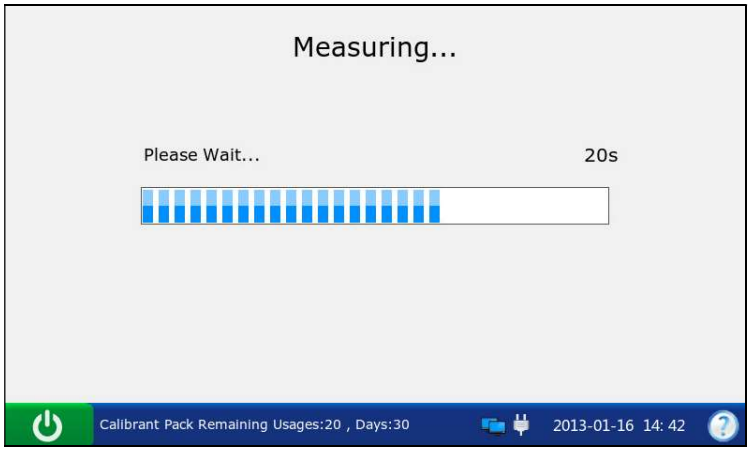
If the system is calibrating sensors, the system will go to the screen below:



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



If the system is analyzing serum samples, the system will go to the screen below:



f). If the test is complete, the system will display test 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 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.

12. After test is finished, the system will beep and prompt you to remove the test cartridge from the system immediately.
13. Press **Home** to return to the Main screen.

5.2.3 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 for the measured parameter is above the upper limit of detection or below the lower limit of detection.
↑ 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 10,000 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 Software (DMS) or HIS/LIS through Wi-Fi 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:

1) Only patient information data can be edited.
2) 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.

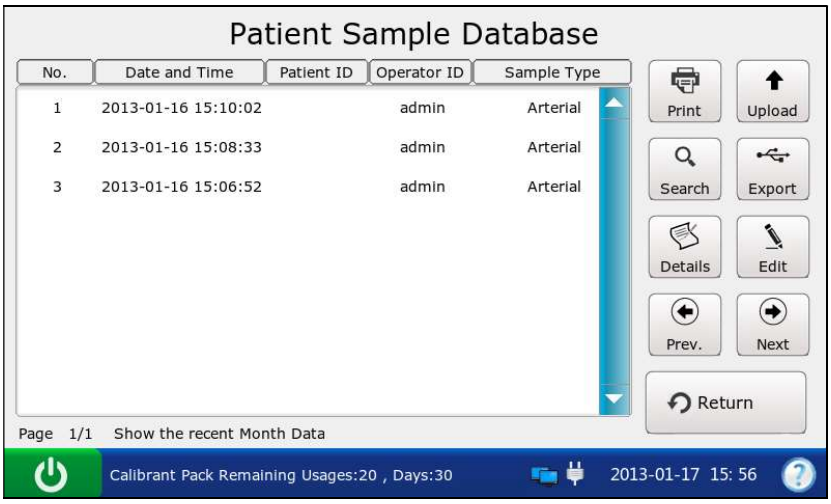


Figure 5-12 Patient Sample Database Screen

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**.

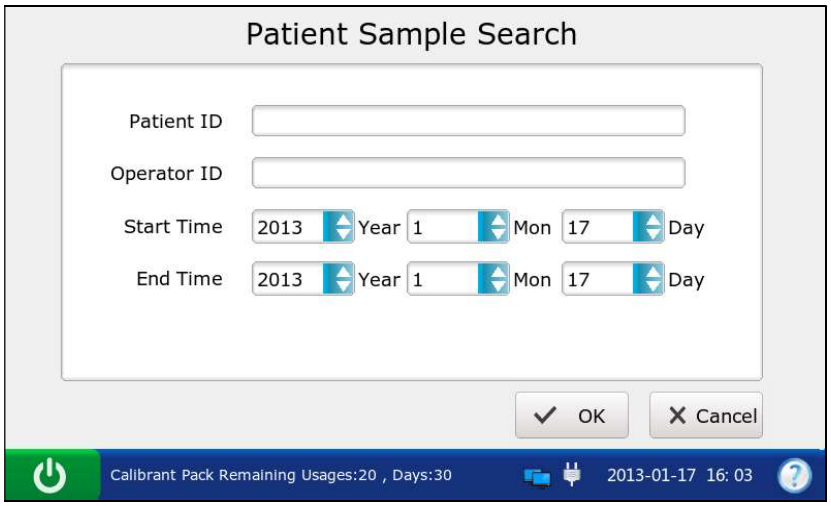


Figure 5-13 Enter Search Conditions

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

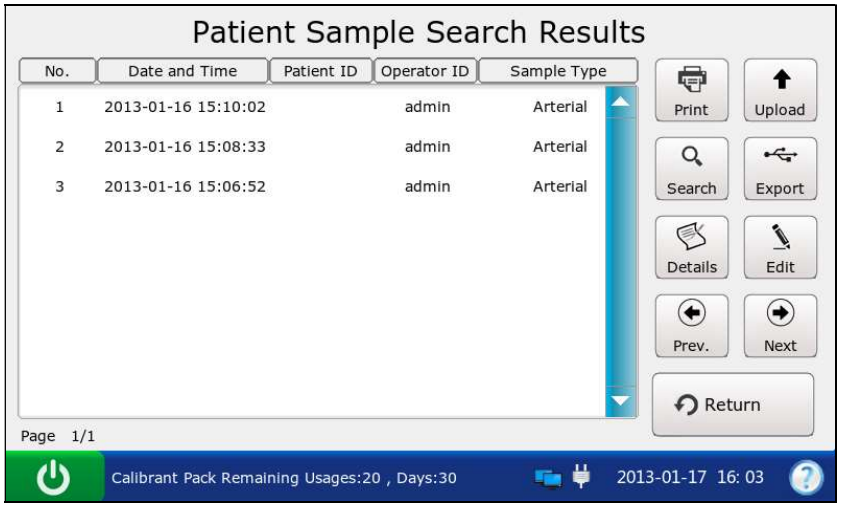


Figure 5-14 Search Results

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 patient sample by default.

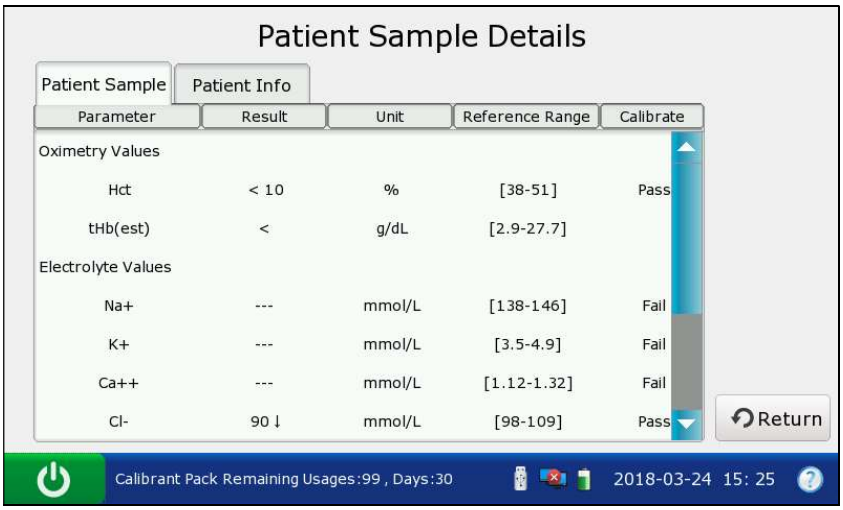


Figure 5-15 Details of Measured Parameters

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

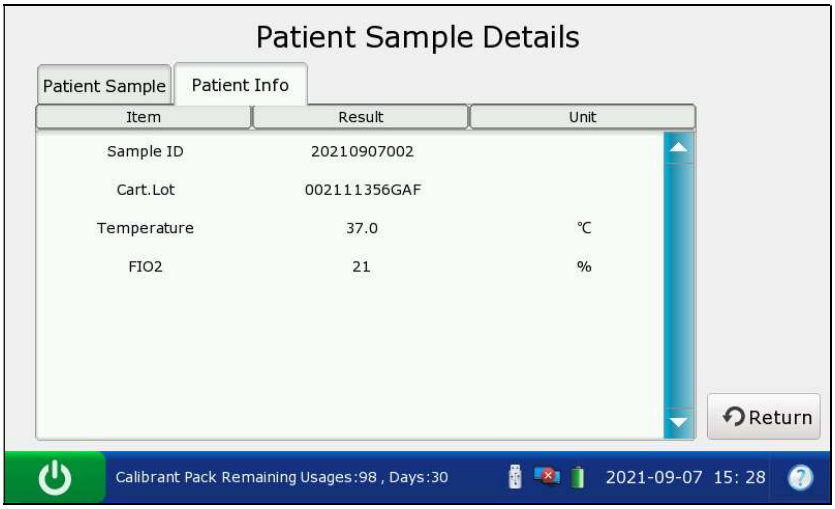


Figure 5-16 Details of Patient Information

4. 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:

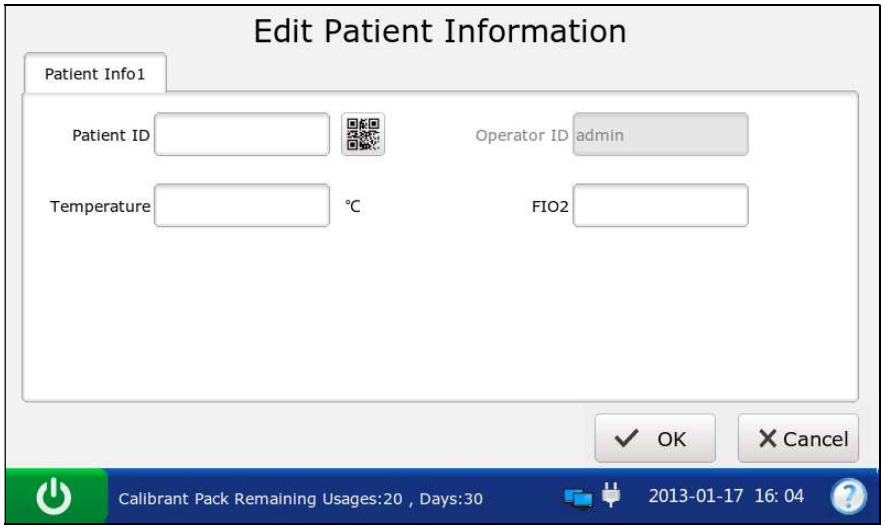


Figure 5-17 Edit Patient Data

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 **Print**, the following window will pop out to prompt users whether all data need to be printed.

If the analyzer does not connect the network before pressing **Upload** to upload the selected data, the following window will pop out to prompt users that the network is failed to connect.

If no patient sample data is selected before pressing **Upload**, the following window will pop out to prompt users whether all data need to be uploaded.

If no removable disk is inserted into the analyzer before pressing **Export**, the following window will pop out to prompt users that no USB disk is identified.

If no patient sample data is selected before pressing **Export**, all data stored in the patient sample database will be exported.

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.
- ✓ To verify the performance of newly received test cartridges.
- ✓ To verify the storage condition of test cartridges.
- ✓ 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 EDAN Blood Gas and Electrolyte Controls and EDAN Hematocrit Controls. RNA Medical® QC823 Blood Gas●Electrolyte●Metabolite●BUN Controls and RNA Medical® QC900 Hematocrit Controls can also be used on the i15/i15A Blood Gas and Chemistry Analysis System. The concentrations of reactive ingredients in various levels of controls are known. Controls contain no human or biological materials. Acceptable ranges for controls specific to the i15/i15A Blood Gas and Chemistry Analysis System are programmed in the bar code on the labels for controls provided by EDAN.

Packaging

1. EDAN Blood Gas and Electrolyte Controls are contained in 2.5mL glass ampoules, and EDAN Hematocrit Controls are contained in 1.5mL sealed bottles.
2. The controls package contains information such as the control name, level, lot number and expiration date, etc.

Storage

Store controls according to the controls user manual.

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 at least 4 hours. If not, the ampoule needs to stand at room temperature for 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:

1) Store and use controls according to the user manual, and use them before the expiration date as labeled on the package.
2) Only controls provided by EDAN or its authorized distributors should be used.
3) Avoid contaminating controls.
4) The test results should fall within the acceptable ranges programmed in the bar code on the controls' Target Table 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 at least 4 hours. If not, the ampoule needs to stand at room temperature for 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.

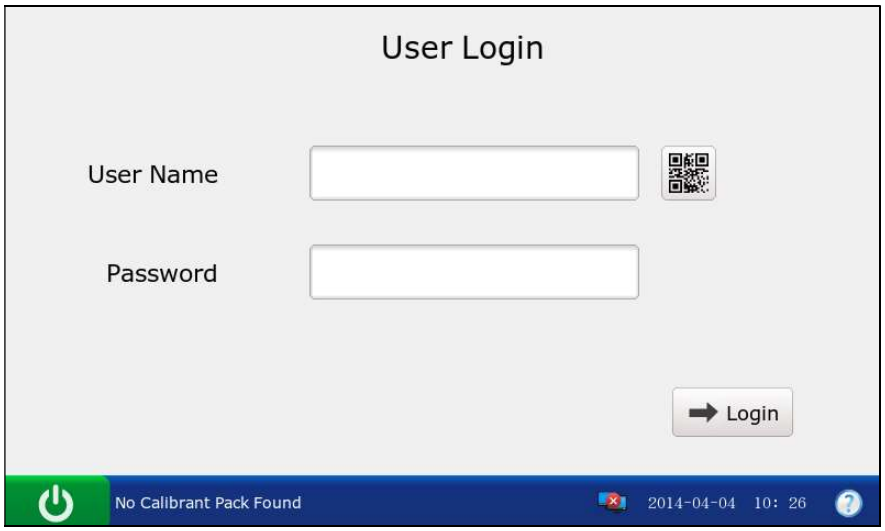


Figure 6-2 Enter User Name and Password

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 blood chemistries.

   Press  to perform a control test for Hct.
7. Scan the bar code on a new cartridge foil pouch.

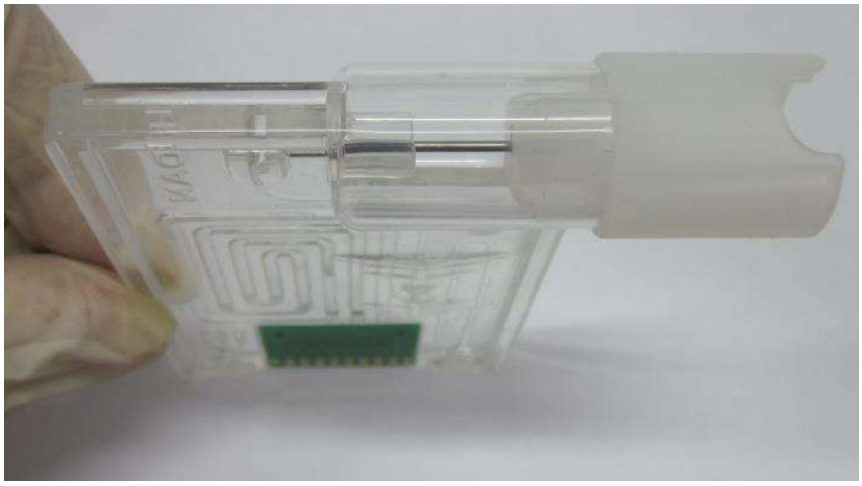
   If the bar code is scanned successfully, the system will beep and the scanner will be automatically turned off. If the scanned data is valid, the system will display the screen for the next procedure. If the scanned data is invalid, a message will pop up to prompt you.

Figure 6-3 Scan Bar Code

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

NOTE:

- ✓ The built-in barcode is activated automatically after Step 6. Therefore, the operator has no need to press **Scan Barcode**.
- ✓ 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. Scan the bar code on the controls' label.

   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. The built-in barcode is activated automatically after Step 7. Therefore, the operator

has no need to press **Scan Barcode**. Hold the ampoule at the top and bottom (with forefinger and thumb) and shake for 10 seconds to mix the solution. Tap the ampoule to restore the liquid to the bottom.

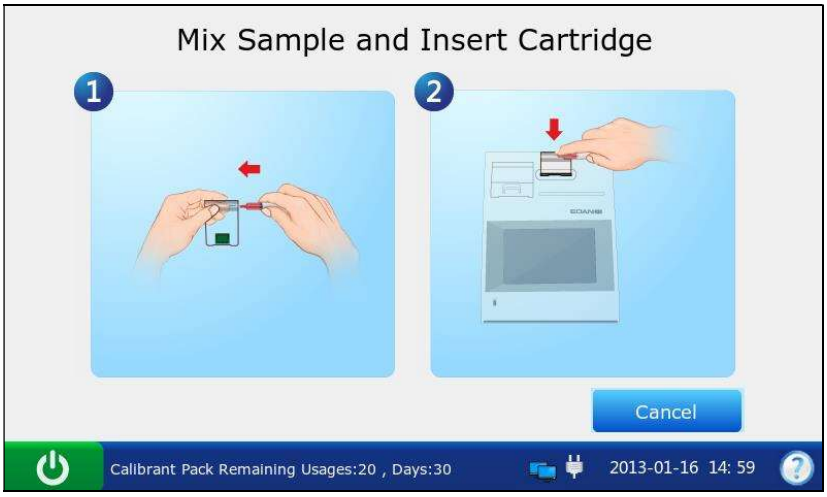


Figure 6-5 Mix Controls and Insert Cartridge

NOTE:

- ✓ Avoid heating the ampoule with your hands when shaking the ampoule. Use gauze, tissue, gloves or other protective means to protect fingers from cuts.

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 cannot 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.

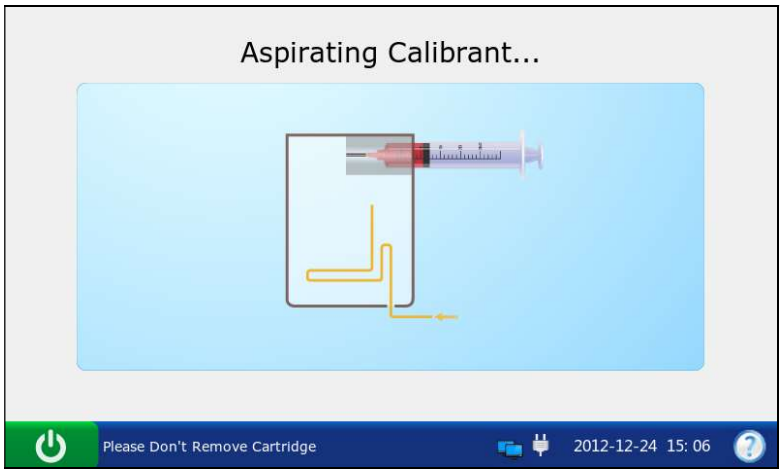


Figure 6-6 Aspirating Calibrant…

15. The system automatically performs calibration.

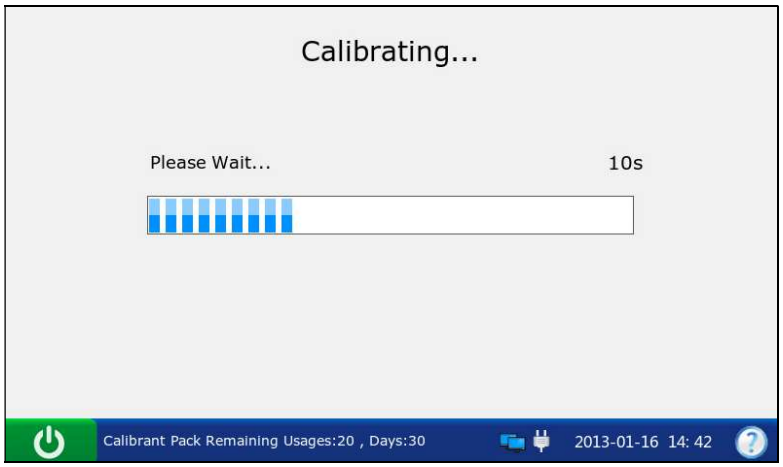


Figure 6-7 Calibration in Progress

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

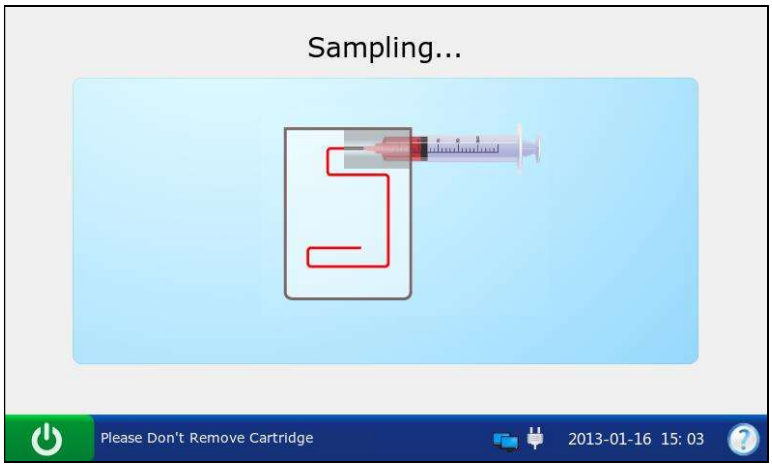


Figure 6-8 Sampling…

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

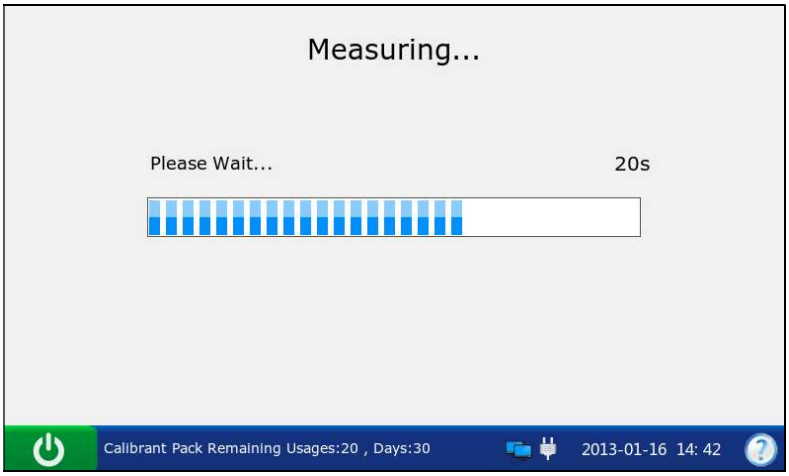


Figure 6-9 Measurement in Progress

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

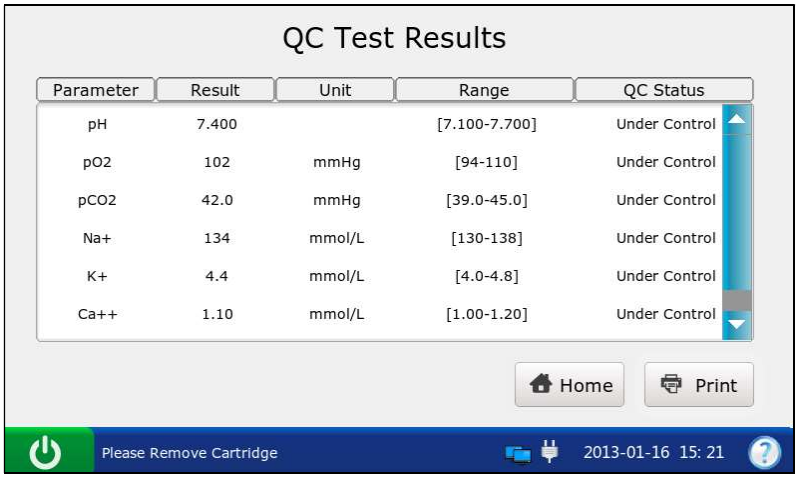


Figure 6-10 Control Test Results

19. View the results.

NOTE:

✓ The system will indicate whether the results are within or outside the acceptable

ranges with **In Control/Out of Control**.

- ✓ If a parameter fails calibration, the system will not be able to determine whether it is in 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. 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.
  - 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.

20. After test is finished, the system will beep and prompt you to remove the test cartridge from the system immediately.
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.

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 Software (DMS) or HIS/LIS through Wi-Fi 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.

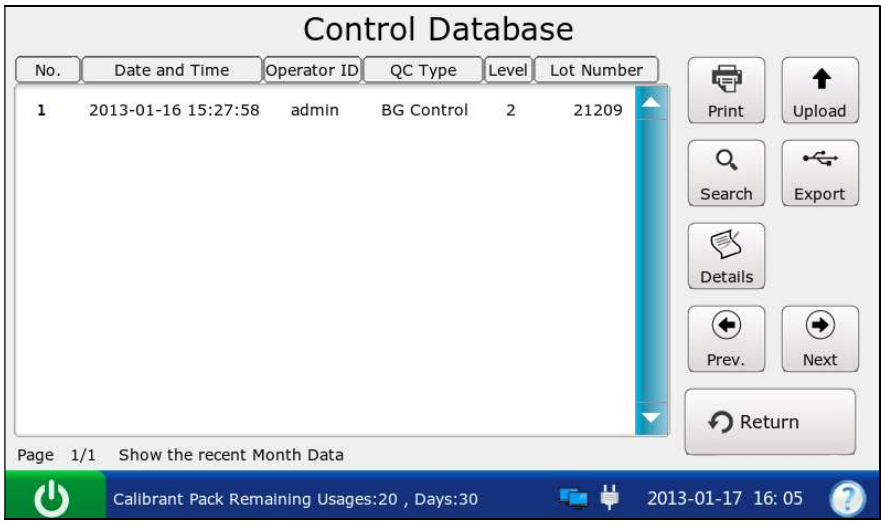


Figure 6-11 Control Database Screen

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**.

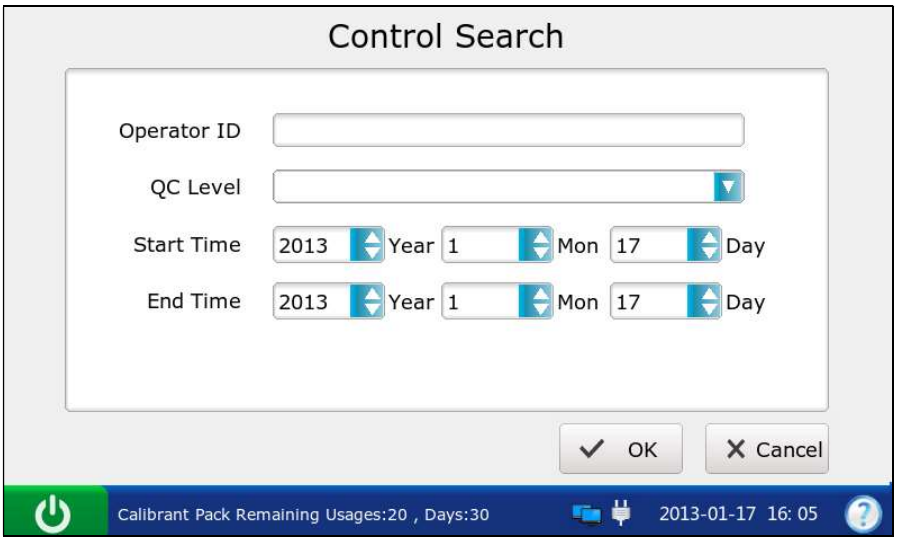


Figure 6-12 Enter Search Conditions

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

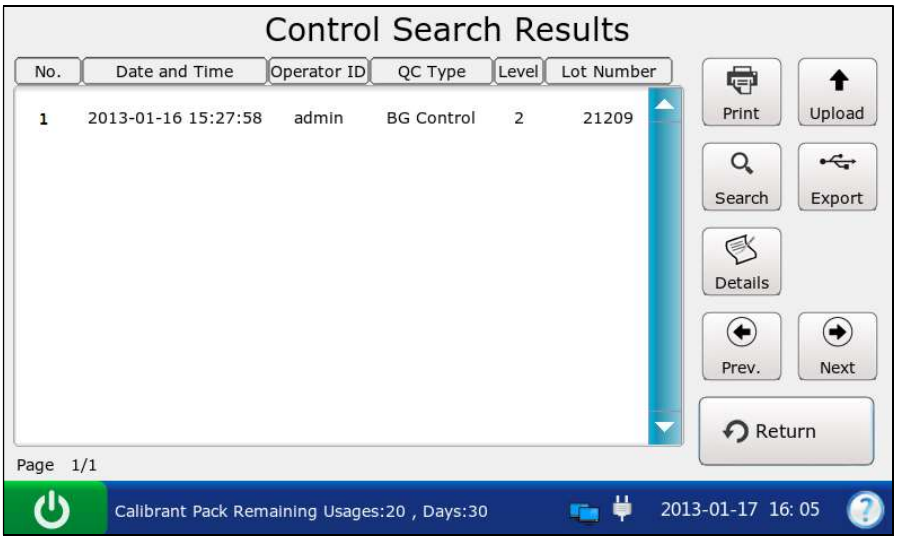


Figure 6-13 Search Results

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

6.1.3.2 Viewing Details of Control Test Data

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

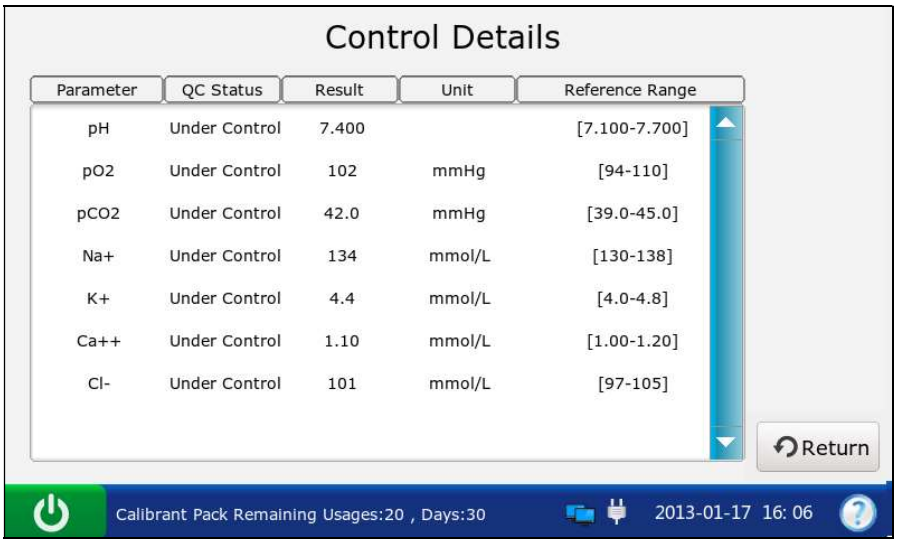


Figure 6-14 Details of Control Test Results

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 data is selected before pressing **Print**, the following window will pop out to prompt users whether all data need to be printed.

If the analyzer does not connect the network before pressing **Upload** to upload the selected data, the following window will pop out to prompt users that the network is failed to connect.

If no control data is selected before pressing **Upload**, the following window will pop out to prompt users whether all data need to be uploaded.

If no removable disk is inserted into the analyzer before pressing **Export**, the following window will pop out to prompt users that no USB disk is identified.

If no control data is selected before pressing **Export**, all data stored in the control database will be exported.

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.

In the i15/i15A System, Proficiency Samples can be optionally run under the Proficiency Test menu in order to allow identification, storage and retrieval of their results independently from other sample types. There is no difference in sample handling or measurement by the i15/i15A System between Patient, Quality Control, Proficiency or Calibration Verification tests.

In preparation for Proficiency Testing, please read and follow the instructions provided by the proficiency materials provider.

6.2.1 Procedures for Proficiency Test

NOTE:

All proficiency testing results must be handled and reported in the same manner as clinical results following the directions provided by the provider in the package insert. The samples are not to be analyzed in duplicate unless clinical specimens are analyzed in duplicate. Actions or decisions must be documented.

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 at least 4 hours. If not, the ampoule needs to stand at room temperature for 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 Login.

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

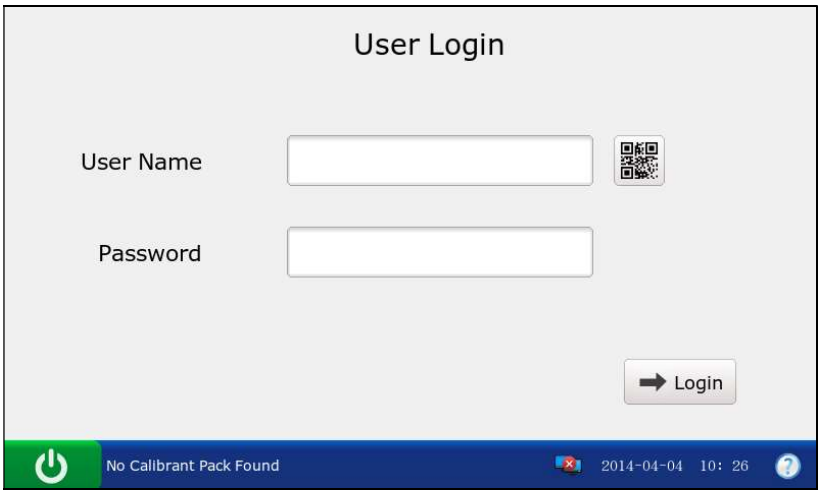


Figure 6-15 Enter User Name and Password

5. On the Main screen, press  to go to the Quality Control screen, and then press  .
6. 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.

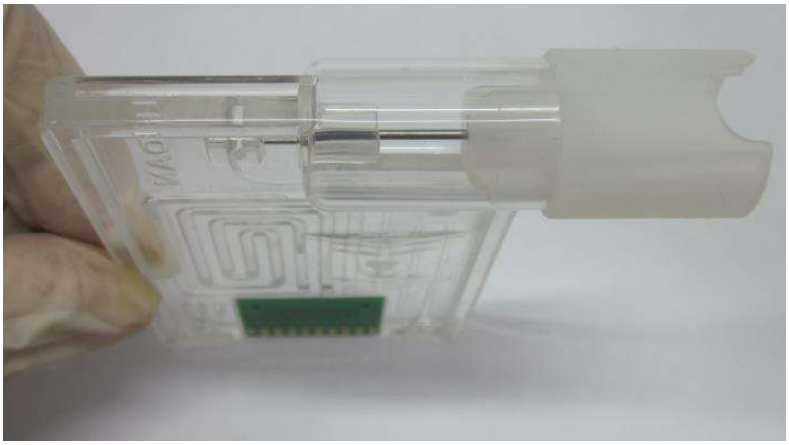
   NOTE:

   ✓ The built-in barcode is activated automatically after Step 5. Therefore, the operator has no need to press **Scan Barcode**.

   ✓ 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:



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

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

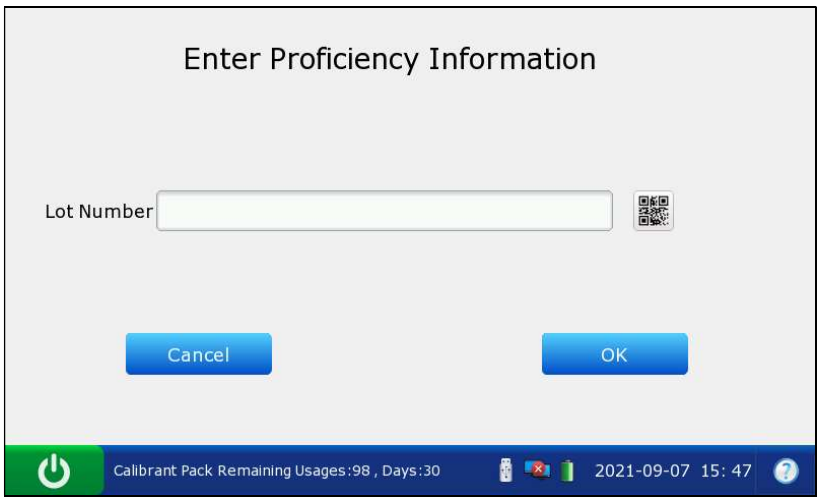


Figure 6-17 Enter Information

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

9. 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.

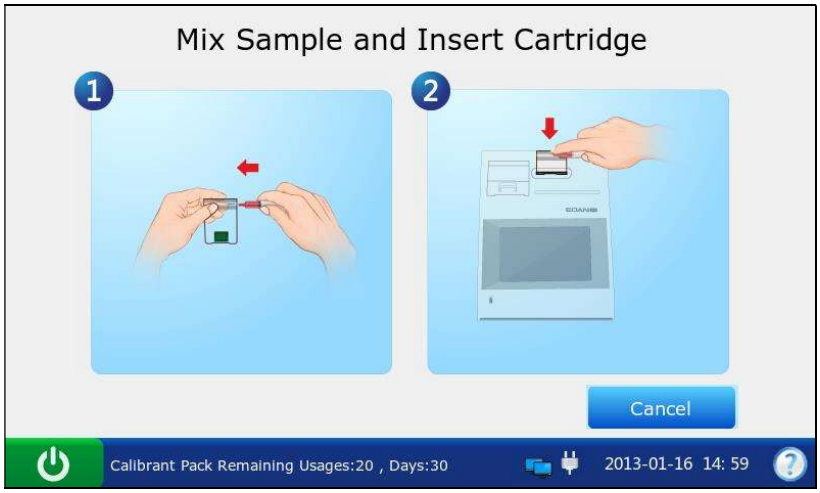


Figure 6-18 Mix Proficiency Sample and Insert Cartridge

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 cannot 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.

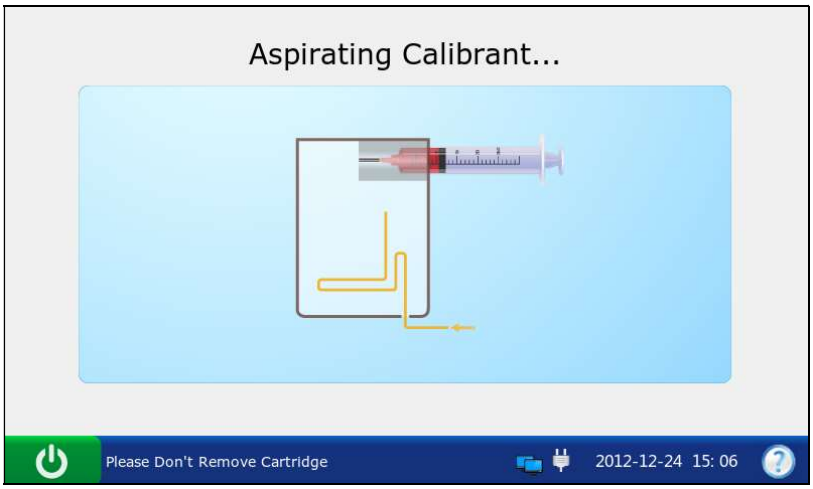


Figure 6-19 Aspirating Calibrant…

14. The system automatically performs calibration.

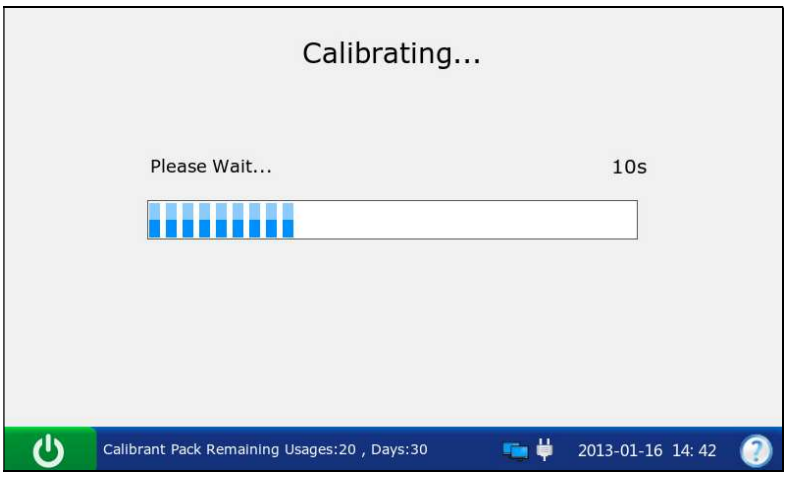


Figure 6-20 Calibration in Progress

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

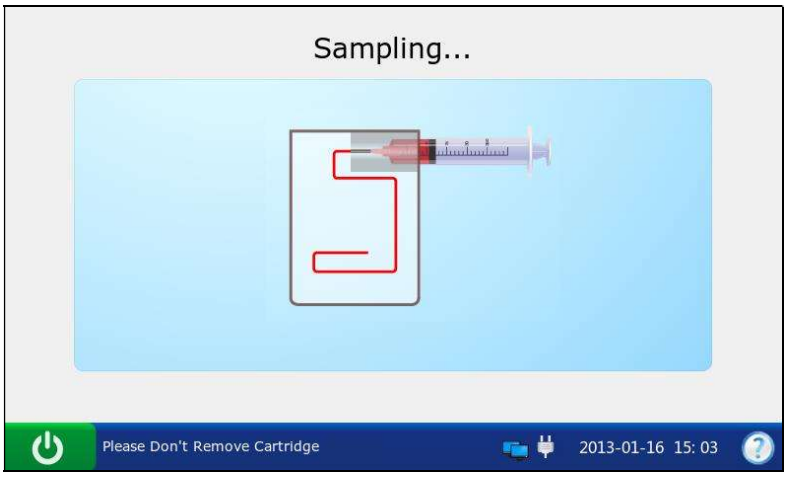


Figure 6-21 Sampling…

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

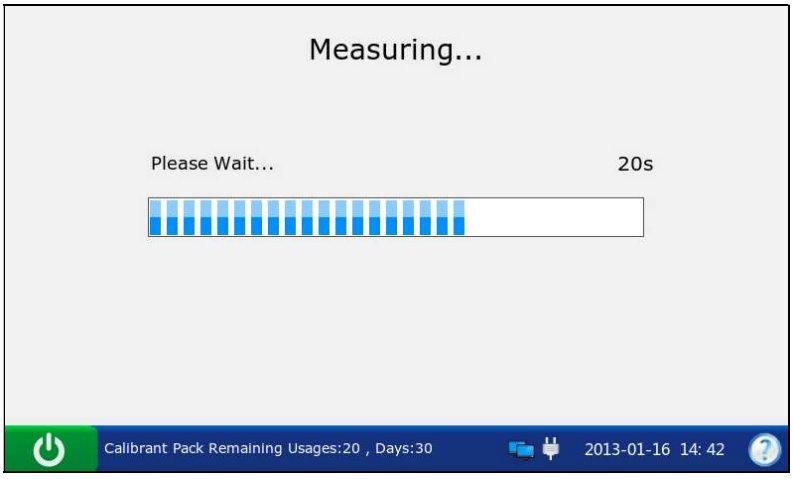


Figure 6-22 Measurement in Progress

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

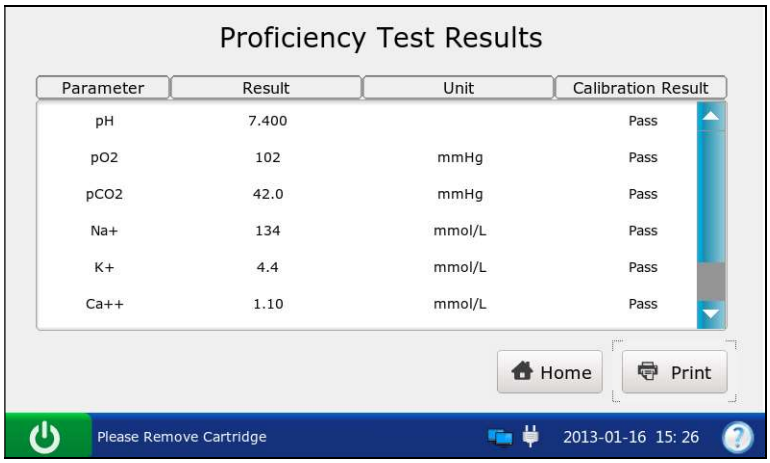


Figure 6-23 Proficiency Test Results

18. View the results.
19. After test is finished, the system will beep and prompt you to remove the test cartridge from the system immediately.
20. Press **Print** to print the results.
21. Press **Home** to return to the Main screen.

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 Software (DMS) or HIS/LIS through Wi-Fi 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.

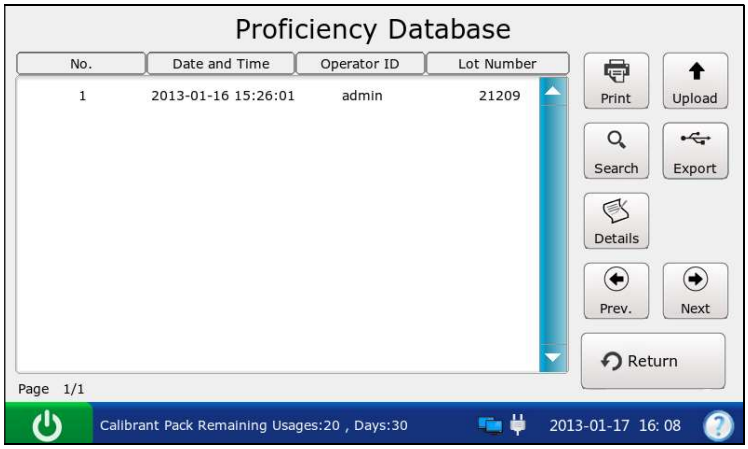


Figure 6-24 Proficiency Database Screen

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**.

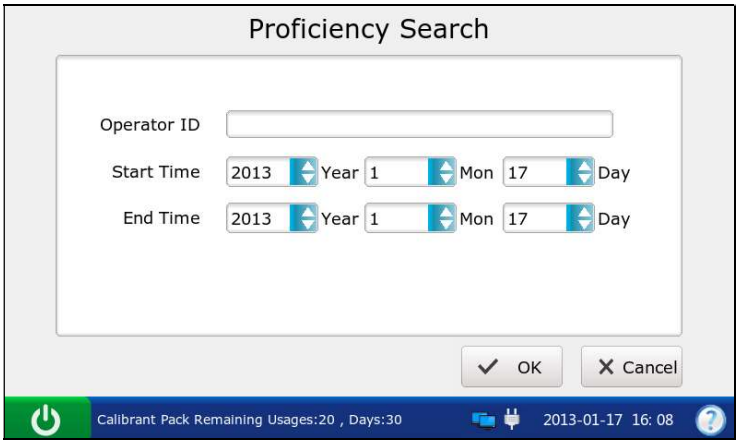


Figure 6-25 Enter Search Conditions

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

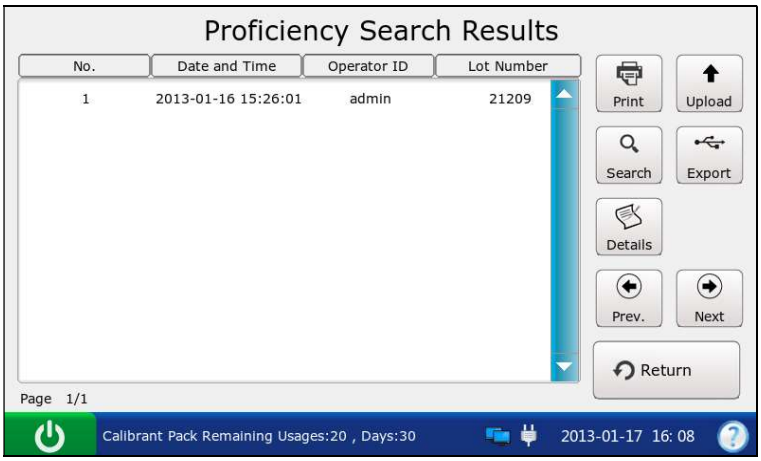


Figure 6-26 Search Results

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:

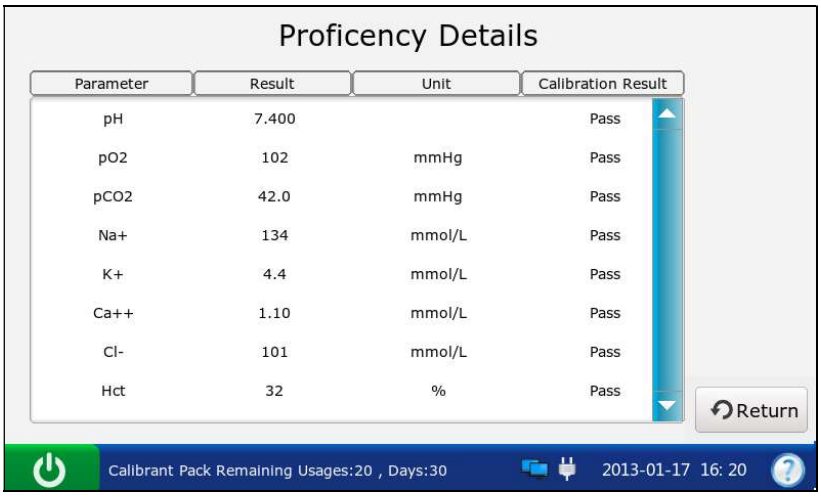


Figure 6-27 Details of Proficiency Test Results

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 **Print**, the following window will pop out to prompt users whether all data need to be printed.

If the analyzer does not connect the network before pressing **Upload** to upload the selected data, the following window will pop out to prompt users that the network is failed to connect.

If no proficiency test data is selected before pressing **Upload**, the following window will pop out to prompt users whether all data need to be uploaded.

If no removable disk is inserted into the analyzer before pressing **Export**, the following window will pop out to prompt users that no USB disk is identified.

If no proficiency test data is selected before pressing **Export**, all data stored in the proficiency database will be exported.

6.3 Calibration Verification Test

Calibration verification tests are intended to verify the accuracy of results over the entire measurement range of a test.

6.3.1 Calibration Verification Controls

Calibration verification controls are intended for use to confirm the lineary of the i15/i15A Blood Gas and Chemistry Analysis System. Calibration verification controls used are RNA Medical® CVC123 Calibration Verification Controls and RNA Medical® CVC9005 Hematocrit Calibration Verification Controls. The concentrations of reactive ingredients in various levels of calibration verification controls are known. Calibration verification controls do not contain human or biological materials. Acceptable ranges for calibration verification controls specific to the i15/i15A Blood Gas and Chemistry Analysis System are programmed in the bar code on the user manual for calibration verification controls provided by EDAN.

Packaging

1. RNA Medical® CVC123 Calibration Verification Controls are contained in 2.5mL glass ampoules, and RNA Medical® CVC9005 Hematocrit Calibration Verification Controls are contained in 1.7mL glass ampoules.
2. The calibration verification controls package contains information such as the calibration verification control name, level, lot number and expiration date, etc.

Storage

Store calibration verification controls according to the calibration verification controls user manual.

Before Use

Calibration verification controls should be equilibrated to room temperature before use. If oxygen is to be measured, the ampoule needs to stand at room temperature for at least 4 hours. If not, the ampoule needs to stand at room temperature for 30 minutes.

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

NOTE:

1) Store and use calibration verification controls according to the user manual, and use them before the expiration date as labeled on the package.
2) Only calibration verification controls provided by EDAN or its authorized distributors should be used.
3) Avoid contaminating calibration verification controls.
4) The test results should fall within the acceptable ranges programmed in the bar code on the user manual for calibration verification controls provided by EDAN.

6.3.2 Procedures for Calibration Verification Test

Follow the steps below to perform a calibration verification test:

1. Examine the package label of calibration verification controls to ensure they have not

expired.

2. Remove an ampoule from the box of calibration verification controls and equilibrate it to room temperature.
   If oxygen is to be measured, the ampoule needs to stand at room temperature for at least 4 hours. If not, the ampoule needs to stand at room temperature for 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 Login.

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

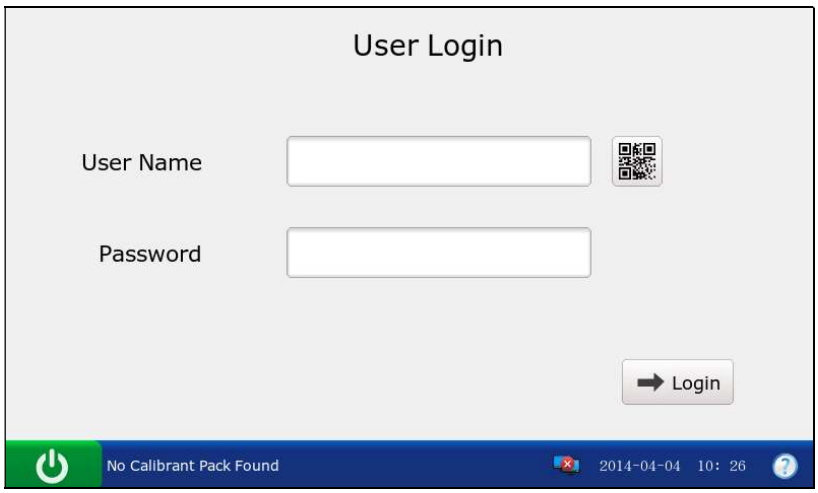


Figure 6-28 Enter User Name and Password

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

   Press to perform a calibration verification test for blood gases and blood chemistries.

   Press to perform a calibration verification test for Hct.
7. 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 6-29 Scan Bar Code

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

   NOTE:

   ✓ The built-in barcode is activated automatically after Step 6. Therefore, the operator has no need to press **Scan Barcode**.

   ✓ 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 calibration verification 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 6-30 Scan Bar Code

NOTE:

✓ Keep the calibration verification controls user manual for a future calibration verification test use.

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

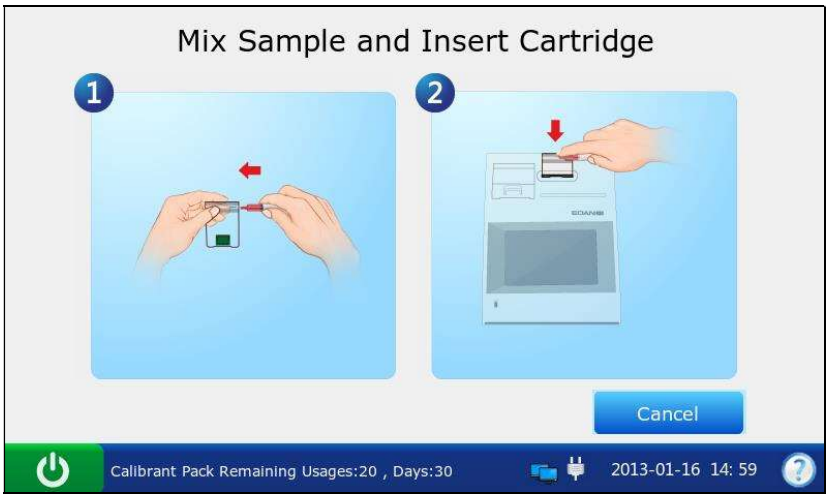


Figure 6-31 Mix Calibration Verification Controls and Insert Cartridge

NOTE:

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

11. Open the ampoule by snapping off the top and immediately transfer calibration verification 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 calibration verification 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 cannot 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.

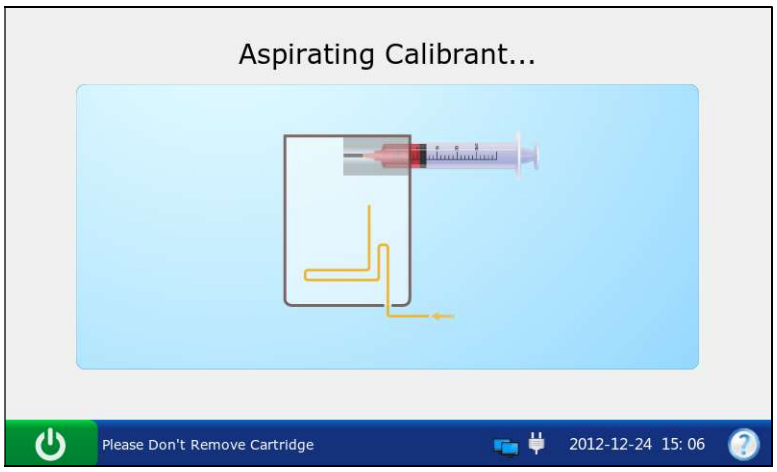


Figure 6-32 Aspirating Calibrant…

15. The system automatically performs calibration.

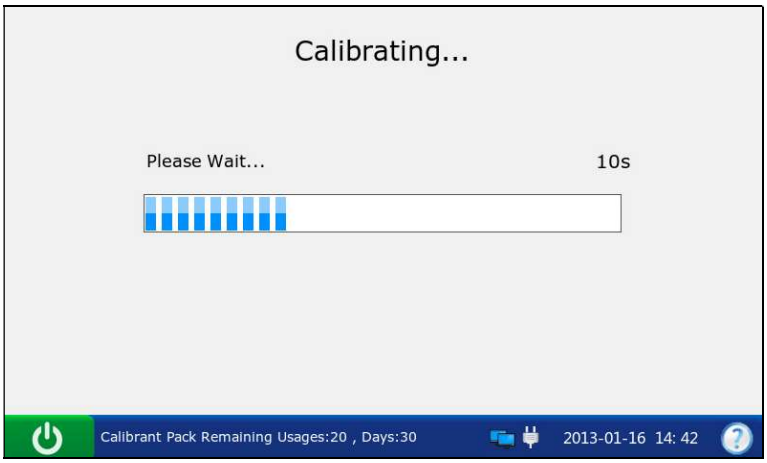


Figure 6-33 Calibration in Progress

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

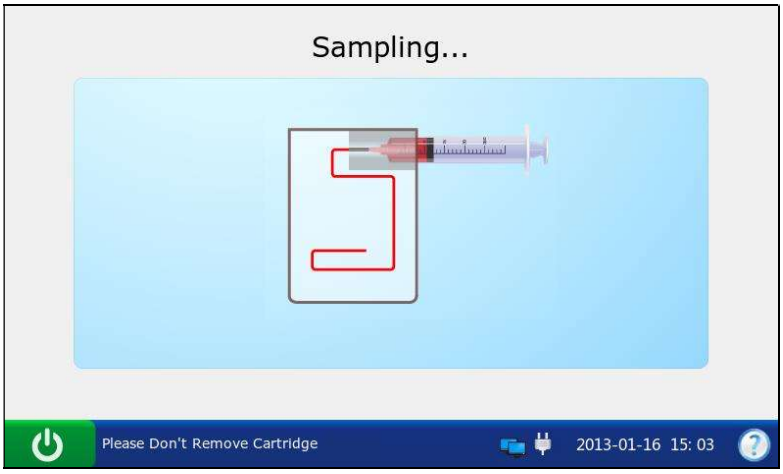


Figure 6-34 Sampling…

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

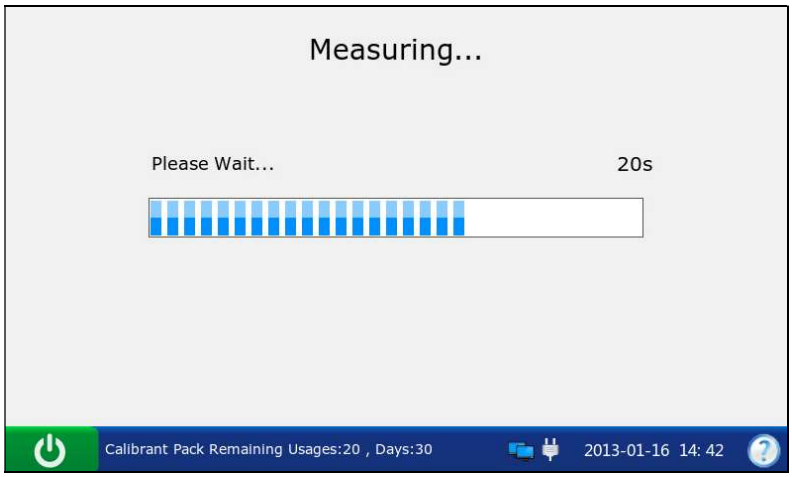


Figure 6-35 Measurement in Progress

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

NOTE:

- ✓ The system will indicate whether the results are within or outside the acceptable ranges with **In Control/Out of Control**.
- ✓ If a parameter fails calibration, the system will not be able to determine whether it is in control, and will display **Calibration Failure** to prompt you.
- ✓ The system will not report the result for a parameter failing the calibration verification test in the patient sample analysis, if QC Lockout function is enabled in Setup. To report the result for the parameter, repeat the calibration verification test till the parameter passes it.
- ✓ If the results are outside the acceptable ranges, check the following items first, and then perform another 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.
  - Refer to the user manual to confirm that the test procedures are correct.
  - Test cartridges and calibration verification controls are stored properly and have not expired.
  - The system passes the electronic simulator test.

20. After test is finished, the system will beep and prompt you to remove the test cartridge from the system immediately.
21. Press **Print** to print the results.
22. Press **Home** to return to the Main screen.

The contents of a calibration verification test report depend on the type of calibration verification 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.

6.3.3 Calibration Verification Database

The calibration verification database displays calibration verification 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 calibration verification database: transmitting calibration verification test data to the Data Management Software (DMS) or HIS/LIS through Wi-Fi or the network, exporting calibration verification test data to a removable disk (such as a USB

drive), viewing the details of calibration verification test data, searching for and printing calibration verification test data, etc.

On the Database screen, press  to get to the Calibration Verification Database screen.

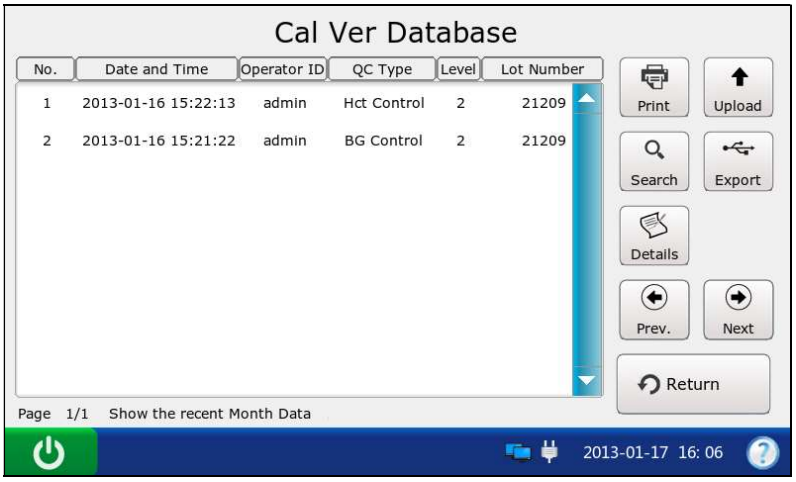


Figure 6-36 Calibration Verification Database Screen

6.3.3.1 Searching for Calibration Verification Test Data

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

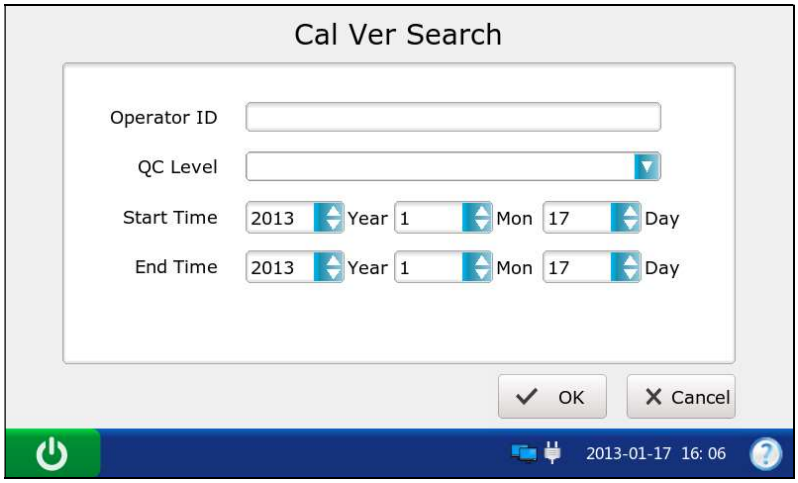


Figure 6-37 Enter Search Conditions

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

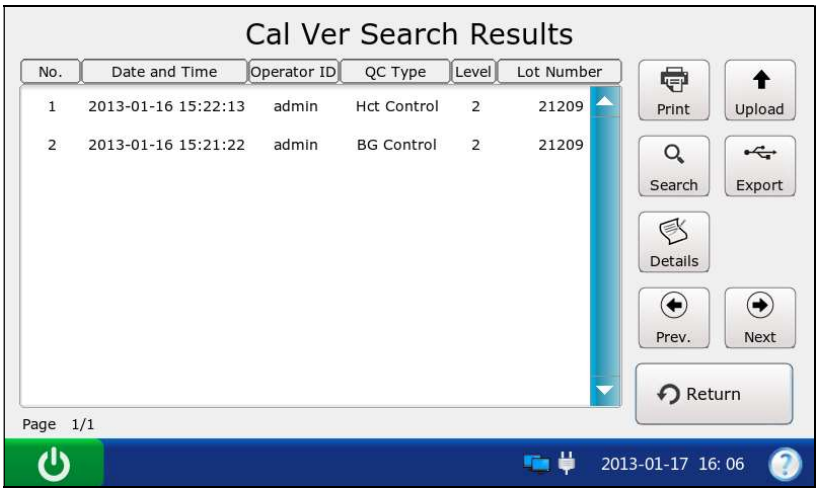


Figure 6-38 Search Results

4. Press **Return** to go back to the Calibration Verification Database screen.

6.3.3.2 Viewing Details of Calibration Verification Test Data

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

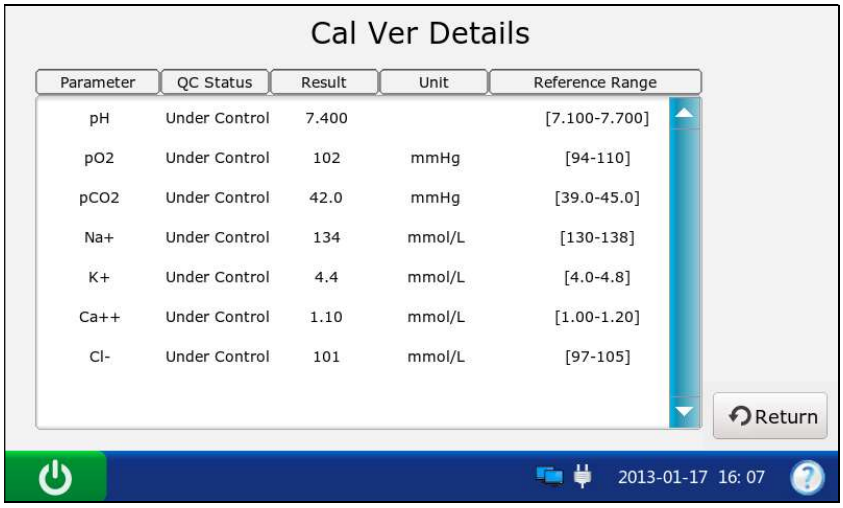


Figure 6-39 Details of Calibration Verification Test Results

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

6.3.3.3 Exporting/Uploading/Printing Calibration Verification Test Data

1. Open the calibration verification database.
2. Select the desired calibration verification 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 calibration verification data is selected before pressing **Print**, the following window will pop out to prompt users whether all data need to be printed.

If the analyzer does not connect the network before pressing **Upload** to upload the selected data, the following window will pop out to prompt users that the network is failed to connect.

If no calibration verification data is selected before pressing **Upload**, the following window will pop out to prompt users whether all data need to be uploaded.

If no removable disk is inserted into the analyzer before pressing **Export**, the following window will pop out to prompt users that no USB disk is identified.

If no calibration verification data is selected before pressing **Export**, all data stored in the calibration verification database will be exported.

6.4 Simulator Test

6.4.1 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 Login.

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

Figure 6-40 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 6-41 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.

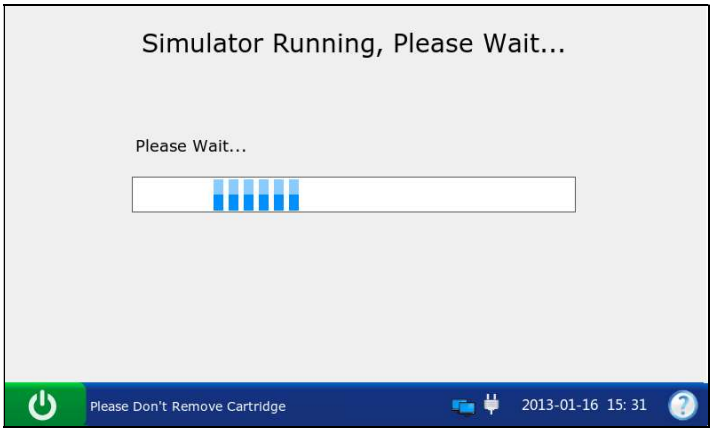


Figure 6-42 Measurement in Progress

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

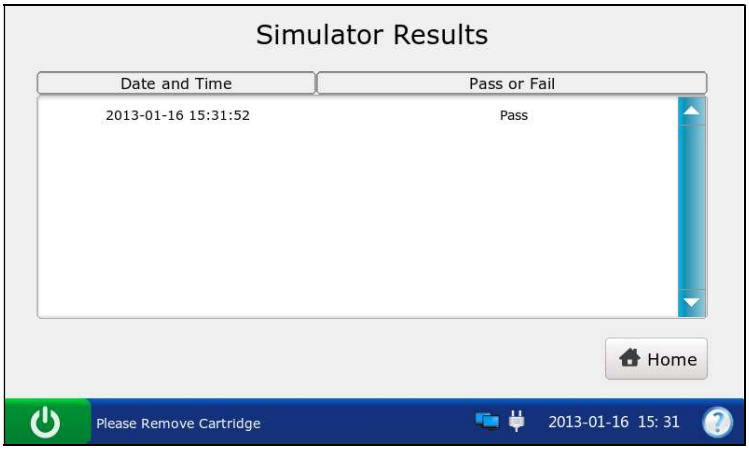


Figure 6-43 External Simulator Test Result

7. 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.

8. Press **Home** to go to the Main screen.
9. Remove the external simulator from the system, and put it back.

   NOTE:

   ✓ Never remove the external simulator until the test is complete.

6.4.2 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 Software (DMS) or HIS/LIS through Wi-Fi 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.

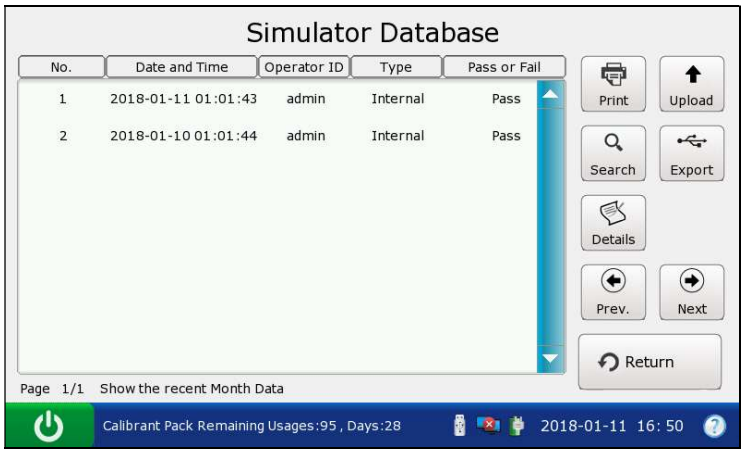


Figure 6-44 Simulator Database Screen

6.4.2.1 Searching for Simulator Test Data

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

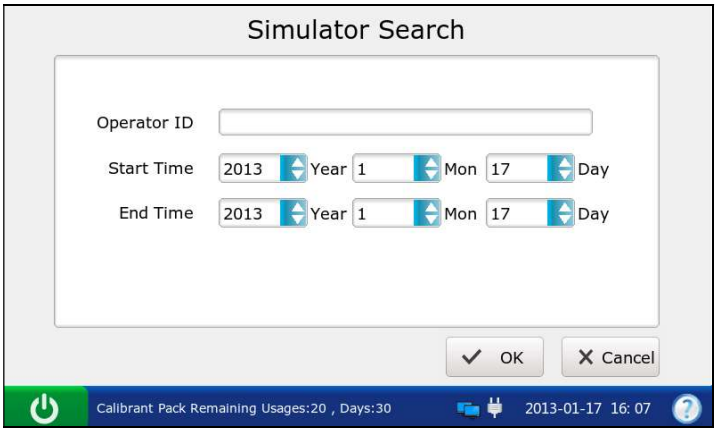


Figure 6-45 Enter Search Conditions

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

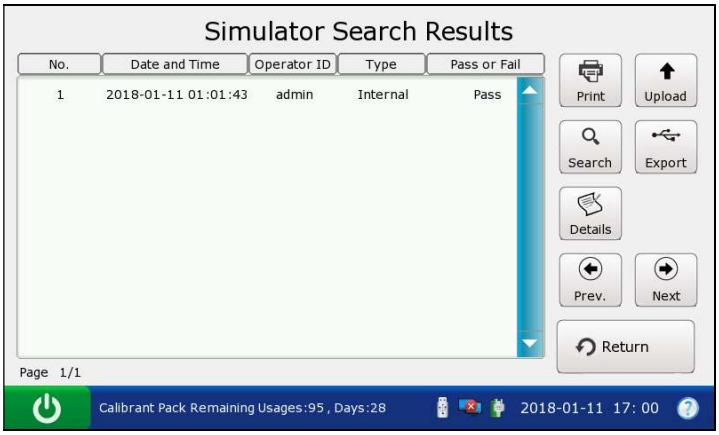
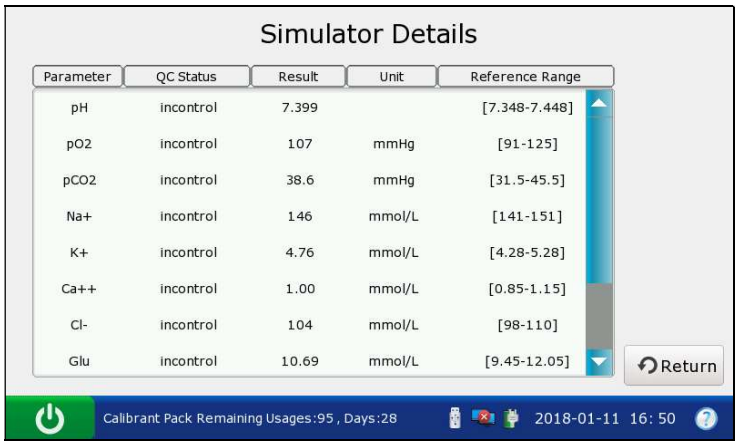


Figure 6-46 Search Results

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

6.4.2.2 Viewing Details of Simulator Test Data

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



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

6.4.2.3 Exporting/Uploading/Printing Simulator Test Data

1. Open the simulator test database.
2. 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 **Print**, the following window will pop out to prompt users whether all data need to be printed.

If the analyzer does not connect the network before pressing **Upload** to upload the selected data, the following window will pop out to prompt users that the network is failed to connect.

If no simulator test data is selected before pressing **Upload**, the following window will pop out to prompt users whether all data need to be uploaded.

If no removable disk is inserted into the analyzer before pressing **Export**, the following window will pop out to prompt users that no USB disk is identified.

If no simulator test data is selected before pressing **Export**, all data stored in the simulator database will be exported.

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 or HIS/LIS.

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.

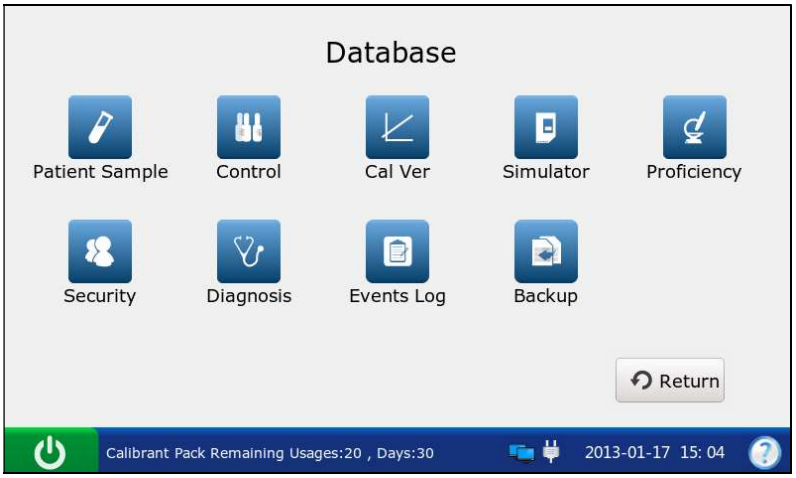


Figure 7-1 Database Screen

7.2 Databases

The following databases have been described in the previous chapters: Patient Sample Database, Control Database, Proficiency Database, Calibration Verification 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.

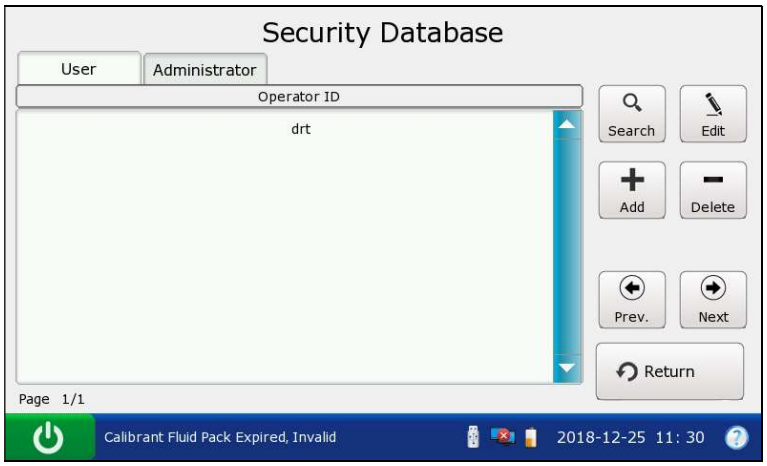


Figure 7-2 Security Database Screen

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:

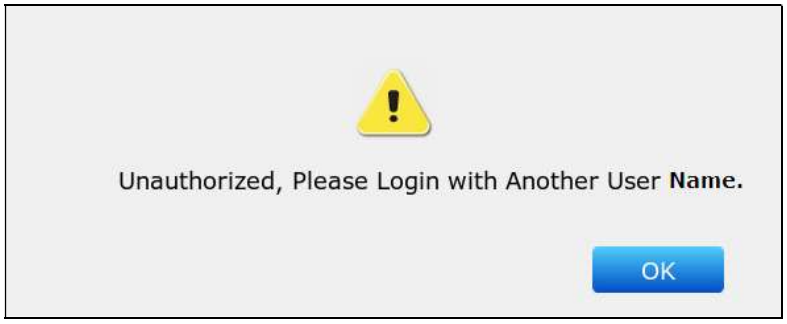


Figure 7-3 No Access Rights

7.2.1.1 Searching for an Operator

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

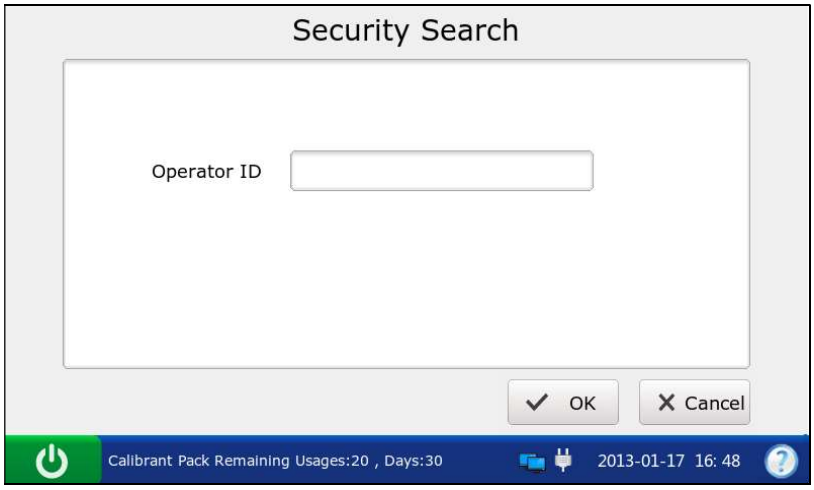


Figure 7-4 Enter Search Conditions

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

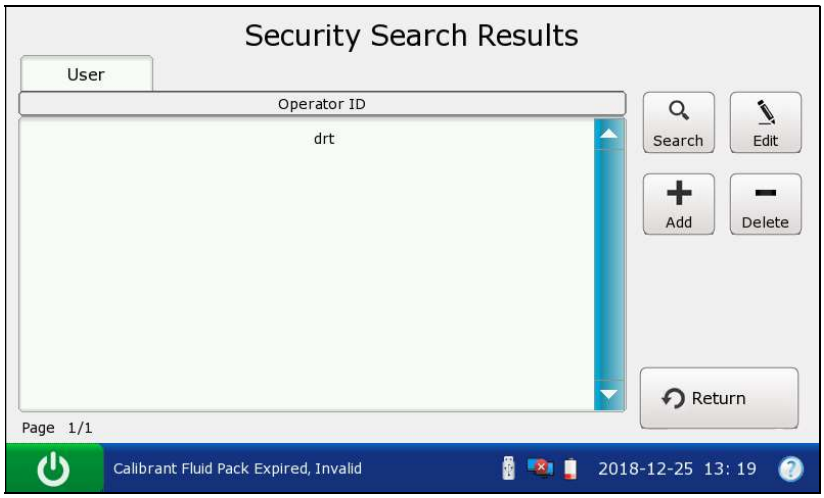


Figure 7-5 Search Results

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.

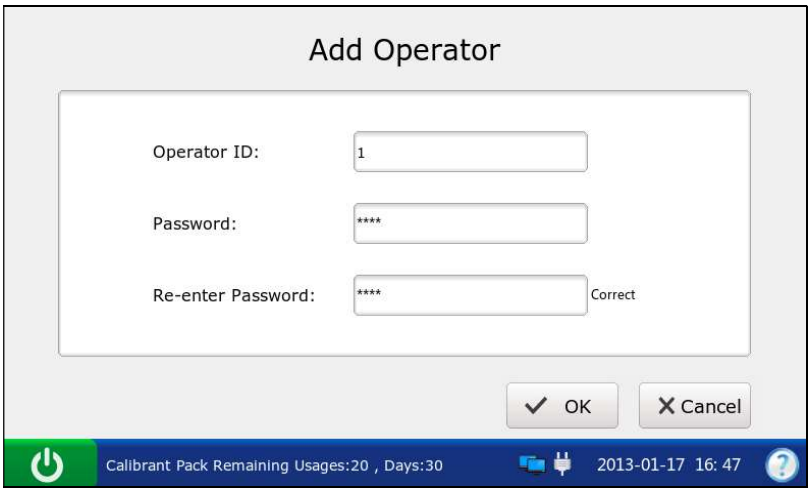


Figure 7-6 Add Operator

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. If this rule is violated, the system will prompt users by popping out a message “Operator ID Format Error”. If the newly-added operator ID contracts with the existing Operator ID, the system will prompt users by popping out a message “This ID Already Exists.”.
- ✓ The password is case sensitive, and should be 4 - 16 characters long (including both letters and numbers). If this rule is violated, the system will prompt users by popping out a message “Password Format Error”.

7.2.1.3 Changing Operator Password

1. Select the operator data you want to edit.
2. Press **Edit**.
3. Enter current password, then enter new password and re-enter the new 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).
- ✓ If the entered password is wrong, the system will pop out a message that “Password Format Error” to prompt users.

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.

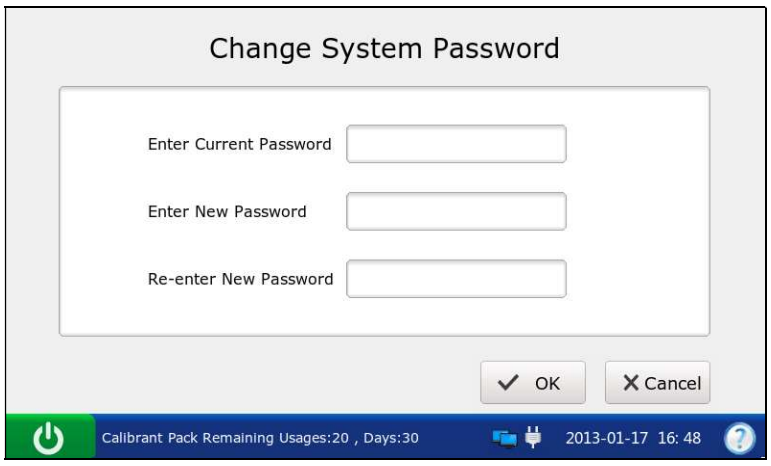


Figure 7-7 Change System Password

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 cannot change it, although they can reset 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. If the operator who doesn't log in with the service account, the

system will pop out the following window when pressing  (**Diagnostics**).

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.

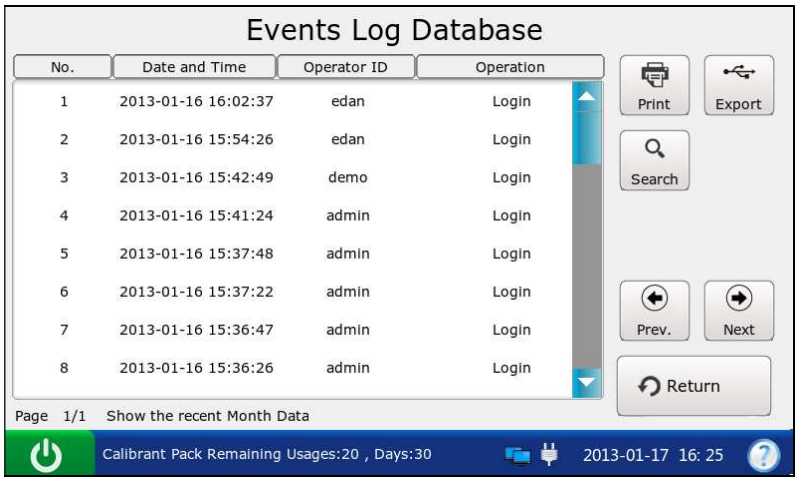


Figure 7-8 Events Log Database Screen

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**.

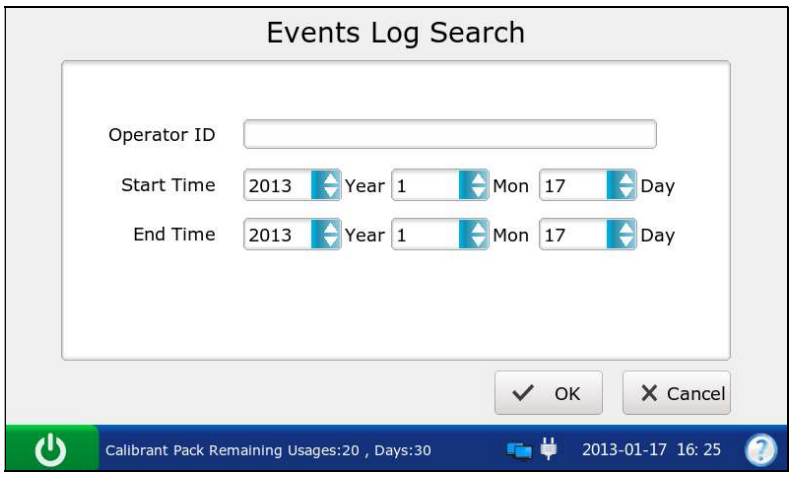


Figure 7-9 Enter Search Conditions

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

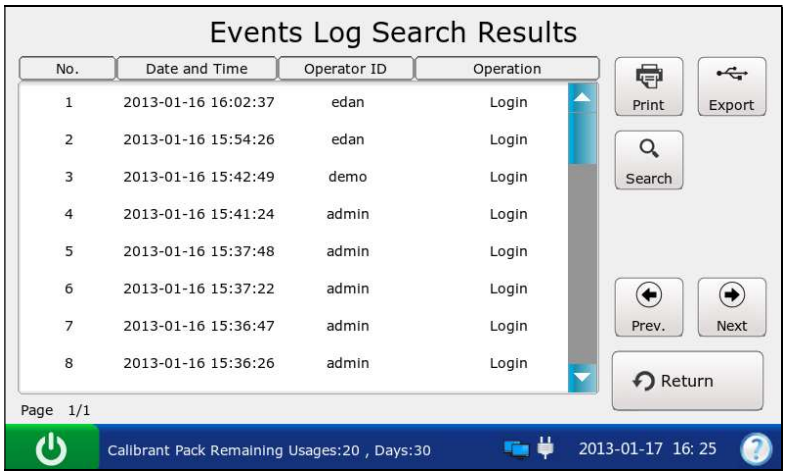


Figure 7-10 Search Results

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

7.2.3.2 Exporting/Printing Events Data

1. Open the events log database.
2. 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 **Print**, the following window will pop out to prompt users whether all data need to be printed.

If no removable disk is inserted into the analyzer before pressing **Export**, the following window will pop out to prompt users that no USB disk is identified.

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

Here is an example of an event log report:

System ID	201303200023
Report Type	Events Log Report
Print Time	2012-03-20 15:20:00
Log Time	2012-03-20 15:20:00
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, Calibration Verification Database, Simulator Database and System Database.

Follow the steps below to backup data:

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

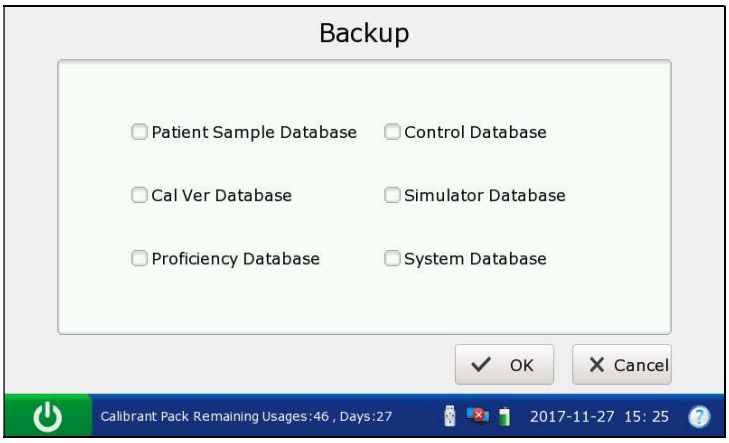
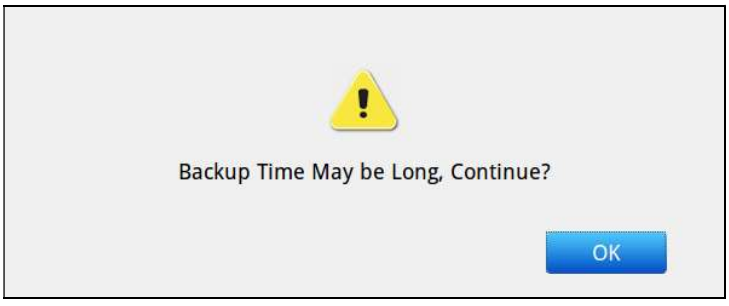


Figure 7-11 Backup Screen

2. Select the database you want to backup. √ indicates the database is selected.
3. Press **OK**.

If no removable disk is inserted into the analyzer, the system will prompt users by popping out a window as the following screenshot displays.

If a removable disk is inserted into the analyzer, the system will prompt users by popping out a window as the following screenshot displays. Press **OK** in the pop-up box, the system will begin to transmit the selected database into the removable disk.



After completion of backup, the system will pop out the following window. Press OK, the selected database will be deleted from the analyzer but be transmitted into the removable

disk. Press Cancel, the selected database will not be deleted from the analyzer and meanwhile transmitted into the removable disk. 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 cannot be recovered after deletion.

7.2.5 Clear Data

On the Database screen, press  to delete patient sample database, control database, calibration verification database, simulator database and proficiency database by performing operations in accordance with software prompts.

Chapter 8 Troubleshooting

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

Table 8-1 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 immediately.
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 immediately.
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 cannot 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 immediately.
5	A test cartridge cannot 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 immediately.
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 Well” appears.	Perform the test again with a new test cartridge. If the prompt appears again,

		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 “Sample aspiration error, probably insufficient sample volume or bubbles contained in sample”	Re-collect sample in accordance with correct and required procedures.
11	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.
12	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.
13	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.
14	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.
15	The prompt “Remaining Days: 0” appears.	The calibrant fluid pack has expired. Replace the calibrant fluid pack following the user manual instructions.
16	The prompt “Calibrant Pack Depleted” appears.	The calibrant fluid pack has been depleted. Replace the calibrant fluid pack following the user manual instructions.
17	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.
18	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.

19	The prompt “Barcode Cannot be Identified” appears.	Ensure that the bar code is that of a calibrant fluid pack.
20	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.
21	The calibrant fluid pack chamber door cannot be opened.	Ensure that the calibrant fluid pack chamber lock has been unlocked before opening the door.
22	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.
23	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.
24	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.
25	The prompt “No Paper in Printer” appears.	Check whether there is paper in the paper 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.
26	There is no sound after you successfully press the touch screen.	Check the volume setup.
27	The system cannot be connected to a network through Wi-Fi.	Ensure that the intensity of the network signal is strong and that the network setup is correct.
28	The system cannot communicate with the DMS.	Ensure that the network or Wi-Fi is successfully connected, and that the IP address of the DMS is correct.
29	Fluids have been spilled on the screen.	Clean and disinfect the screen following the user manual instructions.
30	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.
31	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.
32	The lithium battery cannot 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 cannot be charged, please contact EDAN or its authorized distributors for assistance.
33	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.
34	The prompt “Ambient Temperature Out of Range” appears.	Check that the ambient temperature is within 10 – 31 C (50 – 88 °F), and that the air vents are not obstructed. Reboot the system. If the problem continues, please contact EDAN or its authorized distributors for assistance.
35	The prompt “Heating Abnormally” appears.	Please contact EDAN or its authorized distributors for assistance.
36	The prompt “Abnormal Cam Location” appears.	Please contact EDAN or its authorized distributors for assistance.
37	The date setup cannot be saved after you shut down the system.	Please contact EDAN or its authorized distributors for assistance.
38	The system makes abnormal sounds.	Please contact EDAN or its authorized distributors for assistance.

Chapter 9 Cleaning, Care and Maintenance

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

9.1 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.

9.1.1 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 dust-free and lint-free cloth with detergents or disinfectants.

If Ethanol or Isopropanol is used for both cleaning and disinfecting, then a new cloth is required to be used for the disinfection step.

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.

◆ **The validated detergents for cleaning the system are:**

- ➢ Mild near neutral detergent
- ➢ Alcohol (75%)
- ➢ Isopropyl Alcohol (70%)

- Sodium dichloro-S triazinetrione (effective chlorine content is 200mg/L)
- Phenol (3%)
- Sodium Hypochlorite (0.63%)

◆ **The validated disinfectants for disinfecting the system are:**

- Alcohol (75%)
- Isopropyl Alcohol (70%)
- Sodium dichloro-S triazinetrione (effective chlorine content is 200mg/L)
- Phenol (3%)
- Sodium Hypochlorite (0.63%)

NOTE:

✓ The reagents listed above may cause the biohazard label  fall off or its edge curled. If the biohazard label falls off, please contact Edan's service engineer.

✓ Do not use any disinfectant containing additional active ingredients other than those listed, such as disinfectant didecyl dimethyl ammonium bromide which contains quaternary ammonium salt.

✓ Although the analyzer chemically resistant to most common hospital cleaners, disinfectants and non-caustic detergents, different cleaners or disinfectants are not recommended and may stain the analyzer, such as disinfectant didecyl dimethyl ammonium bromide which contains quaternary ammonium salt.

9.1.2 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 detergents or disinfectants.

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.

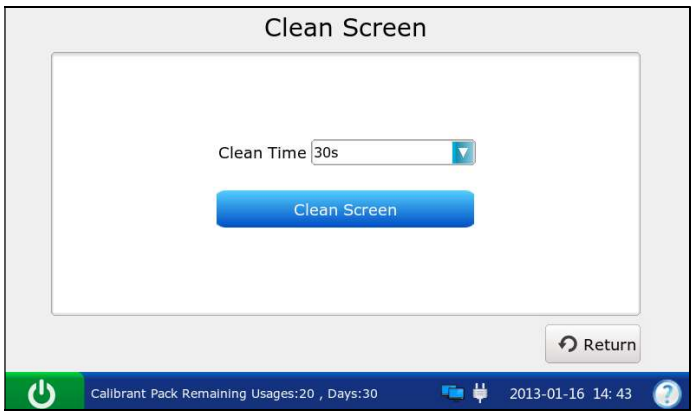


Figure 9-1 Select Clean Time

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

Figure 9-2 Remaining Time

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

9.1.3 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% Ethanol. 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

Prevent the detergent from seeping into the system while cleaning. Do not immerse the analyzer in liquid under any circumstances.

Do not clean the system with abrasive fabric.

9.2 Care and Maintenance

9.2.1 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.

9.2.2 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 fluorescent lighting for a long time.
- ✓ Printer paper should be stored in a dry, dark and cool area, avoiding excessive temperature, humidity and sunlight.
- ✓ Make sure there is no polyvinyl chloride or other chemicals in the storage environment, which will lead to color change of the paper.

9.2.3 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 10 Theory

The system utilizes potentiometry and amperometry to determine the concentrations of pH, blood gases (pCO_2, pO_2) and electrolytes (Na^+, K^+, Ca^{++}, Cl^-) and metabolites (Glu and Lac), and utilizes conductivity 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.

10.1 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 mean cell volume.

Limitations of the Methods for Hematocrit Measurement

Electrolyte Concentration

The conductivity of the whole blood sample is dependent upon the concentration of electrolytes in the plasma portion. The i15/i15A System corrects for the concentration of electrolytes using the measured value of sodium and potassium. The interference is minimized to an insignificant level.

Other Non-Conducting Elements[1-6]

The conductivity method does not distinguish red blood cells from other non-conducting

elements such as proteins, lipids and white blood cells, which occupy volume in the sample. The i15/i15A System is calibrated to read hematocrit accurately when these other elements are at normal levels.

Total Protein

At hematocrit levels less than 40 %PCV, the reading will increase by approximately 1 %PCV for each g/dL (10 g/L) the protein level is increased outside the normal range of 6.5 g/dL to 8.0 g/dL (65 g/L to 80 g/L). At hematocrit levels less than 40 %PCV, the reading will decrease by approximately 1 %PCV for each g/dL (10 g/L) the protein level is decreased outside the normal range of 6.5 g/dL to 8.0 g/dL (65 g/L to 80 g/L). At hematocrit levels greater than 40 %PCV the interference is about three quarters that size.[7]

It is important to be aware of the total protein level when using conductivity systems to monitor a patient on a cardiopulmonary bypass pump.[6] If albumin, or other colloid, is not added to the pump's priming solution, the plasma protein will drop by about 3 g/dL to 4 g/dL (30 g/L to 40 g/L). The conductivity reading will then be systematically low by 3 %PCV to 4 %PCV. For further information on the use of the coronary bypass mode on the i15/i15A System see the Theory section of the i15/i15A System Manual.

It is also important to be aware that the total protein level in premature neonates can be in the range of 3.6 g/dL to 6.0 g/dL (36 g/L to 60 g/L).[8] Total protein levels may be low in burn patients and in patients receiving large volumes of saline-based fluids.

Lipids

Interference from lipids will be about two-thirds the size of the interference from proteins. The protein interference is larger because it is a charged non-conducting element.

References:

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2. Gram HC, Cullen GE: The accuracy of the 'ionometric' method and the protein correction in measuring serum conductivity. J Biol Chem 57:447-491, 1923.

3. Sunderman FW: Studies in serum electrolytes: XIII: Estimation of total base serum. J Biol Chem143: 185-190, 1942.

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5. Rautman E, Newbower R: A practical analysis of the electrical conductivity of blood. IEEE Transactions on Biomedical Engineering BME 30-3: 141-154, 1983.

6. Riley JB, Burgess BM, Smith CA, Crowley JC, Soronen SW: In vitro measurement of the accuracy of a new patient side blood gas, pH, hematocrit and electrolyte monitor. J Extra Corpor Technol 19[3]:322-329, 1987.

7. Zelin M: Interferences on conductivity method of hematocrit determination. Internal report, 1992.

8. Tietz NW: Reference Ranges. Textbook of Clinical Chemistry ed. Norbert W. Tietz, W.B. Saunders Co., Philadelphia, 1986. TB 93-2 October 1993.

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, pCO_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 pO_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.

10.2 Determination of Test Results

10.2.1 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:

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

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

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

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

10.2.2 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:

- The known value of the electrolyte concentration in the calibrant.

- The measured electrolyte concentration of the sample.
- The measured conductivity signal generated by the calibrant.
- 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.

10.3 Equations for Calculated Parameters

cH^+

Hydrogen ion concentration

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

$HCO_3^-{}_{act}$

Bicarbonate ion concentration

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

$HCO_3^-{}_{std}$

Bicarbonate ion concentration normalized to a pCO_2 40 mmHg

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

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

BE (ecf)

Base excess (ecf)

BE (ecf) = HCO_3^-act - 24.8 + (16.2 × (pH - 7.40)) [mmol/L]

BE (B)

Base excess (B)

BE (B) = (1 - 0.014 × tHb (est)) × [HCO_3^-act - 24.8 + (1.43 × tHb (est) + 7.7) × (pH - 7.40)] [mmol/L]

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

BB (B)

Buffer Base

BB (B) = BE (B) + 41.7 + 0.42 × tHb (est) [mmol/L]

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

$ctCO_2$

Total carbon dioxide

$ctCO_2 = HCO_3^-act + 0.0307 \times pCO_2$ [mmol/L]

Ca^{++} (7.4)

The ionized calcium concentration of blood normalized to pH 7.4

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

AnGap

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

AnGap = (Na^+ + K^+) - (Cl^- + HCO_3^-act) [mmol/L]

tHb (est)

An estimation of the hemoglobin contained in the sample

tHb (est) = 34 × Hct / 100 [g/dL]

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

NOTE:

The estimated hemoglobin may vary significantly in cases of abnormal blood composition or disease states such as anemia in which abnormal hemoglobin values may not be reported. These conditions should warrant repeat testing by conventional laboratory methods.

sO_2 (est)

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

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

***p*O2 (A-a)**

Alveolar-arterial oxygen tension difference

pO_2 (A-a) = *p*O_2 (A) - *p*O_2 (a) [mmHg]

***p*O2 (a/A)**

Arterial-alveolar oxygen tension ratio

pO_2 (a/A) = *p*O_2 (a) / *p*O_2 (A) [mmHg]

RI

Respiratory index: the ratio of the alveolar-arterial blood oxygen-pressure difference to arterial *p*O_2

RI = *p*O_2 (A-a) / *p*O_2 (a)

***p*O2 / FIO2**

The ratio of arterial *p*O_2 to the fraction of inspired oxygen

pO_2 / FIO_2 = *p*O_2 / FIO_2 [mmHg]

pH (T)

pH value corrected for entered patient temperature

pH (T) = pH – [0.0147 + 0.0065 × (pH – 7.4)] (T – 37)

cH^+ (T)

Hydrogen ion concentration corrected for entered patient temperature

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

pCO_2 (T)

pCO_2 corrected for entered patient temperature

pCO_2 (T) = $pCO_2 \times 10^{0.019(T - 37)}$ [mmHg]

pO_2 (T)

pO_2 corrected for entered patient temperature

$$pO_2(T) = pO_2 \times 10^{\frac{5.49\times10^{-11}pO_2^{3.88}+0.071}{9.71\times10^{-9}\,pO_2^{3.88}+2.30}(T-37)}$$ [mmHg]

pO_2 (A-a) (T)

Alveolar-arterial oxygen tension difference corrected for entered patient temperature

pO_2 (A-a) (T) = pO_2 (A) (T) - pO_2 (a) (T) [mmHg]

pO_2 (a/A) (T)

Arterial-alveolar oxygen tension ratio corrected for entered patient temperature

pO_2 (a/A) (T) = pO_2 (a) (T) / pO_2 (A) (T) [mmHg]

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

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

pO_2 (T)/FIO_2

The ratio of arterial pO_2 to the fraction of inspired oxygen corrected for the entered patient temperature

pO_2 (T) / FIO_2 = pO_2 (T) / FIO_2 [mmHg]

mOsm

mOsm is generally determined by Na^+, K^+, Glu and Bun.

mOsm = 1.86 × (Na^+ + K^+) +Glu + BUN +9

In the equation:

Glu is the Glu test result by performing test with Blood Gas and Chemistry Test Cartridge on i15/i15A Blood Gas and Chemistry Analyzer and the unit for Glu test result is mmol/L. If Glu cannot be measured directly, its default value for Glu is 5mmol/L.

BUN is the BUN test result by performing test with Blood Gas and Chemistry Test Cartridge on i15/i15A Blood Gas and Chemistry Analyzer and the unit for BUN test result is mmol/L. If BUN cannot be measured directly, its default value for BUN is 3mmol/L.

Chapter 11 Parameters

11.1 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.

11.1.1 Intended Use/ Indications for Use

The pH test is intended for the quantification of pH in arterial, venous and capillary 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

11.1.2 Traceability

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

11.1.3 Temperature Correction

pH is a temperature dependent quantity which is measured at 37 °C (98.6 °F) on the system. The pH value can be corrected to the patient's temperature other than 37 °C (98.6 °F). 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:

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

11.1.4 Performance Characteristics

Imprecision in Aqueous Control Solutions

Imprecision was evaluated by running 3 levels of EDAN i15 Blood Gas and Electrolyte Control in duplicate each run, two runs per day, for a total of 20 days on one EDAN i15 Blood Gas and Chemistry Analysis System. The protocol was based on methods described in CLSI EP5-A3, *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – 3rd Edition.*

pH Precision in Aqueous Blood Gas and Electrolyte Control						
Sample	Mean (pH Units)	N	Within-Run SD	Within-Run CV	Within-laboratory Precision SD	Within-laboratory Precision CV
Level 1	7.144	80	0.006	0.08%	0.006	0.08%
Level 2	7.423	80	0.004	0.05%	0.004	0.06%
Level 3	7.601	80	0.006	0.07%	0.007	0.10%

In each of four point-of-care sites used for evaluation of the EDAN i15, for quality control, a single sample of each of 3 levels Blood Gas and Electrolyte Controls, as well as 3 levels of Hematocrit control were run at the start and end of each day of testing. One site did not include chloride analysis or a mid-level hematocrit control.

pH Precision in Aqueous Blood Gas and Electrolyte Control						
Sample	Mean (pH Units)	N	Within-Run SD	Within-Run CV	Total Imprecision SD	Total Imprecision CV
Level 1	7.135	80	0.006	0.08%	0.007	0.10%
Level 2	7.399	80	0.006	0.07%	0.006	0.08%
Level 3	7.583	80	0.006	0.08%	0.006	0.08%

Linearity in Whole Blood

Whole, venous blood samples collected from healthy volunteers in vacuum blood collection tubes with lithium heparin were modified to obtain a range of values for each measurand approaching their analytical measurement range by the addition of isotonic electrolyte solution for electrolytes, tonometry with various gas mixtures for blood gases and pH, and by mixing with erythrocyte concentrated for depleted plasma to obtain an range of hematocrit.The evaluation demonstrated equivalent, linear performance over the analytical measurement range for all measurands in samples from syringes and from glass capillary tubes.

Whole Blood from Syringe							
Measurand	No. of Levels	Claimed Measuring Range	Specimen Range	% of claimed range	Slope	Intercept	r value
pH	7	6.500 – 7.800	6.455 - 7.944	115%	0.9842	0.11	0.9996

NOTE:

Linearity across claimed measurement range in samples introduced from Syringe. Whole Blood from Capillary

Whole Blood from Capillary							
Measurand	No. of	Claimed Measuring	Specimen Range	% of	Slope	Intercept	r value

	Levels	Range		claimed range			
pH	7	6.500 – 7.800	6.444 - 7.978	118%	1.0039	-0.03	0.9995

NOTE: Linearity across claimed measurement range in samples introduced from glass Capillary.

Correlation to Predicate System and Measuring Range

In seven clinical sites (four POC and three laboratory) used for the evaluation of bias on patient samples, the protocol in CLSI Document EP09c Measurement Procedure Comparison and Bias Estimation Using Patient Samples was applied in which each sample was measured in duplicate on both the EDAN i15 and its predicate device. All testing was performed using discarded patient samples collected into either B-D Vacutainer lithium heparin tubes or B-D balanced heparin arterial sampling syringes. Four POC sites and all LAB sites utilized the RapidPoint 400 as the comparator device and are combined for presentation below. Two data pairs were eliminated from this method comparison because values were outside claimed measurement range. The measuring range is based on the linearity results.

Measurand	Site	Nr.	Range	Claimed Range	Slope	Intercept	Std Error	r-value
pH	POC 1-4	257	6.826 – 7.675		1.0130	-0.0961	0.0218	0.9909
	all LAB	228	6.531 – 7.791	6.500 – 7.800	1.0085	-0.0640	0.0208	0.9949
	all Sites	485	6.531 – 7.791	97%	1.0105	-0.0778	0.0213	0.9933

11.2 pCO_2

pCO_2, the partial pressure of carbon dioxide, is measured by potentiometry. pCO_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.

11.2.1 Intended Use/ Indications for Use

The pCO_2 test is intended for the quantification of pCO_2 in arterial, venous and capillary samples.

pCO_2 is an important indicator to reflect respiratory acid-base balance. If pCO_2 is above the normal range, it is termed respiratory acidosis. If pCO_2 is below the normal range, it is termed respiratory alkalosis. Metabolic factors can also cause pCO_2 increase/decrease: metabolic acidosis leads to decreased pCO_2, and metabolic alkalosis leads to increased pCO_2. pCO_2 along with pH is a more persuasive tool to assess acid-base balance.

11.2.2 Traceability

pCO_2 values assigned to calibrant, controls, and calibration verification controls are traceable to NIST standards.

11.2.3 Temperature Correction

pCO_2 is a temperature dependent quantity which is measured at 37 °C (98.6 °F) on the system. The pCO_2 value can be corrected to the patient's temperature other than 37 °C (98.6 °F). Patient temperature can be entered on the Enter Patient Information screen during each patient sample test.

The pCO_2 at the patient's temperature is calculated as follows:

$pCO_2\,(T) = pCO_2 \times 10^{0.019(T - 37)}$

11.2.4 Performance Characteristics

Imprecision in Aqueous Control Solutions

Imprecision was evaluated by running 3 levels of EDAN i15 Blood Gas and Electrolyte Control in duplicate each run, two runs per day, for a total of 20 days on one EDAN i15 Blood Gas and Chemistry Analysis System. The protocol was based on methods described in CLSI EP5-A3, *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – 3rd Edition.*

pCO_2 Precision in Aqueous Blood Gas and Electrolyte Control						
Sample	Mean (mmHg)	N	Within-Run SD	Within-Run CV	Within-laboratory Precision SD	Within-laboratory Precision CV
Level 1	70.2	80	2.66	3.80%	2.33	3.31%
Level 2	39.5	80	0.88	2.23%	0.93	2.36%
Level 3	21.8	80	0.69	3.18%	0.67	3.06%

In each of four point-of-care sites used for evaluation of the EDAN i15, for quality control, a single sample of each of 3 levels Blood Gas and Electrolyte Controls, as well as 3 levels of Hematocrit control were run at the start and end of each day of testing. One site did not include chloride analysis or a mid-level hematocrit control.

pCO_2 Precision in Aqueous Blood Gas and Electrolyte Control						
Sample	Mean (mmHg)	N	Within-Run SD	Within-Run CV	Total Imprecision SD	Total Imprecision CV
Level 1	73.2	80	2.20	3.01%	2.56	3.50%
Level 2	43.1	80	1.32	3.07%	1.66	3.85%
Level 3	24.7	80	0.69	2.78%	0.89	3.60%

Linearity in Whole Blood

Whole, venous blood samples collected from healthy volunteers in vacuum blood collection tubes with lithium heparin were modified to obtain a range of values for each measurand approaching their analytical measurement range by the addition of isotonic electrolyte solution for electrolytes, tonometry with various gas mixtures for blood gases and pH, and by mixing with erythrocyte concentrated for depleted plasma to obtain an range of hematocrit. The evaluation demonstrated equivalent, linear performance over the

analytical measurement range for all measurands in samples from syringes and from glass capillary tubes.

Whole Blood from Syringe							
Measurand	No. of Levels	Claimed Measuring Range	Specimen Range	% of claimed range	Slope	Intercept	r value
pCO_2	7	10 - 150	3 – 149	104%	0.9533	0.62	0.9969

NOTE: Linearity across claimed measurement range in samples introduced from Syringe

Whole Blood from Capillary							
Measurand	No. of Levels	Claimed Measuring Range	Specimen Range	% of claimed range	Slope	Intercept	r value
pCO_2	7	10 - 150	2 - 150	105%	1.0007	0.14	0.9988

NOTE:

Linearity across claimed measurement range in samples introduced from glass Capillary.

Correlation to Predicate System and Measuring Range

In seven clinical sites (four POC and three laboratory) used for the evaluation of bias on patient samples, the protocol in CLSI Document EP09c Measurement Procedure Comparison and Bias Estimation Using Patient Samples was applied in which each sample was measured in duplicate on both the EDAN i15 and its predicate device. All testing was performed using discarded patient samples collected into either B-D Vacutainer lithium heparin tubes or B-D balanced heparin arterial sampling syringes. Four POC sites and all LAB sites utilized the RapidPoint 400 as the comparator device and are combined for presentation below. Four data pairs were eliminated from this method comparison because values were outside claimed measurement range. The measuring range is based on the linearity results.

Measurand	Site	Nr.	Range	Claimed Range	Slope	Intercept	Std Error	r-value
pCO_2 mmHg	POC 1-4	257	18.0 - 144.8	10 – 150 96%	1.0285	-1.5528	3.6695	0.9841
	all LAB	226	10.9 - 144.9		0.9523	1.0417	3.3262	0.9916
	all Sites	483	10.9 - 144.9		0.9843	0.1813	3.6383	0.9879

11.3 pO_2

pO_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.

11.3.1 Intended Use/Indications for Use

The pO_2 test is intended for the quantification of pO_2 in arterial, venous and capillary samples.

The pO_2 value of arterial blood is important in assesing the efficiency of pulmonary gas exchange.

11.3.2 Traceability

pO_2 values assigned to calibrant, controls, and calibration verification controls are traceable to NIST standards.

11.3.3 Temperature Correction

pO_2 is a temperature dependent quantity which is measured at 37 °C (98.6 °F) on the system. The pO_2 value can be corrected to the patient's temperature other than 37 °C (98.6 °F). Patient temperature can be entered on the Enter Patient Information screen during each patient sample test.

The pO_2 at the patient's temperature is calculated as follows:

$$pO_2(T) = pO_2 \times 10^{\frac{5.49\times10^{-11}pO_2^{3.88}+0.071}{9.71\times10^{-9}\,pO_2^{3.88}+2.30}(T-37)}$$

11.3.4 Performance Characteristics

Imprecision in Aqueous Control Solutions

Imprecision was evaluated by running 3 levels of EDAN i15 Blood Gas and Electrolyte Control in duplicate each run, two runs per day, for a total of 20 days on one EDAN i15 Blood Gas and Chemistry Analysis System. The protocol was based on methods described in CLSI EP5-A3, *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – 3rd Edition.*

pO_2 Precision in Aqueous Blood Gas and Electrolyte Control						
Sample	Mean (mmHg)	N	Within-Run SD	Within-Run CV	Within-laboratory Precision SD	Within-laboratory Precision CV
Level 1	74.2	80	2.92	3.94%	3.15	4.25%
Level 2	108.7	80	2.39	2.20%	3.02	2.78%
Level 3	147.8	80	2.64	1.79%	2.85	1.93%

In each of four point-of-care sites used for evaluation of the EDAN i15, for quality control, a single sample of each of 3 levels Blood Gas and Electrolyte Controls, as well as 3 levels

of Hematocrit control were run at the start and end of each day of testing.

pO_2 Precision in Aqueous Blood Gas and Electrolyte Control						
Sample	Mean (mmHg)	N	Within-Run SD	Within-Run CV	Total Imprecision SD	Total Imprecision CV
Level 1	70.9	80	1.71	2.42%	2.29	3.23%
Level 2	104.8	80	1.83	1.75%	2.22	2.12%
Level 3	146.3	80	1.80	1.23%	2.10	1.44%

Linearity in Whole Blood

Whole, venous blood samples collected from healthy volunteers in vacuum blood collection tubes with lithium heparin were modified to obtain a range of values for each measurand approaching their analytical measurement range by the addition of isotonic electrolyte solution for electrolytes, tonometry with various gas mixtures for blood gases and pH, and by mixing with erythrocyte concentrated for depleted plasma to obtain an range of hematocrit.The evaluation demonstrated equivalent, linear performance over the analytical measurement range for all measurands in samples from syringes and from glass capillary tubes.

Whole Blood from Syringe							
Measurand	No. of Levels	Claimed Measuring Range	Specimen Range	% of claimed range	Slope	Intercept	r value
pO_2	7	10 - 700	6 – 716	103%	0.9969	-6.16	0.9993

NOTE:

Linearity across claimed measurement range in samples introduced from Syringe.

Whole Blood from Capillary							
Measurand	No. of Levels	Claimed Measuring Range	Specimen Range	% of claimed range	Slope	Intercept	r value
pO_2	7	10 - 700	7 – 717	103%	1.0174	-5.40	0.9997

NOTE: Linearity across claimed measurement range in samples introduced from glass Capillary.

Correlation to Predicate System and Measuring Range

In seven clinical sites (four POC and three laboratory) used for the evaluation of bias on patient samples, the protocol in CLSI Document EP09c Measurement Procedure Comparison and Bias Estimation Using Patient Samples was applied in which each sample was measured in duplicate on both the EDAN i15 and its predicate device. All

testing was performed using discarded patient samples collected into either B-D Vacutainer lithium heparin tubes or B-D balanced heparin arterial sampling syringes. Four POC sites and all LAB sites utilized the RapidPoint 400 as the comparator device and are combined for presentation below. One data pair was eliminated from this method comparison because values were outside claimed measurement range. The measuring range is based on the linearity results.

Measurand	Site	Nr.	Range	Claimed Range	Slope	Intercept	Std Error	r-value
pO_2 mmHg	POC 1-4	257	17 - 585	10 – 700 94%	1.0368	-4.1355	6.5734	0.9974
	all LAB	229	10 - 661		1.0018	0.2151	6.9117	0.9989
	all Sites	486	10 - 661		1.0119	-1.0639	6.9830	0.9983

11.4 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.

11.4.1 Intended Use/Indications for Use

The sodium test is intended for the quantification of sodium in arterial, venous and capillary 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.

11.4.2 Traceability

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

11.4.3 Performance Characteristics

Imprecision in Aqueous Control Solutions

Imprecision was evaluated by running 3 levels of EDAN i15 Blood Gas and Electrolyte Control in duplicate each run, two runs per day, for a total of 20 days on one EDAN i15 Blood Gas and Chemistry Analysis System. The protocol was based on methods described in CLSI EP5-A3, *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – 3rd Edition.*

Na^+ Precision in Aqueous Blood Gas and Electrolyte Control

Sample	Mean (mmol/L)	N	Within-Run SD	Within-Run CV	Within-laboratory Precision SD	Within-laboratory Precision CV
Level 1	112.3	80	0.74	0.66%	0.83	0.74%
Level 2	133.6	80	0.69	0.52%	0.67	0.50%
Level 3	154.6	80	1.06	0.69%	1.05	0.68%

In each of four point-of-care sites used for evaluation of the EDAN i15, for quality control, a single sample of each of 3 levels Blood Gas and Electrolyte Controls, as well as 3 levels of Hematocrit control were run at the start and end of each day of testing.

Na^+ Precision in Aqueous Blood Gas and Electrolyte Control						
Sample	Mean (mmol/L)	N	Within-Run SD	Within-Run CV	Total Imprecision SD	Total Imprecision CV
Level 1	121.3	80	0.81	0.67%	1.01	0.83%
Level 2	143.1	80	0.65	0.45%	1.00	0.70%
Level 3	166.0	80	1.43	0.86%	1.56	0.94%

Linearity in Whole Blood

Whole, venous blood samples collected from healthy volunteers in vacuum blood collection tubes with lithium heparin were modified to obtain a range of values for each measurand approaching their analytical measurement range by the addition of isotonic electrolyte solution for electrolytes, tonometry with various gas mixtures for blood gases and pH, and by mixing with erythrocyte concentrated for depleted plasma to obtain an range of hematocrit.The evaluation demonstrated equivalent, linear performance over the analytical measurement range for all measurands in samples from syringes and from glass capillary tubes.

Whole Blood from Syringe							
Measurand	No. of Levels	Claimed Measuring Range	Specimen Range	% of claimed range	Slope	Intercept	r value
Na^+	7	100 - 180	92 – 185	116%	0.9848	0.37	0.9988

NOTE: Linearity across claimed measurement range in samples introduced from Syringe.

Whole Blood from Capillary							
Measurand	No. of Levels	Claimed Measuring Range	Specimen Range	% of claimed range	Slope	Intercept	r value

Na^+	7	100 - 180	94 – 185	114%	1.0059	-3.06	0.9986

NOTE: Linearity across claimed measurement range in samples introduced from glass Capillary.

Correlation to Predicate System and Measuring Range

In seven clinical sites (four POC and three laboratory) used for the evaluation of bias on patient samples, the protocol in CLSI Document EP09c Measurement Procedure Comparison and Bias Estimation Using Patient Samples was applied in which each sample was measured in duplicate on both the EDAN i15 and its predicate device. All testing was performed using discarded patient samples collected into either B-D Vacutainer lithium heparin tubes or B-D balanced heparin arterial sampling syringes. Four POC sites and all LAB sites utilized the RapidPoint 400 as the comparator device and are combined for presentation below. One data pair was eliminated from this method comparison because values were outside claimed measurement range. The measuring range is based on the linearity results.

Measurand	Site	Nr.	Range	Claimed Range	Slope	Intercept	Std Error	r-value
Na^+ mmol/L	POC 1-4	257	110 - 170	100 - 180 99%	0.9787	2.5631	1.6065	0.9802
	all LAB	229	101 - 180		0.9909	0.8032	1.5810	0.9952
	all Sites	486	101 - 180		0.9886	1.1358	1.5927	0.9923

11.5 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.

Hemolysis may cause an increase in potassium levels in the sample, but is not visible in a whole blood sample.

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

11.5.1 Intended Use/Indications for Use

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

11.5.2 Traceability

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

11.5.3 Performance Characteristics

Imprecision in Aqueous Control Solutions

Imprecision was evaluated by running 3 levels of EDAN i15 Blood Gas and Electrolyte Control in duplicate each run, two runs per day, for a total of 20 days on one EDAN i15 Blood Gas and Chemistry Analysis System. The protocol was based on methods described in CLSI EP5-A3, *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – 3rd Edition.*

K^+ Precision in Aqueous Blood Gas and Electrolyte Control						
Sample	Mean (mmol/L)	N	Within-Run SD	Within-Run CV	Within-laboratory Precision SD	Within-laboratory Precision CV
Level 1	2.00	80	0.022	1.12%	0.022	1.10%
Level 2	4.40	80	0.016	0.36%	0.016	0.36%
Level 3	6.21	80	0.045	0.72%	0.045	0.72%

In each of four point-of-care sites used for evaluation of the EDAN i15/i15A, for quality control, a single sample of each of 3 levels Blood Gas and Electrolyte Controls, as well as 3 levels of Hematocrit control were run at the start and end of each day of testing.

K^+ Precision in Aqueous Blood Gas and Electrolyte Control						
Sample	Mean (mmol/L)	N	Within-Run SD	Within-Run CV	Total Imprecision SD	Total Imprecision CV
Level 1	2.23	80	0.02	0.90%	0.03	1.34%
Level 2	4.63	80	0.04	0.86%	0.05	1.08%
Level 3	6.84	80	0.06	0.88%	0.06	0.88%

Linearity in Whole Blood

Whole, venous blood samples collected from healthy volunteers in vacuum blood collection tubes with lithium heparin were modified to obtain a range of values for each measurand approaching their analytical measurement range by the addition of isotonic electrolyte solution for electrolytes, tonometry with various gas mixtures for blood gases and pH, and by mixing with erythrocyte concentrated for depleted plasma to obtain an

range of hematocrit. The evaluation demonstrated equivalent, linear performance over the analytical measurement range for all measurands in samples from syringes and from glass capillary tubes.

Whole Blood from Syringe							
Measurand	No. of Levels	Claimed Measuring Range	Specimen Range	% of claimed range	Slope	Intercept	r value
K^+	7	2.0 - 9.0	1.7 - 10.2	120%	0.9886	0.08	0.9997

NOTE:

Linearity across claimed measurement range in samples introduced from Syringe.

Whole Blood from Capillary							
Measurand	No. of Levels	Claimed Measuring Range	Specimen Range	% of claimed range	Slope	Intercept	r value
K^+	7	2.0 - 9.0	1.9 - 10.0	116%	1.0013	-0.01	0.9998

NOTE:

Linearity across claimed measurement range in samples introduced from glass Capillary.

Correlation to Predicate System and Measuring Range

In seven clinical sites (four POC and three laboratory) used for the evaluation of bias on patient samples, the protocol in CLSI Document EP09c Measurement Procedure Comparison and Bias Estimation Using Patient Samples was applied in which each sample was measured in duplicate on both the EDAN i15 and its predicate device. All testing was performed using discarded patient samples collected into either B-D Vacutainer lithium heparin tubes or B-D balanced heparin arterial sampling syringes. Four POC sites and all LAB sites utilized the RapidPoint 400 as the comparator device and are combined for presentation below. The measuring range is based on the linearity results.

Measurand	Site	Nr.	Range	Claimed Range	Slope	Intercept	Std Error	r-value
K^+ mmol/L	POC 1-4	257	2.4 - 9.0	2.0 - 9.0 94%	0.9838	0.0250	0.0791	0.9968
	all LAB	230	2.6 - 8.2		0.9868	0.0450	0.1181	0.9963
	all Sites	487	2.4 – 9.0		0.9895	0.0164	0.1005	0.9968

11.6 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.

11.6.1 Intended Use/Indications for Use

The ionized calcium test is intended for the quantification of ionized calcium in arterial, venous and capillary 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.

11.6.2 Traceability

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

11.6.3 Performance Characteristics

Imprecision in Aqueous Control Solutions

Imprecision was evaluated by running 3 levels of EDAN i15 Blood Gas and Electrolyte Control in duplicate each run, two runs per day, for a total of 20 days on one EDAN i15 Blood Gas and Chemistry Analysis System. The protocol was based on methods described in CLSI EP5-A3, *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – 3rd Edition.*

Ca^{++} Precision in Aqueous Blood Gas and Electrolyte Control						
Sample	Mean (mmol/L)	N	Within-Run SD	Within-Run CV	Within-laboratory Precision SD	Within-laboratory Precision CV
Level 1	1.53	80	0.029	1.93%	0.034	2.20%
Level 2	1.19	80	0.018	1.52%	0.018	1.55%
Level 3	0.52	80	0.011	2.17%	0.012	2.22%

In each of four point-of-care sites used for evaluation of the EDAN i15, for quality control, a single sample of each of 3 levels Blood Gas and Electrolyte Controls, as well as 3 levels of Hematocrit control were run at the start and end of each day of testing.

Ca^{++} Precision in Aqueous Blood Gas and Electrolyte Control						
Sample	Mean (mmol/L)	N	Within-Run SD	Within-Run CV	Total Imprecision SD	Total Imprecision CV
Level 1	1.46	80	0.06	4.00%	0.07	4.79%
Level 2	1.10	80	0.02	2.10%	0.04	3.64%
Level 3	0.48	80	0.01	2.08%	0.02	4.16%

Linearity in Whole Blood

Whole, venous blood samples collected from healthy volunteers in vacuum blood collection tubes with lithium heparin were modified to obtain a range of values for each measurand approaching their analytical measurement range by the addition of isotonic electrolyte solution for electrolytes, tonometry with various gas mixtures for blood gases and pH, and by mixing with erythrocyte concentrated for depleted plasma to obtain an range of hematocrit.The evaluation demonstrated equivalent, linear performance over the analytical measurement range for all measurands in samples from syringes and from glass capillary tubes.

Whole Blood from Syringe							
Measurand	No. of Levels	Claimed Measuring Range	Specimen Range	% of claimed range	Slope	Intercept	r value
Ca^{++}	7	0.25 - 2.50	0.23 - 2.94	120%	0.9848	-0.05	0.9981

NOTE:

Linearity across claimed measurement range in samples introduced from Syringe.

Whole Blood from Capillary							
Measurand	No. of Levels	Claimed Measuring Range	Specimen Range	% of claimed range	Slope	Intercept	r value
Ca^{++}	7	0.25 - 2.50	0.24 - 2.97	121%	0.9771	-0.06	0.9968

NOTE:

Linearity across claimed measurement range in samples introduced from glass Capillary.

Correlation to Predicate System and Measuring Range

In seven clinical sites (four POC and three laboratory) used for the evaluation of bias on patient samples, the protocol in CLSI Document EP09c Measurement Procedure Comparison and Bias Estimation Using Patient Samples was applied in which each sample was measured in duplicate on both the EDAN i15 and its predicate device. All testing was performed using discarded patient samples collected into either B-D Vacutainer lithium heparin tubes or B-D balanced heparin arterial sampling syringes. Four POC sites and all LAB sites utilized the RapidPoint 400 as the comparator device and are combined for presentation below. Two data pairs were eliminated from this method comparison because values were outside claimed measurement range.

Measurand	Site	Nr.	Range	Claimed Range	Slope	Intercept	Std Error	r-value
Ca^{++} mmol/L	POC 1-4	257	0.47 - 1.82	0.25 - 2.50 94%	0.9568	0.0428	0.0457	0.9695
	all LAB	228	0.30 - 2.42		0.9919	0.0228	0.0416	0.9921
	all Sites	485	0.30 - 2.42		0.9848	0.0200	0.0453	0.9854

Detection limits were determined by obtaining the standard deviation of sample measurements from repeated measurements of samples with a relevant low concentration. To determine LoB, zero level samples were prepared and measured on two EDAN i15 instruments with two lots of Test Cartridges and two lots of Calibrator Fluid Packs to obtain blank measurements (N=120). To determine the LoD and LoQ, whole blood samples with low levels of analyte (approximately 1 to 5 x LoB) were measured on two instruments (N=120). The LoQ was determined based on the inter - assay precision (%CV). The limit of quantitation (LoQ) is based on an accuracy goal of 0.125 mmol/L. The accuracy goal was met and therefore, the results of the study are presented in the following table:

Measurand	LoB	LoD	LoQ	Claimed Measurement Range
Ionized Calcium	0.09 mmol/L	0.17 mmol/L	0.19 mmol/L	0.25 – 2.50 mmol/L

11.7 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.

11.7.1 Intended Use/Indications for Use

The chloride test is intended for the quantification of chloride in arterial, venous and capillary 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.

11.7.2 Traceability

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

11.7.3 Performance Characteristics

Imprecision in Aqueous Control Solutions

Imprecision was evaluated by running 3 levels of EDAN i15 Blood Gas and Electrolyte Control in duplicate each run, two runs per day, for a total of 20 days on one EDAN i15

Blood Gas and Chemistry Analysis System. The protocol was based on methods described in CLSI EP5-A3, *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – 3rd Edition.*

Cl^- Precision in Aqueous Blood Gas and Electrolyte Control						
Sample	Mean (mmol/L)	N	Within-Run SD	Within-Run CV	Within-laboratory Precision SD	Within-laboratory Precision CV
Level 1	76.3	80	0.89	1.16%	0.94	1.23%
Level 2	93.4	80	0.67	0.72%	0.70	0.74%
Level 3	119.7	80	1.04	0.87%	1.12	0.94%

In each of four point-of-care sites used for evaluation of the EDAN i15, for quality control, a single sample of each of 3 levels Blood Gas and Electrolyte Controls, as well as 3 levels of Hematocrit control were run at the start and end of each day of testing.

Cl^- Precision in Aqueous Blood Gas and Electrolyte Control						
Sample	Mean (mmol/L)	N	Within-Run SD	Within-Run CV	Total Imprecision SD	Total Imprecision CV
Level 1	78.1	80	0.74	0.95%	0.80	1.02%
Level 2	99.9	80	0.43	0.43%	0.59	0.59%
Level 3	126.6	80	0.70	0.55%	1.04	0.82%

Linearity in Whole Blood

Whole, venous blood samples collected from healthy volunteers in vacuum blood collection tubes with lithium heparin were modified to obtain a range of values for each measurand approaching their analytical measurement range by the addition of isotonic electrolyte solution for electrolytes, tonometry with various gas mixtures for blood gases and pH, and by mixing with erythrocyte concentrated for depleted plasma to obtain an range of hematocrit. The evaluation demonstrated equivalent, linear performance over the analytical measurement range for all measurands in samples from syringes and from glass capillary tubes.

Whole Blood from Syringe							
Measurand	No. of Levels	Claimed Measuring Range	Specimen Range	% of claimed range	Slope	Intercept	r value
Cl^-	7	65 – 140	58 - 176	158%	1.0028	-1.59	0.9993

NOTE: Linearity across claimed measurement range in samples introduced from Syringe.

Whole Blood from Capillary							
Measurand	No. of Levels	Claimed Measuring Range	Specimen Range	% of claimed range	Slope	Intercept	r value
Cl^-	7	65 – 140	59 - 175	155%	0.9965	-1.59	0.9992

NOTE: Linearity across claimed measurement range in samples introduced from glass Capillary.

Correlation to Predicate System and Measuring Range

In seven clinical sites (four POC and three laboratory) used for the evaluation of bias on patient samples, the protocol in CLSI Document EP09c Measurement Procedure Comparison and Bias Estimation Using Patient Samples was applied in which each sample was measured in duplicate on both the EDAN i15 and its predicate device. All testing was performed using discarded patient samples collected into either B-D Vacutainer lithium heparin tubes or B-D balanced heparin arterial sampling syringes. Four POC sites and all LAB sites utilized the RapidPoint 400 as the comparator device and are combined for presentation below. Three data pairs were eliminated from this method comparison because values were outside claimed measurement range. The measuring range is based on the linearity results.

Measurand	Site	Nr.	Range	Claimed Range	Slope	Intercept	Std Error	r-value
Cl^- mmol/L	POC 1-4	257	77.0 - 137.0	65 - 140 97%	1.0188	-2.2648	1.7342	0.9821
	all LAB	227	66.0 - 139.0		1.0000	0.2599	2.0765	0.9899
	all Sites	484	66.0 - 139.0		1.0012	-0.1469	1.9205	0.9875

11.8 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.

11.8.1 Intended Use/Indications for Use

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

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

11.8.2 Traceability

Hematocrit values assigned to controls and calibration verification controls are traceable

to the standard method: CLSI H7-A3 procedure for measuring packed cell volume by the microhematocrit method.

11.8.3 Performance Characteristics

Imprecision in Aqueous Control Solutions

Imprecision was evaluated by running 2 levels of EDAN i15 Hematocrit Control in duplicate each run, two runs per day, for a total of 20 days on one EDAN i15 Blood Gas and Chemistry Analysis System. The protocol was based on methods described in CLSI EP5-A3, *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – 3rd Edition.*

Hct Precision in Aqueous Hematocrit Control						
Sample	Mean (%)	N	Within-Run SD	Within-Run CV	Within-laboratory Precision SD	Within-laboratory Precision CV
Low	19.3	80	0.57	2.95%	0.74	3.85%
High	46.71	80	0.58	1.24%	0.53	1.14%

In each of four point-of-care sites used for evaluation of the EDAN i15, for quality control, a single sample of each of 3 levels Blood Gas and Electrolyte Controls, as well as 3 levels of Hematocrit control were run at the start and end of each day of testing.

Hct Precision in Aqueous Hematocrit Control						
Sample	Mean (%)	N	Within-Run SD	Within-Run CV	Total Imprecision SD	Total Imprecision CV
Low	21.0	80	0.67	3.19%	0.74	3.52%
Mid	33.7	80	0.33	0.97%	0.33	0.98%
High	47.0	80	0.22	0.47%	0.22	0.47%

Linearity in Whole Blood

Whole, venous blood samples collected from healthy volunteers in vacuum blood collection tubes with lithium heparin were modified to obtain a range of values for each measurand approaching their analytical measurement range by the addition of isotonic electrolyte solution for electrolytes, tonometry with various gas mixtures for blood gases and pH, and by mixing with erythrocyte concentrated for depleted plasma to obtain an range of hematocrit. The evaluation demonstrated equivalent, linear performance over the analytical measurement range for all measurands in samples from syringes and from glass capillary tubes.

Whole Blood from Syringe							
Measurand	No. of Levels	Claimed Measuring Range	Specimen Range	% of claimed range	Slope	Intercept	r value
Hct	7	13 - 72	3 - 77	125%	0.9687	1.54	0.9981

NOTE:

Linearity across claimed measurement range in samples introduced from Syringe.

Whole Blood from Capillary							
Measurand	No. of Levels	Claimed Measuring Range	Specimen Range	% of claimed range	Slope	Intercept	r value
Hct	7	13 - 72	4 - 76	122%	0.9623	1.51	0.9984

NOTE:

Linearity across claimed measurement range in samples introduced from glass Capillary.

Correlation to Predicate System and Measuring Range

In seven clinical sites (four POC and three laboratory) used for the evaluation of bias on patient samples, the protocol in CLSI Document EP09c Measurement Procedure Comparison and Bias Estimation Using Patient Samples was applied in which each sample was measured in duplicate on both the EDAN i15 and its predicate device. All testing was performed using discarded patient samples collected into either B-D Vacutainer lithium heparin tubes or B-D balanced heparin arterial sampling syringes. Four POC sites and all LAB sites utilized the RapidPoint 400 as the comparator device and are combined for presentation below. The measuring range is based on the linearity results.

Measurand	Site	Nr.	Range	Claimed Range	Slope	Intercept	Std Error	r-value
Hct %	POC 1-4	257	21– 60	13- 72 100%	0.9853	0.8173	1.2295	0.9891
	all LAB	230	13- 72		0.9842	0.6787	1.0990	0.9933
	all Sites	487	13 - 72		0.9827	0.8306	1.1707	0.9917

11.9 Glucose (Glu)

NOTE:

The information associated with Glu in this chapter is NOT available in the USA at the release of this user manual.

Glu, the concentration of Glucose, is measured by amperometry. It is the key molecule of carbonhydrate metabolism.

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

11.9.1 Intended Use/Indications for Use

The Glucose test is intended for use by trained medical professionals as an in vitro diagnostic device for the quantitative testing of samples of arterial, venous and capillary blood in the laboratory or at the point of care in hospitals, nursing homes or other clinical care institutions.

Glucose measurements are used in the diagnosis and treatment of carbohydrate metabolism disorders including diabetes mellitus, idiopathic hypoglycemia and of pancreatic islet cell tumors.

11.9.2 Traceability

Glucose values assigned to calibrant, controls, and calibration verification controls are traceable to NIST standards.

11.9.3Performance Characteristics

Imprecision was evaluated by running 3 levels of EDAN i15 Blood Gas and Electrolyte Control in duplicate each run, two runs per day, for a total of 20 days on one EDAN i15 Blood Gas and Chemistry Analysis System. The protocol was based on methods described in CLSI EP5-A3, *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – 3rd Edition.*

Glu Precision in Aqueous Blood Gas and Electrolyte Control						
Sample	Mean (mmol/L)	N	Within-Run SD	Within-Run CV	Within-laboratory Precision SD	Within-laboratory Precision CV
Level 1	4.29	80	0.149	3.48%	0.168	3.92%
Level 2	10.26	80	0.283	2.76%	0.301	2.93%
Level 3	14.70	80	0.398	2.71%	0.470	3.20%

Linearity in Whole Blood

Whole blood samples collected from healthy volunteers in vacuum blood collection tubes with lithium heparin were modified to obtain a range of values for Glu approaching its analytical measurement range by the addition of Glu solution. The evaluation demonstrated equivalent, linear performance over the analytical measurement range for Glu in samples from syringes and from glass capillary tubes.

Whole Blood from Syringe							
Measurand	No. of Levels	Claimed Measuring Range	Specimen Range	% of claimed range	Slope	Intercept	r value
Glu	7	1.1 ~ 38.9	0.7 ~ 41.9	109%	1.0131	-0.015	0.9986

NOTE:

Linearity across claimed measurement range in samples introduced from Syringe.

Whole Blood from Capillary							
Measurand	No. of Levels	Claimed Measuring Range	Specimen Range	% of claimed range	Slope	Intercept	r value
Glu	7	1.1 ~ 38.9	0.5 ~ 40.0	104%	0.9704	0.216	0.9995

NOTE:

Linearity across claimed measurement range in samples introduced from glass Capillary.

Detection limits were determined by obtaining the standard deviation of sample measurements from repeated measurements of samples with a relevant low concentration. To determine LoB, zero level samples were prepared and measured on three EDAN i15 instruments with two lots of Test Cartridges and three lots of Calibrator Fluid Packs to obtain blank measurements (N=180). To determine the LoD and LoQ, whole blood samples with low levels of analyte (approximately 1 to 5 x LoB) were measured on two instruments (N=180). The LoQ was determined based on the inter - assay precision (%CV). The limit of quantitation (LoQ) is based on an accuracy goal of 0.33 mmol/L. The accuracy goal was met and therefore, the results of the study are presented in the following table:

Measurand	LoB	LoD	LoQ	Claimed Measurement Range
Glu	0.3 mmol/L	0.6 mmol/L	0.9mmol/L	1.1 – 38.9 mmol/L

Correlation to Predicate System and Measuring Range

In two clinical sites (one POC and one laboratory) used for the evaluation of bias on patient samples, the protocol in CLSI Document EP09c Measurement Procedure Comparison and Bias Estimation Using Patient Samples was applied in which each sample was measured in duplicate on both the EDAN i15 and its predicate device. All testing was performed using discarded patient samples collected into either B-D

Vacutainer lithium heparin tubes or B-D balanced heparin arterial sampling syringes. One POC site and one LAB site utilized the iSTAT1 as the comparator device and are combined for presentation below. The measuring range is based on the linearity results.

Measurand	Site	Nr.	Range	Claimed Range	Slope	Intercept	Std Error	r-value
Glu mmol/L	POC 4	105	1.60– 33.0	1.10- 38.9 96%	0.9979	0.0216	0.8153	0.9947
	LAB 1b	102	1.40- 37.9		0.9926	0.1324	0.7635	0.9957
	all Sites	207	1.40 – 37.9		0.9955	0.0810	0.7873	0.9952

11.10 Lactate (Lac)

NOTE:

The information associated with Lac in this chapter is NOT available in the USA at the release of this user manual.

Lac, the concentration of Lactate, is measured by amperometry. It is the product from cell anaerobic respiration.

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

11.10.1 Intended Use/Indications for Use

The Lactate test is intended for use by trained medical professionals as an in vitro diagnostic device for the quantitative testing of samples of arterial, venous and capillary in the laboratory or at the point of care in hospitals, nursing homes or other clinical care institutions.

Lactate measurements are used to evaluate the acid-base status and are used in the diagnosis and treatment of lactic acidosis (abnormally high acidity of the blood).

11.10.2 Traceability

Certified standard reference material for lactate is not available at present. Lactate values assigned to controls and calibration verification materials are traceable to a working calibrator prepared from L (+) Lactic acid from Sigma-Aldrich Co., Item Number 46937(1),>99% purity.

11.10.3 Performance Characteristics

Imprecision was evaluated by running 3 levels of EDAN i15 Blood Gas and Electrolyte Control in duplicate each run, two runs per day, for a total of 20 days on one EDAN i15 Blood Gas and Chemistry Analysis System. The protocol was based on methods described in CLSI EP5-A3, *Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – 3rd Edition.*

Lac Precision in Aqueous Blood Gas and Electrolyte Control						
Sample	Mean (mmol/L)	N	Within-Run SD	Within-Run CV	Within-laboratory Precision SD	Within-laboratory Precision CV
Level 1	0.50	80	0.06	12.02%	0.06	12.64%
Level 2	2.34	80	0.05	2.15%	0.06	2.48%
Level 3	6.21	80	0.15	2.38%	0.16	2.61%

Linearity in Whole Blood

Whole blood samples collected from healthy volunteers in vacuum blood collection tubes with lithium heparin were modified to obtain a range of values for each measurand approaching their analytical measurement range by the addition of Lac solution or dilution. The evaluation demonstrated equivalent, linear performance over the analytical measurement range for all measurands in samples from syringes and from glass capillary tubes.

Whole Blood from Syringe							
Measurand	No. of Levels	Claimed Measuring Range	Specimen Range	% of claimed range	Slope	Intercept	r value
Lac	7	0.3 ~ 20	0.16 ~ 20.50	103%	1.0003	-0.102	0.9996

NOTE:

Linearity across claimed measurement range in samples introduced from Syringe.

Whole Blood from Capillary							
Measurand	No. of Levels	Claimed Measuring Range	Specimen Range	% of claimed range	Slope	Intercept	r value
Lac	7	0.3 ~ 20	0.14 ~ 21.72	110%	1.0271	-0.368	0.9979

NOTE:

Linearity across claimed measurement range in samples introduced from glass Capillary.

Correlation to Predicate System and Measuring Range

In two clinical sites (one POC and one laboratory) used for the evaluation of bias on patient samples, the protocol in CLSI Document EP09c Measurement Procedure Comparison and Bias Estimation Using Patient Samples was applied in which each sample was measured in duplicate on both the EDAN i15 and its predicate device. All testing was performed using discarded patient samples collected into either B-D Vacutainer lithium heparin tubes or B-D balanced heparin arterial sampling syringes. One POC site and one LAB site utilized the iSTAT1 as the comparator device and are combined for presentation below. The measuring range is based on the linearity results.

Measurand	Site	Nr.	Range	Claimed Range	Slope	Intercept	Std Error	r-value
Lac mmol/L	POC 4	105	0.60– 19.50	0.30- 20.00 97%	0.9795	0.1426	0.6745	0.9883
	LAB 1b	102	0.30- 18.90		0.9595	-0.0050	0.5079	0.9918
	all Sites	207	0.30 – 19.50		0.9775	0.0328	0.6107	0.9900

Chapter 12 Interfering Substances

The following table represents substances that were tested that demonstrated a significant interference on test results. The blood sample value listed in the following table is the recommended concentration, the actual test sample is very close to the recommended value.

Measurand	Interfering Substance	Concentration Tested	Blood Sample Value	Absolute Difference in pH Units
pH	Acetaminophen	20.01 mg/dL	pH: 7.5	-0.034
			pH: 7.3	< |0.02|
	Bromide (NaBr)	185.20 mg/dL	pH: 7.5	-0.027
			pH: 7.3	< |0.02|
	Ethanol	400 mg/dL	pH: 7.5	-0.024
			pH: 7.3	< |0.02|
	Hematocrit	20% PCV	pH: 7.5	< |0.02|
			pH: 7.3	-0.022
	Heparin (Heparin lithium salt)	58.82 mg/dL	pH: 7.5	< |0.02|
			pH: 7.3	-0.034
	Hydroxyurea	182.52 mg/dL	pH: 7.5	< |0.02|
			pH: 7.3	-0.031
	Iodide (NaI)	37.94 mg/dL	pH: 7.5	< |0.02|
			pH: 7.3	-0.025
	Potassium Chloride	59.64 mg/dL	pH: 7.5	-0.036
			pH: 7.3	< |0.02|
	Sodium Chloride	117 mg/dL	pH: 7.5	-0.024
			pH: 7.3	-0.021
	Sodium Oxalate	168 mg/dL	pH: 7.5	< |0.02|
			pH: 7.3	-0.032
Measurand	**Interfering Substance**	**Concentration Tested**	**Blood Sample Value**	**% Difference**
pCO_2	Acetaminophen	20.01 mg/dL	pCO_2: 70 mmHg	< |8%|
			pCO_2: 40 mmHg	10.15%
	Acetylsalicylic acid	39.09 mg/dL	pCO_2: 70 mmHg	< |8%|
			pCO_2: 40 mmHg	8.01%
	Ethanol	400 mg/dL	pCO_2: 70 mmHg	< |8%|
			pCO_2: 40 mmHg	9.54%
	Iodide (NaI)	37.94 mg/dL	pCO_2: 70 mmHg	-8.69%
			pCO_2: 40 mmHg	-10.00%
	Potassium Chloride	59.64 mg/dL	pCO_2: 70 mmHg	< |8%|
			pCO_2: 40 mmHg	11.15%
	Bicarbonate ($NaHCO_3$)	294 mg/dL	pCO_2: 70 mmHg	17.44%
			pCO_2: 40 mmHg	18.40%

pO_2	Acetylsalicylic acid	39.09 mg/dL	pO_2: 100 mmHg	< |9%|
			pO_2: 70 mmHg	-10.11%
	Hematocrit	20% PCV	pO_2: 100 mmHg	< |9%|
			pO_2: 70 mmHg	12.13%
	Lactic Acid	90 mg/dL	pO_2: 100 mmHg	< |9%|
			pO_2: 70 mmHg	9.74%
	pCO_2	60 mmHg	pO_2: 160 mmHg (Hct≈55% PCV)	< |9%|
			pO_2: 160 mmHg (Hct≈35% PCV)	9.60%
	Salicylic acid	59.94 mg/dL	pO_2: 100 mmHg	< |9%|
			pO_2: 70 mmHg	14.98%
	Sodium Chloride	117 mg/dL	pO_2: 100 mmHg	< |9%|
			pO_2: 70 mmHg	9.22%
	Bicarbonate ($NaHCO_3$)	294 mg/dL	pO_2: 100 mmHg	-14.46%
			pO_2: 70 mmHg	< |9%|
Na^+	Calcium Chloride	55.50 mg/dL	Na^+: 150 mmol/L	3.26%
			Na^+: 130 mmol/L	4.99%
	Dobutamine hydrochloride	22.30 mg/dL	Na^+: 150 mmol/L	< |3%|
			Na^+: 130 mmol/L	5.62%
K^+	Acetylsalicylic acid	65.22 mg/dL	K^+: 5 mmol/L	17.21%
			K^+: 3 mmol/L	< |10%|
	Dobutamine hydrochloride	22.30 mg/dL	K^+: 5 mmol/L	< |10%|
			K^+: 3 mmol/L	13.97%
	Hydroxybutyrate	208 mg/dL	K^+: 5 mmol/L	12.28%
			K^+: 3 mmol/L	16.87%
	Iodide (NaI)	37.94 mg/dL	K^+: 5 mmol/L	< |10%|
			K^+: 3 mmol/L	24.20%
	Lactic Acid	90 mg/dL	K^+: 5 mmol/L	13.05%
			K^+: 3 mmol/L	< |10%|
	pCO_2	60 mmHg	K^+: 5 mmol/L	10.13%
			K^+: 3 mmol/L	< |10%|
	Salicylic acid	29.97 mg/dL	K^+: 5 mmol/L	10.54%
			K^+: 3 mmol/L	< |10%|
	Bicarbonate ($NaHCO_3$)	294 mg/dL	K^+: 5 mmol/L	21.51%
			K^+: 3 mmol/L	10.31%

Ca^{++}	Halothane	14.98 mg/dL	Ca^{++}: 2 mmol/L	< |10%|
			Ca^{++}: 1 mmol/L	11.20%
	Heparin (Heparin lithium salt)	58.82 mg/dL	Ca^{++}: 2 mmol/L	-12.68%
			Ca^{++}: 1 mmol/L	-14.06%
	Magnesium Chloride	47.61 mg/dL	Ca^{++}: 2 mmol/L	13.91%
			Ca^{++}: 1 mmol/L	16.86%
	Bicarbonate ($NaHCO_3$)	294 mg/dL	Ca^{++}: 2 mmol/L	-27.07%
			Ca^{++}: 1 mmol/L	-21.17%
	Phosphate (NaH_2PO_4)	24 mg/dL	Ca^{++}: 2 mmol/L	-12.14%
			Ca^{++}: 1 mmol/L	-12.34%
	Sodium Oxalate	168 mg/dL	Ca^{++}: 2 mmol/L	-94.16%
			Ca^{++}: 1 mmol/L	-86.21%
Cl^-	Acetylsalicylic acid	39.09 mg/dL	Cl^-: 110 mmol/L	7.72%
			Cl^-: 90 mmol/L	5.11%
	Albumin	3 g/dL	Cl^-: 110 mmol/L	5.13%
			Cl^-: 90 mmol/L	7.19%
	Bromide (NaBr)	185.20 mg/dL	Cl^-: 110 mmol/L	< |5%|
			Cl^-: 90 mmol/L	6.38%
	Iodide (NaI)	37.94 mg/dL	Cl^-: 110 mmol/L	-7.60%
			Cl^-: 90 mmol/L	-11.76%
	Potassium Thiocyanate	20.06 mg/dL	Cl^-: 110 mmol/L	10.81%
			Cl^-: 90 mmol/L	13.41%
	Salicylic acid	29.97 mg/dL	Cl^-: 110 mmol/L	11.28%
			Cl^-: 90 mmol/L	9.88%
	Bicarbonate ($NaHCO_3$)	294 mg/dL	Cl^-: 110 mmol/L	7.72%
			Cl^-: 90 mmol/L	8.79%
	Sodium Oxalate	168 mg/dL	Cl^-: 110 mmol/L	5.01%
			Cl^-: 90 mmol/L	6.47%
Hct	Albumin	3 g/dL	Hct: 55% PCV	10.29%
			Hct: 35% PCV	13.65%
	Bromide (NaBr)	185.20 mg/dL	Hct: 55% PCV	< |6%|
			Hct: 35% PCV	-6.98%
	Calcium Chloride	55.50 mg/dL	Hct: 55% PCV	-7.23%
			Hct: 35% PCV	-6.13%
	Dextran	3 g/dL	Hct: 55% PCV	< |6%|
			Hct: 35% PCV	10.24%.
	Dobutamine hydrochloride	22.30 mg/dL	Hct: 55% PCV	< |6%|
			Hct: 35% PCV	7.76%
	Ethanol	400 mg/dL	Hct: 55% PCV	< |6%|
			Hct: 35% PCV	-6.61%
	Magnesium Chloride	47.61 mg/dL	Hct: 55% PCV	-6.40%
			Hct: 35% PCV	-9.39%
	Potassium Chloride	59.64 mg/dL	Hct: 55% PCV	-6.27%
			Hct: 35% PCV	< |6%|
	Sodium Chloride	117 mg/dL	Hct: 55% PCV	< |6%|
			Hct: 35% PCV	-6.36%
	Bicarbonate($NaHCO_3$)	58.8 mg/dL	Hct: 55% PCV	< |6%|
			Hct: 35% PCV	-7.72%

Measurand	Interfering Substances	Concentration Tested	Blood Sample Value	Absolute Difference in Glu(mmol/L) or % Difference
Glu	Ascorbic acid	6mg/dL	Glu：12.2 mmol/L	< |10%|
			Glu：2.2 mmol/L	0.67 mmol/L
	Ascorbic acid	1.75mg/dL	Glu：12.2 mmol/L	/
			Glu：2.2 mmol/L	< |10%|
	Salicylic acid	60 mg/dL	Glu：12.2 mmol/L	< |10%|
			Glu：2.2 mmol/L	< |10%|
	Acetaminophen	20mg/dL	Glu：12.2 mmol/L	< |10%|
			Glu：2.2 mmol/L	0.98 mmol/L
	Acetaminophen	5.2mg/dL	Glu：12.2 mmol/L	/
			Glu：2.2 mmol/L	< |10%|
	Hydroxyurea	405μmol/L	Glu：12.2 mmol/L	14.75%
			Glu：2.2 mmol/L	1.72 mmol/L
	Hydroxyurea	135μmol/L	Glu：12.2 mmol/L	< |10%|
			Glu：2.2 mmol/L	0.53 mmol/L
	Hydroxyurea	101.25μmol/L	Glu：12.2 mmol/L	/
			Glu：2.2 mmol/L	< |0.33 mmol/L |
	Sodium bromide	37.5mmol/L	Glu：12.2 mmol/L	< |10%|
			Glu：2.2 mmol/L	< |10%|
	Ethanol	130mmol/L	Glu：12.2 mmol/L	< |10%|
			Glu：2.2 mmol/L	< |10%|
	Acetylsalicylic acid	167μmol/L	Glu：12.2 mmol/L	< |10%|
			Glu：2.2 mmol/L	< |10%|
	Dopamine	0.09 mg/dL	Glu：12.2 mmol/L	< |10%|
			Glu：2.2 mmol/L	< |10%|
	Dobutamine	10mg/dL	Glu：12.2 mmol/L	< |10%|
			Glu：2.2 mmol/L	< |10%|
	Heparin lithium	330IU/dL	Glu：12.2 mmol/L	< |10%|
			Glu：2.2 mmol/L	< |10%|
	Pralidoxime iodide	128 μg / mL	Glu：12.2 mmol/L	< |10%|
			Glu：2.2 mmol/L	< |10%|
	Sodium thiocyanate	898μmol/L	Glu：12.2 mmol/L	-15.64%
			Glu：2.2 mmol/L	< |10%|
	Sodium thiocyanate	299μmol/L	Glu：12.2 mmol/L	< |10%|
			Glu：2.2 mmol/L	/
	Uric acid	23.5 mg/dL	Glu：12.2 mmol/L	49.72%
			Glu：2.2 mmol/L	4.03 mmol/L
	Uric acid	7.2mg/dL	Glu：12.2 mmol/L	< |10%|
			Glu：2.2 mmol/L	< |10%|
	β-HB	16mmol/L	Glu：12.2 mmol/L	< |10%|
			Glu：2.2 mmol/L	< |10%|
	Acetoacetic acid	10mmol/L	Glu：12.2 mmol/L	< |10%|
			Glu：2.2 mmol/L	< |10%|
	Ibuprofen	50mg/dL	Glu：12.2 mmol/L	< |10%|
			Glu：2.2 mmol/L	< |10%|

Glu	L-Dopa	0.75 mg/dL	Glu：12.2 mmol/L	< |10%|
			Glu：2.2 mmol/L	< |10%|
	Acetylcysteine	920μmol/L	Glu：12.2 mmol/L	< |10%|
			Glu：2.2 mmol/L	< |10%|
	Oxalate	90mmol/L	Glu：12.2 mmol/L	< |10%|
			Glu：2.2 mmol/L	< |10%|
	Citrate salt	50mmol/L	Glu：12.2 mmol/L	< |10%|
			Glu：2.2 mmol/L	< |10%|
	Bilirubin	50 mg/dL	Glu：12.2 mmol/L	< |10%|
			Glu：2.2 mmol/L	< |10%|
	Cholesterol	500mg/dL	Glu：12.2 mmol/L	< |10%|
			Glu：2.2 mmol/L	< |10%|
	Creatinine	15 mg/dL	Glu：12.2 mmol/L	< |10%|
			Glu：2.2 mmol/L	< |10%|
	EDTA	0.1 mg/dL	Glu：12.2 mmol/L	< |10%|
			Glu：2.2 mmol/L	< |10%|
	Galactose	60 mg/dL	Glu：12.2 mmol/L	< |10%|
			Glu：2.2 mmol/L	< |10%|
	Gentisic acid	1.8 mg/dL	Glu：12.2 mmol/L	< |10%|
			Glu：2.2 mmol/L	< |10%|
	Reduced Glutathione	4.6 mg/dL	Glu：12.2 mmol/L	< |10%|
			Glu：2.2 mmol/L	< |10%|
	Maltose	480 mg/dL	Glu：12.2 mmol/L	< |10%|
			Glu：2.2 mmol/L	< |0.33 mmol/L |
	Mannitol	1800 mg/dL	Glu：12.2 mmol/L	-13.23%
			Glu：2.2 mmol/L	< |0.33 mmol/L |
	Mannitol	600 mg/dL	Glu：12.2 mmol/L	< |10%|
			Glu：2.2 mmol/L	/
	Methyldopa	2 mg/dL	Glu：12.2 mmol/L	< |10%|
			Glu：2.2 mmol/L	< |0.33 mmol/L |
	Tolbutamide	72 mg/dL	Glu：12.2 mmol/L	< |10%|
			Glu：2.2 mmol/L	< |10%|
	Triglycerides	1500 mg/dL	Glu：12.2 mmol/L	< |10%|
			Glu：2.2 mmol/L	< |10%|
	Xylose	600 mg/dL	Glu：12.2 mmol/L	23.21%
			Glu：2.2 mmol/L	1.83 mmol/L
	Xylose	167.76 mg/dL	Glu：12.2 mmol/L	< |10%|
			Glu：2.2 mmol/L	0.74 mmol/L
	Xylose	54 mg/dL	Glu：12.2 mmol/L	/
			Glu：2.2 mmol/L	< |10%|
	Sorbitol	0.09 mg/dL	Glu：12.2 mmol/L	< |10%|
			Glu：2.2 mmol/L	< |10%|
	Na^+	180 mmol/L	Glu：12.2 mmol/L	< |10%|
			Glu：2.2 mmol/L	< |10%|
	Tolazamide	9 mg/dL	Glu：12.2 mmol/L	< |10%|
			Glu：2.2 mmol/L	< |10%|

Measurand	Interfering Substance	Concentration Tested	Blood Sample Value	Absolute Difference in Lac (mmol/L) or % Difference
Lac	Ascorbic acid	6mg/dL	Lac:5.0mmol/L	< |12%|
			Lac:1.0mmol/L	< |0.6mmol/L |
	Salicylic acid	60 mg/dL	Lac:5.0mmol/L	< |12%|
			Lac:1.0mmol/L	< |12%|
	Acetaminophen	20mg/dL	Lac:5.0mmol/L	< |12%|
			Lac:1.0mmol/L	1.24 mmol/L
	Acetaminophen	5.2mg/dL	Lac:5.0mmol/L	/
			Lac:1.0mmol/L	< |0.6mmol/L |
	Hydroxyurea	405μmol/L	Lac:5.0mmol/L	21.94%
			Lac:1.0mmol/L	1.00 mmol/L
	Hydroxyurea	135μmol/L	Lac:5.0mmol/L	< |12%|
			Lac:1.0mmol/L	< |12%|
	Sodium bromide	37.5mmol/L	Lac:5.0mmol/L	< |12%|
			Lac:1.0mmol/L	< |12%|
	L-Cysteine	0.75mmol/L	Lac:5.0mmol/L	< |12%|
			Lac:1.0mmol/L	< |12%|
	Acetic acid	10mmol/L	Lac:5.0mmol/L	< |12%|
			Lac:1.0mmol/L	< |12%|
	Acetaldehyde	0.6mg/dL	Lac:5.0mmol/L	< |12%|
			Lac:1.0mmol/L	< |12%|

NOTE：

- ✓ The addition of approx. 50×10^9/L WBC to a blood sample with approx. 6.1×10^9/L WBC causes an increase in Hct %PCV measured by the EDAN i15 relative to spun hematocrit %PCV by 4.43 %PCV (absolute) or 11.07% (relative) exceeding the Total Allowable Error defined in CLIA'88.
- ✓ Hemolysis will increase the potassium measurement on i15 system due to release of potassium from the red blood cells. When the amount of hemoglobin in plasma is increased by approx.500 mg/dL, the increase in K^+ measurement tested on i15 system is about 35.77% ; when the amount of hemoglobin in plasma is increased by 100 mg/dL, the increase in K^+ measurement tested on i15 system is about 29.13%.

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

Appendix 1 Specifications

A1.1 Environment Requirements

Blood Gas and Chemistry Analyzer	Usage	Temperature	10 – 31 °C (50 – 88 °F)
		Humidity	25% - 80% (non-condensing)
		Ambient Pressure	57 - 106.6 kPa (428 – 800 mmHg)
	Transport and Storage	Temperature	-20 – 60 °C (-4 – 140 °F)
		Humidity	25% - 93% (non-condensing)
		Ambient Pressure	40 - 106.6 kPa (300 – 800 mmHg)

A1.2 Analyzer Specifications

Size	315 × 238 × 153mm (12.4 × 9.4 × 6.0 in) (length × width × height)	
Weight	3.8 Kg (8.4 lbs) (rechargeable battery included, adaptor not included)	
LCD Screen	7 inch, 800*480, Color TFT	
Power	Power Supply Input	100V - 240V~
	Input Current	1.2 A - 0.5 A
	Frequency	50 Hz/60 Hz
	Rechargeable Battery	14.8 VDC/ 5000mAh
	Main Unit Input	19 VDC, 5.26 A
USB Interface	4 USB Interfaces	
Serial Port	DB9	
Bar Code Scanner	embedded	

A1.3 Performance Specifications

Sample Volume	80 uL
Test Time	It takes no more than 55s from sampling to display of test results.

A1.4 Printer

Printer	Built-in thermal printer, thermal printer paper
Paper Width	50 mm(1.2 in)

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 24 hours
Rated Capacity	5000mAh
Rated voltage	14.8 V
Charge Mode	Constant voltage/current
Charge Current (standard)	$0.2C_5A$
Charge Temperature	0 °C - +45 °C (+32 °F - +113 °F)
Operating Temperature	-20 °C - +60 °C (-4 °F - +140 °F)
Storage	Short Term (within 1 month): -20°C - +60°C (-4 ºF - +140 ºF) Middle Term(within 3 months): -20°C - +45°C (-4 ºF - +113 ºF) Long Term (within 1 year): -20°C - +25°C (-4 ºF - +77 ºF)
Cycle Life	≥300 times

A1.6 Safety Specifications

Comply with	IEC 61010-1:2017, IEC 61010-2-101:2018, IEC 61326-1:2012, IEC 61326-2-6:2012
Safety temperature	The system meets the requirements of IEC 61010-1: 2017.
Safety humidity range	Maximum relative humidity 80% for temperatures up to 31 °C(88°F) decreasing linearly to 50% relative humidity at 40 °C(104 °F) (non-condensing).
Pollution degree	2
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
OVERVOLTAGE CATEGORY	II
Ethernet	10/100BASE-T Fast Ethernet
Keyboard/mouse	USB mouse
Mode of operation	Continuous (Indoor use only)

Appendix 2 Measurement Ranges

A2.1 Measurement Ranges for Measured Parameters

Parameter	Measurement Range
pH	6.5~ 7.8
pO_2	10mmHg ~ 700mmHg
pCO_2	10.0mmHg ~ 150.0mmHg
K^+	2.0mmol/L ~ 9.0mmol/L
Na^+	100mmol/L ~ 180mmol/L
Cl^-	65mmol/L ~ 140mmol/L
Ca^{++}	0.25mmol/L ~ 2.50mmol/L
Hct	13%PCV ~ 72%PCV
Glu	1.1mmol/L ~ 38.9mmol/L
Lac	0.30mmol/L ~ 20.00mmol/L

A2.2 Measurement Ranges for Calculated Parameters

Parameter	Measurement Range	Unit
tHb(est)	2.9 ~ 27.7	g/dL
$ctCO_2$	1 ~ 100	mmol/L
cH^+	10.0 ~ 316.2	nmol/L
HCO_3^-act	1.0 ~ 99.9	mmol/L
HCO_3^-std	1.0 ~ 99.9	mmol/L
BE(ecf)	(-38.0) ~ (+38.0)	mmol/L
BE(B)	(-38.0) ~ (+38.0)	mmol/L
BB(B)	4.9 ~ 91.3	mmol/L
sO_2(est)	1 ~ 100	%
pO_2 (A-a)	0 ~ 733	mmHg
pO_2 (a/A)	0.00 ~ 1.00	
RI	0 ~ 73.30	
pO_2/FIO_2	10 ~ 3333	mmHg
Ca^{++}(7.4)	0.23 ~ 2.71	mmol/L
AnGap	(-137) ~ (+123)	mmol/L
cH^+ (T)	10.0 ~ 316.2	nmol/L
pH(T)	6.5 ~ 7.8	
pCO_2(T)	10.0 ~ 150.0	mmHg
pO_2(T)	10 ~ 700	mmHg
pO_2(A-a)(T)	0 ~ 733	mmHg
pO_2(a/A)(T)	0.00 ~ 1.00	
RI(T)	0 ~ 73.30	
pO_2(T)/FIO_2	10 ~ 3333	mmHg
mOsm	200.9 ~ 449.4	mOsm/L

Appendix 3 Reference Ranges

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

The hemoglobin calculation is an estimation based on a normal mean corpuscular hemoglobin concentration of 33.3%, and normal blood composition. The EDAN i15 hemoglobin estimation from samples with red cell dyscrasia, microcytosis or other hemoglobinopathies; hemodilution, marked leukocytosis or in-vitro hemolysis may vary significantly from hemoglobin measured by cyanmethemoglobin method. These conditions should warrant repeat testing by conventional laboratory methods.

Parameter	Reference Ranges	
	Arterial	**Venous**
pH	7.35-7.45[1]	7.32-7.43[1]
pO_2(mmHg)	83-108[1]	/
pCO_2 (mmHg)	35-45[2.4]	/
Lac(mmol/L)	0.50 – 1.60[3.4]	0.60-2.20[3.4]
Na^+(mmol/L)	136-145[1]	
K^+(mmol/L)	3.4-4.5[1]	
Cl^-(mmol/L)	98-109[2]	
Ca^{++}(mmol/L)	1.15-1.33[1]	
Glu(mmol/L)	3.9-6.1[4]	
Hct (%PCV)	**Reference Ranges**	
	Female	**Male**
	36-46 [5]	41-53 [5]

Bibliography:

[1] Tietz Textbook of Clinical Chemistry and Molecular Diagnostics-Fourth Edition, Carl A. Burtis and Edward R. Ashwood, eds. (Westline Elsevier Inc., 2006)

[2] B.E. Statland, Clinical Decision Levels for Lab Tests (Oradell, N.J. 07649:Medical Economic Books,1987)

[3] Tietz Textbook of Clinical Chemistry-Second Edition, Carl A, Burtis and E.R.Ashwood, eds.(Philadelphia W.B.Saunders Company, 1994

[4] Medical Affairs authority of National Health and Family Planning Commission of P. R. C. National Guide to Clinical Laboratory Procedures (Fourth Edition), Publication of the People's Health Press, 2014

[5] Reference Ranges Table in Laboratory medicine: the selection and interpretation of clinical laboratories studies, D.A. Noe and R.C. Rock, eds., Williams & Wilkins, Baltimore, 1994, p.878.

Appendix 4 EMC Information

NOTE:

- ✓ The system complies with the emission and immunity requirements of IEC61326.
- ✓ The system has been designed and tested to CISPR 11 Class A. In a domestic environment it may cause radio interference, in which case, you may need to take measures to mitigate the interference.
- ✓ The electromagnetic environment should be evaluated prior to operation of the system.
- ✓ Do not use the system in close proximity to sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these may interfere with the proper operation.

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

<table>
<tr><th colspan="3">Guidance and manufacture's declaration – electromagnetic emission</th></tr>
<tr><td colspan="3">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.</td></tr>
<tr><th>Emission test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions CISPR 11</td><td>Group 1</td><td>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.</td></tr>
<tr><td>RF emissions CISPR 11</td><td>Class A</td><td rowspan="3">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.</td></tr>
<tr><td>Harmonic emissions IEC/EN 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions IEC/EN 61000-3-3</td><td>Complies</td></tr>
</table>

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/EN 61326 test level**	**Compliance level**	**Electromagnetic environment -guidance**
Electrostatic discharge (ESD) IEC/EN 61000-4-2	±4 kV contact ±8 kV air	±4 kV contact ±8 kV 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/EN 61000-4-4	±1 kV for power supply lines	±1 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC/EN 61000-4-5	±1 kV line to line ±2 kV line to ground	±1 kV line to line ±2 kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50 Hz/60 Hz) magnetic field IEC/EN 61000-4-8	3 A/m	3 A/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/EN 61000-4-11	0% UT (100% 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	0% UT (100% 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.

Conducted RF IEC/EN 61000-4-6 Radiated RF IEC/EN 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.0 GHz 1V/m 2.0GHz-2.7GHz	3 Vrms 3 V/m	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] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 UT is the a.c. mains voltage prior to application of the test level. **NOTE 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. **NOTE 3:** Over the frequency range 150kHz to 80 MHz, field strengths should be less than 3 *V/m*.			
[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 cannot 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.			

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 or 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 HIS/LIS Interface Guide

NOTE:

When connecting the i15 system to HIS/LIS, please set the TCP/IP port of HIS/LIS to 8000.

A6.1 Principle

A6.1.1 Communication Design

HL7 messages can be transmitted via network or serial port, and the i15 system utilises network to transmit them. EDAN HL7 protocol defines that the network connection uses C/S mode. The i15 system transmits data to HIS/LIS.

The i15 system and HIS/LIS should be in the same local area network to exchange data. The i15 system converts data to HL7 messages, and transmits them to HIS/LIS. HIS/LIS also transmits HL7 messages to the i15 system.

Figure A6-1 System Design

A6.1.2 Data Transmission

The i15 system transmits ORU messages only in the unsolicited transmission mode, and receives acknowledgements from HIS/LIS. If HIS/LIS engineers require the i15 system should handle the acknowledgements, it will also transmit response messages.

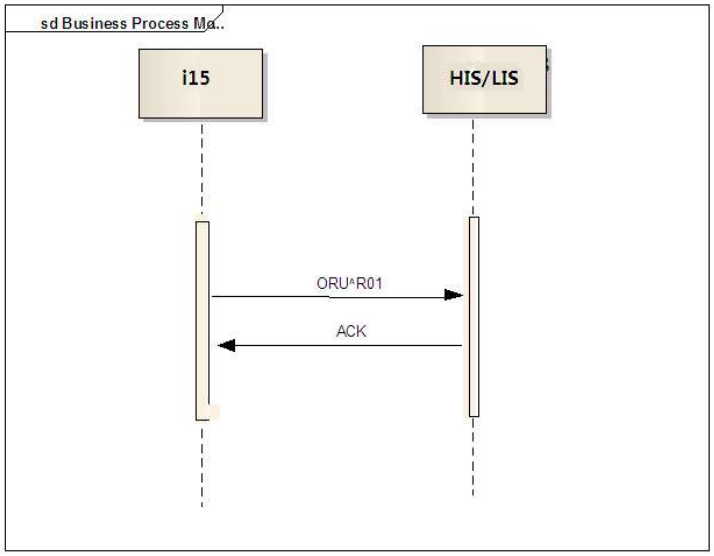


Figure A6-2 Data Transmission

A6.1.3 HL7 Lower Layer Protocol (MLLP)

To label the edges of HL7 messages, HL7 lower layer protocol is utilized.

The format is shown below:

0x0B	HL7 Message	0x1C	0x0D

Figure A6-3 HL7 Message Diagram

- ✓ If messages begin with ASCII<VT> characters, hexadecimal is represented as 0x0B.
- ✓ If messages end with ASCII<FS> and <CR>, hexadecimal is represented as 0x1C and 0x0D.

NOTE:

- ✓ Only when the service application transmits original HL7 data should there be start characters and end characters. If the service application selects XML format, the diagram above is not applicable. There are only HL7 messages, and they are encoded into XML format.

A6.1.4 Message Encoding Types

The i15 system utilizes UTF8 to encode and decode messages. If HIS/LIS does not utilize UTF8, it should add UTF8.

A6.2 HL7 Messages

A6.2.1 Message Syntax

For details about HL7 message syntax, please refer to HL7 Standards.

Each HL7 message consists of some segments, and segments are ended with <CR>.

Each segment consists of a three-character segment name and variable numbers of data fields. Data fields consist of components and subcomponents. Separators are defined in the MSH segment.

For example:

MSH|^~\&|||||||ORU^R01|0001|P|2.4

The five separators behind MSH are used to separate fields, components and subcomponents. Although they can be any non-text character, the following characters are recommended in HL7 Standards:

Character	Definition
|	Field separator
^	Component separator
&	Subcomponent separator
~	Repetition separator
\	Escape character

Message Rules: [ ] represents the segment can be selected.

{ } represents that the segment can be repeated 0, once, or many times.

A6.2.2 Supporting Message Types

The following message types are supported:

Patient Results / QC Results: ORU^R01.

A6.2.3 ACK Messages

The structure of acknowledgement messages is as follows:

MSH Message Header

MSA Message Acknowledgement

Where the MSA segment contains a confirmation code and message control ID. If it is an error, there will be an error string.

MSH|^~\&|EDAN|i15|LIS||20130929174802||ACK^R01|1|P|2.4||||0|| UNICODE UTF-8|||

MSA|AA|1|Message accepted

A6.2.4 Report Transmission

A6.2.4.1 ORU^R01 Messages

Patient results and QC results are transmitted to HIS/LIS in the form of ORU^R01

messages.

The rules for ORU^R01 messages are as follows: "MSH {[PID [PD1] <NK1> <NTE> [PV1 [PV2]]] {[ORC] OBR <NTE> [CTD] {[OBX] <NTE>} <FT1> <CTI>}} [DSC]". Where, PID segment is for patient information. OBR contains sample ID and the time when OBX data are generated. OBX segment depicts the parameter values at OBR.

A6.2.4.2 Patient Results

Patient results contain the following information:

- Item Information (Test Time, Item Name)
- Sample Information (Sample ID, Sample Type, Operator ID)
- Patient Information
- Test Results

The transmission structure of patient results is as follows:

ORU Observational Results (Unsolicited) Description

MSH Message Header (Item Name, Message Date)

PID Patient Information (Patient ID, Sex)

OBR Observation Report (Sample ID, Sample Type, Operator ID)

{OBX} Test Results (Test Date, Patient Information, Measured Results, Calculated Results, Calibration Results)

A6.2.4.3 QC Results

QC results contain the following information:

- Item Information (Current Date, Item Name)
- QC Related Information (Test Date, QC Name, QC Type, Lot Number, Level, Operator ID)
- Test Results (Parameter Name, Value, Unit, Status (In Control, Out of Control, Calibration Failure), Reference Range, Calibration Result)

The transmission structure of QC results is as follows:

ORU Observational Results (Unsolicited) Description

MSH Message Header (Item Name, Test Date)

OBR QC Results (QC Name, QC Type, Lot Number, Level, Operator ID)

OBX Test Results (QC Results)

A6.3 Appendix

A6.3.1 Message Segment

A6.3.1.1 MSH

For example:

MSH|^~\&|EDAN|i15^M17A02080002|LIS||20130929174802||ORU^R01|1|P|2.4||||0||UNICODE UTF-8|||

The following fields of the MSH Segment are utilized:

No.	Length	Type	Field Name	Description
1.			Field Separator 1	It contains segment ID and the first field separator. It defines field separators of the remaining parts of a message.
2.	4	ST	Encoding Characters	It contains component separators, repetition separators, escape characters, and subcomponent separators (^~\&).
3.	180	HD	Sending Application	It is Edan by default.
4.	180	HD	Sending Facility	Product Model
5.	180	HD	Receiving Application	It is HIS/ LIS by default.
6.	180	HD	Receiving Facility	Not Present
7.	26	TS	Date/Time of Message	It is the UTC time of the system.
8.	40	ST	Security	Not Present, Retain
9.	13	CM_MSG_TYPE	Message Type	For example, ORU^R01. ORU^R01 messages are mainly used to transmit test results in HL7. The i15 system uses them to transmit patient results/ QC results to HIS/LIS.
10.	20	ST	Message Control ID	It identifies a message. The i15 system number messages from 1.
11.	3	PT	Processing ID	It is P (Product).
12.	60	VID	Version ID	HL7 Protocol Version: 2.4 (Default Setting)
13.	15	NM	Sequence Number	Not Present, Retain
14.	180	ST	Continuation Pointer	Not Present, Retain
15.	2	ID	Accept Acknowledgment Type	Not Present, Retain

16.	2	ID	Application Acknowledgment Type	The i15 system uses it as result type: 0- Patient Result; 1- Control Result; 2- Calibration Verification Result.
17.	3	ID	Country Code	Not Present, Retain
18.	16	ID	Character Set	It is UNICODE UTF-8 by default.
19.	250	CE	Principal Language Of Message	Not Present, Retain
20.	20	ID	Alternate Character Set Handling Scheme	Not Present, Retain
21.	10	ID	Conformance Statement ID	Not Present, Retain

Remarks: This segment appears in all the messages. The 3rd and 4th fields are made by the HIS/LIS developer. The 5th field should be EDAN, the 6th field should be i15, the 10th and 16th fields should be integer, and other fields should be strings.

A6.3.1.2 OBR (Patient Sample)

OBR segments are used to transmit clinical order information about test reports.

For patient results data (when MSH-16 is 0), Test Time, Sample ID, and Sample Type should be transmitted.

For example: OBR|||20131009001|EDAN^i15|||20131001093000|||||||Artrial|opr001

The following fields are used:

No.	Length	Type	Field Name	Description
1	4	SI	Set ID-OBR	Not Present
2	22	EI	Placer Order Number	Not Present
3	22	EI	Filler Order Number	The i15 system uses it as sample ID.
4	250	CE	Universal Service ID	Manufacturer ^ Model: EDAN^i15
5	2	ID	Priority	Not Present, Retain.
6	26	TS	Requested Date/Time	Not Present, Retain.
7	26	TS	Observation Date/Time	The i15 uses it as test time.
8	26	TS	Observation End Date/Time	Not Present, Retain
9	20	CQ	Collection Volume	Not Present, Retain
10	250	XCN	Collector Identifier	Not Present, Retain

11	1	ID	Specimen Action Code	Not Present, Retain
12	250	CE	Danger Code	Not Present, Retain
13	300	ST	Relevant Clinical Info.	Not Present
14	26	TS	Specimen Rcvd Date/Time	Not Present, Retain.
15	300	CM_SPECIMEN_SOURCE	Specimen Source	The i15 system uses it as sample type. There are six sample types: Arterial, Venous, Mixed Venous, Capillary, Aqueous, CPB.
16	250	XCN	Ordering Provider	The i15 system uses it as operator ID.
17	250	XTN	Order Call Back Phone Num	Not Present
18	60	ST	Placers Field Number1	Not Present
19	60	ST	Placers Field Number2	Not Present, Retain
20	60	ST	Fillers Field Number1	Not Present, Retain
21	60	ST	Fillers Field Number2	Not Present, Retain
22	26	TS	Results Rpt/Status Chg-dt	Not Present, Retain
23	40	CM_CHARGE_PRACTICE	Charge to Practice	Not Present, Retain
24	10	ID	Diagnostic Serv Sect ID	Not Present, Retain
25	1	ID	Result Status	Not Present, Retain
26	400	CM_PARENT_RESULT	Linked Results	Not Present, Retain
27	200	TQ	Quantity/Timing	Not Present, Retain
28	250	XCN	Result Copies to	Not Present, Retain
29	200	CM_PARENT_ORDER	Parent Accession#	Not Present, Retain
30	20	ID	Transportation Mode	Not Present, Retain
31	250	CE	Reason for Study	Not Present, Retain
32	200	CM_RESULT_PERSON	Principal Result Interpreter	Not Present, Retain
33	200	CM_RESULT_PERSON	Assistant Result Interpreter	Not Present, Retain
34	200	CM_RESULT_PERSON	Technician	Not Present, Retain
35	200	CM_RESULT_PERSON	Transcriptionist	Not Present, Retain

36	26	TS	Scheduled Date/Time	Not Present, Retain
37	4	NM	Number of Sample Containers	Not Present, Retain
38	60	CE	Transport Logistics of Collected Sample	Not Present, Retain
39	250	CE	Collector's Comment	Not Present, Retain
40	250	CE	Transport Arrangement Responsibility	Not Present, Retain
41	30	ID	Transport Arranged	Not Present, Retain
42	1	ID	Escort Required	Not Present, Retain
43	250	CE	Planned Patient Transport Comment	Not Present, Retain
44	250	CE	Ordering Facility Name	Not Present, Retain
45	250	CE	Ordering Facility Address	Not Present, Retain
46	250	CE	Ordering Facility Phone Number	Not Present, Retain
47	250	CE	Ordering Provider Address	Not Present, Retain

Remarks: This message segment is contained in ORU^R01 messages only. The 1st, 3rd, 37th fields should be integer, the 9th field should be floating-point, and other fields should be strings.

A6.3.1.3 OBR (QC)

For QC results (when MSH-16 is 1 or 2), QC Name, QC Type, Lot Number, Level, and Operator ID should be transmitted.

For example:

OBR||2|Calver|EDAN^i15|||2013100109300000||||||CommonQC|21219||opr001

OBR||2|LiquidCtl|EDAN^i15|||2013100109300000||||||CommonQC|21219||opr001

The following fields are used:

No.	Length	Type	Field Name	Description
1	4	SI	Set ID-OBR	Not Present
2	22	EI	Placer Order Number	The i15 system uses it as QC level: 1, 2, 3, 4, 5; Low, High.
3	22	EI	Filler Order Number	The i15 system uses it as QC name. Control: Control Calibration Verification: Calver

4	250	CE	Universal Service ID	Manufacturer ^ Model: EDAN^i15
5	2	ID	Priority	Not Present, Retain
6	26	TS	Requested Date/Time	Not Present, Retain
7	26	TS	Observation Date/Time	The i15 system uses it as QC test time.
8	26	TS	Observation End Date/Time	Not Present, Retain
9	20	CQ	Collection Volume	Not Present, Retain
10	250	XCN	Collector Identifier	Not Present, Retain
11	1	ID	Specimen Action Code	Not Present
12	250	CE	Danger Code	Not Present
13	300	ST	Relevant Clinical Info.	The i15 system uses it as QC type. Hct: HctQc Blood Gas and Electrolyte: BGQc
14	26	TS	Specimen Rcvd Date/Time	QC Solution Lot Number
15	300	CM_SPECIMEN_SOURCE	Specimen Source	Not Present
16	250	XCN	Ordering Provider	The i15 system uses it as operator ID
17	250	XTN	Order Call Back Phone Num	Not Present
18	60	ST	Placers Field Number 1	Not Present
19	60	ST	Placers Field Number 2	Not Present
20	60	ST	Fillers Field Number 1	Not Present
21	60	ST	Fillers Field Number 2	Not Present
22	26	TS	Results Rpt/Status Chg-dt	Not Present
23	40	CM_CHARGE_PRACTICE	Charge to Practice	Not Present, Retain
24	10	ID	Diagnostic Serv Sect ID	Not Present, Retain
25	1	ID	Result Status	Not Present
26	400	CM_PARENT_RESULT	Linked Results	Not Present, Retain
27	200	TQ	Quantity/Timing	Not Present, Retain
28	250	XCN	Result Copies to	Not Present, Retain
29	200	CM_PARENT_ORDER	Parent Accession#	Not Present, Retain
30	20	ID	Transportation Mode	Not Present, Retain
31	250	CE	Reason for Study	Not Present, Retain

32	200	CM_RESULT_PERSON	Principal Result Interpreter	Not Present, Retain
33	200	CM_RESULT_PERSON	Assistant Result Interpreter	Not Present, Retain
34	200	CM_RESULT_PERSON	Technician	Not Present, Retain
35	200	CM_RESULT_PERSON	Transcriptionist	Not Present, Retain
36	26	TS	Scheduled Date/Time	Not Present, Retain
37	4	NM	Number of Sample Containers	Not Present, Retain
38	60	CE	Transport Logistics of Collected Sample	Not Present, Retain
39	250	CE	Collector's Comment	Not Present, Retain
40	250	CE	Transport Arrangement Responsibility	Not Present, Retain
41	30	ID	Transport Arranged	Not Present, Retain
42	1	ID	Escort Required	Not Present, Retain
43	250	CE	Planned Patient Transport Comment	Not Present, Retain
44	250	CE	Ordering Facility Name	Not Present, Retain
45	250	CE	Ordering Facility Address	Not Present, Retain
46	250	CE	Ordering Facility Phone Number	Not Present, Retain
47	250	CE	Ordering Provider Address	Not Present, Retain

Remarks: This message segment is contained in ORU^R01 messages only. The 1st, 11th, and 37th fields should be integer, and other fields should be strings.

A6.3.1.4 OBX

OBX are mainly used to transmit test information in report messages.

Patient results:

Patient Information (Patient ID, Temperature, Sex, etc.)

Test Results

For example:

Patient Results:

OBX|1|NM|0|pH|121|mmHg|-9^300|N||||||20131001093000||opr001

OBX|2|ST|2|O2MODE|RoomAir|||||||||20131001093000||opr001

QC Results:

Test Results (Parameter Name, Value, Unit, Status (In Control, Out of Control, Calibration Failure), Reference Range, Calibration Result)

OBX|1|NM|1|pH|121|mmHg|-9^300||||||undercontrol|20131001093000||opr001

No.	Length	Type	Field Name	Description
1	4	SI	Set ID-OBX	It determines different OBX segments.
2	2	ID	Value Type	It is used as result type. NM (numeric) is used for quantitative items, and ST (string) is used for qualitative items.
3	250	CE	Observation Identifier	The i15 system uses it as item ID. Measured Parameter: 0; Calculated Parameter: 1; Patient Information: 2.
4	20	ST	Observation Sub-ID	The i15 system uses it as item name, such as pH, Na^+, Ca^{++}.
5	65536	WILDCARD	Observation Value	The i15 system uses it as test value, such as 134, ???
6	250	CE	Units	Parameter unit, such as mmol/L, mmHg.
7	60	ST	Reference Range	The normal range for a parameter, such as 39^45.
8	5	IS	Abnormal Flags	Descriptions for the test result: L – Low; H – High; N - Normal; ***: Out of control, and QC-Lockout disabled; ↓: Lower than reference range; ↑: Higher than reference range.
9	5	NM	Probability	Not Present
10	2	ID	Nature of Abnormal Test	Not Present
11	1	ID	Observe Result Status	Not Present
12	26	TS	Date Last Obs Normal Values	Not Present, Retain

13	20	ST	User Defined Access Checks	Calibration Results: Pass, Fail; QC Results: In Control ,Out of Control, Calibration Failure
14	26	TS	Date/Time of the Observation	The i15 system uses it as test time.
15	250	CE	Producer's ID	Not Present, Retain
16	250	XCN	Responsible Observer	The i15 system uses it as operator ID.
17	250	CE	Observation Method	Not Present, Retain
18	22	EI	Equipment Instance Identifier	Not Present, Retain
19	26	TS	Date/Time of the Analysis	Not Present, Retain

Remarks: This message segment is contained in ORU^R01 messages only. The 1st, 3rd, and 9th fields should be integer, the 5th and 13th fields should be floating-point, and other fields should be strings.

A6.3.1.5 PID

PID segment is mainly used to build patient information. It is used in patient results only to transmit patient ID and sex. For example: PID|||PatientID|||||M.

The following fields are used:

No.	Length	Type	Field Name	Description
1	4	SI	Set ID-Patient ID	Not Present
2	20	CX	Patient ID(External ID)	Not Present
3	250	CX	Patient Identifier List	Patient ID, required.
4	20	CX	Alternate Patient ID	Not Present
5	250	XPN	Patient Name	Not Present
6	250	XPN	Mother's Maiden Name	Not Present
7	26	TS	Date/Time of Birth	Not Present
8	1	IS	Sex	Male: M; Female: F; Other: O; Unknown: U.
9	250	XPN	Patient Alias	Not Present
10	250	CE	Race	Not Present, Retain
11	250	XAD	Patient Address	Not Present
12	4	IS	County Code	Not Present
13	250	XTN	Phone Number-Home	Not Present
14	250	XTN	Phone Number-Business	Not Present, Retain
15	250	CE	Language-Patient	Not Present, Retain
16	250	CE	Marital Status	Not Present, Retain
17	250	CE	Religion	Not Present
18	250	CX	Patient Account Number	Not Present

19	16	ST	SSN Number-Patient	Not Present
20	25	DLN	Drivers License Number-Patient	Not Present
21	250	CX	Mother's Identifier	Not Present
22	250	CE	Ethnic Group	Not Present
23	250	ST	Birth Place	Not Present
24	1	ID	Multiple Birth Indicator	Not Present, Retain
25	2	NM	Birth Order	Not Present, Retain
26	250	CE	Citizenship	Not Present
27	250	CE	Veterans Military Status	Not Present, Retain
28	250	CE	Nationality	Not Present
29	26	TS	Patient Death Date and Time	Not Present
30	1	ID	Patient Death Indicator	Not Present
31	1	ID	Identity Unknown Indicator	Not Present
32	20	IS	Identity Reliability Code	Not Present
33	26	TS	Last Update Date/Time	
34	40	HD	Last Update Facility	
35	250	CE	Species Code	Not Present
36	250	CE	Breed Code	Not Present
37	80	ST	Strain	
38	250	CE	Production Class Code	

Remarks: This message segment is contained in ORU^R01 messages only. The 1st and 9th fields should be integer, the 24th and 30th fields should be bool data, and other fields should be strings.

A6.3.1.6 MSA

No.	Length	Type	Field Name	Description
1	2	ID	Acknowledgement Code	AA: Accept; AE: Error; AR: Reject.
2	20	ST	Message Control ID	It is the same as the MSH-10 of the sending facility.
3	80	ST	Text Message	A text log for an error or reject. It corresponds to the 6th field, and it is used to log error.
4	15	NM	Expected Sequence Number	Retain
5	1	ID	Delayed Ack Type	Retain
6	250	CE	Error Condition	Retain

Remarks: This message segment can be contained in ACK^R01, QCK^Q02, and ACK^Q03 messages.

A6.3.2 Examples

A6.3.2.1 Patient Results

Patient Results:

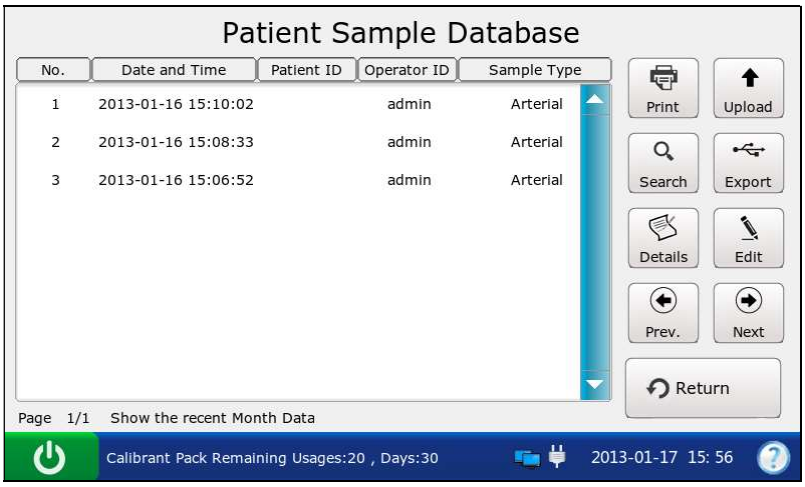


Figure A6-4 Patient Results

Measured Results:

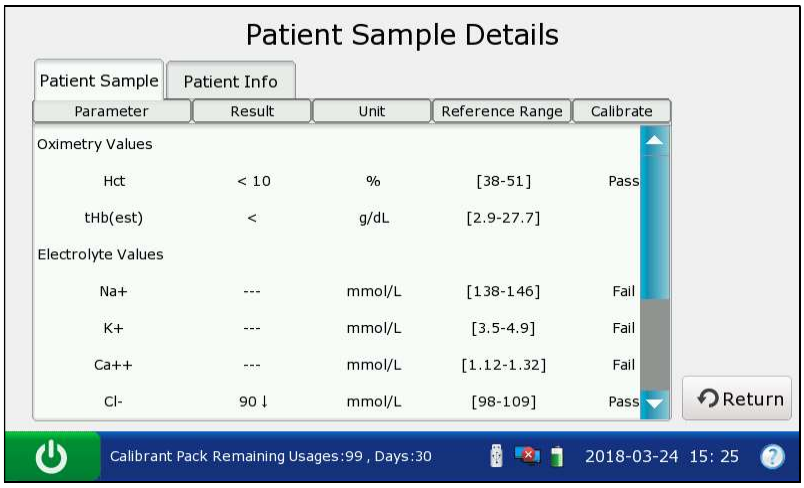


Figure A6-5 Measured Results

Patient Information:

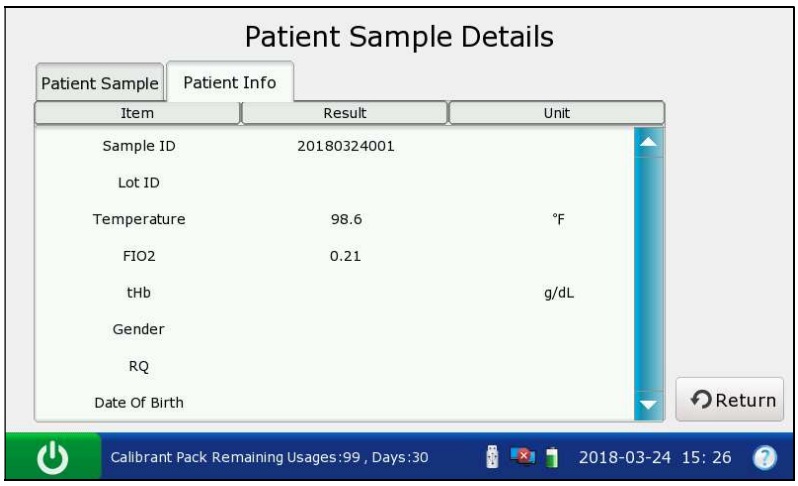


Figure A6-6 Patient Information

HL Data:

MSH|^~\&|EDAN|i15^M17A02080002|LIS||20131213162551||ORU^R01||P|2.4||||0||UNICODE UTF-8||||

PID|||1|||||U||||||||||||||||||||||||||||

OBR|||20131117002|EDAN^i15|||20131117043117|||||||CPB|edan|||||||||||||||||||||||||||||

OBX|0|ST|0|pH|---||6.500^8.000||||||Fail|20131117043117||edan||||

OBX|1|ST|0|pO2|24.3|kPa|1.3^93.3|***|||||Pass|20131117043117||edan||||

OBX|2|ST|0|pCO2|???|kPa|1.33^20.00||||||Pass|20131117043117||edan||||

OBX|3|ST|0|Na|>|mmol/L|100^180|180|||||Pass|20131117043117||edan||||

OBX|4|ST|0|K|8.2|mmol/L|2.0^9.0|***|||||Pass|20131117043117||edan||||

OBX|5|ST|0|Ca|0.58|mmol/L|0.25^2.50||||||Pass|20131117043117||edan||||

OBX|6|ST|0|Cl|>|mmol/L|65^140|140|||||Pass|20131117043117||edan||||

OBX|7|ST|0|Hct|24|%|10^75|***|||||Pass|20131117043117||edan||||

OBX|8|ST|1|tHbest|10|g/dL|3.4^25.5|||||||20131117043117||edan||||

OBX|9|ST|1|cH|120.5|nmol/L|10.0^316.2|||||||20131117043117||edan||||

OBX|10|ST|1|HCO3act10.1mmol/L|1.0^99.9|||||||20131117043117||edan||||

OBX|11|ST|1|HCO3std|12.3|mmol/L|1.0^99.9|||||||20131117043117||edan||||

OBX|12|ST|1|BEecf|???|mmol/L|-30.0^30.0|||||||20131117043117||edan||||

OBX|13|ST|1|BEB|6.3|mmol/L|-30.0^30.0|||||||20131117043117||edan||||

OBX|14|ST|1|BBB|???|mmol/L|13.1^82.4|||||||20131117043117||edan||||

OBX|15|ST|1|ctCO2|???|mmol/L|1^100|||||||20131117043117||edan||||

OBX|16|ST|2|HbType|Adult|||||||||20131117043117||edan||||

OBX|17|ST|2|PunctureSite|LR|||||||||20131117043117||edan||||

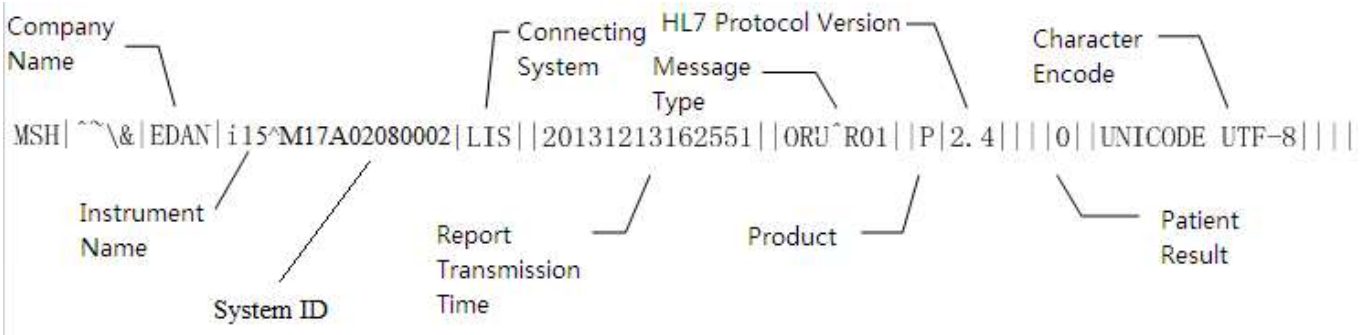
OBX|18|ST|2|VentMode|None|||||||||20131117043117||edan||||

OBX|19|ST|2|O2Mode|Room Air|||||||||20131117043117||edan||||

OBX|20|ST|2|Bypass|Pump Off|||||||||20131117043117||edan||||

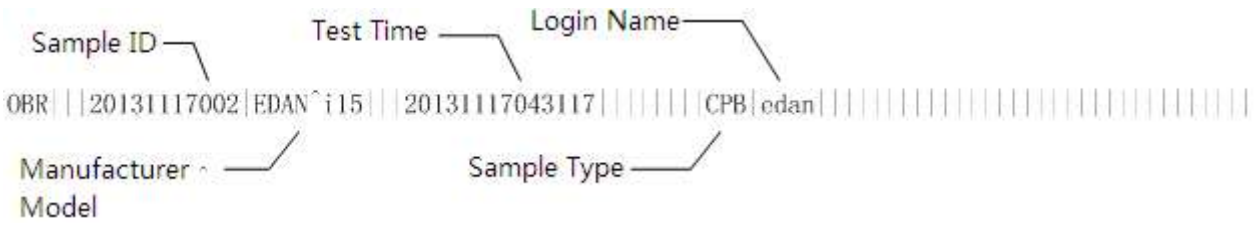
Data Field Definition Analysis

MSH Analysis:

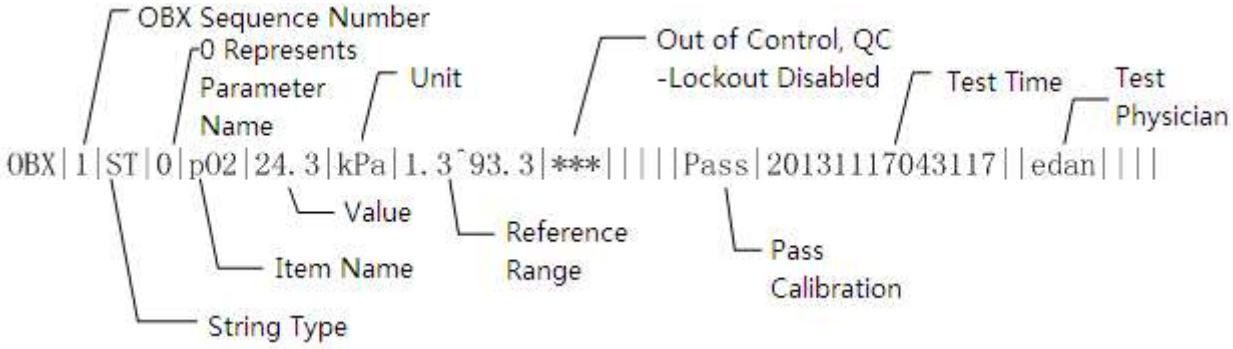


PID Analysis:

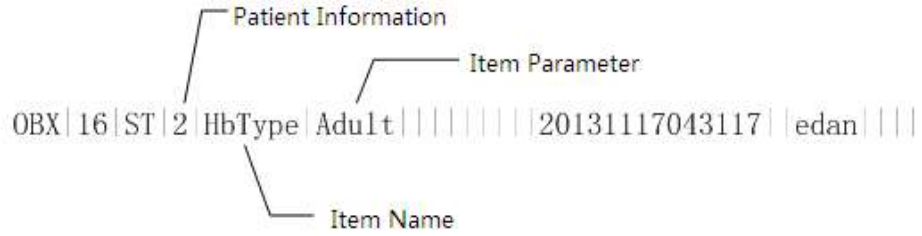
OBR Analysis:



OBX Analysis:



OBX Analysis:



A6.3.2.2 Control Results (BG)

Control Data:

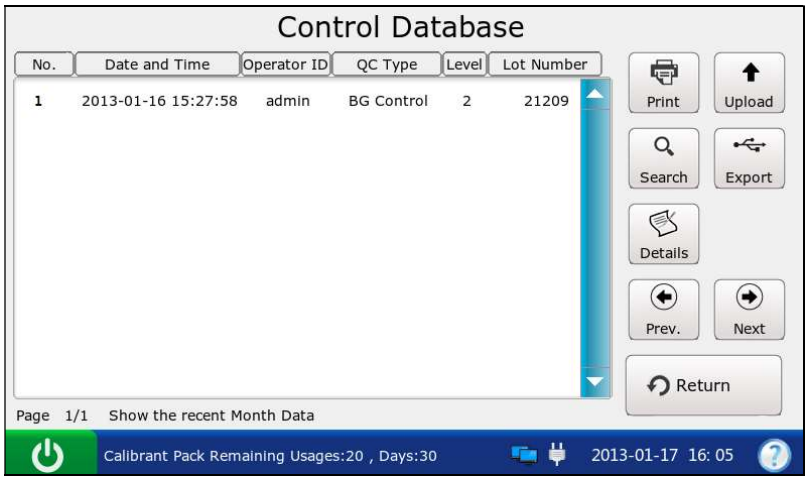


Figure A6-7 Control Data

Control Test Results:

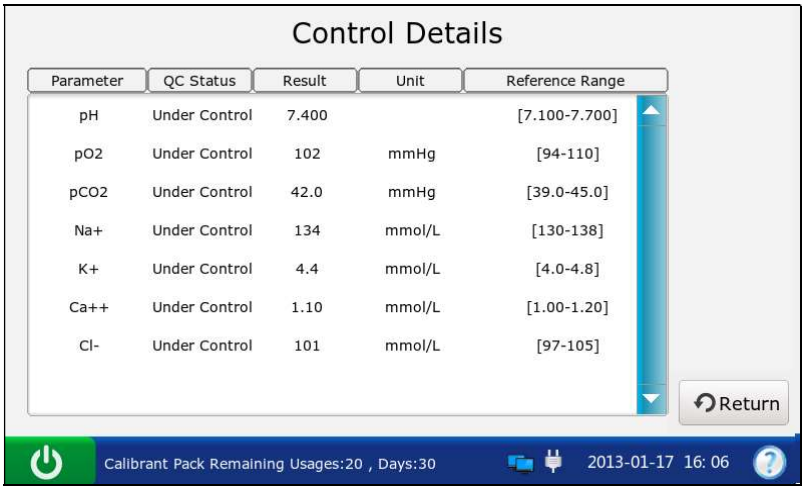


Figure A6-8 Control Test Results

HL7 Data:

MSH|^~\&|EDAN|i15^M17A02080002|LIS||20131213162901||ORU^R01||P|2.4||||1||UNICODE UTF-8||||

PID|||||||||||||||||||||||||||||||||||||||

OBR||1|Control|EDAN^i15^M17A02080002|||20131117040651||||||BGQc|00000000||edan|||||||||||||||||||||||||||||||

OBX|0|ST|0|pH|---||7.120^7.201||||||CaliFail|20131117040651||edan||||

OBX|1|ST|0|pO2|12.7|kPa|7.4^10.1||||||OutControl|20131117040651||edan||||

OBX|2|ST|0|pCO2|7.31|kPa|8.02^10.16||||||OutControl|20131117040651||edan||||

OBX|3|ST|0|Na|131|mmol/L|111^119||||||OutControl|20131117040651||edan||||

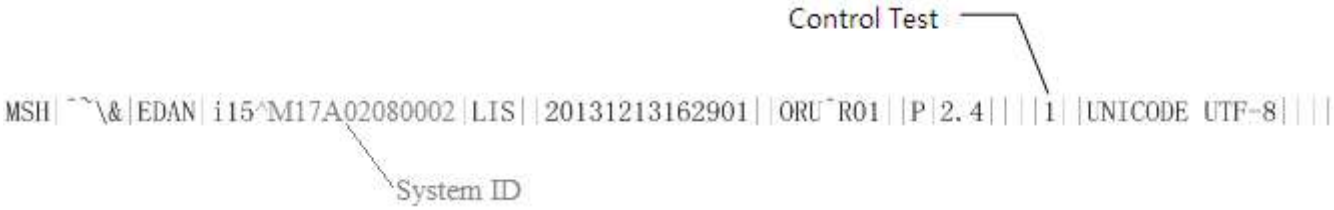
OBX|4|ST|0|K|3.4|mmol/L|1.4^2.4||||||OutControl|20131117040651||edan||||

OBX|5|ST|0|Ca|1.29|mmol/L|1.27^1.77||||||UnderControl|20131117040651||edan||||

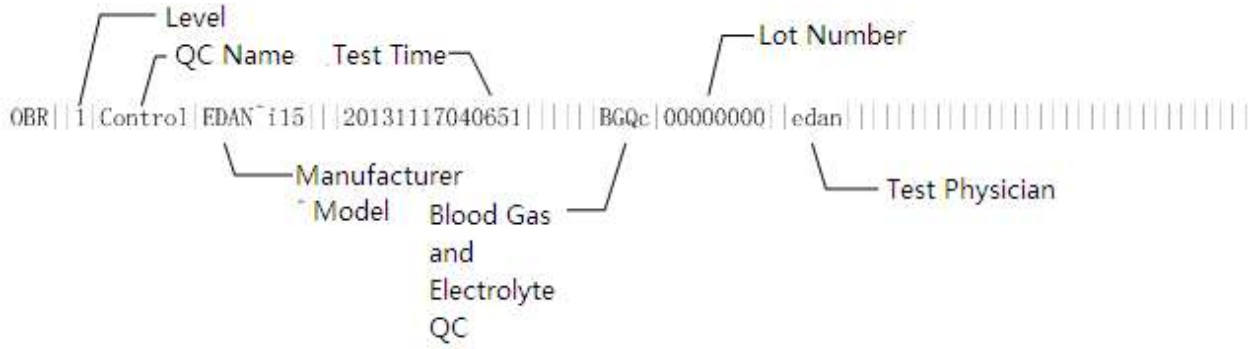
OBX|6|ST|0|Cl|???|mmol/L|73^81||||||OutControl|20131117040651||edan||||

Data Field Definition Analysis

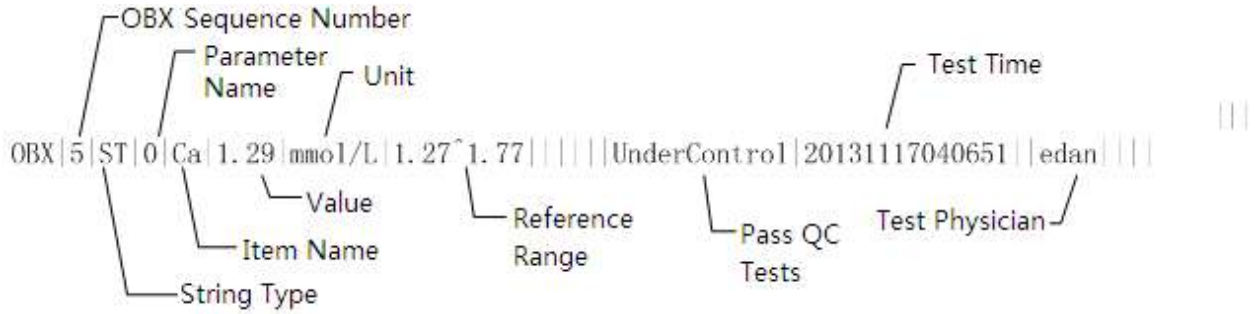
MSH Analysis:



OBR Analysis:



OBX Analysis:



A6.3.2.3 Calibration Verification Results (Hct)

Calibration Verification Data:

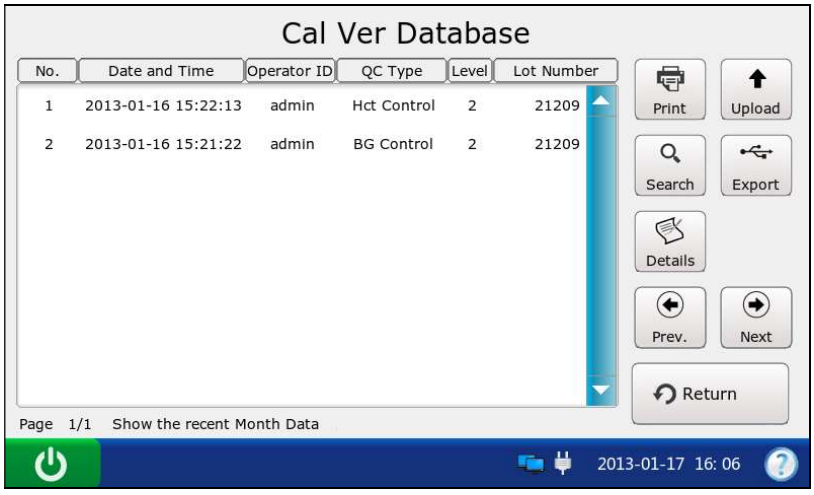


Figure A6-9 Calibration Verification Data

Calibration Verification Test Results:

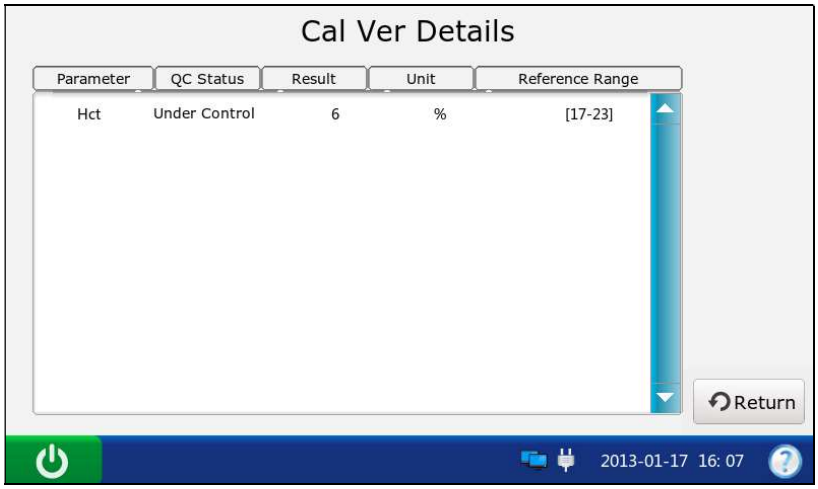


Figure A6-10 Calibration Verification Test Results

HL7 Data:

MSH|^~\&|EDAN|i15^M17A02080002|LIS||20131213163038||ORU^R01||P|2.4||||2||UNICODE UTF-8||||

PID|||||||||||||||||||||||||||||||||||||||

OBR||2|CalVer|EDAN^i15^M17A02080002|||20131117041311||||||HctQc|00000000||edan|||||||||||||||||||||||||||||||||

OBX|0|ST|0|Hct|6|%|17^23||||||OutControl|20131117041311||edan||||

Appendix 7 Order List

The following consumable materials' order information is only available in the USA.

Consumable Materials		Order Number	NOTE
BG8 Test Cartridge		83.67.960244	25 cartridges per box, 4 boxes per carton
BG3 Test Cartridge		83.67.960246	25 cartridges per box, 4 boxes per carton
BC4 Test Cartridge		83.67.960245	25 cartridges per box, 4 boxes per carton
CP50 Calibrant Fluid Pack		83.67.960242	one piece per carton
CP50 Calibrant Fluid Pack		83.67.960241	six pieces per carton
CP100 Calibrant Fluid Pack		83.67.960240	one piece per carton
CP100 Calibrant Fluid Pack		83.67.960239	six pieces per carton
External Electronic Simulator		83.67.341001	One piece
Capillary Adaptors		83.67.960155	pack of 100
Ampoule Adaptors		83.67.960255	pack of 50
EDAN i15 Blood Gas and Electrolyte Controls	Level 1	83.67.960247	5 ampoules per pack
	Level 2	83.67.960248	5 ampoules per pack
	Level 3	83.67.960249	5 ampoules per pack
EDAN i15 Hematocrit Controls	High	83.67.960250	5 ampoules per pack
	Low	83.67.960251	5 ampoules per pack

The following consumable materials' order information is only available in CE areas.

Consumable Materials	Order Number	NOTE
BG8 Test Cartridge (room temperature)	83.67.240995	25 cartridges per box, 4 boxes per carton
BG8 Test Cartridge (refrigerated)	83.67.960017	25 cartridges per box, 4 boxes per carton
BG3 Test Cartridge (room temperature)	83.67.240996	25 cartridges per box, 4 boxes per carton
BG3 Test Cartridge (refrigerated)	83.67.960018	25 cartridges per box, 4 boxes per carton

BC4 Test Cartridge (room temperature)	83.67.211295	25 cartridges per box, 4 boxes per carton
BC4 Test Cartridge (refrigerated)	83.67.960019	25 cartridges per box, 4 boxes per carton
BG10 Test Cartridge (room temperature)	83.67.960162	25 cartridges per box, 4 boxes per carton
BG10 Test Cartridge (refrigerated)	83.67.960164	25 cartridges per box, 4 boxes per carton
BG9 Test Cartridge (room temperature)	83.67.960168	25 cartridges per box, 4 boxes per carton
BG9 Test Cartridge (refrigerated)	83.67.960170	25 cartridges per box, 4 boxes per carton
BG4 Test Cartridge (room temperature)	83.67.960182	25 cartridges per box, 4 boxes per carton
BG4 Test Cartridge (refrigerated)	83.67.960184	25 cartridges per box, 4 boxes per carton
BG5 Test Cartridge (room temperature)	83.67.960275	25 cartridges per box, 4 boxes per carton
BG5 Test Cartridge (refrigerated)	83.67.960274	25 cartridges per box, 4 boxes per carton
BG9-Lac Test Cartridge (room temperature)	83.67.960369	25 cartridges per box, 4 boxes per carton
BG9-Lac Test Cartridge (refrigerated)	83.67.960370	25 cartridges per box, 4 boxes per carton
BC6 Test Cartridge (room temperature)	83.67.960276	25 cartridges per box, 4 boxes per carton
Micro-BC4 Test Cartridge (room temperature)	83.67.960423	25 cartridges per box, 4 boxes per carton
Micro-BG8 Test Cartridge (room temperature)	83.67.960425	25 cartridges per box, 4 boxes per carton
Micro-BG3 Test Cartridge (room temperature)	83.67.960426	25 cartridges per box, 4 boxes per carton
Micro-BG10 Test Cartridge (room temperature)	83.67.960426	25 cartridges per box, 4 boxes per carton
Micro-BG9 Test Cartridge (room temperature)	83.67.960431	25 cartridges per box, 4 boxes per carton
Micro-BG9-Lac Test Cartridge (room temperature)	83.67.960433	25 cartridges per box, 4 boxes per carton
Micro-BG4 Test Cartridge (room temperature)	83.67.960425	25 cartridges per box, 4 boxes per carton
Micro-BG5 Test Cartridge (room temperature)	83.67.960427	25 cartridges per box, 4 boxes per carton
Micro-BC6 Test Cartridge (room temperature)	83.67.960429	25 cartridges per box, 4 boxes per carton

MicroSample-BC4 Test Cartridge (room temperature)	83.67.960441	25 cartridges per box, 4 boxes per carton
MicroSample-BG8 Test Cartridge (room temperature)	83.67.960442	25 cartridges per box, 4 boxes per carton
MicroSample-BG3 Test Cartridge (room temperature)	83.67.960444	25 cartridges per box, 4 boxes per carton
MicroSample-BG10 Test Cartridge (room temperature)	83.67.960446	25 cartridges per box, 4 boxes per carton
MicroSample-BG9 Test Cartridge (room temperature)	83.67.960448	25 cartridges per box, 4 boxes per carton
MicroSample-BG9-Lac Test Cartridge (room temperature)	83.67.960451	25 cartridges per box, 4 boxes per carton
MicroSample-BG4 Test Cartridge (room temperature)	83.67.960453	25 cartridges per box, 4 boxes per carton
MicroSample-BG5 Test Cartridge (room temperature)	83.67.960455	25 cartridges per box, 4 boxes per carton
MicroSample-BC6 Test Cartridge (room temperature)	83.67.960457	25 cartridges per box, 4 boxes per carton
BC6 Test Cartridge (refrigerated)	83.67.960278	25 cartridges per box, 4 boxes per carton
Micro-BC4 Test Cartridge (refrigerated)	83.67.960422	25 cartridges per box, 4 boxes per carton
Micro-BG8 Test Cartridge (refrigerated)	83.67.960424	25 cartridges per box, 4 boxes per carton
Micro-BG3 Test Cartridge (refrigerated)	83.67.960427	25 cartridges per box, 4 boxes per carton
Micro-BG10 Test Cartridge (refrigerated)	83.67.960428	25 cartridges per box, 4 boxes per carton
Micro-BG9 Test Cartridge (refrigerated)	83.67.960430	25 cartridges per box, 4 boxes per carton
Micro-BG9-Lac Test Cartridge (refrigerated)	83.67.960432	25 cartridges per box, 4 boxes per carton
Micro-BG4 Test Cartridge (refrigerated)	83.67.960434	25 cartridges per box, 4 boxes per carton
Micro-BG5 Test Cartridge (refrigerated)	83.67.960436	25 cartridges per box, 4 boxes per carton
Micro-BC6 Test Cartridge (refrigerated)	83.67.960438	25 cartridges per box, 4 boxes per carton
MicroSample-BC4 Test Cartridge (refrigerated)	83.67.960440	25 cartridges per box, 4 boxes per carton
MicroSample-BG8 Test Cartridge (refrigerated)	83.67.960443	25 cartridges per box, 4 boxes per carton
MicroSample-BG3 Test Cartridge (refrigerated)	83.67.960445	25 cartridges per box, 4 boxes per carton

MicroSample-BG10 Test Cartridge (refrigerated)		83.67.960447	25 cartridges per box, 4 boxes per carton
MicroSample-BG9 Test Cartridge (refrigerated)		83.67.960449	25 cartridges per box, 4 boxes per carton
MicroSample-BG9-Lac Test Cartridge (refrigerated)		83.67.960450	25 cartridges per box, 4 boxes per carton
MicroSample-BG4 Test Cartridge (refrigerated)		83.67.960452	25 cartridges per box, 4 boxes per carton
MicroSample-BG5 Test Cartridge (refrigerated)		83.67.960454	25 cartridges per box, 4 boxes per carton
MicroSample-BC6 Test Cartridge (refrigerated)		83.67.960456	25 cartridges per box, 4 boxes per carton
CP50 Calibrant Fluid Pack		83.67.960195	one piece per carton
CP50 Calibrant Fluid Pack		83.67.960193	six pieces per carton
CP100 Calibrant Fluid Pack		83.67.241179	one piece per carton
CP100 Calibrant Fluid Pack		83.67.240999	six pieces per carton
External Electronic Simulator		83.67.341001	One piece
Capillary Adaptors		83.67.960155	pack of 100
Ampoule Adaptors		83.67.960255	pack of 50
EDAN i15 Blood Gas and Electrolyte Controls	Level 1	83.67.960304	5 ampoules per pack
	Level 2	83.67.960303	5 ampoules per pack
	Level 3	83.67.960302	5 ampoules per pack
EDAN i15 Hematocrit Control	High	83.67.960305	5 ampoules per pack
	Low	83.67.960306	5 ampoules per pack

The following test cartridge’s order information is only available in Southeast Asia, Middle East and Africa areas.

Consumable Materials	Order Number	NOTE
MicroSample-SC4Test Cartridge (room temperature)	83.67.960883	25 cartridges per box, 4 boxes per carton
MicroSample-SC4 Test Cartridge (refrigerated)	83.67.960884	25 cartridges per box, 4 boxes per carton

P/N: 01.54.455691
MPN: 01.54.455691031

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