IVD

CE 0168

i-Smart 300

BLOOD GAS ANALYZER

Operator's Manual

Software version 1.0.0.0

P/N 7983 Draft

July 2015

Operators should read the entire manual
before installing and operating the analyzer.

Contents

1. Introduction

Safety

General Warnings

- ❑ Use only the provided power cord and adapter.
- ❑ Do not use damaged power cord, adapter, or loose outlet.
- ❑ Never touch the power supply accessories with wet hands.
- ❑ Keep dust away from the outlet and power cord.
- ❑ Do not use or store any hot equipment or flammable material near the analyzer or power supply accessories.
- ❑ Do not allow water or foreign substances to get into the analyzer or power supply accessories.
- ❑ Do not directly look at the red light emitting from the barcode scanner as direct eye exposure to this light can damage vision.

General Caution

- ❑ Power cord must be plugged into a grounded outlet.
- ❑ The rear vent of the analyzer must be free of obstruction and not covered by cloth or any other material.
- ❑ Do not install or operate the analyzer in an area where ferromagnetic fields are generated (e.g., the MRI room).
- ❑ Before long term storage of the analyzer, remove the cartridge, turn off the power, and clean any contamination from the analyzer.
- ❑ There are no operator seviceable parts inside the product. Do not disassemble, repair, or modify the product.
- ❑ If electromechanical problems are suspected, call a service engineer to report the problems.
- ❑ When disposing the analyzer and provided electrical accessories, contact your local distributor where you purchased them. You must not discard this electrical/electronic product in domestic household waste.
- ❑ Changes or modifications not expressly approved by i-SENS, Inc. could void the purchaser’s authority to operate the equipment.

Safety, *continued*

Biohazard Caution

- ❑ All materials used in collecting blood and/or other samples from humans should be treated as biohazardous materials with the potential carrying infectious agents capable of producing disease.
- ❑ All biohazardous materials should be handled and disposed of in accordance with applicable rules and regulations of the hospital, laboratory, or other testing facility.
- ❑ Wear appropriate personal protective clothing (lab coat, gloves, goggles, etc.) before operating the analyzer.
- ❑ Be careful not to let the sample and/or collecting tools directly touch the mouth, eyes, mucus membranes, or any area with broken skin.
- ❑ Wash hands after collecting the sample or using the analyzer.

Symbols and Terms

Symbols

Symbol	Description
CE	CE mark (In Vitro Diagnostic Directive 98/79/EC)
IVD	*In vitro* diagnostics device
	Consult operating instructions
EC REP	Authorized representative in the European community
SN	Serial number
	Caution: Attention, see operating instructions
	Manufacturer
	Temperature limitation
REF	Catalogue number
LOT	Batch code
	Contains sufficient for <n> tests
	Use by
	Biological risk
	This marking indicates that you must not discard this electrical/electronic product in domestic household waste. Distributors of this product within the EU have taken the necessary step to comply with the Waste Electrical and Electronic Equipment (WEEE), Directive 2002/96/EC.
	Printer
	DC power port
O	Off (power)
I	On (power)

Symbols and Terms, *continued*

Terms

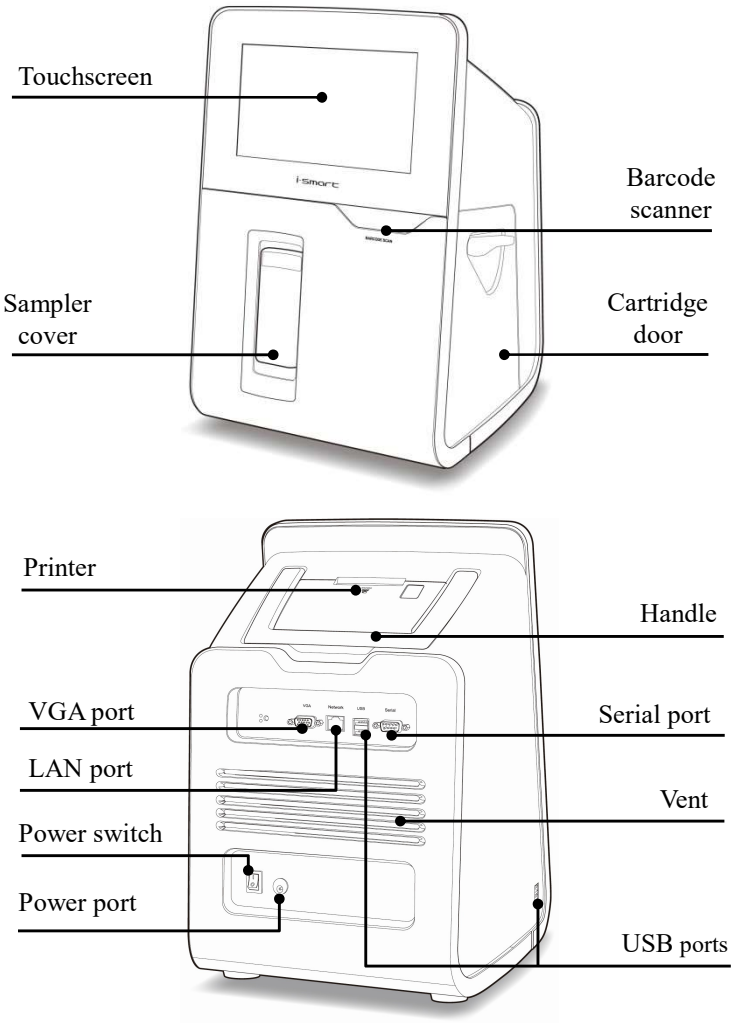
Term	Description
pH	Negative log of the hydrogen ion activity
***p*CO$_2$**	Partial pressure of carbon dioxide
***p*O$_2$**	Partial pressure of oxygen
***c*Na$^+$**	Concentration of sodium ion
cK$^+$	Concentration of potassium ion
***c*Ca^{2+}**	Concentration of calcium ion (ionized calcium)
***c*Cl$^-$**	Concentration of chloride ion
Hct	Hematocrit
Cal	Calibration
Cal 1	1-Point calibration
Cal 2	2-Point calibration
QC	Quality control
Warning	A statement that alerts the operator to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse of the device.
Caution	A statement that alerts the operator to the possibility of device malfunction, device failure, damage to the device or damage to other property associated with the use or misuse of the device.

Product Description

Intended Use

i-Smart 300 is an automated system that measures pH, pCO_2, pO_2, cNa^+, cK^+, cCl^-, cCa^{2+}, and hematocrit in whole blood.
It is intended for use in a point-of-care setting or laboratory environment.

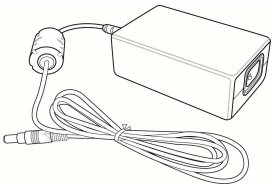
Analyzer



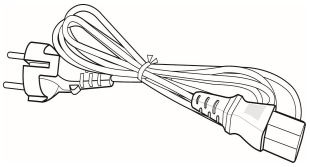
i-Smart 300 Analyzer

Product Description, *continued*

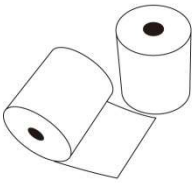
Accessories of analyzer



Power adapter

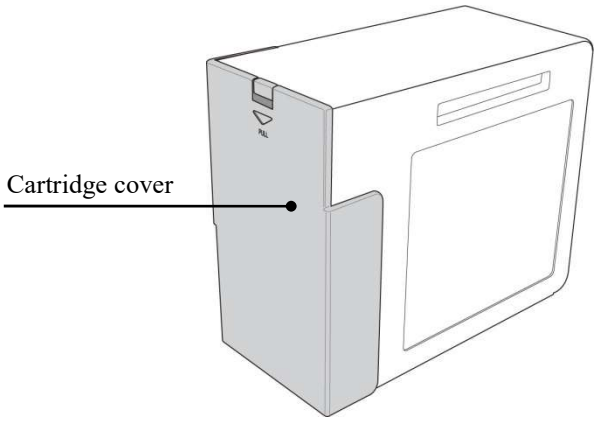


Power code



Printer papers

Cartridge



i-Smart 300 Cartridge

This page is intentionally left blank.

2. Installation

Installation Requirements

Unpacking

- ❑ Inspect the shipping package of the product for any signs of damage from shipment.
- ❑ Ensure all listed components are included in the package.

Environmental Requirements

- ❑ Location : indoors
- ❑ Temperature : 15 ~ 35°C
- ❑ Humidity : 5 ~ 85%, relative humidity
- ❑ Altitude : under 3,000 m

Note:

- ✓ The analyzer should be installed on a horizontal, stable surface in a well-ventilated area without direct sunlight or heat.
- ✓ Allow enough space for the cartridge door of the analyzer to open.
- ✓ Allow at least 10 cm of space from the back of the analyzer for adequate ventilation.
- ✓ This equipment has been tested and found to comply with the limits for a Class A digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference when the equipment is operated in a commercial environment. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instruction manual, may cause harmful interference to radio communications. Operation of this equipment in a residential area is likely to cause harmful interference in which case the user will be required to correct the interference at his own expense.

Electrical Requirements

- ❑ Volt AC : 100 ~ 240 Va.c., grounded electrical supply
- ❑ Amp : 1.5 A
- ❑ Frequency : 50/60 Hz
- ❑ Power cord : 3-wire, approved
- ❑ Power adapter : +24 Vd.c., 2.7 A (Output)

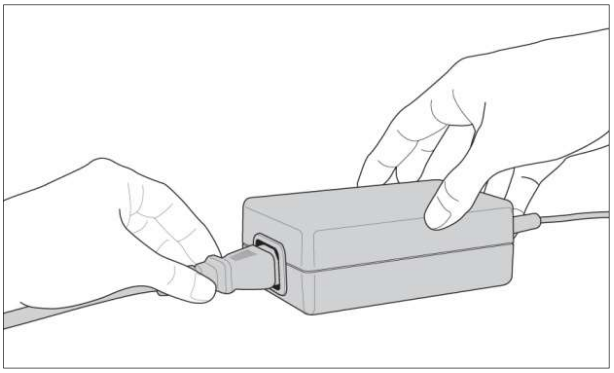
Power Cable Connection

Caution

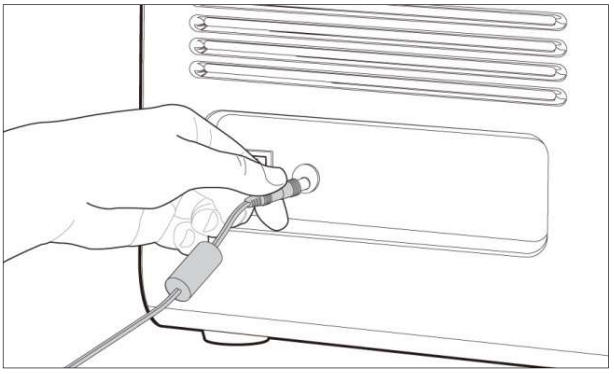
- ❑ Check that the power switch is in " O" (OFF) position.
- ❑ Always connect the power according to the steps described in this manual.
- ❑ Always use a grounded electrical outlet.
- ❑ Use only the power cord and power adapter provided by the manufacture.
- ❑ Electrical plugs and sockets vary by countries. If necessary, use appropriate power plug or power strips to connect the provided power cord to the outlet.

Connect Power Cable

1. Plug the power cord into the socket of the power adapter.



2. Plug the power adapter into the power port on the back of the analyzer.



3. Plug the power cord into an electrical outlet.

Power-On

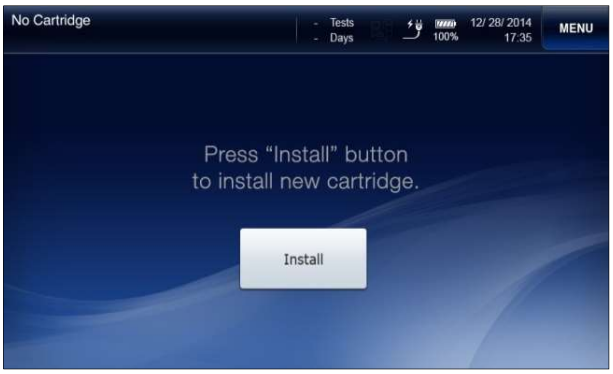
Caution

- ❑ Remove any attached USB memory device or network cable from the analyzer before turning the power switch on.

Turn Power Switch On

2. Facing the back of the analyzer, flip the black power switch on the lower left side, marked " I / O " to the " I " position.
3. The screen will turn on and the analyzer will boot.

4. If the boot is completed, the message of the last shutdown information will appear.



Power-On, *continued*

Turn Power Switch On, *continued*

5. Check that the power cord icon  appears at the bottom row of the screen.

Note:

✓ If the power cord icon  does not appear on the screen, check for any loose power connections between the analyzer and the electrical outlet.

✓ If no loose power connection is found and the power cord icon still does not appear, call a service engineer immediately.

6. Check the date and time of the analyzer and, if necessary, change date and/or time. Refer to ***3. Analyzer Settings***

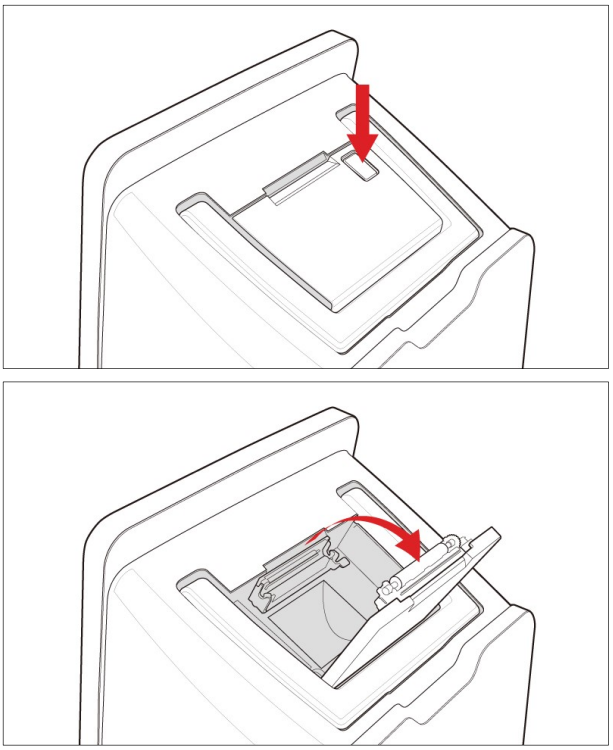
Note:

✓ Changing the date and time of the analyzer is only allowed before cartridge is installed on the analyzer. Once the cartridge is installed, the date and time cannot be changed until the cartridge is removed.

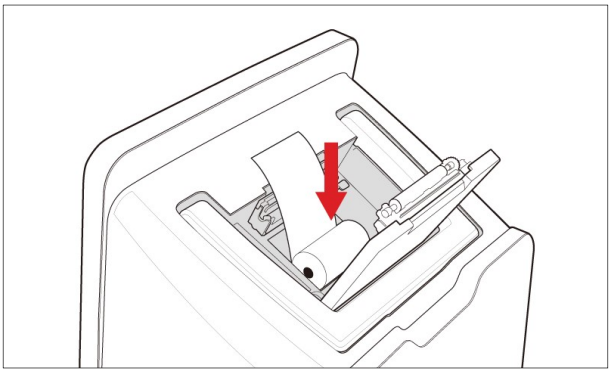
Printer Paper Installation

Install Printer Paper

1. Facing the back of the analyzer, push the **PUSH** button and flip down the printer cover.



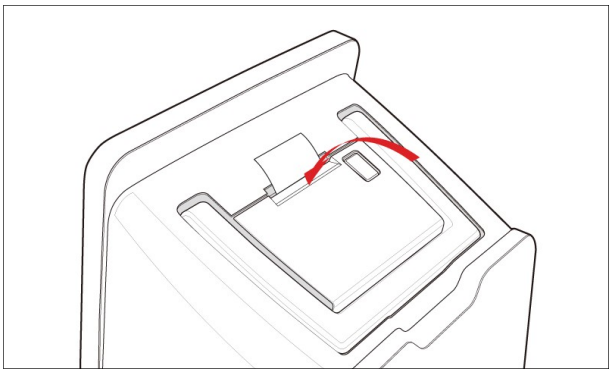
2. Place the paper roll into the paper compartment and place the end of the paper in parallel with the printer slot.



Printer Paper Installation, continued

Install Printer Paper, continued

3. Close the printer cover.



Note:

✓ The printer will cut the paper exposed to the outside automatically.

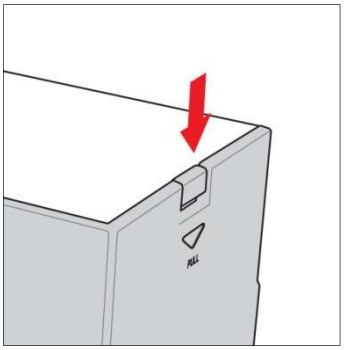
Cartridge Installation

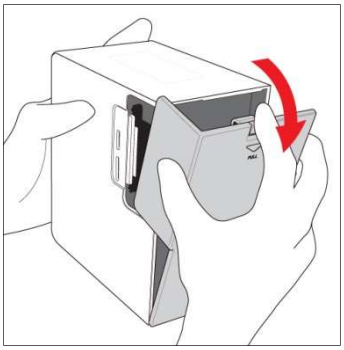
Install Cartridge

Note:

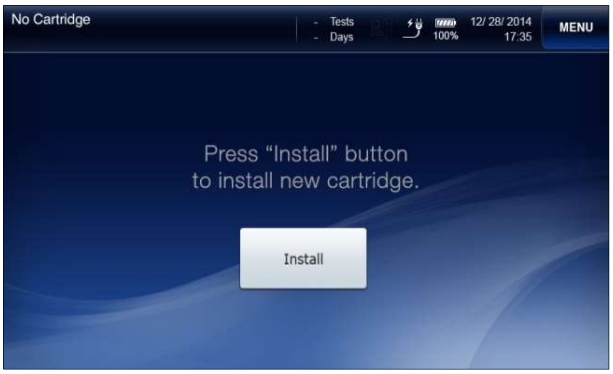
✓ After opening the cartridge, it must be installed directly to the analyzer.

1. Take out the cartridge from the cartridge box.
2. Press down the cover lock and remove the cartridge cover.





3. Press **Install** at the following screen



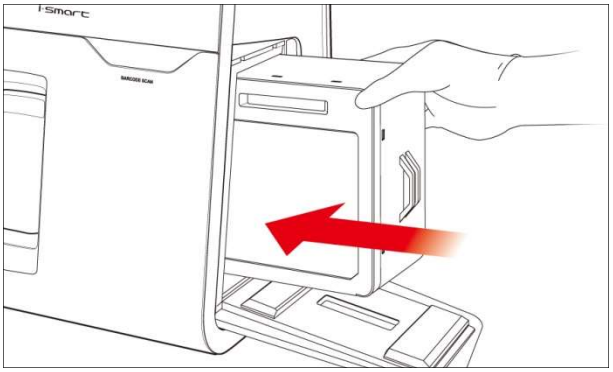
4. Slide down the lever on the cartridge door, open the cartridge door.

Cartridge Installation, *continued*

Install Cartridge, *continued*

5. Insert the new cartridge into the analyzer, follow the instructions on the screen.

6. Facing the cartridge label, insert the cartridge into the analyzer.



7. Close the cartridge door and slide up the lever on the cartridge door. If the door is properly locked, it will make a clicking sound.

Cartridge Installation, *continued*

Install Cartridge, ***continued***

8. If the RFID tag information of the cartridge is valid, the analyzer will change to the **Cartridge Warming-Up** screen.

9. The cartridge warming-up will take approximately 25 minutes.

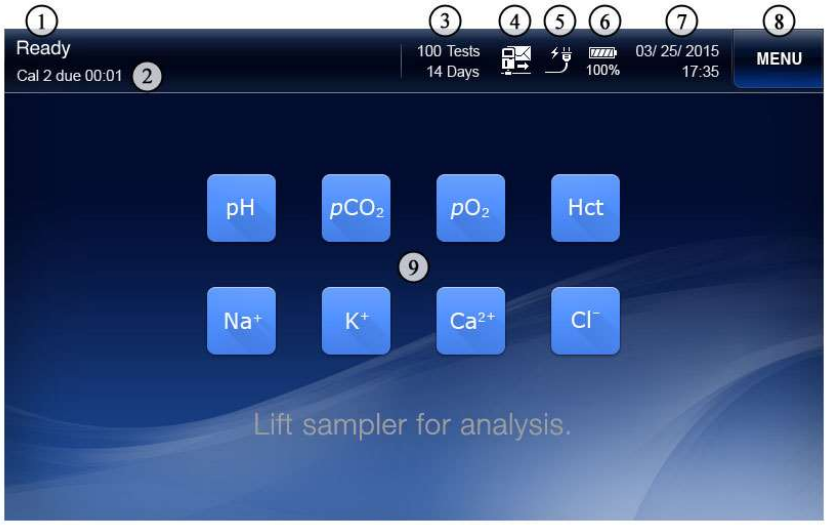
Note:

✓ Once the cartridge cover is removed, be careful with sharp edges of the cartridge parts inside.

3. Analyzer Setting

Screen Menus

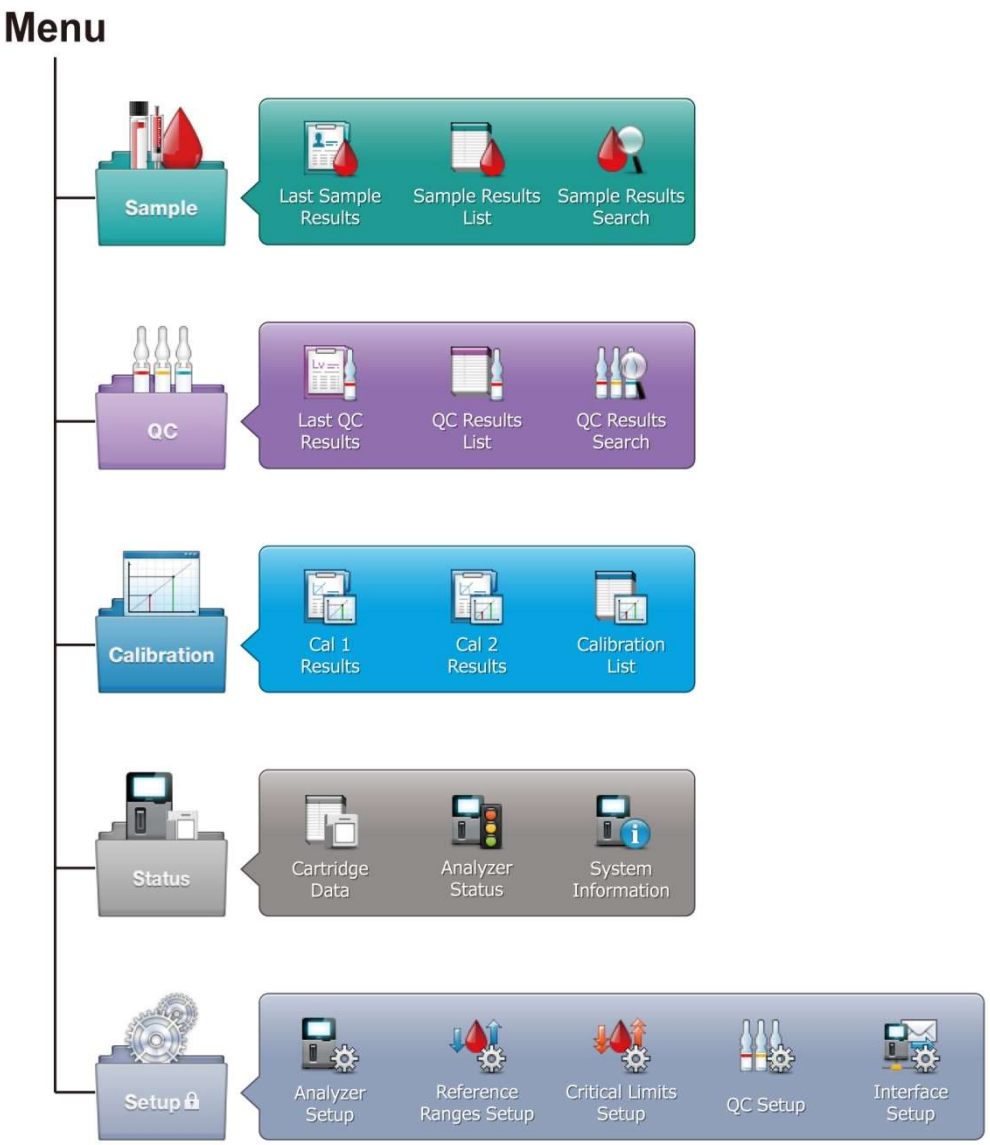
Ready Screen



No.	Description
①	Screen naming
②	Analyzer operation schedule
③	Remaining sample number and date of the installed cartridge
④	Current state of interface setup
⑤	Current state of power connection
⑥	Current state of and battery recharge level
⑦	Current date and time of the analyzer
⑧	Menu access
⑨	Current state of each sensor: Pressing each button twice will display the latest slope of the sensor.

Screen Menus, *continued*

Menu options



Screen Menus, *continued*

Menu Access

1. Press **Menu**. The quick menus and the category menus will appear.

2. Press the current screen box at the top right corner to show the current menu options.

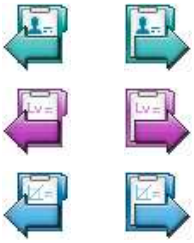
Note:

✓ The **Menu** button is disabled on the following screens:

- Install Cartridge, Remove Cartridge
- Introduce Sample, Sample Information, Sample Results
- Introduce QC Sample, QC Information, QC Results

Screen Menus, *continued*

Icons and Buttons

Icons and Buttons	Description
	Print results or settings on screen
	Transmit results to LIS/HIS / Transfer complete
	Close current screen
	Go to list screen
	Go to search screen
	View result screen
	Scroll to previous or next page
	Go to previous or next result screen

Screen Menus, *continued*

Icons and Buttons, *continued*

Icons and Buttons	Description
	Execute search
	Run 1-point calibration or 2-point calibration
	Run QC
	Accept or discard QC results
	Add or delete QC lot information
	Delete entered data on current tab
	Okay or accept
	Save
	Go to previous screen
	Copy cartridge data to USB memory

Screen Menus, *continued*

Icons and Buttons, *continued*

Icons and Buttons	Description
	Unselected item
	Selected item
	Item that were transmitted to LIS/HIS
	Selected item that were transmitted to LIS/HIS
	Show keyboard for data entry
	Show keyboard for numeric entry
	Interface was enabled
	Analyzer is on AC power
	Battery level

Screen Menus, *continued*

Keyboards

The analyzer offers following keyboards for data entry.

Alphabetic Keyboard

Numeric & Special Character Keyboard

Date and Time Entry Keyboards

Screen Menus, *continued*

Keyboards, ***continued***

Numerical Keyboard

Screen Menus, *continued*

LCD Brightness

When the analyzer has not been in use for more than 10 minutes, the screen turns to screensaver.

Note:

- ✓ The screensaver does not apply to the **Sample Results** screen and the **QC Results** screen.

Message

A message box on the screen informs following information:

- ✓ A current task that is about to begin or in-progress.
- ✓ Action to take in operating the analyzer, such as introducing sample or replacing cartridge.
- ✓ An error that needs an attention or action.

Voice Guide

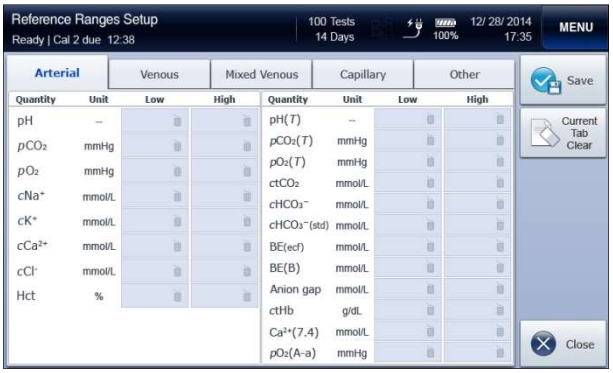
In addition to message boxes, the analyzer plays sound playbacks for following operations:

- ✓ Blood sample introduction
- ✓ QC sample introduction
- ✓ Cartridge removal
- ✓ Cartridge installation
- ✓ Cartridge data copy
- ✓ Battery alarm:: "**The battery is low**"

Sample Setup

Reference Ranges

1. Go to **Menu > Setup** (**Setup** menu is protected by password.) > **Reference Ranges Setup**. The following screen will appear.



2. Press each box and enter low and high limits of the reference range for each parameter.

Sample Setup, *continued*

Reference Ranges, *continued*

Note:

- ✓ To delete the entered data, press **Current Tab Clear**.
- ✓ Before saving the setup, the analyzer will validate the entered values to confirm that:
  - Values for both low and high limits are entered.
  - Low limit value is lower than high limit value.
- ✓ If any of the entered values are not valid, the analyzer will not save the setup and ask to correct the invalid value at the setup screen.

3. Press **Save** to save the setup and go back to the main screen. To exit to main screen without saving the changed setting, press **Close**.

Sample Setup, *continued*

Reference Ranges, *continued*

Note:

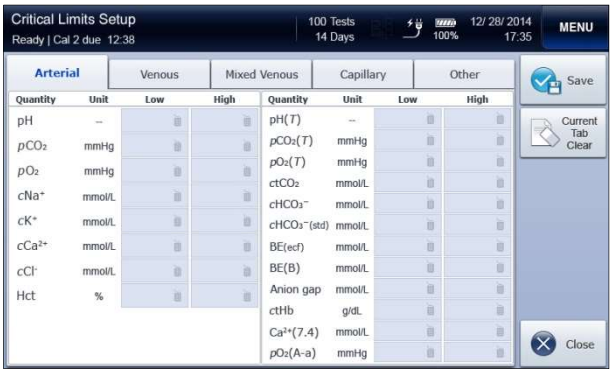
✓ Patient reference ranges should be established by individual institutions. The reference ranges in the table below are shown only as general guidelines.

Parameter	Unit	Reference Range
pH	-	7.350 ~ 7.450
pCO_2	mmHg	35.0 ~ 48.0
pO_2	mmHg	83 ~ 108
cNa^+	mmol/L	136 ~ 145
cK^+	mmol/L	3.4 ~ 4.5
cCa^{2+}	mmol/L	1.15 ~ 1.35
cCl^-	mmol/L	98 ~ 106
Hct	%	35 ~ 51

Sample Setup, *continued*

Critical Limits

1. Go to **Menu > Setup** (**Setup** menu is protected by password.) > **Critical Limits Setup**. The following screen will appear.



2. Press each box and enter low and high values of the critical limits range for each parameter.

Note:

- ✓ To delete the entered data, press **Current Tab Clear**.
- ✓ Before saving the setup, the analyzer will validate the entered values to confirm that:
  - Values for both low and high limits are entered.
  - Low limit value is lower than high limit value.
- ✓ If any of the entered values are not valid, the analyzer will not save the setup and ask to correct the invalid value at the setup screen.

3. Press **Save** to save the setup and go back to the main screen. To exit to main screen without saving the changed setting, press **Close**.

Sample Setup, *continued*

Critical Limits, ***continued***

Note:

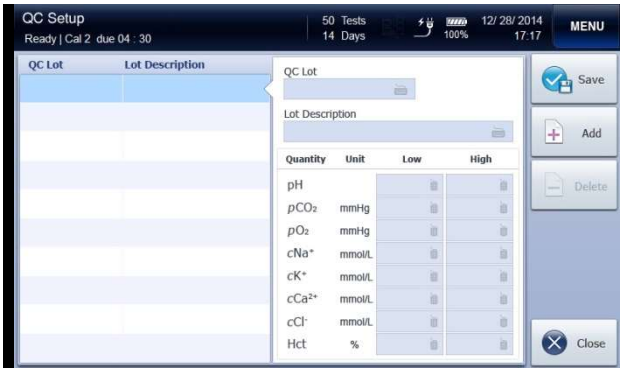
- ✓ High limit value is high than high limits of the reference range.
- ✓ Low limit value is low than low limits of the reference range.

QC Setup

QC Lot Setup

1. Go to **Menu > Setup** (**Setup** menu is protected by password.) **> QC Setup**. The following screen will appear.

2. Select the empty list on the left column. Entry tabs to enter QC lot information is activated on the right side as follow.

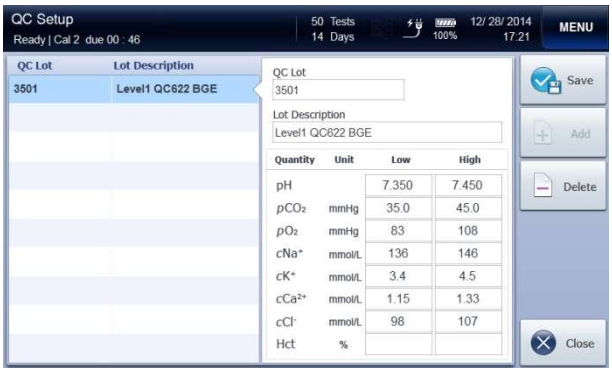


3. Press each entry tab, and enter QC lot information using the keyboard.

QC Setup, *continued*

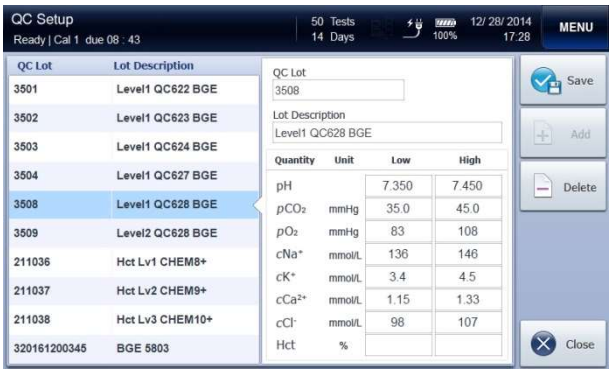
QC Lot Setup, *continued*

4. Press **Add** after entering QC lot information. The entered QC lot will be added to the list on the left column.



Note:

✓ Continue to select the empty list on the left column and add desired QC lot information.



5. To delete the previously saved QC lot information, press the desired QC lot on the left column and press **Delete**.

6. To modify the previously saved QC lot information, delete the saved QC lot on the left column and newly add the modified QC lot.

Note:

✓ The newly added or modified QC lot is shown in bold.

7. Press **Save** to save the setup and go back to the main screen.
To exit to main screen without saving the changed setting, press **Close**.

Analyzer Setup

Date and Time

1. Go to **Menu > Setup** (**Setup** menu is protected by password.) **> Analyzer Setup**. The following screen will appear.

Note:

✓ Changing the **Time**, **Date** and **Date Format** of the analyzer is only allowed before cartridge is installed on the analyzer. Once the cartridge is installed, the time, date and date format cannot be changed until the cartridge is removed.

2. Press **Date Format** box and select the desired date format from the drop-down list.

Analyzer Setup, *continued*

Date and Time, *continued*

3. Press **Date** box and enter the current date using the keyboard.

4. Press **Time** box and enter the current local time using the keyboard.

Analyzer Setup, *continued*

Volume

1. To adjust the volume, press + or — button of the **Speaker Volume**.

2. To turn off sound playback**,** press **Mute**. To turn to maximum volume, press **Max**.

Analyzer Setup, *continued*

LCD Brightness

1. To adjust the LCD brightness, press + or — button of the **LCD Brightness**. Brightness can be adjusted in 15 steps.

Note:

✓ To turn to minimum or maximum brightness, press **Min** or **Max**.

2. Press **Save** to save the setup and go back to the main screen.
   To exit to main screen without saving the changed setting, press **Close**.

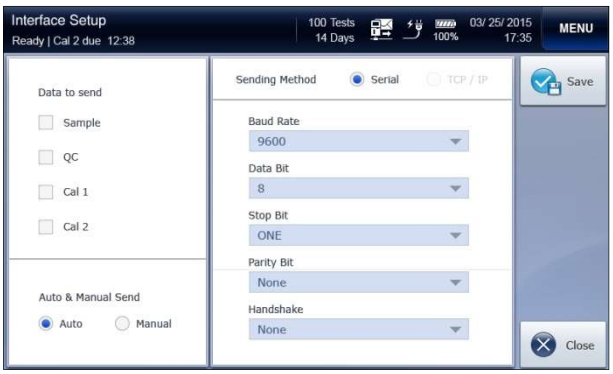
Interface Setup

Option Setup

Note:

✓ Make sure that network cable(s) is appropriately connected to the analyzer before starting interface setup.

1. Go to **Menu > Setup** (**Setup** menu is protected by password.) > **Interface Setup**. The following screen will appear.



2. Check **Sample, QC**, **Cal 1**, and/or **Cal 2** to transmit.
3. Select **Auto** or **Manual** from **Auto & Manual Send** to automatically or manually transmit the data.
4. Select **Serial** from **Sending Method**.

Interface Setup, *continued*

Serial Setup

1. Press **Baud Rate** and select the desired option from the drop-down list. Default is 9600.
2. Press **Data Bit** and select the desired option from the drop-down list. Default is 8.
3. Press **Stop Bit** and select the desired option from the drop-down list. Default is ONE.
4. Press **Parity** and select the desired option from the drop-down list. Default is None.
5. Press **Handshake** and select the desired option from the drop-down list. Default is None.
6. If serial setup is completed, press **Save** to save the setup and return to the previous screen. To exit to main screen without saving the changed setting, press **Close**.

This page is intentionally left blank.

4. Sample Analysis

Patient Samples

Introduce Sample

Note:

✓ Sample analysis is available only when the analyzer is in **Ready** state. When the analyzer is not in **Ready** state, the sampler cover cannot be lifted because it is locked.

1. Check that the analyzer is in **Ready** state.

2. Lift up the sampler cover. The following message will appear.

Note:

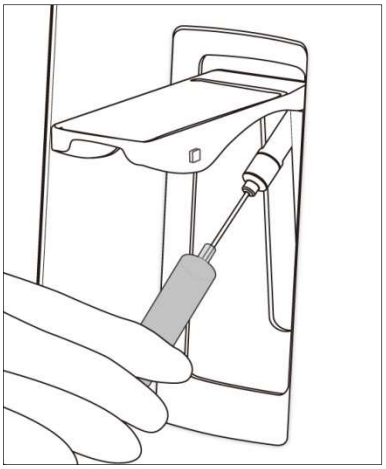
✓ To cancel a patient sample, lower the sampler cover to the original position before pressing **Aspirate**.

✓ Once **Aspirate** is pressed, the sample analysis cannot be cancelled.

Patient Samples, *continued*

Introduce Sample, *continued*

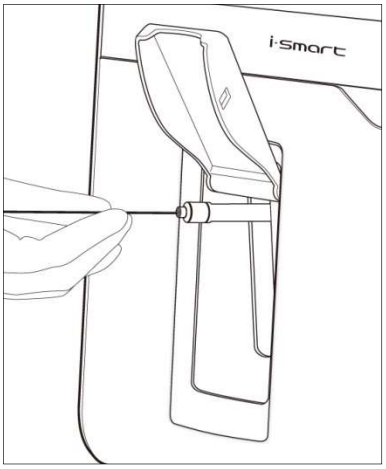
3. For a syringe sample, immerse the end of the sampler probe into the sample container.



Note:

✓ Be careful not to introduce air bubbles, clots, or foreign substances along with sample to the analyzer.

4. For a capillary sample, lift the sampler cover all the way up. Carefully insert the capillary into the septum.



Note:

✓ Do not allow any gap between the capillary and the septum to avoid air flow in with the sample.

Patient Samples, *continued*

Introduce Sample, *continued*

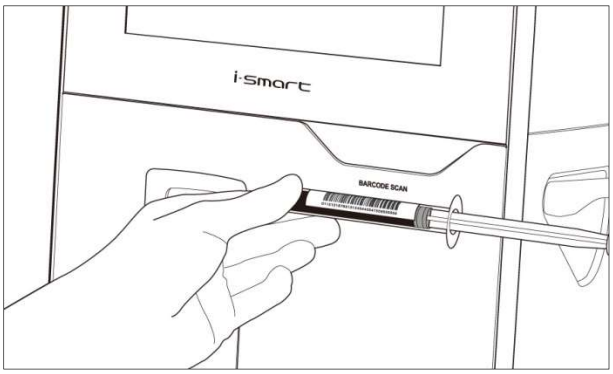
5. If the sampler probe is adequately immersed in the sample, press **Aspirate** to begin aspiration.
6. The "***Aspirating sample... Please wait***" message will appear.
7. If the aspiration is completed, the "***Remove sample now***" message will appear. Remove sample from sampler probe.
8. Wait a second until the "***Close sampler cover*** " message will appear.
9. Lower the sampler cover to close.

Patient Samples, *continued*

Enter Sample Information

1. Once the sampler cover is closed, the **Sample Information** screen will appear.

2. If the sample information is available in barcode, scan the barcode using the barcode scanner that is located in front of the analyzer.



3. To manually enter the sample information, press each of the input boxes and enter the sample information using the screen keyboard.

Patient Samples, continued

View Sample Results

1. When the sample analysis is completed, the sample results will appear at the **Measured Quantity** tab of the **Sample Results** screen.

2. The result values will appear in blue color if the reference ranges have not been setup in the analyzer.

3. If the reference ranges have been setup in the analyzer and a result is within the reference range, the value will appear in blue color.

Note:

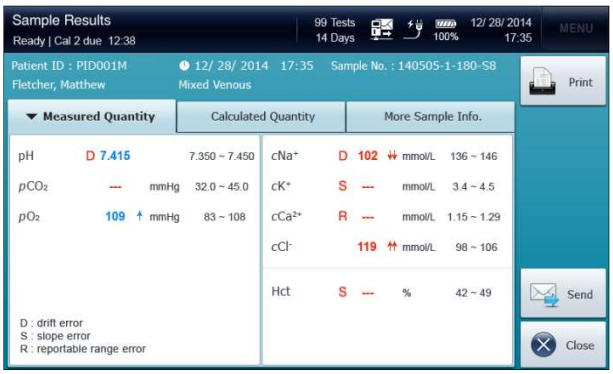
✓ If a result is above reference range, the value will appear in blue color along with an up arrow ↑ .

✓ If a result is below reference range, the value will appear in red color along with a down arrow ↓ .

Patient Samples, *continued*

View Sample Results

4. If any result falls outside of the **Critical Limit**, the value will appear in red color. The phrase will be accompanied by a double arrow ⇈ or ⇊, to indicate above the upper limit or below the lower limit.



5. If the drift error of a sensor has occurred, the corresponding result will be accompanied by "D" in red color.

6. If any result falls outside of the reportable range, the corresponding result will not be reported. Instead "R" will appear in red color.

7. If the slope error of a sensor has occurred, the corresponding result will not be reported. Instead "S" will appear in red color.

8. Select the **Calculated Quantity** tab. The calculated values will appear.

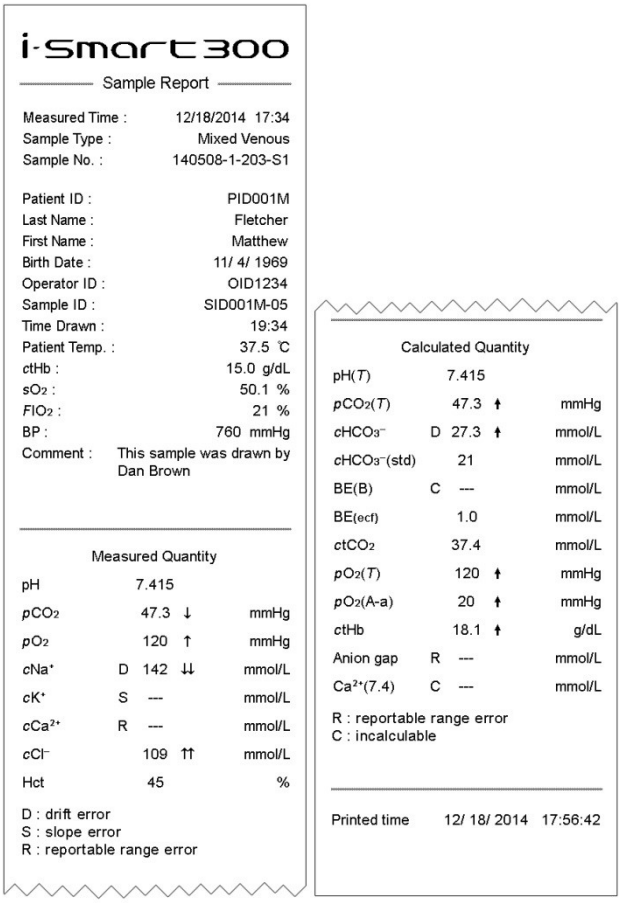
Note:

✓ If a value cannot be calculated, the value will not be reported. Instead "C" will appear in red color.

Patient Samples, *continued*

View Sample Results

9. Press **Print** to print out the results. A printout similar to following will be printed.



i-Smart 300

Sample Report

Measured Time :	12/18/2014 17:34
Sample Type :	Mixed Venous
Sample No. :	140508-1-203-S1
Patient ID :	PID001M
Last Name :	Fletcher
First Name :	Matthew
Birth Date :	11/ 4/ 1969
Operator ID :	OID1234
Sample ID :	SID001M-05
Time Drawn :	19:34
Patient Temp. :	37.5 ℃
ctHb :	15.0 g/dL
sO_2 :	50.1 %
FIO_2 :	21 %
BP :	760 mmHg
Comment :	This sample was drawn by Dan Brown

Measured Quantity

pH		7.415	
pCO_2		47.3 ↓	mmHg
pO_2		120 ↑	mmHg
cNa^+	D	142 ↓↓	mmol/L
cK^+	S	---	mmol/L
cCa^{2+}	R	---	mmol/L
cCl^-		109 ↑↑	mmol/L
Hct		45	%

D : drift error
S : slope error
R : reportable range error

Calculated Quantity

pH(T)		7.415	
$pCO_2(T)$		47.3 ↑	mmHg
$cHCO_3^-$	D	27.3 ↑	mmol/L
$cHCO_3^-$(std)		21	mmol/L
BE(B)	C	---	mmol/L
BE(ecf)		1.0	mmol/L
$ctCO_2$		37.4	mmol/L
$pO_2(T)$		120 ↑	mmHg
pO_2(A-a)		20 ↑	mmHg
ctHb		18.1 ↑	g/dL
Anion gap	R	---	mmol/L
Ca^{2+}(7.4)	C	---	mmol/L

R : reportable range error
C : incalculable

Printed time 12/ 18/ 2014 17:56:42

Note:

✓ If the analyzer is on battery power, the printout is only available in more than 50% battery levels.

10. If the analyzer has been set to auto print, the analyzer will print the results as soon as they are reported.

11. To transmit the results to the LIS/HIS, press **Send**.

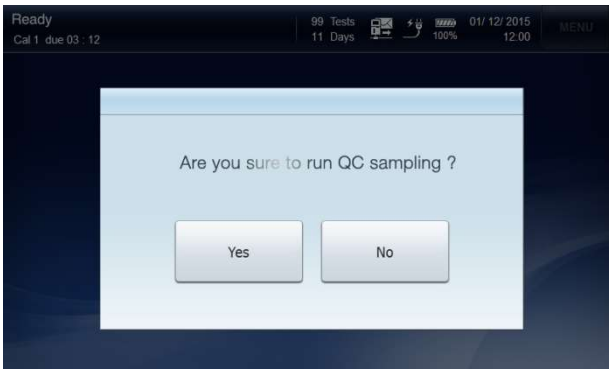
12. Press **Close** to save the results and exit to main screen.

13. The analyzer will go through **Rinse** and **Cal 1** process before returning to the **Ready** state for a next sample.

QC Samples

Introduce QC Sample

1. Press **Menu** and select **Run QC**. The following screen will appear.



2. Press **Yes**. The following screen will appear.

Note:

✓ The **Run QC** menu will be available only when the QC lot(s) has been setup at **QC Setup** menu.

3. When the "***Lift sampler cover for QC sampling***" message appears, lift up the sampler cover.

QC Samples, *continued*

Introduce QC sample, *continued*

4. When "***Position QC sample for aspiration***" message appears, immerse the end of the sampler probe into the QC sample and press **Aspirate**.

5. The "***Aspirating QC sample... Please wait***" message will appear.

Note:

- ✓ To cancel QC sample, lower the sampler cover to the original position before pressing **Aspirate**.
- ✓ Once **Aspirate** is pressed, the sample analysis cannot be cancelled.

QC Samples, *continued*

Introduce QC sample, *continued*

6. If the aspiration is completed, the "***Remove QC sample now***" message will appear. Remove QC sample from the sampler probe.

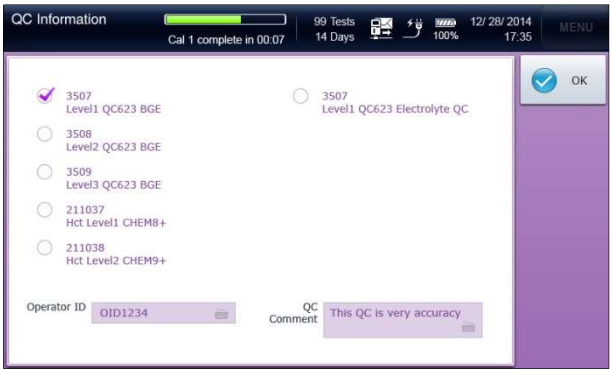
7. Wait a second until the "***Close sampler cover***" message will appear.

8. Push down the sampler cover to the original position.

QC Samples, *continued*

Enter QC Information

1. Once the sampler cover is closed, the **QC Information** screen will appear.



2. Select the QC lot of the QC sample.

3. If necessary, enter **Operator ID** and **QC Comment** using the screen keyboard.

4. Press **OK**. **QC Results** screen will appear.

QC Samples, *continued*

View QC Results

1. When the QC sample analysis is completed, the QC results will appear at the **QC Results** screen as following.

Note:

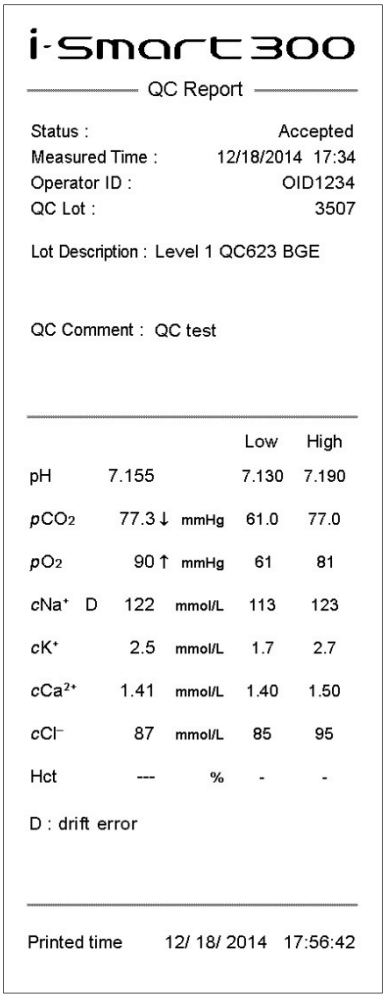
- ✓ If a result is within the QC range, the value will appear in blue color.
- ✓ If a result is above the QC range, the value will appear in red color along with an up arrow ↑.
- ✓ If a result is below the QC range, the value will appear in red color along with a down arrow ↓.

2. Press **Accept** or **Discard** to accept or discard the QC results. The state will switch from **Pending** to **Accepted** or **Discard**.

QC Samples, *continued*

View QC Results, *continued*

3. Press **Print** to print out the results. A printout similar to following will be printed.



i-Smart 300

QC Report

Status : Accepted
Measured Time : 12/18/2014 17:34
Operator ID : OID1234
QC Lot : 3507

Lot Description : Level 1 QC623 BGE

QC Comment : QC test

			Low	High
pH	7.155		7.130	7.190
pCO_2	77.3 ↓	mmHg	61.0	77.0
pO_2	90 ↑	mmHg	61	81
cNa^+ D	122	mmol/L	113	123
cK^+	2.5	mmol/L	1.7	2.7
cCa^{2+}	1.41	mmol/L	1.40	1.50
cCl^-	87	mmol/L	85	95
Hct	---	%	-	-

D : drift error

Printed time 12/ 18/ 2014 17:56:42

Note:

✓ If the analyzer is on battery power, the printout is only available in more than 50% battery levels.

4. To transmit the results to the LIS/HIS, press **Send**.

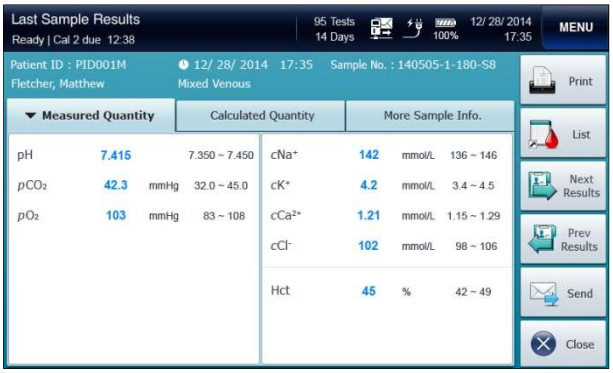
5. Press **Close** to save the results and exit to main screen.

5. Database

Patient Data

Last Patient Results

1. Go to **Menu > Sample >Last Sample Results**.
   The following screen will appear.



Note:

✓ The same screen can be accessed through **Menu > Last Sample Results**.

2. To view the screen of the next patient sample results or the previous patient sample results, press **Next Results** or **Prev Results**.
3. To go to the list of patient sample results, press **List**.
4. To transmit the results to the LIS/HIS, press **Send**.
5. Press **Close** to exit to main screen.

Sample Results List

1. Go to **Menu > Sample > Sample Results List**.
   The following screen will appear.

Patient Data, *continued*

Sample Results List, *continued*

2. The latest patient sample data are listed on the top. Use **Page UP** or **Page Down** to scroll the list of patient results.

3. To view a patient sample results, select a desired row from the list.

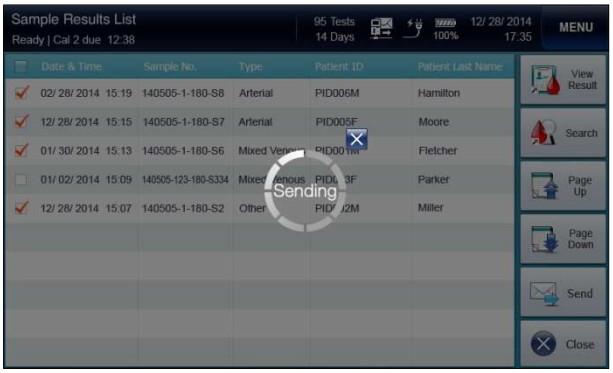
4. To view more the desired sample results, press **View Result**. The corresponding patient sample results screen will appear.

5. To search patient sample results, press **Search** on the **Sample Results List** screen. Refer to the **Sample Results Search** section below.

Patient Data, *continued*

Sample Results List, *continued*

6. To transmit patient sample results to the LIS/HIS, select desired results from the list and press **Send**.



7. Press **Close** to exit to main screen.

Patient Data, *continued*

Sample Results Search

1. Go to **Menu > Sample > Sample Results Search**. The following screen will appear.

Note:

✓ Search criteria for patient results are as following:

- ❑ From & To
- ❑ Sample Type
- ❑ Patient ID
- ❑ Sample ID
- ❑ Patient Last Name
- ❑ Patient First Name
- ❑ Operator ID

2. Enter desired search criteria in appropriate boxes.
3. Press **Search**. The searched patient results will appear.
4. To go to the list of patient results, press **List**.
5. Press **Close** to exit to main screen.

QC Data

Last QC Results

1. Go to **Menu > QC > Last QC Results**.
   The following screen will appear.

2. Press **List** to go to the list of QC results.
3. To view the screen of the next QC results or the previous QC results, press **Next Results** or **Prev Results**.
4. To transmit the results to the LIS/HIS, press **Send**.
5. Press **Close** to exit to main screen.

QC Results List

1. Go to **Menu > QC > QC Results List**.
   The following screen will appear.

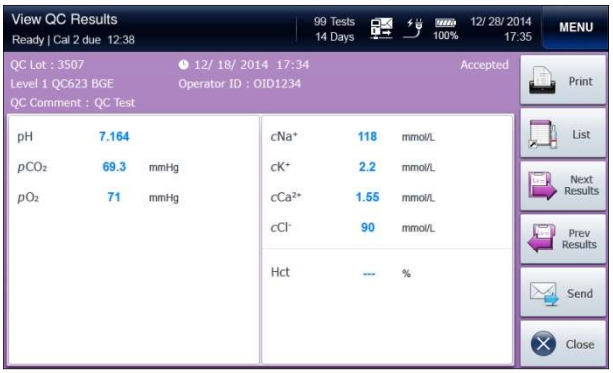
2. The latest QC results are listed on the top. Use **Page Up** or **Page Down** to scroll the list of QC results.

QC Data, *continued*

QC Results List, ***continued***

3. To view a QC results screen, select a desired row from the list and press **View Result**.

4. The corresponding QC results screen will appear.



QC Data, *continued*

QC Results List, *continued*

5. To transmit patient sample results to the LIS/HIS, select desired results from the list and press **Send**.

6. To search QC results, press **Search** on the **QC Results List** screen. Refer to the **QC Results Search** section below.

7. Press **Close** to exit to main screen.

QC Data, *continued*

QC Results Search

1. Go to **Menu > QC > QC Results Search**.
   The following screen will appear.

Note:

✓ Search criteria for QC results are as following:

- ❑ From & To
- ❑ QC Lot
- ❑ Either Accepted or Discarded QC results only or all results
- ❑ Operator ID

2. Enter desired search criteria in appropriate boxes.
3. Press **Search**. The searched QC results will appear.
4. To go to the list of QC results, press **QC List**.
5. Press **Close** to exit to main screen.

Calibration Data

Cal 1 Results

1. Go to **Menu > Calibration > Cal 1 Results**.
   The following screen will appear.

2. To view the screen of the next Cal 1 results or the previous Cal 1 results, press **Next Results** or **Prev Results**.
3. To transmit the results to the LIS/HIS, press **Send**.
4. **To print out the** results, press **Print.**
5. To go to the list of calibration, press **List**.

Note:

✓ If the analyzer is on battery power, the printout is only available in more than 50% battery levels.

6. Press **Close** to exit to main screen.

Calibration Data, *continued*

Cal 2 Results

1. Go to **Menu > Calibration > Cal 2 Results**.
   The following screen will appear.

2. To view the screen of the next Cal 2 results or the previous Cal 2 results, press **Next Results** or **Prev Results**.

3. To transmit the results to the LIS/HIS, press **Send**.

4. **To print out the** results, press **Print.**

Note:

✓ If the analyzer is on battery power, the printout is only available in more than 50% battery levels.

5. To go to the list of calibration, press **List**.

6. Press **Close** to exit to main screen.

Calibration Data, *continued*

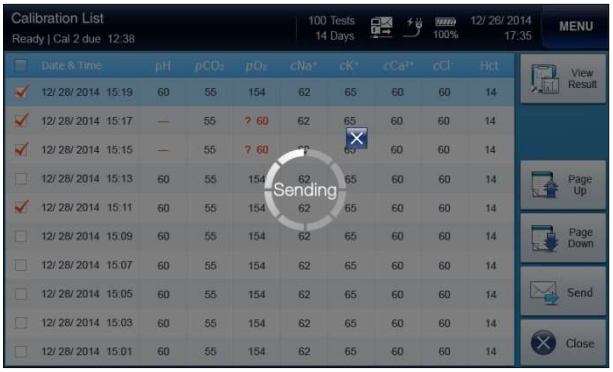
Calibration List

1. Go to **Menu > Calibration > Calibration List**.
   The following screen will appear.

2. The latest Cal 2 results are listed on the top. Use **Page Up** or **Page Down** to scroll the list of Cal 2 results.

3. To view a Cal 2 results screen, select a desired row from the list and press **View Result**.

4. To transmit the results to the LIS/HIS, press **Send**.

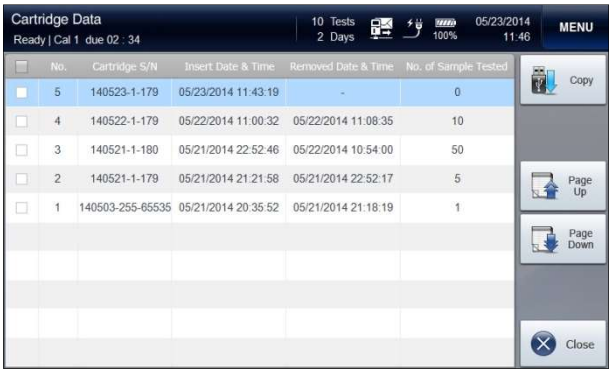


5. Press **Close** to exit to main screen.

Cartridge Data

Cartridge Data Copy

1. Go to **Menu > Status > Cartridge Data**.
   The following screen will appear.



2. The latest cartridge data will appear on the top. Use **Page Up** or **Page Down** to scroll the list of cartridge data.
3. Select desired cartridge data and press **Copy**.
   The following screen will appear.

4. Insert an USB memory into any of available USB ports on the analyzer.
5. The "***Data copy in progress. Please wait***" message will appear along with the copy progress bar.
6. When the data copy is completed, the "***Cartridge data copy has completed. Remove USB memory***" message will appear.
7. Remove the USB memory from the USB port.

This page is intentionally left blank.

6. Shutdown

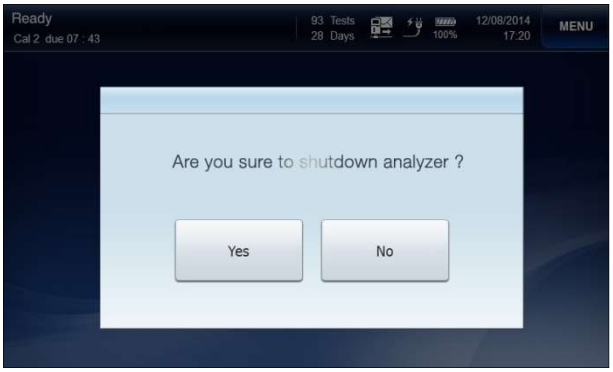
Analyzer Shutdown

Caution

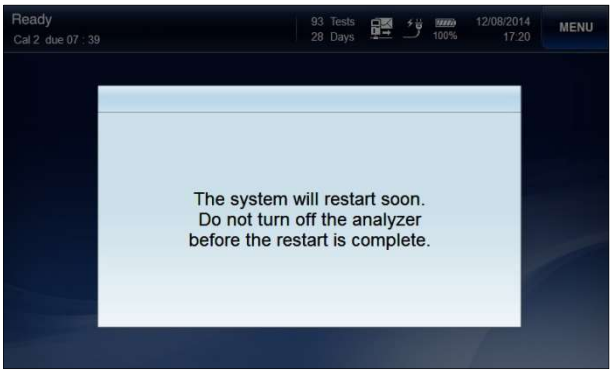
- ❑ The power of the analyzer should be turned off according to the shutdown procedure as described in this manual. Failure to follow the described shutdown procedure can cause damage to the data or the analyzer.
- ❑ To disconnect the power cables from the analyzer, first unplug the power cord from the outlet. Then, unplug the adapter from the analyzer.
- ❑ The cartridge cannot be removed once the shutdown process begins or after the analyzer is turned off.

Shutdown Analyzer

1. Go to **Menu > Shutdown Analyzer**.
   The following screen will appear.



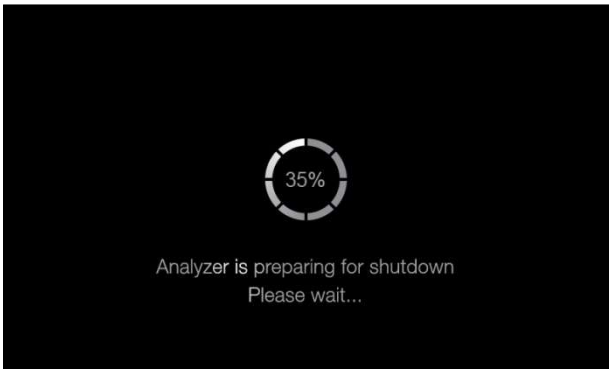
2. Press **Yes** to continue. The following message will appear.



Analyzer Shutdown, *continued*

Shutdown Analyzer, *continued*

3. Wait until the analyzer completes a power cycle and the following screen appears.



4. Wait until the progress circle reaches 100%.

5. Facing the back of the analyzer, flip the black power switch on the lower left side, marked “ I / O”, to the “ O” position.

Cartridge Restart

Power Recovery

- ❑ When the analyzer recovers from power interruption, the cartridge inside the analyzer can be continuously used, only if:
  - ✓ The analyzer was in Ready state or in process of calibration when the power was interrupted and the power returns within 1 hour.
  - ✓ The analyzer was analyzing a sample when the power was interrupted and the power returns within 20 minutes.
  - ✓ The analyzer was analyzing a QC sample when the power was interrupted and the power returns within 1 hour.

1. When the analyzer recovers from power interruption with the cartridge inside, one of following **Cartridge Restart** screens will appear.

2. The **Cartridge Restart** from power recovery will take about 10 minutes.
3. After the **Cartridge Restart**, the analyzer will return to the Ready state.

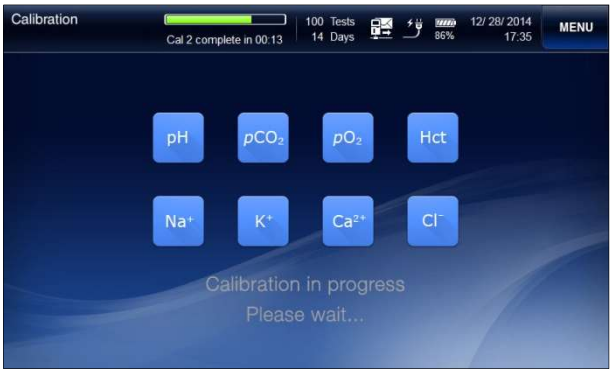
7. Maintenance

Calibration

Run Cal

1. Go to **Menu > Run Cal 1**.
   The following screen will appear.

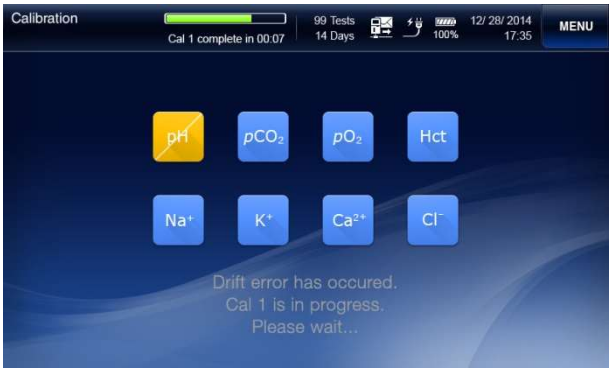
2. Go to **Menu > Run Cal 2**.
   The following screen will appear.



Calibration, *continued*

Cal 1 Auto Repeat

- If the drift error of a sensor has occurred in the previous Cal 1, the analyzer will automatically repeat Cal 1 up to three times.
- While the Cal 2 repeat is in progress, the "***Drift error has occured. Cal 1 is in progress. Please wait...***" message will appear.



Cal 2 Auto Repeat

- If the slope error of a sensor has occurred in the previous Cal 2, the analyzer will automatically repeat Cal 2 up to two times.
- While the Cal 2 repeat is in progress, the "***Slope error has occured. Cal 2 is in progress. Please wait...***" message will appear.

- If the same sensor fails in Cal 2 three times in succession, the sensor state will appear as  on the main screen.

Calibration, *continued*

Sensor State

1. State of each sensor will appear as okay in blue background, drift error in yellow background or slope error in red background at the main screen based on the results of the last calibration.

2. Press the **Sensor State** icon twice quickly. The last slope and the allowable slope range of the sensor will appear.

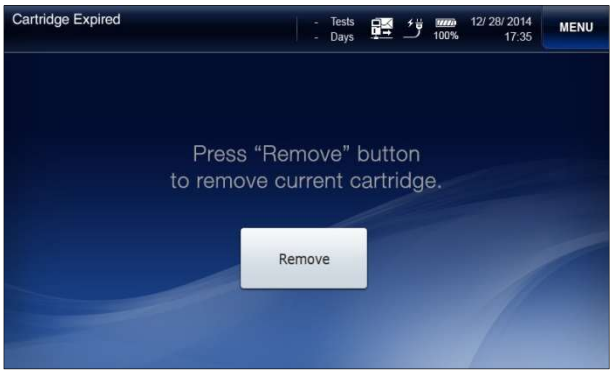
Cartridge Removal

Caution

- ❑ Treat the used cartridge as biohazard material.
- ❑ Dispose of the used cartridge in accordance with the laboratory's established procedures for disposing of biohazardous materials.
- ❑ Before removing the used cartridge, wear appropriate personal protective clothing to protect from biohazard materials.

Remove Expired Cartridge

1. The analyzer will automatically display the **Cartridge Expired** screen in one of following situations:



- ✓ The uselife of the cartridge has expired.
- ✓ All tests of the cartridge have been used up.
- ✓ The analyzer has been without power for more than the allowable time limit to restore the cartridge.

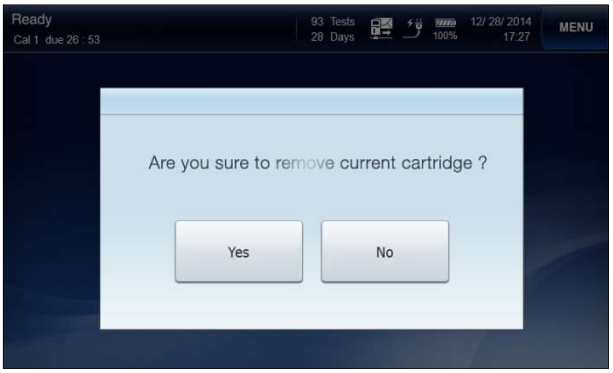
2. Press **Remove** to remove the current cartridge.
   The following screen will appear.

3. Remove the cartridge in accordance with the instructions on the screen.
4. To install a new cartridge, refer to the **Cartridge Installation** (**2. Installation**) section.

Cartridge Removal, *continued*

Remove Cartridge in Use

1. Go to **Menu > Remove Cartridge** to remove a cartridge in use. The following screen will appear.



Note:

- ✓ To cancel the cartridge removal, press **No**.
- ✓ The removed cartridge cannot be reused.

2. Press **Yes**. The following screen will appear.

3. Remove the cartridge in accordance with the instructions on the screen.
4. To install a new cartridge, refer to the **Cartridge Installation** (**2. Installation**) section.

System Information

1. Go to **Menu > Status > System Information**.
   The following screen will appear.

2. The following information will appear:

   - ❑ Software Version and Firmware Version
   - ❑ Cartridge: Serial Number, Lot Number, Installation Date & Time, Expiration Date & Time, Age
   - ❑ Calibration Information

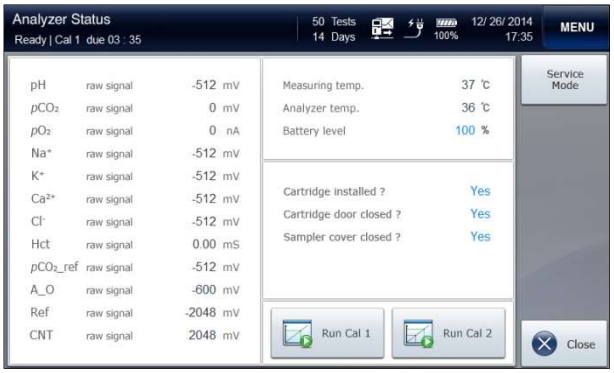
Note:

✓ The information of the removed cartridge is not shown.

3. Press **Close** to exit to main screen.

Analyzer Status

1. Go to **Menu > Status > Analyzer Status**.
   The following screen will appear.



2. The following information will appear:
   - ❑ Raw Signals
   - ❑ Measuring temperature
   - ❑ Analyzer temperature
   - ❑ Battery level
   - ❑ States of Cartridge installation, Cartridge door, and Sampler cover
3. Press **Run Cal 1** or **Run Cal 2** to initiate Cal 1 or Cal 2 on the current screen.
4. Press **Close** to exit to main screen.

Note:

- ✓ If the cartridge is properly installed, **Cartridge, Cartridge Door**, and **Sampler Cover** states will appear as **Yes**.
- ✓ The **Service Mode** is for service engineers ONLY and protected by password.

Cleaning

Caution

- ❑ Wear appropriate personal protective clothing to prevent infection when cleaning.
- ❑ Clean the analyzer after use or periodically.
- ❑ Do not spray cleaning solution directly onto the analyzer.
- ❑ Do not allow cleaning solution to enter the analyzer.
- ❑ Do not use force to wipe the screen.
- ❑ Prepare 0.5% hypochlorite cleaning solution immediately before use.
- ❑ Dispose of all waste after cleaning in accordance with the laboratory's established procedures for disposing of biohazardous materials.

Cleaning Procedure

1. Use 0.5% hypochlorite cleaning solution.

   Note:

   - ✓ Commercial Clorox contains approximately 5% sodium hypochlorite.
   - ✓ To prepare 0.5% hypochlorite solution, mix 1 part of Clorox and 9 parts of water.

2. Dampen a soft cloth with the cleaning solution.
3. Using a dampened soft cloth, wipe sampler cover, screen, and other contaminated areas on the analyzer.
4. Allow to air-dry for about 10 minutes.

   Using a soft cloth dampened with water, wipe the analyzer.
5. Using a dry cloth, dry the surface of the analyzer.

This page is intentionally left blank.

8. Troubleshooting

Troubleshooting

Guideline

- ❑ If the problems described below are encountered during installation and/or operation of the analyzer, try the suggested solutions as described in this manual.
- ❑ If the problem persists, please call a service engineer for further assistance.

Barcode Scanner

When scanning barcode, the scanner does not emit the red light:

1. Move the barcodes to be scanned in front of the marking " BARCODE SCAN".
2. If there does not show a red light beam, press the "SCAN" button on the rear of the analyzer by a sharp object like a needle. Then, retry to read the barcodes. It may not be able to read the barcodes at a dark place. In this case, please enhance the brightness of the light in around.
3. If the same problem occurs, turn off and on the power switch of the analyzer.

Screen

If one of following situations applies:

- ❑ *The screen does not respond.*
- ❑ *The screen is frozen.*
- ❑ *Abnormal screen appears.*

1. Turn off the power switch of the analyzer.
2. Wait 10 seconds.
3. Turn on the power switch of the analyzer.

Troubleshooting, *continued*

Battery

If one of following situations applies:

- ❑ *The analyzer was turned off immediately upon disconnection from the outlet.*
- ❑ *The analyzer was turned off during brief power outages.*
- ❑ *The battery does not recharge.*

1. If not already done, turn off the power switch of the analyzer.
2. Check for loose power connections between the analyzer and the outlet. Tighten any loose power connections.
3. Turn on the power switch of the analyzer.
4. The analyzer will turn on and the battery will begin to recharge.
5. If the analyzer does not turn on, turn off the power switch of the analyzer.
6. Recharge the battery for 10 minutes.
7. Turn on the power switch of the analyzer again.
8. While the analyzer is turned, if the battery level stays low and does not increase at all over the time, call a service engineer for help.
9. Until the battery is replaced, the analyzer will operate normally as long as the power is supplied from the outlet.

If the "Battery is low" appears,

1. Check for loose power connections between the analyzer and the outlet.
2. Tighten any loose power connections.

Troubleshooting, *continued*

Calibration

If the sensor state appears as slope error in red background,

1. Run Cal 2.
2. If needed, repeat additional Cal 2 a few times more.

Cartridge Data Copy

If the analyzer fails to detect a USB memory,

1. Remove the USB memory from the USB port.
2. Insert the USB memory into a different USB port.
3. If it still doesn't work, try a different USB memory.

If "Cartridge data copy has failed" message appears during data copy,

1. Close the message and try again from the beginning.
2. Select desired cartridge data and press **Copy.**

Cartridge Installation

If the analyzer does not change to the warming-up screen after the cartridge is inserted into the analyzer,

1. Check that the cartridge is an i-Smart 300 cartridge.
2. Check that the cartridge is not past its expiration date.
3. Check that the cartridge has not been previously used.
4. Open and close the cartridge door.

Troubleshooting, *continued*

Power

- ❑ *While the analyzer is connected to the outlet, the power cord icon does not appear:*

1. Check for loose power connections between the analyzer and the outlet.
2. Tighten any loose power connections.

If one of following situations applies:

- ❑ *The analyzer has turned off.*
- ❑ *The analyzer does not turn on.*

1. If not already done, turn off the power switch of the analyzer.
2. Check for loose power connections between the analyzer and the outlet. Tighten any loose power connections.
3. Turn on the power switch of the analyzer.
4. If the analyzer does not turn on, turn off the power switch of the analyzer.
5. Recharge the battery for 10 minutes.
6. Turn on the power switch of the analyzer again.

Printer

If one of following situations applies:

- ❑ *The printer does not print.*
- ❑ *The printer does not feed the paper.*

1. Check for loose power connections between the analyzer and the outlet. If the analyzer is on battery power, the printout is only available in more than 50% battery levels.
2. Open the printer cover.
3. Replace a roll of print paper if the paper has run out.
4. Lift up the printer head and check for paper jam. If jammed, remove the jam. Then, press the **RESET** switch on the left side of the printer and close the printer head.

Troubleshooting, *continued*

Sample Analysis If one of following situations applies:

- ❑ *The "Insufficient sample error" appears on the result screen.*
- ❑ *The "Out of range" appears on the results screen.*
- ❑ *A result is suspicious.*

1. Try sample analysis again with the same sample.
2. If the same error is repeated, run Cal 2.
3. Try sample analysis again.
4. Repeat Cal 2 a few times if the same problem occurs.
5. Try QC solutions for analysis. If the QC results are within the QC range, the analyzer is okay for sample analysis.
6. Check the sample collection and handling method.

Error Code

1. If the analyzer encounters an error during operation, the following error code will appear on the screen.

Error Code	Description
ESYS001 ~ ESYS999	Hardware error
EDB001 ~ EDB999	Database error
ESW001 ~ ESW999	Software error

2. Memo the error code.
3. Turn off the power switch of the analyzer.
4. Wait 10 seconds.
5. Turn on the power switch of the analyzer.

This page is intentionally left blank.

9. Specifications

Operating Specifications

Measured Parameters

- Measured Parameters

Parameter	Unit	Reportable Range	Measuring Range	Resolution
pH		6.500 ~ 8.000	6.000 ~ 8.500	0.001
pCO_2	mmHg	5.0 ~ 150.0	0.0 ~ 250.0	0.1
pO_2	mmHg	5 ~ 700	0 ~ 800	1
cNa^+	mmol/L	80 ~ 200	20 ~ 250	1
cK^+	mmol/L	1.0 ~ 20.0	1.0 ~ 60.0	0.1
cCa^{2+}	mmol/L	0.25 ~ 5.00	0.25 ~ 15.00	0.01
cCl^-	mmol/L	50 ~ 150	20 ~ 250	1
Hct	%	10 ~ 70	5 ~ 75	1

- Sample types: whole blood
- Anticoagulant: heparin
- Sample volume: 80 μL
- Sample introduction method: aspiration
- Sample analysis time: 50 seconds
- Sample analysis temperature: 37.0 ± 0.2°C
- Measuring principle: electrochemical (potentiometry, amperometry, conductometry)
- Calibration : automatic or manual

Environmental Conditions

- Operating location: indoors on a flat surface
- Operating temperature: 15 ~ 35°C
- Operating humidity: 5 ~ 85% (relative humidity)
- Operating altitude: under 3,000 m
- Power supply: 100 ~ 240 Va.c., 50/60 Hz

Analyzer Specifications

- Internal PC: 1.6 GHz processor / 2 GB RAM / 8 GB flash storage
- Operating system: Windows® Embedded Standard 7
- Display: 8 inch TFT-LCD, touch screen
- Printer: 2 inch thermal printer (built-in)
- Printer paper: thermal paper (width: 57 mm, diameter: 50 mm)
- Barcode scanner: visible red 630 nm LED laser (built-in)
- RFID reader: 13.56MHz ISO 15693 read/write (built-in)
- Port: USB (4 ports), Serial (RS-232), LAN (RJ45 Ethernet), VGA
- Power adapter:
  - AC-DC power supplies (IEC/EN 60950-1 approved)
  - Input: 100 ~ 240 V a.c., 1.5 A, 50/60 Hz
  - Output: + 24 V d.c., 2.7 A
- Input power: + 24 V d.c., 2.7 A
- Internal battery: 14.8 V d.c., 4.4 Ah (Lithium-ion cells: 4S2P)
  - Discharge time: maximum two hours
- Battery life:
  - 20% reduced capacity for charging/discharging for 300 times.
  - Replace when the capacity drops below 50% (discharging time is less than one hour).
  - The life and replacement cycle of the battery can vary depending on operating conditions.
- Storage temperature: -20 ~ 50°C
- Storage humidity: 0 ~ 90% (relative humidity)
- Size (HxWxD): 394 mm x 257 mm x 252 mm
- Weight: 5.5kg (without accessories)
- FCC Regulatory Domain : compiled with Part 15 of FCC Rules.

  Note: Operation is subject to the following two 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.

Cartridge Specifications

- Unit: 1 cartridge
- Uselife: maximum 2 weeks
- Shelf life: 6 months from manufactured date
- Storage temperature: 15 ~ 25°C
- Components:
  - Sensors
  - Sampler
  - Waste bag
  - Valve and tubing
  - Solution bag
  - Cal 1solution, approx. 500 g
  - Cal 2 solution, approx. 100 g
  - Reference solution, approx. 100 g
- Size (HxWxD): 148 mm x 182 mm x 100 mm
- Weight: 1.4 kg

Measuring Principles

	Electrochemical		
	Potentiometry (ion selective electrode)	Amperometry	Conductometry
pH and Gases	pH, pCO_2	pO_2	
Electrolytes	cNa^+, cK^+, cCa^{2+}, cCl^-		
Hematocrit			Hct

The i-Smart 300 blood gas analyzer calibrates the sensors using Cal 1 and Cal 2 solutions according to the pre-determined two-point calibration schedule during the lifetime of the cartridge. In addition, the analyzer performs one-point calibrations using Cal 1 solution between two-point calibration intervals to correct the baseline drift of the sensors.

This page is intentionally left blank.

Appendix A: Sample Collection and Handling

Caution

- ❑ Observe the general cautions required of the hospital, laboratory, or other testing facility.
- ❑ All biohazardous materials should be handled and disposed of in accordance with applicable rules and regulations.
- ❑ The blood and/or collecting tools, and used cartridges should be treated as biohazardous materials.
- ❑ Wear appropriate personal protective clothing (lab coat, gloves, goggles, etc.). And Be careful not to let the blood and/or collecting tools directly touch the mouth, eyes, mucus membranes, or any area with broken skin.
- ❑ Wash hands after collecting the sample or using the analyzer.

Sample preparation

- ❑ Use whole blood to a blood gas test.
- ❑ To draw blood samples, use containers (syringe, capillary, blood collection tube) treated with heparin. We recommend using a dry-sprayed heparin tube or a solid heparin tube. We do not recommend using a tube treated with anticoagulants such as Citrate, EDTA, Oxalate, NaF, etc., except heparin, since the blood-sampling tube containing such anticoagulants besides heparin can drop the performance of the sensors and/or can influence the analysis result.
- ❑ Make sure there are no small air bubbles trapped in the collected sample. Small bubbles in the sample can affect the results.
- ❑ Samples containing clots and/or samples in which hemolysis is present or suspected must not be used.
- ❑ Use whole blood samples for blood gas analysis should be analyzed as soon as possible. If immediately analysis is not possible, the sealed blood container must be placed in a bath containing ice and water. Ice-water stored samples at 1 to 4°C may give reliable results for up to 30 minutes.

Appendix B: Order Information

1. i-Smart 300 Cartridge

Available Test number & Uselife	REF	Order unit
200 Tests / 2 weeks	6510	1

2. Quality Control

Product Description	REF	Order unit
QC 623 Level 1 (blood gas/electrolyte)	6200	1 box (30 ampuls)
QC 623 Level 2 (blood gas/electrolyte)	6201	1 box (30 ampuls)
QC 623 Level 3 (blood gas/electrolyte)	6202	1 box (30 ampuls)
QC 623 Multi-Level (blood gas/electrolyte),	6204	1 box (30 ampuls, 10 ampuls each levels)
QC 900 HIGH/LOW (hematocrit)	6203	1 box (20 ampules, 10 ampuls each levels)

3. Accessories of analyzer

Description	REF	Order unit
Power adapter	3152	1
Power cord	3153	1
Printer papers	3331	1 pack (5 rolls)

Appendix C: Warranty

The product warranty for the analyzer and its components excluding the cartridge is **one year** from the product purchase date on the VAT invoice.

Product quality assurance applies only if the product has been properly handled and used under normal conditions and appropriately maintained according to the operator's manual.

Responsibility for the charged service (charged on the customer).

- ❑ Failure caused by consumer error.
- ❑ When the product was broken by external shock or fall.
- ❑ When the product was broken by using components or optional items that are not specified by the manufacturer.
- ❑ When the user did not read and understand the precautions, the installation, and operation methods of the instrument in the operator's manual.
- ❑ When the analyzer was disassembled, modified, and/or repaired by a person who is not authorized by i-SENS, Inc.
- ❑ When the product was broken by using incorrect power capacity.
- ❑ When the product was broken by the operator's lack of attention or skill.
- ❑ When the product was broken by natural disaster (lighting, fire, flood damage, etc.).
- ❑ When the consumable parts reached the end of their life spans (battery, etc.).

Please call a service engineer responsible for the product if you have any questions.