i-Smart 30 VET
ELECTROLYTE ANALYZER

Operator's Manual

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i-sens

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i-Smart 30 VET
ELECTROLYTE ANALYZER

Operator's Manual

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The operators should read the entire manual before installing and operating the analyzer.

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1. Introduction

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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 prolems.
- ❑ Discard the analyzer and provided electricial accessaries in accordance with environmental protection and resource recycling regulations.

Safety, *continued*

Biohazard Caution

- All materials used in collecting blood from animals 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 mark
	FCC mark
	Consult operating instructions
	Authorized representative in the European community
	Serial number
	Caution: Attention, see operating instructions
	Manufacturer
	Temperature limitation
	Catalogue number
	Batch code
	Contains sufficient for <n> tests
	Use by
	Biological risk
	Electrical and electronic equipment waste that requires specific disposal instructions from the manufacturer
	Printer
	DC power port
O	Off (power)
I	On (power)

Symbols and Terms, *continued*

Terms

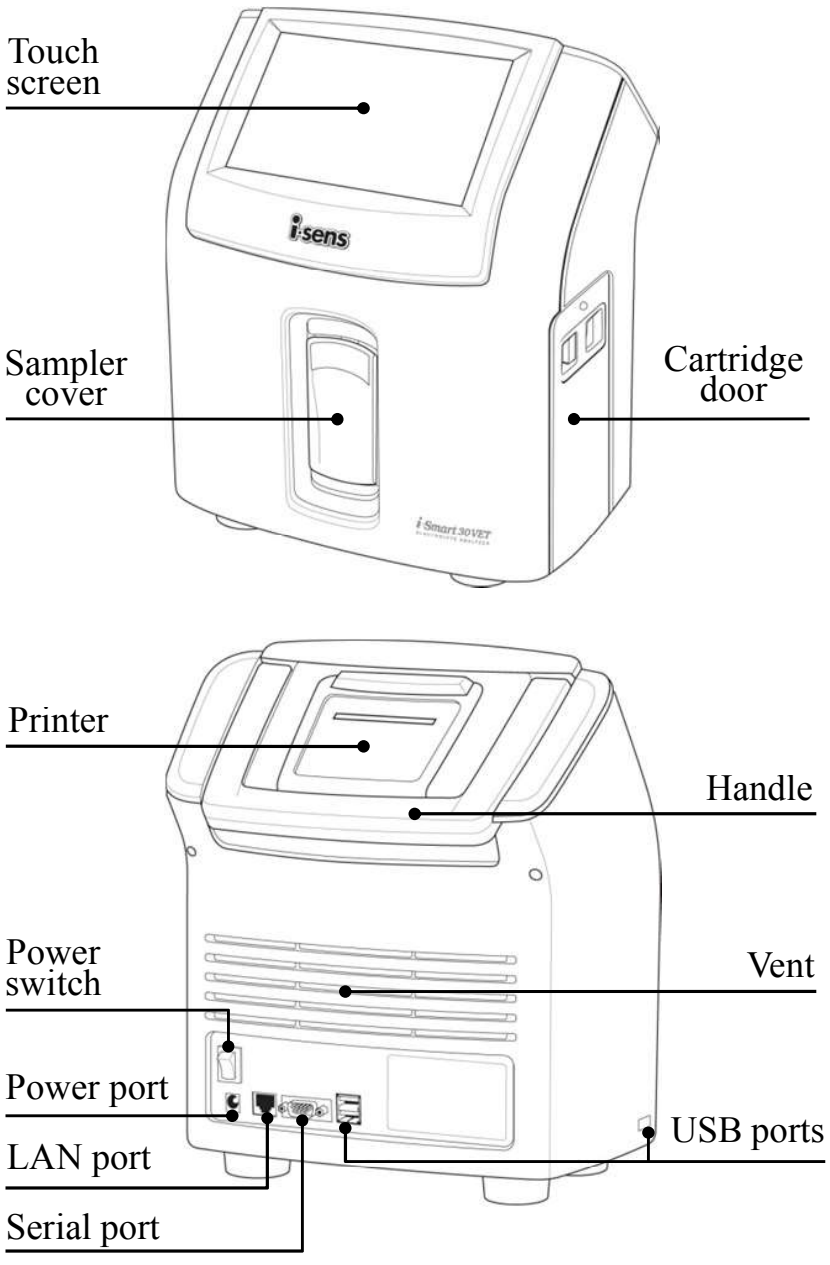
Term	Description
Na^+	Sodium ion
K^+	Potassium ion
Cl^-	Chloride ion
Cal	Calibration
Cal 1	1-Point calibration
Cal 2	2-Point calibration
QC	Quality control
Warning	A statement that alerts the operator to the possibility of injury, death, or other serious adverse reactions associated with the use or misuse 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

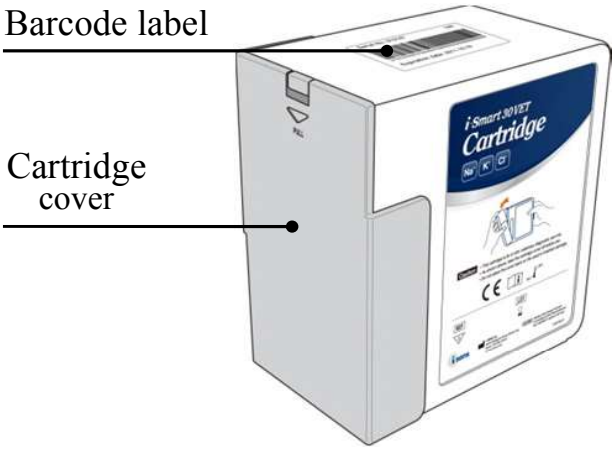
The i-Smart 30 VET electrolyte analyzer is intended to be used for the measurements of sodium, potassium, and chloride in whole blood, plasma, or serum. The analyzer is used by laboratory professionals for *in vitro* veterinary diagnostic testing.

Analyzer

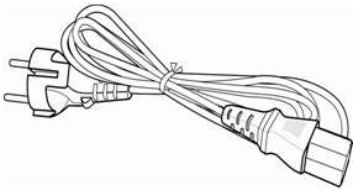


Product Description, *continued*

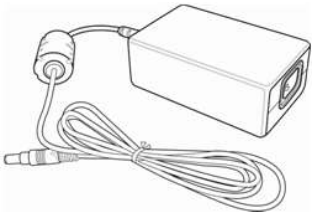
Cartridge



Accessories

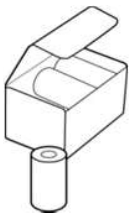


Power cord



Power adapter

Barcode scanner



Printer papers

Analyzer base

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2. Installation

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Installation Requirement

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.

Electrical Requirements

- ❑ Volt AC : 100 ~ 240 VAC, grounded electrical supply
- ❑ Amp : 1.5 A
- ❑ Watt : 150 W
- ❑ Frequency : 50/60 ±10% Hz
- ❑ Power cord : 3-wire, approved
- ❑ Power adapter : Output +24 VDC, 2.7 A, 65 W

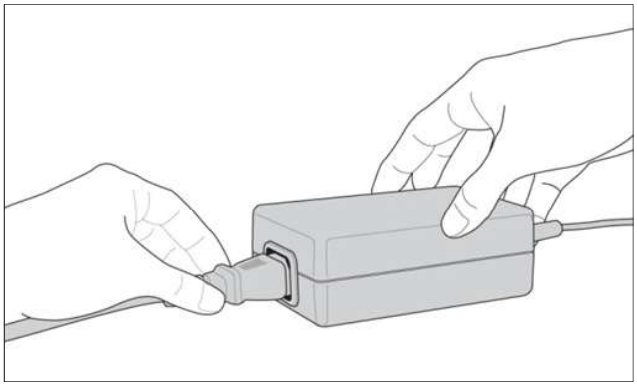
Start-up

Caution

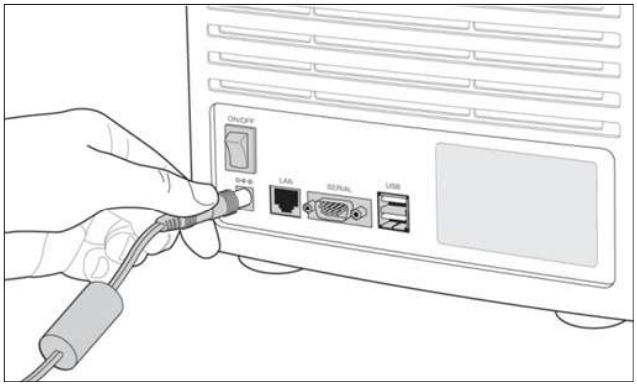
- ❑ Check that the power switch is in " O" (OFF) position.
- ❑ Always connect the power according to the steps described in this manual.
- ❑ Always use a grounded electrical outlet.
- ❑ Use only the power cord and power adapter provided by the manufacture.
- ❑ Electrical plugs and sockets vary by countries.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

Power Connection

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.

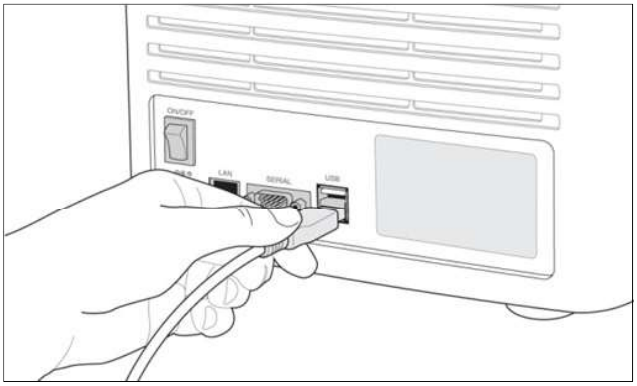


3. Plug the power cord into an electrical outlet.

Start-up, *continued*

Barcode Scanner Connection

1. Insert the USB connector of the barcode scanner into a USB port on the back or side of the analyzer.



Note:

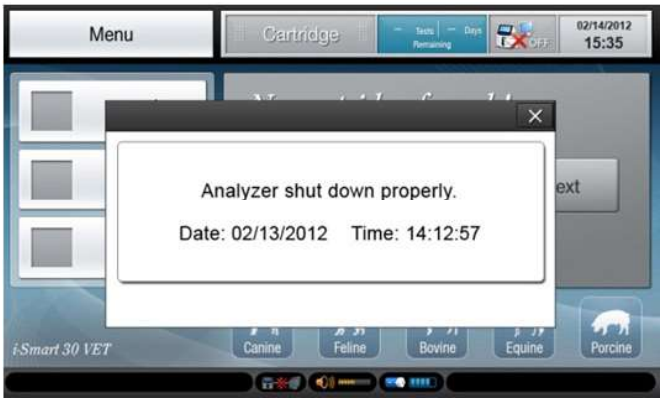
✓ When the analyzer is turned on, the barcode scanner will make a beep sound and the indicator light on the scanner will turn on briefly.

Start-up, *continued*

Turn On

1. Facing the back of the analyzer, flip the black power switch on the lower left side, marked "❙ / ○" to the " ❙ " position.
2. The screen will turn on and the rebooting will start.

3. If the rebooting is completed, the message to inform the previous shutdown condition will appear.



4. Press ✕ at the top right corner of the message to close. The main screen will appear.

Start-up, *continued*

Turn 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 and the battery icon appears instead, it indicates that the analyzer is on battery power. 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. Instrument Settings > Instrument Setup > Date and Time***.

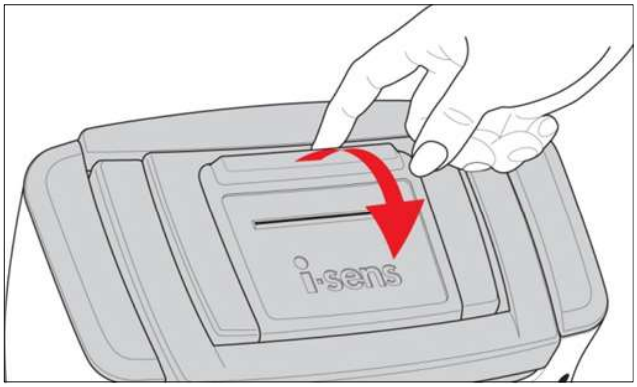
Note:

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

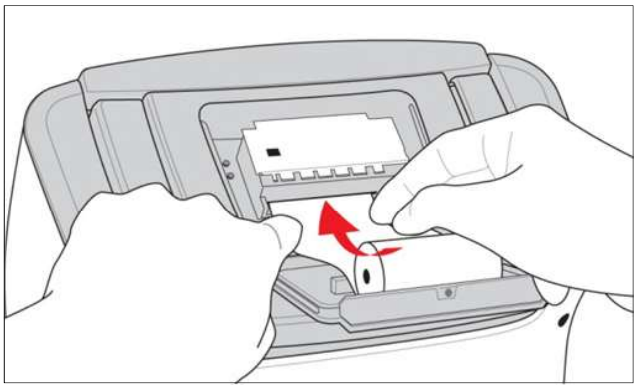
Printer Paper

Install Paper

1. Facing the back of the analyzer, flip down the printer cover.



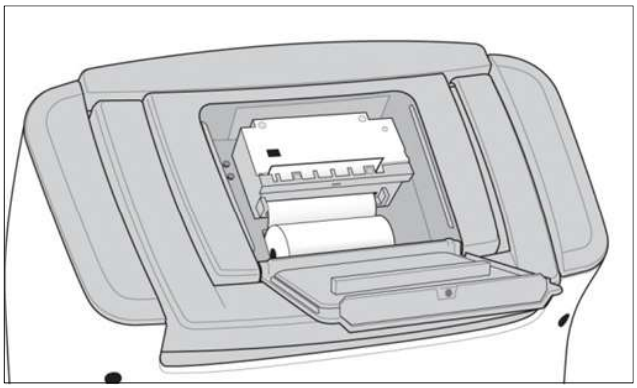
2. Insert the end of the paper in parallel with the printer slot. The printer will begin to feed the paper automatically.



Note:

- ✓ The cut end of the paper should be straight and clean for auto feeding.
- ✓ Paper should be fed from the bottom of the roll.

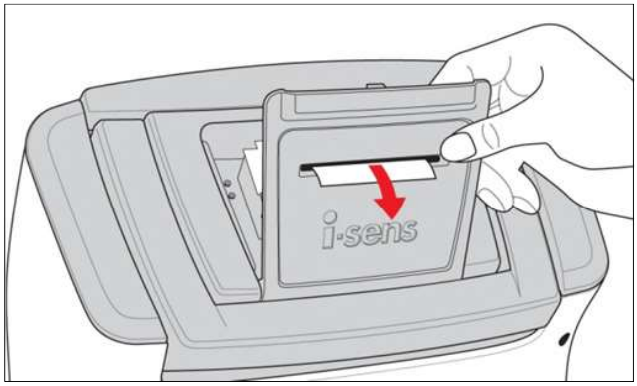
3. Place the paper roll into the paper holder.



Printer Paper, *continued*

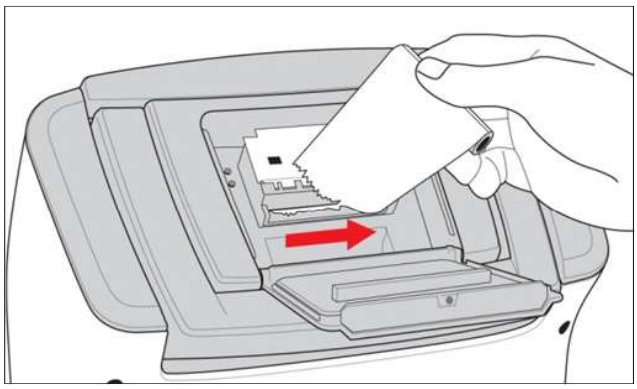
Install Paper, *continued*

4. Insert the end of the paper roll into the paper slot and close the printer cover.

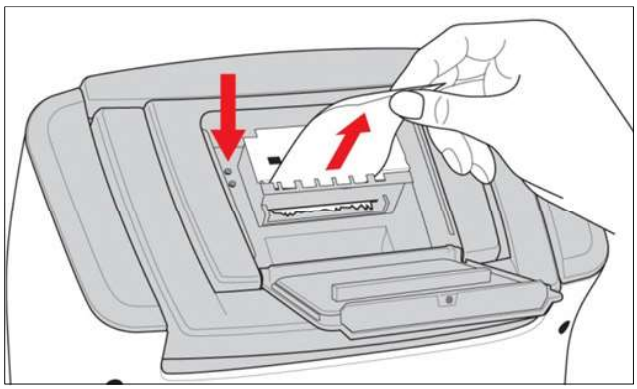


Remove Paper

1. Facing the back of the analyzer, flip down the printer cover and remove the remaining paper roll.



2. Hold down the feed switch to advance the remaining paper.



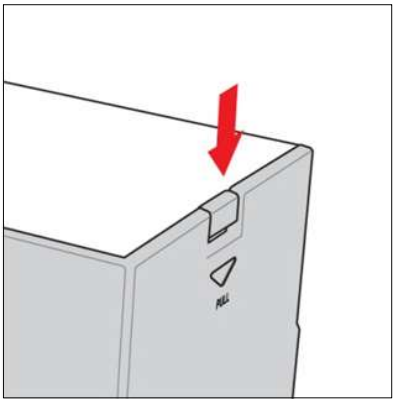
Note:

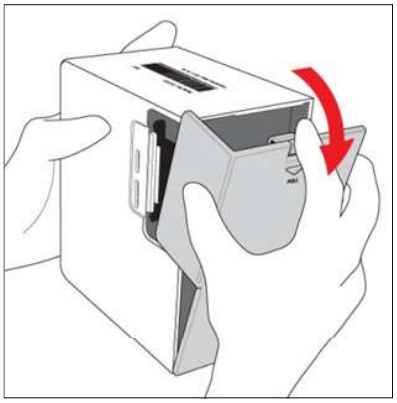
- ✓ Do not use force to pull out the paper from the printer.
- ✓ Never pull the paper in the reverse direction of printing.

Cartridge

Install Cartridge

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





3. At the **No cartridge found** screen, press **Next**.

4. Press **Next** to continue.

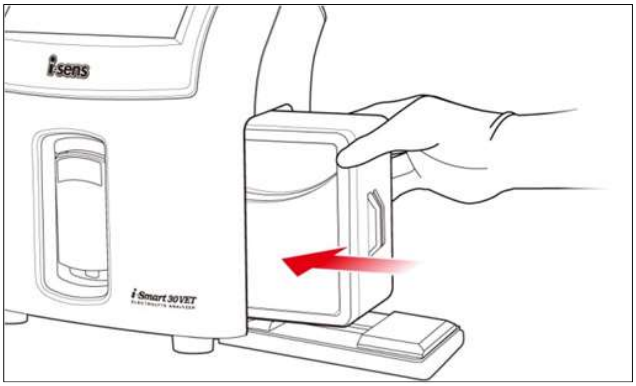
Cartridge, *continued*

Install Cartridge, *continued*

5. When the ***Scan new cartrdige barcode*** message appears, scan the barcode on the new cartridge using the barcode scanner.

6. If the analyzer accepts the barcode, the grey box will turn to green.
7. When the ***Insert scanned cartridge and close door*** message appears, open the cartridge door.

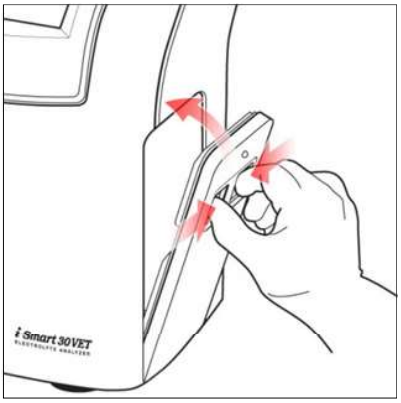
8. Facing the catridge label, insert the cartridge into the analyzer.

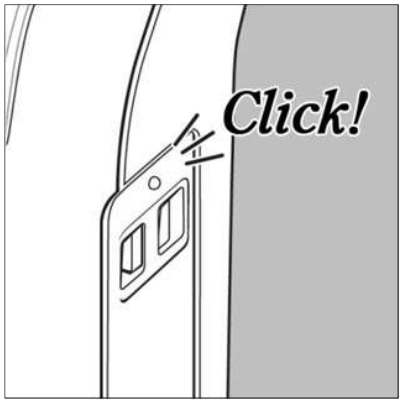


Cartridge, *continued*

Install Cartridge, *continued*

9. Hold the cartridge door lock with two fingers and close the door. If the door is properly locked, it will make a clicking sound.





10. The analyzer will change to the **Warming-Up** screen.

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

Note:

- ✓ Never re-install the cartridge cover back to the cartridge if the cartridge has been inserted into the analyzer. It will cause the calibration solutions to leak in the cartridge.
- ✓ Once the cartridge cover is removed, be careful with exposed sharp edges of the cartridge parts.

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3. Instrument Settings

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Sample Setup ·····3-10
QC Setup ·····3-16
Instrument Setup ·····3-18
Print Setup ·····3-23
Interface Setup ·····3-25

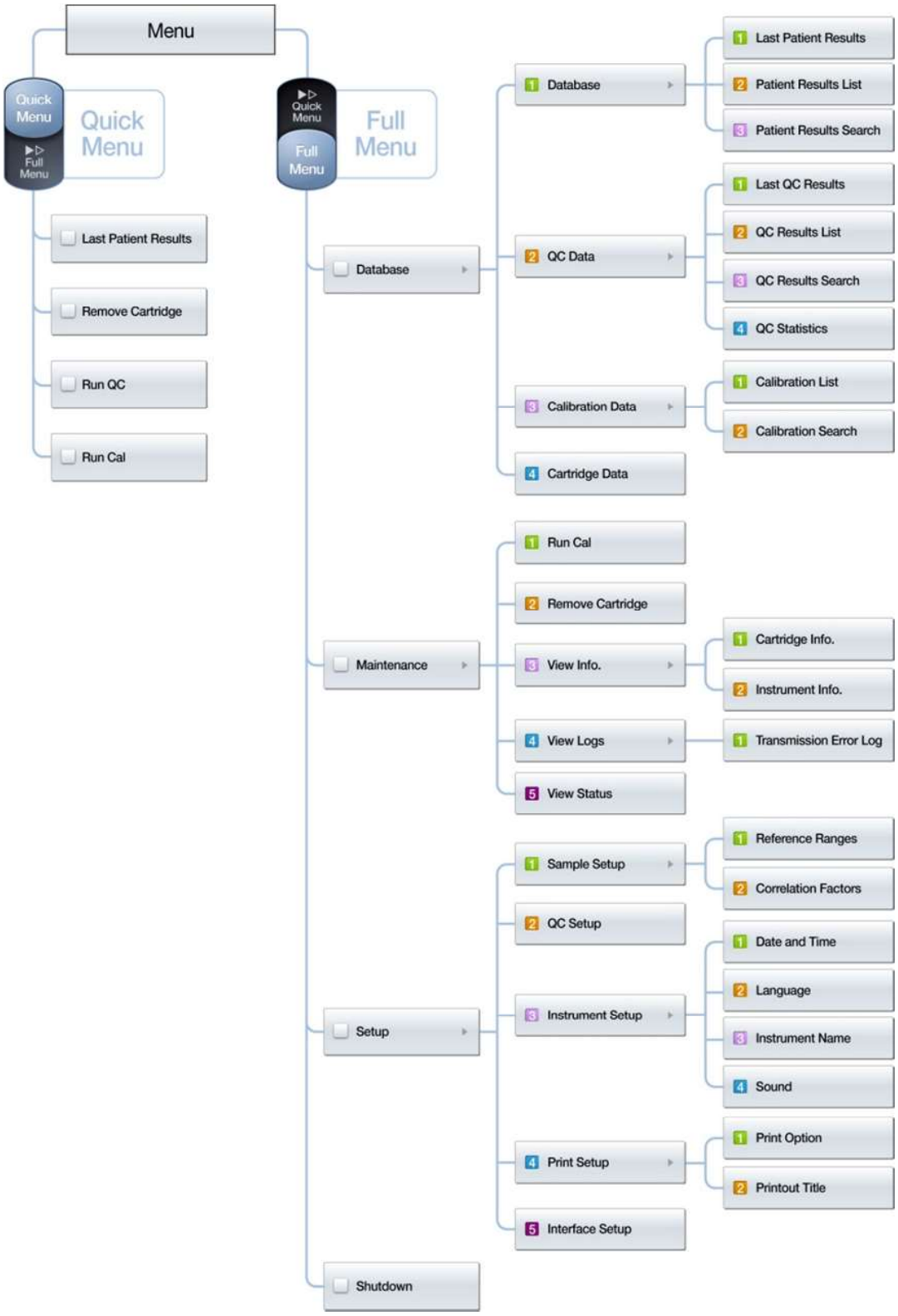
Screen Menus

Ready Screen

No.	Description
①	Menu button
②	Current status of the analyzer
③	Remaining test number of the installed cartridge
④	Remaining uselife days of the installed cartridge
⑤	Status of data type selection at the interface setup: Pressing once will display the interface setup screen.
⑥	Current date and time of the analyzer
⑦	Current status of the sensors: Pressing twice quickly will display the latest slope of the sensor.
⑧	Next scheduled task
⑨	Current status of power connection
⑩	Sound volume: Pressing once will display volume increase/decrease icons.
⑪	Current status of LAN port connection: Pressing once will display the current host IP and port status.
⑫	Expiration date and time of the installed cartridge.
⑬	Animal species: Pressing twice quickly will display the entered reference range.

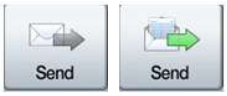
Screen Menus, *continued*

Menu options



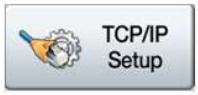
Screen Menus, *continued*

Icons and Buttons

Button	Function
	Close and return to main screen
	Close menu display
	Close message pop-ups
	Save setup
	Print
	Return to previous screen
	Send results to network: grey arrow turns to green if sending has succeeded
	Go to patient results list screen
	Go to QC results list screen
	Go to calibration list screen
	Begin to search
	Go to patient results search screen
	Go to QC results search screen
	Go to calibration search screen

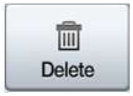
Screen Menus, *continued*

Icons and Buttons, *continued*

Button	Description
	Go to a selected patient results screen
	Go to a selected QC results screen
	Go to previous or next results screen
	Scroll to next page
	Scroll to previous page
	Move highlight bar up or down
	Increase or decrease sound volume
	Begin to aspirate sample
	Accept or discard QC results
	Run 1-point, or 2-point calibration
	Run a QC sample
	Go to serial setup screen
	Go to TCP/IP setup screen
	Continue to next step

Screen Menus, *continued*

Icons and Buttons, *continued*

Button	Description
	Shutdown
	Copy cartridge data
	Add QC lot information
	Edit QC lot information
	Delete QC lot information
	Scan QC barcode
	Clear entered reference ranges
	Restore default values
	Setup DNS automatically
	Setup IP information automatically
	Continue to next step
	Go to service mode

Screen Menus, *continued*

Icons and Buttons, *continued*

Icon	Function
	Indicate data entry by dropdown options available
	Indicate data entry by keyboard available
	Indicate AC adapter powered status
	Indicate battery powered status
	Indicate data types to transmit selected or not selected at the interface setup
	Indicate network LAN cable is connected or disconnected to analyzer
	Indicate sound status: on or off
	Indicate the results has been previously sent to network or not

Screen Menus, *continued*

Keyboards

The i-Smart 30 analyzer will bring up following keyboards on the screen for data entry.

Alphabetic Keyboard

Numeric & Special Character Keyboard

Date and Time Entry Keyboards

Screen Menus, *continued*

Menu Access

1. Press **Menu**. The **Quick Menu** options will appear.

2. For the full menu options, press **Full Menu**.

3. At all screens except for sample analysis, press the current screen box at the upper left corner to access the current menu options.

Screen Menus, *continued*

Screen Saver

When the analyzer is not in use for more than 10 minutes, the screen will switch to screensaver. However, if the analyzer is at the **current sample results** screen, the screen will not switch to the screen saver.

Messages

The analyzer will bring up message boxes on the screen to inform the operator of one of following information:

- ✓ The current task that the analyzer is about to start or in-progress.
- ✓ The step-by-step instructions that the operator needs to follow in carrying out a task, such as sample introduction or cartridge replacement.
- ✓ The errors that the operator needs to know or take a necessary action.

Voice Guide

Besides displaying messages, the analyzer will play sound playbacks to help the operator when performing one of following tasks:

- ✓ Blood sample introduction
- ✓ QC sample introduction
- ✓ Cartridge removal
- ✓ Cartridge installation
- ✓ Cartridge data copy
- ✓ Alarm: “The battery is low”

Sample Setup

Reference Ranges

1. Go to **Menu > Full Menu > Setup > 1 Sample Setup**.
2. Select **1 Reference Ranges**. The following screen will appear.

3. Select the animal species for which the reference ranges will be entered. A screen similar to following will appear.

4. Press each of boxes and enter low and high limits of the reference range for each analyte.

Sample Setup, *continued*

Reference Ranges, *continued*

5. Press **Print** to print out the entered reference ranges.
6. Press **Default** to apply the default values. Refer to the next page to see the default values for each animal species.
7. Press **OK** to save the setup and go back to the **Reference Ranges** screen.

Note:

✓ Before saving the setup, the analyzer will check that the entered values meet following conditions:

- The values for low and high limits are entered.
- The low limit value is lower than the high limit value.

✓ If any of the entered values is not valid, the analyzer will not save the setup and ask the operator to correct the invalid value at the setup screen.

8. At the **Reference Ranges** screen, select another animal species and continue to setup the reference ranges.
9. If the reference ranges setup is completed for all desired animal species, press **Exit** to exit to the main screen.

Sample Setup, *continued*

Default Reference Ranges

Note:

- ✓ The default reference ranges saved in the analyzer for each animal species are shown in tables below.
- ✓ It is the responsibility of individual institutions to determine the reference ranges for each animal species.

Canine

Analytes	Reference Ranges	Unit
Na^+	140 ~ 154	mmol/L
K^+	3.8 ~ 5.6	mmol/L
Cl^-	102 ~ 117	mmol/L

Feline

Analytes	Reference Ranges	Unit
Na^+	146 ~ 159	mmol/L
K^+	3.8 ~ 5.3	mmol/L
Cl^-	108 ~ 130	mmol/L

Bovine

Analytes	Reference Ranges	Unit
Na^+	135 ~ 148	mmol/L
K^+	4.0 ~ 5.8	mmol/L
Cl^-	96 ~ 109	mmol/L

Equine

Analytes	Reference Ranges	Unit
Na^+	133 ~ 147	mmol/L
K^+	2.8 ~ 4.7	mmol/L
Cl^-	97 ~ 110	mmol/L

Porcine

Analytes	Reference Ranges	Unit
Na^+	139 ~ 153	mmol/L
K^+	4.4 ~ 6.5	mmol/L
Cl^-	97 ~ 106	mmol/L

Sample Setup, *continued*

Correlation Factors

1. Go to **Menu > Full Menu > Setup > 1 Sample Setup**.
2. Select **2 Correlation Factors**. The following screen will appear.

3. Select the animal species for which the correlation factors will be entered. A screen similar to following will appear.

4. Check the **Apply** at the bottom screen. The default values will be activated.

Sample Setup, *continued*

Correlation Factors, *continued*

5. Press each of boxes and enter slope and offset values for each analyte using the keyboard.

Note:

✓ The acceptable values for slope and offset of correlation factors for each analyte are as following:

Analytes	Slope	Offset
Na^+	0.70 ~ 1.30	±10.00
K^+	0.70 ~ 1.30	±1.00
Cl^-	0.70 ~ 1.30	±10.00

6. Press **Print** to print out the entered correlation factors.
7. Press **OK** to save the setup and go back to the **Correlation Factors** screen.

Sample Setup, *continued*

Correlation Factors, *continued*

8. Select another animal species and continue to setup the correlation factors.
9. If the correlation factors setups are completed for all desired animal species, press **Exit** to exit to main screen.

QC Setup

QC Lot Setup

1. Go to **Menu > Full Menu > Setup > 2 QC Setup**. The following screen will appear.

2. Select a desired **Level Box** and press **Add**. The following screen will appear.

3. For *i-Smart Electrolyte* QC materials, press **QC Barcode** to scan the QC barcode on the QC insert sheet.

QC Setup, *continued*

QC Lot Setup, *continued*

4. For other QC materials, manually enter QC lot information using the keyboard.

5. Press **Print** to print out the entered QC Lot information.
6. Press **OK** to save and go back to the **QC setup** screen.
7. Continue to setup QC lots for other levels.
8. To edit the previously saved QC lot information, press the desired **QC Level Box** and press **Edit**.

9. To delete the previously saved QC lot information, press the desired **QC Level Box** and press **Delete**.
10. If the QC setup is completed for all desired QC levels, press **OK** to save all changes and exit to main screen.

Instrument Setup

Date &Time

1. Go to **Menu > Full Menu > Setup > 3 Instrument Setup**.
2. Select **1 Date & Time**. The following screen will appear.

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

4. Press **Time Format Box** and select the desired time format from the drop-down list.

5. Press **Date Setup Box** and enter the desired date using the keyboard.

Instrument Setup, *continued*

Date &Time, ***continued***

6. Press **Time Setup Box** and enter the desired time using the keyboard.

7. Press **OK** to save the setup and exit to main screen.

Instrument Setup, *continued*

Language

1. Go to **Menu > Full Menu > Setup > 3 Instrument Setup**.
2. Select **2 Language**. The following screen will appear.

3. Currently, English is the only available language.
4. Press **Exit** to exit to main screen.

Instrument Setup, *continued*

Instrument Name

1. Go to **Menu > Full Menu > Setup > 3 Instrument Setup**.
2. Select **3 Instrument Name**. The following screen will appear.

3. Press **Instrument Name Box** and enter the desired name using the keyboard.

4. Press **OK** to save the setup and exit to main screen.

Note:

✓ Instrument name will appear on the main screen and on printouts.

Instrument Setup, *continued*

Sound

1. Go to **Menu > Full Menu > Setup > 3 Instrument Setup**.
2. Select **4 Sound**. The following screen will appear.

3. Adjust the volume by pressing or .
4. Check **ON** or **OFF** to turn on or off the sound.
5. Press **OK** to save the setup and exit to main screen.

Print Setup

Print Option

1. Go to **Menu > Full Menu > Setup > 4 Print Setup**.
2. Select **1 Print Option**. The following screen will appear.

3. For Patient Data, select **Auto** to setup the printer to print a patient report automatically as the results become available on the screen. Otherwise select **Manual** to manually print a patient report.
4. For QC Data, select **Auto** to setup the printer to print a QC report automatically as the results become available on the screen. Otherwise select **Manual** to manually print a QC report.
5. For Calibration Data, select **Auto** to setup the printer to print a Cal 2 report automatically as the results become in the analyzer. Otherwise select **Manual** to manually print a Cal 2report.
6. Select **ON** to turn on or **OFF** to turn off a duplicate print option.
7. Select **ON** to turn on or **OFF** to turn off an auto cutting option.
8. Press **OK** to save the setup and exit to main screen.

Print Setup, *continued*

Printout Title

1. Go to **Menu > Full Menu > Setup > 4 Print Setup**.
2. Select **2 Printout Title**. The following screen will appear.

3. Press a desired **Line Box** and enter title using the keyboard.

4. Press **OK** to save the setup and exit to main screen.

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 > Full Menu > Setup > 5 Interface Setup**. The following screen will appear.

2. Check data types (**Patient, QC**, **Calibration)** and communication types (**Com Port**, **Ethernet**) to transmit.
3. Select **Auto Send** or **Manual Send** for the analyzer to transmit the selected data types automatically or manually as such data become available in the analyzer.

Serial Setup

1. If **Com Port** is checked, press **Serial Setup**. The following screen will appear.

2. Press **Baud Rate Box** and select the desired option from the drop-down list. Default is 9600.

Interface Setup, *continued*

Serial Setup, *continued*

3. Press **Data Bit Box** and select the desired option from the drop-down list. Default is 8.
4. Press **Stop Bit Box** and select the desired option from the drop-down list. Default is ONE.
5. Press **Parity Box** and select the desired option from the drop-down list. Default is None.
6. Press **Handshake Box** and select the desired option from the drop-down list. Default is None.
7. If serial setup is completed, press **OK** to save the setup and return to the previous screen.

TCP/IP Setup

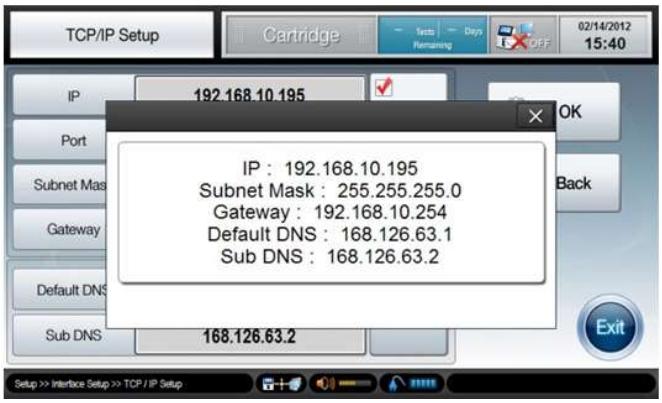
1. At the **Interface Setup** screen, if **Ethernet** is checked, press **TCP/IP Setup**. The following screen will appear.

2. Press **IP Box** and enter necessary information using the keyboard.

Interface Setup, *continued*

TCP/IP Setup, ***continued***

3. Move to other boxes and enter necessary information.
4. To setup automatically, press **Auto IP** and **Auto DNS**. The following message will appear.



Note:

✓ Manual setup is recommended instead of auto setup since auto setup may cause network collision.

5. Press **OK** to save the setup and go back to the **Interface Setup** screen.
6. Press **OK** to save the setup and exit to main screen.

4. Sample Analysis

Patient Samples ·····4-1
QC Samples ·····4-6

Patient Samples

Introducing Sample

Note:

✓ Sample analysis is available only when the analyzer is in **Ready** status. While the analyzer is not in **Ready** status, the sampler cover is locked.

1. Check that the analyzer is in **Ready** status.
2. Lift up the sampler cover. The following message will appear.

3. Select an animal species corresponding to the sample. 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*

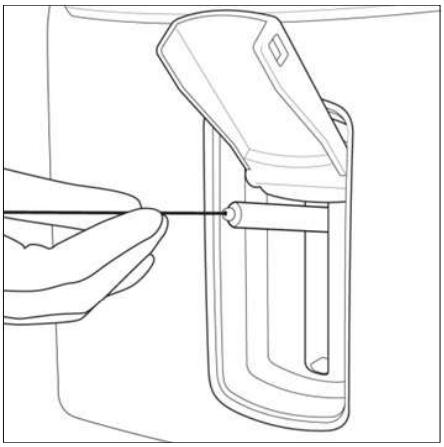
Introducing Sample, *continued*

4. 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.

5. For a capillary sample, lift the sampler cover up all the way. 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.

6. If the sampler probe is adequately immersed in the sample, press **Aspirate** to begin aspiration.

Patient Samples, *continued*

Introducing Sample, *continued*

7. The "***Aspirating sample. Please wait***" message will appear.
8. If the aspiration is completed, the "***Remove sample now***" message will appear. Remove sample from sampler probe.
9. Wait a second until the "***Close sampler cover***" message will appear.
10. Lower the sampler cover to close.

Sample Information

1. After sample introduction, the following screen will appear.

2. To enter sample number, press **Sample No. Box** and enter the sample number using the keyboard.
3. If the sample number is available in barcode, scan the barcode using the attached barcode scanner.
4. In the same manner, continue to enter necessary information for **Patient ID**, **Operator ID**, and/or **Patient Name**.

Patient Samples, *continued*

Patient Results

1. When sample analysis is completed, the analysis results will appear at the **Current Sample** screen.

2. The results will appear in black color if the reference ranges have not been setup in the analyzer.
3. If the reference ranges have been entered in the analyzer, the results will appear with the reference ranges.

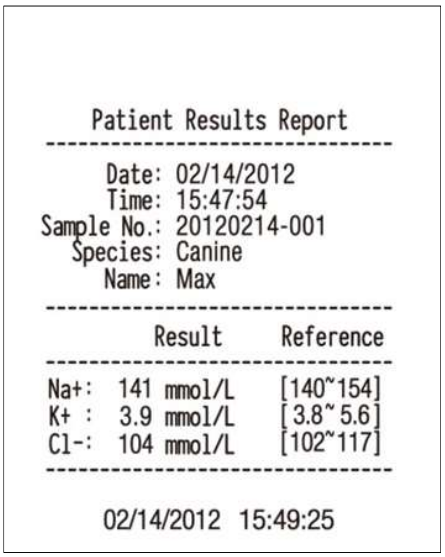
Note:

- ✓ If a result is within the reference range, the result will appear in blue color.
- ✓ If a result is above reference range, the result will appear in red color along with ↑.
- ✓ If a result is below reference range, the result will appear in red color along with ↓.

Patient Samples, *continued*

Patient Results, ***continued***

4. If any result falls outside of the measuring range, "**out of range**" phrase will appear instead of the result in value. The phrase will be accompanied by ↑↑ or ↓↓ to indicate above the upper limit or below the lower limit.
5. If a sensor has failed in the previous Cal 2, the corresponding results will not appear. Instead "**slope error**" phrase will appear.
6. To transmit the results to the network, press **Send**.
7. Press **Print** to print out the results. A printout similar to following will be printed.



```
Patient Results Report
--------------------------------
     Date: 02/14/2012
     Time: 15:47:54
Sample No.: 20120214-001
  Species: Canine
     Name: Max
--------------------------------
          Result      Reference
--------------------------------
Na+:  141 mmol/L    [140~154]
K+ :  3.9 mmol/L    [3.8~5.6]
Cl-:  104 mmol/L    [102~117]
--------------------------------

     02/14/2012  15:49:25
```

Note:

✓ The arrows on the screen will be printed as **[H]** or **[L]** on printouts.

8. If the analyzer has been set to auto print, the analyzer will print the results as soon as they are reported.
9. Press **Exit** to save the results and exit to main screen.
10. The analyzer will go through Rinse and Cal 1 process before returning to the Ready status for a next sample.

QC Samples

Introducing QC Sample

1. Press **Menu** and select **Run QC**. 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.

2. When the "***Lift sampler cover***" message appears, lift up the sampler cover. The following screen will appear.

3. Select the desired QC level to run.

QC Samples, *continued*

Introducing QC sample, *continued*

4. When "***Introduce QC Sample now***" message appears, immerse the end of the sampler probe into the QC sample and press **Aspirate**.

Note:

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

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

Entering QC Information

1. The **QC Lot No.** and **Lot Description** will be automatically filled from the saved QC lot information.
2. If needed, enter **Operator ID** using the keyboard or barcode scanner.

QC Samples, *continued*

QC Results

1. If the QC sample analysis is completed, the results will appear along with the entered QC ranges.

Note:

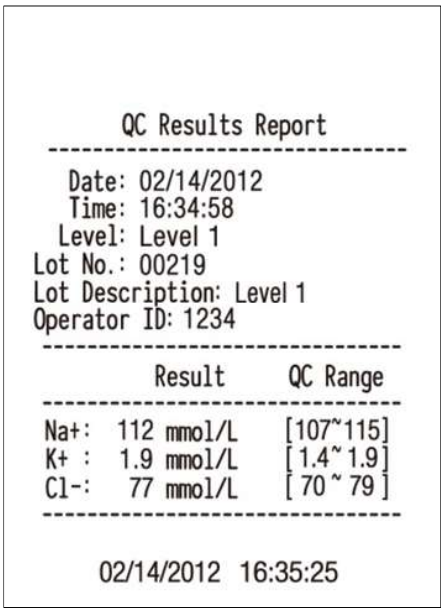
- ✓ If a result is within the QC range, the result will appear in blue color.
- ✓ If a result is above the QC range, the result will appear in red color along with ↑.
- ✓ If a result is below the QC range, the result will appear in red color along with ↓.

2. Press **Accept** or **Discard** to accept or discard the QC results. The status will switch from PENDING to ACCEPTED or DISCARDED.

QC Samples, *continued*

QC Results, ***continued***

3. To transmit the results to the network, press **Send**.
4. Press **Print** to print out the results. A printout similar to following will be printed.



```
        QC Results Report
 ------------------------------
   Date: 02/14/2012
   Time: 16:34:58
  Level: Level 1
Lot No.: 00219
Lot Description: Level 1
Operator ID: 1234
 ------------------------------
          Result      QC Range
 ------------------------------
Na+:  112 mmol/L    [107~115]
K+ :  1.9 mmol/L    [ 1.4~ 1.9]
Cl-:   77 mmol/L    [ 70 ~ 79 ]
 ------------------------------

     02/14/2012  16:35:25
```

Note:

✓ The arrows on the screen will be printed as **[H]** or **[L]** on printouts.

5. Press **Exit** to save the results and return to main screen.
6. If **Exit** is pressed before selecting **Accept** or **Discard**, the results will be automatically saved as "accepted status".

5. Database

Patient Data ·····5-1
QC Data ·····5-4
Calibration Data ·····5-8
Cartridge Data ·····5-10

Patient Data

Last Patient Results

1. Go to **Menu > Full Menu > Database > 1 Patient Data**.
2. Select **1 Last Patient Results**. The following screen will appear.

Note:

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

3. Press ⇦ to move to the previous patient results screen.
4. Press **Patient Results List** to view the list of patient results.
5. Press **Exit** to exit to main screen.

Patient Results List

1. Go to **Menu > Full Menu > Database > 1 Patient Data**.
2. Select **2 Patient Results List**. The following screen will appear.

Patient Data, *continued*

Patient Results List, ***continued***

3. The latest Patient Results are listed on the top. Use **Up** or **Down**, or **Page Up** or **Page Down** to scroll the list of patient results.
4. To view a patient results screen, select a desired row from the list and press **View**. The corresponding patient results screen will appear.

5. To search patient results, press **Patient Results Search** to go to the **Patient Results Search** screen. Refer to the Patient Results Search section below.
6. To transmit patient results to the network, select desired results from the list and press **Send**.

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

Patient Data, *continued*

Patient Results Search

1. Go to **Menu > Full Menu > Database > 1 Patient Data**.
2. Select **3 Patient Results Search**. The following screen will appear.

Note:

✓ Search criteria for patient results are as following:

- ❑ Measured date(s)
- ❑ Animal species
- ❑ Sample No.
- ❑ Patient ID
- ❑ Patient Name

3. Enter desired search criteria in appropriate boxes.
4. Press **Search**. The searched patient results will appear.
5. To view the list of patient results, press **Patient Results List**.
6. Press **Exit** to exit to main screen.

QC Data

Last QC

1. Go to **Menu > Full Menu > Database > 2 QC Data**.
2. Select **1 Last QC Results**. The following screen will appear.

3. Press the **QC Results List** to view the list of QC Results.
4. Press to move to the previous QC results screen.
5. Press **Exit** to exit to main screen.

QC Results List

1. Go to **Menu > Full Menu > Database > 2 QC Data**.
2. Select **2 QC Results List**. The following screen will appear.

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

QC Data, *continued*

QC Results List, ***continued***

4. To view a QC Results screen, select a desired row from the list and press **View**. The corresponding QC results screen will appear.

5. To search QC results, press **QC Results Search** to go to **QC Results Search** screen. Refer to the QC Results Search section below.

6. To transmit QC results to the network, select desired results from the list and press **Send**.

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

QC Data, *continued*

QC Results Search

1. Go to **Menu > Full Menu > Database > 2 QC Data**.
2. Select **3 QC Results Search**. The following screen will appear.

Note:

✓ Search criteria for QC results are as following:

- ❑ Measured date (s)
- ❑ QC Level
- ❑ QC Lot No.
- ❑ Either Pass or Fail QC results only

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

QC Data, *continued*

QC Statistics

1. Go to **Menu > Full Menu > Database > 2 QC Data**.
2. Select **4 QC Statistics**. The following screen will appear.

3. Press **Select Lot No. Box** and select a desired QC lot number from the drop-down list.
4. The statistics of the selected QC lot will appear.

5. Press **Print** to print the QC statistics.
6. Press **Exit** to exit to main screen.

Calibration Data

Calibration List

1. Go to **Menu > Full Menu > Database > 3 Calibration Data**.
2. Select **1 Calibration List**. The following screen will appear.

3. The latest Cal 2 results are listed on the top. Use **Up** or **Down**, or **Page Up** or **Page Down** to scroll the list of Cal 2 results.
4. To print a Cal 2 results, select a desired Cal 2 results from the list and press **Print**.
5. To search Cal 2 results, press **Calibration Search** to go to **Calibration Search** screen. Refer to the Calibration Search section below.
6. To transmit Cal 2 results to the network, select desired results from the list and press **Send**.

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

Calibration Data, *continued*

Calibration Search

1. Go to **Menu > Full Menu > Database > 3 Calibration Data**.
2. Select **2 Calibration Search**. The following screen will appear.

3. Enter starting and ending dates for desired search period.
4. Press **Search**. The searched Cal 2 results will appear.

5. Press **Back** to go back to the **Calibration Search** screen.
6. Press **Exit** to exit to main screen.

Cartridge Data

Cartridge Data Copy

1. Go to **Menu > Full Menu > Database > 4 Cartridge Data**. The following screen will appear.

2. The latest cartridge data will appear on the top. Use **Up** or **Down,** or **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***" message will appear along with the copy progress bar.
6. When the data copy is completed, the "***Copy completed. Remove the USB memory***" message will appear.
7. Remove the USB memory from the USB port.

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6. Shutdown

Analyzer Shutdown ·····6-1
Power Recovery ·····6-3
Data Recovery ·····6-5

Analyzer Shutdown

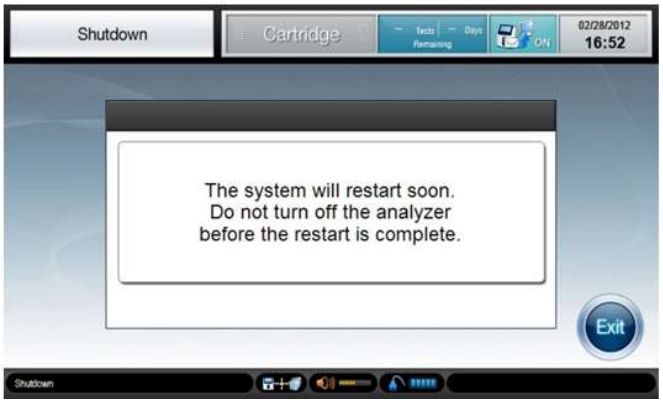
Caution

- ❑ The power of the analyzer should be turned off according to the shutdown procedure as described in this manual. Failure to follow the proper shutdown procedure can cause damage to the data or the component of 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 during the shutdown process or when the analyzer is turned off.

Shutdown Analyzer

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

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



Analyzer Shutdown, *continued*

Shutdown Analyzer, *continued*

3. Do not turn off the analyzer yet. Wait until the analyzer finishes a complete power cycle of turning itself off and on.
4. After the power cycle, the following screen will appear.

5. Wait until the progress bar reaches 100%.
6. Facing the back of the analyzer, flip the black power switch on the lower left side, marked "❙ / ○" to the "○" position.

Power Recovery

Cartridge Restoration

- ❑ If the power went out while the cartridge was in use on the analyzer, upon power recovery the cartridge can be restored back to use, only if:
  - The power interruption has been less than 24 hours and the analyzer had been in ready status or in calibration process when the power went out.
  - The power interruption has been less than 20 minutes and the analyzer had been analyzing a sample when the power went out.
- ❑ The maximum number that each cartridge can be restored upon power recovery is limited to five.

Power Recovery Warming-up

1. If the power has come back within the time limits that the cartridge can be restored, the **warming-up** screen will appear.
2. At the warming-up screen, the message with the previous power shutdown information will appear.

Power Recovery, *continued*

Power recovery warming-up, *continued*

3. The message contains following information:
   - ✓ Whether the proper shutdown procedure was carried out in the previous shutdown or not.
   - ✓ The previous shutdown date and time.
   - ✓ The count that the cartridge has been restored.

4. The cartridge warming-up after power recovery will normally take about 12 minutes.
5. After the warming-up, the analyzer will return to the Ready state.

Data Recovery

Data Corruption Check

- ❑ Whenever the analyzer is turned on, the analyzer will check for corrupted data that may exist in database or cartridge data folder.
- ❑ As long as corrupted data is not found, the analyzer will continue to reboot.
- ❑ If corrupted data is found, the analyzer will alert the operator to initiate **data recovery** process to repair the corrupted data.

Data Recovery Procedure

1. If data corruption is found, the following screen will appear.

Note:

✓ Upon the operator's permission, the analyzer will carry out data recovery process during which following action will be taken:

In database:

- If corrupted data is found, the entire database will be erased.
- If corrupted data is not found, the database will be fully recovered.

In cartridge data folder:

- If corrupted data is found, only corrupted data will be deleted.

Data Recovery, *continued*

Data Recovery Procedure, *continued*

2. Press **Yes** to continue. Data recovery will start and the following screen will appear.

3. If the data recovery is completed, the analyzer will continue to reboot.
4. After rebooting, a screen similar to following will appear. The actions taken in the previous data recovery will appear in the message box.

Data Recovery, *continued*

Data Recovery Procedure, *continued*

5. If a problem occurs during data recovery, the following screen will appear. Turn off the analyzer and immediately call a service engineer to report the error: data recovery failure.

Cancel Data Recovery

1. At the **Data Recovery Mode** screen, press **No** to cancel data recovery. The following screen will appear.

2. Turn off the analyzer and call a service engineer to report the error: data corruption.

7. Maintenance

Calibration ……7-1
Cartridge Removal ……7-3
Analyzer Information ……7-5
Analyzer Status ……7-7
Cleaning ……7-8

Calibration

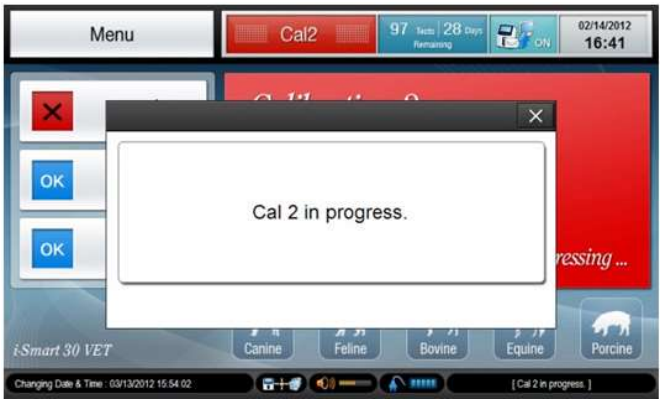
Run Cal

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

Note:

✓ The same screen can be accessed through **Menu > Run Cal**.

2. Select **Cal 1** or **Cal 2**. The following message will appear.



Cal 2 Auto Repeat

- ❑ If a sensor has failed 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 "***Cal 2 Repeat in progress***" message will appear.
- ❑ If the same sensor fails in Cal 2 three times in succession, the sensor status will appear as ✕ on the main screen.

Calibration, *continued*

Sensor Status

1. For each sensor, a pass or failure result from the latest Cal 2 will appear as OK or ✕ at the main screen.

2. Press the **Sensor Status** icon twice quickly. The latest slope result of the sensor and the allowable slope range will appear.

Cartridge Removal

Caution

- ❑ Treat the used cartridge as biohazard material.
- ❑ Before removing the used cartridge, wear appropriate personal protective clothing to protect from biohazard materials.

Remove Cartridge

1. Go to **Menu > Full Menu > Maintenance > 2 Remove Cartridge**. The following screen will appear.

Note:

- ✓ The same screen can be accessed through **Menu > Remove Cartridge**.
- ✓ The analyzer will automatically change to the **Remove the cartridge** 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.

Cartridge Removal, *continued*

Remove Cartridge, *continued*

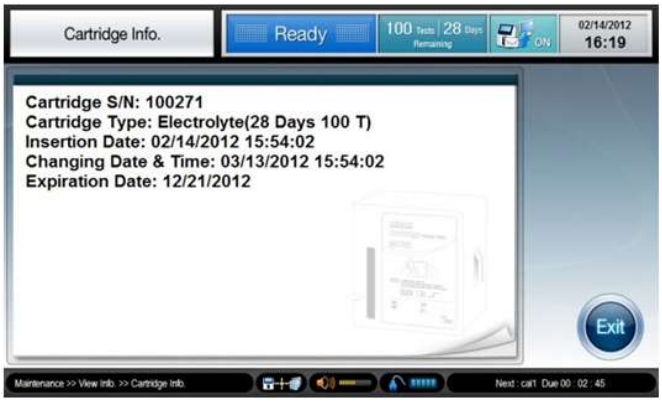
2. Press **Next**. The following screen will appear.

3. Press **Next** to continue.
4. A clicking sound will be heard as the cartridge door lock is released.
5. Open the cartridge door and remove the used cartridge from the analyzer.
6. Close the cartridge door.
7. Dispose of the used cartridge in accordance with the laboratory's established procedures for disposing of biohazardous materials.
8. To install a new cartridge, refer to ***2. Installation > Cartridge*** for detailed procedure.

Analyzer Information

Cartridge Information

1. Go to **Menu > Full Menu > Maintenance > 3 View Info**.
2. Select **1 Cartridge Info**. The following screen will appear.



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

Instrument Information

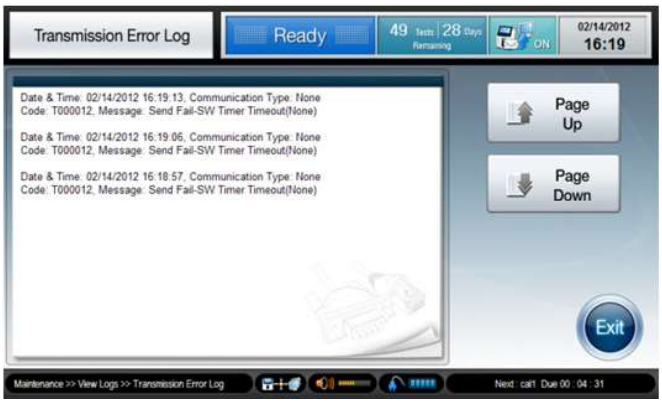
1. Go to **Menu > Full Menu > Maintenance > 3 View Info**.
2. Select **2 Instrument Info**. The following screen will appear.

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

Analyzer Information, *continued*

View Log

1. Go to **Menu > Full Menu > Maintenance > 4 View Logs**.
2. Select **1 Transmission Error Log**. The following screen will appear.



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

Analyzer Status

View Status

1. Go to **Menu > Full Menu > Maintenance > View Status**. The following screen will appear.

2. On the **View Status** screen, the following information is available:
   - ❑ Sensor Signals.
   - ❑ Measuring Temperature.
   - ❑ Battery Charging level
   - ❑ Status of Cartridge installation, Cartridge door, Sampler cover
3. Press **Cal 1** or **Cal 2** to initiate Cal 1 or Cal 2 on the current screen.
4. Press **Exit** to exit to main screen.

Note:

- ✓ If the cartridge is properly installed, **Cartridge Installation** will appear as **Installed**, **Cartridge Door** as **Close**, and **Sampler Cover** as **Close**.
- ✓ The **Service Mode** is for service engineers ONLY and its access is 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 a 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% sodium hypochlorite cleaning solution.

   Note:

   - ✓ Commercial Clorox contains approximately 5% sodium hypochlorite.
   - ✓ Mix 1part 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.
5. Using a soft cloth dampened with water, wipe the analyzer.
6. Using a dry cloth, dry the surface of the analyzer.

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8. Troubleshooting

Trouble Shooting ·····8-1
Error Code ·····8-5

Trouble Shooting

Instruction

- ❑ 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. Remove the USB connector of the barcode scanner from the analyzer.
2. Insert the USB connector into the same USB port of the analyzer. The barcode scanner will make a beep sound and the indicator light on the scanner will turn on briefly
3. Wait 5 seconds for the analyzer to recognize the barcode scanner.
4. If the same problem occurs, repeat the procedure from step 1 with a different USB port of the analyzer.

When scanning barcode, the scanner emits red light, but does not take barcode (no beep sound and no indicator light on):

1. Position the barcode scanner close to and in parallel with the barcode.
2. Check the cartridge barcode for any damage. If damage is found, try again with another new cartridge. Report the damaged cartridge to a service engineer.

Battery

If one of following situations applies:

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

1. Call a service engineer to replace battery.
2. Until the battery is replaced, the analyzer will operate normally as long as the power is supplied from the outlet.

Trouble Shooting, *continued*

Calibration

*If the sensor state appears as **X**.*

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

Cartridge Data Copy

If one of following situations applies:

- ❑ *The analyzer does not detect a USB memory.*
- ❑ *The data copy has failed or stopped.*

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.

Cartridge Installation

If the barcode scanner does not emit red light,

1. Check the connection between the barcode scanner and the analyzer (refer to **barcode scanner** in Trouble Shooting).

If the analyzer rejects the cartridge barcode,

1. Check that the cartridge is an i-Smart 30 VET cartridge.
2. Check that the cartridge is not past its expiration date.
3. Check that the cartridge has not been previously used.

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

1. Open and close the cartridge door.
2. Gently press the cartridge door toward the analyzer until a clicking sound is heard.

Trouble Shooting, *continued*

Power

While the anlayzer 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 one hour.
6. Turn on the power switch of the analyzer again.

Printer

If one of following situations applies:

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

1. Open the printer cover.
2. Replace a roll of print paper if the paper has run out.
3. Lift up the printer head and check for paper jam. If jammed, remove the jam and close the printer head. Then, press the **RESET** switch on the left side of the printer.

Note:

- ✓ The analyzer will resume printing up to 8 reports in the printer queue if the printer has stopped.

Trouble Shooting, *continued*

Sample Analysis

If one of following situations applies:

- ❑ *The "Insufficient sample error" appears on the result screen.*
- ❑ *The "Out of range" message 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.

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.

Error Code

Error Code

1. If the analyzer encounters an error while in use the following error code will appear on the screen.

Error Code	Description
ESYS001 ~ ESYS007	Hardware related error
EDB001 ~ EDB005	Database error
ESW001 ~ ESW030	Software related 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.

9. Specifications

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Instrument Specifications ·····9-2
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Operating Specifications

Measured Parameters

❑ Measured Parameters

Parameter	Range	Resolution
Na^+	20 ~ 250 mmol/L	1 mmol/L
K^+	0.5 ~ 20.0 mmol/L	0.1 mmol/L
Cl^-	20 ~ 250 mmol/L	1 mmol/L

- ❑ Sample types: whole blood, serum and plasma
- ❑ Anticoagulant: appropriate amount of lithium heparin
- ❑ Sample volume: 60 μL
- ❑ Sample container: syringe or capillary tube
- ❑ Sample introduction: aspiration
- ❑ Measuring time: 35 seconds
- ❑ Measuring temperature: 37.0 ± 0.2 °C
- ❑ Measuring method : Ion Selective Electrode
- ❑ 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: 110 ~ 220 VAC (± 17%), 50 ~ 60 Hz

Instrument Specifications

Instrument Specifications

- Internal PC:1 GHz process Mobile PC / 1 GB RAM / 4 GB Flash Memory
- Operating System: Microsoft® Windows® XP Embedded
- Display:7" TFT-LCD, touch screen
- Printer: 2" thermal printer (internal printer)
- Printer paper: thermal (width: 57 mm, diameter: 30 mm)
- Port: USB (3 ports), Serial (RS-232), LAN (RJ45 Ethernet)
- Power adapter:
  - ✓ AC-DC power supplies (IEC/EN 60950-1 approved)
  - ✓ input: 100 ~ 240 VAC 50/60 Hz (±10%), 150 W
  - ✓ output: + 24 VDC, 2.7 A, 65 W
- Input power: + 24 VDC, within 65 W
- Internal fuse: 125 V (AC/DC combo), 3 A (slow blow)
- Internal battery: 14.8 V, 4.4 Ah (Lithium-ion cells: 4S2P)
  - ✓ Discharge time: maximum two hours
  - ✓ Charging 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): 292 mm x 256 mm x 208 mm
- Weight: 5.5 Kg

Cartridge Specifications

Cartridge

- Unit: 1 cartridge
- Uselife: 4 weeks
- Number of tests available: 30T, 50T, 100T, 150T, 200T
- Shelf life: 12 months from the manufacturing date
- Storage temperature: 10 ~ 30 °C
- Components:
  - ✓ Sensors
  - ✓ Cal 1solution, 400 mL
  - ✓ Cal 2 solution, 40 mL
  - ✓ Reference solution, 40 mL
  - ✓ Sampler and waste bag
  - ✓ Valve and tubing

- Analyte Concentrations of the calibration solutions

	Na^+	K^+	Cl^-	Composition
Cal 1	144 mmol/L	3.9 mmol/L	116 mmol/L	Na^+, K^+, Cl^-, buffer, preservative, and surfactant
Cal 2	116 mmol/L	7.0 mmol/L	77 mmol/L	Na^+, K^+, Cl^-, buffer, preservative, and surfactant

- Size (HxWxD): 138 mm x 139 mm x 80 mm
- Weight: 0.8 kg

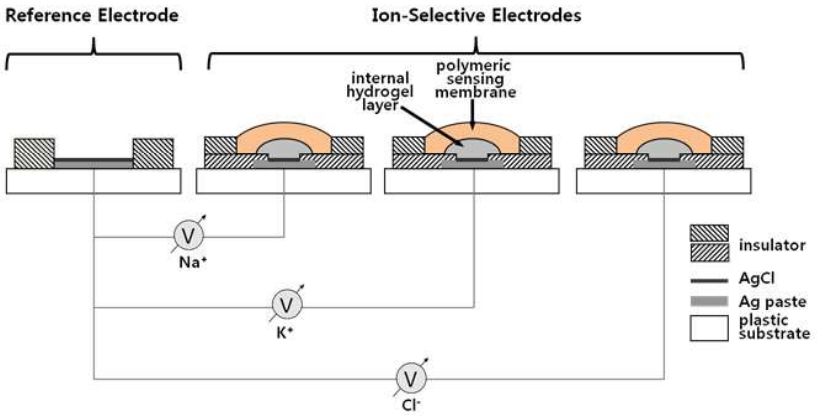
Principles

Measurement Principle

The measurements of sodium, potassium, and chloride by the i-Smart 30 VET electrolyte analyzer is based on the principle of ion-selective electrode (ISE). In an ion-selective electrode, an electrical potential is established across a membrane that is selective to a specific ion.

The i-Smart 30 VET uses the ion-selective electrodes that are composed of polymeric sensing membranes dispensed over internal hydrogel layers on a thin plastic substrate as shown in the figure below. The Ag/AgCl reference electrode is used and a liquid junction is formed where the reference solution flowing over the reference electrode meets the sample solution flowing over the ion-selective electrodes.

The electric potential of the ion-selective electrodes measured against the reference electrode is used to determine the activity (*a*) or *effective* concentration (*c*) of the ions of interest in a sample.



The electrical potential (*E*) of the ion-selective electrode measured against the reference electrode can be described by the following Nernst equation.

Principles, *continued*

Measurement Principle, *continued*

$$E = E^{o} \pm \frac{RT}{nF} \ln(a)$$

where, (+) for cation, (-) for anion

E: monitored potential — E^{o}: potential at $a = 1$

R: gas constant — T: temperature in Kelvin scale

n: valence of ion — F: Faraday constant

a: activity of the target ion

The Nernst equation above can be simplified as follows:

$$E = E' + S \cdot \log(c)$$

The standard electrical potential (E') and slope (S) are determined by measuring the electrical potentials of the ion-selective electrode in two calibration solutions that have known concentrations of the measuring ions at different levels. This process is called two-point calibration. Once the E' and S are determined, the unknown concentration of a sample can be determined by measuring the electric potential of the electrode in a sample.

Since the ion-selective electrodes tend to drift over the time, the i-Smart 30 VET analyzer periodically calibrates the sensors during the lifetime of the cartridge according to the pre-determined two-point calibration schedule. For such two-point calibrations, the analyzer uses two calibration solutions provided in the cartridge. Furthermore, the analyzer carries out one-point calibrations of the sensors using one of the calibration solutions in order to correct drifting baseline of the sensors between two-point calibrations.

Performance

Introduction

The results obtained during evaluation of i-Smart 30 VET electrolyte analyzers at i-SENS' research laboratories are shown below to demonstrate the typical performance characteristics of the i-Smart 30 VET.

QC Materials Precision

Typical Within-Run (S_{wr}), Between-Day (S_{dd}) and Total (S_T) Precisions of an i-Smart 30 VET Electrolyte Analyzer were obtained using three levels of i-Smart Electrolyte QC multi-level. Three levels were run in replicates of two once a day for 20 days on the i-Smart 30 VET (N per level=40).

Na^+ QC Material Precision

Quality Control	Mean (mmol/L)	Within-Run		Between-Day		Total	
		S_{wr}	%CV	S_{dd}	%CV	S_T	%CV
Level 1	116.5	0.59	0.5	0.33	0.3	0.68	0.6
Level 2	137.0	0.35	0.3	0.24	0.2	0.42	0.3
Level 3	156.0	0.52	0.3	0.52	0.3	0.74	0.5

K^+ QC Material Precision

Quality Control	Mean (mmol/L)	Within-Run		Between-Day		Total	
		S_{wr}	%CV	S_{dd}	%CV	S_T	%CV
Level 1	1.91	0.02	0.8	0.02	1.1	0.03	1.4
Level 2	4.00	0.00	0.0	0.00	0.0	0.00	0.0
Level 3	5.90	0.03	0.5	0.00	0.1	0.03	0.5

Cl^- QC Material Precision

Quality Control	Mean (mmol/L)	Within-Run		Between-Day		Total	
		S_{wr}	%CV	S_{dd}	%CV	S_T	%CV
Level 1	79.4	0.52	0.7	0.17	0.2	0.55	0.7
Level 2	101.0	0.16	0.2	0.00	0.0	0.16	0.2
Level 3	126.1	0.27	0.2	0.27	0.2	0.39	0.3

Performance, *continued*

Whole Blood Precision

Whole blood precision was obtained using seven levels of canine whole blood. Seven levels were tested in three or four replicates, depending on the availability of sample amount, on six analyzers. Low or high levels were prepared by adding a concentrated or a diluted electrolyte solution to whole blood, respectively, to expand the tested range.

Na^+ Whole Blood Precision

Level	N Per Level	Mean (mmol/L)	SD	%CV
1	24	126.0	0.20	0.2
2	24	132.0	0.00	0.0
3	24	143.9	0.34	0.2
4	18	154.3	0.69	0.4
5	18	160.3	0.49	0.3
6	18	170.2	0.71	0.4
7	18	177.8	0.81	0.5

K^+ Whole Blood Precision

Level	N Per Level	Mean (mmol/L)	SD	%CV
1	24	2.30	0.020	0.9
2	24	2.97	0.046	1.5
3	24	4.10	0.000	0.0
4	18	4.29	0.024	0.6
5	18	5.88	0.043	0.7
6	18	7.81	0.032	0.4
7	18	8.78	0.038	0.4

Performance, *continued*

Whole Blood Precision, *continued*

Cl^- Whole Blood Precision

Level	N Per Level	Mean (mmol/L)	SD	%CV
1	24	100.8	0.38	0.4
2	24	101.2	0.41	0.4
3	24	109.5	0.51	0.5
4	18	117.1	0.42	0.4
5	18	127.4	0.78	0.6
6	18	141.4	0.92	0.7
7	18	149.7	1.28	0.9

Whole blood Inaccuracy

The data from the whole blood precision study were used to derive the whole blood inaccuracy. Reference values for sodium, potassium, and chloride were obtained using a traditional laboratory electrolyte analyzer. The bias results were calculated by subtracting the mean of six analyzers from the mean of the reference analyzer. The acceptance criteria are established from CLIA 88.

Na^+ Whole Blood Inaccuracy

Level	N Per Level	Mean (mmol/L)	Target (mmol/L)	Bias	Specification (mmol/L)
1	24	126.0	123.3	-2.7	± 4.0
2	24	132.0	128.7	-3.3	± 4.0
3	24	143.9	142.3	-1.6	± 4.0
4	18	154.3	152.3	-2.0	± 4.0
5	18	160.3	157.0	-3.3	± 4.0
6	18	170.2	169.7	-0.5	± 4.0
7	18	177.8	175.3	-2.5	± 4.0

Performance, *continued*

Whole blood Inaccuracy, *continued*

K^+ Whole Blood Inaccuracy

Level	N Per Level	Mean (mmol/L)	Target (mmol/L)	Bias	Specification (mmol/L)
1	24	2.30	2.38	0.08	± 0.5
2	24	2.97	2.97	0.00	± 0.5
3	24	4.10	4.15	0.05	± 0.5
4	18	4.29	4.33	0.04	± 0.5
5	18	5.88	5.90	0.02	± 0.5
6	18	7.81	8.03	0.22	± 0.5
7	18	8.78	8.83	0.05	± 0.5

Cl^- Whole Blood Inaccuracy

Level	N Per Level	Mean (mmol/L)	Target (mmol/L)	Bias	Specification (mmol/L)
1	24	100.8	100.5	-0.3	± 5.0
2	24	101.2	101.3	0.1	± 5.1
3	24	109.5	109.0	-0.5	± 5.5
4	18	117.1	114.7	-2.4	± 5.7
5	18	127.4	125.0	-2.4	± 5.7
6	18	141.4	140.3	-1.1	± 6.3
7	18	149.7	146.0	-3.7	± 7.3

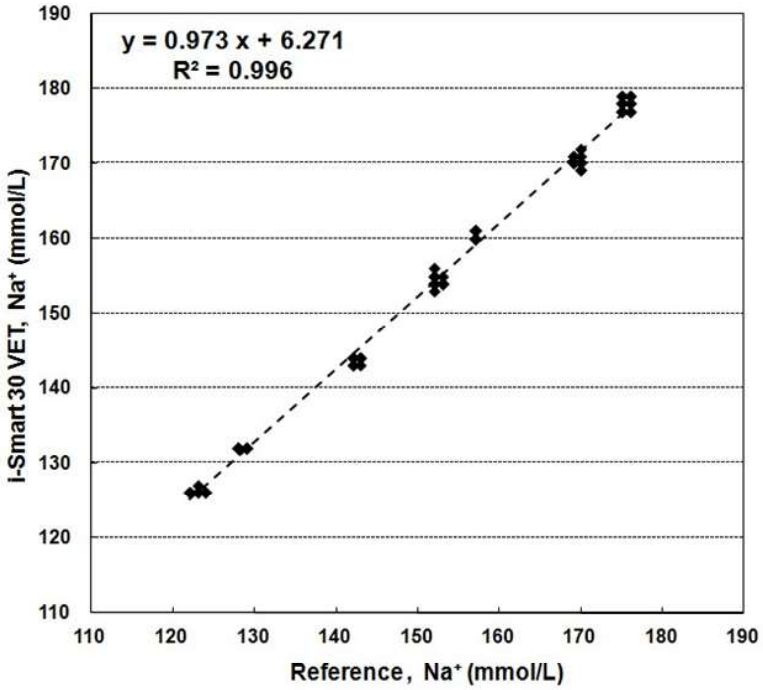
Performance, *continued*

Whole blood Linearity

The data from the whole blood precision in the previous section were used to calculate the whole blood linearity as shown in the following table and graphs.

Analyte	N per level	Slope	Intercept	R^2	Range
Na^+	18 to 24	0.973	+6.271	0.996	122 - 175
K^+	18 to 24	0.986	+0.007	0.999	2.3 - 8.5
Cl^-	18 to 24	1.047	-4.349	0.997	104 - 156

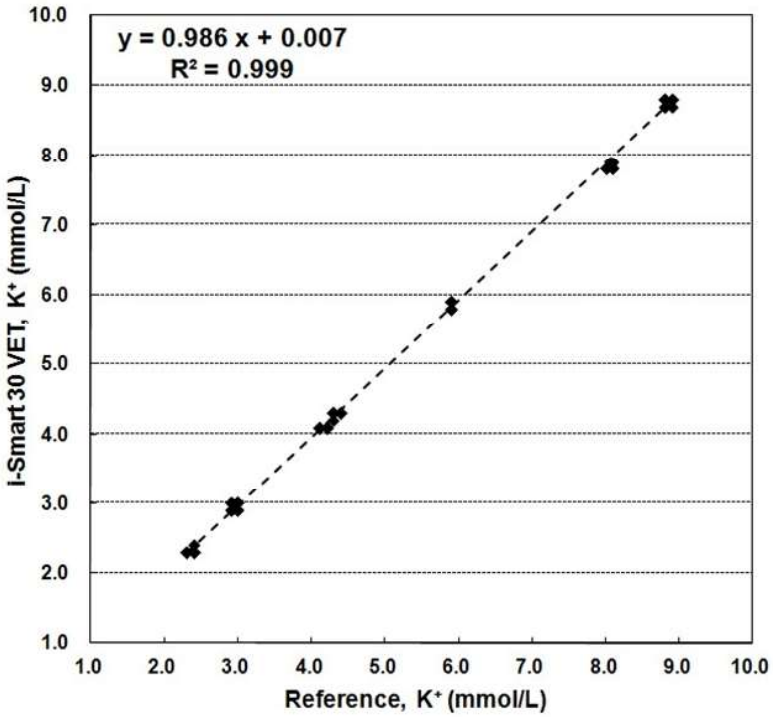
Na^+ Whole Blood Linearity



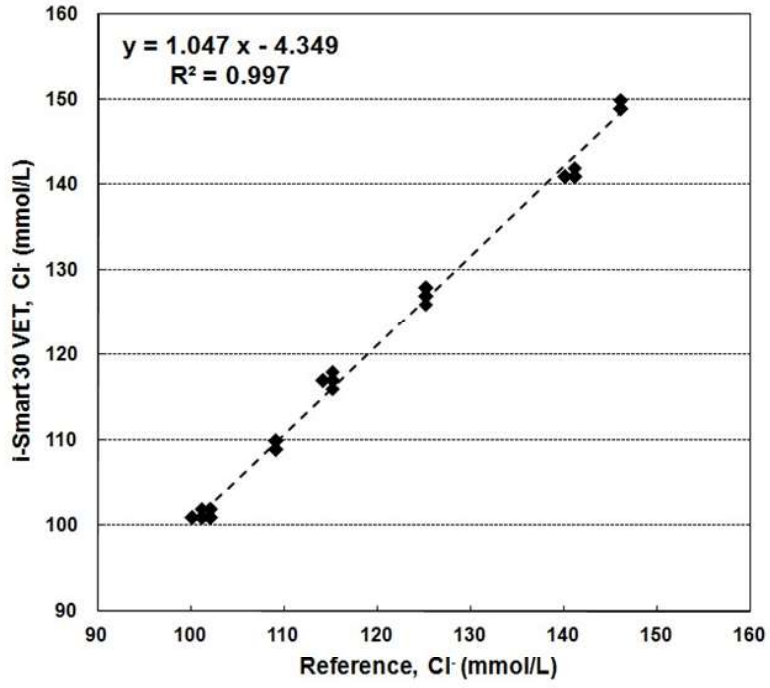
Performance, *continued*

Whole blood Linearity, ***continued***

K^+ Whole Blood Linearity



Cl^- Whole Blood Linearity



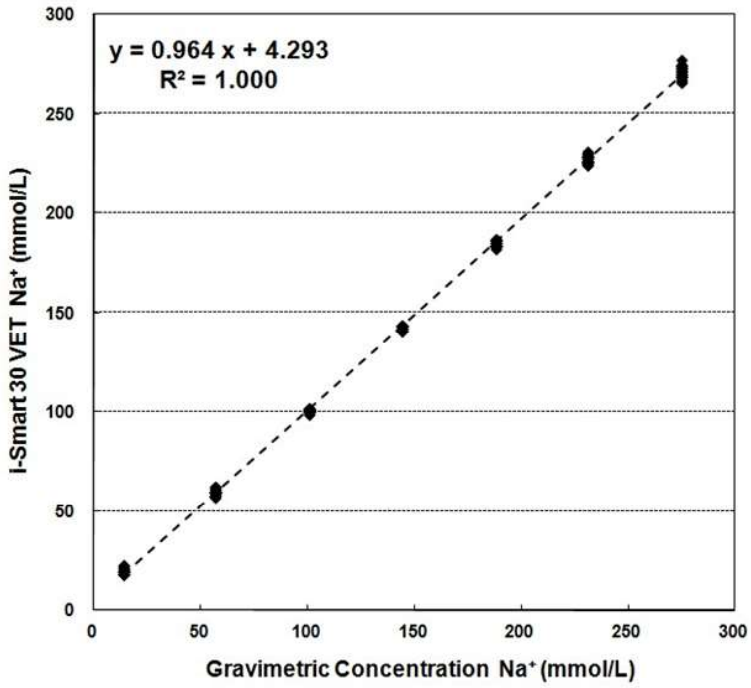
Performance, *continued*

Aqueous Solutions Linearity

The aqueous solution linearity was obtained using seven levels of electrolyte aqueous solutions. Seven levels were tested in four replicates on eleven i-Smart 30 VET analyzers.
The linearity data are shown in the following table and graphs.

Analyte	N per level	Slope	Intercept	R^2	Range
Na^+	44	0.964	+4.293	1.000	14 - 270
K^+	44	0.926	+0.139	0.999	0.3 - 23.0
Cl^-	44	0.909	+0.280	0.999	20 - 285

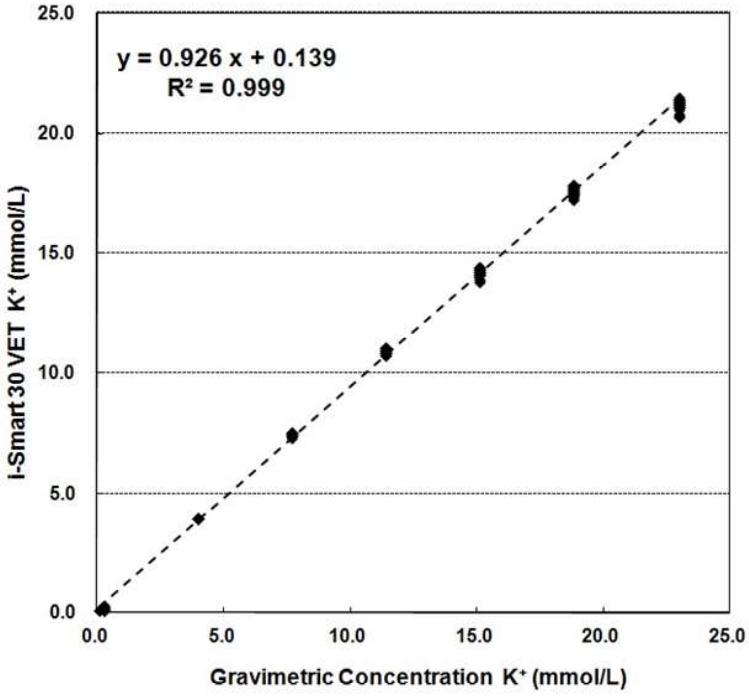
Na^+ Aqueous Solution Linearity



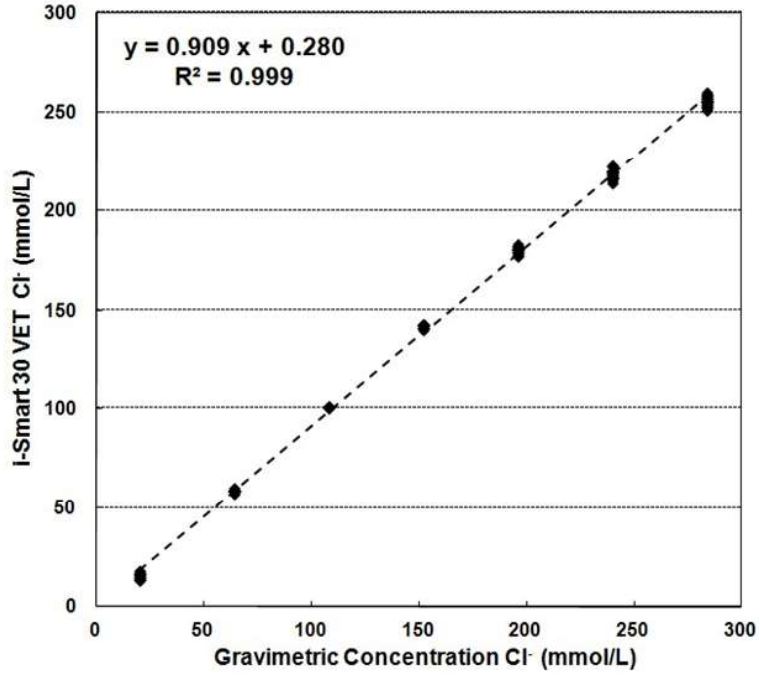
Performance, *continued*

Aqueous Solutions Linearity, *continued*

K^+ Aqueous Solution Linearity



Cl^- Aqueous Solution Linearity



Performance, *continued*

Interferences

Following substances are known to interfere with analysis results of i-Smart 30 VET electrolyte analyzers.

Substance	Interference
Na^+ heparin or Na^+ containing anticoagulants	Erroneously high Na^+ results
Anions, such as Br^-, I^-, SCN^-, Salicylate	Erroneously high Cl^- results

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Appendix A: Sample Collection and Handling

Caution

- Make sure there are no small air bubbles trapped in the collected sample. Small bubbles in the sample can affect the results.
- Do not use liquid anticoagulants as they can dilute the sample and affect the results.
- Hemolysis at any stage of sample preparation may cause erroneously high potassium results.
- If blood is not mixed completely with anticoagulant, blood clots can be partially formed in the sample. Samples containing clots must not be used as clots will cause sampling failure in the cartridge.
- Samples in which hemolysis is present or suspected and samples collected more than one hour before analysis must not be used.

Whole Blood

- Use heparinized vacuum blood collection tubes for whole blood.
- Collect blood up to the fill indicator on the tube label.
- Immediately after collecting blood, roll the tube between palms or gently shake it slowly up and down 8 to 10 times to thoroughly mix the blood and anticoagulant.

Serum

- Use non-heparinized, plain vacuum blood collection tubes for serum separation.
- Collect blood up to the fill indicator on the tube label.
- After collection, gently shake the tube slowly up and down five times.
- Allow the blood collection tube to stand vertically for about 30 minutes to fully clot before centrifugation.
- Centrifuge the blood sample, then collect and transfer the serum (liquid component separated from solid components of blood) to another clean container.

Appendix A: Sample Collection and Handling, *continued*

Plasma

- ❑ Use heparinized vacuum blood collection tubes for plasma separation.
- ❑ collect blood up to the fill indicator on the label.
- ❑ Roll the tube between palms or gently shake the tube slowly up and down 8 to 10 times.
- ❑ Centrifuge the tube immediately after collection.
- ❑ Collect and transfer the plasma (liquid component separated from solid components of blood) to another clean container.

Appendix B: Order Information

Analyzer	REF	Order unit
i-Smart 30 VET Analyzer (220VAC)	6130	1
i-Smart 30 VET Analyzer (110VAC)	6131	1

Accessory Parts	REF	Order unit
Power adapter	6101	1
220 VAC power cord (for Europe)[a]	6102	1
110 VAC power cord (for America)[b]	6103	1
Barcode scanner	6104	1
Printer paper box	6105	1 box (6 rolls)
Analyzer base	6106	1

a is for 6130, *b* is for 6131

Cartridge Types	REF	Order unit
i-Smart 30 VET Cartridge (30 Test)	6814	1
i-Smart 30 VET Cartridge (50 Test)	6810	1
i-Smart 30 VET Cartridge (100 Test)	6811	1
i-Smart 30 VET Cartridge (150 Test)	6812	1
i-Smart 30 VET Cartridge (200 Test)	6813	1

QC Material	REF	Order unit
i-Smart Electrolyte Quality Control, multi-level	6206	1 Box (10mlx3 levels)

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 question.