

Operator's Manual

7970 Rev. 0, March 2012



CE



i-SENS, Inc.

465-6 Wolgye4-dong, Nowon-gu, Seoul, 139-845, Korea **EC REP** Medical Technology Promedt Consulting GmbH, Altenhofstrasse 80, D-66386 St. Ingbert, Germany

Copyright © 2012 i-SENS, Inc. All Rights Reserved

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

Contents

1	Introduction
	Safety
	Symbols and Terms1-3
	Product Description1-5
2	Installation
	Installation Requirement
	Start-Up
	Printer Paper
	Cartridge
3	Instrument Settings
	Screen Menus
	Sample Setup
	QC Setup
	Instrument Setup
	Print Setup
	Interface Setup
4	Sample Analysis
	Patient Samples
	QC Samples
5	Database
	Patient Data
	OC Data
	Calibration Data
	Cartridge Data

6 Shutdown

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

7 Maintenance

Calibration	
Cartridge Removal	
Analyzer Information	7-5
Analyzer Status	
Cleaning	

8 Troubleshooting

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

9 Specifications

Operating Specifications	9-1
Instrument Specifications	9-2
Cartridge Specifications	9-3
Principles	9-4
Performance	9-6

Appendices

Appendix A: Sample Collection	and Handling	10-1
Appendix B: Order Information	-	10-3
Appendix C: Warranty		10-4

1. Introduction

Safety	1-1
Symbols and Terms	
Product Description	1-5

Safety

General	Use only the provided power cord and adapter.
Warnings	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	Power cord must be plugged into a grounded outlet.
Caution	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	CE mark		
FC	FCC mark		
i	Consult operating instructions		
EC REP	Authorized representative in the European community		
SN	Serial number		
	Caution: Attention, see operating instructions		
	Manufacturer		
X	Temperature limitation		
REF	Catalogue number		
LOT	Batch code		
\∑	Contains sufficient for <n> tests</n>		
	Use by		
ଷ୍ଟି	Biological risk		
X	Electrical and electronic equipment waste that requires specific disposal instructions from the manufacturer		
l	Printer		
⊖-€-⊕	DC power port		
0	Off (power)		
I	On (power)		

Symbols and Terms, *continued*

Terms

Term	Description		
Na ⁺	Sodium ion		
\mathbf{K}^+	Potassium ion		
Cľ	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

This page is intentionally left blank.

2. Installation

Installation Requirement	
Start-Up	2-2
Printer Paper	
Cartridge	

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	Volt AC	: 100 ~ 240 VAC, grounded electrical supply
Requirements	Amp	: 1.5 A
	Watt	: 150 W
	Frequency	: 50/60 ±10% Hz
	Power cord	: 3-wire, approved

 \Box 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 " | / O" 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 Pappears at the bottom row of the screen.

Note:

- ✓ 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.
- \checkmark Paper should be fed from the bottom of the roll.
- 3. Place the paper roll into the paper holder.



Printer Paper, continued

Install Paper,
continued4.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:

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

Cartridge

- Install
- 1. Take out the cartridge from the cartridge box.

Cartridge

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

5.

Install Cartridge, *continued* 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.

This page is intentionally left blank.

3. Instrument Settings

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							
1	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.							
1	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.							

Menu options



Icons and Buttons

Button	Function Close and return to main screen Close menu display Close message pop-ups Save setup Print			
Exit	Close and return to main screen			
Monu	Close menu display			
×	Close message pop-ups			
🕸 ок	Save setup			
Print Print	Print			
Back Back	Return to previous screen			
Send Send	Send results to network: grey arrow turns to green if sending has succeeded			
Patient Results List	Go to patient results list screen			
CC Results List	Go to QC results list screen			
Calibration List	Go to calibration list screen			
Q Search	Begin to search			
Patient Results Search	Go to patient results search screen			
Results Search	Go to QC results search screen			
Calibration	Go to calibration search screen			

Icons and Buttons, *continued*



Icons and Buttons, continued

Button	Description
O Shutdown	Shutdown
Сору	Copy cartridge data
+ Add	Add QC lot information
Edit	Edit QC lot information
Delete	Delete QC lot information
Barcode	Scan QC barcode
Clear	Clear entered reference ranges
Dofault	Restore default values
Auto DNS	Setup DNS automatically
Auto IP	Setup IP information automatically
Next	Continue to next step
Service Mode	Go to service mode

Icons and Buttons, continued

Icon	Function				
▼	Indicate data entry by dropdown options available				
	Indicate data entry by keyboard available				
s	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				
(1))	Indicate sound status: on or off				
🗟 🚔	Indicate the results has been previously sent to network or not				

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

Alphabetic Keyboard

i-Smart 30 VET 🗧								
Q	w	E	R	T	Y	U	а.]]	0 P
A	S	D	F	G	H	J	к	L
Caps Lock	Z	x	С	v	В	N	м	L
123 _;#		Space						Close

Numeric & Special Character Keyboard

20120214-001									-
1	2	3	4	5		7	8	9	0
	+ (2 +	•	•	%	:	&		/
3)				-				Ļ
Eng		Space					С	lose	

Date and Time Entry Keyboards



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 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 inprogress.
- ✓ 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.


Reference

- 5. Press **Print** to print out the entered reference ranges.
- Ranges,

continued

- 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.



- ✓ 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.

Unit

Sample Setup, *continued*

Note:

Default

Reference

Ranges

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

Canine	Analytes
	Na^+
	\mathbf{K}^+

	Na^+	140 ~ 154	mmol/L
	\mathbf{K}^+	3.8 ~ 5.6	mmol/L
	Cl	102 ~ 117	mmol/L
Feline	Analytes	Reference Ranges	Unit
Feline	Analytes Na ⁺	Reference Ranges 146 ~ 159	Unit mmol/L
Feline	Analytes Na ⁺ K ⁺	Reference Ranges 146 ~ 159 3.8 ~ 5.3	Unit mmol/L mmol/L

Reference Ranges

Bovine	Analytes	Reference Ranges	Unit
	Na ⁺	135 ~ 148	mmol/L
	\mathbf{K}^+	4.0 ~ 5.8	mmol/L
	Cl	96 ~ 109	mmol/L

Equine	Analytes	Reference Ranges	Unit
	Na ⁺	133 ~ 147	mmol/L
	\mathbf{K}^+	2.8 ~ 4.7	mmol/L
	Cl	97 ~ 110	mmol/L

Porcine	Analytes	Reference Ranges	Unit
	Na ⁺	139 ~ 153	mmol/L
	\mathbf{K}^+	4.4 ~ 6.5	mmol/L
	Cl	97 ~ 106	mmol/L

Correlation

1. Go to **Menu > Full Menu > Setup > 1 Sample Setup**.

Factors

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.



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
\mathbf{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.



Correlation Factors,	8.	Select another animal species and continue to setup the correlation factors.		
continued	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.

Level 1 Lot No		100		😒 ок
Lot Description		1021	Barcode	
Analytes	Low	High	J	Print
Na ⁺	=	-	mmol/L	
К*	-	1021	mmol/L	e Back
CI-		See 1	mmol/L.	6

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

- 02/14/2012 15:46 QC Lot Setup 7 Level 1 Lot No. 00219 -----Lot Description Level 1 1.4 2 2 Analytes Low Nat 107 K* e, CF letup >> QC Gelup >> QC Lot Setup
- 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, <u>press</u> 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.



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.

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

t 1. Go to Menu > Full Menu > Setup > 3 Instrument Setup.

Name

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.

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 <a>
- 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.
- 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*

- up, 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.

TCP/IP Setup	Caintildge	- Nemi - Remaining	- 5	02/14/2012 15:40
P				
Port	192.	168.10	0.191	Clear
Subnet Mask	7		9	(3
Gateway	4	5	6	
Default DNS	1	2	3	لہ
Sub DNS		0	DEL	Close

Interface Setup, continued

4.

TCP/IP Setup, 3. Move to other boxes and enter necessary information.

continued

To setup automatically, press **Auto IP** and **Auto DNS**. The following message will appear.



- ✓ 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 Sar	mples	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.



- ✓ 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.

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.



- ✓ 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.

Introducing	7.	The "Aspirating samp	ble. Please wait" message will appear.
Sample,	8.	If the aspiration is con	npleted, the " <i>Remove sample now</i> "
continued		message will appear.	Remove sample from sampler probe.
	0	W7-14	" Cl

- 9. Wait a second until the "*Close sampler cover*" message will appear.
- 10. Lower the sampler cover to close.

					0.11			
	After sam	nle intr	oduction	the	tollowing	screen v	will anne	ear
1.	The same	pic mu	ouucuon,	une	ionowing	sereen	n nn appo	car.

Sample Information



- 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 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.



- ✓ 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 \uparrow .
- ✓ If a result is below reference range, the result will appear in red color along with ↓.

4.

Patient Results,

continued

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 $\uparrow\uparrow$ or $\downarrow\downarrow$ to indicate above the upper limit or below the lower limit.

- 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.

	atien	t Result	s Report
Sample Spe	Date: Time: No.: No: Name:	02/14/2 15:47:5 201202 Canine Max	012 4 14-001
	F	Result	Reference
Na+:	141	mmol/L	[140 [~] 154] [3.8 [~] 5.6]

- ✓ 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 QC1.The QC Lot No. and Lot Description will be automaticallyInformationfilled 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.



- ✓ 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 \uparrow .
- ✓ 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,

3. To transmit the results to the network, press **Send**.

continued

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

	QC RESULTS I	Report
Dat Tim Leve ot No ot De ot De	te: 02/14/2012 ne: 16:34:58 el: Level 1 b.: 00219 escription: Le tor ID: 1234	vel 1
	Result	QC Range

- ✓ 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	
QC Data	5-4
Calibration Data	5-8
Cartridge Data	

Patient Data

Last Patient Results

- **1.** Go to **Menu > Full Menu > Database > 1 Patient Data**.
 - 2. Select **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 Result	s List	Ready	.91	tasi 27 Maja pracosi	2	02/16/201 15:48	12
Date & Time	Sample No.	Patient ID	Species	Na* mmcl4.	K' menalt.	Ct mmdd.	-
02/15/2012 15:47:54	20120215-004	100419001	Canine	144	4.9	109	13
12/15/2012 15:40:05	20120215-003	100419001	Canine	145	4.8	110	13
2/15/2012 15:20:57	20120215-002	100420002	Canine	144	4.8	111	13
2/15/2012 15:17:46	20120215-001	200902250	Feline	151	4.8	115	13
2/14/2012 17:19:47	20120214-004	200002250	Feline	151	4.9	113	123
22/14/2012 17:17:41	20120214-003	100420002	Canine	145	4.8	110	13
83-21-51 CE0CLEVC	20120214-002	200902140	Feline	452	49	114	1

Patient Data, continued

Patient Results3.The latest Patient Results are listed on the top.Use Up orList,Down, or Page Up or Page Down to scroll the list of
patient results.DownDown

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 1. Go to Menu > Full Menu > Database > 1 Patient Data.

Search

2. Select **3** Patient Results Search. The following screen will appear.



- \checkmark 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.
- 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.

QC Results	List	Ready	.91 sub	27 🕄	02/16/20 03 15:4	6/2012 5:49	
🔲 Date & Time	Level	Lot No.	Nat reneld.	Kº mmail.	Ci reroit		
02/15/2012 10:39:49	Level 3	3110824	150	5.9	125	10	
02/15/2012 10:33:40	Level 2	2110823	137	4.0	101	10	
02/15/2012 10:25:59	Level 1	1110822	115	1.9	80	-	
02/13/2012 11:10:02	Level 3	3110824	156	5.9	126	13	
02/13/2012 11:00:00	Level 2	2110823	136	4.0	101	10	
02/13/2012 10:52:54	Level 1	1110822	115	1.9	80	10	
02/10/2012 15:32:47	Level 3	3110824	155	5.9	126	1	
Send 📓	QC Results Search	View P	ge Up Page Down	tp	Down	**	
Database >> QC Data >> QC Ra	subLin			Next on	1 Due 00: 24: 33		

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.



- 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**.

QC Results	List	Ready	91 tetal	27 2	82/16/28 15:49	02/16/2012 15:49	
📝 Date & Time	Level	Lot No.	Na' model	K* meals	Cl' mnoi1.		
02/15/2012 10:39:49	Level 3	3110824	156	5.9	126	123	
15/2012 10:33:40	Level 2	2110823	137	4.0	101	6	
15/2012 10:25:59	Level 1	1110822	115	1.9	80	15	
A 13/2012 11:10:02	Level 3	3110824-	156	5.9	126	100	
13/2012 11:00:00	Level 2	2110823	136	4.0	101	6	
13/2012 10:52:54	Level 1	1110822	115	1.9	80	5	
10/10/2012 15:32:47	Level 3	3110824	156	5.9	126	15	
i 🛶 Send 🤰	OC Results Search	Yiew Page 0	Page Down	습 UD	Down		
Database >> QC Data >> QC Fie	sulta Dat	G+#) (0)		Next ; call	Due 00 34 33		

7. Press Exit to exit to main screen.

QC Data, continued

QC Results

1. Go to Menu > Full Menu > Database > 2 QC Data.

Search

2. Select **3 QC Results Search**. The following screen will appear.



- ✓ 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

- 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**.
- 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

- 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.

Searched Calibration List		Ready		95 tani 28 min		- in	02/15/2012 18:23	
🔲 Date & Time	Cartridge	S/N	Nat		к.	C	a 📼	
02/15/2012 18:04:55	1002	20	64		66	6	o 🔄	
02/15/2012 17:42:47	1002	20	54 65		65	5	3 🗟	
02/15/2012 17:20:32 100		20 54			65	5	3 🕞	
02/15/2012 17:18:22	1002	20	63		66	4	8 🖳	
02/15/2012 16:42:54	1002	71	53		65	5	3 🗟	
02/15/2012 16:39:37	1002	71	54		66	6	3 🗟	
02/15/2012 16:15:53	1002	71	53		65	4	9 🕞	
i 🛶 Send 🥑	Back	Print	Pape Up	Page Down	1 40		Ext	
Database >> Calibration Data >> See	school Calibration 1		(C) and	(Vann)	time	t call Due 00	12 -25	

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

Cartridge Data

Cartridge Data1.Go to Menu > Full Menu > Database > 4 Cartridge Data.CopyThe 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.

This page is intentionally left blank.

6. Shutdown

Analyzer Shutdown	
Power Recovery	
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, 3. Do not turn off the analyzer yet. Wait until the analyzer finishes a complete power cycle of turning itself off and on.

continued

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 " | / O" to the " O" 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	3.	The message contains following information:
warming-up, continued		 ✓ 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.

Corruption

Data

Check

Data Recovery

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

Procedure

	Data Reco	very Mode
	The analyzer has dete Start data During data recovery, - Il corruption is in database, entire - il corruption is in catridge data.	ected data corruption. recovery? database will be ensed. nhy completed cata will be deleved.
	Yes	No
Control		

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

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

Calibratic	on	7-1
Cartridge	Removal	
Analyzer	Information	
Analyzer	Status	7-7
Cleaning.		

Calibration

Run Cal

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



Note:

- \checkmark 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 in the main screen.

Calibration, continued

Sensor Status 1. For each sensor, a pass or failure result from the latest Cal 2 will appear as 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.
 - \Box 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*



- 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 **I** 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 Use 0.5% sodium hypochlorite cleaning solution. 1. **Procedure** Note: \checkmark Commercial Clorox contains approximately 5% sodium hypochlorite. Mix 1part of Clorox and 9 parts of water. \checkmark 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.

This page is intentionally left blank.

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

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

Scanner

- 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	If c	one of following situations applies:		
Сору		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	If the barcode scanner does not emit red light,			
Instanation	1.	Check the connection between the barcode scanner and the analyzer (refer to barcode scanner in Trouble Shooting).		
	If t	he 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 t the	he analyzer does not change to the warming-up screen after 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 **A***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:

- **D** 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:

- **D** 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	If one of following situations applies:			
Analysis	The "Insufficient sample error" appears on the result screen.			
	□ The "Out of range" message appears on the results screen.			
	\Box 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.			
	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

Operating Specifications	9-1
Instrument Specifications	9-2
Cartridge Specifications	9-3
Principles	9-4
Performance	9-6

Operating Specifications

Measured

Measured Parameters

Parameters

Parameter	Range	Resolution
Na ⁺	20 ~ 250 mmol/L	1 mmol/L
\mathbf{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
- \Box Sample volume: 60 µL
- □ Sample container: syringe or capillary tube
- □ Sample introduction: aspiration
- □ Measuring time: 35 seconds
- \Box 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
- \Box 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
 - D Printer: 2" thermal printer (internal printer)
 - □ Printer paper: thermal (width: 57 mm, diameter: 30 mm)
 - Dert: USB (3 ports), Serial (RS-232), LAN (RJ45 Ethernet)
 - Dever 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
 - \Box 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.
 - **\Box** Storage temperature : -20 ~ 50 °C
 - **Given Storage humidity :** $0 \sim 90\%$ (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
- **\Box** Storage temperature: 10 ~ 30 °C
- **Components:**
 - ✓ Sensors
 - ✓ Cal 1solution, 400 mL
 - ✓ Cal 2 solution, 40 mL
 - ✓ Reference solution, 40 mL
 - \checkmark Sampler and waste bag
 - \checkmark Valve and tubing

□ Analyte Concentrations of the calibration solutions

	Na ⁺	\mathbf{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

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

Principles

MeasurementThe 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 anionE: monitored potential E° : potential at a = 1R: gas constantT: temperature in Kelvin scalen: valence of ionF: Faraday constanta: 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 ionselective 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 predetermined 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 MaterialsTypical Within-Run (Swr), Between-Day (Sdd) and Total (ST)PrecisionPrecisions 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	Mean	Within-Run		Between-Day		Total	
Control	(mmol/L)	\mathbf{S}_{wr}	%CV	S _{dd}	%CV	\mathbf{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	Mean	Within-Run		Between-Day		Total	
Control	(mmol/L)	\mathbf{S}_{wr}	%CV	\mathbf{S}_{dd}	%CV	\mathbf{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	Mean	Within-Run		Between-Day		Total	
Control	(mmol/L)	\mathbf{S}_{wr}	%CV	S _{dd}	%CV	\mathbf{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
PrecisionWhole 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.

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

Na⁺ Whole Blood Precision

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
 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
Whole blood

K⁺Whole Blood Inaccuracy

Inaccuracy, *continued*

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

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	\mathbb{R}^2	Range
Na^+	18 to 24	0.973	+6.271	0.996	122 - 175
\mathbf{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





Cl⁻Whole Blood Linearity



AqueousThe aqueous solution linearity was obtained using seven levelsSolutionsof electrolyte aqueous solutions. Seven levels were tested inLinearityfour 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
\mathbf{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





Cl⁻ Aqueous Solution Linearity



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

This page is intentionally left blank.

Appendix A: Sample Collection and Handling

- □ 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.