

# **Operator's Manual**

For Veterinary Use Only Abaxis Customer and Technical Service: 1-800-822-2947 Available 24 hours a day, 7 days a week.

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# Section 1

# **General Information**

# 1.1 Intended Use

The VetScan<sup>®</sup> i-STAT<sup>®</sup> 1 Handheld Analyzer is intended for use with i-STAT cartridges for in-vitro quantification of various analytes in whole blood, and with Precision PCx Plus Glucose Test Strips for in-vitro quantification of glucose in whole blood.

CAUTION:	If the VetScan i-STAT 1 Analyzer is used in any way other than described in this manual, the analyzer may not oper- ate as intended, may produce inaccurate or no results, and may pose a safety hazard.
Note:	<i>Use only i-STAT Cartridges or Precision PCx Plus Blood Glucose Test Strips with the VetScan i-STAT 1 Analyzer.</i>

# **1.2 Introduction**

The VetScan i-STAT 1 Analyzer incorporates a comprehensive group of components for performing blood analysis at the point of care. A portable handheld analyzer, a cartridge with the required tests, and two or three drops of blood will provide quantitative test records for blood gas, chemistry, and coagulation tests in approximately two minutes. Accuracy is ensured by extensive quality checks and calibrations that occur automatically with each cartridge. The analyzer can provide glucose records using a Precision PCx Plus Glucose Test Strip in as little as 20 seconds.

Portable printers and infrared communication devices allow all patient information obtained at the point of care to be printed on demand, or transmitted to the Central Data Station and then to centralized information systems for record keeping.

To perform cartridge testing, the operator fills a cartridge with the sample, seals the cartridge, inserts the cartridge into the analyzer to activate, and can then enter operator and patient ID information. When the test cycle is complete, the analyzer displays and stores the test records.

To perform glucose test strip testing, the operator selects the glucose strip option from the analyzer menu, scans the teststrip barcode, inserts the test strip into the analyzer test strip port, and applies the sample to the test strip.

# 1.3 Abaxis Technical Service

Abaxis Technical Service personnel can answer your questions regarding the operation of the VetScan i-STAT 1 Analyzer. Call Abaxis Technical Service at 1-800-822-2947, 24 hours a day, 7 days a week.

# 1.4 Symbols on Analyzer Labels

The following symbols may be found on components of the VetScan i-STAT 1 Analyzer System.

Symbol	Definition
$\bigwedge$	Attention: See instructions for use.
	Caution: Risk of electrical shock.
*	Laser radiation hazard symbol.
S	Biological risks.
	Temperature limitations. The upper and lower limits for storage are adjacent to upper and lower arms.
	Upper temperature limit. The upper limit for storage is adjacent to the upper arm.
	Use by or expiration date. An expiration date expressed as YYYY-MM-DD means the last day the product can be used. An expiration date expressed as YYYY-MM means the product cannot be used past the last day of the month specified.
LOT	Manufacturer's lot number or batch code. The lot number or batch appears adja- cent to this symbol.
SN	Serial number. The serial number appears adjacent to this symbol.
MN	Model number. The model number appears adjacent to this symbol.
	Date of manufacture.

Symbol	Definition
	Manufacturer.
IVD	In-vitro diagnostic device.
EC REP	Authorized Representative for Regulatory Affairs in the European Community.
Σ	Contains enough for <i><n></n></i> tests.
	Direct current.
$\sim$	Alternating current.
	Class II construction.
i	Consult documentation for instructions.
CONTROL	Control.
C C LISTED US	Signifies that the product bearing the ETL Listed mark complies with US and Canadian product safety standards. UL 61010A 1; CAN/CSA C22.2 No. 1010.1-92.
immuno	Cartridges bearing this symbol must be run on i-STAT analyzers that also bear this symbol.

Symbol	Definition
• + • -	Low battery icon (flashes on lower left side of display screen).
	Note concerning batteries: The following information is applicable to EEA (European Economic Area) countries. The directive 2006/66/EC requires separate collection of spent batteries.
	Separate waste collection for this electrical/electronic item indicated; equipment manufactured/put on the market after August 13, 2005; indicates compliance with Article 10(3) of Directive 2002/96/EC (WEEE) for the European Union (EU).
BODxxxx-xx	Born On Date: this label defines the year and month of manufacture.
	Do not reuse.
<< >>	As the Martel Printer cannot print $\uparrow$ or $\downarrow$ symbols, this symbol appears on the Martel printout next to records falling outside action range limits.

# 1.5 Abaxis Limited Warranty

Abaxis<sup>®</sup> warrants to the original purchaser the VetScan i-STAT 1 Handheld Analyzer (excluding disposables and consumable supplies) against defects in materials and workmanship for one year from the date of shipment. If Abaxis receives notice of such defects during the warranty period, it shall, at its option, either repair or replace products which prove to be defective. Abaxis may refurbish an analyzer using reconditioned replacement parts or may replace an analyzer with a reconditioned unit; in either case, the new refurbished unit will receive the same limited warranty for the balance of the original warranty period. Abaxis does not warrant that the operating of the software, firmware or hardware shall be uninterrupted or error free.

### **Limitations of the Warranty**

The foregoing warranty shall not apply to defects resulting from:

- 1. Any analyzer which has been subject to abuse, modification, tampering, negligence, or any analyzer not used in accordance with Abaxis operating procedures and instructions,
- 2. Defects due to improper or inadequate maintenance by Buyer or an unauthorized person,
- 3. Defects due to using accessories and/or consumables that are not approved by Abaxis,
- 4. Defects due to unauthorized repair, modifications, misuse, or damage caused by disposable batteries, or
- 5. Defects due to operating outside the environmental specifications of the product.

It is the owner's responsibility to:

1. Update software as instructed in the VetScan i-STAT 1 Handheld Analyzer Operator's Manual.

Abaxis makes no warranty other than the express limited warranty set forth above and disclaims all other warranties, including all implied warranties of fitness for a particular purpose or merchantability.

Abaxis will not be liable for incidental or consequential damages, including loss of time, inconvenience, loss of use, loss of revenues or profits, or property damage, whether or not caused by a failure to an Abaxis product. In no event will Abaxis' liability exceed the price paid by the purchaser for the VetScan i-STAT 1 Handheld Analyzer.

To register your new VetScan i-STAT 1 Handheld Analyzer, log on to: www.abaxis.com/warranty.

# Section 2

# Analyzer Description and Preparation

# 2.1 Unpacking

1. Remove the VetScan i-STAT 1 Analyzer from the shipping carton. Place the analyzer on a level surface relatively free of animal hair, dust, and other contaminants. Do not place near a sunny window or other heat source.

*Note:* With the high-quality finish on the analyzer, care must be taken to minimize scratching.

- 2. Check the components received with the VetScan i-STAT 1 Analyzer against the following list to ensure you have everything required to set up the analyzer:
  - □ VetScan i-STAT 1 Analyzer
  - **Two 9-volt lithium batteries**
  - □ This manual
- 3. Complete the warranty online at **www.abaxis.com/warranty** within 10 days of installation to start the warranty period (see "Abaxis Limited Warranty" on page 1-4). Customers are placed on the customer mailing list to receive information pertaining to the VetScan i-STAT 1 Analyzer, such as software upgrades and new product announcements.

# 2.2 Analyzer Components

The VetScan i-STAT 1 Analyzer System consists of a portable analyzer and a disposable single-use combination test cartridge.



- **Display screen with backlight.** Test results, operator prompts, and other messages are displayed on the analyzer's LCD display screen. Turn the display's backlight on or off by pressing the (backlight) key for 3–5 seconds. The backlight automatically turns off after 90 seconds, or when the analyzer powers down or is turned off. The backlight cannot be turned on while data entry screens are displayed.
- **Keypad.** Keypad is used to enter patient and operator ID numbers and to navigate through the software. See "Keypad and Display Symbols" on page 2-4 for more information.
- **Precision PCx Plus Glucose Test Strip port.** Precision PCx Plus Glucose Test Strips are inserted into the analyzer through the test strip port on the display end of the analyzer when prompted by the analyzer.
- Infrared communication window. This window provides the analyzer with two-way communication to the Central Data Station through a Downloader, allows analyzer-to-analyzer software updates and allows analyzer-to-printer communication for printing.
- Laser barcode scanner window. The barcode scanner is used to scan barcode information into the analyzer. Parameters that can be entered into the analyzer using the scanner include: operator and patient IDs, control, cartridge and test strip lot numbers. Comment codes and patient chart data must be entered using the keypad. The laser beam emerges from the recessed window on the front of the analyzer adjacent to the battery compartment. The laser beam automatically turns off after 3–4 seconds, or after the barcode has been successfully scanned.
- **Battery compartment.** The battery compartment is located at the display end of the analyzer next to the laser barcode scanner window.
- **i-STAT Cartridge port.** The cartridge containing the sample is inserted into the analyzer through the cartridge port. The insertion of the cartridge activates the analyzer and testing begins automatically.
- Electrical connector (internal not shown). When activated, the analyzer makes electrical contact with the cartridge by bringing an internal connector down upon the cartridge contact pads. This connector locks the cartridge in place during the testing cycle.
- Thermal control and barometric pressure sensor subsystems (internal not shown). The VetScan i-STAT 1 Analyzer contains a thermal control subsystem consisting of thermistors and heating contact wires. These components maintain the temperature of the testing zone at a constant 37 °C. The analyzer also contains a solid state barometric pressure sensor which determines the ambient temperature pressure used for *PO*<sub>2</sub> sensor calibration.
- Data storage system (internal not shown). All test records are stored automatically. The VetScan i-STAT 1 Analyzer can store up to 5,000 test records. A test record consists of the following:
  - results
  - □ chart page data
  - information entered by keypad or barcode scanner (including operator and patient IDs)
  - □ number of analyzer uses
- □ test date and time
- □ analyzer serial number
- lot numbers for controls, cartridges, and test strips
- □ CLEW version

- □ cartridge type
- □ software version
- serial number of the electronic simulator (if any)
- name of analyzer's customization profile

Stored test records are accessed through the Data Review option on the Administration Menu page.

# 2.3 Keypad and Display Symbols

The VetScan i-STAT 1 Analyzer's keypad enables you to enter patient and operator information, and to navigate through the software. The keypad includes the following.

Key	Function		
SCAN	Activates the barcode scanner. The barcode scanner can be used to enter information into the analyzer, including operator ID, patient ID, control, immunoassay cartridge and test strip lot number.		
ABCEnters letters on-screen: press ABC (the letter A appears), then use the arrow keys scroll to the correct letter. To enter additional letters, press ABC to move to the ne position, press again to enter the letter A, then use the arrow keys to select the lett To enter a number after a letter, press a numbered key. To erase a letter, press ABC as needed to move the correct position, then press the key to clear the letter.			
$\leftarrow$ , $\rightarrow$	These arrow keys are used to navigate on the display and through screens. The $\rightarrow$ key acts as a page key to move from one screen to the next. When Patient ID Recall is enabled, the $\rightarrow$ key recalls the last patient ID when the analyzer prompts Patient ID. The $\leftarrow$ key is used to backspace and clear keypad entries, and to move back- wards through the screens with a menu.		
•	Enters a decimal or a comma separator (according to the analyzer's Customization Pro- file).		
0–9	Enters digits on data entry screens and selects menu options and stored records.		
Turns the screen backlight on and off. Hold this key down for 3–5 seconds to a green fluorescent text mode. This is seen only if the VetScan i-STAT 1 Analyz dark. To turn the backlight off when the analyzer is still in the dark, press the again.			
ENT	Enter key: use to enter information.		
MENU	Accesses the analyzer's menu.		
PRT	Print — prints to a portable printer (including attached to the Downloader).		
	Analyzer On/Off key. When the analyzer is on, press this for one second to turn the analyzer off. This key is inactive during tests, or when the analyzer prompts for mandatory data.		

In addition, these symbols appear in the analyzer's display.

Symbol	Associated Test
Na	Sodium
К	Potassium
CI	Chloride
Glu	Glucose
Lac	Lactate
Crea	Creatinine
рН	pH
PCO <sub>2</sub>	Partial pressure of carbon dioxide
PO <sub>2</sub>	Partial pressure of oxygen
iCa	Ionized calcium
BUN/UREA	Blood Urea Nitrogen/Urea
Hct	Hematocrit
АСТс	Activated clotting time with Celite <sup>®</sup> activator
Hb	Hemoglobin
TCO <sub>2</sub>	Total carbon dioxide concentration
HCO <sub>3</sub>	Bicarbonate
BE (b&ecf)	Base excess (b for blood, ecf for extra cellular fluid)
AnGap	Anion gap
sO <sub>2</sub>	Oxygen saturation
cTnl	Cardiac Troponin I

2.4	Physical	&	Environmental	<b>Specifications</b>
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Analyzer Dimensions	Height	23.48 cm	9.245 in
	Width	7.68 cm	3.035 in
	Depth	7.24 cm	2.85 in
Weight		635 g	22.4 oz
Power	Two 9-volt lithi	ium batteries	·
Memory/Clock	A lithium batte	ry inside the analyz	zer maintains the clock/cal-
Back-up Power	endar and Customization Profile. This battery should last		
	approximately seven years.		
Display	Dot matrix supertwist liquid crystal (LCD)		
Communication Link	Infrared light-emitting diode (LED)		
<b>Operating Temperature</b>	For Precision PCx Plus Glucose15–40 °C (59–104 °F)		
	Strip testing		
	For VetScan i-STAT1 cartridge 16–30 °C (61–86 °		16–30 °C (61–86 °F)
	testing		
	For analyzer tra	ansportation	-10 to 46 °C (14–115 °F)
Relative Humidity	0–90% non-condensing		
Barometric Pressure	300–1000 mmHg		
T G	Complies with U.S.21 CFR 1040.10 EN 60825-1/IEC 60825-1		

# 2.5 Preparing the Analyzer for Use

### Step 1 — Find a Suitable Location

Check that the analyzer is:

- On a level surface.
- Not placed near a sunny window or another heat source.
- Free of animal hair, dust and other contaminants.

For more information, see Section 8, "Maintenance and Service."

### **Step 2**—**Verify Battery Installation**

Two disposable 9-volt lithium batteries are supplied with the analyzer. If a rechargeable battery is to be used, the disposable batteries can be used while the rechargeable battery pack is charging in the Downloader/Recharger. Charge the rechargeable batteries fully (40 hours) before use.

For instructions on installing or replacing batteries, see "Replacing Disposable Note: Batteries" on page 8-2 or "Replacing Rechargeable Batteries" on page 8-2.

#### Step 3 — Check Date and Time

Press the () (On/Off) key to turn on the analyzer. Check that the date and time shown at the top of the display are correct. To change the date and time, see "Setting the Date and Time" on page 3-12.

Note: The analyzer is preset to Eastern Standard Time.

# 2.6 Internal Electronic Simulator

The Electronic Simulator is a built-in quality control device that simulates high and low levels of electronic signals coming into the analyzer. This simulation tests the ability of the analyzer to receive signals and to make accurate measurements at very high and very low analyte concentrations. The user is assured that the analyzer is performing properly and that records are accurate regardless of the analyte concentration.

The schedule for the Electronic Simulator can be customized to meet local, site, or accreditation requirements. The default schedule tests every assay on a 24-hour cycle. When a cartridge is inserted, the simulator will be run prior to patient testing if the tests on the test cartridge have not been evaluated in the last 24 hours. If the analyzer passes the simulator test, the cartridge test cycle proceeds.

*Note:* If the analyzer displays *Electronic Simulator Fail*, run the test again using the External Electronic Simulator (ancillary product).

# 2.7 Downloader (Ancillary Product)

*Note: References to the Downloader also apply to the Downloader/Recharger.* 

The Downloader converts infrared transmissions of test records from the analyzer to electrical form, and transmits (uploads) them to the Data Manager. The Downloader also converts electrical signals from the Central Data Station to infrared transmissions, and transmits (downloads) them to the analyzer. Transmission is automatic when an analyzer is placed in the Downloader.

The Downloader comes in two versions (see the figures following):

- **Downloader:** a low-profile table-top unit.
- **Downloader/Recharger (DR):** a cradle that holds the analyzer for downloading/recharging.

Both versions are available for use with direct wiring (serial format) or Ethernet cabling (network format). Unless indicated otherwise, all references to the Downloader in this manual apply to the Downloader/Recharger as well.

*Note:* The Downloader/Recharger can recharge a rechargeable battery in the analyzer. If the analyzer contains a rechargeable battery, the battery begins recharging immediately when then analyzer is placed in the Downloader/Recharger. The Downloader/Recharger also has a compartment for recharging a rechargeable battery outside the analyzer.



#### a. Running Cartridges in an Analyzer Docked in a Downloader/Recharger

All i-STAT cartridges can be run in an analyzer docked in a Downloader/Recharger.

**CAUTION:** In departments where glucose test strips are not used, all i-STAT cartridges can be run in analyzers docked in a Downloader/Recharger. However, in departments where i-STAT ACT cartridges and glucose test strips are both used on the same analyzers, do not run ACT cartridges while the analyzer is docked in the Downloader/Recharger.

#### Downloader/Recharger Indicator LEDs

Analyzer battery LED (near top of Downloader/Recharger)		
Off	No rechargeable battery	
Blinking red	Fast charge pending	
Solid red	Fast charging	
Solid green	Trickle charging	
Spare battery (near middle of Downloader/Recharger)		
Off	No rechargeable battery	
Green	Trickle charging	

#### **Power Requirements**

The Downloaders require one power outlet. The Downloader and Downloader/Recharger must be used with the AC power supply adapter supplied with them. The Downloader and Downloader/Recharger have different power supply adapters that are not interchangeable. The Downloaders are capable of supplying power to the portable printer which reduces the number of power outlets required in the downloading and printing area.

#### DR Affect on Ambient Operating Temperature Range

The operating temperature for the analyzer is 18–30 °C. The DR and rechargeable battery may raise the temperature of the analyzer 2–3 °C relative to the ambient temperature if:

- The analyzer is frequently lifted and placed into the DR.
- Multiple thermally controlled cartridges are run in the analyzer while it is in the DR.

#### **Connecting the Serial Downloader**

The following pages describe several methods for connecting the Downloader or Downloader/Recharger, depending on particular configurations needed.

*CAUTION:* Do not place metal objects on or near the exposed gold charging contacts.

Be sure to install all cables and power supplies so they do not pose a trip hazard.

Mount equipment so cables and accessories stay clear of walkways.

The AC power supply adapter plug acts as the disconnect device for the Downloader and Downloader/Recharger and, therefore the socket outlet must be installed (or located) near the Downloader or Downloader/Recharger and must be easily accessible.

Only i-STAT provided printers may be connected to the Downloader printer port.

An Ethernet cable and serial (DB9) cable may NOT be connected to the Downloader at the same time.

**Option 1:** For downloading/uploading only, when there is no power outlet available for the Downloader or Downloader/Recharger. In this particular configuration, both recharging LED lights will be lit. The primary recharging LED will blink red and the alternate will be steady green. This is typical behavior, and does not indicate that any charging is taking place. In fact, batteries cannot be charged in the Downloader/Recharger in this configuration.

The following diagram shows how to connect a serial downloader locally to the Data Manager, and includes required parts.



```
Cable color coding *
```

Red	Green	White
Tellow	Blue	

\* Actual color appears on cable

■ Option 2: The following diagram shows how to connect a serial downloader to the Data Manager, and to connect the portable printer to the Downloader for communication. The diagram also shows all required parts.



\* Actual color appears on cable

■ **Option 3:** The following diagram shows how to connect a serial downloader to the Data Manager, and to connect the portable printer to the Downloader for power and communication. (The printer can also be powered by its own AC adapter.) The illustration also shows all required equipment.



<sup>\*</sup> Actual color appears on cable

#### Transmitting Data from Downloader to the Data Manager

To transmit through a Downloader to the Data Manager, place the analyzer between the arms on the front of the Downloader with the test strip port end touching the Downloader. When properly aligned the red proximity light will turn on and the analyzer will automatically transmit (upload) all unsent results. (The analyzer does not need to be turned on.) Do not move the analyzer while the message "Communication in Progress" is displayed on the screen.

#### Transmitting Data from Downloader/Recharger to the Data Manager

To transmit data through a Downloader/Recharger, place the analyzer in the Downloader/Recharger's cradle. When properly aligned, the blue proximity light will turn on and the analyzer will automatically transmit (upload) all unsent results. (The analyzer does not need to be turned on.) Do not move the analyzer while the message "Communication in Progress" is displayed on the screen.

The following information is transmitted from the analyzer with each test record:

- The date and time the test was performed
- Operator ID and Patient ID or Quality Test fluid lot number
- All information entered by the operator, such as lot numbers, sample type, and comment codes
- Results
- Serial number of the analyzer
- Use count of the analyzer
- Application software version in the analyzer
- Standardization software in the analyzer

#### **Battery Use**

- Charge battery before use. Put new rechargeable battery in external charging bay on the i-STAT 1 Downloader/Recharger for 40 hours. No damage will be caused if an analyzer with disposable batteries installed is placed in the Downloader/Recharger.
- Keep battery charged. Fully charged battery, if not periodically recharged, will self-discharge in approximately three months. Prevent self-discharge by periodically recharging the battery.
- Rechargeable battery life. i-STAT rechargeable batteries come with a service lifeexpectancy of 15 months from the date of manufacture which appears on the battery. The battery may last longer in your application.
- Charging the rechargeable battery. Placing an analyzer in a Downloader/Recharger will automatically initiate recharging of the rechargeable battery. The indicator light on top of the Downloader/Recharger will be green (trickle charge), red (fast charge), or blinking red (fast charge pending) when an analyzer with a rechargeable battery is placed in the Downloader/Recharger. No damage will be caused if an analyzer with disposable batteries installed is placed in the Downloader/Recharger.
- Charging rechargeable battery in external recharge compartment. Placing a rechargeable battery into the recharging compartment will automatically initiate trickle recharging. The indicator light near the recharging compartment will be green when a rechargeable battery is placed in the compartment.
  - *Note:* The battery pack has two labels: one for orientation in the analyzer and one for orientation in the Downloader/Recharger.
- **CAUTION:** If you are using rechargeable batteries, use only rechargeable batteries and recharging equipment supplied by your i-STAT distributor. Other batteries and rechargers may affect test results and pose other hazards to operators and patients. A falling instrument may cause injury. Place the instrument on a flat and stable surface at all times to ensure the instrument does not fall.

# 2.8 Portable Martel Printer (Ancillary Product)

The printer can receive data directly from the analyzer via IR transmission or through a data cable connected to a Downloader. The printer can be recharged from a power adapter connected to an outlet.



#### a. Supplies Provided with Printer

- Adapter and power cord
- One roll of paper

#### Power

*CAUTION:* If the battery needs to be replaced, use only batteries supplied by Abaxis.

The printer is turned on using the switch on its left side. When the printer is on, the Power LED will be green. The plug for the AC adaptor is also on the left side.

- **Printer serial numbers below 240223657:** the rechargeable battery is trickle charged when the printer is turned on or off and connected to an AC outlet. Before putting these serial number printers into use, the printer should be turned off and the battery charged for 16 hours.
- Printer serial numbers above 240223657: the power LED may flicker when connected to the power supply and the switch is in the OFF position. This flicker indicates that the printer is fast charging. Fast charging occurs only when the printer is turned off. Trickle charging occurs when these printers are plugged in and turned on, but not in use. Printers above serial number 240223657 indicating low battery will charge to full capacity in 9 hours, if charged from a 12V supply with the power switch off.

The battery needs to be recharged for all printer serial numbers when the Status LED lights continuously during printing. If the battery becomes exhausted, printing will become faint, erratic, or not possible at all. Should this happen, turn the printer off and allow to recharge for at least one hour and preferably one day before printing again.

#### Paper

Paper may be ordered along with other supplies for the i-STAT System or paper with the following specifications can be used:

- Black print thermal paper
- 2.25 in (5.7 cm) by 80 ft (25 m)
- Paper grade: TF50KS-E2C

The Status light flashes when paper has run out.

To replace the paper, open the paper cup lid by squeezing the lid as shown in the illustration and remove any remaining paper by pressing the Paper Feed button. Do not pull paper through the printer mechanism. Reel off a few centimeters from a new roll of paper and check that the end has clean straight edge. Slide the leading edge of the paper through the paper entry slot, with the leading edge of the paper feeding forwards from the bottom of the roll, untilyou feel resistance. Press the paper feed button and feed the paper through the printer mechanism. Keep the paper feed button depressed until enough paper is fed through the printer mechanism to pass through the paper exit slot. Sit the new paper roll in the paper cup and close the lid.

Should the paper become creased or out of line when feeding a new roll, cut the end off the paper roll, feed out the creased paper using the Paper Feed button, and reload ensuring the paper has a clear straight edge.

Before use, open the paper cup lid and ensure that the paper roll is present. Close the lid, ensuring that the paper passes through the paper exit slot. Turn the printer on. The Power indicator will light and the printer mechanism will reset.



Position of paper roll in printer

When removing a printout from the printer, pull the printout toward the front of the printer and tear from one side to the other across the serrated edge.



#### Printing Directly from the Analyzer

Before printing ensure that the printer is turned on using the switch on the left side of the printer. When the printer is on, the Power LED will be green.

To print directly from the analyzer, point the analyzer's Infrared Communication Window at the printer's IR LED window on its left side, ensure that the results to be printed are displayed, and press the Print key on the analyzer. The printer must be 1–5 inches (2.5–12.7 cm) of the analyzer and must not be too close to the analyzer. Do not move the analyzer or printer until printing is complete.

#### Printing Via a Downloader

See "Connecting the Serial Downloader" on page 2-9 for directions for connecting the printer to a Downloader or Downloader/Recharger. Before printing ensure that the printer is turned on using a switch on the left side of the printer. When the printer is on the Power LED will be green.

Place the analyzer between the arms of the Downloader or in the Downloader/Recharger, ensure that the results to be printed are displayed, and press the Print key. Do not move the analyzer or printer until printing is complete.

#### **Printing Multiple Results**

Select **2** - **Data Review** from the analyzer's Administration Menu, then select **7** - **List**. Use the arrow keys to page up and down through the pages of stored results. Press the numbered key for each test record to be printed. To deselect a record, press that numbered key again. When all test records have been selected, align the printer and analyzer according to the directions under "Printing Directly from the Analyzer" on page 2-16, or place the printer in a Downloader or Downloader/Recharger according to the directions above, and press the **Print** key.

#### **Results Printed**

Name of Test	i-STAT cartridge type or PCx Glucose Strip
Sample ID	Patient ID or type of quality test and lot number of solution tested
Results	Including units and any applicable flags and comment codes
At Patient Temperature	If the patient's temperature was entered on the Chart Page, a sec- ond set of results is displayed for blood gases at the patient's tem- perature.
Sample Type	Sample type selected from Chart Page for patient samples
Free Fields	Information entered into the free fields on the Chart Page for patient samples
Time and Date	Time and Date when test was performed
Operator ID	Operator ID

- Lot Number Lot number of cartridge or test strip if applicable
- Serial Serial number of the analyzer
- Version Analyzer application software
- CLEW Standardization software

#### Precautions

- Use power supply provided with printer.
- Do not operate the printer without paper.
- Do not allow the power supply to become a trip hazard.
- Do not disturb the analyzer or printer until printing is complete since this will interrupt the printout. If printing is interrupted, realign the printer and analyzer or replace the analyzer in the Downloader to resume printing.

# *Note:* If significant time has elapsed, some results may be missing from the printout. Reprint the results.

■ If printed results appear inconsistent with a patient's clinical assessment, verify that the printed results match the data in the analyzer If the results match, retest the patient sample using another cartridge. If they do not match, reprint the results. If the reprint still does not match the analyzer data, the printer requires service and the printed results must not be used.

#### Troubleshooting

Symptom	Solution
Printer not printing.	<ul> <li>Power LED on and Status LED off:</li> <li>Check that results are displayed or that results have been selected from List under Data Review.</li> <li>If printing directly from the analyzer, make sure the distance between the analyzer and printer is 1–5 inches (2.5–12.7 cm).</li> <li>Perform printer self test to ensure that printer is functioning. Turn the printer on while pressing the Paper Feed button, then release the Paper Feed button and ensure that the printout is clear.</li> </ul>
Paper feeds but nothing prints.	Make sure paper is feeding from <b>under</b> the roll.
Printer not printing and Status light on continuously.	Charge the battery.
Printer power LED does not light when printer turned on.	Charge the battery. The power adapter cannot supply sufficient power for printing, so the battery must be partially charged before printing is possible.
Printer not printing and Status light flashing every 0.5 seconds.	Add paper to the printer.
Printer not printing and Status light flashing every 0.25 seconds.	The print head is too hot. Printing suspends until the temperature returns to normal levels.

# Section 3

# Configuring the Analyzer

This section describes how to configure the VetScan i-STAT 1 Analyzer to best suit your particular requirements.

The analyzer has two main menus: Test and Administration. The following menu map shows the structure and contents of these menus.

#### **Administration Menu Test Menu** 1 - Last Result 1 - Analyzer Status Temp Pressure 2 - i-STAT Cartridge Battery 3 - PCx Glucose Strip 1 - Patient Uses 2 - Control Serial CLEW Version Custom Stored Records 2 - Data Review 1 - Patient 2 - Control 1 - i-STAT Cartridge 2 - PCx Glucose Strip 3 - All 3 - Proficiency 1 - i-STAT Cartridge 2 - PCx Glucose Strip 3 - All 4 - Cal Ver 1 - i-STAT Cartridge 2 - PCx Glucose Strip 3 - All 5 - Simulator 6 - All 7 - List 3 - Quality Tests 1 - Control 1 - i-STAT Cartridge 2 - PCx Glucose Strip 2 - Proficiency 1 - i-STAT Cartridge 2 - PCx Glucose Strip 3 -- Cal Ver 1 - i-STAT Cartridge 2 - PCx Glucose Strip 4 - Simulator 1 - View 4 - Customization 2 - Change 1 - Analyzer 2 - ID Entry 3 - Patient Tests 4 - QC Tests 5 - Results 6 - Password 7 - Restore Factory Settings 5 - Set Clock 6 - Transmit Data 1 - Most Recent 2 - This Month 3 - Last Month 4 - All 7 - Utility 1 - Send Software 2 - Clear Memory

# 3.1 Test Menu

The Test Menu is the first screen displayed when the analyzer is turned on. It displays these options:

- 1 Last Record
- 2 i-STAT Cartridge
- 3 PCx Glucose Strip
  - □ 1 Patient
  - □ 2 Control

*Note:* If the analyzer is customized with PCx Glucose Strips disabled, PCx Glucose Strip options will not be displayed. If the analyzer is customized to disable testing under certain conditions, the disabled option will be listed without its number so that it cannot be selected.

To enable PCx Glucose Strips, see "Enabling PCx Glucose Test Strips" on page 3-8.

# 3.2 Administration Menu

Access the Administration Menu by pressing the **Menu** key from the Test Menu screen. This menu contains the following:

- 1 Analyzer Status (see below)
- 2 Data Review (see "Data Review" on page 3-3)
- 3 Quality Tests (see "Quality Tests" on page 3-4)
- 4 Customization (see "Customization" on page 3-5)
- 5 Set Clock (see "Setting the Date and Time" on page 3-12)
- 6 Transmit Data (see "Transmit Data" on page 3-13)
- 7 Utility (see "Utilities" on page 3-13)

### **Analyzer Status**

The Analyzer Status screen contains information about the condition or 'status' of the analyzer.

Temp Room temperature.
 Pressure Barometric pressure.
 Battery Battery voltage.
 Uses Total number of cartridge, simulator and test strip test cycles, whether or not records are reported.
 Serial Serial number of the analyzer.









- CLEW Version of standardization data installed in the analyzer.
- Custom Customization profile name.
- Version Version of application software installed in the analyzer.
- Stored Records Total: The number of test records in the analyzer's memory. The maximum storage capacity is 5,000 test records, which include records and Quality Check codes for patients and controls both liquid and electronic.

Unsent: The number of test records that have not been transmitted to the Central Data Station.

To access the Analyzer Status screen, press the **Menu** key to open the Administration Menu, then select **1 - Analyzer Status**. To return to the Administration Menu, press the **Menu** key. To return to the Test Menu, press the **Menu** key again.

### **Data Review**

The Data Review function allows the operator to review stored records by the categories listed below. The number of test records stored is indicated at the bottom center of the screen as x/y where x is the record on the screen and y is the total number of stored records in the selected category. Use the 1 and 2 keys to scroll through the stored records as indicated on the bottom right and left of the screen. The most recent test record is always in the first position. The  $\rightarrow$  key pages through the screens of the displayed record.

To access the Data Review screen, press the **Menu** key, select **2** - **Data Review**. Select the type of record you want to review. To return to the Administration Menu, press the **Menu** key. To return to the Test Menu, press the **Menu** key again.

1 - Patient	The records for a patient are recalled by scanning or entering the Patient ID.2- Control 3- Proficiency 4- Cal Ver
<i>Note:</i> Press <i>ENT</i> a entered, all p	again to skip Patient ID. If no Patient ID is batient records are recalled.
2 - Control	1 - i-STAT Cartridge
	2 - PCx Glucose Strip
	3 - All
3 - Proficiency	1 - i-STAT Cartridge
	2 - PCx Glucose Strip
	3 - All
4 - Cal Ver	1 - i-STAT Cartridge
	2 - PCx Glucose Strip
	3 - All
5 - Simulator	All external and internal Electronic Simulator records. Use the <b>1</b> and <b>2</b> keys to move through pages.
6 - All	All test records in the analyzers memory, in chronological order. Use the $1$ and $2$ keys to move through pages

Data Review

1- Patient

**7** - List

Records are listed with Cartridge Type, PCx Glucose, and Simulator, **or** with Error Code #, test date and time, patient ID, control lot, proficiency ID, or Cal Ver lot and test level, as applicable. To select a record for viewing or printing, press the number key corresponding to the record. Press again to deselect. After selecting, press **ENT** to open the record.



Select Records To Review or Print

## **Quality Tests**

Non-patient tests can be initiated from the Quality Test Menu.

To access the Quality Tests screen, press the **Menu** key, select **3 - Quality Tests**. Select the type of record you want to review. To return to the Administration Menu, press the **Menu** key on the keypad. To return to the Test Menu, press the **Menu** key again.

- 1 Control External quality control
  - □ 1 i-STAT Cartridge
  - □ 2 PCx Glucose Strip
- 2 Proficiency External quality control
  - □ 1 i-STAT Cartridge
  - □ 2 PCx Glucose Strip
- 3 Cal Ver Calibration Verification for cartridges
  - □ 1 i-STAT Cartridge
  - □ 2 PCx Glucose Strip
- 4 Simulator External electronic simulator

When testing is initiated from one of these options, the analyzer prompts the operator to scan or enter the Operator ID, Control Lot Number, Proficiency ID, Cal Ver Kit Lot Number or Simulator ID as applicable, and the Cartridge Lot Number or Test Strip Lot Number as applicable.

*Note:* To bypass entering this information, press the ENT key.

When the Quality Test option is used, results can be reviewed according to the corresponding options under the Data Review option.

*Note:* The Test Menu option for test strips includes both a Patient and Control option. Results for test strip controls run from the Test and Quality Tests Menus are stored together.



## Customization

Analyzers can be customized for site-specific testing characteristics and requirements, using its keypad or through the Central Data Station. Several items cannot be customized via the analyzer's keypad: operator lists, test strip lists, reference and action ranges, sample types, and order of items on the Chart page. Customization via the Central Data Station is described in "Updating the Analyzer's Software" on page 9-1.

*Note:* Use only one method — the Central Data Station **or** the keypad — to customize the analyzer. If you use both methods, and the Customization function is not disabled on the Central Data Station, any changes made to the customization profile via the keypad will be overwritten the next time the analyzer is placed in the Downloader.

The analyzer's customization is identified in the Customization option under the Administration Menu. DEFAULT0 indicates that the analyzer has factory settings. When the analyzer has been customized via the Central Data Station, the name assigned to the profile by the Central Data Station is listed. If the default or Central Data Station profile is changed on the analyzer, the profile is listed as 00000000.

#### Viewing the Customization Profile

You can view a Customization Profile as follows.

- 1. Press the Menu key on the keypad. This opens the Administration Menu.
- 2. Select **4** Customization.
- 3. Select **1 View** to display the Customization Menu.
- 4. Select an option:
  - 1 Analyzer
  - 2 ID Entry
  - 3 Patient Tests
  - 4 QC Tests
  - **5** Results
- 5. Use the  $\leftarrow$  and  $\rightarrow$  keys to scroll through the preferences for each category.

Use  $\leftarrow$  to return to the Customization Menu.

### 3.3 Customizing the Analyzer

This section describes how to customize settings on the VetScan i-STAT 1 Analyzer.

*Note: Outside the USA, the following changes are recommended: Language, Unit Set, Date Format, Time & Date, and Decimal Place Separator.* 

#### **General Procedure**

Use this general procedure to customize the analyzer.

*Note:* You should generally password-protect the Change function.

*Outside the USA, the following changes are recommended: Language, Unit Set, Date Format, Time & Date, and Decimal Place Separator.* 

*Use the*  $\leftarrow$  *key to return to the previous menu without changing the customization.* 

- 1. Press the **Menu** key to access the Administration Menu.
- 2. Select **4** Customization.
- 3. Select **2** Change to display the Change Customization Menu.
- 4. If the analyzer has already been customized with a password, enter the password. If not, press the **ENT** key.
- 5. In the Change Customization Menu, select the category to customize:
  - "Selecting the Language" on page 3-6
  - "Setting the Date Format" on page 3-7
  - "Setting the Alert/Status Notification Sound" on page 3-7
  - "Enabling Data Transmission" on page 3-7
  - "Handling Full Memory" on page 3-7
  - "Setting Inactivity Timeout" on page 3-7
  - "Enabling PCx Glucose Test Strips" on page 3-8
  - "Setting Clock Password" on page 3-8
  - "Enabling Sync Clock" on page 3-8
  - "Customizing Operator IDs" on page 3-8
  - "Customizing Patient IDs" on page 3-9
- 6. Customize additional items as needed.
- 7. Turn off the analyzer to save and activate the custom settings.

#### Selecting the Language

The analyzer provides several language options. Select the language to use as follows:

- 1. Select **1** Analyzer from the Change Customization Menu.
- 2. Select **1 Language**.
- 3. Select the language from the list.

### **Setting the Date Format**

The analyzer allows two different date formats, mm/dd/yy or dd/mm/yy. To change the date format:

- 1. Select **1 Analyzer** from the Change Customization Menu.
- 2. Select **2 Date Format**.
- 3. Select the date format from the list.

#### Setting the Alert/Status Notification Sound

Use this procedure to enable or disable the alert or status notification sound.

- 1. Select **1 Analyzer** from the Change Customization Menu.
- 2. Select **3 Sound**.
- 3. Select **Disabled** or **Enabled**.

#### **Enabling Data Transmission**

Unsent test records are can be automatically transmitted when an analyzer is placed in the Downloader. Use this procedure to enable or disable automatic transmitting of test records.

- 1. Select **1 Analyzer** from the Change Customization Menu.
- 2. Select **4 Auto-transmit**.
- 3. Select **Disabled** or **Enabled**.

### **Handling Full Memory**

The analyzer's memory is full when it contains 5000 unsent records (shown in the Analyze Status screen). The Memory Full feature controls how records are handled after this occurs.

- 1. Select **1 Analyzer** from the Change Customization Menu.
- 2. Select **5 Memory Full**.
- 3. Select an option:
  - □ 1 Allow Test Memory Full disabled: the oldest record is overwritten by the newest record without warning.
  - **2** Warn User Memory Full enabled: the operator is warned when memory is full.
  - **3** Lockout Memory Full enabled: testing is disabled until the records are uploaded.

#### **Setting Inactivity Timeout**

The analyzer is set to turn off automatically after a period of inactivity. To change the number of seconds before the analyzer turns off automatically after a period of inactivity:

- 1. Select **1 Analyzer** from the Change Customization Menu.
- 2. Use  $\rightarrow$  to move to the next page.
- 3. Select **2** Inactivity Timeout.
- 4. Type in the number of seconds for the analyzer to automatically turn off.

*Note:* The analyzer is set by default to turn off after 120 seconds.

### **Enabling PCx Glucose Test Strips**

This function enables the PCx glucose test strip reader on the VetScan i-STAT 1 Analyzer.

- 1. Select **1 Analyzer** from the Change Customization Menu.
- 2. Use  $\rightarrow$  to move to the next page.
- 3. Select **4 PCx Glucose Strip**.
- 4. Select **Enabled** to run PCx Glucose Test Strips.

#### Enabling Cardiac Troponin (cTnI) Testing

Cardiac Troponin (cTnI) testing requires that Cartridge Information be enabled: see "Cartridge Information" on page 3-10.

#### Setting Clock Password

The Set Clock function can be password protected.

- 1. Select **1** Analyzer from the Change Customization Menu.
- 2. Use  $\rightarrow$  to move to the next page.
- 3. Select **5 Clock Password**.
- 4. Select **Disabled** or **Enabled**.

#### **Enabling Sync Clock**

The analyzer can be customized using the Central Data Station to synchronize or update the real time clock to the Central Data Station's clock at the time of each download. This option eliminates the need to rest the analyzer's clock at the beginning and end of Daylight Savings Time. Otherwise, the clock must be manually changed. To enable this feature:

- 1. Select **1 Analyzer** from the Change Customization Menu.
- 2. Press  $\rightarrow$  twice to move two pages.
- 3. Select 1 Sync Clock.
- 4. Select Enabled.

### **Customizing Operator IDs**

You can adjust the minimum and maximum number of digits required for Operator IDs. (The default settings are 0 and 15 digits, respectively.)

To use Operator IDs of a fixed length, set the minimum and maximum values to that length.

#### **Operator ID - Minimum Length**

- 1. Select **2 ID Entry** from the Change Customization Menu.
- 2. Select **1 Operator ID**.
- 3. Select 1 Minimum Length.
- 4. Enter the minimum number of digits allowed for the Operator ID (0 to 15).

*Note:* If the minimum is set to 0, no Operator ID is required.

*Note:* If the analyzer is customized with a password, pressing *ENT* to bypass the password only displays the time and date screen.
#### **Operator ID - Maximum Length**

- 1. Select **2 ID Entry** from the Change Customization Menu.
- 2. Select **1 Operator ID**.
- 3. Select 2 Maximum Length.
- 4. Enter the maximum number of digits allowed for the Operator ID (up to 15).

#### Repeat ID

This function allows the operator to enter the Operator ID twice. The analyzer prompts the operator to start again if IDs do not match.

- 1. Select **2 ID Entry** from the Change Customization Menu.
- 2. Select **1 Operator ID**.
- 3. Select **3 Repeat ID**.
- 4. Select **Disabled** or **Enabled**.

#### Print ID

This function enables or disables printing of the Operator ID on printouts from the Martel printer.

- 1. Select **2 ID Entry** from the Change Customization Menu.
- 2. Select 1 Operator ID.
- 3. Press  $\rightarrow$  twice to move two pages.
- 4. Select **4 Print ID**.
- 5. Select **Disabled** or **Enabled**.

#### **Customizing Patient IDs**

You can adjust the minimum and maximum number of digits required for Patient IDs. (The default settings are 0 and 15 digits, respectively.)

To use Patient IDs of a fixed length, set the minimum and maximum values to that length.

#### Patient ID - Minimum Length

- 1. Select **2 ID Entry** from the Change Customization Menu.
- 2. Select 2 Patient ID.
- 3. Select 1 Minimum Length.
- 4. Enter the minimum number of digits allowed for the Patient ID (0 to 15).

*Note:* If the minimum is set to 0, no Patient ID is required.

#### Patient ID - Maximum Length

- 1. Select **2 ID Entry** from the Change Customization Menu.
- 2. Select **2 Patient ID**.
- 3. Select 2 Maximum Length.
- 4. Enter the maximum number of digits allowed for the Patient ID (up to 15).

#### **Repeat ID**

This function allows the Patient ID to be entered twice. Repeat ID is enabled by default. To disable:

- 1. Select **2 ID Entry** from the Change Customization Menu.
- 2. Select **2 Patient ID**.
- 3. Select **3 Repeat ID**.
- 4. Select **Disabled**.

#### ID Recall

Enabling ID Recall lets operators recall the last Patient ID by pressing  $\rightarrow$  when the analyzer prompts for Patient ID.

- 1. Select **2 ID Entry** from the Change Customization Menu.
- 2. Select 2 Patient ID.
- 3. Select **4 ID Recall**.
- 4. Select **Disabled** or **Enabled**.

## 3.4 Customizing Patient Tests

Use this menu to customize information contained on the test cartridge. When these features are not enabled, the test cycle begins when the operator inserts a cartridge, and information is entered during the test cycle.

### **Cartridge Information**

With Cartridge Information enabled, the operator is required to enter information before the analyzer will initiate a cartridge test cycle.

- 1. Select **3 Patient Tests** from the Change Customization Menu.
- 2. Select **3 Cartridge Information**.
- 3. Select Not Required or Required.

*Note:* This option is referred to as "Information First" in the cartridge test procedures.

*Either Cartridge Information and Cartridge Lot Number or Cartridge Barcode alone must be required to run the Cardiac Troponin (cTnI) cartridge.* 

#### **Cartridge Barcode**

With the Cartridge Barcode enabled, the operator will be required to scan or enter the cartridge barcode before entering an Operator ID and Patient ID after a cartridge has been inserted into the analyzer.

*Note:* Cartridge Lot Numbers are mandatory prompts for tests performed under *Quality Tests.* 

*Cartridge barcodes must be scanned from the cTnI portion pack in order to run the cartridge.* 

To enable or disable this setting:

- 1. Select **3 Patient Tests** from the Change Customization Menu.
- 2. Select **4 Cartridge Barcode**.
- 3. Select **Not Required** or **Required**.

#### Cartridge Lot Number

With the Cartridge Lot Number enabled, the operator will be required to enter the cartridge lot number before the analyzer will initiate a patient test cycle. To enable or disable the setting:

- 1. Select **3 Patient Tests** from the Change Customization Menu.
- 2. Select **5 Cartridge Lot Number**.
- 3. Select **Not Required** or **Required**.

*Note:* Cartridge Lot Numbers are always required when running Quality Tests.

### 3.5 Customizing QC Tests

#### **Internal Simulator**

The Internal Simulator can be customized to run at an interval of specified hours. The analyzer is set to automatically run the Internal Simulator every 24 hours. To customize the Internal Simulator:

- 1. Select **4 QC Tests** from the Change Customization Menu.
- 2. Select **2** Int Simulator, and choose from the following:
  - □ Select **1 Disabled** to disable the internal simulator.
  - □ Select 2 8/24 hours to run the internal simulator every 8 hours for blood gases, coagulation, hematocrit and immunoassays, and every 24 hours for other tests.
  - □ Select **3 Interval** and set an interval of specified hours.
  - □ Select **4 Patient Tests** and set an interval of specified patient tests.

#### **Internal Simulator Schedule Option**

The behavior of the analyzer, if the test fails, can be specified. If the Internal Simulator Schedule Option Lockout is selected, the analyzer will continue to perform the simulator test and will continue to display 'FAIL' on subsequent cartridges until the test passes. If lockout is not selected, the simulator test will not run again until the next scheduled time, and sample cartridges will be allowed to run. To customize the Internal Simulator Schedule Option:

- 1. Select **4 QC Tests** from the Change Customization Menu.
- 2. Select **3 Int Simulator Schedule Option**.
- 3. Select Allow Test or Lock Out.

## 3.6 Customizing Results

Reference range units can be customized for either common units or SI units. To customize reference range units:

- 1. Select **5 Results** from the Change Customization Menu.
- 2. Select **1** Units and Ranges.
- 3. Select the analyte to modify.

#### **Options**

The Options settings located under Results contain several different types of customizations, including Decimal Separator, Hematocrit Options, Base Excess Calculation and ACT Options. The most relevant options are listed below.

#### **ACT-C Options**

You can select between the default 37 °C (PREWRM) result calibration or a NONWRM (ambient temperature result calibration.

- 1. Select **5 Results** from the Change Customization Menu.
- 2. Select 2 Options.
- 3. Select **5 ACT-C**.
- 4. Select **PREWRM** or **NONWRM**.

## 3.7 Additional Customizations

#### Password

A password can be set to access Set Clock, the Change function in the Customization Menus, and Utility under the Administration Menu. To set a password:

- 1. Select **6 Password** from the Change Customization Menu.
- 2. Enter a password of 0 to 5 digits.

#### **Restore Factory Settings**

Customization settings that have been made to the analyzer can be restored to the factory settings. To restore the factory settings:

- 1. Select **7 Restore Factory Settings** from the Change Customization Menu.
- 2. Select **Yes** to restore factory settings.

## 3.8 Setting the Date and Time

The date and time is factory preset to Eastern Standard Time. To change the date and time:

- 1. Select **5** Set Clock from the Administration Menu.
- 2. Use the arrow keys to move the cursor to the digit to be changed. Use a number key to change the digit. Press **ENT** to accept the changes or **Menu** to cancel the changes.

## 3.9 Transmit Data

Unsent test records are automatically transmitted to the Central Data Station when an analyzer is placed in a Downloader or Downloader/Recharger. In some cases it may be desirable to have the capability to retransmit data. The Transmit Data function allows transmission of data in the following manner:

■ 1 - Most Recent Result from last cartridge or strip tested.

■ 2 - This Month

- 3 Last Month
- 4 All Analyzer can be customized using the Central Data Station to apply a date range limit to the Transmit All functions.

*Note: Auto-transmit is temporarily disabled when the Transmit Data option is selected to allow the user to control transmission data.* 

To retransmit data, select **6** - **Transmit Data** from the Administration Menu, then select the category in which you would like to transmit data.

## 3.10 Utilities

The Utility Menu can be customized using the Customization function on the analyzer or the Central Data Station.

To access the Utility Menu, select 7 - Utility in the Administration Menu.

1 - Send Software	Allows the analyzer to transmit software to another analyzer. See "Updating the Analyzer's Software" on page 9-1.
2 - Clear Memory	Erases results from the analyzer's memory. Options are:
	1 - <b>Previous to 01MMMYY</b> (MMMYY = current month and year)
	<b>2 - Previous to 01MMMYY</b> (MMMYY = previous month and year)
	3 - All
	4 - Cancel
3 - Receive Software	Allows users to remotely request a JAMS and CLEW update for the analyzer from the Central Data Station.

# Section 4

## **Test Procedure**

The single-use cartridge used with the VetScan i-STAT 1 Analyzer contains all components needed to perform one or more tests, including calibrating solution, sample handling system, sensors, and reagents.

The analyzer automatically controls all steps in the testing cycle, such as fluid movement, reagent mixing, calibration, and thermal control.

Precision PCx Plus Glucose Strip testing is a simple procedure involving inserting the test strip into the analyzer test strip port, then applying the sample to the test strip. This degree of automation, along with the ability to test fresh whole blood, eliminates many sources of error as well as time-consuming and costly steps.

## 4.1 Test Cartridges

The VetScan i-STAT 1 Analyzer uses a disposable, single-use cartridge that contains the necessary reagents to provide quantitative test records for blood gas, chemistry, and coagulation tests from two drops of whole blood. Each cartridge is sealed in a foil pouch or clear plastic portion pack.

Labeling on the box and pouch/portion pack identify the following:

- The cartridge name.
- The tests included in the cartridge.
- The lot number.
- The expiration date of the cartridge.

## 4.2 Cartridge Components

	Sensor channel	The sensor channel directs the sample from	/ Sensors	
		the sample chamber to		Contact pads
		the sensors. An exten- sion of this channel becomes a waste cham-		Sensor channel
		ber to receive the cali- brant solution as it is		Air chamber
		ple.	i-STAT	Fill mark
	Air chamber	An air chamber is located in blood gas, electrolyte, chemistry,	EG7+	Sample chamber
		and hematocrit car-		Bladder
		sample chamber and sensor channel. This creates an air segment between the calibrant		Sample well
		solution and the sam-		Snap closure
		ple to prevent the two from mixing. The size of	the air segment is mon	itored by the analyzer.
•	Bladder	The bladder (concealed b The analyzer presses on the sensors, to move the sors, or to mix the sampl	by the label) is connected the bladder to displace of sample form the sample e and reagents.	ed to the sample well. calibrant solution from e chamber to the sen-
•	Air vent	An air vent on the unders allows the calibrant and cartridge.	side of the cartridge, be the sample to flow forw	yond the fluid front, ard, but not out of the
•	Calibrant pack	A pack of calibration flu When pressure is exerted barb, and calibrant fluid	id is located under the to l by the analyzer, the pa is released to flow over	op face of the cartridge. ck is punctured by a the sensor array.
•	Sample chamber	The sample chamber inc from the well up to the fi tains sufficient sample for monitored by the analyze	ludes the sample well a Il mark. When filled, th or testing. Sample volun er.	nd the channel leading the sample chamber con- the and placement are
•	Sample well	Two to three drops of blo sample for testing.	ood are placed into the sa	ample well to provide a

	Snap closure	The snap closure creates an airtight seal necessary for proper fluid movement within the cartridge. The closure also ensures that calibrant and sample remain contained within the cartridge during the testing cycle and subsequent disposal. Immunoassay cartridges, such as cTnI, use a plastic slide enclosure clip.
•	Fill mark	The fill mark ( ) on the cartridge indicates the quantity of blood to be dispensed into the cartridge. Blood is dispensed into the sample well until it fills the sample chamber to approximately the level of the fill mark.
	Waste chamber	A waste chamber (beneath the cartridge label) holds calibrant fluid after it has been used.
	Sensors	The sensors are electrodes microfabricated on silicon chips. Electrodes have chemically sensitive coatings such as ion-selective membranes and enzyme layers. In cartridges that perform coagulation tests, reagents, such as clot activators, are coated on the plastic above the sensors. Each sensor is connected to a contact pad by a signal line. The sensors respond to the calibrant solution and the sample by producing measur- able signals related to analyte concentration.
•	Contact pads	The contact pads conduct the signals generated by the sensors to the analyzer. Be careful not to contaminate the contact pads during car- tridge handling.
	Heating elements	Cartridges that require thermal control at 37 °C contain heating ele- ments on the underside of the sensor chips. These are contacted and heated by the analyzer's thermal probes.

## **Storing Cartridges**

All cartridges should be refrigerated at 2-8 °C (35–46 °F). Cartridges must be warmed to room temperature before removing them from their pouches. Allow five minutes for an individual cartridge — or one hour for a box of 25 cartridges — to reach room temperature.

Note:	Once removed from the refrigerator, cartridges can be stored at room temper- ature (18–30 °C or 64–86°F) for up to two weeks.
CAUTION:	Once a cartridge has been warmed to room temperature, do not return it to the refrig- erator.
Note:	Dispose of cartridges as biohazardous waste, in accordance with local and state guidelines.

## Handling Cartridges

Always follow these guidelines when handling VetScan i-STAT1 test cartridges.

- Remove the cartridge from the refrigerator and allow it to warm to room temperature for a minimum of five minutes. For an entire box of cartridges, allow to warm for one hour.
- Leave the cartridge in its protective pouch until you are ready to use it. Condensation on the cartridge pads may prevent proper contact with the analyzer and cause "star-outs" of the test result.
- Handle the cartridge only by the sides, not by the front or top.
  - □ Contamination of the contact pads with finger prints may prevent the analyzer from making proper contact with the cartridge.
  - □ Contamination of the test sensors may result in erroneous results or "star-outs".
  - Excessive pressure over the central area of the label may burst the calibrant pack. This will be perceived as a 'used' cartridge and will be rejected by the system.



- Do not set the cartridge on a dirty surface, towels, or blankets. These conditions may cause occlusion of the air vent and the sample will not flow through the system.
- Do not use a cartridge on which blood or any other fluid has been spilled, as the analyzer's electrical connectors may be contaminated.

## 4.3 Precision PCx Plus Blood Glucose Test Strips

Each Precision PCx Plus Blood glucose test strip is wrapped in a foil pouch with a barcode label. The label holds the calibration information about the test strip including:

- Lot number
- Expiration date
- Lot-specific calibration information

#### **Using Glucose Test Strips**

Use only whole blood samples. Collect the sample in a collection tube containing sodium heparin, lithium heparin, or EDTA, ensuring that the tube is completely filled. Invert the tube with the sample several times immediately before removing the sample. Use a transfer pipette to obtain a sample from the center of the collection tube. Test within 30 minutes of collection.

#### **Storing Glucose Test Strips**

Follow these guidelines in storing Precision PCx Plus Blood Glucose Test Strips:

- Keep the test strips with intact foil wrap in their original pack.
- Keep the test strips and control solution in a dry place, away from heat and direct sunlight, and between 4–30 °C (39–86 °F).
- Discard any expired test strips or control solution bottles.
- Use the control solution within 90 days after opening, or up to its expiration date. Mark the date of opening on the control solution bottles.

## Handling Glucose Test Strips

Follow these guidelines in handling Precision PCx Plus Blood Glucose Test Strips:

- Cover the entire target area of the test strip with the blood sample. The test results will not be affected if the target area has been briefly touched with the patient's skin, a syringe, a capillary tube or pipette.
- If the test fails to start, apply a second drop of blood to the target area within 30 seconds. If the test fails to start after the second drop is applied, or if more than 30 seconds have passed, discard the used test strip and repeat the test.
- After the blood is applied to the test strip and the test starts, do not touch the strip.
- Use a new test strip when repeating a patient test.
- Refer to the package insert in the test strip box for specific directions on storage and use of the test strips.

### 4.4 Testing Environment

- Store analyzers in use near the testing location or in an area close to the same temperature as the testing area.
- Do not store analyzers near equipment that gives off heat or in the direct sunlight.
- When moving an analyzer to an area that is slightly cooler or warmer (5 °C or 9 °F) than the previous area, allow 30 minutes for the analyzer to reach the temperature of the new area before use. If the temperature difference is greater than this, allow 90 minutes.

## 4.5 Collecting and Handling Samples

The sample used to fill a cartridge or apply to a test strip must be collected and handled properly to ensure that the results represent the patient's current status.

## Sample Collection Tube Fill Order

To prevent contamination, always fill sample collection tubes in this order:

- 1. No additive
- 2. Heparin
- 3. EDTA

#### Note: EDTA may not be used with any cartridge type other than Glucose cartridges.

Fill sample collection tubes (with and without anticoagulant) and syringes (with anticoagulant) to capacity. Incomplete filling of anticoagulant tubes and syringes causes higher heparin-to-blood ratios, which decrease ionized calcium results and may also affect other results. Underfilling sample collection tubes with and without anticoagulant can also cause decreased  $PO_2$ ,  $HCO_3$ , and  $TCO_2$  results.

Partial-draw sample collection tubes with or without anticoagulant are not recommended for blood gas or CHEM8+ cartridge analysis because the potential of decreased  $PO_2$ , HCO<sub>3</sub>, and TCO<sub>2</sub> results.

#### Sample Types

Whole blood samples without anticoagulant or whole blood collected into lithium heparin or balanced heparin are preferred sample types for use with the analyzer. Blood may be either venous or arterial, depending on the analytes to be measured. Venipuncture is typically performed for acid-base, electrolyte, metabolic, coagulation, and hemtologic studies. Use only whole blood without anticoagulant for ACT measurements. Samples for ionized calcium analysis should be collected in balanced heparin. Other types of heparin can falsely decrease ionized calcium results. For the most accurate results, test samples immediately after drawing. Samples for lactate and ACT must be tested immediately. Samples for pH, *P*CO<sub>2</sub>, *P*O<sub>2</sub>, TCO<sub>2</sub>, and ionized calcium should be tested within 10 minutes if stored anaerobically. Other analytes should be tested within 30 minutes.

*Note:* If testing is not immediate, remix sample collection tubes by gently inverting at least 10 times. Roll syringes between the palms for at least 5 seconds each in two different directions, then invert the syringe repeatedly for at least 5 seconds.

### Collecting for pH, PCO<sub>2</sub>, Electrolyte, Chemistry, and Hematocrit Tests

If the sample can be tested immediately, a plain syringe can be used. If the sample cannot be tested immediately, the sample should be collected in a sample collection tube with sodium heparin, lithium heparin or a pre-heparinized syringe labeled for measurement of electrolytes and ionized calcium. Test these samples within 10 minutes of collection.

*CAUTION:* Avoid exposing the sample to air when testing venous samples for ionized calcium, pH,  $PCO_2$ , and  $TCO_2$ .

#### **Collecting for CHEM8+ Tests**

CHEM8+ cartridges require the use of one of the following:

- Whole blood collected in non-heparinized tubes, evacuated tubes, or syringes, as long as the sample is tested immediately upon draw.
- Heparinized whole blood collected in balanced heparin syringes.
- Heparinized whole blood collected in evacuated tubes containing lithium or sodium heparin, as long as the tubes are filled to capacity.

#### Collecting for Cardiac Troponin (cTnI) Tests

cTnI cartridges require the use of one of the following:

- Heparinized whole blood or plasma samples collected in syringes or evacuated tubes containing lithium heparin or sodium heparin.
- Non-heparinized whole blood samples tested within one minute of drawing from a patient into a plastic syringe or plastic evacuated tube containing no additives.

*Note:* Whole blood or plasma samples containing other anticoagulants (such as EDTA or citrate) cause decreased cTnI readings.

The analyzer's Cartridge Information option must be enabled to perform cTnI testing. For details, see "Cartridge Information" on page 3-10.

#### **Collecting for Coagulation Tests**

Draw the sample for testing into a plastic syringe or sample collection tube containing no anticoagulant, clot activators, or serum/plasma separators. Use only plastic transfer devices, and do not use anticoagulant.

*Note:* Samples collected in glass tubes or syringes, or in tubes containing anticoagulants, activators, or separators, **cannot** be used with i-STAT coagulation cartridges.

Dispense the sample immediately into the cartridge's sample well, and then immediately insert the cartridge into the analyzer.

## 4.6 Cartridge Test Procedure — All Cartridges Except cTnl

The following procedures are used when the analyzer has Information First disabled, and the cartridge to be tested is not an immunoassay cartridge (see "Cartridge Information" on page 3-10). For procedures applicable to immunoassay cartridges, see "Cartridge Test Procedure – cTnI Cartridges" on page 4-8. For procedures applicable to PCx blood glucose strips, see "PCx Glucose Test Strip Procedure" on page 4-9.

*CAUTION:* Do not fill cartridges with a needle.

- 1. Remove the cartridge from the refrigerator and allow to reach room temperature (approximately 5 minutes).
- 2. Remove the cartridge from the pouch. Handle the cartridge by its edges. Avoid touching the contact pads or pressing on the center of the cartridge.
- 3. Following thorough mixing of the sample, direct the syringe or pipette tip into the sample well. Dispense the sample until it reaches the fill mark ( ▶ ) on the cartridge.



- 4. Press the rounded end of the closure until it snaps into place. Slightly lift finger or thumb and ensure that the cartridge is closed before completely removing finger or thumb from enclosure.
- 5. Turn on the analyzer by pressing the () key. The Test Menu opens.
- 6. Select 2 i-STAT Cartridge. The insert cartridge screen will appear.
- 7. Insert the cartridge into the cartridge slot
  - *Note:* In departments using i-STAT ACT cartridges and glucose test strips in the same analyzers, do not run ACT cartridges while the analyzer is docked in the Downloader/Recharger.
  - *Note:* For ACT cartridges, make sure the analyzer is placed on a level surface for the duration of testing.
- 8. Enter or scan in the Operator ID, then the Patient ID.
  - *Note:* To scan the operator or patient ID, press and hold down the Scan key to start the barcode scanner. Position the analyzer and barcode reader so the beam forms a red line that spans the entire barcode. When the analyzer accepts the barcode, it will beep and automatically turn off the beam.
- 9. The analyzer displays **Cartridge Locked** and identifies the cartridge type.

*CAUTION:* Once the cartridge is locked, do not attempt to remove the cartridge during the testing cycle. Doing so will damage the analyzer.

- 10. Once the cartridge type has been identified, calibration and analysis begins. The process takes two minutes. When complete, the results appear and the test record is stored.
- 11. Remove the cartridge after the Cartridge Locked message disappears.

The analyzer is ready for the next test.

*Note:* The analyzer includes several optional functions that can be used to enter additional data. If you customize your analyzer, there will be a few additional steps.

## 4.7 Cartridge Test Procedure – cTnI Cartridges

The i-STAT cTnI cartridge can only be used on analyzers bearing the 🔝 symbol. The analysis time for the cTnI cartridge is 10 minutes.

- 1. Use the analyzer's Customization Menu to customize the analyzer for either of the following:
  - Cartridge Information First Required and Cartridge Lot Number Required

or

- Cartridge Barcode Required
- 2. Remove the cartridge from the refrigerator and allow to warm to room temperature (five minutes).
- 3. Press the  $\bigcirc$  key to turn the analyzer on.
- 4. Select **2 i-STAT Cartridge** from the Test Menu.
- 5. Enter or scan in the Operator ID.
- 6. Enter or scan in the Patient ID.

*Note:* To scan the operator or patient ID, press and hold down the Scan key to start the barcode scanner. Position the analyzer and barcode reader so the beam forms a red line that spans the entire barcode. When the analyzer accepts the barcode, it will beep and automatically turn off the beam.

- 7. Scan the Cartridge Lot Number from the back of the cartridge portion pack.
- 8. Remove the cartridge from the portion pack. Handle the cartridge by its edges. Avoid touching the contact pads or pressing on the center of the cartridge.
- 9. Following thorough mixing of the sample, discard one drop from the delivery device to clear unseen bubbles.

**BISTX** 

10. Hang a drop slightly larger than the target well. Touch the drop to the well to allow the cartridge to draw in the sample. Confirm sample volume lines up with the top of the red fill line.

CAUTION: Do not load the cartridge with a needle.

- 11. Slide the plastic closure clip to the right until it locks into place over the sample well, as shown.
- 12. Insert the cartridge into the cartridge port.
- 13. The analyzer will display **Cartridge Locked** and identifies the cartridge type.

*CAUTION:* Once the cartridge is locked, do not attempt to remove the cartridge during the testing cycle. Doing so will damage the analyzer.

14. Once the cartridge type has been identified, calibration and analysis begins.

The process takes 10 minutes. When the test cycle is complete, the results appear and the test record is stored.

15. Remove the cartridge after the Cartridge Locked message disappears. The analyzer is ready for the next test.

## 4.8 PCx Glucose Test Strip Procedure

The analyzer must be configured to run Precision PCx Blood Glucose Test Strips — see "Customizing the Analyzer" on page 3-6.

- 1. Press the  $\bigcirc$  key to turn the analyzer on.
- 2. Select **3 PCx Glucose Strip** from the Test Menu.
- 3. Select 1 Patient.
- 4. Enter or scan the Operator ID.
- 5. Enter or scan the Patient ID.
  - *Note:* To scan the Operator or Patient ID, press and hold down the Scan key to start the barcode scanner. Position the analyzer and barcode reader so the beam forms a red line that spans the entire barcode. When the analyzer accepts the barcode, it will beep and automatically turn off the beam.
- 6. Enter or scan the test strip lot number.
- 7. If prompted, select **1 Arterial/Capillary** or **2 Venous sample**.
- 8. Open the foil packet, and remove the test strip.



9. Insert the test strip into the analyzer test port with the black contact bars facing up and forward.

*CAUTION:* Do not handle the test strip with wet or dirty hands.

Do not use test strips that are wet, scratched or damaged in any way.

Do not re-use test strips.

10. Apply a drop of blood to the target area of the test strip. Cover the entire area.

When the sample is accepted, the analyzer beeps and the test begins.

*CAUTION:* Do not touch the test strip after the sample is applied.

11. View the results on the analyzer's display.

## 4.9 Reviewing Test Results

#### **Results Display**

Test results are displayed with numerical concentration values in the units selected from the Customization Profile.

The  $\leq (\text{backlight})$  key can be used to backlight the display to view results in dim lighting. The backlight turns off after 90 seconds or when the key is pressed again.

Test results are displayed for two minutes or a customized time.

#### **Reportable Ranges**

The reportable range is the concentration range over which test results are valid. When a result falls below or above the reportable range, the result appears as < or > with the upper or lower limit (see "Flags" on the following page.)

#### **Reference Ranges**

By default, there are no reference ranges stored in the VetScan i-STAT 1 Analyzer software. Reference ranges may be stored in the analyzer using the Central Data Station software.

#### **ACT Cartridges**

When testing a Celite ACT cartridge, an option to cancel the test appears on the analyzer screen. The cancel test option will only appear after all the data entry has been completed. If the operator chooses to cancel the test, the result will display as 0.

#### **Typical Result Pages**





## Flags

When the analyzer detects an uncharacteristic sensor signal, the condition is indicated by one of the flags from the following table.

Display	Action	Analyzer Response/Comments
>	The result falls above the reportable range of the test.	If an ACT result is displayed as > 1000, the result should be reported as "greater than 1000 seconds."
<	The result falls below the low end of the reportable range of the test.	If a pH result is displayed as < 6.5, the result should be reported as "less than 6.5."
<>	The result depends on another test that has been flagged. The $<>$ flag is also displayed for TCO <sub>2</sub> , <i>P</i> CO <sub>2</sub> , HCO <sub>3</sub> , anion gap, base excess, and sO <sub>2</sub> if the TCO <sub>2</sub> is outside the reportable range. Because the values outside the reportable range of TCO <sub>2</sub> are essen- tially non-physiological, the TCO <sub>2</sub> range check is used as an additional quality check on the validity of the underlying pH and <i>P</i> CO <sub>2</sub> results.	If a sodium result is displayed as >180, the calcu- lations for potassium, chloride, BUN/Urea, and hematocrit, which depend upon the sodium mea- surement, will be flagged < >.
***	The signals from a particular sensor are uncharacteristic. This can be caused by a compromised sensor or an interferent in the sample. This flag also appears for any test dependent on another test that has been flagged with stars.	Retest the sample with another cartridge.

# Section 5

## **Recalling Results**

The VetScan i-STAT1 Analyzer automatically stores up to 5,000 test records. The Data Review function allows the operator to review stored results. The number of test results stored is indicated at the bottom center of the screen as x/y, where x is the result on the screen and y is the total number of results stored.

The oldest data is overwritten once the memory becomes full unless the analyzer is customized to display Memory Full, or to disable testing until data is transmitted to the Central Data Station (see "Handling Full Memory" on page 3-7).

## 5.1 Recalling the Last Cartridge Results

To recall the last set of results to the screen, use the following procedure:

- 1. In the Test Menu screen, select **1 Last Result**.
- 2. Results for the last cartridge run will display on the screen.
- 3. Press the **Menu** key to return to the Test Menu.

## 5.2 Reviewing Results From the Same Patient

To review results from the same patient when results are displayed, use the following procedure:

- 1. Select 1 Test Options.
- 2. Select **3 History**.
- 3. Scroll through the test records using the **1** and **2** keys.

## 5.3 Reviewing Results From Another Patient

To review another patient's results:

- 1. Turn on the analyzer by pressing the () key.
- 2. From the Test Menu, press the **Menu** key to access the Administration Menu.
- 3. Select **2 Data Review** from the Administration Menu.
- 4. Select **1 Patient** from the Data Review Menu.
- 5. Enter or scan the Patient's ID number.
- 6. Use the **1** and **2** keys to scroll through the test records.

Or, press the **Menu** key followed by the **7** key for **List**. Select the test result(s) to be reviewed and press the **ENT** key.

## **5.4 Transmitting Results**

Transmitting results to the printer or to the Central Data Station are described in the printer and downloader sections of this manual — see "Transmit Data" on page 3-13.

## 5.5 Printing Results

Results can be printed from the VetScan i-STAT1 using the portable Martel Printer. The printer can receive data directly from the analyzer via infrared transmission or through a data cable connected to a Down-loader. The printer is battery powered and can be recharged from a power adapter. Charge the printer for at least 6 hours before first use.

The following information is printed:



#### Printing directly from the analyzer

- 1. Point the analyzer's infrared communication window to the printer's infrared LED window on the left side.
- 2. Ensure that the results to be printed are displayed and press the key on the analyzer. Do not move the analyzer or printer until printing is complete.

*Note:* The printer must be within 2.5 cm to 12.7 cm (1 in. to 5 in.) of the analyzer.

### Printing from the analyzer using the Downloader

*Note:* To connect the Downloader to the printer, see "Connecting the Serial Downloader" on page 2-9.

- 1. Place the analyzer between the arms of the Downloader or in the Downloader/Recharger.
- 2. Ensure that the results to be printed are displayed.
- 3. Press the  $\stackrel{\text{per}}{\longrightarrow}$  key. Do not move the analyzer or printer until printing is complete.

#### **Printing multiple results**

- 1. Select **2 Data Review** from the Administration Menu on the analyzer.
- 2. Select **7** List.
- 3. Use the arrow keys to page up and down through the pages of stored results.
- 4. Press the numbered key for each test result to be printed.

*Note:* To deselect a record, press that number key again.

- 5. When all test results have been selected, point the analyzer's infrared communication window to the printer's infrared LED window on the left side or place into a Downloader or Downloader/Recharger.
- 6. Press the  $\stackrel{\text{PR}}{=}$  key.

# Section 6

## Quality Control

Quality control procedures help ensure the continued accuracy of a test system. The quality control program for the VetScan i-STAT1 Analyzer system includes:

## 6.1 Automatic Quality Checks

A series of automatic quality checks are performed during each test cycle. When there is a quality check failure, a message is displayed with the cause and corrective action. The quality checks detect improper environmental conditions, analyzer function, cartridge filling, cartridge function and sensor function.

For information on specific messages displayed, see "Error Codes and Flags" on page A-1.

## 6.2 Electronic Simulator Check

*Note: Electronic Simulator, PN 600-0002, is purchased separately.* 

An independent check of the analyzer's ability to take accurate and precise readings from the sensors is performed automatically every 24 hours when cartridges are being tested. An external Electronic Simulator is used to verify an internal Electronic Simulator failure and perform the Thermal Probe check. Both the internal and external simulator results are stored in the analyzer's memory.

The internal and external Electronic Simulators send signals that simulate those of a cartridge to the analyzer's signal detection system. The signals are below and above the measurement ranges of the tests.

The internal simulator check is triggered by the insertion of a cartridge once every 24 hours (default setting). If the check passes, the cartridge test cycle continues. If the check fails, FAIL and a failure code are displayed. A cartridge test cannot be performed until the analyzer passes the simulator check (default setting). If the FAIL message is observed when it occurs, the cartridge can be re-inserted. If FAIL is displayed a second time, the external simulator can be used to verify that the failure is being caused by the analyzer and not by a faulty cartridge.

> If there is a delay between the time the cartridge is inserted and the time the FAIL display is read, use a new cartridge and sample or the external simulator rather than re-inserting the original cartridge.

Note:

## 6.3 Thermal Probe Check

The VetScan i-STAT1 contains a thermal control subsystem consisting of two thermal probes with thermistors and heating contact wires. When measurements are performed at a controlled temperature, the thermal probes in the analyzer contact the metalized area under the chips in the cartridge and maintain the temperature of the sensors and the fluids that come into contact with these sensors at the required temperature  $\pm 0.15$  °C.

A quality check is performed on the thermal probes each time the external Electronic Simulator is used. To complete this check, the surface temperature of the external Electronic Simulator must not fluctuate. If this condition is not met, the thermal probe check is not completed. It is recommended that the thermal probe check is verified twice a year.

Check the thermal probes on the VetScan i-STAT1 Analyzer as follows:

- 1. If the analyzer and simulator have been stored in separate areas with an ambient temperature difference of more than 3 °C (5 °F), allow the simulator and analyzer to stand in the same place, out of drafts, for 30 minutes before inserting the simulator into the analyzer. Handle the simulator as little as possible to maintain its thermal uniformity and stability.
- 2. Insert the simulator into the analyzer.
- 3. When results are displayed, press the period key to view the difference between the thermal probes on the analyzer's screen.
- 4. Interpretation the thermal probe check value as follows:
  - **Acceptable:** a value equal to or less than 0.1.
  - □ Not acceptable: a FAIL message with a "t" Quality Check Code or a value greater than 0.1. Repeat the procedure to confirm results. Contact your Technical Support representative if the repeat thermal check value is greater than 0.1.
  - □ **Repeat the procedure:** if "--.--" is displayed. Take care to handle the simulator a little as possible. It may help to partially insert the simulator into the analyzer and let it stand for 15 minutes before inserting all the way.

## 6.4 Calibration

Calibration is performed each time a cartridge requiring calibration is used. During the first part of the testing cycle, the calibrant solution is automatically released from its foil pack and is positioned over the sensors. The signals produced by the sensors' responses to the calibrant solution are measured. The calibration adjusts the offset of the stored calibration curve. Next, the analyzer automatically moves the sample over the sensors and the signals produced by the sensors' responses to the sample are measured.

## 6.5 Controls

The VetScan i-STAT1 includes automatic calibration and quality control checks that eliminate the need for routine external liquid controls. If an external control is needed occasionally, the analyzer provides a memory bank to store the data. Controls are available from Abaxis.

Target values can be found here: **http://abbottpointofcare.com**. Select Value Assignment Sheets under Quick Links. These values are determined by testing multiple ampules of each level using multiple lots of cartridges and i-STAT analyzers that have passed the Electronic Simulator test.

To run a control:

- 1. Press the  $\bigcirc$  key.
- 2. To access the Administration Menu, press the **Menu** key.
- 3. Select **3 Quality Tests**.
- 4. Select 1 Control.
- 5. Select **1 i-STAT Cartridge**.
- 6. Enter or scan the Operator ID.
- 7. Enter or scan the Control Lot Number.
- 8. Enter or scan the Cartridge Lot Number.
- 9. Insert the cartridge.

# Section 7

## Troubleshooting

## 7.1 Troubleshooting the Analyzer

When the analyzer detects a potential or real problem before the test cycle is initiated or at any time during the test cycle, a Quality Check Code number, the type of problem, and the next step to be taken will be displayed.

Note: For a complete list of error code numbers, see "Error Codes and Flags" on page A-1.
 CAUTION: Do not open the analyzer or any other VetScan i-STAT1 product, or perform any unauthorized procedures. Opening any VetScan i-STAT1 product, including analyzer, Electronic Simulator, printer, or communication device, in attempting to repair it or resolve a problem may cause erroneous results. If the troubleshooting procedures found in the manual or requested by an Abaxis Technical Service Representative do not resolve the problem, the product must be returned to Abaxis for repair.

## 7.2 Contacting Abaxis Technical Service

If the troubleshooting recommendations contained in this section do notcorrect the problem with the analyzer, contact Abaxis Technical Service, 24 hours a day, 7 days a week, at 800-822-2947.

When contacting Abaxis Technical Service, have the following information available for review (refer to "Analyzer Status" on page 3-2):

- Description of the problem
- When the problem first occurred and what has been done so far to resolve the problem
- Serial number of the analyzer
- Displayed message and Quality Check Code number (see below)
- Frequency of problem
- Software version
- Result of last Electronic Simulator test
- Battery voltage from Analyzer Status page
- Cartridge information: type, lot number, box number, and expiration date

## 7.3 Troubleshooting the Printer

Use the following to troubleshoot printer problems.

- Printer is not printing, power LED is on, and Status LED is off:
  - □ Check that the results are displayed or that results have been selected from List under Data Review.
  - □ Check that the distance between the analyzer and printer is not too short or too long.
  - □ Run a printer self test: turn the printer on while pressing the Paper Feed button, then release the button and make sure the resulting printout is clear.
- Paper is feeding but nothing is printed: Check that the paper is feeding from under the roll.
- Printer is not printing and Status light on continuously: Battery needs to be recharged.
- Printer Power LED does not come on when the printer is turned on: Battery needs to be recharged. The power adapter cannot supply sufficient power for printing so the battery needs to be partially charged before printing is possible.
- Printer not printing and Status light flashing at a rate of 0.5 seconds: printer is out of paper.
- Printer not printing and Status light flashing at a rate of 0.25 seconds: print head temperature is too hot. Printing will be suspended until print head temperature returns to a normal level.

## 7.4 Out-of-Range Samples

#### Cartridges

When results do not reflect the patient's condition, repeat the test using a fresh cartridge and sample. If results are still suspect, test the lot of cartridges in use with i-STAT control solutions. If the controls are in range, there may be an interfering substance in the sample. Check the Cartridge and Test Information (CTI) sheets for the test in question. Test by another method to verify the result. If the controls are out of range, verify that the following conditions are met, then repeat the test:

- The correct Value Assignment Sheet is being used and the correct cartridge type and lot number listing is being used.
- Expiration date printed on cartridge pouch and control ampule or vial have not been exceeded.
- Room temperature expiration date for cartridge and control have not been exceeded.
- Cartridge and control have been stored correctly.
- The control has been handled correctly: see the directions for use.
- The analyzer being used passes the Electronic Simulator test.
- Use another lot number or repeat the test using another method, and contact Abaxis Technical Support at 800-822-2947.

#### **PCx Plus Glucose Strips**

Possible reasons for higher than expected results:

- $\blacksquare Hematocrit < 20\% PCV or 0.20$
- Serum or plasma samples used instead of whole blood
- Room (ambient) temperature > 104 °F or 40 °C
- **Relative humidity** > 90%
- Venous blood tested in capillary or arterial mode

Possible reasons for lower than expected results:

- $\blacksquare \quad \text{Hematocrit} > 70\% \text{PCV or } 0.70$
- **Room temperature** < 59 °F or 15 °C
- Capillary or arterial blood tested in venous mode
- **Relative humidity** < 10%
- Hyperglycemic-hyperosmolar state (with or without ketosis)
- Severe dehydration, hypotension, or shock
- Water or alcohol remaining on the puncture site
- Venous or arterial whole blood sample not tested within 30 minutes after collection

When the > flag appears, or if the result is outside the action ranges designated for the location, the sample must be tested by another method, such as an i-STAT glucose cartridge, in order to obtain a result.

# Section 8

## Maintenance and Service

The VetScan i-STAT1 Analyzer requires no regular maintenance. Use the procedures in this section as needed. For maintenance of the Downloader or Printer, refer to their respective sections.

## 8.1 Cleaning the Analyzer

**CAUTION:** If the analyzer is placed on a wet surface or if any liquid is spilled on it, dry immediately. The analyzer may be damaged if liquid enters the battery compartment, cartridge port, glucose strip port, or case.

- 1. Carefully clean the display screen and case using a gauze pad moistened with any of the following:
  - Mild non-abrasive cleaner
  - Detergent
  - Soap and water
  - Alcohol
  - 10% bleach solution

*CAUTION:* Avoid getting excess fluids in the seam between the display screen and the case.

- 2. Moisten another gauze pad with water, and wipe down the analyzer and display again.
- 3. Dry the analyzer.

## 8.2 Cleaning the External Simulator

- 1. Cover the connector area with the blue rubber boot. This minimizes the possibility of cleaning fluid entering the simulator housing and contaminating internal circuitry.
- 2. Carefully clean the simulator with a gauze pad moistened with any of the following:
  - Mild non-abrasive cleaner
  - Detergent
  - Soap and water
  - Alcohol
  - 10% bleach solution

**CAUTION:** Never immerse the simulator in any fluid.

- 3. Moisten another gauze pad with water, and wipe down the simulator again.
- 4. Dry the simulator.

*Note:* If the connector itself is contaminated, contact Technical Service at 800-822-2947 and arrange to return the simulator.

## 8.3 Replacing Disposable Batteries

Wait until any test in progress is completed and turn off the analyzer before replacing the batteries or the most recent set of results maybe lost. **Stored results will not be lost** when replacing the batteries.

- 1. Slide the battery compartment door off.
- 2. Tilt the analyzer slightly to slide out the battery carrier, which contains two 9-volt batteries.
- 3. Remove the old batteries from the carrier. Pull each battery out to the side and then lift back and out.
- 4. Note the battery orientation symbol molded into the carrier on each side of the center wall. Starting with one side, orient each battery so it matches the symbol. Slide the battery into the carrier, pushing the terminal end in first, under the plastic bar, and slide it up as far as it will go. Then push the bottom of the bat-



tery inward. The terminals of the battery should be underneath the protective bar on the carrier. Repeat for the second battery on the other side.

- 5. Note the orientation of the battery carrier illustrated on the label on the carrier. The label faces up, and the electrical contact end of the carrier goes into the instrument first. Insert the carrier into the instrument as shown on the label. If the carrier is inserted incorrectly, the battery door will not close.
- 6. Slide the battery compartment door back into place.

## 8.4 Replacing Rechargeable Batteries

Wait until any test in progress is completed and turn off the analyzer before replacing the battery or the most recent test results may be lost. **Stored results will not be lost** when replacing the batteries.

- 1. Slide the battery compartment door off.
- 2. Tilt the analyzer slightly to slide out the rechargeable battery pack.
- 3. The battery pack has two labels: one for orientation in the analyzer and one for orientation in the Downloader/ Recharger. With the label with the analyzer facing up, and the electrical contact end of the pack facing the analyzer, insert the pack into the analyzer as shown on the label. If the pack is inserted incorrectly, the battery door will not close.
- 4. Slide the battery compartment door back into place.



# Section 9

## Updating the Analyzer's Software

This section will guide you through the process of updating the software on your VetScan i-STAT 1 Analyzer. This process should take less than 10 minutes for the first analyzer, and less for each additional analyzer.

## 9.1 Scheduled Update Packets

The VetScan i-STAT 1 Analyzer System is designed to eliminate operator influence on delivered results.

Due to continuous manufacturing process improvements in the VetScan i-STAT 1 Analyzer System, standardization values must be updated from time to time to maintain consistent long-term performance. These updates are equivalent to manually adjusting calibration on a traditional laboratory analyzer.

New CLEW software — delivered twice a year on a CD-ROM — re-establishes these standardization values and incorporates refinements to the internal quality monitoring system. New JAMS application software allows the analyzer to recognize any newly launched cartridge types and to perform any newly launched features.

## 9.2 JammLite Utility Process Overview

Whether updating one, two, or many analyzers, the JammLite Utility procedure must be used to update the first analyzer. The process is as follows:

- 1. Gather equipment for JammLite
- 2. Connect/set up equipment
- 3. Load JAMS/CLEW
- 4. Update the analyzer
- 5. Verify the software update

Once the first analyzer has been updated using JammLite, additional analyzers can be updated the same way, or by using the analyzer-to-analyzer method. Additionally, if using the Central Data Station (CDS), the new software must be added to the CDS Customization Workspace.

## 9.3 Choosing the Best Update Method

■ JammLite Utility:	If you have all the necessary equipment (see page 9-2), it's best to update your analyzers using JammLite if they are readily available and near the PC you'll use to run the JammLite Utility.
■ Analyzer-to-Analyzer:	This is a good choice after the first analyzer has been updated via JammLite and other analyzers are not near the PC used to run the JammLite Utility.

## 9.4 Updating Using the JammLite Utility

#### Step 1 — Required Equipment

Before starting the process make sure all the required equipment is available:

- Computer with:
  - □ Windows 2000 or Windows XP
  - □ 9-pin serial port

- □ CD-ROM drive
- VetScan i-STAT1 System Equipment (see the following figure):
  - □ Serial Downloader (a) or Downloader/Recharger (b)
  - Downloader Power Supply (c)
  - □ VetScan i-STAT 1 Analyzer (d)
  - **9**-pin null modem serial cable supplied with downloader (e)
  - □ Current JAMS/CLEW software CD (f)
  - □ Electronic Simulator (*optional*) (g)



*Note:* If you do not have a computer with a 9-pin serial port or a serial port adapter, contact Abaxis Technical Support at 800-822-2947.

## Step 2 — Check battery voltage

Ensure your VetScan i-STAT1 has at least 7.5 volts of battery power.

- 1. Press the  $\bigcirc$  key.
- 2. Press the **Menu** key.
- 3. Select **1 Analyzer Status**.
- 4. Check the battery voltage.
- 5. If the battery has less than 7.5 volts:
  - If you have rechargeable batteries, charge your analyzer until it has at least 7.5 volts.
  - If you have disposable batteries, replace with new batteries.

#### Step 3 — Connecting/Setting Up Equipment

Connect the VetScan i-STAT1 Serial Downloader or the Serial Downloader/Recharger to the 9-pin serial port on the back of the computer with the 9-pin null modem serial cable, as shown.



#### Step 4 — Connecting the Power Supply

Connect the power supply to the VetScan i-STAT1 Serial Downloader or Serial Downloader/Recharger, and then to the wall outlet or power strip.

*Note:* When power is supplied to the Serial Downloader, a green LED lights. When power is supplied to the Serial Downloader/Recharger, it looks as it did before power was supplied.

#### Step 5 — Loading JAMS/CLEW

- 1. Close all open programs on the computer including CDS (if applicable).
- 2. Before inserting the VetScan i-STAT1 Software Update CD, check that the JAMS application and CLEW match the Product Update.
- 3. Insert the Software Update CD into the CD-ROM drive.
- 4. If a window appears within 30 seconds, double click TRANSFER.BAT in the window. Another window then opens briefly. Proceed to Step 6, below.



My Compute

- 5. If no window appears after inserting the Software Update CD, proceed as follows.
  - a. Double-click My Computer.



b. Double-click CD-ROM Drive.



? ×

- c. Double-click TRANSFER.BAT. A window opens briefly.
- 6. Close Windows Explorer.
- 7. Select **Start > Run...**, then type:

c:\bins\jammlite.exe

- 8. Click **OK**.
  - *Note:* You can also browse to c:\BINS and double-click JammLite.exe.
  - *Note:* If the JammLite program does not launch or you receive an error message, contact Abaxis Technical Service at 800-822-2947.



Run

- 9. In the JammLite utility, use the Instrument dropdown menu to select the **i-STAT 300 Analyzer**.
- 10. The lowest numbered COM port is automatically selected. If the downloader is connected to a different COM port, select that COM instead.
  - *Note:* If no ports are displayed, close JammLite and any other open programs, then re-launch JammLite. If JammLite still shows no available COM ports, contact Abaxis Technical Service for assistance.

nstrument	
-STAT 200 Analyzer	
-STAT 200 Analyzer	
I-STAT 300 Analyzer	✓ Update
Blood Analysis Module	
Fladdrus)	
Application	
JAMSXXXX.BIN	
CLEW	LIL EXIT
AXX CIW	

#### Step 6 — Updating your VetScan i-STAT 1 Analyzer

- 1. Make sure the Application and CLEW listings match those in the current software update information packet.
- 2. Click Update.
  - *Note:* The application and CLEW numbers shown above are for example only. The actual numbers change with each software update.
  - *Note:* If an error occurs, check the serial connection between the downloader and the PC as well as the power connection to the downloader. If connected correctly, select a different COM port (do not select TCP/IP) within the dropdown menu and click **Update**. If after trying each of the COM ports listed in JammLite and you are still not prompted to power off the VetScan i-STAT1 and insert into the downloader, call Abaxis Technical Support at 800-822-2947 for assistance
- 3. Follow the onscreen instructions.

<ol> <li>If an analyzer is already in the Downloader remove it.</li> </ol>	-
2) Ensure the analyzer to be updated is off.	Cancel
3) Place the analyzer in the Downloader.*	£

*Note:* If using the Serial Downloader/Recharger, a blue LED lights when the analyzer is placed correctly within it. If using the Serial Downloader, a red LED lights when the analyzer is placed correctly within it.

- 4. The following screen appears during the update:
  - Note: If you do not see this screen, acknowledge any error messages, click OK, and repeat the entire procedure "Step 6 — Updating your VetScan i-STAT 1 Analyzer" from the beginning.

Cancel

The receiving analyzer shows streams of 1s and 0s to indicate that it is receiving the software.



5. When the update finishes, the success screen appears:

The application update was successful.
The CLEW update was successful.
Close

*CAUTION:* Do not move the analyzer until the success screen appears.

## Step 7 — Verifying the Software Update

Remove the analyzer from the Downloader and verify that is has been properly updated:

- 1. If the analyzer's screen has gone blank, press its () key to activate the display.
- 2. Press the **Menu** key.
- 3. Select 1 Analyzer Status.
- 4. Check the numbers adjacent to VERSION and CLEW to make sure they match the current software update.

#### Congratulations! The VetScan i-STAT1 is now updated.

- If there are no additional analyzers to update: close the software screen and any other open windows, and confirm all messages that appear. *The update process is complete*.
- If you have additional analyzers to update using JammLite: proceed to "Step 8 Updating Additional Analyzers" on page 9-5.

#### Step 8 — Updating Additional Analyzers

From this point in the process, you can update additional analyzers several ways:

■ Using the JammLite software: see "Using JammLite", below.

By connecting the updated analyzer to another needing the update: see "Using the Analyzer-to-Analyzer Process" on page 9-6.

#### Using JammLite

For each additional analyzer to update using JammLite:

- 1. From the software screen displaying "PASS," click **Close**.
- 2. Click Update.
- 3. Repeat Step 6 (page 9-4) through Step 7 (page 9-5).

#### Using the Analyzer-to-Analyzer Process

Once you have one analyzer updated, you can update other analyzers as follows.

- 1. Collect the following equipment:
  - The updated VetScan i-STAT1 (the "sending analyzer"), charged to 7.5 volts or higher\*
  - The analyzer to be updated (the "receiving analyzer"), charged to 7.5 volts or higher\*
  - an Electronic Simulator (*optional*, PN 600-0002)

\* For information on checking battery power, see page 9-3.

- 2. Make sure the receiving analyzer is powered off.
- 3. Place the two analyzers on a flat surface, about 1 foot (30 cm) apart, with their infrared (IR) windows aligned.



- 4. Turn on the sending analyzer, press MENU, and select 7 Utility.
- 5. When prompted for a password, enter the password or press **ENT** and continue.

*Note:* If the correct password was not entered, the Utility Menu will not appear. Check for data entry errors and retry. If still unsuccessful call Abaxis Technical Support at 800-822-2947.

- 6. In the Utility Menu, press **1 SEND SOFTWARE**, then press **1 JAMSXXX/AXX** (where *XXX/AXX* represents the numbers of the software update).
- 7. Make sure the receiving analyzer is powered off.
8. When the sending analyzer displays **WAITING TO SEND**, slide the receiving analyzer towards it without lifting either analyzer, and keeping the IR windows aligned.



9. When the analyzers are in range, the update begins. The sending analyzer displays **SENDING** and a progress bar.



Versame /STAT'I

010011101100010 0011000100111001

The receiving analyzer displays streaming 1s and 0s to indicate that it is receiving the software.



10. When the sending analyzer displays **Last Send Successful**, the update is complete.

- 11. Verify that the receiving analyzer has been properly updated:
  - a. If the analyzer's screen has gone blank, press its  $\bigcirc$  key to activate the display.
  - b. Press the Menu key
  - c. Select 1 Analyzer Status.
  - d. Check the numbers adjacent to VERSION and CLEW to make sure they match the current software update.



#### Congratulations! The receiving VetScan i-STAT1 is now updated.

*Note:* If PASS is not displayed, re-run the Electronic Simulator. If the repeated Electronic Simulator attempt fails, please contact Abaxis Technical Service.

12. If there are other VetScan i-STAT1 units to update, repeat the above steps. If there are no other analyzers to update, the process is complete.

#### 9.5 Updating Using a Network Downloader

#### **Step 1** — **Required Equipment**

Before starting the process make sure all the required equipment is available:

- Computer with:
  - □ Windows 2000 or Windows XP
  - □ CD-ROM drive
- VetScan i-STAT1 System Equipment (see the following figure):

D Network Downloader (a) or Network Downloader/Recharger (b)

- *Note: Make sure the Network Downloader or Downloader / Recharger(s) are installed and in-use on the network.*
- □ VetScan i-STAT 1 Analyzer (c)
- □ Current JAMS/CLEW software CD (d)
- □ Electronic Simulator (*optional*) (e)



■ List of Network Downloader IP addresses.

#### Step 2 — Check battery voltage

Ensure your VetScan i-STAT1 has at least 7.5 volts of battery power.

- 1. Press the  $\bigcirc$  key.
- 2. Press the **Menu** key.
- 3. Select **1 Analyzer Status**.
- 4. Check the battery voltage.
- 5. If the battery has less than 7.5 volts:
  - If you have rechargeable batteries, charge your analyzer until it has at least 7.5 volts.
  - If you have disposable batteries, replace with new batteries.

#### Step 3 — Loading JAMS/CLEW

- 1. Close all open programs on the computer including CDS (if applicable).
- 2. Before inserting the VetScan i-STAT1 Software Update CD, check that the JAMS application and CLEW match the Product Update.
- 3. Insert the Software Update CD into the CD-ROM drive.
- 4. If a window appears within 30 seconds, double click TRANSFER.BAT in the window. Another window then opens briefly. Proceed to Step 6, below.
- 5. If no window appears after inserting the Software Update CD, proceed as follows.
  - a. Double-click My Computer.
  - b. Double-click CD-ROM Drive.
  - c. Double-click TRANSFER.BAT. A window opens briefly.
- 6. Close Windows Explorer.
- 7. Select **Start > Run...**, type

c:\bins\jammlite.exe, then click OK.

- *Note:* You can also browse to c:\BINS and double-click JammLite.exe.
- *Note:* If you cannot access the c:\BINS directory, contact your IT support and request access. If you do not have IT support, contact Abaxis Technical Support.



*Note:* If the JammLite program does not launch or you receive an error message, contact Abaxis Technical Service at 800-822-2947.







8. In the JammLite utility, use the Instrument dropdown menu to select the i-STAT 300 Analyzer.

- 9. Use the Port dropdown menu to select TCP/IP.
- 10. In the IP Address box, type the IP address of the Network Downloader
  - Note: The IP address shown above is a sample only. Use the IP address for your Network Downloader.

#### Step 4 — Updating your VetScan i-STAT 1 Analyzer

- Make sure the Application and CLEW listings match those in the current software update informa-1. tion packet.
- 2. Click Update.
  - Note: The application and CLEW numbers shown are for example only. The actual numbers change with each software update.
- 3. Follow the onscreen instructions.



P JammLite 4.3

TCP/IP	*
COM1	
COM3	
COM6	
COM7	
ТСРИР	

X

IP Address	
172.20.29.154	

172.20.29.154
1
Application JAMS125A.BIN
CLEW A16.CLW

JammLite 4.3 Instrument



Updating the Analyzer's Software

9-11

#### The following screen appears during the update: The application update is in progress. Please do not remove the analyzer from

The receiving analyzer shows streams of 1s and 0s to indicate that it is receiving	-
the software.	0

the Downloader.

5. When the update finishes, the success screen appears:

*CAUTION:* Do not move the analyzer until the success screen appears.

# The CLEW update was successful

The application update was successful.

#### Step 5 — Verifying the Software Update

Remove the analyzer from the Downloader and verify that is has been properly updated:

- 1. If the analyzer's screen has gone blank, press its () key to activate the display.
- 2. Press the **Menu** key.

4.

- 3. Select 1 Analyzer Status.
- 4. Check the numbers adjacent to VERSION and CLEW to make sure they match the current software update.

#### Congratulations! The VetScan i-STAT 1 is now updated.

- If there are no additional analyzers to update: close the software screen and any other open windows, and confirm all messages that appear. *The update process is complete*.
- If you have additional analyzers to update using the same Network Downloader IP address:
  - a. Click Close.
  - b. Click Update.
  - c. Repeat steps 1 through 5.
- If you have additional analyzers to update using a different Network Downloaded IP address:
- a. Click Close.
- b. Repeat steps 1 through 5.



Close

Helbenn /STAT1

Cancel

9-12

# Appendix A

# Error Codes and Flags

The tables on the following pages explain the error codes that can appear on the VetScan i-STAT1 Analyzer, and provide solutions where needed.

#### A.1 Warning Messages

Whenever the VetScan i-STAT1 is turned on using its  $\bigcirc$  key, it automatically performs a series of self checks. If a condition is detected that should be corrected in the near future, but that will not affect results, a warning is displayed. Press the **1** key to continue testing. If the analyzer has been customized to disable testing under any of these conditions, the condition must be corrected and the analyzer turned off and back on before testing will be enabled.

Displayed Message	Explanation
Stored Memory Low	The analyzer can store 5000 unsent test records, beyond which this message appears.
Stored Memory Full	The analyzer's memory for unsent records is full. The analyzer will either block further testing or will overwrite oldest records depending on how the analyzer is customized (see "Customizing the Analyzer" on page 3-6). Download the unsent results to the Central Data Station, or delete to clear the memory.
Upload Required	If the analyzer is customized, it will alert the operator that a scheduled transmission of test records to the Central Data Station is due.
Battery Low	Battery voltage has dropped to 7.4 volts. There is sufficient power to test a few more cartridges and strips, depending on the type of cartridge. Under this condition, a flashing battery icon will also appear on the result page, the Test Menu screen and the Administration Menu screen. Change the disposable lithium batteries or recharge the rechargeable battery.
CLEW Expiring, Update Required	Message appears 15 days before the software expires. Update the analyzer before the expiration using one of the methods in Section 9 of this manual.

#### A.2 Analyzer and Environmental Errors

Note:

Codes 1-15 and 95 usually indicate a condition related to the environment or the state of the VetScan i-STAT1. These conditions are usually benign and do not reappear when the next cartridge is inserted or after the displayed condition is corrected.

Code No.	<b>Displayed Message</b> ( <i>listing cause and action</i> )	Explanation
1	Dead Batteries Replace Batteries	There is insufficient battery power to complete the testing cycle. Replace the disposable lithium batteries in the analyzer or recharge the rechargable batteries — see "Replacing Disposable Batteries" on page 8-2 or "Replacing Rechargeable Batteries" on page 8-2. If you are experiencing this code frequently and use disposable batteries, consider using the rechargable battery system available with the i-STAT 1 Analyzer.
2	Temperature Out of Range Check Status Page	The analyzer is recording a temperature outside its operating range. Move the analyzer to an area within the operating temperature of the test being performed and allow the analyzer to come to the new room temperature. Monitor the analyzer's temperature reading on the Analyzer Status screen.
4, 8	Analyzer Interrupted Use Another Cartridge	The analyzer has detected that the last test cycle was not completed. This can happen if the batteries were removed or were making poor contact while a cartridge was still in place in the analyzer. Check that the batteries are inserted properly and seated well in the battery cage. Batteries that are too short will not make proper contact. Check the battery voltage on the Analyzer Status screen, and replace batteries if low. (see "Replacing Disposable Batteries" on page 8-2 or "Replacing Rechargeable Batteries" on page 8-2). <b>Note: Patient results displayed before this code are valid.</b>
11	Date Invalid Check Clock	If the date in the real time clock precedes the release date programmed into the application software, code 11 is triggered. Check and reset the date — see "Setting the Date and Time" on page 3-12. The accuracy of the clock is checked at the beginning of the Celite ACT test. If the clock is inaccurate, code 11 is triggered.
12	Invalid or Expired CLEW See Manual	The CLEW standardization has expired. Download a valid CLEW. Update immediately using the CD-ROM provided by Abaxis — see "Updating the Analyzer's Software" on page 9-1. The date on the real time clock exceeds the expiration date of the CLEW software. Check and reset the date as needed — see "Setting the Date and Time" on page 3-12.
13	Invalid or Expired CLEW See Manual	This code indicates that the CLEW software has become corrupted or is not compatible with the application software (JAMS), or there is no CLEW in the analyzer. Update software immediately using the CD-ROM provided by Abaxis — see "Updating the Analyzer's Software" on page 9-1. If this code occurs after a software upgrade and the customization application is enabled in the CDS, change the CLEW version in the Customization profile to the latest version and re-transmit the profile to the analyzer.
14	Analyzer Error See Manual	This indicates a corrupt analyzer customization profile. Retransmit the customization profile. If code 14 recurs, Contact Abaxis Technical Service.
15	Barcode Does Not Match Cartridge Type	The barcode scanned by the user does not match the immunoassay cartridge type indicated by the identification chip in the cartridge. The user should run another cartridge, being careful to scan the barcode from the portion pack of the specific cartridge type being run on the analyzer.
95	Test Cancelled by Operator	This message appears in the analyzer's stored test records if the analyzer powers down before mandatory information is entered.

### A.3 Cartridge Errors

The following codes are associated with the cartridge or fluid movement within a cartridge, and can result from operator error or problems with the sample. In most cases, a new cartridge must be used. If a condition persists, the code may be due to analyzer malfunction.

Code No.	<b>Displayed Message</b> (listing cause and solution)	Explanation
21	Cartridge Preburst Use Another Cartridge	This code indicates that the analyzer detected fluid or debris on the sensors before it should have. Possible causes include poor storage conditions (frozen), mishandling of cartridges (pressing on the center of the cartridge), or rerunning used cartridges.
22, 25	Cartridge Error Use Another Cartridge	This code occurs only for Celite ACT test if mixing of the reagent and sample is compromised. This may be caused by a clotted sample, and insufficient volume of sample, or air bubbles in the sample.
24	Cartridge Error Use Another Cartridge	Electrical resistance of calibrant fluid (Rcal) used to verify the electrolyte concentration is out of specification. May occur if calibrant pack was ruptured well before test allowing evaporation to result in a higher electrolyte concentration. Besides the electrolyte concentration, the Rcal is also affected by the temperature and the height and width of the fluid segment over the conductometric sensor. The analyzer accounts for the temperature, but the height and width of the fluid segment can vary from cartridge lot to cartridge lot. The analyzer has been programmed to compensate for these lot-to-lot differences by maintaining a running average of the Rcal values measured from the most recent cartridge runs. Occasionally, the difference between the Rcal values for two cartridge lots is large enough to cause the introduction of a new lot to trigger code 24 on the first few cartridge runs. The Code 24 errors should disappear as the running average adjusts. However, if code 24 persists after more than 3 cartridge runs on each analyzer, contact Abaxis Technical Support.
26	Cartridge Error Use Another Cartridge	This code occurs if there was a coagulation-specific quality check failure: premature substrate activation, abnormally low levels of substrate, or invalid fluid motion.
20, 27, 28, 29, 32, 33, 40, 41, 45, 87	Cartridge Error Use Another Cartridge	These codes identify problems such as calibrant fluid arriving at the sensors too soon, too late or not at all, or noise in calibrant fluid signals. Codes 20, 27, 41, and 87 can be caused by poor contact which can sometimes be corrected — if you have an External Simulator and Ceramic Conditioning Cartridge available, perform the "Pin Conditioning Procedure" described in "Pin Conditioning Using a Ceramic Conditioning Cartridge" on page A-10. Otherwise, contact Abaxis Technical Service. Codes 20, 27, and 33 may be observed after storing cartridges at room temperature for greater than 7 days. The rate of quality check code 45 can be elevated when cartridges are run without allowing sufficient time for the cartridges to equilibrate to room temperature. To minimize the number of codes, review i-STAT cartridge storage conditions and allow sufficient time for refrigerated cartridges to reach room temperature.

Code No	Displayed Message	Fundamention
31, 34, 44	Unable to Position Sample Use Another Cartridge	The analyzer did not detect movement of sample across the sensors. Possible causes include, not closing the snap securely
		after loading the sample, a clot in the sample, or an aberrant cartridge. Codes 31 and 34 may be observed after storing cartridges at room temperature for greater than 7 days.
35, 36	Sample Positioned Short of Fill Mark Use Another Cartridge	Cartridge was underfilled. The sample must reach the fill mark. Try another cartridge. Codes 35 and 36 may be observed after storing cartridges at room temperature for greater than 7 days.
30, 37	Sample Positioned Beyond Fill Mark Use Another Cartridge	Cartridge was overfilled. The sample was past the fill mark. Try another cartridge. Code 30 may be observed after storing cartridges at room temperature for greater than 7 days.
38, 39	Insufficient Sample Use Another Cartridge	Most likely due to insufficient sample left in the sample well but may also be caused by bubbles in the sample. Try another cartridge and ensure sufficient sample is in the sample well.
42, 43	Cartridge Error Use Another Cartridge	The conductometric sensor (code 42) or amperometric sensor (code 43) is out of specification. This could be caused by a pre- burst calibrant pack, dirty cartridge contact pads, or a dirty connector in the analyzer. Contact Abaxis Technical Service.
46	Cartridge Error Use Another Cartridge	The analyzer did not detect movement of sample across the sensors. This could be due to a clot in the sample, not closing the sample well closure on the cartridge, or an aberrant cartridge.
47	Cartridge Not Inserted Properly Reinsert Cartridge	The cartridge or Electronic Simulator may not be pushed all the way into the cartridge port. Reinsert the cartridge or Electronic Simulator. If the message continues to occur or if the user is certain that the cartridge or simulator is inserted correctly, the code may indicate an analyzer problem. Contact Abaxis Technical Service
48	Analyzer Error See Manual	This code indicates that the cartridge or Electronic Simulator may have been "cooked" when inserted into the cartridge port. Push the cartridge or Simulator straight through the cartridge port. If the problem persists, and the user is certain that the cartridge was inserted correctly, the code may indicate an analyzer problem. Contact Abaxis Technical Service.
49	Poor Contact Detected See Manual	The system detected a contact problem with one of the connector pins while reading the identification chip in the immunoassay cartridge. This can sometimes be corrected by performing the "Pin Conditioning Procedure" described in the user manual. If the problem persists, contact Abaxis Technical Service.
79–81	Cartridge Error Use Another Cartridge	Bad contact between thermal probes in the analyzer and the metallization on the back of the chips in the cartridge trigger these codes. This may be caused by poor metallization of the chips, dirt on the metallization, or bent or broken thermal probes in the analyzer. If problem persists, contact Abaxis Technical Service.

### A.4 Electronic/Mechanical Errors

The following error codes are related to electronic or mechanical problems in the VetScan i-STAT1.

Code No.	<b>Displayed Message</b> (listing cause and solution)	Explanation
50	Analyzer Error/Use Electronic Simulator	The motor has moved too far. Running a simulator may not detect this problem. Run the simulator (if available) and if the analyzer passes, run a cartridge to see if the code reoccurs. If not, continue to use the analyzer. If the code reoccurs, contact Abaxis Technical Support. If testing immunoassay cartridges on the analyzer, this code can be related to poor electrical connection between the analyzer and the cartridge. This can sometimes be corrected by performing the "Pin Conditioning Procedure" described on page A-10. Codes 126 and 128 are sometimes related to electrical connection as well. If you experience multiple occurrences of these 3 codes (50, 126, and 128) in a short period of time, consider returning the analyzer for servicing and replacement. The presence of sample bubbles when running immunoassay cartridges may, under some circumstances, also elicit this code.
51	Analyzer Error/Use Electronic Simulator	The motor moved for too long. Run a simulator if available. If the error occurred while running an ACT cartridge, also run a cartridge. If the code does not reoccur, continue using the analyzer. Under some conditions, a low battery will cause this error instead of code 1. Try fresh batteries. If the code reoccurs, contact Abaxis Technical Service.
52	Analyzer Error/Use Electronic Simulator	The motor stalled while moving. Run a simulator if available. If the error occurred while running an ACT cartridge, also run a cartridge. If the code does not reoccur, continue using the analyzer. If the code reoccurs, contact Abaxis Technical Service.
58–62	Analyzer Error/Use Electronic Simulator	The analyzer usually recovers from these error conditions. Check battery voltage and replace batteries if needed. If the code persists, contact Abaxis Technical Service.

Code No.	<b>Displayed Message</b> (listing cause and solution)	Explanation
23, 53, 55–57, 63, 65–68, 70, 72–74, 82, 85, 86, 89–94, 96, 97	Analyzer Error/See Manual	These are mechanical or electronic failure from which the analyzer may not be able to recover. Code 23 may be caused by poor contact between the analyzer pins and the cartridge chip. This can sometimes be correct by performing the "Pin Conditioning Procedure" described on page A-10. Codes 82 and 92 typically indicate a problem with the pressure transducers in the analyzers. If these codes persist, contact Abaxis Technical Support. The rate of quality check code 55 can be elevated when cartridges are run without allowing sufficient time for the cartridges to equilibrate to room temperature. To minimize the number of quality check codes, review the i- STAT cartridge storage conditions and allow sufficient time for refrigerated cartridges to equilibrate to room temperature. Code 56 occurs when the analyzer detects noise on the thermal circuit. The noise may be the result of electronic interference. If this code occurs, the analyzer should be moved to a different location away from potential sources of interference. If the code persists in the new area, the analyzer should be returned. Code 86 can occur when the analyzer is stored in an i-STAT Downloader/ Recharger without adequate ventilation. This problem can usually be resolved by moving the Donwnloader/Recharger to an open location which is free of obstructions and external heat source such as heater vents or other electronic equipment. If the code persists, or is occurring without a Downloader/Recharger, contact Abaxis Technical Service. For other codes, run the Electronic Simulator twice (if available) then run a cartridge with a sample. If the analyzer passes the simulator check and quality check does not reoccur with the sample run, continue to use the analyzer. If the analyzer does not pass the simulator check and/or a quality check does reoccur with the sample run, contact Abaxis Technical Service.

Code No.	Displayed Message (listing cause and solution)	Explanation
69	Cartridge Type Not Recognized/ Use Another Cartridge	This code could be due to a use of cartridge type that is not compatible with the version of software in the analyzer, or the used of expired cartridges. Check the cartridge expiration date on the cartridge box or pouch. If the cartridges have not expired, and if a new cartage type is being run, contact Abaxis Technical Support. When running ACT cartridge, code 69 may be caused by poor contact between the analyzer pins and the cartridge chip. This can sometimes be corrected by performing the "Pin Conditioning Procedure" described on page A-10. During immunoassay cartridge runs, this code will be displayed if incorrect information is entered in response to the prompt "Enter or Scan Cartridge Lot Number." The instrument expects the barcode on the back of the individual cartridge portion pack to be scanned. The correct barcode looks like this:
		entries of the cartridge lot number nor a scan of the barcode on the cartridge box. This condition may be due to an aberrant cartridge. However, if the condition occurs repeatedly on one analyzer, the analyzer may need repair. Contact Abaxis Technical Support.

#### A.5 Internal/External Simulator Errors

The following codes relate to using an Internal Simulator or External Simulator.

Code	Explanation	How to Respond
Numerical Code	See other tables in this appendix. See	other tables in this appendix.
L	Potentiometric channel out of limits. This code may occur if moisture collects on the contact pins inside the analyzer when the analyzer is subjected to ambient temperature change.	Allow the analyzer to equilibrate in the new area for at least 30 minutes then run another cartridge. If the error continues, the analyzer may need servicing.
G	Amperometric channel out of limits. This code can occur if the External Simulator is inserted at an angle.	Remove and reinsert the Simulator if applicable. If the code reoccurs, contact Abaxis Technical Service.
R, r	Resistance reading on conductometric channel out of limits.	Contact Abaxis Technical Service.
T, t	Thermal probe failure.	Contact Abaxis Technical Service.
В	Potentiometric channel out of limits.	Contact Abaxis Technical Service.

*Note:* Any time repetitive codes occur which cannot be addressed or corrected through training, contact Abaxis Technical Service.

#### A.6 Immuno Cartridge Errors

The following codes indicate a failure during an immuno cartridge cycle, such as with Cardiac Troponin I. In most cases, the cartridge is spent and another one must be used.

Code No.	<b>Displayed Message</b> (listing cause and solution)	Explanation
120, 121, 122, 124, 125, 133, 144, 148	Cartridge Error Use Another Cartridge	These codes indicate a problem with the movement of the analysis fluid during the cartridge run. Try another cartridge.
123	Cartridge Error Use Another Cartridge	The quality control during the cartridge run failed to verify the presence of active immuno reagents. Try another cartridge.
126	Cartridge Error Use Another Cartridge	The quality control during the cartridge run failed to verify the integrity of the analysis fluid. This code can be related to poor electrical connection between the analyzer and the cartridge. This can sometimes be corrected by performing the "Pin Conditioning Procedure" described in "Pin Conditioning Using a Ceramic Conditioning Cartridge" on page A-10. Otherwise, contact Abaxis Technical Service. Codes 50 and 128 are sometimes related to electrical connection as well. If you experience multiple occurrences of these 3 codes (50, 126 and 128) in a short period to f time, contact Abaxis Technical Service.
127	Cartridge Error Use Another Cartridge	A wet sensor was detected before the initial sample movement. Possible overfilled or used cartridge. Try another cartridge.

	Displayed Message	
Code No.	(listing cause and solution)	Explanation
128, 131, 132, 134–138	Cartridge Error/Use Another Cartridge	<ul> <li>These codes are most often related to poor filling of an immunoassay cartridge, the presence of sample bubbles or the abrupt insertion of a cartridge into the analyzer.</li> <li>Guidelines for proper filling: <ol> <li>Discard (always) 1 drop from delivery device to clear unseen bubbles.</li> <li>Hang single drop slightly larger than round target well.</li> <li>Touch one drop (only) to round target well allowing cartridge to draw sample in.</li> <li>Confirm sample volume lines up with top of RED FILL LINE diagram.</li> </ol> </li> <li>Guidelines for cartridge insertion: <ol> <li>After closing the cartridge, grasp the cartridge closure between your first finger and thumb. There is a recess for your thumb in the closure.</li> <li>Guide the cartridge into the analyzer gently, until a soft click is heard.</li> </ol> </li> </ul>
129, 142, 143	Cartridge Error Use Another Cartridge	Analyzer detected that analysis fluid has been mixed with sample. Try another cartridge.
130	Cartridge Error Use Another Cartridge	Analyzer detected an air bubble in sample segment. Try another cartridge.
140	Lot Expired	The analyzer detected an expired cartridge lot. Check expiration date. Try another cartridge that is not yet expired.
141	Test Cancelled by Operator	This code will be displayed if the cartridge barcode is not scanned by operator within 60 seconds of cartridge insertion. Correct bar code to scan is located on cartridge portion pack, not cartridge box. An example of the portion pack barcode is found in the table listing for code 69 above.
145	Cartridge Error Use Another Cartridge	Analyzer failed to detect fluid. This may be caused by a cartridge leak, failure to close cartridge completely, or cartridge underfill. Ensure that the slide cover is fully engaged before inserting the cartridge into the analyzer. Do not try to inject the sample into the cartridge. Once a single drop of sample is touched to the target well, immunoassay cartridges will fill automatically by wicking the sample at a fixed speed. Trying to inject the sample into the cartridge or adding more sample to the target well will not make the cartridge fill faster. Wait for the sample to reach the "Fill to" mark, then close the cartridge.
146	Cartridge Error Use Another Cartridge	Overfilled cartridge. Try another cartridge.
147	Analyzer Error See Manual	Analyzer is not customized to run immunoassay cartridges. See "Customizing the Analyzer" on page 3-6.
149, 150, 151	Cartridge Error Use Another Cartridge	The analyzer detected an atypical data stream from the cartridge. Try another cartridge.

#### A.7 Pin Conditioning Using a Ceramic Conditioning Cartridge

If an Electronic Simulator (PN 600-0002) and a Ceramic Conditioning Cartridge (CCC, PN 600-0003) are available, the procedure below can be used to clean the analyzer's electronic sensors. If these parts are not available, contact Abaxis Technical Service.

1. Run the external Electronic Simulator.

If the analyzer is configured with the internal Electronic Simulator enabled, run an external Electronic Simulator. Running the external Electronic Simulator ensures the Internal Simulator cycle will not execute during the pin conditioning process, which could lead to the premature termination of the process.

2. Run the CCC two times.

Initiate the CCC cycle as you would initiate an external Electronic Simulator cycle. The instrument will identify the CCC as an external Electronic Simulator and display a Simulator Failure Code (i.e. rRGL) when the cycle is complete. Disregard the code, as this is expected behavior.

3. Return the analyzer to service.

# Appendix B

## Interferences and Clinical Significances

This appendix outlines known interferents that can affect the results for analytes measured by various VetScan i-STAT 1 Cartridges. Depending on the concentration within the sample, the interferent can either increase or decrease the value of the result as shown in the table below.

#### **B.1 Interferents and Factors that Affect Results**

The table below lists interferences and other factors that can affect measured analytes, causing false increases, false decreases, "star-outs" (suppressed results), or other errors.

#### WARNING: THIS TABLE IS FOR VETERINARY USE ONLY.

Analyte	Causes of False Increase	Causes of False Decrease	Causes of Star-Outs or Other Errors
Sodium	Sodium heparin anticoagulant	β-hydroxybutyrate	Hemodilution of > 20% by use of plasma expanders or other solutions that do not match the ionic characteristics of plasma may cause significant errors.
	Bromide	Lactate	
Potassium	Use of K <sub>3</sub> EDTA anticoagulant	Excess heparin in syringe	
	Clotting (platelets release potassium)		
	Traumatic venipuncture		
	Prolonged delay prior to testing		
Chloride	Excess heparin in syringe		Thiocyanate (degradation product of nitroprusside treatment or thiosulphate treatment of cyanide poisoning).
	β-hydroxybutyrate		Hemodilution of > 20% by use of plasma expanders or other solutions that do not match the ionic characteristics of plasma may cause significant errors.
	Bromide		
	Salicylate		
	Lactate		
BUN		Excess heparin in syringe	
		Thiocyanate (degradation product of nitroprusside treatment of thiosulphate treatment of cyanide poisoning)	
Glucose	pH > 7.4	Prolonged delay in testing (cells consume glucose)	
	Hydroxyurea	Excess heparin in syringe	
	<b>WARNING:</b> Testing should be performed using an alternative method if Hydroxyurea has been administered.		
		Bromide	
		$PO_2 < 20 \text{mmHg}$	
		Thiocyanate (degradation product of nitroprusside treatment or thiosulphate treatment of cyanide poisoning)	
		pH < 7.4	

Analyte	Causes of False Increase	Causes of False Decrease	Causes of Star-Outs or Other Errors
Ionized Calcium	Frozen cartridges	Hemolysis	Hemodilution of > 20% by use of plasma expanders or other solutions that do not match the ionic characteristics of plasma may cause significant errors.
	Prolonged use of tourniquet (> 1 minute) causes localized stasis, localized lactate production, and acidosis-increases ionized fraction of calcium	EDTA or oxalate anticoagulant	
	Magnesium	β-hydroxybutyrate	
	Aged samples (decreased pH, increased ionized fraction of calcium)	Lactate	
		Salicylate	
		Prolonged exposure of sample to air (causes loss of $CO_2$ , increase pH, decreases ionized fraction of calcium)	
		Excess heparin in syringe; administration of heparin	
Hematocrit	Improper mixing of sample	Improper mixing of sample	Electrolyte concentration in sample is used to correct measured conductivity prior to reporting HCT results. Therefore, factors affecting sodium will also affect HCT.
	Abnormally high lipemia (effect is minimal)	Contamination with flush solution when sample is drawn from IV catheter	
	Extremely high total protein (effect is minimal)		
	Marked leukocytosis	Extremely low total protein (effect is minimal)	
	Oxyglobin > 5.2 g/dl	Serum or plasma used	
рН	Prolonged exposure to air (causes drop in $PCO_2$ and subsequent rise in pH)	Prolonged use of tourniquet (> 1 minute) causes localized stasis, localized lactate production and acidosis	Hemodilution of $> 20\%$ by use of plasma expanders or other solutions that do not match the ionic characteristics of plasma may cause significant errors.
		Prolonged delay in testing (pH decreases at a rate of 0.03 units/ hour)	

Analyte	Causes of False Increase	Causes of False Decrease	Causes of Star-Outs or Other Errors
PCO <sub>2</sub>	Prolonged delay in testing	Exposure to air prior to testing	For patients administered propofol or thiopental sodium, i-STAT recommends the use of CG4+, CG8+, and EG7+ cartridges, which are free from clinically significant interference at all relevant therapeutic doses. i-STAT does not recommend the use of EC8+ cartridges for patients receiving propofol or thiopental sodium.
	Cartridge exposed to high humidity before testing		
<b>P</b> O <sub>2</sub>	Iced sample	Venous blood	
		Prolonged exposure to air	
		Cartridges not warmed to room temperature	
		Delay before testing ( <b>P</b> O <sub>2</sub> decreases at a rate of 2–6 mmHg/hour)	
Lactate	Delay in testing (lactate increases by as much as 70% within 30 minutes as a result of glycolysis)	Bromide	Hydroxyurea WARNING: Testing should be performed using an alternative method if Hydroxyurea has been administered.
	Glycolic acid (a product of ethylene glycol metabolism)	Cysteine	
	Use of tourniquet during venipuncture		
	N-acetylcysteine		
Creatinine	atinine $PCO_2$ has a variable effect on creatinine measurement. When $PCO_2$ values are above 40, creatinine values < 2 mg/dl are increased by 6.9% for every 10 mmHg CO <sub>2</sub> . When $PCO_2$ values are below 40, creatining values > 2 mg/dl are increased 3.7% for every 10 mmHg CO <sub>2</sub> .		Hydroxyurea WARNING: Testing should be performed using an alternative method if Hydroxyurea has been administered.
	Ascorbate		
	Creatine		
	Bromide		
	N-acetylcysteine		

Analyte	Causes of False Increase	Causes of False Decrease	Causes of Star-Outs or Other Errors
Celite ACT	Collection into anticoagulant or use of anticoagulant tubes		Hemodilution may affect results.
	Collection from improperly flushed catheters		Platelet Dysfunction may affect results
	Collection into plastic tubes		Aprotinin
			<b>WARNING:</b> Testing should be performed using an alternate method if Aprotinin has been administered.
	Traumatic venipuncture	Traumatic venipuncture	
	Analyzer not held level during analysis (may falsely increase ACT results by > 10%)	Analyzer not held level during analysis (may falsely increase ACT results by > 10%)	
	Low calcium concentration — significant prolongation of ACT observed at ionized calcium concentrations < 0.4 mM		

### **B.2** Clinical Significance

The following table lists possible clinical significances of the presence of various analytes.

#### WARNING: THIS TABLE IS FOR VETERINARY USE ONLY.

*Note:* This list is not intended to be complete, but only to provide examples of possible clinical causes of abnormal values in results.

Analyte	Clinical Significance
Sodium	<ul> <li>Hypernatremia</li> <li>Dehydration</li> <li>CNS diseases</li> <li>Salt poisoning</li> <li>Hyperaldosteronism</li> <li>Hyponatremia</li> <li>Burns</li> <li>Overhydration</li> <li>Sodium loss via the gastrointestinal tract or kidneys</li> <li>Hypoadrenocorticism</li> </ul>
Potassium	<ul> <li>Hyperkalemia</li> <li>Renal failure</li> <li>Post-renal obstruction</li> <li>Hypoadrenocorticisim</li> <li>Hypokalemia</li> <li>Gastrointestinal loss</li> <li>Renal loss</li> <li>Insulin therapy</li> </ul>
Chloride	<ul> <li>Hyperchloremia</li> <li>Fluid loss</li> <li>Bicarbonate loss</li> <li>Hypochloremia</li> <li>Vomiting</li> <li>Upper gastrointestinal obstruction</li> <li>Excessive diuretic therapy</li> </ul>
BUN	Azotemia • Pre-renal • Renal disease • Post-renal • Gastrointestinal bleeding Low BUN • End-stage hepatic failure
PO <sub>2</sub> sO <sub>2</sub>	<ul> <li>Decreased PO<sub>2</sub></li> <li>Decreased pulmonary ventilation (e.g., airway obstruction or brain trauma)</li> <li>Impaired gas exchange (e.g., pneumonia, pulmonary edema)</li> <li>Alterations in the flow of blood within the heart or lungs (e.g., congenital venous shunting)</li> <li>Increased PO<sub>2</sub></li> <li>Patient receiving O<sub>2</sub></li> </ul>

Analyte	Clinical Significance
PCO <sub>2</sub> HCO <sub>3</sub> TCO <sub>2</sub>	Respiratory acidosis         ● Pulmonary disease         ● Hypoventilation         Respiratory alkalosis         ● Hyperventilation         Metabolic acidosis         ● Production of organic acids (lactate or ketones)         ● Loss of HCO <sub>3</sub> (retention of H ions [renal failure] or diarrhea)         ● Ethylene glycol toxicity         Metabolic alkalosis         ● Chronic vomiting         ● Sequestration of gastric acids due to obstruction
Anion Gap	<ul> <li>Anion gap elevation</li> <li>Lactic acidosis</li> <li>Ketoacidosis</li> <li>Ethylene glycol toxicity</li> <li>Uremia</li> </ul>
Lactate	<ul> <li>Elevated</li> <li>Shock</li> <li>Excessive exercise in performance equines</li> <li>Localized hypoperfusion (i.e., colic, gastric dilatation/volvulus)</li> <li>Lactate is also useful as a prognostic indicator; the higher the lactate level, the poorer the prognosis</li> </ul>
Creatinine	Elevated <ul> <li>Renal disease</li> <li>Post-renal obstruction/rupture</li> </ul>
ACT	Evaluation of ability of patients' blood to coagulate.
Glucose	<ul> <li>Hyperglycemia</li> <li>Diabetes mellitus</li> <li>Hyperadrenocorticisim or steroid administration</li> <li>IV glucose administration</li> <li>Pseudohyperglycemia: non-fasted sample; physiologic (i.e., "stress") response in felines</li> <li>Hypoglycemia</li> <li>Insulin overdose or hyperinsulinemia</li> <li>Hepatic failure</li> <li>Starvation</li> <li>Septicemia</li> <li>Pseudohypoglycemia: delay in sample processing</li> </ul>

Analyte	Clinical Significance
Hematocrit	Polycythemia
Hemoglobin	• Dehydration
-	• Splenic contraction
	• Cardiopulmonary disease
	• Neoplasia
	Anemia
	Blood loss
	• Hemolysis
	• Iron deficiency
	• Bone marrow depression
	Chronic disease
Ionized Calcium	Hypercalcemia
	• Neoplasia
	• Parathyroid disease
	Cholecaliciferol rodenticide intoxication
	Hypocalcemia
	• Parathyroid disease
	• Renal disease
	• Eclampsia
	• Milk fever
	• Ethylene glycol toxicity
	• Pancreatitis
	<ul> <li>Pseudohypocalcemia: collection into EDTA</li> </ul>
рН	pH is an index of the acidity or alkalinity of the blood with a decrease pH indicat- ing an acidemia and an increased pH indicating alkalemia. pH should be inter- preted in light of bicarbonate levels and $PCO_2$ to determine if the acidemia/ alkalemia is of respiratory, metabolic, or mixed origin.

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