VetScan®
i-STAT®1
User Guide
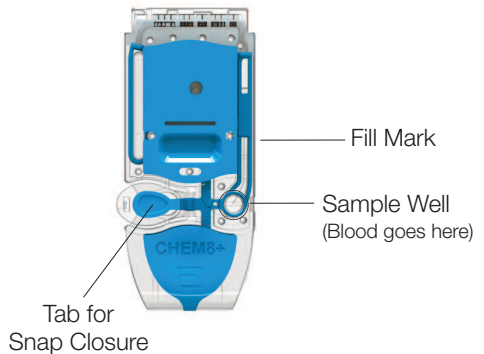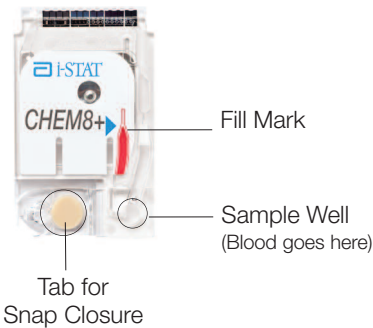
The device display shows:

```
        Pt:12345
    17:22  10JUL99
     i-STAT CG8+

        37.0°C
pH              7.453
PCO2 mmHg       24.1
PO2 mmHg         150

BEecf mmol/L      -7
HCO3 mmol/L     16.9
TCO2 mmol/L       18
sO2 %             99


      ➡ Page
```

Table of Contents

VetScan i-STAT 1
Features

Infrared Communication Window

Battery Compartment

Laser Barcode Scanner Window

Display

Scan Key

Clear Key

Page Key

Numeric Keys (0-9)

Enter Key

Backlight and 0 Key

ON/OFF Key

Menu Key

Print Key

Cartridge Port

Cartridge
Features

Fill Mark

Sample Well
(Blood goes here)

Tab for Snap Closure

Fill Mark

Sample Well
(Blood goes here)

Tab for Snap Closure

Overview of the VetScan i-STAT 1 System

The VetScan i-STAT 1 System incorporates a comprehensive group of components needed to perform blood analysis. A portable handheld analyzer, a cartridge with the required tests, and 1 to 3 drops of blood will allow the veterinarian to view quantitative results for tests commonly needed. A portable printer allows test records to be printed.

To perform a test, the operator fills a cartridge with sample, seals the cartridge with its closure, and inserts the cartridge into the analyzer. The cartridge contains all components to perform the tests. The analyzer automatically controls all steps in the testing cycle including: fluid movement, reagent mixing, calibration and temperature control. Quality checks are performed continuously throughout the testing cycle. Operator, patient identification and other patient information can be entered into the test record. When the test cycle is complete, results are displayed and the test record is stored. This degree of automation, along with the ability to test whole blood, eliminates many sources of error as well as time- consuming and costly steps inherent in other methods.
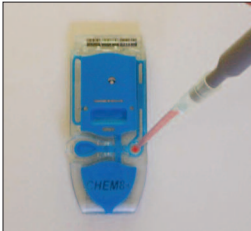
Fill and seal cartridge with patient sample.

Insert into analyzer.
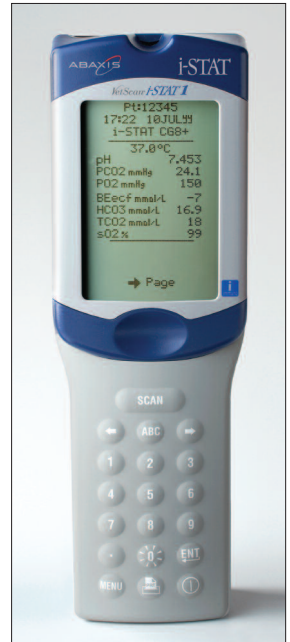
Read Results.

Note Regarding System Reliability: The VetScan i-STAT System automatically runs a comprehensive set of quality checks of analyzer and cartridge performance each time a sample is tested. This internal quality system will suppress results if the analyzer or cartridge does not meet certain internal specifications. To minimize the probability of delivering a result with medically significant error, the internal specifications are very stringent. It is typical for the system to suppress a very small percentage of results in normal operation given the stringency of these specifications. If, however, the analyzer or cartridges have been compromised, results may be persistently suppressed, and one or the other must be replaced to restore normal operating conditions. **Where unavailability of results while awaiting replacement of analyzer or cartridges is unacceptable, Abaxis recommends maintaining both a backup VetScan i-STAT 1 Analyzer and cartridges from an alternate lot number.**

⚠ **Precautions**

Potential Sources of Error in Patient Results	Incorrect cartridge storage. Cartridges should be stored at 2-8 ˚C (35 to 46 ˚F).
	Incorrect sample collection and/or sample handling: • For all cartridges except ACT, test only fresh whole blood samples collected in tubes with lithium or sodium heparin anticoagulant. • For ACT testing, use only fresh whole blood samples collected in plastic syringes or evacuated tubes with no anticoagulants, activators or serum separators. • When measuring TCO_2, fill tubes to capacity. Do not use "short fill" tubes. • When measuring TCO_2, test samples within 10 minutes of collection. When measuring $\mathbf{P}O_2$, test samples within 10 minutes of collection if stored anaerobically. Otherwise, run immediately. When measuring Lactate, test samples immediately. • Any deviations will cause inaccurate results.
	Use of expired cartridges
	If the pouch/portion pack has been punctured, the cartridge should not be used.
	DO NOT OPEN THE ANALYZER or any other VetScan i-STAT product, or perform any unauthorized procedures. Opening a VetScan i-STAT product, including the analyzer, Electronic Simulator, printer, or communication device, in an attempt to repair it or resolve a problem, may cause erroneous results and invalidate your warranty. If the troubleshooting procedures found in this guide or requested by Abaxis Technical Service do not resolve the problem, the product must be returned for repair.
	The use of other software that was not provided as part of the System on the same PC with the Central Data Station software may compromise the System, including permanent loss of patient records.
Potential Sources of Harm to the Operator	To protect yourself and others from infection: Do not perform blood or control fluid testing in areas where food and drink are stored or consumed. Wash hands after handling blood or blood soiled items. Do not use a cartridge if blood is spilled on it. Discard contaminated (blood soiled) items in a biohazard waste container. Decontaminate analyzer or work surface if blood is spilled on it. Since blood spots may not be noticeable on the analyzer and since a cartridge could contaminate the inside of the analyzer, treat the analyzer as capable of transmitting infection.

⚠️ **Precautions**

Potential Sources of Harm to the Operator (continued)	A falling or dropped analyzer. Place analyzer and peripherals on a stable surface.
	Barcode scanner: Do not look into laser beam coming from scanner, or point into eyes of someone else.
	Needles: take care to prevent needle sticks. Use safety tips when transferring sample from a blood collection tube to a cartridge.
	Analyzer and peripherals are not suitable for use in an oxygen enriched atmosphere.
Potential Sources of Damage to the Analyzer	Do not attempt to remove a cartridge during the testing cycle. The force necessary to do so could damage the analyzer. The message "Cartridge Locked" will remain on the screen until the analyzer unlocks the cartridge.
	The analyzer may be rendered inoperative by damage due to mishandling, such as dropping, by exhausting the batteries, or by other causes.
	The analyzer will continue to initialize test cycles when the analyzer is customized to warn, but not block testing when a scheduled external Electronic Simulator is missed, when a FAIL result for the external Electronic Simulator test is ignored, and when the analyzer fails the internal Electronic Simulator test and the lockout feature is not enabled.
	Dispose of analyzer, peripheral electronics, and batteries according to local, state, and/or national guidelines.
	If the analyzer is not to be used for an extended period of time, the batteries should be removed to prevent leakage.
	Allow analyzer to equilibrate to ambient temperature if transported from a location at a significantly different temperature.
	Do not store analyzer in a location that may raise its temperature.

Prepare the Analyzer

Caution: New analyzers or analyzers that have been repaired and returned or replaced will have standard CLEW and application software. If a different CLEW and/or application software is in use in your facility, it must be installed in new, repaired, or replaced analyzers before they are put into use. Check the analyzer Status Page for the installed CLEW and application software.

Before using the analyzer, complete these simple procedures:
- Install/change the batteries
- Check/change the analyzer's date and time
- Check the analyzer's software and status

Install/Change Batteries

The analyzer requires two 9-volt lithium batteries. Before using a new analyzer, or when battery replacement is indicated, install batteries as follows:

1. Slide the battery compartment door off.

2. Tilt the analyzer to slide out the battery carrier.

3. Locate two (2) 9 volt lithium batteries. Insert a battery into each side of battery carrier, matching + and - marks on batteries to the + and - marks on battery carrier.

4. Slide battery carrier into the analyzer as shown (Label facing up).

5. Slide battery door back into place.

Note:

Two 9 volt lithium batteries will provide power for approximately 400 chemistry cartridges. The analyzer will display a "BATTERY LOW" message when the On/Off key is pressed, and a flashing battery icon will appear when battery replacement is needed. Stored results are not lost when batteries are fully discharged or removed. Stored results and clock settings are maintained by an internal lithium battery that should last for seven years.
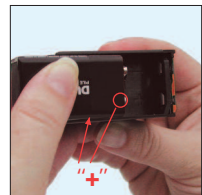
Check/Change Date and Time

1. Press ⏻ to turn on analyzer

2. Press MENU to change screen to Administration Menu

3. Press 5 (Set Clock)

4. Press ENT (No password is required)

5. Use ← or → to move the cursor to a digit if it

   needs to be changed. Use number keys to change digit.

   Note: Analyzer uses a 24 hour clock.
   Therefore, 1:00 PM is displayed as 13:00.

6. Press ENT to accept changes, or MENU to cancel changes.

> 13:26 18JUNyy
> Administration Menu
> 1 - Analyzer Status
> 2 - Data Review
> 3 - Quality Tests
> 4 - Customization
> 5 - Set Clock
> 6 - Transmit Data
> 7 - Utility

> Enter Current
> Time And Date
>
> 13:36
> 06/18/13
> mm/dd/yy
>
> ENTER - Set And Exit
> MENU - Cancel

Check Software and Status

1. From the Administration Menu, press 1
   (Analyzer Status)

2. Check that software (CLEW & Version) in the
   Analyzer is up to date.

> 15:26 18JUNyy
> Administration Menu
> 1 - Analyzer Status
> 2 - Data Review
> 3 - Quality Tests
> 4 - Customization
> 5 - Set Clock
> 6 - Transmit Data
> 7 - Utility

> Analyzer Status
> Temp: 27.1˚C
> Pressure: 761mmHg
> Battery: 8.54V
> Uses: 100
> Serial: 30144-B
> CLEW: A12
> Version: JAMS121B
> Custom: Default0
>
> Stored Records
> Total: 1
> Unsent: 1

Temp: Analyzer's reading of room temperature.
Analyzer will function between 16-30˚C.

Pressure: Analyzer's reading of barometric pressure.
Analyzer will function between 300-1000mmHg.

Battery: Analyzer's reading of battery voltage.

Uses: Total number of cartridge runs on analyzer.

Serial: Serial number of analyzer.

CLEW: Standardization software installed on analyzer.
Maintains accuracy of tests.

Version: Application software installed on analyzer.
Directs functions.

Custom: Name of customization profile in analyzer.
Default0 indicates default settings. Analyzer can be
customized for certain site-specific and cartridge
testing characteristics.

Analyzer Customization Options

Setting Units

New analyzers or analyzers that have been repaired and returned or replaced will have standard unit sets installed. If a different unit of measurement for a particular analyte is in use in your facility, follow these instructions to change the unit in question:

1. Press ⏻ to turn on the analyzer.

2. Press (MENU) to change screen to the Administration Menu.

3. Press 4 (Customization).

4. Press 2 (Change).

5. Press (ENT) (No password is required).

6. Press 5 (Results).

7. Press 1 (Units and Ranges).

8. Press the number key corresponding to the analyte you wish to change units for. Press ➡ key to see additional analytes if the analyte you wish to change is not on the screen.

9. Press 2 (Enabled).

10. Press the number key corresponding to the units in which you would like the analyte reported.

11. Once all analytes are set to the units you wish to report, press (MENU) twice to return to the Main Menu.

15:26 18JUNyy
Administration Menu
1 - Analyzer Status
2 - Data Review
3 - Quality Tests
4 - Customization

Customization
Default0
1 – View
2 – Change

Change
Customization
Default0
1 – Analyzer
2 – ID Entry
3 – Patient Tests
4 – QC Tests
5 – Results

Change
Customization
Results
1. Units and ranges
2. Options

Results
Units and Ranges
1 Cl mmol/L
   Ref 98/109
2 K mmol/L
   Ref 3.5/4.9

Change
Customization
Cl
1. Disabled
2. Enabled

Change
Customization
Cl
1. mmol/L
2. mEq/L

Cartridge Testing

Cartridge use requires operators to turn on the analyzer, enter an Operator ID and Patient ID, and then scan the cartridge lot number before inserting a cartridge into the analyzer for testing. To customize the analyzer:

1. Press (I) to turn on the analyzer.

2. Press MENU to change screen to Administration Menu.

3. Press 4 (Customization).

4. Press 2 (Change).

5. Press ENT (No password is required).

6. Press 3 (Patient Tests).

7. Press 2 (Cartridge Information).

8. Press 2 to change setting to "Required".

9. Press 4 (Cartridge Lot Number).

10. Press 2 to change setting to "Required".

11. Both "Cartridge Information" and "Cartridge Lot Number" should be now appear on display as "Required".

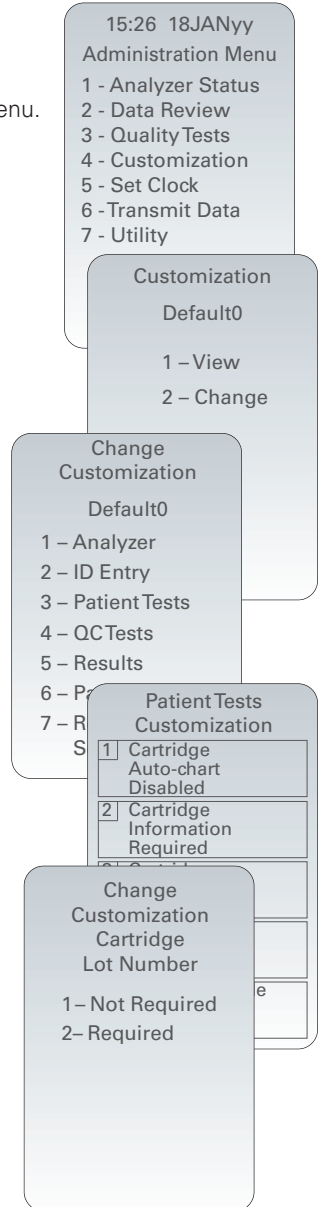12. Press (I) to turn analyzer off and save the settings. (If settings are not shown as "Required", return to Step 7).

15:26 18JANyy
Administration Menu
1 - Analyzer Status
2 - Data Review
3 - Quality Tests
4 - Customization
5 - Set Clock
6 - Transmit Data
7 - Utility

Customization
Default0
1 – View
2 – Change

Change Customization
Default0
1 – Analyzer
2 – ID Entry
3 – Patient Tests
4 – QC Tests
5 – Results
6 – P
7 – R
S

Patient Tests Customization
1 Cartridge Auto-chart Disabled
2 Cartridge Information Required

Change Customization
Cartridge Lot Number
1 – Not Required
2 – Required

Hematocrit Options

Selection of K$_2$EDTA or K$_3$EDTA Hematocrit Customization

The reference method for hematocrit is the microhematocrit (MH) method. All instruments measuring hematocrit are expected to be traceable, or calibrated, to this reference method.

The VetScan i-STAT System provides two customization settings for reporting hematocrit results. The "K$_3$EDTA" customization is the default analyzer setting and it reports hematocrit results traceable to MH-K$_3$EDTA. The "K$_2$EDTA" customization reports hematocrit results traceable to MH-K$_2$EDTA.

For best agreement of the VetScan i-STAT1 and hematology analyzer results, the VetScan i-STAT1 customization setting is selected according to the calibration of the comparative hematology analyzer (MH-K$_3$EDTA or MH-K$_2$EDTA) currently in use at the facility and not the type of EDTA anticoagulant in the collection tube used to draw samples for the hematology analyzer.

Instructions for Customizing the VetScan i-STAT 1 Analyzer for Hematocrit Options

1. Press ⏻ to turn on the analyzer.

2. Press MENU to change screen to the Administration Menu.

3. Press **4** (Customization).

4. Press **2** (Change).

5. Press ENT (No password is required).

6. Press **5** (Results).

7. Press **2** (Options).

8. Press **3** (Hematocrit).

9. Press the number key corresponding to the desired CPB customization setting.
    - 1 – Prompt CPB (Default setting)
    - 2 – CPB Always
    - 3 – CPB Never

10. Press the number key corresponding to the desired hematocrit EDTA customization setting.
    - 1 – K3 EDTA
    - 2 – K2 EDTA

11. Press MENU twice to return to the Main Menu.

Change
Customization
Results

1. Units and ranges

2. Options

Results
Customization

1 Decimal Separator (.) Period

2 Test Selection Disabled

3 Hematocrit
CPB Always
K3 EDTA

Change
Customization
Hematocrit

1. Prompt CPB

2. CPB Always

3. CPB Never

Change
Customization
Hematocrit

1– K3 EDTA

2– K2 EDTA
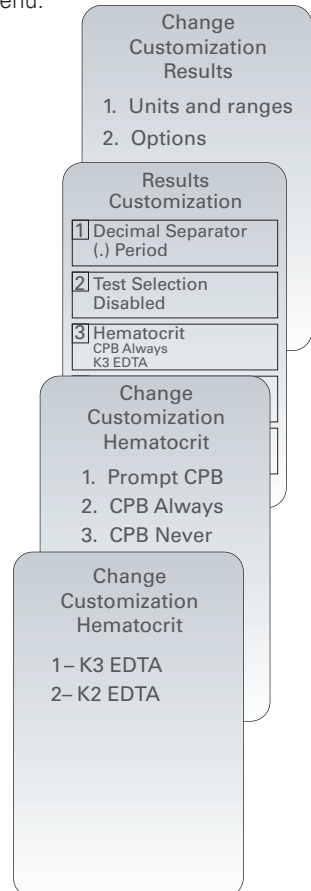
Shipments and Storage of Cartridges

Required procedures for cartridge storage:

Refrigerated Storage

Store cartridges at 2 to 8˚C (35 to 46˚F).

- Refrigerated cartridges may be used until date shown on cartridge box and pouch.
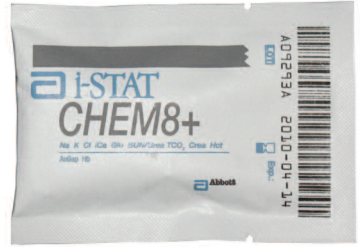
Room Temperature Storage

- Refer to the cartridge box for room temperature storage requirements.
- Read date on the pouch label. Do not use the cartridge if this date has passed.

Using a Cartridge for Patient Tests

- Prior to using a cartridge, it must be removed from refrigerated storage and **kept at room temperature in its protective pouch for at least 5 minutes.** An entire box of cartridges should be kept at room temperature for 1 hour before use.

- A cartridge must be used immediately after removing it from its protective pouch. Do not remove it until you reach the appropriate step in the patient testing process.

Removing a Cartridge from the Protective Pouch

Tear open cartridge pouch at notch.
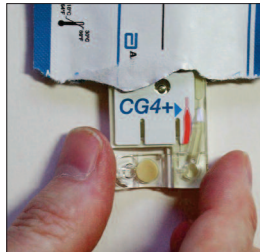
Remove cartridge from pouch. Always hold by sides.

Place on level surface. A level surface includes running the analyzer in the downloader/recharger.

Perform a Patient Test

CG4+, CG8+, G, Crea, E3+, 6+, CHEM8+, EC8+, or ACT Celite cartridges

To perform a patient test you will need:

- VetScan i-STAT 1 Analyzer

- Blood sample in green top tube, or arterial blood sample in syringe *(except for ACT tests)*

- For ACT testing: blood sample in plain, plastic syringe or plastic evacuated tube with no anticoagulant, activators, or serum separators

- Sample transfer device

- i-STAT cartridge

- Gauze

Collect the Sample

Correct sample collection & handling are important for accurate results!

For Venous Samples (except for ACT testing):

- Use a blood collection tube containing lithium or sodium heparin.

- Use an appropriate size gauge needle.

- If alcohol is used to clean the site, allow it to air dry before performing venipuncture.

- Fill blood collection tube to capacity. Gently invert tube about 10 times.

- Perform a new venipuncture if blood does not flow freely into collection tube.

- If testing for lactate, test immediately after sample collection. Test CHEM8+, CG8+, CG4+ and EC8+ cartridges within 10 minutes of sample collection. For other cartridges, test within 30 minutes of sample collection.

For Arterial Samples (except for ACT testing):

- Arterial samples should be collected by personnel trained on proper procedures. Collect from an arterial puncture, skin puncture, arterial cannulation or arterial line.

- Wait at least 20 to 30 minutes after changing FIO2 before taking a blood sample.

- Use plain plastic syringe if testing can be performed immediately. Otherwise, use syringe with dry (lyophilized) heparin labeled for tests to be performed. For measuring ionized calcium, syringe must be labeled for this test or labeled as containing balanced heparin.

- Fill a heparinized syringe to the capacity recommended in the labeling.

- After sample collection, remove the needle and place cap on syringe.

- Do not place filled syringe in ice water.

- Perform the test within 10 minutes of sample collection. If testing for lactate, test immediately after sample collection.

Collect the Sample (continued)

For Venous or Arterial Samples for ACT Testing:

• Use a plain, plastic syringe or plastic evacuated tube with no anticoagulant, activators, or serum separator. Test must be performed immediately upon sample collection.

Prepare the Analyzer

1. Press ⏻ to turn on analyzer.

2. Press ②

3. Follow analyzer prompts:

   Note: If you make a mistake, press left arrow key to clear entry

   a. Scan or manually enter your operator ID as prompted.   Press **ENT**

   (or press the ENT button to bypass this prompt)

   b. Scan or manually enter the patient ID as prompted.   Press **ENT**

   (or press the ENT button to bypass this prompt)

   c. Scan the lot number on the cartridge pouch. Position barcode 3-9 inches from scanner window on the analyzer. Press and hold **SCAN** to activate the scanner. Align the red laser light so it covers the entire barcode. The analyzer will beep when it reads the barcode successfully.

Prepare the Venous Sample and Cartridge

1. Remove cartridge from pouch.

2. Gently invert tube of blood 2–3 times. Proceed to next step without delay.
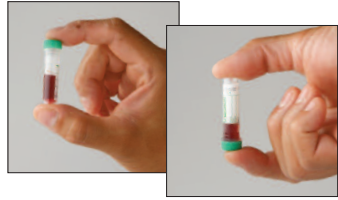
3. Remove stopper or cap from tube and insert pipette end below meniscus level. Draw sample into pipette.

   Note: An air bubble near tip of pipette must be removed - see step 4. If air bubbles are mixed with the blood sample, use another pipette. DO NOT put blood back into tube.

4. Hold pipette so tip is pointing upward. Hold gauze pad at tip to absorb blood. Press pipette plunger slowly until air is removed. If air bubble is stuck, tap pipette gently. If an air bubble was trapped at top of pipette it may start to move toward tip. In this case, wait until bubble reaches tip and remove it.

Prepare the Arterial Sample and Cartridge

1. Remove cartridge from pouch.

2. If sample has been collected in a syringe without anticoagulant, proceed to step 4 immediately.

3. Samples collected in syringes with anticoagulant must be **well mixed**. Briskly roll the syringe back and forth between the palms for 5 seconds in each of three different directions.

4. Remove cap from syringe and dispense a few drops of blood onto a gauze pad. Proceed **immediately** to "Fill and Insert the Cartridge".

Fill and Insert the Cartridge

1. Hold syringe tip directly over sample well of cartridge and gently press plunger to deliver blood into cartridge.

   When blood reaches fill mark on cartridge, stop adding blood. Some blood must be in sample well – add blood to well if necessary. Put cap back on syringe (arterial samples).
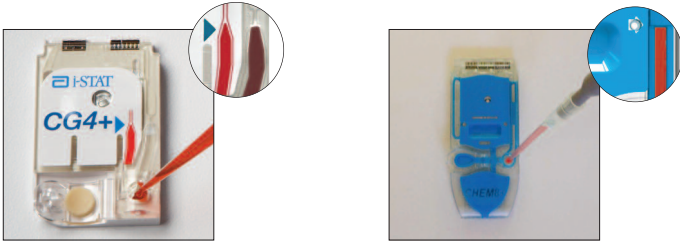
2. Pressing on tab, fold snap closure over sample well until it clicks into place. **DO NOT press directly over sample well.** Slightly lift finger and ensure cartridge is closed before completely removing finger from closure.
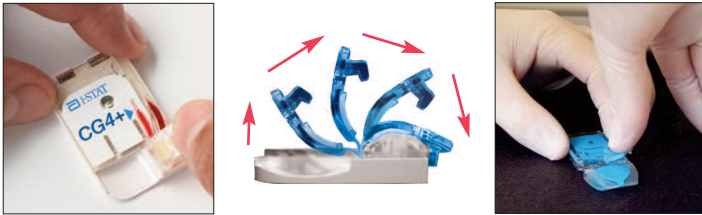
3. Push cartridge into analyzer port as shown until cartridge clicks into place. The analyzer will first display "Identifying Cartridge", then a time-to-result bar. Results will be shown in 2 to 3 minutes.

   For ACT and hematocrit testing, keep the analyzer on a level surface with the display facing up during testing. A level surface includes running the analyzer in the downloader/recharger.

   DO NOT remove cartridge until the "Cartridge Locked" message is removed and results are displayed on screen.

4. When results are shown, the cartridge may be removed and discarded with other test materials.

Perform a Patient Test

Cardiac Troponin I cartridges

To perform a patient test you will need:

- VetScan i-STAT 1 Analyzer
- i-STAT cTnI cartridge
- Heparinized whole blood or plasma sample collected in green top tube or syringe containing lithium or sodium heparin
- Gauze
- 1 cc syringe with safety tip (for sample transfer from tubes)

Collect the Sample

Correct sample collection & handling are important for accurate results!

- Use a plastic blood collection tube containing lithium or sodium heparin.
- Use an appropriate size gauge needle.
- If alcohol is used to clean the site, allow it to air dry before performing venipuncture.
- Fill collection tube to capacity and gently invert tube about 10 times.
- Do not test a sample from a traumatic draw.
- The use of whole blood or plasma samples containing EDTA, oxalate, and citrate will result in decreased cTnI readings.

Prepare the Analyzer and Remove Cartridge from Pack

1. Press ⏻ to turn on the analyzer.

2. Press ② to select "i-STAT Cartridge"

3. Following prompts on screen, use number keys to enter an Operator and Patient ID. Press **ENT** when each ID number is complete. If ID numbers are not required, just press **ENT** to continue.

   Note: Press ⬅ to clear a wrong number.

   Note: ID numbers can also be scanned into the analyzer.
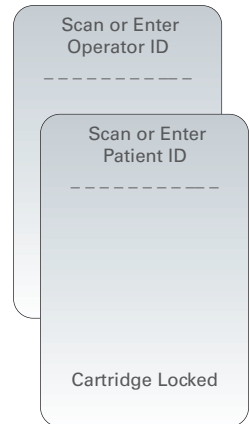
4. Position barcode on back of cartridge pack 3 - 9 inches from analyzer. Press and hold **SCAN** to activate laser barcode scanner. Align the red laser light so it covers the entire barcode on the back of the cartridge pack. The analyzer will beep when it reads the barcode successfully. Try again if the "Scan Cartridge Lot Number" message is still displayed.

   Note: Manually entering the cartridge lot number will cause Quality Check Code 69.

5. Once "INSERT CARTRIDGE" is displayed, analyzer will remain active for 15 minutes before turning off.

6. Remove cartridge from pack just before testing.

   Note: Once cartridge is removed from the pack, it must be used within 15 minutes. If not used within 15 minutes, discard it and use a fresh cartridge. (Cartridges in unopened packs can be stored at room temperature for up to 14 days)

Fill Mark

Inlet Port
(Blood goes here)

Closure Clip
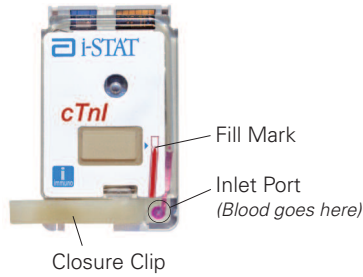
Fill and Close the Cartridge

1. Gently invert tube of blood 2–3 times.

2. There are two ways to transfer blood from a tube to the cartridge, **syringe** or **plastic pipette**.

   If using a **syringe**, invert tube and push the syringe's safety tip through stopper into blood sample. **Slowly** pull back on plunger to draw blood into syringe until it is about half full.

   Bubbles can cause a quality check failure. If air bubbles form throughout sample, discard syringe and repeat this step.

3. Hold syringe so tip is pointing upward. Hold a gauze pad at tip to absorb blood. Press syringe plunger slowly until air is removed and at least one drop of blood is discarded. If air bubble is stuck, tap syringe gently. If an air bubble was trapped at top of syringe it may start to move toward tip. In this case, wait until bubble reaches tip and remove it.

   If using a **plastic pipette**, slowly remove rubber stopper from collection tube, and draw about 1/4" of blood into pipette. Maintain constant pressure on pipette.
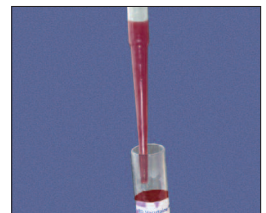
4. With cartridge on flat surface, hold syringe tip or pipette tip over inlet port on cartridge. Gently press syringe plunger or pipette bulb to deliver a single drop of blood to the inlet port.

Blood must reach fill mark on cartridge. Add a second small drop to inlet port if necessary. Some blood may be on outside of port - this will not affect result.
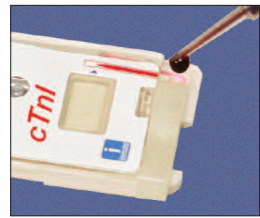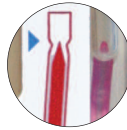
5. Hold cartridge side edges between thumb and index finger away from the inlet port. Use thumb of other hand to slide the plastic closure clip to the right until it locks into place. Keep fingers away from other side of clip to avoid getting blood on gloves.
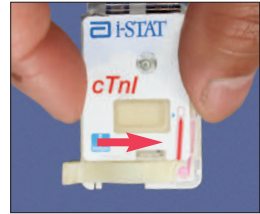
6. Push cartridge into analyzer port until cartridge clicks into place. The analyzer will first display "Identifying Cartridge", then a time-to-result bar. Results will be shown in 10 minutes.

The analyzer must remain on a level surface with the display facing up during testing. A level surface includes running the analyzer in the downloader/recharger. Motion of the analyzer during testing can increase the frequency of suppressed results or quality check codes.

Review Results

- The analyzer shows the numerical values and units for chemistry and blood gas test results.

- If any result is shown as ***, <, >, or <>, see Flagged Results.

- If a message and code are displayed, see the Quality Check section.

```
    Pt: 12345
16:10        25Augyy
     i-STAT G3+
        37.0˚C
pH                   7.461
PCO2 mmHg            27.8
PO2 mmHg             135
BEecf mmol/L          -4
HCO3 mmol/L         20.1
TCO2 mmol/L           21
sO2 %                 99
        → Page
   1 - Test Options
```

```
    Pt: 54321
18:22        25Augyy
    i-STAT EG7+
Na  mmol/L          142
K  mmol/L            4.2
iCa  mmol/L         1.21
Hct  %PCV            46
Hb  g/dL           15.3


       ← Page
```

If all results are not displayed on the first screen, press ⟹ *to page through all screens.*

Note: If Analyzer turns off before review of results is complete, press ⏻ to turn it on, then press **1** for Last Result.

Test Ranges:

- Reportable Range is the lowest to highest values the test system will report.

- Reference Range is the normal values for a species population.

- Critical Values indicate that a patient may need treatment right away if results are at or below the low value, or at or above the high value.

Flagged results:

- If stars (***) are displayed instead of a result, it means that a test failed internal quality checks. All reported results are accurate. Remix the tube of blood and repeat test using a new cartridge. If the result is still not displayed, call Technical Service.

- Results outside the System's reportable ranges are flagged with a < or >, indicating that the result is below the lower limit or above the upper limit of the reportable range respectively. The <> flag indicates that the results for this test were dependent upon the result of a test flagged as either < or >. Action: if results are flagged as <, >, or <>, send the specimen to the laboratory for analysis, if necessary.

VETSCAN i-STAT TEST REFERENCE RANGES †

	Test	Units	Canine	Feline	Equine
Hematology	Hematocrit (Hct)	% PCV	35 - 50	24 - 40	30 - 45
	Hemoglobin (Hgb)	g/dL *	12.0 - 17.0	8.0 - 13.0	10.0 - 15.0
Chemistry	Blood Urea Nitrogen (BUN)	mg/dL *	10 - 26	15 - 34	11 - 27
	Creatinine	mg/dL *	0.5 - 1.3	1.0 - 2.2	0.4 - 2.2
	Ionized Calcium (iCa)	mmol/L *	1.12 - 1.40	1.20 - 1.32	1.25 - 1.75
	Glucose (Glu)	mg/dL *	60 - 115	60 - 130	62 - 134
Electrolytes	Chloride (Cl)*	mmol/L *	106 - 127	112 - 129	100 - 111
	Sodium (Na)	mmol/L *	139 - 150	147 - 162	128 - 142
	Potassium (K)	mmol/L *	3.4 - 4.9	2.9 - 4.2	1.9 - 4.1
Acid Base	pH		7.35 - 7.45	7.25 - 7.40	7.35 - 7.45
	PCO₂	mmHg *	35.0 - 38.0	33.0 - 51.0	36.0 - 46.0
	HCO₃	mmol/L *	15.0 - 23.0	13.0 - 25.0	25.0 - 30.0
	TCO₂	mmol/L *	17 - 25	16 - 25	24 - 32
	Anion Gap	mmol/L *	8 - 25	10 - 27	5 - 15
	Base Excess	mmol/L *	(-5) - 0	(-5) - (+2)	(-5) - (+5)
Blood Gas	PO₂	mmHg *	85 - 100	90 - 110	90 - 110
	sO₂	%	›90	›90	›90
Specialty	Lactate	mmol/L *	0.6 - 2.9	0.5 - 2.7	0.3 - 1.5
	ACT (Celite)	Seconds	90 - 130	100 - 160	120 - 220
	Cardiac Troponin I (cTnI)	ng/ml *	‹ 0.05	N/A	N/A

Highlighted cells reflect ranges for arterial samples. No venous reference ranges are yet available.

*Configurable

† A Bibliography for these ranges appears at the end of this guide.

Quality Checks:

Quality checks are automatically performed during each test. If a quality check fails, the analyzer stops the test and shows a cause and action to be followed. Some examples and explanations include:

SAMPLE POSITIONED BEYOND FILL MARK – USE ANOTHER CARTRIDGE
Too much blood was put into cartridge.

SAMPLE POSITIONED SHORT OF FILL MARK – USE ANOTHER CARTRIDGE
Not enough blood was put into cartridge. Make sure blood reaches the fill mark.

INSUFFICIENT SAMPLE – USE ANOTHER CARTRIDGE
Not enough blood was put into cartridge. Make sure some blood is in the sample well and that there are no air bubbles in the cartridge.

UNABLE TO POSITION SAMPLE – USE ANOTHER CARTRIDGE
Cartridge not closed properly, sample was outside sample well or sample clotted.

"CLEW EXPIRING, UPDATE REQUIRED"
Software will expire 15 days after message is first displayed. Update software.

"CARTRIDGE ERROR, USE ANOTHER CARTRIDGE" (Code 79 or 80)
If code occurs a second time, analyzer has been damaged and needs to be replaced.

A complete list of Quality Checks is in the Operator's Manual.

Troubleshooting

In addition to the quality checks that are automatically performed during each test, other situations may also occur which require operator action:

Problem	Action
Battery Low message and battery icon flashing.	Change the batteries.
Analyzer will not turn on when a cartridge is inserted.	Change the batteries
FAIL is displayed when a cartridge is inserted.	This is a failure of the internal Electronic Simulator. Use external Electronic Simulator to verify failure. See the Operator's Manual for procedure. If FAIL occurs again, contact Technical Support.

Cartridge and Test Information

Detailed information on each test can be found in the Cartridge and Test Information sheets. These sheets are available on the Abaxis website: www.abaxis.com/support/package_inserts. This information includes:

- Intended Use
- Contents of Cartridge
- Expected Values
- Performance Characteristics
- References

- Methodology
- Metrological Traceability
- Clinical Significance
- Factors Affecting Results
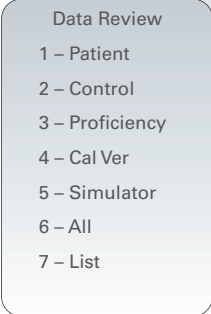
Reviewing Stored Results

A minimum of 1000 test results are stored by the analyzer, and can be reviewed by accessing the Data Review Function. Note: the oldest test records are overwritten when the memory becomes full.

1. Press ⏻ to turn on analyzer

2. Press MENU to change screen to Administration Menu

3. Press **2** (Data Review)

4. At the Data Review screen, choose the category of results for review. Use the 2 key to advance forward through selected results.

```
13:26  18JUNyy
Administration Menu
1 - Analyzer Status
2 - Data Review
3 - Quality Tests
```

```
Data Review
1 – Patient
2 – Control
3 – Proficiency
4 – Cal Ver
5 – Simulator
6 – All
7 – List
```

Data Review Definitions

Patient: Records for patients are recalled by scanning or manually entering a patient ID number. If no Patient ID is entered, all patient test records are recalled when ENT is pressed. Not all tests may be displayed on first screen. Press analyzer's arrow keys to page through all screens.

Control: All quality control sample records.

Proficiency: Proficiency testing is a type of Quality Test. Not required for testing under a Certificate of Waiver.

Cal Ver: Calibration Verification is a type of Quality Test. Not required for testing under a Certificate of Waiver.

Simulator: All external and internal Electronic Simulator records.

All: All test results in the analyzer's memory.

List: Records are listed with cartridge type, date and time of test, and patient or control ID (lot number). Records can be selected for viewing or printing using the numbered keys. Pressing the number key corresponding to a record selects the record; pressing the number key a second time deselects the record. To view one or more records, select the records and press the ENT key.

Printing Results

Results can be transmitted from the analyzer to either an i-STAT Printer or a Martel Printer. The printer can be recharged from a power adapter connected to an outlet.

i-STAT Printer
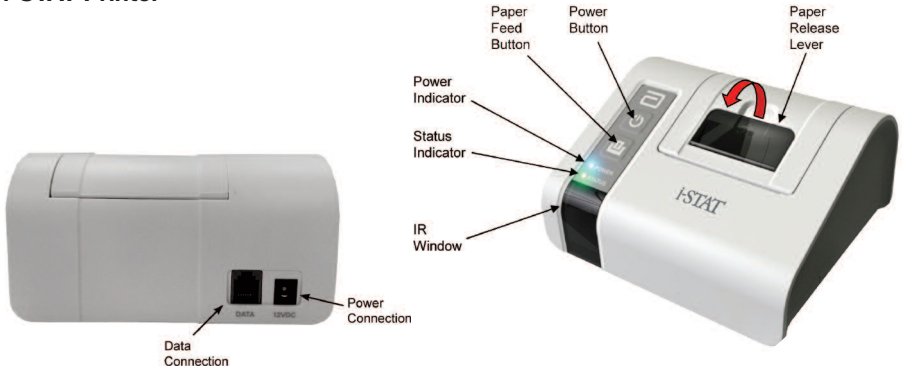
Power

There are three options for powering the i-STAT Printer:
- Using the AC adapter and power cord only,
- Using the Rechargeable Battery only, and
- Using the Rechargeable Battery with the AC adapter and power cord.

The i-STAT Printer can be turned on and off by pressing the POWER button. When the printer is on, the POWER indicator will be illuminated:

Power OK:	**Green**	🟢
Battery Low:	**Orange**	🟠
Battery Empty:	**Red**	🔴

If the printer is inactive for >60 seconds, it will automatically enter the power-saving mode. When in the power-saving mode, the POWER indicator will change from a solid color light to pulsed illumination.

The printer's rechargeable battery needs to be recharged when the POWER indicator turns orange. If the battery becomes exhausted, the POWER indicator will turn red and printing will be disabled.

The printer's battery can be recharged using the supplied AC power adapter. The socket for the AC power adapter is located on the rear of the printer. Note: Charging only occurs when the printer is switched off or in the power-saving mode. A full charge takes approximately 3 hours.

Symptoms Indicating that the Rechargeable Battery Requires Replacement:

1. A steady Orange or Red POWER indicator light on the printer, even after charging it for the recommended 3 hours.

2. Loss of battery capacity, indicated by a shorter interval between charges.

Installing or Replacing the Rechargeable Battery in the i-STAT Printer:

1. Disconnect the printer from the AC adapter.

2. Turn the i-STAT Printer upside down and place it on a flat surface. Remove the battery door by sliding it off while pressing on the grooved section. Set the door aside.

3. If replacing an existing rechargeable battery in the printer, disconnect the existing battery by gently pulling up on the red/white/black wires until the connector releases from the three metal pins. Once the battery is disconnected, remove it completely from the battery compartment.

4. Remove the new rechargeable battery from its packaging. With the thumb and index finger of one hand, grasp the connector at the end of the red/white/black battery wires.

5. Assure proper connector alignment as shown, then slide the connector onto the three metal connector pins.
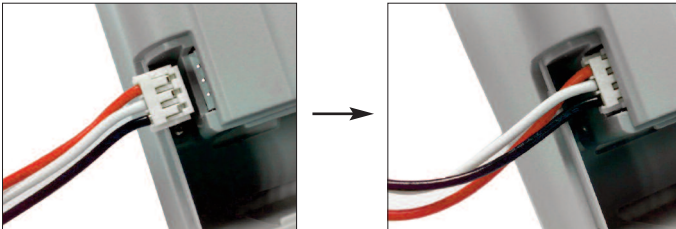
6. Once the wires are connected, place the battery portion of the pack into the rectangular compartment. Make sure the wires are not under the battery or projecting out of the opening. The correct positioning at right.

7. Slide the battery door back onto the compartment until it closes and locks into place.

8. Turn the printer over, plug it back into the AC power adapter, and charge the new battery in the printer for a minimum of 3 hours before use.

Note: If the rechargeable battery is removed or becomes exhausted, it is still possible to print at reduced speed using the AC power adapter.

Powering the i-STAT Printer Using the AC Adapter and Power Cord:

1. Connect the power cord to the AC adapter as shown.

2. Plug the round connector from the AC adapter into the 12VDC port on the back of the i-STAT Printer.

3. Plug the power cord into a wall outlet.

Paper

Paper may be ordered along with other supplies for the VetScan i-STAT 1 System.

The STATUS indicator will illuminate to indicate the print status:

Ready: **Green**   🟢
Out of Paper: **Orange** 🟠
Error: **Red**   🔴

Paper for the i-STAT Printer can be installed or replaced as follows:

1. Open the paper compartment lid by pulling the release lever as shown in the printer illustration on page 1 and remove any remaining paper.

2. Reel off a few centimeters of paper from the new paper roll, with the leading edge of the paper feeding forward from the bottom of the roll.

3. Sit the new paper roll in the compartment such that the leading edge is resting outside the compartment on the printer casing.

4. Close the lid until it snaps into place.

   Note 1: Should the paper become creased or misaligned, simply reload the paper as described above ensuring that the paper has a clean, straight edge.

   Note 2: 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 with the i-STAT Printer

1. Ensure that the printer is turned on and that the POWER indicator is green.

2. Align the analyzer's IR communication window with the printer's IR LED window. Generally, the printer must be within 1 to 5 inches (2.5 – 12.7 cm) of and not too close to the analyzer.

3. Display the results to be printed on the analyzer.

4. Press [PRT] on the analyzer. Do not move analyzer or printer until printing is complete.

5. If printer is not powered from a wall outlet using the AC adapter, turn printer off.

Caution

- Use only a Rechargeable Battery pack purchased from Abaxis.

- Use only power adaptor and power supply provided with the i-STAT Printer kit.

- 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 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 do match, the patient sample should be retested 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.

- Skin irritation, including caustic burns/injury, may occur following exposure to a leaking battery. Always wear gloves when handling a leaking battery, and do not permit a leaking battery to contact skin.

- Fluorescent light sources can cause interference with communications sent to the i-STAT 1 Printer. When light from a fluorescent source of sufficient proximity or brightness has a direct path into the IR (Infrared Radiation) window of the i-STAT 1 Printer, the printer may fail to respond when records are sent for printing over a serial (wired) connection to a Downloader or Downloader/Recharger.

Troubleshooting

Printer not printing. POWER Indicator is green/orange and STATUS indicator is green:

- Check that results are displayed on the analyzer, or that results have been selected from **List** under **Data Review**.

- Perform printer self test to ensure that printer is functioning. Turn the printer off. While pressing the Paper Feed button, press down on the Power button until the printout begins, and then let go of both buttons. Ensure that the resulting printout is clear and complete.

Printer is not printing over a wired connection to a Downloader or Downloader/Recharger. The POWER indicator light is green/orange and the STATUS indicator light is green.

If the printer is in close proximity to a fluorescent light:

- Reposition the printer or shield the IR window to prevent direct line-of-sight between the fluorescent light and the IR window.

- Relocate the printer or fluorescent lamp to a greater distance from each other.
- Turn off fluorescent lights within close proximity of the i-STAT 1 Printer when printing records via a serial connection.
- Print directly from the handheld via an IR connection

Paper is feeding but nothing is printed: check that the paper is feeding from under roll.

Printer not printing and POWER indicator is red: battery needs to be recharged.

Printer POWER indicator does not illuminate when printer is turned on: battery needs to be recharged.

Printer not printing and STATUS indicator is orange: printer is out of paper.

Printer not printing and STATUS indicator is red: print head temperature is out of range. Printing will be inhibited until print head temperature returns to normal level.

Martel Printer

The printer can be recharged from a power adapter connected to an outlet.

Power Connector
On/Off Switch
IR LED
Paper Cup

Side view of Martel Printer

RJ12 Connection

Paper Outlet

Top view of Martel Printer

Back view of Martel Printer
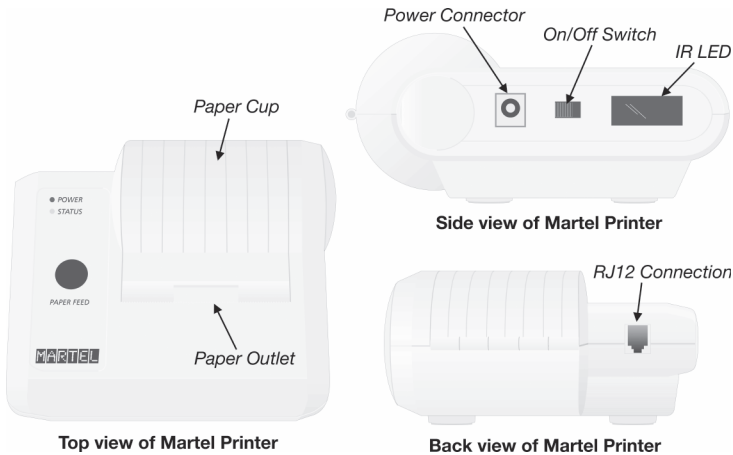
To print a test record shown on the display, point the analyzer's Infrared Communication Window at the printer's IR LED window (on its left side) and press the ⎙ key on the analyzer. To print a stored result, recall the result to the display using the procedure in "Reviewing Stored Results".

The printer must be within 1 to 5 in. (2.5 to 12.7 cm) of the analyzer. Do not move analyzer or printer until printing is complete.

Printer Power

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.

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. Printer 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 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 1 hour before attempting printing again.
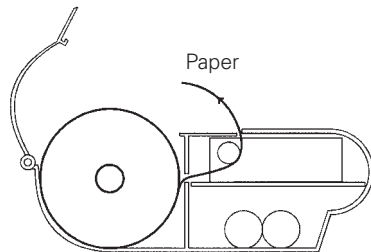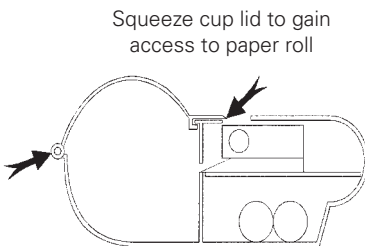

Printer Paper

Paper may be ordered along with other supplies for the VetScan i-STAT 1 System or paper with the following specifications can be used:

- Black print thermal paper
- 2.25" (5.7 cm) wide by 80' (25 m) long
- Paper grade: TF50KS-E2C

The Status light will flash to indicate that the 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 a clean straight edge. Slide the leading edge of the paper through the paper entry slot, with the leading edge of the paper feeding forward from the bottom of the roll, until you 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.

Squeeze cup lid to gain access to paper roll

Paper

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.
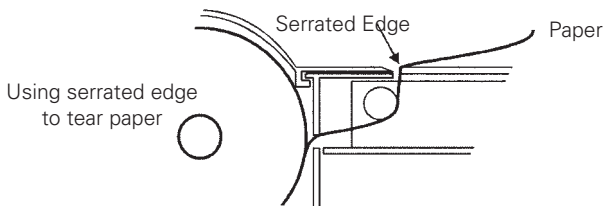
Printing Troubleshooting

Printer not printing. Power LED on and Status LED off:

- Check that results are displayed or that results have been selected from List under Data Review.

- Check that that distance between analyzer and printer, if printing directly from the analyzer, is not too short or too long.

- 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.

Paper is feeding but nothing is printed: check that the paper is feeding from under roll.

Printer not printing and Status light on continuously: battery needs to be recharged.

Printer Power LED does not come on when printer 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 rate of 0.5 seconds: printer is out of paper.

Printer not printing and Status light flashing at rate of 0.25 seconds: print head temperature too hot. Printing will be suspended until print head temperature returns to normal level.

Caution

- Use only batteries supplied by Abaxis.

- 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 printer. If printing is interrupted, realign the printer and analyzer 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, the patient sample should be retested 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.

Downloader and Downloader/Recharger

A Downloader *(serial number beginning with DS)* or a Downloader/Recharger *(serial number beginning with DRS, DRN, or DRC)* is needed to update the software in the analyzer. This procedure is explained in the software update package. The Downloader/Recharger is also required if rechargeable batteries are being used. This section will explain how to use the Downloader/Recharger to recharge rechargeable batteries. Only rechargeable batteries supplied by Abaxis may be used.
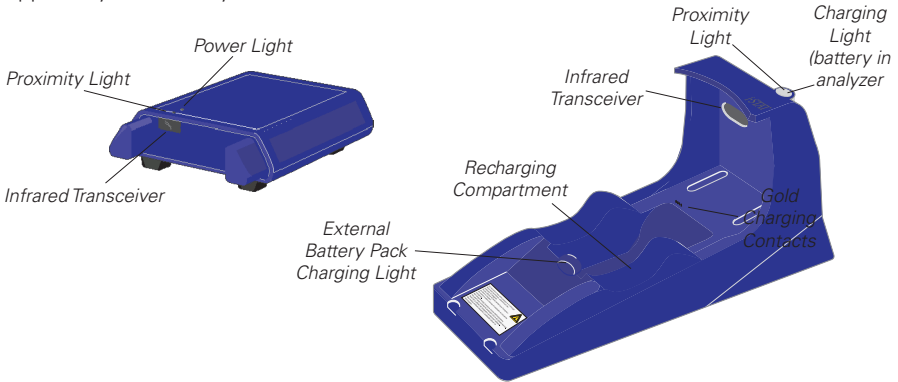
The Downloader/Recharger will recharge a rechargeable battery in the analyzer when the analyzer is placed in the Downloader/Recharger. The Downloader/Recharger also has a Recharging Compartment for an additional rechargeable battery.

Power Requirements: The Downloader and Downloader/Recharger require one power outlet. The i-STAT and Martel printers can be powered from the Downloader/Recharger, so that only one power outlet is needed for both devices. The Downloader and Downloader/Recharger must be used with the AC power supply adapter supplied with them.

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 Abaxis provided printers may be connected to the Downloader printer port.

- An ethernet cable and serial (DB9) cable may NOT be connected to the Downloader (DRS and DRN) at the same time.

- A network cable and USB cable may NOT be connected to the downloader/recharger (DRC) at the same time.

- Users should not connect the Downloader or Downloader/Recharger to a medical electrical system.

- The Downloader and Downloader/Recharger are not intended for use in the patient environment (within 1.5 meters of the physical location of the patient).

Art: 723085-00K Rev. Date: 30-OCT-2014

Charging Batteries

- Put a new or fully discharged rechargeable battery in the Recharging Compartment for 40 hours. Battery will be 100% charged and ready for use.

- To keep batteries charged, either keep the analyzer on the Downloader/Recharger when not in use, or store a rechargeable battery in the Recharging Compartment.

- The battery pack has two labels: one for orientation in the analyzer and one for orientation in the Downloader/Recharger.

- A rechargeable battery is expected to last for 15 months from the date of manufacture, which appears on the battery.

- Indicator lights indicate the following when charging the battery in the analyzer:

Off	No Rechargable Battery
Blinking Red	Fast Charge Pending
Solid Red	Fast Charging
Solid Green	Trickle Charging

- Indicator lights indicate the following when charging a spare battery:

Off	No Rechargable Battery
Solid Green	Trickle Charging

Caution: Do not short circuit, incinerate, or mutilate the rechargeable batteries.

Placing the Analyzer in the Downloader/Recharger

- When the analyzer in placed in the Downloader/Recharger, the proximity light on the Downloader/Recharger will turn blue. Also, the message "Waiting to Send" and two arrows will be displayed on the analyzer. This message is relevant only if the Downloader/Recharger is connected to a data management system. The message will disappear from the analyzer display screen in a few seconds. (This message can be disabled by disabling Auto Transmit in the Customization function.)

- All i-STAT cartridges may be run in analyzers that are docked in a Downloader/Recharger.
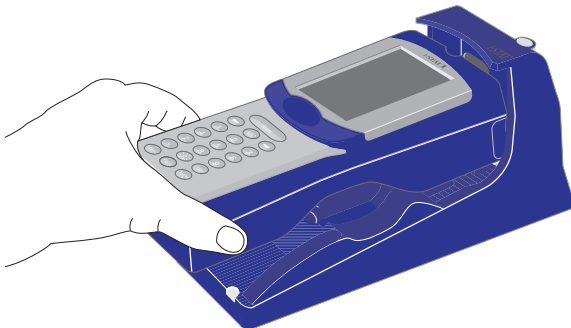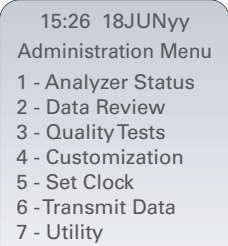
Deleting Results From Analyzer
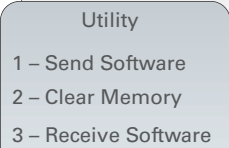
The Utility Function is used to delete stored results. This function can be password protected using the Customization function.

To delete stored results:
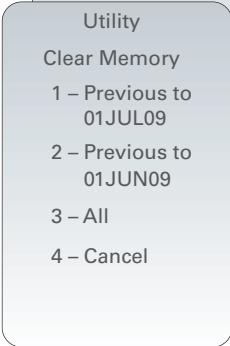
1. Press ⏻ to turn on analyzer

2. Press MENU to change screen to Administration Menu

3. Press **7** (Utility)

4. When prompted for Password, press the Enter key or the enter the password.

5. Press **2** (Clear Memory)

6. Select from the Clear Memory menu:

   1. Previous to current month and year *(as shown)*

   2. Previous to previous month and year *(as shown)*

   3. All

   4. Cancel

```
         15:26  18JUNyy
      Administration Menu
      1 - Analyzer Status
      2 - Data Review
      3 - Quality Tests
      4 - Customization
      5 - Set Clock
      6 - Transmit Data
      7 - Utility
```

```
            Utility

      1 – Send Software
      2 – Clear Memory
      3 – Receive Software
```

```
            Utility
      Clear Memory
      1 – Previous to
          01JUL09
      2 – Previous to
          01JUN09
      3 – All
      4 – Cancel
```

Manufacturer's Quality System Instructions

Quality control procedures are used to ensure the continued accuracy of a test system. The quality control program for the VetScan i-STAT 1 System includes:

- **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. A complete list of quality check messages can be found in the Operator's Manual. The quality checks detect improper environmental conditions, analyzer function, cartridge filling, cartridge function and sensor function.

- **Checking New or Replacement Analyzers with the Electronic Simulator:** Use the Electronic Simulator, internal or external, to verify the operation of a new or replacement analyzer before use.

  The internal Electronic Simulator will automatically activate the first time a new or replacement analyzer is used and after every 24 hours of use thereafter. The analyzer can be customized to remind the operator to perform the simulator test or automatically run the simulator more frequently as required or desired.

- **Performing Daily Quality Control with the Electronic Simulator:** Check each analyzer with the Electronic Simulator, using either the internal or external simulator, once on each day of use.

- **Checking Temperature Strip for a New Shipment of Cartridges:** Verify that the transit temperatures were satisfactory by reading the temperature strip included in each shipping container.

- **Ensuring Thermal Probe Check is Performed:** Ensure the thermal probe check is performed every 6 months on each analyzer. This check can be performed in conjunction with the analyzer software updates as instructed in the Operator's Manual.

- **Training Staff on Avoidance of Pre- and Post-analytical Errors:** Ensure that users are trained to avoid pre-analytical errors such as those associated with sample collection, delays in testing, inadequate sample mixing, and post-analytical errors (results reporting and communication).

- **Updating Software, then Checking with External Electronic Simulator:** Update the VetScan i-STAT System software as provided by Abaxis. Check the analyzer with the external Electronic Simulator after software updates. The thermal probe check can also be taken from this check.

Checking Analyzer with the Electronic Simulator

The external Electronic Simulator is stored at room temperature in its box.

When 24 hours has elapsed since the last Electronic Simulator test (internal or external), the internal test will automatically be performed when a cartridge is inserted. If the test passes, the analyzer proceeds with the measurement of the patient sample. If the test fails, the analyzer displays a FAIL message. The analyzer cannot be used until the simulator test passes. The external Electronic Simulator can be used to verify the failure.

1. Place analyzer on a flat surface.

2. Press ⏻ to turn on analyzer.

3. Press MENU to change screen to Administration Menu.

4. Press 3 for the Quality Tests menu.

5. Press 4 for Simulator.

6. Enter Operator ID number using number keys. If ID numbers are not required, just press ENT to continue.

7. Enter Operator ID number again and press ENT .

8. Remove Simulator from its box. Remove protective cap. Take care not to touch gold contact pads.

9. Enter serial number found on label of Electronic Simulator.

10. Insert Electronic Simulator into analyzer with gold contact pads facing up and forward. When inserted properly, analyzer will display "Contacting Simulator". DO NOT remove simulator until "Simulator Locked" message is removed and result is displayed.

11. If "PASS" is displayed, analyzer may be used. If "FAIL" is displayed, do not use analyzer. Record the letter or number below the result box on display and call Technical Service.

12. Replace the cap and return the simulator to its box.

15:26 18JUNyy
Administration Menu
1 - Analyzer Status
2 - Data Review
3 - Quality Tests

Quality Tests
1 - Control
2 - Proficiency
3 - Cal Ver
4 - Simulator
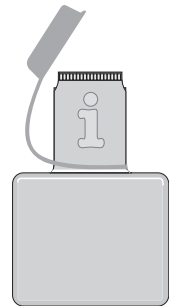
Periodic Procedures

Cleaning the Analyzer

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 or case.

Clean the display screen and case using a gauze pad moistened by any of the following:

- A mild non-abrasive cleaner
- Detergent
- Soap and water
- Alcohol
- 10% bleach solution

Avoid getting excess fluids in the seam between the display screen and the case. Rinse using another gauze pad moistened with water and dry.

Updating the Analyzer Software

The analyzer's software must be updated twice a year. The software expires in June and December. About six weeks before the current software expires, your facility will receive a software update packet with complete instructions on how to perform the update.

15 days before the software expires, the analyzer will display "CLEW Expiring, Update Required". If you see this message and you have not received the update packet, call Abaxis Technical Service at 1-800-822-2947.

Software updates require a VetScan i-STAT Serial Downloader or Serial Downloader/ Recharger and a PC with Windows 2000 or higher.

Thermal Probe Check

The analyzer's thermal probes should be checked every six months. This check can be performed in conjunction with the analyzer software updates.

Symbols

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

Attention: See instructions for use.

Caution: Risk of electrical shock.

Laser radiation hazard symbol.

Biological Risks.

Temperature limitations. The upper and lower limits for storage are adjacent to upper and lower arms.

Upper limit of temperature.
The upper limit for storage is adjacent to the upper arm

Use by or expiration date. Date shown as YYYY-MM-DD means last day product can be used. YYYY-MM means it cannot be used past last day of month specified.

LOT Manufacturer's lot number or batch code. The lot number or batch will appear adjacent to this symbol.

REF Catalog number, list number, or reference number. The number adjacent to this symbol is used to reorder the product.

SN Serial number. The serial number will appear adjacent to this symbol.

MN Model number. The model number will appear adjacent to this symbol.

Manufacturer

IVD *In vitro* diagnostic medical device.

Contains sufficient for < n > tests.

Consult instructions for use or see Operator's Manual for instructions.

CONTROL Control

Signifies that product bearing ETL Listed mark complies with both U.S. and Canadian product safety standards: UL 61010A-1, CAN/CSA C22.2 No. 1010.1-92

i/immuno: Cartridges bearing this symbol must be run on i-STAT analyzers that also bear this symbol.

The CE mark is a mandatory conformity mark on many products placed on the single market in the European Economic Area (EEA). The CE marking certifies that a product has met EU consumer health, safety, or environmental requirements.

EC REP	Authorized representative in European Community
②	Do not reuse.
Battery icon	Battery: Low battery icon (flashes on lower left side of display screen).
BODxxxx-xx	Born On Date: the label BODxxxx-xx defines year and month of manufacture.
14 [d]	14 days room temperature storage at 18-30°C
2 [m]	2 months room temperature storage at 18-30°C
BC	Packaging contains cartridges with barcoded pouches.

Bibliography for VetScan i-STAT Test Reference Ranges

Sodium, Potassium, Chloride

1. N. W. Tietz, E.L. Pruden, O. Siggaard-Andersen, ″Electrolytes″ in Tietz Textbook of Clinical Chemistry, Second Edition, C.A. Burtis and E.R. Ashwood, eds (Philadelphia: W.B. Saunders Company, 1994)

2. D.S. Young, Effects of Drugs on Clinical Laboratory Tests, 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990)

BUN, Glucose, Ionized Calcium, *P*O2, sO2, Lactate, Creatinine

1. D.S. Young, Effects of Drugs on Clinical Laboratory Tests, 3rd ed. (Washington, DC: American Association of Clinical Chemistry, 1990)

Hematocrit / Hemoglobin

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2. J.D. Bower, P.G. Ackerman and G. Totos, eds, "Evaluation of Formed Elements of Blood," in Clinical Methods (St. Louis: The C.V. Mosby Company 1974)

pH

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2. E.L. Pruden, O. Siggaard-Anderson and N.W. Tietz, "Blood Gases and pH" in Tietz Textbook of Clinical Chemistry, Second Edition, ed. C.A. Burtis and E.R. Ashwood (Philadelphia: W.B. Saunders Company, 1994)

PCO$_2$, HCO$_3$, TCO$_2$, Base Excess, Anion Gap

1. National Committee for Clinical Laboratory Standards. Definitions of Quantities and Conventions Related to Blood pH and Gas Analysis, Second Edition, Tentative Standard, NCCLS document C12-T2 (Villanova, PA: NCCLS, 1991)

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1. Hattersly, P. Activated Coagulation Time of Whole Blood. Journal of the American Medical Association 136:436-440, 1996

Troponin I

1. M.A. Oyama, D. Sisson, P.F. Solter, Blood-Based Testing for Heart Disease in Dogs. Veterinary Forum. June 2005:21-28

2. D.B. Adin, M.A. Oyama, M.M. Sleeper, R.J. Milner, Comparison of Canine Cardiac Troponin I Concentrations as Determined by 3 Analyzers. J Vet Intern Med 2006: 20:1136-1142

3. W.E. Herndon, M.D. Kittleson, K. Sanderson, K.J. Drobatz, A.G. Clifford, N.J. Summerfield, A. Linde, M.M. Sleeper, Cardiac Troponin I in Feline Hypertrophic Cardiomyopathy. J Vet Intern Med 2002:16:558-564

4. E. Braunwald, et al. ACC/AHA 2002 guideline update for the management of patients with unstable angina and non-ST-segment evaluation myocardial infarction: a report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines (Committee on the Management of Patients with Unstable Angina) 2002.

5. M.A. Oyama, Evaluation of Heart Function Using Blood-Based Tests: Current Use and Future Applications.

6. M.M Sleeper, C.A. Clifford, L.L. Laster, Cardiac Troponin I in the Normal Dog and Cat. J Vet Intern Med 2001:15:501-503

Warranty

Abaxis warrants to the original purchaser that 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 the analyzer with a reconditioned unit; in either case, the new refurbished unit will receive the same 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 of the environmental specifications of the product.

It is the owner's responsibility to update software as instructed in the VetScan i-STAT 1 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

Abaxis Technical Service

Abaxis Technical Service personnel can help with your questions about the VetScan i-STAT 1 Handheld Analyzer. Call Abaxis Technical Service, 24 hours a day, 7 days a week, at 1-800-822-2947.

REF 600-7015

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