

Troubleshooting

MESSAGE	ACTION	EXPLANATION
SIM	Use Electronic Simulator	Simulator must be used once every 8 hours.
BAT	Replace batteries soon	Approximately 50 more cartridges can be tested.
SFT	Update software	Software will expire 15 days after SFT is first displayed.
Date Invalid	Check clock on status page	The software checks for an unrealistic date. Check Status Page. If date is correct, call Technical Services.
Dead Batteries	Replace Batteries Use another cartridge	The analyzer does not have enough power to complete the testing cycle.
TEMPERATURE OUT OF RANGE	Check status page. Use another cartridge	The analyzer is too warm or too cool, or the room is too warm or too cool.
CARTRIDGE ERROR	Use another cartridge	The analyzer detected a problem with the calibrant solution.
CARTRIDGE TYPE NOT RECOGNIZED	Use another cartridge	The analyzer could not identify the type of cartridge inserted. Check software version.
CARTRIDGE PREBURST	Use another cartridge	Calibrant released too soon. Take care not to press over cartridge label area.
SAMPLE POSITIONED SHORT OF FILL MARK	Use another cartridge	Sample did not reach fill mark. Tilt cartridge to aid sample flow into sample chamber.
SAMPLE POSITIONED BEYOND FILL MARK	Use another cartridge	Cartridge is overfilled. Fill new cartridge to fill mark. Press on snap cover tab not over sample well when closing.
INSUFFICIENT SAMPLE	Use another cartridge	Cartridge is underfilled or bubbles trapped in sample.
UNABLE TO POSITION SAMPLE	Use another cartridge	Inadequate seal; sample overflowed well; sample clotted; snap closure left open.
CARTRIDGE NOT INSERTED PROPERLY	Reinsert cartridge	Push cartridge straight through door until it will go no further.
ANALYZER ERROR	Use Electronic Simulator	If the analyzer passes the simulator check, continue to use. If not, call i-STAT Technical Services.
ANALYZER ERROR	See System Manual	See System Manual
SYSTEM INTERRUPTED	Use another cartridge	Conditions such as batteries removed before analyzer deactivated when cartridge is still in analyzer.

i-STAT

Portable Clinical Analyzer & Test Cartridges



User Guide

i-STAT

For Technical Service call: (800) 366-8020
i-STAT Corporation • 104 Windsor Center Drive • East Windsor, NJ • USA

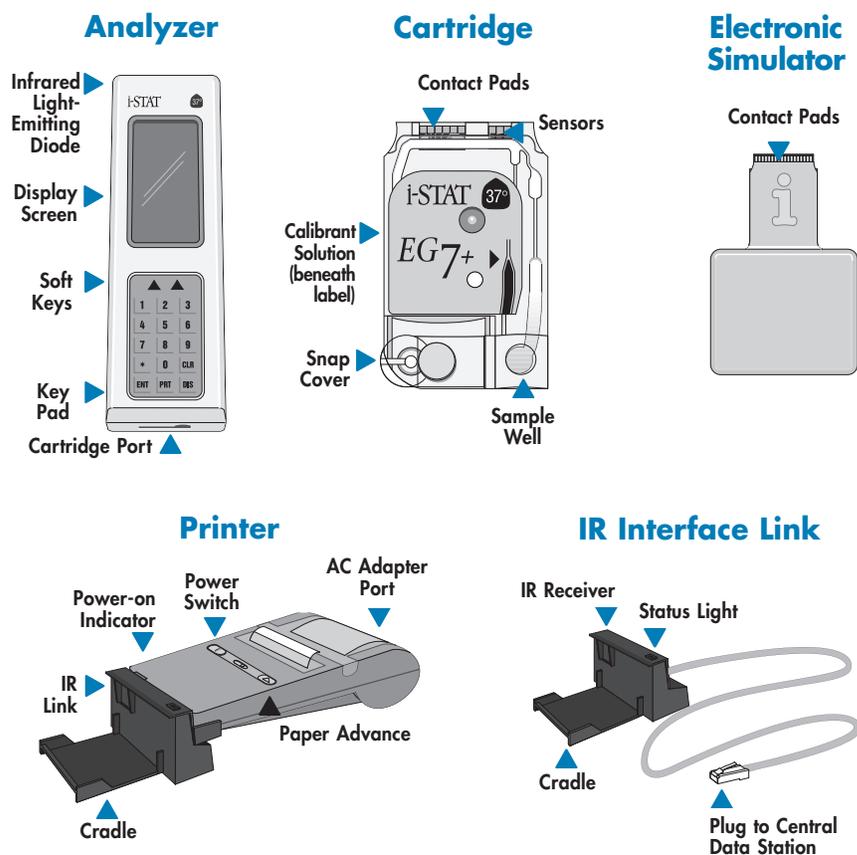
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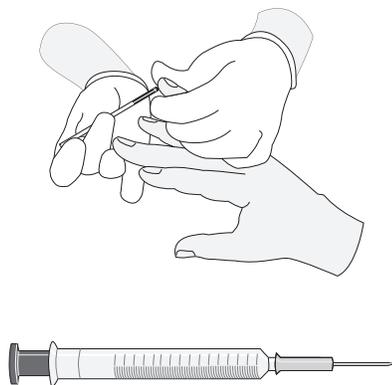
System Components



Blood Collection

Blood Collection Precautions

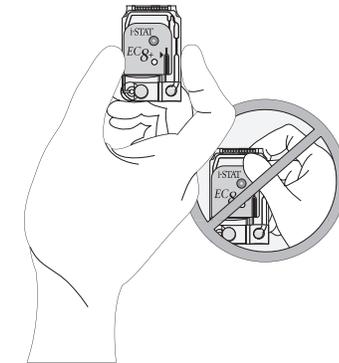
- Allow alcohol to dry over puncture site before collecting blood.
- Do not "milk" finger or heel while collecting blood.
- Do not draw above an I.V.
- Do not leave tourniquet on for more than 1 minute before collection.
- Samples for ACT testing should be collected into plastic devices (no glass) using no anticoagulant. For other tests, use only lithium or sodium heparin anticoagulants or collect using no anticoagulant. For ionized calcium, fill tubes to capacity; use capillary tubes or syringes with balanced heparin; or use no anticoagulant.
- Mix blood collected in tubes with anticoagulant by gentle inversion. Mix blood and anticoagulant by rolling syringe between palms for at least 5 seconds. Then invert the syringe repeatedly for at least 5 seconds.
- Maintain anaerobic conditions (do not expose to air) when measuring pH, PCO_2 , PO_2 and ionized calcium.



Quality Assurance

Handling the Cartridge

- Cartridges should remain in pouches until time of use.
- Store cartridges at 2 to 8°C. Do not use after expiration date.
- Allow cartridges to come to room temperature before opening pouches. Individual cartridges may be used after standing 5 minutes at room temperature. An entire box should stand at room temperature for 1 hour.
- Cartridges may be stored at room temperature for 14 days. Do not return cartridges to the refrigerator once they have been at room temperature. Mark the calendar on box with room temperature expiration date.

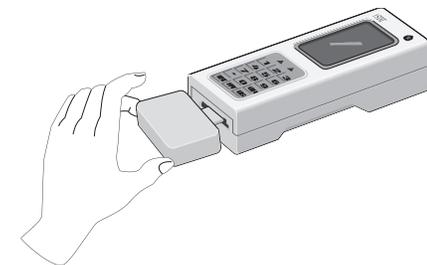


Daily Procedure

- Perform an electronic check on each analyzer using the Internal or External Electronic Simulator as needed for regulatory compliance.

To use the External Simulator:

- Insert Electronic Simulator. Do not touch the contact pads.
- If PASS is displayed, remove simulator and continue using analyzer.
- If FAIL is displayed, remove simulator and repeat. If FAIL is displayed again, contact your i-STAT Technical Service representative. Do not use the analyzer.



Verifying Cartridge Integrity

- Verify the integrity of a new shipment of cartridges, on receipt, by analyzing 2 levels of fluids (i-STAT Controls, i-STAT ACT Controls, or Calibration Verification Set) using any verified i-STAT analyzer and a representative sample of the lot(s) of cartridges received. Use the expected values published in the fluids' package inserts to verify the integrity of the cartridges.
- A procedure should be in place to control and monitor proper storage conditions (See Cartridge Handling). Cartridges maintained according to i-STAT storage requirements will retain their performance at least until the expiration date.

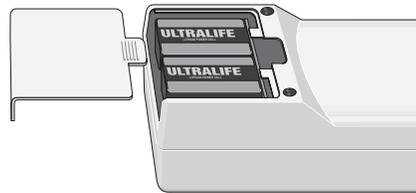


Hardware Procedures

Replacing the Batteries

■ Changing the batteries will not affect stored results or the clock/calendar.

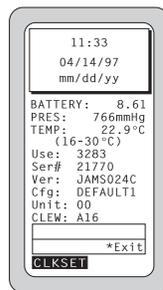
1. Place the analyzer upside down and open the battery compartment door.
2. Remove the old batteries.
3. Orient the (+) and (-) poles of the new batteries with the (+) and (-) labels in the battery compartment and slide the new batteries into place.
4. Close the battery door. The analyzer is ready for use.



NOTE: Only use lithium batteries which are protected against overheating and explosion such as those recommended by i-STAT Corporation.

Changing Date & Time

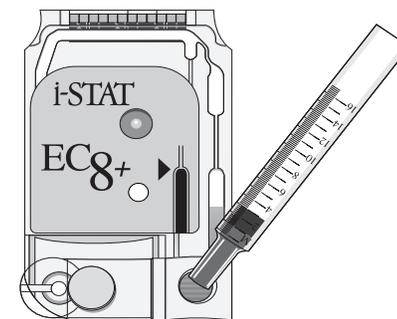
1. Press the Menu softkey and select Status.
2. Press the CLKSET softkey to convert the softkeys into arrows.
3. Using the arrow keys, move the cursor under the digit to be changed.
4. Use the keypad to change the digit.
5. When all changes are made, press the ENT key to store the changes. Note that the clock is 24 hours. The analyzer will not store inappropriate entries.



Blood Collection

Handling the Blood Sample

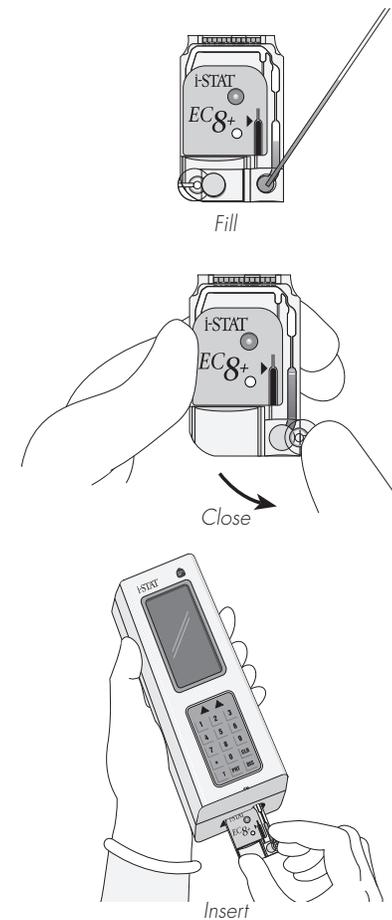
- Volume to fill cartridge is approximately 2 to 3 drops.
- Only fresh whole blood samples should be tested.
- Samples for ACT testing should be analyzed immediately after collection. Samples collected for lactate testing, or those without anticoagulant or in capillary tubes should be tested within 3 minutes.
- Samples for other tests, collected with anticoagulant, should be tested within 10 minutes. If the cartridge is not filled immediately after drawing and mixing the blood, the tube must be re-mixed thoroughly. Mix tubes by gentle inversion 7 times. Mix syringes by rolling between the palms for at least 5 seconds. Then invert the syringe repeatedly for at least 5 seconds. Discard 1-2 drops of blood.
- Test samples before icing.



Test Procedure

Processing a Blood Sample

1. Remove cartridge from pouch. Handle a cartridge by its edges. Avoid touching the contact pads or exerting pressure over the center of cartridge.
2. Direct needle, pipette tip or capillary tube into the sample well. Dispense sample until it reaches the fill mark on cartridge.
3. Fold the snap cover over the sample well until it snaps into place.
4. Push the cartridge into the cartridge port on the bottom of the analyzer.
5. Never attempt to remove a cartridge while the LCK message is displayed.
6. Enter operator ID number up to 7 digits. (Repeat operator ID number for verification.)
7. Enter patient ID number up to 12 digits. (Repeat patient ID number for verification.)
8. Enter blood gas parameters and sample type (when applicable).
9. View results on the analyzer's display.
10. Remove the cartridge after the LCK message disappears. The analyzer is ready for a new cartridge immediately.

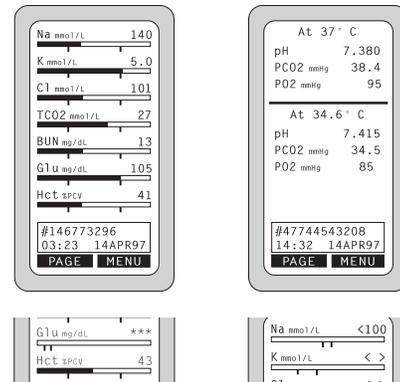


Screen display deactivates after 45 seconds to preserve battery life. Results can be redisplayed by pressing the Display key.

Test Procedure

Reviewing Tests Results

- Test results are displayed numerically, and with bargraphs. Tic marks indicate reference ranges. (Blood gas parameters and their associated calculated values are not displayed with reference ranges.)
- Results that are unreportable due to sensor errors are flagged with "***".
- Results outside the reportable range are flagged with "<" or ">".

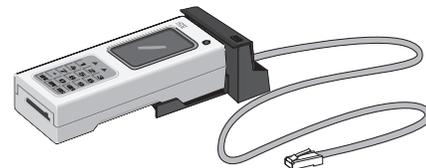


Limitations

Interfering substances in the patient's sample may cause an increase or decrease in a result. Refer to the Cartridge Test and Information Sheets and Technical Bulletins for substances and/or conditions that may interfere with cartridge tests.

Transmitting Test Results

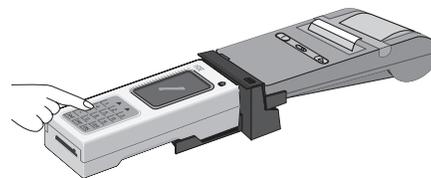
- Place the analyzer in the IR Link cradle. The IR Link light should be green.
- With results displayed, press the * key.
- The IR Link light will blink alternately red and green until transmission is complete.



The IR Link will emit a single high pitched beep when transmission has been successful; an unsuccessful transmission is indicated by 3 low tone beeps. (Try again)

Printing Test Results

- Place the analyzer in the IR Link cradle. Turn the printer on. The green printer light should be lit.
- To print the displayed test record, press the PRT key.
- To print a stored test record(s), select "Print Results" from the Stored Results menu. Select records to be printed by pressing key(s) corresponding to numbers beside record(s). Then press the PRT Key.



Do not move the analyzer until printing is completed.

Test Procedure

Tests Results

TEST	UNITS	REPORTABLE RANGE	REFERENCE RANGE	
			(arterial)	(venous)
Na	mmol/L (mEq/L)	100 – 180	138 – 146	138 – 146
K	mmol/L (mEq/L)	2.0 – 9.0	3.5 – 4.9	3.5 – 4.9
Cl	mmol/L (mEq/L)	65 – 140	98 – 109	98 – 109
pH		6.500 – 8.000	7.350 – 7.450	7.310 – 7.410
PCO ₂	mmHg	5.0 – 130.0	35.0 – 45.0	41.0 – 51.0
	kPa	0.67 – 17.33	4.67 – 6.00	5.47 – 6.80
PO ₂	mmHg	5 – 800	80 – 105	
	kPa	0.7 – 106.6	10.7 – 14.0	
iCa	mmol/L	0.25 – 2.50	1.12 – 1.32	1.12 – 1.32
	mg/dL	1.0 – 10.0	4.5 – 5.3	4.5 – 5.3
BUN	mg/dL	3 – 140	8 – 26	8 – 26
Urea	mmol/L	1 – 50	2.9 – 9.4	2.9 – 9.4
	mg/dL	6 – 300	17 – 56	17 – 56
Glu	mg/dL	20 – 700	70 – 105	70 – 105
	mmol/L	1.1 – 38.9	3.9 – 5.8	3.9 – 5.8
Lac	mmol/L	0.30 – 20.00	0.36 – 1.25	0.90 – 1.70
	mg/dL	2.7 – 180.2	3.2 – 11.3	8.1 – 15.3
Crea	mg/dL	0.2 – 20.0	0.6 – 1.3	0.6 – 1.3
	μmol/L	18 – 1768	53 – 115	53 – 115
Hct	% PCV	10 – 75	38 – 51	38 – 51
	fraction	0.10 – 0.75	0.38 – 0.51	0.38 – 0.51
Celite®ACT	seconds	50 – 1000	74 – 125	74 – 125
Hb*	g/dL	3 – 26	12 – 17	12 – 17
	g/L	34 – 255	120 – 170	120 – 170
	mmol/L	2 – 16	7 – 11	7 – 11
TCO ₂ *	mmol/L (mEq/L)	1 – 85	23 – 27	24 – 29
HCO ₃ *	mmol/L (mEq/L)	1 – 85	22 – 26	23 – 28
BE _{ecf} *	mmol/L (mEq/L)	(-30) – (+30)	(-2) – (+3)	(-2) – (+3)
Anion Gap*	mmol/L (mEq/L)	(-10) – (99)	10 – 20	10 – 20
sO ₂ *	%	0 – 100	95 – 98	

*Calculated values

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