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Clinical Laboratory:	Point of Care Testing
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HEMOCHRON SIGNATURE ELITE
LOW RANGE ACTIVATED CLOTTING TIME (ACT-LR)

PURPOSE

The HEMOCHRON *Signature Elite*, ACT-LR is a quantitative assay for monitoring heparin anticoagulation during various medical procedures. The ACT-LR demonstrates linear correlation to the anticoagulation effects of heparin up to 2.5 units / ml of blood. It is intended for use in monitoring low to moderate heparin doses frequently employed in procedures such as cardiac catheterization, extracorporeal membrane oxygenation (ECMO), hemodialysis, and Percutaneous Transluminal Coronary Angioplasty (PTCA). The ACT-LR test is for *in vitro* diagnostic use and is for use with any model HEMOCHRON Whole Blood Microcoagulation System.

PRINCIPLE

The HEMOCHRON *Signature Elite* Whole Blood Microcoagulation System utilizes a mechanical endpoint clotting mechanism in which clot formation occurs within the disposable ACT-LR cuvette. Following whole blood sample introduction, the instrument precisely measures 15 microliters of blood and automatically moves it into the test channel within the ACT-LR cuvette. The remainder of the blood sample, not needed for testing is automatically drawn into the waste channel of the cuvette. Sample / reagent mixing and test initiation are performed automatically, requiring no operator interaction. After mixing with the reagent, the sample is then moved back and forth within the test channel and monitored for clot formation.

The clot detection mechanism consists of a series of LED optical detectors aligned with the test channel of the cuvette. The speed at which the blood sample moves between the detectors is measured. As clot formation begins, blood flow is impeded and the movement slows. The instrument recognizes that the clot endpoint has been achieved when the movement decreases below a predetermined rate. The instrument reports the Celite equivalent ACT value in seconds.

TESTING PERSONNEL

- Qualified and Licensed Physicians and Registered Nurses.

SPECIMEN

A. Universal Precautions should be observed through all phases of the testing procedure.

B. There is no patient preparation needed prior to testing.

C. Samples should be fresh whole blood. (Do not obtain blood from heparinized access line, lock, or indwelling heparin lock.) If a syringe is used, it should have a 23 gauge or larger needle.

> ***IMPORTANT:*** *Collect blood specimens in a manner that prevents contamination with tissue thromboplastin, indwelling intravenous (IV) solutions, pre-heparinized syringe, citrated tube, or alcohol cleansing solutions. Discard samples that are not properly collected or contain visible clots or debris.*

D. Specimen labeling is not required when testing is performed in the presence of the patient and only the sample from one patient is tested at a time.

E. Syringe sampling from a **venipuncture**:

1. Prepare the venipuncture site by cleansing with alcohol and allowing to air dry completely.

2. Using a two syringe technique fill the first syringe with 2 cc of blood and discard.
3. Obtain 0.2 cc of blood with the second (1 cc tuberculin) syringe and immediately dispense one drop of blood into the sample well of the test cuvette; filling from the bottom of the well up. A sufficient quantity of blood must be added directly to the center sample well to fill it flush to the top. Should a large drop of blood extend above the center sample well, push it over into the outer sample well.

F. Syringe sampling from **indwelling line**:

1. Flush the line thoroughly.

> ***NOTE:*** *The amount of saline required to adequately flush the line until it is free of contaminants is dependent on the amount of solution contained within the line. A typical heparin lock will require approximately 5 cc to clear the line. Greater volumes will be required to clear longer lines.*

2. Using 3 cc syringe, fill the syringe with 2 cc of blood and discard.

3. Using a tuberculin (1 cc) syringe, collect 0.2 cc of blood (do not allow bubbles to form in the syringe) and immediately dispense one drop of blood into the sample well of the test cuvette; filling from the bottom of the well up. A sufficient quantity of blood must be added directly to the center sample well to fill it flush to the top. Should a large drop of blood extend above the center sample well, push it over into the outer sample well.

G. **Stability:** Sample needs to be tested immediately.

EQUIPMENT

A. HEMOCHRON *Signature Elite* Microcoagulation Instrument

B. HEMOCHRON Jr. Quality Control Products – Whole Blood Microcoagulation Liquid Quality Controls (directCHECK), 2 levels (with 4 re-usable protective sleeves for use in processing the control material): Level 1, *Normal* (Catalog number: DCJLR-N) and Level 2, *Abnormal* (Catalog number: DCJLR-A). Acceptable Reference Ranges included in each box of directCHECK QC material.

C. PC Cable (ITC Part No. HJ7405)

D. AC/DC power supply (ITC Part No. HX1025)
- Input Power: 100 to 240 VAC, 50 to 60 Hz
- Output Power: 12.0 Volt DC, 3.5 Amps (42 Watts, 144 BTU/hr) minimum

E. Battery (Lithium Ion)

F. HEMOCHRON Signature Elite Operator's Manual

G. HEMOCHRON Signature Elite Quick Reference Guide

H. HEMOCHRON Jr. Whole Blood Microcoagulation Systems ACT-LR package insert

I. HEMOCHRON Jr. Whole Blood Liquid Quality Control (directCHECK) Tips and Frequently Asked Questions (FAQs)

J. HEMOCHRON Configuration Manager CD V3.0 or higher (Data Management Software)

K. HEMOCHRON *ReportMaker* V6.0 or higher CD (Data Management Software)

L. **TRAINING VIDEOS** are available for viewing/reviewing on the ITC website located at: http://www.itcmed.com/Products/Hemochron/Cuvette/Signature-Elite/Training-Videos

REAGENTS

A. HEMOCHRON Jr. ACT-LR Test Cuvettes. Catalog number: JACT-LR.

1. HEMOCHRON Jr. Microcoagulation ACT-LR test cuvette is a self-contained disposable test chamber preloaded with a dried preparation of Celite, potato dextrin, stabilizers and buffers.
2. Each cuvette is individually packaged in a pouch.
3. Cuvette pouches are stamped with a lot-specific expiration date.

> ***CAUTION:*** *All used test cuvettes should be considered as potentially infectious, handled with care and disposed of using standard medical waste disposal practices.*

B. **Storage and Stability:**

1. When refrigerated (2-8°C), the foil pouched ACT-LR cuvettes are stable until the marked expiration date.
2. Room temperature storage (15-30°C) is optional for unopened, pouched cuvettes. ACT-LR cuvettes should not be exposed to temperatures in excess of 37°C.

> ***NOTE:*** *Room temperature re-dating is to a maximum of 12 weeks, but must never exceed the marked expiration date. Re-dating is necessary if stored at room temperature, and should be indicated by completing the storage information section of the "Performance Verified" table on the side panel of each cuvette box. The opened pouch properly folded at the open end, and refrigerated, is stable for seven days. For optimal shelf life, it is recommended to open the cuvette pouch immediately before use.*

C. **Criteria of Acceptability:**

Cuvettes that do not meet above criteria should be discarded.

QUALITY CONTROL

A. Quality Control testing of the HEMOCHRON Signature Elite consists of the following operations:

1. Testing system performance and verifying system temperature using internal Electronic System Verification every eight hours of operation.
2. Testing cuvettes in accordance with the Package Insert for each assay using two levels of Liquid Quality Controls.

B. **Self-Check:**

The HEMOCHRON Signature Elite instrument performs a "self-check" every time it is activated and a test is performed. When a test is initiated by inserting a cuvette, system checks are automatically performed and include:

1. Verification of adequate battery power to complete a full test.
2. Verification of the test type on the screen display to insure that the LEDs used for identifying the test are functioning properly.
3. Verification that the cuvette temperature is warmed to $37^{o}C \pm 1^{o}C$. If this temperature is not achieved or is exceeded and appropriate error message will be displayed and testing is prohibited.
4. Verification that the sample is present and is of sufficient size to run test. This insures that the pumps and sample sensing LEDs are function properly and that the cuvette is adequately sealed. If these instrument and sample parameters are not appropriate, the test is terminated and an error message displayed.
5. Verification that the internal timers function correctly for each test. If the system timer and assay timer disagree, a real-time clock error message is displayed and the test result is not reported.

C. **Verification of Instrument Temperature:**

1. Instrument temperature is automatically checked whenever EQC is carried out. The instrument temperature check verifies that a temperature of $37^{o}C \pm 1^{o}C$ is maintained during the test.

NOTE: *If the temperature reading is out of range, please contact ITC Technical Support at (800) 631-5945 or (732) 548-5700.*

D. **QC of Instrument – Electronic Quality Control – Performance:**

1. The instrument should be tested at two levels (normal and abnormal) once every eight hours of operation. **Automatic** internal Electronic Quality Control (EQC) is used to provide a two-level electronic verification of instrument performance.
2. *EQC is performed automatically (every 8 hours) if the instrument is plugged into the AC/DC Power* (and has been preprogramed through the Configuration Manager programming). The results are stored to the database and displayed for five minutes (or until "*Cancel*" is pressed).

3. The EQC can be performed manually (in addition to automatically).
4. **EQC Steps:**
   i. Display the QC Status menu by pressing the QC key **before** a cuvette is inserted. (If EQC is run while a cuvette is inserted, the message "*Detector Blocked*" is displayed and the EQC test fails.)
   ii. Press 1-EQC. The test chamber warms to temperature and the EQC test begins. The results are displayed while the test is progressing.
   iii. When the test is completed, the results are displayed on the screen and written to the QC database. Press "*Cancel*" to exit the screen.

   NOTE: *EQC tests two levels (Normal level 30 seconds and Abnormal level 300-500 seconds) of QC and the temperature. If one level fails, the test will stop and record all results as failed. If the user aborts the internal EQC test, the test is not saved to the database or printed.*

E. **QC of Reagents (Cuvettes) – Liquid Quality Control – Performance:**

1. Cuvette validation is carried out using the appropriate HEMOCHRON Jr. Microcoagulation Whole Blood Liquid Quality Control products (LQC).
2. Acceptable performance ranges for the HEMOCHRON Jr. cuvettes are included with each HEMOCHRON QC product (package insert located in the LQC box).
3. The cause of out-of-range results is likely attributable to test technique, control material, cuvette and/or the instrument. Refer to the *Troubleshooting* section of this policy for additional information.
4. Each *lot* of HEMOCHRON Jr. ACT-LR cuvettes should be validated for performance at two LQC levels (level 1 = normal and level 2 = abnormal):
   i. When a new shipment is received, **and**
   ii. Once per 30 calendar days thereafter

5. Following successful performance validation as above, the cuvettes will not require any further LQC unless a shift in clinical results is suspected.
6. **LQC steps:**
   i. The cuvette and the LQC material must be at room temperature. Allow up to 60 minutes for warming, if cuvettes and LQC material were stored in the refrigerator. *
   ii. Visually inspect each vial to insure that the glass ampule inside the plastic vial is intact.
   iii. Insert a cuvette into cuvette slot on instrument

   NOTE: ***Do NOT*** *use cuvettes that are past their marked expiration date, or which have been improperly stored.*

   NOTE: ***Do NOT*** *force a cuvette into the instrument. If resistance to insertion is encountered, gently remove the cuvette and examine the cuvette slot. Remove any obstruction before attempting further use of the instrument (See Service and Maintenance in the HEMOCHRON Jr. Operator's Manual)*

   iv. Scan cuvette lot number

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* When refrigerated (2–8°C) the vials are stable until the marked expiration date. The quality control product should never be exposed to temperatures in excess of 37°C. Reconstituted vials should be used immediately. *direct*CHECK Quality Control products may also be stored at room temperature for up to 4 weeks. (The marked expiration date must not be exceeded.) A redating label is provided and should be marked with 4 weeks dating if room temperature is selected.

1. Scan directCHECK lot number by pressing SCAN or SELECT current lot number if stored on Hemochron

NOTE: *directCHECK Whole Blood Quality Control material contains dried whole blood (0.5 mL) and diluent (0.7 mL). Use Universal Precautions.*

2. Press QC, select "QC NORMAL or QC ABNORMAL" (*Run NORMAL LQC first, then repeat these steps for ABNORMAL LQC*)

NOTE: *LQC result will be stored in the Patient Database if "QC NORMAL or QC ABNORMAL" is not selected.*

3. Scan Operator Bar Code ID (OID)
4. Instrument will signal with an audible tone and display "Add sample…Press Start"
5. Reconstitute the LQC vial (*this must be done quickly*)
6. Remove shrink wrap from vial
7. Insert normal directCHECK vial into white protective sleeve
8. Holding the vial upright, **tap the directCHECK vial on the table top to settle the inner glass ampule to the bottom of the vial**
9. Crush inner glass ampule by bending the vial over the edge of a table top, or crushing between two fingers
10. Repeat action 2-3 times to ensure vial is completely crushed
11. Quickly invert dropper vial end to end 10 times and use a downward snapping motion of the wrist to ensure the control material flows to dropper tip
12. Remove and retain vial cap
13. Squeeze vial to discard the 1st drop of LQC into vial cap
14. Dispense LQC as needed to fill cuvette sample well flush to top (Should a large dome extend over the top of the center sample well, push it over into the outer sample well.)
15. Immediately press the "START" key
16. Remove control vial from protective sleeve
17. Dispose vial and vial cap appropriately
18. Retain protective sleeve for reuse
19. Wait for single beep to signal end of test
20. Results will be displayed as ACT Celite-equivalent seconds.
21. If LQC ranges were not programmed into instrument, compare the result to the package insert (Ranges are lot number-specific.)
22. Record results.
23. Repeat same steps for ABNORMAL LQC.

F. CORRECTIVE ACTIONS When EQC or LQC Are Outside Acceptable Limits:

1. If the **EQC** results are unacceptable, re-run the controls. If they are within limits, the Hemochron may be used for patient testing. If they are still unacceptable, the Hemochron may not be used for patient testing.

2. If **LQC** results are unacceptable, re-run the controls with new vials. If they are within limits, the Hemochron may be used for patient samples. If they are still unacceptable, the controls may be repeated with a new box of control vials/cuvettes or a new lot of cuvettes. If the controls are within limits, the Hemochron may be used for patient testing. If the controls are still unacceptable, the Hemochron may not be used for patient testing.

   NOTE: *In cases where the LQC results are outside of an acceptable range, the cause may be one of the following:*
   - *i. Improper Test or Mixing Technique*
   - *ii. Expired or improperly stored QC material*
   - *iii. Expired or improperly stored test cuvettes*
   - *iv. Instrument temperature*

3. If **EQC** or **LQC** testing fails after repeated attempts, do not use the instrument for patient testing. Refer the problem to the Point of Care Testing Service (415.206.3493 or 415.206.3057) or call ITC Technical Support (800.631.5945 or 732.548.5700).
4. **Document all remedial action taken.**

G. A **Procedure Log Book** is kept with ACT device (established in December 2003) and contains the following information:

   1. Patient Identification
   2. Date and Time of Procedure
   3. ACT Tests Performed
   4. Initials of Nurse and Physician Performing the Tests/Procedures

H. If QC discrepancies arise: The Nurse Manager/designee will follow-up with the nurse who performed the patient test; the Attending Physician will be notified that the patient test results may not be valid; and the Point of Care Coordinator/designee will be notified. All QC discrepancies will be documented by the nurse that performed the test.

I. The Nurse Manager/designee will review the QC Sheets and the Procedure Log Book monthly, ensuring appropriate ACT Quality Control testing was performed prior to any patient testing.

J. The Nurse Manager/designee will provide a monthly accounting of all ACT Quality Control tests and patient tests performed to Point of Care Testing Services with attached attestation page confirming review of data.

PROCEDURE

A. Before patient testing, let cuvette (that has been Quality Control checked) come to room temperature (15 – 30 °C). Allow about 60 minutes of warming, if the cuvettes were taken from the refrigerator.

B. Start the instrument by holding down the "**START**" key (do not use excessive force) or by inserting a cuvette.

C. Insert cuvette with label facing up and push it all the way in until it stops (do **NOT** force). This initiates the pre-warm/self-check mode. The instrument will signal when "ready" with an audible tone.

D. Scan cuvette lot number.

E. Scan the operator Bar Code ID. (The operator's ID will be stored with the results for the test performed.) The operator's ID is briefly displayed and the instrument emits an audible beep after the ID is scanned. Do not share Bar Code IDs.

F. Scan or manually enter the patient's Medical Record Number (MRN) as their patient ID (PID). The instrument emits an audible beep after the patient's ID is scanned and the ID remains displayed along with the name of the test.

> ***NOTE:*** *The PID could be scanned to enter their MRN, but if they do not come with a Bar Code ID on their hospital ID bracelet or the patient is draped and the ID band is inaccessible, manually enter their (PID) MRN. If scanning the MRN-PID, position the scanner approximately 4 inches from the bar code and press "**SCAN**".*
>
> ***NOTE:*** *If manually entering the MRN-PID, input the characters using the numeric/alphabetic keys. (To clear an entry, use the backspace key [CANCEL] to backspace to the first entry and press "**CANCEL**" **twice** to clear.) Once finished entering the MRN-PID, press and hold "**ENTER**" and a stored confirmation message will display.*

G. Once the "**ADD SAMPLE**"…"**PRESS START**" messages are displayed you have 5 minutes to:

   a. Acquire the sample
   b. Fill the sample well
   c. Press "**START**" key

> ***NOTE:*** *The "START Timed Out" message is displayed and the instrument beeps if the sample collection procedure is not accomplished within 5 minutes. If this occurs a new cuvette needs to be inserted into the instrument.*
>
> ***NOTE:*** *Do not obtain the blood sample until the HEMOCHRON Signature Elite instrument displays the "**Add Sample…Press Start**" message or the fresh whole blood sample will begin to clot.*

H. Obtain blood sample (see sample collection under SPECIMEN).

I. Immediately fill the sample well from the bottom up. Add enough blood so that the lower wall of the center sample well is completely filled.

NOTE: *If the blood sample extends above the lower wall, push the excess blood into the overflow area.*

NOTE: *Do not force blood into the pin located on the center of the sample well.*

NOTE: *Avoid generating air bubbles in the sample well when applying the sample.*

J. Press the "**START**" key. The elapsed time is displayed in seconds until the sample clots.

NOTE: *If a message of "**Sample Too Small**", "**Sample Too Large**", or "**Sample Not Seen**" is displayed, an incorrect amount of sample was added. If one of these messages appears, repeat the test using a new cuvette.*

K. When a clot is detected, the instrument beeps and the final results of the test are displayed as Celite equivalent ACT value seconds (not real time seconds).

L. Record results.

NOTE: *Test results may be affected by poor technique during blood collection and delivery to the sample well.*

M. When finished, remove the cuvette and discard it.

N. To shut down instrument: Press "0" on the keypad to display the "MAIN MENU" and then press "4", or press and hold down the "START" key for 4 seconds.

NOTE: *If not in use for 5 minutes, the instrument will automatically shut down.*

REPORTING / DOCUMENTATION RESULTS

A. Reference range: < 188 seconds (based on a study of 20 healthy SFGH outpatients).

B. Heparinized result: > 200 seconds.

NOTE: *Documentation of test results will be recorded per testing site's unit specific IDA page.*

NOTE: *Whole blood ACT-LR test results less than 65 seconds will result in an "Out of Range-Lo" error message. This may indicate excessive blood coagulation activation and should be repeated to confirm the result.*

NOTE: *Celite Equivalent Values (CEV) over 400 seconds are not reported on the instrument. Instead, an "Out of range – Hi" message*

will be displayed. CEV that exceed 400 seconds due to extremely high sensitivity to heparin in the patients do not represent an error in the test.

NOTE: *Results that appear to be inconsistent with patient therapy should be viewed as questionable and the test should be immediately repeated.*

CALIBRATION

The *Signature Elite* instrument is calibrated at the manufacturing facility to test and verify all functions. The instrument is also self-calibrating, as all instrument functions are continuously monitored and verified by the instrument software when a test is performed. The instrument does not require additional calibration by the user.

LIMITATIONS OF METHOD

A. Pooled results from precision studies at SFGH (manufacturer's acceptable coefficient of variation (CV) limit when using Whole Blood coagulation controls ≤ 14 % within-run):

1. Within-run precision

	Mean (sec)	CV(%)
Level I, Low (n=20)	~140	~14.0
Level II (n=20)	~220-270	~6-12%

2. Day-to-day precision

	Mean (sec)	CV (%)
Level I, Low (n=20)	~120-140	~17-21
Level II (n=20)	~220-270	~12-16%

B. The Hemochron Jr. ACT-LR test is intended for use in monitoring patients receiving heparin anticoagulation therapy with low to moderate heparin levels (up to 2.5 units unfractionated heparin / mL). Celite equivalent ACT values over 400 seconds are not reported on the Hemochron system. Instead, an "Out of range – Hi" message is displayed.

NOTE: *The performance of the instrument for samples containing anticoagulants other than heparin has not been verified by the manufacturer and no performance claims have been made when the*

instrument is used to assess the coagulation status for patients on non-heparin anticoagulants (off-label use). It is the responsibility of the physician in charge of the case to verify that appropriate anticoagulation target levels are selected when using the ACT method for monitoring anticoagulation in patients during invasive procedures.

C. The Hemochron *Signature Elite* Microcoagulation ACT-LR test uses Celite as the activator which is known to be artificially prolonged by aprotinin, a protease inhibitor. The ACT-LR is not intended for use with these patients.

D. Samples with a hematocrit less than 20% or greater than 55% are not recommended due to an optical density outside the detection level of the Hemochron *Signature Elite* Microcoagulation instrument. In such cases, a "Sample Not Seen" error message will be displayed.

E. Values displayed at the conclusion of the assay are Celite Equivalent Values (CEV). The CEV is generated based on the correlation established with clinical patients.

F. Test results of the HEMOCHRON *Signature Elite* Microcoagulation instrument are affected by poor technique during blood collection and delivery to the sample well. The accuracy of the test is largely dependent upon the quality of the blood specimen, which is dependent upon the blood sample collection and the transfer of blood to the test cuvette.

G. Test results should always be scrutinized in light of a specific patient's condition and anticoagulation therapy. Any test results exhibiting inconsistency with the patient's clinical status should be repeated or supplemented with additional diagnostic tests.

H. Tests may be affected by any of the following conditions:
   i. Foaming of the sample (air bubbles)
   ii. Hemolysis
   iii. Clotted or partially clotted blood
   iv. Unsuspected anticoagulation with heparin or Low Molecular Weight Heparins (LMWH)

MAINTENANCE

A. Inspect and clean the cuvette opening as required. Remove residual dried blood or other foreign matter using water-moistened cotton swabs. Remove any residual water with dry cotton swabs.

B. If a disinfectant is needed, use a 0.5% solution of sodium hypochlorite or a 10% dilution of household bleach in water. Wipe instrument with a water-**dampened** cloth to remove residual bleach from the plastic surfaces. **Do NOT drench instrument.**

C. Apply solution to clean and disinfect areas contaminated with blood. Do **NOT** use solvents or strong cleaning solutions as they may damage the instruments plastic components. Routine maintenance other than cleaning normally is not required.

D. **Service of Instrument:**

The HEMOCHRON Signature Elite instrument is almost completely self-monitoring and has no user serviceable parts. It monitors internal circuitry and reports problems to the display screen automatically. Malfunctions are indicated by error messages detailed in the section "Troubleshooting."

E. **Charging Battery:**

The battery of the system should be charged before the system is used.

i. Plug the AC/DC Power Module into an electrical service outlet.
ii. Connect the AC/DC Power Module cord to the power connector on the side of the instrument. The charge indicator on the instrument keypad will illuminate.
iii. Allow the battery to charge for at least 8 hours.

NOTE: *The AC/DC Power Module can remain connected all the time.*

iv. To ensure adequate charge, leave the instrument connected to the charger for a minimum of eight hours. This eliminates the risk of the instrument powering down during a test.

F. **Battery Care:**

a. To *optimize* battery life, it is recommended that the HEMOCHRON *Signature Elite* instrument be run on its battery during the day. It can be plugged into a Hospital Grade AC outlet overnight to allow the batteries to recharge. The life of the lithium battery is optimized when the battery is exercised in this manner.
b. The message "**CHARGE BATTERY**" is displayed intermittently when the remaining power is insufficient to ensure test completion.
c. When the batteries are drained to the point that valid testing cannot be performed, the instrument will display "**BATTERY FAULT**". At this point, the instrument must be plugged in for operation and recharging. Once plugged into a Hospital Grade AC outlet, the instrument can be used immediately.
d. If either the battery voltage or the AC/DC Power Module voltage is too high, the instrument beeps continuously and displays the message "**DISCONNECT AC ADAPTER IMMEDIATELY**". The AC/DC Power Module must be disconnected to shut down the instrument in this condition.

CAUTION: *The battery used in this device may present a risk of fire or chemical burn if mistreated. Do not disassemble, heat above 60°C, or incinerate. Replace battery with Cell-Con, Inc Li-Ion Battery Pack Model 85280 only. Use of another battery may present a risk of fire or explosion.*

G. Yearly maintenance is performed by Bio-Medical Engineering, ext. 68745.

TROUBLESHOOTING

A. Company Contact Information:

International Technidyne Corportation (ITC)
8 Olsen Avenue
Edison, NJ 08820 USA
Telephone: 732.548.5700
Fax: 732.248.1928
Web: www.itcmed.com
Email: techsupport@itcmed.com

B. Instrument Error Messages

ITC Technical Support: 732.548.5700

Error Message	Cause	Corrective Action
RTC...FAULT	Cannot communicate with external Real Time Clock.	Contact ITC Technical Support.
CHARGE BATTERY	Battery power depleted below predetermined level.	Connect to AC/DC Power and charge battery for 8 hours.
BATTERY FAULT	Battery is discharged.	Charge battery for 8 hours. If message persists, contact ITC Technical Support.
EXTERNAL TOO HIGH	AC/DC Power voltage exceeds 12.7 volts.	Disconnect the AC/DC Power. Contact ITC Technical Support.
BATTERY TOO HIGH	Battery voltage exceeds 8.8 volts.	Disconnect the AC/DC Power. Contact ITC Technical Support.
Heater Too Cool	Incubator remained below 36°C after 90 seconds of warming on external power or for up to 150 seconds on battery.	Repeat test, then charge battery. If message persists, contact ITC Technical Support.
Heater Too Hot	Incubator exceeded 38°C for 2.5 seconds.	Repeat test with new cuvette. If message persists, contact ITC Technical Support.
Detector Fault	Light path between LED and detectors is blocked.	Repeat test with new cuvette. If message persists, contact ITC Technical Support.
Detector Blocked	EQC is being run while a cuvette is inserted.	Remove the cuvette and repeat the EQC.
Sample Pos Fault	Sample has moved outside of testing area in cuvette.	Contact ITC Technical Support.
ASSAY LOCKED CALL SUPERVISOR	The QC failure limit has been exceeded.	Remove the cuvette. Contact the supervisor.

MACHINE LOCKED CALL SUPERVISOR	The EQC failure limit has been exceeded.	Contact the supervisor.
Sample Not Seen	Sample has not reached front detector in specified time period.	Repeat test with new cuvette. If message persists, contact ITC Technical Support.
Cuvette Removed	Cuvette was prematurely removed from instrument while testing in progress.	Repeat test with new cuvette.
Sample Too Large / Sample Too Small	Excess or insufficient sample.	Repeat test with new cuvette.
Premature Sample	Sample was detected at front detector before specified time period. May occur is sample is added before pump-priming sequence is complete.	Repeat test with new cuvette. If message persists, contact ITC Technical Support.
MEMORY FAULT	Malfunction in the computer's memory.	Contact ITC Technical Support.
START Timed Out	START key was not pressed within 5 minutes after entering ready mode.	Remove cuvette and repeat test with new cuvette.
Unsupported Assay	Cuvette cannot be identified by instrument.	Remove cuvette and repeat test with new cuvette. Use ITC cuvettes only.
No Data Stored	Operator attempted to print data when none is stored in database.	N/A
User Abort	The test was aborted by the user.	Repeat test.
Invalid Lot #	The barcoded cuvette or QC lot number label that was scanned was not recognized.	Check the label for damage, then repeat the scan.
	The incorrect format was entered for the lot number.	Repeat the entry using the correct format.
	The lot that was scanned does not match the cuvette test type.	Verify the test type, then rescan the lot.
Lot Expired	The cuvette and/or QC material that is being used has reached its expiration date.	Remove the cuvette and repeat the test using supplies that are within their expiration date.
Action Denied	Date/Time cannot be changed if QC Lockout is required, or Date/Time function is denied through Configuration Manager.	Supervisor needs to reconfigure instrument using HCM.
Disallowed Assay	Assay performance has been prohibited via *Configuration Manager*.	Supervisor needs to reconfigure instrument using HCM.
	The table of cuvette or QC lots is empty or contains only expired lots.	Supervisor needs to reconfigure instrument using HCM.

	The QC interval is set to zero in *Configuration Manager*.	Supervisor needs to reconfigure instrument using HCM.
Cannot erase DB	Erasing patient and/or QC database is not allowed.	Supervisor needs to reconfigure instrument using HCM.
INR < 0.8 INR > 10.0 APTT < 20	Test result is outside clinical range.	Repeat test with new cuvette.
Out of Range-Lo	Test result is outside clinical range.	Repeat test with new cuvette.
	Sample has clotted prematurely, or did not mix correctly in cuvette.	
	Bubbles may be present.	
Out of Range-Hi	Test result is outside clinical range.	Repeat test with new cuvette.
Check Time/Date	Low Battery or RTC has lost its Time/Date Tracking.	Enter or verify Time & Date.
		Change battery.
Dark Photo Fault	Hardware malfunction.	Contact ITC Technical Support.
Unsupported POCT>>COM	The POCT-1A communication protocol was attempted to be set while the COM Port is selected, or vice versa.	Set POCT-1A to run over NET, or set ITC to run over COM or NET.

REFERENCES

1. HEMOCHRON *Signature Elite* Whole Blood Microcoagulation System, Operator's Manual, International Technidyne Corporation, 8 Olsen Ave., Edison, NJ 08820, 1-800-631-5945, 2006.

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3. Hemochron Whole Blood Microcoagulation Systems, Activated Clotting Time Low Range Testing (ACT-LR), CLSI Formatted Procedure, International Technidyne Corporation, 8 Olsen Ave., Edison, NJ 08820, 1-800-631-5945, 12/2011.

4. Hemochron Jr. Whole Blood Microcoagulation Systems Low Range Activated Clotting Time (ACT-LR) Package Insert, 06/2006.

5. Hemochron Whole Blood Liquid Quality Control Tips and Frequently Asked Questions, directCHECK Whole Blood Liquid Quality Control for HEMOCHRON Jr. Cuvettes, 05/2006.

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7. HEMOCHRON *Signature Elite* Whole Blood Microcoagulation System, Quick Reference Guide, 08/2006.

DISTRIBUTION

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PROCEDURE REVISIONS HISTORY

Procedure: POINT OF CARE ACTIVATED CLOTTING TIME: ITC Hemochron Signature Elite System with Low Range Activated Clotting Time (ACT-LR) Cuvettes

Revision Date	Description
04/2012	**1.** Instrument, Policy, and Procedure updated from ITC Hemochron Signature Plus (+) to ITC Hemochron Signature Elite. **2.** Purpose statement added. **3.** Principle explanation updated. **4.** Testing Personnel statement added. **5.** Specimen: collection process revised, including addition of Universal Precautions and patient preparation. **6.** Equipment list updated including addition of web based training videos. **7.** Reagents information revised and stability length of time updated. **8.** Quality Control information revised and updated. **9.** Corrective Actions updated. **10.** Procedure steps updated. **11.** Reporting/Documentation Results updated. **12.** Calibration information added. **13.** Limitations information updated. **14.** Maintenance information updated. **15.** Troubleshooting section added. **16.** References: Updated: Operator's Manual ... Updated: Linearity and Precision ... Updated: CLSI Formatted Procedure ... Deleted: Bowers J. and Fergusson JJ ... Added: ACT-LR package insert ... Added: FAQs ... Added: directCHECK package insert ... Added: Quick Reference Guide ...