ACTIVATED CLOTTING TIME (ACT)
HEMOCHRON R RESPONSE WHOLE BLOOD COAGULATION SYSTEM
P214 GLASS ACTIVATOR TUBE

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1.0 PURPOSE

The HEMOCHRON\textsuperscript{R} Activated Clotting Time (ACT) is an in-vitro quantitative assay for monitoring heparin anticoagulation therapy during interventional procedures. This test is performed at the patient's bedside on freshly drawn whole blood sample. The HEMOCHRON\textsuperscript{R} P214 ACT reagent tube is intended for patients treated with low to moderate doses of less than 2 units of heparin.

2.0 POLICY

All personnel performing ACT must follow the procedures and policies in this protocol. Testing personnel must be adequately trained and their competency assessed and documented 6 months after training and annually thereafter. Competency may be demonstrated by direct observation, review of QC, proficiency testing/patient test results or by written competency test.

3.0 PRINCIPLE

When blood is exposed to a foreign surface such as a catheter or an extracorporeal circuit, the clotting process is triggered. In invasive procedures, heparin is given to prevent thrombosis. The heparin dose necessary to achieve a specific target level varies with individual patients and must be closely monitored. Heparin overdosing can lead to bleeding while underdosing can lead to thrombosis. ACT, first described by Hattersly in 1966, measures the ability of fresh whole blood to clot when activated by contact with an activator that accelerates clotting.

ACT is monitored with the HEMOCHRON\textsuperscript{R} Response System from International Technidyne Corporation, 8 Olsen Avenue, Edison, NJ 08820, 1-800-631-5945.

The HEMOCHRON\textsuperscript{R} Response System utilizes a mechanical detector mechanism to detect clotting. Magnetic detectors are located in each test well. Disposable reagent tubes contain a stationary plastic post, activator and a precision magnet. During an ACT test, the magnetic detector senses the magnet in the reagent tube as it slowly rotates in the test well. When a clot begins to form around the plastic post, it causes the magnet to lift away from the side of the tube. The instrument senses this displacement and stops the timer, displaying the coagulation time in seconds.

The analyzer is programmable allowing the laboratory to set QC requirements and operator lockout. The database can store 600 patient test results and 64 quality control test results per test well. In addition to test results, it stores date and time of each test, patient ID, and 40 operator IDs. Data may be downloaded to a PC for review or interface to a computer system.

4.0 PERSONNEL

Intended for use by clinical personnel who have received training and demonstrated competency in this procedure. In the hospital setting, this includes Clinical Laboratory Scientists, Registered Nurses, Nurse Practitioners, Physician Assistants and Physicians.

5.0 EQUIPMENT AND REAGENTS

5.1 The HEMOCHRON\textsuperscript{R} Response:

The HEMOCHRON\textsuperscript{R} Response module contains two test wells, and ACTs from different patients may be tested simultaneously. Start and Menu function buttons identified as 1 and 2 correspond to Test Wells 1 and 2. The divider bar on the screen divides the information displayed for the two test wells. Current time and \% battery is displayed on the divider bar. Default reagent type and the next time ESV QC is due are displayed on the Start screen. At test initiation, the instrument takes 60-90 seconds to heat the well to $37 \pm 1^\circ$ C.
The instrument is portable, measures 10.5 inches by 8.7 inches and weighs 6.5 pounds. It can be operated on either A/C or battery power. The latter is rechargeable and a full charge of 16 hours will allow the instrument to operate for approximately 8 hours on battery. When the HEMOCHRON\textsuperscript{R} \textit{Response} is on battery power, it will automatically power down during periods of inactivity. Auto-shut down while on A/C power is programmable.

Programming functions are password protected. The HEMOCHRON\textsuperscript{R} \textit{Response} is programmed to require two levels of ESV QC for each 8-hour interval of testing, two levels of Liquid QC for each day of patient testing, and entry of operator pin number and patient ID.

**Front of Instrument**

- **START 1**
  - Press to power ON or OFF
  - Press to initiate tests on Test Well 1.

- **MENU 1**
  - Press to access menu in Well 1.
  - Press to advance menu pages.

- **Well 1 Display**

- **Split Screen Divider**

- **Well 2 Display**

- **Start 2 Menu 2**

- **YES key**
  - Press to response to display prompt

- **NO key**
  - Press to reject response to display prompt

- **PRINTER**

- **PRINT key**
  - Press to print result.
  - Printouts are control by Menu, Page 2, option 1, Set Outputs, 5 for internal print or 6 for external print.

- **PAPER FEED key**
  - Press to advance paper.
  - Active only if internal print in Set Output is selected.

- **NUMERIC KEYPAD**

- **TEST WELL 1**
  - Illuminates when magnet is detected.

- **HEATER 1**
  - Illuminates when well is heated to $37^\circ \pm 1^\circ C$

- **Test Well 2**

- **CANCEL Key**
  - Press to cancel an operation
  - Press YES to save response

- **BACK SPACE**
  - Press to correct an error

**5.2 ELECTRONIC SYSTEM VERIFICATION TUBE (ESV)**

ELECTRONIC SYSTEM VERIFICATION TUBE (ESV) (PMM\# 352736, Mfr. Cat\# HE-ESV)
The ESV is a verification tube used for daily electronic QC. The plastic tube contains a magnet and battery operated electronic circuitry. When placed in a test well of the HEMOCHRON\textsuperscript{R} Response, it simulates test initiation and clot detection in the same manner as a patient assay. Two levels of electronic QC, 100 and, 300 seconds are incorporated in one electronic tube allowing the user to verify instrument performance at different points throughout the reportable range. Press the button next to the control level to activate the ESV. The acceptance ranges are +/- 10 seconds for each level (90-110 for 100 second ESV, and 290-310 seconds for the 300 ESV). When ESV passes QC, the LED screen displays “Passed”. You must test 2 levels of ESV for each 8-hour interval of patient testing.
5.3 LIQUID CONTROLS

Two levels of HepCheck liquid controls are performed each day of patient testing and with each new box of P214 glass activator reagent tubes. Level 1 with a lavender top and level 2 with a green top represent normal and abnormal controls. Each box contains one level of 15 dropper vials and 5 white protector sleeves.

Level 1 control: catalog# (PMM# 252494, Mfr. Cat# DCP214-N)
Level 2 control: catalog# (PMM# 85242, Mfr. Cat# DCP214-A)

Each plastic dropper vial contains a glass ampoule of dried bovine blood and diluent for reconstituting the control. Acceptance range is listed on the package insert.

Storage conditions:
1. Refrigerator at 2-8°C: Controls are stable until the expiration date printed on the box. Warm controls to room temperature before using.
2. Room temperature at 20-24°C: Controls are stable at room temperature for a maximum period of 4 weeks, but never to exceed the expiration date printed on the box. Write the new expiration date on the box if it is stored at room temperature and the new 4-week expiration date on the control box.

5.4 REAGENT TUBES

P214 (PMM# 46288, Mfr.Cat# P214)

This is a flip top plastic tube that contains a magnet and glass beads as the activator. Use this for monitoring patients on low to moderate doses of heparin (0 to 2 units per cc of blood.) ACT testing requires a sample volume of 0.4cc of fresh whole blood. Tubes are stored at room temperature until the expiration date printed on the box. Each box of tubes must be tested with two levels of liquid controls before using for patient testing. Acceptance range is listed on the control package insert. Each box contains 95 tubes.

5.5 DIGITAL TEMPERATURE VERIFICATION TUBE (Catalog # HR1003)

The digital temperature verification tube is used to verify the temperature of each testing well. Thermometer is calibrated and traceable to NIST and documentation kept by ITC. Tube is warmed for 10 minutes in each Hemochron well before reading the temperature. Acceptance limit is 37° ± 1°C.

6.0 SPECIMENS

6.1 SAMPLE VOLUME

P214 tubes require 0.4 cc of fresh whole blood.

6.2 ACCEPTABLE SAMPLES:

1. Fresh whole blood collected in a plastic syringe without an anticoagulant. Samples must be analyzed immediately. If testing is delayed, discard the sample.
2. If sample is drawn from a catheter or an indwelling line, discard line fluids before drawing test sample.
6.3 UNACCEPTABLE SAMPLES:

1. Samples drawn from an indwelling line contaminated with line fluids due to inadequate flushing before sampling.
2. Samples drawn in a syringe containing heparin.
3. Samples drawn from heparin line.
4. Samples drawn in a glass syringe.
5. Samples drawn but not tested immediately.

7.0 QUALITY CONTROL (QC)

7.1 POLICY

CLIA requires two levels of ESV (Electronic System Verification Tube) for every 8 hours of patient testing and two levels of liquid controls each day of patient testing. In addition, prior to using a new box of P214 tubes, two levels of liquid controls must be tested. Boxes of tubes that have passed QC must be clearly labeled and results documented. Take corrective action for QC failure and document in the HEMOCHRON QC log.

7.2 PROCEDURE FOR DAILY ELECTRONIC SYSTEM VERIFICATION CARTRIDGE (ESV)

Verify instrument performance with two levels of ESV. The 100 and 300 second controls mimic the conditions for testing patients on low to moderate levels of heparin. The HEMOCHRON Response is programmed to require two levels of ESV for every 8 hours of patient testing. The instrument displays the number of hours that the next QC is due.

1. Simultaneously press START 1 on the HEMOCHRON and the 100 second button on the ESV.
2. Wait for ESV to buzz and vibrate. The red light next to the control level indicates test initiation.
3. Insert ESV into Hemochron test well 1. The HEMOCHRON Response detector allows 60 seconds for tube insertion before it cancels the test and returns to the Start screen.
4. Enter operator pin # when prompted by display.
5. Enter ESV serial number when prompted by display.
6. When the ESV reaches its pre-programmed end point, it will beep.
7. If the instrument’s detection system is functioning correctly, the time displayed is within acceptance range and “Acceptable” is displayed on the HEMOCHRON Response screen.
8. Repeat procedure with 300 second control on Test Well 1.
9. Repeat above procedure with 100 and 300 control on Test Well 2.
10. The acceptable range for the 100 ESV is 90-100, and for the 300 ESV, the acceptable range is 290-310.
11. CORRECTIVE ACTION FOR UNACCEPTABLE ESV

a. If the screen prompt does not request an ESV number, remove ESV to cancel the test. The detector did not detect the ESV due to incorrect insertion. Repeat the test.

b. If the ESV exceeds the acceptable range, remove to cancel test. The acceptable range is +/-10 seconds of expected time. Repeat the test. Probable cause is insufficient pressure on control selection key.

c. ESV may need 2 new AA batteries. If the light indicators of all 3 controls levels flash for 15 seconds, the batteries are depleted and must be replaced. See maintenance section for battery replacement instructions.
d. If ESV yields an on-screen ERROR message, take the HEMOCHRON\textsuperscript{R} Response out of service. Contact POCT staff (353-1630) for technical advice, or to get a loaner instrument, or call ITC Technical Services at 1-800-631-5945 (MF 8am to 5pm EST) for technical advice.

7.3 PROCEDURE FOR DAILY LIQUID QC

POLICY
Test 2 levels of liquid controls each day of patient use and prior to using a new box of tubes. Liquid quality control is intended for verifying instrument, and test performance as well as operator technique. QC results must be within the acceptance range listed on the package inset before instrument or tubes are used for patient care.

EQUIPMENT
- Level 1 and Level 2 HepCheck.
- P214 reagent tube
- Gloves

HEMOCHRON\textsuperscript{R} Response PREPARATION
1. Press START if HEMOCHRON\textsuperscript{R} Response is not on.
2. Press Menu.
3. Press 2 for QC Selects.
4. Enter PIN# and press YES.
5. Select 1 for QC Normal or 2 for QC Abnormal.
6. Screen display:
   1. Lower ###
   2. Upper ###
   3. Lot #. ###
   Compare limits and lot number with that from the package insert. (Use the keypad to modify range and lot number, i.e. Press 1 to modify lower range, use keypad to enter range, press yes and repeat with upper range and lot number.)
7. Press YES to accept QC limits and lot number.
8. Press YES again to return to the test screen.
9. Control level is displayed in the upper left-hand corner of the screen. If this is incorrect, press MENU to modify.
10. QC levels, acceptance limits and lot numbers must be individually entered for each well.

LIQUID QC TESTING PROCEDURE
1. Remove required number of Level 1 and Level 2 controls from the refrigerator and warm to room temperature.
2. Tap P214 tube gently to shake the activator and magnet down to the testing zone.
3. Remove label from Level 1 control.
4. Hold the vial upright and tap gently to settle the ampoule and diluent to the bottom.
5. Insert the bottom of the vial into a white protector sleeve.
6. Crush the inner ampoule by either bending the vial over the edge of a table or by crushing the vial with your fingers. Immediately repeat the crushing action twice to ensure complete breakage of the glass ampoule.
7. Quickly tap vial to settle reagents to the bottom.
8. Immediately invert dropper vial end to end 10 times with a downward snapping motion of the wrist.
9. Shake contents down to the dropper end.
10. Remove and retain cap.
11. Immediately squeeze entire contents into a P214 tube.
14. Hold the tube vertically and flick the bottom 5-7 times to mix with the activator.
15. Tap tube gently to ensure that magnet is touching the bottom of the tube.
16. Insert tube into the testing well and turn until the detector light is illuminated.
17. At completion of testing, result is displayed on the screen.
18. If results are within the acceptance range, “Passed” is displayed under the result.
19. Repeat procedure with Level 2.
20. Follow department policy for documenting control results. Document all corrective action.
21. When performing QC on new box of tubes, write “QC OK”, date and your initials on the P214 box.

CORRECTIVE ACTION FOR UNACCEPTABLE RESULTS
1. If “Fail” is displayed, review and verify the following before repeating controls.
   a. Control level tested.
   b. Correct control level is selected on the HEMOCHRON® Response.
   c. Lot # and acceptance range listed on package insert corresponds with limits and lot number displayed by HEMOCHRON® Response.
   d. Expiration date of control and reagent tubes. Discard all expired controls and reagent tubes.
   e. Control and reagent tubes are stored within the temperature range recommended by the manufacturer.
   f. HEMOCHRON® Response test well is within 37 ± 1°C.
2. Probable causes
   a. Poor user technique.
      • Control material improperly prepared.
      • Ampoule not adequately crushed.
      • Control reagents not thoroughly mixed.
      • Delay testing upon control reconstitution.
      • Did not dispense entire contents into P214 tube.
   b. Delay in pressing START upon dispensing control.
   c. Using the incorrect reagent tube for HepCheck.
   d. Reagent tubes are defective. Do not use this box of tubes.
3. Repeat failed control.

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5. Repeat QC on new box or new lot of tubes.

7.4 CALIBRATION VERIFICATION
Calibration verification must be run twice per year (every six months) and must be run after any major service to the instrument.

8.0 PATIENT TEST
8.1 PROCEDURE FOR PATIENT TESTING
1. Press START to turn the HEMOCHRON® Response on.
2. Verify that ESV has been performed.
3. Prior to drawing patient sample, shake the activator down to the testing zone by gently tapping the bottom of the reagent tube.
4. Draw patient sample in a plastic syringe.
5. Open flip top of reagent tube.
6. Immediately dispense 0.4 cc of blood into the tube and simultaneously press START1.
7. Close the flip top.
8. Hold the top of the tube in an upright position and mix the blood with the activator by flicking with the other hand or by swirling the tube 5-7 times.
9. Insert tube into the Test Well 1.
10. Turn tube clockwise until the detect 1 light is green.
11. Enter operator pin number when prompted.
12. Enter patient ID (Medical Record Number) when prompted.
13. If the screen displays a previous patient ID, press YES to accept or use the keypad to enter a new patient ID. Press YES.
14. Test completion is indicated by the sound of a beep.
15. Time in seconds is displayed on the split screen that corresponds to the testing well.
16. Screen continues to display results until the tube is removed.
17. Record results.
18. A second ACT can be tested on Test Well 2 simultaneously.
19. To view previous results, press Menu and select Database.

8.2 REPORTING RESULTS
1. ACT is reported in seconds. Calculations are not necessary.
2. The reportable range is 80 to 1500 seconds.
3. Follow department policy for reporting and recording results.
4. Whenever a user identifies that an incorrect result has been reported, they are responsible for correcting/commenting the incorrect result (if possible), contacting the ordering provider, notifying them of the error, and documenting this notification, including the time and date, in the patient record.

8.3 REFERENCE RANGE
A baseline ACT is performed prior to giving patients heparin. The baseline value serves as reference for monitoring heparin therapy. The therapeutic target value is determined by the medical staff.
8.4 ABNORMAL RESULTS

Results less than 80 seconds or over 1500 seconds should be repeated immediately with a freshly drawn sample. ACT results that appear to be inconsistent with heparin therapy should be viewed as questionable and the test repeated immediately with a fresh whole blood sample.

9 MAINTENANCE

9.1 TEMPERATURE CHECK

The temperature is verified bi-annually with the HEMOCHRON® Digital Temperature Verification Tube (part #HR 1003).

1. Press menu1 to display Main Page 1.
2. Press 2, QC Select
3. Enter PIN
4. Press 4 run TVT
5. Insert Temperature Verification Tube into Test Well 1
6. Display counts down from 500 seconds to 0 seconds.
7. At 0 seconds, read the temperature on the verification tube without removing the tube.
8. Acceptance range: 37° ± 1° C.
9. Repeat on Test Well 2.
10. Corrective Action:
    a. DO NOT use the test well if temperature is not within the acceptance range.
    b. Document the problem and notify the supervisor.
    c. Contact POCT Coordinator (353-1630) for technical assistance or to get a loaner instrument, or ITC technical services at 1-800-631-5945 (MF 8am to 5pm EST) for troubleshooting advice.

9.2 REPLACING ESV BATTERY

1. ESV requires 2 AAA batteries. Replace both batteries at the same time. Do not mix old and new batteries.
2. Procedure for Replacing the ESV Battery:
   (1) Replace batteries when all three indicator lights flash for 15 seconds.
   (2) Battery will need to be replaced approximately every 3 months of continuous use.
   (3) Remove battery cover on the back of the ESV by pressing down and sliding it towards the top of the ESV.
   (4) Remove batteries and replace with 2 AAA batteries aligning the + and – poles to the corresponding markings in the chamber.
   (5) Replace battery cover.

10.0 TECHNICAL NOTES

10.1 OPERATOR PROGRAM OPTIONS

Operator can set the following options by pressing menu once.
1. Page 1: Patient ID, QC range and lot number, Prewarm Well, Database inquiry.
2. Page 2: Set data and print outputs, display options, supervisor options, and system test.

10.2 DATABASE INQUIRY

The HEMOCHRON® will display results with the reagent tube type, patient test record number, time, date, ACT time, patient ID, and operator ID.

10.2.1 QUERY OF ALL PATIENT TEST RECORDS

1. Press MENU once to display Page 1.
2. Press 4 for Database
3. Press 1 for Query Patient by test record number.
4. Number of patient records is displayed.
5. Enter a number to start the search and press yes.
6. The most recent record is given the highest number.
7. HEMOCHRON® Response will start record search from number entered.
8. Press the 0 key for a more recent test record.

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9. Press the 9 key for previous records.
10. Press cancel to return to DATABASE PAGE.
11. Press Cancel again to return to Menu Page 1.

10.2.2 QUERY BY PATIENT ID, OPERATOR ID, or DATE
1. Access Database.
2. Press 1 for Query Patient.
3. Press YES.
4. Press 1 for Search.
5. Press 1 for Patient ID, 2 for Operator ID, 3 by date.
6. Enter ID or date.
7. Press yes.
8. The most record test record is displayed.
9. Press 9 to display previous test records.

10.2.3 QUERY ALL QC RECORDS
1. Press Menu.
2. Press 4 to select Database.
3. Press 3 to select Query QC.
4. Total number of QC records displayed. Each well is able to store only 64 QCs.
5. Enter that number for the most recent QC.
6. Press YES.
7. To start the search, press 0 for the most recent QC.
8. Press YES.
9. Press 9 to display previous QCs.
10. Press Cancel to return to Database Page.
11. Press Cancel again to return to Menu Page 1.

10.2.4 QUERY QC by operator, date or QC type.
1. Press Menu.
2. Press 4 to select Database.
3. Press 3 to select Query QC.
4. Press YES.
5. Total number of QC records displayed. Each well is able to store only 64 QCs.
6. Enter that number.
7. Press 1 for Search.
8. Select one of the following:
   1-Operator ID
   2-Date
   3-Test Type (select reagent type to view liquid QC)
   4-ESV
   5-ESV S/N (serial number)
9. Most recent test record is displayed.
11. Press Cancel to return to Database Page.
12. To return to main menu, press cancel.

10.3 SUPERVISOR PROGRAM OPTIONS

Supervisor’s menu is displayed on 3 pages. Access to this menu requires entry of password. Menu is inaccessible during testing.

1. Press Menu key twice to display page2.
2. Press 4 to select Supervisor.
3. Enter password and press YES.

10.3.1 SUPERVISOR PAGE1 SETS THE DEVICE OPTIONS
1. Set time and date, display time and date format.
2. Auto shutdown time
3. Default reagent type.
4. Time must be reset for daylight savings and standard time.

10.3.2 SUPERVISOR PAGE 2 SETS QC LOCKOUT
1. Mandatory patient ID,
2. Mandatory operator ID
3. QC lockout
4. User ID maintenance.

10.3.3 SUPERVISOR PAGE 3
1. Erases patient database
2. Erases QC database
3. Specifies speed of data transmission to an external source.
4. See page 103 of Users Manual to program options.

10.3.4 USER ID MAINTENANCE
1. Press menu twice to access supervisor on page 2.
2. Press 4 for supervisor.
3. Enter passcode and YES.
4. Press Menu to display page 2.
5. Select 6 QC Lockout.
6. Select 5 User Maint.
7. Press:
   1-Print (if print function is set up)
   2-View
   3-Edit
8. To edit user, select 3.
9. Use the keypad to enter a user number. Instrument can store 40 users.
10. Enter:
   1-OID: a user ID number.
   2-PIN: enter a PIN number for the user. Users are required to enter their unique PIN number before the HEMOCHRON Response will display test results.
   3-Allow User: Press 3 to allow the user to test patient ACTs. Y is displayed for Yes, N for NO.
   4-Allow LQC: Press 4 to allow the user to test liquid controls. Y is displayed for Yes, N for NO.
   5-Allow ESV: Press 5 to allow the user to perform QC using the ESV. Y is displayed for Yes, N for NO.
11. When user maintenance is completed, press YES to return to the EDIT USER CODES page.
12. Press YES to return to the QC USER MAINT page.
13. Press YES to return to the QC LOCKOUT page.
14. Press YES several more times to return to the Start screen.

10.4 HEMOCHRON® Response DATABASE TRANSFER TO PC

ITC provides a software program, Data Manager V2.0 for downloading QC and patient records to a personal computer. The software requires a computer with at least a Pentium 100 MHZ microprocessor, 128 MB RAM for Windows NT, 50 MB of free hard disk space, a RS-232 serial port, RS-232 serial cable, CD-ROM drive, Excel for Windows 95 or higher, and Word Pad Editor for Windows 95 or higher. Follow installation instructions provided with software CD.

1. Connect RS 232 serial cable to a PC loaded with Data Manager.
2. Connect the other end of the serial cable to COM1 located in the back of HEMOCHRON Response.
3. Press START to activate HEMOCHRON® Response.
4. Press Menu twice to display MAIN PAGE 2.
5. Select 4 for supervisor.
6. Enter pass code and press YES.
7. Press Menu two times to display Page 2.
8. Select 4 for Commander HR.
9. Open HEMOCHRON Response Data Manager on the PC.
10. Follow instructions displayed on the monitor.
11. Select READ INSTRUMENTS from the Menu tab.
12. Transmission bar displays data transfer into Word Pad.
13. To view data, click on SELECT INSTRUMENT and VIEW DATABASE.
14. Select and copy QC and patient records and paste it into Excel.
15. Delimit data in Excel by selecting Text to Columns and space.
16. Select File and Save as. Name of the file should include Instrument ID, month and year.
17. Press Cancel on the HEMOCHRON® Response to return to the Main Menu.

11.0 LIMITATIONS AND PRECAUTIONS

The HEMOCHRON® Celite ACT test is intended for monitoring patients receiving heparin anticoagulation therapy. Values less than 80 or exceeding 1500 seconds are outside of the instrument reportable range. Test results greater than 1500 seconds should be immediately repeated with a freshly drawn sample.

ACT is affected by poor sample collection technique. When the sample is collected by venipuncture, use a two syringe technique to prevent tissue thromboplastin contamination. Care must be taken to adequately flush fluids from indwelling lines or catheters with patient blood before collection. Poor collection technique affects precision and accuracy.

The following conditions will affect ACT: hemodilution, cardioplegic solutions, hypothermia, platelet dysfunction, hypofibrinogenemia and other coagulopathies, partially clotted blood, and unsuspected heparin or warfarin therapy. Substances that interfere with ACT values include protease inhibitors such as aprotinin used to reduce post-operative bleeding during cardiopulmonary bypass surgery resulting in prolonged ACT.

Follow biohazard safety guidelines in the UCSF Environment of Care Manual for handling blood. Depose used tubes, syringes, and needles in the appropriate hazardous waste containers. Care must be taken in drawing blood sample and dispensing it into the reagent tube. Open the flip top completely before dispensing blood sample and close it securely before mixing the contents. The FTCA510 tubes are made of glass and can be broken or cracked if mishandled.

The A/C power plug should be inserted into an appropriate outlet. To unplug the instrument, firmly grasp the plug and pull. DO NOT remove the plug from the outlet by pulling on the cord.
## 12.0 ERROR CODES

The operator's manual lists error codes and corrective actions on pages 131 to 138. The following is a list of the most common errors.

<table>
<thead>
<tr>
<th>ERROR MESSAGE</th>
<th>CAUSE</th>
<th>CORRECTIVE ACTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>E2 PROM FAULT</td>
<td>The system detected an incorrect check sum.</td>
<td>System is inoperable and requires factory repair.</td>
</tr>
<tr>
<td>W1 LOW TEMP W2 LOW TEMP</td>
<td>Well temperature less than 36°C for 90 seconds.</td>
<td>Check temperature with temperature verification tube. Notify supervisor and contact ITC. Do not use that test well.</td>
</tr>
<tr>
<td>W1 HI-TEMP W2 HI-TEMP</td>
<td>Well temperature exceeds 38.5°C.</td>
<td>Check temperature with temperature verification tube. Notify supervisor and contact ITC. Do not use that test well.</td>
</tr>
<tr>
<td>STUCK MAGNET</td>
<td>Magnet is stuck against the center post in the tube.</td>
<td>If the timer is &lt;60 seconds pull out the tube and tap to re-position the magnet before inserting it back into the well. If timer is &gt;60 seconds, repeat test with new sample.</td>
</tr>
<tr>
<td>UNSTABLE MAGNET</td>
<td>Detector is unable to detect magnet.</td>
<td>Repeat test with new sample. Insure that the magnet is not stuck. Occasionally this is due to a defective magnet. If the problem persists, notify supervisor and ITC.</td>
</tr>
<tr>
<td>MEMORY FAULT</td>
<td>Malfunction in computer memory.</td>
<td>Notify supervisor and contact ITC. Do not use the instrument.</td>
</tr>
<tr>
<td>FAULT-1500</td>
<td>Assay time exceeded maximum time. The well collar may be broken.</td>
<td>Test a blank tube in the well. If it rotates, repeat test with a new sample. If the tube does not rotate, notify supervisor and contact ITC.</td>
</tr>
<tr>
<td>ESV TIMED OUT</td>
<td>ESV exceeded 8 hours.</td>
<td>Test two levels of ESV before testing patient samples.</td>
</tr>
<tr>
<td>CLOCK FAULT</td>
<td>System real time clock is not operational.</td>
<td>Notify supervisor and contact ITC. Do not use the instrument.</td>
</tr>
<tr>
<td>WELL FAILED CALIBRATION</td>
<td>Test well detectors are not functional.</td>
<td>Notify supervisor and contact ITC. Do not use that test well.</td>
</tr>
<tr>
<td>W1 MOTOR SLOW W2 MOTOR SLOW</td>
<td>Malfunction of well motor.</td>
<td>Notify supervisor and contact ITC. Do not use that test well.</td>
</tr>
<tr>
<td>W1 MOTOR FAST W2 MOTOR FAST</td>
<td>Malfunction of well motor.</td>
<td>Notify supervisor and contact ITC. Do not use that test well.</td>
</tr>
<tr>
<td>RTC/CPU CLOCK ERROR</td>
<td>System real time clock is not operational.</td>
<td>Notify supervisor and contact ITC. Do not use the instrument</td>
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2. Notify your supervisor, or call POCT staff (353-1630) to arrange for technical assistance. Alternatively, you can call ITC technical services at 1-800-631-5945.
3. If the instrument must be returned to ITC for repairs, notify the POCT Coordinator (3-1630), requesting a POCT loaner and return of the broken HEMOCHRON® to ITC. As per HIPPA guidelines and patient confidentiality, all patient data will be downloaded by POCT staff, and then patient data erased from the instrument to be sent to ITC.
4. The university has service contracts on all Hemochrons on the patient units.
5. The POCT Coordinator will arrange for verifying the functionality of the analyzer prior to patient testing when the HEMOCHRON® Response is returned for repairs. This includes running both LQC levels, and ESV controls, as well as successfully running...
(within 20% of each other) at least 5 patient correlations against the gold standard instrument.

13.0 REFERENCES


ITC, HEMOCHRON® Reagent Tube package insert, Edison N.J., 06/05

ITC, HEMOCHRON® CPL1, CPL2 Quality Control Package Insert, Edison N.J., 06/05
# PROCEDURE REVIEW SHEET

**Procedure Title:** Activated Clotting Time  
**HEMOCHRON® Response P214**  
**Version:** 1.3  
**Author:** Sandra Tye  
**Date:** 05/03/2002  
**Director:** Tim Hamill, M.D.  
**Date:** 05/03/2002  
**In Use Date:** 05/03/2002  
**Discontinued Date:**  

**ACTION:** Reviewed or Revised/Approved  

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<th>Tim Hamill, M.D.</th>
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<td>Action Reviewed</td>
<td>Signature</td>
<td>Betty Yalich</td>
<td>03/18/2003</td>
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<tr>
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<td>Signature</td>
<td>Carrie Oto</td>
<td>01/16/2005</td>
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<td>Tim Hamill, M.D.</td>
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<td>Tim Hamill, M.D.</td>
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<td>Signature</td>
<td>Kristin Jensen</td>
<td>09/08/2009</td>
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<td>Tim Hamill, M.D.</td>
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<td>Tim Hamill, M.D.</td>
<td>03/19/2010</td>
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<td>Signature</td>
<td>Tim Hamill, M.D.</td>
<td>04/30/2011</td>
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<td>Action Revised</td>
<td>Signature</td>
<td>Cynthia Ishizaki</td>
<td>12/03/12</td>
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<td>Action Approved</td>
<td>Signature</td>
<td>Tim Hamill, M.D.</td>
<td>12/6/2012</td>
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**SEE SIGNATURE MANIFEST**
Revised Hemochron Response P214

SR Sup Review

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Med Dir Apprvl

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