

# HEMOCHRON®

Whole Blood Microcoagulation Systems

**Prothrombin Time (PT)**  
NCCLS Formatted Procedure

International Technidyne Corporation

**Procedure: HEMOCHRON® Jr. Prothrombin Time (PT) Test**

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Refer to the appropriate model HEMOCHRON® Jr. (HEMOCHRON Jr., HEMOCHRON Jr. Signature or HEMOCHRON Jr. II) Operator's Manual and PT package insert for complete instructions for test and instrument performance.

## **I. PURPOSE:**

The HEMOCHRON Jr. Prothrombin Time (PT) is a unitized microcoagulation test intended for in vitro diagnostic use in performing a quantitative, one-stage assay for monitoring Coumadin® anticoagulation. The PT, a test of the extrinsic coagulation pathway, is performed using a fresh whole blood sample on any model HEMOCHRON Jr. instrument (including HEMOCHRON Jr., HEMOCHRON Jr. II and HEMOCHRON Jr. Signature analyzers). It is intended for use during procedures and therapeutic interventions that require monitoring of oral anticoagulants and for hemostasis assessment before or after blood transfusions. The HEMOCHRON Jr. PT is performed using fresh whole blood at the patient bedside to ensure accurate assessment of patient homeostasis.

## **II. PRINCIPLE:**

All HEMOCHRON Jr. microcoagulation systems utilize a mechanical endpoint clotting mechanism in which testing occurs within the disposable PT cuvette. Following whole blood sample introduction, the instrument precisely measures 15 microliters of blood and automatically moves it into the test channel of the PT 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, eliminating the need for operator interaction. After mixing with the reagent, the sample is then moved back and forth within the test channel and monitored by the analyzer for clot formation.

The HEMOCHRON Jr. utilizes a clot detection mechanism that consists of two LED optical detectors aligned with the test channel of the cuvette. The speed at which the blood sample moves back and forth between the two 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. Electronic optical detection of a fibrin clot in the blood sample automatically terminates the test. The instrument reports the whole blood number mathematically converted to International Normalized Ratio (INR) and plasma equivalent value in seconds in order to provide a familiar clinical format and thus facilitate accurate clinical test result interpretation. The whole blood PT time may be obtained by depressing and holding the "START" button on any model HEMOCHRON Jr.

## **III. SPECIMEN:**

### **A. Patient Preparation:**

***NOTE: Blood samples must not be collected until the instrument display indicates "Add Sample" And "Press Start".***

Blood collection guidelines are described in NCCLS document H21-2A, "Collection, transport, and preparation of blood specimens for coagulation testing and performance of coagulation assays."

## B. Type:

The HEMOCHRON Jr. PT is optimally performed using 0.05cc of **fresh whole blood**. The cuvette requires a minimum volume of 15µl to perform the analysis, and will display a "Sample too small" if insufficient sample is applied. Samples with any of the following characteristics should be discarded immediately, and a **fresh whole blood** sample collected prior to performing any test on any model HEMOCHRON Jr. analyzer.

1. Sample contamination with tissue thromboplastin.
2. Sample contamination with indwelling intravenous (i.v.) solutions.
3. Sample contamination with alcohol cleansing solution.
4. Samples with visible clotting or debris accumulation.

Blood samples demonstrating any of the above may interfere with the PT assay.

## C. Collection Procedure/Handling Conditions:

If a syringe is used, it should have a 23 or 21 gauge needle. DO NOT use excessive force when expelling the blood specimen through the needle. This may lead to sample hemolysis.

Blood samples to be used for coagulation testing must be collected according to the following procedures to assure the integrity of the fresh whole blood sample.

### Syringe sample, from indwelling line:

***NOTE: The amount of blood 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 5.0 cc to clear the line. Greater volumes will be required to clear longer lines.***

1. Using a 1cc (tuberculin) or 3cc syringe, collect a minimum 0.2cc of fresh whole blood from a previously flushed access port. Do not allow bubbles to form in the syringe.
2. **Immediately** dispense one drop of fresh whole blood into the sample well of the test cuvette, filling from the bottom of the well up. This may be done either with or without a transfer needle. A sufficient quantity of blood must be added directly to the center of the sample well to fill it flush to the top. Should a large drop of blood extend above the top of the center sample well, push it over into the outer sample well.
3. See section VI to perform the test.

### Syringe sample, 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 2.0cc of blood and discard.
3. Obtain a minimum 0.2cc of blood with the second syringe.
4. Immediately dispense one drop of blood into the center sample well of the test cuvette, filling from the bottom of the well up. This may be done either with or without a transfer needle. A sufficient quantity of blood must be added directly to the center of the sample well to fill it flush to the top. Should a large drop of blood extend above the top of the center sample well, push it over into the outer sample well.
5. See section VI to perform the test.

### **Fingerstick sample**

1. Insert the cuvette into the cuvette opening on the side of the instrument.
2. During instrument warming, massage and warm the patient's finger to increase blood flow.
3. When the analyzer displays "Add Sample"... "Press Start", obtain a fingerstick sample. After five minutes, a "START timeout" message will appear if sample is not added to the cuvette.
  - a. Cleanse the fingertip with an alcohol swab and allow to air-dry.
  - b. Incise the fingertip with an incision device. The ITC Tenderlett is recommended since it makes a small incision rather than a puncture, resulting in better blood flow.
  - c. Wipe away the first drop of blood using a sterile gauze.
  - d. Massage the finger from base to tip collecting the sample by touching the blood to the chute of the well. Sample volume should be sufficient to fill the well flush to the top.
  - e. Depress the START key.

### **IV. EQUIPMENT/MATERIALS/REAGENTS:**

The HEMOCHRON Jr. PT test cuvette is a self-contained disposable test chamber preloaded with a dried preparation of kaolin, phospholipid, stabilizers and buffers. Each cuvette is individually packaged in a foil pouch with a desiccant. Each box contains 45 individually pouched cuvettes. Cuvette pouches are stamped with a lot specific expiration date.

***CAUTION: All used cuvettes should be considered as potentially infectious, handled with care and disposed of by following standard waste facility disposal policy.***

#### **A. Equipment:**

1. HEMOCHRON Jr. Microcoagulation Instrument (including HEMOCHRON Jr., HEMOCHRON Jr. II or HEMOCHRON Jr. Signature models)
2. Transformer (9 volt)

#### **B. Materials:**

1. Preloaded HEMOCHRON Jr. PT test cuvettes
2. Plastic syringe (1cc or 3cc) with a 23 or 21 gauge transfer needle (optional)
3. Fingerstick device
4. Fresh Whole Blood Sample
5. Biohazard Disposal Receptacle

#### **C. Reagent Preparation:**

No reagent preparation required

#### **D. Storage Requirements:**

When refrigerated (2-8°C), the foil-pouched PT cuvette is stable until the marked expiration date.

Room temperature storage (15-30°C) is optional for sealed-pouched cuvettes. Room temperature cuvettes are good for a maximum of four weeks, but must never exceed the marked expiration date. Re-dating is necessary if stored at room temperature. A re-dating label is included on the side panel of each box of cuvettes and should be completed.

Once a pouch is opened, the cuvette (stored in the folded pouch) is stable for seven days under refrigerated (2-8°C) conditions.

HEMOCHRON Jr. cuvettes should not be exposed to temperatures in excess of 37°C.

## V. QUALITY CONTROL:

The Joint Commission of Accreditation of Healthcare Organizations recommends that medical and laboratory instrumentation be enrolled in a quality assurance program adequate in maintaining accurate and reliable performance of the equipment. Complete records of all quality control must be organized and kept.

Routine quality control testing and tracking should be a part of a comprehensive quality assurance program. HEMOCHRON Jr. Microcoagulation System Quality Control products are available to make routine QC convenient and affordable. All HEMOCHRON Jr. microcoagulation instruments should be quality controlled at two levels of performance, including both the normal and abnormal ranges. Quality control should be performed once every 8 hours on any shift during which the instrument is to be used.

The manufacturer's quality control protocol is described below. Each institution may adopt the manufacturer's suggested protocol or may be required to comply with an alternative protocol specified by local authorities.

### A. Electronic Quality Control:

To assist in accomplishing daily QC, both normal and abnormal Electronic System Verification Cartridges are available to provide a two level check of the instrument. The Electronic System Verification Cartridges should be performed once every 8 hours on any shift during which the instrument is utilized. This will ensure proper instrument operation.

A temperature verification cartridge is also provided to verify that the HEMOCHRON Jr. microcoagulation instrument is maintaining the proper temperature ( $37^{\circ} \pm 1.0^{\circ} \text{C}$ ). Any errors found in the temperature control system of the instrument will also be displayed on the LCD screen.

### B. Use Of The Electronic System Verification Cartridge:

1. Insert an electronic system verification cartridge into the cuvette slot on the side of the instrument. The instrument will enter a QC mode indicated by an "E-QC...TEST" message appearing on the display. The instrument will then perform an internal diagnostic check similar to the system check performed upon test cuvette insertion. The optical and mechanical sensors, pump, and heater system will be checked. Any errors found in these systems will be displayed followed by a series of audible beeps. If the system is verified as functioning normally, the screen will display an "INSTRUMENT OK" message. This message will remain on the screen for two seconds. The message "Press E-QC" and "Start Now" will then appear alternately on the display.
2. Depress only the electronic QC START button on the cartridge. The electronic system verification cartridge will simulate an endpoint at a predetermined time interval. A result, in seconds, will be displayed.
3. The instrument should detect the simulated endpoint within the acceptable range shown on the system verification cartridge. Compare the result displayed to the label on the cartridge.
4. Record results in the log book.

**NOTE: If any electronic QC procedure yields an on-screen ERROR message, or if the electronic system verification cartridge failed to yield the desired results, discontinue use of the instrument for clinical diagnostic purposes and contact the ITC Technical Services Department (1-800-631-5945) for assistance.**

### C. Quality Control of The HEMOCHRON Jr. Test Cuvettes:

Each box of the HEMOCHRON Jr. test cuvettes should be validated at least once prior to use. (Note: If multiple boxes are received within the same shipment, it is recommended to validate each box prior to use.) This can be accomplished using the appropriate Whole Blood Quality Control or *directCHECK*® Whole Blood Quality Control products and the test procedure provided in the Quality Control package inserts. Acceptable performance ranges for the HEMOCHRON Jr. test cuvettes are published on the back page of the Quality Control package. After each individual box of HEMOCHRON Jr. test cuvettes has been verified, the "Performance Verified" table provided on the side panel of each cuvette box should be completed. This box is now "IN CONTROL" and will not require any further liquid quality control until either a new box of reagents is received, or a shift in clinical results is experienced.

### D. Procedure For Performing Liquid Quality Control Tests:

#### Whole Blood Control

1. Remove the PT cuvettes, control vials, diluent vials and calcium chloride vials from the refrigerator and allow them to come to room temperature (15-30°C). This could require up to 60 minutes.
2. After the vials have reached room temperature, dispense against the vial wall exactly 0.5cc from the diluent vial into the lyophilized control vial. Gently swirl the vial on the counter top until the lyophilized preparation is completely wetted. Allow the vials to stabilize at least 15 minutes at room temperature. Rehydrated vials are stable for approximately one hour.
3. Insert cuvette (room temperature) into the cuvette slot on side of instrument.
4. During pre-warm stage, observe for fault/warning messages.
5. The instrument will signal ready with an audible tone, the display indicating "Add Sample" and "Press Start".
6. Swirl control vial to ensure that control material is completely dissolved and no clumps are present.
7. Dispense 0.2cc of the calcium chloride into a clean control vial. While maintaining the syringe needle in the vial, invert the vial and gently agitate the vial end to end approximately 3 times, avoiding bubbles. Gently aspirate approximately 0.3cc of the whole blood control into the same syringe and dispense immediately back into the control vial, to ensure complete removal of calcium chloride from syringe. Immediately fill the same syringe with approximately 0.3cc of whole blood control.

***NOTE: Once calcium chloride is added to the control vial, the sample should be used immediately as clotting will occur.***

8. Dispense the whole blood control into the cuvette sample well, filling the center well from the bottom up with the needle. Do not generate air bubbles in the sample well. A sufficient quantity of whole blood control must be added to fill the center well flush to the top. Should a large drop of blood extend above the top of the center sample well, push it over into the outer sample well.
9. Press the START key.
10. Wait for a single beep signaling the conclusion of the test.

11. Results are displayed as the plasma equivalent value and INR. Report results.
12. Compare the result with the acceptable range for each level of quality control reagent as published on the back page of the package insert in each box of quality control material. (These ranges are Lot # specific and may vary slightly from lot to lot.)

### ***direct*CHECK Whole Blood Control**

1. Remove the PT test cuvettes and the *direct*CHECK vials (Abnormal and Normal) from the refrigerator and allow them to come to room temperature prior to testing. This could take up to 60 minutes.
2. After the reagents have reached room temperature, insert the APTT cuvette into the cuvette slot on the side of the instrument.
3. During the pre-warm stage, observe the display for any fault/warning messages.
4. The instrument will signal when ready with an audible beep, and display alternating messages, "Add Sample" and "Press Start".
5. Remove the top of the plastic seal from the *direct*CHECK vial.
6. Insert the *direct*CHECK vial into the white protective sleeve.
7. Holding the vial upright, tap the *direct*CHECK vial on the table top to settle the inner glass ampule to the bottom of the vial.
8. Crush the inner glass ampule by either bending the vial over the edge of a table top or by crushing the vial between two fingers.
9. Immediately repeat this crushing action one to two more times.
10. Quickly invert the dropper vial end to end 10 times.
11. Remove and retain the vial cap.
12. While inverting the vial (dropper tip down), use a downward snapping motion of the wrist to ensure the control material flows to dropper tip.
13. Squeeze the vial to discard the first drop of control material into the vial cap.
14. Immediately dispense as many drops of control material as needed to fill the cuvette sample well flush to the top. Should a large dome extend over the top of the center sample well, push it over into the outer sample well.
15. Press the START key.
16. Wait for a single beep signaling the conclusion of the test.
17. Results are displayed as plasma equivalent values. Record results.
18. Compare the result with the acceptable range for each level of quality control reagent as published on the back page of the package insert in each box of quality control material. (These ranges are Lot # specific and may vary slightly from lot to lot.)

#### **E. Out-Of-Range Quality Control Procedure:**

1. In cases where quality control results are outside of an acceptable range, the cause is likely attributable to one of the following categories:
  - a. Test Technique
  - b. Control Material
  - c. Test Cuvette
  - d. Instrument
2. If results are outside of the acceptable range, the following items should be verified immediately:
  - a. Control material and cuvette expiration dates
  - b. Instrument temperature
  - c. Proper technique
  - d. Cuvette sample volume
  - e. Presence of clots in the control material
3. If none of the above parameters are suspect, repeat the test using control materials with the identical lot number.
4. If this repeat does not fall within the expected range, verify the above (a-e) parameters again. Obtain a cuvette from a different lot number and repeat the test using a control with the same lot number.
5. If this repeat test still does not fall within the expected range, notify the Department Supervisor (ie. Cardiac Cath Lab Coordinator, Point-of-Care Coordinator, Lab Supervisor etc.) or, in their absence, the Director.
6. Obtain control material with a different lot number, and repeat the controls again.
7. If this repeated control does not fall within the expected range, contact the Laboratory consultant or ITC Technical Services.
8. Document out-of-range results on the Quality Control worksheet.
9. The instrument/cuvette combination must not be used until control values obtained are within range.

Both the electronic and liquid whole blood quality control products are helpful when an instrument problem is suspected. It is recommended that multiple tests be performed with the quality control products, and that the data be discussed with the ITC Technical Service Department (1-800-631-5945) prior to sending an instrument to ITC for service.

#### **F. Use Of The Temperature Verification Cartridge:**

1. Insert the temperature verification cuvette into the HEMOCHRON Jr. analyzer. The instrument will enter a QC mode indicated by an "EQC...TEST" message appearing on the display, and subsequently perform an internal diagnostics check, which includes the optical and mechanical sensors, pump, and heater systems. Any errors in these systems will be displayed followed by a series of audible beeps.
2. If the system is verified as functioning normally, the screen will display "INSTRUMENT OK". This message will be followed by: "Priming Pump" and "Warming".
3. Once temperature has been reached, "Remove E-QC" and "Read E-QC Temp" will appear on the display alternately. At this time the temperature verification cuvette

should be removed from the instrument and the illuminated temperature (on the cuvette) observed. The temperature should be  $37^{\circ} \pm 1^{\circ}\text{C}$ . This indicates that the temperature control system is functioning normally.

**NOTE: After the temperature verification cartridge is removed, a “Cuvette Removed” message is displayed; this is normal.**

## **VI. QUANTITATIVE STEP BY STEP TEST PROCEDURE: PT**

The HEMOCHRON Jr. Microcoagulation Instrument can be operated either on its internal battery or plugged into an AC outlet. The HEMOCHRON Jr. is operated by inserting a cuvette into the instrument, allowing it to warm, introducing a whole blood sample and depressing the START key. The correlated plasma equivalent value will be displayed and will remain on the screen until the test cuvette is removed. Once the cuvette is removed from the instrument, the test result will be displayed for an additional 120 seconds.

**NOTE: Refer to “TROUBLESHOOTING” in the appropriate HEMOCHRON Jr. II or Jr. Signature Operator’s Manual should a fault message appear on the display at any time during this procedure.**

1. Insert the PT cuvette into the cuvette opening on the side of the instrument. The instrument will automatically identify the test cuvette inserted and display the test chosen. This initiates the pre-warm/self-check mode (approximately 30 seconds).
2. During pre-warm stage, observe the display for any fault messages.
3. The instrument will signal when ready with an audible tone, and the screen will display the alternating messages “Add Sample” and “Press Start.” The instrument will remain in the ready mode for five minutes. At the end of five minutes, a “Start timeout” will occur indicating that the current cuvette must be discarded and a new cuvette placed in the instrument.
4. Obtain the fresh whole blood (0.2cc) sample (refer to Specimen Collection Procedure/Handling Conditions).
5. **Immediately** dispense one drop of blood into the sample well of the prewarmed PT test cuvette. Fill the sample well from the bottom up with whole blood. This may be done either with or without a transfer needle. A sufficient quantity of blood must be added directly to the center of the sample well to fill it flush to the top. Should a large drop of blood extend above the top of the center sample well, creating a dome, simply push it over into the outer sample well.

**NOTE: When transferring blood into the sample well, DO NOT force blood into the pin located on the center of the sample well, and DO NOT generate air bubbles in the sample well.**

6. Depress the START key.
7. Test completion will be indicated by a single beep.
8. PT results are automatically displayed as the plasma equivalent value and INR. Record Results.

## VII. READING/REPORTING RESULTS:

The chart below provides performance data on the HEMOCHRON Jr. Microcoagulation instruments. Refer to the specific assay's package insert for detailed product information. Values shown for PT are International Normalized Ratios (INR).

Test	Catalog #	Reagent	HEMOCHRON Jr. model	Blood Volume	Mean Normal (secs ± SD)	Normal Range (sec)	Use
APTT	J103	kaolin, platelet factor substitute	HEMOCHRON Jr. II or Jr. Signature <b>only</b>	0.015ml	31.0 ± 3.9	23.2 <sup>1</sup> -38.7	Monitoring heparin (up to 1.5 units/ml) and screening for intrinsic factor coagulopathies
PT	J201	thrombo-plastin	Any model: HEMOCHRON Jr. (ISI = 2.0) or HEMOCHRON Jr. II and HEMOCHRON Jr. Signature (ISI = 1.0)	0.015ml	INR 1.3	INR Jr. 1.0-1.4 Jr. II/Jr. Signature 0.8-1.4	Monitoring oral anticoagulant therapy and screening for extrinsic factor Coagulopathies
ACT-LR	JACT-LR	Celite, potato dextrin	Any Model HEMOCHRON Jr. analyzer	0.015ml	131.0 ± 9 <sup>2</sup> 129 ± 20 <sup>3</sup>	113-149 <sup>2</sup> 89 - 169 <sup>3</sup>	Monitoring low to moderate dose heparin anticoagulation
ACT+	JACT+	silica, kaolin phospholipid	Any Model HEMOCHRON Jr. analyzer	0.015ml	103.0 ± 11 <sup>2</sup> 124 ± 14 <sup>3</sup>	81-125 <sup>2</sup> 96 - 152 <sup>3</sup>	Monitoring moderate to high dose heparin anticoagulation

<sup>1</sup> Plasma equivalent APTT values less than 20 seconds are not routinely available and should be reported as "less than 20 seconds."

<sup>2</sup> Normal range generated from normal volunteer donors.

<sup>3</sup> Normal range generated from hospitalized patients not receiving heparin.

### A. Reporting Results/Result Format

1. Upon test completion, immediately report all test results to the Physician who ordered the APTT test.
2. Results will be reviewed daily.

### B. Procedures for Abnormal Results

1. Whole blood PT test results under 15 seconds (HEMOCHRON Jr. model) or INR values < 0.5 (HEMOCHRON Jr. II or HEMOCHRON Jr. Signature) indicate excessive blood coagulation activation, possibly due to specimen collection or processing, and should be repeated.
2. Results that appear to be inconsistent with patient therapy should be viewed as questionable and the test should be immediately repeated.

## VIII. PROCEDURAL NOTES:

1. The transformer provided should be plugged into an appropriate outlet to charge the instrument when it is not in use to maintain the battery power level. To unplug the instrument from the transformer, firmly grasp the plug and pull. DO NOT remove the plug from the instrument by pulling on the cord. Although the transformer can be left plugged into an AC outlet when the instrument is unplugged, it is recommended that the transformer be unplugged from the AC outlet when it is not being used to charge the batteries or run the instrument.
2. DO NOT use cuvettes past their expiration date or cuvettes that have been stored improperly.
3. 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 Maintenance)
4. DO NOT use excessive force in depressing the START key.
5. DO NOT drop the HEMOCHRON Jr. microcoagulation instruments
6. DO NOT expose the HEMOCHRON Jr. microcoagulation instruments to extremes in temperature (above 37° C). Such exposure could affect the performance of any type of electronic equipment.
7. The HEMOCHRON Jr. microcoagulation instruments are designed for use only with HEMOCHRON Jr. test cuvettes. Test cuvettes must be properly stored according to the instructions in the appropriate HEMOCHRON Jr. test package insert.
8. The HEMOCHRON Jr. test results 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 sample collection and the transfer of the blood to the test cuvette. Tests may be affected by any of the following conditions:
  - a. Foaming of the sample (air bubbles)
  - b. Hemolysis
  - c. Clotted or partially clotted blood
  - d. Unsuspected anticoagulation with either heparin or warfarin
  - e. Presence of a lupus anticoagulant
9. All biohazard safety guidelines pertaining to the handling of human blood, such as the CDC guidelines of Universal Precautions, should be strictly adhered to when collecting, handling blood specimens and operating the HEMOCHRON Jr. microcoagulation instruments. Refer also to NCCLS standards H21-A2 and H29-A2.
10. Used HEMOCHRON Jr. test cuvettes should be considered as potentially infectious. They should be handled according to individual institutional policies concerning the disposal of potentially infectious materials.
11. The HEMOCHRON Jr. microcoagulation instruments are not rated for use in explosion proof areas.

## **IX. LIMITATIONS:**

The HEMOCHRON Jr. PT test is intended for use in monitoring patients receiving oral anticoagulation/warfarin therapy. Whole blood PT test results under 15 seconds (plasma equivalent value = 10.5 sec.) or over 170 seconds are not reported on the HEMOCHRON Jr. microcoagulation instrument. Instead, a “PT<10.4 sec, Repeat” or “PT – P>80 sec” message is displayed. Whole blood PT test results under 15 seconds (plasma equivalent values 10.3 sec.) or over 76 seconds are not reported on the HEMOCHRON Jr. II or HEMOCHRON Jr. Signature models. Instead, an “INR <0.8” or “INR >10” message is displayed.

Samples with hematocrits less than 20% or greater than 55% may exhibit an optical density outside the level of detection of the HEMOCHRON Jr. microcoagulation instruments. In such cases, a “Sample Not Seen” error message will be displayed.

As with all diagnostic tests, HEMOCHRON Jr. Microcoagulation System test results should be scrutinized in light of a specific patient’s condition and anticoagulant therapy. Any results exhibiting inconsistency with the patient’s clinical status should be repeated or supplemented with additional test data.

## **X. MAINTENANCE:**

### **A. Routine Maintenance**

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 a dry cotton swab. If a disinfectant is needed, use a 0.5% solution of sodium hypochlorite or a 10% household bleach solution. Apply solution to clean towel or cloth and disinfect areas contaminated with residual dried blood. DO NOT use solvents or strong cleaning solutions as they may damage the instrument’s plastic components.

Routine maintenance other than cleaning is normally not required.

### **B. Service**

The HEMOCHRON Jr. microcoagulation instruments are almost completely self-monitoring; automatically monitoring internal circuitry and reporting problems to the display screen. Malfunctions are indicated by fault messages detailed in the section on “TROUBLESHOOTING” in the appropriate HEMOCHRON Jr. Operator’s Manual.

### **C. Battery Care**

HEMOCHRON Jr. Microcoagulation Instruments can be operated either on internal battery or plugged into an AC outlet using the supplied transformer. HEMOCHRON Jr. analyzers should be allowed to charge for a full 16 hours prior to using the instrument for the first time.

To optimize battery life, it is recommended that the HEMOCHRON Jr. microcoagulation instrument be run on its battery during the day. It can be plugged into a standard AC current overnight to allow the batteries to recharge. The life of the nickel-cadmium battery cells is optimized when the battery is exercised in this manner. A fully charged battery will operate for approximately 49 average test cycles of approximately 150 seconds.

The “Battery is Low” message will appear on the display screen at the beginning of a test to alert the user if the battery is running low. At this point, the instrument has approximately ten minutes of battery time remaining to perform coagulation testing.

Once this message appears, plug the instrument as soon as possible.

When the batteries are drained to the point that valid testing may not be performed, the instrument will display "CHARGE BATTERY". At this point, the instrument must be plugged in for operation and recharging. Once plugged into an AC outlet, the instrument can be utilized, and testing resumed.

### **C. Instrument Downtime**

During instrument downtime, patient samples will be run on alternate HEMOCHRON Jr. instruments. If all instruments are down, patient samples will be run in the clinical laboratory.

## **XI. PROFICIENCY TESTING:**

Proficiency testing (currently available through CAP) will be performed at least twice per year on the primary and secondary machines using whole blood samples obtained from an outside testing institution. The results will be returned to the outside testing institute by the specified date. If the results from both the primary and secondary machines are not at least 80% acceptable, the unacceptable grade will be reported to the Technical Consultant or Medical Director.

## **XII. EMPLOYEE CERTIFICATION:**

Employee certification is completed upon inservicing, and should be renewed every six months for all certified operators of the HEMOCHRON Jr. Documentation of certification is maintained in the employee's personnel folder.

## **XIII. REFERENCES:**

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