**Wake Forest Baptist Medical Center**

**Policy and Procedure Bulletin**

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**Subject: HMS Plus Hemostasis Management System Version 4.0**

**Wake Forest Baptist Medical Center**
**Department of Pathology**
**Point of Care Testing**
**Policy and Procedure Bulletin**
**PPB-NCBH-LAB-775-23**

## HMS Plus Hemostasis Management System Version 4.0
## Policy and Procedure Review/Modifications

| Date | Page | Review/Modification/Action | Approved By: |
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## I. POLICY

The Department of Pathology at Wake Forest Baptist Medical Center (WFBMC) is responsible for overseeing explicitly identified non-waived laboratory testing (as defined by CLIA) performed in clinical areas by non-lab personnel. Specific testing sites have been identified and included under the CLIA certificate of the WFBMC Department of Pathology for a highly complex lab. Testing policies and procedures must meet all regulatory guidelines established by CLIA and the accreditation standards established by the College of American Pathologists (CAP). This is to ensure that all lab testing is performed according to manufacturer's recommendations and that each employee follows the same quality control and patient testing procedures. All testing should have a documented physician order. Information not discussed in this policy may be found in the Medtronic HMS Plus Operator's Manual and related package inserts for the cartridges and quality control (QC) material.

**Results may vary with different ACT methods and clot activators.** EXTREME caution should be used if there is a need to switch between ACT methods and clot activators. (For example, Medtronic to Hemochron or i-STAT)

## II. PURPOSE and PRINCIPLE

The HMS Plus Hemostasis Management Systems is a microprocessor-based, multi-channel, clot detection system. It employs an automated dispensing mechanism for introduction of whole blood samples into single use test cartridges. The endpoint of the test is clot formation. This is detected by the change in drop rate of the plunger/daisy assembly of each test cartridge channel. This change in drop rate is detected by a photo-optical system, and the clotting time for each channel is recorded.

The HMS Plus performs the following tests, which are used in the management of patients receiving heparin.

### A. Heparin Dose Response (HDR):

The patient's activated whole blood clotting time is measured at baseline (without heparin) and in the presence of 1.70 and 2.84 units/ml of heparin. The difference in these clotting times is the in-vitro response of the patient's blood to heparin (slope). Results from the Heparin Dose Response test include: the patient's baseline ACT and the projected heparin concentration (based on the patient's blood volume, the dosing protocol, and extracorporeal circuit parameters). The HMS Plus also calculates the amount of heparin required to reach the target ACT and Projected Heparin Concentration. The slope of the ACT clotting times is used to determine the patient's response to heparin, and help identify patients who are potentially sensitive or resistant to heparin.

### B. Heparin Assay (HPT):

The Heparin Assay by Heparin-Protamine Titration (HPT) determines the quantitative amount of heparin present in a blood sample by titration with protamine sulfate. Known quantities of protamine added to each cartridge channel react with the heparin present in the patient's blood sample. The amount of heparin present is determined based on the titration relationship between heparin and protamine. The HMS Plus uses this information to indicate additional heparin required to maintain the patient at the required heparin level. The instrument also calculates the amount of protamine sulfate required to neutralize the heparin.

### C. High Range ACT (HR-ACT):

The High Range ACT is a functional measure of the intrinsic and common pathway of the coagulation mechanism. Activation of Factor XII is initiated by surface contact with an activator (in this case, kaolin). The reagent concentration is optimized to produce a linear response to increasing amounts of heparin in high concentrations, consistent with the amounts required during coronary bypass procedures.

## III. RESPONSIBILITIES (of the testing site and Clinical Laboratory)

**A.** Refer to the Policy and Procedure Bulletin, "Understanding of Responsibilities Between Testing Sites and the Clinical Laboratory for Point-of -Care Testing" (PPB-NCBH-95) for related details.

**B.** See Appendix 1 for testing sites and personnel. Appendix A will be updated as necessary.

**C. LIS Operator ID Usage Information**

Upon satisfactory completion of training for the Medtronic HMS Plus, each user will be given a Laboratory Information System (LIS) identification number/tech code. This tech code is to be entered each time that the Medtronic HMS is used. This code is the equivalent of an electronic signature and is assigned exclusively for each operator. It should not be shared with anyone else, as this would be the equivalent of signing another persons name to work they did not do. The ID/tech codes are considered personal and confidential. This code allows tracing of testing personnel. Staff MUST confirm that they utilize their personnel code when performing testing.

**D.** All WFBMC compliance policies should be followed.

## IV. PROCEDURES

### A. SAFETY PRECAUTIONS/SAFETY EQUIPMENT

**1. Safety Equipment and Procedures**

- **a.** Gloves
- **b.** WFBMC approved safety re-sheathable needles
- **c.** Safety Shield-(Face or Stand Alone Shield) is provided.
- **d.** Gloves should be worn while collecting or analyzing any patient sample.
- **e.** Gloves should be worn while performing any function on the Medtronic HMS, including cleaning, maintenance, and performing quality control (QC) checks.
- **f.** Treat all blood samples, proficiency test materials, and quality control materials as a biohazard. Use Standard Precautions!
- **g.** Biohazard waste containers should be available for disposal of used cartridges or other blood/sample contaminated non-sharp equipment.
- **h.** All sharps should be discarded in WFBMC approved biohazard sharps containers.
- **i.** Germicidal wipes, fresh 10 % bleach, or WFBMC approved disinfectant should be used to decontaminate analyzers.
- **j.** When the Medtronic HMS is used in a sterile environment, such as an OR suite, the analyzer and all supporting equipment should be disinfected prior to and after use in the OR suite.

**2.** **The Medtronic HMS analyzer and related supplies should never come in contact with a patient.**

**3.** The analyzer **must be cleaned between each patient.**

**4.** Follow all WFBMC safety and infection control policies and procedures.

### B. SPECIMEN

**All specimens must be labeled/identified in the presence of the patient. Follow all applicable WFBMC policies related to patient identification.**

**1. Patient Preparation:**

- **a.** All tests: Blood may be obtained either by venipuncture or from arterial or venous access lines. See instructions below.
- **b. Venipuncture Collection:** The venipuncture must be fast and non-traumatic. The first 2 to 3 ml of blood should be collected in a

separate syringe and discarded in order to prevent contamination of the test sample with tissue activator (thromboplastin) and reduce the potential for erroneous results. Blood should flow quickly into the syringe.

c. **Indwelling Catheter Collection**: Flush the line with 5 ml saline, and using separate, single use syringes, collect at least 5 ml or 6 dead space volumes of blood and discard prior to collection of the test sample in order to eliminate the risk of dilution and contamination of the sample with heparin from the catheter or line.

d. **All institutional policies and procedures for specimen collection should be followed.**

2. **Heparin Dose Response (HDR):** Specimens for HDR testing should be free of heparin and tissue thromboplastin. See instructions, above, for venipuncture and indwelling catheter access.

***The sample should be drawn prior to vein harvesting and other invasive procedures to ensure a clean sample and to avoid the potential for erroneous results.***

3. **Specimen Type:**
   a. Fresh whole blood is required.
   b. Blood is collected in a 3 ml Monoject® syringe that is supplied with the cartridges.
   c. ***Note: Use only the 3 ml syringes and blunt tip needles supplied by Medtronic.***
   d. Minimum sample volume requirements:
      **(1.)** HDR --3.0 ml
      **(2.)** HPT (4 channel)--1.5 ml
      **(3.)** HPT (6 channel)--2.5 ml
      **(4.)** HPT and HR-ACT--2.5 ml
4. **Handling Conditions:**
   a. Specimens should be tested as quickly as possible following sample collection.
   b. HDR: within 60 seconds, since the patient is unheparinized.
   c. HPT and HR-ACT: Test within 60 seconds when there is no anticoagulant on board. Test within 2 minutes when the patient is heparinized.

## C. EQUIPMENT AND MATERIALS:

1. **Equipment:**
   a. Medtronic HMS Plus
   b. Medtronic HEPtrac™ Electronic Control
   c. Temperature Verification Cartridge

2. **Materials:**
   a. 3 ml Monoject® Syringes
   b. 19 gauge blunt needles (1-7/16 inch)
   c. HMS Plus Thermal printer paper
   d. HMS Plus salvage reservoir cups

3. **Test Cartridges:**
   a. **HDR (HMS Plus Heparin Dose Response)**: a six-channel cartridge that contains kaolin activator and calcium suspended in HEPES buffer with sodium azide as a preservative. Channels 1 and 2 contain USP porcine heparin at a concentration that gives 2.84 units of anticoagulant activity per milliliter of blood. Channels 3 and 4

contain heparin at a concentration that gives 1.70 units of anticoagulant activity per milliliter of blood. There is no heparin added to channels 5 and 6.

**b. HPT (HMS Plus Heparin Assay Cartridges):** four or six-channel cartridges containing thromboplastin diluted in buffer as an activator with sodium azide as a preservative. US Pharmacopoeia grade protamine sulfate is added to the cartridge channels using a neutralization ratio that is precisely calibrated for each lot of protamine**. The first HPT cartridge should NOT be tested until heparin bolus has circulated for 3 to 5 minutes.**

The table below lists HPT cartridges available from Medtronic. Not all cartridges listed are used at WFBMC.

| Cartridge Color | Heparin Conc. Range (mg/kg) | Heparin Conc. Range (units/ml) |
|---|---|---|
| Red | 0.0-0.9 | 0.0-1.2 |
| Yellow | 0.0-1.5 | 0.0-2.0 |
| Tan | 1.5-3.0 | 2.0-4.1 |
| Silver | 2.0-3.5 | 2.7-4.8 |
| Blue | 2.5-4.0 | 3.4-5.4 |
| Green | 3.5-5.0 | 4.8-6.8 |
| Orange | 0.0-2.5 | 0.0-3.4 |
| Gold | 1.5-4.0 | 2.0-5.4 |
| White | 2.5-5.0 | 3.4-6.8 |
| Purple | 4.5-6.0 | 6.1-8.2 |
| Black | 3.5-6.0 | 4.8-8.2 |

**c. HR-ACT (HMS Plus High Range ACT):** a two-channel cartridge that contains kaolin activator and calcium suspended in HEPES buffer with sodium azide as a preservative.

**d. Cartridge Preparation:**

**(1.) HDR:** Cartridges should be gently shaken or tapped to re-suspend the kaolin and pre-warmed in the heat block of the HMS Plus for at least 3 minutes prior to using. **Do NOT pre-warm for more than 1 hour.**

**(2.) HPT:** Gently shake or tap the cartridge before use. Pre-warming of the HPT cartridge is not required. **Do NOT pre-warm for more than 1 hour.**

**(3.) HR-ACT:** Cartridges should be gently shaken or tapped to re-suspend the kaolin and pre-warmed for at least 3 minutes in the heat block of the HMS Plus. **Do NOT pre-warm for more than 12 hours.**

**e. Performance Parameters:**

**(1.) HDR:** Between channel pair (1&2, 3&4, 5&6) variation should not exceed $\pm$ 12% of the average of the paired channels.

**(2.) HPT:** Due to the United States Pharmacopeia (USP) tolerances of heparin and protamine, test accuracy is typically within $\pm$ ½ channel, or 0.34 units/ml. Heparin concentrations that neutralize between two channels may clot in either of the two channels. In cases where 2 channels clot simultaneously, the HMS Plus will default to the lower concentration. HPT cartridge clotting times should

fall between 30 and 249 seconds. Clotting in all channels in less than 30 seconds may occur when the blood sample is activated. Clotting times of greater than 249 seconds may occur if the heparin level of the specimen is higher than the cartridge range, if the cartridge has expired, or was handled or stored improperly. Any sample that detects in channel 1 should be repeated, since channel 1 reflects the lowest amount of heparin that can be measured for a given cartridge. It cannot be assumed that detection in channel 1 reflects the amount of heparin for channel 1. There may actually be less heparin present than the value for channel 1. Testing should be repeated using a cartridge with a lower measurement range.

**(3.) HR-ACT:** HR-ACT cartridges, in the clotting time range of 0 – 600 seconds, typically do not exceed a variation of ±12% of the average of the cartridge channels. In subjects with extreme sensitivity to heparin, an activated clotting time in excess of 600 seconds is generally not considered to be adequately reliable to predict heparin effect by coagulation times.

**f. Storage Requirements: Do not re-refrigerate cartridges once stored at room temperature. Expiration dating should be clearly noted on the cartridges and control materials. Supplies should never be used after the indicated expiration date. Do not use cartridges or control materials when the expiration date cannot be determined.**

**(1.)** All cartridges should be stored in their original packaging for reference to the appropriate expiration date. Do not use cartridges that have exceeded their expiration date.

**(2.) HDR:** HDR cartridges may be stored refrigerated (2° to 10°C) or at room temperature (10° to 25°C). Refrigerated cartridges are stable until the indicated expiration date on the box. Cartridges kept at room temperature must be used within a week of removal from the refrigerator or by the room temperature expiration, which ever is shorter.

**(a.)** Do not use cartridges that have evidence of evaporation or contamination.

**(b.) DO NOT FREEZE HDR CARTRIDGES**.

**(3.) HPT:** HPT cartridges may be stored refrigerated (2° to 10°C) or at room temperature (10° to 25°C). Refrigerated cartridges are stable until the indicated expiration date on the box. Cartridges kept at room temperature must be used within a week after removing from the refrigerator, or by the room temperature expiration, which ever occurs first. Do not use cartridges that have evidence of evaporation or contamination.

**(4.) HR-ACT:** HR-ACT cartridges are stable at either refrigeration or room temperature (2° to 25°C) until the expiration date. Do not use cartridges that have evidence of evaporation or contamination.

**D. CALIBRATION:** Not Applicable

**E. QUALITY CONTROL**: Quality Control testing for the HMS Plus is performed using liquid controls or a combination of liquid and electronic (HEPtrac™) controls.

According to the CLIA guidelines, controls for coagulation procedures should be performed every eight hours of patient testing. ***The Medtronic analyzer and test cartridges should Never be used for patient testing until appropriate quality control procedures are performed and results are within acceptable limits.***

1. **Electronic Control:** Performed each 8 hours of patient testing. The HEPtrac™ is a software controlled mechanical verification cartridge that checks the following functions of the HMS Plus: flag sensor function, reagent delivery, flag release force, flag height and clotting time ranges. The HEPtrac™ is used to identify instruments that are no longer in calibration. The HEPtrac™ control may be run from any screen by inserting the device and pressing START/STOP key. Results will always be stored as a quality control test, and automatically print at the completion of the test. Document results on the Medtronic HMS Plus daily QC log sheet. Document all QC values, including failed QC results with corrective action. Contact Medtronic Tech Support for assistance in resolving unacceptable electronic quality control values.

**Note:** Before performing an electronic quality control test, the serial number of the HEPtrac™ must be entered as a cartridge lot number.

2. **Liquid Controls:** Two levels of Liquid controls should be tested each 7 days on each cartridge type and each analyzer in use. Liquid controls are performed for the High Range ACT and the Heparin Assay (HPT) Test. When used in conjunction with the HEPtrac™ electronic control, liquid controls should be performed every seven days and with a change in cartridge lot number.

**Note:** Before performing a quality control test, valid lot numbers and expiration dates for both cartridges and controls must be entered. In the case of the HR-ACT controls, the ranges for the controls must also be entered.

   a. **HR-ACT:** Two levels of liquid control (the CLOTtrac® HR normal and abnormal controls) are performed for the HR-ACT. CLOTtrac® controls are prepared from sheep whole blood and are packaged with vials of deionized water for reconstitution.
      **(1.) Storage and Stability:** Store controls in the refrigerator, between 2° and 10°C. Controls are stable until the expiration date on the package when stored at refrigeration temperatures. CLOTtrac® controls are stable for 1 hour following reconstitution.
      **(2.) Preparation:**
         **(a.)** Remove controls and deionized water diluent from the refrigerator and bring to room temperature for approximately 10 minutes.
         **(b.)** Add 1.8 ml of deionized water to the lyophilized sheep blood.
         **(c.)** Allow at least 10 minutes for adequate rehydration. DO NOT AGITATE OR MIX UNTIL COMPLETELY REHYDRATED.
         **(d.)** Shake the control vigorously to mix until the red blood cells are uniformly dispersed and the control is completely reconstituted.

**(3.) Performance:**

**(a.) To perform the control test, the HMS Plus must be in the Quality Control menu.**

**(b.)** Gently shake the HR-ACT cartridge to re-suspend the kaolin and pre-warm the cartridge for 3 minutes.

**(c.)** Enter your user specific User ID.

**(d.)** Fill a 3 ml Monoject® syringe with the reconstituted control, prime the needle and place the filled syringe and needle into the dispenser of the HMS Plus. Lock in place.

**(e.)** Press the START/STOP key, the HMS Plus reads the cartridge code and a normal/abnormal selection screen appears.

**(f.)** Press the appropriate key to select either the normal or abnormal control.

**(g.)** Pressing the START/STOP key again initiates the test. The HMS Plus dispenses the appropriate amount of sample (0.40ml/channel), and automatically performs the required 300-second incubation when QC testing is initiated from the Quality Control menu.

**(h.)** Quality control data will be stored in the Quality Control log as long as the test is initiated from the Quality Control menu. Also, document results on the liquid QC log sheet.

**Acceptable Limits HR-ACT: Refer to lot specific package insert for acceptable limits. Both channels and the average should be within acceptable limits and channels should agree +/-10% for the normal control and +/-12% for the abnormal control.**

**b. HPT:** Controls for the Heparin Assay (HPT) Test contain lyophilized sheep plasma and USP reference porcine mucosal heparin. Five levels of HPT controls are available; each is color-coded and is matched to the appropriate colored cartridge. Deionized water for reconstitution is packaged with the lyophilized controls.

**(1.) Storage and Stability:** Store controls in the refrigerator, between 2° and 10°C. Controls are stable until the expiration date on the package when stored at refrigeration temperatures. Controls are stable for 2 hours at either room temperature or refrigerated following reconstitution.

**(2.) Preparation:**

**(a.)** Remove controls and deionized water diluent from the refrigerator and bring to room temperature for approximately 10 minutes.

**(b.)** Add 2.5 ml of deionized water to the lyophilized plasma.

**(c.)** Allow at least 3 minutes for adequate rehydration. DO NOT AGITATE OR MIX UNTIL COMPLETELY REHYDRATED.

**(d.)** Mix gently by swirling.

**(3.) Performance:**

**(a.)** To perform the control test, the HMS Plus must be in the Quality Control menu.

**(b.)** Insert the appropriate HPT cartridge into the HMS Plus heat block. Press the START/STOP key, the HMS Plus reads the cartridge code and displays the control required.

**(c.)** Fill a 3 ml Monoject® syringe with the reconstituted control, prime the needle and place the filled syringe and needle into the dispenser of the HMS Plus. Lock in place.

**(d.)** Enter your user specific User ID.

**(e.)** Pressing the START/STOP key again initiates the test. The HMS Plus dispenses the appropriate amount of sample into each channel. **Note: the HPT and HR-ACT controls cannot be run simultaneously, due to the required incubation step for the HR-ACT control.**

**(f.)** When the test is completed the following information is displayed: heparin concentration, the channel that detects, and the clotting time of that channel.

**(g.)** Quality control data will be stored in the Quality Control log as long as the test is initiated from the Quality Control menu. Also, document results on the liquid QC log sheet.

**Acceptable Limits HPT: channels should read less than (<) 249 seconds. Use appropriate control for cartridge type (color) tested.**

**c. HDR:** There are not specific controls for the Heparin Dose Response Test (HDR). It is recommended that the following information be tracked for quality assurance purposes.

**(1.) Actions**

**(a.)** Record all patient results in a log book and regularly trend the data for consistent long term performance.

**(b.)** Slope and channel reproducibility should be documented.

**3. Printing the Quality Control Test History: The HMS Plus stores the last 100 quality control results** in the order in which they were performed. Tests may be sorted by several categories before printing. From the "Main Menu" select "Quality Control Menu". Press the "Quality Control Test History" key. From the "Quality Control Test History" screen select the result sort category.

**a. Sort by Total Days**: when selected a second screen appears with a prompt for entering the number of calendar days (from 1-30). Press "Enter" and then the "Print" key. The screen changes to "Printing QC Results". The status of the search and print appears on the screen. When printing is complete the HMS Plus will return to the "Quality Control Test History Menu" screen.

**b. Sort by Test Results (ACT, HPT, HEPtrac)**: The appropriate test is selected from the "Quality Control Test History" screen. When "Enter" is pressed a second screen is displayed that indicates the specific test requested. Press the "Print" key to initiate printing of the QC results. The screen changes to "Printing QC Results". The status of the search and print appears on the screen. When printing

is complete the HMS Plus will return to the "Quality Control Test History Menu" screen.

If no test results are stored in the system for the selected category, a message will be displayed that indicates this condition.

**F. LIQUID QUALITY CONTROL (LQC) REMEDIAL ACTION**

1. Confirm expiration dating on cartridges and QC materials to ensure they are not expired.
2. Repeat liquid QC test procedures using fresh QC material. Pay close attention to sample handling. Carefully follow manufacturer instructions.
3. **If LQC values are still unacceptable, do NOT use the analyzer or cartridges for patient testing.**
4. Contact Medtronic Tech Support for assistance.
5. Document all troubleshooting actions.

**G. MAINTENANCE: All maintenance procedures must be documented on the appropriate Medtronic HMS maintenance log sheet.**

1. **Routine Cleaning: The analyzer should be disinfected between each patient case.** Clean the exposed surfaces of the actuator and dispenser and the instrument case using a cloth dampened with 10% bleach, isopropyl alcohol, methanol, ethanol, Liqui-Nox, hydrogen peroxide, or mild detergent. The HMS Plus cleaning kit may be used to clean difficult to reach areas in the dispenser. The salvage reservoir, located in the notched plate under the dispenser should be changed as needed. Document cleaning on the Medtronic HMS maintenance log sheet.

2. **Dispenser Volume Delivery Verification:** Perform once a month to ensure proper delivery of sample by the automatic dispensing unit. An empty 3 ml Monoject® syringe is required for this procedure. Follow instructions in the Medtronic HMS Plus Operator's Manual.
   a. **If the appropriate volume is not dispensed, contact Medtronic Instrument Service.**
   b. Document results of dispenser volume verification on the Medtronic HMS maintenance log sheet.

3. **Heat Block Temperature Verification/Adjustment:** Perform once a month to ensure that the heat block temperature is maintained at 37 $\pm$ 0.5°C. A Temperature Verification Cartridge or an unused cartridge (with the plungers removed and all cartridge channels filled with water), and a calibrated thermometer may be used for this purpose. The instrument's heat block temperature must be between 35° and 39° C for temperature adjustments to be made. The HMS Plus must be turned on for at least 20 – 25 minutes before performing this procedure. Document results of the temperature verification on the Medtronic HMS maintenance log sheet. Follow instructions in the Medtronic HMS Plus Operator's Manual.

4. **Annual Preventative Maintenance**: by a qualified Medtronic Instrument Service Representative is recommended to ensure accurate performance and reliability of the HMS Plus.

**H. ANALYZER SET-UP: Refer to the Medtronic HMS Plus Operator's Manual for details not included in this procedure.**

1. **Power On and Self Test:**
   - **a.** Attach the power cord and connect to a grounded, hospital grade, main power source.
   - **b.** Power on the HMS Plus using the switch located on the rear panel. The HMS Plus initiates a series of self-diagnostic tests and the dispenser cycles and returns to the "parked" position.
   - **c.** The software version appears on the start-up screen, and the temperature is displayed until the heat block reaches 36.5-37.5°C. **Allow 25 minutes for the HMS Plus to warm up before performing tests.**
   - **d.** The "Main Menu" will be displayed on completion of the self-test.
   - **e.** If any of the instrument self-tests fail or are not completed, a message will be displayed indicating a system error code. **Record this code and notify Medtronic Instrument Service.**
2. **Enter Default Instrument Parameters**: Prior to using the HMS Plus for the first time, the following Default Instrument Parameters must be entered.
   - **a.** From the "Main Menu", select "Instrument Parameters". The first of four required instrument parameter screens will appear. The variable function key for moving from screen to screen is located on the lower right.
   - **b.** All Default Instrument Parameters must be entered prior to using the HMS Plus. **Refer to instrument printout for current WFBMC settings.**
     - **(1.) Heparin Conc Unit**
     - **(2.) Heparin Type**
     - **(3.) Protamine-Heparin Ratio**
     - **(4.) Protamine Units**
     - **(5.) Confirm Patient**
     - **(6.) Print Mode**
     - **(7.) Audio Tone**
     - **(8.) All Ch Detect**
     - **(9.) Dispenser**
     - **(10.) Date-dd/mm/yyyy**
     - **(11.) Time-hh:mm**
     - **(12.) Language**
     - **(13.) Location**
3. **Set Default Protocol Parameters: Refer to instrument printout for current WFBMC settings.** This item is accessed from Instrument Parameters Screen number four of four. Up to five different default protocols may be preset and held in memory using this function. From the "Default Protocol Parameters" screen, select "Set Default Parameters". These steps should be performed for each patient position that will be used. See the next section for entry instructions.
   - **a. Entering Default Protocol Parameters**: from the "Default Protocol Parameters" screen, select "Set Default Parameters". These steps should be performed for each patient position that will be used.
     - **(1.) Protocol Hep Conc**
     - **(2.) Pump Heparin**
     - **(3.) Pump Volume**
     - **(4.) ACT Target Time**

**It is recommended that all "Instrument Parameters" and "Default Protocol Parameters" be printed after instrument set up is completed. "Instrument Parameters" may be printed**

**from any of the first three "Instrument Parameter" screens. The five sets of "Default Protocol Parameters" may be printed from either the "Default Protocol Parameters Setup" screen or the "Default Protocol Parameters Entry" screen.**

4. **Entering Patient Parameters**: Individual patient parameters are entered for **each patient tested**. Up to five different patients may be active in the HMS Plus at one time. From the "Main Menu" select "Patient/Protocol Parameters". Press "Go to Next Patient" until the desired patient position (1- 5) is selected. Press "Set Patient Parameters" to access the "Patient Parameters" screen. Enter the following information:
   a. **PID:** The patient ID is a unique identifier that is entered for each patient. Numeric characters between 0 and 9 up to a total of 12 digits may be entered. Press the "PID" variable function key to select the parameter. Enter the appropriate patient ID using the numeric keypad or use the barcode scanner, and press "Enter" to confirm the entry. A patient ID number must be entered before patient testing can be performed. The medical record number should be used as the PID.
   b. **Sex**: Press the "Sex" variable function key to select the parameter, then press again to toggle to the desired selection. Press "Enter" to confirm the entry.
   c. **Height**: Patient height may be entered in either feet-inches or in centimeters. The acceptable range for feet is 0-9. If the entry for feet is "0" the acceptable range for inches is 0-99. If the entry for feet is >0 the acceptable range for inches is 0-11. The acceptable range for centimeters is 0-302. Press the "Height" variable function key to select the parameter. Press again to toggle to the correct units. Enter the appropriate value and press "Enter" to confirm the entry. Note: when entering inches only, a zero must be entered for the feet value.
   d. **Weight:** Patient weight may be entered in pounds or kilograms. The acceptable range for pounds is 0-999. The acceptable range for kilograms is 0.0-454.1. Press the "Weight" variable function key to select the parameter. Press again to toggle to the correct units. Enter the appropriate value and press "Enter" to confirm the entry.
   e. **UID:** If User Lockout has been turned on, a valid User ID must be entered to save the patient information and before performing liquid quality control testing.
   f. Once all patient parameters have been entered the HMS Plus will calculate and display the patient's Blood Volume (BV), Body Surface Area (BSA) and a heparin bolus for the patient based on the blood volume. Once the HDR is performed the heparin bolus is recalculated based on the blood volume and the patient's HDR result. Extreme caution should be used in entering patient information. **Incorrect entries could result in erroneous values being reported by the Medtronic HMS Plus**

**I. PATIENT TESTING PROCEDURE: Once information noted above has been entered and the analyzer has warmed for at least 25 minutes, proceed with patient testing procedures.**

1. **HDR:--TEST THIS CARTRIDGE PRIOR TO INCISIONS OR VEIN HARVEST**
   a. Gently shake the HDR cartridge to re-suspend the kaolin and place the HDR cartridge into the HMS Plus heat block to pre-warm for 3 minutes.

**b.** Enter the Patient ID (Note: cartridge and control lot numbers must be entered prior to testing, and all required quality control tests must be performed and within acceptable limits **before** patient testing).

**c.** Enter the User specific ID

**d.** **Collect 3.0 ml** of patient blood into a 3 ml Monoject® syringe, attach **and prime the blunt tip needle**.

**e.** Insert the syringe into the dispenser, sliding the needle through the keyhole slot. The hub of the needle should rest on the syringe holder foot. See figure 5-5 on syringe insertion in the HMS Plus Operator's Manual. Rotate the syringe until a cross-member of the plunger is parallel to the face of the syringe holder. Push the lock switch to clamp the syringe plunger cross-member between the drive and idler wheels.

**f.** Press the START/STOP key, the HMS Plus reads the cartridge code and initiates the test when the "Confirm Patient Screen" is turned off. When the "Confirm Patient Screen" is turned on, pressing the START/STOP key the first time reads the cartridge code, a patient confirmation screen appears and provides verification information on the patient being tested and the cartridge type. Note: the confirmation screen automatically appears on test initiation after powering on the instrument, and the first time a test is performed following a change in any patient or protocol parameter.

**g.** The test dispense screen appears and the HMS Plus dispenses the appropriate amount of patient sample into each cartridge channel.

**h.** When all channels have been filled the "HDR In Progress" screen appears, and the "Elapsed Time" for each channel is displayed.

**i.** When clot formation occurs, the channel detected is highlighted and the clotting time is displayed. The end point of the test is clot formation in each channel or 999 seconds.

**j.** **HDR slopes less than 60 seconds/unit/ml may indicate increased resistance to heparin or may be due to difficulties with collection and handling of the sample, and should be repeated.** Possible causes of resistance should be investigated.

**k.** HDR slopes greater than 160 seconds/unit/ml may indicate increased sensitivity to heparin.

**l.** The "HDR Results" screen is displayed when the test is completed. The following information is displayed:

**(1.)** Projected Heparin Concentration

**(2.)** Heparin Bolus

**(3.)** Patient's Baseline ACT

**(4.)** When the key for "More Test Information" is pressed the following information is displayed:

**(a.)** Individual channel clotting times and the average result for each pair

**(b.)** The Slope of the heparin response curve

**(c.)** The results for the HDR test may be edited by depressing the "Edit HDR Channel" screen. Only one clotting time for each channel may be edited. If only one channel in a pair detects, that channel may not be edited. If the "Projected Heparin Conc" value from the HDR Results screen has been changed no edits are allowed.

**2.** **HPT:** The HPT may be run alone or in combination with an HR-ACT when the four channel HPT cartridge is used.

**a.** Gently shake the HPT cartridge and place in the heat block of the HMS Plus. Prewarming the HPT cartridge is not necessary, but may be performed when the HPT is run simultaneously with the HR-ACT.

**b.** Confirm the Patient ID (Note: cartridge and control lot numbers must be entered prior to testing, and all required quality control tests must be performed and within acceptable limits before patient testing).

**c.** Confirm the User specific ID

**d.** Collect the following amount of patient blood into a 3 ml Monoject® syringe:

- **(1.)** Four Channel HPT cartridge--1.5 ml
- **(2.)** Six Channel HPT cartridge--2.0 ml
- **(3.)** Four Channel HPT with HR-ACT--2.5 ml

**e.** Attach and prime the blunt tip needle. Insert the syringe into the dispenser, sliding the needle through the keyhole slot. The hub of the needle should rest on the syringe holder foot. See figure 5-5 on syringe insertion in the HMS Plus Operator's Manual. Rotate the syringe until a cross-member of the plunger is parallel to the face of the syringe holder. Push the lock switch to clamp the syringe plunger cross-member between the drive and idler wheels.

**f.** Press the START/STOP key. The HMS Plus reads the cartridge code and initiates the test when the "Confirm Patient Screen" is turned off. When the "Confirm Patient Screen" is turned on, pressing the START/STOP key the first time reads the cartridge code, a patient confirmation screen appears and provides verification information on the patient being tested and the cartridge type. Note: the confirmation screen automatically appears on test initiation after powering on the instrument, and the first time a test is performed following a change in any patient or protocol parameter.

**g.** The test dispense screen appears and the HMS Plus dispenses the appropriate amount of patient sample into each cartridge channel.

**h.** Once sample dispensing is completed, the "HPT in Progress" screen appears. This screen displays the cartridge type and the heparin concentration for each channel.

**i.** Clot formation in the lowest concentration channel is the endpoint of the test. Note: If "All Channel Detect" is turned to "On" the test will run until clotting has occurred in all channels, or until the test is terminated by pressing "Stop". The "All Channel Detect" is typically turned to "Off".

**j.** When an HR-ACT is run with the HPT all results will be displayed when the HR-ACT is completed.

**k.** The reportable range for each HPT cartridge type is printed on the individual cartridge label. The run time range for each HPT cartridge is between 30 and 249 seconds. **Run times greater than 249 seconds may indicate that the heparin level of the sample is higher than the range of the cartridge.** Note: Channel 1 detects may be produced by the level of heparin indicated in channel 1. However, a Channel 1 detect may also be caused by a heparin level below the value for channel one. **These results should always be verified using a cartridge with a lower heparin range.**

**l.** The following information is displayed on the "HPT Results" screen:

- **(1.)** The heparin concentration
- **(2.)** The channel detected and the clotting time
- **(3.)** Additional heparin required for the patient, pump or total volume

**(4.)** The Protamine dose for heparin reversal can be displayed by pressing the "Protamine Dose" key.

3. **HR-ACT**: The HR-ACT may be run simultaneously with the HPT or by itself. **The HR- ACT cartridge is always run in channel positions 5 and 6.**
   - **a.** Gently shake the HR-ACT cartridge to re-suspend the kaolin and place the cartridge into the HMS Plus heat block to pre-warm for 3 minutes.
   - **b.** Confirm the Patient ID (Note: cartridge and control lot numbers must be entered prior to testing, and all required quality control tests must be performed and within acceptable limits before patient testing).
   - **c.** Confirm the User specific ID
   - **d.** Collect the patient's blood sample in a 3 ml Monoject® syringe, attach and prime the blunt tip needle. The required sample volume for the HR-ACT is 1.5 ml. **When the HR-ACT is performed with the four channel HPT, 2.5 ml of sample is required.**
   - **e.** Insert the syringe into the dispenser, sliding the needle through the keyhole slot. The hub of the needle should rest on the syringe holder foot. See figure 5-5 on syringe insertion in the HMS Plus Operator's Manual. Rotate the syringe until a cross-member of the plunger is parallel to the face of the syringe holder. Push the lock switch to clamp the syringe plunger cross-member between the drive and idler wheels.
   - **f.** Press the START/STOP key, the HMS Plus reads the cartridge code and initiates the test when the "Confirm Patient Screen" is turned off. When the "Confirm Patient Screen" is turned on, pressing the START/STOP key the first time reads the cartridge code, a patient confirmation screen appears and provides verification information on the patient being tested and the cartridge type. Note: the confirmation screen automatically appears on test initiation after powering on the instrument, and the first time a test is performed following a change in any patient or protocol parameter.
   - **g.** The "Test Dispense" screen appears and the HMS Plus dispenses the appropriate amount of patient sample into each cartridge channel.
   - **h.** When all channels have been filled the "HR-ACT In Progress" screen appears, and the "Elapsed Time" for each channel is displayed.
   - **i.** When clot formation occurs, the channel detected is highlighted and the clotting time is displayed. The end point of the test is clot formation in each channel or 999 seconds.
   - **j.** The "HR-ACT Results" screen is displayed when the test is completed. The following information is displayed:
     - **(1.)** The HR-ACT clotting time for each channel
     - **(2.)** The average of the results
     - **(3.) Note: If the difference between the two channels is > ± 12% an audible alert will sound and a message will appear on the screen**. Channel clotting times should not be edited out by pressing the "Edit ACT Channel" key. Testing should be repeated to confirm accuracy of results.

## J. SAMPLE MISIDENTIFICATION

1. Should a sample be misidentified, the Clinical Laboratory Point of Care Testing (POCT) Coordinator MUST be notified.
2. Complete a laboratory incident report form and send to the laboratory POCT Coordinator.

3. It is the responsibility of testing personnel to return incident reports, as necessary.
4. If there are instances that results cannot easily be traced to the correct patient, it will be the responsibility of the point of care contact person in each user site to work with the Clinical Lab POCT Coordinator to resolve such issues.
5. The Medtronic HMS Plus should not be used for personal/non-patient testing. Results can be traced back to the device, location, and user.

**K. CALCULATIONS:** The HMS Plus performs calculations based on clotting time results and patient and protocol parameters. Please refer to Section 4 of the HMS Plus Operator's Manual for calculation details. Calculations include:

1. **Patient's Blood Volume** (equations for both adult and pediatric patients) based on height and weight.
2. **Heparin Dose Response** Calculations, including: slope and projected heparin concentration.
3. **Heparin Bolus Dose** Calculations are based on the values of the heparin concentration, pump and patient values (calculations performed are dependent on the instrument location selected):
   - **a.** CPB-Pump Enter-the pump heparin is entered by the user, and the HMS Plus calculates the needs for the patient and the total bolus dose.
   - **b.** CPB-Pump Calc-the pump, patient and total bolus heparin dose are calculated by the HMS Plus
   - **c.** Heparin Assay Calculations include the required heparin and protamine for the patient, pump and total volume.

**L. REPORTING RESULTS:**

1. Results will be reported in the Perfusion record.
2. Results must be legible and should indicate who performed each test.
3. Results will be accompanied by units of measure and reference ranges, as applicable.
4. **Reporting Format**: Results to be charted on perfusion record:
   - **a.** CPB Heparin Concentration (U/ml)
   - **b.** ACT (seconds)
5. **Expected Values HR-ACT** as stated by Medtronic literature: HR-ACT performance is standardized by running baseline and heparinized samples from a known donor population. The heparinized HR-ACTs are obtained by in vitro heparinization of the sample at the time the blood is drawn. The cartridge is controlled to maintain an average population response of approximately 100 seconds per unit of heparin (136 sec/mg/kg heparin) with a range of 60 sec/u/mL to 120 sec/u/mL or 81.6 sec/mg/kg to 163.2 sec/mg/kg. The baseline range of a controlled group of 10 average donors gave a mean baseline of 117 seconds with a range of 99 to 135 seconds (two standard deviations).
6. **Critical Results**: Not applicable
7. **Procedures for Abnormal Results**: Repeat testing as necessary.
8. Unexpected results should be correlated with other clinical findings and appropriate laboratory repeat testing should occur.

**M. PROCEDURE NOTES:**

1. **HDR:** All patient specimens for HDR testing should be collected prior to invasive procedures, such as vein harvesting. Patient diagnoses and all medications should be noted. Medications may alter the clotting times. Abnormal test results should be repeated on a freshly collected sample.

2. **HPT:** The determination of heparin concentration by the HPT test is not generally affected by hemodilution, hypothermia, the presence of platelet inhibitors or low platelet count. In the presence of warfarin the clotting times may be prolonged but the correct heparin concentration will be identified as long as the heparin level is within the range of the cartridge. If the detected channel is the highest channel (4 or 6) for that cartridge, the value will be the value for that channel or higher. The test should be repeated using a cartridge with a higher range. Run times that exceed 249 seconds may indicate a heparin level in excess of the range of the cartridge, expiration date of the cartridge has been exceeded, or cartridge has been improperly handled or stored. Test samples that neutralize between two channels are likely to clot in either of the two channels. The HMS Plus will report the final result as the lower heparin concentration.
3. **HR-ACT**: When on cardiopulmonary bypass the HR-ACT may be affected by the following: dilution of plasma coagulation factors, the use of citrated blood products, use of antiplatelet agents, hypothermia, and change in platelet number or function.

## V. LIMITATIONS OF THE TEST METHOD/PROCEDURE/REPORTABLE RANGE:

**A. HDR:** HDR slopes less than 60 seconds/unit/ml may indicate increased resistance to heparin or may be due to difficulties with collection and handling of the sample, and should be repeated. Possible causes of resistance should be investigated. HDR slopes greater that 160 seconds/unit/ml may indicate increased sensitivity to heparin.

Patient Activated Clotting Times (ACT) should be closely monitored to ensure target ACT is achieved when dosing to the HDR projected heparin result. The significant difference between an in vitro and in vivo heparin dose response is that the in vitro test does not take into account in vivo factors which may reduce the blood heparin level.

**B. HPT**: The reportable range for each HPT cartridge type is printed on the individual cartridge label. The run time range for each HPT cartridge is between 30 and 249 seconds. Run times greater than 249 seconds may indicate that the heparin level of the sample is higher than the range of the cartridge. Note: Channel 1 detects may be produced by the level of heparin indicated in channel 1. However, a Channel 1 detect may also be caused by a heparin level below the value for channel one. These results should always be verified using a cartridge with a lower heparin range.

**C. HR-ACT:** The reportable range for the HR-ACT test may be determined by testing fresh whole blood samples which have been spiked with increasing concentrations of heparin (from 0.0 or baseline to 6.0 or 7.0 units/ml of heparin). The cartridge is designed to maintain an average population response of approximately 100 seconds per unit of heparin. HR-ACT cartridges, in the clotting time range of 0 – 600 seconds, typically do not exceed a variation of ±12% of the average of the cartridge channels. In subjects with extreme sensitivity to heparin, an activated clotting time in excess of 600 seconds is generally not considered to be adequately reliable to predict heparin effect by coagulation times.

## VI. LIMITATIONS OF THE TEST METHOD/INTERFERING SUBSTANCES:

**A. HDR:** A low HDR slope and an indication of resistance to heparin may be seen in, but is not limited to:

1. An activated blood specimen, either in-vivo or in-vitro due to improper sample collection and handling (sample collection and testing should be repeated)
2. The presence of other medications such as, Nitroglycerin
3. Patients with a deficiency of Antithrombin III (congenital or acquired)
4. Patients who have received IV heparin prior to HDR testing
5. An elevated HDR slope and indication of increased sensitivity to heparin may be seen in, but is not limited to:

**a.** Plasma coagulation factor deficiencies (congenital or acquired)
**b.** Presence of a Lupus Anticoagulant
**c.** Patients who have received thrombolytic agents (streptokinase, tPA) prior to HDR testing
**d.** Patients who have received warfarin prior to HDR testing

**B. HPT**: An activated blood specimen, either in-vivo (patient's coagulation mechanism activated) or in-vitro, due to improper sample collection and handling. Sample collection and testing should be repeated.

**C. HR-ACT:** An activated blood specimen, either in-vivo (patient's coagulation mechanism activated) or in-vitro, due to improper sample collection and handling. Sample collection and testing should be repeated.

**Refer to operator's manual and package inserts for additional precautions.**

## VII. TROUBLESHOOTING

**A.** Refer to the Medtronic HMS Plus Operator's Manual, test cartridge, and QC package inserts for additional information.

**B.** For technical assistance, contact the designated super user for the test site, call the POCT Coordinator at extension 3-4136, or Medtronic technical clinical assistance at 1-800-328-3320, or Medtronic device service and repair at 1-800-433-4311.

**C.** Should the Medtronic device not be operational, Perfusion staff will use the i-STAT ACT-kaolin test method for obtaining ACT values. EXTREME caution should be used if there is a need to switch between ACT methods and clot activators.

## VIII. PROFICIENCY TESTING:

The Medtronic HMS Point of Care Testing (POCT) sites at WFBMC will participate in the College of American Pathologists (CAP) proficiency testing program, where applicable. Users should follow instructions provided with the survey samples. The proficiency samples are rotated among different users, and there is no communication between the Department of Pathology and POCT sites prior to submission of results to CAP for review. If proficiency survey sample results fail, the problem is investigated and resolved as necessary. E.g. Re-training, instrument performance evaluation, or survey sample handling. In the event no commercial proficiency program is available, an alternative proficiency program will be established.

## IX. EMPLOYEE CERTIFICATION/TRAINING/COMPETENCY:

Employee certification documentation is completed upon training on the Medtronic HMS Plus test device. Each user of the Medtronic HMS should be trained prior to using the device for patient testing and should maintain updated competency records. During the first year of an individual's duties, competency must be assessed at least semiannually. After the first year, competency is assessed yearly by observation and/or written test. Other methods may be used to assess competency, per direction from regulatory authorities. Any user that fails to meet the competency requirements will need to be re-educated for use of the analyzer. The Department of Pathology Point of Care Testing Coordinator and user site manager maintains training and competency records.

## X. REFERENCES:

**A.** Medtronic HMS Plus version 4.0 Operator's Manual, 2004, Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432-5604

**B.** Medtronic HEPtrac™ Electronic Quality Control Operator's Manual for the HMS/HMS Plus, 1/2004, Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432-5604

**C.** Product Inserts for the following Medtronic HMS Plus Cartridges and Controls:
Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432-5604

**1.** Heparin Dose Response Cartridges (HDR), 2010 M944216A001 Rev 1.0
**2.** Heparin Assay Cartridges (HPT), 2004
**3.** High Range ACT Cartridges (HR-ACT), 2003
**4.** Heparin Assay Controls, 2004

5. CLOTtrac™ Normal and Abnormal Controls for the High Range ACT, 2004/2007

**D.** NCCLS Point-of-Care *In Vitro* Diagnostic (IVD) Testing; Approved Guideline, AST2-A, Volume 19, Number 9, June 1999.

**E.** NCCLS Collection, Transport, and Processing of Blood Specimens for Coagulation Testing and General Performance of Coagulation Assays; Approved Guideline-Third Edition, H21-A3, Volume 18, Number 20, December 1998

**F.** NCCLS Clinical Laboratory Technical Procedure Manuals; Approved Guideline-Third Edition, GP2-A3, Volume 16, Number 15, December 1996.

**Adopted:** April 2011

**Appendices:** Appendix A --Test sites
Appendix B—Proficiency Testing/Performance Assessment Procedure HDR and HPT Cartridges

## ROUTING SHEET

**POLICY SIGNATURE SHEET (The original shall be maintained by the originating department.)**

| | |
|---|---|
| **Company/Facility(s)** | **WFBMC** |
| **Departments** | **Department of Pathology, Perfusion, Pediatric Heart Program** |
| **Policy** | **PPB-NCBH-LAB-775-23 "HMS Plus Hemostasis Management System Version 4.0"** |
| **Action** | **New Policy** |

**POLICY APPROVALS:**

| Title | Approved by | Signature | Date |
|---|---|---|---|
| **Department of Pathology Associate Administrative Director-POCT** | **Jane Houska** | | |
| **Laboratory Compliance** | **Melanie Haire** | | |
| **Chief of Perfusion** | **Dave Charles** | | |
| **Director Nurse Anesthesia** | **Betty Petree** | | |
| **Department of Pathology Interim Administrative Director** | **Meghan Shapiro** | | |
| **Department of Pathology Chair and CLIA Director** | **A. Julian Garvin, MD** | | |
| **Department of Pathology Vice-Chair and Chief of Clinical Labs/Medical Director** | **Marcus Simpson, MD** | | |
| **Hematology/Oncology Medical Director** | **John Owen, MD** | | |
| **Director, Pediatric Heart Program Professor and Chief, Pediatric Heart Surgery** | **Ross Ungerleider, MD** | | |
| **Professor and Executive Vice Chair of Anesthesiology** | **Roger Royster, MD** | | |
| **Professor and Section Head of Cardiothoracic Anesthesiology** | **Tom Slaughter, MD** | | |
| **Chair, Cardiothoracic Surgery** | **Neal Kon, MD** | | |
| **Legal** | **N/A** | | |
| **Vice President, Operations** | **Steven C. Snelgrove** | | |
| **Vice President Surgical Services** | **Karen Turner** | | |
| **Chief Medical Officer** | **Russ Howerton, MD** | | |

**REVIEW**

| Committee/Taskforce, etc. | Reviewing Individual | Date |
|---|---|---|
| **Clinical Lab Safety and Compliance** | **Linda Kuzio** | **1/28/11** |
| **Infection Control** | **Cindy Adkins** | **3/4/11** |
| **Risk Management** | **Lisa Hammon/Howard Blumstein, MD** | **3/18/11** |
| **WFBMC Point of Care Testing Committee** | **Group** | **3/23/11** |

**DATES OF APPROVAL:**

| | |
|---|---|
| **Initial Effective Date** | April 2011 |
| **Date Reviewed/Revised** | |
| **Date of next Review (Clinical Lab Medical Director)** | Annually by Clinical Lab Medical Director |
| | |
| **POSTING PROCESS:** | |
| **Date sent to Legal Affairs:** | N/A |
| **Date sent to Webmaster: (Point of Care Testing Web Site)** | |
| **Date notice posted on *Infinet*:** | N/A |
| **Was notification by e-mail or hard copy?** | e-mail |