Atrium Health Wake Forest Baptist	**DOCUMENT TYPE:** Procedure	**ORIGIN DATE** 10/02/2019
CLIA Lab Director: Dr. Gregory Pomper	**LAB DEPARTMENT:** **POINT OF CARE TESTING COMPLIANCE**	**CONTACT:** Point of Care Testing Compliance

APPLICABLE LABORATORY(S)):
☒ North Carolina Baptist Hospital (NCBH)
☐ Lexington Medical Center (LMC)
☐ Davie Medical Center (DMC)
☐ Wilkes Medical Center (WMC)
☐ High Point Medical Center (HPMC)
☐ Westchester
☐ Clemmons

PURPOSE

It is the policy of Atrium Health Wake Forest Baptist (AHWFB) for the Clinical Lab to oversee 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 AHWFB Clinical Lab 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 document is intended 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. Information not discussed in this procedure may be found in the Medtronic HMS Plus Operator's Manual and related package inserts for the cartridges and quality control (QC) materials. All testing should have a documented physician order or follow a documented protocol.

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 (see A and B below), which are used in the management of patients receiving heparin. There is no mention of age limitations in the manufacturer's instructions, however, it's the protocol for perfusion bypass cases at AHWFB to use this analyzer predominantly on children. The HMS Plus is rarely used for adult patients – only those with specific issues, including coagulopathies. In these rare circumstances, i-STAT Kaolin testing, which is normally used to manage heparin in adult bypass cases, may not be as effective, and the patient's clinical status and medical history, at the discretion of the patient's surgeon, dictate the need to use an alternate method.

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 Activated Clotting Time (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.

SCOPE

All staff members who are educated and qualified to perform Medtronic HMS Plus testing by their job descriptions are responsible for following this procedure.

Responsible Department/Party/Parties:

- Procedure Owner: Point of Care Testing Compliance Manager
- Procedure: Non-Waived POCT sites covered by the Clinical Laboratory CLIA certificate shall adhere to processes outlined in this document.
- Supervision: The Medical Director and/or laboratory director, as indicated on covering CLIA certificate for Point of Care Testing, shall supervise the person(s) performing activities outlined in this document.
- Implementation: Each applicable Point of Care Testing (POCT) laboratory director and/or site manager is responsible for ensuring compliance with processes stated in this document.

All testing personnel must read the procedure and demonstrate successful Medtronic HMS Plus testing under the direction and supervision of an authorized staff member. Once successful demonstration of testing has been performed, it will be documented on the employee's training checklist. During the first year of an individual's duties, competency must be assessed at least semiannually. After the first year of using the Medtronic HMS Plus test system, competency is assessed annually. Current regulatory standards will be followed. Any user that fails to meet the competency requirements will need to be re-educated for use of the analyzer. The Clinical Laboratory Point of Care Testing (POCT) Office maintains training and competency records.

DEFINITIONS

A. Procedure: A process or method for accomplishing a specific task or objective.
B. WFBH Lab System: Wake Forest Baptist Lab System is a health system that includes Wake Forest Baptist Medical Center and all affiliated organizations including Wake Forest University Health Sciences (WFUHS), North Carolina Baptist Hospital (NCBH), Lexington

Medical Center (LMC), Davie Medical Center (DMC), Wilkes Medical Center (WMC), High Point Medical Center (HPMC), Lab at Westchester and Lab at Clemmons.

C. Point of Care Testing (POCT): Tests designed to be used at or near the site where the patient is located, do not require permanent dedicated space, and are performed outside the physical facilities of the clinical laboratory.
D. Non-Waived Tests: Tests of moderate or high complexity as designated by the FDA.
E. Clinical Laboratory Improvement Amendments (CLIA): United States federal regulatory standards that apply to all laboratory testing performed on humans.
F. College of American Pathologists (CAP): Accrediting agency for the AHWFB Clinical Laboratory. Point of Care sites included on the CLIA certificate of the Clinical Laboratory are accountable to standards set forth by CAP.
G. Quality Control (QC): A process to ensure the test system is performing as expected.
    - External QC -External liquid material or substance with known value(s) for the test(s) being performed.
    - Internal QC - An internal check within the test system to validate the test system is working properly.
H. Quality Assurance (QA): A system for ensuring a desired level of quality. The POCT program incorporates activities to monitor the quality of processes and the test system.
I. Quality Improvement (QI): Activities implemented to improve the quality of processes
J. Analyzer/Device: For the purposes of this document, refers to Medtronic HMS Plus instrument
K. Normal (Reference) Range: The range of values for the average patient population.

REAGENTS/MEDIA

1. Materials:

(a.) 3 ml Monoject Syringes supplied by Medtronic
(b.) 19 gauge blunt needles (1-7/16 inch) supplied by Medtronic
(c.) HMS Plus Thermal printer paper
(d.) HMS Plus salvage reservoir cups

2. 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 AHWFB.

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.) Cartridge Preparation:

- **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.**
- **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.

(d.) Performance Parameters:

- **HDR:** Between channel pair (1&2, 3&4, 5&6) variation should not exceed + 12% of the average of the paired channels.
- **HPT:** Due to the United States Pharmacopeia (USP) tolerances of heparin and protamine, test accuracy is typically within + 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. 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.

- 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.
- **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 removed from the refrigerator and kept at room temperature must be used within a week of removal from the refrigerator or by the room temperature expiration date, whichever is shorter.
  Do not use cartridges that have evidence of evaporation or contamination.
  DO NOT FREEZE HDR CARTRIDGES.
  Cartridges are labeled with a freeze indicator. Upon receipt, check monitor to ensure cartridges were not exposed to freezing temperatures.

- **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 removed from the refrigerator and kept at room temperature must be used within a week after removing from the refrigerator, or by the room temperature expiration date, whichever occurs first. Do not use cartridges that have evidence of evaporation or contamination.

EQUIPMENT

(a.) Medtronic HMS Plus
(b.) Medtronic HEPtrac. Electronic Control
(c.) Temperature Verification Cartridge
(d.) Certified minimum/maximum device to monitor temperature and humidity

Acceptable Temperature Range for Medtronic HMS Plus Analyzer: 14-32°C
Acceptable Humidity Range for Medtronic HMS Plus Analyzer: 10-90%

Maintenance:
All maintenance procedures must be documented on the Medtronic HMS Plus Monthly Maintenance Log.

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 WFBMC-approved germicidal/disposable wipe.
The salvage reservoir, located in the notched plate under the dispenser should be changed, as needed.

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 Plus Monthly Maintenance Log.

3. Heat Block Temperature Verification/Adjustment: Perform once a month to ensure that the heat block temperature is maintained at 37 + 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 Plus Monthly Maintenance Log. 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.

SAMPLE REQUIREMENTS

A. **Specimen Collection**
   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 or liquid QC material. Gloves should be worn while performing any function on the Medtronic HMS, including cleaning, maintenance, and performing quality control (QC) checks.
(e.) Treat all blood samples and quality control materials as a biohazard. Use Standard Precautions!
(f.) Biohazard waste containers should be available for disposal of used cartridges or other blood/sample contaminated non-sharp equipment.
(g.) All sharps should be discarded in biohazard sharps containers.
(h.) Germicidal wipes, fresh 10% bleach, or AHWFB-approved disinfectant should be used to decontaminate analyzers between each patient.
(i.) 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. **Patient Preparation**—There is no patient preparation

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3. All specimens must be labeled/identified in the presence of the patient. Positive patient identification should occur per AHWFB policy, using 2 forms of identification (including Name, Date of Birth, and/or Medical Record Number).

4. **All tests:** Blood may be obtained either by venipuncture or from arterial or venous access lines. See instructions below.
   (a.) **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.
   (b.) **Indwelling Catheter Collection:** Blood should not be taken from heparinized indwelling catheters or other anticoagulated lines without thoroughly flushing the lines so a sample can be drawn that is representative of the patient.
      - 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.
      - **Note:** Due to smaller patient blood volumes of pediatric and neonate patients, these waste volumes may not apply.

   (c.) All institutional policies and procedures for specimen collection should be followed.

5. **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.

6. **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:

- HDR --3.0 ml
- HPT (4 channel)--1.5 ml
- HPT (6 channel)--2.5 ml
- HPT --2.5 ml

7. **Handling Conditions:**
   (a.) Specimens should be tested as quickly as possible following sample collection.
   (b.) **HDR:** Test within 60 seconds of collection, since the patient is unheparinized.
   (c.) **HPT:** Test within 60 seconds of collection when there is no anticoagulant on board. Test within 2 minutes when the patient is heparinized.

SPECIMEN ACCEPTABILITY AND REJECTION CRITERIA

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.

CALIBRATION – N/A

Medtronic HMS Plus Proficiency Testing/Performance Assessment Procedure

The Medtronic HMS Point of Care Testing (POCT) sites at WFBMC will participate in a CMS-approved 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 the proficiency provider. If a proficiency survey sample result fails, 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.

HDR and HPT Test Cartridges:

- Currently, no commercial proficiency testing material is available for the Heparin Dose Response (HDR) and Heparin Protamine Titration (HPT) test cartridges. Alternative performance assessments are implemented for HDR and HPT test

cartridges to determine the reliability of analytic testing. Appropriate alternative performance assessment procedures may include, if available: split sample analysis with reference or other laboratories, split samples with an established in-house method, assayed material, regional pools, clinical validation by chart review, or other suitable and documented means. The laboratory director will approve appropriate performance assessment procedures.

- **OPTIONS for Alternative assessment. The following are options, not all are required:**
    1. **HDR Cartridge**
        (a.) Chart Audit: The HDR cartridge is tested at the beginning of each case to determine the projected heparin concentration. At least two times per year, Perfusion staff will complete a chart audit to verify that the projected heparin concentration matched the actual heparin concentration as reported by the HPT cartridge. Results of the chart audit will be documented and reported to the Clinical Laboratory.
        (b.) Blood Donor assessment
            i. A three ml sample of blood is collected from a donor and the HDR test is performed.
            ii. The projected heparin concentration is used to determine the amount of heparin required to elevate the donors HR ACT to the target level.
            iii. The appropriate concentration of heparin is prepared and added to a tube and a second sample of blood is collected and added to the tube with heparin and mixed thoroughly by gentle inversion.
            iv. A high range ACT is performed on this sample. The target ACT should be reached or exceeded.
        (c.) Tracking of HDR Cartridge Slope: HDR cartridge performance can be evaluated by tracking the slope reported across multiple patients over time.
        (d.) Other assessment options
        As necessary, other assessment tools/procedures may be used to validate performance.
    2. **HPT Cartridges**—Each HPT cartridge type used should be evaluated.
        (a.) Liquid QC (for each HPT cartridge type) will be tested. Results should be within acceptable limits.
        (b.) Spiked Samples
            i. Prepare by spiking fresh whole blood with heparin and testing with the appropriate cartridge.
            ii. These samples maybe prepared using the HEPline linearity kit (Product number 313-50) or by preparing samples in-house.
            iii. HPT results should reflect the concentration of heparin present in the blood sample.
        (c.) Other assessment options
        As necessary, other assessment tools/procedures may be used to validate performance.

QUALITY CONTROL (QC)

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. Results are documented when transmitted to the Medtronic HMS Plus data management system. Contact Medtronic Tech Support for assistance in resolving unacceptable electronic quality control values. Document all troubleshooting actions on the Medtronic HMS Plus Problem Log.

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 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.

(a.) Control Testing:

i. To perform the control test, the HMS Plus must be in the Quality Control menu.

ii. Enter your user specific User ID.

iii. 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.

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

v. Press the appropriate key to select either the normal or abnormal control.

vi. 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.

vii. Quality control data will be stored in the Quality Control log as long as the test is initiated from the Quality Control menu. Results are documented when transmitted to the Medtronic HMS Plus data management system.

(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.

- **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.
- **Preparation:**
  - Remove controls and deionized water diluent from the refrigerator and bring to room temperature for approximately 10 minutes.
  - Add 2.5 ml of deionized water to the lyophilized plasma.
  - Allow at least 3 minutes for adequate rehydration. DO NOT AGITATE OR MIX UNTIL COMPLETELY REHYDRATED.
  - Mix gently by swirling.

(c.) Control Testing:

i. To perform the control test, the HMS Plus must be in the Quality Control menu.
ii. 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.
iii. 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.
iv. Enter your user specific User ID.
v. Pressing the START/STOP key again initiates the test. The HMS Plus dispenses the appropriate amount of sample into each channel.
vi. When the test is completed the following information is displayed: heparin concentration, the channel that detects, and the clotting time of that channel.
vii. Quality control data will be stored in the Quality Control log as long as the test is initiated from the Quality Control menu. Results are documented when transmitted to the Medtronic HMS Plus data management system.
viii. Acceptable Limits HPT: Channels should read less than (<) 249 seconds. Use appropriate control for cartridge type (color) tested.

(d.) 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.

- Actions
  - i. Regularly trend patient data for consistent long term performance.
  - ii. 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 (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.

CORRECTIVE ACTION

1. Liquid Quality Control (QC) Remedial Action

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

- Document all troubleshooting actions on the Medtronic HMS Plus Problem Log.

2. Troubleshooting

- Refer to the Medtronic HMS Plus Operator's Manual, test cartridge, and QC package inserts for additional information.
- For technical assistance, contact the designated super user for the test site, call the POCT Office, or after hours, weekends, and holidays, contact Medtronic Technical Clinical Assistance at 1-800-328-3320, Medtronic Device Service and Repair at 1-800-433-4311, or Medtronic Customer Service at 1-800-854-3570.

3. Sample Misidentification

a. If a sample is misidentified, the physicians of involved patients must be notified.
b. Complete an RL6 report.
c. Email RL6, patient, and incident-specific information to the Clinical Laboratory Point of Care Testing team at LabPOC_Testing_DL@wakehealth.edu.
d. It is the responsibility of testing personnel to complete incident reports, as necessary.
e. If there are instances where results cannot be easily traced to the correct patient, it will be the responsibility of the point of care contact person at the user site to work with the Clinical Lab POCT Office to resolve such issues.
f. The Medtronic HMS Plus should not be used for personal/non-patient testing.
g. Results can be traced back to the device, location, and user.

PROCEDURE GUIDELINES

A. 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 AHWFB settings.**

- **Heparin Conc Unit**
- **Heparin Type**
- **Protamine-Heparin Ratio**
- **Protamine Units**
- **Confirm Patient**

- **Print Mode**
- **Audio Tone**
- **All Ch Detect**
- **Dispenser**
- **Date-dd/mm/yyyy**
- **Time-hh:mm**
- **Language**
- **Location**

3. Set Default Protocol Parameters: Refer to instrument printout for current AHWFB 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.

- **Protocol Hep Conc**
- **Pump Heparin**
- **Pump Volume**
- **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 and 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.**

B. <u>Patient Testing Procedure</u>:

- Once information noted above has been entered and the analyzer has warmed for at least 25 minutes, proceed with patient testing procedures.
- Confirm appropriate environmental operating conditions in area of testing.
- Using a certified monitoring device, document temperature and humidity readings while analyzer and cartridges are in use during a patient case. Use form, Medtronic HMS Plus Temperature and Humidity Monitoring.
    - General inventory of supplies are maintained in a laboratory area that is electronically and continually monitored for temperature and humidity.

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 **<u>before</u>** patient testing).
(c.) Enter the User specific ID
(d.) Collect 3.0 ml of patient blood into a 3 ml Monoject syringe, attach **<u>and prime the blunt tip needle.</u>**
(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:

- Projected Heparin Concentration
- Heparin Bolus
- Patient's Baseline ACT
- When the key for "More Test Information" is pressed the following information is displayed:

  i. Individual channel clotting times and the average result for each pair

  ii. The Slope of the heparin response curve

  iii. 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:

(a.) Gently shake the HPT cartridge and place in the heat block of the HMS Plus. Prewarming the HPT cartridge is not necessary.

(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:

- Four Channel HPT cartridge--1.5 ml
- Six Channel HPT cartridge--2.0 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.) 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.**

(k.) The following information is displayed on the “HPT Results” screen:

- The heparin concentration
- The channel detected and the clotting time
- Additional heparin required for the patient, pump or total volume
- The Protamine dose for heparin reversal can be displayed by pressing the “Protamine Dose” key

DILUTION OR CONCENTRATION (IF APPLICABLE) – N/A

CALCULATIONS (IF APPLICABLE)

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.

INTERPRETATION OF RESULTS – N/A

RESULTS REPORTING

1. Results will be reported on 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:
    - CPB Heparin Concentration (U/ml)
5. **Critical Results:** Not applicable
6. **Procedures for Abnormal Results:** Repeat testing as necessary.

7. Unexpected results should be correlated with other clinical findings and appropriate laboratory repeat testing should occur.

INTERFERING SUBSTANCES/TEST METHOD LIMITATIONS

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.
- 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 than 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.

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

  - An activated blood specimen, either in-vivo or in-vitro due to improper sample collection and handling (sample collection and testing should be repeated)
  - The presence of other medications such as, Nitroglycerin
  - Patients with a deficiency of Antithrombin III (congenital or acquired)
  - Patients who have received IV heparin prior to HDR testing

  (b.) An elevated HDR slope and indication of increased sensitivity to heparin may be seen in, but is not limited to:

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

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.
- 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.

- 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.

DOWNTIME

There is only one Medtronic HMS Plus analyzer at AHWFB Medical Center. If this analyzer becomes inoperable for any reason, the surgeon for the case would determine the appropriate course of action, including the option to use an alternate method for testing (like i-STAT ACT testing).

LITERATURE REFERENCES:

Medtronic HMS Plus version 4.0 Operator's Manual, Copyright 2005, 2008, 2009, 2012 Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432-5604
Medtronic HMS Plus Operator's Manual

Medtronic HEPtrac Electronic Quality Control Operator's Manual for the HMS/HMS Plus Rev. 1.0, 2004, 2010 Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432-5604

Product Inserts for the following Medtronic HMS Plus Cartridges and Controls:
Medtronic Inc. 710 Medtronic Parkway, Minneapolis, MN 55432-5604
Heparin Dose Response Cartridges (HDR), 2010 M944216A001 Rev 1.0
Heparin Assay Cartridges (HPT), 2004, 2012 M947893A001 Rev. 1A
Heparin Assay Controls, 2004, 2010 M945233A001 Rev. 1.0

RELATED PROCEDURES/POLICIES IN NAVEX/POLICY TECH AND/OR ATTACHMENTS/LINKED DOCUMENTS IN TITLE 21:

Medtronic HMS Plus Monthly Maintenance/Problem Log Form
Medtronic HMS Plus Temperature and Humidity Monitoring Form
Medtronic HMS Plus Cartridge/QC Receipt Form
Medtronic HMS Plus Monthly Patient Chart Audit Form

Temperature and Humidity Monitoring for Reagents, Equipment and Environments in Clinical Areas
Point of Care Waived and Non-Waived Testing
Responsibilities of Testing Sites and the Clinical Laboratory for POC Testing
Non-Waived Point of Care Testing (POCT) Quality Management Policy and Quality Control/Quality Assurance Procedures
Competency Assessment for Non-Waived Testing
Quality Control (QC) Range Verification, POC
Handling of POCT Analyzers when Removed from Service or Returned to Manufacturer for Repair

REVISION DATES: REVIEW CHANGE SUMMARY AS REPRESENTED IN TITLE 21