PROCEDURE: HEPCON® HMS PLUS – ACTIVATED CLOTTING TIME (HR-ACT), HEPARIN DOSE RESPONSE (HDR), AND HEPARIN ASSAY (HPT)

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PRINCIPLE:

The Hepcon HMS Plus is an integrated system consisting of a component for tracking clot detection and computing results, a component for sample delivery and the single use test cartridges for actual performance of the tests. The cartridge instructs the system, through an optical code, as to the type of test being performed, the calculations and the format required for results, and the volume of sample needed for each channel.

The detection process uses the plunger assembly within the cartridge. This assembly is lifted and dropped through the sample/reagent mixture by a lifting mechanism, in the HMS Plus actuator. As the sample clots, a fibrin web forms around the daisy located on the bottom of the plunger assembly and impedes the rate of descent of the assembly. This change in fall rate is detected by photo optical system located in the actuator assembly of the instrument. The end point of the test is the time at which clot formation is detected; from these clotting times, derived results are calculated for all tests.

The key features of the Hepcon HMS Plus is that it provides rapid turnaround of test results with minimal operator interface. All necessary reagents are contained within the single use cartridges. An optical code, on each cartridge, instructs the system as to the type of test being performed, the necessary parameters for the calculations and the sample volume required for the test. The operator inserts the appropriate cartridge(s), and a sample filled syringe into the system starting the test. The HMS will fill the cartridge and perform the test as instructed by the optical code, on the cartridge.

Test results consist of clotting time data, which is displayed on the front panel of the system. Heparin and protamine results are derived from the channel clotting time data of the Heparin Assay cartridges. The most pertinent results for each test type are automatically displayed at the completion of the test. Secondary calculations and clotting times can be displayed, if desired.

CLINICAL SIGNIFICANCE:

The Hepcon HMS Plus allows for rapid and precise hemostasis control by providing the following information:

- Indication of heparin response via the Heparin Dose Response (HDR) cartridge.
- Heparin calculation based on dosing protocol, patient blood volume and extracorporeal circuit parameters
- Simultaneous, quantitative and functional evaluation of heparin via the Heparin Assay and HR-ACT cartridges.
- Calculation of additional heparin required to maintain the patient at an adequate heparin concentration.
- Calculation of the protamine dose needed to reverse the circulating heparin.

The Heparin Assay (HPT) test uses the principle of heparin/protamine titration to quantitatively determine the concentration of heparin in the sample.

The High Range ACT is a functional evaluation of the intrinsic coagulation system. It is used to monitor the anticoagulant effect of heparin. Clotting is initiated by surface contact by an activator (in this case, kaolin). The
activator provides consistent results by optimizing activation of Factor XII. The test responds linearly to heparin concentrations.

**SPECIMEN:**

The system uses *only* 3 cc Monoject syringes, and 19 gauge blunt needles, provided by Medtronic HemoTec, Inc. Always use a 3-cc syringe completely full when running a HDR test and at least 1.5 cc when running a Heparin Assay test. Use at least a 2.5 cc blood sample when running a combined Heparin Assay and HR-ACT test. **The specimen must be processed immediately.** Do not take a blood sample from a line through which heparin has been administered. A 2-3-cc discard syringe should be used in order to obtain a clean draw sample.

Specimens, which have an insufficient quantity or have clots, are not acceptable. Unacceptable specimens must be discarded and a new specimen obtained.

**EQUIPMENT:**

- Hepcon HMS Plus (Hemostasis Management System) instrument.
- Heparin Dose Response (HDR) cartridge. Stored at Room Temp 15-25 C until expiration date on Cartridges.
- Activated Clotting Time (HR-ACT) cartridges. Stored at Room Temp 15-25 C until expiration date on Cartridges.
- Heparin Assay (HPT) cartridges.
- Temperature Verification Cartridge (Cat # 300-10)

*Note:* Each cartridge comes with its own 3 cc Monoject syringe and 19 gauge blunt needle.

See Figure 4-1 in Hepcon HMS Plus Operator's Manual for cartridge design.

**QUALITY CONTROL:**

**HEPtrac™ Electronic Quality Control** is an interactive mechanical software controlled verification cartridge that includes both quantitative and qualitative results. Store control between –50 and 60°C. **Perform every 8 hours when used for patient testing. Quality Control is reviewed weekly by Point of Care and monthly by the Lab Medical Director.**

*If Electronic Quality Control Fails, DO NOT PROCEED WITH PATIENT TESTING. CONTACT PERFUSION or Core Lab.*

The **Hepcon® HMS Controls** are manufactured by Medtronic HemoTec, Inc., Englewood, CO. Each control contains two vials - a vial of lyophilized sheep's plasma and USP referenced beef lung heparin and a vial of deionized water. Controls must be stored refrigerated 2-10°C until use and are stable until the expiration date on the vial label. Once reconstituted, controls are stable for two hours at room temperature or refrigerated. Control vials should be marked with date and time of rehydration to monitor the two-hour expiration time. **Perform weekly.**

The **CLOTtrac® Control** and **CLOTtrac® HR Abnormal Control** are manufactured by Medtronic HemoTec, Inc., Englewood, CO. Each control contains two vials - a vial of lyophilized, citrated, whole sheep's blood and a vial of non-sterile, deionized, type 1 reagent grade water. Controls must be stored refrigerated 2-10°C until...
use. The controls are stable until the expiration date on the vial label. Once reconstituted, controls are stable for 2 hours at room temperature, 15-25ºC. Control vials should be marked with date and time of rehydration to monitor the two-hour expiration time. Continued exposure of ambient temperatures will shorten the shelf life. Perform weekly.

- To run a quality control test with the HMS Plus and have the results stored as a quality control test, **the test must be started from the QUALITY CONTROL (QC) MENU screen**. This also applies if a quality control test has to be restarted for any reason (e.g., syringe not locked). If this is not done, the instrument will not identify the test as a quality control test either on the printout or in the Test History – it will be identified as a patient test. **IF QUALITY CONTROL FAILS DO NOT PROCEED WITH TESTING, CONTACT PERFUSION TEAM**

- Or the Core Lab for SERVICE.

- For HR-ACT quality control tests, the instrument will only perform the necessary 300 second incubation when the test is started from the QUALITY CONTROL (QC) MENU screen.

- HEPtrac tests may be run from any screen and the results will always be stored as a quality control test.

**Observe SLCH guidelines for handling blood specimens and disposal of any cartridges, syringes and needles in approved biohazard disposal containers**

**HEPtrac™ Electronic Quality Control**

1. Confirm that the correct software revision level is installed in the HMS Plus.

2. Place the HEPtrac in the HMS Plus.

3. Press the Start/Stop key to initiate the test. The HMS Plus message panel will display “HEPtrac ELECTRONIC QC” upon test initiation.

4. After completing the test (approximately 10 minutes), the HMS Plus will sound an audible tone and the results automatically print out.

5. Record results on the HMS Plus Quality Control Log. The performance of the HMS Plus is dependent on the performance of the reagent delivery, flag release force, flag height and flag sensors for all channels.

5. If any failures occur, the HMS Plus printout will print the failure(s) and the statement “QC TEST ABORTED.” Repeat the test. If the test results still produce failures, contact the Perfusion Team or Clinical Core Laboratory for assistance. Do not proceed with testing.

**Hepcon® HMS Control**

Hepcon HMS Controls for heparin assay monitoring is commercial, lyophilized materials. A quality control is performed weekly. Required clotting time should be <249 seconds. Heparin concentration should be at or near the quantity of heparin added to the particular control type. Control results are sent to the Core Lab/Point of Care testing for input in EP Evaluator for monthly Medical Director review. Quality Control is reviewed weekly by Point of Care testing area.
Use the control/cartridge type combinations as shows below:

<table>
<thead>
<tr>
<th>CAT #</th>
<th>Hepcon® HMS Control</th>
<th>Cartridge Type (U/mL)</th>
<th>Required Channel Detection</th>
</tr>
</thead>
<tbody>
<tr>
<td>306-01</td>
<td>Red/Yellow</td>
<td>RED (0.0-1.5)</td>
<td>4</td>
</tr>
<tr>
<td>306-02</td>
<td>Tan/Silver</td>
<td>SILVER (2.0-3.5)</td>
<td>3 or 4</td>
</tr>
<tr>
<td>306-03</td>
<td>Blue/Gold</td>
<td>BLUE (2.5-4.0)</td>
<td>3 or 4</td>
</tr>
</tbody>
</table>

1. Bring controls stored in the refrigerator to room temperature. Each vial contains enough sample to run two cartridges.

2. Add 2.5 cc of deionized water, packaged with the controls, to each vial.

3. Swirl gently to thoroughly rehydrate the control. **DO NOT SHAKE!**

4. Allow to rehydrate for at least 3 minutes.

5. Insert the appropriate Hepcon HMS cartridge into the HMS Plus instrument heat block.

6. Select “Quality Control Menu” from the Main Menu screen.

7. From the QUALITY CONTROL (QC) MENU screen, press the Start/Stop key to initiate the test.

8. The HMS Plus instrument reads the cartridge code, identifies the appropriate control to use, and displays this information on the QUALITY CONTROL (QC) TEST screen.

9. Prepare the appropriate control for the cartridge type being used per the instructions above. Fill the syringe and prime the needle as instructed.

10. Insert the syringe and needle into the dispenser of the HMS Plus and press the Start/Stop key to initiate the test.

Once dispensing is complete, the QUALITY CONTROL HPT IN PROGRESS screen will appear. This screen functions and appears identical to the HPT IN PROGRESS screen, except no patient number or ID is displayed and the screen’s title identifies it as a quality control test. At test completion, the QUALITY CONTROL HPT RESULTS screen appears.

When the test is complete, the detected heparin concentration and run time will be displayed. Verify that the correct channel is detected and that the run time did not exceed the limit of 249 seconds. If Quality Control fails repeat and if Quality Control still fails contact Perfusion or the Core Lab.

Results are reviewed by the Point of Care Coordinator and signed monthly by the Laboratory Medical Director or designee.
CLOTtrac® HR and CLOTtrac® HR Abnormal Control

CLOTtrac HR Control and CLOTtrac HR Abnormal Control for ACT monitoring is commercial, lyophilized materials. Both levels of controls are run weekly. Acceptable ranges for each level of control is determined from the package insert accompanying the current lot number of control stock. Control results are sent to the Point of Care Coordinator and entered in EP evaluator for review. Hepcon tapes are retained for 2 years. Quality Control is reviewed by Point of Care Coordinator, and monthly signed by the Laboratory Medical Director or designee.

1. Remove the CLOTtrac HR and CLOTtrac HR Abnormal control and de-ionized water vials from refrigerator and allow to come to room temperature, approximately 10 minutes.

2. To the lyophilized whole sheep blood, add 1.8 mL of deionized water. DO NOT AGITATE THE CONTROL UNTIL COMPLETELY REHYDRATED.

3. Allow at least 10-20 minutes for adequate rehydration.

4. Once rehydrated, shake the control vigorously until the red blood cells are uniformly dispersed and the control is completely reconstituted.

5. Shake or tap the cartridge to re-suspend the cartridge reagents, and insert into the machine.

6. Insert the appropriate HR-ACT or LR-ACT cartridge into the HMS Plus instrument heat block.

7. Select “Quality Control Menu” from the Main Menu screen.

8. From the QUALITY CONTROL (QC) MENU screen, press the Start/Stop key to initiate the test.

9. The HMS Plus instrument reads the cartridge code, identifies the appropriate control to use, and displays this information on the QUALITY CONTROL (QC) TEST screen.

10. Fill the syringe and prime the needle as instructed.

11. Insert the syringe and needle into the dispenser of the HMS Plus and press the Start/Stop key to initiate the test.

Once dispensing is complete, the QUALITY CONTROL HR-ACT INCUBATION screen will appear. An incubation time of 300 seconds is required when running a HR-ACT quality control test; the instrument automatically performs this when a HR-ACT test is run in the quality control mode. The QUALITY CONTROL HR-ACT INCUBATION screen shows the elapsed “Incubation Time” on the display.

When the incubation period is complete, the QUALITY CONTROL HR-ACT INCUBATION screen appears. This screen functions and appears identical to the HR-ACT IN PROGRESS screen, except no patient number or ID is displayed and the screen’s title identifies it as a quality control test.

At test completion, the QUALITY CONTROL HR-ACT RESULTS screen appears. Compare the results of the test to the ranges in the Hepcon which appear on the printout.
IF QUALITY CONTROLS FAIL, REPEAT and then CONTACT the Perfusion Team or the Core Lab.

Quality Control is reviewed by the Point of Care Coordinator and monthly by the Laboratory Medical Director or designee. New Cartridge lots are checked by running Quality Control.

PROCEDURE:

Instrument Parameters for the CICU/PICU/NICU ECMO Patients on the Hepcon HMS+

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hep Conc Units</td>
<td>u/ml</td>
</tr>
<tr>
<td>Hep Type</td>
<td>IU</td>
</tr>
<tr>
<td>Prot-Hep Ratio</td>
<td>1.3:1</td>
</tr>
<tr>
<td>Protamine Units</td>
<td>mg</td>
</tr>
<tr>
<td>Confirm Pat</td>
<td>On</td>
</tr>
<tr>
<td>Output Mode</td>
<td>Auto Print</td>
</tr>
<tr>
<td>Audio Tone</td>
<td>On</td>
</tr>
<tr>
<td>All Ch Detect</td>
<td>Off</td>
</tr>
<tr>
<td>Dispenser</td>
<td>On</td>
</tr>
<tr>
<td>Language</td>
<td>English</td>
</tr>
<tr>
<td>Location</td>
<td>CPB-Pump Calc</td>
</tr>
</tbody>
</table>

Running a Heparin Dose Response (HDR)

HDR cartridges should be run on unheparinized samples obtained prior to vein or artery harvesting, or any other invasive procedures. Refer to the HDR cartridge package insert for additional information prior to running an HDR test.

Tests can be run from most screens at any desired time. Exceptions are when data input is active or printing is in progress.

1. Gently shake or tap the cartridge and place into the heat block and allow prewarming for at least 3 minutes prior to drawing the sample.

2. Draw a full 3.0 cc of sample into the syringe and attach the needle. Fill (prime) the needle with sample.

3. Insert the syringe and needle into the dispenser of the HMS Plus and press Start/Stop key to initiate the test.

Note: If the [Confirm Patient] parameter has been set to “On,” the CONFIRM PATIENT screen appears. Even if
the confirm patient selection has been set to “Off,” the CONFIRM PATIENT screen will appear after each power on and the first time a test is run after any parameter has been changed. Press the Start/Stop key again and the TEST DISPENSE screen will appear.

4. Once dispensing is complete, the HDR IN PROGRESS screen will appear. This screen shows the reagent heparin concentration - framed in a box – for each of the six (6) channels of the HDR cartridge.

5. At test completion, the HDR RESULTS screen appears.

6. Dispose of the cartridge and syringe in a biohazard waste container.

7. Record results in patients chart electronically. The O.R. staff records them on the flow chart sheet in the O.R. suite.

**Running a Heparin Assay (HPT)**

It is a four or six channel test, with each channel of the cartridge containing a different amount of protamine and a constant amount of thromboplastin, for activation of the test. The channel to clot is the one in which the amount of protamine most closely neutralizes the heparin in the blood, without an excess of either heparin or protamine.

The heparin concentration is used by the HMS Plus to calculate any additional heparin required to maintain the patient. The data is also used to calculate protamine required for neutralization.

The accuracy of the Heparin Assay is dependent on the cartridge channel resolution. This resolution varies from 0.3 to 0.5 mg/kg (0.4u/mL to 0.7 u/mL) depending on the cartridge range. The determination of heparin concentration by protamine titration remains extremely reliable under conditions of hypothermia, hemodilution and dosing with platelet active drugs. The heparin measurement obtained is considered valid as long as the sample heparin level lies within the range of the selected cartridge.

The following table indicates the available HPT Cartridges and Heparin Range used at this institution:

<table>
<thead>
<tr>
<th>Heparin Level (u/mL)</th>
<th>Cartridge</th>
<th>Range</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Red:</td>
<td>0.0-1.5 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Tan:</td>
<td>1.5-3.0 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Silver:</td>
<td>2.0-3.5 mg/kg</td>
</tr>
<tr>
<td></td>
<td>Blue:</td>
<td>2.5-4.0 mg/kg</td>
</tr>
</tbody>
</table>

1. Gently shake or tap the cartridge and then place into the heat block. If a HR-ACT is also being run, allow both to prewarm for at least three (3) minutes prior to drawing the sample. If ONLY Heparin Assay tests are being performed, the prewarming can be omitted.

2. Collect approximately 3.0 cc of sample into the syringe and attach the needle. Fill (prime) the needle with sample. The minimum sample needed for a four channel Heparin Assay is 1.5 cc; six channel Heparin Assay cartridges require 2 cc. At least 2.5 cc of sample is needed for a combined Heparin Assay (HPT) and HR-
ACT tests.

3. Insert the syringe and needle into the dispenser of the HMS Plus and press the Start/Stop key to initiate the test.

4. Once dispensing is complete, the HPT In PROGRESS screen will appear. At test completion, the HPT RESULTS screen appears. The results for heparin concentration are displayed in the units selected for [Heparin Conc Unit] parameter (mg/kg, u/kg, u/mL)

5. Dispose of the cartridge and syringe in a biohazard waste container.


**Running an Activated Clotting Time (HR-ACT)**

The two channel HR-ACT can be run with a Heparin Assay or can be run by itself. The HR-ACT must be run in channels 5 and 6. The HMS Plus will recognize the presence of the two-channel cartridge and dispense sample into channels 5 and 6 only. Tests can be run from most screens at any desired time. Exceptions are when data input is active or printing is in progress.

1. Gently shake or tap the cartridge and place into the heat block and allow prewarming for at least 3 minutes prior to drawing the sample.

2. Draw approximately 3.0 cc of sample into the syringe and attach the needle. Fill (prime) the needle with sample. *The minimum sample needed for a HR-ACT is 1.0 cc.*

3. Insert the syringe and needle into the dispenser of the HMS Plus and press Start/Stop key to initiate the test

**Note:** If the [Confirm Patient] parameter has been set to “On,” the CONFIRM PATIENT screen appears. Even if the confirm patient selection has been set to “Off,” the CONFIRM PATIENT screen will appear after each power on and the first time a test is run after any parameter has been changed. Press the Start/Stop key again and the TEST DISPENSE screen will appear. Operator will enter their pin number.

4. Once dispensing is complete, the HR-ACT IN PROGRESS screen will appear. This screen shows cartridge channels 5 and 6. As the HR-ACT test proceeds, the “Elapsed Time” is displayed to indicate the test run time.

5. The HR-ACT RESULTS screen appears. The “Average ACT” of the two channels is presented. If only one channel detected, the result will be the clotting time of the channel to detect. If neither channel detected, the screen will display “Average ACT >999” for the result.

6. Record the clotting time for the individual channels and the average clotting time in the patient's chart.

7. Dispose of the cartridge and syringe in a biohazard waste container.

**CALCULATIONS:**

Location of online document:S:\CLINLAB\Point Of Care\procedures and documents\Hepcon HMS Plus\Hepcon HMS Plus - Operating Procedure.DOC
The instrument performs calculations.

RESULTS:

Additional test information is available by pressing the [More Test Information] variable function key. For more information on the manipulation of the Hepcon HMS Plus data displays, consult the Hepcon® HMS Plus Operator’s Manual.

PROCEDURE NOTES:

1. When performing fresh whole blood test, prewarm the cartridge for 5 minutes.
2. Use ONLY syringes and needles packaged with the cartridge to ensure accurate dispensing.

LIMITATIONS OF THE PROCEDURE:

To obtain accurate and consistent activated clotting times; the following must be observed:

1. The instrument heat block should be at 37 ± 0.5ºC.
2. The sample should be run as soon as possible after being drawn and be free of tissue thromboplastin.
3. Patient diagnosis and medications should be noted. Medications can alter clotting times. Tests should be repeated if unexplained abnormal values are obtained.
4. To optimize precision, all technique variables should be held constant from test to test.
5. On bypass, a number of factors can influence the performance of the HR-ACT. These include: patient sensitivity to heparin, dilution of clotting factors by the extra corporeal circuit, the use of citrated blood products, the use of anti-platelet drugs, hypothermia, fluctuating calcium levels, a change in platelet function or count, unknown coagulopathies, etc. These factors must be taken into account when evaluating the performance of the HR-ACT during bypass.
6. The Hepcon HMS Plus has a detection limit of 999 seconds for both HR-ACT and heparin assay tests. After this time the machine shuts down and displays results of >999 sec. The range for ACT assays is 0-999. Normal Ranges vary according to the Surgeon’s protocol in the Operating Room, or when on ECMO.

MAINTENANCE:

Monthly: Performed by Perfusion Team or Core Lab Staff

Dispenser Volume Delivery Verification

1. From the QUALITY CONTROL (QC) MENU screen, press the [Verify Dispenser Volume Delivery] variable function key to display the first dispenser volume delivery verification screen. There are three (3) screens displayed during this procedure.
2. Pull back the plunger of an empty 3 cc (mL) Monoject syringe to the 2 cc (mL) mark and insert the syringe into the syringe holder as if preparing to run a test.

3. Press the Start/Stop key as instructed on the screen. The syringe holder will move to the left and the second screen will appear with the message “Delivering 1 mL” flashing in inverse.

4. When dispensing is complete, the third screen will appear. The dispenser should move the syringe plunger from the 2 cc (mL) mark to the 1 cc (mL) mark. Verify that the plunger has been moved to within 0.1 cc (one graduation mark) of the 1 cc (mL) line.

5. If the appropriate volume is not dispensed, contact the Perfusion Team or Clinical Core Laboratory for assistance. Do not proceed with testing.

**Heat Block Temperature Verification**

1. Turn the Hepcon HMS Plus instrument on and allow 20-25 minutes for it to warm up. **Note:** The instrument’s heat block temperature must be between 35 and 39°C for adjustments to be made.

2. Use the Temperature Verification Cartridge, following the directions in the cartridge’s package insert.

3. From the **QUALITY CONTROL (QC) MENU** screen, press the **[Temperature Adjustment]** variable function key to display the TEMPERATURE ADJUSTMENT screen.

4. Read the temperature from the Temperature Verification Cartridge. The instrument temperature and the actual measured temperature should both read within the 36.5 – 37.5°C range.

5. If the measured temperature is not the same as the “Instrument Temperature” displayed, the measured value can be entered with the numeric keypad. The acceptable value that can be entered must be between 35 and 39°C and the **Enter** key must be pressed to accept the value.

**Note:** If the displayed instrument temperature is not adjusted, simply press the **Cancel** key to retain the current value.

6. If the measured temperature is not between 36.5 - 37.5°C, contact the Clinical Core Laboratory or Perfusion.

7. Maintenance is performed by the Perfusion Team or the Core Lab.

**Routine Cleaning**

The instrument case exposed surfaces of the actuator and dispenser should be kept clean. Clean the case routinely by wiping off dust and dried blood with a cloth dampened with water, isopropyl alcohol or diluted bleach (20% household). Performed by Nursing, Perfusion Team or Core lab.

**REFERENCES:**


Donna Walck  
Written By: 

Technical Supervisor  

Date  

Medical Director  

Date  

Annual Review: Medical Director/Designee  

Date  

Location of hard copy location(s):  

Core Lab Office  
See Test Methods / Test Locations (POC.1.0002.0)  

Date Archived:  

Location of online document: S:\CLINLAB\Point Of Care\procedures and documents\Hepcon HMS Plus\Hepcon HMS Plus - Operating Procedure.DOC