

OREGON HEALTH & SCIENCE UNIVERSITY
Hospitals and Clinics
Point of Care

**Hemostatis Management, Whole Blood
by Medtronic HMS II**

Principle

The Hepcon HMS is a microprocessor based, multichannel, clot timing instrument, with automated syringe handling for pipetting blood into single use cartridges. This integrated system also contains a component for computing the results of the clot detection tracking mechanism. The cartridge instructs the system, through an optical code, as to the type of test being performed. It also determines calculations and format required for results and volume of samples 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 actuator as the sample clots, a fibrin web forms around the daisy, located on the bottom of the plunger assembly and impedes the assembly descent rate. This change in fall rate is detected by photocells within the actuator of the instrument. The end point of the test is the time at which formation is detected.

The Hepcon HMS 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.

Test results consist of clotting time data. Heparin and protamine results are derived from the channel clotting time data of the Heparin Assay cartridges.

Activated Clotting Time (HR-ACT)

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.

The HR-ACT is a two-channel cartridge and the end point to the test is the detection of clot formation. Each cartridge reagent chamber contains 0.1 mL of kaolin suspended in HEPES buffer, calcium, and sodium azide as a bacteriostatic agent.

Heparin Assay (HPT)

The Heparin Assay Test uses the principle of heparin/protamine titration to quantitatively determine the concentration of heparin in the sample. 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 to calculate any additional heparin required to maintain the patient. The data is also used to calculate protamine required for neutralization.

Heparin Dose Response (HDR)

The HDR cartridge is a modification of an activated clotting time (ACT). The test is designed to help identify patients who may be unusually sensitive or resistant to heparin anticoagulation.

Each cartridge reagent chamber contains 88 microliters of HR-ACT reagent (kaolin, calcium in a HEPES buffer, and sodium azide). Channels 1 and 2 contain USP beef lung heparin at a concentration which gives 2.5 units of anticoagulant activity per mL of blood while channels 3 and 4 contain heparin at a concentration which gives 1.5 units of anticoagulation activity per mL of blood. Channels 5 and 6 do not contain heparin.

Specimen Requirements

Whole blood via the patient's arterial or venous blood line. A 2-3 cc discard syringe should be used in order to obtain a clean draw sample. The system uses only a 3 cc Monoject syringe, and a 19 gauge blunt needle, both provided by Medtronic HemoTec, Inc.

Limitations: HR-ACT Test, Heparin Response Dose and Heparin Assay

Patient samples for the HR-ACT test and the Heparin Protamine Titration should be run as soon as possible, preferably within 60 seconds for un-heparinized samples and 2 minutes for heparinized samples.

If blood is obtained by venipuncture, the site should be clean and the first several milliliters of blood discarded to avoid contamination of the sample with tissue thromboplastin. Samples taken from heparinized in-dwelling catheters, or other anticoagulated lines, should be thoroughly flushed so that a sample can be drawn that is representative of the patient.

When on bypass, several factors can influence the performance of the HR-ACT. These include: patient sensitivity to heparin, dilution of the clotting factors by the extracorporeal circuit, use of citrated blood products, use of antiplatelet drugs, hypothermia, fluctuating calcium levels, a change in platelet function or count, and unknown coagulopathies. These factors must be taken into consideration when evaluating the performance of the ACT during bypass.

The HDR test follows the same limitations as the ACT and HPT in regard to specimen

collection and preparation. Since the sample being used (whole blood) does not contain an anticoagulant, it should be run as soon as possible, preferably within 60 seconds.

Individual responses to heparin vary considerably. An *in vitro* test measures only variables present in the whole blood sample, which contribute to variations in response to heparin, and cannot measure all *in vivo* variables. Therefore, it is important that all technique variables be held consistent from test to test.

During patient diagnosis any medications should be noted. Medications and conditions can alter clotting times. Any of the cartridges (HPT, HR-ACT, and HDR) should be repeated when unexplained abnormal values are obtained. If the results are still abnormal, and no cause apparent, a sample can be citrated and saved for further analysis in the clinical laboratory.

Accuracy

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.

HMS 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. At high heparin levels and clotting times in excess of 600 seconds, an ACT is generally not considered to be adequately reliable for monitoring heparin anticoagulation. The cartridge is controlled to maintain an average population response of approximately 100 seconds per unit of heparin (136 sec/mg/kg heparin). The baseline range of a controlled group of ten average donors gave a mean baseline of 117 seconds with a range of 99-135 seconds (2 standard deviations).

The HDR cartridge is controlled to maintain an average response of approximately 100 seconds per unit of heparin. The clotting times from a group of 10 average donors have a mean 2.5 u/mL time of 306 seconds (2 S.D. = 62 seconds) and a mean 1.5 u/mL time of 213 seconds (2 S.D. = 34 seconds). The HDR cartridges typically do not exceed a variation of +/- 12% of the average of the paired channels (channels 1 and 2, channels 3 and 4).

Heparin Ranges

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

Heparin Level				
Cartridge	CH1	CH2	CH3	CH4
Red	0.0	0.3	0.6	0.9 mg/kg
Tan	1.5	2.0	2.5	3.0mg/kg
Blue	2.5	3.0	3.5	4.0 mg/kg

ACT Normal and Therapeutic Ranges

Test Cartridge	Recommended Use For Heparin Levels	Test Use	Monitor Pre-Heparin Administration	Monitor Heparin During Cardiac Surgery
HR-ACT	N/A	Therapeutic Limits	90-150 seconds	480 seconds

Quality Control

Quality Control must be run every eight hours of patient testing. Generally the Electronic Quality Control HEPtrac will be run every eight hours of patient testing. Liquid control for the Heparin Assay and ACT testing should be run once a week and when a new box of cartridges is opened.

A. Electronic Quality Control HEPtrac

The HEPtrac checks the following aspects of the HMS that relate to proper functioning of the test cartridges.

1. Flag Sensor Function
2. Reagent Delivery
3. Flag Release Force
4. Flag Height
5. Clotting Time Ranges Level 1,2,3, and 4 Testing

All four levels are tested when the HEPtrac is run.

Level	Clotting Time in seconds
1	47-53
2	130-138
3	293-307
4	489-511

To conduct the HEPtrac test:

1. Confirm that the HMS printer is set to the AUTO or REQUEST mode of operation.
2. Place the HEPtrac in the HMS.
3. Press the "START/STOP" or "CONT" key to initiate the test. The HMS message panel will display "HEPtrac ELECTRONIC QC".
4. The "START/STOP" and "PAPER ADV" key are active while the HEPtrac is running. If any other key is pressed the HMS will sound an audible tone.
5. After completing the test (approx. 10 minutes), the HMS will make a sound and results will print.
6. Check the printed results.
7. Record on QC log.
8. If any failures occur, the HMS printout will print the failure(s) and the statement "QC TEST ABORTED".
9. Note any failures on the QC log sheet.
10. Repeat the test.
11. If test results still produce failures, do not perform any patient testing and contract Medtronics Technical Support at 1-800-525-7007.

B. HMS HEPARIN CONTROLS should be run weekly and when a new box of cartridges is opened.

Note: An HPT cartridge and control cannot be run at the same time as the HR-ACT cartridge due to the need for an incubation period for the HR ACT controls.

1. Bring controls stored in the refrigerator to room temperature. Each vial contains enough sample to run one cartridge.
2. Add 2.5 cc of de-ionized water, packaged with the controls, to each vial. **DO NOT SHAKE.**
3. Allow to rehydrate for at least **three** minutes.
4. Swirl gently to thoroughly rehydrate the control.
5. Insert the Heparin Assay cartridge in the HMS.
6. Select "Quality Control Menu" from the Main Menu screen.

7. With the Quality Control Menu screen displayed, press the “START/STOP” key to begin the test.
8. The instrument will verify the appropriate control to be used. Fill a syringe with control and prime the needle. Place this control into the dispenser and lock in place.
9. Press “START/STOP” to run the control test.
10. When the test is complete, the detected concentration will be shown in the Heparin CONC display. Verify that detection occurred in the required Heparin Assay channel and that the run times are within the limits stated in the Table below.

Hepcon HMS Control	Cartridge Type (mg/kg)	Required Channel Detection	Clotting Time in seconds
Red/Yellow1	0.0-0.9 (Red)	4	<249
	1.5-3.0(Tan)	4	<249
Blue/Gold	2.5-4.0 (Blue)	3 or 4	<249

11. Record results on QC log.

C. CLOTTRAC HR CONTROLS Normal and Abnormal should be run weekly and when a new box of cartridges is opened.

1. Remove the CLOTtrac HR coagulation control and de-ionized water vials from refrigerator and allow them to come to room temperature, approximately 10 minutes.
2. To the lyophilized whole sheep blood, add 1.8 mL of de-ionized water. DO NOT AGITATE THE CONTROL UNTIL COMPLETELY REHYDRATED.
3. Allow at least 10 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. Once rehydrated the control is stable for 1 at room temperature, 15°-25° C.
6. Shake or tap the cartridge to re-suspend the cartridge reagents, and insert into the machine.
7. Select “Quality Control Menu” from the Main Menu screen.

8. Press the "START/STOP" key to begin test.
9. Fill a syringe with the reconstituted control and prime the needle.
Place the filled syringe, with needle, into the dispenser.
10. Press "START/STOP" again to initiate the test.
11. When the test is complete, the average clotting time for the HR-
ACT will be shown in the "TEST TIME" display.
12. Verify the clotting time is within the range stated on the label on the
last page of the package insert.
13. Verify that there is less than a 12% variation between channel
clotting times.
14. Record on QC log

D. Quality Assurance for Heparin Dose Response

A range of HDR slopes is used for quality assurance tracking. The range should be updated after every 50 days using one patient per day for tracking.

1. Record pertinent cartridge and instrument information on the Quality Assurance
Record and tracking chart.
2. Obtain slope data from the first 50 patients.
3. Calculate mean and standard deviation for the first 50 patients.
4. Establish a range of 3 standard deviations from the mean.
5. Use this range for the next 50 days. 98% of all values recorded should fall within
this range.
6. Samples outside of this range should be retested using a fresh sample.
7. A new slope range should be established and modified every 50 days.
8. The average slope of the new 50 patient group must be within $\pm 12\%$ of the
previous patient group.

Limitations of Liquid Quality Control Procedure

Results are dependent on good technique. Strict adherence to rehydration requirements is recommended.

Failure to obtain in range quality control invalidates the use of both the instrument and the assay until the problem is resolved.

If QC fails:

1. Ensure that the cartridge, instrument and control are at $37^{\circ}\text{C} \pm 5^{\circ}\text{C}$ before initiating the test.
2. Ensure that all controls, cartridges and CaCl_2 have not exceeded their respective expiration dates.
3. Ensure that the control was properly reconstituted.
4. Inspect control for visible clot formation.
5. Repeat the test if the above criteria have been met.
6. If repeat QC fails, do not perform patient testing.
7. Repeat QC test using new lot number of cartridges if available.
8. If repeat fails rerun using new lot # of QC if available.
9. If this also fails, do not perform patient testing. Contact Medtronic Technical Service at 1-800-525-7007.

Instrumentation Verification

The temperature of the heat block is verified along with the volume delivery once a month.

Verification of Heat Block Temperature

1. If the HMS instrument is not already left in the "on" mode, turn the instrument on, and allow 20-30 minutes for it to warm up.
2. Use a temperature verification cartridge from Medtronic HemoTec, Inc.
3. Program the HMS to display the temperature continuously:
 - a. Press "PRGM", then enter "510".
 - b. Press "0" to select the **on** option.
4. Turn the temperature verification cartridge on by pressing the blue power

button.

5. Insert the temperature verification cartridge into the heat block of the instrument.
6. Once the temperature of the heat block is reached, the °C symbol will stop blinking and a beeper will sound.
7. The instrument temperature and actual temperature should both read within the 36.5 to 37.5 °C range.
8. To return the message display to normal operation:
 - a. Press “PRGM”, then enter "510".
 - b. Press "0" to select the **off** option.

Verification of Dispenser Volume Delivery

1. Pull back the plunger of an empty 3 cc Monoject syringe to the 2 cc mark, and insert the syringe into the syringe holder, as if preparing to run a test.
2. Press “PRGM” and enter "740". The syringe holder will move to the left and the message display will show "Pipet 1 ML".
3. Press the “START” key. The dispenser should move the syringe plunger from the 2 cc mark to the 1 cc mark. Verify that the plunger has been moved to within 0.1 cc (One graduation mark) of the 1 cc line.
4. If appropriate volume is not dispensed:
 - a. Verify placement of syringe.
 - b. Ensure that the dispenser is in the locked position.
 - c. Ensure that the syringe is from Medtronic.
 - d. Contact Medtronic HemoTec Service or an authorized representative, if dispenser volume delivery cannot be verified.
5. To exit this program, press “PRGM.”

Procedure

TEST PREPARATION

Prior to running the patient sample, certain default parameters must be entered into the HMS instrument. They are as follows:

1. Patient I.D. Number.
2. Patient Height. Enter height in feet and inches, or in centimeters (exp. 5' 11" is 180 cm).
3. Patient Weight. Enter weight in lbs or in kgs (exp. 176 lbs. is 80.0 kg).

4. Sex of Patient. Enter M (male) or F (female).
5. When pressing the "PAT VOL" button, one can obtain patient blood volume and the patient's BSA (body surface area).
6. Only use the HMS, 3 cc Monoject syringes and 19 gauge 1.5 inch blunt needles provided when obtaining a patient sample. Also, verify the heat block temperature is at $37.0^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$ (Press the " $^{\circ}\text{C}$ " button).
7. Syringe insertion is very important to the success of the test. Follow these guidelines:
 - a. Draw the appropriate amount of sample into the syringe (2.5 - 3.0 cc's), attach and prime the needle.
 - b. Insert the sample filled syringe into the dispenser by sliding the needle through the keyhole slot, so the hub of needle is on the syringe holder foot.
 - c. Rotate the syringe until the cross-member of the syringe plunger is parallel to the face of the syringe holder.
 - d. Press the syringe body into the syringe holder, insuring that the cross-member is positioned between the drive wheel and the syringe clamp.
 - e. Push the syringe lock-lever down to hold the syringe in the holder.
 - f. Upon completion of the test, remove the syringe, then the cartridge(s), and dispose of them in an appropriate hazardous waste container.

SCREEN PROTOCOL

1. To set up the screen mode, press "PRGM" and enter "410". (This does not have to be entered each time a new patient sample is run.) Gently shake or tap the HDR cartridge and place into the heat block, and allow to pre-warm for at least three minutes prior to drawing the sample. The HDR should be performed on unheparinized samples obtained prior to vein or artery harvesting and before any systemic heparin is given.
2. Verify that the correct patient and protocol parameters have been entered as discussed in the procedure protocol, (Protocol View/Enter) section, p18.

3. Draw a full 3 cc of sample into the syringe and attach the needle. Fill the needle with the sample.
4. Insert the needle/syringe into the dispenser of the HMS and press the "START/STOP" to initiate the test.
5. The HMS will go into the "REQ" mode. "TOT" will be illuminated and the running time will be shown in the test time display window.
6. When the test is finished, the test time result will show the average baseline clotting time. Also, a print-out of the results of the HDR test will automatically be sent out from the instrument. Record these parameters on the patient's heparin management record.
7. The system will display the patient's estimated reference heparin concentration for the desired clotting time (REF HDR), which is seconds. The HDR test will print and/or display an "HDR PROJ" (HDR projection). This is the patient's individual sensitivity to heparin, and this mg/kg dose may be less than, or greater than the standard mg/kg guideline. Press "PRINT" to display a new print-out of the projected clotting range and enter this on the patient's heparin management record. At this time, you may also enter the HDR Slope, HDR REF and clotting times from the print-out.
8. At this time, the HMS can compute a bolus dose of heparin for the patient. Either a predetermined amount of heparin can be entered, or the heparin prime dose may be entered as "0", therefore, the HMS does not take any heparin into account when computing the patient-dose. In order to obtain the amount of heparin to be added to the pump, simply press "BOL" and the heparin amount will be displayed. By pressing the "PAT" key, the loading dose of heparin to be given (by the surgeon) will be displayed for this patient. Also, by pressing "TOT", the total amount of heparin the patient will receive, will be displayed. All three of these parameters should be entered on the patient's heparin management record.
9. Error or precautionary conditions associated with the HDR test can be self diagnosed by the HMS. If any such conditions occur, a message will appear in the message display prior to calculations of results. Error and precautionary messages are discussed in Section 9 (Service and Troubleshooting), in the Hepcon HMS Operator's Manual/Quality Control Log Book. If the difference between any channel pair is greater than $\pm 12\%$, "CHECK TIMES CH XX" will appear on the message display and indicate the channel pairs: that are out of specification. Inappropriate channel clotting times can be edited and the results recalculated. Refer to EDIT instructions in the Operator's Manual.

10. After the heparin has been given and allowed to circulate for 3-5 minutes, verify concentration and effect by running a Heparin Assay and HR-ACT cartridge.
11. Heparin Assay cartridges are selected based on the desired protocol. The desired heparin concentration to maintain the patient (REF CONC) should correspond to the third or fourth channel of a 4 channel cartridge or the fourth, fifth, or sixth channel of a 6 channel cartridge. For example, if the projected heparin concentration is 2.0 mg/kg, select a Heparin Assay cartridge where the concentration of 2.0 mg/kg is in Ch 3 or 4 of a 4 CH cartridge or Ch 4, 5, or 6 of a 6 CH cartridge. The test is considered valid only if the test results lie within the range of the selected cartridge.

RUNNING A HEPARIN ASSAY AND HR-ACT

1. Gently shake or tap the HR-ACT cartridge and appropriate Heparin Assay cartridge and place into the heat block and allow both to prewarm for at least three minutes prior to drawing the sample. This initial test should be run within the first 5-10 minutes after going on bypass.
2. Draw approximately 3 cc's of sample into the syringe (at least 2.5 cc's are needed for Heparin Assay and HR-ACT). Prime the needle with sample.
3. Insert the needle/syringe into the dispenser of the HMS and press "START/STOP" to initiate the test.
4. The HMS will go into the "REQ" mode. "TOT" will be illuminated and the running time will be shown in the "TEST TIME" display.
5. While on bypass, verify heparin concentration and effect by running a Heparin Assay and HR-ACT cartridge every 30 minutes. Give additional heparin only if the HR-ACT result is less than the desired clotting time. Use the "HEPARIN" units display as a guide for the amount of heparin to give in order to stay above target ACT.
6. Precaution: Patients with varying metabolic rates may require more frequent testing, accompanied by heparin additions to maintain safe anticoagulation.
7. If the run time for the Heparin Assay is greater than 249 seconds, the test is not considered valid. The message display will indicate "HPT RUN TIME GREATER THAN 249 SEC". A warning condition will appear on the printout.

PROTAMINE REVERSAL

1. Just prior to coming off bypass, perform a Heparin Assay and HR-ACT to determine heparin concentration for calculation of protamine dosage.
2. Before, during, or after the test is initiated, press "PROT" for the protamine neutralization mode. In this mode, "PAT" will be illuminated.
3. Place the appropriate Heparin Assay and HR-ACT cartridge into the heat block and allow at least three minutes to prewarm.
4. Draw about 3 cc of a sample into the syringe and attach the needle. Fill the needle with sample.
5. Insert the needle/syringe into the dispenser of the HMS and press "START/STOP" to initiate the test.
6. The amount of protamine (in mgs) for the patient will be displayed in the "PROTAMINE" window. Pump protamine can also be displayed if blood is given back to the patient.
7. In the "PROT" mode, printouts show "TOT", "PAT", or "PMP" protamine as well as cartridge and reference information.
8. Once off bypass report the protamine dose to be given to the patient.
9. After the protamine has been slowly administered and allowed to circulate for ten minutes, verify neutralization by performing a low range Heparin Assay (Red Cartridge) and HR-ACT.
10. If bleeding occurs and the Heparin Assay indicates additional protamine is needed, report the dose to the surgeon and anesthesia staff. Repeat step 8 until no additional protamine is indicated. If bleeding still occurs, discuss with the surgeon, the possibility of a mechanical bleeding site, or if there is an indication of further coagulation tests needed, since bleeding could be the result of diluted or deficient clotting factors, or thrombocytopenia (poor platelet function or count).

Limitations: Heparin Assay

1. If the heparin concentration is measured at channel 1 in a Heparin Assay cartridge that does not have a zero (protamine) in channel 1, the actual heparin may be lower than the measured value.

2. If the heparin is measured in channel 4 the actual heparin value may be higher than the measured value. In either case, a different cartridge (higher or lower) should be run to confirm results.
3. Heparin concentration may vary significantly following administration of initial heparin dose.
4. Factors which may contribute to a HIGHER than calculated circulating heparin concentration include:
 - a. Patient's actual blood volume is less than the calculated blood volume.
 - b. Heparin activity is greater than expected. (USP grade heparin activity may vary by 10% from published values).
 - c. Heparin is inadequately mixed with patient-prime fluid.
 - d. Metabolic rate and blood temperature may influence the half like of heparin.
5. Factors which may contribute to a LOWER than calculated circulating heparin concentration include:
 - a. Patient's actual blood volume is greater than the calculated blood volume.
 - b. Heparin activity is less than expected. (USP grade heparin activity may vary by 10% from published values).
 - c. If a heparin dose that is smaller than required is added to the prime, there will be an abrupt decline in heparin concentration upon initiating bypass.
 - d. Metabolic rate and blood temperature may influence the half-life of heparin.
 - e. Sequestering of heparin in extremities.

Results Reporting

1. Accuracy and precision depends on the quality of the blood sample, testing technique, and ambient conditions such as temperature.
2. Heparin Assay cartridges give a result in the time frame of 30-300 seconds.
3. If all four Heparin Assay channels clot before 30 seconds, sample may be activated and channel clotting time resolutions may not be great enough to give a reliable result.
4. Heparin Assay run times greater then 300 seconds may indicate heparin level is higher then range of the cartridge, the expiration date has been exceeded or the cartridge was improperly handled or stored.
5. Record results in the patient's record.

Reagents

1. Heparin Assay (HPT) Cartridge: Cartridges are stored at room temperature (20-25°C) for up to eight weeks, or refrigerated or frozen for up to 24 weeks.
2. Activated Clotting Time (HR-ACT) Cartridges: Cartridges are stored at room temperature (20-25°C) until expiration date on box.
3. Heparin Dose Response (HDR) Cartridges: Cartridges are stored at room temperature (20-25°C) up to eight weeks or 24 weeks refrigerated.
4. HMS Controls:
 - a. Heparin Red/Yellow
 - b. Heparin Tan/Silver
 - c. Heparin Blue/Gold
5. Heparin controls are stored refrigerated for 52 weeks
6. ACT CLOTtrac HR Control Pak (contains normal and abnormal controls):
 - a. ACT CLOTtrac controls should be refrigerated for 19 weeks.

Maintenance

1. Actuator cleaning: Weekly or as needed
 - a. Inspect and clean the cartridge opening monthly and as otherwise needed. If blood should get into the actuator assembly it is critical that the instrument be cleaned as soon as possible.
 - b. Use Actuator Cleaning Kit to clean actuator.
 - c. Dip swab, provided in the packet, in the Liqui-Nox Solution.
 - d. Swab the flag lift wire, removing all blood.
 - e. Swab inside the actuator cover, especially the detector and emitter area of the photo-optical system.
 - f. Remove excess Liqui-Nox with a dry swab.
 - g. If blood should get into the photo-optical detector and emitter area and cannot be removed with a swab, error codes may be displayed. If this occurs, contact the Medtronic Blood Management Technical Service at 1-800-525-7007.
2. Installing Printer Paper:
 - a. The HMS internal printer requires thermal printer paper than can be ordered from Medtronic HemoTec, Inc. To install printer paper, see Figure 6-1 in the HMS Operator's Manual.

3. Routine Cleaning: Weekly or as needed
 - a. The Instrument case and exposed surfaces of the actuator and dispenser should be kept clean with a damp cloth, isopropyl alcohol, 3% hydrogen peroxide diluted zephirin chloride, or mild detergent. There is a cleaning kit for the HMS provided by Medtronic HemoTec, Inc.
 - b. The salvage reservoir, located in the right hand side plate of the dispenser, is designed to catch any residual blood from the needle. This disposable reservoir should be changed daily, or as required (between patients).

References

1. Medtronic HEMOTEC Quality Assurance Manual.
2. Medtronic HEPCON HMS Plus Manual.
3. Medtronic HEPTRAC pamphlet.
4. Medtronic CLOTTRAC Coagulation Control inserts.
5. Medtronic Heparin Control package inserts.

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