Medtronic

HMS Plus

HEMOSTASIS MANAGEMENT SYSTEM

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Believing in the technology... investing in the future

The Trusted Standard, From A Company You Trust

Medtronic, the world's leading medical technology company and a key participant in blood management for more than a decade, introduces new features on the HMS Plus Hemostasis Management System that provide improved ease of use. The HMS Plus System is a reliable and versatile platform used to perform multiple tests for anticoagulation management.

Manufactured by Medtronic, the HMS Plus System combines a trusted standard in precise clot-detection technology with state-of-the-art user enhancements such as: bar code scanner, external data management program and connectivity-ready capabilities.

"Versatility makes HMS PLUS an effective tool for diverse patient management." [1]

HMS Plus
Hemostasis Management System

Why is Hemostasis Management Important for Your Patients?

- Assist in prevention of thrombus formation
- Help preserve clotting factors
- Monitor multiple aspects of anticoagulation

The HMS Plus technology was created with the recognition that the activated clotting time (ACT) is a global or functional test that measures the effect of many variables including:

- Medications
- Heparin anticoagulation
- Temperature
- Dilution

Measuring the ACT, or the degree of anticoagulation, is not always an indication of adequate heparinization or whether an appropriate antithrombotic state has been achieved.

Hemostasis management is achieved with the HMS Plus System and is well suited for use in the operating room, during ECMO, and when Point-of-Care heparin testing is important to successful medical treatment.

Optimized patient treatment using the HMS Plus System includes:	Test Cartridges Used
Measuring actual circulating heparin concentration	Heparin Assay Cartridges
Assessing patient's individual response to heparin	Heparin Dose Response (HDR)
ACT tests	High Range ACT (HR-ACT)

Benefits of the HMS Plus System

Benefits of Improved Hemostasis Management

- Fewer complications associated with excessive blood loss.[1]
- Preservation of the coagulation system, resulting in fewer transfusions.[2]
- Fewer surgical reoperations,[3] thus decreasing associated costs.

"Compared with heparin management with the activated clotting time, heparin concentration-based anticoagulation management during CPB leads to a significant reduction of thrombin generation, fibrinolysis and neutrophil activations, whereas there is no difference on platelet activation" [4]

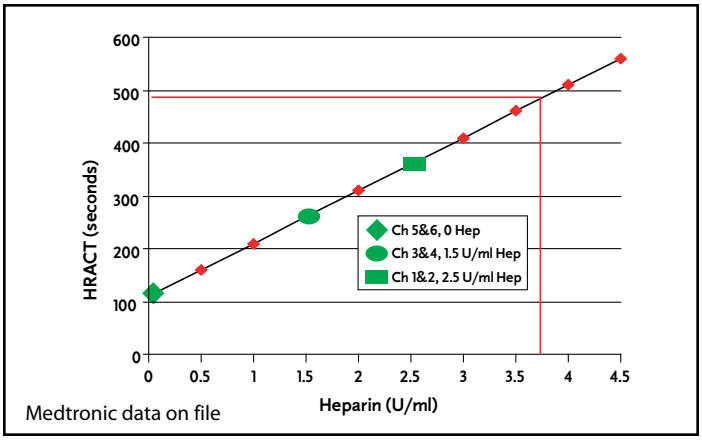
"Retrospective data revealed a marked reduction in the re-exploration rate and post-operative hemorrhage after the introduction of the Hepcon HMS..." [4]

Quantitative Heparin Measurement Versus Activated Clotting Times[2]

Criteria	Control (ACT)	Intervention (HMS)	p Value
Heparin	462 ± 114	612 ± 147	<0.0001
Protamine	0.94 ± .21	0.70 ± 0.64	0.0001
% Transfused	33%	17%	0.005
Closure Time	102 ± 34	92 ± 32	0.02
Platelets	3.7 ± 6.7	1.7 ± 3.6	0.003
FFP	1.4 ± 2.5	0.4 ± 1.3	0.001
Cryo	0.2 ± 1.2	0	0.04
n=254 patients			

Maintenance of patient-specific heparin concentrations, based on heparin concentration measurement during cardiopulmonary bypass led to greater heparin doses and lower doses of protamine relative to heparin dose. Patients in the interventional group received significantly fewer platelets, plasma and cryoprecipitate during the perioperative interval. Patients in the control group required increased hemostatic transfusion during the perioperative period and also required longer closure times.[2]

Heparin Dose Response (HDR) Test

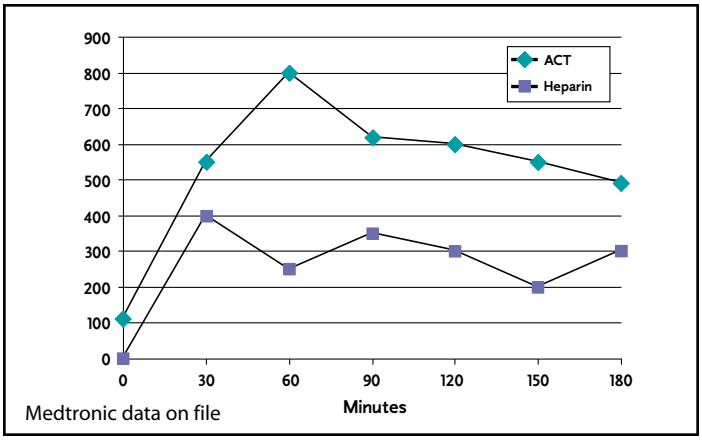


HMS Plus in vitro heparin dose response uses a baseline and two concentrations of heparin to project individual responses to heparin and determine the appropriate heparin dose for each patient.

"Of particular concern is the fact that the ACT has previously been shown to correlate poorly with plasma heparin levels during CPB." [5]

"With typical use of the ACT, the user may obtain values up to 3 times appropriate for the plasma heparin concentration. Potential consequences of this overestimation include the possibility of inadequate intraoperative anticoagulation by heparin, and vastly excessive delivery of protamine, resulting in increased post-operative bleeding." [6]

Heparin Concentration Versus Activated Clotting Times



Illustrates the lack of correlation between heparin concentration and ACT during cardiopulmonary bypass.

Improved Efficiency and Ease of Use

The HMS Plus System dispenses the appropriate volume of blood or control material into each cartridge channel.

Bar Code Scanner

- Saves time by making cartridge and control lot numbers and expiration dates easy to enter
- Efficient entry of patient and user ID

Version 4.0 Software

- Improvements to the user interface allow for more efficient navigation through the menus
- Easy storage and retrieval of results
- Helps maintain the security of patient information and data

Data and QC Management

- Supports the latest requirements for POC testing equipment
- Stores up to 200 patient and 100 QC records
- Offers QC and user lockout options
- Allows purge function of all test records
- Connectivity ready

"Importantly, the limits of agreement between measures are very tight at low heparin concentrations, when it is critical not to incorrectly assume adequate anticoagulation. This level of agreement, in conjunction with other beneficial features, such as the rapid turnaround time for results, individualized heparin-dosing protocols and more accurate protamine dosing, makes the Hepcon (HMS) a useful tool in the monitoring of anticoagulation during CPB." [5]

External Data Management (EDM)

- Stand alone software
- Easier download of data
- Documentation for billing and reimbursement
- QC and patient data management including preformatted reports

Quality Control

Lyophilized controls are available to verify instrument and cartridge function and to meet regulatory guidelines for testing.

The HEPtrac™ Electronic Quality Control provides a multi-level quality check to make quality control easier and faster to perform.

"The rapid disappearance of heparin from the circulation may in part be due to distribution to another body compartment and also possibly to heparin binding to the artificial surfaces. This decline in heparin levels was not detected by either ACT technique… the Hepcon (HMS) dropped accordingly." [5]

Ordering Information

HMS Plus Test Cartridges and Liquid Controls

Disposable cartridges undergo strict manufacturing standards and quality control to provide accurate, dependable performance. Cartridge room temperature and/or refrigerated shelf life are stamped on each box.

Heparin Assay Cartridges and Controls

Cartridges: Each box contains 9 cartridges with syringes and blunt tip needles				Controls: Each box contains 10 vials of control and deionized water	
Catalog #	**Description**	**# of Channels**	**Heparin Level**	**Control Catalog #**	**Description - (10 vials of control and 10 vials of deionized water for reconstitution)**
304-01POR	Red	4	0.0-0.9 mg/kg	306-01POR	Red/Yellow
304-02POR	Yellow	4	0.0-1.5 mg/kg		
304-03POR	Tan	4	1.5-3.0 mg/kg	306-02POR	Tan/Silver
304-04POR	Silver	4	2.0-3.5 mg/kg		
304-05POR	Blue	4	2.5-4.0 mg/kg	306-03POR	Blue/Gold
304-06POR	Green	4	3.5-5.0 mg/kg	306-04POR	Green/White
304-07POR	Orange	6	0.0-2.5 mg/kg	306-05POR	Orange
304-08POR	Gold	6	1.5-4.0 mg/kg	306-03POR	Blue/Gold
304-09POR	White	6	2.5-5.0 mg/kg	306-04POR	Green/White
304-10POR	Purple	4	4.5-6.0 mg/kg	306-09POR	Purple/Black
304-11POR	Black	6	3.5-6.0 mg/kg		

Heparin Dose Response Cartridge

Cartridges: Each box contains 9 cartridges, syringes, and blunt tip needles		
Catalog #	**Description**	**# of Channels**
304-20POR	HDR	6

High Range ACT

Cartridges: Each box contains 18 cartridges and 9 syringes, and blunt tip needles			Control: Each box contains 15 vials of control and deionized water	
Catalog #	**Description**	**# of Channels**	**Control Catalog #**	**Description**
304-30	HRACT	2	550-07	CLOTtrac HR Coagulation Control
			550-08	CLOTtrac HR Abnormal Coagulation Control
			550-13	CLOTtrac HR Control Pak Coagulation Control (1 box each of 550-07 and 550-08)

HMS Plus Instruments

Each instrument includes an internal printer, one-year warranty, operating manual, and case analysis pad.

Catalog #	Description		
30514	HMS PLUS	100-120 volt	
30522	HMS PLUS	200-240 volt	English
30515	HMS PLUS	200-240 volt	German
30517	HMS PLUS	200-240 volt	French
30518	HMS PLUS	200-240 volt	Italian
30524	HMS PLUS	200-240 volt	Spanish
30527	HMS PLUS	200-240 volt	Dutch

HEPline Kit

Kit contains 5 tubes of increasing amounts of heparin concentrations designed to give final concentrations of 1, 2, 3, 4, and 5 U/ml when fresh whole blood is added to a final volume of 5 ml.

Catalog #	Description
313-50	HEPline Kit

Accessories

Catalog #	Description	Quantity
HMSPLUSSC	Bar Code Scanner	1
HMSPUSSCRS	Bar Code Scanner - European Union	1
HMSPLUSSCYY	Bar Code Scanner - Japan	1
HMSPLUSEDM	External Data Manager	1
31351	Electronic Quality Control	1
300-01	3cc Monoject Syringes	100 per Box
300-02	Blunt Needles, 1-7/16", 19 GA	100 per Box
300-04	Thermal Printer Paper	5 Rolls per Box
300-05	HMS Case Analysis Pad	50 Sheets per Pad
300-10	Temperature Verification Cartridge	1
313-18	QA Records Packet	1
31506	Salvage Reservoir Cups	100 per Box
30032	HMS PLUS Custom Cart	1

Manuals

Manuals can be ordered through the CardioVascular Service Department.

Part Number	Description
86506001	Operator's Manual

Support Information

Customer Support

Medtronic is proud of our commitment to customer-focused quality. We have dedicated team members in sales, product services and technical support to assist you and help you identify your product needs.

Customer Service

For ordering information on instruments, test cartridges and controls, contact your Customer Service Representative or your local Medtronic Product Sales Representative.

CardioVascular Service

Field-based service representatives provide on-site instrument service for routine maintenance and ongoing support. Annual service contracts are available. To contact your local Field Service Representative, call 800-433-4311.

Technical or Regulatory Information

For questions on the use of our products or on hospital and laboratory regulations regarding their use, call 800-328-3320.

Caution:

Federal law (USA) restricts this device to sale by or on the order of a physician.

For more information contact your local Medtronic Sales Representative or call Customer Service toll-free at 1-800-328-1357.

Warnings: Proper Instrument and Cartridge Use

The HMS Plus instrument and cartridges must only be used in the manner and purpose for which they are intended. Instructions for proper use are included in the manual and in the cartridge package inserts. Read all warnings, precautions and Instructions for Use carefully prior to use.

System Specifications

Physical Dimensions:

Height: 40 cm (15.75") Depth: 38 cm (15.0")
Width: 33 cm (13.0") Weight: 15.47 kg (34.1 lbs.)
Serial Data Port: 19200 baud, 8 data bits, 1 stop bit, no parity

Environmental:

- Operating temperature: 14°C to 32°C (57°F to 90°F)
- Storage temperature: 0°C to 49°C (32°F to 120°F)
- Operating humidity: 10% to 90%, noncondensing
- Storage humidity: 5% to 90%, noncondensing

Power:

- Voltage: 100 - 240 V~ Single Phase
- Frequency: 50 - 60 Hz
- Maximum current: 1.2/0.6 A (100 - 120/200 - 240)

References

1. Hill AG, et al. More precise heparin and protamine management during cardiopulmonary bypass. Proceedings of the American Academy of Cardiovascular Perfusion. 1990;12-16.
2. Despotis GJ, et al. The impact of heparin concentration and activated clotting time monitoring on blood conservation. J Thoracic Cardiovascular Surg. 1995;110:46-54.
3. Bowie JE, et al. Automated management of heparin anticoagulation in cardiovascular surgery. Proceedings of the American Academy of Cardiovascular Perfusion. 1985;6:1-5.
4. Koster A, et al. Hemostatic activation and inflammatory response during cardiopulmonary bypass. Anesthesiology. 2002; 97: 837-841.
5. Raymond PD, et al. Heparin monitoring during cardiac surgery. Part 1: validation of whole-blood heparin concentration and activated clotting time. Perfusion. 2003; 18: 269-276.
6. Raymond PD, et al. Heparin monitoring during cardiac surgery. Part 2: calculating the overestimation of heparin by the activated clotting time. Perfusion. 2003; 18: 277-281.

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