



**Medtronic**

# HMS Plus

HEMOSTASIS MANAGEMENT SYSTEM



Believing in the technology... investing in the future

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.

"Versatility makes HMS PLUS  
an effective tool for diverse  
patient management."<sup>1</sup>

## Why is Hemostasis Management Important for Your Patients?

- 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:

- 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.

| 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.<sup>1</sup>
- Preservation of the coagulation system, resulting in fewer transfusions.<sup>2</sup>
- Fewer surgical reoperations,<sup>3</sup> 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"*<sup>4</sup>

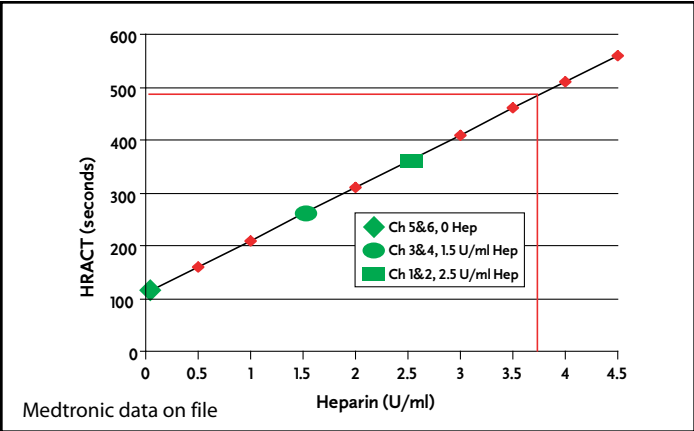
*"Retrospective data revealed a marked reduction in the re-exploration rate and post-operative hemorrhage after the introduction of the Hepcon HMS..."*<sup>4</sup>

## Quantitative Heparin Measurement Versus Activated Clotting Times<sup>2</sup>

| 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.<sup>2</sup>

## Heparin Dose Response (HDR) Test

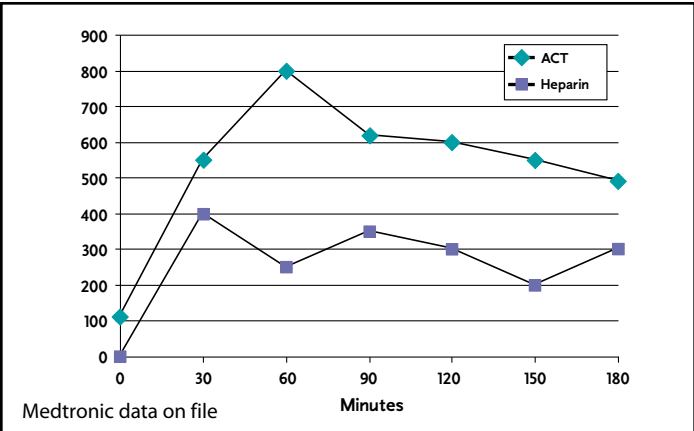


HMS Plus in vitro heparin dose response uses a baseline and two concentrations of heparin to project individual responses to heparin and determine the appropriate heparin dose for each patient.

*"Of particular concern is the fact that the ACT has previously been shown to correlate poorly with plasma heparin levels during CPB."*<sup>5</sup>

*"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."*<sup>6</sup>

## 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."*<sup>5</sup>

### 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."*<sup>5</sup>

## 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                 |
| HMSPLUSCRS | Bar Code Scanner - European Union  | 1                 |
| HMSPLUSCY  | 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.

### www.medtronic.com

#### World Headquarters

Medtronic, Inc.  
710 Medtronic Parkway  
Minneapolis, MN 55432-5604  
USA  
Tel: (763) 514-4000  
Fax: (763) 514-4879

Medtronic USA, Inc.  
Toll-free: 1 (800) 328-2518  
(24-hour technical support for  
physicians and medical professionals)

#### Europe

**Medtronic International Trading Sàrl**  
Route du Molliat 31  
Case postale  
CH-1131 Tolochenaz  
Switzerland  
Tel: 41.21.802.7000  
Fax: 41.21.802.7900

#### Canada

Medtronic of Canada Ltd.  
6733 Kitimat Road  
Mississauga, Ontario L5N 1W3  
Canada  
Tel: (905) 826-6020  
Fax: (905) 826-6620  
Toll-free: 1 (800) 268-5346

#### Asia Pacific

Medtronic International, Ltd.  
16/F Manulife Plaza  
The Lee Gardens, 33 Hysan Avenue  
Causeway Bay  
Hong Kong  
Tel: (852) 2891 4456  
Fax: (852) 2891 6830  
enquiryap@medtronic.com

#### Latin America

Medtronic USA, Inc.  
Doral Corporate Center II  
3750 NW 87th Avenue Suite 700  
Miami, FL 33178  
USA  
Tel: (305) 500-9328  
Fax: (786) 709-4244

#### LifeLine

#### CardioVascular Technical Support

Tel: (877) 526-7890  
Tel: (763) 526-7890  
Fax: (763) 526-7888  
E-mail: rs.cstechsupport@medtronic.com