

Automated Coagulation Timer



Precise, reliable—the trusted standard.

# 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 a new generation Automated Coagulation Timer. The ACT Plus™ System is a microprocessor-controlled electromechanical coagulation instrument designed to determine coagulation endpoints in whole blood, citrated whole blood, and plasma samples. Clotting-time results are presented on the instrument's Clot Time Display (CTD) and Liquid Crystal Display (LCD) screens.

The ACT Plus™ System provides long-term data storage and retrieval, with access to previous patient and quality control test data. Test results are stored in the order in which they are performed. The ability to externally transfer or save data to a floppy disk enhances the system's versatility.

Manufactured by the Medtronic® Biologic
Therapeutics and Diagnostics business,
the ACT Plus™ System combines a trusted
standard in precise clot detection technology
with state-of-the-art user enhancements
including data management and
connectivity-ready capabilities.

### ACT Plus™

#### **AUTOMATED COAGULATION TIMER**

The ACT Plus™ System is portable and well suited for all point-of-care testing situations. It offers the reliability required in:

- Cardiovascular and vascular surgery
- Cardiac catheterization laboratories
- Critical care units
- · Hemodialysis units

#### **BUILT-IN EFFICIENCY**

- Immediate results mean anticoagulant dosages can be adjusted quickly.
- Dual-well testing provides the extra confidence that only duplicate results provide.
- Because less than 1 ml of blood is required for each test, the ACT Plus™ System is especially suited for patients with small blood volumes.
- Bar Code Scanner (optional) is used for accurate entry of cartridge and control lot numbers and expiration dates.

#### SCIENTIFIC ACCURACY

- Full range of lyophilized controls and an electronic control are available to verify instrument, cartridge and operator performance and meet regulatory guidelines for testing.
- Lyophilized controls are easy to reconstitute and provide enough volume to test multiple instruments.
- Electronic control provides multiple-level testing in one device.

#### **NEW, MODULAR DESIGN**

- Quiet operation
- Easy to clean
- User-friendly switches
- Convenient, comfortable carrying handle

### PRECISE, RELIABLE...THE TRUSTED STANDARD

#### PRECISE IN NORMAL AND ABNORMAL RANGES

	Baseline ACT (sec) (0 u/ml Heparin)		Heparinized ACT (sec) (4 u/ml Heparin)	
	Within Lot	Between Lot	Within Lot	Between Lot
Mean	130	130	582	582
SD	3.3	6.6	19.0	27.1
%CV	2.6%	5.1%	3.3%	4.7%
N	63	63	162	162

#### **INTRA-INSTRUMENT COMPARISON**

Three Cartridge Lots/Three Instrument Comparison ACT II — HR-ACT					
Cartridge lot	N	Sum	Average	Variance	SD
212000085	23	4334	188.43	5864	76.58
212000091	23	4365	189.78	5687	75.42
212000088	23	4498	195.57	5293	72.75

**CONTROLS** 

#### **MULTIPLE TESTING CAPABILITY**

ACT cartridges are available in a variety of sensitivities to monitor heparin at the appropriate level. High Range Activated Clotting Time (HR-ACT), Low Range Activated Clotting Time (LR-ACT), Heparinase Test Cartridge (HTC), and Recalcified Activate Clotting Time (RACT) tests can be run quickly, reliably and easily on the ACT Plus™. HR-ACT cartridges with heparinase allow you to establish your patient's baseline value in the presence of heparin, to verify heparin reversal and to determine the presence of pre- and post-surgical heparin.

#### CARTRIDGES

High Range Activated Clotting Time (HR-ACT): for use with fresh whole blood samples in cardiovascular surgery, vascular surgery, and percutaneous transluminal coronary angioplasty (PTCA)	CLOTtrac® HR-ACT Control (normal) CLOTtrac® HR Abnormal Control
Low Range Activated Clotting Time (LR-ACT): for use with fresh whole blood samples in dialysis, ECMO, and therapeutic heparin monitoring	CLOTtrac® CWB Control (normal) CLOTtrac® LR Abnormal Control Note: CaCl <sub>2</sub> required
Heparinase Test Cartridge (HTC): for use with fresh whole blood samples to identify the presence of heparin in various clinical settings	CLOTtrac® HR-ACT Control (normal) CLOTtrac® HTC Control
Recalcified Activated Clotting Time (RACT): for use with citrated whole blood samples in dialysis, and therapeutic heparin monitoring	CLOTtrac® CWB Control (normal) CLOTtrac® RACT Abnormal Control
General Purpose Cartridge (GPC): for use with citrated whole blood or plasma samples for performing PT or APTT tests	

### PLUS... INSTRUMENT SUPPORT WHEN

#### **INSTRUMENT SERVICE**

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

#### **TECHNICAL SUPPORT**

For technical and regulatory support, our in-house staff can answer your questions on instrument performance, test use, cartridge selection, interpretation of results, and information on CLIA, CAP and JCAHO guidelines.

A number of system features and complimentary documentation help you optimize instrument operation. Additional QC and Data Management products and services include:

- Full line of liquid controls
- Electronic Control Device (optional—see How to Order)
- POC set-up guide—available from your sales representative
- Training in-services and materials
- External Data Management application

For technical support, or more information, call: 800-328-3320.

#### **CUSTOMER SERVICE**

For ordering information on instruments, test cartridges and controls, please see back page of this brochure. To place an order with Medtronic Customer Service, call: 800-854-3570.





### ...PLUS DATA MANAGEMENT/CONNECTIVITY-READY FEATURES

## TEST RESULTS AND QUALITY CONTROL DATA STORAGE

- Store up to 500 patient and QC records
- Download data to a diskette for transfer to a PC
- Download through RS 232 port to LIS system
- Optional Bar Code Scanner for quick and accurate entry of cartridge and control lot numbers and expiration dates.
- Supports the latest requirements for POC testing equipment

#### **ENHANCED DATA DISPLAYS**

- Large LED readouts to view test results from a distance
- LCD screen and keyboard for managing key parameters
- Easy navigation between screens

#### PC-BASED DATA MANAGEMENT

- Data management software loads onto PC
- Software loads data into four spreadsheets
- · Cumulates data over time
- Generates Levy-Jennings plot
- Provides powerful PC-based software to summarize data-without an LIS interface
- Upgradeable software

### **QC MANAGEMENT**

- Instrument serial number
- Patient and user identification
- QC lockout and user lockout
- Cartridge type, lot number and expiration date
- Test date and time



#### SYSTEM SPECIFICATIONS

#### PHYSICAL DIMENSIONS:

Depth: 13.6 in (34.5 cm)
Width: 9.0 in (22.9 cm)
Height: 11.9 in (30.2 cm)
Weight: 11.5 lb (5.22 kg)

#### **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

#### **Data Ports:**

- Serial Data Port: 19200 baud, 8 data bits, 1 stop bit, no parity
   Bar Code Scanner Port: used with the optional ACT Plus™
- Bar Code Scanner
- Floppy Drive: PC compatible, 1-44 MB, 3.5-inch floppy disk

#### Power:

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

#### **ORDERING INFORMATION**

Product	Catalog Number
ACT Plus™ Instrument	ACT100
ACT Plus™ Bar Code Scanner	ACTSC

#### **HOW TO ORDER CARTRIDGES AND CONTROLS**

Product	Packaging	Catalog Number
High Range Activated Clotting Time (HR-ACT)	50 cartridges/box	402-03
Low Range Activated Clotting Time (LR-ACT)	50 cartridges/box	402-01
Heparinase Test Cartridge (HTC)	20 cartridges/box	402-07
Recalcified Activated Clotting Time (RACT)	50 cartridges/box	402-02
General Purpose Cartridge (GPC)	50 cartridges/box	402-06
CLOTtrac <sup>®</sup> HR-ACT Control (normal)	15 vials each control/diluent	550-07
CLOTtrac <sup>®</sup> HR Abnormal Control	15 vials each control/diluent	550-08
CLOTtrac <sup>®</sup> HR Control Pack	15 vials each control/diluent	550-13
CLOTtrac <sup>®</sup> CWB Control (normal)	15 vials each control/diluent	550-01
CLOTtrac <sup>®</sup> LR Abnormal Control	15 vials each control/diluent	550-09
CLOTtrac <sup>®</sup> HTC Control	15 vials each control/diluent	550-12
CLOTtrac <sup>®</sup> RACT Abnormal Control	15 vials each control/diluent	550-10
ACTtrac® Electronic Control	Each	31363
Calcium Chloride (for LR-ACT Controls)	5 ml vial	550-11
Temperature Verification Cartridge	1 per package	313-11
Actuator Cleaning Kit	Each	303-58



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