Medtronic CARDIAC SURGERY	Applies to: ☐CS - ALL ☒BPK ☐SLP ☐PKR ☐CST ☐MEX ☐SA ☐GR ☐BTD	Number 86572	Rev. 3.0	Page 1 of 57

Title: Engineering Specification, Manual, ACT Plus, Operator's DOM

Type: ☐ Policy ☐ SOP ☐ Procedure ☐ Form ☒ Eng. Spec. ☐ Design ☐ Equip. Doc. ☐ Test ☐ Tech File ☐ Other

Department Owner: R&D

REV	ECO #	DESCRIPTION OF CHANGE	DOC APPRV.	EFF. DATE
1.0	24884	Initial Release	KDR	07/18/03
2.0	24944	Add UL updates	KDR	07/31/03
3.0	25287	Incorporate text changes from customer evaluations	KDR	10/20/03

Medtronic

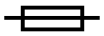
ACT Plus™

Automated Coagulation Timer

Operator's Manual

Printing instructions: doc#163256; refer to "Instrument manuals" row in the applicable table.

Explanation of symbols on package labeling

	Attention: See instructions for use
	Fuse
	On
	Off
	Alternating current
	Medical equipment with respect to electric shock, fire and mechanical hazards only in accordance with UL2601-1, and CAN/CSA C22.2 No. 601.1
IVD	In vitro diagnostic device
! USA	For US audiences only
	Quantity
SN	Serial number
REF	Catalog number
	Fragile, handle with care
	This way up

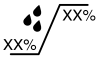
	Main Menu
QC	Quality Control Menu
	Stop
	Cancel
	Enter
	Clear
	Relative humidity range
	Storage temperature range
	Date of manufacture
	Serial port
	Type B Applied Part

Table of Contents

Section 1: System Description

The Medtronic ACT Plus™ Automated Coagulation Timer is a microprocessor-controlled electromechanical coagulation instrument intended for determining coagulation endpoints in fresh whole blood, citrated whole blood, and citrated plasma samples. The ACT Plus™ instrument is designed for use with the following Medtronic disposable cartridges: General Purpose, High-Range ACT, Low-Range ACT, Recalcified ACT, and High-Range Heparinase. Tests are performed in duplicate, and the clotting time data are displayed on the red seven-segment Light Emitting Diode (LED) display and on the Liquid Crystal Display (LCD) screens of the ACT Plus™ instrument. The ACT Plus™ instrument also provides long-term data storage and retrieval, enabling access to previous test data for both patient and quality control tests. Test data are stored in the order in which the tests are performed. Patient and quality control test data also may be transferred to a floppy disk, or to a Laboratory Information System or Hospital Information System via serial communication.

Intended Use

The ACT Plus™ instrument is intended for *in vitro* diagnostic testing in either a hospital laboratory setting or a point of care (decentralized) setting (eg, in the operating room, cardiac catheterization lab, intensive care unit, or clinic, etc.).

Principle of Clot Detection

The endpoint of a test performed on the ACT Plus™ instrument is formation of fibrin. Fibrin formation is detected by measuring the rate of fall of the plunger-flag mechanism in each cartridge channel. The plunger assembly falls rapidly at programmed timed intervals through an unclotted sample. The fibrin web formed during clotting impedes the fall rate of the plunger. This is detected by a photo-optical system located in the ACT Plus™ instrument's actuator assembly. The clotting time tests are performed in duplicate, and the results are displayed for each channel, the average of the two channels, and the difference between the two.

Test Cartridge

Test cartridges for the ACT Plus™ instrument consist of the reagent chamber, the reaction chamber, and the plunger assembly. Initiation of a test forces the contents of the reagent chamber into the reaction chamber. The photo-detectors in the actuator, located in the bottom section of the cartridge, detect movement of the plunger assembly. Clot formation impedes the fall of the plunger assembly, and the change in the fall rate of the plunger is photo-optically detected. This type of detection system is insensitive to the optical properties of the test sample, ie, lipemia. Figure 1 identifies the test cartridge components.

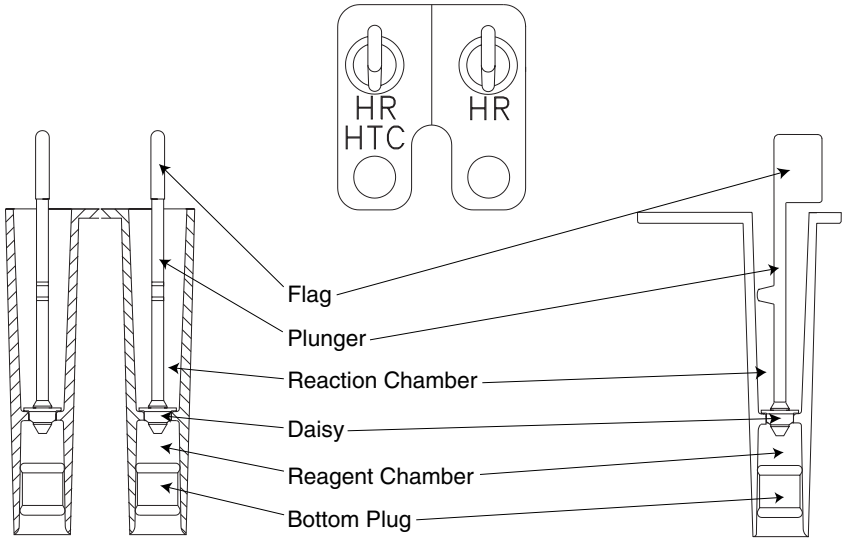


Figure 1. *Test Cartridge*

Reagent Chamber

The reagent chamber is the bottom section of the cartridge. It contains the activator and other reagents, which initiate and contribute to the activation of clotting. The reagent chamber is enclosed on the top by the “daisy.” The “daisy” is attached to the bottom portion of the plunger assembly and is seated in the diaphragm. The bottom of the reagent chamber consists of a flexible plug.

Reaction Chamber

The reaction chamber is located above the reagent chamber. The test sample is introduced into the reaction chamber. When the test is initiated, the plunger assembly is lifted and the bottom plug of the reagent chamber is pushed up, delivering the contents of the reagent chamber into the reaction chamber. This action also mixes the reagents with the test sample.

Plunger Assembly

The plunger assembly consists of two distinct parts: the “daisy” and main body of the assembly, which includes the “flag.”

Daisy: The “daisy” provides the upper seal for the reagent chamber and is the mechanical sensing element for the formation of a clot. As the plunger rises and falls, the “daisy” moves up and down through the test sample/reagent mixture. Clot formation impedes the movement of the “daisy” through the sample.

Flag: The “flag” is located on the top portion of the plunger. A photo-optical system senses motion of the plunger through the test sample. When a decrease in the plunger’s fall rate is detected, the timer stops and the clotting time is displayed.

Actuator Heat Block Assembly

The actuator heat block is the receptacle for test cartridges. The ACT Plus™ software maintains the actuator heat block temperature at 37.0°C ± 0.5°C. The actuator heat block rotates between the ***open*** and ***closed*** positions. Cartridges can be inserted into and removed from the actuator heat block when it is in the ***open*** position. To initiate a clotting test, the operator rotates the actuator heat block to the ***closed*** position. At termination of a test, the actuator heat block will automatically rotate to the ***open*** position, and the results will be displayed. A test can be terminated manually and the actuator heat block rotated to the ***open*** position by depressing the ***Stop*** switch on the front panel.

Section 2: Specifications

Instrument

Number of Channels:	2
Timing Range (Seconds):	6 - 999
Actuator Heat Block Temperature:	
Range:	37.0°C ± 2°C
Resolution:	0.1°C
Accuracy:	± 0.5°C

Electrical

Note: Technical data, features, and options referenced in this manual are based on the latest information available at the time of printing. Medtronic reserves the right to change specifications without notice.

Electrical Classification:	Class 1 equipment
Power:	
Voltage:	100 - 240 V~ Single phase
Frequency:	50 - 60 Hz
Maximum current:	1.0 A (100 - 240)
Fuse	T2A 250 V
Power cord:	Two wires plus a ground (earth) connector
Length:	3.1 m (10 ft.)
Type:	3-prong hospital grade (USA only)
Physical Dimensions:	
Depth:	33 cm (13.0 in)
Width:	20 cm (8.0 in)
Height:	27 cm (11.0 in)
Weight:	5.22 kg (11.5 lb)
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
USB port:	For future expansion, not supported at this time. USB Devices must meet the Safety Standards (IEC 60601-1-1).
Bar code scanner port:	Used with the optional symbol LS 1902T Bar Code Scanner.
Floppy drive:	PC compatible, 1-44 MB, 3.5-inch floppy disk.

Section 3: Precautions

General Precautions

- The ACT Plus™ instrument is intended for *in vitro* diagnostic use only.
- The ACT Plus™ instrument is intended for use while positioned on a level surface.
- To obtain valid results, the ACT Plus™ instrument's operating parameters must be set up appropriately.
- The screen values shown in this manual are intended for illustration only; they are not intended to match actual test results.
- An adequate quantity of blood must be drawn into the syringe, and cartridge channels must be filled to the proper level for the test. Refer to the individual cartridge package inserts for details.
- Dropping, soaking, or otherwise misusing the ACT Plus™ instrument may prevent it from functioning properly.

Biohazard

All test samples (eg, patient samples, controls, used cartridges, syringes, and needles) should be considered biohazardous and should be disposed of according to the guidelines established for the specific institution.

Explosive Anesthetics

The instrument must not be used in the presence of explosive gases or anesthetics.

Cleaning/Decontamination

Do not steam, autoclave, or immerse the ACT Plus™ instrument. Refer to Maintenance on page 39 for cleaning instructions.

No User-Serviceable Parts

There are no user-serviceable parts inside the ACT Plus™ instrument case. Only a Medtronic Service Representative or authorized representative should repair or service the instrument.

Section 4: Installation

Unpacking

1. The ACT Plus™ instrument is shipped with the following items:
   - Operator's manual
   - Power cord
   - Temperature verification cartridge
   - Data management application CD
   - Actuator cleaning kit
2. Check the box for damage, and report any damage to the carrier.
3. Remove the protective bag.
4. Set the ACT Plus™ instrument on a level surface.
5. Check the ACT Plus™ instrument for visible damage.
6. Retain all shipping materials.

Power ON: Initial Checkout Procedure

1. Connect the power cord to an AC power source with the same voltage rating that is listed on the serial plate located on the bottom of the ACT Plus™ instrument.
2. Rotate the actuator heat block to the ***closed*** position.
3. [Optional] Attach the optional bar code scanner.
4. Turn the power switch, located on the rear panel, to the ***ON*** position. The actuator heat block should rotate to the ***open*** position, followed by illumination of all clotting time display segments, with the LCD indicating “Self-Test Pass.” An audible tone indicating the end of the self-test should accompany this sequence.
5. From the Main Menu, select [**Cartridge Lot**]**.** Scan the bar code label on the cartridge package. The cartridge lot number and expiration date should be entered in the appropriate cartridge-type fields (for detailed bar code scanner instructions, see Specifications on page 10 for Bar Code Scanner Requirements, and Data Entry on page 18.
   Note: The lot number and expiration date must be entered before a cartridge is used; if no bar code scanner is used, see Data Entry on page 18 for detailed instructions.
6. Insert an empty cartridge into the actuator heat block.
7. Rotate the actuator heat block to the ***closed*** position. The instrument should begin a test. Wait for the timers to begin counting.

8. Terminate the test by pressing the ***Stop*** switch. The actuator heat block should rotate to the ***open*** position.
9. Insert the temperature verification cartridge. After 10 minutes, check both the temperature indicator on the front panel and the temperature verification cartridge to confirm that both show a temperature of 37°C ± 0.5°C. Adjust the temperature, if necessary (see Temperature Verification Cartridge on page 40 for detailed instructions).
10. Insert a floppy disk into the floppy dive.
11. From the Main Menu, select [**Transmit Test Results**], then [**Transmit Unsent Patient Tests**]. The results of the previous test should be sent to the floppy disk (see Specifications on page 10 for floppy disk requirements, and Data Entry on page 18 for detailed data entry instructions).
12. If the instrument does not function properly, contact a Medtronic Service Representative (see Service and Troubleshooting on page 42).

Setup

Medtronic suggests taking the following steps prior to running tests with the ACT Plus™ instrument. Consult your Point of Care Coordinator for details.

1. Set Instrument Parameters (see page 23).
2. Set QC Manager parameters:
   a. Enter Instrument Location (see page 29).
   b. Enter User IDs (see page 29).
   c. Select QC Interval (see page 31).
   d. Set QC Lockout to ON (see page 31).
   e. Enable Cartridge Type (see page 31).
   f. Set Permanent Record (see page 32).
3. Enter Cartridge Lot Information (see pages 20-21).
4. Enter Control Lot Information (see pages 25-26).
5. Run Controls.

Default Operating Parameters

The ACT Plus™ instrument is shipped with the following default parameter settings:

Patient Parameters	
Patient ID	None
User ID	None
Cartridge Lot Number	1111111111
Cartridge Exp Date	11/11/11
Control Lot Number	1111111111

Patient Parameters

Patient ID	None
Control Exp Date	11/11/11

Instrument Parameters

Date - yy-mm-dd	Preset by manufacturer
Time - hh:mm	Preset by manufacturer
Audio Tone	[ON]
Language	Preset by manufacturer
Screen Contrast Adjustment	Preset by manufacturer
Output Location	[Floppy]

Quality Control (QC) Manager Parameters

User Lockout	[OFF]
Permanent Record	[None]
QC Lockout	[OFF]
QC Liquid	[OFF]
QC EQC/ACTtrac®	[OFF]
Cartridges Enabled	All
Location	CVOR
Clear ID Interval	[None]

Section 5: Instrument Controls

Figure 2 identifies the User Interface components. A bar code scanner (not shown) is optional.

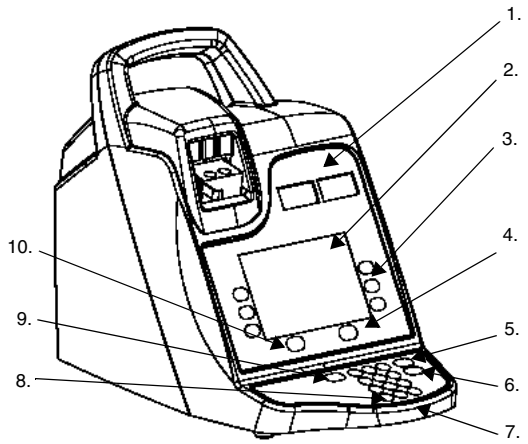


Figure 2. *User Interface*

1. Clot Time Display
2. Data Entry Display
3. Variable Function Keypad
4. Quality Control Key
5. Cancel Key
6. Enter Key
7. Numeric Keypad
8. Clear Key
9. Stop Key
10. Main Menu Key

User Interface

1. The **Clot Time Display** is a red, seven-segment display of the clotting times for Channels 1 and 2.
2. The **Data Entry Display**, an LCD screen, displays clotting times. It also is used to select a test, enter data, and navigate through the screens (see Data Entry on page 18 for detailed instructions).

3. The **Variable Function Keypad** is used to select the desired field in the various screen options.
4. The **Quality Control Key** is used to access the Quality Control Menu.
5. The **Cancel Key** is used to cancel any currently active function.
6. The **Enter Key** is used to accept entered numbers or data in an active field.
7. The **Numeric Keypad** is used to enter data into acceptable fields (ie, lot numbers, user identification numbers [UIDs], and patient identification numbers [PIDs]).
8. The **Clear Key** is used to clear the field.
9. The **Stop Key** is used to stop a test in progress.
10. The **Main Menu Key** is used to access the Main Menu.

Rear Panel

Figure 3 identifies the Rear Panel components.

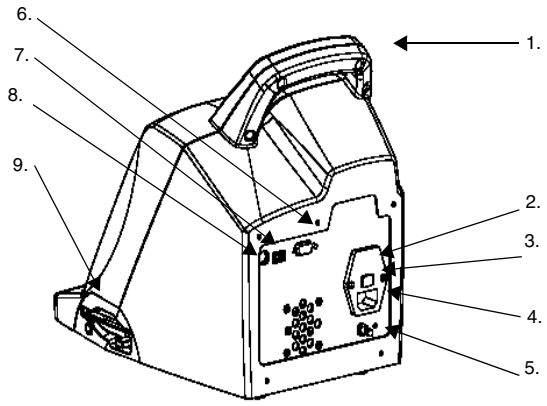


Figure 3. *Rear Panel Components*

1. Handle
2. Fuse Holder
3. Main Power Switch (ON/OFF)
4. Power Inlet Module
5. Equal Potential Terminal
6. Serial Port (RS-232)
7. Serial Port (USB)
8. Bar Code Scanner Port
9. Floppy Drive

Rear Panel Components

1. **Handle**.
2. The **Fuse Holder** is located in the Power Inlet Module. See Maintenance on page 39 for fuse replacement.
3. The **Main Power Switch** is a rocker-type switch: “I” indicates ON and “O” indicates OFF. It is located in the Power Inlet Module.
4. The **Power Inlet Module** is used to connect the power cord to the ACT Plus™ instrument.
5. The **Equal Potential Terminal** is used to connect the ground of the ACT Plus™ instrument to other instruments that may be used in a clinical setting.
6. The **Serial Port (RS-232)** is a female DB-9 connector (see Specifications on page 10 for detailed specifications).
7. The **USB Port** is for future applications; it is not supported at this time.
8. The **Bar Code Scanner Port** is the connection for the optional bar code scanner (see Specifications on page 10 detailed specifications).
9. The **Floppy Drive** is used to transfer and store patient and QC test history data.

Instrument Bottom

The Serial Number Label, which contains the serial number, date of manufacture, and safety agency approvals, is located on the bottom of the ACT Plus™ instrument.

Optional Bar Code Scanner

See Appendix A: Optional Bar Code Scanner on page 47 for additional information.

Section 6: Data Entry

Main Menu

The following variable function keys appear on the Main Menu: [**Enter ID**], [**Cartridge Type**], [**Cartridge Lot**], [**View Current Test Results**], [**Transmit Test Results**], and [**Instrument Parameters**].

The Main Menu can be accessed from any screen by pressing the [**Main Menu**] key on the left-hand side, below the display screen.

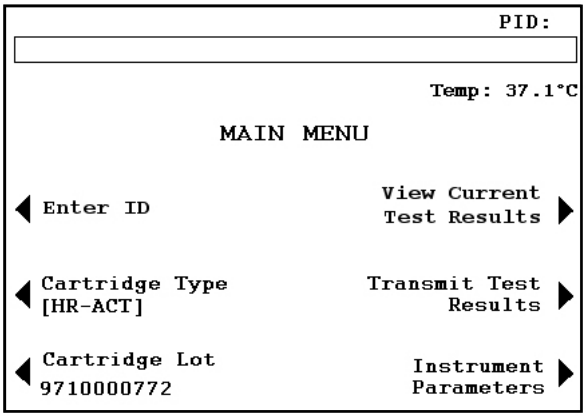


Figure 4. *Main Menu Screen*

The [**Enter ID**] variable function key is used to enter patient (PID) and user (UID) identification numbers. This information may be alphanumeric and is entered using the numeric keypad.

The [**Cartridge Type**] variable function key is used to select the appropriate type of cartridge for the test that is being performed (HR-ACT, LR-ACT, HTC, RACT, GPC, or ACTtrac®). For test method instructions, refer to Section 7 of this manual and to the product insert for the specific cartridge.

The [**Cartridge Lot**] variable function key is used to enter the cartridge lot number and expiration date. Up to two lots of each cartridge type may be entered in the database at one time.

The [**View Current Test Results**] variable function key is used to display the results of the last test performed.

The [**Transmit Test Results**] variable function key is used to transmit patient and Quality Control (QC) results to an external location. Results may be exported to a 1.44 MB, 3.5-inch PC-formatted diskette using the floppy drive on the lower right side of the instrument panel, or results may be exported via the serial port to a secure network interface (SNI) for transmission to a Laboratory Information System (LIS).

The [**Instrument Parameters**] variable function key is used to enter the following instrument settings: current date, current time, audio tone, language, screen contrast adjustment, and output location.

Enter Patient and User IDs

A Patient ID must be entered before a test can be run. A User ID must be entered if the User ID option has been turned ***ON***.

From the Main Menu:

1. Select [**Enter ID**]. The Enter ID screen will appear with options for entering Patient and User ID numbers.

To enter a Patient ID:

1. Select [**Patient ID**].
2. Enter the Patient ID using the numerical keypad.
3. For alpha entry, press the decimal point "." An alpha character will appear in the Patient ID field.
4. To select a character, press the [**A…Z**] and [**Z…A**] keys until the desired character is shown.
5. To continue entering alpha characters, select the decimal point. Repeat step 4 until all characters are entered.
6. To continue entering numbers, select the number using the numerical keypad.
7. After entering the last alpha character or number in the Patient ID, press [**Enter**] to confirm the ID.

To enter a User ID:

1. Select [**User ID**].
2. Enter the User ID using the numerical keypad.
3. For alpha entry, press the decimal point "." An alpha character will appear in the User ID field.
4. To select a character, press the [**A…Z**] and [**Z…A**] keys until the desired character is shown.
5. To continue entering alpha characters, select the decimal point. Repeat step 4 until all characters are entered.
6. After entering the last alpha character or number of the User ID, press [**Enter**] to confirm the ID.

7. The Patient ID will appear in the upper right-hand corner of the Enter ID screen, and a message will appear, “Load Cartridge, Close Actuator.”
8. To return to the Main Menu, press [**Main Menu**]. A message will appear at the top of the screen, “Verify Patient and User ID.”

Select Cartridge Type

The cartridge type (including the electronic control) should be selected or verified before each test.

From the Main Menu:

1. Select [**Cartridge Type**].
2. To view the complete list of choices, [**HR-ACT**], [**LR-ACT**], [**HTC**], [**RACT**], [**GPC**], and [**ACTtrac®**], continue to press [**Cartridge Type**].
3. To confirm the selection, press [**Enter**].

Enter ACTtrac® Serial Number

From the Main Menu:

1. Select [**Cartridge Lot**].
2. To navigate through the list, use the arrows on either side of the box.

When the ACTtrac® cartridge type is activated, the following variable function keys appear: [**Add Lot Number**] and [**Exit to Main Menu**].

1. To enter the serial number, select [**Add Lot Number**].
2. If the serial number has an “AT” at the beginning of it, press the “.” key and the “AT” will appear in the serial number field.
3. Enter the rest of the serial number using the numeric keypad.
4. To confirm the entry, press [**Enter**].

Manually Enter a Cartridge Lot Number and Expiration Date

From the Main Menu:

1. Select [**Cartridge Lot**].
2. To navigate through the list, use the arrows on either side of the box.

When there are no lot numbers for a cartridge type, the following variable function keys appear: [**Add Lot Number**], [**Add Exp Date**], and [**Exit to Main Menu**].

1. To enter the lot number, select [**Add Lot Number**].
2. Enter the cartridge lot number using the numeric keypad.
3. To confirm the entry, press [**Enter**].

4. To enter the expiration date for the selected lot number, select [**Add Exp Date**]. The date format is yy-mm-dd.
5. Enter the cartridge expiration date.
6. To confirm the entry, press [**Enter**].

When a cartridge type has a single lot number entered and a second lot is to be entered, the following variable function keys will appear: [**Add Lot**], [**Remove Lot**], [**Edit Lot/Exp Date**] and [**Exit to Main Menu**].

1. To enter the second lot number, select [**Add Lot**].
2. Enter the cartridge lot number using the numeric keypad.
3. To confirm the entry, press [**Enter**].
4. To enter the expiration date for the selected lot number, select [**Add Exp Date**]. The date format is yy-mm-dd.
5. Enter the cartridge expiration date.
6. To confirm the entry, press [**Enter**].

When there are two lot numbers entered for a cartridge type, the following variable function keys will appear: [**Toggle Active**], [**Remove Lot**], [**Edit Lot/Exp Date**] and [**Exit to Main Menu**].

To change the lot number of the currently active cartridge:

1. Select [**Toggle Active**].
2. Move the "*****" to the cartridge lot number that is currently in use.

To remove a cartridge lot:

1. Select [**Remove Lot**].
2. To select the lot to be removed, use the up/down arrows (↑↓) to toggle to the appropriate lot number.
3. To delete the selected cartridge lot number, select [**Remove Selected Lot**].

Enter a Cartridge Lot Number and Expiration Date Using the Optional Bar Code Scanner

From the Main Menu:

1. Select [**Cartridge Lot**]. Page 1 of the Cartridge Lot/Expiration Date screen will appear.

When there is no or one lot number for a cartridge type:

1. Scan the bar code on the cartridge box. The lot number and expiration date will automatically populate their respective fields.
2. To return to the Main Menu, press [**Main Menu**].

When two lot numbers exist for a cartridge type:

1. Select [**Remove Lot**].
2. To remove one of the lot numbers, toggle to the appropriate lot number.
3. To delete the selected cartridge lot number, select [**Remove Selected Lot**].
4. Scan the bar code on the cartridge box. The lot number and expiration date will automatically populate their respective fields.
5. To return to the Main Menu, select **[Main Menu]**.

View Current Test Results for the Last Test Performed

1. To display the results of the last test, select [**View Current Test Results**].

Transmit Patient and Quality Control (QC) Test Results

Patient and QC test results can be transmitted to a floppy drive or serial port. The transmit destination is set from the Instrument Parameters Menu.

If transmitting to a floppy drive, insert a floppy disk before continuing.

From the Main Menu:

1. Select [**Transmit Test Results**]. The following variable function keys will appear: [**Transmit All Patient Tests**], [**Transmit Unsent Patient Tests**], [**Transmit By Patient ID**], [**Transmit All QC Tests**], [**Transmit Unsent QC Tests**], and [**Exit to Main Menu**].
2. Insert a 3.5-inch floppy disk, IF the floppy disk is selected.
3. To transmit all patient test results in the memory, select [**Transmit All Patient Tests**].
4. To transmit the patient test results that have not previously been sent to the selected output location, select [**Transmit Unsent Patient Tests**].
5. To transmit all results for a specific patient, select [**Transmit By Patient ID**]. Then enter the Patient ID and press [**Enter**].
6. To transmit all QC test results (liquid and electronic), select [**Transmit All QC Tests**]. All QC tests in the memory will be sent to the selected output location.
7. To transmit all QC test results that have not been previously sent to the selected output location, select [**Transmit Unsent QC Tests**].
8. To return to the Main Menu, press [**Main Menu**].

Set Instrument Parameters

Parameters for the ACT Plus™ instrument are set at the time of installation. This must be completed prior to any other data entry.

1. Select [**Instrument Parameters**]. The following variable function keys appear: [**Date - yyyy-mm-dd**], [**Time – hh:mm**], [**Audio Tone**], [**Language**], [**Go to Page 2 of 2**], and [**Exit to Main Menu**].
2. To set the current date, select [**Date - yyyy-mm-dd**]. The following ranges are acceptable for the year, month, and day entries: yyyy = year (accepted range, 1998 to 2097), mm = month (accepted range, 01 to 12), and dd = days (accepted range, 01 to 31).
3. To confirm the date entry, press [**Enter**].
   Note: The current date must be entered before cartridge and/or control lot numbers and expiration dates are entered.
4. To set the current time, select [**Time – hh:mm**]. The current time is based on a 24-hour clock where hh = hours (accepted range, 00 to 23) and mm = minutes (accepted range, 00 to 59).
5. To confirm the time entry, press [**Enter**].
6. To set the audio tone to ON or OFF, select [**Audio Tone**].
7. To confirm the selection, press [**Enter**].
8. To select a language, select [**Language**]. The options are English, French (Français), Italian (Italiano), German (Deutsch), or Spanish (Español).
9. To view the choices, continue to press [**Language**]. The default language is English.
10. To confirm the selection, press [**Enter**].

The following variable function keys appear on page 2 of the Instrument Parameters screens: [**Screen Contrast Adjustment**], [**Output Location**], [**Back to Page 1 of 2**], and [**Exit to Main Menu**].

1. To adjust the contrast on the LCD screen, select [**Screen Contrast Adjustment**]. The (-) key will lighten the text, and the (+) key will darken the text.
2. To select the output mode for transferring patient and QC data, select [**Output Location**].
3. To view the choices, [**Floppy**] or [**Serial**], continue to press [**Output Location**].
4. To confirm the selection, press [**Enter**].
5. To return to the Main Menu, press [**Main Menu**].

Quality Control (QC) Menu

The following variable function keys appear on the Quality Control Menu: [**Control Type**], [**Control Lot**], [**Temperature Adjustment**], [**QC Due Status**], [**QC Manager Set Up**], and [**Exit to Main Menu**].

Note: All QC testing (liquid and electronic) must be performed from the Quality Control Menu to log the controls into the Data Manager. To access the Quality Control Menu, select the [**Quality Control**] key on the right-hand side, below the display screen.

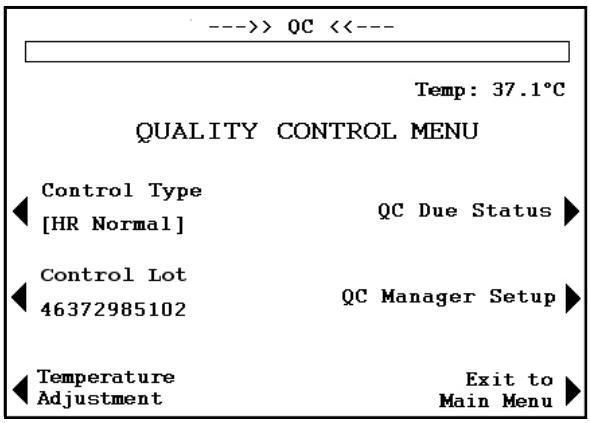


Figure 5. *Quality Control Menu Screen*

General Quality Control (QC) Functions

The [**Control Type**] variable function key is used to select the type of control to be performed. The following control types are available and will be determined by the test cartridge being used:

- The ACTtrac® electronic control has three settings: 98-102, 190-204, and 490-510.
- High-Range ACT (HR-ACT) cartridge: Normal (HR-NM) and Abnormal (HR-AB) controls.
- Low-Range ACT (LR-ACT) cartridge: Normal Citrated Whole Blood (CWB) and Abnormal (LR-AB) controls.
- High-Range Heparinase (HR-HTC) cartridge: Normal (HR-NM) and Heparinase (HTC) controls.
- Recalcified ACT (RACT) cartridge: Normal Citrated Whole Blood (CWB) and Abnormal (RACT-AB) controls.
- General Purpose (GPC) Cartridge: Level 1 and Level 2 controls.

The [**Control Lot**] variable function key is used to enter, remove, or edit the lot number, expiration date, and range of the selected control. Up to two lots of each control type may be entered into the database at one time.

The [**Temperature Adjustment**] variable function key is used to verify the actuator heat block temperature (see Actuator Heat Block Temperature on page 40).

The [**QC Due Status**] variable function key displays the status of liquid and electronic controls, including the date and time controls that must be performed.

Select the Control Type

The correct control type must be selected before the control test is initiated.

From the Quality Control Menu:

1. To select the type of control to be performed, select [**Control Type**].
2. To view the complete list of choices, continue to press [**Control Type**].
3. To confirm the selection, press [**Enter**]. This selection will display only the available control types for the test selected in the Main Menu.

Manually Enter a Control Lot Number, Expiration Date, and Range

From the Quality Control Menu:

1. Select [**Control Lot**].
2. To select the desired control, highlight the control in the list.

When there are no lot numbers entered for a control, the following variable function keys appear: [**Add Lot Number**], [**Add Exp Date**], [**Set Range**], and [**Exit to Quality Control Menu**].

1. To enter the lot number, select [**Add Lot Number**].
2. Enter the lot number using the keypad.
3. To confirm the selection, press [**Enter**].
4. To enter the expiration date for the selected lot number, select [**Add Exp Date**]. The date format is yy-mm-dd.
5. Enter the expiration date.
6. To confirm the entry, press [**Enter**].
7. To enter the range for the control, select [**Set Range**]. The format for entering the control range is “lll-hhh,” where “lll” is the low end and “hhh” is the high end of the control range.
   Note: If the low range is less than 100, a zero must precede the 2-digit number, eg, “099.”
8. Enter the range.
9. To confirm the entry, press [**Enter**].

10. To return to the “Add Lot” selection, select [**Add Selection**].

When a control type has a single lot number entered and a second lot is to be entered, the following variable function keys appear: [**Add Lot/EXP Date**], [**Remove Lot**], [**Edit Range**] and [**Exit to Quality Control Menu**].

1. To add a second control lot for a cartridge type, select [**Add Lot/EXP Date**].
2. To enter the second lot number, see the instructions above (when there are no lot numbers).

When there are two lot numbers entered for a control type, the following variable function keys appear: [**Toggle Active**], [**Remove Lot**], [**Edit Range**], and [**Exit to Quality Control Menu**].

To change the lot number of the active control:

1. Select [**Toggle Active**] to move the “*****” to the control lot number that is currently being used.

To remove a control lot:

1. Select [**Remove Lot**].
2. To select the lot to be removed, use the up/down arrows (↑↓) to toggle to the appropriate lot number.
3. Select [**Remove Selected Lot**] to delete the selected control lot number.

To edit the range of an existing control lot:

1. Select [**Edit Range**].
2. To select the lot of the control to be edited, use the arrows to change the highlighted lot.
3. Enter the range for the control.
4. To confirm the entry, press [**Enter**].

Enter a Control Lot Number, Expiration Date, and Range Using the Optional Bar Code Scanner

From the Quality Control Menu:

1. Select [**Control Lot**].

When there is no or one lot number for a control type:

1. Scan the bar code on the control box. The lot number and expiration date will automatically populate their respective fields.
2. To enter the range for the control, select [**Set Range**]. The format for entering the control range is “lll-hhh,” where “lll” is the low end and “hhh” is the high end of the control range.
3. To confirm the entry, press [**Enter**].
4. To return to the Quality Control Menu, select [**Exit to Quality Control Menu**].

When a control type has two lot numbers entered for a control type:

1. To remove one of the lot numbers for the control type, select [**Remove Lot**].
2. To delete the selected control lot number, toggle to the appropriate lot number and select [**Remove Selected Lot**].
3. To enter the new lot number, scan the bar code on the control box. The lot number and expiration date will automatically populate their respective fields.
4. To enter the range for the control, select [**Set Range**]. The format for entering the control range is “lll-hhh,” where “lll” is the low end and “hhh” is the high end of the control range.
5. To confirm the entry, press [**Enter**].
6. To return to the Quality Control Menu, select [**Exit to Quality Control Menu**].

To verify/record the ACT Plus™ actuator heat block temperature:

From the Quality Control Menu:

1. Select [**Temperature Adjustment**]. The following options will appear: [**Thermometer Reading**], [**Transmit Temperature Log**], [**Repeat Adjustment**], and [**Exit to Quality Control Menu**]. The **Thermometer Reading** field is active when this screen is entered.
2. Enter the reading from the temperature verification thermometer using the numeric keypad.
3. To confirm the entry, press [**Enter**].
4. To repeat the temperature adjustment (see Section 9 for Actuator Heat Block Temperature Calibration), select [**Repeat Adjustment**].
5. To transmit the temperature log to the output location selected in the Instrument Parameters, select [**Transmit Temperature Log**].

To view the due status for quality control testing:

From the Quality Control Menu:

1. Select [**QC Due Status**]. The ACT Plus™ instrument will display all liquid and electronic controls for the cartridges that have been enabled with the following message options:

- The date and time when the next control tests are due**.**
- QC due, if the controls for a test are past due**.**
- QC not performed, if controls have never been run for a cartridge type**.**

QC Manager Functions

The QC Manager Setup Menu is accessed from the Quality Control Menu; it is a password-protected area. The default password is provided in a separate envelope. If this card is lost, contact Medtronic Technical Service for assistance (800-328-3320).

The following variable function keys appear in the QC Manager Setup Menu: [**Location**], [**User ID Setup**], [**Clear ID Interval**], [**QC Lockout**], [**QC Interval Setup**], [**Cartridge Enable Setup**], [**Download Settings**], [**Permanent Record**], and [**Instrument Upgrade**].

Note: QC Manager parameters must be set before general QC information is entered and before any tests are performed.

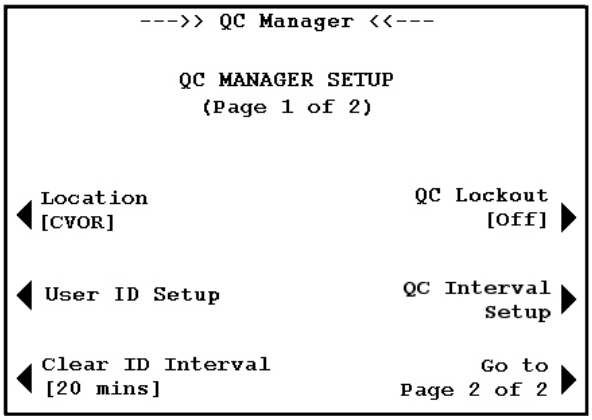


Figure 6. *QC Manager Setup Screen*

The [**Location**] variable function key is used to select the location of the ACT Plus™ instrument. Location options include the following: CVOR (cardiovascular operating room), Cath Lab (Cardiac Catheterization Lab), ECMO (Extracorporeal Membrane Oxygenation), Dialysis, ICU/CCU (Intensive Care/Coronary Care Units), Lab, and Other.

The [**User ID Setup**] variable function key displays the screens for the following functions: adding and deleting User IDs, turning ON or OFF User Lockout, changing the QC Manager Password, downloading User IDs to a floppy disk, and uploading User IDs from a floppy disk to the ACT Plus™ user database.

The [**Clear ID Interval**] variable function key is used to select the time interval (none, 5 minutes, 10 minutes, or 20 minutes) that will elapse before the Patient and User IDs are cleared; they will need to be reentered prior to testing.

The [**QC Lockout**] variable function key is used to set QC Lockout to one of the following options: OFF, Warning, or ON.

The [**QC Interval Setup**] variable function key is used to set the required interval for performing liquid and electronic QC tests. The options for liquid are the following: None, 8 hours, or 7 days. The options for Electronic are 0 or 8 hours.

The [**Cartridge Enable Setup**] variable function key is used to enable or disable the various cartridge types that may be run on the ACT Plus™ instrument.

The [**Download Settings**] variable function key is used to download all instrument parameters and settings to a floppy disk.

The [**Set Perm Record**] variable function key designates the official mode of tracking the results that have been downloaded. The options are None, Floppy, or Electronic.

The [**Instrument Upgrade**] variable function key is used to install upgrades to the ACT Plus™ software.

To select the location for the ACT Plus™ instrument:

From the QC Manager Setup:

1. To change the desired location, select [**Location**].
2. Continue to press [**Location**] until the correct location is found.
3. To confirm the selection, press [**Enter**].

To add/delete User IDs:

From the QC Manager Setup screen:

1. Select [**User ID Setup**].

From the User ID Setup screen:

1. Select [**Add/Delete User IDs**]. The following keys appear: [**Add**], [**Delete**], and [**Exit to User ID Setup**].

To add a User ID:

From the Add/Delete User IDs screen:

1. Select [**Add**].
2. Enter the User ID using the numeric keypad. Press the decimal point "." on the keypad to activate alpha characters.
3. To select the desired character, use the [**A…Z**] and [**Z…A**] keys.
4. To confirm the selection, press [**Enter**].

To delete a User ID:

From the Add/Delete User ID screen:

1. Select [**Delete**].
2. Use the arrows on either side of the displayed box to navigate up or down to select the desired User ID.
3. To remove the User ID from the list, select [**Delete Selection**].
4. To return to the User ID Setup screen, select [**Exit to User ID Setup**].

To enable User Lockout:

From the User ID Setup screen:

1. Select [**User Lockout**].
2. To view the choices, [**ON**] or [**OFF**], continue to press [**User Lockout**].
3. To confirm the selection, press [**Enter**].

To change the QC Manager Password:

From the User ID Setup screen:

1. Select [**QC Mgr Password**].
2. Enter up to a 6-digit numeric password.
3. Enter the password a second time to verify.
4. To confirm, press [**Enter**].
5. Record the new password in a secure location.

Download User IDs to a Floppy Disk

From the User ID Setup screen:

1. Insert a formatted disk into the floppy drive.
2. Select [**Download User IDs**]. All of the User IDs entered will be downloaded to the floppy disk.

Upload User IDs from One ACT Plus™ Instrument to Multiple Instruments

From the User ID Setup screen:

1. Insert a formatted disk containing downloaded User IDs into the floppy drive.
2. Select [**Upload User IDs**].

User IDs also can be uploaded to the ACT Plus™ instrument using a file generated from the ACT Plus™ External Data Manager (EDM). Refer to the EDM Instructions for Use.

Select the Time Interval for Clearing Patient and User IDs

From the QC Manager Setup screen:

1. Select [**Clear ID Interval**].
2. To view the choices, [**None**], [**5 minutes**], [**10 minutes**], and [**20 minutes**], continue to press [**Clear ID Interval**].
3. To confirm the choice, press [**Enter**].

Select the QC Lockout Function

From the QC Manager Setup screen:

1. Select [**QC Lockout**].
2. To view the choices, [**ON**], [**Warning**], or [**OFF**], continue to press [**QC Lockout**].
3. To confirm the choice, press [**Enter**].

Set the QC Interval for Liquid and Electronic Controls

From the QC Manager Setup screen:

1. Select [**QC Interval Setup**]. The following variable function keys appear: [**Liquid Interval**], [**ACTtrac® Interval**] and [**Exit to QC Manager Setup**].

To set the liquid QC interval:

1. Select [**Liquid Interval]**.
2. To view the choices, [**None**], [**8 hours**] or [**7 days**], continue to press [**Liquid Interval]**.
3. To confirm the choice, press [**Enter**].

To set the ACTtrac® electronic QC interval:

1. Select [**ACTtrac® Interval**].
2. To view the choices, [**None**] or [**8 hours**], continue to press [**ACTtrac® Interval**].
3. To confirm the choice, press [**Enter**].

Enable or Disable Test Cartridge Types

From page 2 of the QC Manager Setup screens:

1. Select [**Cartridge Enable Setup**].
2. To select the desired cartridge, use the arrows on either side of the display of cartridges to navigate up or down.
3. Select [**Desired Cartridge**].
4. To view the choices, [**ON**] or [**OFF**], continue to press [**Desired Cartridge**].
5. To confirm the choice, press [**Enter**].

Download All of the Instrument Settings to a Floppy Disk

From page 2 of the QC Manager Setup screens:

1. Insert a formatted disk into the floppy drive.
2. Select [**Download Settings**].

Set the Permanent Record or the Mode by Which the ACT Plus™ Instrument Maintains a Record of Downloaded Data

From page 2 of the QC Manager Setup screens:

1. Select [**Perm Record**].
2. To view the choices, [**None**], [**Floppy**], or [**Electronic**], continue to press [**Perm Record**].
3. To confirm the choice, press [**Enter**].
   Note: This does not affect the output location previously selected in Instrument Parameters. This selection will warn only if test records will be overwritten.

Upload Software Upgrades from a Floppy Disk

From page 2 of the QC Manager Setup screens:

1. Insert the floppy disk containing the Medtronic-released software upgrade for the ACT Plus™ instrument into the floppy drive.
2. Select [**Instrument Upgrade**].

Section 7: Test Methods

General

Note:

- Lot numbers and expiration dates for cartridges and controls must be entered prior to running a test (refer to Data Entry on page 18 for detailed instructions).
- The User ID and Patient ID numbers must be entered prior to running a test (refer to Data Entry on page 18 for detailed instructions).

1. Power ON the ACT Plus™ instrument. Allow at least 10 minutes for the actuator heat block to reach a temperature of 37.0°C ± 0.5°C.
2. From the Main Menu, select [**Cartridge Type**]. Continue to press this key until the correct cartridge is selected. Press [**Enter**] to confirm.
3. Prewarm the cartridges for at least 3 minutes before collecting the test sample. Cartridges for HR-ACT, LR-ACT, and ACT may be prewarmed for up to 12 hours without affecting performance. For specific information, consult the package insert that accompanies the cartridges.
4. Tap the cartridge to resuspend the reagent in the chamber before adding the test sample.
5. Fill each cartridge chamber with the appropriate sample volume. The sample level should be between the upper and lower fill lines in each reaction chamber. Allow the sample to flow down the back of the chamber, taking care to avoid getting the sample on the flag or the plunger assembly (see Figure 1).
6. Insert the cartridge into the actuator heat block and rotate the block to the ***closed*** position.
7. Reagent is delivered into the reaction chamber, and the time to clot formation is measured.
8. When clot formation is detected, or if the test is terminated, an audible tone sounds, and the actuator heat block automatically rotates to the ***open*** position.

Activated Clotting Times: High-Range (HR-ACT), Low-Range (LR-ACT), and Recalcified (RACT) Cartridges

Table 1 lists the Medtronic Activated Clotting Time Cartridges available for use with the Medtronic ACT Plus™ instrument.

Table 1. Medtronic Activated Clotting Time Cartridges

Product	Sample Type	Channel Sample Volume	Intended Use
LR-ACT	Fresh drawn	0.2 mL	Therapeutic (0-1.5 Units Heparin/mL)
RACT	Citrated	0.2 mL	Therapeutic (0-1.5 Units Heparin/mL)
HR-ACT	Fresh drawn	0.4 mL	Cardiovascular or Cath Lab (1 Unit Heparin/mL or more)

Table 2 displays the cartridge reagents (0.1 mL per channel) and maximum prewarm times for each cartridge type and cartridges with sample:

Table 2. Cartridge Type Specifications

Cartridge Type	Reagent	Cartridge Max. Prewarm Limits	Cartridge + Sample Prewarm Limits
HR-ACT	12% Kaolin 0.05M $CaCl_2$ HEPES buffer[a] Sodium azide[b]	12 hours	Nonapplicable Perform test immediately.
LR-ACT	0.75% Kaolin[c] 0.0025M $CaCl_2$ HEPES buffer Sodium azide	12 hours	Nonapplicable Perform test immediately.
RACT	2.2% Kaolin 0.05M $CaCl_2$ HEPES buffer Sodium azide	12 hours	5 minutes

[a] HEPES (hydroxyethyl-piperazine-ethanesulfonic acid) buffer.
[b] Sodium azide is a bacteriostatic agent.
[c] Kaolin concentration may vary slightly.

Results

Duplicate channel results should fall within 10% of each other for baseline (unheparinized) samples and within 12% of each other for extended or heparinized samples.

Sample Calculation:

Channel 1 clotting time	210 seconds
Channel 2 clotting time	200 seconds
Mean clotting time	205 seconds
Difference	10 seconds
12%	25 seconds

The difference of 10 seconds is less than 12%, 25 seconds. These results are acceptable. The instrument's operable range is 25 to 999 seconds.

High-Range Heparinase (HR-HTC)

The HR-HTC cartridge is a modification of the High-Range Activated Clotting Time Cartridge used to identify the presence of heparin in a fresh whole blood sample. One of the cartridge channels contains a purified bacterial heparinase. The heparinase rapidly and specifically destroys up to 6 units/mL of heparin present in the sample.

1. Shake or tap the HR-HTC cartridge to resuspend the reagent before use, and prewarm it for 3 to 5 minutes (up to a maximum of 2 hours).
2. Fill each chamber with 0.4 mL of sample (the sample level should be between the upper and lower fill lines in each chamber).
   Note: To ensure that no heparinase is inadvertently transferred between channels, fill the channel labeled with "HR" first, and the channel that is stamped with the purple "HR-HTC" second.
3. Initiate the test immediately by rotating the actuator heat block to the ***closed*** position.

Note:

- The HR-HTC displays two results: one for the sample with heparinase and one for the sample without heparinase.
- The difference between the two channels indicates the effect of heparin on the clotting time. The baseline clotting time may or may not be at or near the normal range. If the baseline is not within the normal range in the HR-HTC channel, some condition other than the presence of heparin is responsible for extending the baseline clotting time.

General Purpose Cartridge (GPC)

The General Purpose Cartridge is used to perform Prothrombin Time (PT) or Activated Partial Thromboplastin Time (APTT) tests on citrated whole blood or plasma samples. Each channel of a GPC contains 100 µl of 0.02 M calcium chloride. User-defined reagents specific for PT and APTT testing are added to the cartridge channels before the patient sample is added.

Prothrombin Time (PT)

1. Pipette 100 µl of thromboplastin **without calcium** into each cartridge channel.
2. Add 100 µl of citrated sample to each channel.
3. Tap the cartridge to mix the reagent and test sample.
4. Prewarm the cartridge in the actuator heat block for a minimum of 3 minutes, but no more than 5 minutes.
5. After 3 minutes, rotate the actuator to the ***closed*** position to initiate the test.

Activated Partial Thromboplastin Time (APTT)

1. Pipette 100 µl of reagent for APTT (activator plus phospholipid) into each cartridge channel.
2. Add 100 µl of citrated sample to each channel.
3. Tap the cartridge to mix the reagent and test sample.
4. Incubate the cartridge in the actuator heat block for the number of minutes specified in the product insert for the specific reagent.
5. Initiate the test after the incubation period has elapsed by rotating the actuator to the ***closed*** position.

At completion of the test, the ACT Plus™ instrument will display the clotting time for each channel, and the average and difference for each channel.

Section 8: Quality Assurance

Instrument Self-Test

The ACT Plus™ instrument performs the following self-tests when powered ON:

1. The actuator cycles and opens the actuator heat block if it is ***closed***.
2. Three audio beeps will sound, the Startup screen will appear, and the message, “Self-Test in Progress” will be displayed.
3. The message, “Self-Test Pass,” is displayed followed by automatic transition to the Main Menu.
   Note: If any of the instrument’s self-tests fail or are not completed, the software will display the message “Self-Test: FAIL XXX,” where XXX is a 3-digit number indicating a System Error Code. Record this code (if displayed), and notify the Medtronic Service Department or an authorized representative before continuing (refer to Service and Troubleshooting on page 42).
4. The temperature will be displayed automatically until the actuator heat block reaches the appropriate temperature for testing (36.5°C to 37.5°C), unless a higher-priority message appears.
   Note: Allow a minimum of 10 minutes of warm-up time for the actuator heat block to reach the desired temperature before performing any tests. The actual warm-up time will depend on the instrument’s ambient temperature.

Liquid QC

Liquid coagulation controls are used to verify instrument cartridge performance and end-user technique. When only liquid controls are used, minimum requirements are two levels of control for every 8 hours of patient testing. CLOTtrac® Coagulation Controls are available for High-Range, Low-Range, Recalcified, and High-Range Heparinase cartridges.

Electronic QC (ACTtrac®)

The ACTtrac® Electronic Quality Control is an interactive, mechanical, software-controlled verification device that includes both quantitative and qualitative results. It interacts with the ACT Plus™ instrument by mechanically emulating certain functions of a test cartridge. The ACTtrac® checks the following aspects of the ACT Plus™ instrument that relate to proper test cartridge function: flag sensor function, reagent delivery pin height, lift wire height, and three-level tests (emulated clotting time ranges).

Note:

- The ACTtrac® must be used as a supplement to liquid controls. Refer to the current regulatory agency guidelines on the acceptability and use of electronic controls.

- Refer to the ACTtrac® Operator's Manual for the specific instructions and additional information.

Section 9: Maintenance

Instrument Case Cleaning

The instrument case and exposed surfaces of the actuator should be kept clean. The ACT Plus™ instrument is approved for cleaning with the following agents: isopropyl alcohol, methanol, propyl alcohol, glutaraldehyde, bleach, ethanol, Liqui-Nox®[1], parachlorometaxylenol, hydrogen peroxide, and mild detergent.

Actuator Cleaning

The exposed surfaces of the actuator (with the actuator heat block in the ***open*** position) should be cleaned with one of following cleaning detergents: isopropyl alcohol, methanol, propyl alcohol, glutaraldehyde, bleach, ethanol, Liqui-Nox®, parachlorometaxylenol, hydrogen peroxide, or mild detergent. To ensure proper performance of the ACT Plus™ instrument, it is important to clean the actuator a minimum of every 30 days, or more frequently if required. If blood should get into the actuator assembly (see Figure 7), it is critical that the instrument is cleaned as soon as possible.

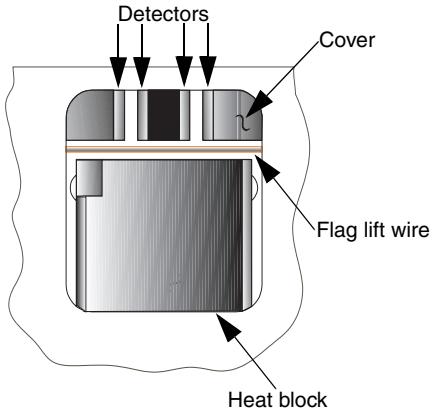


Figure 7. *ACT Plus™ Actuator Assembly*

An instrument cleaning kit (Part Number 201673) is provided with each ACT Plus™ instrument. Use the materials in the kit to perform the following cleaning procedure:

1. Dip the swab provided in the enclosed packet in the Liqui-Nox® solution.
2. Swab the flag lift wire, removing all blood.
3. Swab inside the actuator cover, especially the detector and emitter areas of the photo-optical sensor.

[1] Liqui-Nox® is a registered trademark of Alconox, Inc.

4. Remove any excess Liqui-Nox® solution with a dry swab.
5. If blood should get into the detector of the lamp area and cannot be removed with a swab, Error Code “4” may be displayed.

Note: Cleaning kits can be obtained from Medtronic Customer Service or an authorized representative.

Actuator Heat Block Temperature

The actuator heat block temperature should be checked once a month to verify that it is 37°C ± 0.5°C. The ACT Plus™ instrument records all temperature adjustments into its temperature log.

Verification with Thermometer

1. Turn the ACT Plus™ instrument ON and allow it to warm for 15 minutes.
2. Use a cartridge, with the plunger assembly removed and filled with 0.2 to 0.3 mL of water. Insert the cartridge into the actuator heat block.
3. Place a calibrated thermometer in one of the cartridge reaction chambers.
4. Wait for temperature equilibration to occur (minimum 10 minutes) and check the thermometer reading.
5. The instrument-displayed temperature and thermometer-measured temperature should both read within 36.5°C to 37.5°C. The thermometer-measured temperature should be within ± 0.5°C of the instrument-displayed temperature.

From the Quality Control Menu:

6. To change the temperature, if needed, or record that the temperature has been verified, select [**Temperature Adjustment**].
7. Enter the thermometer reading using the keypad (values must be between 35°C and 39°C).
8. To accept the value, press [**Enter**]. The time, date, and temperatures of the thermometer and the display will be logged in the temperature log.

Note: If the instrument is still not in the range specified (see Step 40), adjustments can be repeated after a minimum of 10 minutes. To repeat adjustments, select [**Repeat Adjustment**].

9. If you are unable to calibrate the display to match the thermometer-measured temperature, contact the Medtronic Service Representative or an authorized distributor.

Temperature Verification Cartridge

1. Turn the ACT Plus™ instrument ON and allow the instrument to warm up for 15 minutes.
2. Place the Temperature Verification Cartridge (Catalog No. 313-11) into the actuator heat block.

3. Wait for temperature equilibration to occur (minimum 10 minutes) and check the Temperature Verification Cartridge reading.
4. The instrument-displayed temperature and the Temperature Verification Cartridge temperature should both be within 36.5°C to 37.5°C. The Temperature Verification Cartridge temperature should be within ± 0.5°C of the instrument-displayed temperature.

From the Quality Control Menu:

5. To change the temperature, if needed, or to record that the temperature has been verified, select [**Temperature Adjustment**].
6. Enter the thermometer reading using the numeric keypad (values must be between 35°C and 39°C).
7. To accept the entry, press [**Enter**]. The time, date, and temperatures of the thermometer and the display will be recorded in the temperature log.

Note: If the instrument is still not in the range specified in Step 5, adjustments can be repeated after a minimum of 10 minutes. To repeat adjustments, select [**Repeat Adjustment**].

8. If you are unable to calibrate the display to match the temperature on the Temperature Verification Cartridge, contact the Medtronic Service Representative or an authorized distributor.

Preventive Maintenance

See Service and Troubleshooting on page 42.

Fuse Replacement

Two fuses are located in the Power Inlet Module on the ACT Plus™ instrument's rear panel. To replace or examine the fuses:

1. Disconnect the power cord.
2. Open the cover of the fuse holders using a small flathead screwdriver.
3. Slide the fuse holders out and, if necessary, replace the fuses with T4A 250-V fuses.
4. Insert the fuse holders back into the Power Inlet Module.
5. Close the cover.
6. Power ON the instrument to determine whether replacing the fuse(s) solved the problem.

Note: If fuses blow repeatedly, contact a Medtronic Service Representative or an authorized representative.

Section 10: Service and Troubleshooting

Service

Annual preventive maintenance is recommended for your ACT Plus™ system to ensure accurate performance and reliability. A qualified Medtronic Service Representative should perform all maintenance or service. The inspection and maintenance may be performed at your site or at the factory.

Training for Medtronic products is available to qualified hospital personnel upon request.

More detailed information, such as circuit diagrams, component parts lists, and calibration instructions, is available for appropriately qualified technical personnel.

Do not attempt to service the ACT Plus™ instrument during the warranty period, as any manufacturer's warranty will be voided.

WARNING: Do not adjust, modify, repair, or touch the internal circuitry. These actions could injure the operator or cause faulty operation of the ACT Plus™ instrument.

For information related to test procedures, quality control, and regulatory information contact your Medtronic Sales Representative at 800-349-2795.

Refer all repair requests to:
United States
Medtronic Instrument Service Representative
Medtronic Physio-Control
11811 Willows Road NE
P.O. Box 97023
Redmond, WA 98073-9723
USA
Service Information
Toll-free: 1-800-433-4311
Fax Toll-free: 1-800-772-3347

Instrument Return

To return an ACT Plus™ instrument for service, contact Medtronic Physio-Control for the appropriate return procedure, or obtain appropriate authorization from the Medtronic Service Representative. Original shipping materials should be used to return the ACT Plus™ instrument; it should be enclosed within the foam inserts and placed in the box. The actuator heat block should be in the ***closed*** position when it is shipped. If the original box is no longer available, notify Medtronic Instrument Service or an authorized representative to obtain shipping materials.

Troubleshooting

The ACT Plus™ instrument self-diagnoses many error and precautionary conditions, which are displayed on the LCD screen.

Message Types

The ACT Plus™ instrument provides three types of messages to indicate its operating conditions: Information/Status; Alerts; and System Alarms. These messages, with the exception of System Alarms, appear in the screen's Status Message area.

- **Information/Status:** Screen message with no audio tone.
- **Alerts:** Screen message with a three-beep audio tone (audio is active when the [**Audio Tone**] parameter is set to ON).
- **System Alarms:** Screen message with a single, long audio tone (audio is always active). System Alarms are presented when the ACT Plus™ instrument's self-testing mechanism detects a condition that may affect the ability of the instrument to function properly. These messages are displayed, if possible, and may be accompanied by a 3-digit Error Code, which service personnel use to identify the system error.

Message Priorities

Messages are displayed in a priority structure. If multiple error or precautionary conditions occur simultaneously, only the highest-priority message appears on the display.

System Messages	Cause/Resolution
Both lot numbers are filled. OR Both cartridge lots full.	The user is trying to add a lot number when two already exist for the selected cartridge. Remove one of the lot numbers.
Bar code is not a cartridge type.	The user is trying to scan a control lot on the cartridge setup screen.
Bar code is not a control type.	The user is trying to scan a cartridge lot on the control setup screen.
Bar code is not valid.	The bar code information was not valid as a cartridge or control. Rescan the bar code. Reprogram the bar code scanner.
Expired cartridge lot. OR Expired control lot.	The user is attempting to run a test with a cartridge/control that is beyond the expiration date. Make sure that the expiration date on the packaging matches the date in the cartridge lot entry screen.
Cartridge lot already exists. OR Control lot already exists.	The user is trying to scan a lot number when that lot number already exists for the selected cartridge/control.

Cartridge is not enabled.	The cartridge selected is not enabled in the QC Manager Setup screen. Contact your QC Manager to enable the selected cartridge.
Cartridge for control is not enabled.	The user is trying to scan in a lot number for a control when the cartridge that uses that control is not enabled in the QC Manager Setup. Contact your QC Manager to enable the selected cartridge.
Expiration date edited. QC due.	The expiration date for the cartridge lot has been changed; control tests must be repeated for this lot. Repeat the controls for this lot number.
Expiration date is not valid. OR Invalid expiration date.	The expiration date is not in a valid format. The proper format for the expiration date for a cartridge or control lot is yy-mm-dd.
Test will overwrite saved test history.	The current test will overwrite test results in the permanent record. Transmit all unsent test records to the output source.
Invalid password.	The password that was entered is not correct. Enter the correct password.
Run ACTtrac® from QC Menu.	The user is attempting to run an ACTtrac® test from the Main Menu. Go to the QC Menu screen to run ACTtrac® tests.
No cartridge lot number active.	The user is attempting to run a test without an active cartridge lot number. Enter the cartridge lot number for this test type.
Cartridge not recognized. OR There are no active cartridges to edit. OR There are no active cartridges.	All cartridges have been disabled. Have the QC Manager enable the appropriate tests.
No control lot number active.	The user is attempting to run a control test without an active control lot number. Enter a valid lot number for the control.
There are no other active cartridges.	Only the selected test is enabled. Have the QC Manager enable tests.
No test results available.	No test results are available to view on the View Current Test Results screen.
Patient ID required.	Patient ID is required the run a patient test. Enter a Patient ID in the Enter ID screen.
Preventive maintenance due.	Preventive maintenance is due. Call Medtronic Instrument Service to schedule a preventive maintenance check.

Value Out of Range. Enter 35 – 39.	The Actuator Heat Block temperature cannot be adjusted out of the 35-to-39 range. If the Actuator Heat Block cannot be adjusted within the 35-to-39 range, call Medtronic Instrument Service.
There are no intervals set.	The QC Manager has not set the intervals for liquid or electronic controls. Have the QC Manager set QC intervals in the QC Manager screen.
QC Due: HH:MM.	The QC for this cartridge will run out at the prescribed time (hh = hour; mm = minute).
QC not performed.	The QC test for this cartridge has not been performed or has failed. Perform QC tests for this cartridge.
The passwords do not match.	When changing the password for the QC Manager, the Confirm Password screen did not match the Change Password screen. Reenter the same password in the Confirm Password screen that was entered in the Change Password screen.
QC past due.	The QC for this cartridge has passed its interval. Perform QC tests for this cartridge.
Test terminated before clot is detected.	The test stopped before clots were detected in both channels. Repeat test.
No User IDs to download.	The QC Manager is trying to download User IDs to the floppy disk, but no User IDs are in the memory. Add User IDs to the memory and download to the floppy drive.
No valid User IDs in file.	The QC Manager is trying to upload User IDs from the floppy disk, but there are no User IDs in the file. Download User IDs from an ACT Plus™ instrument or an ACT Plus™ External Data Manager (EDM) to the floppy disk, and use that floppy disk to upload them.
Test requires valid User ID.	The QC Manager has set User Lockout to ON so that a User ID is required to run a patient test. Enter a valid User ID in the Enter ID screen.

Alerts

Bar code scan timeout.	A bar code input sequence was detected, but it did not complete correctly. Rescan the bar code.
> 10% spread error.	The channels of the controls tested are not within 10%. Repeat the control test.
> 12% spread error.	The channels of the controls tested are not within 12%. Repeat the control test.
Error - File not found.	The ACT Plus™ instrument is trying to read a file on a floppy disk, but cannot find it.

Error Messages

Disk error - Disk is faulty.	The ACT Plus™ instrument is trying to read a floppy disk and cannot read it. Insert a floppy disk that meets the specification listed in Specifications on page 10.
Serial port error.	An error occurred in accessing the serial port. Retry transfer.
Motor stall. Power OFF then ON (E9).	The motor has been inhibited. To reset the system, turn the power OFF then ON.
System error. Power OFF then ON.	The system has become unstable. To reset the system, turn the power OFF then ON.
Bad Reference in Ch1 and Ch2. OR Bad Reference in Ch1. OR Bad Reference in Ch2.	The ACT Plus™ instrument could not get a baseline drop time for Channel 1, Channel 2, and both channels. Repeat test.
Error: E1	No cartridge is detected. Place a cartridge in the actuator and retest.
Error: E2 or E3	A software error has occurred. Call Medtronic Instrument Service.
No flags. OR No flag in Ch1. OR No flag in Ch2. OR No flags in Ch1 or Ch2.	The ACT Plus™ instrument did not sense a flag in Channel 1, Channel 2, or both channels. Repeat the test.
Insufficient data.	The channels of the control timed out at 999. Repeat the control.

Error: Invalid reply.	Internal communication error. Call Medtronic Instrument Service.
Light path failure in Ch1 and Ch2 (E4). OR Light path failure in Ch1 (E4). OR Light path failure in Ch2 (E4).	The flag sensor has failed. Clean the actuator cover per the instructions in the Maintenance section of this manual. If the error is not corrected, call Medtronic Instrument Service.
Motor stall.	The motor is inhibited. Press STOP to reset. Repeat the test.
Motor stall, cycle power (E8).	The motor is inhibited. To reset, power OFF then ON.
No reply.	Internal communication error. Call Medtronic Instrument Service.
File system error.	Call Medtronic Instrument Service.
Comm. Error; Invalid data.	Call Medtronic Instrument Service.

Notes: If a System Alarm occurs that cannot be resolved by cycling the power OFF then ON, record the 3-digit Error Code (if displayed), and contact Medtronic Instrument Service for assistance.

Temperature

Actuator Heat Block Temp XX.X°C.	The current actuator heat block temperature (XX.X°C) is displayed when it is between 20°C and 41°C.
Actuator Heat Block Temp > 44°C (E99).	The actuator heat block temperature is greater than 44°C.
Actuator Heat Block Temp < 5°C (E00).	The actuator heat block temperature is less than 5°C.

Appendix A: Optional Bar Code Scanner

Introduction

The Symbol™ LS1900 Series scanner is compatible with the ACT Plus™ instrument.

Parts of the LS1900 Series Scanner

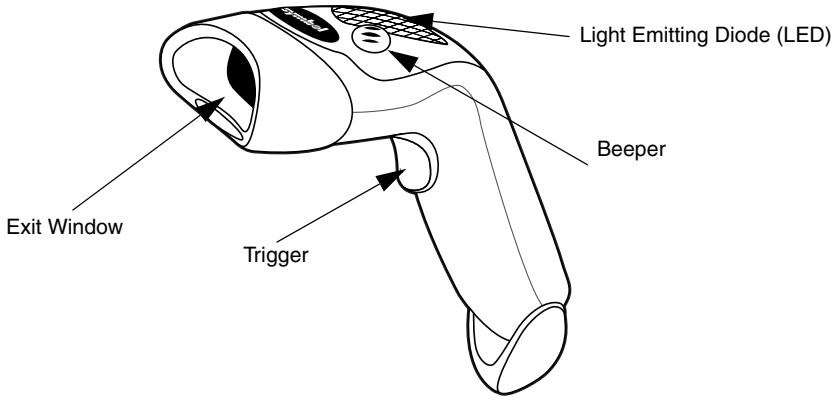


Figure 8. *Bar Code Scanner*

Scanning in Hand-Held Mode

1. Aim the scanner at the bar code on the cartridge box or control box and press the trigger.
2. Be sure that the red line from the scanner goes across the entire bar code label.

Figure 9. *Correct scan location*

When the scanner has successfully decoded the label, the scanner will beep, and the cartridge/control information will be entered into the ACT Plus™ instrument.

Troubleshooting

Nothing happens when you follow the operating instructions.	Interface/power cables are loose. Check for loose cable connections.
The laser comes on, but the symbol does not decode.	The scanner is not programmed for the correct bar code type. Be sure the scanner is programmed to read the type of bar code you are scanning. The bar code symbol is unreadable. Check the symbol to make sure it is not defaced. Try scanning test symbols of the same bar code type. The distance between the scanner and bar code is incorrect. Move the scanner closer to the bar code. The symbol is decoded, but not transmitted to the host. The scanner is not programmed for the correct bar code type. Be sure the scanner is programmed to read the type of bar code being scanned.

Defaults

If the bar code scanner does not read the bar code on the ACT Plus™ disposable packaging, reset the defaults before calling Medtronic Instrument Service. To reset the defaults, follow this procedure, and try to rescan the packaging.

Procedure for setting the defaults:

1. To ensure that the scanner is reset, first scan the Set All Defaults bar code.

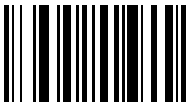


Figure 10. *Set All Defaults bar code*

2. Scan the “IBM AT” bar code. This is the appropriate interface for the ACT Plus™ software.

Figure 11. *IBM AT bar code*

3. Scan the “Low Volume” bar code, unless a different volume is desired.

Figure 12. *Low Volume bar code*

4. Scan the “Enable UCC/EAN-128” bar code. The cartridges and controls use this format.

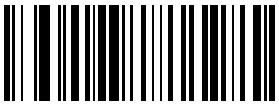


Figure 13. *Enable UCC/EAN-128 bar code*

5. Scan the “Scan Prefix” bar code, then scan the following numbers: 1, 0, 0, 2.

Figure 14. *Scan Prefix bar code*

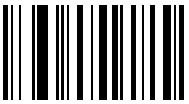


Figure 15. *1 bar code*

Figure 16. *0 bar code*

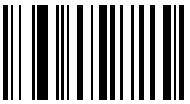


Figure 17. *0 bar code*

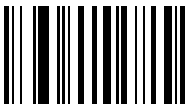


Figure 18. *2 bar code*

6. Scan the “Scan Suffix” bar code, then scan the following numbers: 1, 0, 0, 3.

Figure 19. *Scan Suffix bar code*

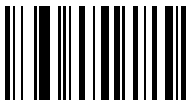


Figure 20. *1 bar code*

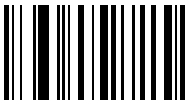


Figure 21. *0 bar code*

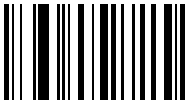


Figure 22. *0 bar code*

Figure 23. *3 bar code*

7. Scan the “Scan Options” bar code, then scan the <PREFIX><DATA><SUFFIX> bar code.

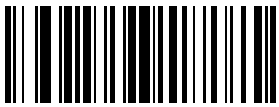


Figure 24. *Scan Options bar code*

Figure 25. *Prefix Data Suffix bar code*

8. Scan the “Enter” bar code. This completes the procedure. The bar code scanner will now work with the ACT Plus™ instrument.

Figure 26. *Enter bar code*

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