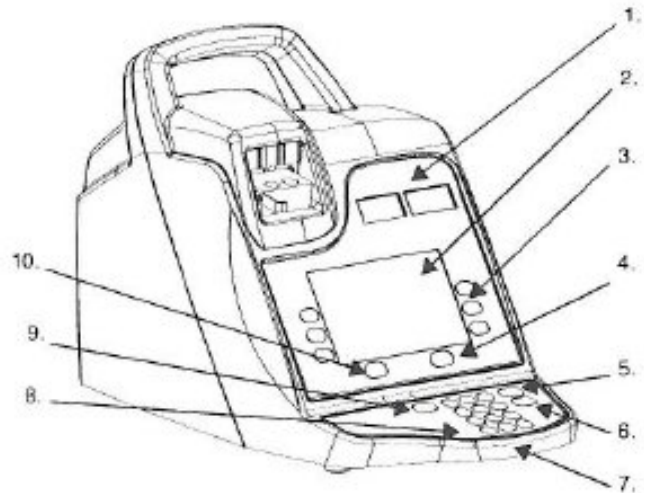


Medtronic ACT Plus Low Range: Appendix A - Instrument Review

Medtronic ACT Plus Instrument Controls & Components

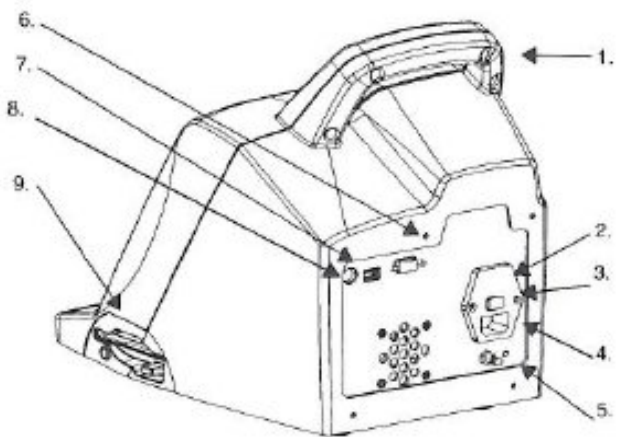
Front

1. Clot Time Display	Channel 1 & 2 display.
2. Data Entry Display	LCD Screen to navigate through the screens.
3. Variable Function Keypad	Selects the desired field in the various screen options.
4. Quality Control Key	Accesses the Quality Control Menu.
5. Cancel Key	Cancels any currently active function.
6. Enter Key	Accepts numbers or data in an active field.
7. Numeric Keypad	Data entry: lot #'s; user ID; patient ID
8. Clear Key	Clears the field.
9. Stop Key	Stops a test in progress.
10. Main Menu Key	Accesses the main menu.



Rear Panel

1. Handle	
2. Fuse Holder	Fuse replacement. C&W Biomedical Engineering.
3. Main Power Switch	ON/OFF Toggle
4. Power Inlet Module	Connects the power cord.
5. Equal Potential Terminal	These ports are not used at this time.
6. Serial Port (RS-232)	
7. Serial Port (USB)	
8. Bar Code Scanner Port	
9. Floppy Drive	Download once per week.



Medtronic ACT Plus System Description	
Intended Use	<ul style="list-style-type: none"> Determining coagulation endpoints in fresh whole blood.
Data Storage	<ul style="list-style-type: none"> Currently, data is manually recorded on the Form A – record sheet. <p><i>Note: ACT II Plus with connectivity has the potential to:</i></p> <ul style="list-style-type: none"> <i>Provide long-term data storage and retrieval for patient and quality control tests.</i> <i>Transfer to a floppy disk, Lab Information System, or Hospital Information System.</i>
Clot Detection	<ul style="list-style-type: none"> Endpoint of a test performed is the formation of fibrin. Fibrin formation is detected by measuring the rate of fall of the plunger-flag mechanism in each cartridge channel. Plunger assembly falls rapidly at programmed timed intervals through an unclotted sample. Fibrin web formed during clotting impedes the fall rate of the plunger. Detection is by a photo-optical system located in the instrument's actuator assembly. Test is performed in duplicate. Results are displayed for each channel, including the average and the difference between the two channels.
Test Cartridge	<ul style="list-style-type: none"> Low Range Activated Clotting Time (LR-ACT) for use in ECLS Extracorporeal Life Support at Children's & Women's Health Centre. See directional insert.
Actuator Heat Block Assembly	<ul style="list-style-type: none"> The receptacle for test cartridges. Temperature is maintained at 37.0°C ± 0.5°C. Actuator heat block assembly rotates between the open and closed positions. Open position - Cartridges are inserted. Closed position - Testing is initiated. At termination of a test, the heat block will automatically rotate to the open position, and the results will be displayed. Manual termination of a test is done by depressing the [STOP] switch.
Medtronic ACT Plus Main Menu – Data Entry	
<i>Note: All Patient testing is performed from the Main Menu.</i>	
[Enter ID]	<ul style="list-style-type: none"> Enter patient ID Enter Operator ID
[Cartridge Type]	<ul style="list-style-type: none"> Select appropriate type cartridge.
[Cartridge Lot]	<ul style="list-style-type: none"> To enter cartridge lot number and expiration date. Up to two lots of each cartridge type may be entered in the database at one time.
[View Current Test Results]	<ul style="list-style-type: none"> Displays results of the last test performed.

[Transmit Test Results]	<ul style="list-style-type: none"> To transmit patient and Quality Control to an external location via floppy drive or Lab Information System.
[Instrument Parameters]	<ul style="list-style-type: none"> To enter current date, current time, audio tone, language, screen contrast adjustment, and output location.
Medtronic ACT Plus Quality Control (QC) Menu	
<i>Note: All Quality Control testing is performed from the Quality Control Menu.</i>	
[Control Type]	<ul style="list-style-type: none"> Selects the Quality Control type to be performed. Low-Range ACT (LR-ACT) cartridge requires controls: (CWB) - Normal Citrated Whole Blood. (Low Range Cartridge Normal Level Quality Control). (LR-AB) – Abnormal. (Low Range Cartridge Abnormal Level Quality Control).
[Control Lot]	<ul style="list-style-type: none"> To enter, remove, or edit the Lot number, expiration date, and the range of the selected control. Up to two lots of each control type may be entered in the database at one time.
[Temperature Adjustment]	<ul style="list-style-type: none"> To verify the actuator heat block temperature.
[QC Due Status]	<ul style="list-style-type: none"> Status of the controls; includes date and time that the control tests must be performed.
[QC Manager Functions]	<ul style="list-style-type: none"> [Location], [User ID Setup], [Download Settings], [Perm Record], and [Instrument Upgrade]. Point of Care Technologist use only.

REVISION & APPROVAL LOG

Version	Revision Type	Description of Change	Revision Date	Technical Approval	Medical Approval
1.0		New document	30 Dec 2013	Elvira Kozak	Dr. Cathy Halstead
1.1	Minor	Document title and number change. Upload to QMS document control	22 Dec 2016		Dr. Benjamin Jung

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