

Medtronic ACT Plus Low Range: Instrument Setup Procedure

PROCEDURE: This procedure provides instructions on what is required before proceeding to patient testing.

MATERIALS.

- ACT Plus Instrument
 Temperature Verification Calibrator
 Liquid Quality Control material –
- Normal Level - CLOTtrac CWB Coagulation Control. 550-01
 - Abnormal Level – CLOTtrac LR Abnormal Control. 550-09

	Action	Related Documents Title Number						
1.	<p>Turn the instrument ON. ON/OFF toggle is at the rear of the instrument.</p> <ul style="list-style-type: none"> ○ The actuator assembly cycles and opens the actuator heat block assembly if it is closed. ○ Three audio beeps will sound. ○ Startup screen will appear. ○ Self-Test in Progress will be displayed. 	Medtronic ACT Plus Low Range: Appendix A - Instrument Review						
	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 40%;">If</td> <td>then</td> </tr> <tr> <td>Self-Test Passes.</td> <td> <ul style="list-style-type: none"> ○ automatic transition to the Main Menu is displayed. ○ Proceed to next step. </td> </tr> <tr> <td>Self-Test Fails or incomplete</td> <td> <ul style="list-style-type: none"> ○ “Self-Test: FAIL XXX” is displayed. ○ Cycle the power OFF then ON to repeat the Self-Test. </td> </tr> </table>	If	then	Self-Test Passes.	<ul style="list-style-type: none"> ○ automatic transition to the Main Menu is displayed. ○ Proceed to next step. 	Self-Test Fails or incomplete	<ul style="list-style-type: none"> ○ “Self-Test: FAIL XXX” is displayed. ○ Cycle the power OFF then ON to repeat the Self-Test. 	Medtronic ACT Plus Low Range: Appendix D - Troubleshooting Guide
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Self-Test Passes.	<ul style="list-style-type: none"> ○ automatic transition to the Main Menu is displayed. ○ Proceed to next step. 							
Self-Test Fails or incomplete	<ul style="list-style-type: none"> ○ “Self-Test: FAIL XXX” is displayed. ○ Cycle the power OFF then ON to repeat the Self-Test. 							
	<p><i>Note: If the instrument self-test fails a second time refer to the 3 digit System Error Code in the trouble guide and notify Cath lab supervisor/ POCT Technologist.</i></p>							
2.	<p>Press “Instrument Parameters”. View the following variable function keys and confirm that the information is correct.</p> <ul style="list-style-type: none"> ○ Date [yyyy-mm-dd] ○ Time [hh:mm] ○ Audio Tone [On] ○ Language [English]. 							
	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 40%;">If</td> <td>then</td> </tr> <tr> <td>Correct</td> <td> <ul style="list-style-type: none"> ○ Proceed to next step. </td> </tr> <tr> <td>Incorrect</td> <td> <ul style="list-style-type: none"> ○ Press [Enter] to confirm. ○ Input data using keypad. </td> </tr> </table>	If	then	Correct	<ul style="list-style-type: none"> ○ Proceed to next step. 	Incorrect	<ul style="list-style-type: none"> ○ Press [Enter] to confirm. ○ Input data using keypad. 	
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	<p><i>Note: This is usually performed during initial instrument setup, during power interruptions, or time changes.</i></p>							
3.	<p>Press “Exit to Main Menu”.</p>							
4.	<p>Document Instrument Temperature. Temperature displays on the Main Menu. Acceptable range of operation is 37 +/- 0.5°C. <i>Note: Instrument requires a warm up time of approximately 10 minutes.</i></p>							
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	incorrect Perform Temperature Verification <i>Note: Temperature Verification at a minimum is performed monthly.</i>							
5.	<p>Perform Daily Liquid Quality Control.</p> <ul style="list-style-type: none"> ○ Normal Level - CLOTtrac CWB Coagulation Control. ○ Abnormal Level – CLOTtrac LR Abnormal Control. <p>Note: CARDIAC CATH LAB: <i>One level of either normal control or abnormal control is required each day of patient testing. Each control type is run on alternating days.</i></p> <p>PICU PRISMA / ECLS: <i>One level of each control – normal level and abnormal level controls are required at initial instrument set up for onset of each patient event. Subsequently, each control type is run on alternating 12 hour shifts.</i></p> <table border="1" style="width: 100%;"> <thead> <tr> <th style="text-align: left;">If</th> <th style="text-align: left;">Then</th> </tr> </thead> <tbody> <tr> <td>Within limits</td> <td>Proceed to next step.</td> </tr> <tr> <td>Not within limits given</td> <td>Do not continue to patient testing until problem is solved. Refer to ACT Plus Quality Control Testing for trouble shooting assistance.</td> </tr> </tbody> </table>	If	Then	Within limits	Proceed to next step.	Not within limits given	Do not continue to patient testing until problem is solved. Refer to ACT Plus Quality Control Testing for trouble shooting assistance.	<p>Medtronic ACT Plus Low Range: Quality Control Test Procedure</p> <p>Medtronic ACT Plus Low Range: New Lot Number Quality Control Entry Procedure</p> <p>Medtronic ACT Plus Low Range: Appendix C - Quality Control</p>
If	Then							
Within limits	Proceed to next step.							
Not within limits given	Do not continue to patient testing until problem is solved. Refer to ACT Plus Quality Control Testing for trouble shooting assistance.							
6.	Instrument is ready for patient testing.	Medtronic ACT Plus Low Range: Patient Test Procedure						

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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