



Technical Service Bulletin

Cardio Products

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Bulletin Type: As Needed

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Date: 2009-08-24

SAP DIR #: 20011563

Subject: TSB - CP200 Operating Current Test

CAR Number: N/A

Distribution Scope: WA Internal
WA Technical Support, Product Service, & International Service Centers

Product(s) Referenced: CP200 Electrocardiograph

SW Version: N/A

Serial No. / Lot Code: ALL

Summary: Replacement of new CP200 LCD decreases the acceptable low end operating current level to 625 mA from 675 mA.

Issue: The new CP200 LCD 711714 draws less current than the previous LCD 700122. With ECO 5005559 Welch Allyn Production has revised the In-Process Adjustment Guide (DIR 70017119 Rev. D) to reflect this change.

Rev. D description states "Change IPA 20 to include lower Operating Current requirement of 625mA, for CP200 model only"

Currently the Service Manual (Material Number 704340 Rev. D) does not reflect the lower operating limit as stated above. In Section 3 (under *Operating/Non-Printing Mode Current Test*) the CP200 low operating current lists 675 mA. The correct low operating current when using LCD 711714 is 625 mA. This shall be corrected in the next Service Manual revision.

Action: When replacing a CP200 LCD with LCD 711714, The acceptable low end operating current (as described in Section 3 of the Service manual) is 625mA and **not** 675mA as stated.

Reference to Standards:

- 21 CFR Part 820, ISO 13485, MPD SOP-0002

Updates:

- | | | | |
|-------------------|-------------------------------------|-------------------|--------------------------|
| Technical Manual | <input checked="" type="checkbox"/> | Repair Tool | <input type="checkbox"/> |
| Service Plan | <input type="checkbox"/> | Internet/Intranet | <input type="checkbox"/> |
| Procedures | <input type="checkbox"/> | Price List | <input type="checkbox"/> |
| Training Material | <input type="checkbox"/> | Other | |

Service Strategy: N/A

Required Training: N/A

Required Tools: N/A

Required Materials: N/A

Quality Process for failed units or components: N/A

Procedure: See *Issue Statement*

Quality Documents: **All service centers using SAP to record service transactions:** For each monitor serviced, record the service activity in SAP.
All other service centers and Field Service: For each monitor serviced, complete and file a service report and attach to the service DHR.

Notes:

1. Contact the Welch Allyn Complaints Department to initiate or process a medical device complaint resulting from this or other issues.
2. Drawings, illustrations, and part numbers in this document are for reference purposes only and subject to change.

End of Bulletin

Revision History					
Version	Description	Change #	Init	Release Date	Appr
A	TSB - CP200 Operating Current Test	D*	D*	D*	D*
D* - See SAP DIR for Change number, Approver Name and Date of Approval					