Welch Allyn Inc.
Medical Products

Technical Service Bulletin

10 February 2007 **Number: M070202P**

Subjects addressed in this document: New Main PCBA (P/N 402280) replaces Main PCBA (P/N 401220)

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Reference:

Change Number: ___1009633___ Corrective Action Number: ____N/A_____

Applies to:

All models of CP100 and CP200 Electrocardiographs.

Background:

Since the launch of CP100 and CP200 Electrocardiographs an effort to remove rework and enhance the Main PCBA has been on going. Through the first year of usage in the field a couple of enhancements were identified as a result of feedback. So along with the effort to remove rework we have included some changes to hardware components on the PCBA. These changes include but are not limited to the following:

Symptom and Enhancement:

1. It was identified that the USB connector would become damaged with little force from side to side if a cable was plugged into the port. We were able to identify an alternate USB connector with better specs that has been added to this new Main PCBA. This part can also be ordered to repair failed connectors on Main PCBA (P/N 401220). The Part Number for the USB connector is 706615.
2. It was identified that the SD Card receptacle was becoming damaged in some way preventing insertion of the SD card into the device. In an effort to prevent damage, during handling, a cover over the SD card receptacle is now being applied during the manufacturing process of the PCBA. Due to the method of applying this cover, it was determined this could not be done in the field.

Rework Instructions:

1. USB connector failures: This part may be replaced with P/N 706615 at WA repair facilities.
2. SD card receptacle failures: This part may not be replaced and requires the replacement of the Main PCBA with P/N 402280.

Inventory on Hand:
All Main PCBA's (P/N 401220) currently in stock and WIP will be used as is.

Service Strategy:
No immediate action is required. When a failure occurs take the appropriate action as described above.

Inspection and preventative replacement as applicable:

Classification of Action:	**When:**
_____ Mandatory	_____ Immediate
__X__ Optional	__X__ On Next Service
_____ Does Not Apply	_____ At Agreed Upon Time

Note:
Drawings and/or illustrations and/or part numbers in this document are for reference only and current to the date of this bulletin. Contact the Welch Allyn Customer Service department for any questions on this bulletin, or to verify that you have the most current service information.

Complaint Records:
Alleged deficiencies related to the identity, quality, durability, reliability, safety, effectiveness, or performance of this product shall be documented, processed and readily available if requested according to the applicable complaint procedures for medical devices. Complaint records shall include:

1. The name of the device;
2. The date the complaint was received;
3. Any device identification(s) and control number(s) used;
4. The name, address and phone number of the complainant;
5. The nature and details of the complaint;
6. The dates and results of the investigation;
7. Any corrective action taken; and
8. Any reply to the complainant.

Service Reports:
Service reports on this product shall be documented and maintained so that they are readily available if requested. Service reports shall include:

1. The name of the device serviced;
2. Any device identifications(s) and control numbers(s) used;
3. The date of service;
4. The individuals(s) servicing the device;
5. The customer's "chief complaint" or "reason for return" and the defect found after inspection;
6. The service performed; and
7. The test and inspection data (after servicing).

Revision History

VERSION	DESCRIPTION	CHANGE #	INIT	DATE	APPR
A	Draft for Internal Reviews	1010131	CJT	2/13/07	RJS
B	RELEASE TO PRODUCTION	1010426	CJT	2/16/07	MEB

End of Bulletin

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