



Technical Service Bulletin

Cardio Products

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Bulletin Type: As Needed

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Date: 2012-01-12

SAP DIR #: 20012840

Subject: TSB - PRO Patient Cable Connector
CAR Number: N/A
Distribution Scope: WA Internal
WA Technical Support, Product Service, & International Service Centers.

Product(s) Referenced:

Welch Allyn Part #	Material Description
RE-PC-AHA-BAN	Resting, AHA, Banana
RE-PC-IEC-BAN	Resting, IEC, Banana
RE-PC-IEC-BANL	Resting, IEC, Banana, Long
SE-PC-AHA-CLIP	Stress, AHA, Clip
SE-PC-AHA-CLPL	Stress, AHA, Clip, Long
SE-PC-IEC-CLIP	Stress, IEC, Clip
SE-PC-IEC-CLPL	Stress, IEC, Clip, Long
SE-PC-IEC-PUSH	Stress, IEC, Push
SE-PC-IEC-PSHL	Stress, IEC, Push, Long

SW Version: N/A

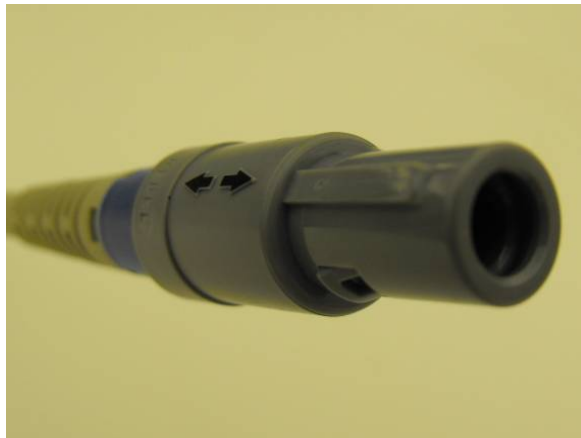
Summary: The trunk end of the patient cables listed above that plug into the CardioPerfect PRO Recorder have been modified with an additional mechanical key and label to avoid potential cable damage and pin misalignment.

Issue: With enough force, it was possible to insert the PRO patient cable into the CardioPerfect PRO Recorder against its mechanical keying system. In some orientations, the connector's pins mated and resulted in an ECG of seemingly good quality when in fact the signals were coming from incorrect locations on the body.

Action: An additional mechanical key and label has been added to the PRO patient cable connector. The additional mechanical key will further reduce the possibility of incorrect patient cable connector insertion. The label imagery on the patient cable connector matches the image at the patient cable socket on the Pro Recorder, making the proper alignment and action required to connect and disconnect the patient cable more intuitive.

See images below.

Old style:



New style:



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Reference to Standards: • 21 CFR Part 820, ISO 13485, MPD SOP-0002

Service Strategy: Use up existing materials while stock exists.

Required Training: N/A

Required Tools: N/A

Required Materials: N/A

Procedure: Information only.

Quality Documents: **All service centers using SAP to record service transactions:** For each part serviced, record the service activity in SAP.

All other service centers and Field Service: For each part 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	Initial release	D*	D*	D*	D*
D* - See SAP DIR for Change number, Approver Name and Date of Approval					