



Technical Service Bulletin

Cardio Products

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Bulletin Type: As Needed

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Date: 2012-05-14

SAP DIR #: 20013022

Subject: TSB – CPWS PerfectLink Installer

Distribution Scope: WA Internal

Product(s) Referenced:

SE-PRO-600	CARDIOPERFECT PRO RECORDER
PRO-60023, PRO-60024, PRO-60025	PROLINK USB CBL ASSY
703554	SPIROPERFECT KIT, USB, CPWS

CardioPerfect Resting ECG & Spirometry hardware and Resting ECG & Spirometry software modules used in conjunction with the following CPWS versions.

SW Version: CPWS Versions 1.6.3 & 1.6.4

Summary: The PerfectLink 1.0 Installer loads the PerfectLink Driver onto the customer's computer. The installer included on the above versions of the CPWS software may abort the installation process.

Issue: The PerfectLink 1.0 Installer may abort the installation. This is a known issue, stemming from a User Profile being improperly deleted from the local computer. When the profile folder is removed manually, some registry settings may not be removed from the system profile list. Rather than skipping User Profiles that do not have a folder, the installer aborts the installation process.

Action: To resolve this issue, it is necessary to remove the empty User Profile(s) from the local computer using the "System Properties"/ "User Profiles" tool or manually from the registry. This should be done by the user site's IT as they will need to determine which profiles are causing the issue and also ensure that the correct profile is removed. Due to the data risks involved in

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deleting User Profiles, WA Technical Support must not perform this process nor instruct the site's IT on how to perform this process. Once the offending User Profile has been removed, the software will install properly onto the computer.

Reference to Standards:

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

Service Strategy:

Standard TSB Distribution

Quality Documents:

All service centers using SAP to record service transactions: For each product serviced, record the service activity in SAP.

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