



Technical Service Bulletin

CARDIOPULMONARY

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Bulletin Type: AS NEEDED

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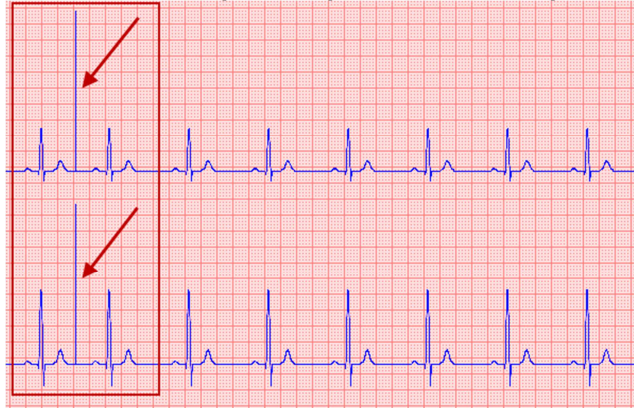
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Subject:	TSB-PROLINK_PC COMPATIBILITY ISSUE
Distribution Scope:	Welch Allyn Global Technical Support, Product, Field & Customer Service Teams, WA ASP's
Product(s) Referenced:	<ul style="list-style-type: none"> • PRO-60023 / PROLINK USB CBL ASSY (2M) • PRO-60024 / PROLINK USB CBL ASSY (3M) • PRO-60025 / PROLINK USB CBL ASSY (5M) <p>All CPWS 1.6.X Resting and Stress configurations.</p>
Serial No.:	<p>Range of PROlink serial numbers affected:</p> <ul style="list-style-type: none"> • 201310XXXXX through 201411XXXXX (see exemption tables in the Action section)
Summary:	Affected PROlink cables may not install properly onto certain PCs. In some instances, the cable may install but cause issues during the viewing and/ or recording process in CPWS. This TSB communicates the recognition of, and the solution to, these issues.
Issue:	<p>It has been determined that the PROlink cables manufactured from October 1, 2013 through November 2014 may fail to go through the full USB enumeration process on certain PCs. The net effect is that, after the cable is plugged in, nothing happens and the PROlink device will not show up in the system's Device Manager in any way. This has been seen on a few PCs, and only on PCs with an AMD processor and AMD USB chipset.</p> <ul style="list-style-type: none"> • <u>Note: Not every computer with an AMD processor and chipset will experience this issue.</u>

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On other systems, a few of these cables appear to function normally but may cause occasional framing errors and/or create “spikes”, during the ECG recording. When monitoring the ECG, framing errors may be counted in the status bar of the recording window. During recording, the ECG acquisition may reset to 0 (zero) one or more times before completing.

- Example of “spike” during viewing and/or recording:



- Example of framing error count at the bottom of the monitor window:



Action: Customers experiencing any of the issues detailed above while using PROlink cables labeled with serial numbers in the defined range will have their PROlink cables replaced free of charge, regardless of warranty or PIC coverage status.

Note: There are 30 cables, 10 of each part number, that fall within this serial number range but are not affected by the issues detailed in this TSB.

Cables with the following serial numbers should be replaced per normal warranty or PIC coverage policies:

PRO-60023:

20141001635	20141001646	20141001663	20141001667	20141001669
20141001644	20141001648	20141001666	20141001668	20141001670

PRO-60024:

20140100043	20140100045	20140100050	20140100073	20140100075
20140100044	20140100048	20140100056	20140100074	20140100076

PRO-60025:

20141000227	20141000232	20141000241	20141000254	20141000257
20141000230	20141000233	20141000252	20141000256	20141000264

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Reference to Standards:	<ul style="list-style-type: none"> • 21 CFR Part 820, ISO 13485, MPD SOP-0002
Required Materials:	<p>Appropriate PROlink cable for replacement of customer's cable:</p> <ul style="list-style-type: none"> • PRO-60023 / PROLINK USB CBL ASSY (2M) • PRO-60024 / PROLINK USB CBL ASSY (3M) • PRO-60025 / PROLINK USB CBL ASSY (5M)
Quality Documents:	<p>All service centers using SAP to record service transactions: For each product serviced, record the service activity in SAP.</p> <p>All other service centers and Field Service: For each product serviced, complete and file a service report and attach to the service DHR.</p>

Notes:

1. Contact Welch Allyn regarding any questions or concerns 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					