



**Customer Service Bulletin**

**Blood Pressure Products**

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**Bulletin Type: Information Only**

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**Date: 2010-11-15**

**SAP DIR #: 20012230**

**Subject:** CSB – Spot LXi RS232 Port Usage

**CAR Number:** N/A

**Distribution Scope:** WA Customers, ASP's, and Distributors  
WA Technical Support, Product Service, & International Service Centers

Spot Vital Signs Monitor LXi:

- 45MT0
- 45NT0
- 45ME0
- 45NE0
- 450E0
- 450T0

Approved Spot Vital Signs Monitor LXi Accessories:

**Product(s) Referenced:**

- Braun 4000 thermometer or SureTemp® Plus thermometer probes
- Masimo and Nellcor SPO2 sensors
- Welch Allyn-supplied radios powered from Spot LXi
- Null modem, W/A material number 703878 (SP24729)
- Welch Allyn-specified barcode readers, powered from Spot LXi
- Weight scales - Tanita WB300MH and Health-o-meter 349KLX
- Welch Allyn-supplied printers
- Spot LXi external power supply

**SW Version:** ALL

**Serial No. / Lot Code:** N/A

**Summary:** Clarification of approved Spot LXi Accessories and identify customer responsibilities and situations to avoid in the event alternative accessories are implemented.

**Issue:** Clarification of which Spot LXi add-on accessories are validated and supported by Welch Allyn.

**Action:** Use the information provided in the Service Strategy section to define approved and supported Spot Vital Signs LXi accessories.

**Reference to Standards:**

- 21 CFR Part 820, ISO 13485, IEC 60601-1-1

**Updates:**

Technical Manual	<input 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	<input type="checkbox"/>

**Service Strategy:** Based on testing, Welch Allyn recommends for use with the Spot LXi only the Accessories identified in sales literature and reiterated in this document. Use of unapproved accessories are at the customers own risk, not supported by Welch Allyn and may void the warranty of the Welch Allyn device and render it inoperable.

The customer has sole responsibility to perform the testing necessary to ensure that use of the Spot LXi and the commercially-available accessories, other than those specified by Welch Allyn, in any system satisfies applicable standards. Such standards include IEC 60601-1-1 or other standards as appropriate to the device/system.

Welch Allyn has become aware that the Spot LXi can be damaged if it is used with certain commercially-available RS-232 adapter accessories that are sold with separate power supplies in configurations where the separate power supply is used to provide power. This damage does not create a risk to patient safety but it can disable the Spot LXi communications with electronic medical records and other health information systems. Therefore, RS-232 adapters should always be configured to draw power from the Spot LXi and customers should never use the separate power supply provided with the adapter.

**Required Training:** N/A

**Required Tools:** N/A

**Required Materials:** N/A

**Quality Process for failed units or components:** N/A

**Procedure:** N/A

**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	Initial Release	n/a	SWB	D*	D*
D* - Refer to SAP DIR digital signature log for approval details.					