



**Technical Service Bulletin**

*Monitoring Products*

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**Bulletin Type: Information Only**

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**Date: 2011-01-24**

**SAP DIR #: 20012310**

**Subject:** TSB - LXi Main PCB RoHS Compliance

**CAR Number:** N/A

**Distribution Scope:** WA Customers, ASP's, and Distributors  
[Define the intended audience.](#) WA Technical Support, Product Service, & International Service Centers

**Product(s) Referenced:** Spot LXi Vital Signs Monitor

**SW Version:** ALL

**Serial No. / Lot Code:** ALL

**Summary:** Manufacturing process change for Spot LXi main PCB assembly

**Issue:** Improve 'environmentally-friendly' aspect of product by replacing main PCB assembly (p/n 404940) that uses a lead-based solder to a main PCB assembly (p/n 403912) that utilizes a lead-free solder (ROHS Compliant).

**Action:** No specific action required. This is informational only.

**Reference to Standards:**  
• 21 CFR Part 820, ISO 13485, MPD SOP-0002  
[Add additional references as needed.](#)

**Updates: If required**

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	

**Service Strategy:** All service centers should return existing stock of 404940 to the manufacturing facility, and replace stock with material 403912.

**Required Training:** N/A

**Required Tools:** N/A

**Required Materials:** N/A

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

**Procedure:** Recognition of the different versions of the Spot LXi main PCB assembly is based on material number:

- The old board is labeled 404940.
- The new board is labeled 403912.

**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	NEA	2011-01-24	D*
D* - Refer to SAP DIR digital signature log for approval details.					