



Technical Service Bulletin

Monitoring Products

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Bulletin Type: Information Only

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Date: 2011-01-24

SAP DIR #: 20012323

Subject: TSB - LXi Serial 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 serial PCB assembly

Issue: Improve 'environmentally-friendly' aspect of product by replacing serial PCB assembly (p/n 400198) that uses a lead-based solder to a serial PCB assembly (p/n 403911) 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 400198 to the manufacturing facility, and replace stock with material 403911.

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 serial PCB assembly is based on material number:

- The old board is labeled 400198.
- The new board is labeled 403911.

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	BMF	2011-01-25	D*
D* - See SAP DIR for Change number, Approver Name and Date of Approval					