Subject: TSB – 42 Series SPOT Version 1 main PCBA replacement

CAR Number: N/A

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

Product(s) Referenced: Spot Vital Signs® Version 1 devices using part number 421267-501 style Main PCBAs.

SW Version: N/A

Serial No. / Lot Code: 42 Series SPOT Vital Signs® Version 1 devices with serial numbers below 200705000 not already modified by this process.

Summary: Spot Vital Signs® Version 1 was replaced with Spot Vital Signs® Version 2 in March 2007. This change involved a new Main PCBA for the Spot Vital Signs® Version 2 that is not directly compatible for use in the Spot Vital Signs® Version 1 device. Additional component changes to the Spot Vital Signs® Version 1 device are required to use the Version 2 Main PCBA.

Product Change:

- Affected 42 Series SPOT Vital Signs® devices requiring Main PCBA replacement must use Kit # 4200-400.
- This kit includes the new style Main PCBA (404925), a new front housing (403304), a new switch array (707253), and associated documentation (DFU 706272, and Customer Replacement Letter-80012180).
**Issue:**
The old style Main PCBA (421267-501) for the 42 Series Spot Vital Signs® Version 1 is no longer available.

**Action:**
Contact Welch Allyn to order the Main PCBA replacement. Any orders for Main PCBA with the part number of 421267-501 will receive the Main PCBA replacement kit 4200-400 instead.

Part number references are detailed below:

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Description</th>
<th>Available</th>
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<tbody>
<tr>
<td>421267-501</td>
<td>Spot Vital Signs® Version 1 Main PCBA</td>
<td>No</td>
</tr>
<tr>
<td>4200-400</td>
<td>Spot Vital Signs® Version 1 Main PCBA replacement Kit</td>
<td>Yes</td>
</tr>
<tr>
<td>404925</td>
<td>Spot Vital Signs® Version 2 Main PCBA</td>
<td>incl</td>
</tr>
<tr>
<td>403304</td>
<td>Spot Vital Signs® Version 2 Front Housing (plain/Nellcor)</td>
<td>incl</td>
</tr>
<tr>
<td>707253</td>
<td>SPOT Switch Array (blue)</td>
<td>incl</td>
</tr>
<tr>
<td>706272</td>
<td>Spot Vital Signs® Version 2 Directions for Use (DFU)</td>
<td>incl</td>
</tr>
<tr>
<td>80012180</td>
<td>Spot Main PCBA customer replacement letter</td>
<td>incl</td>
</tr>
<tr>
<td>706576</td>
<td>Label (Icon IDs)</td>
<td>incl</td>
</tr>
<tr>
<td>711742</td>
<td>PCBA standoff (QTY: 3) [Nelcor equipped device only]</td>
<td>incl</td>
</tr>
<tr>
<td>620377-1</td>
<td>Nelcor Label [Nelcor equipped device only]</td>
<td>incl</td>
</tr>
<tr>
<td>716948</td>
<td>SPOT REPAIR SOFTWARE</td>
<td>Yes *</td>
</tr>
</tbody>
</table>

* – Not included in Service Kit. Customer must have this product to reset PCBA and calibrate the serviced unit if an ATE is not available. Version 1.4.1.0 contained on the CD (p/n 716948) is a different packaging of an earlier release of this software version that includes additional supporting files to enable the feature that allows for the Cycle Count to be changed.

**Reference to Standards:**
- 21 CFR Part 820, ISO 13485, MPD SOP-0002

**Updates:**
- Technical Manual
- Service Plan
- Procedures
- Training Material
- Repair Tool
- Internet/Intranet
- Price List
- Other
Service Strategy:

- Part number 421267-501 will be set to “Service Only” while any inventory still remains. A note will be entered in SAP to indicate that that this part has been replaced by part number 4200-400.

- Existing quantities of part number 421267-501 should be used until depleted within the service center that holds the inventory. Once in-house inventory has been depleted, Service Centers shall repair 42 Series SPOT Vital Signs® Version 1 devices with serial numbers below 200705000 using Spot Vital Signs® Version 1 Main PCBA replacement Kit (4200-400).

- New PCBA requires the use of either the Repair Tool software or Automated Test Equipment (ATE) to set into the PCBA the unit serial number, reset the cycle count, and calibrate the unit.

- If using the Repair Tool Software, you must complete a device calibration after re-setting the cycle count using the SPOT Repair Tool

Required Training: N/A

Required Tools:

- SPOT REPAIR TOOL
- Automated Test Equipment (ATE)

Required Materials: See Table in Action Section of this TSB

Quality Process for failed units or components: N/A

Procedure: See DIR number 20010761 Spot 42 Series Service & Repair Procedure or 4200-145E SPOT TECHNICAL SERVICE MANUAL for further repair instructions

Quality Documents:

- All service centers using SAP to record service transactions: For each SPOT serviced, record the service activity in SAP.
- All other service centers and Field Service: For each SPOT 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

<table>
<thead>
<tr>
<th>Version</th>
<th>Description</th>
<th>Change #</th>
<th>Init</th>
<th>Release Date</th>
<th>Appr</th>
</tr>
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<tbody>
<tr>
<td>A</td>
<td>Initial Submission</td>
<td></td>
<td>NEA</td>
<td>2010-07-06</td>
<td>D*</td>
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<tr>
<td>B</td>
<td>Update due to changes in the SPOT Repair Tool</td>
<td>n/a</td>
<td>NEA</td>
<td>2010-11-15</td>
<td>D*</td>
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D* - See SAP DIR for Change number, Approver Name and Date of Approval.