Technical Service Bulletin

EENT Products

Welch Allyn, Inc.
4341 State Street Road
Skaneateles Falls, New York 13153-0220 USA

Tel: 1-315-685-4100       Fax: 1-315-685-4653
www.WelchAllyn.com

Date: 2012-09-04       SAP DIR #: 20012820

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Subject: TSB-SURESIGHT ZIF CONNECTOR IMPROVEMENTS

Distribution Scope: WA Internal
WA Technical Support, Product Service, & International Service Centers

<table>
<thead>
<tr>
<th>Material number</th>
<th>Description</th>
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<tbody>
<tr>
<td>140041-502</td>
<td>LCD Assembly</td>
</tr>
<tr>
<td>718400</td>
<td>LCD Assembly</td>
</tr>
<tr>
<td>14001</td>
<td>SURESIGHT, VISION SCREENER</td>
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<tr>
<td>14011</td>
<td>SURESIGHT, AUTOREFRACCTOR</td>
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Product(s) Referenced:

Summary: SureSight power up issues.

Issue: The current LCD Assembly (140041-502) is suspected to be the cause of
“SureSight Power up” issues.
**Action:**

1. As a result of Failure Investigation 60039907, the current design of ZIF connector on LCD ASSY 140041-502 was found to cause power-up failures due to poor connection attributed to the design of this connector.

2. An alternate connector was found and verified to correct these failures.

3. Subsequently during this process Welch Allyn determined we would no longer purchase the current LCD Assembly (140041-502).

4. 718400, LCD Assembly was designed and tested as a replacement.

5. **Serial Number cut in of the new LCD Assembly in the SureSight devices will be:**

<table>
<thead>
<tr>
<th>Material</th>
<th>S/N Cut in</th>
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<tr>
<td>14001</td>
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<td>201220114</td>
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<td>14001C</td>
<td>201200098</td>
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<tr>
<td>14011C</td>
<td>201220119</td>
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6. Repair BOM’s have been updated to replace 140041-502 with 718400

7. If you have a unit that is exhibiting an inability to power up

   Verify there is a solid connection between the DSP board and the LCD Assembly. The LCD connection may only be partially connected.

   If this is the case, replace the 140041-502 with 718400.

   Each repair should be assessed and if this connection is the cause of the problem and the determination made to cover under warranty or not.

In the pictures on the next page, you can see a comparison between a fully seated and partially seated ZIF connector and flex cable.
ZIF connector and flex fully seated.

ZIF connector partially unlocked after bending the flex cable 90° plus

ZIF connector can be seen through the battery door after assembly.

Reference to Standards:
21 CFR Part 820, ISO 13485, MPD SOP-0002
Required Materials: 718400 LCD ASSEMBLY.

Quality Documents: All service centers using SAP to record service transactions: For each product serviced, record the service activity in SAP.

All other service centers and Field Service: For each product 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

<table>
<thead>
<tr>
<th>Version</th>
<th>Description</th>
<th>Change #</th>
<th>Init</th>
<th>Release Date</th>
<th>Appr</th>
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<tbody>
<tr>
<td>A</td>
<td>Initial Release</td>
<td>D*</td>
<td>MEB</td>
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D* SEE SAP DIR FOR CHANGE NUMBER, APPROVER NAME AND DATE OF APPROVAL