Technical Service Bulletin
Monitoring 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: 2010-09-11

SAP DIR #: 20012125

THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION
It can be distributed or made available to only those individuals, companies, and organizations which have current Welch Allyn Confidentiality Agreements, and have a need to know.

Subject: TSB-VSM6000 Wrench Error #14

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

Product(s) Referenced: CVSM (VSM 6000) All Models built with MCE PCBA Material No. 407520

SW Version: All

Serial No. / Lot Code: Serial numbers 1XXXXXXXXX09 to 1XXXXXXXXXX10

Summary: A defect in the USB system on the MCE (medium compute engine) board prevents the USB system from starting successfully sometimes. When this happens it is detected by the host software during start up and goes to a black screen and displays a wrench icon with a failure code 14.

Issue: The root cause of the problem is with the USB HUB chips located on the MCE board (material no. 407520). The manufacturer confirmed that this was a know issue in the chip that they did not intend to fix. They also confirmed that the failure rate we were seeing was consistent with this known defect. Testing confirms the average failure rate will range from 0.18% to 0.45%.

Action: The occurrence of this error is very low but may appear more often on some boards than others. If the error appears power cycle the CVSM and the error should not reappear. If the error appears frequently replace the MCE board.
Reference to Standards:  
- 21 CFR Part 820, ISO 13485, MPD SOP-0002

Service Strategy:  
Attempt to clear the error by power cycling the CVSM. If the error occurs at a much higher rate than the average failure rate replace the MCE board. Engineering is making a design change to correct this issue in future releases of the MCE. Service will be notified with the new material number when the new boards are available.

Required Training:  
Read and understand this service bulletin.

Required Tools:  
If it is determined the MCE board should be replaced refer to the VSM 6000 Service Manual for the required tools.

Required Materials:  
VSM 6000 Service Manual, Material Number 716152 Ver. C  
Serv Kit, VSM6000, MAINBOARD MCE , Material Number 103352

Quality Process for failed units or components:  
Retain failed components for analysis.

Procedure:  
If it is determined the MCE board should be replaced refer to the VSM 6000 Service Manual for the required procedure.

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

<table>
<thead>
<tr>
<th>Version</th>
<th>Description</th>
<th>Change #</th>
<th>Init</th>
<th>Release Date</th>
<th>Appr</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Description</td>
<td>D*</td>
<td>GS</td>
<td>D*</td>
<td>D*</td>
</tr>
</tbody>
</table>

D* - Refer to SAP DIR digital signature log for approval details.