Subject: TSB-WA1500PM, MAIN BOARD ECG ENHANCEMENT


Product(s) Referenced: Welch Allyn 1500 Patient Monitor (WA1500PM)

Summary: SCHILLER has updated the ZM2-1 Main board (material 3.2810) to enhance the reliability of ECG lead detection within the WA1500PM. This enhancement was introduced in main board revisions FG and GD.

Issue: Customer complaints regarding ECG lead detection resulted in investigation of the lead detection circuitry within the WA1500PM. SCHILLER determined that minor changes to the lead detection circuitry would result in a performance enhancement of lead detection. SCHILLER has requested that for main boards that meet certain criteria, service requests related to an allegation that the device fails to acquire an ECG signal upon connection to a patient be addressed as detailed below.

Action: If a customer returns a WA1500PM for service with the allegation that it fails to acquire an ECG signal upon connection to a patient, identify the two letter revision of the 3.2810 main board:
If the main board revision meets any of the following criteria, it does not include the ECG enhancement:

- First letter is E or below
- First letter is F and second letter is F or below
- First letter is G and second letter is C or below

*Example:* 3.2810 revision FD (shown above) does not include the ECG enhancement, per the second bullet point.

If the device is under warranty, the main board should be replaced and may be returned to SCHILLER for credit. Include the text “Warranty ECG enhancement” in the comments section of SCHILLER’s Service Return Report to indicate the PCBA is being returned due to an ECG enhancement.

If the device is no longer under warranty, this enhancement is to be considered a billable repair.

If the main board revision does not meet any of the above criteria, the main board already includes the ECG lead detection enhancement. Follow standard service and repair processes to diagnose and repair the monitor.

**Reference to Standards:**

- 21 CFR Part 820, ISO 13485, MPD SOP-0002

**Required Training:**

Employees engaged in the service and repair of products referenced in this bulletin should complete a read and sign training of this bulletin.

**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>Revision History</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Version</strong></td>
</tr>
<tr>
<td>A</td>
</tr>
</tbody>
</table>

*D* SEE SAP DIR FOR CHANGE NUMBER, APPROVER NAME AND DATE OF APPROVAL

---

**THIS INFORMATION IS THE PROPERTY OF WELCH ALLYN, INC. AND AS SUCH SHALL NOT BE REPRODUCED, COPIED, OR USED AS A BASIS FOR THE MANUFACTURE OR SALE OF EQUIPMENT OR DEVICES WITHOUT THE EXPRESS WRITTEN PERMISSION OF WELCH ALLYN, INC.**