This Technical Service Bulletin applies to Welch Allyn 1500 Patient Monitor (1500PM) models and provides new Directions for Use (DFU) for the following conditions:

**Subject:** TSB-1500PM Service DFU Distribution

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

**Product(s) Referenced:**
Welch Allyn 1500 Patient Monitor (1500PM)

**Summary:**
To meet regulatory labeling requirements, a new Directions for Use (DFU) may need to be provided with devices where the software or licensing was updated as part of a service activity.

**Issue:**
New 1500PM DFUs are created for each major software release. In the event that a software or licensing change affects monitor form, fit or function, the customer’s DFU may no longer be accurate.

**Action:**
Provide a new DFU with each monitor if any of the following criteria are met as a part of service:
- Main software version 1.0.x is updated to version 1.1.x or above, OR
- Main software version 1.1.x is updated to version 1.3.x or above, OR
- The Acuity license is enabled
Ensure the DFU included with the monitor matches the main software version installed on the device. Below is a table of 1500PM DFUs at the time of release of this bulletin. Reference the appropriate RBOM for the most recent DFU:

<table>
<thead>
<tr>
<th>DFU material number</th>
<th>Software Version</th>
</tr>
</thead>
<tbody>
<tr>
<td>105090</td>
<td>1.1.x</td>
</tr>
<tr>
<td>104592</td>
<td>1.3.x</td>
</tr>
<tr>
<td>105074*</td>
<td>1.4.x</td>
</tr>
</tbody>
</table>

* DFU 105074 (version 1.4.x) is anticipated to release in Aug. 2012

Document inclusion of the new DFU by material number on the Service Order components tab in SAP or on the Field Service Service Report.

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

Required Training: Employees engaged in the service and repair of the products referenced in this bulletin should complete a read & sign training of this document.

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

<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>Initial Release - Per MPD SOP-20155 Rev. 5, D* statement below has been modified to meet compliance requirements until this template is updated</td>
<td>D*</td>
<td>CB</td>
<td>D*</td>
<td>D*</td>
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D* SEE SAP DIR FOR CHANGE NUMBER, APPROVER NAME AND DATE OF APPROVAL