**Technical Service Bulletin**  
**Monitoring Products**

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**Bulletin Type:** MANDATORY

**Date:** 2010-10-28  
**SAP DIR #:** 20012178

**Subject:** TSB- CVSM 1.5 Release

**CAR Number:** NA

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

**Product(s) Referenced:** CVSM (VSM 6000) All Models

Note: the terms CVSM, VSM 6000, and PMP all refer to the same device. The specific name is used in context of where it appears; e.g. The service manual is titled VSM 6000, the Welch Allyn Service Tool (WAST) refers to it as PMP. The official name is: Connex Vital Signs Monitor or CVSM.

**SW Version:**  
PMP Host version 1.0X.XX  
Welch Allyn Service Tool version 1.0.1.X and earlier

**Serial No. / Lot Code:** NA

**Summary:**  
The CVSM 1.5 project adds support for the Braun Thermoscan Pro 4000 IR thermometer as an external option. The Welch Allyn Service Tool was updated to version 1.0.2.0 with a Braun plug-in. The DFU and service manual have been updated to support the Braun thermometer. New accessories and service parts have been created.

All CVSMs will be updated to software version 1.5X.XX, to fix connectivity issues with Ethernet and support the Braun thermometer.

**Issue:**  
The CVSM 1.5 project makes the following changes to CVSM 1.0:

- Adds Braun Pro 4000 Thermometer as an external option  
The Braun thermometer and dock are available as an external option that may be ordered as a CVSM configuration or as an after sale add on. See new parts at the end of this section for part numbers.
Updates CVSM host Software to version 1.5X.XX
Software release 1.5X.XX was initiated to support the Braun thermometer; this release corrects several Ethernet issues and a number of minor anomalies.

Updates Welch Ally Service Tool to version 1.0.2.0
The Welch Allyn Service Tool was updated to version 1.0.2.0 to support the Braun thermometer. The service tool added a plug-in to support the Braun dock and thermometer connected to the CVSM or as a finished subsystem (FSS).
Additional changes:
- Creates a WAST instance of SQL (if not installed previously)
- Adds two new device plug-ins: Braun Pro4000, and ProBP 3400
- Updates WACP USB driver to version 1.8
- Updates Partners Connect to version 1.1
- Functional test for ProBP 3400
- Functional test for Braun Pro 4000 & dock

Note: The Braun Pro 4000 functional verification test included with the service tool will produce inaccurate results and should not be used. The service tool procedure does not call for the thermometer to be placed in CAL mode. When using the 9600 plus Calibration tester it is necessary to place the thermometer in CAL mode to obtain accurate results. The measured reading must be read from the thermometers display; the service tool will not receive the reading from the thermometer in CAL mode. Use the functional test in the service manual to obtain accurate results.

Updates VSM 6000 DFU
The DFU was updated to support the Braun thermometer. The part number was changed from 715813 to 716620. For a complete list of redlines see ECM DIR# 90079471. The REF part number is unchanged: 103501. The DFU and service manual are available on CD P/N 103730.

Updates VSM 6000 service manual
The service manual was updated to support the Braun thermometer. The part number was changed from 716152 to 716671. For a complete list of redlines see ECM DIR# 90079728. The REF part number is unchanged; 103500. The DFU and service manual are available on CD P/N 103730.
The most significant change is the addition of a functional verification test for the Braun thermometer. This procedure was added after it was determined the functional test for the Braun docking station and thermometer could result with the thermometer reporting temperatures higher than the 9600 plus calibration tester set points.
New parts added to the VSM 6000 Repair BOM

<table>
<thead>
<tr>
<th>Part</th>
<th>Description</th>
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<tbody>
<tr>
<td>04000-900</td>
<td>BRAUN PRO 4000 DOCK W/ PRO 4000 THERM</td>
</tr>
<tr>
<td>36000</td>
<td>BRAUN PRO 4000 DOCK</td>
</tr>
<tr>
<td>104037</td>
<td>SERV KIT PLFM BRAUN PRO4000 MN</td>
</tr>
<tr>
<td>86100</td>
<td>BRAUN PRO 4000 DOCK WALL MOUNT KIT</td>
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<tr>
<td>86200</td>
<td>BRAUN PRO 4000 DOCK MOBILE STAND KIT</td>
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<tr>
<td>104026</td>
<td>USB CABLE,MINI B TO USB A  410mm (service part for dock)</td>
</tr>
<tr>
<td>104027</td>
<td>BRAUN DOCK CRADLE RING (service part)</td>
</tr>
<tr>
<td>104028</td>
<td>BRAUN DOCK BASE (service part)</td>
</tr>
<tr>
<td>104029</td>
<td>BRAUN PRO4000 MOUNTING HARDWARE (for wall and stand kit)</td>
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<tr>
<td>53020-0000</td>
<td>RECHARGEABLE BATTERY PACK FOR PRO4000</td>
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Action:

Update all CVSM models host software to version 1.5X.XX. Update all installations of the Welch Allyn Service Tool to version 1.0.2.0.

The software updates will be pushed out to CVSM monitors and PCs registered with Partner Connect (RSDS) remote server. See the procedure section below for information on performing the updates.

When performing a functional verification of the Braun Pro4000 Thermometer use the procedure in the VSM 6000 service manual in place of the procedure in the Welch Allyn service tool.

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:

The CVSM host software version 1.5X.XX becomes the minimum supported version. Any devices serviced by Welch Allyn or WA ASPs will be updated to this minimum software level before being returned to the customer.

The Welch Allyn Service Tool (WAST) software version 1.0.2.0 becomes the minimum supported version. All Welch Allyn and WA ASPs will update all instances of WAST running on PCs used to service CVSM to the minimum supported version.

Repair service for the Braun Pro4000 Thermometer and docking station is limited to functional verification testing. Braun thermometers and docking stations that fail under warranty will be replaced under the terms of the warranty. A replacement thermometer and docking station are available for sale for non-warranty or post warranty failures.

Service parts for the Braun Pro 4000 thermometer are limited to the battery door and rechargeable battery pack.

Service parts for the docking station are limited to the base, cradle ring, and...
USB cable. See new parts above.

**Required Training:**

All Welch Allyn employees and contractors engaged in service and repair of CVSM shall complete a Read & Sign training record indicating they have read and understand this document. This Read & Sign is to be filed locally.

**Required Tools:**

The Welch Allyn Service Tool version 1.0.2.0 P/N 407925 is available on CD P/N 103521. If a previous version is currently installed and registered with Partner Connect (RSDS) the update will be pushed to the PC.

**Required Materials:**

CVSM host software version 1.5X.XX. Available from Partner Connect (RSDS). If the CVSM is registered with Partner Connect (RSDS) the update will be pushed to the PC.

**Quality Process for failed units or components:**

No special quality process is required.

Follow the Standard Operating Procedure and any supplemental Work Instructions in effect for the service center location.

**Procedure:**

**VSM 6000 host software update**

Check the PMP firmware version on the CVSM or using the service tool. If the firmware version is below 1.5X.XX it must be updated.

To check the firmware version on the monitor:

1. If the monitor is not already on, power it on.
2. Touch the Settings tab.
3. Touch the Advanced tab.
4. In the right pane, check the number under Software version.

To check the firmware version using the service tool:

Refer to the service-tool installation guide or the Help file in the service tool.

To update the firmware:

Upgrade the firmware by using the Welch Allyn Service Tool. For instructions, refer to the service-tool installation guide (REF 103820 P/N 716446) or the Help file in the service tool (Help > Service Tool Help).

**Welch Allyn Service Tool software update**

The update to the Welch Allyn Service Tool will be pushed out through Partner Connect (RSDS) remote server to all registered installations. The update process is transparent to the user. Users can check the software version by launching the service tool, selecting the Help menu and choosing, About Service tool. If the service tool version is 1.0.2.0 it has been updated.

**For unregistered service tool installations or new installations**

obtain the latest version of the service tool CD P/N 103521. For instructions, refer to the service-tool installation guide (REF 103820 P/N 716446) included on the CD.
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>
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</thead>
<tbody>
<tr>
<td>A</td>
<td>Initial release</td>
<td>XXXXXXXX</td>
<td>XXX</td>
<td>XXXX-XX-XX</td>
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D* - Refer to SAP DIR digital signature log for approval details.