Technical Service Bulletin
Monitoring Products

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Date: 2011-06-29

SAP DIR #: 20012514

Subject: TSB- CVSM 1.7 Release

CAR Number: NA

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

Product(s) Referenced: Connex Vital Signs Monitor 6000 Series(CVSM) All Models

SW Version: PMP Host version 1.05.02 and earlier
Welch Allyn Service Tool version 1.0.2.X and earlier

Serial No. / Lot Code: 103099992411 and earlier

Summary: The CVSM 1.7 project adds support for a weight scale as an external option, non-invasive hemoglobin (SpHb) option for models with Masimo SpO2, Support for third party applications, Chinese language UI, and updated radio software supporting WEP security. The Welch Allyn Service Tool was updated to version 1.5.0.0 with a weight scale plug-in to support the weight scale adapter. The DFU and service manual have been updated to support the new features and options. New accessories and service parts have been created to support the new options.

All CVSMs will be updated to software version 1.70.00, as described in the procedure section of this document, with the exception of those devices listed in DIR 20012591, TSB-CVSM 1.7/Connex VM 1.1 Upgrade Strategy.

All installations of the Welch Allyn Service Tool shall be upgraded to version 1.5.0.0 as described in the procedure section of this document.

Issue: The CVSM 1.7 project makes the following changes to CVSM 1.5

CVSM host software version 1.70.00

Software release 1.70.00 was initiated to add support for an external weight scale, Masimo hemoglobin (SpHb), third party applications and updated radio software
supporting WEP security. For release notes see DIR 20012577, CVSM 1.70.00 Release Notes

Known Issues:

This release does not support using patient query with Connex VM version 1.x. Connex VM 1.x customers using patient query will need to upgrade to Connex VM 2.0 before installing this upgrade.

CVSM 1.70.00 or later is required for Connex VM 2.0.

CVSM 1.70.00 or later is required to support Lamarr2 radio SW version 2.30.00

Significant changes:

- Added support for Masimo non-invasive total hemoglobin (requires purchase of a licensing). License available outside the US upon receipt of country registration.
- Added support for select external Health o meter digital weight scale (requires licensing). License available outside the US upon receipt of country registration. When license is enabled, the device will accept height weight and BMI readings from the scale. BMI is a read only value.
- Added support for radio software version 2.30.00 with Authentication types; WEP64, WEP128, WPA2AES Mixed Mode (AES + TKIP) and WPA2PSK Mixed Mode (AES + TKIP). See DIR 20012538 TSB – PLFM Radio Ver 2.30.00 Upgrade.
- Added Chinese language (requires additional file, standard on Chinese models)
- Add server connection test to server tab in advanced settings
- Radio settings may be cloned
- Added Power line frequency setting (50Hz or 60Hz)
- Added Masimo’s Signal IQ (SIQ) for SpO2 and total hemoglobin (SpHb)
- Increased the size of the SpO2 numeric when displayed as a secondary label
- Moved Pulse tone volume settings from advanced settings to Alarms tab
- Added “Retrieve List” feature that enables the retrieval of a read-only list from Connex VM
- Updated Patient List to include Patient Name, Patient ID and Location
- Updated Review tab to display Patient ID if Patient Name not available, or Location if Patient Name or Patient ID not available
- Added two additional NIBP program options and a feature that allows the programs to be locked once set
- Added clinician password option for Cerner server applications
- Added an advance Settings to clear or retain the Patient name and Patient ID upon a manual save
- Manual parameters frame is removed from the Home screen when no manual parameters are selected in Advanced settings
- Added search by patient ID when connected to Connex VM 2.0. Replaces the existing patient information with the query results.
- Added search by clinician ID
- Added request for confirmation when navigating away from the Summary, Modifiers, Manual tabs without saving the entry
- Added Retrieve List option when connected to Connex VM 2.0.
- Multiple bug fixes

**Adds Non-invasive Hemoglobin parameter to Masimo SpO2 module**

The Masimo SW was updated to version 1.7.3 to support the hemoglobin (SpHb) parameter. Older versions of the Masimo SW will be supported by 1.70.00; however the Masimo SW will need to be upgraded to enable the SpHb parameter. The new SW is available on PartnerConnect.

**SpHb upgrades**

The following hardware and software upgrades are available to add the SpHb parameter:

<table>
<thead>
<tr>
<th>Part</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>104210</td>
<td>Upgd Kit, Masimo MX with SpO2, SpHb Mod</td>
</tr>
<tr>
<td>104361</td>
<td>Masimo SpHb SW upgrade - sold by WA</td>
</tr>
<tr>
<td>104362</td>
<td>SpHb Remote Software Upgrade by Masimo (Sold by Masimo)</td>
</tr>
<tr>
<td>104372</td>
<td>SPO2/SPHB Module Upgrade by Masimo (Sold by Masimo)</td>
</tr>
<tr>
<td>104373</td>
<td>SpHb Onsite SW Upgrade by Masimo (Sold by Masimo)</td>
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</tbody>
</table>

1 – Masimo sells the upgrade WA delivers the upgrade via PartnerConnect
2 – Masimo sells and performs the upgrade

**Adds Weight scale as an external option**

- Health o meter® will sell the weight scale and connectivity kits in the US and Canada.
- Connectivity kits and co-branded scales will be sold by Welch Allyn outside US and Canada.
- The CVSM weight scale connectivity license is included in the Health O Meter scales DFU.
- The CVSM is not compatible with scales that communicate via RS-232.
- The Health o meter® 349 KL is compatible ONLY with Spot LXi and ONLY via direct RS-232 connection.

A weight scale connectivity kit is available to support scales from Health O Meter

C-HOMWA-1 Connectivity Kit, Connex (USB)
Kit contains:

HOMWA-1 Connectivity Adapter
SP62941 1ft (.31m) USB Cable (Connects Scale to Adapter)
UMHOMWA User Instructions
VSM 6000 DFU

The part number (English) was changed from 715813 to 717085. For a complete list of redlines see ECM DIR# 90083245. The REF part number is unchanged: 103501. The DFU and service manual are available on CD P/N 103730. The DFU is available from The Pulse.

VSM 6000 service manual

The part number has changed from 716671 to 717129. For a complete list of redlines see ECM DIR# 90083247. The REF part number is unchanged; 103500. The DFU and service manual are available on CD P/N 103730. The Service manual is available from The Pulse.

Significant changes:

- Add Service interval for SpHb Masimo parameter
- Add new model configurations
- Updated service screens
- Updated troubleshooting (Added SpHb and Weight scale)
- Updated Technical Alarms (New SpHb and Weight scale messages)
- Added basic functional verification test (No WAST gold license required)
- Updated Option and upgrades (Added new licenses and SpHb)
- Added FRUs for SpHb upgrades and repair kit
- Appendix added identification section

Appendix added defaults for SpHb, clinician ID, and Patient Id settings

New service parts

<table>
<thead>
<tr>
<th>Part</th>
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<tbody>
<tr>
<td>104370</td>
<td>Serv Kit, Masimo MX SpO2, SpHb repair (replacement only)</td>
</tr>
<tr>
<td>104560</td>
<td>Serv Kit, PLFM Radio 2.30</td>
</tr>
<tr>
<td>C-HOMWA-1</td>
<td>Connectivity Kit, Connex (USB)</td>
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On-line Training

The on-line training will be updated to reflect the changes made in release 1.5 and 1.7

Repair Training

- See TSB 20012516 TSB - Upgrade Masimo License for adding hemoglobin parameter to devices with Masimo SpO2 modules.
- See TSB 20012538 PLFM Radio Ver 2.30.00 Upgrade for the radio upgrade procedure
- To add the hemoglobin parameter to device without a Masimo SpO2 module install 104210 Upgd Kit, Masimo MX with SpO2, SpHb Mod
- To replace a failed Masimo SpO2 module with hemoglobin use 104370
Radio SW updated to 2.30.00

CVSM series 6000 shipping with radios will have Lamarr2 radio SW version 2.30.00. The software upgrade includes:

- Support for additional authentication types; WEP64, WEP128, WPA2AES Mixed Mode (AES + TKIP) and WPA2PSK Mixed Mode (AES + TKIP), and fixes connectivity issues.
- Fix for an issue where radio setting reverted to originally provisioned settings
- Fix for a DCP issue where it was re-writing DCP packets and connecting to the wrong IP address

For additional information and upgrade procedure see DIR # 20012538 TSB – PLFM Radio Ver 2.30.00 Upgrade

Welch Ally Service Tool to version 1.50.0.0

The Welch Allyn Service Tool was updated to version 1.5.0.0 to support licensing for the Masimo SpHb option, a weight scale, and third party applications. The service tool added a plug-in to interface with the weight scale adapter.

The SQL database was removed from the tool reducing the size of the application, allowing for a faster download and installation

Additional changes:
- Adds a new device plug-ins for the weight scale adapter
- Updates WACP USB driver to version 1.8
- Updates Partners Connect to version 1.1
- Functional test for ProBP 3400
- Corrected functional test for Braun Pro 4000 & dock

Updated WA Service Tool Install Guide

Material 717342, DIR 80016783 PTSS INSTALLATION GUIDE 1.5 version A

Action:
- Update all CVSM models host software to version 1.70.00 with the exception of those devices listed in DIR 20012591, TSB-CVSM 1.7/Connex VM 1.1 Upgrade Strategy. The CVSM 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.

- Update all installations of the Welch Allyn Service Tool to version 1.5.0.0. The service tool is not available on PartnerConnect, it may be downloaded from: http://www.welchallyn.com/promotions/services/serviceTool.htm or order the CD material no. 408308 Welch Allyn Service Tool CD Version 1.5.0.0

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

- Technical Manual
- Repair Tool
- Service Plan
- Internet/Intranet
- Procedures
- Price List
- Training Material
- Other

Service Strategy:

The CVSM host software version 1.70.00 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, with the exception of those devices listed in DIR 20012591, TSB-CVSM 1.7/Connex VM 1.1 Upgrade Strategy.

The Welch Allyn Service Tool (WAST) software version 1.5.0.0 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.

Technical support will deliver on-line upgrades to customers purchasing the Masimo hemoglobin parameter from either Welch Allyn or Masimo (see TSB 20012516).

The Weight scales are sold and serviced through Heath-O-Meter and Pelstar in the US and Canada. Welch Allyn will provide replacement cables and the adapter box in the EMEA.

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 1.5.0.0 is available on CD material number 408308.

Required Materials:

CVSM host software version 1.70.00. Available from PartnerConnect (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:

CVSM host software upgrade

Check the PMP software version on the CVSM or through the service tool. If the software version is below 1.70.00 it must be updated, with the exception of those devices listed in DIR 20012591, TSB-CVSM 1.7/Connex VM 1.1 Upgrade Strategy.

To check the software 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 software version using the service tool:
  Refer to the service-tool installation guide or the Help file in the service
tool.

To update the software:
  Upgrade the software using the Welch Allyn Service Tool. For
instructions, refer to the service-tool installation guide (REF 103820
P/N 717342) or the Help file in the service tool (Help > Service Tool
Help).

Welch Allyn Service Tool Upgrade
Download the Welch Allyn Service Tool version 1.5.0.0 from the Welch Allyn
web site http://www.welchallyn.com/promotions/services/serviceTool.htm or
order the CD material No.: 408308

To upgrade to the Welch Allyn Service Tool follow the instructions in the
Welch Allyn Service Tool Installation and Configuration Guide to first
uninstall previous versions of the WelchAllyn Service Tool and install the
latest version.

Important note: Previous versions of the service tool and Axeda software
must be uninstalled before installing version 1.5.0.0 for the program to
function correctly

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>
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<tr>
<th>Version</th>
<th>Description</th>
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<td>Initial release</td>
<td>400113042</td>
<td>GCS</td>
<td>2011-06-29</td>
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D* - Refer to SAP DIR digital signature log for approval details.