Subject: TSB-CVSM 2.10.00 RELEASE

Distribution Scope: Welch Allyn Global Customer Care, Product, Field & Customer Service WA ASP’s

Product(s) Referenced: CVSM – Connex Vital Signs Monitor

SW Version: 2.10.00

Serial No. / Lot Code: Serial numbers are not indicative that the device was originally provisioned with software version 2.10.00. All Device models starting with 67 or 68 manufactured after 12/2013 will have software version 2.10.00

Summary: CVSM release 2.10.00 adds the Early Sense (patient movement) option to the existing CVSM configurations (6700 and 6800 Series). Early Sense requires the continuous monitoring license to support bi-directional communication with Connex Central Station (CS).

CVSM 2.10.00 products will be released to a full market comprised of US, UK, CA, NZ, Germany and Australia acute care customers.

For those customers in the LMR program any CVSMs to be upgraded must meet the requirements stated in 20012631 CVSM/CIWS minimum HW/SW requirements. Not all devices qualify for this upgrade.

CVSM 1.7x and 2.x device will be manufactured concurrently through 2014.

Issue: The CVSM 2.10 project makes the following changes to CVSM

Host Software version 2.10.00 - Required to support all new features and functionality.
New Models
All models include NIBP and either Nellcor or Masimo SpO2. Available options: Suretemp Plus, Braun Thermoscan Pro 4000, Early Sense, Masimo SpHb, Masimo RRa, Oridion CO2, printer. Upgrades include all the above options plus a radio for the 6700
- 6700 Radio is only available as an upgrade
- 6800 Includes wireless option

New Features and Options
These features are summarized here. More information is provided in the referenced documents
- Added Early Sense Technology as an option in the CVSM. The Early Sense Movement frame displays the following data and controls used to monitor patient:
  - Patient motion level
  - Exit sensitivity
  - Movement-related alarm conditions
  - Patient turn events and status (time overdue or time remaining until next scheduled turn)
  - Sensor source indicator
- Updated alarming scheme and menu structures, where applicable to accommodate new features and functions.
- Radio DHCP Option 43 (NRS IP, and DNS Name) for Radio Configurations. New feature. Allows for use of DHCP for device to learn IP address of NRS
- Radio settings support 32 characters SSID to Radio Config Screen - Support 32-character SSIDs. Previous limit was 16 characters.
- Ability to have Custom Modifiers (xml File saved to flash drive) – Add support for customizable modifiers/parameters to all profiles
- Ability to set SpO2 and motion (ES) pulse rate alarm condition delay
- Current profile is now written to the event log.
- Manual Override feature allows manual entry of vital sign measurement

Open Known Software Issues - Note: For a list of unresolved anomalies in CVSM 2.10.00, see the Unresolved Anomalies Report, DIR 60043357. Ver. K

Minimum hardware and software requirements
- CVSM/CIWS Minimum Hardware/Software level Requirement (DIR 20012631) updated for CVSM 2.1

New Supporting documentation
Service Manual
A new service manual and DFU was written to support CVSM 2.1. The 1.x
service manual will remain available to service 1.x devices.

- Service Manual/DFU CD Material 105534
  - Service Manual Printed Copy 105533
  - Service Manual Hardcopy Material number 720262
  - Service Manual DIR 80018501
- DFU DIR 80018500

Support for Early Sense

- See CVSM DFU for information on configuration and use of Early Sense
- All models must have CVSM host software 2.10.00 or later and continuous monitoring profile license. See the service manual for complete details on Early Sense upgrades.
- Available as an option or an upgrade Models 6700/6800.
- Available as an upgrade for models 6400/6500 (CVSMs with MCE hardware version older than P3 do not qualify) See 20012631 for complete upgrade requirements. See the service manual for installation details.
- May not be added to devices with CO2, or RRa
- All failed Components (Modules and Sensors) will be replaced by product service. Failed components will be returned to Early Sense using the Early Sense RMA Process – SAP DIR 20013615
- No Verification and or calibration required

CVSM Model Numbering Sequence

<table>
<thead>
<tr>
<th>Model</th>
<th>Parameter</th>
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</thead>
<tbody>
<tr>
<td>63 = Basic</td>
<td>N = Nellcor T = SureTemp</td>
</tr>
<tr>
<td>64 = Standard</td>
<td>M = Masimo X = None</td>
</tr>
<tr>
<td>65 = Wireless</td>
<td>H = Hemoglobin/ Masimo</td>
</tr>
<tr>
<td></td>
<td>X = None</td>
</tr>
<tr>
<td>67 = Standard</td>
<td>N = Nellcor C = CO2</td>
</tr>
<tr>
<td>68 = Wireless</td>
<td>M = Masimo R = RRA</td>
</tr>
<tr>
<td></td>
<td>H = Hemoglobin/ Masimo</td>
</tr>
<tr>
<td></td>
<td>X = None</td>
</tr>
</tbody>
</table>

Service parts

Note: Product labels are no longer in label kits and are only available to internal sales due to ETL labeling rules

- 105504 Serv Kit, Extended Chassis Upgrade
- 105480 Serv Kit, Early Sense module

Partners in Care service and support agreements

Comprehensive Support Agreement Part Numbers

- S1-6000-ES CVSM ES, Comp Partner Pgm 1YR
- S1-6000 CVSM, Comp Partner Pgm 1yr
- S1-6000-C CVSM, Comp w/CAL Partner Pgm 1yr
- S1-6000ES-C CVSM ES, Comp w/CAL Partner Pgm 1YR
- S1-6000ES-2 CVSM ES, Comprehensive Partner Pgm 2YR
- S1-6000ES-2C CVSM ES, Comp w/CAL Partner Pgm 2YR
- S1-6000ES-5C CVSM ES, Comp w/CAL Partner Pgm 5YR
- S1-6000-O2C CVSM CO2, Comp w/Cal Partner Pgm 1YR
- S1-6000-2C CVSM, Comp w/CAL Partner Pgm 2yr
- S1-6000-O2-2C CVSM CO2, Comp w/CAL Partner Pgm 2yr
- S1-6000-5C CVSM, Comp w/CAL Partner Pgm 5yr
- S1-6000-O2-5C CVSM CO2, Comp w/CAL Partner Pgm 5yr
- S1-6000ES-5 CVSM ES, Comprehensive Partner Pgm 5YR
- S1-6000-O2 CVSM, Comprehensive Partner Pgm with CO2
- S1-6000-2 CVSM, Comp Partner Pgm 2yr
- S1-6000-O2-2 CVSM, Comp Partner Pgm 2yr with CO2
- S1-6000-5 CVSM, Comp Partner Pgm 5yr
- S1-6000-O2-5 CVSM, Comp Partner Pgm 5yr with CO2

**Bio-Med Support Agreement Part Numbers**

- S2-6000ES CVSM ES, Bio-Med Partner Pgm 1YR
- S2-6000ES-2 CVSM ES, Bio-Med Partner Pgm 2YR
- S2-6000ES-5 CVSM ES, Bio-Med Partner Pgm 5YR
- S2-6000-O2 CVSM, Bio-Med Partner Pgm with CO2
- S2-6000-2 CVSM, Bio-Med Partner Pgm 2yr
- S2-6000-O2 CVSM, Bio-Med Partner Pgm 2yr with CO2
- S2-6000-5 CVSM, Bio-Med Partner Pgm 5yr
- S2-6000-O2-5 CVSM, Bio-Med Partner Pgm 5yr with CO2
- S2-6000 CVSM, Bio-Med Partner Pgm 1yr

**Extended Warranty and Preventive protection support agreements** *(available in selected international countries)*

- S4-6000-O2-5 CVSM, WARRANTY EXTENSION 5 YR WITH CO2
- S4-6000-O2-2 CVSM, WARRANTY EXTENSION 2 YR WITH CO2
- S4-6000-O2 CVSM, WARRANTY EXTENSION 1 YR WITH CO2
- S4-6000-ES-5 CVSM ES, WARRANTY EXTENSION 5 YR
- S4-6000-ES-2 CVSM ES, WARRANTY EXTENSION 2 YR
- S4-6000-ES CVSM ES, WARRANTY EXTENSION 1 YR
- S4-6000-5 CVSM, WARRANTY EXTENSION 5YR
- S4-6000-2 CVSM, WARRANTY EXTENSION 2YR
- S4-6000-5 CVSM, WARRANTY EXTENSION 5 YR
- S4-6000 CVSM, WARRANTY EXTENSION 1YR
- PRV-001 PREVENTIVE SVC WA BENCH PER UNIT
- PRV-002 PREVENTIVE SVC PLANNED ONSITE PER UNIT
- PRV-003 PREVENTIVE SUPPORT
- PRV-ESS PREVENTIVE ANNUAL SENSOR REPLACEMENT

**Tools**

A new version of the Welch Allyn Service tool will be released to support CVSM 2.1 (See DIR 20013381 TSB-WAST v1.7.0.0 PMP release). The...
WAST Installation and Configuration guide 103820 (Material 717352, DIR 80016783) will not be updated at this time.

**Action:**

**Customer Care:**
Reference the current service manual and DFU and current versions of service documentation when providing support for CVSM 2.10.00.

**Upgrading CVSM 1.X to 2.10.00**
Customer Care is authorized to provide the CVSM 2.10.00 upgrade to the Welch Allyn field sales team and other Welch Allyn employees or contractors on an as needed basis via PartnerConnect. Advise anyone upgrading from CVSM 1.x software that only upgrades following the validated upgrade path from 1.71.03 to 2.10.00 will maintain the device as production equivalent. LMR sites using CS 1.2 may **not** be upgraded to CVSM 2.10.00 until they upgrade to CS 1.5. Contact Kristin Alisanski or Robert Wilmington in Marketing for approval before upgrading these customers.

All CVSM must first be upgraded to 1.71.03 and meet minimum HW/SW requirements for a 1.x to 2.x upgrade per 20012631 CVSM/CIWS Min HW/SW Levels.

Customer owned CVSMs must meet at least one of the following requirements to qualify for a 1.71.03 to 2.10.00 upgrade:

- Cerner customer, wants CVSM 2.10.00 features; manual entry and/or custom modifiers
- Connex VM v. 2.0.1 customer wants CVSM 2.10.00 feature; manual entry, (Connex VM does not support custom modifiers).
- CVSM will be connected to Connex CS
- Customer is purchasing CVSM 2.10.00 devices and wants to standardize on 2.10.10

CVSM devices in the following categories shall **not** be updated to 2.10.00 at this time.

- Office Profile license installed
- Device only used in ambulatory setting
- Devices used with Connex VM other than version 2.0.1
- Devices used with Connex VM 2.0.1 customer wants CVSM 2.10 feature; customer modifiers
- CVSM does not meet minimum HW/SW requirements

See the procedure section below to push the package from PartnerConnect

**Product service and service centers:** When servicing, repairing or upgrading CVSM 2.x devices use the service manual and DFU listed above and the most current versions of service documentation for the CVSM.

Do not update any 1.x devices returned for repair to 2.x unless an upgrade material was purchased. When upgrading from 1.x to 2.x enclose the CD with DFU and service manual material number 104730 with the serviced device.

**Reference to Standards:**

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

- 60027700 CVSM Repair and Service Plan
- 80018501 Service Manual Welch Allyn Connex® Vital Signs Monitor 6000 Series™
- 80018500 DFU Welch Allyn Connex® Vital Signs Monitor 6000 Series™
- 80018295 Welch Allyn Connex Network Installation, Best Practices Overview
- 20013432 TSB-Flexnet Radio DNS 3.00.02 CVSM/CIWS
- 20012631 CVSM/CIWS Min HW/SW Level Requirements
- 60058932 SRN, CVSM, 2.10.00, RELEASE NOTES
- 20013381 TSB - WAST 1.7 Release

Updates

- Technical Manual
- Repair Tool
- Training Material
- Internet/Intranet

Service Strategy:

Only software upgrades from 1.71.03 or 2.00.05 to version 2.10.00 are currently supported. All lesser versions must be upgraded to the appropriate base version first. Software only upgrades will be delivered by Customer Care on an as-needed basis through PartnerConnect. The upgrade package may be pushed to the field sales team or other Welch Allyn users; all external customers must meet the criteria specified in the action section above or be approved by Marketing or Service Engineering. Customers using the device on ambulatory patients in conjunction with SDK, VM, or Office profile are currently excluded from receiving this upgrade. Limited market release (LMR) customers using Central station (CS) 1.2 will not be upgraded to CVSM 2.10.00 until they can upgrade to CS 1.5. CVSM 2.10.00 is not compatible with CS 1.2.

Service centers will only provide the software upgrade as part of hardware or parameter upgrade. No CVSMs returned for service with 1.x software will be upgraded to 2.x without a sales order.

Any devices returned to service for an issue will be made available to engineering.

The CVSM/CIWS Minimum HW/SW requirements document 20012631 has been revised to provide service and upgrade requirements for CVSM 2.10.00. Only the 1.x devices that meet the upgrade requirements described in 20012631 will qualify for a 1.x to 2.10.00 upgrade.

Loaners will be made available from Product Service.

The online technical training course has been updated for customers purchasing a Biomed Partners in Care agreement.

Software updates distributed to customers via PartnerConnect will be packaged with the most current FSS software updates to provide a complete set of compatible software. Since the release of Welch Allyn Service Tool version 1.6.0.0, the customer no longer has the ability to update the FSS and host software independently; the only option is to perform a complete update of all the software contained in the update package.

Required Tools:

- Welch Allyn Service tool version 1.7.0.0. DIR 50011232
Required Materials:  The software is available in SAP: 50011205 SWF, CVSM, 2.10.00
Download CVSM2.10PMP Package from PartnerConnect
Package includes:
PMP 2.10.00131121.pim
EarlySense 01.06.007.pim
MerlionCore_1.00.03.pim (Braun dock)
ModPG.pim (version 2.05)
pSPO2 2.0.9.pim (Masimo)
PSpO2 1.00.14.pim (Nellcor)
PSTP 2.02.pim (SureTemp)
MicroMediCO2 BL 1.24 + CO2 1.10.2.pim
Continuous monitoring license (auto install)
20013645A CVSM 2.10.00 Release Notes.pdf
The package is down loaded to:
Windows XP: C:\Program Files\Welch Allyn\RSDS\DefaultProject\PMP < device serial number >\Upgrade\CVSM2.10.00
Windows 7: C:\Program Files (x86)\Welch Allyn\RSDS\DefaultProject\PMP < device serial number >\Upgrade\CVSM2.10.00

Quality Process for failed units or components:
All failed parts will be retained by Product Service for further analysis as requested by engineering

Procedure:  Procedure to push a device model package to the PC connected to or managing the device:
Download CVSM 2.10.00PMP Package (manual push only)
1. Log on to PartnerConnect: https://welchallynsolutions.com
2. Go to the Service tab.
3. In the asset field enter the serial number of the device to be upgraded.
4. Select the device by clicking on the device name in the list, to open the device dashboard screen.

5. In the upgrade this asset section on the right side of the dashboard, select “CVSM2.10.00PMP”.

6. Confirm the package appears in the recent actions pane (center screen). The initial status will be: waiting to deliver. After a minute the status will change to: started, and finally to complete.

The package will be downloaded to:

Windows XP: C:\Program Files\Welch Allyn\RSDS\DefaultProject\PMP \< device serial number >\Upgrade\CVSM2.10.00

Windows 7: C:\Program Files (x86)\Welch Allyn\RSDS\DefaultProject\PMP \< device serial number >\Upgrade\CVSM2.10.00

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 regarding any questions or concerns 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

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<th>Version</th>
<th>Description</th>
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<td>Updated action section and service strategy to explain requirements for an upgrade. Updated required materials to provide file names, material numbers and Windows file paths. Provided detailed instructions for pushing the upgrade package from PartnerConnect. See the redlines in ECM 90107084 for detailed changes.</td>
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D* SEE SAP DIR FOR CHANGE NUMBER, APPROVER NAME AND DATE OF APPROVAL