Technical Service Bulletin

PATIENT MONITORS SYSTEMS

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Manufacturer: Welch Allyn

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SAP DIR #: 20013364

 Subject: TSB-CVSM 2.0 RELEASE


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

SW Version: 2.00.00

Serial No. / Lot Code: Serial numbers are not indicative that the device was originally provisioned with software version 2.0. All models starting with 67 or 68 will have software version 2.0.

Summary: The CVSM 2.0 project includes the creation of 2 new configurations (6700 and 6800 Series), the release of Oridion Capnography and Masimo Acoustic Respiration parameters, a new continuous monitoring profile and bi-directional communication with Connex Central Station (CS), and predefined list of issues identified in previous software releases.

CVSM 2.0 products will be released to a limited market comprised of US acute care customers. The limited market release (LMR) period will extend throughout 2013.

Full Market Release (FMR) is anticipated to occur in 2014 when CVSM 2.0 will be made available globally for all customers in countries where registration is complete.

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 2013.

Issue: The CVSM 2.0 project makes the following changes to CVSM
Host Software version 2.00.00 - Required to support all new features and functionality.

Radio software version 3.00.01- Required for continuous monitoring

New Models

All models include NIBP and either Nellcor or Masimo SpO2. Available options: Suretemp Plus, Braun Thermoscan Pro 4000, 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

- Oridion Microstream® capnography (etCO2, FiCO2) Requires, Continuous Monitoring profile license (included with all CVSM 2.0 devices), SpO2, extended chassis and Nasal cannula. Cannot be configured on monitors with Masimo RRa

- Integrated Pulmonary Index (IPI) integrates four parameters (etCO2, RR, SpO2, and PR) and their interactions to provide a numeric value indicating a patient's overall respiratory status. Requires Oridion CO2 and either Masimo or Nellcor SpO2

- Masimo RRa (Acoustic Respiration) parameter. Utilizes an adhesive sensor with an integrated acoustic transducer that is applied to the patient’s neck. Requires Masimo SpO2, Continuous Monitoring profile license (included with all CVSM 2.0 devices), Masimo embedded RRa license (included), WA RRa UI license (included), dual cable, patient cable, and RAS-125 disposable sensors. Cannot be configured on monitors with CO2.

- Continuous Monitoring UI profile license, required to allow the streaming of data from continuous parameters SpO2, CO2 and RRa data to Connex Central Station (CS). For additional information on Connex CS see CVSM DFU (718079) and Connex CS DFU DIR (409500)

- Extended chassis providing the capability to add up to 2 modules.

- Bi-Directional communication capabilities with the Connex Central Station including: Measurement Data, Patient Trend Information, Parameter and Device Settings Information, Alarm Information, and Host Initiated Message (HIM) support

- New demonstration Modes to simulate device profiles

- New Patient trend review table and automatic data storage

- Printing of Trend Data and Waveforms

- Service ‘Phone Home’ feature where the device connects to and interacts with a local service server.

- Updated alarming scheme and menu structures, where applicable to accommodate new features and functions.
New Supporting documentation

Service Manual
A new service manual was written to support CVSM 2.0. The 1.x service manual will remain available to service 1.x devices.

- CD Material 104730
- Printed Copy 104747 Material number 718095
- DIR 80017486 Ver. A

Significant changes include:
- Service interval for CO2 module
- Controls, indicators and connections
- Updated service screens
- New troubleshooting for RRa and CO2
- New Technical Alarms for RRa and CO2
- Updated disassembly and repair for CO2 and extended chassis
- Instructions for building a blood pressure y tube
- Improved basic functional verification test (no WAST gold license required)
- New CO2 calibration check
- New options and upgrades (CO2 and RRa)
- New licenses for continuous monitoring profile and RRa
- Added FRUs for RRa, CO2, extended bottom housing, top housing extension, fasteners, upgrades and repair kits
- New partners in care support and service agreements
- Cleaning for CO2 input connector (Appendix)
- New modal configurations (Appendix)
- Factory defaults for CO2, RR, IPI, RRa, and Patient ID settings (Appendix)
- Updated circuit board connections
- Main harness connectors
- Interconnect diagram

Directions for use
A new DFU was written to support CVSM 2.0.

- CD Material 104730
- Printed Copy 104731 Material number 718079
- DIR 80017136 Ver. H

Significant changes include:
- New symbols for warning, caution, and "follow instructions"
- New screen elements
  - Global navigation, controls, and indicators; process indicator, display lock,
  - monitoring and CS connectivity indicators and controls
  - Capnography (CO2) indicators
  - RRa indicators
  - Patient data management options
- Controls indicators and connectors
- Mounting instructions
- Connection/disconnection instructions for the SpO2 cable or the SpO2/RRa dual cable
- Power down instructions
- Setting the date and time
- Setting the default configuration
- Changes to the device status area
- 30 min battery alarm is changed to a very low priority alarm
- Changes to Alarm and information messages
- Changes to home screen during continuous monitoring
- Changes to locking the display
- Connex CS (new)
- Continuous Monitoring profile
- Profile feature comparison Continuous Monitoring
- Select a profile
- Add a patient to the patient list
- Select a patient
- Manage patient records (Continuous Monitoring profile)
- Modifiers tab was deleted
- Alarms, new behavior for continuous monitoring
- Alarm types for etC02, IPI
- New alarm levels
- Reset (pause or turn off) audio alarms
- New Physiological alarms for etCo2, fiCo2, no breath detected,
- New Technical alarms
- Patient monitoring
  - Capnography (CO2)
  - Respiration rate
  - IPI
  - RRa,
  - NIBP frame in Continuous Monitoring profile
  - Set up NIBP
  - Set up NIBP intervals
- Temperature frame in Continuous Monitoring profile Program intervals
- Set up temperature
- Set up SpO2
- SpHb frame SpHb is available only in the Intervals Monitoring and Continuous Monitoring profiles.
- Set up SpHb
- Continuous Monitoring profile
- Set up pulse rate
- You cannot manually enter respiration rate on a monitor configured with CO2 or RRa.
- Test the speaker by selecting each alarm volume level and listening for the different tones
- Clean the accessories RRa cable
- New advanced settings
  - etC02,
  - respiration
  - IPI
  - RRa
- Data management
Specify patient settings
- "Clinician IDs" is now Clinician tab
- Connect to CS

Server settings; UDP broadcast port

Troubleshooting
- CO2 messages
- RRa messages
- Network messages
- Message

Specifications
- New Physical specifications for extended chassis
- Battery specifications for continuous monitoring
- Ethernet connection specifications
- Braun calibration accuracy
- RRa
- C02
- IPI
- RR

Configuration options CO2/RR or RRa, NIBP, SpO2, SpHb, pulse rate, and temperature

Minimum hardware and software requirements

- Version M of 20012631 CVSM/CIWS Minimum Hardware/Software level Requirement initiates support for CVSM 2.0

Accessories list (718411), DIR 80017835 Ver. A
- Adds accessories for:
  - Oridion CO2
  - Masimo RRa
  - Mounting options

Support for Oridion etCO2

- See CVSM DFU (718079) for information on configuration and use of etCO2
- All models must have SpO2 (Masimo or Nellcor), CVSM host software 2.00.00 or later and continuous monitoring profile license
- Available as an option or an upgrade for models 6700/6800. Upgrades require an extended chassis upgrade. See the service manual for installation details. Installation may only be performed by Welch Allyn Service centers.
- Available as an upgrade on Models 6400/6500 (CVSMs with MCE hardware version older than P3 do not qualify) requires extended chassis, see 20012631 for complete requirements. See the service manual for installation details. Installation may only be performed by Welch Allyn Service centers.
- May not be added to devices with RRa
- Upgrades may only be installed by Product Service order SAP material: UPGCO2CVSM. The service kit is material number: 104608 (Service Kit, Oridion CO2 module. May be used as an upgrade or replacement).
- For etCO2 filter lines see accessories list (718411), DIR 80017835 Ver. A
- Partners in care service and support agreements for this option are listed in the
Support for Masimo acoustic respiration (RRa)

- See CVSM DFU (718079) for information on configuration and use of RRa.
- All models must have CVSM host software 2.00.00 or later, Masimo SpO2 module with software version 2.0.9 (WUI) MX software version 7.8.0.5 or later, Masimo RRa license and WelchAllyn RRa license, and continuous monitoring profile license. See the service manual for complete details on Masimo parameter 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
- RRa Upgrades and service kits, may only be installed by customers that have passed the CVSM 2.0 technical training course, Product service, or field service.
  - 104693 Upgd Kit, Masimo MX with SpO2, RRa Mod (Module with RRa enabled). See upgrade instructions 719331.
    To have this upgrade performed by Product Service under an RMA order SAP material: UPGRRSHCVSM.
    To have this upgrade performed on site order 104693 & 901-0172-00
  - 104699 Masimo RRa SW upgrade - sold by WA (SW only, see 719330 for upgrade instructions, upgrade is delivered to customers remotely via PartnerConnect see TSB 20012516.
    To have this upgrade performed by Product Service under an RMA order SAP material: UPGRRSWCVSM
    To have this upgrade performed on site order SAP material: 104699 & 901-0172-004700
  - 104700 Serv Kit, Masimo MX SpO2, RRa repair (This kit is a replacement only and does not include a WA RRa license)
- Verify RRa using material 20019317 RRA Simulation Tool, Masimo REF2389. See instructions in the Procedure section below.
- For cables and sensors see accessories list (718411), DIR 80017835 Ver. A

New service parts

Note: Product labels are no longer in label kits and are only available to internal sales due to ETL labeling rules
- 105362 Serv Kit, VSM6000, Labels, 6700, 6800
- 104609 Serv Kit, VSM6000, Extended bottom housing
- 104650 Serv Kit, VSM6000, Extended top housing
- 103572 VSM 6000 USB cable separator (this is no an 11 hole separator)
- 103395 Serv Kit, VSM6000, Screws and fasteners (added M4 standoff for extended chassis)
• 104693 Upgd Kit, Masimo MX with SpO2, RRa Mod
• 104699 MasimoRRa SW upgrade - sold by WA
• 104700 Serv Kit, Masimo MX SpO2, RRa repair (replacement only)
• 104608 Serv Kit, Oridion CO2 module
• 105363 Continuous Monitoring profile license
• 105364 CVSM 6700/6800 standard license

Partners in Care service and support agreements

Comprehensive support agreements
• S1-6000-O2 CVSM, Comprehensive Partner Pgm with CO2
• S1-6000-O2-2 CVSM, Comp Partner Pgm 2yr with CO2
• S1-6000-O2-5 CVSM, Comp Partner Pgm 5yr with CO2

Biomed support agreements
• S2-6000-O2 CVSM, Bio-Med Partner Pgm with CO2
• S2-6000-O2-2 CVSM, Bio-Med Partner Pgm 2yr with CO2
• S2-6000-O2-5 CVSM, Bio-Med Partner Pgm 5yr with CO2

Preventive protection support agreements (available in selected international countries)
• S4-6000-O2 CVSM, Warranty Extension 1 yr with CO2
• S4-6000-O2-2 CVSM, Warranty Extension 2 yr with CO2
• S4-6000-O2-5 CVSM, Warranty Extension 5 yr with CO2

Tools

A new version of the Welch Allyn Service tool will be released to support CVSM 2.0 (See DIR 20013381 TSB-WAST v1.6.0.0 PMP release). The WAST Installation and Configuration guide 103820 (Material 717352, DIR 80016783) will not be updated at this time. Note: The service tool will no longer be included on the product BOM. The CD (part number 103521) may be ordered separately or the software may be downloaded from WelchAllyn.com.

Action:

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

When upgrading from 1.x to 2.x enclose the CD with DFU and service manual material number 104730 with the serviced device.

For instructions on functional verification for CVSMs configured with Masimo RRa reference the procedure section of this document

Technical support: Reference the new service manual and DFU and current versions of service documentation when providing support for CVSM 2.0. For all escalations follow the current procedures. Technical Support will route calls to those representatives that have received advanced training.

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

During LMR 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 2.0. Only the 1.x devices that meet the upgrade requirements described in 20012631 will qualify for a 1.x to 2.x upgrade. Upgrades to 2.x will only be made available to those customers participating in the LMR program.

During the LMR year service will be looking for opportunities to improve the service documentation and other service offerings prior to full market release (FMR) in 2014.

Loaners will be made available from Product Service for LMR customers only.

The online technical training course will be updated for LMR customers purchasing a Biomed Partners in Care agreement. The training is scheduled to for release in March 2013.

Software updates distributed to LMR customers via PartnerConnect will be packaged with the most current FSS software updates to provide a complete set of compatible software. With 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 1.6.0.0. DIR 50010968
- RRa Simulation tool. material number: 20019317

Required Materials:

- NA

Quality Process for failed units or components:

All failed parts will be retained by Product Service for further analysis as requested by engineering

Procedure: Functional verification of the RRa parameter

Product service will use this procedure to functionally verify the RRa parameter whenever a device configured with RRa is serviced.

1. Verify the Continuous Monitoring profile is selected.
   a. With the CVSM powered on touch the settings tab, then the device tab.
   b. If the radio button for Continuous Monitoring is not selected, touch to select and go to step 2.
   c. If the profiles are not selectable touch the advanced tab and enter the code to access the advanced settings. From the
General tab touch the Device tab and select the allow profile change check box and set the default profile to continuous monitoring.

d. If the allow profile change radio button is already selected and the profiles in the settings tab were not selectable, power cycle the device and return to step a and repeat steps a and b.

2. Return to the Home tab, verify the RRa pane appears in the upper right of the display. It will display RRa in yellow.
   a. If no RRa pane appears verify the RRa UI license is enabled in the advanced settings for service and licensing.
   b. Verify the RRa is enabled on the module by connecting to the service tool and selecting Masimo from the device information tab to see the installed licenses.

3. Plug the RRa simulation tool (20019317) directly to the Masimo module. Verify metrics are shown in the RRa. The tool provides 30 minutes of trending data so the values will change. Touch the inset pane with graph, and verify the averaging method changes between; off, slow, medium, fast, and trending.
   If no metrics are shown the SpO2 module will need to be replaced

4. If the metrics are present add a notation to the service record the test passed.

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

Revision History

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