TSB-CVSM SpO2 Fails in Stby, Rel 1.50.02

CAR Number: N/A

Distribution Scope: WA Internal
WA Technical Support, Product Service, & International Service Centers

Product(s) Referenced: CVSM Models with Nellcor or Masimo SpO2

SW Version: 1.50.01 and below

Serial No. / Lot Code: All serial numbers prior to 103000001511

Summary:
CVSM devices with host controller software version 1.50.01 or below may experience a SpO2 failure upon pressing the power button to enter the Display Power Saver mode. Upon failure, a technical alarm message is identified by visual and audio cues, and the SpO2 module ceases functioning until the device is power cycled.

Issue:
When the power button is used to place the device into the Display Power Saver mode, the software writes the log files to the flash memory. During this time, communication between the compute engine and SpO2 module is temporarily interrupted. If the interruption in communication persists too long, the SpO2 module stops sending data to the compute engine, causing a SpO2 module failure.

Action:
Customers affected by this issue should be asked to verify the CVSM software version on their device. See the procedures section below for instructions.
If the software version is 1.50.02 or later the issue is outside of the scope of this service bulletin and should be addressed using standard procedures.

If the software version is earlier than 1.50.02 direct them to use PartnerConnect to download and install the software update version 1.50.02 or later. There is no charge for the software update. See the procedures section below for instructions.

Customers that cannot connect to PartnerConnect should be directed to return their CVSMs to a Welch Allyn Service Center to have the device software updated. There is no charge for the software update.

Customers that cannot update the software immediately should be advised not to use the power button to turn off the display. Instead of using the power button to turn off the display set the Display Power Saver in advanced settings to turn off the display. See the procedure section below for how to do this.

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

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

Service Strategy:
Firmware updates to 1.50.02 will be available to all customers via Partner Connect. Customers experiencing this issue should be directed to update their devices using the Welch Allyn Service Tool. The update is recommended for all customers using PartnerConnect and is provided to the customer at no charge.

Devices received at Welch Allyn Service Centers must be updated to a firmware version of 1.50.02 or higher. The software update will be provided at no charge, for CVSMs under warranty or covered by other service agreements. Devices not under warranty may be charged for parts or other services. Cost for the software update should be charged to the warranty account. Loaners are available to customers participating in a Partners in Care agreement entitling them to this service at no charge. Loaners may be provided to customers without a Partners in Care agreement for a fee, based on availability.

Loaners and devices already received for service must be updated prior to shipment to customers. See the Procedure section below for update instructions.

Required Training: N/A

Required Tools:
- PC running the Welch Allyn Service Tool & Partner Connect
- USB cable, mini-B. P/N 4500-925 or equivalent
Required Materials:

- Host software version 1.50.02 or later available through PartnerConnect

Quality Process for failed units or components:

N/A

Procedure:

Verify CVSM host software level

1. Power on the CVSM
2. Touch the Settings tab
3. Touch the Advanced tab. The software version is displayed in the right hand frame

Change the Display Power Saver setting

From the Home screen:
1. Touch the Settings tab
2. Touch the Advanced tab
3. Enter the advanced settings code ‘6345’ and touch OK
4. Touch the Display tab
5. Select the desired time interval from the Display Power Saver drop down list.

The display will automatically turn off when the device is inactive for the set time interval. The display will not shut off while a patient is being actively monitored. Touching the screen will restore the display.

CVSM host software update

1. Connect the CVSM to be updated to the PC running the Welch Allyn Service Tool via the USB cable. Ensure the device is plugged in and powered on and the service tool is open.
2. On the CVSM go to the Advanced settings> General tab>Display tab set the Device power down setting to Never
3. In the service tool window, highlight the device to be updated in the device list and click “Select.”
4. In the service tool select the upgrade tab
5. Highlight the device name and click “Upgrade All.”

Note: This option may not be available if the device is already at the current firmware version or if an internet connection is unavailable.

6. After completion of the upgrade, verify the Host Controller firmware version is 1.50.02 or later
7. If required print and file the service record detailing the update
8. Confirm desired device settings before placing in use

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

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D* - Refer to SAP DIR digital signature log for approval details.