Technical Service Bulletin

PATIENT MONITORS AND SYSTEMS

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Date: 2013-06-28 SAP DIR #: 20013464

Subject: TSB-CVSM, SECURE SURETEMP USB CABLE

CAR Number: 1386


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

Serial No. / Lot Code: All serial numbers before 103001951813

Summary:
In rare cases pins protruding from the communications board USB connections have been found to penetrate the USB cable connecting the Temp Module to the MCE board. Use the procedure in this TSB to inspect the USB cable and secure it to the temp housing to prevent it from contacting the communications board.

Issue:
In rare cases pins from the communications board (407524) USB connections have been found to penetrate the insulation of the USB cable (712980) used to connect the Temp module to the MCE board. Very few if any devices have the USB cable directly in contact with the coms module. In the few cases where the cable is in contact, significant vibration or wear must occur at the exact site of the USB ports on the coms module before penetration of the USB cable insulation occurs.

The following 3 failure modes have been identified:

Mode 1: Coms ground or Coms shield to Cable shield: In a worst case this failure mode could eventually lead to the ground pin on the coms board penetrating the USB cable interior and shorting one of the non-shield conductors to ground. This could result in complete failure of the
temp module.

Mode 2: Cable shield to Coms +5V: This will short out the USB device connected to that USB port. This may result in a complete inability to boot the CVSM device, or instead in the failure of the connected USB accessory to POST.

Mode 3: Cable shield to Coms Data: This will short a data line to ground resulting in communications failure for the connected USB device. This would result in a failure of the external USB device to operate.

Action: **Product service and Global Service Centers:** When servicing a CVSM with the Suretemp option inspect the USB cable connecting the SureTemp module to the MCE board for any damage and replace as necessary. Secure the USB cable to the temperature housing to prevent contact with the comms board. See procedure below. This procedure will be covered under warranty.

**Technical Support:** Customers reporting devices with intermittent or lost communications with the SureTemp module will be provided an RMA. If the failure is due to this issue the service will be completed under warranty. Customers participating in the Partners in Care Biomed partnership program that wish to service their own devices may be informed of this issue and provided with a copy of DIR 80018575 CSB- CVSM, SECURE SURETEMP USB CABLE. If the reported failure is due to this issue they may be provided a replacement USB cable (103548) or a replacement SureTemp module (103391(includes USB cable)) under warranty.

**Note:** There is a separate issue where the temperature pane on the home screen may be missing when device is powered on. If cycling the power restores SureTemp without further incidence of a missing temperature pane that is symptomatic of the other issue. Before asking the customer to return
the device verify restarting the device does not eliminate the issue.

**Tech Comms:** Update the CVSM service manual to add this procedure.

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

### References:
- 70019563 MPS: CVSM HOW2-PMP How to Assemble
- 103730 (CD) CVSM 6000 Series Service Manual
- 104730 (CD) CVSM (2.0) 6000 Series Service Manual
- 80018575 CSB-CVSM, SECURE SURETEMP USB CABLE

### Updates:
- Technical Manual
- Training Material

### Service Strategy:
- Product service and service centers will inspect all CVSMs returned to service for any damage to the USB cable connecting the SureTemp module to the MCE, and replace any damaged cables. All CVSMs with the SureTemp option, whether or not the subject damage has occurred, shall be fitted with tape to secure the USB cable to the temp housing to prevent the USB cable from contacting the pins on the communications board. This service will be performed under warranty.

- Customers servicing their own devices may be advised of this issue and provided with a copy of CSB 80018575 CSB-CVSM, SECURE SURETEMP USB CABLE. Replacement parts including tape, fasteners, USB cable and replacement SureTemp module will be provided under warranty.

- The service manual will be updated to add the procedure to secure the Suretemp USB cable.

### Required Tools:
No additional tools other than listed in the service manual

### Required Materials:
- 103576 VSM 6000 TAPE
- 103395 SERV KIT, VSM6000, SCREWS AND FASTENERS

### Replacement Parts:
- 103548 VSM 6000 USB MINI B TO USB A RIGHT ANGLE
- 103391 SERV KIT, VSM6000 SURETEMP MODULE

### Procedure:
1. Inspect the USB cable connecting the Suretemp module to the MCE board for any damage, including small cuts, tears, abrasions and/or holes that compromise the insulation. Replace any damaged USB cables.
2. Clean the surface on the Suretemp module where the tape will be applied with isopropyl alcohol.

3. Secure the USB cable connecting the temp module to the MCE board as shown in the photos below using a single 2 inch length of tape (103576).
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 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

Revision History

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