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Date: 2012-06-25 SAP DIR #: 20013147

Subject: TSB-CVSM_CIWS, NIBP not functional. Call for service.

Distribution Scope: WA ASP’s and Distributors
WA Technical Support, Product Service, & International Service Centers
Partners In Care customers

Product(s) Referenced: CVSM (Connex Vital Signs Monitor) - All Models
CIWS (Connex Integrated Wall System) - All Models

SW Version: Host SW version 1.70.03 and earlier
NIBP 2.00, 2.02 and 2.03

Serial No. / Lot Code: All

Summary: CVSM/CIWS may display “NIBP not functional. Call for service.” error due to a kinked or pinched hose, potentially leading to an unnecessary call for service.

Issue: The NIBP error code, species 6 code 10, is mapped to display a technical error “NIBP not functional. Call for service.” error. The species 6 code 10 is detected when the pressure difference between the primary and safety transducers is 40 mmHg or greater. The different pressure reading between the transducers may be caused by any of the following: a pinched or kinked hose, an open dump valve, or one or both of the transducers may be out of calibration.

Action: Check the hose for kinks, pinches, obstructions, or damage, clear the kink or replace the hose as necessary and try the NIBP again. If the error persists it may be due to either a calibration error or an open dump valve. Run the NIBP calibration test in the service tool, to determine if the NIBP may be re-calibrated or has an open dump valve.
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:  
Prior to returning devices for repair, customers should be informed that the error may be caused by a pinched or kinked hose. After eliminating this possibility, follow the procedure section to determine the issue.

If the NIBP module must be replaced, customers that have a Partners in Care Biomed agreement and have received CVSM technical training may replace the module themselves, all others will need to return the device for service.

Required Training:  
All Welch Allyn employees and contractors engaged in the service and repair of the CVSM / CIWS shall complete a training record indicating they have read and understand this document. The local service center shall maintain a file of training records for their service personnel.

Required Tools:  
Welch Allyn Service Tool version 1.5.0. or later:
• Order the CD, REF 103521
  Download from Welch Allyn:  
  http://www.welchallyn.com/promotions/services/serviceTool.htm

Required Materials:  
Welch Allyn Service Tool Installation and configuration guide, available from  
http://www.welchallyn.com/promotions/services/serviceTool.htm

Procedure:  
1. Check the hose for kinks, pinches, obstructions, or damage. Clear the kink or replace the hose as necessary.

The following procedures are described in the service manual:

2. Perform a leak test, use the service tool (no gold license required), to determine if an open dump valve is the problem.

3. Perform an accuracy test using the service tool (no gold license required), to check the primary transducer.
   Note: This test may not be conclusive as it does not check the safety transducer.

4. Customers with a gold license service tool may run the NIBP functional verification and calibration test to identify and correct the problem. Calibration would be performed if necessary.

5. If the issue cannot be resolved by re-calibrating the NIBP module, the module must be replaced.
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.

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**End of Bulletin**

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

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