Date: 2012-06-25

Subject: TSB-CVSM_CIWS, NIBP Start Timing

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: At initial power up the NIBP start button is available to the user prior to NIBP being functional. Early selection of the NIBP start button may result in the NIBP function not being responsive or; a technical alarm being displayed “NIBP not functional. Call for Service” and the NIBP function being grayed out.

Issue: Upon device power up, the NIBP start button appears on the device screen, however, the NIBP module (ModPG) may not be ready when the button is presented. The User can select the NIBP Start button 6 seconds after power on.

If the user presses the NIBP button while the module is still completing POST (Power on Self-Test), either it appears as if the NIBP start button was not pressed or the technical alarm “NIBP not functional. Call for service.” is displayed. Subsequent clearing of the technical alarm causes the NIBP start button to be greyed out. This can be identified by error code state [4], proxy error[7].

Note: The NIBP module (ModPG) requires the NIBP pressure to be stable during POST (Power on self-test).
Action:

Advise customer to wait at least 6 seconds AFTER the NIBP start button is displayed on the device screen before pressing the start button. If an error occurs do to pressing the NIBP start button too soon, a power cycle will clear the error and allow the use of NIBP.

Advise customer to wait at least 6 seconds before handling the cuff or applying cuff to patient. If an error occurs, a power cycle will clear the error and allow the use of NIBP.

If a power cycle of the device does not clear the error and allow use of NIBP: Check the hose for kinks, pinches, obstructions, or damage, clear the kink or replace the hose as necessary and try the NIBP again.

If none of the above actions allows the NIBP to operate, refer to TSB 20013147 for additional procedures to perform.

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:

To avoid returning devices unnecessarily, inform customers that the error may be caused by pushing the NIBP start button too soon after initial power up. Welch Allyn is planning a software upgrade to eliminate the occurrence of this error condition in the future.

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.

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