Subject: TSB-CVSM_CIWS, PATIENT REVIEW RECORD FULL

Distribution Scope: WA ASP's and Distributors
WA Technical Support, Product Service, & International Service Centers

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

SW Version: All

Summary: A wrench #000000001 error may occur when a large number of saved patient review records, approximately 350 to 400, are present at initial startup.

Issue: Patient review records are automatically deleted from the device after 24 hours. The device reviews it's patient review records Date/Time information once every minute. Exactly one minute after initial start-up patient review records that are 24 hours old or older are deleted. If the number of patient review records for deletion is large, approximately 350 to 400, a wrench #000000001 error is generated. The device will not recover until the entire review record is erased for that day.

This will occur with any configuration and all current hardware and software versions.

Action: Once the wrench #000000001 error occurs the entire review record must be erased for that day, within the first minute of start-up, to recover the device.

Reference to Standards: 21 CFR Part 820, ISO 13485, MPD SOP-0002
Service Strategy: Advise customers of procedure in this document to recover device from error.

Advise customers that have a large number of patient review records stored in their device, to manage patient review records quantities before turning the device off.

Advise connected customers that have a large number of patient review records stored in their device, to send their patient review records within 24 hours of taking the measurements. Then manage the patient review record quantity before turning the device off. This will prevent data from being deleted without transfer.

Suggest connected customers configure the device to “delete reading after successful send”. This will prevent the buildup of records and the generation of a wrench #00000001 error. See Procedure, To configure the device to “delete reading after successful send”.

Required Training: Complete a MPD FCD-1493 Individual Employee Compliance Training Record for this TSB.

Procedure: To recover device from error, all patient records must be deleted within one minute from powering on the device.

1. Restart device.
2. Select Review tab.
3. Select top left box by “Patient”; check marks appears for all patients.
4. Select Delete.
   Pop-up window displays:
   Delete Selected Records.
   Are you sure you want to delete selected records? (x)
5. Select Ok.
   Review tab display is clear of all patient records. Device is now available for use.

To configure the device to “delete reading after successful send”.

1. Select Settings tab.
2. Select Advanced tab.
3. Enter advanced setting code, select OK.
4. Select Data Management tab.
5. Select Clinical Data tab.
6. Check “Automatically send on manual save”.
7. Check “Delete readings after successful send”.
8. Select Exit, Advanced Setting.
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

<table>
<thead>
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<th>Description</th>
<th>Change #</th>
<th>Init</th>
<th>Release Date</th>
<th>Appr</th>
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</thead>
<tbody>
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D* - Refer to SAP DIR digital signature log for approval details.