Customer Service Bulletin

Monitoring Products

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Date: 2011-08-30

SAP DIR #: 20012687

Subject:       CSB-CVSM, Recessed Mounting Insert

CAR Number:    None

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

Product(s) Referenced:
Connex Vital Signs Monitor 6000, all models
When used with:
4800-60 MOBILE STAND W/CABLE MGMT STORAGE SYS
4700-60 MOBILE STAND, ELECTRONIC VITAL SIGNS
008-0834-01 WALL MOUNT WITH BASKET

SW Version:     Not Applicable

Serial No./Lot Code: Connex Vital Signs Monitor (CVSM) Models 6300, 6400, and 6500 with serial numbers before SN 103001283411

Summary: Connex Vital Signs Monitors serial numbers 103001283411 and earlier have a recessed mounting insert, effectively reducing the length of the captive screw on the mounting plate used on the 4800-60 and 4700-60 mobile stands, and 008-0834-01 wall mount. Two new mounting plates with longer captive screws have been created for use with CVSMs that have rear housings with the recessed mounting insert.

Issue: The length of thread engagement between the CVSM device and the mounting plate was found to be less than that of other devices using this same mounting configuration. The CVSM may become loose on the mounting plate shipped with the 4800-60 and 4700-60 mobile stands or the 008-0834-01 wall mount.

Action: Upon request, Technical Support or Customer Care will provide a replacement mounting plate assembly to customers experiencing this issue with the 4800-60 and 4700-60 mobile stands, or the 008-0834-01 wall mount.
This will be provided at no charge to the customer.

Replace 708600, (MOUNTING PLATE, W/ CAPTIVE SCREW, MS2) included with 4800-60 (MOBILE STAND W/CABLE MGMT STORAGE SYS) and 4700-60 (MOBILE STAND, ELECTRONIC VITAL SIGNS) with 717821 (Mounting Plate, w/Long Captive Screw, MS2).

Replace the mounting plate included with 008-0834-01 (WALL MOUNT WITH BASKET) with 717846 (TILT PLATE, GCX WALL MOUNT, LONG SCREW) when released. Note: 717846 is expected to release in October 2011

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:
The rear housing on the CVSM has been redesigned to position the mounting insert so it is flush with the exterior of the housing. This will allow the existing mounting plate’s captive screw to engage more threads on the insert.

A replacement mounting plate 717821 (Mounting Plate, w/Long Captive Screw, MS2) has been released to replace the old mounting plate on the mobile stands 4800-60 and 4700-60. Another replacement mounting plate 717846 (TILT PLATE, GCX WALL MOUNT, LONG SCREW) will be released to replace the mounting plate on the wall mount (008-0834-01). The new mounting plates look similar to the old mounting plates, but can be identified by a white dot in the center as shown in the illustrations in the procedure section of this document.

Mounting plates 717821 and 717846 will work with both old and new rear housings.

Required Training:
None

Required Tools:
Phillis #2 Screw Driver, Flat Head #2 Screw driver

Required Materials:
717821 - MTNG PLATE, W/ LONG CAPTIVE SCREW, MS2. Use with PN 4800-60 (ACM mobile stand); or with PN 4700-60 (MS2 mobile stand) Note: 717821 is field replacement for original 708600 - MOUNTING PLATE, W/ CAPTIVE SCREW, MS2

717846 - TILT PLATE, GCX WALL MOUNT, LONG SCREW. Use with PN 008-0834-01 WALL MOUNT WITH BASKET

Quality Process for failed units or components:
Mobile stands or Wall Mounts will NOT be returned to Welch Allyn for the purpose of installing a new mounting plate assembly.

Procedure:
Identifying replacement part 717821 - MTNG PLATE, W/ LONG CAPTIVE SCREW, MS2. Indicator DOT is present on new mounting plate where shown.
Identifying replacement part 717846 - TILT PLATE, GCX WALL MOUNT, LONG SCREW. Indicator DOT is present on new mounting plate where shown.
Replacement of CVSM device mounting plate

1. Holding the CVSM device loosen the mounting plate captive screw and slide the CVSM forward to disengage the forward edge of the mounting plate from the slot on the CVSMs bottom housing

CVSM Back Housing

2. Remove mounting plate base screws and retain for reuse
3. Remove old mounting plate
4. Install new appropriate mounting plate (with indicator dot)
5. Secure new mounting plate with original mounting plate base screws
6. Slide the CVSM onto new mounting plate so the forward edge of the mounting plate slides into the slot on the CVSMs bottom housing
7. Secure CVSM device by tightening the mounting plate captive screw

4800-60 mobile stand
008-0834-01 Wall Mount
Identify the CVSM back housing by observing the brass insert position

OLD PN 712961 Back Housing Brass insert recessed
NEW PN 717676 Back Housing Brass insert almost flush

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.