Baxter	DIVISION OR FUNCTION: Service	DOCUMENT NO.: 35022-SVC	ISSUE DATE: See Stamp
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	OWNING GROUP: Service	DOCUMENT TYPE: ITP	
TITLE: Visual Component Inspection of a SIGMA Model Spectrum Pump			PAGE 1 OF 33

1.0 PURPOSE

1.1 This document outlines the visual inspection requirements for the Spectrum Infusion Pump, during Service Evaluation, or when required, to determine if the components of the device meet current requirements.

2.0 Scope

2.1 This procedure applies to the Spectrum Infusion Pump 35700BAX and 35700BAX2.

3.0 REFERENCES

Document	Document Title
42049	Double Rotating Pole Clamp Retrofit Kit # 55224 Installation Instructions
ET 35700-016	Case Halves Visual Inspection Study
ITP 35716-SVC	Final Assembly & Packaging Inspection Test Procedure, Spectrum Infusion Pump
SOP 11057	Control of Nonconforming Product and Process
SWI 010	Pole Clamp Repair
SWI 107	Service Disassembly Instructions, Spectrum Infusion Pump

4.0 Inspection NOTES:

NOTE: Pictures may not be the current revision, use for reference.
NOTE: Process all non-conforming components per SOP 11057
NOTE: Level of inspection is determined by the level of assembly/disassembly. If pump is not required to be disassembled to the level of inspection, the visual inspection need not be performed.
NOTE: Inspection does not follow a specific sequence.
NOTE: Instruction to "Replace/Rework" indicates that the action will be performed by trained personnel in accordance with all applicable procedures, but is not required to be performed during this inspection.
NOTE: When inspecting screw installation, with exception to the link screws, ensure the head of the screw is flush with, or touching the mating surface; constitutes a proper installation.
NOTE: for any further questions regarding rear or front case replacement, consult Appendix A.

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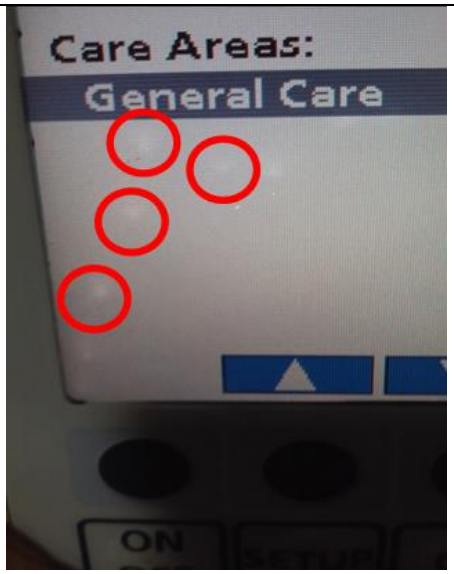
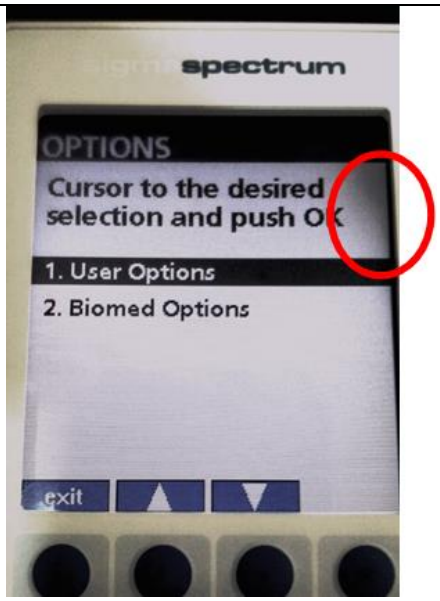
TITLE: Visual Component Inspection of a SIGMA Model Spectrum Pump			PAGE 2 OF 33

5.0 DISPLAY INSPECTION, WHILE DEVICE IS POWERED ON

5.1 White/bright colored spots on the screen require a display replacement.	 White/bright colored spots
5.2 Significant dark colored areas on the screen require a display replacement.	 Dark colored area on screen

5.1 If screen dents, dings, scratches exist:

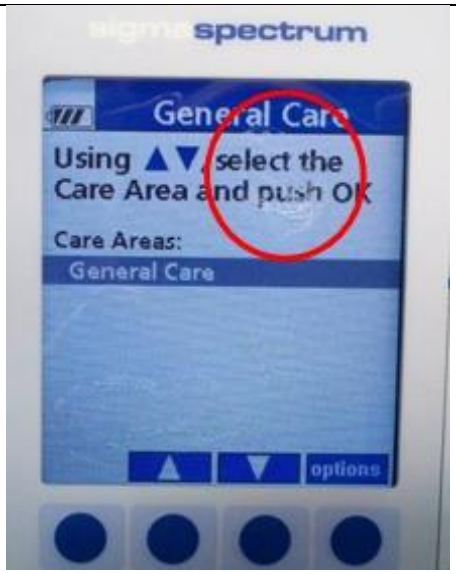
5.1.1 While in the general care screen, if dents, dings, or scratches do not affect visibility or functionality turn off pump, remove the battery, and proceed to the next step.

5.2 If screen foreign material/debris is found:

5.2.1 While in the general care area screen, if the debris is minor and does not affect visibility, turn off the pump, remove the battery, and proceed to the next inspection step.

5.2.2 Debris such as hair, long fibers, smears, or fingerprints are not acceptable.

5.3 Replace or rework the Keypad as required.



Example of a Defective Dented/Scratched Keypad Display

Release Status : Issued and Effective

6.0 POLE CLAMP ASSEMBLY INSPECTION PROCEDURE

6.1 Inspect the Pole Clamp for threaded hole for the Cord Clip installation. 6.2 Reject Pole Clamp if threaded hole does not exist for processing as per SWI 010.	 Pole clamp with cord clip installed
6.3 Acceptable Pole Clamp Assembly includes: 6.3.1 Uniform flat black in color. 6.3.2 Pole clamps without corrosion or discoloration, has all components but has wear on the edges because of usage	 Flat black pole clamp  Worn edges - Acceptable per criteria

Release Status : Issued and Effective

6.4 Unacceptable conditions of the Pole Clamp Assembly include the following:

- 6.4.1 Blotchy
- 6.4.2 Uniformly Discolored / Purple Hue
- 6.4.3 Broken or Missing Parts
- 6.4.4 Rusty Washer
- 6.4.5 Rusty Screw
- 6.4.6 Inoperable Clamping Mechanism

6.5 Reject all unacceptable Pole Clamp Assemblies for processing as per SWI 010.

Blotchy pole clamp

Discolored pole clamp (purple)

Missing Knob, Broken Clamp

Rusty Washer

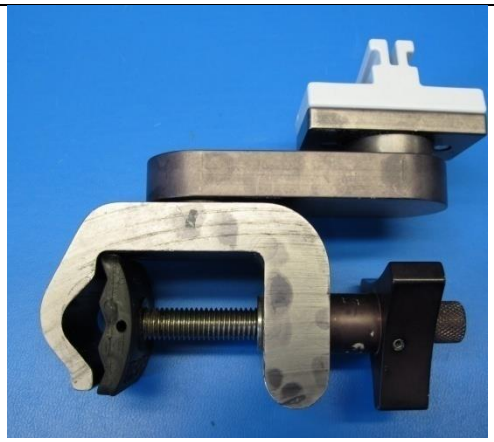
Rusty Screw

Release Status : Issued and Effective

7.0 DOUBLE ROTATING POLE CLAMP ASSEMBLY INSPECTION

7.1 Inspect the Double Rotating Pole Clamp for discoloration (fading/blotchy spots).

7.2 Inform your supervisor or the Materials Manager if discoloration is found, replacement may be required.



Discoloration

7.3 Inspect the Pole Clamp Label for tears and legibility.

7.4 Replace label if required.

Inspect label for tears and legibility

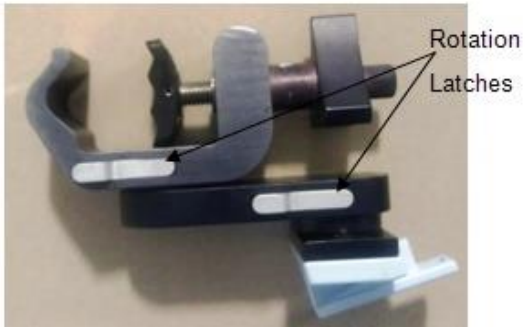
7.5 The Pole Clamp Assembly shall include a Pole Side Adapter, attached with 2 screws and 2 lock washers. Install or replace any loose, missing or damaged components.

7.6 Unacceptable conditions of the Pole Clamp Assembly include the following:

- 7.6.1 Broken or Missing Parts
- 7.6.2 Cracked or Broken Rotation Latches
- 7.6.3 Inoperable clamping mechanism
- 7.6.4 Inoperable Rotation Latches

7.7 Place acceptable / Unacceptable pole clamps in designated area.

NOTE: The pole side adapter may be retained if in acceptable condition.

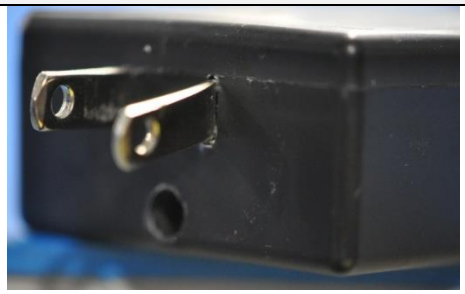


Pole Clamp Assembly

7.8 Ensure proper movement (90°) of the Position Arm or Position Wheel while depressing the Trigger Lever 1 or Trigger Lever 2.

7.9 If movement is limited or non-functional, then the pole clamp may be reworked per 42049.

8.0 AC POWER ADAPTOR INSPECTION

8.1 Discard/replace the AC Power Adapter if the following inspection criteria are not met.	
8.2 Ensure there are no breaks or cracks in the AC Power Adaptor collar and that it connects and disconnects to the rear case properly.	 Power Adaptor with damaged collar
8.3 Verify the LED on the AC Power Adaptor Illuminates.	 Three prong adaptor (PN 35727)  Two prong adaptor (PN 35714)
8.4 Ensure there are no cuts in the insulation or exposed wires.	
8.5 Ensure the prongs and ground pin (PN 35727 only) on the transformer are intact, straight and not loose. 8.6 Ensure transformer is not cracked and the labeling is fully intact.	 Missing ground prong, bent power prong

Release Status : Issued and Effective

9.0 REAR CASE ASSEMBLY EXTERIOR INSPECTION

9.1 Inspect the following areas for cracks, tears and/or breaks:

- 9.1.1 Rear Case
- 9.1.2 Power/Bolus Connector
- 9.1.3 Scanner Bracket, Window and O-ring (if applicable)
- 9.1.4 Pump Side adaptor/ Thumb screw
- 9.1.5 Battery Gasket

9.2 Replace the associated component if inspection fails

9.3 **Cracks by keyhole PEMs – Conditionally accept**, with the criteria as follows: Only discard if a crack appears through the rear case mold entirely, allowing flexion of the rear case or if the crack is customer facing. In other instances, as long as the crack is not customer facing (i.e. is interior, or in recess for keyhole installation) the part will be deemed acceptable.

9.4 **Case dents/scuffs – Conditionally Accept.** Minor case dents/scuffs do not adversely affect pump function. However, major dents/scuffs are customer facing and may need replacement for customer satisfaction.

Cracked pump side pole clamp adaptor

Major case damage

Crack at case screw

9.5 Using your finger, ensure the bolus connector is tight and visually inspect the pins to ensure all 6 are present, not bent or corroded.

9.6 Replace or rework the Rear Case if condition exists.

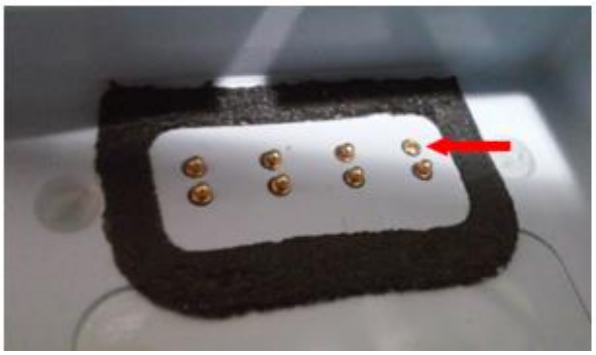
Figure 19: Pump side power adaptor with all 6 pins intact and undamaged

Release Status : Issued and Effective

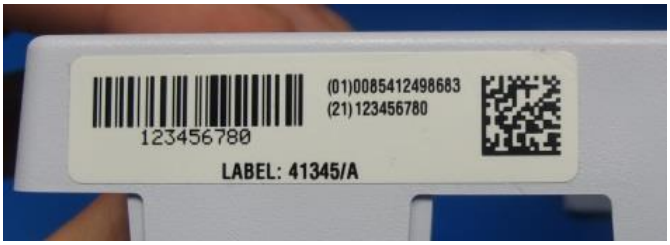
9.7 Ensure the Rear Case has a Power and Bolus Label, PN 41004, installed.	 Bolus Label PN 41004	
9.8 Ensure the Rear Case has the Company ID Label, PN 41007 for 35700BAX devices and PN 41007-CFG2 for 35700BAX2 devices, installed.	 35700BAX Compay ID	 35700BAX2 Company ID
9.9 Inspect the Rear Case for a Certification Label. 9.9.1 For 35700BAX Devices, the following part numbers are acceptable Rear Case Certification labels. 9.9.1.1 41009 9.9.1.2 41338 9.9.1.3 41340 9.9.1.4 41350 9.9.1.5 41351 9.9.1.6 41385		
9.9.2 For 35700BAX2 Devices, the following part numbers are acceptable Rear Case Certification labels. 9.9.2.1 41373 9.9.3 All other certification labels are to be removed from the rear case during the service process.		

9.10 Ensure the following Rear case screws are present and seated properly. 9.10.1 Thumb Screw 9.10.1.1 Ensure the thumb screw moves freely, without backing all the way out (1 ½ to 2 turns) by hand in both directions. 9.10.1.2 If stuck, attempt to loosen to normal operation (see above), with a 9/64" hex driver. 9.10.2 Back Flex Nylon screws 9.11 Replace or rework the pump side adaptor and Back Flex nylon screws as required.	 Thumb screw (Red circle), Nylon Screws (Green circles), Rear Case (Blue circles)
9.12 If applicable, inspect the scanner bracket window for debris, such as solder or glue. 9.13 **Chipped case by scanner window – Reject**. Any chips in the rear case that expose internal components could adversely affect essential requirements of Withstand ESD, Withstand Fluid Ingress, and Withstand RF/EMI. **NOTE:** Scratches to the scanner bracket window does not warrant a replacement. 9.14 Remove or replace the Scanner Bracket Window as applicable.	 Scanner Bracket Window

Release Status : Issued and Effective

9.15 Ensure the Battery Contact Pins are NOT compressed/Depressed or corroded. 9.16 Replace or Rework the Rear Case as required.	 Compressed Battery Contact pins
9.17 Consult your supervisor if the Rear case plastic has severe discoloration or markings, a replacement may be warranted.	

10.0 FRONT CASE ASSEMBLY EXTERIOR INSPECTION

10.1 Inspect the Front Case for cracks or breaks. 10.2 **Case dents/scuffs – Conditionally Accept.** Minor case dents/scuffs do not adversely affect pump function. However, major dents/scuffs are customer facing and may need replacement for customer satisfaction. 10.3 Replace the Front Case if cracks or breaks exist.	
10.4 Ensure the Serial Number and tubing ID label are: 10.4.1 Installed properly 10.4.2 Adhered completely 10.4.3 Free of cracks or fading 10.4.4 Not torn or lifted 10.4.5 Legible. 10.5 The Tubing ID Label must match the calibration of the pump, and must read "Warning." 10.6 Ensure the Serial number has both a One-Dimensional (1D) Barcode and a Two-Dimensional (2D) Barcode. 10.7 Replace the Serial Number Label or Tubing ID Label as required.	 **Properly attached Tubing ID Label.**  **Properly attached Serial Number Label** **Serial Number Label with 1D and 2D Barcodes shown above**
10.8 Applicable to 35700BAX2, ensure the certification label is in place and adhered properly. 10.9 Ensure that the label is not covering the tubing channel or weep hole. 10.10 Replace all torn, missing, and improperly adhered labels.	 **Properly attached Certification Label**

10.11 The following criteria shall be followed for the Keypad:

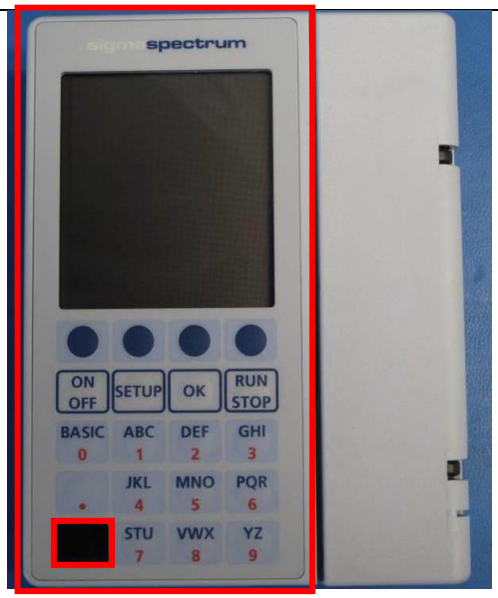
10.11.1 Keypad shall be centered within the recess and completely adhered to the Front Case.

10.11.1.1 Inspect Keypad for being outside the recess or lifting above the recess.

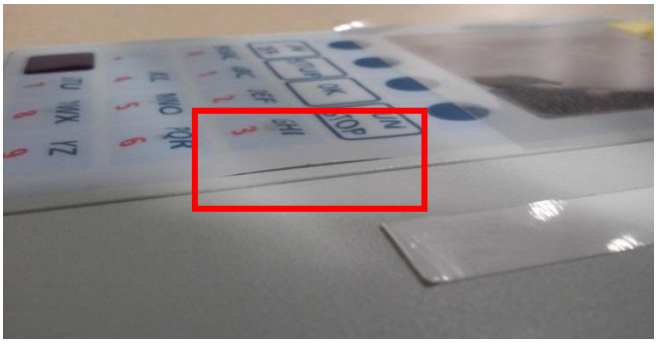
10.11.2 The Infrared window shall be free of punctures, severe dents and debris.

10.11.3 All numbers and letters of the Keypad shall be legible, clean and not discolored.

10.11.4 All Keypad buttons shall be free of cracks and cuts.



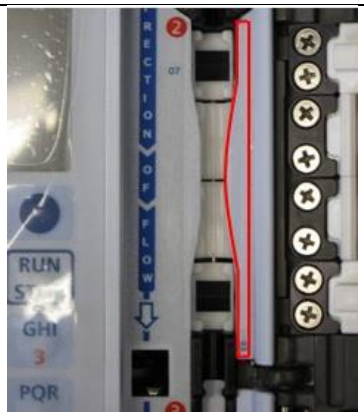
Keypad located correctly within the Front Case recess



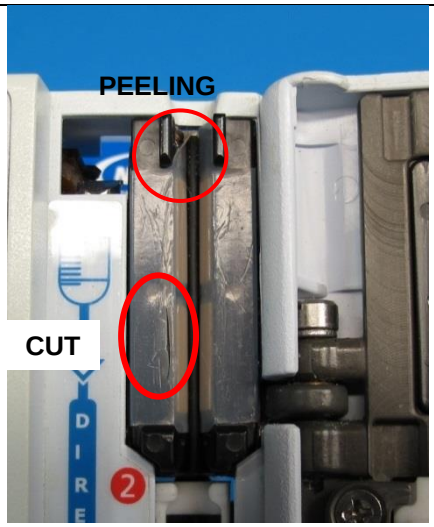
Lifted Keypad above the recess at Key 3 area (Reject)

Lifted Keypad above the recess (Reject)

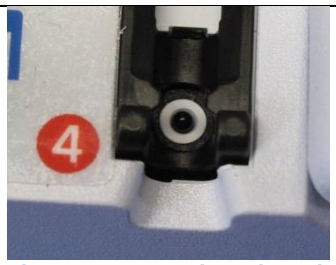
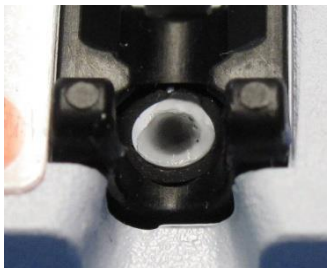
Release Status : Issued and Effective

10.12 Ensure the Direction of Flow Label and Shim are present, printed clearly, and adhered properly. 10.13 Replace the Direction of Flow Label or Shim if either label is found to have debris under the label or is adhered incorrectly.	 Direction of Flow Label
10.14 Ensure the Top Door Spacer Label is present, printed clearly, and adhered properly. 10.15 Replace the Top Door Spacer if the above criterion is not met or if debris is found under the label.	 Top Door Spacer Label

11.0 ULTRASONIC SENSOR INSPECTION

11.1 Ensure the tape of the Ultrasonic Sensor is not torn, peeling or cut on the surface or corners. 11.2 Replace the Ultrasonic if tears or cuts exist.	 Damaged ultrasonic sensor tape

12.0 FORCE SENSOR DOWNSTREAM TUBING GUIDE INSPECTION

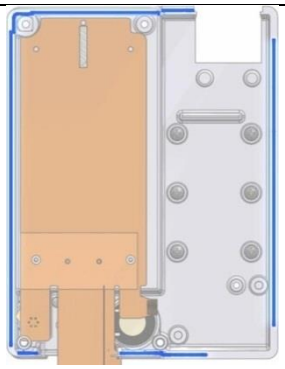
12.1 Ensure there is no glue on the head of the Downstream Thermistor. 12.2 Replace the Downstream sensor if glue is found.	 Good Downstream Thermistor head  Bad Downstream Thermistor head (Excess glue)
12.3 Inspect the Downstream Tubing Guide for cracks and breaks. 12.4 Replace the Downstream Tubing Guide if cracks or breaks exist.	

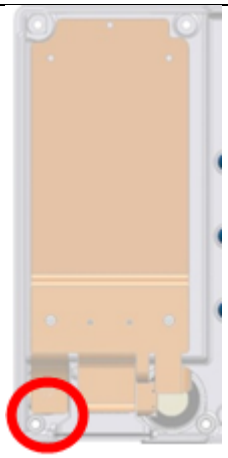
CAUTION: Use ESD precautionary procedures when handling outside a protective environment. This applies to all interior inspections.

13.0 KEYHOLE ASSEMBLY INSPECTION

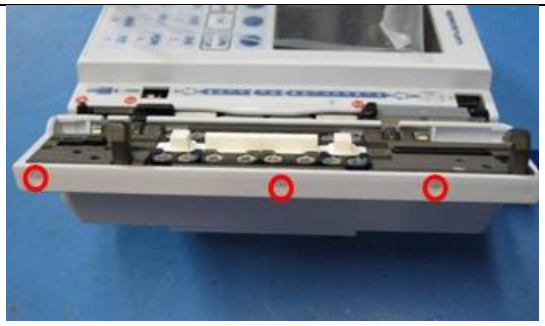
13.1 Inspect the Keyhole Assembly for cracks in the plastics. 13.2 Replace the Keyhole Assembly if cracks exist 13.3 Ensure all screws are installed and seated properly. 13.4 Replace the screws or Keyhole assembly as required.	 Crack in Keyhole Assembly	
13.5 Inspect the Keyhole Cup Label; ensure it is the latest Revision per DWG 35709. 13.6 Replace the Keyhole Assembly if Label requires replacement.	 Old revision labels (red, blue)	 New revision (silver)
13.7 Inspect the Keyhole Cup for debris or residue. 13.8 Clean the Keyhole Cup or replace Keyhole assembly as required.		

14.0 REAR CASE ASSEMBLY INSPECTION [Interior]

14.1 Inspect the screw holes and Tongue portion of Rear Case Plastic for chips and or breaks. 14.2 Discard the Rear Case if breaks or cracks in the plastic prevent proper case closing. 14.3 **Damaged tongue – Conditionally accept**, with the criteria as follows: if the damage does not impact case closing, the rear case is acceptable. A 0.016" feeler gauge can be used during final acceptance testing, to determine efficacy of case closing. 14.4 **Impression, screw through holes – Conditionally accept**, with the criteria as follows: if the damage does not impact case closing, the rear case is acceptable. A 0.016" feeler gauge can be used during final acceptance testing, to determine efficacy of case closing. 14.5 **Cracked PEM Boss (1 or 2) – Accept**. PEM Bosses are not customer facing and are not linked to any essential requirements/functions for the pump.	 Tongue portion of rear case plastic
14.6 Ensure all 6 Pump Side Adapter screws are present and seated properly. 14.7 **Cracks by screws for pump side adaptor – Accept**. Internal cracks did not affect essential requirement of Mount the LVP.	 Pump side power adaptor screws

14.8 Inspect the Backflex ASSY number. The numbers (35149) or (35149-1) will be on the top right corner of the Backflex. 14.8.1 If the ASSY is 35149 then inspect the REV letter. 14.8.1.1 If REV H, then inspect for jumper wire on the six pin connector. If wire is not there, then replace Rear Case. 14.8.1.2 If REV F, then replace the rear case assembly. 14.8.2 **Cracks on 6-pin mount. – Accept**. Interior cracks on the 6-pin mount do not adversely affect any pump requirement/function.	 Jumper wire location
14.9 Inspect the Back Flex tails (J1&J6) and six pin (J8) connector for breaks, tears or scratches. 14.10 **Abrasions on Back Flex – Reject**. Abrasions on the back flex could cause power-related symptoms. This could adversely affect essential requirements of Operate on AC Power and Operate on Battery Power. 14.11 Rework or replace the Rear Case/Backflex as required.	
14.12 Ensure the following are secure without cracks or breaks: 14.12.1 Speaker (Speaker Boss) 14.12.2 O-Ring (if present) 14.13 Rework or replace the Rear Case as required.	
14.14 Ensure nylon screws are installed to attach scanner bracket, if scanner bracket is present. Replace steel screws with nylon screws if not present.	
14.15 Idendifiing a rear case with a 0.5 watt speaker. 14.15.1 Notice the raised boss of the 1.0 watt speaker. 14.15.2 Any rear cases without a scanner window will have the 1.0 watt speaker.	 Rear case with 0.5 Watt Speaker installed  Rear case with 1.0 Watt Speaker installed

15.0 DOOR COVER INSPECTION

15.1 If attached to the door, ensure the (3) nylon screws along the edge of the door are present and secured flush. 15.2 Replace nylon screw if required. If Screw is found broken, then remove the door cover and broken screw per SWI 107.	 Nylon screws on edge of door
15.3 The Door Cover must have ribs on the interior, hinge side, per ECN 18707. 15.4 Replace Door Cover if ribs are not present.	 Door Cover ribs
15.5 The Door Cover must be free of cracks and breaks. 15.6 Replace if cracks or breaks exist.	

16.0 MECHANISM DOOR AND DOOR COMPONENTS INSPECTION

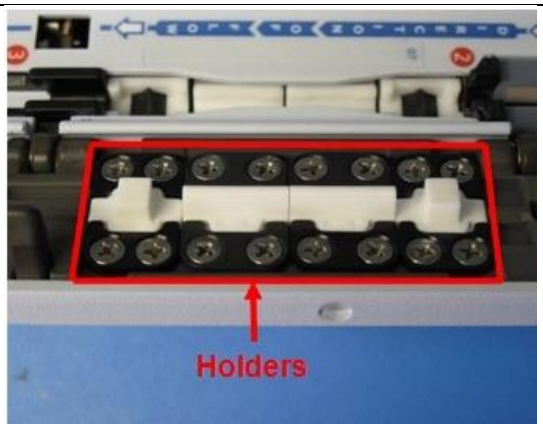
16.1 Insert the appropriate slide clamp into the keyhole assembly. Door must open completely and without delay, when slide clamp is pressed.

16.2 Any delay or failure to open must be evaluated and repaired as required.

Pump with door open

16.3 All (16) Pressure Plate Holder screws must be present and installed securely.

16.4 Finger and Valve pressure plates must be free of breaks and cracks.



Pressure plate holders

16.5 Inspect the Pressure Plate Holders for:

16.5.1 Cracks

16.5.2 Breaks

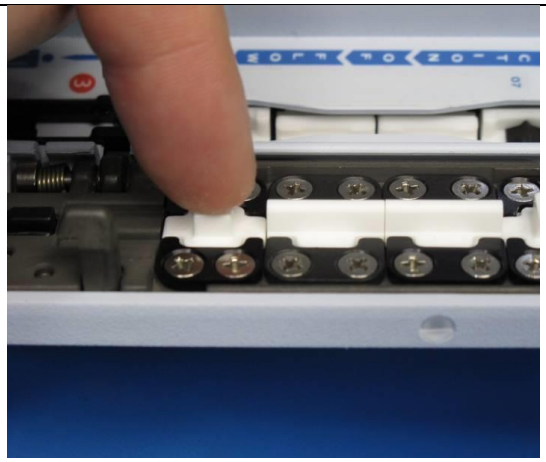
16.5.3 Consistent Type and Color

16.6 Replace Holders and/or screws as required.

All holders the same color (gray)

All holders the same color (black)

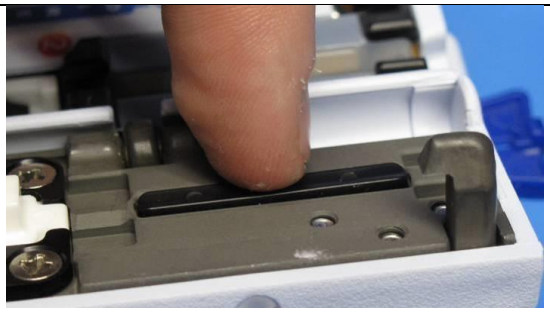
Release Status : Issued and Effective

16.7 Depress the Valve Pressure Plates and Finger Pressure Plates multiple times to ensure they move freely. 16.7.1 If any Valve or Finger Pressure Plates fail to move, then rework or replace the Valve/Finger pressure plates.	 Depressing a valve pressure plate

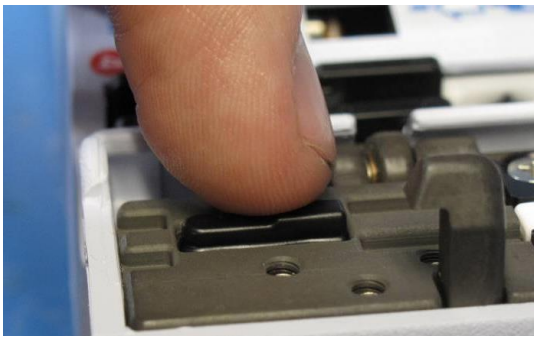
16.8 Inspect the Upstream and Downstream pushers by:

- 16.8.1 Ensuring they are in place and secure
- 16.8.2 The screws securing the pushers shall NOT protrude above the pusher.
- 16.8.3 Pusher should not have any abnormalities.

16.9 Replace one or both of the pushers if the above criteria are not met.

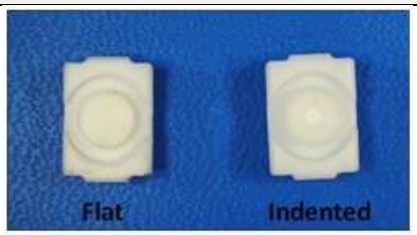


Upstream Pusher

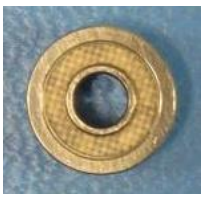


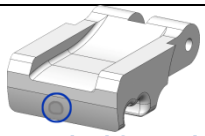
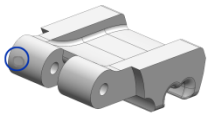
Downstream Pusher

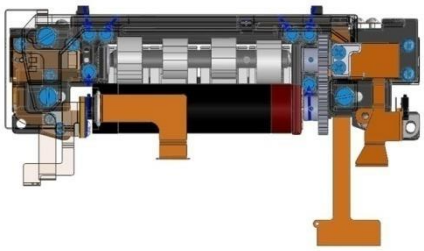
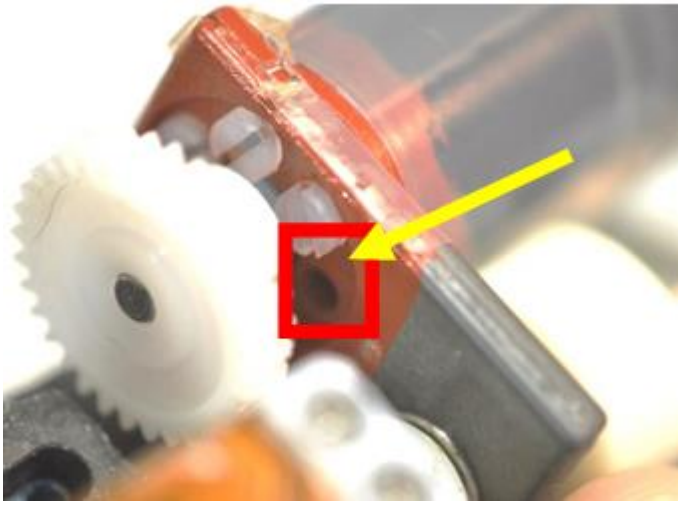
Dimpled downstream pusher

16.10 Inspect the Hooks for: 16.10.1 Six screws are present and flush 16.10.2 Breaks, bends and/or cracks 16.11 Replace the screws or Hooks as required	
16.12 Inspect the Pressure plates for indentation on the backside. 16.13 Replace all Pressure Plates where the indent does NOT exist.	 Comparison of flat and indented pressure plates

17.0 POPULATED FRONT CASE INSPECTION

17.1 Inspect lower Bearing to verify sealed bearings (55139) are installed on the mechanism assembly. 17.2 If Sealed Bearings (55139) are not installed, then replace the bearings and lower bearing mount.	 Lower Bearing  Old bearing without seal around inner race. NOTE: DO NOT USE  Sealed bearing with white Teflon seal around inner race .

17.3 Inspect Fingers. 17.4 If the fingers are not molded, replace them with PN 45714-3 or newer.	 Gate marked for molded	 Gate marked for machined

17.5 Inspect the following mechanism hardware (Blue), to ensure they are installed completely and securely: 17.5.1 Ultrasonic Sensor screws (2) 17.5.2 Upper Aux bracket screws (2) 17.5.3 Upper Bearing Mount Screws (3) 17.5.4 Gear Set Screws (4) 17.5.5 Link screws (3) 17.5.6 Lower Bearing Mount Screws (3) 17.5.7 Force Sensor screws (3)	 Mechanism Hardware highlighted in blue
17.6 Inspect the nylon cheesehead screws holding the motor to the Upper Bearing Mount. The nylon screws must be present and fully installed. 17.6.1 Replace any missing or broken screws.	 Example of broken/missing motor screw

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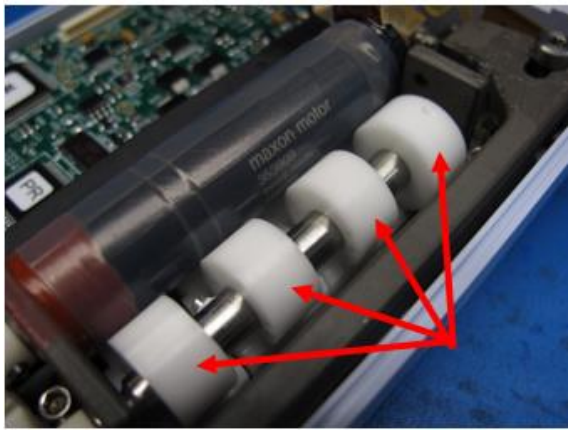
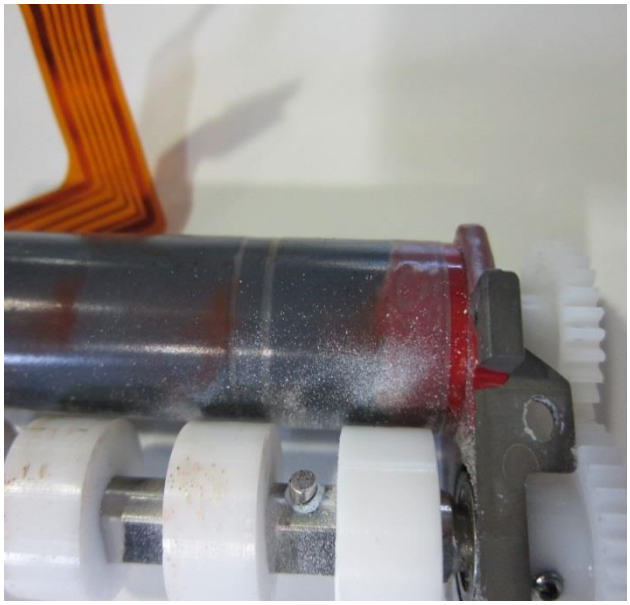
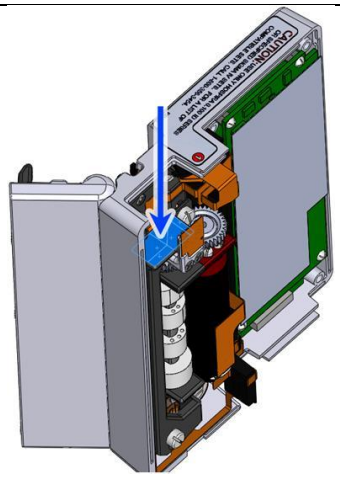
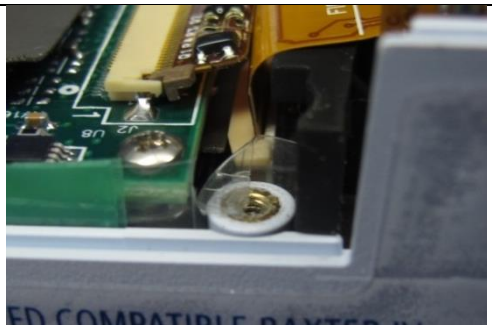
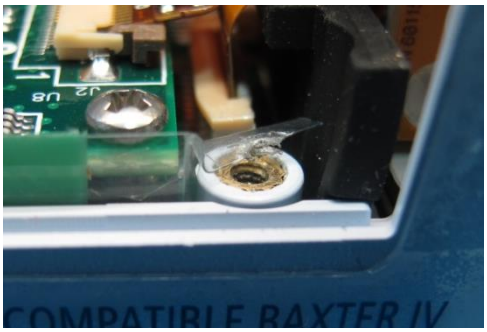
17.7 Inspect the Gears using light pressure to ensure they do not move on the cam shaft or motor shaft. 17.8 Verify that the gears: 17.8.1 Rotate freely. 17.8.2 Are not missing teeth. 17.8.3 Are not missing the set screws. 17.9 Replace any damaged or loose gears. Investigate if Fingers and/or Valves fail to move freely.	
17.10 Inspect the Cam Shaft Assembly for the following: 17.10.1 The Cam Shaft and Cam lobes shall rotate with gear rotation. 17.10.2 Magnet is securely on the Cam Shaft 17.10.3 Ensure Dow Corning 111 is applied to the entire surface of ALL FOUR Cam lobes. 17.10.3.1 If Dow Corning 111 is not present on Cam lobes, replace gears, bearings, Cam Shaft Assembly, fingers and valves.	 Example: Grease must be applied to the following locations. Picture illustrates no grease is present.

17.11 Inspect the Cam Lobes for deterioration. 17.11.1 White particulate from the Cam lobes is evidence of detrioration. 17.11.2 Cracks are also unacceptable. 17.12 Replace affected components as necessary.	 **Figure 56: Cam shaft with white particulate from cam lobes (Replace affected components).**
17.13 Inspect the following flexes for tears, breaks and other damage. 17.13.1 Upper Aux Flex 17.13.2 Ultrasonic Flex 17.13.3 Motor Flex 17.13.4 Keypad Flex 17.13.5 Lower Aux Flex 17.13.6 Force Sensor Flex 17.14 Replace any component with a damaged flex.	
17.15 Inspect the Color Sensor Bracket to ensure it is not: 17.15.1 Bent 17.15.1.1 Pressing on the gear. 17.15.1.2 Interfering with keyhole installation.. 17.16 Replace the Upper Aux if the Color Sensor Bracket is bent or broken.	

17.17 Inspect for lateral movement of the cam shaft. 17.18 If lateral movement does not exist, then replace determine the cause and replace the associated component.	 Motor assembly with axial play noted
17.19 Press on the link to ensure it moves freely and the door opens. 17.19.1 Rework as required if link does not move freely, or door does not open.	 Top of link highlighted blue
17.20 If present, inspect the ESD Barrier for: 17.20.1 Cracks 17.20.2 Breaks 17.20.3 Crushed areas 17.21 Replace if Cracks, Breaks or if the barrier is crushed.	 Cracked ESD Barrier  Crushed ESD Barrier

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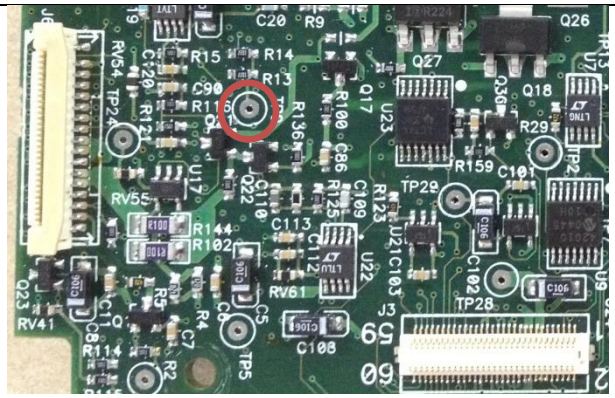
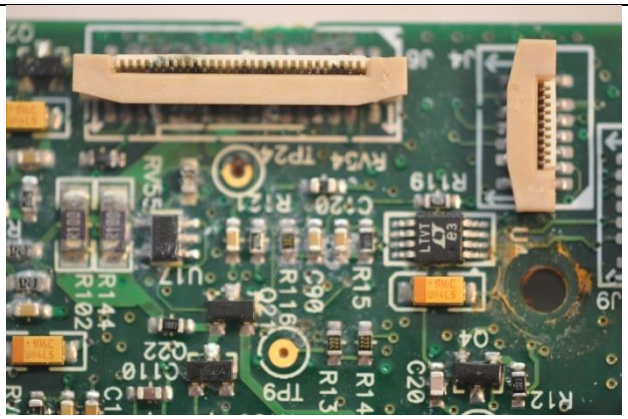
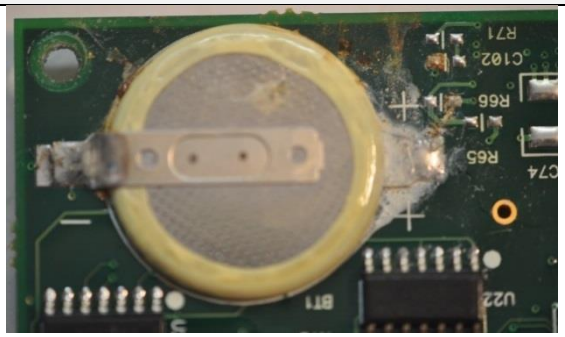
17.22 Inspect the I/O Board for Silver test points (TP*x*). 17.23 Replace the I/O Board if Silver test points exist.	 I/O Board containing silver test points
17.24 Inspect all visible areas for signs of water marks, corrosion. 17.25 If water marks, corrosion and/or residue exist, then remove the Processor Board and I/O Board from the Front case and inspect further.	 I/O Board with corrosion

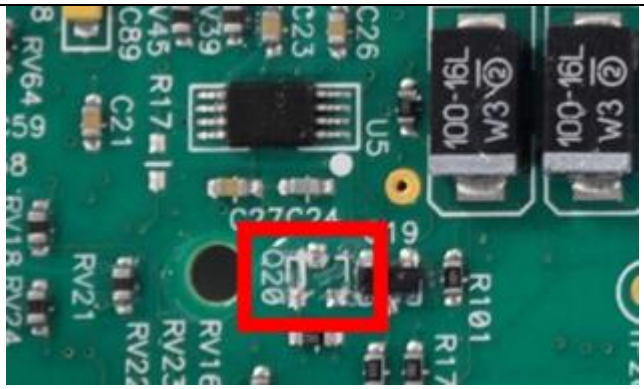
18.0 PROCESSOR BOARD INSPECTION

18.1 Inspect the Processor Board for Shielding. Shielding dependent on Rev. of I/O Board. If revision of the I/O Board is at a revision level K or higher, ensure shielding material is installed to the I/O and Processor Boards. 18.2 Install Shielding as required.	
18.3 Inspect the board for signs of fluid intrusion, water marks, corrosion and/or residue. 18.4 Replace boards containing water marks, corrosion and/or residue.	 Figure 64: Processor Board with corrosion
18.5 Inspect for broken, damaged or missing components.	

19.0 SEALING WALL INSPECTION

19.1 Replace the sealing wall if: 19.1.1 Tears are found 19.1.2 Sealing wall is missing 19.1.3 If a Rear Case that contains a 0.5 watt speaker is replaced.	

20.0 I/O BOARD/DISPLAY INSPECTION

20.1 See POPULATED FRONT CASE INSPECTION for additional inspection criteria.	
20.2 Inspect the board for signs of fluid intrusion, water marks, corrosion and/or residue. 20.3 Replace board / Display containing water marks, corrosion and/or residue.	 Display with rust caused by fluid intrusion
20.4 Inspect for broken, damaged or missing components.	 I/O Board with missing Q20
20.5 Inspect the Display for cracks, breaks and/or stains on the screen. 20.6 Replace or clean the Display as required.	 Display with I/O Board attached

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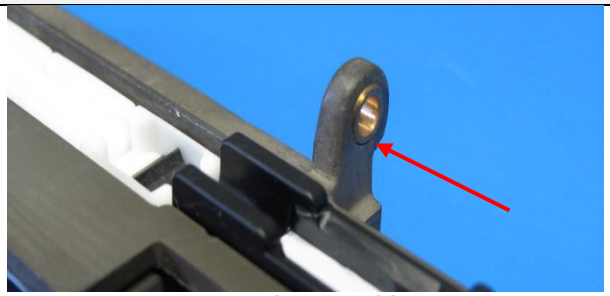
21.0 MECHANISM INSPECTION

21.1 Perform all mechanism related inspection per the Populated Front Case inspection along with the below inspections.	
21.2 Inspect the front panel for cracks and breaks. Inspection area should include: 21.2.1 The ears (hinge) of the front panel 21.2.2 The face of the front panel 21.3 Replace the Mechanism Sub Assembly if Cracks or breaks exist.	
21.4 Ensure the Hinge Bushings intact. 21.5 Replace the Mechanism Sub Assembly if Hinge Bushings are not intact or loose.	 Intact Hinge Bushing
21.6 Inspect the Front Panel for two dots next to the bottom of the Downstream Tubing Guide. 21.6.1 Mechanisms that contain these dots cannot fit the latest revision. Downstream Tubing Guide. 21.7 If tubing guide replacement is required, replace the Mechanism sub-assembly.	 Mechanism with 2 dots present

22.0 FRONT CASE INTERNAL INSPECTION (Reference Appendix A for more information)

22.1 Inspect the Mechanism mounting PEMS of the Front Case:

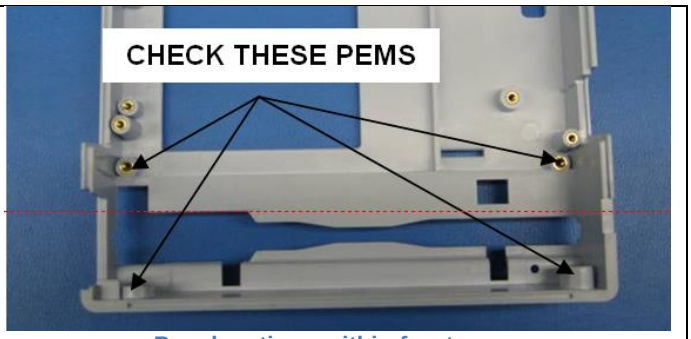
- 22.1.1 PEMS shall be in place and secure
- 22.1.2 PEM Boss shall be free of cracks that cause the PEM insert to become loose.

22.2 Replace the Front Case if PEMS are not secure or missing.

22.3 If unsure whether cracked boss affects security of PEM, this can be checked with an installed mechanism by attempting to close the door with a fluid-filled set.

- 22.3.1 If the door can close with the fluid filled set, the case will not require replacement for the Mech Mounting PEM Boss crack.

22.4 **Cracked PEM Boss (Mechanism Installation) – Conditionally Accept**, with the condition as follows: if the Mechanism is able to be lifted from the front case, the front case must be replaced for the brass insert moving freely. This is a like symptom to failure to install mechanism mounting screw, which may cause issues related to door closing. If the mechanism is firmly secured to the front case PEMs and the door can close, fully engaging the switches, no replacement is required. This can be tested by loading a fluid filled set and closing the door.



Pem locations within front case

22.5 **Cracked PEM Boss (I/O Board Installation) – Conditionally Accept**, with the condition as follows: if the I/O PCB is able to be lifted from the front case, the front case must be replaced for the brass insert moving freely. There is no associated failure mode with this defect.

22.6 **Cracked PEM Boss (Case Closing) – Conditionally Accept**, with the criteria as follows: if the damage does not impact case closing, the rear case is acceptable. A 0.016" feeler gauge can be used per ITP 35716-SVC to determine efficacy of case closing. Upon opening case halves, if the front case PEMs are moving freely from the boss, the case must be replaced as well.	
22.7 Ensure the Front Case Display Gasket is intact. 22.8 Replace the Display Gasket if affects visibility within the display.	
22.9 The Front Case shall be free of residue. 22.10 Clean as required per SWI107.	

23.0 Case Halves Visual Inspection Study Reference

23.1 ET 35700-016 was performed to collect examples of parts discarded for visual inspection criteria.

Baxter

TcU ELECTRONIC SIGNATURE REPORT

REVISION INFORMATION

Item ID: ITP 35022-SVC	**Revision ID:** D
Item Name: Visual Component Inspection of a Spectrum Infusion Pump	**Release Date:** 26-Apr-2018
Description:	

CHANGE INFORMATION

CN/CR Number (if applicable): PR 1410747

Description of Change (This field will be blank if required data is not available):
Close gaps that were identified during procedure compliance review.

Reason for Change (This field will be blank if required data is not available):
Updates being made per PA PR 1411246.

APPROVALS & SIGNATURES for Document Release

Name	Role	Workflow Step	Date of Signature	Decision Taken
Rathinavelu, Barkhavi	Author	Initiate Review	17-Apr-2018	Approved
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