
Urgent Field Safety Notice

Subject: Progressa™ Bed Mattress—CLRT and Turn Assist Correction

FCA-identifier: Mod 1220

Type of action: Device Modification

Date:

To: Hill-Rom Authorized Distributor

Affected Devices: Progressa™ Bed Mattress

Models Affected: P7520A3, P7520A7, P7520A11, P7520A15, P7520A19, P7520A21, P7520A22S, P7520A23, P7520A24S, P7520A31, P7520A39, P7520A47

Models **NOT Affected:** P7520A1, P7520A2S, P7520A4S, P7520A5, P7520A6, P7520A8, P7520A9, P7520A13, P7520A17, P7520A18, P7520A20, P7520A22, P7520A24, P7520A25, P7520A28, P7520A29, P7520A30, P7520A32, P7520A33, P7520A35, P7520A37, P7520A41, P7520A43, P7520A45

Production Dates: prior to February 7, 2014

Background:

Hill-Rom has become aware that some models of Progressa™ bed mattresses have a potential to not operate according to design specifications, therefore we are issuing a field corrective action to be taken on units in the field.

Action to be taken:

Please forward the applicable language translation of the English version customer letter 181396 (attached) to your accounts that have affected product. Other languages are available from Hill-Rom. Please contact your Hill-Rom representative to receive the required translated copy of the customer letter.

Note that the customer letter indicates that Hill-Rom will visit the customer's facility to modify their units. We are expecting you to take on that role according to the terms of your contract.

Please work with your retrofit coordinator as needed during this correction. Parts will be sent to you as they are available, and we expect all parts to be shipped by the end of July. Please be aware that the instructions needed for completing the field correction have also been translated and can be ordered. If required, indicate the languages needed for the instruction sets. The English versions of the instructions are attached here.

Due to some data missing from the database, the following should be used to help you determine which units/models will need to have which correction.



The following mattress models will **only need the bladder replacement**: Use the *Progressa® Bed—Turn Assist Bladder Replacement Instructions* for the bladder sense line issue.

- P7520A3
 - P7520A7
 - P7520A11
 - P7520A15
-

The following mattress models will **only need the software upgrade**: Use the *Progressa® Bed—Software Upgrade Instructions* to upgrade affected beds' software.

- P7520A21
 - P7520A22S
-

The following mattress models **may need both** the bladder replacement and software upgrade (if they fall in the applicable date range as defined below):

- P7520A19
 - P7520A23
 - P7520A24S
 - P7520A31
 - P7520A39
 - P7520A47
-

The following mattress models **do not need either** modification:

- P7520A1
 - P7520A2S
 - P7520A4S
 - P7520A5
 - P7520A6
 - P7520A8
 - P7520A9
 - P7520A13
 - P7520A17
 - P7520A18
 - P7520A20
 - P7520A22
 - P7520A24
 - P7520A25
 - P7520A28
 - P7520A29
 - P7520A30
 - P7520A32
 - P7520A33
 - P7520A35
 - P7520A37
 - P7520A41
 - P7520A43
 - P7520A45
-

The following **guidelines** are to be used **for identifying** units to be modified:

- For **bladder** replacement units: production dates up to and including 06-Feb-2014 or serial numbers up to and including P037MW5939.
- For **software** upgrade units: production dates up to and including 11-Nov-2013 or serial numbers up to and including 0315MWxxxx.

NOTE: If the serial number in the database is missing or erroneous you will have to refer to the date of manufacture on the mattress tag.

Timing:

- For the **software** correction the parts **are available** at this time.
- For the **bladder** replacement, **supply is limited** and will be limited until July 31, 2014. You may receive fewer units than are needed in the beginning to allow us to supply multiple regions with parts. Please **coordinate the orders and shipment of parts with your Hill-Rom Representative**.

Contact reference person:

If you have any questions concerning this request or the procedure as outlined, please contact your local retrofit coordinator.

Regards,

Hill-Rom Technical Support

Attachment: 181396 REV 1 (or applicable translation), 181397 REV 1, 184589 REV 1

Urgent Field Safety Notice

Subject: Progressa™ Bed Mattress—CLRT and Turn Assist Correction

FCA-identifier: Mod 1220

Type of action: Device Modification

Date:

To: Chief Executive, Facility Risk Manager, Facility Administrator, Facility Engineer, Vigilance Manager, Biomedical Engineering, Medical Device Liaison Officer

Affected Devices: Progressa™ Bed Mattress

Models Affected: P7520A3, P7520A7, P7520A11, P7520A15, P7520A19, P7520A21, P7520A22S, P7520A23, P7520A24S, P7520A31, P7520A39, P7520A47

Models NOT Affected: P7520A1, P7520A2S, P7520A4S, P7520A5, P7520A6, P7520A8, P7520A9, P7520A13, P7520A17, P7520A18, P7520A20, P7520A22, P7520A24, P7520A25, P7520A28, P7520A29, P7520A30, P7520A32, P7520A33, P7520A35, P7520A37, P7520A41, P7520A43, P7520A45

Production Dates: prior to February 7, 2014

Background:

Hill-Rom has become aware that certain Progressa™ bed mattresses may have potential for an error to occur during Turn Assist mode. An error code 31C9 may be displayed on the graphical user interface and the wrench light will turn on indicating service required. The 31C9 error means the Turn Assist bladder is unable to hold the required pressure to operate as intended.

This seems to occur more frequently with higher weight patients (136+ kg / 300+ lb) who are very immobile, and when the head section of the bed is set at 30 degrees or higher. These conditions can cause air to be trapped in a sense line within the mattress causing the error.

Another potential issue can occur when exiting Continuous Lateral Rotation Therapy (CLRT). If the caregiver selects the “stop therapies” function during the centering mode of the CLRT (approximately a 10-second window), the software may begin to inflate and deflate the left Turn Assist bladder every two to three minutes. There is no indication that the bed/mattress is not functioning properly other than the left Turn Assist bladder continues to inflate and deflate every two to three minutes.

Hill-Rom has evaluated the above two issues and has determined that it is not likely for either issue to cause an adverse health consequence.

Action to be taken:

You may continue to use your bed/mattress until Hill-Rom or a designee visits your facility to update your affected bed/mattress with either a software update, a mattress repair, or both depending upon the model of integrated surface you have installed. The software update will require approximately 15 minutes per bed/mattress, and the mattress repair requires approximately 35 minutes per unit. The bed must be unoccupied for the mattress repair.



If you encounter the 31C9 error, readjust the patient on the mattress surface and then cycle the power of the bed to reset the system by unplugging and plugging in the power cord.

If you notice that the Left Turn Assist is unintentionally inflating and deflating every two to three minutes, the Caregiver can select another therapy mode (other than normal), or cycle the power to the bed by unplugging and plugging in the power cord.

Please complete and **return the attached Customer Response Form/Receipt** within 30 days.

NOTE: When our technicians visit they will have information to help determine which specific units are affected at your facility, so you do **not** need to search for them. However, if needed, the mattress date of manufacture, model, and serial number are on the tags attached to the head end of the mattress.



Important: The *Customer Response Form/Receipt* provides Hill-Rom with the means to monitor the progress of Field Corrective Actions. It is imperative that you return this form/receipt for our records.

Transmission of this Field Safety Notice:

Please pass this notice on to all those who need to be aware within your organization and/or to any organization where the affected devices have been transferred.

Please maintain awareness of this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.

Hill-Rom confirms that the relevant Competent Authorities have been informed of this Field Safety Corrective Action.

Contact reference person:

If you have any questions concerning this Urgent Field Safety Notice, please contact Hill-Rom Technical Support, your Distributor, or your Hill-Rom Representative.

Regards,

Hill-Rom Technical Support

Attachment: Customer Response Form/Receipt



Customer Response Form/Receipt

Subject: Progressa™ Bed Mattress—CLRT and Turn Assist Correction (Mod 1220)

It is imperative that you return this form/receipt for our records.

Please complete and **return this form/receipt within 30 days.** See specific instructions at bottom of page. Thank you.

Hill-Rom account number: _____

Name of the facility: _____

Address of the facility: _____

City: _____ State: _____ Zip: _____

Facility Authorized Name: _____

Please print legibly

Signature: _____ Date: ____/____/____

Title: _____ Phone: _____

Email: _____ Fax: _____

Check applicable box(es):

We acknowledge receipt of this notification and it has been forwarded to all users.

Other: _____

Return this form to:



Subject: Progressa™ Bed—Turn Assist Bladder Replacement Instructions

Tools required: Window cleaner
Rags
Side cutters

Parts required: (1) 185440 Service Kit, TA Bladder Assembly
kit contains:
(4) 0010080019 Rivet, snap, female
(4) 0010080021 Rivet, snap, male
(1) 170004 Seat turn assist bladder assy
(2) 185425 Coupler, barbed, reducer, 6.35–3.18
(2) 66262 Fitting, .375" x .375", barbed

Reference Documents: *Progressa™¹ Bed System Service Manual (171748)*

Removal & Replacement



WARNING:

Failure to set the brakes could cause injury or equipment damage.



CAUTION:

Use care when you disconnect the hose from the fittings. Excessive force can damage the fitting.

In these procedures, you will need to disconnect hoses from the bladder fittings. Use care when you do this. For easier disconnection, put the wire cutters between the fittings and hose, then wiggle the wire cutters back and forth to loosen the hose enough for easy removal.

1. Make sure there is no patient on the bed.
2. Set the brakes.
3. Raise the bed to a comfortable working height.
4. Remove linens from the mattress.
5. Unzip the MCM® topper to disconnect the two hoses at the foot end to the topper.
6. Remove the MCM® topper.
7. Unzip and remove the top ticking.
8. Pull the fire barrier down to the seat/foot section to expose the seat section.
9. Use the GCI to activate Seat Deflate.

NOTE:

The seat will remain deflated for 30 minutes.

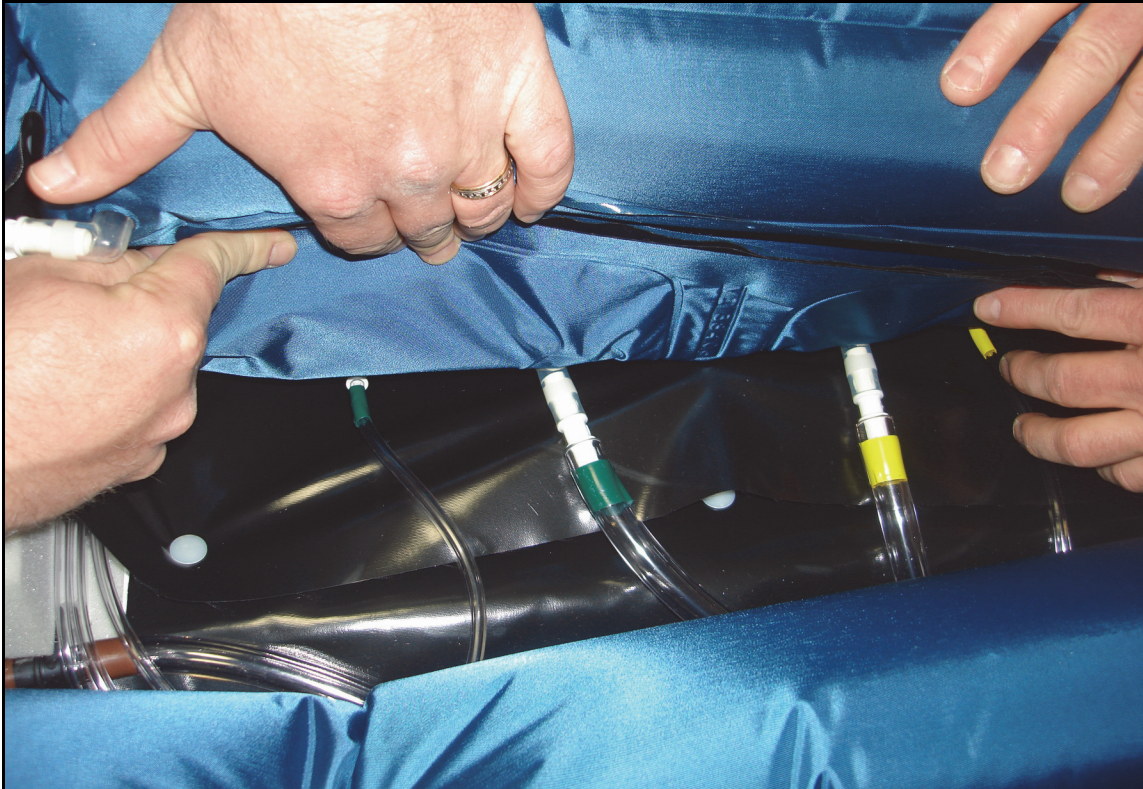
1. Progressa™ is a trademark and MCM® a registered trademark of Hill-Rom Services, Inc.

10. Pull the seat section away from the foot section to view the lower bladders (see figure 1 on page 2).

NOTE:

The area shown in the photo below is aligned approximately at the foot end of the intermediate siderail.

Figure 1. View of Turn Assist Bladder



11. Remove and DISCARD the four snaps (2 on outer sides, 2 upper and lower middle) that attach the turn assist bladder to the substrate.
12. Slide the turn assist bladder out from under the support cushion, flip it over and onto the foot section (see figure 2 on page 3).
13. Disconnect the two fill hoses and two smaller sense lines from the couplers.
14. Remove and DISCARD the turn assist bladder.
15. Place the new turn assist bladder (marked **Rev 4**) from the kit onto the foot section in the same orientation.

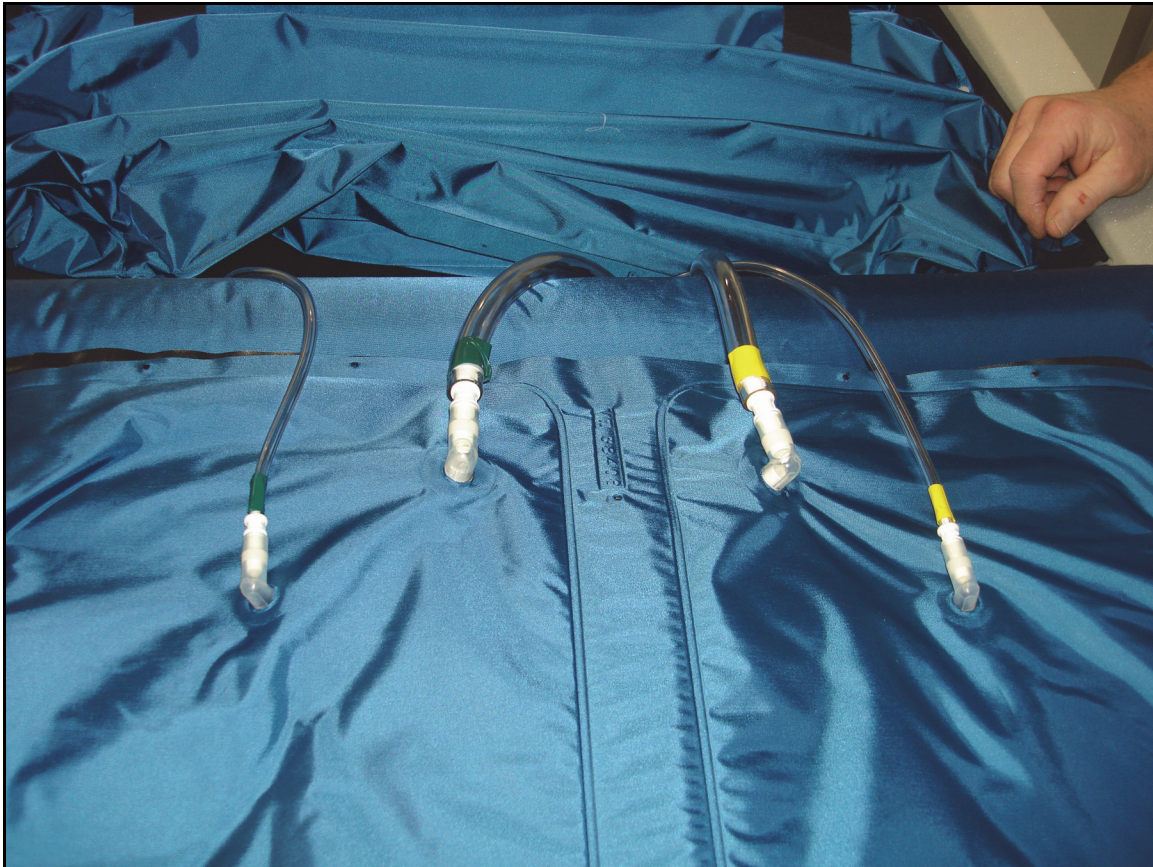


NOTE:

For the following steps, to assist installation use window cleaner to moisten the couplers.

16. Install two 3/8-to-3/8 couplers onto the center ports.
17. Install two 1/4-to-1/8 couplers onto the outer ports.

Figure 2. From Foot End: New Bladder Turned over onto Foot Section



18. Lightly spray the ends of the fittings with window cleaner.
19. Attach the fill and sense hoses to the couplers (GREEN = patient right; YELLOW = patient left).
20. Flip the new bladder over and reposition it under the support cushion as before. Make sure the sense hoses run under the bottom.

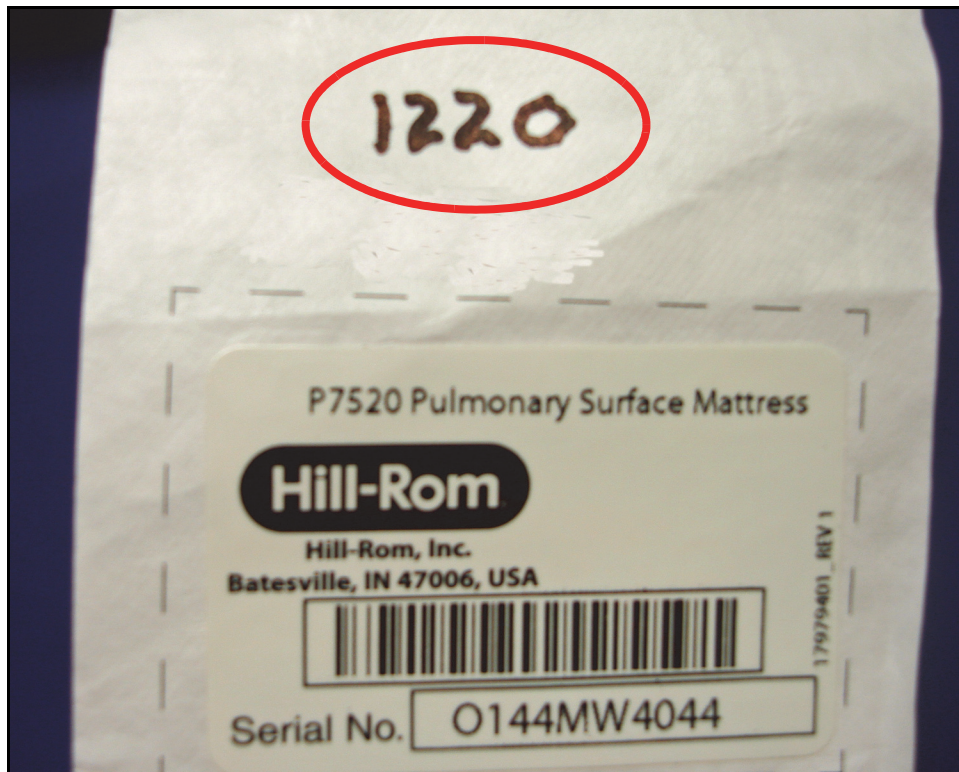
NOTE:

When the new bladder is replaced under the support cushion, the **REV 4** marking should show on the top end.

21. Install four NEW snaps to replace the ones that were removed earlier.
22. Attach the cushion to the substrate.
23. Make sure the straps are properly aligned over each side of the top bladders.



24. At the GCI, do as follows:
 - a. Disable Seat Deflate.
 - b. In Normal mode, run the Turn Assist function for both sides, and verify that they operate correctly.
 - c. While each side is inflated, go into the Service menu, select Surface Service/Bladder Pressure and monitor the pressure to check for leaks.
25. After you are sure everything is working as designed, replace the fire barrier, ticking, and topper.
26. At the head end of the mattress, find the serial number tag. Use a permanent marker to write **1220** on the tag. This will verify that the mod has been completed for future reference.



Progressa™ Bed—Software Upgrade Instructions

Tools: T15 Torx®¹ screwdriver

Parts required: (1) 184607 REV 1 USB flash drive with software

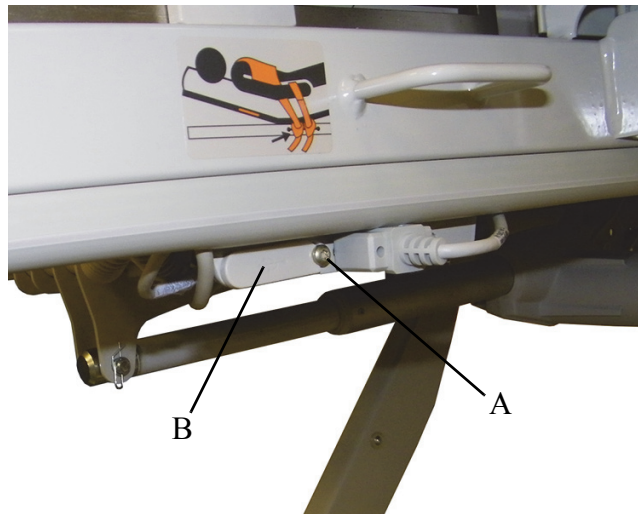
Reference Documents: *Progressa™² Bed Service Manual* (171748)

NOTE:

Updating the GCI application will reset all patient data on the bed.

1. Raise the bed to the full up position.
2. Make sure the brakes are set.
3. Make sure the patient is not on the bed.
4. Make sure the bed is connected to AC power.
5. Make sure the GCI is active.
6. On the patient-right side of the bed, next to the pendant connector, remove the screw (A) and USB connector cover (B) (see figure 1 on page 1).

Figure 1. USB Connector



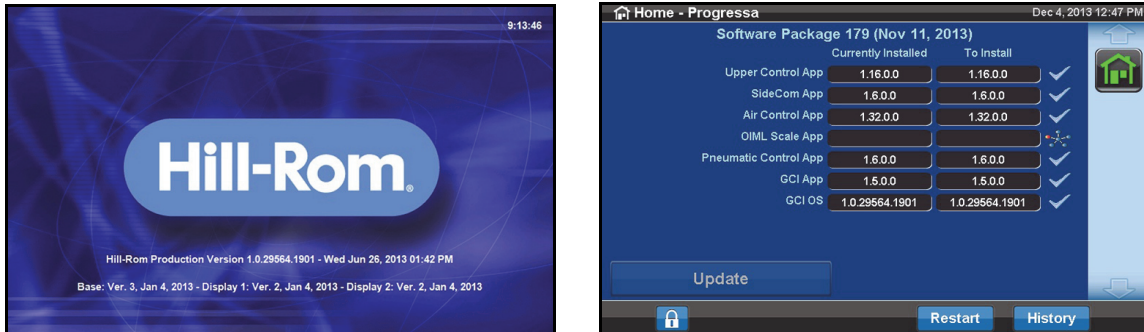
7. Insert the flash drive in to the USB port:
 - After approximately 1 minute, the Hill-Rom logo screen will show (see figure 2 on page 2).
 - After approximately 2 minutes, the Update screen will show.

1. Torx® is a registered trademark of Acument Intellectual Properties, LLC.

2. Progressa™ is a trademark of Hill-Rom Services, Inc.

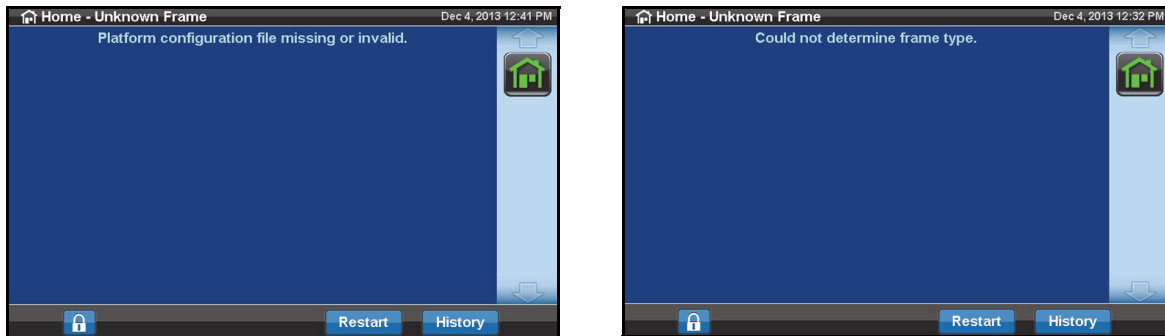


Figure 2. Logo and Update Screen



8. If an error shows on the GCI, press the **Restart** button (see figure 3 on page 2).

Figure 3. Error Screens



Configuration Error

Frame Type Error











9. Press the **Home Screen** button (see figure 4 on page 3).

Figure 4. Update Home Screen



10. The screen will show the software that needs updated (see figure 5 on page 3).

Figure 5. Software Update Identification

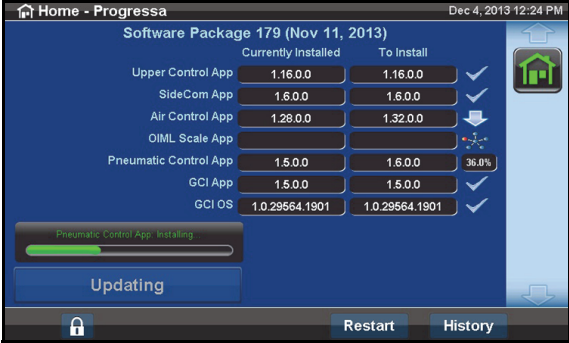
-  Firmware/software update not required.
-  Firmware/software update required.
-  Firmware/software update required. Hardware switch disables the updates.
-  Firmware/software update required. P.C. board in bootloader mode.
-  P.C. board was not located on the CAN network.
-  Firmware/software for the P.C. board is missing on the USB device.
-  Firmware/software on USB device is not compatible with the P.C. board.
-  Firmware/software installation for the P.C. board failed.

11. If the OIML Scale App is being updated, get access to the scale board and set switch 1 on dip switch SW4 to the **ON** position. See “Scale Board—NAWI Compliant (EN 45501)” in the service manual.



- 12. Press the **Update** button, the screen shows the progress of the update (see figure 6 on page 4).

Figure 6. Software Update In Process

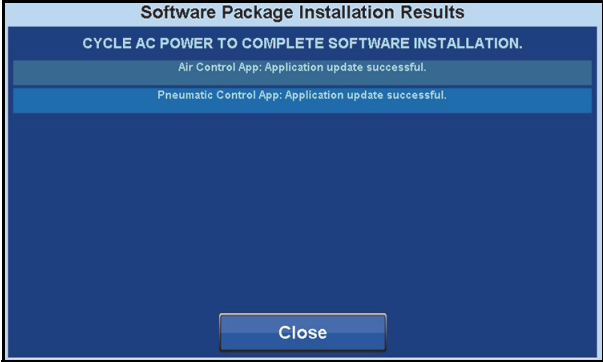


NOTE:

It may take up to 10 minutes to update the software and any bed restarts.

- 13. After the updates are finished, the screen will show the software that was updated (see figure 7 on page 4)

Figure 7. Installation Results



- 14. Press the **Close** button to exit the screen.
- 15. Make sure the software version shown on the GCI matches the software version on the USB flash drive (see figure 8 on page 5).



Figure 8. Software Version

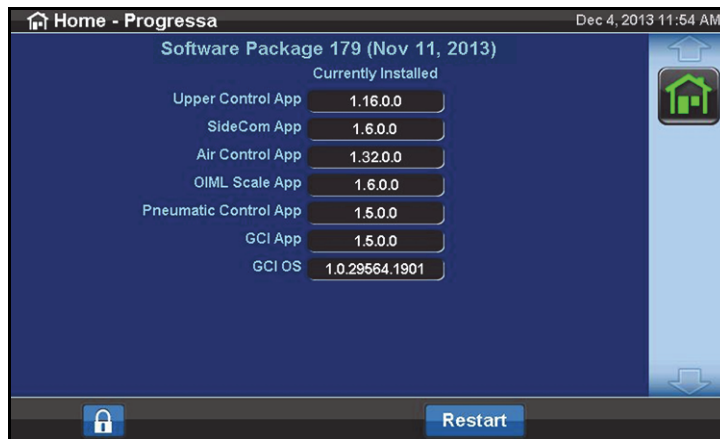


Table 1: USB Flash Drive Software

Location	Version
Upper Control App	1.16.0.0
SideCom App	1.6.0.0
Air Control App	1.32.0.0
OIML Scale App	1.6.0.0
Pneumatic Control App	1.6.0.0
GCI App	1.5.0.0
GCI OS	1.0.29564.1901

16. If software fails to install, an icon on the GCI will show next to the failed application (see figure 9 on page 5).

Figure 9. Software Failure to Install



17. If the software failed to update, press **Update** to start again. If the software fails to install a second time, contact Hill-Rom Technical Support.
18. Disconnect the bed from AC power.
19. Remove the flash drive.
20. Install the USB connector cover (B) and screw (A) (see figure 1 on page 1).
21. Connect the bed to AC power.
22. If you did step 11, set switch 1 on dip switch SW4 to **OFF** and calibrate the scale. See “Scale Calibration—EN45501 Class Scale” in the service manual.
23. Do the “Function Checks” in the service manual.



NOTES:
