SERVICE MANUAL, PREVENTIVE MAINTENANCE, 3850/51/55 and 3860+/61/65 MRIDUIUM INFUSION PUMP

INTRODUCTION

This section contains preventive maintenance instructions, service mode operating procedures, troubleshooting routines, disassembly and reassembly procedures, and comprehensive operational performance tests for the MRidium 3850/3860+, 3851/3861 and 3855/3865 Pumps and accessories. Please refer to Section 5 of the 1125 Service Manual for drawings and exploded views of the various assemblies, components, and PCB’s.

CAUTION

Printed circuit board assemblies (PCBA’s) are easily damaged when integrated circuits are removed and replaced. Excessive heat applied to the circuit board, traces, or pads can cause de-lamination of the metal foil and base material. Damage of that type is essentially irreparable; therefore, only low-temperature soldering irons and vacuum solder removal tools should be used when removing and replacing components on PCBA’s. Leads on integrated circuit components should be cut before attempting to un-solder and remove.

1.0 Preventive Maintenance

The MRidium 3850/3860+ Infusion Pump/Controller, 3851/3861 Sidecar Secondary Pump, and 3855/3865 Remote Display/Charger are designed and assembled with the goal of minimizing maintenance requirements. The integral microprocessor of the 3860+ incorporates a diagnostic routine that monitors the instrument’s subsystems and operating parameters. Detection of operating system irregularities or failures that affect the instrument’s functional operation activates audio and visual Alarms or Malfunction Alerts for operator notification. Problems of this nature are recorded in the non-volatile RAM history log for subsequent use by technical personnel in performing troubleshooting and repair actions.

Maintenance-free operation between regularly scheduled Preventive Maintenance (PM) inspections can be enhanced by performing routine cleaning on an “as required basis”. The recommended interval for PM inspections is annually based on normal use and operation. Verification of Proper instrument operation is the responsibility of the user. At the user’s discretion, routine testing and verification may be performed at the factory for a nominal cost. The following paragraphs describe in detail the procedures for performing general maintenance requirements on the MRidium 3850/3860+, 3851/3861, and 3855/3865.

PM may be performed with the “basic” tools listed in section 1.2. Should a PM reveal issues requiring further service steps, more tools may be required. Additionally, a review and understanding of Section 1 of the Service Manual should accompany the instructions of this PM Section.
1.1 Cleaning Instructions

**CAUTION**

DO NOT spray the instrument with any fluids. DO NOT immerse or place the instrument in any fluids. Always unplug the DC power cable prior to cleaning. DO NOT attempt to sterilize with Ethylene Oxide gas, head steam, radiation, or autoclaving. To do so may damage the pump and void the warranty.

1) Exterior Surfaces of the MRidium 3850/3860+, 3851/3861, and 3855/3865 may be cleaned using any of the following recommended solutions. This list is considered adequate to permit clean up of all expected contaminate.

2) Isopropyl alcohol, warm soapy water, household bleach (10% solution, i.e. 1 part household bleach to 9 parts water).

3) These solutions may be applied using a soft, lint free cloth; a soft bristle brush and/or a cotton swab. Once the contamination has been removed, a cloth soaked with fresh water should be used to rinse the entire instrument removing and diluting all of the residual cleaning solution. The entire instrument surface should be completely rinsed using another cloth thoroughly moistened with fresh water. Lastly, the instrument must be thoroughly dried with a soft, lint free cloth.

**WARNING**

Prior to reattaching the AC power cable to the power/charger, ensure the male base of the power input module is clean of any electrolyte and thoroughly dry. Check the female contacts on the power cable for contamination; if contaminated, replace the power cable.

1.2 Tools and Equipment required for basic repairs and PM’s:

- #1 Phillips screw driver.
- #2 Phillips screw driver.
- PH00 Phillips.
- 9/64 inch Allen driver or T-bar.
- 2 mm Allen driver or T-bar.
- 3/16 inch Nut driver.
- MRidium IV Sets (IVP 1056).
- 100 ml and/or 25 ml graduated cylinder (simple flow testing).
- Pressure gauge (0 to 10 psi) and pressure means (i.e. hand bulb) with modified IVP1056 set (example assembly pictured in step 1.4.1 #2, on page 9).
1.3 Mechanical and Physical Inspection

1.3.1 Perform the following inspections:

1) Chassis: 3850/3860+, 3851/3861, and 3855/3865:
   - Inspect for damaged controls, missing components/screws, holes, cracks or damage beyond cosmetic scratches or blemishes.

2) Door: 3850/3860+, 3851, 3861:
   - Ensure ease of opening/closing the door, presence of set screw, inspect the door for cracks, and inspect the hinge pin for signs of corrosion. If the Door is stiff, attempt to use synthetic oil as a lubricant. Excessively stiff/stuck doors should be replaced.

3) Door Clamp Clip (IVP1068): 3850/3860+, 3851, 3861:
   - Inspect clip for wear, replacement of this clip is recommended annually.

4) Door Latch Pawl (IVP1038): 3850/3860+, 3851, 3861:
   - The Pawl should hold the Door Clamp Handle at ~45 degree angle. Ensure proper function and inspect for wear.
5) Door Clamp Handle (Channel A: IVP1031A, Channel B: IVP1074A): 3850/3860+, 3851, 3861:
   ➢ Inspect for physical damage or deformities that may cause interference of proper door closure.

6) Door Pin (Optical: IVP1099OP, Mechanical: IVP1099): 3850/3860+, 3851, 3861:
   ➢ Ensure the pin is present, not bent, and free of cracks or tears.

7) Clamp Latch Slider (IVP1094): 3850/3860+, 3851, 3861:
   ➢ Inspect latches for damage and ensure ease of opening/closing.

8) Clamp Latch Cover (IVP1095): 3850/3860+, 3851, 3861:
   ➢ Inspect for damage or cracks. The Cover is circled below.
9) Flow Carrier (AS120) and Spring Arm Actuator (IVP1046): 3850/3860+, 3851, 3861:
   - Inspect for damage or cracks of the Carrier circled below and ensure the Actuator (indicated by the arrow below) can be easily depressed and springs back into position.

10) Tube Retainer Clip (IVP1022): 3850/3860+, 3851, 3861:
    - Inspect for damage or cracks.

11) Pump Finger Gasket (IVP1070): 3850/3860+, 3851, 3861:
    - Inspect for wear, holes, tears, or brittleness of the window.
12) Pump Finger Seal Ring (IVP1014): 3850/3860+, 3851, 3861:
   ➢ Inspect for cracks/damage especially around screws.

13) Spring Latch (AS104): 3850/3860+, 3851, 3861:
   ➢ Ensure the spring latch is functional; the latch should be able to be pulled/wedged away from the pump body and spring back into place.

14) DC Main Feed Power Connector (AC43): 3850, 3860+:
   ➢ Inspect for damage and ensure the connector is tight. If loose, it must be tightened from the inside.
15) Antenna Connector (AC28): 3850/3860+, 3851, 3861:
   ➢ Inspect for damage and ensure the connector is tight. If loose, it must be tightened from the inside.

16) SD Card Slot: 3850/3860+, 3851, 3861:
   ➢ Ensure that the card can slide in and out. The internal spring load should retain the card when pushed in.

17) Pole Clamp Knob Assembly: 3850, 3860+:
   ➢ Ensure proper function of the knob to be tightly fastened to an IV pole and there are no damaged or cracked components of the assembly.

18) Handle (IVP1012): 3850, 3860+:
   ➢ Inspect the pumps' handle for damage or cracks.

19) Overlay: 3850/3860+, 3851, 3861:
   ➢ Inspect for excessive wear of keys, punctures in overlay, or scratches/dents in the display window which interfere with the legibility of the display.

20) Display: 3850/3860+, 3851, 3861:
   ➢ Check for missing or incorrect pixels when powered on.
21) Motor Hinge Pin (Internal): 3850/3860+, 3851, 3861:

- Ensure the hinge pin of the motor is centered in the assembly. The pin should extend slightly and equally from each end. Place epoxy at the protrusions of the pin (at the red arrows pictured below) to retain proper placement.

22) Coin Cell Battery 3V (HB02, CR2032): 3850/3860+, 3851, 3861:

- The Coin Battery is located inside the Pump on the Processor Board; the Processor Board is directly below the Power Board which is the first one visible once the pump is opened.
- Remove the 4 screws (1 at each corner) holding the Power Board to access the battery located below.
- Measure the voltage of the Coin Battery and replace if below 3V.
- The Coin Battery within the Remote is visible on the first board as the unit is opened.

*Note*: History and User specified settings will be retained despite changing this battery as long as the pump remains off while the battery is out of the pump. If the pump is powered on while the battery is removed, or if the battery is dead or dying prior to replacement, history and user settings may be lost.

1.4 Functional Verification: 3850/3860+, 3851, 3861, 3855, 3865:

*Note*: If not labeled, “F1 – F6” are the white soft keys to the left of the display (orientated with “F1” at the top).

1.4.1 3850, 3860+ Service Mode Verifications:

- Enter Service Mode by powering on the pump then immediately press and hold “CANCEL” until “Service Mode A” appears at the top of the screen.

1) Motor Speed Verification: 180 ±10:

- Use the down arrow key until “Manual Pump Run” is highlighted.
- Press and hold “ENTER” to read the speed. There are two lines of values at the bottom of this screen; the motor speed is the first one (on the left) of the top line.
- Depending on the motor build date, a speed as low as 135 ±30 may be acceptable.
2) Pressure Sensor Verification: 5.0 ±0.5 PSI:
   - Refer to the picture below for an example assembly of a closed loop (air filled) IV Set assembly, with pressure gauge and bulb attached (using an IVP1056 set).
   - With 0 pressure applied, insert the modified IV Set assembly and close the door.
   - Close the pressure bulb and apply 5.0 PSI, verify P1 and P2 display 5.0 ±0.5.
   - Open the pressure bulb and verify P1 and P2 now display 0.0 ±0.2.
   - Open the Door and verify P1 and P2 display < -0.2.

   - If the values are incorrect, calibration of the pressure sensors is required.
   - To calibrate, close the door with the modified IV Set assembly installed.
   - Press “F1” to reach the “Calibrate A” screen. Select “F4” for “Tare Offset”.
   - Press “CANCEL” and verify P1 and P2 display +00.0.
   - Close the pressure bulb and apply 5.0 PSI, verify P1 and P2 display 5.0 ±0.5.
   - Press “F1” to reach “Calibrate A” screen. Select “F5” for “Span Cal”.
   - Press “CANCEL”, open the pressure bulb and verify P1 and P2 now display 0.0 ±0.2.
   - Open the Door and verify P1 and P2 display < -0.2.

3) Bubble Detect Verification:
   - With no IV Set installed, verify bubble detection indicated by an upper case “B” at the bottom center of the screen.
   - With a fluid filled set installed, verify no bubble detected indicated by a lower case “b” at the bottom center of the screen.
4) Time and Date Verification:
   - Press “F3” then “F1”.
   - If the time or date appears incorrectly, perform the following.
   - Use the up/down arrows to manipulate the hours, press enter to set (which will now highlight the minutes).
   - Use the up/down arrows to manipulate the minutes, press enter to set, and enter again as needed if the seconds or date require adjustments as well.
   - Once the date and time is set correctly, press “MENU” to save and exit.
   - Press “CANCEL” to return to “Service Mode A” screen and verify that the time now appears correctly at the top of the screen.

5) Battery Verification:
   - With DC power connected and Battery inserted, the LED at the bottom left of the pump should appear amber in color, to indicate recognition of both: input power and charging of the battery (if fully charged the LED will be green).
   - Ensure battery is easily removed (the LED will change to green) then re-inserted (LED back to amber) and does not show signs of swelling (refer to section 1.5.4 for swollen battery removal if necessary).
   - Press “F2” to arrive at the battery status screen and verify the following values:
     *Note* the following is only applicable to a battery charged at least 50%.
     - State of Charge (%): [50 – 100].
     - Term Voltage (V): [15 – 16.9].
     - Cells 1 – 4: [3.8 – 4.25] all cells should be within 0.2 of each other.
     - Current (ma): [+20 or greater], while charging (0.0 at 100% charge).
     - Cycle count: [1 or greater].
     - S/N: Make a note of the 4 digit serial number.
   - Turn off the pump, remove the battery, and verify the last 4 digits of the battery's serial number (located on the label) matches the S/N displayed by the pump.
   - If the battery is swollen or the values are out of tolerance, a replacement battery (part #: 1133R) is recommended.

1.4.2 3850, 3860+ Normal Operating Mode Verifications:
   - Power on the unit and allow it to load normally.
   - Press “F1” to enter New Patient Rate Mode.
   - *Note*: If not labeled, "F1" – "F6" are the white soft keys to the left of the display (orientated with “F1” at the top).
1) Keypad Verification, **3860+ Only**:

- Using the 10 button key pad, input the following: (Ensure an audible tone is associated with each entry, and the values are displayed as intended on screen)
- With Rate highlighted– press “123 ENTER”
- VTBI will now be highlighted– press “456 ENTER”
- Rate will now be highlighted– press “789 ENTER”
- VTBI will now be highlighted– press “20.1 ENTER”
- Rate will now be highlighted– press “C”, ensure the value now reads 0, and then press “100 ENTER”.

2) Flow Preventer Switch Verification:

- Open the Channel A door.
- Install a fluid filled IV Set.
- Push in the black pinch clamp on the IV Set flow preventer assembly.
- Verify “Check Door A” flashes at the top of the screen, red LEDs flash above the door, and an audible alarm sounds.
- Press “Alarm Silence”
- Close the door.
- Verify the Rate is still 100 ml/hr, and the VTBI is still 20.1 ml; if not, input them as such.
- Press “START/STOP CHANNEL A”, verify that the pump is infusing and a green LED flashes above the door.

3) Flow Stop Pull Test:

- With the Pump still running, open the door; verify the “Check Door A” alarm occurs once again.
- Press “CANCEL” then “ALARM SILENCE”, verify the black pinch clamp has been fully retracted (flow stop is closed), and verify the Set’s flow preventer housing is retained within the violet/grey flow stop carrier.

*Note* If the pull test fails (black pinch clamp is not fully retracted) on a new IV Set, the Door Clamp Clip (IVP1068) is worn and requires replacement.

4) Occlusion Tests: Inlet and PT:

- Close the door and start the pump again. Clamp or pinch the tubing above the pump. Verify an “Inlet Occlusion” message with associated alarming.
- Press “ALARM SILENCE”, clear the input line, start the pump once more.
- Clamp or pinch the tubing below the pump. Verify a “PT Occlusion” message with associated alarming, then silence the alarm and clear the output line.
5) Sound, KVO Rate, and Occlusion Limit Adjustment Verification:

- Press “MENU”, then “F3”.
- Using the up and down arrow keys, ensure that the volume can be raised and lowered.
- Return the volume setting to the desired level, press “ENTER” to save and exit.
- Press “F6” then “F1” for KVO Rate. Using the up/down arrows, verify the Rate may be changed from 0 – 5mL/hr (in 1mL/hr increments). Return this setting to 1mL/hr (unless otherwise specified by your facility) and press “ENTER”.
- Press “F6” then “F2” for Occlusion Limit. Using the up/down arrows, verify the Limit may be changed from 1 – 10 PSI (in 0.1 PSI increments). Return this setting to 10 PSI (unless otherwise specified by your facility) and press “ENTER”, then press “CANCEL” twice to return to the “Resume Therapy” screen.

6) SpO2 Verification, 3860+ Only:

- Connect 1170 test Fiber Optic (F.O) cable to the Pump, verify Sp02 is displayed in the lower portion of the screen.
- Connect F.O. probe to Pronk Technologies OxSim, ensure IR and Red LEDs are illuminated. On OxSim, press “MODE” to select 98% 80 bpm. Verify the Pump displays Sp02: 98 ±1%, 80 ±1 bpm, and PI: 4.0 ±0.5%.
- On OxSim, press “MODE” to select 99% Low Perf. Verify Pump displays Sp02: 99 ±1%, 80 ±1 bpm, and PI: 0.3 ±0.2%.
- On OxSim, press “MODE” to select 98% 140 bpm. Verify Pump displays Sp02: 98 ±1%, 140 ±1 bpm, and PI: 3.0 ±0.5%. Once bpm exceeds 130, verify the audible alarm sounds, the red LED alarm above the door flashes, and the message “High HR” alternates with the battery indicator at the top of the screen.
- On OxSim, press “MODE” to select 95% 40 bpm. Verify Pump displays Sp02: 95 ±1%, 40 ±1 bpm, and PI: 3.0 ±0.5%. Once the bpm falls below 40, verify the audible alarm sounds, the red LED alarm above the door flashes and the message “Low HR” alternates with the battery indicator at the top of the screen.
- On OxSim, press “MODE” to select 85% 80 bpm. Verify Pump displays Sp02: 85 ±1%, 80 ±1 bpm, and PI: 3.0 ±0.5%. Once Sp02 falls below 90%, verify the audible alarm sounds, the red LED alarm above the door flashes and the message “Low SpO2” alternates with the battery indicator at the top of the screen.
- Remove F.O probe from the OxSim and verify the audible alarm sounds, the red LED alarm above the door flashes and the message “Probe Off” alternates with the battery indicator at the top of the screen. Press “ALARM SILENCE”; all alarms should be cleared.
- Disconnect the F.O. from the Pump and verify the audible alarm sounds, the red LED alarm above the door flashes and the message “No Probe” alternates with the battery indicator at the top of the screen. Press “ALARM SILENCE”; all alarms should be cleared.

1.4.3 3850, 3860+ Flow Tests:

- Pump Flow tests may be performed using an Infusion Pump Analyzer or a graduated cylinder. Place Pump on an IV Pole with an IVP1056 infusion set connected to a 1000 ml distilled water bag. Place output of IVP1056 infusion set into the graduated cylinder or the Infusion Pump Analyzer.
- Load primed infusion set (IVP1056) into Pump.
- If using a graduated cylinder, be sure to empty it before each test.
- A volume within ±5% of intended output is considered acceptable.

1) 1400 ml/hr for 46.6 ml: (44.27 – 48.93 ml or 1330 – 1470 ml/hr.) 3860+ Only:
   - Press “F1” to enter “New Patient Rate Mode”.
   - Set the Rate to 1400 ml/hr and VTBI to 46.6 ml (make sure to press “ENTER” after each entry).
   - Press “START/STOP CHANNEL A”. The pump will run for ~2 minutes then go into KVO.
   - Stop the pump by pressing “START/STOP CHANNEL A” and verify the output lies within 44.27 – 48.93 ml or 1330 – 1470 ml/hr.

2) 999 ml/hr for 33.3 ml: (31.63 – 34.97 ml or 949.05 – 1048.95 ml/hr.):
   - Set the Rate to 999 ml/hr and VTBI to 33.3 ml.
   - The pump will run for ~2 minutes.
   - Verify the output lies within 31.63 – 34.97 ml or 949.05 – 1048.95 ml/hr.

3) 500 ml/hr for 16.6 ml: (15.77 – 17.43 ml or 475 – 525 ml/hr.):
   - Set the Rate to 500 ml/hr and VTBI to 16.6 ml.
   - The pump will run for ~2 minutes.
   - Verify the output lies within 15.77 – 17.43 ml or 475 – 525 ml/hr.

4) 125 ml/hr for 10.4 ml: (9.88 – 10.92 ml or 118.75 – 131.25 ml/hr.):
   - Set the Rate to 125 ml/hr and VTBI to 10.4 ml.
   - The pump will run for ~5 minutes.
   - Verify the output lies within 9.88 – 10.92 ml or 118.75 – 131.25 ml/hr.
5) 25 ml/hr for 4.2 ml: (3.99 – 4.41 ml or 23.75 – 26.25 ml/hr.):
   - Set the Rate to 25 ml/hr and VTBI to 4.2 ml.
   - The pump will run for ~10 minutes.
   - Verify the output lies within 3.99 – 4.41 ml or 23.75 – 26.25 ml/hr.

1.4.4 3851, 3861 (Sidecar – Channel B) Service Mode Verifications:
   - With the Sidecar attached, enter Service Mode by powering on the pump then immediately pressing and holding “CANCEL” until “Service Mode A” appears at the top of the screen.
   - When testing the 3861 Sidecar (Channel B), press “Start/Stop Channel B”. “Service Mode B” should now appear at the top of the screen.
   - Ensure you remain in “Service Mode B” for the duration of this section.

1) Motor Speed Verification: 180 ±10:
   - Use the down arrow key until “Manual Pump Run” is highlighted.
   - Press and hold “ENTER” to read the speed. There are two lines of values at the bottom of this screen; the motor speed is the first one (on the left) of the top line.
   - Depending on the motor build date, a speed as low as 135 ± 30 may be acceptable.

2) Pressure Sensor Verification: 5.0 ±0.5 PSI:
   - Refer to the picture below for an example assembly of a closed loop (air filled) IV Set assembly, with pressure gauge and bulb attached (using an IVP1056 set).
   - With 0 pressure applied, insert the modified IV Set assembly and close the door.
   - Close the pressure bulb and apply 5.0 PSI, verify P3 and P4 display 5.0 ±0.5.
   - Open the pressure bulb and verify P3 and P4 now display 0.0 ±0.2.
   - Open the Door and verify P3 and P4 display < -02.1.

   - If the values are incorrect, calibration of the pressure sensors is required.
   - To calibrate, close the door with the modified IV Set assembly installed.
   - Press “F1” to reach the “Calibrate B” screen. Select “F4” for “Tare Offset”.

   ![Image of pressure sensor verification setup]
Press “CANCEL” and verify P3 and P4 display +00.0.
Close the pressure bulb and apply 5.0 PSI, verify P3 and P4 display 5.0 ±0.5.
Press “F1” to reach “Calibrate B” screen. Select “F5” for “Span Cal”.
Press “CANCEL”, open the pressure bulb and verify P3 and P4 now display 0.0 ±0.2.
Open the Door and verify P3 and P4 display < -02.1.

3) Bubble Detect Verification:
- With no IV Set installed, verify bubble detection indicated by an upper case “B” at the bottom center of the screen.
- With a fluid filled set installed, verify no bubble detected indicated by a lower case “b” at the bottom center of the screen.

1.4.5 3851, 3861 (Sidecar – Channel B) Normal Operating Mode Verifications:
- Power on the unit and allow it to load normally.
- Press “F1” to enter New Patient Rate Mode.
- Press “F6” to switch to Channel B; “Primary B” should appear just above the Rate input.
- Ensure you remain in “Primary B” for the duration of this section.

1) Flow Preventer Switch Verification:
- Open the Channel B door.
- Install a fluid filled IV Set.
- Push in the black pinch clamp on the IV Set flow preventer assembly.
- verify “Check Door B” flashes at the top of the screen, red LEDs flash above the door, and an audible alarm sounds.
- Press “Alarm Silence”.
- Close the door.
- Enter a rate of 100 ml/hr and a VTBI of 20.1 ml (make sure to press “ENTER” after each entry).
- Press “START/STOP CHANNEL B”, verify that the pump is infusing and a green LED flashes above the door.
2) Flow Stop Pull Test:
- With the pump still running, open the door; verify the "Check Door B" alarm occurs once again.
- Press “CANCEL” then “ALARM SILENCE”, verify the black pinch clamp has been fully retracted (flow stop is closed), and verify the flow preventer housing is retained within the violet/grey flow stop carrier.

*Note* With the Pump still running, open the door; verify the “Check Door B”. *If the pull test fails (black pinch clamp is not fully retracted) on a new IV Set, the Door Clamp Clip (IVP1068) is worn and requires replacement.

3) Occlusion Tests: Inlet and PT:
- Close the door and start the pump again. Clamp or pinch the tubing above the pump. Verify an "Inlet Occlusion" message with associated alarming.
- Press “ALARM SILENCE”, clear the input line, start the pump once more.
- Clamp or pinch the tubing below the pump. Verify a “PT Occlusion” message with associated alarming.
- Press “ALARM SILENCE”, clear the output line, and press “CANCEL” twice to return to the “Resume Therapy” screen.

1.4.6 3851, 3861 (Sidecar – Channel B) Flow Tests:
- Pump Flow tests may be performed using an Infusion Pump Analyzer or a graduated cylinder. Place Pump on an IV Pole with an IVP1056 infusion set connected to a 1000 ml distilled water bag. Place output of IVP1056 infusion set into the graduated cylinder or the Infusion Pump Analyzer.
- Load primed infusion set (IVP1056) into Channel B.
- If using a graduated cylinder, be sure to empty it before each test.
- A volume within ±5% of intended output is considered acceptable.

1) 1400 ml/hr for 46.6 ml: (44.27 – 48.93 ml or 1330 – 1470 ml/hr.) 3861 Only:
- Press “F1” to enter “New Patient Rate Mode”.
- Press “F6” to switch to Channel B; “Primary B” should appear just above the Rate input.
- Ensure you remain in “Primary B” for the duration of this section.
- Set the Rate to 1400 ml/hr and VTBI to 46.6 ml (make sure to press “ENTER” after each entry).
- Press “START/STOP CHANNEL B”. The pump will run for ~2 minutes then go into KVO.
- Stop the pump by pressing “START/STOP CHANNEL B” and verify the output lies within 44.27 – 48.93 ml.
2) 999 ml/hr for 33.3 ml: (31.63 – 34.97 ml or 949.05 – 1048.95 ml/hr.)
   - Set the Rate to 999 ml/hr and VTBI to 33.3 ml.
   - The pump will run for ~2 minutes.
   - Verify the output lies within 31.63 – 34.97 ml.

3) 500 ml/hr for 16.6 ml: (15.77 – 17.43 ml or 475 – 525 ml/hr.)
   - Set the Rate to 500 ml/hr and VTBI to 16.6 ml.
   - The pump will run for ~2 minutes.
   - Verify the output lies within 15.77 – 17.43 ml.

4) 125 ml/hr for 10.4 ml: (9.88 – 10.92 ml or 118.75 – 131.25 ml/hr.)
   - Set the Rate to 125 ml/hr and VTBI to 10.4 ml.
   - The pump will run for ~5 minutes.
   - Verify the output lies within 9.88 – 10.92 ml.

5) 25 ml/hr for 4.2 ml: (3.99 – 4.41 ml or 23.75 – 26.25 ml/hr.)
   - Set the Rate to 25 ml/hr and VTBI to 4.2 ml.
   - The pump will run for ~10 minutes.
   - Verify the output lies within 3.99 – 4.41 ml.

1.4.7 3855, 3865 Remote Radio Verification:
   - With both the Remote and the Pump off, connect a cable with 106 db of attenuation from the Pump’s antenna connector to the Remote’s antenna connector.
   - Turn on the pump. Once booted up completely, observe the channel indicator towards the top left of the screen (single digit number 1 - 6), to the right of the battery status indicator.
   - Turn on the remote. Following the tone, press “F5” to select Change Channel.
   - Using the “F” keys, select the channel number which coincides with the Pump’s.
   - Press “Enter”; the Remote and Pump should now be in sync.
   - Perform the following steps using only the remote for all keypad entries (Ensure that all inputs, messages, and alarms are mirrored precisely on both the pump and remote displays).

1) Keypad Verification: 3865 Only:
   - Press “F1” to enter “New Patient Rate Mode”.
   - Using the 10 button key pad, input the following: (Ensure an audible tone is associated with each entry, and the values are displayed as intended on screen)
     - With Rate highlighted– press “123 ENTER”
     - VTBI will now be highlighted– press “456 ENTER”
- Rate will now be highlighted– press “789 ENTER”
- VTBI will now be highlighted– press “20.1 ENTER”
- Rate will now be highlighted– press “C”, ensure the value now reads 0, and then press “100 ENTER”.

2) Flow Preventer Switch Verification:
- Open the Channel A door.
- Install a fluid filled IV Set.
- Push in the black pinch clamp on the IV Set flow preventer assembly.
- Verify “Check Door A” flashes at the top of the screen, red LEDs flash above the door, and an audible alarm sounds. Alarms both audible and visible should be mirrored on the Remote.
- Press “Alarm Silence”.
- Close the door.
- Verify the Rate is still 100 ml/hr, and the VTBI is still 20.1 ml; if not, input them as such.
- Press “START/STOP CHANNEL A”, verify that the pump is infusing and a green LED flashes above the door.
- Stop the pump by pressing “START/STOP CHANNEL A”.

3) Remote Sound Adjustment Verification:
- Press “MENU”, then “F3”.
- Using the up and down arrow keys, ensure that the volume can be raised and lowered.
- Return the volume setting to the desired level, press “ENTER” to save and exit.

1.5 1133 Battery Pack Maintenance:

Over-discharge, over-charge, and over-current (short-circuit) are all conditions detected by the internal “smart power gauge” of the battery. These conditions all result in the battery shutdown (battery will not deliver power) until placed into charge. Over discharge can cause cell to outgas during subsequent charge cycles. Severe out gassing can result in the battery pack swelling. Replace any battery pack with visible signs of deformation or swelling.

It is important to understand the basic chemistry of lithium polymer batteries. These batteries are a limited-life technology. The useful life of the battery pack is affected by chemical processes which start on the day of each of the cells inside the battery pack are made. The life can be further shortened by the way the cells are used and stored. These cells will die faster if they are not held at some small level of charge (50%) during non-use periods. If they are stored with any cell below 3.0V, a higher percentage of the cells will start to outgas and swell. If they go to very low voltages, they may not charge well and make even more gas.
The 1138 Operator’s Manual includes many cautions and suggestions for caring for the battery. Lithium polymer batteries are sensitive to use and storage conditions, and inherently have a limited useful life. From the chemical standpoint and normal distribution of failure, we expect less than 5% should need replacement in less than 6 months. If you see that more than 10% of your batteries need replacement within 6 months of installation, we must look closely at the use and storage conditions.

1.5.1 Battery Pack Inspection:

- The 1133 Battery Pack should be inspected any time the pack is removed, or at least every 90 days for the following:
  
  *Note* Any failure of the inspections described below require discontinuance of use and replacement of the 1133 Battery Pack.

1) Battery communicates with the pump:

- This is indicated by the Battery Icon being shown on the Pump or Remote Display in the upper left-hand corner.

2) Battery Pack holds sufficient operating charge capacity:

- This is indicated by allowing the Pump to operate on battery power for the recommended minimum time (>12 hrs. @ 125 mL / hr. rate).

3) Battery Pack “gas gauge” indicator functions:

- These functions can be confirmed by removing the battery and pressing the test button on the battery. A fully charged battery will have 5 green bars displayed below the test button. The battery gas gauge is also displayed in the upper left corner of the display screen.

4) Physical Inspection of the Battery Pack case:

- Remove the Battery Pack from the Pump or Remote Display, and inspect for physical damage or signs of mechanical shock, cracked casing, or swollen casing.

1.5.2 Battery Pack Replacement:

- If the Battery Pack does not operate for the specified time after a full nine (9) hour charge cycle, replacement of the Battery Pack is recommended.

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**CAUTION**

If placed into storage, to maintain battery life, assure that the battery pack remains charged above 25% (one battery segment is visible) as indicated by the “gas gauge” LED display.
1.5.3 Battery Pack Related Precautions:

The 1133 Battery Pack contains several lithium-polymer cells and an integral safety circuit. As these cells age, they can expand due to internal gas release, which is anticipated for this type of cell. However, if excessive expansion occurs, it can result in the battery case, cells, or safety circuit. If this is observed, remove the Battery Pack from use and replace it as soon as possible.

The 1133 Battery Pack contains protective circuitry to prevent catastrophic battery failure. If the Battery Pack is damaged, this protective circuitry may not prevent battery failure. Remove the Battery Pack from use if the Pack becomes damaged, or the potential for Battery Pack damage is suspected.

Do not use a damaged or swollen 1133 Battery Pack:

Avoid damage to the 1133 Battery Pack by impact, dropping, overheating, or mechanical abuse. Never compress, drop, shock, or strike the 1133 Battery Pack. Never use objects that could puncture the internal battery cells. Any of these actions can cause the battery cells to heat, smoke, or cause catastrophic battery failure, which could result in fire. Do not attempt to disassemble the 1133 Battery Pack. Damage cause by disassembly or tool use can result in catastrophic battery failure, which could result in fire.

If the 1133 Battery Pack case begins to expand and/or swell, discontinue battery charging and use immediately, and replace the Battery Pack. Continued charging will cause further Battery Pack case expansion, with possible battery case fracture, and potential electrolyte leakage.

If the 1133 Battery Pack becomes damaged, avoid contact with the battery cell electrolyte. If the electrolyte contacts the skin or eyes, seek medical attention immediately.

If the 1133 Battery Pack shows sign of the battery case expanding (swelling), remove the Battery Pack from use and replace it as soon as possible. In extreme conditions, this swelling can cause the 1133 Battery Pack to become jammed or stuck within the 3850/3860+ Pump or 3855/3865 Remote Display, and/or cause the Battery Pack plastic case to burst open. If this occurs, do not use tools that could cause damage to the internal battery cells (see Section 1.5.4 below for removal instructions).

1.5.4 Removing a Swollen Battery Pack:

- In the event a Battery Pack swells and becomes lodged in the chassis of the 3850/3860+ or 3855/3865, removal can become difficult. To assure that removing the battery will not cause any damage to the Pump or Remote, the following steps should be taken:

  1) Ensure the Pump or Remote is OFF prior to attempting removal.

  2) Place either Pump or Remote, face down, on a solid surface with some kind of soft protective covering (to prevent damage to the face of the Pump or the Remote).

  3) Using a small, approximately 3/16 inch, flat head screwdriver in one hand, work the area between the top of the battery and back of the case as shown in Figure 3-1 until the battery begins to release from the chassis (with your other hand you will need to release the battery latch at the same time).
4) Once a small gap is established and the battery has moved enough to release the latch and a larger gap appears between the battery and the back case, use a larger, approximately 1/4 inch, flat head screwdriver, and begin softly tapping the end of the screwdriver with a small hammer or mallet as shown in Figure 3-2. Move the screwdriver in a downward angular motion, being sure to keep the screwdriver blade on the reinforced ribbed portion of the battery, forcing the battery out of the Pump or Remote. Move to each side of the battery to ensure even rearward force is applied as shown in Figure 3-3.

5) If the battery is so swollen that the above mentioned methods prove unsuccessful so that the battery’s plastic case begins to crack at the point of contact, or the screwdriver penetrates the plastic, please discontinue attempting removal and contact Irradimed Corporation Technical Service immediately at:

   +1.407.677.8022.

Figure 3-1