

Fill the Pump with insulin

1. Remove another refill syringe (IN2) from a refill kit package.
 2. Firmly attach the two-way stopcock to the refill syringe and attach an 18 gauge needle to the stopcock. Label the syringe IN2.
 3. Draw 20 mL of INSULIN (two vials) into the IN2 syringe.
 4. Remove the 18 gauge needle and expel all air bubbles in the syringe.
 5. Close the stopcock.
 6. Retract the plunger until it locks into place. This should be no further than 55 mL. Do not go beyond the vent hole. Press the lock into the plunger groove to be sure it is firmly secured.
 7. Shake vigorously for a minimum of 30 seconds to degas the INSULIN.
 8. Point the syringe tip upward and slowly open the stopcock to vent the syringe.
 9. Release the locking ring on the refill syringe.
 10. Expel the air in the syringe and carefully observe it to ensure no air bubbles remain in the syringe. If air bubbles are noted, repeat steps 5 - 10.
 11. Fill the hub of the refill needle with INSULIN and attach it to the stopcock.
 12. Prime the needle and close the stopcock.
 13. Place a sterile beaker or sterile barrier towel on the scale and tare it (position balance at 0.)
 14. Weigh the refill syringe and record the weight on the Implant Worksheet.
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15. Press the refill syringe into the Pump fill port, open the stopcock and allow the Pump vacuum to draw INSULIN into the reservoir until the fluid level stops moving. Close the stopcock.
16. Remove the IN2 syringe and prepare for aspiration without expelling any fluid. Obtain a vacuum by pulling back on the plunger until it locks. Press the lock into the plunger groove to be sure it is firmly secured.
17. Reenter the Pump fill port with the stopcock closed.
18. Open the stopcock and withdraw 2 mL in order to activate the negative pressure safety feature of the Pump. Close the stopcock and remove the syringe.
19. Weigh the IN2 syringe to calculate the Pump refill amount. Subtract the weight after the fill and 2 mL withdrawal from the weight before the fill and record the difference on the Implant Worksheet.

Measure stroke volume

1. Place the PPC in the sterile bag. Enter the Supervisor Mode. The screen displays “PUMP REFILL”. Press **ACT** until the “SET REFILL AMOUNT” screen appears. When filling the Pump for the first time, set the “EXTRACTED AMOUNT” to zero. Otherwise, enter the amount of insulin extracted. Then use the ▲ and ▼ buttons to enter the refill amount from the Implant Worksheet. Program the Pump.
 2. Again, enter the Supervisor Mode and program “STOP PUMP”. From the screen “PUMP STOPPED”, press **SEL**. “PUMP STOPPED” will begin flashing. Press both the ▲ and ▼ buttons at the same time, until the screen changes to the password screen. Reenter the password and the screen will change to “PUMP REFILL.” Press **SEL** to reach the “PRIMING” screen. “NO” will be flashing. Use the ▲ and ▼ buttons to select “YES,” then press **ACT**. When the word “CONFIRM” is highlighted, press **ACT** again. Place the PPC near the Pump to complete the communication process. Record the
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time the priming bolus was initiated on the implant worksheet.



If you have removed the plastic tubing placed on the Pump outlet, DO NOT TRY TO REPLACE THE TUBING BACK ON THE PUMP OUTLET. You can displace or damage the “O” ring placed around the outlet. To measure the stroke volume, you need to use the procedure described in Appendix G, after the Catheter has been attached.

3. Listen for five beeps and observe that fluid is being pumped from tubing attached to the Pump outlet.
4. Attach the 18 gauge needle (from the 3 ml syringe filled with RINSE BUFFER) to the plastic tubing from the Pump outlet.
5. Remove the 3 ml syringe and fill the needle hub.
6. Insert the pipette into the hub. A meniscus of fluid will be present in the pipette. This should be done on a flat surface with the pipette/tubing assembly horizontal. (see Figure 8).

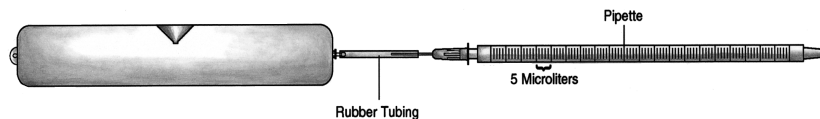


Figure 8: Testing Pump Stroke Volume with a Pipette

7. Note the exact location of the fluid meniscus in the pipette.
8. Measure the stroke volume by noting the volume displaced by a minimum of 10 pulses. Record the total volume delivered and the number of pulses on the Implant Worksheet. Divide the total volume delivered by the total number of pulses used to deliver that volume. The volume per stroke must be between 0.40 and 0.60 μL . Record this value on the Implant Worksheet.

Prepare the Side Port Catheter

The Side Port Catheter (“Catheter”) is attached to the Pump before implantation; however, it must be primed with INSULIN and inspected before being attached to the Pump.



Never insert a needle into the connector end of the Catheter for priming or for testing. there may be a precision sealing surface in the connector that will be damaged by the insertion of any needle.

1. Keep the Catheter in its package until the Pump is prepared and stroke volume has been verified. Remove the Catheter from its sterile package and document the serial number on the Implant Worksheet.
 2. Using the last insulin syringe (IN2) from the Pump preparation procedure, enter the Catheter port cone and push a small volume of insulin out of the connector end of the Catheter. This primes the proximal portion of the Catheter and cleans any debris from the connector outlet. Remove the syringe.
 3. Remove the plastic tubing and tubing retainer from the Pump outlet. Remove the tubing retainer, by rotating it one-quarter turn clockwise to disengage it from the connector flange. Then lift and remove the tubing and retainer together from the Pump outlet. Dispose of the tubing and retainer.
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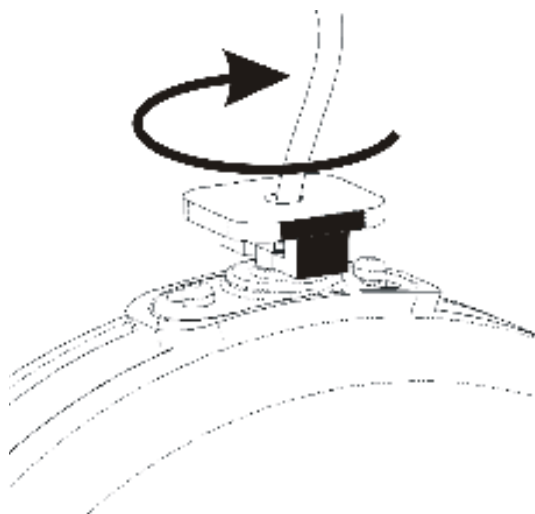


Figure 9: Rotate Tubing Retainer

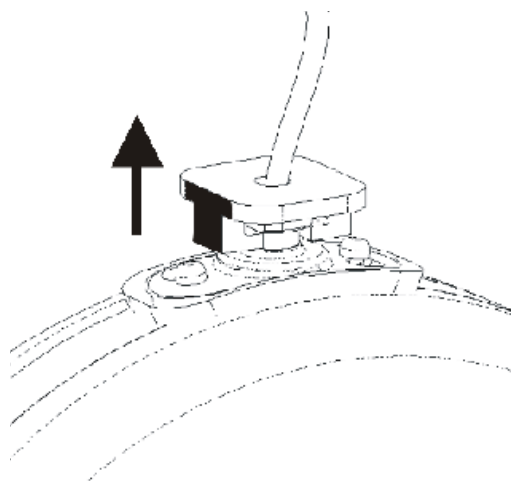


Figure 9-2: Pull Tubing Retainer off Pump.

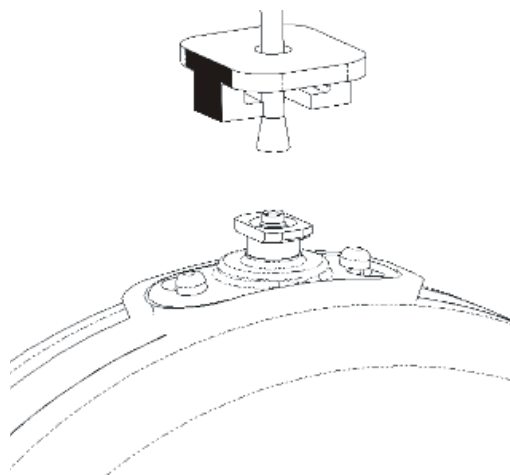


Figure 9-3: Tubing and Retainer Removed.

- Step 4** Inspect the outlet of the Pump for debris. Debris, especially fibers, left in the fluid path will compromise the function of the Catheter check valve. Rinse the outlet tube of the Pump with water from a syringe, if necessary. Avoid wiping the Pump with gauze or drapes that will leave fibrous debris.



Use caution when removing debris from the outlet of the Pump. There is a precision rubber seal on the outlet that will be damaged by handling with surgical instruments.

- Step 5** Pull the locking bar out and **gently** push the Catheter straight down onto the Pump outlet. **Never** twist the connector.
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Step 6 Only after the Catheter is seated, squeeze the connector, **1**, firmly against the Pump between the thumb and fore-finger of one hand. Then push the locking bar, **2**, into place with the thumb of the other hand.

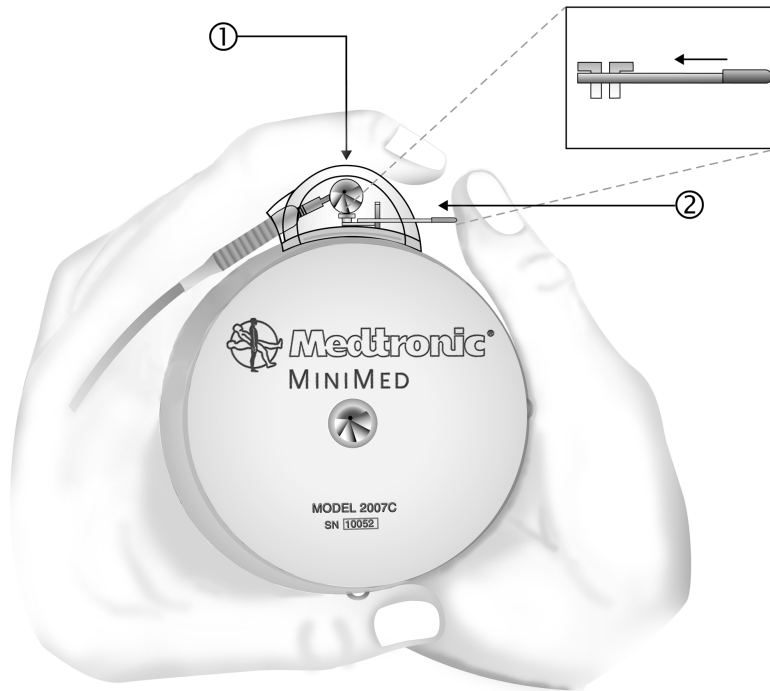


Figure 10: Proper Attachment of the Side Port Catheter to Pump

- Step 7** Verify the Catheter is securely attached to the Pump. Look into the connector and observe the position of the locking bar with respect to the Pump connector outlet. Check the side port connector hub for abnormalities (e.g., cracks, misalignment.)
- Step 8** Using the IN2 refill syringe, enter the Catheter side port cone and push a small amount of INSULIN out the Catheter tip. Verify that no insulin flow is observed at Pump/Catheter interface. Remove and reseal Catheter if flow is noted. Remove the syringe.
- Step 9** Confirm insulin delivery from the tip of the Catheter and note it on the Implant Worksheet. The INSULIN will form a dome on the tip of the Catheter. Pulsatile delivery will not be obvious. If the priming bolus has already ended, program an immediate bolus (about 20 units) to confirm delivery. (This bolus may be canceled after delivery is verified.)
- Step 10** At the end of the bolus, rinse the outside of the Pump thoroughly with sterile water to remove traces of INSULIN. The Catheter tip should not be placed in the water. Protect the Pump with sterile drapes until the surgeon is ready to implant it. Verify that the priming bolus is finished or canceled prior to the implantation.

The Pump and Catheter are now ready for implantation.

Performing the surgical procedure

Pre-operative evaluation

The Pump implant depth should not exceed 5 cm (2 inches) beneath the surface of the skin. If the Pump is implanted too deeply in the subcutaneous tissue it may be difficult to access the refill port.

Formation of the pump pocket

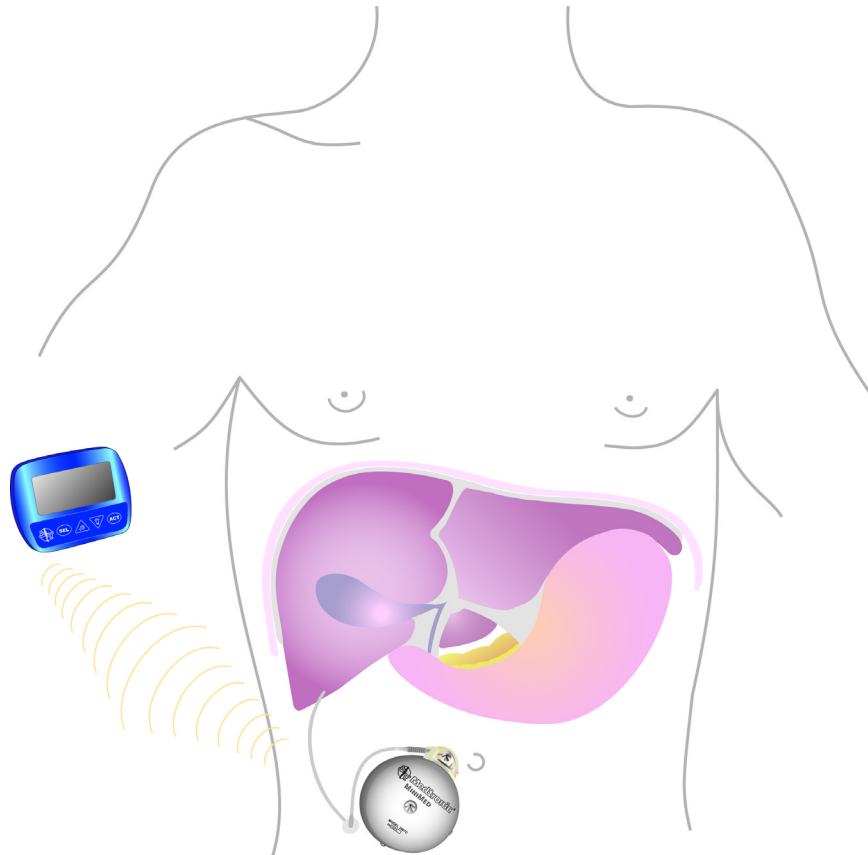
Pump implantation can be performed either under local or general anesthesia. After satisfactory anesthesia, a pre-selected abdominal site is prepped and draped in the customary surgical method.

A transverse or longitudinal incision is made and deepened through the skin and subcutaneous tissue. Care should be taken in choosing the location of the incision so the suture line is next to but not over the Pump inlet fill port or the Catheter side port. A subcutaneous blunt dissection is performed to create a pocket large enough to accommodate the Pump. Meticulous hemostasis should be established with electrocautery.

Figure 11 indicates a possible Pump placement and corresponding incision sites.

The Pump is secured to the fascia of the abdominal musculature using the three suture tabs provided. Securing the Pump with all three suture tabs is recommended, as it will prevent migration, rotation or inversion in the pocket and possible dislodgment of the Catheter.

Figure 11: Example of Pump Placement



Catheter placement

The Catheter is not designed to be tunneled subcutaneously. The Catheter insertion should be at the extreme edges of the Pump pocket.

At a site not directly beneath the Pump, the layers of abdominal musculature are divided to expose the peritoneum. Concentric purse string sutures are placed and the peritoneum is exposed with a 1 cm incision. The distal tip of the Catheter is placed in the peritoneal space. The flange of the Catheter is sutured firmly to the fascia of the abdominal musculature. Sutures should only be placed on the reinforced flange of the Catheter. Sutures must not be placed directly on the Catheter itself.



Never trim or cut the tip of the Catheter.

The implant site should be irrigated with an *antibiotic* solution. Interrupted absorbable sutures should be used to approximate the subcutaneous tissues and the skin closed with a running subcuticular absorbable suture. The wound is dressed using standard surgical technique. At the end of the surgery, place an abdominal binder over the implant site. This binder must be worn until the capsule has formed (about 1 month.) The binder is recommended because it will obtain a better cosmetic result and minimize the post operative swelling.

Post-operative management

Post-operative hospitalization

After implantation, the surgical incision should be inspected for any signs of unusual swelling, tenderness, pain, or drainage. Potential post-operative complications include Pump pocket seroma, wound dehiscence, wound infection, and catheter dislodgment.

Length of post-operative hospitalization depends upon how rapidly the patient adjusts to the Pump and how quickly blood glucose levels

stabilize. During post-operative hospitalization, the Pump can be reprogrammed to accommodate the needs of the patient. As post-operative stress decreases, insulin requirements may decline. It may be necessary to make several changes in insulin delivery rates during the first few days following implantation.

Patients must be thoroughly educated in all aspects of follow-up care with the Pump. The MiniMed Patient Manual should be used to supplement patient education. Prior to discharge, patients should:

- Fully understand how to use their PPC;
- Know what to do in the event of Pump or PPC difficulties;
- Have scheduled their first refill appointment;
- Have set an appointment for their first follow-up visit;

Post-operative x-rays

The Catheter has been designed with a radio-opaque stripe for identification after implantation. A lateral and anterior X-ray is recommended after implantation to locate and document the position of the Catheter. This radiograph should be kept with the patient's records for future reference.

Pump Refill Procedure

Introduction

Initial appointments for Pump Refills should be made with patients at the time of implantation. Subsequent appointments should be made in advance, normally during each refill procedure. The Pump stores approximately 6,000 units of insulin medication and typically requires a refill every two to three months. In order to maintain the physical stability of the insulin, the Pump must be refilled at a maximum interval of no more than 90 days. The PPC will display warning messages to alert the patient of calculated low or emptied reservoir volumes.

The low reservoir message will appear when the PPC calculates that 800 (2 ml) or fewer units of insulin medication remain in the Pump. The empty reservoir message will appear when the PPC calculates that 400 or fewer units (1 ml) of insulin remain. The time to medication depletion depends upon the delivery rate of the Pump.



The Pump refill procedure should always be scheduled in advance of PPC “low reservoir” or “empty reservoir” messages.

Supplies and solutions

The refill kit (MMT-4105) is intended exclusively for use with the Medtronic MiniMed 2007C Implantable Insulin Pump System. The refill kit consists of a specially designed syringe and stopcock for removing fluids from and placing fluids into the Pump. Use only refill needles (MMT-4102) available from MiniMed to perform all Pump refill procedures. This 22 gauge needle, featuring a rounded, lubricated tip and a beveled side hole, has been specially developed to mate with the Pump fill port.



Use of other needles may result in damage to the Pump septum in the fill port, and may allow body fluids to enter the Pump.

Below is a list of the supplies and solutions necessary to perform the refill procedure:

Supplies:

- Steri-Strips[®] and Markers
- The Patient's PPC
- Glucose Monitoring Equipment
- Drapes
- One (1) Scale (0.01 gram resolution)
- One (1) 250 ml Sterile Beaker
- One (1) Port Locating Template - MMT-4106
- Two (2) Refill Kits - MMT-4105
- Three (3) MiniMed MMT-4102 Refill Needles (Extra needles should be available for use.)
- Four (4) Sharp 18 Gauge Regular Bevel Needles

Solutions:

- One (1) 10 ml Vial, Aventis Rinse Buffer Solution
 - Two (2) 10 ml Vials, Aventis HOE 21 PH, U-400 Insulin
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Prepare for pump refill

NOTE: Before beginning any refill, rinse, flush, or pressure measurement procedure, carefully read Appendix D, Precautions and General Procedures.



Never push on the refill syringe plunger to fill the Pump. When the refill needle is properly seated in the Pump fill port, the vacuum in the Pump reservoir will draw the insulin from the syringe into the reservoir.

To prepare for emptying and refilling the Pump, perform the following steps:

- Use the “HISTORY” feature of the PPC to determine the amount of insulin medication remaining in the Pump. Make sure that **ACT** is pressed on the “READ PUMP DATA” screen to update PPC history from the Pump. Record this value on the refill worksheet (Appendix C).
 - Prepare a sterile field. The physician should scrub, mask and glove for the refill procedure. Refilling the Pump is an aseptic procedure.
 - (See Appendix D, *Precautions and General Procedures*.)
 - Aseptic skin preparation of the patient’s Pump refill site should be performed using your institution’s standard operating procedures.
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Perform the refill procedure

Fill out the refill form

Fill out the top part of the Refill Form (Appendix C) with the patient's I.D., refill date, insulin lot number, previous refill volumes, insulin medication remaining, and the name of the person performing the refill procedure. This information can be helpful for diagnostic purposes.

Label syringes

Use a sterile marker and Steri-Strips[®] to label one refill syringe “RB” (rinse buffer syringe) and the other “IN” (insulin syringe).

Prepare the refill syringe for emptying the Pump

1. Firmly attach the stopcock to the RB refill syringe and attach the 18 gauge needle to the stopcock. Check connections to ensure they are secure. Draw 5 ml of Rinse Buffer into the RB refill syringe.
2. Expel all air bubbles from the refill syringe. Remove the 18 gauge needle from the stopcock.
3. Fill the hub of the refill needle with Rinse Buffer from the RB refill syringe and attach it to the stopcock. Prime the refill needle completely. Close the stopcock.
4. Obtain the weight and record it on the Refill Form. Set the syringe aside.

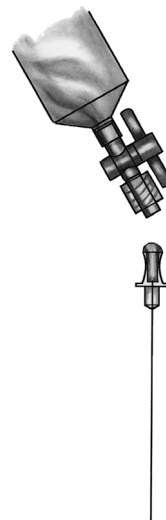


Figure 12: Filling the Hub of the Refill Needle

Prepare the refill syringe for filling the Pump

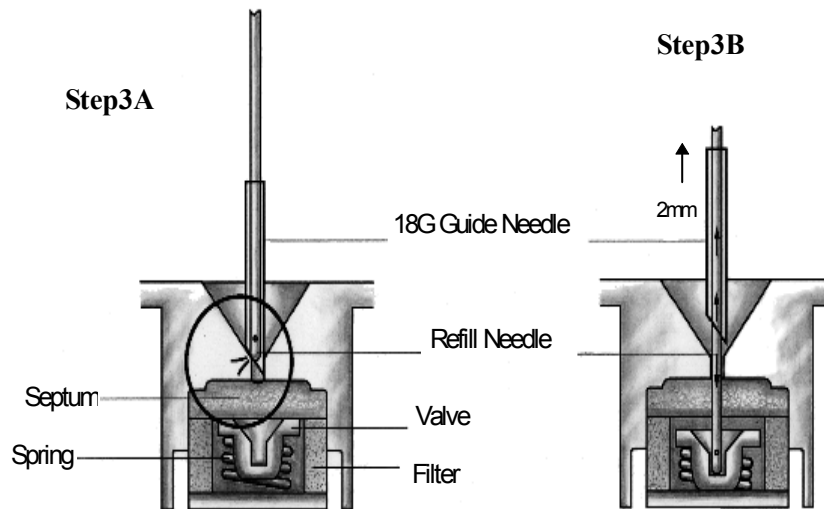
- 1.** Firmly attach the stopcock to the IN refill syringe and attach an 18 gauge needle to the stopcock. Draw 20 ml of Aventis HOE PH U-400 insulin into the syringe.
 - 2.** Expel all air from the refill syringe. Close the stopcock and remove the 18 gauge needle.
 - 3.** Retract the plunger until it locks into place. This should be no further than 55 ml - do not go beyond the vent hole. Press the lock into the plunger groove to be sure it is firmly secured.
 - 4.** Shake vigorously for a minimum of 30 seconds.
 - 5.** Point the syringe tip upward and slowly open the stopcock to allow air to enter the syringe.
 - 6.** Release the locking ring on the refill syringe. With the syringe pointed upward, push on the plunger to expel the air and prime the stopcock.
 - 7.** Open the stopcock and prime the refill needle. Attach the refill needle to the stopcock. Close the stopcock.
 - 8.** Inspect the syringe to ensure there are no air bubbles. If air bubbles are noted, remove the refill needle and repeat steps 2 - 7.
 - 9.** Weigh the refill syringe and record on the refill form.
 - 10.** Set the syringe aside.
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Empty the Pump

1. Obtain a vacuum in the RB syringe by pulling back on the plunger until it locks. Press the lock into the plunger groove and be sure it is firmly secured.
2. Locate the fill port by centering the template over the Pump. The center hole in the template should be directly over the Pump fill port. Insert the 18 gauge guide needle into the Pump fill port. Local anesthesia may be used prior to insertion of the 18 gauge needle.
3. Press the primed refill needle (attached to the RB syringe) into the Pump fill port, by sliding it through the 18 gauge guide needle. Pull back slightly (approximately 2 mm) on the guide needle to allow the refill needle to enter the Pump fill port and actuate the inlet valve.
4. Actuate the valve by applying a gentle downward force on the refill needle. This depresses the valve approximately 0.5 mm.
5. Open the stopcock and allow residual insulin from the Pump to be drawn into the RB refill syringe. Maintain a downward pressure on the syringe to ensure that the inlet valve in the Pump remains open. Wait 30 additional seconds after the insulin level appears to have stopped rising in the RB refill syringe to ensure the Pump is completely emptied.
6. When all residual insulin is withdrawn from the Pump, close the stopcock. Remove the RB refill syringe.

NOTE: Do not remove the 18 gauge guide needle.

7. Weigh the RB syringe and record on the refill form.
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Step 3A: Locate the port using the 18Ga guide needle slide the refill needle down the guide needle.

Step 3B: Pull back approximately 2mm on the guide needle to enter the Pump.

Step 3C: Apply firm pressure to move the valve back and allow the insulin to pass above the valve through the filter and into the reservoir.

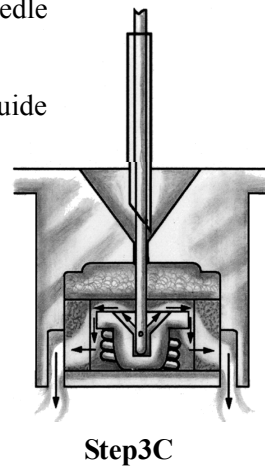
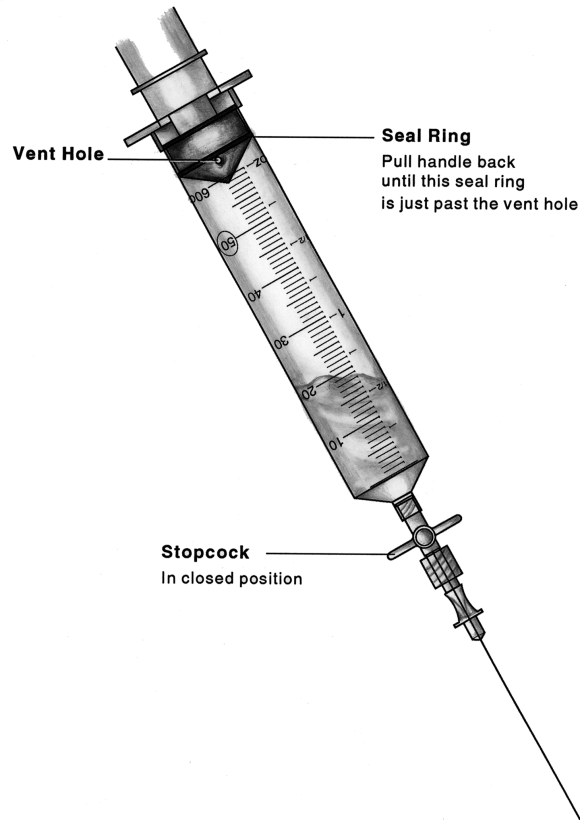


Figure 13: Operation of the Pump Inlet Valve

Refill the Pump

- 1.** Use the IN refill syringe containing 20 ml of degassed insulin.
 - 2.** Enter the Pump by passing the refill needle with the attached IN refill syringe through the 18 gauge guide needle. Pull back slightly (approximately 2 mm) on the 18 gauge needle to allow the refill needle to enter the Pump and actuate the inlet valve (see Figure 13).
 - 3.** Open the stopcock. Maintain downward pressure on the IN refill syringe to ensure the inlet valve in the Pump remains open. Allow the Pump to draw in insulin until the fluid level stops moving. Close the stopcock.
 - 4.** Remove the IN syringe and prepare for aspiration without expelling any fluid by pulling back on the plunger until it locks. Re-enter the Pump, open the stopcock and withdraw 2 ml in order to activate the negative pressure safety feature of the Pump.
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**OPTIONAL**

Use this step only if the plunger is not moving during the fill of the reservoir.

With the refill needle pointing down, vent the syringe head space by pulling back firmly on the plunger until the second sealing ring on the black rubber cap passes beyond the vent hole (see Figure 14).

Figure 14: Venting the MiniMed Refill Syringe

5. Remove the IN syringe. Remove the 18 gauge needle and apply pressure to the insertion site.
6. Weigh the IN syringe and record on the Refill Form.

Calculate extracted and refill amounts

1. Calculate the extracted amount by using the calculation section of the refill form.
2. Calculate the refill amount by using the calculation section of the refill form.
3. Enter the extracted amount (amount withdrawn as calculated on the refill worksheet at line E) and the refill amount (as calculated on the refill worksheet at line G) into the PPC (see Chapter 3).

Calculate refill accuracy

The PPC automatically calculates the refill accuracy following the PPC refill programming. You can also follow the calculation section of the refill form to calculate the refill accuracy.

Enter the refill accuracy value (IN %) on the line provided on the refill form. It is important to record this value to evaluate the functioning of the Pump system.

Explanting the Pump System

Explant considerations

When the battery in the Pump is depleted or if acceptable glycemic control cannot be achieved, it may become necessary to explant the Pump system.

Prior to explantation, it may be possible to perform interventions that could correct certain conditions. These procedures are described in Appendices E and F.

If all appropriate interventions have been exhausted without an acceptable outcome, please contact MiniMed prior to scheduling a Pump explantation.

Returning devices/components to MiniMed

Explanted Pumps and Catheters or other components should be returned to MiniMed for evaluation. Please call MiniMed and obtain a *Returned Materials Authorization* (RMA) number prior to each return.

Explanted devices must be sealed in an appropriate biohazard container and packed with a gauze pad soaked with sterile saline. The shipping container should be water tight. Chemical and reliability analysis require that the device not dry out during transportation.

Be certain to include required patient information as well as the RMA number, date, and reason for the explant and place all pertinent documentation in a water tight document package. Put the RMA number on the shipping label.

Please take the necessary precautions when shipping the Pump System via commercial carrier to avoid damage to the Pump. Please return explanted Pump Systems to:

United States:
MiniMed Inc.
18000 Devonshire Street
Northridge, CA 91325
Telephone: 1-818-578-6700

or

Europe:
MiniMed S.A.
30, Boulevard Vital Bouhot
92200 Neuilly-sur-Seine, France
Telephone: 33 (1) 46 43 16 16

Warnings And Precautions

Warnings

The Physician should be completely familiar with the function of the Pump, Catheter, and PPC prior to use. Patients should be provided a complete copy of the Patient Manual and have demonstrated the ability to program the PPC, recognize and respond to safety alarms, and take care of the device prior to discharge.

The Implantable Insulin Pump can only be used with MMT-4027A and 4024A Side Port Catheters.

Only Aventis HOE 21 PH U-400 insulin may be used in the Medtronic MiniMed 2007C Implantable Insulin Pump System. Use of other insulin types may cause damage to the Pump mechanism resulting in impaired insulin delivery or Pump failure.

Any unauthorized changes or modifications made to any component of the Medtronic MiniMed 2007C Implantable Insulin Pump System may prevent effective use of that and other components.

Electrotherapy

The Medtronic MiniMed 2007C Implantable Insulin Pump System has been tested in close proximity with electrosurgical, electrocoagulation, and cardiac defibrillation medical equipment. Typical use of this type of device has not affected the Pump. However, patients should be instructed

to test Pump function (e.g., program a bolus and then cancel the bolus) after such procedures, to determine that the Pump and PPC are operating properly. If the system is not performing correctly, contact MiniMed.

Diagnostic ultrasound

The Medtronic MiniMed 2007C Implantable Insulin Pump System has been tested during diagnostic ultrasound procedures. These procedures have no effect on Pump performance. However, patients should be instructed to test the Pump function (e.g., program a bolus and then cancel the bolus) after such procedures, to determine that the Pump and PPC are operating properly. If the system is not performing correctly, contact MiniMed.

Ultrasound therapy

The Medtronic MiniMed 2007C Implantable Insulin Pump System should not be exposed to therapeutic ultrasound procedures, such as lithotripsy. Exposure to ultrasound therapy may damage the Pump, and not be immediately apparent.

Diagnostic radiation

The Medtronic MiniMed 2007C Implantable Insulin Pump System has been tested during diagnostic radiation procedures, such as Computed Tomography and X-ray. These procedures have no effect on Pump performance. However, patients should be instructed to test the Pump function (e.g., program a bolus and then cancel the bolus) after such procedures, to determine that the Pump and PPC are operating properly. If the system is not performing correctly, contact MiniMed.

Therapeutic radiation

The MiniMed 2007 Implantable Insulin Pump has been tested during therapeutic radiation procedures. These procedures have no effect on Pump performance. However, patients should be instructed to test the Pump function (e.g., program a bolus and then cancel the bolus) after such procedures, to determine that the Pump and PPC are operating properly. If the system is not performing correctly, contact MiniMed.

Elevated anti-insulin antibodies

The result of clinical investigations suggest a small population of patients may develop anti-insulin antibodies when using the MiniMed 2007 Implantable Pump System and HOE 21 PH U-400 insulin. Patients with multiple autoimmune disorders may be more susceptible to developing high titers of anti-insulin antibodies, which in turn may cause symptoms. There was no correlation between length of exposure to the study drug and the resultant titer of anti-insulin antibodies. Elevated levels of anti-insulin antibodies alone have been proven not to interfere with diabetes management using continuous intraperitoneal insulin infusion with this system.

Environmental conditions

The Medtronic MiniMed 2007C Implantable Insulin Pump System should not be exposed to extreme electrical or magnetic fields. Although it is not possible to include every environmental condition that may affect the Pump, most are listed below. Please contact MiniMed when in doubt if certain environmental exposure will affect the pump.

DO NOT EXPOSE THE MINIMED 2007 IMPLANTABLE INSULIN PUMP SYSTEM TO ANY OF THE FOLLOWING CONDITIONS

- Magnetic Resonance Imaging (MRI) Procedures.
- Lithotripsy Treatment.
- Large Rotating Magnetic Fields ■ Refers to large industrial rotating magnetic fields, such as those found in Industrial Power Plants.
- Magnets Held Directly Over the Pump.
- High Power Radio or Satellite Transmitting Towers.
- Altitudes Above 2,400 meters (8,000 feet).

The Medtronic MiniMed 2007C Implantable Insulin Pump System is not designed for use at elevations above 2,400 meters (8,000 feet). Use of the Pump System at higher elevations may result in insulin over delivery, which may cause personal injury or death. Therefore, patients who live at

elevations above 8,000 feet or 2,400 meters should not use the Pump. Patients who use the Pump and who plan to travel to an elevation above 2,400 meters (8,000 feet) should first have their Pump reservoir emptied of insulin, and they must self-administer insulin by other means for the duration of the trip and until their Pump reservoir is refilled again.

- This warning does not apply to travel on commercial aircraft because normal cabin pressurization is adequate to ensure proper operation of the Pump.
- Diving Below 7.6 Meters (25 Feet).
- Physical Damage to the Pump or Pump Pocket.

Physicians should instruct patients to avoid any sharp blows or pressure directly at the Pump location. A direct hit by an object such as a baseball may damage the Pump and/or injure the Pump pocket. Extreme pressure on the Pump may cause the sutures and the tissue pocket to be damaged. As a result, the Pump may move from its pocket and possibly dislodge from the Catheter.

If the Pump has been damaged by such a blow, the patient should be instructed to contact their physician. Physicians may order a pressure bandage or a reduction in the patient's physical activity until the pump pocket reheals completely.

- Exposure to Extreme Body Temperatures

Exposure to elevated body temperature in excess of 104°F (40°C) will compromise the negative pressure reservoir safety feature of the MiniMed 2007 Implantable Pump. Glucose levels should be monitored closely if this occurs.

Sterilization

The Pump, Catheter and the refill kit are sterilized with ethylene oxide (EtO).

The Pump System is NOT Reusable.

If the sterile package has been opened, damaged or tampered with DO NOT USE the packaged device.

NOTE: Do Not Re-Sterilize the Implantable Insulin Pump

NOTE: Do Not Re-Sterilize the Side Port Catheter

NOTE: Do Not Re-Sterilize Components of the Refill Kit.

The Pipette (MMT -4104), may be resterilized using autoclave or EtO.

The Template MMT-4106 may be resterilized using steam autoclave or EtO. This template is made from polycarbonate plastic and will have a limited life in steam autoclave cycle. The template will not withstand dry heat autoclave cycles.

Precautions

Emergencies and the use of conventional insulin supplies

Physicians should advise patients who wear the Medtronic MiniMed 2007C Implantable Insulin Pump System how to deal with emergency conditions such as hyperglycemia. Patients should always carry conventional insulin supplies with them, including insulin and a means to inject it, in the event of impaired insulin delivery by the Pump System. Delivery of insulin can become impaired due to a failure of a Pump and/or PPC, or a Catheter occlusion. Replacement of the Pump, PPC or Catheter may be required. Physicians should review the Pump replacement and Catheter clearing procedures in this Physicians Manual

PPC reliability requirements

The PPC is a sensitive electronic device, and can incur physical damage. If the PPC is dropped or receives an impact, immediately perform a SELF TEST to check the displays for proper operation. If the PPC does not display correctly, a replacement PPC is required. Patients should initiate alternative diabetes management until a replacement PPC is received.

The PPC housing is not watertight and it may malfunction if immersed in water. “Condensing humidity” conditions such as steam rooms should also be avoided, because condensation can also damage the PPC’s micro-

electronics. If either situation occurs, contact MiniMed immediately and arrange for the repair or replacement of the PPC. If the PPC is accidentally splashed, sprayed or immersed, remove excess moisture with a soft towel and then place the PPC in a warm place to thoroughly dry. When dry, perform a “SELF TEST.” If the PPC does not display correctly, call MiniMed to replace the device.

Maximum dosages

The physician can program specific limitations to insulin Basal Rates and Bolus amounts, as well as total daily insulin usage. These limitations provide some control of patients’ ability to program their insulin regimens, and to avoid overdosing.

Electrical and magnetic fields

Common electrical and magnetic fields that do not affect the Pump include microwave ovens, satellite receiving dishes, common household appliances, security devices found in department stores and airports, standard medical X-rays, cellular phone, and radiowaves.

Adverse Reactions

Adverse reactions

In clinical studies, adverse reactions associated with the Medtronic MiniMed 2007C Implantable Pump included hypoglycemia, diabetic ketoacidosis, hyperglycemia, skin erosion, infection, abnormal healing, elevated anti-insulin antibodies, intestinal obstruction, post-operative discomfort and pain, and corrective surgery for Pump and Catheter malfunctions. Pump System malfunctions in order of frequency and seriousness include insulin aggregation resulting in Pump under-delivery, Catheter occlusion or tissue overgrowth, premature depletion of the Pump battery, and failure of Pump electronics. Adverse events associated with the use of Aventis HOE 21 PH U-400 insulin are described in the package insert accompanying the insulin medication.

Prevention

The majority of adverse reactions in patients using the Medtronic MiniMed 2007C Implantable Pump System can be prevented by teaching patients dependable blood glucose monitoring. The patient plays a significant role in diagnosing and correcting Pump System performance problems. Should Pump performance change, the patient would be able to detect a change in blood glucose levels.



Patients should be instructed to contact their physician's office, if they experience unresolvable difficulties with the Pump System. Emergency patient visits and diagnostic procedures may be necessary to correct adverse conditions.
