
APPENDIX D

Precautions and General Procedures

Special note and precautions

Before beginning the implant, refill, stroke volume measurement, rinse/flush, or pressure measurement procedure, carefully read this Appendix and keep the information in mind as you perform each procedure.

1. All procedures should be performed using ASEPTIC TECHNIQUE.
 2. Air in the Pump System has been shown to be a significant contributing factor to aggregation of insulin. Proper degassing of all solutions that enter the Pump is essential. Read the insert in the syringe packaging about the degassing procedure.
 3. When using the refill kit, never release the syringe-locking ring while there is a vacuum within the refill syringe. The plunger of the syringe will snap back forcefully and may rupture the syringe and eject the contents.
 4. It is important that the syringe needle is perpendicular to the fill port to prevent binding when entering or exiting.
 5. The Side Port Catheter attachment site contains up to 20 units of INSULIN. The distal portion of the Catheter and the tubing can contain up to 13 units of INSULIN. However, the INSULIN in the Pump fluid pathway and the side port receptacle can be cleared by following the procedure to pull RINSE BUFFER through the side port. During
-

a flush procedure to push out a catheter tip blockage, the 13 units in the distal catheter will be delivered to the patient. The 13 units can be managed by programming cautious bolus amounts prior to the procedure, or with the use of oral or IV glucose as needed during the procedure. Individual patient response to INSULIN bolus amounts must be considered.

6. Patient blood glucose monitoring must be performed during, and up to one hour after the procedure. Oral and intravenous glucose should be available for glycemic management.
7. After the flush procedure, at least 13 units of RINSE BUFFER will remain in the distal portion of the catheter. Programmed bolus amounts to remove the RINSE BUFFER may be completed before the patient leaves the clinic. A prescribed INSULIN basal rate should be programmed when the system is clear of RINSE BUFFER.
8. Never push down on the plunger to fill the Pump. When the MiniMed refill needle is properly seated in the fill port, the vacuum in the reservoir will draw the fluid from the syringe.
9. Each step of the procedure will list the syringes and appropriate fluids needed for that step. It is suggested that the syringes be prepared and labeled prior to the start of the procedure.
10. The Side Port Catheter is intended to be accessed only during the implant procedure, the combined rinse/flush procedure, the catheter flush procedure, and for diagnostic procedures. The catheter is not intended to provide access to the peritoneum for bolus injections of fluids or for withdrawal of body fluids.

General procedures

Before beginning any of the procedures, be sure you are familiar with the general techniques for locating the Pump fill port and the Side Port Catheter, accessing the Pump inlet, venting the refill syringe, and preparing the syringes.

Locating the pump fill port and the side port

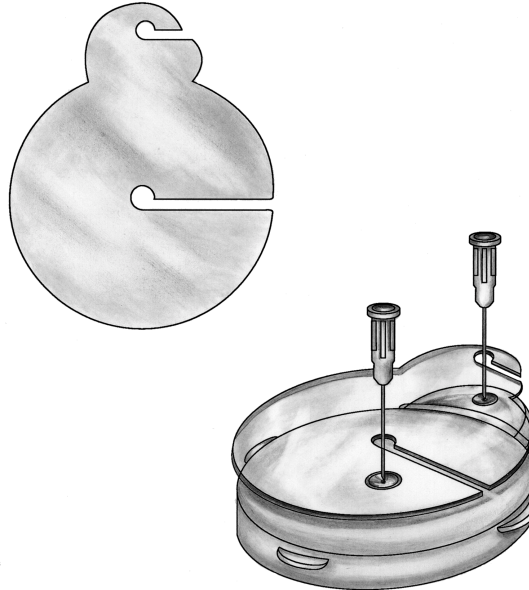


Figure 16: Template and Placement on Skin with Guide Needles in Position

1. Locate the Pump, then aseptically prep and drape the Pump area. Use topical or local anesthetic if desired.
 2. To locate the Pump fill port, located in the center of the Pump, align the sterile template (MMT-4106) over the Pump by palpating the Pump circumference. Then insert an 18 gauge needle into the central Pump fill port as shown in below:
 3. To locate the side port, palpate around the circumference of the Pump. It is helpful to grasp the side port between the thumb and index finger when aligning the template.
 4. Using the template as a guide, insert the second 18 gauge needle into the side port as shown. The side port can be accessed by inserting the guide needle just inside the outer edge of the side port connection.
-

This outer edge is raised around the outer aspect of the side port, in order to help guide the needle into the port.

Accessing the pump inlet

To enter the Pump fill port or the side port, make sure the refill syringe stopcock is closed, then pass the MiniMed refill needle (MMT- 4102) through the 18 gauge guide needle. Pull back slightly (approximately 2 mm) on the guide needle to allow the MiniMed refill needle to enter the Pump fill port or the side port. The refill needle entry opens the inlet valve of the Pump fill port.

After passing through the septum and seating in the valve, you can feel the increased force, about 0.5 pounds, required to move the valve 0.5 millimeter to open. Maintain this downward pressure in the pump fill port to ensure that the inlet valve remains open.

In the case of the side port, a downward pressure is not required after the needle is completely inserted.

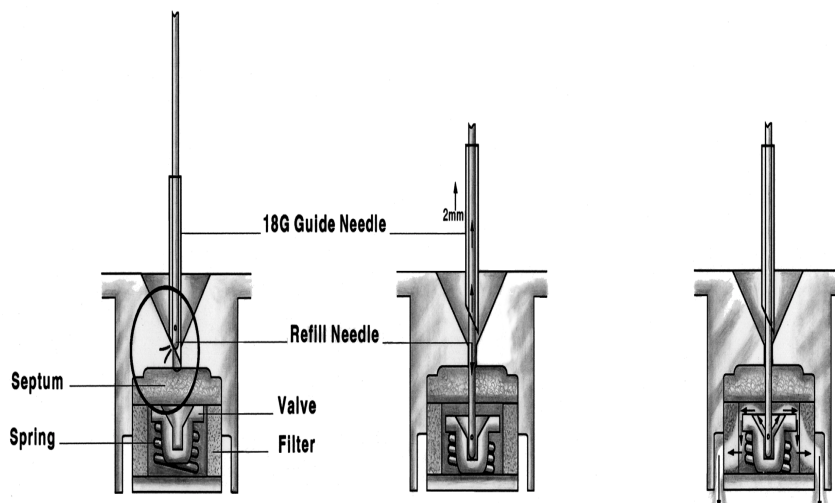


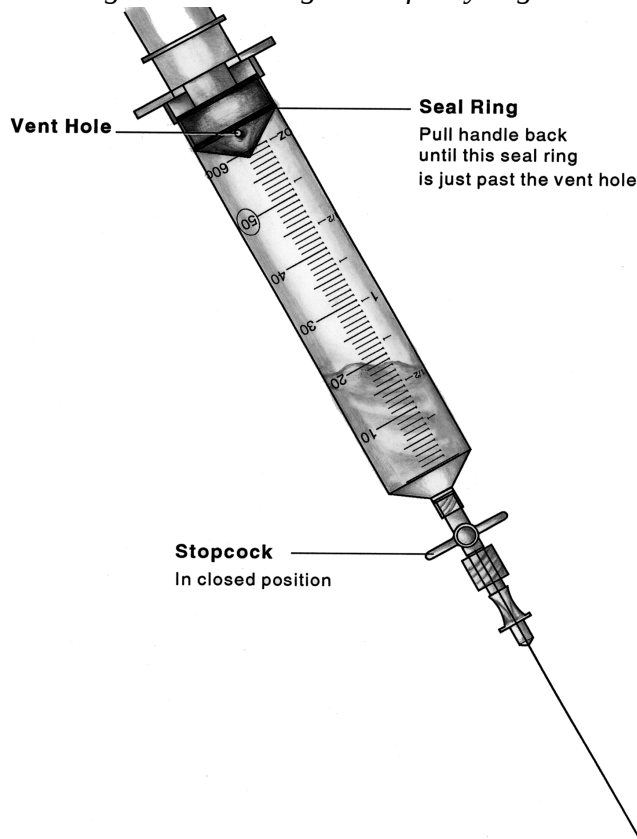
Figure 17: Inlet Valve

Venting the Minimed refill syringe (optional)

In order to fill the Pump, it may be necessary to vent the headspace in the MiniMed refill syringe. Refill syringes do not have lubricant on the syringe housing or on the plunger tip. Some syringes may be “sticky” and require the venting procedure described below to assist the vacuum in the Pump to overcome this condition.

To vent, hold the syringe with the refill needle pointing down. Vent the syringe headspace by pulling back firmly on the plunger until the second sealing ring on the rubber cap passes beyond the vent hole as shown in Figure 18.

Figure 18: Venting the Refill Syringe



NOTE: Be sure that the plunger is retracted far enough that the vent hole is exposed. The syringe must be held with the needle facing down and used within 10 minutes once it is vented. If this time limit is exceeded, repeat the degassing procedure.

Pump Rinse Procedure

The purpose of this procedure is to dissolve insulin deposits within the Pump reservoir, pumping mechanism, and the Side Port Catheter “port.”

Supplies and solutions

Prior to performing this procedure, assemble the necessary supplies and solutions as outlined below:

Supplies

- Steri-Strips[®] and markers
 - Local anesthesia (if necessary)
 - Sharps container
 - Safety glasses
 - PPC
 - Oral or IV glucose
 - Glucose monitoring equipment
 - Drapes
 - One (1) scale - 0.01 gram resolution
 - One (1) 250 ml sterile beaker
 - One (1) sterile bag for PPC (intestinal or cassette bags work well)
 - One (1) Side port locating template, MMT-4106
 - Seven (7) Refill kits, MMT-4105
-

- Seven (7) MiniMed MMT-4102 refill needles. (Extra needles should be available to use as needed)
- Eight (8) sharp 18 gauge regular bevel needles

Solutions

- 50 mL's sterile 0.1 M NaOH (0.4 grams NaOH per 100 ml of Sterile water for injection)
- Seven (7) 10 ml vials, Aventis rinse buffer solution
- Five (5) 10 ml vials, Aventis HOE 21 PH, U-400 Insulin



The 0.1 M of NaOH used in this procedure can cause permanent eye damage. Safety glasses must be worn during this procedure.

Preparing for the procedure

NOTE: Before beginning any refill, flush, stroke volume measurement, carefully read Appendix D, Precautions and General Procedures, and keep this in mind as you perform each procedure.

In order to prepare for the Side Port Catheter rinse and flush procedure, a total of seven syringes will need to be labeled and then prepared with different solutions. Table 1 defines the syringe numbers and corresponding solutions:

Syringe #	Syringe Type	Volume	Solution
	Refill	5 ml	RINSE BUFFER
	Refill	20 ml	NaOH
	Refill	30 ml	NaOH
	Refill	20 ml	RINSE BUFFER
	Refill	30 ml	RINSE BUFFER
	Refill	20 ml	INSULIN
	Refill	30 ml	INSULIN

Prepare syringes for emptying the Pump

Syringe 1 is used for emptying the Pump. Label and prepare syringe 1 per Table 1.

Prepare syringes for filling the Pump

During the Catheter rinse/flush procedure, syringes 2, 3, 4, 5, 6, and 7 are used for filling the Pump. Each of these syringes needs to be labeled with its solution and syringe number, and then filled and degassed per Table 1.

Program minimal basal rate

Place the PPC in a sterile bag and program the Pump to “SUSPEND” mode, the basal rate will be 0.2 U/h.

Remove insulin from the Pump and fill with NaOH

INSULIN is removed from the Pump and then the Pump is filled with NaOH. The following volumes are used:

- Syringe 1 - 5 ml RINSE BUFFER
- Syringe 2 - 20 ml Naoh
- Syringe 3 - 30 ml NaOH

Follow the steps below to perform this procedure:

Syringe 1: Rinse Buffer

1. Prime the needle. Weigh the syringe and record the weight on the refill form (Line A).
2. Close the stopcock. 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.
3. Enter the Pump with the refill needle.
4. Open the stopcock; withdraw the INSULIN. After the INSULIN appears to have stopped rising in the syringe, wait an additional 30 seconds to make sure all of the INSULIN and air is removed.

NOTE: Air in the Pump System has been shown to be a significant contributing factor to aggregation of INSULIN. Proper degassing of all solutions that enter the Pump is essential.

5. When the 30 second time has elapsed, close the stopcock, remove the syringe. Weigh the syringe and record the weight on the refill form. Discard the INSULIN in the syringe except for a 5 ml barrier. This syringe will be used to pull NaOH through the side port. Attach and prime a new refill needle.
-



The 0.1 M NaOH used in this procedure can cause permanent eye damage. Safety glasses must be worn during this procedure.

Syringe 2: NaOH

- 6.** Prime the needle. Close the stopcock
 - 7.** Enter the Pump with the refill needle.
 - 8.** Open the stopcock and allow the Pump to fill completely with NaOH. When the fluid level stops moving, the Pump is filled.
 - 9.** Close the stopcock. Remove the syringe.
 - 10.** Prepare syringe 2 for aspiration. Remove the air from the syringe. Close stopcock and 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.
 - 11.** Re-enter the Pump.
 - 12.** Open the stopcock and remove the NaOH. After the fluid level stops moving, wait an additional 30 seconds for all the NaOH to be removed.
 - 13.** When the time has elapsed, close the stopcock and remove the syringe. Discard syringe 2.
-

Syringe 3:NaOH (degassed)

14. Prime the needle. Close the stopcock.
15. Enter the Pump fill port with the refill needle.
16. Open the stopcock and allow the Pump to fill completely with NaOH. When the Pump is filled, approximately 10 ml will remain in the syringe. Leave this NaOH in the syringe, and **leave this syringe in place for the next step.**

Equilibrate and pull NaOH through system

The reservoir pressure in the Pump is equilibrated with outside ambient pressure and NaOH is pulled through the pumping mechanism. This procedure uses the following volumes in syringes 3 and 1:

- Syringe 3 with residual NaOH from the previous section.
- Syringe 1 with 5 ml insulin/buffer mixture from previous section.

Syringe 3: NaOH (residual)

1. Verify that the stopcock on syringe 3 is open .
 2. Prime the needle. Close the stopcock .
 3. 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.
 4. Enter the side port with the stopcock closed.
 5. Open the stopcock.
 6. Program and deliver a 4 unit bolus to open the valve in the Pump mechanism.
 7. Observe syringe 3. When the level of the NaOH approaches 2 ml, close the stopcock to prevent air from entering the Pump. Observe syringe 1. At least 1 ml of NaOH must pass into syringe 1 in order to thoroughly clean the Pump mechanism. If less than 1 ml enters, repeat
-

the bolus from Step 6, some pumps may require 3 successive bolus to obtain 1 ml.

NOTE: In order to completely dissolve deposits in the Pump mechanism, it is important to maintain a vacuum with syringe 1 and deliver the entire bolus.

8. After the bolus, close the stopcock on syringe 1. Remove both syringes. Set aside syringe 3 for use in removing the NaOH from the Pump fill port in the next step. Discard syringe 1.

Remove NaOH and fill with rinse buffer

The NaOH is removed from the Pump and the system is filled with RINSE BUFFER. This procedure uses the following volumes in syringes 3, 4, and 5:

- Syringe 3 with residual of at least 5 ml NaOH from the previous step
- Syringe 4 with 20 ml RINSE BUFFER
- Syringe 5 with 30 ml RINSE BUFFER

Syringe 3: NaOH (residual)

1. Prepare syringe for aspiration.
 2. Close the stopcock and 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.
 3. Enter the Pump with the refill needle.
 4. Open the stopcock and withdraw all the NaOH. After the NaOH appears to have stopped rising in the syringe, wait an additional 30 seconds to make sure all the NaOH and air is removed.
 5. When the time has elapsed, close the stopcock, remove the syringe, and discard.
-

Syringe 4: Rinse Buffer degassed)

6. Prime the needle. Close the stopcock.
7. Enter the Pump with the refill needle and syringe.
8. Open the stopcock and allow the Pump to fill completely with RINSE BUFFER. When the fluid level stops moving, the Pump is filled.
9. Close the stopcock. Remove the syringe.
10. Prepare syringe 4 for aspiration. 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.
11. Re-enter the Pump.
12. Open the stopcock and remove the RINSE BUFFER. After the fluid level stops moving, wait an additional 30 seconds for all the RINSE BUFFER and air to be removed.
13. When the time has elapsed, close the stopcock and remove the syringe and set aside.

Syringe 5: Rinse Buffer (degassed)

14. Prime the needle. Close the stopcock.
 15. Enter the Pump fill port with the refill needle.
 16. Open the stopcock and allow the Pump to fill completely with RINSE BUFFER. When the fluid level stops moving, the Pump is filled. When the pump is filled, approximately 10 ml of RINSE BUFFER will remain in the syringe. Leave the RINSE BUFFER in the syringe and **leave the syringe in place for the next step.**
-

Equilibrate and pull rinse buffer through system

The reservoir pressure in the Pump is equilibrated with outside ambient pressure and RINSE BUFFER is pulled through the fluid system. This procedure uses the following volumes in syringes 4 and 5:

- Syringe 4 with RINSE BUFFER. Expel all RINSE BUFFER except 5 ml. Change refill needle if desired.
- Syringe 5 with residual RINSE BUFFER from previous step

Syringe 5: Rinse Buffer

1. Verify that the stopcock on syringe 5 is open.
2. Prime the needle of syringe 4. Close the stopcock.
3. 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.
4. Enter the side port with the stopcock closed.
5. Open the stopcock.
6. To open the valve in the Pump mechanism, program and deliver a 4 unit bolus using the PPC.
7. Observe syringe 4. When at least 1 ml of RINSE BUFFER has entered syringe 4, close both stopcocks and remove the syringes. If less than 1 ml enters, repeat the bolus from Step 6. Some Pumps may require 3 successive boluses to obtain 1 ml. Discard syringe 4 and set aside syringe 5 to be used later to remove RINSE BUFFER.

Remove rinse buffer and fill with insulin

The RINSE BUFFER is removed from the Pump fluid system and the system is filled with INSULIN. This procedure uses the following volumes in syringes 5, 7, and 8:

- Syringe 5 with residual RINSE BUFFER from the previous steps
 - Syringe 6 with 20 ml INSULIN
-

- Syringe 7 with 30 ml INSULIN

Syringe 5: Rinse Buffer (residual)

1. Prime the needle. Close the stopcock.
2. 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.
3. Enter the Pump with the refill needle and syringe.
4. Open the stopcock and remove the RINSE BUFFER. After the fluid level stops moving, wait an additional 30 seconds to make sure all the RINSE BUFFER and air is removed.
5. When the time has elapsed, close the stopcock, remove the syringe, and discard.

Syringe 6: Insulin (degassed)

6. Prime the needle. Close the stopcock .
 7. Enter the Pump fill port with the refill needle and syringe.
 8. Open the stopcock and allow the Pump to fill completely with INSULIN. When the fluid level stops moving, the Pump is filled.
 9. Close the stopcock and remove the syringe.
 10. Prepare syringe 6 for aspiration. Prime needle and close stopcock. 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.
 11. Re-enter the Pump.
 12. Open the stopcock, remove the INSULIN. After the fluid level stops moving, wait an additional 30 seconds for all the INSULIN and air to be removed.
 13. When the time has elapsed, close the stopcock and remove the syringe. Discard all but 5 ml of solution. Remove any air, prime nee-
-

dle and close stopcock. Set aside the syringe.

Syringe 7: Insulin (degassed)

- 14.** Prime the needle on syringe 7. Weigh and record the combined weight of syringes 6 and 7 on the Refill Form.
- 15.** Close the stopcock. Enter the Pump fill port with the refill needle.
- 16.** Open the stopcock and allow the Pump to fill completely with INSULIN. When the fluid level stops moving, the pump is filled. When the Pump is filled, approximately 10 ml of INSULIN will remain in the syringe. **Leave the syringe in place for the next step.**

Equilibrate and pull insulin through system

The reservoir pressure in the Pump is equilibrated with outside ambient pressure and INSULIN is pulled through the fluid system. This procedure uses the following volumes in syringes 6 and 7:

- Syringe 7 with residual INSULIN from previous step
- Syringe 6 with 5 ml solution. To perform this procedure with syringes 6 and 7, follow the steps below:

Syringe 6: Insulin (residual)

Syringe 7: Insulin (residual)

- 1.** Maintain syringe 7 with approximately 10 ml of residual INSULIN in the Pump fill port. Verify that the stopcock on syringe 7 is open.
 - 2.** Prime the syringe 6 needle. Close the stopcock.
 - 3.** Obtain a vacuum in syringe 6 by pulling back on the plunger until it locks. Press the lock into the plunger groove to be sure it is firmly secured.
 - 4.** Enter the side port with syringe 6 - stopcock closed.
 - 5.** Open the stopcock on syringe 6.
-

6. Using the PPC, program and deliver a 4 unit bolus.
7. Observe syringe 7. If the level of INSULIN approaches 2 ml, close the stopcock to prevent air from entering the Pump. Observe syringe 6. At least 1 ml of INSULIN must pass into syringe 6 to assure removal of all the RINSE BUFFER from the side port. If less than 1 ml enters, repeat the bolus from Step 6, some Pumps may require 3 successive boluses to obtain 1 ml.
8. Close both stopcocks. Remove syringe 7 from the Pump. Set aside the syringe to be weighed.
9. With the stopcock closed, remove syringe 6 from the side port. Syringe 6 will have a vacuum from the previous step. Enter the Pump fill port with syringe 6 and open the stopcock to remove 2 ml. This will restore the negative pressure safety feature of the Pump.
10. Close the stopcock, remove syringe 6 from the Pump, and set it aside to be weighed.

Remove guide needles and record fill amount

At this point, the 18 gauge guide needles should be removed and the refill amount should be calculated and recorded. Follow the steps below:

1. Remove the 18 gauge guide needles. Apply pressure to the needle insertion sites.
2. Weigh syringes 6 and 7 and record on the refill form. Subtract the combined weight from the weights obtained in step 14 of the section, "Remove RINSE BUFFER and Fill with Insulin." The result is the new refill amount.
3. Record the extracted and new refill amounts in the PPC.

Program new basal rate

Using the patient's PPC, cancel the SUSPEND mode, to return to the normal patient's basal rate and modify if needed.

APPENDIX F

Side Port Catheter Flush Procedure

When delivery of insulin is impaired due to catheter tip obstruction, the Catheter may be flushed using 5 - 10 mL of RINSE BUFFER.

Supplies and solutions

Prior to performing this procedure, assemble the necessary supplies and solutions as outlined below:

Supplies

- Steri-Strips[®] and markers
 - Local anesthesia
 - Sharps container
 - PPC
 - Oral or IV glucose
 - Glucose monitoring equipment
 - Drapes
 - One (1) scale - 0.01 gram resolution
 - One (1) 250 mL sterile beaker
 - One (1) sterile bag for PPC (intestinal or cassette bags work well)
 - One (1) Side port locating template, MMT-4106
 - Five (5) Refill kits, MMT-4105
 - Six (6) MiniMed MMT-4102 refill needles. (Extra needles
-

should be available to use as needed)

- Eight (8) sharp 18 gauge regular bevel needles
- One (1) 10 or 20 mL Luer Lock[®] syringe
- One (1) stopcock - 2 way

Solutions

- Seven (7) 10 mL vials, Aventis rinse buffer solution
- Five (5) 10 mL vials, aventis HOE 21 PH, U-400 Insulin

NOTE: One-handed flush with a 10-20 mL syringe only.

Preparing for the procedure

NOTE: Before beginning any refill, flush, stroke volume measurement, carefully read Appendix D, Precautions and General Procedures, and keep this in mind as you perform each procedure.

In order to prepare for the Side Port Catheter rinse and flush procedure, a total of five different refill syringes and one 10 or 20 ml syringe will need to be labeled and prepared with different solutions. Table 2 defines the syringe numbers and corresponding solutions.

Table 2: Preparation and Labeling of Syringes

Syringe #	Syringe Type	Volume	Solution
#1	Refill	5 mL	RINSE BUFFER
#2	Refill	20 mL	RINSE BUFFER
#3	Refill	30 mL	RINSE BUFFER
#4	10ml or 20 ml	5-10 mL	RINSE BUFFER
#5	Refill	20 mL	INSULIN
#6	Refill	30 mL	INSULIN

Record patient's blood glucose

Record the patient's blood glucose value at the start of the procedure. Monitor blood glucose every 30 minutes, or as needed.

Prepare syringes for emptying the Pump

Syringe 1 is used for emptying the Pump. Label and prepare syringe 1 per Table 2. Special attention should be observed regarding the Precautions and General Procedures section in Appendix D of this manual.

After the syringe is prepared, weigh the syringe and enter the weight on the Refill Form.

Prepare syringes for filling the Pump

During the Catheter rinse/flush procedure, syringes 2, 3, 5, and 6 are used for filling the Pump. Each syringe should be labeled with its solution and syringe number, then filled and degassed per Table 2 and the General Procedures section in Appendix D of this manual.

Prepare syringe for flushing the Side Port Catheter

During the Catheter flush procedure, syringe 4 is used for flushing the Side Port Catheter. This syringe needs to be labeled and then prepared by following the steps below:

1. Firmly attach a stopcock to the 10 or 20 ml Luer Lock connector of a 10 or 20 ml syringe. Then attach an 18 gauge needle to the stopcock.

NOTE: Use only a 10-20 ml Luer Lock syringe for this procedure. Smaller syringes will damage the Catheter or Pump.

2. Draw 5-10 mL of RINSE BUFFER into the syringe.
 3. Expel all air from the syringe.
 4. Close the stopcock and remove the 18 gauge needle from the syringe.
 5. Fill the hub of the MiniMed refill needle with RINSE BUFFER from the syringe and attach it to the syringe.
 6. Prime the MiniMed refill needle completely.
 7. Close the stopcock.
 8. Set the syringe aside.
-

Flushing the Side Port Catheter

Program minimal basal rate

Place the PPC in a sterile bag and program the pump to “SUSPEND” mode, the basal rate will be 0.2 U/h.

Remove insulin and fill with rinse buffer

The INSULIN is removed from the Pump and the system is filled with RINSE BUFFER. This procedure uses the following volumes in syringes 1, 2, and 3:

- Syringe 1 with 5 mL RINSE BUFFER
- Syringe 2 with 20 mL RINSE BUFFER
- Syringe 3 with 30 mL RINSE BUFFER

Syringe 3: Rinse Buffer (residual)

1. Prime the needle and close the stopcock. Weigh the syringe.
2. Obtain a vacuum by pulling back on the plunger until it locks. Press the lock into the plunger groove and be sure it is firmly secured.
3. Enter the Pump with the refill needle.
4. Open the stopcock and withdraw the INSULIN. After the INSULIN appears to have stopped rising in the syringe, wait an additional 30 seconds to make sure all of the INSULIN and air are removed.

NOTE: Air in the Pump System has been shown to be a significant agonist to aggregation of INSULIN. Proper degassing of all solutions that enter the Pump is essential.

5. When the time has elapsed, close the stopcock, remove the syringe. Weigh the syringe and record the weight on the Refill Form.
-

Syringe 5: Insulin

6. Prime the needle and close the stopcock.
7. Enter the Pump with the refill needle.
8. Open the stopcock and allow the Pump to fill completely with RINSE BUFFER. When the fluid level stops moving, the Pump is filled.
9. Close the stopcock and remove the syringe.
10. Prepare syringe 2 for aspiration. Obtain a vacuum by pulling back on the plunger until it locks. Press the lock into the plunger groove and be sure it is firmly secured.
11. Re-enter the Pump.
12. Open the stopcock and remove the RINSE BUFFER. After the fluid level stops moving, wait an additional 30 seconds for all the RINSE BUFFER and air to be removed.
13. When the time has elapsed, close the stopcock and remove the syringe.

Syringe 3: Rinse Buffer

14. Prime the needle and close the stopcock .
 15. Enter the Pump fill port with the refill needle.
 16. Open the stopcock and allow the Pump to fill complete with RINSE BUFFER. When the fluid level stops moving, the Pump is filled. When the Pump is filled, approximately 10 mL of RINSE BUFFER will remain in the syringe. Leave the RINSE BUFFER in the syringe, and **leave the syringe in place for the next step.**
-

Equilibrate and pull rinse buffer through system

The reservoir pressure in the Pump is equilibrated with outside ambient pressure and RINSE BUFFER is pulled through the fluid system. This procedure uses syringes 2 and 3:

- Syringe 2 with RINSE BUFFER. Expel all RINSE BUFFER except 5 mL. Change the refill needle if desired.
- Syringe 3 with residual RINSE BUFFER from the previous section.

Syringe 3: Rinse Buffer

1. Maintain syringe 3 with approximately 10 mL of RINSE BUFFER in the Pump fill port. Verify that the stopcock on syringe 3 is open.

Syringe 2: Rinse Buffer (residual)

2. Prime the needle. Close the stopcock.
 3. 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.
 4. Enter the side port with the stopcock closed.
 5. Open the stopcock.
 6. Program and deliver a 4 unit bolus to open the valve in the Pump mechanism.
 7. Observe syringe 3. When the level of the RINSE BUFFER approaches 2 mL, close the stopcock to prevent air from entering the Pump. Observe syringe 2. When at least 1 mL of RINSE BUFFER has entered syringe 2 close both stopcocks and remove the syringes. If less than 1 ml enters, repeat the bolus from Step 6, some Pumps may require 3 successive boluses to obtain 1 ml. Discard syringe 2 and set aside syringe 3 to be used later to remove the RINSE BUFFER.
-

Flush side port catheter

The Side Port Catheter is flushed using syringe 4 which is completely filled with RINSE BUFFER.

NOTE: Approximately 13 units of INSULIN remain in the distal Side Port Catheter. This INSULIN will be delivered to the patient rapidly in the next three steps. Alternatively, the INSULIN may be removed prior to flushing by programming cautious bolus amounts. Closely monitor blood glucose during INSULIN delivery, and administer intravenous glucose, or glucagon as needed.

10-20 ml Syringe 4: Rinse Buffer

1. Prime the needle. Close the stopcock.
2. Enter the side port with the needle.
3. When the needle is firmly positioned in the side port, open the stopcock and quickly push the plunger all the way down. This should take no longer than one to two minutes.
4. After flushing, close the stopcock, remove and discard the syringe.

NOTE: This is the only time a plunger should be manually pushed down.

Remove rinse buffer and fill with insulin

The RINSE BUFFER is removed from the Pump fluid system and the system is filled with insulin. This procedure uses the following volumes in syringes 3, 5, and 6:

- Syringe 3 with residual RINSE BUFFER from the previous step
 - Syringe 5 with 20 mL INSULIN
 - Syringe 6 with 30 mL INSULIN
-

Syringe 3: Rinse Buffer (residual)

1. Prime the needle. Close the stopcock.
2. Obtain a vacuum by pulling back on the plunger until it locks. Press the lock into the plunger groove and be sure it is firmly secured.
3. Enter the Pump with the refill needle and syringe.
4. Open the stopcock and remove the rinse buffer. After the fluid level stops moving, wait an additional 30 seconds to make sure all of the RINSE BUFFER and air is removed.
5. When the time has elapsed, close the stopcock, remove the syringe, and discard it.

Syringe 5: Insulin

6. Prime the needle and close the stopcock.
 7. Enter the Pump fill port with the refill needle.
 8. Open the stopcock and allow the Pump to fill completely with INSULIN. When the fluid level stops moving, the Pump is filled.
 9. Close the stopcock and remove the syringe.
 10. Prepare syringe 6 for aspiration. 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.
 11. Re-enter the Pump.
 12. Open the stopcock and remove the INSULIN. After the fluid level stops moving, wait an additional 30 seconds for all INSULIN and air to be removed.
 13. When the time has elapsed, close the stopcock and remove the syringe. Discard all but 5 mL of the solution. Remove the air and **set aside the syringe.**
-

Syringe 6: Insulin

14. Weigh and record the combined weight of syringes 5 and 6 on the Refill Form. Prime the needles.
15. Close the stopcock. Enter the Pump fill port with the refill needle.
16. Open the stopcock and allow the Pump to fill completely with INSULIN. When the fluid level stops moving, the Pump is filled. Approximately 10 mL of INSULIN will remain in the syringe. **Leave the syringe in place for the next step.**

Equilibrate and pull insulin through system

The reservoir pressure in the Pump is equilibrated with outside ambient pressure and INSULIN is pulled through the fluid system. This procedure uses the following volumes in syringes 5 and 6:

- Syringe 6 with residual INSULIN from the previous step
- Syringe 5 with 5 mL solution

Syringe 6: Insulin (residual)**Syringe 5: Solution**

1. Maintain syringe 6 with approximately 10 mL of residual insulin in the Pump fill port. Verify that the stopcock on syringe 6 is open.
 2. Prime the syringe 5 needle and close the stopcock.
 3. Obtain a vacuum in syringe 5 by pulling back on the plunger until it locks. Press the lock into the plunger groove and be sure it is firmly secured.
 4. Enter the side port with syringe 5 - stopcock closed.
 5. Open the stopcock on syringe 5.
 6. Press **SEL**. When the PPC screen is flashing “PUMP SUSPEND” press **ACT**. The system is now in normal mode.
-

7. Using the PPC, program and deliver a 4 unit bolus.
8. Observe syringe 6. If the level of INSULIN approaches 2 mL, close the stopcock to prevent air from entering the Pump. Observe syringe 5. At least 1 mL of INSULIN must pass into syringe 5 to be sure that all of the RINSE BUFFER is removed from the side port. If less than 1 ml enters, repeat the bolus from Step 6, some Pumps may require 3 successive boluses to obtain 1 ml.
9. Close both stopcocks. Remove syringe 6 from the Pump. Set the syringe aside to be weighed.
10. With the stopcock closed, remove syringe 5 from the side port. It will have a vacuum inside from the previous step. Enter the Pump fill port with syringe 5 and open the stopcock and remove 2 ml. This will restore the negative pressure safety feature of the Pump.
11. Close the stopcock, remove syringe 5 from the Pump, and set it aside to be weighed.
12. Press **SEL** until the "SUSPEND PUMP" screen is displayed. Then Press **ACT**.

Remove guide needles and record refill amount

At this point, the 18 gauge guide needles should be removed, and the refill amount should be calculated and recorded.

1. Remove the 18 gauge guide needles and discard them. Apply pressure to the insertion sites.
 2. Weigh syringes 5 and 6 and record the combined weight on the Refill Form. Subtract the combined weight from the weight obtained in step 14 of this section, Remove Rinse Buffer and Fill with Insulin. The result is the new refill amount.
 3. Record the new and extracted refill amount in the PPC.
-

Program new basal rate

Using the patient's PPC, cancel the "SUSPEND" mode and allow the Pump to return to the patient's original basal rate.

Remove rinse buffer from catheter

Approximately 13 units of RINSE BUFFER remain in the distal Side Port Catheter. Depending on blood glucose values, program the appropriate bolus amount to remove the RINSE BUFFER from the Catheter. Release the patient when blood glucose levels are stable.

Stroke Volume Measurement

If under-delivery of insulin is noted in a refill procedure or suspected due to blood glucose control, it may be useful to verify the proper stroke volume of the Pump by accessing the side port.

In this procedure, a pipette is attached to a stopcock and refill needle. This system is inserted into the side port. The insulin pulses in the pipette are measured to calculate the pump stroke volume.

Supplies and Solutions

Prior to performing this procedure, assemble the necessary supplies and solutions as outlined below:

Supplies

- Local anesthesia
 - Sharps container
 - PPC
 - Oral or IV glucose
 - Glucose monitoring equipment
 - Drapes
 - 5 mL or 3 mL syringe
 - One (1) sterile bag for PPC (intestinal or cassette bags work well)
 - One (1) Side port locating template, MMT-4106
 - One (1) sterile 100 microliter pipette
-

- One (1) MiniMed MMT-4102 refill needle. (Extra needles should be available to use as needed)
- One (1) sterile stopcock - 3 way

Solutions

- One (1) 10 mL vial, Aventis rinse buffer solution

Preparing for the Procedure

NOTE: Before beginning any refill, flush, stroke volume measurement, carefully read Appendix D, Precautions and General Procedures, and keep this in mind as you perform each procedure.

Record Patient's Blood Glucose

Record the patient's blood glucose value at the start of the procedure. Monitor blood glucose every 30 minutes, or as needed.

Measuring Stroke Volume

1. In a sterile field immediately before the procedure; prepare the apparatus. Prime the stopcock, pipette, and needle.

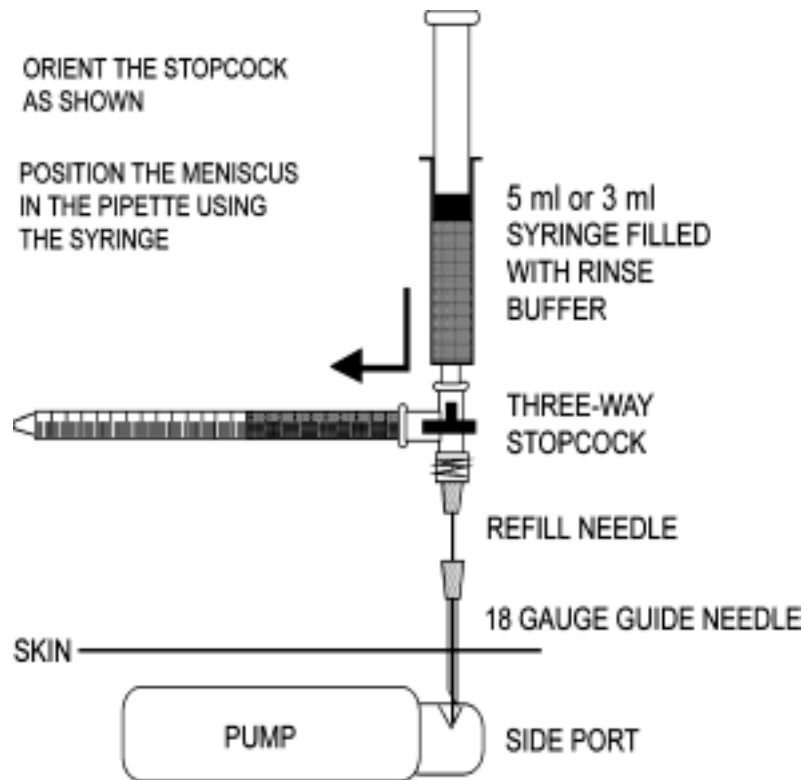


Figure 19: Measuring the Stroke Volume

2. Turn the stopcock to close off the needle.
3. Insert the needle into the side port.
4. Turn the stopcock, as shown in Figure 19.

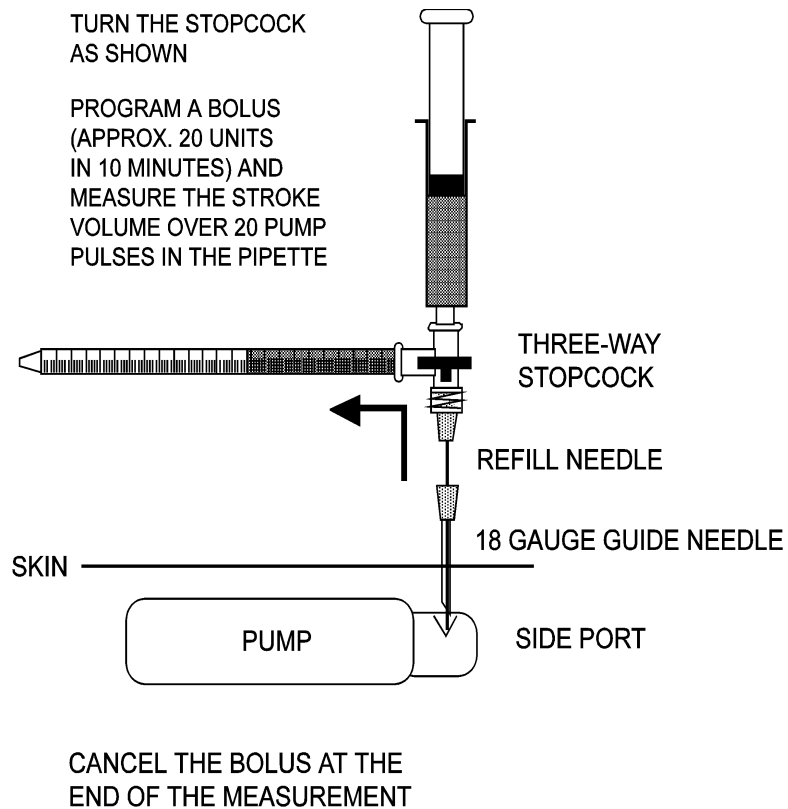


Figure 20: Closed Stopcock

5. Program a high rate bolus (approximately 20 units) and measure the stroke volume over 20 pulses in the pipette.
6. Cancel the bolus at the end of the measurement.
7. Turn the stopcock back to the position shown in Figure 20 to close. Remove the apparatus.

Record Patient's Blood Glucose

It is likely that some insulin is pumped out of the Catheter and into the patient in this procedure. Monitor the patient's blood glucose and release the patient only after blood glucose values are stable.

APPENDIX H

Pressure Measurement Using The Side Port Catheter

If under-delivery of insulin is noted by increased insulin needs or by lower than expected actual usage at refills, you may suspect one of two causes:

Insulin deposits have led to under-delivery from the Pump.

Catheter blockage has led to under-delivery from the Catheter

Pressure measurement in the side port can detect pressure build-up due to Catheter tip obstruction. This test, along with the Stroke Volume test, helps to differentiate Pump problems from Catheter problems.

NOTE: During this procedure, a 5 unit bolus is programmed. You need to monitor carefully the blood sugar pre/per/post procedure.

Supplies and solutions

Prior to performing this procedure, assemble the necessary supplies and solutions as outlined below:

Supplies

- Steri-Strips[®] and markers
 - Local anesthesia
 - Sharps container
 - Safety glasses
 - PPC
 - Oral or IV glucose
 - Glucose monitoring equipment
 - Drapes
 - One (1) scale - 0.01 gram resolution
 - One (1) 250 ml sterile beaker
 - One (1) sterile bag for PPC (intestinal or cassette bags work well)
 - One (1) Side port locating template, MMT-4106
 - Five (5) Refill kits, MMT-4105
 - Nine (9) MiniMed MMT-4102 refill needles. (Extra needles should be available to use as needed)
 - Two (2) 10 or 20 ml Luer Lock[®] syringe
 - One (1) stopcock - 2 way
 - One (1) stopcock - 3 way
 - Syringe filter with luer lock, 0.2 micro (long configuration - not disk configuration)
 - Chart recorder
 - Pressure monitor
 - Pressure transducer
-

Solutions

- Seven (7) 10 ml vials, Aventis rinse buffer solution
- Five (5) 10 ml vials, Aventis HOE 21 PH, U-400 Insulin

Preparing for the procedure

NOTE: Before beginning any refill, flush, stroke volume measurement, or pressure measurement procedure, carefully read Appendix D, Precautions and General Procedures, and keep this in mind as you perform each procedure.

In order to prepare for the Side Port Catheter flush procedure, a total of five different refill syringes and one 10 - 20 ml syringe will need to be labeled and then prepared with different solutions. Table 3 defines the syringe numbers and corresponding solutions.

Table 3: Preparation and Labeling of Syringes

Syringe	Labeling	Solution
#1	60 ml	RINSE BUFFER
#2	60 ml	RINSE BUFFER
#3	60 ml	RINSE BUFFER
#4 10-20 ml	5 - 10 ml	RINSE BUFFER
#5	60 ml	INSULIN
#6	60 ml	INSULIN

Record patient's blood glucose

Record the patient's blood glucose value at the start of the procedure. Monitor blood glucose every 30 minutes, or as needed.

Prepare syringes for emptying the pump

Syringe 1 is used for emptying the Pump. Label and prepare syringe 1 per the Precautions and General Procedures section in Appendix D of this manual. After the syringe is prepared, weigh it and record the weight on the Refill Form.

Prepare syringes for filling the pump

During the pressure test procedure, syringes 2, 3, 5, and 6 are used for filling the Pump. Each of these syringes need to be labeled with its solution and syringe number, and then filled and degassed per the General Procedures in Appendix D of this manual.

Prepare syringe for priming the test setup

During the pressure test procedure, syringe 4 is used to prime the needle, filter, and the 3-way stopcock. This syringe needs to be labeled and then prepared by following the steps below:

1. Attach an 18 gauge needle to the syringe. Draw 5 - 10 ml of RINSE BUFFER into the syringe.
 2. Expel all air from the syringe.
 3. Attach a 3-way stopcock to the syringe.
 4. Turn the stopcock to close off the syringe.
-

Measuring pressure in the side port

Program minimal basal rate

Place the PPC in a sterile bag and program the Pump in SUSPEND mode, the basal rate will be 0.2 U/h.

Remove insulin and fill with rinse buffer

The INSULIN is removed from the Pump and the system is filled with RINSE BUFFER. This procedure uses the following volumes in syringes 1, 2, and 3:

- Syringe 1 with 5 ml RINSE BUFFER
- Syringe 2 with 20 ml RINSE BUFFER
- Syringe 3 with 30 ml RINSE BUFFER

Syringe 1: Rinse Buffer

1. Prime the needle and close the stopcock.
2. 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.
3. Enter the Pump with the refill needle.
4. Open the stopcock and withdraw the INSULIN. After the INSULIN appears to have stopped rising in the syringe, wait an additional 30 seconds to make sure all of the INSULIN and air is removed.
5. When the time has elapsed, close the stopcock, remove the syringe. Weigh the syringe and record the weight on the Refill Form.

Syringe 2: Rinse Buffer

6. Prime the needle and close the stopcock.
 7. Enter the Pump with the refill needle.
 8. Open the stopcock and allow the Pump to fill completely with RINSE BUFFER. When the fluid level stops moving, the Pump is filled.
-

9. Close the stopcock and remove the syringe.
10. Prepare syringe 2 for aspiration. 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.
11. Re-enter the Pump.
12. Open the stopcock and remove the RINSE BUFFER. After the fluid level stops moving, wait an additional 30 seconds for all the RINSE BUFFER and air to be removed.
13. When the time has elapsed, close the stopcock and remove the syringe.

Syringe 3: Rinse Buffer

14. Prime the needle and close the stopcock.
15. Enter the Pump fill port with the refill needle.
16. Open the stopcock and allow the Pump to fill complete with RINSE BUFFER. When the fluid level stops moving, the Pump is filled. When the Pump is filled, approximately 10 ml of RINSE BUFFER will remain in the syringe. Leave the RINSE BUFFER in the syringe, and **leave the syringe in place for the next step.**

Equilibrate and pull rinse buffer through system

The reservoir pressure in the Pump is equilibrated with outside ambient pressure and RINSE BUFFER is pulled through the fluid system. This procedure uses the following volumes in syringes 2 and 3:

- Syringe 2 with RINSE BUFFER. Expel all RINSE BUFFER except 10 ml. Change the refill needle if desired.
 - Syringe 3 with residual RINSE BUFFER from the previous section.
-

Syringe 3: Rinse Buffer (residual)

1. Verify that the stopcock on syringe 3 is open.
2. Prime the needle. Close the stopcock.
3. 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.
4. Enter the side port with the stopcock closed.
5. Open the stopcock.
6. Press **SEL** key. When “PUMP SUSPENDED” is flashing on the screen press **ACT**. This will place the system in normal mode.
7. Program and deliver a 4 unit bolus to open the valve in the Pump mechanism.
8. Observe syringe 3. When the level of the RINSE BUFFER approaches 2 ml, close the stopcock to prevent air from entering the Pump. Observe syringe 2. When at least 1 ml of RINSE BUFFER has entered syringe 2. If less than 1 ml enters, repeat the bolus from Step 6, some Pumps may require 3 successive boluses to obtain 1 ml. Close both stopcocks and remove the syringes. Discard syringe 2 and set aside syringe 3 to be used later to remove the RINSE BUFFER.

Perform pressure test

Syringe 4: Rinse Buffer

1. Plug in the chart recorder and the monitor. Attach the monitor cables. The pressure gauge is set to 1 volt = 1 psi. When knob 2 is set to 6 volts, then the full scale reading on the paper chart is 6 psi.
 2. Set the switches and knobs of the chart recorder as follows: Switch 1 to “V” position, Knob 2 to “6” volts full scale, Knob 5 to “6” cm/minute setting, Switch 9 to “_ _ _” icon (Direct Current)
-

3. Open the chart recorder cover at "A." Remove the pen cap. Retain the pen cap as it must be replaced after the procedure to prevent the pen from drying out.
 4. Inspect the tubing and the stopcock coming from the pressure transducer. It must be completely free of bubbles. Inject sterile water with a very long needle to displace any bubbles present. Use a syringe to add water to the stopcock to form a positive meniscus.
 5. Assemble the following sterile components in a sterile field per : Syringe, Filter, 3-way Stopcock, MiniMed refill needle (MMT-4102) Prime the stopcock, filter and needle using the RINSE BUFFER from the syringe. Form a positive meniscus on the end of the filter.
 6. Carefully join the 2-way stopcock to the filter. A sterile person must hold the filter assembly and a non-sterile person must hold the stopcock. From this point, the sterile person will manipulate the needle and stopcock to perform the measurements.
 7. Push switch 7 to "I Pen." This puts the pen in contact with the paper.
 8. Set the "0" adjustment. Maintain switch 3 to the right position and adjust the thumbwheel 4, until the pen is at "0."
 9. Initialize the chart by pushing switch 6 to the right "Prot" momentarily. The pen will write the chart settings.
 10. Tape the transducer securely to a table or any stable surface roughly at the level of the implanted Pump. Hold the refill needle at the level of the patient's pump and open both the 2-way and the 3-way stopcocks. (The 3-way stopcock is opened to allow flow between the filter and needle but not to the syringe.) The monitor should display 0 (zero) or a very low number. Close both stopcocks. (The 3-way stopcock is opened between the syringe and the filter; the needle is closed.)
-

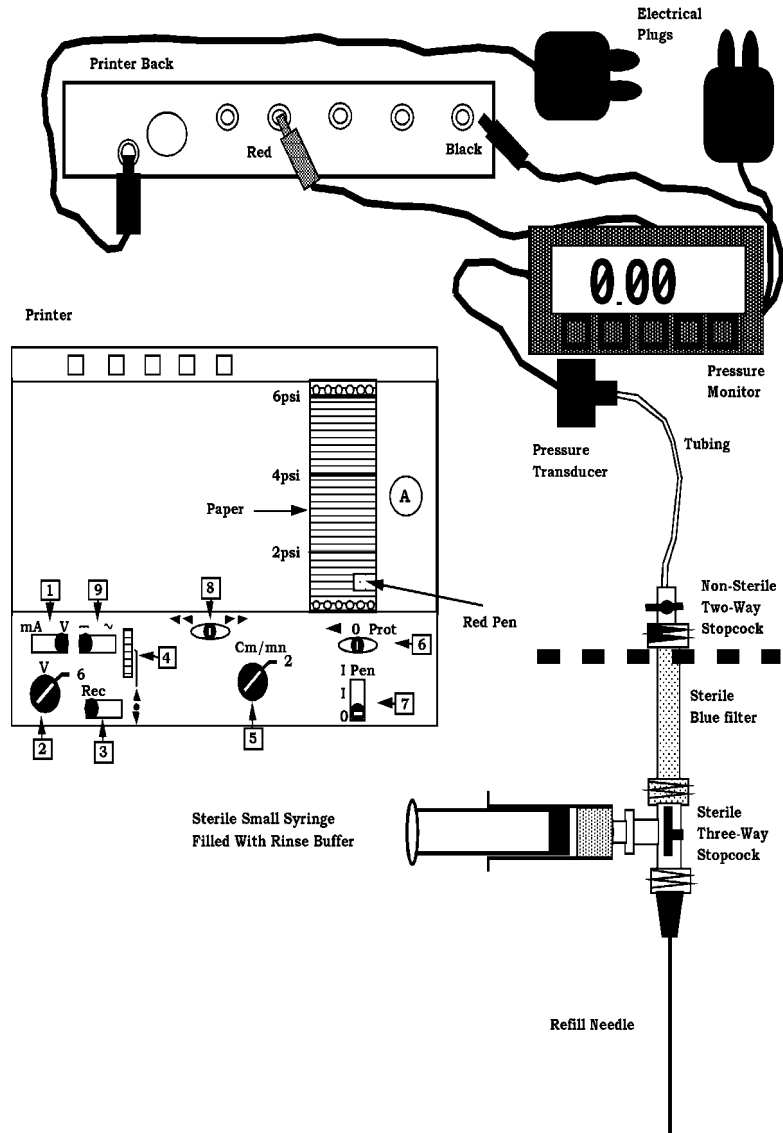


Figure 21: Attaching the Monitor Cables to the Chart Recorder

11. Slide switch 6 to its left position to start the paper. Fast forward the paper as necessary using switch 8.
12. Place the refill needle in the side port.
13. Program a bolus (5 units) and open both stopcocks. (The 3-way stopcock is opened between the filter and needle and the syringe is closed.) Maintain the needle in the side port without movement during the entire bolus and observe the curve for the duration of the bolus and for 10 minutes after the bolus. If leakage is suspected, the 3-way stopcock may be turned so that the filter is off. If the pressure curve flattens, all of the connections between the transducer and the stopcock are leak tight.

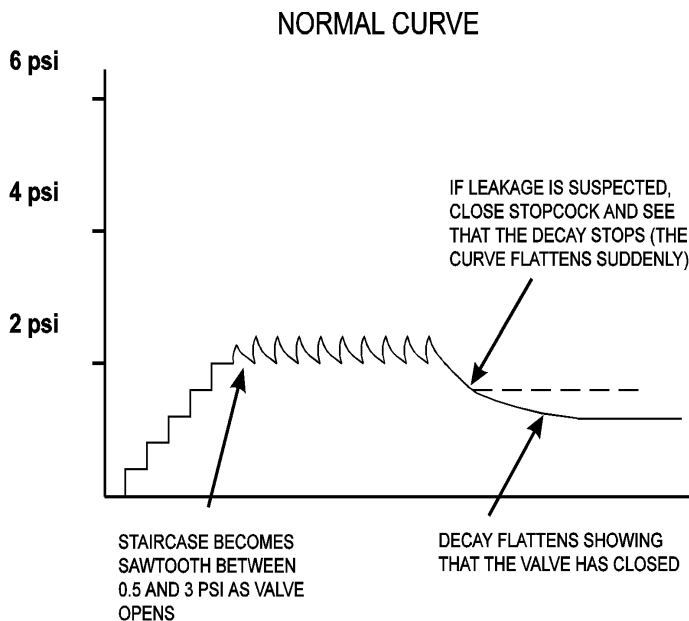


Figure 22: Normal Pressure Curve Example

A flush of the Catheter tip can be performed at this time. (See Appendix F, *Side Port Catheter Rinse Procedure*). A repeat pressure tracing should be made subsequent to the flush. Place system in Suspend Mode by press-

ing **ACT** on the “SUSPEND” screen.

Remove rinse buffer and fill with insulin

The RINSE BUFFER is removed from the Pump fluid system and the system is filled with INSULIN. This procedure uses the following volumes in syringes 3, 5, and 6:

- Syringe 3 with residual RINSE BUFFER from the previous steps
- Syringe 5 with 20 ml INSULIN
- Syringe 6 with 30 ml INSULIN

Syringe 3: Rinse Buffer (residual)

1. Expel all air from the syringe and prime the needle.
2. Close the stopcock. 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.
3. Enter the Pump with the refill needle and syringe.
4. Open the stopcock and remove the RINSE BUFFER. After the fluid level stops moving, wait an additional 30 seconds to make sure all of the RINSE BUFFER and air is removed.
5. When the time has elapsed, close the stopcock, remove the syringe, and discard.

Syringe 5: Insulin

6. Prime the needle and close the stopcock.
 7. Enter the Pump fill port with the refill needle.
 8. Open the stopcock and allow the pump to fill completely with INSULIN. When the fluid level stops moving, the Pump is filled.
 9. Close the stopcock and remove the syringe.
 10. Prepare syringe 6 for aspiration. 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.

11. Re-enter the Pump.
12. Open the stopcock and remove the INSULIN. After the fluid level stops moving, wait an additional 30 seconds for all the INSULIN and air to be removed.
13. When the time has elapsed, close the stopcock and remove the syringe. Discard all but 5 ml of the solution. Remove the air and **set aside the syringe**.

Syringe 6: Insulin

14. Weigh and record the combined weight of syringes 5 and 6 on the refill form. Prime the needles.
15. Close the stopcock. Enter the Pump fill port with the refill needle.
16. Open the stopcock and allow the Pump to fill completely with INSULIN. When the fluid level stops moving, the Pump is filled. Approximately 10 ml of INSULIN will remain in the syringe. Leave the INSULIN in the syringe, and **leave the syringe in place for the next step**.

Equilibrate and pull insulin through system

The reservoir pressure in the Pump is equilibrated with outside ambient pressure and INSULIN is pulled through the fluid system. This procedure uses the following volumes in syringes 5 and 6:

- Syringe 6 with residual INSULIN from the previous step
- Syringe 5 with 5 ml solution

Syringe 5: Solution

Syringe 6: Insulin (residual)

1. Maintain syringe 6 with approximately 10 ml of residual INSULIN in the Pump fill port. Verify that the stopcock on syringe 6 is open.
 2. Prime the syringe 5 needle. Close the stopcock.
 3. Obtain a vacuum in syringe 5 by pulling back on the plunger until it locks. Press the lock into the plunger groove to be sure it is firmly secured.
 4. Enter the side port with syringe 5 - stopcock closed.
 5. Open the stopcock on syringe 5.
 6. Program and deliver a 4 unit bolus to open the valve in the Pump mechanism.
 7. Observe syringe 6. If the level of INSULIN approaches 2 ml, close the stopcock to prevent air from entering the Pump. Observe syringe 5. At least 1 ml of INSULIN must pass into syringe 5 to be sure that all of the RINSE BUFFER is removed from the side port. If less than 1 ml enters, repeat the bolus from Step 6, some Pumps may require 3 successive boluses to obtain 1 ml.
 8. Close both stopcocks. Remove syringe 6 from the Pump. Set aside the syringe to be weighed.
 9. With the stopcock closed, remove syringe 5 from the side port. Syringe 5 will have a vacuum inside from the previous step. Enter the Pump fill port with syringe 5 and open the stopcock to remove 2 ml. This will restore the negative pressure safety feature of the Pump.
 10. Close the stopcock, remove syringe 5 from the Pump, and set it aside to be weighed.
-

Remove guide needles and record refill amount

At this point, the 18 gauge guide needles should be removed, and the refill amount should be calculated and recorded.

- 1.** Remove the 18 gauge guide needles and discard them. Apply pressure to the insertion sites.
- 2.** Weigh syringes 5 and 6 and record their combined weight on the Refill Form. Subtract the combined weight from the weight obtained in step 14 of this section, Remove Rinse Buffer and fill with INSULIN. The result is the new refill amount.
- 3.** Record the extracted and new refill amounts in the PPC.

Using the patient's PPC, cancel the SUSPEND mode, to return to the normal patient's basal rate.