Medtronic

SYNCHROMED® II 8637

Programmable pumps

Implant manual

! USA Rx only

CE 0123

2003

Explanation of symbols on product or package labeling

Refer to the appropriate product for symbols that apply.

Open here

Do not reuse

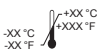
Sterilized using ethylene oxide

Consult instructions for use

Use by

Date of manufacture

Manufacturer



Temperature limitation

Keep away from magnets

Serial number

Conformité Européenne (European Conformity). This symbol means that the device fully complies with AIMD Directive 90/385/EEC (NB 0123) and R&TTE Directive 1999/5/EC.

For USA audiences only

Authorized representative in the European community

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Refer to the Indications, Drug Stability, and Emergency Procedures reference manual for indications and related information.

Refer to the appropriate information for prescribers booklet for contraindications, warnings, precautions, adverse events summary, individualization of treatment, patient selection, use in specific populations, and component disposal.

Refer to the appropriate drug labeling for indications, contraindications, warnings, precautions, dosage and administration information, and screening procedures.

Description

The implantable Medtronic Model 8637 SynchroMed II programmable pump is part of an infusion system that stores and delivers a prescribed drug to a specific site. The implanted infusion system consists of a Model 8637 SynchroMed II pump and a catheter.

The catheter connects to the pump catheter port. The pump is anchored in the pump pocket using the suture loops on the outside of the pump (Figure 1).

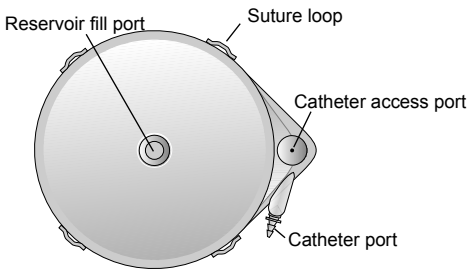

Figure 1. *Pump exterior view.*

The drug is stored in the pump reservoir (Figure 2). Per a programmed prescription, the drug moves from the pump reservoir, through the pump tubing, catheter port, and catheter, to the infusion site. The catheter access port (CAP) allows injection of drug directly into the implanted catheter for drug administration and diagnostic purposes. Drug injected into the CAP bypasses the pump mechanism and goes directly through the catheter port into the implanted catheter to the infusion site. The CAP allows entry of a 24-gauge noncoring needle to prevent accidental injection during refill procedures (which use the 22-gauge noncoring needle supplied in the refill kit).

The manufacturer and model code recorded on a radiopaque identifier are visible using standard x-ray procedures.

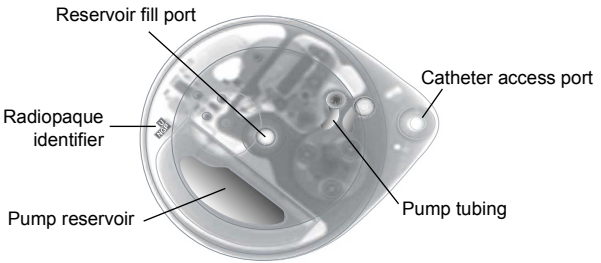

Figure 2. *Pump interior view.*

Package contents

- Pump
- Needle, 22-gauge (black sheath)
- Needle, 24-gauge (purple sheath)
- Product literature
- Registration form
- Patient identification card
- ! USA Warranty card

Patient identification card

A patient identification card is packaged with this device. Advise the patient to carry the identification card at all times.

! USA The patient identification card packaged with the device is temporary; a permanent card is mailed to the patient when Medtronic receives the registration form.

! USA The implant registration form registers the device warranties and creates a record of the device in the Medtronic implant data system.

Device specifications

Table 1. Shipping and operating values for the Model 8637 SynchroMed II pump

	Shipping	**Operating**
Fluid in reservoir	Sterile water	—
Shipping flow rate	0.006 mL/day	—
Infusion modes	Simple continuous	Single bolus Priming bolus Bridge bolus Simple continuous Flex Minimum rate Stopped pump
Alarms		
Critical alarm	Disabled	Enabled with an interval programmed
Non-critical alarm	Disabled	Enabled with an interval programmed

Table 2. Device specifications for the Model 8637 SynchroMed II pump[a]

	8637-20	8637-40
Pump		
Thickness (including septum)	19.5 mm	26.0 mm
Weight (empty/full)	165/185 g	175/215 g
Displacement volume	91 mL	121 mL
Diameter (including CAP)	87.5 mm	87.5 mm
Pump reservoir		
Volume	20.0 mL	40.0 mL
Residual volume	1.4 mL	1.4 mL
Fill volume at shipping	17.5 mL	37.5 mL
Pump tubing		
Volume[b]	0.25 mL	0.25 mL
Reservoir fill port		
Septum puncture life	500 punctures	500 punctures
Catheter access port		
Prime volume	0.14 mL	0.14 mL
Septum puncture life	500 punctures	500 punctures
Flow rate		
Maximum programmable[c]	24 mL/day	24 mL/day
Minimum programmable[c]	0.048 mL/day	0.048 mL/day
Stopped pump maximum leakage	0.030 mL/day	0.030 mL/day
Bacterial retentive filter		
Pore size	0.22 µm (micron)	0.22 µm (micron)
Power source		
Battery	Lithium hybrid cathode	Lithium hybrid cathode
Longevity	Rate dependent (Figure 3)	Rate dependent (Figure 3)

Table 2. Device specifications for the Model 8637 SynchroMed II pump[a] (continued)

	8637-20	**8637-40**
Radiopaque identifier	NGP	NGV
Reservoir pressure	20.68 kPa to 34.75 kPa	20.68 kPa to 34.75 kPa

[a] All measurements are approximate.

[b] **If the pump has been replaced and the catheter has not been replaced and has not been aspirated,** use a priming bolus of 0.300 mL to fill the pump tubing with drug **before** connecting the catheter and implanting the pump.

[c] Actual limits depend on pump calibration constant and selected infusion mode.

Table 3. Material of components in the Model 8637 SynchroMed II sterile package

Component	**Material**	**Material contacts human tissue**	**Material contacts drug**
Pump			
Exterior	Titanium	Yes	No
Reservoir	Titanium	No	Yes
Reservoir valve	Titanium	No	Yes
Tubing	Silicone rubber	No	Yes
Reservoir fill port septum	Silicone rubber	Yes	Yes
Catheter access port septum	Silicone rubber	Yes	Yes
Catheter port	Titanium	Yes	Yes
Bacterial retentive filter	Polyvinylidene fluoride	No	Yes
Suture loops	Titanium	Yes	No
Propellant	Inert gas	No	No
Needles	Stainless steel	Yes	Yes

Device longevity

Device longevity is a function of flow rate. Flow rates affect the battery voltage and motor revolutions (Figure 3).

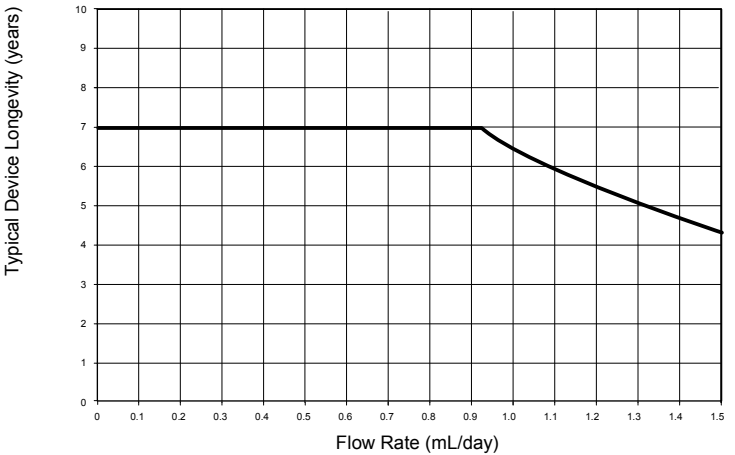

Figure 3. *Typical device longevity based on flow rate.*

Device longevity is the calculated number of service months remaining based on actual usage rates.[1] An elective replacement indicator (ERI) message displays on the programmer when the pump nears the end of its service life (EOS). At ERI, the pump continues to operate within specifications. The ERI thresholds allow the pump to operate for a minimum of 90 days, at rates up to 1.5 mL/day, between ERI activation and EOS (Figure 4). When activated, ERI is date stamped and displayed by the programmer after interrogating the pump. The EOS activation indicates the pump has reached the end of its service life. At EOS, the pump stops, but telemetry is available until the pump battery is depleted.

[1] Device longevity sources include battery life (voltage), device life (years), and motor life (revolutions).

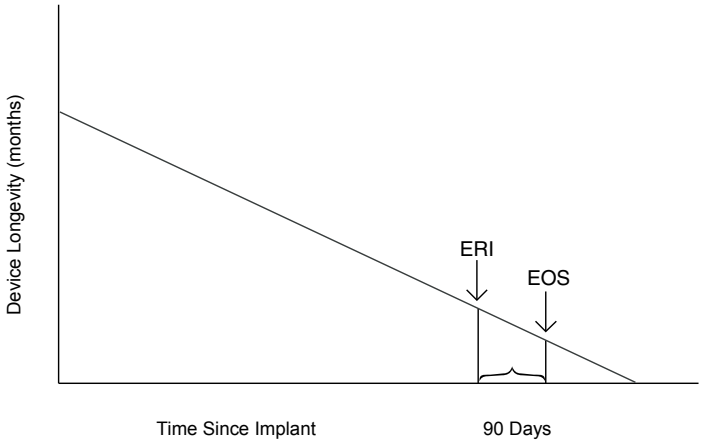

Figure 4. *ERI and EOS.*

Flow rate accuracy

The flow rate accuracy of the pump is within ±14.5% of the programmed flow rate at 0.048-24 mL/day, 37 °C, 50% reservoir volume, and 300 meters above sea level. Measurement error, fluid volume, and changes in environmental conditions (eg, body temperature and atmospheric pressure) all affect the flow rate. The effects of these changes on flow rate are cumulative if the conditions exist simultaneously.

Measurement error

The apparent flow rate based on clinical measurements can vary due to measurement error (eg, syringe measurement accuracy, human error, and the volume of fluid in the extension tubing and filter).

Fluid volume

The flow rate of the pump varies slightly with the volume of fluid in the pump reservoir. The pump flow rate decreases as the reservoir volume approaches 1 mL. The pump flow rate decreases rapidly and then stops as the reservoir volume decreases from 1 mL to 0 mL. Therefore, the pump should be refilled prior to reaching 1 mL or less. Typically, the flow rate

decreases by about 4% as the volume is reduced from the half-full volume to a volume of 1 mL. The usable volume is the reservoir volume minus 1 mL (Figure 5).

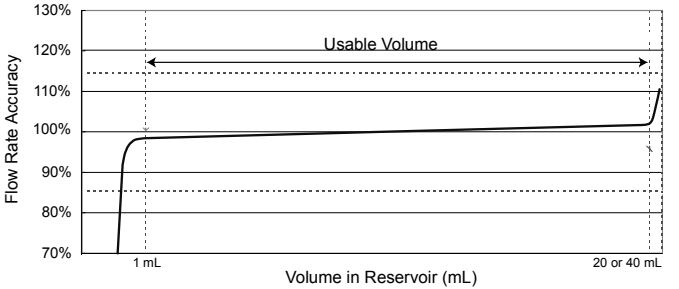

Figure 5. *Flow rate accuracy as a function of fluid volume in reservoir.*

Environmental conditions

Body temperature

The flow rate of the pump varies with body temperature. The flow rate increases as the temperature increases above 37 °C and decreases as the temperature decreases below 37 °C (Figure 6).

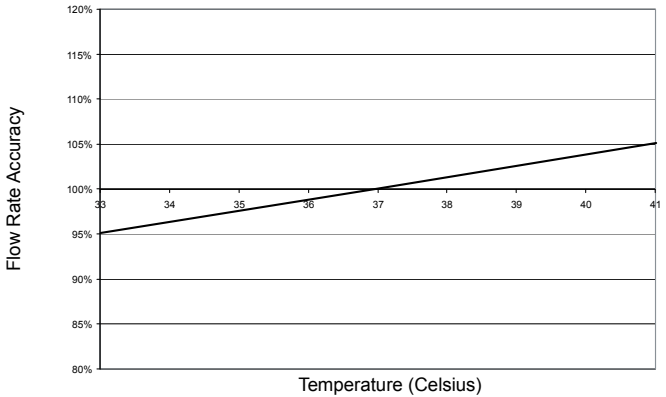

Figure 6. *Flow rate accuracy as a function of temperature (typical effect).*

Atmospheric pressure

Patients living or traveling (eg, airline flights, mountain climbing) at altitudes above sea level are exposed to lower atmospheric pressures. Within days of exposure to the lower pressures, the flow rate of the pump can increase and then stabilize at the higher flow rate. In circumstances where a potential increase in flow rate may pose a risk to a patient, reprogramming the infusion prescription offsets this higher flow rate (Figure 7).

In rare instances, exposure to the lower atmospheric pressure can cause the pump to deliver more than 14.5% of the programmed flow rate while the patient is exposed to the lower pressure. Consider changes in drug concentrations or changes to pump programming for patients exposed to lower pressures.

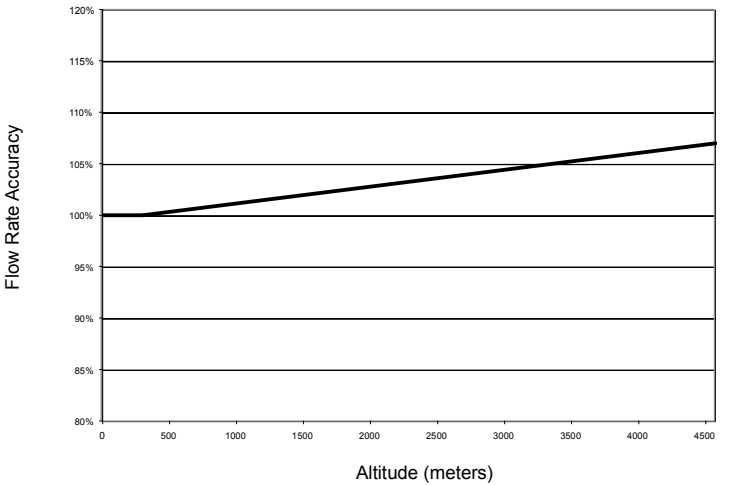

Figure 7. *Flow rate accuracy as a function of altitude (typical effect).*

Declaration of Conformity

Medtronic declares that this product is in conformity with the essential requirements of Directive 1999/5/EC on Radio and Telecommunications Terminal Equipment and Directive 90/385/EEC on Active Implantable Medical Devices.

For additional information, contact the appropriate Medtronic representative listed on the inside back cover of this manual.

Instructions for use

Implanting physicians should be experienced in pump and catheter implant procedures and should be thoroughly familiar with all product labeling.

Cautions:

- Do not implant a pump that was dropped onto a hard surface or shows signs of damage. Implanting a pump that has been dropped or damaged can result in lack of intended therapy, and require additional surgery to replace the pump.
- Do not implant the pump unless pump operation has been confirmed. Failure to confirm pump operation before implant can result in additional surgery to replace the pump.
- Do not prematurely activate the pump reservoir valve. Activation of the pump reservoir valve seals the pump reservoir valve closed. Unusual resistance or the inability to inject the entire fill volume may indicate activation of the pump reservoir valve. If the valve closes, a portion of the reservoir contents must be delivered or removed before filling can be completed. Procedural delays can occur. To prevent activation of the pump reservoir valve during emptying and filling procedures:
  - completely aspirate all contents of the pump reservoir before filling.
  - do not allow air into the pump reservoir through an open needle in the septum or an unclamped extension.
  - do not exceed the maximum reservoir volume indicated in the pump labeling.
- To use the nonsterile clinician programmer in a sterile field, place a sterile barrier between the patient and the programming head to prevent infection. Do not sterilize any part of the clinician programmer. Sterilization may damage the programmer.

Preparing for pump implant

1. Assemble equipment and supplies.

   Sterile items

   - The pump package containing the pump, 22-gauge noncoring needle (for filling the pump), and 24-gauge noncoring needle (for flushing the catheter access port)
   - Empty 20-mL syringes (for emptying the pump)
   - 0.22-µm (micron) filter
   - Syringe containing prescribed fluid (volume not to exceed the reservoir volume of the pump)
   - 10-mL syringe with 1–2 mL of sterile, preservative-free saline (for flushing the catheter access port)

   Nonsterile items

   - Medtronic clinician programmer

2. Before opening the shelf package, use the clinician programmer to interrogate the pump and verify pump battery status and current settings.
   a. Confirm that there are no active alarm events.

   Note: If the pump is still in Shelf Mode, audible alarms are disabled. The pump must be interrogated to determine if an alarm has been activated.

   b. Confirm that the pump calibration constant displayed on the screen matches the calibration constant printed on the shelf package.

      ⚠ **Warning:** The calibration constant displayed on the programmer screen after reading the pump status must match the calibration constant printed on the shelf package. If calibration constants differ, contact the appropriate Medtronic representative listed on the inside back cover of this manual. Using an incorrect calibration constant can result in a clinically significant or fatal drug underdose or overdose.
3. Attach a "FOR YOUR RECORDS" label (enclosed in the shelf package) to the patient's record. This label displays the pump model number, reservoir size, calibration constant, and serial number.

   Note: Updating the pump with the new parameters can be performed at this time or after the implant procedure. Refer to "Programming the pump" on page 20 for instructions.

Sterile procedure

1. Open the sterile pump package and remove the pump.
2. Remove the protective cap from the catheter port (a small amount of water might be present in the protective cap).

Emptying the pump

1. Assemble the 22-gauge noncoring needle and the empty syringe.
2. Insert the needle into the reservoir fill port until the needle touches the metal needle stop.
3. Withdraw the sterile water from the pump into the empty syringe (the pump is shipped nearly full).

   Note: If the volume of fluid in the pump reservoir exceeds the volume of the syringe used for emptying, remove the filled syringe and needle. Attach an empty syringe and needle, and repeat until the pump reservoir is empty.
4. Empty the pump reservoir until air bubbles no longer appear in the syringe, ensuring all water and air is removed from the pump reservoir.
5. Remove the syringe and needle from the reservoir fill port.

Preparing to fill the pump

1. **If using Prialt[1] (preservative-free ziconotide sterile solution),** refer to the drug labeling for instructions for use of this drug with the pump.
2. **For all indicated drugs** refer to Table 4 to determine the fill method.

   Notes:

   - A change in concentration is not recommended at the time of replacement.
   - The pump reservoir capacity is 20 mL or 40 mL. Because some sterile water remains in the pump reservoir, the final concentration of drug varies based on the fill method.

Table 4. Expected concentration of drug in pump reservoir based on fill method

Pump reservoir capacity	Filling without rinsing	Rinsing with 3 mL of drug	Rinsing with 10 mL of drug
8637-20	93%	98%	99%
8637-40	97%	99%	100%

3. If you are rinsing the pump reservoir before filling, rinse and discard the appropriate volume based on the fill method shown in Table 4.

Filling the pump

1. Attach the filter to the syringe containing the prescribed fluid.
2. Attach the needle to the syringe containing the prescribed fluid and filter, and purge the air from the fluid pathway.
3. Read the actual fill volume in the syringe.
4. Insert the needle into the reservoir fill port, and inject the prescribed fluid slowly into the pump reservoir.
5. If the reservoir valve is activated before the pump is filled completely, discontinue injection, remove the needle from the reservoir fill port, and return to "Emptying the pump" on page 16, step 4.
6. When filling is complete, remove the needle from the reservoir fill port.
7. Flush the catheter access port using a 24-gauge noncoring needle and a syringe filled with 1 to 2 mL of saline (or a heparinized solution for vascular applications, if not contraindicated).
   a. Gently insert the needle into the catheter access port until the needle touches the metal needle stop.
   b. Inject fluid into the catheter access port until fluid is observed at the catheter port.
   c. Remove the needle from the catheter access port.

[1] Prialt is a brand name drug for ziconotide. Prialt is listed here for USA audiences only.

8. If implanting a new pump, go to "Preparing the pump pocket" on page 19.

Replacing an implanted pump

1. If applicable, remove the suture at the catheter connector.
2. Disconnect the implanted pump from the implanted catheter. To avoid damage to the pump connector, leave the connector attached to the catheter.

   Note: If you are replacing a SynchroMed EL Model 8626, 8626L, 8627, or 8627L Implantable Pump, interrogate the replaced pump for catheter volume information that may be stored in the pump. If you are replacing a SynchroMed II Model 8637 Implantable Pump, interrogate the replaced pump for catheter volume information. Enter the catheter volume information into the clinician programmer.
3. If not replacing the catheter, slowly aspirate 1 to 2 mL of fluid from the catheter using a 1-mL tuberculin syringe. Leave the syringe in place to avoid CSF loss. Aspirating directly from the catheter clears the catheter of drug and confirms catheter patency.

   Note: Conditions might exist under which the catheter is not patent or is not aspirated. If the catheter is not patent it must be replaced. Refer to the technical manual packaged with the catheter for catheter replacement instructions.

   ⚠ **Warning:** During vascular applications, do not aspirate blood through the catheter access port or catheter. Blood sampling or aspiration through the catheter access port is contraindicated in vascular applications. Residual blood from aspiration or blood sampling can occlude the catheter or pump and inhibit drug delivery, resulting in a loss of or change in therapy, which may lead to a return of underlying symptoms, drug withdrawal symptoms, or a clinically significant or fatal drug underdose, and require surgical revision or replacement.
4. Continue the implant with one of the two following procedures:
   - **If the catheter has been replaced or aspirated,** proceed to "Implanting the pump" on page 19.
   - **If the catheter has not been replaced and has not been aspirated,** use a priming bolus of 0.300 mL to fill the pump tubing with drug **before** connecting the catheter and implanting the pump. Refer to the appropriate programming guide for information on how to calculate and program this bolus. The pump internal tubing prime must be complete before attaching the catheter to the pump. If not, drug present in the catheter is bolused into the intrathecal space. Proceed to "Implanting the pump" on page 19.

   ⚠ **Warnings:**

   - If this is a pump replacement and the catheter has not been replaced and has not been aspirated, the pump tubing should be primed **before** connecting the catheter and implanting the pump. **Do not** program a postoperative priming bolus after the catheter has been connected to the pump. Programming a postoperative priming bolus in this situation can result in a clinically significant or fatal overdose.

- Use the catheter length recorded at implant or catheter revision when calculating catheter volume. The actual implanted catheter length and catheter model number are required to accurately calculate catheter volume. **A universal value does not exist that can be used as a substitute for this knowledge.** An inaccurate calculation of the catheter volume can result in a clinically significant or fatal drug underdose or overdose.

Preparing the pump pocket

Prepare the subcutaneous pocket using an incision in the lower abdomen.

Ensure that the subcutaneous pump pocket allows the pump to be implanted within 2.5 cm from the surface of the skin and in an area where sutures will not be directly over the reservoir fill port or catheter access port.

△ **Caution:** Select a location in the lower abdomen that is:

- away from bony structures (eg, 3 to 4 cm) to minimize discomfort at the pump site.
- away from areas of restriction or pressure to minimize the potential for skin erosion and patient discomfort.
- away from existing scar tissue.

For programmable pumps, select a location that is also:

- a minimum of 20 cm away from another programmable device to minimize telemetry interference and incorrect or incomplete programming.
- in an area accessible to the patient for proper operation of a patient control device (if applicable).

In the pediatric population, care must be taken to select an appropriate location by taking into consideration:

- available body mass.
- presence of ostomies.
- growth and development.

Implanting the pump

1. Connect the implanted catheter to the pump according to the catheter implant manual instructions.
2. Place the filled pump into the prepared pocket.

   △ **Cautions:**

   - Implant the pump no more than 2.5 cm from the surface of the skin in order to maintain access to the reservoir and catheter access ports. Implantation of the pump is contraindicated if the pump cannot be implanted 2.5 cm or less from the surface of the skin.
   - Place the pump in the prepared pocket so:

- the reservoir fill port is anteriorly oriented and the reservoir fill port and catheter access port will be easy to access after implant.
- no sutures to the skin will be directly over the reservoir fill port or the catheter access port.
- the catheter is not kinked or twisted and is secured well away from the pump ports.

Improper component placement can result in inaccessible pump ports, inadequate drug delivery, component damage, or procedural delays, and require surgical revision or replacement.

3. Suture the pump in the subcutaneous pocket using the following steps:
   a. Suture first to the fascia in the bottom of the subcutaneous pocket.
   b. Use these two sutures and the lower suture loops on the pump to draw the pump into the pocket.
   c. Tie the sutures.
   d. Suture the remaining two loops at the top of the pump pocket.
   e. Tie the sutures, securing the pump into the pocket.
4. Irrigate the pump pocket.
5. Close the incisions per normal procedure and apply dressing.

Programming the pump

1. Enter the following into the clinician programmer: patient information, catheter model number, implanted catheter length (in centimeters), drug name and concentration, and the volume of prescribed fluid placed in the pump reservoir at implant.

   Note: If you are replacing a SynchroMed EL Model 8626, 8626L, 8627, or 8627L Implantable Pump, interrogate the replaced pump for catheter volume information that may be stored in the pump. If you are replacing a SynchroMed II Model 8637 Implantable Pump, interrogate the replaced pump for catheter volume information. Enter the catheter volume information into the clinician programmer.

   ⚠ **Warning:** Use the catheter length recorded at implant or catheter revision when calculating catheter volume. The actual implanted catheter length and catheter model number are required to accurately calculate catheter volume. **A universal value does not exist that can be used as a substitute for this knowledge.** An inaccurate calculation of the catheter volume can result in a clinically significant or fatal drug underdose or overdose.

2. If the catheter is new or has been aspirated, program a postoperative priming bolus to advance the drug from the reservoir to the catheter tip.
3. If the catheter has not been replaced or aspirated, program the pump to deliver the prescribed infusion.

   ⚠ **Warning:** If this is a pump replacement and the catheter has not been replaced and has not been aspirated, the pump tubing should be primed **before** connecting the catheter and implanting the pump. **Do not** program a postoperative priming

bolus after the catheter has been connected to the pump. Programming a postoperative priming bolus in this situation can result in a clinically significant or fatal overdose.

4. Set the Low Reservoir Alarm (to at least 1 mL).
5. Program the pump with new parameters.

   Note: Refer to the programming guide supplied with the programmer software for instructions on programming the pump.
6. Print out the patient's prescription and pump settings (pump status).
7. Place the prescription and pump settings (pump status) in the patient's records.
8. Determine the refill date from the printout.
9. Schedule a refill appointment.

Refilling the pump or accessing the catheter access port

When refilling a Medtronic pump, use the appropriate Medtronic refill kit and associated refill kit instructions for use.

When accessing the catheter access port of a Medtronic pump, use the appropriate Medtronic CAP kit and associated CAP kit manuals and instructions for use.

Technical support

To obtain a copy of the refill kit or CAP kit instructions for use, or to receive additional technical support:

- US only: Contact Medtronic Technical Services at 1-800-707-0933. Technical support service is available 24 hours a day for clinicians managing patients with Medtronic implantable infusion pumps.
- Outside of the US: Contact your local representative by using the phone numbers listed on the last pages of this manual.

Contacts:

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