Patient

INSTRUCTIONS FOR USE

ONAPGO™ (on-AP-goh)

This Instructions for Use contains information on how to use the ONAPGO Infusion System.

Please see the Important Safety Information, full Prescribing Information, and Patient Information for ONAPGO.

MDD US Operations, LLC

Table of Contents

Reference ID: 5523357

Indication for Use

The ONAPGO Infusion Pump is for the subcutaneous infusion of ONAPGO (apomorphine hydrochloride). ONAPGO is a prescription medicine used to treat motor fluctuations in adults with advanced Parkinson's disease (PD).

Only use the ONAPGO Infusion Pump if you have received instruction and training on how to correctly and safely use it. If you cannot use ONAPGO by yourself, contact your healthcare provider.

Only the accessories supplied by Cane' S.p.A. (plastic cartridge holder and supplies provided in the infusion pump kit) may be used in conjunction with this pump. The pump must be set (programmed) by a trained healthcare provider or trained nurse provided by the company (nurse navigator).

Introduction to the Infusion System

Below are common terms used throughout this Instructions for Use.

- **Pump:** controls the rate and amount of ONAPGO delivered to the body. It is programmed by a healthcare provider based on the patient's prescription. The pump displays the status of medicine delivery.
- **Priming:** refers to the task of removing all air from the infusion line (fluid pathway) before the infusion line is connected to the body.
- **Flow Rate:** the constant flow of ONAPGO given to the body over an extended period of time. The flow rate is expressed as milligrams per hour (mg/hr).
- **Infusion Time:** the total time that ONAPGO is infused per day.
- **Extra Dose (+ Dose):** a boost of ONAPGO (bolus dose) given over a short period of time in addition to the prescribed flow rate. Your healthcare provider will decide the number of extra doses that you could have each day. Your healthcare provider might prescribe an extra dose to be used as follows:
  - when you start the infusion each day, which can help the medicine work faster.
  - When you restart your medicine after not having it for 1 hour or more.
  - if you have an OFF episode during an infusion.

- **Extra Dose (+ Dose) Lock:** the amount of time before another extra dose can be given.
- **Pump Settings:** the patient's prescribed Flow Rate, Maximum Infusing Time Per Day, **+** Dose Quantity, **+** Dose Volume, and **+** Dose Lock. These settings can only be changed by a healthcare provider or clinical nurse navigator.

Important Information

- Read this entire Instructions for Use before using the infusion system.
  If any of the information is not clear, or if you have any questions, please contact Customer Support at 1-833-3ONAPGO (1-833-366-2746)
- Understanding how to use the pump and the potential alarms will help you avoid harm.
- You may hear motor noise when the pump is On and delivering ONAPGO. This noise is normal and means the pump is working correctly.
- The pump screen falls asleep (goes dark) after 30 seconds of inactivity. Press the UP ARROW button (▲) to wake up the screen.

Pump Warnings and Precautions

Failure to follow the warnings and precautions below could cause return of your symptoms, damage to the pump, serious injury, or may lead to death in rare cases.

⚠ WARNINGS:

- Always check that the pump settings match the prescription before starting an infusion.
  See the **Check Pump Settings** section on pages 15 to 19 for how to check the pump settings to make sure they are correct. If any of these settings do not match the prescription, contact your healthcare provider and/or clinical nurse navigator.
- The patient should receive no more than 98 mg of ONAPGO every 24 hours. This corresponds to one complete cartridge per day. Only use the pump with ONAPGO (apomorphine hydrochloride). ONAPGO comes in a glass cartridge that contains 98 mg/20 mL (4.9 mg/mL) of medicine. Only use the pump system within the temperatures on page 14 and other conditions for use in this Instruction for Use. Using the

medicine and pump outside of these conditions may result in a system alarm.

- Only use the pump with the supplied plastic cartridge holder. Any other cartridge holder could damage the Pump and cause harm. Any non-approved cartridge holder voids warranty. MMD US Operations, LLC or its manufacturer is not responsible for any damages or injuries that happen if a different cartridge holder is used.
- Use the infusion set that is provided by your specialty pharmacy. The use of an inappropriate infusion set can cause loss or leakage of drug. Use a new infusion set at the beginning of every infusion. Ask your healthcare provider and/or clinical nurse navigator for more information.
- **Do not** prime the infusion line when it is connected to the body.
- **Do not** insert the cannula into a blood vessel.
- If the medicine is cloudy, green, or contains particles, throw the glass drug Cartridge in a sharps container. (See the **Disposal** section on page 74 for information on how to safely throw away ONAPGO). Get a new cartridge for your infusion.
- Clean the top of the glass drug cartridge with a new alcohol wipe before attaching the plastic cartridge holder.
- Always clean the selected infusion site with a new alcohol wipe. Make sure the site is dry before going on to the next step.
- Before starting your infusion, check for any leaks. **Do not** use the pump if there are leaks. Contact Customer Support at 1-833-3ONAPGO (1-833-366-2746).
- Be careful when handling the Infusion Set to prevent needle sticks.
- Supplies included with your pump could pose a choking hazard for small children. Make sure that the pump and all supplies are kept away from small children.
- Supplies included with your pump (such as the infusion line) could pose a strangulation hazard. Arrange the infusion line to minimize the risk of strangulation. Make sure that these parts are stored in a secure place when not in use.
- Throw away (discard) the battery if it becomes damaged. Use a new, unopened battery. See **Replacing the Battery** section on pages 81 to 86 (Steps 17.1 through 17.9) for instructions on how to replace the battery.
- The pump can detect a blockage in the line. If a partial blockage occurs, the pump will work the way it should until

the line has a full blockage. An alarm will sound if the line has a full blockage.

- Be sure to disconnect the infusion line from the body before clearing a blockage alarm. If a blockage alarm is cleared while the infusion line is still attached, you may receive a small amount of additional medicine. See the **Alarms and Troubleshooting** section on page 91.
- Confirm that the plastic cartridge holder and infusion line packaging are sealed and have not been damaged. If the packaging looks damaged, throw it away in a sharps container, and do not use it for your infusion. See the **Disposal** section on page 74 for information on how to safely throw away ONAPGO. Use a new, undamaged product.
- If the battery becomes hot, do not continue with your infusion and call Customer Support at 1-833-3ONAPGO (1-833-366-2746).
- If your glass drug cartridge breaks while assembled in the plastic cartridge holder, do not separate it from the plastic cartridge holder. Disconnect the assembled cartridge from the pump and throw both away in a sharps container. See the **Disposal** section on page 74 for information on how to safely throw away ONAPGO.
- **Do not** snag or kink the infusion line while wearing the pump. Snagging or kinking the infusion line can cause a blockage (occlusion) or an interruption to the infusion.
- Always check the expiration date on the infusion set, plastic cartridge holder and glass drug cartridge prior to use. **Do not** use expired materials.
- **Do not** use expired or rechargeable batteries with the pump.
- If the glass drug cartridge is dropped, it should not be used and should be thrown away in a sharps container.
- If the pump gets wet, pause the infusion, disconnect the infusion line from the body, and store the pump in a dry place. This includes when swimming, showering, or excessively sweating.
- If your ONAPGO pump has expired, do not use it. Call your healthcare provider and/or clinical nurse navigator for a replacement ONAPGO pump.

⚠ PRECAUTIONS:

- **Do not** use sharp objects to press the pump buttons. Only use your fingertips to press the pump buttons.
- **Do not** use a damaged pump. If you have any concern about the correct functioning of the pump, or how to respond to an error, contact Customer Support at 1-833-3ONAPGO (1-833-366-2746).
- Read the infusion set Instructions for Use before using the infusion line.
- All pump settings, including sounds, are locked for your safety.
- **Do not** attempt to change the pump's prescribed settings. These can only be changed by a healthcare provider and/or clinical nurse navigator.
- **Do not** disconnect the infusion line from the plastic cartridge holder while the pump is infusing.
- Only clean the infusion site with an alcohol wipe. **Do not** clean the infusion site with or apply disinfectants, perfumes, deodorants, or lotions to it.
- Free-flow is if gravity causes the drug to come out of the cartridge. The pump's pusher is made to have a secure connection with the rubber plunger in the cartridge to prevent free flow of the drug.

Pump Kit (Figure A)

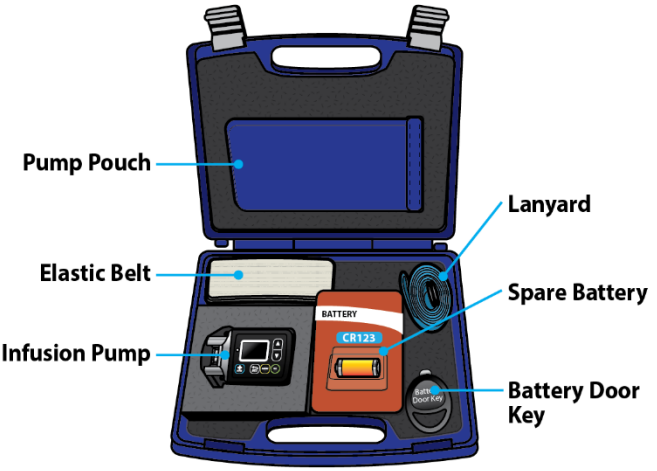


Figure A

Pump Diagram (Figures B, C, and D)

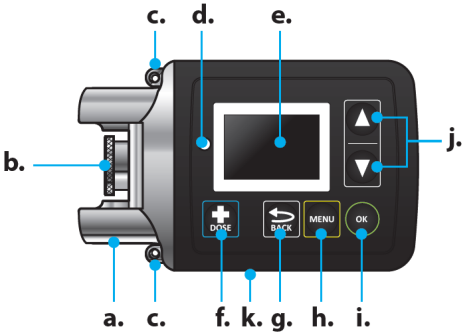


Figure B

Figure C

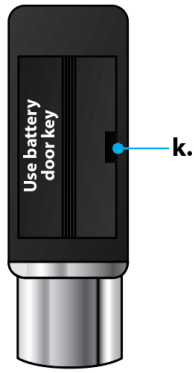


Figure D

All buttons will respond with a single press. If the screen is dark, press the UP ARROW button (▲) to wake up the screen.

Item	Pump Feature	Description
a	Cartridge Connection	Area where assembled glass drug cartridge and plastic cartridge holder is attached to the pump.
b	Pump Pusher	Pushes ONAPGO from the glass drug cartridge into the infusion line.
c	Neck Lanyard Clips	Slots to clip on the lanyard.
d	LED	Lights up when an error cannot be displayed on the screen.
e	Screen	Where messages and menus appear.
f		**+** DOSE button gives an extra dose (+ dose) (if prescribed).
g		BACK button allows you to return to a previous screen, menu, or cancel an action.
h		MENU button allows you to access the menus.
i		OK button allows you to confirm menu selections or go on to the next value.
j		UP and DOWN ARROW buttons allow you to scroll through menus.
k	Battery Door	Door to access the battery.

Pump Screen Icons

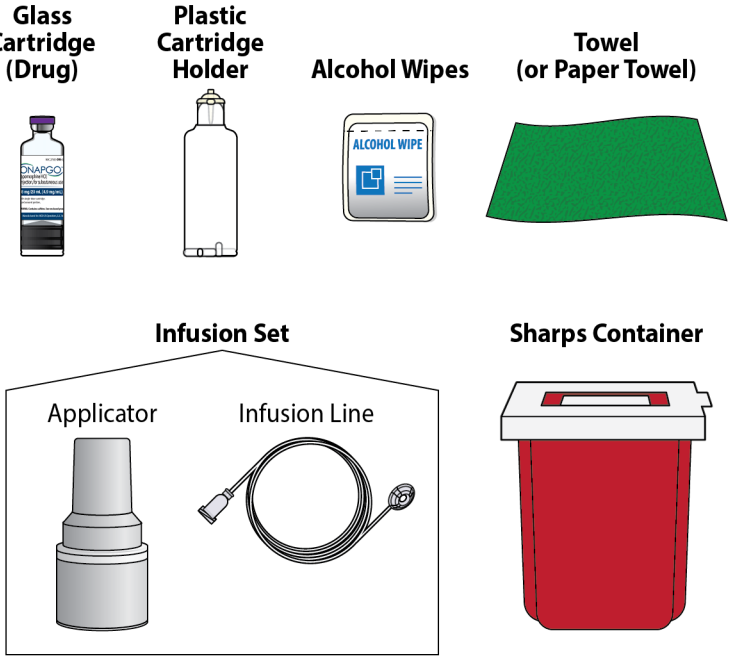
The following table shows Icons that appear on the pump Screen.

Icon	Name	Description
	Back Arrow	The back arrow is shown when checking the pump settings. This icon is used to show that pressing the BACK button will return to a previous screen (Item ‘g’ in Figure B).
	Caution	Caution is shown when an error or alarm is occurring.
	Check Mark	A check mark is shown when the pump successfully completes a task.
	Droplet	A blinking droplet is shown on the Infusing Screen when an infusion is on.
	Dead Battery	The dead battery is shown when the pump battery is dead and must be replaced.
	Low Battery	The Low Battery is shown when the pump battery is low and should be replaced before the next infusion.
	OK Arrow	The OK Arrow is shown when checking the pump settings. This icon is used to show that pressing the OK button will confirm a selection or go on to the next value (Item ‘i’ in Figure B).
	Padlock	Padlock is shown when the + Dose (extra dose) is not available. 
	Pause	Pause is shown when the infusion is paused.

Icon	Name	Description
	+ Dose (Extra Dose)	A + refers to the + Dose (extra dose) function.

Other Supplies Provided Separately

Additional supplies not in the pump kit include (Figure E):



Note: The plastic cartridge holder, glass drug cartridge, and infusion set parts are sterile.

Figure E

Storage

Glass Drug Cartridge Storage

Store the glass drug cartridges at room temperature between 68°F to 77°F (20°C to 25°C). Store in original container.

Pump Storage

If the pump will not be used for 1 month or more, remove the battery. See **Replacing the Battery** section on pages 81 to 86 (Steps 17.1 through 17.9) for instructions on how to remove the battery.
Store the pump in a dry place between -13°F to 158°F (-25°C to +70°C).
Keep the Pump away from:

- Children and pets.
- Sources of heat or cold such as radiators, burners, stoves, freezer, or other heat or cold sources. Ask your healthcare provider or clinical nurse navigator if you are not sure.
- Direct sunlight.
- Strong electromagnetic fields such as magnets, speakers, mobile devices.
- Ionizing radiation, a type of device for radiotherapy or diagnostic radiology.
- Ultrasound devices.
- Magnetic Resonance Imaging (MRI) devices. The pump should not be used with an MRI.

If you are not sure about what to keep your pump away from, please contact your Customer Support at 1-833-3ONAPGO (1-833-366-2746).

Important Information You Need to Know Before Infusing ONAPGO

Important Safety Information

This Instructions for Use is for patients, caregivers, and healthcare providers or clinical nurse navigators and describes how to use the infusion system.

- The Instructions for Use are important for the safe and correct use of this infusion system.

- Read the entire Instructions for Use before using the infusion system.

Check Pump Settings

Step 1: Check Pump Settings

Confirm your pump settings match your prescription by doing the following steps.

⚠ **Do not** start an infusion if any of the pump settings do not match your prescription. If this happens, contact your healthcare provider or clinical nurse navigator.

Step 1.1

Look at the pump.

If the pump screen is dark, press the Up Arrow button (▲) to wake up the screen (Figure F).

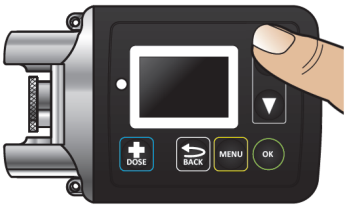


Figure F

You will then see the Infusion Off screen (Figure G).

Figure G

Step 1.2

Press the MENU button (MENU) to find the pump settings (Figure H).

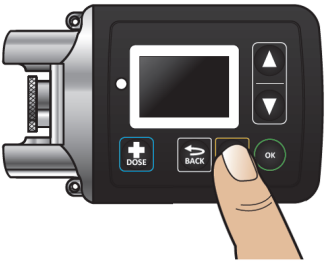


Figure H

Step 1.3

Highlight Settings on the screen using the DOWN ARROW button (▼) (Figure I).

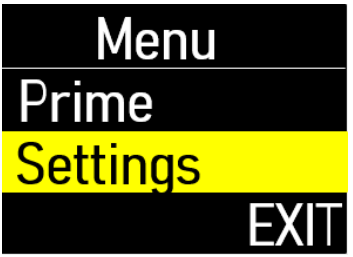


Figure I

Press the OK button (OK) to begin reviewing the pump settings (Figure J).

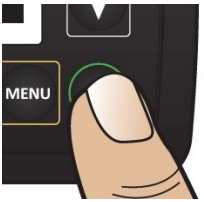


Figure J

Step 1.4

Make sure the flow rate (mg/hr) matches your prescription (Figure K).

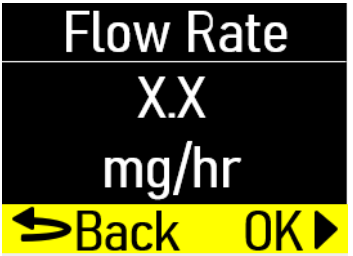


Figure K

Reference ID: 5523357

Press the OK button (OK) to move to the next screen (Figure L).

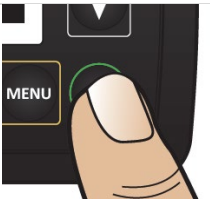


Figure L

Step 1.5
Make sure the infusion time (hr) matches your prescription (Figure M).

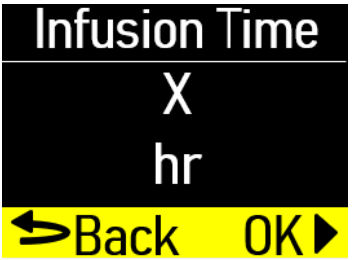


Figure M

Press the OK button (OK) to move to the next screen (Figure N).

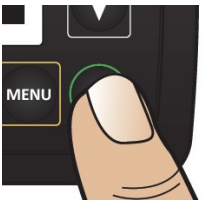


Figure N

Step 1.6
Make sure the number of **+** Doses/Day (extra doses/day) matches your prescription (Figure O).

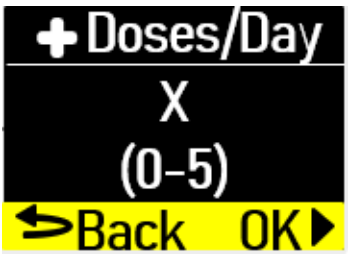


Figure O

Press the OK button ( ) to move to the next screen (Figure P).

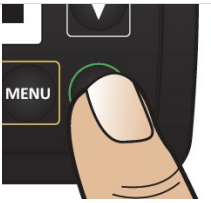


Figure P

Step 1.7
Make sure the **+** Dose (extra dose) amount (mg) matches your prescription (Figure Q).

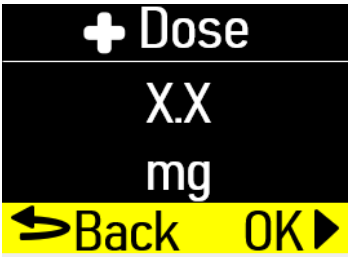


Figure Q

Press the OK button ( ) to move to next screen (Figure R).

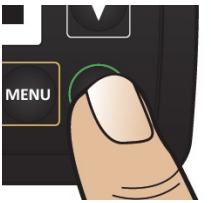


Figure R

Step 1.8
Make sure **+** Dose Lock (extra dose lock) time (hr, min) matches your prescription (Figure S).

Figure S

Press the OK button ( ) to move to next screen (Figure T).

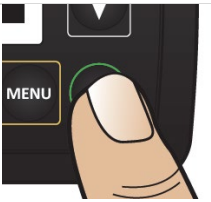


Figure T

Step 1.9
You will see the software version (Figure U).

Figure U

Press the OK button (

) to move to the next screen (Figure V).

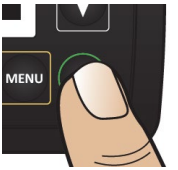


Figure V

Step 1.10
Exit will be highlighted on the Menu screen (Figure W).

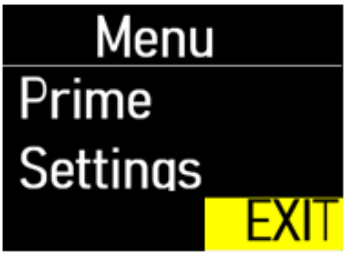


Figure W

Press the OK button (

) to exit the menu (Figure X**)**.

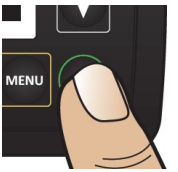


Figure X

You will then see the Infusion Off screen (Figure Y). Set the pump aside on a clean surface and continue to the Set up the Pump section.

Figure Y

Tab 1 - Front

Setup

Tab 1 - Back

Setup

Setup

Within this section you will find:

Step 2: Wash Your Hands and Gather Supplies

Step 2.1
Go to a sink and wash your hands with soap and water, then dry your hands (Figure Z).

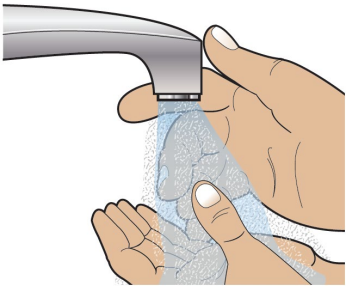


Figure Z

Step 2.2
Prepare a clean, flat surface such as a table to work on (Figure AA).

Figure AA

Step 2.3
Take the blue case and open it (Figure AB). Gather the additional supplies not included in the case (Figure AC).

Infusion System Kit Supplies Included in the Case (Figure AB):

- Pump Pouch
- Elastic Belt
- Pump
- Lanyard
- Spare Battery
- Battery Door Key

Additional Supplies not Included in the Case (Figure AC):

- Glass drug Cartridge (Sterile)
- Plastic Cartridge Holder (Sterile)
- Infusion Set parts (Sterile)
- Alcohol Wipes
- Towel (or Paper Towels)

- Sharps Container. See the **Disposal** Section on page 74 for information on how to safely throw away ONAPGO.

⚠ **Do not** use other drug cartridges with the pump. The pump must only be used with an ONAPGO glass drug cartridge containing apomorphine hydrochloride 98 mg/20 mL (4.9mg/mL).

⚠ **Do not** use other cartridge holders with the pump. The Pump must only be used with the plastic cartridge holder that is provided.

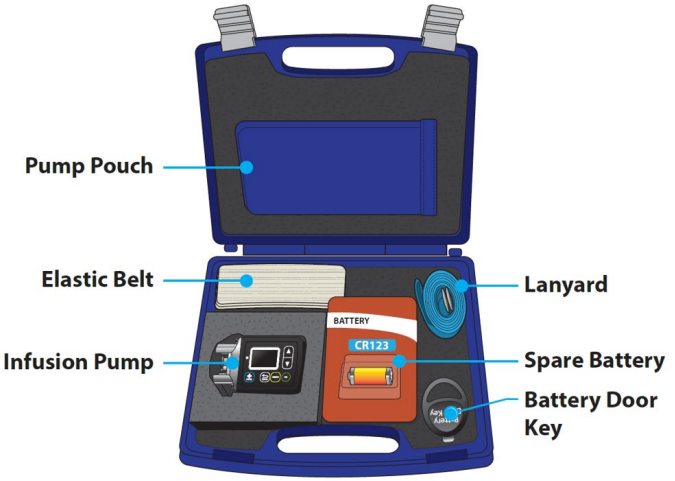


Figure AB

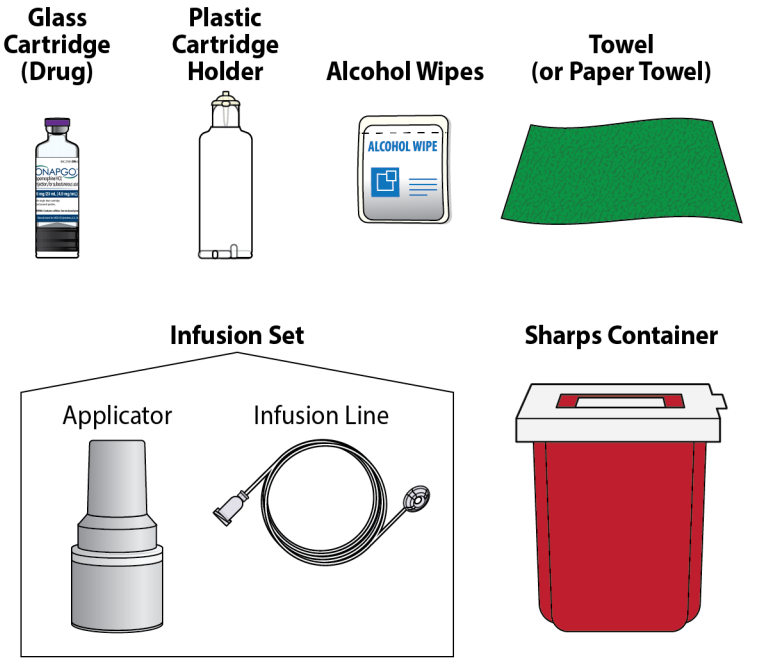


Figure AC

Step 3: Assemble Plastic Cartridge Holder

Step 3.1 Prepare Plastic Cartridge Holder

Look at the plastic cartridge holder package. Make sure the expiration date (EXP) has not passed (Figures AD and AE).

If the expiration date has passed: Throw the plastic cartridge holder away in a sharps container and get a new plastic cartridge holder. See the **Disposal** section on page 74 for information on how to safely throw away ONAPGO.

Figure AD

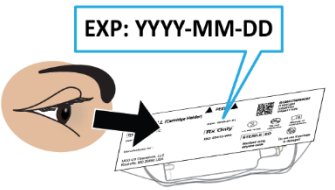


Figure AE

Remove the plastic cartridge holder from its package (Figure AF).

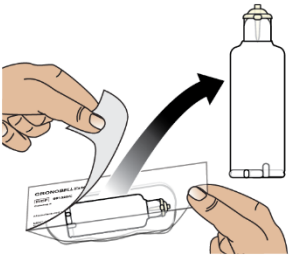


Figure AF

Step 3.2 Prepare Infusion Line

Look at the infusion line package. Make sure the expiration date has not passed (Figure AG).

If the expiration date has passed: Throw the infusion line away in a sharps container and get a new infusion line. See the **Disposal** section on page 74 for information on how to safely throw away ONAPGO.

Remove the infusion line from its package and tear off the paper tab.

Unravel the infusion line so it is straight (Figure AH).

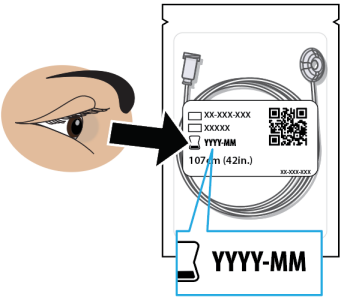


Figure AG

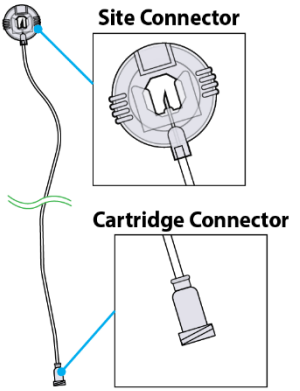


Figure AH

Step 3.3 Connect Infusion Line and Plastic Cartridge Holder

Find the cartridge connector end of the infusion line (Figure AI).

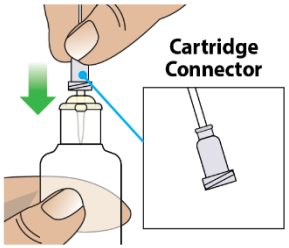


Figure AI

Place the cartridge connector end of the infusion line over the tip of the plastic cartridge holder and turn the cartridge connector until it is snug (Figures AJ and AK).

Note: It only takes a small movement to secure the parts together.

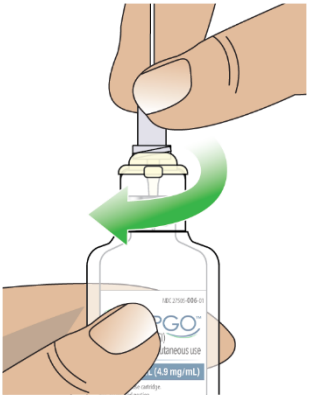


Figure AJ

Do not connect the infusion line to the body at this time. You must prime the infusion line before connecting it to your body.

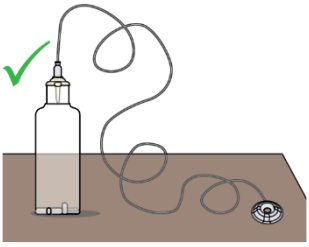


Figure AK

Step 3.4 Prepare Glass Drug Cartridge

Remove the glass drug cartridge from its carton and look at the label. Make sure the expiration date has not passed on the glass drug cartridge (Figures AL and AM).

Figure AL

If the expiration date has passed: Throw the glass drug cartridge away in a sharps container and get a new glass drug cartridge. See the **Disposal** section on page 74 for information on how to safely throw away ONAPGO.

Figure AM

Step 3.5 Check Medicine

Look at the glass drug cartridge. Make sure the liquid medicine inside the glass drug cartridge is clear, almost colorless, and free from particles (Figure AN).

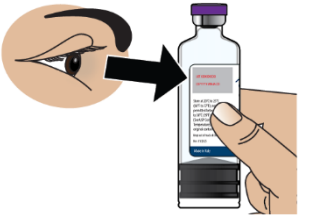


Figure AN

Important Information:

If the medicine is cloudy, discolored, or contains particles, throw away the glass drug cartridge in a sharps container and get a new one. See the **Disposal** section on page 74 for information on how to safely throw away ONAPGO.

Step 3.6 Remove Flip Cap from Glass Drug Cartridge

Hold the glass drug cartridge and remove the flip cap (Figure AO). You may need to push hard to remove the flip cap.

You can throw the flip cap away in your household trash.

Figure AO

Step 3.7 Clean Glass Drug Cartridge

Clean the top of the glass drug cartridge with a new alcohol wipe (Figure AP).

Figure AP

Step 3.8 Place Glass Drug Cartridge

Place the glass drug cartridge on a flat surface on top of a towel or paper towel (Figure AQ).

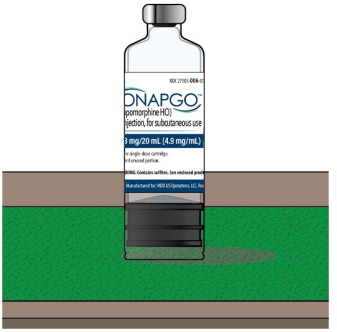


Figure AQ

Step 3.9 Attach Plastic Cartridge Holder to Glass Drug Cartridge

Take the plastic cartridge holder. Place the plastic cartridge holder, with the infusion line attached, over the glass drug cartridge and push all the way down (Figures AR and AS).

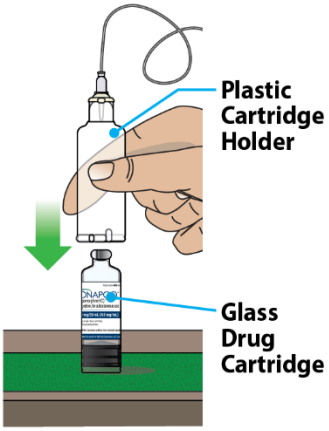


Figure AR

Note: After letting go, the plastic cartridge holder may come up a bit so that it is not even with the bottom of the glass drug cartridge. This is normal.

A small amount of liquid medicine might come out of the glass drug cartridge. This is normal.

You have now created an "assembled cartridge" (Figure AT).

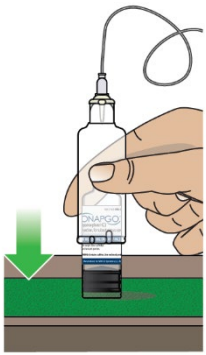


Figure AS

Note: Change the cartridge, cartridge holder, and administration set daily or between uses.

Note: If the infusion line is dropped or dirty, throw away (discard) the infusion line.

Warning: Do not puncture the cartridge with anything but the specified plastic cartridge holder.

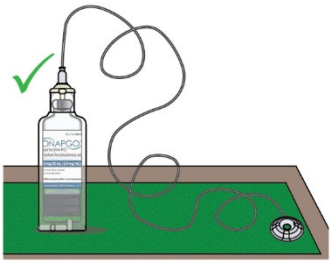


Figure AT

Step 3.10 Place Assembled Cartridge on Pump

Hold the pump upright as shown (Figure AU).

Note: There are ridges at the bottom of the plastic cartridge Holder. You will use these ridges in the next step to align the assembled cartridge with the pump.

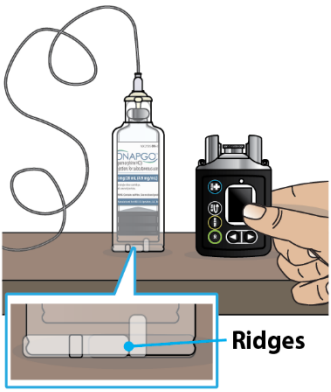


Figure AU

Take the assembled cartridge. Position the assembled cartridge above the pump with the ridges facing you (Figure AV).

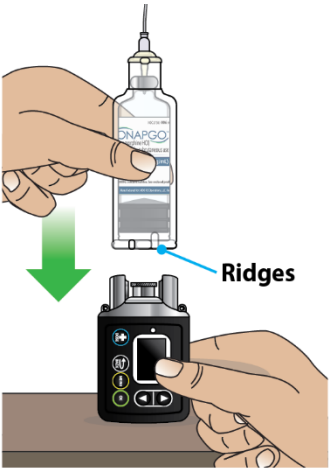


Figure AV

Place the assembled cartridge onto the pump, as shown, with the ridges showing in the pump opening (Figure AW). The assembled cartridge should sit flush against the pump with no gap.

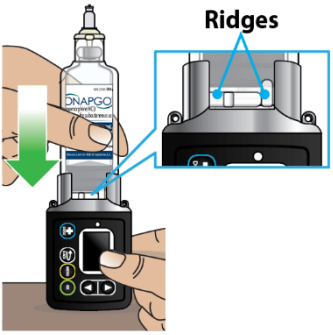


Figure AW

Step 3.11 Attach Assembled Cartridge to Pump

Push down the assembled cartridge firmly **and twist** until you feel it lock into place and the ridges are no longer showing (Figure AX).

Figure AX

Look at the Pump opening.

- If you only see a smooth surface with no gap between the assembled cartridge and the pump, then the assembled cartridge is correctly attached (Figure AY) and you can continue to **Step 4**.
- If you see any portion of the ridges in the space (Figure AZ), then push down firmly again as you twist the assembled cartridge until the ridges are no longer showing (Figure AY).

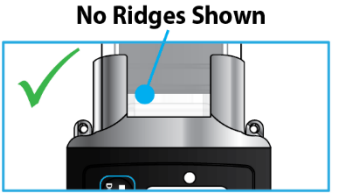


Figure AY

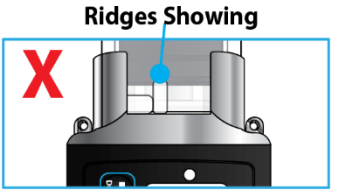


Figure AZ

Step 4: Prime the Infusion Line

Priming the infusion line (Figure BA) pushes liquid through the system to remove all air from the glass drug cartridge and infusion line. All air must be removed from the system before the infusion line is connected to the infusion site on the body.

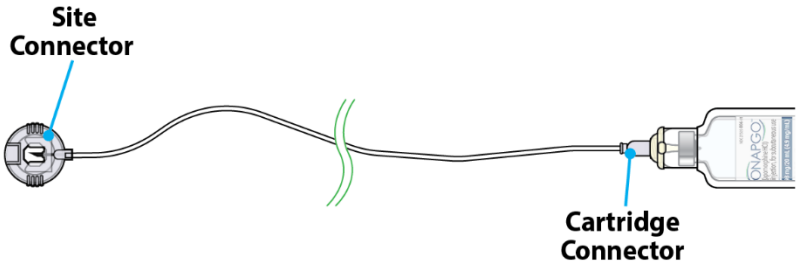


Figure BA

⚠ Read the Instructions for Use for the infusion set before using the infusion line.

⚠ **Do not** prime the infusion line when it is connected to the infusion site on the body.

Step 4.1

Take the site connector end of the infusion line and place it on a towel (Figure BB).

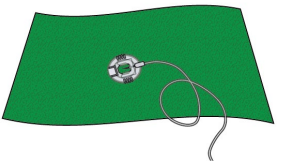


Figure BB

Step 4.2

Take the pump. Press the UP ARROW button (▲) to wake up the screen (Figure BC).

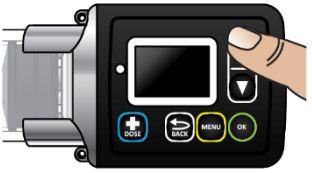


Figure BC

You will then see the Infusion Off screen (Figure BD).

Figure BD

Step 4.3

Press the MENU button (MENU) to enter the pump menu (Figure BE).

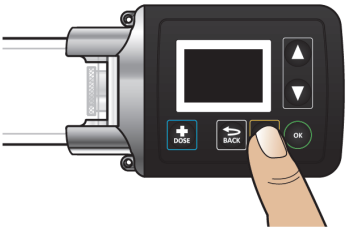


Figure BE

Step 4.4

The **Prime** option will be highlighted on the Menu screen (Figure BF)**.**

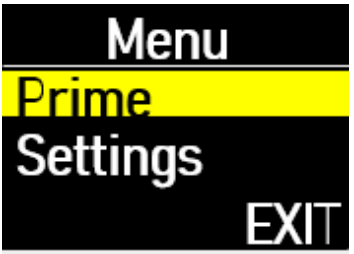


Figure BF

Press the OK button (OK) to continue (Figure BG).

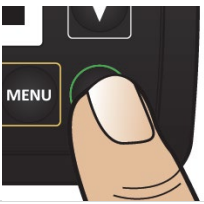


Figure BG

Step 4.5

You will see the Ready to Prime screen (Figure BH).

Figure BH

Press the OK button (

) to prime the infusion line (Figure BI).

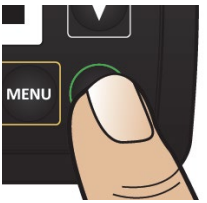


Figure BI

Note: Make sure that the site connector is held over the towel and not attached to the body. During priming, you will be looking for drops to come out of the site connector.

You will then see the Priming screen flashing (Figure BJ). This means that the pump is priming.

Figure BJ

During Priming…

Check the connector end of the infusion line for drops of liquid medicine (Figure BK).

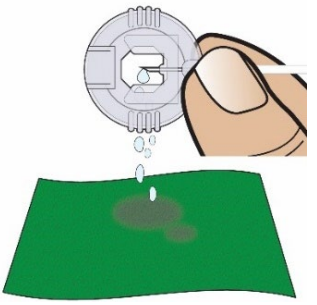


Figure BK

Important Information:

⚠ **Do not** allow the medicine to come into contact with your clothing, carpeting, or furniture, as it can stain.

Step 4.6

When priming is done you will see this screen (Figure BL).

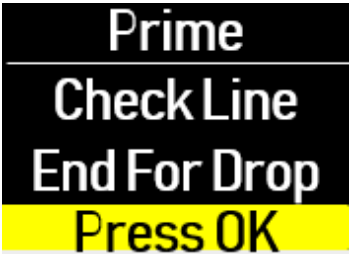


Figure BL

After priming…

Check that all air gaps or large air bubbles are removed from the line (Figure BM).

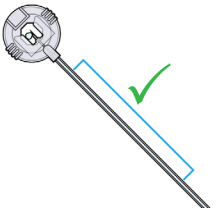


Figure BM

Press the OK button (OK) (Figure BN) for menu options.

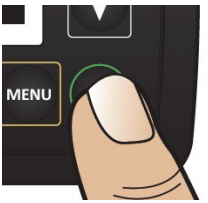


Figure BN

Step 4.7

Did you see drops and confirm no large air bubbles or gaps in the line?

<u>If Yes</u>, Press OK button (OK) to Continue (Figures BO and BP).

<u>If No</u>, Highlight **Repeat Prime** on the screen using the DOWN ARROW button (▼). Then press the OK button (OK) to prime again. If after two priming attempts the line is still not primed, see page 99 for troubleshooting information.

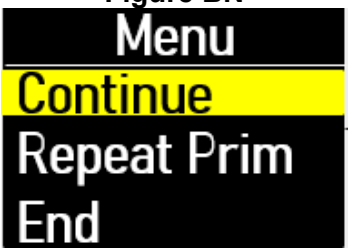


Figure BO

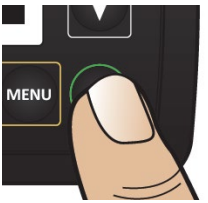


Figure BP

Step 4.8

You will see a screen that says Wait! Connect Line to Body (Figure BQ).

Figure BQ

Put down the pump (Figure BR) and follow the next sections to “Prepare the Infusion Site” and “Connect the Infusion Line to Body”.

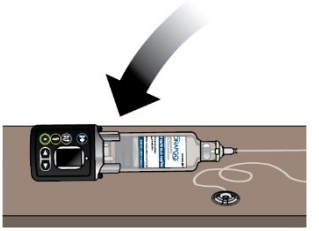


Figure BR

Prepare the Infusion Site

You will insert the cannula (a small tube that allows the medicine to be delivered) into the selected infusion site.

Step 5: Select and Clean the Infusion Site

Step 5.1

Select one of the following infusion sites (see blue shaded areas in Figure BS):

- Lower stomach (Abdomen), at least 2 inches away from belly button
- Top of thigh
- Lower back
- Upper back (only to be used when a caregiver or healthcare provider is preparing the infusion).

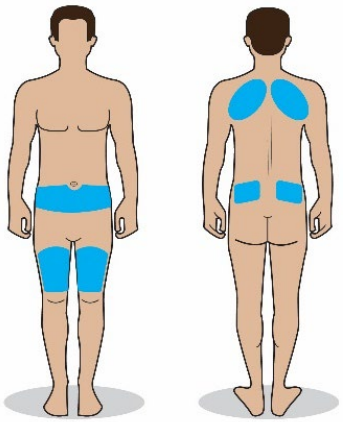


Figure BS

Important Information:

⚠ Change the infusion site every day (rotate sites) to avoid skin-related problems, such as bumps or nodules.

⚠ **Do not** select an infusion site that is bruised, has bumps or nodules, or is irritated.

⚠ **Do not** select an infusion site other than those listed and shown in Figure BS.

Step 5.2

Get an alcohol wipe. Clean the selected infusion site with a new alcohol wipe (Figure BT).

Make sure the area is dry before moving on to **Step 6**.

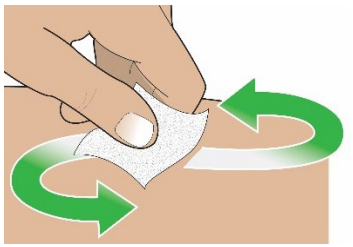


Figure BT

Note: If the infusion line is dropped or dirty, throw away (discard) the infusion line.

Step 6: Connect the Cannula to the Body

Step 6.1

Following the infusion set Instructions for Use, insert the cannula into the cleaned infusion site (Figure BU).

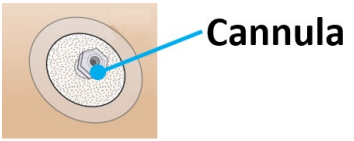


Figure BU

⚠ Read the Instructions for Use for the infusion set before using the infusion line.

⚠ **Do not** insert the cannula into a blood vessel.

⚠ **Do not** insert the cannula into a bump or nodule, as it can result in a blockage (occlusion).

Step 7: Connect the Infusion Line to the Cannula

Step 7.1

Take the site connector end of the infusion line. Pinch the sides of it and pull on the end of the site connector to open it (Figure BV).

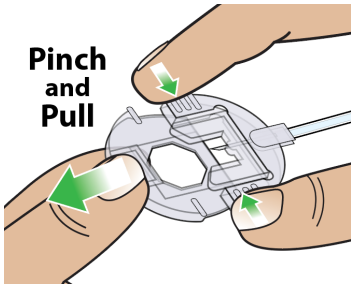


Figure BV

Step 7.2

Connect the primed infusion line to the cannula on the body by placing the site connector over the cannula and then closing it (Figures BW and BX). For more information, follow the Instructions for Use provided with the infusion set.

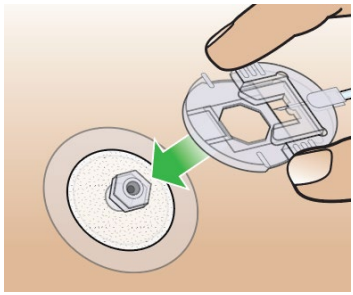


Figure BW

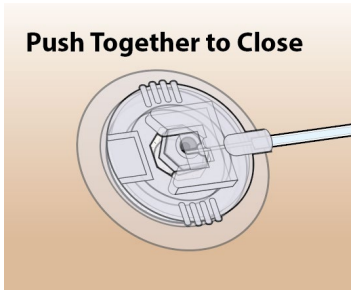


Figure BX

Step 8: Start the Infusion

Step 8.1
Pick up the pump.

Press the UP ARROW button (▲) to wake up the screen (Figure BY).

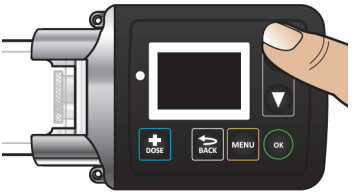


Figure BY

You will see a screen that says Connect Line to Body (Figure BZ).

Figure BZ

Now that have connected the line to your body, press the OK button

(

) (Figure CA).

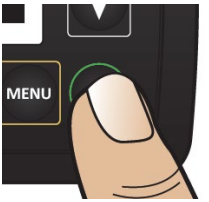


Figure CA

You will see a screen that says Confirm Line Connected (Figure CB).

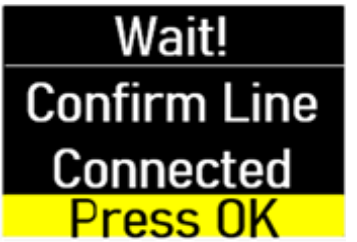


Figure CB

Make sure that the site connector is attached to the body.

Then press the OK button (OK) (Figure CC).

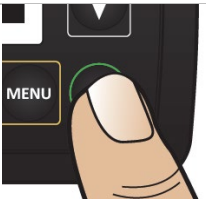


Figure CC

Step 8.2

You will see a screen that says Start Infusion (Figure CD).

Figure CD

When ready, press the OK button (OK) to start the infusion (Figure CE).

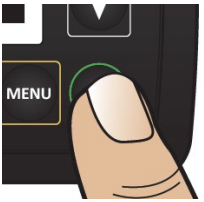


Figure CE

You will then see the Infusion Started screen. The checkmark at the bottom of the screen means that the infusion has successfully started (Figure CF).

Figure CF

After the infusion has started, you will see the Infusing Screen. The flashing droplet means that the pump is now infusing (Figure CG). Next to the droplet, you will also see the amount of time before the infusion ends.

	Figure CG

Wear the Pump

Step 9: Wear the Pump

You must place the pump inside the pump pouch and then attach it to either the elastic belt or the lanyard, whichever you prefer.

Using the Elastic Belt

Take the elastic belt and pump pouch. Insert the elastic belt into the loop on the back of the pump pouch (Figure CH).

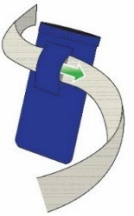


Figure CH

Take the pump. Place the pump inside of the pump pouch (Figure CI).

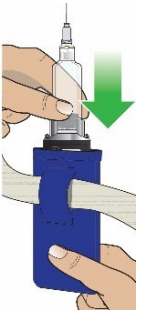


Figure CI

Secure the elastic belt around the waist (Figure CJ).

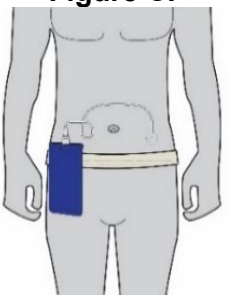


Figure CJ

Do not snag or kink the infusion line while wearing the Pump. Snagging or kinking the infusion line can cause a blockage (occlusion) or an interruption to the infusion.

Using the Neck Lanyard

Take the neck lanyard and pump. Hook the lanyard to the neck lanyard Clips (Figure CK) located on the pump.

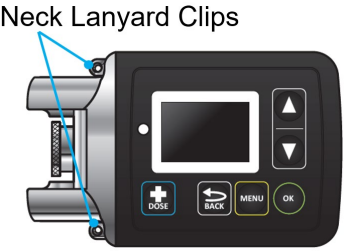


Figure CK

Take the pump pouch. Place the pump inside of the pump pouch (Figure CL).

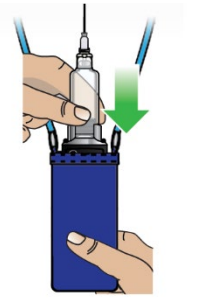


Figure CL

Place the lanyard around patient's neck (Figure CM).

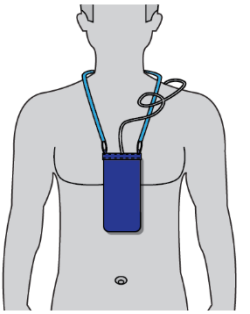


Figure CM

Do not snag or kink the infusion line while wearing the pump. Snagging or kinking the infusion line can cause a blockage (occlusion) or an interruption to the infusion.

Reading the Pump Screen

There are 4 main modes for the pump: On (Infusing Screen), Paused, Primed, and Infusion Off. Each mode is described below.

ON (Infusing Screen)

When the pump is On, and the infusion is running, the following icons and information will be seen (Figure CN):

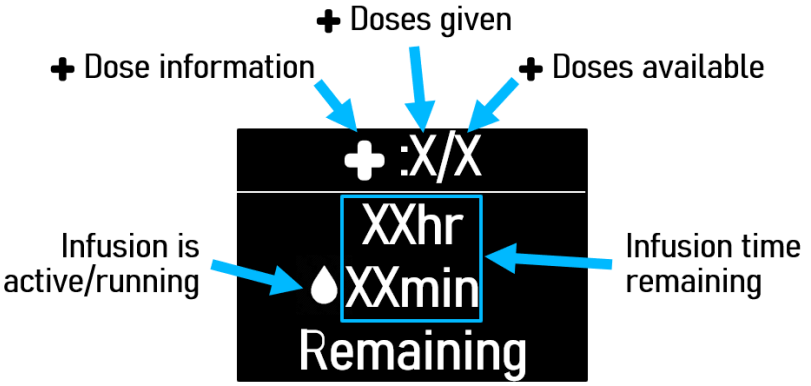


Figure CN

When the pump is On and you attempt to give an extra dose (**+** Dose), the following icon will be seen when the extra dose (**+** Dose) is locked out (Figure CO):

Figure CO

Paused

When the infusion is paused, the following screen will be seen (Figure CP):

Figure CP

To pause the infusion, see the Pausing the Infusion instructions on page 57.

Primed

When the pump is primed, but the infusion has not started, the following screen will be seen (Figure CQ):

Figure CQ

OFF

When the pump is not infusing, the following screen will be seen (Figure CR):

Figure CR

Tab 2 – Front

+ Dose / Pause / End

Tab 2 – Back

+ Dose / Pause / End

+ Dose / Pause / End

Within this section you will find:

Step 10: Give an Extra Dose (+ Dose)

An extra dose (**+** Dose) is only available if it has been prescribed by the healthcare provider. If an extra dose (**+** Dose) has NOT been prescribed, skip this section.

Note: An extra dose (**+** Dose) can only be given after the pump has been primed and while the pump is infusing.

Step 10.1

Take the pump. Press the UP ARROW button (▲) to wake up the screen (Figure CS).

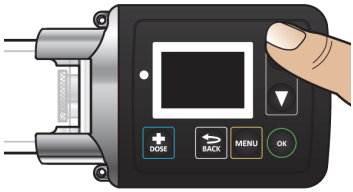


Figure CS

Step 10.2

Press the **+** Dose button (DOSE) (Figure CT).

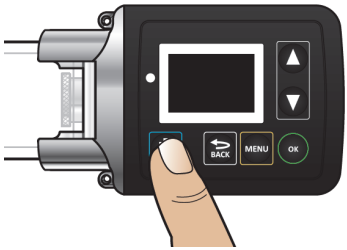


Figure CT

You will then see the **+** Dose screen. Press the DOWN ARROW button (▼) to highlight **Yes** (Figure CU).

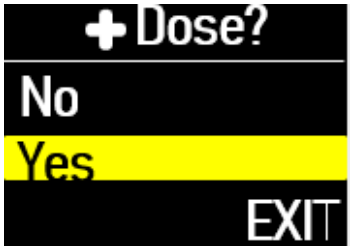


Figure CU

Step 10.3

Press the OK button ( ) to continue (Figure CV).

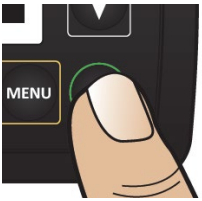


Figure CV

The pump will now give the extra dose (**+** Dose) (Figure CW).

Figure CW

When the extra dose is delivered, you will then see the **+** Dose Delivered screen with a check mark on the bottom (Figure CX).

Figure CX

The pump will then automatically go back to the Infusing screen (Figure CY).

Note: Administer extra doses (**+** Doses) at least 3 hours apart. Administer no more than 3 extra doses a day.

Figure CY

Another Way of Giving an Extra Dose (+ Dose)

Do not repeat the steps below if you have already given an extra dose using the **+** Dose button (DOSE).

- Take the pump.
  Press the menu button (MENU) (Figure CZ).

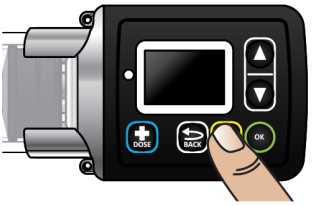


Figure CZ

- Use the DOWN ARROW button (▼) to highlight **Give + Dose** (Figure DA).

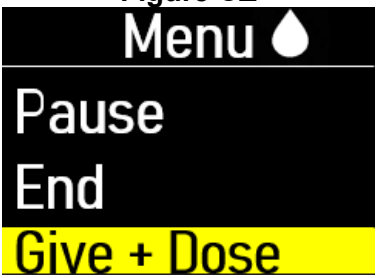


Figure DA

- Press the OK button (OK) to continue (Figure DB).

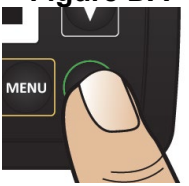


Figure DB

- You will then see the **+** Dose screen.
  Press the DOWN ARROW button (▼) to highlight **Yes** (Figure DC)

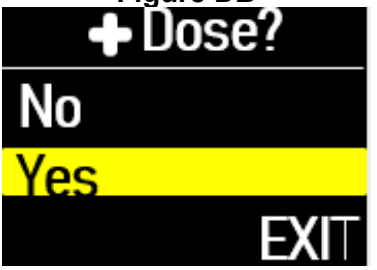


Figure DC

- Press the OK button (OK) to deliver the extra dose (**+** Dose) (Figure DD).

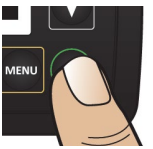


Figure DD

If you see the **+** Dose Locked icon (Figure DE) on the home screen, it means that an extra dose is not allowed.

This is because the minimum amount of time has not passed since the last extra dose (**+** Dose) was given.

The time between allowable extra doses (**+** Doses) is prescribed by the healthcare provider.

Figure DE

When the **+** Dose is locked, you can see the amount of time remaining before another extra dose (**+** Dose) can be given, by pressing the **+** Dose button (DOSE) (Figure DF).

Figure DF

If you see the **+** Dose None Remaining message (Figure DG), it means the maximum number of extra doses has been reached and none remain for that infusion.

Figure DG

Pause and Resume the Infusion

If the pump is at risk for getting wet, pause the infusion, disconnect the infusion line from the body, and store the pump in a dry place. This includes swimming, showering, or excessive sweating.

Step 11: Pausing the Infusion

Step 11.1
Take the pump. Press the UP ARROW button (▲) to wake up the screen (Figure DH).

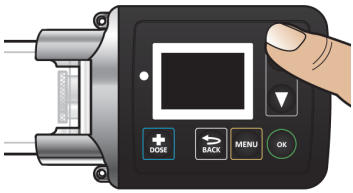


Figure DH

Step 11.2

Press the MENU button (MENU) to enter the pump menu (Figure DI).

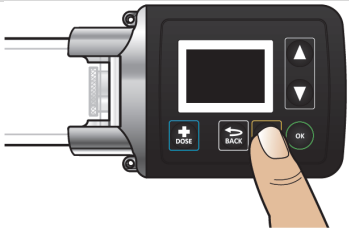


Figure DI

Step 11.3

Pause option will be highlighted on the Menu screen (Figure DJ).

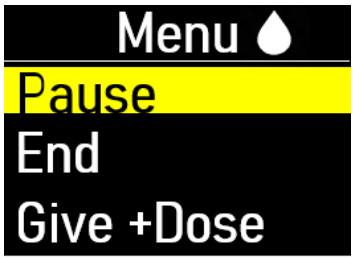


Figure DJ

Step 11.4

Press the OK button (

) to pause the infusion (Figure DK).

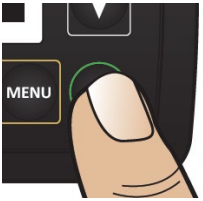


Figure DK

You will then see the Paused screen (Figure DL).

Figure DL

Step 11.5 (If Needed)

If needed, remove the infusion line from your body (Figure DM) while leaving cannula on your skin. There is no need to cover the site connector once removed, as it is self-sealing.

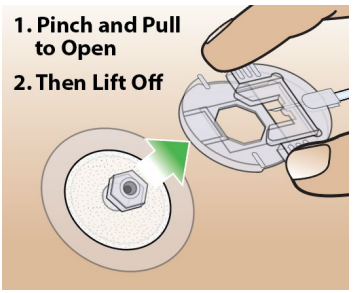


Figure DM

Step 12: Resuming the Infusion

Step 12.1 (If Needed)

Take the site connector end of the infusion line. Reattach the infusion line to the infusion site (Figure DN).

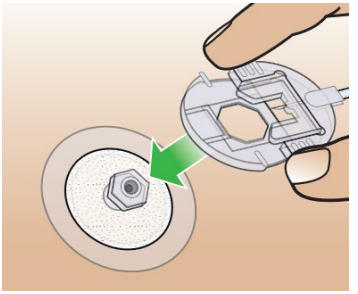


Figure DN

Step 12.2

Take the pump. Press the UP ARROW button (▲) to wake up the screen (Figure DO).

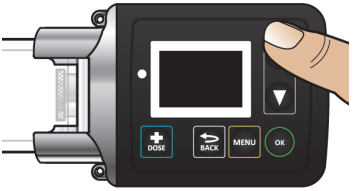


Figure DO

Step 12.3

Press the MENU button (MENU) to enter the pump menu (Figure DP).

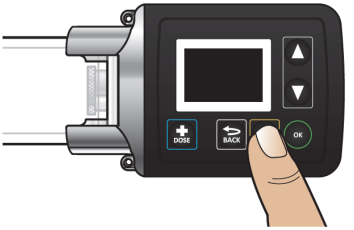


Figure DP

Step 12.4

Resume option will be highlighted on the Menu screen (Figure DQ).

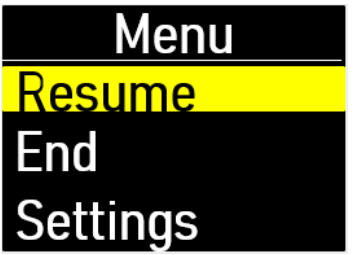


Figure DQ

Step 12.5

Press the OK button (

) to resume the infusion (Figure DR).

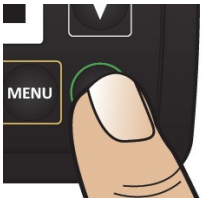


Figure DR

You will then see the Infusion Resumed screen with a check mark on the bottom (Figure DS).

Figure DS

The pump will automatically return to the Infusing Screen (Figure DT).

Figure DT

Ending the Infusion

The infusion will run for the programmed amount of time, or it can be ended early.

Step 13: Ending the Infusion Early

Step 13.1
Take the pump. Press the UP ARROW button (▲) to wake up the screen (Figure DU).

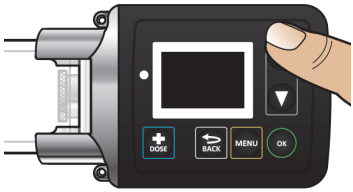


Figure DU

Step 13.2

Press the MENU button (MENU) to enter the pump menu (Figure DV).

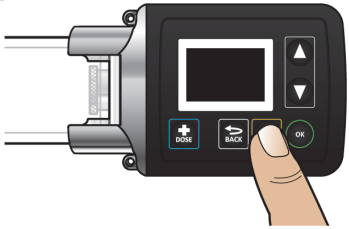


Figure DV

Step 13.3

Press the DOWN ARROW button (▼) to highlight **End** (Figure DW).

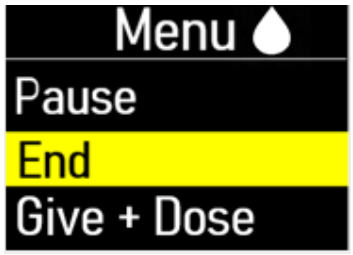


Figure DW

Press the OK button (OK) to end the infusion (Figure DX).

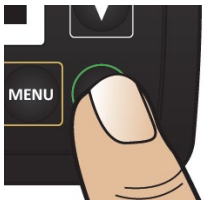


Figure DX

Step 13.4

Press the DOWN ARROW button (▼) to highlight **Yes** (Figure DY).

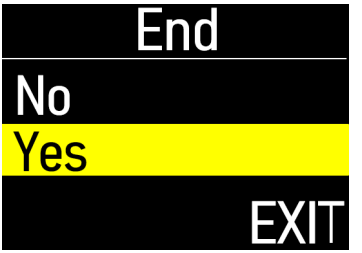


Figure DY

Press the OK button (OK) to select **Yes** (Figure DZ).

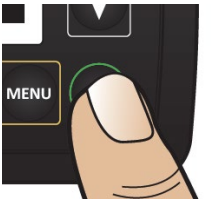


Figure DZ

You will then see the Stop! Remove Line From Body screen (Figure EA).

Do not press the OK button at this time.

Figure EA

Step 13.5

Remove the infusion line from the body (Figure EB).

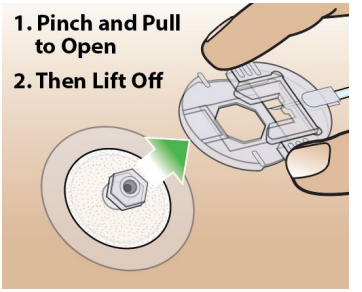


Figure EB

Step 13.6

Press the OK button (OK) to confirm that the infusion line has been removed from the body (Figure EC).

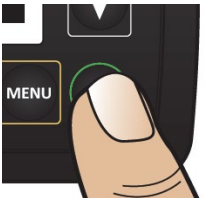


Figure EC

You will then see the Ending Infusion screen, indicating the ending of the infusion (Figure ED). It may take several minutes to retract the pusher and end the infusion.

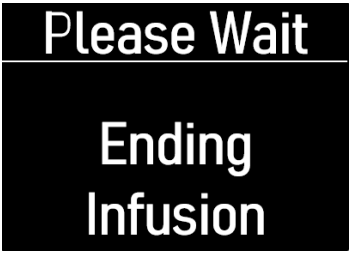


Figure ED

When the pump has ended the infusion, you will see the Infusion Off screen (Figure EE).

Figure EE

Note: If you press the back (BACK) button as the infusion is ending, the pusher reset will pause. Press (OK) to resume ending the infusion and resetting the pusher.

Step 13.7

Remove the cannula from the body (Figure EF).

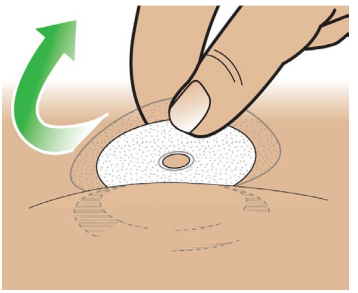


Figure EF

Step 13.8

Take a new alcohol wipe. Clean the infusion site with a new alcohol wipe (Figure EG).

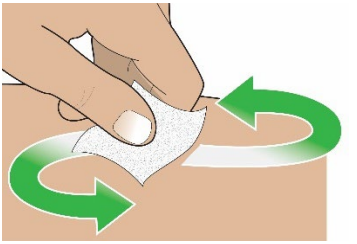


Figure EG

Step 13.9

Gently massage the area of the infusion site to break up any excess fluid buildup. This will help prevent skin nodules or bumps and irritations (Figure EH).

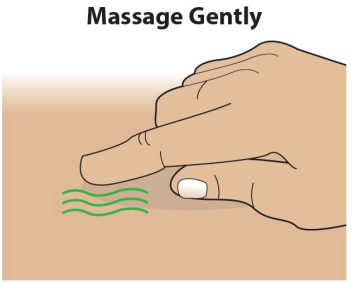


Figure EH

Step 13.10

Take the pump. Twist the assembled cartridge to the left (counterclockwise) and lift it straight up to remove the plastic cartridge holder, glass drug cartridge, and infusion line altogether (Figure EI).

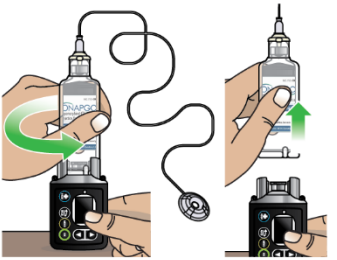


Figure EI

⚠ **Do not** separate the infusion line or the glass drug cartridge from the plastic cartridge holder.

Note: If the plastic cartridge holder detaches from the glass drug cartridge when removing, continue to remove the plastic cartridge holder. Set aside the plastic cartridge holder and remove the glass drug cartridge by pulling it up and off the pump. Continue to **Step 13.11**.

Step 13.11

Throw away the used Infusion line, glass drug cartridge, plastic cartridge holder, and cannula into a sharps container right away after use (Figure EJ).

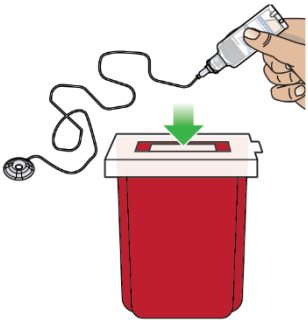


Figure EJ

Do not throw away (dispose of) the infusion line, glass drug cartridge, or plastic cartridge holder in your household trash.

See the **Disposal** section on page 74 for information on how to safely throw away ONAPGO.

Visually Check the Pump

Right after you use the pump, look it over (visually check) to see if you notice any soiling on the pump. Wipe off any soiling that you see with isopropyl alcohol. (See the Clean and Disinfect the Pump section on page 75.)

Step 14: Ending the Infusion Regularly

Step 14.1

At 1 hour, 10 minutes, and 5 minutes remaining in the infusion, the pump will give a reminder on the screen and you will hear occasional beeping (Figure EK).

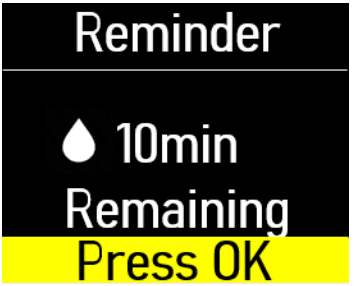


Figure EK

You must press the OK button (OK) to dismiss the message (Figure EL).

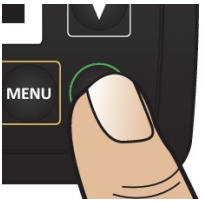


Figure EL

Note: The 10 minute remaining screen is shown in Figure EK as an example.

Step 14.2

When the infusion ends, the Ended screen will appear with 0 minutes remaining (Figure EM) and you will hear a beep.

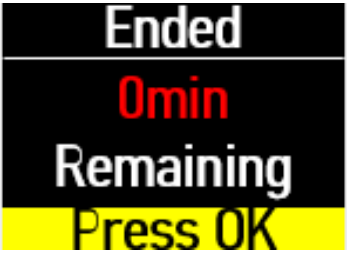


Figure EM

Press the OK button (OK) to select **Yes** (Figure EN).

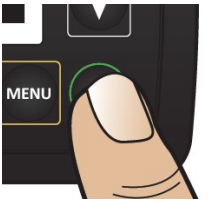


Figure EN

Step 14.3

You will then see the Stop! Remove Line From Body screen (Figure EO).

Do not press the OK button at this time.

Figure EO

Step 14.4

Remove infusion line from the body (Figure EP).

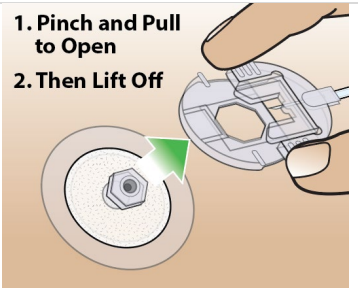


Figure EP

The infusion line must be removed from the infusion site before pressing the OK button.

Step 14.5

Take the pump. Press the OK button (OK) to confirm that the infusion line has been removed from the body (Figure EQ).

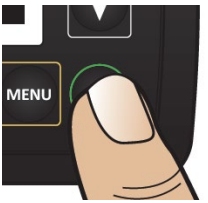


Figure EQ

The pump will begin to reset, and you will see the Ending Infusion screen (Figure ER). It may take several minutes to retract the pusher and end the infusion.

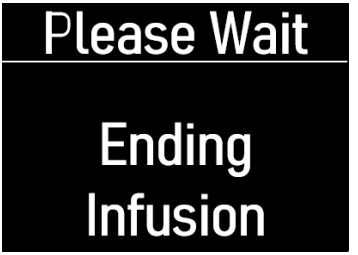


Figure ER

Next, you will see the Infusion Off screen (Figure ES).

Figure ES

Note: If you press the back (BACK) button as the infusion is ending, the pusher reset will pause. Press (OK) to resume ending the infusion and resetting the pusher.

Step 14.6

Remove the cannula from the body (Figure ET).

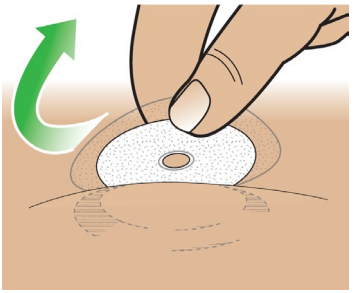


Figure ET

Step 14.7

Take a new alcohol wipe. Clean the infusion site with a new alcohol wipe (Figure EU).

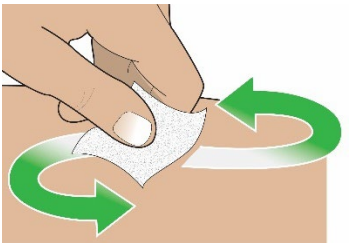


Figure EU

Step 14.8

Gently massage the area of the infusion site to break up any excess fluid buildup. This will help prevent skin bumps or nodules and irritations (Figure EV).

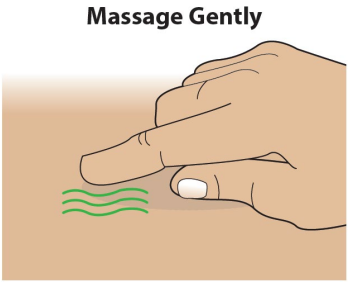


Figure EV

Step 14.9

Take the pump. Twist the plastic cartridge holder to the left (counterclockwise) and lift it straight up to remove the plastic cartridge holder, glass drug cartridge, and infusion line (Figure EW).

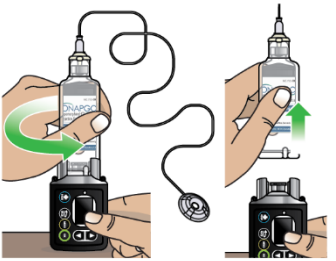


Figure EW

⚠ **Do not** separate the infusion line or the glass drug cartridge from the plastic cartridge holder.

Note: If the plastic cartridge holder detaches from the glass drug cartridge when removing, continue to remove the plastic cartridge holder. Set aside the plastic cartridge holder and remove the glass drug cartridge by pulling it up and off the pump. Continue to **Step 14.10.**

Step 14.10

Put the used infusion line, glass drug cartridge, plastic cartridge holder, and cannula into a sharps container right away after use (Figure EX).

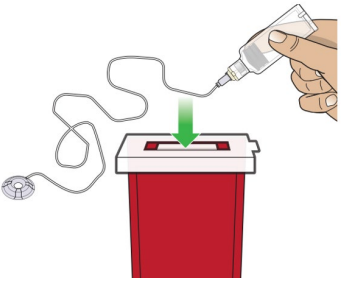


Figure EX

Do not throw away (dispose of) the infusion line, glass drug cartridge, or plastic cartridge holder in your household trash.

See the **Disposal** section on page 74 for information on how to safely throw away ONAPGO.

Visually Check the Pump

Right after you use the pump, look it over (visually check) to see if you notice any soiling. Wipe off any soiling that you see with isopropyl alcohol. (See the Clean and Disinfect the pump section on page 75.)

Disconnecting in an Emergency

If you are having a medical emergency, follow the steps below to disconnect from the pump.

Step 15: Disconnecting in an Emergency

Step 15.1

In the United States, dial 9-1-1 from any telephone for immediate medical assistance (Figure EY).

Figure EY

Step 15.2

Remove the infusion line from your body (Figure EZ).

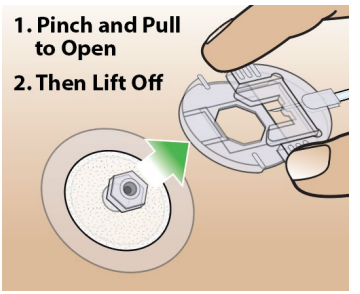


Figure EZ

Step 15.3

Follow the **Ending the Infusion Early** instructions on pages 61 to 65.

Tab 3 – Front

Pump Care

Tab 3 – Front

Pump Care

Pump Care

Within this section you will find:

Glass Drug Cartridge, Plastic Cartridge Holder, and Infusion Line Disposal

- After the infusion, put the combined glass drug cartridge, plastic cartridge holder, and infusion set into a sharps container right away after use (Figure FA). **Do not** throw away (dispose of) the glass drug cartridge, plastic cartridge holder, or infusion set in your household trash. **Do not** separate the parts.

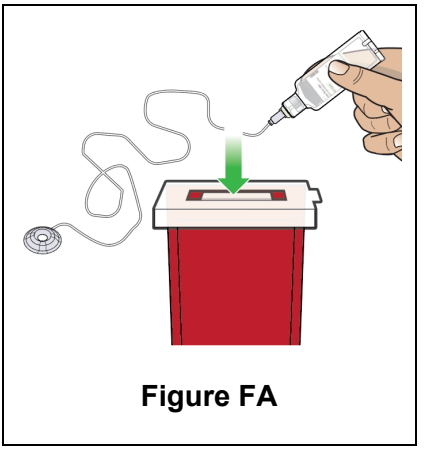


Figure FA

- If you do not have an FDA-cleared sharps container, you may use a household container that is:
  - Made of a heavy-duty plastic.
  - Can be closed with a tight-fitting, puncture-resistant lid.
  - Upright and stable during use.
  - Leak resistant.
  - Properly labeled to warn of hazardous waste inside the container.
- When your sharps container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps container. There may be state or local laws about how you should throw away used needles.
- For more information about safe sharps disposal, and for specific information about sharps disposal in the state that you live in, go to the FDA's website at: http://www.fda.gov/safesharpsdisposal.
- **Do not** dispose of your used sharps container in household trash unless your community guidelines permit this.
- **Do not** recycle your used sharps container.

Pump Disposal

At the end of the expected life of the pump, contact Customer Support at 1-833-3ONAPGO (1-833-366-2746) for information and instructions about safe pump disposal.

Cleaning and Disinfecting the Pump

The Pump is a reusable device and should be cleaned and disinfected whenever you see any traces of dirt.

Follow the instructions below and on the following pages for cleaning and disinfecting the pump.

- Do not clean and disinfect the pump if it is missing any parts (e.g., battery compartment door) or if you see damage to the front label.
- **The pump is not waterproof. Do not** immerse the pump in liquid.
- **Do not** place the pump under running water.
- **Do not** get any liquid inside of the pump. If the pump becomes wet, dry it right away.
- When cleaning the pump, **dry your hands often** to avoid the build-up of liquid on the pump surface.
- **Do not** clean the pump with bleach or harsh (abrasive) detergents.
- **Do not** sterilize the pump.
- **Do not** clean the pump in a dishwasher.
- **Do not** dry the pump in a microwave.

Step 16: Clean and Disinfect the Pump

Always carefully follow the steps below when cleaning and disinfecting the pump.

Step 16.1 Preparing to Clean the Pump

Wash and Dry Your Hands

Wash your hands with soap and water, then dry your hands (Figure FB).

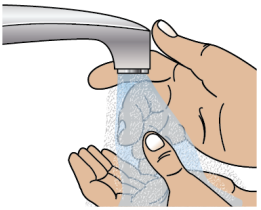


Figure FB

Set up a Clean Work Area

Set up a clean work area on a clean flat surface (Figure FC).

Figure FC

Gather Supplies

Gather the following supplies (available at most supermarkets or pharmacies) (Figure FD):

- Neutral detergent
- Isopropyl alcohol, 70% (rubbing alcohol)
- Purified or distilled water
- Toothbrush with soft bristles
- Several pieces of gauze (at least 8)

Optional Supplies

- Disposable gloves (to be used during cleaning)
- Disposable cups (to hold water and detergent)
- Absorbent towel (to keep on the table and dry your hands)

Note: If you have difficulty finding the supplies to clean your Pump, contact your Specialty Pharmacy or

Figure FD

Customer Support at 1-833-3ONAPGO (1-833-366-2746).

Do not reuse the disposable gauze when cleaning the Pump. Throw away each piece of gauze after use.

Make sure to follow the instructions provided by the manufacturers of the detergent and the isopropyl alcohol.

Step 16.2 Thoroughly Clean the Pump with the Toothbrush

Always clean and disinfect the toothbrush each time you clean the pump, or use a new toothbrush each time you clean the pump. Replace the toothbrush if the bristles get worn or dirty.

Wet the Toothbrush

Use the purified or distilled water to slightly moisten the bristles of the toothbrush.

Add a Drop of Detergent

Add a drop of detergent to the toothbrush.

Brush Gently Until Clean

Use the toothbrush head to gently brush any areas of the pump that are dirty (Figure FE) until you see the pump is clean.

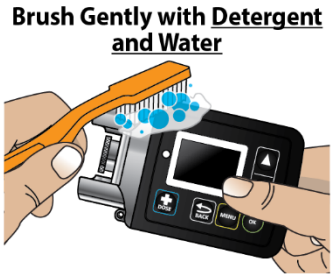


Figure FE

Do not vigorously scrub the pump with the toothbrush.

Step 16.3 Dry the Pump

Wipe Dry with Gauze

Wipe all areas of the pump with a new dry gauze, to remove excess detergent residue or moisture (Figure FF), then throw away the gauze.

Figure FF

Visually Check the Pump

Visually check that all dirt and residue has been removed.

Step 16.4 Thoroughly Clean the Pump with Gauze

Dampen a Gauze with Detergent and Water

Dampen a new gauze with detergent and purified or distilled water.

Wipe the Pump with Gauze

Wipe the outer surfaces of the pump using the dampened gauze (Figure FG), then throw away the gauze.

Figure FG

Step 16.5 Dampen a New Gauze with Water

Dampen a new gauze with purified or distilled water.

Step 16.6 Wipe the Pump with Gauze

Wipe the outer surfaces of the pump with the dampened gauze to remove any detergent residue (Figure FH), then throw away the gauze.

Figure FH

Step 16.7 Dry the Pump

Wipe Dry with Gauze

Dry all areas of the pump with a new dry gauze (Figure FI), then throw away the gauze.

Visually Check the Pump

Visually check the pump for any soiling. Repeat the cleaning process if you see any traces of soiling.

Figure FI

Step 16.8 Disinfect the Pump with 70% Isopropyl Alcohol

Soak a Gauze with Alcohol

Soak a new gauze with 70% isopropyl alcohol.

Wipe Pump with Gauze for at least 1 Minute

Wipe the outer surfaces of the pump using the soaked gauze **for at least one minute** (Figure FJ), then throw away the gauze.

Figure FJ

⚠ **Do not** immerse the pump in isopropyl alcohol.

Step 16.9 Let Pump Air Dry

Let Pump Air Dry for at least 5 Minutes

Set the pump aside on a clean dry surface and let the pump air dry for **at least 5 minutes** (Figure FK).

Figure FK

⚠ The isopropyl alcohol must be in contact with the device surfaces **for at least 5 minutes** to disinfect the pump.

Step 16.10 Disinfect the Pump with 70% Isopropyl Alcohol

Soak a Gauze with Alcohol

Soak a new gauze with 70% isopropyl alcohol.

Wipe Pump with Gauze again for at least 1 Minute

Wipe the outer surfaces of the pump using the soaked gauze **for at least one minute** (Figure

Figure FL

FL), then throw away the gauze.

⚠ **Do not** immerse the pump in isopropyl alcohol.

Step 16.11 Let Pump Air Dry

Let Pump Air Dry for at least 5 Minutes

Set the pump aside on a clean dry surface and let the pump air dry for **at least 5 minutes** (Figure FM).

Figure FM

Make sure Pump is Dry

Make sure the pump is completely dry, and all the isopropyl alcohol has evaporated.

⚠ The isopropyl alcohol must be in contact with the device surfaces **for at least 5 minutes** to disinfect the pump.

Step 16.12 Use Water to Remove Alcohol Residue

Dampen Gauze with Water

Dampen a new gauze with purified or distilled water.

Wipe the Pump with Gauze

Wipe the outer surfaces of the pump with the dampened gauze to remove any disinfectant residue (Figure FN), then throw away the gauze.

Figure FN

Step 16.13 Dry the Pump

Wipe Dry with Gauze

Dry all areas of the pump with a new dry gauze (Figure FO), then throw away the gauze.

Visually Check the Pump

Visually inspect the pump to make sure it is clean.

Figure FO

⚠ **If you see any traces of dirt, repeat the entire cleaning and disinfecting procedure.**

⚠ If the pump has not been cleaned for a long period of time, some stains caused by the liquid medicine may not come off during the cleaning and disinfecting process.

Maintenance and Repair

If the pump is used correctly as outlined in these Instructions for Use, the pump does not need programmed service maintenance from the manufacturer (CANÈ S.p.A. Medical Technology Company).

⚠ If the pump stops working, is damaged or shows a numbered error code contact your **Specialty Pharmacy** or **Customer Support at 1-833-3ONAPGO (1-833-366-2746)**.

Replacing the Battery

Always have a replacement lithium CR 123A battery available for use.

⚠ **Do not** replace the battery while the Infusion Line is connected to your body or during an active infusion as this could cause harm.

⚠ **Do not** use a battery other than lithium CR 123A.

⚠ **Do not** use expired or rechargeable batteries with the Pump.

Step 17: Replacing the Battery

To replace the battery, follow these steps:

Step 17.1

You should see the Infusion Off screen (Figure FP).

Figure FN

Step 17.2

Take a new 3 volt lithium battery (model CR 123A) (Figure FQ) and the battery door key (Figure FR).

Figure FQ

Figure FR

Step 17.3

Take the battery door key and pump. Insert the battery door key into the battery door keyhole on the bottom of the pump (Figure FS).

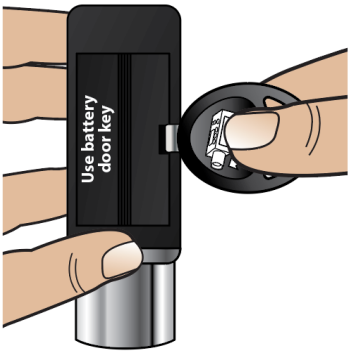


Figure FS

Push the battery door key away from the pump (Figure FT) to open the battery door.

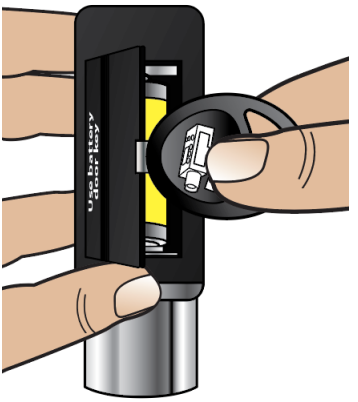


Figure FT

Step 17.4

Pull the battery door up and all the way out so that the ribbon attached to the battery door pops out the battery (Figure FU).

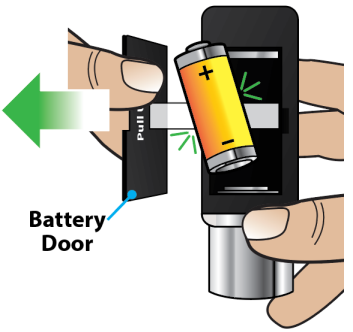


Figure FU

Do not use any other object to remove the battery.

If the battery does not pop out:
Hold the pump and the battery door firmly in one hand (Figure FV) and

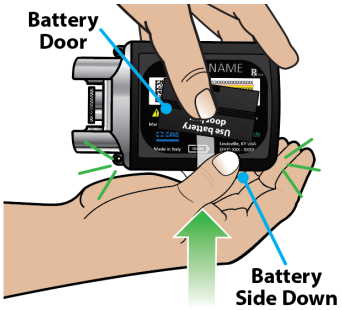


Figure FV

Strike the palm of your other hand with the pump, to jolt the battery from the compartment (Figure FW).

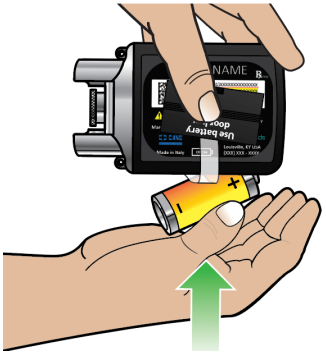


Figure FW

Step 17.5

Throw away the expired battery per local guidelines (Figure FX).

Figure FX

Step 17.6

Wait 10 seconds before inserting a new battery (Figure FY). This allows the pump to reset.

Figure FY

Step 17.7

Take your new, unopened 3 volt lithium battery, model CR 123A (Figure FZ).

Open the package.

Figure FZ

Step 17.8

Take the pump. Insert the new battery by placing it on top of the ribbon with the negative end (**-**) of the battery towards the silver side of the pump where the plastic cartridge holder is attached, and the positive end (**+**) towards the flat end of the pump (Figure GA).

Note: The battery should be placed on top of the ribbon to help with future removal and replacement.

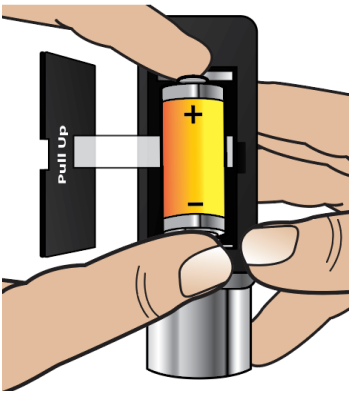


Figure GA

Step 17.9

Close the battery door by pushing it back into place (Figure GB).

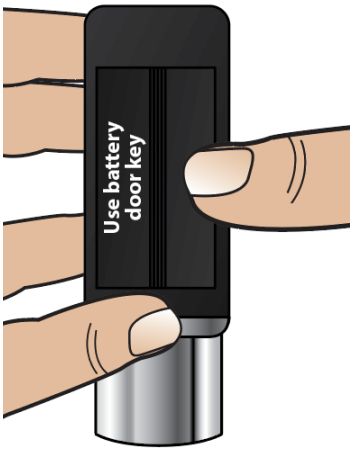


Figure GB

You will hear a series of beeps when the new battery is fully inserted (Figure GC).

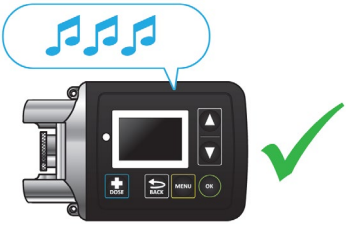


Figure GC

The pump screen will wake up and show the logo screen followed by the Infusion Off screen (Figure GD).

Figure GD

Tab 4 – Front

Alarms & Errors

Tab 4 – Front

Alarms & Errors

Alarms & Errors

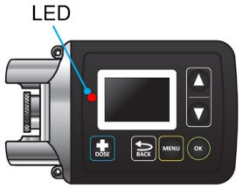
Within this section you will find:

Error Codes

An error code will display on the screen if there is something wrong with the pump. You will hear a beep when there is an error code, and the LED next to the screen may light up. The table below gives an overview of the possible error codes that may happen, what they mean, and what to do to fix them.

If the corrective actions provided below do not fix the issue, contact Customer Support at 1-833-3ONAPGO (1-833-366-2746).

⚠ **Do not** try to start or continue with your infusion when the screen displays an error. This will help avoid overdose or underdose.

Blank Screen Error		
If a Blank Screen Error occurs, follow the steps below.		
 **Figure GE**	**What is happening ?**	You will hear intermittent beeps. The screen is blank and the LED lights up (Figure GE).
	What does it mean?	The pump has detected an error that needs to be addressed.
	What to do?	Contact Customer Support at 1-833-3ONAPGO (1-833-366-2746).

Error 2		
If Error 2 occurs, follow the steps below.		
 **Figure GF**  **Figure GG**	**What is happening ?**	You will hear a continuous tone and the screen will stay on and show a notification (Figure GF) until the error is addressed.
	What does it mean?	The pump has detected an error that needs to be addressed.
	What to do?	**1.** Press the OK button () to clear the error (Figure GF). The pump will try to fix itself. **2.** If the error clears, you can continue with your infusion as normal. **3.** If the error message remains, contact Customer Support at 1-833-3ONAPGO (1-833-366-2746). (Figure GG).

Error 3, Error 5, Error 7		
If Error 3, Error 5, or Error 7 occurs, follow the steps below.		
 **Figure GH**  **Figure GI**	**What is happening ?**	You will hear intermittent beeps. The screen will show a notification (Figure GH), and the LED may light up.
	What does it mean?	The pump has detected an error that needs to be addressed.
	What to do?	**1.** Press the OK button () to clear the error (Figure GH). The pump will try to fix itself. **2.** If the error clears, you can continue with your infusion as normal. **3.** If the error message remains, contact Customer Support at 1-833-3ONAPGO (1-833-366-2746). (Figure GI).

Error 4		
If Error 4 occurs, follow the steps below.		
 **Figure GJ**	**What is happening ?**	You will hear intermittent beeps and the screen will stay on and show a notification (Figure GJ) until the error is addressed.
	What does it mean?	The pump has detected an error that needs to be addressed.
	What to do?	Contact Customer Support at 1-833-3ONAPGO (1-833-366-2746) (Figure GJ).

Error 6, Error 8, Error 9, Error 11		
If Error 6, Error 8, Error 9, or Error 11 occurs, follow the steps below.		
***Note: Images below show Error 6 as an example.**  **Figure GK**  **Figure GL**	**What is happening ?**	You will hear intermittent beeps and the screen will stay on and show a notification (Figure GK) until the error is addressed.
	What does it mean?	The pump has detected an error that needs to be addressed.
	What to do?	1. If attached to the body, remove the infusion line. 2. Press the OK button (OK) to clear the error (Figure GK). The

		pump will try to fix itself. 3. If the error clears, you can continue with your infusion as normal. 4. If the error message remains, contact your healthcare provider or clinical nurse navigator (Figure GL).

Blockage		
If the Blockage Error occurs, follow the steps below.		
 **Figure GM**  **Figure GN**  **Figure GO**	**What is happening ?**	You will hear intermittent beeps and the screen will stay on and show a notification (Figure GM) until the error is addressed.
	What does it mean?	Too much pressure has been detected in the Infusion Line. Something may be blocking the infusion flow.
	What to do?	1. ⚠ If attached to the body, remove the infusion line site connector from your body while leaving the cannula connected to your skin (Figure GM). Press the OK button (OK). 2. Straighten the infusion line out completely to remove any kinks from the line.

Reference ID: 5523357

 **Figure GP**		3. Make sure the infusion line site connector end is over a sink or a towel before pressing the OK button. After the blockage is cleared, some drug may come out. 4. Press the OK button () to clear the error (Figure GN). The pump will try to fix itself. 5. If the blockage is cleared, the infusion will continue. Reattach the infusion line to your body and press the OK button () (Figure GO). 6. If the error message remains, Contact your healthcare provider or Clinical nurse navigator (Figure GP).

Warning: If something is blocking the infusion of ONAPGO, such as a kink, be sure to disconnect the infusion line before clearing the blockage alarm. If the infusion line is attached to the body when the error is cleared, you may receive a small additional amount of medicine.

Low Battery		
If the Low Battery Alert occurs, follow the steps below.		
	What is happening ?	You will hear a beep and see a notification (Figure

 **Figure GQ** **OR**  **Figure GR**		GQ or Figure GR) on the screen.
	What does it mean?	The battery is getting low.
	What to do?	**During an Infusion (Figure GQ):** 1. Press the OK button (OK) to clear alert (Figure GQ). 2. Replace the battery before the next infusion. See **Replacing the Battery** section on pages 81 to 86 for detailed instructions. **Not during an Infusion (Figure GR):** 1. A battery symbol will appear in the top right corner (Figure GR). 2. Replace the battery before next infusion. See **Replacing the Battery** section on pages 81 to 86 for detailed instructions on how to replace the pump battery.

Replace Now (Battery Dead)

If the Replace Now Alarm occurs, the battery is dead. Follow the steps below.

Figure GS

What is happening ?	You will see a notification (Figure GS) on screen.
What does it mean?	The battery is dead and must be replaced right away. **Note:** The pump will not work if the battery is dead.
What to do?	**The screen will show a notification (Figure GS):** **1.** Before setting up or starting an infusion, replace the battery. See **Replacing the Battery** section on pages 81 to 86 for detailed instructions on how to replace the battery.

Note: The alarms have no intentional delays and are raised as soon as the safety system detects the issue.

Note: The pump's firmware keeps the safety system under constant control, and an Error 2 alarm is raised if any issue is detected.

Note: The LED is used only when it is not possible to show the error on the display. The fact that the LED is not used in other alarms does not necessarily mean that they are of a lower priority.

Follow the steps below if your infusion line did not prime correctly:

Wake up the pump (if needed) and then repeat the priming procedure. To do this, go to the menu and select Repeat Prime (Figure GT). When priming is complete, continue the procedure by skipping to Step 4.8.

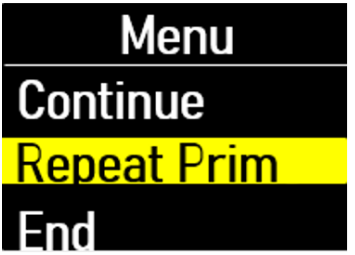


Figure GT

If no liquid drops came out of the site connector end after priming two times, select **End** on the Menu screen and throw away the infusion line in a sharp's container. Then connect a new infusion line and start the priming process again beginning with Step 4.1 on page 34.

See the **Disposal** section on page 74 for information on how to safely throw away ONAPGO.

Symbols Used on the ONAPGO Pump

Caution: Consult accompanying documents for important safety-related information.

CF Applied Part, refer to Technical Manual for more information.

CF Type

Caution: Consult Instructions for Use.

Do not use in or next to a Magnetic Resonance Imaging (MRI) medical device.

IP42

Ingress Protection (IP) rating.

Keep dry

Keep pump dry. If wet, wipe off with a dry cloth. The pump must not be immersed in water and must not be used while showering, swimming, or in a sauna.

Prescription device.

Only use the pump with a CR123A battery.

Dimensions and weight

Dimensions	81 x 49 x 31 mm
Dimensions with holder attached	149 x 49 x 31 mm
Weight	127g

Technical data

Power Supply	CR 123A 3V lithium battery
Battery life	Approximately 90 infusions
Display	Color OLED 96x64 pixels
Ingress protection	IP 42
Buzzer sound pressure level	53 dBA +/- 5 dBA
Data retention	The value settings and counters are retained even without the battery.
Maximum service life	One year from date of purchase

Infusion Data

Note: The information below describes what the pump can do, but it may not be the same as your prescription.

Administrable volume	Max. 20 ml
Infusion flow rate range	1.0 – 8.0 mg/h (drug concentration is 98 mg/20 mL (4.9 mg/ml)
Flow rate programming increment	0.1 mg/h
Shot volume	20 µl
Extra dose (bolus dose) amount	0.5 - 4.0 mg. May also be set to 0 mg
Bolus dose amount programming increment	0.1mg
Maximum number of extra dose (bolus doses) per day	0-5
Bolus doses per infusion programming increment	1
Infusion Time Setting	1 - 24 h

Maximum infusion time programming increment	1h
Minimum interval between extra doses (bolus doses)	3 h
Bolus dose interval programming increment	30 minutes
Bolus dose flow rate	Max. 163 mL/hr
Bolus dose accuracy	Low dose 0.5 to 1.0 mg +/- 25% High dose 1.5 to 4.0 mg +/- 15%
Flow rate accuracy	Low flow rate 1.0 to 3.5 mg/hr: +/- 15% High flow rate 4.0 to 8.0 mg/hr: +/- 10%
Maximum difference in height between pump and infusion site	50 cm
Priming volume	Fixed 1 ml (first delivery), 0.6 ml (second delivery)
Flow rate during priming	163 ml/h
Occlusion pressure levels	2.5 +/- 1.5 bar (36 +/- 22 psi)
Maximum occlusion detection time (hh:mm)	at a flow rate of 1mg/h: 4h 50m at a flow rate of 8mg/h: 32m
Post-occlusion bolus (ml)	0.85ml

Factory Settings

Infusion flow rate	1.0 mg/h
Maximum infusion time	1 h
Bolus dose amount	0.0 mg
Minimum interval between bolus doses	3 h
Maximum number of bolus doses per infusion	0

Environmental Conditions for Use

Temperature	+5 – +40 °C (+41 – +104°F)

Relative humidity	15 – 68%
Pressure	0.7 – 1.06 bar (10 – 15 psi)

Environmental Conditions for Storage

Temperature	-25 – +70 °C (-13 – +158°F)
Relative humidity	Max 68%
Pressure	0.5 – 1.06 bar (7 – 15 psi)

Electromagnetic Compatibility

This section prescribes the correct environments for use in accordance with the declared regulations on electromagnetic compatibility.

Reference standards

The electromagnetic compatibility tests were carried out in accordance with the following standards:

- IEC 60601-2-24:2012 (medical electrical equipment)
- IEC 60601-1-2:2014 (medical electrical equipment)

Electromagnetic emissions

The manufacturer's declarations and requirements are set out below:

Emission test	Conformity	Indications regarding electromagnetic environment
RF emissions CISPR 11	Group 1	The pump uses radio frequency only for its internal operation. As a consequence, its RF emissions are very low and would thus not be expected to cause any interference to electronic devices in the vicinity.
RF emissions CISPR 11	Class B	The pump can be used in all environments, including domestic environments that are directly connected to a low-voltage public mains power network.

Electromagnetic Immunity

The manufacturer’s declarations and requirements are set out below:

<table>
<tr><th>Immunity test</th><th>Test level</th><th>Conformity level</th><th>Indications regarding electromagnetic environment</th></tr>
<tr><td>Electrostatic discharge (ESD) IEC 61000-4-2</td><td>15 kV air 8 kV contact</td><td>15 kV air 8 kV contact</td><td rowspan="2">The pump must be used in an environment with wood, concrete, or ceramic flooring. Where floors are covered with synthetic material, the relative humidity should be at least 30%.</td></tr>
<tr><td>Magnetic fields</td><td>30 A/m 50 and 60 Hz</td><td>30 A/m 50 and 60 Hz</td></tr>
<tr><td rowspan="6">Radiated immunity

IEC 61000-4-3</td><td>80-2700 MHz AM 80% 1 KHz</td><td>10 V/m</td><td rowspan="6">The pump may be subject to interference in the vicinity of devices marked with the following symbol:
 
⚠ WARNING! Underdose or overdose due to abnormal pump operation. If the pump is used in the vicinity of other devices, it should be kept under observation in order to verify that no alarms are shown and that the infusion proceeds normally, delivering the drug in the expecting time. If in doubt, do not use the device.</td></tr>
<tr><td>380-390 MHz 18Hz PM 50%</td><td>27 V/m</td></tr>
<tr><td>430-470 MHz 18Hz PM 50%</td><td>28 V/m</td></tr>
<tr><td>704-787 MHz 217Hz PM 50%</td><td>9 V/m</td></tr>
<tr><td>800-960 MHz 18Hz PM 50%</td><td>28 V/m</td></tr>
<tr><td>1700-1990 MHz 217Hz</td><td>28 V/m</td></tr>
</table>

Immunity test	Test level	Conformity level	Indications regarding electromagnetic environment
	PM 50%		
	2400-2570 MHz 217Hz PM 50%	28 V/m	
	5100-5800 MHz 217Hz PM 50%	9 V/m	

Recommended separation distances from radio frequency devices

Portable radio frequency communication devices (including external antennas and their cables) may interfere with the pump if they are too close to it. These include mobile and cordless phones, LAN routers, and intercom systems for children.

To avoid electromagnetic interference, use the pump at a distance at least 30 cm from such devices.

Tests of Accuracy

The accuracy of pump delivery has been evaluated based on tests carried out during an infusion in accordance with the following standards:

- IEC 60601-2-24:2012 (medical electrical equipment)

Note: Pump and drug cartridge have only been tested with Cleo90 infusion set which is recommended for use. Alternative accessories and extensions may cause inaccuracies in flow rate.

The total administrable volume of the drug is a maximum of 20 mL, and the drug concentration is 98 mg/20 mL (4.9 mg/mL). The flow rate programming increment is 0.5 mg per hr. The maximum infusion programming time is in increment of one hour. The accuracy of the pump was tested for a flow rate between 1.0 mg and 8.0 mg per hour. (See the Prescribing Information for recommended dosage). The flow rate stabilizes within minutes from initiation of the infusion, remains stable and delivers accurately for the duration of infusion as described in the technical specifications provided.

Limited Warranty

The pump is covered by a manufacturer's warranty for one (1) year. After this period, the manufacturer shall not be responsible for any repairs.

The manufacturer shall not be liable for damage to persons or property after a pump lifetime of one (1) year.

Contact & Support

For help and additional information on the pump or system, contact **Customer Support at 1-833-3ONAPGO (1-833-366-2746)**.

Manufactured for:

MDD US Operations, LLC, a subsidiary of Supernus Pharmaceuticals, Inc.
Rockville, MD 20850

Version 12

This Instructions for Use has been approved by the U.S. Food and Drug Administration Approved : 2/2025

BACK COVER