



Instructions for Use

Lasix[®] ONYU (lay-six on-yoo)

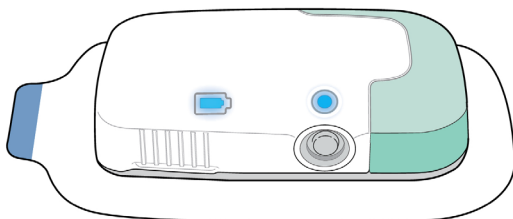
(furosemide injection)

80 mg/2.67 mL

(30 mg/mL)

**for subcutaneous use
with Infusor**

These Instructions for Use contains information
on how to use Lasix ONYU with the Infusor.



Contact Information:

SQ Innovation, Inc.

Burlington, MA 01803, USA

Phone: 1-855-452-7496 (1-855-4LASIX6)

www.Lasix-ONYU.com

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Chapter 1

Important Information You Need to Know

1 Important Information You Need to Know

Before Using the Lasix ONYU Infusor

- Keep the Lasix ONYU Infusor out of sight and reach of children.
- The Lasix ONYU treatment is for adult patients only as prescribed by a healthcare provider.
- **For subcutaneous (under the skin) use only.** The Lasix ONYU Infusor delivers the medicine just under the skin.
- **Use on the stomach only.** Do not use on any other area of the body.
- The Lasix ONYU Infusor is intended to be used by a single person and **should not be shared.**
- **Do not use** the Prefilled Cartridge **if the solution is cloudy, yellow-brown or contains floating particles.** It should be clear or light yellow. If it is not clear or light yellow, contact your healthcare provider to get a new one.
- **Do not use** any part of the Lasix ONYU Infusor **if it has expired.** If it is expired, contact your healthcare provider to get a new one.
- **Do not use** any part of the Lasix ONYU Infusor (Prefilled Cartridge, Disposable Unit, Reusable Unit or Charger) **if it appears to be broken or damaged** or does not work right. Use a new one or call SQ Innovation at 1-855-452-7496.
- **Do not use** a Disposable Unit if it was dropped as it may be damaged or contaminated. Use a new one.
- **Do not use** the Lasix ONYU Infusor **if you can see the needle.** Do not touch the needle or put the Lasix ONYU Infusor on your stomach, as you may get an injury. Go to **Troubleshooting: You Can See the Needle** for instructions on what to do.
- **Do not use more than 1 Lasix ONYU Infusor at a time.**
- **Do not do** more than 2 infusions in a 24-hour period.
- **Do not use a Disposable Unit or Prefilled Cartridge more than 1 time.**

1 Important Information You Need to Know (continued)

Warning: Do not use insulin cartridges or other medicine cartridges **in the Lasix ONYU Infusor**. Doing so could cause severe injury. Only use the Lasix ONYU Prefilled Cartridge with the Lasix ONYU Infusor.

Before Starting a Treatment

- **Talk with your healthcare provider before using** the Lasix ONYU Infusor.
Do not start an infusion unless directed to do so by your healthcare provider.
- **A healthcare provider should train you** before using the Lasix ONYU Infusor by yourself.
- **Read the step-by-step instructions** (go to **Chapter 2: How to Use the Lasix ONYU Infusor**) **before using** the Lasix ONYU Infusor by yourself.
- You may watch the optional training video.



Training Video

Scan the code with your phone or visit the website:
www.Lasix-ONYU.com/infusor-training

During a Treatment

- **Start the infusion within 7 hours** of preparing the Lasix ONYU Infusor.
- The infusion will last about 5 hours. During this time, you should limit your activities so that your bending movements are limited. Wearing the Lasix ONYU Infusor while riding in a car or airplane is not recommended. Be sure you have access to a bathroom after starting the infusion. You should urinate (pee) a lot and will need to make frequent bathroom visits.
- Frequent urination is to be expected during use of the Lasix ONYU Infusor. **Be sure you have access to a bathroom for up to 8 hours** after starting the infusion.
- **Call your healthcare provider if you did not urinate a lot** (at least 2 times during the 5-hour infusion).

1 Important Information You Need to Know (continued)

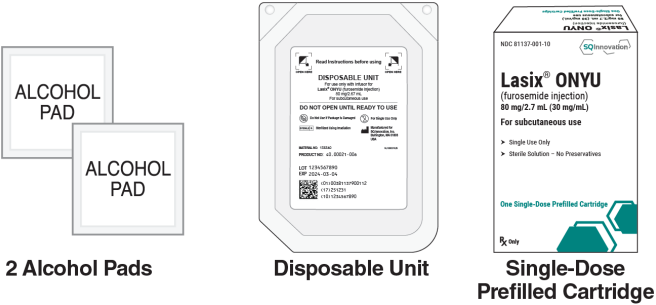
- **Do not** apply lotions, oils, or ointments to the stomach area where you will apply the Lasix ONYU Infusor.
- **Do not get the Lasix ONYU Infusor wet.** Doing so may damage the Lasix ONYU Infusor. Do not shower, bathe, or swim while wearing the Lasix ONYU Infusor.
- **Do not remove the Lasix ONYU Infusor** from the stomach until the infusion is done. Removing the Lasix ONYU Infusor before stopping it will expose the needle, and may injure you or others. Go to **How to Stop the Lasix ONYU Infusor Early** if you need to stop the infusion early.
- **Do not** use the Lasix ONYU Infusor in or around a Magnetic Resonance Imaging (MRI) machine.
- **Do not** use the Lasix ONYU Infusor within 12 inches of mobile phones, tablets, computers, or wireless accessories (for example: TV remote control, Bluetooth computer keyboard or mouse) during the 5-hour infusion. It may cause the Lasix ONYU Infusor to break.

Chapter 2

How to Use the Lasix ONYU Infusor

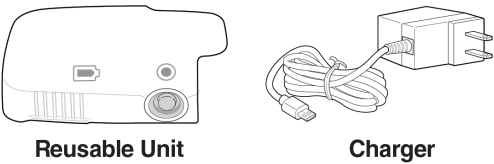
2 Inside the Box

Contents of the Lasix ONYU Kit



Note: The Single-Dose Prefilled Cartridge is referred to as Prefilled Cartridge throughout this Instructions for Use.

Contents of the Reusable Unit and Charger Box



2 Inside the Box (continued)

Contents of the Lasix ONYU Starter Kit

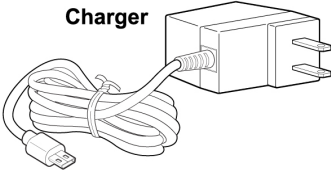


Supplies not included:

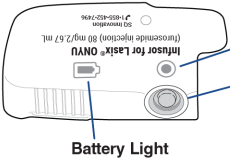
- Cotton ball and small adhesive bandage (if needed) for **Step 21 in End the Infusion.**
- You will also need a sharps disposal container for **Step 25 in Throw Away (Disposal), Cleaning, and Storage.** You may obtain a free sharps disposal container from SQ Innovation. Visit www.Lasix-ONYU.com/sharps/ or call 1-855-452-7496 to have a container mailed to you at no charge.

2 Get to Know the Lasix ONYU Infusor Parts

Charger



Reusable Unit (Front)

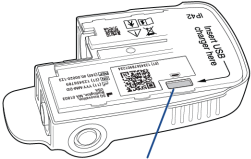


Status Light

Start / Stop
Button

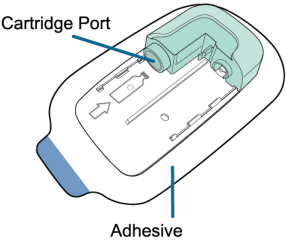
Battery Light

Reusable Unit (Back)



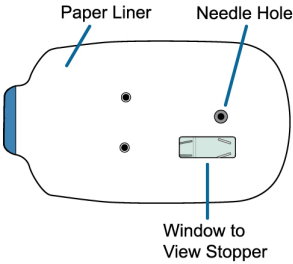
Insert Charger Here

Disposable Unit (Front)



Adhesive

Disposable Unit (Back)



Paper Liner

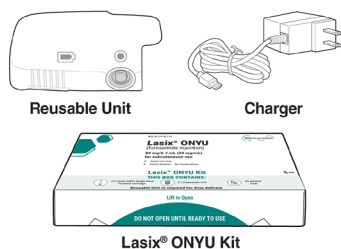
Needle Hole

Window to
View Stopper

Follow the step-by-step instructions starting on the next page >>

2 Get Ready for the Infusion

Do not start an infusion unless directed to do so by your healthcare provider.

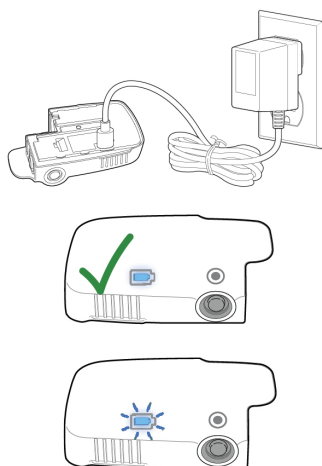


Step 1

Gather the white Reusable Unit, Charger, and 1 Lasix ONYU Kit.

Only use the Charger that has been provided.

Do not use if the Disposable Unit was dropped or if any parts appear to be broken or **damaged**. Use a new one.



Step 2

Charge the Reusable Unit.

Plug the Charger into the back of the white Reusable Unit and a power outlet. Check the Battery Light:

- When the **Battery Light turns solid blue**, **unplug the charger** from the Reusable Unit. The Reusable Unit is ready to use.
- If the **Battery Light is flashing blue**, **wait** for charging to finish.
- If any lights are **red**, **unplug the Charger** and plug it back in. If the lights are still red, go to **Troubleshooting: Lights and Tones Table** for instructions.

Always charge the Reusable Unit before each infusion.

2 Prepare the Medicine



Step 3

Wash your hands with soap and water.



Step 4

Check the expiration date on the Lasix ONYU Kit.

Do not use if the expiration date has passed.



Alcohol Pads



Single-Dose Prefilled Cartridge



Disposable Unit

Step 5

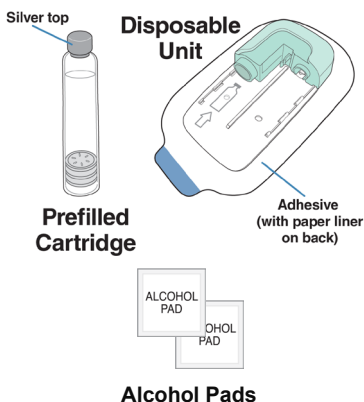
Gather all supplies needed. On a clean, flat, well-lit work surface, **open 1 Lasix ONYU Kit** and remove the contents.

Do not open the contents until you are ready to start the infusion.

Do not use the Disposable Unit if the sealed packaging appears to be damaged. Use a new one.

Do not use the Disposable Unit if it was dropped or if any parts appear to be broken. Use a new one.

2 Prepare the Medicine (continued)

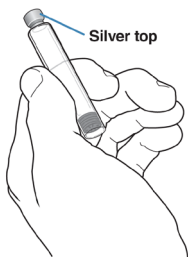


Step 6

Remove the Prefilled Cartridge, Disposable Unit, and 2 alcohol pads from packaging:

- Remove the Prefilled Cartridge from its box and sealed tray.
- Remove the Disposable Unit from its sealed package.

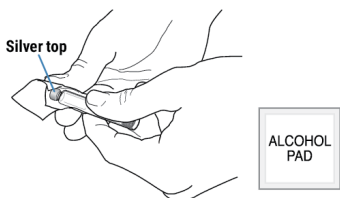
Do not remove the paper liner from the back of the Disposable Unit.



Step 7

Check the Prefilled Cartridge appearance.

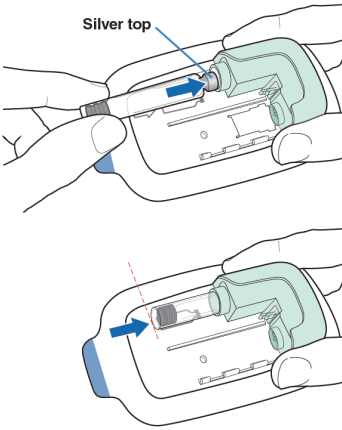
Do not use the Prefilled Cartridge **if the medicine is cloudy, appears yellow-brown, or you see floating particles.**



Step 8

Wipe the silver top of the Prefilled Cartridge with an alcohol pad.

2 Prepare the Medicine (continued)

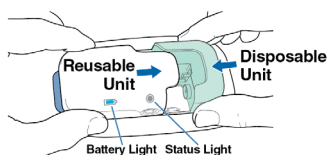


Step 9

Push the **Prefilled Cartridge** into the green Disposable Unit with the silver top inserted first.

The Prefilled Cartridge is fully inserted when the bottom of the Prefilled Cartridge is at the tip of the arrow on the Disposable Unit.

2 Prepare the Lasix ONYU Infusor



Step 10

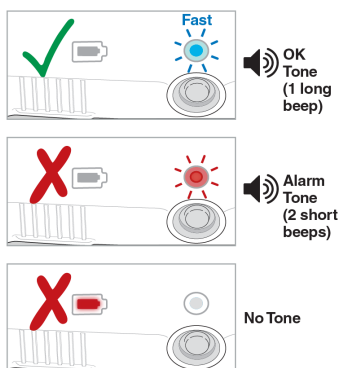
Check the following:

- The Reusable Unit Battery Light is solid blue, and
- The Charger is disconnected from the Reusable Unit.

Slide together the white Reusable Unit and green Disposable Unit together until the Status Light on the Reusable Unit turns on.

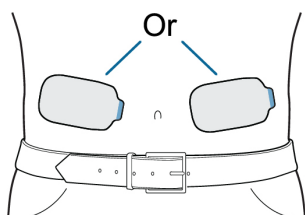
Step 11

Check the Status Light.



- If the **Status Light is blue and flashing fast, and you hear the OK Tone (1 long beep), continue to Step 12.** The Lasix ONYU Infusor is ready to start your infusion.
- The Lasix ONYU Infusor will remain ready to start infusion for 7 hours.
- If the **Status Light is flashing red and you hear the Alarm Tone (2 short beeps), do not use the Lasix ONYU Infusor.** Go to **Troubleshooting: The Status Light is Flashing Red** for instructions.
- If the **Battery Light is solid red, do not use the Lasix ONYU Infusor.** Go to **Troubleshooting: Checking the Reusable Unit Battery** for instructions.

2 Prepare the Application Site



Step 12

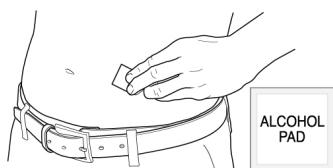
Choose a site on the stomach, above the beltline, to the left or right of the belly button.

Trim excessive hair at the site. This will help the Lasix ONYU Infusor stick to the skin.

Alternate (rotate) sites between left and right sides of the stomach with each infusion.

Do not choose a site where:

- the skin is irritated, broken, tender, red, bruised, or hard,
- the skin is wet or sweaty,
- there are folds in the skin when standing up straight, or
- belts, waistbands, or tight clothing may rub against or move the Lasix ONYU Infusor.

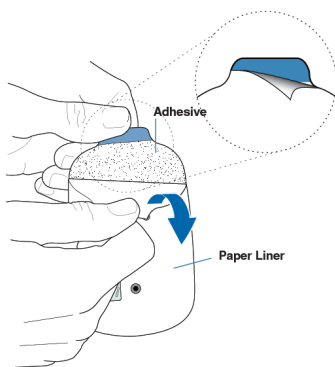


Step 13

Wipe the site with an alcohol pad.

Let dry for at least 10 seconds.

2 Attach the Lasix ONYU Infusor

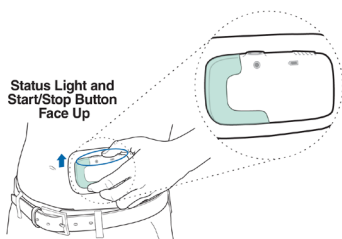


Step 14

Hold the blue tab with one hand and use the other hand to **peel off the paper liner** from the adhesive on the back of the Lasix ONYU Infusor.

Leave the sticky adhesive on the Lasix ONYU Infusor. Only remove the paper liner.

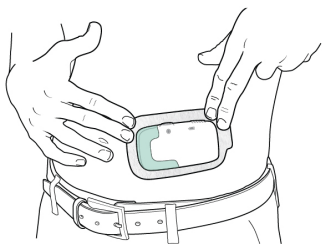
Do not touch the sticky adhesive with your fingers or let it touch any surfaces before sticking the Lasix ONYU Infusor to your stomach.



Step 15

While standing up straight, press the Lasix ONYU Infusor onto the site on your stomach you wiped with the alcohol pad.

Make sure the **Status Light** and the **Start/Stop Button are facing up** in a horizontal position as shown, so you can see them when the Lasix ONYU Infusor is on your stomach.

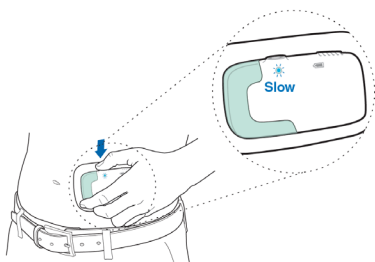


Step 16

Rub the edges of the adhesive with a finger to get the Lasix ONYU Infusor to stick well.

2 Start the Infusion

Start your infusion within 7 hours of connecting the Reusable Unit and Disposable Unit. If more than 7 hours pass without starting your infusion, the Lasix ONYU Infusor will time out and the infusion cannot be delivered (go to **Troubleshooting: The Status Light is Flashing Red**).



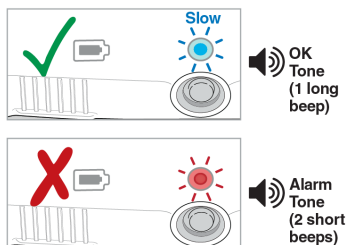
Step 17

Press and hold the Start/Stop Button until you **hear the motor** and **see the blue Status Light** change to **flashing slow**.

The needle will automatically insert into your skin after the Start/Stop Button is pressed. You may feel a slight pinch.

You **will hear the motor start and stop often** during your infusion. The motor runs for a few seconds at a time then pauses for several minutes.

2 Start the Infusion (continued)



Step 18

Check the Status Light.

- If the **Status Light** is **blue and flashing slow**, and you hear the **OK Tone (1 long beep)**, the infusion has **started**. You will hear the motor running.
- If the **Status Light** is **flashing red**, and you hear the **Alarm Tone (2 short beeps)**, the infusion **did not start**. Go to **Troubleshooting: The Status Light is Flashing Red** for instructions.
- If the **Status Light** is **blue and flashing fast**, and you hear the **OK Tone (1 long beep)**, the infusion **did not start**. Repeat **Step 17**.
- For additional assistance go to **Troubleshooting: Lights and Tones Table** for instructions or call 1-855-452-7496.

2 During the Infusion



Wait 5 Hours

Step 19

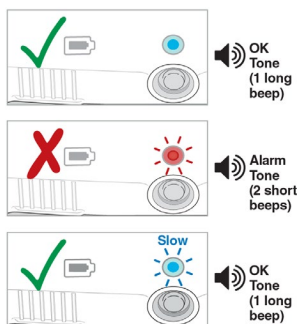
Wait 5 hours for the Lasix ONYU Infusor to deliver the full infusion.

You will see the blue Status Light flashing slow and sometimes hear the motor running.

Check the Lasix ONYU Infusor every now and then to make sure it is working properly.

Do not remove the Lasix ONYU Infusor from your stomach until the infusion is done. The infusion is complete when the Status Light is solid blue and you hear the OK Tone (1 long beep). Go to **Troubleshooting: How to Stop the Infusor Early** if you need to stop the infusion early.

2 End the Infusion



Step 20

After 5 hours, **check** the Status Light.

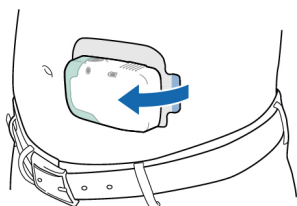
- If the **Status Light** is **solid blue**, and you hear the **OK Tone (1 long beep)**, the infusion is **done**.
- If the **Status Light** is **flashing red**, and you hear the **Alarm Tone (2 short beeps)**, an error happened. Go to **Troubleshooting: The Status Light is Flashing Red**.
- If the **Status Light** is **blue** and **flashing slow**, and you hear the **OK Tone (1 long beep)**, the infusion is **not done yet**. Continue to wait.

The **needle automatically pulls in (retracts)** when the infusion is done. You may feel a slight pinch.

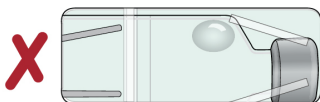
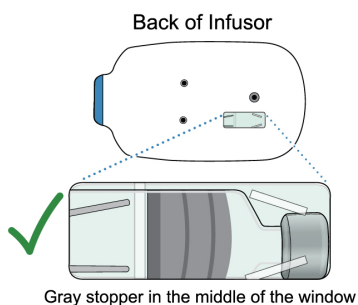
Step 21

When the infusion is done, **remove the Lasix ONYU Infusor** from your stomach. Peel the Lasix ONYU Infusor off the skin by holding down the skin and pulling the blue tab away from the stomach.

You might have some discomfort after you remove the Lasix ONYU Infusor. This discomfort should quickly go away, but some redness of the skin may remain. If there is any bleeding, pat with a small cotton ball or apply a small adhesive bandage over the site.



2 Confirm the Infusion Worked



Step 22

Look in the window on the back of the Lasix ONYU Infusor to check whether all the medicine was delivered.

- If the middle of the window is all **gray** (whole gray stopper is visible with very little or no liquid), all of the medicine was delivered.
- If you **see anything else** (like a lot of liquid, a large bubble in the liquid, no gray stopper, or only part of the gray stopper), some of the medicine was not delivered. **Call your healthcare provider right away.**

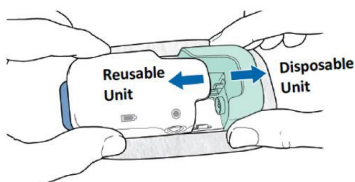


Step 23

Confirm the medicine worked.

- If you **urinate a lot** (at least 2 times during the 5-hour infusion), the **medicine worked**.
- If you **urinate less than 2 times** (during the 5-hour infusion), the medicine may not have worked. **Call your healthcare provider right away.**

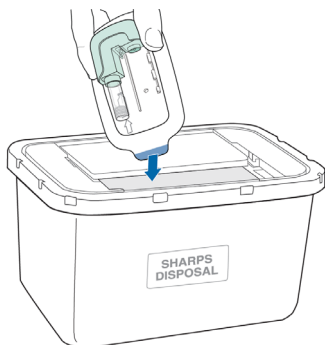
2 Throw Away (Disposal), Cleaning, and Storage



Step 24

Pull apart the green Disposable Unit and white Reusable Unit.

The Reusable Unit automatically turns off when the two parts are separated.



Step 25

Do not save and re-use the green Disposable Unit or Prefilled Cartridge. **They are for one-time use only.**

Throw away the green Disposable Unit into an FDA-cleared **sharps disposal container**.

You may obtain a free sharps disposal container from SQ Innovation. Visit www.Lasix-ONYU.com/sharps/ or call 1-855-452-7496 to have a container mailed to you at no charge. Alternatively, if you do not have an FDA-cleared sharps disposal container, you may use a household container that is:

- made of heavy-duty plastic,
- can be closed with a tight fitting, puncture-resistant lid, without sharps being able to come out,
- upright and stable during use,
- leak-resistant, and
- properly labeled to warn of hazardous waste inside the container.

2 Throw Away (Disposal), Cleaning, and Storage (continued)

When your Sharps container is almost full, you will need to follow your community guidelines for the right way to dispose of your sharps disposal container. There may be state or local laws about how you throw away used needles and syringes. For more information about safe sharps disposal and for specific information about sharps disposal in the state that you live in, go to the FDAs website at:

<https://www.fda.gov/medical-devices/safely-using-sharps-needles-and-syringes-home-work-and-travel/best-way-get-rid-used-needles-and-other-sharps>

Do not dispose of your used sharps disposal container in your household trash unless your community guidelines permit this.

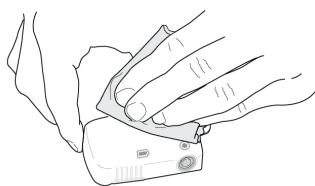
Do not recycle the green Disposable Unit and used sharps disposal container or throw them away into household trash.

Important: Always keep the sharps disposal container out of the reach of children.

Scan the code below with your phone for a sharps disposal location near you or call Safe Needle Disposal at 1-800-643-1643.



2 Throw Away (Disposal), Cleaning, and Storage (continued)



Do not use harsh cleaners that contain bleach, alcohol, ammonia, or other solvents. These cleaners may damage the Reusable Unit.

Do not submerge the Reusable Unit **in liquids** or spray liquids directly on the surface. It contains parts that should not get wet.

Step 26

Wipe the white Reusable Unit with a clean, water-damp cloth to remove visible dirt right after use. Let dry completely before storing.

If needed, a mild detergent, like dish soap, may be added to the damp cleaning cloth.

Step 27

Store the Reusable Unit, Charger, and any remaining Lasix ONYU Kits for next use.

- Keep at room temperature between 68°F and 77°F (20°C and 25°C).
- **Do not** refrigerate or freeze.
- Keep in a dark place to protect from light.
- Keep dry.
- Keep extra Prefilled Cartridges and Disposable Units in their original packaging until it is time to use them.



Chapter 3

Troubleshooting

3 Customer Service Contact Information

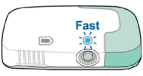
Contact Information:

SQ Innovation, Inc.
Burlington, MA 01803, USA

Phone: 1-855-452-7496 (1-855-4LASIX6)

www.Lasix-ONYU.com

3 Lights and Tones Table

Lights		Tones	What it Means
Battery Light Flashes Blue		No Tone	Battery is charging.
Battery Light Solid Blue		No Tone	Battery is charged and ready for use.
Battery Light Solid Red		No Tone	Low battery. Reusable Unit must be charged before use.
Battery Light and Status Light Solid Red		No Tone	Reusable Unit has expired and must be replaced.
Status Light Blue and Flashes Fast		Ok Tone (1 long beep)	Infusor is ready for medicine delivery.
Status Light Blue and Flashes Slow		Ok Tone (1 long beep)	Infusor is delivering medicine.
Status Light Solid Blue		Ok Tone (1 long beep)	Delivery of medicine is done.
Status Light Flashes Red		Alarm Tone (2 short beeps)	1. Device or delivery cycle error. 2. Delivery of medicine stopped by user.

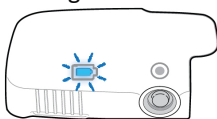
3 Checking the Reusable Unit Battery

If the Battery Light is charged, the white Reusable Unit is able to deliver a full infusion. If the Battery Light is low, the Reusable Unit cannot deliver a full infusion and it needs to be charged.

Always charge the Reusable Unit before you use a new Disposable Unit (before each infusion).

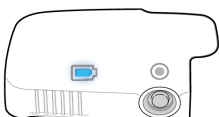
Charging may take up to 20 minutes.

-
- A. Battery Light is flashing blue



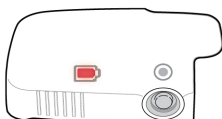
The Reusable Unit **battery is being charged**. Wait until the Battery Light turns solid blue before using the Lasix ONYU Infusor.

-
- B. Battery Light is solid blue



The Reusable Unit **battery is done charging** and ready to use.

-
- C. Battery Light is solid red **before preparing the Lasix ONYU Infusor for use**



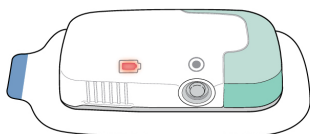
The Reusable Unit **battery is low** and cannot deliver a full infusion.

Charge the Reusable Unit:

1. Plug the Charger into the back of the Reusable Unit.
2. Plug the other end of the Charger into a power outlet.
3. Wait until the Battery Light turns solid blue.

3 Checking the Reusable Unit Battery (continued)

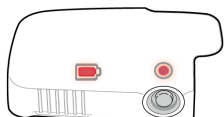
- D. Battery Light is solid red **when the Disposable Unit and Reusable Unit are connected**



The Reusable Unit **battery is low** and the Lasix ONYU Infusor will not start.

1. Pull apart the white Reusable Unit and green Disposable Unit.
2. Put the Disposable Unit to the side while you charge the Reusable Unit (**do not** remove the Prefilled Cartridge from the Disposable Unit).
3. Charge the Reusable Unit:
 - a. Plug the Charger into the back of the Reusable Unit.
 - b. Plug the other end of the Charger into a power outlet.
 - c. Wait until the Battery Light turns solid blue.
 - d. Follow instructions beginning with **Step 10 in Prepare the Lasix ONYU Infusor** to connect the Reusable Unit to the Disposable Unit.

3 The Reusable Unit Has Expired



When the Reusable Unit expires, the Lasix ONYU Infusor can no longer be used. The Reusable Unit needs to be replaced.

The Reusable Unit is expired if it does not light up at all after charging or the **Status Light and the Battery Light are both solid red** when the Reusable Unit is plugged in or when the Reusable Unit and Disposable Unit are pulled apart.

Call 1-855-452-7496 for a replacement Reusable Unit, which will be shipped overnight when possible. Also call your healthcare provider.

The Reusable Unit should not be thrown away (disposed of) with household waste and should not be recycled in your local recycling program. Throw away the Reusable Unit according to local regulations for electronic devices with lithium batteries.

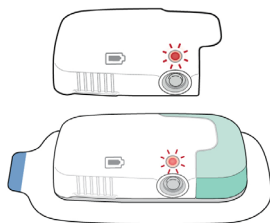
Alternatively, the Reusable Unit may be returned to SQ Innovation, free of charge, for proper and safe recycling. Go to **Chapter 4** for more information.

3 The Status Light is Flashing Red

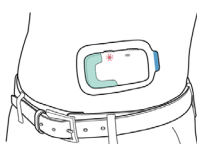
When an **error happens inside the Lasix ONYU Infusor** or the white Reusable Unit and green Disposable Unit have been **connected for 7 hours without starting the infusion**, the Status Light will flash red and you will hear a repeating Alarm Tone (2 short beeps).

This can happen in the following 2 situations:

- **Before** the white Reusable Unit and green Disposable Unit are **connected**, see Section A below for what to do.
- **After** the white Reusable Unit and green Disposable Unit are **connected**, see Section B below for what to do.

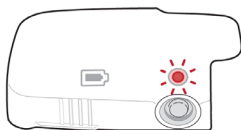


Or



A. If the Status Light flashes red **before** the white Reusable Unit is **connected** to the green Disposable Unit, **a device error happened**. Follow the instructions below:

1. Unplug the Charger (if it is connected).
2. Press and hold the Start/Stop Button until the flashing red light turns off (1 second).
3. Plug the charger into the Reusable Unit and a power outlet. Check the Lights:



 Alarm Tone
(2 short beeps)

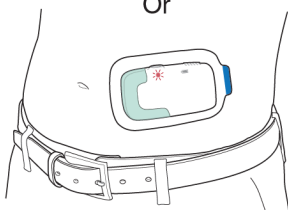
- If the **Battery Light** is **solid** or **flashing blue**, the Reusable Unit is **ready to use**. Continue with **Step 2 in Get Ready for the Infusion**.
- If the **Status Light** is still **flashing red**, the Reusable Unit cannot be used. Call 1-855-452-7496 for a replacement Reusable Unit, which will be shipped overnight when possible. Also call your healthcare provider.

3 The Status Light is Flashing Red (continued)

- B.** If the Status Light flashes red **after connecting** the white Reusable Unit and green Disposable Unit, **a device error happened** or the **Lasix ONYU Infusor timed out** (because it was connected for 7 hours without starting the infusion). The Lasix ONYU Infusor cannot be used. Follow the steps below:



Or



 Alarm Tone
(2 short beeps)

1. If the Lasix ONYU Infusor is on the body, **remove it from** the stomach.
2. If you can see the needle, **do not touch the needle** because you could get an injury.
3. **Pull apart** the Reusable Unit and Disposable Unit.
4. **Throw away the Disposable Unit** with the Prefilled Cartridge **into an FDA-cleared sharps disposal container** (see **Step 25 in Throw Away (Disposal), Cleaning and Storage**). You should not throw away the Disposable Unit in the household trash.
 - **Do not** save and re-use the Disposable Unit or Prefilled Cartridge as the medicine may be contaminated. They are for one-time use only.
5. Determine the next steps:
 - a. If the error happened **before the infusion was started**, get a new Lasix ONYU Kit and **start over at Step 1 in Get Ready for the Infusion**.
 - b. If the error happened **after the infusion was started**, **call your healthcare provider** to see what to do because some of the medicine was not delivered.

3 You Can See the Needle

You may see the needle in one of these situations:

- You **press the Start/Stop Button before the Lasix ONYU Infusor is placed on the stomach**, see Section A below for what to do.
- You **remove the Lasix ONYU Infusor before infusion is done** or the **Lasix ONYU Infusor falls off** during the 5-hour infusion, see Section B below for what to do.
- The **needle did not retract automatically** after infusion, see Section C below for what to do.

Do not touch the needle because you could get an injury.

- A.** If you see the needle **before the Lasix ONYU Infusor is placed on the stomach**, you should start over with a new Lasix ONYU Kit. Follow the steps below:
1. **Press and hold the Start/Stop Button** (4 seconds) until the Status Light flashes red and you hear the Alarm Tone (2 short beeps).
 2. **Pull apart** the white Reusable Unit and green Disposable Unit.
 3. **Throw away the Disposable Unit** with the Prefilled Cartridge **into an FDA-cleared sharps disposal container**. You should not throw away the Disposable Unit in the household trash.
 - **Do not** save and re-use the Disposable Unit or Prefilled Cartridge as the medicine may be contaminated. They are for one-time use only.
 4. **Return to Step 1 in Get Ready for the Infusion** to start over with a new Lasix ONYU Kit. Be careful not to press the Start/Stop Button until after the Lasix ONYU Infusor is on the stomach.

3 You Can See the Needle (continued)

- B.** If you see the needle because **the Lasix ONYU Infusor fell off or it was removed before infusion was done**, follow the steps below:

You should not stick the Infusor back on the stomach because it may fall off again.

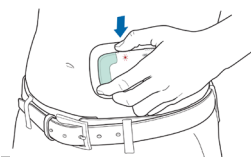
1. **Press and hold the Start/Stop Button** (4 seconds) until the Status Light flashes red and you hear the Alarm Tone (2 short beeps).
 2. **Pull apart** the white Reusable Unit and green Disposable Unit.
 3. **Throw away the Disposable Unit** with the Prefilled Cartridge **into an FDA-cleared sharps disposal container**. You should not throw away the Disposable Unit in the household trash.
 - **Do not** save and re-use the Disposable Unit or Prefilled Cartridge as the medicine may be contaminated. They are for one-time use only.
 4. **Call your healthcare provider** to see what to do because some of the medicine was not delivered.
-

- C.** If you see the needle **after the 5-hour infusion is done**, the needle did not retract automatically. Follow the steps below:

1. **Carefully pull apart** the white Reusable Unit and green Disposable Unit.
 2. **Throw away the Disposable Unit** with the Prefilled Cartridge **into an FDA-cleared sharps disposal container**. You should not throw away the Disposable Unit in the household trash.
 - **Do not** save and re-use the Disposable Unit or Prefilled Cartridge as the medicine may be contaminated. They are for one-time use only.
 3. **Continue with Step 26 and Step 27 in Throw Away (Disposal), Cleaning, and Storage** to clean and store the Reusable Unit.
-

3 How to Stop the Lasix ONYU Infusor Early

Follow these steps below if you need to stop the Lasix ONYU Infusor before the 5-hour infusion is finished. **Do not remove the Lasix ONYU Infusor** from the stomach **before stopping it**. Removing the Lasix ONYU Infusor from the body before stopping it will expose the needle, and you could get an injury if you touch it.



1. **Press and hold the Start/Stop Button** (4 seconds) until you hear the Alarm Tone (2 short beeps) and the Status Light is flashing red.



Alarm
Tone
(2 short
beeps)



2. **Confirm** infusion was stopped. Check the Status Light:
 - If the **Status Light** is **flashing red** and you hear the Alarm Tone (2 short beeps), the infusion has **stopped**. The needle will retract shortly after you press the Start/Stop Button.
 - If the **Status Light** is **blue and flashing slow**, the infusion **did not stop**. Repeat **Step 1** in **How to Stop the Lasix ONYU Infusor Early** above.

3. The infusion cannot be restarted. You must **remove the Lasix ONYU Infusor** and contact your healthcare provider. Follow the steps below:
 - a. **Remove** the Lasix ONYU Infusor from your stomach.
 - b. **Pull apart** the white Reusable Unit and green Disposable Unit.
 - c. **Throw away the Disposable Unit** with the Prefilled Cartridge in an **FDA-cleared sharps disposal container**. You should not throw away the Disposable Unit in the household trash.
 - **Do not** save and re-use the Disposable Unit or Prefilled Cartridge as the medicine may be contaminated. They are for one-time use only.
 - **Call your healthcare provider** because you did not get all of the medicine.

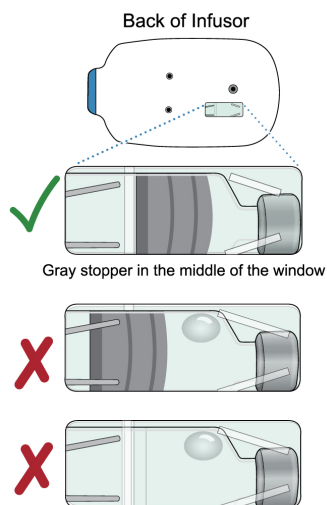
3 You Did Not Urinate (Pee) Much During the Infusion

The Lasix ONYU Infusor delivers a diuretic medicine which should make you urinate a lot. If you do not urinate a lot (at least 2 times during the 5-hour infusion), there are two reasons this could have happened:

- The diuretic medicine, Lasix ONYU, was not effective for you, or
- The Lasix ONYU Infusor did not work properly.



In either case, **it is important that you call your healthcare provider.** Follow the steps below to determine whether the Lasix ONYU Infusor worked and if all the medicine was delivered:

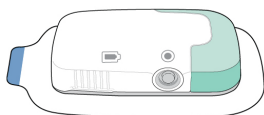


1. **Remove the Lasix ONYU Infusor** from your stomach.
2. **Look at the window** on the back of the Lasix ONYU Infusor:
 - If the middle of the window is all **gray** (whole gray stopper is visible with very little or no liquid), all the medicine was delivered. The Lasix ONYU Infusor worked.
 - If you **see anything else** (like a lot of liquid, a large bubble in the liquid, no gray stopper, or only part of the gray stopper), some of the medicine was not delivered. You did not get a full infusion.
3. **Check your stomach:** If you see or feel a lot of liquid on your stomach, you may not have received a full infusion due to the medicine leaking.

3 The Reusable Unit Does Not Light Up

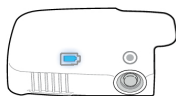
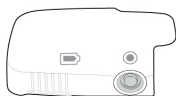
This can happen in the following situations:

- The **Reusable Unit has not been used for a long time** or the **Reusable Unit is expired**, see Section A below for what to do.
- The **Reusable Unit and Disposable Unit have been connected for more than 7 hours** and the infusion has not been started, see Section B below for what to do.

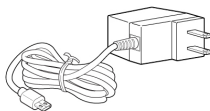


A. If the white **Reusable Unit does not light up**, try charging it, even if it has recently been charged. The Battery Light on the Reusable Unit must always be solid blue before connecting it to the Disposable Unit. Follow the steps below:

1. **Plug** the Charger into the back of the Reusable Unit and plug the other end of the Charger into a power outlet.
2. **Wait** 20 minutes.
3. **Disconnect** the Charger from the Reusable Unit and power outlet.
4. **Check** the Battery Light:



- If the **Battery Light is solid blue**, the Reusable Unit is **ready to use**.
- If the **Battery Light did not light up** after 20 minutes of charging, the Reusable Unit expired. Call 1-855-452-7496 for a replacement Reusable Unit, which will be shipped overnight when possible. **Also call your healthcare provider.**



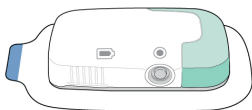
Go to **Troubleshooting: The Reusable Unit Has Expired** for more information.

- If you see other lights, go to **Troubleshooting: Lights and Tones Table**.

3 The Reusable Unit Does Not Light Up (continued)

- B.** If the **Reusable Unit and Disposable Unit have been connected for more than 7 hours** and the infusion has not been started, the Lasix ONYU Infusor will automatically time out. The Lasix ONYU Infusor cannot be restarted. Follow the steps below:

1. If the Lasix ONYU Infusor is on the body, **remove the Lasix ONYU Infusor** from your stomach.
2. If you can see the needle, **do not touch the needle** because you could get an injury.
3. **Pull apart** the Reusable Unit and Disposable Unit.
4. **Throw away the Disposable Unit** with the Prefilled Cartridge **in an FDA-cleared sharps disposal container**. You should not throw away the Disposable Unit in the household trash.
 - **Do not** save and re-use the Disposable Unit or Prefilled Cartridge as the medicine may be contaminated. They are for one-time use only.
5. Get a new Lasix ONYU Kit and **start over** at **Step 1 in Get Ready for the Infusion**.



3 The Lasix ONYU Infusor Will Not Start the Infusion

You press the Start/Stop Button and the infusion does not start.

This can happen in the following situations:

- The **Reusable Unit and Disposable Unit are not properly connected**, see Section A below for what to do.
- The **Reusable Unit is powered off** and both the Battery Light and Status Light are off, go to **Troubleshooting: The Reusable Unit Does Not Light Up** for what to do.
- A **device error has happened** and the Status Light is flashing red, go to **Troubleshooting: The Status Light is Flashing Red** for what to do.

A. If the infusion does not start, follow the steps below:

1. **Firmly push** the Reusable Unit and Disposable Unit **together**. There should be no gap or space between the parts when they are properly connected.
2. Check the Status Light:
 - If the **Status Light** is **blue** and **flashing fast** and you hear the OK Tone (1 long beep), the Lasix ONYU Infusor is properly connected. The **Lasix ONYU Infusor is ready** to deliver the infusion.

If the Lasix ONYU Infusor is **not on the body**, go to **Step 12** in **Prepare the Application site**.

If the Lasix ONYU Infusor is **on the body**, go to **Step 17** in **Start the infusion**.

- If the **Status Light** is **flashing red** and you hear the Alarm Tone (2 short beeps), there is a **problem with the Infusor**. Go to **Troubleshooting: The Status Light is Flashing Red** to see what to do.



 **OK Tone**
(1 long beep)



 **Alarm Tone**
(2 short beeps)

This Instructions for Use has been approved by the U.S. Food and Drug Administration.

Issued: ##/202#

Chapter 4

Technical Information

4 Part Numbers

Part Number	Description	Materials Included
CP-FK-001	Lasix ONYU Starter Kit	Three (3) Lasix ONYU Kits One (1) Reusable Unit One (1) Charger Instructions for Use
CP-FK-002	Lasix ONYU Kit*	One (1) Disposable Unit One (1) Single-Dose Prefilled Cartridge Two (2) Alcohol Pads Prescribing Information
CP-FK-003	Reusable Unit and Charger Box	One (1) Reusable Unit One (1) Charger Instructions for Use

*** Materials of the Lasix ONYU Kit are not sold separately.**

4 Specifications

Item	Specification
Number of Uses	Disposable Unit: single use Reusable Unit: (including power supply) 2 years/ 48 uses.
Ingress Protection	Reusable Unit: IP42 (protection against water dripping (15° tilted), protection against solid foreign objects $\geq 1.0\text{mm}$ diameter)
EIRP (Equivalent Isotropic Radiated Power)	Reusable Unit: 3.5 dBm
Alarm type	Reusable Unit: Audible (piezo buzzer)
Drug dosage	80 mg over 5 hrs (30 mg in the first hour and 12.5 mg/hr over the next 4 hours)
Fill volume of Prefilled Cartridge	2.75-2.95 mL
Needle	Disposable Unit: Surgical Steel (36L), 29 Ga. Insertion depth 4-8mm
Operating temperature range	All Components: 5°C to 40°C (41°F to 104°F)
Transport/Storage temperature range	Device Components: -25°C to 55°C (-13°F to 131°F) Recommended storage: 68°F to 77°F (20°C to 25°C)
Operating humidity range	All Components: 15% to 90%, non-condensing
Transport/Storage humidity range	All Components: 0% to 90%, non-condensing
Operating, Transport and Storage atmospheric pressure range	All Components: 700 to 1,060 hPa

4 Specifications (continued)

Item	Specification
Operating and storage atmospheric pressure	All Components: 700 - 1,060 hPa
Non-pyrogenic	Disposable Unit: fluid pathway only
Delivery Speed	1 mL over the first hour and ~0.42 mL/hr over the next 4 hours
Reusable Unit Dimensions	(L) 78 mm x (W) 49 mm x (H) 21 mm
Reusable Unit Weight	38 g
Power Supply	Mfg.: FRIWO Gerätebau GmbH Model: FW8002/05 Input: 100-240 Vac; 50-60 Hz; 160-80 mA, Class II Output: 5.0V, 1400 mA
Battery	Capacity: 120 mAh; 3.8 V The internal battery of the Reusable Unit cannot be removed or replaced. The Reusable Unit is good for 48 infusions.
Operating Mode	Continuous

California Proposition 65

To the best of the manufacturer's knowledge, this product is in compliance with Proposition 65, and reasonably anticipated use of this product will not result in exposure to any Proposition 65 chemicals that would require a Proposition 65 warning.

4 Symbols

Symbol	Meaning	Explanation
	Warning	Safety hazard indicated

Symbol	Meaning
	Prescription use only
	Refer to Instructions for Use
	Do not use if the package is damaged
	Keep dry
	Magnetic Resonance (MR) unsafe
	Type body floating (BF) applied part (Patch)
	Alternating Current (AC – power supply only)

Symbol	Meaning
	Manufacturer
	Date of Manufacture
	Warning
	Serial Number
	IP Code
	Sterilized using gamma radiation (DU)
	Single patient, multiple use (Reusable Unit only)

4 Symbols (continued)

Symbol	Meaning	Symbol	Meaning
	Temperature Range		Direct Current (DC – power supply only)
	Product reference or part number		Battery Light (Reusable Unit only)
	Waste batteries and accumulators		Drug Cartridge (Disposable Unit only)
	Status Light (Reusable Unit only)		USB Port Symbol (Reusable Unit only)
	Class II Equipment (Power Supply only)		Do not reuse

Information on disposal of electrical and electronic equipment and disposal of batteries and accumulators:

The crossed out wheeled bin symbol with under bar shown on the product or accompanying documents indicates the product requires appropriate treatment, collection and recycle for waste electrical and electronic equipment (WEEE) under the Directive 2012/19/EU:



This product should not be disposed of as unsorted household waste.

- The Reusable Unit should be disposed of according to local regulations for electronic equipment with lithium batteries or call-1-855-452-7496 for instructions on how to recycle the Reusable Unit safely (free program). Do not recycle in local recycling programs.
- The Charger should be disposed of according to local regulations for electronic equipment or through a community electronics recycling center.

4 EMC Safety

Guidance and manufacturer's declaration - electromagnetic emissions

The Infusor is intended for use in an electromagnetic environment as specified below. The customer or the user of the Product should ensure that it is used in such an environment.

Emissions test	Test level/ requirement	Electromagnetic environment - guidance
Radiated disturbance CISPR 11:2015	Group 1 Class B	<i>The Infusor utilizes no intention RF fields.</i> Therefore, its RF emissions are very low and are not likely to cause any interference to nearby electronic equipment.
Mains terminal disturbance voltage CISPR 11:2015	Group 1 Class B	
Harmonics Current Emission IEC 61000-3-2:2014	Class A	<i>Infusor</i> is suitable for use in all establishments, including clinical and domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Voltage change, Voltage fluctuations and Flicker Emission IEC 61000-3-3:2013	Pst:1dmax: 4%	

4 EMC Safety (continued)

Guidance and Manufacturer’s Declaration - Electromagnetic Immunity

Infusor is intended for use in the electromagnetic environment specified below. The customer or the user of the **Infusor** should assure that it is used in such an environment.

Immunity test	Operating Mode	Supply Voltage	Test level/ requirement	Electromagnetic environment - guidance
Electrostatic Discharge Immunity IEC 61000-4-2:2008	Furosemide injection/ Charging mode & Battery operating	120V, 60Hz d.c.3.7V	±8kV/Contact ±2, ±4, ±8 ± 15kV/Air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Radiated RF Electromagnetic Field immunity IEC 61000-4-3:2010	Furosemide injection/ Charging mode & Battery operating	120V, 60Hz d.c.3.7V	10 V/m 80 MHz-2.7 GHz 80% AM at 1 kHz	Infusor is suitable to use in home and healthcare environment

4 EMC Safety (continued)

Immunity test	Operating Mode	Test Voltage	Test level/ requirement	Electromagnetic environment - guidance
Immunity to Proximity Fields from RF wireless Communications Equipment IEC 61000-4-3:2010	Furosemide injection/ Charging mode & Battery operating	120V, 60Hz d.c.3.7V	A1) 380 MHz –18Hz PM (Pulse Modulation) A2) 450 MHz –18Hz PM @ 50% A3) 710, 745 & 780MHz – 18 Hz PM A4) 810, 870 & 930MHz – 18Hz PM A5) 1720, 1845, 1970 & 2450 MHz – 18 Hz PM A6) 5240, 5500 & 5785MHz – 18 Hz PM	Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Infusor , including cables specified by SQ Innovation. Otherwise, degradation of the performance of this equipment could result
Electrical Fast Transient/ Burst Immunity IEC 61000-4-4:2012	Furosemide injection/ Charging mode	120V, 60Hz	± 2 kV, 100kHz repetition frequency	The quality of supplied power be suitable for home healthcare environment.
Surge Immunity IEC 61000-4-5:2014	Furosemide injection/ Charging mode	120V, 60Hz	Line to Line ±0.5kV, ±1kV	The quality of supplied power be suitable for home healthcare environment.

4 EMC Safety (continued)

Immunity test	Operating Mode	Test Voltage	Test level/ requirement	Electromagnetic environment - guidance
Power Frequency Magnetic Field Immunity IEC 61000-4-8:2009	Furosemide injection/ Charging mode & Battery operating	120V, 60Hz d.c.3.7V	30 A/m 50 Hz & 60Hz	If degradation of the primary performance occurs, it may be necessary to position the Infusor further from sources of power frequency magnetic fields.
Immunity to Conducted Disturbances induced by RF fields IEC 61000-4-6:2013	Furosemide injection/ Charging mode	120V, 60Hz	3 V 0.15-80 MHz 6 V in ISM bands & Amateur radio bands between 0.15 and 80 MHz 80% AM at 1kHz	The strength of RF field in the frequency range 150 kHz~80 MHz, the strength of the RF field should be smaller than 3 V. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Infusor

4 EMC Safety (continued)

Immunity test	Operating Mode	Test Voltage	Test level/ requirement	Electromagnetic environment - guidance
Voltage dips, IEC 61000-4-11:2004	Furosemide injection/ Charging mode	100V, 60Hz 240V, 50Hz	0 % UT: 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 Cycles Single phase: at 0°	The quality of supplied power should be suitable for home healthcare environment. For the user to operate the equipment continuously even the electric power supply is interrupted, it is recommended that the uninterruptable power supply device (UPS) or battery is prepared.
Voltage interruption IEC 61000-4-11:2004	Furosemide injection/ Charging mode	100V, 60Hz 240V, 50Hz	0% UT; 250/300 cycle	The quality of supplied power should be suitable for home healthcare environment. For the user to operate the equipment continuously even the electric power supply is interrupted, it is recommended that the uninterruptable power supply device (UPS) or battery is prepared.

4 EMC Safety (continued)

Immunity test	Operating Mode	Test Voltage	Test level/ requirement	Electromagnetic environment - guidance
Immunity to Proximity Magnetic Field - AIM 7351731 and IEC 61000-4-39	Furosemide injection/ Charging mode & Battery operating	120V, 60Hz d.c.3.7V	30 kHz, CW, 8 A/m 134.2 kHz, pulse modulation 2.1 kHz, 65 A/m rms 13.56 MHz, pulse modulation 50 kHz, 7.5 A/m rms	If degradation of the primary performance occurs, it may be necessary to position the Infusor further from sources of magnetic fields.

4 EMC Safety (continued)

The Infusor uses no RF communication thus the potential for disturbance is low but may exist, even with equipment that complies with FCC and CISPR emissions requirements.

The Infusor complies with the immunity requirements of the general standard for electromagnetic compatibility, IEC 60601-1-2.

The Infusor complies with Canadian ICES-003 and IC-RSS-210 as well as FCC regulations on medical device emissions.

The Infusor complies with all relevant sections of IEC 60601-1:2005+AMD1:2012+AMD2:2020 for electrical safety.

The Infusor complies with relevant provisions of IEC 60601-2-24 for flow accuracy and performance. The Infusor is rated for 2.67 ml +/- 10% delivery over 5 hours.

Primary Performance:

Primary Performance of the Lasix ONYU Infusor is: Deliver Lasix ONYU to the patient per specification when operating normally (continuous accurate delivery).

Warning: Use of the Infusor adjacent to other electrical or magnetic equipment should be avoided because it could result in improper operation. If such use is necessary, the Infusor and the other equipment should be observed to verify that they are operating normally.

Warning: Portable RF communications equipment (including cell phones, antenna cables, antennas) should be used no closer than 12 inches (30 cm) to the Infusor. Otherwise, Infusor performance could be degraded.

Warning: Use of a charger other than the one specified or provided by the manufacturer of the Infusor could result in increased electromagnetic emissions or decreased electromagnetic immunity of the Infusor and result in improper operation.

Warning: The Infusor contains NO serviceable parts or modifiable parts. Do not attempt to service or modify the device.

Chapter 5

Additional Information

5 Watch Training Video

Scan the code below with your phone to see the training video
or visit the website: www.Lasix-ONYU.com/infusor-training



5 Warranty Information

Limited Warranty

SQ Innovation, Inc. (SQI) warrants that the Reusable Unit of the Infusor for Lasix® ONYU will be free from defects in materials and workmanship for a period of two years from the date of manufacture or 48 uses, whichever occurs first (the “Warranty Period”). Warranty claims must be made in writing to SQI within the Warranty Period. Buyer’s sole and exclusive remedy (and SQI’s sole and exclusive liability) for any warranty claim is replacement or refund of purchase price, at SQI’s option. Such remedies shall not extend the warranty period.

This warranty is valid only if the Reusable Unit is used in accordance with SQI’s Instructions for Use for the labeled indications. It does not apply in event of:

- modifications by Buyer or a third party;
- use with non-SQI provided materials;
- improper use, including but not limited to abuse, neglect, misuse, or accident, such as improper storage, excessive wear, submersion in water (or any other liquid), or physical abuse such as dropping; or
- *Force Majeure* or other event beyond the control of the manufacturer.

This warranty is personal to the original Buyer and shall terminate upon transfer to or use by a user other than the original Buyer, or use outside the country of purchase. This warranty does not apply to other components, such as Prefilled Cartridges, Disposable Units or accessories. NEITHER SQI NOR ITS SUPPLIERS OR DISTRIBUTORS SHALL BE LIABLE FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, OR SPECIAL DAMAGES OR LOST PROFITS ARISING OUT OF A DEFECT, WHETHER BASED ON TORT, WARRANTY, CONTRACT OR OTHERWISE.

All other warranties, expressed or implied, are disclaimed, including the warranties of merchantability and fitness for a particular purpose. To the extent such disclaimers are not allowed by applicable law, any implied warranties are limited to the duration of the express warranty. The limited duration of implied warranty and limitation of indirect damages do not apply where prohibited by applicable law.

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