CURLIN® 8000 Ambulatory Infusion Pump
BY MOOG

PATIENT INFORMATION GUIDE

CONTINUOUS THERAPY

For use with
the CURLIN 8000
Ambulatory Infusion Pump

MOOG®
Enhancing Healthcare.
Enriching Lives.™

CURLIN® 8000
Ambulatory Infusion System
Patient Information Guide

Continuous Therapy Mode

Special Instructions from Your Health Care Provider

For assistance with your pump, medications, or IV catheter call:

Name:	
Facility Name:	
Phone Number:	

Instructions for handling your pump and medication:

During the day:	
At night:	
While bathing:	

Other instructions:

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Intended Use and Environment

Intended Use

The CURLIN 8000 ambulatory infusion system is intended for use on adult and pediatric patients in Home Care and Clinical settings to provide the infusion of a broad range of fluids and medications. The pump will provide infusion delivery through accepted clinical routes of administration.

For Home Care settings this includes:

- intravenous
- subcutaneous
- epidural
- perineural

For Clinical (non-home care) settings this includes:

- intravenous
- intra-arterial
- subcutaneous
- epidural
- perineural

Intended Use Environment

Home Care setting where the infusion pump is managed by the patient/caregiver:

- Residential home

Clinical settings where the infusion pump is managed by a clinician, such as:

- Ambulatory Infusion Suite (AIS)/Ambulatory Infusion Center (AIC)
- Post-acute Rehabilitation Centers and Long-Term Care facilities
- Acute Care

Indications For Use

The CURLIN® 8000 ambulatory infusion pump system is indicated for use in home care and clinical settings for the controlled administration of prescribed medical fluids through clinically accepted routes of administration: intravenous, intra-arterial, subcutaneous, epidural, and perineural, to adult and pediatric patients. The pump is intended to deliver a variety of therapies (drugs and fluids) which have been approved for these routes of administration. Examples of the therapies, which may be delivered using the CURLIN® 8000 pump, include hydration, parenteral nutrition, anti-infectives, pain management, inotropes, chemotherapy, immune globulin, and biologics. The CURLIN 8000 is not indicated for the delivery of cellular blood products.

RxManager Enterprise Solution Software allows the user to create and manage pump configurations and therapy-based protocols to be used with the CURLIN 8000 Ambulatory Infusion Pump.

CURLIN Administration Sets are intended to be used with CURLIN infusion pumps to deliver medication from a container to a patient.

Warnings/Cautions

The complete list of Warnings, Cautions, and Notices is contained in the CURLIN® 8000 Ambulatory Infusion System User Manual.

Warnings

Visually inspect the CURLIN 8000 and pumping chamber before use:

- Do not use the CURLIN 8000 if it has been dropped.
- Do not use the CURLIN 8000 if it appears the pump has been tampered with. If the pump has been tampered with or it has been dropped, return the CURLIN 8000 to the provider, e.g., the pharmacy, contracted distributor, or Moog Medical.

If the settings on your pump do not match the medication order, call the patient's health care provider before starting the infusion.

Do not submerge the pump or place the pump under running water when connected to external AC power. This may lead to electric shock or damage to the pump. For additional information, see the "Cleaning the Pump and Accessories" section.

To avoid potential fire hazard, do not use the pump near flammable anesthetics, explosive gases or in an oxygen rich environment such as Hyperbaric Oxygen Therapy. Note: Use with supplementary oxygen and ventilation is allowed.

The CURLIN 8000 is NOT safe for use in an MRI environment. The CURLIN 8000 should not enter the MRI scanner room. The device presents a projectile hazard.

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 CURLIN 8000 Ambulatory Infusion System, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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

Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

Use only approved CURLIN administration sets. The 340-XXXX series of CURLIN Administration sets cannot be used in the CURLIN 8000 pump. The use of non-CURLIN administration sets could result in air infusion, under delivery, over delivery or free flow, and could result in patient harm.

Visually inspect the administration set before use:

- Do not use administration sets that are damaged or appear to be tampered with.
- Do not use if package seal is broken, if the caps are removed from the tubing, if the white slide clamp(s) is closed, or if the break-away tab is missing from the yellow flow-stop.
- Do not use the administration set beyond its recommended life or beyond its expiration date. The expiration date is on the outside of the administration set package.

Never prime the administration set while it is connected to the patient. Before connecting the administration set to the patient, check to see if the administration set has been primed and all the air is removed. Failure to properly prime could result in patient injury.

If using tape to secure the administration set to the patient, do not place tape over the 0.2 or 1.2 micron filter. This could block the filter vent and prevent it from working properly leading to improper medication delivery. (Refer to the administration set pouch to determine if your set contains a filter).

If your administration set includes an in-line 0.2 or 1.2 micron air eliminating filter, avoid raising the filter above the height of the patient's catheter entry point. The catheter entry point is the location on the patient's body where the IV catheter is inserted. Raising the filter up above this height can cause the filter contents to drain into the patient causing unintentional delivery of medication.

Never touch either uncapped end of the administration set (the spike or luer) or allow either end to touch any surface. Doing so may contaminate the set and put the patient at risk for developing an infection. While priming the set, keep the blue cap on the luer to maintain its sterility.

The administration set contains small parts such as caps, which could be a choking hazard. Keep all small parts away from children.

Tubing could pose a trip hazard. Coil and secure excess amounts of tubing to prevent it from catching on a person or object, leading to the IV being pulled from the patient.

Avoid leaving tubing and cords where infants, children, or those deemed at high risk for medical line entanglement, can become entangled. Be aware that if these items become wrapped around a patient's neck, there is an increased risk of strangulation or death. Caregivers of patients who are at risk for entanglement should discuss with their health care provider how to properly manage their lines and properly monitor patients based on their needs while in use.

⚠ **WARNING:** This product can expose you to chemicals including Polyvinyl chloride, which is known to the State of California to cause cancer. For more information go to www.P65Warnings.ca.gov.

Cautions

Before use, patients and caregivers must be educated on the use of the CURLIN 8000 pump, accessories, and administration sets by a qualified health care provider. A qualified health care provider should monitor the patient throughout the use of the pump.

Use only fingertips to press the keypad buttons. Do not use sharp objects, which will damage the keypad.

When possible, bring the medication/solution to room temperature prior to starting the infusion to minimize Air In Line alarms. Do not operate the pump outside of the specified temperature range. Doing so can affect the accuracy of medication delivery.

Use only approved cleaners and cleaning methods. Using unapproved cleaners or cleaning methods can damage the screen, keypad and case, resulting in an illegible screen, unusable keypad and degradation of the case.

Symbols

Symbol	Definition
	The CURLIN 8000 is a medical device
	This user manual is available in electronic format
	Manufacturer
	Authorized Representative in the European Community
	Sterile Administration set sterilized by ethylene oxide
	Keep Dry
	Do not use Administration Set (tubing) if package damaged
	Serial Number
	Manufacturing Lot
	Administration Set priming volume
	Professional Use only

Symbol	Definition
CE 0123	CE Mark
REF	Catalog number
	Storage temperature with temperature limits
	Storage pressure, store pump within pressure limits
	Storage humidity, store pump with humidity limits
	Administration sets are non-pyrogenic
	Do not reuse the administration set (tubing)
	Use by date
Rx ONLY	Prescription Only. Caution: Federal law restricts this device to sale by or on the order of a physician.
	Defibrillation-proof Type CF applied parts
	Consult the accompanying Instructions for Use

Symbol	Definition
	Refer to User Manual or Instructions for Use included with Administration Set
	Refer to User Manual or Instructions for Use included with Administration Set
	The CURLIN 8000 is covered by the Waste Electrical and Electronic Equipment Directive (WEEE Directive), a European law setting collection, recycling, and recovery targets for all type of electrical goods.
	The CURLIN 8000 was independently evaluated by TUV, a Nationality Recognized Testing Laboratory (NRTL).
	MR unsafe. The CURLIN 8000 is not safe for use in an MRI environment.

Quick Start

Caution Before use, patients and caregivers must be educated on the use of the CURLIN 8000 pump, accessories, and administration sets by a qualified health care provider. A qualified health care provider should monitor the patient throughout the use of the pump.

Review the steps below to start the infusion. Refer to the associated sections in this Patient Information Guide for details about each step.

Step	Patient Information Guide Section
1. Prepare tubing.	Preparing the Administration Set and IV Bag, p. 22
Note: If instructed to prime using the pump, skip step 2. Go to step 3. 2. Prime administration set (fill tubing with fluid).	Gravity Priming before Inserting Set into the Pump, p. 24
3. Insert batteries.	Replacing Batteries or Rechargeable Battery Pack, p. 20
4. Power pump on.	Press 
5. Verify information is correct.	Verifying the Program Settings, p. 27
6. Review and confirm program (Rx).	
7. Insert administration set into pump and close the door.	Inserting the Administration Set into the Pump, p. 25

Warning Never prime the administration set while it is connected to the patient. Before connecting the administration set to the patient, check to see if the administration set has been primed and all the air is removed. Failure to properly prime could result in patient injury.

Step	Patient Information Guide Section
Note: If the administration set is already primed, skip step 8. Go to step 9. 8. Prime your tubing (administration set).	Priming using the Pump, p. 29
9. Prepare the patient's catheter as instructed by the health care provider.	Starting the Infusion, p. 29
10. Connect the administration set to the patient's catheter.	
11. Open all clamps.	
12. Press **RUN**. **Important:** Green screen = Good. The infusion is running without any issues, even if you cannot hear it making sounds.	

CURLIN 8000 Tour

Your doctor ordered medication for you, which will be delivered to you using the Moog CURLIN 8000 ambulatory infusion pump.

The CURLIN 8000 pump is designed to be carried with you in a bag or backpack wherever you go. You may also place it on an IV pole in a special holder if one was provided to you. Your health care provider programmed the pump according to your physician's prescription. Your health care provider will adjust the settings on the pump if your prescription changes.

Your health care provider will show you how to use the pump and instruct you on the steps you will take to deliver your medication. Always follow your health care provider's instructions and use this guide as additional information. Only perform steps your health care provider has instructed you to perform.

Your pump has been programmed in the Continuous therapy mode. This guide is designed to provide information specific to this therapy mode.

Before using the pump, read the warnings and cautions provided in this guide. Always contact your health care provider if you are unclear about any interactions with the pump.

Warning Visually inspect the CURLIN 8000 and pumping chamber before use:
- Do not use the CURLIN 8000 if it has been dropped.
- Do not use the CURLIN 8000 if it appears the pump has been tampered with.

If the pump has been tampered with or it has been dropped, return the CURLIN 8000 to the provider, e.g., the pharmacy, contracted distributor, or Moog Medical.

Familiarize yourself with the CURLIN 8000:

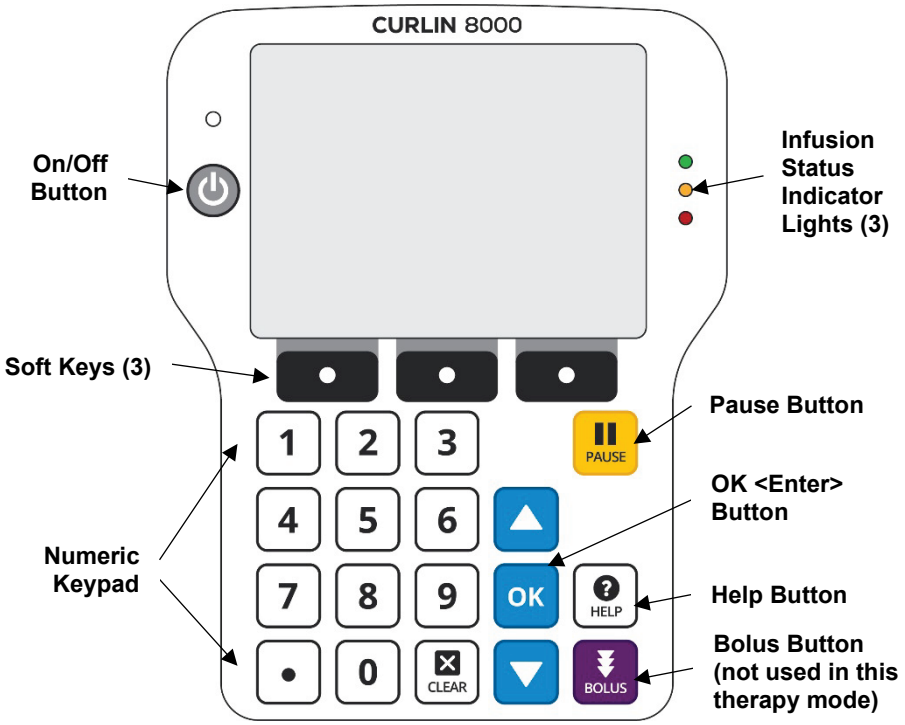


Figure 1: Front View

Caution	Use only fingertips to press the keypad buttons. Do not use sharp objects, which will damage the keypad.

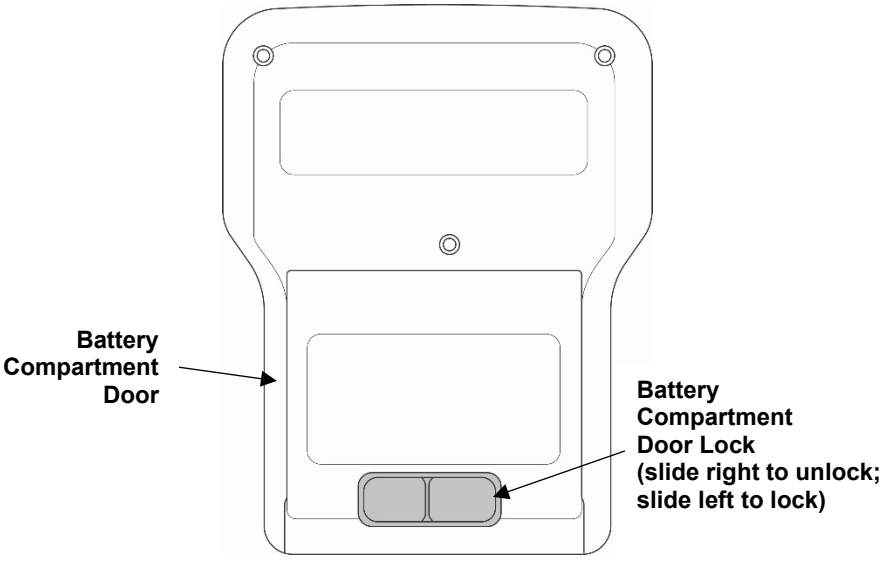


Figure 2: Back View

Note: In this figure, the CURLIN 8000 door is not visible because it is shown completely open.

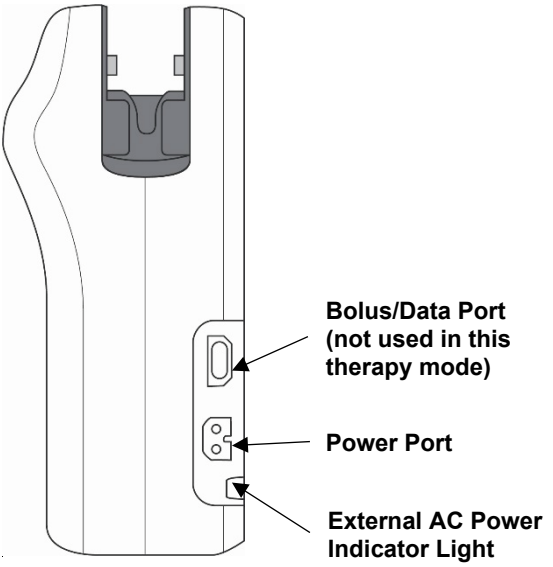


Figure 3: Left Side View

Home Screen

Familiarize yourself with the major parts of the pump home screen:

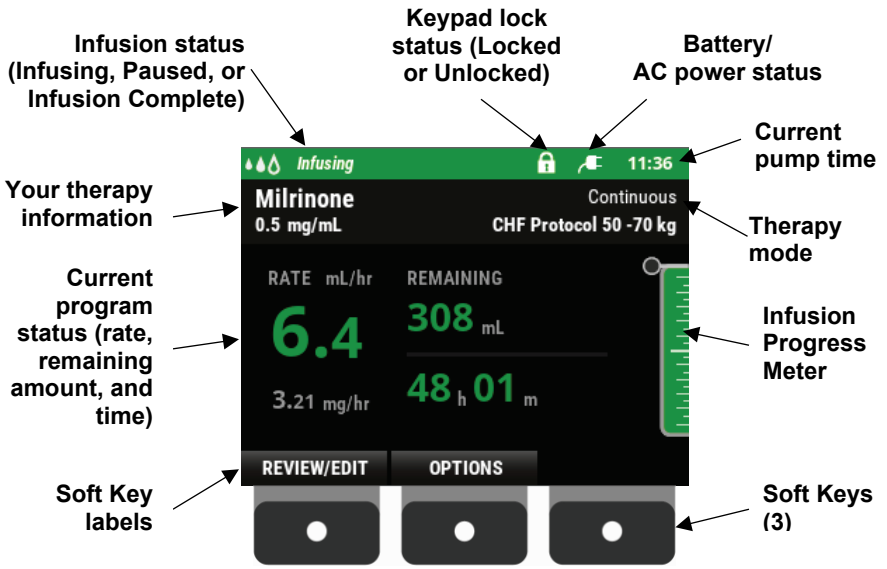


Figure 4: "Home" Screen Showing Running Infusion

Note: After 2 minutes of no key presses, the screen will dim. Press **OK** to return the screen to its original brightness level.

The Figure 4 example shows that the pump is infusing, the keypad is locked, the pump is running on battery power only, and the battery is over half charged.

Here are additional battery status icons:

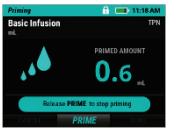
Battery Icon	Description
	Battery is almost fully charged.
	Battery is more than 50% charged.
	Rechargeable battery is fully charged. Pump is running on external AC power.
	Rechargeable battery is less than 40% charged. External AC power is connected and is charging the battery.
	Rechargeable battery is low. External AC power is connected and is charging the battery.

Battery Icon	Description
	Rechargeable or disposable batteries are low and have less than 20% life remaining. AC power is not connected. Replace the batteries or connect pump to AC power very soon. Icon blinks when the battery life is less than 30 minutes.
 Alternating icons	Disposable batteries are low and have less than 20% power remaining. AC power is connected. Replace the batteries soon.
	Battery is empty. Infusion has stopped. You should connect to external AC power or replace the batteries.
 Alternating icons	Disposable C-Cell batteries have approximately 60% power remaining. Pump is running on external AC power.
	Pump is connected to external AC power and no battery is installed. You should install batteries.

Colors on the Screen

The colors on the screen indicate the current status of the pump:

Color:	Indicates:
Green 	 The pump is running. Green = All is good. The infusion is running without any issues.
Yellow 	 The pump is paused.

Color:	Indicates:
Red 	 An urgent situation such as a high priority alarm. When you see red, the pump has stopped infusing and you must take action immediately. For a list of some common high priority alarms and how to resolve them, see p. 40.
Blue 	 The infusion (Rx) has ended.
Aqua 	 The pump is being used to prime (fill) the administration set tubing.
Orange 	 An urgent situation, such as a medium priority alarm condition. For a list of some common medium priority alarms and how to resolve them, see p. 37.

Infusion Status Indicator Light Colors

The three infusion status indicator lights are located to the right of the screen (Figure 1). They provide visual confirmation of the status of the infusion.

Color:	Indicates:
Green	The CURLIN 8000 is running and delivering the programmed rate of infusion.
Yellow	The infusion is paused.
Red	The infusion is stopped due to an alarm condition or when the infusion is complete with no keep vein open (KVO) programmed.
Yellow and Green	Delay start with no KVO programmed.
Green and Red	When infusion is complete and the KVO rate is greater than 0 mL/hr.
Yellow and Red	When infusion is complete, a KVO is programmed, and the infusion is paused due to an alarm.

Help Button

Important If you are unsure about the information on a screen, press the Help button.

1. To view the information associated with a screen, press **HELP**. If a screen does not have any help associated with it, an audio tone sounds when you press **HELP**.

2. Press ▼ or ▲ to scroll through the text.
3. When you are finished, press **BACK**.

Preparing for Your Infusion

Warning To avoid potential fire hazard, do not use the pump near flammable anesthetics, explosive gases or in an oxygen rich environment such as Hyperbaric Oxygen Therapy. Note: Use with supplementary oxygen and ventilation is allowed.

Preparing the Work Area

1. Refer to the instructions provided to you and the medication label for handling and storing the medication.
2. Clean your work area.
3. Clean your hands as instructed by your clinician.

Gathering Supplies

- ✓ Medication bag
- ✓ Pump tubing (administration set)
- ✓ Pump
- ✓ Disposable C-Cell alkaline batteries or rechargeable battery pack
- ✓ External AC power cord
- ✓ Pump carrying bag
- ✓ Alcohol wipes

Other items including:

- ✓ _____
- ✓ _____

Inspecting Medication

Caution When possible, bring the medication/solution to room temperature prior to starting the infusion to minimize Air In Line alarms. Do not operate the pump outside of the specified temperature range. Doing so can affect the accuracy of medication delivery.

Inspect medication bag and label for:

- ✓ Correct patient name
- ✓ Correct drug name
- ✓ Correct rate and dose
- ✓ Expiration date
- ✓ Medication is clear (no particles or discoloration)

Replacing Batteries or Rechargeable Battery Pack

Note: Moog Medical recommends Duracell® Procell alkaline batteries. (Duracell is a registered trademark of Duracell Inc.)

If connected to external AC power, you can change the batteries without turning the pump off.

1. If the pump is running, stop the pump by pressing **PAUSE**; then press and hold the **ON/OFF** button until the pump screen goes blank.
2. To open the battery door, slide the lock on the battery door from left to right, then using your thumbs, grip and slide the door downward and remove.
3. Remove the batteries.
4. Insert the new C-Cell batteries, making sure to place the positive (+) poles at the top and negative (–) poles of the batteries at the bottom (Figure 5).

   Or

   Insert a new rechargeable battery pack (Figure 6).

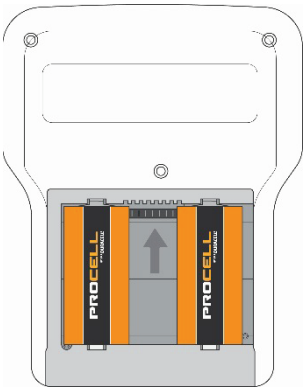


Figure 5: Battery Compartment with Disposable Batteries Installed (Door Removed)

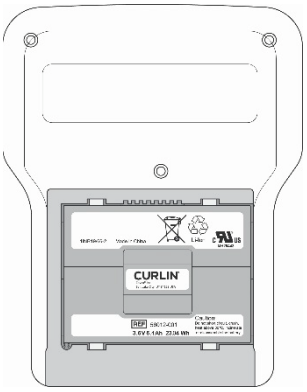


Figure 6: Battery Compartment with Rechargeable Battery Pack Installed (Door Removed)

5. Replace the battery door by sliding it on from the bottom towards the top of the pump. Slide the lock to the left to secure the door.

Using the AC Power Cord

An AC power cord may have been provided with your pump. You may use it to power the pump and to recharge the rechargeable battery pack (if using). When using the AC power cord, you should always have either C-Cell batteries or the rechargeable battery pack installed in the pump for backup power. See p. 14 to view the battery status icons, including the fully charged icon.

1. Connect the AC power cord connector to the port labeled **POWER** on the left side of the CURLIN 8000 (Figure 3).
2. Connect the AC power cord to a working power outlet.
3. The blue light, below the POWER port of the pump, indicates that the pump is receiving power from the power outlet.

   Note: The pump can deliver the infusion while the rechargeable battery pack is charging.

4. When you want to move from place to place, you may disconnect the pump from the AC power cord. To save battery life, reconnect the AC power cord when stationary for long periods of time (for example, during the night).

Preparing the Administration Set and IV Bag

Warning The administration set contains small parts such as caps, which could be a choking hazard. Keep all small parts away from children.

Figure 7 is an example of an administration set. Yours might look slightly different, but will have most of the labeled parts. (Not all administration sets include air eliminating filters.)

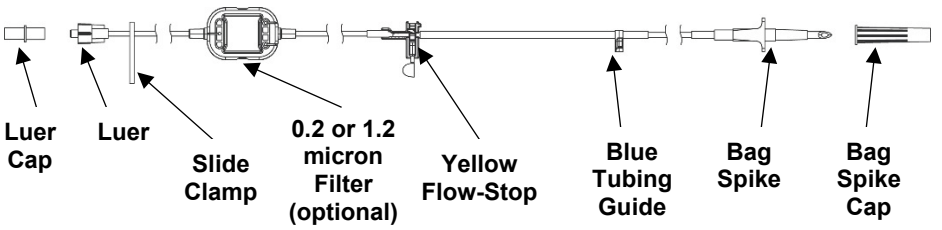


Figure 7: Example Administration Set

Warning Use only approved CURLIN administration sets. The 340-XXXX series of CURLIN Administration sets cannot be used in the CURLIN 8000 pump. The use of non-CURLIN administration sets could result in air infusion, under delivery, over delivery or free flow, and could result in patient harm.

Your health care provider may set up the administration set for you. Follow your health care provider's instructions on which steps you need to perform.

1. Inspect the tubing package. Do not use if:
   - the package has been opened or damaged
   - there are any loose or broken parts
   - the caps on either end of the tubing set have been removed
   - the expiration date on the package has passed
2. Open the package and unwrap the IV tubing.
3. Close white slide clamp
4. Twist and break off the tab on the yellow flow-stop. See Figure 7 and Figure 8.

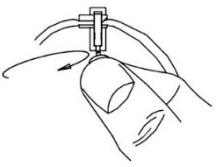


Figure 8: Twist Tab Off Yellow Flow-Stop

5. Most IV bags have two ports. Locate the port you will use as instructed by your healthcare provider. Pull the seal off the port. See Figure 9.
6. Pull the cap off the administration set bag spike. Do not allow the spike to touch any surface as this will contaminate it. If contaminated, the administration set should not be used.
7. Push and twist the bag spike into the administration port of the IV bag. See Figure 10.

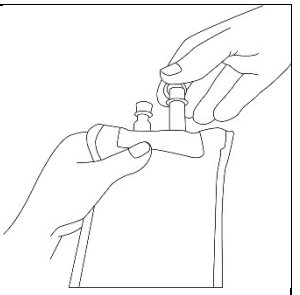


Figure 9: Remove Seal from Port

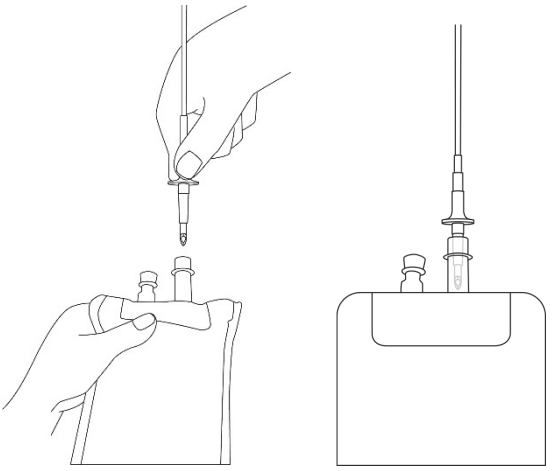


Figure 10: Insert Bag Spike into IV Bag

Warning If using tape to secure the administration set to the patient, do not place tape over the 0.2 or 1.2 micron filter. This could block the filter vent and prevent it from working properly leading to improper medication delivery. (Refer to the administration set pouch to determine if your set contains a filter).

If your administration set includes an in-line 0.2 or 1.2 micron air eliminating filter, avoid raising the filter above the height of the patient's catheter entry point. The catheter entry point is the location on the patient's body where the IV catheter is inserted. Raising the filter up above this height can cause the filter contents to drain into the patient causing unintentional delivery of medication.

Priming the Administration Set

The tubing must be filled with the medication before connecting it to the patient's catheter. This is called "priming the set". This step **must** be completed to prevent air from being delivered to the patient. Your pharmacy may have already primed the set for you.

Warning Never prime the administration set while it is connected to the patient. Before connecting the administration set to the patient, check to see if the administration set has been primed and all the air is removed. Failure to properly prime could result in patient injury.

There are two ways to fill the set. Follow your health care provider's instructions on which method to use for priming:

- Gravity priming before inserting the set into the pump (go to next section)
- Pump priming after inserting the set into the pump as part of the startup process (skip to "Inserting the Administration Set into the Pump", p. 25)

Note: For instructions on priming after an air in line alarm, see AIR IN LINE DETECTED, p. 41.

Gravity Priming before Inserting Set into the Pump

Warning Never touch either uncapped end of the administration set (the spike or luer) or allow either end to touch any surface. Doing so may contaminate the set and put the patient at risk for developing an infection. While priming the set, keep the blue cap on the luer to maintain its sterility.

Refer to the administration set pouch and insert for more detailed instructions.

1. Keep the blue cap on the luer (connector) during setup, while priming and until ready to connect to the patient's catheter. This will help to keep it clean.
2. Open white slide clamp.
3. Pinch the yellow flow-stop between your thumb and forefinger to allow the fluid to flow. See Figure 7 and Figure 11.
4. If the administration set you are using has a filter, follow the priming instructions included in the set package. Depending on the filter type, you may need to hold the filter upright or inverted while priming it.
5. Release the flow-stop.
6. Close the slide clamp. See Figure 7.

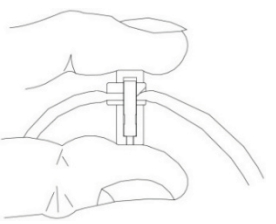


Figure 11: Pinch the Yellow Flow-Stop to Open

Troubleshooting If Fluid is not Flowing

If the administration set contains an anti-siphon valve (ASV), the administration set needs to be primed using the pump. See “Priming using the Pump", p. 29, or contact your health care provider for further assistance.

Otherwise, try the following:

- Ensure white slide clamp is in open position.
- Raise the IV bag up higher.
- Ensure that you are pressing down on top of yellow flow-stop to the open position (see Figure 11).

  If the previous steps do not solve the problem, refer to the description on the front of the administration set pouch.

Inserting the Administration Set into the Pump

1. Ensure that the slide clamp is closed. See Figure 7.
2. Place the pump in front of you, with the screen facing you. Lift the pump door latch and open the pump door.
3. Insert the blue tubing guide pin into the hole under the right side of the pump indicated by the blue arrow inside the pump door. See Figure 12.
4. Without pressing down on top of the yellow flow-stop, insert the flow-stop into the square hole on the left side of the pump indicated by the yellow arrow inside the pump door. See Figure 12.
5. There are spaces on either side of the door hinge where it attaches to the pump. Route the tubing through one of these spaces to prevent the tubing from being pinched when the door is closed. Move the tubing to either side before closing the door and latching it.

Warning Tubing could pose a trip hazard. Coil and secure excess amounts of tubing to prevent it from catching on a person or object, leading to the IV being pulled from the patient.

Tubing, power cable, and bolus cable could pose a strangulation hazard. Patients who could potentially become entangled should be under continuous observation. Coil and secure excess amounts of tubing to prevent entanglement.

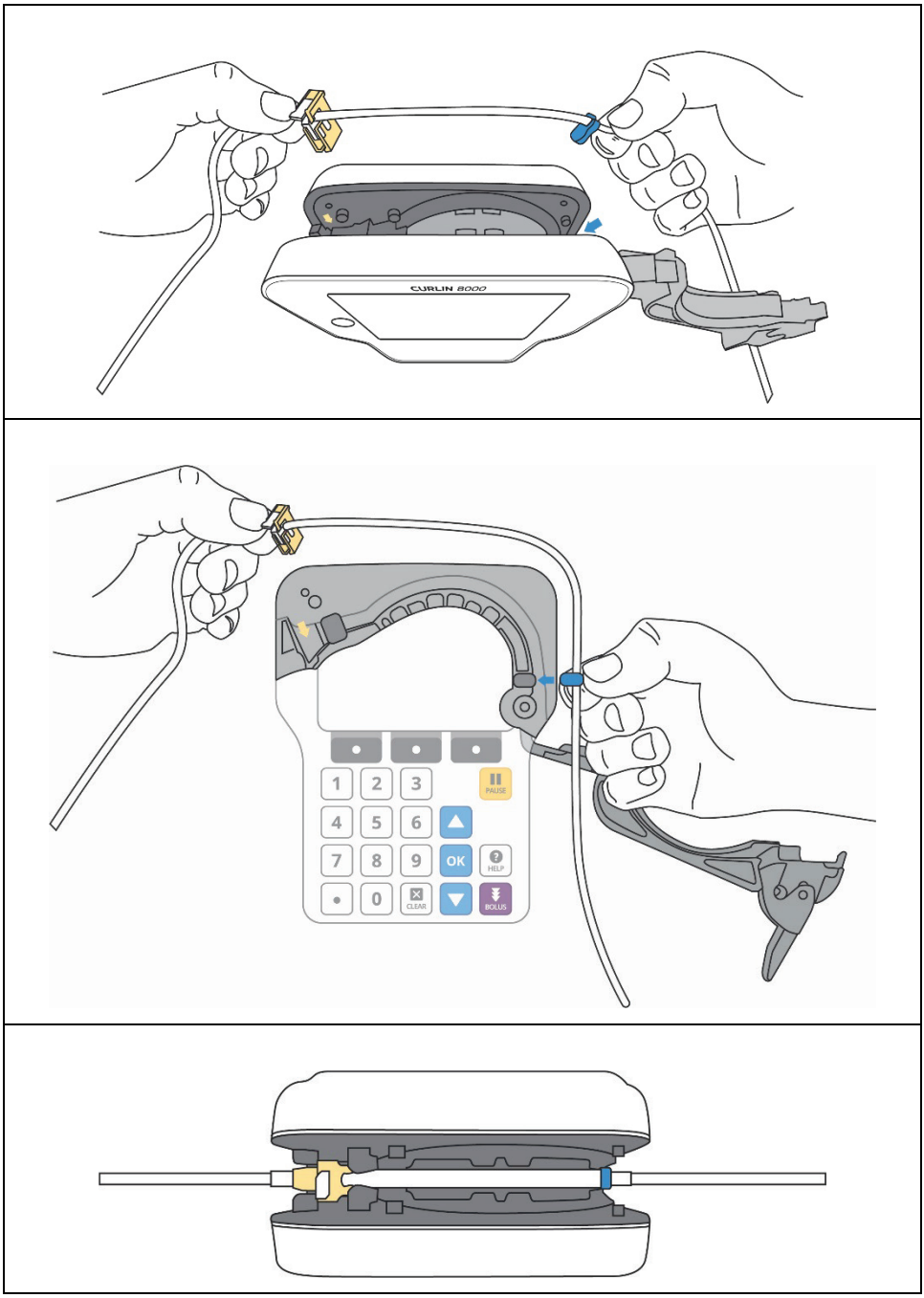


Figure 12: Inserting the Administration Set into the Pump

Pump Startup

The screens shown in this section are for example only. Your pump will display settings specific to your therapy.

Important After 30 seconds of no key presses, the screen will dim. Press **OK** to return the screen back to its brightness level. If you want to change the screen brightness, see “Setting the Screen Brightness”, p. 45.

Verifying the Program Settings

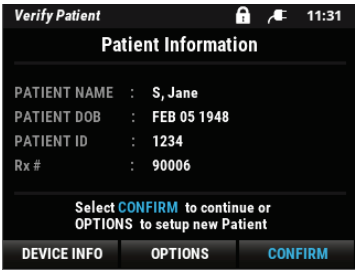
1. If the pump is off, press the ON/OFF button. When the pump is functioning properly, startup screens display for several seconds, the infusion status indicator lights to the right of the screen flash in sequence, and an audio tone sounds.

   Make sure the graphics shown on the startup screens are complete (no areas are missing). If the graphics are incomplete or the pump makes unusual sounds, do not use the pump. Contact your health care provider.

2. **Verify Patient Screen:** Check that the patient information matches the information provided by your health care provider.

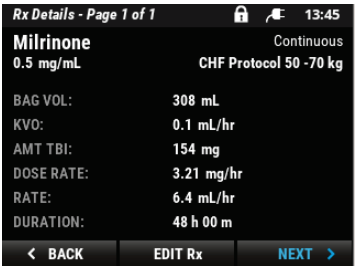
   If it is not correct, STOP and contact your health care provider.

   If it is correct, press the soft key below **CONFIRM**.

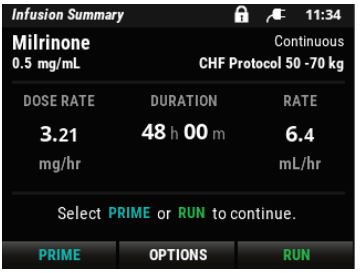


3. **Select Patient’s Rx Screen:** In most cases, there will be only one program in the pump for the patient. If more than one program has been set up for this patient, the Select Rx screen will show both. It is very important to select the correct Rx. If more than one program is listed here, press ▼ or ▲ to highlight the program you want to start (the selected program is aqua), then press **SELECT**.

4. **Rx Details Screens:** Review all of the programmed values for the infusion (Rx). Press **NEXT** to view multiple screens; then press **NEXT**.



5. **Infusion Summary Screen:** This screen provides an overview of the Rx program, which the health care provider set up for your medicine. For your safety, these settings are locked.



Warning If the settings on your pump do not match the medication order, call the patient's health care provider before starting the infusion. If the settings match your medication order, proceed with the next section, "Priming using the Pump".

Priming using the Pump

If the administration set has already been primed (filled with fluid) skip to the next section, “Starting the Infusion”.

Warning Never prime the set while it is connected to the patient. Before connecting the administration set to the patient, check to see if the administration set has been primed and all the air is removed. Failure to properly prime could result in patient injury.

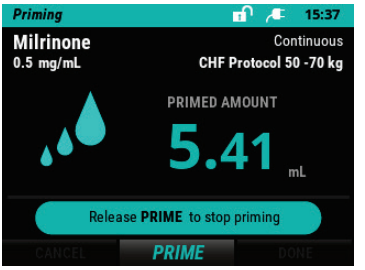
---

1. If air remains in the set, open the slide clamp. From the Infusion Summary Screen, press **PRIME**.

Note: If PRIME is not shown on the left soft key, you can access prime from OPTIONS/Rx TASKS. If the pump prompts you to enter the Access Code, you do not have permission to use the pump priming feature. See “Gravity Priming before Inserting Set into the Pump”, p.24 or contact your health care provider for assistance if you have not been trained on gravity priming.

2. Follow the instructions on the screen.
3. Continue to prime until all of the air has been removed between the IV bag and the connector (luer) at the end of the tubing, which will connect to the patient.

   If the administration set you are using has a filter, follow the priming instructions included in the set package. Depending on the filter type, you may need to hold the filter upright or inverted while priming it.



4. Press **DONE** when priming is complete.
5. Close the slide clamp on the administration set.

Starting the Infusion

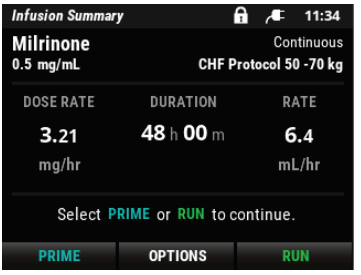
Warning If your administration set includes an in-line 0.2 or 1.2 micron air eliminating filter, avoid raising the filter above the height of the patient's catheter entry point. The catheter entry point is the location on the patient's body where the IV catheter is inserted. Raising the filter up above this height can cause the filter contents to drain into the patient causing unintentional delivery of medication.

When you are ready to start the infusion:

1. Follow your clinician's instructions for cleaning the injection cap on the patient's catheter and then preparing the catheter for the infusion.

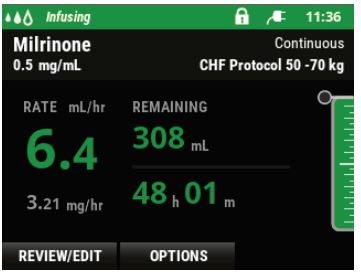
Warning Never touch either uncapped end of the administration set (the spike or luer) or allow either end to touch any surface. Doing so may contaminate the set and put the patient at risk for developing an infection.

2. Remove the luer cap on the administration set (see Figure 7).
3. Insert the luer to the injection cap on the patient's catheter. Twist until secure. Do not overtighten.
4. Open all clamps on the administration set and patient's catheter.
5. Review the Infusion Summary details on the screen and if details are correct, press **RUN** to start the infusion.



6. When the pump is running, it will usually display the Infusing home screen. The pump status bar at the top of the screen turns green, animated drops move, and the information on the screen is in green. The infusion status indicator light flashes green.

   Important: Green = Good. The infusion is running without any issues, even if you cannot hear it.



7. The home screen will continue to provide infusion details for your reference throughout the infusion:
   - The current rate
   - Volume of fluid remaining to be delivered
   - Amount of time remaining in the current infusion
   - Infusion Progress Meter shows the amount remaining out of total volume to be delivered

---

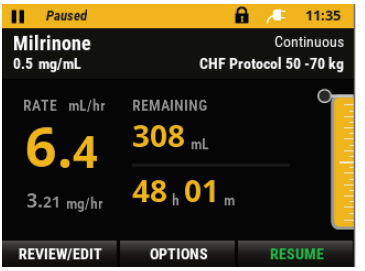
Warning Do not carry the pump during magnetic resonance imaging (MRI) or computerized tomography (CT) scan procedures. Device damage, patient injury or procedure interference may occur.

Pausing the Infusion

Press the yellow **PAUSE** button if you need to pause the infusion. If you have paused an infusion, you can start it again by pressing **RESUME**.

When the pump is paused, it will usually display the Paused home screen:

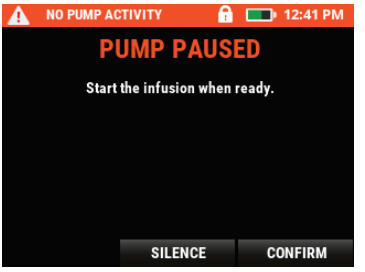
- the pump status bar is yellow
- the information on the screen is yellow
- the infusion status indicator light flashes yellow



While paused, the pump will alarm PUMP PAUSED every two minutes to remind you to either resume the infusion or turn the pump off.

Press **SILENCE** to snooze the alarm for two minutes.

Press **CONFIRM** to silence the alarm and display the Paused screen. When you press **RESUME**, your infusion will continue from where it left off when the pump was paused.



Follow your health care provider's instructions on when to repeat an infusion and when to discontinue an infusion.

If you are finished delivering the medication, you may power off the pump by pressing and holding the On/Off button until the pump screen is blank.

Resuming an Interrupted Infusion

After the pump is paused, you can continue the infusion at the point where it stopped. When you press **RESUME**, the pump will immediately start infusing.

If the pump was powered down before an infusion was completed, you also have the option to continue the infusion from where it stopped:

1. After the pump powers on, confirm the information on the Verify Patient screen. The Paused home screen appears, and the Rx program is at the point where it was interrupted.
2. When you are ready to continue the infusion, press **RESUME**.

Always follow your health care provider's instructions before discontinuing an infusion. If you are instructed to discard the remaining interrupted program and start over from the beginning, make sure the infusion is paused, then select:

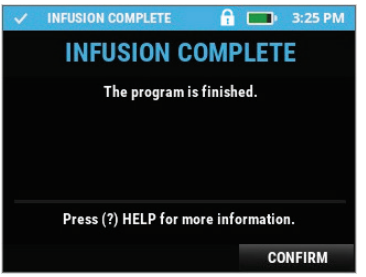
- **OPTIONS**
- **PROGRAM**
- **REPEAT Current Rx** (LAST Rx INCOMPLETE message displays; press **YES** to end the last infusion. This resets the amount to be Infused (AMT TBI/VTBI) to the original amount and starts the program over from the beginning.)

Review the Rx Details screens by pressing **NEXT**; then press **RUN** to restart the program.

Note: Repeating an infusion before the current infusion has ended may require an access code.

Completing the Infusion

When the infusion is complete, the INFUSION COMPLETE message appears. This screen may be blue as shown, or red if an end of infusion alarm was set.



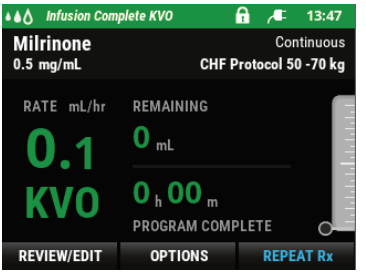
The pump will either:

- Stop and alarm.
- Continue to infuse a small amount of fluid to keep the catheter from clotting off until you have time to complete the next steps. This small amount of fluid being delivered is called the KVO “keep vein open” rate.

The red infusion status indicator light flashes, indicating infusion is complete. If the green infusion status indicator light is also flashing, it indicates that the KVO rate is running. Press **CONFIRM** to return to the home screen and view the KVO in progress.

Infusion Complete with KVO

If your health care provider programmed a keep vein open (KVO) rate to run after the infusion is completed, the Infusion Complete KVO home screen will be displayed:

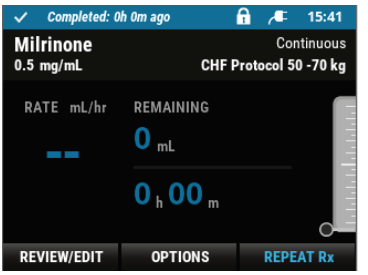


- Pump status bar is green, indicating that the pump is infusing
- Pump status bar displays **Infusion Complete KVO**
- KVO rate is displayed
- Totals remaining for the program shows zero and the infusion progress meter is grey, indicating that all of the intended medication was delivered
- Infusion status indicator lights flash green and red, indicating that the pump is running but there is something for you to attend to

The pump will beep periodically to remind you that the infusion is done. Press **PAUSE** to stop the KVO infusion and display the Completed home screen.

Infusion Complete without KVO

When the programmed amount of medication is delivered, the pump notifies you that the infusion is complete and the pump is now paused. The Completed home screen will be displayed:



- Pump status bar is blue
- Pump status bar displays **Completed** with the time elapsed since completion
- The rate is cleared, remaining values are zero, and the infusion progress meter is gray
- The infusion status indicator light flashes red

This indicates that the full amount of the infusion was delivered and the pump is no longer delivering medication. Follow your health care provider's instructions for either disconnecting from the pump or preparing a new IV bag. See "Repeating the Infusion", p. 35, if you will connect a new IV bag and run the same Rx program again.

Disconnecting the Administration Set

When you are ready to disconnect the administration set from the patient:

1. Close the slide clamp on the administration set and disconnect it from the patient's IV catheter.
2. Follow your health care provider's instructions for flushing the patient's catheter.
3. Clamp catheter as directed.
4. Remove tubing from pump and dispose of as instructed by your health care provider.

Repeating the Infusion

Your health care provider will instruct you on when and how you will start a new bag of medicine. You may be instructed to use a new administration set with each new IV bag. Always confirm that the air has been removed (primed) from the tubing before repeating an infusion. Follow the instructions in “Priming the Administration Set”, p. 24, if you are using an administration set that has not been primed.

Usually when you start a new IV bag, you will also start the Rx program over from the beginning.

1. To re-start the program from the Completed home screen, press **REPEAT Rx**.

   To re-start the program from the Infusion Complete KVO screen, press **PAUSE**, then press **REPEAT Rx**.

   This will reset the Rx program back to the beginning; resetting the volume/amount to be infused back to the original amount.

2. Review the RxDetails screen.
3. Press **NEXT** to view the Infusion Summary screen.
4. Press **RUN** when you are ready to start the infusion again.

Troubleshooting

You may encounter some common conditions that will require you to interact with the pump. You should be able to resolve most pump conditions. If these tips do not help you to solve the problem or if you have any questions, call your health care provider.

Most screens have help text associated with them. To view information about a specific screen, press **HELP**.

The following sections contain some common notifications and alarms. The entire list of notifications and alarms are in the CURLIN® 8000 Ambulatory Infusion System User Manual.

Notifications

Sometimes a message will appear on the screen, notifying you of something that requires attention.

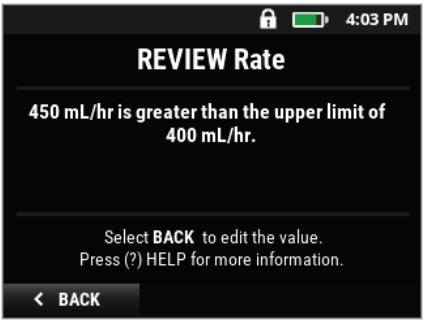


Figure 13: Notification Screen Example

Notification message on the screen:	When it is displayed:
CAUTION! AIR DETECTOR IS OFF	When the Air In Line sensor is set to OFF. This means that the pump will not detect air in the administration set. Moog Medical recommends using an administration set with an air eliminating filter to reduce the potential of air delivered to the patient. The patient could be harmed if air remains in the administration set.
DISCONNECT FROM PATIENT	When you press PRIME or select OPTIONS/Rx TASKS/PRIME. Never prime the administration set while it is connected to the patient.

Notification message on the screen:	When it is displayed:
PM REMINDER	If the pump is due for its annual preventive maintenance (PM) checkup. You can continue using the pump, but it should be returned to the health care provider at the next convenient opportunity. This message will continue to appear each time the pump is powered on until after the PM service is performed.

Medium Priority Alarms

When a medium priority alarm occurs, the pump status bar turns orange, a low/high tone sounds, and the screen displays information on the medium priority alarm condition.

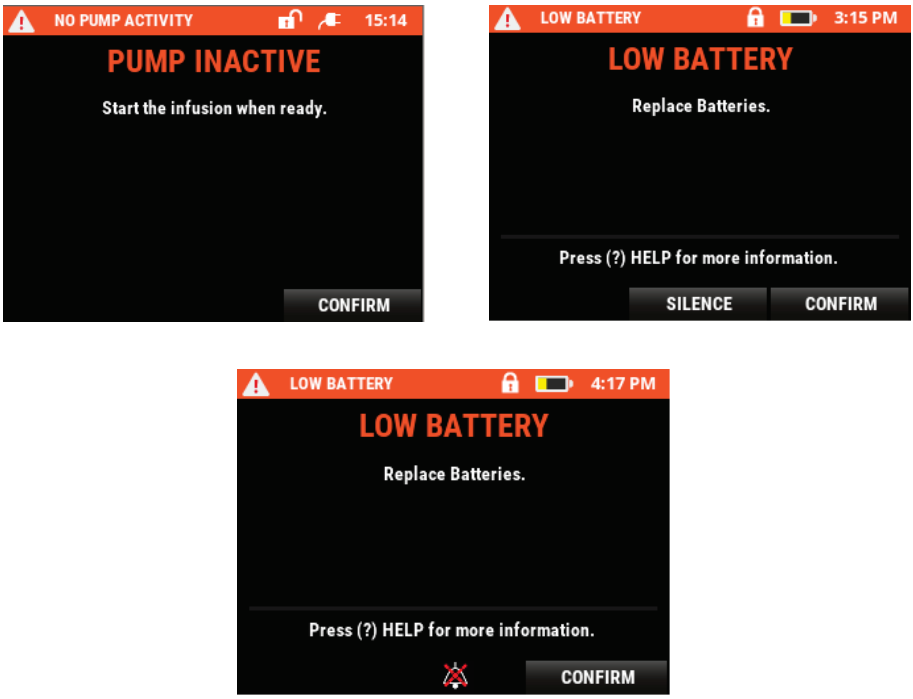


Figure 14: Medium Priority Alarm Screen Examples (Bottom Example Shows Alarm in Silence)

To silence the alarm sound for two minutes, press **SILENCE**. Follow the instructions on the screen to resolve the medium priority alarm condition. Press **CONFIRM** when you are finished with the medium priority alarm screen. The following list contains some of the possible medium priority alarms that may be displayed.

Medium Priority Alarm Title and Message on Screen	Cause	User Response
INFUSION SCHEDULED START PUMP Start infusion to maintain dosing schedule.	The pump was off or paused and the scheduled infusion has passed or is due to start within 5 minutes.	The pump must be running to deliver the dose as programmed. If the scheduled time has passed, the dose will begin when the pump is placed in RUN mode. The delay start time can be changed in OPTIONS/Rx TASKS/DELAY START.
LOW BATTERY Replace Batteries	The batteries are running low and should be replaced. C Cells: Approximately 20% of the battery life is remaining. This represents a minimum of 30 minutes up to several hours. Battery Pack: Approximately 30 minutes of battery life is remaining. After the initial low battery alarm is confirmed, the yellow battery icon will be displayed. A self-dismissing low battery alert will sound every 10 minutes until the batteries are replaced, the AC Adapter is connected, or the battery is depleted. See "EMPTY BATTERY" Alarm.	Press **CONFIRM**. If using C Cell batteries, pause the infusion, power off the pump and replace the batteries. Power up the pump and resume the infusion. If using a rechargeable battery pack, plug the pump into AC power to recharge the battery pack. The battery pack can be charged in the pump while it is running.
MISSED DOSE START DOSE IS LATE Press CONFIRM and RUN to start the dose.	The pump was not running when the scheduled dose was due to start.	Follow health care provider's instructions for managing a late dose.

Medium Priority Alarm Title and Message on Screen	Cause	User Response
NEAR END OF INFUSION Rx ALMOST FINISHED Prepare the next infusion if required.	The infusion is near the end. In Continuous, TPN, Variable and Intermittent therapy modes, the alarm will sound approximately 30 minutes prior to the end of the infusion. In the PCA therapy mode, the alarm will sound when approximately 10% of programmed bag volume remains.	Press **CONFIRM**.
NO PUMP ACTIVITY PUMP PAUSED Start the infusion when ready.	When the pump has been displaying a Paused infusion screen for two minutes without any keys being pressed. Pump paused reminder.	Press **CONFIRM**, then press **RESUME** to continue the infusion when ready.
PUMP IS PAUSED DOSE IS DUE SOON The dose is scheduled to start in less than 5 minutes. Start pump to maintain schedule.	The pump was paused and a dose is due to start in less than 5 minutes.	Press **RUN** to begin the next dose. If dose start time needs to be rescheduled, select OPTIONS/Rx TASKS/NEXT DOSE START.

High Priority Alarms

When a high priority alarm occurs, the pump status bar turns red, the red infusion indicator light flashes, an audio tone sounds, and the screen displays information on the alarm condition.

Figure 15: High Priority Alarm Screen Examples

To silence a high priority alarm, press **SILENCE** to stop the audio alarm for two minutes while you read the alarm screen. Follow the instructions on the screen to resolve the alarm condition. Press **CONFIRM** when you are finished with the alarm screen. The alarm will repeat if the condition was not resolved. The following list contains some of the possible alarms that may be displayed.

High Priority Alarm Title and Message on Screen	**Cause**	**User Response**
[screen is blank; alarm sounds and red infusion indicator light flashes]	Most common cause is that power has been lost.	Press the Power button to clear the alarm. Replace the batteries. Press the Power button to turn pump on.

High Priority Alarm Title and Message on Screen	Cause	User Response
AIR IN LINE DETECTED Check the administration set for air. If air is present, PRIME to remove air.	The pump detected air that exceeds the programmed air in line limit.	1. Press **SILENCE**. 2. Disconnect the administration set from the patient. 3. Press **PRIME** (or go to OPTIONS/Rx TASKS/PRIME). 4. Press **CONFIRM** if set is detached from patient. 5. Press and hold **PRIME**. (Release **PRIME** and repress if more than 5 mL is required.) 6. Check administration set from pump to patient connector to ensure all air has been removed. **Note:** Even though fluid is coming out of the administration set, there could be air remaining between pump and patient connector. 7. Continue priming or Press **DONE**. 8. Re-connect the administration set to the patient. 9. Press **RESUME**. **Note:** If you are not allowed to access the Prime function or have not been trained to prime, contact your health care provider for instructions to resolve the air in line condition.

High Priority Alarm Title and Message on Screen	Cause	User Response
AIR MAY BE PRESENT CHECK IV BAG The pump is not detecting fluid. Check bag and tubing.	The pump is not sensing fluid coming from the IV bag. The IV bag may be empty or the tubing may be blocked.	If the bag is empty, hang a new bag or clamp the line and turn off the pump. If air is present, prime as needed. Always disconnect the administration set from the patient before priming. **Note:** You may need to contact your health care provider to resolve the air in line condition. Follow your health care provider's instructions for resolving.
DOWN STREAM OCCLUSION BLOCKAGE IN TUBING Check for closed clamps or a kink in tubing.	The pump senses a blockage between the pump and the patient.	1. Unbend patient's arm or adjust patient's position if possible. 2. Examine tubing from pump down to patient's catheter. 3. Resolve any kinks in tubing. 4. Check to see if the slide clamp is closed (pinching the tubing). Check the clamp on the patient's catheter. 5. Resume the infusion if paused. If unable to resolve the alarm condition, call the heath care provider. During the first minute of the alarm, the pump will detect reduced pressure in the set and automatically restart the infusion – a "two-tone" notification will sound.After the first minute the alarm will be "latched" and must be acknowledged. The infusion will need to be resumed.

High Priority Alarm Title and Message on Screen	Cause	User Response
EMPTY BATTERY Install new batteries immediately.	The batteries no longer have sufficient power to run the pump. The infusion stopped.	The battery power is too low to run the pump. Change the C Cell batteries / rechargeable battery pack or connect to an external AC power source. Note: If batteries are not installed or external AC power is not connected, the pump will power off 2-1/2 minutes after the alarm appears on the screen. It is recommended that new C Cell batteries or the rechargeable battery pack be installed even when connected to AC power.
INFUSION COMPLETE The program is finished	The infusion is complete.	The programmed infusion is complete. The infusion may be repeated from the home screen. Press CONFIRM to return to the home screen. If a KVO (keep vein open) rate has been programmed, the pump will continue to deliver at that rate until the pump is paused.
TUBING NOT INSERTED INSERT TUBING 1. Open door fully 2. Insert blue pin 3. Insert flow stop 4. Close door 5. Latch door 6. Done	When the administration set is not properly installed during any type of infusion delivery or programmed with delay or next dose start, or during priming.	Check to ensure the blue tubing guide and the flow stop are inserted appropriately. The blue pin must be inserted into the tubing guide receptacle above the door hinge (indicated by the blue arrow). The yellow flow-stop must be placed in the flow-stop receptacle (indicated by the yellow arrow). Use only approved CURLIN administration sets.

Malfunctions

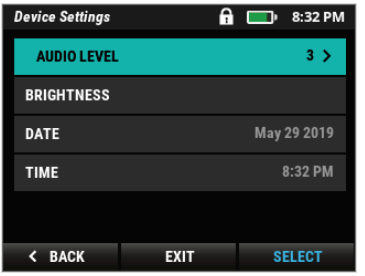
If an error code appears, turn the pump off and back on. If it re-appears, contact your health care provider.

Figure 16: Error Code Screen Example

User Preferences

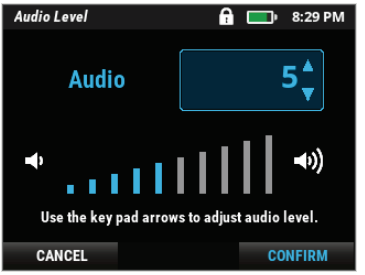
You can customize the pump audio volume of alarms and the screen brightness.

1. Press **OPTIONS**.
2. Press ▼ and select **TOOLS** and then press **OK** to view the Tools screen.
3. Press ▲ or ▼ and select **DEVICE SETTINGS** and then press **SELECT** to view the Device Settings screen.



Setting the Audio Level

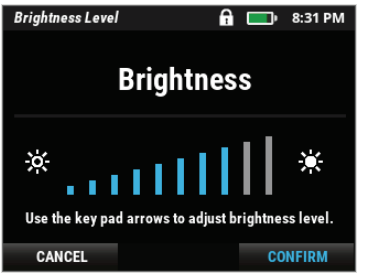
1. From the Device Settings screen, press ▲ or ▼ and select **AUDIO LEVEL** and then press **SELECT** to view the Audio Level screen.
2. Press ▲ or ▼ to adjust the audio level. This is the level at which an audio alarm starts. If the alarm is not acknowledged by pressing the appropriate button, the alarm audio level continues to increase (get louder) to gain the user's attention.



3. Press **CONFIRM** to save the audio level.

Setting the Screen Brightness

1. From the Device Settings screen, press ▲ or ▼ and select **BRIGHTNESS** and then press **SELECT** to view the Brightness Level screen.
2. Press ▲ or ▼ to adjust the brightness level.
3. Press **CONFIRM** to save the brightness level.



To return to the home screen, press **EXIT**.

Cleaning the Pump and Accessories

The CURLIN 8000 is resistant to fluid spillage from any direction. Keep the pump surfaces clean, dry, and free of fluid spillage at all times.

- Do not immerse the pump in any fluid.
- Do not use the pump in the shower, sauna, or steam bath.
- Do not position the pump where it could accidentally be dropped into a container of fluid (e.g., basin, tub, or toilet).

To clean the CURLIN 8000, remote bolus cord, external AC power adapter, and battery pack, use a soft clean cloth with any of the below cleaning agents (do not spray any cleaning agents directly on the CURLIN 8000):

- Warm soapy water (do not submerse)
- Quaternary Ammonium Compound (Super Sani-Cloth® Germicidal Disposable Wipes)

To clean small carrying packs follow the manufacturer's instructions. For detailed cleaning instructions go to www.triacmed.com/bag_care/.

Caution Use only approved cleaners and cleaning methods. Using unapproved cleaners or cleaning methods can damage the screen, keypad and case, resulting in an illegible screen, unusable keypad and degradation of the case.

CURLIN 8000 Specifications

Item	Specification
Operating Environment Temperature:	15°C to 40°C (59°F- 104°F)
Relative Humidity:	15% to 90% non-condensing
Atmospheric Pressure Range:	70 kPa to 106 kPa
Storage Environment Storage Temperature Range: Storage Relative Humidity: Storage Pressure Range:	Normal Storage Environmentally Controlled for Temperature and Humidity Temporary or Transportation: -20°C to 60°C (-4°F to 140°F) 15% to 93% non-condensing 50 kPa to 106 kPa
Solid object and fluid ingress protection	IP24
Average operating time with fully charged C-cell batteries	10 hours at 500 mL/hr 30 hours at 125 mL/hr 50 hours at 2 mL/hr
Average operating time with fully charged rechargeable battery pack	10 hours at 500 mL/hr 30 hours at 125 mL/hr 85 hours at 2 mL/hr
Rechargeable battery pack charge time	8 hours
Display	Graphic LCD
Flow rates	0.1 to 500 mL/hr

Item	Specification
KVO Rates	0 to 9.9 mL/hr Can be set at “0” in Continuous, TPN, Variable and Intermittent therapies
Priming Rate	500 mL/hr *Note: Air detector is off and accumulated air is reset when using the prime feature.*
Infusion Accuracy Delivery rate 1 – 500 mL/hr 0.1 – 0.9 mL/hr Bolus volume >2.5 ml <2.5 ml Accuracy testing conditions	 ± 5% ± 15% ± 5% ± 15% Temperature: 22°C (72°F) Head height: 12 inches Back pressure: none *Delivery and environmental factors may have additional impact on delivery accuracy. See “Factors Impacting Infusion Accuracy” in the next section below.* *Infusion accuracy established at statistical levels of 90% reliability and 90% confidence.* *Accuracy specification applies to all therapy modes, for the administration set usage period of 96 hours (or 9 Liters).*
Administration Set Usage	Set use should not exceed 96 hours or 9 liters (whichever comes first). Pump performance may be affected beyond these limits
Administration Sets	Warning: Use only approved Moog CURLIN 380 series Infusion sets

<table>
<tr><th>Item</th><th colspan="4">Specification</th></tr>
<tr><td>Fill Volume for Administration Sets</td><td colspan="4">See individual administration set label for specific fill volume</td></tr>
<tr><td rowspan="3">Up Occlusion Detection Time
- occlusion below spike</td><td colspan="2">Rate</td><td colspan="2">Time to Alarm</td></tr>
<tr><td colspan="2">0.1 mL/hr.
1 mL/hr.
25 mL/hr.</td><td colspan="2">3-14 min
30-90 sec
3-8 sec</td></tr>
<tr><td colspan="4">Note: Occlusion time ranges represent ±1 std dev.</td></tr>
<tr><td rowspan="3">Down Occlusion Detection Time
- occlusion at distal Luer for non-filtered sets:</td><td>Rate</td><td colspan="3">Time to Alarm</td></tr>
<tr><td></td><td>Low Sensitivity</td><td>Medium Sensitivity</td><td>High Sensitivity</td></tr>
<tr><td>0.1 mL/hr
1 mL/hr
25 mL/hr</td><td>1-2 hrs
8-11 min
16-20 sec</td><td>32-46 min
2-6 min
8-12 sec</td><td>20-32 min
2-3 min
5-9 sec</td></tr>
<tr><td colspan="4">Note: Occlusion time ranges represent ±1 std dev.</td></tr>
<tr><td rowspan="3">Down Occlusion Detection Time
- occlusion at distal Luer for filtered sets:</td><td>Rate</td><td colspan="3">Time to Alarm</td></tr>
<tr><td></td><td>Low Sensitivity</td><td>Medium Sensitivity</td><td>High Sensitivity</td></tr>
<tr><td>0.1 mL/hr.
1 mL/hr.
25 mL/hr.</td><td>3.5-4.5 hrs
15-20 min
40-60 sec</td><td>1.5-2.5 hrs
6-10 min
20-35 sec</td><td>1-1.5 hrs
3-7 min
15-25 sec</td></tr>
<tr><td colspan="4">Note: Occlusion time ranges represent ±1 std dev.

Note: Administration sets containing anti-siphon valves are not recommended at “high” sensitivity setting as false occlusion alarms may occur.</td></tr>
</table>

Factors Impacting Infusion Accuracy

The accuracy of the CURLIN 8000 pump when delivering an infusion can be impacted by the following factors:

- Pump use outside the stated operating environmental conditions can have a negative impact on pressure alarm and delivery accuracy performance.

Caution At rates below 1 mL/hr the infusion accuracy of the CURLIN 8000 can vary by as much as 15%.

Use of air eliminating filters below 1 mL/hr can result in under delivery variation up to -18%.

For infusions requiring higher accuracy at flow rates below 1 mL/hr, alternate infusion methods should be considered if tighter accuracy ranges are required.

- The time required to achieve the desired delivery rate varies based on the rate selected and the initial position of the pumping mechanism. The table below, as recommended in AAMI TIR101, provides guidance for the startup time to achieve steady state delivery. Note: negative time represents a period of higher delivery rate and positive time a period of lower delivery rate.

Administration Set Used	**Fluid**	**Programmed Flow Rate** (mL/hr)	**Start-up Delay** (min)
380 Series	Distilled Water		
Operating Conditions (22C, 12” head height, no back pressure)		0.1	-7.8 to 8.5
		1	-3.2 to 3.2
		10	-0.3 to 0.1
		100	0.0 to 0.1
		500	0.0 to 0.0

Effect of Head Height on Infusion Rate Accuracy

The position of the reservoir fluid level is limited by the maximum length of the upstream tubing segment of the Curlin 8000 administration sets.

The reservoir’s fluid level nominal position is 12 inches above the pump. Raising or lowering the reservoir could result in a delivery rate deviation of ± 1% per 12 inches.

Effect of Back Pressure on Infusion Rate Accuracy

The position of the pump and reservoir relative to the infusion site is limited by the maximum length (approximately 54 inches) of the downstream tubing segment of the Curlin 8000 administration sets.

The patient's infusion site nominal position is to be level with the pump. Raising or lowering the pump relative to the infusion site could result in a delivery rate deviation of ± 1% per 54 inches (100mmHg).

Viscosity Effects on Infusion Rate Accuracy

The Curlin 8000 is effective in delivering fluids used within its intended use therapies. Fluids with increased viscosity such as IVIG (up to 3.5cP) have been shown to deliver according to the device's specifications (tested using D50W). However, fluids with viscosities above 3.5cP may result in a lower delivery accuracy.

Additional guidance for small delivery volumes, therapy startup, back pressure, bolus delivery, flow continuity, non-continuous delivery modes and administration set life impacts are provided below consistent with IEC 60601-2-24.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The CURLIN 8000 pump is intended for use in the electromagnetic environment specified below. The customer or the user of the CURLIN 8000 pump should be assured that it may be used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
Radiated / Conducted RF emissions EN 55011 CISPR 11	Group 1	The CURLIN 8000 pump uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Radiated / Conducted RF emissions EN 55011 CISPR 11	Class B	The CURLIN 8000 pump is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Distortion IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The CURLIN 8000 pump is intended for use in the electromagnetic environment specified below. The customer or the user of the CURLIN 8000 pump should be assured that it may be used in such an environment.

Immunity test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±2kV, ±4kV, and ±8kV contact ±2kV, ±4kV, ±8kV, and ±15 kV air	±2kV, ±4kV, and ±8kV contact ±2kV, ±4kV, ±8kV, and ±15 kV air	For best protection from ESD, avoid using the CURLIN 8000 pump in environments that promote high levels of static discharge (e.g., synthetic floor materials in low humidity environments).
Electrostatic fast transient / burst IEC 61000-4-4	± 2 kV @100kHz PRR for power supply lines ± 1 kV @100kHz PRR for input/output lines	± 2 kV @100kHz PRR for power supply lines ± 1 kV @100kHz PRR for input/output lines	Mains power quality should be that of a typical hospital, acute care, long term care, or residential environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s)	± 1 kV line to line	Mains power quality should be that of a typical hospital, acute care, long term care, or residential environment.

Immunity test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	100% for 0.5 cycle at 0/40/90/135/180/225/ 270 & 315 degrees 100% for 1 cycle 30% for 25/30 cycles 100% for 250/300	100% for 0.5 cycle at 0/40/90/135/180/225/ 270 & 315 degrees 100% for 1 cycle 30% for 25/30 cycles 100% for 250/300	Mains power quality should be that of a typical hospital, acute care, long term care, or residential environment. The CURLIN 8000 pump allows continued operation during power mains interruptions via the internal battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50/60 Hz	30 A/m 50/60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in the typical residential, commercial or hospital environment.
Proximity Magnetic Fields IEC 61000-4-39	30 kHz CW 8 A/m 9kHz – 150kHz Clause 5.3 L4 30 A/m 150kHz – 26MHz Clause 5.4 L4 3 A/m	30 kHz CW 8 A/m 9kHz – 150kHz Clause 5.3 L4 30 A/m 150kHz – 26MHz Clause 5.4 L4 3 A/m	RFID, WPT and similar equipment may be used near the CURLIN 8000 pump so long as the radiated energy levels do not exceed those shown as complied with.
Conducted RF IEC 61000-4-6	150 kHz to 80 MHz 3Vrms / 6Vrms (ISM) 80% AM at 1 kHz	150 kHz to 80 MHz 3Vrms / 6Vrms (ISM) 80% AM at 1 kHz	Avoid using the CURLIN 8000 pump in close proximity to electronic devices or equipment that emit high levels of radiofrequency (RF) energy, such as X-ray and magnetic resonance imaging equipment.
Radiated RF IEC 61000-4-3	80 MHz to 2.7 GHz 80% AM at 1 MHz 10 V/m	80 MHz to 2.7 GHz 80% AM at 1 MHz 10 V/m	

IEC 61000-4-3 Radiated RF - Proximity fields (IEC 60601-1-2 Clause 8.10 Table-9)

Proximity test frequency (MHz)	Band (MHz)	Service	Modulation	Compliance Level (V/m)
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	27
450	430 to 470	GMRS 460, FRS 460	FM ±5 kHz deviation 1 kHz sine	28
710	704 to 787	LTE Band 13, 17	Pulse modulation 217 Hz	9
745				
780				
810	800 to 960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	28
870				
930				
1720	1700 to 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25, UMTS	Pulse modulation 217 Hz	28
1845				
1970				
2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	28
5240	5100 to 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	9
5500				
5785				

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the CURLIN 8000 pump is used exceeds the applicable RF compliance level above, the CURLIN 8000 pump should be observed to verify normal operation and essential performance. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the CURLIN 8000 pump. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

For over 20 years, Moog Medical has been designing industry-leading curvilinear peristaltic infusion pumps. Our infusion expertise and collaboration with customers and patients continues to benefit healthcare delivery and enhance caregiver and patient outcomes.

Speak live with a Moog Clinical Representative for pump questions and troubleshooting guidance 24 hours per day, 7 days per week.

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