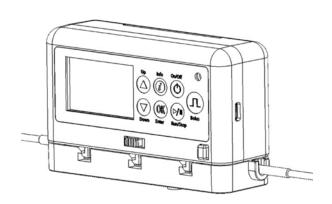


# Nimbus<sup>TM</sup> EU Ambulatory Infusion Pump

Patient Manual





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# **Section 1: General Description**

#### Indications for use

The Nimbus™ EU Ambulatory Infusion Pump is intended to deliver medications and/or fluids to a patient under the direction or supervision of a physician or other certified healthcare professional in clinical or nonclinical environments, such as homes. The device is intended for subcutaneous, percutaneous, perineural, epidural and intravenous infusion, including but not limited to patient-controlled analgesia (PCA) delivery.

# **Symbols**

Symbol	Standard	Reference number and title of symbol	Description of symbol
[]i	ISO 15223-1:2012  Medical devices Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General requirements	5.4.3 Consult instruction for use	Indicates the need for the user to consult the instructions for use.
$\triangle$	ISO 15223-1:2012  Medical devices Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General requirements	5.4.4 Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
∱	IEC 60417:2002 DB Graphical symbols for use on equipment	5333 Type BF applied part	To identify a type BF applied part complying with IEC 60601-1.



Symbol	Standard	Reference number and title of symbol	Description of symbol
<del>*</del>	ISO 15223-1:2012 Medical devices Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General requirements	5.3.4 Keep dry	Indicates a medical device that needs to be protected from moisture.
*	ISO 15223-1:2012  Medical devices Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General requirements	5.3.2 Keep away from sunlight	Indicates a medical device that needs protection from light sources.
X	ISO 15223-1:2012 Medical devices Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General requirements	5.3.7 Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.
SN	ISO 15223-1:2012  Medical devices Symbols to be used with medical device labels, labelling and information to be supplied Part 1: General requirements	5.1.7 Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified
Rx Only	N/A	Prescription only	Federal (U.S.A) law restricts this device to sale by or on the order of a physician.



	ISO 7010: 2011 Graphical Symbols – Safety Colours and Safety Signs – Registered Safety Signs – Part 5: Registered Safety Signs	M002 Refer to instruction manual / booklet	Indicates that failure to follow operating instructions could place the PATIENT or OPERATOR at risk.
<b>C E</b> 0123	MDD 93/42/EEC Annex XII	CE Marking of Conformity	Indicates the device meets essential requirements of MDD 93/42/EEC



# Warnings

A Warning ( $\triangle$ ) alerts you to a potentially hazardous condition, safety hazard or equipment damage.

- Ambulatory Infusion Pump. InfuTronix assumes no responsibility for incidents that may occur if its product is not used in accordance with its product labeling.
- ⚠ This Manual and the Clinician Quick Reference Guide are not intended for patient use. These documents contain information regarding programming and locking functions not contained in the Patient's Manual or Patient Quick Reference Guides.
- If a patient or caregiver is to operate the Nimbus<sup>™</sup> EU pump without the direct supervision of a medical professional, the patient or caregiver should be trained by a medical professional to operate the pump. This training should include all necessary operations of the pump. The patient or caregiver should have the means to contact the patient's health care provider at all times when not under direct supervision.
- As applicable, provide the patient or caregiver with instructions for proper handling and/or disposal of the pump, the cassette/administration set, and the pouch.
- ⚠ If the Nimbus<sup>™</sup> EU pump is used to provide medication or fluid therapy to any patient under the age of 18, that patient should, during therapy and while having physical access to the pump and administration set, be under the direct supervision of an adult caregiver trained to operate the pump.
- ⚠ If the mental or physical condition of a patient or caregiver could interfere with or preclude the proper operation or safe use of the Nimbus<sup>TM</sup> EU pump, an alternate means of therapy should be utilized.
- ⚠ The pump is not to be used for delivery of blood or cellular blood products.
- The pump is not intended for delivery of life-sustaining medication.
- ▲ If the pump is used to deliver critical medication, a backup pump should be available.
- ▲ Do not use the pump or cassette/administration set to administer any infusion to the epidural space unless the medication and/or fluid infused is indicated for epidural administration.
- △ Do not use the pump in or near a MRI (Magnetic Resonance Imaging) device.



# Warnings, continued

- ▲ Do not expose the pump to X-Rays, Gamma Rays, or other Radiation.
- ⚠ Operating the pump near equipment that radiates high-energy radio frequencies (electrosurgical/cauterizing equipment, etc.) may cause false alarm conditions. If this happens, reposition the device away from the source of interference or use an appropriate clinical alternative.
- △ Do not operate this pump in the presence of flammable anesthetics mixture with air, oxygen, or nitrous oxide.
- ▲ Do not operate the pump at temperatures below 5°C or above 40°C.
- ▲ Incorrect device handling may lead to allergen exposure and patient allergic response.
- Only use InfuTronix approved cassettes/administration sets with the pump.
- ▲ Do not use a cassette/administration set beyond its expiration date.
- Each cassette/administration set is to be used with a single medication/fluid container.
- ▲ Always read and follow the instructions that accompany the fluid container you are using.
- △ Only use the pump and cassette/administration set with a non-vented collapsible reservoir or syringe.
- Attach the medication/fluid container to the cassette/administration set before attaching the cassette to the pump.
- Prime the cassette/administration set according to the instructions provided in this manual prior to connecting the cassette/administration set to the pump. Ensure that the entire fluid path is free of all air before connecting to the patient.
- ▲ Carefully follow the instructions in this document for loading and removing the cassette/administration set. A detached or improperly attached cassette could result in unregulated gravity infusion of medication from the fluid container. Replace the administration set according to the set label or by following the facility protocol.
- When attaching the cassette to the pump, press and hold the cassette latch lock button to properly make the attachment.
- Attach the cassette/administration set to the pump before connecting the administration set to a patient.
- ♠ Prior to use, always verify the proper function of the display, audible, and visual alerts during Power On Self-Test (POST).
- Always verify the displayed infusion parameters (Rate, VTBI, Time) with the prescription before starting infusion. A two-person verification is recommended.
- ▲ Do not over-program the VTBI. Program the actual amount of the fluid in the medication/fluid container.



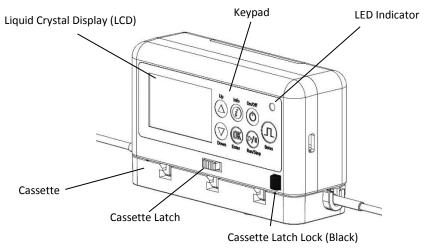
# Warnings, continued

- Always confirm that the established infusion route matches the intended administration route prior to the start of the infusion.
- △ Clearly differentiate established administration routes when using the pump with a patient that has multiple administration routes established.
- △ Do not operate the pump outside of the environmental limits detailed in the pump specifications.
- ▲ Upon starting an infusion, the slide clamp should be opened.
- ▲ Before packaging the drug/fluid bag and pump into the pouch, check the fluid path for kinks, closed clamp or other occlusions.
- ▲ Do not put excessive pressure on the pump that may cause the device, bag or tubing to compress (i.e. leaning against pouch, sleeping on pouch, etc.).
- ▲ Do not leave the pump or cassette/administration set unattended at home or other places where children or pets may come in contact with the device.
- ▲ Disconnect the administration set from the patient before removing the cassette from the pump.
- Always close the slide clamp before removing the cassette from the pump.
- ▲ Do not store the pump with a cassette/administration set attached.
- ⚠ Do not place objects over the pump that may muffle the pump.
- ⚠ If the pump is not functioning as expected, the pump should not be used, and should be returned for inspection or repair.
- ⚠ There are no user serviceable parts inside the pump. Refer all services, repairs, and calibrations to qualified technical personnel. Do not make unauthorized modifications to the infusion pump.
- Avoid spills on the pump. Follow the instructions specified in Section 6 of this manual for cleaning and disinfection of the pump.
- ▲ To avoid mechanical or electronic damage, do not steam, autoclave, or immerse the pump in any fluids or cleaning solutions, and do not spray such fluids directly on the pump.
- ▲ Failure to properly follow the cleaning instructions may result in an electrical hazard, damage to the pump, and voided warranty coverage.
- Do not use this device for neonates.
- ⚠ If the pump is dropped or hit, inspect the pump for damage. Immediately stop using the pump if it is physically damaged or not functioning properly. Contact distributor to return the pump.
- Avoid using and/or storing the pump where it may come in contact with excessive lint, dust, direct sunlight, heat and moisture.

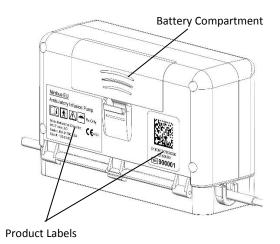


# **Device Diagrams**

#### **Front View**

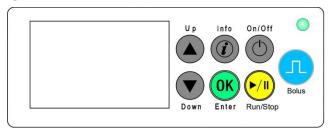


#### **Rear View**





# **Keypad Diagram**



Key	Name	Description
On/Off	ON/OFF	Hold for 3 seconds to power on or off the device.
Pun/Stop	RUN/STOP	Press to start or resume the infusion.  Hold for 3 seconds to pause the infusion.
Bolus	BOLUS	Press and release the BOLUS key to request a Demand Bolus delivery. Hold the BOLUS key for 3 seconds to cancel a Delay Start infusion.

**Note:** The pump has additional functions beyond those shown above. These functions are intended to be used by medical professionals only. Do not attempt to use these functions unless specifically instructed to do so and trained to do so by a physician or other certified healthcare professional.



# **LCD Screen Symbols**

Item	Name	Symbol	Description
1	Therapy Mode		The fluid bag symbol displays when the pump is infusing.
2	Configuration Mode	Ø	Displays when the pump is in the configuration mode.
			This symbol indicates a full battery level.
3 Battery Level Indicator	Battery Level		This symbol indicates a medium battery level.
	Indicator	ndicator	This symbol indicates a low battery level.
			This symbol indicates an empty battery level.
4	Alert	$\triangle$	This symbol will display if an alert condition is present.
5	Prescription mode		The pump is in Prescription mode.
6	Pause		The infusion is paused.

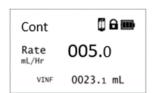
**Note:** This table includes references to functions that are intended to be used by medical professionals only. Do not attempt to use these functions unless specifically instructed and trained to do so by a physician or other certified healthcare professional.



# Section 2: Get familiar with your Nimbus<sup>™</sup> EU Ambulatory Infusion Pump:

#### **Infusion Mode**

When the pump is infusing medication, there will always be information available on the screen to assure you that the pump is functioning properly.



- The LCD will display the infusion rate in mL/Hr at the center of the screen.
- The medication bag symbol will display while the pump is infusing your medication.
- A green LED light will show at the top right corner of your pump indicating the infusion is running, then it will turn off after 10 minutes to save battery power.
- After any button press, the green LED will turn on again for 10 more minutes to inform you the infusion is delivering before the LED powers off again. This is normal.

Along the bottom of the screen, additional information is displayed about your infusion:

- The letters "VTBI" followed by a number will tell you the remaining Volume To Be Infused (VTBI) before the therapy ends.
- The letters "VINF" followed by a number will tell you how much medication has been infused so far during your infusion.
- "Next AB" followed by a time will indicate when the next Auto-Bolus dose is scheduled to be infused.
- "Next DB" followed by a time will indicate the lockout time remaining before the next Demand Bolus will be allowed.
- From time to time, you may hear a sound as the motor turns to infuse the numbing medication.

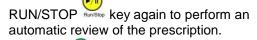
#### Pause Mode

If the fluid bag icon is missing from the display and a yellow LED light is showing, these signals indicate that the pump is in pause mode and is not infusing medication. If after 10 minutes the infusion is not resumed, the pump will sound an audible alert and the screen will display a "Pump Unattended" message to tell you it is in standby mode waiting to be told what to do next.



# **Options:**

- Press the RUN/STOP key to silence the alert and return to the main programming screen.
- To resume your infusion, press and release the





- Press OK key to confirm the prescription and begin the infusion.
- Or, to turn the pump off, press and hold the ON/OFF key for 3 seconds.

# **Pump Set Up and Programming**

The Nimbus<sup>™</sup> EU Ambulatory Infusion Pump should be set up and programmed by a member of your clinical care team. Do not attempt to perform any of these functions unless specifically instructed and trained to do so by a member of your clinical care team.

Your pump can be programmed to infuse medication using any combination of the following methods:

- Basal Rate- A continuous, low-volume infusion of medication.
- **Bolus** A bolus dose of medicine that is delivered quickly. A bolus can be programmed to function 2 different ways:
- **Demand Bolus** When enabled, a patient can press the BOLUS key to request an extra "bonus" dose of medication.
- Auto Bolus- A bolus that is scheduled to infuse repeatedly over a preset period of time.
- Delayed Infusion Start- A delay start can be programmed to extend the duration of your therapy up to 24hrs longer without adding extra medicine to the IV bag.

If delay start is activated, the pump will automatically begin infusing the medicine when the timer counts down to zero. Additionally, you will be instructed on how to cancel the timer and start your infusion immediately if needed.

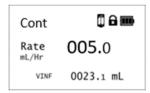


# **Section 3: Operating your Pump**

**Note:** Any values in the screenshots provided are for general guidance only and may not match specific configurations.

#### Start or Resume the Infusion

To start the infusion, press the RUN/ STOP key. A fluid bag icon will be displayed on the screen to indicate the infusion is running; The LED will show a green light and will be on for 10 minutes, then the LED will turn off until the next key press.



#### Demand Bolus - if enabled

Press the blue Bolus key to request an extra (**bolus**) dose of medication. If allowed in your prescription, a bar displays on the screen to countdown the Bolus volume indicating the medicine is being delivered.

# Delay Start Infusion - if enabled

A delay start feature can be activated to extend the duration of therapy up to 24 hours longer without adding extra medicine to the IV bag. The delay start function places the pump on hold to run in standby mode. When the timer counts down to zero, the infusion will automatically run without requiring any user intervention.

**Note:** While a Delay Start is active, the LCD screen will display a timer counting down the hours and minutes that remain before the programmed infusion is scheduled to begin.



# Cancel a Delay Start

To override the Delay Start, as instructed by your support team, press and hold

the BOLUS key for 3 seconds to cancel the delay timer. The delay countdown will be cancelled. A bolus (if enabled) will be delivered immediately,

followed by the infusion therapy as prescribed by your clinical care team.

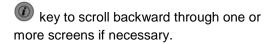


# Retrieving and selecting the Current Rx

The saved prescription can be retrieved at any time in the future to program and deliver a Current Rx.

To proceed with a therapy using the current prescription:

 Access the main menu by either powering on the pump to start fresh or pressing the INFO





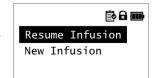
2. Press the ENTER

The user will be redirected to the main screen.

#### **Resume Infusion / New Infusion Menu**

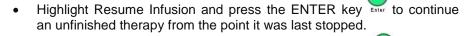
The user can be prompted start an infusion in two different manners:

 Resume Infusion: Can be selected if a therapy was interrupted and the choice is to continue. The pump picks up where it left off and continues the therapy.



2. New Infusion: Can be selected to infuse a new Rx. All the therapy parameters are set to infuse from the beginning of the therapy.

**Note**: The pump will detect from the infusion history whether or not a previous infusion was interrupted and left incomplete. If completed or never run, New Infusion will be the sole option displayed on the menu. Alternatively when an infusion has previously been interrupted and left incomplete the pump will display a second option for the user to resume from the point it was stopped.



Or, highlight New Infusion and press the ENTER key pump to run a new prescription from the beginning of the therapy.



## **Infusion Display screen**

While the infusion is running and medication is delivered, the screen will never go blank. The protocol name will show at the top left corner of the screen and the Basal Rate will display in the center. Additional therapy specific information such as VTBI, VINF, Next Intermittent Bolus (PCA), PCA Bolus Lockout (PCA), and Dose Infused will alternate along the bottom of the LCD screen during the infusion.



The drug/fluid bag icon will display at the top right corner of the screen. A green LED light will display for 10 minutes indicating the infusion is actively running.

**Note:** The LED will turn off after 10 minutes of operation and will remain off until any new key is pressed or an alert condition is detected. This is normal.

# Acknowledge an Alert

In the event a condition that could interrupt an infusion is detected, the screen will change to display an alert message. The LED will flash a red light. An audible signal may also sound. Please refer to Section 5: Trouble Shooting for detailed explanations of the error message and corresponding user response.



**Note:** Press the RUN/STOP key to acknowledge the alert. The audible alert, if present, will be silenced for 10 minutes.



# Stop or Pause the Infusion

If the user chooses to pause the infusion, hold the RUN/STOP key Runslop for 3 seconds to stop the active infusion.

- The drug/fluid bag icon will disappear from the display screen, replaced by the pause icon indicating the infusion has stopped.
- The LED will turn yellow and the infusion will be paused. The pump will display the programming screen.
- To resume the infusion, press the RUN/STOP key again to perform a new automatic review
- Press the ENTER key enter to confirm the Rx and begin the infusion.
- Or, to turn the pump off, press and hold ON/OFF key for 3 seconds.

## **Infusion Complete**

When the infusion is completed, the VTBI reaches 0 mL and the pump stops infusing. The LCD screen displays the screen shown on the right, indicating that the end-of-infusion state has been reached. Three beeps of audio alert will sound and the LED flashes a red light. The alert symbol will also display on the screen.



Press the RUN/ STOP key to acknowledge the condition and silence the audio alert. At this time, the user is returned to the main menu that displays therapy options.

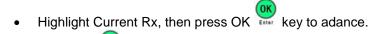
# **Power off the Pump**

If no further infusion is needed, the pump may be powered off. Hold the ON/OFF key for 3 seconds to power off the pump.



# Power the Pump back on and Resume the Infusion:

Hold ON/OFF key for 3 seconds to power on the pump.



• Press RUN/STOP RUN/STOP key initiating a review of the prescription, and then press OK key to confirm and resume the infusion.



#### Pack and Wear Pouch

▲ Warning: Before packaging the drug/fluid bag and pump into the pouch, check the fluid path for kinks, closed clamp or other occlusions. An undetected occlusion may result in under-infusion or non-delivery of medication and cause an undesirable outcome.

Open the pump pouch and place it flat on a table.

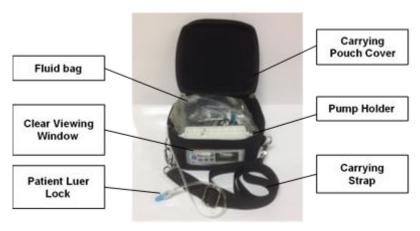
Open the Velcro strap, position the pump against the clear window with the display screen facing out, and then close the Velcro straps tightly to hold the pump securely in the window.

Place the drug/fluid bag in the bag chamber with the bag spike pointing left. Fold the bag spike over the top of the medicine bag and route the upstream end of the tubing between drug/fluid bag and pump carefully so that the tubing does not have kinks or occlusions.

Route the downstream end of the tubing carrying fluid to the patient through the tubing outlet. Close the pouch cover and zip closed.

Secure the pouch around the patient's waist or over the patient's shoulder. The carry strap may be adjusted for size.

**Caution:** Leave the pump inside the carry pouch at all times except for programming, loading and unloading the cassette/administration set, or troubleshooting.





# **Section 4: Battery Replacement**

The battery should be replaced if the pump alerts the user and displays the message "Battery Depleted" or "Power Off and Replace Battery".

# **Authorized Battery**



Only use batteries authorized by the manufacturer.

The quality of the battery is a significant factor in determining battery life and runtime. Use of batteries from any other brands may yield unexpected performance and will invalidate the warranty.

To replace the battery:

Please contact your clinical care team for battery replacement



# **Section 5: Troubleshooting**

When a condition that may interrupt the infusion is detected, the Nimbus<sup>TM</sup> EU pump will alert with audio and a visual signals to indicate the presence of the condition. If an alert message is generated, write down the message displayed on the LCD screen and refer to the following table for the corresponding explanation as well as the necessary steps to resolve the condition.

Note: Press the RUN/ STOP key to acknowledge the condition and silence the audio alert.

Alert Codes	Indication	Signal	Response
	The cassette may not be properly loaded or has	The screen	Press the RUN/STOP key to acknowledge the condition and silence the alert.
Cassette Loading Error	become dislodged.  Note: The infusion will be stopped automatically.	displays "Cassette Loading Error"; the LED flashes a red light; the audio alert sounds.	Clamp the tubing; unload and reload the cassette; unclamp the tubing. Press the RUN/STOP key to return to the programming menu. Press the RUN/STOP key again to resume the infusion.
Upstream Occlusion	Decreased pressure is detected in the supply line between the pump and IV bag.  Note: The infusion will be stopped	The screen displays "Upstream Occlusion"; the LED flashes a red light; the audio alert will sound immediately (optional delay) if the upstream	Press and release the RUN/STOP key to silence the audio alert (if present). Resolve the cause of the occlusion, such as kinked tubing. When resolved, the pump will resume the infusion
	automatically.	occlusion is not resolved.	automatically.



Downstream Occlusion	Increased pressure is sensed in the line between the pump and the patient.  Note: The infusion will be stopped automatically.	The screen displays "Downstream Occlusion"; the LED flashes a red light; the audio alert will sound immediately (optional delay) if the downstream occlusion is not resolved.	Press and release the RUN/STOP key to silence the audio alert (if present).  Resolve the cause of the occlusion.  When resolved, the pump will automatically resume the infusion.
Pump Unattended	The pump is standing by and not infusing for more than 10 minutes.	The screen displays "Pump Unattended"; the LED shows a solid yellow light; the audio alert sounds.	Press and release the RUN/STOP key to acknowledge the condition and silence the alert. The pump will return to the programming screen. Press the RUN/STOP key then follow the prompts to start or resume the infusion. Or press and hold the ON/OFF key for 3 seconds to power off the pump.  Note: The audible alert will return after 10 minutes if no further action is taken after acknowledging the alert.
System Error	The pumping mechanism may not work properly.  Note: The infusion will be stopped automatically.	The screen displays "System Error"; the LED flashes a red light; the audio alert sounds.	Press and release the RUN/STOP key to acknowledge the condition and silence the alert. Power off the pump. Take the pump out of service. Use a replacement pump if needed.



Firmware Error	The system fails to operate in a controlled fashion.  Note: The infusion will be stopped automatically.	The screen displays "Firmware Error"; the LED flashes a red light; the audio alert sounds.	Press any key to acknowledge the alert and power off the pump.  Take the pump out of service. Use a replacement pump if needed.
Battery Depleted	The infusion will continue for 30 minutes before the device powers off.	The screen displays "Battery Depleted" for 5 seconds and repeats displaying every 20 seconds; the empty battery level indicator symbol flashes; the LED shows a solid yellow light; the audio alert sounds.	Press the RUN/STOP key to suspend the infusion. Press the ON/OFF key for 3 seconds to power off the pump. Replace the battery following the instructions provided in Section 4: Battery Replacement in this user manual.
Power Off and Replace Battery	This battery has been used for over 240 hours /infusion volume has reached 1500 mL. The pump has reached the end of its performance life.	The screen displays "Power Off and Replace Battery", the LED flashes a red light; the audio alert sounds.	Press the RUN/STOP key to acknowledge the condition and silence the audio alert.  Replace the battery following the instructions provided in Section 4: Battery Replacement in this user manual



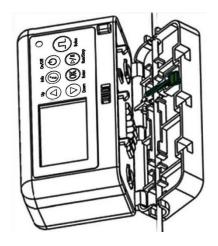
Max Vol Reached, Pump Standby	The pump has reached a maximum volume per hour or interval limit.  Note: The infusion will be stopped automatically.	The screen displays "Max Vol Reached, Pump Standby" until the new hour or interval is reached when the infusion can begin again; the LED shows a solid yellow light.	The pump will remain in standby mode until the new hour or interval is reached before beginning the infusion. No user action is required.  To change a volume limit, hold the RUN/STOP key for 3 seconds to stop the infusion. Scroll down to highlight the Max Vol/h or Max Vol/Int parameter. Press the ENTER key to change the parameter. Enter the Clinician Code to unlock the prescription. Change the value. Press ENTER to confirm the new parameter. Press the RUN/STOP key to activate the change in the therapy.
Invalid Infusion Parameter	The parameter value entered exceeds the remaining pump life.	The screen displays "Invalid Infusion Parameter"; the LED flashes a red light; the audio alert sounds.	Press and release the RUN/STOP key to acknowledge the condition and silence the audio alert.  Enter a valid infusion parameter value and start the infusion as applicable.
Infusion Complete	The infusion is completed.	The screen displays "Infusion Complete"; the LED flashes a red light; the audio alert sounds.	Press the RUN/STOP key to acknowledge the condition and silence the audio alert.

If the alert condition is not resolved by following the above instructions, the user should stop using the pump immediately and contact the pump provider for further instructions.

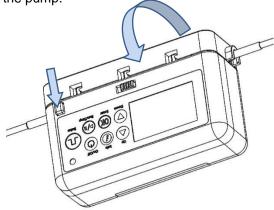


#### **How to Load the Cassette**

1. Engage the cassette "fingers" with the pump hinge.



2. Press the cassette latch lock down and firmly push the cassette towards the pump.



- 3. Release the cassette latch lock.
- 4. Confirm that the 3 hooks on the cassette latch are fully engaged with the cassette.



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# What Should You Expect Going Home with a Nimbus™ EU Pump?

- When the pump is running there will always be information available on the screen to reassure you it is functioning properly.
- A fluid bag icon will display on the screen for as long as the medicine is infusing.

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