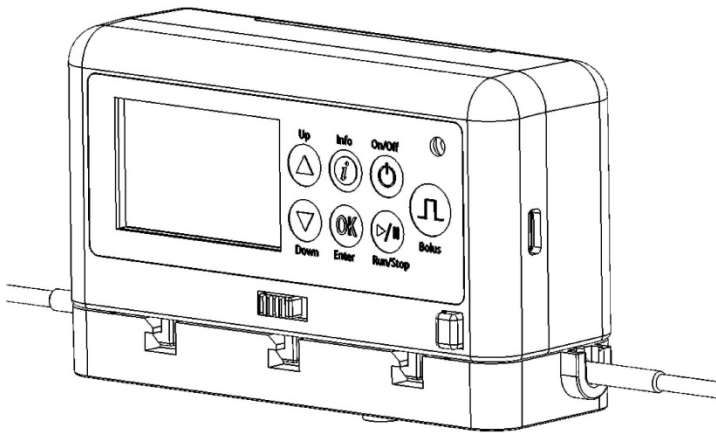


# Nimbus™ II Flex Ambulatory Infusion Pump

## Patient Manual



## Continuous Mode Infusions

Read this entire manual prior to operating the Nimbus™ II Flex Ambulatory Infusion Pump.  
Failure to follow instructions or heed a warning may result in death or serious injury.

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## Section 1: General Description

### Indications for use

The Nimbus™ II Flex 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 indicated for subcutaneous, percutaneous, perineural, epidural and intravenous infusions, including but not limited to patient controlled analgesia (PCA) delivery.

### Symbols

Symbol	Standard	Reference number and title of symbol	Description of symbol
	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.
	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
	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.
	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.
	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.

## Warnings

**A Warning (⚠) alerts you to a potentially hazardous condition, safety hazard or equipment damage. Failure to heed a warning may result in death or serious injury.**

- ⚠ Read the entire Patient Manual prior to operating the Nimbus™ II Flex ambulatory infusion pump. InfuTronix assumes no responsibility for incidents that may occur if its product is not used in accordance with its product labeling.
- ⚠ If a patient or caregiver is to operate the Nimbus™ II Flex ambulatory infusion pump without the direct supervision of a medical professional, the patient or caregiver must be trained by a medical professional to operate the pump. This training should include all necessary operation of the pump as well as pump placement, alert/signal recognition, and when/how to contact a medical professional regarding pump use or status. The patient or caregiver should have the means to contact the patient's health care provider at all times when not under direct supervision.
- ⚠ If the Nimbus™ II Flex Ambulatory Infusion 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™ II Flex Ambulatory Pump, an alternate means of therapy should be utilized.
- ⚠ Only use pump as directed by physician or other certified health care professional.
- ⚠ If you have any questions regarding use of the pump or experience any problems using the pump, contact your physician or other certified health care provider for further instructions.
- ⚠ 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.
- ⚠ 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.

## Warnings, Continued

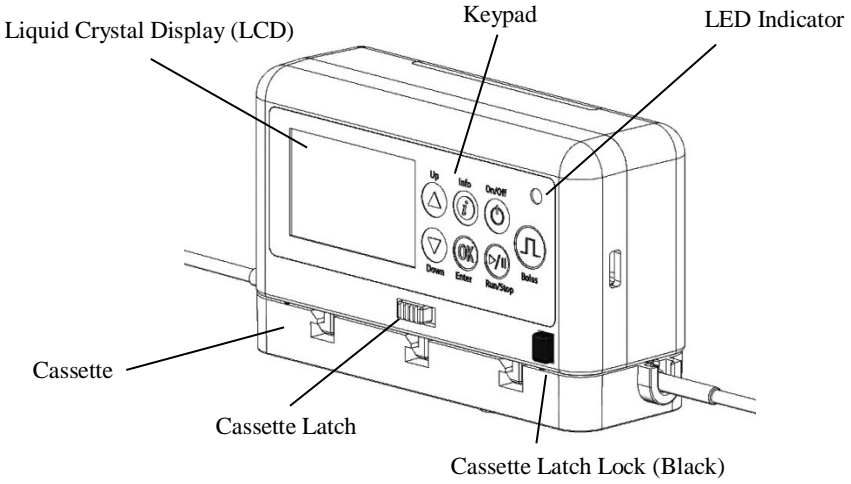
- ⚠ If the pump is used to deliver critical medication, a backup pump should be available.
- ⚠ Do not use the pump in or near a MRI (Magnetic Resonance Imaging) device.
- ⚠ Do not expose the pump to X-Rays, Gamma Rays, or other Radiation.
- ⚠ Operating the pump near equipment that radiates high-energy 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. This may result in death or serious injury.
- ⚠ The pump is not to be used if variance within the specified fluid delivery accuracy range could cause harm to the patient.
- ⚠ For those patients who are likely to be adversely affected by unintended operations and failures, including interrupted medication or fluid delivery from the device, close supervision and provision for immediate corrective action should be provided by their healthcare provider.
- ⚠ Only use InfuTronix approved cassettes/administration sets with the pump.
- ⚠ Always close the slide clamp before removing the cassette from the pump.
- ⚠ Do not operate the pump outside of the environmental limits detailed in the pump specifications.
- ⚠ Always disconnect the administration set from the patient before removing the cassette from the pump.
- ⚠ 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 young children or pets may come in contact with the device.
- ⚠ Do not store the pump with a cassette/administration set attached.
- ⚠ Do not use a Nimbus™ II Flex pump or cassette/administration set beyond its shown use by date.

## Warnings, Continued

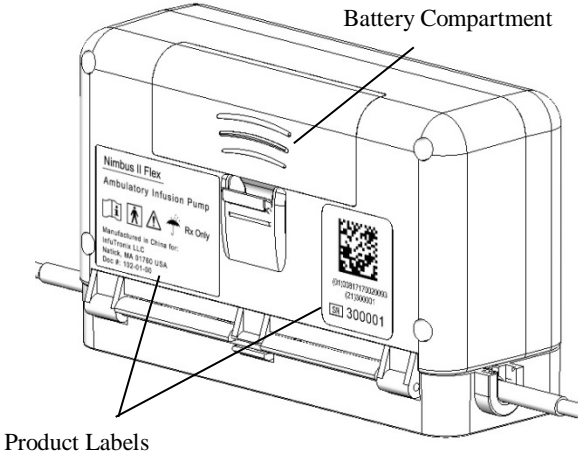
- ⚠ Do not place objects over the Nimbus™ II Flex pump that may muffle the pump.
- ⚠ System delivery inaccuracies may occur as a result of excessive pressure on the bag, back pressure or fluid resistance, which depends upon drug viscosity, catheter size, and extension set tubing.
- ⚠ If the pump is dropped or subjected to other forms of mechanical impact, inspect the pump for damage. Immediately stop using the pump if it is physically damaged or not functioning properly. Contact the distributor to return the pump.
- ⚠ If the pump is not functioning as expected, the pump should not be used, and should be returned for inspection and repair.
- ⚠ Follow instructions specified in Section 4: Maintenance in this Patient Manual for cleaning and disinfection of the pump.
- ⚠ There are no user serviceable parts inside. Refer all service, repair, and calibration to qualified technical personnel. Do not make unauthorized modifications.
- ⚠ Avoid spills on the Nimbus™ II Flex ambulatory pump and do not provide a patient with a wet device.
- ⚠ 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 cleaning instructions may result in an electrical hazard, damage to the pump, and voided warranty coverage.
- ⚠ Do not use this device for neonates, as risk assessment of leachables and extractables has not been performed to characterize additional risk associated with this population.
- ⚠ Do not store the pump beyond the expiration date. Battery leakage could occur.
- ⚠ Do not expose the pump to humidity levels below 15% or above 93% relative humidity.
- ⚠ Do not expose the pump to atmospheric pressure of less than 700hPa or more than 1060hPa.
- ⚠ Avoid using and/or storing of the Nimbus pump where it will come in contact with excessive lint, dust, direct sunlight, heat and moisture.

## Device Diagrams

### Front View

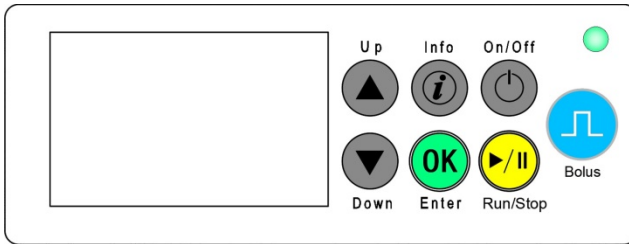




### Rear View
















## Keypad Diagram



Key	Name	Description
 Run/Stop	RUN/STOP	Press to start to review Rx, resume, or hold for 2-3 seconds to stop the infusion. Press OK to begin infusion.
 On/Off	ON/OFF	Press and hold the ON/OFF key for 2-3 seconds to power on or off the device.

**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 health care professional.

## LCD Screen Symbols

Item #	Name	Symbol	Description
1	Therapy Mode		The symbol indicates the pump is infusing.
2	Configuration Mode		The pump is in configuration mode.
3	Programming Lockout		Clinician code is required to change parameter values.
			No clinician code needed to change parameter values.
4	Battery Level Indicator		The symbol indicates a full battery level.
			The symbol indicates a medium battery level.
			The symbol indicates a low battery level.
			The symbol indicates an empty battery level.
5	Alert		The symbol will flash if an alert condition is present.
6	Setting		The pump is in the setting mode.
7	Pause		The pump is in the infusion mode.


**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 health care professional.

## Section 2: Operate the Pump

The Nimbus Ambulatory Infusion pump should be set up and programmed by a medical professional. Do not attempt to perform any of these functions unless specifically instructed to do so and trained to do so by a physician or other certified health care professional.

### Start Infusion

Press the RUN/ STOP  key to start the infusion.

The LCD screen will display the infusion rate in mL/Hr and display the mode of the current infusion. The therapy mode symbol  is visible throughout the infusion. The LED will flash green indicating the infusion is running. The LED will turn off 10 minutes after the infusion is started, and will only be on again if the user has pressed any key or an alert condition occurs. Parameters VTBI (Volume to Be infused) and VINF (Volume Infused during the current infusion) will also be alternatively displayed below the rate value.



**Note:** There will be an infusion delay upon powering on the pump and/ or loading the cassette. Upon pump power on and/or loading of cassette, the pump will need a 10-40 second delay on starting/resuming infusion to obtain upstream and downstream pressure baseline.


### Acknowledge Alert


During an ongoing infusion, the pump can indicate a condition by showing an alert message on the LCD screen. The LED will flash red light.

Press the RUN/STOP key  to acknowledge the alert. Contact your health care provider for further instruction.




## Stop Infusion

Press the RUN/STOP key  for 2-3 seconds infusion to stop the infusion.

The LED will turn yellow. The therapy mode sign  disappears from the display screen, indicating that the infusion has been stopped. The current infusion will be paused and the pump will display the programming screen.

## Power off Pump

Press and hold ON/OFF key  for 2-3 seconds to power off the pump.

## Section 3: Battery Replacement

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


### 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 non-authorized batteries may yield unexpected performance and will invalidate the warranty.


To replace the battery, follow these steps in order:

1. If Power Off and Replace Battery or Battery Depleted alert appears on the pump, press

RUN/Stop  key. If changing the battery

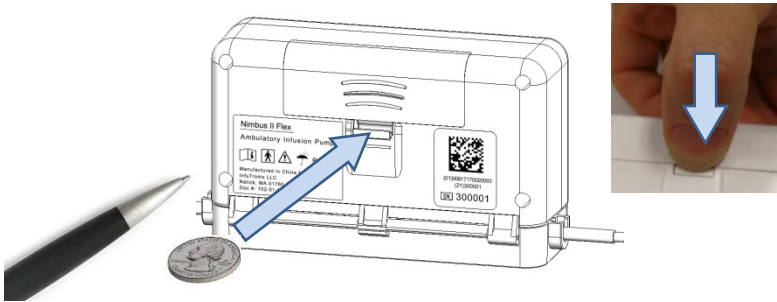
during an infusion without an alert, hold the RUN/STOP  key for 2-3 seconds to suspend the infusion.



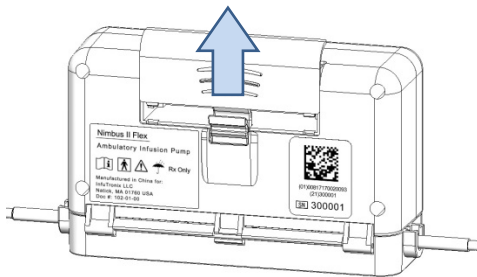
2. Hold the ON/OFF  key for 2-3 seconds to power off the Pump.

*Make sure the pump is powered off and disconnected from USB outlet before replacing the battery. **Do not remove the battery during an ongoing infusion.***

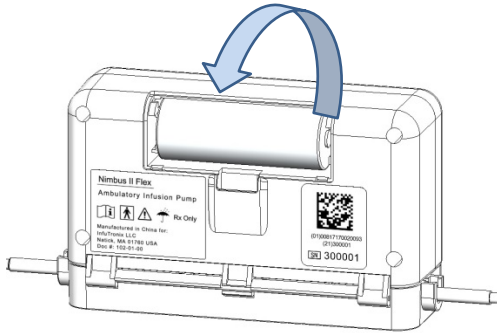
3. Push the button to unlock the battery cover by the fingertip or something like a ball pen point or a coin.



4. Slide the battery cover towards the top of the pump to remove it.

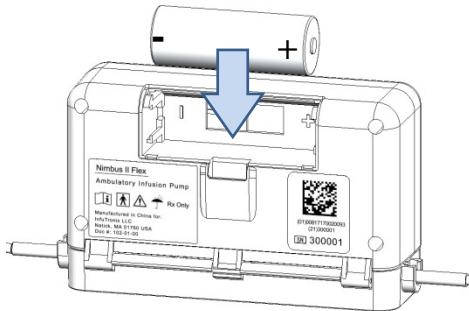


5. Remove the battery.

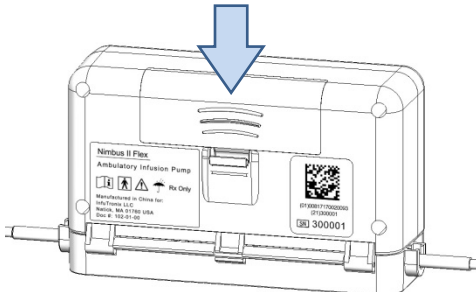


6. Insert a new battery.


Note: The battery should be inserted in the proper direction. Follow the polarity signs for the battery replacement with the positive pole facing to the right.



7. Fix the battery cover into the bottom housing and make sure it is locked. Note: Slide the battery cover towards the bottom of the pump until hear the clear 'click' sound.



## 8. Battery Reset.

Press the ON/OFF  key 2-3 seconds to power on the pump. When the pump completes the “POST test”,


press and hold the  key for 5 seconds. Using

the  key scroll to Battery Reset and press the

 key.



## 9. Resume/Start Infusion

Press and hold the  for 5 seconds to exit Battery Reset. The pump will return to the main screen.


The battery replacement is completed.

## Section 4: Troubleshooting

When a potentially unsafe condition is detected by the pump, the pump will exhibit an audio signal and a visual signal that indicate the presence of a condition that may interrupt the infusion.

**Note:** The following table is included for reference only and includes references to functions that are intended to be used by medical professionals only.



The user may press RUN/STOP key  to acknowledge an alert message. Do not attempt to use these functions unless specifically instructed to do so and trained to do so by a physician or other certified health care professional.

Alert Message	Indication	Signal
Cassette Loading Error	The cassette may not be properly loaded or has become dislodged. <b>Note:</b> The infusion will be stopped.	The screen displays “Cassette Loading Error”; The LED flashes red light; The audio alarm sounds.
System Error	The pumping mechanism may not work properly. <b>Note:</b> The infusion will be stopped.	The screen displays “System Error”; The LED flashes red light; The audio alarm sounds.
Firmware Error	The system fails to operate in a controlled fashion. <b>Note:</b> The infusion will be stopped.	The screen displays “Firmware Error”; The LED flashes red light; The audio alarm sounds.
Upstream Occlusion	A decrease in pressure is sensed in the tubing between the pump and IV bag. <b>Note:</b> The infusion will be stopped.	The screen displays “Upstream Occlusion; The LED flashes red light; The audio alarm will sound after 1 minute if the upstream occlusion is not resolved.



Downstream Occlusion	<p>An increase in pressure is detected in the tubing between the pump and the patient.</p> <p><b>Note:</b> The infusion will be stopped.</p>	<p>The screen displays “Downstream Occlusion”; The LED flashes red light; the audio alarm will sound after 1 minute if the downstream occlusion is not resolved.</p>
Battery Depleted	<p>The infusion will continue for 30 minutes prior to shut down.</p>	<p>The screen displays “Battery Depleted” for 5 seconds and repeats every 20 seconds; The empty battery level indicator flashes on the screen; The LED shows solid yellow light; the audio alarm sounds.</p>
Power Off and Replace Battery	<p>This battery has been used for over 240 hours /infusion volume has reached 1500 mL. Battery needs to be replaced.</p>	<p>The screen displays “Power Off and Replace Battery”; the LED flashes a red light; the audio alert sounds.</p>
Invalid Infusion Parameter	<p>An infusion parameter has been entered that exceeds the remaining pump life.</p>	<p>The screen displays on “Invalid infusion Parameter”; The LED flashes red light; The audio alarm sounds.</p>
Pump Unattended	<p>The pump is standing by and not infusing for more than 10 minutes.</p>	<p>The screen displays “Pump Unattended”; The LED shows solid yellow light; The audio alarm sounds.</p>
Infusion Complete	<p>The infusion is completed.</p>	<p>The screen displays “Infusion Complete”; The LED flashes red light; The audio alarm sounds.</p>
Due-for-Service	<p>The infusion pump reaches one year of accumulative power-on time or 20,000mL of infusion volume</p>	<p>The screen displays “Due-For -Service”; the LED flashes a red light; the audio alert sounds.</p>

## Section 5: Maintenance

### Cleaning and Disinfection

The pump should be cleaned and disinfected daily, whenever the pump becomes visibly soiled, or following facility protocols.

Turn the pump off before cleaning.

DO NOT spray cleaning fluids directly onto the pump.

DO NOT steam autoclave, EtO sterilize, immerse the pump, or allow fluid to enter the pump.

DO NOT use hard or pointed objects to clean any part of the pump.

DO NOT use acetone, other plastic solvents, or abrasive cleaner to clean the pump, as damage to the pump may occur.

Acceptable cleaning and disinfection solution is:

10% bleach solution (1 part household bleach to 9 parts water)

### Cleaning

1. Keep the pump keypad facing up and do not allow any part of the pump to become saturated with or submersed in fluid during the cleaning operation.
2. Use soft cloth dampened with 10% bleach solution to clean all exposed surfaces until visually clean.
3. After application, wipe all surfaces with a water-dampened soft cloth.

### Disinfection

1. Wipe all exposed surfaces with a new piece of soft cloth dampened with 10% bleach solution.
2. Allow the pump surfaces to remain visibly wet for a minimum of 20 minutes
3. Remove bleach residue by using a water-dampened soft cloth

Failure to follow these instructions may result in an electrical hazard, damage to the pump, and / or voided warranty coverage.

**Note:** Please do not attempt to disassemble or alter the device in any means. If you have any problems or questions regarding the pump, please contact your health care provider.

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