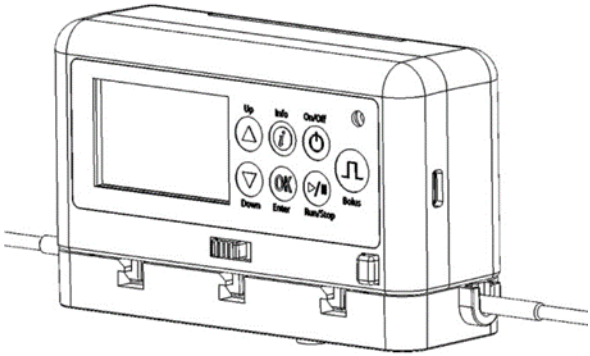
Nimbus™ EU

Ambulatory Infusion Pump

Clinician Manual



This manual is not intended for patient use. InfuTronix provides a separate manual for patient use.

Read this entire manual prior to operating the Nimbus™ EU Ambulatory Infusion Pump.

InfuTronix
Intelligent Devices For Precision Medicine

Contents

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
	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.

	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.
CE 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 (⚠) alerts you to a potentially hazardous condition, safety hazard or equipment damage.

- ⚠ Read the entire Clinician Manual prior to operating the Nimbus™ EU 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™ 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™ 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™ 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

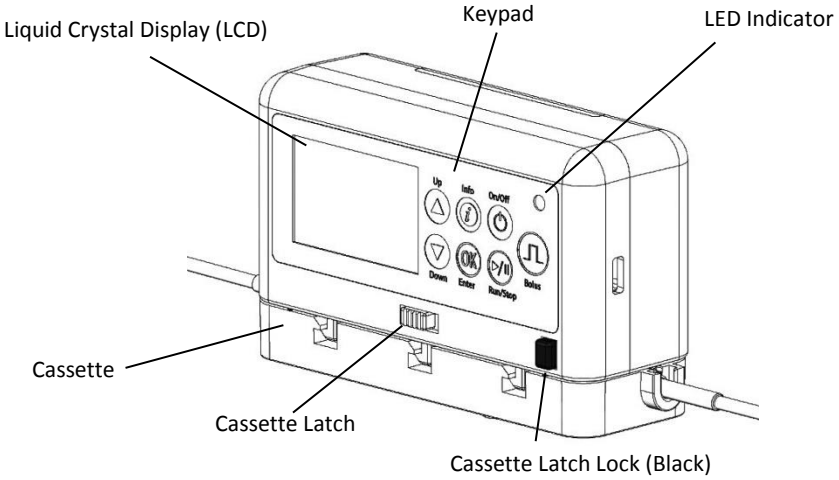
- ⚠ Do not expose the pump to X-Rays, Gamma Rays, or other Radiation.
- ⚠ Operating the pump near equipment that radiates high-energy radio frequencies (electrosurgical/cauterizing equipment, etc.) may cause false alarm conditions. If this happens, reposition the device away from the source of interference 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

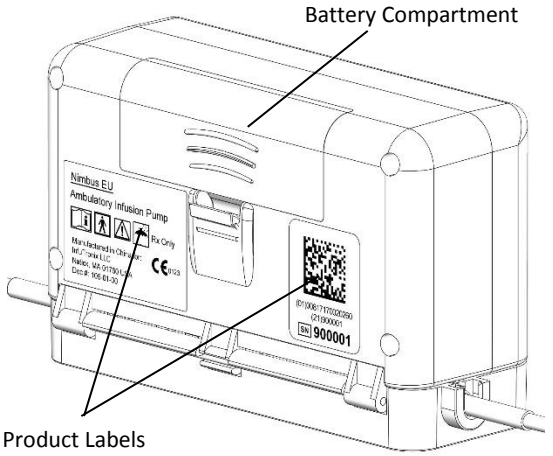
- ⚠ Always confirm that the established infusion route matches the intended administration route prior to the start of the infusion.
- ⚠ Clearly differentiate established administration routes when using the pump with a patient that has multiple administration routes established.
- ⚠ Do not operate the 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

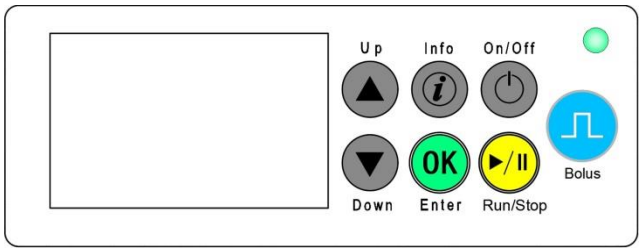
Front View



Rear View



Keypad Diagram



Key	Name	Description
On/Off	ON/OFF	Hold for 3 seconds to power on or off the device.
Run/Stop	RUN/STOP	Press to start or resume the infusion. Hold for 3 seconds to pause the infusion.
Enter	ENTER	Press to confirm an input value or to advance to the next screen.
Down	DOWN	Press to decrease the value of a parameter or move the cursor downward.
Up	UP	Press to increase the value of a parameter or move the cursor upward.
Info	INFO	In Programming mode, press to return to the previous screen. In Run mode, press to access the Infusion History menu to view Shift Totals, review the Rx, and/or Titrate protocol values.
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.

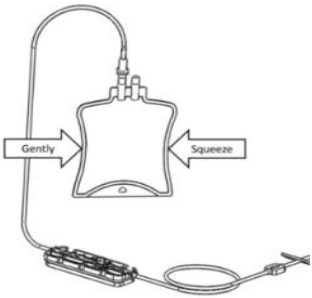
LCD Screen Symbols

Item	Name	Symbol	Description
1	Therapy Mode		The fluid bag symbol displays when the pump is infusing.
2	Configuration Mode		Displays when the pump is in the configuration mode.
3	Battery Level Indicator		This symbol indicates a full battery level.
			This symbol indicates a medium battery level.
			This symbol indicates a low battery level.
			This symbol indicates an empty battery level.
4	Alert		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.

Section 2: Setting Up the Pump

Prime the Administration Set

Prime the cassette/administration set according to the following instructions prior to connecting the cassette to the pump. Attach the primed cassette to the Nimbus™ EU pump before connecting to the patient.

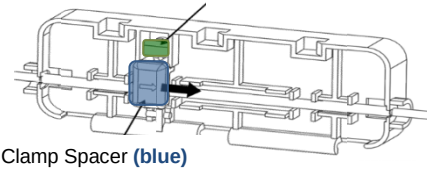


⚠ **Warning**: The Nimbus Administration set is sterile. Do not use if the package has been opened or damaged.
⚠ **Warning**: Only a non-vented collapsible medication reservoir can be used.
⚠ **Warning**: Do not use excessive pressure when squeezing the fluid bag to prime the cassette.

Caution: Use aseptic technique.

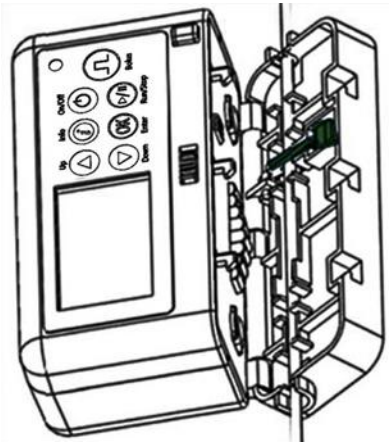
1. Prepare the drug/fluid bag.
2. Remove the cassette/administration set from the package. Close the slide clamp. When using a bag spike cassette, remove the spike cap. Fully insert the spike into the drug/fluid bag. When using a cassette with a proximal luer connector, remove the female luer lock cap. Connect the female luer lock to the medication reservoir.
3. Lay the cassette on a clean surface for priming.
4. Open the slide clamp.
5. Hold the medication/fluid bag in hand with the spike port facing up.
6. Gently squeeze the bag in order to purge air from the bag and prime the set. Continue squeezing the bag until fluid fills the entire length of the tubing and all the air has been removed from the system. The Nimbus™ EU Ambulatory Infusion Pump does not have an electronic air sensor, however does use an in-line air-eliminating filter to evacuate air from the infusion line. Close the slide clamp after priming.
7. Engage the anti-free flow clamp on the cassette by pressing the **green** clamp head and sliding out the **blue** anti-free flow clamp spacer

Caution: The blue anti-free flow clamp spacer is a small object and may cause choking if swallowed. Properly dispose of the spacer and any other unneeded small parts. Keep away from children.

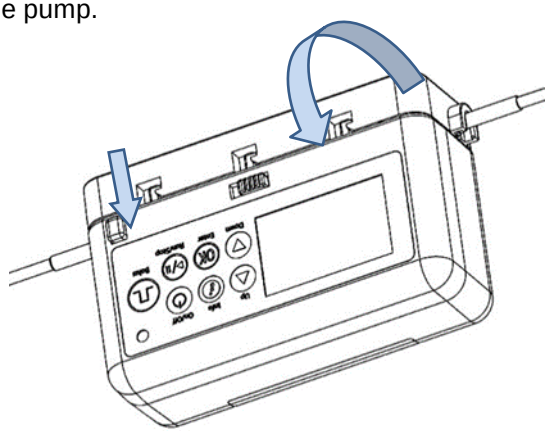


Load the Cassette

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 three hooks on the cassette latch are fully engaged with the cassette.

Section 3: Program and Operate the Pump

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

Infusion Safeguards

Before entering a prescription on the Nimbus™ EU pump, the user should be aware of the internal and external safety measures designed into the system to control the infusion delivery as protection against under or over infusion of local anesthetic.

Feature	Description
Integrated free-flow protection	Protects against gravity infusion in the event the cassette is removed or displaced from the pump.
Auto-locking keypad	Automatically safeguards the prescription against unauthorized changes.
Default Protocol Library	Pre-validated therapy values stored on the pump for rapid confirmation then automatically loaded to the active prescription minimizing keystroke entries and risk of error.
Custom Protocol Library	A user can request custom therapy modes and values are stored on the pump tailored to meet clinician and facility specifications.
Drug Name & Concentration display	Enhances clinician mindfulness to the brand, properties and strength of medication infused in the Rx.
Infusion History display	Provides clinical recognition to the therapy history to review and confirm for patient appropriateness.
Shift Totals Menu	Enables confirmation the Rx matches the med order and document infusion history for the EMR.
Basal Rate Min / Max	A protocol value cannot exceed the maximum safe limit programmed into the library or global guard.
Demand Bolus Min / Max	A protocol value cannot exceed the maximum safe limit programmed into the library or global guard.
Demand Bolus Lockout	Restricts any subsequent attempts for Boluses until a user-defined safe time interval has elapsed.
Auto-Bolus Min / Max	A protocol value cannot exceed the maximum safe limit programmed into the library or global guard
Auto-Bolus Interval	A user-defined safe interval of time that must elapse prior to the next scheduled intermittent bolus dose of medication is allowed.

Feature	Description
Max Vol/hour	Safe limits programmed into the library to set the maximum volume of medicine delivered per hour and per interval through any combination of basal rate, Demand Bolus and Auto-Bolus infusion.
Max Vol/Interval	
Delayed Infusion Start	A user-defined standby timer placing the pump in hold mode while the surgical block is in effect restricting the volume of local anesthetic delivery over the top of the primary block dose.

Protection against under-infusion or non-delivery of medication is also a deliberate goal to prevent an undesirable pain relief outcome. When a condition that could interrupt the infusion is detected, the Nimbus™ EU Ambulatory Infusion Pump will alert with a visual and audio signal to indicate the presence of the condition. Depending on the condition, the infusion may resume automatically when the event is resolved without requiring user intervention.

Alert Messages	Indication
Upstream Occlusion	Decreased pressure is detected in the supply line between the pump and IV bag. **Note**: *The infusion will be stopped automatically and will resume immediately when the condition is resolved.*
Downstream Occlusion	Increased pressure is sensed in the line between the pump and the patient. **Note**: *The infusion will be stopped automatically and will resume immediately when the condition is resolved.*
Pump Unattended	The pump is standing by and not infusing for more than 10 minutes.
Max Vol Reached, Pump Standby	The pump has reached a maximum volume per hour or interval limit. **Note**: *The infusion delivery will be paused automatically and will resume immediately when the new hour or interval timeframe is reached. The remaining volume of any active bolus or intermittent dose will be*

	scrapped.
Alert Messages	**Indication**
Battery Depleted	The infusion will continue for 30 minutes before the device powers off.
System or Firmware Error	The pumping mechanism may not work properly. **Note**: *The infusion will be stopped automatically.*

Refer to Section 5: Troubleshooting for a complete list of alerts, descriptions and troubleshooting steps.

Programming Parameter Labels

A prescription can be defined using some or all of the parameters displayed in the table below. Parameter limits programmed into the protocol Library can be more restrictive than system limits allowing the protocol to be customized to a specific therapy or patient type.

Parameter Name	Parameter Label
Basal Rate (PCA)	Rate
Volume to be Infused	VTBI
Auto-Bolus Volume	AB Vol
Auto-Bolus Interval	Q Int
Demand Bolus Volume	DB Vol
Demand Bolus Lockout	DB Lck
Maximum Volume per Hour limit	Max/h
Maximum Volume per Interval limit	Max/Int
Loading Dose	LDS
Delay Start Timer	Delay
Keep Vein Open (KVO) Rate	KVO
Intermittent Dose Volume	Dose Vol
Intermittent Dose Rate	Rate
Intermittent Interval	Q Int
Infusion Runtime	Time

Delivery Modes, characteristics and designations

Note: Delivery modes may be a combination of some or all the parameters listed in the table below.

Mode	Characteristics		
Continuous	Medication delivery at a constant, programmed rate		
	Parameters	**Minimum**	**Maximum**
	VTBI (mL)	1	1500
	Rate (mL/hr)	1	135
	Time (hh:mm)	00:00	240:00
	Delay (hh:mm)	00:00	24:00
	Max/h (mL)	1	135
PCA	A combination which may contain some or all of the following: continuous mode at a constant rate, patient requested boluses, and automatic scheduled boluses **Minimum for parameter can be 0 only if both AB Vol and Q Int parameters are also 0*		
	Parameter	**Minimum**	**Maximum**
	VTBI (mL)	1	1500
	Rate (mL/hr)	1	135
	AB Vol* (mL)	1	100
	Q Int* (hh:mm)	1	1440
	LDS (mL)	1	100
	DB Vol (mL)	0	100
	DB Lck (hh:mm)	00:00	24:00
	Delay (hh:mm)	00:00	24:00
	Max/h (mL)	1	135
	Max/Int (mL)	1	1500
Intermittent	A scheduled dose with a specified rate and volume and an optional rate in between doses		
	Parameter	**Minimum**	**Maximum**
	(Intermittent) Dose Vol (mL)	1	1500
	(Intermittent) Rate (mL/hr)	1	135
	KVO (mL)	1	10
	(Intermittent) Q Int (hh:mm)	00:00	24:00
	Time (hh:mm)	00:00	240:00
	Delay (hh:mm)	00:00	24:00

	Max/h (mL)	1	135
	Max/Int (mL)	1	1500

Basal Infusion mode

Basal Infusion delivery infuses medication at a constant, programmed rate.

Demand Bolus

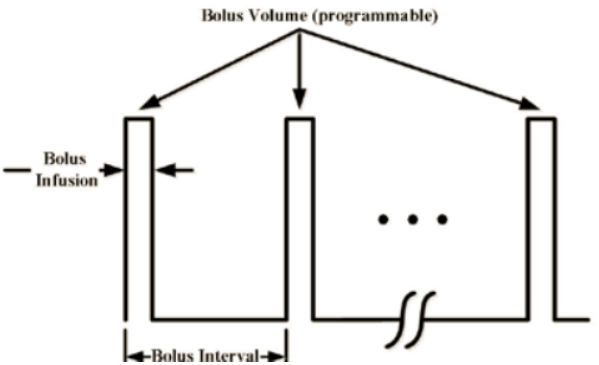
Demand Bolus delivery is a feature that allows a continuous Basal infusion supplemented with patient-controlled demand boluses. The user may define a demand bolus volume (DB Vol), Demand Bolus lockout time (DB LCK) and maximum volume per hour value (Max/h) to control the overall volume of infusion.

Auto-Bolus

Auto-Bolus delivery is a feature that allows the user to schedule intermittent volume doses of anesthetic to be delivered at regular, repeated intervals. At the discretion of the user, Basal Infusion and/or Demand Bolus delivery modes can be programmed to supplement the scheduled Auto-Bolus doses.

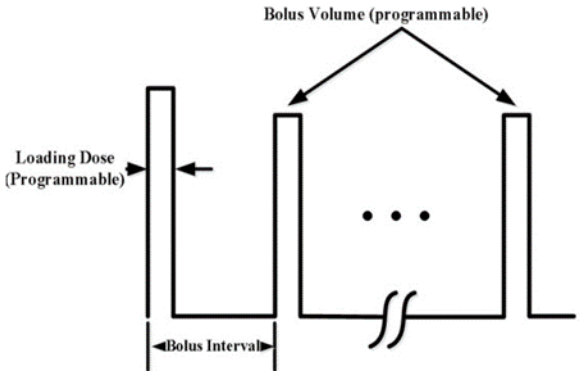
In the Auto-Bolus mode, a user may define a continuous Basal Flow, Auto-Bolus volume (AB Vol), interval (Q Int), maximum volume per hour value (Max/h) and maximum volume per interval value (Max/Int) to control the overall volume of infusion.

Upon starting the infusion, the pump will infuse the Auto-Bolus dose at the beginning of the therapy followed by the Auto-Bolus interval (Q Int).



Loading Dose

When Auto-Bolus mode is selected, the user can define a Loading Dose to be delivered at the beginning of the prescription as the primary dose immediately followed by the Bolus Interval period. When the Bolus Interval time has expired, the next scheduled Auto-Bolus dose will be delivered. At the users discretion a Basal Flow can be set to supplement the therapy during the interval periods.



Maximum Volume/hour and Volume/interval limits

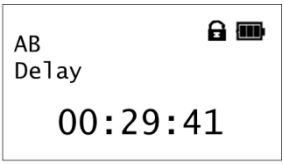
To safeguard the volume of medication delivered to the patient, the Nimbus™ EU Ambulatory Infusion Pump enables the user to define volume limits allowed per hour and/or per interval. The Nimbus™ EU Ambulatory Infusion Pump accumulates the volume of medication infused using any combination of delivery modes and stops the infusion when a maximum limit is reached.

- A message will display on the screen signaling a maximum volume limit is reached.
- The pump will remain in standby mode until the next hour or next interval is reached.
- The undelivered volume of any active Demand Bolus, Auto-Bolus or Basal infusion will be discarded.
- The infusion will automatically resume when the next hour or next interval is started and the accumulators will restart.

Delay Start Infusion

If the pain after surgery is expected to last several days, 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 while the surgical block remains in effect. 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

When the patient's pain is at a tolerable level after the surgery, the pump will count down to zero and start the infusion without any additional intervention required. However, if during the delay period the surgical pain becomes uncomfortable, the decision can be made to override the Delay Start countdown to begin the infusion immediately.

Instruct the patient to 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 the anesthesia care team.

Keypad operation

Refer to the Keypad Diagram on page 10 for a review of keypad functions to enter a prescription and navigate through the menus.

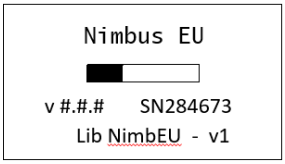
Power on the Pump

Hold the ON/OFF key 

for 3 seconds to turn on the pump. The pump starts a Power-On-Self-Test (POST). During the POST:

- The LCD displays the screen as shown to the right
- The LED flashes a red, green, yellow, off, and then red light.

- An audio tone of 1 long beep, followed by 4 short beeps.
- The software version number and the serial number of the pump are displayed.
- The protocol library information is displayed at the bottom of the screen, with the name and the version number of the library. The figure shows the default library is loaded, where “Lib NimbEU” stands for the sample library name and “v#.#.#” stands for the software version number.



If an error is detected during POST, the screen displays a corresponding alert message. Refer to Section 5: Troubleshooting for an explanation of the alert message and the correct user response.

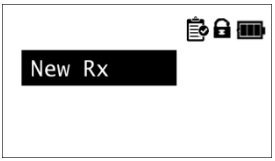
Upon a successful completion of POST, the screen displays the main menu and the LED turns to orange. The user may then program a new manual prescription or choose a default prescription from the library.

Caution: Please check the battery level prior to initial usage. Consider replacing the battery with a new one if needed.

Starting a New Infusion (New Rx)

After the pump is powered ON, the LCD displays one of the screen menus shown to the right.

- When the pump is powered on for the first time, the screen will display only “New Rx” in the menu.



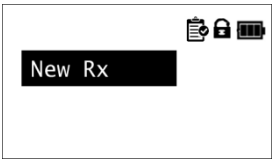
- If the pump has previously been powered on and a prescription entered, the screen will display “Current Rx” and “New Rx” in the menu.

Note: After a prescription is initiated on the Nimbus EU pump it will be saved as the Current Rx.

Note: If an infusion is started and the pump is powered off, the pump will remember the parameters where it left off when the infusion was stopped.

To program a new prescription:

1. Highlight New Rx then press the ENTER key (OK Enter).
2. If Clinician Code Lock is enabled, enter values for a valid three-digit Clinician Code to unlock the Rx.
3. Press the ENTER key (OK Enter) to continue.



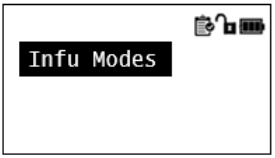
Note: The clinician codes can be disabled or customized upon request.

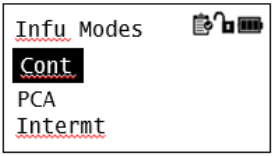
After entering a clinician code, the pump advances to the programming screen. The menu provides the option to choose to a category and then a protocol.

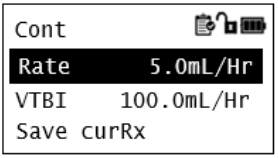
Library

To select a library protocol:

1. After entering the clinician code, the pump advances to the programming menu screen to choose a category. Use the DOWN key (Down) to move the highlight to the desired category if needed. (Screen will differ based on configuration)
2. Press the ENTER key (OK Enter) to enter the category.
3. Use the DOWN key (Down) to move the highlight to the desired protocol.
4. Press the ENTER key (OK Enter) to enter the protocol.







5. To execute the prescription after all parameters are filled, press the RUN/STOP key (Run/Stop).
6. Press the ENTER key (OK Enter) on “OK to Confirm” to confirm the Rx and begin the infusion.

To save the prescription as the current prescription (curRx):

Option only available in New Rx.

1. Use the DOWN key (Down) to move the highlight down and select Save curRx.
2. Press the ENTER key (OK Enter).

The user will be redirected to the main screen.

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:

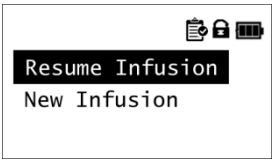
1. Access the main menu by either powering on the pump to start fresh or pressing the INFO key (Info) to scroll backward through one or more screens if necessary.

2. Highlight Current Rx.
3. Press the ENTER key (OK Enter).

Resume Infusion / New Infusion Menu

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

1. 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.

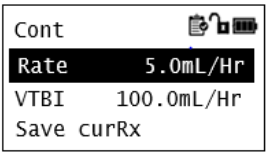


Note: The pump will detect from the infusion history whether or not a previous infusion was interrupted and left incomplete. If completed or never run, New Infusion will be the sole option displayed on the menu. Alternatively when an infusion has previously been interrupted and left incomplete the pump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

- Highlight Resume Infusion and press the ENTER key OK Enter to continue an unfinished therapy from the point it was last stopped.
- Or, highlight New Infusion and press the ENTER key OK Enter to set the pump to run a new prescription from the beginning of the therapy.

Start the Infusion

The LCD displays the therapy specific infusion parameters on the next screen. An example of the display is shown to the right.



Note: The parameter values for the Rx can be modified by entering the Clinician Code to unlock the pump then set and confirm the new values.

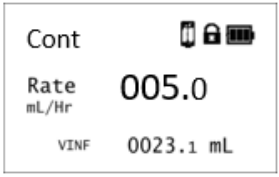
Use the down arrow key to scroll through the parameter values listed further down in the menu not shown on the display on the screen. When the appropriate settings are confirmed press the RUN/ STOP key ▶/II Run/Stop to begin the infusion.

Note: When all of the protocol values listed in the Rx have been manually confirmed, the pump will begin the infusion.

Note: If any protocol values are left unconfirmed, the pump will perform an automatic review of the prescription and prompt the user to press the ENTER key OK Enter to Confirm the prescription before starting the infusion

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.

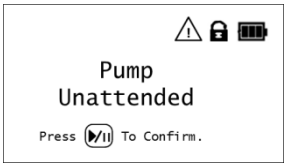


The drug/fluid bag icon will display at the top right corner of the screen. A green LED light will display for 10 minutes indicating the infusion is actively running.

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.

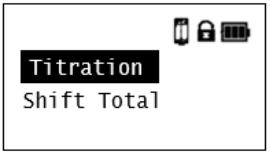


Note: Press the RUN/STOP key Run/Stop to acknowledge the alert. The audible alert, if present, will be silenced for 10 minutes.

Titrate During the Infusion

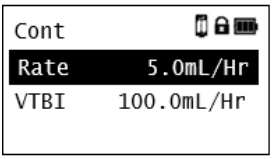
While the infusion is ongoing, the user may adjust the infusion settings through the following steps:

1. Press the INFO key (Info) to arrive at the running infusion menu.
2. Press the ENTER key (OK / Enter) to select Titration.



3. Use the UP key (Up) and DOWN key (Down) to move the highlight to the parameter that requires a new input value.

   Note: Only select parameters are titratable



4. Press the ENTER key (OK / Enter).
5. If Clinician Code Lock is enabled, enter values for a valid three-digit Clinician Code to unlock parameter editing screen

6. Press the ENTER key (OK / Enter) to continue
7. Use the UP key (Up), DOWN key (Down), and ENTER key (OK / Enter) to set a new value for the parameter.

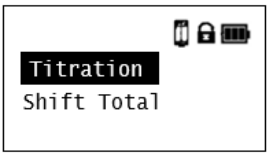
8. Press the ENTER key (OK / Enter) to confirm the change of parameter value.
9. Press the RUN/ STOP (Run/Stop) key to confirm the value change.

If there is no key press activity or confirmation by the user during the 7 second waiting period during any of these steps above, the pump will abort the infusion settings modification and maintain the previous infusion settings.

Shift Totals / Clear Shift Totals

To view active Infusion History,

- Press and release the INFO key (Info) to access the history menu.
- Highlight Shift Totals, press the ENTER key (OK Enter).
- The menu displays the Total Volume infused since the last time the totals were cleared; number of Bolus Attempts and Boluses Delivered.
- Move the cursor down through the menu to view the time since the Shift Totals were last cleared (STime) and/or Clear out the running accumulators.



Suspend/ Resume the Infusion

If the user chooses to pause the infusion, hold the RUN/STOP key (Run/Stop) 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. The infusion will be paused and the pump will display the programming screen.

- To resume the infusion, press the RUN/STOP key (Run/Stop) again to perform a new automatic review
- Press the ENTER key (OK Enter) to confirm the Rx and begin the infusion.

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.

Unload the Cassette

Follow the steps below, in the sequence shown, to unload the cassette from the pump:

1. Clamp the tubing using the slide clamp.
2. Disconnect the administration set from the patient.
3. Open the carry pouch and remove the pump (if needed).
4. Simultaneously, press the black cassette latch lock button and slide the cassette latch open.
5. Unload the cassette from the pump and properly dispose of the drug/ fluid bag and the administration set.

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.

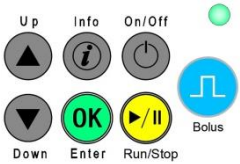
The quality of the battery is a significant factor in determining battery life and runtime. Use of batteries from any other brands may yield unexpected performance and will invalidate the warranty.

To replace the battery, follow these steps in order:

1. Hold the RUN/STOP 

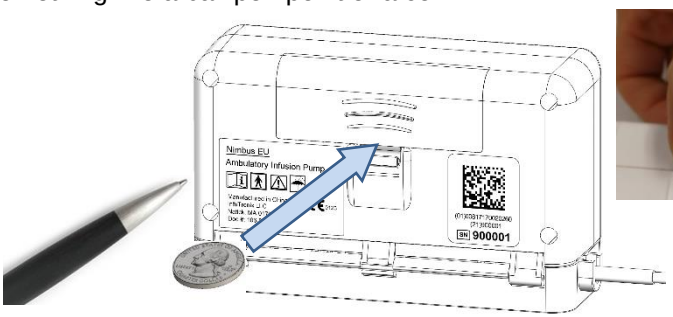
key for 3 seconds to suspend the infusion.
2. Hold the ON/OFF key 

for 3 seconds to power off the Pump.

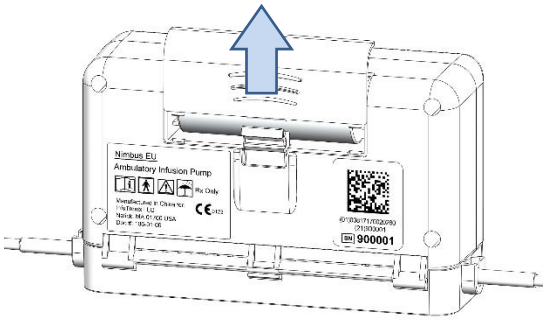


Note: Make sure the pump is powered off and disconnected from the USB outlet before replacing the battery. Do not remove the battery during an ongoing infusion.

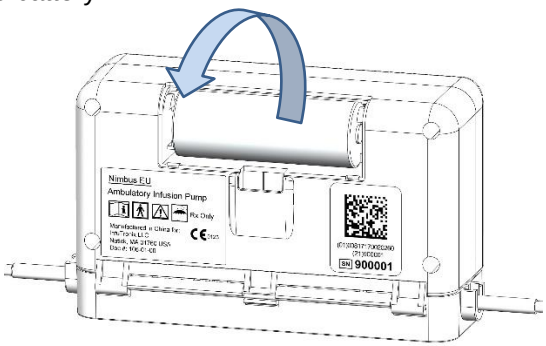
3. Push the button to unlock the battery cover by the fingertip or something like a ball pen point or a coin.



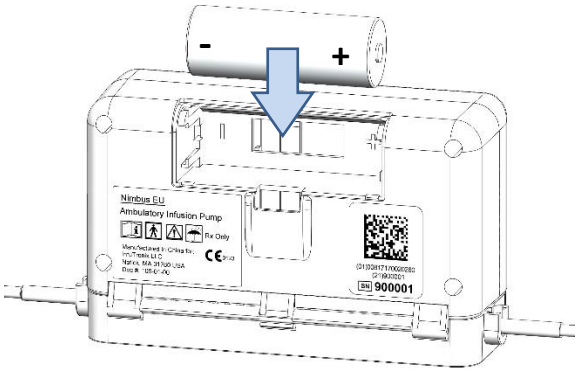
4. Slide the battery cover towards the top of the pump to remove it.



5. Remove the battery.

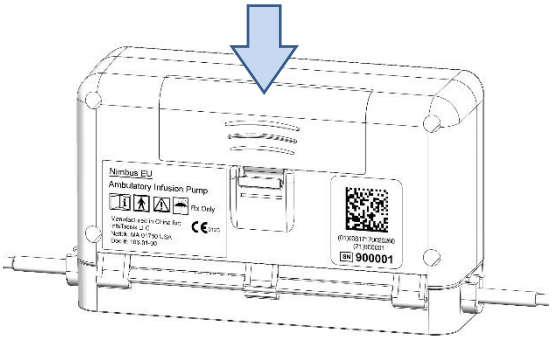


6. Insert a new battery.
Note: The battery should be inserted in the proper direction. Follow the polarity signs for the battery replacement with the positive pole facing to the right.



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 for 3 seconds to power on the pump.

   When the pump completes the POST, Press and hold the  for 5 seconds

   Using the down  key scroll to Battery Reset and press the  key. Battery icon will reset to 3 bars.

9. Resume/Start Infusion

   Press and hold the  for 5 seconds to exit Battery Reset and go back to the main screen.

The battery replacement is completed.

Section 5: Troubleshooting

When a condition that may interrupt the infusion is detected, the Nimbus™ 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
Cassette Loading Error	The cassette may not be properly loaded or has become dislodged. **Note**: *The infusion will be stopped automatically.*	The screen displays “Cassette Loading Error”; the LED flashes a red light; the audio alert sounds.	Press the RUN/STOP key to acknowledge the condition and silence the alert. 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 automatically*.	The screen displays “Upstream Occlusion”; the LED flashes a red light; the audio alert will sound immediately (optional delay) if the upstream occlusion is not resolved.	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.

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.

Section 6: Maintenance

Storage and Transportation

Store the pump away from excessive heat, cold or humidity.
When transporting the pump, please apply sufficient protection to the pump. The original package that comes with the pump is recommended. Avoid excessive heat, excessive cold, excessive humidity, shocking, dropping, or other physical impacts.

Cleaning and Disinfection

The pump should be cleaned and disinfected between patient uses, whenever the pump becomes visibly soiled, or following facility protocol.

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 a 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 the 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.

Recycling

When the pump reaches the end of its service life or the pump is no longer needed, only return the pump and discard everything else. Please contact the pump distributor for further details regarding recycling of the pump.

Service Information

If a pump fails to respond as described in this clinician manual, do not use the device. Contact qualified service personnel at our certified service provider which is posted on our website www.infutronix.com.

When submitting any request for service, include:

- A description of the difficulty experienced
- Pump serial number
- Pump settings and solution(s) used
- Description, model and lot number(s) of the cassette/administration sets in use
- Message displayed at the time of difficulty.

General information on pumps can also be requested via email: info@infutronix.com.

Product complaints or adverse incidents should be reported to the InfuTronix Complaint Handling Unit at infutronixcomplaint@infutronix.com. With each complaint, please include the pump serial number and a full description of the difficulty encountered, including all settings, types of fluids, times, and alert messages. Contact the InfuTronix Complaint Handling Unit for an RMA number prior to return.

Limited Warranty

InfuTronix LLC (hereinafter referred to as “InfuTronix”) warrants that:

A. Each new InfuTronix Nimbus™ EU Ambulatory Infusion Pump is free from defects in material and workmanship under normal use for a period of one (1) year from the date of delivery by the InfuTronix’s distributor to the original purchaser

B. Each new accessory is free from defects in material and workmanship under normal use and for a period ninety (90) days from the date of delivery by the InfuTronix’s distributor to the original purchaser.

If any product requires service during the applicable warranty period, the purchaser should communicate directly with the distributor to determine the appropriate action. Except as provided otherwise in this warranty, repair or replacement will be carried out at the expense of InfuTronix. The product

requiring service should be returned promptly, properly packaged and postage prepaid by purchaser. Loss or damage in return shipment to the repair facility shall be at purchaser's risk.

In no event shall InfuTronix be liable for any incidental, indirect, or consequential damages in connection with the purchase or use of any InfuTronix product. This warranty shall apply solely to the original purchaser. This warranty shall not apply to any subsequent owner or holder of the product. Furthermore, this warranty shall not apply to, and InfuTronix shall not be responsible for, any loss or damage arising in connection with the purchase or use of any InfuTronix product which has been:

(a) repaired by anyone other than a service representative authorized by InfuTronix;
(b) altered in any way so as to affect, in InfuTronix judgment, the product's stability or reliability;
(c) subjected to misuse or negligence or accident, or which has had the product's serial or lot number altered, affected, or removed;
(d) improperly maintained or used in any manner other than in accordance with the written instructions furnished by InfuTronix.

This warranty is in lieu of all other warranties, express or implied, and of all other obligations or liabilities of InfuTronix, and InfuTronix does not give or grant, directly or indirectly, the authority to any representative or other person to assume on behalf of InfuTronix any other liability in connection with the sale or use of InfuTronix products.

INFUTRONIX DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR A PARTICULAR PURCHASE OR APPLICATION.

Section 7: Specifications

Pump Mechanism	Linear Peristaltic
Operating Modes	Continuous Infusion mode, PCA mode, Intermittent Mode
Maximum Infusion Pressure	18 psi
Maximum Time to Occlusion Alert	20 minutes
VTBI	1 -1500 mL by 0.1 mL increment;
Basal Rate	1 mL/Hr to 135 mL/Hr in 0.1 mL/Hr increments
Bolus Infusion Rate	210 mL/Hr
Flow Rate Accuracy	+/-5%
Dimensions	4.25 in. x 2.28 in. x 1.57 in. (108 mm x 58 mm x 40 mm)
Weight	6.14 ounces (174 grams)
Power Supply	Internally powered by battery (battery not rechargeable)
Battery Life	240 h or 1500 mL of volume infused, whichever is reached first
Display	LCD
Alerts	• Cassettes Loading Error • System Error • Firmware Error • Upstream Occlusion • Downstream Occlusion • Power off and Replace Battery • Battery Depleted • Max Vol Reached, Pump Standby • Invalid Infusion Parameter • Pump Unattended • Infusion Complete
Administration Set *Feature Options (See Appendix A for details)*	• Bag Spike • Set-based Free Flow Protection • Slide clamp • 0.2 or 1.2 Micron Filter (air-eliminating) • Luer Lock Adaptor • Backcheck Valve
Optional Accessories	• Carrying pouch for pump and medication bag • Bolus cord • AC/DC Adaptor

Standards	Electrical Safety: IEC 60601-1 ed3.1 Pump Performance: IEC 60601-2-24 ed2 Electromagnetic Compatibility: IEC 60601-1-2 ed3.0 Usability and Human Factor: IEC 60601-1-6 ed3 / IEC 62366 ed1 Alarm System: IEC 60601-1-8 ed3 Home Healthcare Environment: IEC 60601-1-11 ed1 Transport: MIL-STD-810G		
Environmental Conditions		Operating	Storage/ Transportation
	Temperature	5 to 40℃	-25 to 70 ℃
	Relative Humidity	15% to 93%, non-condensing	up to 93%, non-condensing
	Atmospheric Pressure	70 kPa to 106 kPa	48 kPa to 110 kPa

Appendix A: Approved Administration Sets

⚠ Warning: Only use approved Nimbus cassettes/administration sets with the pump. The use of any other set with the Nimbus™ EU Ambulatory Infusion Pump may cause improper device operation, resulting in inaccurate fluid delivery or other potential hazards.

The following describes the only cassette/administration sets currently approved for use with the Nimbus™ EU Ambulatory Infusion Pump. For complete administration set configurations, please visit InfuTronix's web site at www.infutronix.com

Caution: Do not use a Nimbus Cassette/Administration set for longer than 240 hours. Replace the set by following CDC guidelines and/or institutional protocol.

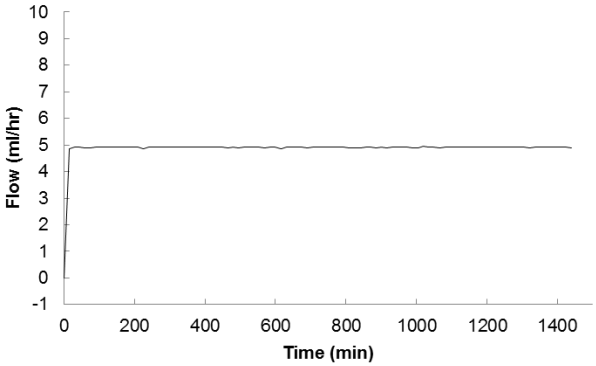
Part #	Administration set description
HS-001-EU	67" (170cm) long, fluid path is sterile (EtO sterilized), non-pyrogenic, not made of DEHP, not made with natural latex; spike cap, spike, cassette, anti-free-flow clamp, 1.2 micron air-eliminating filter, Slide clamp, male luer lock adaptor, and luer cap.
HS-002-EU	67" (170cm) long, fluid path is sterile (EtO sterilized), non-pyrogenic, not made of DEHP, not made with natural latex; spike cap, spike, cassette, anti-free-flow clamp, 0.2 micron air-eliminating filter, Slide clamp, male luer lock adaptor, and luer cap.
HS-003-EU	46" (118cm) long, fluid path is sterile (EtO sterilized), non-pyrogenic, not made of DEHP, not made with natural latex; tip protector, female luer lock adaptor, cassette, anti-free-flow clamp, slide clamp, male luer lock adaptor, and luer cap.
HS-004-EU	67" (170cm) long, fluid path is sterile (EtO sterilized), non-pyrogenic, not made of DEHP, not made with natural latex; tip protector, spike cap, spike, cassette, anti-free-flow clamp, 1.2 micron air eliminating filter, slide clamp, backcheck valve, male luer lock adaptor, and luer cap.

Appendix B: Accuracy Test Results

The following graphs are present to show flow rate accuracy of the infusion system.

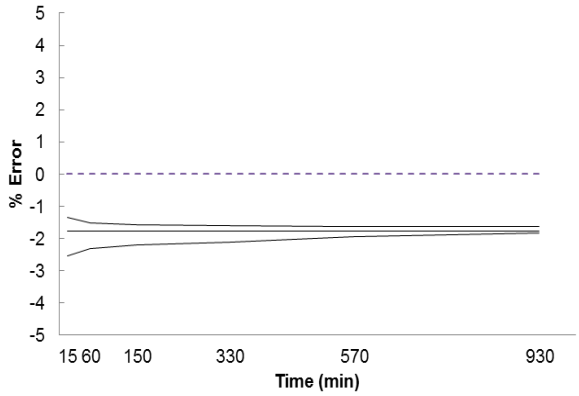
Flow rate: Intermediate

Time interval: 15 min
Total time: 1440 min
Programmed rate: 5 mL/ Hr



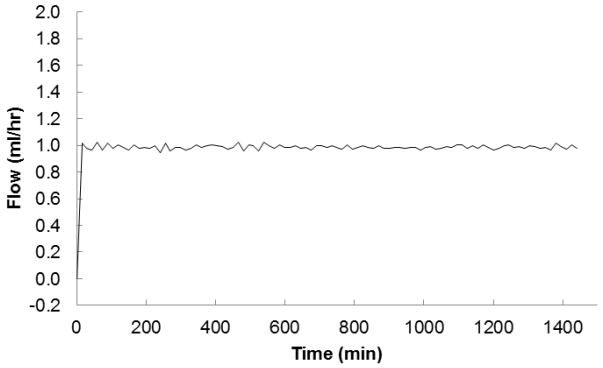
Trumpet curve: Intermediate rate

Programmed rate: 5 mL/Hr
Average flow rate: 4.912 mL/Hr
Mean flow rate error: -1.76%



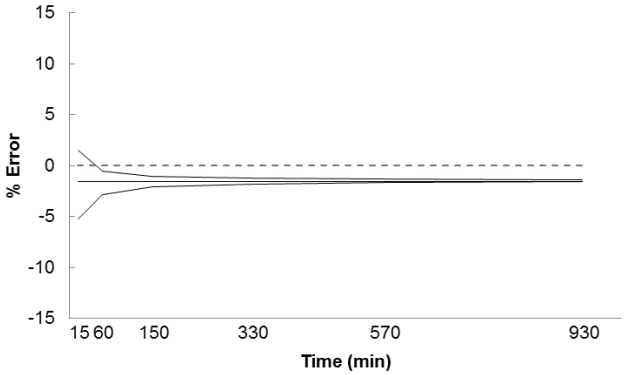
Flow rate: Minimum

Time interval: 15 min
Total time: 1440 min
Programmed rate: 1 mL/Hr



Trumpet curve: Minimum rate

Programmed rate: 1 mL/Hr
Average flow rate: 0.985 mL/Hr
Mean flow rate error: -1.51%



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Information in this manual is intended to guide clinicians in using the Nimbus™ EU Ambulatory Infusion Pump.