



Patient's Manual for Using the Nimbus™ PainPRO Ambulatory Pump for Continuous Peripheral Nerve Block Applications

PCA Mode Infusion (Software Version v4.1.2)



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

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Section 1: General Description

Indications for use

The Nimbus™ PainPRO 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. The device is intended for subcutaneous, perineural, epidural and intravenous infusion. The device is intended for 240 hours or 1500mL of infusion, whichever limit is reached first.

Symbols



Consult Instructions for Use



Serial Number



Warning



Use by YYYY-MM-DD



Federal (U.S.A) law restricts this device to sale by or on the order of a physician



Keep Away From Heat



Keep Dry



Temperature Limitations



Do Not Re-Sterilize

IP22

Ingress Protection Level



Do Not Re-Use



Type BF Applied Part



CE certificate

Note: A Note highlights information that helps explain a concept or procedure.

Caution: Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury or product damage.

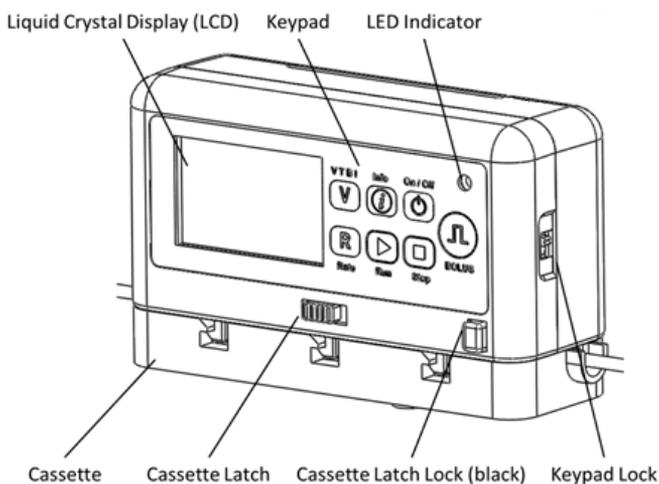
Warnings

A Warning  alerts you to a condition that could potentially interrupt the medication delivery.

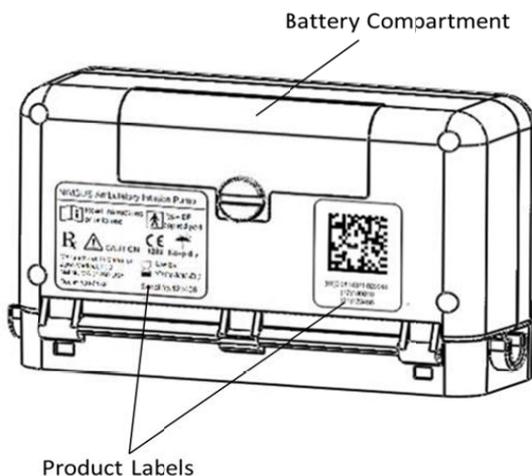
-  Read the entire Patient's Manual prior to operating the Nimbus™ PainPRO Ambulatory Infusion Pump. InfuTronix assumes no responsibility for incidents that may occur if its product is not used in accordance with its product labeling.
-  Only use the pump as directed by a physician or other certified health care professional.
-  If you have any questions regarding the use of the pump or experience any problems using the pump, contact your anesthesia care team for further instructions.
-  Do not use the pump in or near a MRI (Magnetic Resonance Imaging) device.
-  If the pump is dropped, inspect it for damage before continuing the infusion. Stop using the pump and call your anesthesia care team if it is damaged or is not functioning properly.
-  There are no user serviceable parts inside. Refer all service, repair, and calibration to qualified technical personnel. Do not make unauthorized modifications.
-  The Nimbus™ PainPRO Ambulatory Pump and cassette/administration set should only be manipulated and/or operated by a patient or caregiver under the direction or supervision of a physician or other certified health care professional
-  If a patient or caregiver is to operate the Nimbus Ambulatory Infusion pump without the direct supervision of a medical professional, the patient or caregiver should have the means to contact the patient's health care provider at all times.
-  If the Nimbus™ PainPRO 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 a physician or other certified health care professional or an adult caregiver trained by a medical professional to operate the pump.
-  Only use InfuTronix approved cassettes/administration sets with the pump.
-  Before packaging the drug/fluid bag and pump into the pouch, check the fluid path for kinks, closed clamp or other occlusions.
-  Clamp the administration set before removing the cassette from the pump.
-  Avoid spills on the Nimbus ambulatory pump; consult your health care provider should this occur.
-  Small objects may cause choking if swallowed. Keep all small parts and objects away from children.

Device Diagrams

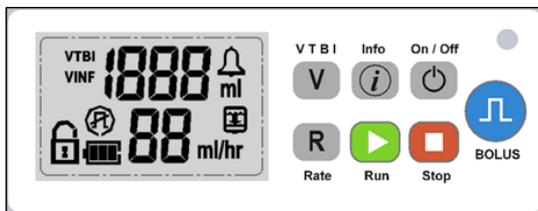
Front View



Rear View

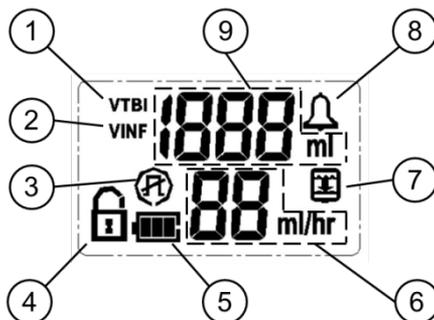


Keypad Diagrams



| Key | Name | Description |
|--|--------|---|
|  Run | RUN | Press to start the infusion. |
|  Stop | STOP | Press and hold for 3 seconds to stop the infusion. |
| On / Off  | ON/OFF | Press and hold for 3 seconds to power on or off the pump. |
|  BOLUS | BOLUS | Press to request a patient demand bolus or hold for 3 seconds to cancel a delayed infusion start. |

Full LCD Diagram



| Item # | Name | Symbol | Description |
|--------|-------------------------|---|--|
| 1 | VTBI | | When VTBI is displayed on the screen, Item 9 shows the remaining Volume to be infused. |
| 2 | VINF | | When VINF is displayed on the screen, Item 9 shows the Volume that has already been infused. |
| 3 | Bolus |  | The symbol is displayed when a bolus dose is delivered. |
| | |  | The symbol flashes if a bolus has been requested while the bolus delivery is in a "lockout" period. |
| 4 | Keypad lockout |  | Keypad is locked; VTBI and Rate keys are disabled. |
| | |  | Keypad is unlocked. |
| 5 | Battery level indicator |  | Indicates battery level: Full |
| | |  | Indicates battery level: Medium |
| | |  | Indicates battery level: Low |
| | |  | Indicates battery level: Empty |
| 6 | Flow rate | | Displays the flow rate of the infusion; or Displays "bL" during delivery of a bolus dose. |
| 7 | Infusion indicator |  | The symbol is displayed when the pump is infusing. |
| 8 | Alert |  | The symbol flashes if an alert condition is present. |
| 9 | Volume or Alert Code | | Displays volume to be infused when Item 1 is displayed; Displays volume infused when Item 2 is displayed; Displays Alert Code when an alert condition occurs and Item 8 flashes. |

Section 2: Your Nimbus™ PainPRO Ambulatory Infusion Pump

Your surgeon has prescribed a Nimbus™ PainPRO Ambulatory Infusion Pump to assist you with your pain management needs after surgery. The Nimbus™ PainPRO is an electronic pump that delivers a **numbing** medication, **not a narcotic**, to the nerves that control the feeling and movement to the area where you had surgery. The medicine delivered by the Nimbus™ Pump **will not** make you feel drowsy, nauseated, or dizzy, allowing you to feel better **faster**, resume normal activities **sooner**, and have the potential for a **quicker** recovery.

Since the surgical extremity **will be numb** (decreased sensation), it is at greater risk of injury. The following safety precautions are recommended to reduce the risk of injury and provide a more pleasant surgical experience.

Upper Extremity Blocks:

- Support your arm by wearing a sling properly; ensuring your wrist is fully supported.
- Use a pillow to pad and support your numb extremity.
- Avoid placing hot or cold packs directly on your numb extremity.
- If a dressing, cast, or brace is provided, check your fingernails frequently and alert your surgeon of any change in color.



Lower Extremity Blocks:

- Use crutches or a walker since you will **not be** able to bear weight on the numb extremity. After full sensation returns, follow your surgeons' weight bearing instructions.
- If a knee brace is provided, **do not** attempt to walk without it.
- Check your toenails frequently and **alert your surgeon** of any change in color.
- The numb extremity should be carefully padded and routinely repositioned. This practice will promote good circulation.



If shortness of breath, ringing in the ears, or a metallic taste in your mouth occurs, turn the pump off immediately and contact your anesthesiologist.

Get familiar with your Nimbus™ 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 letters “VTBI” followed by a number at the top of the screen will tell you the remaining Volume To Be Infused (VTBI) before the therapy ends.
- A green light will be on at the top right corner of the pump for 10 minutes after any key has been pressed and WILL THEN BE TURNED OFF until the next key press. After any key is pressed the green light will flash again for 10 minutes and then go back to “sleep.” This is normal.
- From time to time you may hear a sound as the motor turns to infuse the numbing medication.
- A fluid bag icon  will display on the screen for as long as the medicine is infusing.

Pause Mode

If the fluid bag icon  is missing from the display and a red or 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 an E09 alert message to tell you it is in standby mode waiting to be told what to do next. Options:

- Press the STOP  key to silence the alert and return to the main screen.
- To resume your infusion press and release the RUN  key.
- To turn the pump off press and hold the ON/OFF  key for 3 seconds.

Pump Set Up and Programming

The Nimbus™ PainPRO Ambulatory Infusion Pump should be set up and programmed by a member of your anesthesia care team. Do not attempt to perform any of these functions unless specifically instructed and trained to do so by a member of your anesthesia care team. Your pump can be programmed using any combination of the following features and advanced functions:

Volume to be Infused (VTBI) – Measured in mL, refers to the amount of numbing medication the pump will deliver during your therapy.

Basal Rate – refers to the rate the pump is running and answers the question, “how much medication will the pump infuse in 1 hour”?

Bolus – A bolus is a dose of medicine that is delivered quickly to help relieve your pain. 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 numbing medicine for rapid pain relief.

Auto Bolus – is a bolus that is programmed to infuse repeatedly over a preset period of time.

Delayed Infusion Start – If the pain after your surgery is expected to last several days, a delay start can be programmed to extend the duration of your therapy up to 24 hours longer without adding extra medicine to the IV bag.

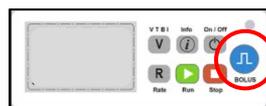
If a delay start is activated, the pump will automatically begin infusing the medicine when the timer counts down to zero. Additionally, you will be instructed on how to cancel the timer and start your infusion immediately if you begin to feel the post-surgical pain.

Section 3: Operating your pump

Cancel a Delay Start

If a delay start is set to run at the beginning of your therapy, a countdown timer will be displayed on the screen to show the time that remains before the pump automatically starts the infusion. If your pain is at a tolerable level after the surgery, the pump will count down to zero and start the infusion without any action from you. However, if during the delay period you start to feel uncomfortable due to the pain, you can choose to override the Delay Start feature to begin the infusion immediately.

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.
- The pump immediately starts the infusion as set by your anesthesia care team.

Start or Resume the Infusion

To start the delivery of medication, press the RUN  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.

Stop or Pause the Infusion

If at any time you want to stop the infusion, press and hold the STOP  key for 3 seconds, and the infusion will be paused until further action is taken. After 10 minutes an alert will sound to indicate the pump is on but not infusing medicine.

- To silence the alert, press and release the STOP  key.
- To continue with the infusion (resume), press the RUN  key.
- To turn the pump off, press and hold the ON/OFF  key for 3 seconds.

Demand Bolus – (if enabled)

If you experience pain during the infusion, you can press the blue Bolus  key to request an extra (**bolus**) dose of numbing medication. A  symbol flashes on the screen and the letters “bL” are displayed to indicate the extra dose is being delivered.

Infusion is Complete

Your infusion will be complete on the day indicated by your anesthesiologist or when the pump is empty, whichever happens first. If the bag runs until empty, the VTBI reaches 0mL and the pump stops the infusion.

- “000” flashes on the display screen indicating the end-of-infusion has been reached.
- An alert symbol flashes on the screen.
- The audio alert sounds.
- The LED flashes red.



When either situation occurs, follow the instructions given to you by your anesthesia care team regarding the steps to follow at the end of your therapy.

Power off the Pump

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



Section 4: Battery Replacement

The battery should be replaced if the pump alerts and displays the alert code E06 (as shown below).



Authorized Battery

⚠️ Only use batteries authorized by the manufacturer.

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

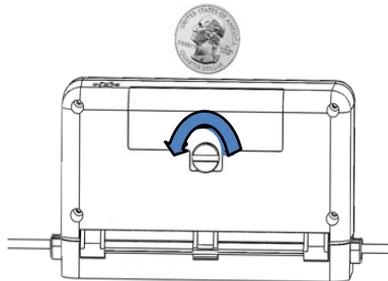
To replace the battery, follow these steps in order:

1. Press and hold the STOP  key for 3 seconds to pause the infusion.
2. Press and hold the ON/OFF  key for 3 seconds to power off the Pump.

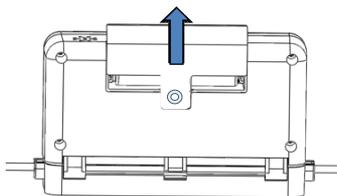


Make sure the pump is powered off before replacing the battery.

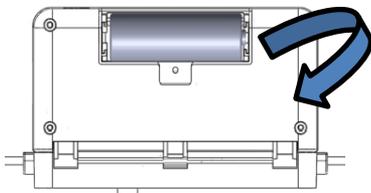
3. Turn the screw counter-clockwise to release the battery cover (a coin can be used as a screwdriver if needed).



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

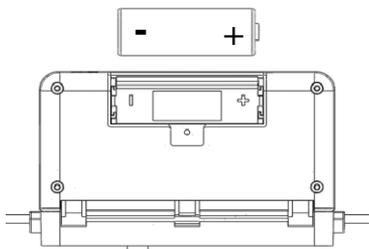


- Remove the battery.



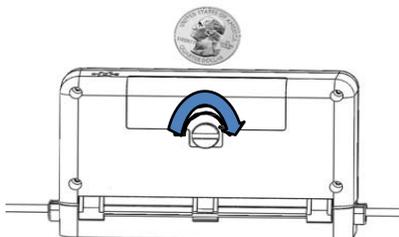
- Insert a new battery.

Note: The battery should insert in the proper direction. Follow the polarity signs for the battery replacement.



- Replace the cover and tighten the retention screw.

Turn the screw clockwise until it no longer turns freely and is seated against the back of the cover. A coin may be used to turn screw if desired.



8. Resume the infusion.

Press the ON/OFF  key to power on the pump.



When the pump completes the pretest, press the RUN  key to resume the infusion.



The battery replacement is completed.

Section 5: Troubleshooting

When a condition is detected by the pump that could interrupt the infusion, the pump will alert the user with an audio and visual signal to indicate the presence of the condition. If this occurs, contact your anesthesia care team for support.

Note: The following table is included for reference only. You can press the STOP key to acknowledge and silence the audible tone. Do not attempt to perform other functions unless specifically instructed to do so by a member of your support team.

Alert Codes

| Alert Code | Indication | Alerts |
|------------|--|---|
| 000 | End-of-infusion: The infusion is completed. | The alert code “000” flashes on the screen; The alert symbol  flashes on the screen; The LED flashes red light; The alert tone sounds. |
| E01 | Cassette Loading Error: The cassette may not be properly loaded or has become dislodged. The infusion will be stopped if this happens during an infusion. | The alert code “E01” is displayed on the screen; The alert symbol  flashes on the screen; The LED flashes red light; The alert tone sounds. |
| E02 | System Error: The pumping mechanism may not work properly. The infusion is stopped. | The alert code “E02” is displayed on the screen; The alert symbol  flashes on the screen; The LED flashes red light; The alert tone sounds. |
| E03 | Firmware Error: The system may not work properly. The infusion is stopped if this happens during an infusion. | The alert code “E03” is displayed on the screen; The alert symbol  flashes on the screen; The LED flashes red light; The alert tone sounds. |
| E04 | Upstream Occlusion: A decrease in the pressure is sensed in the supply line between the pump and IV bag. Note: The infusion is stopped. | The alert code “E04” is displayed on the screen; The alert symbol  flashes on the screen; The LED flashes red light; The alert tone will sound after 3 minutes if the upstream occlusion is not resolved. |
| E05 | Downstream Occlusion: An increase in the pressure is detected between the pump and the catheter as if the line from the pump to the catheter is kinked. The infusion is stopped. | The alert code “E05” is displayed on the screen; The alert symbol  flashes on the screen; The LED flashes red light; The alert tone will sound after 15 minutes if the downstream occlusion is not resolved. |
| E06 | Battery Depleted: The infusion will continue for 30 minutes prior to shut down. | The alert code “E06” is displayed on the screen for 5 seconds and repeats every 20 seconds; The alert symbol  flashes on the screen; The empty battery indicator flashes on the screen; The LED shows solid yellow light; The alert tone sounds. |

| Alert Code | Indication | Alerts |
|------------|---|---|
| E07 | Pump End-of-life: The pump has reached the end of its service life. | The alert code “E07” is displayed on the screen; The alert symbol  flashes on the screen; The LED flashes red light; The alert tone sounds. |
| E08 | Invalid Infusion Parameter: The infusion parameter entered has exceeded the remaining performance life of the pump. | The alert code “E08” is displayed on the screen; The alert symbol  flashes on the screen; The LED flashes red light; The alert tone sounds. |
| E09 | Pump Unattended: The pump is powered on but not infusing or counting down a Delay Start. It is standing by. | The alert code”E09” is displayed on the screen; The alert symbol  flashes on the screen; The LED shows solid yellow light; The alert tone sounds. |
| EOL | End-of-Life: The pump is approaching the end of its service life. The remaining infusion volume is less than 100mL or the remaining infusion time is less than 24 hours. | The alert code “EOL” is displayed on the screen for 3 seconds; The alert symbol  flashes on the screen; The LED light flashes yellow light; The alert tone sounds; The battery indicator decreases to 1 bar and flashes. |

Appendix A: Approved Administration Sets

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

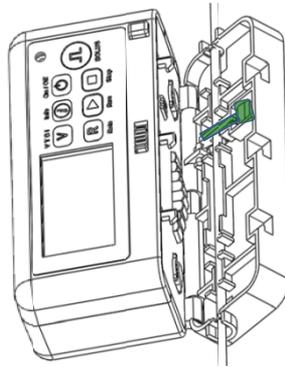
The following describes the only cassette/administration sets currently approved for use with the Nimbus™ PainPRO Ambulatory Infusion Pump.

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.

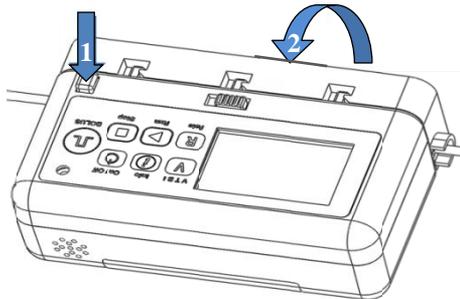
| PART # | Administration set description |
|--------|--|
| HS001 | 67" (170cm) Long, fluid path is sterile (EtO sterilized), non-Pyrogenic, not made of DEHP, not made with natural latex; Spike cap, spike, cassette, anti-free-flow clamp, 1.2 micron air eliminating filter, slide clamp, Male Luer Lock Adaptor, Luer cap |
| HS003 | 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, Luer cap |

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.

What Should You Expect Going Home with a Nimbus™ 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.
- Your surgical pain should be controlled but may not be completely eliminated.
- The Nimbus™ pain pump does not replace your pain medication after surgery. If you continue to experience pain, you can take your pain medications as prescribed. If the pain persists, contact your anesthesiologist.
- On the day of the surgery the surgical extremity will be extremely numb. On the days that follow, the extremity will be less numb. This is normal. If the sensation has not returned to normal 14 days following a nerve block, contact your anesthesiologist.
- Support for the Nimbus pump is available 24 hours a day, 7 days a week by contacting us at (844) 479-8500 or visiting our website at www.InfuTronix.com. Please keep in mind that we cannot answer therapy-specific questions.

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24/7 Technical Support:
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