

Invia[®] Liberty[™]

NEGATIVE PRESSURE WOUND THERAPY SYSTEM

EN Patient instructions for use



Assistance

Read the entire instruction manual before trying to operate the device.

If you have any questions about your Invia Liberty Negative Pressure Wound Therapy system, please contact your healthcare provider/physician at the number below:

HEALTHCARE PROVIDER/PHYSICIAN
CONTACT INFORMATION:

Keep this Patient instructions for use (IFU) booklet in an easily accessible location.

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Warnings, cautions and safety instructions

WARNING

Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTIONS

Indicates a potentially hazardous situation which, if not avoided, could result in minor or moderate injury.

General warnings

WARNING

The individual responsible for operating this device on a daily basis (patient, caregiver) must be able to read, understand and follow directions provided in this IFU, on the pump display and by the healthcare professional. The individual must be able to hear and respond to auditory signals.


Only use the Invia Liberty NPWT system on the person for whom it was ordered and only for its intended use.

Do not perform the therapy without first consulting with healthcare personnel and caregivers trained on the instructions for use and the healthcare professional's supervision.

No modification of this equipment is allowed.

WARNING

Visually check at the wound dressing and the Invia Liberty system frequently. If you see large amounts of blood in the dressing, tubing or canister:

- 1 Turn off the pump by pressing  and hold for 3 seconds.
- 2 Apply pressure to your wound.
- 3 Seek immediate Emergency Medical assistance.

If you have difficulty breathing, seek immediate Emergency Medical Assistance.






WARNING

Immediately contact your healthcare professional if you experience the following symptoms:

- Significant vision or hearing loss
- Pain, soreness or redness around the wound
- Swelling, itching, or rash around the wound
- Fever
- Strong odor from the wound
- Thick green drainage or any unusual change in color of drainage
- Nausea or vomiting or diarrhea
- Sore throat with swelling
- Dizziness or confusion
- Allergic reactions like redness, rash or hives, swelling or severe itching



WARNING

Once the healthcare professional has set the pump pressure and mode settings do not press any other button than the on/off button [], the standby button [] or the mute button [].



WARNING

The pump must be used 24 hours per day. Do not stop the pump unless instructed by your healthcare professional or if excessive bleeding occurs.

If the pump is stopped for more than 2 hours, the dressing must be changed by a healthcare professional. Contact your healthcare professional to request a dressing change.



WARNING

If the pump stops working and cannot be switched on, immediately call your healthcare professional.

CAUTION U.S. Federal law restricts this device for sale or rental by or on the order of a physician.

Purpose of the device

Your healthcare provider has prescribed Negative Pressure Wound Therapy (NPWT) for you.

Negative Pressure Wound Therapy has been shown to help promote healing in several different kinds of wounds. Negative pressure (suction) is delivered to a wound through a pump. The suction, or negative pressure, helps to remove fluid and close your wound. Your healthcare professional will place a special dressing on your wound and a tube will go from your wound to the canister on the pump. The pump is then turned on to the prescribed pressure to remove the fluid from your wound. The fluid then goes into the canister. The treatment will be on 24 hours a day.

Intended use

Intended user

The Invia Liberty NPWT system is intended to be used by healthcare professionals or adequately trained lay users. Healthcare professionals are responsible to train lay users according to the patient instructions for use and explain all related safety information.

Intended patient population

The Invia Liberty NPWT system is intended to be used on patients only exhibiting conditions as described in the indications for use. The device has not been studied in pediatric patients.

Intended environment

The Invia Liberty NPWT system is intended for use in acute, extended and home care settings.

When to use the device (Indications for use)

The Invia Liberty Negative Pressure Wound Therapy (NPWT) system is indicated for patients who would benefit from a suction device (Negative Pressure Wound Therapy) as when used on open wounds it creates an environment that promotes wound healing by secondary or tertiary (delayed primary) intention by preparing the wound bed for closure, reducing edema, promoting granulation tissue formation and perfusion, and by removing exudate and infectious material.

When used on closed surgical incisions, the Invia Liberty NPWT system is also intended to manage the environment of surgical incisions that continue to drain following sutured or stapled closure by maintaining a closed environment and removing exudate via the application of Negative Pressure Wound Therapy.

The Invia Liberty NPWT system is appropriate for use for the following indications:

- Acute or subacute wounds
- Chronic wounds
- Dehisced wounds
- Pressure ulcers
- Diabetic/Neuropathic ulcers
- Venous insufficiency ulcers
- Traumatic wounds
- Partial thickness burns
- Flaps and grafts
- Closed surgical incisions

When not to use the device (Contraindications)

The Invia Liberty NPWT system is contraindicated in the presence of:

- Necrotic tissue with eschar present
- Untreated osteomyelitis
- Non-enteric and unexplored fistulas
- Malignancy in the wound
- Exposed vasculature
- Exposed nerves
- Exposed anastomotic site of blood vessels or bypasses
- Exposed organs

If you have concerns, speak with your healthcare professional.

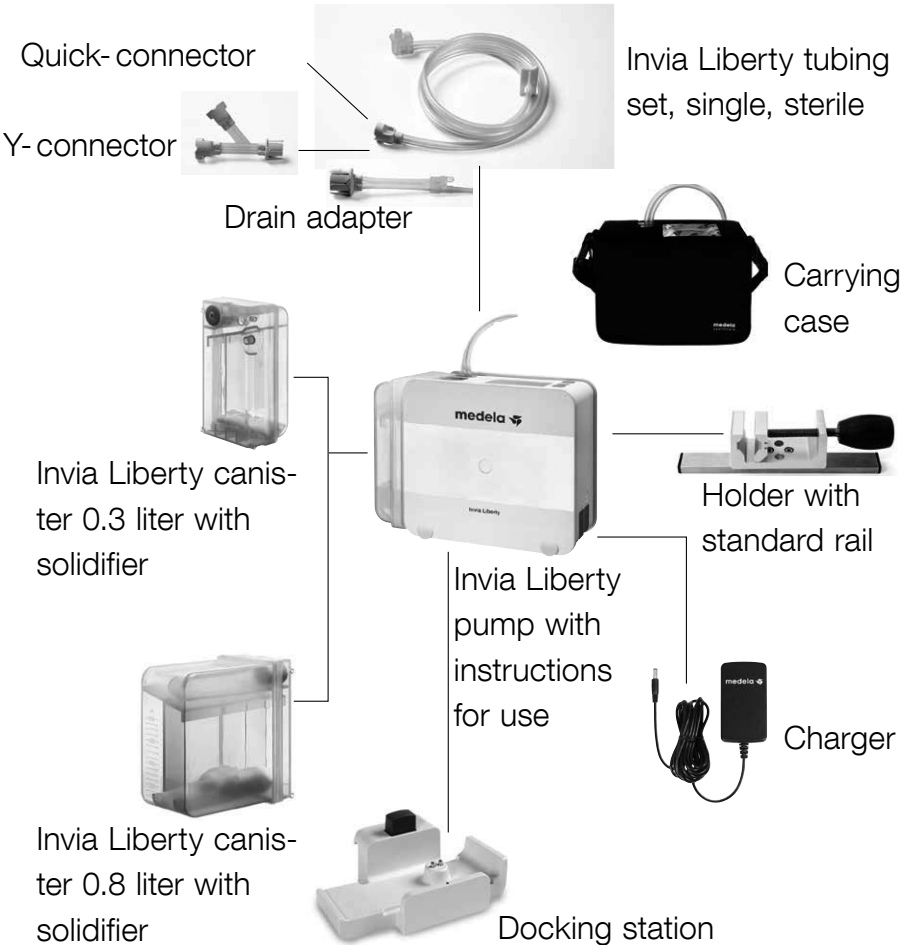
Description of the device

Check the delivery package of the Invia Liberty system for completeness and general condition.



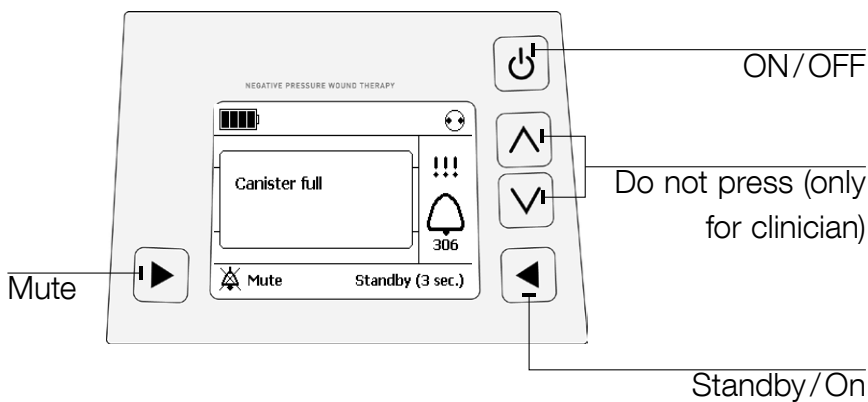
WARNING

Do not use any other accessories than the ones described below.



Display

Buttons to operate the Invia Liberty pump

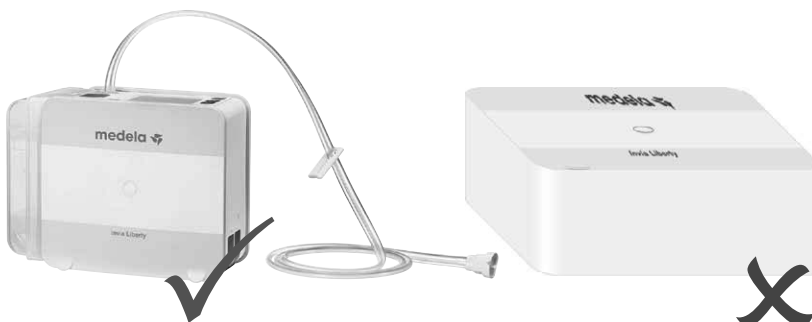


Conditions that affect use



CAUTION

The Invia Liberty pump must remain in an upright position during use.



General safety at home



Please read and observe these warnings and safety instructions before operation. These instructions for use must be kept with the device. Please note that these instructions for use are a general guide for the use of the product. Medical situations must be addressed by a physician.



CAUTIONS / WARNINGS

- Do not use extension cords with the Invia Liberty pump.
- Position the power cord so that it will not cause someone to trip and fall.
- Never place the power supply cord around your neck.
- Keep the power supply cord away from hot surfaces.
- Do not unplug the power supply cord from the wall outlet by pulling on the cord.
- Do not try to fix or repair the Invia Liberty pump. Contact your healthcare professional if the pump is not working.
- Keep the Invia Liberty pump clean and dry.
- Never place the Invia Liberty pump in water or liquids.
- If the Invia Liberty pump gets wet, dry with a towel.
- Do not dry the Invia Liberty pump in a microwave.
- Keep the Invia Liberty pump away from children and pets.
- Supervision is necessary when the Invia Liberty pump is used in the vicinity of children.
- Keep the Invia Liberty pump protected from direct sunlight.
- Explosion hazard – the Invia Liberty pump is not for use in potentially explosive environments including oxygen enriched environments and in areas of flammable anesthetics.
- Wireless communication equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, and walkie-talkies can interfere with the Invia Liberty pump and should be kept at a minimum distance of 1 foot (30 cm) away from the Invia Liberty pump. This may

cause insufficient battery charging or may lead to an internal fault. See the chapter Notifications and troubleshooting for actions to take in the case of an internal fault.

- This product contains lithium-ion batteries which bear risk of fire, explosion and burns. Do not disassemble, crash, heat above 100°C (212°F), incinerate or dispose of in fire.

If you observe a change in the vacuum level or an error condition, move the Invia Liberty pump at least 1 foot (30cm) from the mobile phone when making or receiving calls. Turn the Invia Liberty pump on and off again to reset it after an error condition. Whenever possible, a safety distance of minimum 1 foot (30cm) between the Invia Liberty pump and a mobile phone is recommended.

Sleeping



- Make sure the Invia Liberty pump tubing will not become kinked.
- Prevent the Invia Liberty pump from falling to the floor during sleep.
- Always charge the Invia Liberty pump when going to bed.

Showering, bathing and washing



- Do not use the Invia Liberty pump while bathing or showering.
- The Invia Liberty pump can be disconnected from the dressing for a short period of time (up to 20 minutes) in order to change clothes or perform personal hygiene. Discuss bathing plans with your healthcare professional.
- Prevent the Invia Liberty pump from getting wet.
- Do not put the Invia Liberty pump where it can fall into a shower, sink or tub.
- Do not touch the Invia Liberty pump when it has fallen into water. Unplug device immediately from electrical outlet and disconnect the pump from the dressing.



When you leave the house

- Check the battery status and recharge if necessary before leaving the house.
- For your convenience, place the Invia Liberty pump into the carrying case.
- Do not forget to take a spare canister and power supply with you.

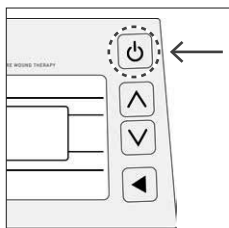
Set up instructions



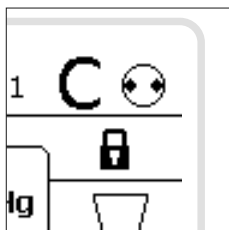
WARNING


Check the Invia Liberty pump and dressing frequently to make sure it is working. Visually check the wound dressing, area around the wound and fluid in the canister for signs of infection or other complications as provided by your health-care professional.

Turn ON



Switch Invia Liberty pump ON by pressing [].



Display view when the pump is running.
Run/Standby indicator is rotating [].



WARNING

Do not try to perform therapy without the supervision of your healthcare professional.



WARNING

NPWT must run 24 hours a day. Do not stop the therapy unless instructed by your healthcare professional or if excessive bleeding occurs.



WARNING

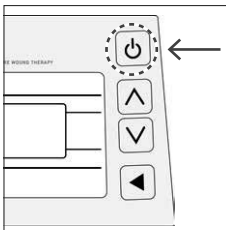
The dressing should be changed and therapy restarted by the healthcare professional if therapy is discontinued for more than 2 hours.




WARNING

Invia Liberty pump does not detect blockage along tubing connected to the drain adapter or connected to the curved arm of the Y-connector. Check dressing tubing connected to the drain adapter or the curved arm of the Y-connector frequently throughout the day to make sure tubing is not kinked or blocked.

If blockage is identified along tubing connected to the drain adapter or tubing connected to the curved arm of the Y-connector, contact your healthcare professional.



Turn OFF

Switch Invia Liberty pump OFF by pressing [] for 3 seconds. Press only once.

Set up carrying case

The Invia Liberty pump is intended to be worn in a carrying case during operation.



- 1 Open the carrying case.
- 2 Slide the Invia Liberty pump into the designated pocket.
- 3 Close the velcro over the pump.

The shoulder strap can also be used as a belt strap.

To accomplish this, release the strap at the sides of the carrying case and pull it through the two loops located on the back of the carrying case.

Charge battery

When the battery is fully charged the battery run-time generally exceeds 14 hours. If the Invia Liberty pump is running continuously due to an air leakage, the battery may need to be recharged earlier.

Battery status symbols



full

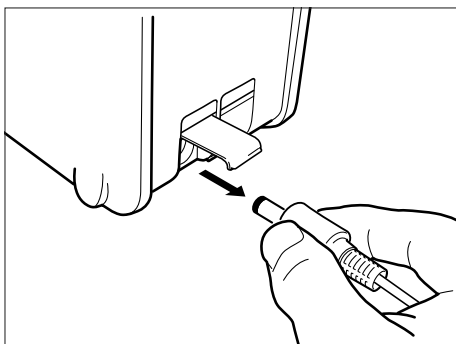


half full




fully discharged (empty)

If the battery becomes fully discharged (empty), please follow the instructions below.



Open the electrical outlet port. Connect the Invia Liberty pump to the supplied electrical plug from the power supply provided with the pump. Plug the other end of the power supply into a wall outlet. Moving bars on the battery display will indicate charging is occurring.

The battery is fully charged after approximately 4 hours. Once battery is fully charged and continues to be connected to the power source  will appear constantly on the display. After charging is completed, unplug the power supply from the wall and disconnect the Invia Liberty pump from the power supply. Close the electrical outlet port by pressing the protection cover down.



CAUTION

NPWT therapy must be continued while charging the pump's battery. Do not turn the pump off while charging.


Always charge the battery overnight.

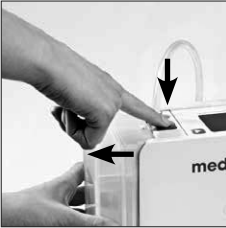
Electrical outlet port

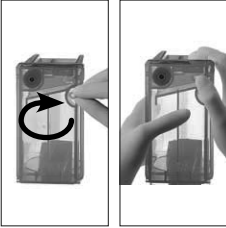


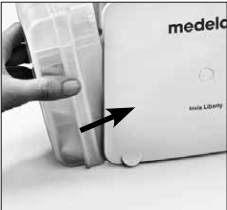
Change canister

Change canister minimum once a week, when it appears full or when the alarm sounds, in accordance with instructions on the pump display.

- 1 Wash hands.
- 2 Press the "Standby" button [ > 3 seconds] and the pump motor will stop running.

- 3  Press release button at the top of the pump and remove canister.

- 4  Seal used canister with a cap located on the side of the canister.

- 5  Unpack new canister and remove the safety sticker, position the feet at the bottom of the canister into the grooves at the base of the pump. Push the canister up and click into the Invia Liberty pump.




CAUTION

Do not use an Invia Liberty canister if the sterile packaging is damaged.



6




Switch the Invia Liberty pump on by pressing "On" [] to resume therapy and slide the pump into the carrying case.

- 7 Discard the used canister according to instructions provided by your healthcare professional.

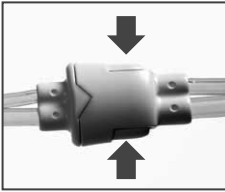
Connect/disconnect Quick-connector

The Quick-connector can be disconnected for a short period of time (up to 20 minutes) in order to change clothes or perform personal hygiene. During this time the pump can be placed in the "Standby" mode for a 5 minute interval, after which time the "Standby mode" alarm will go off and can be muted for an additional 5 minutes.

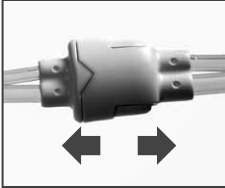
- 1 Wash hands.
- 2 Close the clamp on canister tubing and close the clamp on the dressing tubing.
- 3 Press the "Standby" button [ > 3 seconds] and the pump motor will stop running.



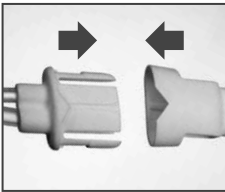
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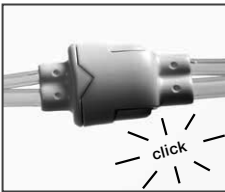
Disconnect the Quick-connector by pressing under the sides of the connector.



5



To reconnect the Quick-connector push together the Quick-connector until you hear the click.

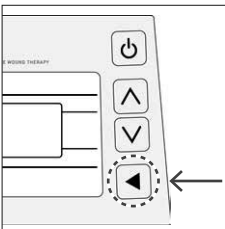



6



Open the clamp on canister tubing and open the clamp on the dressing tubing.

7




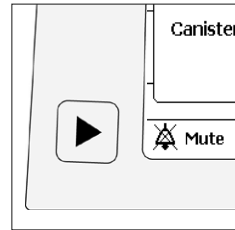
Press "On" [] to resume therapy.

Notifications and troubleshooting

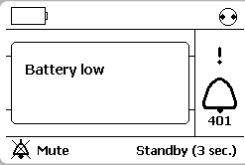
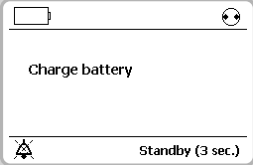
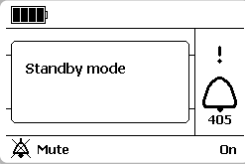
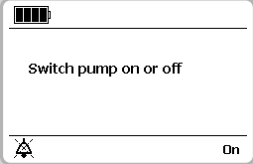
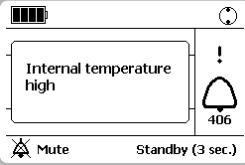
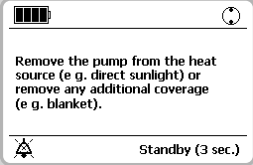
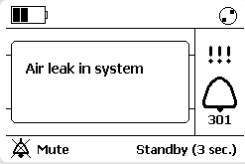
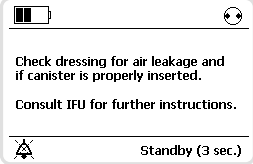
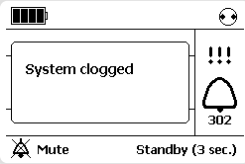
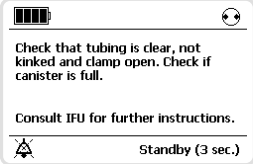
Do not panic if an acoustic signal sounds.


Follow the instructions below.

- 1 If the Invia Liberty pump is in the carrying case open the lid of your carrying case.
- 2 Press [] to mute the acoustic signal for 60 seconds (can be pressed every time the signal sounds).



Alarm table

Warning	401	 <p>Battery low</p> <p>401</p> <p>Mute Standby (3 sec.)</p>	 <p>Charge battery</p> <p>Standby (3 sec.)</p>	
	405	 <p>Standby mode</p> <p>405</p> <p>Mute On</p>	 <p>Switch pump on or off</p> <p>On</p>	
	406	 <p>Internal temperature high</p> <p>406</p> <p>Mute Standby (3 sec.)</p>	 <p>Remove the pump from the heat source (e.g. direct sunlight) or remove any additional coverage (e.g. blanket).</p> <p>Standby (3 sec.)</p>	
Alarm	301	 <p>Air leak in system</p> <p>301</p> <p>Mute Standby (3 sec.)</p>	 <p>Check dressing for air leakage and if canister is properly inserted.</p> <p>Consult IFU for further instructions.</p> <p>Standby (3 sec.)</p>	
	302	 <p>System clogged</p> <p>302</p> <p>Mute Standby (3 sec.)</p>	 <p>Check that tubing is clear, not kinked and clamp open. Check if canister is full.</p> <p>Consult IFU for further instructions.</p> <p>Standby (3 sec.)</p>	


	Remarks/potential cause of fault
	<p>Recharge the battery either by placing the Invia Liberty pump in the docking station or plug in the charger to the electrical outlet port on the pump.</p> <p>Remaining time of battery is approximately 30 minutes.</p>
	<p>If the pump is in Standby mode for more than 5 minutes, an alarm will go off.</p> <p>To continue therapy press “On” []</p>
	<p>Cool Invia Liberty pump down as per instructions on the display.</p>
	<p>Dressing:</p> <ul style="list-style-type: none"> – Check dressing for air leakage. Press firmly around the edges of the dressing, around the drain tubing or on the Invia FitPad. – May apply additional film dressing to seal the leaking area. <p>Connectors:</p> <ul style="list-style-type: none"> – Ensure that the tubing connected to the dressing is connected properly to the canister tubing. – Ensure that the canister tubing is inserted straight into the pump. <p>Canister:</p> <ul style="list-style-type: none"> – Ensure that the canister is properly inserted, release the canister and reposition. – Ensure that the orange O-ring/gasket, placed beside the canister tubing on the pump is not missing. Additional O-ring is available via Medela representative.
	<p>Call your healthcare professional.</p>

Alarm	305		
	306		
	311		
	313		
Internal fault			



CAUTION

If you are unable to identify any symbol or do not understand the alarm on the display, contact your healthcare professional.

	Remarks/potential cause of fault
	<p>Recharge the battery either by placing the Invia Liberty pump in the docking station or plug in the charger to the electrical outlet port on the pump.</p> <p>Remaining time of battery is approximately 15 minutes.</p>
	<p>Change the canister, see chapter “Change canister”.</p>
	<p>Canister: - Release the canister and reposition. Tubing: - Ensure that the tubing is not twisted, kinked or clamped.</p>
	<p>Change canister, see chapter “Change canister”.</p>
	<p>Restart the pump. If internal fault remains, turn off by pressing [ > 3 seconds] and contact your healthcare professional.</p>



WARNING

If the pump fails or cannot be switched on call your healthcare professional immediately.

Cleaning / Disinfection



The Invia Liberty pump can be wiped with a damp cloth using a mild household cleaner.

Guarantee



Warranty period is for 2 years after date of delivery.

The manufacturer is not liable for any damage or consequential damage caused by incorrect operation, inappropriate usage as well as use by unauthorized persons.

Maintenance / Safety-related check



Service work may only be carried out by authorized personnel.

A safety-related check is confined to visual inspection of the housing and charger for damage and must be performed prior to each use. If Invia Liberty pump has not been in use, the battery must be charged approximately once every 6 months to ensure optimum function.

Disposal



Ask your healthcare professional how to dispose of used dressings, canisters and tubing.

Technical specifications



Accessories storage conditions

Accessories must remain in the packaging and stored at a temperature range of -4° Fahrenheit and +122° Fahrenheit (-20° Celsius and +50° Celsius).



Operation environmental conditions

The Invia Liberty pump and accessories must be operated within a temperature range of +41° Fahrenheit and +104° Fahrenheit (+5° Celsius and +40° Celsius). Do not operate the products in extreme cold or heat. Avoid high relative humidity (15–93 % is permissible).



CAUTION

Do not operate the Invia Liberty pump above 9,842 feet above sea level (3000 meter above sea level).

Protection Class IP33

IP33

The Invia Liberty pump is protected against ingress of solids larger than 0.1 inch (2.5 millimeter) and dripping water.

Signs and symbols



This symbol indicates a CAUTION or WARNING associated with the device.



This symbol indicates a class II device.



Do not dispose the device together with unsorted municipal waste (for EU only).



This symbol indicates the date of manufacture.



This symbol indicates the name and the address of the manufacturer.



This symbol indicates the device is sterilized using ethylene oxide.



This symbol indicates that this is a prescription device. CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician (for US only).



This symbol indicates a type BF applied part.



This symbol indicates manufacturer's catalog number.



This symbol indicates manufacturer's serial number.



This symbol indicates manufacturer's batch code.

IP33

This symbol indicates the protection against the ingress of solid foreign objects and against harmful effects due to the ingress of water.



This symbol indicates that the device should not be used after the date shown.



This symbol indicates that the marked item or its material is part of a recovery or recycling process.



This symbol indicates to follow the Instruction for use.



This symbol indicates the humidity limitation for operation and storage.



This symbol indicates the compliance with additional USA and Canada safety requirements for medical electrical equipment.



This symbol indicates the atmospheric pressure limitation for operation and storage.



This symbol indicates to not use the device if package is damaged.



This symbol indicates to keep the device dry.



This symbol indicates MR unsafe.

pcs

This symbol indicates the number of items.



This symbol indicates the direct current socket.



This symbol indicates a single use device. Do not reuse the device.



This symbol indicates the temperature limitation for operation, transport and storage.



This symbol indicates to keep the device away from sunlight.



This symbol indicates to handle the fragile device with care.



This symbol indicates that the device is in conformance with the Medical Device Directive 93/42/ EEC.



This symbol indicates the correct upright position of the transport package.

Electromagnetic compatibility (EMC)

Invia Liberty is EMC-tested in conformity with the requirements of IEC 60601-1-2:2007 and IEC 60601-1-2:2014 4th Edition according clause 7 and 8.9.



WARNING

The Invia Liberty pump should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Invia Liberty pump should be observed to verify normal operation in the configuration in which it will be used.



WARNING

Do not use other accessories than those specified or sold by the manufacturer as replacement parts for internal components as it may result in increased emissions or decreased immunity of the Invia Liberty pump.



WARNING

Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Invia Liberty. Otherwise, degradation of the performance of this equipment could result.

Notes

Notes



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If you need assistance contact