

Invia[®] Liberty[™]

NEGATIVE PRESSURE WOUND THERAPY SYSTEM

- EN Clinician instruction for use
- ES Instrucciones para uso clínico
- FR Mode d'emploi à l'usage du personnel médical



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Introduction

With Invia Liberty you have selected a system for use in Negative Pressure Wound Therapy (NPWT). The lightweight Invia Liberty pump provides an adjustable negative pressure range and two therapy modes along with an electronic measuring and monitoring system. The pump is quiet during operation and has optical and acoustic status alarms for patient safety.

Invia Liberty is portable and can be operated independent of the electrical outlet thanks to a rechargeable battery. Acoustic and optical signals are triggered for variances from the set values as well as for faults.

To Consider Before Use

Federal law restricts this device for sale or rental by or on the order of a physician or professional. These instructions for use are a general guide to the use of the Invia Liberty Pump with associated products. Medical matters must be addressed by a physician.

The Invia Liberty Pump is verified within the scope of conformity evaluation and is only to be used with products included in the Invia Liberty NPWT System and distributed by Medela. Medela can only guarantee the effective and safe performance of the system with these products.

In order to ensure safe and proper operation of Medela products, a quality management system is used. Please meet the conditions below (failing to do so will void the warranty). Invia Liberty NPWT is to be used exclusively as described in these instructions for use.

- Before initiating NPWT treatment, read the instructions for use, indications, contraindications, warnings, precautions and safety instructions. Nonobservance and incorrect use can lead to considerable dangers and cause pain and injury to the patient.
- Safe and effective operation of this device requires specific instructions from a physician.
- For use only by persons who have been adequately trained in wound care and negative pressure wound therapy.
- Therapy changes (pressure level, constant or intermittent mode) should only be done as prescribed by physician's order.
- In these instructions for use "pressure" in general implies "negative pressure".
- Please keep in mind that each wound is unique and must be assessed by a qualified medical professional who must use his / her best judgment when applying this therapy. The pressure level and therapy mode must be adapted to each individual patient according to his / her medical knowledge and according to the wound healing phase.

Intended Use

The Medela® INVIA Liberty Wound Therapy is indicated to help promote wound healing, through means including drainage and removal of infectious material or other fluids, under the influence of continuous and/or intermittent negative pressures, particularly for patients with chronic, acute, traumatic, subacute and dehisced wounds, partial-thickness burns, ulcers (such as diabetic or pressure), flaps and grafts.

Invia Liberty is intended for use on people in all units of the hospital and in the home area and may only be used by trained persons after getting instructions. They may not be hard of hearing or deaf and must have normal visual acuity.

Indications for use

The types of wounds indicated are:

- Diabetic/Neuropathic ulcers
- Pressure ulcers
- Chronic wounds
- Acute wounds
- Dehisced wounds

Contraindications

Contraindicated for patients with:

- Malignancy of the wound
- Untreated osteomyelitis
- Unmanaged malnutrition
- Non-enteric fistula
- Unexplored fistula
- Necrotic tissue with eschar present
- Do not place Invia Wound Therapy dressing over exposed blood vessels or organs
- Do not place directly over anastomoses or sutured vessels

Warnings, Cautions and Safety Instructions



WARNINGS

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.



Safety Related Tip

Indicating useful information about the safe use of the device.

The Invia Liberty Negative Pressure Wound Therapy System (subsequently named Invia Liberty NPWT System) is intended for the use described in these Instructions for Use.

Medela is only responsible for the effect on BASIC SAFETY, reliability and performance of the Invia Liberty NPWT System if it is used in accordance with the Instructions for Use.

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.

Warnings



WARNINGS

- Do not modify this equipment without authorization from the manufacturer.
- This manual provides general guidelines for the use of the Invia Wound Therapy.
- The safe and effective operation of this device requires specific instruction from physician.
- No modification of this equipment is allowed.
- For use only by healthcare professionals who have been adequately trained in suction procedures, wound care, negative pressure wound therapy and in the use of aspirators or adequately trained lay users. Healthcare professionals are responsible to train lay users according to the Patients Instructions for Use and explain all related safety information.
CAUTION: Incorrect use can cause pain and injury to the patient.
- Consult the indications for use, precautions and contraindications when using the Invia Liberty as a vacuum source with the Invia Wound Therapy. Failure to read and follow all instructions in this manual prior to use may result in death or injury of the patient.
- Failure to obtain consent and any additional instructions from the treating physician prior to use, may lead to death or injury of the patient.
- Before you plug in the device, please check that your local power supply is the same as the voltage given on the specification plate.
- The device is not for use while bathing, showering or suitable for a hazardous explosive environment.
- Do not dry Invia Liberty with microwaves.
- Data transfer via USB is not possible in the running mode.
- A patient undergoing NPWT requires frequent supervision. Objective indications or signs of possible infection or complication must be addressed immediately (e.g. fever, pain, redness, increased warmth, swelling or purulent drainage). Monitor the device, wound, surrounding skin and patient status and comfort level frequently to ensure efficient, safe treatment and patient comfort.
- Do not place the foam/gauze dressing directly on exposed blood vessels, organs, nerves, tendons, bones or ligaments. When using the Invia Liberty NPWT system in close proximity to these structures a protective barrier, such as a non-adherent wound contact layer, must be used.
- Serious or fatal injury can result from bone fragments or sharp edges (e.g. staples or hardware) that could puncture protective barriers, vessels or organs.
- Patient must be closely monitored for bleeding. If sudden or increased bleeding is observed, immediately stop use of the pump, apply pressure on wound dressing and seek immediate Emergency Medical Attention.
- Should a spinal cord injury patient experience autonomic hyperreflexia, discontinue treatment with the Invia Liberty NPWT System and consult a physician immediately.

- Never place the Invia Liberty pump in water or liquids. Clamp the drain and disconnect from the dressing prior to bathing or showering.
- Consider use of a protective barrier on skin that may come in contact with the tubing, especially in those patients with fragile skin.
- Do not use oxidizing agents, such as hydrochlorite solutions or hydrogen peroxide in the wound before use of foam dressing.
- Invia Wound Therapy instructions advise 24 hours therapy without interruption. If therapy is discontinued for more than 2 hours using foam or 24 hours using gauze, the dressing should be replaced and therapy restarted by a healthcare professional.
- This device has not been studied in pediatric patients.
- Clamp the drain and disconnect the Invia Liberty pump prior to patient entering hyperbaric oxygen chamber (HBO) or Positron Emission Tomography (PET).
- The Invia Liberty NPWT system is not for use in the Magnetic Resonance (MR) Environment, so do not take the Invia Liberty NPWT system into this environment.
- In the event that defibrillation is required, disconnect the pump from the wound dressing before the patient is defibrillated.
- Special care is advised for dressing placement and removal in order to avoid situations such as unintentional gauze or foam retention.

Medela makes no assurances as to the efficacy of the Invia Wound Therapy.

Contact your local Medela customer service representative for assistance with product operations.

Cautions



CAUTIONS

The following statements describe medical conditions that may require special care for the safe and effective use of the Invia Wound Therapy.

- Patients at high risk for bleeding and hemorrhage.
- Patients taking anticoagulants or platelet aggregation inhibitors, or in patients experiencing active bleeding or difficult wound hemostasis.
- Wounds that involve a fistula.
- Using Invia Wound Therapy in close proximity to blood vessels and organs or exposed organs, vessels, nerves, tendons, or ligaments. Provide necessary protection of all vessels and organs using a protective barrier.
- Patients with a history of vascular anastomosis or friable, irradiated, sutured or infected blood vessels.
- Use near vagus nerve (bradycardia) or use on patients with a history of spinal cord injury (stimulation of sympathetic nervous system).
- Circumferential dressing application.

Incorrect use may cause pain and injury to the patient. Excessive negative pressure, a too tight adhesive cover dressing, or an infection of the wound may cause pain to the patient. In either case, the dressing must be removed and the wound assessed.

The patient should be monitored regularly according to physician instructions and facility guidelines to monitor patient comfort, therapy compliance and signs of wound infection.

Do not use a Invia Liberty canister or tubing if the sterile packaging is damaged. The Negative Pressure Wound Therapy must be used 24 hours per day without interruption. If the pump is stopped for more than the time frames shown below, the dressing must be changed and therapy restarted.

Gauze dressing: Change dressing if the pump has stopped for more than 24 hours.

Foam dressing: Change dressing if the pump has stopped for more than 2 hours.

Consider the patient's size and weight when prescribing this device.

Consider mode of therapy – intermittent versus continuous.

Safety instructions

- Before you plug in the device, please check that your local power supply is the same as the voltage given on the specification plate.
- The Invia Liberty Pump is verified within the scope of conformity evaluation and is only to be used with products included in the Invia Liberty NPWT System and distributed by Medela. Medela can only guarantee the effective performance of the system with these products.
- The use of mobile telephones, local area networks (LAN) including wireless (WLAN), walkie-talkies (two-way radios) and cordless telephone sets may affect the Invia Liberty NPWT Pump. A safe distance of 3.3 feet (1 m) from the Invia Liberty NPWT Pump to the device is recommended.
- The patient should be regularly monitored according to facility or institution guidelines.
- Invia Liberty Pump must remain in an upright position during use.
- Supervision is necessary when the Liberty Pump is used in the vicinity of children.
- Do not use Invia Liberty Pump if:
 - The power cord or plug are damaged
 - The device is not functioning properly
 - The device is damaged
 - The device has apparent safety defects
- Never pull the plug out of the main socket by pulling on the connecting cable.
- Keep the Invia Liberty Pump with associated products away from hot surfaces.
- Never place the Invia Liberty Pump, charger or docking station device in water or other liquids and keep the charger connector away from moisture or immersion in water.
- The Invia Liberty Pump must not be used for suctioning explosive, easily flammable or corrosive liquids.
- The tubing connected to the canister must never come in direct contact with the suction area.

Wound Assessment



CAUTION

Patient Monitoring: The patient should be monitored regularly according to the physician's instructions and facility guidelines to check for patient comfort, therapy compliance and signs of infection.



WARNING

Objective indications or signs of a possible infection or complication must be addressed immediately (e.g. fever, pain, redness, increased warmth, swelling or purulent discharge). Non-observance can lead to considerable danger to the patient.

Observe wound/periwound tissue and exudate for signs of infection or other complications. Most common signs of infection include redness, tenderness, fever, swelling, itching, increased warmth in the wound area, strong odor or purulent discharge. Additional symptoms include nausea, vomiting, diarrhea, headache, dizziness, fainting, sore throat with swelling of the mucous membranes, disorientation, high fever ($>102^{\circ}$ F, 38.8° C), refractory hypotension, orthostatic hypotension, or erythroedema (a sunburn-like rash). More serious complications of infection include pain, discomfort, fever, gangrene, toxic or septic shock. If more serious complications of infection occur, discontinue therapy and consult a physician immediately.

Safety-related Checks

For the safety-related checks, the device should be maintained and repaired throughout its service life in compliance with the Service procedures.

The Invia Liberty Pump is a device in protection class II (EN IEC 60601-1), the safety-related checks are confined to visual inspection of the housing and charger for damage. This check must be performed prior to each use.

Devices of protection class II do not have a protective earth conductor; there is therefore no need to check the earth leakage current.

The Invia Liberty Pump enclosure is made entirely of insulated material. Tests of the enclosure leakage current using common measuring instruments will therefore not reveal measurable values. Even when suctioning a conductive fluid until the overflow protection device activates, measurements of the patient leakage current using common measuring instruments will not reveal measurable values.


Invia Liberty Pump does not have patient circuits or functional earth connections.

Dressing Technique


Consult the appropriate Invia or Avance® Dressing Kit Instructions for Use for information regarding dressing applications. Perform a thorough wound cleansing per physician orders prior to dressing applications.

Routine dressing changes should occur every 48 to 72 hours. Dressing changes for infected wounds should be considered more frequently.

Dressing change

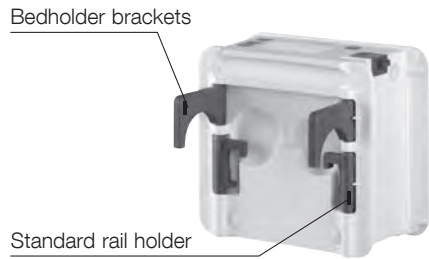
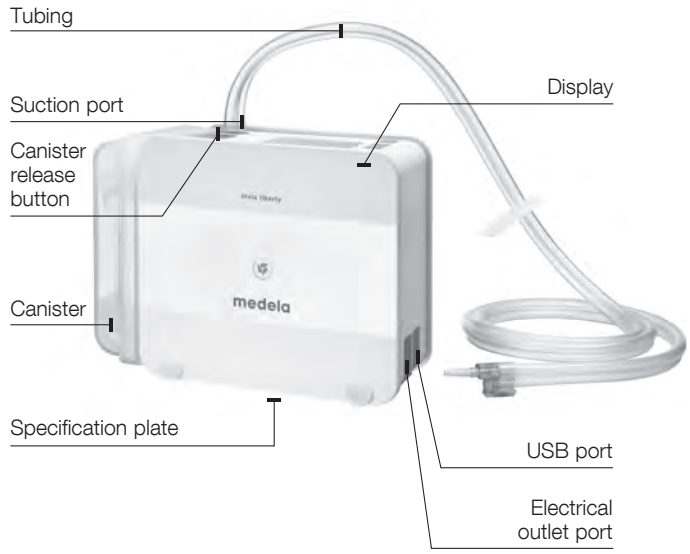
 Dressings (wound contact layer, wound filler, wound cover, drain, External Suction Interface (ESI)) should be changed every 48 to 72 hours, but no less than 3 times a week, or as instructed by the healthcare professional.

When treating infected wounds or wounds more susceptible to tissue in-growth into wound filler material, more frequent dressing changes may be needed. The frequency of dressing changes should be based on an evaluation of the wound characteristics rather than standard recommendations.

 Important things to remember:

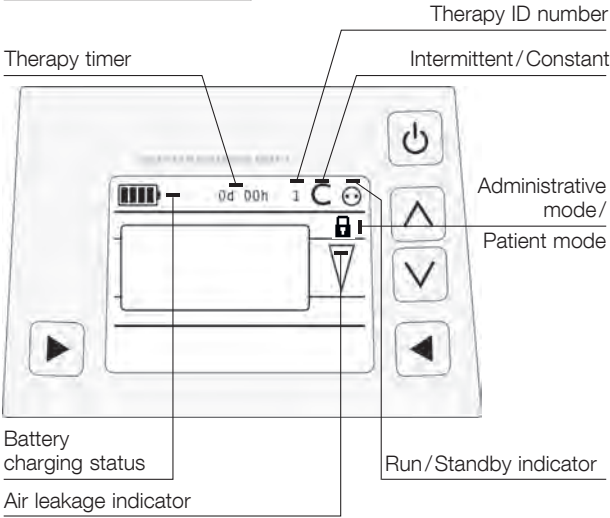
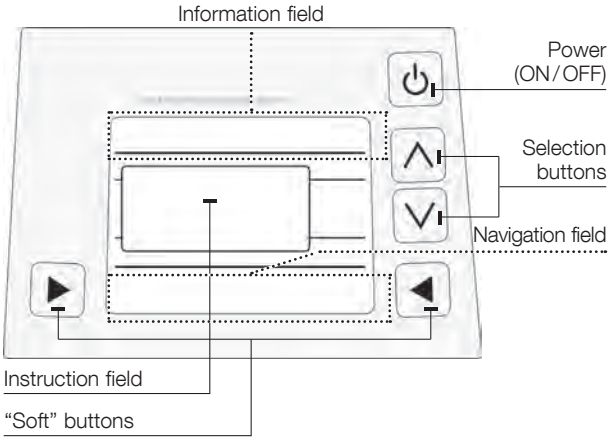
- Routinely check that the pump is on, negative pressure level and therapy mode is set as prescribed by physician.
- Monitor dressing periodically for leaks.

Invia Liberty Pump



The max flow of Invia Liberty Pump is 5 liters/minute with an adjustable pressure range of -60 to -200mmHg (-8 to -27 kPa).

Display



Invia Liberty Pump Disposables

Invia Liberty Canister with solidifier 300 ml and 800 ml



Material: Polypropylene
Accuracy of graduation: $\pm 2.5\%$ (in the upright position)
Composition of solidifier: Cross-linked sodium polyacrylate



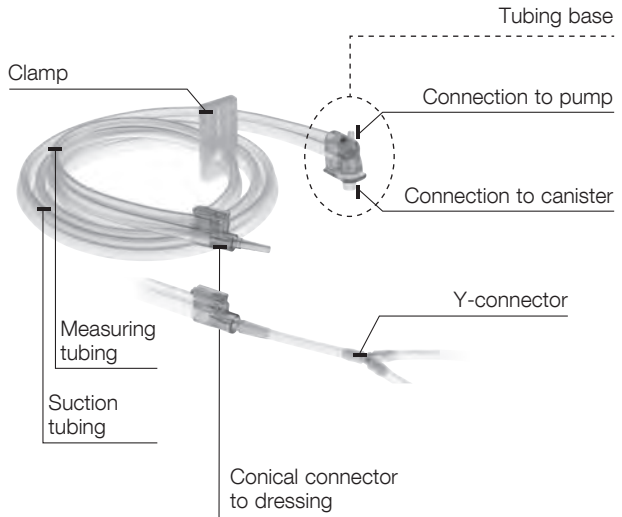
CAUTIONS

For appropriate, safe operation Invia Liberty Pump must remain in an upright position during use.

If the pump tips over, set it upright again. The special construction of the safety chamber in the upper region of the canister protects the overflow protection/bacteria filter from clogging immediately, if tipped over.

When the canister is full and the pump tips over, this function is made inoperative, since the secretions will flow into the safety chamber and clog up the hydrophilic filter. In this case an alarm will sound and the canister will need to be replaced.

Invia Liberty Tubing/Y-connector



Material: PVC (medical grade)
Length: 1.5 m
Diameter: 3.6/5.1 mm

The tubing is comprised of two lumens:

The smaller lumen (measuring tubing) regulates the pressure and the larger lumen (suction tubing) removes the fluid from the wound into the canister. A hydrophilic overflow protection/ bacteria filter in the tubing base helps prevent contamination of Invia Liberty Pump. Air flushing of the tubing occurs automatically every 5 minutes and helps prevent clogging of the tubing.

Power Supply



CAUTIONS

Before you charge the device, please check that your local power supply is the same as the voltage given on the specification plate.

Invia Liberty Pump is operable while connected to the electrical power supply or by the internal re-chargeable lithium-ion battery. While in use and connected to the electrical power supply, the battery is re-charged.

The charge on the battery is dependent upon the run-time of the pump. The run time refers to the effective operation of the motor. Invia Liberty Pump only turns on when the measured pressure is lower than the set pressure. If the Invia Liberty Pump is running continuously, Medela suggests a maximum of 4 hours of battery usage before it is necessary to re-charge. The average run time of the battery exceeds 10 hours. This is influenced by the size of the wound, the air leakage in the system and the set pressure. If there is a leakage in the system, the pump will run more often which will reduce the battery run-time.

USB Port

Additional equipment connected to medical electrical equipment must comply with the respective IEC or ISO standards (e.g. IEC 60950 for data processing equipment). Furthermore all configurations shall comply with the requirements for medical electrical systems (see IEC 60601-1-1 or clause 16 of the 3Ed. of IEC 60601-1, respectively). Anybody connecting additional equipment to medical electrical equipment configures a medical system and is therefore responsible that the system complies with the requirements for medical electrical systems. Attention is drawn to the fact that local laws take priority over the above mentioned requirements. If in doubt, consult your local representative or the Medela Customer Service Department.

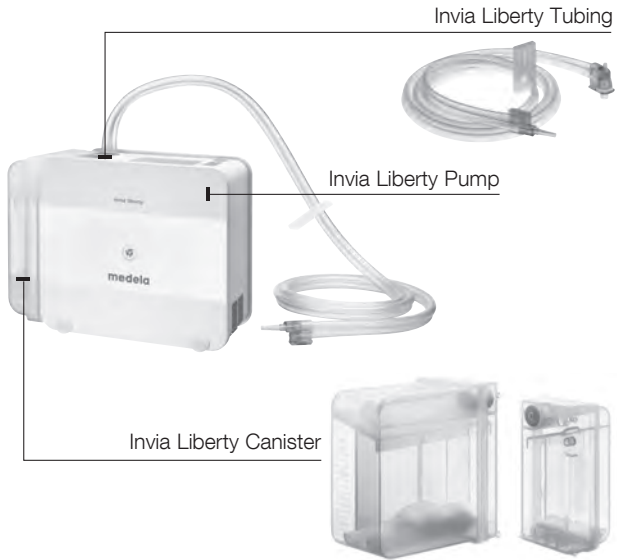
Preparation for Use



WARNING

Use only after instruction by trained personnel. Wear gloves for all operations and utilize universal precautions..

1. Check necessary parts.



2. Connect Invia Liberty Tubing

1.



1. Open external packaging. Keep the inner packaging, as it is used for the functional check.

2.



2. Insert the tubing base into the pump as shown (straight push).

3. **Click in Invia Liberty Canister**
Open external packaging.

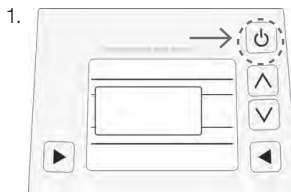


1. Slip the pegs at the bottom of the cannister into the slots at the base of the pump. Lift cannister towards pump until it clicks into place.



2. “Click” into place.
Canister secures tubing

4. **Switch Invia Liberty Pump ON**
by pressing [].



1. The pump will do self-test and start running immediately. You should hear the motor running for a short time until the pressure is built up. If the motor keeps running for more than 30sec. – check system and retry.

5. **Conduct functional check to ensure adequate seal.**



1. Seal off the conical connector of the tubing with your thumb (through the inner packaging).



CAUTION

Ensure tubing is not bent during the functional check.

6. If functional check was successful, **switch OFF Invia Liberty Pump** by pressing [> 3 seconds]. If the self-test is not successful, follow instructions shown on the display or see the Alarms chapter.
7. Connect the Invia Liberty Tubing Connector to the wound drain tubing or the tubing of the External Suction Interface (ESI). For dressing applications, please refer to Instruction for Use provided with the Invia and Avance® Dressing Kits. Switch Invia Liberty pump on as described in the User Modes.

Invia Liberty Pump User Modes

Administrative mode

Used by healthcare professional to either set up new patients or to change pump settings such as pressure, constant and intermittent modes, language and time zone.

You can enter the administrative mode in both user modes and in standby mode.

Patient mode

In Patient mode the pump can be turned on and off, placed in standby mode and alarm can be muted. In this mode the canister and tubing can be changed and the pump can be charged.

When the pump is turned off in this mode, last settings are used by default.

Administrative Mode

 The default settings of the Invia Liberty Pump are -60 mmHg and constant mode.





CAUTION

The pressure level should always be set according to Physician's instruction.

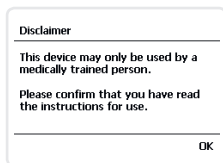
The set pressure is measured and controlled at the end of the conocal connector on the canister tube.




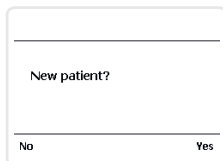
1. **Switch Invia Liberty Pump ON** in Administrative mode, press and hold [], press [].

Self-test starts

If the self-test is not successful, follow instructions shown on the display or see the Alarm chapter.



2. **Acknowledge disclaimer.** Press “OK” [] to confirm.



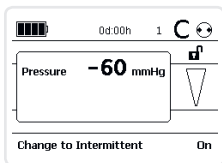
“New patient? Yes/No”

“Yes” means that Invia Liberty Pump will issue a new therapy ID number (= new patient).

This number can be noted in the patient's file.

The therapy ID number is displayed in the information field.

“No” means that the therapy ID number and settings remains unchanged (= same patient).



3. If yes

Press “Yes” [] to confirm.

Press “OK” [] to enter the main display.

4. If no

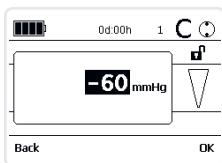
Press “No” [] to confirm and enter the main display.



CAUTIONS

Set the pressure level and therapy mode according to prescribing healthcare professional instruction.

To change the pressure level



5. Press the Selection buttons [] or [] to set pressure level.

6. Press “OK” [] to confirm and enter the main display.

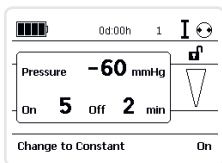
7. To return to the main display, press “Back” [].



CAUTIONS

If the pressure level is not confirmed, the pump will switch back to the old settings and returns automatically to the main display after 5 seconds.

To change the therapy mode



Constant mode – C

The pre-selected pressure is built up and kept constant.

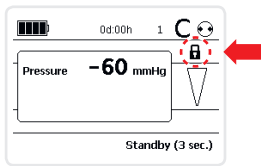
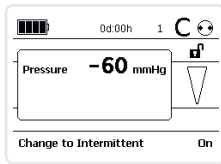
8. To change from intermittent mode to constant mode, press []

“Change to Constant” and press “On” [].

Intermittent mode – I

The pre-selected pressure is built up and the pre-selected time intervals are used.

9. To change from constant mode to intermittent mode, press [] “Change to Intermittent” and press “On” [].



10. Apply the dressing, refer to the individual Dressing Kit IFU. Connect the canister tubing to the dressing.
11. Press “On” [] to start the pump.

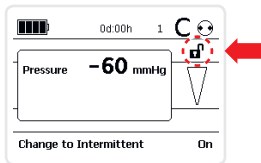
1 minute after the last button has been pressed, the Invia Liberty Pump switches into patient mode automatically and the display is locked.

1 minute after the last button has been pressed, the backlight turns off. When alarm is activated or any button is pressed, the backlight will illuminate.

The settings can only be changed when the pump is in the administrative mode.

The settings possible to change are the Pressure, Unit pressure, On time, Off time, Language and Time zone. Pump number, Pump run-time and Version can only be viewed and not changed.

Change settings

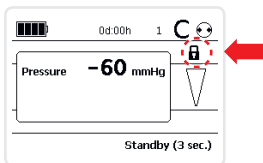


1. To enter the administrative mode, unlock the display by press and hold [], press [].
2. Press the soft buttons [+] at the same time.
3. To change setting, choose with the Selection buttons [] or [].

Settings 1/2		Selection
Pressure	-60	-60 to -200mmHg (-8 to -27kPa)
Unit Pressure	mmHg	kPa/mmHg
On time	2 min	1 – 8 min
Off time	3 min	1 – 8 min
Language	English	Languages according to list
Back	OK	

Settings 2/2		Selection
Time zone	+0 h	+12 until -12 hours GMT
Pump number	00867	as displayed
Pump run-time	1 h	as displayed
Version	1.02	as displayed
Back	OK	

Settings 1/2	
Pressure	-60
Unit Pressure	mmHg
On time	2 min
Off time	3 min
Language	English
Back	OK



4. Press “OK” [] to select.
5. To change value, choose with the Selection buttons [] or [].
6. Press “OK” [] to confirm.

If the changed setting is not confirmed, the pump will switch back to the old settings.

7. Press “Back” [] to exit settings.

1 minute after the last button has been pressed, the Invia Liberty Pump switches into patient mode automatically and the display is locked.

Therapy Log file

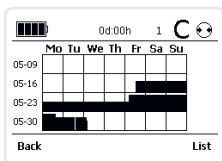
In the Therapy Log file information regarding runtimes (on/off), pressure settings, therapy modes, alarms and errors is listed. The last 51 events are logged and displayed.

To open the Therapy Log file

Date	Time	M	Duration
2011-06-02	06:41	Standby	0:01
2011-06-02	06:15	I (-80)	0:26
2011-06-02	06:15	Standby	0:00
2011-06-01	15:00	C (-130)	15:15
2011-06-01	14:48	Off	0:12
2011-06-01	13:40	C (-130)	1:08

Back -1- Graph

List



Graph


1. Enter the administrative mode, unlock the display by press and hold [], press [].
2. Press Selection buttons [] + [] at the same time.
3. To view the additional pages, scroll with the Selection buttons [] or [].
4. To view the Therapy Log file as a graph, press “Graph” [].
5. To exit the Therapy Log file, press “Back” [].

The Invia Liberty Pump switches automatically into main display (in administrative mode) 30 seconds after the last button has been pressed. After additional 30 seconds, the pump switches into patient mode and the display is locked.

Patient Mode




Turn ON

Switch Invia Liberty Pump ON by pressing []

Self-test starts

If the self-test is not successful, follow instructions shown on the display or see the Alarms chapter.

 When the pump is turned on in this mode, last settings (therapy mode and pressure level) are used by default.

Check pressure

The set pressure will be shown on the display. The motor will run for a few seconds to build up the pressure. If it runs continuously for more than 30 seconds, check system for leaks and try again. The set pressure is measured and controlled at the end of the conical connector on the canister tube.

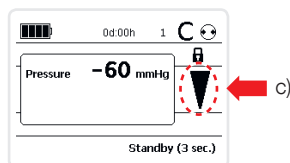
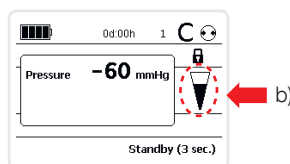
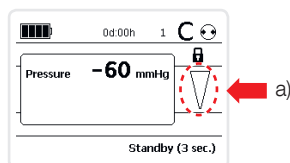
Air Leakage Indicator

An air leakage indicator is shown on the display to visualize if there is an air leakage in the system.

a) When the indicator is “empty”, the system is air tight.

b) When the indicator is “half full” there is an air leak in the system, but the pressure and therapy is maintained in accordance with the set pressure.

c) When the indicator is “full” and flashes, there is a big air leak in the system. The air leakage alarm will go off within 2 minutes if the set pressure is not maintained. Follow the instructions shown on the display, or see Alarms chapter.



Standby

Change the Invia Liberty Pump into the standby mode.

Press the Standby button [ > 3 seconds] and the pump motor will stop running.

If the pump is in Standby mode for more than 5 minutes, an alarm will go off, follow instructions shown on the display or see the Alarms chapter.

Turn OFF

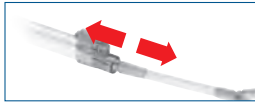
Press [ > 3 seconds] and the pump will be turned off.

Change Invia Liberty Canister and Invia Liberty Tubing

Change Invia Liberty Canister and Invia Liberty Tubing, when the canister is full, by visual inspection or when alarm sounds, in accordance with instructions on the pump display.

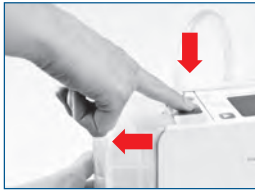
1. Provide sterile canister and sterile tubing.


2.



2. Clamp canister tubing.

3.

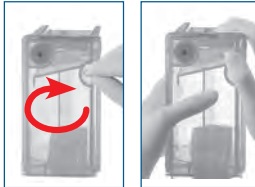


3.1 Press the Standby button [ > 3 seconds] and the pump motor will stop running.

3.2 Disconnect the canister tubing from the tubing connected to the dressing.

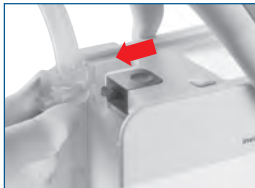
3.3 Release and remove canister.

4.



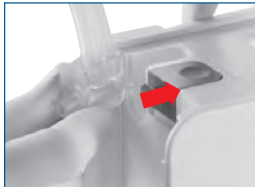
4. Seal used canister with cap.

5.



5. Remove canister tubing in direction of the arrow.

6.




6. Unpack new canister tubing and connect to Invia Liberty Pump. Insert the tubing base into the pump (straight push).



7.1 Unpack new canister, position and click into Invia Liberty Pump.

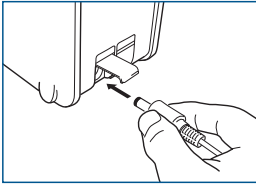
7.2 Connect the canister tubing to the tubing connected to the dressing. **Ensure that the canister tubing is un-clamped.**

7.3 Press "ON" with []. Pressure is built up.



8. Dispose canister and canister tubing in accordance with local procedures. In the home care settings, return disposables to care giver for correct disposal.
- Must not be disposed together with household refuse.

Battery charging



- ☞ To charge the battery place the Invia Liberty Pump in the Docking Station or plug in the charger to the electrical outlet port on the pump. You can continue to use the pump while it is charging.

The capacity of the battery is not negatively affected if it is charged when partially empty and do not need to be fully charged at each occasion.

- ☞ The battery can be charged when appropriate, or in accordance with alarm signal for “Battery low” or “Battery empty” and follow instructions in the pump display.

There is approximately 30 minutes of charge remaining on the battery at the onset of the “Battery Low” warning.

If the battery is completely empty it will take 3 to 4 hours to charge to full status.

If the Invia Liberty Pump is fully charged AND the pump is still connected to an electrical source, a lightning bolt will appear in the battery icon.

If the pump is disconnected from an electrical source, 4 bars are visible in the battery icon which indicates that the battery is fully charged.

If Invia Liberty Pump has not been in use, the battery must be charged approximately once every 6 months to ensure optimum function.

To disconnect Invia Liberty Pump from the electrical source

Remove the charger connector and close the safety cover. Invia Liberty Pump switches off automatically.



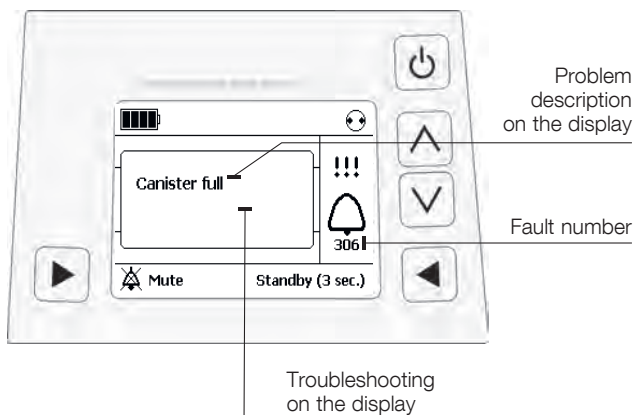
WARNING

Do not pull on the cable or the anti-bend protection.

Alarms

The pump distinguishes between “Warning”, “Alarm” and “Internal fault”. If the Invia Liberty detects any situations where the therapy can not be maintained, an acoustic alarm sounds, a fault number and a description of the problem appears on the display. For explanation of the fault number, see the Alarm Table in this chapter.

Example:



CAUTIONS

Invia Wound Therapy Instructions advise 24 hours therapy without interruption. If therapy is discontinued for more than 2 hours using foam or 24 hours using gauze, the dressing should be replaced and therapy restarted by a healthcare professional.

“Warning”

Pump operation continues, an acoustic alarm sounds and the fault number is shown on the display.





“Alarm”

Pump operation halts an acoustic alarm sounds and the fault number is shown on the display.



When the Warnings/Alarms goes off an acoustic alarm sounds. A description of the “Warning” or “Alarm” will be shown on the display.




1. Press “Mute” [] to mute and acknowledge the alarm.
The acoustic alarm will sound again in 1 minute if the problem is not solved.
2. Follow the instruction shown on the display and see Alarm Table.
3. If the problem can not be solved, turn off [ > 3 seconds]
Invia Liberty Pump and consult your contact person for further instructions.

“Internal fault”

Pump operation stops and an acoustic alarm sounds, “Internal fault” is shown on the display.



When the Warnings/Alarms goes off an acoustic alarm sounds.
A description of the “Warning” or “Alarm” will be shown on the display.

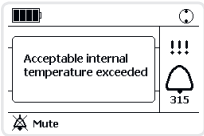
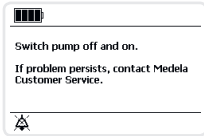
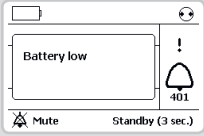
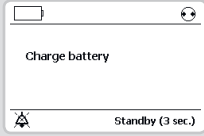
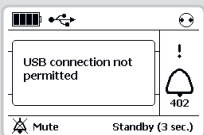
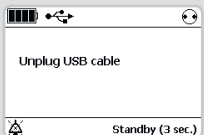
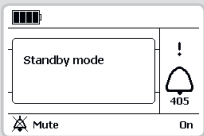
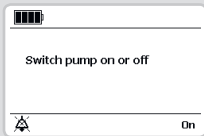
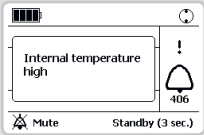
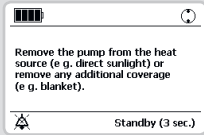
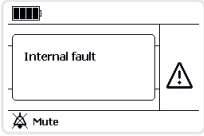
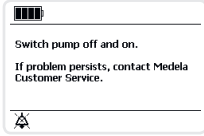
1. Press [ > 3 seconds] and the pump will be turned off.
2. Restart the pump by pressing [] and the pump will be turned on.
3. If the Internal fault alarm remains, turn off [ > 3 seconds]
Invia Liberty Pump and contact Medela Customer Service.

Alarm table

	Fault number	Problem description on the display	Troubleshooting on the display	Pressure	
Alarm	301			✓	
	302			✓	
	305			✗	
	306			✓	
	311			✗	
	312			✗	
	313			✗	

Remarks/potential cause of fault	
<p>Dressing: - Check dressing for air leakage. Press firmly around the edges of the dressing, around the drain tube or on the External Suction Interface (ESI). - Apply some additional film dressing to seal the leaking area.</p> <p>Connectors: - Ensure that the wound dressing tubing is connected properly to the Canister tube. - Ensure that the canister tube is inserted straight into the pump.</p> <p>Canister: - Ensure that the canister is properly inserted, release the canister and reposition. - Ensure that the O-ring/gasket, placed beside the canister tubing on the pump is not missing. Additional O-ring is available via Medela customer service.</p>	
<p>Tubing: - Ensure that the tubing is not twisted, kinked or clamped. - If the canister tube is clogged, change the tube.</p> <p>Canister: - If canister is full or filter clogged, replace canister.</p>	
	<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 Invia Liberty Canister and Invia Liberty Tubing".</p>
<p>Canister: - Release the canister and reposition.</p> <p>Tubing: - Ensure that the tubing is not twisted, kinked or clamped.</p>	
<p>Dressing: - Check dressing for air leakage. Press firmly around the edges of the dressing, around the drain tube or on the Transfer Pad. - Apply some additional film dressing to seal the leaking area.</p> <p>Connectors: - Ensure that the wound dressing tubing is connected properly to the Canister tube. - Ensure that the canister tube is inserted straight into the pump.</p> <p>Canister: - Ensure that the canister is properly inserted, release the canister and reposition. - Ensure that the O-ring/gasket, placed beside the canister tubing on the pump is not missing. Additional O-ring is available via Medela representative.</p>	
	<p>Change canister, see chapter "Change Invia Liberty Canister and Invia Liberty Tubing"</p>

Alarm table

	Fault number	Problem description on the display	Troubleshooting on the display	Pressure	
Alarm	315				
Warning	401			✓	
	402				
	405			✗	
	406			✓	
Internal fault					






CAUTION


If fault repeats, note the fault number, switch off the pump and contact Medela Customer Service.




CAUTION

Invia Wound Therapy Instructions advise 24 hours therapy without interruption. If therapy is discontinued for more than 2 hours using foam or 24 hours using gauze, the dressing should be replaced and therapy restarted by a 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 30 minutes.</p>
	<p>Unplug USB cable</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” [] or switch off the pump by pressing [ > 3 seconds].</p>
	<p>Cool Invia Liberty down.</p>
	<p>Restart the pump. If internal fault remains, turn off by pressing [ > 3 sec.] and contact Medela Customer Service.</p>

Operation continues 

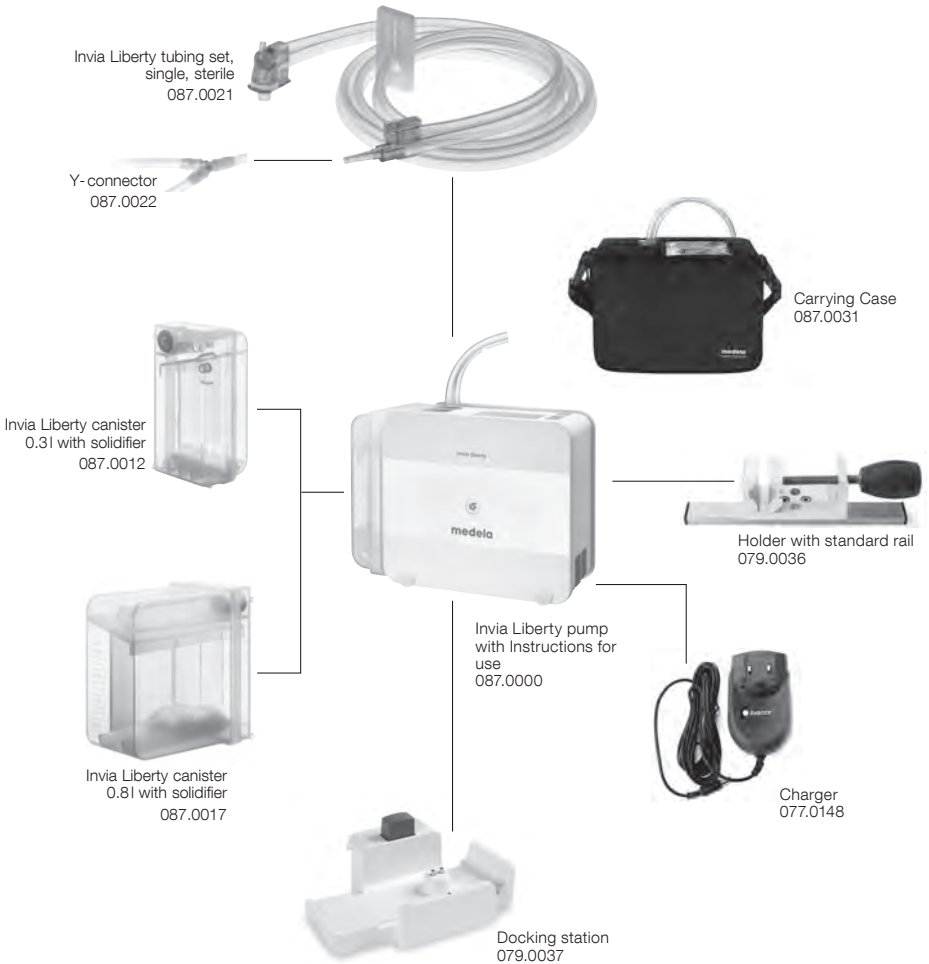
Operation halts 

Accessories Overview




CAUTION

The Invia Liberty Pump is verified within the scope of conformity evaluation and is only to be used with products included in the Invia Liberty NPWT System and distributed by Medela. Medela can only guarantee performance of the system with these products.



Wound Dressing Kits


 Wound Dressings to be applied and changed by healthcare professionals only.

The Invia Liberty NPWT System is intended to be used in conjunction with the Invia and Avance® dressings:

- Invia foam dressing kit
- Invia gauze dressing kit
- Avance® foam dressing kit

Sterility and Requirements for Usage

The Invia Liberty disposables products are sterile and single use devices.

Tubing Canister Y-connector Drain External Suction Interface (tubing) Wound Dressing		These are single use devices that should be disposed of after use. If reused performance of the product may deteriorate, cross-contamination may occur.
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CAUTION

Do not re-sterilise. Do not use if inner package is damaged or opened prior to use. Do not reuse. If reused performance of the product may deteriorate, cross-contamination may occur.

Cleaning and Disinfection



CAUTION

Invia Liberty Pump with associated products (Docking Station, Rail Holder and Charger) should be cleaned/disinfected after every use. Before cleaning the device, unplug the pump from the wall outlet.

	Cleaning	Disinfection	Sterilisation	Dishwasher
Pump	✓	✓	✗	✗
Docking Station				
Rail Holder				
Charger	Wipe off with a damp cloth.	Wipe off with a disinfecting agent	Sterilisation/cleaning in a dishwasher is NOT allowed.	
Carrying Case*				

* If needed, the Carrying Case can be washed in washing machine



CAUTION

Invia Liberty Pump, Docking Station, Rail Holder, Charger and Carrying Case cannot be sterilized. Immersion disinfection, thermal disinfection and ultrasound cleaning are not permitted.

Disinfection (Pump housing, docking station and charger)



CAUTION

Invia Liberty Pump can be disinfected with “alcohol”

Disinfection

Invia Liberty can be disinfected with the disinfecting agent group “alcohol”. Do not use other cleaning agents (e.g. Terralin) as they can damage the plastic housing. Immersion disinfection, thermal disinfection and ultrasound cleaning are not permitted.

Sterilization

Invia Liberty and Invia Liberty accessories cannot be sterilized.



CAUTION

Do not use other cleaning agents (e.g. Terralin) as they can damage the plastic material.

Cleaning procedure for Invia Liberty Pump, Docking Station and Charger

1. Wear suitable protection (clothing, gloves, face mask and goggles) according to local guidelines.
2. Apply the disinfectant agent in accordance with instructions from the manufacturer¹⁾. Pay attention particularly to edges, narrow corners and bottom side.
3. Leave the disinfectant on. Follow the recommended residence time for the disinfectant as instructed by the manufacturer¹⁾.



CAUTION

Do not spray disinfectants directly into openings as this may harm electronic components.

4. Thoroughly clean the surface, all edges, housing niches, corners, bed holder, brackets, port covers and bottom side.
5. Wipe dry or air dry as instructed from the manufacturer¹⁾.
6. If needed, repeat step 2-5 to ensure proper cleaning.
7. Dispose contaminated material in accordance with local environmental procedures.

For a detailed Cleaning Instruction, contact your Medela representative.

¹⁾ Manufacturer of the disinfectant agent.

Disposal

Invia Liberty Pump is made from various metals and plastics. Before disposal the rechargeable battery and electronics must be removed according to instructions. Then Invia Liberty Pump is no longer operational. Dispose of electronics and plastic components should be handled in accordance with local guidelines.

Invia Liberty disposables and dressings should be handled and disposed in accordance with local environmental procedures.



PRECAUTION

Must not be disposed together with household refuse.

Maintenance / Safety-Related Check

Service work may only be carried out by authorized personnel. A safety-related check are 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.

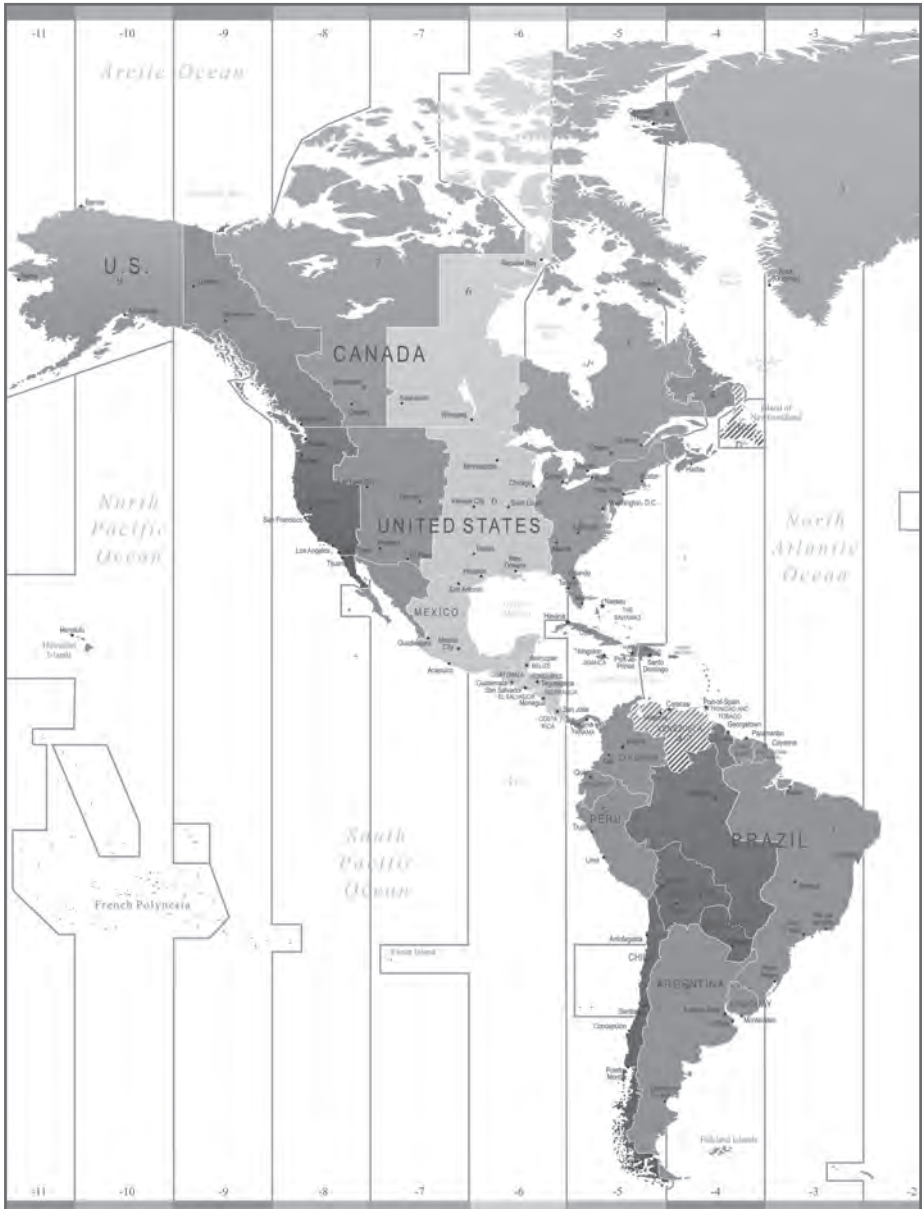
Guarantee

Guarantee for 2 years after date of delivery in used in accordance with these instructions. The manufacturer is not liable for any damage or consequential damage caused by incorrect operation, inappropriate usage as well as use by unauthorized persons.


Service life


The service life of the device is five years; the internal batteries life included.


Map Time Zone





Signs and Symbols


 This Symbol indicates a Safety related Tip.

 This Symbol indicates a CAUTION or WARNING associated with the Device (see page 3).

 This Symbol indicates a class II Device.


 This Symbol indicates to not dispose the Device together with Household Refuse (for EU only).


 This Symbol indicates the Date of Manufacture (four Digits for the Year and two Digits for the Month).

 This Symbol indicates the Name and the Address of the Manufacturer.

STERILE EO

This Symbol indicates the Device is sterilized using ethylene oxide.

 This Symbol indicates a Prescription Device. Federal Law restricts this Device to sale by or on the order of a licensed healthcare practitioner. (for US only).


 This Symbol indicates a type BF applied Part.


REF This Symbol indicates manufacturer's Catalog Number.


SN This Symbol indicates manufacturer's Serial Number.


LOT 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 End of the Year and Month shown.

 This Symbol indicates to follow the Instruction for use.

 This Symbol indicates the C TUV US NRTL marking of the Device (equivalent to UL and CSA Mark).


 This Symbol indicates to not use the Device if package is damaged.

 This Symbol indicates the number of items n that the content is sufficient for.

pcs This Symbol indicates the number of items.



This Symbol indicates to keep the Device away from sunlight.

 This Symbol indicates the Direct Current 9 VDC Socket.



This Symbol indicates that the Device is in Conformance with the Medical Device Directive 93/42/EEC.



This symbol indicates a Single Use Device. Do not reuse the Device.



This Symbol indicates MR Unsafe.



This Symbol indicates the Temperature Limitation for Operation, Transport and Storage.



This Symbol indicates the Humidity Limitation for Operation, Transport and Storage.



This Symbol indicates the atmospheric Pressure Limitation for Operation, Transport and Storage.



This Symbol indicates to keep the Device dry.



This Symbol indicates to handle the fragile Device with care.

Technical specifications



vacuum range
- 60 to -200 mmHg
- 8 to -27 kPa



low flow
5 L/min



without canister
1000 g
2.2 lbs



 **IP33**



H x W x D
150 x 170 x 95 mm
5.91 x 6.69 x 3.74 inch



ISO 9001
ISO 13485
CE (93/42/EEC), IIa



max. noise level
- 42.5 dB(A) 1 l



alarm noise level
78 dB(A)



15 93 706 Operation
±5 °C +40
70 kPa



15 93 706 Transport/
Storage
-20 °C +50
70 kPa



Switching adapter AC
Model: TR30RAM120
IEC: 60601-1
Input: 100-240V~, 0.8-0.4A,
47-63Hz
Output: 12V~, 2.5A