

# Invia® Liberty™

### NEGATIVE PRESSURE WOUND THERAPY SYSTEM

Clinician instructions for use





# NPWT University

Medela.com website provides all the educational tools you need to set-up and operate the Invia Liberty NPWT system. The Medela University page includes instructions for use, quick cards and training videos to support you in becoming a confident and knowledgeable NPWT user.

### www.medela.com





NPWT University can be found at www.medela.com via the "University" tab. It is available on all formats including desktop, smartphone and tablet. We recommend saving NPWT University as a shortcut on desktop, smartphone and tablets for an even quicker access.

## Table of contents

| Introduction   | 6          |
|--|------------|
| To consider before use                                   | 6          |
| Intended use   | 6          |
| Indications for use                                      | 7          |
| Contraindications  | 7          |
| Warnings, cautions and safety instructions               | 7          |
| Warnings   | 8          |
| Cautions   | 9          |
| Safety instructions                                      | 10         |
| Wound assessment   | 10         |
| Safety-related checks                                    | <b>1</b> 1 |
| Dressing technique                                       | <b>1</b> 1 |
| Invia Liberty pump                                       | 12         |
| Display  | 13         |
| Invia Liberty pump disposables                           | 14         |
| Invia Liberty canister with solidifier 300 ml and 800 ml | 14         |
| Invia Liberty canister tubing/Y-connector/Drain adapter  | 15         |
| Power supply   | 16         |
| USB port   | 16         |
| Preparation for use                                      | 17         |
| Invia Liberty pump user modes                            | 18         |
| Administrative mode                                      | 18         |
| Patient mode   | 18         |
| Administrative Mode                                      | 19         |
| Device setup   | 19         |
| New patient therapy                                      | 19         |
| Administrative mode                                      | . 20       |
| Change pressure level                                    | . 20       |
| Change pressure set-up mode                              | 21         |
| Select air leakage volume                                | 21         |
| Change therapy mode                                      | . 23       |
| Change settings  | 24         |
| Therapy Log file   | . 25       |
| To open the Therapy Log file                             | . 25       |

| Patient mode   | 25 |
|--|----|
| Turn ON  | 25 |
| Check pressure   | 25 |
| Air leakage indicator                                  | 25 |
| Standby  | 26 |
| Turn OFF   | 26 |
| Set up carrying case                                   | 26 |
| Change Invia Liberty canister and Invia Liberty tubing | 27 |
| Battery charging                                       | 29 |
| Alarms   | 30 |
| Warning  | 31 |
| Alarm  | 31 |
| Internal fault   | 31 |
| Alarm table  | 32 |
| Accessories overview                                   | 36 |
| Wound dressings  | 37 |
| Sterility and requirements for usage                   | 37 |
| Cleaning and disinfection                              | 38 |
| Disposal   | 39 |
| Maintenance/Safety-related check                       | 39 |
| Guarantee  | 39 |
| Service life   | 39 |
| Map time zone  | 40 |
| Signs and symbols                                      | 41 |
| Technical specifications                               | 42 |
| Electromagnetic Compatibility (EMC)                    | 43 |
| Electromagnetic emissions                              | 43 |
| Electromagnetic immunity                               | 44 |
| Recommended senaration distance                        | 46 |

### Introduction

With the 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

These instructions for use are a general guide for the use of the Invia Liberty pump with associated products. Medical matters must be addressed by a physician.

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 system is to be used exclusively as described in these instructions for use.

- Before initiating NPWT treatment, read the instructions for use, indications, contraindications, warnings, cautions 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 a physician.
- 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 clinical 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

#### 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.

### 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

### 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

### 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 (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

- Do not modify this equipment without authorization from the manufacturer.
- This manual provides general guidelines for the use of the Invia NPWT system.
- The safe and effective operation of this device requires specific instruction from a 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 patient 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, cautions and contraindications when using the Invia Liberty as
  a vacuum source with the Invia NPWT system. 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 or showering
- Do not dry Invia Liberty in a microwave.
- 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 the use of a protective barrier on skin that may come in contact with the tubing, especially in patients with fragile skin.
- Invia NPWT instructions advise 24 hours therapy without interruption. If therapy is discontinued for more than 2 hours using foam or 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.

- Explosion hazard the Invia Liberty pump is not for use in potentially explosive environments including oxygen enriched environments and in areas of flammable anesthetics.
- 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.
- 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.

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



#### **CAUTIONS**

- The following statements describe medical conditions that may require special care for the safe and effective use of the Invia NPWT system.
- Patients at high risk for bleeding and hemorrhage.
- Patients taking anticoagulants or platelet aggregation inhibitors, or with patients experiencing active bleeding or difficult wound hemostasis.
- Wounds that involve a fistula.
- Using Invia NPWT system 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.
- For maximum benefit on closed surgical incision, the Invia negative pressure therapy should be applied immediately post-surgery to clean surgically closed wounds. It is to be continuously applied for a minimum of two days up to a maximum of seven days, with dressing changes if required. All dressing changes should be applied under direct medical supervision. The Invia therapy system will not be effective in addressing complications associated with the following:
  - Ischemia to the incision or the incision area
  - Untreated or inadequately treated infection
  - Inadequate hemostasis of the incision
  - Cellulitis of the incision area

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 an 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 two hours, the dressing must be changed and therapy restarted.

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

Consider mode of therapy – intermittent versus continuous.

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

#### 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.
- 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.
- 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 wound 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° 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.

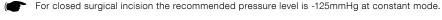
Devices of protection class II do not have a protective earth conductor; there is therefore no need to check the earth leakage current.

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 wound dressing instructions for use for information regarding dressing applications included in every Invia dressing carton. Perform a thorough wound cleansing per physician orders or facility protocol prior to dressing applications.





For information regarding the dressing change, consult the specific Invia wound Dressing Instructions for Use.

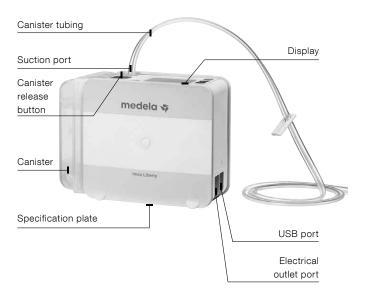
When treating infected wounds or wounds more susceptible to tissue in-growth into wound filler material, more frequent dressing changes may be needed. The frequency of dressing changes should be based on an evaluation of the wound characteristics rather than standard recommendations.



Important things to remember:

- Routinely check that the negative pressure level and the therapy mode is at the prescribed setting.
- Monitor the integrity of the dressing and that the pump is on and running.

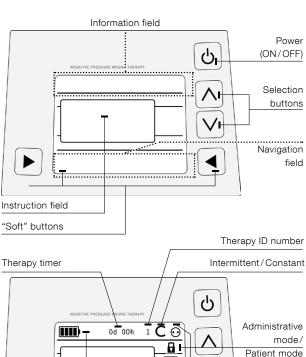
## Invia Liberty pump





The max flow of Invia Liberty pump is 5 liters/minute with an adjustable pressure range of -40 to -200 mmHg (-5 to -27 kPa).

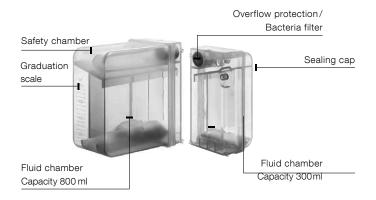
### Display



Battery

### Invia Liberty pump disposables

Invia Liberty canister with solidifier 300 ml and 800 ml



Material: Polypropylene

 $\begin{array}{lll} \mbox{Accuracy of graduation:} & +/-2.5\,\% \mbox{ (in the upright position)} \\ \mbox{Composition of solidifier:} & \mbox{Cross-linked sodium polyacrylate} \\ \end{array}$ 



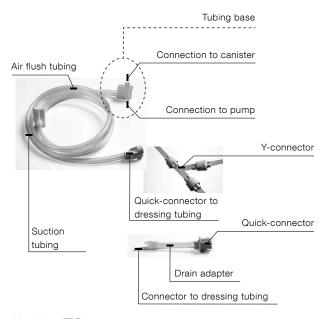
#### **CAUTIONS**

For appropriate, safe operation the 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 canister tubing/Y-connector/Drain adapter



Material: TPE Length: 1.5 m Diameter: 2.0/3.0 mm

#### The canister 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 to prevent contamination of Invia Liberty pump.

#### The Invia Y-connector with Quick-connector

For warnings and cautions of the Invia Y-connector with Quick-connector consult the Invia Y-connector with Quick-connector instructions for use.

### 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.



#### WARNINGS

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.

Invia Liberty pump is operable while connected to the electrical power supply or by an internal rechargeable 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 motor only turns on when the measured pressure is lower than the set pressure.

Under typical operating conditions, the battery run-time generally exceeds 14 hours. Battery run-time 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 motor 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 Ed. 3.1 of IEC 60601-1, respectively). Anyone 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.

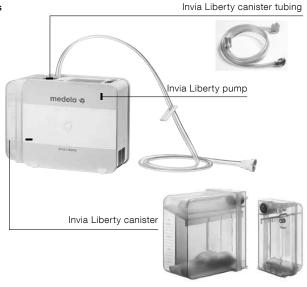
### Preparation for use



#### 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 canister tubing



A. Open the tubing packaging

В.



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

3. Click in Invia Liberty canister



A. Unpack new canister and remove the safety sticker. Slip the pegs at the bottom of the canister into the slots at the base of the pump. Lift the canister towards the pump until it clicks into place.

В.

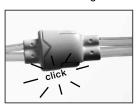


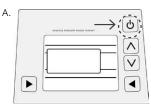
B. "Click" into place.

Canister secures tubing

4. Connect the dressing tubing to the canister tubing.







A. The pump will do a 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 30 sec. – check system and retry.



If the above 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.

For dressing applications, please refer to the instructions for use provided with the Invia dressings. Turn the Invia Liberty pump on as described in the user modes section.

### Invia Liberty pump user modes

#### Administrative mode

Used by healthcare professional to either set up new patient therapy or to change pump settings such as pressure, air leakage volume, therapy Constant and Intermittent modes, intermittent times, language and time zone. You can enter the Administrative mode when first turning the pump on or while therapy is running.

#### Patient mode

In Patient mode the pump can be turned on and off, placed in standby mode and an 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 factory default settings of the Invia Liberty pump are -125 mmHg and constant mode.



#### CAUTION

The pressure level should always be set according to prescribing healthcare professional instruction.

When an Invia FitPad is used, the set pressure is controlled at the wound site.

### Device setup

#### New patient therapy



1. Switch Invia Liberty pump ON in Administrative mode, press and hold [ ], and then press [ U]. Self-test starts

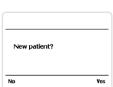
the display or see the Alarm chapter.

If the self-test is not successful, follow instructions shown on





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).

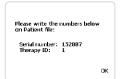
This number can be noted in the patient's file.

The therapy ID number is displayed in the information field.

Press "Yes" [ ] to confirm.

Press "OK" [ ] to enter the main display.

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



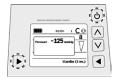
#### If no

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

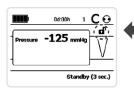


- 3. Press the Selection buttons [ \land ] or [ \lor ] to set pressure level.
- 4. Press "OK" [ ] to confirm and enter the main display.

#### Administrative mode



1. To enter the Administrative mode, unlock the display, press and hold [ ], and then press [ ].



#### Change pressure level



#### **CAUTIONS**

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

Default pressure mode is Standard with preset pressure levels:

| mmHg  | -40 | -60 | -80 | -100 | -125 | -150 | -175 | -200 |
|-------|-----|-----|-----|------|------|------|------|------|
| (kPa) | -5  | -8  | -11 | -13  | -17  | -20  | -23  | -27  |

- 1. To enter the Administrative mode, unlock the display, press and hold [ ], and then press [ U].
- 2. Press the Selection buttons [ \( \sum \) ] or [ \( \sum \) ] to set pressure level.
- 3. Press "OK" [ ] to confirm.
- 4. To return to the main display, press "Back" [ ].



### ↑ CAUTIONS

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

#### Change pressure set-up mode

Detailed pressure mode allows to select pressure level from -40 to -200 mmHg in increments of 5mmHg (5kPa to 27kPa in increments of 1kPa)

- 1. To enter the Administrative mode, unlock the display, press and hold [ ], and then press [ U].
- 2. Press the soft buttons [ + ] at the same time to enter the Settings menu.
- To switch pressure modes, scroll down with [ V ] and select Pressure set-up.
- 4. Press "OK" [ ] to select.
- 5. To change between Standard and Detailed pressure modes, press Selection buttons [ ] or [ ] to choose Standard or Detailed mode.
- 6. Press "OK" [ ] to confirm.
- Refer to Change pressure level instructions to select pressure values.

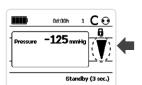




#### Select air leakage volume



High air leakage mode is recommended when X-large dressing is used.



Default air leakage volume is Standard. If the vacuum on the wound is < 75% of the set pressure level or the air flow is > 1500ml/min, leakage indicator is "full" and flashes, indicating there is a big air leak in the system. The air leakage alarm will go off within 2 minutes if the air flow is above the defined level or after 1 minute if the set pressure is not maintained. Follow the instructions shown on the display, or see the Alarms chapter.

For wounds with air leakage volume between 1500ml/min and 2200ml/min, High air leakage volume mode is available. If the vacuum on the wound is < 75% of the set pressure level or the air flow is > 2200ml/min value, leakage indicator is "full" and flashes, indicating there is a big air leak in the system. The air leakage alarm will go off within 2 minutes if the air flow is above the defined level (2200ml/min) or after 1 minute if the set pressure is not maintained. There will be no leakage alarm during the first 5 minutes which allows establishing the set pressure on a wound with high volume without an alarm.

Selecting between Standard and High air leakage volume:

- 1. To enter the Administrative mode, unlock the display, press and hold [ ], and press [ ].
- 2. Press the soft buttons [ + ] at the same time to enter the Settings menu.
- 3. To change air leakage volume, scroll down with [ V ] and select Air Leakage.
- 4. Press "OK" [ ] to select.

| Settings 1/3    |          |
|-----------------|----------|
| Pressure        | -125     |
| Unit Pressure   | mmHq     |
| Pressure set-up | Standard |
| Air Leakaye     | Standard |
| l anguage       | Fnglish  |

Settings 1/3

Unit Pressure

l anguage

Back

Pressure set-up Air Leakaye

mmHg

Standard

Standard

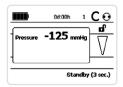
Fnglish

ОК

5. To change between Standard or High air leakage, choose the mode with the Selection buttons [ \lambda ] or [ \lambda ].

- Settings 1/3 -125 Pressure Unit Pressure mmHg Pressure set-up Standard Air Leakaye Hiyh l anguage Fnglish
- 6. Press "OK" [ ] to confirm.
- 7. To return to the main display, press "Back" [ ].

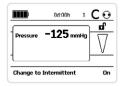
#### Change therapy mode



- 1. To enter the Administrative mode, unlock the display, press and hold [ ], and then press [ U].
- To change the therapy mode, press "Standby"
   [ 3 seconds ] to put the Invia Liberty pump into the Standby mode.

#### Constant mode - C

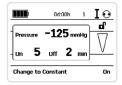
The default therapy mode is Constant.



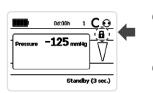
 To change from Constant mode to Intermittent mode, press [ ] "Change to Intermittent" and then press "On" [ ].

#### Intermittent mode - I

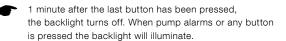
The default times for Intermittent mode are 5 minutes on and 2 minutes off.



4. To change from Intermittent mode to Constant mode, press [ ] "Change to Constant" and press "On" [ ].



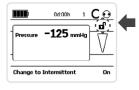
 1 minute after the last button has been pressed, the Invia Liberty pump switches into Patient mode automatically and the display is locked.



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

The settings possible to change are, Unit pressure, Air leakage volume, Constant and Intermittent modes, intermittent times, language and time zone. Pump number, pump run-time and pump version can only be viewed but not changed.

#### Change settings

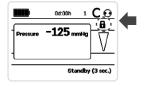


- 1. To enter the Administrative mode, unlock the display, press and hold [ ], and then press [ 6 ].
- Press the soft buttons [ + ] at the same time to enter the Settings menu.

| Settings 1/3    |          | Selection                        |  |  |
|-----------------|----------|----------------------------------|--|--|
| Pressure        | -125     | –40 to –200 mmHg (–5 to –27 kPa) |  |  |
| Unit Pressure   | mmHg     | kPa/mmHg                         |  |  |
| Pressure set-up | Standard | Standard / Detailed              |  |  |
| Air Leakage     | Standard | Standard / High                  |  |  |
| Language        | English  | Languages according to list      |  |  |
| Back            | OK       |                                  |  |  |
| Settings 2/3    |          | Selection                        |  |  |
| On time         | 5 min    | 1 – 8 min                        |  |  |
| Off time        | 2 min    | 1 – 8 min                        |  |  |
| Time zone       | +1 h     | +12 until -12 hours GMT          |  |  |
| Pump number     | 152887   | as displayed                     |  |  |
| Pump run-time   | 27 h     | as displayed                     |  |  |
| Back            | OK       |                                  |  |  |
| Settings 3/3    |          | Selection                        |  |  |
| Version         | 1.22     | as displayed                     |  |  |
|                 |          |                                  |  |  |
| Back            | OK       |                                  |  |  |

| Settings 1/3    |          |
|-----------------|----------|
| Pressure        | -125     |
| Unit Pressure   | mmHg     |
| Pressure set-up | Standard |
| Air Leakage     | Standard |
| Language        | English  |

- 4. Press "OK" [ ] to select.
- 5. To change value, choose with the Selection buttons [ \( \times \) ] or [ \( \times \) ].
- 6. Press "OK" [ ] to confirm.
- If the changed setting is not confirmed with "OK", the pump will switch back to the previous setting.
- 7. Press "Back" [ ] to exit settings.

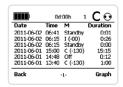


1 minute after the last button has been pressed, the Invia Liberty pump switches into Patient mode automatically and the display is locked.

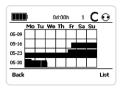
#### Therapy Log file

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

#### To open the Therapy Log file



List



Graph

- 1. To enter the Administrative mode, unlock the display, press and hold [ ], and then press [  $\circlearrowleft$  ].
- 2. Press Selection buttons [ \lambda ] + [ \lambda ] simultaneously.
- To view additional pages, scroll with the Selection buttons [ \lambda ] or [ \lambda ].
- To view the Therapy Log file as a graph, press "Graph"
- 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

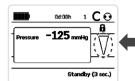
If the self-test is not successful, follow instructions shown on the display or see the Alarms chapter.



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

#### Check pressure

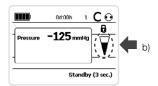
The set pressure will be shown on the display. The motor will run for a few seconds to build up the pressure. If it runs continuously for more than 30 seconds, check system for leaks.

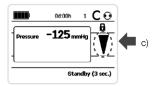


#### Air leakage indicator

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. When pump is first turned on and a big air leak is present the air leakage alarm will go off within 2 minutes in the Standard air leakage mode or within 5 minutes in the High air leakage mode if the set pressure is not maintained. When therapy is running and a big air leak is detected, alarm will go off within 2 minutes. Follow the instructions shown on the display, or see the Alarms chapter.

#### Standby

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

#### Turn OFF

Press [ 🖒 > 3 seconds] and the pump will turn off.

### Set up carrying case

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



- 1. Open the carrying case.
- 2. Slide the Invia Liberty 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.

# Change Invia Liberty canister and Invia Liberty tubing

Change Invia Liberty canister minimum once a week, when canister looks full on visual inspection or when "Canister full" / "Filter clogged" alarm signal is activated.

Change Invia Liberty tubing minimum once a week, when tubing looks clogged on visual inspection or when "System clogged" alarm signal is activated.

- 1. Provide sterile canister and sterile tubing.
- Press "Standby" [ > 3 seconds] for the pump motor to stop running. Clamp the canister tubing.
- 3.1 Position the clamp next to the quick-connector and close the clamp on the pump tubing and close the clamp on the dressing tubing.





3.2 Disconnect the canister tubing from dressing tubing.





- 3.3 Protect the end of dressing tubing from contamination.
- 4. Release and remove canister.





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



6. Remove canister tubing in direction of the arrow.

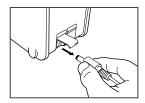


Unpack new canister tubing and connect to Invia Liberty pump. Insert the tubing base into the pump (straight push).



- **8.1** Unpack new canister and remove the safety sticker.
- **8.2** Slip the pegs at the bottom of the canister into the slots at the base of the pump. Lift the canister towards pump until it clicks into place.
- **8.3** Connect the canister tubing to dressing tubing. **Ensure that** the tubing is un-clamped.
- 8.4 Press "ON" with [ ]. Pressure will begin to built up.
- Dispose canister and canister tubing in accordance with local procedures. In the home care setting, return disposables to care giver for correct disposal.

### Battery charging





The battery must be fully charged before first usage. To charge the battery, plug the charger into the electrical outlet port in the Invia Liberty 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 discharged and the pump does 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 fully discharged (empty)" and 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 discharged 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, 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.



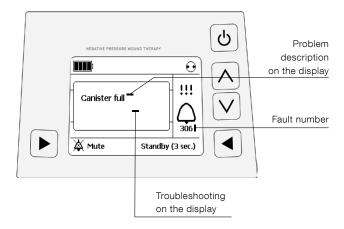
#### WARNING

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 pump detects any situations where the therapy cannot 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 Liberty instructions advise 24 hours therapy without interruption. If therapy is discontinued for more than 2 hours using foam or gauze, the dressing should be replaced and therapy restarted by a healthcare professional.

#### "Warning"

An acoustic alarm sounds and the fault number is shown on the display.



#### "Alarm"

An acoustic alarm sounds and the fault number is shown on the display.



When a Warning/Alarm goes off, an acoustic alarm sounds. A description of the "Warning" or "Alarm" will be shown on the display.

- Press "Mute" [ ] to mute and acknowledge the alarm.
   The acoustic alarm will resume in 1 minute if the problem is not solved.
- 2. Follow the instruction shown on the display or see the Alarm table.
- If the problem cannot be solved, turn off the Invia Liberty pump [ 0 > 3 seconds] and contact the Medela customer service for further instructions.

#### "Internal fault"

Pump operation stops and an acoustic alarm sounds, "Internal fault" is 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.

## Alarm table

|         | Fault number | Problem description on the display   | Troubleshooting on the display  | Pressure |  |
|---------|--------------|--|---|----------|--|
|         | 401          | Battery low  | Charge battery  Standby (3 sec.)  | <b>√</b> |  |
| Warning | 402          | USB connection not permitted 402   | Unplug USB cable  |          |  |
| War     | 405          | Standby mode 1 405   | Switch pump on or off   | ×        |  |
|         | 406          | Internal temperature high 406  | Remove the pump from the heat source (e.g. direct sunlight) or remove any additional coverage (e.g. blanket).                               | <b>✓</b> |  |
|         | 301          | Air leak in system  Air leak in system  Standby (3 sec.)                                 | Check dressing for air leakage and if carister is properly inserted.  Consult IFU for further instructions.  Standby (3 sec.)               | <b>√</b> |  |
| Alarm   | 302          | System dogged  System dogged  System dogged  System dogged  System dogged  System dogged | Check that tubing is clear, not brinded and clamp open. Check if canister is full.  Consult IFU for further instructions.  Standby (3 sec.) | <b>√</b> |  |
|         | 305          | Battery empty  Battery empty  Mute   | Charge battery  | ×        |  |
|         | 306          | Canister full    Canister full   | Change canister   | <b>✓</b> |  |

| Remarks/potential cause of fault   |
|--|
| 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.   |
| Remaining time of battery is approximately 30 minutes.   |
| Unplug USB cable   |
| If the pump is in Standby mode for more than 5 minutes, an alarm will go off.  To continue therapy press "On" [  ] or switch off the pump by pressing [  ) > 3 seconds ].  |
| Cool Invia Liberty pump down as per instructions on the display.   |
| Dressing:  - Check dressing for air leakage. Press firmly around the edges of the dressing, around the drain tubing or on the Invia FitPad.  - Apply some additional film dressing to seal the leaking area.  Connectors:  - Ensure that the dressing tubing is connected properly to the canister tubing.  - Ensure that the canister tubing is inserted straight into the pump.  Canister:  - 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 customer service. |
| Tubing:  - Ensure that the tubing is not twisted, kinked or clamped If the canister tubing is clogged, change the tubing.  Canister: - If canister is full or filter clogged, replace canister If dressing tubing is clogged, change the dressing. Then press "On" to restart the therapy.   |
| 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.  Remaining time of battery is 15 minutes.   |
| Change the canister, see chapter "Change Invia Liberty canister and Invia Liberty tubing".   |

### Alarm table

|                | Fault number | Problem description on the display           | Troubleshooting on the display   | Pressure |  |
|----------------|--------------|--|--|----------|--|
|                | 311          | Seiftest failed                              | Snap the canister out and in again   | ×        |  |
| Alarm          | 312          | Pump in Standby Leak in system 312           | Check dressing for air leakage and if consister is properly inserted.  Consult ITU for further instructions. | ×        |  |
| Als            | 313          | Filter dogged 1111                           | Change canister  | ×        |  |
|                | 315          | Acceptable internal temperature exceeded 315 | Switch pump off and on.  If problem persists, contact your Health Care representative.                       | ×        |  |
| Internal fault |              | Internal fault                               | Switch pump off and on.  If problem persists, contact Medele Customer Service.                               | ×        |  |



If fault repeats, note the fault number, switch off the pump and contact the Medela customer service.



### CAUTION

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

| Remarks/potential cause of fault  |
|---|
| Canister: - Release the canister and reposition.  Tubing: - Ensure that the tubing is not twisted, kinked or clamped.                             |
| Occurs when alarm 301 was pending for 5 minutes. For troubleshooting, refer to instructions for Alarm 301. Restart the pump by pressing "On" [ ]. |
| To restart the therapy after canister has been changed, press right selection button "On" [ ◀ ].  |
| Occurs when Warning 406 was pending for 30 minutes. Cool Invia Liberty pump down.   |
| Restart the pump. If internal fault remains, turn off by pressing [ 🖒 > 3 seconds ] and contact the Medela customer service.                      |





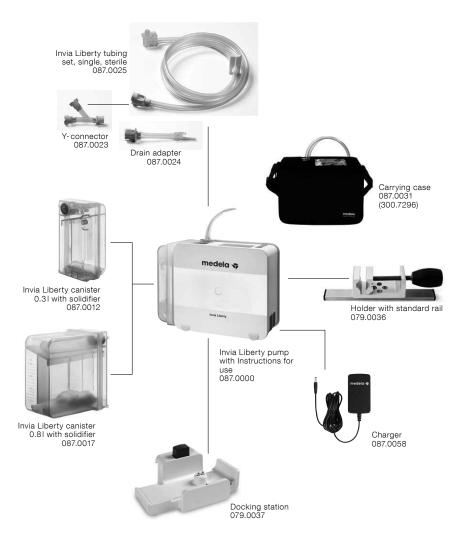
Operation continues

### 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 dressings



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 dressings only. For specific dressing indications, contraindications, warnings and cautions, consult the appropriate Invia dressing instruction for use.

# Sterility and requirements for usage

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

| Canister tubing         |     |   |
|-------------------------|-----|---|
| Canister                |     |   |
| Y-connector             | _   | These are single use devices that should be disposed of |
| Drain adapter and drain | (2) | after use. If reused performance of the product may     |
| Invia FitPad            | _   | deteriorate, cross-contamination may occur.             |
| (tubing)                |     |   |
| Wound dressing          |     |   |



## 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        | Sterilization  | Dishwasher           |
|-----------------|---------------|---------------------|--|----------------------|
| Pump            |               |                     | 4.0  | 4.0                  |
| Docking station | <b>✓</b>      | $\checkmark$        | X  | X                    |
| Rail holder     | Wipe off with | Wine off with a die | Starilization / algania                                | a in a dishwashar is |
| Charger         | a damp cloth. | infecting agent     | Sterilization/cleaning in a dishwasher is NOT allowed. |                      |
| Carrying case*  | a damp didin. | intecting agent     | NOT allowed.   |                      |

<sup>\*</sup> 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.
- Apply the disinfectant agent in accordance with instructions from the manufacturer<sup>1</sup>.
   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 manufacturer<sup>1)</sup>.
- 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 guidelines.



## CAUTION

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

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. Disposal of electronics and plastic components should be handled in accordance with local environmental guidelines.

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



#### CAUTION

Must not be disposed of together with household refuse.

# 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.

## Guarantee

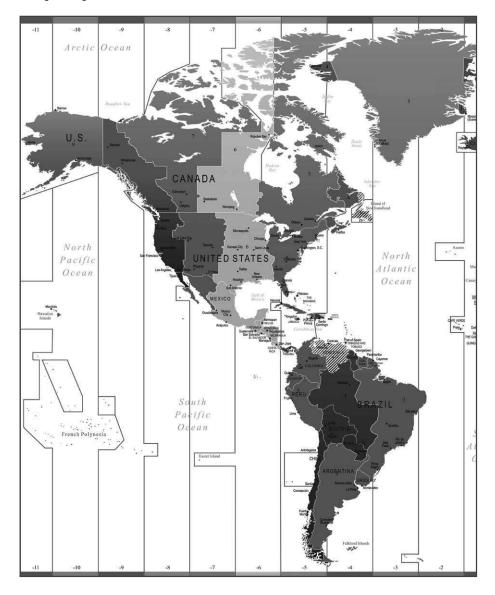
Guarantee for 2 years after date of delivery in used in accordance with these instructions. The manufacturer is not liable for any damage or consequential damage caused by incorrect operation, inappropriate usage as well as use by unauthorized persons.

## Service life

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

# Map time zone

The figure below indicates the different time zones. Please follow the indications in chapter "change settings" to select the correct time zone.



## Signs and symbols



This symbol indicates a safety related tip.



This symbol indicates a CAUTION or WARNING associated with the device



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.



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

## STERILEEO

This symbol indicates the device is sterilized using ethylene oxide.



This symbol indicates 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.



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



This symbol indicates to follow the instruction for use.



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



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

## 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 MR unsafe.



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



This symbol indicates the humidity limitation for operation and storage.



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



This symbol indicates to keep the device dry.



This symbol indicates to handle the fragile device with care.



This symbol indicates to keep the device away from sunlight.



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



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



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

# Technical specifications



vacuum range

- 40 to -200 mmHg

- 5 to -27 kPa



low flow 5 L/min



without canister 1000 g 2.2 lbs







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



ISO 13485 CE (93/42/EEC), Ila





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



alarm noise level 78 dB(A)





Operating Conditions





Transport/ Storage Conditions



Switching adapter AC

Model: MSA-C2500IS12.0-30C-ZZ

IEC: 60601-1

Input: 100-240VAC max. 0.8A,

50/60Hz

Output: 12.0VDC, 2.5A

## 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.

Electromagnetic compatibility (EMC, IEC 60601-1-2:2007 3rd Edition and IEC 60601-1-2:2014 4th Edition, Table 1)

## Electromagnetic emissions

The Invia Liberty pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Invia Liberty pump should assure that it is used in such environment.

| Emission tests   | Compliance | Electromagnetic environment – guidance  |
|--|------------|---|
| RF emissions<br>CISPR 11                                     | Group 1    | The Invia Liberty pump uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference with nearby electronic equipment. |
| RF emissions<br>CISPR 11                                     | Class B    | The Invia Liberty pump is suitable for use in all establishments, including domestic establishments and those   |
| Harmonic emissions<br>IEC 61000-3-2                          | Class A    | directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.   |
| Voltage fluctuations /<br>flicker emissions<br>IEC 61000-3-3 | Complies   |   |



### 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

Invia Liberty is a medical device that requires special safety precautions and must be installed and placed in operation in accordance with the attached EMC information.



### 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

### **EMC**

HF (high-frequency) surgical equipment, radio networks or the like can influence the operation of the device and may not be operated in combination with 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 Motion. Otherwise, degradation of the performance of this equipment could result.

## Electromagnetic compatibility

(EMC, IEC 60601-1-2:2014 4th Edition, Table 2)

## Electromagnetic immunity

The Invia Liberty pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Invia Liberty pump should assure that it is used in such environment.

| Immunity tests  | IEC 60601<br>test level   | Compliance<br>level   | Electromagnetic environment – guidance  |
|---|---|---|---|
| Electrostatic<br>Discharge (ESD)<br>IEC 61000-4-2   | ± 8kV contact<br>± 15 kV air  | ± 8 kV contact<br>± 15 kV air   | The Invia Liberty NPWT system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.  |
| Electrical fast<br>transient/burst<br>IEC 61000-4-4   | ± 2 kV for power<br>supply lines<br>± 1 kV for input/<br>output lines   | ± 2 kV for power<br>supply lines<br>± 1 kV for input/<br>output lines not<br>applicable   | The Invia Liberty NPWT system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.  |
| Surge<br>IEC 61000-4-5  | ± 1 kV differen-<br>tial mode<br>± 2 kV line-to-<br>earth   | ± 1 kV differen-tial<br>mode<br>± 2 kV line-to-<br>earth not ap-<br>plicable  | The Invia Liberty NPWT system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.  |
| Voltage dips,<br>short interrup-<br>tions and voltage<br>variations on<br>power supply<br>input lines<br>IEC 61000-4-11 | $\begin{array}{l} 0\% \ \textit{U}_{\rm T} \\ \text{for 0.5 cycle} \\ \text{at 0°, 45°, 90°,} \\ 135°, 180°, 225°, \\ 270° \ \text{and 315°} \\ \\ 0\% \ \textit{U}_{\rm T} \\ \text{for 1 cycle} \\ \\ 70\% \ \textit{U}_{\rm T} \\ \text{for 25 cycles at 50 Hz} \\ \text{Single phase:} \\ \text{at 0°} \\ \\ 0\% \ \textit{U}_{\rm T} \\ \text{for 250 cycles at 50 Hz} \\ \end{array}$ | $0\% \ U_{\rm T}$ for 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° $0\% \ U_{\rm T}$ for 1 cycle 70% $U_{\rm T}$ for 25 cycles at 50 Hz Single phase: at 0° $0\% \ U_{\rm T}$ for 250 cycles at 50 Hz | The Invia Liberty NPWT system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. If the user of the Invia Liberty pump requires continued operation during power mains interruptions, it is recommended that the Invia Liberty pump be powered from an uninterruptible power supply or a battery. |
| Power frequency<br>(50/60 Hz)<br>magnetic field<br>IEC 61000-4-8  | 30 A/m  | 30 A/m  | The Invia Liberty NPWT system is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.  |
| <b>NOTE:</b> $U_{\mathrm{T}}$ is the a.c. mains voltage prior to application of the test level.                         |   |   |   |

# Electromagnetic compatibility (EMC, IEC 60601-1-2:2014 4th Edition, Table 4)

## Electromagnetic immunity

The Invia Liberty pump is intended for use in the electromagnetic environment specified below. The customer or the user of the Invia Liberty pump should assure that it is used in such environment.

| Immunity<br>tests                | IEC 60601<br>test level        | Compliance<br>level | Portable and mobile RF communications equipment should be used no closer to any part of the Invia Liberty pump including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. |  |  |
|----------------------------------|--------------------------------|---------------------|--|--|--|
|                                  |                                |                     |  |  |  |
|                                  |                                |                     | Recommended separation distance  |  |  |
| Conducted                        | 10 Vrms                        | 10 Vrms             | $d = 0.35$ $\sqrt{P}$  |  |  |
| RF                               | 150 kHz to                     | TOVITIS             | $d = 0.35$ $\sqrt{P}$ 80 MHz to 800 MHz  |  |  |
| IEC 61000-<br>4-6                | 80 MHz                         |                     | d = 0.7 800 MHz to 2.5 GHz   |  |  |
| Radiated RF<br>IEC 61000-<br>4-3 | 10 V/m<br>80 MHz to<br>2.5 GHz | 10 V/m              | Where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and $d$ is the recommended separation distance in meters (m).   |  |  |
| 40                               |                                |                     | Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level in each frequency range. b   |  |  |
|                                  |                                |                     | Interference may occur in the vicinity of equipment marked with the following symbol:  (((•)))   |  |  |

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

- <sup>a</sup> Field strengths from fixed RF transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Invia Liberty pump is used exceeds the applicable RF compliance level above, the Invia Liberty pump should be observed to verify normal operation. If abnormal operation is observed, additional measures may be necessary, such as reorienting or relocating the Invia Liberty pump.
- <sup>b</sup> Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

# Electromagnetic compatibility (EMC, IEC 60601-1-2:2014 4th Edition, Table 6)

# Recommended separation distance between portable and mobile RF communications equipment and the Invia Liberty pump

The Invia Liberty pump is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Invia Liberty pump can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Invia Liberty pump as recommended below, according to the maximum output power of the communications equipment.

| Rated maximum out-<br>put power | Separation distance according to frequency of transmitter |                            |                      |  |  |
|---------------------------------|---|----------------------------|----------------------|--|--|
| of transmitter                  | m   |                            |                      |  |  |
| W                               | 150 kHz to 80 MHz   | 80 MHz to 800 MHz          | 800 MHz to 2.5 GHz   |  |  |
|                                 | $d = 0.35 \qquad \sqrt{P}$                                | $d = 0.35 \qquad \sqrt{P}$ | $d = 0.7$ $\sqrt{P}$ |  |  |
| 0.01                            | 0.035   | 0.035                      | 0.07                 |  |  |
| 0.1                             | 0.11  | 0.11                       | 0.22                 |  |  |
| 1                               | 0.35  | 0.35                       | 0.7                  |  |  |
| 10                              | 1.11  | 1.11                       | 2.21                 |  |  |
| 100                             | 3.5   | 3.5                        | 7.0                  |  |  |

For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

**NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

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If you need assistance contact