DHG

Moving Health Forward

VENTURI® MINO

User Manual

DHG-HEALTHCARE.COM

Contents

1. Explanation of Label Symbols and Statements

Warning

Refer to instruction manual / booklet

CE 1639 — Medical Devices Directive 93/42/EEC
Medical Device Regulation 2017/745

ETL CLASSIFIED c ETL us Intertek — North America ETL listed

Class II Equipment (Double Insulated)

Do not dispose of with the normal household waste

Manufacturer

Date of Manufacture

Suitable for connection to type BF applied parts

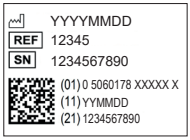
IP22 — IP: Ingress Protection
2: Protection against fingers or other object not greater than 80mm in length and 12mm in diameter
2: Protection from vertically dripping water when tilted to 15°

MD — Medical Device

REF — Catalogue number

SN — Serial number

Operating Instructions



Example of a UDI label

WARNING — This is a statement that alerts the user to the possibility of serious injury or other adverse reactions with the use or misuse of the device

CAUTION — This is a statement that alerts the user to the possibility of a problem with the system associated with its use or misuse

EC REP — Authorised Representative in the European Community

℞ only — Caution: Federal (USA) law restricts this device to sale on or by the order of a licensed healthcare professional

Single use only - do not reuse

Fragile, handle with care

Keep dry

Protect from heat and radioactive sources

Temperature limitation

Humidity limitation

Atmospheric pressure limitation

Note: Abbreviation:

Negative Pressure Wound Therapy is abbreviated to '**NPWT**' throughout this document.

2. Introduction

Thank you for choosing to use the **VENTURI** MINO Negative Pressure Wound Therapy (NPWT) system from Direct Healthcare Group. The **VENTURI** MINO NPWT system is indicated for use in a wide range of patients with acute or chronic wounds.

NPWT is applied by the application of negative pressure to a sealed (occlusive) dressing placed over the wound area. **VENTURI** MINO Wound Care Sets include a choice of gauze or foam dressing, silicone portal drain and transparent adhesive film.

The **VENTURI** COMPACT NPWT system is intended to be reusable and will benefit from careful installation and use, providing a long and effective service life. Please read and understand this document completely before applying NPWT.

3. Important Information

3.1 Intended Use

The VENTURI MINO NPWT system may be used:

- to help expedite wound closure (when healing by secondary intention)
- to reduce wound size
- for preparing a wound for closure by primary intention
- in wound management (exudate management)
- to downscale complexity of reconstructive surgery

Wounds which may benefit from the application of NPWT include pressure ulcers; dehisced surgical wounds; diabetic/ neuropathic foot ulcers; venous leg ulcers; post-op surgical wounds (including flaps and grafts); traumatic wounds; pre-op flap/graft; necrotising fasciitis; burns.

3.2 Intended Environments

The devices are intended for use by qualified healthcare professionals and lay persons in a healthcare or home environment.

3.3 Contraindications for Use

Do not place NPWT dressings directly in contact with exposed blood vessels, anastomotic sites, organs or nerves.
NPWT is contraindicated for patients with:

1. Malignancy in the wound
2. Untreated osteomyelitis
3. Non-enteric and unexplored fistulas
4. Wounds with difficult haemostasis
5. Necrotic tissue with eschar present

NB: After debridement of necrotic tissue and complete removal of eschar, NPWT can be used.

3.4 List of Components

Your **VENTURI** MINO NPWT system should comprise the following items - please ensure you have all of these before installation.

NB: Wound Care Sets are supplied separately.

- **VENTURI** MINO (TG600/14)
- 5V Mains adapter FW7662M/05
- 150ml Canister (supplied fitted to power unit)
- Carry bag (may not be included in all markets)

WOUND CARE SETS (supplied separately: available in singles and packs of 10)

- Gauze Wound Care Set
- Slim Foam Wound Care Set

Note: Other Wound Care Sets may be available; please contact Direct Healthcare Group for latest information.

ALSO AVAILABLE

150ml canister with solidifier; 5V Mains adapter FW7662M/05; Carry bag

3.5 General Warnings, Cautions and Information

- There are no special skills required to operate the power unit however, Negative Pressure Wound Therapy should only be used under the advice, recommendation and supervision of a licensed Physician and / or a registered nurse.
- The medical professional is responsible for applying his/her best medical judgment when using this system. Prior to use, the medical professional(s) treating the wound must assess how to best use the system for an individual wound.
- Select correct setting for therapy required. Care should be taken not to accidently change pressures once set as the efficiency of the therapy may be reduced. This could also be caused by pets, pests or children.
- The electricity supply is of the type indicated on the power adapter.
- Check the power adapter cord is free from damage and is positioned so as not to cause an obstruction, or injury, e.g. strangulation. Do not position the vacuum power unit or power adapter such that makes it difficult to disconnect the supply or drain plug.
- Ensure the power adapter cord, drain tube or vacuum power unit cannot become trapped or crushed, e.g. via raising or lowering of bed or bed rails or any other moving object. All tubes must be free of kinks, twists, properly connected and positioned so as not to cause an obstruction or injury.
- Do not place the vacuum power unit or power adapter on or near a heat source.
- Never use the power adapter whilst placed on top of or near to material which is flammable or can be damaged by heat. (The supplied power adapters plug directly into the power source partly mitigating this issue).
- The **VENTURI** MINO TG600/14 vacuum power unit must only be used with the approved power adapter supplied by Direct Healthcare Group (see Specification on page 12)
- The **VENTURI** MINO NPWT system (Vacuum power unit and power adapter) is not used in the presence of flammable anesthetics or in an oxygen enriched environment.
- No part of the medical device should be serviced while it is in use by the patient.
- The medical equipment requires 5 hours to warm from the minimum storage temperature before it is ready for its intended use.
- The medical equipment requires 1 hour to cool from the maximum storage temperature before it is ready for its intended use.
- Electric shock hazard; do not remove back of power unit.
- Suitable for continuous or intermittent use.
- Not suitable for sterilisation.
- The materials used in the manufacture of all components of the system comply with the required fire safety regulations.
- Direct Healthcare Group advise against smoking whilst the system is in use, to prevent the accidental secondary ignition of associated items which may be flammable.
- WARNING: No modification of this equipment is allowed. Do not use unspecified parts.
- Choking may result from a child swallowing a small part that has become detached from the ME equipment.
- A Wound Care Set must be used with the **VENTURI** MINO system to carry out NPWT.
- Please refer to the Wound Care Set 'Instructions for Use' leaflet (supplied with Wound Care Set) for dressing application and setup. Note that the dressings in the set are sterile and for single patient / single use only, not intended for reuse.
- Check canister regularly and at each canister change for signs of increased bleeding from the wound.
- If the wound exhibits swelling, pain, heat or redness of the surrounding skin, check wound for local infection.

- Use of NPWT in new borns, infants and children is not recommended.
- Intended for home healthcare and professional healthcare facility environments.
- The device is intended to be used with its carry bag.
- Do not connect to any other medical device or equipment.
- The power unit and power adapter are intended to be reusable and should be cleaned between patient use (refer to Care and Maintenance Section).
- The **VENTURI** MINO vacuum power unit is non-serviceable.
- Wireless equipment such as mobile phones should be kept at least 1 foot or 0.3 metres away from this equipment.
- The above warnings, cautions and any safety considerations should be observed on a routine and regular basis, not only upon installation.

4. How to Apply NPWT

4.1 Getting Started

NB. A Wound Care Set must be used with the **VENTURI** MINO system to carry out NPWT (see page 4 for available options). Please refer to the 'Wound Care Set Instructions for Use' leaflet (supplied with Wound Care Set) for dressing application and setup.

CAUTION! The medical professional is responsible for using his/her best medical judgment when using this system. Prior to use, the medical professional(s) treating the wound must assess how to best use the system for an individual wound.

1. Remove all packaging from the power unit and mains adapter.

   NB: If the battery charge appears to be partially depleted on first use, the power unit should be used with the power adapter, to fully charge the battery during operation.

2. Attach the drainage canister to the **VENTURI** MINO power unit by lining up the two parts, pushing together and twisting to lock (Fig. 1). Remove the bung from the connector port (this can be retained to cap the used canister prior to disposal). Ensure canister is correctly located and secured otherwise NO CANISTER alert will appear and power unit will not operate.
3. Prepare and seal wound as described in Wound Care Set 'Instructions for Use'.
4. Attach the portal drain to the power unit canister by pushing the tubing firmly and fully onto the tubing connector located on the top of the canister. Push the tubing down into the channel to assist with the routing of the tubing.

Fig. 1

4.2 Operating the Vacuum Power Unit:

1. If using the mains adapter, insert the smaller end (DC outlet) of the supplied power adapter cable into the side of the **VENTURI** MINO power unit, and the other end into the appropriate power outlet. The power adapter indicator should be illuminated.

   NB. The battery will charge when the unit is connected to the power source (indicated by battery charge icon on the top right of the display screen) and provides automatic power back-up if the external power supply or adapter fails. It is recommended to use the power adapter when convenient to do so as this will ensure the battery is fully charged when needed. A fully discharged battery will take a number of hours to fully charge.
2. Press the RUN/STOP/UNLOCK button to initialise and run the power unit (the operating pressure and battery charge status will be displayed).
3. The default operating vacuum is 80mmHg. The vacuum level can be adjusted between a choice of 80mmHg or 120mmHg by pressing the UP/DOWN arrow button.

NB. The power unit will automatically lock 1 minute after last button operation when running to prevent inadvertent operation of button functions as indicated by the lock symbol on the display screen. Press and hold the RUN/STOP/UNLOCK button until the lock symbol disappears fom the screen if further button operation is needed (i.e. change of vacuum level, or to switch off the power unit). The power unit will lock again 1 minute after last button operation. Pressing the RUN/STOP/UNLOCK button will also illuminate the display screen for 10 seconds.

4. Once the power unit is running, observe the wound site. The dressing should contract noticeably, becoming firm to the touch. If the dressing fails to contract, the dressing has not been completely sealed. Reinforce the dressing seal and/or adjust the drain and initiate suction again.
   NB. During system set-up, various checks and internal tests take place and if any intervention is required an alert will occur, but not until several minutes after set-up.
   ⚠ WARNING: Particularly when used outside of a medical institution, get immediate medical assistance from those responsible for the prescription and setting of the NPWT system should any of the following occur:- obvious bleeding or pain; the wound site or exudate presents unexpected changes in its condition, colour or odour; the wound dressing becomes detached or ineffective; the tubing becomes blocked.
5. To change or remove dressing, unlock power unit (press and hold the RUN/STOP/UNLOCK button for 3 seconds until lock symbol disappears), and switch off power unit (press and hold the RUN/STOP/UNLOCK button until power unit beeps). Clamp the drain tubing and remove by lifting the tubing up from the routing channel and pulling from the tubing connector on the canister. Dispose of used Wound Care Set according to local clinical waste policy. If required, apply new Wound Care Set and continue NPWT.
6. Canisters should be replaced as required or weekly. To change canister, clamp and remove Wound Care Set tubing as above (this can be reconnected to new canister and unclamped if wound dressing is not being changed). Rotate canister to unlock and remove from power unit. Dispose of used canister according to local clinical waste policy. If continuing NPWT, attach new canister and connect Wound Care Set tubing as previously described.
7. To switch off the power unit, unlock (press and hold the RUN/STOP/UNLOCK button for 3 seconds until the lock symbol disappears) release key and press and hold the RUN/STOP/UNLOCK button again until power unit beeps.
8. Place the user manual in a safe place for future use.

5. Operation Guidelines

5.1 User Information

The **VENTURI** MINO power unit will automatically lock 1 minute after last button operation when running to prevent inadvertent operation of button functions as indicated by the lock symbol on the display screen. Press and hold the RUN/STOP/UNLOCK button until the lock symbol disappears fom the screen if further button operation is needed (i.e. change of vacuum level, or to switch off the power unit). The power unit will lock again 1 minute after last button operation. Pressing the RUN/STOP/UNLOCK button will also illuminate the display screen for 10 seconds.

The **VENTURI** MINO power unit is suitable for ambulatory use at the advice of a Physician and is supplied with a carry bag which can be worn on the shoulder, across the body or around the waist. When placing the power unit in the carry bag, make sure that it is oriented so that the tubing exits the top of the bag without kinking, bending or straining against the connector port to ensure correct operation.

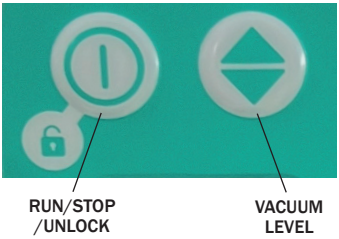
To ensure correct operation, the **VENTURI** MINO power unit should always be kept in an upright position. The power unit will display an alert if the unit is over tilted (refer to Fault Finding on page 9).

⚠ Please take care when transporting the device not to drop the system onto a hard surface, bend the canister connector or pull on the dressing tube excessively. If the connector is broken a visual and audible alarm will be activated and the canister connector should be replaced. Due to contamination the broken connector should be disposed of as clinical waste.

5.2 Operation Controls

N.B. Before any operation buttons will function, the power unit must be unlocked* - press and hold the RUN/STOP/UNLOCK button for 3 seconds until lock symbol 🔒 disappears.
The operation buttons on the face of the power unit (Fig. 2) provide the following functions.

Fig. 2



*RUN/STOP/UNLOCK
Press the RUN/STOP/UNLOCK button to initialise and run the power unit (the operating pressure and battery charge status will be shown on the display screen). To unlock the power unit press and hold the RUN/STOP/UNLOCK button for 3 seconds until the lock symbol 🔒 disappears from the display screen. To stop and switch off the power unit (once unlocked) press and hold the RUN/STOP/UNLOCK button until the power unit beeps. Pressing the RUN/STOP/UNLOCK button during operation will also illuminate the display screen for 10 seconds.

VACUUM LEVEL
The vacuum level can be adjusted between a choice of 80mmHg or 120mmHg by pressing the UP/DOWN vacuum level arrow button. The power unit will begin operation at the default pressure of 80mmHg. The selected vacuum level is shown on the display screen.

5.3 Battery Information

- A fully charged battery should operate the power unit continuously for at least 24 hours.
- Charge status is shown on the display of the power unit when it is in operation.
- The power adapter will display a green light when delivering a charge to the **VENTURI** MINO power unit.
- The battery is not serviceable and cannot be removed, changed or replaced.
- Use only the mains adapter supplied with the system.

CHARGING THE BATTERY - The battery will charge when the unit is connected to the power source, indicated by the battery charge icon on the top right of the display screen, (Fig. 3) (only displayed when the power unit is switched on) and provides automatic power back-up if the external power supply fails. It is recommended to use the power adapter when convenient to do so as this will ensure the battery is fully charged when needed. A daily charge is recommended. A fully discharged battery will take a number of hours to fully charge and can be left to charge overnight. NB. A full charge is indicated by the 'lightening bolt' symbol only.

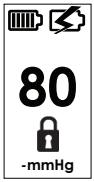


Fig. 3

6. Care and Maintenance

6.1 Power Unit

Always disconnect the **VENTURI** MINO power unit from the power adapter and the power adapter from the power source before carrying out cleaning. Check all electrical connections and power cord for signs of excessive wear. The power unit / power adapter can be wiped down with detergent or disinfectant solution or wipe*. Do not use solvents. Unsuitable for sterilisation. Dispose of the power unit / power adapter in accordance with the local regulations including WEEE requirements. The power unit / power adapter should be cleaned between patient use as a minimum.

* In line with the MHRA Medical Device Alert (MDA/2013/019), Direct Healthcare Group advises customers to use pH neutral, high level disinfectant cleaning products to sanitise reusable medical devices to prevent damage to materials and the degradation of plastic surfaces after prolonged use. The use of inappropriate cleaning and detergent materials on medical equipment could damage surfaces and may compromise the ability to decontaminate medical devices adequately or may interfere with device function. Direct Healthcare Group recommends the use of TECcare® CONTROL antimicrobial wipes and fluid to clean and decontaminate all products it supplies to health and social care facilities. TECcare CONTROL products provide class leading broad spectrum, high level disinfection with an exceptional safety profile. Being pH neutral TECcare CONTROL can be universally used on all hard and soft surfaces without any detrimental effect. TECcare CONTROL is CE marked for cleaning medical equipment.

6.2 Wound Care Sets and Canisters

Wound Care Sets and canisters are disposable and intended for single use only. After use please dispose of in an appropriate manner in accordance with local regulations and hospital best practice.

6.3 Servicing

The **VENTURI** MINO power unit is non-serviceable. Should a fault occur, please refer to the ‘Fault Finding’ section on page 9. If the power unit fails to operate correctly please contact Direct Healthcare Group or an authorised dealer.

6.4 Transport and Storage

Handle with care. Please report instances of damage or impact to Direct Healthcare Group Service Department.
–25 °C without relative humidity control; and
+70 °C at a relative humidity up to 93 %, non-condensing.
An atmospheric pressure range of 700 hPa to 1,060 hPa.
Suitable for all standard modes of transport when in the correct packaging.

6.5 Operational Conditions

A temperature range of +5 °C to +40 °C;
A relative humidity range of 15% to 93%, non-condensing; and
Operational Atmospheric Pressure: 700 hPa to 1,060 hPa
Suitable for pollution degree 2
Operational altitude ≤ 2 000 m
IP Rating: IP22 power unit only

7. Fault Finding

The **VENTURI** MINO power unit features audible and graphic indicators to alert when user intervention is required. Once corrective action has been taken the alert will self-cancel and normal operation will resume. The display screen will toggle between the alert graphic and the instruction to refer to the user manual for more information (Fig. 4). The illuminated display and sounder will persist whilst the alert state is active (NB. Tilt indicator is a graphic alert only, not audible). Should an alert persist or immediately re-occur, contact Direct Healthcare Group. All sounders can be silenced and messages cleared by pressing and holding the RUN/STOP/UNLOCK button to switch the power unit off, whilst corrective action is taking place. The time period before the alert is indicated is shown in italics.

Fig. 4

NO CANISTER (Fig. 5) (*immediate*) – indicates canister is missing or is not correctly fitted. The power unit will fail to operate whilst this message is displayed. Check that canister is correctly located and secured, as detailed on page 5.

CANISTER FULL (Fig. 6) (*60 secs*) – indicates that the canister is full and should be removed/replaced, as detailed on page 6. The power unit will cease to run until corrective action has been taken.

CONSTRICTED TUBE/LOW FLOW* (Fig. 7) (*31 mins*) – indicates tube blockage/constriction or state of low flow. Check that low flow is not caused by pinched or bent tubing. If exudate is pooling in the wound bed, the dressing should be changed. This alert will self-cancel after 5 minutes and will re-occur if the condition persists. NB. This alert may arise under normal operation if the wound exudate levels are very low.

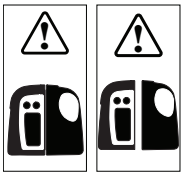


Fig. 5

Fig. 6

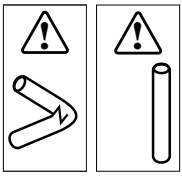


Fig. 7

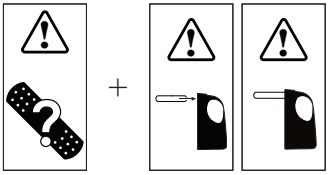


Fig. 8 Fig. 9

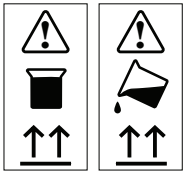


Fig. 10

Fig. 11

Fig. 12

CHECK DRESSING* (Fig. 8) **/ DISCONNECTED TUBE*** (Fig. 9) (*6 mins*) – indicates vacuum pressure has fallen below minimum allowable levels, due to either a leak in the dressing or a tube disconnection. The power unit will continue to run whilst this message is displayed. Check that wound dressing is completely sealed and that all tubing connections are secure..

TILT (Fig. 10) (graphic alert only) (*30 secs*) – activates when the power unit is placed at an angle that could affect the canister full indication. The power unit will continue to run whilst this message is displayed. Return the power unit to an upright position.

LOW BATTERY (Fig. 11) (only appears during battery operation) – battery icon at the top left of the normal operation display screen flashes on/off, indicating battery charge is low and battery needs recharging. Plug into a power source to charge.

FATAL ERROR (Fig. 12) – the screen displays a letter E followed by a number, indicating an irrepairable fault. This screen should never appear during normal operation but if it does, please contact Direct Healthcare Group.

* the sounder can be silenced temporarily by briefly pressing the UP/DOWN button.

8. Technical Specifications

8.1 VENTURI MINO Power Unit

CE 1639

(Medical Device Classification: Class IIb)

Model Ref.:	Venturi v.II TG600/14
Construction:	Flame retardant ABS
Dimensions:	W112mm/4.4" x H112mm/4.4" x D52mm/2" (with canister fitted)
Weight:	250 g / 5.5 lbs
DC Input Voltage:	5V Nominal
Vacuum Application:	Continuous
Pressure Range:	80mmHg or 120mmHg (+ / - 5mmHg)
Fixed Internal Battery:	3.7V 11.3mAh Lithium Ion - Rechargeable Cell
IP Rating:	IP22
Noise Level:	50 dBa

8.2 Canister (ACCESSORY to TG600/14)

Construction:	ABS, textured (includes absorbant media)
Capacity:	150 ml
Dimensions:	W54mm/2.1" x H112mm/4.4" x D52mm/2"

8.3 Power Adapter (ACCESSORY to TG600/14)

Mains Adapter Type:	FW7662M/05 (supplied)
Input:	100-240V / 50-60Hz / 700mA
Output:	5V dc / 1.1A
Cable Length:	2 metres / 6.5'
Part Number:	10246

The above mains adapter is considered part of the ME equipment.

The **VENTURI** MINO power unit must only be used with the specific external power adapter as supplied by Direct Healthcare Group.

EXPECTED SERVICE LIFE: The expected service life of the medical device and its ACCESSORIES is two years.

SPECIFIED SHELF LIFE: The product has no specified shelf life.

Products are free from TSE species derived materials, medicinal substances, human blood derivatives and phthalates.

Talley manufacture products to comply with National and International safety standards and are certified to ISO13485, Medical Devices Directive 93/42/EEC and Medical Device Regulation 2017/745.

This medical device is compliant with:
IEC 60601.1 3rd edition Medical electrical equipment safety and essential performance
IEC 60601.1.11 Home healthcare environment

8.4 Manufacturer's Guarantee

The **VENTURI** MINO power unit is covered by a 12 month manufacturer's guarantee.

8.5 EMI/EMC Statement and Manufacturer's Declaration

This equipment has been tested and found to comply with the limits of EN 60601-1-2.

These limits are designed to provide reasonable protection against harmful interference in both a medical and residential environment. This equipment generates, uses and can radiate radio frequency energy and, if not used in accordance with manufacturer's instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception or other equipment, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment.
- Connect the equipment to an outlet on a circuit different from that to which the receiver or equipment was connected.

The equipment having been tested to operate within the limits of electromagnetic compatibility. (Immunity to interference from nearby sources radiating radio frequency energy). Sources exceeding these limits may give rise to operation faults. Where possible the system will sense the interference and if it is of short duration transparently take countermeasures whilst operating near normally, or failing this will issue a warning and take measures for the continued safely of the user. Further increased levels of energy may cause the system to stop operating, continuously generate random faults or continuous resets.

Try to ascertain the source of the interference by turning nearby or suspect equipment off, and see if the interference effects stop. In any such event the user is encouraged to try to correct the interference by one of the following measures:

- Have the interfering equipment repaired or replaced.
- Reorient or relocate the interfering equipment.
- Increase the separation between the equipment and the possible source of the interference.
- Connect the equipment to an outlet on a circuit different from that to which the interfering equipment was connected.

Information regarding Electro Magnetic Compatibility (EMC) according to IEC60601-1-2

With the increased number of electronic devices such as PCs and mobile telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. The EMC (Electro Magnetic Compatibility) standard IEC60601-1-2 defines the levels of immunity to these electromagnetic interferences. On the other hand, medical devices must not interfere with other devices. IEC60601-1-2 also defines the maximum levels of emissions for these medical devices. The **VENTURI** conforms to this IEC60601-1-2 standard for immunity and emission. Nevertheless, special precautions need to be observed:

- The **VENTURI** needs to be installed and put into service according to the EMC information below.
- The **VENTURI** is intended for use in the electromagnetic environment specified in the tables below. The user of the **VENTURI** should assure that it is used in such environment.
- In general, although the **VENTURI** complies to the EMC standards, it can be affected by portable and mobile RF communications equipment (such as mobile telephones).
- The **VENTURI** should not be used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary, the **VENTURI** should be observed to verify normal operation.

Declaration – Electromagnetic Emissions

Guidance and Manufacturer's Declaration: Electromagnetic Emissions (IEC 60601-1-2)		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF emissions CISPR 11	Class B	The VENTURI systems are 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.
Harmonics emissions 61000-3-2	Class A	
Voltage fluctuations / flicker emissions 61000-3-3	Complies	

Declaration – Electromagnetic Immunity

Guidance and Manufacturer's Declaration: Electromagnetic Immunity (IEC 60601-1-2)			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8kV contact ± 15kV air	± 8kV contact ± 15kV air	The relative humidity should be at least 5%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV For mains supply lines 100kHz repetition frequency	± 2 kV For mains supply lines 100 kHz repetition frequency	Mains supply quality for the mains adapter should be that of a typical commercial and/or hospital environment.
Surge IEC61000-4-5	± 2kV Line(s) to ground ± 1kV line(s) to line	± 2kV Line(s) to ground ± 1kV line(s) to line	Mains supply quality for the mains adapter should be that of a typical commercial and/or hospital environment.
Voltage dips, short interruptions and voltage variations on mains supply IEC 61000-4-11	0 % U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	0 % U_T; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°	Mains supply quality for the mains adapter should be that of a typical commercial and/or hospital environment. In the event of a mains interruption the VENTURI system will automatically use internal battery power, unless the battery is exhausted.
	0 % U_T; 1 cycle 70 % U_T; 25/30 cycles Single phase: at 0°	0 % U_T; 1 cycle 70 % U_T; 25/30 cycles Single phase: at 0°	
Voltage interruptions	0 % U_T; 250/300 cycle	0 % U_T; 250/300 cycle	
Mains frequency (50/60Hz) magnetic field IEC61000-4-8	30 A/m	30 A/m	Mains frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial and/or hospital environment.
Note: U_T is the A.C. mains voltage prior to application of the test level.			

Declaration – Electromagnetic Immunity

Guidance and Manufacturer's Declaration: Electromagnetic Immunity (IEC 60601-1-2)			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment - Guidance**
Conducted RF IEC 61000-4-6	3 V rms 150 kHz ~ 80 MHz 6 V rms 150 kHz to 80 MHz in ISM and amateur radio bands between 0,15 MHz and 80 MHz	3 V rms 6 V rms	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:
Radiated RF IEC 61000-4-3	10 V/m 80 MHz ~ 2.7 GHz	10 V/m	

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.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/ cordless) telephones and land mobile 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 VENTURI is used exceeds the applicable RF compliance level above, the VENTURI should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the VENTURI.
[b] Over the frequency range 150 kHz to 80MHz, field strengths should be less than 3 V/m.

Every care has been taken to ensure that the information contained in this manual was correct at the time of going to press. However, Direct Healthcare Group reserves the right to modify the specification of any product without prior notice in line with a policy of continual product development. Information is available in alternative formats on request.

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