VENTURI® Compact

User Manual



DHCARE.COM

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1. Explanation of Label Symbols and Statements

Warning

Refer to instruction manual / booklet

1639
Medical Devices Directive 93/42/EEC

UK CA 0120
Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002)

ETL CLASSIFIED 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 15º)

MD Medical Device

REF Catalogue number

SN Serial number

Operating Instructions

YYYYMMDD
REF 12345
SN 1234567890
(01) 0 5060178 XXXXX X
(11) YYMMDD
(21) 1234567890

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** COMPACT Negative Pressure Wound Therapy (NPWT) system from Direct Healthcare Group. The **VENTURI** COMPACT system is intended for use for patients with acute or chronic wounds that may be benefitted by the application of continuous or intermittent negative pressure wound therapy to the wound for removal of fluids, including wound exudate, irrigation fluids, and infectious materials.

NPWT is applied utilising a choice of **VENTURI** Wound Care Sets (supplied separately) which include a choice of gauze or soft foam dressing, a silicone portal drain and transparent adhesive film. Both foam and gauze Wound Care Sets are available in a range of sizes according to the wound type being treated.

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 COMPACT NPWT system may be used:

- to help expedite wound closure (when healing by secondary intention)
- when preparing a wound for closure by primary intention
- for wound management (odour control, exudate management, etc.)

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

NB: Wound Care Sets are supplied separately.

- **VENTURI** COMPACT (TG600/08) vacuum power unit
- 12V Mains adapter FW7556M/12 / VEP15US12
- 300ml 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 - portal drain (standard; large; abdominal)
- Soft Foam Wound Care Set - portal drain (small; medium; large; x-large; abdominal)

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

ALSO AVAILABLE

300ml canister with solidifier; Spare battery; Y-connector x 5; Carry bag; IV pole attachment bracket

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 accidentally change pressures once set as the efficiency of the therapy may be reduced. This could also be caused by pets, pests or children.
- If therapy is interrupted for >2 hours at any given time, the dressing must be removed to prevent the development of an infection. A new dressing must then be reapplied and therapy re-initiated.
- 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** COMPACT TG600/8 vacuum power unit must only be used with the approved power adapter supplied by Direct Healthcare Group (see Specification on page 12)
- The **VENTURI** COMPACT 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.
- Refer servicing to qualified service personnel.
- When servicing use only identical parts.
- 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** COMPACT 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 or holder.
- Do not connect to any other medical device or equipment.
- When the canister is not fitted on the vacuum power unit, it is essential that the aperture on the rear face of the unit (Fig. 1) is not blocked or covered (e.g. with a label).
- 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** COMPACT power unit battery is installed inside the unit and is not accessible by users. Battery replacement should only be carried out by qualified Direct Healthcare Group service personnel.
- Wireless equipment such as mobile phones should be kept at least 1 foot or 0.3 metres away from this equipment.

Fig.1



- 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** COMPACT 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: The power unit internal battery may be mostly discharged or in an inert state on first use. This will require the power unit to be used with the power adapter, which will automatically wake an inert battery, operate the system and charge the internal battery.
2. If not already in place, attach canister to flat face of power unit by matching up the rear location pegs and rotating locking knob 1/4 turn clockwise to secure. Ensure canister is correctly located and secured otherwise NO CANISTER message will appear and power unit will not operate.
3. Prepare and seal wound as described in Wound Care Set 'Instructions for Use'.
4. Attach Wound Care Set to the **VENTURI** COMPACT power unit canister by lining up locator stud on the tubing connector with the notch on the canister tubing port located on top corner of canister, pushing down gently and twisting clockwise to lock. A tube guide is fitted to assist with the routing of the tubing.

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** COMPACT 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 status icon on display screen scrolling from left to right) 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 RUN/STOP button to invoke and display STAND-BY mode (the power unit will beep and therapy mode, operating pressure and battery charge status will be displayed).
3. The power unit will default to continuous therapy mode at 80mmHg. To switch between continuous and intermittent therapy modes, press and hold the THERAPY MODE button until power unit beeps to confirm change of mode. Adjust vacuum level if required using the UP and DOWN arrow buttons.
4. Press RUN/STOP button again to initialise and run the power unit.
   NB. Vacuum level and therapy mode can be adjusted when in stand-by mode and for up to 1 minute after power unit is running. Power unit will automatically lock 1 minute after last button operation when running to prevent inadvertent operation of button functions (except MUTE), as indicated by 🔒 on the display screen. Press and hold the UNLOCK button until power unit beeps if further button operation is needed. Display screen is only illuminated for a short period after button operation in battery mode.
5. 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.
   ⚠ 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.
6. To change or remove dressing, unlock power unit (press and hold UNLOCK until power unit beeps), then press and hold the RUN/STOP button until power unit beeps three times to return to stand-by mode. Clamp Wound Care Set tubing and remove by turning anticlockwise and lifting out of tubing port on canister. Dispose of used Wound Care Set according to local clinical waste policy. If required, apply new Wound Care Set and continue NPWT.
7. Canisters should be replaced as required or weekly. To change canister, make sure power unit is in stand-by mode (if still running, press and hold the UNLOCK button, followed by the RUN/STOP button). Clamp Wound Care Set tubing and remove by turning anticlockwise and lifting out of tubing port (this can be reconnected to new canister and unclamped if wound dressing is not being changed). Remove sealing plug from its location on canister and use to cap tubing port to seal in contents. Rotate locking knob 1/4 turn anticlockwise and remove canister. 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.
8. To stop the power unit, press and hold the UNLOCK button until power unit beeps and 🔒 clears from display screen. Then press and hold the RUN/STOP button until power unit beeps three times to return to stand-by mode (if using the power adapter, disconnect it from the power unit and unplug from the power source). The power unit will then power off automatically after one minute of inactivity or may be forced off by pressing the MUTE button.
9. Place the user manual in a safe place for future use.

5. Operation Guidelines

5.1 User Information

The **VENTURI** COMPACT power unit will automatically lock 1 minute after last button operation when running to prevent inadvertent operation of button functions (except MUTE), as indicated by 🔒 on the display screen. Press and hold the UNLOCK button until power unit beeps if further button operation is needed (i.e. change of therapy mode or vacuum level, or returning power unit to stand-by mode). The power unit will lock again 1 minute after last button operation.

Please note that when running, the **VENTURI** COMPACT power unit must be unlocked before it can be returned to stand-by mode, i.e. the power unit cannot be put into stand-by mode when the 🔒 is displayed on the screen.

During operation, the power unit should be placed upright on a horizontal surface with the display uppermost. The VENTURI COMPACT power unit can be attached to an IV pole using the optional bracket. The **VENTURI** COMPACT power unit is suitable for ambulatory use at the advice of a Physician. To allow patient full mobility during therapy, the

power unit can also be placed in the carry cases provided. In all instances the power unit/canister assembly should be kept upright during use to ensure correct operation - the power unit will display a warning if the unit is over tilted.

⚠ 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 (except MUTE), the power unit must be unlocked* - press and hold the UNLOCK button until the power unit beeps and the lock symbol clears from the display screen.

The operation buttons on the face of the power unit (Fig. 2) provide the following functions.

Fig. 2



RUN/STOP

Press to invoke stand-by mode prior to running power unit. Press again to run power unit. Press and hold whilst power unit is running (and unlocked) to cease operation and return to stand-by mode. In battery operation the power unit will then power off after 1 minute of inactivity. If using mains power, switch off by disconnecting power cable from power unit or turning off mains power.

VACUUM LEVEL

Vacuum level can be adjusted when in stand-by mode and for up to 1 minute after last button operation when power unit is running using the UP and DOWN arrow buttons. Pressure can be adjusted in 5mmHg increments between 10mmHg and 180mmHg according to treatment requirements, the most widely used being between 60-80mmHg. The power unit will begin operation at the default pressure of 80mmHg. The selected vacuum level is shown on the display screen.

MUTE

Press to silence the sounder and to clear the message from the display screen. The MUTE button can also be used to force power-off in stand-by mode.

THERAPY MODE

The power unit offers a choice of continuous or intermittent therapy modes. On power-on, the power unit will default to continuous therapy mode. To switch between therapy modes, press and hold the THERAPY MODE button until power unit beeps to confirm change of mode. When in intermittent therapy mode, the power unit will provide vacuum therapy for periods of 5 minutes followed by a 2 minute rest period. The selected therapy mode is displayed on the power unit screen and can be altered in either stand-by or (unlocked) run modes.

*UNLOCK / LIGHT

The power unit will automatically lock 1 minute after last button operation when running to prevent inadvertent operation of button functions (except MUTE), as indicated by 🔒 on the display screen. Press and hold the UNLOCK button until power unit beeps if further button operation is needed (i.e. change of therapy mode or vacuum level, or returning power unit to stand-by mode). The power unit will lock again 1 minute after last button operation. Pressing this button will also illuminate the display screen for 10 seconds if power unit is in battery operation (screen will always be illuminated in mains operation).

5.3 User Selectable Functions

The following functions are selectable in a user menu:-

- Language selection
- Tilt indicator, switch on or off
- Tube constriction indicator, switch on or off
- Battery inert. Note that it is essential that the battery is put to this condition before international transportation.

The menu is accessed by a three second press of the UNLOCK button. The arrow buttons scroll to the functions shown above, and the THERAPY MODE button allows the function to be toggled on or off, or selected. Pressing the UNLOCK button returns the device to stand-by mode.

5.4 Setting / Changing Power Unit Display Language

The power unit display default language is English, but can easily be changed to the language of your choice, as follows:-

a) Access the user menu by pressing the UNLOCK button for three seconds.
b) Scroll through the user functions using the arrow buttons until 'Set Language' is displayed (Fig. 3). Press the THERAPY MODE key to select this function.
c) To select the required language, press and hold the THERAPY MODE button until the language is displayed. Releasing the THERAPY MODE button will then set the display for the language. Pressing the UNLOCK button returns the device to stand-by mode.



Fig. 3

5.5 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 stand-by and run mode.
- As the batteries are automatically charged as required when the system is operating on mains power, the battery module should not require removing or changing in normal use.
- Use only the mains adapter supplied with the system.
- When power unit operation times when running from the internal battery are noticeably shorter than normal, it is time to replace the battery pack. Contact Direct Healthcare Group or authorised dealer for battery replacement service.
- Never use any battery pack that is damaged or worn out. Use the battery pack only for its intended purpose.
- The battery pack is not serviceable and should be replaced if faulty (indicated by applicable battery faults displayed in place of battery charge status icon). Contact Direct Healthcare Group or authorised dealer for battery replacement service.
- The internal Lithium Ion Battery may be received or become inert if left for extended periods in storage or a fully discharged condition. Connection of a power adapter will wake / charge the battery and immediately allow the full use of the vacuum power unit. It is possible to force the vacuum power unit into making the battery inert should this be required by some airline and other carriers. See 'User Selectable Functions' Menu for details (Page 8).

CHARGING THE BATTERY - If not fully charged, the battery will automatically charge when the power unit is plugged into a power source via the power adapter. The battery will charge whilst the vacuum power unit is in standby or a run mode.

REPLACING THE BATTERY - The battery is installed inside the unit and is not accessible by users. Battery replacement should only be carried out by qualified service personnel. Contact Direct Healthcare Group or authorised dealer for battery replacement service.

6. Care and Maintenance



6.1 Power Unit

Always disconnect the **VENTURI** COMPACT power unit from the power adapter and the power adapter from the power source before carrying out maintenance, repairs, servicing or 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

Once the initial guarantee period expires, Direct Healthcare Group recommend that power units should be serviced every two years or as indicated by the 'hours to service' display.) The unit contains no user serviceable parts and should only be serviced by either Direct Healthcare Group or an authorised dealer. Direct Healthcare Group or the authorised dealer will make available on request service manuals, component parts lists and other information necessary for a competent electrical engineer to repair or service the system. For service, maintenance and any questions regarding this, please contact Direct Healthcare Group or an authorised dealer.

It is the customer's responsibility to ensure the following prior to collection:

- the system is cleaned of any obvious contaminants.
- contamination status is documented.
- assistance is given to Direct Healthcare Group personnel to bag the equipment if the mattress has been in a known or suspected infectious environment.

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

All sounders can be silenced and messages cleared by pressing the MUTE button once. Should any fault occur, press the MUTE button to reset the power unit. If fault remains/re-occurs, contact Direct Healthcare Group.

7.1 Warning Indicators

NO CANISTER – 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.

LOW BATTERY (only appears during battery operation) – the power unit will continue to run whilst this warning is displayed. Press the MUTE button to silence the sounder and clear the message. Note that the system will automatically shut down when the battery is fully discharged. Plug into a power source to charge.

CANISTER FULL – indicates that the canister has reached its capacity and should be changed. The power unit will cease to run and the message/sounder will continue until the RUN/STOP button is pressed or the canister is removed, both of which cancels the message and sounder and returns the power unit to stand-by mode. Change canister as detailed on page 6.

NB. The 'Canister Full' sounder can be silenced by pressing the MUTE button, however if the canister is not removed/ changed the sounder will reoccur after 10 minutes.

LOW VACUUM / CHECK DRESSING (alternating messages) – indicates vaccum pressure has fallen below minimum allowable levels. Power unit will continue to run whilst these messages is displayed. Check that wound dressing is completely sealed and that all tubing connections are secure. Press the MUTE button to silence the sounder and clear the messages. If fault re-occurs, contact Direct Healthcare Group.

TUBE CONSTRICTION – indicates that pump demand has abruptly ceased. Note that a certain level of flow in the drain is required for the indicator to be active. The message will occur for example in the case of a blocked tube, kinked tube or if the dressing is obstructed. Note that the tube constriction indicator can be selected on or off as required (see 'User Selectable Functions' on page 8). Default is on.

TILT – activates when the device is in active mode and is placed at an angle that could affect the canister full indication. The sounder delays for 5 seconds, and is self-muting when the unit is returned to an upright position. Note that the tilt indicator can be selected to be on or off as required (see 'User Selectable Functions' on page 8). Default is on.

7.2 Fault Indicators

EMI FAULT – indicates that the unit detects the pressure sensor amplifier is adversely affected by external RF fields. The power unit will continue to run whilst this message is displayed. Press the MUTE button to silence the sounder. This indicator will clear when interference ceases.

CHECK MOISTURE – indicates that moisture or exudate has been detected in the power unit. The power unit will cease to operate on this indication. Refer to Direct Healthcare Group for service assistance.

If any of the following faults are displayed the power unit will cease to operate:- PUMP OPEN; NO CANISTER; PUMP OFF FAULT (PUMP SHORT); RELEASE KEY; BATTERY FAULT. Should any of these faults occur, press the MUTE button to reset the power unit. If fault remains/re-occurs, contact Direct Healthcare Group.

The power unit may also display the following information (the power unit will continue to run whilst these messages are displayed):-

- SERVICE DUE - Contact Direct Healthcare Group to arrange service
- UNCALIBRATED - Contact Direct Healthcare Group for recalibration.

8. Technical Specifications

8.1 VENTURI COMPACT Power Unit

CE 1639

[Medical Device Classification: Class IIb - conforms with Directive (93/42/EEC) Annex II (excluding Section 4)

Model Ref.:	Venturi v.II TG600/08
Construction:	Flame retardant ABS
Dimensions:	W161mm/6.3” x H155mm/6.1” x D90mm/3.5”
Weight:	1.0kg / 2.2 lbs
DC Input Voltage:	12V Nominal
Vacuum Application:	Continuous (default therapy) or intermittent
Pressure Range:	10 to 180mmHg (+0mmHg / -20mmHg)
Fixed Internal Battery:	3.7V 10Wh Lithium Ion Rechargeable Cell
IP Rating:	IP22
Noise Level:	43 dBa

8.2 Canister (ACCESSORY to TG600/08)

Construction:	ABS, textured (includes desiccant)
Capacity:	300 ml
Dimensions:	W156mm/6.1” x H163mm/6.4” x D32mm/1.3”

8.3 Power Adapter (ACCESSORY to TG600/08)

Mains Adapter Type:	FW7556M/12 / VEP15US12 (supplied)
Input:	100-240V / 50-60Hz / 400mA
Output:	12V dc / 1.5A
Cable Length:	4 metres / 13’
Part Number:	10245

The above mains adapters are considered part of the ME equipment.

The **VENTURI** COMPACT 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 five 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** COMPACT power unit is covered by a 24 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.

Our standard terms and conditions apply.

Notes

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