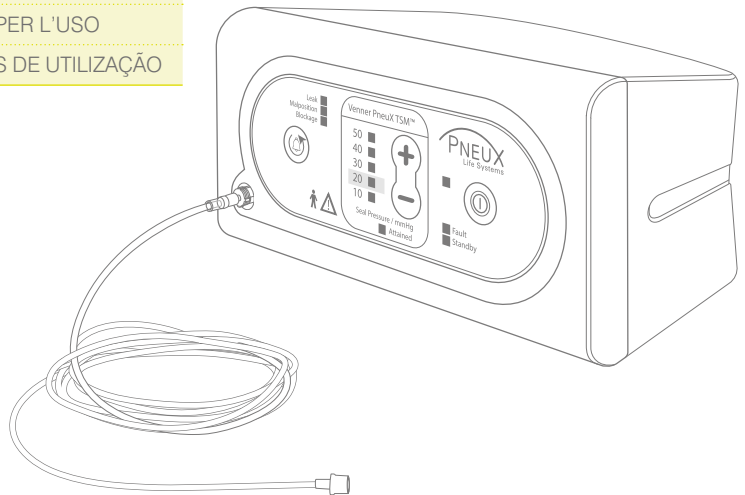


Venner PneuX TSM™ Cuff Pressure Controller Venner PneuX™ Extension Tube

en	INSTRUCTIONS FOR USE
de	BEDIENUNGSANLEITUNG
es	INSTRUCCIONES DE USO
fr	MODE D'EMPLOI
it	ISTRUZIONI PER L'USO
pt	INSTRUÇÕES DE UTILIZAÇÃO



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These instructions for use are for the following Venner PneuX™ products:

Product code	Description	Quantity/box
903200	Venner PneuX TSM™ Cuff Pressure Controller	1
903010	Venner PneuX™ Extension Tube (clean, non-sterile)	10

Only Venner PneuX™ ETT and TT are to be used with the Venner PneuX TSM™ Cuff Pressure Controller and Venner PneuX™ Extension Tube.

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1. Device description

1.1 Venner PneuX TSM™ Cuff Pressure Controller

The Venner PneuX TSM™ (Figures 1a and 1b) is an automated cuff pressure controller designed to be used with the Venner PneuX™ Endotracheal Tube (ETT) and Tracheostomy Tube (TT) as a complete system.

It is designed for the monitoring, maintenance and regulation of pressure within the cuffs of the Venner PneuX™ ETT/TT in adult patients requiring tracheal intubation for extended periods (not more than 30 days). It should be used in medical institutions such as hospitals and extended care facilities by trained medical professionals.

The Venner PneuX TSM™ Cuff Pressure Controller has an attached Mains charger, audible alarms, LED light indicators and function buttons (refer to Section 3: Alarms, Buttons and Indicators). It is supplied with four international plug adapters (Figure 1c), a pole clamp and two long screws (5 mm x 14 mm) for mounting purposes if required.

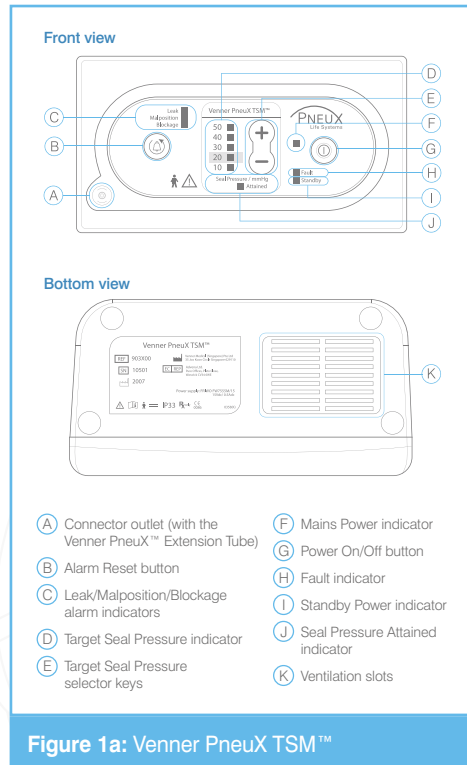


Figure 1a: Venner PneuX TSM™

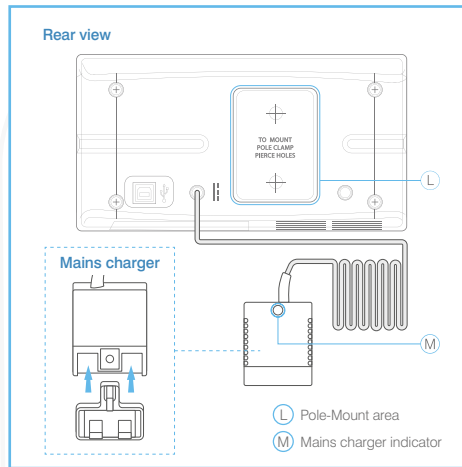


Figure 1b: Venner PneuX TSM™

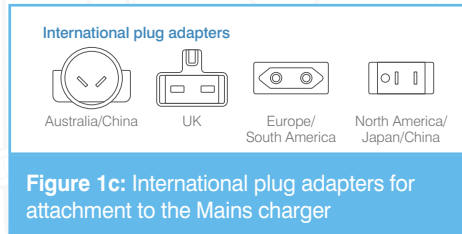


Figure 1c: International plug adapters for attachment to the Mains charger

1.2 Venner PneuX™ Extension Tube

The 2-metre single use Venner PneuX™ Extension Tube (Figure 2) connects the Venner PneuX TSM™ with the Venner PneuX™ ETT/TT. One end of the tube is a uniquely designed Luer lock connector for attachment to the Connector outlet on the Venner PneuX TSM™ and the other end is a Luer slip connector which has a protective sleeve impeding connection to Luer lock devices for attachment to the pilot valve of the Venner PneuX™ ETT/TT.

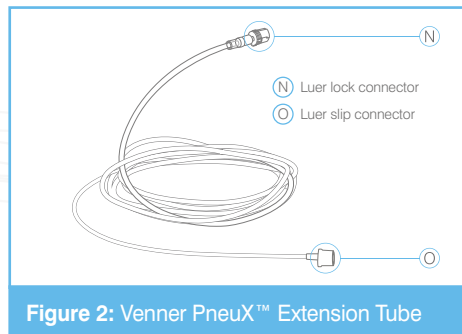


Figure 2: Venner PneuX™ Extension Tube

The Luer lock connector incorporates several features:

- A twist-to-connect one way valve prevents accidental disconnection with the Venner PneuX TSM™
- Free coupling rotation avoids the potential of tube kinking
- Turning latch clicks when connected prevents damage from over torquing

1.3 Technical specifications

Venner PneuX TSM™	
Weight	1.4 kg (device) 2.0 kg (in box)
Size	220 x 110 x 115 mm (device) 300 x 285 x 130 mm (in box)
Power input	100-240 V / 50-60 Hz / 400 mA
Power output	15V / 1.0A
Power supply	Friwo (model: FW7555/15)
Ingress protection	IP33

2. Operating instructions

The Venner PneuX TSM™ is calibrated to be accurate within +/- 5% of the setting.

CAUTION: All alarms and indicators may have false positive and false negative errors and should not be regarded as a substitute for the continuous attention of a skilled professional.

2.1 Preparation for use

Prior to using the Venner PneuX TSM™, ensure the patient is intubated with a Venner PneuX™ ETT/TT with the cuff inflated to a clinical seal. The unique characteristics of the Venner PneuX™ ETT/TT cuffs ensure that a low and consistent intracuff pressure is transmitted to the tracheal wall. An intracuff pressure of 80 cmH₂O provides a calculated tracheal wall seal pressure of approx. 30 cmH₂O (~20 mmHg) depending on the patient's trachea anatomy and the ventilation pressures. For details, refer to the Venner PneuX™ ETT/TT IFU.

CAUTION: Due to varying patient anatomies, requirements for different ventilation pressures and the Venner PneuX TSM™ accuracy to be within +/-5% of setting, a clinical seal may be achieved between 80-90 cmH₂O.

Position Venner PneuX TSM™ on a suitable flat surface or on a drip pole. For attachment to a drip pole pierce through the two target points on the Pole-Mount area (Figure 1b:L) of the device. Attach the clamp to the device using the long screws provided and thereafter, secure tightly to the drip pole.

2.2 Using the device

Attach the appropriate international plug adapter (Figure 1c) to the Mains charger by sliding its vertical slots through the bottom of the Mains charger (Figure 1b). Begin operating the Venner PneuX TSM™ by connecting the Mains charger to a power outlet and observe a GREEN light appearing on the Mains charger indicator (Figure 1b:M) to confirm there is power supply. A RED light from the Standby Power indicator (Figure 1a:I) should also illuminate. If no light appears on either indicators, check the connection.

Proceed to attach the Luer lock connector (Figure 2:N) of the Venner PneuX™ Extension Tube to the Connector outlet (Figure 1a:A) on the Venner PneuX TSM™, and the Luer slip connector (Figure 2:O) to the pilot valve of the ETT/TT. Ensure that there is no accidental pulling or tugging of the Extension Tube.

Switch on the Venner PneuX TSM™ by pressing the Power On/Off button (Figure 1a:G). All LED indicator lights will flash rapidly five times before adjusting to the default seal pressure illuminated by the Target Seal Pressure indicator (Figure 1a:D). The default seal pressure setting is 20 mmHg (approx. 30 cmH₂O) unless a user change this using the Target Seal Pressure Selector Keys (Figure 1a:E). During normal operation, all 3 lights (Mains Power indicator (Figure 1a:F), Target Seal Pressure indicator and Seal Pressure Attained indicator (Figure 1a:J)) will illuminate at all times.

CAUTION: Should any of the three lights not illuminate, press the Alarm Reset button (Figure 1a:B) to reset Venner PneuX TSM™. If this does not work, do not use the Venner PneuX TSM™ and disconnect the Extension Tube (refer to Section 2.4: Disconnection). Contact the local distributor for technical support.

2.3 During use

Cuff pressure changes

An increase or decrease in cuff pressure can occur due to trans-cuff diffusion of gases, or changes in:

- Tracheal compliance
- Location of the cuff within the airway
- The ventilator/patient interactions

The Venner PneuX TSM™ regulates the ETT/TT cuff pressure, thereby minimising the risk of complications associated with excessive pressure (necroses) or inadequate pressure (aspiration pneumonia) exerted on the tracheal wall.

Patient transfer

The Venner PneuX TSM™ must be disconnected before moving patients for operative procedures, scans or during transfer to other departments/hospitals (refer to Section 2.4: Disconnection).

Overpressure safety (audible “clicks”)

Should the tracheal wall seal pressure exceed 57 mmHg, a safety valve will audibly “click” open and vent the excess pressure. It will subsequently reset itself with a second “click”, at 27 mmHg for safe operation. The first and second “clicks” may be simultaneous and be heard as a double click.

CAUTION: If persistent clicking of the safety valve is heard for any reasons other than a user setup error or substantial patient movement, then there may be a fault with the Venner PneuX TSM™. Contact the local distributor for technical support.

ETT/TT pilot valve failure

In the event of a failed pilot valve, the Venner PneuX TSM™ may not be able to maintain an effective seal. Perform re-intubation with a new Venner PneuX™ ETT/TT as soon as the clinical circumstance allows.

▶ 2.4 Disconnection

Prior to disconnection, perform subglottic secretion drainage to clear the subglottic space. If required, proceed to disconnect the ETT/TT from the Luer slip connector of the Extension Tube and subsequently, disconnect the Luer lock connector of the Extension Tube from the Venner PneuX TSM™.

Cuff pressure should be maintained temporarily (at hourly intervals) with a standard cuff manometer until a new Venner PneuX™ ETT/TT is reconnected to Venner PneuX TSM™.

CAUTION: Note that the intracuff pressure is normally maintained at 80 cmH₂O with the Venner PneuX™ ETT/TT, this corresponds to a tracheal wall seal pressure of approx. 30 cmH₂O, or 20 mmHg on the Venner PneuX TSM™.

Take care when using a cuff manometer or syringe for inflation due to the potential for variations in pressure.

Positive End-Expiratory Pressure (PEEP) may provide additional protection during manual cuff pressure adjustments if it is indicated and deemed clinically safe.

▶ 2.5 Shutdown

Press the Power On/Off button to switch off the Venner PneuX TSM™. Disconnect the system properly (refer to Section 2.4: Disconnection) before unplugging the Mains charger from the wall outlet.

Dispose of the Extension Tube as a contaminated item and clean the Venner PneuX TSM™ following the cleaning instructions (refer to Section 4: Decontamination).

3. Alarms, buttons and indicators

Alarm Reset button (Figure 1a:B)

When pressed, this button will cancel sounding alarms for about 1-2 minutes and if no intervention has taken place during this time, the alarms will re-sound to alert users for attention.

CAUTION: DO NOT ignore alarms or continuously press the Alarm Reset button.

Leak, Malposition and Blockage alarm indicators (Figure 1a:C)

These alarm indicators should be checked and actioned upon immediately if sounded. DO NOT ignore alarms and they should not replace the need for continual patient monitoring.

Leak alarm indicator

This alarm indicator will illuminate RED and produce an audible alarm when an exceptional air leak is detected. This may suggest:

- **A detachment with the connection.** Check both connections of the ETT/TT pilot valve with the Luer slip connector of the Extension Tube as well as the Luer lock connector of the Extension Tube with the Connector outlet on the Venner PneuX TSM™. Perform reconnection if required.
- **A puncture with the Extension Tube or ETT/TT.** The cuff of the ETT/TT will deflate and an air leak with patient ventilation may be audible. Should this occur, disconnect the system (refer to Section 2.4: Disconnection), remove the damaged Extension Tube or ETT/TT and inflate the cuff with a cuff manometer. Proceed to reconnect a new Extension Tube and ETT/TT to the Venner PneuX TSM™ (refer to Section 2: Operating instructions).

CAUTION: Note that the Venner PneuX™ ETT/TT will remain inflated for up to an hour without connecting to the Venner PneuX TSM™, however, cuff pressure should still be monitored and maintained (where necessary) with a cuff manometer.

Malposition alarm indicator

This alarm indicator will illuminate RED and produce an audible alarm if a sustained and increased air requirement for cuff inflation is detected. The alarm will trigger for as long as there is an increased air requirement (until the cuff is fully inflated within the larynx or stoma).

If an ETT is in place, the cuff may have moved into the larynx/pharynx resulting in a partial extubation. If a TT is in place, there could be a withdrawal into an open stoma or an accidental extubation.

Should this occur, disconnect the system (refer to Section 2.4: Disconnection) and deflate the cuff for re-intubation using a cuff manometer. Proceed to reconnect a new Venner PneuX™ ETT/TT to the Venner PneuX TSM™ (refer to Section 2: Operating instructions).

CAUTION: A malposition false alarm is possible if a patient is coughing excessively or experiencing laboured breathing.

Blockage alarm indicator

This alarm indicator will illuminate RED and produce an audible alarm if the standard cyclical pressure variability associated with mechanical ventilation is lost. This may suggest:

- **An occlusion with the Extension Tube or ETT/TT inflation line.** Check to confirm and if so, disconnect the system (refer to Section 2.4: Disconnection) and replace with a new Extension Tube or ETT/TT for reconnection with the Venner PneuX TSM™ (refer to Section 2: Operating instructions).
- **An occlusion with the inflation lumen within the airway tube** due to external compression, e.g., an overtightened lock nut or external tie around the ETT/TT. If so, loosen the lock nut or tie to correct this.
- **A blockage of the airway lumen possibly with secretions,** causing the cyclical cuff pressure changes to be lost. Confirm by other clinical observations and if so, re-intubate the patient or use standard techniques to re-establish a patent airway.

CAUTION: A blockage false alarm is possible if the patient is breathing very gently.

Target Seal Pressure indicator (Figure 1a:D)

This indicator illuminates GREEN next to the seal pressure being set: 10, 20, 30, 40 or 50 mmHg. The default seal pressure setting is 20 mmHg (approx. 30 cmH₂O) and should not be changed unless necessary following clinical review. Use the Target Seal Pressure Selector Keys to change and set the required seal pressure.

The following situations may require an increase in seal pressure above 20 mmHg (approx. 30 cmH₂O) temporarily:

- Patients with high intrathoracic pressures who have a translaryngeal air leak with ventilation (particularly with high PEEP and peak pressure requirements).
If increased seal pressure is required to prevent a translaryngeal air leak, check the cuff position for unintentional carinal or laryngeal placement.
- Patients with abnormal tracheal anatomy
- Patients intubated with an incorrect (smaller) ETT/TT size (normally size 8.0 mm for a female and size 9.0 mm for a male)

- A volume recruitment manoeuvre which requires greater sustained intrathoracic pressure to prevent a translaryngeal air leak past the cuff (some clinicians may choose to allow an air leak during recruitment manoeuvre to create a “PEEP purge” and propel residual upper airway secretions into the oral cavity for removal)

- To introduce fluid into the subglottic space at a higher pressure in order to perform subglottic irrigation

CAUTION: If the seal pressure is set to 40 or 50 mmHg for more than three minutes, its indicator will flash to visually alert users that the current seal pressure is higher than normal.

Target Seal Pressure Selector Keys (Figure 1a:E)

The (+) and (-) selector keys allow users to move up or down to select the five levels of seal pressure setting.

Mains Power indicator (Figure 1a:F)

This indicator illuminates GREEN when the device is switched on and working normally.

Power On/Off button (Figure 1a:G)

This button switches the device on or off.

Fault indicator (Figure 1a:H)

This indicator illuminates RED when the device detects an internal fault. Other display lights may show at the same time. Should this happen, do not use the device and contact the local distributor for technical support.

Standby Power indicator (Figure 1a:I)

This indicator illuminates RED when the device is on standby mode for power on.

Seal Pressure Attained indicator (Figure 1a:J)

This indicator illuminates GREEN after the set seal pressure has been achieved. It normally illuminates alongside the Target Seal Pressure indicator and Mains Power indicator during normal operations.

Mains charger indicator (Figure 1b:M)

This indicator illuminates GREEN when there is power supply to the Venner PneuX TSM™ once connected to a power outlet.

4. Decontamination

The Venner PneuX TSM™ must be cleaned and disinfected before first use and between each patient use, in accordance with local cleaning regime for non-autoclavable, non-metallic devices.

Visit www.VennerPneuX.com/IFU for a list of recommended cleaners and disinfectants.

All Venner PneuX™ ETT/TT and Extension Tube are single use, they should be disposed of in accordance with standard departmental practices after use.

5. Service and maintenance

5.1 General maintenance

The Venner PneuX TSM™ should be inspected at regular intervals for visible signs of external damage.

Any other doubts or faults with the device will require diagnosis by an authorised service centre, contact the local distributor for technical support.

5.2 Preventive maintenance

The Venner PneuX TSM™ is recommended to be serviced every two years.

When returning for servicing, pack the device in its original product box or wrap the device carefully for protection. The device should be sent to the authorised service centre as advised by the local distributor.

6. Warnings and precautions

The Venner PneuX TSM™ must only be used with the Venner PneuX™ ETT/TT and Venner PneuX™ Extension Tube.

The Venner PneuX™ Extension Tube is a single use device. Reuse may cause cross-infection, reduce product reliability and functionality.

The Venner PneuX TSM™ alarms operate in the event of critical conditions such as over-inflation, sudden deflation or pressure loss. Do not ignore alarms and take appropriate actions (refer to Section 3: Alarms, buttons and indicators).

Do not attempt to control the Venner PneuX TSM™ by pressing multiple buttons at the same time.

In the unlikely event of a complete power failure, the cuff pressure will be maintained by the Venner PneuX TSM™ provided there are no system leaks. Restart operations when power is restored (refer to Section 2: Operating instructions).

In the unlikely event of any indicators and function buttons ceasing to operate, such as no light illumination or non-responsive buttons, disconnect the device (refer to Section 2.4: Disconnection) and contact the local distributor for technical support.



















7. Warranty

PneuX Life Systems warrants the hardware products to be free from defects in material and workmanship under normal use and service. PneuX Life Systems' obligation under this warranty is limited to correcting the defect in the product or any part thereof which is defective in material or workmanship during the warranty period. Replacement shall be determined by PneuX Life Systems wherein such supplies fail to meet applicable specifications and were purchased directly from PneuX Life Systems or an PneuX Life Systems authorised party, for use with Venner PneuX™ products, and provided the Buyer or Customer has complied with the handling, storage and shelf life requirements as specified by PneuX Life Systems. Any attempts to modify or open up the device will void its warranty automatically. PneuX Life Systems shall have no responsibility whatsoever for consumable supplies purchased from any other source.

THE ABOVE WARRANTIES ARE EXCLUSIVE OF, AND IN LIEU OF, ALL OTHER WARRANTIES, WRITTEN OR ORAL, EXPRESS OR IMPLIED, STATUTORY OR OTHERWISE. NO IMPLIED STATUTORY WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE SHALL APPLY. PNEUX LIFE SYSTEMS SHALL NOT BE LIABLE FOR ANY DAMAGES SUSTAINED BY BUYER ARISING FROM DELAY IN THE REPLACEMENT OR REPAIR OF PRODUCTS UNDER THE ABOVE WARRANTY.

Terms and conditions may change without prior notice.

8. Symbols used on labelling


	Caution		Device should be stored and used between +10°C and +40°C (50°F – 104°F)
	Consult Instructions for Use (IFU)		Keep dry
	Non-sterile		Keep away from sunlight
	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician		Date of manufacture
	Type B: Provides a basic degree of protection against electric shock as specified in the standard IEC60601-1. The applied part typically has direct earth connection		Legal manufacturer (EU) and Manufactured for (US)
	Direct current		Authorized representative in the European Community
	Power On/Off button		European Conformity mark Notified Body: BSI Group (2797)
	Protection of equipment against ingress of solid foreign objects ≥ 2.5 mm diameter. Protection against access to hazardous parts with a tool, thick wire, etc. Protection against water falling as a spray at any angle up to 60° from the vertical shall have no harmful effect.		Fragile, handle with care
			Catalogue number
			Serial number

9. Technical information

The Venner PneuX TSM™ should be used and stored between +10°C and +40°C (50°F – 104°F) with relative humidity between 30% and 75%. This device is not affected by atmospheric pressure changes.

The Venner PneuX TSM™ conforms to the requirements of the electromagnetic compatibility standard for medical electrical equipment, EN 60601-1-2 and is intended for use in the electromagnetic environment specified below. Users should ensure that the Venner PneuX TSM™ is used in such an environment.

Electromagnetic emissions		
Emissions test	Compliance	Electromagnetic environment guidance
Radiofrequency (RF) emissions CISPR 11	Group 1	Venner PneuX TSM™ uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	
Harmonic Emissions IEC 61000-3-2	Class A	Venner PneuX TSM™ 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 fluctuations/flicker emissions IEC 61000-3-3	Complies	

Electromagnetic immunity			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Venner PneuX TSM™ uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines There is no input/output line	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) There is no connection to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycles 40% UT (60% dip in UT) for five cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for five seconds	<5% UT (>95% dip in UT) for 0.5 cycles 40% UT (60% dip in UT) for five cycles 70% UT (30% dip in UT) for 25 cycles <5% UT (>95% dip in UT) for five seconds	Mains power quality should be that of a typical commercial or hospital environment. If the user of Venner PneuX TSM™ requires continued operation during mains power interruptions, it is recommended that Venner PneuX TSM™ be powered from an uninterruptible power supply.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
CAUTION: UT is the a.c. mains voltage prior to application of the test level.			
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of Venner PneuX TSM™, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance d = 1.2√P d = 1.2√P 80 MHz to 800 MHz d = 2.3√P 800 MHz to 2.5 GHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	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: 
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined 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.			

a. Field strengths from fixed 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 Venner PneuX TSM™ is used exceeds the applicable RF compliance level above, the Venner PneuX TSM™ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Venner PneuX TSM™.

Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.

The Venner PneuX TSM™ is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. Users of Venner PneuX TSM™ can help to prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the device as recommended below, according to the maximum output power of the communication equipment.

Recommended separation distances between portable and mobile RF communications equipment			
Rated maximum output power of transmitter (m)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz d = 1.2√P	80 MHz to 800 MHz d = 1.2√P	800 MHz to 2.5 GHz d = 1.2√P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be determined 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.

STATEMENT: Venner PneuX TSM™ is classed as Medical Electrical Equipment that requires special precautions to be taken regarding EMC, and needs to be installed and put into service according to the electromagnetic compatibility information provided in the accompanying documents.

