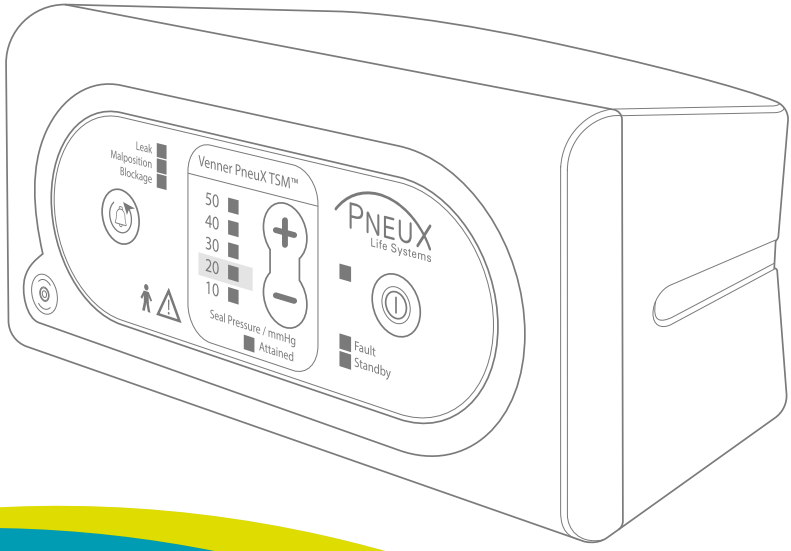
PNEUX
Life Systems

Venner PneuX TSM™

EN (UK) INSTRUCTIONS FOR USE



Manufactured for:
Venner Medical (Singapore) Pte Ltd
35 Joo Koon Circle, Singapore 629110
www.vennermedical.com

EU Authorised Representative:
Advena Ltd
Pure Offices, Plato Close,
Warwick CV34 6WE UK
www.advenamedical.com

Contents

1. Device description

Venner PneuX TSM™ (903200) is a precision electronic device that provides automated cuff pressure control for the Venner PneuX™ Endotracheal (ETT) / Tracheostomy Tube (TT) during extended use.

It is designed for the monitoring, maintenance and regulation of pressure within the cuffs of the Venner PneuX™ ETT/TT in adult patients required 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 (Figure 1).

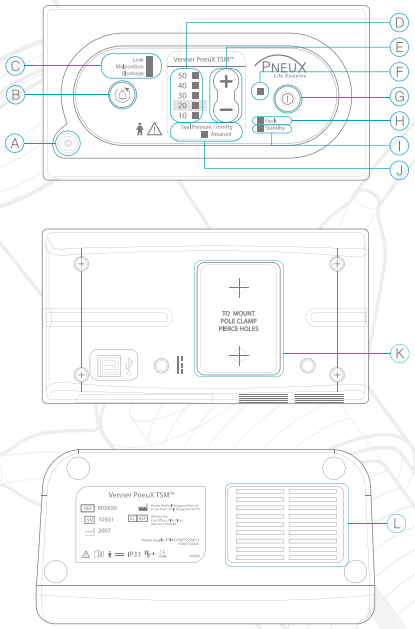
Venner PneuX™ Extension Tube

The 2 m Venner PneuX™ Extension Tube (903010) for Venner PneuX TSM™ is a non-sterile, single use item. It has a safety-Luer connector that attaches to the air outlet on Venner PneuX TSM™ and a safety Luer slip connector (with a protective sleeve impeding connection to Luer lock devices, such as intravascular cannulae and taps) that attaches to the pilot valve of the Venner PneuX™ ETT/TT.

Pole clamp

Use only the pole clamp supplied.

Figure 1: Venner PneuX TSM™



- (A) Venner PneuX™ Extension Tube Connector
- (B) Alarm Reset Key
- (C) Alarms
- (D) Target Pressure Indicators
- (E) Target Pressure Selector Keys
- (F) Mains Power Indicator
- (G) Power On/Off Button
- (H) Fault Indicator
- (I) Standby Power Indicator
- (J) Pressure Attained Indicator
- (K) Pole-Mount Indicator
- (L) Ventilation Slots

Figure 2: Venner PneuX TSM™ main functions

2. Preparation for use

The patient should be intubated with a Venner PneuX™ ETT/TT with the cuff inflated to a clinical seal. The elastic characteristics of the Venner PneuX™ cuff are calibrated such that only a constant portion of the intracuff pressure is transmitted to the tracheal wall. An intracuff pressure of 80 cmH_2O provides a calculated tracheal wall pressure of approx. 20 mmHg (approx. 30 cmH_2O) depending on the diameter of the patient's trachea.

Position Venner PneuX TSM™ on a suitable flat surface or secure it tightly with the clamp to a drip pole. To use the pole clamp supplied, it must be attached in the labelled position shown on the rear of the monitor, using the two 5 mm x 14 mm long screws provided. The screw holes are located, where shown, through the label, which should be punctured (Figure 2: [K]).

Connect the power supply to a wall outlet. The red standby light illuminates indicating that Venner PneuX TSM™ is now connected and ready for power on. If the red standby light does not illuminate, check the power supply connection to the wall outlet.

Securely attach the single-use Venner PneuX™ Extension Tube, using the safety-Luer connector, to the air outlet on Venner PneuX TSM™ (Figure 2: [A]). Attach the Luer slip connector of the Venner PneuX™ Extension Tube to the pilot valve of the Venner PneuX™ ETT/TT. Make sure that patient movement does not allow the Venner PneuX™ Extension Tube to be tugged or pulled.

Press the on/off button (Figure 2: [G]). Check that ALL the LED indicator lights flash rapidly 3 times. If any do not flash, do not use Venner PneuX TSM™ and seek assistance (Figure 2: [C],[D],[F],[H],[I],[J]).

Venner PneuX TSM™ defaults to a setting of 20 mmHg (approx. 30 cmH_2O) calculated tracheal wall pressure.

NOTE: During normal use, 3 lights (Figure 2: [F],[H],[I]) must be lit up at any one time. Should this NOT occur, it must be assumed that there is a fault. Press the alarm reset key to reset Venner PneuX TSM™. If the reset does not work, Venner PneuX TSM™ should no longer be used, and the Venner PneuX™ Extension Tube should be disconnected (Section 5: Disconnection).

3. Disconnection

Prior to disconnection, perform subglottic secretion drainage to ensure that the subglottic space is clear of secretions.

Ensure that you disconnect the Venner PneuX™ Extension Tube from the pilot valve of the Venner PneuX™ ETT/TT before disconnecting it from the air outlet on Venner PneuX TSM™. Cuff pressure control should be maintained temporarily (at hourly intervals) with a standard handheld cuff pressure inflator/manometer until the Venner PneuX™ ETT/TT is reconnected to Venner PneuX TSM™.

4. During use

Cuff pressure changes

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

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

Venner PneuX TSM™ regulates cuff pressure, keeping it stable, thus minimising the risk of complications associated with excessive pressure (necroses) or inadequate pressure (aspiration pneumonia) exerted on the tracheal wall.

Patient transfer

Venner PneuX TSM™ must be disconnected (Section 5: Disconnection) before moving patients for operative procedures, scans or during transfer to other departments or hospitals.

Care should be taken when using a handheld cuff pressure inflator/manometer and syringes for inflation because there is the potential for a slight variation in pressure when using such devices.

NOTE: After disconnection, the seal is no longer protected by Venner PneuX TSM™ and the following precautions should be observed. Cuff pressure can be maintained temporarily with a standard handheld cuff pressure inflator/manometer until the Venner PneuX™ ETT/TT is reconnected to Venner PneuX TSM™.

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

5. Shutdown procedure

When Venner PneuX TSM™ is no longer required, press the on/off button (Figure 2: [G]) to switch off.

Do not unplug from the wall socket until disconnection (Section 5: Disconnection) has occurred. Dispose of the Venner PneuX™ Extension Tube as a contaminated item.

Clean Venner PneuX TSM™, as described in the cleaning instructions (Section 10: Cleaning, maintenance and service), and store in a secure place away from extreme conditions or where the device could be damaged.

6. Alarms and indicators

Fault indicator

Should Venner PneuX TSM™ detect an internal fault (Figure 2: [H]), the red fault light illuminates and an audible alarm is heard. Other display lights may also show at the same time. Press the alarm reset key to reset Venner PneuX TSM™. If the reset does not work, follow the instructions for disconnection (Section 5: Disconnection). Do not continue to try to use the monitor and seek assistance.

Power

Venner PneuX TSM™ is normally connected to the mains power supply (Figure 2: [F]) during use and, in this circumstance, the green power light is illuminated. Should there be no power supply, follow the instructions for disconnection (Section 5: Disconnection).

Leak alarm

Should Venner PneuX TSM™ detect an exceptional air leak (Figure 2: [C]), it will produce an audible alarm and the leak indicator will illuminate.

Should the Venner PneuX™ Extension Tube become disconnected from the pilot valve of the Venner PneuX™ ETT/TT, the cuff will remain inflated for up to an hour; however, cuff pressure should still be monitored and, if necessary, maintained with a standard handheld cuff pressure inflator/manometer. Simply reconnect the Venner PneuX™ Extension Tube to the pilot valve of the Venner PneuX™ ETT/TT.

Should the Venner PneuX™ Extension Tube become disconnected from the air outlet of Venner PneuX TSM™, The cuff will remain inflated for up to an hour; however, cuff pressure should still be monitored and, if necessary, maintained with a standard handheld cuff pressure inflator/manometer. It will produce an audible alarm and the leak indicator will illuminate, simply reconnect the Venner PneuX™ Extension Tube (Section 4: Preparation for use) to the air outlet of the Venner PneuX TSM™.

Should there be a fracture in the Venner PneuX™ Extension Tube, the cuff will deflate and an air leak with patient ventilation may be audible. Should this occur, the damaged Venner PneuX™ Extension Tube should be removed (in accordance with the disconnection instructions, Section 5: Disconnection) and the airway cuff should be re-inflated with a manual cuff pressure inflator/manometer. Reconnect a new Venner PneuX™ Extension Tube, select the desired tracheal wall pressure, and connect the Venner PneuX™ Extension Tube to the pilot valve of the Venner PneuX™ ETT/TT (Section 4: Preparation for use).

Should there be a pilot tubing fracture or cuff puncture (which may occur if the cuff or inflation tube is punctured e.g., by surgical instruments), the cuff will deflate and an air leak with patient ventilation may be audible. Should this occur, disconnect Venner PneuX TSM™, replace the Venner PneuX™ ETT/TT, then reconnect Venner PneuX TSM™.

Malposition alarm

Venner PneuX TSM™ can detect if a sustained and increased air requirement for cuff inflation has occurred. This is indicated by the illumination of the malposition light (Figure 2: [C]) and an audible alarm. The malposition alarm will trigger for as long as there is an increased air requirement (until the cuff is fully inflated within the larynx or stoma).

With an ETT in place, this can indicate that the airway cuff may have moved into the larynx or pharynx and a partial extubation may have occurred.

With a TT in place, this can indicate withdrawal into an open stoma or accidental extubation. Excessive coughing or laboured breathing may trigger a false malposition alarm.

NOTE: The malposition alarm can only be triggered once the set pressure has been achieved.

Blockage alarm

Venner PneuX TSM™ can detect if the standard cyclical pressure variability associated with mechanical ventilation is lost. This is indicated by the illumination of the tube blockage (Figure 2: [C]) light and an audible alarm. If a blockage alarm occurs, check the following:

a. The patency of the airway ventilation lumen. A blockage of the ventilation lumen, for example with secretions, can trigger this alarm because the cyclical cuff pressure changes can be lost. This can be confirmed by other clinical observations and a patent ventilation lumen should be re-established by the clinician using standard techniques or by re-intubating the patient.

b. The Venner PneuX™ Extension Tube or ETT/TT pilot tubing may be kinked, crushed or occluded. Replace the Venner PneuX™ Extension Tube (following Section 5: Disconnection) or un-kink the pilot tubing.

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

NOTE: The blockage alarm can only be triggered once the set pressure has been achieved.

Cuff pressure attained indicator

A confirmatory visual LED indicator (Figure 2: [J]), to confirm that the calculated tracheal wall pressure has been achieved.

Calculated tracheal wall pressure indicator

The default tracheal wall pressure is set at 20 mmHg (approx. 30 cmH_2O) and this should not be changed unless it is deemed appropriate following clinical review. For example, occasional patients may require a temporary increase in calculated tracheal wall pressure. Changes may be made by pressing the + or – keys (Figure 2: [E]) until the desired tracheal wall pressure is shown by the illumination of the applicable indicator (Figure 2: [D]). After 3 minutes of wall pressure of 40 and 50 mmHg, a flashing light will appear on Venner PneuX TSM™ to visually alert users that the cuff wall pressure is higher than normal (unless a particular patient case requires the increase, or to perform subglottic secretion irrigation).

For example:

a. Patients with high intrathoracic pressures who have a translaryngeal air leak with ventilation (particularly with high PEEP and peak pressure requirements).

b. Patients with abnormal tracheal anatomy.

c. If excessive calculated tracheal wall pressures are required to prevent a translaryngeal air leak, the cuff position should be checked (e.g, unintentional carinal or laryngeal placement).

d. A volume recruitment manoeuvre requiring a sustained intrathoracic pressure of greater than 20 mmHg (approx. 30 cmH_2O) will also require a temporary increase in the lateral calculated tracheal wall pressure if the clinician wishes to avoid a translaryngeal air leak past the cuff.

e. A clinician wishing to introduce fluid into the subglottic space at a pressure that may exceed 20 mmHg (approx. 30 cmH_2O), may choose to increase the calculated tracheal wall pressure temporarily during the irrigation up to a maximum of 50 mmHg.

f. The tracheal tube is too small for the trachea in which it is placed.

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

Recommended tube sizes for Venner PneuX™ ETT/TT are: size 8.0 ID for females and size 9.0 ID for males.

Alarm reset

The alarms (Figure 2: [B]) are cancelled for 90 seconds and will re-sound if no further intervention has taken place.

NOTE: Do not ignore alarms and keep resetting.

All these alarms and indicators may have false positive and false negative errors and are not a substitute for the continuous attention of a skilled professional.

Overpressure safety (audible clicks)

Should the cuff wall pressure ever exceed 57 mmHg then a safety valve will audibly (click) open and vent any excess pressure. It will then reset, with a second “click”, at 27 mmHg for safe operation. Should this happen for any reason other than operator set-up error, or substantial patient movement, i.e., regular clicking as the valve opens and closes persistently, Venner PneuX TSM™ should be replaced and returned for service.

NOTE: In certain circumstances, the opening and closing “clicks” may be simultaneous and heard as a double click.

7. Complications

Airway pilot valve failure

Should this occur, the airway pilot valve needs to be clearly labelled as faulty but the airway can still be safely used if continuously connected to Venner PneuX TSM™. The clinician may wish to re-intubate with a new airway when clinical circumstances are suitable.

8. Cleaning, service and maintenance

Cleaning

Venner PneuX TSM™ should be cleaned before and after use with a new patient. Venner PneuX TSM™ should be disconnected from the mains power supply prior to cleaning. The outer surface of the monitor can be cleaned as per hospital policy or with alcohol and/or chlorhexidine-based cleaning products, and wiped dry with a soft cloth. Care should be taken not to introduce fluid into the interior of the monitor, which should never be submerged.

Venner PneuX™ Extension Tube is a non-sterile, single-patient-use item, it should be disposed of in accordance with standard departmental practices after use.

Service

Venner PneuX TSM™ is recommended to be serviced every 2 years. Please record a date for this. The device must be returned to your Venner PneuX™ System distributor..

Weight	2 kg in box, 1.4 kg Venner PneuX TSM™
Dimensions	300 x 285 x 130 mm in box 220 x 110 x 115 mm Venner PneuX TSM™
Power	Input 100-240 V / 50-60 Hz / 400 mA Output: 15 V / 1.0 A
Power Supply	Friwo (Model: FW7555/15)

Maintenance

Venner PneuX TSM™ is a sealed unit and no parts can be repaired. The only user maintenance required is normal cleaning.

9. Environmental conditions of use

Transport, store, and use Venner PneuX TSM™ between 10°C and 40°C (50°F – 104°F) and between 30% and 75% relative humidity. This device is not affected by atmospheric pressure changes.

Venner PneuX TSM™ conforms to the requirements of the electromagnetic compatibility standard for medical electrical equipment, EN 60601-1-2.

10. Classifications

Venner PneuX TSM™ is a Class II (a) medical device under the regulations described in the European Medical Device Directive 93/42/EEC.

Venner PneuX TSM™ EN 60601-1 electrical safety classifications are as a portable item of medical equipment designed for continuous operation with a type B part protection against electric shock.

Venner PneuX TSM™ is suitable for use within the patient environment.

NOTE: US Federal law restricts this device to sale by or on the order of a physician.

11. Warnings and safety notices

It is necessary to read these Instructions for Use before preparation.

Venner PneuX TSM™ must only be used with:

- A Venner PneuX™ ETT/TT as it is only calibrated for the Venner PneuX™ ETT/TT.
- The Venner PneuX™ Extension Tube because of the safety feature that prevents misconnection to standard leur locks.

In case any alarm sounds, follow the procedure for disconnection (Section 5: Disconnection), and determine and correct the reason for the alarm (Section 8: Alarms and indicators).

Venner PneuX TSM™ must be disconnected (Section 5: Disconnection) before moving patients for operative procedures, scans or during transfer to other departments or hospitals.

After disconnection (Section 5: Disconnection), the seal is no longer protected by Venner PneuX TSM™ and the following precautions should be observed. Cuff pressure control should be maintained temporarily (at hourly intervals) with a standard handheld cuff pressure inflator/manometer until the Venner PneuX™ ETT/TT is reconnected to Venner PneuX TSM™.

Care should be taken when using a handheld cuff pressure inflator/manometer and syringes for inflation because there is the potential for a slight variation in cuff pressure when using such devices. Please follow your standard hospital procedures for monitoring cuff pressure.

Do not ignore alarms. The use of alarms does not relieve hospital staff of the need for continual patient monitoring.

Alarms operate in the event of dangerous conditions such as over-inflation, sudden deflation or pressure loss (Section 8: Alarms and indicators).

Should the leak alarms occur, action should be taken immediately (Section 5: Disconnection). Do not continue to try to use Venner PneuX TSM™, and seek assistance.

Should the malposition alarm occur, both patient ventilation and the tube position should be checked immediately.

In the unlikely event of:

- Complete power failure, the cuff pressure will be maintained provided there are no system leaks. In such an event, Venner PneuX TSM™ will need to be reset in start mode when power is restored.
- Control panel ceasing to operate, i.e., the unit is operating (cuff pressure is maintained) but no lights are illuminated, or the keypad is not responding, disconnect (Section 5: Disconnection) the device from the external power supply, disconnect the system, and return the device for repair.

If there is any doubt about Venner PneuX TSM™ maintaining cuff pressure, or creating an unintentional over-pressure, or if there is any other uncertainty about the operation of the device, disconnect (Section 5: Disconnection) and switch it off (Section 7: Shutdown procedure). Seek assistance for the faulty device as soon as possible.

Users are advised to check the integrity of the Venner PneuX TSM™ outer casing, connections and the power supply and cabling, once each month. Return the device for service if any damage is suspected, by contacting your local Venner PneuX™ Systems Distributor.

Only press control buttons one at a time in the sequence required.

Do not attempt to open. No modification of this equipment is allowed. Opening will break the manufacturer's seals and will void any guarantee offered by the manufacturer.

12. Manufacturer's warranty

PneuX Life Systems warrants Venner™ products against faulty materials or manufacturing defects. Single-use products are warranted against faulty materials or manufacturing defects at the time of delivery to the customer. Warranty is applicable only if purchased from an authorised distributor.

VENNER MEDICAL (SINGAPORE) PTE LIMITED DISCLAIMS ALL OTHER WARRANTIES, WHETHER EXPRESSED OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

13. Symbols used on labelling

	Consult Instructions for Use (IFU)
CE 0086	Complies with the European Medical Device Directive 93/42/EEC
EC REP	The name and address of the European Authorised Representative as required by the European Medical Device Directive 93/42/EEC
	Year of manufacture
	Manufacturer
	Keep away from sunlight
SN	Device serial number
REF	Product Code
	Non-sterile (Venner PneuX™ Extension Tube)
	Direct current power supply
IP33	The Venner PneuX TSM™ is tested to the requirement of IEC60529 according to the degree of protection against harmful ingress of water and particulate matter
	Type B Applied Part with respect to electrical shock protection as specified in IEC60601-1
	Keep dry
	Device should be stored and used between 10°C and 40°C (50°F – 104°F)
	Read instructions before use
Rx only	Federal law restricts this device to sale by or on the order of physician
	Power on/off control
	Fragile, handle with care

14. Manufacturer's information

The information given in this document is correct at the time of going to press. The manufacturer reserves the right to improve or modify the products without prior notification.

Manufactured for

Venner Medical (Singapore) Pte Ltd
35 Joo Koon Circle
Singapore 629110

EU Authorised Representative

Advena Ltd
Pure Offices
Plato Close
Warwick
CV34 6WE
UK

15. Manufacturer's declaration

Guidance and manufacturer's declaration: Electromagnetic emissions

Venner PneuX TSM™ is intended for use in the electromagnetic environment specified below. The customer or the user of Venner PneuX TSM™ should ensure that it is used in such an environment.

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	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.
Harmonic Emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration: Electromagnetic immunity

Venner PneuX TSM™ is intended for use in the electromagnetic environment specified below. The customer or the user of Venner PneuX TSM™ should ensure that it is used in such an environment.

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% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	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 or battery.
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.

NOTE: UT is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration: Electromagnetic immunity

Venner PneuX TSM™ is intended for use in the electromagnetic environment specified below. The customer or the user of Venner PneuX TSM™ should ensure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 V 3 V/m	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 $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz 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™.

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

Recommended separation distances between portable and mobile RF communications equipment and the Venner PneuX TSM™

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

Rated maximum output power of transmitter (m)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 1.2\sqrt{P}$
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.

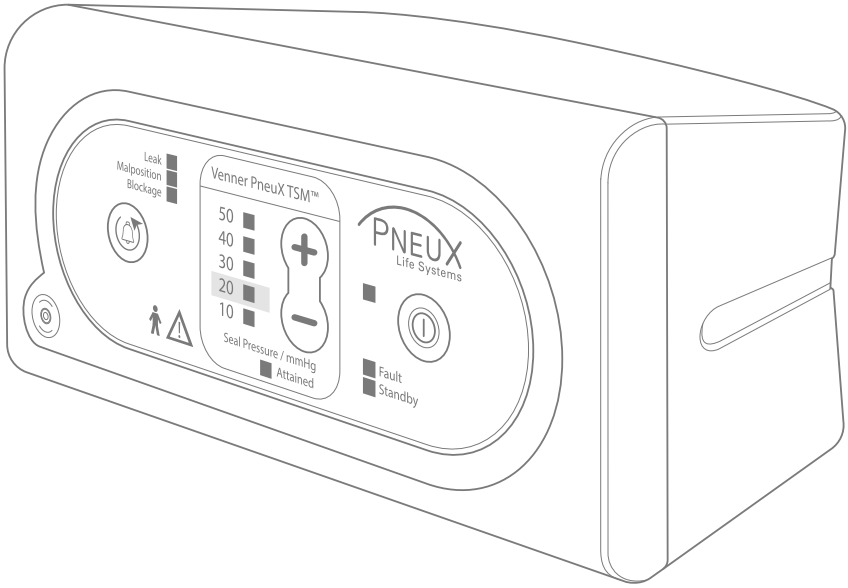
NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

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.

VENNER
Medical International

Inspired by ideas. Driven by quality



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