Tracheal Seal Monitor

Designed exclusively for use with the

Venner™ PneuX P.Y.™ System

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1. DEVICE DESCRIPTION

Venner™ Tracheal Seal Monitor, part # 903000 (White)/ 903100 (Grey)/ 903200 (Blue)

Venner™ Tracheal Seal Monitor is a precision electronic automatic pressure controller for controlling the safe inflation volume and pressure within Venner™ PneuX P.Y.™ Endotracheal (ETT) or Tracheostomy Tube (TT) cuff during extended use.

Extension tube (available separately), part # 903001 (Sterile) and part # 903010 (Non-Sterile)

The 2 metre extension tube for Venner™ Tracheal Seal Monitor is a sterile, single patient use item. It uses a non-Luer connector at the proximal end to the air outlet on the Venner™ Tracheal Seal Monitor and a safety Luer slip connector (with a protective sleeve impeding connection to the Luer lock devices such as intravascular cannulae and taps) at the distal end to the pilot valve of Venner™ PneuX P.Y.™ ETT or TT

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

2. INDICATIONS

Venner™ Tracheal Seal Monitor is indicated for use to monitor, maintain and regulate the pressure within the Venner™ PneuX P.Y.™ ETT or TT cuff in adult patients patients undergoing tracheal intubation during extended periods (not more than 30 days).

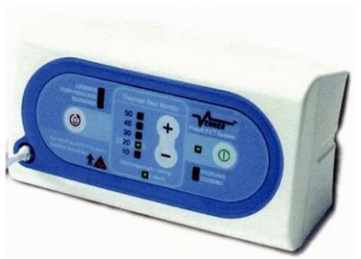
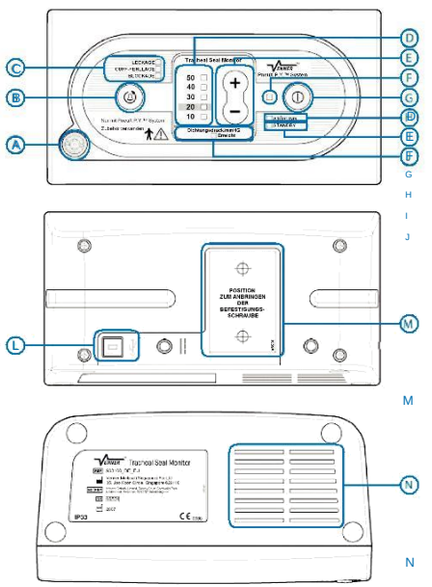


Figure 1: Venner™ Tracheal Seal Monitor



- A 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 key
- H Fault indicator
- I Standby power indicator
- J Pressure attained indicator
- L USB port
- M Pole-mount indicator
- N Ventilation slots

Figure 2: Venner™ Tracheal Seal Monitor main functions

3. CONTRAINDICATIONS

Venner™ Tracheal Seal Monitor is contraindicated if use of Venner™ PneuX P.Y.™ ETT or TT are contraindicated.

4. WARNINGS AND SAFETY NOTICES

Venner™ Tracheal Seal Monitor must only be used with Venner™ PneuX P.Y.™ ETT or TT as it is only calibrated for Venner™ PneuX P.Y.™ ETT or TT.

It is necessary to read these Instructions for Use before preparation to check the default settings and connection to the patients. In case any alarm sounds, follow the procedure for disconnection, determine and correct the reason for the alarm (See Section 7: Alarms and Indicators)

WARNING: Venner™ Tracheal Seal Monitor must be disconnected before moving patients for operations, scans or transfer to other hospitals.

WARNING: Always disconnect the extension tube firstly, at the distal end from the pilot valve of Venner™ PneuX P.Y.™ ETT or TT before disconnecting at the proximal end from the air outlet on Venner™ Tracheal Seal Monitor.

Alarms operate in the event of dangerous conditions such as over-inflation, sudden deflation or pressure loss (See Section 7: Alarms and Indicators). IN THE EVENT OF A FAILURE, PARTICULARLY IF PRESSURE IS LOST AND THE LEAK ALARM SOUNDS, ACTION MUST BE IMMEDIATELY TAKEN. In such cases, the extension tube MUST be disconnected firstly, at the distal end from the pilot valve of Venner™ PneuX P.Y.™ ETT or TT , before disconnection at the proximal end from the air outlet on the Venner™ Tracheal Seal Monitor. Cuff pressure control can be maintained temporarily with a standard handheld cuff pressure manometer until another Venner™ Tracheal Seal Monitor is available. Do not continue to try to use the Venner™ Tracheal Seal Monitor again and seek assistance.

In the unlikely event of complete power failure, the cuff pressure will be maintained provided there are no system leaks and the extension tube is being disconnected at the distal end firstly, from the pilot valve of Venner™ PneuX P.Y.™ ETT or TT, before disconnection at the proximal end from the air outlet on Venner™ Tracheal Seal Monitor. In such an event, Venner™ Tracheal Seal Monitor will need to be re-set in start mode when power is restored.

In the unlikely event of the control panel ceasing to operate, i.e. the unit is operating (cuff pressure is maintained) but no lights are lit, or the keypad is not responding, disconnect the device from the external power supply, disconnect the system, and return the device for repair. Disconnection MUST follow the procedure described above, the extension tube being disconnected at the distal end firstly, from the pilot valve of Venner™ PneuX P.Y.™ ETT or TT before disconnection at the proximal end from the air outlet of Venner™ Tracheal Seal Monitor. Cuff pressure control can be maintained temporarily with a standard handheld cuff pressure manometer until another Venner™ Tracheal Seal Monitor is available.

The use of alarms does not relieve hospital staff of the need for continual patient monitoring. Please follow your standard hospital procedures for setting and monitoring cuff pressure. If there is any doubt about the Venner™ Tracheal Seal Monitor maintaining cuff pressure, or creating an unintentional over-pressure, or if there is any other uncertainty about the operation of the device, switch it off, disconnect the extension tube connector from the airway pilot valve and, if necessary, manually check/re-inflate the cuff with a standard pressure gauge inflator. Seek assistance with the faulty device as soon as possible.

Venner™ Tracheal Seal Monitor is NOT tested as being suitable for use in the presence of a flammable anaesthetic mixture with air, or with ambient enriched oxygen, or nitrous oxide or any other flammable gases or vapours.

Users are advised to check the integrity of Venner™ Tracheal Seal Monitor enclosures, connections and the power supply and cabling, once each month. Return the device for service if any damage is suspected.

5 PREPARATION FOR USE

- The patient should already be intubated with a Venner™ PneuX P.Y.™ ETT or TT with the cuff inflated to 80 cmH_2O. The elastic characteristics of Venner™ PneuX P.Y.™ 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 upon the diameter of the patients trachea.
- Position Venner™ Tracheal Seal Monitor on a suitable flat surface or tightly secure by the clamp to a drip pole.
- To use the pole clamp supplied, it must be attached in the labelled position shown at the rear of the monitor, using the two 5mm x 14mm long screws provided. The screw holes are located, where shown, through the label which should be punctured (shown as [M] in figure 2).
- Attach the single use extension tube , part # 903001 securely, using the non-Luer connector, to the white air outlet on Venner™ Tracheal Seal Monitor (shown as [A] in figure 2).
- Connect the power supply to wall outlet. The red standby light illuminates indicating Venner™ Tracheal Seal Monitor 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 again.
- Venner™ Tracheal Seal Monitor defaults to a setting of 20 mmHg calculated tracheal wall pressure.
- Attach the distal end of the extension tube to the pilot valve of Venner™ PneuX P.Y.™ ETT or TT. Make sure that patient movement does not allow the extension tube to be tugged or pulled.
- Press the on/off button (shown as [G] in figure 2). Check that ALL the LED indicator lights flash rapidly 3 times. If any do not flash, do not use Venner™ Tracheal Seal Monitor and seek assistance (shown as [C] [D] [F] [H] [I] [J] in figure 2).

NOTE: During normal use at least two lights must be lit at any one time (three once cuff pressure is attained). Should this NOT occur it must be assumed that there is a fault then press the alarm reset key to reset Venner™ Tracheal Seal Monitor. If reset does not work, Venner™ Tracheal Seal Monitor should no longer be used and the extension tube should be disconnected firstly, at the distal end from the pilot valve of the Venner™ PneuX P.Y.™ ETT or TT before disconnection at the proximal end from the air outlet on Venner™ Tracheal Seal Monitor. Cuff pressure control can be maintained temporarily (hourly) with a standard handheld cuff pressure manometer until another Venner™ Tracheal Seal Monitor is available.

6 DURING USE

Duration of use

Venner™ Tracheal Seal Monitor is designed to be used for patients undergoing tracheal intubation with Venner™ PneuX P.Y.™ ETT or TT for not more than 30 days.

Cuff pressure changes

Rises and falls 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™ Tracheal Seal Monitor regulates cuff pressure, keeping it stable, thus minimising complications due to excessive tracheal wall pressures such as tracheal pressure necroses and inadequate tracheal wall pressures, such as aspiration pneumonia.

Patient transfer

Firstly, disconnect the distal end of the extension tube from the pilot valve of Venner™ PneuX P.Y.™ ETT or TT before disconnection at the proximal end from the air outlet of Venner™ Tracheal Seal Monitor. The cuff should remain inflated for at least up to an hour but cuff pressure control should still be monitored and, if needed, maintained with a standard handheld cuff pressure manometer. Before using a handheld cuff pressure controller perform subglottic aspiration and take care not to allow accidental deflation of the cuff. PEEP may be additionally protective during manual cuff pressure adjustments if clinically safe and indicated

SHUTDOWN PROCEDURE

When Venner™ Tracheal Seal Monitor is no longer required, press the on/off button (shown as [G] in figure 2) to switch off. **DO NOT UNPLUG FROM THE WALL SOCKET UNTIL THE FOLLOWING STEPS HAVE BEEN TAKEN.** Firstly, disconnect the distal end of the extension tube from the pilot valve of Venner™ PneuX P.Y.™ ETT or TT before disconnecting at the proximal end from the air outlet of Venner™ Tracheal Seal Monitor. Then dispose of the extension tube as a contaminated item. DO NOT REUSE.

Press the power ON/OFF button to shut down the unit before disconnecting the power supply from the wall outlet and then clean Venner™ Tracheal Seal Monitor, as described in the cleaning instructions in section 9, and store in a secure place away from extreme conditions or where the device could be damaged.

7 ALARMS AND INDICATORS

WARNING: Do not ignore alarms

7.1 FAULT INDICATOR

(Shown as [H] in figure 2), if Venner™ Tracheal Seal Monitor detects an internal fault, 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™ Tracheal Seal Monitor. If reset does not work, the extension tube firstly, disconnect the distal end of the extension tube from the pilot valve of Venner™ PneuX P.Y.™ ETT or TT before disconnection at the proximal end from the air outlet of Venner™ Tracheal Seal Monitor. Cuff pressure control can be maintained temporarily (hourly) with a standard handheld cuff pressure manometer until another Venner™ Tracheal Seal Monitor is available. Do not continue to try to use the monitor and seek assistance.

7.2 POWER

(Shown as [F] in figure 2), Venner™ Tracheal Seal Monitor normally is connected to the mains power supply during use and in this circumstance the green power light is illuminated.

If there is no power supply, firstly, disconnect the distal end of the extension tube from the pilot valve of Venner™ PneuX P.Y.™ ETT or TT before disconnection at the proximal end from the air outlet of Venner™ Tracheal Seal Monitor. Cuff pressure control can be maintained temporarily (hourly) with a standard handheld cuff pressure manometer until another Venner™ Tracheal Seal Monitor is available.

7.3 LEAK ALARM

(Shown as [C] in figure 2), If Venner™ Tracheal Seal Monitor detects an exceptional air leak, it will produce an audible alarm and the leak indicator will light.

If there is a distal disconnection of the extension tube from the pilot valve of Venner™ PneuX P.Y.™ ETT or TT, the cuff will remain inflated for a short time. Simply reconnect the distal end of the extension tube to the pilot valve of Venner™ PneuX P.Y.™ ETT or TT. If there is a proximal disconnection of the extension tube from the white air outlet on Venner™ Tracheal Seal Monitor), the cuff will deflate and an air leak with patient ventilation may be audible. The extension tube should be removed and the airway cuff should be re-inflated with a manual cuff pressure gauge inflator. Then simply reconnect the proximal end of the extension tube to the white air outlet on Venner™ Tracheal Seal Monitor, select the desired tracheal wall pressure and connect the distal end of the extension tube to the pilot valve of Venner™ PneuX P.Y.™ ETT or TT.

If there is an extension line fracture, pilot tubing fracture or cuff puncture: This will 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. If this occurs, the damaged extension tube should be removed and the airway cuff should be re-inflated with a manual cuff pressure gauge inflator. Then reconnect with a new extension tube, select the desired tracheal wall pressure and connect the distal end of extension tube to the pilot valve of Venner™ PneuX P.Y.™ ETT or TT.

WARNING: If the leak alarms occur, action should be taken immediately. Firstly, disconnect the distal end of the extension tube from the pilot value of Venner™ PneuX P.Y.™ ETT or TT before disconnecting at the Proximal end from the air outlet of Venner™ Tracheal Seal Monitor and re-inflating the cuff using a standard pressure gauge inflator to confirm cuff integrity.

7.4 MALPOSITION ALARM

(Shown as [C] in figure 2), Venner™ Tracheal Seal Monitor can detect if an increased air requirement for cuff inflation has occurred. This is indicated by illumination of the malposition light 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). During endotracheal (translaryngeal) intubation, 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

WARNING: If the Malposition alarm occurs, both patient ventilation and the tube position should be immediately checked.

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

7.5 BLOCKAGE ALARM

(Shown as [C] in figure 2), Venner™ Tracheal Seal Monitor can detect if the standard cyclical pressure variability associated with mechanical ventilation is lost. This is indicated by illumination of the tube blockage light and an audible alarm.

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

If a blockage alarm occurs, the following should be checked:

(a) Patency of the airway ventilation lumen. A blockage of the ventilation lumen, for example with secretions, can trigger this alarm as the cyclical cuff pressure changes can be lost. This will normally be confirmed by other clinical observations and should be corrected by the clinician by re-establishing a patent ventilation lumen by standard techniques and / or re-intubation.
(b) The extension tube or ETT/TT pilot tubing may be kinked, crushed or occluded. Replace with a new extension tube or un-kink the pilot tubing.
(c) The cuff inflation lumen within the wall of the tracheal tube is occluded. This rarely occurs with an over-tightened flange on the TT (try loosening the flange slightly) or if the tube wall has been crushed for example by excessive biting..
(d) A blockage false alarm is possible if the patient is breathing very gently.

7.6 CUFF PRESSURE ATTAINED INDICATOR

(Shown as [J] in figure 2), this is a confirmatory visual LED indicator to confirm that the calculated tracheal wall pressure has been achieved.

7.7 CALCULATED TRACHEAL WALL PRESSURE INDICATOR

The default is at 20 mmHg and this should normally not be changed except after clinical review when indicated. For example, occasional patients might need a temporary increase in calculated tracheal wall pressure. Changes may be made by pressing the + or – keys (shown as [E] in figure 2) until the desired target wall pressure is shown by the illumination of the applicable indicator (shown as [D] in figure 2).

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 30 cmH_2O (approx. 22 mmHg) 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 which might exceed 20 mmHg may choose to increase the calculated tracheal wall pressure temporarily during the irrigation.
(f) The tracheal tube is too small for the trachea in which it is placed.

Adult males normally require a Venner™ PneuX P.Y.™ Tube size 9.0

Adult females normally require a Venner™ PneuX P.Y.™ Tube size 8.0

NOTE: Venner™ Tracheal Seal Monitor is calibrated to be accurate to within +/- 5% of setting.

7.8 ALARM RESET

(Shown as [B] in figure 2), the alarms are cancelled for 90 seconds and will resound if no further intervention has taken place. **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.

7.9 OVERPRESSURE SAFETY (AUDIBLE CLICKS)

The 40 and 50mmHG wall pressure settings on Venner™ Tracheal Seal Monitor has a non-audible alarm. There is a flashing light which will continue to visually alert users that the cuff wall pressure is higher than normal (only if a particular patient case demands the increase).

Should the cuff wall pressure ever exceed 57 mmHg then a safety valve will audibly (click) open and vent any excess pressure and subsequently 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™ Tracheal Seal Monitor 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.

8. COMPLICATIONS

Airway pilot valve failure

If this occurs the airway pilot valve needs to be clearly labelled as faulty but the airway can still be safely used if continuously connected to Venner™ Tracheal Seal Monitor. The clinician may wish to re-intubate with a new airway when clinical circumstances are suitable.

9. CLEANING, MAINTENANCE AND SERVICE

9.1 CLEANING

As a minimum, Venner™ Tracheal Seal Monitor should be cleaned before and after using with a new patient.

Venner™ Tracheal Seal Monitor 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.

9.2 MAINTENANCE

WARNING: Venner™ Tracheal Seal Monitor is a sealed unit and no parts can be repaired. The only user maintenance is the normal cleaning described above. Do not attempt to open; no modification of this equipment is allowed. Opening will break the manufacturer’s seals and void any guarantee offered by the manufacturer.

Venner™ Tracheal Seal Monitor should be checked and recalibrated after 2 years. Please record a date for this. The device must be returned to the service centre (as detailed at the end of these instructions) for any other service. The manufacturer is able to supply the identification of software version to a designated person by referring to the serial number of the device.

10. ACCESSORIES

Use only the pole clamp supplied

Use only with the extension tube, part # 903001.

11. ENVIRONMENTAL CONDITIONS OF USE

Transport, store, and use Venner™ Tracheal Seal Monitor 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™ Tracheal Seal Monitor conforms to the requirements of the electromagnetic compatibility standard for medical electrical equipment, EN 60601-1-2. However, it is advised that it may emit, or be affected by, electromagnetic interference. Do not keep or use close to sensitive electronic medical equipment. Keep away from mobile telephones or other radiation emitting appliances.

12. CLASSIFICATIONS

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

Venner™ Tracheal Seal Monitor 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™ Tracheal Seal Monitor is suitable for use within the patient environment.

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

13. MANUFACTURER'S DECLARATION

Guidance and manufacturer's declaration: Electromagnetic emissions		
The 'TSM 903X00' is intended for use in the electromagnetic environment specified below. The customer or the user of the 'TSM 903X00' should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The 'TSM 903X00' 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	The 'TSM 903X00' 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			
The "TSM 903X00" is intended for use in the electromagnetic environment specified below. The customer or the user of the "TSM 903X00" should assure 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	The 'TSM 903X00' 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 61000-4-2	± 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 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 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 % UT (>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 typical commercial or hospital environment. If the user of the 'TSM 903X00' requires continued operation during power mains interruptions, it is recommended that the 'TSM 903X00' be powered from an uninterruptible power supply or battery.
Power frequency (50/60Hz) magnetic field IEC 6100-4-8	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: *U*T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration:
Electromagnetic immunity

The "TSM 903X00" is intended for use in the electromagnetic environment specified below. The customer or the user of the "TSM 903X00" should assure 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 150kHz to 80MHz 3V/m 80MHz to 2.5GHz	3V 3V/m	Portable and mobile RF communications equipment should be used no closer to any part of the 'TSM 903X00' including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.2\sqrt{P}$ $d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz 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 80MHz and 800MHz, 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 "TSM 903X00" is used exceeds the applicable RF compliance level above, the "TSM 903X00" should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the "TSM 903X00".

[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 'TSM903X00'

The "TSM 903X00" is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the 'TSM 903X00' can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the 'TSM 903X00' 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		
	150kHz to 80MHz $d = 1.2\sqrt{P}$	**80MHz to 800MHz** $d = 1.2\sqrt{P}$	**800MHz to 2.5GHz** $d = 1.2\sqrt{P}$
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 80MHz and 800MHz, 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.

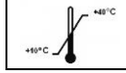
WARNING: The 'TSM 903X00' should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary the 'TSM 903X00' should be observed to verify normal operation in the configuration in which it will be used.

STATEMENT: The 'TSM 903X00' is a MEDICAL ELECTRICAL EQUIPMENT and needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS.

STATEMENT: Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT!

DECLARATION: Essential performance for 'TSM 903X00' is the following: No essential performance.

14. SYMBOLS USED ON LABELLING

CE 0086	Complies to 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
	Caution – consult accompanying documents
	Type B Applied Part with respect of electrical shock protection
	Direct current power supply
SN	Device serial number
	XXXX Year of manufacture
	Power on/off control
	Device should be stored and used between 10 °C and 40 °C (50 °F – 104 °F)

15. SERVICING INFORMATION

Venner™ Tracheal Seal Monitor must be returned for service every 2 years.

Weight	2kg in box, 1.4kg Venner™ Tracheal Seal Monitor
Dimensions	300x285x130mm in box 220x110x115mm Venner™ Tracheal Seal Monitor
Power	Input 100-240V/50-60Hz / 400mA Output: 15V/1.0A
Power Supply	Friwo (Model: FW7555/15)

16. MANUFACTURER'S WARRANTY

Venner Medical (Singapore) Pte Limited warrants the Venner™ products against faulty materials or manufacturing defects. Single use products are warranted against faulty materials or manufacturing defects at time of delivery to customer. Warranty is applicable only if purchased from an authorised distributor.

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17. 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.

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At the end of its useful life the device should be disposed of using the medical institution's recycling/disposal procedures in an environmentally conscious manner that respects local or national regulation.

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