This device is a 2.4 GHz wideband transmission system (transceiver), intended for use in all EU member states and EFTA countries, except in France and Italy where restrictive use applies.

In Italy the end-user should apply for a license at the national spectrum authorities in order to obtain authorization to use the device for setting up outdoor radio links and/or for supplying public access to telecommunications and/or network services.

This device may not be used for setting up outdoor radio links in France and in some areas the RF output power may be limited to 10 mW EIRP in the frequency range of 2454 – 2483.5 MHz. For detailed information the end-user should contact the national spectrum authority in France.

6.1.7 Cybersecurity

Network connections potentially expose medical devices to threats from many sources – not just through a local router or server in a hospital or medical office, but from any computer, tablet or smart phone connected to the Internet anywhere in the world. As a result, cybersecurity is deemed to be a shared responsibility.

Sentec is committed to a holistic risk sharing approach and conducts extensive cybersecurity risk management.

Sentec secures the tCOM+ with state-of-the-art cybersecurity measures such as a firewall, VPN, and encrypted communication.

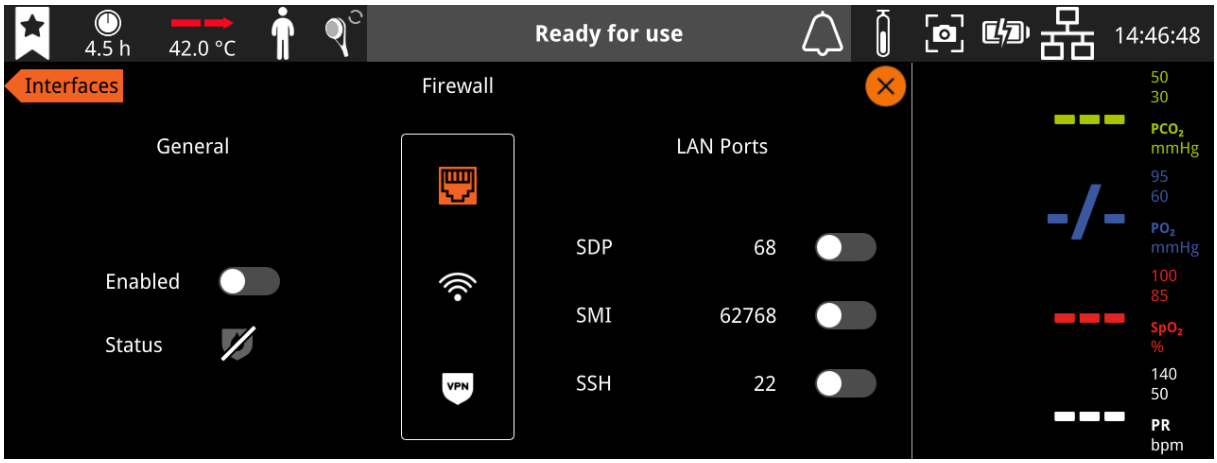
In addition, security related incidents are displayed to the user by the tCOM+ monitor as technical alarms and are logged.

In case that there is a concern that an external party is trying to connect to or interfere with the monitor, stop using the tCOM+ and contact the local Sentec representative immediately.

6.1.7.1 Firewall

Per factory default, all network interfaces of the tCOM+ are protected by a firewall and no service is accessible. A connection through LAN, Wi-Fi or VPN is only possible after configuration of the Firewall settings.

The Firewall settings can be configured in the password-protected menu via the ´Advanced Settings´ - ´Interfaces´ - ´Firewall´.



Within the Firewall menu, the Firewall can be entirely disabled to allow all traffic for LAN and Wi-Fi (e.g., for legacy connectivity applications). Furthermore, single ports in the firewall can be opened individually for LAN, Wi-Fi and VPN to give access to the available services of the tCOM+, such as Sentec Discovery Protocol (SDP), Sentec Monitor Interface (SMI) or SSH (only available for Sentec-Service).

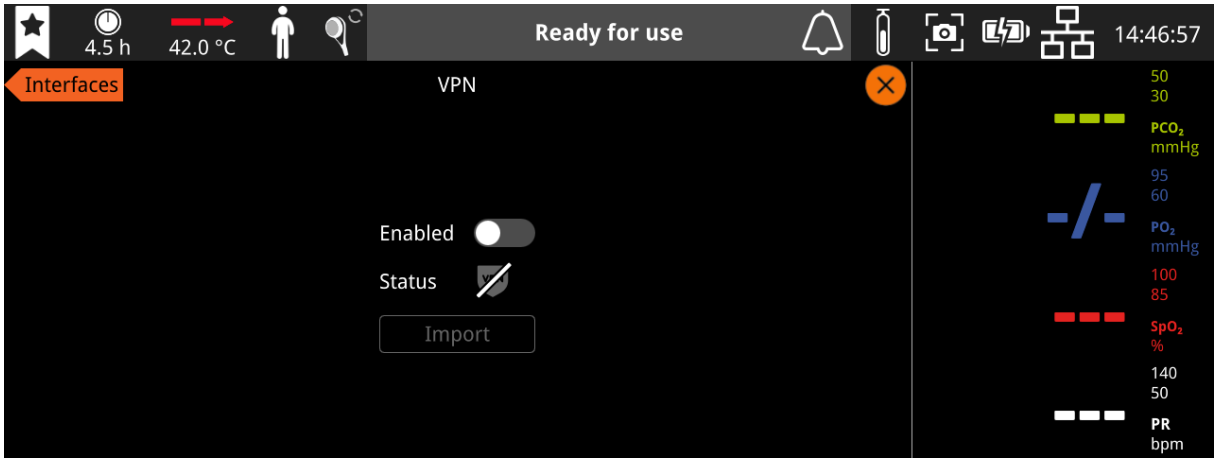
6.1.7.2 VPN

A VPN creates a secure encrypted connection between the tCOM+ and a single computer or a network.

The VPN security model provides:

- confidentiality by encrypting data to ensure that even if the network traffic is sniffed at the packet level, an attacker cannot access raw data
- sender authentication to prevent unauthorized users from accessing the VPN
- message integrity to detect and reject any instances of tampering with transmitted messages

The VPN settings can be configured in a password-protected area, which is accessible via: ´Advanced Settings´ - ´Interfaces´ - ´VPN´.



In this menu, a VPN configuration (OpenVPN config file) can be imported to the tCOM+ by clicking the "Import" function and selecting a configuration file on the attached flash drive. After the successful import, a VPN connection can be established from the device by activating the "Enabled" toggle. Refer to https://openvpn.net/ for more information, documentation and examples.
Note: The tCOM+ can only act as a VPN client.

6.1.7.3 Encrypted communication

To secure interfaces where no VPN technology is applicable, such as the Serial Data Port (RS-232), and to offer more flexibility for connectivity solutions, Sentec also supports the encryption of the Sentec Monitor Interface (SMI) directly with ASCON.

Encrypted communication can be configured in the via the ´Advanced Settings´ - ´Interface´ - ´Crypto´.

In the Crypto menu, encryption for UDP and Serial can be enabled or disabled individually. Per default, encryption is enabled.

Furthermore, an Encryption Key and a Nonce can be configured. These settings must be configured with the same settings within the connected medical device to allow decryption of messages sent and received.

7 Minimum hardware and software requirements

The tCOM+ is a standalone device and there are no hardware or software requirements for operation of the monitor.

8 System access

The tCOM+ provides two levels of access: Operator and Responsible Organization (RO). The RO must set a password during the initial guided setup of the tCOM+. Within

the ‘Advanced Settings’, the RO can edit passwords as well as various settings (date and time, pressure unit, LED brightness, interfaces). Furthermore, the RO can configure and edit profiles. Profiles allow configuration of safety relevant options such as the possibility to deactivate alarms. Within a profile, the maximum ‘Sensor Temperature’ or the maximum ‘Site Time’ selectable at the bedside, for example, can be adapted to settings, which are safe for the organization´s typical patients.

Operators will only have the possibility to access the monitor settings specified by the Responsible Organization.

9 Specifications

9.1 tCOM+

Physical Characteristics

Weight: 2.5 kg (5.5 lbs) – including gas cylinder
Size (height x width x depth): 15.3 cm x 27.8 cm x 16.2 cm (6.02” x 10.95” x 6.38”)
Ingress Protection: IPx2
Carrying: Foldable handle to carry the monitor
Mounting: Mountable on 75x75 VESA compatible roll/ infusion stands, wall mounts/ railings, transport incubators, etc.
Tilting: Optional feet to add on the VESA holes to adjust angle for improved table-top viewing (screen perpendicular to the standing surface)
Cable storage: Optional cable holder can be attached on the right or left rear side of the monitor to stow cable during transport or storage

Electrical

Monitor: 12 VDC Power, max. 3 A, by external power supply
Power supply for hospital use: Class II FE (with functional earth), Electrical Safety (IEC 60601-1)
Power supply for home use: Class II (without functional earth), Electrical Safety (IEC 60601-1)
Type BF, Applied Part, Defibrillation Proof.
Internal battery type: rechargeable, sealed Li Ion Battery /
Capacity (new fully charged battery): up to 4 hours (if Sleep Mode=OFF)
Charging Time: approx. 4 hours

Environmental

Transport/ storage temperature: 0 to +50 °C (32 to 122 °F)
Transport/ storage humidity: 10 to 90% non-condensing
Operating temperature: +5 to +40 °C (41 to 104 °F)
Operating humidity: 15 to 90% non-condensing
Operating altitude: -400 to 5000 m (-1300 – 16404 ft)
Built-in barometer: Range: 350-820 mmHg (47-109 kPa) /
Accuracy: ± 3 mmHg (0.4 kPa)

9.2 $tcPCO_2$

Measurement range	0 – 200 mmHg (0 – 26.7 kPa)
Resolution	0.1 mmHg (0.01 kPa) below 100 mmHg (10 kPa) / 1 mmHg (0.1 kPa) above 100 mmHg (10 kPa)
Drift	Typically < 0.5%/hour
Response time (T90)	Typically < 75 sec.
Linearity	Typically < 1 mmHg (0.13 kPa)
Interferences by anesthetic gases	Negligible
Stabilization/ artifact detection	After sensor application or occurrence of a $tcPCO_2$ artifact, $tcPCO_2$ is displayed in grey until it (re)stabilizes.
Non-linearity/ hysteresis	+/- 5 mmHg in the range of 0 mmHg – 60 mmHg*

*Essential Performance according to IEC 60601-1

9.3 $tcPO_2$

Measurement range	0 – 800 mmHg (0 – 106.7 kPa)
Resolution	1 mmHg (0.1 kPa)
Drift	Typically < 0.1%/hour
Response time (T90)	Typically < 150 sec.
Linearity	Typically < 1 mmHg (0.13 kPa)
Interferences by anesthetic gases	Negligible
Stabilization/ artifact detection	After sensor application or occurrence of a $tcPO_2$ artifact, $tcPO_2$ is displayed in grey until it (re)stabilizes.
Non-linearity/ hysteresis	+/- 5 mmHg in the range of 0 mmHg – 160 mmHg*

*Essential Performance according to IEC 60601-1

9.4 Pulse Oximetry

9.4.1 Oxygen Saturation (SpO_2)

Approved sites for SpO_2/PR monitoring with Sentec TC sensors	Earlobe, low on forehead, cheek, upper arm, scapula (shoulder blade)
Measurement range	1 – 100%
Resolution	1%
Accuracy (A_{RMS} over 70 to 100% range; all above specified sites)	

V-Sign™ Sensor 2	2%*
OxiVenT™ Sensor	2.25%*

*Essential Performance according to IEC 60601-1

Note: The SDMS measures functional oxygen saturation.
Note: The plethysmography waveform is normalized in amplitude.
Note: SpO_2 accuracy specification is based on controlled hypoxia studies on healthy, adult volunteers over the specified saturation range by applying a defined sensor type to the specified measurement sites. Pulse oximeter SpO_2 readings were compared to SaO_2 values of blood samples measured by hemoximetry. SpO_2 accuracy is expressed as Arms (root-mean-square). The indicated variation equals plus or minus one standard deviation (1SD), which encompasses 68% of the population.
Note: A functional tester cannot be used to assess the SpO_2 accuracy.

9.4.2 Pulse Rate (PR)

Measurement range	30 – 250 bpm (beats per minute)
Resolution	1 bpm
Accuracy	± 3 bpm

Note: PR accuracy was determined using a Pulse Oximeter Simulator (optical simulator for bench tests).
Note: A functional tester cannot be used to assess the PR accuracy.

9.4.3 Function Test SpO_2 + PR

Apply the sensor to the earlobe of a healthy person: Compare SpO_2 and PR readings against the readings of a reference pulse oximeter (e.g., N595 with Durasensor 100 from Nellcor). The SpO_2 and PR reading should be within ± 3% SpO_2 and ± 3 bpm, respectively.

9.4.4 A_{RMS} values using Sentec TC Sensors

The following table shows A_{RMS} values measured using the V-Sign™ Sensor 2 with the tCOM+, whereas SpO_2 accuracy is expressed as A_{RMS} (root-mean-square):

A_{RMS} in SpO_2 Ranges	70 – 100%	70 – 80%	80 – 90%	90 – 100%
Earlobe	1.87	2.20	1.86	1.57
Forehead	1.82	1.95	1.62	1.90
Cheek	1.92	2.42	1.88	1.32
Upper arm	1.38	1.84	1.03	1.03
Shoulder blade	1.91	1.57	1.33	1.11
Average over all sites	1.83	2.29	1.60	1.49

The table below shows A_{RMS} values measured using the OxiVenT™ Sensor with the tCOM+, whereas SpO_2 accuracy is expressed as A_{RMS} (root-mean-square):

A_{RMS} in SpO_2 Ranges	70 – 100%	70 – 80%	80 – 90%	90 – 100%
Earlobe	2.44	2.99	2.23	1.76

Forehead	1.35	1.54	1.32	1.22
Cheek	1.29	1.43	1.38	1.11
Upper arm	2.41	2.85	2.34	2.05
Shoulder blade	2.13	2.73	2.04	1.19
Average over all sites	1.95	2.35	1.88	1.48

9.5 Power Supply

- **WARNING:** tCOM+ may only be used with the authorized external power supply, as indicated in the table below:

	Type	Electrical appliance	Environment
Power supply	GlobTek RR9LE3000LLWCR6Bxxxx Output Rating: $12V_{DC}$ / 36W	Class II with functional earth connection	Hospital Use
Adapter Europe	GlobTek R-EU-3(R)		
Adapter North America	GlobTek R-NA-3(R)		
Adapter UK	GlobTek R-UK-3(R)		
Adapter Australia/NZ	GlobTek R-SAA-3(R)		
Power supply	GlobTek RR9KE3000LLWCR6Bxxxx Output Rating: $12V_{DC}$ / 36W	Class II without functional earth connection	Home Use
Adapter Europe	GlobTek R-EU-2(R)		
Adapter North America	GlobTek R-NA-2(R)		
Adapter UK	GlobTek R-UK-2(R)		
Adapter Australia/NZ	GlobTek R-SAA-2(R)		

9.6 Alarm System

IEC 60601-1-8 defines 'Alarm Condition Delay' as the time from the occurrence of a triggering event either in a) the patient, for physiological alarm conditions, or b) in the equipment, for technical alarm conditions, until the alarm system detects an alarm condition. It furthermore defines 'Alarm Signal Generation Delay' as the time from the onset of an alarm condition to the generation of the associated alarm signal(s).

Alarm Signal Generation Delay

Within the tCOM+, the 'Alarm Signal Generation Delay' is < 2 s applies to all alarm conditions, i.e., once the tCOM+ has detected an alarm condition, the corresponding alarm signal is generated instantly. The alarm signals available at the communication interfaces (serial, LAN, Wi-Fi) are activated during an alarm condition with a delay of max. 2 seconds. For delays until the alarm signal is activated on an external (remote) instrument that is connected to the tCOM+, please refer to the respective instrument's manual/instructions for use.

Alarm Condition Delays for physiological alarm conditions

Whenever one of the monitor's physiological parameters (PCO_2, PO_2, SpO_2, PR) violates its upper/lower alarm limit, the tCOM+ detects an alarm condition for the respective parameter. As summarized in the following table, delays for physiological alarm conditions therefore depend on the respective parameter's response time:

Alarm Condition Delays for physiological alarm conditions

Physiological Alarm Condition	Factors influencing corresponding parameter's response time at a specific measurement site	Typical Alarm Condition Delay
PCO_2 low/high alarm	The response to changes in the carbon dioxide pressure in the skin at a specific measurement site depends on the selected sensor temperature and on the sensor's in-vitro PCO_2 response. The slower the sensor's in-vitro PCO_2 response, the longer the PCO_2 alarm condition delay. **Note:** The indicated alarm condition delay corresponds to the time required to display a 10% to 90% response to a step change in either direction between a test gas containing 5% and 10% CO_2. **Note:** If the tCOM+ detects that the sensor's in-vitro PCO_2 response is slow, the Status Message 'PCO_2 slow' is displayed and PCO_2 values are subsequently marked as questionable. **Note:** If 'SP11: Calibration Failed (PCO_2 too slow) occurs, a low priority alarm sounds, the Status Message 'SP11: Calibration Failed' appears and sensor calibration is inhibited/aborted. PCO_2 values are subsequently marked as invalid.	< 75 sec (V-Sign™ Sensor 2) < 80 sec (OxiVenT™ Sensor) 120 sec (if Status Message 'PCO_2 slow' is displayed) 120 sec (if Status Message 'Check Application' is displayed in Enforce-Sensor-On-Patient Mode)
PO_2 low/high alarm	The response to changes in the oxygen pressure in the skin at a specific measurement site depends on the selected sensor temperature and on the sensor's in-vitro PO_2 response. The slower the sensor's in-vitro PO_2 response, the longer the PO_2 alarm condition delay. **Note:** The indicated alarm condition delay corresponds to the time required to display a 10% to 90% response to a step change in either direction between a test gas containing 6% and 12% O_2. **Note:** If 'Sensor problem 74' (PO_2 too slow) occurs, a low priority alarm sounds, the Status Message 'Sensor problem 74' is displayed and sensor calibration is inhibited/aborted. PO_2 values are subsequently marked as invalid.	< 150 sec (OxiVenT™ Sensor)

Physiological Alarm Condition	Factors influencing corresponding parameter's response time at a specific measurement site	Typical Alarm Condition Delay
SpO_2 low/high alarm	The response to changes in oxygen saturation of the arterial blood present at a specific measurement site depends on the menu item 'SpO_2 Averaging' (profile setting adjusted by responsible organization in the password-protected area). The longer the averaging time, the slower the monitor's response to changes in saturation and, hence, the longer the SpO_2 alarm condition delay, e.g., to detect desaturations.	Typically 5 sec, but < 10 sec (if 'SpO_2 Averaging' = 2 sec) Typically 32 sec, but < 40 sec (if 'SpO_2 Averaging' = 32 sec) < 30 sec (if Status Message 'SpO_2 signal quality' is displayed in Enforce-Sensor-On-Patient Mode)
PR low/high alarm	The response to changes in the pulse rate at a specific measurement site is determined by the PR averaging time, which is set to 10 seconds.	Typically 10 sec, but < 20 sec

Note: The response of transcutaneous PCO_2/PO_2 and SpO_2 measurements to respiratory events such as hyper-/ hypoventilation or apnea depend on the blood circulation time from the pulmonary alveoli to a specific measurement site, i.e., on the distance between the pulmonary alveoli to a specific measurement site and the blood flow/velocity. In patients with poor peripheral perfusion, the blood perfusion time between the pulmonary alveoli and the finger or toe is one to two minutes longer than between the pulmonary alveoli and central sites such as the forehead, cheek or earlobe.

Note: If PCO_2 and PO_2 is activated in the selected profile the connected V-Sign™ Sensor or OxiVenT™ Sensor needs to be calibrated after startup to measure PCO_2 and/or PO_2. The low priority alarm message 'Calibrate sensor' is displayed as long as the sensor in not calibrated successfully and assiciated physioclogical alarms (PCO_2 high/low, PO_2 high low) are inactive.

Note: The monitor's data update period for physiological parameters (PCO_2, PO_2, SpO_2, PR) is 1 sec and cannot be changed by the operator. The response time of physiological parameters and, hence, the alarm condition delay of physiological alarm conditions does not depend on the data update period.

Alarm Condition Delays for technical alarm conditions

With the exception of the following alarm conditions, alarm condition delays of all technical alarm conditions are < 5 seconds:

Alarm Condition Delays > 5 sec for technical alarm conditions

Technical Alarm Condition	Typical Alarm Condition Delay
Sensor off patient	V-Sign™ Sensor, OxiVenT™ Sensor: < 10 sec

Position of User relative to alarm system
The alarm system is designed so that a user can recognize physiological and technical alarm states from a distance of 4 m (color/behavior of LED bar and display) and determine a specific alarm message from a distance of 1 m.

The specified values for the alarm volume apply to a distance of 1 m.

Sound levels
Typical sound levels of acoustic alarm signals are:

	'Alarm Volume'=6 (high)	'Alarm Volume'=1 (low)
High Priority Alarm [dBA]	69.9	63.0
Medium Priority Alarm [dBA]	67.5	59.6
Low Priority Alarm [dBA]	62.5	54.8

10 Packaging & packaging damage

Do not use the device if:

- the packaging or sealing label on the monitor are damaged or appear to have been tampered with,
- the packaging has been exposed to environmental conditions outside of those specified for the monitor.

In such a case, return the tCOM+ to Sentec.

Items must be shipped in the original packaging or in other packaging providing the same degree of protection.

11 Waste disposal

The SDMS is manufactured with material compliant with the Restriction of certain Hazardous Substances (RoHS). It contains electronic printed circuit boards, a display, cables, and lithium batteries.

Do not incinerate equipment or gas bottles.

WEEE Disposal: European consumers are obliged by law to dispose Waste Electrical and Electronic Equipment (WEEE) according to the WEEE Directive:

1. All electrical and electronic waste, must be stored, collected, treated, recycled, and disposed of separately from other waste.

2. Consumers are obliged by law to return electrical and electronic devices at the end of their service lives to the public collection points set up for this purpose or point of sale. Details of this are defined by the national law of the respective country.

Note: By recycling materials or other forms of utilizing old devices, you are making an important contribution to protecting our environment.

tCOM+

Return the tCOM+ to your local Sentec representative or dispose of it according to local regulations. Use original packaging or other packaging providing the same degree of protection for shipping.

- **WARNING:** Dispose of battery in accordance with local requirements and regulations.

Cables

Dispose of the cables according to local regulations. The copper contained can be recycled.

Sentec Transcutaneous Sensors

Return the Sentec Transcutaneous Sensors to your local distributor.

Calibration Gas Bottle

Dispose empty gas bottles according to local waste disposal regulations. Make sure to only dispose empty bottles.

Gas may be discharged from the container as follows:

Ensure that the container is securely positioned. Then, open the container valve **slowly** to permit gas discharge at an appropriate rate.

- **WARNING:** Environmental contamination due to waste products and/or medical device disposal. Dispose of Calibration Gas bottle according to local regulations.
- **CAUTION:** Ensure that the operation is carried out in a well-ventilated area and vented gases may disperse. Noise level should be controlled to meet local regulations.
- **WARNING:** Pressurized container. Protect from sunlight and do not expose to temperatures exceeding 50 °C. Do not pierce or burn, even after use. Do not spray on a naked flame or any incandescent material.

Consumables

All material used is considered "non-critical". The consumables may be disposed with the regular garbage collection.

12 Incident Reporting

Any serious incident that has occurred in relation to the Sentec Digital Monitoring System has to be reported to Sentec (regulatory@sentec.com) and/or to the competent authority of the country where the incident occurred. If you are not sure whether an incident is a reportable event, you can contact Sentec first.

12.1 Cybersecurity Vulnerability and Incident Reporting

If a cybersecurity incident has occurred or you have detected a cybersecurity vulnerability in our product(s), please report it to us using the dedicated link on Sentec's website: https://www.sentec.com/quality/. The presented "Link to Vulnerability Reporting" will direct you to the MedISAO (Information Sharing and Analysis Organization) portal, which collects vulnerability data of Sentec products. You may also report cybersecurity incidents or cybersecurity vulnerabilities directly to Sentec using the e-mail address:

regulatory@sentec.com

13 Appendix

13.1 Abbreviations

AHP	Absolute Heating Power
CO_2	Carbon dioxide
DS	Docking Station (calibration unit integrated in the tCOM+)
HP	Heating Power
LED	Light emitting diode
MRI	Magnetic Resonance Imaging
O_2	Oxygen
$PaCO_2$	Arterial carbon dioxide partial pressure
PaO_2	Arterial oxygen partial pressure
$PcCO_2$	Cutaneous carbon dioxide partial pressure (i.e., the CO_2 partial pressure at the skin surface)
PCO_2	Used to display/label $tcPCO_2$ on the tCOM+ and – unless explicitely stated otherwise – throughout this manual
PcO_2	Cutaneous oxygen partial pressure (i.e., the O_2 partial pressure at the skin surface)
PI	Pulsation Index
PO_2	Used to display/label $tcPO_2$ on the tCOM+ and – unless explicitely stated otherwise – throughout this manual
POST	Power-On Self-Test
RO	Responsible Organization
PR	Pulse rate
RHP	Relative Heating Power
RMI	Remote monitoring interrupted
SaO_2	Arterial oxygen saturation
tCOM+	Sentec Patient Monitor
SDMS	Sentec Digital Monitoring System
SpO_2	Functional oxygen saturation of arterial hemoglobin as measured with a pulse oximeter
TC	Transcutaneous
tCOM+	Transcutaneous carbon dioxide and oxygen monitor
$tcPCO_2$	Transcutaneous carbon dioxide partial pressure, i.e., an estimate of $PaCO_2$ calculated from the measured $PcCO_2$ and displayed/labeled on the tCOM+ and – unless explicitly stated otherwise – throughout this manual as 'PCO_2'
$tcPO_2$	Transcutaneous oxygen partial pressure, i.e., an estimate of PaO_2 calculated from the measured PcO_2 and displayed/labeled on the tCOM+ and – unless explicitly stated otherwise – throughout this manual as 'PO_2'

13.2 List of Components

The Sentec Digital Monitoring System comprises the following components:

REF	Product (Brand) Name	Description	Intended Purpose	Variants	Expected useful life	Reusable	Environmental/ Storage conditions
103164	tCOM+	Stand-alone patient monitor.	The Sentec patient monitor, model tCOM+, is a portable stand-alone patient monitor indicated for continuous, non-invasive patient monitoring of carbon dioxide partial pressure (PCO_2), oxygen partial pressure (PO_2), functional oxygen saturation (SpO_2) and pulse rate (PR), using either a single, digital sensor (V-Sign™ Sensor 2) for PCO_2, SpO_2 and PR measurement, OR a single, digital sensor (OxiVenT™ Sensor) for PCO_2, PO_2, SpO_2 and PR measurement. PO_2 measurement with tCOM+ is only possible when used in combination with an OxiVenT™ Sensor.	n/a	7 years	Yes	Transport/storage temperature: 0 – 50 °C Transport/storage humidity: 10 – 90% non-condensing Operating temperature: 5 – 40 °C Operating humidity: 15 – 90% non-condensing Operating altitude: -400 – 5000 m (-1300 – 16404 ft).
VS-A/P/N	V-Sign™ Sensor 2	Digital carbon dioxide tension and oximetry sensor	The V-Sign™ Sensor 2, model VS-A/P/N, is indicated for use with the tCOM+ when continuous, non-invasive monitoring of $tcPCO_2$, SpO_2, and PR are required for adult and pediatric patients. In neonatal patients, the use of V-Sign™ Sensor 2 is indicated for $tcPCO_2$ monitoring only.	n/a	up to 36 months	Yes	Transport temperature: 0 – 50 °C Long term storage temperature: 15 – 26 °C Transport/ store sensor with membrane and protected from light/ radiation.
OV-A/P/N	OxiVenT™ Sensor	Digital carbon dioxide tension, oxygen tension and oximetry sensor	The OxiVenT™ Sensor, model OV-A/P/N, is indicated for use with the tCOM+ when continuous, non-invasive monitoring of $tcPCO_2$, and $tcPO_2$, as well as SpO_2, and PR monitoring are required for adult and pediatric patients. In neonatal patients, the use of OxiVenT™ Sensor is indicated for $tcPCO_2$ and $tcPO_2$ monitoring only. $tcPO_2$ monitoring is contraindicated for patients under gas anesthesia.	n/a	12 months	Yes	Transport temperature: 0 – 50 °C Long term storage temperature: 15 – 26 °C Transport/ store sensor with membrane and protected from light/ radiation.

REF	Product (Brand) Name	Description	Intended Purpose	Variants	Expected useful life	Reusable	Environmental/ Storage conditions
103420 103421 103422	Sensor Adapter Cable	Adapter cable required to connect digital Sentec sensors to the tCOM+. It transfers the power needed to run the micro-/optoelectronic components (LEDs) and to heat the sensor. It furthermore transmits digitized data between the digital sensor and the tCOM+.	The Sensor Adapter Cable is required to connect digital Sentec sensors (V-Sign™ Sensor 2, OxiVenT™ Sensor) to the Sentec tCOM+.	Regular: 150 cm Long: 250 cm Extra Long: 750 cm	7 years	Yes	Transport/storage temperature: 0 – 50 °C Transport/storage humidity: 10 – 95%
PSG Cable A to PSG Cable X	PSG Adapter Cable	Adapter Cable to interface the tCOM+ to Polygraphs (PG) or Polysomnographs (PSG). A PSG Cable transfers analogue data from the tCOM+ to the PG or PSG system.	PSG Cables are intended to interface the tCOM+ to Polygraphs (PG) or Polysomnographs (PSG).	PSG Cable A PSG Cable B PSG Cable C PSG Cable D PSG Cable E PSG Cable F PSG Cable G PSG Cable H PSG Cable J PSG Cable K PSG Cable L PSG Cable M PSG Cable N PSG Cable P PSG Cable X	7 years	Yes	Transport/storage temperature: 0 – 50 °C Transport/storage humidity: 10 – 95%
V-STATS _CD	V-STATS	V-STATS: PC based download, data analysis, remote monitoring, and monitor management software.	V-STATS is an optional PC-based software, which is indicated for use with the monitor TCOM+ when remote monitoring and/ or trend reporting and statistical analysis of data measured by the monitor is required. V-STATS is not intended to provide diagnosis; it is intended to supplement and not to replace any part of the monitoring procedures.	n/a	Not specified	Yes	Not specified

REF	Product (Brand) Name	Description	Intended Purpose	Variants	Shelf life	Reusable	Environmental/ Storage
EC-MI	Ear Clip	Single use sensor application Ear Clip, recommended for adult and pediatric patients with mature/intact skin	Sentec's Ear Clip, model EC-MI, is intended for use with the V-Sign™ Sensor 2 when continuous, non-invasive $tcPCO_2$, SpO_2, and PR monitoring are required, and with the OxiVenT™ Sensor when continuous, non-invasive $tcPCO_2$ and $tcPO_2$ monitoring as well as SpO_2 and PR monitoring are required. The Ear Clip is indicated to attach the V-Sign™ Sensor 2 or OxiVenT™ Sensor to the earlobe of the patient. The use of the Ear Clip is **contraindicated** in case of: - patients whose earlobes are too small to ensure adequate sensor application (e.g., neonates). - conditions where the patient is in the Trendelenburg's position (head lower than the heart). - injured or sensitive/fragile skin or on patients who exhibit allergic reactions to EC-MI. Furthermore, application of a Sentec TC Sensor on pierced earlobes may result in incorrect PCO_2 /PO_2 measurements.	n/a	2 years	No. Reusing the Ear Clip may cause: - Re- and/or cross-infection - loss of functionality - improper sensor application and incorrect measurements	Temperature: 10 – 30 °C Humidity: 25%-60%

REF	Product (Brand) Name	Description	Intended Purpose	Variants	Shelf life	Reusable	Environmental/ Storage
MAR-MI	Multi-Site Attachment Ring for mature/ intact skin	Single- use sensor application ring, recommended for adult, pediatric and neonatal patients with mature/intact skin	Sentec's Multi-Site Attachment Rings, models MAR-MI and MARe-MI, are intended to attach V-Sign™ Sensor 2 to conventional measurement sites for carbon dioxide tension monitoring when continuous, non-invasive $tcPCO_2$ monitoring is required for adult, pediatric, and neonatal patients. The Multi-Site Attachment Rings, models MAR-MI and MARe-MI, are intended to attach the OxiVenT™ Sensor to conventional measurement sites for carbon dioxide and/or oxygen tension monitoring when continuous, non-invasive $tcPCO_2$ and/or $tcPO_2$ monitoring is required for adult, pediatric, and neonatal. If SpO_2 and PR monitoring are (additionally) required for adult and pediatric patients, the Multi-Site Attachment Rings, models MAR-MI and MARe-MI, are intended to attach the V-Sign™ Sensor 2 or the OxiVenT™ Sensor to the forehead, cheek, upper arm as well as on the shoulder blade. The use of MAR-MI and MARe-MI is recommended for mature/intact skin applications. The use of the MAR-MI and MARe-MI is **contraindicated** in case of: - injured or sensitive/fragile skin or on patients who exhibit allergic reactions to MAR-MI/MARe-MI.	n/a	2 years	No. Reusing a MAR may cause: - Re- and/or cross-infection - loss of functionality - improper sensor application and incorrect measurements	Temperature: 10 – 30 °C Humidity: 25%-60%
MARe-MI	Multi-Site Attachment Ring Easy for mature/intact skin	Single use sensor application ring, recommended for adult, pediatric and neonatal patients with mature/intact skin		n/a	2 years	No. Reusing a MAR may cause: - Re- and/or cross-infection - loss of functionality - improper sensor application and incorrect measurements	Temperature: 10 – 30 °C Humidity: 25%-60%

REF	Product (Brand) Name	Description	Intended Purpose	Variants	Shelf life	Reusable	Environmental/ Storage
MAR-SF	Multi-Site Attachment Ring for sensitive/fragile skin	Single use sensor application ring, recommended for adult, pediatric and neonatal patients with sensitive/fragile skin	Sentec's Multi-Site Attachment Rings, models MAR-SF and MARe-SF, are intended to attach V-Sign™ Sensor 2 to conventional measurement sites for carbon dioxide tension monitoring when continuous, non-invasive $tcPCO_2$ monitoring is required for adult, pediatric, and neonatal patients. The Multi-Site Attachment Rings, models MAR-SF and MARe-SF, are intended to attach the OxiVenT™ Sensor to conventional measurement sites for carbon dioxide and/or oxygen tension monitoring when continuous, non-invasive $tcPCO_2$ and/or $tcPO_2$ monitoring is required for adult, pediatric, and neonatal patients. If SpO_2 and PR monitoring are (additionally) required for adult and pediatric patients, the Multi-Site Attachment Rings, models MAR-SF and MARe-SF, are intended to attach the V-Sign™ Sensor 2 or the OxiVenT™ Sensor to the forehead, cheek, upper arm as well as on the shoulder blade. The use of MAR-SF and MARe-SF is recommended for sensitive/fragile skin applications. The use of the MAR-SF and MARe-SF is **contraindicated** in case of: - injured skin or on patients who exhibit allergic reactions to MAR-SF/MARe-SF.	n/a	1.5 years	No. Reusing a MAR may cause: - Re- and/or cross-infection - loss of functionality - improper sensor application and incorrect measurements	Temperature: 10 – 27 °C Humidity: 40%-60%
MARe-SF	Multi-Site Attachment Ring Easy for sensitive/fragile skin	Single use sensor application ring, recommended for adult, pediatric and neonatal patients with sensitive/fragile skin		n/a	1.5 years	No. Reusing a MAR may cause: - Re- and/or cross-infection - loss of functionality - improper sensor application and incorrect measurements	Temperature: 10 – 27 °C Humidity: 40%-60%

REF	Product (Brand) Name	Description	Intended Purpose	Variants	Shelf life	Reusable	Environmental/ Storage
SA-MAR	Staysite™ Adhesive for Multi-Site Attachment Rings	Single-use adhesive for Multi-Site Attachment Rings (attaches complementary the MAR-SF / MARe-SF / MAR-MI / MARe-MI to the skin with an additional adhesive film)	Sentec's Staysite™ Adhesive for MAR, model SA-MAR, is an optional, single-use adhesive which is indicated for use with Multi-Site Attachment Rings, models MAR-MI, MARe-MI, MAR-SF, and MARe-SF, if more secure attachment is required. The use of the SA-MAR is **contraindicated** in case of: - injured or sensitive/fragile skin or on patients who exhibit allergic reactions to SA-MAR.	n/a	1.5 years	No. Reusing the SA-MAR may cause: - Re- and/or cross-infection - loss of functionality - improper sensor application and incorrect measurements	Temperature: 10 – 27 °C Humidity: 40%-60%
MC-R	Membrane Changer	Membrane change tool, reloadable	The Membrane Changer and Membrane Changer Insert, MC-R and MC-I, serves as tool to change the electrolyte and membrane of Sentec transcutaneous sensors. The Membrane Changer (MC-R) can be reused by replacing its insert (MC-I). MC-R and MC-I are not intended for sterilization (e.g., by irradiation, steam, ethylene oxide or plasma method).	n/a	2 years	Yes, max. 10 times reloadable with MC-I.	Temperature: 10 – 30 °C Humidity: 10%-95%
MC-I	Membrane Changer Insert	Separately bagged, single-use inserts required to reload a Membrane Changer prior reuse.		n/a	2 years	No. Reusing the MC-I may cause: - loss of functionality of the sensor and incorrect measurements	Temperature: 10 – 30 °C Humidity: 10%-95%
103149	Calibration Gas	Calibration gas for Docking Station, cylinder of 0.2 l at 9.5 bar. Mixture of 8-vol % CO_2, 12-vol% O_2 and 80-vol% N_2	The Calibration Gas serves as calibration gas for the Sentec transcutaneous sensors that monitor tcPCO_2 and/or tcPO_2 (V-Sign™ Sensor 2 and OxiVenT™ Sensor). The Calibration Gas is for use only with the Docking Station integrated in the tCOM+.	n/a	12 months	Yes, for about one month, depending on use scenarios and sensor condition. Do not use Calibration Gas if it is expired.	Temperature: 0 – 50 °C Humidity: not specified
GEL-04	Contact Gel	Contact gel for Sentec transcutaneous sensors, bottle of 2 mL or 5 mL	The Contact Gel, GEL-04 and GEL-SD, serves as contact gel to achieve proper gas conduction and heat transfer between the patient's skin and the Sentec transcutaneous sensors. Contact Gel makes di-	2 mL 5 mL	3 years	Yes. Do not use Contact Gel if it is expired, to avoid infections or potential allergic reactions.	Temperature: 10 – 30 °C Humidity: 10%-95%

REF	Product (Brand) Name	Description	Intended Purpose	Variants	Shelf life	Reusable	Environmental/ Storage
GEL-SD	Single Dose Contact Gel	Contact gel for Sentec transcutaneous sensors, single-dose vials of 0.3 g each	rect patient contact (intact skin, prolonged exposure <30 days). Avoid contact with injured skin. Do not use on patients who exhibit allergic reactions.	n/a	3 years	No. Do not use Contact Gel if it is expired, to avoid infections or potential allergic reactions. Reusing the GEL-SD may cause: - Re- and/or cross-infection	Temperature: 10 – 30 °C Humidity: 10%-95%

Note: The components listed above do not necessarily correspond to the scope of delivery.

13.3 Interferences with other devices

13.3.1 Electromagnetic interferences

- **WARNING:** Electrostatic discharge and transient bursts from mains may temporarily interfere with the measurement. This can lead to wrong measurements.
- **WARNING:** Equipment emits electromagnetic fields. This can, for example, disturb other medical devices or Radio Services.
- **WARNING:** The tCOM+ should not be used adjacent to or stacked with other equipment as these can cause electromagnetic interference and thereby result in incorrect measurements. If adjacent or stacked use is necessary, the tCOM+ should be observed to verify normal operation in the configuration it is to be used.
- **WARNING:** This device has been tested and found to comply with the requirements for medical devices according to IEC 60601-1-2, and the Medical Device Regulation (EU) 2017/745. These requirements are designed to provide reasonable protection against harmful interference in a typical medical installation.

Interference from interventional devices

- **WARNING:** The tCOM+ is protected against electrostatic/defibrillator discharge. Parameter display may be temporarily affected during discharge/defibrillation but will rapidly recover. Recovery time after electrostatic/defibrillator discharge: 30 sec (for SPO_2/PR); 60 sec (for TC values).

Note: certain events may cause the monitor to prompt a calibration request. Precisely follow the instructions given in the defibrillator manual.
During electro-surgery the tCOM+, sensor and cables are to be physically separated from the electro-surgical equipment. The sensor must not be placed between the cutting and counter electrodes.