

Radio equipment

- **WARNING:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the tCOM+, including cables specified by the manufacturer. Wireless mobile devices must be held away from the system by at least 1 m (39.4 inches). Otherwise, degradation of the performance of this equipment and at worst, incorrect measurements could result.

13.4 Means of Isolation (mains)

The electrical isolation of the tCOM+ is designed and tested during manufacturing process in accordance with IEC 60601-1. The following table provides an overview of the isolation barriers:

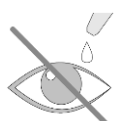
Isolation barrier	Isolation
External Power Supply	2 MOPP
Sensor interface	2 MOPP
Isolated Connectivity port	2 MOPP
Analog Output port	2 MOOP
Serial Data Port (RS-232)	2 MOOP
Ethernet port	1 MOOP

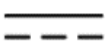
The sensor including cable and Sensor Adapter Cable is an applied part according to IEC 60601-1.

13.5 Glossary of Symbols

The table below summarizes symbols used on the system (including all its related parts), on the packaging, and in the associated documentation. These symbols indicate information essential for proper use; the order of their appearance is not prioritized.

Symbol	Name	Description of Symbol
	Manufacturer	Indicates the medical device manufacturer.
	Date of Manufacture	Indicates the date when the medical device was manufactured.
	European Authorized Representative	Indicates name and address of authorized representative within the European Union
	UK Representative	Indicates name and address of authorized representative within the UK
	Importer	Indicates the entity importing the medical device into the locale.
	Use-by date	Indicates the date after which the medical device is not to be used.
	Period after opening	Identifies the useful lifetime of a product after its package has been opened for the first time (M=months).
	Batch code	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.
	Keep dry	Indicates a medical device that needs to be protected from moisture.
	Keep away from sunlight	Indicates a medical device that needs to be protected from sunlight.
	Temperature limit "Storage" / "Transport"	Indicates the temperature limits to which the medical device can be safely stored or transported (upper and lower limits of temperature are indicated adjacent to the upper and lower horizontal lines).

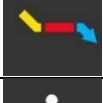
Symbol	Name	Description of Symbol
	Humidity limitation	Indicates the range of humidity to which the medical device can be safely exposed (humidity limitation indicated adjacent to the upper and lower horizontal lines).
	Do not re-use (Single- use)	Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.
	Single patient multiple use	Indicates that the medical device may be used multiple times (multiple procedures) on a single patient.
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.
	Mandatory action: Refer to instruction manual	Indicates that the instruction manual must be read.
	General warning sign	Read all warnings and precautions in instructions for use.
	General warning sign	Taking care regarding the hazard specified by the supplementary sign.
	WARNING	Indicates a WARNING in the accompanying documentation.
	Medical Device	Indicates that the product is a medical device according to the Medical Device Regulation MDR EU 2017/745.
	Prescription only	Caution: Federal Law (U.S.) restricts these devices to sale by or on the order of a physician.
	CAUTION	Indicates a CAUTION in the accompanying documentation.
	UL Label	Certifies that representative samples of the products have been investigated by UL in accordance with the referenced standards. The products have been found to comply with the requirements covering the category.
	Keep out of reach of children	Keep out of reach of children
	Do not swallow	Do not swallow Contact Gel.
	Avoid contact with eyes	Avoid contact with eyes

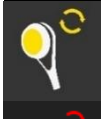
Symbol	Name	Description of Symbol
	WEEE Disposal	European consumers are obliged by law to dispose Waste Electrical and Electronic Equipment (WEEE) according to the WEEE Directive 2002/96/EC: 1. All electrical and electronic waste must be stored, collected, treated, recycled and disposed of separately 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.
	Defibrillation Proof Type BF	Degree of protection against electrical shock: Defibrillation-proof, Type BF applied part
IP	Ingress Protection	Degree of protection against harmful ingress of water
	Bluetooth	Device is equipped with Bluetooth functionality.
	RFID tag, general	To indicate the presence of the RFID tag incorporated within the packaging, container, or equipment without identifying the specific air interface or data structure employed.
	Non-flammable, non-toxic gases	Indicates gases which are neither flammable nor poisonous.
	Compressed gas GHS04	This GHS04 Compressed Gas Symbol Sign helps in the identification of containers and alert users of the chemical hazards to which they may be exposed.
	Atmospheric pressure limitation	To indicate the acceptable upper and lower limits of atmospheric pressure for transport and storage.
	Temperature limit	To indicate the maximum and minimum temperature limits at which the item shall be stored, transported or used.
	Battery	Indicates the presence of a battery
	Stand-by	Indicates the switch by means of which part of the equipment is switched on in order to bring it into the stand-by condition.
IOIOI	Serial interface	To identify a connector for a serial data connection.
	Universal Serial Bus (USB)	Indicates a port or plug that meets the generic requirements of the Universal Serial Bus (USB).
	Power input	Indicates input voltage and current.

Symbol	Name	Description of Symbol
	Non-ionizing electromagnetic radiation	Indicates equipment that includes RF transmitters.
	RFID	Indicates the location of an RFID transmitter.
	CE Marking	Indicates that the product complies with the requirements of the relevant EU Directives and Regulations as outlined in the EU Declaration of Conformity. If applicable, the 4-digit Notified Body number is added near or below the CE symbol.
	UK Conformity Assessed	UK Conformity Assessed (UKCA) marking is a conformity mark that indicates conformity with the applicable requirements for products sold within Great Britain.
FCC ID XZZYYNNNNN	FCC (U.S.A.)	Indicates that the equipment has been FCC certified.
IC: XXXXXX- YYYYYYYYYYYY	ISED Label (Canada)	Indicates wireless certification in Canada.
 R YYY-XXXXXX	MIC certification (Japan)	Indicates market authorization for radio products in Japan.
 R-NZ	ACMA (Australia) and MBIE (New Zealand) certification	Indicates certification by the Australian Communications and Media Authority (ACMA) as well as the New Zealand Ministry of Business, Innovation and Employment (MBIE). It equates to Australian and New Zealand market approval for manufacturers of wireless technology products.

13.6 User Interface icons

The following table provides an overview of the Status Bar icons, some of which are displayed by default, some may vary depending on status/connection:

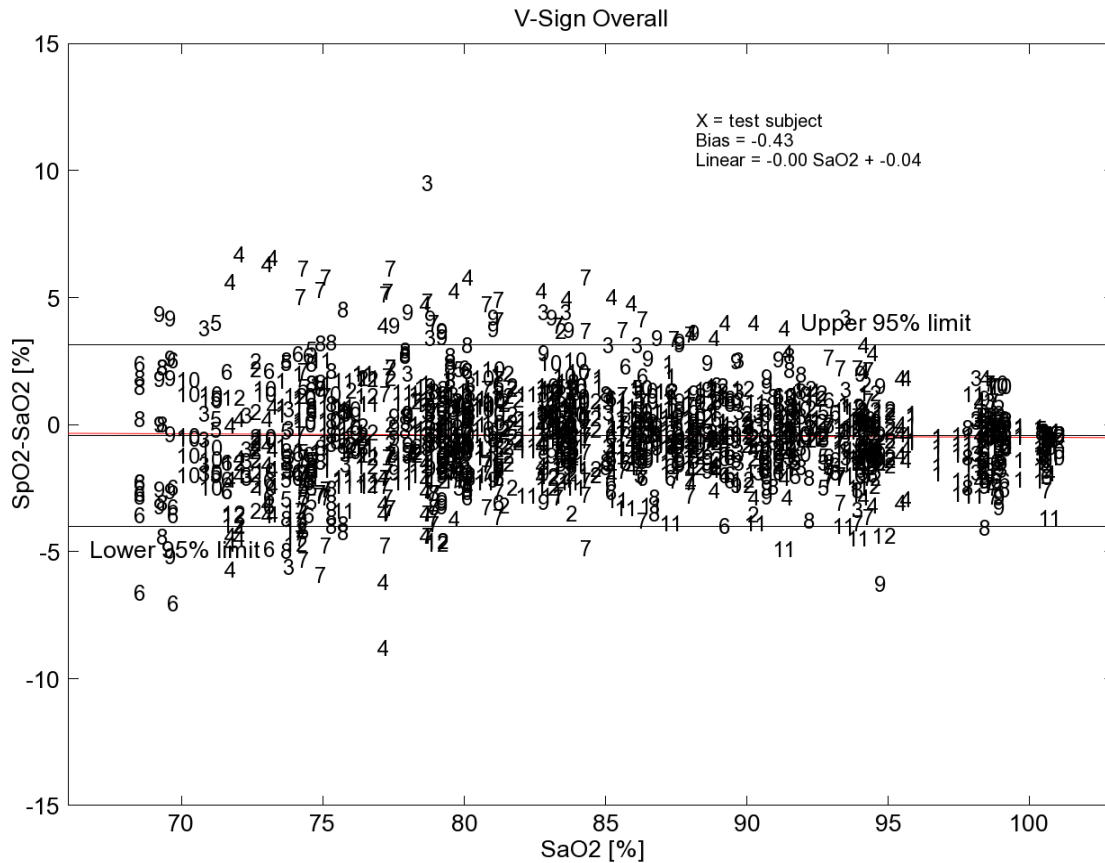
Icon	Icon Description
	Favorites
	Monitoring time - indicates the remaining measuring time (in h) The symbol is displayed in red if the available monitoring time has elapsed. The symbol is displayed in yellow if a sensor calibration is recommended but not mandatory.
	Heating mode / Sensor Temperature - indicates the measured sensor temperature (°C) and the current setting of 'Initial Heating' and 'Site Protection'. 'Initial Heating' is marked with an initial yellow downward line. A red-blue downward arrow appears if 'Site Protection' is enabled, a red rightward arrow if it is disabled. The sensor temperature is marked blue if 'Site Protection' has reduced the sensor temperature and red if the temperature surveillance detected a sensor temperature-related problem.
	'Initial Heating' - off 'Site Protection' - off
	'Initial Heating' - off 'Site Protection' - on
	'Initial Heating' - on 'Site Protection' - on
	Patient type - Adult

	Patient type - Neonate
  	Sensor maintenance – Membrane change The grey symbol indicates that the membrane is good to be used for more than 3 days. The yellow symbol indicates that the membrane change is due in three days or less. The red symbol indicates that a membrane change is required.
	Sensor maintenance This menu allows the initiation of a sensor calibration, confirmation of a membrane change as well as performing a sensitivity test.
	Alarm – active and combined with associated error message
	Alarm – temporarily muted
	Alarm – permanently muted
   	Gas level - indicates the remaining content of the gas bottle Tapping on the icon will prompt a pop-up message indicating the filling state in %.
	Screenshot
	Battery - connected to AC power, fully charged
	- connected to AC power, charging
	- not connected, charged >75%

	- not connected, charged < 75 %
	- not connected, charged < 30 %
	- not connected, battery low
	- not connected, battery critical
 	LAN connected /disconnected
 	Bluetooth connected/disconnected
 	Wi-Fi connected/disconnected

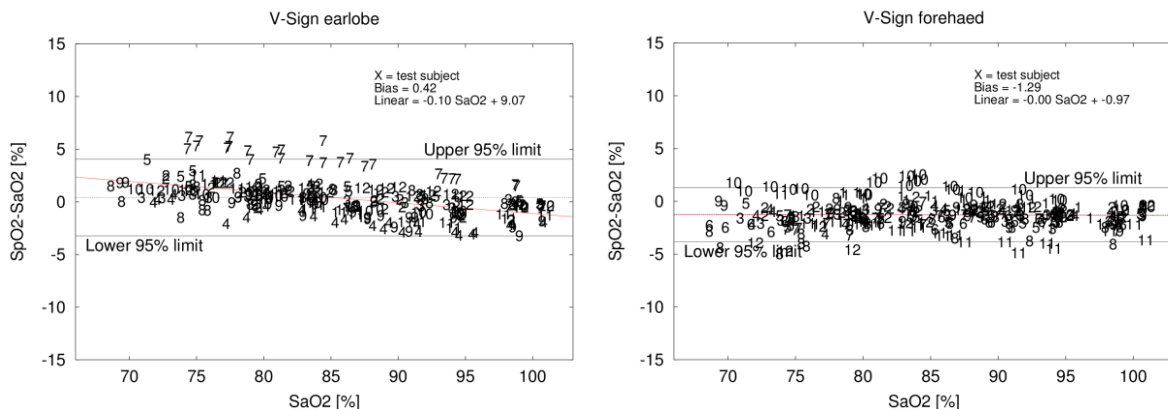
13.7 Detailed SpO₂ Accuracy Plots

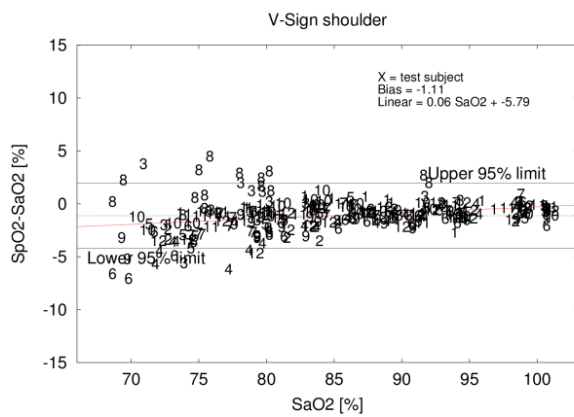
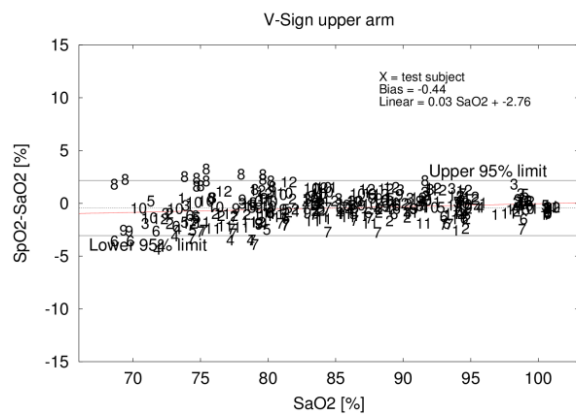
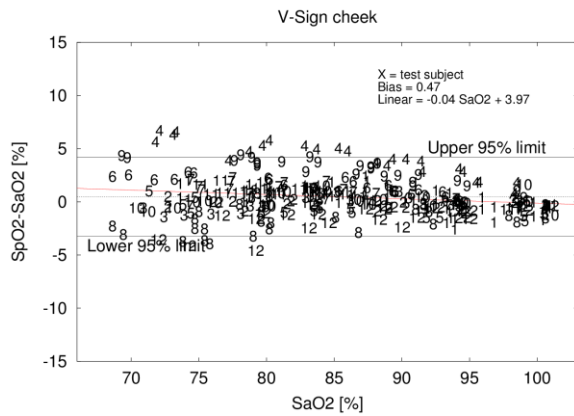
13.7.1 V-Sign™ Sensor 2



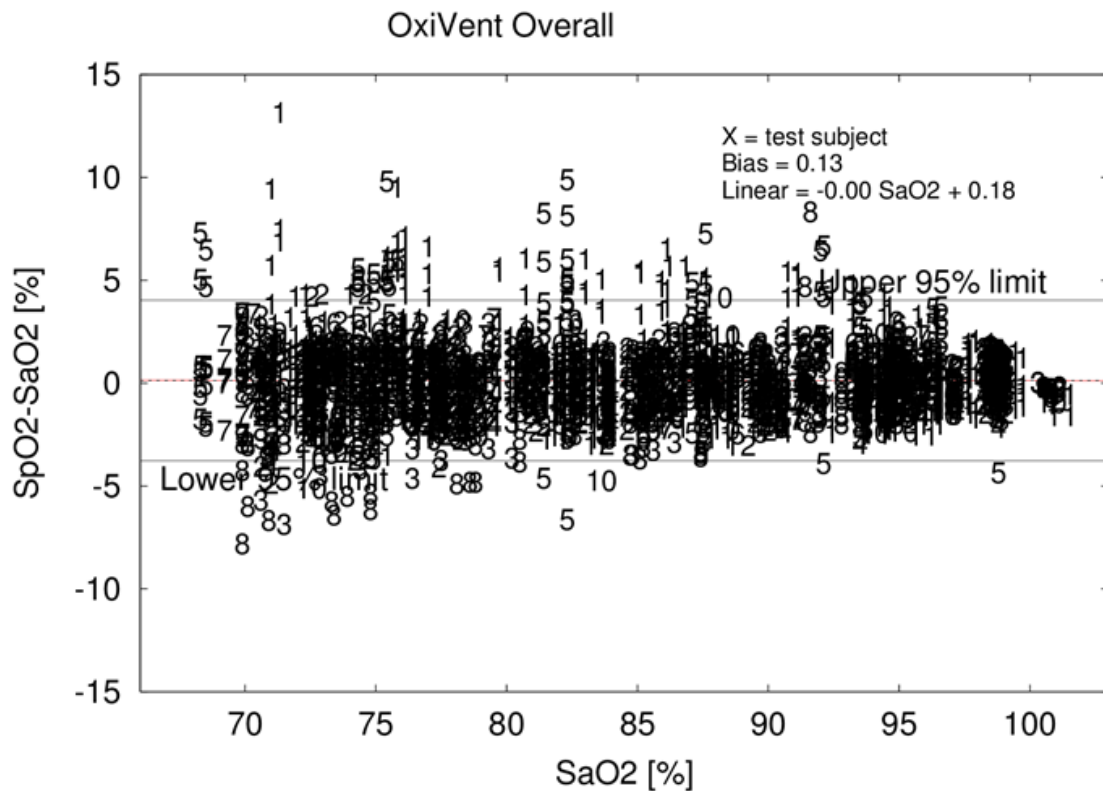
SpO₂ accuracy analysis for V-Sign™ Sensor 2: Data points are identified with the ID of each individual test subject. Data from 12 healthy volunteers (7 males/5 females) of different skin pigmentation (3 light, 4 light-medium, 2 medium, 3 dark) were included in the analysis. The subjects were between 23 and 29 years old.

Detailed plots for SpO₂ accuracy of the V-Sign™ Sensor 2 per individual measuring site are given as follows:



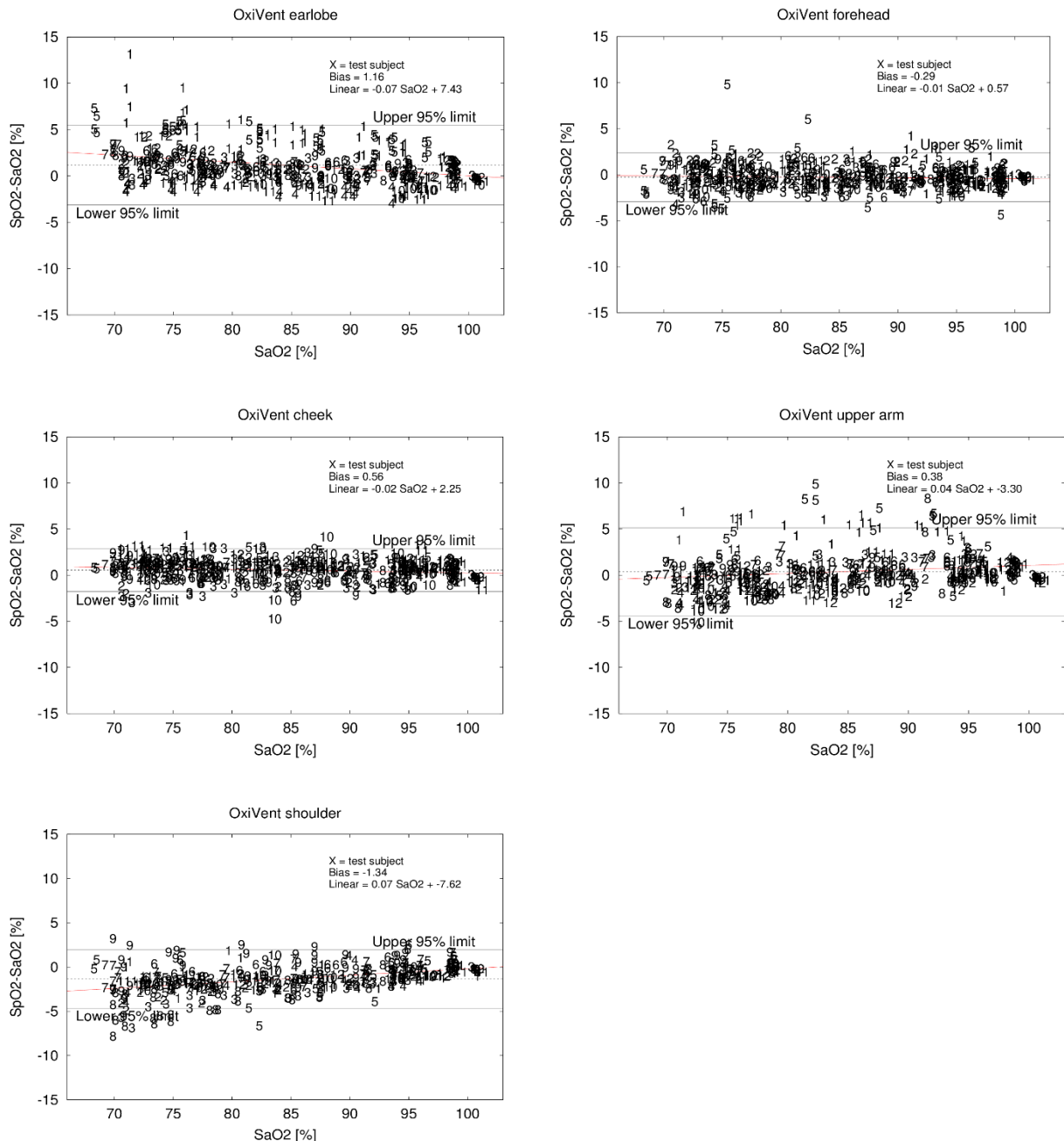


13.7.2 OxiVenT™ Sensor



SpO₂ accuracy analysis for OxiVen™ Sensor: Data points are identified with the ID of each individual test subject. Data from 12 healthy volunteers (7 males/5 females) of different skin pigmentation (5 light, 5 medium, 2 dark) were included in the analysis. The subjects were between 23 and 34 years old.

Detailed plots for SpO₂ accuracy of the OxiVen™ Sensor per individual measuring site are given below:



13.7.3 Pigmentation dependence of SpO₂

Sentec is aware that the current pulse oximeter technique based on two measuring wavelengths is affected by skin pigmentation within the absorption path. To review

such potential effects in Sentec's own pulse oximeter devices, data from controlled desaturation studies were pooled and analyzed for racial bias. The data was split into three groups of volunteers: highly pigmented skin, low pigmented skin, and all skin types containing data of all subjects as reference group. From the Bland Altman plots, the bias, standard deviation was extracted, and root mean square error (Arms) was calculated for each group and application site. Across all approved application sites, a difference between low and high pigmentation of 0.7% was noted. On earlobe and upper arm, a larger difference of 2.29% and 1.23% were observed, respectively, while on three other sites almost no significant bias was present. Therefore, this bias cannot solely be explained by pigmentation only.

In conclusion, a small racial bias in pulse oximetry for certain application sites could be observed within this data set. Most of the deviations are within Sentec's claims of accuracy, however, and all deviations are within FDA's limits of accuracy.

13.8 Electromagnetic Compliance Declaration

- **WARNING:** The use of accessories, sensors, and cables other than those specified by Sentec may result in increased emission and/or decreased immunity of the SDMS.

13.8.1 Electromagnetic emissions

The SDMS is intended for use in the electromagnetic environment specified below. The customer or the user of the SDMS should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
RF emissions CISPR 11	Group 1	The SDMS uses RF energy intentionally for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The SDMS is suitable 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.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

13.8.2 Electromagnetic immunity

The SDMS is intended for use in the electromagnetic environment specified below. The customer or the user of the SDMS 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	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.

Immunity Test	IEC 60601 test level	Compliance level	Electromagnetic Environment – Guidance
Electrical fast transient (Bursts) IEC 61000-4-4	± 2 kV power supply lines ± 1 kV input/output lines	± 2 kV power supply lines ± 1 kV input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surges IEC 61000-4-5	± 0,5 kV, ± 1 kV line-to-line ± 0,5 kV, ± 1 kV, ± 2 kV line to ground	± 0,5 kV, ± 1 kV line-to-line ± 0,5 kV, ± 1 kV, ± 2 kV line to ground	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	0 % UT; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles at 0°	0 % UT; 0,5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles at 0°	Mains power quality should be that of a typical commercial or hospital environment.
Note: U _T is the a.c. mains voltage prior to application of the test level.			
Power frequency (50/60) Hz magnetic fields IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Portable and mobile RF communications equipment should be used no closer to any part of the SDMS, including cables, than the recommended separation distance d calculated from the equation applicable to the frequency of the transmitter.			
Conducted RF IEC 61000-4-6	V = 3 V _{rms} 150 kHz to 80 MHz 6 V ^{c)} in ISM bands between 0,15 MHz and 80 MHz	V = 3 V _{rms} 150 kHz to 80 MHz 6 V ^{c)} in ISM bands between 0,15 MHz and 80 MHz	$d = 1,17 \sqrt{P}$
Radiated RF IEC 61000-4-3	E = 3 V/m 80 MHz to 2,5 GHz Immunity to proximity fields ^{d)}	E = 3 V/m 80 MHz to 2,5 GHz Immunity to proximity fields ^{d)}	$d = 1,17 \sqrt{P}$ 80 MHz to 800 MHz $d = 2,33 \sqrt{P}$ 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. Interference may occur in the vicinity of equipment marked with the following symbol ^b :			
Note: At 80 MHz and 800 MHz, the higher frequency range applies. Note: 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 SDMS is used exceeds the applicable RF compliance level above, the SDMS should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the SDMS.			
^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			
^c The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.			
^d Immunity to proximity fields from RF wireless communication equipment			



Table: Test specification RF wireless communication equipment

Test Frequency [MHz]	Band [MHz]	Service	Modulation	Maximum Power [W]	Distance [m]	Immunity Test Level [V/m]
385	380 - 390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430 - 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1kHz sine	2	0.3	28
710	704 - 787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810	800 - 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Bands 5	Pulse modulation 18Hz	2	0.3	28
870						
930						
1720	1700 - 1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1,3,	Pulse modulation 217Hz	2	0.3	28
1845						
1970						
2450	2400 - 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240	5100 - 5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
5500						
5785						

13.8.3 Recommended separation distances

For Services listed in the Table under 13.8.2, a minimum separation distance of 0.3m should be respected. For other frequencies, please use the following table to calculate the minimum separation distance:

Rated maximum output power of transmitter [W]	Separation distance according to frequency of transmitter [m]		
	150 kHz – 80 MHz $d = 1,17 \sqrt{P}$	80 MHz – 800 MHz $d = 1,17 \sqrt{P}$	800 MHz – 2,5 GHz $d = 2,33 \sqrt{P}$
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,70	3,70	7,37
100	11,7	11,7	23,3

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated 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: At 80 MHz and 800 MHz, the higher frequency range applies.

Note: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

13.8.4 Cables

Cables (used together with the SDMS) comply with

- RF emissions, CISPR 11, Class B/Group 1
- Harmonic emissions, IEC 61000-3-2
- Voltage fluctuations/flicker emissions, IEC 61000-3-3
- Electrostatic discharge (ESD), IEC 61000-4-2
- Electric fast transient/burst, IEC 61000-4-4
- Surge, IEC 61000-4-5
- Voltage dips, short interruptions and voltage variations on power supply input lines, IEC 61000-4-11
- Power frequency (50/60 Hz) magnetic field, IEC 61000-4-8
- Conducted RF IEC 61000-4-6
- Radiated RF, IEC 61000-4-3

Sensors/Cables	Maximum Length
Sentec TC Sensors	0.8 m
Digital Sensor Adapter Cable	7.5 m

ComplianceThe tCOM+ monitor complies with the following standards: IEC 60601-1 (general safety), IEC 60601-1-2 (EMC), IEC 60601-1-6 (usability), IEC 60601-1-8 (alarms), IEC 60601-1-11 (home healthcare), IEC 60601-2-23 (transcutaneous monitors), ISO 80601-2-61 (pulse oximeters), ISO 14971 (risk management), IEC 62366 (usability engineering) IEC 62304 (software in medical devices), ISO 10993-1 (biocompatibility), ISO 20417 (information supplied by manufacturers), ISO 15223-1 and -2 (symbols).

This product complies with the requirements of the Medical Device Regulation (EU) 2017/745.

Care with
Confidence



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HB-012697-
Date of release: 2023-06