CareFusion

Avea® Pulse Oximetry Option

Operator's Manual Appendix

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Notices

EMC Notice

This equipment generates, uses, and can radiate radio frequency (RF) energy. If this equipment is not installed and used in accordance with the instructions in this manual, electromagnetic interference may result.

This equipment has been tested and found to comply with the limits of acceptance set forth in Standard EN 60601-1-2 for Medical Products. These limits provide reasonable protection against electromagnetic interference (EMC) when operated in the intended use environments described in this manual.

This ventilator is also designed and manufactured to comply with the safety requirements of Standard EN 60601-1, EN/ISO 9919, IEC 60601-2-12, CAN/CSA-C22.2 No. 601.1-M90, and UL 2601-1.

This ventilator can be affected by portable and mobile RF communications equipment.

This ventilator should not be stacked with other equipment.

The following cables were used in the evaluation of this ventilator.

- 15619 – Normally Open Patient Call Cable (Length – 1.7 meters)
- 15620 – Normally Closed Patient Call Cable (Length – 1.7 meters)
- 70600 – Cable, Communications (Length – 1 meter)
- 70693 – Cable, Communications (Length – 3 meters)
- Standard Centronix™ Printer Cable (Length – 2 meters)
- Standard SVGA Monitor Cable (Length – 2 meters)

Use of other cables may result in increased emissions or decreased immunity.

See Tables 201, 202, 203, and 205 (below) for further information regarding the Avea Ventilator and EMC.

Table 201. 60601-1-2 IEC:2001 (E)

Guidance and manufacturer's declaration – electromagnetic emissions		
The Avea Ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of the Avea Ventilator should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Avea Ventilator 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 Avea Ventilator is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-3	Class A	
Voltage Fluctuation/ Flicker emissions IEC 61000-3-3	Complies	

Table 202. 60601-1-2 IEC:2001 (E)

Guidance and manufacturer's declaration - electromagnetic immunity			
The Avea Ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of the Avea Ventilator 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	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 6 kV for power supply lines ± 1 kV for input/output lines	± 6 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95% dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycle <5 % U_T (>95% dip in U_T) for 5 seconds	<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 cycle <5 % U_T (>95% dip in U_T) for 5 seconds	Mains power quality should be that of a typical commercial or hospital environment. **Compliance is dependent on the operator following recommended charging and maintenance of the installed battery backup.**
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at level characteristic of a typical location in a typical commercial or hospital environment.
Note: U_T is the AC. mains voltage prior to application of the test level.			

Table 203. 60601-1-2 IEC:2001 (E)

Guidance and manufacturer's declaration – electromagnetic immunity			
The Avea Ventilator is intended for use in the electromagnetic environment specified below. The customer or the user of the Avea Ventilator 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 V rms 150 kHz to 80 MHz outside ISM bands[a] 10 V rms 150 kHz to 80 MHz In ISM bands[a] 10 V/m 80 MHz to 2,5 GHz	3 V 10 V 10 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the Avea Ventilator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = 1.16\sqrt{P}$ $d = 1.20\sqrt{P}$ $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). [b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [c] should be less than the compliance level in each frequency range. [d] Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1: At 80 MHz and 800 MHz, 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. The ISM (industrial, scientific, and medicinal) bands between 150 kHz 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.
b. The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.
c. 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 FR transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Avea Ventilator is used exceeds the applicable RF compliance level above, the Avea Ventilator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Avea Ventilator.
d. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Table 205 60601-1-2 IEC:2001 (E)

Recommended separation distance between portable and mobile RF communications equipment and the Avea Ventilator

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

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)			
	150 kHz to 80 MHz outside ISM bands $d = 1.16\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = 1.20\sqrt{P}$	80 MHz to 800 MHz $d = 4\sqrt{P}$	80 MHz to 800 MHz $d = 7.66\sqrt{P}$
0.01	0.12	0.12	0.12	0.23
0.1	0.37	0.38	0.38	0.73
1	1.16	1.20	1.20	2.30
10	3.67	3.79	3.79	7.27
100	11.60	12.00	12.00	23.00

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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.

Note1. At 80 MHz and 800 MHz, the separation distance of the higher frequency range applies.

Note 2. The ISM (industrial, scientific, and medical) bands between 150 kHz 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.

Note 3. An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

Note4. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Regulatory Notice

Federal law restricts the sale of this device, except by or on order of a physician.

Manufacturer

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USA

If you have a question regarding the Declaration of Conformity for this product, please contact CareFusion (see page ii for the contact information).

Safety Information

Please review the following safety information before operating the ventilator. Attempting to operate the ventilator without fully understanding its features and functions may result in unsafe operating conditions.

Warnings and Cautions, which are general to the use of the ventilator under all circumstances, are included in this section. Some Warnings and Cautions are also inserted within the manual where they are most meaningful.

Notes are also located throughout the manual to provide additional information related to specific features.

If you have a question regarding the installation, set up, operation, or maintenance of the ventilator, contact CareFusion Customer Care (see page ii for the contact information).

Definition of Terms

The following list describes the use of notes, cautions, and warnings in this document.

Notes provide supplemental information to help you understand how the ventilator works.

Cautions identify conditions or practices that can cause damage to the ventilator or other equipment.

Warnings identify conditions or practices that can cause a serious, adverse reaction or are potential safety hazards.

Warnings

The Warnings and Cautions listed here apply generally anytime you operate the ventilator.

The warnings contained in this addendum are in addition to the warnings in the *Avea Operator's Manual*.

Excessive ambient light, poor perfusion states, patient movement, venous pulsations, a disconnected pulse oximeter probe and other clinical causes (significant levels of dysfunctional hemoglobin or low hemoglobin levels, intravascular dyes such as indocyanine or methylene blue, venous pulsations at the frequency of the arterial pulsations), may lead to incorrect SPO_2 measurements. If any measurement seems questionable, first check the patient's vital signs by alternate means and then check the equipment for proper functioning.

Loss of the pulse signal may occur during periods of severe vasoconstriction, severe anemia, hypotension, hypothermia, cardiac arrest or when there is arterial occlusion proximal to the sensor.

Place the sensor on patient site that has unrestricted blood flow, as specified in the direction for use provided in the packaging of the adhesive sensor.

Do not constrict the monitoring site when securing the probe because inaccurate readings or tissue damage may occur.

Do not position the cable in any manner that may cause entanglement, strangulation, or accidental self-extubation.

The pulse oximeter can be used during defibrillation, but the readings may be inaccurate for a short time.

Use only Masimo® pulse oximetry sensors.

Cautions

The following cautions apply anytime you work with the ventilator:

- Do not use damaged sensors or cables.
- Do not immerse sensors or the oximeter module housing in any liquid.
- Do not attempt to sterilize sensors by irradiation, steam, or ethylene oxide.
- Do not apply excessive tension to any sensor cable.
- Do not open the oximeter module housing. There are no user-serviceable parts inside.

Contents

Avea® Pulse Oximetry Option

Theory of Operation

Masimo-SET™

This device is calibrated to display functional oxygen saturation. The device uses a two-wavelength system by passing red (660 nm wavelength) and infra-red (905 nm wavelength) light through the capillary bed and measuring changes in light absorbance through the cardiac cycle.

The function principle of the pulse oximeter with Masimo-SET is based on (1) the fact that oxyhemoglobin and deoxyhemoglobin differ in their capability of absorbing red and infrared light, (2) that the volume of arterial blood in the tissues varies from pulse-to-pulse (thus also the light absorption by the blood), and (3) that arteriovenous shunting is very variable and the fluctuating absorption by the venous blood is the dominant noise component.

Since oxyhemoglobin and deoxyhemoglobin absorption capabilities are different, the amount of red and infrared light absorbed by the blood is related to the oxygen saturation of the hemoglobin. Masimo-SET divides the red and infrared pulsating portion of the absorption signal into an arterial and a noise signal thereby calculating the ratio of the arterial signals without the noise portion. The ratio of the two arterial absorption values is used by an empirically-derived equation to determine the oxygen saturation.

Calibration of this device is neither required nor possible, and a functional tester cannot be used to assess the accuracy of a pulse oximeter probe or system with a co-oximeter.

Configuration and Setup

The settings are found in the Monitoring tab in the Utility Screen. Depress the Screens button, touch the Utility button, and select the Monitoring tab.

Pulse Oximeter – Enable / Disable

This control activates and de-actives the Pulse Oximeter system.

- Range: Enable / Disable
- Default: Disable

Algorithm

This control allows you to select the sensitivity mode of the pulse oximeter based on individual needs of the patient.

Maximum	**Normal**	**APOD (Adaptive Probe Off Detection)**
This mode should be used for the sickest patients, where obtaining a reading is most difficult. Maximum Sensitivity is designed to interpret and display data for even the weakest of signals.	This mode provides the best combination of sensitivity, and probe-off detection performance. This mode is recommended for the majority of patients. It is also recommended during procedures and when clinician and patient contact is continuous.	This mode is the least sensitive in picking up a reading on patients with low perfusion but has the best detection for probe-off conditions. This mode is useful for patients that are at particular risk of the sensor becoming detached (pediatric, combative, etc.)

- Range: Max / Normal / APOD
- Default: Normal

Note:

If using the AutoFiO_2 option, the Algorithm is automatically set to Normal and cannot be changed as long as the AutoFiO_2 option is enabled.

Averaging

Determines the time period in which the SpO_2 reading is averaged.

- Range: 2, 4, 8, 10, 12, 14, or 16 seconds
- Default: 8 seconds

Note:

If using the $AutoFiO_2$ option, Averaging is automatically set to eight (8) seconds and cannot be changed as long as the $AutoFiO_2$ option is enabled.

SpO_2 Delay

The SpO_2 Alarm Delay determines the duration that a High or Low SpO_2 Alarm or SpO_2 Signal Quality alarm must persist before the alarm is activated.

- Delay Range: 10 to 120 seconds
- Resolution: 5 seconds
- Default: 60 seconds

Monitors

Pulse oximetry data may be displayed on any of the five monitors to the left of the graphic displays on the main screen. This data is also selectable on the trending screen. Monitored values are:

SpO_2

The patient's SpO_2 as measured and reported by the pulse oximeter.

- Range: 1 to 100%
- Resolution: 1%
- Accuracy: ± 3% from 70 – 100%. Unspecified < 70%.

Pulse Rate

The patient's pulse rate as measured and reported by the pulse oximeter.

- Range: 25 to 240 bpm
- Accuracy: ± 4 bpm
- Resolution: 1 bpm

Perf. Index

The perfusion index (PI) indicates the percentage of pulsatile signal to non-pulsatile signal (pulse strength). The PI is useful in determining optimal probe placement and troubleshooting.

- Range: 0.02 to 20.0%
- Resolution: 0.01% or three significant digits, whichever is greater.

Note:

The SpO_2, Pulse Rate and Perfusion Index values may be subject to a delay of up to one breath period or ten seconds (whichever occurs first), because the update period is governed by the ventilatory monitoring functions.

Waveforms

Pulse oximetry waveforms may be selected as one of the scalar waveforms on the Avea Ventilator.

Plethysmographic Waveform

The plethysmographic waveform is displayed as a scalar wave. The waveform is a continuous, auto-scaled waveform. It is displayed to 90% of full scale for a signal strength ≥10%. Below 10%, the waveform is scaled monotonically with signal strength.

Signal IQ

The height of the vertical line of the Signal IQ indicates the quality of the measured arterial pulse signal. A high vertical bar indicates that the SpO_2 measurement is based on a good quality signal. A small vertical bar indicates that the SpO_2 measurement is based on data with low signal quality. Low signal quality may compromise the accuracy of the SpO_2 measurements.

Alarms

Low SpO_2 Alarm

The Low SpO_2 Alarm is activated if the measured SpO_2 is at, or lower than, the Low SpO_2 Alarm setting for more than the SpO_2 Alarm Delay setting. This is a high priority alarm.

- Range: 60 to 97% or Off
- Resolution: 1%
- Default: 87% (neonatal); 90% (pediatric and adult)

High SpO_2 Alarm

The High SpO_2 Alarm is activated if the measured SpO_2 is at, or higher than, the High SpO_2 Alarm setting for more than the SpO_2 Alarm Delay setting. This is a high priority alarm.

- Range: 70 to 100% or Off
- Resolution: 1%
- Default: 96% (neonatal); Off (pediatric and adult)

Note:

If you are using the AutoFiO_2 Option, the High and Low SpO_2 Alarms may only be disabled if the High and Low AutoFiO_2 alarms are set (not disabled).

The High SpO_2 Alarm must be set at least 2% higher than the Low SpO_2 Alarm.

High Pulse

The device gives an alarm if the monitored pulse rate is greater than or equal to the High Pulse alarm setting. This is a high priority alarm.

Range: 30 to 240 bpm, Off

Resolution: 5 bpm

Default: 180 bpm (neonatal); 140 bpm (pediatric and adult)

Low Pulse

The device gives an alarm if the monitored pulse rate is less than or equal to the Low Pulse alarm setting. This is a high priority alarm.

Range: Off, 25 to 235 bpm

Resolution: 5 bpm

Default: 100 bpm (neonatal); 50 bpm (pediatric and adult)

Note:

The Low Pulse Alarm must be set at least 5 bpm below the High Pulse Alarm

Note:

The Alarm signal generation delay for low and high SpO_2 and for low and high pulse rate equal to the sum of the oximeter averaging time plus the SpO_2 alarm delay time.

Poor SpO_2 Signal Quality Alarms

Poor SpO_2 Signal Quality alarms indicate a problem with the pulse oximetry signal. Only one alarm appears at a time. If more than one occurs simultaneously, the highest ranking alarm appears. These are low or high priority alarms.

Alarm messages (ranked from highest to lowest priority):

- SpO_2: Sensor off
- SpO_2: Low SIQ
- SpO_2: Low perfusion
- SpO_2: Pulse search
- SpO_2: Interference
- SpO_2: Ambient Light

Note:

The alarm starts as a low priority alarm and transitions to a high priority alarm when the alarm has been active for more than the SpO_2 Alarm Delay period.

SpO_2 Invalid Alarms

These alarms indicate a problem with the sensor, cable, or interface box. These are high priority alarms.

- SpO_2: No sensor
- SpO_2: Defective sensor
- SpO_2: Unrecognized sensor
- SpO_2: Not connected