HAMILTON-C1
EMC Declarations

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EN EMC declarations IEC 60601-1-2:2007, 3rd edition

HAMILTON-C1 EMC Declarations

This guide provides information about EMC declarations. It is designed for use together with your ventilator *Operator's Manual*, and refers to information provided there.

The HAMILTON-C1 ventilator is intended for use in the electromagnetic environment specified in Tables 1, 2, and 3. The HAMILTON-C1 ventilator user should ensure that it is used in such an environment.

Table 1 Guidance and manufacturer's declaration – electromagnetic emissions (IEC 60601-1-2)

Emissions test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 1	The HAMILTON-C1 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, conducted	Class A	The HAMILTON-C1 ventilator is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings for domestic purposes.
RF emissions CISPR 11, radiated	Class A	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

NOTICE

- U_T is the AC mains voltage prior to application of the test level.
- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table 2 Guidance and manufacturer's declaration – electromagnetic immunity (IEC 60601-1-2)

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±2 kV, ±4 kV, ±6 kV contact ±2 kV, ±4 kV, ±6 kV ±8 kV air	±2 kV, ±4 kV, ±6 kV contact ±2 kV, ±4 kV, ±6 kV ±8 kV air	The relative humidity should be at least 5%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines ±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 line(s) to line(s) ±2 kV line(s) to earth	±1 kV line(s) to line(s) ±2 kV (line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	< 5% U_T[1] (>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 s	<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 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the HAMILTON-C1 ventilator requires continued operation during power mains interruptions, it is recommended that the HAMILTON-C1 ventilator be powered from an uninterruptible power supply or battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	10 A/m	The power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Table 2 Guidance and manufacturer's declaration – electromagnetic immunity (IEC 60601-1-2) *(cont.)*

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the HAMILTON-C1 ventilator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance:
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands[2] 10 Vrms 150 kHz to 80 MHz in ISM bands[5]	10 Vrms 150 kHz to 80 MHz outside ISM bands 10 Vrms 150 kHz to 80 MHz in ISM bands	$\mathbf{d = 0.35\sqrt{P}}$ $\mathbf{d = 1.2\sqrt{P}}$

Table 2 Guidance and manufacturer's declaration – electromagnetic immunity (IEC 60601-1-2) *(cont.)*

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment guidance
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m 80 MHz to 2.5 GHz	80 MHz to 800 MHz $d = 1.2\sqrt{P}$ 800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$ 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).[3] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[4], should be less than the compliance level in each frequency range[5]. Interference may occur in the vicinity of equipment marked with the symbol 

1. U_T is the AC mains voltage prior to application for the test level.
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.
3. 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 has been incorporated into the formulas used in calculating the recommended separation distance for transmitters in these frequency ranges.
4. 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 HAMILTON-C1 ventilator is used exceeds the applicable RF compliance level above, the HAMILTON-C1 ventilator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the HAMILTON-C1 ventilator.
5. Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Table 3 FDA additional tests

FDA Excerpts Related to EMI	FDA Excerpts Related to EMI test level	FDA Excerpts Related to EMI compliance level
Slow Sags and Surges	150/120/90 Vrms 500 ms	150/120/90 Vrms 500 ms
Quasi-static electric fields	2000 V/m; 0.5 Hz	2000 V/m; 0.5 Hz
Steady-state voltage	95 V / 60 Hz 132 V / 60 Hz	95 V / 60 Hz 132 V / 60 Hz

The HAMILTON-C1 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ventilator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ventilator as recommended in Table 4, according to the maximum output power of the communications equipment.

Table 4 Recommended separation distances between portable and mobile RF communications equipment and the HAMILTON-C1 ventilator

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter (m)			
	150 kHz to 80 MHz outside ISM bands $d = 0.35\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.035	0.12	0.12	0.23
0.1	0.11	0.38	0.38	0.73
1	0.35	1.2	1.2	2.3
10	1.1	3.8	3.8	7.3
100	3.5	12	12	23

NOTICE

- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.
- 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.
- At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
- 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.

- An additional factor of 10/3 has been incorporated into the formulas 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.

EN EMC declarations IEC 60601-1-2:2014, 4th edition

HAMILTON-C1 EMC Declarations

This guide provides information about EMC declarations. It is designed for use together with your ventilator *Operator's Manual*, and refers to information provided there.

Functioning of the device may be impaired by the operation of high-frequency surgical equipment, microwaves, shortwaves, or strong magnetic fields in close proximity.

The HAMILTON-C1 ventilator is intended for use in the electromagnetic environment specified in Tables 5, 6, and 9; essential performance is not affected.

The customer or the user of the HAMILTON-C1 ventilator should ensure that it is used in such an environment.

⚠ WARNING

- To prevent interrupted operation of the ventilator due to electromagnetic interference, avoid using it adjacent to or stacking other devices on it. If adjacent or stacked use is necessary, verify the ventilator's normal operation in the configuration in which it will be used.
- To prevent increased emissions, decreased immunity, or interrupted operation of the ventilator or any accessories, use only accessories or cables that are expressly stated in this manual.
- Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- 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 HAMILTON-C1 ventilator, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Table 5 Guidance and manufacturer's declaration – electromagnetic emissions (IEC 60601-1-2:2014)

Emissions test	Compliance	Electromagnetic environment guidance
RF emissions CISPR 11	Group 1	The HAMILTON-C1 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, conducted	Class A	The emissions characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.
RF emissions CISPR 11, radiated	Class A	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

NOTICE

- U_T is the AC mains voltage prior to application of the test level.
- At 80 MHz and 800 MHz, the higher frequency range applies.
- These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Table 6 Guidance and manufacturer's declaration – electromagnetic immunity (IEC 60601-1-2:2014)

Immunity test	IEC 60601-1-2:2014 Test level	IEC 60601-1-2:2014 Compliance level
For electromagnetic environment guidance, see Table 8		
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±2 kV, ±4 kV, ±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines
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) ±2 kV (line(s) to earth
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	Cycle 0.5 U_T=0% Phase=0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°. Cycle 1 U_T=0% Phase=0° Cycle 25 (50Hz) Cycle 30 (60Hz) U_T= 70% Phase=0° Cycle 250 (50Hz) Cycle 300 (60Hz) U_T=0% Phase=0°	Cycle 0.5 U_T=0% Phase=0°, 45°, 90°, 135°, 180°, 225°, 270°, 315°. Cycle 1 U_T=0% Phase=0° Cycle 25 (50Hz) Cycle 30 (60Hz) U_T = 70% Phase=0° Cycle 250 (50Hz) Cycle 300 (60Hz) U_T=0% Phase=0°
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m

Table 6 Guidance and manufacturer's declaration – electromagnetic immunity (IEC 60601-1-2:2014) *(cont.)*

Immunity test	IEC 60601-1-2:2014 Test level	IEC 60601-1-2:2014 Compliance level
For electromagnetic environment guidance, see Table 8		
Conducted RF IEC 61000-4-6:	3 Vrms 150 kHz to 80 MHz outside ISM bands 6 Vrms 150 kHz to 80 MHz in ISM bands	6 Vrms 150 kHz to 80 MHz outside ISM bands 6 Vrms 150 kHz to 80 MHz in ISM bands
Radiated RF IEC 61000-4-3	3 V/m 80 MHz - 2.7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz - 3.0 GHz 80 % AM at 1 kHz
Immunity to proximity fields IEC 61000-4-3	See Table 7	See Table 7

Table 7 Compliance and test levels, Radiated RF IEC 61000-4-3

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						

Table 7 Compliance and test levels, Radiated RF IEC 61000-4-3

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
1720	1700-1990	GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, 25, UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
5500						
5785						

Table 8 Recommended separation distances between portable and mobile RF communications equipment and the HAMILTON-C1 ventilator

Rated maximum output power of transmitter P(W)	Electric field strength E(V/m) at frequency band	Minimum separation distance (m) $d = \frac{6}{E}\sqrt{P}$ or 0.3, whichever is greater
	380 to 390 MHz	
0.01	27	0.3
0.1	27	0.3
1	27	0.3
10	27	0.7
100	27	2.22

Rated maximum output power of transmitter P(W)	Electric field strength E(V/m) at frequency band	Minimum separation distance (m) $d = \frac{6}{E}\sqrt{P}$ or 0.3, whichever is greater
	430 to 470 MHz	
0.01	28	0.3
0.1	28	0.3
1	28	0.3
10	28	0.68
100	28	2.14

Rated maximum output power of transmitter P(W)	Electric field strength E(V/m) at frequency band	Minimum separation distance (m) $d = \frac{6}{E}\sqrt{P}$ or 0.3, whichever is greater
	704 to 787 MHz	
0.01	9	0.3
0.1	9	0.3
1	9	0.67
10	9	2.11
100	9	6.67

Rated maximum output power of transmitter P(W)	Electric field strength E(V/m) at frequency band	Minimum separation distance (m) $d = \frac{6}{E}\sqrt{P}$ or 0.3, whichever is greater
	800 to 960 MHz	
0.01	28	0.3
0.1	28	0.3
1	28	0.3
10	28	0.68
100	28	2.14

Rated maximum output power of transmitter P(W)	Electric field strength E(V/m) at frequency band	Minimum separation distance (m) $d = \frac{6}{E}\sqrt{P}$ or 0.3, whichever is greater
	1700 to 1990 MHz	
0.01	28	0.3
0.1	28	0.3
1	28	0.3
10	28	0.68
100	28	2.14

Rated maximum output power of transmitter P(W)	Electric field strength E(V/m) at frequency band	Minimum separation distance (m) $d = \frac{6}{E}\sqrt{P}$ or 0.3, whichever is greater
	2400 to 2570 MHz	
0.01	28	0.3
0.1	28	0.3
1	28	0.3
10	28	0.68
100	28	2.14

Rated maximum output power of transmitter P(W)	Electric field strength E(V/m) at frequency band	Minimum separation distance (m) $d = \frac{6}{E}\sqrt{P}$ or 0.3, whichever is greater
	80 MHz to 2.7 GHz	
0.01	10	0.3
0.1	10	0.3
1	10	0.6
10	10	1.9
100	10	6

Rated maximum output power of transmitter P(W)	Electric field strength E(V/m) at frequency band	Minimum separation distance (m) $d = \frac{6}{E}\sqrt{P}$ or 0.3, whichever is greater
	5.1 to 5.8 GHz	
0.01	9	0.3
0.1	9	0.3
1	9	0.67
10	9	2.11
100	9	6.67

The HAMILTON-C1 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the ventilator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the ventilator, according to the maximum output power of the communications equipment.

NOTICE

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

Table 9 FDA additional tests

FDA Excerpts Related to EMI	FDA Excerpts Related to EMI test level	FDA Excerpts Related to EMI compliance level
Slow Sags and Surges	150/120/90 Vrms 500 ms	150/120/90 Vrms 500 ms
Quasi-static electric fields	2000 V/m; 0.5 Hz	2000 V/m; 0.5 Hz
Steady-state voltage	95 V / 60 Hz 132 V / 60 Hz	95 V / 60 Hz 132 V / 60 Hz

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