body clock

Babycare TENS®

Accompanying Electromagnetic Information

This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided. The unit can be affected by portable and mobile RF communications equipment.

The SensaTONE device is intended to be used in a home healthcare environment.

Caution: This unit has been thoroughly tested and inspected to assure proper performance and operation!

Caution: This device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the device should be observed to verify that it is operating normally.

WARNING: 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

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 SensaTone device including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

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Equipment Type

This unit is intended for use in the electromagnetic environment specified below.
The customer or the user of this unit should ensure that it is used in such an environment.
This device is intended for use within the home health care environment.
This document is intended as a supplement to the instructions for use (IFU).
Do not stack this device.

Emissions test	Test	Electromagnetic environment – guidance
Conducted and radiated RF EMISSIONS CISPR 11	Group 1 Class B	This unit uses RF energy 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.
Harmonic fluctuations/ Distortion IEC 61000-3-2	n/a	This unit is intended for connection to public low voltage distribution systems
Voltage fluctuations flicker IEC 61000-3-3	n/a	

Recommended separation distances between portable and mobile RF communications equipment and this unit
This unit is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this unit can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this unit 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)**		
	150kHz to 80MHz $d=1.2xP^{1/2}$	80MHz to 800MHz $d=1.2xP^{1/2}$	800MHz to 2.5GHz $d=2.3xP^{1/2}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Guidance and manufacturer's declaration - electromagnetic immunity

This unit is intended for use in the electromagnetic environment specified below. The customer or the user of this unit should ensure that it is used in such an environment.
Note 1: At 80MHz and 800MHz, the higher frequency applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
a). Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. 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 this unit is used exceeds the applicable RF compliance level above, this unit should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating this unit.
b). Over the frequency range 150 kHz to 80 MHz, field strengths should be less than
[V1] V/m.
This unit is intended for use in the home healthcare environment. The customer or the user of this unit should ensure that it is used in such an environment

Immunity test	IEC 60601	Compliance	Electromagnetic environment guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8kV direct & indirect contact ±2kV ±4kV ±8kV ±15kV air	±8kV direct & indirect contact ±2kV ±4kV ±8kV ±15kV air	Floor should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
RF electromagnetic fields / Proximity Fields from RF communications IEC 61000-4-3	3V/m 80MHz to2.7GHz (professional use) 10V/m 80MHz to 2.7GHz (Home healthcare environment	3V/m 10V/m	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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Conducted disturbances induced by RF fields. IEC 61000-4-6	3 Vrms150kHz to 80MHz 3 V RMS outside the ISM band, 6 V RMS in the ISM and amateur radio bands 3 V RMS outside the ISM band, 6 V RMS in the ISM band Professional Healthcare Environment	Home health care environment)) Professional Healthcare Environment	Portable and mobile RF communications equipment should be used no closer to any part of this unit including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance $d=[3,5/V]xP^{1/2}$ 1 $d=1.2xP^{1/2}$ 80MHz to 800MHz $d=2.3xP^{1/2}$ 80MHz to 2.5GHz

Guidance and manufacturer's declaration - electromagnetic immunity (cont)			
Immunity test	IEC 60601	Compliance	Electromagnetic environment guidance
Electrical fast transient IEC 61000-4-4	±2kV for power supply lines 100 kHz Input a.c. Power ports ±2kV for power supply lines 100 kHz d.c. power lines ±1kV for power supply lines 100 kHz Signal input/output ports.	n/a	n/a
Surge Immunity Test IEC 61000-4-5	±0.5kV and 1.0 kV line to line + 0.5kV ±1kV and 2.0kV line(s) to earth 2.0kV (Line to Earth)	n/a	n/a
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	‹5% UT (›95% dip in UT) for 0.5 cycle 40% UT (60% dip in UT for 5 cycles) 70% UT (30% dip in UT) for 25 cycles ‹5% UT (›95% dip in UT) for 5s	n/a	n/a
Power-Frequency Magnetic Fields IEC 61000-4-8	30A/m 50Hz-60Hz	Tested at nominal voltage	Power frequency magnetic fields are tested at a distance of at least 15cm.
NOTE UT is the a.c. mains voltage prior to application of the test level			