Warnings/Advice
Healthcare statement

This Synapse microcurrent device is intended for use by healthcare professionals only.

Electrical Hazards: Emissions and Immunity
This Synapse micro-current device may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the device or shielding the location.
The use of accessories such as cables or conducting electrode pads other than those specified and/or supplied with the device or specified by Synapse Micro-current Ltd and/or sold by the manufacturer of the device as replacement parts for internal components, may result in increased emissions or decreased immunity of the micro-current device.

The Synapse Micro-current device should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary,
the device should be observed to verify normal operation in the configuration in which it will be used.

Guidance and Manufacturer's Declaration Electromagnetic Emissions IEC 60601-1-2 for the Tendonworks and Accel-Heal Units		
The unit is suitable for use in the specified electromagnetic environment. The customer and / or the user of the unit should assure that it is used in an electromagnetic environment as described below:		
Emissions Test	Compliance	Electromagnetic Environment Guidance
RF emissions CISPR 11	Group 1	The unit does not use RF for its 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 unit is suitable for use in all establishments, including domestic establishments and those directly connected to the low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and Manufacturer's Declaration Electromagnetic Immunity IEC 60601-1-2 Tendonworks and Accel-Heal Units			
Emissions Test	IEC 60601-1-1 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	Not Applicable	Not Applicable	Not Applicable
Surge IEC 61000-4-5	Not Applicable	Not Applicable	
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not Applicable	Not Applicable	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical domestic, commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity for Tendonworks and Accel-Heal units

The unit is intended for use in the electromagnetic environment specified below. The customer or the user of the unit 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	3Vrms 150kHz to 80 MHz	3Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the unit, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3V / m 80 MHz to 2.2 GHzw	**Recommended separation distance:** $d = \frac{3.5}{3}\sqrt{p}$ $d = \frac{3.5}{3}\sqrt{p}\ 80MHz\ to\ 800MHz$ $d = \frac{7}{3}\sqrt{p}\ 800MHz\ to\ 2.2GHz$ 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,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:  If abnormal performance is observed such as the unit turning off, additional separation distance or screening may be necessary

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.

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 unit is used exceeds the applicable RF compliance level above, the unit should be observed to verify normal operation. If abnormal performance is observed such as the unit turning off, additional measures may be necessary, such as reorienting or relocating the unit.
Over the frequency range 150kHz to 80MHz, field strength should be less than 3V/m

Recommended separation distances between
portable and mobile RF communications equipment
and the Tendonworks and Accel-Heal units

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

Rated maximum output power of transmitter	Separation distance according to frequency of transmitter		
	150 kHz to 80 MHz Not Applicable	80 MHz to 800 MHz $d = \frac{3.5}{3}\sqrt{p}$	800 MHz to 1.4 GHz $d = \frac{7}{3}\sqrt{p}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.7	3.7	7.4
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.