

## 1. General Safety

**1.1 The Touch Bionics Myoelectric Prosthetic Devices are electrical devices, which under certain circumstances could present an electrical shock hazard to the user. Please read the accompanying user manual thoroughly and follow directions stated in the manual to assure maximum safety during charging and operation.**

### 1.2 BS EN 60601-1:2006/IEC EN 60601-1:2005

1.2.1 Protection against electrical shock – Class II

1.2.2 Degree of protection against electrical shock – Type BF provides additional protection against electric shock

1.2.3 Degree of protection against ingress of water (IEC 60529:2001) – IP40

1.2.4 Not suitable for use in the presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide

### 1.3 EMI/EMC

1.3.1 Compliance against standard BS EN 60601-1-2:2007/IEC 60601-1-2:2007

### 1.4 Radio Spectrum Matters (ERM)/Bluetooth

1.4.1 Compliance against standard EN 301 489-1 V1.8.1

## 2. Electromagnetic Compatibility (EMC)

### 2.1 Important information regarding Electro Magnetic Compatibility (EMC)


In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the BS EN 60601-1-2:2007/ IEC 60601-1-2: 2007 standard has been implemented. This standard defines levels of electromagnetic emissions for medical devices.

The Touch Bionics Myoelectric Prosthetic Devices are manufactured by Touch Bionics Ltd conforms to this BS EN 60601-1- 2:2007/ IEC 60601-1-2: 2007 standard for both immunity and emissions.

Refer to further guidance below regarding the EMC environment in which the device should be used.

Guidance and manufacturer's declaration – electromagnetic emissions		
<p><b>Touch Bionics Myoelectric Prosthetic Devices is intended for use in the electromagnetic environment specified below. The customer or the user of the Touch Bionics Myoelectric Prosthetic Devices should assure that it each are used in such an environment.</b></p>		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Not applicable  Battery Powered	<p><b>Touch Bionics Myoelectric Prosthetic Devices</b> use 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.</p> <p><b>Touch Bionics Myoelectric Prosthetic Devices</b> are suitable for use 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.</p>
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable  Battery Powered	
Voltage fluctuations/ flicker emissions	Not applicable	
IEC 61000-3-3	Battery Powered	

Guidance and manufacturer's declaration – electromagnetic immunity			
<p>Touch Bionics Myoelectric Prosthetic Devices are intended for use in the electromagnetic environment specified below. The customer or the user of the Touch Bionics Myoelectric Prosthetic Devices should assure that each are used in such an environment.</p>			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD)  IEC 61000-4-2	±6 kV contact ±8 kV air	±4 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 %.  Portable and mobile RF communications equipment should be used no closer to any part of the <b>Touch Bionics Myoelectric Prosthetic Devices</b> , including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter
Electrical fast transient/burst  IEC 61000-4-4	Not applicable	Not applicable  Battery Powered	Not applicable  Battery Powered  No Cables >3m
Surge  IEC 61000-4-5	Not applicable	Not applicable  Battery Powered	Not applicable  Battery Powered
Voltage dips, short interruptions and voltage variations on power supply  IEC 61000-4-11	Not applicable	Not applicable  Battery Powered	Not applicable  Battery Powered  No Cables >30m
Power frequency (50/ 60 Hz) magnetic field  IEC 61000-4-8	3 A/m	3 A/m  50/60Hz	Battery Powered

Guidance and manufacturer's declaration – electromagnetic immunity			
<p>Touch Bionics Myoelectric Prosthetic Devices are intended for use in the electromagnetic environment specified below. The customers or the users of Touch Bionics Myoelectric Prosthetic Devices should assure that each are used in such an environment.</p>			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	Not applicable	Not applicable  Battery Powered  No Cables >3m	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Touch Bionics Myoelectric Prosthetic Devices including cables, than the recommended separation distance calculated from the equation appropriate to the frequency of the transmitter.</p> <p>Recommended separation distance  <math>d = 1.2 \sqrt{P}</math>  <math>d = 1.2 \sqrt{P}</math> 80 MHz to 800 MHz  <math>d = 2.3 \sqrt{P}</math> 800 MHz to 2.5 GHz</p>
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m 80 MHz to 2700MHz  1kHz 80% AM  Upper frequency extended to 2700MHz)	<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).</p> <p>Field strengths from fixed RF transmitters as determined by an electromagnetic site survey <sup>a</sup> should be less than the compliance level in each frequency range <sup>b</sup></p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 
<p>Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.</p>			
<p><sup>a</sup> 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 Touch Bionics Myoelectric Prosthetic Devices are used exceeds the applicable RF compliance level above, Touch Bionics Myoelectric Prosthetic Devices should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Touch Bionics Myoelectric Prosthetic Devices</p>			

Recommended separation distance between portable and mobile RF communications equipment and the Touch Bionics Myoelectric Prosthetic Devices			
Touch Bionics Myoelectric Prosthetic Devices are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customers or the user of Touch Bionics Myoelectric Prosthetic Devices can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Touch Bionics Myoelectric Prosthetic Devices as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter in Watt	Separation distance according to frequency of transmitter in meters		
	150 kHz to 80 MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5GHz $d = 2.3 \sqrt{P}$
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 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 1: At 80MHz and 800MHz, 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.			

### 3. Customer Service/Contact Information

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