

IRIDEX Wireless Footswitch

Operator Instructions

IRIDEX Laser consoles can be operated with either a wired Footswitch or wireless Footswitch/Receiver pair. The wireless Receiver or wired Footswitch is connected to the Footswitch IN jack on the rear of the laser console. The system always tests for a properly connected wireless Receiver or wired Footswitch in the released state before entering Treat mode. If you try to select Treat mode when the wireless Receiver or wired Footswitch is damaged or improperly connected, the Status Display on the console will display the message “Connect Footswitch.” If you try to enter Treat mode with the Footswitch depressed or depress the Footswitch while the green Treat light is still flashing on entry to Treat mode, the Status Display will display the message “Release Footswitch”.

■ **Note:** Each Footswitch/receiver pair is uniquely linked and will not work with other IRIDEX Footswitches or similar components. Make sure to clearly identify each pair to prevent separation of the linked components. Changes to internal components may result in increased emissions or decreased immunity.

The wireless device is made up of two parts: a battery powered Footswitch and a console- powered receiver. The Footswitch has LEDs to assist in trouble shooting and to indicate battery conditions. The LEDs provide status as follows:

Footswitch LED indicators	
Footswitch LED Display	Status
Green Flash following pedal depression	Footswitch OK, Batteries OK
Amber Flash following pedal depression	Footswitch OK, Batteries Low
Blink Red LED for 10 seconds following footswitch release	No RF Communication

- The console only provides power to the receiver when in “treat” mode.
- When the Footswitch is activated the Footswitch processor initiates a communication link with the receiver.
- The Footswitch is designed to operate within a minimum of 15 feet of the console.
- Each Footswitch and receiver pair is uniquely linked in order to prevent any other Footswitch from activating the laser console.
- The Footswitch is designed to maximize battery life. In the unlikely event that the batteries need to be replaced, please contact your sales representative or IRIDEX Customer Service for a replacement.

To install, connect the receiver to “Footswitch IN” located on the rear of the laser console.

Inspecting and Cleaning the IRIDEX Wireless Footswitch

The IRIDEX Wireless Footswitch) is submersible (IPX8 IEC529). The wireless receiver is NOT submersible.

To decontaminate and disinfect the Footswitch:

1. Using water, isopropyl alcohol, or enzymatic detergents with mild pH such as ENZOL, remove all traces of blood and other body fluids from all exposed surfaces of the Footswitch assembly.
2. Immerse the Footswitch in a CIDEX (2.4% glutaraldehyde) solution to achieve the desired level of disinfection: a minimum of 45 minutes at 25°C to achieve a high level of disinfection, or a minimum of 10 minutes at 20°C to 25°C to achieve an intermediate level of disinfection.
3. Remove the Footswitch from the CIDEX solution.
4. Stand the Footswitch on end to drain all fluids.
5. Immerse the Footswitch in a large amount of water for a minimum of 1 minute. Repeat this step two or more times using clean water for each rinse.
6. Stand the Footswitch on end.
7. Allow the Footswitch to air-dry completely before reusing.

Wireless Footswitch Safety Information

Electromagnetic Interference

IRIDEX lasers and accessories (including the Wireless Footswitch) have been tested and found to comply with the limits for medical devices in IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

The laser console and accessories generate, use and can radiate radio-frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to other devices in the vicinity. There is no guarantee that interference will not occur in a particular installation. If the laser and/or footswitch does cause harmful interference to other devices, which can be determined by turning the system off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving device.
- Increase the separation between the equipment.
- Connect the laser console into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult IRIDEX Customer Service for help.

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

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This Class B digital apparatus meets all requirements of the Canadian Interference-Causing Equipment Regulations.

Cet appareil numérique de la classe B respecte toutes les exigences du Règlement sur le matériel brouilleur du Canada.

- **CAUTION:** Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- **Note:** MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual."
- **Note:** "Portable and mobile RF communications equipment can affect MEDICAL ELECTRICAL EQUIPMENT."

- **Note:** The frequency range RF transmission is 2.41GHz to 2.46GHz
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The system does not utilize spread-spectrum or frequency hopping modalities. Transmissions are continuous transmissions at discrete frequencies within the transmission frequency range.

Table 201 per Section 6 of IEC 60601-1-1:2001

Guidance and manufacturer's declaration – electromagnetic emissions		
The EQUIPMENT is intended for use in the electromagnetic environment specified below. The customer or the user of the EQUIPMENT should assure that it is used in such an environment.		
Emissions Test	Compliance	
RF emissions CISPR 11	Group 1	The Wireless Footswitch 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	
Harmonic emissions IEC 61000-3-2	Class B	
Voltage Fluctuations/ Flicker emissions	Complies	
The Wireless Footswitch is 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.		

Table 202 per Section 6 of IEC 60601-1-1:2001

Guidance and manufacturer's declaration – electromagnetic immunity			
The EQUIPMENT is intended for use in the electromagnetic environment specified below. The customer or the user of the EQUIPMENT 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	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines Not Applicable	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 % <i>UT</i> (>95 % dip in <i>UT</i>) for 0,5 cycle 40 % <i>UT</i> (60 % dip in <i>UT</i>) for 5 cycles 70 % <i>UT</i> (30 % dip in <i>UT</i>) for 25 cycles <5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 5 sec	<5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 0,5 cycle 40 % <i>UT</i> (60 % dip in <i>UT</i>) for 5 cycles 70 % <i>UT</i> (30 % dip in <i>UT</i>) for 25 cycles <5 % <i>UT</i> (>95 % dip in <i>UT</i>) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the EQUIPMENT requires continued operation during power mains interruptions, it is recommended that the EQUIPMENT be powered from an uninterruptible power supply or a battery.
(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 commercial or hospital environment.
NOTE <i>UT</i> is the a.c. mains voltage prior to application of the test level.			

Table 204 per Section 6 of IEC 60601-1-1:2001


Guidance and manufacturer's declaration – electromagnetic immunity			
The Wireless Footswitch is intended for use in the electromagnetic environment specified below. The customer or the user of the Wireless Footswitch should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
<p>Conducted RF IEC 61000-4-6</p> <p>Radiated RF IEC 61000-4-3</p>	<p>3 Vrms 150 kHz to 80 MHz</p> <p>3 V/m 80 MHz to 2,5 GHz</p>	<p>3 Vrms</p> <p>3 V/m</p>	<p>Portable and mobile RF communications equipment should be used no closer to any part of the EQUIPMENT, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = [3.5/V1]\sqrt{P}$ $d = [3.5/E1]\sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = [7/E1]\sqrt{P} \quad 800 \text{ MHz to } 2.5 \text{ GHz}$ <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 metres (m).</p> <p>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.^b</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>^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. 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 EQUIPMENT is used exceeds the applicable RF compliance level above, the EQUIPMENT should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the EQUIPMENT.</p>			
<p>^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Table 206 per Section 6 of IEC 60601-1-1:2001

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT			
The Wireless Footswitch is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Wireless Footswitch can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Wireless Footswitch 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 $d = [3.5/V1]\sqrt{P}$	80 MHz to 800 MHz $d = [3.5/E1]\sqrt{P}$	800 MHz to 2.5 GHz $d = [7/E1]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.39
100	11.67	11.67	23.33
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.			

Section 1 – Cleaning, Sterilization, and Shelf Life

14.1 Cleaning

Inspecting and Cleaning the IRIDEX Wireless Footswitch

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3. Remove the Footswitch from the CIDEX solution.
4. Stand the Footswitch on end to drain all fluids.
5. Immerse the Footswitch in a large amount of water for a minimum of 1 minute. Repeat this step two or more times using clean water for each rinse.
6. Stand the Footswitch on end.
7. Allow the Footswitch to air-dry completely before reusing.

14.2 Sterilization – Not Applicable

The IRIDEX Wireless Footswitch is not a sterile device.

14.3 Shelf-Life – Not Applicable

The IRIDEX Wireless Footswitch does contain any age dated materials.