O-pel

User Manual

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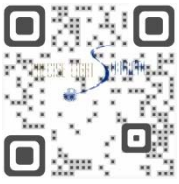
O-pel ® User Manual
LBL-11013 Rev. 01



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1.0 Introduction

Improper use of the laser system can result in adverse effects. Follow the instructions for use described in this consumer manual.

1.1 Intended Use

The Opel laser system including a fiber delivery system is intended to be used in surgical procedures such as open, laparoscopic, and endoscopic, to perform incision, excision, resection, ablation, vaporization, coagulation, and hemostasis of tissue in medical specialties including ENT.

1.2 Description

The Precise Light Surgical Opel Laser system and its fiber optic delivery system is a Class IV, pumped diode, solid state IR laser, which emits laser radiation with a wavelength of approximately 2um. The laser delivers power up to 5 Watts which is transmitted to the tissue through different optical fibers.

Keys and a Key-switch are provided to protect the laser from unauthorized use.

1.3 Warnings and Cautions

WARNINGS:

- *Federal Law restricts this device to sale by or on the order of a physician.*
- *Before using, read the user manual.*
- *Electrical equipment may be hazardous if misused. Only connect the device to a proper mains outlet and use only the electrical power cord supplied by PLS.*
- *Carefully inspect the probe for nicks, breaks, scratches, or rough surfaces that may injure the patient.*
- *Do not re-use, reprocess or resterilize the probe as it may compromise the structural integrity of the device which may lead to device failure.*
- *Do not re-use, reprocess or resterilize the probe as it may create a risk of contamination.*
- *Always wear protective eye wear when the laser is activated.*

- *A risk of fire and/or explosion exists when the laser output is used in the presence of flammable materials, solutions or gases, or in an oxygen rich environment.*
- *Periodically inspect cables and electrical cords. If visible damaged, replace to mitigate the potential for shock.*
- *Do not block vents to prevent system from overheating.*
- *The O-pel system is designed and tested as a system. Do not substitute and non-PLS parts.*
- *The device is not intended to be attached to any networks or data transfer devices.*
- *There are no user accessible or service-able parts. Return the device to PLS for Service.*
- *Always handle the laser fiber with care. Introducing sharp bends or exerting excessive force on the fiber optic may damage the optics and/or may lead to harm to the patient and/or operator.*

CAUTIONS:

- *Federal Law restricts this device to sale by or on the order of a physician.*
- *US federal law restricts this device to sale by or on the order of a healthcare practitioner licensed by the law of the State in which he/she practices to use or order the use of the device.*
- *Use of controls or adjustments or performing of procedures other than those specified herein may result in hazardous radiation exposure.*
- *Do not operate the equipment in the presence of flammables or explosives, such as volatile anesthetics, alcohol, and surgical preparation solutions.*
- *Use of Controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.*
- *Laser fume and /or plume may contain viable tissue particulates.*

1.4 Precise Light Surgical, Inc. Contact Information

PRECISE LIGHT SURGICAL, Inc.
310 W. Hamilton Ave. Suite 210
Campbell, CA 95008

Telephone: 1-(844) 669-1845
Technical Support: 1-(844) 669-1845

Warranty and Service:

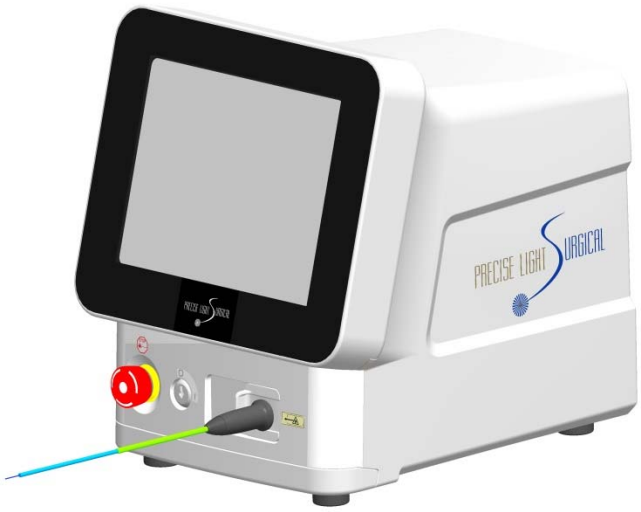
Contact Precise Light Surgical or your distributor for disposal information

WEE GUIDANCE:

2.0 Setup

2.1 Unpacking the System

Make certain that you have all components that were ordered. Inspect all components for damages before use. In case of problems communicate with your distributor directly.



Laser

Footswitch

AC Power Cord

Keys

User Manual

Figure 1 System Unpacking

2.2 Choosing a Location

- Always choose a well-ventilated location within the specified operating range of the console. Do not block the air vents.
- The tabletop should be stable.

2.3 Connecting the Components

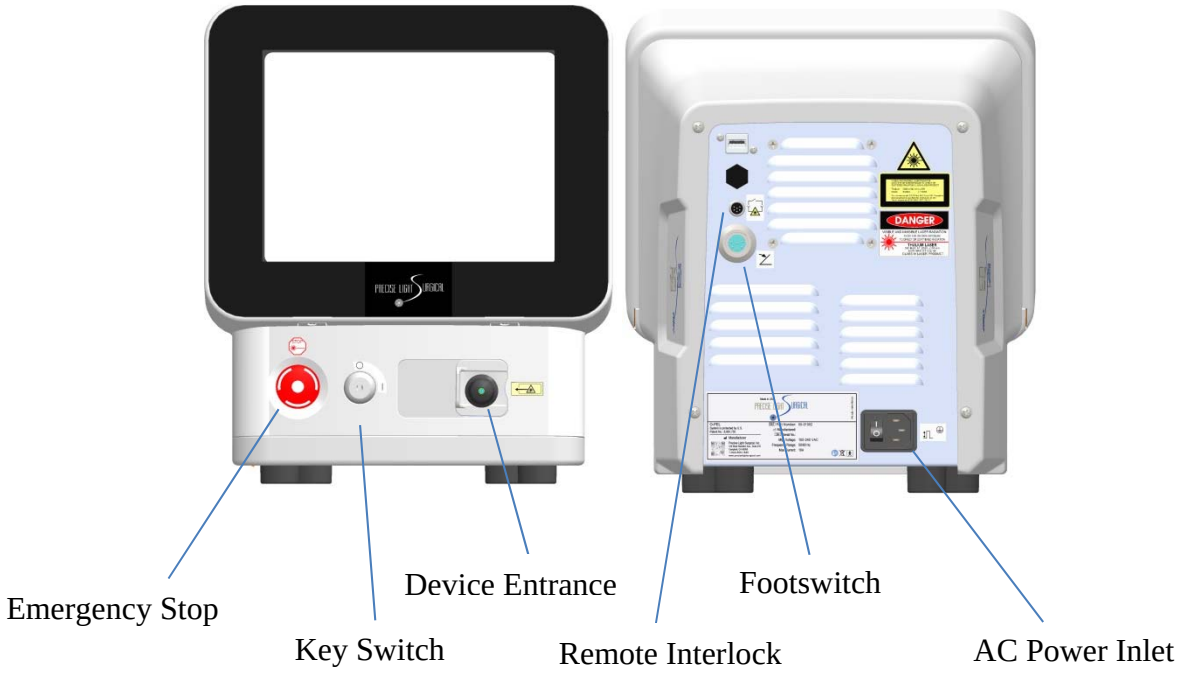


Figure 2 Components Connection

- Connect the power cord to an AC supply mains with protective earth to avoid the risk of shock.
- Verify that the Remote Interlock connector is plugged in.
- Post Laser warnings signs or verify that they are posted.

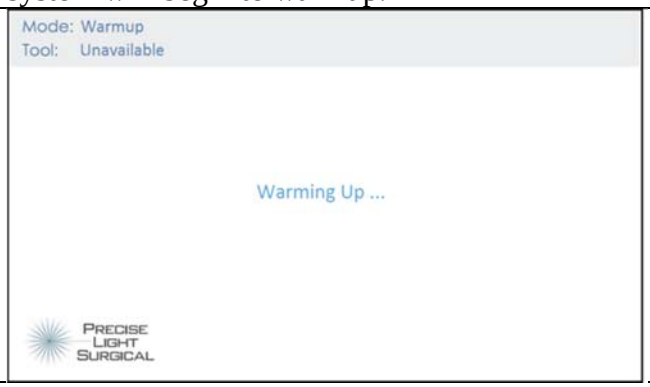
3.0 Operation

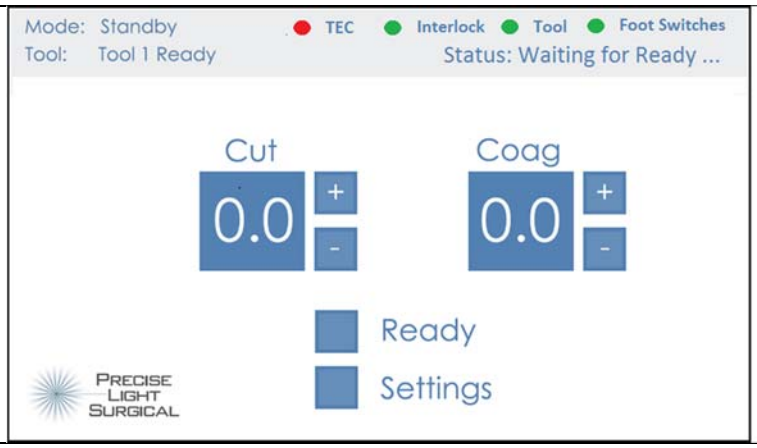
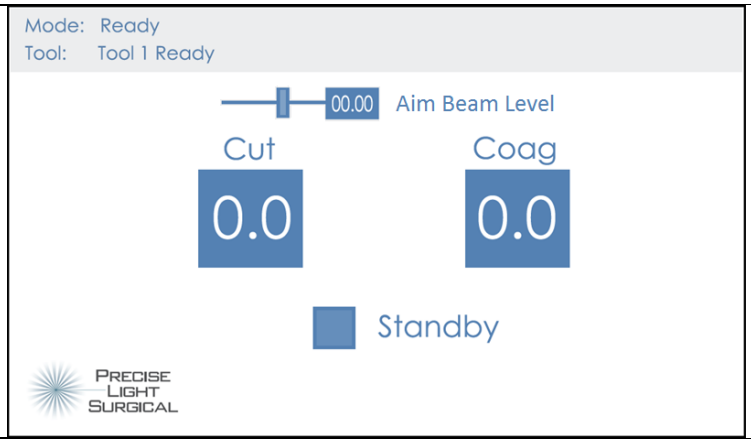
3.1 Front Panel Controls

Figure 3 Front Panel

3.2 Instructions for Use

Table 1- Instructions for Use

1	Verify that the footswitch and power cord is plugged in.
2	Verify that all safety equipment is installed (i.e. safety eye wear)
3	Turn ON main power switch located at the rear of the device
4	Obtain keys and install into the key switch; Turn key switch to the ON position. The system will begin to warmup.
5	
6	Wait for the console to complete warm-up. The system will enter the Standby screen automatically after the warmup.

7	
8	Carefully remove fiber probe from the sterile package and plug securely into the fiber port.
9	Using the touch screen, adjust the cut and coagulate settings as needed. Note: start at the lowest settings and adjust as needed. Select Settings to adjust tone volume, aiming beam intensity.
10	Verify the parameters are correct and that the TEC, Interlock, Tool, and Foot switches indicator lights are “green.” Select Ready. It may take several minutes for all of the interlock indicators to turn “green”.
11	
12	For contact probes navigate the fiber probe tip to the target tissue. For non-contact probes verify that the aiming beam is ON (if turned ON). Use the aiming beam to verify target tissue location. Note: The aiming beam level may be adjusted from the display.
13	Depress the foot switch (either cut or coagulate) to activate lasing.
14	Release the foot switch to inactivate lasing.
15	Note: the laser has an emergency switch that can automatically stop lasing.
16	Once the target tissue results are satisfactory, discontinue laser activation (footswitch).
17	Select Standby box to return to the Standby screen and remove the probe.
18	Turn key switch into the OFF position and store keys in a safe location.

4.0 Troubleshooting

4.1 Event Codes

The system has three user addressable error conditions:

- No device attached – resolve by attaching a valid delivery device
- Remote Interlock - resolve by either verifying the remote interlock plug is plugged in the back panel of the system or that the remote interlock circuit for the room is working properly
- Footswitch not attached – resolve by plugging the footswitch connector into the back panel of the system.

In the event of a system fault that is not user addressable an error code will be displayed on the screen. Please write down the error code number or description and power cycle the system to see if the error will clear and allow normal operation. If the error reoccurs continually or at all please contact Precise Light Surgical for service.

5.0 Maintenance

5.1 Inspecting and Cleaning the Laser

Clean the outside console covers with soft cloth moistened with a mild detergent. Avoid abrasive or ammonia-based cleaners.

WARNING: *Do not remove covers! Removing covers and shields may result in exposure to dangerous optical radiation levels and electrical voltages. Only Precise Light Surgical personnel may access the interior of the laser.*

CAUTIONS: *Turn off the laser before inspecting any delivery device components. Always handle fiber-optic cables with extreme care. Do not coil the cable in a diameter less than 15 cm (6 in.).*

5.2 Inspecting and Cleaning the Air Filter

Check and clean at least every 3 months.

WARNING: *If the filters are heavily soiled increase the frequency of inspection and cleaning.*

1. Verify the system is turned off.
2. Remove the air filter tray.

Figure 4 Air Filter Tray Removal

3. Remove the air filter.

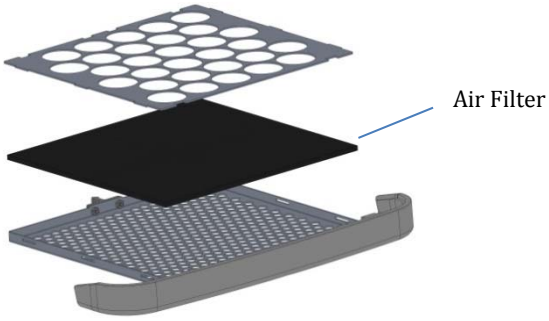


Figure 5 Air Filter Removal

4. Rinse thoroughly in warm water to remove all debris.
5. Allow the air filter element to dry completely.
6. Reinsert air filter into the air filter tray.
7. Reinsert the air filter tray into the system.

5.3 Inspecting and Cleaning the Footswitch

TO DECONTAMINATE AND DISINFECT THE FOOTSWITCH:
1. Verify the system is turned off.
2. Disconnect the footswitch from the laser.
3. Using water, isopropyl alcohol, remove all traces of blood and other body fluids from all exposed surfaces of the footswitch assembly, including the cable (if applicable).
4. Stand the footswitch on end to drain all fluids.
5. Allow the footswitch to air-dry completely before reusing.
6. Reconnect the footswitch to the laser.

NOTE: *The connector is not sealed and should not be immersed into any cleansing agent.*

5.4 Technical Specifications

Table 2 - Technical Specifications

System	
Input Power	100 -240VAC; 50 or 60hz
Weight	25lbs / 11.3Kg
2-Pedal Footswitch	>IPX6
AC Power Cord	2.5 m +/- 0.5 m
Treatment Laser	
Wavelength	2.0um +/- 0.1µm, Infrared
Treatment Modes	
-Cut	Up to 5 watts
-Coagulate	Up to 5 watts
Beam Divergence	4° half angel
Maximum Output	5 watts
Aiming Beam	
Wavelength	532nm (green) / 640nm (red) +/-20nm
Power	< 5mW, class IV (per IEC 60825-1)
Treatment Fiber	
Length	3 m +/- 0.5 m
Sterilized	Ethylene Oxide
Usage	Single Use Device
Environmental Conditions	
Operating Temperature	60°-80°F / 15.5°-26.7°C
Storage Temperature	40°-104°F / 4.4°-40°C
Humidity	15% - 85%

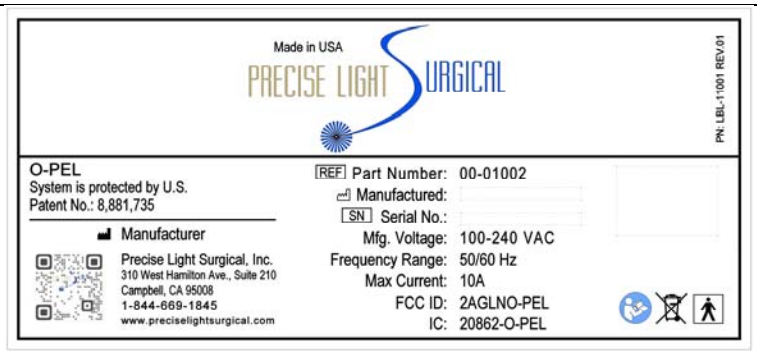
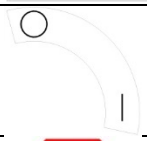
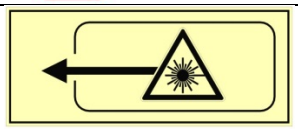
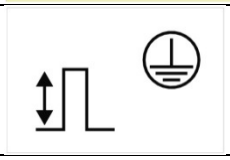
6.0 Safety and Compliance

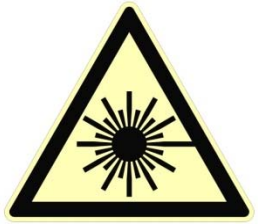
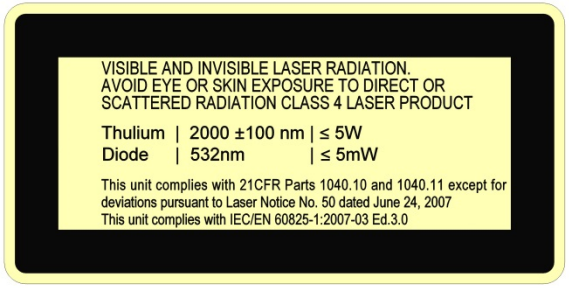
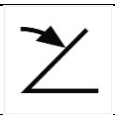
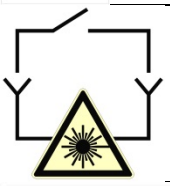
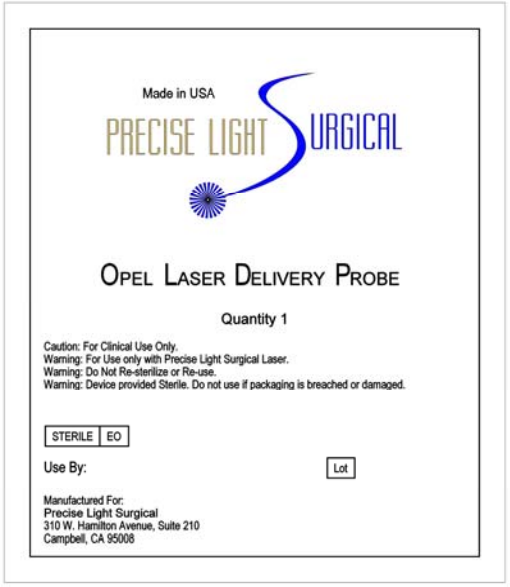
6.1 Protection for All Treatment Room Personnel

The Laser Safety Officer should determine the need for safety eyewear based on the Maximum Permissible Exposure (MPE), Nominal Ocular Hazard Area (NOHA), and Nominal Ocular Hazard Distance (NOHD) for each of the delivery devices used with the laser system, as well as the configuration of the treatment room. For additional information, refer to European Standard IEC 60825-1.

6.2 Labels

Table 3 - Labels

LBL-11001 O-pel A Unique Device Identifier (UDI) Note: Representative sample shown.	
LBL-11002 Key Switch Label, O-pel A	
LBL-11003 Emergency Stop Label	
LBL-11004 Laser Aperture Label	
LBL-11005 AC Power and Earth Ground Label	

LBL-11006 Visible and Invisible Laser Label	
LBL-11007 Hazard Symbol Label	
LBL-11008 Yellow Laser Radiation Label	
LBL-11009 Footswitch Label	
LBL-11010 Interlock Label	
LBL-11012 Opel Laser Delivery Probe Label	

6.3 Symbols (As Applicable)

 Manufacturer

 Manufactured

 Disposal Info.

Serial No.

Part No.

 Read Manual

 Type BF Equipment

 Laser Warning

 Earth Ground

 Power

Emergency Stop

 Remote Interlock

 Footswitch

 Non Ionizing Radiation

Use by:

Lot No.

7 EMC Requirements

7.1 EMC Requirements for Console and Accessories

The O-pel System needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.

Portable and mobile RF communications equipment can affect the O-pel System.

The use of accessories, transducers and cables other than those specified by the Precise Light Surgical, Inc., may result in increased EMISSIONS or decreased IMMUNITY of the O-pel System.

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

This device complies with part 15 of the FCC Rules and Industry Canada's license-exempt RSSs. 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.

This device was verified for RF exposure and found to comply with FCC OET-65 RF Exposure and RSS-102 requirements. This Product meets the SAR exemption based on its output power.
Ce produit a été vérifiée pour l'exposition de puissance radio et jugé conforme aux norms FCC OET-65 et RSS-102 exigences. Sur la base de la puissance de sortie de la radio, ce produit répond aux taux d'absorption spécifique exemption.

The radio transmitter has been approved by Industry Canada to operate only with the antenna supplied. Use of any other antenna is strictly prohibited for use with this product.
L'émetteur radio a été approuvé par Industrie Canada pour fonctionner uniquement avec l'antenne fournie. L'utilisation de toute autre antenne est strictement interdit d'utiliser ce produit.

Changes or modifications to the radio transmitter not expressly approved by
Precise Light Surgical, Inc could void the user's authority to operate the equipment.

Table 4 - Guidance and Manufacturer's Declaration – Electromagnetic Emissions

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The O-pel System is intended for use in the electromagnetic environment specified below. The customer or the user of the O-pel System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment – Guidance**
RF emissions CISPR 11	Group 1	The O-pel System 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 A	The O-pel System 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/ Flicker emissions IEC 61000-3-3	Complies	

Table 5 - Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The O-pel System is intended for use in the electromagnetic environment specified below. The customer or the user of the O-pel System 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 ±1 kV for input/output lines	Mains power quality should be that of a typical domestic, 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 domestic, commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<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 sec	<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 sec	Mains power quality should be that of a typical domestic, commercial or hospital environment. If the user of the O-pel System requires continued operation during power mains interruptions, it is recommended that the O-pel System 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 domestic, commercial or hospital environment.
NOTE *U*T is the a.c. mains voltage prior to application of the test level.			

Table 6 - Guidance and Manufacturer's Declaration – Electromagnetic Immunity

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The O-pel System is intended for use in the electromagnetic environment specified below. The customer or the user of the O-pel System should assure that it is used in such an environment.			
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 O-pel System, 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	3 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz 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). 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] Interference may occur in the vicinity of equipment marked with the following symbol: 
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.			
[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 O-pel System 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 re-orienting or relocating the O-pel System. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Table 7 - Distances Between Portable- Mobile RF Equipment-The O-pel System

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and The O-pel System			
The O-pel System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the O-pel System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the O-pel System 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 = 1.2√P**	**80 MHz to 800 MHz** **d = 1.2√P**	**800 MHz to 2.5 GHz** **d = 2.3√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 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.			