

OL1000 & OL1000 SC

Bone Growth Stimulators



Please read before using device

Caution: Federal law (U.S.A. and Canada) restricts this device to sale, distribution or use by or on the order of a physician.

REF 01-203-0001

01-211-0002

01-211-0003

01-211-0004

Device Name

Device Trade Name:

OL1000 BONE GROWTH STIMULATOR

OL1000 SC BONE GROWTH STIMULATOR

Common or Generic Device Name:

Noninvasive bone growth stimulator

Indication for Use

The OL1000 and OL1000 SC BONE GROWTH STIMULATORS are indicated for the noninvasive treatment of an established nonunion acquired secondary to trauma, excluding vertebrae and all flat bones. A nonunion is considered to be established when the fracture site shows no visibly progressive signs of healing.

User Profile

Patients, a patient's caretaker, or a family member providing assistance can use this device. The user should be able to:

- Read and understand the directions, warnings and cautions.
- Place the device on the patient.
- Be able to see or hear device signals.
- Understand the treatment schedule as prescribed.

Technical Description of the OL1000 and OL1000 SC Bone Growth Stimulator

The OL1000 and OL1000 SC (Figure 1) are portable, battery powered, microprocessor-controlled, noninvasive bone growth stimulators. The device is worn by a patient for 30 minutes a day and provides local electromagnetic field treatment for a non-healing fracture. The device produces very low energy combined static and dynamic electromagnetic fields on the order of the earth's magnetic field. The device has a push button that starts the treatment and an audible tone to notify the patient that a treatment has started or has ended. A liquid crystal display (LCD) is utilized to display the status of the device, e.g., treatment record, daily treatment time countdown.

Figure 1. OL1000 & OL1000 SC Bone Growth Stimulators



OL1000



Figure 2. OL1000

The OL1000 device is open at the top to allow the limb to be treated to be placed inside the device. There are four major components to the device:

- an electronic control module (ECM)
- treatment transducers
- a patient interface
- a rigid plastic housing

The ECM includes a signal generator that produces an electrical signal that is transmitted to the treatment transducers. The transducers are an identical pair of rectangular copper wire coils that convert the electrical signal into an electromagnetic field. The coils face each other and are arranged so that a uniform electromagnetic field is produced between them. The ECM also contains a microprocessor and memory that controls the level of the electromagnetic field, as well as monitors and records the patient use.

An LCD is utilized to display the status of the device. An electromagnetic field sensor located between the coils monitors the static electromag-

netic field and the ECM maintains it at 20 microT. The dynamic field is a sine wave, having a frequency of 76.6 Hz and an amplitude of 40 microT peak to peak which is superimposed in parallel with the static field.

A treatment is started after the microcontroller performs a self-test and verifies that no treatment has been administered that day, that an object is within the treatment space between the coils as monitored by an infrared (IR) light beam and detector, and that the system battery has enough power to administer a treatment. The treatment, when completed, is recorded in the microcontroller nonvolatile memory and the device turns itself off. The OL1000 runs on two standard 9-volt battery. When necessary, a “replace battery” icon is shown on the LCD and the patient is able to replace the batteries easily. The device is lined with a foam patient interface. All components are housed within a rigid plastic housing.

OL1000 SC



Figure 3. OL1000 SC Size 2

There are two major components to the OL1000 SC device:

- A remote electronic control module (ECM)
- A foam coated treatment transducer

The RECM includes a signal generator that produces an electrical signal that is transmitted to the treatment transducer. The transducer is a curved copper wire coil that converts the electrical signal into an electromagnetic field. The coil is arranged so that a uniform electromagnetic field is produced inside the coil. The RECM also contains a microprocessor and memory that controls the level of the electromagnetic field, as well as monitors and records the patient use. An LCD is utilized to display the status of the device. An electromagnetic field sensor located near the coil monitors the static electromagnetic field and the RECM maintains it at 20 microT. The dynamic field is a sine wave, having a frequency of 76.6 Hz and amplitude of 40 microT peak to peak which is superimposed in parallel with the static field.

A treatment is started after the microcontroller performs a self-test and verifies that no treatment has been administered that day, and that the system battery has enough power to administer a treatment. When completed, the treatment is recorded in the microcontroller nonvolatile memory and the device turns itself off. The OL1000 SC is powered by one standard 9-volt battery. A sufficient quantity of batteries is supplied with the device to last for the duration of treatment.

Device Design Rationale

The OL1000 and OL1000 SC provide noninvasive electro-magnetic field treatment of nonunion. The static and dynamic electromagnetic fields generated are distributed uniformly throughout the treatment volume irrespective of the tissue properties or tissue characteristics. This provides latitude in the placement of the treatment system and eliminates the need for patient-specific calibration. Utilization of this device allows full weightbearing on the extremity unless extreme motion (e.g., greater than 5 degrees in any plane) is present at the nonunion site.

In such cases, weightbearing is not advised and should not be permitted because this may compromise the effectiveness of the treatment. The devices can also be used with any external or internal immobilization, provided their construction is of non-magnetic materials.

Contraindications

The use of this device is contraindicated in individuals having synovial pseudarthrosis.

Demand-type pacemaker or implantable cardioverter defibrillator (ICD) operation may be adversely affected by exposure to magnetic fields. Physicians should not prescribe the OL1000 or OL1000 SC for applications which may place the treatment transducers in close proximity to the pacemaker or ICD. This would include fractures of the upper extremities (hand, wrist, arm). Further screening by the attending cardiologist is recommended (such as with an electrocardiogram).

The OL1000 and OL1000 SC should not be used in the presence of internal fixation devices (rods, plates, screws, wire) that are constructed from magnetic materials. However, almost all fracture fixation devices used today are made of non-magnetic materials.

Warnings

The safety and effectiveness of the use of this device on individuals lacking skeletal maturity has not been established.

Teratological studies have not been performed with this device. The safety of the use of this device during pregnancy or nursing in humans has not been established.

- **WARNING!** This device is intended only for single patient use. Secondary use can cause serious injury, including infection.
- Care must be taken when operating this device adjacent to other equipment. Potential electromagnetic or other interference could occur with this or other equipment. Try to minimize this interference by increasing the separation between this device and nearby equipment, and by not using other equipment (i.e. cell phones, MRI, electrosurgery, defibrillation, etc.) when you are using this device.
- The equipment should not be used adjacent to or stacked with other equipment and, if adjacent or stacked use is necessary, the equipment should be observed to verify normal operation in the configuration in which it will be used.
- Device is designed to comply with electromagnetic safety standards. However, there is no guarantee that interference will not occur in a particular installation. Harmful interference to other devices can be determined by turning this equipment on and off. Try to correct the interference using one or more of the following:
 - Reorient or relocate the receiving device.
 - Increase the separation between the equipment.
 - Contact DJO Customer Care.
- Some people, with very sensitive skin, may experience redness. Generally, this redness is totally harmless and usually disappears after 10 to 20 minutes. However, never start another treatment on the same area if the redness is still visible.

- If the performance of the device varies in any way from the described operation, call Customer Care at 800.263.6004.
- The use of other cables and accessories may affect Electronic Control Module (ECM) performance.
- This device and its accessories must be kept out of the reach of children, pets, and pests.
- Do not use device in contact with open wounds.
- Contamination by patient could be sweat, expired gases, and saliva on the stimulator. Clean the applied part of the coil once a week using antibacterial soap and a damp cloth. Do not submerge the device in any liquid.
- Do not use device while in bath or shower.
- Battery operated device (9V alkaline battery). Do not to use lithium batteries.

Cautions

- Weightbearing is not advised in the presence of extreme motion at the nonunion site.
- In the presence of a malaligned nonunion, careful consideration of the use of this device must be undertaken on an individual basis, as treatment with this device is not intended to alter or affect the degree of malalignment.
- The safety and effectiveness of the use of this device on individuals with nonunion secondary to, or in conjunction with, a pathological condition has not been established.
- This device should not be used if there are mental or physical conditions which preclude patient compliance with the physician and device instructions.
- Compliance with the treatment schedule, timely battery change, and proper care of the device are essential. The device will not perform properly and treatment may be unnecessarily prolonged if the patient fails to adhere to the care routine.
- When conditions of atrophy are present or when fractures have remained unhealed for long periods of time, there may be less successful results.
- It is not recommended that the device be used while smoking or near excessive heat or an open flame.
- Components in this system are to be used only with DJO's parts. No attempt should be made to modify or repair this device by the physician or patient.
- DO NOT operate this unit in an environment where other devices are being used that intentionally radiate electromagnetic energy in an unshielded manner. Portable and mobile RF communications equipment can affect Medical Electrical Equipment.
- No User Serviceable parts inside. Do not attempt to modify or repair this product. Please contact the Manufacturer for assistance in setting up, using, or maintaining this product. Contact manufacturer for assistance to report unexpected operation or events.

Directions for Use

The OL1000 and OL1000 SC have been designed to provide an optimum therapeutic electromagnetic field at the treatment site. The OL1000 is available in one size (dual coil). The OL1000 SC is available in three sizes (2, 3, and 4). The size of the device used depends upon the specific anatomical site being treated.

For the OL1000 Dual Coil, the device should be selected to allow for the treatment site to fit between the transducer coils. The treatment site should be placed at the center of the device between the coils. Most sites can be best treated with an anterior-posterior orientation of the transducer. Treatment of the distal tibia, ankle, foot or hand may require an oblique placement.

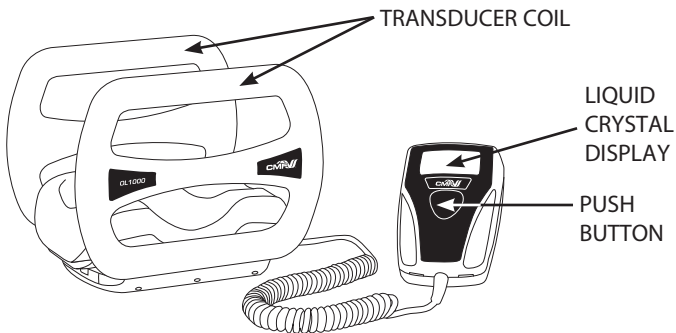


Figure 4.

For the OL1000 SC sizes 2, 3, and 4, the device size should be chosen so that the treatment site fits comfortably inside the device coil. The treatment site should be placed near the center of the device coil, and the device secured in place.

See Table 1 for recommended sizing.

The OL1000 and OL1000 SC may be applied over any type of cast (plaster or plastic) or over any cast-brace system fabricated from non-magnetic materials. Mark the patient's cast, brace, or skin with an indelible marker so that he or she will be able to position the OL1000 or OL1000 SC consistently each day.

The OL1000 and OL1000 SC are shipped with batteries already in place and spare batteries. They are ready for use immediately upon removal from the shipping and storage container. If an audible tone sounds, and the LCD screen indicates a problem, **DO NOT ATTEMPT TO REPAIR IT YOURSELF**. Refer to the Troubleshooting Information section on page 18 or contact Customer Care. When the device is in place, the patient should be able to move around as necessary during his or her daily treatment.

However, because of the short 30-minute per day treatment time, the patient should be encouraged to sit or rest comfortably during treatment. The device must remain properly positioned for the treatment to be most effective.

Table 1: Recommended OL1000 SC and OL1000 Dual Coil Sizes for Treatment Sites

Fracture Site		OL1000 Dual Coil	OL1000 SC		
			Size 2	Size 3	Size 4
Clavicle	Proximal		X	X	
	Mid		X	X	
	Distal		X	X	
Humerus	Proximal		X		
	Mid	X			
	Distal	X			
Radius & Ulna	Proximal	X	X		
	Mid	X	X		
	Distal	X			
Hand & Wrist	Hand	X			
	Wrist	X			
Femur	Proximal			X	X
	Mid			X	X
	Distal	X	X	X	
Tibia & Fibula	Proximal	X	X	X	
	Mid	X	X		
	Distal	X	X		
Foot & Ankle	Foot	X	X		
	Ankle	X	X		

Operation

This device should be operated in a temperature range of 41°F to 104°F (5°C to 40°C) and should be within this range for one hour prior to initiating treatment. The patient should be shown how to properly place the device around the treatment site. Once the device is secured around the treatment site, the patient can follow these simple steps to conduct his or her daily treatment.

1. To start a treatment, press the “push button” next to the LCD screen (see Figure 4 for the OL1000 and see Figure 5 for the OL1000 SC), hold it down until it beeps, and then let go.

- a. The treatment record will be displayed until it beeps.



- b. The 30-minute treatment countdown will begin.



- c. After 30 minutes, the “treatment complete” icon will appear on the LCD screen, the device will beep twice and it will automatically shut off.



2. Remove the device and store it until the next day.

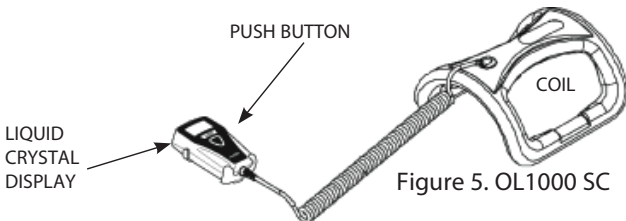


Figure 5. OL1000 SC

Display Screen

When using the device, the LCD screen will show the time remaining for the patient’s daily treatment. The screen may look like this:



In this example, there are 29 minutes and 37 seconds remaining in the 30-minute treatment.

Checking the Treatment Record

You or the patient may check the treatment record at any time, except during the daily 30-minute treatment. To view the treatment record, press the “push button” and then let go before it beeps. The LCD screen will look like this:

OL1000SC

NUMBER OF DAYS
SUCCESSFULLY
TREATED

124/204

NUMBER OF DAYS
SINCE TREATMENT
BEGAN



OL1000

NUMBER OF DAYS
SUCCESSFULLY
TREATED

12

Rx [|||||]

40%

PERCENTAGE OF
SUCCESSFUL
TREATMENTS
COMPLETED

30

[|||||]

NUMBER OF DAYS
SINCE TREATMENT
BEGAN

The number in the upper left-hand corner of the OL1000 treatment record is the number of days you have successfully treated. The number in the lower left-hand corner is the number of days since you first used the device. The number in the upper right-hand corner is the percentage of successful treatments completed. In this example, it has been 30 days since the device was first used, and 12 treatments have been successfully completed. This means you have successfully completed 40% of all possible treatments.

If the daily treatment has already been completed for that day, and the “push button” is pressed, the treatment record will be shown followed by the “treatment complete” icon. This is a reminder that your daily treatment has already been completed for that day.

You should have the patient bring the OL1000 or OL1000 SC to each follow-up visit. You can use the push button to obtain the treatment history and record it in the patient’s chart. Frequent patient review will also allow early assessment of patient care and handling of the device.

Note: Any audible tone given before the 30-minute treatment is completed may indicate that the device needs attention. If, during a treatment, the patient hears any tones, he or she should look at the LCD screen for a picture that describes the problem. See Table on page 19 for troubleshooting information.

Follow Up

Patients should be seen at least once each month during the first few months of treatment in order to assess their compliance. Have the patients bring the device with them to the follow-up visits.

The treatment period with this device should be a minimum of three months. Treatment should not be suspended until the nonunion is healed or until such time as you determine that no progression to healing is occurring. In the clinical investigation of this device the earliest healed case occurred at three months post treatment initiation, and the average time to heal was six months. The device is programmed to deliver only 270 consecutive days of treatment. The maximum recommended treatment period is nine months.

Patients who are clinically and roentgenographically diagnosed as healing (versus healed) during treatment may continue to progress to become healed. It is advised that the nonunion continue to be adequately immobilized and regularly assessed.

Patients must be thoroughly advised that their participation in the appropriate care and handling of the device and any immobilization used, particularly if it is a cast or brace, is critical to assure proper treatment.

Battery Replacement

The OL1000 is powered by a standard 9-volt battery. The OL1000 SC is powered by one 9-volt battery. The LCD screen will show the following picture when it is time to replace the battery. This picture will be shown at the start of the treatment or during the treatment if there is not enough battery power to complete another treatment.



THE BATTERIES SHOULD NOT BE REMOVED ANY TIME THE UNIT IS STILL RUNNING A TREATMENT. WAIT UNTIL THE DEVICE STOPS OPERATING.

After the display turns off, the battery may then be replaced.

See Figure 6 for correct replacement of OL1000 SC batteries. It is recommended that only the DJO supplied batteries be used for replacement.

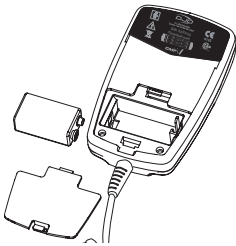


Figure 6. OL1000 SC
Battery Replacement

Battery Safety & Handling

The battery compartments have been designed to prevent the incorrect installation of batteries. The battery compartments have also been labeled with the correct polarity configuration. Always install batteries properly.

Patients should not misuse the batteries. This could cause a fire, personal injury, leakage, or explosion. Patients should not do any of the following:

- Never heat or dispose of batteries in a fire.
- Never charge batteries.
- Never let the battery ends contact each other, or let a piece of metal touch both ends of a battery at the same time.
- Never damage or use damaged batteries.
- Never mix old and new batteries together or use batteries other than in their correct position.
- Patients should always keep batteries at room temperature, approximately 70°F (20°C) in less than 80% relative humidity and out of direct sunlight.
- Patients should use only batteries supplied by DJO.

Note: Be sure to remove plastic from batteries before replacing them.

Replacing the Batteries

- **WARNING:** Battery operated device (9V alkaline battery), not to use lithium batteries.
- Remove primary batteries when equipment is not likely to be used for some time to avoid battery leakage.

Note: Be sure to remove plastic from batteries before replacing them.

Device Care and Storage

- The patient should store the device in its carrying case in a cool, dry place between the temperatures of 41°F (5°C) and 104°F (40°C).
- The patient should use only antibacterial soap and a damp cloth to clean the device. Do not submerge the device in any liquid.
- The patient should never store the device or any of its parts in an automobile in cold or hot weather.
- The patient should not incinerate the device, the batteries, or any other components of this device.
- The patient should not administer a treatment while bathing, showering, or swimming when these activities are allowed by the physician.
- To avoid the risk of choking or strangulation, the patient should store the device in its carrying case out of reach of children.

Customer Care

For service or additional information concerning the use of the OL1000 or OL1000 SC, please contact your sales representative or Customer Care. When patient has completed treatment, the device should be taken to a local recycle center where the unit can be taken in as an electronic recycle, like a television or computer. The patient may also contact Customer Care for assistance with device disposal. The OL1000 and OL1000 SC are not reusable. These devices are for single patient use only. They cannot be re-sold or used on multiple patients.

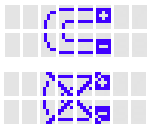



Customer Care Telephone Numbers

United States	800.263.6004
Canada	800.263.6004
Europe	+44.1483.459.659

Troubleshooting Information

Any audible tone given before the 30-minute treatment is completed may indicate that the device needs attention. If, during a treatment, the patient hears any tones, he or she should look at the LCD screen for a picture that describes the problem. See the table below for more details.





Table 1. Display Message

Display Picture	Action to be Taken
	<p>Magnetic Interference – announced by three beeps. The “X” will flash.</p> <ol style="list-style-type: none"> 1. If the device looks damaged, call Customer Care. 2. If not, try moving to another location in your house. Make sure you are not near metal objects. 3. If the picture is still displayed, replace the batteries with new ones. 4. If the device still shows the picture, call Customer Care.
	<p>Replace Battery – announced by three beeps. Replace the batteries with new ones.</p>
	<p>Infrared Beam – announced by three beeps.</p> <ol style="list-style-type: none"> 1. For the OL1000, make sure that your broken bone is in the device. If your limb is small, wrap a towel around the limb you are treating. Try treating again. 2. If the device still will not turn on, call Customer Care.
	<p>Phone For Help – announced by three beeps. Call Customer Care.</p>

Troubleshooting Information, continued







Problem	Action to be Taken
The device will not turn on, but there is no error message. You may still hear a beep.	<ol style="list-style-type: none"> 1. Try replacing the batteries with new ones. 2. Wait until tomorrow and try treating again. 3. If the device still will not turn on, call Customer Care.
There are lines or bars on the display or the display is too dark to read.	Call Customer Care.
You do not hear any beeps.	<ol style="list-style-type: none"> 1. The beeper may not work if you live where it is very humid. The device will still work. 2. If you do not live where it is humid, listen again tomorrow for beeps. Have somebody else listen too. 3. If the device still does not beep, call Customer Care.
The device appears damaged.	Call Customer Care.
Your broken bone hurts more than it used to.	<ol style="list-style-type: none"> 1. Make sure that you are treating in a comfortable, relaxed position. 2. If you still have more pain than you used to, call your doctor.
You run out of batteries.	Call Customer Care.









A summary is shown below of other pictures that may appear on the LCD screen.

Display Picture	Definition
	Treatment record.
	Time remaining in 30-minute daily treatment.
	Daily treatment successfully completed – announced by two beeps.
	Please wait.

Symbols

The markings on the SpinalLogic Bone Growth Stimulator are your assurance of its conformity to the highest applicable standards of medical equipment safety and electromagnetic compatibility. One or more of the following markings may appear on the device and/or packaging:

	Equipment Safety Electric Shock Classification Type BF Applied Part
	Warning or Caution
	Refer to Instruction Manual/ Booklet
	Manufacturer
	Temperature Range
	Waste of electrical and electronic equipment must not be disposed as unsorted municipal waste and must be collected separately. Contact an authorized representative of the manufacturer for information concerning the decommissioning of your equipment.
IP22	Protected against solid foreign objects of 12.5mm dia and greater. Protected against vertically falling water drops when enclosure tilted up to 15°.

	Keep Dry
	Authorized Representative in the European Community
	CE Mark of Conformity
	Conforms to ANSI/AAMI Std. ES60601-1 Certified to CAN/CSA Std. C22.2 No. 60601-1
	Catalogue Number
	Serial Number
	Atmospheric Pressure Range
	Humidity Range

Compliance Statements

Electromagnetic Compatibility (EMC)

The Bone Growth Stimulator has been tested and found to comply with the electromagnetic compatibility (EMC) limits for medical devices to IEC 60601-1-2. These limits are designed to provide reasonable protection against harmful interference in a typical medical installation.

Caution: Medical electrical equipment requires special precautions regarding EMC and must be installed and operated according to these instructions. It is possible that high levels of radiated or conducted radio-frequency electromagnetic interference (EMI) from portable and mobile RF communications equipment or other strong or nearby radio-frequency sources, could result in performance disruption of the system. Evidence of disruption may include image degradation or distortion, erratic readings, equipment ceasing to operate, or other incorrect functioning. If this occurs, survey the site of disruption, and take the following actions to eliminate the source(s).

- Turn equipment in the vicinity off and on to isolate disruptive equipment.
- Relocate or reorient interfering equipment.
- Increase distance between interfering equipment and your system.
- Manage use of frequencies close to the system frequencies.
- Remove devices that are highly susceptible to EMI.
- Lower power from internal sources within the facility control (such as paging systems).
- Label devices susceptible to EMI.
- Educate clinical staff to recognize potential EMI-related problems.
- Eliminate or reduce EMI with technical solutions (such as shielding).
- Restrict use of personal communicators (cell phones, computers) in areas with devices susceptible to EMI.
- Share relevant EMI information with others, particularly when evaluating new equipment purchases which may generate EMI.
- Purchase medical devices that comply with IEC 60601-1-2 EMC Standards (3V/meter EMI immunity, limit interference level to 0.0014 V/meter).

Declarations EMC Tables

ELECTROMAGNETIC COMPATIBILITY (EMC) TABLES for RF Emissions Class B

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
<p>The Bone Growth Stimulator is intended for use in the electromagnetic environment specified below. The customer or the user of the Bone Growth Stimulator should assure that it is used in such an environment.</p>		
Emissions Tests	Compliance	Electromagnetic Environment Guidance
RF Emissions CISPR 11	Group 1	The Bone Growth Stimulator 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	The Bone Growth Stimulator 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	N/A	N/A
Voltage Fluctuations IEC 61000-3-3	N/A	N/A
N/A	N/A	The Bone Growth Stimulator emits a sinusoidal magnetic field with a peak to peak amplitude of 400mG and a 200mG D.C. offset at a frequency of 76.6 Hz. Magnetic energy is considered to be non-ionizing radiation.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity


The Bone Growth Stimulator is intended for use in the electromagnetic environment specified below. The customer or the user of the Bone Growth Stimulator 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	±2kV, ±4kV, ±6kV contact ±2kV, ±4kV, ±8kV air	±2kV, ±4kV, ±6kV contact ±2kV, ±4kV, ±8kV 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	N/A	N/A	N/A
Surge IEC 61000-4-5	N/A	N/A	N/A
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	N/A	N/A	N/A
Power Frequency (50/60Hz) Magnetic Fields 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: U_T is the a.c mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The Bone Growth Stimulator is intended for use in the electromagnetic environment specified below. The customer or the user of the Bone Growth Stimulator 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	3 Vrms 150 kHz to 80 MHz	3V	Portable and mobile RF communications equipment should be used no closer to any part of the Bone Growth Stimulator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: $d = [3.5/V1]\sqrt{P}$ 150 KHz to 80 MHz $d = [3.5/E1]\sqrt{P}$ 80 MHz to 800 MHz $d = [7/E1]\sqrt{P}$ 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: 
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2.5 GHz	3 V/m	

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 Bone Growth Stimulator is used exceeds the applicable RF compliance level above, the Bone Growth Stimulator should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Bone Growth Stimulator.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [V1] V/m.

Recommended separation distances between portable and mobile RF communications equipment and the Bone Growth Stimulator

The Bone Growth Stimulator is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Bone Growth Stimulator can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Bone Growth Stimulator 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	0.38	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.

Warranty

It is DJO, LLC policy that all complaints about our devices be communicated to Customer Care at 800- 263-6004. The Customer Service Representative will provide technical assistance to determine the extent of the problem or educate the patient on the use of the device. If the device cannot be made to function properly, a replacement device is sent to the patient free of charge and the malfunctioning device is brought back for testing and evaluation. This procedure can be done at any time, and as many times as necessary, during the course of treatment. The course of treatment is defined as the nine (9) month period between the time the device is initiated and the Two Hundredth and Seventieth (270th) treatment.

Product Specifications

Manufacturer	DJO, LLC • 1430 Decision Street Vista, CA 92081-8553 U.S.A.
Model Type	OL1000 SC1
Operating Conditions	<p><u>Temperatures:</u> +41°F (5°C) to +104°F (40°C) <u>Relative Humidity:</u> 15% to 93% non-condensing <u>Atmospheric Pressure:</u> 700hPa to 1060 hPa <u>Altitude:</u> Maximum of 3000m NOTE: CMF Bone Growth Stimulators must remain at Operating Temperature one hour prior to use</p>
Transport and Storage Conditions	<p><u>Temperatures:</u> -13°F (-25°C) without relative humidity control, up to 158°F (70°C) <u>Relative Humidity:</u> 15% - 93% non-condensing <u>Atmospheric Pressure:</u> 500 hPa to 1060 hPa</p>
Dimensions	11 in x 12 in x 1.5 in (28 cm x 31 cm x 4 cm)
Weight	2.0 lbs (0.9 kg)
Equipment not suitable for use in the presence of a flammable anaesthetic mixture with air or with oxygen or nitrous oxide.	
Degree of Protection Against Ingress of Liquids	IP22. Protected against solid foreign objects of 12.5mm dia and greater. Protected against vertically falling water drops when enclosure tilted up to 15°.
Degree of Protection Against Electric Shock	TYPE BF Applied Part
Power Supply	Battery operated, replaceable, 9 volts direct current. Battery operated device (9V standard battery), not to use lithium batteries.
Mode of Operation	Short time continuous operation, 30 minutes per day.
Electromagnetic Compatibility (EMC) Electromagnetic Immunity (EMI)	This product is in conformity with Directive 89/336/EEC.
No effect from lint, dust, light.	
This device is not intended for use in an Oxygen Rich Environment.	
Degree of Protection against Electric Shock: internally powered ME equipment.	
Expected Service Life is 270 days from initial use.	
Expected shelf life is 2.5 years.	
No Sterilization is required.	

Suggested Reference

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