

# **SPINALOGIC<sup>®</sup>**

## Bone Growth Stimulator



**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.

## Indication for Use

SpinaLogic® is a portable, battery powered, microcontrolled, non-invasive bone growth stimulator indicated as an adjunct electrical treatment to primary lumbar spinal fusion surgery for one or two levels.

The SPINALOGIC BONE GROWTH STIMULATOR (Figure 1, below) is a portable, battery powered, microprocessor-controlled, noninvasive bone growth stimulator. The device produces very low energy combined static and dynamic magnetic fields on the order of the earth's magnetic field. The device has a push-button that starts the treatment and audible tones to notify the patient that a treatment has started or has ended. A Liquid Crystal Display (LCD) is used to display the device status, e.g., treatment record, daily treatment time countdown.

## 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.

## Device Description

There are three major components to the device: (A) An electronic control module (ECM), (B) a transducer coil. The ECM includes a signal generator that produces an electrical signal which is transmitted to the treatment transducer. The transducer coil converts the electrical signal into a magnetic field. The coil is placed facing the spine so that the magnetic field is directed at the fusion site. The waist belt is designed to secure this coil relative to the patient's fusion site during treatment.

The ECM also contains a microprocessor and memory that controls the level of the magnetic field as well as monitors and records the patient use. An LCD is used to display the status of the device. A magnetic field sensor located in the middle of the coil monitors the static magnetic field. Using the sensor data, the ECM maintains the static magnetic field at 200 milligauss (mG). The dynamic field is a sine wave, having a frequency of 76.6 Hz and an amplitude of 400 mG peak to peak, which is superimposed in parallel with the static field. See Table 1 on page 4 for detailed functional specifications of SpinaLogic.



Figure 1. SpinaLogic

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## Mode of Operation

SpinaLogic® Bone Growth Stimulator treatment is started after the push-button is activated and the microcontroller performs a self-test to verify that no treatment has been administered that day. When completed, the treatment is recorded in the microcontroller's nonvolatile memory and the device turns itself off. The device is powered by one 9-volt battery. The batteries and electronic components are housed within the rigid plastic housing of the control module.

SpinaLogic provides treatment by exposing the fusion site to a low-energy magnetic field, which is undetectable during treatment. The patient will typically have no sensation related to the treatment.

The push-button starts the treatment and an audible tone will notify the user that a treatment has started (one beep) or ended (two beeps). The device is designed to give a different tone when it is not providing sufficient magnetic field treatment. SpinaLogic has a Liquid Crystal Display (LCD) in addition to the audible tone to display a specific problem. The LCD counts down the time remaining for a treatment and monitors the number of days of proper treatment.

After reading the contraindications, warnings and precautions, please consult your local sales representative or Customer Care if you have any questions.

## Technical Specifications for SpinaLogic

**Table 1. Summary of Functional Specifications**

Function	Parameter and Tolerance
Treatment	400 mG peak to peak $\pm 80$ mG      Alternating magnetic field (AC) maximum 2% harmonic distortion      Alternating magnetic field (AC) 76.6 Hz $\pm 1.0$ Hz      Alternating magnetic field (AC) $\pm 200$ mG $\pm 20$ mG      Static magnetic field (DC)
Ambient Magnetic Field Operating Range	$\pm 600$ mG
Treatment Frequency	Once a treatment has been dispensed, the patient will not be allowed another treatment until the device's 24-hour clock passes midnight
Request Treatment	A push button activates the device
Power Source	One, user-replaceable 9-volt battery
Period of Operation	270 days maximum
Operating Conditions	Temperatures: $+41^{\circ}\text{F}$ ( $5^{\circ}\text{C}$ ) to $+10^{\circ}\text{F}$ ( $40^{\circ}\text{C}$ ) Relative Humidity: 15% to 93% non-condensing Atmospheric Pressure: 700hPa to 1060 hPa Altitude: Maximum of 3000m

## Contraindications

- Demand-type pacemaker and implantable cardioverter defibrillator (ICD) operation may be adversely affected by exposure to combined static and dynamic magnetic fields. Physicians should not prescribe SpinaLogic® for patients with such devices.
- The safety and effectiveness of SpinaLogic in pregnant women have not been studied, and the effects of the device on the mother or the developing fetus are unknown, thus, this device should not be used in pregnant women. If a woman becomes pregnant during treatment with SpinaLogic, treatment should be discontinued immediately.

## Warnings

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

Animal studies conducted to date do not suggest any long-term significant adverse effects from use of this device. However, long-term effects in humans are unknown.

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 at 800.263.6004.

- 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.
- 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 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.



## **Adverse Effects**

No known significant adverse effects have resulted from the use of this device. Clinical studies, animal studies, and tissue culture experiments conducted with the SpinaLogic Bone Growth Stimulator magnetic fields have not indicated any evidence of significant adverse effects.

## **Summary of Non-Clinical Studies**

The SpinaLogic Bone Growth Stimulator incorporates the same technological features of the OL1000 Bone Growth Stimulator, and the treatment signal for SpinaLogic is identical to that of the OL1000. A series of laboratory studies were previously conducted in support of the safety and effectiveness of the OL1000. Toxicological studies on isolated cells, as well as animals, were performed to evaluate the safety of combined static and dynamic magnetic fields. Further, in vitro and in vivo studies were conducted to determine whether the application of these magnetic fields in animal models would stimulate bone healing and other related biological responses. Many of these previous laboratory experiments included whole body exposure to the test animals (and thus included vertebrae and nerve tissue). Additional details of the pre-clinical studies gathered using the OL1000 can be found in the Summary of Safety and Effectiveness for the OL1000 Bone Growth Stimulator (P910066).

## **Summary of Clinical Investigation**

### **Clinical Protocol Design**

The clinical study conducted was a prospective, randomized, double-blind, placebo-controlled trial. The purpose of this clinical study was to investigate the safety and effectiveness of SpinaLogic as an adjunct to spinal fusion.

The endpoint for the determination of effectiveness was the status of the fusion after nine months of treatment as judged by a panel of evaluators. The panel was comprised of the investigator (treating orthopedic surgeon) and two masked reviewers: a musculoskeletal radiologist and an orthopedic surgeon.

The patients were seen at enrollment, three, six and nine months post-surgery for imaging of the fusion site and clinical assessment. Additionally, a three-month post-treatment follow-up visit was conducted to confirm the findings of the nine-month post-surgery follow-up. Imaging techniques included plain radiographs (anteroposterior (AP), lateral and obliques) and CT scans. Lateral flexion-extension radiographs were also taken when clinically indicated.

## **Patient Inclusion Criteria**

Patients meeting the following inclusion criteria and not specifically excluded (see Exclusion Criteria below) were enrolled in this study:

- Over 18 years of age;
- Having undergone a primary intertransverse fusion without internal fixation of one or two vertebral levels between the third lumbar vertebra (L3) and the sacrum (S1) within the last 30 days;
- Grafted with autograft alone or in combination with allograft.

## **Exclusion Criteria**

Patients who met any of the following exclusion criteria were not eligible for participation in this study:

- Pregnant women did not participate in this study, and if a patient became pregnant, she was immediately withdrawn from the study. Additionally, female subjects of childbearing potential should have used an acceptable form of birth control, i.e., birth control pills, diaphragm with spermicidal gel or condom;
- Diagnosed as having metastatic cancer, metabolic bone disease, spondylitis, Paget's disease, moderate to severe osteoporosis, renal dysfunction and uncontrolled diabetes mellitus or having an implanted cardiac pacemaker;
- Underwent a spinal fusion for vertebral trauma or scoliosis.

## **Enrollment, Treatment and Follow-Up Visits**

For purposes of the clinical study, the device was dispensed within 30 days following fusion surgery. The patient used SpinaLogic® for 30 minutes per day according to the instructions in the patient manual. The device was used for nine months following enrollment. (SpinaLogic is programmed to cease operation at the end of 270 days.)

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## Radiographic Assessment

The status of the fusion was graded into one of four categories, from no fusion (0) to solid fusion (3). When two levels were involved, the lowest grade at either level was utilized for the fusion assessment. For purposes of outcome and as defined in the protocol, the grades of “0” and “1” were combined into a single category, “No Fusion.”

Grades “2” and “3” were combined into another category, “Fusion”. The outcome was a combination of the rating assigned by the investigator (masked treating orthopedic surgeon) and two independent masked reviewers: a musculoskeletal radiologist and an orthopedic surgeon. When the radiologist and the investigator agreed, the fusion was assigned their agreed-upon status.

When the investigator and radiologist disagreed, the masked orthopedic surgeon’s rating was used as a tiebreaker. During the “Radiographic” assessment, the treating surgeon had access to all radiographic imaging, clinical, and surgical information. The radiologist utilized only the radiographic imaging information, as stated in the Radiographic investigational protocol, and the independent surgeon utilized only radiographic imaging information to make the fusion assessment.

During the “Radiographic and Clinical” assessment, the two independent panel members were provided all available radiographic information. Consistent with standard clinical practice and medical training, the independent orthopedic surgeon was also provided patient information including demographic, clinical and operative information (this did not include follow-up assessments of the fusion status by the treating surgeon). Consistent with clinical practice, the radiologist was provided the radiographic data alone.

In both assessments, a patient was considered fused when at least two of the three panel members agreed on the outcome. Effectiveness was defined by a statistically significant difference between fusion status outcomes in the active and placebo groups.

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## **Pooling Data Across Investigational Sites**

The issue of poolability was examined by comparing treatment differences among study sites. The treatment effect difference among sites was examined using all subjects in the following ways: for all sites, pooling the four smallest sites as one, and omitting the four smallest sites. In each case, the statistical test addresses the difference in success rates between active and placebo interventions. In each case, exact p-values were obtained using the “Exact Test for Homogeneity of Odds Ratios”, StatXact-3 for Windows software. The statistical findings indicate that the outcomes at the sites are not significantly different and in fact are poolable.

## **Patient Disposition**

Of the 243 patients, 201 patients were evaluable. All patients are accounted for in this study. Patient adherence with the three, six and nine month follow-up visit requirement was greater than 94%.

## Demographic, Medical, and Socioeconomic Characteristics

The statistical test results demonstrate that the randomized assignments of patients to the two treatment arms resulted in a very well-balanced distribution of patient characteristics between placebo and active devices. No statistically significant differences were found for the clinical variables cited.

## Treatment Compliance

For the majority of both active and placebo patients, treatment compliance was between 75% and 100% compliance for at least 85% of the placebo treated patients and 75% of the active treated patients.

## Study Endpoint (Nine-Month Findings)

Percent Fusion Success as Determined by the “Radiographic” Panel as proposed within the Investigational Protocol is as follows:

### Percent Fusion Success as Determined by the Radiographic Panel at Nine Months

	Placebo	Active	P-Value
All Patients	43 (44%)	54 (52%)	0.324
Males Only	22 (55%)	16 (39%)	0.184
Females Only	21 (37%)	38 (60%)	0.011

The data demonstrate a trend towards a positive effect as an adjunctive treatment in the total patient population and the female population, however, there is a trend towards a negative effect in the male population. Additionally, the data demonstrate that this treatment effect is only statistically significant in the female population.

In an effort to provide an analysis which allows the independent surgeon the opportunity to review a patient’s clinical background prior to making a determination of the patient’s fusion status, a “Radiographic and Clinical” panel analysis (described above) was performed. Provided below is a summary of Fusion Success as determined by the “Radiographic and Clinical” panel.

### **Percent Fusion Success as Determined by the Radiographic and Clinical Panel at Nine Months**

	<b>Placebo</b>	<b>Active</b>	<b>P-Value</b>
All Patients	42 (43%)	67 (64%)	0.003
Males Only	22 (55%)	67 (64%)	0.656
Females Only	20 (35%)	42 (67%)	0.001

In this instance, the data demonstrate a trend towards a positive effect as an adjunctive treatment in the overall, male and female populations. The data also demonstrate that this treatment effect is statistically significant in the overall population and in women (p-values < 0.05), while the treatment is not statistically significant in the male population.

Provided below is a gender breakdown, by active or placebo status, of those patients whose status changed during the “Radiographic and Clinical” panel evaluation.

## Comparison of Independent Surgeons' Findings - Male Patients

	Not Fused -> Fused	Fused -> Not Fused	No Change
Active	11	1	29
Placebo	6	4	30
Total	17	5	59

## Comparison of Independent Surgeons' Findings - Female Patients

	Not Fused -> Fused	Fused -> Not Fused	No Change
Active	10	6	47
Placebo	6	11	40
Total	16	17	87

Seventeen (17) men's status' changed from "Not Fused" to "Fused" while five (5) had a status change of "Fused" to "Not Fused." Sixteen (16) women's status' changed from "Not Fused" to "Fused" while an almost equal number (17) had a status change of "Fused" to "Not Fused."

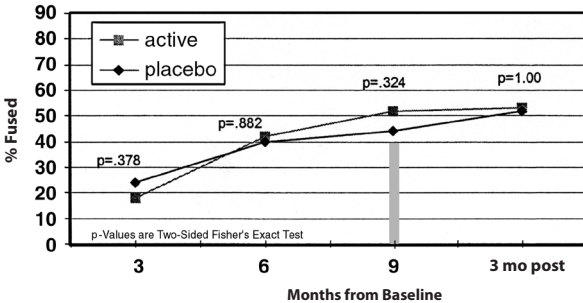


## Longitudinal Analysis

The following graphs present longitudinal data gathered from the Radiographic panel analysis and the Radiographic and Clinical panel analysis.

### Radiographic Panel Assessment

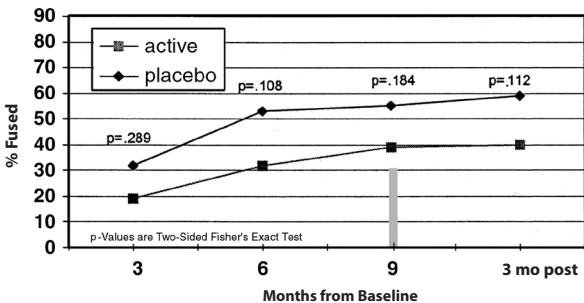
Fusion by Visit - All Patients



The "Radiographic" panel analysis shows that, for all patients and male

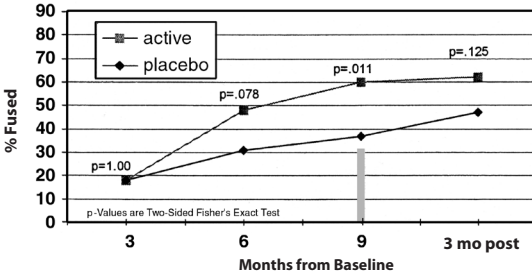
### Radiographic Panel Assessment

Fusion by Visit - Male Patients



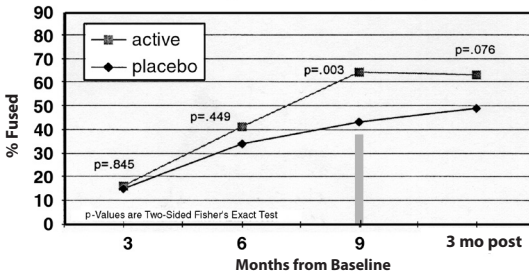
## Radiographic Panel Assessment

Fusion by Visit - Female Patients



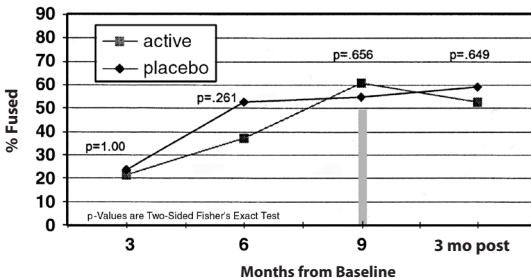
## Radiographic & Clinical Assessment

Fusion by Visit - All Patients



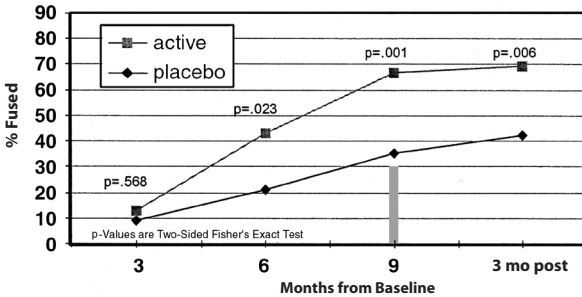
## Radiographic & Clinical Assessment

Fusion by Visit - Male Patients



## Radiographic & Clinical Assessment

### Fusion by Visit - Female Patients



patients, there is no statistically significant difference between the active and placebo groups at any timepoint. For the female patients, there is a statistical significance between the active and placebo groups only at the nine month (study endpoint) timepoint.

The "Radiographic and Clinical" panel analysis shows there is a statistically significant difference between the active and placebo groups at the nine month (study endpoint) timepoint for the overall patient population. For the male population, there is no statistically significant difference between the active and placebo groups at any timepoint. For the female population, there is a statistically significant difference between the active and placebo groups at the six-month, nine-month (study endpoint) and twelve-month (three-month post-treatment) timepoints.

## Logistic Regression

To further examine the effects assessed by the "Radiographic and Clinical" review panel, an analysis using logistic regression was performed.

The logistic regression findings demonstrate that, in distinct models, the only significant main effects are treatment, gender, and current

smoking. The only nearly significant interaction is gender by treatment. There are no significant interactions of treatment with current smoking, number of levels fused, or anatomical levels fused. This justifies dealing in a unified manner with the subsamples of patients with one and two levels fused, and also unifying the data for patients with varying anatomical levels.

## **Intent-To-Treat Analysis**

In order to examine the sensitivity of our findings to missing or excluded values, series of tabular analyses were run to examine nine-month outcomes. When outcomes were missing, in separate analyses, fusion status was imputed as fused, not fused, or assigned its most recent known value (which was seen at later of three or six months post-entry). Additionally, patients who had been excluded in previous analyses because their nine-month visit was outside the 28-day compliance window were now included and assigned their observed outcome at the visit recorded on the nine-month visit form. Using each of the three imputation schemes, tabulations were done separately for all subjects, males and females.

Using the data from the “Radiographic and Clinical” analysis, there was a statistically significant treatment effect in favor of the active device for all patients: p-values were 0.006, 0.015, and 0.007 for imputation as fused, not fused, and “LVCF”. For males, there was no statistically significant treatment effect: p-values were 0.521, 0.684, and 0.838 for imputation as fused, not fused, and “LVCF”. For females, there was a statistically significant treatment effect in favor of the active device: p-values were 0.004, 0.0005, and 0.0003 for imputation as fused, not fused, and “LVCF”.

In conclusion, the effectiveness findings cited above for SpinaLogic<sup>®</sup>, are unaffected by several reasonable imputations of missing data in an intent-to-treat analysis.

## Directions for Use

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.

1. Open the waist belt and align the center of the coil with the center of the fusion site and secure the waist belt. NOTE: The waist belt should fit comfortably around the waist and securely hold the transducer coil in place.

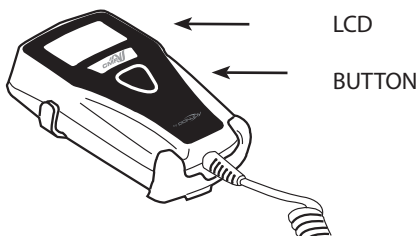


Figure 2. Control Box

2. To start a treatment, press the “push button” next to the liquid crystal display (LCD) screen (Figure 2, above), 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.



3. Remove the device and store it until the next day. Please see the Device Care and Storage section on page 22 for instructions on the proper storage of the device.

## Display Screen

When using the device, the LCD screen will show the time remaining for your 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 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:



The number in the upper left-hand corner is the number of days the patient has successfully treated. The number in the upper right-hand corner is the number of days since the patient first used the device. In this example, 204 days have elapsed since the device was first used, and 124 treatments have been successfully completed.

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 the daily treatment has already been completed for that day.

## Battery Replacement

SpinaLogic® 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 treatment or during the treatment if there is not enough battery power to complete another treatment.



Never change the batteries when the device is running. Wait until the device stops operating to change the battery.

Note: Remove plastic from battery before replacing it.

The picture in Figure 3, below, shows the correct way to replace the battery. When replacing the batteries, you will see the correct way to put them in on the inside of the battery compartment. Use **ONLY** the batteries supplied with SpinaLogic. They are located in the carrying case.

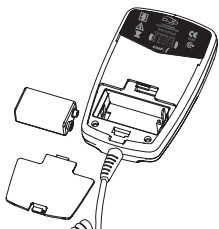


Figure 3. Battery Compartment

Remove primary batteries when equipment is not likely to be used for some time to avoid battery leakage.

## Replacing the Battery

**WARNING:** Battery operated device (9V alkaline battery), not to use lithium batteries.

The battery compartment has been designed to prevent the incorrect installation of batteries. The battery compartment has 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.

## Device Care and Storage

- The patient should store the device in its carrying case in a cool, dry place. Never keep it where the temperature is less than 41°F (5°C) or greater than 104°F (40°C). Temperatures below or above could damage the device.
- The patient should use only 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.

## **User Assistance Information**

For service or additional information concerning the use of SpinaLogic<sup>®</sup>, please contact your sales representative or Customer Care.

When patients 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. SpinaLogic is not reusable. The device is for single patient use only. It cannot be re-sold or used on multiple patients.

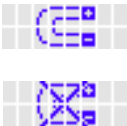


## **Customer Care Telephone Numbers**

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 Messages**

Display Picture	Definition
	<p>Magnetic Interference – announced by three beeps. The “X” will flash.</p> <ol style="list-style-type: none"> <li>1. If the device looks damaged, call Customer Care.</li> <li>2. If not, try moving to another location in your house. Make sure you are not near metal objects.</li> <li>3. If the picture is still displayed, replace the battery with a new one.</li> <li>4. If the device still shows the picture, call Customer Care.</li> </ol>
	<p>Replace Battery – announced by three beeps. Replace the battery with a new one.</p>
	<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"> <li>1. Try replacing the batteries with new ones.</li> <li>2. Wait until tomorrow and try treating again.</li> <li>3. If the device still will not turn on, call Customer Care.</li> </ol>
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"> <li>1. The beeper may not work if you live where it is very humid. The device will still work.</li> <li>2. If you do not live where it is humid, listen again tomorrow for beeps. Have somebody else listen too.</li> <li>3. If the device still does not beep, call Customer Care.</li> </ol>
The device appears damaged.	Call Customer Care.
Your broken bone hurts more than it used to.	<ol style="list-style-type: none"> <li>1. Make sure that you are treating in a comfortable, relaxed position.</li> <li>2. If you still have more pain than you used to, call your doctor.</li> </ol>
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.
<b>IP22</b>	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

<b>Guidance and Manufacturer's Declaration – Electromagnetic Emissions</b>		
<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>		
<b>Emissions Tests</b>	<b>Compliance</b>	<b>Electromagnetic Environment Guidance</b>
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

### 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.  <b>Recommended separation distance:</b> $d = [3.5/V1]\sqrt{P}$ 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, <sup>a</sup> should be less than the compliance level in each frequency range. <sup>b</sup>  Interference may occur in the vicinity of equipment marked with the following symbol:  <div style="text-align: center;">  </div>
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

<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 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.

<sup>b</sup> 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.

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## 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	<u>Temperatures:</u> +41°F (5°C) to +10°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 <b>NOTE:</b> CMF Bone Growth Stimulators must remain at Operating Temperature one hour prior to use
Transport and Storage Conditions	<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
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.	

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## Suggested References

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