



PATIENT APPLICATION

CMF™ Spinalogic® Bone Growth Stimulator



USING YOUR CONTROL UNIT

This is your control unit—this control unit consists of an LCD display and a button. To begin your treatment, press the “push button” below the LCD screen, holding it down until it beeps. A record of your treatment will be displayed until it beeps.

The 30-minute treatment countdown will begin as shown here. When using the device, the LCD screen will continue to show the time remaining on your daily treatment. You should complete your entire 30-minute treatment in one session.



After 30 minutes, the “treatment complete” icon will appear as a smile face on the display—the device will beep twice and automatically shut off.

At any time, you may check your treatment record by pressing the push button once, quickly, before it beeps. The LCD screen will show you two numbers. The number in the upper left-hand corner is the number of days you have successfully treated. The number in the upper right-hand corner is the number of days since you first used the device.

If your daily treatment has already been completed for that day, the treatment record will be shown followed by the treatment complete smile face.



INSERTING/REPLACING YOUR BATTERIES

When it is time to replace your battery, the treatment screen on your control unit will show a picture of a low battery. Never change the batteries when the device is running. Your carrying case will contain additional 9V batteries for your use. Remove any plastic from the new battery before replacing. Remove the battery cover from the back side of the control unit. The battery compartment has been designed to prevent the incorrect installation of the batteries. It is labeled with the correct polarity configuration to ensure proper insertion. Install the battery as shown and replace the battery cover on the control unit. Your device is now ready for use.



You should only use batteries supplied by DJO®. Additional information about the proper handling of batteries can be found in your user manual provided by your representative or found in your device carrying case.

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

APPLYING YOUR DEVICE

Open your device carrying case and remove the coil along with its belt and attached control unit.

Open the waist belt and align the center of the coil with the center of the fusion site. If necessary, you may choose to apply the small black pillow to the center of the device to fit comfortably in the curve of your lumbar spine. Velcro can be found in your carrying case if needed.

Secure the waist belt comfortably. The device may be worn over clothing or bracing. Ensure the control unit clips comfortably to the waist belt. You are now ready to operate your device.

Additional information about the Spinalogic® can be found in your user manual provided by your representative or found in your device carrying case.





djoglobal.com/cmfi

INDICATION: CMF™ SpinaLogic® is a portable, battery powered, microcontrolled, noninvasive bone growth stimulator indicated as an adjunct electromagnetic treatment to primary lumbar spinal fusion surgery for one or two levels.

CONTRAINDICATIONS: Use of this device is contraindicated in individuals having a synovial pseudarthrosis. Demand-type pacemaker or implantable cardioverter defibrillator (ICD) operation may be adversely affected by exposure to magnetic fields. Physicians should not prescribe CMF™ SpinaLogic® for applications that may place the treatment transducers in close proximity to the pacemaker. Further screening by the attending cardiologist is recommended (such as with an electrocardiogram). CMF™ SpinaLogic® should not be used in the presence of external or internal fixation devices that are constructed from magnetic materials. (NOTE: Almost all fracture fixation devices implanted today are made from non-magnetic materials.)

WARNINGS: Do not use the CMF™ SpinaLogic® near products that may have strong magnetic fields, such as audio speakers. The device may not work properly around these products. **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, electro surgery, 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. Do not use the CMF™ SpinaLogic® while smoking or near heat, fire or flammable gases because the device may be damaged. Do not use the CMF™ SpinaLogic® if there are exposed wires or the device appears damaged. Do not modify or repair this device because you may damage it. Do not put the device or any of its parts in any liquid. Do not drop the device or bend the coils because this may damage it. 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. The use of other cables and accessories may affect EMC 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, saliva, on the CMF™ SpinaLogic®. Clean the applied part of the coil once a week using soap and a damp cloth. Do not use device while in bath or shower.

CAUTIONS: DO NOT operate this unit in an environment where other devices are being used that intentionally radiates electromagnetic energy in an unshielded manner. Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

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 CMF™ SpinaLogic®, which has the same treatment signal as the OL1000™ and OL1000™ SC, have not indicated any evidence of significant adverse effects.



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