OCS2 Ojemann Cortical Stimulator Operator's Manual

60901256 Rev. G (5/2012)

Caution:
U.S. Federal law restricts this device to sale by or on the order of a physician.

PRODUCT INFORMATION DISCLOSURE

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RETURN POLICY

- Authorization from customer service must be obtained prior to returning product.
- Sterile product must be returned in unopened, undamaged cartons, packed to prevent damage.
- Non-sterile product must be returned in unused saleable condition in original package.
- Custom or special orders products will not be accepted for credit.
- Credit will be issued for goods returned prior to ninety days from ship date with a restocking charge. This assumes that the product returned is not damaged and can be verified to have not been used or opened.

CE
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CUSTOMER SERVICE CONTACT INFORMATION

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EC REP **Authorized Representative in the European Community**

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Notice

Trademarks

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About the OCS2

Important
Please read this section before operating the Ojemann Cortical Stimulator (OCS2). This device should be operated by professional users only.

Device Classification

Classifications as per UL 60601-1 Ed. 1.0 (2003) describe the Ojemann Cortical Stimulator (OCS2) as:

Type of protection against electric shock:	Internally Powered
Degree of protection against electric shock:	Type BF
Degree of harmful ingress of liquids:	Ordinary
Mode of operation:	Continuous Use
Degree of safety in the presence of flammable anesthetic mixture with air, oxygen or nitrous oxide:	Not Suitable for Use

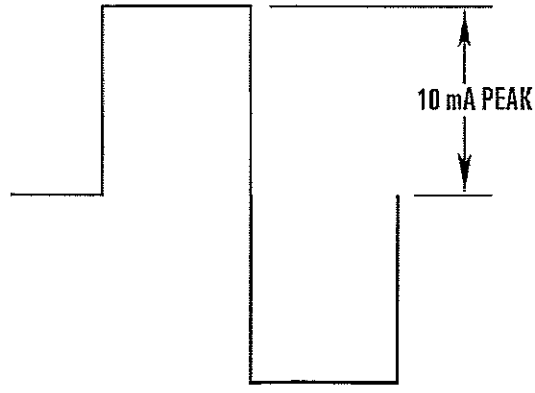
Electrical Safety and EMC

The Integra Ojemann Cortical Stimulator (OCS2) and Ojemann Cortical Stimulator Probe (OCS2PND) have been tested to and meet the requirements of the following:

EN 60601-1 Ed. 2.0 (1990)	Medical Electrical Equipment: General Requirements for Basic Safety + A1 (93) + A2 (95)
CAN/ CSA C22.2 No.601.1-M90 Ed. 2.0 (1990)	Medical Electric Equipment, Part 1: General Requirements for Safety
IEC 60601-1 Ed. 2.0 (1988)	Medical Electrical Equipment: General Requirements for Basic Safety + A1 (91) + A2 (95)
IEC 60601-1: 2005	Medical Electrical Equipment: General Requirements for Basic Safety and Essential Performance (EN 60601-1: 2006)
IEC 60601-1-2 Ed. 2.1 (2007)	Medical Electrical Equipment: General Requirements for Safety – Electromagnetic Compatibility
UL 60601-1 Ed. 1.0 (2003)	Medical Electrical Equipment: General Requirements for Safety

Precautions
This Operator's Manual is to be used in conjunction with the Ojemann Cortical Stimulator Probe (OCS2PND) Instructions for Use (IFU).

Warning
The displayed output of this device is measured in peak milliamperes. Since the output signal is biphasic, the actual peak to peak current is two times the displayed peak current. Therefore, this device is capable of a maximum output current of 20 mA peak to peak. Simultaneous connection of a patient to this device and High Frequency surgical equipment may result in burns at the side of the stimulator electrodes and possible damage to this device. Operation in close proximity to short wave or microwave therapy equipment may produce instability in the stimulator output.



Intended use
The Ojemann Cortical Stimulator (OCS2) is intended for intraoperative cortical stimulation mapping procedures to aid in the cortical resections in the vicinity of the essential cortex.

Description
The Ojemann Cortical Stimulator (OCS2) is a portable, battery-operated bipolar stimulator which occupies a space less than 12" high by 14" wide by 14" deep including all handle positions and weighs 5.0 lb. It supplies a constant current in two ranges: 0-1 milliamperes and 0-10 milliamperes, baseline to peak, into a 0 to 2 KΩ load. An LCD displays the delivered current baseline to peak. The Pulse Duration selections are 0.1, 0.2, 0.5, 1 and 2 milliseconds with Pulse Rate selections of 5, 10, 20, 50, 60, 75, and 100 Hertz.

The unit is also equipped with an output LED and a volume control for the output audio indicator. The LED will illuminate anytime power is supplied to the probes and the audio indictor will activate during active stimulation.

The Range switch allows immediate switching between Low and Full output current ranges (0-1.0 or 0-10 mA).

The Polarity switch allows leading edge waveform polarity switching.

The Output switch has three positions: Start, Stop, and Check Current positions.

With the Output switch in the Start position, the unit will produce stimuli at the Output receptacles. The Output switch in the Stop position disables the output from producing stimuli. In the Check Current position, the output receptacles are disabled and a 1000Ω resistor is placed internally across the output. The Check Current position is a momentary type toggle switch position (i.e., must be held down to be actuated).

The Output receptacles accept the Ojemann Cortical Stimulator Probe (OCS2PND).

The OCS2 device uses the OCS2PND Bipolar Probe (sold separately by Integra). The probe, used for stimulation, features a pliable shaft for precise localization and 2 mm diameter polished stainless steel balls at the tip.

Notice
Previous versions of the Ojemann Cortical Stimulator probe (OCSP) are **not** to be used with this model of the device (OCS2).

Accessories

Item	Ref #
Bipolar Probe	OCS2PND

Contraindications
This device is not intended for any use other than that indicated.

Complications, Adverse Events
Complications associated with cortical stimulators may occur during the use of this device. Complications include, but are not limited to: pain, infection, burns, neurological complications, mechanical or electrical failure and complications associated with anesthesia.

Testing
Integra recommends testing the unit prior to any surgical procedures. Rotate the handle by pressing the two buttons on the sides and set the device to a viewable angle. Toggle the Power switch to the ON position. All three green Battery Level LEDs should be illuminated. If all the LEDs do not illuminate, please consult the battery replacement instructions in this manual for battery substitution. Set the Range switch to the LOW position. Turn the LOW range mA PEAK knob to zero. Set the Volume control up to about half way. Press and hold the Output switch to the Check Current position. This places the internal load across the output, and displays the current output on the front panel LCD.

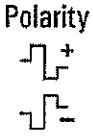
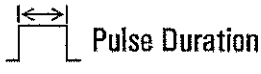
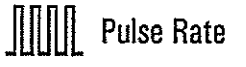
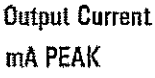
Notice
The stimulator does not regulate until the mA PEAK control is set above 0.2 mA.

Slowly rotate the LOW range mA PEAK knob clockwise. There should be no value displayed in the Output Current window or audible tone until 0.1mA PEAK is reached. At this point, the Output Current window will display the selected value and the audio tone shall activate. Repeat this procedure with the Range switch in the FULL position and the FULL range mA PEAK knob.

Notice
The stimulator does not regulate at output impedances above 2000Ω at max setting.

Operating the OCS2

Symbols

Symbols	Description
	Volume - Adjusts the output active tone intensity
	Volume Adjustment - Direction of rotation to amplify active tone
	Polarity - Allows switching of the leading edge waveform polarity
	Pulse Duration - Knob that determines the length of the pulse applied. Measured in milliseconds
	Pulse Rate - Knob that determines the pace at which the pulses are generated. Measured in Hertz
	mA PEAK - Milliamperes (measured from baseline to peak)
	Output - Output receptacles of the OCS2.
	Output Current mA PEAK - Display of the actual current being applied through the output. Milliamperes (measured from baseline to peak)
	Battery Level - Display of the battery charge for device functionality
	Battery Level Indicator - LEDs that convey the battery charge that remains to the user. All LEDs lit indicates a full charge. None of the LEDs lit indicates that battery replacement is necessary.

Symbols	Description
RANGE	RANGE - Switch that toggles the output being controlled between the LOW and FULL settings
LOW	LOW - Low output adjustment (0 - 1.0 mA Peak)
FULL	FULL - Full output adjustment (0 - 10.0 mA Peak)
 Start	Start - Begins stimulation through the output receptacles
 Stop	Stop - Ends stimulation / Standby
 Check Current	Check Current - Allows the user to check the current that will be applied to the patient with the current settings. Adds an internal 1000Ω resistor across the output to simulate stimulation and displays the current applied on the display.
Hz	Hz - Hertz
ms	ms - Milliseconds
 Audio Output	Audio Output - Output receptacle for a UL approved or passive device
0-50mV	Audio Output Signal Range
	Direction of rotation to access battery receptacles
	Operating Instructions - Consult operating instructions for use and maintenance of the OCS2

Symbols	Description
	Caution, consult accompanying documents.
	WEEE - Waste Electrical and Electronic Equipment Directive (WEEE) Accordance Marking.
	ETL Listed Marking
	Device is compliant with the European Communities Council Directive 93/42/EEC, Medical Device Directive.
	Type BF (Body Floating) Applied Part
	Manufacturer

To Prepare the OCS2 For Use

1. Sterilize the Ojemann Cortical Stimulator Probe (OCS2PND), product sold separately.
2. Insert the probe (OCS2PND) into the output receptacles ensuring jack is fully engaged into the Ojemann Cortical Stimulator (OCS2).

Current Setting

1. Select the desired range using the Range switch.
2. Select the desired pulse rate and pulse duration settings using the Associated Control knobs.
3. Turn the unit on by toggling the Power switch and ensure Battery Levels are acceptable (it is recommended to replace the batteries if only 1 of the LED's is illuminated).
4. Depress and hold the Output momentary switch in the Check Current position.
5. Adjust the selected current output knob (mA PEAK: LOW or FULL) for the desired current output.

Warning

When stimulating, keep the Ojemann Cortical Stimulator Probe (OCS2PND) in firm contact with the cortical tissue. Do not turn the output on until the probe is in firm contact with tissue. Avoid incidental contact of the OCS2PND with the cortical surface.

Begin stimulation with the lowest current level and increase in small increments until the desired physiological response is elicited. Stimulate at current levels that do not evoke after discharges.
Integra recommends that current levels of 5mA are not exceeded when using a pulse duration of 2 msec. Reduce the pulse duration at current levels above 5mA.

6. **Optional:** Insert a plug of a UL/IEC approved or passive device into the audio receptacle located in back of the unit. Final system configuration should comply with EN 60601-1-1.

7. After the desired current setting is determined, place the probe tips in position on the patient and set the Output switch to the Start position. The OCS2 is now delivering stimulation current to the patient.

Notice

Use the LCD readout for precise output current values. The markings on the ma Peak knobs are approximate (for reference only).

Cleaning and Maintenance

1. Sterilization and Cleaning

Ojemann Cortical Stimulator (OCS2)

Wipe the OCS2 clean with Clorox wipes or equivalent. Exercise care to avoid the ingress of liquids into the enclosure of the device.

Ojemann Cortical Stimulator Probe (OCS2PND)

The Ojemann Cortical Stimulator Probe (OCS2PND) is supplied non-sterile and must be cleaned and sterilized before use.

- **Initial Probe Sterilization:** Gently wipe the device with a lint free material impregnated with isopropyl alcohol. Wrap and sterilize the product in the following validated hospital sterilization cycle:
  - The OCS2PND can be steam sterilized by autoclave at 134°C (273°F) for 18 minutes.
  - The OCS2PND can also be sterilized at low temperature gas plasma. Sterilization was validated with Sterrad 100S Sterilization System (Advanced Sterilization Products). The validated cycle is: 10 min pre-exposure plasma phase followed by two identical exposure phases (6 min injection, 2 min diffusion and 2 min plasma).
- **Decontamination / Resterilization:** Thoroughly scrub the Ojemann Cortical Stimulator Probe with a non-aldehydic disinfectant. Decontaminate according to the following procedures: Soak product 20 minutes in a non-aldehydic alkaline detergent. Rinse with non-pyrogenic sterile water. Soak product one hour in Sodium Hydroxide 1N solution. Rinse with non-pyrogenic sterile water. Autoclave 18 minutes at 134°C (273°F).

Integra LifeSciences recommends that information on the original Lot Number be noted on a label affixed to the package of the hospital-resterilized product.

CAUTION: Do not flash autoclave the Ojemann Cortical Stimulator Probe (OCS2PND). To prevent deformation, the OCS2PND probe should be sterilized horizontally without constraint.

2. Maintenance

Ojemann Cortical Stimulator (OCS2)

The OCS2 contains no user serviceable parts. If maintenance is required, call Customer Service and they shall provide the instructions to ship the unit to Integra LifeSciences Corporation for repair.

Ojemann Cortical Stimulator Probe (OCS2PND)

The probe requires no maintenance as it is reusable up to a maximum of 5 uses and then must be discarded. Before each use, inspect the device for evidence of connector distortion or insulation deterioration such as cracks or fraying. The probe should not be used if such deterioration is discovered.

Battery Information

The OCS2 is supplied with and powered by four (4) 9 VDC transistor type alkaline, non-rechargeable batteries located behind the rear panel of the unit.

Battery Replacement

To replace the batteries, the rear panel of the OCS2 must be removed. To begin, loosen the two thumb screws on the rear panel by rotating them counter clockwise. Once unfastened, detach the rear plate from the unit by the thumb screws and place it momentarily off to the side. At this point, the batteries and their receptacles will be visible. Remove the four batteries by pulling them out from their holders (pull out at the base of the battery). Replace the batteries with new ones observing polarity during installation. To that end, push the battery leads into the correct polarity terminals and guide the body of the battery completely into the holder. Replace the rear plate on the unit and secure it with the thumb screws by aligning them to the body of the unit and rotating them clockwise until fastened.

Battery Life

The Battery Level indicator provides the user with the approximate battery life expectancy of the unit. Once all the LEDs are extinguished, the batteries should be replaced immediately before further operation.

Notice
A full set of replacement batteries should be kept with the unit for field replacement.

Notice
To conserve battery life, turn the OCS2 power switch OFF when not in use.

Notice
Dispose of the OCS2 and batteries in accordance with the local regulations.

Caution
Store the OCS2 in a cool, dry area. Remove the batteries from the unit if it is to be stored for a long period of time.

Calibration and Inspection

Ojemann Cortical Stimulator (OCS2)

Warning
No Modification of this equipment is allowed.

The OCS2 contains no user serviceable parts and requires no periodic calibrations. However, a functional diagnostic should be performed on the device to verify all stimulator parameters are within the manufacturer's specifications every six months or if the device has been physically stressed (i.e., banged or dropped).
Call Integra Customer Service if service is required.

Specifications

Electrical Supply

Power Supply	±18 VDC
Batteries	(4) 9 VDC transistor type alkaline non rechargeable batteries

Stimulator Output

Max Output Current	10 mA Peak (20 mA peak to peak)
Max Output Voltage	20 V (peak to peak)
Max Output Load	2 KΩ (output regulation at max setting)
Pulse Duration	0.1, 0.2, 0.5, 1.0, 2.0 msec ±10%
Pulse Rate	5, 10, 20, 50, 60, 75, 100 Hz ±10%
Output Current	Display Accuracy ±10%

Operating Environment

Temperature:	10 to 30°C
Humidity:	15 to 80% relative humidity - non condensing

Transport and Storage

Temperature:	-29 to 60°C
Humidity:	15 to 85% relative humidity - non condensing

Manufacturer's Declaration Tables

The information contained in this section (such as separation distances) is in general specifically written with regard to the Integra Ojemann Cortical Stimulator. The numbers provided will not guarantee faultless operation but should provide reasonable assurance of such. This information may not be applicable to other medical electrical equipment; older equipment may be particularly susceptible to interference.

General Notes

Medical electrical equipment requires special precautions regarding electromagnetic compatibility (EMC) and needs to be installed and put into service according to the EMC information provided in this document and the remainder of the instructions for use this device.

Portable and mobile RF communications equipment can affect medical electrical equipment.

Cables and accessories not specified within the instructions for use are not authorized. Using other cables and/or accessories may adversely impact safety, performance and electromagnetic compatibility (increased emission and decreased immunity).

Care should be taken if the equipment is used adjacent to or stacked with other equipment; if adjacent or stacked use is inevitable, the equipment should be observed to verify normal operation in the configuration in which it will be used.

<table>
<tr><th colspan="3">Guidance and manufacturer's declaration - electromagnetic emissions</th></tr>
<tr><td colspan="3">The OCS2 is intended for use in the electromagnetic environment specified below. The customer or the user of the OCS2 should assure that it is being used in such an environment.</td></tr>
<tr><th>Emissions Test</th><th>Compliance</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The OCS2 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.</td></tr>
<tr><td>RF emissions
CISPR 11</td><td>Class B</td><td rowspan="3">The OCS2 is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-3</td><td>NA</td></tr>
<tr><td>Voltage fluctuations/flicker emissions
IEC 610-3-3</td><td>NA</td></tr>
</table>

Guidance and manufacturer's declaration - electromagnetic immunity			
The OCS2 is intended for use in the electromagnetic environment specified below. The customer or the user of the OCS2 should assure that it is being 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%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and manufacturer's declaration – electromagnetic immunity			
The OCS2 is intended for use in the electromagnetic environment specified below. The customer or the user of the OCS2 should assure that it is being used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance**	**Electromagnetic environment - guidance**
Radiated IEC 61000-4-3	80 MHz - 2.5 GHz	3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the OCS2, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** d=1.2/ √P 80 MHz to 800 MHz d=2.3 √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 metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey[1], should be less than the compliance level in each frequency range[2]. Interference may occur in the vicinity of equipment marked with the following symbol: 

Recommended separation distances between portable and mobile RF communications equipment and the equipment.

[1] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz

[2] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the equipment is used exceeds the applicable RF compliance level above, the equipment should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the equipment

Rated Maximum Output Power of Transmitter W	Separation distance according to frequency of transmitters in meters		
	150 kHz - 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800MHz $d=1.2\sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.17	1.17	2.33
10	3.69	3.69	7.38
100	11.67	11.67	23.33

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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