PAJUNK®

MultiStim ECO

Nerve stimulation

Instructions for Use

Special notice

Please read the following information and operating instructions carefully.

Caution: Federal law restricts this device to sale by or on the order of a physician. The device may only be used by qualified medical staff in accordance with these user instructions.

PAJUNK® does not recommend any particular treatment method. Professional medical staff are responsible for the way in which the device is used and for patient selection.
In addition to these instruction for use, the relevant information also applies according to the corresponding specialist literature and current state of the art and knowledge.
Failure to comply with the user instructions invalidates the warranty and puts patient safety at risk.
If used in combination with other products, it is essential that the compatibility information and user instructions for these other products are taken into account. A decision regarding the combined use of devices from different manufacturers (where they do not constitute treatment units) is the responsibility of the user.

The device must not be used under any circumstances if there are good reasons to suspect incompleteness or damage.

Product specification / compatibility / accessories

The MultiStim ECO is intended to be used only with PAJUNK® GmbH Medizintechnologie devices (e.g. UniPlex or SonoPlex cannulas). Safe and successful functioning can only be guaranteed if these devices are used.

The MultiStim ECO is delivered with the following basic equipment:

- MultiStim ECO nerve stimulator
- 2 x 1.5V N batteries (LR1, LADY, N size)
- Instructions for use / technical description
- Case to store the MultiStim ECO

The MultiStim ECO can be connected to the cannula cable or a disposable extension cable (either as an extension or to use a stimulation catheter):

The PlugX accessory can also be connected to the MultiStim ECO. This allows using MultiStim ECO as a hand-held device. There are separate instructions for use for PlugX.

Designation	Art. no.
MultiStim ECO with case	1151-94-50
Disposable extension cable to connect stimulation cannulas or catheters; sterile	01151-861Q
PlugX hand-held adapter	1151-94-21
SonoPlex LUER cannulas/sets	001185-xx 001187-xx
SonoPlex Surety® cannulas/sets	001186-xx 001189-xx
All PAJUNK® GmbH Medizintechnologie cannulas/catheter sets used for peripheral regional anaesthesia/nerve blocks using nerve stimulation.	

Conformity with the following standards:

EN 60601-1; 14971:2000; EN 60601-2-10; EN 60601-1-2; UL 60601; Directive 93/42/EEC; EN 62366:2008; EN 60529:2014; ISO 15233-1:2012

Intended use

The MultiStim ECO is used to identify and locate peripheral nerves and nerve cords in local and regional anaesthesia, for example (diagnostic, intraoperative and therapeutic block).

Indications

Peripheral regional anaesthesia/nerve blocks

Contraindications

There are no device-specific contraindications.

Specific contraindications exist for certain block anaesthesia techniques. Users should consider them based on the state of the art and an individual risk-benefit analysis for every patient.

General contraindications for peripheral nerve blocks include:

- Infections at the puncture site
- Clinically manifest coagulation disorders
- Patient refusal
- Neurological deficits

Complication

Typical complications of peripheral nerve blocks include:

- Toxic reactions (to injection solution)
- Late neurological damage

Specific complications related to certain block anaesthesia techniques may also occur. Users should consider them based on the state of the art.

Warnings and safety instructions

Connect the connection socket of the stimulation cannula only to the mating connector of the nerve stimulator. If you use an extension cable, please make sure that it is correctly connected!

The snap on the back of the device may only be connected to the adhesive electrode. By no means may these plugs/connections get in contact with live parts (e.g. sockets) or metal objects.

Stimulation must not take place on the head, eyes, mouth or heart.

To avoid a gas explosion of anaesthetic gases or inflammation of flammable liquids, the MultiStim ECO must not be used in explosive atmospheres.

To avoid unintended injury to the patient, all connected equipment in the patient's environment must comply with the applicable regulations. All equipment and accessories must comply with requirements to EN 60601-1 and EN 60601-1-1 as well as the applicable sub-standards.

Please note that, in the worst case, all leakage currents and/or the patient's auxiliary currents might add up so that inadmissibly high values put the patient at risk, even if all requirements for the individual devices are met. Therefore, it must be checked in advance whether admissible limit values are exceeded when equipment is interconnected. Improper interconnection of devices and equipment (formation of systems) can cause life-threatening injuries to the patient.

The patient must not get in contact with metal objects which are earthed or have an electrically conductive connection with other devices or enable capacitive coupling. We therefore recommend using a sufficiently insulating, antistatic cover for the operating table.

⚠ *Under no circumstances may the MultiStim ECO be used with other instruments and accessories than those approved, supplied or recommended by the manufacturer. Only PAJUNK® accessories have been tested for EMC (electromagnetic compatibility). Third-party accessories may lead to serious impairment of the device and system features and cause permanent damage to patient, user or device.*

⚠ *Do not make any unauthorised changes to the technical equipment of the device. In case of manipulation, warranty and producer liability expire, and patient safety is put at risk.*

If HF surgical devices are used at the same time, there is an imminent risk of burns from the MultiStim ECO connections, the connecting cable, cannula tip and adhesive electrode. It is therefore necessary to disconnect all connections to the MultiStim ECO and to remove the stimulation cannula from the tissue before using HF surgical devices.

The MultiStim ECO must not be used for patients with implanted electrical devices (such as pacemakers) without prior medical advice from a specialist. Possible faults of the implanted devices due to stimulation current may constitute a risk for the patient.

Fastening electrodes near the thorax (chest, heart) may increase the risk of cardiac fibrillation.

Observe positions of metal implants in the tissue (e.g. plates or electrode cables). They might guide the stimulation signals to other areas and cause damage there.

To avoid that bad contact of the adhesive electrode leads to an incorrect positioning of the stimulation cannula, make sure that the adhesive electrode has a sufficiently stable contact with a low tissue impedance.

Use the MultiStim ECO only with the original (CE-certified) PAJUNK® accessories.

Dynamic electric and magnetic interference fields might cause device/system interactions. They can affect the measurement of the actual stimulation current and, in the worst case, lead to a faulty display and a switch-off of the stimulation for safety reasons (see section "Electromagnetic compatibility").

Check the MultiStim ECO regularly based on the guidelines in these instructions for use. To avoid malfunction of the MultiStim ECO, check all functions before use and make sure that the accessories are suitable for the application. The accessories used must comply with safety class BF.

Before and during use, keep the device, the connecting cables and the plugs completely clean and dry. Humidity and dirt impair the function of the nerve stimulator and the stimulation result.

Advance the cannula slowly and in a controlled way. Proceed with the greatest care and caution when you try to overcome any tissue resistances.

You can interrupt active stimulation any time by pressing the ON/Off button of the device or by manually separating the cannula from the stimulator.

The MultiStim ECO and its listed accessories must be disposed of in compliance with national provisions. Return the old device to the corresponding registered EAR (German register for waste electric equipment) collection container or return it to the manufacturer.

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Technical description

The MultiStim ECO generates reproducible rectangular pulses with a frequency of 1 Hz and incrementally adjustable stimulation current. The setting range for the pulse current is 0.2 to 2.0 mA for stimulation cannulas and catheters.

If a current pulse is delivered and the patient circuit closed, the green LED next to the stimulation button blinks for visual control; for acoustic control, a short signal tone synchronous to the stimulation rhythm can be heard, i.e. stimulation current flows through the patient.

If the green LED next to the stimulation button is on, either the patient circuit is not closed or there is a resistance > 12 kΩ; in these cases, there is no acoustic signal, i.e. no stimulation current or a stimulation current lower than selected one flows through the patient. This is additionally indicated by the yellow LED next to the unequal sign (≠).

Technical data

Type	**MultiStim ECO**
Degree of protection against electric shock EN 60601-1	BF
Protection class IEC 60529	IP54
Battery	2 x 1.5V LR1 (N size, LADY battery)
Stimulation current	Max. 2 mA
Resistance range:	0 Ω - 12 kΩ
Stimulation voltage	Max. 24 V
Stimulation frequency	1 Hz
Stimulation pulse width	0.1 ms
Operating conditions	Temperature: 10 °C to 30 °C Humidity: 20 % – 65 % Pressure range: 700 hPa to 1060 hPa
Transport and storage conditions	Temperature: 10 °C to 30 °C Humidity: 20 % – 65 % Pressure range: 700 hPa to 1060 hPa

Service life	2 years

User interface

The current setting is indicated by LEDs.

When the MultiStim ECO is switched on, factory settings are always activated; these are as follows:

Stimulation current intensity: 0.5 mA (green LED below 0.5 mA is on)

Volume: medium (central green LED above the loudspeaker symbol is on)

Stimulation: OFF (LED next to stimulation button is off)

Function keys

Button	Function
	ON / OFF
	Volume selection (medium · high · low · medium · high · low · etc.)
	Selection of the simulation current intensity (0.2 mA · 0.5 mA · 0.7 mA · 1.0 mA · 1.5 mA · 2.0 mA)
	Stimulation ON / OFF (Pause)

Function symbols

Symbol	Meaning
	Battery status indicator Green LED is on: battery okay. Batteries are working, the required power is available. Red LED blinks: battery capacity is very low; replace the batteries as soon as possible. Red LED is on: batteries are discharged, the stimulator can no longer be used. Replace the batteries immediately to be able to use the stimulator again.
	Yellow LED off: electric circuit closed, selected current = output current Yellow LED is on: electric circuit not closed (e.g. cannula not yet inserted, adhesive electrode is not correctly positioned, cable is not correctly connected, too high resistance in the system, etc.)
	Warning symbol! LED off: there is no active warning, you can use the stimulator. Red LED is on: there is an internal or external fault. You may not or cannot use the device under any circumstances. Send the Multi-Stim back to the manufacturer.

Operation

Check and start-up

⚠ *Please note: Devices showing other reactions must not be put into operation. Please contact the customer service in such cases. Electromedical devices may only be opened and/or repaired by the manufacturer or by a body expressly authorised by the manufacturer.*

Please check the following points before each start-up of the device:

1. Press the ON button to switch the device on. The device is switched on and switches to PAUSE mode. The factory settings are displayed (medium volume, current intensity: 0.5 mA, stimulation: OFF). If the red LED of the battery status indicator blinks after switching on, you should replace the batteries. If the red LED of the battery status indicator is permanently lit, you have to replace the batteries immediately (see section "Batteries"). If the stimulator detects a malfunction, the red warning LED is on. The device is no longer ready for use and must be returned to the manufacturer.

2. Connect the adhesive electrode to the snap at the rear of the MultiStim ECO. Remove the protective film of the adhesive electrode and attach it together with the stimulator to a suitable location on the patient's body. For optimum handling of the stimulator, a position near the puncture site is recommended.
3. If you prefer to use a disposable extension cable, plug the yellow connector of the extension cable in the contact jack on the bottom of the stimulator. Connect the white connector of the extension cable to the cannula cable or the clamping adapter of the catheter (only for stimulable catheters). If you do not use an extension cable, plug the connector of the cannula cable directly in the opening provided for it at the bottom of the stimulator.
4. After connecting all components and activating the stimulation when the cannula has not yet been inserted, only green LEDs and the yellow LED next to the ≠ symbol should be on (open circuit). If this is the case, you can start using it.
5. As soon as you touch the skin surface with the cannula and/or puncture, the MultiStim ECO starts delivering current pulses. You can perceive this visually, by the rhythmic blinking of the stimulation LED, as well as acoustically.

Operating the nerve stimulator

	**Switching on/off** To switch the MultiStim ECO on, press the ON/OFF button briefly. To switch the MultiStim ECO off, keep this button pressed for napprox. 2 seconds. If you do not switch off the stimulator and do not press any button for 30 minutes, the MultiStim ECO switches off automatically to save battery power.
	**Selecting the stimulation current intensity** A stimulation current intensity of 0.5 mA is preset as the start value. If you want to increase the stimulation current intensity, press the right selection button (+); to decrease, press the one on the left (-). The highest (2.0 mA) and lowest (0.2 mA) stimulation current intensities are limit values; it is not possible to continuously decrease and/or increase the current intensity. For safety reasons, it is not possible to go from 0.2 mA directly to 2.0 mA when pressing the left selection button (-), for example.

	**Starting simulation / PAUSE function** After switching on, the MultiStim ECO is always in PAUSE mode. You can recognize this by the fact that the LED next to the stimulation button is off, and you do not hear any acoustic signal. Press the stimulation button to start stimulation. Press it again to switch the MultiStim ECO back to PAUSE mode. Important: In PAUSE mode, you can change the stimulation current intensity without giving stimulation pulses to the patient. If the patient circuit is already closed after starting stimulation, the green stimulation LED blinks in accordance with the frequency in a 1-Hz rhythm; at the same time, you can hear an acoustic signal in the same rhythm. If the patient circuit is still open after starting stimulation, the green stimulation LED is lit, but there is no acoustic signal, and the yellow LED next to the unequal sign (≠) is also on. As soon as the circuit is closed and pulses are delivered to the patient, the yellow ≠ goes out. At the same time, the green stimulation LED starts blinking and the acoustic signal can be heard.
	**Setting the volume** When the MultiStim ECO is switched on, a medium volume is set for the acoustic signal. You can adjust the volume by pressing the volume button (medium · high · low · medium · high · low · , etc.). The adjusted volume is indicated by the three green LEDs above. The left LED means low, the right means high. The LED of the selected volume is lit in green.

If the yellow LED of the ≠ symbol is lit during operation and the acoustic signal can no longer be heard, the set amperage is no longer reached. This might be due to the following causes:

- No stimulation cable is connected or it is defective
- The electrodes are not or not correctly connected.
- The electrical resistance of the patient's tissue is too high.

The active stimulation can also be ended by pressing the ON/OFF button (keep the button pressed for at least 2 seconds).

Batteries

Please check regularly that the batteries are properly charged. The battery status indicator helps you with this. If it is green, the battery status is okay. As soon as it starts blinking red, you should replace the batteries as soon as possible to further guarantee reliable stimulation. If the battery status indicator is lit in red, no more stimulation is possible. You can only continue to use the MultiStim ECO if you replace the batteries immediately.

If you do not use the MultiStim ECO for a longer period, remove the batteries from the device to avoid leakage.

Replacing the batteries

The battery compartment is located at the rear of the MultiStim ECO. Open the compartment by unscrewing the screw of the compartment using a suitable tool. Replace the batteries.

⚠ *Always replace both batteries and only use new batteries.*

⚠ *When putting in new batteries, make sure they are positioned correctly.*

⚠ *Only use alkaline manganese batteries (e.g. Varta LR1 / 4001 / LADY / N; Duracell LR1 / LADY / N; Energizer LR1 / LADY / N).*

⚠ *Each time after replacing the batteries, check the MultiStim ECO before start-up to make sure that it is still working correctly.*

⚠ *Attention: If the battery is leaking, the MultiStim ECO should no longer be operated for safety reasons.*

Cleaning and disinfecting

Only use soft, humid cloths for cleaning and disinfecting the device. Water, soapy water and methylated spirit are particularly suitable. Make sure that no humidity enters the device. Use alcohol or commercially available alcohol-based disinfectants for disinfection.

⚠ *Attention: The following products must not be used for cleaning: trichlorethylene, acetone, butanone, methanol, nitro dilutions.*

Maintenance and safety inspections

Check the device for proper function before every use. A defective device must not be operated. Electromedical devices may only be repaired by the manufacturer or by a body expressly authorised by the manufacturer. Add a detailed error description to your repair order.

Safety inspections

Safety inspections are not required.

Signal path and pulse pattern

Stimulation is performed by means of monophasic, negative rectangular pulses in all waveforms. Electrical energy is released only for the duration of the stimulation pulse.

Stimulation pulse form: rectangular
Stimulation frequency: 1 Hz
Pulse width: 0.1 ms

Electromagnetic compatibility (EMC)

The MultiStim ECO complies with EN 60601-1-2:2007, the standard for electromagnetic compatibility (EMC).

Tests for electromagnetic compatibility were carried out by:

LCIE (Laboratoire Central des Industries Electroniques), Aire de la Thur, F-68840 Pulversheim

Guidelines and manufacturer's declaration – electromagnetic interference (acc. to EN 60601-1-2:2007; 5.2.2.1 table 1)		
The MultiStim ECO is intended for use in electromagnetic environment as specified below. Customers or users of the MultiStim ECO must ensure that it is operated in such an environment.		
Interference measurement	**Compliance**	**Electromagnetic environment – guideline**
HF emissions according to CISPR 11	Group 1	The MultiStim ECO uses HF energy only for its internal function. Therefore, its HF emission is very low, and it is improbable that interferences with adjacent electronic devices are generated.

HF emissions according to CISPR 11	Class B	The MultiStim ECO is suitable for use in facilities other than residential areas and those directly connected to the public supply network, which also supplies buildings used for residential purposes.
Harmonic current emissions acc. to IEC 61000-3-2	Not applicable	
Emission of voltage fluctuations and flicker acc. to IEC 61000-3-3	Not applicable	

Guidelines and manufacturer's declaration – electromagnetic immunity (acc. to EN 60601-1-2:2007; 5.2.2.1 table 2)

The MultiStim ECO is intended for use in electromagnetic environment as specified below. Customers or users of the MultiStim ECO must ensure that it is operated in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidelines**
Electrostatic discharge (ESD) acc. to IEC 61000-4-2	± 6 kV contact discharge ± 8 kV air discharge	± 6 kV contact discharge ± 8 kV air discharge	Floors should be made of wood or concrete or have ceramic tiles. If the floors consist of synthetic material, relative humidity must be at least 30 %.
Electrical fast transient/burst according to IEC 61000-4-4	± 2 kV for power cables ± 1 kV for input and output cables	Not applicable	Not applicable

Voltages/surges according to IEC 61000-4-5	± 1 kV external conductor - external conductor voltage ± 2 kV external conductor - earth voltage	Not applicable	Not applicable

Voltage dips, short interruptions and variations of supply voltage according to IEC 61000-4-11	< 5 % U_r (>95 % dip of U_r) for ½ period 40 % U_r (60 % dip of U_r) for 5 periods 70 % U_r (30 % dip of U_r) for 25 periods < 5 % U_r (>95 % dip of U_r) for 5 s	Not applicable	Not applicable
Magnetic fields at supply frequency (50/60 Hz) acc. to IEC 61000-4-8	3 A/m	Not applicable	Not applicable
U_r is the AC mains voltage before applying the test levels			

Guidelines and manufacturer's declaration – electromagnetic immunity (acc. to EN 60601-1-2:2007; 5.2.2.1 table 4)

The MultiStim ECO is intended for use in electromagnetic environment as specified below. Customers or users of the MultiStim ECO must ensure that it is operated in such an environment.

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidelines**
Immunity to conducted interference acc. to IEC 61000-4-6	3 $V_{effective\ value}$ 150 kHz to 80 MHz within ISM bands[a]	Not applicable	Portable and mobile radio devices should not be used closer to the MultiStim ECO and its cables than the recommended safety distance calculated based on the equation valid for the transmitter frequency. Recommended safety distance: d = 3.5/U1√P for 150 kHz to 80 MHz d = 12/U1√P for 80 MHz to 800 MHz d = 23/U1√P for 800 MHz to 2.5 GHz with P being the maximum nominal power of the transmitter in watt (W) acc. to the information of the transmitter manufacturer and d the recommended safety distance in metres (m)[b].
	10 $V_{effective\ value}$ 150 kHz to 80 MHz within ISM bands[a]	Not applicable	

Immunity to radiated interference acc. to IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	 The field strength of stationary radio emitters should be below the compliance level at all frequenciesd according accor-ding to an on-site surveyc. Interference is pos-sible near devices with the following label:

Note 1	At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2	These guidelines might not be applicable in all cases. Elec-tromagnetic propagation is influenced by absorptions and reflections of buildings, objects and people.

a) ISM frequency bands (for industrial, scientific and medical applications) 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.

b) Compliance levels in ISM bands between 150 kHz and 80 MHz and in the frequency range from 80 MHz and 2.5 GHz are intended to reduce the probability that mobile/portable communication devices cause interference if they are unintentionally brought into the patient's area. For this reason, an additional factor of 10/3 is used for calculating the recommended safety distances in these frequency ranges.

c) The field strength of stationary transmitters, such as base stations of radio telephones and land mobile radios, amateur radio stations, AM and FM radio and television transmitters, cannot be accurately predetermined in theory. To determine the electromagnetic environment with regard to stationary trans-mitters, an investigation of the site of use should be considered. If the measu-red field strength at the location where the MultiStim ECO is used exceeds the above-mentioned compliance level, the MultiStim ECO should be observed to determine whether it works properly. If unusual performance characte-ristic are observed, additional measures, such as an altered alignment or a different location for the MultiStim ECO, may be necessary.

d) The field strength should be lower than 10 V/m across the entire frequency range from 150 kHz to 80 MHz.

Addition: IEC 60601-2-10 National Deviation Canada

IEC 60601-2-10 National Deviation Canada cl. 6.8.3 bb)

The maximum output charge per pulse and maximum average current across a 500 ohm resistive load and at the maximum output setting

Maximum Output Charge per pulse:

$$Q_{2.0\ mA} = I \times t$$

$$Q_{2.0\ mA} = 2.0\ mA \times 100\ \mu s$$

$$Q_{2.0\ mA} = 0.2\ \mu As$$

Maximum Average Current across a 500 ohm resistive load and at the maximum output setting (2.0 mA)

$$I_{average} = I \times \frac{t_w}{T_{Stim}}$$

$$I_{average} = 2.0\ mA \times \frac{100\ \mu s}{1\ s}$$

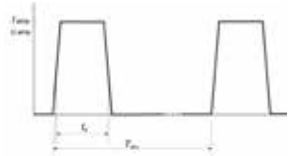
$$I_{average} = 0.2\ \mu A$$

Graphical representation of typical output sign

		200 Ω	500 Ω	1000 Ω	2000 Ω	OPEN
half setting	1.0 mA	200 mV	500 mV	1000 mV	2000 mV	0 mV
full setting	2.0 mA	400 mV	1000 mV	2000 mV	4000 mV	0 mV

t_w=100 µs

T_{Stim}=1 *s*



General information

The devices are manufactured in accordance with globally applicable guidelines for hazardous substances.

BF-type application part

Dispose of all components and materials sorted and in an environmentally friendly way or have them recycled. If the medical device is no longer used, it must be disposed of according to the country-specific environmental regulations.

Any serious incident that has occurred while using the device should be reported to the manufacturer and the corresponding authorities of the country the user and/or patient are residing in.

PAJUNK® GmbH Medizintechnologie, Karl-Hall-Strasse 1, 78187 Geisingen, Germany.

Key to symbols used in labelling

Manufacturer	Consult instructions for use
REF Catalogue number	Rx only Dispensing with prescription only (The product may only be used by qualified medical staff for the intended purpose.)
Do not use if package is damaged	Do not dispose of with domestic waste
Keep dry	Advice
Humidity limitation	Information
Caution	CE 0124 Product is in conformity with the applicable requirements set out in Community harmonization legislation and is monitored by a notified body
Protection against electric shock, type BF	Consult instructions for use (SO 7010-M002)
Date of manufacture	QTY Quantity
LOT Batch code	Translation
NON STERILE Non-sterile	MD Medical device
Keep away from sunlight	
Temperature limit	
Pressure range	

CE 0124

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