PAJUNK®

MultiStim SWITCH and MultiStim SENSOR –

Setting the trend in nerve stimulation

Plexus and Epidural Anaesthesia

The essential advantage regarding safety

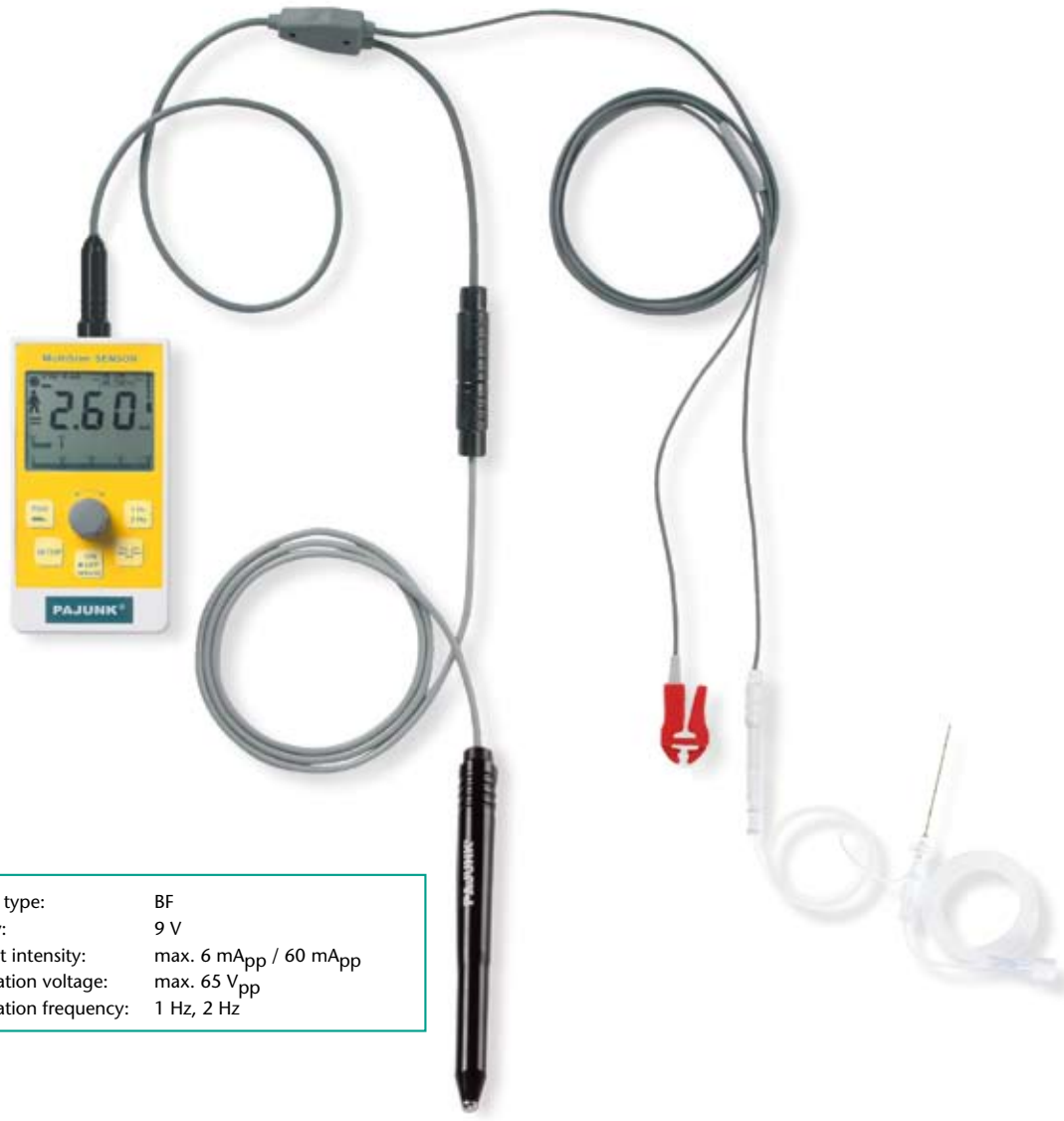
MultiStim SENSOR and MultiStim SWITCH

With **MultiStim SENSOR** and **MultiStim SWITCH**, PAJUNK® has founded a new generation of nerve stimulators in regional anaesthesia.

Both devices offer a variety of functions for more safety and efficiency, and are convincing due to the following advantages:

Aside of a number of identical functions, the two devices are, however, different in

The **MultiStim SENSOR** supports patient friendly, percutaneous localization and identification of nerves with the aid of a stimulation handle: the PEG-electrode (**P**ercutaneous **E**lectronic **G**uidance) - a fundamental distinctive feature in relation to conventional stimulation devices.



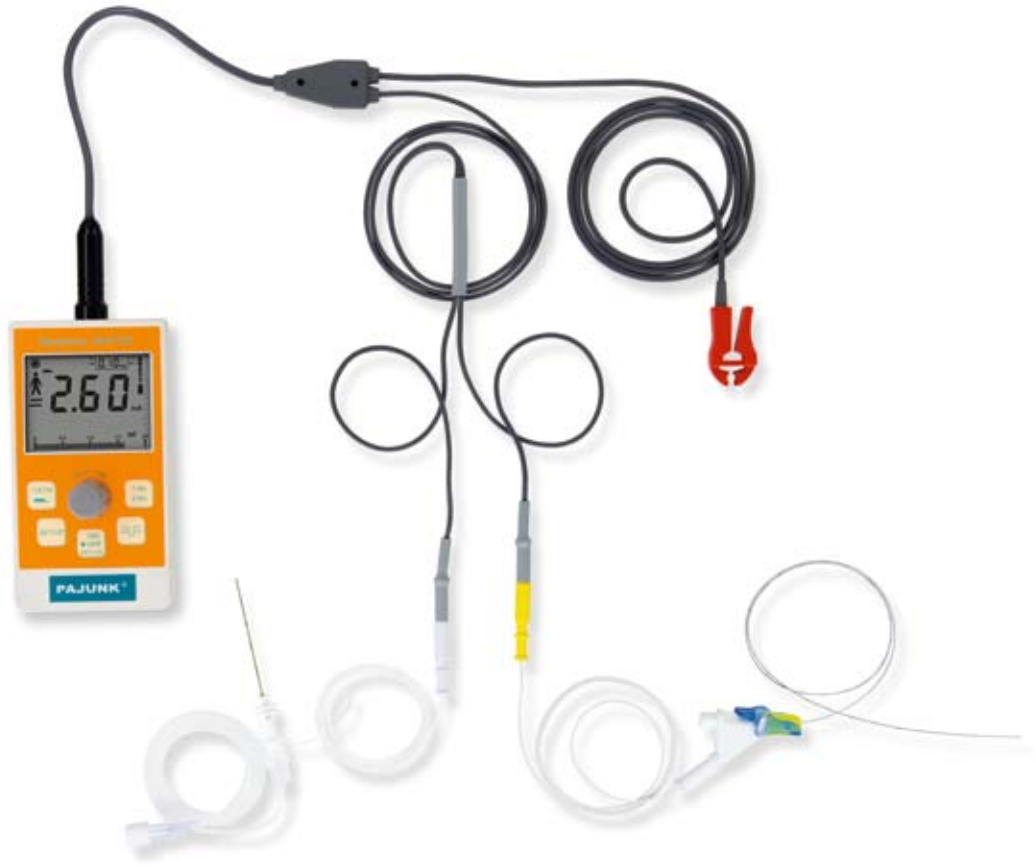
Device type:	BF
Battery:	9 V
Current intensity:	max. 6 mA_{pp} / 60 mA_{pp}
Stimulation voltage:	max. 65 V_{pp}
Stimulation frequency:	1 Hz, 2 Hz

- Large, clearly arranged display
- Analogous setting of the intensity of the stimulation current by means of a notched turning-knob
- Integrated safety functions
- High-precision, microprocessor-controlled adjustment of constant current

the following functions:

The **MultiStim SWITCH** has revolutionized nerve stimulation through two outstanding innovations:
➔ The new function indicating the patient resistance permits the instant detection of intraneural, intravascular and intrathecal cannula placement, which can be corrected immediately.

➔ A switch-over function enables the anaesthetist to either select the catheter or the cannula for the stimulation by a simple keystroke. The maximum current intensity will thereby correspond with the distinct, varying requirements of peripheral and epidural nerve stimulation.



Device type:	BF
Battery:	9 V
Current intensity:	max. 6 mA_{pp} / 20 mA_{pp}
Stimulation voltage:	max. 95 V_{pp}
Stimulation frequency:	1 Hz, 2 Hz

Easy to view – simple in application

The MultiStim SENSOR

MultiStim SENSOR

While the exact insertion point is determined by means of anatomical landmarks when conventional stimulation equipment is being used, the **MultiStim SENSOR** optionally also permits the location of the puncture site with the aid of the PEG-electrode (**P**ercutaneous **E**lectrode **G**uidance).

Percutaneous nerve localization with handle

When using the PEG-electrode, the nerve is stimulated through the skin without requiring a puncture, which will evoke a reflexive response when the nerve is encountered.

The cannula is introduced at the insertion point identified by means of this method, and the stimulation current is then switched over to the cannula by keystroke. The placement of the cannula is performed in the usual manner.

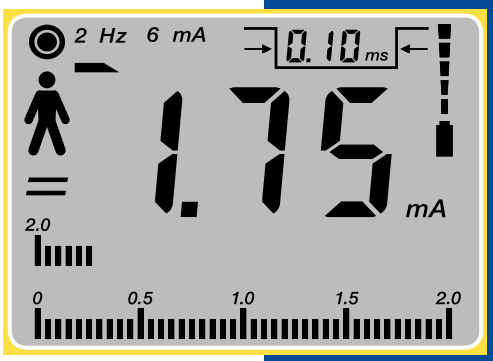
PEG- and Cannula button*

Pressing the PEG- or Cannula button will cause the stimulation to be switched to the handle or to the cannula, as may be required.
The respectively active electrode will thereby be indicated by means of a corresponding status indicator in the display. The intensity and the frequency of the stimulation current, as well as the pulse width can be adjusted separately for both outputs. This button will remain without function if no PEG-handle has been connected.

* only if the optional PEG-cable and electrode are used

Nominal/actual stimulation current intensity

The intensity of the stimulation current actually flowing through the patient is measured constantly, and is indicated numerically as well as by bar graph indicator on the display. The nominal and actual currents are also constantly compared and indicated visually or acoustically, if the intensity of the actually flowing current differs from the adjusted current intensity.



SETUP

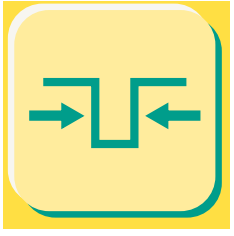
The device has been provided with a SETUP-function. This function permits the user himself to determine his individual initial parameters for the percutaneous and invasive applications.

ON/OFF
PAUSE

The stimulation can be interrupted at any time with the PAUSE - button. The settings of all stimulation parameters can be changed without emitting impulses, while the device remains attached to the patient.

Adjustable stimulation pulse width

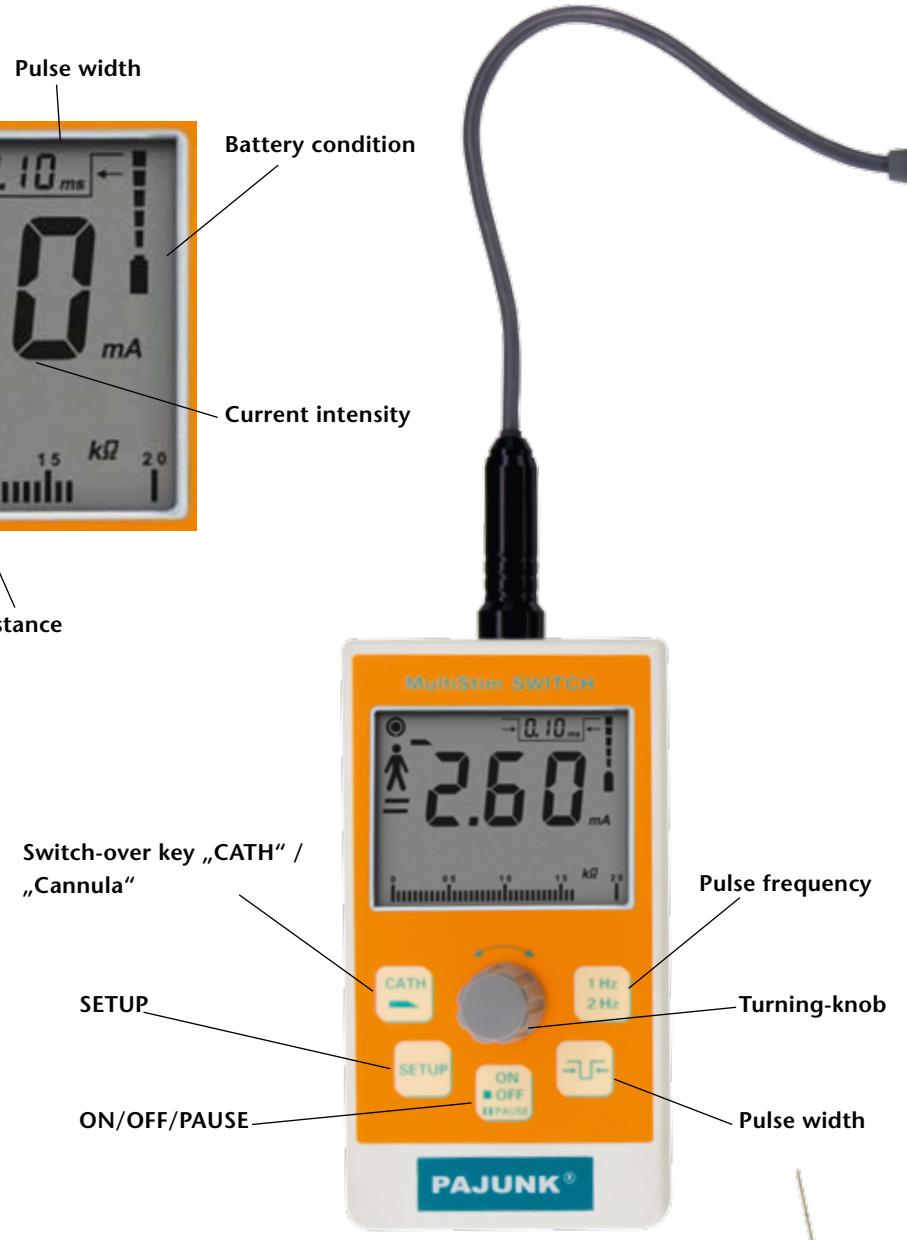
The stimulation pulse width can be adjusted fast and simple with a button of its own in a number of steps – with intervals ranging from 0.05 ms, 0.1 ms, 0.2 ms, 0.3 ms, 0.5 ms to 1.0 ms, e.g. for the selective stimulation of sensory and motor nerve fibres in mixed nerves.



MultiStim SWITCH

Brings the future of stimulation right to the

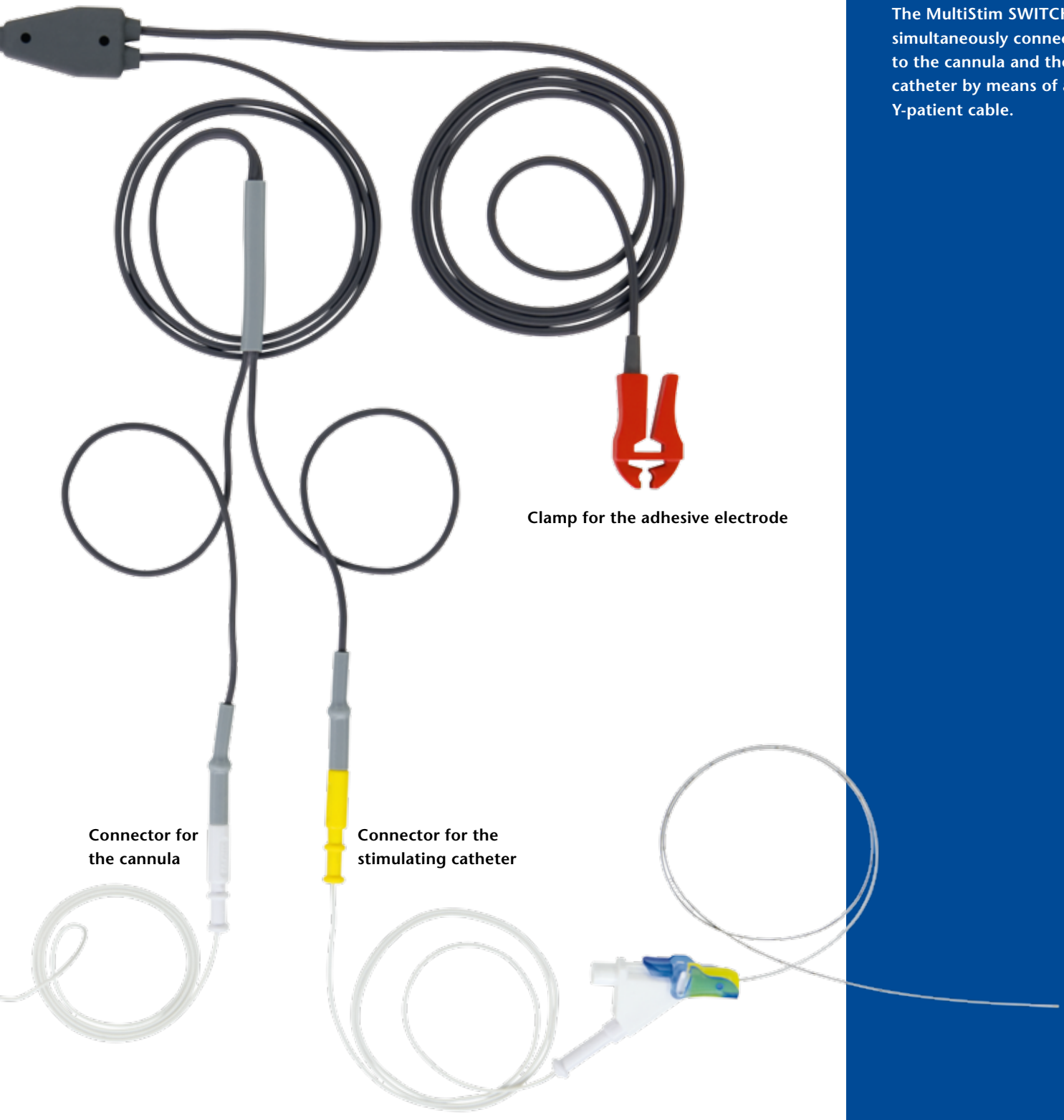
PAJUNK® **MultiStim SWITCH** can be used for the location of peripheral nerves and also for epidural stimulation. Its application is recommended for all purposes requiring the identification of nerves, bundle of nerv fibers and nerve roots. With this device,



point

PAJUNK® has set new standards in electrical nerve stimulation, because for the first time ever, it provides the option for alternative stimulation by means of cannula or by stimulating catheter.

The **MultiStim SWITCH** is comparable with the **MultiStim SENSOR** with respect to safety and basic construction, and it has been furthermore provided with additional functional utilities.



Clamp for the adhesive electrode

Connector for the cannula

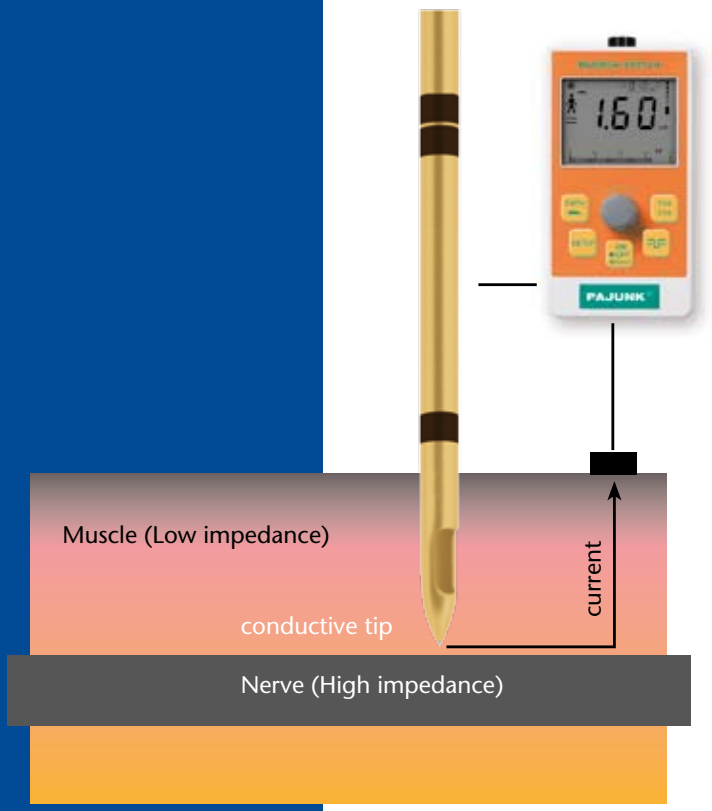
Connector for the stimulating catheter

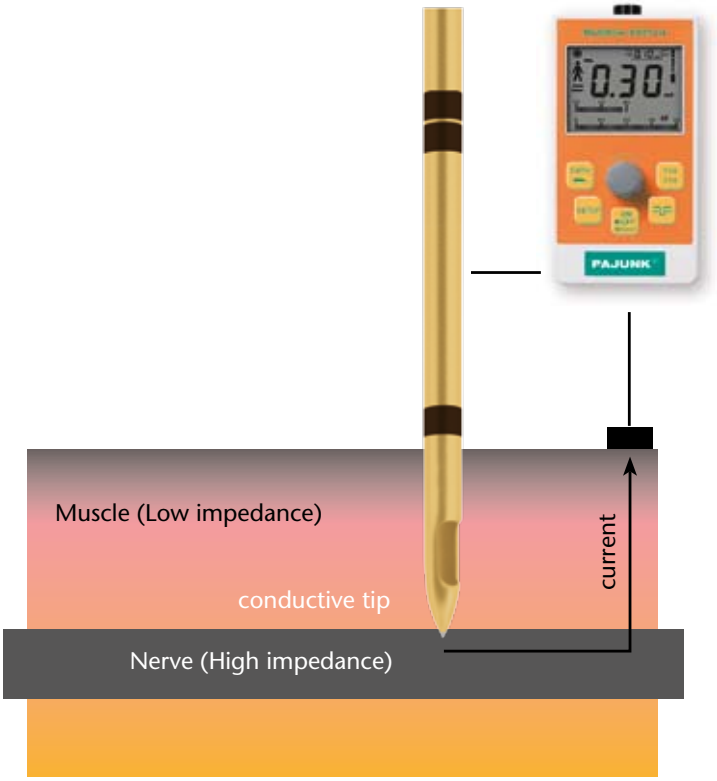
The MultiStim SWITCH is simultaneously connected to the cannula and the catheter by means of a Y-patient cable.

The revolution in the nerve stimulation

More safety through the indication of pat

The **MultiStim SWITCH** has revolutionized nerve stimulation. Because **MultiStim SWITCH** is the first device, which permits the immediate identification and correction of a misplaced cannula, before mechanical or chemical injuries are caused. Because it has been confirmed on the basis of medical studies conducted under the direction of Dr Tsui, that patient resistance will increase distinctly in cases of intraneural, intravascular and intrathecal punctures.

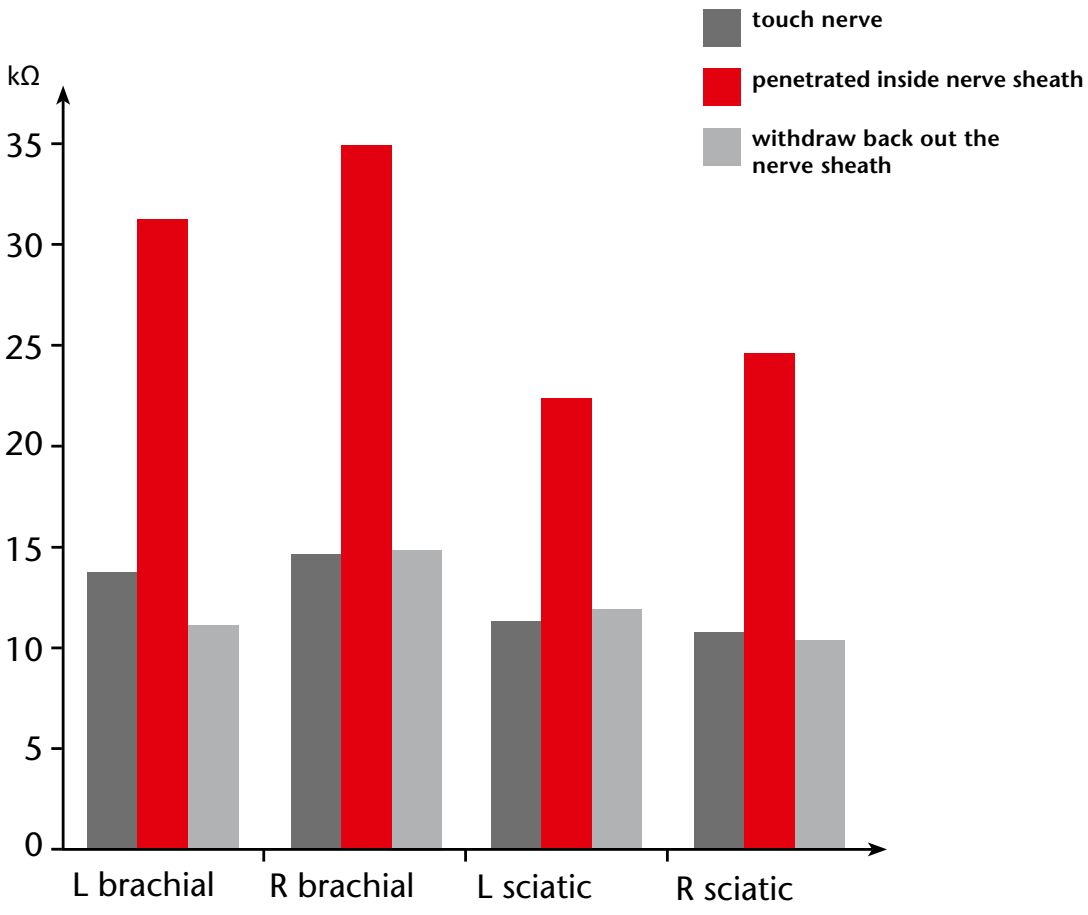




ient resistance

Based on this knowledge, PAJUNK® has enhanced the functional utilities of the **MultiStim SWITCH** by adding a continuous indication of the patient resistance by means of two analogous bar graphs.

The measurement of the resistance connected therewith is only possible, if the highly precise PAJUNK® stimulation cannula are used.



An individual threshold value can be predefined in advance for double safety by means of the SETUP-button, which will cause an acoustic signal to be emitted if the threshold value is exceeded. The **MultiStim SWITCH** therefore provides an essential advantage regarding safety for the patient.

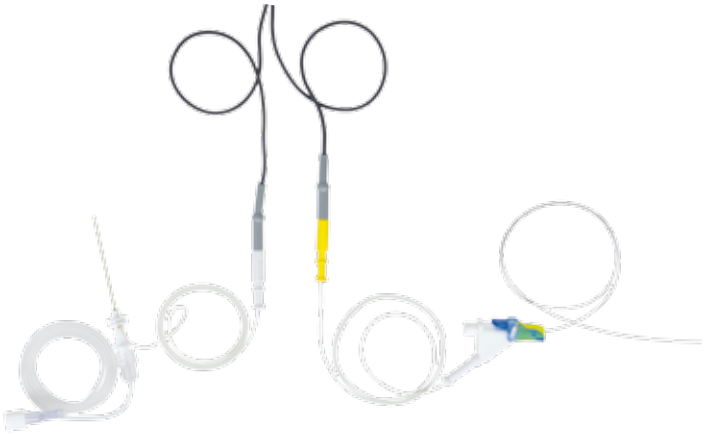
TSUI innovation

Useful options

The MultiStim SWITCH can do more

Stimulation by cannula or catheter
The **MultiStim SWITCH** provides two alternative options for stimulation: by way of a cannula or through a stimulating catheter. The corresponding switch-over is actuated simply by pressing the CATH/Cannula – function key.

If stimulation by cannula is activated, then a **cannula symbol** will appear on the display. The maximum stimulation current intensity will be 6 mA.



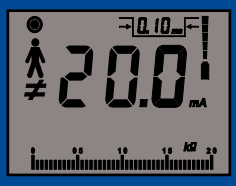

Cannula symbol

CATH
Catheter symbol

If stimulation by catheter is activated, then the word „**CATH**“ will appear on the display. In the catheter-mode, the range of stimulation current intensity will be increased to 20 mA, and will therefore correspond with the specific requirements of epidural stimulation.

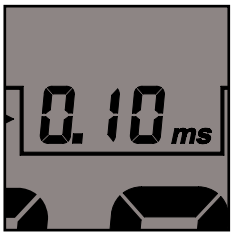
MultiStim SWITCH

The intensity and the frequency of the stimulation current, as well as the pulse width can be adjusted and configured separately at any time for both outputs (cannula and catheter).

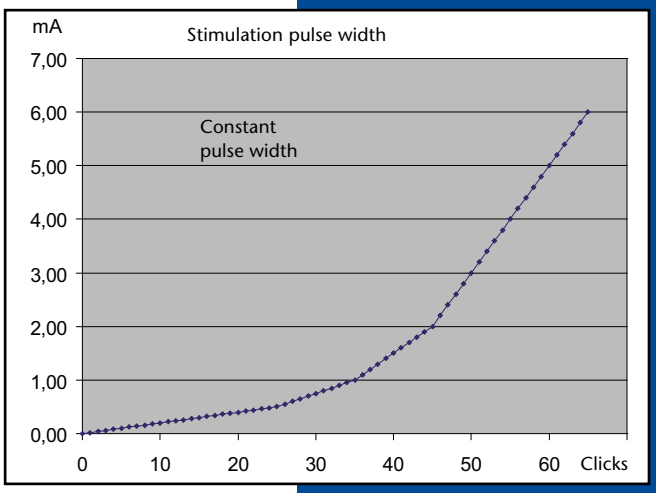


Maximum voltage and current intensity
The device emits a stimulation voltage of at most 95 Vpp in order to still obtain a good stimulation effect on patients with high resistance conditions. The intensity of the stimulation current for the catheter amounts to 20 mA for safety reasons, and is therefore also suitable for epidural stimulation.

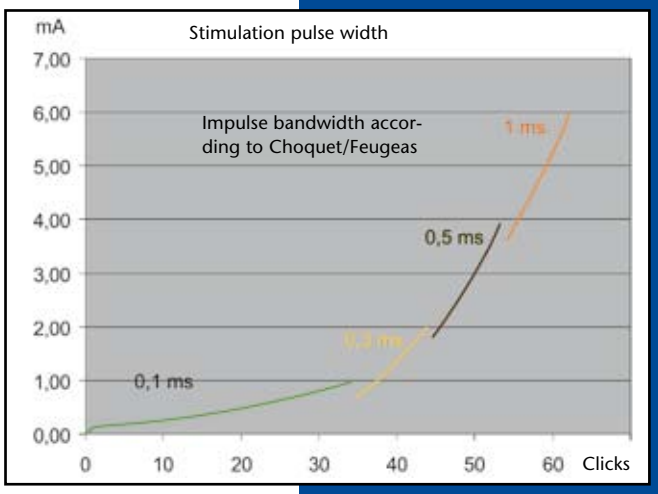
SETUP-button
Individual programming options differing from the manufacturer's default settings can be defined by actuation of the SETUP-button.
- Level 1: Volume of the warning- and monitoring sounds
- Level 2: Stimulation frequency, pulse width and current intensity in the "Cannula-mode"
- Level 3: Stimulation frequency, pulse width and current intensity in the "Catheter-mode"
- Level 4: Threshold value, at which the acoustic signal for the patient resistance will change
- Level 5: Activation of the Choquet/Feugeas table; "Cannula-mode"



Individual definition of a constant pulse width
In the manual mode, stored as manufacturer's default setting, the pulse width can be defined by the user. It will remain constant during the complete application. The change of the current values is effected manually in fixed, predefined steps, whereas these steps will be correspondingly large at great distances to the nerve, and will become smaller as the cannula approaches the nerve. (see accompanying table)



Automatic adjustment of the current intensity and impulse bandwidth according to the Choquet/ Feugeas table
In the automatic mode, the pulse width depends on the intensity of the current, and has, on the basis of the Choquet/Feugeas table, been stored permanently in the nerve stimulator. The intention of this method is to achieve a fast, efficient approach to the nerve, on the basis of a constant charge. The device will correspondingly function with a great pulse width at the beginning, which will be reduced according to the intensity of the current in the course of approaching the target nerve. This option ensures, that the anaesthetist can approach the nerve in constant steps under continued muscular response, and can therefore concentrate his full attention completely on the puncture.



MultiStim SENSOR

MultiStim SWITCH

MultiStim SENSOR and MultiStim SWITCH

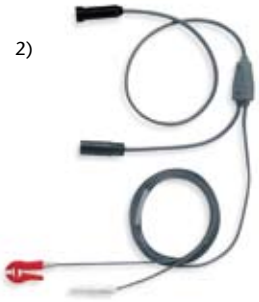
All the information at a glance

Nerve stimulator: MultiStim SENSOR

Accessories:

1)

2)



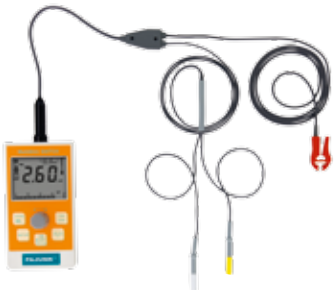
3)

MultiStim SENSOR	Item no.
incl. equipment case and patient cables for the connection of stimulation cannula	1151-94-30
incl. equipment case, PEG-cable for the connection of stimulation cannula and monopolar handle	1151-94-32
Accessories	
1) Patient cable for the connection of stimulation cannula	1151-94-13
2) PEG-cable for the connection of stimulation cannula and monopolar handle	1151-94-14
3) PEG-electrode - percutaneous, monopolar stimulation handle, autoclavable	1151-94-17
Extension cord for the connection of stimulation cannula, autoclavable*)	01151-861F
Disposable extension cord for the connection of stimulation cannula, sterile*)	01151-861Q

*) Usable for SWITCH and SENSOR

Nerve stimulator: MultiStim SWITCH

MultiStim SWITCH	Item no.
incl. equipment case and SWITCH-cables for the connection of cannula and StimuLong catheter	1151-94-40
SWITCH-cabel for the connection of stimulation cannula and stimulating catheter	1151-94-07



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PAJUNK®

MultiStim SWITCH

Peripheral – Epidural – Spinal

English

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User Instruction – MultiStim SWITCH

1. General information
Please note: Due to US Medical Device Legislation and specific requirements for devices marketed in the USA the wording of the user instructions for the US may slightly differ from the standard English version.

Please read the following information and instructions carefully.

The product may only be used by experienced medical staff in accordance with these instructions. PAJUNK® GmbH Medizintechnologie does not give any recommendation for a method of treatment. The treating medical specialist staff is responsible for the course and manner of application and the selection of the patient.

Nonobservance or contravention of these instructions will cause the guarantee to expire and will lead to endangering the safety of the patient.

If used in combination with further products, please always observe and comply with the directions for use and the compatibility statements of these products.

Please check the product and the packaging for completeness, intactness and the status of sterility before application. Do not use product if you have reason to doubt the completeness, the intactness and the non hazardous status of sterility.

MultiStim SWITCH is intended to be used exclusively with PAJUNK® GmbH Medizintechnologie products (e.g. StimuLong catheters, UniPlex cannulae). The accessories may be connected with the device exclusively by way of the enclosed equipment cable. Safe and successful functioning can only be ensured with these products.

2. Product specification/compatibility
MultiStim SWITCH is delivered with the following basic equipment:
- MultiStim SWITCH nerve stimulator
- 9 volt block battery
- Patient main cable SWITCH
- Short-circuit plug
- Operating instructions
- Suitcase for storing SWITCH and accessories

Please observe by all means: The patient main cable of the MultiStim SWITCH is compatible with that of the MultiStim SENSOR due to its technical design. Please make absolutely sure that the correct cable is respectively used, since the device will otherwise not work as intended!

2.1 Indication
The MultiStim SWITCH serves for reliable neuro-localization, as for example in local- and regional anesthesia (diagnostic, intra-operative and therapeutical block). It may be used for locating peripheral nerves and also for epidural stimulation (Tsui-test). The PAJUNK® MultiStim SWITCH can be used in all cases where the identification of nerves, of nerve fascicles or of nerve roots is required.

2.2 Contraindications
The use of a nerve stimulator on patients with known cardiac- or circulatory insufficiencies should be considered carefully. Further contraindications may be caused by anatomical anomalies.

2.3 Warnings and precautionary measures
The connecting port of the stimulation cannula or the catheter adapter may only be connected to the corresponding mating connector of the patient main cable. If an intermediate cable is used inbetween, please also absolutely ensure correct connection here!

The device connector of the connector cable may only be connected to the nerve stimulator, and the clip connection may only be connected to the adhesive electrode on the skin of the patient.

These plugs/connections may under no circumstances be brought into contact with live / current bearing components (e.g. electrical outlets) or with metallic objects.

The MultiStim SWITCH may not be used in explosive surroundings to avoid gas explosions of anesthesia gasses or the ignition of combustible liquids.

All connected facilities in the environment of the patient must comply with the applicable regula-

tions to avoid injuring the patient. All facilities and accessories must comply with the regulations of EN 60 601-1, EN 60 601-1-1, as well as with those of the applicable sub-norms. It is to be taken into account, that in the most unfavorable case, all leakage currents or the auxiliary patient currents may perhaps add up cumulatively and the patient may be endangered by these inadmissibly high values, even if all the rules for the individual facilities have been complied with. It is therefore to be checked in advance, whether the interconnection of the facilities will perhaps cause the permissive limiting values to be exceeded. Improper interconnection of equipment and facilities (system formation) can injure the patient vitally.

The patient himself may not come into contact with metallic objects which are earthed or which have an electrically conductive connection with other facilities, or which permit capacitive coupling. That is why we recommend the use of a sufficiently insulating/non-conductive, antistatic pad on the operating table.

The MultiStim SWITCH may under no circumstances be operated with instruments and accessories other than those which have been authorized, supplied or recommended by the manufacturer. Only PAJUNK® accessories have been technically tested with regard to EMC (electromagnetic compatibility). Accessories of other vendors may lead to seriously harming the equipment- and system properties and may cause lasting impairment to the patient, the user or the equipment.

The simultaneous application of surgical RF-devices will evoke the acute risk of burns caused by touching the connections of the MultiStim SWITCH, the connector cable, the cannula tip or the adhesive electrode. It is therefore necessary to disengage all connections to the MultiStim SWITCH and to remove the stimulation cannula from the tissue before surgical RF-devices are used. The stimulation cannula with its connector cable acts as an antenna for RF-energy, which may cause the induction of a very high current density at the tip of the cannula. Nerve fibers in the vicinity may be irreversibly destroyed. The connected stimulator may simultaneously cause the rectification of the RF-energy, which will lead to extremely high direct currents and voltage potentials at the electrodes. The direct current stimulus emitted thereby can be very painful and may trigger intense, irreversible electrophysiological reactions.

To avoid that poor contact of the adhesive electrode will lead to a malpositioning of the stimulation cannula, please ensure that the adhesive electrode, which functions as a neutral electrode here, is in sufficiently sound contact with a low tissue impedance. Fatty tissue, hair, uncleanness, repeatedly used adhesive electrodes and electrodes of inferior quality can influence this tissue impedance adversely and thereby evoke the risk of nerve damage. We therefore recommend, that the contact surface is selected carefully: select only muscular areas with sufficient blood perfusion, and clean, shave and degrease the skin. The position of the adhesive electrode should also not be too far away from the location of the puncture. However, please avoid the thoracal application of the skin-electrode.

The MultiStim SWITCH should not be used on patients with implanted electrical devices (e.g. cardiac pacemaker) without previously seeking corresponding medical advice from a specialist. Possibly occurring disturbances of the implanted electrical devices through the stimulating current may constitute a hazard for the patient. The attachment of electrodes in the vicinity of the thorax (rib cage, heart) may increase the risk of ventricular fibrillation (cardiac fibrillation).

The stimulator may no longer be used if it displays a direct current- or perhaps a direct voltage-component at the output, please send it in for repair.

The patient current should not fall below the following values: 0.15 mA invasive (catheter and cannula) Operate the MultiStim SWITCH only with the genuine, CE-labeled PAJUNK®-accessories. All accessories must be subjected to a visual inspection at regular intervals. The insulation of the patient lines may not show any damage.

Use only high-quality, commercially available, CE-labeled single-use ECG-adhesive electrodes with pregelled silver/silver chloride contacts. For optimal nerve stimulation, please use only electrodes which are intact and have not dried out.

The adhesive electrodes may not be attached in the area of injuries.

When discarding the MultiStim SWITCH and the listed accessories, the users must comply with the respective current regulations for the disposal of waste.

Special precautions apply for electric medical equipment with regard to EMC (electromagnetic compatibility). Portable and mobile RF-communication facilities may influence the MultiStim SWITCH. This may lead to a malfunction of the device or of the system.

Dynamic electrical- and dynamic magnetic interference fields may interact with the device and the system. These interactions may have an influence on the measurement of the actual stimulus current, and in the extreme case, they may lead to an error in indication and perhaps to a safety-shutdown of the device.

The MultiStim SWITCH may not be used near equipment emitting strong magnetic fields, e.g. radio-telephones, surgical RF-devices, short wave- or microwave-therapy devices. Any potential introduction of high-frequency currents into the stimulation cannula may lead to a damaging of the nerves.
The device may not be connected with other equipment. If the MultiStim SWITCH is operated nearby to another device, then the devices or the system must be monitored and the correct functioning as intended must be verified in this arrangement as it is being used.

Under unfavorable conditions, the MultiStim SWITCH may disturb other equipment in its function. We therefore recommend to check all other equipment and facilities for compatibility with the MultiStim SWITCH, and if necessary, to remove these from the patient.

The operation of other equipment or systems with the accessories may lead to increased emissions or to reduced interference immunity of these systems. Please observe the enclosed EMC (electromagnetic compatibility) information regarding installation, start-up and operation of the equipment or system (see chapter Electromagnetic Compatibility (EMC)).

To avoid damaging the connector cable and the device, please do not hold or carry the device by its connector cables or by its accessories. Do not wind the cable around the device or around other facilities.

The winding of the connector cable during normal operation of the stimulator will produce inductive components and may, if very short stimulation pulses are being used, lead to a reduction of stimulation performance or to faulty measurement of the actual stimulation current. Misinterpretations of the reported values can be the consequence.

In case of battery leakage, the device should not be operated anymore for security reasons the device must be returned to the manufacturer for proper cleaning.

Avoid unclean connections. Water and dirt will deteriorate the contact properties of the plug-in connections and lead to unintentional short-circuits or leakage-currents. These may lead to partial- or even total diversion of the stimulation currents, which will cause the stimulation effect to decline, or even to fail completely. In this case, the device cannot display the actually flowing patient current correctly any more.

To avoid damaging the MultiStim SWITCH and its accessories, do not use aggressive cleaning agents, further details may be found under item “Cleaning and Disinfection of the Device”. Check all accessories in regular intervals. The insulation of the lines and hardware connections may show no damages.

The User Instructions are to be followed for the operation of the MultiStim SWITCH and the corresponding accessories. When sterile accessories are being used, please always provide for sterile environmental conditions.

Avoid unintentional bone contact with the stimulation cannula, since the cannula may thereby be substantially damaged which may consequently cause a traumatization of the tissue.

Keep the accessories and MultiStim SWITCH away from live / current bearing objects. The electrostatic and electromagnetic fields radiated therefrom may have an influence on the stimulation result, and these themselves may even lead to unwanted stimulation effects in the tissue.

The device, the connector cables and the plugs must be kept completely clean and dry before and during the application. Moisture and uncleanness will affect the function of the nerve stimulator and/or the stimulation result.

Please note the position of metal implants in the tissue (e.g. plates or electrode cables). They may perhaps conduct the stimulation signals to other locations and can cause detrimental effects there. Implanted electronic equipment may be impaired by the stimulation current, which in turn will lead to a malfunctioning of these implants or may even destroy them.

To avoid malfunctions of the MultiStim SWITCH, please check all functions before the intervention and make sure that the accessories are suitable for the application. The accessories used must correspond to safety class type BF.

To protect the patient from electrophysiological shock by electrostatic discharge (ESD), it is necessary to wear corresponding clothing and to move about in an appropriately protected environment. An electrostatic discharge (ESD) can cause extremely high current densities to appear at the tip of the cannula, which can damage the surrounding tissue.

Conformity with the following standards:
EN 60 601-1; 14971:2000; EN 60601-1-1; EN 60601-2-10; EN 60601-1-4
EN 60601-1-2; 13485:2003/ AC2007; 9001:2000; UL 60601; MPG; HWG, Directive 93-42-EC

2.4 Constant voltage or constant current

According to Ohm's law $U = R \times I$, it is possible to use both, the voltage and the current intensity as the quantity to be measured to determine the intensity (amplitude) of the electrical stimulus. The devices are respectively referred to as voltage-constant or current-constant.

The electrical resistance (impedance) in the electrical circuit of a stimulation, which represents the sum of skin-, tissue-, cannula-, electrode cable-resistance etc., will vary within wide ranges. It may vary between < 1 kΩ and infinite. The factors skin humidity, conductivity of the skin and of the tissue and the potential resistance of the adhesive electrode can hardly be influenced.
If the voltage (V) is selected as the measure for the intensity of the stimulus impulse, then currents may appear during an application, which – in accordance with Ohm's law and depending on the resistance – will differ by a manifold.

It is therefore better to use a nerve stimulator which permits the exact adjustment of the current intensity (mA) between the two electrodes, the adhesive electrode (anode) and stimulation cannula (cathode).

The stimulator with constant current setting must, however, be provided with a very high output impedance – ideally infinite – so that the resistances which may perhaps occur in the external electrical circuit will be negligible, and so that the actually flowing current will be indicated exactly on the display.

Current-constant devices which permit the selection of the current intensity (mA) for the stimulus impulse have gained acceptance within the last few years.

For the MultiStim SWITCH, the external load resistance can amount to as much as 12 kΩ. If this load resistance is exceeded, then the actually flowing patient current (the actual stimulation current) can be lower than the adjusted nominal stimulation current. In this case, the nominal stimulation current and the actual stimulation current are indicated separately and visual and acoustic warning indications are emitted. And the relevant impedance is continuously calculated and indicated on the LCD-display in addition.

The MultiStim SWITCH is a precision instrument for the localization of nerve tracts in the human organism. It was developed to stimulate nerve fibers in the living organism using cannulae and special catheters for invasive stimulation which normally show a very high contact impedance, to be able to determine the spatial position of these nerve fibers in relation to the tip of the electrode. The stimulation cannulae are designed so that a local anesthetic can be injected in the proximity of the nerve fiber, which will cause a reversible interruption of the conductive system.

2.5 Accessories

The MultiStim SWITCH can (unlike the model SENSOR) be exclusively connected with a patient cable for cannula and catheter:

Yellow connection: CATHETER

White connection: CANNULA

Clamp for adhesive electrode

In addition patient main cable for cannula stimulation only is available:

White connection: CANNULA

Clamp for adhesive electrode

There is an extension cable available for each, the connection to the cannula and to the catheter (variant autoclavable and variant single use).

3 Technical description

The MultiStim SWITCH generates reproducible square pulses with adjustable frequency and continuously adjustable stimulation current. The adjustment range of the impulse current: 0.0 – 6.0 mA if stimulation cannulae are being used, and 0,0 – 20 mA if stimulation catheters are being used.

The corresponding symbol will be shown synchronously with a short beeping sound in the rhythm of the stimulus for visual and acoustic control.
If only the outer circle is visible, then the electrical stimulation circuit is not closed, i.e. there is no stimulation current running through the patient.
If the circle is completely full, then the stimulation electrical circuit is closed, i.e. stimulation current is running through the patient. The control sound will become more intensive in this case.

Due to a high stimulus voltage of max. 95 Vss , this renders an exceptionally large adjustment range for extremely small stimulating electrodes.
Please make sure, that only CE-labeled adhesive electrodes are used for stimulation, which have been provided with contact gel in order to keep the transition resistance as low as possible.

3.1 Technical data

Type:	**MultiStim SWITCH**	
Type of device	BF	
Battery:	9 V	
Stimulating current:	max. 20 mAss/	
Resistance range	0 Ω – 60 kΩ	
Stimulation voltage:	max. 95 Vss	
Stimulation frequency:	1 Hz/2 Hz	
Stimulation impulse bandwidth:	0,05 ms / 0,10 ms / 0,20 ms/ 0,30 ms/0,50 ms/1,00 ms	
Operating conditions:	Temperature: Atmospheric humidity: Air pressure:	10°C – 30°C 20% – 65% n.a.
Transportation- and storage conditions:	Temperature: Atmospheric humidity: Air pressure:	10°C – 30°C 20% – 65% n.a.

CE0123

3.2 Display

Display, all indications activated (simulated condition)

MultiStim SWITCH has additionally been provided with a permanent analogous indication of the patient resistance by means of two bar graphs below the digital.

3.3 The control keys

Button	Function
	Mode: CATH (catheter) or KAN (cannula, represented by symbol)
	Access to the basic setting
	„On“ / „Off“ / Pause
	Selection of the impulse bandwidth
	Mode: Impulse-frequency

3.4 The elements of the display

Symbol	Meaning
	Indicates must-current is displayed in mA
	Indication of the electrical patient-circuit: Electric circuit not closed.
	Indication of the electrical patient-circuit: Electrical circuit closed.
	The value actually measured corresponds („=“) or („≠“) does not correspond to the nominal/set point value (inactive when no pulses are being emitted) (nominal current = actual current)

Symbol	Meaning
	Indication of the battery charge level each of the five segments correspond to 20% of the battery capacity. This means, if all five segments are visible, then 100% of the utilizable battery capacity are available, if no segment is visible anymore, then there is 0% battery power available.
	Operating modes: PEG (ONLY SENSOR!), cannula or catheter.
	Indicates, that setup mode is activated.
	Indication of impulse bandwidth. The numerals and units shown within the symbol render the values selected with the control keys (see description).

3.5 Menu structure setup

SETUP level 1	Adjustment/storage of the volume		
	Options to choose from:	A4, A3, A2, A1	(decreasing volume, beep sounds)
		0	(global mute)
		1, 2, 3, 4	(increasing volume, pulse sounds)
SETUP level 2	Adjustment/storage of "Cannula – current pulse"		
	Options to choose from:	set value (control device) storage	
SETUP level 3	Adjustment/storage of "CATH – current pulse"		
	Options to choose from:	set value (control device) storage	
SETUP level 4	Adjustment/storage of "Rp – Threshold"		
	Options to choose from:	0 – 5 (description see table in chapter Setup Level 4)	
SETUP level 5	Adjustment/storage of „PW Selection Mode"		
	Options to choose from:	0, 1 (description see table in chapter Setup Level 5)	

4. Operation

4.1 Pre-operational check

Please observe: Equipment with divergent behavior may not be put into operation. In this case, please contact the customer service. Electro-medical devices may only be repaired by the manufacturer or by an institution expressly authorized by the manufacturer.

Please go through the following checking procedure before the initial startup:

1. Press the ON button to start the device. At this moment, the device will automatically start a self-test sequence. After successful completion of the self-test sequence, the device will switch to the PAUSE mode. The LCD display will inform you about the current settings. Please replace the battery immediately if there is no indication visible after the device has been switched on. (Observe section Battery) If the self-test sequence should perhaps have identified a faulty function, then the corresponding error code will be indicated on the LCD. After this occurrence, the device is not operational any more. (Observe section Error Messages.)
2. Check the electrode cable by visual inspection. Damaged cables may not be used. Attach the electrode cable at the top end of the MultiStim device as follows: position the plug of the electrode

cable in such manner in the device socket, so that the red markings on the device socket and on the connector shell are aligned.

Abb.1 Abb. 2

The plug can be plugged in only in this position; it may not be inserted in any case by using force. Now insert the plug all the way. When the plug has been inserted, it is locked in position and can not be inadvertently disconnected by pulling at the electrode cable. To disconnect the electrode plug, take hold of it at the structured surface near the red dot using your thumb and index finger. The locking mechanism of the plug will be disengaged automatically by pulling away from the device, and the plug can then be removed without problems. The electrode cable cannot be removed otherwise, or the device or the electrode cable may be damaged. The LCD display shows the adjusted nominal stimulation current. The available adjustment range (peak value) may vary (6.0 mA or 20.0 mA), depending on the selected mode.

3. **Performance of the short-circuit test:** Connect the socket of the stimulating electrode to the stimulating electrode clamp with the aid of the supplied red test-plug (= short circuit). Then increase the nominal stimulating current by turning the knob clockwise to at least 1.0 mA and check the »=«-symbol on the display. The display must exhibit an »=« a few moments later.

Abb. 3

If the display should permanently show a dissimilar function (»≠« symbol), there must be a fault in the patient stimulation circuit.

4. Disconnect the electrical connection between the electrode plug and the electrode clamp and remove the red test-plug. A »≠« symbol may now be seen on the LCD. This indicates, that the selected nominal stimulating current is dissimilar to the actual stimulating current. If the behavior is different from the one described in 3 and 4, then a faulty cable could be the cause (short-circuit/ interruption). Check the function once more with a second cable. Finally, remove the red short-circuit plug from the socket of the electrode.
5. Switch the MultiStim off by pressing the ON/OFF/PAUSE button for a longer period of time (min. 2 seconds). (Please observe section Switching ON and OFF) You should turn the device off after use to spare the battery. If you don't use the device for a longer period of time, you should remove the battery to avoid leakage.
6. Please observe the Warnings and precautionary measures before you use the device on a patient.

The stimulation mode stored last will remain stored after turning the device off. When the device is switched on again, this setting is reloaded and the stimulation current is set to 0.00 mA, or to a value you have previously selected. The stimulation pulse width is set to the following default-values after the device is switched on:
Mode:
KAN cannula 0 – 6 mA
CATH catheter 0,0 – 20mA
Before every application on a patient, the device settings have to be checked and altered if necessary.

4.2 Operation of the nerve stimulator

Switching ON and OFF
Pressing the ON/OFF/PAUSE-button will switch the MultiStim SWITCH on.
After switching on, the device will first perform an automatic self-test. Upon the successful completion of the self-test, the device will immediately change to the PAUSE-mode. For the protection of the battery, the device will automatically switch itself off with a previous acoustic warning after 20 minutes have elapsed since the last pressing of a button. The device is switched off by pressing the ON/OFF/PAUSE button for at least two seconds while the device is turned on.

4.3 PAUSE function
While the device is turned on, a short depression of the ON/OFF/PAUSE-button or pressing the turning knob will activate the PAUSE-mode of the MultiStim SWITCH. Stimulation is stopped in this condition. To indicate that the device is in the PAUSE-mode, the »=« or »≠«-symbol will disappear and the value of current intensity, as well as the mA-symbol will begin to flash up.

Important:
All stimulation parameters can be changed during the PAUSE mode without emitting stimulation impulses to the patient. Renewed short pressing of the ON / OFF / PAUSE-button or renewed pressing of the turning knob will end the PAUSE-mode, and the normal stimulation mode is resumed.

4.4 1 Hz/2 Hz mode


When the 1 Hz-/2 Hz button is pressed, MultiStim will generate a continuous sequence of stimulating impulses with a constant frequency. Upon initial activation, the selected 1 Hz function is displayed on the LCD for 2 seconds instead of the impulse bandwidth indication. Renewed pressing of the 1 Hz- / 2 Hz-button will double the pulse repetition rate to 2 Hz.

4.5 Mode cannula/KAN

MultiStim SWITCH offers the option for stimulation using an invasive stimulation cannula (e. g. PAJUNK® UniPlex NanoLine). The puncture cannula is connected to the Y-cable by means of the connection as provided for such. The adhesive electrode is affixed to the surface of the patient's skin at an appropriate location (good contact) in order to ensure current conduction. The red electrode clamp (positive pole, anode) is fastened to the adhesive electrode. In stimulation by means of cannula, the current is conducted between the cannula tip (negative pole, cathode) and the red electrode clamp (positive pole, anode). Pressing the »  « -button permits switching back and forth between the cannula output and the catheter output.
If the stimulation by cannula is activated, the symbol »KAN« as well as the max. stimulation range »6 mA« will appear. The initial intensity of the stimulation current, the stimulation frequency and the impulse bandwidth are separately adjustable for both of the two outputs (see SETUP-functions).

4.6 Mode catheter CATH


Aside of stimulation using an invasive stimulation cannula, MultiStim SWITCH additionally offers the option for stimulation by means of a catheter (e.g. PAJUNK® StimuLong). The stimulation catheter or the catheter clamping adapter is also connected to the Y-cable over the intermediate cable. The adhesive electrode is affixed to the surface of the patient's skin at an appropriate location (good contact) in order to ensure current conduction. The red electrode clamp (positive pole, anode) is fastened to the adhesive electrode.
In stimulation by means of catheter, the current is conducted between the catheter tip (negative pole, cathode) and the red electrode clamp (positive pole).
If the stimulation by catheter is activated, the symbol »CATH« will appear as the status indicator in the display.
The catheter can now be introduced by way of a previously positioned puncture cannula.

Please observe:
If no catheter connection cable is detected when switching to the CATH mode, i.e. the catheter is not connected or is defective, this will cause »no« to appear on the display and an acoustic signal may be heard; the »KANÜLE/CATH« button is without function.

If the catheter is disconnected in the »CATH« -mode, »no« will appear on the display and acoustic warning-signals will be emitted indicating the absence of the electrode. Now:
a) the stimulation catheter may be connected again. This will cause the device to return to the original mode,
or
b) the device may be switched to stimulation by cannula by pressing the »KANÜLE/CATH« - button.

4.7 Amplitude selection (setting of the nominal stimulation current)
The intensity of the stimulation current may be adjusted with the aid of the notched turning-knob located in the center of the device. Turning the knob one increment to the right-hand side (i.e. clockwise) will increase the intensity of the stimulation current by one incremental step. Turning the knob to the left-hand side (i.e. counter-clockwise) will reduce the intensity of the stimulation current by one

incremental step. The presently selected intensity of the stimulation current is indicated on the LCD. This specified value will only correspond with the actually emitted stimulation current, if the electrical stimulation circuit is properly closed over the patient. In this case, the selected stimulation current (set point), which is shown on the display, corresponds exactly to the stimulation current actually flowing through the electrical circuit of the patient. This correct function is indicated by the »=« symbol. As soon as the selected stimulation current differs from the actually flowing stimulation current , the »≠«-symbol will appear on the display. Please note, that in this case the current actually flowing through the patient might be lower than the desired stimulation current which you have previously selected. An increase of the selected stimulation current might therefore not effect the stimulation current actually flowing through the patient. If this happens, it is absolutely necessary to reduce the nominal stimulation current, and to discover the cause of the inadequate or missing patient connections. Do not increase the nominal stimulation current under any circumstances before the reason for the faulty current flowing through the patient has been identified clearly and has been remedied.

4.8 Display modes for stimulation current

The adjusted value (PRESET value) is indicated on the LCD, as the intensity of the stimulation current is adjusted by turning the knob. If the knob is not turned anymore, the device will automatically switch to indicating the intensity of the stimulation current actually flowing through the patient (ACTUAL value). During the indication of the actually flowing current, a symbol resembling a human being is additionally displayed on the LCD on the left-hand side of the current intensity.

Cannula	
Range	Incremental step
> 0,00 mA – 0,50 mA	0,02 mA
> 0,50 mA – 1,00 mA	0,05 mA
> 1,00 mA – 2,00 mA	0,10 mA
> 2,00 mA – 4,00 mA	0,20 mA
> 4,00 mA – 6,00 mA	0,50 mA

Catheter	
Range	Incremental step
> 0 mA – 2 mA	0,1 mA
> 2 mA – 5 mA	0,2 mA
> 5 mA – 10 mA	0,5 mA
> 10 mA – 20 mA	1,0 mA

4.9 Display of the ACTUAL resistance, patient resistance

The current ACTUAL resistance (patient resistance) is shown in analog representation with the aid of two bar graphs at the bottom edge of the display.

Indicating range resolution
Upper bar graph 20-60 KΩ Resolution 1kΩ
Lower bar graph 0-20 kΩ Resolution 0,5kΩ

An acoustic warning (double sound) is additionally emitted when specific limits are exceeded (SETUP Level 4)

4.10 Indication of the battery condition

The battery condition is permanently shown on the display by indicating the remaining utilizable battery capacity. Each of the five segments represents 20% of the battery capacity. This means: if all five segments are visible, then 100% of the utilizable battery capacity are available, if no segment is visible, then 0% capacity is available. If there are only 20% of the battery capacity available, the battery condition indicator will start to flash. Then the battery should be replaced soon, or a substitute battery should be kept at hand for replacement. If no segment is visible anymore, the device will emit acoustic warning signals, as the battery-symbol is flashing. If the battery capacity falls even lower, then the device will shut down automatically for reasons of safety.

4.11 Adjustment of the stimulation impulse bandwidth

Pressing this button will activate a program option which allows you to preset the stimulation impulse bandwidth. The current intensity value and the mA-dimension will disappear from the display. Now the stimulation impulse bandwidth indicated in the upper right-hand corner of the display can be adjusted to one of the following values with the aid of the turning-knob:

0,05 ms (= 50 µs)
0,1 ms (= 100 µs)
0,2 ms (= 200 µs)
0,3 ms (= 300 µs)
0,5 ms (= 500 µs)
1,0 ms (= 1000 µs)

The adjustment-function is exited and the adjusted value is stored 1 second after the last turning motion, or if the button is pressed once more.

Please observe:
The stimulation is not interrupted during the adjustment, and the impulse bandwidth is constantly adapted according to the displayed value. It is recommended, to adjust the bandwidth of the stimulation impulses before connecting to the patient, or to conduct the adjustment in the PAUSE-mode. In addition, you should take into account that battery life is shortened considerably when using large impulse bandwidths due to a high emission of energy.

5 SETUP-functions

5.1.1 SETUP LEVEL 1: Volume control

Pressing the SETUP-button once will activate a program option which allows you to control the volume of the monitoring sound as well as of the warning sounds.
Your display will show a number appearing on the left-hand side next to the „VOL" indication (see table). This number corresponds to a certain predefined volume.
This volume may be increased or reduced with the aid of the turning-knob. A value of 4 corresponds to maximum volume. Turning the value to 0 will shut the monitoring sound off. Depressing the SETUP-button for a longer period of time (min. 2 seconds) will permanently store the volume-value currently indicated on the display. A monitoring sound is audible during the store-procedure.
The device will automatically exit the SETUP-mode and switch to the PAUSE-mode. A short depression of the SETUP-button will guide you to the next item of the SETUP-menu without having stored the volume-settings.

Volume of the monitoring- and warning sounds			
Display	**Monitoring sounds**	**Warning sounds**	
4	very loud	very loud	monitoring- and warning sounds
3	loud	loud	
2	medium	medium	
1	low	leise	
0	off	off	
A1	off	low	warning sounds only
A2	off	medium	
A3	off	loud	
A4	off	very loud	

5.1.2 SETUP LEVEL 2: Setting of the initial parameters for "Cannula mode"

Double-clicking the **SETUP**-button will activate a program option which allows you to individually preset the stimulation parameters for the cannula after the device is switched on. The parameters and the manufacturer's settings are listed below.
Depressing the **SETUP**-button for a longer period of time (min. 2 seconds) will permanently store the values currently indicated on the display. A monitoring sound is audible during the store-procedure, then you are redirected to the PAUSE-mode. A short depression of the **SETUP**-button will guide you to the next item of the SETUP-menu without having changed the existing settings (see 3.8.3).

Please observe:
The settings for the frequency and the impulse bandwidth must be adjusted in normal operation, i.e. before pressing the **SETUP**-button for the first time. The intensity of the current can still be varied in the SETUP-function with the aid of the turn-knob.

ATTENTION:
Having selected a too high initial intensity of the stimulation current may lead to painful stimulation of the patient during subsequent introduction of the cannula.

Initial parameters for stimulation using the cannula		
Cannula-parameter	**Adjustment range**	**Manufacturer's settings**
Stimulation current intensity	0 – 6,00 mA	1,50 mA
Stimulation frequency	1 Hz, 2 Hz	2 Hz
Stimulation impulse bandwidth	50 µs/100 µs/200 µs/300 µs/ 500 µs/1,00 ms	100 µs

5.1.3 SETUP LEVEL 3: Setting of the initial parameters for "Catheter mode"
A triple-click of the **SETUP**-button will activate a program option which allows you to individually preset the stimulation parameters for the catheter after the device is switched on. The parameters and the manufacturer's settings are listed below.
Depressing the **SETUP**-button for a longer period of time (min. 2 seconds) will permanently store the values currently indicated on the display. A monitoring sound is audible during the store-procedure, then you are redirected to the PAUSE-mode. A short depression of the **SETUP**-button will guide you to the next item of the SETUP-menu without having changed the existing settings (see 3.8.4).

Please observe:
The settings for the frequency and the impulse bandwidth must be adjusted in normal operation. i.e. before pressing the SETUP-button for the first time. The intensity of the current can still be varied in the SETUP-function with the aid of the turn-knob.

ATTENTION:
Having selected a too high initial intensity of the stimulation current may lead to painful stimulation of the patient during subsequent introduction of the cannula.

Initial parameters for stimulation using the catheter		
Catheter-parameter	**Adjustment range**	**Manufacturer's settings**
Stimulation current intensity	0 – 20,00 mA	2,00 mA
Stimulation frequency	1 Hz, 2 Hz	1 Hz
Stimulation impulse band-width	50 µs/100 µs/200 µs/300 µs/500 µs/ 1,00 ms	0,5ms

5.1.4 SETUP LEVEL 4: Resistance indication with warning sound notification
Pressing the SETUP-button briefly four times will activate a program option which allows you to adjust the signal sound for the patient resistance.
Here, the threshold value at which the acoustic signal for the patient resistance will change can be adjusted. Single sound pulses are emitted below this value (one single sound pulse for every patient stimulation impulse). If the resistance of the patient circuit is higher than the adjusted threshold, this is signalized acoustically with two short sound pulses for every patient stimulation impulse. The function is deactivated with the setting value 0. This setting applies for cannula and for CATH.

Value	Threshold value	Effect of the setting
0	--- kΩ	No resistance in patient circuit-threshold value monitoring: single sound pulses are emitted at all times.
1	10 kΩ	If a resistance greater than 10 kΩ is measured in the patient circuit, then a double sound pulse is emitted.
2	15 kΩ	If the measured resistance in the patient circuit is greater than 15 kΩ, then a double sound pulse is emitted.
3	20 kΩ	If the measured resistance in the patient circuit is greater than 20 kΩ, then a double sound pulse is emitted.
4	25 kΩ	If the measured resistance in the patient circuit is greater than 25 kΩ, then a double sound pulse is emitted.
5	30 kΩ	If the measured resistance in the patient circuit is greater than 30 kΩ, then a double sound pulse is emitted.

The double sound pulse is not emitted if the nominal current is not reached because, for example, the resistance in the patient circuit is far too high. This case is signalized with a single sound pulse with a deeper frequency, indicating the error.

5.1.5 SETUP LEVEL 5: Activation of the Choquet table KAN mode

ATTENTION: This setup level does not have any effect on the catheter mode.

Pressing the SETUP-button briefly five times will activate a program option which allows you to adjust the pulse width for the cannula mode. Here, the pulse width selection mode can be selected by means of the turnable key button. You can either choose manual selection (Selection 0) or automatic selection of the pulse width according to the Choquet table (Selection 1).

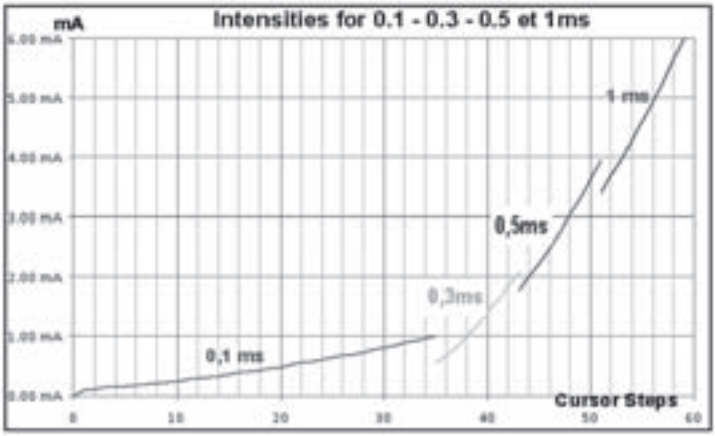
In the manual mode, the pulse width can be defined by the user. In the automatic mode, the pulse width is dependent on the pulse current and can not be selected and changed directly.

Value	Display	Setting of the pulse width for KAN
0	„SET“.	The KAN pulse width is set manually.
1	„AUT“.	The KAN pulse width is determined automatically, depending on the KAN pulse current.

5.1.5.1 MultiStim SWITCH Feugeaus/Choquet

Big distance nervous location

MULTISTIM SWITCH has a particular function allowing big distance nervous location. The rotation of the cursor habitually used to make vary issued intensity involve not only modifications of issued intensity, but also of stimulus duration. For the final positioning of the needle near the nerves, it is important to keep a stimulus duration at 0,1ms value which is validated by scientific data and by the common practice. On the contrary, during the initial detection of nerves, it is desirable to have a maximum of range of detection got with big stimulus durations (0,3 or 0,5 or 1ms).



During the initial research of nerve, for a maximum stimulation reach, the cursor is therefore turned right completely: 1ms and 6mA.
Then, according to the rotation of the cursor towards the left, the stimulus duration automatically decrease from 1ms to 0,5ms then to 0,3ms and to finish to 0,1ms which is the value used in the classical procedure approach. Issued intensities were calculated to avoid jolts between each stimulus duration, so that increase or decrease of the amplitude of neuromuscular responses keeps linear and smooth. So without tiring manipulation and in automatic way, the operator begins a target neuromuscular response from the maximum distance detection allowed by his neurostimulator. Then during rotation to the left of the cursor (related to the improvement of neuromuscular stimulation) parameters (intensity and stimulus durations) are decreased up to a stimulus duration of 0,1ms. The operator is then in the classical positioning procedure.

6 Error messages
After switching the MultiStim SWITCH on, the device will automatically carry out a self-test. If the device recognizes a faulty function during the self-test or during normal operation, the corresponding error code will be indicated on the LCD. After that, the device is not operational anymore and may not be used further. The device must by all means be returned to the manufacturer for repair. Please ask your dealer if you need assistance, he will be glad to help you.

Please indicate the error code in the repair order. The following error codes are possible:
E1 Program memories faulty
E3 Faulty pulse voltage
E4 Faulty internal current setting
E5 Faulty pulse current (perhaps damaged cable)
E6 Battery is empty

7 The battery
The proper charge of the battery must be examined regularly. Proceed as described in section Indication of battery condition. A battery capacity of less than 20 % (1 segment visible) will cause the battery condition indicator to start flashing, and the battery should be replaced. If the battery capacity drops to a value which will impair the functionality, the device will switch itself off automatically. If the MultiStim-device is not used for a longer period of time, the battery must be removed to avoid leakage.

7.1 Battery replacement
The battery compartment is located on the bottom side of the MultiStim SWITCH. Open the compartment by unscrewing the screw situated on the back side of the device with a suitable tool. Replace the battery. Be sure to check for correct polarity. Exclusively use 9 V alkali-manganese batteries (e.g., VARTA 4022, DURACELL MN 1604). With these batteries you will obtain a prolonged duration of functionality and extremely reliable operation.

Attention:
In case of battery leakage, the device should not be operated anymore for safety reasons. If acid leaks into the inside of the device, essential functional assemblies may be damaged or impaired. The device must be returned to the manufacturer for inspection.

8 Cleaning and disinfection of the device
Only use soft, moistened cloths to clean and disinfect the device and the electrode cables. Water, soapsuds or denaturated alcohol are particularly suitable for this purpose. Take care that no water or moisture enters into the device. Alcohol, or commercially available alcohol based disinfectants containing no methyl alcohol may be used for disinfection.

Attention:
The following agents may not be employed for cleaning purposes: trichlorethylene, acetone, butanone (methyl ethyl ketone), benzene, methyl alcohol or cellulose thinner (Cellosolve, etc.).

9 Maintenance and technical safety checks
Check proper condition of the device and the accessories before use. A faulty device may not be operated. Electro-medical devices may only be repaired by the manufacturer or by an institution expressly authorized by the manufacturer. A detailed description of the fault is to be included in the repair order.

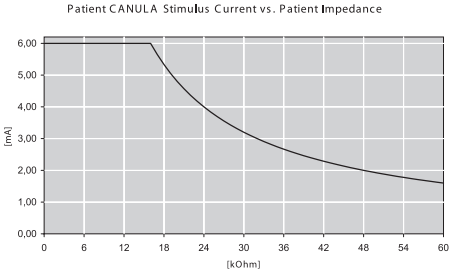
9.1 Technical safety checks
Technical safety checks are not required. The functioning of the device is to be checked according to the details given in the operating instructions before every application.

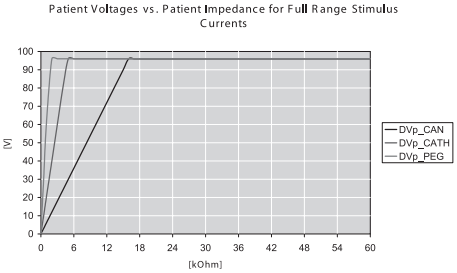
9.2 Device roster book in accordance with MPG
The operator of class IIa technical medical equipment in accordance with MPG is required to keep a device roster book.
The following entries are to be made into the device roster book:
1. Date and time of the functionality test before the first operational use of the device
2. Date and time of the familiarization, as well as the names of the persons familiarized with the operation of the device
3. Date and time of the performance of the prescribed technical safety checks (if applicable), and of maintenance measures, as well as the name of the person or the company which has carried out the measures
4. Date, time, type and consequences of malfunctions and repeated operating errors of the same type
   The CE-conformity certificate is component of the device roster book.

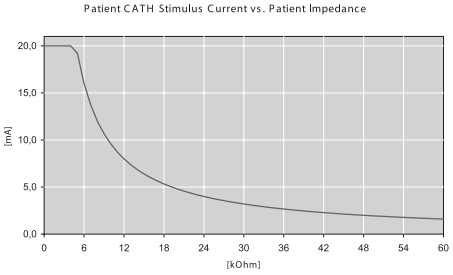
10 Accessories and spare parts list for MultiStim
The following PAJUNK® products may be used as genuine accessories for the MultiStim devices, and they are available in a wide variety of measurements:
- All PAJUNK® stimulation cannulae for one-time/single use nerve block anesthesia.
- All PAJUNK® stimulation cannulae for continuous nerve block anesthesia.
- Stimulatable PAJUNK® catheters for continuous peripheral nerve blocks.
- Main patient line for connecting stimulation cannulae, stimulation catheters and commercially available, CE-labeled adhesive stimulation electrodes.
- Various extensions and adapter lines.

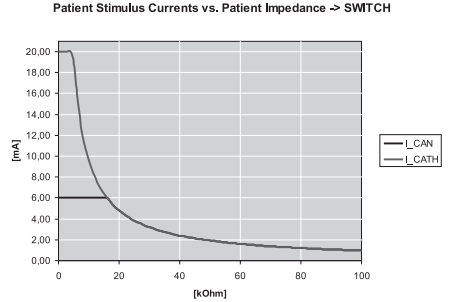
11 Signal gradients, impulse patterns and power diagrams
For all signal gradients, stimulation is effected by means of monophase negative square pulses. Electric energy is emitted only for the duration of the stimulation impulse. Therefore, please note, that the comparison of nominal/effective current (indicated by »=« or »≠«) is exclusively carried out during the period in which the negative stimulation impulse is emitted. This status is saved and displayed during the interpulse period until the next impulse is emitted.

Pulse form: square pulse
Frequency: 1 Hz or 2 Hz
Breadth according to selected output



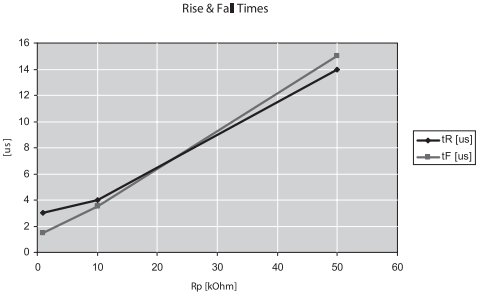






11.1 Build-up and fall times

The build-up and fall times measured effectively typically amount to **4 µs ± 2 µs**.
The build-up and fall times hardly depend on the adjusted pulse width (PW) and pulse frequency (PF). They are to a lesser degree dependent on the current amplitude and on the select channel {KAN, CATH}. Their greatest correlation is with the patient resistance (Rp). The upper limiting values apply for the nominal resistance range [1 kΩ ...12 kΩ]. For greater resistances, the times will increase as indicated in the following illustration. At 50 kΩ, values exceeding 15 µs are possible (particularly for fall time).



12 Notes, warnings

If you have adjusted a stimulation current intensity > 0.06 mA or > 0.2 mA during operation in the CATH mode and 0.00 mA are indicated in the display mode »Indication of the stimulation current intensity actually flowing through the patient«, the following circumstances may be on hand due to the tolerances Full Scale causing this fault:

- there is no cable or a faulty stimulation cable connected,
- the electrodes are not attached correctly, or they are not attached at all,
- the electrical resistance of the patient tissue is too high.

The user can use every commercially available CE-labeled self-adhesive electrode for medical purposes.

Do not use the product in case of commun incompatibilities and/or interactions of the material.

The increased attention of the user is required at effective current densities beyond 2 mA/cm^2 for all adhesive electrode surfaces.

A theoretical maximum current density of 32.4 mA/mm^2 can be reached if the stimulation cannula is used!

Only perform wiping disinfection, no spraying disinfection under all circumstances! Avoid condensation!

13 Electromagnetic compatibility (EMC)
MultiStim SWITCH complies with the standard for electromagnetic compatibility (EMC) EN 60601-1-2:2007.
The tests for electromagnetic compatibility were performed by: Nemko GmbH & Co. KG – Testing- and Certification Authority – Reetzstrasse 58 - 76327 Pfinztal - Germany

Guidance and Manufacturer's Declaration - Electromagnetic Emissions (according to EN 60601-1-2:2007; 5.2.2.1 Table 1)		
MultiStim SWITCH is intended for use in the electromagnetic environment specified below. The customer or user of the MultiStim SWITCH should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emission according to CISPR 11	Group 1	MultiStim SWITCH 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 emission according to CISPR 11	Class B	The MultiStim SWITCH 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 according to IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions according to IEC 61000-3-3	Not applicable	

Guidance and Manufacturer's Declaration - Electromagnetic Emissions (according to EN 60601-1-2:2007; 5.2.2.1 Table 2)			
MultiStim SWITCH is intended for use in the electromagnetic environment specified below. The customer or user of the MultiStim SWITCH should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) according to 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 %.
Electrical fast transient / burst according to IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	Not applicable	Not applicable
Surges according to IEC 61000-4-5	± 1kV line(s) to line(s) ± 2kV line(s) to earth	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines according to IEC 61000-4-11	< 5% U_r (>95% dip in U_r) for 0,5 cycle 40% U_r (60% dip in U_r) for 5 cycles 70% U_r (30% dip in U_r) for 25 cycles < 5% U_r (>95% dip in U_r) for 5s	Not applicable	Not applicable
Power frequency (50/60 Hz) magnetic field according to 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 cornmercial or hospital environment.
U_r is the a.c mains voltage prior to application of the test level.			

Guidance and Manufacturer's Declaration - Electromagnetic Emissions (according to EN 60601-1-2:2007; 5.2.2.2 Table 3)			
MultiStim SWITCH is intended for use in the electromagnetic environment specified below. The customer or user of the MultiStim SWITCH should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF according to IEC 61000-4-6	$3V_{rms}$ 150 kHz to 80 MHz outside the ISM-bands[a] $10V_{rms}$ 150 kHz to 80 MHz in the ISM-bands[a]	Not applicable Not applicable	Portable and mobile RF communications equipment should not be used no closer to any part of the MultiStim SWITCH, including cables, than the recommended separation distance calculated from the equation applicable to frequency of the transmitter. Recommended separation distance: $d = 3,5/U1\sqrt{P}$ for 150kHz to 80MHz $d = 12/U1\sqrt{P}$ for 80MHz to 800MHz $d = 23/U1\sqrt{P}$ for 800MHz to 2,5GHz 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)[b].
Radiated RF according to IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10V/m	Field strengths from fixes RF transmitters, as determined by an electromagnetic site survey,[c] should be less than the compliance level in each frequency range.[d] Interference may occur in the vicinity of equipment marked with the following symbol: 
Note 1	At 80 MHz and 800 MHz, the higher frequency range applies.		

Note 2	These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people

a) 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.

b) The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in the calculating the recommended separation distance for transmitters in these frequency ranges.

c) Field strengths from fixed transmitters, such as base stations of 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 MultiStim SWITCH is used exceeds the applicable RF compliance level above, the MultiStim SWITCH should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the MultiStim SWITCH.

d) Over the frequency range of 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

Limitation of Warranty/Disclaimer
PAJUNK® GmbH Medizintechnologie guarantees to manufacture its products with greatest possible care.
THIS IS THE ONLY VALID GUARANTEE, AND IT SHALL REPLACE ALL OTHER WARRANTIES GIVEN AND REPRESENTATIONS MADE. It shall be observed, that due to the biological differences of the persons to be treated, no product is always absolutely effective under all environmental conditions and circumstances. Components of the sets manufactured by PAJUNK® GmbH Medizintechnologie, as well as their individual components are compatible with each other. Before the use of individual products/sets of PAJUNK® GmbH Medizintechnologie in connection with products from other companies, the user must ensure the application-specifical compatibility of the individual products. PAJUNK® GmbH Medizintechnologie has no influence on the application of the product, on the diagnosis of the patient and on the handling of the product outside of the company. PAJUNK® GmbH Medizintechnologie can neither guarantee a beneficial nor a complication-free application of the product. PAJUNK® GmbH Medizintechnologie therefore assumes no liability for damages and costs.
PAJUNK® GmbH Medizintechnologie will replace products showing a deficiency, which is to be represented by PAJUNK® GmbH Medizintechnologie. Employees of PAJUNK® GmbH Medizintechnologie shall not be authorised to amend the aforementioned conditions, to extend liability, or to accept or consent to additional product-related obligations.

General Notes
In accordance with U.S. law, this product may only be sold by a physician or upon his prescription.
All rights to change or modification of the product shall remain reserved.
Products are free of latex.
Made in Germany – manufactured by PAJUNK® GmbH Medizintechnologie

Storage conditions

Symbol for:

- Keep away from sunlight
- Keep away from rain
- Consult instructions for use
- Do not use if package is damaged
- Do not resterilize
- STERILE EO — Sterilized using ethylene oxide
- Do not re-use
- CE 0124 — Manufactured and monitored acc. to European Legislation for Medical Devices
- CE — Manufactured acc. to European Legislation for Medical Devices
- PHT — Does not contain Phthalates (acc. to sec. 7.5 of Annex I 93/42/EWG)
- PHT — Does contain Phthalates as identified
- LATEX — Does not contain latex
- LATEX — Contains latex
- Non-pyrogenic
- Σ_n — Pieces
- REF — Catalog number, Unique identifier
- LOT — Batch-Identification
- „Use-by"-date
- Date of manufacture
- Device Type "BF"

Catalogue Excerpt/Examples of Products

Product	Item No.	PU
MultiStim SWITCH in equipment case and SWITCH patients cable for the connection of the cannulae and the StimuLong catheter	1151-94-40	
Patients cable for Multistim SWITCH	1151-94-07	
Cable for connection of stimulating cannulae	1151-94-05	
Extension cable, autoclavable	01151-861F	
Extension cable, disposable	01151-861Q	

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