Stimuplex® Dig RC

Nerve Stimulator for
Regional Anesthesia,
Regional Analgesia, Neurology

User manual

B BRAUN

Caution!

This User's manual contains important information regarding the use of the **Stimuplex® Dig RC** nerve stimulator. Please read this manual thoroughly before using the unit in order to become familiar with its functions. A sound knowledge of anatomy and block technique together with the correct use of the **Stimuplex® Dig RC** is essential for successful neural blockade.

For requests please contact:

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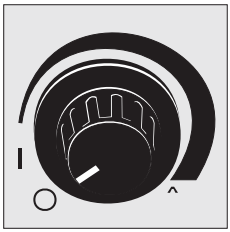
Current Regulator

To turn on the device, move the current regulator clockwise from "0" to "I".

To increase the current, turn the dial in the direction of the arrow.



Digital Display

The digital display indicates current settings. The set value flashes when the circuit is open. If the cable contacts are shorted, the flashing will stop because the circuit is closed.

It is also closed when the needle is connected to the device and inserted into the patient, allowing the current impulse to flow through the patient via the skin electrode, back to the device. The scale in the lower region of the current regulator has been expanded to allow fine adjustment of current in 0.01 mA increments using the digital display.

Fine adjustment allows optimal location of the needle in relationship to the nerve and, thus, the highest success rates for nerve blocks. The stimulus pulse current is held constant via an electronically-controlled constant current generator despite variable tissue resistance. If the control range of the constant current generator is exceeded (higher resistance due to faulty contact), the digital display will flash.

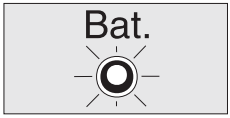
Signal Tone

Simultaneously to every current impulse you can recognize a short signal when circuit is open. On a close circuit a longer signal is heard. The frequency of the signal is proportional to the amplitude of the set current and flowing current respectively.

Red "Bat" LED

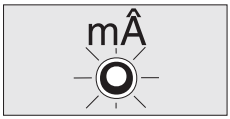
The red LED is the battery voltage check light.

It should flash for a short time when the unit is switched on, but if it flashes continuously, the battery needs to be replaced.



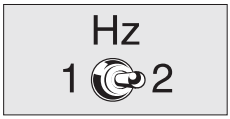
Yellow LED

With a closed circuit this LED flashes simultaneously with each impulse and thus indicates the pulsed current (0.1 mA and up) that is flowing.



Frequency Switch

Toggle switch for switching the impulse frequency to 1 Hz or 2 Hz.

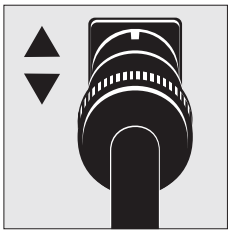


Integrated Electrode Cable

The electrode cable is firmly connected with the device.
For replacement please see Technical Service Manual.

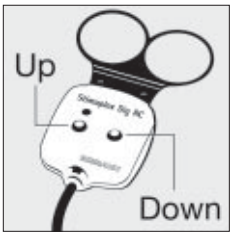
Connecting socket for Remote Control

Tripolar plug of the **Stimuplex® Dig RC.** When the Remote Control is connected to the device the initial value of 0.2 mA (± 10%) is indicated on the display.



Remote Control

Single-handed Remote Control with finger rings to be placed onto the palm under the sterile glove in order to set the required current in a sterile way.
– "Up" button: 5.0 mA final value (20 sec.)
– "Down" button: 0.2 mA initial value (20 sec.)
– Finger rings for ideal fixation



Replacement

Please see Service Manual.

Check the external condition of the device

- Housing clean and undamaged
- Lables legible
- Dials (current regulator, frequency switch) functional
- Cable set functional

Function Test

Turn on the device (current regulator to "I"):
- red LED "Bat" will flash briefly for control
- digital display shows initial value 0.2 mA
- brief audio signal (beep) sounds in synchrony with selected frequency (e.g. 1 Hz = 1 signal/second)

Slowly increase the current regulator:
- digital display flashes and shows the present current value
- maximum current available is 5.0 mA
- the frequence of the signal changes proportionally to the preselected current value

The yellow LED should not light up at any setting during an open circuit.

To check the Electrode Cable

Short the contacts at the ends of the electrode cables:
- insert the closed alligator clip into the black socket in order to close the circuit
- the yellow LED flashes and the digital display stops flashing and indicates the current
- prolonged signal tone

If the yellow LED does not light when the cable ends are shorted, the cable connection is defective and the cable set should be replaced. (For replacement of the integrated electrode cable see point 4 of the Technical Service Manual.)
Functional safety should be verified before each use.
In case of functional failure, the unit should be tested by technical staff according to the check-list as follows.

To check the Remote Control

After the Stimuplex® Dig RC short test connect the Remote Control to the nerve stimulator. Turn on the device by using the current regulator:
– the digital display shows the initial value 0.20 mA

Press the buttons "Up"/"Down" in succession and the pitch of the audio signal will change proportionally to the preselected current value:
– the digital display shows the preselected current

1. Application without Remote Control

1.1 Verify the **Stimuplex® Dig RC's** functional safety (short test).

1.2 Connect the electrode cable to the skin electrode using the red alligator clip (anode).

1.3 Connect the socket of the **Stimuplex®** needle to the insulated jack at the electrode cable. (If the **Contiplex® A** cannula is used, the socket of the **Contiplex® A** connection cable is connected to the tube in the needle hub.
The black plug from the electrode cable is inserted into the insulated jack of the connection cable.)

1.4 Switch the **Stimuplex® Dig RC** unit by turning the current regulator and select the desired current (approx. 1 mA):
- digital display flashes
- short signal tone to be heard

1.5 Insert the needle at the puncture site:
- the digital display stops flashing and displays the value of the current flow
- prolonged signal tone to be heard, the tone level is proportional to the set current
- the yellow LED flashes in synchrony with each current impulse. If the LED does not flash, the circuit is interrupted (defective adhesive electrode, broken cable, etc.)

1.6 Advance the needle in the direction to the nerve until distinct muscle contractions occur in the innervated area.

1.7 Reduce the current by using the current regulator and optimize the needle position until muscle contractions occur at lower current levels.
If necessary rotate the needle to optimize its position. The tip of the needle has reached an optimal position when noticeable contractions occur at a current of approximately 0.2-0.5 mA.

1.8 Inject a test dose of local anaesthetic (1-2 ml). Muscle contractions will cease almost immediately (5-10 sec.).

1.9 After the entire dose of local anaesthetic has been administered, no contractions should occur even with an increase of current.

Caution:

If the digital display flashes (short signal tone to be heard) with an increased current, the skin electrode does not have sufficient skin contact and the actual current flow is lower than the displayed value.
Apply a new skin electrode or reduce the current value until the digital display stops flashing (prolonged signal tone to be heard). The displayed value now corresponds to the actual current flow.

2. Application with Remote Control

2.1 Verify the **Stimuplex® Dig RC's** functional safety (short test).

2.2 Connect the electrode cable to the skin electrode using the red alligator clip (anode).

2.3 Connect the socket of the **Stimuplex®** needle to the insulated jack at the electrode cable. (If the **Contiplex® A** cannula is used, the socket of the **Contiplex® A** connection cable is connected to the tube in the needle hub.
The black socket from the electrode cable is inserted into the insulated jack of the connection cable.)

2.4 Insert the tripolar plug of the Remote Control into the output socket of the **Stimuplex® Dig RC's** front panel.

2.5 Switch on the device and carry out a short test (see page 10):
- digital display flashes
- short signal tone to be heard

2.6 Slip the Remote Control with its finger rings on two fingers of the left hand – left-handers onto the right – in order to position the Remote Control on the palm.
Put a sterile glove on the hand **which is holding** the Remote Control, **covering it with the glove** in a way that the buttons can be operated easily either with the index finger and the middle finger or with the middle finger and the ring finger. (Carry out a short test before using). **Making sure that** the cable of the Remote Control is orientated and fixed in direction of the wrist to avoid contact with the sterile area.

2.7 Test confirmation to be carried out whilst watching the tone level of the signal tone:
- button "Up" → increasing current → increasing signal tone level
- button "Down" → decreasing current → decreasing signal tone level

- set required initial current (approx. 1 mA)
- insert the needle at the appropriate puncture site

Advance the needle slowly towards the nerve which is to be blokked whilst pushing the "Down" button (see par. 1.5 to 1.7).
If required the position of the needle may be optimized by pressing the "Up" or "Down" buttons whilst observing the subsequent muscular contractions and then the local anaesthetic is injected as described in par. 1.8 and 1.9.

Note

When the Remote Control is connected, the setting of the current is exclusively controlled by the "Up" and "Down" buttons of the Remote Control, whereas the current regulator knob on the nerve stimulator, in this mode functions only as an "On"/"Off" switch.
In case the current setting is required to be operated only by the current regulator knob the connection cable of the Remote Control needs to be disconnected.
Moreover the nerve stimulator **Stimuplex® Dig RC** needs to be switched off by the current regulator knob and then switched to "On" again.

When using the nerve stimulator Stimuplex® Dig RC in regional Anaesthesia and regional pain therapy peripheral nerves are stimulated and located via electrical current impulses flowing through an insulated needle. The stimulation current is concentrated at the uninsulated tips. Accurate localisation of nerves is only possible when during the pulsating discharge of minimal current (0.2-0.5 mA), nerve stimulation causes visible muscle contraction.

Important Notes:

- To avoid nerve lesions, use needles with a short bevel (**Contiplex® cannulae** or **Stimuplex® needles)**. To avoid tissue entering the needle, fill it with saline or local anaesthetic, which then act like a stylet.
- The recommended disposable ECG tape skin electrodes are commercially available, high-grade, CE-marked products. These include a silver/silver chloride sensor precoated with gel. To achieve optimum nerve stimulation with **Stimuplex® Dig RC**, always make sure the electrodes are undamaged and have not dried out.
- Avoid traumatised areas when attaching the skin electrodes to the patient.
- This device is not approved for insertion in or around the heart.
- **Stimuplex® Dig RC** may be used only by trained staff. Instruction can be provided by employees of the distributor or by the biomedical engineer of the hospital.
- Functional safety and appropriate device status must be verified before operating the unit (see short test).
- **Caution!** Not to be used for patients with cardiac pacemakers because malfunction of the pacemaker may occur.
- This device must not be connected to AC power: only a 9 volt battery may be used as a power supply.
- Do not use **Stimuplex® Dig RC** in conjunction with other devices.

- If the patient is simultaneously connected to a high-frequency surgery device, burns under the stimulation current electrodes can result.

- Shortwave or microwave therapy devices located near the unit (i.e. within 1 m) can cause fluctuations in the stimulation current output values.

Troubleshooting

Yellow "closed circuit" LED does not light:
- if it is defective (see functional check)
- if the cable connections to the needle or electrode are defective

The **digital display** flashes (short signal tone) when the circuit is closed:
- if the skin electrode does not have sufficient contact with the patient's skin or the cable connection is defective

Red "Bat" LED flashes (continuously):
- if battery voltage drops below 5,6 volts. A blockade which is in progress can be continued, but the battery must be replaced afterwards. (Care and Maintenance, p. 12)

There is no audio signal after the unit is switched on:
- if the battery is low. Replace the battery

Care and Maintenance

The **Stimuplex® Dig RC nerve stimulator** is essentially maintenance-free. The plastic housing and cables can be disinfected with common disinfectants such as **Meliseptol® or Meliseptol® Rapid**.

Battery replacement:
The battery should be replaced if the red LED flashes continuously. Loosen the safety screw next to the battery lid on the bottom of the unit. Open the battery lid and replace the battery. Use only a 9 volt battery, type 6LR-61. Close the battery lid and tighten the safety screw.

Note:
For long term storage of the device, remove the battery.
Repairs may be carried out only by manufacturer-authorized service personnel. Service documents please see **Technical Service Manual.**

Only use the equipment with accessories authorized by the manufacturer (see page 18 and 19). EU contries: If other prducts are used, a declaration must be supplied in accordance with article 12 of Council Directive 93/42 EEC.
Other contries: Please refer to national law.

Warranty

Stimuplex® Dig RC is guaranteed for two years against defects in material and workmanship if the device is used in accordance with the operating instructions.

Wear and tear parts such as electrode cables, batteries, etc. are not covered by this warranty. In addition, relevant sections of our General Sales Conditions (Allgemeine Verkaufsbedingungen) apply particularly in chapter IV No. 8.

For usage of Stimuplex® Dig RC please refer to the individual local law restricts (eg. maintaining a logbook, etc.).

In case of conducting safety checks on the device, please refer to the enclosed inspection sheet.

Declaration of Conformity for Medical Devices

according to COUNCIL DIRECTIVE 93/42/EEC
of 14 June 1993 concerning medical devices

Manufacturer	B. Braun Melsungen AG Carl-Braun-Straße 1 D-34209 Melsungen
Product Group	Stimuplex DIG RC Nerve stimulator set for plexus anaesthesia (incl. software and accessories)
Conformity Assessment Procedure	according to ANNEX II of the COUNCIL DIRECTIVE
Classification	according to ANNEX IX of the COUNCIL DIRECTIVE class IIa
Notified Body	TÜV Product Service GmbH Ridlerstraße 65 D-80339 München Identification number 0123
Date of first CE-marking	1994-12

We herewith declare that the above mentioned product group meets all requirements of the COUNCIL DIRECTIVE 93/42/EEC concerning medical devices which apply to it.

Melsungen, 2002-11-15

B. Braun Melsungen AG

i. V.

J. Heil
Quality Management

Dr. M. Zügel
Board of Directors

Hauser, S., & B. Landauer. 1988
Axilläre Blockade des Plexus brachialis mit Hilfe eines Nervenstimulators.
Anästh. Intensivmed. 29: 184-189.

Hauser, S., & B. Landauer. 1988
Die Plexusanästhesie – Wie effizient ist ein Nervenstimulator?
9. Internat. Symposium für Anästh., Notfall-, Schmerz- und Intensivmed. in St. Anton.

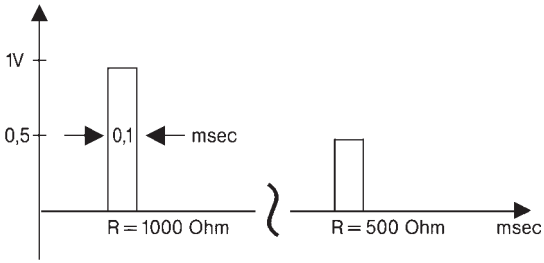
Kaiser, H., H. C. Niesel & L. Klimpel. 1988.
Einfluß der Reizstromstärke der Nervenstimulation auf Latenz und Erfolg der hinteren Ischiadikusblockade.
Regional-Anästhesie II: 92-97

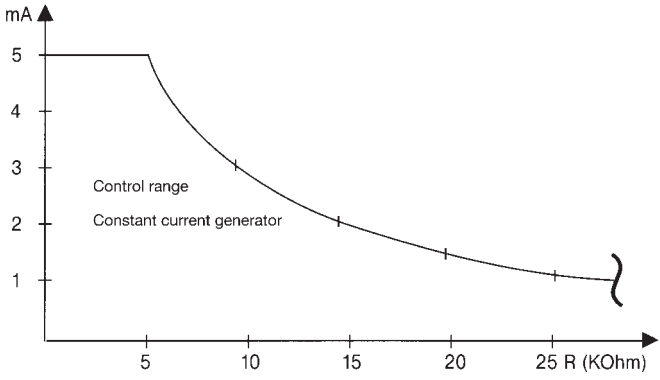
Köster, F. 1987.
Vergleich zweier Verfahren zur axillären Plexusanästhesie:
1. Pervasculäre Injektion mit einer 45°-Kurzschliffkanüle nach der „Loss of Resistance"-Technik
2. Anästhesierung der vier Hauptnerven des axillären Plexus brachialis mit Hilfe eines elektrischen Nervenstimulators.

Dissertation, Universität Köln.

Mehrkens, H.-H., W. Schleinzer & P. Geiger. 1987.
Successful peripheral regional anaesthesia by aid of an improved nerve stimulator.
Scientific Paper No.: 063, ESRA, Paris

Impulse amplitude	0.20–5.0 mA constant current infinitely adjustable
Impulse frequency	1 Hz and 2 Hz, switchable
Impulse width	0.1 msec
Impulse form	Monophasic rectangular impulse
Digital display	3 digits from 0.20–4.99 mA 2 digits from 5.0 mA
Resolution	0.01 mA
Accuracy	± 10% ± 1 digit
Output voltage	40 Vp max.
Battery	9 volt, type 6LR-61
Electrode cable	integrated
Monitoring equipment:	
Symbol explanation	Degree of protection against electric shock, type BF
Open circuit	● brief audio signal (beep) indicates an open circuit ● flashing digital display indicates the preselected current value
Closed circuit	● prolonged audio signal indicates closed circuit ● frequency of the signal changes proportionally to the flowing current ● flashing digital display indicates an exceeding of the control range (actual flowing current < value indicated). ● Yellow LED indicates the current pulse
Battery check	red LED
Case (Housing)	Plastic
Mounting bracket	Foldable
Dimensions	12,6 x 7,2 x 3,8 cm
Output impulse	Current 1 mA at 1000 and 500 ohms load resistance





Constant current depending on load resistance

Option:

Single-handed Remote Control for sterile use of the **Stimuplex® Dig RC**

Fixing:	Via finger rings on the palm
Sterility:	To be placed under the sterile glove
Adjustment:	Set required current value by pressing the buttons "Up" or "Down"
Connection:	Via steering-cable to the tripolar output socket on the front panel of the **Stimuplex® Dig RC**
Case (Housing):	Plastic

Stimuplex® Dig RC and Accessories, Stimuplex® needles and Contiplex® cannulae sets

Product description	Cannula Ø x length	Code number	Sales unit
Stimuplex® Dig RC nerve stimulator - with integrated electrode cable for Stimuplex® D, Stimuplex® A and Contiplex® D		4891996B	1
Remote Control for sterile one-hand-operation		4892216B	1
Finger rings		4892224B	1
Electrode cable for Stimuplex® D, Stimuplex® A and Contiplex® D		4892917B	1
Adaptor cable for Contiplex® A		4892925	1
Stimuplex® D, 15° bevel			
D 25/035; 25 G x 1 1/3"	0.5 x 35 mm	4894103N	25
D 25/055; 25 G x 2 1/8"	0.5 x 55 mm	4894111N	25
D 26/040; 23 G x 1 1/2"	0.6 x 40 mm	4894120N	25
D 26/070; 23 G x 2 3/4"	0.6 x 70 mm	4894138N	25
D 27/050; 22 G x 2 "	0.7 x 50 mm	4894146N	25
D 27/080; 22 G x 3 1/8"	0.7 x 80 mm	4894154N	25
D 27/120; 22 G x 4 3/4"	0.7 x 120 mm	4894162N	25
D 29/150; 20 G x 6 "	0.9 x 150 mm	4894170N	25
Stimuplex® D, 30° bevel			
D 17/040; 22 G 1 1/2"	0.7 x 40 mm	4894189N	25
D 17/050; 22 G 2 "	0.7 x 50 mm	4894197N	25
D 17/080; 22 G 3 1/8"	0.7 x 80 mm	4894200N	25
Stimuplex® A, 30° bevel			
A 25, 24 G x 1"	0.55 x 25 mm	4894251	25
A 25, 22 G x 1"	0.70 x 25 mm	4894539	25
A 35, 22 G x 1 1/3"	0.70 x 35 mm	4894367	25
A 50, 22 G x 2"	0.70 x 50 mm	4894502	25
A 50, 21 G x 2"	0.80 x 50 mm	4894375	25
A 100, 21 G x 4"	0.80 x 100 mm	4894260	25
A 150, 20 G x 6"	0.90 x 150 mm	4894278	25
Contiplex® D cannula, 15° bevel			
D 28/055/C; 18 G x 2 1/8"	1.3 x 55 mm	4894219N	25
D 28/110/C; 18 G x 4 3/8"	1.3 x 110 mm	4894294N	25
Contiplex® D cannula, 30° bevel			
D 18/055/C; 18 G x 2 1/8"	1.3 x 55 mm	4894227N	25

Product description	Cannula Ø x length	Code number	Sales unit
Contiplex® D, Sets			
– with Contiplex® Catheter 0,41 x 0,71 x 400 mm			
with cannula D 20/033/C, 20 G x 1 $^1/_3$", 15° bevel	1.1 x 33 mm	4892402N	10
with cannula D 20/055/C, 20 G x 2 $^1/_8$"	1.1 x 55 mm	4892410N	10
– with Contiplex® Catheter 0,45 x 0,85 x 400 mm			
with cannula D 28/055/C, 18 G x 2 $^1/_8$", 15° bevel	1.3 x 55 mm	4894235N	10
with cannula D 18/055/C, 18 G x 2 $^1/_8$", 30° bevel	1.3 x 55 mm	4894243N	10
– with Contiplex® Catheter 0,45 x 0,85 x 1000 mm			
with cannula D 28/80/C, 18 G x 3", 15° bevel	1.3 x 80 mm	4895819N	10
with cannula D 28/110/C, 18 G x 4 $^3/_8$", 15° bevel	1.3 x 110 mm	4894391N	10
Contiplex® A cannula with 30° bevel			
A 55/C; 18 G x 2 $^1/_8$"	1.3 x 55 mm	4893643	25
A 45/C; 18 G x 1 $^3/_4$"	1.3 x 45 mm	4893611	25
Contiplex® A Catheter Set, 30° bevel			
– with polyamide catheter 0,45 x 0,85 x 400 mm			
needle A 55/C; 18 G; 30° bevel	1.3 x 55 mm	4893638	10
needle A 45/C; 18 G; 30° bevel	1.3 x 45 mm	4893603	10
Contiplex® Tuohy Set			
– with Contiplex® Catheter 0,45 x 0,85 x 1000 mm and sideport			
with cannula 18 G x 1 $^1/_2$", insulated Tuohy type CNB 150	1.3 x 38 mm	331695	12
with cannula 18 G x 2", insulated Tuohy type CNB 200	1.3 x 52 mm	333691	12
with cannula 18 G x 4", insulated Tuohy type CNB 400	1.3 x 102 mm	331693	12
with cannula 18 G x 6", insulated Tuohy type CNB 600	1.3 x 152 mm	331694	12

CE 0123

Caution:
Federal (U.S.A.) law restricts
this device to sale by or on the order
of physicians.

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