

# STIMUPLEX® Dig RC Nerve Stimulator



## OPERATION MANUAL

**B | BRAUN**

# Contents

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Table of Contents	Page
<b>I. Introduction</b>	
Introduction .....	1
Warranty .....	2
Intended Use .....	5
<b>II. Product Description</b>	
Design and Functions .....	7
Remote Control .....	9
Technical Data .....	10
<b>III. Principles of Operation</b>	
Operation without Remote Control .....	12
Operation with Remote Control .....	14
<b>IV. Care and Maintenance</b>	
STIMUPLEX Dig RC Short Test .....	16
To Check Remote Control .....	17
Cleaning .....	17
Battery replacement .....	17
Replacement of the Electrode Cable .....	18
Instructions for Electrode Cable Replacement .....	18
Troubleshooting .....	19
Service and Technical Support .....	20
<b>V. Technical</b>	
Technical Testing .....	21
Short Test .....	21
Cable Continuity Test .....	22
Functional Test .....	23
<b>VI. Forms</b>	
Customer Return Form .....	24

## Introduction

As the popularity of regional anesthesia continues to escalate, there is an expanded patient population receiving nerve block anesthesia for surgery, chronic pain, or prolonged pain relief.

The use of a peripheral nerve stimulator can be an aid to the clinician during difficult or complicated nerve blocks. Nerve stimulators can also be a valuable tool when teaching inexperienced clinicians. A nerve stimulator is only an aid, and its use is no substitute for a knowledge of basic anatomy or regional block techniques. A nerve stimulator may be indicated for blocking any peripheral nerve, nerve plexus, or any cranial nerve having a motor component.

## CAUTION:

This operation 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.

Rx only

## For additional Product information Please Contact:

B. Braun Medical Inc.  
Clinical and Technical Support  
824 Twelfth Avenue  
P.O. Box 4027  
Bethlehem, PA 18018  
800-854-6851  
[www.bbraunusa.com/stimuplex](http://www.bbraunusa.com/stimuplex)

# Introduction

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## Warranty

B. Braun Medical Inc., hereby warrants to the original Customer that each STIMUPLEX Dig RC shall be free from defects in material and workmanship when used and maintained in accordance with the Operation Manual. All warranties shall expire one year from the date of shipment from B. Braun.

B. Braun's sole obligation, and Customer's sole remedy, for a breach of the foregoing warranty shall be, at B. Braun Medical's option, either to repair or replace the defective STIMUPLEX Dig RC at no charge.

Customer shall bear all risk of loss or damage to returned goods while in transit. In the event no defect or breach of warranty is discovered by B. Braun upon receipt of the product, the product will be returned to Customer at Customer's expense and Customer will reimburse B. Braun for the transportation charges, labor and associated charges incurred in testing the allegedly defective product. The defective product should be returned promptly to B. Braun Medical, properly packaged, postage prepaid, with appropriate identification per the instructions of B. Braun Clinical and Technical Support. All services, not covered under the warranty, will be billed at B. Braun's then current rates.

B. Braun's warranty hereunder shall not apply if: (i) the STIMUPLEX Dig RC is not used in accordance with the instructions in the Operation Manual; (ii) any repairs, alterations or other work has been performed by Customer or others on such item, other than work performed with B. Braun's authorization and according to its approved procedures (i.e. Changing cables per 'Instructions for Electrode Cable Replacement'); (iii) the alleged defect is a result of abuse,

# Introduction

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misuse, improper maintenance, accident or the negligence of any party other than B. Braun; or (iv) used with any needles or devices not manufactured by B. Braun Medical or not intended for use with the STIMUPLEX Dig RC. The warranty set forth herein is conditioned upon proper storage, installation, use and maintenance in accordance with applicable written recommendations of B. Braun.

EXCEPT AS EXPRESSLY PROVIDED HEREIN, B. BRAUN MAKES NO WARRANTY OF ANY KIND, EXPRESSED OR IMPLIED, WITH RESPECT TO THE STIMUPLEX Dig RC, INCLUDING, BUT NOT LIMITED TO, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. THE SOLE AND EXCLUSIVE REMEDY FOR BREACH OF ANY WARRANTY IS LIMITED TO THE REMEDIES PROVIDED IN THE ABOVE PARAGRAPHS.

B. BRAUN SHALL NOT BE LIABLE TO CUSTOMER FOR ANY INDIRECT, INCIDENTAL, SPECIAL, CONSEQUENTIAL OR PUNITIVE DAMAGES (INCLUDING ANY DAMAGE FOR LOST PROFITS) ARISING OUT OF OR IN CONNECTION WITH FURNISHING OF THE STIMUPLEX Dig RC OR SERVICE HEREUNDER, OR THE PERFORMANCE, USE OF, OR INABILITY TO USE THE STIMUPLEX Dig RC, OR OTHERWISE, WHETHER BASED ON CONTRACT, WARRANTY, TORT, INCLUDING WITHOUT LIMITATION, NEGLIGENCE, OR ANY OTHER LEGAL OR EQUITABLE THEORY.

# Introduction

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## Note:

The Warranty is extended to the nerve stimulator unit only. Any wear and tear items are not covered.

These include:

- Battery
- Electrode Connecting Cable
- Remote Control (Optional Accessory)
- Remote Control Finger Rings (Optional Accessory)

# Introduction

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## Intended Use

The STIMUPLEX Dig RC is intended for use with B. Braun Medical STIMUPLEX and CONTIPLEX® insulated needle sets for use in regional anesthesia and regional pain therapy. Peripheral nerves are stimulated and located via electrical current impulses flowing through an insulated needle.

## Important Notes

- Attention must be focused on the usual contraindications for peripheral nerve blocks: Hysteria, tendency for agitation, neurological complications, infection in the area of the injection site, septicemia, and coagulopathies.
- To avoid nerve lesions, use B. Braun Medical needles with a short bevel (CONTIPLEX or STIMUPLEX needles). To avoid tissue entering the needle, fill it with saline or local anaesthetic, which will then act like a stylet.
- If the needles are connected to the activated STIMUPLEX DIG-RC nerve stimulator, the stimulation current is concentrated at the uninsulated tips. Accurate localization of nerves is only possible when, during the pulsating discharge of minimal current (0.2-0.5 mA), nerve stimulation causes visible muscle contraction.
- This device is not intended for use with any needles or devices not manufactured by B. Braun Medical. (see Warranty)

# Introduction

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## CAUTION:

- This device is not approved for insertion in or around the heart.
- Avoid traumatized areas when attaching the skin electrodes to the patient.
- Do not operate the STIMUPLEX Dig RC unit in the presence of explosive substances.
- Functional safety and appropriate device status must be verified before operating the unit (see Short Test).
- 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.
- STIMUPLEX Dig RC may be used only by trained staff.
- If the patient is simultaneously connected to a high-frequency surgery device, burns under the stimulation current electrodes can result.
- Short-wave or microwave therapy devices located near the unit (i.e. within 1 m) can cause fluctuations in the stimulation current output values.

# Product Description

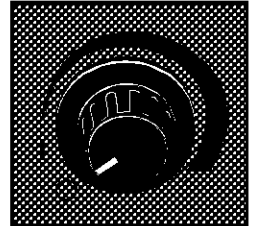
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## Design and Functions

### 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 relation 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.

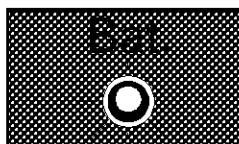
## Product Description

### Signal Tone

Simultaneous to every current impulse you will hear a short signal when the circuit is open. On a closed circuit a longer signal is heard. The frequency of the signal is proportional to the amplitude of the set current and the respective flowing current.

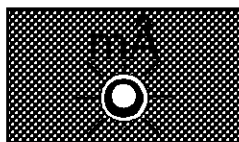
### Red "Bat" LED

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 (0.2 mA and up) that is flowing.



### Frequency Switch

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



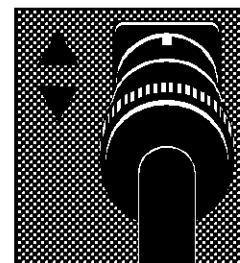
## Product Description

### Integrated Electrode Cable

The electrode cable is firmly connected within the device. For replacement please see page 18 of this manual, Replacement of the Electrode Cable.

### Connecting Socket for Remote Control

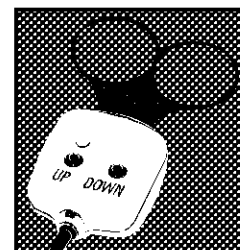
Tripolar plug for connection of Remote Control. When the Remote Control is connected to the device the initial value of 0.2 mA ( $\pm 10\%$ ) is indicated on the display.



### Remote Control (Optional Accessory)

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 adjustable for ideal fixation



### For additional product information please contact:

B. Braun Medical Inc.  
Clinical and Technical Support  
824 Twelfth Avenue  
Bethlehem, PA 18018  
800-854-6851  
[www.bbraunusa.com/stimuplex](http://www.bbraunusa.com/stimuplex)

# Product Description

## Technical Data

Impulse amplitude	0.20 - 5.0 mA constant current, infinitely adjustable
Impulse frequency	1 Hz or 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 at 5.0 mA
Resolution	0.01 mA
Accuracy	$\pm 10\% \pm \text{digit} (> 0.1 \text{ mA})$
Output voltage	32 Vs max.
Battery	9 volt
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

# Product Description

- flashing digital display indicates an exceeding of the control range (actual flowing current < value indicated)

- Yellow LED indicates the current pulse

red LED

plastic

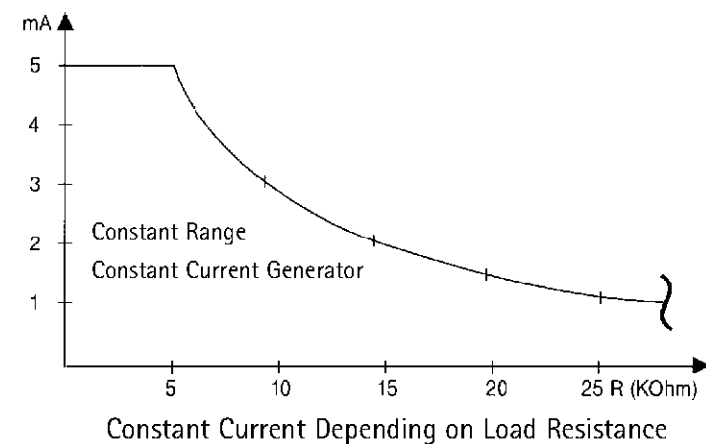
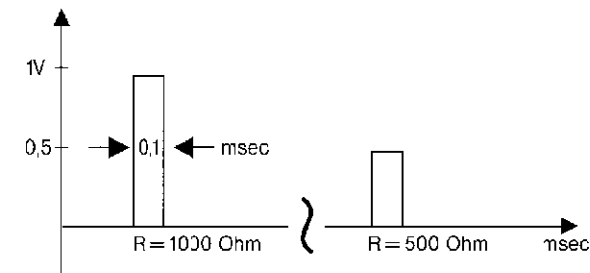
5 in. x 2.8 in. x 1.5 in.

12.6 cm x 7.2 cm x 3.8 cm

Battery check

Case (Housing)

Dimensions





# Principles of Operation

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## Operation without Remote Control

1. Check the external condition of the device
  - Housing clean and undamaged
  - Labels legible
  - Dials (current regulator, frequency switch) functional
  - Cable set functional.
2. Verify the STIMUPLEX Dig RC functional safety (Short Test, see page 16).
3. Connect the electrode cable to the skin electrode using the red alligator clip (anode).
4. Connect the socket of the STIMUPLEX needle to the insulated jack at the electrode cable. (If the CONTIPLEX A needle 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.)
5. Switch the STIMUPLEX Dig RC unit on by turning the current regulator and selecting the desired current (approx. 1 mA):
  - Digital display flashes
  - Short signal tone to be heard.
6. 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.).

# Principles of Operation

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7. Advance the needle in the direction of the nerve until distinct muscle contractions occur in the innervated area.
8. 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.
9. Inject a test dose of local anaesthetic (1-2 ml). Muscle contractions will cease almost immediately (5-10 sec.). If not the needle tip is probably intraneural and must be withdrawn slightly.
10. After the entire dose of local anaesthetic has been administered, no contractions should occur even with an increase of current.

## CAUTION:

During the procedure, 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.

# Principles of Operation

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## Operation with Remote Control

1. Verify the STIMUPLEX Dig RC functional safety (Short Test, see page 16).
2. Connect the electrode cable to the skin electrode using the red alligator clip (anode).
3. Connect the socket of the STIMUPLEX needle to the insulated jack at the electrode cable. (If the CONTIPLEX A needle 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.)
4. Insert the tripolar plug of the Remote Control into output socket of the STIMUPLEX Dig RC front panel.
5. Switch the STIMUPLEX Dig RC unit on by turning the current regulator:
  - Digital display flashes
  - Short signal tone to be heard.
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 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 oriented and fixed in direction of the wrist to avoid contact with the sterile area.

# Principles of Operation

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7. Test confirmation to be carried out while 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 blocked while pushing the "Down" button. If required, the position of the needle may be optimized by pressing the "Up" or "Down" buttons while observing the subsequent muscular contractions and then the local anaesthetic is injected as described above in Operation without Remote Control section.

## 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.

## Care and Maintenance

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### STIMUPLEX Dig RC Short Test

Put in the battery and turn on the device (current regulator to "I"):

- Red LED "Bat" will flash briefly
- 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).

Switch the toggle switch "frequency switch" repeatedly:

- Audio signal sounds accordingly to the selected frequency (1 Hz or 2 Hz).

Slowly increase the current regulator:

- Digital display flashes and shows the present current value
- Maximum current available is 5.0 mA
- The frequency of the signal changes proportionally to the preselected current value.

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

With the electrode cable connected, adjust the current to about 1.0 mA:

- Digital display flashes, short signal tone to be heard

Short the contacts at the ends of the electrode cables. To do this, insert the closed alligator clip into the black socket making sure the clip comes in contact with the metal clip.

- The yellow LED flashes
- The digital display stops flashing and indicates the current
- Prolonged signal tone is heard.

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.

## Care and Maintenance

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### 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

- Digital display shows the initial value of 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

### Cleaning

The STIMUPLEX Dig RC nerve stimulator is essentially maintenance-free. The plastic housing and cables can be disinfected with common disinfectants.

### 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 a 9 volt battery. 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.

## Care and Maintenance

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### Replacement of the Electrode Cable

Please contact B. Braun Medical Clinical and Technical Support with questions.

### Instructions for Electrode Cable Replacement

A defective electrode cable should be replaced by the hospital's electronic and biomedical engineering department per the following instructions.

Position the STIMUPLEX Dig RC on a soft base and turn the device with its bottom panel at the top:

- Remove the four black pads located on bottom of unit.
- Unscrew the four screws of the bottom panel with a screwdriver for recessed-head screws.
- Pull off the bottom panel carefully upwards and position it by the side of the device (be careful of the battery connecting cable).
- Disconnect the electrode cable plug from the plate and take the cable out of the clamping arrangement (clamped joint) of the front panel.
- Press the new electrode cable with its rubber funnel (rubber bushing) into the clamping arrangement of the front panel and adjust the cable position.
- Attach the plug of the electrode cable to the counter plug/socket on the plate. Don't use excessive force and be careful of the codings.
- Replace the bottom panel carefully to seal. Take care that no cables are being compressed (battery cable).
- Screw in all four screws.
- Carry out an operation check.

## Care and Maintenance

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### Troubleshooting:

**PROBLEM:** Yellow light (LED) does not light during short test.

**SOLUTION:** See technical testing on page 21 of this manual.

**PROBLEM:** During the procedure, the digital display flashes and the signal tone does not change its length.

**SOLUTION:** (i) Check skin electrode to confirm you have sufficient contact with the patient's skin.  
(ii) Check that the alligator clip is secured to the skin electrode  
(iii) Check that there is a secure connection between the needle and the cable.  
Perform the technical testing (see page 21) to confirm cable operation.

**PROBLEM:** Red "Bat" LED flashes (continuously).

**SOLUTION:** The red LED will flash if battery voltage drops below 6 volts. A blockade which is in progress can be continued, but the battery must be replaced afterwards.

**PROBLEM:** There is no audio signal after the unit is switched on.

**SOLUTION:** The battery is low, replace the battery.

### Service and Technical Support

If the STIMUPLEX Dig RC fails to respond to the operating or troubleshooting procedures listed in this manual and the cause cannot be determined, discontinue using the unit and contact B. Braun Medical Clinical and Technical Support:

B. Braun Clinical and Technical Support

Phone: 800-854-6851

Fax: 610-758-9020

You will be asked to provide the following information with each complaint:

1. Unit Serial Number
2. Verification of last battery replacement date
3. Verification of completion of unit Short Test (see page 16)
4. Verification of last cable replacement.
5. Contact name, address, phone number and e-mail address
6. Account name and/or number
7. Any other information which might aid in the investigation of the complaint
8. For your convenience, please photocopy page 24, complete, and return with Stimulator.

Should it be necessary to return the unit, Clinical and Technical Support will provide instructions for the return.

Carefully package the unit (preferably in the original case), and ship according to B. Braun instructions. B. Braun Medical cannot assume any responsibility for loss or damage to returned units while they are in transit.

### Technical Testing:

If the user of the STIMUPLEX Dig RC believes that the unit is not Stimulating, there could be three possible problems:

- 1) Defective Cable.
- 2) Device not being used properly.
- 3) Defective Stimulator.

The following tests can be performed by a hospital's electronic and biomedical engineering department.

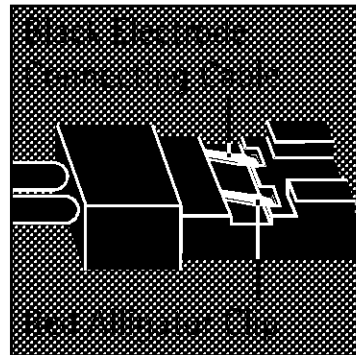
### Short Test

The short test is used to confirm flow of current from the Nerve Stimulator through the cables. Perform Short Test as described above (Reference "STIMUPLEX Dig RC Short Test", page 16 of this manual.). If the unit passes the short test, both the unit and cable are working. However, if the unit passes the short test and proper operation is still in question, the connection between the needle and the cable may not be making optimal contact, thus compromising the current flow through the needle. Replacing the cable will resolve this problem. If the unit fails the short test, either the unit itself, or the cable is defective. If the unit fails the short test, proceed to next test to confirm what part is defective.

## Cable Continuity Test

The cable continuity test is used to confirm the cable is able to provide current to the patient.

- Remove the Electrode Cable by following the instruction described above (Reference "Instructions for Electrode Cable Replacement", page 18 of this manual). This test will require a standard Multi-Meter or other device for measuring Ohms.
- Place cable on table.
- Connect one lead of your multi-meter to the black connecting cable. Connect the other lead to the metal prong shown on the attached picture. The reading of the multi-meter should be less than 1.0 ohms
- Disconnect leads
- Connect one lead of your multi-meter to the red alligator clip. Connect the other lead to the metal prong shown on the attached picture. Again, the reading of the multi-meter should be less than 1.0 ohms.
- If either reading is greater than required, the cable is defective and should be replaced.
- Replace the cable as necessary.



If the cable fails the continuity test, the cable is defective and should be replaced. If the cable passes the continuity test and the unit failed the short test, there is something wrong with the unit. Discontinue using the unit and contact B. Braun Medical Clinical and Technical Support.

## B. Braun Clinical and Technical Support

Phone: 800-854-6851

Fax: 610-758-9020

## Functional Test:

If the unit passes the short test, passes the continuity test and there are still concerns that the unit is operating properly, a functional test can be performed on the unit. The following is required:

- Oscilloscope (storage oscilloscope)
- Resistor (Load resistance) 1000 Ohms
- Battery (9 Volt)

All tests must be done to avoid faults and are performed only with a 9 volt battery correctly installed.

- Blank off the electrode cable to a load resistance of 1000 ohms and connect the oscilloscope in parallel to the load resistance.
- Adjust a time base of 0.1 msec. and a front-end area (incoming area) of 1 v/sec.
- Set a pulsed current of 5.0 mA with the current regulator on the device and check the output signal with the oscilloscope:
- impulse form monophasic rectangular impulse
  - impulse width 0.1 msec. ( $\pm 10\%$ )
  - impulse amplitude 5.0 volt (Vs) ( $\pm 10\%$ )
  - impulse frequency 1 Hz and 2 Hz ( $\pm 10\%$ )
- Set further current values as needed and carry out a check with the oscilloscope. The voltage drop of the load resistance corresponds to the pre-selected current.

# Customer Return Form

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Electromedical equipment may only be serviced by the manufacturer or by an organization expressly authorized by the manufacturer.

A detailed description of the fault must be added to the service order:

Type of device: STIMUPLEX Dig RC

Serial Number: \_\_\_\_\_

Last battery replacement: \_\_\_\_\_

Check of the Electrode Cable: OK ☐ Defect ☐

Detailed description of the fault: \_\_\_\_\_

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Contact Person: \_\_\_\_\_

(Name/Telephone) \_\_\_\_\_

Address: \_\_\_\_\_

\_\_\_\_\_

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