# Patient Programmer

# Model MN0600

# User Manual

**Spinal Modulation, Inc.**
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CAUTION – Investigational Device
Limited by Federal (US) Law to Investigational Use



LP0015 Rev E, June 2011

TABLE OF CONTENTS

EXPLANATION OF SYMBOLS ON PRODUCT OR PACKAGE LABELING ..... 3
GLOSSARY ..... 4
INTRODUCTION ..... 5
INDICATIONS FOR USE ..... 5
DESCRIPTION ..... 5
WARNING ..... 5
PRECAUTIONS – FOR YOUR PATIENT PROGRAMMER AND YOUR STIMULATOR DEVICE ..... 6
PRECAUTIONS – FOR YOUR THERAPY ..... 7
PATIENT PROGRAMMER FEATURES ..... 10
CHARGING THE BATTERY ..... 10
PROGRAMMER POWER UP ..... 10
MAIN MENU ..... 12
CONNECTING TO YOUR STIMULATOR DEVICE ..... 13
PAIN CONTROL SCREEN ..... 15
BACK TO MAIN MENU ..... 15
SELECT GROUP ..... 15
PROGRAMMER STATUS BAR ..... 16
ADJUSTING YOUR STIMULATOR DEVICE SETTINGS ..... 16
TURNING OFF STIMULATION ..... 16
PAIN CONTROL TAB ..... 17
ADJUST STIMULATION LEVEL FOR A BODY REGION ..... 17
INFO TAB ..... 18
DEVICE TAB AND PHYSICIAN TAB ..... 18
CLINIC TAB ..... 18
USING YOUR TNS DEVICE ..... 19
USING YOUR INS DEVICE ..... 19
AUTHORIZED EUROPEAN REPRESENTATIVE ..... 19
COMPANY CONTACT INFORMATION ..... 19
GUIDANCE AND MANUFACTURER'S DECLARATION ..... 20
ELECTROMAGNETIC EMISSIONS ..... 20
ELECTROMAGNETIC IMMUNITY ..... 21
APPENDIX I: INS BATTERY LIFE ..... 23
APPENDIX II: TROUBLESHOOTING ..... 32

# Explanation of Symbols on Product or Package Labeling

Model Number

Serial Number


Read the Manual


Consult the Manual

Contents of Package are Non-Sterile


Manufacturing Date


Manufacturer


Warning. Pay attention.

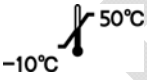

Protected against Electric Shock

Not waterproof. Applies to the Programmer when it is not in its carrying case.

Limited waterproof. Applies to the TNS.
Applies to the Programmer in its carrying case.


Turns the Programmer ON and OFF.
Turns stimulation OFF on the TNS.


Keep Dry



Store between -10°C and 50°C (14°F and 122°F)

Store between 0 and 93% humidity


The device is a radio transmitter


Magnet. Shows the location of the Programmer magnet.


Australia C-tick

Authorized European Representative

# Glossary

Lead – Surgical wire: takes electrical signals from the neurostimulator to the stimulation area.

Stimulation – Small electrical pulses: produces a tingling sensation and replaces pain signals.

Stimulator –Device that makes electrical pulses that stimulate the nerves in your spine: defined as Trial Neurostimulator or Implantable Neurostimulator.

Trial Neurostimulator (TNS) - External stimulator device that clips onto your belt: attaches to the connector cable and which is connected to leads implanted in the area near your spine.

Implantable Neurostimulator (INS) - Stimulator device implanted in your back or abdomen: attaches to leads implanted in the area near your spine.

Connector Cable – Cable that connects the leads to your trial stimulator device.

Patient Programmer – Portable, hand-held device: allows you to adjust the stimulation settings.

Clinical Programmer – Portable, hand-held device: allows the clinician to program the stimulator device.

Computer Tomography (CT) Imaging – Computerized X-ray imaging: produces electronic images of tissues and organs.

Diathermy – High energy heat: used to cut or cauterize during surgery or a type of therapy.

Electromagnetic Interference (EMI) – Electrical signals that interfere with the device function.

Magnetic Resonance Imaging (MRI) – Medical imaging: produces electronic images of tissues and organs.

Paresthesia – Tingling sensation felt during therapy delivery: produced by spinal cord stimulation.

Precaution –Situation that could cause uncomfortable stimulation and possible damage to the stimulator device or Patient Programmer.

Program – Instructions or changes to stimulation settings that are programmed into the Patient Programmer and transmitted to the stimulator device.

Stimulation Level – Measure of stimulation: can be increased or decreased within a range specified by your doctor.

Warning – Potentially serious hazard that could cause injury or death.

## INTRODUCTION

Your Patient Programmer is used to program your stimulator device, if required. This User Manual gives detailed instructions on how to safely use your Patient Programmer and your stimulator device. It also instructs you on how to recharge your Patient Programmer. See your doctor if you have any questions.

## INDICATIONS FOR USE

The Spinal Modulation Neurostimulator System was designed to be used to manage prolonged pain as stated in the following indication statement:

*The Spinal Modulation neurostimulation system is indicated as an aid in the management of chronic, intractable, neuropathic pain of the lower limbs-including unilateral or bilateral pain, associated with the following conditions: radicular pain, peripheral neuropathies.*

## DESCRIPTION

The Clinical and Patient Programmers are used to connect to the stimulator device.

- The Clinical Programmer controls the stimulator device. Only your doctor and/or Spinal Modulation clinical personnel may use the Clinical Programmer.

- The Patient Programmer allows you to adjust the settings of the stimulator device. Your doctor specifies the range of settings. It also allows you to turn OFF all stimulation, if required.


The Patient Programmer is a portable, handheld device. It is designed to be easy to use. It can be plugged into a power outlet or powered by an internal, rechargeable battery. The Patient Programmer uses an internal magnet to connect to the stimulator device. This allows the patient to control stimulation settings.

⚠

## WARNING

- Do not use your Patient Programmer or the stimulator device until your doctor has trained you.
- Do not use your Patient Programmer until your doctor has set up your stimulator device.
- Do not undergo any elective magnetic resonance imaging (MRI) procedure. If MRI is necessary, your physician must remove any lead(s). Your doctor must also disconnect the TNS or INS device. Use of MRI in the area of the lead(s) may dislodge the lead(s) or damage the TNS or INS. If a voltage is induced through the lead, it may cause uncomfortable (“jolting” or “shocking”) levels of stimulation.
- Do not undergo any diathermy (high energy heat) procedures. Diathermy may cause bodily injury or damage to the stimulator device.
- Do not remove the lead(s) or Connector Cable during the trial period. An infection may result.
- Changes in body position can increase pain or cause uncomfortable stimulation. Use the Patient Programmer to adjust stimulation levels or to turn OFF stimulation, if required.

**Warnings (continued)**

- Strong electromagnetic fields may interfere with the stimulator device. This interference can affect the stimulation level and cause discomfort. Avoid theft detection devices at store and library exits. Also avoid airport security screeners. Do not stand near the screening equipment.
- Other equipment that may cause interference includes but is not limited to: power generators, arc welders and large magnetized speakers. Do not stand near these devices.
- Do not leave your Programmer Charger where pets, children or you may become entangled in the cord, causing a fall or strangulation.
- Report a rash due to system components to your doctor. If your throat or tongue starts to swell get emergency aid immediately.

**PRECAUTIONS – FOR YOUR PATIENT PROGRAMMER AND YOUR STIMULATOR DEVICE**

Follow these precautions to avoid damage to and assure proper function of your Patient Programmer and stimulator device.

- Do not drop or mishandle your Patient Programmer or stimulator device. Physical damage to the devices may impair their function.
- Do not wash the Patient Programmer or TNS device with excessive water. Do not get either device wet. Excessive moisture may impair their function. If cleaning is necessary, remove soil with a soft damp cloth.
- Do not shower or bathe with the TNS device. (You may take a sponge bath if the TNS device does not get wet.)
- Avoid contact with body fluids for the TNS and Patient Programmer. Contamination may cause damage to the devices.
- Do not use abrasive or caustic cleaning products on your Patient Programmer or TNS device.
- Do not use any equipment or accessories that are not supplied with your Patient Programmer. Do not plug anything into the connector at the bottom of the programmer. It is for Clinic use only.
- Do not open the cases of the Patient Programmer or TNS device or modify them in any way. This may expose the devices to elements that alter their function.
- Do not place your Patient Programmer close to credit cards or other cards with magnetic strips. The Patient Programmer magnet may demagnetize your cards. Keep the Patient Programmer away from computer hard drives and magnetic storage devices.
- Do not operate the Patient Programmer or stimulator device outside the temperature range of -5°C to 45°C (23°F to 113°F). Rapid temperature changes may affect proper device operation.
- Do not store the Patient Programmer outside the temperature range of -10°C to 50°C (14°F to 122°F).
- Do not leave the Patient Programmer in a car or other places where temperatures can exceed 50°C (122°F).

**Device Precautions (continued)**

- Failure of your stimulator system, although unlikely, is possible due to random component failure. If any part of your stimulator system stops working or you see a change in how it works, discontinue use and contact your doctor during normal business hours.
- Return your Patient Programmer and TNS device to your doctor at the end of the trial period. Do not discard or burn the Patient Programmer or TNS device. Fire may cause the internal batteries to explode.
- Do not try to replace the TNS device battery, even if the TNS device does not function. Only Spinal Modulation personnel may replace the TNS device battery.
- Do not use any other company's device to program your stimulator device. Use only the Patient Programmer provided by Spinal Modulation.
- Do not allow unauthorized use of your Patient Programmer. This may cause unwanted programming changes.
- Do not use the Patient Programmer or stimulator device near explosive or flammable gases. Serious injury may occur.
- Do not use the Programmer Charger if the power cord is damaged, excessively worn or frayed. This may cause injury or damage your stimulation device.
- To remove power from the Programmer Charger when not in use, unplug from the wall.
- Frequent programming of your implanted device will cause the battery to deplete faster. Avoid unnecessary programming.

**PRECAUTIONS – FOR YOUR THERAPY**

Follow these precautions to maintain appropriate therapy:

- Follow proper wound care techniques, as instructed by your doctor.
- Do not rub or press on the implant site. This may cause the leads to dislodge or your skin to erode. It may also cause inversion of the INS.
- Avoid excessive bending, twisting and stretching. Do not lift objects over ten pounds. These activities may cause the leads to move. Understimulation or overstimulation may result.
- Avoid driving a car or operating other potentially dangerous machinery while stimulation is ON. You could be distracted from vehicle or device operation if sudden changes in stimulation were to occur.
- Your stimulator device may affect the operation of other implantable devices, such as pacemakers or implantable cardiac defibrillators. Tell your doctor about any other implantable devices that you have or are scheduled to get.

**Therapy Precautions (continued)**

- Tell your regular doctor(s) or healthcare providers that you have a stimulator device. Do not undergo any elective medical procedures without first discussing them with your physician. Some medical devices or therapies, such as those listed below, may interfere with your stimulator device:
  - Electrocautery – Electric probe to cauterize blood vessels and stop bleeding during surgery.
  - Lithotripsy – Shock waves to break up gallstones and kidney stones.
  - Therapeutic Radiation – Used to destroy cancer cells.
  - High-output ultrasound – Sound waves to treat bone and muscle injuries, or to stimulate muscle or improve blood flow.
  - RF Ablation – Radio frequency energy to cause controlled tissue damage.
  - Microwave Ablation – Alternating electric field to cause controlled tissue damage.
  - Dental procedures, electrolysis, static field therapeutic magnets and diagnostic X-ray.
- Appoint a family member or friend to tell emergency medical personnel that you have a stimulator device, in case you need emergency care. You will be given a Medical Alert Card to carry with you. This card will inform emergency medical personnel that you have a stimulator device.

*If you have any concerns about your stimulator device, contact your doctor during normal business hours.*

## RF Operating Frequencies

Nearby equipment emitting strong magnetic fields can interfere with RF communication, even if the other equipment complies with CISPR emission requirements. The operating characteristics are as follows:

MICS band: 402-405 MHz

The effective radiated power is below the limits as specified in

Europe: EN ETSI 301 839-2

USA FCC 47 CFR Part 95; 95.601-95.673 Subpart E, 95.1201-95.1219

FCC ID: Y8L-MN0700

This device may not interfere with stations operating in the 400.150–406.000 MHz band in the Meteorological Aids, Meteorological Satellite, and Earth Exploration Satellite Services and must accept any interference received, including interference that may cause undesired operation.

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**PATIENT PROGRAMMER OVERVIEW**

Your Patient Programmer is a portable, handheld device. It is powered by an internal, rechargeable battery. It can also be plugged into a power outlet. Your Patient Programmer works with your stimulator device to control stimulation. Your doctor will explain how to use the Patient Programmer to adjust stimulation for optimal pain relief.

Keep your Patient Programmer near you at all times. This allows you to adjust stimulation, if necessary. Carry your Patient Programmer in the case provided as the case provides protection from water.

Your Patient Programmer system consists of:

- Patient Programmer with Stylus (and internal magnet) MN0600
- Auxiliary Magnet MN3300
- Programmer Charger MN3400

  Input: 100-240 VAC, 50-60 Hz, 0.6A

  Output: 5V ⎓ 3.0A
- Carrying Case MN3500
- Patient Programmer User Manual (this document)
- Patient Information Sheet
- Patient Medical Alert Card


Programmer Power
- Battery Status Bar
- AC – Battery Charging
- 100% – Battery Charge Complete

Stylus

Programmer Charger

Patient Programmer

### PATIENT PROGRAMMER FEATURES

With your Patient Programmer, you can:

- Turn OFF all stimulation, if required.
- Turn stimulation ON or OFF for each body region.
- Adjust the stimulation level for each body region.
- Change the Group for stimulation. See “Select Group” under the “Pain Control Screen” section.
- View your stimulator device ID information.
- View your name or your ID number.
- View your lead implant date.
- View your physician name, clinic name and contact information.

### CHARGING THE BATTERY

You will need the Programmer Charger provided to charge the Patient Programmer battery. Charging the battery takes approximately 2–4 hours for a full charge. The Programmer Status Bar at the bottom of the screen shows the battery charge level.

1. Connect the Programmer Charger to a power outlet.
2. Connect the Charger to your Patient Programmer.

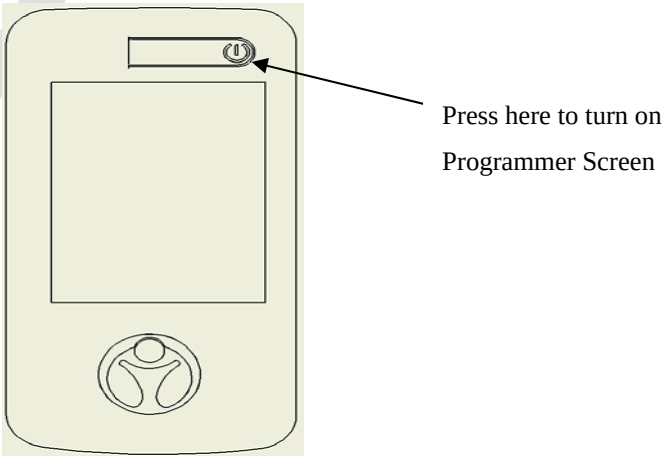
When the battery is charging, the battery icon on the screen shows “AC”. When charging is complete, 100% shows next to the battery icon.

Your Patient Programmer will operate normally and does not use battery power when it is connected to a power outlet. Connect your Patient Programmer to the Charger and attach to an outlet regularly to keep it charged.

Your Patient Programmer and Programmer Charger have an expected service period of up to three years. Improper charging may reduce this period.

### PROGRAMMER POWER UP

Press the “⏻” button to turn ON your Patient Programmer screen. The Main Menu will display.

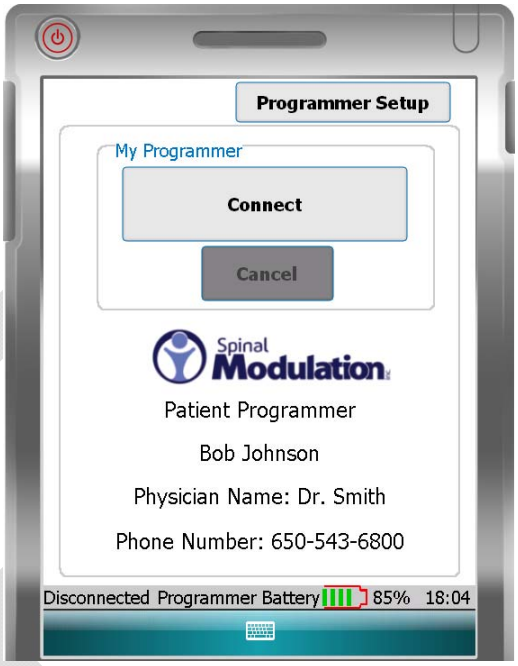


NOTE:  If the Patient Programmer does not turn ON, charge the battery, and try again.

## MAIN MENU

The Programmer Main Menu displays two main functions:

- **Connect:** Allows you to connect to your stimulator device; also allows you to adjust stimulation settings.
- **Programmer Setup:** Allows you to set your Patient Programmer date and time; also allows you to view information about your stimulator device.

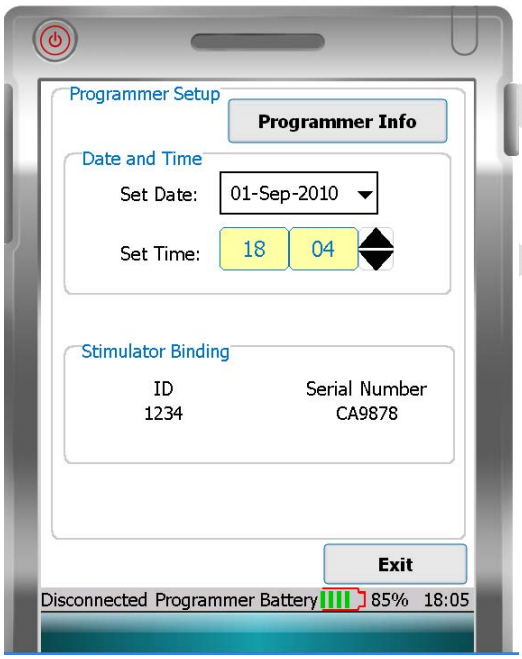



The Main Menu identifies the device as your Spinal Modulation Patient Programmer. Your physician, clinic and the clinic phone number are also shown.

The Programmer status bar is located at the bottom of the Main Menu. The status bar shows the Programmer–stimulator connection status. It also shows the battery charge level and the time. See the "Programmer Status Bar" section in this User Manual for more detail.

You can change the time and date and access the Programmer Info screen from the Programmer Setup screen. You can also view your stimulator device serial number and your name or patient ID.

The Programmer Info screen shows your programmer serial number, software version and manufacturing date. It also shows the basestation firmware version.




**Stimulator Device Binding**

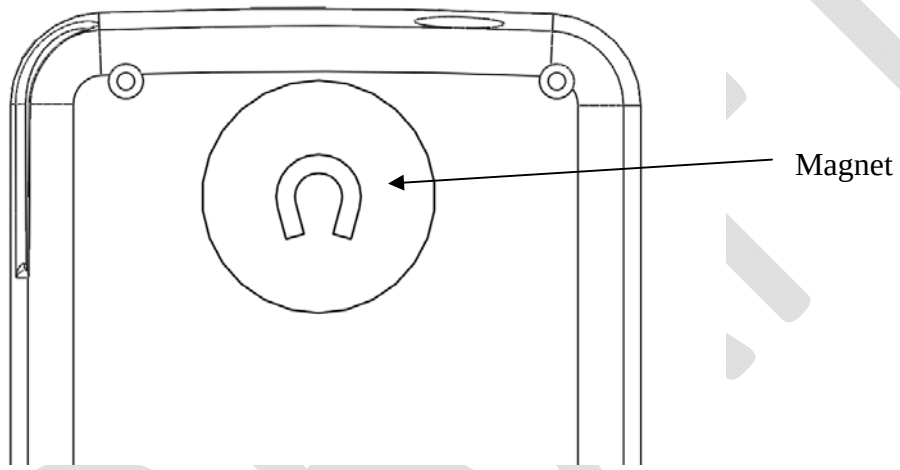
Your doctor will bind your stimulator device to your Patient Programmer. You cannot edit this information.

**Connect**

Press the "Connect" button on the Main Menu to connect to your stimulator device. Once connected, you can adjust stimulation settings. See the "Connecting to Your Stimulator Device" section below for more detail.

**Magnet**

A magnet is located under the magnet symbol on the back side of the Patient Programmer. Place the magnet over the stimulator device to check for connection between the Patient Programmer and stimulator device. See the "Connecting to Your Stimulator Device" section below for more detail.




**Connecting to Your Stimulator Device**

Use your Patient Programmer to connect to your stimulator device.

- Make sure that your Patient Programmer is turned ON and that the Main Menu displays. Your Patient Programmer must be within 6 feet of your stimulator device.
- Press the "Connect" button. The Patient Programmer will begin searching for the stimulator device. An icon shows on the screen to indicate that it is busy.
- Position the magnet on the Patient Programmer over your stimulator device and move around in a circular motion to initiate communication.

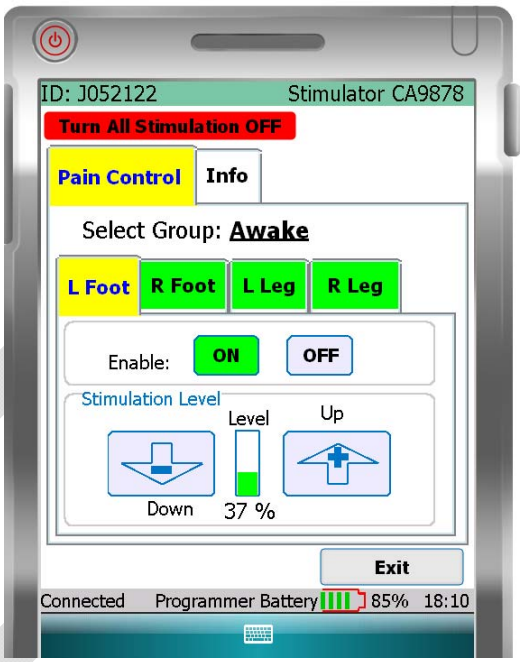
The Patient Programmer chimes when it is connected to your stimulator device. The Pain Control screen displays. "Connected" shows in the status bar at the bottom left of the screen. If your Patient Programmer cannot connect to your stimulator device, an error message displays. "Disconnected" shows in the status bar.

If your Patient Programmer cannot connect to your stimulator device, go back to the Main Menu. Press "Connect" again. Move the magnet in a circular fashion over your stimulator device. Repeat until the Patient Programmer connects to the stimulator device.

NOTE: If after 2 minutes your Patient Programmer cannot connect to the stimulator device, place the Patient Programmer over the stimulator device again. An error message may display. The message asks you

to confirm that your Patient Programmer is near enough to the stimulator device. After confirming that your Patient Programmer is within 6 feet of the stimulator device, press “OK”. Press “Connect” again.

### PAIN CONTROL SCREEN




At the top of the Pain Control screen. The ID Heading shows your name or ID number and your stimulator device's serial number.

The "Turn All Stimulation OFF" button is below the ID Heading.

Two tabs are below the "Turn All Stimulation OFF" button: the "Pain Control" tab and the "Info" (Information) tab. See the "Adjusting Your Stimulator Device Settings" section in this User Manual for more detail.

The "Exit" button at the bottom right side of the screen returns you to the Main Menu.

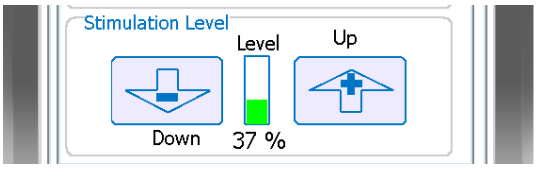
ID Heading, located at the top of the screen, shows the following information:

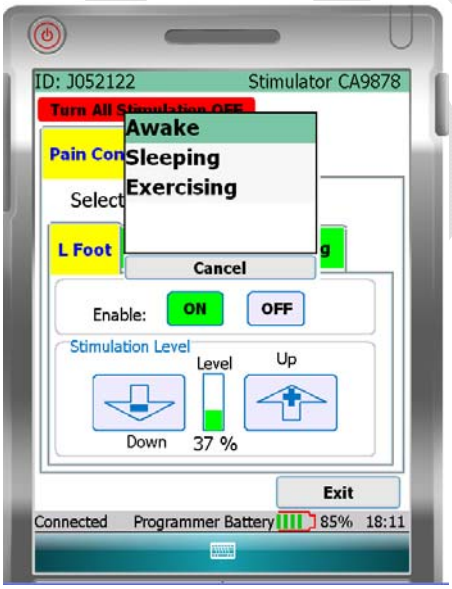
- Your Identification (ID) Number
- Your Stimulator Device Serial Number

### BACK TO MAIN MENU

The "Exit" button closes the Pain Control window, ends the session, and returns to the Main Menu.

NOTE: When programming is complete, select the "Exit" button and power off the programmer to conserve power.




### SELECT GROUP

The "Select Group" button is located in the center of the Pain Control screen. Press "Select Group" to display a drop down menu. The drop down menu has up to four groups defined by your doctor. When you select a group name, the stimulator device switches settings to the new group.

### PROGRAMMER STATUS BAR

The Programmer Status Bar is located at the bottom of the Patient Programmer screen. The status bar shows the Programmer-stimulator connection status, the battery charge level and the time.


- **Programmer - Stimulator Connection Status**: Shows "Connecting" when the Patient Programmer is trying to connect to the stimulator device; shows "Connected" when the Patient Programmer is connected to the stimulator device; and shows "Disconnected" when the Patient Programmer is disconnected from the stimulator device.
- **Programmer Battery Level**: Shows the Patient Programmer battery charge level.
- **Programmer Clock**: Shows the time. See the "Main Menu" section in this User Manual for more detail.

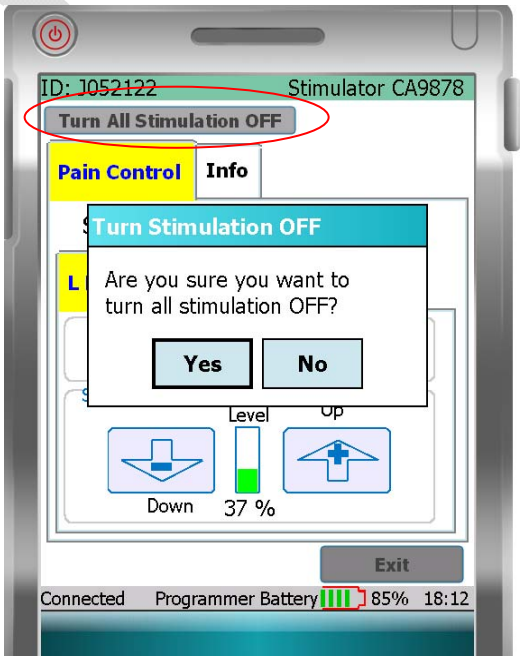
### ADJUSTING YOUR STIMULATOR DEVICE SETTINGS

You can adjust your stimulator device settings from the Pain Control screen. Stimulation can be turned ON or OFF for up to four regions of your body. You can also adjust the stimulation level for any of those regions.

### TURNING OFF STIMULATION

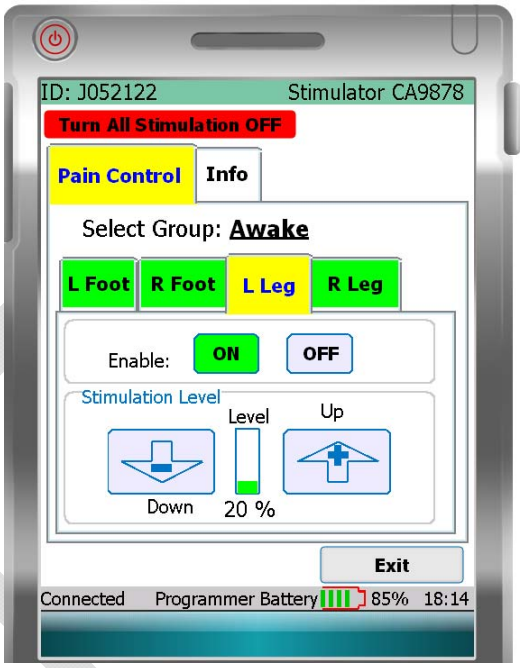
- Press the "Turn All Stimulation OFF" button to stop all stimulation therapy. A confirmation window appears, asking do you want to turn OFF all stimulation.

  NOTE: After turning OFF all stimulation, you can restore stimulation therapy for each of the body regions individually. See the "Turn Stimulation ON or OFF for a Body Region" section below.



### PAIN CONTROL TAB

Select the “Pain Control” tab located at the top of the Pain Control screen. From the “Pain Control” tab, you can turn stimulation ON or OFF for each body region. You can also adjust the stimulation level for each body region.




### TURN STIMULATION ON OR OFF FOR A BODY REGION

Your Patient Programmer shows the names of one to four body regions in which your leads have been placed. To turn stimulation ON or OFF for a body region:

- Select the body region by pressing the desired tab.
- Press the “OFF” button to stop stimulation to that region. When stimulation is OFF, the “OFF” button is black.
- Press the “ON” button to start stimulation to that region.

  When stimulation is ON, the “ON” button is green.

### ADJUST STIMULATION LEVEL FOR A BODY REGION

Verify that you have selected the correct body region tab on the Pain Control screen.

- Press the “Down” button to decrease the stimulation level.
- Press the “Up” button to increase the stimulation level.

  <u>Stimulation Level Indicator:</u>

  The stimulation level indicator is located between the “Up” and “Down” buttons. The indicator moves up or down as you adjust the stimulation level for the selected body region. The indicator shows the current stimulation level as compared to the maximum set by your doctor.

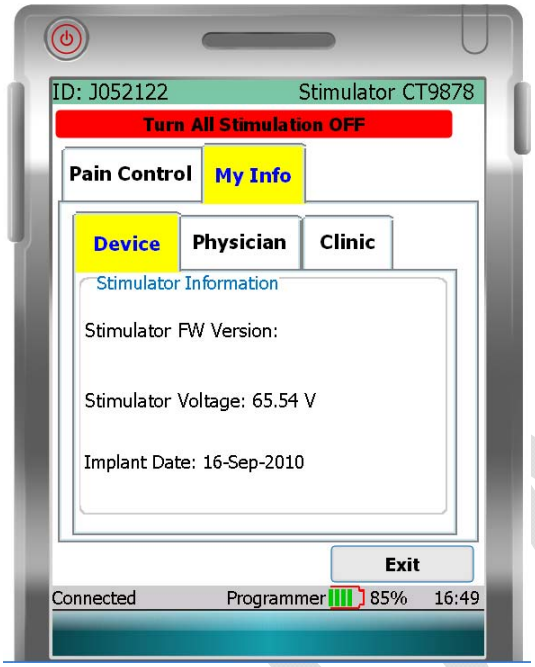
  NOTE: The indicator bar is green when you have reached the maximum stimulation level.

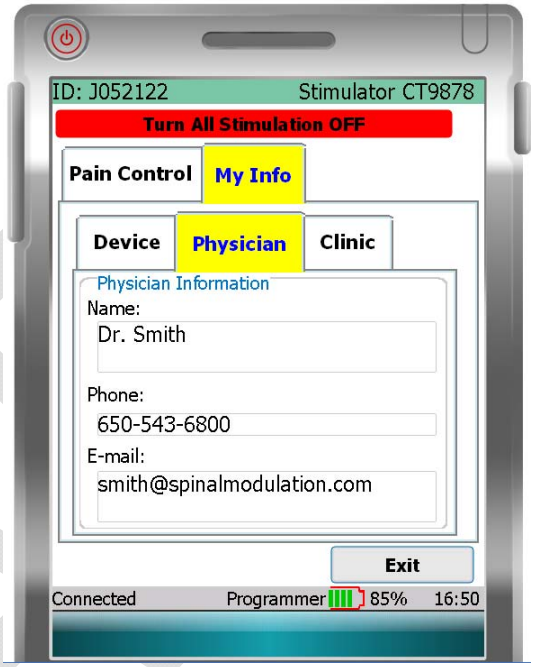
## INFO TAB

The “Info” (Information) tab contains three tabs, the “Device” tab, the “Physician” tab, and the “Clinic” tab.

### DEVICE TAB AND PHYSICIAN TAB

The “Device” tab and “Physician” tab show the following information:




Stimulator Voltage Information

NOTE: INS battery information (does not pertain to external TNS device).

Stimulator Identification Information

- Stimulator Device Firmware Version.
- Date INS device was implanted (does not pertain to external TNS device).

Physician Information

- Your doctor’s name.
- Your doctor’s contact phone number.
- Your doctor’s email contact.


### CLINIC TAB

The “Clinic” tab shows the following information:

Clinic Information

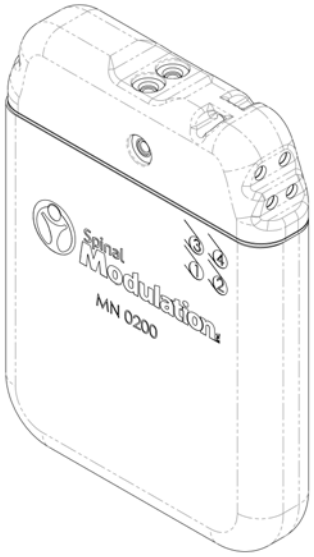
- Your clinic’s name.
- Your clinic’s address.
- **After Hours Contact:** A phone number to contact someone in case of an emergency.


### USING YOUR TNS DEVICE

To connect your Programmer to your TNS, push the "Connect" button on the Patient Programmer. Move the Patient Programmer magnet over the TNS in a circular motion. This will allow you to adjust stimulation settings using the Patient Programmer. To quickly turn stimulation off, press the red button on the TNS for more than 2 seconds or push the "Turn all Stimulation OFF" button on the Programmer screen. To enable stimulation after pressing either button, you must connect with your Patient Programmer and turn the stimulation back on.

### USING YOUR INS DEVICE

To connect your Programmer to your INS, push the "Connect" button on the Patient Programmer. Move the Patient Programmer magnet over the implant location in a circular motion. This will allow you to adjust stimulation settings using the Patient Programmer.




Your Spinal Modulation Neurostimulator System complies with the following International Standards

- IEC 60601-1: 2005
- IEC 60601-1-11: 2010
- IEC 60601-1-2: 2007
- ISO 14708-1: 2000
- ISO 14708-3: 2008

### AUTHORIZED EUROPEAN REPRESENTATIVE

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6291 EN Vaals, Netherlands

### COMPANY CONTACT INFORMATION

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Fax: (650) 327-2336
Email: clinicalsupport@spinalmodulation.com

| GUIDANCE AND MANUFACTURER'S DECLARATION<br>ELECTROMAGNETIC EMISSIONS | | |
|---|---|---|
| The Spinal Modulation Neurostimulator System is intended for use in the electromagnetic environment specified below. The customer or the user of the Spinal Modulation Neurostimulator System should assure that it is used in such an environment. | | |
| **Emissions test** | **Compliance** | **Electromagnetic environment – guidance** |
| RF Emissions 1 | Group 2 | The Spinal Modulation Neurostimulator System must emit electromagnetic energy in order to perform its intended function. Nearby electronic equipment may be affected. |
| RF emissions<br>CISPR 11 | Class B | |
| Harmonic emissions<br>IEC 61000-3-2 | Class B | |
| Voltage fluctuations/<br>flicker emissions<br>IEC 61000-3-3 | Complies | |
| | | The Spinal Modulation Neurostimulator System 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. |
| CISPR 14-1 | Complies | The Patient Programmer is not intended to be connected to other equipment except the Model 3400 Programmer Charger |

| Guidance and Manufacturer's Declaration<br>ELECTROMAGNETIC IMMUNITY | | | |
|---|---|---|---|
| The Spinal Modulation Neurostimulator System is intended for use in the electromagnetic environment specified below. The customer or the user of the Spinal Modulation Neurostimulator System should assure that it is used in such an environment. | | | |
| **Immunity** | **IEC 60601<br>Test Level** | **Compliance<br>Level** | **Electromagnetic environment guidance** |
| Electrostatic discharge (ESD) | IEC 61000-4-2 | ± 6 kV<br>contact<br>± 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<br>IEC 61000-4-4 | ± 2 kV for power supply lines<br>± 1 kV for input/output lines | Pass | Mains power quality should be that of a typical commercial or home environment |
| Surge<br>IEC 61000-4-5 | ± 1 kV line(s) to line(s)<br>± 2 kV line(s) to earth | | Mains power quality should be that of a typical commercial or home environment |
| Voltage dips, short interruptions and voltage variations on power supply | input lines<br>IEC 61000-4-11<br><5% *U*T (>95% dip in *U*T)<br>for 0.5 cycle<br>40% *U*T (60% dip in *U*T)<br>for 5 cycles<br>70% *U*T (30% dip in *U*T)<br>for 25 cycles<br><5% *U*T (>95% dip in *U*T)<br>for 5 s<br>NOTE *U*T is the a.c. mains voltage prior to application of the test level. | | Mains power quality should be that of a typical commercial or home environment |
| Power frequency (50/60 Hz) magnetic field<br>IEC 61000-4-8 | 3 A/m | | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial, hospital, or home environment. |

| Guidance and Manufacturer's Declaration<br>ELECTROMAGNETIC IMMUNITY | | | |
|---|---|---|---|
| The Spinal Modulation Neurostimulation System is intended for use in the electromagnetic environment specified below. The customer or the user of the Spinal Modulation Neurostimulation System should assure that it is used in such an environment | | | |
| **Immunity test** | **IEC 60601 TEST LEVEL** | **Compliance level** | **Electromagnetic environment guidance** |
| Conducted RF<br>IEC 61000-4-6 | 3 Vrms<br>150 kHz to 80 MHz | 3 V | Portable and mobile RF communications equipment should be used no closer to any part of Spinal Modulation Neurostimulation System, than 0.2 meter, based on transmitters of 80 MHz to 2.5 GHz. |
| Radiated RF<br>IEC 61000-4-3 | 3 V/m<br>80 MHz to 2,5 GHz | 3 V/m | Interference may occur in the vicinity of equipment marked with the following symbol:<br>  |

| Recommended separation distances between portable and mobile RF communications equipment and the Spinal Modulation Neurostimulation System | | | |
|---|---|---|---|
| The Spinal Modulation Neurostimulation System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Spinal Modulation Neurostimulation System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the System | | | |
| **Rated maximum output power of transmitter W** | **Separation distance according to frequency of transmitter** m | | |
| | **150 kHz to 80 MHz** | **80 MHz to 800 MHz** | **800 MHz to 2.5 GHz** |
| 0.01 | 0.12m | 0.12m | 0.23m |
| 0.1 | 0.37m | 0.37m | 0.74m |
| 1 | 1.17m | 1.17m | 2.33m |
| 10 | 3.70m | 3.70m | 7.37m |
| 100 | 11.70m | 11.70m | 23.30m |
| NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.<br>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |

# Appendix I: INS Battery Life

The following four tables estimate INS battery life under the given load impedance conditions.
Tables 1 through 4 list estimated longevity based on 1-lead stimulation, active 24 hours a day. To estimate longevity for multiple active leads and to account for daily usage, use the following formula:

$$\text{Longevity for Multiple Leads} = \frac{3014}{C1 + C2 + C3 + C4 + 35}$$

Where,

$$C1 = \left(\frac{3014}{\text{Longevity for Lead 1 Settings}} - 35\right) * \text{Daily Usage Lead 1}$$

$$C2 = \left(\frac{3014}{\text{Longevity for Lead 2 Settings}} - 35\right) * \text{Daily Usage Lead 2}$$

$$C3 = \left(\frac{3014}{\text{Longevity for Lead 3 Settings}} - 35\right) * \text{Daily Usage Lead 3}$$

$$C4 = \left(\frac{3014}{\text{Longevity for Lead 4 Settings}} - 35\right) * \text{Daily Usage Lead 4}$$

And,
Daily Usage Lead 1, 2, 3 and 4 are fractional values equal to the number of hours stimulation is enabled for each lead daily divided by 24 hours.
*Note: Do not enter values for C1, C2, C3 or C4 for corresponding leads that are inactive.*

Example:
Estimate longevity for 2 lead stimulation with lead 1 settings of 0.8mA, 40Hz, 200µs across 600 ohms continuously stimulating, and lead 2 settings of 1.0mA, 60Hz, 400µs across 1Kohm stimulating for 16 hours per day.

From Table 1 (600 ohms), longevity for lead 1 settings = 58.9 months
From Table 2 (1 Kohm), longevity for lead 2 settings = 34.1 months
Calculated C1 = (3014 / 58.9 – 35) * (24 / 24) = 16.2
Calculated C2 = (3014 / 34.1 – 35) * (16 / 24) = 35.6

Estimated longevity for this example = 3014 / (16.2 + 35.6 + 35) = 34.7 months

**Table 1: Load Impedance = 600 ohms**

All longevity values are in months

| | | Pulsewidth | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Amplitude** | **Frequency** | 40uS | 100uS | 200uS | 300uS | 400uS | 500uS | 600uS | 700uS | 720uS |
| 0.1mA | 4Hz | 83.9 | 83.8 | 83.6 | 83.4 | 83.2 | 83.0 | 82.8 | 82.7 | 82.6 |
| | 20Hz | 81.5 | 80.9 | 80.1 | 79.2 | 78.3 | 77.5 | 76.7 | 75.9 | 75.8 |
| | 40Hz | 78.6 | 77.6 | 76.0 | 74.5 | 73.0 | 71.6 | 70.2 | 68.9 | 68.6 |
| | 60Hz | 76.0 | 74.6 | 72.4 | 70.3 | 68.3 | 66.5 | 64.7 | 63.1 | 62.7 |
| | 80Hz | 73.5 | 71.8 | 69.1 | 66.6 | 64.2 | 62.1 | 60.0 | 58.1 | 57.8 |
| | 100Hz | 71.2 | 69.2 | 66.1 | 63.2 | 60.6 | 58.2 | 56.0 | 53.9 | 53.5 |
| 0.2mA | 4Hz | 83.8 | 83.6 | 83.2 | 82.8 | 82.5 | 82.1 | 81.7 | 81.4 | 81.3 |
| | 20Hz | 81.1 | 80.1 | 78.3 | 76.7 | 75.1 | 73.6 | 72.2 | 70.8 | 70.5 |
| | 40Hz | 78.0 | 76.0 | 73.0 | 70.2 | 67.6 | 65.2 | 63.0 | 60.9 | 60.5 |
| | 60Hz | 75.1 | 72.4 | 68.3 | 64.7 | 61.5 | 58.5 | 55.9 | 53.4 | 53.0 |
| | 80Hz | 72.4 | 69.1 | 64.2 | 60.0 | 56.4 | 53.1 | 50.2 | 47.6 | 47.1 |
| | 100Hz | 69.8 | 66.1 | 60.6 | 56.0 | 52.0 | 48.6 | 45.6 | 42.9 | 42.4 |
| 0.4mA | 4Hz | 83.7 | 83.2 | 82.5 | 81.7 | 81.0 | 80.3 | 79.6 | 78.9 | 78.8 |
| | 20Hz | 80.4 | 78.3 | 75.1 | 72.2 | 69.4 | 66.9 | 64.6 | 62.4 | 61.9 |
| | 40Hz | 76.7 | 73.0 | 67.6 | 63.0 | 58.9 | 55.4 | 52.2 | 49.4 | 48.9 |
| | 60Hz | 73.3 | 68.3 | 61.5 | 55.9 | 51.2 | 47.2 | 43.8 | 40.9 | 40.4 |
| | 80Hz | 70.1 | 64.2 | 56.4 | 50.2 | 45.2 | 41.2 | 37.8 | 34.9 | 34.4 |
| | 100Hz | 67.3 | 60.6 | 52.0 | 45.6 | 40.5 | 36.5 | 33.2 | 30.4 | 29.9 |
| 0.6mA | 4Hz | 83.5 | 82.8 | 81.7 | 80.7 | 79.6 | 78.6 | 77.6 | 76.6 | 76.4 |
| | 20Hz | 79.7 | 76.7 | 72.2 | 68.2 | 64.6 | 61.3 | 58.4 | 55.7 | 55.2 |
| | 40Hz | 75.4 | 70.2 | 63.0 | 57.1 | 52.2 | 48.1 | 44.6 | 41.6 | 41.0 |
| | 60Hz | 71.5 | 64.7 | 55.9 | 49.1 | 43.8 | 39.6 | 36.1 | 33.2 | 32.6 |
| | 80Hz | 68.1 | 60.0 | 50.2 | 43.1 | 37.8 | 33.6 | 30.3 | 27.6 | 27.1 |
| | 100Hz | 64.9 | 56.0 | 45.6 | 38.4 | 33.2 | 29.2 | 26.1 | 23.6 | 23.1 |
| 0.8mA | 4Hz | 83.4 | 82.5 | 81.0 | 79.6 | 78.2 | 76.9 | 75.7 | 74.4 | 74.2 |
| | 20Hz | 79.0 | 75.1 | 69.4 | 64.6 | 60.3 | 56.6 | 53.3 | 50.4 | 49.8 |
| | 40Hz | 74.2 | 67.6 | 58.9 | 52.2 | 46.9 | 42.5 | 38.9 | 35.9 | 35.3 |
| | 60Hz | 69.9 | 61.5 | 51.2 | 43.8 | 38.3 | 34.1 | 30.7 | 27.9 | 27.4 |
| | 80Hz | 66.1 | 56.4 | 45.2 | 37.8 | 32.4 | 28.4 | 25.3 | 22.8 | 22.3 |
| | 100Hz | 62.7 | 52.0 | 40.5 | 33.2 | 28.1 | 24.4 | 21.5 | 19.3 | 18.9 |

**Table 1: Load Impedance = 600 ohms (Continued)**

All longevity values are in months

| | | Pulsewidth | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | 40uS | 100uS | 200uS | 300uS | 400uS | 500uS | 600uS | 700uS | 720uS |
| 1.0mA | 4Hz | 83.2 | 82.1 | 80.3 | 78.6 | 76.9 | 75.4 | 73.8 | 72.4 | 72.1 |
| | 20Hz | 78.3 | 73.6 | 66.9 | 61.3 | 56.6 | 52.5 | 49.0 | 46.0 | 45.4 |
| | 40Hz | 73.0 | 65.2 | 55.4 | 48.1 | 42.5 | 38.1 | 34.5 | 31.6 | 31.0 |
| | 60Hz | 68.3 | 58.5 | 47.2 | 39.6 | 34.1 | 29.9 | 26.6 | 24.0 | 23.6 |
| | 80Hz | 64.2 | 53.1 | 41.2 | 33.6 | 28.4 | 24.6 | 21.7 | 19.4 | 19.0 |
| | 100Hz | 60.6 | 48.6 | 36.5 | 29.2 | 24.4 | 20.9 | 18.3 | 16.3 | 15.9 |
| 1.5mA | 4Hz | 82.8 | 81.2 | 78.6 | 76.1 | 73.8 | 71.7 | 69.6 | 67.7 | 67.3 |
| | 20Hz | 76.7 | 70.1 | 61.3 | 54.5 | 49.0 | 44.6 | 40.8 | 37.7 | 37.1 |
| | 40Hz | 70.2 | 59.9 | 48.1 | 40.2 | 34.5 | 30.3 | 26.9 | 24.3 | 23.8 |
| | 60Hz | 64.7 | 52.3 | 39.6 | 31.9 | 26.6 | 22.9 | 20.1 | 17.9 | 17.5 |
| | 80Hz | 60.0 | 46.4 | 33.6 | 26.4 | 21.7 | 18.4 | 16.0 | 14.2 | 13.8 |
| | 100Hz | 56.0 | 41.7 | 29.2 | 22.5 | 18.3 | 15.4 | 13.3 | 11.7 | 11.4 |
| 2.0mA | 4Hz | 82.5 | 80.3 | 76.9 | 73.8 | 71.0 | 68.3 | 65.9 | 63.6 | 63.2 |
| | 20Hz | 75.1 | 66.9 | 56.6 | 49.0 | 43.3 | 38.7 | 35.0 | 32.0 | 31.4 |
| | 40Hz | 67.6 | 55.4 | 42.5 | 34.5 | 29.1 | 25.1 | 22.1 | 19.7 | 19.3 |
| | 60Hz | 61.5 | 47.2 | 34.1 | 26.6 | 21.9 | 18.6 | 16.1 | 14.2 | 13.9 |
| | 80Hz | 56.4 | 41.2 | 28.4 | 21.7 | 17.5 | 14.7 | 12.7 | 11.1 | 10.9 |
| | 100Hz | 52.0 | 36.5 | 24.4 | 18.3 | 14.6 | 12.2 | 10.5 | 9.2 | 8.9 |
| 4.0mA | 4Hz | 56.6 | 53.8 | 49.7 | 46.2 | 43.1 | 40.5 | 38.1 | 36.0 | 35.6 |
| | 20Hz | 46.3 | 38.2 | 29.6 | 24.1 | 20.4 | 17.6 | 15.5 | 13.9 | 13.6 |
| | 40Hz | 37.7 | 28.0 | 19.6 | 15.1 | 12.3 | 10.3 | 8.9 | 7.8 | 7.7 |
| | 60Hz | 31.8 | 22.1 | 14.7 | 11.0 | 8.8 | 7.3 | 6.3 | 5.5 | 5.3 |
| | 80Hz | 27.5 | 18.3 | 11.7 | 8.6 | 6.8 | 5.6 | 4.8 | 4.2 | 4.1 |
| | 100Hz | 24.3 | 15.6 | 9.8 | 7.1 | 5.6 | 4.6 | 3.9 | 3.4 | 3.3 |
| 6.0mA | 4Hz | 52.6 | 47.4 | 40.8 | 35.8 | 31.8 | 28.7 | 26.1 | 24.0 | 23.6 |
| | 20Hz | 35.3 | 25.9 | 17.9 | 13.7 | 11.1 | 9.3 | 8.0 | 7.0 | 6.9 |
| | 40Hz | 25.0 | 16.5 | 10.5 | 7.7 | 6.1 | 5.0 | 4.3 | 3.7 | 3.6 |
| | 60Hz | 19.4 | 12.1 | 7.4 | 5.4 | 4.2 | 3.5 | 2.9 | 2.5 | 2.5 |
| | 80Hz | 15.8 | 9.6 | 5.8 | 4.1 | 3.2 | 2.6 | 2.2 | 1.9 | 1.9 |
| | 100Hz | 13.3 | 7.9 | 4.7 | 3.3 | 2.6 | 2.1 | 1.8 | 1.6 | 1.5 |

**Table 2: Load Impedance = 1 Kohm**

All longevity values are in months

| | | Pulsewidth | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Amplitude** | **Frequency** | 40uS | 100uS | 200uS | 300uS | 400uS | 500uS | 600uS | 700uS | 720uS |
| 0.1mA | 4Hz | 83.9 | 83.8 | 83.6 | 83.4 | 83.2 | 83.0 | 82.8 | 82.7 | 82.6 |
| | 20Hz | 81.5 | 80.9 | 80.1 | 79.2 | 78.3 | 77.5 | 76.7 | 75.9 | 75.8 |
| | 40Hz | 78.6 | 77.6 | 76.0 | 74.5 | 73.0 | 71.6 | 70.2 | 68.9 | 68.6 |
| | 60Hz | 76.0 | 74.6 | 72.4 | 70.3 | 68.3 | 66.5 | 64.7 | 63.1 | 62.7 |
| | 80Hz | 73.5 | 71.8 | 69.1 | 66.6 | 64.2 | 62.1 | 60.0 | 58.1 | 57.8 |
| | 100Hz | 71.2 | 69.2 | 66.1 | 63.2 | 60.6 | 58.2 | 56.0 | 53.9 | 53.5 |
| 0.2mA | 4Hz | 83.8 | 83.6 | 83.2 | 82.8 | 82.5 | 82.1 | 81.7 | 81.4 | 81.3 |
| | 20Hz | 81.1 | 80.1 | 78.3 | 76.7 | 75.1 | 73.6 | 72.2 | 70.8 | 70.5 |
| | 40Hz | 78.0 | 76.0 | 73.0 | 70.2 | 67.6 | 65.2 | 63.0 | 60.9 | 60.5 |
| | 60Hz | 75.1 | 72.4 | 68.3 | 64.7 | 61.5 | 58.5 | 55.9 | 53.4 | 53.0 |
| | 80Hz | 72.4 | 69.1 | 64.2 | 60.0 | 56.4 | 53.1 | 50.2 | 47.6 | 47.1 |
| | 100Hz | 69.8 | 66.1 | 60.6 | 56.0 | 52.0 | 48.6 | 45.6 | 42.9 | 42.4 |
| 0.4mA | 4Hz | 83.7 | 83.2 | 82.5 | 81.7 | 81.0 | 80.3 | 79.6 | 78.9 | 78.8 |
| | 20Hz | 80.4 | 78.3 | 75.1 | 72.2 | 69.4 | 66.9 | 64.6 | 62.4 | 61.9 |
| | 40Hz | 76.7 | 73.0 | 67.6 | 63.0 | 58.9 | 55.4 | 52.2 | 49.4 | 48.9 |
| | 60Hz | 73.3 | 68.3 | 61.5 | 55.9 | 51.2 | 47.2 | 43.8 | 40.9 | 40.4 |
| | 80Hz | 70.1 | 64.2 | 56.4 | 50.2 | 45.2 | 41.2 | 37.8 | 34.9 | 34.4 |
| | 100Hz | 67.3 | 60.6 | 52.0 | 45.6 | 40.5 | 36.5 | 33.2 | 30.4 | 29.9 |
| 0.6mA | 4Hz | 83.5 | 82.8 | 81.7 | 80.7 | 79.6 | 78.6 | 77.6 | 76.6 | 76.4 |
| | 20Hz | 79.7 | 76.7 | 72.2 | 68.2 | 64.6 | 61.3 | 58.4 | 55.7 | 55.2 |
| | 40Hz | 75.4 | 70.2 | 63.0 | 57.1 | 52.2 | 48.1 | 44.6 | 41.6 | 41.0 |
| | 60Hz | 71.5 | 64.7 | 55.9 | 49.1 | 43.8 | 39.6 | 36.1 | 33.2 | 32.6 |
| | 80Hz | 68.1 | 60.0 | 50.2 | 43.1 | 37.8 | 33.6 | 30.3 | 27.6 | 27.1 |
| | 100Hz | 64.9 | 56.0 | 45.6 | 38.4 | 33.2 | 29.2 | 26.1 | 23.6 | 23.1 |
| 0.8mA | 4Hz | 83.4 | 82.5 | 81.0 | 79.6 | 78.2 | 76.9 | 75.7 | 74.4 | 74.2 |
| | 20Hz | 79.0 | 75.1 | 69.4 | 64.6 | 60.3 | 56.6 | 53.3 | 50.4 | 49.8 |
| | 40Hz | 74.2 | 67.6 | 58.9 | 52.2 | 46.9 | 42.5 | 38.9 | 35.9 | 35.3 |
| | 60Hz | 69.9 | 61.5 | 51.2 | 43.8 | 38.3 | 34.1 | 30.7 | 27.9 | 27.4 |
| | 80Hz | 66.1 | 56.4 | 45.2 | 37.8 | 32.4 | 28.4 | 25.3 | 22.8 | 22.3 |
| | 100Hz | 62.7 | 52.0 | 40.5 | 33.2 | 28.1 | 24.4 | 21.5 | 19.3 | 18.9 |

**Table 2: Load Impedance = 1 Kohm (Continued)**

All longevity values are in months

| | | Pulsewidth | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | 40uS | 100uS | 200uS | 300uS | 400uS | 500uS | 600uS | 700uS | 720uS |
| 1.0mA | 4Hz | 83.2 | 82.1 | 80.3 | 78.6 | 76.9 | 75.4 | 73.8 | 72.4 | 72.1 |
| | 20Hz | 78.3 | 73.6 | 66.9 | 61.3 | 56.6 | 52.5 | 49.0 | 46.0 | 45.4 |
| | 40Hz | 73.0 | 65.2 | 55.4 | 48.1 | 42.5 | 38.1 | 34.5 | 31.6 | 31.0 |
| | 60Hz | 68.3 | 58.5 | 47.2 | 39.6 | 34.1 | 29.9 | 26.6 | 24.0 | 23.6 |
| | 80Hz | 64.2 | 53.1 | 41.2 | 33.6 | 28.4 | 24.6 | 21.7 | 19.4 | 19.0 |
| | 100Hz | 60.6 | 48.6 | 36.5 | 29.2 | 24.4 | 20.9 | 18.3 | 16.3 | 15.9 |
| 1.5mA | 4Hz | 82.8 | 81.2 | 78.6 | 76.1 | 73.8 | 71.7 | 69.6 | 67.7 | 67.3 |
| | 20Hz | 76.7 | 70.1 | 61.3 | 54.5 | 49.0 | 44.6 | 40.8 | 37.7 | 37.1 |
| | 40Hz | 70.2 | 59.9 | 48.1 | 40.2 | 34.5 | 30.3 | 26.9 | 24.3 | 23.8 |
| | 60Hz | 64.7 | 52.3 | 39.6 | 31.9 | 26.6 | 22.9 | 20.1 | 17.9 | 17.5 |
| | 80Hz | 60.0 | 46.4 | 33.6 | 26.4 | 21.7 | 18.4 | 16.0 | 14.2 | 13.8 |
| | 100Hz | 56.0 | 41.7 | 29.2 | 22.5 | 18.3 | 15.4 | 13.3 | 11.7 | 11.4 |
| 2.0mA | 4Hz | 58.4 | 57.2 | 55.1 | 53.3 | 51.5 | 49.9 | 48.3 | 46.9 | 46.6 |
| | 20Hz | 53.1 | 48.2 | 41.8 | 36.9 | 33.0 | 29.8 | 27.3 | 25.1 | 24.7 |
| | 40Hz | 47.7 | 40.3 | 32.1 | 26.6 | 22.8 | 19.9 | 17.6 | 15.9 | 15.5 |
| | 60Hz | 43.2 | 34.6 | 26.0 | 20.8 | 17.4 | 14.9 | 13.0 | 11.6 | 11.3 |
| | 80Hz | 39.6 | 30.4 | 21.9 | 17.1 | 14.0 | 11.9 | 10.3 | 9.1 | 8.9 |
| | 100Hz | 36.5 | 27.0 | 18.9 | 14.5 | 11.8 | 9.9 | 8.6 | 7.5 | 7.4 |
| 4.0mA | 4Hz | 53.0 | 49.1 | 43.6 | 39.2 | 35.7 | 32.7 | 30.2 | 28.0 | 27.6 |
| | 20Hz | 36.3 | 28.4 | 20.9 | 16.5 | 13.6 | 11.6 | 10.1 | 9.0 | 8.8 |
| | 40Hz | 26.1 | 18.6 | 12.6 | 9.6 | 7.7 | 6.4 | 5.5 | 4.8 | 4.7 |
| | 60Hz | 20.3 | 13.9 | 9.1 | 6.7 | 5.3 | 4.4 | 3.8 | 3.3 | 3.2 |
| | 80Hz | 16.7 | 11.0 | 7.1 | 5.2 | 4.1 | 3.4 | 2.9 | 2.5 | 2.5 |
| | 100Hz | 14.1 | 9.2 | 5.8 | 4.2 | 3.3 | 2.7 | 2.3 | 2.0 | 2.0 |
| 6.0mA | 4Hz | 51.4 | 46.5 | 40.2 | 35.4 | 31.6 | 28.6 | 26.1 | 24.0 | 23.6 |
| | 20Hz | 32.7 | 24.5 | 17.4 | 13.4 | 10.9 | 9.2 | 8.0 | 7.0 | 6.9 |
| | 40Hz | 22.4 | 15.4 | 10.1 | 7.6 | 6.0 | 5.0 | 4.3 | 3.7 | 3.7 |
| | 60Hz | 17.1 | 11.3 | 7.2 | 5.3 | 4.2 | 3.4 | 2.9 | 2.5 | 2.5 |
| | 80Hz | 13.8 | 8.9 | 5.5 | 4.0 | 3.2 | 2.6 | 2.2 | 1.9 | 1.9 |
| | 100Hz | 11.6 | 7.3 | 4.5 | 3.3 | 2.6 | 2.1 | 1.8 | 1.6 | 1.5 |

**Table 3: Load Impedance = 1.5 Kohm**

All longevity values are in months

| | | Pulsewidth | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Amplitude** | **Frequency** | 40uS | 100uS | 200uS | 300uS | 400uS | 500uS | 600uS | 700uS | 720uS |
| 0.1mA | 4Hz | 83.9 | 83.8 | 83.6 | 83.4 | 83.2 | 83.0 | 82.8 | 82.7 | 82.6 |
| | 20Hz | 81.5 | 80.9 | 80.1 | 79.2 | 78.3 | 77.5 | 76.7 | 75.9 | 75.8 |
| | 40Hz | 78.6 | 77.6 | 76.0 | 74.5 | 73.0 | 71.6 | 70.2 | 68.9 | 68.6 |
| | 60Hz | 76.0 | 74.6 | 72.4 | 70.3 | 68.3 | 66.5 | 64.7 | 63.1 | 62.7 |
| | 80Hz | 73.5 | 71.8 | 69.1 | 66.6 | 64.2 | 62.1 | 60.0 | 58.1 | 57.8 |
| | 100Hz | 71.2 | 69.2 | 66.1 | 63.2 | 60.6 | 58.2 | 56.0 | 53.9 | 53.5 |
| 0.2mA | 4Hz | 83.8 | 83.6 | 83.2 | 82.8 | 82.5 | 82.1 | 81.7 | 81.4 | 81.3 |
| | 20Hz | 81.1 | 80.1 | 78.3 | 76.7 | 75.1 | 73.6 | 72.2 | 70.8 | 70.5 |
| | 40Hz | 78.0 | 76.0 | 73.0 | 70.2 | 67.6 | 65.2 | 63.0 | 60.9 | 60.5 |
| | 60Hz | 75.1 | 72.4 | 68.3 | 64.7 | 61.5 | 58.5 | 55.9 | 53.4 | 53.0 |
| | 80Hz | 72.4 | 69.1 | 64.2 | 60.0 | 56.4 | 53.1 | 50.2 | 47.6 | 47.1 |
| | 100Hz | 69.8 | 66.1 | 60.6 | 56.0 | 52.0 | 48.6 | 45.6 | 42.9 | 42.4 |
| 0.4mA | 4Hz | 83.7 | 83.2 | 82.5 | 81.7 | 81.0 | 80.3 | 79.6 | 78.9 | 78.8 |
| | 20Hz | 80.4 | 78.3 | 75.1 | 72.2 | 69.4 | 66.9 | 64.6 | 62.4 | 61.9 |
| | 40Hz | 76.7 | 73.0 | 67.6 | 63.0 | 58.9 | 55.4 | 52.2 | 49.4 | 48.9 |
| | 60Hz | 73.3 | 68.3 | 61.5 | 55.9 | 51.2 | 47.2 | 43.8 | 40.9 | 40.4 |
| | 80Hz | 70.1 | 64.2 | 56.4 | 50.2 | 45.2 | 41.2 | 37.8 | 34.9 | 34.4 |
| | 100Hz | 67.3 | 60.6 | 52.0 | 45.6 | 40.5 | 36.5 | 33.2 | 30.4 | 29.9 |
| 0.6mA | 4Hz | 83.5 | 82.8 | 81.7 | 80.7 | 79.6 | 78.6 | 77.6 | 76.6 | 76.4 |
| | 20Hz | 79.7 | 76.7 | 72.2 | 68.2 | 64.6 | 61.3 | 58.4 | 55.7 | 55.2 |
| | 40Hz | 75.4 | 70.2 | 63.0 | 57.1 | 52.2 | 48.1 | 44.6 | 41.6 | 41.0 |
| | 60Hz | 71.5 | 64.7 | 55.9 | 49.1 | 43.8 | 39.6 | 36.1 | 33.2 | 32.6 |
| | 80Hz | 68.1 | 60.0 | 50.2 | 43.1 | 37.8 | 33.6 | 30.3 | 27.6 | 27.1 |
| | 100Hz | 64.9 | 56.0 | 45.6 | 38.4 | 33.2 | 29.2 | 26.1 | 23.6 | 23.1 |
| 0.8mA | 4Hz | 83.4 | 82.5 | 81.0 | 79.6 | 78.2 | 76.9 | 75.7 | 74.4 | 74.2 |
| | 20Hz | 79.0 | 75.1 | 69.4 | 64.6 | 60.3 | 56.6 | 53.3 | 50.4 | 49.8 |
| | 40Hz | 74.2 | 67.6 | 58.9 | 52.2 | 46.9 | 42.5 | 38.9 | 35.9 | 35.3 |
| | 60Hz | 69.9 | 61.5 | 51.2 | 43.8 | 38.3 | 34.1 | 30.7 | 27.9 | 27.4 |
| | 80Hz | 66.1 | 56.4 | 45.2 | 37.8 | 32.4 | 28.4 | 25.3 | 22.8 | 22.3 |
| | 100Hz | 62.7 | 52.0 | 40.5 | 33.2 | 28.1 | 24.4 | 21.5 | 19.3 | 18.9 |

**Table 3: Load Impedance = 1.5 Kohm (Continued)**

All longevity values are in months

| | | Pulsewidth | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | 40uS | 100uS | 200uS | 300uS | 400uS | 500uS | 600uS | 700uS | 720uS |
| 1.0mA | 4Hz | 83.2 | 82.1 | 80.3 | 78.6 | 76.9 | 75.4 | 73.8 | 72.4 | 72.1 |
| | 20Hz | 78.3 | 73.6 | 66.9 | 61.3 | 56.6 | 52.5 | 49.0 | 46.0 | 45.4 |
| | 40Hz | 73.0 | 65.2 | 55.4 | 48.1 | 42.5 | 38.1 | 34.5 | 31.6 | 31.0 |
| | 60Hz | 68.3 | 58.5 | 47.2 | 39.6 | 34.1 | 29.9 | 26.6 | 24.0 | 23.6 |
| | 80Hz | 64.2 | 53.1 | 41.2 | 33.6 | 28.4 | 24.6 | 21.7 | 19.4 | 19.0 |
| | 100Hz | 60.6 | 48.6 | 36.5 | 29.2 | 24.4 | 20.9 | 18.3 | 16.3 | 15.9 |
| 1.5mA | 4Hz | 58.2 | 57.1 | 55.4 | 53.8 | 52.3 | 50.8 | 49.5 | 48.2 | 47.9 |
| | 20Hz | 52.0 | 47.9 | 42.5 | 38.1 | 34.6 | 31.6 | 29.1 | 27.0 | 26.6 |
| | 40Hz | 45.9 | 40.0 | 32.9 | 27.9 | 24.3 | 21.5 | 19.3 | 17.4 | 17.1 |
| | 60Hz | 41.1 | 34.2 | 26.8 | 22.1 | 18.7 | 16.3 | 14.4 | 12.9 | 12.6 |
| | 80Hz | 37.2 | 30.0 | 22.7 | 18.2 | 15.2 | 13.1 | 11.5 | 10.2 | 10.0 |
| | 100Hz | 33.9 | 26.6 | 19.6 | 15.5 | 12.8 | 10.9 | 9.5 | 8.5 | 8.3 |
| 2.0mA | 4Hz | 56.4 | 54.6 | 51.9 | 49.5 | 47.2 | 45.2 | 43.3 | 41.6 | 41.3 |
| | 20Hz | 45.7 | 40.4 | 33.8 | 29.1 | 25.6 | 22.8 | 20.5 | 18.7 | 18.4 |
| | 40Hz | 36.9 | 30.4 | 23.6 | 19.2 | 16.2 | 14.1 | 12.4 | 11.1 | 10.9 |
| | 60Hz | 30.9 | 24.4 | 18.1 | 14.4 | 11.9 | 10.2 | 8.9 | 7.9 | 7.7 |
| | 80Hz | 26.6 | 20.4 | 14.7 | 11.5 | 9.4 | 8.0 | 6.9 | 6.1 | 6.0 |
| | 100Hz | 23.4 | 17.5 | 12.3 | 9.5 | 7.8 | 6.5 | 5.7 | 5.0 | 4.9 |
| 4.0mA | 4Hz | 52.6 | 49.1 | 44.2 | 40.2 | 36.9 | 34.1 | 31.6 | 29.5 | 29.1 |
| | 20Hz | 35.3 | 28.5 | 21.6 | 17.4 | 14.5 | 12.5 | 10.9 | 9.7 | 9.5 |
| | 40Hz | 25.0 | 18.7 | 13.2 | 10.1 | 8.3 | 7.0 | 6.0 | 5.3 | 5.2 |
| | 60Hz | 19.3 | 13.9 | 9.5 | 7.2 | 5.8 | 4.8 | 4.2 | 3.6 | 3.6 |
| | 80Hz | 15.8 | 11.1 | 7.4 | 5.5 | 4.4 | 3.7 | 3.2 | 2.8 | 2.7 |
| | 100Hz | 13.3 | 9.2 | 6.1 | 4.5 | 3.6 | 3.0 | 2.6 | 2.2 | 2.2 |
| 6.0mA | 4Hz | 52.6 | 49.1 | 44.2 | 40.2 | 36.9 | 34.1 | 31.6 | 29.5 | 29.1 |
| | 20Hz | 35.3 | 28.5 | 21.6 | 17.4 | 14.5 | 12.5 | 10.9 | 9.7 | 9.5 |
| | 40Hz | 25.0 | 18.7 | 13.2 | 10.1 | 8.3 | 7.0 | 6.0 | 5.3 | 5.2 |
| | 60Hz | 19.3 | 13.9 | 9.5 | 7.2 | 5.8 | 4.8 | 4.2 | 3.6 | 3.6 |
| | 80Hz | 15.8 | 11.1 | 7.4 | 5.5 | 4.4 | 3.7 | 3.2 | 2.8 | 2.7 |
| | 100Hz | 13.3 | 9.2 | 6.1 | 4.5 | 3.6 | 3.0 | 2.6 | 2.2 | 2.2 |

**Table 4: Load Impedance = 2 Kohm**

All longevity values are in months

| | | Pulsewidth | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| **Amplitude** | **Frequency** | 40uS | 100uS | 200uS | 300uS | 400uS | 500uS | 600uS | 700uS | 720uS |
| 0.1mA | 4Hz | 83.9 | 83.8 | 83.6 | 83.4 | 83.2 | 83.0 | 82.8 | 82.7 | 82.6 |
| | 20Hz | 81.5 | 80.9 | 80.1 | 79.2 | 78.3 | 77.5 | 76.7 | 75.9 | 75.8 |
| | 40Hz | 78.6 | 77.6 | 76.0 | 74.5 | 73.0 | 71.6 | 70.2 | 68.9 | 68.6 |
| | 60Hz | 76.0 | 74.6 | 72.4 | 70.3 | 68.3 | 66.5 | 64.7 | 63.1 | 62.7 |
| | 80Hz | 73.5 | 71.8 | 69.1 | 66.6 | 64.2 | 62.1 | 60.0 | 58.1 | 57.8 |
| | 100Hz | 71.2 | 69.2 | 66.1 | 63.2 | 60.6 | 58.2 | 56.0 | 53.9 | 53.5 |
| 0.2mA | 4Hz | 83.8 | 83.6 | 83.2 | 82.8 | 82.5 | 82.1 | 81.7 | 81.4 | 81.3 |
| | 20Hz | 81.1 | 80.1 | 78.3 | 76.7 | 75.1 | 73.6 | 72.2 | 70.8 | 70.5 |
| | 40Hz | 78.0 | 76.0 | 73.0 | 70.2 | 67.6 | 65.2 | 63.0 | 60.9 | 60.5 |
| | 60Hz | 75.1 | 72.4 | 68.3 | 64.7 | 61.5 | 58.5 | 55.9 | 53.4 | 53.0 |
| | 80Hz | 72.4 | 69.1 | 64.2 | 60.0 | 56.4 | 53.1 | 50.2 | 47.6 | 47.1 |
| | 100Hz | 69.8 | 66.1 | 60.6 | 56.0 | 52.0 | 48.6 | 45.6 | 42.9 | 42.4 |
| 0.4mA | 4Hz | 83.7 | 83.2 | 82.5 | 81.7 | 81.0 | 80.3 | 79.6 | 78.9 | 78.8 |
| | 20Hz | 80.4 | 78.3 | 75.1 | 72.2 | 69.4 | 66.9 | 64.6 | 62.4 | 61.9 |
| | 40Hz | 76.7 | 73.0 | 67.6 | 63.0 | 58.9 | 55.4 | 52.2 | 49.4 | 48.9 |
| | 60Hz | 73.3 | 68.3 | 61.5 | 55.9 | 51.2 | 47.2 | 43.8 | 40.9 | 40.4 |
| | 80Hz | 70.1 | 64.2 | 56.4 | 50.2 | 45.2 | 41.2 | 37.8 | 34.9 | 34.4 |
| | 100Hz | 67.3 | 60.6 | 52.0 | 45.6 | 40.5 | 36.5 | 33.2 | 30.4 | 29.9 |
| 0.6mA | 4Hz | 83.5 | 82.8 | 81.7 | 80.7 | 79.6 | 78.6 | 77.6 | 76.6 | 76.4 |
| | 20Hz | 79.7 | 76.7 | 72.2 | 68.2 | 64.6 | 61.3 | 58.4 | 55.7 | 55.2 |
| | 40Hz | 75.4 | 70.2 | 63.0 | 57.1 | 52.2 | 48.1 | 44.6 | 41.6 | 41.0 |
| | 60Hz | 71.5 | 64.7 | 55.9 | 49.1 | 43.8 | 39.6 | 36.1 | 33.2 | 32.6 |
| | 80Hz | 68.1 | 60.0 | 50.2 | 43.1 | 37.8 | 33.6 | 30.3 | 27.6 | 27.1 |
| | 100Hz | 64.9 | 56.0 | 45.6 | 38.4 | 33.2 | 29.2 | 26.1 | 23.6 | 23.1 |
| 0.8mA | 4Hz | 83.4 | 82.5 | 81.0 | 79.6 | 78.2 | 76.9 | 75.7 | 74.4 | 74.2 |
| | 20Hz | 79.0 | 75.1 | 69.4 | 64.6 | 60.3 | 56.6 | 53.3 | 50.4 | 49.8 |
| | 40Hz | 74.2 | 67.6 | 58.9 | 52.2 | 46.9 | 42.5 | 38.9 | 35.9 | 35.3 |
| | 60Hz | 69.9 | 61.5 | 51.2 | 43.8 | 38.3 | 34.1 | 30.7 | 27.9 | 27.4 |
| | 80Hz | 66.1 | 56.4 | 45.2 | 37.8 | 32.4 | 28.4 | 25.3 | 22.8 | 22.3 |
| | 100Hz | 62.7 | 52.0 | 40.5 | 33.2 | 28.1 | 24.4 | 21.5 | 19.3 | 18.9 |

**Table 4: Load Impedance = 2 Kohm (Continued)**

All longevity values are in months

| | | Pulsewidth | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|---|
| | | 40uS | 100uS | 200uS | 300uS | 400uS | 500uS | 600uS | 700uS | 720uS |
| 1.0mA | 4Hz | 58.9 | 58.2 | 57.2 | 56.1 | 55.1 | 54.2 | 53.3 | 52.4 | 52.2 |
| | 20Hz | 55.0 | 52.2 | 48.2 | 44.8 | 41.8 | 39.2 | 36.9 | 34.8 | 34.4 |
| | 40Hz | 50.7 | 46.3 | 40.3 | 35.7 | 32.1 | 29.1 | 26.6 | 24.5 | 24.2 |
| | 60Hz | 47.1 | 41.5 | 34.6 | 29.7 | 26.0 | 23.1 | 20.8 | 18.9 | 18.6 |
| | 80Hz | 44.0 | 37.7 | 30.4 | 25.4 | 21.9 | 19.2 | 17.1 | 15.4 | 15.1 |
| | 100Hz | 41.2 | 34.5 | 27.0 | 22.2 | 18.9 | 16.4 | 14.5 | 13.0 | 12.7 |
| 1.5mA | 4Hz | 56.7 | 55.4 | 53.2 | 51.3 | 49.5 | 47.8 | 46.2 | 44.7 | 44.4 |
| | 20Hz | 46.7 | 42.4 | 36.8 | 32.5 | 29.1 | 26.4 | 24.1 | 22.2 | 21.8 |
| | 40Hz | 38.2 | 32.8 | 26.6 | 22.3 | 19.2 | 16.9 | 15.1 | 13.6 | 13.3 |
| | 60Hz | 32.4 | 26.8 | 20.8 | 17.0 | 14.4 | 12.4 | 11.0 | 9.8 | 9.6 |
| | 80Hz | 28.1 | 22.6 | 17.1 | 13.7 | 11.5 | 9.8 | 8.6 | 7.7 | 7.5 |
| | 100Hz | 24.8 | 19.6 | 14.5 | 11.5 | 9.5 | 8.1 | 7.1 | 6.3 | 6.2 |
| 2.0mA | 4Hz | 54.5 | 52.3 | 49.1 | 46.2 | 43.6 | 41.3 | 39.2 | 39.2 | 37.0 |
| | 20Hz | 40.1 | 34.7 | 28.4 | 24.1 | 20.9 | 18.4 | 16.5 | 16.5 | 14.6 |
| | 40Hz | 30.1 | 24.5 | 18.6 | 15.1 | 12.6 | 10.9 | 9.6 | 9.6 | 8.3 |
| | 60Hz | 24.1 | 18.9 | 13.9 | 11.0 | 9.1 | 7.7 | 6.7 | 6.7 | 5.8 |
| | 80Hz | 20.1 | 15.4 | 11.0 | 8.6 | 7.1 | 6.0 | 5.2 | 5.2 | 4.5 |
| | 100Hz | 17.2 | 13.0 | 9.2 | 7.1 | 5.8 | 4.9 | 4.2 | 4.2 | 3.6 |
| 4.0mA | 4Hz | 53.2 | 50.5 | 46.5 | 43.1 | 40.2 | 37.7 | 35.4 | 33.4 | 33.0 |
| | 20Hz | 36.7 | 31.0 | 24.5 | 20.3 | 17.4 | 15.1 | 13.4 | 12.1 | 11.8 |
| | 40Hz | 26.5 | 20.9 | 15.4 | 12.2 | 10.1 | 8.7 | 7.6 | 6.7 | 6.6 |
| | 60Hz | 20.7 | 15.7 | 11.3 | 8.8 | 7.2 | 6.1 | 5.3 | 4.6 | 4.5 |
| | 80Hz | 17.0 | 12.6 | 8.9 | 6.8 | 5.5 | 4.7 | 4.0 | 3.6 | 3.5 |
| | 100Hz | 14.4 | 10.6 | 7.3 | 5.6 | 4.5 | 3.8 | 3.3 | 2.9 | 2.8 |
| 6.0mA | 4Hz | 53.2 | 50.5 | 46.5 | 43.1 | 40.2 | 37.7 | 35.4 | 33.4 | 33.0 |
| | 20Hz | 36.7 | 31.0 | 24.5 | 20.3 | 17.4 | 15.1 | 13.4 | 12.1 | 11.8 |
| | 40Hz | 26.5 | 20.9 | 15.4 | 12.2 | 10.1 | 8.7 | 7.6 | 6.7 | 6.6 |
| | 60Hz | 20.7 | 15.7 | 11.3 | 8.8 | 7.2 | 6.1 | 5.3 | 4.6 | 4.5 |
| | 80Hz | 17.0 | 12.6 | 8.9 | 6.8 | 5.5 | 4.7 | 4.0 | 3.6 | 3.5 |
| | 100Hz | 14.4 | 10.6 | 7.3 | 5.6 | 4.5 | 3.8 | 3.3 | 2.9 | 2.8 |

# Appendix II: Troubleshooting

| Pop Up Message | Possible Solution |
|---|---|
| Connection with your stimulator was lost. Please reconnect. | • Swipe the programmer over the stimulator to establish connection and reconnect to the device.<br>• If you still cannot connect, move the programmer closer to the stimulator. Continue to swipe the magnet over the stimulator.<br>• Move to another location; there may be interference in your current location. |
| Unable to connect to your stimulator.<br>Please contact your physician during normal business hours. | • Press "OK" and attempt to reconnect to the stimulator.<br>• Swipe the programmer over the stimulator to establish connection and reconnect to the device.<br>• If you still cannot connect, move the programmer closer to the stimulator and continue to swipe the magnet over the stimulator.<br>• Move to another location; there may be interference in your current location.<br>• Contact your doctor during normal business hours if the problem continues. |
| Unable to connect to your stimulator. Please try again. | • Swipe the programmer over the stimulator to establish connection and reconnect to the device.<br>• If you still cannot connect, move the programmer closer to the stimulator and continue to swipe the magnet over the stimulator.<br>• Move to another location; there may be interference in your current location. |
| Your stimulator battery is low. It will need to be replaced soon. Please contact your physician during normal business hours (only applies to the INS). | • Contact your doctor during normal business hours to set up an appointment. Your stimulator has reached Elective Replacement Interval (ERI). |
| Your stimulator battery needs to be replaced. Stimulation has been turned OFF permanently.<br>Please contact your physician during normal business hours (only applies to the INS). | • Contact your doctor during normal business hours to set up an appointment. Your stimulator has reached End of Service (EOS) and will not stimulate. It must be replaced. |
| Stimulation for one or more leads has been turned OFF.<br>Please contact your physician during normal business hours. | • Swipe the programmer over the stimulator to establish connection and reconnect to the device.<br>• Go the Pain Control screen and turn on the lead that has been turned off.<br>• If you are unable to turn it back on, contact your doctor during normal business hours. |
| All stimulation has been turned OFF. Please contact your physician during normal business hours. | • Contact your doctor during normal business hours. |
| Stimulation has been turned OFF due to a magnet. Please use your programmer to restore stimulation. | • Swipe the programmer over the stimulator to establish connection and reconnect to the device.<br>• Go to the Pain Control screen. Turn on each lead one at a time. |
| You have turned all Stimulation OFF.<br>Please use your programmer to restore stimulation. | • You have turned off the device by pressing the switch on the TNS or by pressing the "Turn All Stimulation OFF" button on the programmer.<br>• Swipe the programmer over the stimulator to establish connection and reconnect to the device.<br>• Go the Pain Control screen. Turn on the leads that have been turned off. |
| Programmer battery is low. Please recharge. | • The battery has reached 30% on the programmer and needs to be recharged. |