

NeuroMetrix



ASCEND

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Part Number: PN 2202661 Rev. X16

Protected by US and international patents pending.



CAUTION: Federal law restricts the use of output of ASCEND to a physician or other properly licensed practitioner.

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CHAPTER ONE

Indications for Use, Principle of Operations, ASCEND Description

This manual is intended for users of the NeuroMetrix ASCEND Peripheral Nerve Stimulator (“ASCEND”).

Indications For Use

NeuroMetrix ASCEND is a peripheral nerve stimulator used for localization and verification of needle placement for perineural application of pharmacological agents.

Contraindications

Absolute and relative contraindications for using a peripheral nerve stimulator for percutaneous nerve localization procedures using insulated hypodermic needles include:

- Refusal of regional anesthesia by the patient
- Infection at the puncture site
- Preoperatively known neurological dysfunctions
- Anatomical abnormalities
- Severe coagulation disorders
- Insufficient liver function

Nerve Stimulation: Overview

Peripheral nerve stimulation (PNS) facilitates the performance of peripheral nerve and plexus blocks. Using nerve stimulation (NS), the physician does not need to rely on feedback from the patient about paresthetic sensations. As a result, the danger of mechanical nerve lesions is significantly diminished. When the stimulation needle is placed sufficiently close to the target nerve, predefined electrical pulses evoke compound muscle action potentials (CMAP) and consequent muscle contractions. During this procedure, direct contact of the injection needle with the nerve is intentionally avoided.

NS is not a substitute for the anatomical knowledge required to perform regional anesthesia. Therefore an accurate knowledge of the topography and nerve distribution area is essential.

The advantages of NS include:

- Muscle response is obtained without the user having to rely on information or cooperation from the patient
- Reduction in probability of direct needle-nerve contact, painful paresthesias, mechanical nerve lesions, and intraneuronal injections.

Nerve Stimulation: Principle of Operation

The resting potential at the nerve membrane is around 80 mV. The cell’s interior is negatively charged compared to the surrounding medium. Sufficiently large ion movement reduces the

membrane potential to about 55 mV, making the membrane freely permeable and generating an action potential.

The various types of nerve fiber differ with regard to their sensitivity to electrical stimulation. The A α motor fibers have the shortest chronaxia (50–100 μ s). The afferent fibers that transmit pain sensation (A δ and C-fibers) require a longer pulse (150 and/or 400) at a minimum current. Mixed peripheral nerves can be localized using short pulses (100 μ s) without triggering pain sensations. For pure sensory nerves, a longer pulse is recommended (200 μ s, 500 μ s or 1000 μ s).

When unipolar needles (insulated and with conductive tip) are used, the current necessary to trigger muscle responses correlates with the distance from the tip of the needle to the nerve. The lower the current, the more accurately the target nerve can be localized. This allows quicker onset and ensures a more reliable success of the blockade.

Nevertheless, it is important to observe and stay within the predefined threshold currents so as to avoid a too close proximity to the nerve and prevent nerve damage. The shorter the electrical pulse (i.e., stimulus duration), the faster is the rise in current to the nerve. This allows better discrimination by the physician as to whether the needle tip is sufficiently close to the nerve. The stimulation needle should always be connected to the negative pole. If the needle is connected to the positive pole, higher currents are required. The conductive tip of the stimulation needle affects the geometry of the electrical field. The smaller the emission site of the electrons at the tip of the needle, the higher is the current density at this point and the lower the threshold level once the nerve has been localized exactly.

ASCEND Description

ASCEND is a battery powered nerve stimulator for localization of peripheral nerves. It is comprised of the following components.

1. Stimulator

The Stimulator includes the electronic circuits that provide electrical nerve stimulation, user controls which include a stimulation current magnitude control and function buttons that control stimulation parameters such as duration and frequency, and a 320 by 240 color LCD touch screen for user input and display of the target current, impedance and other important parameters. The Stimulator includes a permanent 3.7V Li-Polymer battery. The stimulator has a connector to a needle and electrode interface cable as well as a micro USB port.



Figure 1

2. Needle and Electrode Interface Cable (“Cable”)

The Cable provides an interface between the Stimulator and the insulated hypodermic needles and surface electrodes used in nerve localization procedures. One end of the Cable plugs into connector on the top of Stimulator. The other end of the connector ends in yoke with two connectors: one into which a needle with a pre-attached leads is connected and one into which a cable terminating in an alligator clip is connected (the alligator clip is then attached to a disposable surface electrode).

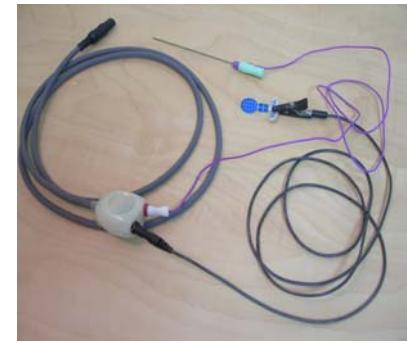


Figure 2

3. Charging Cradle (“Cradle”)

The Cradle is connected to an AC outlet via a medical grade AC/DC adapter. The Cradle has LEDs that indicate its on/off status and the charging/charge status of Stimulator (see Chapter 2 for a description of the Cradle LED indicator).



Figure 3

4. USB port

The USB port is for programming and communication. Stimulation is disabled and cannot be performed when the USB port is connected

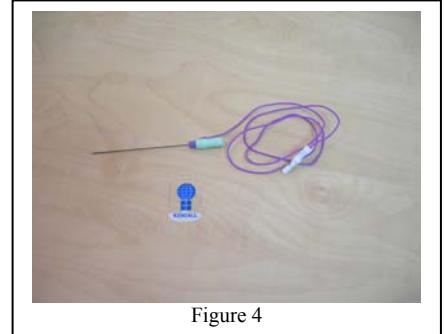
ASCEND may be used with the following accessories.

1. Hypodermic Insulated Needles (“Needles”)

ASCEND is optimized for nerve localization procedures using disposable hypodermic needle electrodes distributed by NeuroMetrix. These needles typically serve as the stimulation cathode.

2. Surface Electrodes (“Electrodes”)

ASCEND utilizes a disposable tab surface electrode as the stimulation anode. ASCEND can be used with any suitable disposable surface electrode.



CHAPTER TWO

Preparing ASCEND for Use

Overview

Prior to use, the ASCEND Stimulator, Cradle, and other packaged components should be inspected to ensure that they have not been damaged in shipping. If damage is encountered, or if any component fails to operate as described in this manual, contact NeuroMetrix Customer Service immediately. Within the USA, customers should contact NeuroMetrix via:

Phone: 1-888-786-7287
Fax: (781) 890-1556
Email: service@neurometrix.com

International customers should contact the nearest authorized NeuroMetrix representative. If the shipping container is damaged, customers should also notify the shipping carrier.

The ASCEND system package should contain the following components:

- Installation Card
- User's Manual
- Stimulator
- Cable
- Cradle
- Power Supply for Cradle

Operating software is pre-installed in the device before it is shipped from the factory.

Cradle Setup

Before use, visually inspect the Cradle. Make sure that the Cradle's plastic housing is undamaged. The Cradle should then be plugged into a power outlet using the medical grade power supply provided.

Stimulator Setup

Before use, visually inspect the Stimulator. Make sure wire insulation is intact and that the plastic housing of the device is undamaged. Place the Stimulator in the Cradle to charge its internal battery. Charge the battery for a minimum of 6 hours. When an incompletely charged Stimulator is placed in the Cradle, the Stimulator charge status LED will display an amber light; a green light signifies a fully charged battery.

Once the Stimulator battery is charged, power up the Stimulator by pressing the POWER button. After the Stimulator powers up, it will conduct a self test. Once completed, the LCD will display the START screen. If the device fails the self test, the device will disable the stimulator circuit, and the LCD will display the message STIMULATOR ERROR. If the Stimulator fails to power up when the power button is pressed, confirm that the battery is fully charged and try again. If the Stimulator fails to power up again, please contact Customer Service.

Registration

NeuroMetrix Customer Service will register your system at the time of installation.

CHAPTER THREE

User Interface and Controls

Overview

This section describes the Stimulator User Interface. Physical buttons are indicated in bold **blue**. On screen buttons, which are activated by tapping the touch screen with the stylus, are indicated in bold **green**. On screen messages are indicated in **orange**.

Control Buttons

POWER – powers Stimulator on and off.

FUNCTION – the Stimulator has four context sensitive function buttons along the left side of the device (Chapter 1, Figure 1). The button's current function is indicated on the screen to the right of the button. (Figure 6, red rectangle). The function of these buttons varies depending upon the Stimulator's operating mode and can change within an operating mode.

DIAL – regulates the target stimulation current.

RESET – resets Stimulator.

Screens

The Stimulator has one screen from which the operator controls the device. In this screen the operator controls nerve stimulation.



Figure 6 – Stimulation Control Screen

In the Stimulation Control Screen, (Figure 6), the four **function** buttons described above have the following functions. The top button controls stimulation frequency. Values of Single, 1Hz or 2 Hz may be selected. The second button controls stimulus duration. Values of 50, 100, 200, 500,

1000 μ sec may be selected. The third button starts and stops stimulation. The bottom button is reserved for future use.

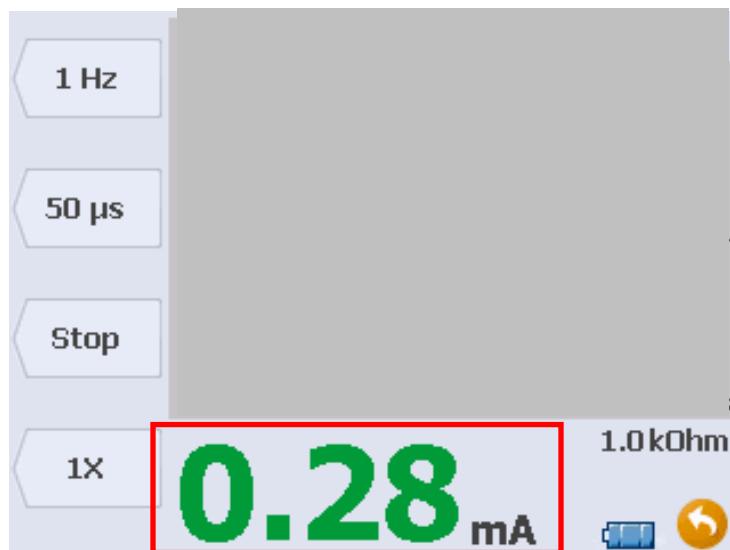


Figure 7 – Patient Stimulation Current Indicator

The patient stimulation current indicator (Figure 7, red rectangle) shows the current delivered to the patient.



Figure 8 – Stimulus Indicator

The stimulus indicator (Figure 8, red rectangle) blinks when a stimulus is delivered. The color of the indicator is:

- Green, when the patient current is above the threshold current and is within the tolerance (see Appendix B) of the target current.

- Orange, when the patient current is equal to or less than the threshold current and is within the tolerance of the target current.
- Red when the patient current is out of the tolerance of the target current.
- Gray and steady when no stimulus is being delivered.

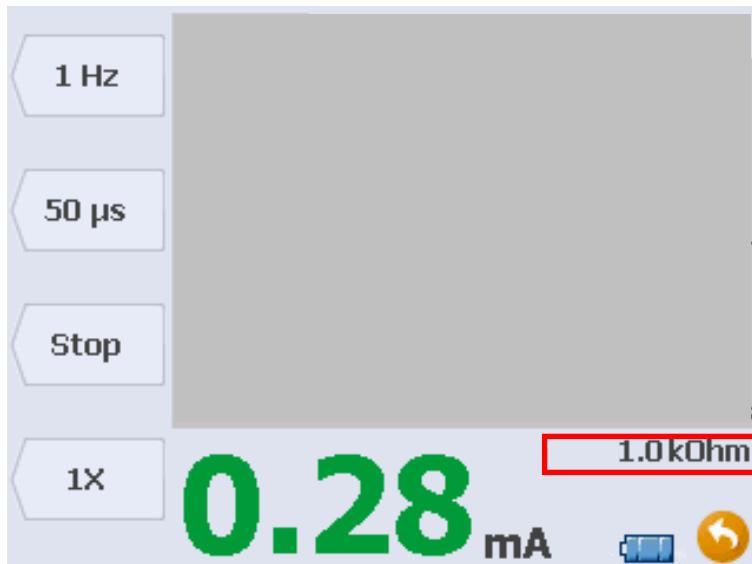


Figure 9 – Impedance Display

The impedance display (Figure 9, red rectangle) indicates the impedance in kOhm between the needle and the return electrode (anode). The target stimulation current will also be shown if the patient delivered current is out of tolerance.

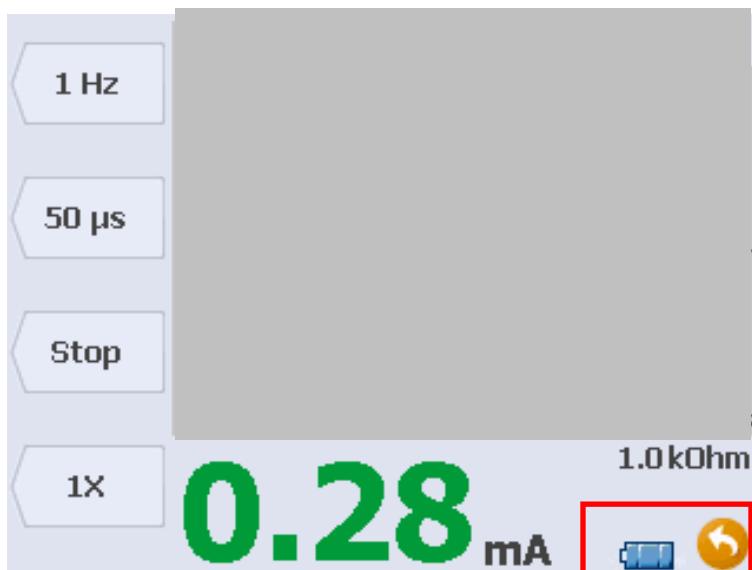


Figure 10 – Battery Fuel Gauge & Back Arrow

This bottom right corner of the screen (Figure 10, red rectangle) shows the battery fuel gauge and the back arrow to return the operator to the main screen.

CHAPTER FOUR

Device Operation

Overview

This chapter describes basic operation of ASCEND.

The operator should verify that all ASCEND components are in a serviceable condition before each use. Defective components should not be used. The equipment may only be repaired by NeuroMetrix. Please contact customer service at 1-888-786-7287 if you have any concerns regarding the device.

Connecting Cables

Connect the stimulation cable to the device.

Connect an appropriately sized NeuroMetrix hypodermic needle to the stimulation cable yoke (black jack) See Appendix F for list and ordering instructions.

Connect the surface electrode (anode) lead wire to the stimulation cable yoke (red jack).

Power On

Press the **POWER** button.

Upon power up, a self-test will be performed (see Chapter 5 for a detailed description). If the self-test fails then an audible alarm will sound and a text message (see Appendix B for a detailed description) will appear on the screen. Stimulation is disabled if the self test fails.

Power Off

Press the **POWER** button.

Stimulation Current

The magnitude of the target stimulation current level is set using the **DIAL**. The target current is set to 0.00 mA on power up and may range from 0.00 to 5.00 mA. The resolution of the current increments varies according to the current level as shown below.

Target Current Range	Target Current Increments
0.0 – 0.1 mA	0.01 mA
0.1 – 0.5 mA	0.02 mA
0.5 – 2.0 mA	0.1 mA
2.0 – 5 mA	0.25 mA

Stimulus Duration

The stimulus duration is set by pressing the **DURATION** button. Each time this button is pressed it will change the duration to the next value in the following repeating sequence: 50 μ sec, 100 μ sec, 200 μ sec, 500 μ sec, 1000 μ sec. On power up the duration is set to 100 μ sec.

Stimulation Frequency

The stimulation frequency is set by pressing the **FREQUENCY** button. Each time this button is pressed it will change the frequency to the next value in the following repeating sequence: 1 Hz, 2 Hz, Single. On power up the frequency is set to 1 Hz.

When the stimulation frequency is set to Single, the device does not automatically stimulate the nerve. A single stimulus will be generated whenever the **TRIGGER** button is pressed.

There are a number of ways for the operator to stop stimulation:

- Press **STOP** button when stimulating in 1 Hz or 2 Hz modes.
- Decrease the stimulation current to 0 mA with the control dial.
- Withdraw the needle. If the needle is withdrawn, no current will be delivered to patient.
- Disconnect the needle lead wire from the stimulator cable yoke.
- Power Stimulator off.

CHAPTER FIVE

Device Checks

Overview

If the Stimulator and its accessories parts do not function as described below, please contact customer service at 1-888-786-7287 for assistance.

Power up self test

When the application starts, the device will perform the following self test:

- Check power supplies
- Check stimulation circuit
- Check CPU memory
- Check MSP ADC

Stimulating Electrodes Connection Check

Unplug the needle or the stimulation surface electrode and increase the stimulation current using the **DIAL** from 0 to 0.05 mA. 0.00mA is displayed in orange color, the stimulus indicator blinks in red color, and the audio alarm sounds, and the impedance is out of range (too high).

Check Stimulation High Voltage

The stimulation high voltage is verified by the Stimulator. If the voltage does not reach the minimum acceptable level (81 volts), the test is halted and a “**Stim Aborted Code: 0x0021**” error message displayed. In the event of this error, the user should recharge the battery. If the same error message occurs following battery recharging, contact NeuroMetrix Customer Service to arrange for device servicing.

Stimulation Circuitry Check

The device performs a power-up self-check on the stimulation circuitry by delivering a stimulus to an internal resistor (10 kOhm). If the delivered current magnitude is not within tolerance of the target current, the test is halted and a “**Stim Aborted Code: 0x0061**” message will be displayed. The device should be returned to NeuroMetrix for service.

See Appendix B for a description of the error descriptions, codes, warnings and cautions.

APPENDIX A

Warranty, Service, Care, and Device Registration

The ASCEND system has been manufactured to the highest quality standards. To ensure continued trouble-free operation, avoid exposure to excessive shock, vibration, or moisture. Particular care should be taken to protect the Cable. To clean the Stimulator and Charger, observe the following guidelines:

- Use a soft damp cloth or sponge to clean the exterior of the unit.
- Insure no water penetrates the devices
- Use only wipes for disinfection, no spray should be used (to avoid condensation)
- Methanol free substances should be used for disinfection.
- Caution! Do not use abrasive cleaners or strong solvents to clean the device.
- Under no circumstance should the LCD screen be touched with any object other than the supplied stylus.

The ASCEND system is designed to be used in a clinical environment. Proper care should be used when maintaining these components. Inspect all parts for any visible damage. Never use any damaged or modified parts!

Electrode/Needle Disposal

Used stimulation needles and surface electrodes should be discarded in accordance with national, regional, and local regulations. The used needles are considered biohazardous waste and should be discarded in a suitable biohazardous waste container (sharps).

Coverage during the Warranty Period

During the 1 year period beginning on the invoice date, NeuroMetrix, Inc. will repair or replace products covered under this limited warranty that are returned to NeuroMetrix, Inc. or an authorized service facility. To request warranty service, you must call the NeuroMetrix Customer Service department within the warranty period. If warranty service is required, NeuroMetrix will issue a Return Material Authorization number. You must ship the products back to NeuroMetrix in the original or equivalent packaging, prepay shipping charges, and insure the shipment, or accept the risk of loss or damage during shipment. NeuroMetrix will ship the repaired or replacement products to you freight prepaid to U.S. or Canadian addresses. Shipments to other locations will be made freight collect.

NeuroMetrix, Inc. Limited One Year Warranty

NeuroMetrix, Inc. manufactures its hardware products from new components in accordance with industry standard practices. NeuroMetrix, Inc. warrants the ASCEND System to be free from defects in materials and workmanship. The warranty term is one year beginning on the date of invoice, as described in the following text.

Damage due to shipping the products is covered under this warranty. Otherwise, this warranty does not cover damage due to external causes, including accident, abuse, misuse, problems with electrical power, servicing not authorized by NeuroMetrix, Inc., usage not in accordance with product instructions, failure to perform required preventive maintenance, and problems caused by use of parts and components not supplied by NeuroMetrix, Inc.

This warranty does not cover any items that are in one or more of the following categories: software, external devices (except as specifically noted) or accessories or parts added to a NeuroMetrix system through authorized NeuroMetrix service centers.

NeuroMetrix, Inc. will repair or replace products covered under this limited warranty that are returned to NeuroMetrix's facility or an authorized NeuroMetrix representative. To request warranty service, you must call the NeuroMetrix Customer Service Department or an authorized technical support representative within the warranty period. NeuroMetrix will issue a Return Material Authorization Number. The product must be shipped to NeuroMetrix in the original or equivalent packaging with prepaid shipping charges and insured against loss or damage during shipment. NeuroMetrix will ship the repaired or replacement units to the originator (freight prepaid) to addresses within the US or Canada. Shipments to other locations will be made freight collect.

All parts removed from repaired products will become the property of NeuroMetrix, Inc. If NeuroMetrix repairs or replaces a product, the original warranty is not extended.

NEUROMETRIX, INC. MAKES NO EXPRESS WARRANTIES OR CONDITIONS BEYOND THOSE STATED IN THIS WARRANTY STATEMENT. NEUROMETRIX DISCLAIMS ALL OTHER WARRANTIES AND CONDITIONS, EXPRESS OR IMPLIED, INCLUDING WITHOUT LIMITATION IMPLIED WARRANTIES AND CONDITIONS OR MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE. SOME STATES (OR JURISDICTIONS) DO NOT ALLOW LIMITATIONS ON IMPLIED WARRANTIES OR CONDITIONS, SO THIS LIMITATION MAY NOT APPLY TO YOU.

NEUROMETRIX RESPONSIBILITY FOR MALFUNCTIONS AND DEFECTS IN HARDWARE IS LIMITED TO REPAIR AND REPLACEMENT AS SET FORTH IN THIS WARRANTY STATEMENT. THESE WARRANTIES GIVE YOU SPECIFIC LEGAL RIGHTS IN ADDITION TO OTHER RIGHTS WHICH VARY FROM STATE TO STATE.

NEUROMETRIX INC. DOES NOT ACCEPT LIABILITY BEYOND THE REMEDIES SET FORTH IN THIS WARRANTY STATEMENT OR LIABILITY FOR INCIDENTAL OR CONSEQUENTIAL DAMAGES, INCLUDING WITHOUT LIMITATION ANY LIABILITY FOR PRODUCTS NOT BEING AVAILABLE FOR USE OR FOR LOST DATA OR SOFTWARE.

These provisions apply to Neurometrix's limited one-year warranty only.

FDA Notification

The ASCEND and Biosensors are manufactured in compliance with the U.S. Federal Quality System Regulation (21 CFR Part 820). As a health care provider, you may have responsibilities under the Safe Medical Devices Act (SMDA) for reporting to NeuroMetrix, and possibly the FDA, the occurrence of certain events. FDA reportable events are detailed in 21 CFR Part 803.

In accordance with our Quality System, NeuroMetrix should be notified of any device failures or malfunctions. Issues encountered should be reported to NeuroMetrix Customer Service at (888) 786-7287. Outside of the United States, device issues should be reported to the nearest ASCEND distributor. This information will help ensure that NeuroMetrix continues to provide products and service of the highest possible quality.

FCC Part 15 Class B Statement

RADIO AND TELEVISION INTERFERENCE

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.**
- Increase the separation between the equipment and the receiver.**
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.**
- Consult the dealer or an experienced radio/TV technician for help.**

Changes and Modifications not expressly approved by NeuroMetrix, Inc. can void your authority to operate this equipment under Federal Communications Commissions rules.

FCC Radiation Exposure Statement

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment complies with FCC requirements for SAR (Specific Absorption Rate).

This transmitter FCC ID: XUL-RF-SYNC will be co-located or operating in conjunction with the following on board Bluetooth antenna/transmitter made by BlueRadios, Inc., FCC ID: POOWML-C40.

Service

It is the responsibility of users requiring service to report the need for service to NeuroMetrix or to one of our authorized agents. In the events of equipment malfunction, all repairs should be performed by NeuroMetrix or their authorized agent. Service can be facilitated by contacting NeuroMetrix at:

NeuroMetrix, Inc.
62 Fourth Avenue
Waltham, MA 02451
USA
Telephone: 1-888-786-7287

When you call NeuroMetrix to request service, please be prepared to provide the following information:

- Device model
- Serial number
- Observation that led to the call

Do not return any component of the ASCEND system without first obtaining a Return Material Authorization (RMA) number from Customer Service. Be sure the RMA number is clearly visible on the exterior of the return package. If an ASCEND component must be shipped to a service center, pack it in the original shipping container or with sufficient protective packing to prevent damage during shipment.

Software License Agreement

NeuroMetrix, Inc.
ASCEND®
License Agreement

1. Proprietary Rights.

The software (including firmware) installed on the ASCEND, including without limitation any updates or upgrades thereto provided by NeuroMetrix, Inc. (collectively, the "Software"), and any associated documentation, is subject to the protection of the copyright laws of the U.S. and foreign jurisdictions, which prohibit unauthorized copying and distribution of copyrighted works. The Software and documentation incorporate proprietary and confidential algorithms and techniques of NeuroMetrix, Inc (the "Licensor") that are subjected to legal protection as trade secrets. The person acquiring and/or using the Software (the "User") is granted only those rights expressly conferred by the license grant set forth in Section 2 of this license agreement (this "Agreement").

2. License Grant.

Licensor grants the User a license to use the Software and any associated documentation for the User's personal use or internal business or professional purposes solely as intended to operate and use the ASCEND, and solely as installed on and/or provided with the ASCEND purchased from Licensor or its authorized distributor or reseller, consistent with the terms of this Agreement.

3. Reserved Rights.

Licensor reserves any rights not expressly granted in Section 2. Without limiting the foregoing, Licensor reserves the right to license the Software and any associated documentation to others on such terms as Licensor may establish in its sole discretion.

4. Restrictions.

The User may not:

- a. copy the Software or documentation in any manner or for any purpose;
- b. resell or distribute the Software, or any copy, by transfer, lease, loan or any other means, or make it available for use by others in any time-sharing, service bureau or similar arrangements;
- c. disassemble, decrypt, extract, reverse engineer or reverse compile the Software, or otherwise attempt to discover the confidential algorithms and techniques incorporated in the Software, or disclose or use any confidential information of Licensor in any manner other than as expressly authorized in this Agreement; or
- d. modify, translate, adapt, or create derivative works from the Software or the documentation.

5. Term.

This agreement is effective until terminated. This Agreement and the User's right to use the Software and documentation will automatically terminate without notice in the event of any failure by the User to comply with any of the above restrictions or any term of this Agreement. Upon termination, the User shall return the ASCEND, including all of the Software and documentation in the User's possession. All provisions of Sections 1, 6, 7 and 8 of this Agreement shall survive termination.

6. Limited Warranty.

- a. The Software and documentation is provided "AS IS" and in its present state and condition and Licensor makes no other warranty whatsoever with respect to the Software and documentation. This is Licensor's entire liability and the User's sole and exclusive remedy in connection with any breach of this Agreement, including, but not limited to, any breach of warranty. Licensor does not warrant that operation of the Software will be uninterrupted or error-free, or that it will satisfy the User's requirements.

b. LICENSOR DISCLAIMS ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, TITLE OR NONINFRINGEMENT OF THIRD PARTIES' INTELLECTUAL PROPERTY RIGHTS.

7. Limitation of Liability.

In no event will Licensor be liable for personal injury, or any damages including lost profits or other incidental, special, punitive, exemplary, direct, indirect or consequential damages, arising out of or related to the Software, documentation or the use or misuse thereof, even if Licensor has been advised, or is otherwise aware, of the possibility of such damages and even if the warranty remedy of Section 6 fails of its essential purpose. The User and Licensor agree that the Limited Warranty of Section 6 and the Limited Liability of this Section 7 are reasonable in light of the license fees paid under this Agreement.

Some states do not allow exclusion or limitation of liability for personal injury or of implied warranties or limitation of liability for incidental, special, punitive, or other indirect or consequential damages, so the limitations or exclusions of Sections 6 and 7 of this Agreement may not apply to the User. IN SUCH STATES, THE LIABILITY OF LICENSOR SHALL BE LIMITED TO THE GREATEST EXTENT PERMITTED BY LAW.

8. Controlling Law and Severability.

This Agreement will be governed by and construed in accordance with the laws of the Commonwealth of Massachusetts, as applied to agreements entered into and to be performed entirely within Massachusetts between Massachusetts residents. This Agreement shall not be governed by the United Nations Conventions on Contracts for the International Sale of Goods, the application of which is expressly excluded. If for any reason a court of competent jurisdiction finds any provision, or portion thereof, to be unenforceable, the remainder of this Agreement shall continue in full force and effect.

9. Export Law Assurances.

You may not use or otherwise export or re-export the Software except as authorized by United States law and the laws of the jurisdiction in which the Software was obtained. In particular, but without limitation, the Software may not be exported or re-exported (a) into (or to a national or resident of) any U.S. embargoed countries or (b) to anyone on the U.S. Treasury Department's list of Specially Designated Nationals or the U.S. Department of Commerce Denied Person's List or Entity List. By using the Software, you represent and warrant that you are not located in, under control of, or a national or resident of any such country or on any such list.

10. Government End Users.

The Software and related documentation are "Commercial Items", as that term is defined at 48 C.F.R. §2.101, consisting of "Commercial Computer Software" and "Commercial Computer Software Documentation", as such terms are used in 48 C.F.R. §12.212 or 48 C.F.R. §227.7202, as applicable. Consistent with 48 C.F.R. §12.212 or 48 C.F.R. §227.7202-1 through 227.7202-4, as applicable, the Commercial Computer Software and Commercial Computer Software Documentation are being licensed to U.S. Government end users (a) only as Commercial items and (b) with only those rights as are granted to all other end users pursuant to the terms and conditions herein. Unpublished-rights reserved under the copyright laws of the United States.

11. Complete Agreement: Governing Language.

This Agreement constitutes the entire agreement between the parties with respect to the use of the Software licensed hereunder and supersedes all prior or contemporaneous understandings regarding such subject matter. No amendment to or modification of this Agreement will be binding unless in writing and signed by Licensor.

APPENDIX B

Error Messages, Warnings and Cautions

Error Messages

Battery Low

If the battery capacity falls below 10% remaining a dialog will popup with the following text:
"Battery Low! Return to Charger"

Battery Empty

If the battery capacity falls below 5% remaining a dialog will pop up with the following text:
"Battery too Low! Turning Off"

USB Connected

If the user is attempting to stimulate while the USB connector is plugged into a suitable USB host a dialog will pop up with the following text: "Stim aborted Code: 0x0330"

Charger Connected

If the user is attempting to stimulate while the device is plugged into the charger a dialog will pop up with the following text: "Stim aborted Code: 0x0010"

OverCurrent Error

If the user delivers any stimulation to the patient and the delivered current is out of tolerance and in excess of the target current a dialog will pop up with the following text: "Stim Error! Current over Tolerance"

Self Test Error

If the user is attempting to stimulate and the stimulator self test has failed stimulation is aborted and a dialog will pop up with the following text: "Stim aborted Code: 0x0060"

Stimulation Frequency Error

If the user is stimulating a patient in the "continuous" mode and the frequency is measured to be out of tolerance stimulation will halt and a dialog will pop up with the following text:
"Stim aborted Code: 0x0200"

MSP Communication Error

If the user is stimulating a patient and the internal MSP430 microprocessor experiences a communication error stimulation will halt and a dialog will pop up with the following text:
"Stim aborted Code: 0x0041"

HV Protection Error

If the user is stimulating a patient and the high voltage circuit experiences an error stimulation will halt and a dialog will pop up with the following text: "**Stim aborted Code: 0x0020**"

HV Undervoltage Error

If the user is stimulating a patient and the high voltage circuit voltage is measured below the minimum level, stimulation will halt and a dialog will pop up with the following text: "**Stim aborted Code: 0x0021**"

Stimulation Circuit Communication Errors

If an error occurs while attempting to communicate with the Stimulation Circuit, stimulation will be halted and a dialog with the following text will appear: "**Stim aborted Code: 0x0100**"

Stimulation Circuit Critical Communication Errors

If an error occurs while attempting to send a command to stop stimulation, this is a critical error and the device will power down. A dialog with the following text will be displayed briefly: "**Stim not responding: Powering Down**"

Warnings



WARNING: Electric shock hazard. Do not attempt to open the ASCEND Stimulator or Charging Station. No user serviceable parts inside. Refer to warranty and service information located in the user manual.

WARNING: To avoid electric shock, verify that the AC adapter is disconnected from Charging Station, and the ASCEND device is powered off prior to cleaning.

WARNING: Do not immerse any portion of the ASCEND and the Charging Station in water or other fluids. Avoid spilling fluids on ASCEND electrodes. Spilled fluids may damage the device or present a fire or shock hazard.

WARNING: Current density of the needle electrode can reach 37 mA r.m.s./cm² and may require the special attention of the OPERATOR

WARNING: PATIENTS with an implanted electronic device should not be subjected to electrical stimulation unless specialist medical opinion has first been obtained.

WARNING: Be aware of the location of metallic implants in the tissue (e.g. plates or electrode cables), which may potentially channel stimulation signals to other sites where it can cause damaging effects. Implanted electronic equipment can be impaired by the stimulation current, which, in turn, will lead to malfunction or possible destruction of the implants.

WARNING: Connection of a PATIENT to High frequency surgical equipment and ASCEND may result in severe burns and nerve damage at the site of the ELECTRICAL STIMULATOR NEEDLE or BIOPOTENTIAL INPUT PART electrodes and possible damage to the ELECTRICAL STIMULATOR. It is therefore imperative to disconnect all ASCEND connections (i.e. Needle and Reference Electrodes) from the PATIENT prior to using high frequency surgical equipment.

WARNING: The connecting socket of the stimulation needle may only be connected to the counter plug of the connecting cable. The connecting cable plug may only be connected to the nerve stimulator and the clip may only be connected to the skin electrode on the skin of the patient. Under no circumstances should you allow these plugs/connections to come in contact with voltage channeling components (e.g. electrical outlets) or metallic objects.

WARNING: Only use high-grade, commercially available, single-use skin electrodes with silver/silver chloride pads coated with gel.

WARNING: The Electrodes are for single use only. Do not reuse Electrodes.

WARNING: Only open Electrode packages immediately prior to use.

WARNING: Do not apply the Electrode over broken skin, lesions, or wounds.

WARNING: Trans-thoracic stimulation should be avoided.

WARNING: Only position the Reference Electrodes near the Needle Electrode Stimulation site.

WARNING: Ensure the patient's skin is shaved, degreased, clean and completely dry before applying the Electrode. Poor skin contact can lead to incorrect positioning of the stimulation needle.

WARNING: Under occasional circumstances, transient skin irritations may occur after Electrode removal.

WARNING: The Electrodes should be stored in unopened packages at room temperature.

WARNING: Do not use Electrodes after expiration date shown on the package.

WARNING: Avoid any inadvertent contact of the stimulation needle with bone, since this could irreversibly damage the needle and consequently traumatize the tissue.

APPENDIX C

Specifications

Dimensions

Size: Stimulator: 3.3" H x 6.0" W x 1.7" D
Charger: 3.0" H x 7.2" W x 5.1" D

Weight: Device: 10.4 oz. (294.8 g)
Charger: 12.0 oz. (340.2 g)

Environmental: (Shipping and Storage):
Temperature: -30°C to 60°C, 72 hours at each temperature extreme
Humidity: 0% at -30 °C to 95% at 60 °C, One 24 hour cycle, non-condensing
Altitude: 50.6 kPa to 101.3 kPa; 16 hours

(Operating)
Temperature: 10°C to 40°C

Charging Station

Power Source AC Adapter Manufactured by Ault Inc.
PN MW125RA0503-B01 (US), -F01 (Worldwide)
AC Adapter Classification Class II, IEC 60601-1

Device:

Device Power Source Internal electrical power source (Li-Polymer battery)
Data Transfer Medium Bluetooth RF
Test Memory 16 MB Max
AP/APG Equipment Not AP or APG rated
Water Resistance IEC 529 IPX0 Not protected from ingress of liquids
Classification Type Type BF

Electrical Stimulator Specifications

Stimulator Power Source	Lithium-Polymer Battery										
Line Current Isolation	Yes, battery operated										
Output current range:	Constant current 0 – 5 mA, into a 16 kOhm load maximum, controlled by the user										
Stimulation pulse rise/decay time:	Maximum 3 μ s with 1 kOhm load										
Maximum output voltage	90V with 10% tolerance										
Vmax:	Range: 0 – 1 mA +/- 0.02 mA										
Output current accuracy:	Range: 1.1 mA – 5 mA +/-0.1 mA										
Target Current Increment:	<table><thead><tr><th>Target Current Range</th><th>Target Current Increment</th></tr></thead><tbody><tr><td>0.0 – 0.1 mA</td><td>0.01 mA</td></tr><tr><td>0.1 – 0.5 mA</td><td>0.02 mA</td></tr><tr><td>0.5 – 2.0 mA</td><td>0.1 mA</td></tr><tr><td>2.0 – 5 mA</td><td>0.25 mA</td></tr></tbody></table>	Target Current Range	Target Current Increment	0.0 – 0.1 mA	0.01 mA	0.1 – 0.5 mA	0.02 mA	0.5 – 2.0 mA	0.1 mA	2.0 – 5 mA	0.25 mA
Target Current Range	Target Current Increment										
0.0 – 0.1 mA	0.01 mA										
0.1 – 0.5 mA	0.02 mA										
0.5 – 2.0 mA	0.1 mA										
2.0 – 5 mA	0.25 mA										
Stimulation pulse width:	100, 200, 500, 1000 μ s +/- 1%, 50 μ s +/- 1 μ s, controlled by the user										
Stimulation frequency:	1 Hz, 2 Hz with accuracy +/-5%. Single, controlled by the user										
Stimulation waveform:	Monophasic square pulse										
Patient current measurement accuracy:	Range: 0 – 1 mA: +/-0.02 mA; Range: 1.01 mA – 5 mA: +/-0.1 mA										
Impedance measurement:	Range: 1k – 90 kOhm Accuracy: +/- 10% for current > 1 mA, +/-20% for current \leq 1mA										



CAUTION: Consult accompanying documents. Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC standards (e.g. IEC950 for data processing equipment and IEC601-1 for medical equipment). Any person who connects additional equipment to the signal input or signal output part configures a medical system, and is therefore required to ensure compliance to IEC601-1-1. If in doubt, consult the technical services department or your local representative.

APPENDIX D

Symbols and Acronyms

Symbols



Attention/User Manual/device labeling



Warning: Shock Hazard



Class II, IEC 601-1



Type BF Applied Part



Mark identifying compliance with council directive 93/42/EEC
0123 is the identification mark of the Notified Body, TUV SÜD
responsible for evaluation of the CE Technical File.

MN

Abbreviation for model number



WEEE (Waste Electronic and Electrical Equipment) symbol
in accordance with council directive 2002/96/EC

Acronyms

ADC	Analog to Digital Conversion
ASCEND	The brand of the NeuroMetrix Nerve Localization Stimulator
BF	Body Float (Type of medical device)
CRC	Cyclic Redundancy Check
GUI	Graphic User Interface
LCD	Liquid Crystal Display
LED	Light Emitting Diode
NC	Nerve Stimulator
NNI	Near Nerve Injection
RF	Radio Frequency
UI	User Interface

APPENDIX E

Accessories

<u>Description</u>	<u>Catalog Number</u>
Charging Station	AS-H01
Tab Electrode Cable	AS-TEC
Electrode	AS-001
Electrode Needle, Hypodermic, 20G, 150mm	RA-20150
Electrode Needle, Hypodermic, 22G, 50mm	RA-2250
Electrode Needle, Hypodermic, 22G, 75mm	RA-2275
Electrode Needle, Hypodermic, 25G, 50mm	RA-2550

Please contact NeuroMetrix customer service at 888-786-7287 to order accessories.

APPENDIX F

Electromagnetic Compatibility Declaration

ASCEND is intended for use in the electromagnetic environment specified below. The user should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	ASCEND uses RF energy for its function. Its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment
RF emissions CISPR 11	Class B	ASCEND 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.
Electrostatic Discharge Immunity (ESD) IEC 61000-4-2	$\pm 4\text{kV}$ contact $\pm 8\text{kV}$ air	Floors should be wood, concrete or ceramic tile.
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m compliance level
Electrical fast transient/burst IEC 61000-4-4	$\pm 2\text{kV}$ power supply lines	Input power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	$\pm 1\text{kV}$ differential mode $\pm 2\text{kV}$ common mode	Input power quality should be that of a typical commercial or hospital environment.
Conducted RF IEC 61000-4-6	3 V RMS 150 kHz to 80 MHz	3 V/m compliance level
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m compliance level
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	>95% dip in U_T for 0.5 cycle 60% dip in U_T for 5 cycles 30% dip in U_T for 25 cycles >95% dip in U_T for 5 s	Input power quality should be that of a typical commercial or hospital environment.
Harmonics and Flicker EN61000-3-2 EN61000-3-3	Class A N/A	Input power quality should be that of a typical commercial or hospital environment.