NALU MEDICAL INC

EXTERNAL TRANSMITTER MODULE (ETM)
INSTRUCTIONS FOR USE

Contents

1 Device Description

The Nalu Spinal Cord Stimulation (SCS) system consists of External Transmitter Module (ETM), Implantable Neuro Stimulator (INS), ETM clip and ETM charger.

The INS is intended to provide relief from chronic pain by electrically stimulating the spinal cord. The INS is implanted in the body and derives its power wirelessly from the ETM, which is worn on the body using a clip. The ETM is a portable, body-worn, battery-powered device, which delivers power and various stimulation parameters and programs to INS. The instructions provided herein refer to model Nalu ETM.

1.1 Components of the Nalu SCS System:

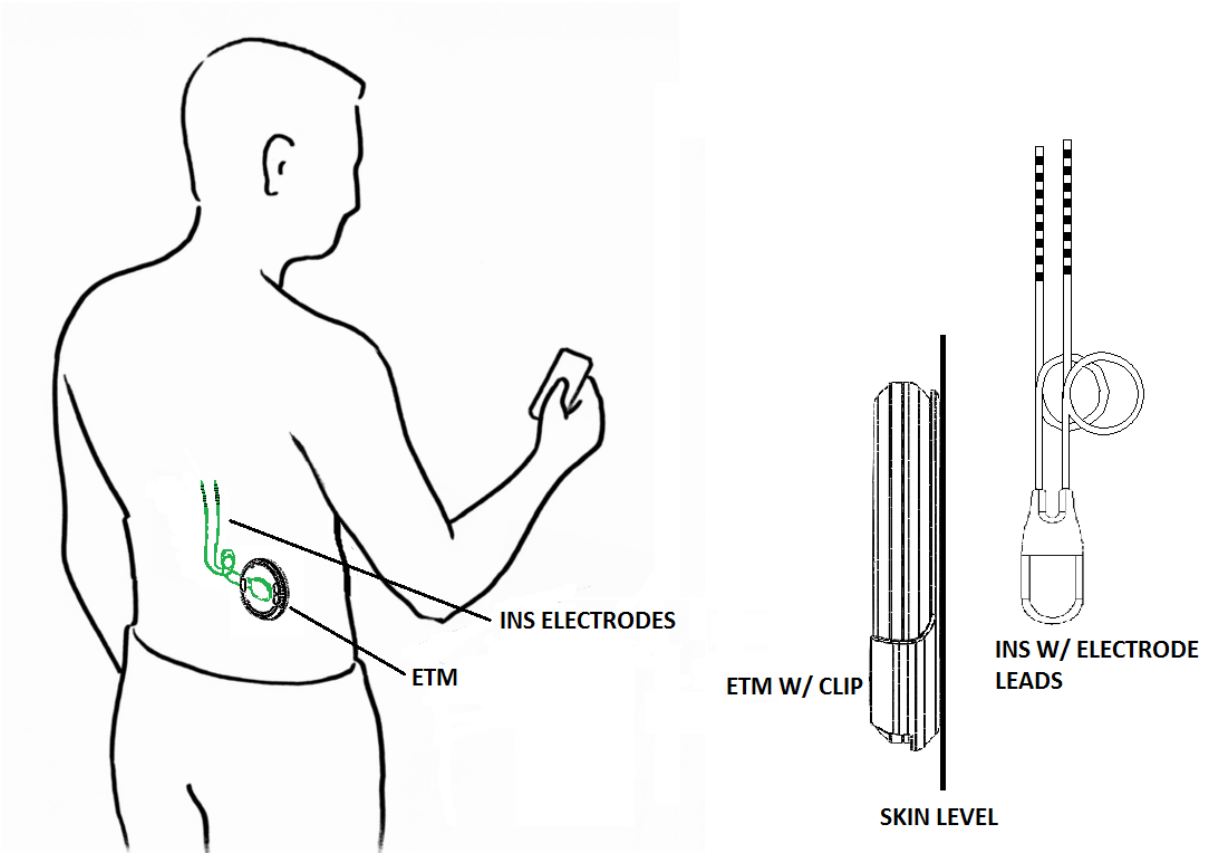

Figure 1 Nalu SCS System Components

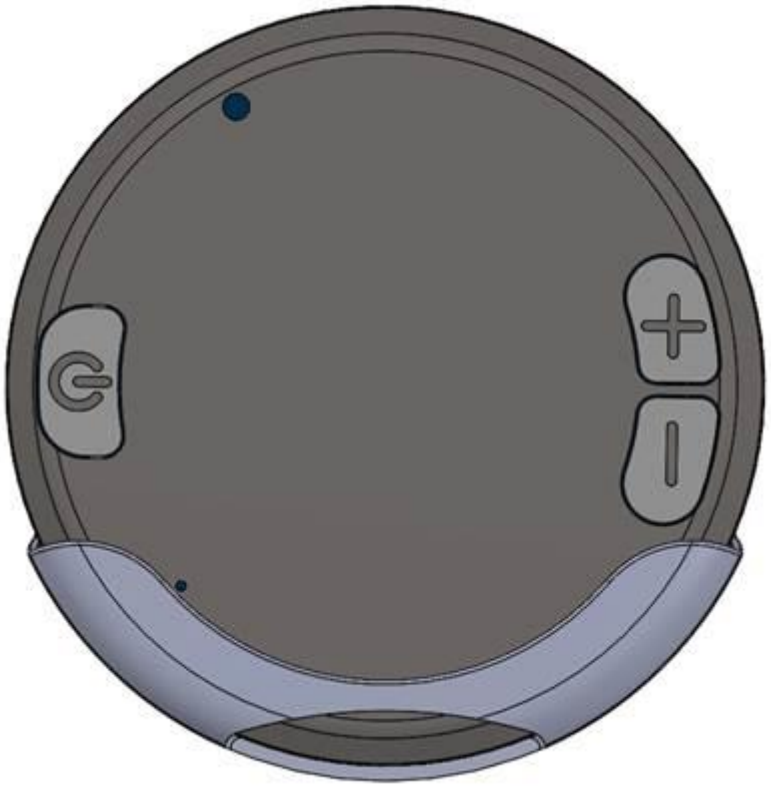

Figure 2 ETM in Clip

- Implantable Neuro Stimulator (INS): INS is implanted in the body and connects to leads in the epidural space. The INS derives power wirelessly through body tissue from ETM.
- External Transmitter Module (ETM): Is worn outside the body that delivers power to the INS and controls the stimulation parameters.
- ETM Clip: is attached to body by adhesive and is used to securely wear the ETM.
- Charger: consists of an AC adapter and cradle that is used to charge the ETM battery when not in use.

2 Intended Use

The Nalu ETS System is intended as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach for chronic, intractable pain of the trunk and/or lower limbs, including unilateral or bilateral pain.

3 Precautions

Remove the ETM prior to the following procedures

- Diagnostic imaging such as X-Ray, CT, MRI or PET scans
- Diathermy
- Cardiac Defibrillation
- Hyperbaric Chambers

- Electronic Article Surveillance (EAS) Systems

4 Potential Adverse Effects and Complications

A list of side effects that may occur during use of the ETM:

- Undesirable changes in stimulation sensation and/or location with or without patient movement.
- Undesirable changes in stimulation sensation and/or location when passing through metal detectors, library scanners, airport scanners, etc.
- Skin irritation or allergy

5 ETM User's Guide

5.1 User Interface

The ETM User Interface (UI) consists of:

- Push button to turn stimulation ON/OFF
- Up (+) and down (-) push buttons to increase and decrease stimulation levels respectively
- Tri-color LED for status (Green, Orange, Blue)
- Buzzer for status

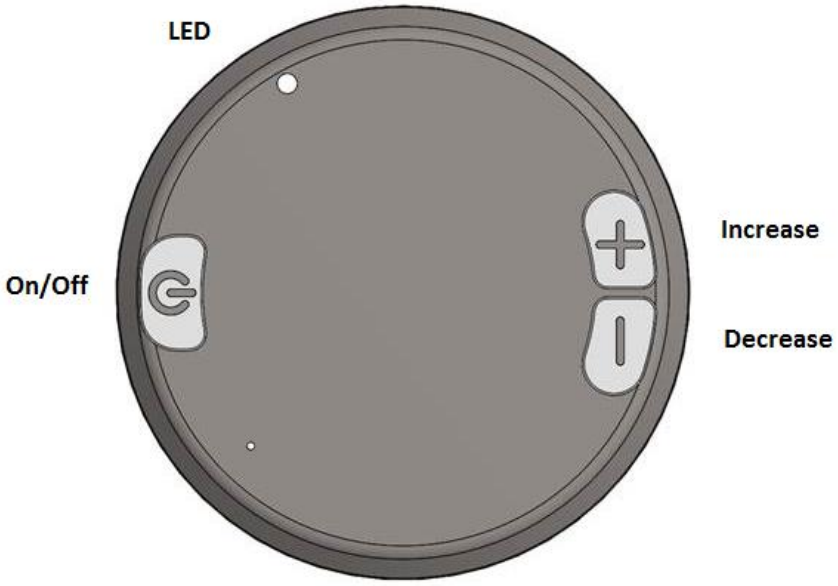

Figure 3 ETM Button Layout

5.2 Turning ON the ETS and Starting Stimulation

To start stimulation, press and release the stimulation ON/OFF button. Stimulation will start with the last used program.

5.3 Turning Stimulation OFF

Press and hold the stimulation ON/OFF button to turn the unit off.

5.4 Changing Stimulation Level

Changing stimulation levels requires that stimulation is turned on. Press and release the up (+) button to increase stimulation. Press and release the down button (-) to decrease stimulation. If the maximum or minimum stimulation levels have been reached a beep will sound and the orange LED will blink rapidly (if they are enabled during programming).

5.5 Changing Program

With the unit turned on, press and release the program button to change programs. The ETS can have up to 4 programs. Upon program change the green LED will blink to indicate the program number.

- 1 blink indicates program 1
- 2 blinks indicates program 2
- 3 blinks indicates program 3
- 4 blinks indicates program 4

Once the desired program is selected, press the On/Off button to start it. If only one program is stored on the ETM pressing the program button has no effect. Press the stimulation ON/OFF button to restart stimulation.

5.6 ETM Battery charging and status

ETM has an internal battery that provides power the unit. This battery is not user replaceable or user serviceable. To charge the battery use the provided charging cradle.

5.6.1 Battery Status Indication

At start up the battery status is indicated by the orange LED:

- 1 blink indicates 0%-30% capacity
- 2 blink indicates 30%-60% capacity
- 3 blink indicates 60%-100% capacity

5.6.2 Low Battery

When the battery is low the orange LED will blink at a slow rate and a beep will sound if it is enabled during programming.

5.6.3 Charging the ETM

The ETM system utilizes internal rechargeable batteries to power the device. A charging station is provided for recharging the unit. The charging station requires the included wall charger to micro-USB cable for power.

- Plug the wall charger into a standard 120V AC outlet (or internationally compatible 240V AC outlet).
- Plug the attached micro-USB connector into the micro-USB port on the charging station.

Figure 4 AC wall charger

- Place the ETM into the charging station, making sure that ETM is aligned with mating pins on the charger.

Figure 5 Inserting ETM unit into charging station

- Once seated, observe the LED indicator for the charging status. It takes approximately 3 hours to fully charge the unit.

5.6.4 ETM Charging Status

The charging station features an LED indicator that provides battery charging information:

- Orange Light – ETM is inserted properly and is currently being charged.

- Green Light – The ETM is fully is charged and can be removed for use.
- Flashing Orange Light – remove the device and reinsert. If flashing orange indicator continues to flash, remove the device and do not attempt to use it. Contact Nalu Medical for a replacement unit.

5.7 Cleaning and Care

- When necessary clean the device with damp cloth. Mild soap or detergent may be used if needed.
- Do not drop, strike or step on the device.
- Do not try to open the device. There are no user accessible or serviceable parts in the device.
- Keep the charging contacts clean and void of any deposits.
- Keep the device away from children and pets.
- The ETM should not be exposed to extreme temperatures (outside of 0 – 50 °C range) or pressures.

5.8 Troubleshooting

Stimulation is too strong.	Decrease the amplitude by pressing the decrease “-” button. Repeat the button press until desired stimulation is reached.
Stimulation is too weak.	Increase the amplitude by pressing the increase “+” button. Repeat the button press until desired stimulation level is reached.
Sudden unexpected changes in stimulation level.	Use the amplitude increase/decrease buttons to adjust the stimulation level.
Device does not turn on, when power button is pressed.	Battery might be depleted. Charge the device and try again once fully charged.
No therapy is being provided.	Device might have been inadvertently turned on. Turn on the device by pressing the On/Off button. Amplitude might be too low. Increase the amplitude by pressing the + button. Check if the clip and ETM is placed within required range of implant. Refer to clip manual for proper placement instructions.
Yellow light flashes while charging and device fails finish charging.	Stop using the device. Remove from the charger and contact authorized

	service personal.

6 Technical Specifications

6.1 Specifications

Dimensions (approximate)	75mm Diameter, 8mm thickness
Weight (approximate)	75 gms
Operating Temperature	0 to 40°C
Storage Temperature	-10 to 50°C
Relative Humidity	20% to 90%
IPX Rating	IP-67
Charging accessory power source	120-240V, 50-60Hz AC
Transmit Carrier Frequency	40.68 MHz
Transmit Bandwidth	40 KHz
Transmit Modulation	AM
Bluetooth Frequency	2.402 GHz
FCC ID	2AMB3-34001-001
Bluetooth FCC ID	2AAQS-ISP1507

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.

Any changes/modifications to this equipment not approved by Nalu Medical Inc could void the user's authority to operate the equipment.

6.2 Stimulation Parameters:

Parameter	Range
Frequency	1Hz - 10kHz
Pulse Width	10µsec – 2ms
Amplitude	0µA - 10.2mA

7 Contact Information

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