nalu

Nalu™ Medical, Inc.

NALU™ REMOTE CONTROL APPLICATION

USER GUIDE

EXPLANATION OF SYMBOLS ON PRODUCT OR PACKAGE

Refer to the appropriate product for symbols that apply.

Symbol	Title	Explanation	Standard	Reference
	Manufacturer	Medical device manufacturer, as defined in EU Directive 93/42/EEC	ISO 15223-1	5.1.1
	Date of manufacture	Date when the medical device was manufactured.	ISO 15223-1	5.1.3
	Use-by date	Date after which the medical device is not to be used.	ISO 15223-1	5.1.4
LOT	Batch code	Manufacturer's batch code so that the batch or lot can be identified.	ISO 15223-1	5.1.5
REF	Catalogue number	Manufacturer's catalogue number so that the medical device can be identified.	ISO 15223-1	5.1.6
	Do not use if package is damaged	Medical device should not be used if the package has been damaged or opened.	ISO 15223-1	5.2.8
	Keep away from sunlight	A medical device that needs protection from light sources.	ISO 15223-1	5.3.2
	Keep dry	A medical device that needs to be protected from moisture.	ISO 15223-1	5.3.4
	Temperature limit	The temperature limits to which the medical device can be safely exposed.	ISO 15223-1	5.3.7
	Humidity limitation	Indicates the range of humidity to which the device can be safely exposed	ISO 15223-1	5.3.8
	Atmospheric pressure limitation	Indicates the range of atmospheric pressure to which the device can be safely exposed	ISO 15223-1	5.3.9
	Do not re-use	A medical device that is intended for one use, or for use on a single patient during a single procedure.	ISO 15223-1	5.4.2
	Consult instructions for use	Indicates the need for the user to consult the instructions for use.	ISO 15223-1	5.4.3
	Refer to instruction manual/booklet.	Indicates the instruction manual/booklet must be read. (This symbol is blue and white on the device label)	ISO 7010:2011	M002
	Caution	User to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.	ISO 15223-1	5.4.4
	MR Conditional	Medical device demonstrated safety in the MR environment within defined conditions.	ASTM F2503-13	Fig. 6

Symbol	Name	Description	Standard	Reference
MR (crossed out)	MR Unsafe	Medical device poses unacceptable risks to the patient, medical staff or other persons within the MR environment.	ASTM F2503-13	Fig. 9
((•))	Radio Transmitter	Device contains a radio-frequency (RF) transmitter, which may cause RF interference with other devices near this device	IEC 60601-1-2:2007	5.1.1
R$_X$ Only	Prescription use only	Caution: Law prohibits dispensing without prescription	21 CFR 801.109	N/A
QTY	Quantity	Indicates the total number of products provided in a package.	N/A	N/A
SN	Serial Number	Manufacturer's serial number so that a specific medical device can be identified.	ISO 15223-1	5.1.7
BEST BEFORE	Best Before	This device is best used before this date.	N/A	N/A
EC | REP	Authorized Representative in the European Community	Authorized representative in the European Community	ISO 15223-1	5.1.2
(person symbol)	Protected against electric shock	Device contains a type BF applied part to protect you from shock. The device is internally powered and is intended for continuous operation	IEC 60417	5333
IP22	Protected against access to certain hazardous parts	Protected against solid objects over 12.5mm (e.g., a finger) and protected against falling drops of water, if the case is disposed at any angle up to 15 degrees from vertical	IEC 60529	N/A
IP67	Protected from dust and temporary immersion in water	Protected from dust and against effects of immersion in water up to 1m depth for 30 mins	IEC 60529	N/A
FC	FCC	This symbol indicates that 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.	47 CFR 2.926	N/A
(crossed out trash bin)	Do not throw in the trash	This product shall not be treated as household waste. Instead it is the user's responsibility to return this product to Nalu Medical for reprocessing. By ensuring that this product is disposed of properly, you will help prevent potential negative consequences for the environment and human health, which could be caused by inappropriate waste handling of this product. The recycling of materials will help to conserve natural resources. For more information about how to return this product for recycling, please contact Nalu Medical.	BS EN 50419 Marking of Electrical and Electronic Equipment in Accordance with Article 11(2) of Directive 2002/96/EC (WEEE)	Fig. 1

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INDICATIONS FOR USE

Spinal Cord Stimulation (SCS)

This system is indicated 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 limbs, including unilateral or bilateral pain.

The trial devices are solely used for trial stimulation (no longer than 30 days) to determine efficacy before recommendation for a permanent (long term) device.

Peripheral Nerve Stimulation (PNS)

This system is indicated for pain management in adults who have severe intractable chronic pain of peripheral nerve origin, as the sole mitigating agent, or as an adjunct to other modes of therapy used in a multidisciplinary approach. The Nalu Neurostimulation System for PNS is not intended to treat pain in the craniofacial region.

The trial devices are solely used for trial stimulation (no longer than 30 days) to determine efficacy before recommendation for a permanent (long term) device.

INTRODUCTION

This guide is intended for people using the Nalu Remote Control Application (App) device accessory to control therapy sessions for their Nalu Neurostimulation System. This guide provides instructions needed to properly use the App installed on their device.

The Nalu Remote Control Application (App) runs on Android and iOS platforms and can be optionally used to control and manage the Therapy Disc and the various settings of the Nalu Neurostimulation System including turning stimulation programs on/off, and adjusting stimulation levels.

The App connects to the Therapy Disc through Bluetooth® Low Energy. The Therapy Disc connects to the Nalu Implantable Pulse Generator through radiofrequency (RF).

Once installed on your device, setup of the Nalu Remote Control Application will be completed in the presence of and under the guidance of your Nalu Representative using the Nalu Clinician Programming Application.

Contact Nalu Medical before upgrading your phone or tablet operation software and ensure to download the latest Nalu Remote Control Application from the public App Store.

CONTRAINDICATIONS

Patients contraindicated for this therapy are those who:

- Are unable to operate the system

- Have failed trial stimulation by failing to receive effective pain relief

- Are poor surgical risks

- Are pregnant

Exposure to shortwave, microwave, or ultrasound diathermy – Diathermy should not be operated within the vicinity of a patient implanted with a Nalu Neurostimulation System or when wearing a Therapy Disc. The energy from diathermy can be transferred through the stimulator and cause tissue damage, resulting in severe injury.

Occupational exposure to high levels of non-ionizing radiation that may interfere with therapy – Patients who regularly work in environments with elevated levels of non-ionizing radiation should not be implanted with the device. The energy in high-level areas can be transferred through the device and cause tissue damage, resulting in severe injury. Examples of environments having high level non-ionizing radiation include the following:

- Radio or cell phone transmission stations

- Facilities using radiofrequency heat sealers or induction heaters

- Electric power infrastructure controlled environments (i.e. step down transformers or high voltage power lines)

Implanted Cardiac or Other Neurostimulation Systems—Patients who have implanted cardiac or other neurostimulation systems should not use the Nalu Neurostimulation System. Electrical pulses from the Nalu Neurostimulation System may interact with the sensing operation of an implanted cardiac or neurostimulation system, causing the system to respond inappropriately.

WARNINGS

For a complete list and explanation of all Nalu Neurostimulation System Warnings and Precautions, please refer to your Patient Guide for the system.

When you are considering additional medical tests or treatments, please share the complete list and explanation of all Nalu Neurostimulation System Warnings and Precautions with your clinician.

Painful Stimulation - If you experience painful stimulation do the following:

- **For Permanent Therapy Disc** – Remove or decrease the stimulation amplitude

- **For Trial Therapy Disc** – Disconnect or decrease the stimulation amplitude

Contact your clinician if this continues to occur

Do not modify or tamper with the Nalu Neurostimulation System Remote Control application software.

PRECAUTIONS

Physician Instructions – Always follow the programs and therapy instructions established by your physician. Failure to do so may cause the therapy to be less effective in providing pain relief.

Random Component Failure – Although unlikely, a failure of the Nalu Neurostimulation System is possible due to random component failure. If any part of your Nalu Neurostimulation System stops working or changes how it works, remove the Therapy Disc and contact your Nalu representative.

Remote Control Interference – If interference is suspected during use of the remote control, confirm that the Bluetooth® data transmission is operating properly. If the Nalu Remote Control application is not connecting to the Therapy Disc:

- Terminate the current stimulation program and shut down the Nalu Remote Control application.

- Check for sources of Bluetooth interference in the surrounding area.

- Remove or turn off the source of interference.

- Re-establish the Bluetooth link with the Therapy Disc through pairing.

- Reopen the Nalu Remote Control application and resume the therapy.

Notice: In the event of any serious incident that has occurred in relation to the Nalu Neurostimulation System, the user and/or patient should report the incident to Nalu Medical at +1.760.448.2360 or visit www.nalumed.com

MAGNETIC RESONANCE IMAGING (MRI) SAFETY INFORMATION

Your Nalu implant is MR Conditional which means you may safely receive an MRI examination only under certain conditions. All external components including the Therapy Disc, Wearable Garment, Adhesive Clip and Programmers are MR Unsafe and must not be brought into the MR system room. If you need an MRI examination, tell your physician you have a Nalu implant. Also tell the MRI site personnel you have a Nalu implant when you call to make an appointment and when you arrive for your MRI examination. Show your implant card to the MRI site personnel when you arrive for your MRI examination.

MRI Safety Information (SCS)

For Complete instructions, please refer to the User instructions for use PN: MA-000007

MRI Safety Information (PNS)

For Complete instructions, please visit www.nalumed.com and refer to the Nalu MRI checklist.

DOCUMENT CONVENTIONS

Item	Convention
Commands and keywords	**Boldface** font
Displays a placeholder for a value	*<Italic>* font
Information you type	*Italic* font
Menu items and button names	**Boldface** font
Additional information, suggestions, or references that require attention from you	📄 Note
An alternate way of performing a task	✍Tip

NALU REMOTE CONTROL APPLICATION ICONS AND DESCRIPTIONS

Icon	Name/ Description
☰	Menu
(blue therapy disc icon)	Blue Therapy Disc
(green therapy disc icon)	Green Therapy Disc
(pulse generator icon)	Nalu Implantable Pulse Generator Device
▶	Used to start a program.
↻	Refresh
👁	Identify
🔔	Alert
-	Used to decrease the therapy amplitude.
+	Used to increase the therapy amplitude.
>	Used to Navigate through program screens
■	Used to stop a program.
🕐	Represents the most recent stimulation program, press to resume therapy.

APPLICATION INSTALLATION

The Nalu Remote Control Application can be installed on both iOS and Android devices.

Refer to the App Store or Google Play for the currently supported operating systems.

For other symbols and definitions related to the tablet, phone, refer to the manual provided by the manufacturer.

iOS App Installation

Search for, "Nalu Remote Control" in the App Store and download.

Android App Installation

Search for, "Nalu Remote Control," on Google Play and download.

FIRST TIME LOG IN

After setting up the application for the first time with the help of your Nalu Representative, you will be redirected to the **Change PIN** screen.
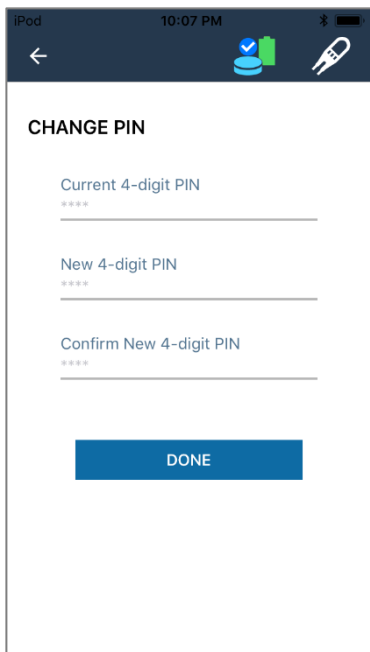

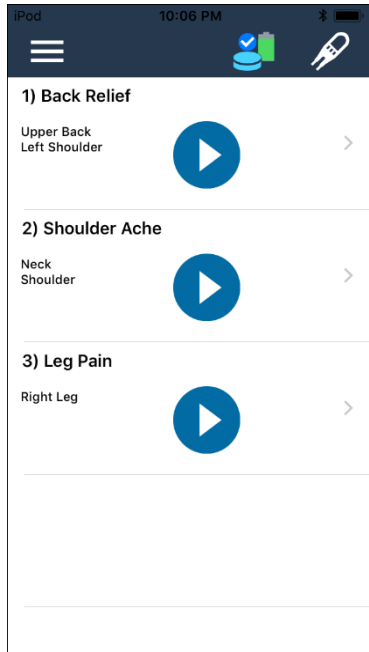
Figure 1 Change PIN for first-time login

Figure 2 Nalu Remote Control Application Home Screen

To change the PIN:

1. In the **New 4-digit PIN** field, type the new PIN.

2. In the **Confirm PIN** field, retype the new PIN.

3. Tap **Done**.

📄 *The pin needs to be changed before every 180 days. If the pin is not changed, you will have to contact Nalu and get it reset. Please call 1-800-618-3402 if you need the pin reset.*

The PIN will be changed and you will be redirected to the Home screen as shown in Figure 2.

Page Elements	Description
Menu (1)	Here, you can change the PIN, select a language, turn ON the clinical mode, logout, and view the about details. For more information, see *Working with the Menu*.
Devices (2)	You can tap on a device to view the device details. It will display the Therapy Disc and the Implantable Pulse Generator device details. For more information, see *Viewing the Device Details.*
Program list (3)	You can view the list of programs configured for you here. For more information, see *Viewing the Program List*.

The next time you log into the application, you will see the Login screen as shown in Figure 3.
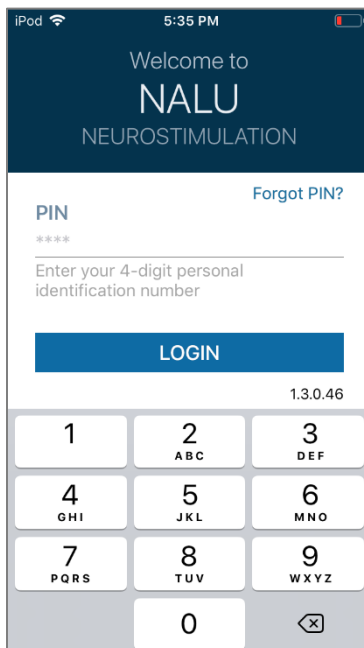

Figure 3 Login Screen

WORKING WITH THE MENU

1. Tap the ☰ icon to view the menu details.

2. Using the menu, you can:

   - change the PIN

   - select a language

   - switch ON the clinical mode

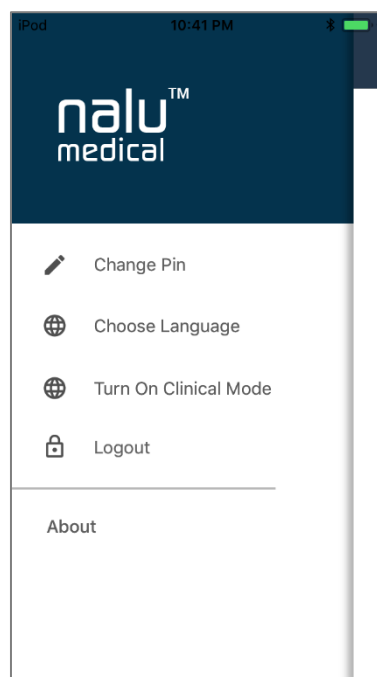   - log out of the application

   - view the about details.

Figure 4 Menu

CHANGING THE PIN

If you want to change the PIN, tap **Change PIN** in the menu. The Change PIN screen will appear as shown in Figure 5.

To change the pin:

1. In the **Current 4-digit PIN** field, type the current pin.
2. In the **New 4-digit PIN** field, type the new pin.
3. In the **Confirm PIN** field, retype the new pin.
4. Tap **Done**.

The PIN will be changed, and you will be redirected to the Home screen.

Figure 5 Change PIN screen
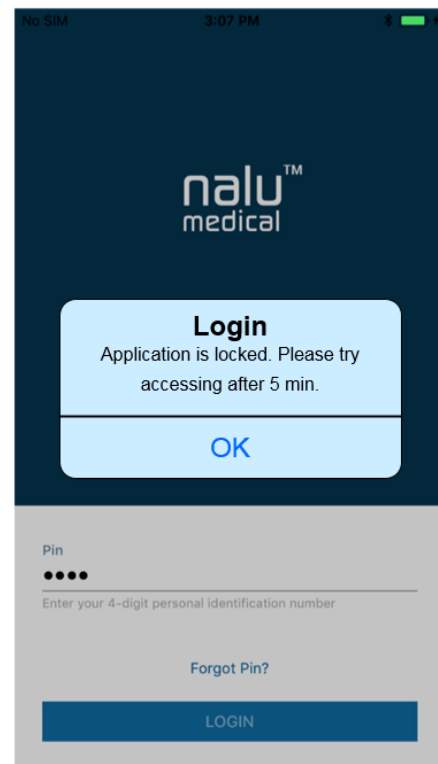
If you attempt to log in five times with an incorrect PIN, the application will be locked for five minutes, as shown in Figure 6.

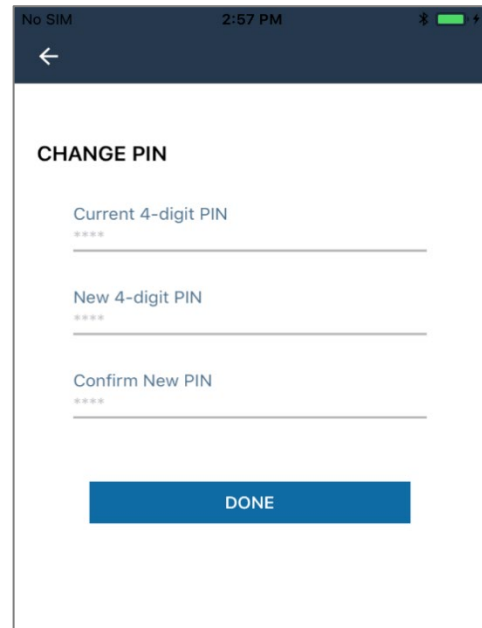You can log in to the application after five minutes, using the valid PIN.

Figure 6 Application locked message

CHOOSING A LANGUAGE

You can select English, French, German, Italian, Danish, Korean, Dutch, Portuguese, Swedish, or traditional Chinese from the list of available languages.

To select a language:

1. Tap **Choose Language** on the menu. The Language screen will appear.

2. Tap on the **Select Language** drop-down list

3. Tap on the desired language.

📄 *The default language is English.*

Figure 7 Language Selection Screen

TURNING THE CLINICAL MODE ON/OFF

The Clinical Mode is for clinician use only.

If you turn on the Clinical Mode, please turn it off by clicking the blue "Turn Off Clinical Mode" button at the bottom of the screen.

LOGGING OUT OF THE APPLICATION

To log out of the Nalu Remote Control Application, tap **Logout** in the menu.

You will be logged out of the application and redirected to the Welcome screen.

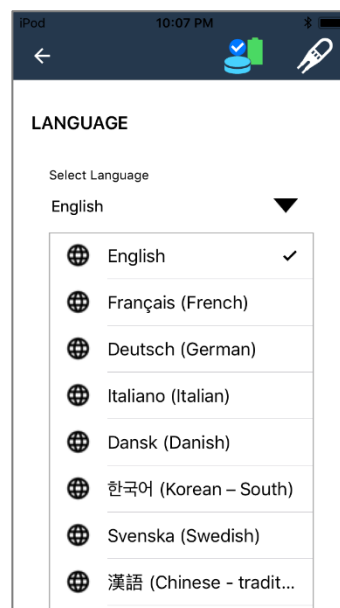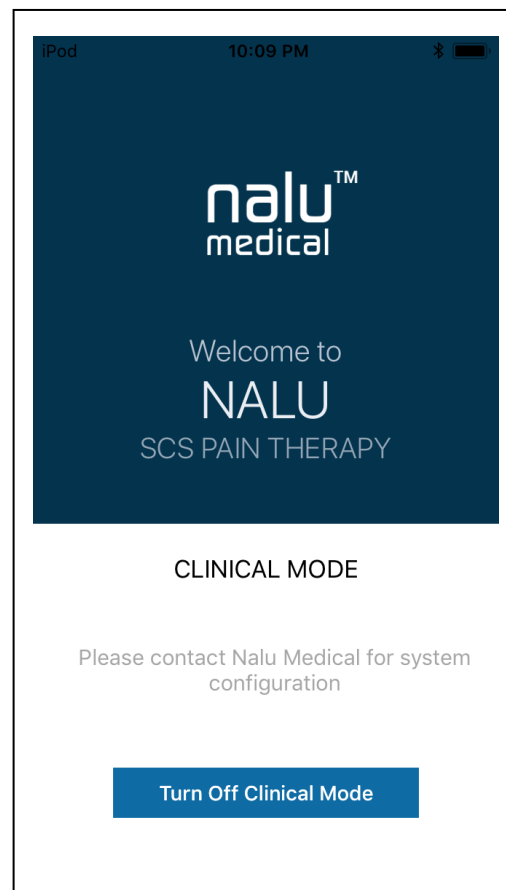📄 *You will be automatically logged out of the Nalu Remote Control Application if it remains inactive for 5 minutes.*

Protecting access to the Nalu Remote Control App

To prevent unauthorized access to your remote control app, set up a passcode to your phone or tablet using the instructions provided in the manufacturer's manual.

VIEWING THE ABOUT INFORMATION

To view the Nalu Remote Control Application details:

1. Tap **About** in the menu. The Nalu Medical Patient Application screen will appear.

2. The top section of the screen will display the application details, while the bottom section will display the help information that can be used to contact customer service.

You can view the following application details:

- **Version**

- **Operating system**

- **Device ID**

To contact customer service, visit the Nalu Medical website at www.nalumed.com to find the contact information for your area.
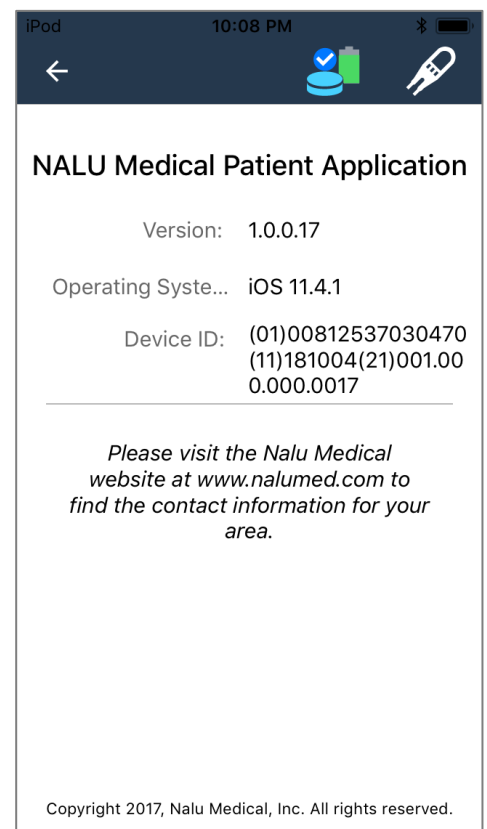
Figure 8 About Screen

VIEWING THE DEVICE DETAILS

On the Home screen, you can view the devices paired with the Nalu Remote Control App device. You are provided with two Therapy Discs in the initial Nalu Neurostimulation System kit, so that you can use one while the other is charging. Here, you can view the two Therapy Discs (Green and Blue), and the Nalu Implantable Pulse Generator. When you tap the **Identify** 👁 icon the Therapy Discs will blink either Blue or Green to help you identify them.

📄 *Your Therapy Discs are configured to work with only your implant (Nalu Implantable Pulse Generator) and Remote Control. Your Therapy Discs will not work with another implant or Remote Control, unless they are re-configured by a clinician.*

Viewing the Green and Blue Therapy Disc Device Details

Tap the 🔵 or 🔵 icon to view the green or blue Therapy Disc device details.

Figure 9 Green and Blue Therapy Disc

You can then view the following details:

Table 2: Green or Blue Therapy Disc details

Field	Description
Status	Displays the status of the Therapy Disc.

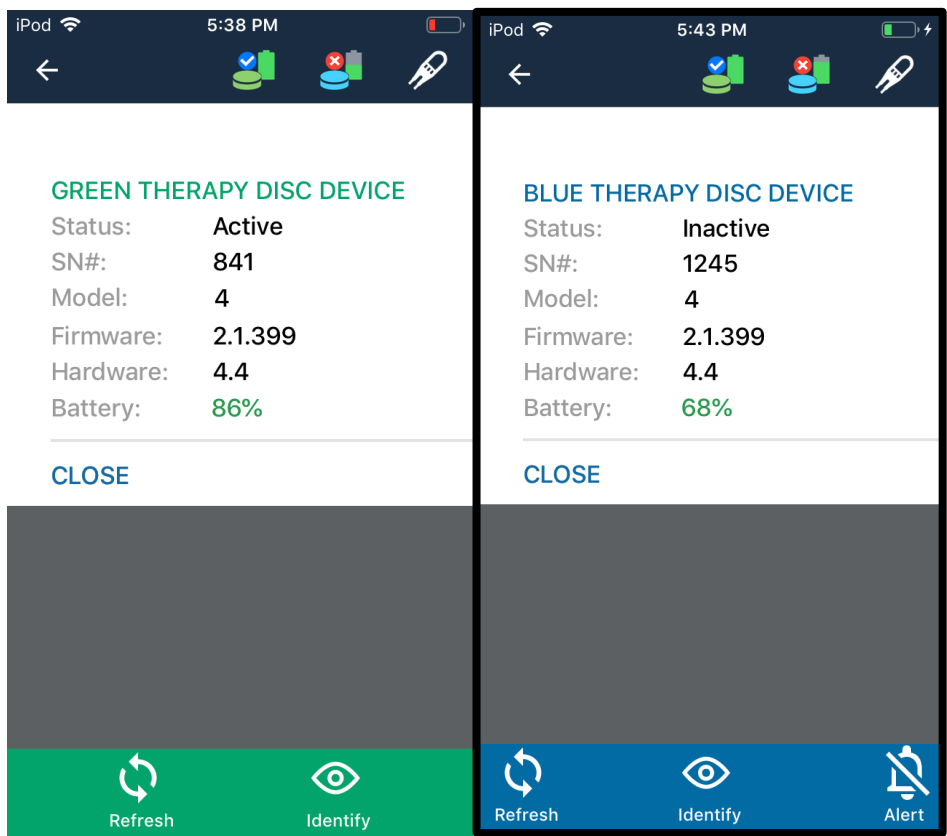| Field	Description
Serial number (SN #)	Displays the serial number of the Therapy Disc.
Model	Displays the Therapy Disc model number.
Firmware	Displays the firmware version of the Therapy Disc.
Hardware	Displays the hardware version of the Therapy Disc.
Battery	Indicates the % of battery charge available in the Therapy Disc.

1. Tap the **Refresh** icon to refresh the program information.

2. To identify a device from available devices, tap the **Identify** icon. The identified device will beep and blink.

3. Tap the **Alert** icon to disable alerts.

4. To re-enable alerts, tap the icon again.

📄 *The **Refresh** and **Identify** tabs are displayed only if the Therapy Disc is in Active or Inactive Mode. The **Alert** tab is only displayed if the Therapy Disc is in an Alert mode (e.g., if the Therapy Disc is indicating that it is searching for an IPG). If the Therapy Disc is Unavailable or Busy, then the tabs are not displayed.*

5. Tap the **Close** button to close the pop-up.

The status of the green and blue Therapy Discs can be different:

Table 3: Therapy Disc Statuses

Status	Green Therapy Disc Icon	Blue Therapy Disc Icon
Busy		
Active (Therapy Disc "on" and actively communicating)		
Inactive (Therapy Disc "on" but not actively communicating)		
Unavailable (Therapy Discs are either "off" or out of range)		

Viewing the Nalu Implantable Pulse Generator Device Details

1. Tap the [icon] icon to view the
    Nalu Implantable Pulse Generator device details.

📄 *The Nalu Implantable Pulse Generator icon is displayed only if the Therapy Disc is in Active Mode. If it is Inactive, Unavailable or Busy, then the icon is not displayed.*

IPG

SN#:   a1b2c3

Model: 71001-000

Lead Type: IPG (Int,40cm,Single 8) Kit

CLOSE
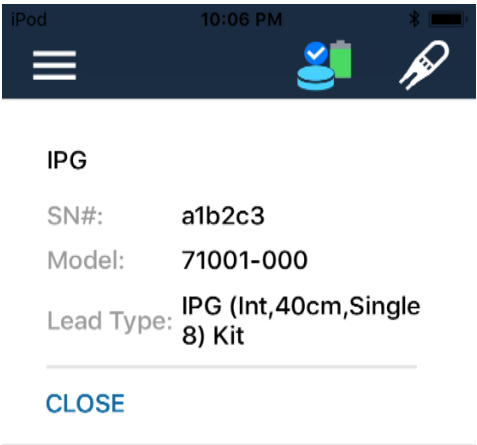
Figure 10 Nalu Implantable Pulse Generator Device Details

2. You can then view the following details:

Table 4: Nalu Implantable Pulse Generator device details

Field	Description
Serial number (SN #)	Displays the serial number of the Nalu Implantable Pulse Generator.
Model	Displays the Nalu Implantable Pulse Generator model number.
Lead Type	Displays the lead type of the Nalu Implantable Pulse Generator.

3. Tap the **Close** button to close the pop-up.

Viewing the Program List

You can view the list of programs configured for you. You can also view program details, such as the program name or program area.

1. You can start or stop the program by tapping the ▶ or 🕐 icon.

2. To view the program details screen,
   tap the navigation ❯ icon at the right of each program.

If a Session is downloaded onto a patient's Therapy Discs with a Schedule configured, then the RC will display a "Schedule" tab at the top of the Program List screen.

To see what Program is currently running on the Schedule, press the Schedule tab's ARROW button to go to the Program/Area screen. Programs can be executed individually as before by pressing their respective PLAY buttons.
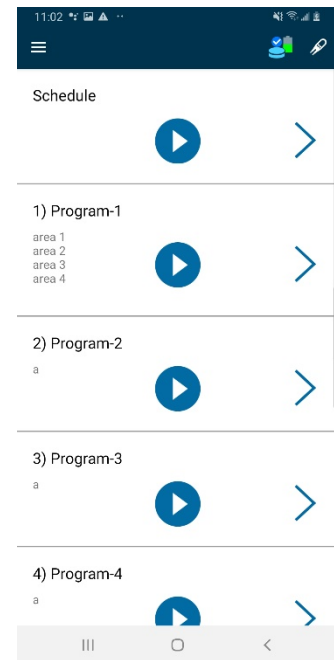
Figure 11 Program List

MANAGING PROGRAMS

Viewing the Program Details Screen

1. On the Home screen, tap on the navigation ❯ icon to view the program details screen.

2. The Program Details screen displays:

   - **The Predefined Program Name**

   - **Predefined Program Areas**: These names indicate various pain areas.
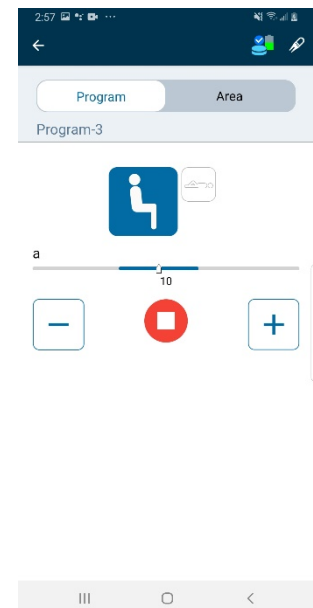
Figure 12 Program Details Screen

The Program Details screen also displays the postures available for the program (if your clinician has activated this feature):

Table 5: Postures

Posture Icon	Description
![supine posture icon]	A variation of this program for supine posture is available.
![upright posture icon]	A variation of this program for upright posture is available.
![greyed supine posture icon]	Not available for this program.
![greyed upright posture icon]	Not available for this program.

You can view the range of therapy amplitude (blue) in the progress bar as well. It also displays — and + tabs, which you can use to modify the amplitude.

After you start the program by tapping the ▶ or ⏱ icon, the posture and therapy amplitude tabs will be enabled.

📄 *On the Program Details screen, you can change the posture and/or change amplitude - but **only** if the program is running.*

Upon pressing the ❯ button, you will see the Program Details screen. For a Schedule, you will see the Program details of the currently stimulating program.

If the + button is pressed once, you will see that all amplitude levels increased by 1. You can interact with each area's amplitudes individually by switching to the "Area" view.

If a Schedule was configured to have idle programs in it, and the Schedule is currently 'executing' that idle program, the RC will display "(Idle)" next to the last executed Program.

Figure 13 Amplitude and posture tabs enabled

Changing the Therapy Amplitude

You can increase or decrease the pulse amplitude percentage by tapping the ⊞ or ⊟ button

If you change the therapy amplitude while running a program, it will start with the most recently selected amplitude and posture when you start the same program again later.

📄 • *You can increase or decrease the pulse amplitude only within the specified (blue) range.*

• *The amplitude bar displayed is not a slider bar.*

• *You can change the therapy amplitude, but **only** while the program is running.*

Starting a Therapy Program

You can begin the therapy by starting the appropriate program.

📄 *Make sure that the Bluetooth options of the Therapy Disc and the Nalu Remote Control App device are ON. If the Bluetooth is disconnected, you will be logged out of the application.*

You can begin the therapy in **two** ways:

1. You can begin therapy from the Home screen.

OR

2. You can begin therapy from the Program Details screen.

📄 *After you tap the ▶ or 🕐 icon, a ramp up must be completed before the Nalu Remote Control App device can modify the therapy.*

Starting the Program from the Home Screen

To start the program from the Home screen:

1. Select the program that you want to start.

2. Tap the ▶ or 🕐 icon.

3. The therapy will start.

📄
- *You cannot adjust pulse amplitude while running therapy from the Home screen.*
- *After you start the program execution, the therapy amplitude will be displayed.*

Starting the Program from the Program Details Screen

To start the program from the Program Details screen:

1. On the Home screen, select the program you want to execute.

2. Tap the navigation ❯ icon. The Program Details screen will appear, displaying the posture and pulse amplitude settings.

3. Tap ▶ or 🕐 to start the program.

4. Select the posture and adjust the pulse amplitude.

5. The therapy will start.

TROUBLESHOOTING

<table>
<tr><th colspan="3">Therapy Disc</th></tr>
<tr><th>Problem</th><th>Causes</th><th>Possible Actions</th></tr>
<tr>
<td>Uncomfortable Stimulation</td>
<td>The selected parameters are not suitable for your activity or posture.</td>
<td>Remove the Therapy Disc from your body.

Unplug the Trial Therapy Disc.

Reduce the stimulation from the Remote Control Application or the Therapy Disc.</td>
</tr>
<tr>
<td rowspan="3">No Stimulation</td>
<td rowspan="2">Stimulation is off.</td>
<td>Turn the Therapy Disc power OFF, then turn the power back ON.</td>
</tr>
<tr>
<td>Using the remote control, turn stimulation on.</td>
</tr>
<tr>
<td>The Permanent Therapy Disc is not placed over the implant.</td>
<td>Place the Permanent Therapy Disc directly over the implanted Pulse Generator.

Make sure Trial Therapy Disc is plugged in.</td>
</tr>
<tr>
<td></td>
<td>The stimulation amplitude is set too low.</td>
<td>Increase the amplitude.</td>
</tr>
<tr>
<td>The Therapy Disc is Unresponsive</td>
<td>The Therapy Disc is not powered ON.</td>
<td>Turn the power ON.</td>
</tr>
<tr>
<td>The Therapy Disc is Unresponsive</td>
<td>The Therapy Disc functionality is frozen.</td>
<td>Turn the power OFF, then and turn it back ON.</td>
</tr>
<tr>
<td rowspan="2">The Therapy Disc will not connect to the RC</td>
<td>The battery is not charged.</td>
<td>Recharge the battery by placing the Therapy Disc on the charger.</td>
</tr>
<tr>
<td>Bluetooth connection problem.</td>
<td>Restart the Remote Control Application.

Restart the Therapy Disc.

Ensure Bluetooth is enabled for the RC app in the Remote Control device's settings.</td>
</tr>
<tr>
<td>The Therapy Disc Has Been Dropped</td>
<td>Damage to the device.</td>
<td>Contact your Nalu representative.</td>
</tr>
<tr>
<td>The Trial Therapy Disc becomes wet</td>
<td>The Trial Therapy Disc is not waterproof.</td>
<td>Discontinue use of the device and contact your Nalu representative.</td>
</tr>
</table>

Remote Controller Application		
When connected to the Therapy Disc/Trial Therapy Disc: Application does not display program list or device status correctly	Connectivity Error	Press the Refresh button. Log out of the application and log in again. Shut down the application and restart. [Therapy Disc] Place the Therapy Disc over the implant. [Trial Therapy Disc] Disconnect and reconnect the EIC.

WIRELESS TECHNOLOGY INFORMATION

Radiofrequency (RF) and Wireless Data Parameters

Bluetooth® Low Energy (BLE)– Clinician Programmer, Remote Control, Therapy Disc
Industrial, Scientific, & Medical (ISM) – Therapy Disc, Nalu Implantable Pulse Generator

Nalu's reliance on a single ISM band and Bluetooth for system operation are believed to be compatible with regulations worldwide.

Parameter	Band	Description
Frequency	BLE ISM	2.402-2.480 MHz (data) 40.66-40.70 MHz (power and data transfer)
Bandwidth	BLE ISM	2 MHz 1 MHz (low-depth amplitude modulation)
Power	BLE ISM	4.6 dBm max EIRP -14.1 dBm max EIRP (330 mW max conducted)
Data transfer	BLE ISM	1000-2000 kbps, 6 ms latency, CRC, encryption 250 kbps, 32-bit CRC protection
Effective Range	BLE ISM	<3 meters <3 cm

FCC ID	
Therapy Disc	FCC ID: 2AMB3-34001-001 Contains FCC ID: 2AAQS-ISP1507
Trail Therapy Disc	Contains FCC ID: 2AAQS-ISP1507

Classification per IEC 60601-1: Therapy Disc and Trial Therapy Disc	
In use	Type BF
Charging	Class II

Quality of Service for Wireless Technology

Bluetooth Smart wireless technology enables communication between the SCS Remote Control App and the Therapy Disc. The requirements for the quality of service (QoS) vary depending on the use environment (operating room, recovery room, and home environment).

After the remote control app is paired with a Therapy Disc, the Bluetooth wireless technology symbol is visible on the remote control app in the upper right-hand corner of the screen. When the Bluetooth Smart wireless technology connection is not active, the symbol appears dimmed.

The standard Bluetooth Smart wireless technology data rate is 1 Mbit/s. Other requirements include a semi-duplex transmission with a required acknowledge, a transmission latency in each direction (2x), and a receive-to-transmit mode (RX-to-TX) time. Data is resent if not sent successfully.

Wireless Security Measures

The wireless signals are secured through device system design that includes the following:

- The Therapy Disc will encrypt its wireless communication.
- Only one Remote Control App may communicate with the Therapy Disc at the same time.
- A unique key for each Remote Control App to Therapy Disc connection.
- Built-in pairing that specifies valid and legitimate pairing among units.
- Proprietary authentication in addition to the pairing procedure specified in Bluetooth Smart wireless technology.
- A proprietary algorithm that detects and prevents an unauthorized user from attempting to communicate with the Therapy Disc.

Troubleshooting for Wireless and Coexistence Issues

If you experience issues with the wireless communication between the Remote Control App and the Therapy Disc, try the following:

- Decrease the distance between the devices
- Move the devices so they share line of sight
- Move the devices away from other devices that may be causing interference
- Wait a few minutes and try connecting again
- Do not operate other wireless devices (i.e., laptop, tablet, mobile phone, or cordless phone) at the same time

NOTE: Wireless communications equipment, such as wireless home network devices, mobile and cordless telephones, and tablets, can affect the device.

Statement of FCC Compliance

The Nalu's Therapy Disc 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 radiofrequency 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 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.

Operation is subject to the following two conditions:

- This device may not cause harmful interference.

- This device must accept any interference received, including interference that may cause undesired operation.

Modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment under FCC rules.

CONTACT INFORMATION

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⚠ This product can expose you to chemicals including ethylene oxide, which is known to the State of California to cause cancer and birth defect or other reproductive harm. For more information, go to www.P65Warnings.ca.gov.

Caution: Federal law restricts this device to sale by or on the order of a physician

R_X Only

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