nalu
neurostimulation

Quick Reference Guide

Nalu Second Generation Therapy Disc (TD2)
Charger Setup and Remote Control Application

This quick reference guide will provide summary level instructions for:

- Understanding the TD2.
- Using and removing the Adhesive Clip.
- Starting, changing, and adjusting stimulation programs and settings.
- Setting WiFi and adjusting brightness on the Base Station Charger (BSC).
- Viewing an MRI report.

Important Notes

- Use only the supplied BSC to charge the TD2s. Other chargers will damage them.
- Use only the A/C power adapter provided. Off the shelf adapters may not provide adequate power and may damage the Therapy Disc or BSC.
- Connecting to WiFi may aid in troubleshooting.
- If no MRI label is listed, your device configuration has not been set. See page 24 for additional information on MRI conditionality.
- Do not use the Turn on Clinical Mode button or Logout unless instructed by a provider or Nalu representative.

TD2 Features

Vibration and Buzzer (beeps)

- Indicates TD2 Status.

LED (white, blue, green, orange)

- Indicates TD2 Status.

Preparing the Skin

1. Make sure the skin is clean, use only mild soap and water. Do not use lotions, soaps, or body wash with additives in the area where the clip will be placed as these additives may interfere with the adhesive bonding.

2. Make sure the skin is dry. Wet skin will interfere with the adhesive bonding.

3. If necessary, trim hair as close as possible to the skin with scissors. Do not shave with a razor since this can lead to skin irritation.

Note:
- Avoid placing the adhesive with the skin under tension.
- Ensure the adhesive is smooth when applying and does not have bunches or folds. Press along the center and edges to ensure there is full contact with the skin.
- Warm the clip before applying, hold against skin or in a pocket as an example, do not use external heat sources.

Applying the Clip

1. Remove the adhesive liner.

2. Grasp the clip between your thumb and finger and place your index finger through the center hole. Your index finger can be used to locate the implant.

3. Press the clip against your skin, ensuring the heel (where the TD2 Therapy Disc sits) is towards the bottom.

## Placing the TD2 Therapy Disc

1. Allow the adhesive to warm to body temperature once applied before inserting the TD2 Therapy Disc.

2. Slide the TD2 Therapy Disc into the open side of the clip until it clicks into place.

3. Ensure that the Nalu logo is facing away from your skin.
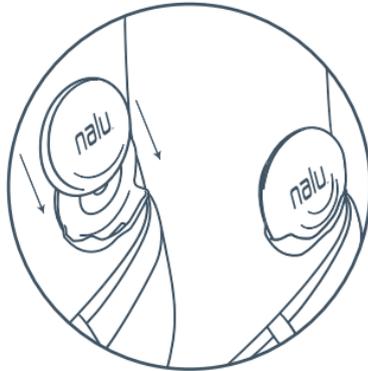
Removing the TD2 Therapy Disc

1. Grip the sides of the TD2 Therapy Disc.

2. Gently work one finger between the plastic of the clip and the TD2 Therapy Disc to unlock the TD2 Therapy Disc.

3. Gently lift the TD2 Therapy Disc away from the surface of your skin and out of the clip.
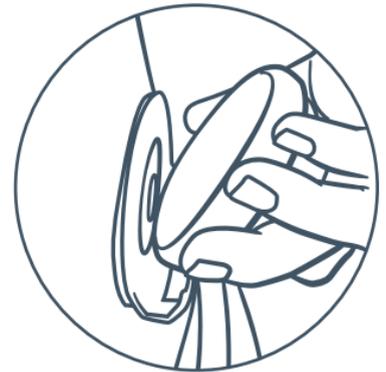
Adhesive Wear Time

1. The wear time for the TD2 Adhesive Clip varies per activity level and skin type.
2. Wear the clip until it feels like the adhesive is coming loose or starts to feel uncomfortable.
3. It is recommended that you use a commercially available adhesive remover (spray) to remove the clip.
4. Literature recommends assessing the skin under adhesives at regular intervals. Until you have determined how your individual skin and activity level affects the adhesives, you may want to limit initial duration of wear to 3 to 4 days and adjust the time as needed as you learn more.

Removing the Clip

1. Remove the TD2 Therapy Disc from the clip.
2. **Apply the adhesive remover wipe or spray to the adhesive before and during clip removal to help loosen the adhesive**.
3. Using your finger, gently work between the adhesive and your skin to loosen the clip until it detaches. **Note: DO NOT peel the adhesive off quickly**.
4. Discard the used clip.
5. Any adhesive residue should be cleaned using an adhesive remover wipe or spray. **DO NOT use alcohol**.
6. Gently clean the skin, using **only mild soap and water**.

1. The TD2 will power on when removed from the charger.

2. Once you hear the beeps or see the lights and feel the vibration of the TD2, it is ready to use.

3. Place the TD2 over your implanted IPG using your clips or wearable.

4. When the TD2 is located properly over the IPG, you will get 3 audible beeps, visual lights, and vibration feedback.

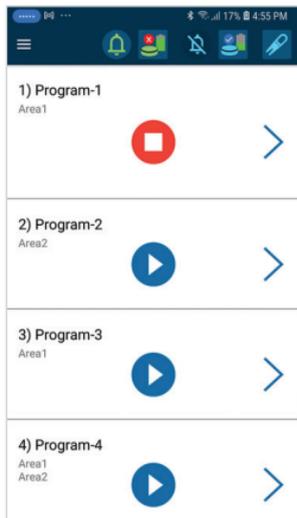5. Stimulation will then start at the last program run.
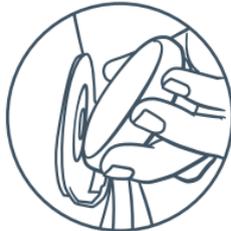
Utilize the Nalu Remote Control application.
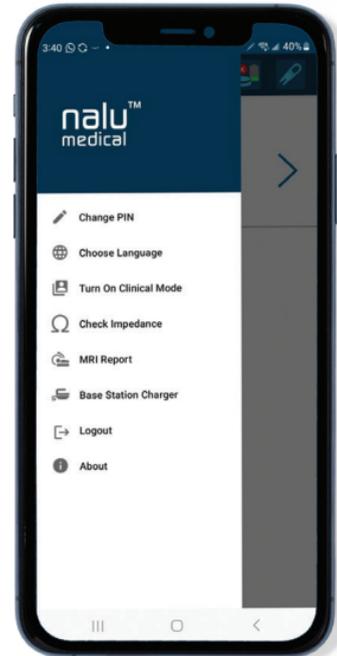
To start or change a stimulation program from the Home screen:

1. Select the program that you want to start.

2. Tap the ▶ icon.

3. The therapy will start. Touch once, there is a very small delay to stop any running programs and for therapy to start.

Tap the therapy ⟩ icon. The Program Details screen will appear, displaying the posture and pulse amplitude settings.

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

After you start the program by tapping the ▶ icon, the posture and therapy amplitude tabs will be enabled. When stimulation is running, the ⬛ icon will appear.
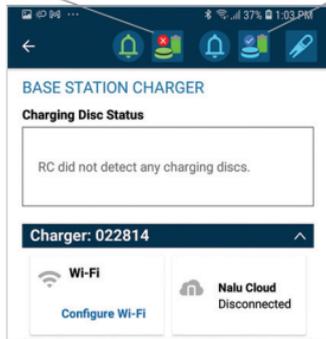
TD2 Therapy Disc Status

Status of green TD2.

Status of blue TD2.

BASE STATION CHARGER

Charging Disc Status

RC did not detect any charging discs.

Charger: 022814

Wi-Fi — Configure Wi-Fi

Nalu Cloud — Disconnected

TD2 is off or out of range.
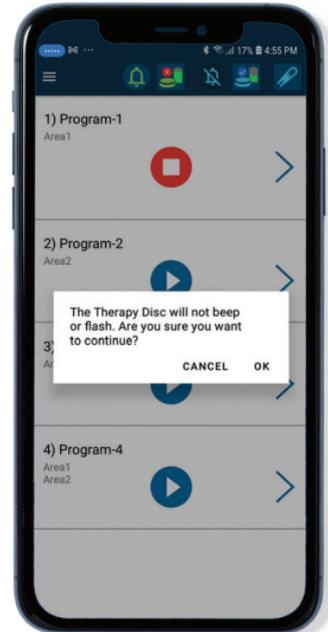
TD2 is not producing therapy.

TD2 is producing therapy.

Silence/Do Not Disturb mode Off/On.

How to Silence

To silence the therapy disc and disable the beeps, lights, and vibrations, tap the 🔕 icon.

- When you tap the Bell icon, you will get a confirmation screen to verify you want to put the TD2 in silent mode.
- To take the TD2 out of Silent mode, tap the Bell icon that now has a line through it.
- Silent mode will be turned off when the TD2 is placed in the charger.

1) Program-1
Area1

2) Program-2
Area2

The Therapy Disc will not beep or flash. Are you sure you want to continue?

CANCEL   OK

3)
Area

4) Program-4
Area1
Area2

Connect your BSC to your Wi-Fi network.

- You will need the name and password for the Wi-Fi network your BSC will connect to.

NOTE: You will be unable to set up the system if you DO NOT have access to a Wi-Fi connection or do not know the Wi-Fi name and password.

To configure the BSC:

1. Ensure that the phone's Bluetooth is turned on.
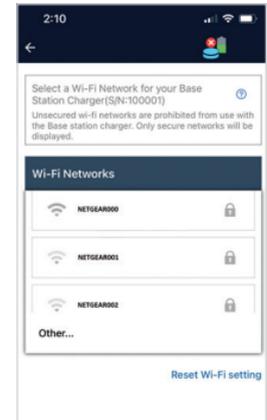2. Ensure the BSC is plugged in and nearby when setting up.

3. Remove the TD2 from the BSC.
4. Tap Base Station Charger in the menu on the Remote Control app. The BSC screen will appear.
5. The first screen will ask if your device is blinking green.
6. If your device is blinking green, you are ready to begin setup. Select Yes. For more information refer to the 'Nalu Neurostimulation System User instructions' available on the Nalu Medical website, www.nalumed.com/ifus.
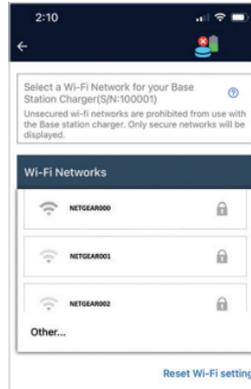7. After selecting Yes, you will see the Wi-Fi selection screen.

NOTE: Your WiFi network names will match what is available in proximity to you.

8. Select your Wi-Fi name from the list and have your password ready.

9. After selecting your WiFi, enter your password where prompted and select Save to Charger.

10. The BSC will take time to connect to your WiFi network.

11. A "Setup is Complete" screen will appear when you have connected.

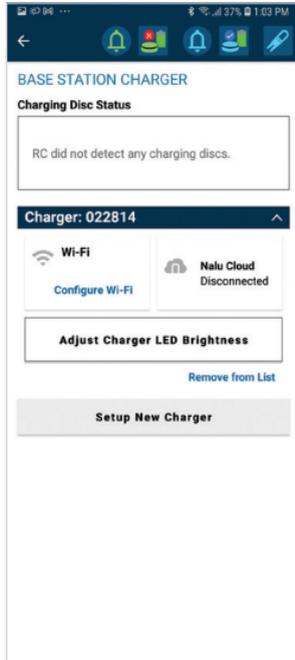If unsuccessful, you will be notified and will have to repeat the process from the Main Menu.

Once the BSC is connected to Wi-Fi, you can adjust the brightness of the BSC LED light.

1. Enter the menu and select Base Station Charger if the BSC is connected to WiFi.


2. Select Adjust Charger LED Brightness and use the slider to set brightness to your desired level.

3. Click Done when you are finished adjusting. Brightness adjusts after selecting Done.

4. Repeat steps for additional brightness adjustments.
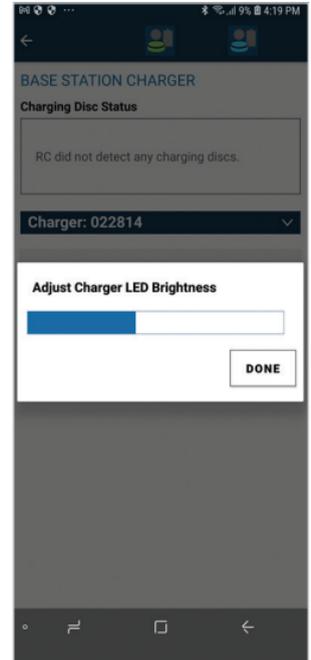
The Remote Control application allows the user to view an MRI report that has been downloaded onto the TD2 by the Clinician Programmer.

WARNING: The contents of the MRI report should be cross-referenced with the information in the MRI Safety Information Manual (MA-000105) https://nalumed.com/patients/resources/#manuals. Never rely solely on the MRI report for MRI Conditionality parameters and information.
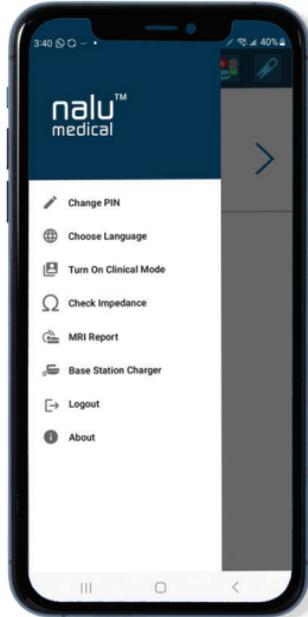

For patients with more than one Nalu Neurostimulation System, consult the MRI Safety Information Manual.

To view the MRI report, tap on MRI report from the menu.

If there is no report the system configuration has not yet been setup. Contact your Nalu representative or Nalu technical services who can work with your physician provider to provide accurate information. Not all Nalu systems are MRI conditional. Providers must always refer to the latest MRI manual for individual conditionality.

Icon Definitions & Troubleshooting
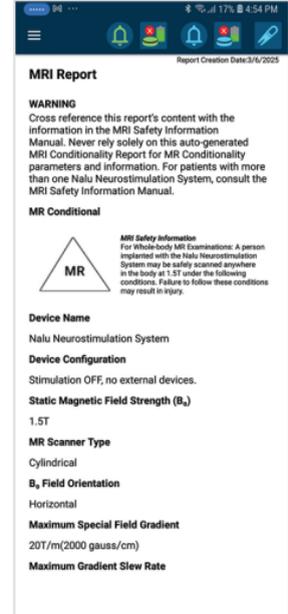
Icon Definitions

Start button for most recent therapy

Start Button — press to begin therapy

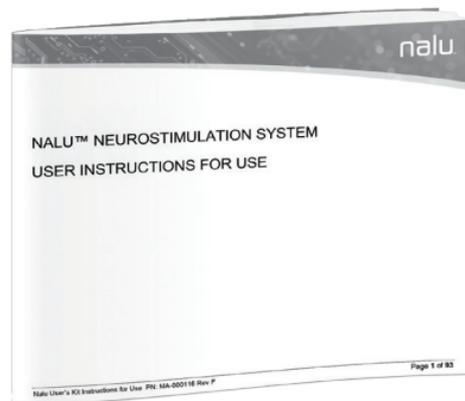Stop Button — press to stop therapy

Silent mode On/Off

Troubleshooting

If application is not working correctly, please restart the application and the TD2.

If the TD2 is not connecting, ensure the TD2 and device are within range, charged and no objects are blocking the connection.

Applicable Warnings and Precautions

Please refer to the Patient Manual for complete instructions and applicable warnings and precautions.

Complete manuals can be found at www.nalumed.com/ifus.

NOTE: The Nalu privacy policy can be found at https://nalumed.com/privacy-policy.

Scan for instructions

NALU™ NEUROSTIMULATION SYSTEM
USER INSTRUCTIONS FOR USE

nalu

Nalu User's Kit Instructions for Use PN: MA-000116 Rev F

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