PHYSICIAN MANUAL

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NTX150

TONIC MOTOR ACTIVATION SYSTEM

TABLE OF CONTENTS

INTRODUCTION

Carefully read all instructions prior to using the NTX150 Tonic Motor Activation (TOMAC) System. Observe all contraindications, warnings, and precautions noted in this chapter and throughout the Instructions for Use (IFU). Failure to do so may result in the possibility of injury to the patient, inferior treatment outcomes, or damage to the Therapy Unit.

For questions contact Noctrix Customer Service at 1-866-EASE-RLS (1-866-3273-757).

CHAPTER 1–SAFETY INFORMATION

Indications for use

The NTX150 Tonic Motor Activation (TOMAC) System is intended to reduce symptoms of primary moderate-severe Restless Leg Syndrome and improve sleep quality in adults refractory to medications.

Important safety information

The following symbols are found in this manual:

Symbol	Definition
WARNING!	A warning indicates a situation which, if not avoided, could result in death or serious injury.
PRECAUTION!	A precaution indicates a situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property.

Contraindications

The NTX150 Tonic Motor Activation System (NTX150 TOMAC System) is contraindicated for use in patients with the following:

- Diagnosis of epilepsy or other seizure disorder.
- Active medical device implant anywhere in the body, including but not limited to pacemakers, spinal cord stimulators, deep brain stimulators.
- Metal implant in the leg at the therapy site (not including knee replacements).
- Known allergy to device materials (or severe previous reaction to medical adhesives or bandages).
- Cellulitis, open sores, or injury at or near the location of device application.

The device cannot be used while driving, operating machinery, or during any activity in which electrical stimulation can put the patient at risk of injury.

Warnings

Warning	Description
Electrical	The NTX150 TOMAC System is not waterproof. DO NOT expose to water. There are no user-serviceable parts in or on the NTX150 Tonic Motor Activation System (NTX150 TOMAC System). Do not attempt to service or modify the Therapy Unit beyond the basic cleaning instructions in this manual. Operation of this equipment in electrical environments discussed in Appendix A may result in improper operation. Special precautions are needed regarding: • The NTX150 TOMAC System is not intended for use in a Magnetic Resonance Environment. • Operation in close proximity to a shortwave or microwave medical electrical equipment. The long-term effects of electrical stimulation are unknown. Since the effects of stimulation of the brain are unknown, stimulation should not be applied across the head, and electrodes should not be placed on opposite sides of the head. Stimulation should not be applied directly on the eyes, covering the mouth, on the front of the neck, or from electrodes placed on the chest and the upper back or crossing over the heart. The safety of electrical stimulation during pregnancy has not been established. Patients with suspected or diagnosed heart disease should follow precautions recommended by their physicians. Please do not use it on the area if the skin is not clean or not easy to reach.

Warnings (continued)

Warning	Description
NTX150 TOMAC System Parts	The NTX150 Tonic Motor Activation System is intended for use only with the provided components. Substituting different components for those supplied by Noctrix Health, Inc. may damage the Therapy Unit and/or create a safety hazard. Avoid using the device next to, or stacked with, other equipment. Prior to use, inspect the product package for signs of damage or tampering. If damaged, do not use. Do not use if you are allergic to acrylic or adhesives. Do not connect the USB charging cable while wearing and/or using the Therapy Unit. Application of electrodes near the chest may increase the risk of cardiac fibrillation. Accessory cables represent a strangulation hazard. Keep out of reach of pets and children.
Charge-Dispersing Interfaces (CDIs)	Do not place Charge-Dispersing Interfaces (CDIs) over open sores or an acute injury. Stop use if skin irritation develops at or around the therapy site. Remove the system and consult your health care professional.

Precautions

Precaution	Description
NTX150 TOMAC System	Carefully read all instructions before using the NTX150 TOMAC System. Follow all contraindications, warnings and cautions in this manual. Failure to do so may result in possible injury, less effective treatment, or damage to the Therapy Unit. The NTX150 TOMAC System should not be exposed to water. Position the Therapy Unit so it is easy to disconnect the charging cable. Note that premature onset of RLS symptoms while wearing the Therapy Unit may occur for some people as this Therapy Unit may interfere with voluntary leg movements used to relieve RLS symptoms, thus leading to a temporary increase in RLS symptoms. In some cases, this Therapy Unit may lead to a temporary increase in RLS symptoms during active stimulation for other reasons. This risk may be reduced by adjusting the stimulation intensity and changing the time of day when the Therapy Unit is used. Operation of this equipment in electrical environments discussed in Appendix A may result in improper operation. Special precautions are needed regarding: • Electromagnetic compatibility (EMC). • Proximity to strong electrostatic discharges (ESD) that are ≥ 15 KeV in magnitude. If the system malfunctions after exposure to ESD as described above, the Therapy Unit reset procedure may be performed to resume normal operation. • Proximity to portable and mobile radio frequency (RF) communications equipment. • The NTX150 TOMAC System is not recommended for use in close proximity to RFID readers.

CHAPTER 1–SAFETY INFORMATION

Adverse events

There is a potential for the following adverse events, which are typically mild to moderate and resolve over time:

- Administration Site Reaction (e.g. skin irritation).
- Discomfort.
- Temporary interference with sleep while wearing the Therapy Unit. For some people, the device may be uncomfortable. For others, it may interfere with preferred sleep positions.
- Patients should stop using the NTX150 TOMAC System and should consult with a physician if they experience adverse reactions from the system.

Proper use of the NTX150 TOMAC System as described in the Instructions for Use (IFU) can help reduce or prevent the following complications:

- Discomfort, paresthesia (tingling or prickling sensation), or otherwise irritating or uncomfortable sensations during treatment. This risk is reduced by adjusting the stimulation intensity.

Symbols

The following symbols are associated with the (NTX150 TOMAC System):

Symbol	Definition
	Caution Electrical Output
	Do not use if you have been fitted with a demand style pacemaker, unless directed to do so by a healthcare provider
	Consult Instructions for Use
	Caution – Refer to manual for important safety information
	Catalog Number
	Batch Code
	CAUTION! Federal (US) law restricts this device to sale by or on order of a licensed healthcare practitioner.
	Unique Device Identifier
	Serial Number
	Do not use if the package is damaged or open
	Date of Manufacture
	Country of Origin
	Single Patient Use Only
	Keep Dry
	Indicates the upper limit and lower limit of temperatures to which the medical device can be exposed
	Use-By Date
	CLASS II medical device
	Do not dispose of in a landfill

Clinical study: RLS symptoms and sleep quality[1]

A multi-center, prospective, randomized, double-blind, sham-controlled trial enrolling 133 subjects was conducted in subjects diagnosed with moderate-severe RLS and confirmed as refractory to RLS medication (clinicaltrials.gov Identifier: NCT04874155). In the first phase of the study (baseline to week 4) subjects were randomized 1:1 and were treated with either the NTX100 Tonic Motor Activation System set to either the Active or Sham mode. The stimulation parameters for the Active mode device were as follows:

- Mean calibration intensity: 30mA; (Range 15mA to 40 mA)
- Frequency: 4000 Hz
- Pulse width: 125 µs

A total of 68 subjects were treated with the NTX100 Tonic Motor Activation System and 65 subjects were treated with the sham device, with ages ranging from 29 to 79. Data from all 133 subjects enrolled were collected and analyzed. The primary endpoint (the responder rate on the CGI-I scale at Week 4 of Phase 1 relative to Baseline and compared between the study arms) was met and the results are provided in Table 1. The primary efficacy endpoint results demonstrate that, in the ITT and PP populations, the NTX100 TOMAC Cohort had a CGI-I Responder Rate at 4 weeks that was significantly greater than that of the Sham cohort (44.6% versus 16.2%, p=0.0002; CI: 32.5, 56.8 versus 7.1, 25.2).

All of the six secondary endpoints were also met, including statistically significant improvements in sleep quality as measured on the clinically validated MOS-I and MOS-II sleep scales. These results are shown in Table 2. A post-hoc analysis demonstrated that use of the NTX100 TOMAC significantly reduced trouble falling asleep, reduced daytime sleepiness/ somnolence and reduce sleep problems.

Table 1 Primary Efficacy Endpoint (ITT Population)

Endpoint	NTX100 TOMAC (N=68) n (%)	Sham (N=65) n (%)	p-value
CGI-I Responder at Week 4			0.0002
Yes	29 (44.6)	10 (15.9)	
No	36 (55.4)	53 (84.1)	
Imputed CGI-I Responder Rate at Week 4			0.0001
Responder Rate (%)	44.6	16.2	
95% CI (%)	32.5, 56.8	7.1, 25.2	

Table 2 Key Secondary Efficacy Endpoints (ITT Population)

Key Secondary Endpoint	NTX100 TOMAC (N=65)	Sham (N=63)	p-value
1. PGI-I Responder at Week 4	33 (50.8%)	12 (19.0%)	<0.0001
2. Reduction in mean Total IRLS score from Baseline to Week 4	7.2	3.8	0.0009
3. Reduction in mean MOS-II score from Baseline to Week 4	13.7	4.0	0.0002
4. Reduction in mean MOS-I score from Baseline to Week 4	11.8	2.8	0.0004
5. CGI-I mean score at Week 4	2.6	3.5	<0.0001
6. Reduction in mean IRLS question #7 score from Baseline to Week 8	0.9 (n=64)	–	<0.0001

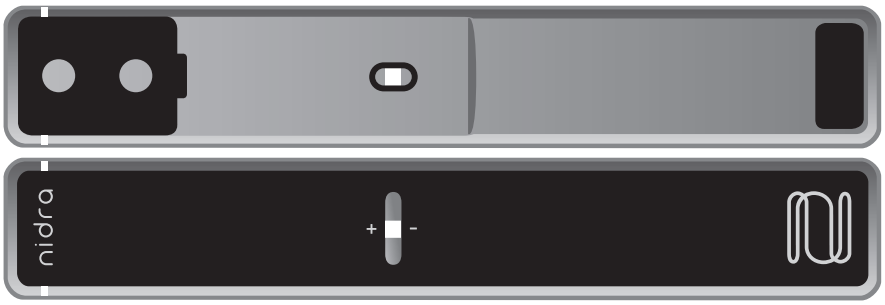
There were no serious device-related adverse events. Device-related AEs were typically mild and resolved rapidly with minimal or no follow-up. There were 89 device-related AEs affecting 50 subjects (37.3% of the safety analysis population), 88 of which were Mild and 1 was Moderate. Device-related AEs resolved rapidly; the average time to device-related AE resolution was 2.7 days, 72% of AEs resolved within 1 day or less, and 100% of AEs resolved. Device-related AEs resolved with minimal intervention; the most common actions taken were no action (57%), adjustment of treatment stimulation intensity (13%), and adjustment of treatment positioning (11%). No medications were prescribed for device-related AEs. A summary of the device-related AEs are shown in Table 3. The safety and efficacy of this device has not been studied in pregnant women.

Table 3 Summary of Device-Related Adverse Events (AE)

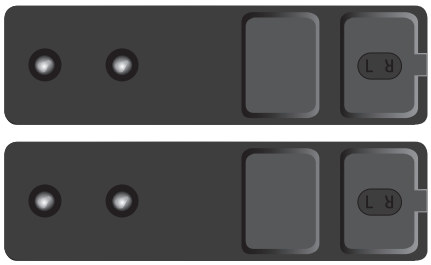
Description of AE	Device-Related AEs (N=89)n AEs (% of total)
Administration site discomfort	44 (49.4)
Administration site irritation	17 (19.1)
RLS symptoms (general)	15 (16.9)
RLS symptoms (specifically muscle cramps/spasms)	7 (7.9)
Other	6 (6.7)

CHAPTER 2–SYSTEM OVERVIEW
SYSTEM COMPONENTS

Compressive Conductive Garments (CCGs)

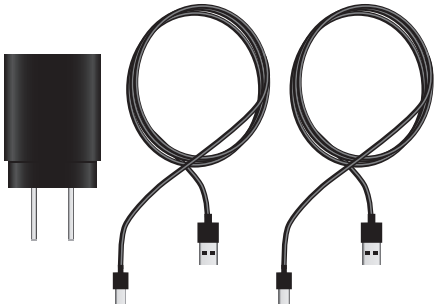


e-modules



Charge Dispersing Interfaces (CDIs)

Charging accessories
– USB wall charger
– USB cables



The NTX150 Tonic Motor Activation (TOMAC) System consists of two Therapy Units, intended to be used bilaterally (on both legs).

The two units work separately but the mechanism of action is identical. An individual Personalized Activation Session is required and can result in different treatment settings for each leg. The Therapy Unit and buttons on each Therapy Unit are mirrored (from left to right) to assist with placement on each leg.

The NTX150 TOMAC System consists of the distinct, non-sterile parts, listed below:

e-module

This module contains electronics and a rechargeable battery. The module is placed within the compressive conductive garment (CCG) and has buttons that turn the system ON/OFF, adjust treatment level, or read status.

Compressive Conductive Garment (CCG)

This conduction garment is worn on both legs (below the knee). The e-module sits within the CCG. When combined, these components are collectively referred to as the NTX150 TOMAC Therapy Unit. The Therapy Unit provides the TOMAC stimulation.

Charge Dispersing Interface (CDI)

This is a specially-designed reusable, adhesive electrode that allows current to flow from the Therapy Unit to the treatment target. The Charge-Dispersing Interface has a shelf life of 23 months.

Charging accessories

An AC wall adapter for US use (110V) with (2x) USB-charging cables to recharge the battery on each Therapy Unit.

Carrying case

A carrying case (not pictured) is provided when water protection is needed.

CHAPTER 2–SYSTEM OVERVIEW
CONTROL FEATURES AND STATUS LIGHTS

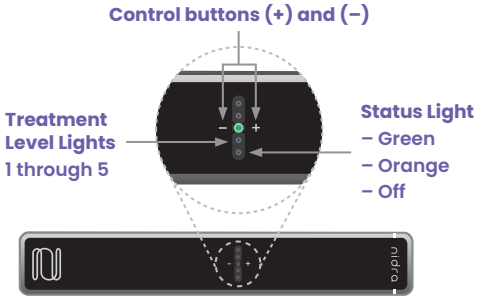
Therapy control features

Icon description	Icon	Action	Description
Turn On	+	Press and hold for three seconds	Turns on the Therapy Unit
Wake-up	+/–	Press both at the same time	Shows the treatment level lights and allows changing the treatment levels
Increase treatment level	+	Press once	Increases treatment by one level when Therapy Unit is awake
Decrease treatment level	–	Press once	Decreases treatment by one level when Therapy Unit is awake
Turn off	–	Press and hold for three seconds	Turns off the Therapy Unit

Indicator Lights

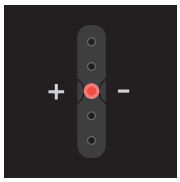
The Status Light is one colored light that can be either ORANGE, GREEN, or off.

The Treatment Level Lights are five white lights that can be either on or off.

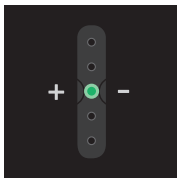


Charging

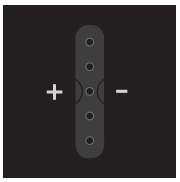
When the Therapy Unit is plugged into the charger



Orange Status Light:
Battery is charging but is not fully charged.



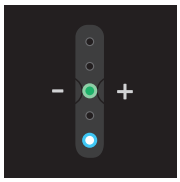
Green Status Light:
Battery is fully charged.



Status Light OFF:
Battery is not charging. Try to plug the Therapy Unit into the charger again or check the power supply to the outlet.

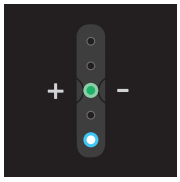
Treatment

Ramp at the start of treatment (0-20 seconds)



Treatment Level Lights (Left Therapy Unit)

Blinking white Treatment Level Light and blinking green Status Light appear for the first ~20 seconds of treatment:
Therapy Unit is on and ramping up to your treatment level.



Treatment Level Lights (Right Therapy Unit)

If these lights do not appear, the Therapy Unit was not turned on.
Try turning the Therapy Unit on again.

Treatment (continued)

Treatment level

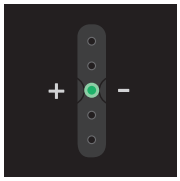
Treatment Level Lights (Left Therapy Unit)

Treatment Level Lights (Right Therapy Unit)

For all of treatment, the **Treatment Level Lights** remain off unless the Therapy Unit is woken up by pressing the +/- buttons at the same time. The **number of Treatment Level lights** indicates your treatment level, from 1-5.

Other

Charge status



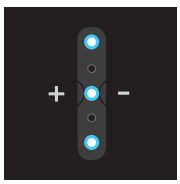
Charge status is displayed when the Therapy Unit is plugged-in and charging. If unplugged with therapy off, clicking the "+" button will display the charge status momentarily.

Solid GREEN: Typically enough charge for a full session.

Solid ORANGE: Low charge, but okay to proceed.

Blinking ORANGE: A session cannot start.

Reboot



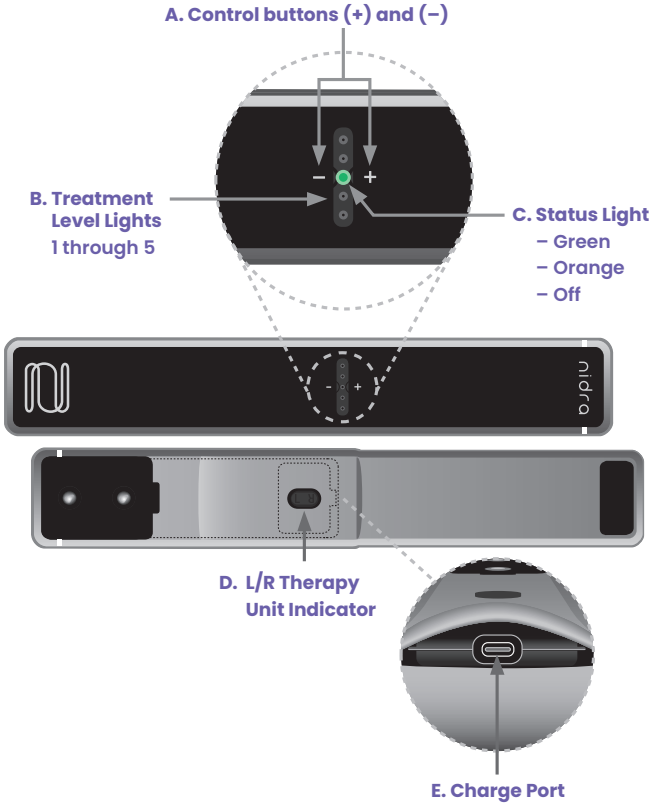
Rebooting the Therapy Units is performed by pushing the "–" button for 12 seconds. The three **Treatment Level Lights** at positions one, three, and five will confirm successful reboot.

Do not reboot unless instructed to do so.

Left/Right Therapy Unit Indicator

The L/R light is lit for 5 minutes after the Therapy Unit is unplugged and for 5 minutes after the "+" button is pressed. If the "L" is lit then it is the Left Therapy Unit. If the R is lit then it is the Right Therapy Unit.

Therapy Units (Left and Right)



A. Control buttons: (+) and (–) buttons used to start/stop a session and adjust treatment level.

B. Treatment Level Lights: five lights which each can be white or off and indicates the treatment level.

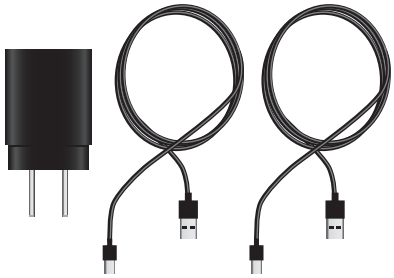
C. Status Light: one light which can be **GREEN**, **ORANGE**, or off and indicates charging and battery status.

D. L/R Therapy Unit Indicator Light: Left or Right Therapy Unit.

E. Charge port: opening in Therapy Unit for inserting the charging cable.

CHAPTER 3–
CARING FOR YOUR DEVICE

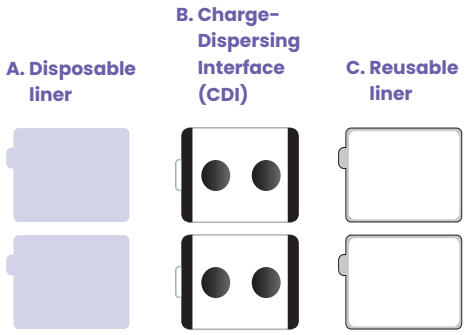
Charging accessories



Wall Charger: 120V Dual-USB charger that charges Therapy Units when attached to a charging cable.

Charging cables: USB connector that charges Therapy Units when attached to power outlet via the wall charger.

Charge Dispersing Interface (CDI)



D. CDI pouch

A. Disposable liner: blue see-through CDI liner without text.

B. Charge-Dispersing Interface (CDI): adhesive patch that attaches to the Therapy Unit and is replaced once per week.

C. Reusable liner: non-see-through CDI liner.

D. CDI pouch: container including two CDIs, one for each leg.

IMPORTANT	Although the NTX150 Tonic Motor Activation (TOMAC) System arrives partly charged, it is recommended that the Therapy Units be FULLY CHARGED before using them for the first time.

You should charge both Therapy Units daily after each use and keep charging the Therapy Units until the next session (keep the Therapy Units on the charger). A full charge may take at least 2+ hours until the Status Light turns GREEN, depending on your therapy settings and usage.

For best results, replace the Charge-Dispersing Interfaces (CDIs) as directed.

Charging the system

Please follow these steps to charge your Therapy Units. As noted in Section 9, the ORANGE light will come on once charging begins, and when charged, the light will change to GREEN.

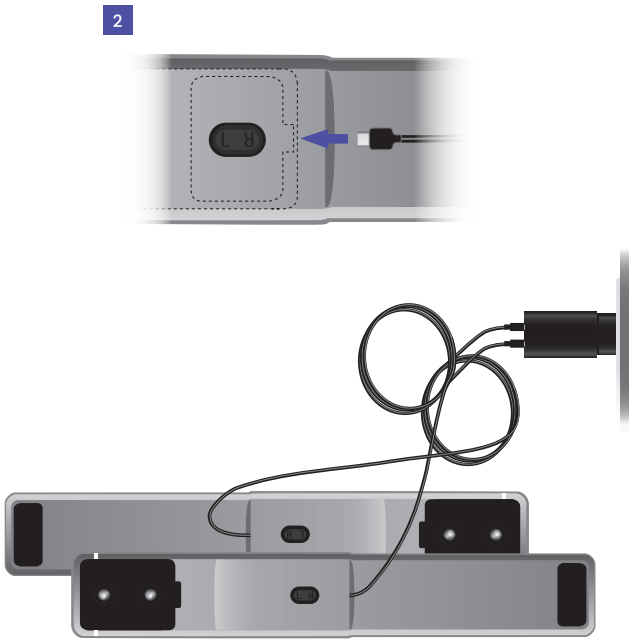
WARNING!	Do not connect the USB charging cable while wearing and/or using the Therapy Unit.
WARNING!	The NTX150 TOMAC System is intended for use only with the provided parts. Using parts other than those supplied by Noctrix Health, Inc. may damage the Therapy Unit and/or create a safety hazard.

CHAPTER 3–
CARING FOR YOUR DEVICE

NTX150 TOMAC System charging steps

1. Connect the male USB plugs into the female USB plug on the wall charger, and connect to a standard wall outlet.

2. Connect the male USB-C plug into the female USB-C port on the e-module.



3. Once connected, the **ORANGE** Status Light should turn on, showing that the Therapy Unit is charging. You should charge both Therapy Units daily after each use and keep charging the Therapy Units until the next session (keep the Therapy Units on the charger). A full charge may take at least 2+ hours until the Status Light turns **GREEN,** depending on your therapy settings and usage.

CHAPTER 3–
CARING FOR YOUR DEVICE

CARING FOR THE NTX150 TOMAC SYSTEM

⚠ **WARNING!**	The NTX150 TOMAC System is not waterproof. Keep dry; DO NOT expose to water.

Therapy Units

- The NTX150 TOMAC System Therapy Units are not waterproof and should not be placed in water.
- Attempts to wash the Therapy Units by hand, or in a laundry machine, will result in damage to the Therapy Unit.
- Be sure the Therapy Unit has been turned OFF before you start the cleaning.
- Only use a clean and dry cloth to remove dust as needed.
- Do not use soap, hand sanitizer, detergents, or other cleaners when cleaning the Therapy Unit.
- Do not use corrosive substances to clean the Therapy Unit or cables.

Charge Dispersing Interfaces (CDIs)

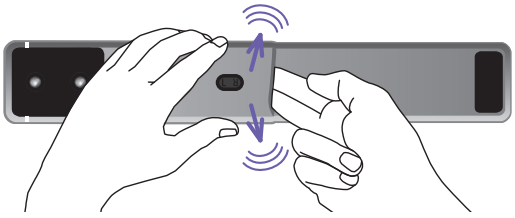
- CDIs are not intended to be cleaned and should be disposed of as directed.
- CDIs are single patient use only and should not be shared.
- If the sticky portion of the CDI that contacts the leg loses its ability to stick, then use a new CDI.
- Place the reusable liner on the patient side of the CDI between uses.
- CDIs are intended to be replaced as directed.

Removing the e-module

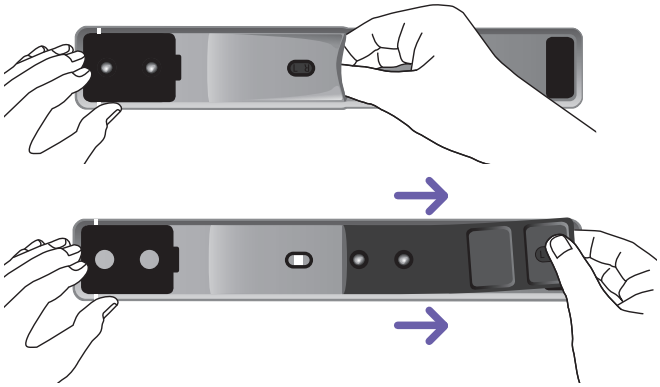
The patient is instructed at their Personalized Activation Session on the assembly/disassembly methods for the e-module and CCG. The instructions below are provided for their reference

1. Place the CCG containing the e-module flat on the table with the pocket facing you.

2. Slide your fingers under the e-module until it unsnaps from the CCG fabric.



3. Grasp the e-module while holding the end of the CCG to slide the e-module out of the CCG pocket.



The CCG should not be washed in a washing machine. Only use a clean and dry cloth to remove dust as needed.

Storage instructions

The Therapy Unit is intended for use in a dry, room-temperature home setting. To avoid battery degradation, avoid long exposures to temperatures above 104° Fahrenheit (40° C). Store the Therapy Unit in a dry location.

Instructions for safe disposal

Used CDIs and CCGs may be disposed may be disposed of in normal trash bins. Consult your local laws regarding battery and electronic waste disposal.

CHAPTER 4– WHEN TO USE YOUR NTX150 TOMAC SYSTEM

OVERVIEW

The patient has been advised to consult their physician regarding best times of use. They are provided with the following information:

It is important to use your System when you have RLS symptoms.

- The NTX150 TOMAC System delivers 30-minute treatment sessions.
- Each session is designed to quickly relieve RLS symptoms.
- Relief typically begins soon after turning the Therapy Unit on and can last up to 2 hours after the end of the 30-minute session.[2, 3]
- The device is not designed to prevent symptoms before they start.
- It is recommended that the device be used for treating symptoms after they start but before they become severe.

Therefore, it is important to start a therapy session shortly after the start of RLS symptoms.

The Therapy Unit can deliver at least one and often two full sessions on a full charge. Therefore, it is important to ensure the Therapy Unit is fully charged at times of day that would have the most impact on your quality of life. These could include:

- Bedtime, to help with sleep onset.
- Middle of the night, to help fall back asleep.
- Other times of day when RLS symptoms are severe.

If used with the proper timing, clinical data suggests that use of NTX150 TOMAC System results in the following potential benefits:

1. Reduction in acute RLS symptoms[3]
2. Improved sleep[1]

Long-term use of NTX150 TOMAC System at proper times of day can also result in fewer days per week with RLS symptoms.[4]

If used with improper timing, the following may occur:

- Low battery. If the Therapy Unit is used at times when not needed and not fully recharged, the battery charge may not allow for a full session when needed.

CHAPTER 4–WHEN TO USE YOUR NTX150 TOMAC SYSTEM
OVERVIEW

General timing instructions

- Run a session after RLS symptoms start and before symptoms become severe.
- Always run a full 30-minute session. Therapy Units will turn off by themselves after a session.
- On nights without RLS symptoms, do not use the Therapy Units.
- Prioritize sessions where reduced RLS symptoms could improve sleep (i.e. bedtime or middle of the night).
- When a single 30-minute session does not relieve symptoms, you have the option of running a second 30-minute session.
- A full charge typically allows for 1-2 sessions of use.
- You should charge both Therapy Units daily after each use and keep charging the Therapy Units until the next session (keep the Therapy Units on the charger).
- Consider raising the Treatment Level to level 4 or level 5 if RLS symptoms are more severe than usual.
- Consider decreasing the Treatment Level to level 2 or level 1 if RLS symptoms are mild.

Examples of common times to use the Therapy Unit

1. Before bedtime

- **Run a 30-minute session after your RLS symptoms start but before they become severe.**
  - Based on your history of RLS symptoms, this may be in the two hours before bedtime, but could be earlier or later on some nights.
  - On nights when you don't have RLS symptoms, don't use the Therapy Units.
  - Start at level 3; if level 3 does not give enough relief, you may try a higher setting (level 4 or level 5).
- If your symptoms remain at bedtime, run a second session at bedtime at a setting that allows you to go to sleep (e.g. level 3 or level 2).

2. At bedtime

- **Wear your Therapy Units to bed. As soon as your RLS symptoms start, run a 30-minute session** at a level that allows you to go to sleep (typically level 3 or level 2).
  - If level 3 does not provide enough relief, you may try a higher setting (level 4 or level 5). If level 3 is too distracting to go to sleep, try a lower setting (level 2 or level 1).
  - On nights when you don't have RLS symptoms, don't use the Therapy Units.
- If RLS symptoms remain after the session ends, you have the option of a second session.

3. After falling asleep (in the middle of the night)

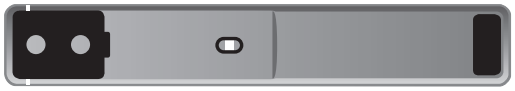
- **Wear your Therapy Units to bed** but do not run a session until you have RLS symptoms. You can also keep the Therapy Units next to your bed instead of wearing them to bed.
- **When you wake up with RLS symptoms,** run a 30-min session at a setting that lets you go back to sleep (typically level 3 or level 2).
  - If level 3 does not provide enough relief, you may use a higher setting (level 4 or level 5). If level 3 is too distracting to go to sleep, use a lower setting (level 2 or level 1).
  - On nights when you don't have RLS symptoms, don't use the Therapy Units.
- If RLS symptoms remain after the session ends, you have the option of a second session.

CHAPTER 5–TREATMENT

Prior to beginning in-home use, the patient will attend a personalized activation session with a specially-trained technician who will train the patient to assemble/disassemble the e-module and CCG and work with the patient to identify the appropriate stimulation intensity that is needed to reduce symptoms of RLS and is tolerable. (Specific details regarding a Personalized Activation Session can be found in IFU-3 Titration Manual.) The technician will program the patient-specific settings into the Therapy Unit and the patient can then perform a treatment by following the instructions in this chapter.

Inserting the e-module

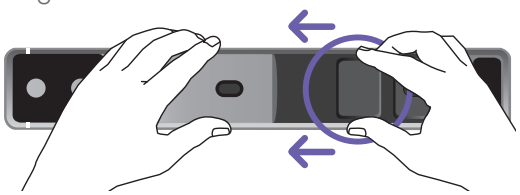
1. Lay the Compressive Conductive Garment (CCG) and e-module flat as shown.

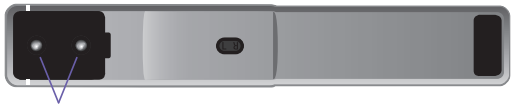


Compressive Conductive Garment (CCG)

e-module

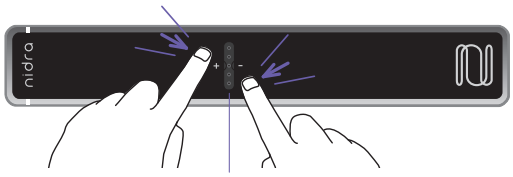
2. Hold the CCG along the seams. While holding the battery (circled), slide the e-module into the pocket on the CCG until the metal contacts of the e-module can be seen through the circular openings in the black material.





Metal Contacts

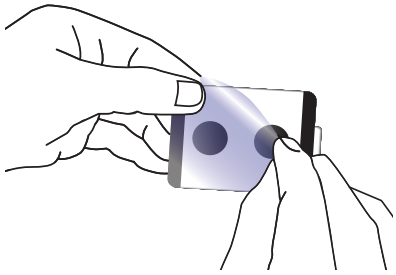
3. **Turn the band over so that the Nidra logo is facing up.** Confirm the LED bar is aligned with the window in the CCG. Gently press down on the fabric all around the LED bar until you feel it snap into place.



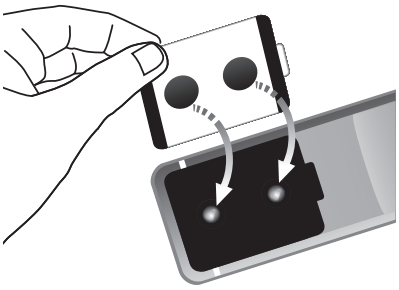
LED Bar

Placement of Charge-Dispersing Interface (CDI) on the Therapy Unit

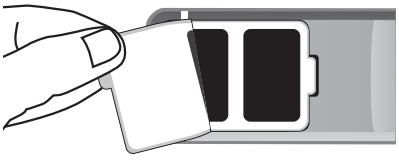
1. If no CDI is on the Therapy Unit, or if you need to replace the CDI, choose a pouch from the box of CDI pouches.
2. Tear open the pouch at the top and remove one CDI.
3. Grab the blue see-through disposable liner without the text by the tab, peel away the blue liner and discard.



4. You will see that the circular windows in the white foam backing of the CDI are exposed.
5. Line up these circular windows on the CDI with the metal contacts and firmly press the CDI onto the Therapy Unit.



6. Remove the non-see-through reusable liner to expose the rectangular, sticky part of the CDI, and save the liner to protect the CDI after use.



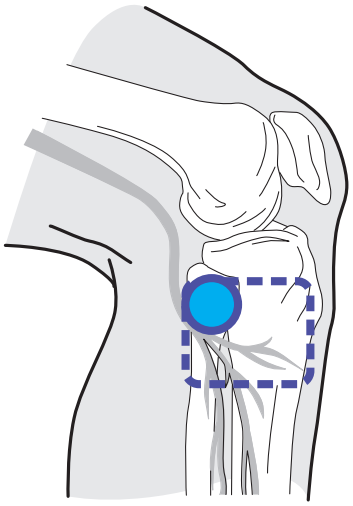
7. Repeat steps 3-6 on the other Therapy Unit if (a) no CDI is present or (b) you need to replace the CDI.

CHAPTER 5–TREATMENT

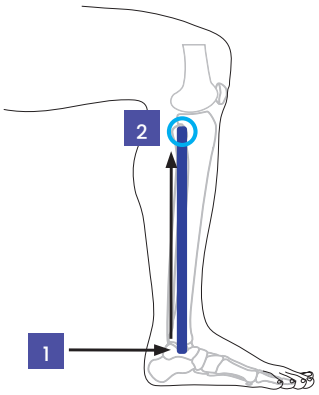
Finding the treatment target

Treatment target

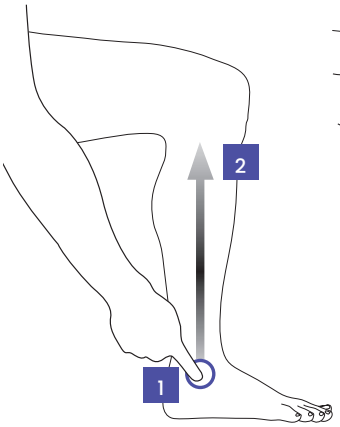
The Peroneal nerve curves around the head of the fibula (marked by the **BLUE** circle in the image). The **PURPLE** area indicates the ideal location of the CDI.

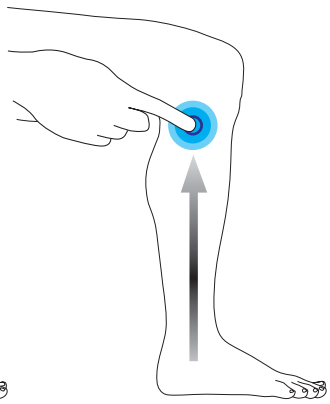


To find the head of the fibula (**BLUE** circle) instruct the patient to sit with the **lower leg perpendicular to the floor (at a 90 degree angle):**



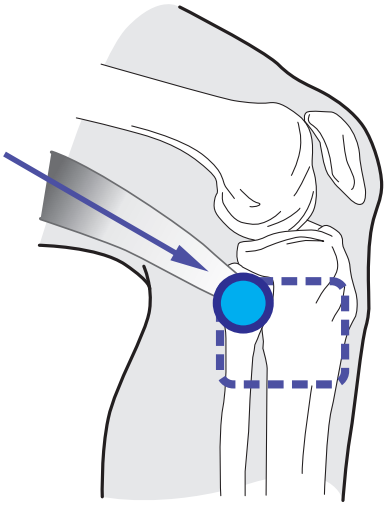
1. Identify the bony prominence on the outside of the ankle (lateral malleolus) at the base of the fibula.
2. Move directly upwards along the outside of the leg (along the fibula shown in **PURPLE**) until you reach the next bony prominence, below the bones of the knee. This is the head of the fibula (**BLUE** circle).





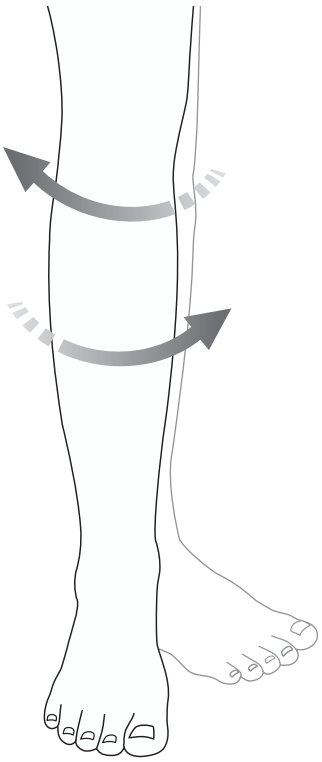
Treatment target confirmation

The lateral biceps femoris of the hamstring muscle attaches to the head of the fibula (**BLUE** circle) and can be a useful secondary anatomical reference. The **PURPLE** area indicates the position of the CDI with respect to the head of the fibula and the hamstring attachment point is shown in **BLUE**.



Verification of location: Medial and Lateral Rotation

Performing the movement of a medial and lateral rotation, which can be explained to the patient as, "moving from the gas to the brake pedal," will make a visible and tactile movement at the head of the fibula. Repeat this movement on both legs to verify that the head of the fibula has been located.

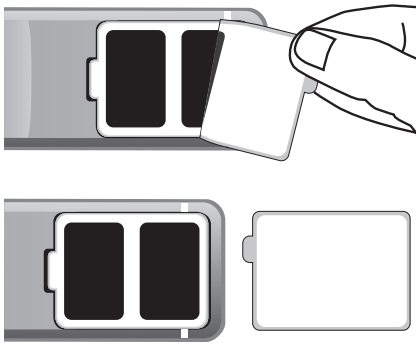


Once you have found the correct location:

- Use a marking pen to mark the center position of the head of the fibula (**BLUE** dot in images above).
- Take a photo of the marking on the patient's camera for reference.

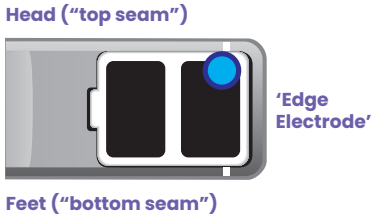
Donning Therapy Units to both legs (images show the "R" [Right] Therapy Unit)

- Carefully peel the reusable liner from the Charge-Dispersing Interface (CDI) and save it to protect and reuse the CDI.
- Check that the skin is clean.



- Carefully peel the reusable liner from the CDI and save it to protect and reuse the CDI.
- Keep the liner on the CDI when not in use to extend the life of the CDI.
- To help keep skin safe, change the CDI's every week. And if you live in a dry place, you can dampen your skin with a little water before starting therapy.

- The CDI contains two electrodes (the black rectangles). The electrode closest to the edge of the Therapy Unit is called the 'Edge Electrode'.



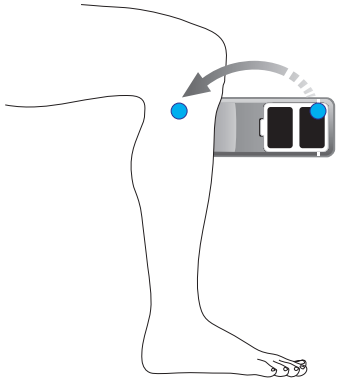
- The **BLUE** circle is where the edge electrode will meet up with the **treatment target** (head of the fibula).

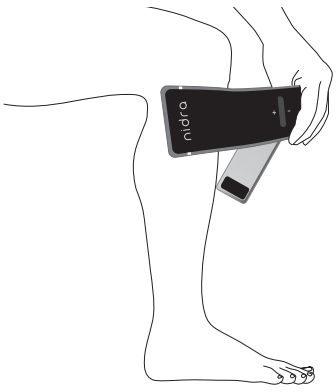
IMPORTANT	Only turn on your Nidra devices when they are positioned over the treatment target. Do not turn them on prior to placement or remove them while therapy is active.

- **Place the CDI directly on clean skin. Do not place the CDI over a skin wound or over a bandage or skin covering.**

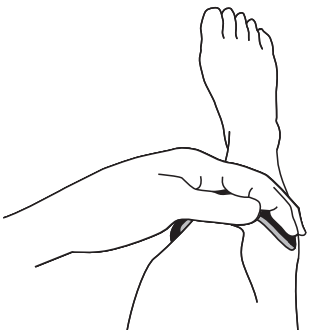
WARNING!	Do not place Charge-Dispersing Interfaces (CDIs) over open sores or an acute injury.

- Place the edge electrode – while attached to the Therapy Unit – so that the top edge corner (**BLUE** circle) covers the **treatment target** (head of the fibula) that was marked on the patient's leg.





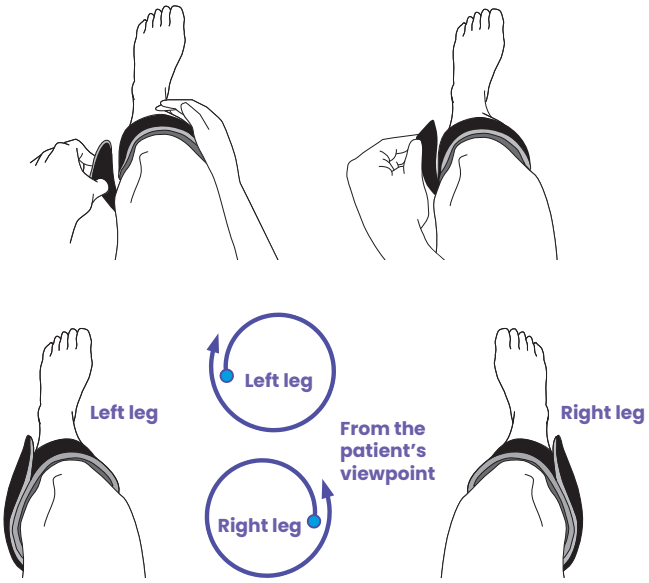
- Apply firm pressure around the surface of the CDI to ensure good adhesion.



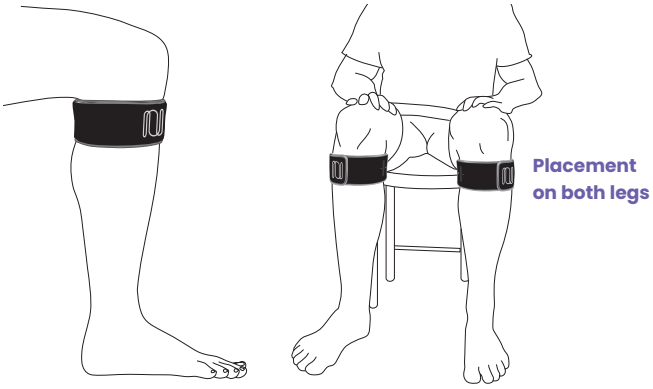
CHAPTER 5–TREATMENT

Secure the Therapy Unit:
(images show the "L" [Left] Therapy Unit)

- Place one hand over the CDI to hold the Therapy Unit firmly in place.
- Pull the other end of the Therapy Unit and wrap it around the leg in the correct direction:
  - Left leg Therapy Unit wraps clockwise.
  - Right leg Therapy Unit wraps counterclockwise.
- Pull firmly to ensure a secure fit.
- Secure the Therapy Unit with velcro.



This is how the Therapy Unit will look after it is on the patient. Depending on leg circumference, the position of edge of the Therapy Unit will vary.



Confirm the correct positioning during personalized activation session

- If the CDI is placed too anterior (toward the tibia) the patient will feel potential throbbing over the shin bone (tibia) before noticing strong sensations. If this occurs adjust the positioning of the CDI to be more posterior (toward the calf muscle).
- If the CDI is placed too posterior (toward the calf muscle) the patient will feel potential leg muscle twitching before noticing strong sensations. If this occurs adjust the positioning of the CDI to be more anterior (toward the tibia).
- Adjusting by approximately 0.5" can improve outcomes.

Starting a treatment

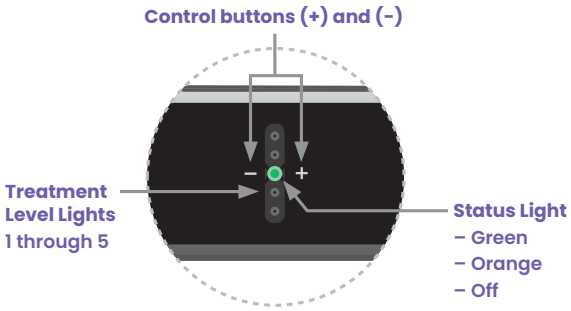
1. Advise the patient to check that Therapy Units for both legs have enough charge by checking for the **GREEN** Status Light while charging.
2. The patient should then remove the Therapy Units from the charging cables.
3. The patient should verify the battery status by clicking the (+) button while the Therapy Unit is disconnected from the cables.
   - The Status Light will indicate charge status:
     - Solid **GREEN**: Typically enough charge for a full session.
     - Solid **ORANGE**: Typically enough charge for half a session.
     - Blinking **ORANGE**: Very low charge. A session cannot start.
4. The patient should then place the **LEFT** Therapy Unit on the left leg and the **RIGHT** Therapy Unit on the right leg.
   - If there is no Charge-Dispersing Interface (CDI) on the Therapy Unit, see the "Placement of CDIs on the Therapy Unit" instructions at the beginning of this chapter.
5. Once Therapy Units are attached to both legs:
   - The patient will start a session for each Therapy Unit by pressing and holding the (+) button for three seconds. The Status Light will indicate charge status.
     a. From zero to 20 seconds, the patient will see blinking white Treatment Level Lights and a blinking **GREEN** Status Light as the intensity gradually increases to the mid-point of their calibrated range.

b. From 20 to 30 seconds, the Treatment Level Lights will show the therapy level of the Therapy Unit. During this 10 second period you will be able to set their treatment level from 1 to 5 within their range.

c. After 30 seconds, the patient can change their treatment level, but they will need to unlock the controls first;

1) If no white lights are lit, unlock the Therapy Unit by clicking (+) and (-) buttons at the same time and quickly – do not hold the buttons down.

2) The white lights that match the Treatment Level Lights will appear for 10 seconds while the Therapy Unit is unlocked.



5. The patient can relax and continue with their normal activity during the session, including falling asleep. The Therapy Unit will turn off by itself after 30 minutes.
6. If the patient falls asleep during the session or wants to run another session later in the night, it's okay to continue wearing the Therapy Units after the session ends.
7. To remove the Therapy Units:
   - Press (+) and (-) at the same time briefly to unlock.
     - If white Treatment Level Lights appear, then the session is still in progress. Wait until the session is complete to remove the Therapy Units.
     - If no Treatment Level Lights appear, then the session is complete and you can remove the Therapy Units.
   - Detach the Therapy Unit from your legs with the CDIs attached to the Therapy Units.
8. The patient should then replace the reusable liners on the CDIs.
9. After removal, the patient should connect the Therapy Unit to the charging cables via the charging port and plug into the wall adapter.

Adjusting treatment level during a treatment session

Level 3 will be your patient's most common treatment level. However, they may need to raise this level if their RLS symptoms are severe or lower this level if treatment at level 3 is distracting or causes discomfort.

- If no white Treatment Level Lights are visible, unlock the Therapy Unit by clicking the (+) and (-) buttons at the same time and quickly – do not hold the buttons down. The white Treatment Level Lights that match the treatment level will appear and be visible for 10 seconds while the Therapy Unit is unlocked.
- Click the (+) button to raise treatment level by one level. Note that the number of Treatment Level Lights increases by one.
- Click the (-) button to decrease treatment level by one level. Note that the number of Treatment Level Lights decreases by one.

Stopping a treatment

The patient does not need to stop the session. The treatment will turn off by itself after 30 minutes and you can wear the Therapy Units through the night.

- If treatment intensity is uncomfortable at any point, try decreasing the level to level 2 or level 1.
- If the intensity remains uncomfortable at level 1, it is possible to stop treatment with the following steps:

1. Press and hold the (-) button for 3 seconds to turn OFF Therapy Unit.
2. As soon as the Treatment Level Lights turn off, release the (-) button and remove the Therapy Unit from your leg.
3. Replace the reusable liner on each CDI.
4. Charge the Therapy Units for future use.

During a treatment session

The patient can relax and continue with their normal activity during the session, including falling asleep.

- Treatment will turn off by itself after 30 minutes and you can wear the Therapy Units through the night.
- If the treatment level remains comfortable but RLS symptoms persist, try raising the treatment level while it is still comfortable.
- It is normal for the Therapy Units to feel warm; however if the Therapy Units feel uncomfortably warm, stop the session and contact Noctrix Customer Support at your earliest convenience.

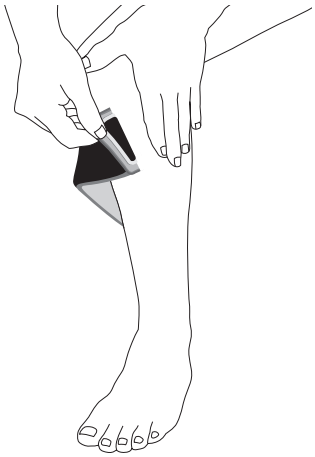
CHAPTER 5–TREATMENT

After a treatment session

Click (+) and (-) buttons at the same time to confirm that the 30-minute treatment session is complete. If the white Treatment Level Lights appear, the treatment session is not complete and you should wait. If not, it is complete.

DO NOT REMOVE THE DEVICES IF THEY ARE STILL POWERED ON.

1. After verifying that the Therapy Unit is not powered on, unwrap the Therapy Unit from your leg.
2. Use your hand to hold down the skin next to the CDI. Gently peel off the CDI from your skin.



3. Replace the reusable liner on each CDI to keep them free of lint and dust.
4. Charge the Therapy Units for future use.

CHAPTER 6–TROUBLESHOOTING

PATIENT TROUBLESHOOTING

For each of these scenarios the patient should try these steps in order until the problem is solved.

1. The treatment sensation feels weaker:

1. Adjust the treatment to levels 4 and 5.
2. Stop therapy and change the location of the Therapy Units on your leg. Then, start therapy again.
3. Check that the Therapy Unit is fully charged and the lights show it is turning on and staying on.

If those steps do not work then change the CDIs. If this does not work contact Noctrix Customer Support to report the problem.

2. Therapy Unit does not provide enough symptom relief

1. Unlock the Therapy Unit by pressing (+) and (-) buttons at the same time and then press the (+) button to raise level to level 4 or level 5 – to the highest level that is comfortable and not distracting.
2. If you waited until RLS symptoms were severe to start treatment, consider starting treatment earlier in the future.
3. Check placement of the Therapy Unit on your leg. If placement is incorrect, turn off the Therapy Unit, adjust the Therapy Unit placement, and restart the Therapy Unit.
4. If the problem remains, contact Noctrix Customer Support.

3. The treatment sensation is not comfortable

A. Treatment is consistently distracting or uncomfortable

1. Press the section of the Therapy Unit over the CDI firmly against your skin to improve contact.
2. Check placement of the Therapy Unit on your leg. If placement is incorrect, turn off the Therapy Unit, correct the Therapy Unit placement, and restart the Therapy Unit.
3. Adjust the intensity level:
   - If you feel pins/needles or tickling sensations, increase to level 4 or level 5.
   - Otherwise, lower the intensity to level 2 or level 1 using the (-) button until the sensation is comfortable.

4. If therapy is still distracting or uncomfortable at level 1, then power OFF Therapy Unit by pressing and holding (-) button for 3 seconds and contact Noctrix Customer Support before your next use.

B. Temporary discomfort at the start of therapy

- Start at level 1 or 2 and raise to higher level after a few minutes.

C.Temporary discomfort during leg movements or in the middle of therapy

1. Press the section of the Therapy Unit over the CDI firmly against your skin to improve contact.
2. Check placement of the Therapy Unit on your leg. If placement is incorrect, turn off the Therapy Unit, correct the Therapy Unit placement, and restart the Therapy Unit.
3. Reduce movements that cause discomfort.
4. Contact Noctrix Customer Support before your next use.

4. The Therapy Unit gets in the way of sleeping

- If the size and shape of the Therapy Unit makes it difficult to sleep, then first check that the Therapy Unit is placed correctly on the leg. Also consider using the Therapy Unit just before bedtime instead of while trying to sleep.
- If the Therapy Unit feels too hot, then avoid tight clothing or bedding around the Therapy Unit (to allow air flow).

5. RLS symptoms get worse during or after treatment

- Are you using Therapy Unit when RLS symptoms are minimal to none? If so, then wait to use the Therapy Unit until symptoms are moderate or severe.
- Are you using Therapy Unit above level 3? If so, then use at level 3.
- Check CDI positioning and adjust if incorrect.
- Are you moving legs less than usual while wearing the Therapy Unit? If so, then move legs to a normal extent.
- Reduce to level 2. If still unresolved, then reduce to level 1. If still unresolved, then contact Noctrix Customer Support.

6. My Therapy Unit feels hot and is uncomfortable

- Press and hold (-) button for 3 seconds to turn OFF Therapy Unit.
- Contact Noctrix Customer Support before your next use.

7. Status Lights begin blinking during treatment

- Press and hold (-) button for 3 seconds to turn OFF Therapy Unit.
- Contact Noctrix Customer Support before your next use.

8. The CDI is drying up or losing its stickiness

The CDI should last approximately one week with typical use. If your CDIs are drying out faster than expected it may help to store them in a sealed bag when not in use.

For help with setting up, using, or caring for the NTX150 TOMAC System; or to report unexpected events, contact Noctrix Customer Support at **support@noctrixhealth.com**, visit **noctrixhealth.com** or call **1-866-EASE-RLS (1-866-3273-757).**

Patent

This product may be covered by one or more of the following patents: US11103691B2, US11213681B2, US11872399B2, US11266836B2 and other US and international patents pending.

References

1. Bogan RK, et al. Efficacy and safety of tonic motor activation (TOMAC) for medication-refractory restless legs syndrome: a randomized clinical trial. Sleep. 2023;46(10).
2. Data on file. CL-9, Rev1.0, Report, Quantifying duration of relief from a single 30-minute session of NTX100 TOMAC.
3. Buchfuhrer MJ, Baker FC, Haramandeep S, et al. Noninvasive neuromodulation reduces symptoms of restless legs syndrome. J Clin Sleep Med. 2021;17(8):1685-1694.
4. Roy A, Ojile J, Kram J, et al. Long-term efficacy and safety of tonic motor activation for treatment of medication-refractory restless legs syndrome: A 24-Week Open-Label Extension Study. Sleep. 2023;46(10).

APPENDIX A
GUIDANCE AND MANUFACTURER'S DECLARATION

Table 1
Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The NTX150 Tonic Motor Activation (TOMAC) System is intended for use in the electromagnetic environment specified below. The customer or the user of the NTX150 Tonic Motor Activation (TOMAC) System should assure that it is used in such an environment.

Emissions test	Compliance	Comments
RF emissions CISPR 11	Group 1	NTX150 Tonic Motor Activation (TOMAC) System uses RF Energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	NTX150 Tonic Motor Activation (TOMAC) System is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emission IEC 61000-3-3	Complies	

Table 2
Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The NTX150 Tonic Motor Activation (TOMAC) System is intended for use in the electromagnetic environment specified below. The customer or the user of the NTX150 Tonic Motor Activation (TOMAC) System should assure that it is used in such an environment.

Test type	Compliance level	Electromagnetic environment – Guidance
Electrostatic Discharge (ESD) IEC 61000-4-2	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input output lines	Mains power quality should be that of a typical household, commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2kV common mode	Mains power quality should be that of a typical household, commercial or hospital environment.
(50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical household, commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Voltage Dips 30% reduction, 25/30 periods at 0°	Mains power quality should be that of a typical household, commercial or hospital environment. If the user of NTX150 Tonic Motor Activation (TOMAC) System requires continued charging during power mains interruptions, it is recommended that the Therapy Unit be powered from an uninterruptible power supply.
	Voltage Dips >95% reduction, 0.5 period at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°	
	Voltage Dips >95% reduction, 1 period at 0°	
	Voltage interruptions > 95% reduction, 250/300 periods	
Conducted RF IEC 61000-4-6	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the NTX150 Tonic Motor Activation (TOMAC) System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of transmitter. Recommended separation distance = 1.2√P

APPENDIX A
GUIDANCE AND MANUFACTURER'S DECLARATION

Table 2 (continued)
Guidance and Manufacturer's Declaration – Electromagnetic Immunity

The NTX150 Tonic Motor Activation (TOMAC) System is intended for use in the electromagnetic environment specified below. The customer or the user of the NTX150 Tonic Motor Activation (TOMAC) System should assure that it is used in such an environment.

Test type	Compliance level	Electromagnetic environment – Guidance
Radiated RF IEC 61000-4-3	10 V/m	d = 1.2√P 80 MHz to 800 MHz d = 2.3√P 800 MHz to 2.7 GHz Where P is the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey* should be less than the compliance level in each frequency range**

* Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which NTX150 Tonic Motor Activation (TOMAC) System is used exceeds the applicable RF compliance level above, NTX150 Tonic Motor Activation (TOMAC) System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating Therapy Unit.

** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m

Table 2 (continued)
Immunity to RF Wireless Communications Equipment

Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	Immunity Test Level (V/m)
385	380 - 390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430 – 470	GMRS 460 FRS 460	FM, ±5kHz deviation, 1kHz sine	2	0.3	28
710	704 - 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
745						
780						
810	800 - 960	GSM 800/900 TETRA 800 iDEN 820 CDMA 850 LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
870						
930						
1720	1700 - 1990	GSM 1800 CDMA 1900 GSM 1900 DECT LTE Band 1, 3, 4, 25 UMTS	Pulse modulation 217 Hz	2	0.3	28
1845						
1970						

APPENDIX B
SYSTEM SPECIFICATIONS

NTX150 Tonic Motor Activation (TOMAC) System Mass: <150 g per Therapy Unit (<11 oz per two Therapy Units)

Electrical Classification (Charging Accessories)

Power Requirements: Input 100-120 VAC, 60 Hz, 0.15-0.35A

Replaceable Parts: None

Electrical Mains Adapters: Only use Noctrix Health, Inc. provided electrical mains adapter for the Charger.

Manufacturer:	Globtek
Manufacturer Model:	GTM46161-155.0-USB2A
Input:	100-240 V AC, 0.45 A
Output:	5V, 3.2 A
Certification:	CB 60950, CB 60601-1, CB 62368
Means of Protection:	2 x MOPP

Charging Cable: Input: 5V DC
Output: 5V DC

Isolation from Mains is accomplished by unplugging the Approved Charging Adapter.

Electrical Classification (Therapy Units)

Classification: Internally Powered when delivering therapy; conforming to Class II when charging

Electrical Isolation: Type BF Applied Part. User is operator when charging.

Ingress Protection: IP20: NTX150 TOMAC System outside of carrying case

IP22: NTX150 TOMAC System inside of carrying case

The factory-supplied CCG and drawstring carrying bag provide for the carrying case when IP22 ingress protection is needed.

Internal Battery (not serviceable): 3.7V 1000mAh

Patient Leakage Current: < 50 uA DC; < 500 uA AC

Rated Duty Cycle: 100% duty cycle square wave for 30-minute therapy session

Waveform:	Current Controlled, Charge-Balanced Square Wave
Pulse Width:	125 uS nominal
Pulse Repetition Frequency:	1,000 - 8,000 Hz; 4,000 Hz nominal
Output Current:	40mA maximum, current-controlled, physician-programmable
Output Voltage:	Current-controlled output depending on skin impedance; compliance voltage 60V peak

Rated Load: The therapeutic waveform is current-controlled and showed to conform to the stated parameters over the load range of 200 – 1,200 Ohms impedances.

Wireless Radio: Contains FCC ID: XPYBMD380

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.

Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

Nominal service life:

- Charge-Dispersing Interfaces: 1 week
- NTX150 TOMAC System, charger, charging cables and battery: 3 years

Operating, Storage, and Transit Conditions	Operating	Storage and Transit
Temperature	41 °F - 95 °F (5 °C - 35 °C)	14 °F - 104 °F (10 °C - 40 °C)
Humidity	5 - 95% Non-condensing RH	5 - 95% Non-condensing RH
Pressure	64 - 102 kPa (1 ATM)	59 - 102 kPa (8.6 - 15 psia)

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