Patient Manual

NTX100 Tonic Motor Activation System
(NTX100 TOMAC)

Table of contents

Introduction

This manual is for people who have received the NTX100 TOMAC to treat symptoms of Restless Legs Syndrome (RLS). Each person is unique. Always talk to your doctor if you have questions about your condition. This manual explains how to use the system.

The appendix provides more information about the device. Carefully read all instructions before using the NTX100 TOMAC. Follow all the safety information in this manual. Failure to do so may result in the possibility of injury, less effective treatment, or damage to the device.

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

Chapter 1 – Safety information

Indications for use

The NTX100 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 NTX100 Tonic Motor Activation System (NTX100 TOMAC) 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 therapy 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 NTX100 TOMAC is not waterproof. DO NOT expose to water. There are no user-serviceable parts in or on the NTX100 Tonic Motor Activation System (NTX100 TOMAC). Do not attempt to service or modify the device 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 NTX100 TOMAC 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.

Warning	Description
NTX100 TOMAC System Parts	The NTX100 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 device 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 device. 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
NTX100 TOMAC	Carefully read all instructions before using the NTX100 TOMAC. 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 device. The NTX100 TOMAC should not be exposed to water. Position the device so it is easy to disconnect the charging cable. Note that premature onset of RLS symptoms while wearing the device may occur for some people as this device may interfere with voluntary leg movements used to relieve RLS symptoms, thus leading to a temporary increase in RLS symptoms. In some cases, this device 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 device 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 ≥ 8KeV in magnitude. If the system malfunctions after exposure to ESD as described above, the device reset procedure may be performed to resume normal operation. • Proximity to portable and mobile radio frequency (RF) communications equipment. • The NTX100 TOMAC is not recommended for use in close proximity to RFID readers.

Chapter 1 – Safety information

Adverse events

Adverse events, or side effects, are risks associated with the use of this device. There is a potential for the following side effects, which are typically mild to moderate and resolve over time:

- Mild skin irritation from use of adhesives.
- Temporary interference with sleep while wearing the device. For some people, the device may be uncomfortable. For others, the device may interfere with preferred sleep positions.
- You should stop using the device and should consult with a physician if you experience adverse reactions from the device.

Proper use of the device 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 (NTX100 TOMAC):

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
REF	Catalog Number
LOT	Batch Code
Rx Only	CAUTION! Federal (US) law restricts this device to sale by or on order of a licensed healthcare practitioner.
	Single Patient Use Only

Symbol	Definition
	Do not use if the package is damaged or open
	Date of Manufacture
	Country of Manufacture
	Use-By Date
	Keep Dry
	Indicates the upper limit and lower limit of temperatures to which the medical device can be exposed
	Humidity Limitations
	Latex Free
	Do not dispose of in a landfill

Clinical study: RLS symptoms and sleep quality[1]

A clinical trial with 133 patients with moderate to severe RLS was conducted. Patients were treated either with the NTX100 TOMAC or a mock device that looked like the NTX100 TOMAC but was inactive.

Several clinical metrics were used to compare the two systems. In all metrics the NTX100 TOMAC improved RLS more than the mock device.

Device-related side effects were typically mild and resolved rapidly with minimal or no follow-up.

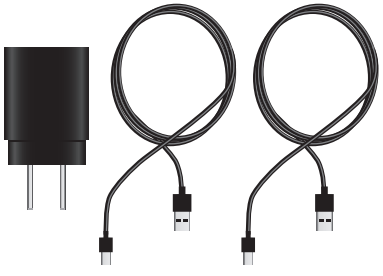
The safety and efficacy of this device has not been studied in pregnant women. Contact your doctor if you would like more information about this clinical study.

Chapter 2 – System overview
System components

Therapy units

Charge Dispersing Interfaces

Charging accessories
– USB wall charger
– USB cable



The NTX100 Tonic Motor Activation system (NTX100 TOMAC) consists of two devices, intended to be used bilaterally (on both legs).

The two units work separately but the mechanism of action is identical. Individual calibration is required and can result in different treatment settings for each leg. The device and buttons on each device are mirrored (from left to right) to assist with placement on each leg.

The NTX100 TOMAC system consists of four distinct, non-sterile parts, as listed below:

1. Device

(2x per system) Contains electronics, a rechargeable battery and a conduction garment that is worn on both legs (below the knee). The devices have buttons that turn the system ON/OFF, adjust treatment level or read status during treatment or charging sessions.

2. Charge Dispersing Interface

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

3. Charging accessories

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

4. Carrying case

A resealable zipper bag (not pictured) is provided for the carrying case when water protection is needed.

Chapter 2 – System overview
Control features and Status Lights

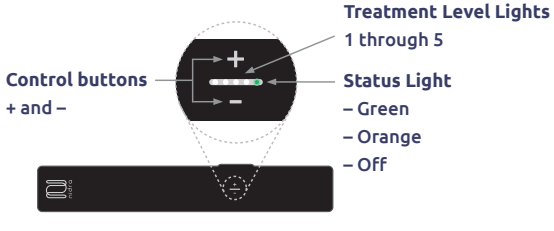
Control features

Icon description	Icon	Action	Description
Turn On	**+**	Press and hold for three seconds	Turns on the device
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 device is awake
Decrease treatment level	**–**	Press once	Decreases treatment by one level when device is awake
Turn off	**–**	Press and hold for three seconds	Turns off the device

Indicator Lights

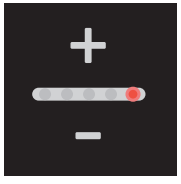
The Status Light is one colored light that can be either ORANGE, GREEN, or off.

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

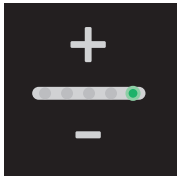


Charging

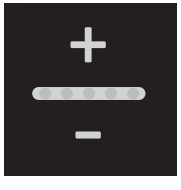
When the device is plugged into the charger



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



Green Status Light:
Battery has full charge or close to full charge.

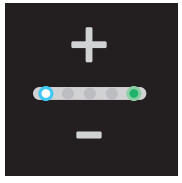


Status Light OFF:
Battery is not charging. Try to plug the device into the charger again or check the power supply to the outlet.

Chapter 2 – System overview
Status Lights

Treatment

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

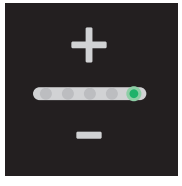


Blinking white Treatment Level Light and blinking green Status Light appear for the first ~20 seconds of treatment: Device is on and ramping up to your treatment level.

If these lights do not appear, the device was not turned on.

Try turning the device on again.

Charge status (20-30 seconds)



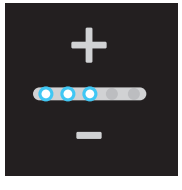
After ~20 seconds of treatment, the Status Light shows the charge status. During the next 10 seconds, you can adjust treatment level.

Solid GREEN: Typically enough charge for a full session.

Solid ORANGE: Low charge, but okay to proceed.

Blinking ORANGE: Very low charge. Device is turning off.

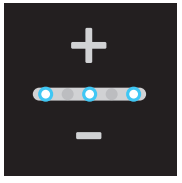
Treatment level



For all of treatment, the **Treatment Level Lights** remain off unless the device 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

Reboot

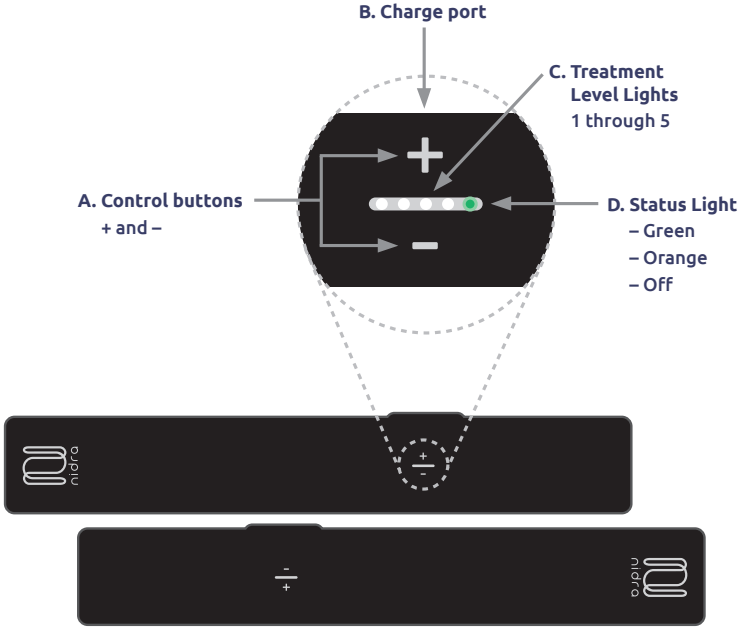


Rebooting the devices is performed by pushing both the + & - buttons together for up to 12 seconds. The three **Treatment Level Lights** at positions one, three, and five will confirm successful reboot.

Do not reboot unless instructed to do so.

Chapter 2 – System overview
Glossary

Devices (Left and Right)



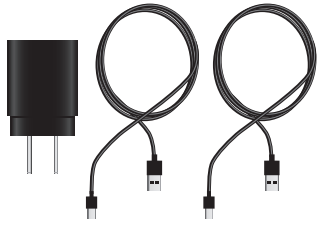
A. Control buttons: (+) and (–) buttons used to start a session and adjust treatment level.

B. Charge port: opening in device for inserting the charging cable.

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

D. Status Light: one light which can be **GREEN**, **ORANGE**, or off and indicates charging and device readiness status.

Charging accessories



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

Charging cable: USB connector that charges devices when attached to power outlet via a USB adapter.

Charge Dispersing Interface (CDI)

Disposable liner: blue CDI liner without text.

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

Reusable liner: clear CDI liner with text.

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

Chapter 3 – System maintenance

IMPORTANT	Although the NTX100 Tonic Motor Activation System arrives partly charged, the amount of charge at delivery may vary. It is recommended that the devices be FULLY CHARGED before using them for the first time.

You should charge both devices daily after each use and keep charging the devices until the next session (keep the devices on the charger).
A full charge can take at least 2+ hours until the Status Light turns GREEN.

For best results replace the Charge-Dispersing Interfaces (CDIs) weekly.

Charging the system

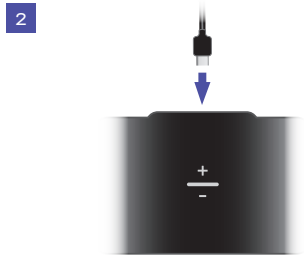
Please follow these steps to charge your devices. As noted in Section 9, the ORANGE light will come on once charging begins, and when charged, the light will change to GREEN.

WARNING!	Do not connect the USB charging cable while wearing and/or using the device.
WARNING!	The NTX100 TOMAC is intended for use only with the provided parts. Using parts other than those supplied by Noctrix Health, Inc. may damage the device and/or create a safety hazard.

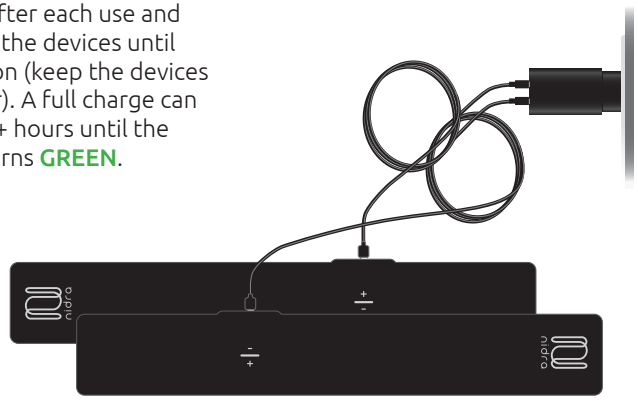
NTX100 TOMAC charging steps

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 Micro-USB plug into the female Micro-USB port, lining up the narrow top and wider bottom on both connections.



3. Once connected, the ORANGE Status Light should turn on, showing that the device is charging. You should charge both devices daily after each use and keep charging the devices until the next session (keep the devices on the charger). A full charge can take at least 2+ hours until the Status Light turns GREEN.



Chapter 3 – System maintenance
Cleaning the NTX100 system

WARNING!	The NTX100 TOMAC is not waterproof. Keep dry; DO NOT expose to water.

Devices

- The NTX100 TOMAC devices are not waterproof and should not be placed in water.
- Attempts to wash the devices by hand, or in a laundry machine, will result in damage to the device.
- Be sure the device 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 device.
- Do not use corrosive substances to clean the device or cables.

Charge Dispersing Interfaces (CDIs)

- CDIs are intended to be replaced weekly.
- CDIs are single patient use only and should not be shared.
- If the sticky portion of the CDI that touches the patient 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 not intended to be cleaned and should be disposed of after one week.

Storage instructions

The device 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 device in a dry location.

Instructions for safe disposal

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

Chapter 4 – When to use your device
Overview

Your doctor will discuss the best times to use your device.

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

- The NTX100 Tonic Motor Activation System delivers 30-minute treatment sessions.
- Each session is designed to quickly relieve RLS symptoms.
- Relief typically begins soon after turning the device 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 device can deliver at least one and often two full sessions on a full charge. Therefore, it is important to ensure the device 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 the NTX100 TOMAC results in the following potential benefits:

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

Long-term use of NTX100 TOMAC 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 device is used at times when not needed and not fully recharged, the battery charge may not allow for a full session when needed.

General timing instructions

- Run a session after RLS symptoms start and before symptoms become severe.
- Always run a full 30-minute session. Devices will turn off by themselves after a session.
- On nights without RLS symptoms, do not use the devices.
- 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 change both devices daily after each use and keep charging the devices until the next session (keep the devices 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 device

1. Before bedtime

- **Run a 30-min 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 devices.
  - 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 devices 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 give 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 devices.
- If RLS symptoms remain after the session ends, you have the option of a second 30-minute session.

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

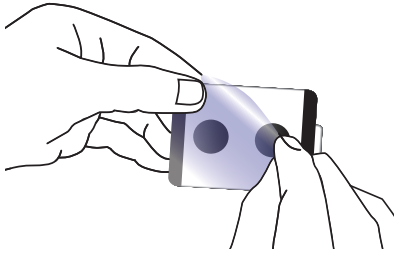
- **Wear your devices to bed** but do not run a session until you have RLS symptoms. You can also keep the devices next to your bed instead of wearing them to bed.
- **When you wake up with RLS symptoms,** run a 30-min session at a setting that lets you go back to sleep (typically level 3 or level 2).
  - 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 devices.
- If RLS symptoms remain after the session ends, you have the option of a second 30-minute session.

Chapter 5 – Treatment

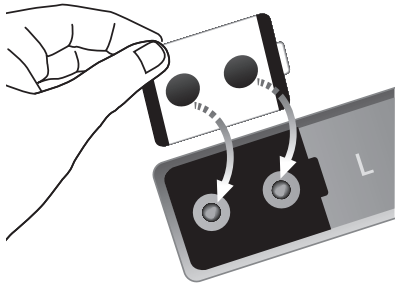
Before you begin using the device on your own you will attend a titration session where a specially-trained technician will work with you to find the best settings to reduce your RLS symptoms. The technician will program these settings into your device and you can then follow the instructions in this chapter to complete a treatment.

Placement of Charge-Dispersing Interfaces (CDIs) on the device

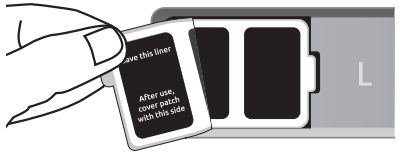
1. If no CDIs are on the device, or if you need to replace the CDIs on the device after a week of use, choose a pouch from the box of CDI pouches.
2. Tear open the pouch at the top and remove one CDI.
3. Grab the blue disposable liner by the tab, peel away the blue liner and discard.



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 circular parts on the inside of the device and firmly press the CDI onto the device.



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

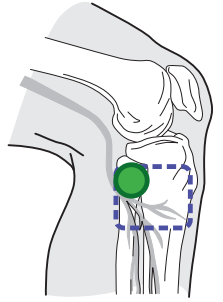


7. Repeat steps 3-6 on the other device if (a) no CDI is present or (b) you need to replace the CDI after a week of use.

Finding the treatment target

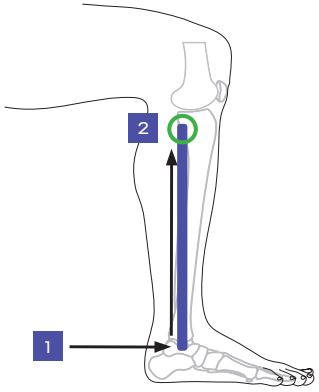
Treatment target

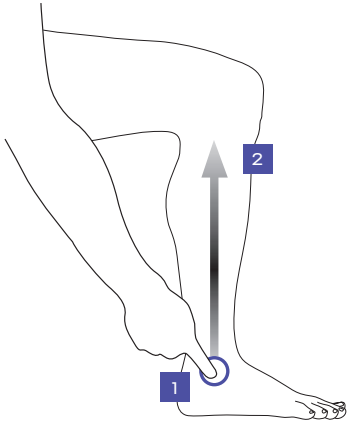
The nerve target for treatment curves around the top of the fibula (marked by the **GREEN** circle in the image). The **BLUE** area indicates the ideal location of the CDI.

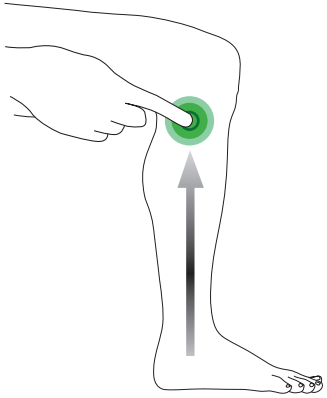


To find the treatment target (**GREEN** circle) sit with your **lower leg at a 90 degree angle to the floor**:

1. Identify the ankle bone on the outside of the ankle.
2. Move directly upwards along the outside of the leg (shown in **BLUE**) until you reach the next bony landmark (**GREEN** circle).

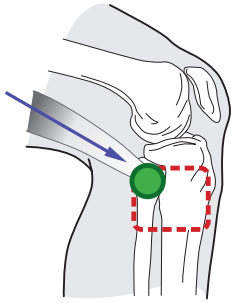






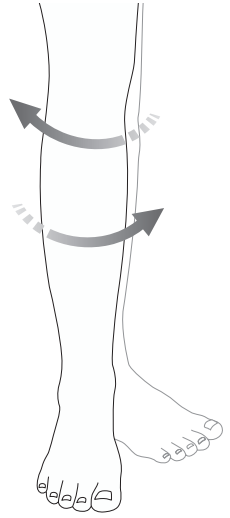
Treatment target confirmation

The outside of the hamstring muscle attaches at the treatment target location (**GREEN** circle) and can be a useful way to confirm that you have found the treatment target. The **RED** area indicates the position of the CDI and the hamstring attachment point is shown in **BLUE**.



Troubleshooting

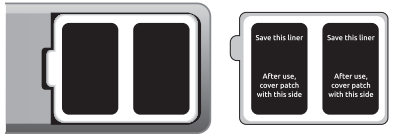
If it is hard to find the bony landmark (**GREEN** circle from previous steps) try to rotate your leg (with your heel in place on the ground) from outside to inside. This will make it easier to see and feel the bony landmark. Repeat this movement on both legs to verify that the treatment target has been located.



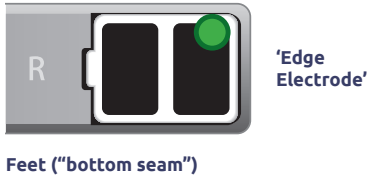
Chapter 5 – Treatment

Putting on your devices
(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 dry and clean and keep the liner on the CDI when not in use; this will extend the life of the CDI.



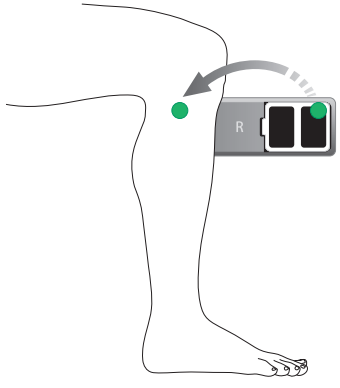
- The CDI contains two electrodes (the black rectangles). The electrode closest to the edge of the device is called the 'Edge Electrode'.
- The green circle is where the edge electrode will meet up with the **treatment target**.

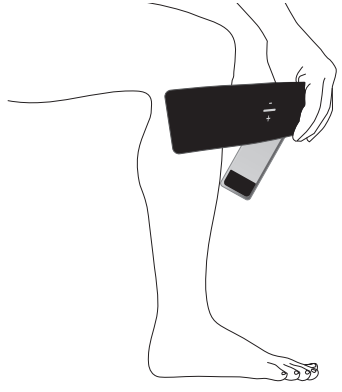


- **Place the CDI directly on clean skin. Do not place the CDI over a skin wound or over a bandage or skin covering.**

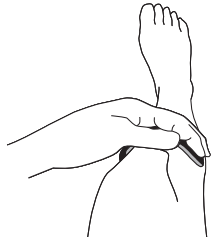
WARNING!	Do not place Charge-Dispersing Interfaces (CDIs) over open sores or an acute injury.

- Place the edge electrode – while attached to the device – so that the top edge corner (**GREEN** circle) covers the **treatment target** that was marked on your leg.



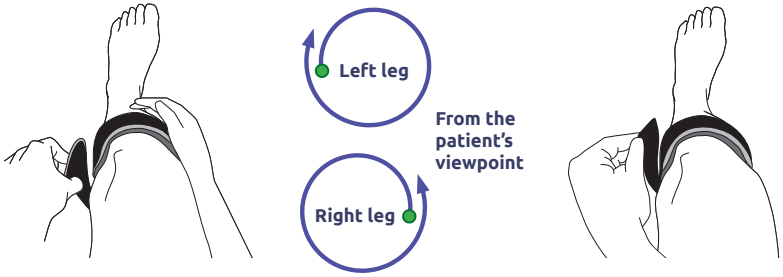


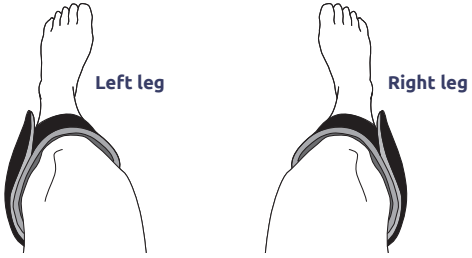
- Apply firm pressure around the CDI to ensure it sticks and stays in place.



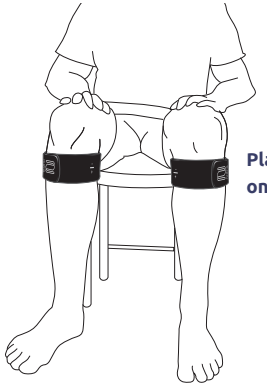
Secure the device: (images show the "L" [Left] Therapy Unit)

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





This is how the device will look after you are done. Depending on leg size, the position of edge of the device will vary.

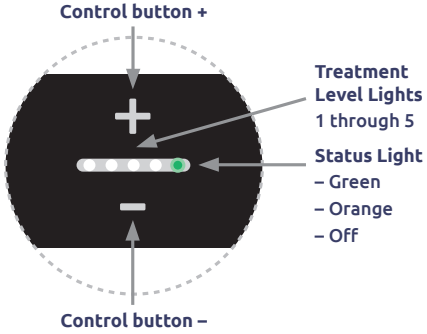


Chapter 5 – Treatment

Starting a treatment

1. Check that devices for both legs have enough charge by checking for the **GREEN** Status Light while charging.
2. Remove the devices from the charging cables.
3. Put the **LEFT** device on the left leg and the **RIGHT** device on the right leg.
   - If there is no Charge-Dispersing Interface (CDI) on the device, see the "Placement of CDIs on the Device" instructions at the beginning of this chapter.
4. Once devices are attached to both legs:
   - Start a session for each device by pressing and holding the (+) button for three seconds.
     a. From zero to 20 seconds, you will see blinking white Treatment Level Lights and a blinking **GREEN** Status Light as the intensity gradually increases to the low-point of your calibrated range.
     b. From 20 to 30 seconds, the Status Light will show the charge status of the device. During this 10 second period:
        1) You will be able to set your treatment level from 1 to 5 within your range.
           Click the (+) button twice to increase intensity to level 3 which is your average level of intensity. The number of Treatment Level Lights will change to match your level.
        2) 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. Device is turning off.

     c. After 30 seconds, you can change your treatment level, but you will need to unlock the controls first;
        1) If no white lights are lit, unlock the device by pressing (+) 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 device is unlocked.



5. Relax and continue with your normal activity during the session, including falling asleep. The device will turn off by itself after 30 minutes.
6. If you fall asleep during the session or want to run another session later in the night, it's okay to continue wearing the devices after the session ends.
7. To remove the devices:
   - 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 devices.
     – If no white lights appear, then the session is complete and you can remove the devices.
   - Detach the devices from your legs with the CDIs attached to the devices.
8. Replace the reusable liners.
9. After removal, connect the devices to the charging cables via the charging port and plug into the wall adapter.

Adjusting treatment level

Level 3 will be your most common treatment level. However, you may need to raise this level if your 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 device 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 device is unlocked.
- Click the (+) button to raise treatment level by one level. Note that there is one more Treatment Level Light when you do this.
- Click the (-) button to decrease treatment level by one level. Note that there is one fewer Treatment Level Light when you do this.

Stopping a treatment

You do not need to stop the session. The treatment will turn off by itself after 30 minutes and you can wear the devices 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, you can stop treatment with the following steps**:**

1. Unlock the controls by pressing the (+) and (-) buttons at the same time and quickly.
2. Then, press and hold the (-) button for 3 seconds to turn OFF device.
3. As soon as the Treatment Level Lights turn off, release the (-) button and remove the device from your leg.
4. Replace the reusable liner on each CDI.
5. Connect the device to the charger.

During a treatment session

Relax and continue with your normal activity during the session, including falling asleep.

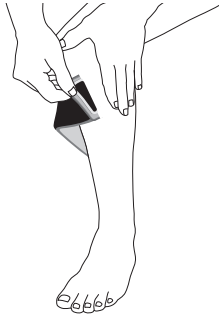
- Treatment will turn off by itself after 30 minutes and you can wear the devices through the night.
- If the treatment level remains comfortable but RLS symptoms persist, try raising the treatment level while it is still comfortable.
- It is normal for the devices to feel warm; however if the devices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

After a treatment session

Click the (+) 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 no lights appear, the treatment session is complete.

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

1. After verifying that the device is not powered on, unwrap the device 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 devices for future use.



Chapter 6 – System warnings and troubleshooting
Patient troubleshooting

For each of these scenarios 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 devices on your leg. Then, start therapy again.
3. Check that the device 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. Device does not provide enough symptom relief

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

4. The device gets in the way of sleeping

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

5. RLS symptoms get worse during or after treatment

- Are you using device when RLS symptoms are minimal to none? If so, then wait to use the device until symptoms are moderate or severe.
- Are you using device 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 device? 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 device feels hot and is uncomfortable

- Press and hold (-) button for 3 seconds to turn OFF device.
- 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 device.
- 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.

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).

For help with setting up, using, or maintaining the NTX100 TOMAC system; or to report unexpected events, contact Noctrix Customer Support at **support@noctrixhealth.com**, visit **www.nidrarls.com** or call **1-866-EASE-RLS (1-866-3273-757).**

Appendix A
Guidance and manufacturer's declaration

Table 1
Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The NTX100 Tonic Motor Activation System is intended for use in the electromagnetic environment specified below. The customer or the user of the NTX100 Tonic Motor Activation System should assure that it is used in such an environment.

Emissions test	Compliance	Comments
RF emissions CISPR 11	Group 1	NTX100 Tonic Motor Activation 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	NTX100 Tonic Motor Activation 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 NTX100 Tonic Motor Activation System is intended for use in the electromagnetic environment specified below. The customer or the user of the NTX100 Tonic Motor Activation 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.

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

The NTX100 Tonic Motor Activation System is intended for use in the electromagnetic environment specified below. The customer or the user of the NTX100 Tonic Motor Activation System should assure that it is used in such an environment.

Test type	Compliance level	Electromagnetic environment – Guidance
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 NTX100 Tonic Motor Activation System requires continued charging during power mains interruptions, it is recommended that the device 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 NTX100 Tonic Motor Activation System, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of transmitter. Recommended separation distance = $1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 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 NTX100 Tonic Motor Activation System is used exceeds the applicable RF compliance level above, NTX100 Tonic Motor Activation System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating device.

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

Appendix A
Guidance and manufacturer's declaration

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

NTX100 Tonic Motor Activation System Mass: <100 g per Therapy Unit (< 7 oz per two Therapy Units)

Electrical Classification (Charging Accessories)

Power Requirements: Input 100 - 240 VAC, 50/60 Hz, 0.35 – 0.15 A

Replaceable Parts: None

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

Manufacturer:	Globtek
Manufacturer Model:	GTM96180-1507
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: NTX100 TOMAC outside of carrying case

IP22: NTX100 TOMAC inside of carrying case

The factory-supplied packaging, including resealable zipper bags, provide for the carrying case when IP22 ingress protection is needed.

Internal Battery (not serviceable): 3.7V 750mAh

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: 2AA9B05

Nominal service life:

- Charge-Dispersing Interfaces: 1 week
- NTX100 TOMAC, charger, charging cables, physician programmer components: 3 years

Operating, Storage, and Transit Conditions	Operating	Storage and Transit
Temperature	35 °F - 95 °F (10 °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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