Instructions for Use

NiNA

CAUTION: Investigational Device. Limited by United States law to investigational use.

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DESCRIPTION

The EBT Medical Non-Invasive Neuromodulation Assistant (NiNA) uses transcutaneous electrical stimulation of the saphenous nerve to treat symptoms of overactive bladder. NiNA delivers mild, adjustable electrical stimulation pulses to the saphenous nerve just below the knee that help to restore the bladder-brain connection. The NiNA System™ (Figure 1) consists of the rechargeable NiNA, Dock, Pad, and reusable Wrap that holds the Pad and NiNA in place on the inside of either leg just below the knee crease (Figure 2).

The NiNA System treatment plan is self-administered in the home and has two stages: Restore and Maintain. During the Restore stage, the 30-minute treatment is performed once a day for the first 28 days. After 28 days, the treatment plan advances to the Maintain stage where the treatment frequency is decreased to three times per week for 30 minutes.

The NiNA Care™App can be used to control NiNA and is designed to provide an enhanced therapy experience. It has additional features to support the use of the NiNA System including reminders for performing therapy, progress tracking, tutorials and checks for ensuring proper therapy delivery, educational content, and instructional videos. The NiNA App is available for Android and iOS users.

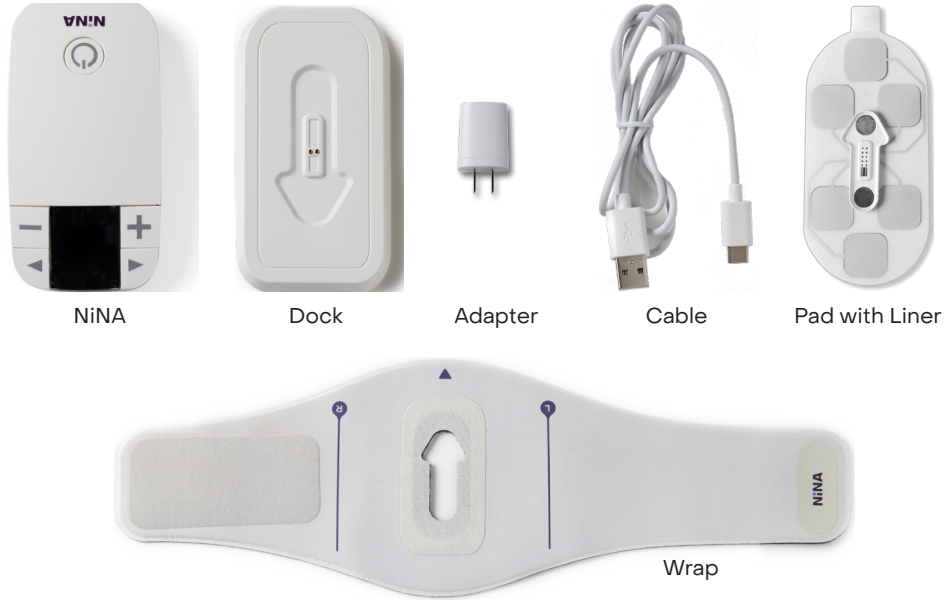


Figure 1. The NiNA System consists of the rechargeable NiNA, Dock with Cable/ Adapter, Pad, and Wrap that holds NiNA and the Pad in place.

Figure 2. NiNA is placed on the inside of the leg just below the knee crease.

INTENDED USE / INDICATIONS FOR USE

The EBT Medical NiNA System is intended for the treatment of overactive bladder and associated symptoms of urinary urgency, urinary frequency, and urge incontinence.

CONTRAINDICATIONS

The NiNA System is contraindicated in persons who have an implanted electronic device such as a cardiac pacemaker or defibrillator. Do not use the NiNA System if there is an implanted metallic device in the leg. Use under these conditions can cause electric shock, interference with the implanted device operation, or death.

WARNINGS

Do not use the NiNA System in any areas of the body other than below the knee. Do not place the NiNA System across the chest or near the heart as this may cause rhythm disturbances which could be fatal.

Do not use the NiNA System near or over a cut or open wound, rash, infected or inflamed skin as this could cause discomfort or lead to infection.

Do not use the NiNA System if there is damage to or absence of the saphenous nerve in the leg as this could prevent successful treatment.

Do not use the NiNA System near or in water or in a very humid environment (e.g., sauna) as this could damage the NiNA System.

Do not charge the NiNA System in or near water as this could lead to electrical shock.

Do not use the NiNA System while using any other electrical therapy device such as a TENS unit as this could cause interference with therapy or unintended stimulation of other areas.

Do not use the NiNA System near metal as this could interfere with therapy or cause heating. Remove jewelry or any other metallic items near the treatment area.

Do not use the NiNA System near X-ray, MRI, CT, or diathermy devices. These devices may alter the energy delivered by the NiNA System and/or cause tissue damage, severe injury, or burns.

Do not use the NiNA System close to short wave or microwave therapy equipment (within three feet) which may produce variability in stimulation strength or output.

Use only NiNA System components. Use of other components may cause allergic reactions and/or compromise or cause improper stimulation during treatment sessions.

Do not use the NiNA System while exercising, cycling, driving, operating machinery, or during any other activity in which stimulation could result in the risk of injury.

Discontinue use of the NiNA System if pain, skin irritation, or other adverse reactions occur. Use of the NiNA System over tattoos containing ferromagnetic compounds has not been studied.

Do not modify, disassemble, crush, or use the NiNA System in any other way other than how described in the Instructions for Use.

The NiNA System cannot be serviced or repaired. Do not attempt this yourself.

PRECAUTIONS

Use the NiNA System only at room temperature. Allow the NiNA System to acclimate for at least two hours if stored in hot or cold temperatures.

Do not leave, store, or charge the NiNA System in direct sunlight, near a fire, or in any other high temperature environment.

The NINA System and Pads are for a single-user only, do not share with others.

Discontinue use of the Pad if it becomes dirty, contaminated, or loses its adhesive properties. These conditions could interfere with proper stimulation.

Discontinue use of the Wrap if it becomes damaged or can no longer be securely attached to the leg during treatment sessions.

Do not fasten the Wrap so tightly that it interferes with proper circulation.

The power adapter is used for the primary power connection and disconnection. Do not position the Dock such that unplugging it from the wall outlet is difficult.

OPERATIONAL INSTRUCTIONS

Unpack the NiNA System

The NiNA System package includes the following non-sterile components:

1 - NiNA	1 - Dock
1 - Wrap	1 - Adapter
2 - Pads	1 - USB Charger Cable
	1 - NiNA System Carrying Case

Unpack the NiNA System and check each component for damage. If a component is damaged, it may not function properly and should be returned to EBT Medical. The Pads have a use-by date which is located on the Pad pouch label. Do not use the Pads beyond the use-by date as they may not provide effective stimulation.

Charge NiNA

Before using NiNA it should be fully charged. Plug the Dock into any household AC socket using the provided Cable/Adapter. Place NiNA on the Dock as shown in Figure 3. When NiNA is fully charged, the battery icon on the NiNA display will change to completely green (Figure 4). When fully discharged, NiNA takes approximately 3 - 4 hours to fully charge.

Figure 3. Charge NiNA.

Figure 4. NiNA is fully charged when the battery icon is completely green

Pair NiNA with the NiNA App

1. NiNA must be initially paired with the NiNA App before use. Go to the website ebtmedical.com/installninacare and follow the directions to download the NiNA App to an iOS or Android phone. Once paired with the NiNA App, NiNA may be controlled using the NiNA App or using the controls on NiNA.

The NiNA App is designed to provide an enhanced therapy experience. It has additional features not found on NiNA including reminders for performing therapy, progress tracking, tutorials and checks for ensuring proper therapy delivery, educational content, and instructional videos.

2. Follow the instructions on the NiNA App to log in and begin the pairing process using Bluetooth®. Turn on NiNA by holding down the power button until it turns on. Place NiNA close to the phone and follow the instructions in the NiNA App to pair the phone with NiNA. During the pairing process, the icon on the NiNA display will blink (Figure 5). When pairing is successful, a green check mark appears on the NiNA display (Figure 6).

Figure 5. Pair NiNA with the NiNA App. During the pairing process, the icon will blink.

Figure 6. A green check mark will appear when NiNA is paired with the NiNA App.

Treatment Frequency

The NiNA System treatment plan has two stages: Restore and Maintain. During the first stage, Restore, the 30-minute treatment is performed once a day for the first 28 days. After the Restore stage has been successfully completed, the treatment plan advances to the Maintain stage where the treatment frequency is decreased to three times per week for 30 minutes. Ideally, the three treatment days should be spread out over the entire week.

Assemble and Prepare the NiNA System for Use

1. With the arrow side of the Pad on top, place the Pad on a hard, flat surface with the arrow pointing in the “up” direction. Keep the Liner on the back of the Pad in place (Figure 7).

2. With the white side of the Wrap facing up, lay the Wrap over the Pad matching the arrow on the Pad with the arrow cut-out in the Wrap. Press down on the Wrap until the arrow on the Pad is inserted into the cut-out area (Figure 7).

Figure 7. Place the Pad with the arrow pointing up on a hard, flat surface. Lay the Wrap over the Pad matching the arrow on the Pad with the arrow cut-out in the Wrap.

3. With NiNA turned off, match the arrow on the underside of NiNA with the arrow on the Pad. Place NiNA on top of the Pad. The magnetic attachment feature will help connect NiNA to the Pad – a click will be heard when the connection is made (Figure 8). Check that NiNA is securely attached to the Pad.

Figure 8. The assembled NiNA, Pad, and Wrap

Place the NiNA System On the Leg

1. Turn the assembled NiNA, Pad, and Wrap over so that the Pad side is facing up (Figure 9). Remove the Pad Liner and save it for later use. After the treatment session is over, the Liner is placed back on the Pad to keep it clean. Avoid touching the sticky Pad until it is placed on the leg.

2. Correct placement of NiNA is key to effective treatment. The NiNA/Pad is placed on the skin over the saphenous nerve just below the knee on the inside of either leg. To ensure correct placement, first locate the area between the edge of the shin bone and the edge of the calf muscle on the inside of either leg. With the knee bent, place the NiNA/Pad so that the top of the Wrap is just below the crease of the knee and the NiNA/Pad is over the area that lies between the edge of the shin bone and the edge of the calf muscle. If the right leg is used, align the red “R” dot with the front of the right leg and if the left leg is used, align the blue “L” dot with the front of the left leg (Figure 10).

Figure 9. Place the wrap with the Pad side up and remove the Liner.

Figure 10. Place the top of the Wrap just below the knee crease. Align the Wrap with the front of the leg using the alignment dots.

3. With the NiNA display facing up towards the head, firmly press the Pad in place and secure it with the Wrap using the hook and loop fasteners to hold it in place (Figure 11). The Wrap should be snug on the leg but not so tight that it is uncomfortable (Figure 12).

Figure 11. Secure the Wrap with the hook and loop fasteners.

Figure 12. The Wrap should be snug but not uncomfortable.

Begin Treatment

1. Press and hold the power button until NiNA turns on (Figure 13). NiNA can be controlled with the buttons on NiNA or by using the NiNA App controls. If using the NiNA App, press **Treat** from the HOME screen (Figure 14).

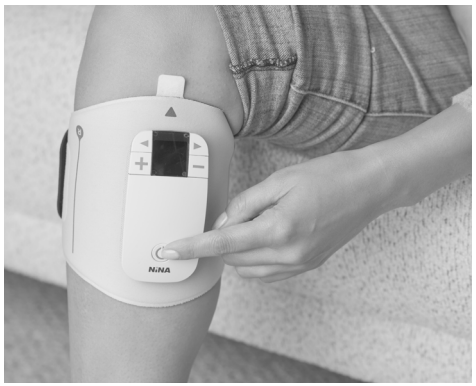


Figure 13. Press and hold the power button until NiNA turns on.

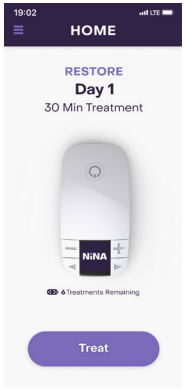


Figure 14. If using the NiNA App, to start treatment press **Treat** from the HOME screen.

2. After NiNA is turned on, the NiNA display will briefly show the battery status. If there is not enough battery power left for a full treatment, a red battery will be displayed and NiNA will need to be charged before use.

3. The NiNA display will briefly show how many treatments are remaining for the Pad. It can be used seven times before a new Pad is required. If a **Replace Pad** alert is displayed, replace the Pad with a new one before beginning treatment (Figure 15).

Figure 15. The NiNA display will show the Pad status. Replace the Pad if the **Replace Pad** alert is displayed.

4. If the battery status is good and the Pad has not been used more than seven times, NiNA is ready to start treatment and will display the following (Figure 16):

Figure 16. NiNA is ready to start treatment.

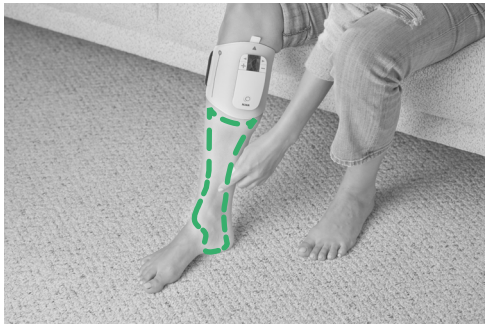


Figure 17. The stimulation should be felt beyond NiNA, down the leg, and into the ankle or foot.

5. For optimum treatment, the stimulation (tingling sensation) should be felt beyond NiNA, down the leg, and into the ankle or foot (Figure 17).

- To begin stimulation, press the **+** button and keep pressing it until the stimulation is strong but not uncomfortable. To decrease the stimulation intensity, press the **–** button.
- Next, if needed, adjust the stimulation by pressing the **<** and **>** buttons to move the stimulation or tingling sensation left < and right > along the leg. Adjust the stimulation until it is felt into the ankle or foot.
- Use the buttons (**+**, **–**, **<**, and **>**) to find the setting that produces the strongest, yet comfortable stimulation down the leg into the ankle or foot (Figure 18).
- If the stimulation still cannot be felt into the ankle or foot, slightly reposition the NiNA/Pad or try the other leg. In some people, the stimulation is felt differently in the opposite leg.

There are six treatment location settings. The location circles on the NiNA display or the NiNA App indicate which treatment squares on the Pad are producing the primary stimulation as illustrated in Table 1.

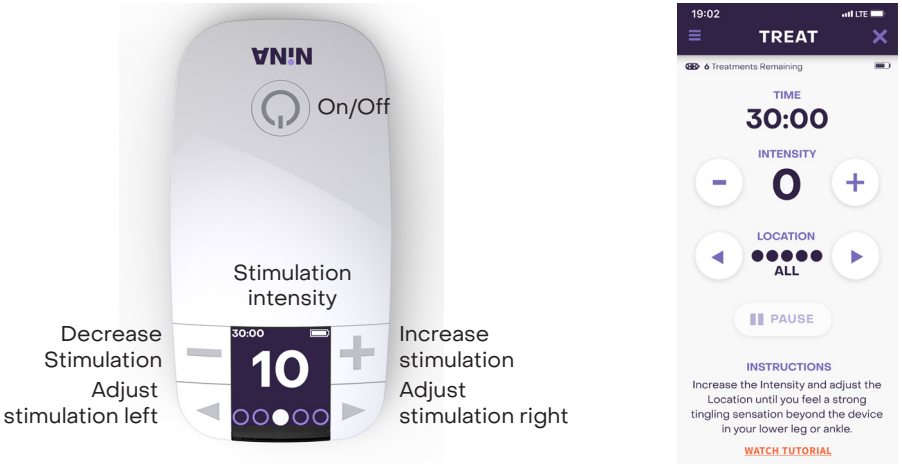


Figure 18. The stimulation intensity and location can be controlled with the **+**, **–**, **<**, and **>** buttons on NiNA or the NiNA App. Adjust the buttons to find the setting that produces the strongest, yet comfortable stimulation down the leg into the ankle or foot.

Table 1. Treatment Squares Activity

NiNA Display	Treatment Square Activity
●●●●●	All treatment squares are producing equal stimulation
●○○○○	The treatment squares on the left are producing the primary stimulation
○●○○○	The treatment squares on the left and center are producing the primary stimulation
○○●○○	The treatment squares in the center are producing the primary stimulation
○○○●○	The treatment squares on the right and center are producing the primary stimulation
○○○○●	The treatment squares on the right are producing the primary stimulation

During Treatment

1. The NiNA System is designed to allow for movement during the 30-minute treatment session. However, for the most consistent treatment effect, it is recommended that you sit or lie down.

2. If at any time during the treatment session the stimulation becomes uncomfortable, press the **–** button to decrease the stimulation intensity. The stimulation can be turned off by pressing the **–** button until the stimulation intensity is zero or by holding down the power button until NiNA powers down.

3. If the NiNA App is used, therapy can be paused for up to 10 minutes by pressing the PAUSE button. Press the RESUME button to continue the therapy session (Figure 19). If therapy is paused for more than 10 minutes, the therapy session stops and must be restarted for the full 30-minute treatment session.

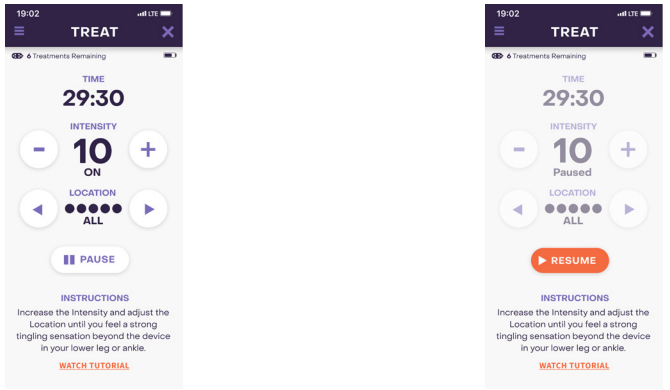


Figure 19. If using the NiNA App, the treatment can be paused for up to 10 minutes by pressing the **PAUSE** button. To resume treatment, press the **RESUME** button.

After Treatment

1. NiNA will automatically turn the stimulation off after 30 minutes of treatment. A green check mark with the text Treatment Complete will appear on the NiNA display or in the NiNA App (Figure 20).

Figure 20. When treatment is complete, a green check mark with the text **Treatment Complete** will appear.

2. Press and hold the power button until NiNA powers off (Figure 21). Release the Wrap and pull on the Pad Tab to remove the Pad from the leg (Figure 22).

Figure 21. Press and hold the power button until NiNA powers off.

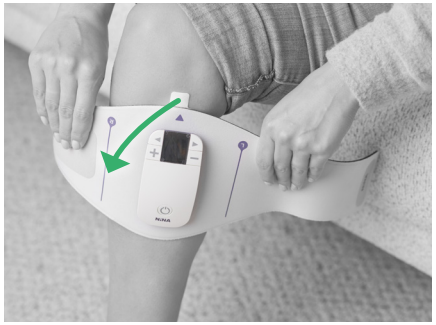


Figure 22. Release the Wrap and pull on the Pad Tab to remove the Pad from the leg.

3. Place the Liner back on the Pad (Figure 23).

4. If the Pad has been used for seven treatments, separate NiNA from the Pad by pulling NiNA straight up. Discard the Pad in the trash. If the Pad has been used for less than seven treatments, fold the arms of the Wrap around the Pad and optionally store the assembled NiNA in the NiNA Case (Figure 24).

Figure 23. Place the Liner back on the Pad.

Figure 24. Fold the arms of the Wrap around the Pad and optionally store in the NiNA Case

5. Therapy is limited to once per day. Once a session is completed, therapy cannot be initiated until the following day.

NiNA DISPLAY

NiNA Operation	NiNA Icon	Explanation
NiNA App Connection Status		NiNA needs to be paired with the NiNA App to activate the NiNA System. The icon will blink once the pairing process is initiated from the NiNA App.
		The NiNA App was successfully paired with NiNA.
Battery Status		The battery is fully charged.
		The battery is depleted and needs to be charged before initiating a treatment.
		The battery is charging. The color and amount of coloring indicates the charge level of the battery.
		Charging is complete.
Pad Use Status		The Pad icon shows how many treatments are remaining before the Pad needs replacement.
		The Pad has been used seven times and must be replaced before treatment can begin.
Pad Placement Status		The Pad is not attached to NiNA. After the Pad is successfully attached, the **Pad Inserted** icon appears on the NiNA display.
		
		The Remove Pad Liner icon alternates with the Apply NiNA to Leg icon. This indicates that adequate contact is not being made with the skin. • The liner may still be attached to the Pad. Remove the Liner and reapply the Pad to the skin on the leg. • The Wrap and/or Pad may not be snugly applied to the leg. Check that the Pad is firmly attached to the skin on the leg and the Wrap is snug.
		

NiNA Operation	NiNA Icon	Explanation
Treatment Status	29:59	The NiNA display shows how much time is remaining in the current treatment session.
	Treatment Complete	The treatment session is complete.
		The treatment session has been paused using the NiNA App.

MAINTAINING THE NINA SYSTEM

When not in use, turn NiNA off and store the NiNA System at room temperature away from direct sunlight and damp conditions. Ensure that the Liner is placed back on the Pad between uses.

To clean NiNA, ensure that it is turned off and wipe with an alcohol based cleaner. To clean the Dock, unplug and wipe with an alcohol based cleaner. The Wrap may be hand washed in cold water and hung to dry. Do not place the Wrap in the dryer. Cleaning the NiNA System components once per month is recommended.

DISPOSAL

When the Pad has been used more than seven times it can be disposed of in the trash. If the Wrap becomes damaged, it can be disposed of in the trash. NiNA cannot be disposed of in the trash and must be recycled at a facility certified to accept lithium-based batteries or devices.

TROUBLESHOOTING

Please contact the study coordinator at +1 (407) 674-1687 for assistance, as needed, when setting up or using the NiNA System, or if you experience unexpected operations, or need replacement parts or accessories.

Problem or Error Message	Possible Cause and Solution
NiNA does not connect to the NiNA App	Check that NiNA is charged, turned on, and close to the phone. Ensure that the phone's Bluetooth is turned on. The phone needs to be the same one as was first paired with NiNA.
NiNA does not turn on	Check that NiNA is charged and press and hold the power button for at least three seconds. Place NiNA on the Dock to recharge the battery if fully discharged.

Problem or Error Message	Possible Cause and Solution
No stimulation	Check that the Pad Liner has been removed and that the Pad has been used less than seven times. If it has been used more than seven times, discard the old Pad and use a new one. Ensure that NiNA is firmly attached to the Pad. Press + to increase the stimulation intensity. Check that the Pad is firmly attached to the leg and the Wrap holds the Pad firmly in place. Therapy is limited to once per day. If today's session is already completed, therapy cannot be initiated until the following day.
Stimulation or tingling does not extend to the ankle or foot	Press **+** to increase the stimulation intensity and use the **<** and **>** buttons to adjust the location of the stimulation until it can be felt beyond the device and down into the ankle or foot. Check that the NiNA/Pad is in the correct location on the leg. Slightly reposition the NiNA/Pad. Switch to the other leg. In some people, the stimulation is felt differently in the opposite leg.
Stimulation is painful	Press the **–** button to decrease the stimulation intensity. Use the **<** and **>** buttons to move the stimulation location.
The skin under the Pad is irritated	Switch to the other leg for treatment. If the irritation persists, discontinue use of the NiNA System until the condition resolves.
NiNA will not turn off	Press and hold the power button for at least three seconds.
NiNA disconnects from the NiNA App	Bring the phone close to NiNA and check that the phone's Bluetooth setting is turned on.
	NiNA battery power is low. Charge NiNA before using.
	The Pad has been used more than seven times. Discard the old Pad in the trash and use a new one.
	The Liner may still be attached to the Pad. Remove the Liner and reapply the Pad.
	The Pad is not properly secured to the leg. Apply the Pad more firmly to the leg and secure with the Wrap.
	The Pad is not securely attached to NiNA. Check the connection and make sure that the Pad is securely attached to NiNA.

OPERATING AND STORAGE ENVIRONMENT

Parameter/ Condition	Temperature	Relative Humidity	Atmospheric Pressure
Operation	32°F to 104°F (0°C to 40°C)	10% to 90% RH (non-condensing)	700 hPa to 1060 hPa
Storage and Transport	-13°F to 158°F (-25°C to 55°C)	0% to 90% RH (non-condensing)	N/A

PRODUCT SPECIFICATIONS

Product name	NiNA System
Model numbers	Model 20010 - NiNA Pulse Generator Model 20020 - NiNA Charging Dock (5V, 1000 mA Rated) Model 20030 - NiNA Hydrogel Pad Matrix (Applied Part) Model 20040 - NiNA Carrying Case Model 20060 - NiNA Wrap
Power source	AC adapter (INPUT AC 100-240 V, 50/60 Hz, 0.2A input rating) for battery recharging. Class II Medical Equipment. 1 Lithium-ion battery (4.1 V; Approx. 320 mAh)
Number of therapy sessions per charge	At least 7 sessions at typical use conditions, 30 minutes per session
Charging input	5V through USB or provided AC Adaptory connection (micro-USB to USB-A charging cable provided with the NiNA System).
Stimulation frequency	20 Hz
Pulse duration	200 µsec
Maximum stimulation compliance voltage	75V
Stimulation amplitude	0 - 100 mA per channel, 200 mA device total output at 750Ω. Maximum amplitude will decrease for impedances above 750Ω. Stimulation control is achieved over 100 intensity adjustment levels.
Stimulation channels	6 Independent channels
Stimulation waveform	Asymmetrical biphasic with zero mean
Bluetooth	Built-in Bluetooth LE 5.0 Module
Weight of NiNA	Approximately 3 oz (80 g)
Dimensions of NiNA	Approximately 2.25 in x 4.4 in x .88 in (5.7 cm x 11.2 x 2.2 cm)
IP classification	IP22. Protected from touch by fingers and objects greater than 12 mm and from water spray less than 15 degrees from vertical.
Durable period (Service life)	NiNA/Dock: 5 years, Wrap: 2 years Pads: 7 treatments

These specifications are subject to change without notice.

ELECTROMAGNETIC COMPATIBILITY

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
The NiNA System is intended for use in the electromagnetic environment specified below. The customer or the user of the NiNA System should assure that it is used in such an environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - Guidance**
Radiated Emissions CISPR 11	Group 1 Class B	NINA RF emissions are low and are not likely to cause interference in nearby electronic equipment. The NINA 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.
Conducted Emissions CISPR 11	Group 1 Class B	
Harmonic emissions IEC 61000-3-2		
Voltage fluctuations/flicker emissions IEC 61000-3-3		

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The NiNA System is intended for use in the electromagnetic environment specified below. The customer or the user of the NiNA System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±2, ±4, ±6, ±8 kV Contact, ±2, ±4, ±8, ±15 kV Air	B	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	± 2kV, AC Power	A	Mains power quality should be that of a typical commercial, domestic, or hospital environment.
	± 1kV Signal and I/O Cables	A	
Surge IEC 61000-4-5	+/-2 kV Line 1 to Earth Neutral to Earth	A	Mains power quality should be that of a typical commercial, domestic, or hospital environment.
	+/-1 kV Line 1 to Neutral	A	
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	100% reduction for 0.5 cycles	A	Mains power quality should be that of a typical commercial, domestic, or hospital environment. To use NiNA during power outages, ensure the internal battery is fully charged.
	100% reduction for 1 cycle	A	
	30% reduction for 25/30 cycles	A	
	100% reduction for 250/300 cycles	A	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The NiNA System is intended for use in the electromagnetic environment specified below. The customer or the user of the NiNA System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Proximity magnetic fields IEC 61000-4-39	8 A/m 30kHz Continuous	A	Magnetic fields from common appliances are not expected to affect the system.
	65 A/m 134.2kHz, Pulse Modulation 2.1kHz	A	
	7.5 A/m 13560kHz, Pulse Modulation 50kHz	A	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	A	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial, domestic, or hospital environment.
Conducted immunity IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	A	Portable and mobile RF communications equipment should be used no closer to any part of NiNA, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = 1.7\sqrt{P}$ 150 kHz to 80 MHz $d = 1.7\sqrt{P}$ 80 MHz to 800 MHz $d = 2.33\sqrt{P}$ 800 MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range.[b]
	6 Vrms 1.9, 3.75, 5.35, 6.798825, 7.15, 10.125, 13.56, 14.1, 18.12, 21.2, 24.94, 27.12, 28.82, 40.68, 52 MHz	A	
Radiated RF immunity IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	A	
	28 V/m 450, 810, 870, 930, 1720, 1845, 1970, 2450 MHz	A	
	27 V/m 385 MHz	A	
	9 V/m 710, 745, 780, 5240, 5500, 5785 MHz	A	

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
The NiNA System is intended for use in the electromagnetic environment specified below. The customer or the user of the NiNA System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 Test Level**	**Compliance Level**	**Electromagnetic Environment – Guidance**
Radiated RF immunity IEC 61000-4-3			Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.			
[a] 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 the NiNA System is used exceeds the applicable RF compliance level above, the NiNA System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the NiNA System. [b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the NiNA System			
The NiNA System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the NiNA System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the NiNA System as recommended below, according to the maximum output power of the communications equipment.			
Rated Maximum Output Power of Transmitter W	**Separation Distance According to Frequency of Transmitter m**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	1.2	1.2	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80MHz and 800MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structure, objects, and people.			

FCC Caution

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

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.

Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy, and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

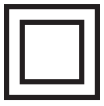
This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. The end user must follow the specific operating instructions for satisfying RF exposure compliance. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

The device is designed to meet the requirements for exposure to radio waves established by the Federal Communications Commission (USA) RF Exposure Guidelines. The System was tested by a certified test lab and found to be safely under these limits.

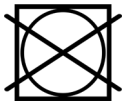
SYMBOLS GLOSSARY

Regulated Symbols and Certifications

Symbol	Title	Reference	Description
	Manufacturer	ISO 15223-1: 5.1.1	Indicates the medical device manufacturer.
	Date of manufacture	ISO 15223-1: 5.1.3	Indicates the date when the medical device was manufactured.
	Use-by date	ISO 15223-1: 5.1.4	Indicates the date after which the medical device is not to be used.
	Lot number	ISO 15223-1: 5.1.5	Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Catalog number	ISO 15223-1: 5.1.6	Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Serial number	ISO 15223-1: 5.1.7	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Temperature limit	ISO 15223-1: 5.3.7	Indicates the temperature limits to which the medical device can be safely exposed.
	Humidity limitation	ISO 15223-1: 5.3.8	Indicates the range of humidity to which the medical device can be safely exposed.
	Consult instructions for use	ISO 15223-1: 5.4.3	Indicates the need for the user to consult the instructions for use.
	Follow instructions for use	IEC 60601-1: Table D.2, Symbol 10	Refer to instruction manual/ booklet.
Rx Only	Prescription Use Only	21 CFR 801.109	Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Symbol	Title	Reference	Description
	Product is not made with natural rubber latex	ISO 15223-1: 5.4.5 Reference Annex B for the general prohibition symbol and negation symbol	Indicates that natural rubber latex was not used in the manufacturing of the product, its container, or its packaging.
	WEEE Waste of Electrical and Electronic Equipment	BS EN 50419:2006 Marking of Electrical Equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE)	Indicates that when end user wishes to discard this product it must be sent to separate collection facilities for recovery and recycling in the EU.
	MET Certification Mark for Canada and USA	N/A	The MET Mark for product safety is accepted throughout the United States & Canada and indicates compliance to federal regulations for safe use in the workplace.
	Type BF applied part	IEC 60601-1: Table D.1, Symbol 20	To identify a type BF applied part complying with IEC 60601-1.
	Stand-by	IEC 60601-1: Table D.1, Symbol 29	To identify the switch or switch position by means of which part of the equipment is switched on in order to bring it into the stand-by condition, and to identify the control to shift to or to indicate the state of low power consumption.
	Direct Current	IEC 60601-1: Table D.1, Symbol 4	To indicate on the rating plate that the equipment is suitable for direct current only; to identify relevant terminals. Voltage and current rating for the device is included under symbol.
	Class II Equipment	IEC 60601-1: Table D.1, Symbol 9	To identify equipment meeting the safety requirements specified for class II equipment according to IEC 61140.

Other Symbols

Symbol	Description
	Global trade item number.
	Device is a Bluetooth compatible device.
	Wash by hand.
	Do not use professional wet clean.
	Do not dry clean.
	Do not iron.
	Do not bleach.
	Do not tumble dry.
	Line dry in shade.

NiNA System is a trademark of EBT Medical, Inc.

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