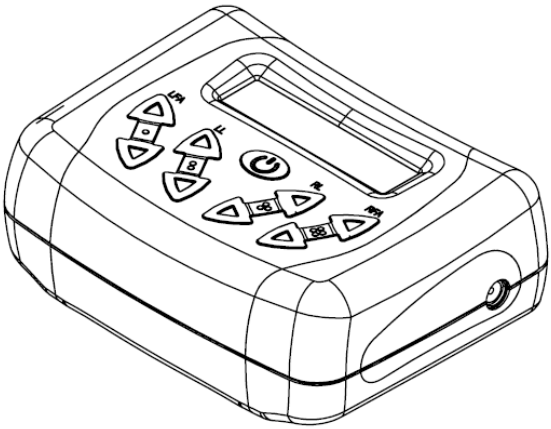
NEUROLUMEN

Instruction Manual

Neurolumen PN-1000



Please read all instructions before using the Neurolumen Product

Caution: Federal Law (US) restricts this device to sale by or on order of a physician.

Manufactured by Neurolumen, LLC:
9636 N. May Ave. #230. Oklahoma City, OK 73120
Phone: (405) 463-6525 Fax: (405) 463-6528

NEUROLUMEN

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Key to Symbols

Attention: Consult Accompanying Documents
(These instructions)

Type BF Patient Applied Part

Warning: Invisible Laser Radiation
Please see Page 7

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Device Description

The Neurolumen is a medical therapy device that delivers Transcutaneous Electrical Nerve Stimulation (TENS) and Low Level Laser Therapy (LLLT) to a patient's body.

The Neurolumen consists of a control unit and wrap(s). Each wrap contains two laser diodes, 4 light emitting diodes, and one or two TENS gel pads. After applying the wraps to the body, the control unit is able to provide up to 30 minutes of therapy on a single charge of the internal lithium-ion battery. A charger is provided for recharging the internal battery.

Indications for Use

The Neurolumen is indicated for the temporary relief of minor muscle and joint pain, arthritis and muscle spasm, relieving stiffness, promoting relaxation of muscle tissue, and to temporarily increase local blood circulation where heat is indicated.

The Neurolumen is also indicated for the symptomatic relief and management of chronic, intractable pain and adjunctive treatment for post-surgical and post-traumatic acute pain.

Contraindications

The Neurolumen is not indicated for the treatment of undiagnosed pain syndromes until ethology is established.

Warning: The Neurolumen should not be used by patients who have demand-type cardiac pacemakers.

The safety of TENS devices for use during pregnancy or birth has not been established.

Precautions

Please read all warnings before operating the Neurolumen Device.

Environment

- **Warning**: Do not use in or around water.
- **Warning**: Do not use in an oxygen enriched environment, or in the presence of flammable anesthetic mixtures.
- **Warning**: Do not use with high frequency surgery devices at the same time.
- **Warning**: Do not use near shortwave or microwave devices.
- **Warning**: Electronic monitoring equipment, such as ECG monitors or alarms, may not operate properly when TENS stimulation is in use.
- **Warning**: To isolate the unit from mains power, disconnect the wall adapter.

Application

- **Warning**: Do not use TENS on face, head, or on any damaged skin.
- **Warning**: Do not use TENS near the thorax, as this may increase risk of cardiac fibrillation.
- **Warning**: Do not place wraps over necklaces, rings, jewelry, or any other conductive metals.

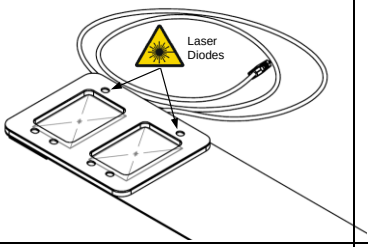
- **Warning**: Do not apply wraps unless skin is free of all liniments, salves, ointments, lotions, or oils.
- **Warning**: This unit should not be used by children without adult supervision. It should never be used on infants.

Use

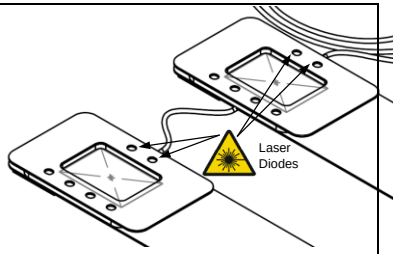
- **Warning**: Use the controls and adjustments as specified in this manual. Do not perform any procedures other than those specified in this manual.
- **Warning**: Do not tamper with the Neurolumen in any way. There are no serviceable parts inside.
- **Warning**: Monitor the skin under the wraps during use. While highly unlikely, burns can occur regardless of control settings.
- **Warning**: Do not look directly into the laser diodes or light emitting diodes.
- TENS is not effective for pain of central origin, including headaches.
- TENS devices should only be used under the continued supervision of a physician.
- TENS devices have no curative value.
- TENS is a symptomatic treatment and as such suppresses the sensation of pain which would otherwise serve as a protective mechanism.
- **Warning**: The TENS output contains a small DC component. In order to avoid burns, use only electrode pads supplied from Neurolumen. Burns may result with the use of other pads.
- **Warning**: Use only the approved charger supplied by Neurolumen. Any other charger may cause electric shock or battery damage.

Laser Safety Warning

The Neurolumen wraps contain class 3R Laser Diodes. Do not look directly into the lasers, located where shown below.



Single Wrap
Laser Location



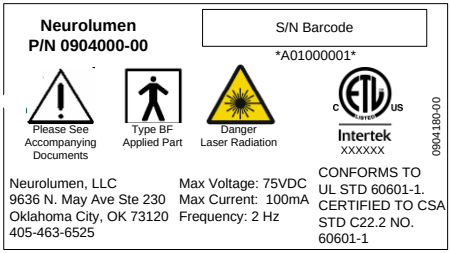
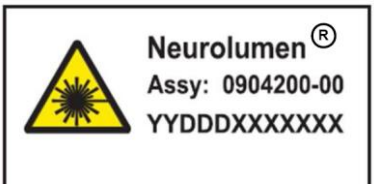
Double Wrap
Laser Location

The Laser Diodes have the following beam divergence:

Beam Divergence (FWHM)	Parallel	12 degrees
	Perpendicular	40 degrees

The laser diodes are not adjustable or serviceable. A failing wrap may only be replaced by Neurolumen LLC. Please see part number listing in these instructions for ordering replacement wraps.

The Neurolumen unit contains the following Laser Warning Labels:

Label	Location on Unit
	Bottom Side
	Bottom Side
	Wrap cables

Classification

The Neurolumen is classified as a Class-II medical device, with Type BF applied parts. The Neurolumen does not provide any protection against the ingress of water. The Neurolumen may be disinfected by wiping with alcohol. The Neurolumen is not intended to be operated in the presence of a flammable anesthetic mixture.

Specifications

Unit	
Model	Neurolumen PN-1000
Part Number	0904000-00
Battery	Lithium-Ion 3.6V
Charger	220/110 VAC, 50/60Hz input 9VDC 1.5A output
Laser Diodes	
Quantity per wrap	2
Wavelength	808nm
Output Power	60mW
LEDs, Red	
Quantity per wrap	2
Wavelength	660nm
Output Power	15mw
LEDs, IR	
Quantity per wrap	2
Wavelength	940nm
Output Power	22mW
TENS (Load Impedance 500-550 ohms)[1]	
Frequency	2 Hz
Output Current	100mA max
Pulse Voltage	75VDC max
Pulse width	100us biphasic

1. Operation above or beyond the specified impedance range may decrease voltage / current output.

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Electromagnetic Emissions

Guidance and manufacturer's declaration – electromagnetic emissions		
The Neurolumen is intended for use in the electromagnetic environment specified below. The customer or the user of the Neurolumen should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Neurolumen 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	The Neurolumen 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 emissions IEC 61000-3-3	Complies	

Warning: The Neurolumen was verified to be in compliance with the above standards using the wraps and charger supplied by Neurolumen, LLC. The use of other cables or another charger may result in increased emissions or decreased immunity of the Neurolumen medical device.

Warning: The Neurolumen should not be operated while stacked with other electronic equipment.

Electromagnetic Immunity

Guidance and manufacturer's declaration – electromagnetic immunity			
The Neurolumen is intended for use in the electromagnetic environment specified below. The customer or the user of the Neurolumen should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
ESD IEC 61000-4-2	± 6kV contact ± 8kV air	± 6kV contact ± 8kV air	Floors should be wood, concrete, or ceramic tile. If floors are overed with synthetic material, the relative humidity should be at east 30 %.
Electrical fast transient/burst IEC 61000-4-4	± 1 kV for power supply lines ± 0.5 kV for input/output lines	± 1 kV for power supply lines ± 0.5 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 s	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Neurolumen requires continued operation during power mains interruptions, it is recommended that the Neurolumen be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	N/A	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or

			hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Operating Conditions

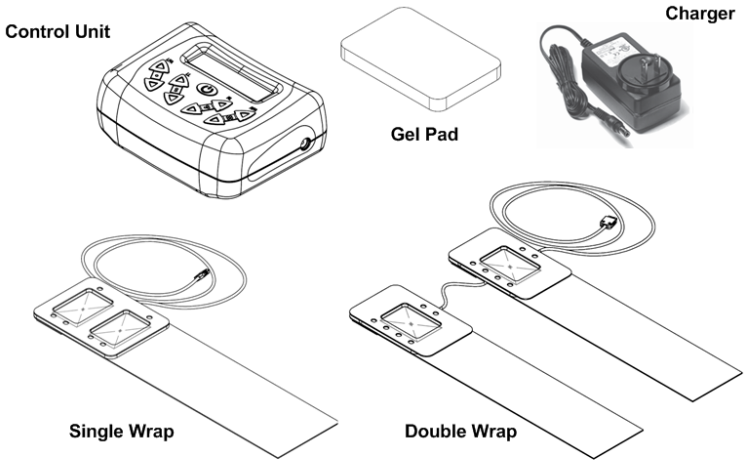
0 to +39˚C (32 to 102.2˚F)
65 +/- 20% Relative Humidity

Transportation and Storage Conditions

0 to +40˚C (32 to 104˚F)
65 +/- 20% Relative Humidity

Components

The following components may be part of your Neurolumen equipment depending of purchased unit:



Controls

The Neurolumen contains 5 controls that make the unit very easy to use and adjust. These are shown in Figure 1.

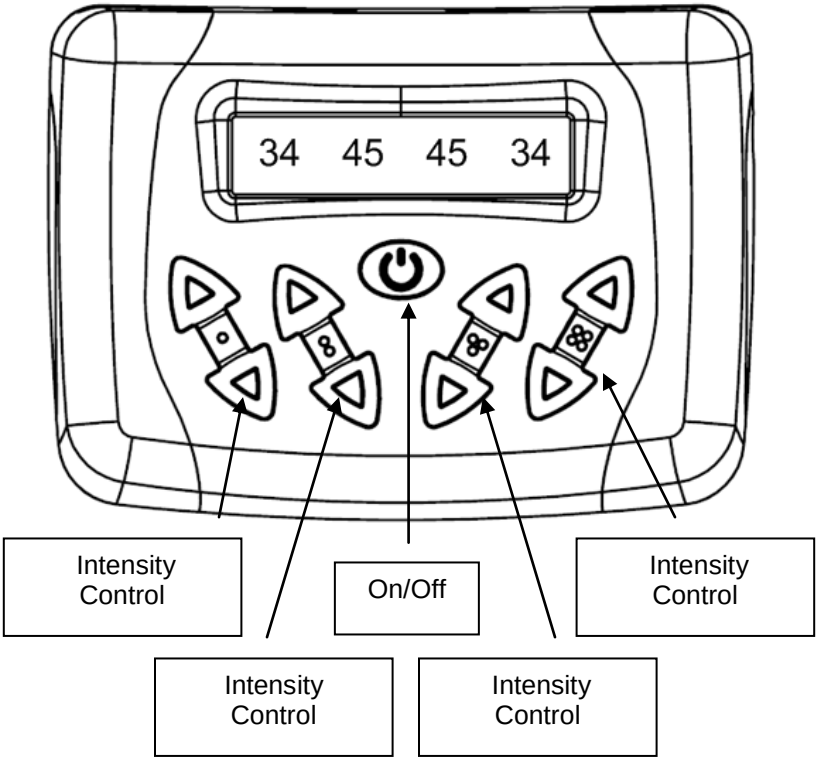


Figure 1: Neurolumen Controls

On/Off Control

The On/Off button turns the unit on and off. Pressing the button when the unit is off will turn it on, and pressing the button when the unit is on will turn it off.

Intensity Controls

The four Intensity controls adjust the strength of the TENS pulse. The intensity of each TENS circuit can be adjusted independently using these controls. Pressing the up arrow on each control increases the intensity, while pressing the down arrow decreases the intensity. The numeric value of the intensity for each control is displayed on the LCD screen, from 0 to 99. At 0 intensity, there is no TENS output.

Indicators

The Neurolumen contains several indicators that communicate the various working conditions of the unit. The indicators appear within the five buttons of the device.

On/Off Indicator

OFF: When the On/Off button is not illuminated, the unit is off.

GREEN: When the On/Off button is illuminated green, the unit is on and functional.

GREEN BLINKING: When the On/Off button is illuminated green and blinking, the battery is getting low.

YELLOW BLINKING: When the On/Off button is illuminated yellow and blinking, the unit is charging the battery by means of the external power supply.

YELLOW: When the On/Off button is illuminated yellow and not blinking, the unit is fully charged and the power supply can be disconnected.

RED: When the On/Off button is illuminated red, there is a malfunction with the unit and it should not be used.

Intensity Control Indicators

OFF: When the intensity control for a particular wrap is off, this indicates that the intensity is at 0, and there is no TENS output.

YELLOW BLINKING: When the intensity control is illuminated yellow and blinking, the TENS circuit associated with that control has not detected current in that circuit, indicating there is not good contact between the gel pads and the skin.

YELLOW: When the intensity control is illuminated yellow and not blinking, the TENS circuit has detected current through the circuit and there is contact between the gel pads. This is the normal operating condition.

RED: When the intensity control is illuminated red, there is a malfunction in that wrap and it should not be used. Contact Neurolumen for service.

Instructions for Use

Battery Charging

To charge the internal Lithium-Ion battery, connect the power supply to the Neurolumen by inserting the charger plug into the jack on the right side of the unit. Plug the

charger into a wall outlet. While the battery is charging, the On/Off button will blink yellow. The battery is fully charged when the On/Off button stops blinking and is a solid yellow.

It is possible to turn on the unit and use it while the charger is plugged into the unit. In this case the On/Off button will be illuminated green, indicating the Neurolumen is on and functioning.

The amount of battery charge remaining is displayed on the LCD screen. Each bar in the display represents 20% of the battery capacity. At 20% capacity (1 bar), the On/Off button will begin to blink green, indicating the battery is getting low. Once the battery is discharged to a point that may cause damage to the battery (3.0V), the unit will power itself off to prevent further discharging. The TENS pulse timing and amplitude and light output of the wraps are not affected by the battery voltage in the operational range.

Always ensure the battery is fully charged before starting a therapy session.

Caution: Only use battery charger provided to charge the Neurolumen.

Preparation

Attach gel pads to each wrap by removing the clear plastic film from the side of the gel pad with the cross hatch pattern. Place the gel pad into the cutout in the wrap, cross hatch pattern side down, as shown in Figure 2. Repeat for all gel pads.

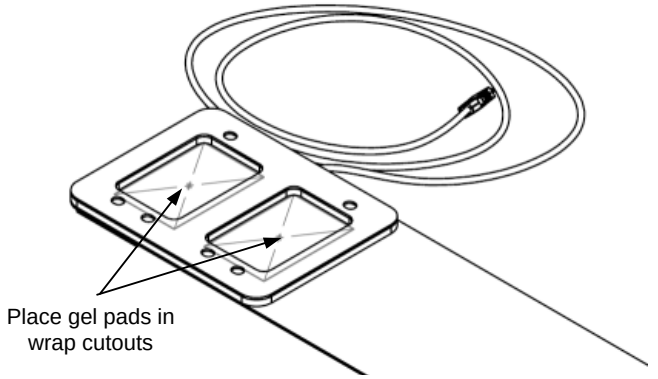


Figure 2: Place gel pads onto wraps

Remove the plastic film from the top of the two gel pads on a single wrap. Press the foam portion of the wrap and gel pads against the body, with the cord exiting the top of the wrap. Holding the wrap in place, stretch the fabric around the body part and back over the foam portion, holding the wrap in place with the Velcro fastener. Ensure that the wrap fits snugly in place, without being uncomfortably tight.

If there are other wraps with your device repeat the above steps.

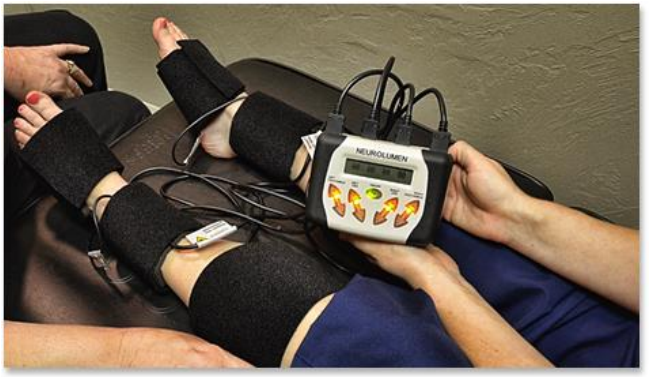


Figure 3: Correct Wrap Location

Connect the wrap cords to the control unit by inserting the wrap plugs into the connectors on the back of the control unit. Note: Double wraps have larger plugs and connect to the two outside connectors. Single wraps have smaller plugs and attach to the two inside connectors. See Figure 4.

Note: Always turn unit OFF before connecting or disconnecting plugs to/from the control unit.

Figure 4: Connecting wrap plugs to control unit

Operation

Turn the unit on by pressing the On/Off button. A green illuminated button indicates the unit is on and functioning.

The control unit will turn on all lasers and LEDs when the unit is on. Avoid direct eye contact with the lasers or LEDs. It is preferable to attach wraps to body before turning unit on.

After several seconds, four digits will appear on the LCD screen. These digits represent the intensity levels of the TENS pulses. Pressing an intensity control on the up arrow will increase the intensity, while pressing the control on the down arrow will decrease the intensity. Intensity ranges are from 0 to 99.

Each intensity control will be illuminated yellow for an intensity above 0. A blinking control indicates a poor electrical connection between gel pads. A solid control indicates good electrical contact between gel pads. If a control is blinking, adjust the wrap so that the gel pads are in good contact with the skin.

Adjust the intensity of each wrap to a comfortable level.

A few seconds after the intensities have been adjusted, the LCD screen will display the therapy session timer and the battery fuel gauge. Once the timer counts down to 00:00, the unit will shut itself off automatically.

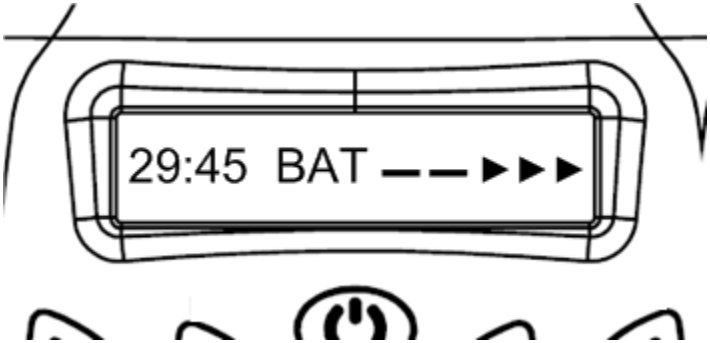


Figure 5: Therapy Session Timer

Removal

Once the therapy session has completed and the unit is off, remove each wrap one at a time, placing the clear plastic covers over each gel pad. Plug the charger into the control unit in preparation for the next therapy session, or return the unit to its carrying case.

Maintenance and Care

- The control unit may be wiped clean with a damp cloth or alcohol. Do not submerge unit in water.
- The gel pads may be cleaned with alcohol. They may be reused many times. Replace the gel pads when they become un-sticky.
- Replace the clear film covers over the gel pads when not in use. This will prevent dust and lint from contaminating the gel pads.
- Do not expose the Neurolumen control unit and wraps to direct sunlight, high temperatures, and high humidity.

- Store the Neurolumen in its carrying case when not in use.
- Charge the battery before each therapy session.

Troubleshooting

Problem	Possible Causes	Solutions
Unit does not power on	Dead battery	Attach charger and charge battery
Intensity control is not illuminating yellow	Wrap not connected or intensity is set at 0	Plug in wrap or check wrap connection to control unit. Adjust intensity above 0
Intensity control only blinks yellow	Poor connection between gel pads and skin	Ensure gel pads are installed in wrap correctly, with cross hatch pattern down. Ensure gel pads are in contact with skin and wrap is attached to limb snugly.
Intensity control is illuminated red	Failure in wrap	Contact Neurolumen for service.
On/Off control is illuminated red	Failure in control unit or battery	Contact Neurolumen for service.

The Neurolumen contains no user-serviceable parts. Opening the unit or tampering with the unit in any way will void the warranty.

For parts or service, please contact:

Neurolumen, LLC

NEUROLUMEN
9636 N. May Ave. Suite 230.
Oklahoma City, OK 73120
Phone: 855-855-4648
Fax: (405) 463-6528
Replacement Parts

0904800-00	Gel Pads
0904400-00	Battery Charger
0904100-00	Control Unit
0904200-00	Single Wrap
0904300-00	Double Wrap

Waste Disposal Considerations

The Neurolumen contains a Lithium-Ion battery. This battery should be disposed of at a battery recycling location and not with the household trash. There are no other environmental considerations with the rest of the unit.

Neurolumen Limited Warranty

This product is warranted against defects in materials and workmanship for a period of 12 months from the date of original purchase. This warranty does not cover institutional or commercial usage, nor damages caused by misuse, neglect, or accident. This warranty excludes all incidental or consequential damages.

This warranty gives you specific legal rights and you may also have other rights which vary from state to state. Some states do not allow the exclusion or limitation of incidental or consequential damages, so the foregoing exclusion may not apply to you.

Should this product become defective during the warranty period, contact Neurolumen to receive a Return Material Authorization (RMA) number.

Neurolumen will not accept any returns without an RMA.

NEUROLUMEN

Neurolumen Registration Card

Please complete this information, detach, and return to

Neurolumen, LLC
9636 N. May Ave. Suite 230.
Oklahoma City, OK 73120.

Name (First/Initial/Last)

Street

City State Zip

Date of Purchase (Month/Day/Year)

Serial Number