



Download the NeoHeat app to activate your free 1-year warranty, improve your postpartum health journey, and get the most out of your NeoHeat device.

# **Glossary of Symbols**



Refer to User Guide



Catalog Number



Caution



Humidity Limits



Manufactured for Jovlux. Inc.

Serial Number SN





ON/OFF (Push Button)

木

Type BF Applied Parts

Lot Number LOT

Unique Device Identifier UDI

NeoHeat: MM-9000 Patents issued and pending. For a complete list, please visit iovlux.com/patents

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# Hey, mama!

We've been there with the tears, surgical cuts, and long-term side effects—like bladder leakage and painful sex—that come with vaginal births. It's time to throw out that ice pack and experience the brightest innovation in postpartum healing.

NeoHeat is an app-enabled red and infrared LED light therapy device designed by an Ob-Gyn and made with medical-grade, flex-fit silicone to activate internal and external healing, stimulate circulation, reduce inflammation, and provide rapid pain relief while reducing the risk of infection, incontinence, and painful sex.

Wear the pad just 10 minutes a day while you're feeding your baby, taking a quick power nap, or enjoying a cup of coffee, and you'll be back to feeling like yourself in no time.

Your friend in postpartum healing,

XO, Team Mommy Matters

# **Intended Use**

NeoHeat is a perineal heater intended to help soothe and heal the perineum after an episiotomy.

NeoHeat is FDA registered as a medical device.





# What's in the box?

Besides renewed health, in this box you will find:

NeoHeat pad
NeoHeat controller
USB-C charging cord
User guide

Power cube and other accessories are not included.



## Accessories

We have a full suite of complementary products to support your healing. Visit mommymatters.com to learn more.

# Before you start

Prior to first use, please charge your NeoHeat for 6 hours—or until red indicator light turns green—to ensure proper operation and full battery life. We also recommend charging between each use so it's always full and ready to go when you need it most.

It is important that you read and understand the instructions, warnings, precautions, and safety information in this booklet before using the device for the first time.

If you have any questions about whether NeoHeat is right for you, contact your physician. For any other questions, please reach us at hellomama@joylux.com.

# What to Expect

The device emits a gentle heat through its 8 high-powered red and infrared LEDs. The device reaches maximum temperature between 2-4 minutes and then will taper off, gradually going down. While the heat is very pleasant to many women, each of us is unique and experiences things differently. If the pad feels too warm, stop treatment, and restart later that same day. The goal is to reach 10 cumulative minutes of therapy per scheduled day, and while treatment is most effective when applied in one sitting, your comfort is more important.

For best results, start treatment as soon as you have delivered and are comfortable, but no later than 3 days after delivery.

Heat and light increase circulation, which may cause cramping. This is nothing to be worried about. If you experience uncomfortable cramping while using NeoHeat, simply pause and resume treatment when cramping stops.

# **Tearing & Episiotomies 101**

**1st Degree** 





2nd Degree/ Episiotomy Perineum torn or cut

Second-degree tears are to the posterior vaginal walls and perineal muscles, but the anal sphincter is intact.



#### **3rd Degree** Anal sphincter torn

Third-degree tears extend to the anal sphincter that is torn, but the rectal mucosa is intact.



Fourth-degree tears occur where the anal canal is opened, and the tear may spread to the rectum.

# Let's Get Started!

## 1. Charging NeoHeat.

- Ensure the NeoHeat Controller is at room temperature of between 50° F and 86° F (10° C and 30° C) before charging or operating.
- Attach the USB charging cable to the tip of the controller and plug into a powered USB port or USB wall charger (not included).
- Once power is detected, the indicator light will illuminate red. If you are unsure if it's charging, wait 1 minute, unplug the device and try again.
- Once fully charged, the red indicator light will turn solid green. NeoHeat is now ready for use.

## 2. Make sure it's clean!

- Gently clean your device prior to and after each use. Use a soft, nonabrasive damp cloth with antibacterial soap to wipe down the controller and the pad. Do not submerge in water. Let the device controller and pad air dry and then store in a cool, dry location protected from dirt or dust.
- Never submerge the controller in water.
- Never share the pad with another person.

# Let's Get Started! (Continued)

## 3. Wear with an absorbent pad.

After birth, you will continue to experience bleeding (called lochia). Place the NeoHeat on a sanitary napkin that is wider than the pad to help absorb any fluids. Do not cover the LED light window with the sanitary napkin, and make sure the lights are facing up.



sanitary napkin not included

## 4. Get comfortable.

We recommend you position yourself comfortably in a seated or reclining position. Please try to stay still during the treatment, as the NeoHeat pad may shift and apply treatment to the wrong area if you walk or move around.

It's OK to be holding your baby, provided your baby's eyes cannot see the LED light window.

## You are now ready to begin treatment!

Without an absorbent pad, you may experience leakage of fluids into the area surrounding the pad.

# **Using NeoHeat**

## 1. Starting treatment.

NeoHeat is easiest to use in connection with the NeoHeat app. Simply download the app from either the iOS or Android store and follow the instructions.

• To turn on, press and hold the power button down for 2 seconds. The indicator light will illuminate green.



• Connect the app to the device and then follow instructions for your 10-minute treatment.

If at any point during use the device becomes too warm, stop using it and try again later that day to achieve a cumulative 10 minutes of therapy per programmed day. If you don't want to connect to the app, follow the instructions for manual operation:

## **Manual Operation**

• Once on, press and hold the power button down for 2 more seconds, and the indicator light will illuminate to red. The red treatment lights will activate, marking the beginning of the 10-minute treatment.



- The controller will automatically turn off after your 10-minute treatment.
- To turn off manually before the end of the 10-minute cycle, press and hold the button for 2 seconds.

# Using NeoHeat (Continued)

#### 2. Recommended treatment sessions.

For maximum results, we recommend starting the NeoHeat treatment within the first 3 days after vaginal birth.

We do not recommend using NeoHeat more than once a day. The device needs to cool for at least 2 hours after use.

Each day, use for 10 consecutive minutes over the course of your first 2 weeks post delivery. For weeks 3 and 4, use the device for 10 minutes a day every other day—a total of 3 times per week. At the end of 4 weeks, if you have not achieved your healing goals, continue use every other day until week 6 or as needed.

A recommend treatment plan is outlined in the NeoHeat app and provided here.

#### Week 1-2: Use for 10 minutes every day.



#### Week 3-4: Use for 10 minutes every other day.



If symptoms persist, continue use every other day through week 6 or as needed.

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# Support

#### Warranty and Product Registration

Activate your 1-year warranty against manufacturer defect-related problems resulting from normal use of the product by either downloading our app or registering your NeoHeat today at mommymatters.com/warranty.

### Warranty Exclusions

Not covered under the 1-year warranty: damage caused by misuse, abuse, neglect, alterations, or unauthorized repair; normal wear and tear, including chips, scratches, abrasions, discoloration, or fading.

## **Troubleshooting Guide**

We hope you don't experience any trouble with your NeoHeat, but if you do, try these steps.

# **PROBLEM:** NeoHeat won't turn on. Try one or more of the following:

- Make sure your NeoHeat is charged. See "Charging NeoHeat" section of User Guide.
- Make sure you are pressing and holding the On/Off button.
- If it still doesn't turn on, contact Customer Care.

## Support (Continued)

# **PROBLEM:** The red LED lights won't turn on. Try one or more of the following:

- Make sure your NeoHeat is fully charged. See "Charging NeoHeat."
- Make sure your NeoHeat is on. See above or "Let's Get Started."
- If in manual mode, press and hold down the power button again. If the lights still do not turn on, contact Customer Care.

Do not disassemble NeoHeat as this may cause damage, malfunction, electrical shock, fire, or personal injury. There are no user-serviceable parts inside the unit. If NeoHeat is malfunctioning, contact Customer Care. If you experience problems or require assistance, please contact NeoHeat Customer Care at hellomama@joylux.com

#### **Contact Information**

hellomama@joylux.com 844 872 8578 www.mommymatters.com

120 Lakeside Ave, Suite 300 Seattle, WA 98122 USA

#### **About Mommy Matters**

Mommy Matters is owned by Joylux, Inc. the leading women's intimate health company creating innovative products for women from motherhood to menopause. For more information, please visit www.joylux.com or www.mommymatters.com.

# Precautions

Please read the following safeguards before using. Please use caution and good judgment when using the device.

- Use this product only for its intended use as described in these directions.
- This device is not intended for use by anyone under the age of 18, and close adult supervision is necessary if children under the age of 18 are near the device. Keep the USB charging cord away from children, as it poses a strangulation risk.
- ▲ The controller and power cord of the device are not waterproof and should not be submerged. They can be cleaned with a damp cloth.
- ▲ Only connect the device with the USB cable provided and to USB power adapters certified in compliance with IEC 60950-1 or IEC 60601-1 based national standards.

- Do not use the device if the lights have been damaged in any way.
- ▲ Do not attempt to disassemble, modify, service or conduct any maintenance on this device. Unforeseeable hazards may arise from modification of equipment.
- ▲ Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- ▲ Portable RF communications equipment that emit radio waves should be used no closer than 30 cm (12 inches) to any part of NeoHeat, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

## Precautions (Continued)

- Mobile RF communications equipment can affect medical electrical equipment.
- Do not use if you have autonomic neuropathy, sensory neuropathy, or pseudomotor dysfunction.
- The device is designed for individual use only. Please do not share.
- After each use, the device should be thoroughly cleaned.
- The device should not be used in the presence of an active sexually transmitted infection, as an active infection may have symptoms that are aggravated by use of the device.
- Do not use the device if you are using cancer-fighting drugs, medications, or topical creams that increase photosensitivity. These may cause an adverse reaction.

- This device is intended for external use only.
- Do not use silicone-based lubricants with the device.
- Do not stare directly into the device lights.
- Do not use if you are pregnant or believe you may be pregnant.
- If you are experiencing abdominal pain or have other medical issues or health concerns, please consult your physician before using this device.
- If you experience numbness, skin irritation, dizziness, or feel pain, stop using this device immediately and consult your physician.
- Exercise caution when using near body piercings as the piercing may get hot when exposed to the heat.

## Precautions (Continued)

- If you are experiencing prolonged redness or sensitivity in the treatment area, discontinue use and contact hellomama@joylux.com.
- If the device begins to overheat, turn off immediately.
- If any part of the device is cracked, broken, or damaged or if there are signs of moisture or condensation on the inside of the device, discontinue use immediately.

# **Caring for Your NeoHeat**

The NeoHeat pad is made with body-safe, medical-grade silicone and is easy to clean.

Gently clean your device prior to and after each use. Use a soft, damp nonabrasive cloth to gently clean your device with warm water and antibacterial soap prior to first use and after each subsequent use. Let the device air dry and store in a cool, dry location protected from dirt or dust away from pets, pests, and children.

Do not place the pad in a dishwasher or sterilizer.

Do not use other cleaning solutions that may damage the device and its electronics.

Remember, do not immerse the controller or power cord in water and do not allow the electronic controls and charging port to get wet.

Just like your baby, NeoHeat is delicate. While the flex-fit allows for comfortable wear in your undergarments, flexing or bending at more than a 45 degree angle will cause it to break. Please be gentle.

# **Electromagnetic Cautions**

Regulatory Standard	Test Levels			
CISPR 11: Radiated RF emissions	Group 1 Class B			
IEC 61000-4-2: Electrostatic discharge for enclosure port and patient coupling port <sup>1</sup>	± 4 kV ± 8 kV contact ± 2 kV, ±4 kV, ±8 kV, ±15 kV air			
IEC 61000-4-3: Radiated RF EM fields for enclosure port	10 V/m from 80 MHz – 2.7 GHz, 80 % AM at 1 kHz 3 V/m from 2.7GHz – 6 GHz, 80 % AM at 1 kHz			
IEC 61000-4-3: Proximity fields from RF wireless communications equipment	27 V/m @ 385 MHz, 100 % PM, 50% DC at 18 Hz 28 V/m @ 450, 810, 870 and 930 MHz, 100 % PM, 50% DC at 18 Hz 9 V/m @ 710, 745, 780, 5240, 5500 and 5785 MHz, 100 % PM, 50% DC at 217 Hz 28 V/m @ 1720, 1845, 1970 and 2450 MHz, 100 % PM, 50% DC at 217 Hz			
IEC 61000-4-4: Electrical fast transients/bursts for Input a.c. power port	± 2 kV (peak), 5/50 Tr/Th ns, 100 kHz (repetition rate)			
IEC 61000-4-5: Surge for Input a.c. power port	$\pm$ 1 kV (line to line) and $\pm$ 2 kV (line to ground), 1.2/50 (8/20) Tr/Th $\mu s$			
IEC 61000-4-6: Conducted disturbances induced by RF fields for Input a.c. power port and patient coupling port	3 V, 0.15 – 80 MHz, 80 % AM at 1 kHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz			
IEC 61000-4-11: Voltage dips and interruptions	Voltage dip 0 % for 0.5 cycles @ 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° Voltage dip: 0% for 1 cycle Voltage dip: 70% for 25/30 cycles @ 0° Short Interruption 0 % during 250/300 cycles			

# Waste Disposal Guidelines

NeoHeat MM-9000 contains a lithium-ion battery. This product has required the extraction and use of natural resources for its production. It may contain hazardous substances that could impact health and the environment if not properly disposed of. In order to avoid the dissemination of those substances in our environment and to diminish the pressure on natural resources, product should not be disposed of in a municipal waste site. Rather we encourage you to use the appropriate take-back systems for product disposal that will reuse or recycle in a sound way.

Please seek more information on the collection, reuse, and recycling systems, by contacting your local or regional waste administration.

# **Unique Device Identifier (UDI)**

Each NeoHeat device has a UDI, which is a tool used to mark and identify medical devices within the healthcare supply chain. Within the UDI, you can identify the lot number (LOT) and the serial number (SN). The UDI is etched on the side of the device controller with a corresponding sticker on the NeoHeat outer box.

# (01)XXXXXXXXXXXXXXX(10)XXXX(21)XXXX LOT SERIAL

## **Technical Specifications**

#### Model: MM-9000

Environment: Home use device

Data communication to mobile device: Bluetooth

**Main Power:** Lithium-ion rechargeable battery, 3.7Vdc, 2200mAh, 8.14Wh

Electrical Class: Internally Powered

LED Type: Diode

Wavelengths: 662nm, 855 nm

**Light Energy (Fluence):** 10 minutes = 13.5 J/cm<sup>2</sup> +/- 20%

Operational Frequencies: 96MHz; 2.4 GHz

USB Input Power: 5VDC, 450 mA

Treatment Cycle: 10 minutes

Ingress Protection: IP22

Cooling: Passive

Weight: 0.11 kg +/- 0.04 kg (4 lbs +/- 0.04 lbs)

**Dimensions:** Length 58 cm (22.8 in), Width 5.6 cm (2.2 in), Depth 3.6 cm (1.4 in)

**Power Requirement:** Internally Powered 5VDC

#### Temperature:

**Operating:** 5°C (41°F) to +40°C (104°F) **Storage:** -25°C (-13°F) to +70°C (158°F) **Atmospheric Pressure Range:** 700 hPa to 1,060 hPa

#### **Relative Humidity:**

**Operating:** 15% to 93%, Non-Condensing **Storage:** 15% to 93%, Non-Condensing

Light Source Risk Group: Exempt

#### Safety Certifications:

UL/IEC/EN 60601-1; IEC/EN 60601-1-2 IEC/EN 60601-1-11; IEC 60825-1; IEC EN 62471; EN 60601-2-57; CAN/CSA-C22.2 No. 601.1-M90

**Average Service Life:** 2 years - may vary depending upon usage patterns.

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