motif MEDICAL

Motif Phototherapy Blanket BiliTouch™

OPERATIONAL MANUAL

Please note: color and patterns may vary.

Meet The Motif Phototherapy Blanket, The BiliTouch™

The ultraportable, lightweight, battery-powered, phototherapy device.

Helping promote mom and newborn bonding while providing the therapy needed.*

*It is suggested to limit the length of time holding the patient during treatment to help prevent heat buildup.

Please note: color and patterns may vary.

Proprietary Material

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2. Intended Use

The BiliTouch™ Motif Phototherapy Blanket is intended for use to treat infants who have been diagnosed with hyperbilirubinemia, commonly known as neonatal jaundice, which can cause a yellow discoloration of the skin and the whites of the eyes. The Phototherapy Blanket can be used in a hospital or at home.

The device is designed to use for patient population described in the infant, who is age up to 3 months and weight less than 10 kg.

Product Description

Jaundice refers to the yellow appearance of the skin that occurs with the deposition of bilirubin in the dermal and subcutaneous tissue. Bilirubin is the orange-yellow pigment of bile, formed principally by the breakdown of hemoglobin in red blood cells at the end of their normal life-span.

Normally in the body, bilirubin is processed through the liver, where it is conjugated to glucuronic acid by the enzyme in the liver. This conjugated form of bilirubin is then excreted into the bile and removed from the body via the gut. When this excretion process is low following birth, does not work efficiently, or is overwhelmed by the amount of endogenously produced bilirubin, the amount of bilirubin in the body increases, resulting in hyperbilirubinemia and jaundice.

In newborns, the lifespan of red blood cell is shorter than that of adult, which makes a lot of bilirubin, the function of enzyme to conjugate the bilirubin is poor, and the function to excrete bilirubin out of the body is also weak.

Phototherapy refers to the use of light to convert unconjugated bilirubin molecules into water soluble isomers that can be excreted in bile or urine without the need for conjugation. Bilirubin absorbs light most strongly in the blue region of the spectrum near 460 nm, a region in which penetration of tissue by light increases markedly with increasing wavelength. Only wavelengths that penetrate issue and are absorbed by bilirubin have a phototherapeutic effect. Lamps with output predominantly in the 460-to-490-nm blue region of the spectrum are probably the most effective for treating hyperbilirubinemia.

The Phototherapy Blanket light pad consists of LEDs that emits light of peak wavelength 455 to 465 nm. Microcontroller generates the PWM, and it is rectified to direct current through a resistor and a capacitor. When the rectified PWM is output through the LED driver, the LED can be stably turned on. The intensity of light can be adjusted by changing the duty cycle of PWM, and the Phototherapy Blanket has two types of intensity, high and low.

Contraindications

It should not be used in cases of congenital porphyria, a family history of porphyria, and treatment with photosensitive drugs or medicines.

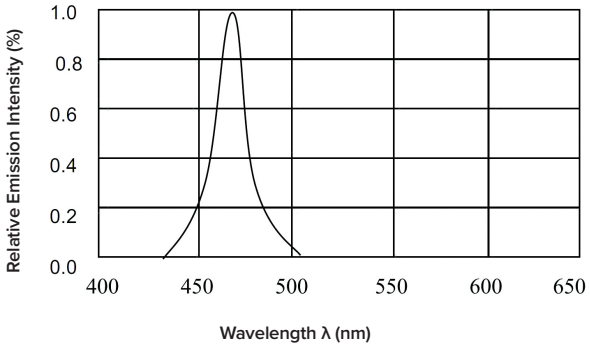


FIgure 1. Relative light intensity according to the wavelength of the LED component. This graph is from the datasheet.

3. Safety Information

Before using the Phototherapy Blanket, read this entire manual and be fully understood and follow instructions and safety information to prevent injury.

Warning: To avoid health risk and reduce the risk of injury

- Eye Protection: Do not look directly into the LED. During the treatment, always use eye protection to protect a baby's eyes.
- Periodically, check the hospital or treatment protocol and makes sure that the baby's eyes are protected from contamination.
- Patients near the light should use protective pads or equipment to protect their eyes.

Caution: Can lead to minor injury or product/ property damage

- Do not use the device outdoors, where aerosol (spray) products are being used, or where oxygen is administered.
- When disposing of the Phototherapy Blanket, please follow all laws regarding recycling.
- When disposing of packaging materials, comply with local waste disposal law and regulations. Keep the packaging material out of reach of children.
- Dispose of or recycle replaced batteries properly according to local regulations.
- Always use accessories provided by Motif Medical®.
- Unpack carefully to avoid damaging the device. Inspect the packaging before unpacking. In case of damage, immediately contact Motif Medical®. Unpack correctly, carefully remove the unit and components from the box and check the list. Make sure there is no damage to the device, and do not use it if it is damaged.
- Excessive pressure on the light pad may damage it.
- Use the cover provided only, otherwise, treatment may not be effective due to decreased light output.

Warning: Can lead to serious injury or death

- The patient's body temperature should be measured periodically so that the temperature does not rise too much.
- To minimize the heat between the light pad and the patient, the patient should not be wrapped in a thick blanket or wrapped too tightly.
- The patient's body temperature may rise if the patient and light pad are wrapped in a material that does not allow heat to escape, such as a thick blanket or clothes. When the temperature alert is on, check the patient's body temperature.
- Do not use the device while bathing the patient.
- Do not use the device near water.
- Do not use the device device without a disposable cover.
- Do not use the device with other thermotherapy devices. (incubators, heaters, mattresses that may affect the patient's body temperature, etc.)
- Do not use the device in the presence of flammable materials.
- Class I equipment: There is a risk of electric shock, so this equipment should be connected to a power supply with protective earth.
- The Phototherapy Blanket should be used under the direction of appropriately trained personnel and qualified medical personnel who are familiar with the currently known risks and benefits of neonatal jaundice therapy.
- If the normal operation of this device with other devices nearby is not confirmed, the Phototherapy Blanket cannot be used adjacent to or with other devices.
- Do not touch or manipulate the Phototherapy Blanket with wet hands, as it may cause electric shock.
- Using a reflective film can cause an increase in body temperature when the film affects a type of phototherapy radiation.

Caution: Can lead to minor injury or product/ property damage

- There should be no material (ex. Blanket, clothes, etc.) between the covered light pad and the patient. Covered light pads should always be on bare skin.
- Patients should always wear diapers. This is especially important for male patients because prolonged exposure to light on the male genitals can be harmful.
- Treatment should be as directed by the doctor.
- Do not let the device come into contact with liquids.
- Do not throw or shake the device.
- If the device is crushed or damaged, such as a hole, stop using it.
- When charging the device, connect the AC adapter to the control box and charge it until the battery charging stage indicator shows full.
- The Phototherapy Blanket is a non-transit-operable equipment that can be used at home.
- Lay operators (non-experts, people who are not good at operating the machine) can also operate.
- The patient's condition should be monitored during phototherapy.
- Do not place drugs or fluids in the irradiated area.
- While the Phototherapy Blanket is in operation, wear protective equipment to protect the patient's eyes, and frequently check whether it is properly worn.
- Keep all components dry after cleaning and disinfecting.
- When charging is complete, immediately disconnect the power adapter from the device.
- The battery charging stage displayed on the LCD may differ from the actual battery capacity. Use a fully charged device whenever possible.
- If a low battery status is displayed, charge the battery immediately.
- If you are not using the device for a long time, make sure the battery is fully charged before keeping the device.
- The Phototherapy Blanket can only be repaired or replaced by qualified personnel.

Warning: Can lead to serious injury or death

- If the device falls into water, do not touch any electrical appliances and immediately disconnect the power from the power outlet.
- Use the Phototherapy Blanket for neonatal jaundice treatment only as the intended use described in this manual.
- Keep the device out of direct sunlight.
- The Phototherapy Blanket and accessories are not heat resistant. Avoid contact with radiators, open flames, or heated surfaces.
- Supervision is required when using the device near children or pets. Keep all parts out of reach when not in use.
- Eye protection: Do not look directly into the LED. During treatment, always protect your baby's eyes with an eye patch or protective equipment. Periodically, check the hospital or treatment protocol and makes sure that the baby's eyes are protected from contamination. Patients near the light should use protective pads or equipment to protect their eyes.
- Sensitive people may develop headaches, nausea, or mild dizziness if left in the irradiated area for too long. Wearing yellow lens glasses can reduce the potential impact.
- Bilirubin Photo isomers may have toxic effects.
- Water balance: Water balance may be disturbed for some patients.
- Photosensitive Drugs: Irradiation may reduce the effectiveness of light-sensitive drugs. Do not store the medication near light irradiation.
- Flamable gas: Do not use the light near combustible gases. (eg oxygen, nitrogen dioxide, or other anesthetics)
- Blue light might interfere with the clinical management of a patient with cyanosis.
- Power off: When cleaning the light source, always turn off the power and remove the power cable.
- Even an adult may be affected by staying in the light for a long time.
- Do not use flammable solution directly on the LED lamp. The LED lamp may be damaged or its function may deteriorate. For cleaning or maintenance, follow the instructions described in chapter 10 of this manual.
- Use of the wrong LED or accessories not provided by Motif Medical® may damage the LED and cause injury to the user or patient.

4. Symbols

The following symbols and safety signs are placed on product, label, packing and this manual in order to stand for the information about:

Symbol	Standard/Symbol Reference No.	Description
	ISO 7010 — Graphical symbols — Safety colors and safety signs — Registered safety signs / W001	Used to display safety information for warnings. Before using the Phototherapy Blanket, please be fully understand the information provided with the device.
	ISO 15223-1, Medical Devices — Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.4.4	Used to display safety information for caution. Before using the Phototherapy Blanket, please be fully understand the information provided with the device.
IP21 IP22 IP23	IEC 60529 Degrees of protection provided by enclosures	Indicates the protection level against the ingress of solid object and liquid. IPX1 is protection against some falling water drops vertically. IPX3 is protection against spraying water at any angle up to 60° from the vertical shall. IPX2 is protection against some falling water drops vertically when enclosure tilted up to 15°. IP2X is protection against solid foreign object like a finger.
	ISO 15223-1, Medical Devices — Symbols to be used with medical device labels, labeling and information to be supplied — Part 1: General requirements / 5.4.3	Refer to operation manual. Read manual before placing the device.
	IEC 60417 — Graphical Symbols for Use on Equipment / 5032	IEC 60417 — Graphical Symbols for Use on Equipment / 5032
	IEC 60417 — Graphical Symbols for Use on Equipment / 5031	IEC 60417 — Graphical Symbols for Use on Equipment / 5031
	ISO 15223-1, Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.1.3	Indicates the production date.
	ISO 15223-1, Medical Devices — Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.1.7	Indicates the serial number of the device.

Symbol	Standard/Symbol Reference No.	Description
	ISO 15223-1, Medical Devices — Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.1.6	Indicates a reference number.
	IEC 60417 — Graphical Symbols for Use on Equipment / 5333	Indicates the BF applied part. This applies to the pad. (PAD)
	ISO 7010 — Graphical symbols — Safety colours and safety signs — Registered safety signs / M002	Refer to operation manual. Read manual before placing the device.
	81 FR 38911, June 15, 2016	Prescription only (USA)
	ASTM F2503 — Standard practice for marking medical devices and other items for safety in the magnetic resonance environment	Indicates an item is known to pose hazards in all MRI environments.
	IEC 60417 — Graphical Symbols for Use on Equipment / 5172	This symbol means the power adapter is a Class II device.
	ISO 15223-1, Medical Devices — Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.3.4	Indicates to keep the device dry.
	ISO 15223-1, Medical Devices—Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.3.1	Indicates the medical device that can be broken or damaged if not handled carefully.
	ISO 7000 — Graphical symbols for use on equipment -- Registered symbols / 0623	Indicates to keep upright.
	ISO 15223-1, Medical Devices — Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.3.2	Indicates the temperature limitation for transport and storage.

Symbol	Standard/Symbol Reference No.	Description
	ISO 15223-1, Medical Devices — Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.3.7	Indicates the temperature limitation for transport and storage.
	ISO 15223-1, Medical Devices — Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.3.8	Indicates the humidity limitation for transport and storage.
	ISO 15223-1, Medical Devices — Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements / 5.3.9	Indicates the range of atmospheric pressure to which the medical device can be safely exposed for transport and storage.
	Universal Recycling symbol	Indicates the packing material is recyclable.
	IEC TR 60878, Graphical symbols for electrical equipment in medical practice	Indicated that always protect the infant's eyes with eye protection.

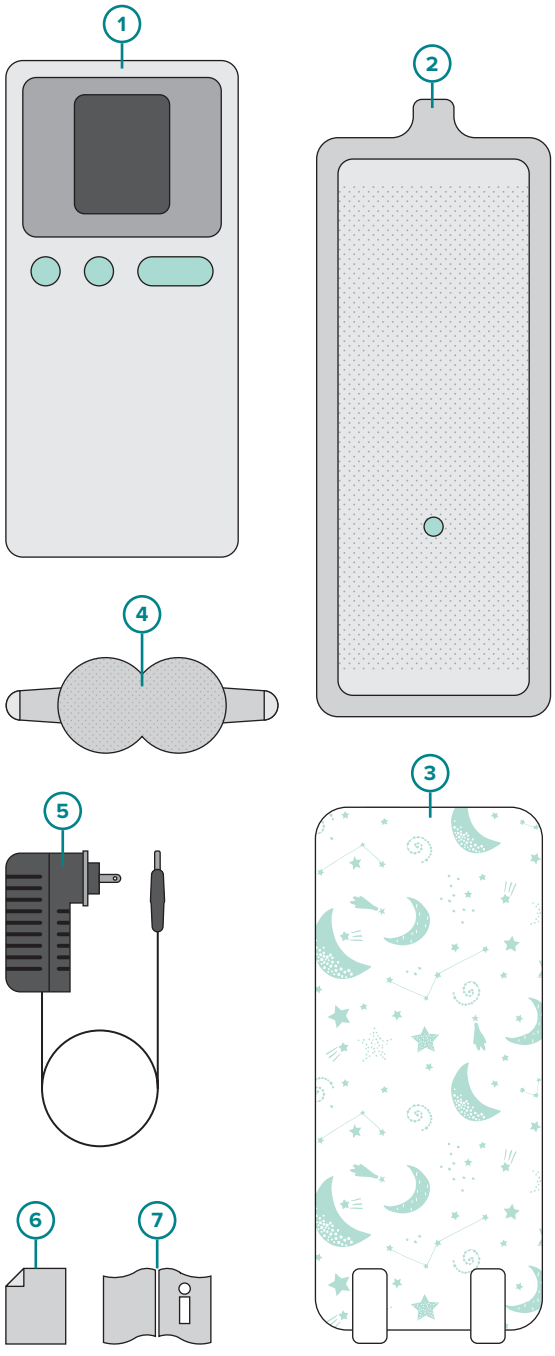
SYMBOLS ON THE ADAPTOR

Symbol	Standard/Symbol Reference No.	Description
	IEC 60417 — Graphical Symbols for Use on Equipment / 5172	This symbol indicates that the power adapter is a class II device.
	IEC 60417 — Graphical Symbols for Use on Equipment / 5957	This symbol indicates that the power adapter is for indoor use only.
	UL Mark (200-195S 10M/8/98)	This symbol indicates compliance with both Canadian and U.S. component requirements. (Recognized Component Mark for Canada and the United States)

5. Product Configuration

When unpacking, make sure you have all the following items. The eye protection and cover are single-patient. The standard components are as follows:

1. **Control Box**
2. **Light Pad**
3. **Cover** (disposable)
   Please note: color and patterns may vary.
4. **Eye Protection** (disposable)
5. **Power Adapter**
6. **Quick Guide**
7. **User Manual**

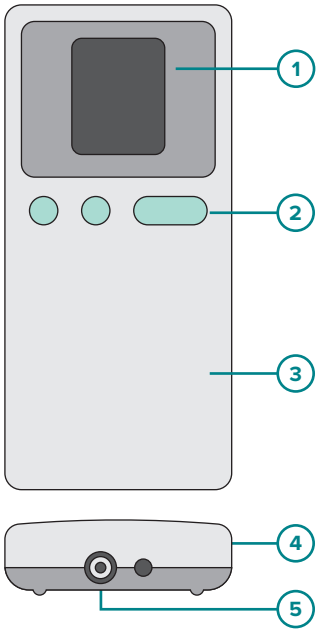


Caution

- Use only Motif Medical® accessories.
- Check the eye protection and cover for wear or damage before use and replace them if necessary. Do not use them if there signs of damage or defects.
- The eye protection and cover are disposable, multiple uses are prohibited.
- To maintain optimum performance, it is recommended to replace consumables periodically.

5.1 Description of Each Part

CONTROL BOX



1. **LCD Display**
   Shows the current operation status (Adapter and Battery status, running and remaining time, light intensity, etc.)

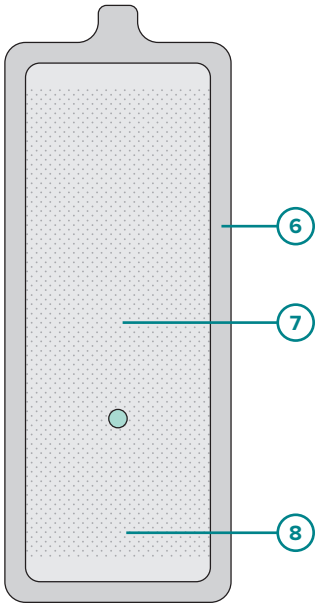
2. **Operating Buttons**
   Power ON/OFF, Light Intensity, and Operating Time can be set

3. **Control Box**
   Has buttons to control the device and an LCD display shows the current operation status

4. **Power Adapter Terminal**
   Terminal to plug in the power adapter for charging

5. **Pad Connection Terminal**
   Terminal to connect the light pad

LIGHT PAD

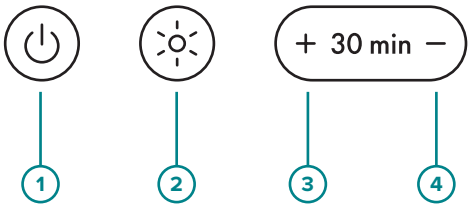


6. **Light Pad**
   Has a built in LED module and temperature sensor

7. **Temperature Sensor**
   Measures temperature in the light pad to protect the patient from the heat of the LED

8. **Illuminated Area**
   Lighting area from the built in LED

5.2 Button Description



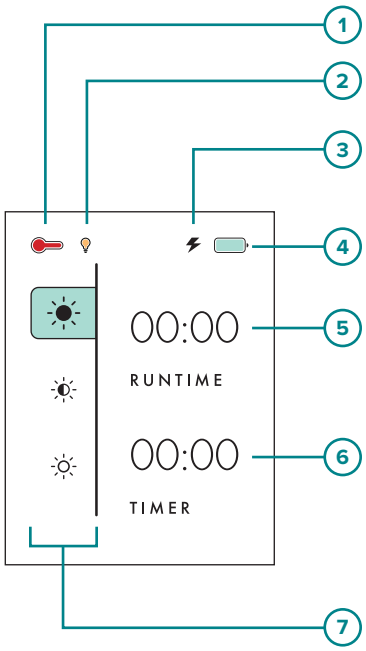
1. **Power Button**
   For power ON/OFF

2. **Light Intensity Control Button**
   Sets the Light Intensity to High, Low, or OFF

3. **30-Minute Increase Button**
   Decrease the scheduled Operating Time by 30 minutes in timer mode

4. **30-Minute Decrease Button**
   Increase the scheduled Operating Time by 30 minutes in timer mode

5.3 LCD Description



1. **Temperature Alert**

   The light pad will automatically turn off and an alarm will sound to alert when the temperature becomes too close to 104°F.

2. **Light Pad Alert**

   Appears on the screen if there is an issue with the lightpad functioning properly

3. **Charging Indicator**

   Appears when the power adaptor is attached and device is charging

4. **Battery Status and Low Battery Alert**

   Displays the current battery level

   When the battery is low, the battery icon flashes and it sounds an information signal. The low battery information signal turns off after 10 seconds.

5. **Operating Time**

   Shows the total elapsed time light pad was on for current session

6. **Remaining Time**

   Shows the remaining time on the timer mode

7. **Light Intensity**

   Show the current set light intensity (High, Low, OFF)

> ⚠ **Warning**
>
> - If the temperature alert is on, check the patient's body temperature.
> - If the patient's body temperature is too high, the light pads should be separated from the patient.
> - If the low battery alert is on, connect the adapter to the device.

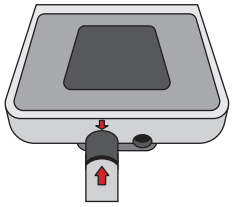
6. How to Use

6.1 Preparation Before Use

BEFORE USE

1. Ensure the arrow symbols on the pad connector and the control box are aligned, then connect them. When disconnecting, pull the metal collar toward the light pad to disengage it.
2. Put the light pad in the disposable cover. The end of the cover that does not contain the velcro straps and the LED side of the light pad should be touching. If you fold the light pad and insert it, it would be easier. If the cover gets dirty during use, discard the cover and use a new one. If there is any foreign substance on the light pad, it must be washed according to “Chapter 10: Maintenance and Cleaning” before use.
3. Install the eye protection on the patient’s eyes.

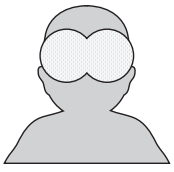
1.



2.

Please note: color and patterns of the disposable cover may vary.

3.



6.2 Basic Operation

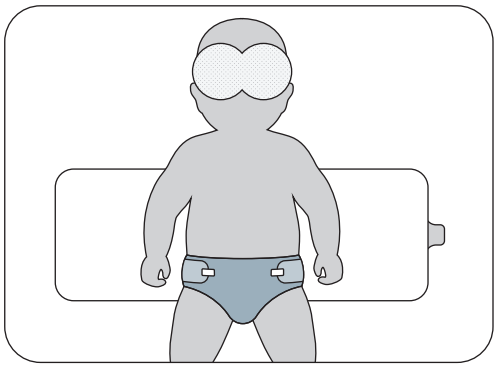
PATIENT PLACEMENT

1. As shown in the picture, place the patient into the light emitting area of the light pad. Ensure the light pad is already wrapped with the disposable cover. When placing the patience on light pad, be sure patient's back and temperature sensor location are aligned.
2. After wrapping the light pad around the patient, fix it with velcro. The power cord should be facing the floor.

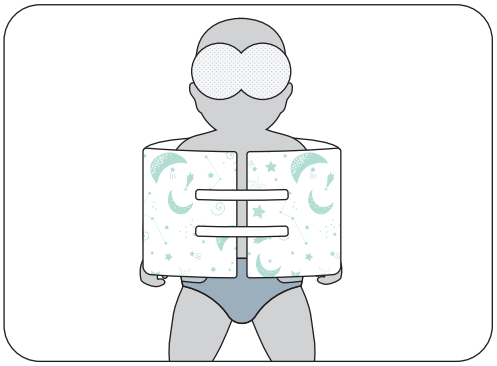
Warning

- To minimize the heat between the light pad and the patient, the patient should not be wrapped in a thick blanket or wrapped too tightly.
- The patient's body temperature may rise if the patient and light pad are wrapped in a material that does not allow heat to escape, such as a thick blanket or clothes.
- Do not use the device without a disposable cover.
- Do not use the device with other thermotherapy devices. (incubators, heaters, mattresses that may affect the patient's body temperature, etc.)

1.



2.



Please note: color and patterns of the disposable cover may vary.

6.3 Operation Mode

MODES

Normal Mode

The light pad is on and operates continuously

Timer Mode

The light pad is on, after intensity level is selected and, when the timer indicates the time mode higher than 0 minute; the device operates in Timer Mode. In Timer Mode, the light pad operates as long as the set time. When the set time reaches 0 minutes, the light pad turns off.

The maximum setting time is 24 hours

The light pad automatically turns off after 24 hours

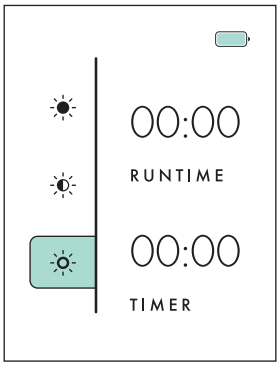
6.4 How to Operate

POWER ON/OFF

1. Press and hold the power button for about 1 second to turn the Power ON or OFF.
2. When booting, the Total Run Time is displayed at the bottom of the LCD display.

Boot Screen

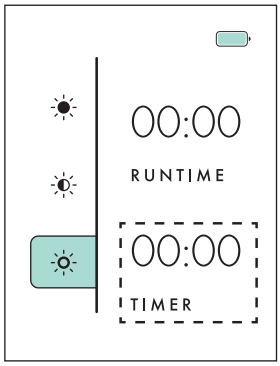
Basic Screen



MODE SETTING

Normal Mode

Use the ☼ button to set the intensity level and it will run continuously.

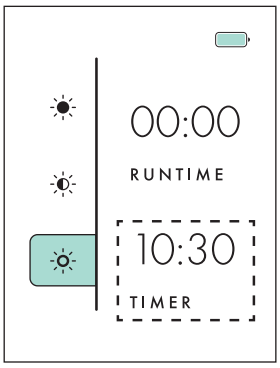


Timer Mode

Use the + 30 min − button to set the desired Timer time in increments of 30 minutes.

Timer can be set a maximum 24 hours.

Set the light intensity to High or Low by using the ☼ button.



LIGHT PAD OUTPUT SETTING

1. When the power is ON, the status of the light pad is OFF.
2. Press the light intensity control button to determine the light pad output.
3. Light pad intensity can be set as one of OFF, High and Low. (High: 60±10 μW/cm^2/nm, Low: 30±10 μW/cm^2/nm)
4. When the device power is turned OFF while the light pad output is set to High or Low, this light pad output set status is recorded. So when the power is turned on again and preset the intensity control button, the light pad output indicates the previous set status.
5. However, when the device power is turned OFF with the light pad output is set to OFF, the light pad output status will indicate the High when the light intensity control button is pressed after the device is turned ON again.

Contact customer service if light output is out of SPEC.

LCD AUTO-OFF

1. When there is no button input for 10 minutes, the LCD automatically turns off, but the device will continue to operate normally. The LCD can be turned ON by briefly pressing any of the four buttons.

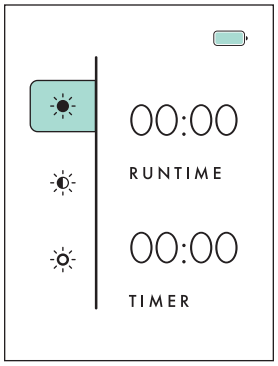
Charge the battery immediately when the Low Battery alert flashes.

If the device has not been used for a long time, make sure the battery is fully charged before use.

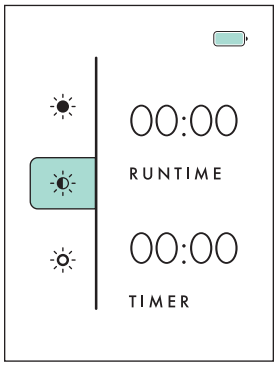
The battery level indication displayed on the LCD may differ from the actual battery capacity. Make sure that the device is fully charged before use.

Measure the patient's bilirubin level regularly.

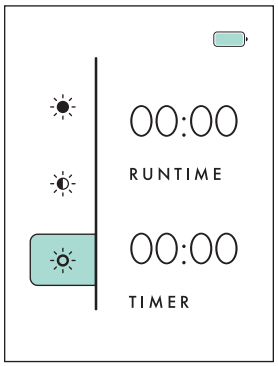
Light Pad — High



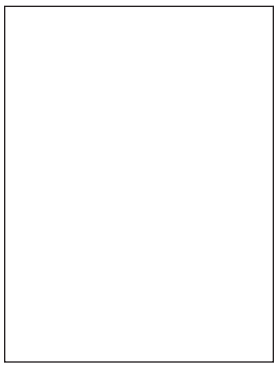
Light Pad — Low



Light Pad — Off



LCD — Off



7. Precautions for Light Pad

1. Light Intensity check: Before use, measure the output power of the LED using a measuring device. LED output is 60±10 μW/cm^2/nm when it is High, and 30±10 μW/cm^2/nm when it is Low.
2. Protect the infant with eye protection designed for use for phototherapy.
3. Make sure the patient does not get off the light pad during treatment. The light intensity decreases when the patient is away from the light source.
4. If the Light Pad Alert appears on the screen, please check the connection of light pad and control box (see Chapter 11. Troubleshooting). Try disconnecting and then reconnecting the light pad to the control box. If the issue remains, turn off the device and contact Motif Medical® Customer Service.

Warning: To protect eyes

- Do not look directly at the LED. During treatment, the baby's eyes should always be protected with eye protection device.
- Make sure that the baby's eyes are protected from contamination regularly. Patients near the light should use protective pads or equipment to protect their eyes.

Caution

- There should be no other material (blanket, clothing, etc.) between the covered light pad and the patient. Covered light pads should always be on patient's bare skin.

8. Alerts

Alert symbols for different conditions of the Motif Phototherapy Blanket will appear on the LCD screen.

ALERT CONDITION

1. **Alert Name: High Temperature**
   Alert Description: If the contact part temperature of the pad is high, the pad is automatically turned off before the temperature exceeds 40 °C. The high temperature icon appears on the display, and beep alarm sounds until the user turns off the control box.

2. **Alert Name: Low Battery**
   Alert Description: When the battery becomes low, the low battery icon appears on the display, beep alarm will sound for 10 seconds, and the control box and the pad will automatically turn off.

3. **Alert Name: Light Pad**
   Alert Description: If the communication between the control box and the pad is irregular, the light pad alert icon appears on the display, and beep alarm will sound once. The light pad icon disappears when the control box and the pad are properly reconnected.

ALERT CHARACTERISTICS

1. **Alert Name: High Temperature**
   Alert Priority: Low priority
   Audible Alarm: Beep-beep
   Alert Icon: The temperature icon is displayed and blinked until the user turns off the control box.

2. **Alert Name: Low Battery**
   Alert Priority: Information signal
   Audible Alarm: Beep
   Alert Icon: The battery icon is displayed and blinked.

3. **Alert Name: Light Pad**
   Alert Priority: Information signal
   Audible Alarm: Beep
   Alert Icon: The light pad alert icon is displayed.

Warning

- If the high temperature alert is on, check the patient's body temperature.
- If the patient's body temperature is too high, the pad should be separated from the patient.
- When the high temperature information alarm signal sounds, turn off the control box. And use it by setting the intensity to LOW.
- When the temperature information alarm signal sounds, remove the thick blanket or clothes surrounding the pad.
- When using the phototherapy equipment, periodically measure and check the patient's temperature.

9. Essential Performance

The essential performance of the Motif Phototherapy Blanket is the amount of light in the specific wavelength band performing the treatment.

Low Intensity: 30±10 µW/cm^2/nm

High Intensity: 60±10 µW/cm^2/nm

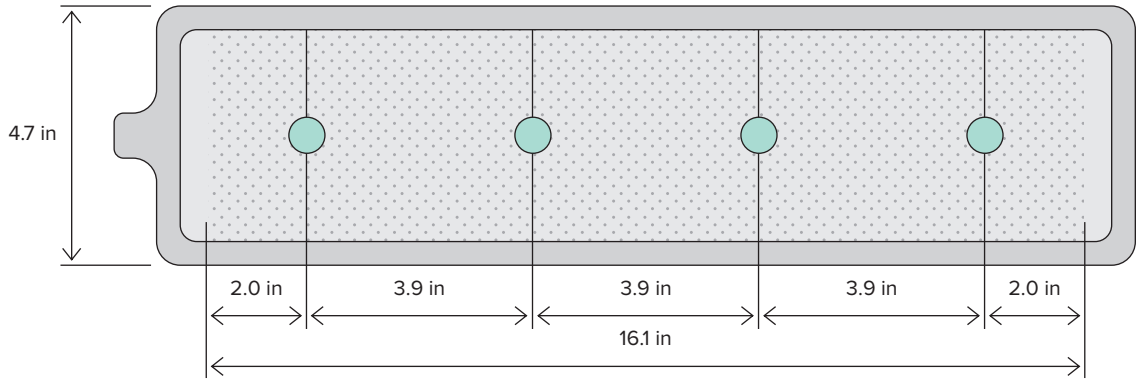
The basis for this determination is that the recommended minimum amount of light for decomposition of bilirubin is 30 µW/cm^2/nm and the maximum amount of light is 60 µW/cm^2/nm.

10. Maintenance and Cleaning

10.1 Brightness Check

Before use, it is recommended to measure the light intensity of the light pad using a calibrated measuring device. The light intensity of the light pad must be measured with the disposable cover on, and at the locations noted below. Light pad levels are to be measured with a GE Ohmeda Medical Biliblanket Meter II. **If measured light pad intensity is outside of the essential performance specification range, please contact Motif Medical® customer service.**

It is suggested to replace the light pad every 3 years, or if the light pad is not meeting the High or Low light intensity specification.



LEDs of the light pad are not subject to repair, and instead the light pad should be replaced.

If necessary, contact Motif Medical® customer service.

Warning: To protect eyes

- Do not open the light pad arbitrarily or attempt to change the LEDs. Only qualified personnel should perform service and repair the light source.
- Do not attempt to modify, repair, or change the LEDs, as it could affect the safety and effectiveness of the device.

10.2 Cleaning

WIPE

- Before cleaning, turn OFF the device and disconnect the pad connector.
- Remove residues on the surface of the control box and pad with a soft brush or soft clean-cloth wet with a proper amount of clear water.

DISINFECTION

- Before disinfecting, turn off the device and disconnect the pad connector.
- Always follow the hospital's hygiene regulations when handling devices contaminated with bodily fluids or other substances.
- Clean the surface of the control box and pad with a soft brush or soft clean-cloth wet with a proper amount of 70-90% alcohol (Ethanol alcohol or isopropyl alcohol).

Warning

- Disconnect the AC power cable before cleaning.
- Turn off the device and disconnect the pad connector before cleaning.

Caution

- Clean the light pads before use on a new patient.

11. Troubleshooting

Problem	Solution
The battery cannot be charged	• Check if the power adapter is properly connected • If the charging problem persists, replace the power adapter with a new one • If the charging problem persists, the battery needs to be replaced. Contact the Motif Medical® Customer Service Center.
The power does not turn ON	• Check the battery charging status • Inspect the power button and the outside of the control box for foreign substances • Replace the parts as necessary
The Control Box gets wet	• Remove the plug of the power adapter from the socket • Turn off the power of the control box • Wipe the body with a dry cloth and store it in a warm dry place for least 12 hours
LED does not light up	• Check if the light pad is properly connected to the control box • Replace the parts as necessary • If parts of the LED module do not light on, the light pad needs to be replaced
Heat over 104°F	• Turn OFF device, wait 30 minutes, then turn it back ON

If the problem is not solved or have additional questions, contact Motif Medical® by calling (844) 272-8390 or emailing info@motifmedical.com.

12. Manufacturer's Declarations on EMC

The Phototherapy Blanket needs special precautions regarding EMC (Electromagnetic Compatibility) and needs to be used according to the EMC information provided in this user manual. Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect the Phototherapy Blanket and should be kept at least 1 m away from the equipment. It is not suitable for use in an MRI environment.

Warning

- The Phototherapy Blanket should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Phototherapy Blanket should be observed to verify normal operation in the configuration in which it will be used.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the pump, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Use of adapter other than those specified or provided by the manufacturer of this equipment could results in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

12.1 Electromagnetic Emissions

The Phototherapy Blanket is intended for use in the electromagnetic environment specified below. The customer or the user of the Phototherapy Blanket should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environmental-Guidance
RF Emissions CISPR 11	Group 1	The Phototherapy Blanket uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The Phototherapy Blanket is suitable for use in all establishments, including domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic Emission IEC61000-3-2	Class A	
Voltage Fluctuations/Flicker Emissions IEC61000-3-3	Complies	

12.2 Recommended Separation Distances between Portable and Mobile RF Communications Equipment and the Phototherapy Blanket

The Phototherapy Blanket is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Phototherapy Blanket can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the Phototherapy Blanket 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 ~ 80 MHz $d = 1.2\sqrt{P}$	80 MHz ~ 2.7 GHz $d = 2.0\sqrt{P}$
0.01	0.12	0.20
0.1	0.38	0.63
1	1.2	2.0
10	3.8	6.3
100	12	20

For transmitters 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.

*At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

*These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

12.3 Electromagnetic Immunity

The Phototherapy Blanket is intended for use in the electromagnetic environment specified below. The customer or the user of the Phototherapy Blanket should assure that it is used in such an environment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment-Guidance
Electrostatic discharge IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, a relative humidity of at least 30% is recommended.
Electrical fast ransient/burst IEC61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000-4-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	±1 kV differential mode ±2 kV common mode	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 IEC61000-4-11	0% UT (100% dip in UT) for 0.5/1 cyclesa 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 23/30 cyclesa (for 0.5 sec) 0 % UT (100% dip in UT) for 250/300 cycles (for 5 sec)	0% UT (100% dip in UT) for 0.5/1 cyclesa 40% UT (60% dip in UT) for 5 cycles 70% UT (30% dip in UT) for 23/30 cyclesa (for 0.5 sec) 0 % UT (100% dip in UT) for 250/300 cyclesa (for 5 sec)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Phototherapy Blanket requires continued operation during power mains interruptions, it is recommended that the Phototherapy Blanket is powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC61000-4-8	30 A/m, 50 or 60 Hz	30 A/m, 50 or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.

*UT is the a.c. mains voltage prior to application of the test level.

[a]For example 10/12 means 10 cycles at 50Hz or 12 cycles at 60Hz.

Immunity Test	Test Level	Compliance Level	Electromagnetic Environment-Guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz Outside ISM bandsa 6 Vrms 150 kHz to 80 MHz in ISM and amateur radio bands 80% AM at 1kHz	3 Vrms 150 kHz to 80 MHz Outside ISM bandsc 6 Vrms 150 kHz to 80 MHz in ISMc and amateur radio bands 80% AM at 1kHz	Portable and mobile RF communications equipment should be used no closer to any part of the Phototherapy Blanket, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance: d = 1.2√P IEC 60601-1-2 : 2007 d = 1.2√P 80 MHz ~ 800 MHz d = 2.3√P 800 MHz ~ 2.7 MHz IEC 60601-1-2:2014 d = 2.0√P 800 MHz ~ 2.7 MHz Where P is the maximum output power rating of the transmitter (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site surveya, should be less than the compliance level in each frequency rangeb. Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80%, 1 kHz AM	10 V/m 80 MHz to 2.7 GHz 80%, 1 kHz AM	

*At 80 MHz and 800 MHz, the higher frequency range applies.

*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 Phototherapy Blanket is used exceeds the applicable RF compliance level above, the Phototherapy Blanket should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Phototherapy Blanket.

[b]Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 10 V/m.

[c]The ISM(industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6.765MHz to 6.795 MHz; 13.553MHz to 13.567MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz

Warning

- Excessive ambient EM (Electromagnetic) disturbances can cause the pressure of the unit to be temporarily excessively high or low. Please use in environments below the above test standards.

13. Product Specifications

Function

Category		Phototherapy Blanket for Neonatal Jaundice Treatment	
Light Source	Light intensity	With disposable cover on light pad: High : 60±10 μW/cm²/nm Low : 30±10 μW/cm²/nm	
	Effective illuminated area	16.22 in x 4.04 in	
Display		Format	2.4” TFT Color LCD
		Light Intensity Level	Picture
		Operating Time	Hours display (hour: minute display)
		Battery Charging	3 steps
Function	Mode	Normal Mode Timer Mode	
	Alarm and information signal: 43 ± 1 dBA		

Power

Power Adapter	For electrical safety, use only Motif Medical® supplied power adaptor.	
	Input : (100 to 240) V~, 50/60 Hz, 500 mA Output : 15 Vdc, 1.2 A	
Rechargable Battery	11.1 V Li-ion Polymer 4000 mAh	Do not attempt to replace the battery.
	Operation time: 10 hours	Charging time: 4 hours

Standard Configuration	
User Manual	1 Ea
Control Box	1 Ea
Light Pad	1 Ea

Option Configuration	
Power Adapter	1 Ea
Disposable Cover	1 Ea
Eye Protection	1 Ea

ENVIRONMENTAL CONDITION

Operation	
Operating Temperature	15 °C to 30 °C (59 °F to 86 °F)
Operating Humidity (R.H.)	5% to 85% non-condensing
Atmospheric Pressure	70 kPa to 106 kPa

Storage and Transport	
Operating Temperature	-20 °C to 60 °C (-4 °F to 140 °F)
Operating Humidity (R.H.)	0% to 95% non-condensing
Atmospheric Pressure	70 kPa to 106 kPa

DIMENSION AND WEIGHT

Component	Size	Weight
Control Box	3.31 in x 7.24 in x 1.06 in	0.79 lbs
Light Pad	4.84 in x 18.07 in x 0.47 in	1.12 lbs

14. Product Warranty

Product Name	BiliTouch™
Model	Motif Phototherapy Blanket
Serial Number	
Date of Manufacture	
Packing Unit	1 pc
Warranty Period	1 Year from date of purchase
Purchase Date	
Customer Information	Name : Address : Contact
Seller	

SERVICE CONTACT

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Thank you for choosing the Motif Phototherapy Blanket, BiliTouch™.

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