Caution: Federal law restricts this device to be sold only by or on the order of a physician.
BiliBed® - Instructions for Use

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Remarks:
WORKING WITH THE BILI BED REQUIRES PRECISE KNOWLEDGE OF ITS AREAS OF APPLICATION AS WELL AS
ADHERENCE TO THESE INSTRUCTIONS. IN CASES WHERE THERE IS ANY UNCERTAINTY, TRAINED STAFF FAMILIAR
WITH THE EQUIPMENT MUST BE CONSULTED.
The BiliBed is not suitable for use in the presence of a flammable anaesthetic mixture or for use in an incubator.
Federal law restricts this device to be sold only by or on the order of a physician.
1. **Description**

Medela's BiliBed® is a modern, quality phototherapy system. It has been developed according to the latest medical findings for the treatment of neonatal hyperbilirubinemia. Because the BiliBed can be fitted to most baby cribs or hospital bassinets, it is very suitable for hospital rooming-in or home phototherapy. The phototherapy bed works with very low energy consumption. Follow-up costs are also extremely low, since only a single blue light fluorescent tube has to be replaced.

2. **Applications**

Medela's BiliBed is designed for the efficient and safe treatment of excessive serum-bilirubin concentrations in newborn babies. It is not intended to prevent this condition.

**Warning:** The use of these lamps for anything but their intended purpose can be hazardous.

3. **Equipment**

The light unit contains a highly-polished aluminum reflector and an energy-saving blue light fluorescent tube. A silent rotary fan provides air exchange around the fluorescent tube. The special tube emits light mainly in the 425 - 475 nm range.

Two hour meters are integrated in the BiliBed light unit. The “total h”-meter is not re-settable and helps determine the time for changing the light tube. The “h”-meter is re-settable and indicates the passed therapy time.

The light unit, including the irradiation and the electronics, is covered with a transparent, waterproof, Perspex plate.

The baby support is comprised of an aluminum frame covered with a transparent polyurethane (PUR) plastic.

For optimum positioning of the baby, the BiliBed has a Bilicombi™ therapy blanket. The light is directed at the patient through the white fabric below the therapy blanket. This permits optimum treatment and protects surroundings from disturbing blue light. Never alter or exchange the white fabric of the Bilicombi! The therapeutical effect cannot be guaranteed when this is done.

The Bilicombi therapy blanket helps keep the baby warm and properly positioned. The Bilicombi is fastened onto the baby support and allows the therapeutic light to focus directly on the baby through the white fabric section on the underside of the therapy blanket.
4. Assembly

4.1 Light unit

The BiliBed® is equipped with a socket. Plug the START/STOP switch to the socket.

**Note:** The electronics of the BiliBed are protected against damage through voltage spikes in the electricity supply. If there is an excessive voltage surge in the power network, your BiliBed will switch off automatically. It can be turned on again for further use by pressing the START/STOP switch.
4.2 Baby support

■ Press the two red buttons on the underside of the frame at the same time and raise the side of the frame.

■ Fitting the plastic cover to the aluminum frame: Unpack and unroll the clear plastic cover. There is a groove on each of the long sides of the aluminum frame. Insert the long sides of the plastic into these grooves. Insert enough plastic to evenly cover the aluminum frame. Close the frame by pressing the open side down with both hands until it clicks shut. The plastic is now correctly tightened.

5. Installation in the baby’s crib or the hospital bed

5.1 Installation of the light unit

■ Remove the mattress from the baby’s crib or the bassinet.

Warning: The BiliBed was not designed for use in an incubator. Do not use the BiliBed without a baby crib or bassinet.

■ Place the BiliBed light unit in the baby’s crib or bassinet. To make sure that surrounding panels protect the baby, never use the BiliBed without a crib or bassinet.
**Important:** Sufficient air must circulate around the BiliBed. This is ensured if the base of the crib or the bassinet is provided with ventilation openings. If this is not the case, the BiliBed should be surrounded by enough free space to maintain temperature balance. The total ventilation openings must have a minimum area of 20 cm², or about the space necessary to fit the width of a regular pencil or pen. The amount of heat given off by the BiliBed is not significant nor is it problematic when it is used in the hospital or home according to these instructions.

- Insert the power cord and the START/STOP switch through the openings in the base of the crib. If there are no openings in the base, pass the power cord over the edge of the crib at the foot end.

- Connect the power cord to a three-prong grounded outlet at 120 VAC. An extension cord can be used if necessary (minimum 0.25A grounded).

- The light unit can be switched on or off with the START/STOP switch. When the switch is turned off, the BiliBed is still connected to the power supply. The equipment is only completely switched off when the power cord is disconnected from the power supply.

**Note:** The START/STOP switch can be omitted entirely. The light unit can be started and stopped by plugging in or unplugging the power cord to the unit. As soon as the light unit is plugged in, the “total h” and “h”-meter are started.

### 5.2 Installation of the baby support

- Place the baby support on top of the light unit so the two twin strips of Velcro® (on the plastic cover) are next to the drawing of the baby’s head on the light unit.
**Important:** The baby support must be positioned exactly to ensure that the baby is in the correct position for treatment.

### 5.3 Installation of the Bilicombi™ therapy blanket

- Fasten the Bilicombi blanket to the baby support by aligning the wide, white strips of Velcro® under the Bilicombi with the four Velcro tabs on the baby support.

**Important:** The Bilicombi must be positioned correctly to ensure successful treatment. The baby must lie above light unit with his/her head corresponding to the drawing on the light unit.

**Warning:** Sufficient air must circulate around the BiliBed (total ventilation openings must have a minimum area of about the space necessary to fit the width of a regular pencil or pen). If the space around the BiliBed does not meet the requirements for proper air circulation, the flaps of the Bilicombi can be folded under the plastic surface of the Baby support.

Lay the baby on his/her back unless the physician orders otherwise.

You should talk to the doctor about which sleeping position is best for the new baby. There are certain health conditions that might require tummy-down sleeping positions. If the baby was born with a birth defect, was born pre-term, frequently spits up after eating or has breathing, lung or heart problems, be sure to talk to the doctor about which sleeping position to use.
6. Providing phototherapy

6.1 Dressing the baby

■ All of the baby’s clothes should be removed for maximum skin exposure to the light. If a diaper is recommended, roll down the top of the diaper below baby’s naval so that the maximum amount of bare skin will be exposed to the therapeutic light.

■ Some other types of phototherapy equipment require infant eye patches. There is no need to cover the baby's eyes when the BiliBed® is used according to instructions.

6.2 Putting the baby in the Bilicombi™ blanket

Note: The BiliBed is designed for use only with the Medela Bilicombi blanket. The Bilicombi keeps the baby warm and correctly positioned for effective phototherapy.

■ Attach the Bilicombi blanket to the baby support.

■ Unzip the Washable Bilicombi blanket or unfasten the Velcro on the jacket of the Disposable Bilicombi.

■ Always lay the baby on his/her back in the Bilicombi blanket unless the physician tells you otherwise.

■ You should talk to the doctor about which sleeping position is best for the new baby. There are certain health conditions that might require tummy-down sleeping positions. If the baby was born with a birth defect, was born pre-term, frequently spits up after eating or has breathing, lung or heart problems, be sure to talk to the doctor about which sleeping position to use.

■ Put the arms of the baby into the sleeves of the Bilicombi blanket.

■ Zip/Fasten Velcro® on the Bilicombi blanket. Close the Velcro fastener under the baby's chin.

CAUTION: During phototherapy, do not raise the baby's legs or head. The BiliBed should only be used with baby lying down.
Frequently check on the baby during phototherapy treatment. If the baby seems too warm, make sure that there is enough room around the BiliBed for air to circulate and make sure that the fan is running in the light unit. The BiliBed continues to provide beneficial therapy even if the fan is off. If the ambient temperature of the room is very high, fold the flaps of the Bilicombi under the plastic surface of the Baby support to increase air circulation.

The Bilicombi blanket helps keep the baby warm. If additional warmth is necessary, a blanket can be placed over the Bilicombi.

7. **Hour meters**

The BiliBed® is equipped with two hour meters. When the fluorescent tube lights up both will start counting. This is indicated by the blinking hourglasses (in a 4-second interval).

The hour meter “total h” measures the total time the BiliBed has been in use. It cannot be reset. By reviewing and separately recording this display, you have accurate means of determining when the fluorescent tube should be changed (recommended: every 1,500 hours).

The hour meter “h” shows the therapy time. This meter can be reset. For resetting to “0”: press the START/STOP switch and hold down for 15 seconds. The BiliBed must be plugged in. Because this display can be reset, it should not be used to determine when the bulb should be replaced.

**Note:** Both displays only light up when the BiliBed is plugged in.
8. Maintenance

8.1 Changing the light tube

In a 1,500 hour-interval, the light tube needs changing. By using the “total h” hour meter this time interval can be monitored accurately.

The BiliBed is equipped with a “Light Tube Change Log”-card. On this card you will find a table as follows:

<table>
<thead>
<tr>
<th>Light Tube Change Log</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recommended hours</td>
</tr>
<tr>
<td>1,500</td>
</tr>
<tr>
<td>3,000</td>
</tr>
<tr>
<td>4,500</td>
</tr>
<tr>
<td>6,000</td>
</tr>
<tr>
<td>7,500</td>
</tr>
</tbody>
</table>

In this table you will see the recommended hours for a tube change on the left. When a tube change is performed, the actual hours on the hour meter (“total h”) should be filled in the appropriate column. Also included are two columns for inserting date and signature.

- Unplug the light unit from the power supply.
- Remove the baby support from the light unit.
- Release the 10 screws with a screwdriver and remove the light unit cover.
- Lift the metal clamp and carefully remove the light tube from its socket and from its clip.

**Warning:** Use only Medela light tubes.

- Put the old tube aside immediately in order to avoid confusion.
- Insert the new tube into the clip and push into the socket.
- Readjust metal clamp for a secure hold.
If the reflector is not clean and shiny, wipe with a dry cloth.

Refit the light unit cover with the 10 screws.

8.2 Cleaning and disinfecting

A Light Unit and Baby Support Cleaning

- Unplug the unit from the power supply.
- Wipe surfaces with a damp cloth. Cloth can be moistened with cleaning or disinfecting solutions, such as Medela’s Cavicide®.

Important: Do not use cleaning solutions such as appliance disinfectants, which use formaldehyde. Do not autoclave the baby support or disinfect by using heat.

B Bilicombi™ therapy blanket

If you are using a Disposable Bilicombi, discard the Bilicombi after 24 hours or if it becomes soiled. The Disposable Bilicombi is designed for single patient use.

If you are using a terry cloth, Washable Bilicombi, follow the cleaning instructions below:

- Remove Bilicombi from BiliBed
- Zipper Bilicombi and attach under-chin Velcro® fastener.

- Wash for Standard Machine cycle. Minimum wash cycle of 10 minutes is recommended.
- Machine wash in hot water. Minimum temperature 140 °F (60 °C). Maximum temperature 210 °F (95 °C)
- Standard cleaning detergent to be used. Refer to washing machine manufacturer for instructions.
Use of Chlorine Bleach can cause color to bleed and/or fade and can reduce life of Bilicombi by 75%.

Tumble dry low heat.

If any of the Velcro fasteners show decreased adherence, a new Bilicombi should be used.

9. **Technical specifications for Series 038**

9.1 **Light unit**
- UL Listed to UL 2601.1
- Power supply 120 V/50-60 Hz
- Power consumption 25 W
- Protection class Standard, class I (with protective earth), Type B
- Starter Electronic
- Tube Compact fluorescent tube, Order no. 936.0015
- Tube life Approx. 1,500 hours
- Fuses Type Ø 5 x 20, 250 V/T 800 mA
- Irradiance approx. 40 - 60 mm/cm²/nm or more (~2 - 3 mW/cm² at 425 - 475 nm)

Dimensions:
- Length 63 cm (24.8 inches)
- Width 32.6 cm (12.8 inches)
- Height 13 cm (5.1 inches), including baby support
- Weight 5 kg (11 lbs)

9.2. **Baby support**
- Cover Polyurethane (PUR) plastic
- Weight 1.2 kg (2 lbs, 10 oz)

9.3 **Washable Bilicombi therapy blanket**
- Material excluding trim 100% cotton
- White fabric material 100% cotton

9.4 **Disposable Bilicombi therapy blanket**
- Top Material excluding trim 100% nonwoven spunlaced fabric
- White fabric material 100% nylon
9.5  **Key to symbols**

Ensure that the patient is positioned correctly (see sections 5 - 6). The baby can be laid on his back or on his stomach, if the doctor recommends, with his head towards the top, according to the drawing on the light unit.

The BiliBed should not be used in an incubator

On/Off switch for lamp

Refer to instructions

Model B unit
According to IEC 601.1 and UL 2601.1

Alternating current

Earthing terminal
The designated screw for testing the earthing terminal (on the bottom of the BiliBed®) is only for controlling the earthing. The screw cannot be removed from the outside.
10. Ordering references

**Article #**

| Series 038 | Purchased Medela BiliBed  
|           | consisting of a light unit, power cord, start/stop switch and a baby support with a plastic cover, Instructions for Use, 120 V/60 Hz, 1 each |
| Series 038 | Rental Medela BiliBed  
|           | Includes all above plus Carrying Case |
| 936.0015   | Compact fluorescent tube, 1 each |
| 800.0338   | Bilicombi™ washable therapy blanket, pre-washed, 1 each |
| 800.0336   | Bilicombi disposable therapy blanket, 10 per case |
| 808.0018   | Plastic cover, 1 each |
| 190.0549   | Parent’s Guide to Home Phototherapy, 1 each |
| 190.0767   | Instructions for Use |
| 190.7337   | Baby’s Phototherapy Log, 100 each |
| 800.0341   | BiliBed Carrying Case |

11. Warranty

The BiliBed® is warranted by Medela to the original purchaser to be free from defects in material and workmanship for the period of 2 years from the date of delivery. In the event of defect or failure to conform to this warranty, Medela will repair or, at Medela’s option, replace this product.

This warranty does not apply to the normal wear and use of the product or the accessories such as the light tube, plastic cover, Bilicombi therapy blanket, etc. This warranty does not apply to product, which has been subject to misuse, abuse or alteration.