





No. 1 choice of hospitals & mother

Medela® BiliBed®

EN Instructions for use



Safety Note

Working with the BiliBed® 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.

Caution

The BiliBed may not be used in environments

- where there is a risk of explosion
- enriched with oxygen
- · in an incubator

Attention

The use of these lamps for anything but their intended purpose can be hazardous. Portable and mobile RF communication devices may influence the device.

Separation from the mains is only assured through the disconnection of the plug and socket connection.

A small percentage of the population is sensitive to blue light. Do not use the BiliBed without the Bilicombi.

In each of the following cases, the device must not be used and it must be repaired by persons authorized by Medela:

- If the power cable or the plug are damaged
- If the device is not functioning properly
- If the device is damaged
- · If the device shows clear safety defects

I 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 hyperbilirubinaemia. 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.

Indications

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. It is indicated for use for all babies which do not require treatment in an incubator and have no further complications.

Contra-indications

Babies with rapidly rising bilirubin levels must be monitored frequently and may require a more intensive therapy.

Warning

The use of these lamps for anything but their intended purpose can be hazardous. The BiliBed® may not be used:

- inside an incubator or warming bed
- in environments where there is a risk of explosion or enriched with oxygen
- portable and mobile RF communication devices may influence the device

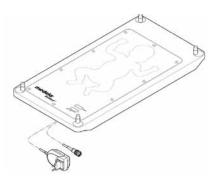
Equipment



Bilicombi therapy blanket



Baby support



Light unit

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.

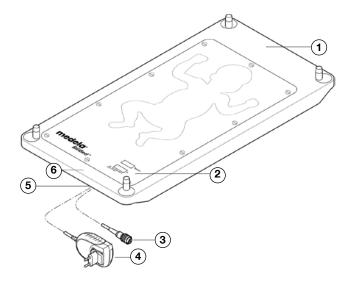
The light unit, including the irradiation and the electronics, is covered with a transparent, waterproof, Perspex plate.

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.

Assembly

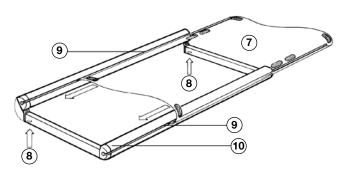


5.1 Light unit

The BiliBed is equipped with a power cord attached to a 12V DC power adapter. It is connected to the light unit. In order to remove, pull on the plug housing (not the cord itself or the anti-bend protection). Next to the power adapter, the START/STOP switch can be plugged into the socket in order to switch fluorescent tube on and off.

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.



5.2 Baby support

Preparation of the frame:

• Press the two red buttons underneath 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.

The baby support can carry the weight of approx. 10 kg.

- 1) Head of BiliBed
- 2) Hour meters
- 3) Start/Stop switch
- 4) 12V DC power adapter
- 5) Socket
- 6) Foot end of BiliBed
- 7) Plastic cover
- 8) Button
- Groove
- 10) Aluminum frame

6.1 Installation of the light unit

· Remove the mattress from the baby's crib or the bassinet.

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 insured 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 our 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 two-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.



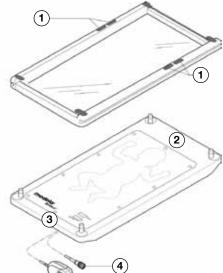
The START/STOP switch can be omitted entirely. The light unit can be started and stopped by plugging in or unplugging the power cord to the unit. As soon as the light unit is plugged in, the "total h" and "h"-meter are started. For resetting the "h"-meter, however, the START/STOP switch is necessary (see chapter 9).



 Place the baby support on top of the light unit so the two twin strips of Velcro® (on the plastic) 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.





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

Important

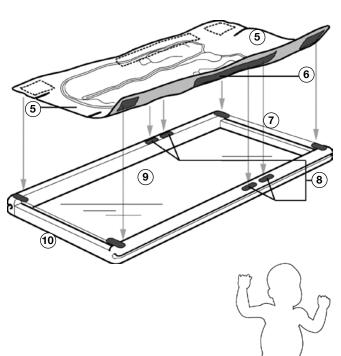
The Bilicombi must be positioned correctly to ensure successful treatment. The baby must lie above light unit with his/her head corresponding to the drawing on the light unit.

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 $^{\mathsf{TM}}$ 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.



Baby support

1) Twin Velcro strips

Light unit

- Head of BiliBed
- Foot of BiliBed 3)
- Start/Stop switch

Bilicombi therapy blanket

- Flaps
- Wide strips of Velcro

Baby support

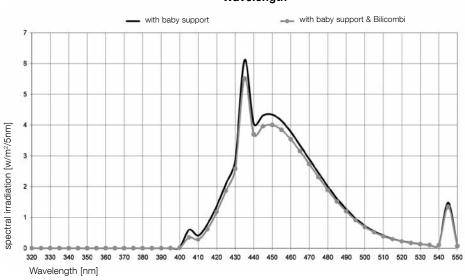
- 7) Head of BiliBed
- 8) Velcro strips
- 9) Plastic cover
- 10) Foot of BiliBed

VII Irradiation levels

According to the study from M. Jeffrey Maisels (Pediatrics Vol. 98, No. 2, August 1996: Why use Homeopathic Doses of Phototherapy) the efficacy of phototherapy depends on three factors:

- Spectrum of light delivered by the phototherapy unit. Because of the optical properties of bilirubin and skin, the most effective wavelengths are in the blue-green spectrum.
- Power output of the light. This also depends on the distance of the light from the infant. The lower the distance, the higher the efficacy.
- Surface area of the infant exposed to phototherapy. The efficacy is higher when more skin is subjected to phototherapy.

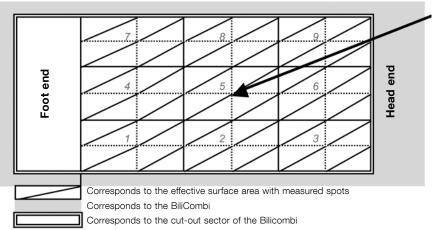
Wavelength



Irradiation, effective surface area

= max. irradiation in a central area E_{bi max (400-550nm)} within this area $E_{bi} \ge 0.4 E_{bi max}$ Effective surface area:

Room temperature: (25± 2) °C



Maximum values

 $E_{bi \max (400-550nm)} = 49.1 \text{ W/m}^2$

Average values

 $E_{bi \ max \ (400-550nm)} = 33.9 \ W/m^2$

Effective surface area 21 × 27 cm

Effective surface area

Light is focused on the baby through the cut-out sector on the backside of the Bilicombi. The size of this sector corresponds to the effective surface area. In order to achieve the best therapeutical effect, the baby should wear small diapers. If necessary, 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.

7.1 Measuring the irradiance

Measuring the light irradiance is not required as long as the light tube is changed every 1,500 hours. Should your facility require regular measurements a radiometer capable of measuring fluorescent light in the $425-475 \mathrm{nm}$ light spectrum with intensity greater than $40 \mu \mathrm{W/cm^2/nm}$ is required. The Olympic Medical Bili-Meter Model 22 with Type B-22 sensor is recommended.

Place the meter in the area of highest irradiation, as shown above in square 5. Move the meter around this area to find the spot of highest irradiation. This is the only required point at which a measurement needs to be taken. Once found, press down slightly to simulate the weight of the baby on the bed and take a final reading. A typical measurement will read between 40 – 60 $\mu W/cm^2/nm$. When using a new fluorescent tube it is expected to have a much higher reading. This is of no harm to the baby and quickly plateaus to the typical range. Though a light tube with >1,500 hours of use may measure in the 40 – 60 $\mu W/cm^2/nm$ range it should still be changed to maintain an optimal therapeutic affect.

VIII Providing phototherapy

8.1 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.

8.2 Putting the baby in the Bilicombi™ blanket

Note

The BiliBed® is designed for use with the Medela Bilicombi therapy blanket only. The Bilicombi keeps the baby warm and correctly positioned for effective phototherapy. The therapeutical effect of the BiliBed can only be guaranteed if the Medela Bilicombi is used. The Bilicombi protects its surroundings from disturbing blue light. When the Bilicombi is positioned incorrectly, leaking blue light may cause nausea or headaches of blue-light sensitive nursing staff.

- Check the Bilicombi before each use. The light-permeable fabric must be without
 damages and soft to the touch. The Velcro fasteners should guarantee a tight
 attachment to the baby support. If this is not the case, replace with a new
 Bilicombi.
- 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 baby's arms into the sleeves of the Bilicombi blanket.
- Zip/Fasten Velcro on the Bilicombi blanket. Close the Velcro fastener under the baby's chin.

Providing phototherapy

Caution

During phototherapy, do not raise the baby's legs or head. The BiliBed should only be used with baby lying down.

Caution

Frequently check on the baby during phototherapy treatment. If the baby seems too warm, make sure there is adequate air circulation, i.e.:

- the ventilation slots in the device are not covered by pillows or covers.
- there is enough room around the BiliBed (especially at the foot and head end) for air to circulate (at least 1 cm)

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.

When using a blanket, you must take care to guarantee the air circulation around the BiliBed. Monitor the baby regularly.

Make sure the baby is lying on the baby support correctly. Check the foil of the baby support before each use. If this is no longer stretched tight and sags, a new support should be used. The support can carry a weight of up to 10 kg. For heavier babies we recommend using the Medela Phototherapy Lamp.

8.3. Beginning therapy

- · Connect the cable to the power supply, ensuring in advance that the voltage matches the details given on the specification plate.
- The light unit can be switched on or off with the START/STOP switch. Even if the fluorescent tubes are switched off at the switch, the BiliBed® remains operational, i.e. connected to the power supply. The equipment is only completely switched off when the plug 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.

Caution

The therapy blanket must be positioned correctly to ensure successful treatment. The baby must lie above the therapy lamp. The position of its head and feet must be according to the drawing on the light unit.

Caution

Supervise the infant during therapy. Regular checks are necessary:

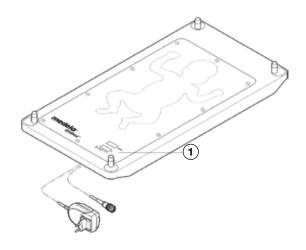
- Check the bilirubin levels. Photoisomeres of bilirubin may cause toxic effects.
- Phototherapy influences the baby's temperature. A regular check is necessary.
- Phototherapy influences the infant's water balance. In order to prevent dehydration, it may be necessary to feed the baby more often.

Attention

Auxiliary devices which are used in the same area as the BiliBed must comply with the general requirements for safety according to IEC 60601-1.

ΙX

Hour meters



1) 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 light tube should be replaced.

Note

Both displays only light up when the BiliBed is plugged in.

X Maintenance

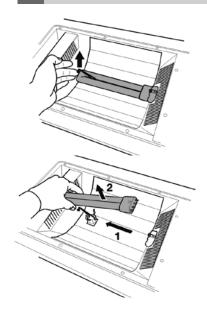
10.1 Changing the light tube

Change the light tube every 1,500 hours. 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:

Light Tube Change Log Lampenwechsel-Kontrolltabelle Fiche de suivie – Remplacement du tube Tarjeta de control de cambio de lampara			
Recommended hours Empfohlene Stunden Nb. heures recom. Duracion recomendada	Actual hours Aktuelle Stunden Nb. heures réel Total horas consumidas	Date of change Datum Date Fecha	Signature Unterschrift Signature Firma
1500			
3000			
4500			
6000			
7500			

X Maintenance



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 plexiglass cover.
- Lift the metal clamp and carefully remove the light tube from its socket and from its clip.
- Put the tube aside immediately in order to avoid confusion.
- Insert the new tube into the clip and push into the socket.

Warning

Use only Medela replacement light tubes, otherwise the safety and success of the therapy cannot be guaranteed! We recommend changing the light tube every 1,500 hours in order to guarantee therapeutic effectiveness.

- · 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.



A Light Unit and Baby Support Cleaning

• Unplug the unit from the power supply.



The outside surfaces can be cleaned with a damp cloth. For disinfecting, alcohol may also be used. Cleaning or disinfecting agents should not be used in concentrated form! If the baby support shows signs of wear, sags or is damaged, replace with a new one.

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 the Washable Bilicombi, follow the cleaning instructions below:

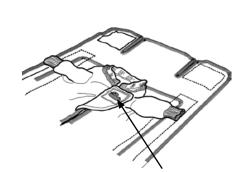
- Remove Bilicombi from BiliBed.
- Zipper Bilicombi and attach under-chin Velcro® fastener.
- Wash for Standard Machine cycle. Minimum wash cycle of 10 minutes is recommended.
- Machine wash in hot water. Minimum temperature 140 degrees F (60 °C).
 Maximum temperature 210 degrees F (95 °C).
- Standard 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 BilicombiTM by 75%.
- Tumble dry low heat.
- If any of the Velcro fasteners shows decreased adherence or the light-permeable fabric is damaged/too stiff, a new Bilicombi should be used.

10.3 Troubleshooting

If the light goes out during therapy:

Check if the fan is working properly. If it does not run at the proper speed or if it
is blocked, an electronic safety circuit switches the lamp off in order to protect
the system from overheating. Replace fan if necessary.

If necessary, change tube.



The BiliBed® is of modular design. It can thus be disassembled into its individual components. The BiliBed is mainly made of technical plastics which can be disposed of in accordance with local regulations. The fan, lamp and electric parts should be disposed of separately.

Technical specifications

12.1 Light unit

UL Listed to UL 2601.1

Power supply 12V DC through power adapter 100–240V

~47-63Hz

Power consumption 30 W

Irradiation $E_{bi max} = 49 \text{ W/m}^2 \text{ (according to IEC 60601-2-50)}$

with compact fluorecent lamp (Osram Dulux L18W/71 or Radutec long 18W/71/2G11)

Tube life Approx. 1,500 hours
Air pressure 70–106 kPa
Relative humidity 20–95%
Operating temperature +5 to +30 °C

Operating temperature +5 to +30 °C Storage/transport temperature -20 to +50 °C Noise level <20 dB(A)

CE (93/42/EWG) EN 60601-1:1990

(IEC 60601-1:1988 + A1:1991 + A2:1995)

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IEC 60601-2-50:2000

12.2 Baby support

Standards

Cover polyurethane (PUR) plastic Weight 1.2 kg (2 lbs, 10 oz)

12.3 Washable Bilicombi™ therapy blanket

Material excluding trim 75% cotton, 25% polyester

White fabric material 100% cotton

12.4 Disposable Bilicombi™ therapy blanket

Top Material excluding trim 100% nonwoven spunlaced fabric

White fabric material 100% cotton

12.5 Complete device

Dimensions:

Length 63 cm (24.8 inches)
Width 32.6 cm (12.8 inches)

Height 13 cm (5.1 inches), including baby support

Weight 4 kg (9 lbs)
Working conditions +5 °C to +30 °C
Storage and transport conditions -20 °C to +50 °C

Electromagnetic Compatibility (EMC)

The Medela BiliBed is a medical device which complies with special safety measurements concerning EMC and must be installed and made ready for use according to the EMC information at the end of these instructions for use. Portable and mobile RF communication devices may influence the device.

Technical specifications

12.6 Key to symbols

BiliBed



Ensure that the patient is positioned correctly. The baby can be laid on his back or on his stomach, if the doctor recommends, with its head towards the top, according to the drawing on the light unit. We recommend to place the baby on its back. If the baby is restless and active this will prevent any abrasions on its knees.



The BiliBed should not be used in an incubator



On/Off switch for lamp



Refer to instructions



Medela BiliBed

With respect to electric shock, fire, and mechanical hazards only In accordance with UL 60601-1/CAN/CSA C22.22 No. 601.1/ IEC 60601-2-50



Model B unit

IPX4

Protection against splashing water

Power adapter



Direct current



Protection class II



Must not be disposed of together with household refuse



For indoor use only

XIII Ordering references

Article #	
038.4002	Purchased Medela® BiliBed® consisting of a light unit, power cord, Start/Stop switch and a baby support with a plastic cover, Instructions for Use, Service Manual, 1 each
038.4002R	Rental Medela BiliBed Includes all above plus Carrying Case
936.0015	Compact fluorescent tube, 1 each
800.0229 800.0336	Bilicombi™ washable therapy blanket, 1 each Bilicombi disposable therapy blanket, 10 per case
808.0018	Plastic cover, 1 each
190.0549 200.0100 190.7337	Parent's Guide to Home Phototherapy, 1 each Instructions for Use Baby's Phototherapy Log, 100 each
800.0341	BiliBed Carrying Case

XIV 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.

Technical Documentation

Technical Description Electromagnetic Compatibility (EMC, IEC 60601-1-2) IEC 60601-1-2, Table 201

Electromagnetic Emissions

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

Emission Tests	Compliance	Electromagnetic environment-guidance	
RF emissions CISPR 11	Group 1	The BiliBed 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		
Harmonic emissions IEC 61000-3-2	Class A	The BiliBed 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.	
Voltage fluctuations / flicker emissions IEC 60000-3-3	Complies	supplies bullulings used for doffiestic purposes.	

Warning: The BiliBed should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the BiliBed should be observed to verify normal operation in the configuration in which it will be used.

IEC 60601-1-2, Table 202

Electromagnetic Immunity

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

IEC 60601 test level	Compliance level	Electromagnetic environment-guidance
± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
± 2 kV for power supply lines ± 1 kV for input/output lines	lines Mains power quality should be that of a	
± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
$<5\% U_T$ $(>95\% dip in U_T)$ 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 sec	$<5\% U_T$ $(>95\% dip in U_T)$ 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 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the BiliBed requires continued operation during power mains interruptions, it is recommended that the BiliBed be powered from am uninterruptible power supply or a battery.
3 A/m	3 A/m	Power frequency magnetic fields should be at levels of a typical commercial or hospital environment.
	test level ± 6 kV contact ± 8 kV air ± 2 kV for power supply lines ± 1 kV for input/output lines ± 1 kV differential mode ± 2 kV common mode <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 sec	test level Compliance level $\begin{array}{lll} \pm 6 \text{ kV contact} \\ \pm 8 \text{ kV air} \end{array} \qquad \pm 6 \text{ kV contact} \\ \pm 8 \text{ kV air} \end{array} \qquad \pm 6 \text{ kV contact} \\ \pm 8 \text{ kV air} \end{array} \qquad \pm 6 \text{ kV contact} \\ \pm 8 \text{ kV air} \end{array} \qquad \pm 6 \text{ kV contact} \\ \pm 8 \text{ kV air} \end{array} \qquad \pm 6 \text{ kV contact} \\ \pm 8 \text{ kV air} \end{array} \qquad \pm 6 \text{ kV contact} \\ \pm 8 \text{ kV air} \end{array} \qquad \pm 6 \text{ kV contact} \\ \pm 1 \text{ kV for power supply lines} \\ \pm 1 \text{ kV for input/output lines} \qquad \pm 1 \text{ kV for input/output lines} \\ \pm 1 \text{ kV differential mode} \\ \pm 2 \text{ kV common mode} \qquad \pm 1 \text{ kV differential mode} \\ \pm 2 \text{ kV common mode} \qquad \pm 2 \text{ kV common mode} \\ \hline <5\% U_T \\ (>95\% \text{ dip in } U_T) \\ (>95\% \text{ dip in } U_T) \\ (>95\% \text{ dip in } U_T) \\ (>90\% \text{ dip in } U_T) \\ (>95\% \text{ dip in } U_T) \\ $

Electromagnetic Immunity

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

Immunity Tests	IEC 60601 test level	Compliance level	Electromagnetic environment-guidance	
			Portable and mobile RF communications equipment should be used no closer to any part of the BiliBed, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance	
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	$d=1.2\sqrt{P}$ $d=1.2\sqrt{P}$ $d=2.3\sqrt{P}$ 80 MHz to 800 MHz $d=2.3\sqrt{P}$ 800 MHz to 2.5 GHz	
Radiated RF IEC 61000-4-6	3 V/m 80 MHz to 2.5 GHz	3 V/m	where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey a, should be less than the compliance level in each frequency range. b Interference may occur in the vicinity of equipment marked with the following symbol:	
			((·))	

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

IEC 60601-1-2, Table 206

Recommended separation distance between portable and mobile RF communications equipment and the BiliBed

The BiliBed is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BiliBed can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BiliBed as recommended below, according to the maximum output power of the communications equipment.

Rated maximum	Electromagnetic environment-guidance			
output power of transmitter W	150 kHz to 80 MHz $d=1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2 \sqrt{P}$	800 MHz to 2.5 GHz $d=2.3\sqrt{P}$	
0.01	0.12	0.12	0.23	
0.1	0.38	0.38	0.73	
1	1.2	1.2	2.3	
10	3.8	3.8	7.3	
100	12	12	23	

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

^a Field strengths from fixed RF 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 BiliBed is used exceeds the applicable RF compliance level above, the BiliBed should be observed to verify normal operation. If abnormal operation is observed, additional measures may be necessary, such as reorienting or relocating the BiliBed.

^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m erscht

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