Instruction for use

Neonatal phototherapy device

BILI-COMPACT

D2017_00

BILI-COMPACT	**WY 1816/ _____**
Year of manufacture	_____

WEYER GmbH

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Normal use

The phototherapy device BILI-COMPACT is used for the treatment of the neonatal hyperbilirubinemia. It is suitable for continuous operation and conforms to the "Particular requirements for the safety of infant phototherapy equipment" EN 60601-2-50.

General safety instructions

The user must be thoroughly acquainted with this instruction for use. The phototherapy device must only be used under medical supervision by qualified persons who are acquainted with the use and risks of phototherapy devices.

The patient's eyes must be protected carefully against the radiation of the phototherapy device by suitable eye masks which are available in trade.

In order to verify the safe operation of the phototherapy device BILI-COMPACT we recommend an inspection by qualified persons once per year.

In order to guarantee the safe operation of the phototherapy device, in addition to the yearly inspection we recommend a preventive maintenance by authorized qualified persons.

We can only be held responsible for the physical and safety features of this device when it is operated with the specific phototherapy energy saving lamps Blue BAM/PL9/52 and when maintenance is carried out by qualified persons, by using original spare parts.

Operating the device with non-specific fluorescent lamps will cause the loss of warranty claims.

Transport and storage

For transport and storage the following conditions should be observed:

Temperature:	0℃ to 70℃
Relative air humidity:	15 % to 95 %
Atmospheric pressure:	900 to 1100 hPa

The device must not be exposed to strong vibrations.

Ambient requirements

The device can be used under the following operation conditions:

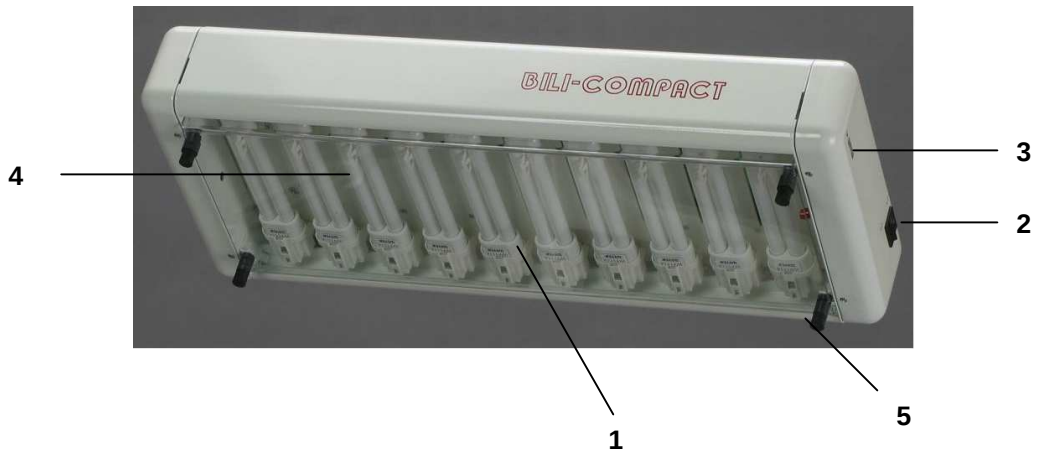
Temperature:	18℃ to 30℃
Relative air humidity:	15 % to 95 %
Atmospheric pressure:	900 to 1100 hPa

This device is not suitable for the use in explosion-hazardous areas.

Mobile telephones may interfere the function of electro-medical devices. Therefore no mobile telephones should be used within a distance of 10 meters around the device.

Structure and operating principle

The phototherapy device BILI-COMPACT includes the following components:



1 10 specific energy saving lamps

2 Switch on-off

3 Operating hour counter

4 Perspex cover

5 Rubber feet

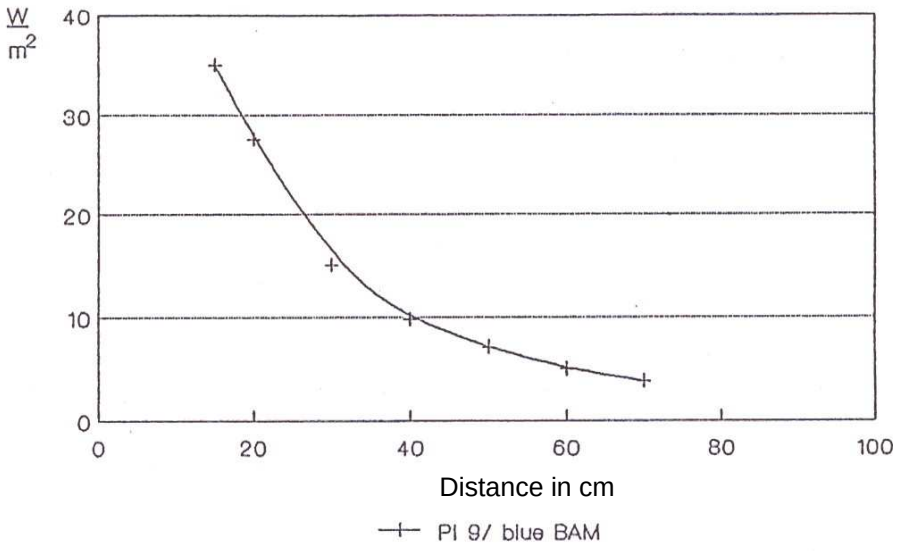
The phototherapy lamp BILI-COMPACT provides 10 special energy saving lamps (1) for performing the phototherapy in the case of hyperbilirubinemia. By means of the rubber feet (5) it can be placed on incubators and warming beds with suitable canopy (load 5 kg, level surface or max. 5° slant).

If this is not possible or not desired, it is also possible to mount the device at a mobile stand with the possiblity of horizontal and vertical adjustment (refer to page 7).

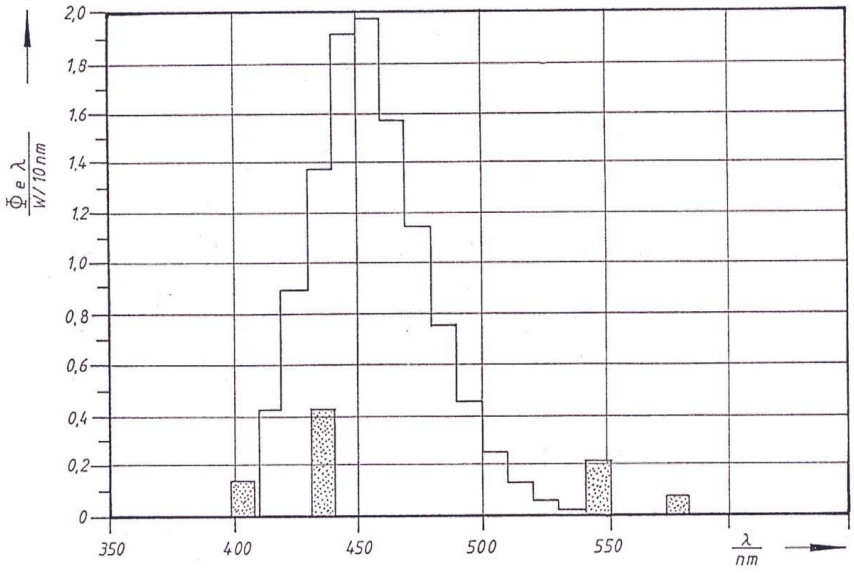
The fluorescent lamps are protected by a unbreakable perspex cover (4). They are switched on with switch (2), and the elapsed operating time is indicated by the operating hour counter (3).

The phototherapy lamp BILI-COMPACT does not emit any heat towards the patient. The generated heat will be led away through the vent holes on the top of the device. Therefore the device can be operated at a very short distance to the patient (min. 200 mm). The radiation intensity generated at the respective distance can be taken from the following diagram.

Radiation intensity



Distribution of spectral intensity



With increasing operating hours the radiation intensity of the bilirubin-effective spectrum begins to decrease. Therefore the 10 specific energy saving lamps tubes should be replaced by qualified persons after approx. 1000 operating hours (see page 7). For checking the elapsed time a digital operating hour counter (3) is provided.

Start-up and functional check

Start-up

Qualified persons only should install and start-up the device and instruct the user's personnel.

For installation it has to be considered that a sufficient distance to warming devices, as e.g. radiant warmers is kept clear. In no case it should be placed in an area exposed to a radiant warmer.

When the phototherapy device BILI-COMPACT shall be placed on an incubator or warming bed, check whether the canopy is suitable for a load of approx. 5 kg and verify whether it is positioned securely.

When mounted at a mobile stand the phototherapy device can also be used for open care systems with radiant warmer. In that case the mobile stand is placed lateral to the infant care system and by means of the flexible fixing head the device is adjusted in a way that the radiation is focussed to the patient in diagonal direction.

Prior to start-up the device itself as well as the mount (if available) must be checked for correct and secure position. Now clean the device in cold condition according to chapter *"Cleaning and disinfection"* (page 8).

Functional check

For functional check switch-on the phototherapy device and check whether all lamps light.

Take care that the focus is exposed directly to the baby's skin and is not disturbed by any other items in the ambience. When the patient pad is irradiated by a radiant warmer, make sure that the phototherapy device is placed beyond the irradiated area.

The patient's eyes must be protected carefully against the therapy light by suitable eye masks which are available in trade.

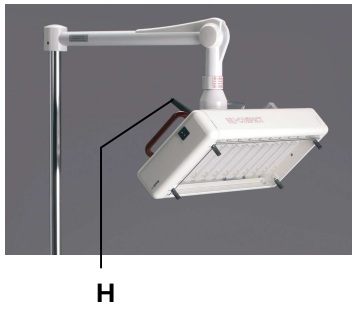
For functional check of the mobile stand (if available) proceed as follows:

Unfasten the knob of the height-adjustment (1) by anti-clockwise turning and adjust the stand to the lowest position. Fasten the knob again by clockwise turning.

Release the kickstop of the castors, move the device to the desired position and brake the castors again. The device must be moved in lowest position only.

Now adjust the phototherapy device to the desired height, as described above, whereas a minimum distance to the patient pad of 200 mm must be kept clear. Take care that the knob of the height-adjustment (1) is fastened again by clockwise turning.

Rotate the phototherapy lamp to the desired position by using the two handles. When the radiation shall be focussed to the patient in diagonal instead of vertical direction, unfasten the release handle (**H**) by anti-clockwise turning and adjust the device to the desired direction. Afterwards fasten the release handle again by clockwise turning.



Use

Place the phototherapy device on the incubator or the warming bed.

When mounted at a mobile stand bring the device into the desired position to the patient by means of the adjustment facilities.

Switch on the device and check the irradiation time at the hour counter. The therapy period mainly depends on the concentration of the serum bilirubin and the radiation intensity.

The device allows to interrupt and resume the therapy at any time.

The infant must be supervised in regular intervals, the following parameters must be checked in particular:

- Concentration of the serum bilirubin.
- Secure position of the eye protection.
- Body temperature.

Due to the absorption of the therapy light the body temperature might change slightly. In that case adjust the temperature of the incubator or the warming bed.

Warnings for use

- Make sure that the phototherapy device is not placed within an area exposed to a radiant warmer.
- Take care that the patient's eye protection is positioned securely.
- The patient's temperature must be monitored or checked in regular intervals.
- When a phototherapy device is used in connection with a radiant warmer, it must be observed that patient temperature and humidity loss can increase.
- Never cover the device during operation.
- Do not place any items or liquid containers on the device and take care that no liquid is splashed over it.
- Never change the tilting position of the incubator or warming bed when the phototherapy device is placed on the canopy because in that case the device might slip from the canopy.

Upgrade items

Order No.	Upgrade items
WY 2003	Height-adjustable mobile stand, 4 antistatic castors, 2 with kickstop, rotation of phototherapy device 360°, vertical adju stment ± 45°.

Cleaning and Disinfection

The phototherapy device BILI-COMPACT should be cleaned and disinfected for every new patient, however, minimum once per week.

After use switch-off the phototherapy device and disconnect the mains plug.

Clean the device with a cloth slightly saturated with a cleaning agent and wipe it dry.

No liquid must enter into the top of the device housing.

Never use inflammable disinfectants!

Do not use scouring cleaning agents. Use only disinfectants on the basis of aldehydes and quaternary ammonium merges. Unsuitable are tincture of iodine 5 %, carbolic acid, spirit, ether, acetone and other alcoholic agents as well as disinfectants on the basis of halogen-splitting merges, strong organic acids and oxygen-splitting merges.

After disinfection let the device dry for at least 1 hour.

After cleaning and disinfection perform a functional check.

Waste disposal

Energy saving lamps: Hazardous waste

Maintenance

Nomenclature

Qualified person	= Skilled worker, engineer, bio-medical engineer, with corresonding qualification.
Authorized qualified person	= Qualified person, who has acquainted special knowledge of a certain product.
Inspection	= Ascertainment of the actual state
Preventive maintenance	= Measures to maintain the nominal state
Repair	= Measures to restore the nominal state
Maintenance	= Inspection, preventive maintenance, repair

In order to verify the safe operation of the phototherapy device BILI-COMPACT, we recommend an inspection by qualified persons once per year which include the following checks:

- *Verification that the actual use is in conformance with the normal use.*
- *Visual examination of the general condition of the device.*
- *Function and secure position of the mounting elements (as far as available).*
- *Function and secure fixing of the rotating, swiveling, height-adjustment facilities (as far as available).*
- *Possible damages at the device, mounting elements or mains cord.*
- *Functions of device.*
- *Operating hours (< 1000 hours).*
- *Measurement of the electrical safety according to the local standards.*

In order to guarantee the safe operation of the phototherapy device, in addition to the yearly inspection we recommend a preventive maintenance by qualified persons which includes the following checks:

- *Check of: Interior wiring, connections and heating elements.*
- *Check of all parameters according to IEC 601-2.*

We can only be held responsible for the physical and safety features of this device when it is operated with the specific energy saving lamps Blue BAM/PL9/52 and when maintenance is carried out by qualified persons, by using original spare parts.

Devices respectively device components have to be cleaned and disinfected prior to each maintenance measure or when they are sent out to our factory for repair.

Replacement of the phototherapy lamps

With increasing operating hours the radiation intensity of the bilirubin-effective spectrum begins to decrease. Therefore the 10 specific energy saving lamps should be replaced by qualified persons after approx. 1000 operating hours. Disconnect the mains plug and screw-off the 4 rubber feet. Take-off the perspex cover. Now pull the lamps from their sockets and replace them by new ones. Fix the cover again and screw-on the rubber feet. Then set the operating hour counter to zero by pushing the red button in the housing.

Prior to operation perform a functional check.

Illuminants

Order No.	
WY 1114	Energy saving lamp Blue BAM/PL9/52

Technical Data

Transport and storage

Temperature	0°to 70℃
Relative air humidity	15 to 95%
Atmospheric pressure	900 to 1100 hPa

Ambient requirements

Temperature	18°to 30℃
Relative air humidity	15 to 95%
Atmospheric pressure	900 to 1100 hPa

General data

BILI-COMPACT Order No. WY 1816	
Depth	525 mm
Width	220 mm
Height	90 mm
Weight	4.8 kg
Mobile stand Order No. WY 2003	
Depth	560 mm
Width	560 mm
Overall height	1535 to 1935 mm
Necessary under-pin height	> 95 mm
Castors	4 x 52 mm Ø (2 with kickstop)
Weight	16 kg
Height adjustment of the bottom side of the phototherapy device	1315 to 1675 mm

Operating / Performance data

Operating voltage / power supply	~ 230 V / 50 Hz
Max. power input	0.6 A / 140 W
Safety distance to the patient pad	200 mm
Wave length spectrum	460 nm
Bilirubin-effective radiation intensity E_{bi}:	
at 350 mm distance	16 W/m²
at 250 mm distance	20 W/m²
at 200 mm distance	30 W/m²
Irradiated area:	
at 350 mm distance	400 x 700 mm
at 200 mm distance	300 x 600 mm
Lamp assembly	10 specific energy saving lamps Blue BAM/PL9/52

Classification

Protection class	1
Device type	B
MDD class	IIa

Standards

The device conforms to	EN 60601(Ausg. 1996)
	EN 60601-2-50

Registration

CE 0197

EG-Konformitätserklärung

EC Declaration of Conformity

DECLARATION CE DE CONFORMITE

Wir · *We* · NOUS,

WEYER

Herrenhöhe 4

D - 51515 Kürten-Herweg / Germany

erklären, dass das Produkt · *declare that the product* · DECLARONS QUE LE PRODUIT

Phototherapiegeräte • *Phototherapy devices* • APPAREILS PHOTOTHERAPIE

BILI-COMPACT

Klasse · *Class* · CLASSE **II a**

entsprechend den Vorgaben der Richtlinie 93/42/EWG Anhang II, Artikel 3, vollständiges Qualitätssicherungssystem, Medizinprodukte, unter Registrier-Nr. HD 60004903 0001 gefertigt wird. Das Produkt trägt das unten aufgeführte CE-Zeichen.

is produced in accordance with the requirements specified in EC Directive 93/42/EEC, Annex II, Article 3, Full Quality Assurance System, Medical Devices, under Registration No. HD 60004903 0010. The product bears the below mentioned CE-mark.

EST PRODUIT CONFORMEMENT AUX EXIGENCES DE LA DIRECTIVE EUROPEENNE 93/42/CEE, ANNEXE II, ARTICLE 3, SYSTEME COMPLET D'ASSURANCE QUALITE, DISPOSITIFS MEDICAUX, SOUS N° D'ENREGISTREMENT HD 60004903 0001. LE PRODUIT PORTE LE MARQUAGE CE MENTIONNE CI-DESSOUS.

CE 0197

Kürten, 19. Mai/May 2003

Ort und Datum *Place and date* LIEU ET DATE	Geschäftsleitung *General Management* DIRECTION GENERALE	Qualitätssicherung *Quality Assurance* ASSURANCE QUALITE

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