PHOTOTHERAPY LAMP

BabyGuard U-1131

Operator's Manual

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DIXION VERTRIEB MEDIZINISCHER GERÄTE GMBH

CE 0483

Please take well care of it.

Guidance and manufacture's declaration – electromagnetic emissions-
for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic emission		
The *BABYGUARD U-1131 Neonate Bilirubin Phototherapy Equipment* is intended for use in the electromagnetic environment specified below. The customer of the user of the *BABYGUARD U-1131* should assure that it is used in such and environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The *BABYGUARD U-1131 Neonate Bilirubin Phototherapy Equipment* 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 emission CISPR 11	Class B	The *BABYGUARD U-1131 Neonate Bilirubin Phototherapy Equipment* 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacture's declaration – electromagnetic immunity –
for all EQUIPMENT and SYSTEMS

Guidance and manufacture's declaration – electromagnetic immunity			
The *BABYGUARD U-1131 Neonate Bilirubin Phototherapy Equipment* is intended for use in the electromagnetic environment specified below. The customer or the user of *BABYGUARD U-1131 Neonate Bilirubin Phototherapy Equipment* should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floor are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines	±2kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±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.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<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 *BABYGUARD U-1131 Neonate Bilirubin Phototherapy Equipment* requires continued operation during power mains interruptions, it is recommended that the *BABYGUARD U-1131 Neonate Bilirubin Phototherapy Equipment* be powered from an uninterruptible power supply or a battery.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacture's declaration – electromagnetic immunity –
for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacture's declaration – electromagnetic immunity

The *BABYGUARD U-1131 Neonate Bilirubin Phototherapy Equipment* is intended for use in the electromagnetic environment specified below. The customer or the user of *BABYGUARD U-1131 Neonate Bilirubin Phototherapy Equipment* should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	$3V_{rms}$ 150 kHz to 80 MHz	$3\ V_{rms}$	Portable and mobile RF communications equipment should be used no closer to any part of the *BABYGUARD U-1131 Neonate Bilirubin Phototherapy Equipment*, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	3 V/m	$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80 MHz to 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 800 MHz to 2.5 GHz 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 metres (m). [b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[c] should be less than the compliance level in each frequency range.[d] 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.

[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 *BABYGUARD U-1131 Neonate Bilirubin Phototherapy Equipment* is used exceeds the applicable RF compliance level above, the *BABYGUARD U-1131 Neonate Bilirubin Phototherapy Equipment* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the *BABYGUARD U-1131 Neonate Bilirubin Phototherapy Equipment*.

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

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM – for EQUIPMENT or SYSTEM that are not LIFE-SUPPORTING

<table>
<tr><th colspan="4">Recommended separation distances between
portable and mobile RF communications equipment and the BABYGUARD U-1131 Neonate Bilirubin Phototherapy Equipment</th></tr>
<tr><td colspan="4">The BABYGUARD U-1131 Neonate Bilirubin Phototherapy Equipment is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the BABYGUARD U-1131 Neonate Bilirubin Phototherapy Equipment can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the BABYGUARD U-1131 Neonate Bilirubin Phototherapy Equipment as recommended below, according to the maximum output power of the communications equipment.</td></tr>
<tr><td rowspan="2">Rated maximum output power of transmitter (W)</td><td colspan="3">Separation distance according to frequency of transmitter (m)</td></tr>
<tr><td>150 kHz to 80 MHz
$d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$</td><td>80 MHz to 800 MHz
$d = \left[\frac{3.5}{E_1}\right]\sqrt{P}$</td><td>800 MHz to 2.5 GHz
$d = \left[\frac{7}{E_1}\right]\sqrt{P}$</td></tr>
<tr><td>0.01</td><td>0.12</td><td>0.12</td><td>0.23</td></tr>
<tr><td>0.1</td><td>0.38</td><td>0.38</td><td>0.73</td></tr>
<tr><td>1</td><td>1.2</td><td>1.2</td><td>2.3</td></tr>
<tr><td>10</td><td>3.8</td><td>3.8</td><td>7.3</td></tr>
<tr><td>100</td><td>12</td><td>12</td><td>23</td></tr>
<tr><td colspan="4">For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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.</td></tr>
</table>

WARRANTY

The product being described in this manual is warranted against defects in materials or workmanship for one year from the date of shipment, with the following exceptions.

1. All consumable and disposable products are guaranteed to be free from defects upon shipment only.

2. Calibrations are considered normal maintenance and are not included in the 1-year warranty.

During the warranty period any defective parts other than those listed above will be replaced at no charge to the customer.

This warranty is rendered void and our company cannot be held liable for conditions resultant therefrom if:

1. Damage to the unit is incurred as a result of mishandling.

2. The customer fails to maintain the unit in a proper manner.

3. The customer uses any parts, accessories, or fittings not specified or sold by our company.

4. Sale or service is performed by the non-certified service/dealer agency.

This warranty is in lieu of all other warranties, expressed or implied, and our company shall in no event be liable for incidental or consequential damages including loss of use, property damage, or personal injury resulting from breach of warranty.

The Accreditation Manual for Hospitals requires each piece of equipment to be tested prior to initial use and at least annually thereafter. To comply with this standard, we recommend that you participate in our accreditation Testing compliance Program during the warranty period. This service can be performed through our company and authorized dealers.

SERVICE

For optimal performance, product service should be performed only by qualified service personnel.

OPERATING PRECAUTIONS

1. The NEONATE BILIRUBIN PHOTOTHERAPY EQUIPMENT misuse may result in harm to an infant. The NEONATE BILIRUBIN PHOTOTHERAPY EQUIPMENT should be used only by properly trained personnel as directed by an appropriately qualified physician aware of currently known hazards and benefits.

2. Devices which are easily interfered by magnetic field should not be used near the phototherapy because they may interfered by the phototherapy.

3. The phototherapy couldn't be used under the high electromagnetism field.

4. The PHOTOTHERAPY EQUIPMENT shall not be used in the presence of gases which can support combustion (e.g. oxygen, nitrous oxide, anaesthetic agents).

5. It is not allowed to treat the PHOTOTHERAPY EQUIPMENT with flammable solutions (antiseptics, cleaning agents, etc).

6. DO NOT store the drugs and infusion liquids in the radiation area of the NEONATE BILIRUBIN PHOTOTHERAPY EQUIPMENT.

7. For infant safety, the NEONATE BILIRUBIN PHOTOTHERAPY EQUIPMENT must be used for infants in a protective barrier, such as a bassinet, an open crib, an incubator, or a radiant warmer etc.

8. The varying ambient conditions (e.g., temperature, radiation source) around the PATIENT all can affect patients' temperature and the bilirubin value. To make sure to keep the body temperature of infant stable when the infant receives the phototherapy treatment, try to make the ambient environment suitable and stable where the NEONATE BILIRUBIN PHOTOTHERAPY EQUIPMENT is located. If not, it will affect the infant. If the ambient temperature is much lower, it will decrease the body temperature of infant and make the infant catch cold; while If the ambient temperature is much higher, it will increase the body temperature of infant and make the infant overheat. Moreover, the ambient air flow rate decrease the body temperature of infant and make the infant catch cold.

9. Although the infrared radiation intensity from The NEONATE BILIRUBIN PHOTOTHERAPY EQUIPMENT is much lower, with long time radiation, it will cause the body temperature of baby to rise. In addition, when The NEONATE BILIRUBIN PHOTOTHERAPY EQUIPMENT is used together with thermotherapy devices, such as an incubator, a radiant warmer or a heated mattress, it will affect the temperature uniformity of these thermotherapy devices to rise the body temperature of infant. Therefore, the operator needs to measure the body temperature of infant regularly.（we suggest at least once an hour）

10. Make thermotherapy devices mentioned above work under the baby mode, otherwise the set air temperature of the thermotherapy devices has to be reduced according to body temperature measurements.

11. Please do not put your hand on the gap between the lamp and its mounting bracket as the figure indicates to avoid hurting your finger.

12. For optimum the mobile NEONATE BILIRUBIN PHOTOTHERAPY EQUIPMENT stability, and for prevent the infant from falling off the EFFECTIVE SURFACE AREA, always lock the mobile stand wheels during use.

13. For safety and affectivity of the NEONATE BILIRUBIN PHOTOTHERAPY EQUIPMENT, the customers can only use the spare parts sold by our company, such as fluorescent tubes.
14. For affectivity of the NEONATE BILIRUBIN PHOTOTHERAPY EQUIPMENT, make sure all fluorescent tubes have to be changed when the expected lifetime has been exceeded.
15. Before replacing the fuse, you must cut off the power supply, and then change fuses as marked.
16. The device, accessories and the packaging have to be disposed of waste correctly at the end of the usage. Please follow Local Ordinances or Regulations for disposal.

ELECTRICAL PRECAUTIONS

1. To ensure grounding reliability, connect the ac power cord only to a properly grounded 3-wire hospital grade or hospital use outlet. Do not use extension cords. If any doubt exists as to the grounding connection, do not operate the equipment.
2. An electric shock hazard exists within the Lamp when the cover is removed. Servicing should be performed only by qualified personnel with appropriate service documentation.
3. Make sure the building power source is compatible with the electrical specifications shown on the rear of the Lamp.
4. The safety of auxiliary devices shall comply with the general requirements for safety according to IEC60601-1.
5. Switch only cut off one pole of the mains supply, it is not a safety disconnecting switch, the appliance inlet is used as the disconnect device, always remain coupler readily operable. Use of appliance inlet as the intended isolation means.

SEASONAL SAFETY CHECK

1. Please clean the plug of power cord at least once a year. Too much dust on plug may cause the fire.
2. The following safety checks should be performed at least every 12 months by a qualified person who has adequate training, knowledge, and practical experience to perform these tests. The data should be recorded in an equipment log. If the device is not functioning properly or fails any of the above tests, the device has to be repaired.

○,1. Inspect the equipment and accessories for mechanical and functional damage.

○,2. Inspect the safety relevant labels for legibility.

○,3. Inspect the fuse to verify compliance with rated current and breaking characteristics.

○,4. Verify that the device functions properly as described in the instructions for use.

○,5. Test the protection earth resistance according IEC 60601-1:1988 + A1:1991 + A2:1995: Limit 0.1Ω.

○,6. Test the earth leakage current according IEC 60601-1:1988 + A1:1991 + A2:1995: Limit: NC 500μA, SFC: 1000μA.

○,7. Test the enclosure leakage current according to IEC 60601-1:1988 + A1:1991 + A2:1995: Limit: NC 100μA, SFC: 500μA.

TABLE OF DEFINITIONS AND SYMBOLS

TECHNICAL DEFINITIONS

EFFECTIVE SURFACE AREA: Surface on which the PATIENT rests according to the intended position and which is radiated by the PHOTOTHERAPY EQUIPMENT.

TOTAL IRRADIANCE FOR BILIRUBIN E_{bi} : Irradiance equal to the evaluated irradiance in the range between 400 nm and 550 nm.

UNIFORMITY G_2 OF THE TOTAL IRRADIANCE FOR BILIRUBIN: Ratio of the lowest TOTAL IRRADIANCE FOR BILIRUBIN $E_{bi\ min}$ to the highest TOTAL IRRADIANCE FOR BILIRUBIN $E_{bi\ max}$ on the EFFECTIVE SURFACE AREA.

LIFETIME OF NEONATE BILIRUBIN PHOTOTHERAPY EQUIPMENT: the period from sell-by date to the date of discarding as useless.

LIFETIME OF LIGHT SOURCE: Time after the average total irradiance for bilirubin E_{bi} is attenuated by 25%.

NOTE, IMPORTANT, CAUTION AND WARNING

NOTE: A note is inserted in text to point out procedures or conditions, which may otherwise be misinterpreted or overlooked. A note may also be used to clarify apparently contradictory or confusing situations.

IMPORTANT: Similar to a Note but be used where greater emphasis is required.

CAUTION: A caution is inserted in text to call attention of a procedure which, It not followed exactly, can lead to damage or destruction of the equipment.

WARNING: A warning is inserted in text to call attention to dangerous or hazardous conditions inherent to the operation, cleaning, and maintenance of the equipment which may result in personal Injury or death of the operator or patient.

SYMBOLS

	Refer to instruction manual		
CLASS I	Class I Equipment		Caution: DO NOT catch your finger
220-230V~ 50Hz	Input Power	**F 1AL/250V**	Type F Fuse 1AL/250V
	Power on		Power off
	Date of Manufacture		Serial Number
	Eye mask mark		CE Marking
	Non-ionizing radiation		Manufacturer
	Authorised representative in the European community		

TABLE OF CONTENTS

SECTION **PAGE**

1. GENERAL INTRODUCTION

This manual provides instructions for installation, operation, cleaning and maintenance of the NEONATE BILIRUBIN PHOTOTHERAPY EQUIPMENT. We cannot be responsible for the performance of the NEONATE BILIRUBIN PHOTOTHERAPY EQUIPMENT if the user does not operate the unit in accordance with the instructions, fails to follow the maintenance recommendations in this manual, or effects any repairs with unauthorized components. Repair should be performed only by qualified service personnel. Technical information is available through your local distributor.

Before using the device, all personnel, who will be working with the unit, should read and thoroughly understand this manual.

This manual should be stored with the NEONATE BILIRUBIN PHOTOTHERAPY EQUIPMENT for consulting anytime.

2. INTENDED USE

Emits a visible light of high-intensity in the range of 400nm - 550nm via blue fluorescent tubes intend for the treatment of neonatal hyperbilirubinemia.

3. COMPOSITION OF PRODUCTS

The NEONATE BILIRUBIN PHOTOTHERAPY EQUIPMENT consists of the lamp, and the mobile stand. It can be used with mobile stand (Mobile PHOTOTHERAPY UNIT), or lamp-only without mobile stand for use on incubator hood (Incubator mounted PHOTOTHERAPY UNIT).

4. DESCRIPTION

○,1. Mobile PHOTOTHERAPY UNIT

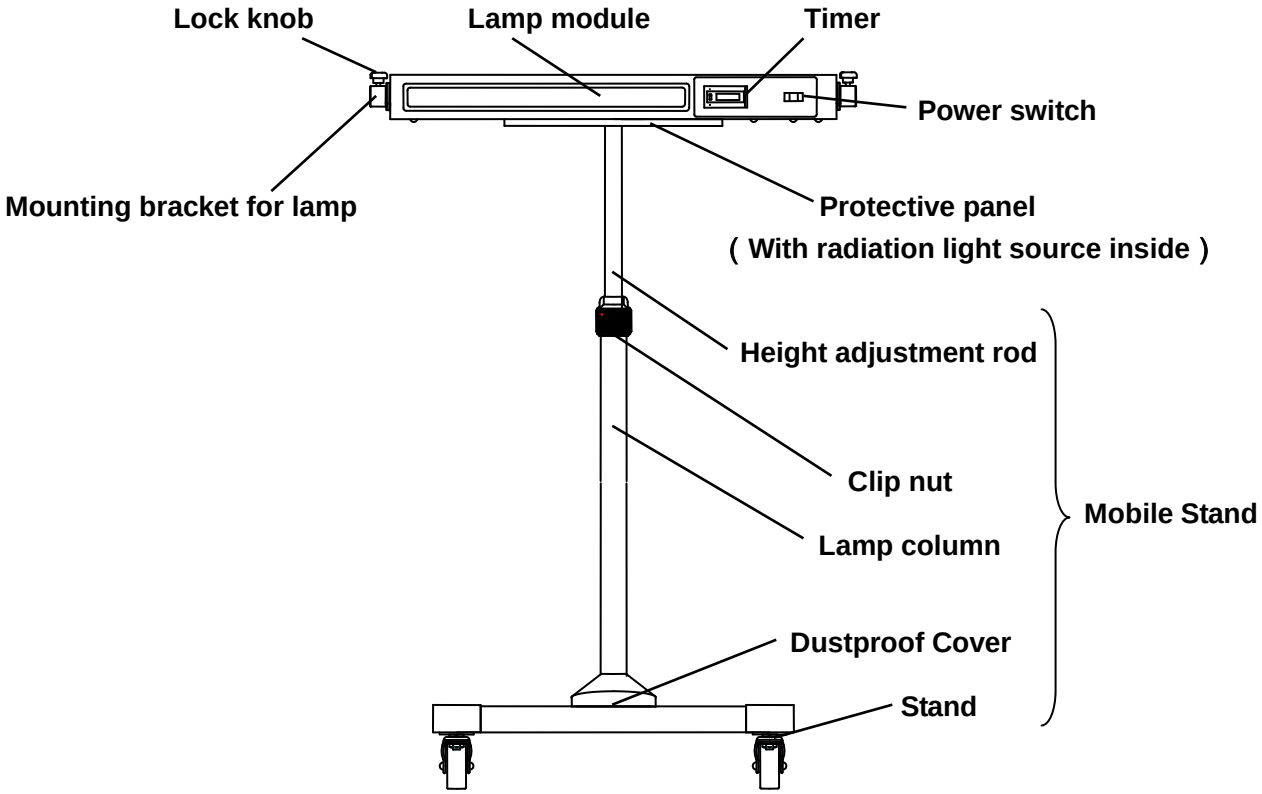


FIGURE 1

DESCRIPTION OF PART	EXPLANATION
Lamp module	This main part is composed of radiation light source, reflective panel, built-in timer and so on, and it is the core for NEONATE BILIRUBIN PHOTOTHERAPY EQUIPMENT.
Mounting bracket for lamp, lock knob	For adjusting the radiation angle of lamp module.
Height adjustment rod, clip nut, Lamp column	For adjusting the height of NEONATE BILIRUBIN PHOTOTHERAPY EQUIPMENT.
Stand	For moving the NEONATE BILIRUBIN PHOTOTHERAPY EQUIPMENT. With 4pcs casters with brakes.

○,2. Incubator Mounted PHOTOTHERAPY UNIT

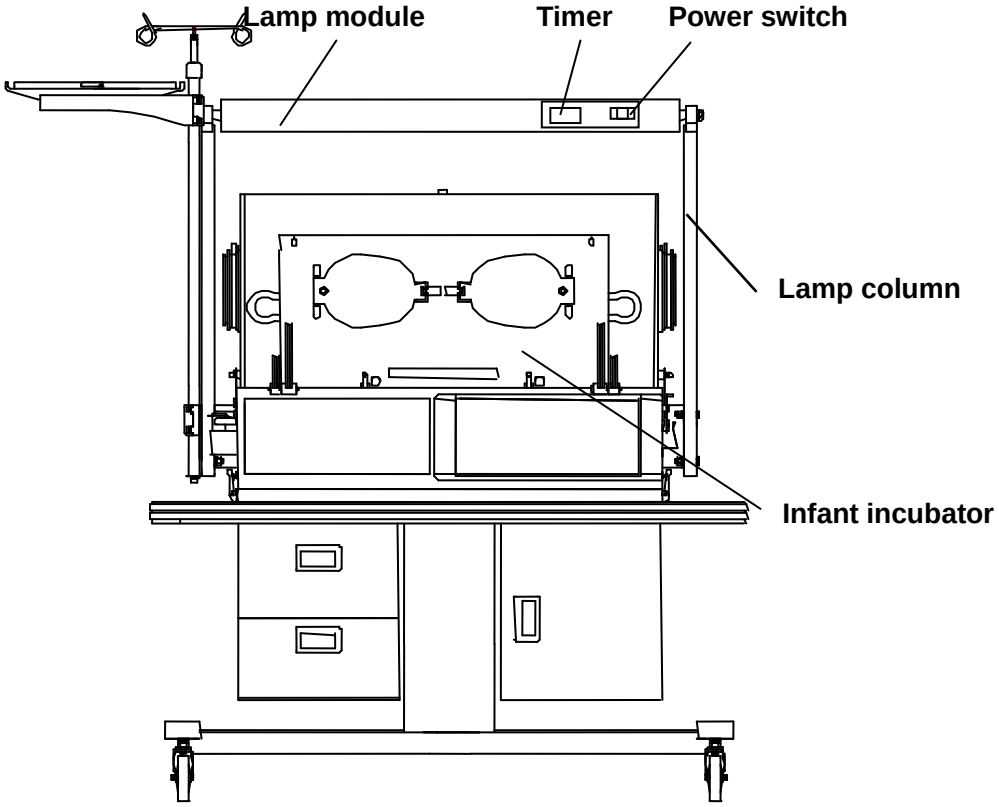


FIGURE 2

DESCRIPTION OF PART	EXPLANATION
lamp module	This main part is composed of radiation light source, reflective panel, built-in timer and so on, and it is the core for NEONATE BILIRUBIN PHOTOTHERAPY EQUIPMENT.
Lamp column	For installing the phototherapy unit on top of the infant incubator.

5. SPECIFICATIONS

Specifications for the NEONATE BILIRUBIN PHOTOTHERAPY EQUIPMENT are provided in table 1.1. **(IP20)**

TABLE 1.1 SPECIFICATIONS

This equipment belongs to Class I, normal advice (IP20) continuously operated and moveable.

Power requirements.....AC 220-230V, 50Hz, 150VA

Light source.....blue fluorescent tubes

Peak spectrum.....436 nm

Lifetime of the light source.....2000 hours

Treatment distance.....40 cm

46 cm (on top of incubator hood)

The highest total irradiance for bilirubin $E_{bi\ max}$ on the effective surface area.....1.1mW/cm^2

（for Mobile PHOTOTHERAPY UNIT）

0.73mW/cm^2

（for Incubator Mounted PHOTOTHERAPY UNIT）

The total spectral irradiance on the effective surface area.....≥1mW/cm^2

（for Mobile PHOTOTHERAPY UNIT）

≥0.6mW/cm^2

（for Incubator Mounted PHOTOTHERAPY UNIT）

Total irradiance for bilirubin between all points $E_{bi\ min}$ and $E_{bi\ max}$ measured on the effective surface area.....≥0.9mW/cm^2（for Mobile PHOTOTHERAPY UNIT）

≥0.64mW/cm^2（for Incubator Mounted PHOTOTHERAPY UNIT）

Uniformity G_2 of the total irradiance for bilirubin..... > 0.4

Infrared radiation on the effective surface area.....≤1mW/cm^2

Ultraviolet radiation on the effective surface area.....≤1.0×10^{-5}mW/cm^2(180nm＜λ≤400nm）

Working noise .....ambient noise≤40dB(A), working noise≤50dB(A)

Adjusting range for the radiation angle of lamp module.....0 - 60^o up from horizontal

（only for Mobile PHOTOTHERAPY UNIT）

Adjusting range for the height of lamp module.....1350mm～1650mm

（only for Mobile PHOTOTHERAPY UNIT）

Built-in timer range.....0～9999 hour 59 minute

ENVIRONMENT TEMP (Not to use in the environment exceed specified)

Operating Range.....28℃～34℃

Storage Range.....-40℃～+55℃

TABLE 1.1 SPECIFICATIONS (continued)

ENVIRONMENT HUMIDITY

Operating Range.....30%~75%

Storage Range.....≤93%

ATMOSPHERE PRESSURE

Shipment and store atmospheric pressure range.....500hPa~1060hPa

Working atmospheric pressure range.....700hPa~1060hPa

AIR FLOW RATE

Ambient air movement rate.....<0.3m/s

OTHER SPECIFICATION

Mobile PHOTOTHERAPY UNIT measurement.....W620 mm×D705mm×H1350 mm
（height adjustment rod is in the lowest position）
W620 mm×D705mm×H1650 mm
（height adjustment rod is in the highest position）

Incubator Mounted PHOTOTHERAPY UNIT measurement.....W420mm×D1000mm×H810mm

Mobile PHOTOTHERAPY UNIT weight.....18kg

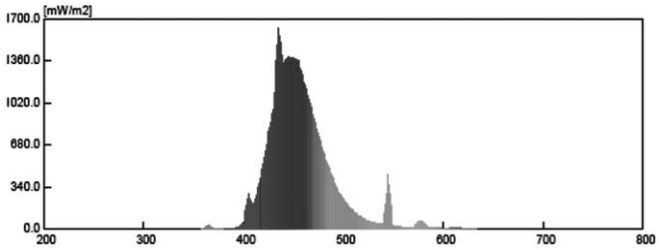
Incubator Mounted PHOTOTHERAPY UNIT weight.....10kg

The lifetime.....6years

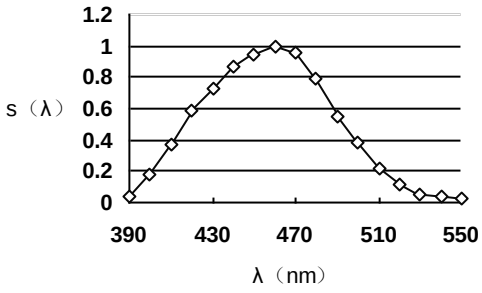
The total spectral irradiance Ebi over a wavelength interval of 5 nm for the wavelergth range between 320nm and 550nm.

320	0.0000000000	440	1.3437560000
325	0.0002263115	445	1.3883840000
330	0.0003517015	450	1.3795570000
335	0.0007115999	455	1.3621770000
340	0.0005458509	460	1.2156100000
345	0.0007096233	465	1.0839190000
350	0.0009008565	470	0.9247026000
355	0.0012197530	475	0.7754273000
360	0.0024330560	480	0.6321588000
365	0.0318963300	485	0.5123221000
370	0.0055510150	490	0.4077117000
375	0.0022163800	495	0.3114630000
380	0.0026974830	500	0.2422230000
385	0.0032235330	505	0.1879411000
390	0.0061878290	510	0.1472856000
395	0.0136484000	515	0.1131187000
400	0.0517163900	520	0.0866815200
405	0.2871739000	525	0.0671371500
410	0.1833341000	530	0.0543263300
415	0.3342484000	535	0.0438082300
420	0.5276484000	540	0.0448307100
425	0.7809934000	545	0.4463736000
430	0.9680536000	550	0.0298159600
435	1.6197250000		

Spectral distribution



The calibration curve of the measurement device



6. INSTALLATION

Generally, the mobile phototherapy unit is usually packed to one carton, and the fixed phototherapy unit is usually packed with the infant incubator together. When taking out the equipment from the cartons, take care not to damage the spare parts of it.

At least two professionals do the installation of the NEONATE BILIRUBIN PHOTOTHERAPY EQUIPMENT with screwdriver and spanners.

A. Installation of the mobile phototherapy unit

a. Install the lamp column on the stand

See figure 3, first, unscrew the 4pcs cross groove pan head bolt M6 X16 for fixing the stand, Spring washer Φ6, Flat washer Φ6 with screwdriver, and then put the lamp column on the stand, move the dustproof cover upward, and fix the lamp column on the stand with the previous unscrewed bolt, Spring washer and Flat washer, at last put down the dustproof cover lightly.

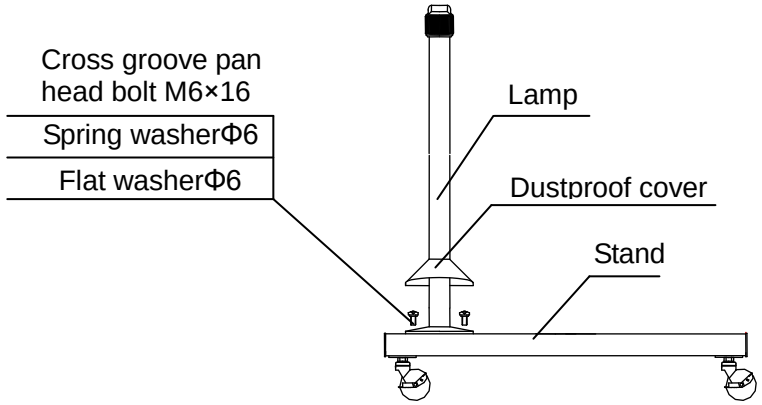
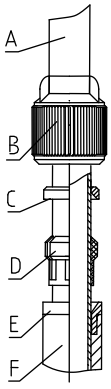


FIGURE 3

b. Install the height adjustment rod

①Rotate the clip nut anticlockwise in figure 4, and take out the clip nut, clamping ring, clamping claw, clamping seat.

② Make the clamping seat, clamping claw, clamping ring and clip nut through the height adjustment rod, and then insert the rod inside the lamp column, and then tighten the fixed nut clockwise.



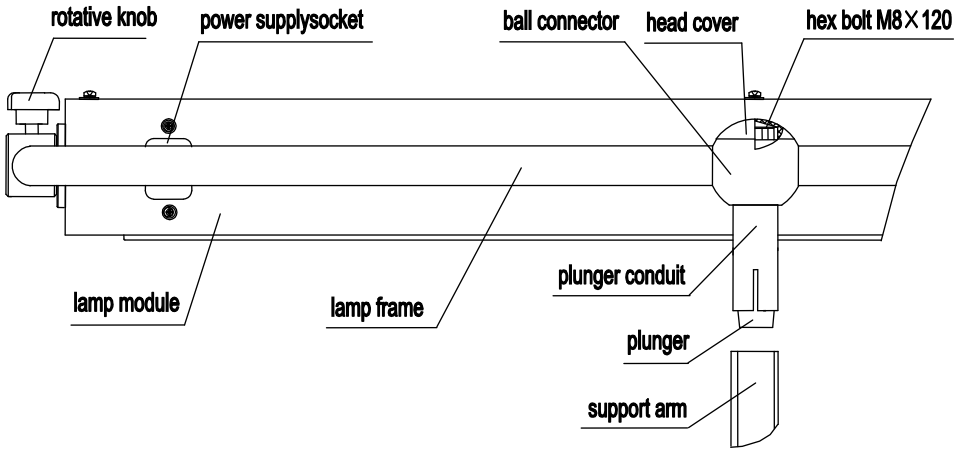
A. Height adjustment rod
B. Clip nut
C. Clamping ring
D. Clamping claw
E. Clamping seat
F. Lamp column

FIGURE 4

c. Install the lamp module

① See figure 5, insert the lamp module into the height adjustment rod.

② Unscrew the cover cap anticlockwise, and fix the hexagon bolt M8×120 with spanner to fix the lamp module on the height adjustment rod, and install the cover cap to its own position.



WARNING: Please ensure the M8×120 hexagon bolts are tightly fixed, or the whole device would rollover because of horizontal turning of the lamp module.

FIGURE 5

d. Insert the power cord

Insert the power cord into the socket in figure 5.

B. Installation of fixed phototherapy unit

a. Install the frame of square ruler

See figure 6, put the square rulers on the left and right side of hood respectively, and fix it with spring washer and flat washer and the hexagon bolt.

b. Install the lamp column

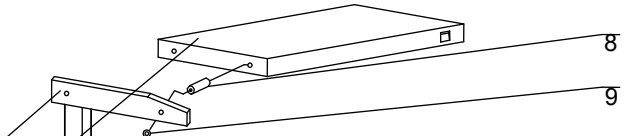
See figure 6, fix the lamp column and square ruler with the spring washer, flat washer, and hexagon nut. The installation of left and right lamp column are same.

c. Install lamp module

See figure 6, fix the lamp module between the left and right lamp column with the spring washer, flat washer, lamp column, bush and hexagon bolt.

d. Insert the power cord

Insert the power cord into the auxiliary power output socket of infant incubator.



1	Lamp column 2	2	Lamp module.....1	3	Hexagon bolt M10×90...4
4	Hexagon bolt M8×16.....4	5	Hexagon bolt M8×35.....4	6	Flat washer 8.....12
7	Frame of square ruler.....2	8	Bush.....4	9	Flat washer 4
10	Spring washer 10.....4	11	Hexagon nut M8.....4	12	base.....1
13	Spring washer 8.....8				

FIGURE 6

7. GENERAL OPERATING PROCEDURES

WARNING

1. **The direct radiation of light source would damage the eyes. So the patients who are close to the equipment or during phototherapy treatment should wear the eye mask to avoid the keratitis or thermal damage of retina.**
2. **Please cover the genitalia with diaper or its likes during phototherapy treatment to prevent harm on the genitalia.**
3. **The patients' water balance may be disturbed during phototherapy treatment, the nurses should supply the water for the patient in time.**
4. **Photoisomers of the bilirubin may cause toxic effects. For example, the patient maybe has diarrhea, kernicterus shortage, hemolysis, anaemia, and so on, so the nurse should give more wardship.**
5. **Measure the bilirubin concentration of patient regularly.**
6. **To avoid the phenomenon of being dizzy and sand-blind, the nurse should not stay long time in the radiation area.**

7.1 Preparation before operation

7.1.1 Make sure to clean and sterilize the PHOTOTHERAPY UNIT according to the instruction in Section 8 of this user's manual.

7.1.2 Make sure that the PHOTOTHERAPY UNIT can work. For example, all light sources can work and the timer can work too.

7.1.3 If you purchase the Mobile PHOTOTHERAPY UNIT，please proceed the following procedure before giving the patient phototherapy treatment:

Through loose the lock knob in figure 1, and adjust the angle of lamp module to the parallel position above the effective surface area in figure 7, and then adjust the height of mobile PHOTOTHERAPY UNIT by loose the clip nut anticlockwise in figure 1 until the distance between the lamp module and the effective surface area is 40cm.

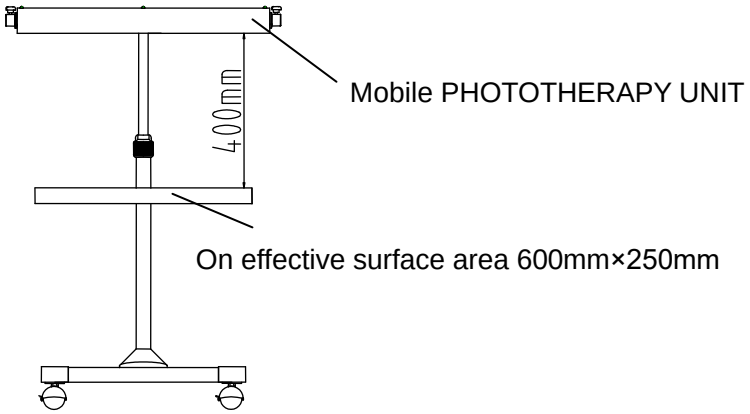


FIGURE 7

IMPORTANT：1. To make sure the safety of patient and the efficiency of phototherapy treatment, and keep the distance between the lamp module and the effective surface area at 40cm.

2. To reach the best phototherapy treatment, you must make sure the centre point of the lamp module and the one on effective surface area are on the same line.

3. The area size of effective surface and the distance of the irradiation light source both can affect the average value of total bilirubin irradiance. The larger the effective surface is, the smaller the average value is. The longer the distance is, the smaller the average value is. Otherwise the opposite.

WARNING

Please do not loose your hand during rotating the clip nut to avoid the lamp module and the height adjustment rod pop up from the lamp column. (See figure 1)

7.1.4 If you purchase the Incubator Mounted PHOTOTHERAPY UNIT, and you do not need to process the preparation in point 7.1.3.

7.2 Operation

7.2.1 Put the naked patient on the effective surface area in figure 7. If it is Incubator Mounted PHOTOTHERAPY UNIT，please put the patient on the mattress.（Note：The whole surface of mattress for infant incubator is the effective surface area）

IMPORTANT：To reach the best phototherapy treatment, make the patient lie on effective surface

area.

7.2.2 Wear the eye mask for the patient, and cover the genitalia with diaper or its likes.

7.2.3 Connect the power supply and switch on the equipment to start the phototherapy treatment on the patient.

NOTE: As for the time of phototherapy treatment, please follow the instruction of physician.

WARNING

You must use the power cord along with this model, or else, it will decrease the safety of whole unit.

7.2.4 The operator should exit the radiant area after finishing above procedure to avoid the long time light radiation. Please do not stare at the light source when operate the unit again.

7.2.5 Timer operation

The timer can count the elapsed time accumulatively or reset itself then recount. And if turn off the power switch, the timer displays the accumulative elapsed time and stops working until turn on power switch again, then it will keep on counting. If you want to reset the timer, please press the reset key.

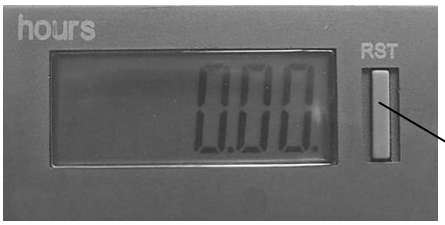


FIGURE 8

NOTE: 1. To make sure the accuracy of accumulative time or the current working time, please do not switch on the device before connecting the power supply.

2. To record the accumulative time of lamp accurately, please do not press reset key to clear the current record time when the lift time of lamp does not expire.

8. CLEANING

Please clean and sterilize the whole unit for initial use or use it for one week.

Please cut off the power supply and turn off the switch before cleaning.

Use a disinfectant-detergent registered by nation to thoroughly clean all surfaces including all corners and hollow part; then dry with a clean cloth or paper towel.

NOTE: To avoid the crack on the acrylic hood, please do not clean it with the alcohol, acetone,

or other organic solution; do not put it under the ultraviolet radiation.

CAUTION: Avoid the liquid flowing into the inside of device through the radiator hole during cleaning.

9. STERILIZATION

NOTE: Please do not use steam autoclave.

Please use the cold sterilization.

10. MAINTENANCE

The total bilirubin radiation of the phototherapy equipment must be measured by the trained and experienced personnel every 12 months. And make sure that the surveyor's certificate is available during the measurement.

Draw the effective surface on the infant bed as showed in picture 5, mark off square subregion which the distance is 50mm, then measure the total bilirubin radiation for each subregion and find out the maximum value with a irradiatometer (The sensitivity of irradiatometer requires to meet "The calibration curve of the measurement device" shown). Please replace the light source if the measured total bilirubin radiation value is lower than 25% of the claimed value.

In order to ensure the good effect of phototherapy treatment, when the lifetime of lamp ends, it must be replaced although it can work normally. The reasons are:

The light radiation capacity will be reduced with the prolonging working time and will make the average total bilirubin radiation attenuated, leading to the equipment lose the expected effect during the treatment.

For the lamp's replacing, it should be replaced by qualified service personnel.

11. TROUBLESHOOTING

Troubleshooting of the PHOTOTHERAPY UNIT is presented in the following table. If the fault cannot be localized from the table, the PHOTOTHERAPY UNIT should be removed from service and servicing should be referred to our company or authorized qualified service personnel.

SYMPTOM	POSSIBLE CAUSE	REMEDY
All light source does not work	Power switch is cut off	Turn off the switch of power supply
	Non-connection of power cord	Connect the power cord
	The switch is not turned on	Turn on the switch of power supply
	Fuse damaged	Replace the fuse
Timer does not work	The switch is not turned on	Turn on the switch of power supply

SPECIAL STATEMENT: All of the content in the manual is checked carefully, if there is any error or content of printing misunderstanding, our company retains finally explanation of this card-usage.

NOTE: The product's appearances maybe differ from the one in this manual, but it dose not affect the capability of product. Please understand if it brings you troubles.

Revision History

This manual has a revision number. This revision number changes whenever the manual is updated due to software or technical specification change or any other important changes of information. Contents of this manual are subject to change without prior notice.

- Document number: OM11-31_BabyGuard_U-1131_Phototherapy Lamp_Operator’s Manual_V1.1
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