



# GIMA

PROFESSIONAL MEDICAL PRODUCT

**LAMPADA LED PER FOTOTERAPIA INFANTILE - su carrello**

**LED INFANT PHOTOTHERPY LIGHT - trolley**

**LAMPE LED DE PHOTOTHÉRAPIE INFANTILE - sur socle à roulettes**

**LUZ LED FOTOTERAPIA INFANTIL - carro**

**REF**

**KS-IP48 (GIMA 31192)**



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## User Notice

◆ Thank you for choosing the company's equipment. In order to ensure safe operation and long-term stability of the instrument performance, it is necessary to fully understand the function, operation and maintenance of the instrument by reading this manual before operating the instrument.

◆ Particular attention must be paid to the "Warning" and "Caution" in the manual.

◆ The company is not responsible for any damage or injury caused by improper operation or the user's failure to follow the manufacturer's or its agent's instructions to maintain the instrument.

### ■ Warning!

"Warning" Used to indicate that if ignored, it will cause serious personal injury, death or actual property damage.

### ■ Caution!

"Caution" is used to remind users of installation, operation or maintenance information. This information is very important, but if ignored, it will cause slight personal injury or property damage.

## Guarantee

◆ The company guarantees to users that the warranty period is 12 months from the date of purchase and shipment.

◆ This guarantee is only applicable to failures that occur when the instrument is operated under the conditions specified in the manual. Please ensure that the instrument is only used in the scope of use recommended in the accompanying manual.

◆ This warranty does not apply to damage to the instrument due to accidents, misuse, abuse, falling, and attempts to modify or change any parts or components of the instrument.

- ◆ Damage to the surface of the instrument is not included in the scope of repair or replacement. The cost of supply of training materials, etc. is not included.
- ◆ The company is not responsible for damage caused by other instruments or unauthorized connection of other instruments.
- ◆ When there is a problem with the company's products during the warranty period, please notify the company, stating the instrument model, serial number, date of purchase and the problem.

## ***Operation Precautions***

### **■ Caution!**

- Neonatal jaundice treatment instrument (jaundice treatment instrument) can be used in combination with infant incubator.
- Improper use of the jaundice treatment device may cause harm to the patient. The operator of the jaundice treatment device must be specially trained and used under the guidance of qualified medical personnel who are familiar with the commonly known risks and benefits in the use of jaundice lamps.
- It is forbidden to use the jaundice treatment device in the presence of combustion-supporting gas (for example: oxygen, nitric oxide and anesthetic gas).
- The jaundice treatment device cannot be used in a place where a strong electromagnetic field is generated, and equipment that is susceptible to magnetic interference can not be used near the jaundice treatment device.
- Direct sunlight or other radiation sources may affect the patients undergoing treatment. Therefore, the jaundice treatment device cannot be used in places exposed to direct sunlight or other radiation sources.
- It is forbidden to use flammable agents (for example: antiseptics, cleaning agents, etc.) on the equipment.
- In the area irradiated by the light source, it is forbidden to place any medicines and injections.
- The jaundice treatment device cannot use reflective foil. The use of reflective foil will affect the radiation effect of the phototherapy equipment and cause an unexpected rise in body temperature.
- When the jaundice treatment device is used on a baby incubator, it will produce less heat, and under continuous light irradiation, it will affect the uniform temperature in the incubator, resulting in an unexpected rise in the patient's body temperature. Therefore, the operator needs to regularly measure the patient's body temperature. (It is recommended to be once every hour)
- During use, make sure that the jaundice treatment device is placed firmly. When moving the baby incubator, the jaundice lamp must be removed
- To ensure the safety and effectiveness of the jaundice treatment device, only the parts provided by our company, such as irradiation light sources, can be used.
- The jaundice meter produces less heat, but under continuous light irradiation, it will still cause an unexpected rise in the patient's body temperature. In addition, when it is used in combination with a warming device, such as an incubator, a warming table, or a heating mattress, it will affect the temperature uniformity of these warming devices, which may also cause an unexpected rise in the patient's body temperature. Therefore, the operator needs to regularly measure the patient's body temperature. (The company recommends at least once per hour)
- The service life of the jaundice treatment device is 6 years. The jaundice treatment instrument and its accessories and packaging after the expiration of use will cause damage to the local environment if discarded at will. Therefore, it must be disposed of in accordance with local laws or returned to our company for disposal.
- The purchaser or user of the jaundice treatment device should use the jaundice treatment device in the specified electromagnetic environment, otherwise it may cause the jaundice treatment device to not work normally.
- Portable and mobile radio frequency communication equipment may affect the normal use of the jaundice treatment device. Please use the jaundice treatment device in the recommended electromagnetic environment.

### **■ Warning !**

## ***Phototherapy Precautions***

































- In order to prevent damage to the patient's retina, the patient must wear an eye mask during the light period.
- During the illumination period, the operator should not look directly at the light source.

## Regular Safety Inspection

- Before starting to use, the performance and mechanical integrity of the product should be tested, and at least once every 12 months thereafter, and a record should be made during the test.
- The area between the power plug terminals should be cleaned at least once a year. If dust accumulates between the power plug terminals, it may cause a fire.
- The safety inspection shall be carried out by at least one trained professional and technical personnel with sufficient knowledge and practical experience every year. The test data shall be preserved. If any item of the product is unqualified or not in conformity with the function of the test, it must be repaired.

## 1. Symbols and definitions

### 1.1. Symbol

	Indicates that "injury or damage to the item may occur" if used incorrectly.		Caution: read instructions (warnings) carefully
	Directly related to user and patient safety		Class II applied
	Series Number		Manufacturer
	WEEE disposal		Follow instructions for use
	Product code		Keep away from sunlight
	Lot number		Keep in a cool, dry place
	Medical Device compliant with Regulation (EU) 2017/745		Authorized representative in the European community
	Date of manufacture		Medical Device
	Eye protection must be worn for the patient		B for blue light abbreviation, this is the on and off key of blue light
	Blue light intensity adjustment		Blue light timing adjustment
	W for White light this is the on and off key of white light		White light Illumination enhancement
	White light Illumination reduction		Direct current
	Alternating current		Fragile, handle with care
	Imported by		Put up
	Stacking layer limit		Do not step on
	Gross weight		Size

## 1.2. Definitions

- Infant phototherapy equipment

The main radiation spectrum emitted is in the range of 400nm to 550nm, which is used to reduce the concentration of bilirubin in infants. .

- Effective light area

The surface used to place the patient in a designated position, and the surface is irradiated by the phototherapy equipment.

Note: "Effective illumination area" is the designated treatment surface illuminated by the phototherapy lamp.

- Total bilirubin irradiance E<sub>bi</sub> total irradiance for bilirubin E<sub>bi</sub>

The irradiance is equivalent to the irradiance evaluated in the range of 400nm to 550nm, expressed by the following integral:

$$E_{bi} = \int_{400nm}^{550nm} E_{\lambda}(\lambda) d\lambda$$

$E_{\lambda}(\lambda)$  is the irradiance measured at each wavelength ( $\lambda$ ), in W/m<sup>2</sup>.

- Uniformity of total bilirubin irradiance G<sub>2</sub>

In the effective light area, the ratio of the lowest total bilirubin irradiance E<sub>bi min</sub> and the highest total bilirubin irradiance E<sub>bi max</sub> is represented by the following equation

Show: G<sub>2</sub>=E<sub>bi min</sub>/E<sub>bi max</sub>

- Light source lifetime: the time after the total bilirubin irradiance E<sub>bi</sub> has decayed by 25%

## 2. Overview

The neonatal jaundice treatment instrument is suitable for light therapy of premature infants and neonatal hyperbilirubinemia. Jaundice is a common phenomenon in the neonatal period. It is observed that more than 90% of newborns can have different degrees of jaundice. It can be a physiological phenomenon in the newborn period (called physiological jaundice). It can also be an important symptom of many diseases in the neonatal period (called pathological jaundice). Because this pathological jaundice can cause bilirubin encephalopathy (kernicterus) and cause brain damage in infants, leading to early death and serious sequelae, it is necessary to make timely and effective treatment of neonatal pathological jaundice.

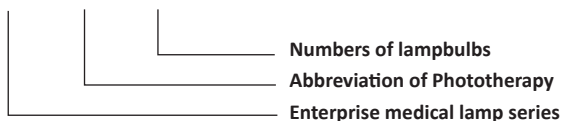
The effect of light therapy on neonatal hyperbilirubinemia (hyperbilirubinemia) is clinically recognized. The principle is that bilirubin can absorb light to produce photochemical isomerization, so that indirect bilirubin can be oxidized into a water-soluble product under the action of blue light. It is recognized by the medical community that phototherapy is an effective method for the treatment of neonatal pathological jaundice, and it is an indispensable medical device for every medical unit.

The KS series neonatal blue light therapy device adopts 400-475nm LED light source, which is the latest high-efficiency, energy-saving and long-life product developed by our company. The product complies with GB 9706.1-2007 "Medical Electrical Equipment Part 1: General Requirements for Safety" and the special safety requirements for neonatal blue light therapy devices should comply with YY0669-2008 Medical Electrical Equipment Part 2: Special Requirements for the Safety of Infant Phototherapy Equipment; electromagnetic Compatible with YY 0505-2012.

### 2.1. Product features

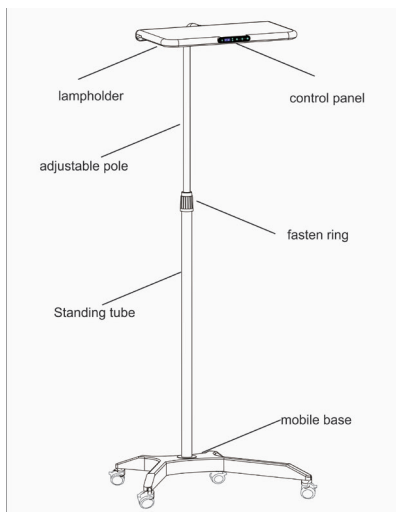
- Classified according to the type of protection against electric shock: Class II;
- According to the degree of protection against electric shock: the equipment has no applied part;
- Classification according to the degree of protection against ingress of liquid: ordinary equipment;
- The equipment cannot be operated under flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide;
- Classified by operating mode: continuous operation;
- Rated voltage and frequency: 220V~, 50Hz;
- Equipment input power: 80VA;
- The equipment does not have an applied part to protect against the discharge effect of the defibrillator;
- The device does not have a signal output or signal input part

## 2.2. Model division

**KS - IP 48**

## 2.3. Main structure

The product is mainly composed of blue light source, control box, supporting part and base.



## 2.4. Intended Use

It is used for the treatment of jaundice caused by excessively high blood bilirubin concentration in newborns caused by pathological and/or physiological factors.

## 2.5. Contraindications: Nothing found yet

## 3. Performance parameters

### 3.1. Working conditions

- Ambient temperature:  $+10^{\circ}\text{C} \sim +40^{\circ}\text{C}$ .
- Relative humidity: 30%~75%RH.
- Atmospheric pressure: 700hPa~1060hPa.
- Working power supply conditions: AC220V, 50Hz.
- Input power: 80VA.

### 3.2. Basic parameters

3.2.1 The outer dimensions of the radiant lamp holder

Lamp head length: 540 mm; width: 300 mm, lamp head swing angle up and down:  $320^{\circ}$ , horizontal rotation angle left and right:  $>320^{\circ}$ , tolerance:  $\pm 5\%$ .

3.2.2 Lighting system

The radiation source of the neonatal blue light therapy instrument consists of 24 blue LED lamp beads and 24 white light LED lamp beads. The blue light is the main illumination light source of the therapeutic apparatus, and the white light is the auxiliary observation illumination light source.

3.2.3 Wavelength range

The wavelength of the LED light source of the neonatal blue light therapy instrument is in the range of 400nm~500nm. The peak wavelength should be  $450\text{nm} \pm 5\text{nm}$

3.2.4 Effective surface

When the blue light is turned on alone, the effective area of the neonatal blue light therapy device should not be less than 24X40CM at a distance of 35cm from the radiation output surface.

At 50cm away from the radiation output surface, the effective area should not be less than 30X40CM.

### 3.2.5 Maximum total bilirubin irradiance

Maximum total bilirubin irradiance: The output light power of the neonatal blue light therapy instrument should be adjustable in 5 levels. The maximum total bilirubin irradiance on the effective surface at a distance of 35cm and 50cm from the light source should meet the requirements of Table 1, with errors Not more than  $\pm 25\%$ .

Table 1: The total irradiance of the effective surface

Radiation distance from effective area	Level	Level 1	Level 2	Level 3	Level 4	Level 5
35 cm	Maximum total irradiance of bilirubin mw/cm <sup>2</sup>	2.7	3.3	3.7	4.6	5.1
50 cm		1.8	2.2	2.4	3.2	3.7

### 3.2.6 Uniformity of total bilirubin irradiance

The uniformity of total bilirubin irradiance on the effective surface  $G2 = E_{bi \min} / E_{bi \max}$  is greater than 0.4.

### 3.2.7 Auxiliary observation of white light

There are 10 levels of dimming for white light. When the working distance is 35-50CM, the maximum illumination of white light: 8000-12000lux, color temperature: 5500-6500K

### 3.2.8 Noise

Working noise is not more than 60dB (A).

### 3.2.9 Timing function

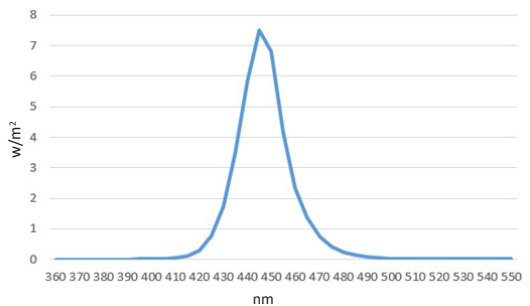
The neonatal blue light therapy instrument is equipped with a timing display of working hours, one gear is 10 minutes, and there are 6 gears in total. The longest timer is 60 minutes.

### 3.2.10 Height adjustment range

The height of the neonatal blue light therapy instrument can be adjusted, and the height adjustment range is 1140mm (when the telescopic rod is lowered to the lowest) ~ 1690mm (when the telescopic rod is raised to the highest), the allowable error is  $\pm 5\%$ .

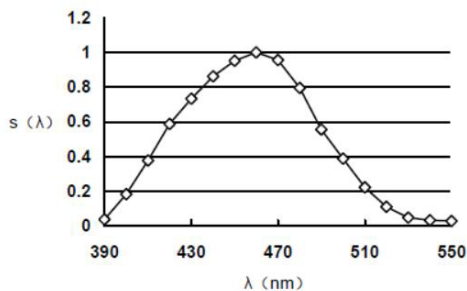
3.2.11. The average value of the wavelength range from 380nm to 550nm and the wavelength interval is 5nm.

380	0.00068	470	0.740239
385	0.00347	475	0.404431
390	0.00382	480	0.236291
395	0.00641	485	0.138762
400	0.01514	490	0.076682
405	0.02438	495	0.046303
410	0.05182	500	0.028763
415	0.11892	505	0.022785
420	0.300877	510	0.017053
425	0.760127	515	0.014159
430	1.737953	520	0.011526
435	3.513861	525	0.011909
440	5.824381	530	0.012415
445	7.501207	535	0.012958
450	6.809004	540	0.010775
455	4.167444	545	0.011567
460	2.340476	550	0.010074
465	1.381883		



Unit: W/M<sup>2</sup>

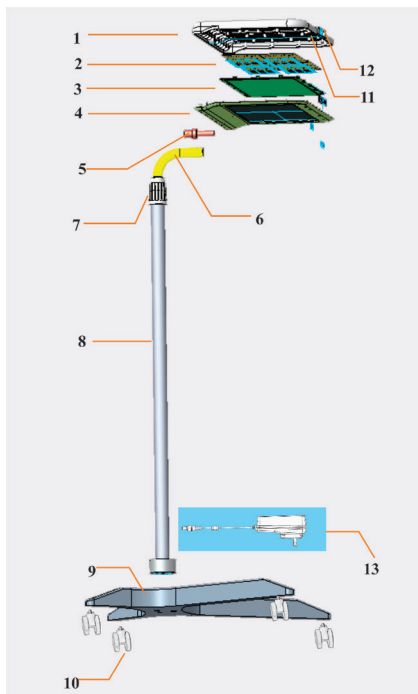
3.2.12. Measurement equipment integration Ebi integration calibration curve



## 4. Installation and use













### 4.1. Product installation diagram

No.	Description of parts	Quantities
1	the upper side of lamp holder	1
2	LED light source panel	4
3	Transparent pmma board	1
4	the down side of lamp holder	1
5	Connector of holder	1
6	Stainless steel rod	1
7	Fasten circle of lifting	1
8	Stand Tube	1
9	Mobile base	1
10	Castors with break	4
11	Digital control PCB	1
12	Control panel	1
13	Electronic Adaptor	1



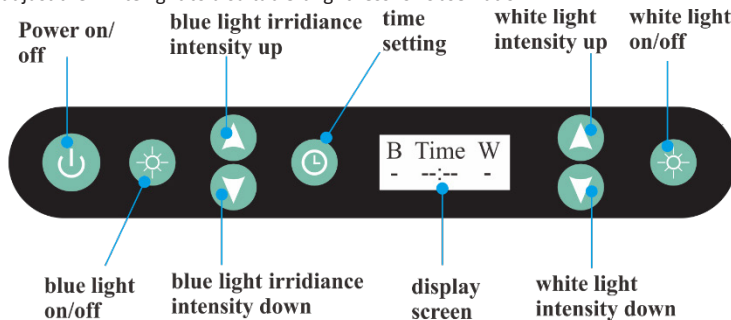
### 4.2. Assembly steps



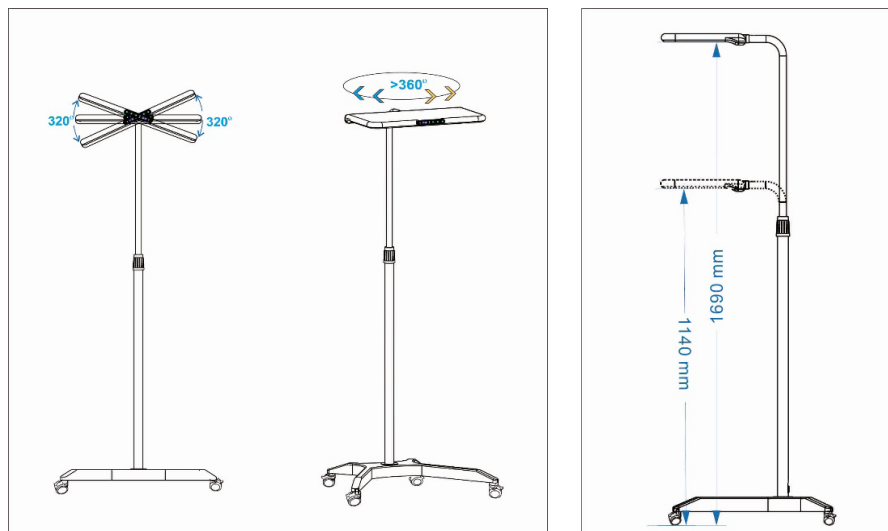
<p>1. Take out the base and wheels, and install the 4 wheels on the base.</p>	<p>2. The wheels are installed</p>	<p>3. Take out the lift riser</p>
		
<p>4. Insert the riser into the fixing hole of the base, and lock the fixing screws from the bottom of the base.</p>	<p>5. Fix the 3 screws at the bottom of the base, and the installation of the mobile base is completed. stand up.</p>	<p>6. Take out the lamp head and connect the lamp head wire connector to the lift rod outlet wire connector</p>
		
<p>7. Insert the connection port of the square lamp head into the lift rod tube.</p>	<p>8. Align the fixing holes and fix them with 2 hex screws</p>	<p>9. The lamp head is connected to the mobile base</p>
		
<p>10. The lamp head and lifting pole can be flexibly rotated</p>	<p>11. Take out the adapter, insert the connector into the wire socket of the outlet of the base pole, and then rotate to fix the connection.</p>	<p>12. After the adapter is installed, you can plug the adapter into the power outlet to power on.</p>
		

#### 4.3. Instruction

- Take out the adapter, insert the connector into the interface on the control box, and rotate the fixing ring to fix it. The adapter plugs into the AC220's power supply.
- Lightly press the blue light switch on the control panel of the lamp head, press the blue light timing setting button, you can see the timing time on the display screen, there are 6 levels in total, each level is 10 minutes, and the longest time is 60 minutes. Follow the instructions below.
- When you need to observe the baby's jaundice, you can turn off the blue light switch and turn on the white light switch to adjust the white light to a suitable brightness for observation.



- The height of the neonatal blue light therapy device is adjustable, Height adjustment range is 1140mm (when the telescopic rod is lowered to the lowest level) ~1690mm (when the telescopic rod is raised to the highest), the allowable error is  $\pm 5\%$ .



- Swing angle of lamp head up and down:  $320^\circ$ , Horizontal rotation angle left and right:  $>320^\circ$ , Tolerance:  $\pm 5\%$ .

#### 4.4. Precautions before operation



**Caution**

- Confirm that the jaundice treatment instrument has been cleaned and disinfected in accordance with Article 5.1 of this manual.
- Confirm that the jaundice treatment device can work normally. The light source can be bright, and the timer

can count normally.

- The jaundice treatment device should be used at an ambient temperature of  $+10^{\circ}\text{C}$ — $+40^{\circ}\text{C}$ . It cannot be used in an environment with direct sunlight, strong electromagnetic fields or other radiation sources, otherwise it will affect the patient.

- Nursing staff can adjust the irradiation treatment distance according to clinical needs, but the change of the distance will cause a certain degree of total irradiance on the crib surface.

Impact.

- To ensure the safety and effectiveness of phototherapy for patients, the distance between the radiation source of the jaundice lamp and the baby should be kept at 35cm

Within ~50cm.

- In order to achieve the best light treatment effect, it is necessary to ensure that the center point of the jaundice lamp radiation light source is in the same position as the center point of the baby's effective surface.

A vertical line.

- When used with incubators, baby radiant warmers or heated mattresses, it is recommended to use the skin control mode. Otherwise, according to body temperature

As a result, it is necessary to reduce the setting of the air temperature in the incubator or the setting of the heat output of the radiant warmer or the setting of the heat output of the heated mattress.

- Put the naked patient on the effective surface of the crib.

Note: In order to achieve the best phototherapy effect, the patient must be completely within the effective surface. The area size of the effective surface and its

The distance of the light source affects the average value of the total bilirubin irradiance, the larger the effective surface is, the smaller the average value, and the longer the distance, the smaller the average value; vice versa on the contrary.

- Use protective devices to prevent patients from leaving the effective surface area, such as the crib baffle, the front door of the infant incubator, and regularly check the safety functions.

- After the above operations are handled properly, the operator should promptly exit the area where the light can be irradiated to avoid long-term exposure to light radiation. If you need to

When re-operation of the equipment or patient care/examination is required, the irradiating light source should not be looked directly at.

- Turn on the power supply of the device and turn on the power switch of the device, and the device will begin to perform phototherapy on the patient.

Note: The time of phototherapy should follow the instructions of the attending doctor.

- Warm-up time is 5 hours, debugging time is 0.5 hours



### Warning

- The direct irradiation of the light source of the equipment will cause damage to the eyes of the patients, and the patients near the equipment and the patients during the illumination period must be worn Protective eyewear to prevent patients from developing symptoms such as photo-induced keratitis or retinal heat damage.

- During the light period, diapers or other similar items must be used to cover the patient's genitals to prevent damage to the patient's genital function.

- During the light period, the water balance in the patient's body may be disrupted, and the nursing staff should replenish the patient's water in time.

- During light, photosomers of bilirubin may cause toxic effects. For example, patients may experience diarrhea, kernicterus deficiency

With symptoms such as hemolysis and anemia, nursing staff should strengthen monitoring.

- The bilirubin value of the patient should be measured regularly.

- To avoid dizziness, nausea, blurred vision and other discomforts, nursing staff should not stay in the light-irradiated area for too long

- All serious accidents concerning the medical device supplied by us must be reported to the manufacturer and competent authority of the member state where your registered office is located.

## 5. Cleaning and maintenance

### 5.1. Cleaning

When the equipment is used for the first time, or the equipment has been used continuously for one week, it must be thoroughly cleaned and disinfected.

Before performing the cleaning procedure, the connection between the equipment and the power supply must

be cut off, and the power switch of the equipment must be turned off.

The following cleaning solvents can be used safely:

General formula	Maximum concentration
Sodium hypochlorite (bleached)	0.5% aqueous solution
Glutaraldehyde	2%
hydrogen peroxide	6%
Iodine solution	0.27%



### Caution

- If you use cleaning/disinfecting solvents with chemical components not listed in the above table (such as ethanol, acetone, etc.), or the concentration of the chemical components exceeds the value listed in the above table, it may damage the equipment.
- Do not immerse the parts in cleaning solvents. Be sure to wipe off all cleaning solvents on the parts. Following these two recommendations can greatly extend the life of the components.
- Any parts cleaned with iodine solvent will produce yellow stains.
- Do not let too much cleaning solvent leak to the position between the plastic parts that is not easy to wipe with a cloth.
- The translucent board cannot be polished or cleaned with high-alkali detergent, benzene, gasoline, acetone, carbon tetrachloride, butyl cellosolve, only a soft cleaning cloth and neutral soap.

## 5.2. Maintenance

5.2.1 At least once a year, a trained professional with sufficient knowledge and practical experience shall measure the total bilirubin irradiance of the jaundice treatment device, and perform electrical safety and inspection in accordance with the requirements in YY0669 and GB9706.1 Calibration of irradiance.

5.2.2 The lifetime of the light source is 50000 hours.

After the light source has exceeded its life span, in order to ensure the effect of phototherapy, it must be completely replaced even if it still works normally. This is because: the light irradiation ability of the light source will gradually decline with the extension of working hours, which will cause the total bilirubin irradiance of the jaundice treatment device to attenuate by about 25%, which will lead to the use of this device for light therapy of patients It may lose the expected effect. The replacement of the light source should be submitted to authorized and qualified maintenance personnel.

5.2.3 Regular and preventive inspections: check every two months to check the fasteners of each connection part of the product to prevent accidents due to their looseness, and check the panel function and power input interface. Before each startup, check the working environment of the blue light and whether the wiring is correct, etc., to ensure safety before the startup.

## 5.3. Common faults and solutions

5.3.1. When the instrument fails to work normally, do not disassemble or assemble it easily, and contact the customer service department of our company in time to find out the cause of the failure.

5.3.2. Before requesting repair service, please check the instrument according to the table below to see if you can handle the problem yourself.

Phenomenon	Cause Analysis	Solution
The switch is on, but the light is off	1. The power is not plugged in	1. Check whether the power supply is normal 2. Check if the power cord is properly connected
	2. Power failure	Turn off the power switch and turn it on again after a call
	3. Control circuit failure	Check whether the control panel function is displayed and whether it is normal

After use, the time cannot be set or the brightness cannot be adjusted	Control circuit board failure	Contact the factory to replace the control circuit
The blue light works normally but the child's jaundice subsides and is ignored	1. The cause of the child's own condition	Cooperate with the doctor to treat according to the condition
	2. The surface of the lamp holder is not clean	Wipe the lamp cap immediately

## 6. Storage and transportation

### 6.1. Storage

The instrument should be stored in the original packaging box and placed in a well-ventilated clean room. The packaging box should be high. The ambient temperature is  $-10^{\circ}\text{C}\sim 50^{\circ}\text{C}$ , the relative humidity is 30%~75%, and the atmospheric pressure is 70kPa~106kPa. , No harmful gases, flammable, explosive materials and corrosive gases are allowed.

### 6.2. Transportation

The instrument in the packaging condition is suitable for road, railway, aviation and waterway transportation. During loading and unloading and transportation, it should be protected from severe vibration and shock, and it should not be exposed to moisture, and it should not be mixed or transported with flammable and corrosive substances. The specific requirements shall be as stipulated in the order contract.

## 7. After-sales service

7.2.1 After purchasing the instrument, you need to fill in the warranty card and send it to the manufacturer or agent to have the warranty effect; it is a product quality problem of our company from the date of issuing the invoice. The free warranty period of the product is one year. Calculated on the day the invoice is issued. (Note: Warranty with purchase invoice and warranty card)

7.2.2 The following conditions are not within the scope of the warranty, and paid maintenance is implemented. Failure caused by man-made damage, improper operation or irresistible natural disasters. Failure caused by remodeling, disassembling, and assembling the product by yourself. .

7.2.3 After the warranty period expires, please contact the manufacturer directly to provide service guarantee.

7.2.4 To repair this machine, you must contact the customer service department of our company, do not repair it without authorization, open the package by yourself, our company does not provide warranty.

## 8. Packaging and accessories

Each inspection lamp is divided into five parts when packaging: 1), lamp body, 2), column assembly, 3), square tube, 4), casters/5) Screw fittings and plastic connectors, 6) Adapter. A set of lights in a small box, 4 small boxes and a large box



*Disposal: The product must not be disposed of along with other domestic waste. The users must dispose of this equipment by bringing it to a specific recycling point for electric and electronic equipment.*

### GIMA WARRANTY TERMS

The Gima 12-month standard B2B warranty applies.