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Shenzhen Comen Medical Instruments Co., Ltd.

Version: B00

No.: 046-001240-00

Revision date: 2021.05

Product name: Infant Phototherapy Equipment

Product model: BL70/BL70A/BL70B

Software version: V 1

Software name: Infant Phototherapy Equipment System Software

Date of manufacture: See nameplate

Service life: 10 years

Statements

Warranty

Comen will be responsible for the safety, reliability and performance of the product only if all of the following conditions are met:

- The product is used in accordance with the User Manual.
- The product is installed, maintained or upgraded by personnel authorized by Comen.

- The product's storage, operating and electrical environment meet product specifications.
- The product's serial number label or manufacturing mark is clearly legible. It has been verified that the product is manufactured by Comen.
- Damage is caused by non-human factors.

Comen Company provides free of charge services for all products based on Comen's Warranty Service Regulations. In addition, it also provides paid services for products beyond the scope of the warranty. The products need to be transported to Comen for maintenance and the user shall bear the freight (including customs expense).

Return

If you need to return the product to Comen, please follow the below steps:

To get the right to return: Contact Comen's after-sales service department and tell them the serial number of device, which has been marked on the nameplate. If the serial number is not legible, the return request will be rejected. Please specify the serial number and date of manufacture of the device, and gives a brief description of the reason for return.

After-Sales Service Department

Name: Shenzhen Comen Medical Instruments Co., Ltd. After-Sales Service Department

Address: Floor 10 of Building 1A, FIYTA Timepiece Building, Nanhuan Avenue, Matian Sub-district, Guangming District, Shenzhen, Guangdong, 518106, P.R. China

Tel.: +86-755-26431236 +86-755-86545386 +86-755-26074134

Fax: +86-755-26431232

Customer service hotline: 4007009488

Preface

The user manual introduces in detail the performance, operation methods and safety information of device. New users shall read this manual before using the device.

This manual introduces the product in the most complete configuration. The product you have purchased may not have some configuration or function.

Place the user manual near the equipment so that it is accessible when needed.

Intended Users

This user manual is intended for professional clinical staff or personnel experienced in using monitoring equipment. The reader should have knowledge and work experience in medical procedures, practices and terminology necessary to monitor patients.

Figures

All illustrations provided in this user manual are for reference only, and the menus, options, values, and functions in the figures may not exactly match what you see on the device.

Conventions

- →: This symbol is used to indicate operating steps.
- [Character]: Is used to represent a string in the software.

[Maintenance] Password: 5188

Blank Page

Content

Chapter 1 Safety

1.1 Safety Information

⚠ Warning

- **Used to indicate any serious consequences, adverse event, or situation that may endanger your safety. Failure to follow the warning may result in serious injury or death to the user or patient.**

⚠ Caution

- **Used to indicate a potential hazard or unsafe operation that, if not avoided, could result in minor personal injury, product failure or damage, or property damage. It can also lead to more serious damage in the future.**

⚠ Attention

- **Emphasizes important considerations and provides instructions or explanations for better use of the product.**

⚠ Warning

- **This manual is intended for read by professional medical staff or personnel experienced in using medical equipment. The reader should have knowledge and work experience in medical procedures, practices and terminology necessary for examining patient.**
- **The product should be operated by medical personnel with relevant expertise.**
- **The product is delivered without disinfection. Please clean and disinfect it before use for the first**

time.

- **Before using this device, you should read the entire manual carefully. As with all medical devices, an attempt to use the device before thoroughly understanding its operations may result in harm to the baby or user.**
- **Improper use of the device may result in harm to the patient. Operators must be specially trained and use under the guidance of qualified medical personnel who are familiar with the risks and benefits commonly known in the use of device.**
- **Before use, the user must check the instrument and its accessories for proper and safe operation.**
- **Please do not place the power cord of the device that has been unplugged from the AC power supply in a location that is difficult for the operator to access.**
- **Additional considerations that apply to specific steps are also specifically listed in this manual.**
- **Calibration procedure specified in this manual should be completed before the device is put into operation. If any part of the calibration procedure does not pass, you must stop using the device and start faults handling.**
- **Be sure to disconnect the device from power supply before performing repair or maintenance procedures described in this manual. The device can only be powered up when the procedure has a specific instruction.**
- **Do not use the device in the presence of flammable anesthetic gases or other corrosive gases and dust; otherwise there will be a risk of explosion.**
- **It is prohibited to use with the equipment with large power, high radiation, big noise, generating high temperature and volatilizing corrosive gases.**
- **It is prohibited to use in the environment of magnetic resonance imaging (MRI) or CT.**
- **It is prohibited to use in combination with high-frequency electrotome and defibrillator.**
- **The device shall not be installed in places exposed to sun light (including emitted lights) and should be installed at a distance of more than 1.5 meters from solar or other heat sources.**
- **Make sure that the irradiation surface of the device is flat; avoid tilting the bed surface; and avoid shining on the mattress or bed surface that may absorb light radiation.**

- **Patients near the device may need to be protected, such as wearing protective covers and goggles with blue light radiation protection.**
- **Using a Phototherapy device or heated mattress may increase the patient's temperature. Please measure the patient's temperature with the temperature probe.**
- **Treatment should be stopped during the bathing.**
- **Pay attention to the following risks during phototherapy: apnea, bronze disease, dysentery, pigmentation, skin blistering, thrombocytopenia, etc.**
- **Operator shall not stay in the radiating area of the phototherapy device for too long, as it may have a bad influence.**
- **The nurse or visitors avoid staring at the light emitted by the phototherapy device for a long time to avoid side effects such as headache, nausea or dizziness.**
- **It is prohibited to use flammable agents (preservatives, detergents, etc.) in the phototherapy device.**
- **When blue light is turned on, the blue light will hinder the color change of the patient's skin (such as cyanosis). Please monitor the patient closely.**
- **It is prohibited to store drugs and injections in the radiating area of the device.**
- **It is prohibited to smoke in the room where the device is installed. Do not place any fire source in this room.**
- **Devices that are susceptible to magnetic interference shall not be used near the device which may interfere with them.**
- **Do not place and use the device in a place where strong electromagnetic fields are generated.**
- **To ensure patient safety during phototherapy, put the patient in a protective barrier such as a crib, open-type crib, infant incubator, or radiant warmer.**
- **It is prohibited to place the device in an environment where combustion-supporting gases (such as oxygen, nitrogen oxides, or anesthetic gas) are present. Use of the device in the presence of such gases may result in an explosion or fire.**
- **Changes in environmental conditions (such as temperature, radiation source, etc.) of a patient will affect the patient's body temperature and the patient's bilirubin value. To ensure that the body temperature of the patient receiving care and treatment remains stable, the suitability and stability**

of the surrounding environment in which the device is located should be maintained as much as possible. Unsuitable and unstable surroundings may have a certain impact on the patient. If the ambient temperature is too low, the patient may get cold due to reduction of body temperature; if the ambient temperature is too high, the patient may have hypothermia due to body temperature rising. In addition, if the ambient air speed is too high, the patient may also get cold due to a rapid reduction of body temperature.

- **Although the device generates less heat, under continuous illumination, it may still causes an unexpected increase in the patient's body temperature. In addition, when it is used in combination with a warmer, such as an infant incubator, a radiant warmer, or a heated mattress, the temperature uniformity of these devices is affected, which may also cause an unexpected increase in the patient's body temperature. Therefore, the operator needs to periodically measure the patient's temperature. (The company recommends to measure at least once an hour)**
- **The above-mentioned warmers should be better operated in the skin temperature mode (infant mode), otherwise the temperature set on the warmers should be appropriately adjusted according to the measured body temperature. It is necessary to reduce the set value of air temperature in the incubator and the set value of heat output of the Infant phototherapy Equipment or the set value of heat output of the heated mattress.**
- **The device is non-stationary installation. To ensure the best effectiveness of the device, please ensure that the distance between the device and the effective surface is within the allowable range.**
- **To ensure the optimal stability of the device and to prevent separation from the effective surface, please secure the device during use.**
- **To ensure the safety and effectiveness of the device, only parts supplied by the company, such as LEDs, can be used.**
- **To ensure the effectiveness of the device, please guarantee that all LEDs are updated after they are expired.**
- **To ensure the effectiveness of the device, please replace the radiation source after the total irradiance for bilirubin is attenuated by 25%, and contact our after-sales department.**
- **The device will generate a certain amount of radiation during operation. So, the operator must follow the instructions in the operations section.**

- **During irradiation, the operator shall not look directly at or directly view the light beam through an optical instrument.**
- **Direct irradiation of light source can cause damage to eyes. Patients near the device and during irradiation must wear safety goggles to prevent symptoms such as photokeratitis or retinal thermal injury, whenever the patient's eye can be exposed to the radiation.**
- **During irradiation, the genital area of the patient must be covered with a diaper or other similar item to prevent damage to the patient's genital function.**
- **During irradiation, water balance in the patient's body may be disrupted, so the nurse should timely replenish water for the patient.**
- **The photoisomer of bilirubin may cause a poisoning reaction. For example, the patient may have symptoms such as diarrhea, jaundice, hemolysis, anemia, etc., so the nurse should strengthen monitoring.**
- **During irradiation, in order to avoid discomfort such as dizziness, nausea, blurred vision, etc., the time for the nurse to stay in the light irradiation area should not exceed 30 seconds. If it is necessary to care for the patient for a long time, it is recommended to temporarily turn off the blue light irradiation of the device.**
- **Do not directly irradiate the patient's whole body.**
- **Measure the patient's bilirubin concentration value on a regular basis.**
- **Newborns with obvious symptoms such as high fever, diarrhea, rash, etc. should be temporarily suspended to avoid aggravating the condition.**
- **During phototherapy, pay attention to observe the occurrence of side effects such as high fever, diarrhea, rash, etc. If yes, it is recommended to follow the doctor's advice to stop using.**
- **Do not use reflective metal foil, which may cause hazardous body temperatures.**
- **In normal use, the operator's position should be within one meter of the instrument.**
- **The instrument needs to be placed on a stable, vibration-free table or in a well-ventilated cabinet.**
- **When the lamp cover of the device is opened, the LED may cause a risk of electric shock. Product repair and maintenance must be performed by qualified service personnel.**
- **If you do not use or adjust, or perform various steps of the device as described above, it may cause**

harmful LED radiation damage.

- **It is prohibited to apply excessive force to the device.**
- **No modification of this equipment is allowed.**
- **The device has been thoroughly adjusted so it is prohibited to touch the fixed part.**
- **When exceptions are found on the device, please cut off the power in time and contact our after-sales department immediately.**
- **If the device fails, do not repair it without authorization, and contact our after-sales department in time.**
- **If the expired device and its components are discarded at will, it will cause damage to the local environment. Please dispose of them according to the relevant local laws and regulations or the hospital's rules and regulations or return to the company for disposal.**
- **To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.**

⚠ Caution

- **To avoid damage to the device and to keep infant safe, please use the accessories specified in this manual.**
- **Please properly keep or place the device to prevent falling, collision, damage by strong oscillations or other external mechanical forces.**
- **Before the device is powered up, please confirm the power supply used meets the requirements for voltage and frequency specified on the nameplate or in the user manual of the device.**
- **To ensure grounding reliability, please only use a hospital-grade or hospital-specific 3-wire grounded power output device. Do not use a power extension cord. Do not operate the instrument if you have any questions about the grounded power supply.**
- **The safety of auxiliary device complies with the safety standard required in IEC 60601-1.**
- **The mains plug is used to disconnect the device from supply mains. Therefore, in order to ensure safety, the power cord must be unplugged when the device is not used or maintained.**

⚠ Attention

- **Place the device in a location for easy observation, operation, and maintenance.**
- **Keep the user manual near the device so that it is accessible when needed.**
- **This manual introduces the product in the most complete configuration. The product you have purchased may not have some configuration or function.**
- **After each use, turn off the power to prolong service time.**
- **The instrument cannot be used at home.**
- **The device is for medical institutions only.**
- **The instrument is limited to be used for one patient at a time.**
- **The instrument has a service life of 10 years.**

1.2 Contraindications

- Hyperbilirubinemia with direct bilirubin elevation；
- Phototherapy has the side effect of causing rash and diarrhea, so severe diarrhea and obvious rash, allergic newborns are not suitable for phototherapy, especially premature infants.

1.3 Adverse events

Some adverse events that may occur during irradiation to child patients:

- Fever: for the child patients with fever, do not continue irradiation by blue light until their body temperature return to normal.
- Diarrhea: This symptom stops shortly after the end of phototherapy. The reason is that the phototherapy decomposition product stimulates the intestinal wall when discharged through the intestinal tract. So, care should be taken to replenish water.
- Rash: visible spotted rash on the face, trunk, etc., sometimes as petechia. This symptom can present

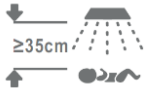
unit the end of phototherapy.

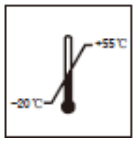
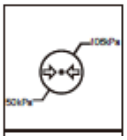
- Riboflavin deficiency: phototherapy for more than 24 hours can cause riboflavin deficiency inside body. So, riboflavin should be supplemented in a short time during and after phototherapy.
- Hypocalcemia: generally no clinical manifestations; during phototherapy, feed calcium by oral take or administrate by ravenous injection, and after phototherapy, the low calcium symptom can be restored.
- Bronze baby syndrome: more common in children with elevated serum bilirubin (conjugated) and liver dysfunction. For example, the skin is bronze after the phototherapy. So, when this occurs, treatment should be stopped.

In addition, conjunctivitis, genital and perianal skin ulceration, diaper rash, diarrhea, skin allergies, etc. may occur during phototherapy.

1.4 Symbols

(1) Symbols of Instruments

Symbols	Description	Symbols	Description
	Refer to the operation manual/ booklet		Caution/warning
COMEN	Product brand	BI70 BL70A BL70B	Product model
	Minimum radiation distance		Movement prohibited during blue light irradiation
	ON/OFF		Start/Pause button
	Time Reset button		Audio paused
	Main menu		USB port
	Eye Mask Identify		Class 1 Laser product, marked on main label
	AC indicator	SENSOR	Irradiance probe port
	Non-ionizing radiation	100-240V~	Main power input (China national standard)

SN	Serial number		Manufacturer
CE 1639	Conformité Européenne Complies with medical device directive 93/42/EEC	EC REP	Authorized representative in the European Community
	Environmental Protection	20	Environmental protection for 20 years
	Humidity limitation		Waste electrical and electronic equipment sorting collection
	Temperature limits		Atmospheric pressure limitation

(2) Symbols of Packing

	This way up		Stacking limit by number
	Fragile, handle with care		Keep away from rain
	Center of gravity		DO NOT ROLL

Chapter 2 Product Overview

The design of the Infant Phototherapy Equipment complies with domestic and international safety standards pertaining to medical electrical equipment.

2.1 Product structure

This product is mainly composed of a main unit and a blue light irradiance probe (optional).

2.2 Intended use

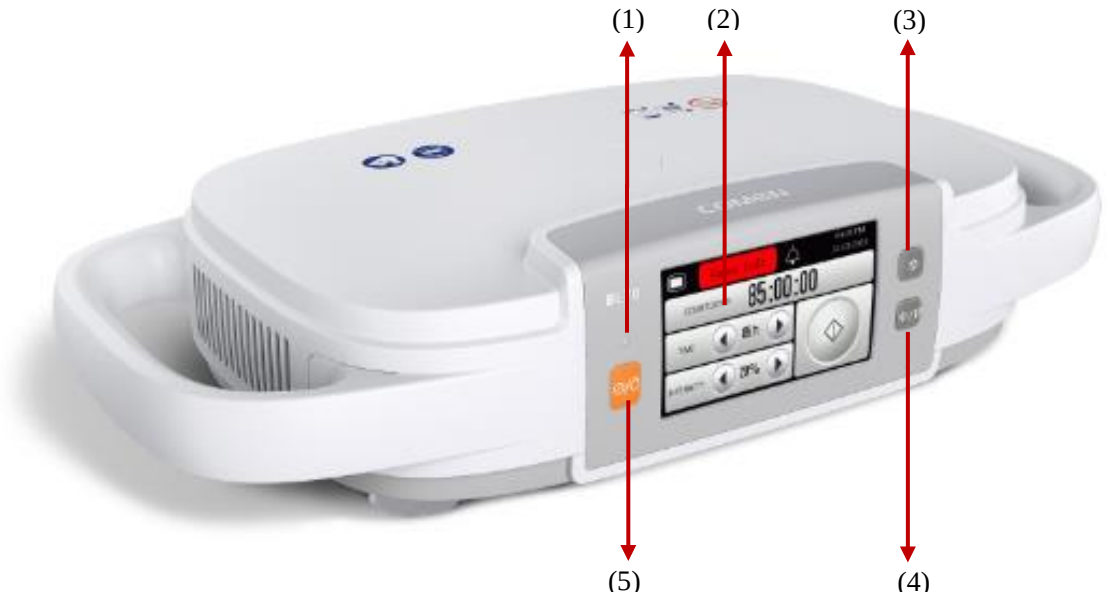
The product is intended for treating neonates with pathological jaundice.

2.3 Device appearance

2.3.1 Main view

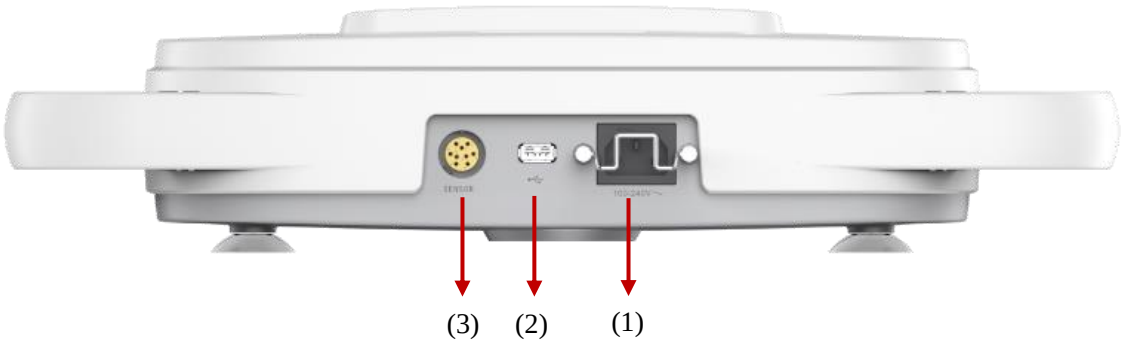
Control components comprise:

- 3 buttons
- 1 Touch screen
- 4 monochrome LED indicators: 1 power indicator, 3 button backlights



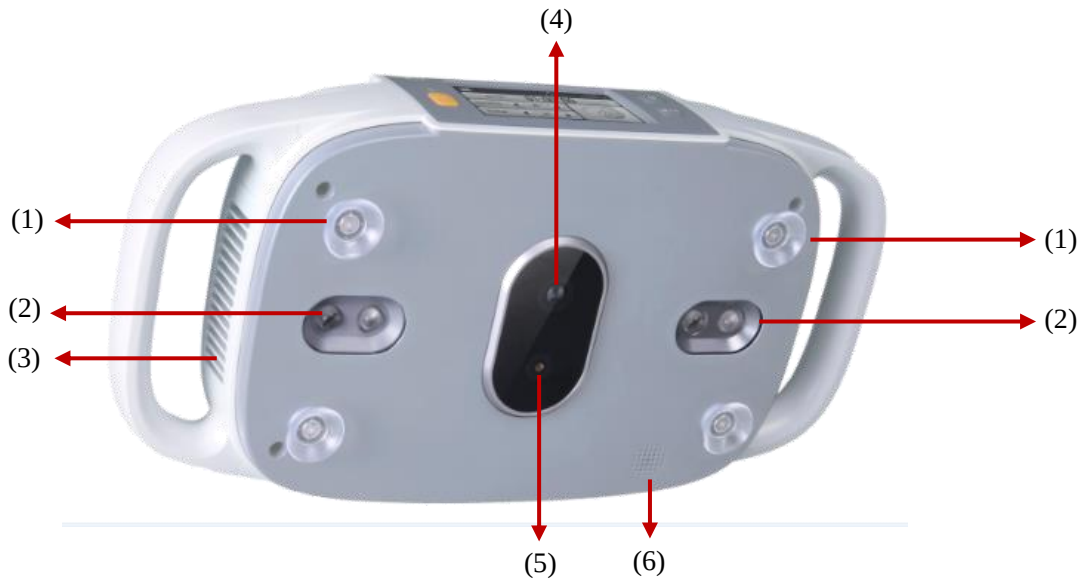
No.	Name	Description
（1）	AC power indicator	On: AC power supply is connected, and the white indicator lights up Off: AC power supply is not connected
（2）	Touch screen	Various operations can be performed by tapping on the screen.
（3）	Time reset button	After the device is turned on, the white backlight of this button is always on. (The button for clearing the counted use time of the LED in this time): when the stop button is pressed, the blue light LED is off, and the counted time of the current phototherapy cycle is cleared (the total is not affected). In addition, pressing and holding the stop button for 5s can quickly activate the touch screen calibration function.
（4）	Start/Pause button	After the device is turned on, the white backlight of this button is always on. Control the blue light LED to be turned on (start time counting) and off (pause time counting). Press the start button to turn the blue light LED on and start phototherapy procedure. At this point, the start button changes to a pause button. During treatment, press the pause button to go to a pause. The blue light LED is off, time counting pauses and the pause button changes to the start button.
（5）	Device switch	After the device is connected to AC power supply, the white backlight of this button is always on. Press the button to turn the device on, and press it again to turn the device off.

2.3.2 Rear view



(1)	AC power port
(2)	USB port: provides program upgrade function. It can be used to upgrade system software of the main unit. It features on-site upgrade of software without disassembly. Professional service personnel maintained only.
(3)	Irradiance probe port: In auto mode, the LED blue light irradiance in the center of blue elliptical spot on the bed surface at any distance (350-600mm from the lamp exit surface) for real-time feedback and automatic adjustment is consistent with the irradiance value set by the medical personnel

2.3.3 Bottom view



(1)	Suction cup	（4）	Camera
(2)	Blue light LED module	（5）	Red light

(3)	Thermal vent	（6）	Speaker

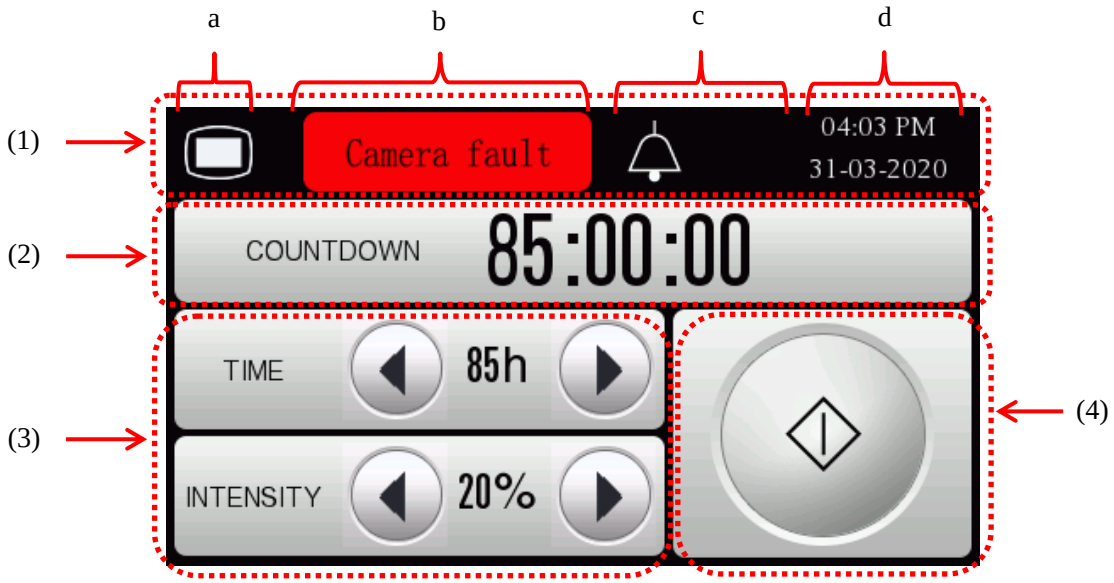
Attention

- **If you want to connect the device to other medical devices to form a system, please check for compliance. The auxiliary device connected to the signal input/signal output port must comply with corresponding IEC standard (i. e IEC 60950 for IT equipment). In addition, all configurations should comply with IEC 60601-1. However, the devices that are not specified as part of the system shall not be connected. Anyone who connects another device to the signal input and signal output (I/O) port to form a medical system is responsible for ensuring that the system complies with IEC60601-1. If you are not sure, consult your local Comen dealer.**

2.4 Screen Display

The device comes with a touch screen for touch operations. The screen used is a colored LCD screen that can simultaneously display blue light LED parameters, phototherapy settings, warning messages, clocks, and other reminder messages.

The main screen is divided into four areas: (1) message reminder area or menu bar; (2) time counting reminder area; (3) phototherapy settings area; (4) software Start/Pause operation area, as shown below:



Message reminder area or menu bar introduction (1)

From left to right:

a. Menu settings: Various operations on the system settings of the device can be performed.

b. Warning message reminder area: Displays current warning messages of the device. When there are multiple warnings, the warning messages are displayed in a loop.

c. Icon reminder area: Displays the status of current warning. When you need to silence the warning, just click the audio paused icon  on the interface, and a countdown starts for audio paused.

d. Clock: Displays the current system time of the device; Users can enter the [Date/Time] menu to reset the system time of the device according to local time.

Time counting reminder area (2)

This area displays counting of the set phototherapy time.

Phototherapy settings area (3)

The time and irradiance of a phototherapy procedure can be set in this area.

Software Start/Pause operation area (4)

You can control the start or pause of the blue light **LED** lamp by tapping on the screen.

Chapter 3 Connection and Use

⚠ Attention

- **To ensure normal operation of the device, please read this chapter before use and install as required.**
- **Place the device on a stable surface and handle it gently.**
- **The device should not be installed in the following places: places where harmful gas leaks, places with excessive steam, places with leakage of air containing salt, places with explosive gas leakage, places with excessive vibration and impact, and places where power supply and voltage are abnormally changed.**
- **When it is needed to have an electrical or mechanical connection to other equipment, be sure to contact our after-sales department. Unauthorized connection or modification does not guarantee patient safety and performance of the equipment. Please be careful.**
- **Place the device in a site which ensures ease of installation, does not produce strong vibrations, and is well ventilated.**
- **Avoid places where rapid environmental changes (temperature/humidity) are likely to occur.**
- **Select a place where flames or volatile substances, dust, ammonia gas, direct light, etc. are not easily generated.**
- **It is prohibited to apply brute force to the device during loading and unloading.**
- **To prevent damage during transportation of the device, it is necessary to verify the packaging.**
- **Check the contents in package with the packing list, including accessories, and contact the local Comen After-Sales Service Department in time when abnormalities are found.**

3.1 Inspection

3.1.1 Unpacking for inspection

Carefully take out the instrument and its accessories from the packaging box and save the packaging materials for later transportation or storage. Please check the accessories according to the packing list. Check for any mechanical damage. Check all exposed wires and some inserted accessories. For any problems, please contact our sales department or agent immediately.

⚠ Warning

- **If you find any damage, please contact relevant person of the hospital or Comen's After-sales Department.**

3.1.2 Environmental requirements

Service environment of the device must comply with the environmental requirements specified in this manual. Ambient temperature out of a specified range may affect the accuracy of the device and cause damage to its components and wiring.

The environment where the device is used shall reasonably avoid vibration, dust, corrosive or explosive gases, extreme temperatures, humidity, and the like.

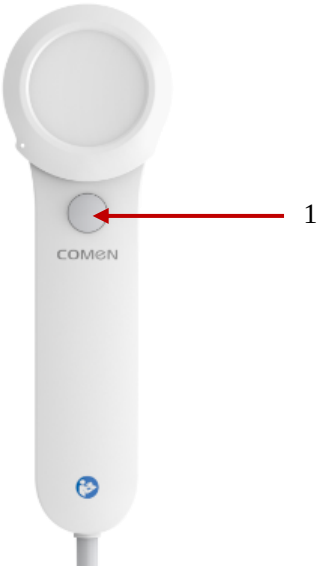
When the device is installed in a cabinet, the air in the cabinet should be circulated, and there must be enough space in front and back of device for easy operation. With the cabinet door open, there should be enough space for maintenance. Leave at least 2 inches (5 cm) of space around the instrument to ensure air circulation.

3.2 Instrument components connection

Connection of the blue light irradiance probe (optional)

A port for irradiance probe is left on the back of the main unit for the connection of an irradiance probe. The instrument can be equipped with a blue light irradiance probe that can be placed in the center of the spot to

calibrate the main unit (see 5.2.5 Device Calibration for details).



1 Calibration function shortcut key

3.3Device preparation

3.3.1 Connect AC power supply

Steps of connecting AC power supply:

1. Make sure the AC power supply complies with the specifications marked on nameplate of the device.
2. Uses the supplied power cord with one end connected to the device and plug the other end of the power cord into a grounded electrical outlet.

⚠ Attention

- **Plug the power cord into a hospital-specific outlet.**
- The power cord supplied with the device must be used; otherwise the safety of the device may be reduced.

3.3.2 Protective grounding

The device is equipped with a 3-wire power cord, when plugged into a matched 3-wire outlet, which grounds the device through the ground wire (protective grounding). If no 3-wire outlet is available, please contact the hospital's electrical management personnel.

⚠ Warning

- **Do not connect the 3-wire power plug of device to a 2-wire outlet. The power cord can only be plugged into a 3-phase outlet that has a grounding terminal and is properly grounded to ensure reliable grounding.**
- **Do not use a power extension cord.**
- **Do not use this device if you have any doubts about grounding.**
- **The device's connection to or disconnection from power supply is completed by a power cord. Therefore, in order to ensure safety, the power cord must be unplugged when the device is not used or maintained.**

If it is unclear whether a specific instrument combination is dangerous, for example, a danger is caused due to the accumulation of leakage current, the user should consult the relevant manufacturer or other experts in this field to ensure that the necessary safety of all instruments therein is not damaged by the recommended combination.

3.3.3 Condensation

During operation, it is necessary to ensure that the device is free from condensation. Condensation may form as the instrument is moved from one room to another. This is because the instrument is exposed to moist air and different temperatures. To avoid unnecessary troubles, if condensation occurs, leave the instrument dry before use.

Note: Condensation means gas or liquid condenses when it cools. For example, water vapor is changed into water when it cools, and the water is changed into ice when it cools. The lower the temperature, the faster the condensation goes.

3.4Power on and power off

3.4.1 Device startup

1. Before turning the device on, check whether the components are correctly connected and whether there are mechanical damages.
2. Check if the device can start properly:

   After the power cord is plugged into an AC power outlet, the white AC power indicator lights up and the white backlight of the device ON/OFF button lights up. Long press this button to turn the instrument on. Then, the white backlight of the stop button and the Start/Pause button lights up, and the monitor screen lights up and the company's LOGO screen is displayed.
3. Check if the screen display and the display of each parameter interface are normal.

3.4.2 Startup self-check

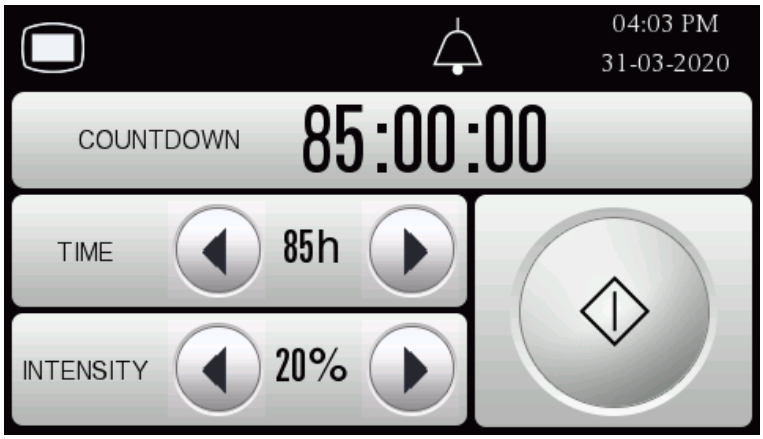
Each time the device is turned on, it will perform self-check to check the status of each function module, with focus on whether the system voltage is normal to ensure the system can be used normally. The figure below shows the startup self-check screen:

⚠ Warning

- **If there is an error message, do not use this device and contact the biomedical engineer in the hospital or our service engineer.**

- **If the self-check fails, it is better to turn it on again 1 minute after power off.**

After startup self-check is completed, the system starts to load each function module, and then the device enters the main screen of working mode. The power on process takes about 15-20 seconds:



For detailed descriptions of function buttons on the main screen, please refer to Section 2.5 “Screen Display”.

After the device is started, the red light lamp will start synchronously. The red light lamp is used to locate the center point of blue light irradiation, ensuring that the baby receiving phototherapy is in the center of the elliptical irradiation area

3.4.3 Device shutdown

If the device is no longer used, follow the steps below to turn it off:

1) Confirm that the use of the device is finished;

2) Press (about 1 second) the device ON/OFF button. The device enters a power off state, and the white backlight is off;

3) Unplug the power cord from the AC power outlet and the white AC power indicator is off.

Chapter 4 Basic Operations

4.1 Working mode

The device is generally divided into two working modes: automatic mode and normal mode, and default as normal mode. When a blue light irradiance probe is connected, and the light intensity part shows values with a unit changed, it indicates that the device has entered the automatic mode.

Figure 1

Figure 2

- Normal mode: no blue light irradiance probe, a default mode of the device, irradiance unit is %, as shown in Figure 1 above;
- Automatic mode: a blue light irradiance probe is connected and the irradiance unit is μW/cm^2/nm (mW/cm^2), as shown in Figure 2 above.

⚠ Warning

- **Do not plug or unplug the irradiance probe during operation. Plugging and unplugging during power-on may affect probe life and main control board performance.**
- **To ensure the accuracy of irradiance readings, it is recommended to use the irradiance probe to calibrate the main unit once after the probe is connected.**

4.2 Operating steps

⚠ Warning

- **Ensure the device is in a stable and steady state.**
- **When using the device, guarantee that the baby is cared at all times by medical personnel. Regularly check the baby's body temperature to ensure safety and comfort.**
- **When warning is in silence, the baby's conditions must be closely monitored.**
- **Direct sunlight or other sources of radiant heat can cause the temperature of the device to rise to a dangerous level.**
- **Radiant energy may have an influence on blood components. When using an IV system to deliver blood components into the patient under the device, seal the infusion tube with aluminum foil.**
- **Do not connect other devices not listed in this manual to the device's external interface.**

⚠ Attention

- **During irradiation, in order to avoid discomfort such as dizziness, nausea, blurred vision, etc., the time for the nurse to stay in the light irradiation area should not exceed 30 seconds. If it is necessary to care for the patient for a long time, it is recommended to temporarily turn off the device.**
- **If you do not use or adjust, or perform various steps of the device as specified in the manual, a harmful LED radiation damage may be caused.**
- **The time of phototherapy should follow the instructions of attending physician.**
- **To achieve optimal phototherapy effect, the patient must be completely within the effective surface.**
- **Measure the bilirubin value of the patient on a regular basis during phototherapy.**
- **The device can affect the patient's body temperature, so the user should measure the patient's body temperature.**
- **Operators should not stay close to a running device for a long period of time.**

1. Place a fully naked patient within the effective surface.

2. Wear a protective eye mask on the patient and cover the patient's genital area with a diaper or other similar item.

3. Connect the device to power supply, press ON/OFF button on the device and conduct corresponding interface settings. Then, the device starts to implement phototherapy on the patient.

4. After the above operations are properly handled, the operator should promptly exit the area where the light emitted to avoid long-term exposure to light. If the device needs to be operated again or the patient needs to be cared for or examined, do not look directly at the beam or view the beam through an optical instrument.

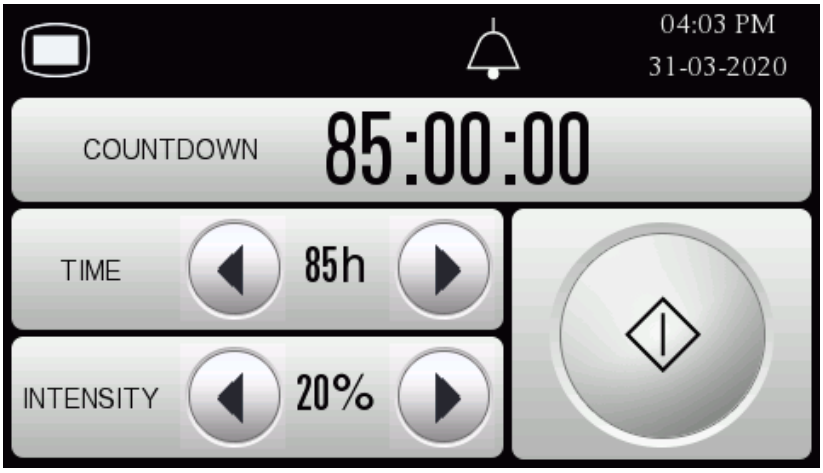
Chapter 5 Menu Setup

⚠ Warning

- **If it is needed to modify the parameters when the device is running for treatment, press the pause button before modification. After modification, press the start button to allow the device to run the modified parameters.**
- **The device will generate a certain amount of radiation during irradiation. So, the operator must follow the instructions in the operations section.**
- **During irradiation, the operator shall not look directly at or directly view the light beam through an optical instrument.**
- **Direct irradiation of light source can cause damage to eyes. Patients near the device and during irradiation must wear safety goggles to prevent symptoms such as photokeratitis or retinal thermal injury.**

5.1 Main screen operations

Operations that can be performed on the main screen include: menu setup, audio paused, phototherapy time setup, irradiance setup and Start/Pause setup. For details of audio paused, please refer to Section 7.6 “Audio Paused”.



5.1.1 Menu setup

Click the menu tab "  " in the upper left corner of the main screen to enter the menu setup interface. The menu setup includes two submenus: Setup and Maintenance. Click different tabs to enter different menu items.

5.1.2 Phototherapy time setup

According to the actual needs, set the time for a course of phototherapy (the minimum is 1 hour). The setting range is (1~99), and the step is 1 hour. The phototherapy time is reduced or increased by one hour each time the "  " or "  " is pressed. The phototherapy time can be reduced or increased at any time.

After setup, the phototherapy time will be displayed in the time counting reminder area on top of the main interface in the form of countdown or counting.

After the phototherapy time is up, the device automatically turns off the blue light **LED** lamp.

5.1.3 Irradiance setup

Set the irradiance of blue light. Each time "  " or "  " is pressed, the blue light irradiance is decreased or increased by one level, and the blue light irradiance can be reduced or increased at any time. The system provides 5 levels of setup; the working distance in the automatic mode is 350mm.

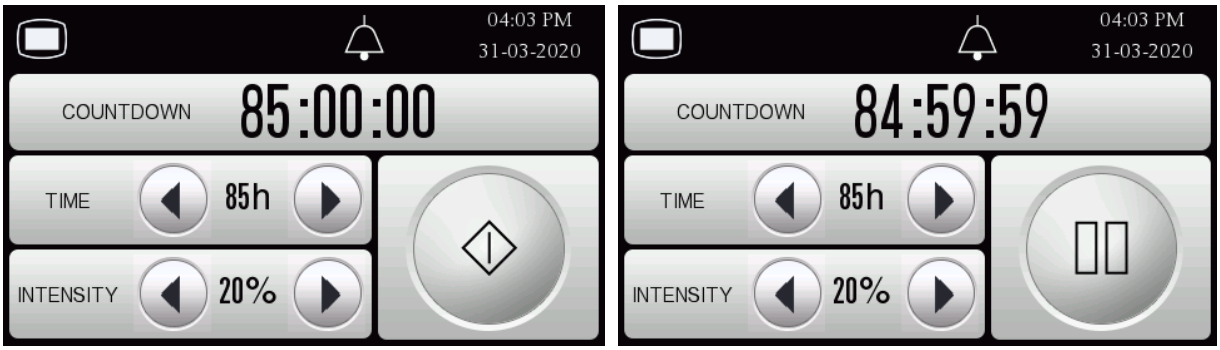
- When the probe is not inserted (normal mode), the unit is %;
- When the probe is inserted (automatic mode), the unit is μW/cm^2/nm (mW/cm^2).

5.1.4 Start/Pause setup

Software button  allows users to control the blue light LED to be turned on (start time counting) and off (pause time counting).

- Tap the button to turn the blue light LED on and start phototherapy procedure. At this point, the button changes to a Pause button "  ".
- During treatment, tap the Pause button to go to a pause. The blue light LED is off, time counting pauses and the button changes to the Start button "  ".

This button is consistent in function with the Start/Pause button on the control panel and the two can be used collaboratively.



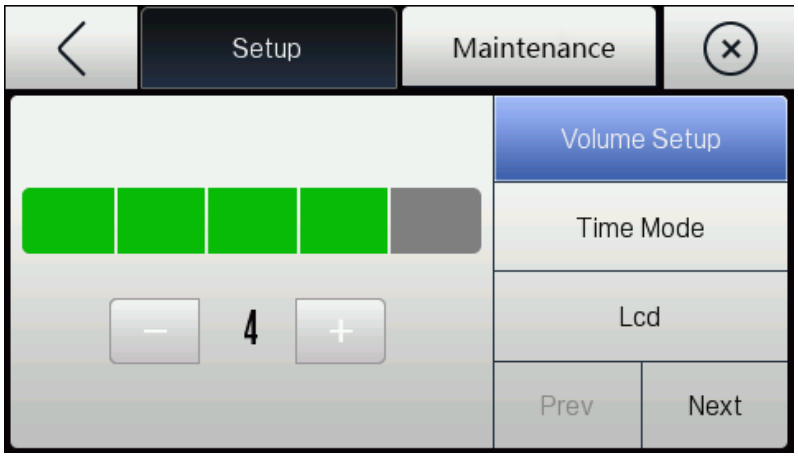
5.2 Setup

There are 7 submenus under the [Setup] menu: [Volume Setup] [Time Mode] [Lcd] [Intensity Unit] [Device Calibration] [Real-time Display] and [Device Information]. Tap “Next” or “Prev” to view more setup items.

5.2.1 Volume Setup

This setup submenu is for the volume of warning sound.

Tap [Menu “ ”] → [Setup] → [Volume Setup] to enter the volume setup page. The system provides a total of 5 levels of volume setup. Each time you tap “+” or “-”, the volume is increased or decreased by one level. Once set, tap the icon on the top right corner to exit the page.



5.2.2 Time Mode

The Time Mode is used to set a counting sequence for the system phototherapy time.

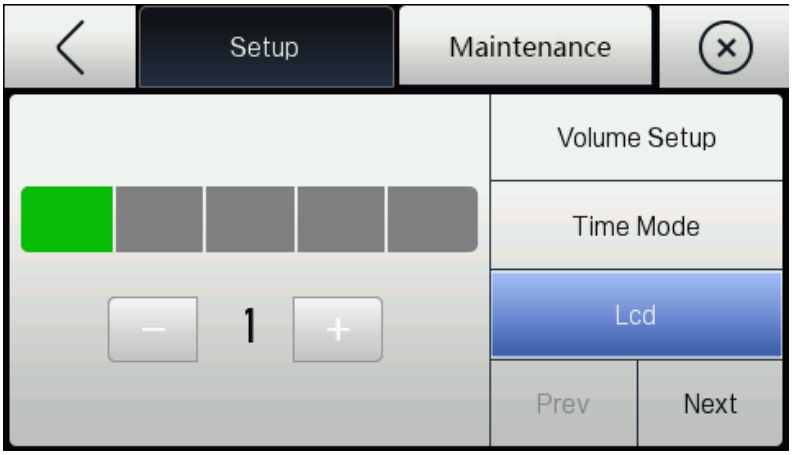
Tap [Menu “ ”] → [Setup] → [Time Mode] to enter the time mode setup page. The time counting modes provided by the system include “COUNT” and “COUNTDOWN”, which can be determined according to the

needs or habits in actual use. Once set, tap the icon "⊗"on the top right corner to exit the page.

5.2.3 Lcd

The device provides adjustment of the screen brightness.

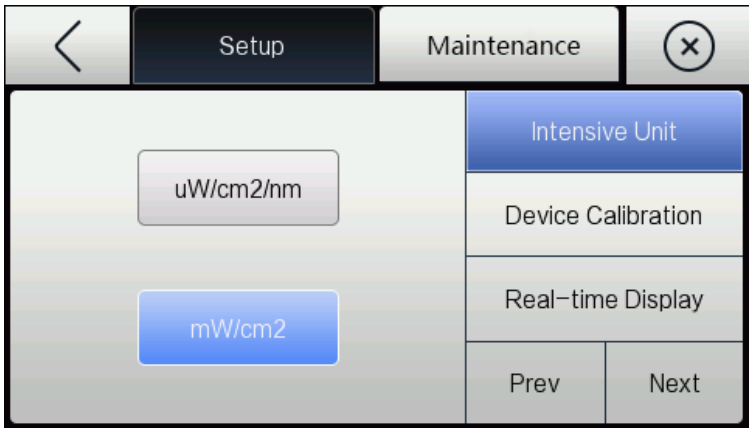
Tap [Menu "▭"] → [Setup] → [Lcd] to enter the screen brightness setup page. The system provides a total of 5 levels of screen brightness setup. Each time you tap "+" or "-", the screen brightness is increased or decreased by one level. Once set, tap the icon"⊗" on the top right corner to exit the page.



5.2.4 Intensity Unit

In the automatic mode, the irradiance unit of the blue light can be set.

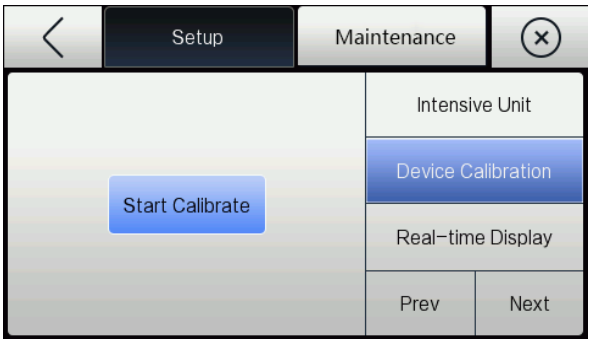
Tap [Menu "▭"] → [Setup] → [Intensity Unit] to enter the irradiance unit setup page, where the irradiance unit of blue light **LED** lamp can be set. The system provides μW/cm^2/nm or mW/cm^2 for chose. Once set, tap the icon "⊗"on the top right corner to exit the page.

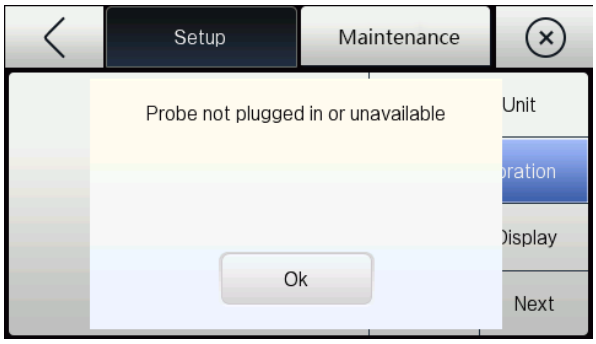


5.2.5 Device Calibration

After the probe is inserted, the system enters automatic mode and the main unit can be calibrated using the probe. Calibration height: Within 25cm-75cm.

Tap [Menu "  "] → [Setup] → [Device Calibration] to enter the device Calibration Setup page and follow the steps below to perform calibration. If the probe is not inserted or disconnected, a reminder will pop up as "Probe not connected or unavailable". Once set, tap the icon"  " on the top right corner to exit the page.





Calibration steps:

1. Connect the probe, arrange the position of lamp head (the lamp head is perpendicular to the bed surface or tilted 60-90 degrees), the distance is any value within 350-600mm, and there is no obstruction between the lamp head and the bed surface (except for the protective cover of infant incubator made of optical materials such as transparent PC and PMMA);

2. Press the power ON/OFF button  to turn the device on. By default, the device enters the automatic mode main screen;

3. Click the menu to enter "Device Calibration", or simply press the shortcut button in the front of the probe

to directly enter “Device Calibration”;

4. Tap “Start Calibrate” on the interface to bring up a reminder “Place the probe in the center of the red light”, and the red light is turned on;
5. Manually place the probe in the center of a red target spot, just above the bed surface (within 5mm from the bed);
6. Tap "OK" on the interface. The interface will prompt “Calibrating. Do not move or disconnect probe”, and also display the progress bar for completion status;
7. The red light is automatically turned off, and the blue light is automatically turned on until the progress bar goes to the end. At this point, the calibration is completed;
8. If the interface prompts “Calibration Completed”, tap “Confirm” on the interface. The calibration will be finished, and the red light is turned on.
9. If the interface prompts “Calibration Failed”, tap “Exit” on the interface, and the red light is turned on. Check whether the probe is placed in the center of the red spot and whether there is an obstruction. Repeat steps 1-7 until the interface prompts “Calibration Completed”.

⚠ Attention

- **After each automatic mode calibration is completed, the distance shall be kept unchanged or the tilt angle not be adjusted. If any distance or angle changes after calibration, you will need to perform a calibration again.**
- **Led light lamp is the class I laser beam.**

⚠ Warning

- **If the calibration is performed not following the calibration steps specified in the manual, the blue light irradiance may be caused to be too high or too low, which may affect the therapeutic effect or bring new side effects.**

Calibration function

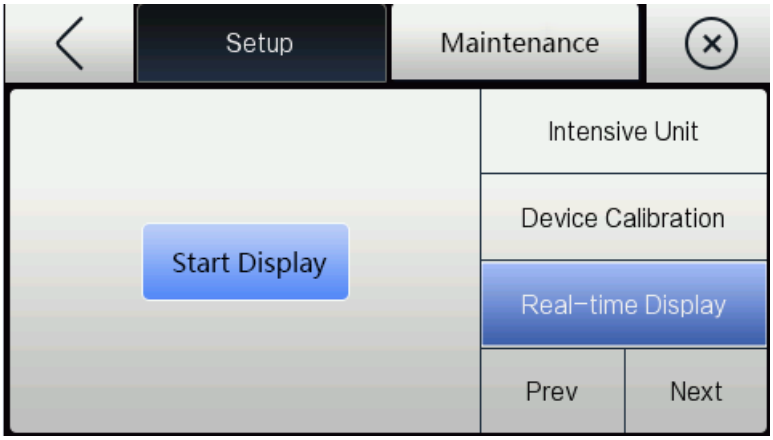
When the instrument is in automatic mode, the irradiance value of the light spot center detected by the probe

is fed back to the instrument, and the instrument carries out algorithm analysis and processing of the value and corresponding LED output current value to compensate and calibrate data difference and write compensation algorithm into the algorithm of LED current value and radiant power such that any set value of phototherapy irradiance is consistent with the actually measured value.

5.2.6 Real-time Display

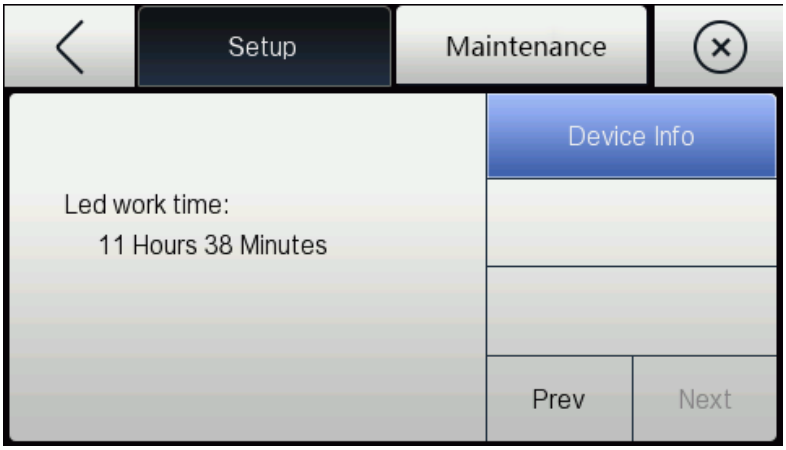
The function is used to display the conditions of the baby captured by camera in real time.

Tap [Menu "  "] → [Setup] → [Real-time Display] to enter the Real-time Display setup page. Tap "Start Display", and the interface will be converted into a baby real-time monitoring screen. To exit the Real-time Display screen, tap the icon "  " on the top right corner.



5.2.7 Device Information

Tap [Menu "  "] → [Setup] → [Device Info] to view the total LED work time, that is, total time counted.



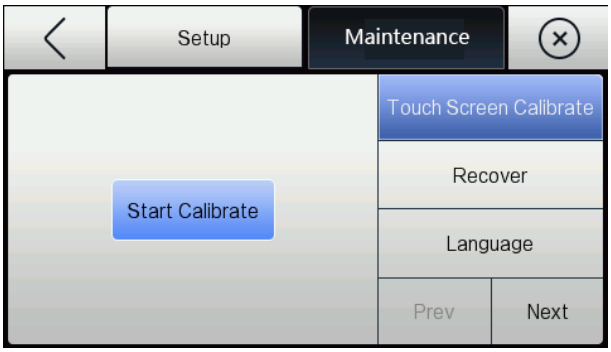
5.3Maintenance

Maintenance menu is mainly used by manufacturer or device maintenance personnel to maintain the device.

Tap [Menu “ ”] → [Maintenance], input the maintenance password, and tap “Enter” button to enter the Maintenance menu. There are 4 submenus under this menu: [Touch Screen Calibrate], [Recover], [Language] and [Date/Time]. Tap “Prev” or “Next” to view more setting items.

5.3.1 Touch Screen Calibrate

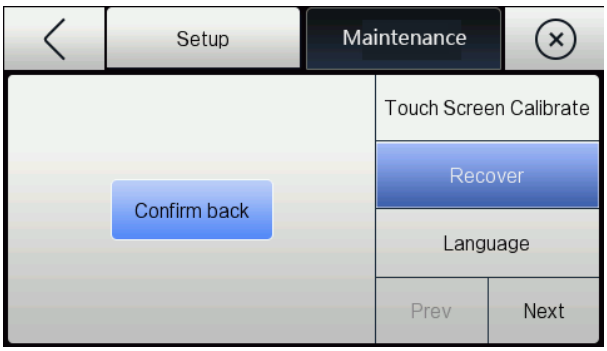
Tap [Menu “ ”] → [Maintenance], input the maintenance password, and tap “Enter” button to enter the Maintenance menu. Select [Touch Screen Calibrate] and tap “Start Calibrate” to enter the calibration interface. Tap five calibration points “ ”following the prompt on the screen to complete the calibration. The screen will automatically return after the calibration is completed.

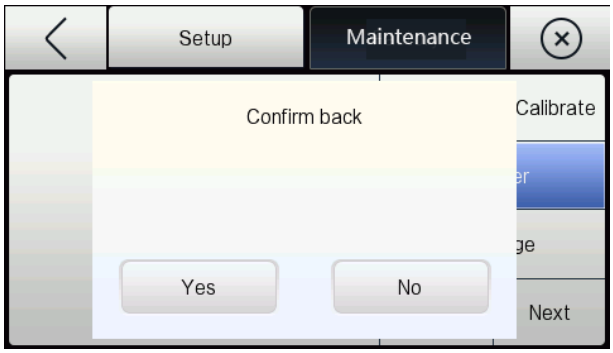


5.3.2 Recover

Tap [Menu “ ”] → [Maintenance], input the maintenance password, and tap “Enter” button to enter the Maintenance menu. Select [Recover] and tap “Confirm Back” → “Yes”. The system prompts “Recovery is

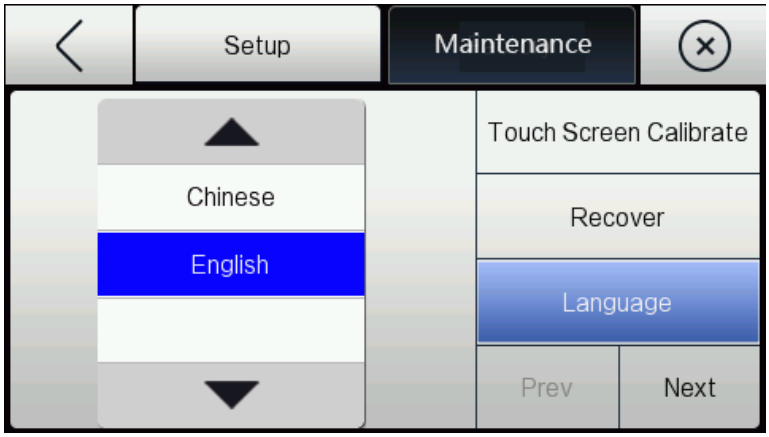
Complete", and at this point, the system has been restored to default settings, and the original configuration will be overwritten; if you select "No", the system saves the original configuration, and returns to the settings interface.





5.3.3 Language

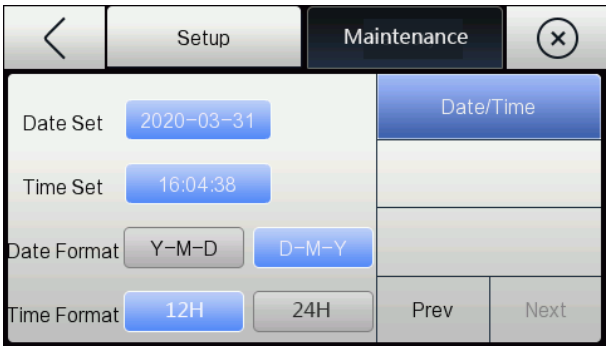
Tap [Menu "  "] → [Maintenance], input the maintenance password, and tap "Enter" button to enter the Maintenance menu. Select [Language] to set language of the system. At present, the language options in the system include "Chinese" and "English". Directly tap the language to complete selection, and tap "  " or "  " to switch.

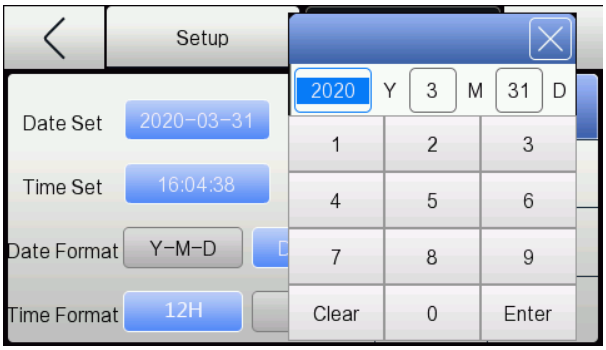


5.3.4 Date/Time

The system can be setup according to local date and time. The real-time clock is powered by a separate button battery, so it can continue to calculate time regardless of whether the device is energized.

Tap [Menu "  "] → [Maintenance], input the maintenance password, and tap "Enter" button to enter the Maintenance menu. Select [Date/Time] to enter the date/time setup page.





- Tap [Date Setup], and in the pop-up dialog box, you can set the year, month and day according to local time;
- Tap [Time Setup], and in the pop-up dialog box, you can set the hour, minute and second according to local time;
- [Date Format] can be directly selected, the options include: year-month-day (Y-M-D) or day-month-year (D-M-Y);
- [Time Format] can be directly selected, the options include: 12H or 24H.

Once set, tap the icon "⊗" on the top right corner to exit the page.

Chapter 6 Data Storage and Record

6.1 Data saved when power is off

The configurations that can be maintained when power is off include:

1. Volume setup
2. Screen brightness
3. System date/time format
4. System date/time
5. Language
6. Intensity unit
7. Phototherapy time

An interruption and a restoration of the power supply up to 10 min stops the treatment, and do not change preset values.

6.2 Data not saved when power is off

The warning review contents are volatile data that will not be saved after the device is powered off.

Chapter 7 Warning and Troubleshooting

7.1 Warning overview

Warning refers to the reminders given by the device by making a sound or other methods to the medical personnel when the device itself fails resulting in that phototherapy to baby cannot be smoothly performed.

The device is equipped with a speaker for sounding a warning.

Multi-level volumes can be set. For warning volume, there are 1-5 levels available for a total of 5 volume settings.

⚠ **Attention**

- **When multiple warnings occur at the same time, the warning reminder area on the device will display the warnings in a loop.**
- **When the warning volume is turned down, it may be covered by the ambient sound. The adjustable minimum volume should be higher than the ambient sound volume.**
- **Do not rely solely on an audible warning system to monitor the baby. Adjusting the warning sound to a lower volume may bring danger to the baby. Users should pay close attention to actual clinical conditions of the baby.**
- **When the device loses all power or is turned off, the stored warning messages will be deleted and the current warning message will not be saved either.**

7.1.1 Warning type

Warning information of the device can be classified into warning and reminder.

(1) Warning

Warning, also known as a system error message, refers to a warning that is triggered when a system function fails to function properly or the monitoring result has distortion due to improper operation or system failure. Warning message is displayed in the warning display area at the top of the main screen.

(2) Reminder

An addition to warning, the device can also display some information related to the state of the system, which generally does not relate to the vital signs of baby. Reminder message is displayed in the system reminder message area.

7.1.2 Warning cause

The device will give warnings on the following situations to help users handle them in a timely manner.

- When the device fails in that the internal voltage changes or the temperature on the aluminum substrate for cooling is too high.

7.2 Warning mode

When a warning occurs, the device reminds the user by audible and visual warning modes as follows:

- Audible warning
- Warning message

7.2.1 Audible warning

Audible warning refers to that when a warning occurs, the device will sound to alert the user.

Warning sound: beep-beep-beep--beep-beep.

7.2.2 Warning message

Warning message refers to that when a warning occurs, the device will display corresponding warning information in the warning display area.

Warning message background color: red

7.2.3 Warning status icons

In addition to the above warning modes, the following warning status icons will appear on the screen to indicate the status of a warning.

: indicates an audio warning paused state of warning.


: indicates a canceled state of audio warning paused.

7.3 Warning system self-check

When the device is turned on, the system will perform a self-check on the warning system. If there is a problem detected in self-check, the device will display the fault code.

7.4 Actions for warning

When the device has a warning, please refer to the following steps to take appropriate actions:

1) Check the conditions of the baby.
2) Confirm the parameters being warned or the warning type.
3) Identify the cause of warning.
4) Eliminate the cause of warning.
5) Check if the warning is eliminated.

7.5 Warning system information

1. Warning message

Warning message	Causes	Actions
Over temperature warning	The temperature of the blue light LED is too high	Turn off the instrument
MCU FLT	MCU Communication failure	Turn off the instrument and contact our after-sales service department
Camera module failure	Camera loss of communication	
Thermistor failure	Thermistor is damaged	
EEPROM read and write failure	EEPROM module failure	

Probe failure	Light intensity probe failure	
Light module failure	LEDs failure	
Power supply failure	Power supply failure	

2. Reminder

Source	Reminder messages	Cause/description
Program upgrade	No USB flash device found	The system reminder is only the message reminded by the device to users for a function or an action that is being operated.
	No upgrade files found	
Restore to default settings	Confirm Back?	
	Recovery is complete	
Password keyboard	Wrong password	
Calibration function	Probe not connected or unavailable	
	Place the probe in the center of the red light, and click OK when done.	
	Calibrating. Do not move or disconnect probe	
	Exit or not?	
	Calibration succeeded	
	Calibration failed	

7.6 Audio Paused

Provide an operation for turning off warning sound. The operator can turn off the warning sound in the case of restrictions.

The device's audio paused function allows all current warnings to be silenced for 120s, and the visual warning form retains its original state. If a new warning is generated or silence duration is more than 120 seconds, the current silent state will be ended and the warning enters normal state.

Tap the warning icon at the top of the main screen, and the audio paused will start to enter the countdown for 120s. At this time, the icon will change to "  ", and the countdown time will be displayed below the icon.

7.7 Troubleshooting

⚠ Warning

- **This section is only for the specified user to remove simple faults. If a fault that is not included in this section is encountered, or the fault is still not eliminated after trying the troubleshooting methods listed below, please contact the user service organization designated by Shenzhen Comen Medical Instruments Co., Ltd. Do not repair the device without authorization.**
- **Maintenance and repair can only be performed by authorized personnel from Shenzhen Comen Medical Instruments Co., Ltd. Maintenance and repair of the device by unauthorized personnel may cause personal injury or equipment damage.**
- **The maintenance and repair must be strictly based on the technical data provided by Shenzhen Comen Medical Instruments Co., Ltd. For relevant technical information, please contact the user service organization or local agent designated by Shenzhen Comen Medical Instruments Co., Ltd.**

Source	Possible causes	Actions
The power cord is connected but all light sources are not on	Power failure	Turn off the device
	Power switch is not turned on	Turn the power switch on
	Poor power cord connection	Check if the power cord in the cover are disconnected or broken, and take actions.

	Power supply is not connected	Connect the power cord
	LED temperature is too high, temperature control switch is open	Wait for a moment

Chapter 8 Cleaning and Disinfection

Only the materials and methods listed in this chapter that are approved by the company can be used to clean or disinfect the device. The company does not provide any warranty if damage is caused by the use of unapproved materials or methods.

The company assumes no responsibility for the effectiveness of the listed chemicals or methods as a means of controlling infection. For information on how to control infection, please consult your Infection Prevention Department or epidemiologist, or refer to all local policies for your hospital and country.

8.1 Overview

Please keep the device and its accessories free of dust. Check the device carefully after each cleaning. If any signs of aging or damage are found, stop using it immediately. If you need to return it to Comen for repair, please clean it first. Please follow the attentions below:

- Before cleaning the device, you must turn off the power, and disconnect the power cord from the AC power.
- Please follow the manufacturer's instructions to dilute the detergent and disinfectant, or use those with the lowest possible concentration.
- Do not allow liquid to enter the cover.
- Do not allow any liquid to pour over any part of the device.
- Do not immerse the device in liquid.
- Do not use abrasive materials and bleaching powders, as well as any strong solvents (such as acetone or detergents containing acetone).

⚠ Warning

- **Only the detergents and disinfectants recommended in this manual can be used. Using other detergents and disinfectants may cause damage to the device or cause a safety hazard.**

- **Do not use an organic solvent such as acetone to clean the device.**
- **Do not splash or spray liquid directly onto the device.**
- **Do not allow disinfectant to remain on any surface or accessories of the device. Wipe it off with a damp cloth.**
- **Detergents shall not be mixed up, as dangerous gases can be produced.**
- **To avoid cross-infection, disposable accessories shall not be used again after cleaning and disinfection.**
- **To protect the environment, disposable accessories must be properly disposed of in accordance with local laws and regulations.**
- **After cleaning, if there is sign of sensor cable damage or aging, replace it with a new one.**
- **High temperature sterilization for the device and all of its accessories is not allowed.**
- **Do not use EtO (ethylene oxide) to sterilize the device.**
- **Do not use any cleaning solvents other than those recommended herein, as this may cause permanent damage to the device, probe, and cable.**
- **Do not immerse the sensor or connector in any solution for cleaning or disinfecting.**
- **During cleaning, it is necessary to prevent liquid from flowing into the interior of the unit through thermal vents.**
- **Do not expose the device to direct UV radiation.**

⚠ **Caution**

- **If you accidentally pour liquid onto the instrument or accessories, contact your service representative or the company immediately.**

⚠ **Warning**

- **Before cleaning the device or sensor, it must be turned off and disconnected from AC power to**

allow the LED to cool sufficiently.

- **The power shall be cut off before dismantling or reinstalling the bottom of the device.**
- **If any dirt is found on the device, clean and disinfect it in time to prevent infection.**

⚠ Caution

- **Prevent any damage to the device.**
- **Most detergents must be diluted before use. Dilute according to the manufacturer's instructions.**
- **Never use abrasive materials (such as steel wool or silver polish).**
- **Do not allow liquid to enter the device. If you accidentally pour liquid onto the device or accessories, contact your service representative or the company immediately.**
- **Do not leave any cleaning solution on the surface of any part of the device.**
- **High temperature sterilization for the device and all of its accessories is not allowed.**
- **Electrostatic discharge can easily damage electronic devices in the microprocessor controller. These devices are adequately protected but may be damaged if dismantling is beyond the recommended cleaning and maintenance level.**

⚠ Attention

- **Using organic solvents such as alcohol, acetone, etc. may cause cracks on the plexiglas cover. Do not put the device under direct exposure to ultraviolet radiation.**
- **The company is not responsible for the effectiveness of using these chemicals as a means of controlling infectious diseases. Please consult the person in charge of infectious disease control or infectious disease expert in your hospital.**
- **The device in use should be wiped and disinfected weekly.**
- **To protect the environment, disposable accessories must be recycled or properly disposed of.**

If the device is contaminated by baby body fluids, check your hospital's infection control procedure. Please wear protective clothing and goggles, or use special disinfectant solvents and cleaning procedures.

Dismantling steps

1) Turn off the device, and disconnect the power cord from the AC outlet.
2) If the device is in a power-on state, it should be cooled before dismantling.
3) Remove and wash the parts that need to be cleaned.

8.2 Cleaning and disinfection of the device

The device should be kept clean. It is recommended to clean the outer surface of cover frequently, and especially in areas with harsh environmental conditions or windy and dusty areas, the frequency of cleaning should be increased. Please consult or understand the hospital's regulations on equipment cleaning before cleaning.

This device must be thoroughly cleaned and disinfected before first use, or when it has been continuously used for one week.

- **Optional detergents:**
  - Hydrogen peroxide 3%
  - Glutaraldehyde 2%
  - Sodium hypochlorite 0.5%
- **Cleaning steps:**
  1) Turn off the device and disconnect the power cord first.
  2) Take a soft cloth, absorb an appropriate amount of detergent, and wipe all surfaces of the device, including corners and recesses.
  3) Wipe off excess detergent with a soft, dry cloth.
  4) Place the device in a cool, ventilated environment.
- **Disinfection**

  Disinfection operations may cause a certain degree of damage to the device. It is recommended to

disinfect the device only when necessary in the hospital's maintenance plan. Clean the device before disinfecting it. The cleaning agents optional for each part of the device are listed in the table below:

Parts to be cleaned/disinfected	Optional detergents and disinfectants
Cover	Hydrogen peroxide 3% Glutaraldehyde 2% Sodium hypochlorite 0.5%
Probe	
Power cord	

⚠ Attention

- **The device cannot be dismantled and modified without the authorization of Comen.**

Chapter 9 Maintenance

9.1 Maintenance inspection

A complete inspection of the device, including functional safety inspection, must be performed by trained and qualified technical service personnel prior to use of the device or after continuous use for 6-12 months or after each maintenance, repair or upgrade.

Inspection items should include:

1) Check if the operating environment and power supply of the device meets requirements;
2) All components of the device should be installed correctly and firmly, and the operation of each control component should be flexible and reliable, and the fasteners should be free from looseness;
3) Check if the accessories used are manufacturer-specified ones;
4) The exterior of the device should be free from scratches and cracks;
5) The texts and markings on the device should be clear, accurate and firm;
6) Check all exposed wires;
7) Check all functions of the device and ensure that the device is in a good operating state.
8) Confirm that the device has been cleaned and disinfected;

If any sign indicating that a function of the device is damaged is found, the device shall not be used to perform any monitoring on the baby. Then, contact the hospital's biomedical engineer or the company.

All safety inspections or maintenance that requires disassembly of the device should be performed by qualified service personnel. Unauthorized disassembly and maintenance may result in electric shock and equipment damage.

Comen will conditionally provide circuit diagrams when requested to assist users to perform maintenance those components of the device that have been classified as "can be maintained by users" by trained and qualified service personnel.

⚠ Warning

- **Hospitals or institutions using this device should follow this user manual; otherwise it may cause malfunction and unpredictable consequences of the device, and may endanger personal safety.**
- **Hospitals or institutions using this device should follow the instructions for maintenance and troubleshooting of accessories, buttons, touch screen and other components that should be in good operating condition, so as not to cause adverse events to the operator and patients.**
- **Hospitals or institutions using this device should establish a comprehensive plan; otherwise it may cause malfunction and unpredictable consequences of the device, and may endanger personal safety.**

9.2Maintenance plan

9.2.1 Maintenance checking

⚠ Warning

- **This time schedule lists the maintenance items of the lowest frequency. Always follow the frequency required by the hospital or local regulations.**

The following tasks can only be completed by professional maintenance personnel approved by the company. If the following maintenance items are required, please contact the maintenance personnel in time. The device must be cleaned and disinfected before checking or maintenance.

Check and maintenance items	Frequency
Perform safety inspection according to IEC 60601-1	At least once a year. After replacement of power supply of the device or as needed.
Performance checking of all measurement functions	At least once a year, or when you suspect that the measurements are inaccurate.
Touch screen calibration	At least once a year, or after replacement of touch screen

Measurement of total irradiance of bilirubin	At least once a year. When the highest measured total irradiance of bilirubin is less than 30% of the claimed value, the irradiance probe is used for calibration.

⚠ **Attention**

- **Measurement of the total irradiance value of bilirubin should be performed by a professional, and ensure that the irradiance probe is within the validity period shown on the certificate.**
- **Replacement and adjustment of the light source should be performed authorized qualified service personnel.**

9.2.2 Accessory service life

Check and maintenance items	**Service life**
BL70 probe	2 years

Appendix I Accessories

No.	PN	Material description
1	115-007082-00	BL70 probe
2	009-000074-00	Power supply cord

Appendix II Product Specifications

1) Product type

Name	Type
Medical device classification	Management category: Class II
CE classification	IIa
Classified by type of electric shock	Externally powered Class I equipment
Classified by the degree of protection against electric shock	No applied part
EMC classification	Class A
Classification of the degree of liquid ingress protection	Common equipment (equipment with cover not protected against ingress, IPX0)
Classified by the degreed of safety in use in the case of flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide:	It cannot be used in existence of flammable anesthetic gas mixed with air or flammable anesthetic gas mixed with oxygen or nitrous oxide.
Classified by operating mode	Continuous
Does the device have a signal output or input part	There is a signal input or signal output part.
Equipment of permanent or non-permanent installation	Equipment of non-permanent installation
Mobility	Portable
Relevant standards compliance	IEC/CISPR 11, Directive 2011/65/EU, MDD 93/42/EEC as amended by 2007/47/EC2007/47/EC, ISO 780, ISO 14971, IEC 60601-1, IEC 60601-1-2, IEC 60601-1-6+A1,IEC 62366+A1, IEC 62366-1, IEC 62304+AMD1, ISO 15223-1, BS EN 1041+A1, IEC 60601-2-50+A1

2) Physical specifications

Physical parameters	
Main unit dimensions	Length ×width ×height: 433mm ×217mm ×99mm Error: ±5mm
	Weight: 2.6 kg±0.5kg
Irradiance probe	52mm×183mm×30mm
	Error: ±5mm

Display	
The Infant Phototherapy Equipment's display module consists of 3 buttons, 1 touch screen, and 4 monochrome LED indicators.	
Type	Color active matrix TFT display (adjustable brightness of the screen)
Resolution	480×272
Size	4.3-inch touch screen, with LED backlight, and buttons
Touch screen	
Size	4.3 inches
Type	Resistive screen

3) Electrical specifications

Leakage current	
100-240V: < 500μA	
Power supply	
AC power and frequency	100-240V~ 50Hz/60Hz
Power	0.9-0.5A
Power cord	3m

4) Environmental specifications

Work environment	
Environmental Temperature	5℃～40℃
Relative humidity	0%～93%, non-condensing
Atmospheric pressure	70.0kPa～106.0kPa

Storage and transportation environment	
Temperature	-20℃～55℃
Relative humidity	0%～93%, non-condensing
Atmospheric pressure	50.0kPa～106.0kPa
Transportation conditions	It is applicable to land, air and sea transportation. It must be protected from severe impact, vibration and rain and snow during transportation.

5) Technical parameters

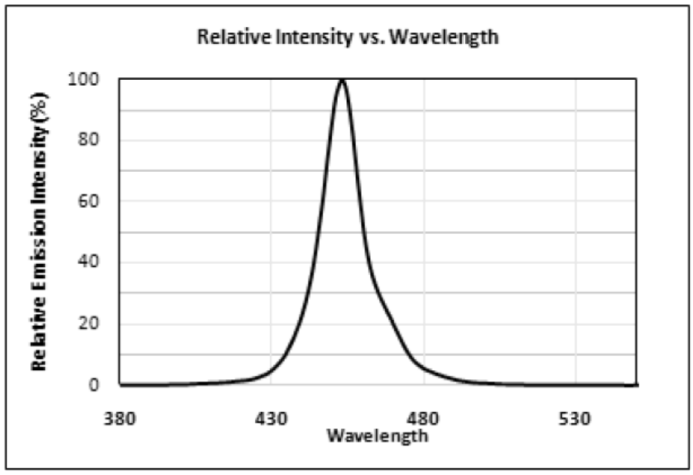
Mode switching	Normal mode (no irradiance probe)	
	Automatic mode (equipped with irradiance probe)	
	Default is normal mode, and when an irradiance probe is connected to the instrument, the instrument switches to automatic mode	
Blue light wavelength	400~550nm, in a unit of mW/cm^2; 430~490nm, in a unit of μW/cm^2/nm	
Blue light irradiation effective surface	30cm ×16cm (35cm from the light emitting surface of lamp)	
	30cm ×24cm (45cm from the light emitting surface of lamp)	
	40cm ×24cm (60cm from the light emitting surface of lamp)	
Positioning red light spot	1. With red light positioning function (Irradiance probe measurement positioning function), and automatically turns off after blue light is turned on. 2. Blue light spot positioning function.	
	Peak wavelength	640nm ~ 660nm
	Maximum optical power	0.5mW(class I laser product)
	Beam deflection angle	±3°
Camera	With the function of real-time display of the content captured by the camera	
Irradiance adjustment range	Normal mode: 20% ~ 100%, with a step of 20%, 5 levels adjustable	
	Automatic mode: 0.76-3.8mW/cm^2 (12-63μW/cm^2/nm), 5 levels adjustable, with a step of 0.76mW/cm^2 (12.6μW/cm^2/nm); working distance 350mm	
Maximum total irradiance for bilirubin	Normal mode （set 100%）	3.8 mW/cm^2 (63 μW/cm^2/nm) (35cm from the light emitting surface of lamp)

within the effective surface		2.5mW/cm^2 (41μW/cm^2/nm) (45cm from the light emitting surface of lamp)	
		1.5mW/cm^2 (25μW/cm^2/nm) (60cm from the light emitting surface of lamp)	
		Error	±25%
	Automatic mode (set 3.8mW/cm^2 (63μW/cm^2/nm))	3.8mW/cm^2 (63μW/cm^2/nm) (35cm from the light emitting surface of lamp)	
		2.5mW/cm^2 (41μW/cm^2/nm) (45cm from the light emitting surface of lamp)	
		1.5mW/cm^2 (25μW/cm^2/nm) (60cm from the light emitting surface of lamp)	
		Error	±25%
	There is a linear relationship between the maximum irradiance and the declared value at other levels (20%, 40% and 60%).		
Average of total irradiance for bilirubin within the effective surface	Normal mode （set 100%）	2.7mW/cm^2 (45μW/cm^2/nm) (35cm from the light emitting surface of lamp)	
		2.1mW/cm^2 (35μW/cm^2/nm) (45cm from the light emitting surface of lamp)	
		1.4mW/cm^2 (23μW/cm^2/nm) (60cm from the light emitting surface of lamp)	
		Error	±25%
	Automatic mode (set 3.8mW/cm^2 (63μW/cm^2/nm))	2.7mW/cm^2 (45μW/cm^2/nm) (35cm from the light emitting surface of lamp)	
		2.1mW/cm^2 (35μW/cm^2/nm) (45cm from the light emitting surface of lamp)	
		1.4mW/cm^2 (23μW/cm^2/nm) (60cm from the light emitting surface of lamp)	
		Error	±25%
	There is a linear relationship between the average irradiance and the declared value at other levels.		
Uniformity of total irradiance for bilirubin	＞0.4		

(Radio of E_{bi} min and E_{bi} max)	
Noise level	≤20dB（A）
Over temperature protection	Cut off the LED drive power of the LED drive chip when the temperature of the LED copper substrate is up to 70±5℃

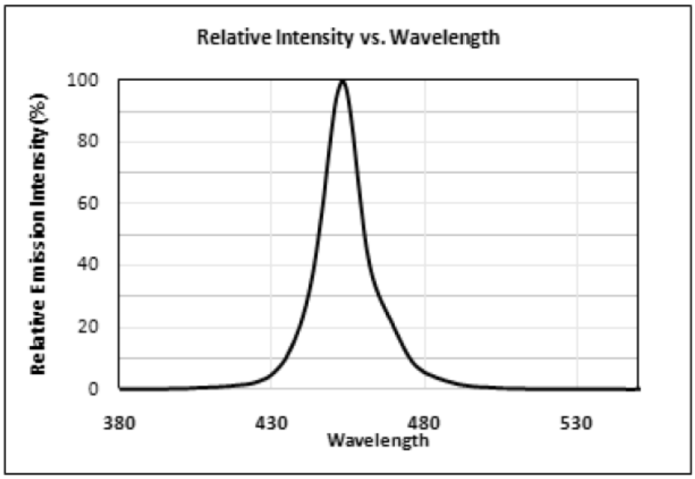
6) Spectral characteristics

The blue light with an effective wavelength of 400nm~550nm used on the device.

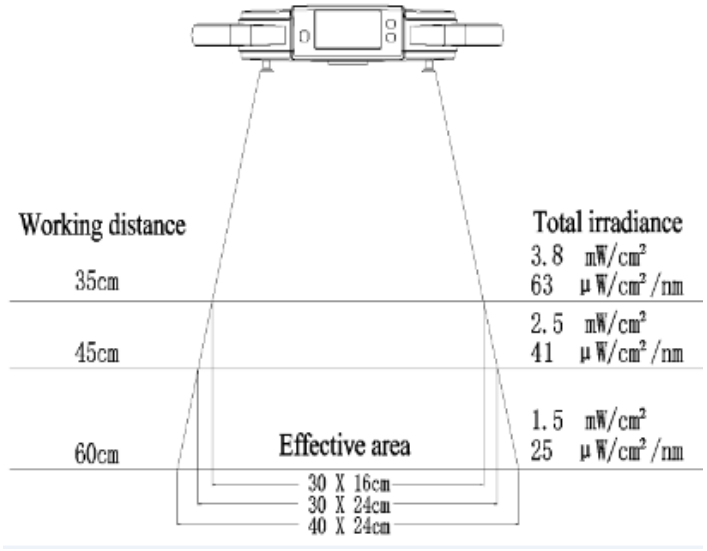


Typical LED lamp life is about 50,000 hours in normal mode

7) Total irradiance Ebi



8) Effective surface distribution and relative position diagram



9) Warning

Equipped with a speaker as the sounding unit, and the sound emitted is used for reminding an instrument failure.	
Warning sound	Support multi-level warning volumes which can set in 1-5 levels.
Review function	Can display the last 200 warning records under the current power on state

Appendix III EMC

⚠ Attention

- **The BL70/BL70A/BL70B Infant Phototherapy Equipmentmeets the requirements of IEC 60601-1-2 for electromagnetic compatibility.**
- **Users should install and use according to electromagnetic compatibility information provided in the attached document.**
- **Portable and mobile RF communication equipments may affect the performance of the BL70/BL70A/BL70B Infant Phototherapy Equipment. So, avoid strong electromagnetic interference during use, such as mobile phones, microwave ovens, etc.**
- **For guide and manufacturer statement, see the attachment.**

⚠ Warning

- **The BL70/BL70A/BL70B Infant Phototherapy Equipment should not be used close to or stacked with other devices. If it is necessary to do so, observe and confirm that the device can operate normally in the configuration in which it is used.**
- **Class A equipment is intended for use in industrial environments. Due to conducted disturbances and radiated disturbances of the BL70/BL70A/BL70B Infant Phototherapy Equipment, it may be potentially difficult to ensure electromagnetic compatibility in other environments.**
- **Except for the transducers and cables sold by the manufacturers of the BL70/BL70A/BL70B Infant Phototherapy Equipment as spare parts for internal components, the use of accessories, transducers, and cables other than those specified may result in increase of emission or reduction of immunity of the BL70/BL70A/BL70B Infant Phototherapy Equipment.**
- **Even if other equipment meets the radiation requirements of corresponding national standard, the unit or system may still be interfered by other equipment.**

Attachments:

The following cables must be used to meet electromagnetic emissions and interference immunity requirements:

No.	Name	Cable length (m)	Shielded or not
1	Power cord	3M	No
2	Irradiance probe cable	1.5M	Yes

Attachments:

Guidance and manufacturer ́s declaration - Electromagnetic emission		
The BL70/BL70A/BL70B Infant Phototherapy Equipment is intended for use in the electromagnetic environment specified below, and the customer or user of the BL70/BL70A/BL70B Infant Phototherapy Equipment should assure that it is used in such an environment:		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emission CISPR 11	Group 1	The BL70/BL70A/BL70B Infant Phototherapy Equipment uses RF energy for its internal functions only. Therefore, its RF emissions are low and do not cause any interference to nearby electronic devices.
RF emission CISPR 11	Class A	The BL70/BL70A/BL70B Infant Phototherapy Equipment is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emission IEC 61000-3-2	N/A	
Voltage fluctuation / flicker emission IEC 61000-3-3	N/A	

<table>
<tr><th colspan="4">Guidance and manufacturer ś declaration - Electromagnetic Immunity</th></tr>
<tr><td colspan="4">The BL70/BL70A/BL70B Infant Phototherapy Equipment is intended for use in the electromagnetic environment specified below, and the customer or user of the BL70/BL70A/BL70B Infant Phototherapy Equipment should assure that it is used in such an environment:</td></tr>
<tr><td>Immunity test</td><td>IEC 60601-1-2 test level</td><td>Compliance level</td><td>Electromagnetic environment – guidance</td></tr>
<tr><td>Electrostatic discharge (ESD)
IEC 61000-4-2</td><td colspan="2">±8 kV contact discharge
±15 kV air discharge</td><td>Floors should be wood, concrete or ceramic. If floors are is covered with synthetic material, the relative humidity should be at least 30%.</td></tr>
<tr><td>Electrical fast transient burst
IEC 61000-4-4</td><td colspan="2">±2kV to power cord
±1kV to input/output line</td><td rowspan="2">Mains power quality should be that of a typical commercial or hospital environment.</td></tr>
<tr><td>Surge
IEC 61000-4-5</td><td colspan="2">±1 kV differential mode voltage
±2 kV common mode voltage</td></tr>
<tr><td rowspan="4">Voltage dips, short interruption and voltage variations on the power supply input line
IEC61000-4-11</td><td>0%U_T;0.5 cycle
at 0 °,45 °, 90 °,135 °, 180 °,225 °, 270 °and 315 °</td><td><5 % U_T, last for 0.5 cycle (on the U_T, >95% sag)</td><td rowspan="4">Mains power quality should be that of a typical commercial or hospital environment. If the user of the BL70/BL70A/BL70B Infant Phototherapy Equipment requires continued operation during power mains interruptions, it is recommended that the BL70/BL70A/BL70B Infant Phototherapy Equipment be powered from an uninterruptible power supply or battery.</td></tr>
<tr><td>40%U_T;1 cycle
single-phase: at 0 °</td><td>40 % U_T, last for 5 cycles (on the U_T, 60% sag)</td></tr>
<tr><td>70%U_T;25/30 cycles
single-phase: at 0 °</td><td>70 % U_T, last for 25 cycles (on the U_T, 30% sag)</td></tr>
<tr><td>0%U_T;250/300 cycles</td><td><5 % U_T, last for 5s (on the U_T, >95% sag)</td></tr>
<tr><td>Power frequency magnetic field
IEC 61000-4-8</td><td>3A/m
(50Hz/60Hz）</td><td>3A/m
(50Hz/60Hz）</td><td>Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.</td></tr>
<tr><td colspan="4">Note: U_T refers to the AC mains voltage prior to application of the test level.</td></tr>
</table>

Guidance and manufacturer's declaration - Electromagnetic Immunity

The BL70/BL70A/BL70B Infant Phototherapy Equipment is intended for use in the electromagnetic environment specified below, and the customer or user of the BL70/BL70A/BL70B Infant Phototherapy Equipment should assure that it is used in such an environment:

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment –guidance**
RF Conduction GB/T 17625.6 IEC61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communication equipment should not be used closer to any part of the BL70/BL70A/BL70B Infant Phototherapy Equipment, including cables, other than at the recommended separation distance calculated from the equation applicable to the transmitter frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ $d = 0.35\sqrt{P}$ 26 MHz to 800 MHz $d = 0.7\sqrt{P}$ 800 MHz to 1 GHz Wherein, 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 transmitter, 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. 
RF Radiation GB/T 17626.3 IEC 61000-4-3	10 V/m 26 MHz to 1 GHz	10V/m	

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

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

a. For strengths from fixed RF transmitter, such as base stations for radio (cellular / cordless) telephones and land mobile radios, amateur radio, AM (amplitude modulation) and FM (frequency modulation) radio broadcasts and television broadcasts 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 BL70/BL70A/BL70B Infant Phototherapy Equipment is used exceeds the applicable RF compliance, the BL70/BL70A/BL70B Infant 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 BL70/BL70A/BL70B Infant Phototherapy Equipment.

b. Over the frequency range 0.15 MHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distance between the portable and mobile RF communication equipment and the BL70/BL70A/BL70B Infant Phototherapy Equipment

The BL70/BL70A/BL70B Infant Phototherapy Equipment is intended for use in an electromagnetic environment where radiated RF disturbances are controlled. The customer or user of the BL70/BL70A/BL70B Infant Phototherapy Equipment can help prevent electromagnetic interference by maintaining a minimum distance between the portable and mobile RF communication equipment (transmitters) and the BL70/BL70A/BL70B Infant Phototherapy Equipment as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter / W	**Separation distances according to frequencies of transmitter /m**		
	150 kHz ～ 80 MHz $d = 1.2\sqrt{P}$	**26 MHz ～ 800 MHz** $d = 0.35\sqrt{P}$	**800 MHz～ 1 GHz** $d = 0.7\sqrt{P}$
0.01	0.12	0.04	0.07
0.1	0.38	0.11	0.22
1	1.2	0.35	0.7
10	3.8	1.1	2.2
100	12	3.5	7

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 80MHz and 800MHz frequencies, the separation distance for the higher frequency range applies

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by the absorption and reflection of structures, objects and people.

Appendix IV Product Configuration

Functional parameters	Infant Phototherapy Equipment		
	BL70	BL70A	BL70B
Camera	▲	—	—
Blue light irradiance probe	▲	▲	—
Red light positioning	√	√	√
Note: 1. "√" in the table indicates that the instrument is configured with this function; 2. "▲" in the table indicates that the instrument can be configured with this function; 3. "—" indicates that the instrument does not have this configuration.			

Appendix V Terminology

Terms and definitions

Total time count	When the blue light LED is powered on, time counting starts, and when it is powered off, time counting stops. The time counted is the accumulated time of the LED.
COUNT	In the current phototherapy cycle, when the blue light LED is powered on, time counting starts, and the time increases continuously until the set phototherapy cycle is completed. The time counting will pause in the need of suspending phototherapy during feeding, injection, etc. and the time counted will be retained. If phototherapy continues after feeding, the time counting will go on until the phototherapy cycle is completed. At this time, the phototherapy stops and the time counting stops.
COUNTDOWN	In the current phototherapy cycle, when the blue light LED is powered on, time counting starts, and the time decreases continuously until the set phototherapy cycle is completed. The time counting will pause in the need of suspending phototherapy during feeding, injection, etc. and the time counted will be retained. If phototherapy continues after feeding, the time counting will go on until the phototherapy cycle is completed. At this time, the phototherapy stops and the time counting stops.
Time clearing	The time counted in the current phototherapy cycle will be cleared (the total time is not affected).
Effective surface	Refers to the surface irradiated by the device for treatment when the patient is placed at the designated position.
Total irradiance	Refers to the irradiance evaluated in the wavelength range from 400 nm to 550 nm.
Total irradiance for bilirubin Ebi	Refers to the irradiance at the center of the effective surface area measured using an irradiance meter having a spectral sensitivity wavelength ranging from 400nm to 550nm.
Total irradiance for bilirubin average	Refers to an arithmetic mean of the total irradiance for bilirubin measured at each measurement point, which is calculated according to the single-point irradiance at the center of each sub area measured using an irradiance meter having a spectral sensitivity wavelength ranging from 400nm to 550nm.

Total irradiance for bilirubin uniformity	Refers to the ratio G2 of the total irradiance minimum value Ebi min to the maximum value Ebi max on the effective surface.
Remarks: Refer to the spectral indicators in the therapeutic elements of the American Academy of Pediatrics (AAP) Clinical Guideline. The recommended wavelength is within 430-490 nm. The value range for wavelength conversion of the unit μW/cm^2/nm corresponding to the total irradiance for bilirubin and the average of total irradiance for bilirubin is 430-490 nm.	