OKUMAN
for Home Healthcare & Hospital Solutions

BC 050
BILICARE INTENSIVE CARE PHOTOTHERAPY
USER MANUAL

About Manufacturer

Manufacturer: Okuman Medikal Sistemler Anonim Sirketi

Product Name: Bilicare Intensive Care Phototherapy

Model: BC 050

Adress HQ: Zübeyde Hanım Mahallesi Kazım Karabekir Caddesi 95 / 95 06060 İskitler, Ankara, TURKIYE

Factory: İvedik Organize San. Bölgesi Arı Sanayi Sitesi 1.Etap 1417 Sok. No:51 Yenimahalle, Ankara, TURKIYE

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Notified Body: Kiwa Belgelendirme Hizmetleri A.Ş.

İstanbul Tuzla Organize Sanayi Bölgesi (İTOSB) 9. Cad. No:15, 34957 Tepeören, Tuzla, İstanbul/TURKIYE

Phone: +90 (216) 593 25 75 Fax: +90 (216) 593 25 74

Web: www.kiwa.com.tr E-mail: posta@kiwa.com.tr

CE
1984

Read this user manual to use this medical device correctly.

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- If all installation procedures, improvements, modifications, alterations and repairs of this product have been made by Okuman's authorized personnel,
- The electrical installation of the relevant room complies with appropriate national and local conditions and;
- The product has been used in accordance with the operating instructions.

Attention

- It is important for the hospital or institution using this device to implement a reasonable service / maintenance plan. Neglecting this can lead to machine breakdown or personal injury.

Note:

- This device must be operated by qualified / trained clinical professionals.

Warranty and Service

Limited Warranty

In case of use of any new devices, service guarantee is given by the OKUMAN Medikal Sistemler Anonim Şirketi, against labor and material errors and for one (1) year from the date of delivery and this guarantee can not be transferred. In addition, there is a warranty for supply for all parts for a fee for a period of 10 years. The device has a lifetime of 10 years.

This warranty does not cover consumables (eg LED lamps, etc.) or breakage / disruption of parts due to improper handling. The only sanction of this guarantee is; replacement or repair of defective products during warranty period. Product modifications made without the written consent of Okuman Medikal Sistemler Anonim Şirketi will not be warranted. Modifications made by the user in the device should not be pursued, and the broken or defective components should be replaced by the Okuman Medikal Sistemler Authorized Service. If the customer interferes with the device, the seller will not be liable for any damage or injury that may occur directly or indirectly.

Technical Service Support

The devices covered by the warranty must be repaired at authorized repair centers. In case of necessity, local distributors or OkumanTechnical Service can be contacted by the customer. In order to receive service support, the model name and serial number of the device must be notified.

Note:

In order to improve the devices, the manufacturer reserves the right to make changes without notice.

Technical Service Department

Adress: Okuman Medikal Sistemler Anonim Şirketi

Headquarter: Kazim Karabekir Caddesi Koyunlu Han 95/95 Iskitler, 06060 Ankara/TURKEY

E-mail: info@okuman.com.tr

Phone: +90 312 384 0520

Fax: +90 312 384 1975

Preface

Guide Objective

This manual contains the instructions necessary to operate the product safety and in accordance with its function and intended use. Following this guide is a precondition for proper product performance and proper operation and ensures the safety of the patient and operator.

This manual is based on the maximum configuration, so some content may not fit the product perfectly. If you have any questions, please contact us.

This manual is an integral part of the product. It should always be kept close to the equipment so that it can be easily accesssed when needed.

Target group

This manual is intended for clinical professionals who are expected to have knowledge of the medical procedures, practices and terminology required to monitor critical patients.

Figures

All forms in this manual serve only as examples. Pictures may not reflect the setups or data shown on your phototherapy device.

Writing Formats

■ Horizontal texts are used in this manual to convey reference chapters or sections.

■ [] is used to cover screen text.

■ → is used to specify operating procedures.

Password

Technical service password is required to reach particular menus.

TABLE OF CONTENTS

NOTES

1. SAFETY

BiliCare is a trademark of Okuman Medikal Sistemler Anonim Şirketi Company and it has been designed to be used in Neonatology and Newborn Clinics for phototherapy treatment. The user is responsible for the consequences of using the device outside of its intended use.

1.1. Safety Information

DANGER

It indicates possible hazards which, if not avoided, will result in death, serious injury or property damage.

CAUTION

Indicates potential hazards or unsafe operations that, if not avoided, could result in minor worker injuries and/or product/property/damage.

WARNING

Indicates unintentional injuries to small casualties and / or potential hazards or unsafe practices that could result in product / property damage

NOTE: It emphasizes the important precautions to be taken and provides explanation for better use of the product.

1.1.1. DANGER

In general, there is no danger attributable to the product. Specific “Danger” statements may be given in the relevant sections of this manual.

1.1.2. General Warnings

- Privacy Information: Intellectual Property Rights regarding all kinds of information presented in this User Guide belongs to Okuman Medikal Sistemler A.Ş. This manual can not be reproduced in any form without the permission of the Okuman Medikal Sistemler Anonim Şirketi.
- Maintenance and Repair: Maintenance and repair of BiliCare Standing Phototherapy unit shall be serviced by Okuman Medikal Sistemler Anonim Şirketi. Okuman Medikal Sistemler Anonim Şirketi is not responsible for any injury or damage during maintanence not performed by Okuman Medikal Sistemler Anonim Şirketi, and the device shall be out of warranty. User Responsibility: Using the device without completely understand its specifications can cause injury to the baby being treated. For this reason, the user manual must be read carefully before using the device.
- Phototherapy devices should only be used by suitably trained personnel under the supervision of qualified medical personnel who are familiar with their risks and advantages. Any user of BiliCare must be trained and familiar with the contents of the user manual before using the device. For this reason, it must be ensured that the user manual is kept in a safe environment that can be reached when necessary.

1.1.3. Warnings for Use Regarding Patient Health

- In order not to damage the baby’s eyes, the eye protection band must be used.
- Patients lying near the phototherapy device should be protected by protective screens to prevent the phototherapy light from passing. It is also recommended that other people in the room wear protective goggles.

- The blue light can damage the eyes when staying too long around the phototherapy device.
- The patient's bilirubin level should be measured continuously.
- Newborn babies may have stains during phototherapy due to the high rate of jaundice on the skin.
- Bilirubine and photoizormers can have a toxic effect during treatment.
- If the operator stays in the working environment of the phototherapy device for a long time, it may be exposed to some effects due to the phototherapy light. The blue light emitted by the lamps in the phototherapy can inhibit the clinical observations such as cyanosis by masking the color changes in the skin. Also blue light may cause; headache, nausea, eye problems and fluid loss.
- During phototherapy treatment, peripheral blood flow may be accelerated, in addition to water loss, damage to the eyes, changes in intestinal passages.
- The skin temperature should be constantly monitored for the possibility that its body temperature may rise.
- The use of reflective foil can cause a dangerous increase in body temperatures.

1.1.4. Warnings regarding the use of equipment

- The power cable should only be connected to the city network and the grounded socket.
- The device should not be used if it is not sure that some parts of the BiliCare phototherapy device are working properly and in such case the technical service should be notified urgently.
- The original lamp should always be used within the knowledge of the manufacturer.The use of different lamps can change the light and temperature conditions.
- Okuman Medikal Sistemler Anonim Şirketi is not responsible for any damage that may occur if parts other than the accessories recommended by Okuman Medikal Sistemler Anonim Şirketi are used together with the BiliCare device. Only accessories recommended by Okuman Medikal Sistemler should be used.
- The BiliCare device should not be used with flammable anesthetic gases or cleaning materials.
- The device must be switched off before moving.
- Liquid infusions and medicines should not be stored in the area of radiation.
- Radiation can damage the device. The device must be protected from radiation and should not be exposed to sunlight.
- Protect against electromagnetic waves. Some tools located near the BiliCare may affect its operation (eg surgical blades, defibrillators). Keep such tools away from Bilicare.
- No products, such as drops or medicines, should be present in the area of radiation.
- The phototherapy device should not be used in the presence of flammable gases (eg oxygen, nitrous oxide, anesthetic agents). Treatment should be started after these gases are removed.
- Flammable solvents (antiseptic, cleaning agents, etc.) should not be used in the cleaning of the phototherapy device.

1.2. Rısks-Precautıons-Warnıngs

The assessment of Bilicare BC 050 phototherapy module on the basis of the risks in the ISO 14971-2013 standard is given in the table below with precautions and warnings.

	Risk	Precaution-Warning
1	Fall	The stand of the phototherapy unit is designed to not cause it to fall off in normal use. The foot length and foot weights are designed to set in the midst on the center of gravity of the device. In addition, the presence of brake wheels significantly reduces this risk.
2	Hanging Mass	The hood of the phototherapy module is connected to the bearing body by the knob. The hood carrier handle is connected by means of a round socket screw clamping system. There is no risk of falling when the knob is placed in the ball nail even if no compression is applied. However, care must be taken to perform compression before use. **Warning: Make sure that there is no baby underneath when the module is placed in the cradle. Avoid possible accidents and injuries.**
3	Single-use Hanging Mass Carrier Track	There is no disposable material in the device.
4	Vibration	Damping mountings that damp the vibrations are used for mounting the device. The device is designed for use in a vibration-free environment. It is necessary to moved slowly and in a controlled manner on its wheels on a smooth floor in order not to be affected by possible vibrations during relocaion, and if possible , this processshould be done by removing the power cable. Care must be taken to ensure that the wheel brakes are pressed in order to protect them from vibration during use.
5	Stored Energy	The phototherapy module needs to be used effectively at a distance of 30cm ± 10cm from the baby bed. The increase in this distance will increase the potential energy and risk of the module falling. For this reason, the module should not be used by hanging it to high levels even in use without feet
6	Moving Parts	The moving parts in the device are wheels, brakes, shock absorbers, dampers, ball joints and are designed in a way that will not pose a critical risk. The moving parts have a long service life. The wheels are freely rotatable in all directions and the brakes are in two positions as open and closed. The shock absorber can move between the upper and lower levels when the pedal is pressed. When the pedal is not pressed, the damper is braked and the position is fixed. The mechanism to which the metal ball is attached is a plastic material, which can rotate in the connection position but does not protrude.
7	Bending, Shear and Stress	The damper used in the device is in the gas piston structure and its reliability is under the guarantee of the manufacturer firm. The upper and lower levels of the shock absorber mechanism are specified and the movement is at a speed that does not pose a risk. In addition, the pedal mechanism provides braking of the shock absorber.

8	**Noise**	Since the cooling of electronic components is provided by passive cooling system, there is no sound generating component in the system.
9	**High Pressure**	In the part containing the pressure in the system is in the shock absorber part. The pressure values are in the range of no risk. In addition, the risk is very low because the shock absorber is not in direct contact with the user or baby.
10	**Reducing Pressure**	Since the part lifted by the shock absorber system is relatively light, the risk of failure or pressure reduction in the long run is very low.
11	**Support Systems**	The link rod that carries the hood of the phototherapy unit is designed to carry only the weight of the phototherapy hood. A different module, serum or heavy objects should not be attached to the link rod. Otherwise, the connection can break, weaken and cause injury. For height adjustment, the handle should be moved by pressing it near the main body. **WARNING: Do not step on the carrier legs and place heavy objects.**
12	**Sharp surfaces and corners**	The phototherapy unit has been carefully designed not to have sharp corners on the module and feet. Nevertheless, it is beneficial for the user to minimize the risk of injuries. Especially when carrying the device over long distances, the feet can hit the people and can cause damages. For this reason, long-distance transport should be pursued with extra care.
13	**Detachable attachable material**	Detachable and attachable material contained in the device is the hood of phototherapy. It is designed to be removable to enable external use. The connection nests and fittings are designed to protect the hood from falling. There is no risk of falling when properly installed.
14	**Push**	Sudden repulsive movements must be avoided when moving the device. In order to move the device by pushing it, it must be moved by pushing it near the feet on the body where the Okuman logo is located.
15	**Hit**	If the grounds on which the feet are located are inclined in order to avoid risk of impact, the foot brakes should not be operated without being activated. In case of use without brakes on curved surfaces, the device may move uncontrollably and may damage the patient / user.
16	**Connection Units**	There are various mechanical and electronic connection parts on the device. These connectors must not be disassembled without the permission of the manufacturer and / or the connection of a new part must not be carried out. Otherwise, the operating performance of the device may be affected and / or failure of the device may be observed.
17	**Liquid and Particle Entry**	The device is not liquid-proof. Liquids can damage the head of phototherapy, especially electronic parts. Because of this reason, contact with liquid should be avoided. There is no particle entry risk as it is designed to block particle entry. Cleaning of the module should be done with a moistened cloth, with non-flammable liquids.

18	**Side Effects**	Phototherapy treatment has side effects. Applying too long or too high intensity phototherapy treatment may cause skin temperature increase or other problems. For this reason, the device should be used by expert personnel by taking the safety precautions specified at the beginning of the manual.
19	**Intentional crossing of safety lines**	The software of the phototherapy module ensures that the values used in therapy are kept within safe limits. The shock absorber motion field module guarantees the movement of the module within the safe limits. However, in external use, the user may be responsible for having very close or remote use of the module, with the baby. For this reason, it is the user's responsibility to ensure that the module is not moved closer than 30 cm to the baby during external use. Also, heavy objects must not be connected and should not be placed to the connection handle and feet.
20	**Presentation of parameters regarding safety**	The safety related operating parameters are given on the interface screen of the device. Apart from this, red warning symbols are placed to draw attention to the parts that are mechanically risky. These warning signs must be observed.
21	**Accidental selection of overflow data**	With the software installed in the module, the phototherapy light intensity can be selected between 5% and 100%. It does not allow the baby body temperature alarm limits to be adjusted beyond the critical levels (32 ° C to 38.5 ° C). Since selection is not permitted outside these values, there is no risk that the inappropriate values are selected by the user.
22	**Incorrect output data**	The device is capable of measuring and displaying the body temperature of the baby through the skin probe. The temperature data may not be read correctly for some reason (probe failure, misuse). In order to minimize this risk in device design, there is a 2 stage filter measurement system and verification algorithm. Apart from this, if there is an error in the measurement, it will not cause any critical consequences for the baby. Because a system for heating the baby (heater, etc.) is not used in the system. It only shows body temperature. **WARNING: To ensure that skin temperature can be measured accurately, always use a suitable skin probe and make sure that it touches the baby's skin.**

1.3. Symbols Of Equipments

	**Type BF device**
	**Universal serial bus (USB) port**
	**Manufacturer**
	**Read the user manual before use the device**
	**Conformity in Europe symbol**
	**Do not throw away**
	**Warning symbol**

2. GENERAL

Before using the phototherapy unit, general introduction, installation, transport and adjustment of the unit are presented in this section

2.1. Scope of Use

Bilicare is routinely used in the treatment of neonatal hyperbilirubinemia, in which concentrated radiation in the blue spectrum of visible light is administered for a period to be determined by the physician based on the patient's condition. During the treatment of jaundice, the patient is placed in a heated baby bed or incubator, depending on his clinical condition. Bilicare is designed for the treatment of jaundice in hospitals.

It is not safe for home use.

BiliCare is designed to be used for phototherapy treatment in Neonatology and Neonatal Clinics.

Target user information: This device should only be used by medical personnel trained in the operation of the device who are familiar with all the risks and benefits of the operation of this type of device. The intended users of this guide are end users of the device, care providers in delivery rooms and neonatal intensive care units, and personnel responsible for hospital biomedical and clinical engineering services. The product is for professional use.

2.2. Contraindications

- Bronze baby syndrome
- Dehydration
- High Fever
- Temporary skin redness

2.3. Indications

- Hyperbilirubinemia treatment
- Kernicterus prevention
- Patients with light sensitivity disorders (eg. congenital erythropoietic porphyria)

2.4. Side effects

In case of non-compliance with hygiene rules, inter-patient contamination may occur. Skin probes must be disinfected before use. Phototherapy treatment has side effects. Applying too long or too high intensity phototherapy treatment may cause skin temperature increase or other problems. For this reason, it is necessary to use the safety precautions specified at the beginning of the manual.

Absolute contraindications for this product are not available.

2.5. Product description

Phototherapy devices are used in the treatment of newborn hyperbilirubin. These devices allow the bilirubin to move towards the blood plasma from the skin using a suitable light source and thus to be expelled from the body. Bilirubin reaches the maximum absorption range when a light source with a visible wavelength of 400-500 nanometers is used. The patient is exposed to the light source in this range and the bilirubin on the skin is removed from the body in the most efficient way.

In phototherapy practice, special neon / fluorescent lamps or LED lamps are used, which are usually made for this purpose. The Bilicare Phototherapy Unit also uses LED lamps with this special radiation range (450-460 nm). Figure 2-1 shows the electromagnetic spectrum. As can be seen, the corresponding wavelength interval falls predominantly to the blue light region.

Phototherapy application decision; is taken in accordance with serum bilirubin level and the rate of uptake, prenatal and postnatal age of the newborn, the underlying causes of hyperbilirubin and hydration. The treatment is not side effect free. For this reason, an effective treatment and care plan must be implemented to avoid any complications. The only way to determine the desire to apply is; to measure radiation at the skin level using a Phototherapy Radiometer.

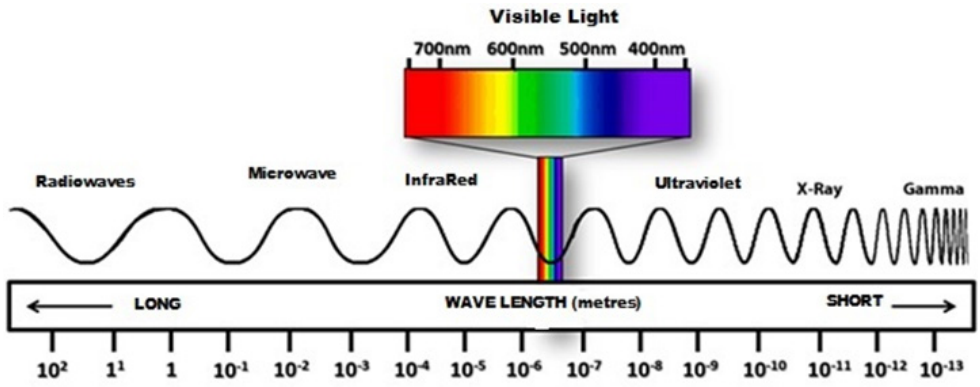


Figure 2-1. Electromagnetic Spectrum

2.6. View of Product

The general view of Bilicare BC 050 phototherapy unit is given in Figure 2-2.

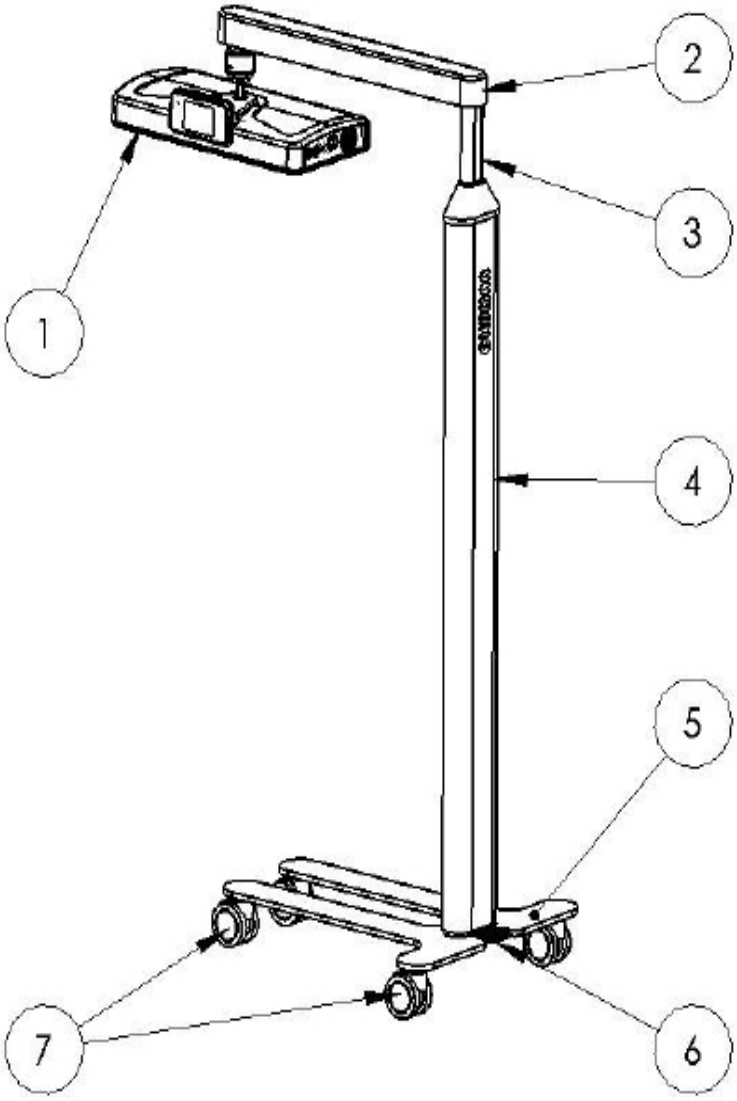


Figure 2-2. Overview of Bilicare BC 050 phototherapy unit

1-Phototheraphy unit main module

2-Connection column

3-Moving body

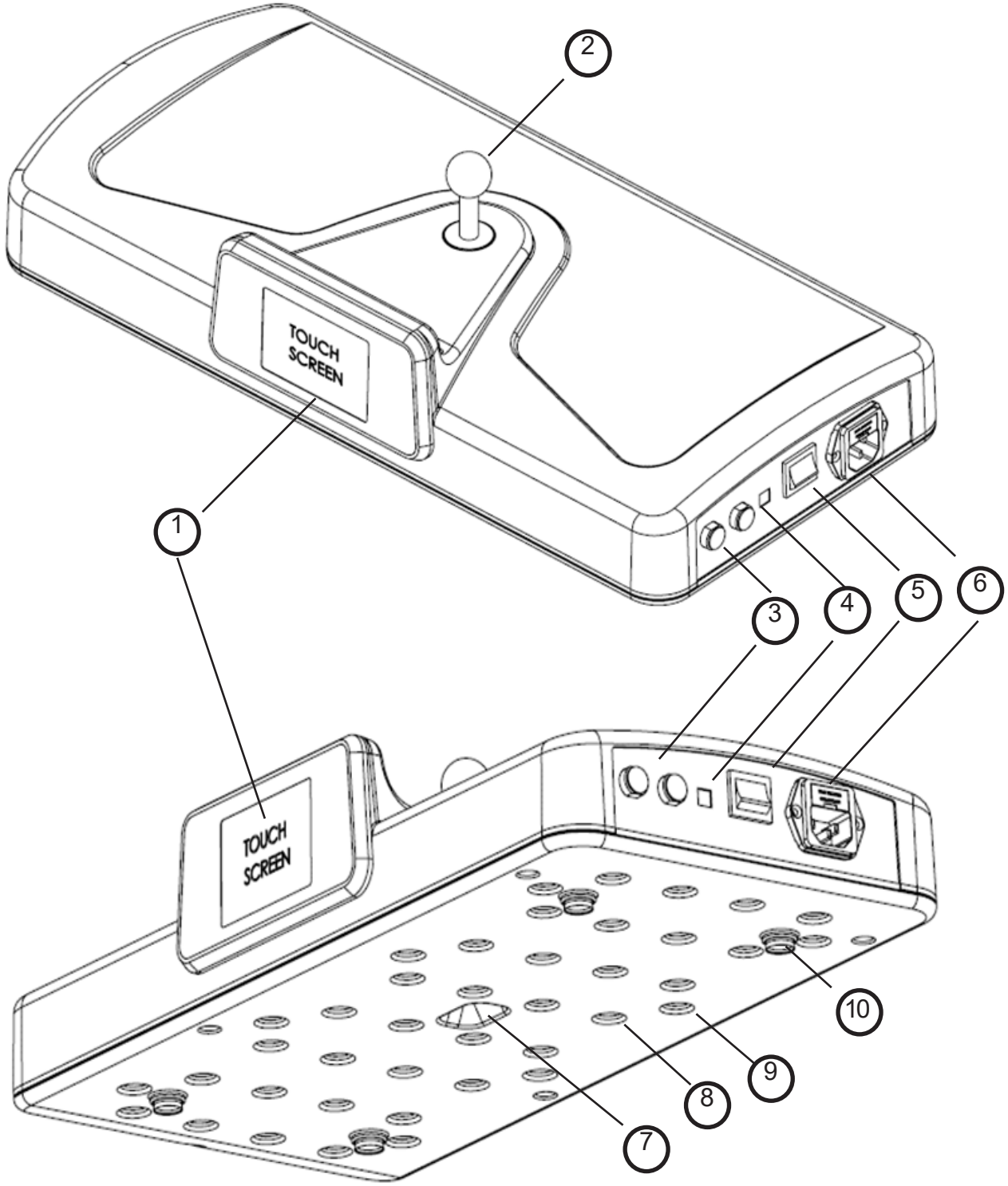
4-Carrier main body

5-Supporting feet

6-Damper pedal

7-Impact absorbing braked wheels

2.6.1. View of Main Module



1.	Color LCD Touchscreen	6.	Power connector
2.	Connection knob	7.	Treatment area focus light window
3.	Temperature probe connectors	8.	Phototherapy led lamps (32 pcs)
4.	USB connection port	9.	Inspection light led lamps (8 pcs)
5.	ON/OFF switch	10.	Anti-slip silicone parts

Figure 2-3. Top and bottom views of Bilicare BC 050 phototherapy unit main module

2.6.2. Bottom View of Main Module

Figure 2-3 shows a close view of the phototherapy main module. Figure 2-4 shows the bottom view and lamp placement.

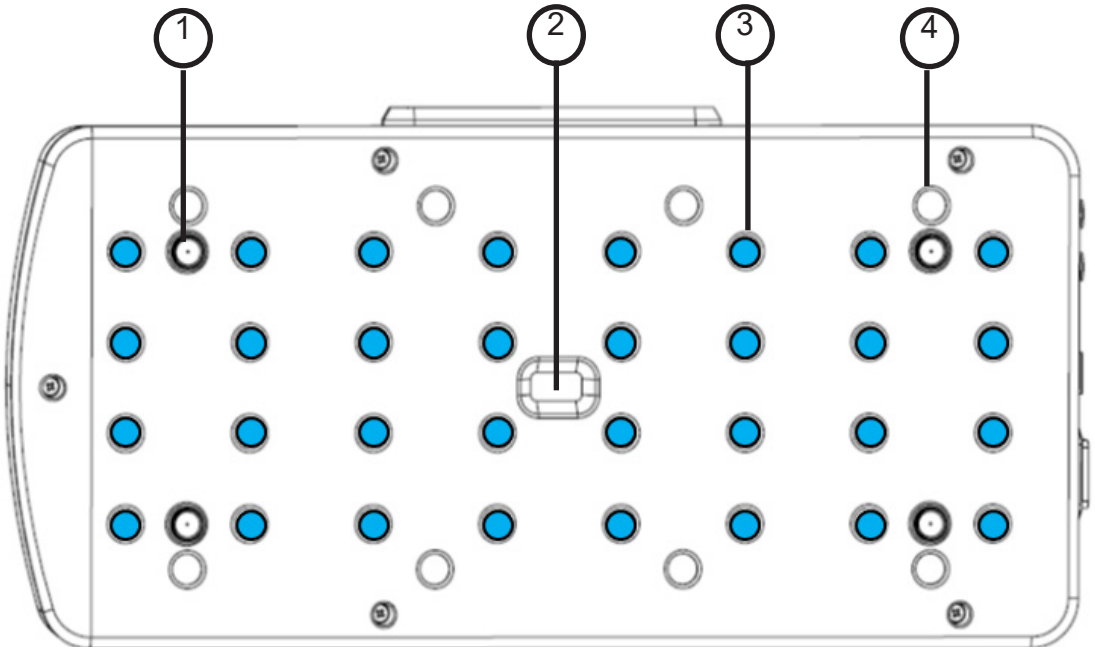


Figure 2-4. Bilicare BC 050 phototherapy unit main module LED lamp placement

1.Anti-slip silicone parts

2.Treatment area focus light (red) window

3.Phototherapy led lamps (32 pcs)

4.Inspection light (White light) led lamps (8 pcs)

2.7. Label Information

The product identification label contains the following information (Figure 2-5):

• Label of the Device, • Serial number, • Production year, • Power voltage, • Power used, • Electrical isolation class, • Address

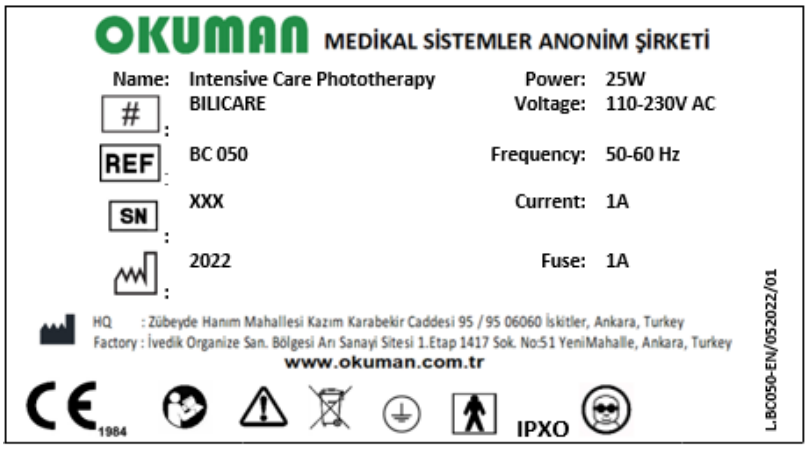


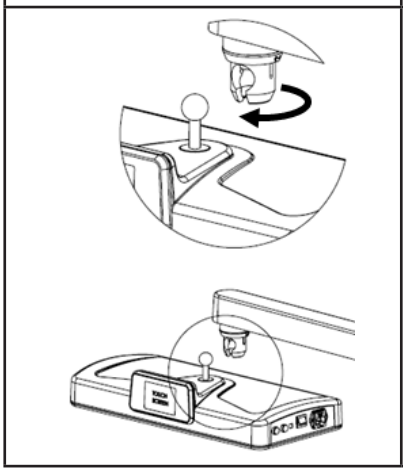
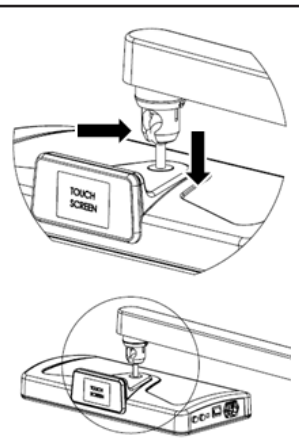
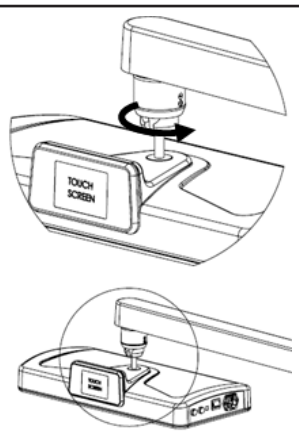
Figure 2-5. Product label

3. INSTALLATION

Bilicare BC-050 phototherapy unit has detachable foot mechanism. For installation, it must be placed on the connection module, which is providing free movement capability, via the connection knob that is on top of the phototherapy main module.

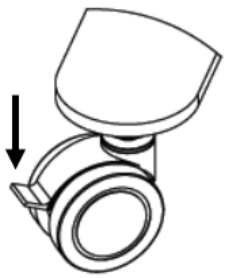
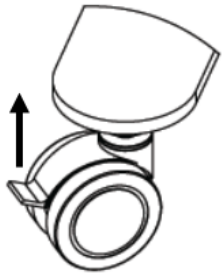
3.1. Attaching the Main Module to Stand

The phototherapy unit is designed for both foot and external use without a foot. For the pedestal use of the unit, the phototherapy main module must be placed in the connecting rod in the carrier body. Follow the steps below to place the unit main module in the connecting linkage:

Turn the rotating head on the end of the linkage to open the slot into which the ball will enter.	Place the connecting ball into the slot and release it.	Turn the swivel head so that the ball stays in the slot.
		

3.2. Fixing the Position Using Wheel Brakes

Use the wheels' brakes to fix the position of the main body. Open the brakes to change position.

Lock the wheel by pressing with your foot on the brake pedal.	Unlock the wheel by pushing the brake up with your foot.
	

WARNING : Activate the brakes on all three wheels to reliably stabilization.

3.3. Connection of the Skin Temperature Probe

During the treatment, the body temperature of the baby can be monitored on the LCD screen. Also, by setting the upper and lower alarm limits for the body temperature, the buzzer can be activated. The temperature probe should be used by placing on the connector that is on the left side of the screen.

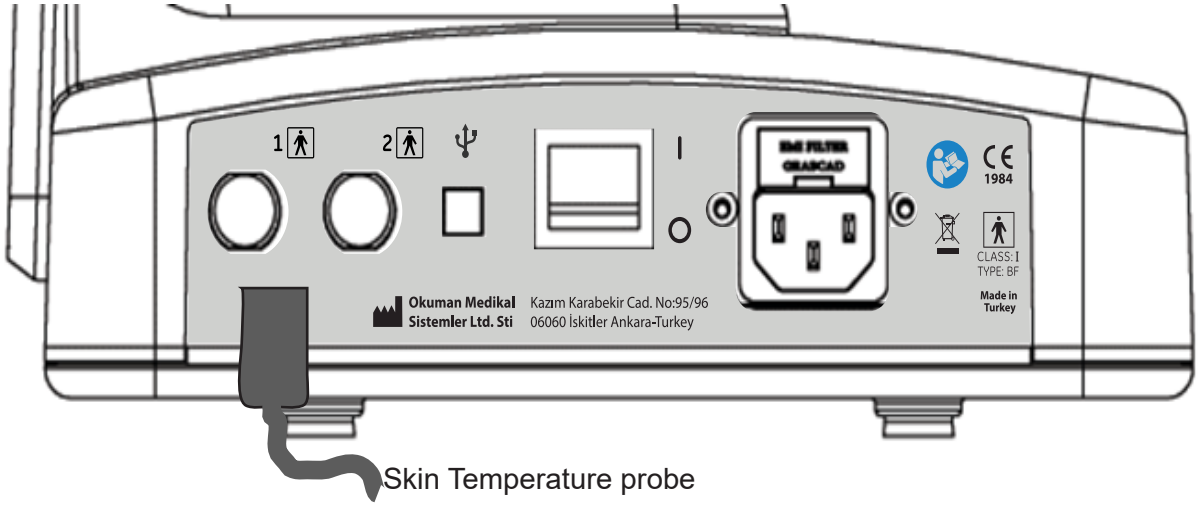


Figure 3-1. Skin temperature measurement probe connector

3.4. Powering On the Device

While the power switch of the device is switched off, the connection of the AC supply cable must be made with a grounded power point. After the connection is made, the device must be switched on with the power (On / Off) switch. Figure 3-2 shows the On / Off switch with the power connector on the side of the phototherapy main module.

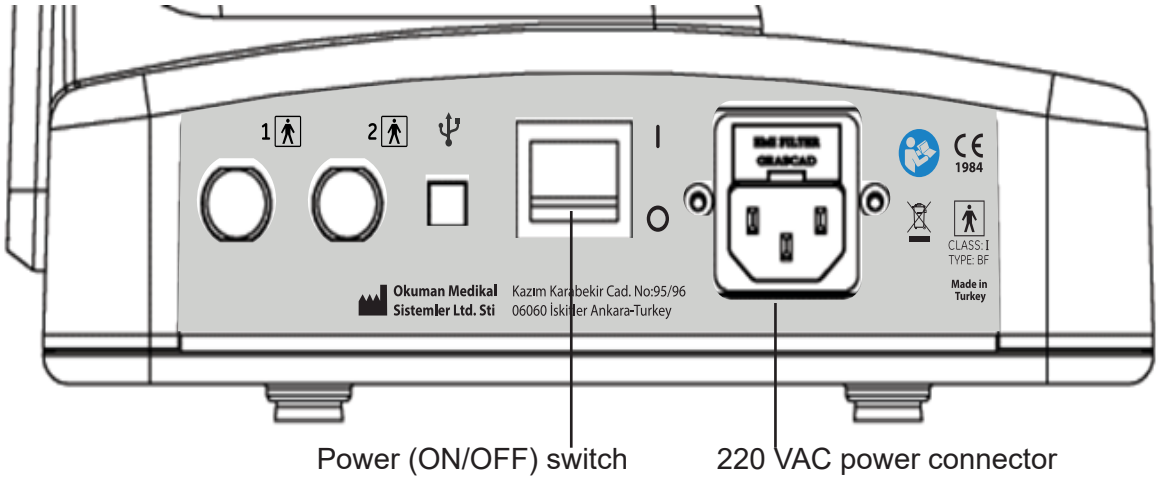


Figure 3-2. Bilicare BC 050 Phototherapy Unit power connection and ON / OFF switch

3.5. Positioning and Orientation of Unit

The unit can be used on a solid support leg, or it can be used on an incubator independently of the supporting foot. While it remains in a fixed position when used on an incubator, it can be oriented at various angles and 360 degrees of freedom when used on a foot (Figure 3-3).

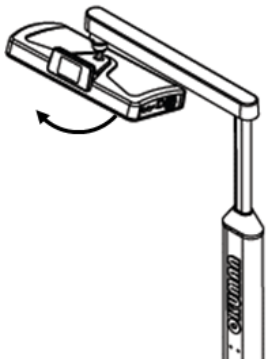
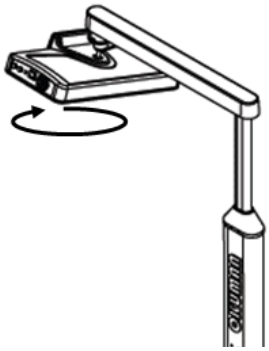
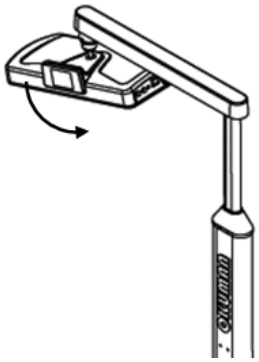
Limited angled movement to the front and back.	360 degree free movement	Limited angled movement to the right and left
		

Figure 3-3. Orientation of the module at various angles on the carrier body

Follow the steps in Figure 3-4 to adjust the position of the module on the feet.

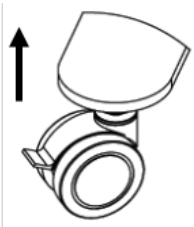
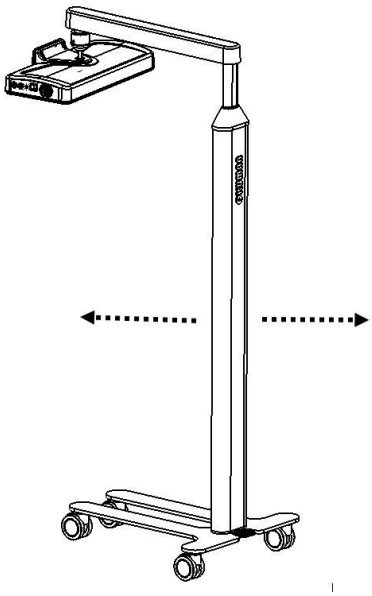
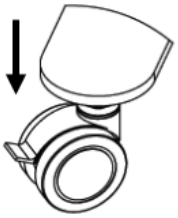
To change the position of the module, pull the brakes of the wheels.	Bring the body to the desired position by pushing from the position close to the feet.	Depress the brakes to stabilize its position.
		

Figure 3-4. Positioning of the Module

WARNING: Make sure to move the phototherapy unit on a flat surface.To move the unit, push the main body near the feet.

3.6. Height Adjustment

The unit height adjustment can be made with a shock absorber system with pedal locking mechanism, which can move up to 36 cm in height. When the damper pedal located in the middle of the foot body is pressed, the connecting rod will move upwards. This movement lifts the connecting rod up to a maximum of 36 cm. If the connecting rod is desired to be lowered, the connecting rod can be moved downwards by pressing the pedal and applying force from the top. If the rod is in the position to be fixed, the position is fixed by releasing the pedal.The lowest position of the phototherapy unit is 120 cm and the highest position is 153 cm. On the figure, it could be seen that the height adjustment of the unit is done. (Note: There may be slight variations in these height levels on some models of the device.)

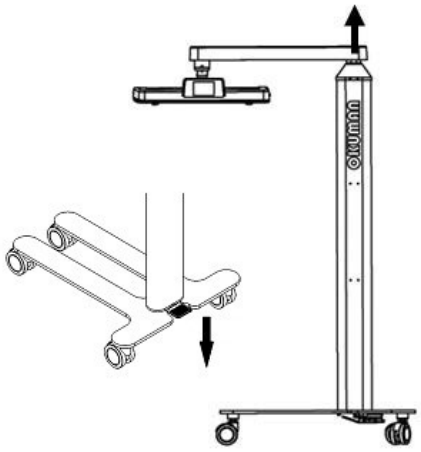
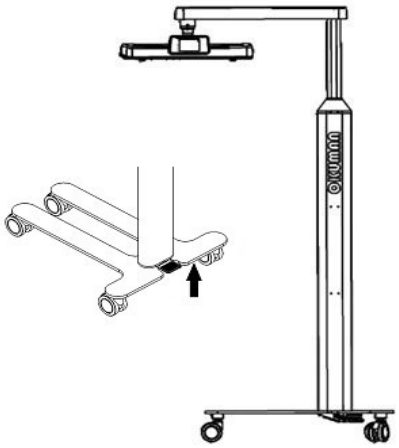
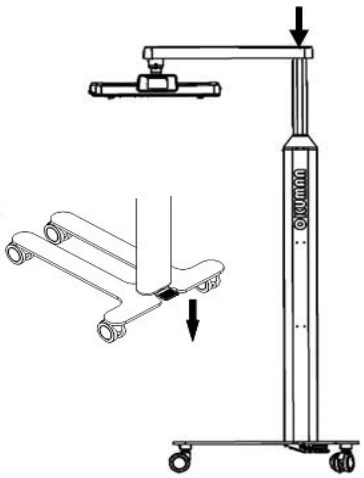
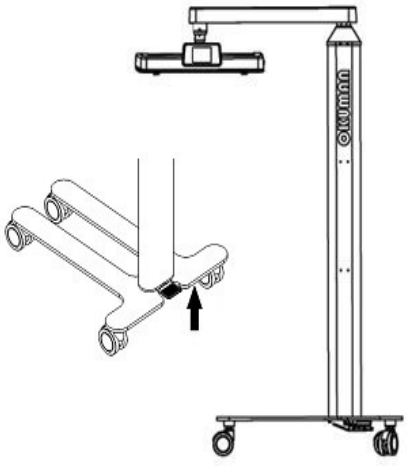
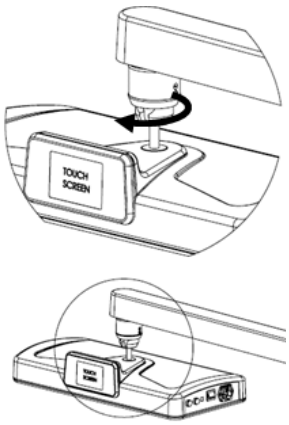
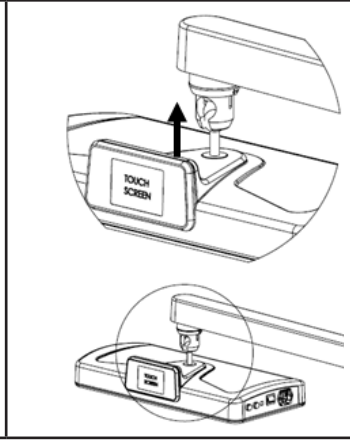
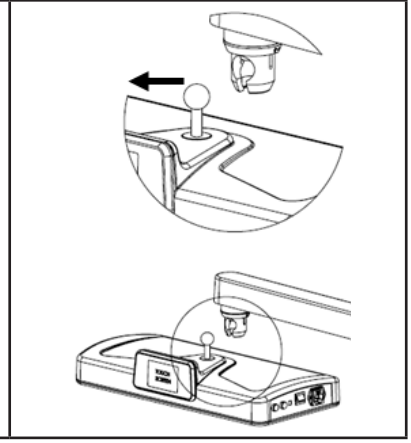
Press the pedal to move the module up. The shock absorber will lift the arm holding the module upwards.	Leave the pedal when the module reaches the desired height. The position will now be fixed.
	
Press the pedal to move the module down. Push down the connecting rod by applying force from the indicated area with arrow.	Leave the pedal when the module reaches the desired level. The location will now be fixed.
	

Figure 3-5. Height adjustment

3.7. Mobile (External) Use

The phototherapy unit can be used as a mobile when separated from the cradle connected to the carrier. In this case, it can be placed on the incubator and used in the same way. However, care must be taken to prevent the device from slipping and falling while the incubator is being transported. To use the phototherapy unit externally, follow these steps:

Turn the swivel head to open the slot where the knob will move.	Move the connecting ball into the socket first and then towards the exit hole.	
		

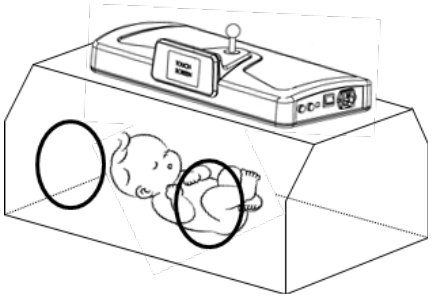


Figure 3-6. Mobile (external) use of the module

Carefully place the module on the incubator so that it is centered on the baby as shown on the side figure. Make sure that it is not slipping on the floor and that all of the silicon retaining parts are in contact. You can start using the power button.

WARNING: The baby phototherapy protective eye band and the baby diaper must be absolutely attached

NOTES

4. USER INTERFACE

4.1. Control Panel Specifications

Bilicare BC-050 phototherapy unit has a color touchscreen LCD screen that provides easy access to all functions. When the device is turned on, the Okuman logo will appear on the display along with the ON / OFF symbol (Figure 4-1). The screen is locked in order not to interfere with any setting during power-on. All functions are accessed and monitored through this screen.

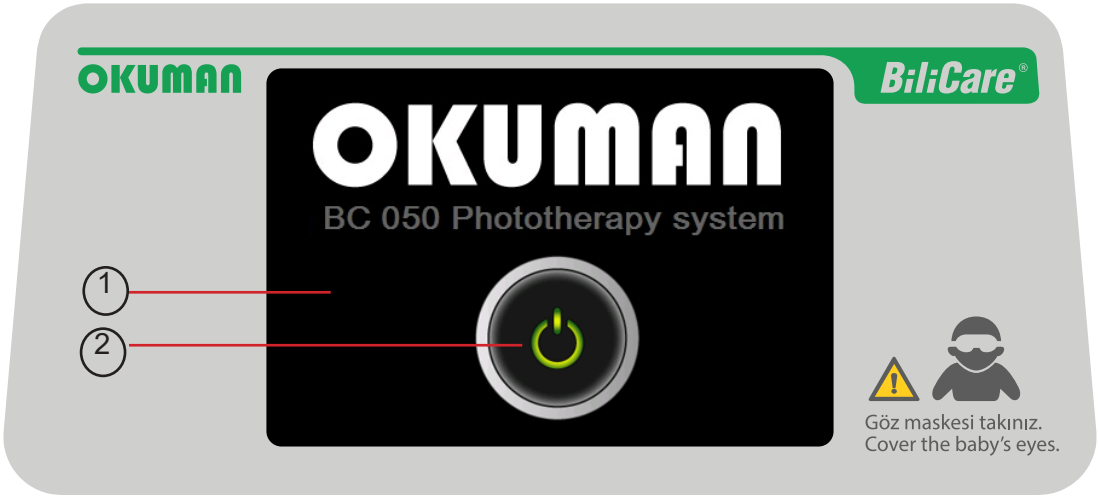


Figure 4-1. Bilicare Phototherapy Unit front panel

1. Color LCD touchscreen

2. ON/OFF button

4.2. Main Menu of the Unit

When the ON / OFF symbol is touched, the main menu of the system will appear on the screen (Figure 4-2).

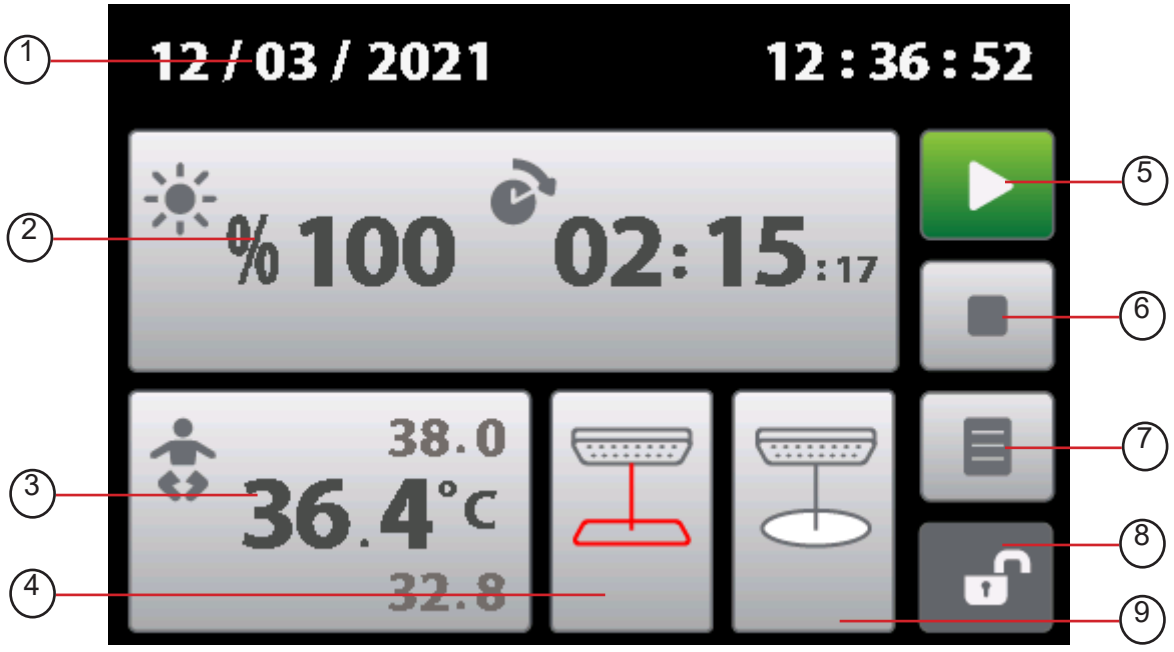


Figure 4-2. Bilicare Phototherapy Unit user interface screen

Functions of the buttons/fields	
Button/field	Function
1. Date time display	Shows current time and date
2. Ligth intensity and treatment time indicator	Shows Ligth intensity and treatment time and opens related configuration menu
3. Temperature probe display	Shows current skin temperature and opens upper and lower alarm limit menu
4. Treatment zone light	Activate/deactivate red light showing the treatment zone limits
5. Treatment start/stop button	Starts and pauses the treatment
6. Reset treatment time button	Resets the treatment timer
7. Settings menu	Opens the settings menu
8. Screenlock button	Locks/Unlocks the screen
9. Inspection lamp on/off button	Activate/deactivate white led lamps for inspection

4.3. Adjustment of the Therapy Light Intensity and Duration Menu

This menu is opened by pressing the 2 numbered button in the main menu.

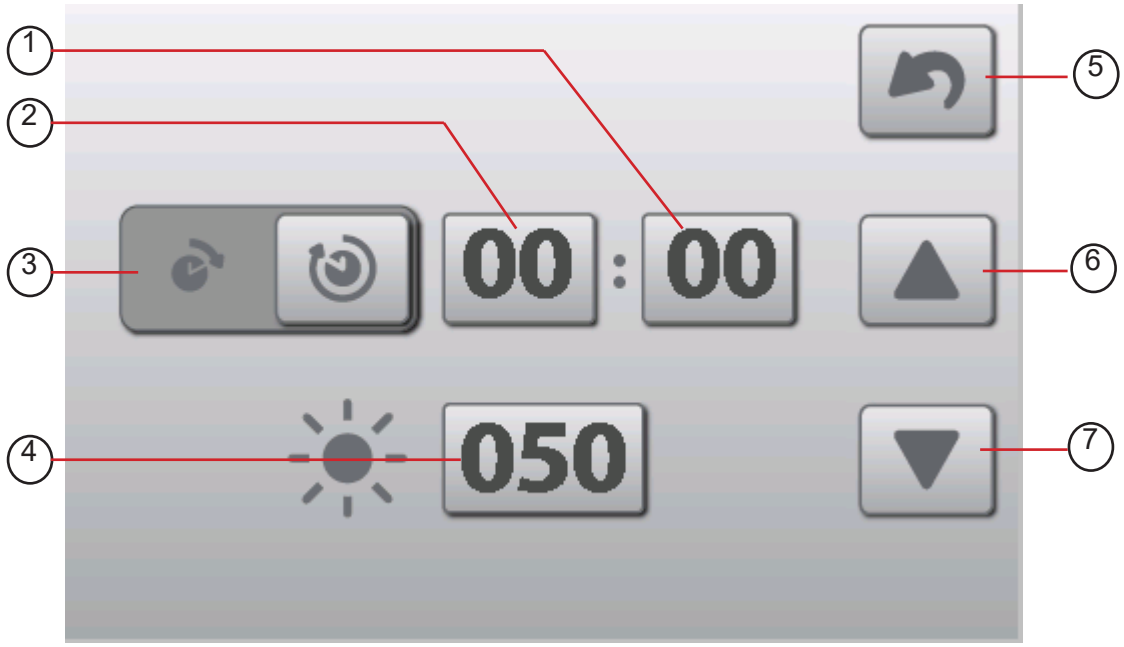


Figure 4-3. Therapy light intensity and duration of therapy menu.

Functions of the buttons/fields	
Button/Field	Function
1. Treatment duration mins selection field	Selects mins field for adjustment
2. Treatment duration hrs selection field	Selects hours field for adjustment
3. Treatment timer mode button	Selects timer mode: treatment duration timer and treatment duration countdown timer.
4. Light intensity selection field	Selects the light intensity for adjustment
5. Return to previous menu button	Returns to previous menu
6. Value increment button	Increments the value in selected field
7. Value decrement button	Decrements the value in selected field

4.4. Skin Temperature Menu

This menu is opened by pressing the 3 numbered button in the main menu.

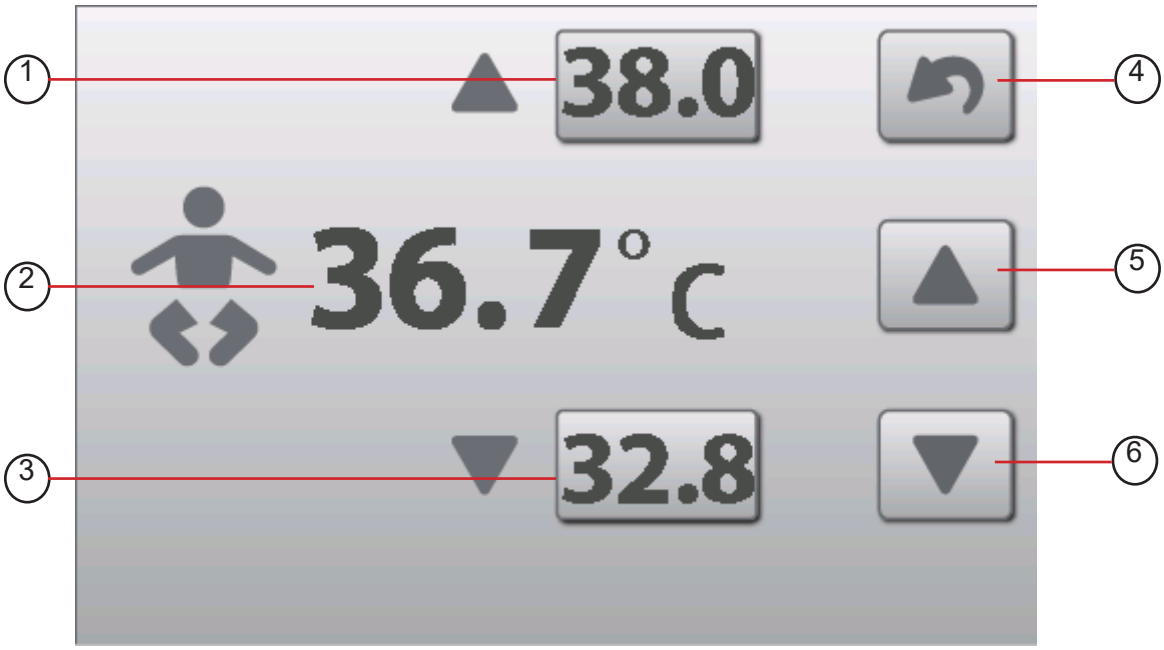


Figure 4-4. Baby skin temperature monitoring and control menu

Functions of the buttons/fields	
Button/Field	Function
1. Upper alarm limit selection field	Selects the upper alarm limit field
2. Baby's instant body temperature value	Shows baby's instant body temperature

Functions of the buttons/fields	
3. Lower alarm limit selection field	Selects the lower alarm limit field
4. Return to previous menu button	Returns to previous menu
5. Value increment button	Increments the value in selected field
6. Value decrement button	Decrements the value in selected field

4.5. Settings Menu

This menu is opened by pressing the 7 numbered button in the main menu.

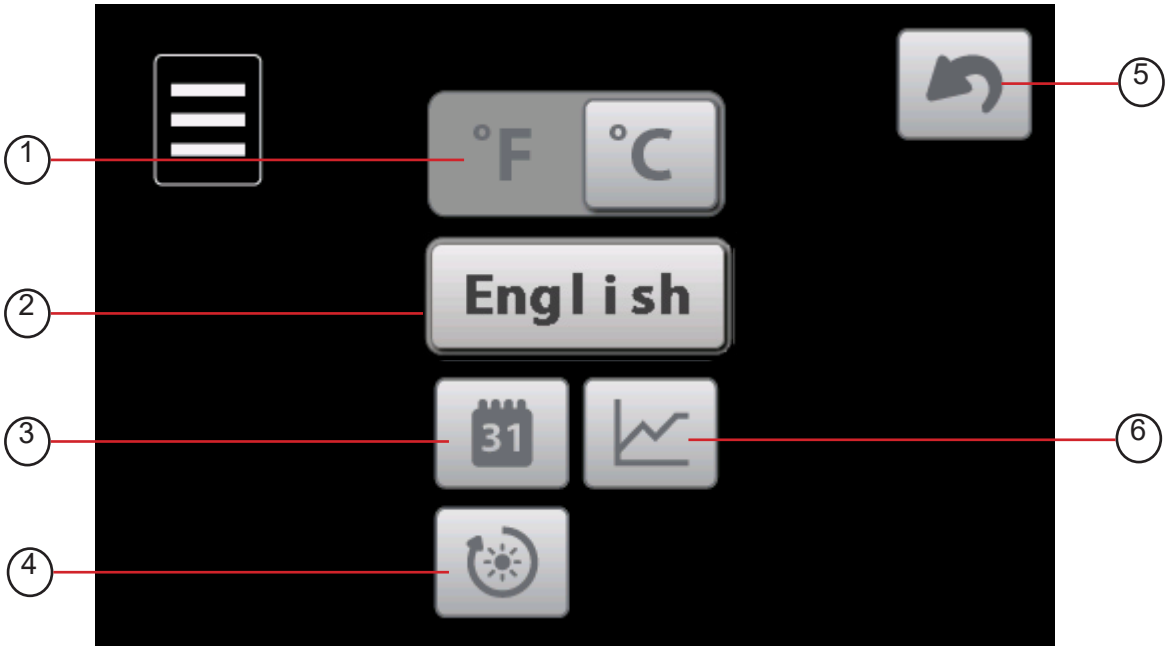


Figure 4-5. Settings menu screen

Functions of the buttons/fields	
1. Fahrenheit-Celsius selection button	Selects the system's main temperature unit to F or C
2. Language selection button	Changes the language of the menu
3. Date / time menu button	Opens the date/time adjustment window
4. Button to reset the lamp timer	Opens the reset lamp timer window
5. Return to previous menu button	Returns to previous menu
6. Trend button	Opens the trend window

4.6. Date/Time Adjustment Menu

This menu is opened by pressing the 3 numbered button in the settings menu.

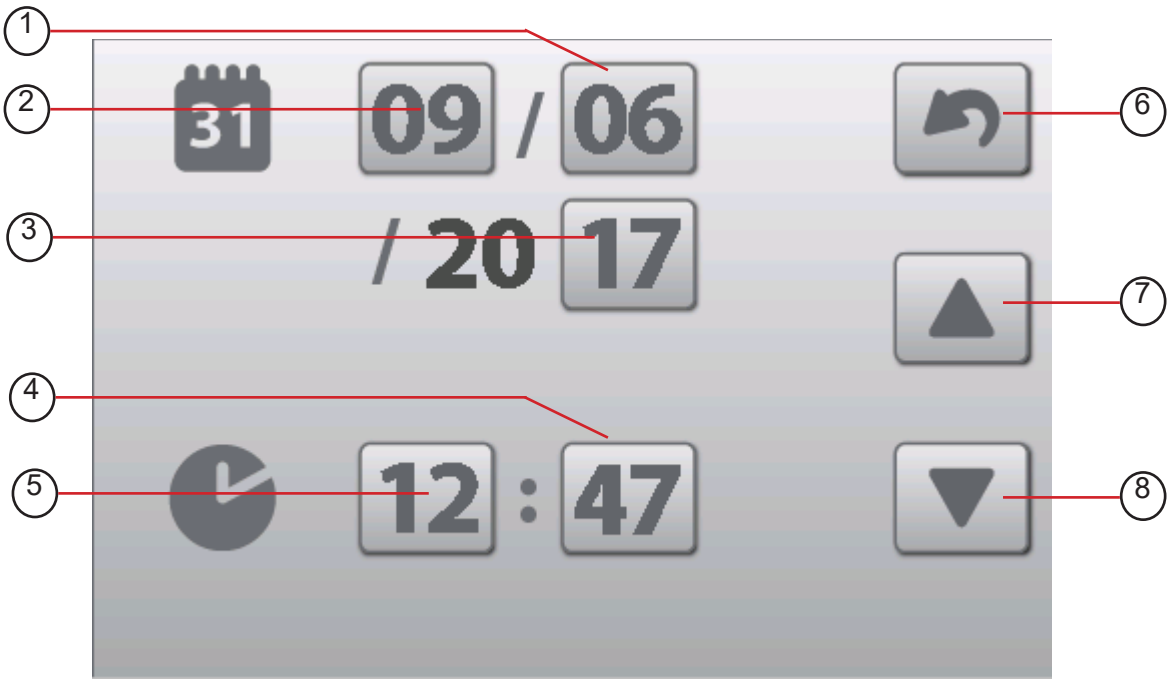


Figure 4-6. Date / time change screen

Functions of the buttons/fields	
1. Month selection field	Selects the month field
2. Day selection field	Selects the day field
3. Year selection field	Selects the year field
4. Minute selection field	Selects the minute field
5. Hour selection field	Selects the hour field
6. Return to previous menu button	Returns to previous menu
7. Value increment button	Increments the value in selected field
8. Value decrement button	Decrements the value in selected field

NOTES

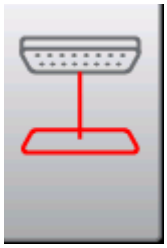
5. USING THE PHOTOTHERAPY UNIT

Please read carefully the following usage suggestions for effective and correct use of the unit. Before switching on the ultraviolet light, make sure that the patient / baby's protective eye band and the baby's nappy are fastened and the skin temperature probe is inserted.

5.1. Starting and Finalizing the Phototherapy

Make sure that the power cable is plugged in before the therapy starts. Switch-On the Power button. The lock screen in Figure 4-1 will appear. Switch to the main menu by touching the ON / OFF icon. At this stage, no LED lamp in the unit should be lit. To start treatment, follow the steps below.

1. Definition of Phototherapy Treatment Area



Press the "Treatment area" button to make sure that the treatment area is correctly identified. When this button is pressed, a red led in the center of the unit will illuminate and make the treatment area visible. Move the treatment area to the zone where therapy is to be performed. Then press the "treatment area button" again to turn off the red light. (Do this if the treatment area is not already specified)

Note: The effective treatment area is 50x25 cm. Changing the height of the device will also cause this area to change.

2. Starting the Phototherapy

Press the "Start Therapy" button to start the therapy. When the therapy starts, the ultraviolet LED lamps will start to work at the light intensity set on the screen. The duration of the therapy will start to be kept in hrs-min-sec format on the main screen.

3.Pausing the Phototherapy

When the Therapy start button is pressed, the button will appear as seen on the side. When this button is pressed again, the therapy is stopped and the ultraviolet LEDs are turned off. To continue the terapy press this button again.

Taking too much of these rays can damage the eyes. It is therefore advisable to wear safety goggles.

4.Resetting the Phototherapy Timer

Pressing the time reset button resets the duration of treatment and the phototherapy unit becomes ready for use for the next patient.

5.2. Adjustment of Phototherapy Light Intensity

The intensity of the light used can be adjusted digitally. It can be set between 5% and 100% (25 to 120 µW / cm2 / nm) with 5% increments on the touch screen. The default light intensity is 50% when the system is turned on. Therapy beam intensity and duration of therapy can be adjusted in the same menu. Fig. 4-3 shows the therapy light intensity and the therapy duration menu.

Follow the steps below to set the phototherapy light intensity:

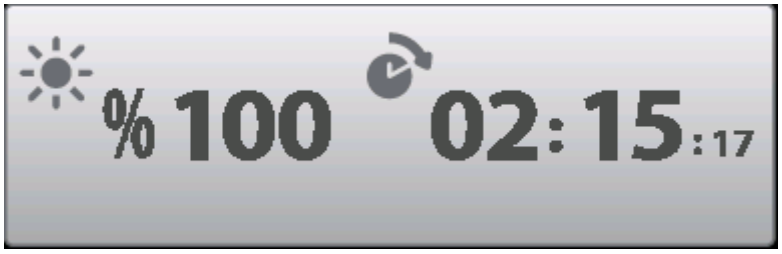
1. Enter sub-menu
 Touch the light intensity and treatment duration indicator to enter the sub-menu shown in Figure 4-3.
2. Make incremental value selection
 Activate by touching the beam power selection button shown in Fig.4-3
3. Set the value
 Set the desired phototherapy light intensity in % by touching the value increase / decrease buttons.
4. Exit
 You can exit this menu by touching the return to previous menu button. The intensity of the light you set is now active.

5.3. Programming Phototherapy Duration

Bilicare 050 phototherapy unit has two option for the treatment timing function which are the therapy duration timer or the therapy time countdown timer. When the unit is turned on, the treatment duration timer is automatically selected.

Follow the steps below to set the therapy duration countdown timer:

1. Enter sub-menu



Touch the light intensity and treatment duration indicator to enter the sub-menu shown in Figure 4-3.

2. Select timing mode

Touch the this button to activate the treatment countdown timer.

When this mode is active, the view of the buttons should look like this. (Countdown timer is in the selected position)

3. Select hour-minute

Select the hour and minute digits by tapping them separately to set the timer for the duration of the therapy countdown.

4. Set the value

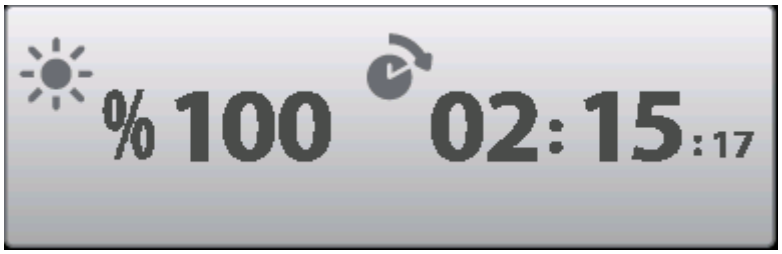
Set the phototherapy duration by touching the value increase / decrease buttons. The maximum setting time is 99 hours and 59 minutes.

5. Exit

Go back to the main menu by touching the return button on the top menu. The phototherapy timer you set will start to work and count down. After the counts reached the zero the phototherapy lamps will be powered down and buzzer will alarm.

Follow the steps below to activate the Therapy Duration timer:

1. Enter sub-menu



Enter the sub-menu shown in Fig. 4-3 by touching the light intensity and the therapy duration indicator.

2. Select timing mode

Touch the button that appears to activate the timer for the therapy session.

When this mode is active, the view of the buttons should look like this. (Therapy duration timer is in the selected position)

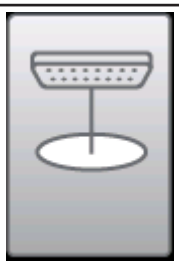
3. Exit

Go back to the main menu by touching the return button on the top menu. The phototherapy timer will start to work and count forward. Therapy time will be displayed in the main menu now.

5.4. Using Inspection Lamps

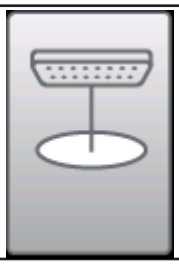
Bilicare 050 phototherapy unit also has white led lamps. These lamps are used for lighting purposes in cases such as examining the baby, if necessary intervention. To turn the inspection lamps on and off, in the main menu, follow these steps:

1. Turn on the lamps



Touch the on / off button for the inspection lamps in the main menu. After this process, the LEDs that give white light will start to work. If the phototherapy lamps are working, the therapy will be paused.

2. Turn off the lamps



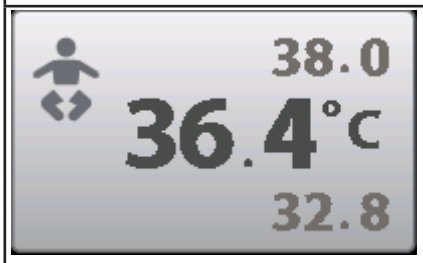
Touch the same button to turn off the inspection lamps. After this process, the LEDs which give white light will become deactive. If phototherapy is paused, continue by touching the therapy start key.

5.5. Monitoring Baby Body Temperature

Phototherapy can cause additional temperature increase in addition to ambient temperature. In Bilicare BC 050 phototherapy unit, it is possible to monitor the baby body temperature instantly and to determine the upper and lower temperature limit values to provide audible warning. Owing to the audible warning system, it is possible to intervene only in critical situations without constantly waiting at the baby's side. Figure 4-4 shows the interface screen for monitoring baby body temperature and setting alarm limits.

Follow these steps to monitor baby body temperature and set alarm limits:

1. Enter the menu



While in the main menu, touch the button shown on the side. The menu shown in Figure 4-4 will appear on the screen.

2. Set upper limit

Touch the upper alarm limit selection field at the top of the screen. The value increase and decrease buttons will change this field.

Use the value increment / decrement buttons on the right side of the screen to set the upper temperature limit value you want to set.

3. Set lower limit

Touch the lower alarm limit selection field at the bottom of the screen. The value increment and decrement buttons will change this field.

Use the value increment / decrement buttons on the right side of the screen to set the lower temperature limit value you want to set.

4 Exit

You can exit this menu by touching the return to top menu button. Alarm limits are now set.

When the unit is started, the upper temperature limit is 37.5 ° C and the lower temperature limit is 32.5 ° C. **Caution: The skin temperature probe must be plugged so that the baby body temperature can be measured.**

When the skin probe is not plugged the baby body temperature menu is shown as follows:

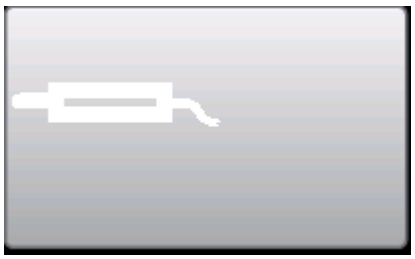


Figure 5-1. Temperature windows when skin probe is unconnected

Baby body temperature values which are outside of alarm limits shown as red colored.

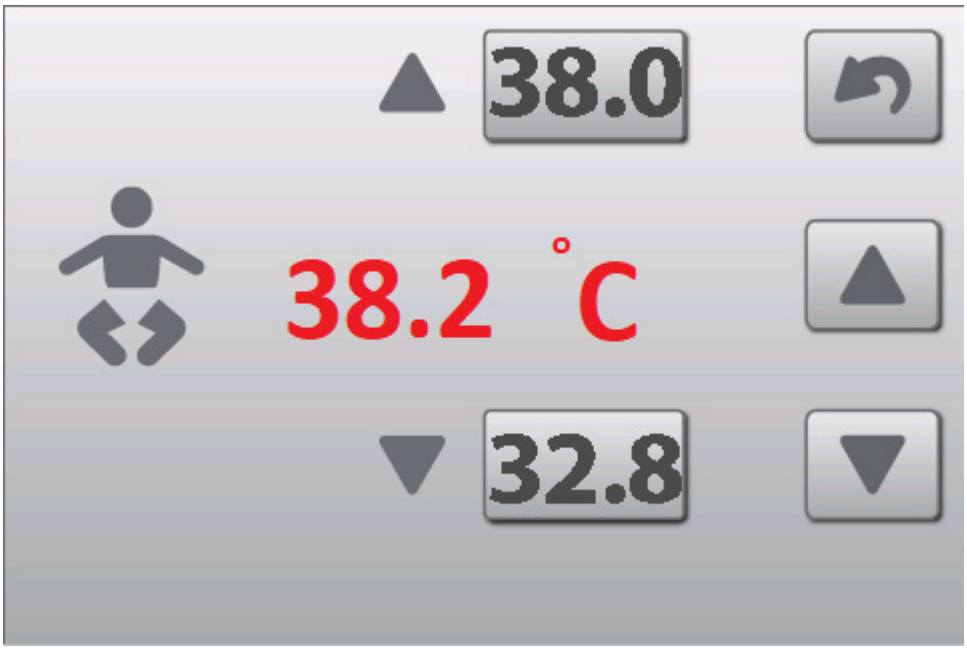


Figure 5-2. Baby body temperature display with out-of-limit values

5.6. Screen Lock

During phototherapy, there is a screen lock option to prevent accidental menu entry. To turn the screen lock on and off, in the main menu, follow these steps:

1. Activate the screen lock
 Lock the screen by touching the screen lock button in the main menu. After this process all other menus and buttons will be disabled except for this button. The symbol of the screen lock button will change to locked.
2. Deactivate the screen lock
 Remove the screen lock by touching the lock button again. At the end of this process all the menus and buttons will be activated again. The symbol of the lock button will also be restored.

6. SYSTEM OPTIONS AND SETTINGS

Menu language selection, temperature unit selection and date-time settings can be performed under the settings menu. Figure 4-5 shows the settings menu screen. To open this screen, you must touch the Settings button while in the main menu.

6.1. Changing Date and Time

Bilicare BC 050 phototherapy unit has real-time date and time module. This module is powered by an external rechargeable battery and keeps the current date and time in memory when the power cable is disconnected or the device is turned off. Sometimes it may be necessary to change the date and time and update it, although it is not often encountered. To change the date and time, follow these steps:

1. Enter the Settings menu
 While in the main menu, touch the settings menu button to enter the settings menu screen. The screen shown in Fig.4-5 will be displayed.
2. Enter Date/Time Change Menu
 On this screen, touch the date / time menu button shown next to it. The date / time change screen shown in Figure 4-6 will be displayed on the screen.
3. Adjust the date
Touch the Day / Month / Year selection buttons to make them selected.
 On this screen, touch the date / time menu button shown next to it. The date / time change screen shown in Figure 4-6 will be displayed on the screen.
4. Adjust the time
Select hour / minute by touching the selection buttons.
 Enter the hour and minute values using the increment / decrement buttons on the right side of the screen.
5. Exit date/time change menu
 You can exit this menu by touching the return to top menu button.
6. Exit settings menu
 Go back to the main menu by touching the return to the top menu at the top right of the Settings menu.

6.2. Changing Menu Language

Bilicare BC 050 phototherapy unit has language support in Turkish and English. To change the menu language, follow these steps while on the main menu screen:

1. Enter the Settings Menu

While in the main menu, touch the settings menu button to enter the settings menu screen. The screen shown in Fig.4-5 will be displayed.

2. Select Language of Use

In this screen touch the language button shown on left to go down to languages sub menu.

In languages sub menu, select the language you desire between 6 languages

3. Exit Settings Menu

Go back to the main menu by touching the return to the top menu at the top right of the Settings menu.

6.3. Changing Temperature Unit (°F/°C)

The temperature indicator of Bilicare BC 050 phototherapy unit can be changed to Fahrenheit and Celsius. There is a conversion between Fahrenheit and Celsius as F = 1.8 * Celcius + 32. When this setting is selected, Celsius and Fahrenheit values are changed by the software and displayed on the screen. To change the temperature unit, follow these steps while on the main menu screen:

1. Enter the Settings Menu

While in the main menu, touch the settings menu button to enter the settings menu screen. The screen shown in Fig.4-5 will be displayed.

2. Choose Temperature Unit

On this screen, touch the ° F button for the Fahrenheit unit as shown.

For the Celsius unit, touch the ° C button as shown in the Figure. The non-selected unit button will be dimmed.

3. Exit Settings Menu

Go back to the main menu by touching the return to the top menu at the top right of the Settings menu.

6.4. Resetting Lamp Timer

The lifetime of the lamps used in Bilicare BC 050 phototherapy unit is approximately 50.000 hours. However, there may be changes in lamp performance after 20,000 hours. For this reason, the unit's software calculates the lamp life and gives a warning message when the lamp life reaches 20,000 hours that the lamp life has expired and needs to be changed. The warning message appears on the main display in the header line (Fig 6-1). In this case it is recommended to replace the LED lamps. Replacement of the lamp should be done by Okuman Medikal Sistemler A.Ş. authorized service. The lamp timer must be reset after the lamp replacement.

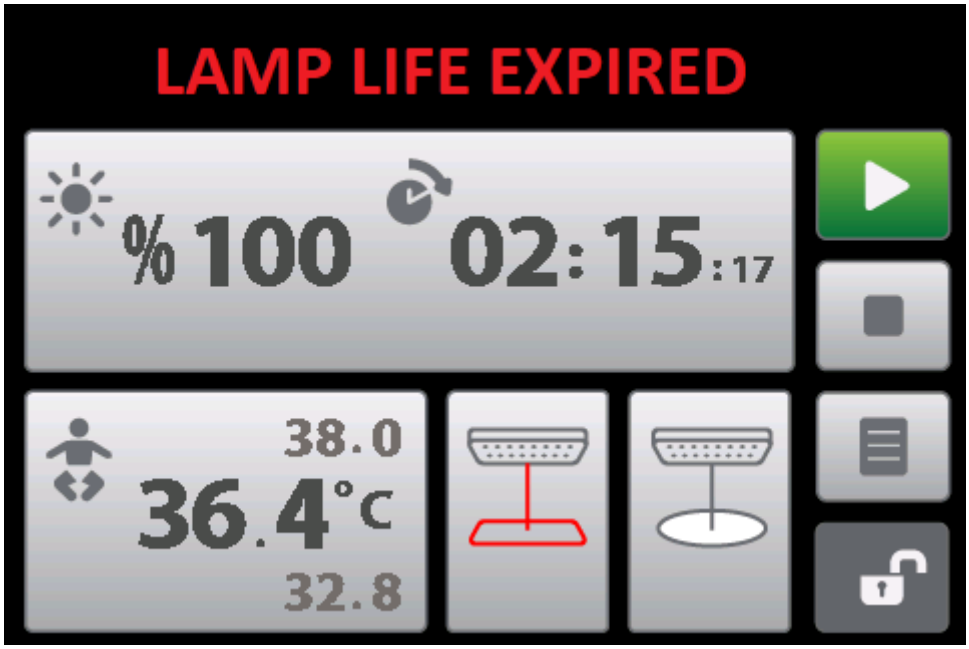


Figure 6-1. Lamp timer warning

NOTES

7. CLEANING and DISINFECTION

There is no need for special cleaning materials in cleaning the device. The BiliCare device should not be used in combination with flammable anesthetic gases or cleaning materials.

Flammable solvents (antiseptic, cleaning agents, etc.) should not be used in the cleaning of the phototherapy device.

Cleaning should be completed by using alcohol

NOTES

8. MAINTENANCE

The life and performance of the device depends on regular maintenances to be carried out by specialists trained and approved by Okuman Medikal Sistemler Anonim Şirketi.

All repairs should be made by Okuman Medikal Sistemler Anonim Şirketi Technical Assistance or by approved technicians and only the components of Okuman Medikal Sistemler Anonim Şirketi should be used.

8.1. Technical Assistance maintenance

We recommend you to buy Okuman Medikal Sistemler Anonim Şirketi Technical Assistance maintenance contract.

8.2. Systematic Maintenance

The following general maintenance should be carried out once every 12 months.

- Disassemble the device and clean it thoroughly.
- Check the following.
- General condition of the device
- Life cycle of LED Tubes and if necessary, their replacement
- Hinges, bolts and arms
- Temperature measurement system
- Fuse

Warning: It is very important to keep the repair information in order to keep the record of all the examinations and repairs made.

The device is sent to the user with the factory calibrations made.

Warning: It is recommended to calibrate the device at least once a year.

Warning: The motor inside the device may cause vibration over time. It should be checked at regular intervals by authorized technical service personnel.

NOTES

9. TROUBLESHOOTING

9.1. Alarms


When the Skin Temperature limit value is adjusted to above > 32.0 °C, if the skin temperature measured is below this value, an alarm state occurs. The device does not start the treatment until the alarm state is cleared. This alarm state can be silenced
In order to turn off the Skin Temperature Low Alarm, the Limit value of Skin Temperature Low Alarm has to be adjusted to 32.0 °C.

The skin temperature value will be active when the Skin Temperature is above the Upper Limit value. The treatment is terminated. The treatment cannot be started at all until the alarm state is over. In the alarm state, only the alarm can be silenced.
The baby being treated inside the device has to be checked immediately and necessary intervention has to be made.

This warning will be displayed when the effective lamp life is over. The Treatment lamps should be replaced with new ones after this warning appeared on the screen

The device gives this alarm when the treatment duration is finished. After 3 times audible warning the visual alarm continues on screen and alarm led. The baby has to be checked and taken out of the device.

9.2. Errors

Error	Reason	Solution Suggestion
Device is not operating	Power Supply Error	Unplug the device
	On/Off switch is in off position	Switch to on position
	The fuse of the device is broken	Change the fuse
	There is an electrical problem with the device	Call Okuman Medikal Sis temler Technical Service
Treatment is not starting	Baby's bed is not placed in the right position	Put the baby's bed in the right position by pushing it
Treatment is not starting Lamps are not lighting	Software Error	Call Okuman Medikal Sis-temler Technical Service
Lamps are not lighting	One or more lamps burned out	Replace the lamps
	There is an electrical problem with the device	Call Okuman Medikal Sis temler Technical Service
Air temperature value does not appear on screen	The air temperature probe is removed or broken off	Correct the cable with your hand and bring it to vertical position
		If the cable is broken off, call Okuman Medikal Sistemler Technical Service

NOTES

10. OPTIONAL ACCESSORIES

Description	ERP Codes
Main Board	20111002
LCD 3,5” Color Touch Screen	30425036
Carrying stand	20103328
LED Lamp Set	20116066
Power supply (SMPS)	30304001
Lamp cover	30102004
Castors	30501003
Emi filtrer	30302001
Skin Temperature Prob (Reusable)	101040007
Skin Temperature Prob (Disposable) (pack of 10)	106060007
Skin Temperature Prob Fixing stamp (pack of 50) disposable	106060008
Rectal Temperature Prob (Reusable)	106070045
Bonnet type Eye protection mask size: large 30x38 cm (pack of 20)	106010003
Bonnet type Eye protection mask size: medium 24x33 cm (pack of 20)	106010002
Bonnet type Eye protection mask size: small 20x28 cm (pack of 20)	106060009
Photherapy protection diaper for premature size:small 750-1250 gr (pack of 30)	106060005
Photherapy protection diaper for premature size:medium 1250-2250 gr (pack of 30)	106060004
Glove	106060010
Power Cord (TR)	30306056
Power Cord (EN)	30306057
Power Cord (US)	30306059
Dust Cover	106060222

NOTES

A. SPECIFICATIONS OF THE PRODUCT

A.1. Technical Specifications

Model Name	Bilicare BC 050 000
Light Source	32 Pieces of blue led
Lighting Feature	8 Pieces of white led
Control Panel	3.5” LCD TFT Color touch screen
Light Power	25-120 µw/cm^2/nm
Light Wavelength	450-470 nm (458nm peak)
Lamp Life	50.000 hrs (on average)
Skin Temperature Measure	In between 10-45 °C
Light Intensity Setting	In between %0-%100 (±%5 increments)
Screen Safety	Touchscreen Lock
Alarms (Audible/Visual/Written)	High skin temperature Low skin temperature Thermal deviation (0.5/1 °C) Lamp Life Overheating Skin probe failure
Alarm Silence	Through the touchscreen
Noise Level	≤ 30dB
Fan	Fanless cooling system
Height Setting	Blocklift foot-controlled height adjustment
Body Feature	Aluminum stainless steel body
Head Rotation	360° rotatable treatment head
Wheel Feature	Shock absorber wheel mechanism
	Electrical Properties
Current	1A
Voltage	110-230 ±10 VAC
Power	25 W
Frequency	50-60 Hz
Class of electric	Class 1, Type BF

A.2. Skin Temperature Measurement

Display Range	10-45°C±0.1°C
Adjustable Measuring Range	30-38°C
Measurement Accuracies	≤ 0.2°C
Measurement Precision	±0.1°C
Alarm Values	32-38.5°C

A.3. Timer Properties

Phototerapy timer	0 to 999 h
Treatment timer, adjustable	0 to 999 h

A.4. Equipment Physical Features

Phototherapy Unit Size	45×25×8.5 cm
Phototherapy Unit Weight	4 kg
Stand Foot min and max Height	150 – 190 cm
Stand Weight	17 kg
Standard Acessories	Transport trolley and skin temperature probe (reusable)

A.5. Standards

Bilicare phototherapy unit meets the standards of the following table.

TS EN 60601-1	Electrical medical equipment - Part 1: General rules for basic safety and performance required
TS EN 60601-2-50 ed.2 (2/10)	Electrical Medical Equipment, Part 2-50: Specific features for the basic safety and performance required of baby phototherapy equipment
TS EN ISO 14971 (04/13)	Medical devices - Application of risk management to medical devices

A.6. Working Conditions

Place of Use	In neonatal clinics of hospitals In dust-free environments without combustible or flammable gases
Environment Temperature	10 ~ 40 °C
Environment Humidity	%40~%90 RH
Position of Use	Standing or horizontal on top of the incubator (external).
Power Requirement	110-230 VAC, 50/60 Hz (±%20)

A.7. Storage Conditions

Environment Temperature	-10 ~ +40 °C
Humidity	0~%90 RH

B. EMC TEST REPORTS

Medical electrical devices are subject to special precautions regarding electromagnetic compatibility. See the EMC Manual.
In the following cases, if protective measures against electrostatic discharge are not taken, incorrect studies that may endanger the patient may occur.

- When touching the device connector pins bearing the ESD warning symbol,
- When creating connections with device connectors.
- The following precautions should be taken and the relevant personnel should be trained to prevent incorrect operation.
- Observe ESD protection measures. Such precautions may include using antistatic clothing and shoes, touching the potential equalization pin before and while connecting, or using electrically insulated and antistatic gloves.
- Pay attention to the necessary conditions for electromagnetic environments.

WARNING: Electromagnetic fields can affect the operation of the device and as a result endanger the life of the patient.

WARNING: This device is intended for use by professional healthcare professionals only. This device may cause radio interference or disrupt the operation of nearby equipment. It may be necessary to take measures to mitigate the adverse effects by shielding the area or relocating or reorienting the device.

Precautions to be taken regarding electromagnetic

The use of accessories that do not comply with the relevant safety requirements may result in a reduced safety level of the device:

- All medical accessory equipment located near the patient must comply with the safety requirements of IEC 60601-1 and have the relevant safety certificates.
- The use of accessories listed and not approved for use with this product as original or replacement products may result in increased electromagnetic emissions or decreased electromagnetic immunity.
- Devices connected to the serial port must comply with the requirements of IEC 60601-1-2.
- Special precautions are required in terms of electromagnetic compatibility for electrical medical equipment and the equipment must be installed and commissioned according to the electromagnetic compatibility information in this manual.
- In addition, portable and mobile RF communications equipment may affect medical electrical equipment.

WARNING: Making changes or modifications to this device that Okuman has not expressly approved may cause EMC failure in this or other devices in the vicinity. EMC compatibility has been evaluated with the probe specified in the accessory list.

WARNING: The medical device may only be used near or on other devices if approved by Okuman. If adjacent or overlapping use of unapproved configurations is unavoidable, normal operation of the medical device in the specified configuration should be verified. The user manuals of the devices must be followed.

GUIDANCE AND MANUFACTURER DECLARATIONS – ELECTROMAGNETIC EMISSIONS		
This Bilicare Incubator-Top Phototherapy Unit is intended for use in the environment specified below. The customer or user of the unit should ensure that the Bilicare Incubator-Top Phototherapy unit is used in such an environment.		
Emission Test	**Compliance**	**Electromagnetic Environment - Guidance**
RF (radio frequence emissions) CISPR 11	1. Group	Bilicare Incubator-Top Phototherapy unit uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause interference with nearby electronic equipment.
RF (radio frequence emissions) CISPR 11	A Class	Bilicare Incubator-Top Phototherapy unit is suitable for use in all establishments, including domestic, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions TS EN 61000–3–2	-	
Voltage surges/ flicker emissions TS EN 61000–3–3	-	

GUIDANCE AND MANUFACTURER DECLARATIONS – ELECTROMAGNETIC IMMUNITY			
This Bilicare Incubator-Top Phototherapy Unit is intended for use in the environment specified below. The customer or user of the unit should ensure that the Bilicare Incubator-Top Phototherapy unit is used in such an environment.			
Immunity Test	**TS EN 60601 test level**	**Compliance level**	**Electromagnetic Environment—Guidance**
Electrostatic discharge (ESB) TS EN 61000–4–2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	The floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic, the relative humidity should be at least 10%.
Electrical fast transient burst immunity TS EN 61000–4–4	For electricity supply lines ±2 kV For input / output lines ±1 kV	For electricity supply lines ±2 kV For input / output lines ±1 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge TS EN 61000–4–5	Differential kip ±1 kV Common kip ±2 kV	Differential kip ±1 kV Common kip ±2 kV	Mains power quality should be that of a typical commercial or hospital environment.
For sudden voltage dips, short droupouts and voltage changes in electrical supply input lines TS EN 61000–4–11	0,5 cycle <5 %UT (UT dip >95%) 5 cycle 40% UT (UT dip = 60%) 25 cycle 70 %UT (UT dip 30%) In 5 seconds < 5% UT (UT dip > 95%)	0,5 cycle <5 %UT (UT dip >95%) 5 cycle 40% UT (UT dip = 60%) 25 cycle 70 %UT (UT dip 30%) In 5 seconds < 5% UT (UT dip > 95%)	Mains power quality should be that of a typical commercial or hospital environment. In case the user has to use the incubator If the user needs to use the incubator in such a way that he or she is exposed to power interruptions, it is recommended that the power be supplied from the uninterruptible power supply or from the battery.
Electrical frequency (50/60 Hz) magnetic field TS EN 61000–4–8	3 A/m electrical frequency	3 A/m electrical frequency	Mains power quality should be that of a typical commercial or hospital environment.
Note: Alternative current prior to UT test level application is mains voltage.			

GUIDANCE AND MANUFACTURER DECLARATIONS – ELECTROMAGNETIC IMMUNITY

This Bilicare Incubator-Top Phototherapy unit is intended for use in the environment specified below. The customer or user of the unit should ensure that the Bilicare Incubator-Top Phototherapy unit is used in such an environment.

Immunity Test	**TS EN 60601 test level**	**Compliance level**	**Electromagnetic Environment— Guidance**
Transmitted RF TS EN 61000–4–6	3 average square root voltage Outside of EBT bands a 150 kHz to 80 MHz 10 average square root voltage Outside of EBT bands a 150 kHz to 80 MHz	3 average square root voltage 10 average square root voltage	Portable and mobile RF communications equipment should be separated from the incubator, including its cables, by no less than the recommended distances. Recommended separation distance: d = 1,2 √P d = 1,2 √P d = 1,2 √P 80 MHz to 800 MHz d = 2,3 √P 800 MHz to 2,5 GHz
Radiated RF TS EN 61000–4–3	10 V/m 80 MHz to 2,5 GHz	10 V/m	where P is the output power of the transmitter in watt (W); d is recommended separation distance in meter (m) b. Field magnitudes, determined by using a field measurement c, originated from a constant RF transmitter have to be lower than compatibility level d of the every frequency levels. Interference may be occurred near to equipments that have following symbol. 

NOTE 1: Higher frequency from in between 80 MHz to 800 MHz shall be applied.
NOTE 2: These general information may not be applicable in all circumstances. Electromagnetic propagation is affected by absorption and reflections caused by structures, objects and people.

a. EBT bands (industrial, scientific and medical) in between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

b. Compatibility levels in the EBT bands between 150 kHz and 80 MHz and in the 80 MHz to 2.5 GHz frequency range are intended to reduce the likelihood of interference from mobile / portable communication devices brought to the patient's site. For this reason, an additional factor of 10/3 was used to calculate the recommended separation distance for transmitters in this frequency domain.

c. Theoretically, it can not predicted whether the field intensities are caused by stationary transmitters such as radio telephone base stations (cellular / wireless) and terrestrial mobile radios, amateur radios, AM and FM radio broadcasts and TV broadcasts. The results of the electromagnetic field survey made to evaluate the electromagnetic environment caused by fixed RF transmitters should be considered. If the measured field strength in the room where the incubator is used exceeds the applicable RF compliance level stated above, it should be checked whether the incubator is operating normally. If there is an abnormality in the operation, it may be necessary to take additional precautions such as changing the orientation or position of the incubator.

d. Field strengths above the 150 kHz to 80 MHz frequency range should be less than 3 V / m.

RECOMMENDED SEPERATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATION EQUIPMENTS AND BILICARE INCUBATOR-TOP PHOTOTHERAPY UNIT

This Bilicare Incubator-Top Phototherapy Unit is designed for use in electromagnetic environments where RF emission disturbances are controlled. In order to contribute to the prevention of the customer or user electromagnetic interference, the Bilicare Incubator-Top Phototherapy Unit must maintain a minimum distance between portable and mobile communication devices (transmitters), as determined by the maximum output power of such devices, as follows.

Maximum rated output power of the transmitter (W)	**Seperation distance according to the frequency of the transmitter (m)**			
	Outside of EBT bands 150 kHz to 80 Mhz d = 1,2 √P	Within EBT bands 150 kHz to 80 Mhz d = 1,2 √P	80 MHz to 800 MHz d = 1,2 √P	800 MHz to 2,5 GHz d = 2,3 √P
0,01	0,12	0,12	0,12	0,23
0,1	0,38	0,38	0,38	0,73
1	1,2	1,2	1,2	2,3
10	3,8	3,8	3,8	7,3
100	12	12	12	23

The maximum rated output power can be determined by using the equation for the frequency of the transmitter (d), the recommended separation distance in meters (m) for transmitters not specified above. Here; According to the manufacturer P is the maximum rated output power, in watts (W), of the transmitter.

NOTE 1: The higher frequency range of 80 MHz to 800 MHz is applied.

NOTE 2: In between 150 kHz and 80 MHz EBT (industrial, scientific, medical) bands are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.

NOTE 3: An additional factor of 10/3 was used in the calculation of the recommended separation distance for transmitters in the EBT bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to reduce the likelihood of interference from mobile/portable devices brought near the patient unintentionally.

NOTE 4: This general information may not apply in all cases. Electromagnetic propagation is affected by absorption and reflections caused by structures, objects and people.

CE 1984

OKUMAN Medikal Sistemler A.S.

HQ OFFICE

Kazım Karabekir Caddesi 95/95

06060 Iskitler Ankara/TURKEY

T: +90 312 384 05 20

F: +90 312 384 19 75

info@**okuman**.com.tr

www.**okuman**.com.tr

FACTORY

Ivedik OSB, Ari Sanayi Sitesi 1417 Sk, No: 51

Yenimahalle, Ankara / TURKEY

T: +90 312 394 00 37

info@**okuman**.com.tr

www.**okuman**.com.tr

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