ERTUNÇ ÖZCAN

BLUE ANGEL LED PHOTOTHERAPY DEVICE
USER, MAINTENANCE AND SERVICE MANUAL

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1. COMPANY INFORMATION

1.1. INTRODUCTION

ERTUNÇ ÖZCAN Company was founded by Ertunç Özcan in 1968. Since that year, it has been operating as a private association in the fields of import, export, production and service with the aim of selling medical devices and equipment to hospitals and laboratories in Turkey. Ertunç Özcan has been manufacturing medical devices in its own factory since 2002.

For more information about our company and its products, you can contact us at the following phone numbers, addresses and e-mail addresses.

1.2. LIMITED WARRANTY

Ertunç Özcan warrants that all new equipment will be free from defects in materials and/or workmanship during the warranty period provided to the institution from the date of shipment under normal use and service conditions. This warranty does not cover consumables (e.g. sensors, seals, batteries, filters, sleeves, probes, etc.) or parts that are broken/cracked/discolored due to misuse/cleaning.

The obligation of this warranty is to repair or replace defective or malfunctioning products within the warranty period. Products that have been modified without the written permission of Ertunç Özcan and whose warranty label has been removed are not covered by the warranty.

The seller is not responsible for any direct or indirect damage or injury. This warranty is not transferable.

1.3. TECHNICAL SUPPORT

Repair of Ertunç Özcan equipment under warranty must be performed at our authorized repair centers. If the equipment requires repair, contact the Ertunç Özcan Technical Service Center. Before calling the Ertunç Özcan Technical Service Center, make a note of the modal and serial number of the defective device and provide this serial number to the Ertunç Özcan Technical Service Center.

If you need to ship the device, pack it carefully with its accessories to avoid damage during transportation. Include all accessories of the unit in the package. Ertunç Özcan is not responsible for improper shipment or damage to the shipment for any reason.

NOTE
Ertunç Özcan recommends that technical service be performed by Ertunç Özcan Technical Service Personal.

1.4. CONTACT INFORMATION FOR THE CUSTOMER

If you have any questions about the safety or operation of this device, or if you need more information, please contact us using the information below.

1.4.1. CENTER, DESIGN AND PRODUCTION

Design and production activities within the scope of ISO 9001:2015, ISO 13485:2016 Standards, MDD 93/42/EEC, MDR EU 2017/745 and FDA Regulations; it covers Design, Production; Sales, Distribution and Technical Service activities of Phototherapy and Incubator Devices and Accessories.

Address : ASO 2. and 3. OSB 2036. Street No:1 Temelli / Sincan / Ankara / Turkey
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Fax : + 90 312 431 91 22 / + 90 312 641 40 06
Web : www.ertuncozcan.com
E-mail : info@ertuncozcan.com

1.4.2. ELECTRONIC DESIGN AND SOFTWARE

Ertunç Özcan Medical Devices Ltd. Co. is our company that is affiliated within the company and works on electronic software and hardware.

Address: Serhat Neighborhood Technopark Ankara TGB Campus 2224. Street. No: 1 F Blok Ground Floor No: F-Z21, 06374 Yenimahalle / Ankara
Phone : +90 312 354 82 71
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1.4.3. STORE

Imports of products from the companies we have covered storage distributor in Turkey, and its activities include monitoring of distribution to interested customers.

Address: ASO 2. and 3. OSB 2036. Street No:1/A Temelli / Sincan / Ankara / Turkey
Phone : + 90 312 641 41 34 / + 90 312 433 42 26 pbx
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2. INFORMATION ABOUT INSTRUCTION FOR USE

2.1. USE OF TERMS

The term “Accessories” is used by Ertunç Özcan not only for the parts in the sense of IEC 60601-1 but also for removable and attached parts and consumables.

2.2. TRADEMARKS OWNED BY ERTUNÇ ÖZCAN

PRODUCT	CERTIFICATION
Magic Loggia Ultimate M	CE Certified
Magic Loggia Ultimate	CE Certified
Magic Loggia M	CE Certified
Magic Loggia Deluxe	CE Certified
Babynest H100 Transport Incubator	CE Certified
Babyrest M100 Model Radiant Warmer Open Bed	CE Certified
Blue Angel LED Phototherapy Device	CE Certified

2.3. DEFINITIONS AND ICONS

2.3.1. DEFINITIONS OF INSTRUCTIONS FOR SAFETY

In each section of this document includes safety instructions for risks of device with their consequences in case of non-compliance.

Warning signs and signal words given below are classified according to their precautionary statements and the possible consequences of non-compliance.

SYMBOL	SIGNAL WORD	DEFINITIONS OR CONSEQUENCES OF NON-COMPLIANCE
	WARNING	May result in death or serious injury.
	CAUTION	May result in moderate or minor injury.
	NOTE	Is used under the circumstances where clarification is needed for conflictive or confusing situations or where the processes/conditions may be misinterpreted or neglected.
	IMPORTANT	Is used to highlight a situation that is more important than the NOTEs.

2.3.2. ICONS

	**Caution: Danger of Electrical Shock**		**Caution: Federal Law restricts this device to sale by or on the order of a physician, nurse or biomedical engineer**
	Alternative Flow		**Refer to the User Manual**
	Power On (Connect to a wall power switch)		**Type BF Application Part (with skin sensor)**
	**Power Off (Disconnect from the Wall power switch)**		**Type B Application Part (without skin sensor)**
	**Serial Number**		**Manufacturer**
	**WARNING Information**		**Do not throw out**
	**Protect the patient's eyes**		**European Conformity**

NOTE
This manual shall explain all the functions and their usage instructions of the Ertunç Özcan brand Blue Angel LED Phototherapy Device.

2.4. MANUFACTURER'S RESPONSABILITY

The assembly, modification and repair/maintenance activities of all the phototherapy devices that have been manufactured and sold by Ertunç Özcan, is done by qualified technical personnel with the tools which are in accordance with the standards. Ertunç Özcan is responsible for reliability, safety and performance.

"Ertunç Özcan" is not responsible for the use of the phototherapy device without following the instructions and maintenance guidelines. The device can only be repaired by authorized service personnel. Repairs and modifications in this manual may only be carried out by authorized service personnel to prevent safety hazards.

All the users who operate the device must read and understand this user manual. When the phototherapy device is not in use, it must be stored with the user manual. For further information, please contact the manufacturer.

2.5. STATEMENT

This user manual contains confidential information. It is intended for users only as a reference for the operation, maintenance and repair of our company's products. Nobody will disclose the content contained herein to any other person.

No part of this manual may be reproduced, transmitted, transcribed, stored in a retrieval system or translated into another language in any form or by any means, electronic or mechanical, including photocopying and recording, without the written permission of our company.

Our company will be liable for any incidental or consequential damage arising from errors or provisions in this manual, current performance and use of this manual. This User Manual is not meant to transfer any property rights under patent law to any third party. Our company will not accept legal liability for the legal consequences caused by the violation of patent law or the rights of any third party.
The content in this manual is subject to change without prior notice.

CAUTION

- During the warranty period if the phototherapy device is interfered by an unauthorized people, the warranty will be invalid.

IMPORTANT

The service life of Blue Angel LED Phototherapy Device is **10 years**. This is the period of time required to obtain the spare parts necessary to operate the device as described.

3. INFORMATION ON SAFETY INSTRUCTIONS AND PRECAUTIONARY STATEMENTS

3.1. INSTRUCTIONS FOR SAFETY OF USERS AND PATIENTS DURING GENERAL OPERATION

The following precautionary statements depend on the general operation of Blue Angel LED Phototherapy Device. Specific precautionary statements for subsystems and particular features are mentioned in related parts of the user manual.

WARNINGS

- Before using the phototherapy device, this user manual must be read throughout and understood and all sections of instructions for use and all statements on medical device labels must be strictly followed by users in order to prevent injuries.
- The misuse of phototherapy devices may injure the patient.
- Blue Angel LED Phototherapy must only be used for the purpose mentioned in Intended Use (Section 4.2)
- The phototherapy device shall not be used if it is not functioning properly. Technical service must be provided by authorized and qualified personnel.
- Use of an accessory or spare part not supplied by Ertunç Özcan may cause injury to the patient or user.
- When the device is not in use, it should be turned off from the On/Off key.
- When the treatment is complete, the device should be turned off by using the On/Off key and for safety, the power cable of the device should be unplugged from the switch until using it again.
- The distance of the lamps of the phototherapy device to the patient should not be less than 40cm. The height of the device should be adjusted according to this value.
- The activity area should be considered when using the phototherapy device.
- As blue phototherapy light is harmful to the human eye, the patient's eyes should never be exposed to blue phototherapy light and should be completely closed at all times during treatment.
- Blue light may prevent clinical observation of skin discoloration such as cyanosis (skin bruising), the patient's condition should be checked regularly.
- The patient's bilirubin levels should be measured regularly.
- The phototherapy device may cause some patients to lose their water balance.
- Medicines and infusion fluids should not be stored in the radiation field.
- Measure the patient's body temperature at set intervals to avoid fluctuations in body temperature during therapy.
- It is recommended to clean the canopy surface before placing the phototherapy device on the incubator.

- Changing environmental conditions such as room temperature and different heat sources may adversely affect the patient.
- Do not look directly at the lamps as the blue phototherapy light is harmful to the human eye.
- When the phototherapy device is placed in an incubator or patient bed, the locking mechanisms on the two rear wheels should always be kept locked.
- During the transport of the phototherapy device, the head section with the lamps of the device should be kept parallel to the ground and at the lowest possible level and the device should be transported by holding the carrying handle.
- Do not place the phototherapy device directly under the radiant heating source.
- To ensure that treatment is not interrupted by power failures, it is recommended that the device is used with a UPS system.
- Electrical and electronic control circuits are located in the head unit of the phototherapy device where the lamps are located. Technical service must be carried out by trained technical personnel, as there is a risk of electric shock if the cover of this part of the appliance (under the tray unit where the lamps are installed) is opened.
- To avoid the risk of electric shock, this device may only be connected to a supply main with protective earthing.
- It must be ensured that the electrical values of the hospital building are compatible with the electrical values on the power cable input of the phototherapy device.
- When cleaning the lamps, the device shall always switch off by using the on/off switch and unplug the power cable.
- Do not sterilize the device with gas or steam. Do not use flammable solutions for cleaning.
- Since the phototherapy device is an electrically operated device, do not use any product that may cause an explosion or flash hazard near the device.
- All lamps must be replaced at the same time to maintain the effectiveness of the treatment.
- The use of lamps not approved by our company may affect the treatment effectiveness and safety of phototherapy.

3.2. RESTRICTIONS FOR USE

The phototherapy device shall be used only by an educated staff member who is in the guidance of a physician who has the appropriate qualifications and who knows the risks and benefits of the phototherapy that are known so far.

3.3. BASIC SAFETY INSTRUCTIONS

3.3.1. PATIENT SAFETY PRECAUTIONS

WARNINGS

- The design of the medical device, instructions for use and the device labels assume that the medical device is only used by the persons who have knowledge about the medical device. Therefore, instructions and precautions given in this user manual are limited to the features of Blue Angel LED Phototherapy Device. This user manual does not contain any instructions about the following points;
  - Obvious risks for users
  - Consequences of obvious misuse of the device
  - Foreseen negative effects on patients who have different underlying diseases
- Modification or improper use of the medical device can lead to serious injuries.
- It should be avoided to make therapeutic decisions by depending on only measured and monitored parameters. In order to make therapeutic decisions, both visual assessment and medical expertise are needed as well as measured and monitored parameters.

3.3.2. SERVICE PRECAUTIONS

WARNINGS

- Periodical service should be performed in order not to encounter malfunctions, otherwise personal injuries or property damages may be seen.
- Blue Angel LED Phototherapy should be serviced regularly and repairs and maintenance should be carried out by authorized and experienced service personnel.
- For longer lifespan, Ertunç Özcan recommends that periodical service should be performed by Ertunç Özcan Technical Service Department and for maintenance and repair, parts approved by Ertunç Özcan should be used.
- The device shall not be serviced while it is in use with a patient.

3.3.3. CLEANING AND REPROCESSING PRECAUTIONS

WARNINGS

- The manufacturer's instructions about cleaning, disinfection and reprocessing shall be followed.
- It should be ensured that no liquid penetrates the device in order to prevent damage to the device, malfunctions and electrical shock.
- Before cleaning the phototherapy device, unplug the power cable.

3.3.4. MODIFICATION PRECAUTIONS

WARNINGS

- No modifications should be made to the device, otherwise it may result in injury to the patient or the user or in property damage.
- If there is a modification on the device, all necessary testing procedures should be performed before using the medical device for the safety.

3.3.5. PRECAUTIONS FOR THE RISK OF ACCIDENTAL DISCONNECT

WARNINGS

- In order to prevent possible trip and fall hazards, the power cable should be properly secured.

3.3.6. ELECTRICAL PRECAUTIONS

WARNINGS

- It shall be operated only with the supplied power cable.
- For the safety of grounding, the power cable must be plugged only to electric switches which meet with hospital class type switches with protective grounding. In case of any doubt on the grounding connection, the device should not be turned on.
- To ensure grounding reliability, the power cable shall be plugged only into a properly grounded 3-wire hospital-grade or hospital-use outlet.
- The service of the device shall be done by a qualified and sufficient technical personnel due to the risk of electrical shock.
- It should be ensured that the electrical features stated in the product features are fulfilled. Otherwise, personal injury or equipment damages may occur.
- Some chemical cleaning substances might be conductive. These cleaning substances should not be contacted with the electric constituent and sprayed on surfaces. Otherwise, personal injury or equipment damage may occur.
- Electrical equipment has a potential risk of electrical shock. In this regard, please educate your employee concerning with the risk of using electrical equipment.
- The maximum total earth leakage current of the system, including all items plugged into the auxiliary mains outlets and any items plugged into external sockets, must not exceed 500 µA.
- Circuit breakers shall not be reset or the fuses shall not be fused without assessing and correcting the reason why the circuit breaker or fuse is activated.

- Due to potential shock hazard within the phototherapy light, the device shall not be used if the phototherapy light or other components fail to function properly.

3.3.7. PRECAUTIONS FOR CONNECTION WITH OTHER ELECTRICAL EQUIPMENT

WARNINGS

- Unapproved electrical connections can lead to patient injury or device failure.

3.3.8. ELECTROMAGNETIC COMPATIBILITY (EMC) PRECAUTIONS

WARNINGS

- All medical accessories must comply with the safety requirements in the scope of IEC 60601-1 and have safety certifications.
- Any equipment shall not be used near other devices unless normal operation is verified in the configuration in which it is to be used.
- Devices connecting to the serial port must be compliant with IEC60601-1-2, the EMC requirement for Medical Devices.
- Electrosurgical units or other devices that can spread electromagnetic waves may cause the skin temperature probe to detect a different value of temperature because of the absorbed electrical energy.
- Portable and mobile RF communications equipment may affect medical electrical equipment.
- Medical electrical equipment is subject to precautionary measures concerning electromagnetic compatibility. “EMC Declaration” is stated in Annex-B.
- Electromagnetic fields may result in malfunction of the device; therefore, it may endanger the patient. Electromagnetic field sources which should be separated from the device are given below;
  - Cellular phones
  - High-frequency electrosurgical equipment
  - Defibrillators
  - Shortwave therapy equipment

3.3.9. ANTI-STATIC WHEELS PRECAUTIONS

WARNINGS

- ESD results from the surroundings and can be managed solely by the user or owner within that setting. Maintaining a conductive floor, providing employees with ESD clothing and control devices, and other measures enable effective ESD control in that environment.

3.3.10. EXPLOSION AND FIRE PRECAUTIONS

WARNINGS

- The phototherapy device shall not be used in environments consisting of easily flammable substances and gases (such as anesthetic gases) environments. It can lead to personal injury or equipment damage.
- All the ignition sources such as matches, lighter, electric stoves etc. shall be kept from the location of the phototherapy device. Textile, oil and other flammable substances catch fire easily and burn intensively in air which is enriched with oxygen.
- During cleaning or maintenance procedures, if the device is powered on, a shock hazard may occur. So, the device shall be unplugged from its power source before cleaning and maintenance.

3.3.11. DRUG STORAGE PRECAUTIONS

WARNINGS

- Infusion liquids or other drugs shall be avoided to be stored in radiation areas, as exposure can degrade their efficacy.

3.3.12. PRECAUTIONS FOR USING PHOTOTHERAPY LIGHT WITH AN INCUBATOR

WARNINGS

- Phototherapy light should be positioned according to the manufacturer instructions.
- If the phototherapy device is positioned to the top of the canopy, it may interfere with upward motion of incubator during the height adjustment. Therefore, the phototherapy device should be removed before positioning the incubator.
- Phototherapy lights placed on top of the incubator may fall off accidentally when the incubator is moved. Therefore, the light shall always be disconnected from the mains.

3.3.13. PRECAUTIONS FOR THE MOVEMENT OF THE PHOTOTHERAPY DEVICE

WARNINGS

- Before moving, confirm that all adjustable parts, such as the height and angle, are securely locked in position.
- It should be verified that the device is stable and the wheels are functional and unlocked.
- The device shall not be moved over uneven surfaces or thresholds to prevent instability.
- All cables and accessories shall be secured to prevent tripping or entanglement during transport.

3.3.14. SAFETY INSTRUCTIONS FOR ACCESSORIES

WARNINGS

- Using incompatible accessories may result in medical device failure and increase the risk of patient injury or property damage.
- Ertunç Özcan recommends using Blue Angel LED Phototherapy Device only with the compatible accessories listed in Section 4.6, the compatibility of which has been tested by Ertunç Özcan in accordance with the relevant standards.
- Single-use components or accessories should not be used if packaging is damaged.
- Since disposable products are designed for one-time use only, reusing, reprocessing or sterilizing them may cause a failure of the device or patient injury.
- There should be a safe connection between the accessory and the device. Otherwise, incorrect installation of accessories may affect the performance of the accessory.
- Instructions given in Chapter 8 should be followed for the cleaning and reprocessing of reusable accessories.

3.4. TARGET GROUPS FOR BLUE ANGEL LED PHOTOTHERAPY DEVICE

The following tasks and competencies are expected from the target groups defined for the device.

TARGET GROUP	TASK	COMPETENCY
Physicians and Nurses	Use of the product in accordance with the intended use	Physicians and nurses who have medical knowledge in neonatology or in the use of device
Reprocessing Personnel	Cleaning and Reprocessing	Biomedical Engineers who have knowledge in the reprocessing of medical devices
Technical Service Personnel	• Installation • Maintenance • Inspection • Repair	• Biomedical Engineers experienced in the servicing of medical devices • If complex service is required, special knowledge in electrical engineering and mechanics

3.5. TRAINING

- The phototherapy device should be used only by trained personnel in order to prevent the harm to the patient due to misuse.
- Training for users is organized by authorized Ertunç Özcan personnel.

4. GENERAL INFORMATION

4.1. INTRODUCTION

This user manual gives instructions about the usage, cleaning, maintenance, and troubleshooting of the Ertunç Özcan Brand Blue Angel LED Model Phototherapy Device. The manufacturer is not responsible for improper performance of the phototherapy device if the user does not operate the device in accordance with the instructions, does not follow the maintenance recommendations in Chapter 8 of this manual, or repairs with unauthorized parts. Repair should only be done by Ertunç Özcan Technical Service Personal.
This user manual must be read and clearly understood by the ones who are going to use the phototherapy device. This user manual must be kept somewhere easily accessible by the ones who will be using the phototherapy device.
In case of further clarification needs regarding any stated information in this manual, please contact with Ertunç Özcan Technical Service Personal.

4.2. INTENDED USE OF THE DEVICE

Blue Angel LED is a phototherapy device for neonates (birth to 28 days) who's classified as;

- Preterm (< 37 completed weeks)
- Term (37-41 weeks) with critical illness
- Post-term (≥ 42 weeks) with critical illness
- Low birth weight (< 2.500 g (< 5.51 lbs))
- Very low birth weight (> 1,000 g (>2.2 lbs) and < 1,500 g (< 3.3 lbs))

WARNING

- High-intensity phototherapy (>30 µW/cm²/nm) is not suitable for all patients, such as premature neonates weighing less than 1000 g (2.2 lb). The physician's instructions shall always be followed to determine appropriate irradiance levels.

Phototherapy devices are devices used to ensure that prematures and neonates are treated with intensive phototherapy to reduce high bilirubin levels.
The phototherapy device is a mobile device that can stand on its own foot unit.
Phototherapy is a system using blue LED technology. It breaks down the bilirubin accumulated in the skin with intense light waves and allows the substance to be excreted through urine. The most effective phototherapy treatment will be the penetration of light waves (ultraviolet light in the range of 400-500 nm) into the body as much as possible.

4.3. ENVIRONMENT OF USE

The usage of Ertunç Özcan Blue Angel LED Phototherapy device is appropriate for any hospital department that serves neonatal and infant care, including all levels of the Neonatal Intensive Care Unit (NICU), Special Baby Care Unit, Step Down Nursery, Newborn Nursery, and Pediatrics.
Blue Angel LED Phototherapy device is not intended for home use.

4.4. INDICATIONS, CONTRAINDICATIONS, SIDE EFFECTS AND WARNINGS

4.4.1. INDICATIONS

Phototherapy devices are indicated for the treatment of:

- **Neonatal Hyperbilirubinemia**:
  - ✓ Elevated bilirubin levels in full-term or preterm neonates.
  - ✓ Jaundice caused by physiological immaturity or conditions like hemolytic disease, breastfeeding jaundice, or prematurity.
- **Prevention of Severe Hyperbilirubinemia**:
  - ✓ Prophylactic use in neonates at high risk for bilirubin levels reaching neurotoxic thresholds.

4.4.2. CONTRAINDICATIONS

Phototherapy devices should not be used in the following situations:

- **Absolute Contraindications**:
  - ✓ Neonates with a confirmed diagnosis of porphyria or other photosensitivity disorders, as light exposure may exacerbate symptoms.
  - ✓ Known hypersensitivity to light or specific wavelengths emitted by the device.
- **Relative Contraindications**:
  - ✓ Severe skin conditions or lesions that may worsen with light exposure (e.g., extensive burns or dermal conditions incompatible with phototherapy).
  - ✓ Cases where bilirubin reduction is contraindicated or unnecessary (e.g., conditions that mimic jaundice but are not bilirubin-related).
- **Situational or Temporary Contraindications**:
  - ✓ When there is obstruction to light exposure, such as bandages or surgical areas, that cannot be safely removed.
  - ✓ Neonates with unstable critical conditions where phototherapy may interfere with life-sustaining interventions.

4.4.3. SIDE EFFECTS

There are mild and reversible effects associated with phototherapy use:

- **Skin-related Effects**:
  - ✓ Skin rash or erythema (redness of the skin).
  - ✓ Bronze baby syndrome (temporary gray-brown discoloration of the skin, particularly in cholestatic neonates).
- **Temperature Regulation**:
  - ✓ Risk of hypothermia or hyperthermia due to inadequate environmental temperature control during therapy.
- **Dehydration and Electrolyte Imbalance**:
  - ✓ Increased water loss through the skin, potentially leading to mild dehydration if fluid intake is not adjusted.
- **Eye Irritation**:
  - ✓ Temporary eye irritation or mild inflammation (if eye protection is improperly applied).
- **Sleep Disruption**:
  - ✓ Altered sleep-wake patterns due to continuous light exposure.

4.4.4. ADVERSE EFFECTS

These are less common but potentially serious complications:

- **Retinal Damage**:
  - ✓ Occurs if protective eye shields are not properly applied or maintained.
- **Thermal Burns**:
  - ✓ Overheating of the device or improper setup could lead to localized skin burns.
- **DNA Damage or Cell Stress**:
  - ✓ Excessive or prolonged exposure to light may cause oxidative stress or cellular damage in rare cases.
- **Sepsis Misdiagnosis**:
  - ✓ Phototherapy-induced skin changes (e.g., transient erythema) may obscure symptoms of sepsis or other conditions.
- **Bronze Baby Syndrome Complications**:
  - ✓ Though rare, it may be associated with underlying liver dysfunction that requires immediate attention.

4.5. FEATURES

All the features given below can be changed by the manufacturer without any given notice.

4.5.1. CLASSIFICATION OF DEVICE

CLASSIFICATIONS	Class I

4.5.2. STANDARDS

Designed in accordance with the requirements below stated standards	
EN 60601-1:2006	Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
EN 60601-1-2:2015	Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests
EN 60601-1-6:2010	Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability
EN 60601-1-8:2007	Medical Electrical Equipment – Part 1-8: General Requirements for Basic Safety and Essential Performance–Collateral Standard: General Requirements, Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems
EN 62366-1:2015	Application of Usability Engineering to Medical Devices
EN 10993-1:2020	Biological Evaluation of Medical Devices-Part 1-Evaluation and Testing
EN ISO 14971:2019	Medical Devices-Application of Risk Management to Medical Devices
EN 62304:2006	Medical Device Software-Software Life-Cycle Processes
EN 62304:2006/A1:2015	Medical Device Software-Software Life-Cycle Processes

EN 1041+A1:2013	Information Supplied by the Manufacturer with Medical Devices
EN ISO 80601-2-56:2017	Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature
EN ISO 15223-1:2021	Medical devices — Symbols to be used with information to be supplied by the manufacturer — Part 1: General requirements
TS EN 60601-1-10:2008	Medical electrical equipment – Part 1-10: General requirements for basic safety and essential performance – Requirements for the development of physiologic closed-loop controllers
TS EN IEC 60601-2-50:2021	Medical electrical equipment – Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment

4.5.3. ELECTRICAL FEATURES

Power Requirements	230 (±10%) VAC, 50/60 Hz, 45 W, max 0.2 Amp
	110 (±10%) VAC, 50/60 Hz, 45 W, max 0.4 Amp

4.5.4. BATTERY FEATURES

Battery Type	CR2032 Lithium Metal Battery
Battery Capacity	3V, 0.028 ~ 0.6 Ah

4.5.5. PHOTOTHERAPY FEATURES

Phototherapy Dimensions	730 (G) x 925 (D) x 1550 (Y) cm 287.4 (W) x 364.2 (D) x 610.2 (H) in
Head Unit Dimensions	48(G) x 28 (D) x 6 (Y) cm (±0.5cm) 18.9 (W) x 11.0 (D) x 2.4 (H) in (±0.2 in)
Adjustable Height	Min 1300 cm – Max 1550 cm Min 511.8 in – Max 610.2 in
Weight	Head Unit 3 Kg (6.61 lb)
	~ 18.5 Kg (40.79 lb)
Light source, 24 special super bright LEDs - 1 red therapy focusing light	
Wavelength	460nm (±2)
Highest light length (40cm)	120µw.cm^{-2}.Nm^{-1} (±%10)
Minimum light length (40cm)	30 µw.cm^{-2}.Nm^{-1} (±%10)
Effective Area	20 x 45 cm 7.87 x 17.72 in
Light Source Lifespan	20.000 hr

4.5.6. MEASURING SKIN TEMPERATURE

Skin Temperature Sensor Measurement Range	17°C - 47 °C (62.6 °F – 116.6 °F)
Indication Sensitivity	0.1°C (32°F)
Skin Temperature Sensor Measurement Accuracy	±0.1°C (±32°F)

4.5.7. ENVIRONMENTAL OPERATION TERMS

Operating Temperature Range	Environment between +20˚C and +45˚C (+68°F and +113 °F)
Storage Temperature Range	Environment between -20˚C and +70˚C (-4°F and +158 °F)
Operating Humidity Range	< 90% Relative Humidity Non-condensable
Storage Humidity Range	< 90% Relative Humidity Non-condensable

4.5.8. IP PROTECTION CLASS

IPX0	It is not protected against water and dust.

4.5.9. SOFTWARE FEATURES

Languages	Turkish, English

4.5.10. DISPLAY PANEL FEATURES

- Determining the duration of treatment
- Timer
- Therapy focusing light
- Light intensity
- Time and date display
- Skin temperature measurement

4.5.11. STANDARD FEATURES

- Height adjustment
- Movable resistance

4.5.12. OPTIONAL FEATURES AND ACCESSORIES

OPTIONAL FEATURES

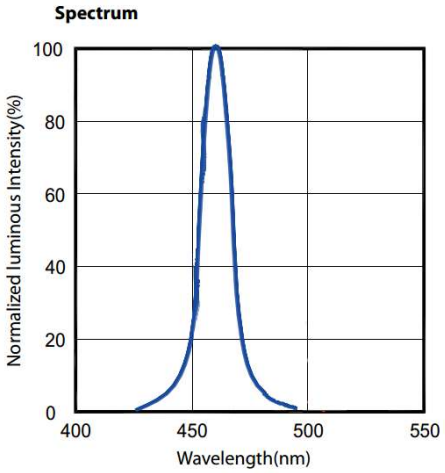
- Skin Temperature Measurement

ACCESSORIES

- Reusable Skin Temperature Probe
- Disposable Skin Temperature Probe
- Eye Strach

4.5.13. EFFECTIVE AREA

The graph below shows the normalized spectrum of blue LED lights and the spectral sensitivity of the spectrophotometer.



Light measurements were made using a standard spectrophotometer.

The peak intensity of light was > 30 µW/cm2 /nm at low setting and 120 µW/cm2 /nm at high setting at a distance of 40 cm. This measurement was taken at the center of the effective surface area.

The table below shows the intensity of the light at the center of the effective surface area at the high setting at a distance of 40 cm.

								12,9								
	23,0	24,6					26,4	27,5	25,9					21,6	18,1	
36,3	54,1	64,6	64,5	64,8	65,8	67,3	65,7	67,0	64,5	63,7	60,4	61,9	62,2	57,7	53,2	32,7
53,9	78,5	95,6	96,0	107	104	110	101	105	97,5	104	96,8	101	93,9	93,5	74,7	52,0
64,1	96,9	112	117	122	123	127	121	118	115	120	118	116	112	110	95,6	64,8
69,1	100,0	114	113	121	118	129	122	120	113	124	123	123	113	113	96,1	68,1
72,8	104,5	114	115	117	122	125	123	112	114	125	122	118	115	110	95,7	65,3
58,5	81,9	94,7	91,9	97,0	94,5	99,9	94,1	92,5	101	114	101	97,1	89,1	88,0	72,0	53,8
34,9	50,2	50,8	52,3	53,1	55,8	56,1	56,0	55,1	69,6	73,8	53,3	61,1	58,2	53,2	49,0	34,3
		18,3						25,2						24,3		
								12,1								

EbiMax	129 µW/cm2 /nm
EbiMin	53,2 µW/cm2 /nm
Measuring Distance	40 cm
Effective Matrix	15*6
Effective Area	45*20
Radiation	5. Level

Figure 1: Blue Angel LED Model Phototherapy Device General View

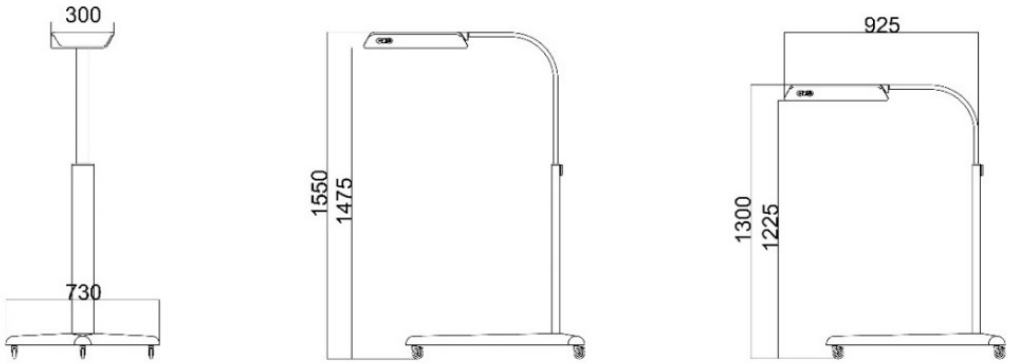


Figure 2: Blue Angel LED Model Phototherapy Device Dimensions

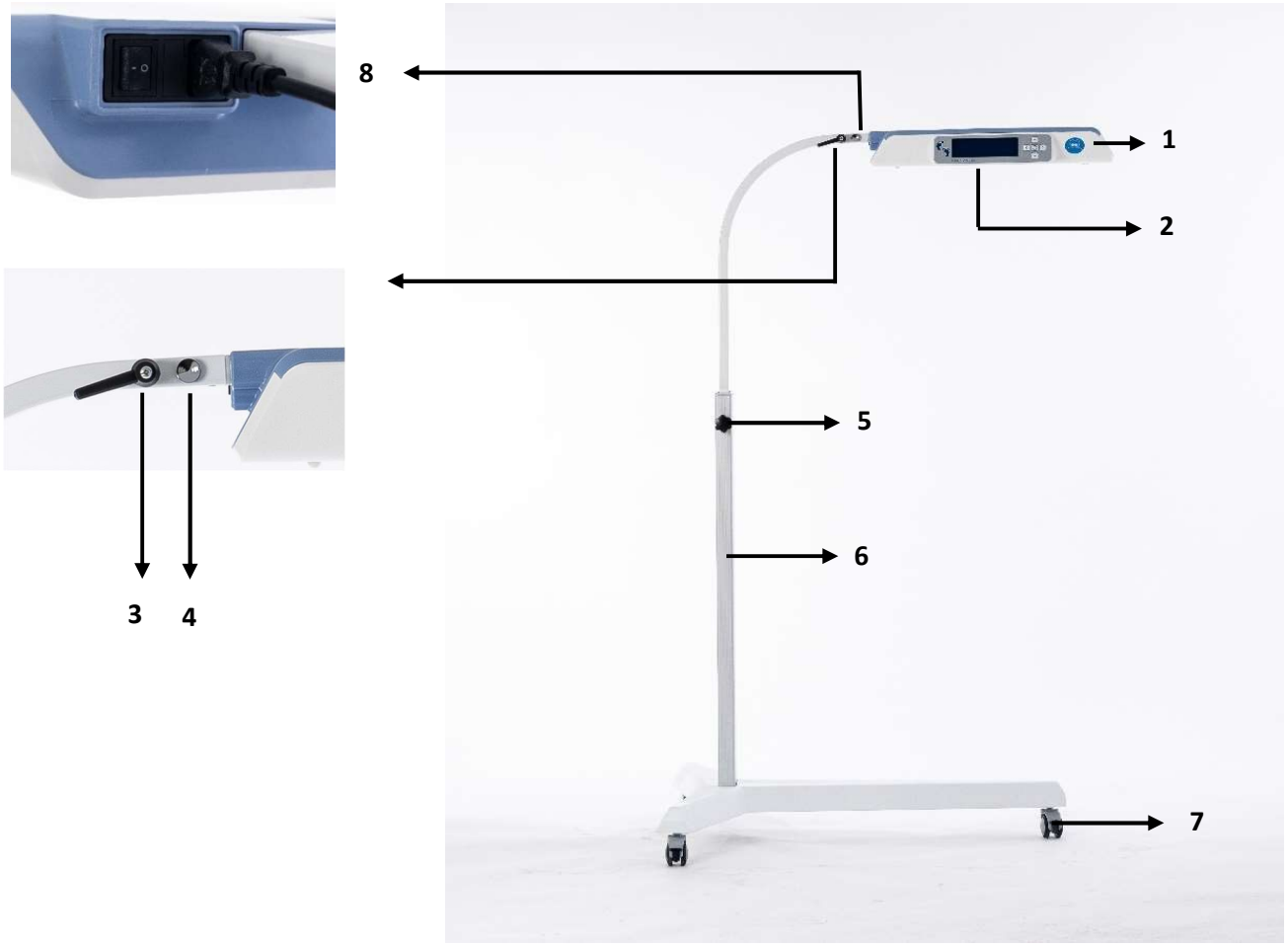


Figure 3: Blue Angel LED Phototherapy Device Front Side

No	Explanation
1	Display Panel
2	Lamp
3	Head Unit Adjustment Screw
4	Head Unit Placement Button
5	Height Adjustment Screw
6	Stand
7	Wheels With Brakes
8	On/Off Key and Power Cable Input

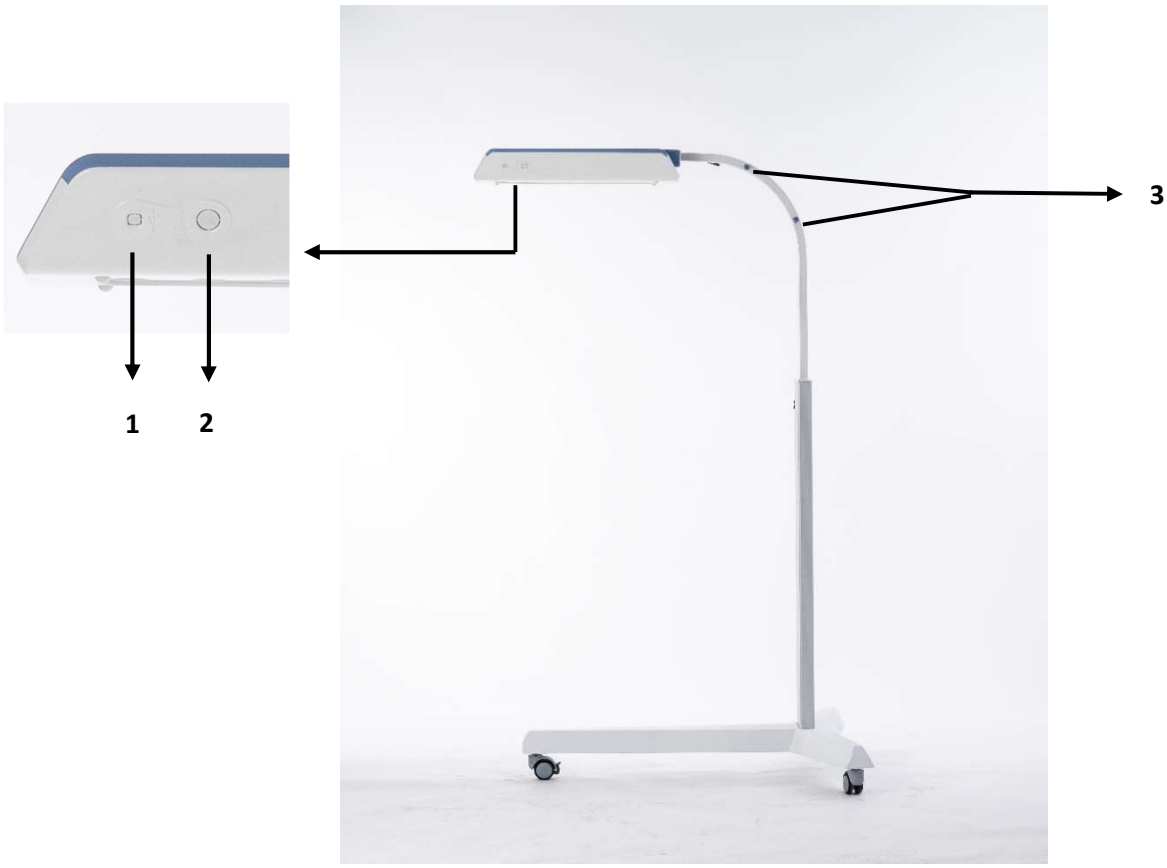


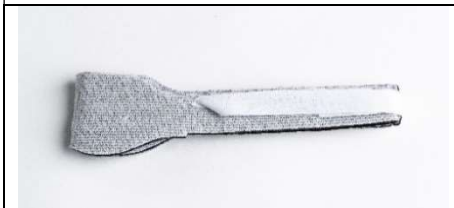
Figure 4: Blue Angel LED Phototherapy Device Back Side

No	Explanation
1	USB Input
2	Skin Temperature Sensor Input
3	Cable Holder

Figure 5: Blue Angel LED Phototherapy Device Display Module and Keypad

No	Explanation
1	Right Direction Key
2	Up Direction Key
3	Left Direction Key
4	Down Direction Key
5	Confirmation Key

4.6. ACCESSORIES LIST

	TYPE	MAKE / MODEL	PATIENT CATEGORY
	**Reusable Skin Temperature Probe**	Metko Products Model Number: FMT-INC/S	For target patient population
	**Disposable Skin Temperature Probe**	Tarry Medical Products Model Number: T-100	For target patient population
	**Eye Patch**	DilaMed Model Number: DLM-2002	For target patient population

5. FUNCTIONAL EXPLANATION

5.1. GENERAL

This chapter contains a general explanation about Blue Angel LED Model phototherapy devices.

5.2. FUNCTION EXPLANATION

The device emits blue light that penetrates the neonate's skin, facilitating the conversion of bilirubin into water-soluble isomers that can be excreted via the patient's urine or stool. This process, known as photo-oxidation, reduces the levels of bilirubin in the blood, helping to alleviate neonatal jaundice.

5.3. MAIN MENU

All functions of the device mentioned below are displayed on the main screen.

- Start
- Close
- Language
- Timer
- Time
- Information
- Focus

Switching between functions is done with right and left arrow keys on the keypad. To select the intended function, the confirmation key shall be pressed.

5.3.1. START / STOP FUNCTION

When the 'Start' function is selected on the main screen and the confirmation key is pressed, the therapy is started. When the therapy starts, the 'Stop' function appears on the main screen instead of the 'Start' function. To terminate the therapy process, the 'Stop' function must be selected and the confirmation key must be pressed.

Figure 6: Blue Angel LED Phototherapy Device Start Function

Figure 7: Blue Angel LED Phototherapy Device Stop Function

When mentioning such keys, it may be easier for the user to understand if a visual of the key is included in the text.

5.3.2. LANGUAGE

The language options of the device are Turkish and English. When the language function is confirmed, press the right and left arrows to select the desired language from the screen and press the confirmation key to use the selected language. When the language is selected, the device saves it and the device will work with the selected language even if the power is cut off.

Figure 8: Blue Angel LED Phototherapy Device Language Function

5.3.3. TIMER

When the timer function is selected and the confirmation key is pressed, the timer screen opens. This menu is used for determining the duration of therapy. In this time determination process, which can be done in hours and minutes, the hour and minute selection is made using the right and left arrows, and the duration setting is made using the up and down arrows. After the desired value is set, it returns to the main screen when the confirmation key is pressed. As long as the timer is running, the 'T' icon will appear in the upper left corner of the main screen. The timer will start running when the therapy is started and will automatically terminate the therapy when the countdown is over. The 'T' icon on the screen will disappear when the countdown is over.

NOTE
It is recommended to measure the treatment time with an external timer for phototherapy treatment used by setting the time duration with the timer function.

Figure 9: Blue Angel LED Phototherapy Device Timer Function

5.3.4. TIME

When the time function is selected and the confirmation key is pressed, the time and date setting menu of the device is opened. On the time menu, hour, minute, day, month, year can be set respectively. Right and left arrow keys are used to switch between these values, up and down arrow keys are used to set the values. After the desired time and date setting is made, the time and date setting are saved by pressing the confirmation key and returns to the main screen.

Figure 10: Blue Angel LED Phototherapy Device Time Function

5.3.5. INFORMATION

When the Information function is selected and the confirmation key is pressed, the total therapy time is displayed in hours (this is not the operating time of the device. If therapy has not been initiated with the start function while the device is running, this is not added to the therapy time). This value is read only and cannot be changed or reset. The confirmation key should be pressed to return to the main screen.

Figure 11: Blue Angel LED Phototherapy Device Information Function

5.3.6. FOCUS

The red therapy focus light illuminates for 10 seconds when the device is turned on and turned off automatically at the end of this period. In addition, if focusing is desired, when the focus function is selected from the menu and the confirmation key is pressed, the red therapy focusing light will illuminate for 10 seconds during treatment and will automatically turn off at the end of this period. For the patient to benefit effectively from the therapy, the patient should be positioned so that the red therapy focus light is directed towards the navel. The focus function makes it easy to position the patient.

NOTE

If the focusing light does not work, the therapy may not be effective because the patient cannot be positioned correctly for therapy.

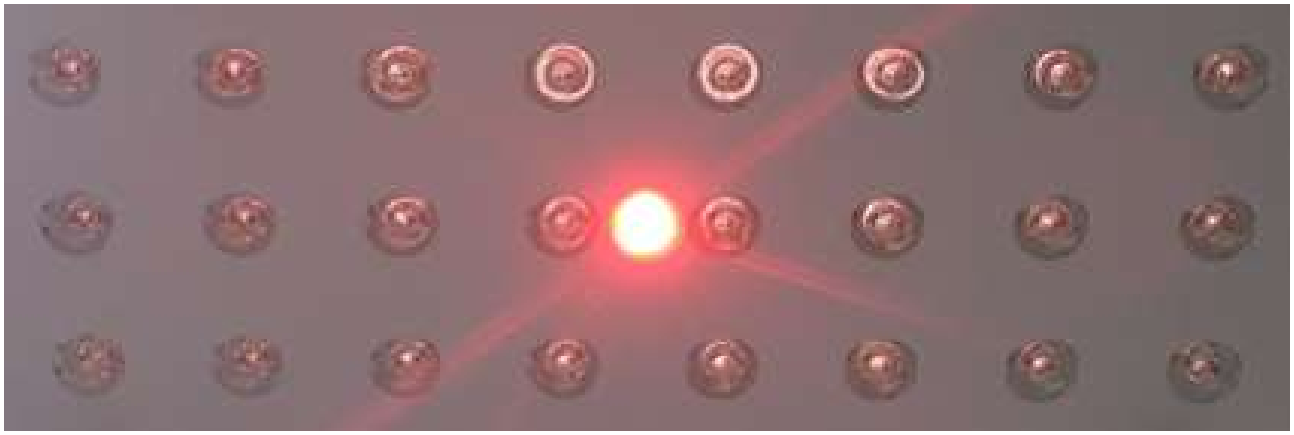
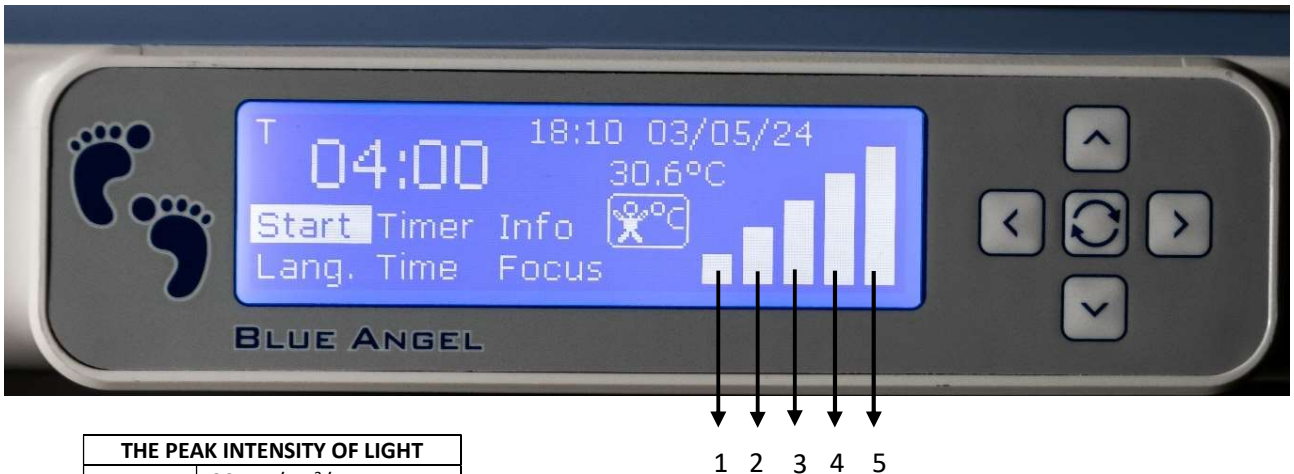


Figure 12: Blue Angel LED Phototherapy Device Focus Light

5.3.7. THE PEAK INTENSITY OF LIGHT

The peak intensity of the light is indicated by bars on the screen. The peak intensity of light was > 30 µW/cm^2/nm at low setting showing by the smallest bar and 120 µW/cm2 /nm at high setting showing by the biggest bar.

Figure 13: Blue Angel LED Phototherapy Device Light Intensity Function



THE PEAK INTENSITY OF LIGHT	
1	30 µW/cm^2/nm
2	50 µW/cm^2/nm
3	70 µW/cm^2/nm
4	90 µW/cm^2/nm
5	120 µW/cm^2/nm

5.3.8. SKIN TEMPERATURE MEASUREMENT (OPTIONAL)

As an optional feature of the device, the patient's skin temperature is measured with a skin temperature probe during treatment. When the skin temperature probe is attached to the device, the patient's skin temperature is monitored on the screen.

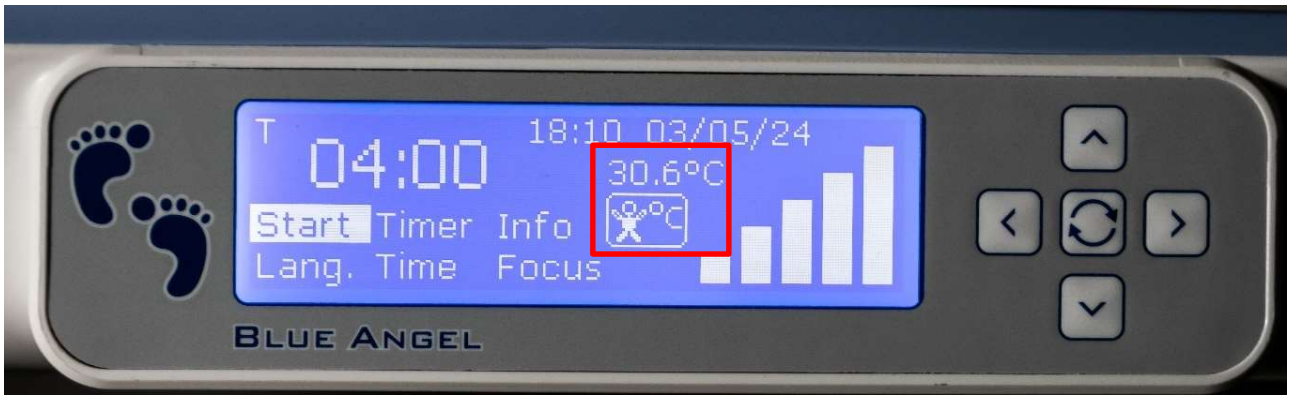


Figure 14: Blue Angel LED Phototherapy Device Skin Temperature Measurement Function

6. INSTALLATION AND CONTROL OF THE DEVICE

WARNING

- Before using the phototherapy device make sure to read this user manual. Using the phototherapy device without understanding the whole user manual may cause injury of the patient or the user.

6.1. PRELIMINARY INSTALLATION INFORMATION

Ertunç Özcan Blue Angel LED Model Phototherapy device is partially transported in pieces.

6.2. CONTENTS OF THE PACKAGE AND UNPACKING

The phototherapy device is shipped in a cardboard box. The contents of the box are as follows;

- Head Unit
- Stand
- Foot Unit
- User Manual

The Blue Angel LED model phototherapy device is packed in a cardboard box consisting of the above mentioned parts. When the package is opened, the parts should be checked for any damage. If there is any damage, the installation process should not be performed.

IMPORTANT

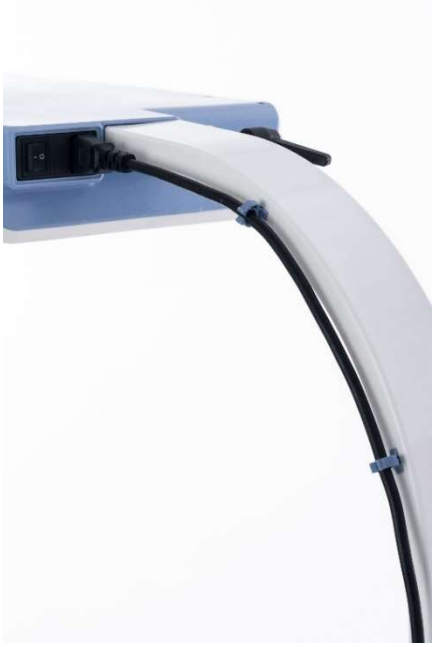
The device should not be used if any part of the device is damaged or if there is any reason to believe that the device is not working properly. If so, please contact Ertunç Özcan Technical Service.

6.3. DEVICE INSTALLATION

1. Combine the foot unit and the stand.	

2. Assemble the foot unit and stand with two M12 washers and two M12x25 bolts.	
3. Connect the foot unit and stand supplied in the package with the two screws on the stand and tighten with the allen screw.	
4. Insert the shaft in the head unit into the slot in the neck profile of the stand.	

5. Push it in until it clicks.	
6. Adjust the head unit to the desired angle by turning head unit adjustment screw in clockwise.	

7. Plug the power cable into the power input.	
8. Secure the power cable by passing it through the cable holder.	

6.4. CONTROL OF THE DEVICE

After the installation of the device is completed, check the operation of the device according to the following sequence. This should also be done during routine maintenance and replacement of lamps.

1. Plug the power cable supplied with the device into a socket that meets the power requirements specified in the technical specifications.	
2. Switch the device on via the On/Off key.	

3. Using the height adjustment locking mechanism, observe that the head unit can be easily moved to the lowest and highest level.	
4. Move the head unit with both hands and observe that it can rotate around its own axis at 360º and remain stationary in its position when released at desired angle.	
5. Check the wheel brakes works properly or not.	

6. Check whether the focus lamp is lit.	
7. Start the therapy by confirming the start function on the main screen. Check that all lamps are lit.	
8. Check the total therapy time by confirming the information function on the main screen. **CAUTION** The total duration of the therapy is the same as the duration of use of the lamps and must not exceed the maximum duration of use of the lamps.	
9. Confirm the Stop function on the main screen to end the therapy and check that all lamps are closed.	

IMPORTANT
Do not use the device if any part of the device is damaged or if there is any reason to believe that the device is not working properly. Contact Ertunç Özcan Technical Service.

6.5. CONTROL OF THE ACCESSORIES

- Check all the accessories. Make sure that they are not missing or damaged.
- Make sure all the accessories are attached safely.

7. OPERATION OF BLUE ANGEL LED PHOTOTHERAPY DEVICE

7.1. PREPARATION OF THE PATIENT FOR THERAPY

- Place the patient in an incubator or open bed with radiant warmer where the therapy will be performed.
- Close the patient's eyes with an eye patch designed for phototherapy treatment before starting the treatment. Check that the patient's eyes are closed at regular intervals.
- The patient to be treated with phototherapy should be naked except for diapers.
- The patient's eyes and genital area should be protected from light. Care should be taken that the eye patch does not block the nostrils.
- If it is used with an incubator, regular temperature control should be done to prevent overheating.
- Since phototherapy increases body temperature, the patient's body temperature should be monitored.
- Bilirubin level should be monitored at least every 12 hours.
- Place the phototherapy device with the red focusing light on the patient's belly button. However, there may be changes in the patient's position as a result of the patient's movement over time. Check the patient's position at regular intervals.

WARNING

- Products such as baby oil, cream, lotion should not be used in the care of the patient to prevent possible burns.

NOTE

It is recommended to measure the light intensity before each treatment.

7.2. OPERATION OF BLUE ANGEL LED PHOTOTHERAPY DEVICE

WARNING

- High-intensity phototherapy (>30 µW/cm²/nm) is not suitable for all patients, such as premature neonates weighing less than 1000 g (2.2 lb). The physician's instructions shall always be followed to determine appropriate irradiance levels.

CAUTION

- The patient's bilirubin levels should frequently be measured to assess therapy effectiveness.
- The patient's body temperature should be monitored as environmental factors such as draughts or sunlight can affect temperature regulation.
- Due to blue light may mask color changes like cyanosis and make clinical evaluation more difficult, the patient's skin should be observed carefully.
- The patient should always wear protective eye patches to prevent exposure to phototherapy radiation.
- Unapproved items, such as blankets, clothing should not be placed on the device. These can obstruct proper cooling or accidentally fall onto the patient.
- Only approved accessories should be used with the device.
- It should be taken measures to maintain a positive water balance, as phototherapy may disrupt hydration levels.
- The LED panel of the phototherapy light can become hot. The light shall always be adjusted by handling the housing of the head unit or stand, and it should be avoided to touch the LED panel.

7.2.1. POSITIONING OF BLUE ANGEL LED PHOTOTHERAPY DEVICE

7.2.1.1. POSITIONING ON INFANT INCUBATOR

- Blue Angel LED Phototherapy device is suitable for use with Ertunç Özcan brand Magic Loggia Infant incubators.
- The phototherapy light is positioned on the incubator canopy with the long side of the light parallel to the long side of the canopy.
- The phototherapy head unit can be removed from its stand and placed directly on the canopy, or it can be positioned on the incubator with its stand. When placed directly on the canopy, the non-slip feet on each corner of the unit ensure that the device remains stable.
- The height of the phototherapy device should be adjusted according to the height of the incubator by using the adjustment screw.
- The distance between the stand of phototherapy device and incubator should be minimum.
- The wheels of phototherapy device should be locked.

Figure 15: Positioning Blue Angel LED Phototherapy Device on Infant Incubator with Its Stand

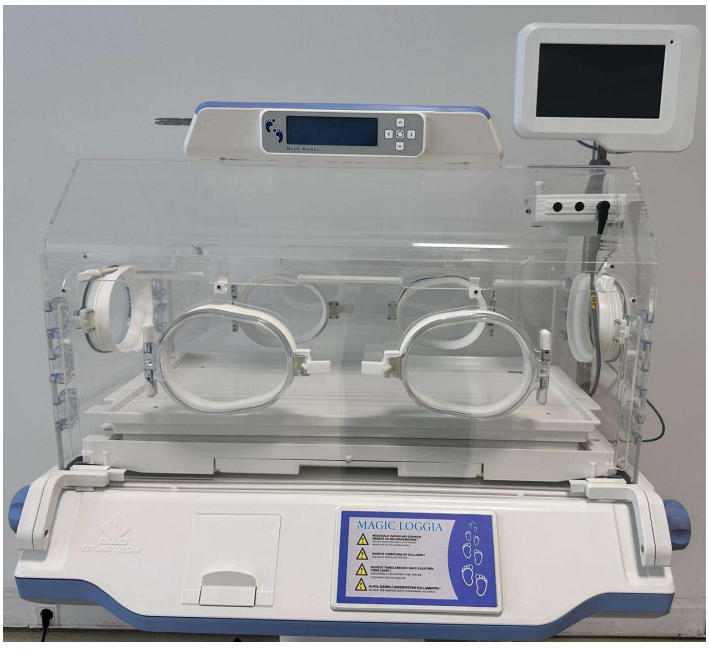


Figure 16: Positioning Blue Angel LED Phototherapy Device on Infant Incubator without Its Stand

7.2.1.2. POSITIONING WITH RADIANT WARMER OPEN BED

WARNING

- Positioning the phototherapy light under the radiant warmer may block heat transfer to the patient and may damage the phototherapy light.
- It should be ensured that the phototherapy light is not positioned where it directly receives heat rays from the radiant warmer, as this can affect both the device's performance and patient safety.
- If the phototherapy light must be positioned under a radiant warmer, the radiant warmer shall be turned off and the patient's body temperature shall frequently be checked to prevent overheating or inadequate thermal support.

- Blue Angel LED Phototherapy device is suitable for use with Ertunç Özcan brand Babyrest M100 Radiant Warmer Open Bed.
- The height of the device should be adjusted according to the height of the radiant warmer by using the adjustment screw.
- The distance between the stand and radiant warmer should be minimum.
- The wheels of phototherapy device should be locked.

7.2.2. PHOTOTHERAPY

- The height of the phototherapy device is adjusted to the suitable height.
- After adjusting the height of the device, it is ensured that the height adjustment screw lock is secured tightly.
- The wheels of the device are locked.
- If the patient's skin temperature is to be measured during therapy, the skin temperature sensor is attached to the head unit of the device.
- The phototherapy light is placed above the patient and turned ON.
- For the most effective therapy, the lamp should be positioned above the patient so that it covers as much of the body surface as possible.
- It is ensured that the distance of the light enclosure is not less than 40 cm from the patient.
- The red therapy focus light illuminates for 10 seconds, focusing on the patient's belly button when the device is turned on for easy patient positioning.
- If a skin temperature sensor is connected to the device, the sensor is placed on the patient's skin.
- 'Start' function is selected on the main screen and the confirmation key is pressed, then therapy is started.
- The light intensity of the therapy is adjusted in accordance with the protocol of the attending physician by using "Up Direction Key" or "Down Direction Key".
- When 'Timer' function is selected from the main screen and the confirmation key is pressed, the timer screen opens. Therapy duration time is set in hours and minutes.
- When the therapy is terminated, the 'Stop' function is selected from main screen and the confirmation key is pressed.

IMPORTANT

When using any phototherapy device, the following factors should be considered to ensure effective treatment:

- ✓ The maximum area of the patient's body exposed to the phototherapy light
- ✓ The distance between the patient and the light source
- ✓ The intensity of the emitted light
- ✓ The duration of the phototherapy session
- ✓ The patient's total serum bilirubin levels
- ✓ The thickness and pigmentation of the patient's skin

8. CLEANING AND REPROCESSING, MAINTENANCE, REPAIRING

This section contains instructions for the cleaning, maintenance, repairing and reprocessing of the Blue Angel LED Phototherapy Device.

WARNING

- The power cable should be unplugged to disconnect the power before performing service or maintenance.
- Thoroughly air dry the Blue Angel LED Phototherapy device after cleaning it with flammable agents. Small amounts of flammable agents, such as ether, alcohol or similar cleaning solvents left in the phototherapy device can cause a fire.

8.1. GENERAL

This section contains cleaning and maintenance instructions.

IMPORTANT

Maintenance and repair of device should only be performed by qualified Ertunç Özcan Service Personnel.

The device should not be used if it is defective.

8.1.1. DEFINITIONS OF SERVICE TERMINOLOGY

CONCEPT	DEFINITION
Service	All measures (inspection, maintenance, repair) intended to maintain and restore the functional integrity of a product
Maintenance	Periodic specified measures intended to maintain the functional integrity of a product
Repair	Measures to restore the functional integrity of a product after a failure
Inspection	Measures taken to determine and evaluate the actual condition of a device.
Reprocessing	Reprocessing is defined as validated processes used to make a previously used or contaminated medical device fit for a subsequent single use.

8.2. MAINTENANCE

This section describes the maintenance procedures required to maintain the functional integrity of the medical device. Maintenance procedures must be performed by authorized Ertunç Özcan personnel.

The table below shows the service life of the components. The period after the service life is not covered by the warranty.

COMPONENT	INTERVAL	TARGET GROUP
Skin Temperature Probe (Disposable)	Weekly	User
Skin Temperature Probe (Reusable)	3-Year	User
Display Module Battery	Yearly	Technical Service Personnel
Device Service and Maintenance	Yearly	Technical Service Personnel

WARNING

- Replace if materials become brittle, sticky, torn, dirty, or if strips of material peel off.
- There are lifetimes of the products specified in the table above along with their terms. Products must be changed at the specified times. Otherwise, problems may occur in the efficient operation of the device. Ertunç Özcan Company is not responsible for the problems that may occur and are not covered by the warranty.
- The phototherapy device materials in the table above must be used in accordance with the instructions in the user manual, otherwise the product is not covered by the warranty in case of any user error that may occur within the specified period or years.
- Our company is not responsible for any parts other than those installed on the device by Ertunç Özcan Technical Service Personnel. These products are out of warranty.

8.2.1. MAINTENANCE KITS

The warranty periods have been completed and the kits prepared for incubator maintenance have been prepared according to certain annual periods and are as follows. After the warranty period, the user can supply the kit products by purchasing them from Ertunç Özcan Company. Ertunç Özcan Company is not responsible for any deformation that may occur in the maintenance kits supplied by the user.

- **Annual Maintenance Kit:** Skin Probe
- **2-Years Maintenance Kit:** Skin Probe, Display Module Interval Battery
- **3-Years Maintenance Kit:** Skin Probe, Display Module Interval Battery, Blue Led, Red Led
- **5-Years Maintenance Kit:** Skin Probe, Display Module Interval Battery, Blue Led, Red Led

8.2.2. SHELF LIFE/SERVICE LIFE INFORMATION FROM TECHNICAL DATASHEETS OF CRITICAL COMPONENTS

Component/ Part No.	Manufacturer/ Trademark	Shelf Life
Battery (Lithium)	GP BATTERIES	5 years or when needed
LED(BLUE)	Edison	30000 hours or when needed
LED(RED)	Edison	30000 hours or when needed
Skin Temperature Probe (Reusable)	Metko	3 years or when needed
Skin Temperature Probe (Disposable)	Tarry	-

8.3. REPAIRING

All repairs should be carried out by Ertunç Özcan Technical Service Personal. Only original Ertunç Özcan repair parts should be used.

8.4. CLEANING & REPROCESSING

8.4.1. CLASSIFICATION OF MEDICAL DEVICES

Classification is based on the intended use of the medical device. The risk of transmission of infection by application of the product to the patient without proper reprocessing is the basis for the Spaulding classification.
Medical devices and components are classified as they exist;

CLASSIFICATION	EXPLANATION
Non critical	Non-critical devices are instruments and other devices whose surfaces are in contact only with intact skin and do not penetrate the skin.
Semi-critical	Semi-critical devices are devices that contact intact mucous membranes or non-intact skin.
Critical	Critical devices are devices that are introduced directly into the bloodstream or which contact a normally sterile tissue or body-space during use.

8.4.2. CLASSIFICATION OF DEVICE-SPECIFIC COMPONENTS

Pay attention to the classification and usage guidelines of the components below. The following is a recommendation from Ertunç Özcan.

CLASSIFICATION	EXPLANATION
Non critical	Stand, wheels, head unit, foot unit
Semi-critical	None
Critical	None

8.4.3. OVERVIEW OF THE CLEANING PROCEDURES OF THE COMPONENTS

Components	Surface Disinfection With Cleaning (Low Level Disinfection)	Machine Cleaning with Steam Sterilization	Description Of the Procedure
Display Module	Yes	No	Surface disinfection with cleaning
Head Unit	Yes	No	Surface disinfection with cleaning
Stand	Yes	No	Surface disinfection with cleaning
Foot Unit	Yes	No	Surface disinfection with cleaning

CAUTION

- Unauthorized use of materials that may damage the product will not be eligible for free repair service even if the product is within the warranty period.
- Do not steam clean any part of the device. Excessive humidity may cause damage.
- Keep the cables free of dust and dirt. Clean the cables with a wet cloth. Please clean the cables with clinical alcohol once a week.
- Do not immerse the device or sensor in liquids or detergents. Do not spill any liquid on the device or sensor.

8.4.4. CLEANING AND DISINFECTING INDIVIDUAL COMPONENTS

8.4.4.1. HEAD AND FOOT UNIT

- Use a low or medium strength disinfectant to clean all surfaces. The recommended disinfectants are given in Section 8.4.4.3.
- Thoroughly clean and dry the device.

WARNING

- When cleaning and disinfecting the surfaces around the Display Module, On/Off keys, do not spray the cleaning solution directly onto the surface of the device, but wipe with a damp cloth.
- Cleaning with steam sterilization is not possible.

8.4.4.2. DISPOSABLE/ REUSABLE SKIN TEMPERATURE PROBES

- Firstly, ensure to check whether the patient probe is disposable or reusable. Disposable skin temperature probes cannot be cleaned or reused.
- Clean with a slightly damp cloth using non-alcoholic hand soap and warm water or hospital-approved non-abrasive solutions.
- After cleaning, wipe with a damp cloth and rinse. Be sure to wipe and dry all thorough cleaning agents.

WARNING

- Avoid applying excessive pressure to the stylus tips. Be careful not to pull or bend the probe tip when cleaning. Always remove the probe from the phototherapy device by holding the connector on the head unit. Do not pull on the probe cable.
- Do not autoclave or sterilize the Skin Temperature Probe with other sterilization methods. Do not immerse the probes in liquid detergent.
- The disposable skin probes are not designed or approved for reuse. Reusing these probes may adversely affect measurement accuracy and overall system performance. Physical damage caused by cleaning, disinfecting, sterilizing, or reusing these probes may result in malfunction.
- The user must ensure that the probes are kept clean and undamaged between uses on the same patient.
- Do not clean disposable/ reusable skin temperature probes by steam sterilization.

8.4.4.3. DISINFECTANTS

Disinfection should be performed with a soft cloth dampened with one of the following disinfectants. After disinfection, rinse with a damp cloth. Be sure to rinse thoroughly. Recommended disinfectants are given below;

TRADEMARK	TRADEMARK OWNER	CERTIFICATION
Oxycide	Ecolab USA	EPA Reg. No. 1677-237
Dismozon	BODE Chemie	CE

WARNING

- Do not clean the phototherapy device with organic solvents, abrasive cleaners, strong acids, or strong bases. These compounds can damage parts. Observe the contents of the disinfectant used.
- Do not submerge parts in cleaning solutions. Dry wipe any cleaning solutions on the parts.
- Do not allow cleaning solutions to penetrate the plastic parts in any way and leave them without thoroughly drying.
- Do not autoclave the device.

8.4.5. REPROCESSING AND CONTROLLING THE DEVICE AFTER CLEANING

After cleaning, the phototherapy device shall be reprocessed according to “Device Installation” Section 6.3 and checked before use according to “Control of Device” Section 6.4.

9. TROUBLESHOOTING

The troubleshooting procedure for the phototherapy device is shown below. If the error cannot be found in the tables below, the device must be disconnected and the appropriate service procedure must be performed by a qualified technical service representative of Ertunç Özcan. If the phototherapy device does not work, please contact the Technical Service Department.

SIGN	PROBABLE CAUSE	SOLUTION
Lamps do not light when the power switch is switched on.	No electricity	Check whether there is electricity in the socket
	Power cable not connected or defective	Replace the power cable or check its connection
	Power fuse defective	Check the power fuses
	Power switch defective	Replace the power switch
	AC power socket defective	Replace the AC power socket
	On/Off key not in the correct position	Check that the on/off switch is in the on position
The lamps do not light when the device is switched on.	Defective lamp or lamps not positioned correctly.	Consult technical service
	Defective ballast transformer	Consult technical service
When the device is switched on, the lamp glows but is not fully lit.	Faulty lamp	Replace the faulty lamp
	Defective starter	Replace the connected starter
	Faulty lamp socket	Replace the faulty lamp socket
	Lack of connection at the lamp sockets	Check the lamp socket connection
The light output intensity does not meet the standard of the control.	Dirty lamps	Clean the lamps
	The output intensity of the lamps is below the accepted standard	Replace all lamps and check the light output again. Consult technical service.
If the amortisation of the foot unit is defective and/or the head unit drops suddenly when the height adjustment lock is released.	There may be a defect or malfunction in the height adjustment locking mechanism.	Consult the technical service.

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ANNEX A- NOTIFIED BODIES INFORMATION

ACCORDING TO THE MDD (93/42/EEC) MEDICAL DEVICE DIRECTIVE;

When the device features or performances are noticed to have tensions or functioning failures which may cause deaths or cause health issues to the patient or the end-user. When there is a deficiency in instruction that may cause these dangers, deactivate the device and contact with our authorized representatives if you are stated in the European community or our head office. Depending on the problem of the device, repairing shall be conducted at the location of the device or at our head office.

MDD (93/42/EEC)

APPROVED ORGANIZATION INFORMATION

Organization Name	KIWA CERTIFICATE SERVICES INC.
Address	İTOSB 9. Street No:15 Tepeören Tuzla/İSTANBUL
Organization No.	1984

ANNEX B- ELECTROMAGNETIC SUITABILITY

ELECTROMAGNETIC SUITABILITY (EMC) GUIDE

Safety standards: IEC 60601-1, IEC 60601-2-50

EMC Standards: IEC 60601-1-2

WARNING

Electrical medical devices require special precautions regarding the EMC and they need to be built and used appropriately to the stated EMC information.

WARNING

Portable and mobile RF communication devices may affect the electrical medical devices. Be careful when using these devices around electrical medical devices.

WARNING

This device/system is designed to be used only by a professional health officer. This device/system may cause radio interferences and may cause disorder to the working order of the devices close by. Precautions to reduce negative effects may include the air can be secured or the place of the device/system can be changed orientation can be carried out again.

Electromagnetic Suitability and Tests

Blue Angel LED Phototherapy has been tested and has fulfilled the conditions of the TS EN 60601-1-2:2016 Electromagnetic suitability.

Guide and Manufacturers Declaration on Electromagnetic Emissions

Blue Angel LED Phototherapy is aimed to be used in the below stated electromagnetic environment. The customer or user of the Blue Angel LED Phototherapy, must guaranty to use this device in these environments.		
Emission Tests	**Suitability**	**Electromagnetic environment-Guide Information**
RF emissions CISPR 11 EN 55011:2016	Group 2	Electromagnetic energy is used for the Blue Angel LED Phototherapy to serve its aimed function. The electronic devices around it may be affected.
RF emissions CISPR 11 EN 55011:2016	Class A	Blue Angel LED Phototherapy is suitable for use in any building other than the ones that are directly connected to a public low voltage power network which provide energy for the connected building such as houses etc.
Voltage waves /flicker emissions IEC 61000-3-3:2013/A1:2019	In accordance with the terms	
RF emissions CISPR 11 EN 55011:2016	Group 2	

Guide and Manufacturers Declaration on Electromagnetic Immunity

Blue Angel LED Phototherapy is aimed to be used in the below stated electromagnetic environment. The customer or user of the Blue Angel LED Phototherapy, must guaranty to use this device in these environments.			
Immunity Tests	**IEC 60601-1-2 Test Level**	**Suitability Level**	**Electromagnetic environment-Guide Information**
Electrostatic discharge (ESD) IEC 61000-4-2:2009	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	The site where the Blue Angel LED Phototherapy is located must be, wooden, concrete or ceramic tiled. If these sites are covered with a synthetic material, the relative humidity rate must at least be 30%.
Electrical fast transient burst/explosion IEC 61000-4-4:2012	For ± 2 kV power supply feeding line For ± 0.5 kV, ±1 kV, ±2 kV, ±4kV input/output line	100 kHz Implementation Time: ≥ 60s	The capacity of the power network must be at the capacity of the ones used in typical commercial environment or a hospital.
Sudden impact	Line-to-line, ±0.5 kV, ±1 kV	Repetition rate	The capacity of the

IEC 61000-4-5:2014/A1:2017	differential mode Line-to-ground, ±0.5 kV, ±1 kV, ±2 kV differential mode Phase angles 0, 90, 180, 270	1 min It fits the circumstances.	power network must be at the capacity of the ones used in typical commercial environment or a hospital.
Voltage dips of the power source input lines, short interruptions and voltage variations IEC 61000-4-11:2004/A1:2017	For the voltage pit 0% Ut (for 0.5 cycles, 10 ms duration, angles: 0,45,90,135,135,180,225,270,315) 0% Ut (For 1 cycle, in 20 ms time, angles: 0 70% Ut (For 25 cycles, 500 ms duration, angles: 0 0% Ut (For 250 cycles, 5000 ms duration, angles: -	12V, 0,5 cycle 12V, 1 cycle 168V, 25 cycle 12V, 5 second It fits the circumstances.	The capacity of the power network must be at the capacity of the ones used in typical commercial environment or a hospital. If the user of the Blue Angel LED Phototherapy needs to keep working in a main supply shortage situation it is suggested that the device is feed by continual power supply or a battery.
Network frequencies (50/60 Hz) magnetic field IEC 61000-4-8:2010	30 A/m	30 A/m It fits the circumstances.	Magnetic field network frequencies must be at the level used in typical commercial environment or a hospital.
Note- Ut, is the main voltage before the test levels are applied.			

Guide and Manufacturers Declaration on Electromagnetic Protection

Blue Angel LED Phototherapy is aimed to be used in the below stated electromagnetic environment. The customer or user of the Blue Angel LED Phototherapy, must guaranty to use this device in these environments.

Immunity Test	IEC 60601-1-2 Test Level	Suitability Level	Electromagnetic environment-Guide Information
Immunity to conducted disturbances induced by RF fields EN 61000-4-6:2014	3 Vrms 150 kHz with 80MHz 6 Vrms 150 kHz with 80MHz	3 V 6V	Portable and movable RF communication devices including their cables must not be any closer to any part of the Blue Angel LED Phototherapy than the suggested and measured suitability of the equality of transmitter's frequency. Suggested stand apart distance $d=[\frac{3,5}{V1}]\sqrt{P}$ 80 MHz with 800 MHz $d=[\frac{3,5}{E1}]\sqrt{P}$
Radiated, radiofrequency, electromagnetic field immunity EN 61000-4-3:2006/A2:2010	3V/m 80 MHz with 2.7 GHz	3 V/m	$d=[\frac{7}{E1}]\sqrt{P}$ 800 MHz with 2,5 GHz Here, according to the manufacturer of the P transmitter; W kind transmitter is the biggest output power and d meter kind is the suggested stay apart distance. A carried out electromagnetic field research states that the field strength spread form stable RF transmitters must be smaller than the suitability level of each frequency gap. The interference can be seen on the device with the icon shown below. 

Note 1- On 80MHz and 800MHz, a higher frequency gap is applied.
Note 2- These guide information can be applied in every situation. Buildings, objects and people can affect the electromagnetic radiation to be reflected or absorbed.

- ISM (industrial, scientific and medical) bands between 150kHz and 80MHz; 6.765 MHz and 6.795 MHz; 13.553 MHZ and 13.567 MHz, 26.957 MHz and 27.283 MHz and 40.66 MHz and 40.70 MHz
- The suitability levels of ISM frequencies between150kHz and 80 MHz and 80 MHz and 2.5 GHz, are aimed to reduce the risk of causing interference if movable/portable communication devices are accidently taken into the patient fields. For this reason a 10/3 additional factor, is calculated in the suggested stand apart distance of the frequency gaps located on the feeder.
- The field strength spread from the stable feeder cell towers for the radio telephones (cellular/wireless) and land radios, amateur radio AM and FM radio broadcast and TV broadcast may not be theory accurately estimated. To evaluate the electromagnetic fields caused by RF feeders, an electromagnetic field research must be considered. If the measured

field strength of the environment where the Blue Angel LED Phototherapy is used goes over the, above stated. Applicable RF suitability level the Blue Angel LED Phototherapy must be investigated to make sure it is operating normally.
If an abnormal situation is seen in the performance, additional measure may be needed for the Blue Angel LED Phototherapy Device device such as re-guiding or relocating.

- Between the 150 kHz and 80 MHz frequency gap, the field strengths must be lower than [V1] 3 V/m.

The suggested stay apart distance between portable and movable RF communication devices and Blue Angel LED Phototherapy Device.

Frequency Feeder	**150 kHz and 80 MHz**	**150 kHz and 800 MHz**	**800 MHz and 2,5 GHz**
Equation	$d=[\frac{3,5}{V1}]\sqrt{P}$	$d=[\frac{3,5}{E1}]\sqrt{P}$	$d=[\frac{7}{E1}]\sqrt{P}$
Feeders highest declaration output power (W)	**Distance (m)**	**Distance (m)**	**Distance (m)**
0.01	0.117m	0.117m	2.33m
0.1	0.37m	0.37m	7.37m
1	1.17m	1.17m	23.3m
10	3.7m	3.7m	73.7m
100	11.7m	11.7m	23.3m

For the feeders which broadcast in a highest output power which is not stated above, the suggested stay apart distance "d" in meter (m) must be defined by the applicable equivalent according to the feeder frequency. Here, the P, according to the feeder manufacturer watt (w) kind is the highest output power declaration of the feeder.

Note- These guide information, can be applies in all situations. Buildings, objects and people can affect the electromagnetic radiation to be reflected or absorbed.

Electromagnetic Immunity

Blue Angel LED Phototherapy is aimed to be used in the below stated electromagnetic environment.

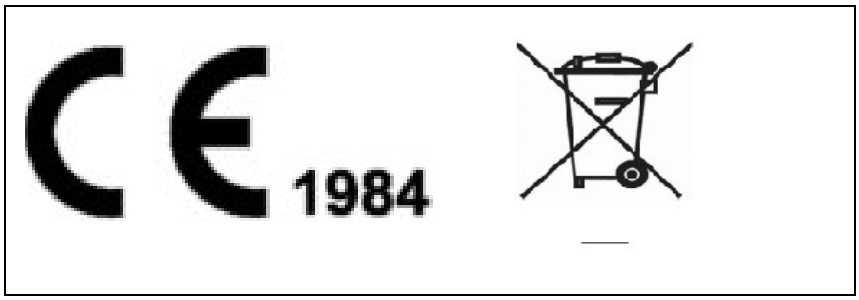
The customer or user of the Blue Angel LED Phototherapy, must guaranty to use this device in these environments

Immunity Test	IEC 60601-1-2 Test Level	Suitability level	Electromagnetic environment-Guide Information
Immunity to conducted disturbances induced by RF fields EN 61000-4-6:2014 Radiated, radiofrequency, electromagnetic field immunity EN 61000-4-3:2006/A2:2010	3 Vrms 150 kHz and 80MHz 3V/m 80 MHz and 2.7 GHz	3 Vrms 3 V/m	Blue Angel LED Phototherapy must be used only in environments that have the lowest RF isolation. Also, for each cable that enters the isolated environment, an isolation location which has the lowest [isolation efficiency/filter attenuation features] RF filter attenuation must be used. When stated by electromagnetic field research, the field strengths, that passes through the isolated surface, spread by the stable RF feeders must be lower than V/m value. The interference can be seen on the device with the icon shown below. 
The field strength spread from the stable feeder cell towers for the radio telephones (cellular/wireless) and land radios, amateur radio AM and FM radio broadcast and TV broadcast may not be theory accurately estimated. To evaluate the electromagnetic fields caused by RF feeders, electromagnetic field research must be considered. If the measured field strength of the environment where the Blue Angel LED Phototherapy is used goes over the, above stated. Applicable RF suitability level the Blue Angel LED Phototherapy must be investigated to make sure it is operating normally. **Note 1-** This guide information can be applied in every situation. Buildings, objects and people can affect the electromagnetic radiation to be reflected or absorbed. **Note 2-** For the actual isolation efficiency and the isolated surface filter attenuation to supply the lowest feature, it must be approved.			

Electrostatic Discharge

The equipment complies with the requirements of TS EN 60601-1-2:2016 Article 3.6 and EN 61000-4-2:2009 Electrostatic Discharge Immunity.

ANNEX C- INFORMATION OF COMPLIANCE OF STANDARDS AND DIRECTIVES



Ertunç Özcan has approved that; the device, its use, maintenance and service is in accordance with the European Commission Directive 93/42 EEC Medical Device Directive.

The second icon states that the electric or electronic equipment shall not be thrown away in a classified municipal waste and that it must be collected separately. Please contact your authorized representative to gain information on taking your equipment off service.

⚠	The labels on The Device, CE label, User Manual can be translated into the language of the country that the device is being dispatched to.