ERTUNÇ ÖZCAN

BABYREST M100 MODEL RADIANT WARMER OPEN BED 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 model and serial number of the defective unit and provide this serial number to the Ertunç Özcan Technical Service Center.

If you need to ship the unit, 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.

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.

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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
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1.4.3. WAREHOUSE

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
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1.5. MASIMO PATENTS

www.masimo.com/patents.htm

MASIMO NO IMPLIED LICENSE STATEMENT: “Possession or purchase of this device does not convey any express or implied license to use the device with unauthorized sensors or cables which would, alone or in combination with this device, fall within the scope of one or more of the patents relating to this device.”

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 H-100 Transport Incubator	CE Certified
Babyrest M100 Model Radiant Warmer Open Bed	CE Certified
Babyrest M50 Model Radiant Warmer Open Bed	CE Certified
Baby Led Force Phototherapy Device	CE Certified
Baby Led Force Mini Phototherapy Device	CE Certified
Blue Angel Phototherapy Device	CE Certified
Tresus Model Resusitator	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**		**Refer to the User Manual**
	Alternative Flow		**Type BF Application Part**
	Power On (Connect to a wall power switch)		**Caution: Hot Surface**
	**Power Off (Disconnect from the Wall power switch)**		**Manufacturer**
	**Serial Number**		**Do not throw out**
	**WARNING Information**		**European Conformity**
	**Weight Limit**	**MAX.**	**Maximum**
	**Use only distilled water**	**SpO_2**	**SpO_2 Input**
	**Production date**	**IPXO**	**Unprotected against water and dust particles**

NOTE

This manual shall explain all the functions and their usage instructions of the Ertunç Özcan brand Babyrest M100 model radiant warmer open bed.

2.4. MANUFACTURER'S RESPONSABILITY

The assembly, modification, repair/maintenance and calibration activities of all the incubator devices that has 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 the reliability, safety and performance.

"Ertunç Özcan" is not responsible for the use of the radiant warmer open bed without following the instructions and maintenance guidelines. The device can only be repaired and calibrated by an authorized service personnel.

All the users who operate the device must read and understand this user manual. When the radiant warmer open bed is not in use, it must be stored with the user guide.

For further or detailed information, please kindly contact with 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 damages 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 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 incubator is interfered by an unauthorized people, the warranty will be invalid.

IMPORTANT

The service life of Babyrest M100 model radiant warmer open bed 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 depends on the general operation of Babyrest M100 Radiant Warmer Open Bed. Specific precautionary statements for subsystems and particular features are mentioned in related part of the user manual.

WARNINGS

- Before using the radiant warmer open bed, 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 the radiant warmer open bed may injure the patient.
- Babyrest M100 must only be used for the purpose mentioned in Intended Use (Section 4.3)
- The radiant warmer open bed shall not be used if it is not functioning properly. Technical service must be given by an authorized and qualified personnel.

3.2. RESTRICTIONS FOR USE

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

3.3. BASIC SAFETY INSTRUCTIONS

3.3.1. OPERATION PRECAUTIONS

WARNINGS

- Operate only with the supplied power cord.
- Keep the baby mattress in a horizontal position before placing the baby in the device. The section designed for the baby to lie down is just the mattress.
- This product is for the professional use by the authorized and qualified health personnel, who are informed about the existing dangers and benefits of the infant radiant warmers.
- All the personnel must read, understand this guide and gain information about the operation of this warmer before using the device on patients.
- A false use of the device may harm the infant. The device must be used only by the personnel, who were trained properly under the control of the qualified medical personnel, who are already familiar with the known risks and benefits of the use of the radiant warmer.
- If a radiant warmer does not work properly, it must not be used. The technical service must be provided by the authorized and qualified personnel.
- To prevent the infant from being excessively warmed, it must be constantly monitored and controlled in the skin or air mode. The skin temperature must certainly be controlled through rectum.

- Direct sun lights or a near phototherapy device and similar heat producing devices can affect the skin temperature of the newborn. This situation must be given attention.
- The values of maximum weight that the parts of the device can carry must be given attention.
- A skin temperature probe must not be used as a rectal temperature probe.
- An excessive load of the shelves and connections can affect the balance of the warmer, negatively.
- It has utmost importance to independently monitor the temperature for any infants, who are under the infant radiant warmer.
- Ensure that the clinical condition of the infant is regularly checked, both in the Manual Mode and the Skin Mode.
- While using the warmer in the Manual Mode, continuously monitor the clinical condition and the temperature of the infant.
- As the environmental conditions (such as airflow) can affect the heat balance of the infant, continuously monitor the clinical condition and the temperature of the infant.
- The distance between the radiant infant warmer's heating system and mattress must be 71 cm. Any changes in this distance can cause the infant to be heated so much or less. Do not change the distance between the warmer and the mattress.
- It is recommended that the operator should regularly control the latches and closing equipment of the barriers to prevent the infant from falling.
- The heat, radiated by the warmer, can increase the insensible water loss of the infant. Take the necessary measurements in order to preserve the sufficient liquid balance.
- Do not lay any auxiliary equipment or object directly on the mattress. They can block the thermal energy of the radiant warmer and cause the infant's body temperature to decrease.
- When you turned the heater's head for any kinds of intervention, turn off the device from the power button. When you turn on the device again, check the set values.
- Do not put anything between the heater and the patient, which can prevent the efficiency of the radiant heat.
- Provide the heater head to be directly on the patient or in a central position above the cradle.
- There should be put any device, blanket etc. below the heater head. It can cause burns due to being exposed to excessive heating.
- The thermal balance of an infant can be affected from the environmental conditions. Do not locate the radiant warmer, directly under the sunlight; next to another heat source; or in the course of an air stream.
- In order to ensure the equilibrium state, the lowest subject should be brought when carrying the radiant heating at the height when changing. If not done, it may cause injury to the baby or the baby's or baby's treaters or damage to the product.
- The auxiliary equipment like the phototherapy lamps and heated mattresses can affect the performance of the heat radiance in the mattress of the cradle. Body temperature of the baby must be monitored.
- Never put an object on the heat resource. The object can be heated and can prevent the infant's being warmed.
- It is not recommended to put more than one infant on the open bed. However, if a common usage is required, continuously monitor the infants' clinical condition and temperature.
- Never connect unapproved equipment into the outputs of the auxiliary equipment.

- Remote monitoring does not substitute a qualified health personnel's directly monitoring a patient.
- If the system alarms are not turned off even when their requirements are met, do not use the radiant warmer. Contact with the technical service.
- When the device is continuously operated at the high heating power, it can cause excessive heating. While using the heater head, do not use the device in the high heating power, unless it is needed.
- Do not touch the protective wire on the heater head.
- When it is not used, turn off the device by the power button.
- After the completion of a treatment, turn off the device by the power button, and for safety, unplug the device's power cable until it is used again.
- The angle of the head unit should not be changed (turned). When it is necessary to change the head unit's angle, the device must be turned off by the power button and the infant's skin temperature must be monitored independently.
- The maximum weight for the devices, to be put into the device system, is 1,2kg for the shelves and 5 kg for the manual stand, and 2,5kg for the drawers. These limits must not be exceeded.
- Our Baby Led Force Mini phototherapy device can be used together with our Babyrest M100 Radiant Warmer Bed device. The phototherapy device also needs to be powered from the power supply.

3.3.2. ELECTRICAL PRECAUTIONS

WARNINGS

- To provide the grounding safety, connect the power cable only to the hospital type power outlets, which are earthed appropriately. In case of a suspicion about the grounding connection, do not turn on the device.
- When it is possible that the voltage or frequency of the power source can get out of the specified range, provide the use of a power regulator.
- Because of the danger of an electricity shock, the technical service must be always provided by qualified and authorized technical personnel.
- It must be ensured that the electricity specifications, which are stated in the product specifications, are provided. Otherwise, it can cause personal injury or equipment damage.
- Some chemical cleaning materials can be conductive. Do not allow these cleaning materials contact with the electrical components and do not use them on the surfaces. It can cause personal injury or equipment damage.
- The control module of the device must not be cleaned with a spray or similar tools. The cleaning materials, which can be conductive, may cause personal injury or equipment damage.
- There is a potential of an electricity shock in the electrical equipment. Inform your personnel about the risks of the electrical equipment.
- Ensure that the additional equipment, which is connected to the infant or the heater, is electrically safe.
- Do not use another cable than the power cable, which is provided with the device.
- There is a potential of an electricity shock under the panel. Ensure that any kinds of maintenance and repair operations are provided by the authorized personnel.

- To connect the heater into a power source, do not use an extension cable. Use only the hospital type power cables and outlets.
- Do not use the device in the electromagnetic environments that are stated in the IEC 60601-1-2 standard.
- Use of electrosurgical units or other devices, with a radiating electricity field, can affect use of this device.
- If there is a use of the electrosurgical units or other devices, with a radiating electricity field, security measures must be taken, and the patient's body temperature must be monitored.
- Electricity cables must be extended over the mattress.
- Portable and mobile RF connection equipment can affect the electrical medical equipment.

3.3.3. SAFETY PRECAUTIONS

WARNINGS

- Before using the device, all this manual must be read and understood. Otherwise, there can be injuries.
- A mistaken use of the device can hurt the newborn.
- Do not leave the infant alone under the infant radiant warmer.
- While the side panels are open, do not leave the infant alone in the mattress.
- While the newborn is inside do not move the device.
- While moving the radiant warmer, there must be at least to persons for sufficient control. Avoid moving the device while the newborn is inside.
- Ensure that all the locks of all the wheels are open.
- Always hold the heater head, while carrying the device.
- Lock the wheels before using.
- The transportation process must be done by the means of the carriage arms. The heater head must not be used in the transportation process.
- Before carrying, ensure that the mattress is flat, and the side panels are locked. Use the carriage arm.
- Do not move the heater mattress by pushing or dragging from the side panels. This process can damage and break the parts, which serve as a safety barrier around the infant.
- Changing the position of the mattress from flat to inclined position can affect the performance of the heater by changing the distribution of the heat in the mattress.
- Before and after changing the position of the mattress to the inclined position, check all the tubes, IV connections and wires that are connected to the infant. Inclining and moving the heater mattress may pull the tubes or wires.
- Do not use the mattress without its mattress.
- Be careful that the patient and operator's arms and legs are away from the side panels, during opening and closing the side panels.
- Never put another device on the shelf system, alongside with the monitor.
- Never put devices on the shelf system, which exceeds the size and the carriage capacity of the shelf.
- Before laying a newborn on the mattress, ensure that the mattress surface is covered with the flannel type cloths.

- Only the authorized personnel can intervene in the part, where the batteries are located. In case of the chemical leakage risks, there must not be any intervention in the battery part.
- Before putting a newborn on the mattress, lock the wheel brakes.
- Because of the absorbed electrical energy, the electro surgical units or the devices, which can radiate electromagnetic waves, can cause skin temperature probe detecting heat at different values.
- It must be given attention that the weight of the maximum total auxiliary equipment on the heater must not exceed the maximum value; see the Technical Specifications of Babyrest M100 Infant Heater, which is on the back of this instruction manual.
- The maximum mattress load is 10 kg.
- Before putting or connecting the materials into each of the auxiliary equipment, ensure that all of the auxiliary installation equipment is safely fixed to the installation socket.
- The maximum load that can be applied on the installation elbows is 10 kg for the auxiliary hardware and equipment.

3.3.4. USING SKIN PROBE PRECAUTIONS

WARNINGS

- If the skin probe is not correctly put onto the infant or a reflection probe cover is not used, the heater cannot measure or check the infant's skin temperature.
- To measure the infant's skin temperature, use the appropriate skin probes.
- Regularly check that the skin probe and probe cover are correctly located on the infant. Ensure that the skin probe always contacts with the infant's skin, directly.
- Apart from the cover of the reflection probe, never put an obstacle between the skin probe and the heater.
- Heating process can be prevented in case that there is a blanket, laid between the infant's heater and skin probe.
- While in the manual mode, the monitored skin temperature is only for monitoring and cannot be used to check the heater's power.
- Do not pull the skin probe cable, to put it off from the infant's skin. Pick the cable up from the infant's skin, by kindly removing it.
- Do not pull the skin probe cable, to remove it from the control panel. By gripping the probe jack, remove it from the control panel.
- Regularly check the skin probe, if the skin probe is not contacting with the infant's skin, the values will be read wrong.
- Do not use a rectal thermometer to measure the infant's body temperature.
- The device may not be able to determine the distinction between an increase in the core temperature, which is accompanied by a cold skin (fever), and low intracorporeal and HYPOTHERMIA, so the body temperature of the newborn must be monitored, on a regular basis.

3.3.5. PRECAUTIONS FOR THE USE OF OPTIONAL FEATURES

WARNINGS

- Always use a patient artificial respiration circuit with an appropriate pressure reducer. Failure to do so may result in injury or damage to the product.
- Improper use of the resuscitator can harm the baby. The resuscitator should only be used by appropriately trained personnel under the supervision of qualified medical personnel who are familiar with the known risks and benefits associated with its use.
- Always check the airway depressurization valve setting before patient use. Failure to do so may result in patient injury.
- Check that the oxygen/air mixer control of the mixed gas supply unit is set correctly before use. Failure to do so may result in patient injury.
- Before use, check that the patient circuit contains all necessary parts. Failure to do so may result in patient injury.
- For the safety of the baby, please do not intervene without reading the operating instructions.
- Improper use of oxygen can increase the risk of fire.
- Spark-generating auxiliary equipment must not be placed on or near the resuscitation device.
- Do not place or hang weights on or anywhere near the device.
- The device must be disinfected after treatment is completed.
- Alcohol-based disinfectants should be used to sterilize the device.
- Always operate the system with medical grade gases. Failure to do so may result in injury to the baby or damage to the equipment.
- Monitor the concentration of oxygen delivered and the partial pressure of oxygen in the patient's blood (PaO_2). Failure to do so may result in injury to the baby.
- Check that the oxygen/air mixer control of the mixed gas supply unit is set correctly before use. Failure to do so may result in injury to the baby.
- If any of the control knobs on the mixer become loose, do not attempt to reinstall them. The calibration (setting) of these controls depends on the position of the knob on the shaft. If the knobs come loose, authorized service personnel must adjust the unit. Failure to do so could result in injury to the baby or damage to the equipment.
- Uninformed use of supplemental oxygen can cause serious side effects, including blindness, brain damage and death. The dangers may vary depending on the baby. The method, concentration and duration of oxygen therapy should be determined by the treating doctor.
- If oxygen therapy is necessary in an emergency, the attending physician should be notified immediately.
- The concentration of oxygen the baby breathes in does not determine the partial pressure of oxygen in the blood (SpO_2). When deemed appropriate by the doctor, blood SpO2 should be measured using appropriate clinical techniques.
- Oxygen flow rates cannot be used as an accurate indicator of oxygen concentrations in a transport incubator. Oxygen concentrations should be measured with a calibrated oxygen analyzer at intervals specified by the attending physician.
- A dirty air intake filter can increase oxygen concentrations and lead to the formation of carbon dioxide. Air filters should be changed regularly.
- Oxygen therapy can increase the noise level inside the infant compartment.

3.3.6. CLEANING AND MAINTENANCE PRECAUTIONS

WARNINGS

- Maintenance and repair processes must be performed only by the authorized personnel.
- To prevent the possibility of burn, while performing the service and maintenance procedures, ensure that the power source is removed from the heater and the heater part is left to be cooled.
- The heater head, lamb and the surrounding area can be as much heated as it can cause burns. Remove the unit from the power outlet and wait until the head is cooled for cleaning and maintenance.
- While performing the cleaning and maintenance procedures, ensure that the heater is removed from the power source to prevent the possibility of an electricity shock.
- Before starting to the cleaning and maintenance works, ensure that all the oxygen and air sources are closed and disconnected from the heater.
- In case of performing the cleaning and maintenance works in an environment, where oxygen exists, explosion and fire dangers may occur.
- Before starting the device, the controls must be made, and the technical service must be informed in case of detecting a problem.
- It must be checked that the device's power cable is not plugged in the cleaning and maintenance process.
- Ether, alcohol and similar cleaning materials may cause a heater burn.
- Use of the cleaning liquids of the device in a place, where there are anesthetic gases or other flammable ones, can cause explosion and fire dangers.

3.4. TARGET USER GROUPS FOR BABYREST M100 RADIANT WARMER OPEN BED

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 product
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

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

3.5. TRAINING

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

4. GENERAL INFORMATION

4.1. INTRODUCTION

This manual contains instructions about the use, cleaning, maintenance and troubleshooting of Ertunç Özcan brand's Babyrest M100 model, radiant warmer with 6" Monochrome and 7" Color Touch Screen options. In case that the user does not operate the device in accordance with the instructions; does not comply with the maintenance recommendations in the 9th Part of this book; or repairs with the parts, which are forbidden to be used, the manufacturer shall not be responsible for the false performance of the device. The calibration and repair must be performed only by the qualified service personnel.

This manual must be read and clearly understood by those, who are going to operate the device.

This manual must be in a place, where the operators can easily access.

In case that there is something that you do not understand, place contact with ERTUNÇ ÖZCAN Company for more detailed information.

4.2. EXPLANATION

The radiant warmer is designed to provide a controlled heat source. It should be used to prevent the water loss of a newborn at the birth and for the first few weeks after the birth. The radiant warmer is designed to work under the normal conditions of the operating temperature, between 20˚C and 30˚C degrees.

The radiant warmer, the operating mode and the temperature control of skin or manual modes are selected from the control module.

4.3. INTENDED USE OF THE DEVICE

Babyrest M100 Radiant Warmer Open Bed is a radiant warmer for infants (29 days to 2 years) and 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)
- Very low birth weight (< 1.500 g)
- Extremely low birth weight (<1.000g)

Ertunç Özcan Babyrest M-100 Radiant Baby Warmers are designed to provide babies with a controlled heat source, especially in the first few weeks after birth.
In addition, thanks to the additional features of the Babyrest M100 device, it is possible to resuscitate the newborn baby (resuscitation), to provide manual breathing with oxygen-air mixture, to remove the fluid in the vacuum mouth / pharynx / lung, and to facilitate the intervention of the baby by adjusting the height.

Warmers are used for newborns and sick babies in the neonatal intensive care unit to achieve the same temperature as in the womb and are a baby care unit that provides complete care. Babyrest M100 model baby warmer includes an integrated cradle with trend feature, electronic trendelenburg and appropriate accessories.

4.4. ENVIRONMENT OF USE

The usage of Ertunç Özcan Babyrest M100 Radiant Warmer Open Bed 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.
Babyrest M100 Radiant Warmer Open Bed is not intended for home use.

4.5. INDICATIONS, CONTRAINDICATIONS, SIDE EFFECTS AND WARNINGS

4.5.1. INDICATIONS

- The need for short-term intubation and auxiliary respiratory support
- Severe respiratory insufficiency requiring auxiliary respiratory support
- Regenerating apnea requiring positive pressure ventilation support
- Low birth weight
- 32-36. Pregnancy week prematures
- Cyanosis that persists despite oxygen therapy
- Conginathral heart disease
- Suspicion of metabolic disease

4.5.2. CONTRAINDICATIONS

- Burn
- Hypothermia
- Hyperthermia

4.5.3. SIDE EFFECTS

Failure to connect the skin probe can lead to hyperthermia in infants experiencing high fever. Excessive oxygen levels can result in eye injuries, while dehydration, skin rashes, or irritation may also occur.

4.5.4. ADVERSE EFFECTS

No adverse effects detected.

4.6. FEATURES

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

4.6.1. CLASSIFICATION OF DEVICE

CLASSIFICATION	Class IIb

4.6.2. STANDARDS

It is designed in compliance with the requirements of the following standards.
(93/42/EEC) Directive of Medical Devices, council decisions
IEC 60601-1: 2009
IEC 60601-1-2: 2011
IEC 60601-2-21: 2021
(Optional) TS EN ISO 10079-3 Medical Suction Equipment - Part 3 : Suction Equipment Fed by Vacuum or Positive Pressure Source
(Optional) TS EN 10651-4 Lung Ventilators for Medical Use - Part 4 Lung Ventilators for Medical Use - Part 4 - Specific Features for Operator Operated Resuscitators

4.6.3. ELECTRICAL FEATURES

MODEL	6" Monochrome Screen	7" Colored Touch Screen
Power requirements	110/120 (±10%) VAC	110/120 (±10%) VAC
Frequency	50/60 Hz	50/60 Hz
Power consumption	800 W	800 W
Heating Power	450 W	450 W
Lamp Power	5 W	5 W

Protection Classes	
Electrical protection class device	Class I
Ingress of Liquids and Particulate Matter (IEC 60601-1)	IPX0
Skin temperature sensor	Type BF
SpO2, Masimo SET (optional)	Type CF

4.6.4. DEVICE FEATURES

MODEL M100	**6" Monochrome Screen**	**7" Colored Touch Screen**
Height (Adjustable)	169 to 186 (±1cm) cm with electric elevator module, 180 (±1cm) with standard features	
Width	76 (±1cm) cm	
Depth	80 (±1cm) cm, 132 (±1cm) with all accessories	
Weight	~ 100Kg	
Mattress Size	65 (W) x 65 (H) x 3 (D) cm (±1cm)	
Mattress Tray	66 (W) x 66 (H)x 1 (D) (±1cm) cm	
Mattress Capacity	10 Kg	
Mattress Height	101 cm (±1cm) with standard features, 85 to 104 (±1cm) cm with electric elevator module	
Side panel height of bed	Highest 20 cm (±1cm) Lowest 18 cm (±1cm)	
Mattress inclination	± 12º (±2º) for electrical trendelenburg mechanism	
	-10º/+14 º (±2º) for mechanical trendelenburg mechanism	
Turning angle of heater head	-130° to +130°(from the center position)	
Castors	4 X ø125 mm, locking	
Distance between Heater and Bed	71 cm (±2), 69 (±2) with scale module	

MODEL M50	6" Monochrome Screen	7" Colored Touch Screen
Height (Adjustable)	169 (±1cm) cm	
Width	60 (±1cm) cm	
Depth	83 (±1cm) cm	
Weight	~ 22Kg	
Turning angle of heater head	-130° to +130°(from the center position)	
Castors	4 X ø75 mm, locking	

4.6.5. MANUAL MODE HEATER CONTROL

MODEL	6" Monochrome Screen	7" Colored Touch Screen
Heater function range	0% - 100%	0% - 100%
Increment of Heater	5%	5%
Monitoring Sensitivity	5%	5%

4.6.6. SKIN MODE CONTROL

MODEL	6" Monochrome Screen	7" Colored Touch Screen
Skin Mode Function Range	30°C– 37°C	30°C – 37°C
	37°C – 38°C excessive mode	37°C – 38°C excessive mode
Monitoring Sensitivity	0,1°C	0,1°C
Skin Temperature Measurement Range	25°C – 45°C	25°C – 45°C
Measurement Correctness	0,3°C (Maximum)	0,3°C (Maximum)

4.6.7. OPERATING NOISE

Operating noise at the center of the mattress	≤40 dB(A) Measured without ventilation
Operating noise during T-piece resuscitation (optional)	≤40 dB(A) measured in a free field according to ISO 3744 in a distance of 1 m at a height of 1.5 m
Maximum operating noise during AutoBreath resuscitation or suction (optional)	≤60 dB(A) measured in a free field according to ISO 3744 in a distance of 1 m at a height of 1.5 m

4.6.8. ALARM VOLUME

Adjustment range of alarm volume	50 to 65 dB(A) Measured in accordance with IEC 60601-2-21
Power failure alarm	
Alarm volume	65 dB(A)
Alarm duration	10 minutes

4.6.9. GAS MIXER ALARM AND ACOUSTIC SIGNALS - RESUSCITATION MODULE (OPTIONAL)

Volume of gas mixer alarm and pressure relief valve signals	≤80 dB(A) measured 15 cm above the center of the mattress
Gas mixer alarm condition	Either O2 or Air pressure is below 100 kPa ± 50 kPa (14.5 psi ± 7.3 psi)

4.6.10. RADIANT WARMER OPERATION

Radiant Power	
Heat level 30 %	≤10 mW/cm2
Heat level 60 %	≤18 mW/cm2
Heat level 100 %	≤32 mW/cm2
Bed Canopy (option)	
CO_2 concentration with bed canopy on device	max. 0.5 %

4.6.11. GAS SUPPLY (OPTIONAL)

Duration of gas supply	Time per liter of cylinder volume

4.6.12. ENVIRONMENTAL OPERATION TERMS

During Operation	
Ambient temperature	18 to 35 °C (64 to 95 °F)
Relative humidity	20 to 95 %, without condensation
Ambient pressure (without Resuscitation module)	620 to 1060 hPa (9.0 to 15.4 psi)
Ambient pressure (with Resuscitation module)	690 to 1060 hPa (10.0 to 15.4 psi)
During Storage and Transportation	
Ambient temperature	–20 to 60 °C (–4 to 140 °F)
Ambient pressure	500 to 1100 hPa (7.3 to 16.0 psi)
Relative humidity	10 to 95 %, without condensation

4.6.13. SOFTWARE FEATURES

MODEL	**6" Monochrome Screen**	**7" Colored Touch Screen**
Language Options	Turkish, English	Turkish, English
Software Version	-	V.2.1.1

Key Lock	Automatically, at least 1 or 20 seconds after the last use of keys or manually

4.6.14. CONTROL PANEL SCREEN FEATURES

Parameters monitored on the LCD indicators:

- Temperature, set in the Skin Mode
- Measured skin temperature
- Heater operating power
- Menu settings
- Alarm
- Clock – date
- Timer
- Scale
- Trend Graphic
- Battery Level

4.6.15. IP PROTECTION CLASSES AGAINST WATER AND FOREIGN MATERIAL PARTICLES: IPX0 and IP0X

Standard Features:

- Screen
- Integrated heater
- Intervention lamp
- Mattress Tilt feature
- X-Ray tray
- Skin Probe
- Integrated Balance Scale
- Grounded Power Cable

Optional Features:

- IV Pole
- Monitor tray
- Ventilator connection pipe
- Resuscitation device
- Scale
- Multiple Drawers
- Mini Phototherapy Device
- External SpO_2
- Lifting Mechanism
- Electronic Trendelenburg System
- 360˚ Rotatable Drawer
- Table surface with conductive mattress with baby head/ shoulder support.
- Filled Mattress: Foam Density Approx. 25 kg/m3
- Mattress Cover: Memory Foam Bed, Waterproof, Erasable
- Internal Medical Air Compressor
- Internal Oxygen Blender providing concentration between 21% and 60%
- Electronic height adjustment by means of feet on both sides of the body.
- Support stand for Oxygen and Air Tubes (5 Lt&10 Lt).
- Acrylic Helmet
- Onboard SpO_2 module

4.6.16. MINI LED PHOTOTHERAPY FEATURES

- Intensity ratio
- 0.4 (minimum to maximum)
- Heat output at 12 in (30.5 cm) over 6 hrs
- < 18° F (10° C) warmer than ambient

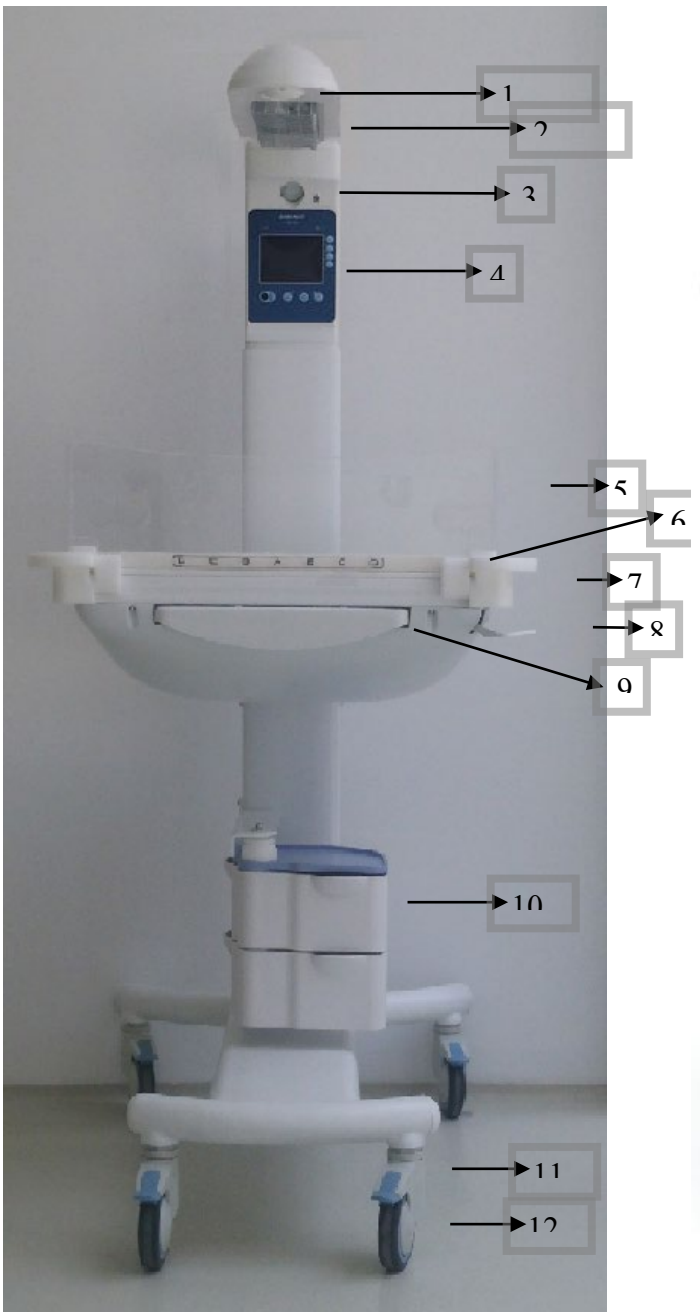


Figure.1 General appearance

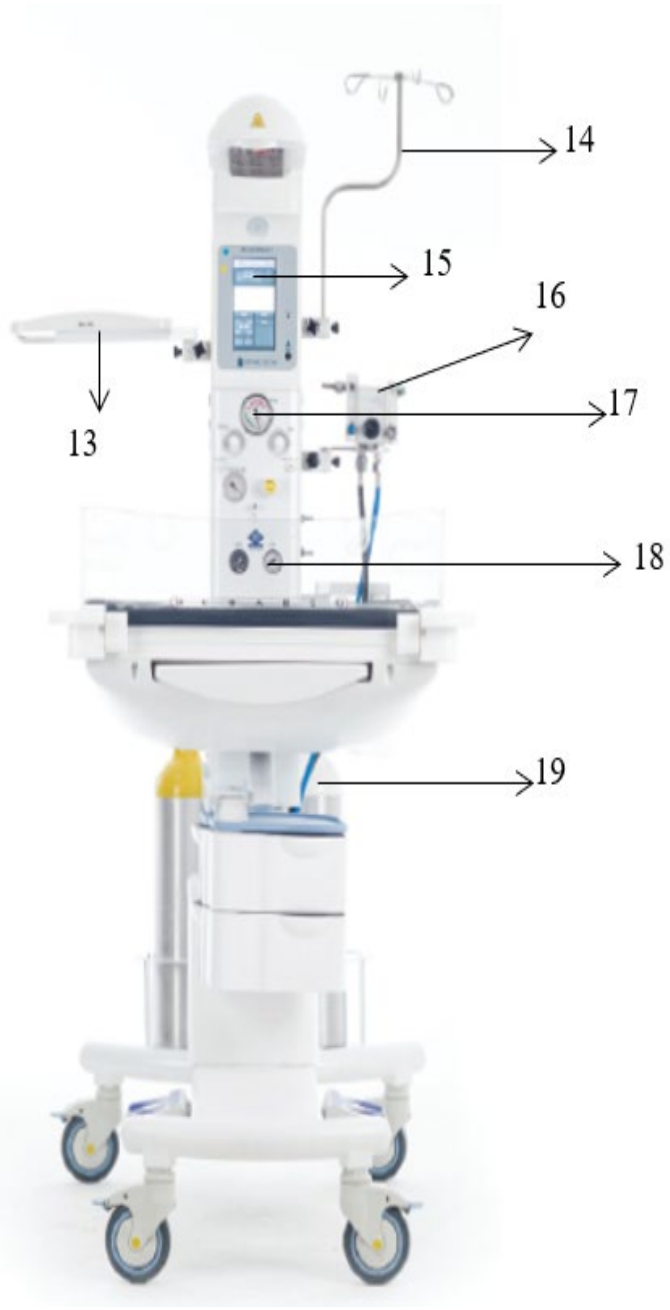


Figure 2. 7" Colored Touch screen

Number	Definition	Number	Optional Features
1	Examination Lamp	13	Monitor Tray
2	Heater	14	IV Pole
3	Examination Lamp	15	7" Colored Touch-Operated Control Module
4	6" Monochrome Control Panel	16	Blender
5	Side Panels	17	Resuscitation
6	Mattress	18	Vacuum Unit
7	Carriage Arm	19	Air and Oxygen Tube Stand
8	Mattress Tilt Mechanism Arm		
9	X-Ray Tray		
10	Drawer		
11	Wheel Lock Switch		

12	Wheel		

4.7. ACCESSORIES LIST

The accessories and auxiliary equipment used with the device are CE certified and their list and definitions are given below.

PHOTO	ACCESSORY AND AUXILIARY EQUIPMENT	MANUFACTURER
	SpO_2 Adapter cable: Use to connect disposable SPO2 probe to a variety of pulse oximeters and multi-parameter monitors equipped with Masimo SET®.	Masimo
	Disposable SpO_2 Probe : It measures how much oxygen molecules in the patient's blood are held by hemoglobin molecules (SpO_2) and calculates the heart rate in this way.	Masimo
	Reusable Skin probe: Measures the patient's skin temperature.	Metko Medical Devices
	Power Cable: It provides the device to be fed from the mains voltage.	Tamtel Cable
	Disposable skin probe: Measures the patient's skin temperature. Skin temperature probe stabilizer band: The skin temperature probe ensures that the probe remains stable on the neonate skin surface.	Metko Medical Devices
	IV Stand: Provides the transport of serum liquid.	TMS Medical Devices Co.
	Oxygen sensor: It measures the amount of oxygen delivered to the patient.	Analytical Industries Inc.

5. SYSTEM INSTALLATION AND CONTROL

WARNING: Read this manual completely before using this device. Using the device without completely understanding how to operate can get the patient or the operator injured.

Be careful about not damaging the equipment and scratching the unprotected sensitive surfaces, while taking out of the package. There can be personal injuries or equipment damages.

5.1. MECHANICAL CONTROL

Apply the steps below for the control process.

- Unplug the power cable.
- Check if there is any damage on the power cable. If damage is detected, change the cable.
- Check all the parts for installation. Ensure there is not any missing part and damage.
- Check the movements of the wheels. Ensure that the device is balanced. As the device stops while the wheels are locked, ensure that the device is moved, when the wheels are unlocked.
- Each edge must be lifted and it must be manually controlled that any of the wheels are not loose. This control process must be done by two persons. Use of a loose wheel can cause a turnover danger. The device must not be used until the loose wheels are replaced.
- Check that the side panels are automatically moving down when the buttons, on the right and left sides of the panel, are pressed at the same time.
- Ensure that the tilt mechanism operates safely. Ensure that the mattress stands stable when this mechanism is used.
- Check that the mattress moves with ease, by removing and mounting the X-Ray tray under the mattress.
- Check the movement of the heater head, in a direction, parallel to the ground.
- Check that the heater device is directly on the patient or in a central position above the cradle.

5.2. AUXILIARY EQUIPMENT CONTROL

- Check all the auxiliary equipment. Ensure it is not missing or damaged.
- Ensure that all the auxiliary equipment is mounted safely.

6. FUNCTIONAL EXPLANATION

6.1. GENERAL

This part provides general description about the functions of Babyrest M100 radiant warmer. Start the device from On/Off buttons. At the opening, the device performs a system check with a self-test. Wait for this test to be completed.

6.2. USING MANUAL MODE

Manual mode allows monitoring the infant's skin temperature by using the heating source power and skin probe that can be adjusted by the user.

6.2.1. USING MANUAL MODE FOR 6" MONOCHROME SCREEN

By pressing mode function button, choose the Manual mode.

To increase the heating power in the front panel, adjust the desired level of the heating source between 0 % and 100 %, by using the function button. The level of the heating power is monitored in the upper left part of the screen. The heater works at the adjusted power of the heating source. While using the manual mode, the skin temperature of the infant must be monitored with the skin probe. Put the skin probe socket closely into the front panel outlet and place the skin probe onto the infant's skin.

Within 15 minutes after beginning to use this mode, visual and audible alarm of the "manual mode reminder" becomes active. When the manual mode button being pushed after 15 minutes heater continue to operate in the set level. Unless being pushed to the manual mod button heater continue to operate by reducing power to 30% The audible alarm signal can be silenced. 15 minutes after silencing, the audible alarm signal again becomes active. This process continues until the mode is changed.

Figure.3 Manual mode – Heater setting

6.2.2. USING MANUAL MODE FOR 7" COLORED TOUCH SCREEN

Choose the Manual mode by pressing the Manuel mode function (Figure.3) key.

To increase the heating power on the front panel, adjust the desired level of the heating source between 0 % and 100 %, by using the function button. The level of the heating power is monitored in the upper left part of the screen. The heater works at the adjusted power of the heating source.

While using the manual mode, the skin temperature of the infant must be monitored with the skin probe. Put the skin probe socket closely into the front panel outlet and place the skin probe onto the infant's skin.

Within 15 minutes after beginning to use this mode, visual and audible alarm of the "manual mode reminder" becomes active. When the manual mode button being pushed after 15 minutes heater continue to operate in the set level. Unless being pushed to the manual mod button heater continue to operate by reducing power to 30% The audible alarm signal can be silenced. 15 minutes after silencing, the audible alarm signal again becomes active. This process continues until the mode is changed.

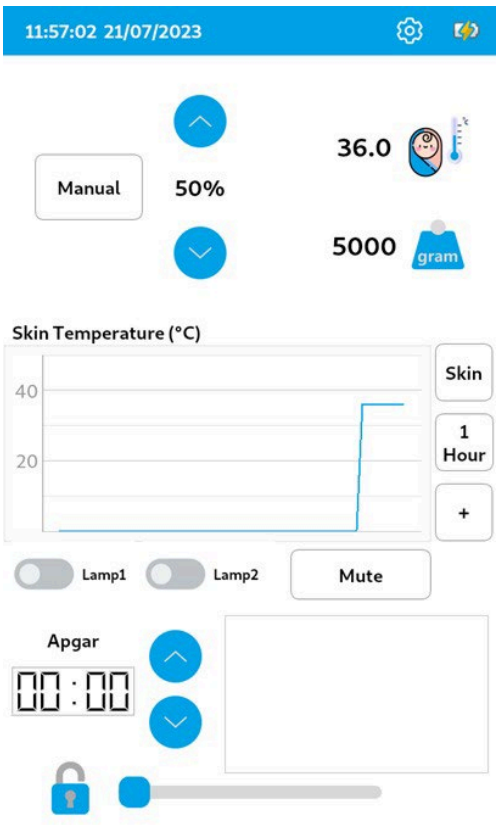


Figure.4 Manuel Mode Heater Set

WARNINGS

- It is very important to monitor the skin temperature of the infant, under the radiant heating. While using the heating in the Manual mode, the clinic condition and the skin temperature of the infant must be constantly monitored by using a skin probe.
- While in the Manual mode, the monitored skin temperature cannot be used to check the power of the heating source.
- Not to allow the baby to contact with a cold surface, provide the mattress to be warmed by operating the device in Prewarm mode.

6.3. USING SKIN MODE

In the Skin Mode, in order to reach to the adjusted skin temperature, the heater's power is automatically controlled to adjust it according to the infant's skin temperature.

6.3.1. USING SKIN MODE FOR 6" MONOCHROME SCREEN

Put the skin probe into the socket, on the front panel.

Put the infant on the mattress and place the skin probe correctly on the infant's skin.

By pressing mode function button, choose the Manual mode.

Adjust the desired skin temperature by using the heat increasing function button on the front panel. The skin temperature can be adjusted between 30°C and 38°C with 0,1 °C differences. The adjusted temperature is seen on the upper left part of the screen. If the temperature value is wanted to be adjusted above 37 °C, press the indicator button of >37 °C and increase the temperature up to the desired value.

After correctly putting the skin probe socket into the outlet, on the front panel, and placing the skin probe on the baby, the skin temperature of the baby is seen in the upper left part.

The heater automatically adjusts the heating source's power to be able to stabilize the infant's skin temperature in the adjusted temperature.

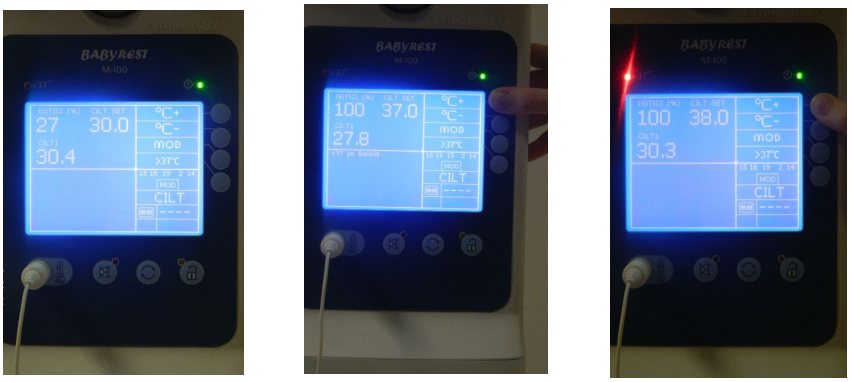


Figure.5 Skin Mode – Temperature Setting

6.3.2. USING SKIN MODE FOR 7" COLORED SCREEN

Put the skin probe into the socket, on the front panel.

Put the infant on the mattress and place the skin probe correctly on the infant's skin.

Choose the Skin mode by pressing the Skin mode function (Figure.6) key.

Adjust the desired skin temperature by using the heat increasing function button on the front panel. The skin temperature can be adjusted between 30°C and 38°C with 0,1°C differences. The adjusted temperature (SKIN SET) is displayed at the top center of the screen.

If the temperature value is to be set above 37°C, the set is set to the desired temperature by pressing > 37°C in the upper left corner of the menu.

After correctly putting the skin probe socket into the outlet, on the front panel, and placing the skin probe on the baby, the skin temperature of the baby is seen in the upper left part.

After correctly putting the skin probe socket into the outlet, on the front panel, and placing the skin probe on the baby, the skin temperature of the baby is seen in the upper left part.

The heater automatically adjusts the heating source's power to be able to stabilize the infant's skin temperature in the adjusted temperature.

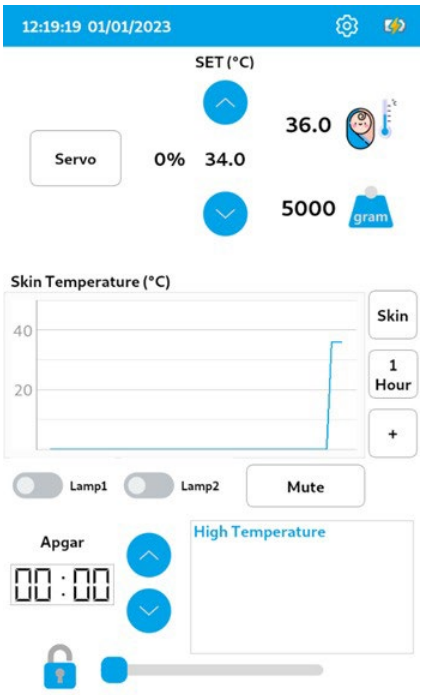


Figure.6 Skin Mode Temperature Setting

WARNING

- Because it is controlled by the infant parameters, the Skin Mode must be used as much as possible. It is recommended to frequently check the infant's condition and keep monitoring.
- The skin temperature of the infant, who is under the infant radiant warmer, must be monitored independently.
- Not to allow the baby to contact with a cold surface, provide the mattress to be warmed by operating the device in Prewarm mode.

NOTE

- If the infant's body skin temperature is below the adjusted temperature in the Skin Mode, the Low Skin Temperature Alarm gets activated for 15 minutes or until the infant's skin temperature increases to the adjusted temperature.
- When the Low Skin Temperature Alarm is silenced, the infant's skin temperature must be monitored independently.
- The heating period of 15 minutes provides the infant to be heated, safely and continuously, without unnecessary alarms.

HEATING PERIOD

The infant's weight, age, clinic condition and environmental conditions affect the period, which is necessary for reaching to the desired temperature**.**

6.4. USING PREWARM MODE

6.4.1. USING PREWARM MODE FOR 6" MONOCHROME SCREEN

In the Prewarm mode, the power of the heater is adjusted to operate at a stable value of 25 %. The Prewarm mode does not make adjustments, according to the body temperature of the newborn. It works to provide Prewarm, in order not to allow the newborn from contacting with the cold mattress surface. After the radiant warmer is operated in the Prewarm mode to provide the necessary surface heating, the newborn must be put onto the mattress and either the manual mode or the Skin Mode must be selected.

6.4.2. USING PREWARM MODE FOR 7" COLORED TOUCH SCREEN

The device operates in Prewarming mode when it is first turned on. If the user wants to switch from manual mode or skin mode to Prewarm Mode, select the prewarm mode by pressing the manual or servo button at the top left.

In the Prewarm mode, the power of the heater is set to operate at a constant value of 25%. Prewarm mode does not adjust according to the body temperature of the newborn. It works to provide pre-heating so that the newborn does not come into contact with the cold mattress surface. After the open mattress with radiant heater operating in the Prewarming mode has run for the time to provide the required surface heating, the newborn should be put to mattress and manual mode or skin mode should be selected.

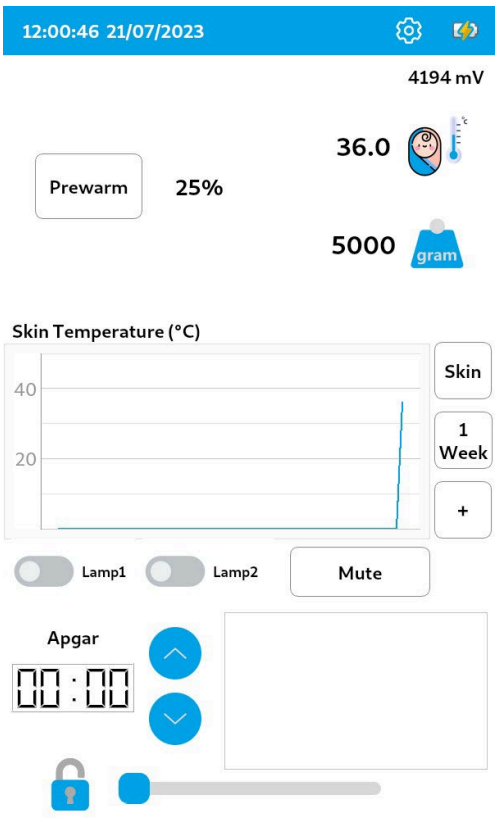


Figure.7 Prewarm Mode

6.5. USING TIMER

6.5.1. ADJUSTMENT OF TIMERS FOR 6" MONOCHROME SCREEN

The timer provides the timing of the treatment period and gives an audible warning after the completion of the preset period. At the first minute and then at each five minutes, it gives an audible alarm to warn the user. After the completion of the timer's set period, an audible alarm is given by the system for a long time. The timer can be adjusted with 5 minutes intervals for a period of time, between 5 – 90 minutes.

Setting Timer

Go to the timer setting buttons by using function change button, to change the functions.

Adjust the desired treatment period for the selected procedure by using the Timer setting function button, in the upper right part of the screen.

Press the Timer start function button to start the treatment period.

Use the Timer pause function button to pause the timer, and use the Timer start function button, to make the timer continue. Use the Timer cancellation function button, to cancel the timer.

Timer Memory

When the timer is paused and restarted with the Pause function button, the adjusted treatment period continuous from where it was paused.

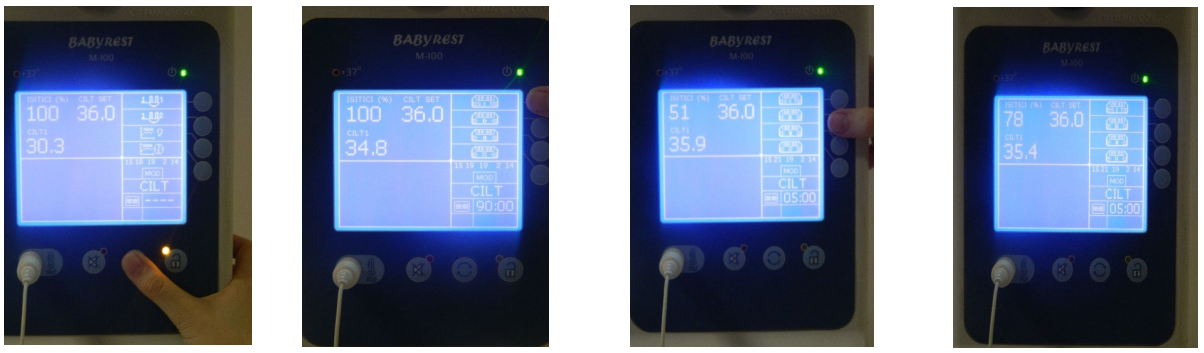


Figure 8. Timer Setting

Completion of the Timer

When the treatment period is completed, it gives an audible alarm to warn the user, at the first one minute and at each five minutes.

WARNING: Check the therapy period with regular intervals.

6.5.2. ADJUSTMENT OF THE TIMERS FOR 7" COLORED SCREEN

Timer provides timing the treatment timer and give audible warning once it is completed. It can be adjusted between 0-90 minutes by 5-minute sensitivity. It's at the bottom left of the screen.

Setting Timer

The timer is active in all modes. The treatment time is adjusted by using the value increase and value decrease keys. When the desired treatment time is set and the Timer start button is pressed, the determined time decreases until 00:00. Use the timer pause function key to pause the timer while it is present, and the timer start function key to continue from where it left off.

Completion of the Timer

The device has a timer, as shown in Figure 9, to help the relevant officer extract the Apgar score. It can be adjusted up to 90 minutes at December intervals of 5 minutes with the help of buttons. After the adjustment process is completed, it can be controlled by the play, pause and stop buttons activated on the lower side. With the help of the buzzer, it gives an audible warning every first minute, fifth minute and tenth minute.

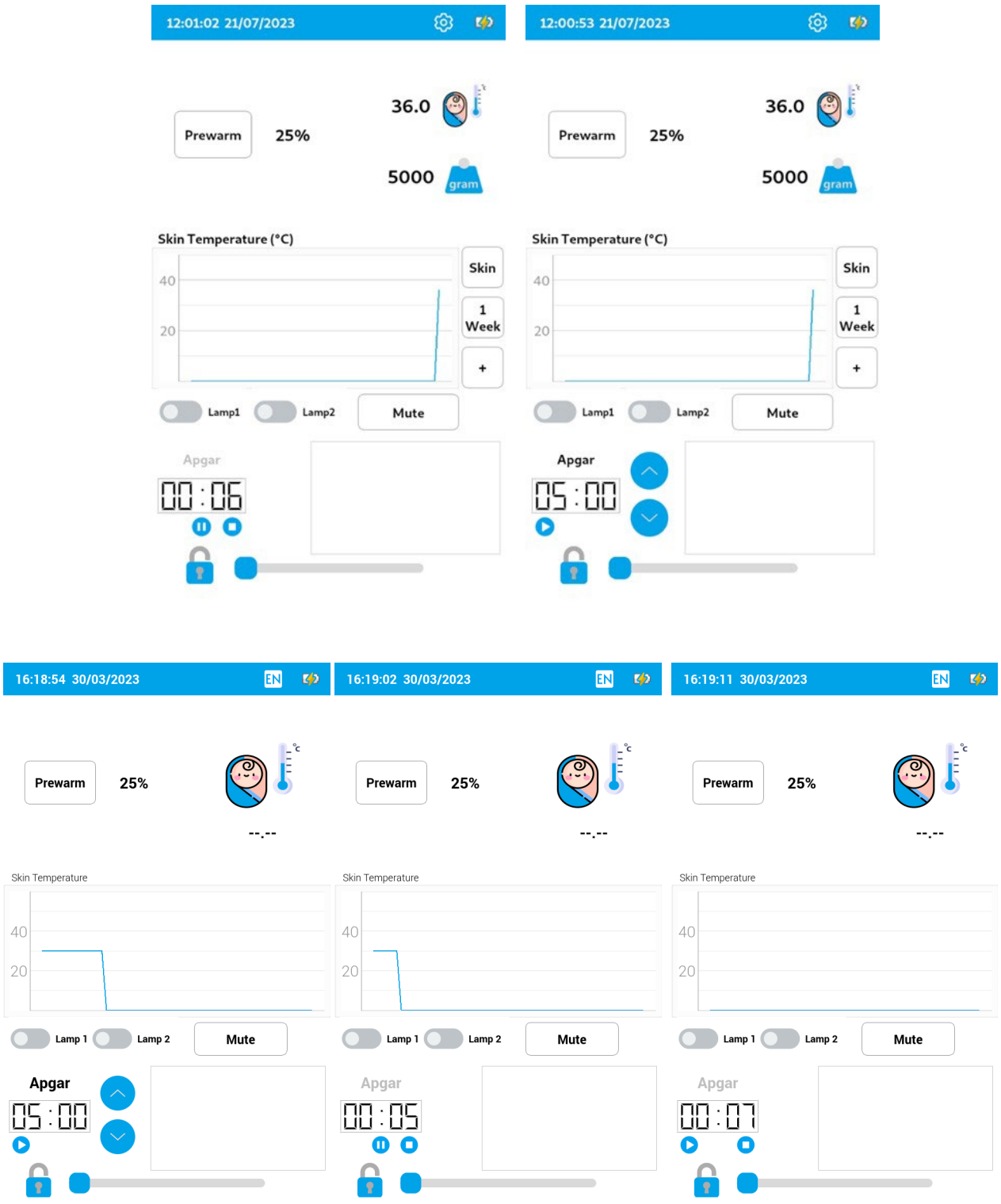


Figure.9 Timer Control

6.6. 7" COLORED TOUCH SCREEN APGAR TIMER

Apgar timer is active in all modes. The process of Apgar timer starts once you push the Apgar timer button shown in Figure 15. It gives audible alarm in every 1,5,10 minutes after you start timer. Apgar timer warning can be silenced in 10 minutes. Can be turned off by pushing Apgar timer shown in Figure 9.

Figure.10 Apgar Timer

6.7. USING EXAMINATION LAMPS

6.7.1. USING EXAMINATION LAMPS FOR 6" MONOCHROME SCREEN

The device has two units of examination lamps, one of which is on the front panel and the other one is on the warmer. To turn on the examination lamp on the front panel, press the function button 1. Press the same function button again to turn off the lamp.

To turn on the examination lamp on the heater, press the function button 2. To turn off the lamp, press the same function button, again.

NOTE:
When the device is turned on for the first time, both examination lamps turn on and off for the control purposes.

Figure 11. Use of the Examination Lamps

6.7.2. USING EXAMINATION LAMP FOR 7" COLORED TOUCH SCREEN

The device has two units of examination lamps, one of which is on the front panel and the other one is on the warmer.

To turn on the examination lamp on the heater, press the function button 1. To turn off the lamp, press the same function button, again.

To turn on the examination lamp on the front panel, press the function button 2. Press the same function button again to turn off the lamp.

NOTE:

When the device is turned on for the first time, both examination lamps turn on and off for the control purposes.

Figure 12. Use of the Examination Lamps

AC 220V 5W examination lamps driven by solid state relays are controlled with lamp1 and lamp2 buttons as shown in Figure 4'.

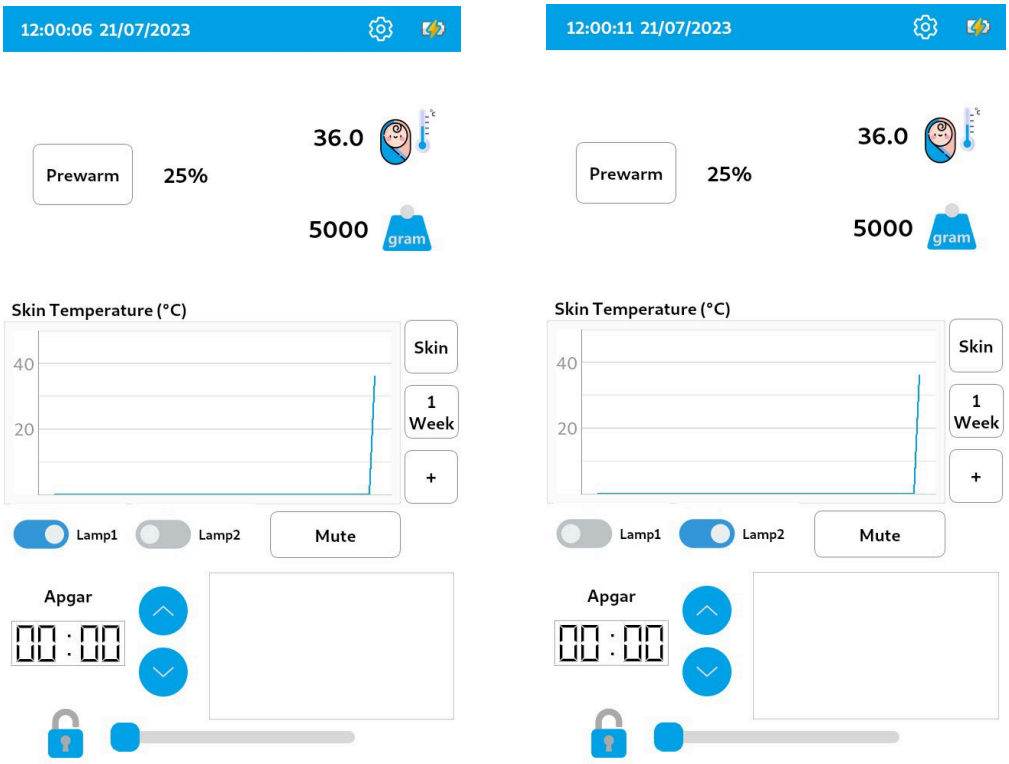


Figure.13 Lamp Control

6.8. KEY LOCK

In order to protect the system from accidental interventions, the key lock mechanism has been developed as shown in Figure 14. The scroll bar located at the bottom of the interface can be moved to the right to put the components into passive mode, and by sliding to the left to put them into active mode.

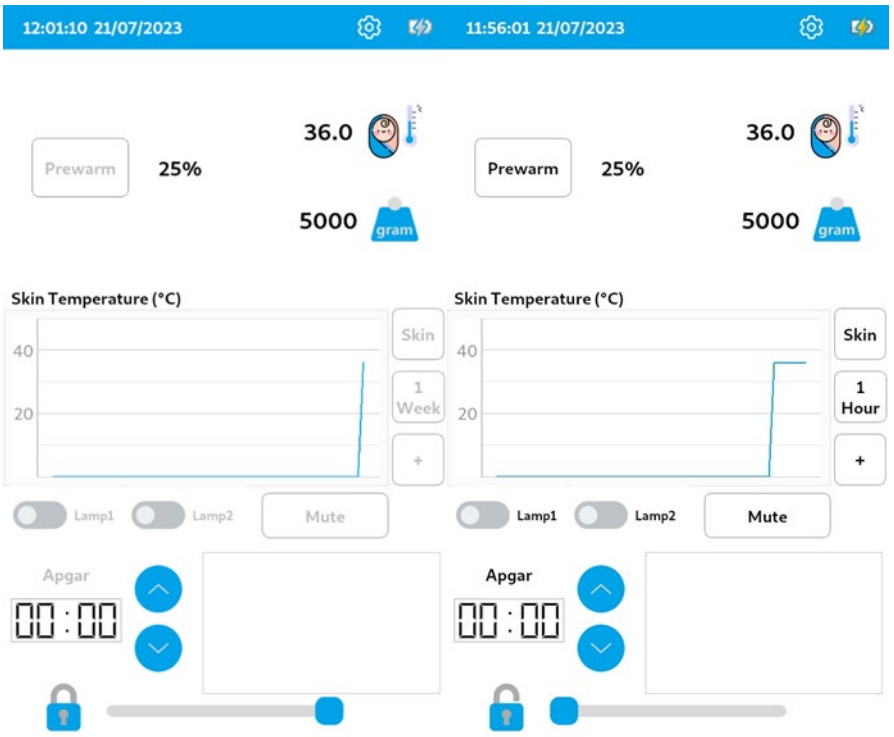


Figure 14. Key Lock

6.9. DATE –TIME SETTING

By switching to the “Setting” screen shown in Figure 15 with the help of the date-time button located in the upper left corner, the parameters of the real-time clock integration connected to the device can be adjusted. In case of possible incorrect date-time entry, the” Failed“ message will be displayed on the screen, and ”Successful" messages will be displayed when entering successful date-time values. The unique serial number used in the tracking of the device is also available on this screen.

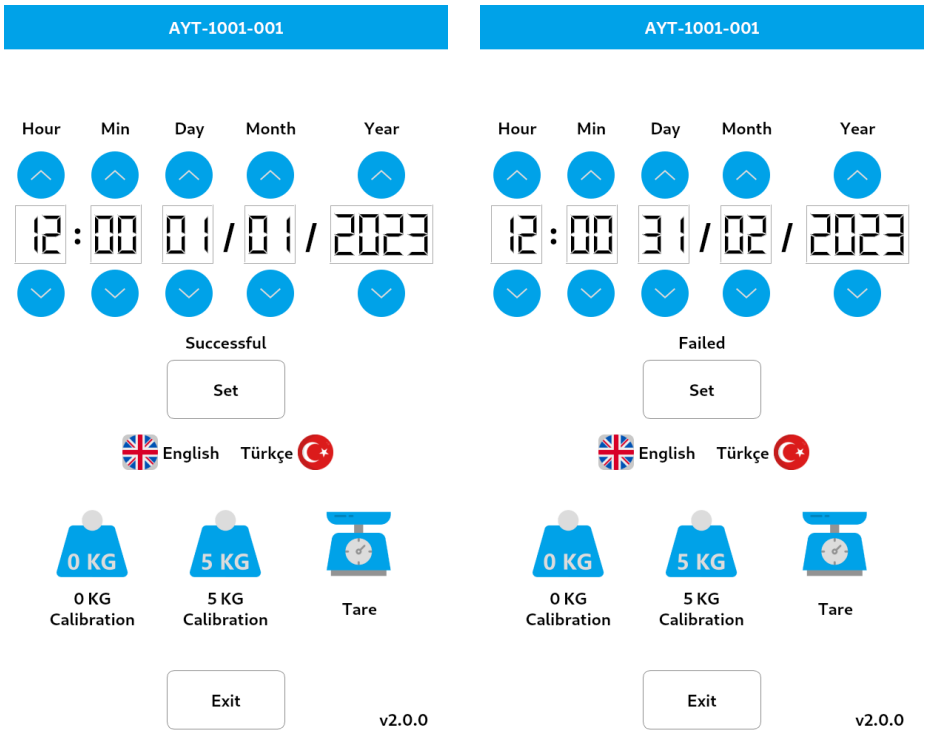


Figure 15. Setting Screen

6.10. LANGUAGE OPTION

The device has two language options, English and Turkish. As shown in Figure 16, you can switch between language options with the help of the “EN” - “TR” button. The device stores the last selected language in its memory and starts from the last selected language when it is turned on again.

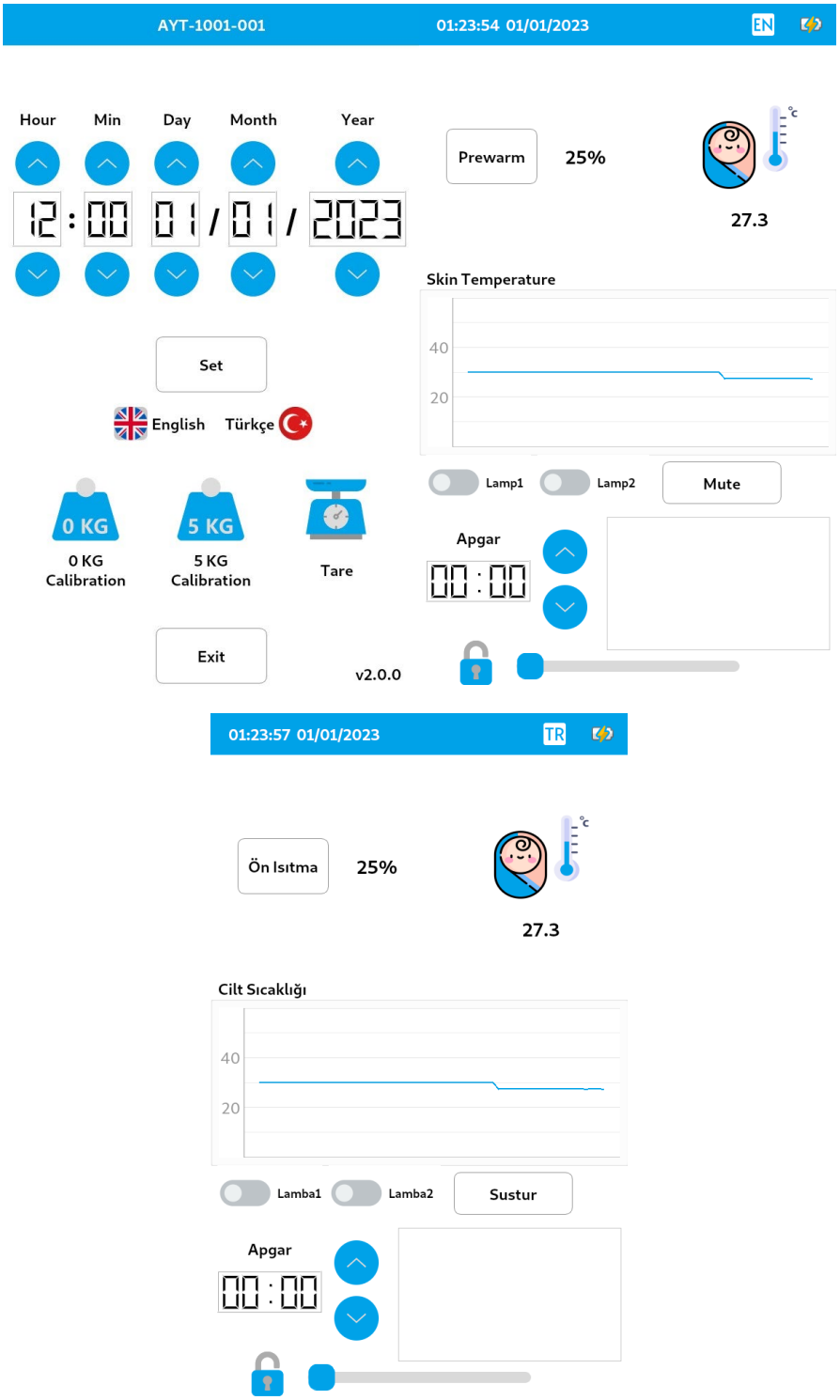


Figure 16. Language Options

6.11. SCALE

The device can measure up to 10 kilograms. Scale symbol is shown in figure 17 in the upper right part of the screen. In addition, calibration should be done so that the scale can measure more accurately. As can be seen in Figure 18, 0 and 5 kg calibrations are performed. After the calibration is completed, a pass/fail statement is seen at the bottom of the 0 and 5 kg screen.

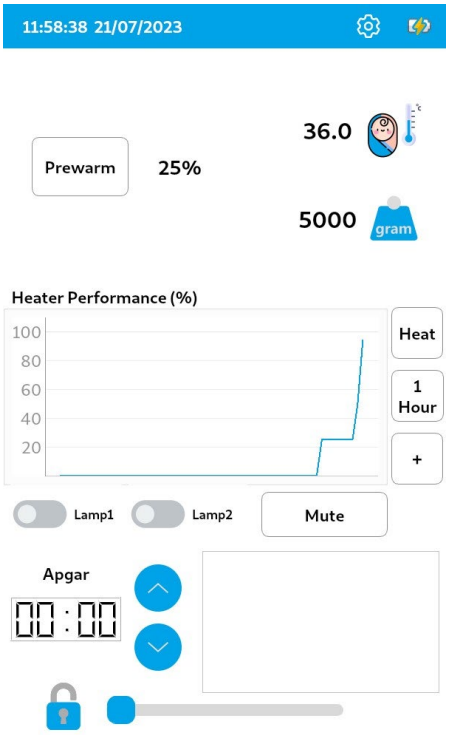


Figure 17. Scale Screen

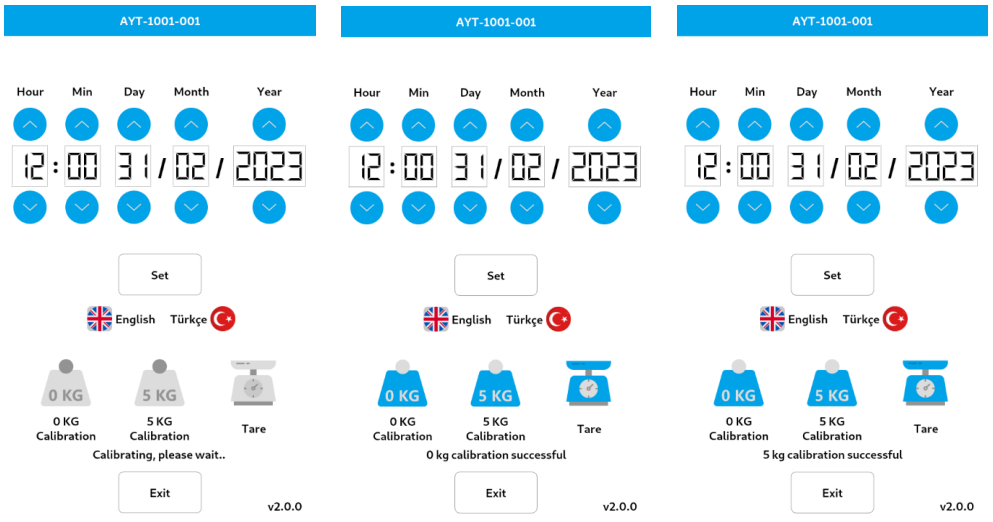


Figure 18. Calibration Screen

6.12. USING TRENDELENBURG

The mattress can be adjusted between -8, 5° and +14° to provide the Trendelenburg and Fowler types of positions.

To give an inclination to the mattress, grab and squeeze the lock mechanism, located in the right front of the cradle, and adjust the desired inclination. When the desired inclination is provided, release the arm.

Figure 19. Trendelenburg

6.13. TRANSPORTATION OF BED

Before moving the bed, ensure that the side panels of the bed are closed and the wheels are not locked. After the transportation process is completed, lock the wheels.

Figure 20. Locked or unlocked positions of the wheel locks

WARNINGS

- A transportation process must not be done while an infant is inside.
- A transportation process must be performed with the carriage arms, located in the front of the bed. A heater head or bed barriers must not be used for transportation.
- The heater head must be held in the transportation process.

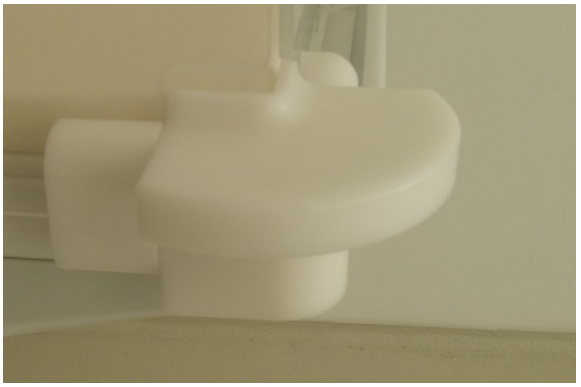


Figure 21. Carriage Arms

6.14. USING SIDE PANELS

Opening Side Panels:

- In order to open side panels pull the requested panel slightly and pull toward yourself

Closing Side Panels:

- Hold and move slightly the selected side panel.
- Make sure you hear the click voice when you place the panel in their socket and make sure that its not moving downwards.

Removing the Side Panels:

- In order to remove side panels hold and pull it slightly pull toward yourself once it's in parallel position to the mattress.

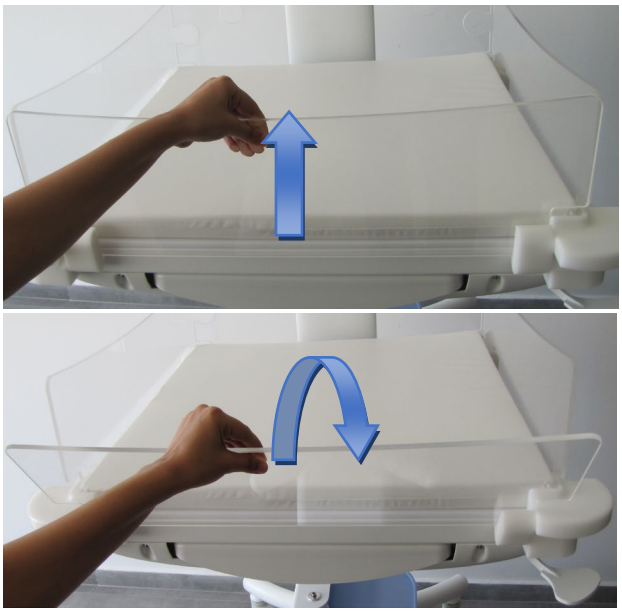


Figure 22. Opening the Side Panel

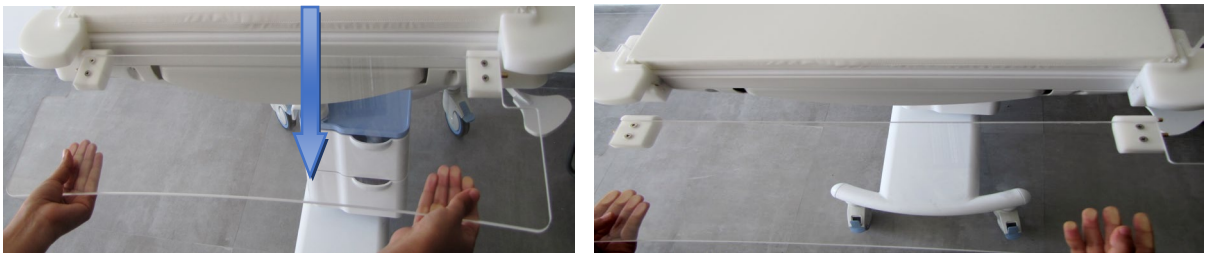


Figure.23 Removing the Side Panel

6.15. GROMMETS

The grommets, located in the front and back panels, are designed to hold the cables and hoses up to the diameter size of 34 mm and to reduce the cable crowd around the infant.

NOTE: The grommets can be removed for the cleaning purposes.

Use of the grommets, does not limit the capability of decreasing the back and front panels' height, but it is necessary to be careful about the points, connected to the infant, while the panels are moved down. Moving the panel down can drag the hose or cables. Such dragging may cause the infant's skin to be irritated.

Figure 24. Grommet

WARNINGS

- It is necessary to be careful about the points, connected to the infant, while the panels are moved down. Moving the panel down can drag the hose or cables. Such dragging may cause the infant's skin to be irritated.

6.16. USING INFANT BED

The maximum load that the bed can carry is 10 kg.

WARNINGS

- Before carrying the bed, ensure that it is flat and the side panels are locked. Use the carriage arm.
- Changing the position of the bed from flat to inclined position can affect the performance of the heater by changing the distribution of the heat in the bed mattress.
- Before and after changing the position of the bed to the inclined position, check all the hoses and cables. Inclining or moving the heater bed can drag the hose or cables. Such dragging can cause the infant's skin to be irritated or the hose or cables to be removed from their sockets.
- While the side panels are folded down wards, the infant must not be left alone in the bed.
- It is necessary to cover the mattress with a flannel tissue before laying the bed on it.

6.17. X-RAY TRAY MODULE

The X-Ray Tray is used to correctly place the X-Ray film into the tray, which is located under the cradle, without moving the infant. To make the X-Ray easier, the heater head can be turned to left or right.

USING X-RAY TRAY

- Pull out the X-Ray tray, located in front of the mattress.
- Place the X-Ray cassette by using the reference label, with squares, which is located in the sides of the panel.
- Place the cassette drawer under the mattress by pushing it. Turn the heater head to left or right for the X-Ray process.

Figure 25. Use of X-Ray Tray

WARNING: Never put the infant on the X-Ray cassette tray.

6.18. AUXILIARY EQUIPMENT

WARNING: The total of maximum auxiliary equipment weight on the heater must not exceed the permitted maximum limit.

6.18.1. MONITOR TRAY

This auxiliary equipment provides a surface to place the devices such as monitors, syringe pump etc.
The manual stand is attached to the cradle by using a shelf support block.
Installation of the manual stand;
Slide the shelf support block directly into the installation socket and screw the locking button to the desired height of the manual stand.
Place the pin of the manual stand into the shelf support block.

Warning: Minimum weight load 5kg

Figure 26. Placing the Monitor Tray

6.18.2. IV POLE

IV Pole is attached to the cradle by using a shelf support block.
Installation of the IV Pole;
Slide the shelf support block directly into the installation socket and screw the locking button to the desired height of the manual stand.
Place the pin of the manual stand into the shelf support block.

Figure 27. Placing the IV Pole

6.19. OPTIONAL FEATURES

6.19.1. RESUSCITATION DEVICE

PURPOSE OF USE; T-Piece Infant Resuscitator Unit is an easy-to-use, gas-operated medical device that provides control and precise resuscitation of infants up to a maximum of 10 kg in hospital rooms, pediatric rooms and neonatal intensive care units.
The T-Piece Resuscitator device is designed to regulate, stabilize and mechanically provide postnatal respiration of the infant if necessary.

SYSTEM CONTROL; The T-piece gas release is not intended for use with self-inflating or flow control manual resuscitators.
Before use, adjust Flow, PIP and PEEP parameters to check circuit integrity.
Always check that the T-piece is clean and unobstructed before patient use.
The use of peak inspiratory pressure (PIP) and positive end expiratory pressure (PEEP) may pose a hazard. Always use the airway pressure manometer to verify PIP and PEEP.

6.19.2. PULSE OXIMETER

Use pulse oximeter when administering oxygen.
Oxygen concentration should be verified with an independent oxygen analyzer.

PURPOSE OF USE; The Oxygen/Air Mixer device is a self-contained gas mixing device that provides automatic adjustment of the concentration and flow rate of gases from air and oxygen sources and delivery to the patient.
This device homogenizes an air/oxygen gas for neonatal, pediatric and adult patients and provides intermittent or continuous controlled flow. It can also be used to adjust the O2 concentration.

WORKING PRINCIPLE
In order for the Oxygen/Air Mixer to work, the gas connections (oxygen and air gases) must be realized by connecting to the central gas system or cylinders.
The gas supply enters the air and oxygen inlet connectors located on the bottom of the Oxygen/Air Mixer. Each inlet connector contains a particulate filter and check valves that prevent possible reverse gas flow.
The two gases then enter the two-stage pressure diaphragm housing module. In this module, the pressures of both gas sources are equalized. The pressure is equalized at low pressure. The diaphragm inside the module reacts to the difference in pressure, directing the movement of each set of check valves in the air and oxygen compartments.
Mixing gas is prepared according to the percentage of oxygen selected on the oxygen concentration dial. At this point, the two gases are mixed according to the percentage of oxygen selected on the oxygen concentration dial. Counterclockwise (21%) with the oxygen concentration dial, the double-ended valve will completely shut off the oxygen flow, allowing only air to flow. By setting the oxygen concentration dial fully clockwise (100%), the air flow is blocked and only oxygen flows through the outlet of the Oxygen/Air Mixer.
The flowmeters on the device help to set and monitor the amount of flow that can be delivered to the patient. When the flowmeter buttons are turned clockwise, the flowmeters are turned on. The amount of flow is adjusted with the buttons of this flowmeter. We can track how much flow we give

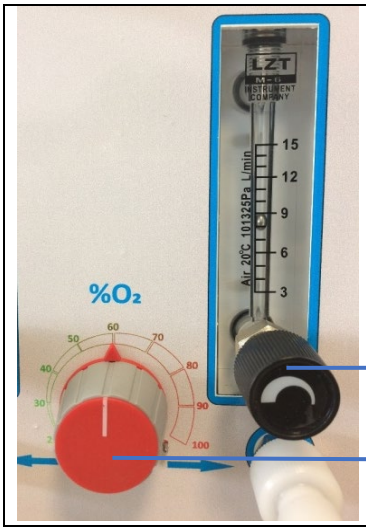
thanks to the notches on the flowmeter. The amount of mixture gas flow desired to go to the patient helps to set the desired value by fixing the measurement from the numbers on the flowmeters.

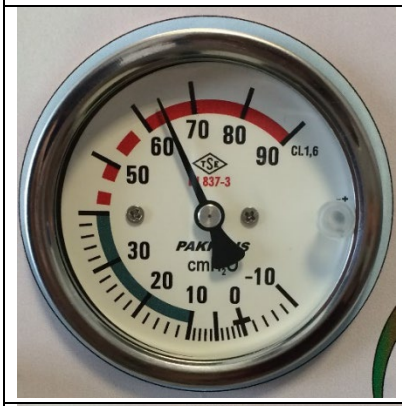
OPERATING THE DEVICE

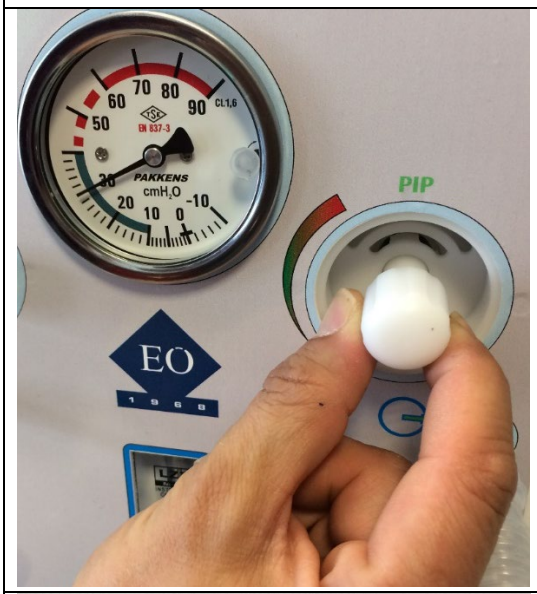
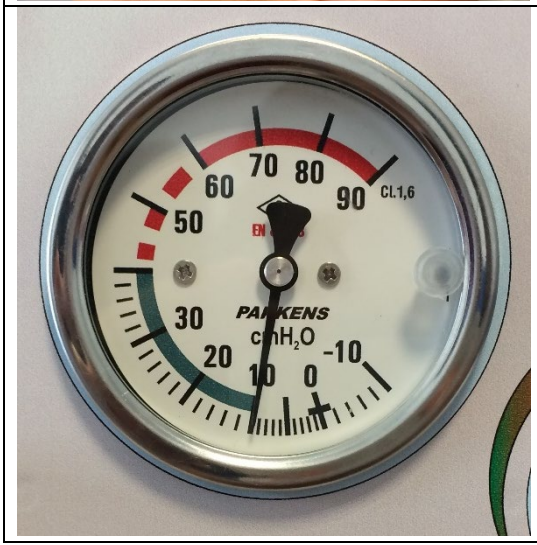
1. For the operation of the FM1000 Mix Oxygen/Air Mixer, the gas connections (oxygen and air) are connected to the central gas system or cylinders, according to their color code and to the appropriate NIST inlets. Different diameters of sockets are used for oxygen and air. This prevents incorrect installation of NIST inlets.
2. FM1000 Mix Oxygen/Air Mixer operates at equal gas pressures, if there is a difference in gases, the whistle under the device will start to sound.
3. The rotary knob on the FM1000 Mix Oxygen/Air Mixer adjusts the FiO2 ratio
4. The selection of the flowmeter on the device is determined according to the type of flow to be used.
5. Thanks to the rotary knob on the flowmeter, the flow rate to the patient is adjusted according to the patient type.
6. If there is no gas flow in the device, the display remains constant at 0.

Caution: When switching off the device, all gas flow must be cut off by means of the button on the device.

DEVICE OPERATION

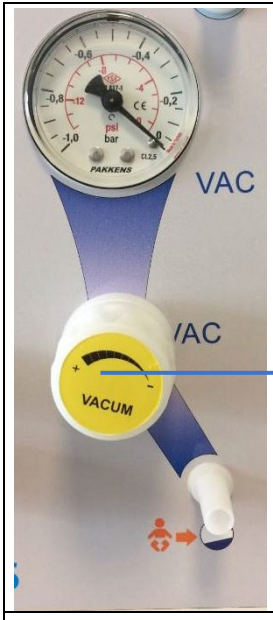
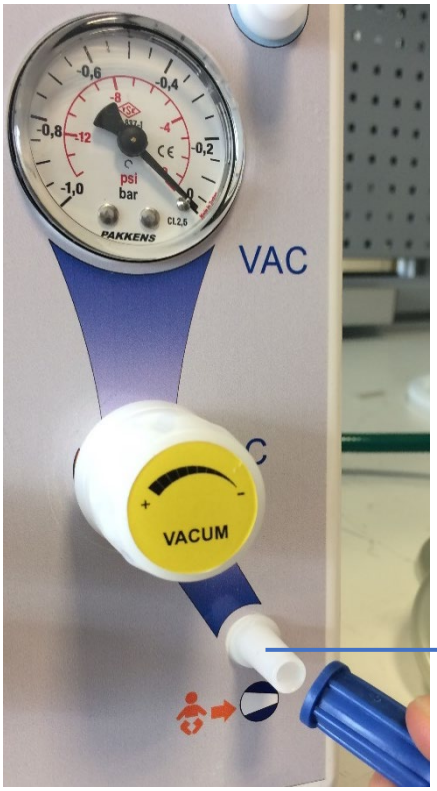
	The mixing ratio from the O_2/Air mixer unit is given to the flowmeters using the flowmeter adjustment knob. The flowmeter to the "T" piece resuscitation unit is set to 8 LPM.

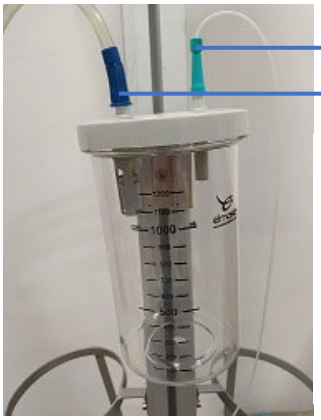
 "T" piece circuit output	It is connected to the resuscitation unit to the "T" piece circuit output section.
	The PEEP on the "T" piece is turned off. The hole on the top of the "T" piece is closed by taking it in the palm of the hand.
	The pressure in the system is monitored by the pressure gauge on the "T" piece resuscitation unit.
	Max. P Safety is slowly opened and the desired initial safety distance from the manometer is set.

 	The hole on the PEEP is opened and closed to ensure the accuracy of the initial safety. This process is repeated several times.
	After Max.P is set, PIP is slowly opened and the desired PIP setting is made.
	While the desired PIP setting is being made, the PIP value is verified by opening and closing the circuit with the "T" piece in the palm again. This process is repeated several times.

 	PEEP is adjusted by adjusting the cover on the "T" piece circuit. PEEP setting is monitored by manometer. PEEP setting can be adjusted between 1 and 9 cmH2O.

6.19.3. USING THE ASPIRATION SYSTEM

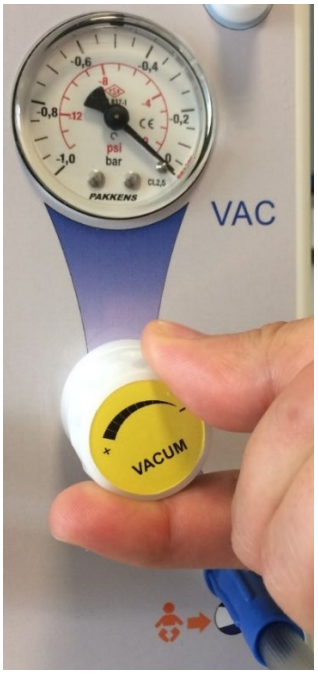
	Vacuum Adjustment Button	Close the adjustment button on the Suction (Vacuum) unit.
	Aspiration Container Connection Port	Connect the hose to the suction cup to the connection port on the Suction unit.

	There is a strap on the foot of the Tresus device to attach the Suction Cup. Attach the Suction Cup here.
 1. The part to be connected to the device (Aspiration Container Connection Port) 2.Patient Connection (Suction Catheter)	1. Attach the hose that will go to the Suction Cup that you connected to the Connection Port on the Suction unit to the port marked "VACUUM" on the Suction Cup. 2.Attach the suction catheter to the port labeled "PATIENT" on the Suction Cup.

WARNINGS

- If any liquid or foreign matter is drawn into the vacuum pump or the device during aspiration, stop using the device immediately and seek support from Ertunç Özcan Technical Service.

6.19.4. OPERATING THE SUCTION (VACUUM) UNIT

	The Suction (Vacuum) unit will not vacuum unless the adjustment knob on the unit is turned on.
	The Suction (Vacuum) unit can go up to -400mmHg. Suction (Vacuum) unit is supplied with air connected to the device. The desired vacuum setting is made by following the manometer on the Suction (Vacuum) unit. Vacuum is canceled by closing the adjustment button on the Suction (Vacuum) unit.

Note: The air pressure to the device must not be variable.

6.19.5. USING THE MINI LED PHOTOTHERAPY DEVICE SYSTEM

PURPOSE OF USE; Baby Led Force Mini Model Phototherapy Device is a mobile device designed to be used in the treatment of jaundice diseases of newborn babies, providing 400-500 nanometer light that can regulate billuribin by photooxidation.

PREPARING THE INFANT FOR THERAPY

- Place the baby in an incubator or open bed with radiant heating where the therapy will be performed.
- Close the baby's eyes before starting the treatment with an eye patch designed for phototherapy. Check that the baby's eyes are closed at regular intervals.
- The newborn to be treated with phototherapy should be naked except for diapers.
- The baby'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, body temperature should be monitored.
- Bilirubin level should be monitored at least every 12 hours.
- Products such as baby oil, cream, lotion should not be used in the care of the baby to prevent possible burns.
- Place the baby under the phototherapy device. There should be at least 40 cm distance between the baby and the device during the treatment. Over time, the baby's position may change as the baby moves. Check the baby's position at regular intervals.

6.19.6. USING THE SpO_2 SYSTEM

Pulse oximetry is a continuous, non-invasive measurement of the level of arterial oxygen saturation in the blood. The measurement is taken by placing a sensor on the patient, usually on the fingertip in adults and on the hand or foot in newborns. The sensor is connected to the pulse oximetry device via a patient cable. The sensor collects signal data from the patient and sends it to the device.

The principle used in SpO_2 pulse monitoring is to fix the tip of the probe to the patient's finger, use the finger as a transparent hemoglobin reservoir, measure the intensity of light transmission in the tissue bed using 660nm wavelength red light with a maximum output power of 300mw and 880nm near infrared light as stimuli, and calculate the hemoglobin and SpO_2 concentration from this data.

The device displays the calculated data in two ways:

1) as a percentage value of arterial oxygen saturation (SpO_2)

2) As pulse rate (PR)

6.19.7. USING THE ELECTRONIC TRENDELENBURG SYSTEM

The device has an electronic trendelenburg system as an optional feature. The system can provide inclination with an angle of ±12 degrees.

Trendelenburg system is controlled by two buttons on both sides of the body. The button below provides downward movement and the button above provides upward movement.

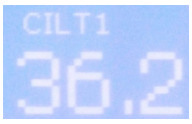
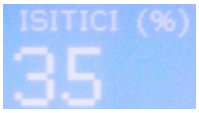
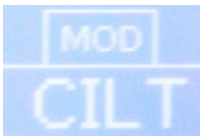
7. MENUS

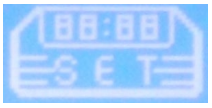
7.1. FUNCTION KEYS AND INDICATORS

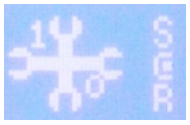
7.1.1. FUNCTION BUTTONS AND INDICATORS FOR 6" MONOCHROME SCREEN

Figure 28. Manual Mode

Figure 29. Skin Mode

Functions Key	Function
	**On/Off Button**: The heater begins to work automatically in its last based mode.
	**Silence**: When this button is pressed all of the audible alarms are silenced for 15 minutes (apart from high skin temperature which is 40°C and above).
	**Function Change**: These buttons provide change between menu screens.
	**Button Lock**: While the device is operating, when there is not any activity on the control panel for 15 seconds, the button lock is activated and the same button must be pressed again to lock the buttons.
	**Skin Probe Socket Input**: It is the socket, where the skin probe is connected in the front panel.
	**Infant Skin Temperature Indicator**: In the Skin Mode or Manual Mode, when a skin probe is placed and it is connected to the baby, it monitors the infant's skin temperature.
	**Adjusted Skin Temperature Indicator:** It monitors the currently adjusted temperature in the infant mode. The adjustable skin temperature range is between 30 °C and 38 °C.
	**Heating Power Indicator:** It monitors the current power level between 0 % and 100 % with 5 % differences.
	Mode: It is the menu that changes the device's operation mode.
	**Prewarm Mode:** It is the mode which is automatically opened when the device is turned on. To provide that the heating source and mattress are heated without any problem, the power level is adjusted to be 25 % in advance. It is not possible to change this value by the user.
	**Skin Mode:** When the mode button is pressed on the screen, the Skin Mode is chosen. To reach to the desired adjusted skin temperature, the heating power level is controlled automatically in accordance with the infant's skin temperature.
	**Manual Mode:** When the mode button is pressed on the screen. The heating power level can be adjusted to be between 0 % and 100 % with 5 % differences, by using the function button, to increase/decrease the heater's power.
	Exceed Mode: If the heat is 37ºC and the function button of this symbol is pressed, the device switches to the exceed mode. The red indicator light gets activated to indicate that the device was switched to the exceed mode.

	**Examination Lamp 1:** When the specified part is pressed on the screen, the lamp on the control panel is turned on and off.
	**Examination Lamp 2:** When the specified part is pressed on the screen, the lamp on the control panel is turned on and off.
	**Increasing the Heating Power**: When the related function button is pressed, the heating power is increased by 5 %.
	Decreasing the Heating Power: When the related function button is pressed, the heating power is decreased by 5 %.
	**Increasing the Temperature Set Value:** When the related function button is pressed, the skin temperature value is increased 0,1 ºC in the Skin Mode.
	**Decreasing the Temperature Set Value**: When the related function button is pressed, the skin temperature value is decreased 0,1 ºC in the Skin Mode.
	**Changing the Trend:** If the system is not in the trend indication mode, it switches into this mode. In the trend indication mode, this button changes the trend parameter. In the trend indication mode, if the function button of this symbol is pressed, while it is in one of the parameters, the Skin Temperature graphic is displayed as the parameter. Trend Indication Mode – Parameter List 1) Skin Temperature (2, 4, 8, 12, 24, 48, 72 hours, 1 week) 2) Heating Power (2, 4, 8, 12, 24, 48, 72 hours, 1 week)
	**Trend Hour Interval Setting:** If the device is in the trend indication mode, this button changes the trend hour interval of the parameter. When it is in the trend indication mode, if this button is pressed for 3 seconds, the time interval is automatically adjusted to 2 hours.
	**Timer Setting**: It is the menu which sets the period, in which the timer is going to operate, with 5 minutes of intervals, within the range of 5 minutes to 90 minutes.
	**Timer Start:** It is the menu to start the timer. When it is pressed shortly, it starts the timer by counting forward, and when it is pressed long, it starts it by counting backward.
	**Timer Stop**: It is the menu, in which the timer is paused at its current moment or continued from where it was stopped.
	**Timer Reset:** It is the menu, which resets the timer.
	**Clock-Date Setting:** When the related function button is pressed, the clock and date are set.

	**User Language Selection:** By pressing the related function button, the language of use is changed from English to Turkish.
	**User Language Selection:** By pressing the related function button, the language of use is changed from Turkish to English.
	**Service**: The related function button is used to enter the service menu with a password. In the service menu, the serial number and the software version information of the device are found.
	**Decrease**: It is the symbol, which is displayed when the clock-date setting and service password menu are entered. By pressing the function button that is belonged to this symbol, it is provided that the numerical values are decreased in the mentioned menus.
	**Increase**: It is the symbol, which is displayed when the clock-date setting and service password menu are entered. By pressing the function button that is belonged to this symbol, it is provided that the numerical values are increased in the mentioned menus.
	**Switch:** It is the symbol, which is displayed when the clock-date setting and service password menu are entered. By pressing the function button that is belonged to this symbol, it is provided that the numerical values are changed in the mentioned menus.
	**Confirm:** It is the symbol, which is displayed when the clock-date setting and service password menu are entered. By pressing the function button that is belonged to this symbol, it is provided that the numerical values are confirmed in the mentioned menus.

7.1.2. FUNCTION BUTTONS AND INDICATORS FOR 7" COLORED TOUCH SCREEN

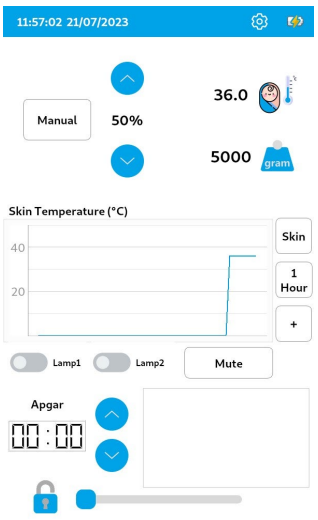


Figure 30. Manuel Mode

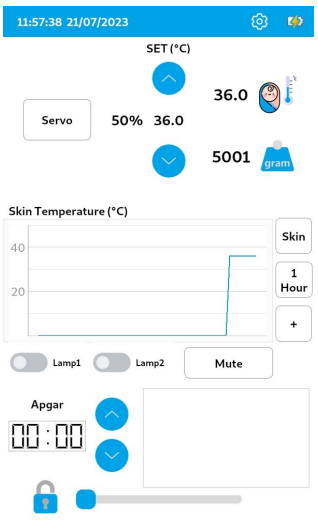


Figure 31. Skin Mode

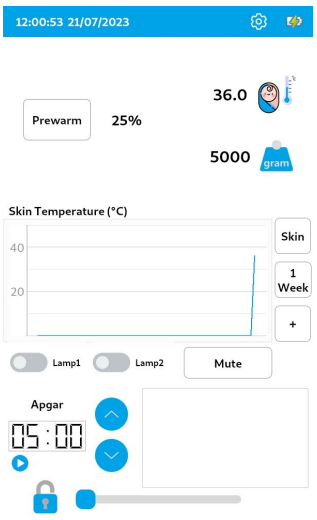


Figure 32. Prewarm Mode

WARNING: Do not use the device when the function buttons do not work. Turn off the device from the on/off button. Unplug the power cable from the outlet. Contact with an Ertunç Özcan technical service.

8. ALARMS

In the following part, the alarm systems, potential reasons and recommended processes are described.

8.1. 6" MONOCHROME SCREEN ALARM LIST

8.1.1. "CONTROL THE INFANT" ALARM

"Control the Infant" is activated when the infant's skin temperature falls below 30°C in all of the modes (skin, manual Prewarm modes).
With the silence button, the audible alarm can be silenced, if the infant's body temperature does not increase above 30°C, at the end of 15 minutes, the alarm is again activated audibly and visually.

WARNING: If the alarm is silenced when the infant's skin temperature drops below 30°C, the infant skin temperature is independently monitored under the radiant warmer.

The necessary controls;

- It must be checked that the skin probe is correctly placed on the infant's skin.
- A skin probe can be malfunctioning, change the skin probe, if the alarm does not match with the independently measured body temperature.

8.1.2. "HIGH SKIN TEMPERATURE" ALARM

In the Skin Mode

"High skin temperature" alarm is activated in the Skin Mode, when the difference between the skin temperature and the adjusted skin temperature is 1°C, while the infant's skin temperature is stable.
The device provides a visual and audible alarm by blinking the red indicator light.
The heating power source gets disabled.
With the silence button, the audible alarm can be silenced, if the difference drops below 1°C, the visual alarm disappears from the screen.
The necessary controls;

- It must be checked that the skin probe is correctly placed on the infant's skin.
- A skin probe can be malfunctioning, change the skin probe, if the alarm does not match with the independently measured body temperature.

WARNING: The skin temperature of the infant must be monitored independently.

In the Manual and Prewarm Modes

"High Skin Temperature" alarm is activated when the measured skin temperature is above 40 °C, in the Manual and Prewarm modes.
The device provides a visual and audible alarm by blinking the red indicator light.
The audible alarm cannot be silenced by pressing the silence button.
The necessary controls;

- It must be checked that the skin probe is correctly placed on the infant's skin.
- A skin probe can be malfunctioning, change the skin probe, if the alarm does not match with the independently measured body temperature.

WARNING: The infant's skin temperature must be monitored independently.

8.1.3. "LOW SKIN TEMPERATURE" ALARM

Skin Mode

"Low Skin Temperature" alarm is activated in the Skin Mode, when the difference between the skin temperature and the adjusted skin temperature is 1°C, while the infant's skin temperature is stable.

The device provides a visual and audible alarm by blinking the red indicator light.

With the silence button, the audible alarm can be silenced, if the difference drops below 1°C, the visual alarm disappears from the screen.

WARNING: This alarm is inactive in the Prewarm or Manual Mode.

The necessary controls;

- It must be checked that the skin probe is correctly placed on the infant's skin.
- A skin probe can be malfunctioning, change the skin probe, if the alarm does not match with the independently measured body temperature.

WARNING: The infant's skin temperature must be monitored independently.

8.1.4. "MANUAL MODE REMINDER" ALARM

"Manual Mode Reminder" alarm is activated only in the manual mode, if the heating source's power level is above 30 % for more than 15 minutes.

The device provides a visual and audible alarm by blinking the red indicator light and decreases the heating power below the level of 30 %.

The audible alarm can be silenced with the silence button, so the red indicator light turns off and the audible alarm is stopped.

The power of the heating power must be active and the user must adjust it to the desired level, above 30 %.

This alarm is not active in the Prewarm or Skin modes.

8.1.5. "NO SKIN PROBE" WARNING

Skin Mode

"No Skin Probe" alarm is activated in the skin mode when the skin probe is removed or never connected.

The device provides a visual and audible alarm by blinking the red indicator light and the heater source is disabled.

The audible alarm can be silenced with the silence button, this warning occurs in the screen until the skin probe is connected or changed, if it is malfunctioning.

This alarm is not active in the Prewarm or Manual modes.
The necessary controls;

- It must be checked that the skin probe is correctly placed on the infant's skin.
- The skin probe can be malfunctioning, change the skin probe and have the probe, which is thought to be malfunctioning, checked.

8.1.6. SKIN PROB FAULT WARNING

In All Modes
"Malfunctioning Skin Probe" alarm is activated in the skin mode, when the skin probe short-circuits.
The device provides a visual and audible alarm by blinking the red indicator light and the heating source is disabled.
The audible alarm can be silenced with the silence button, this warning occurs in the screen until the skin probe is changed.

The necessary controls;

- It must be checked that the skin probe is correctly placed on the infant's skin.
- The skin probe can be malfunctioning, change the skin probe and have the probe, which is thought to be malfunctioning, checked.

8.1.7. "LOW BATTERY" WARNING

In All Modes
"Low Battery" alarm is activated in all of the modes, when the external power input is failed or the battery level drops below 25 % when the device is operated with a battery.
The device provides a visual and audible alarm by blinking a red indicator light, and the heating source is disabled.
The audible alarm can be silenced with the silence button, but until the external power failure is solved, this warning occurs in the screen.
The necessary controls;

- The user must check the battery charge status before starting the device.
- Battery charge may be dead, place a new battery by checking it.

8.1.8. "POWER FAILURE" WARNING

In All Modes
"Power failure" alarm is activated in all of the modes, when the device's external power input fails.
The device provides a visual and audible alarm by blinking the red indicator light and the heating source is disabled.
The audible alarm cannot be silenced with the silence button, and until the external power failure is solved, this warning occurs in the screen.
The integrated battery is enabled to be able to read the indicators, in an external power failure. The heater is not active.
The audible alarm cannot be silenced with the silence button, when the external power is enabled, the warning disappears.

The necessary controls;

- The heater may have mistakenly removed from the outlet. Check that the cable is connected to the outlet.

8.1.9. RESUSCITATION DEVICE ALARM

In case of oxygen cut-off, air cut-off or inequality of oxygen/air pressure (in cases such as gas leakage), a difference in oxygen/air pressure occurs. In this case, a mechanical whistle is activated as a warning system.

In the flowmeter, there is a difference in oxygen/air pressure in case of oxygen interruption, air interruption or inequality of oxygen/air pressure. In this case, a mechanical whistle is activated as a warning system.

8.1.10. MASIMO ALARMS

The device has SpO_2 module as an optional feature. Depending on the module, the device has the following options.

LOW BPM VALUE	When the BPM value falls below the set value, a written and audible alarm sounds.
HIGH BPM VALUE	When the BPM value exceeds the set value, it gives a written and audible alarm.
LOW SpO_2 RATIO	When the SpO_2 value falls below the setpoint, a written and audible alarm sounds.
HIGH SpO_2 RATIO	When the SpO_2 value exceeds the set value, it gives a written and audible alarm.
MasimoSET: EXPIRED CABLE	When the cable expires, a written and audible alarm sounds. This alarm cannot be silenced.
MasimoSET: INAPPROPRIATE CABLE	When an unsuitable cable is used, it gives a written and audible alarm. This alarm cannot be silenced.
MasimoSET: UNIDENTIFIED CABLE	When an unidentified cable is used, a written and audible alarm sounds. This alarm cannot be silenced.
MasimoSET: FAULTED CABLE	When a faulty cable is used, a written and audible alarm sounds. This alarm cannot be silenced.
MasimoSET: EXPIRED SENSOR	When the sensor expires, it gives a written and audible alarm. This alarm cannot be silenced.
MasimoSET: INAPPROPRIATE SENSOR	When an inappropriate sensor is used, it gives a written and audible alarm. This alarm cannot be silenced.
MasimoSET: UNIDENTIFIED SENSOR	When an unidentified sensor is used, a written and audible alarm sounds. This alarm cannot be silenced.
MasimoSET: FAULTED SENSOR	When a faulty sensor is used, a written and audible alarm sounds. This alarm cannot be silenced.

MasimoSET: INTERFERENCE DETECTED	Gives a written and audible alarm when interference is detected.
MasimoSET: LOW PERFUSION INDEX	Sounds a written and audible alarm when the perfusion index is low.
MasimoSET: RUNNING IN DEMO MODE	Sounds a text and audible alarm only once when a demo or test sensor is connected.
MasimoSET: CHECK SENSOR CONNECTION	Sounds a text and audible alarm when the sensor connection is not correct. This alarm cannot be silenced.
MasimoSET: SpO_2 ONLY MODE	When rainbow parameters cannot be calculated with the rainbow sensor, a written and audible alarm sounds.
MasimoSET: ELECTRONIC FAULT-X	There are many error codes. It gives a written and audible alarm in case of card failure. This alarm cannot be silenced.

WARNING: Because the heater is disabled in a power failure, put the baby on an alternative heating source, if necessary.

Alarm and Warning	Operation Mode	Reason	Silence Button
Check the Infant	Skin	The measured skin temperature's being below 30 °C	Cancels the audible button and reset the heating
High Skin Temperature	Skin	The measured skin temperature is 1°C above the adjusted	Cancels the audible button and reset the heating
	Skin	When the measured skin temperature is above 40 °C	Turns off the device
	Manual	When the measured skin temperature is above 40 °C	Turns off the device
	Prewarm	When the measured skin temperature is above 40 °C	Turns off the device
Low Skin Temperature	Skin	The measured skin temperature is 1°C below the adjusted	Cancels the audible button and reset the heating
	Manual	Inactive	Inactive
	Prewarm	Inactive	Inactive
No Skin Probe	Skin	Skin probe is not connected	Turns off only the audible
	Manual	Inactive	Inactive
	Prewarm	Inactive	Inactive
Malfunctioning Skin Probe	Skin	Malfunction of the skin probe, short circuit	Turns off only the audible alarm
	Manual	Inactive	Inactive
	Prewarm	Inactive	Inactive
Low Battery	All	The device does not have a	No effect
Power Failure	All	Failure to feed power to the	Audible alarm cannot be
Manual Mode Reminder	Skin	Inactive	Inactive
	Manual	The heating source's power is above 30 % for more than 15	Cancels the audible button and reset the heating
	Prewarm	Inactive	Inactive

Tablo – 2 Alarm Table

8.2. 7" COLORED TOUCH SCREEN ALARM LIST

There is an area in Figure 33 where alarms are monitored to show possible risky situations and to warn the relevant personnel both audibly and visually. While critical alarms cannot be silenced, alarms that have low priority and will not cause serious problems can be silenced for 15 minutes with the help of the "Mute" button. When the alarm is silenced, the buzzer is deactivated and the text color changes from red to blue.
The list of alarms in the system is available in Table 3.

Table 3.

Alarm	Status	Can be muted
Critical Temperature	Skin Temperature ≥ 40 °C	No
High Temperature	(In Servo Mode) Skin Temperature ≥ Set Temperature +1	Yes
Low Temperature	(In Servo Mode) Skin Temperature ≤ Set Temperature -1	Yes
Skin Error	When the skin probe malfunctions	No
Skin Unplugged	(In Servo Mode) When the skin probe is removed	Yes
Power Fail	When the mains power is cut off	No
Low Battery	When the battery voltage drops below 3500 mV	No
Manual Mod	When it stays in manual mode for 15 minutes	Yes

8.2.1. “HIGH SKIN TEMPERATURE” ALARM

In Skin Mode

“High skin temperature” alarm is activated in the Skin Mode, when the difference between the skin temperature and the adjusted skin temperature is 1°C, while the infant’s skin temperature is stable.

The device provides a visual and audible alarm by blinking the red indicator light.

The heating power source gets disabled.

With the silence button, the audible alarm can be silenced, if the difference drops below 1°C, the visual alarm disappears from the screen.

The necessary controls;

It must be checked that the skin probe is correctly placed on the infant’s skin.

- It must be checked that the skin probe is correctly placed on the infant’s skin.
- A skin probe can be malfunctioning, change the skin probe, if the alarm does not match with the independently measured body temperature.

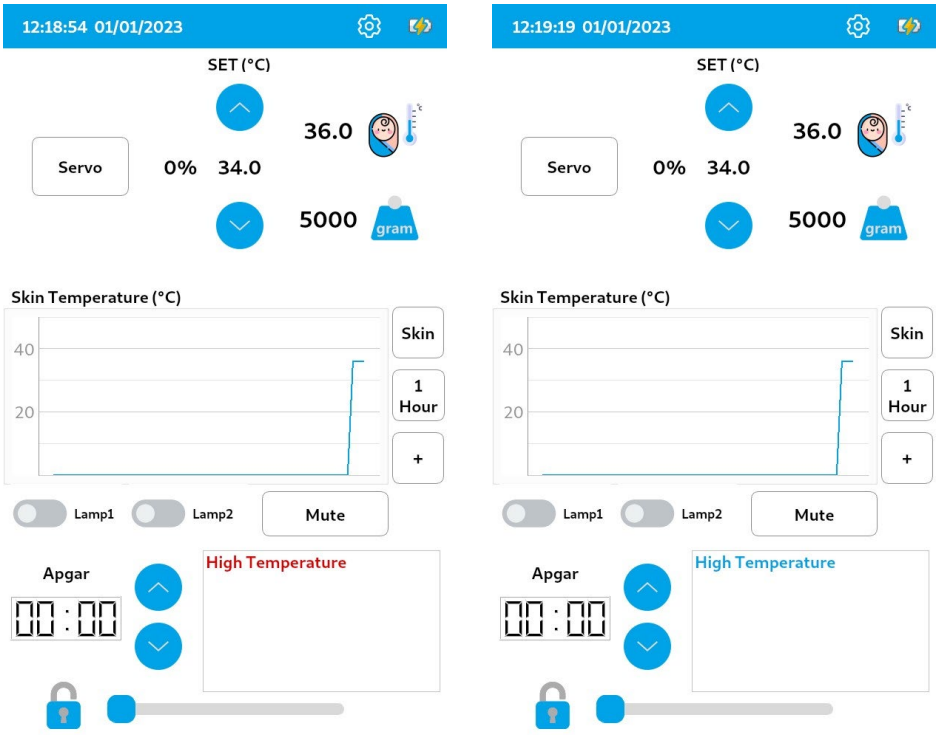


Figure 33. High Temperature Alarm

WARNING: The infant's skin temperature must be monitored independently.

8.2.2. "CRITICAL SKIN TEMPERATURE" ALARM

"Critical skin temperature" alarm is activated in the Skin Mode, when the difference between the skin temperature and the adjusted skin temperature is 2°C, while the infant's skin temperature is stable.

The device provides a visual and audible alarm by blinking the red indicator light.

The heating power source gets disabled.

With the silence button, the audible alarm can be silenced, if the difference drops below 1°C, the visual alarm disappears from the screen.

The necessary controls;

It must be checked that the skin probe is correctly placed on the infant's skin.

- It must be checked that the skin probe is correctly placed on the infant's skin.
- A skin probe can be malfunctioning, change the skin probe, if the alarm does not match with the independently measured body temperature.

WARNING: The infant's skin temperature must be monitored independently.

8.2.3. "LOW SKIN TEMPERATURE" ALARM

Skin Mode

"High skin temperature" alarm is activated in the Skin Mode, when the difference between the skin temperature and the adjusted skin temperature reaches to 1°C, while the infant's skin temperature is stable.

The device provides a visual and audible alarm by blinking the red indicator light.

With the silence button, the audible alarm can be silenced, if the difference drops below 1°C, the visual alarm disappears from the screen.

WARNING: This alarm is not active in Prewarm and Manual Modes.

The necessary controls;

It must be checked that the skin probe is correctly placed on the infant's skin.

- It must be checked that the skin probe is correctly placed on the infant's skin.
- A skin probe can be malfunctioning, change the skin probe, if the alarm does not match with the independently measured body temperature.

WARNING: The infant's skin temperature must be monitored independently.

8.2.4. "NO SKIN PROBE" WARNING

Skin Mode

"No Skin Probe" alarm is activated in the skin mode when the skin probe is removed or never connected.

The device provides a visual and audible alarm by blinking the red indicator light and the heater source is disabled.

The audible alarm can be silenced with the silence button, this warning occurs in the screen until the skin probe is connected or changed, if it is malfunctioning.

This alarm is not active in the Prewarm or Manual modes.

The necessary controls;

- It must be checked that the skin probe is correctly placed on the infant's skin.
- The skin probe can be malfunctioning, change the skin probe and have the probe, which is thought to be malfunctioning, checked.
-

8.2.5. "SKIN PROBE FAILURE" WARNING

All Modes

"Skin Probe Failure" alarm is activated in the skin mode when the skin probe short-circuits.

The device provides a visual and audible alarm by blinking the red indicator light and the heating source is disabled.

The audible alarm can be silenced with the silence button, this warning occurs in the screen until the skin probe is changed.

The necessary controls;

- It must be checked that the skin probe is correctly placed on the infant's skin.
- The skin probe can be malfunctioning, change the skin probe and have the probe, which is thought to be malfunctioning, checked.

8.2.6. "LOW BATTERY" WARNING

In All Modes

"Low Battery" alarm is activated in all of the modes, when the external power input is failed or the battery level drops below 25 % when the device is operated with a battery.

The device provides a visual and audible alarm by blinking a red indicator light, and the heating source is disabled.

The audible alarm can be silenced with the silence button, but until the external power failure is solved, this warning occurs in the screen.

The necessary controls;

- The user must check the battery charge status before starting the device.
- Battery charge may be dead, place a new battery by checking it.

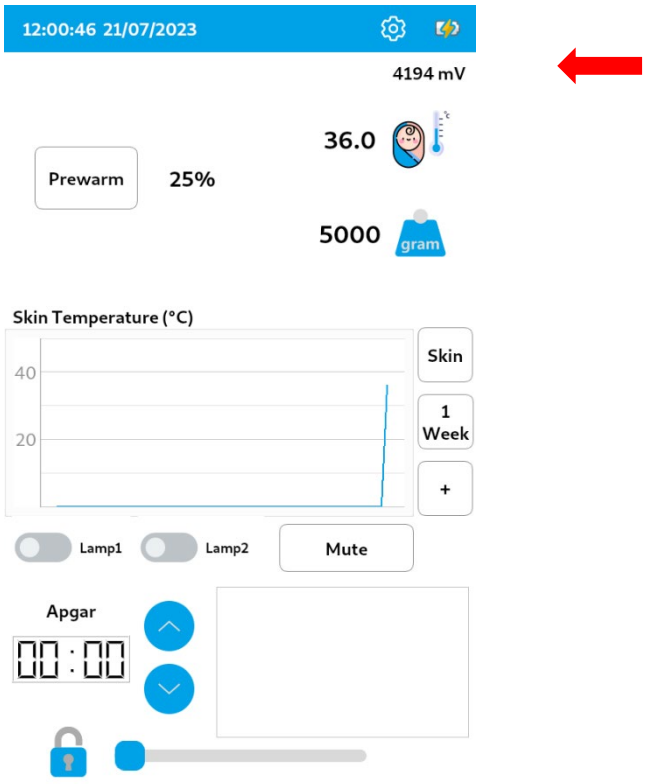


Figure 34. Battery Level

8.2.7. "POWER FAILURE" WARNING

In All Modes

"Power failure" alarm is activated in all of the modes, when the device's external power input fails.

The device provides a visual and audible alarm by blinking the red indicator light and the heating source is disabled.

The audible alarm cannot be silenced with the silence button, and until the external power failure is solved, this warning occurs in the screen.

The integrated battery is enabled to be able to read the indicators, in an external power failure. The heater is not active.

The audible alarm cannot be silenced with the silence button, when the external power is enabled, the warning disappears.

The necessary controls;

- The heater may have mistakenly removed from the outlet. Check that the cable is connected to the outlet.

Figure 35. Power Fail

8.2.8. MASIMO ALARMS

The device has SpO_2 module as an optional feature. Depending on the module, the device has the following options.

LOW BPM VALUE	When the BPM value falls below the set value, a written and audible alarm sounds.
HIGH BPM VALUE	When the BPM value exceeds the set value, it gives a written and audible alarm.
LOW SpO_2 RATIO	When the SpO2 value falls below the setpoint, a written and audible alarm sounds.
HIGH SpO_2 RATIO	When the SpO_2 value exceeds the set value, it gives a written and audible alarm.
MasimoSET: EXPIRED CABLE	When the cable expires, a written and audible alarm sounds. This alarm cannot be silenced.
MasimoSET: INAPPROPRIATE CABLE	When an unsuitable cable is used, it gives a written and audible alarm. This alarm cannot be silenced.

MasimoSET: UNIDENTIFIED CABLE	When an unidentified cable is used, a written and audible alarm sounds. This alarm cannot be silenced.
MasimoSET: FAULTED CABLE	When a faulty cable is used, a written and audible alarm sounds. This alarm cannot be silenced.
MasimoSET: EXPIRED SENSOR	When the sensor expires, it gives a written and audible alarm. This alarm cannot be silenced.
MasimoSET: INAPPROPRIATE SENSOR	When an inappropriate sensor is used, it gives a written and audible alarm. This alarm cannot be silenced.
MasimoSET: UNIDENTIFIED SENSOR	When an unidentified sensor is used, a written and audible alarm sounds. This alarm cannot be silenced.
MasimoSET: FAULTED SENSOR	When a faulty sensor is used, a written and audible alarm sounds. This alarm cannot be silenced.
MasimoSET: INTERFERENCE DETECTED	Gives a written and audible alarm when interference is detected.
MasimoSET: LOW PERFUSION INDEX	Sounds a written and audible alarm when the perfusion index is low.
MasimoSET: RUNNING IN DEMO MODE	Sounds a text and audible alarm only once when a demo or test sensor is connected.
MasimoSET: CHECK SENSOR CONNECTION	Sounds a text and audible alarm when the sensor connection is not correct. This alarm cannot be silenced.
MasimoSET: SpO_2 ONLY MODE	When rainbow parameters cannot be calculated with the rainbow sensor, a written and audible alarm sounds.
MasimoSET: ELECTRONIC FAULT-X	There are many error codes. It gives a written and audible alarm in case of card failure. This alarm cannot be silenced.

WARNING: Because the heater is disabled in a power failure, put the baby on an alternative heating source, if necessary.

Alarm and Warning	**Operation Mode**	**Reason**	**Silence Button**
Check the Infant	Skin	The measured skin temperature's being below	Turns off only the audible alarm for 15 minutes
High Skin Temperature	Skin	The measured skin temperature is 1 °C above the adjusted temperature	Turns off only the audible alarm for 15 minutes
	Manual	The measured skin temperature is 1°C above the adjusted temperature	Turns off only the audible alarm for 15 minutes
	Prewarm	The measured skin temperature is 1°C above the adjusted temperature	Turns off only the audible alarm for 15 minutes

Excessive Skin Temperature	Skin	The measured skin temperature is 2°C above the adjusted temperature	Turns off only the audible alarm for 15 minutes
	Manual	The measured skin temperature is 2°C above the adjusted temperature	Turns off only the audible alarm for 15 minutes
	Prewarm	The measured skin temperature is 2°C above the adjusted temperature	Turns off only the audible alarm for 15 minutes
Low Skin Temperature	Skin	The measured skin temperature is 1°C below the adjusted temperature	Turns off only the audible alarm for 15 minutes
	Manual	The measured skin temperature is 1°C below the adjusted temperature	Turns off only the audible alarm for 15 minutes
	Prewarm	The measured skin temperature is 1°C below the adjusted temperature	Turns off only the audible alarm for 15 minutes
No Skin Probe	Skin	Skin probe is not connected	Turns off only the audible alarm for 15 minutes
	Manual	Inactive	Inactive
	Prewarm	Inactive	Inactive
Skin Probe Failure	Skin	Inactive	Turns off only the audible alarm 15 minutes
	Manual	Inactive	Inactive
	Prewarm	Inactive	Inactive
Low Battery	All Mode	The device does not have a power	Inactive
Power Failure	All Mode	Failure to feed power to the heater	Turns off only the audible alarm 15 minutes
Manual Mode Reminder	Skin	Inactive	Inactive
	Manual	The heating source's power is above 30 % for more than 15 minutes	Turns off only the audible alarm for 15 minutes
	Prewarm	Inactive	Inactive

Tablo – 4 Alarm Table

WARNING: When an alarm is silenced, the patient's condition must be monitored.

9. CLEANING AND MAINTENANCE-REPAIR

WARNING: Do not change the location of the device, before removing all of the auxiliary devices. Before implementing the maintenance or repair processes, unplug the power cable of the device to cut the power.

Remained accumulations of ether, alcohol or similar cleaning solutions may cause fire.

9.1. GENERAL

This part provides cleaning and maintenance instructions. When it is necessary, it also includes disassembly instructions. Apart from those, explained in this part, all maintenance operations must be performed by the qualified service personnel. Cleaning must be performed by the qualified personnel after each use or in every situation when it is necessary.

Within the scope of guarantee, repair services must be performed only by an Ertunç Özcan Technical Service. Do not use a device, which you think is malfunctioning.

9.2. MAINTENANCE

The recommended maintenance periods are given below. For the necessary intervals, always follow the hospital and local directives.

Clean the device **weekly or after each patient**.

Disinfect the device, if necessary or after it is used with a patient, having contagious disease.

General Maintenance

- After the maintenance process is completed, ensure that the device works in accordance with the specified performance values.
- Be careful about using only the approved spare parts in the repair and maintenance operations.
- For the repair and maintenance issues, you can contact with the authorized Ertunç Özcan representative.

Annual Maintenance

To ensure that it is working safely, the cradle must be checked once a year. The following procedure must be applied by the authorized technician:

- Check that the side panels of the mattress are operating and placed correctly. If they are malfunctioning, contact with an Ertunç Özcan Technical Service.
- Check that the X-Ray tray works properly, and the X-Ray cassette is placed correctly. If they are malfunctioning, contact with an Ertunç Özcan Technical Service.
- Check that the carriage arm works as well as all of the lock buttons.
- Ensure that the mattress inclination mechanism works properly, and the mattress is parallel to the ground. If they are malfunctioning, contact with an Ertunç Özcan Technical Service.
- Check that the wheels turn freely and the wheel lock mechanisms work properly.
- Ensure that the heater head works properly by moving it to left and right.

9.3. CLEANING

After each patient or at least once a week, the device must be cleaned and disinfected. The most efficient way is to clean by disassembling. The disassembly steps are described in part 3.6, 3.7 and 3.8.

Wipe the surfaces of the heater with a soft tissue, washed in disinfectant etc. For use, comply with the instructions of the cleaning solution manufacturer.

Apply the cleaning procedures below to clean the infant heater and its auxiliary equipment on a weekly basis or after each treatment:

- Comply with the hospital, local and national regulations in the determination of the product cleaning frequency.
- Cleaning must be done in a room temperature. Begin to clean, after ensuring that the heated surface has cooled down.
- Before cleaning, take out all used consumables, by using the waste disposition method of the hospital.
- Clean the dust of all surfaces with a clean, soft, and wet cloth tissue.
- Ensuring that all the instructions of the manufacturer, about the cleaning materials, are applied, clean all of the plastic surfaces.
- Heater head, heater set, side panels, column head and front panel belts also contain plastic components, made from polycarbonate and acrylic.
- If it is necessary to clean the specified plastic surfaces, due to a suspicion of infection, it is recommended to use approved chemical cleaning tissues.
- After cleaning, dry all the surfaces with a clean, soft tissue or paper towel.

ATTENTION:

- Do not clean the specified plastic surfaces with the cleaning products, of which hydroxide, hypochlorite, peroxide, glutaraldehyde or alcohol bases are above 30 %.
- These chemical materials, used in registered cleaning products, may cause discoloration, cracks and breaking of the specified plastic surfaces, in time.
- Do not use abrasive cleaning solutions.
- Before sending the device to a technical service, ensure that all of the auxiliary equipment is complete.
- Any part of the infant heater and related auxiliary equipment must not be dipped into a cleaning liquid or solutions.
- Do not remove any parts of the radiant warmer heat for the cleaning purpose.

9.3.1. SKIN PROBES

Reusable skin probes must be cleaned by carefully wiping with a soft and wet tissue, with a disinfection material that can be safely applied on probe materials is applied. Ensure that all the cleaning materials are cleaned and dried.

 WARNING: The user must ensure that this product is not damaged or polluted between the uses for the same patient.

ATTENTION:

- Do not expose a skin probe to an autoclave or do not sterilize with gas.
- Be careful that a skin probe is removed from the control equipment by holding only from the plug, in the front panel. During the use, cleaning or control, provide that there is not an excessive pressure on the skin probe cable.

9.3.2. MATTRESS

Clean the mattress with an approved and correctly diluted disinfectant or detergent solution.

Clean the surface of the mattress with a clean cloth tissue or sponge, wetted by a cleaning solution. Later on, dry all of the surfaces with a clean, soft tissue or paper towel.

ATTENTION:

- Do not expose mattress to an autoclave.

ATTENTION: Do not expose any parts of a heater to an autoclave or do not sterilize with gas.

9.3.3. RESUSCITATION DEVICE

When the baby is discharged or at least weekly, the Resuscitation Device should be thoroughly cleaned and disinfected.

Wipe the front surfaces of the device with a soft cloth dampened with disinfectant etc. For use, always

Follow the cleaning solution manufacturer's instructions.

WARNING: Before cleaning the Resuscitation Device, always disconnect the hoses supplying the device at the back.

9.3.4. OXYGEN/AIR MIXER DEVICE

- Remove all gas connections and equipment before cleaning the Oxygen/Air Mixer.

- Do not expose to cleaning process such as autoclave or ethylene oxide. Wipe the outer surface with antiseptic cleaners. Do not clean by immersing in liquid. Do not use solvent-containing cleaners on plastic parts, labels, front protective cover. Have maintenance work done only by technical personnel who have been trained on the subject. Avoid maintenance operations not approved by the manufacturer. Contact the manufacturer for effective and safe maintenance and repair. Calibration should only be performed by our trained technical service personnel or by personnel authorized and certified by our company. The recommended calibration interval is every 6 months. In case the device remains in inappropriate value ranges in terms of performance, it should not be used without calibration by a technical service personnel authorized by our company.

9.3.5. CLEANING MATERIALS

Iodophor or detergent with four effects should be used. While using any kinds of antiseptic cleaning material, read the instructions of its manufacturer.

ATTENTION:

- Do not clean the device with organic solutions, strong acids or bases. These compounds can damage the parts.
- Do not dip the parts into cleaning solutions. Dry the cleaning solutions on the parts by wiping.
- Do not let the cleaning solutions leak between the plastic parts and left without drying.

10.TROUBLESHOOTING

Troubleshooting for the device is given in Table 5. In case the trouble is not detected from the tables, the unit must be repaired by qualified service personnel, who were trained by an Ertunç Özcan technical service. If the device cannot be turned on, contact with the technical service.

TROUBLESTHOOTING TABLE

Situation	Possible Reason	Necessary Operation
The infant's skin temperature cannot be controlled in a stable way.	The skin probe and/or probe cover could not be placed on the infant, correctly.	Place the skin probe and probe cover correctly again.
	The heat route is obstacle between the infant and the heating source.	Remove the obstacle on the heat route.
	The skin probe does not contact with the infant.	Ensure that the skin probe is properly contacting with the infant.
While a skin probe is connected to the front panel, the infant's skin temperature values cannot be monitored on the screen.	The connection between the skin probe and the heater is not correct.	Tightly connect the skin probe socket to the front panel outlet.
	The skin probe is malfunctioning.	Check the skin performance of the skin probe and change it if it is malfunctioning.
	The skin probe card is malfunctioning.	Apply to an Ertunç Özcan Technical Service.
The heating function of the device does not work due to a power failure.	The electricity connection, coming to the heater from the wall outlet, must have been turned off.	Turn on the wall outlet.
	The device's Power button must be off.	While it is connected to the outlet, press the Power button.
	There can be a problem in the internal fuses, Circuit Breakers, power cable or internal cable structure.	Apply to an Ertunç Özcan Technical Service.

11.AUXILIARY EQUIPMENT TO BE ORDERED

Part No	Description of Parts
700-110-007	REUSABLE SKIN SENSOR
410-301-001	BABYREST M-100 IV POLE KIT
410-301-002	BABYREST M-100 MANUAL STAND KIT
301-407-000	BABYREST M-100 CUSHION

12.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 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	KİWA BELGELENDİRME HİZMETLERİ A.Ş.
ADDRESS	ITOSB 9.CAD. NO:15 TEPEÖREN, TUZLA/İST.-TÜRKİYE
Organization NO.	1984

13. ANNEX A - Electromagnetic Suitability

ELECTROMAGNETIC SUITABILITY (EMC) GUIDE

Safety standards: IEC 60601-1, IEC 60601-2-21

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 use 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

Babyrest M-100 Radiant Warmer Open Bed has been tested and has fulfilled the conditions of the TS EN 60601-1-2:2011 Electromagnetic suitability.

Guide and Manufacturers Declaration on Electromagnetic Emissions

<table>
<tr><td colspan="3">Babyrest M100 radiant warmer open bed is aimed to be used in the below stated electromagnetic environment. The customer or user of the Babyrest M100 radiant warmer open bed, must guaranty to use this device in these environments.</td></tr>
<tr><td>Emission Tests</td><td>Suitability</td><td>Electromagnetic environment-Guide Information</td></tr>
<tr><td>RF emissions CISPR 11 EN 55011:1995</td><td>Group 2</td><td>Electromagnetic energy is used for the Babyrest M100 radiant warmer open bed to serve its aimed function. The electronic devices around it may be affected.</td></tr>
<tr><td>RF emissions CISPR 11 EN 55011:1995</td><td>Class A</td><td rowspan="3">Babyrest M100 radiant warmer open bed 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.</td></tr>
<tr><td>Harmonic emissions IEC 61000-3-3</td><td>IEC 61000-3-2</td></tr>
<tr><td>Voltage waves /flicker emissions IEC 61000-3-3</td><td>In accordance with the terms</td></tr>
</table>

Guide and Manufacturers Declaration on Electromagnetic Immunity

Babyrest M-100 radiant warmer open bed is aimed to be used in the below stated electromagnetic environment. The customer or user of the Babyrest M-100 radiant warmer open bed, 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	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 kV air	The site where the Babyrest M-100 radiant warmer open bed 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	For ± 2 kV power supply feeding line For ± 1 kV input/output line	Invalid for ± 2 kV power supply feeding lines.	The capacity of the power network must be at the capacity of the ones used in typical commercial environment or a hospital.
Sudden impact IEC 61000-4-5	± 1 kV differential mode	± 1 kV differential mode	The capacity of the 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	< 5% Ut (0.5 to turn, Ut) dip > 95%) 40% Ut (5 to turn, Ut dip 60%) 70% Ut (25 to turn, Ut dip 30%) <5% Ut (5 for second, Ut dip >95%)	12V , 0,5 cycle 96V , 5 cycle 168V, 25 cycle 12V, 5 second	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 Babyrest M-100 radiant warmer open bed 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	3 A/m	3 A/m	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

Babyrest M-100 radiant warmer open bed is aimed to be used in the below stated electromagnetic environment. The customer or user of the Babyrest M-100 radiant warmer open bed, must guaranty to use this device in these environments.

Immunity Test	**IEC 60601-1-2 Test Level**	**Suitability Level**	**Electromagnetic environment-Guide Information**
Transmitted RF IEC 61000-4-6	3 Vrms 150 kHz with 80MHz	3 V	Portable and movable RF communication devices including their cables must not be any closer to any part of the Babyrest M-100 radiant warmer open bed 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 $d=[\frac{3,5}{E1}]\sqrt{P}$ $d=[\frac{7}{E1}]\sqrt{P}$ 800 MHz with 2,5 GHz
exuded RF IEC 61000-4-3	3V/m 80 MHz with 2,5 GHz	10 V/m	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.
IEC 60601-2-19	3 V/m 26 MHZ with 1 GHz 10 V/m 26 MHz with 1 GHz	3V/m Work regularly 10 V/m No Danger	

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 Babyrest M-100 radiant warmer open bed is used goes over the, above stated. Applicable RF suitability level the Babyrest M-100 radiant warmer open bed 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 Babyrest M-100 radiant warmer open bed 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 Babyrest M-100 radiant warmer open bed

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

Babyrest M-100 radiant warmer open bed is aimed to be used in the below stated electromagnetic environment.

The customer or user of the Babyrest M-100 radiant warmer open bed, must guaranty to use this device in these environments

Immunity Test	**IEC 60601-1-2 Test Level**	**Suitability level**	**Electromagnetic environment-Guide Information**
Transmitted RF IEC 61000-4-6	3 Vrms 150 kHz and 80MHz	3 Vrms	Babyrest M-100 radiant warmer open bed 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 an 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. 
exuded RF IEC 61000-4-3	3V/m 80 MHz and 2,5 GHz	10 V/m	

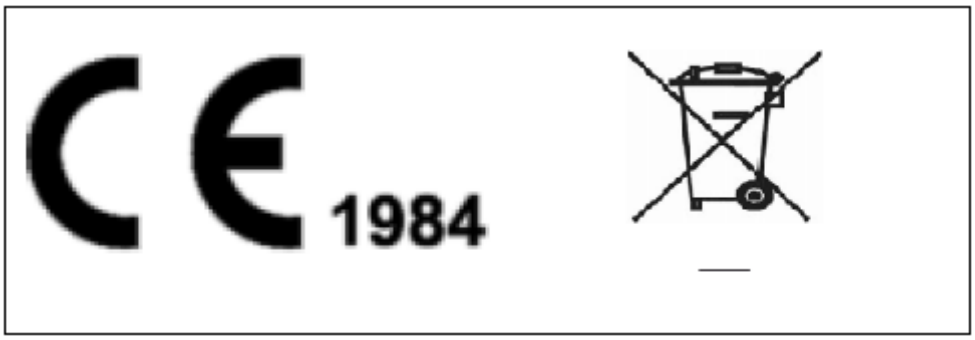
The field strength spread from the stable feeder cell towers for the radio telephones (cellular/wireless) and land radios, amateur radio AM and FM radio broadcast and TV broadcast may not be theory accurately estimated. To evaluate the electromagnetic fields caused by RF feeders, an electromagnetic field research must be considered. If the measured field strength of the environment where the Babyrest M-100 radiant warmer open bed is used goes over the, above stated. Applicable RF suitability level the Babyrest M-100 radiant warmer open bed 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 is in accordance with the TS EN 60601-1-2 term 36.202.1 requirements and Electrostatic Discharge Connection lightning.

14.ANNEX B -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 Guide and/or Service Guide shall be translated into the language of the country that the Device is being dispatched to.**