ERTUNÇ ÖZCAN

MAGIC LOGGIA ULTIMATE MODEL INFANT INCUBATOR USER, MAINTENANCE AND SERVICE MANUAL

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TABLE OF CONTENTS

1. COMPANY INFORMATION 5

1.1. INTRODUCTION 5
1.2. LIMITED WARRANTY 5
1.3. TECHNICAL SUPPORT 5
1.4. CONTACT INFORMATION FOR THE CUSTOMER 5
1.4.1. CENTER, DESIGN AND PRODUCTION 6
1.4.2. ELECTRONIC DESIGN AND SOFTWARE 6
1.4.3. STORE 6

2. INFORMATION ABOUT INSTRUCTION FOR USE 7

2.1. USE OF TERMS 7
2.2. TRADEMARKS OWNED BY ERTUNÇ ÖZCAN 7
2.3. DEFINITIONS AND ICONS 7
2.3.1. DEFINITIONS OF INSTRUCTIONS FOR SAFETY 7
2.3.2. ICONS 8
2.4. MANUFACTURER'S RESPONSABILITY 8
2.5. STATEMENT 9

3. INFORMATION ON SAFETY INSTRUCTIONS AND PRECAUTIONARY STATEMENTS 10

3.1. INSTRUCTIONS FOR SAFETY OF USERS AND PATIENTS DURING GENERAL OPERATION 10
3.2. RESTRICTIONS FOR USE 10
3.3. BASIC SAFETY INSTRUCTIONS 11
3.3.1. PATIENT SAFETY AND MONITORING PRECAUTIONS 11
3.3.2. SERVICE PRECAUTIONS 12
3.3.3. CLEANING and REPROCESSING PRECAUTIONS 12
3.3.4. MODIFICATION PRECAUTIONS 13
3.3.5. PRECAUTIONS FOR THE RISK OF ACCIDENTAL DISCONNECT 13
3.3.6. ELECTRICAL PRECAUTIONS 13
3.3.7. PRECAUTIONS FOR CONNECTION WITH OTHER ELECTRICAL EQUIPMENT 14
3.3.8. ELECTROMAGNETIC COMPATIBILITY (EMC) PRECAUTIONS 14
3.3.9. ANTI-STATIC WHEELS PRECAUTIONS 15
3.3.10. EXPLOSION AND FIRE PRECAUTIONS 15
3.3.11. HUMIDITY PRECAUTIONS 15
3.3.12. OXYGEN PRECAUTIONS 16
3.3.13. PRECAUTIONS FOR TEMPERATURE STABILIZATION 17
3.3.14. PRECAUTIONS FOR USING PHOTOTHERAPY DEVICE 17
3.3.15. PRECAUTIONS FOR THE MOVEMENT OF THE INCUBATOR 18
3.3.16. PRECAUTIONS FOR TRENDELENBURG SAFETY 18
3.3.17. WEIGHING PRECAUTIONS 18
3.3.18. SAFETY INSTRUCTIONS FOR ACCESSORIES 18
3.3.19. CYBERSECURITY PRECAUTIONS 19
3.3.20. PRECAUTIONS FOR VOLATILE ORGANIC COMPOUNDS (VOCs) 19
3.4. TARGET GROUPS FOR MAGIC LOGGIA ULTİMATE 19
3.5. TRAINING 20

4. GENERAL INFORMATION 21

4.1. INTRODUCTION 21
4.2. EXPLANATION 21
4.3. INTENDED USE OF THE DEVICE 21
4.4. TWINS IN MAGIC LOGGIA ULTIMATE 22

4.5. ENVIRONMENT OF USE 22
4.6. INDICATIONS, CONTRAINDICATIONS, SIDE EFFECTS AND WARNINGS 22
4.6.1. INDICATIONS 22
4.6.2. CONTRAINDICATIONS 23
4.6.3. SIDE EFFECTS 23
4.6.4. ADVERSE EFFECTS 23
4.7. FEATURES 23
4.7.1. CLASSIFICATION OF DEVICE 24
4.7.2. STANDARDS 24
4.7.3. ELECTRICAL FEATURES 24
4.7.4. BATTERY FEATURES 25
4.7.5. INCUBATOR FEATURES 25
4.7.6. CONTROL OF AIR TEMPERATURE AND SKIN TEMPERATURE 25
4.7.7. SERVO CONTROLLED OXYGEN MODULE (OPTIONAL) FEATURES 26
4.7.8. SERVO CONTROLLED HUMIDITY UNIT (OPTIONAL) FEATURES 26
4.7.9. CARBONDIOXIDE LEVEL 26
4.7.10. SCALE (OPTIONAL) FEATURES 26
4.7.11. HEIGHT ADJUSTMENT (OPTIONAL) FEATURES 26
4.7.12. ENVIRONMENTAL OPERATION TERMS 26
4.7.13. IP PROTECTION CLASS 27
4.7.14. SOFTWARE FEATURES 27
4.7.15. DISPLAY PANEL SCREEN FEATURES 27
4.7.16. MEMORY (TREND) FEATURES (OPTIONAL) 27
4.7.17. SYSTEM CONTROL 27
4.7.18. STANDARD FEATURES 27
4.7.19. OPTIONAL FEATURES AND ACCESSORIES 28
4.8. ACCESSORIES LIST 31

5. INSTALLATION AND CONTROL OF THE SYSTEM 32

5.1. MECHANIC CONTROL 32
5.2. CONTROL OF THE MEASURING MODULE 32
5.3. CONTROL OF THE ACCESSORIES 32

6. FUNCTIONAL EXPLANATION 33

6.1. GENERAL 33
6.2. FUNCTION EXPLANATION 33
6.3. AIR CIRCULATION SYSTEM 33
6.4. TEMPERATURE REGULATION 33
6.4.1. AIR CONTROL MODE 34
6.4.2. SKIN CONTROL MODE 35
6.5. UTILIZATION OF SCALE (OPTIONAL) 35
6.6. USE OF THE VERTICAL HEIGHT ADJUSTMENT (OPTIONAL) 36

7. USAGE OF THE MAGIC LOGGIA ULTİMATE DISPLAY PANEL 37

7.1. DISPLAY PANEL INTERFACE 37
7.2. ELECTRIC POWER ASSEMBLY 37
7.3. SENSOR MODULE ENTRY 38
7.4. THE VIEW OF SENSOR MODULE 38

8. OPERATION OF THE CONTROL MODULE 39

8.1. OPERATION 39
8.2. IN CASE OF POWER FAILURE 40

9. FUNCTION MENUS 41

9.1. LOGIN PAGE 41
9.2. MAIN PAGE 41
9.2.1. AIR MODE 41
9.2.2. SKIN MODE 43
9.2.3. SET MODE 44
9.2.4. HUMIDITY MODE (RH) 44
9.2.5. OXYGEN MODE 44
9.2.5.1. CALIBRATION OF OXYGEN VALUES 45
9.2.6. WEIGHT 46
9.2.6.1. 0 KG CALIBRATION 46
9.2.6.2. 5 KG CALIBRATION 47
9.2.6.3. TAKING TARE FUNCTION 48
9.2.6.4. TREND FUNCTION 48
9.3. ALARMS 49
9.4. TRENDS 49
9.5. SMART SCREEN 50
9.6. NOTES 51
9.7. SETTINGS 52
9.8. OTHER ICONS 54

10. WARNINGS, ALARMS, ERRORS 55

10.1. WARNINGS 55
10.2. ALARMS 55
10.3. SILENCE / RESET OF ALARMS 56
10.4. ERRORS 56
10.5. SYSTEM ERROR CODES 57

11. USAGE OF THE INCUBATOR 58

11.1. GENERAL USE 58
11.2. ACCESS TO THE PATIENT 60
11.3. LIFTING AND LOWERING OF THE CANOPY 61
11.4. TRENDELENBURG MECHANISM 62
11.5. X-RAY TRAY USAGE 64
11.6. USAGE OF THE HUMIDIFIER 65
11.6.1. REMOVING AND FILLING OF WATER RESERVOIR OF HUMIDIFIER 66
11.6.2. STERILIZATION OF WATER RESERVOIR OF HUMIDIFIER 67
11.7. AIR INTAKE MICROFILTER 67
11.8. OXYGEN 68
11.9. 360º ROTATABLE DRAWERS (OPTIONAL) 70
11.10. CONTROL COMPLETE 70
11.10.1. OPERATING IN USE 70

12. CLEANING AND REPROCESSING, MAINTENANCE, REPAIRING 71

12.1. GENERAL 71
12.1.1. DEFINITIONS OF SERVICE TERMINOLOGY 72
12.2. MAINTENANCE 72
12.2.1. MAINTENANCE KITS 74
12.2.2. SHELF LIFE/SERVICE LIFE INFORMATION FROM TECHNICAL DATASHEETS OF CRITICAL COMPONENTS 75
12.3. REPAIRING 76
12.4. CLEANING & REPROCESSING 76
12.4.1. CLASSIFICATION OF MEDICAL DEVICES 77

12.4.2. CLASSIFICATION OF DEVICE-SPECIFIC COMPONENTS 77
12.4.3. OVERVIEW OF THE REPROCESSING PROCEDURES OF THE COMPONENTS 77
12.4.4. METHODS OF CLEANING 79
12.4.5. CLEANING AND DISINFECTING INDIVIDUAL COMPONENTS 79
12.4.5.1. CANOPY AND INNER WALL 79
12.4.5.2. SENSOR MODULE, SCALE MODULE AND 360º ROTATING DRAWER 79
12.4.5.3. HUMIDIFICATION MECHANISM 80
12.4.5.4. DISPOSABLE/ REUSABLE SKIN TEMPERATURE PROBES 81
12.4.5.5. ELECTRONIC HARDWARE SURFACE CLEANING DISINFECTION PROCESS 81
12.4.5.6. CLEANING PROCESS OF HEATER BLOCK (RADIATOR) AND FAN BLOWER 82
12.4.5.7. CLEANING PROCESS OF THE AIR INLET FILTER CHAMBER AND COVER 83
12.4.6. DISASSEMBLY STEPS 83
12.4.7. CLEANING, DISINFECTION AND DRYING OPERATION PROCEDURES 91
12.4.7.1. CLEANING PROCEDURES 91
12.4.7.2. DISINFECTANTS 92
12.4.8. INSPECTION BEFORE USE 92
12.4.8.1. VISUAL INSPECTION 92
12.4.9. CONTROL AFTER CLEANING AND DISINFECTION 93
12.4.9.1. ASSEMBLY OF INCUBATOR SUBCOMPONENTS / EQUIPMENT 93
12.4.9.2. PREPARATIONS BEFORE REUSE 94
12.4.9.3. PUTTING INTO SERVICE (MAKING AVAILABLE) 94
12.4.10. RISK CONTROL OF CLEANING PROCESS 95

13. TROUBLESHOOTING 96

14. ELECTRONIC CIRCUIT SCHEMATICS 98

15. NOTIFIED BODIES INFORMATION 100

ANNEX A - ELECTROMAGNETIC SUITABILITY 101

ANNEX B -INFORMATION OF COMPLIANCE OF STANDARDS AND DIRECTIVES 106

ANNEX C – CYBERSECURITY INSTRUCTIONS 107

1. COMPANY INFORMATION

1.1. INTRODUCTION

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

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

1.2. LIMITED WARRANTY

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

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

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

1.3. TECHNICAL SUPPORT

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

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

1.4. CONTACT INFORMATION FOR THE CUSTOMER

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

1.4.1. CENTER, DESIGN AND PRODUCTION

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

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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
Phone : +90 312 354 82 71
Fax : +90 312 354 81 97

1.4.3. STORE

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

Address: ASO 2. and 3. OSB 2036. Street No:1/A Temelli / Sincan / Ankara / Turkey
Phone : +90 312 502 05 97

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	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**		**Caution: Federal Law restricts this device to sale by or on the order of a physician, nurse or biomedical engineer**
	Alternative Flow		**Refer to the User Manual**
	Power On (Connect to a wall power switch)		**Type BF Application Part**
	**Power Off (Disconnect from the Wall power switch)**		**Caution: Hot Surface**
	**Serial Number**		**Manufacturer**
	**WARNING Information**		**Do not throw out**
	**Weight Limit**		**European Conformity**
	**Use only distilled water**	**MAX.**	**Maximum**
	**Production date**	**IPXO**	**Unprotected against water and dust particles**
SENSOR MODULE INPUT	**Sensor Module Input**		

NOTE
This manual shall explain all the functions and their usage instructions of the Ertunç Özcan brand Magic Loggia Ultimate model incubator.

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 incubator 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 incubator 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 Magic Loggia Ultimate 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 Magic Loggia Ultimate. Specific precautionary statements for subsystems and particular features are mentioned in related part of the user manual.

WARNINGS

- Before using the incubator, 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 incubator may injure the patient.
- Magic Loggia Ultimate must only be used for the purpose mentioned in Intended Use (Section 4.3)
- The incubator shall not be used if it is not functioning properly. Technical service must be given by an authorized and qualified personnel.
- It should be ensured that the attached parts of the incubator shall not exceed the maximum weight capacity of the incubator. To prevent the incubator from falling or prevent physical injuries, it should be ensured that the weight capacity of the incubator shall not be exceeding or overloaded more than 5 kg for monitor tray, 1.2 kg for drawer tables, 2.5 kg for drawers, 1 kg for IV Pole.
- The necessary measurements stated below shall be taken while using the incubators monitor tray;
    - While normal usage or after changing the position, it should be ensured that the screws which stabilize the shelf position are well tightened.
    - The monitor shall always be placed in the center of the shelf to be able to provide its stability.
    - Another device shall not be put along with a monitor on the tray.
    - Devices shall not be exceeded the maximum weight capacity of the tray.
- It should be ensured that the mattress is covered with cotton flannel type textile before putting the patient in.
- When the device is not in use, it should be turned off from the On/Off button.
- When the treatment is complete, the device should be turned off by using the On/Off button and for safety, the power cable of the device should be unplugged from the switch until using it again.
- Before placing the patient in the device, the mattress should be in a horizontal position. It is not suitable to lay the patient on trays and similar surfaces other than the mattress. The section designed for the patient 's use is only the mattress in the incubator.
- The device shall not be used if access panels are removed or broken.
- When in use the air flow channels, access panels shall be open for the safety of the patient and to maintain the incubators performance.

3.2. RESTRICTIONS FOR USE

- The incubator 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 incubator that are known so far.

3.3. BASIC SAFETY INSTRUCTIONS

3.3.1. PATIENT SAFETY AND MONITORING PRECAUTIONS

WARNINGS

- The design of the medical device, instructions for use and the device labels are based on the assumption that the medical device is only used by the persons who have knowledge about the medical device. Therefore, instructions and precautions given in this user manual are limited to the features of Magic Loggia Ultimate Infant Incubator. This user manual does not contain any instructions about the following points;
  - Obvious risks for users
  - Consequences of obvious misuse of the device
  - Foreseen negative effects on patients who have different underlying diseases.
- Modification or improper use of the medical device can lead to serious injuries.
- It should be avoided to make therapeutic decisions by depending on only measured and monitored parameters. In order to make therapeutic decisions, both visual assessment and medical expertise are needed as well as measured and monitored parameters.
- The canopy shall not be opened by lifting it when the patient is inside the incubator. The patient shall be accessed by the access panels. Otherwise, it can lead to patient injury or equipment damage.
- Access to the patient should be provided by access panels and QT Windows.
- When opening or closing the access panels or QT windows, in order to prevent the patient from getting injured, the patient's clothes, hoses, cables etc. must be kept in the boundaries of the mattress.
- The patient must not be unattended when the access panels are remained open.
- To place the patient into the incubator, access panels should be used. The canopy shall not be opened for the placement of the patient.
- The wheel breaks should be always activated before placing the patient into the incubator.
- The device should not be unattended when parking on an incline.
- Drawers should always be closed when not in use, particularly when the incubator is being moved.
- Before moving, heightening, lowering or taking out of the bed, it should be ensured to check all the hoses and cables of the patient to prevent the patient from getting injured.
- The canopy shall not be lifted when the skin probe or patient circuit are attached to the patient or when the trendelenburg is positioned.
- It is the user's responsibility to select an appropriate patient monitoring system that provides information about medical device performance and patient condition.
- The responsibility for selecting the best level of patient monitoring belongs only to the user of the medical device.

3.3.2. SERVICE PRECAUTIONS

WARNINGS

- Periodical service should be performed in order not to encounter malfunctions, otherwise personal injuries or property damages may be seen.
- Magic Loggia Ultimate should be serviced periodically by service personal and repairs and maintenances should be performed by authorized and experienced service personal.
- For longer lifespan, Ertunç Özcan recommends that periodical service should be performed by Ertunç Özcan Technical Service Department and for maintenance and repair, parts approved by Ertunç Özcan should be used.
- The device shall not be serviced while the patient is in the incubator.

3.3.3. CLEANING and REPROCESSING PRECAUTIONS

WARNINGS

- Before performing the medical device for the first time, it shall be disinfected and cleaned and disinfection and cleaning should be done every time when the patient changes.
- In order to decrease the risk of infection, reusable components must be reprocessed by validated processes.
- The manufacturer's instructions about cleaning, disinfection and reprocessing shall be followed.
- It should be ensured that no liquid penetrates the device in order to prevent damage to the device, malfunctions and electric shock.
- When opening the canopy for cleaning purposes, be careful not to hit the display module. Otherwise, it can lead to personal injury or equipment damage.
- Before cleaning the incubator, unplug the power cable.
- The main heater can be hot enough to burn if touched; do not disassemble the control board until at least 45 minutes after the unit has been turned off. Do not touch the heater.
- The incubator should be thoroughly cleaned and disinfected after each patient change, but at least once a week. For the most effective cleaning, disassemble the device parts prior to cleaning. The steps for disassembling the device parts are described in Section 12.4.6.

3.3.4. MODIFICATION PRECAUTIONS

WARNINGS

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

3.3.5. PRECAUTIONS FOR THE RISK OF ACCIDENTAL DISCONNECT

WARNINGS

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

3.3.6. ELECTRICAL PRECAUTIONS

WARNINGS

- Operate only with the supplied power cable.
- For the safety of grounding, the power cable must be plugged only to electric switches which meet with hospital class type switches with protective grounding. In case of any doubt on the grounding connection, the device should not be turned on.
- To ensure grounding reliability, the power cable shall be plugged only into a properly grounded 3-wire hospital-grade or hospital-use outlet.
- The service of the device shall be done by a qualified and sufficient technical personnel due to the risk of electrical shock.
- It should be ensured that the electrical features stated in the product features are fulfilled. Otherwise, personal injury or equipment damages may occur.
- Some chemical cleaning substances might be conductive. These cleaning substances should not be contacted with the electric constituent and sprayed on surfaces. Otherwise, personal injury or equipment damage may occur.
- The cleaning of the control module of the device shall not be conducted by means of spraying or with a similar way. Cleaning substances which may be constituent may cause personal injury or equipment damage.
- Electrical equipment has a potential risk of electrical shock. In this regard, please educate your employee concerning with the risk of using electrical equipment.
- The maximum total earth leakage current of the system, including all items plugged into the auxiliary mains outlets and any items plugged into external sockets, must not exceed 500 µA.
- A power cable from the incubator controller shall not be connected directly to an AC wall connection, otherwise an accidental disconnection may be seen or the incubator may be damaged.

- Circuit breakers shall not be reset or the fuses shall not be fused without assessing and correcting the reason why the circuit breaker or fuse is activated.
- Additional equipment connected to the patient must be electrically safe.
- Only the authorized staff member can access the battery (cell battery) part, in case of a chemical leakage.

3.3.7. PRECAUTIONS FOR CONNECTION WITH OTHER ELECTRICAL EQUIPMENT

WARNINGS

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

3.3.8. ELECTROMAGNETIC COMPATIBILITY (EMC) PRECAUTIONS

WARNINGS

- All medical accessories must comply with the safety requirements in the scope of IEC 60601-1 and have safety certifications.
- Any equipment shall not be used near other devices unless normal operation is verified in the configuration in which it is to be used.
- An increase in electromagnetic emissions or decrease in electromagnetic immunity may be seen if any accessory or replacement items other than listed in Section 4.8 is used.
- Devices connecting to the serial port must be compliant with IEC 60601-1-2, the EMC requirement for Medical Devices.
- Electrosurgical units or other devices that can spread electromagnetic waves may cause the skin temperature probe to detect a different value of temperature because of the absorbed electrical energy.
- Portable and mobile RF communications equipment may affect medical electrical equipment.
- Medical electrical equipment is subject to precautionary measures concerning electromagnetic compatibility. “EMC Declaration” is stated in Annex-A.
- Electromagnetic fields may result in malfunction of the device; therefore, it may endanger the patient. Electromagnetic field sources which should be separated from the device are given below;
  - Cellular phones
  - High-frequency electrosurgical equipment
  - Defibrillators
  - Shortwave therapy equipment

3.3.9. ANTI-STATIC WHEELS PRECAUTIONS

WARNINGS

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

3.3.10. EXPLOSION AND FIRE PRECAUTIONS

WARNINGS

- The infant incubator shall not be used in environments consist of easily flammable substances and gasses (such as anesthetic gasses) environments. It can lead to personal injury or equipment damage.
- The infant incubator shall not be cleaned with flammable substances, as even a small amount of flammable gas, such as ether and alcohol, remained inside of the infant incubator might cause fire when it meets with oxygen.
- During the cleaning and maintenance, oxygen supply of the incubator shall be turned off. When cleaning and/or maintaining is completed in an environment enriched with oxygen, the risk of fire and explosion might occur.
- All the ignition sources such as matches, lighter, electric stoves etc. shall be kept from the location of the incubator. Textile, oil and other flammable substances catch fire easily and burn intensively in air which is enriched with oxygen.
- The patient compartment shall be free of flammable agents.
- There should be an adequate ventilation in order to prevent the accumulating oxygen around the incubator in order to prevent a fire and explosion hazard.
- Oxygen connectors shall be free from grease and oil in order to prevent a fire and explosion hazard.
- During cleaning or maintenance procedures, if the device is powered on, a shock hazard may be occurred. So, the device shall be unplugged from its power source before cleaning and maintenance.
- Trendelenburg mechanism shall not be lubricated with flammable substances such as lubricants. Otherwise, the risk of fire is increased in environments enriched with oxygen.

3.3.11. HUMIDITY PRECAUTIONS

WARNINGS

- The water reservoir should be filled to the maximum filling limit line (1300 mL). In order to prevent water spillage or personal injury, the water reservoir of humidifier shall not be overfilled.
- All access panels should be closed and grommets should be connected to the canopy, otherwise, any open gaps in the canopy may reduce the internal relative humidity of the incubator and it leads to dehydration, respiratory distress and impaired thermoregulation of patients, especially for pre-matures.
- In high relative humidity conditions, evaporative heat loss of the neonates will reduce and it may cause an increase the temperature of the neonates. This effect is mainly seen on neonates who have very low birth weight and who are premature. The body temperature of the neonates shall be checked regularly. Otherwise, it can lead to an injury.

3.3.12. OXYGEN PRECAUTIONS

WARNINGS

- The misuse of additional oxygen can lead to severe side effects including blindness, cerebral damage and death. The dangers may vary according to the patient. The method of oxygen treatment, concentration and practice time shall be decided by the attending physician.
- When a high oxygen environment is required, analyze arterial gas levels repeatedly in order to maintain the oxygen concentration in the incubator at a desired level. Physician's instructions in measuring the oxygen concentration shall be followed because the risk of retinopathy of premature may increase by ignoring the essential requirements.
- Physician shall be contacted immediately in case of an emergency where an oxygen treatment is needed.
- The oxygen flow rates cannot be used as a right scale of the oxygen concentration in the incubator. The oxygen concentrations shall be measured with a calibrated oxygen analyzer regularly as stated by the physician.
- Expired air filter, may increase the oxygen concentration and cause carbon dioxide. The air filters shall be changed quarterly.
- The oxygen treatment may increase the noise level of the hood.
- The incubator should be disconnected from the hospital oxygen source when oxygen is not in use.
- In patient compartment, only electrical devices approved for use in an oxygen-enriched atmosphere shall be used.
- Auxiliary equipment which has a potential to spark shall not be placed in or beside of the infant incubator.
- It should be noted that oxygen delivered to the patient is not humidified.
- It should be ensured that grommets are properly installed and access panels are closed, otherwise any open gaps in the hood may result in reduce the incubator internal oxygen.
- Oxygen sensors is a sealed sensor which contains potassium hydroxide electrolyte. Therefore, in order to prevent death or serious injury, the following instructions shall be complied;
  - ✓ If there is a leak in the sensor, it should be discarded immediately.
  - ✓ Only Ertunç Özcan recommended oxygen sensors should be used.
  - ✓ If the oxygen sensor is contacted with the skin or clothing, the affected area should be rinsed with a large quantity of water.
  - ✓ If the oxygen sensor is contacted with eyes, minimum 15 minutes the eyes should be flushed holding the eyes open and the physician should be called immediately.
- Using poorly maintained oxygen components raises the likelihood of fire hazards and may result in severe injuries or fatalities. To ensure safety;
  - ✓ Gas/oxygen components should be regularly inspected during preventive maintenance intervals to check for corrosion or damage.
  - ✓ Oxygen cells should be examined routinely for any signs of degradation or leakage, and replace them as needed.
- It should be ensured that oxygen supplier system pressured should be **4-6 bar**.
- Oxygen use may increase the risk of fire. Materials that are compatible with oxygen and not flammable should be used with an oxygen system.
- The oxygen sensor shall not be touched while utilizing the trendelenburg mechanism.
- When oxygen is administered, an oxygen monitor should be used.

3.3.13. PRECAUTIONS FOR TEMPERATURE STABILIZATION

WARNINGS

- The set temperature cannot be achieved if the access panels are remained open due to the effect of environment temperature. For that reason, do not leave the access panels remained open more than needed. When the access panels are remained open the temperature values may not be reliable.
- The airflow pattern in the incubator may be altered due to the optional components or other unapproved accessories, otherwise the inside temperature of the incubator is going to change and homogenization will fail, so this may affect the skin temperature of the patient.
- Blocking the ventilation slots in the incubator while in clinical use may affect patient's safety and the incubator's performance.
  - ✓ It should be avoided that placing blankets, positioning aids, or cuddly toys that may obstruct the ventilation slots.
  - ✓ It should be avoided that inserting any objects into the ventilation holes or any other openings on the Magic Loggia Ultimate Infant Incubator.
- There is an air curtain higher than the typical incubator air temperature flowing along the length of the mattress toward the top of the access panel openings when the access panels are open. Therefore, the patient should be kept from this warm air curtain to prevent possible injuries.
- If surgical covers or blankets are used over the patient, it should be ensured that they do not interfere with the warm air curtain or side vents.
- A surgical cover or a blanket shall not be placed on the patient. The heat source may lead to injuries and burns.
- Direct sunlight or phototherapy devices and devices which produce similar heat can cause an increase in the temperature inside of the incubator to dangerous levels. This also may affect patient's skin temperature. Therefore, the incubator shall not be positioned in direct sunlight or under other sources of radiant heat.
- When using kangaroo mode, temperature of the patient may fluctuate outside the incubator, therefore the temperature of the patient should be monitored constantly.
- It should be ensured that all cables and hoses are routed correctly and safely.
- Critical care O_2 vital signs should be considered.
- To prevent the patient from overheating, the skin temperature must be monitored and checked in skin or air mode. The skin temperature sensor shall not be used as a rectal temperature sensor.

3.3.14. PRECAUTIONS FOR USING PHOTOTHERAPY DEVICE

WARNINGS

- Using phototherapy device with incubators may affect the temperature of hood wall, incubator and patient's skin. Therefore, while using phototherapy, incubator temperature and patient's skin temperature should be monitored.
- Phototherapy device should be positioned according to the manufacturer instructions.
- If the phototherapy device is positioned to the top of the hood, it may interfere with upward motion of device during the height adjustment. Therefore, the phototherapy device should be removed before positioning the device.

3.3.15. PRECAUTIONS FOR THE MOVEMENT OF THE INCUBATOR

WARNINGS

- Moving the incubator and the patient together is not recommended but if a situation is encountered that needs to be moved, two or more people are needed in order to have sufficient control of the incubator to prevent injuries and damage to the device.
- The patient should be checked if he/she is safe or not.
- All loose system components should be secured or removed before moving the incubator.
- The incubator should be at lower position.
- All drawers should be closed.
- All components should be removed from the rails.
- It should be ensured that the mattress is in flat position not in the Trendelenburg or Reverse Trendelenburg position.
- The canopy shall never be lifted when the patient is inside the incubator. The patient must always be reached through the front access panel.
- In case the wheels encounter any obstruction, moving the incubator sideways or at an angle (across its width) may lead to accidental tipping over. For safe movement, the incubator should be always pushed or pulled from the ends in a straight line.

3.3.16. PRECAUTIONS FOR TRENDELENBURG SAFETY

WARNINGS

- While positioning the mattress to trendelenburg position or reverse trendelenburg position, only one end of the mattress should be tilted instead of tilting both ends.
- Before placing the mattress in trendelenburg or reverse trendelenburg position, the patient's limb should be checked in order not to be squeezed between the mattress and the hood walls.
- The position of skin temperature probe should be checked while trendelenburg adjustment is activated.
- To prevent damages of things such as the patient access hoses, the hoses should be sufficiently extended by considering the existence of trendelenburg mechanism.

3.3.17. WEIGHING PRECAUTIONS

WARNINGS

- The trendelenburg mechanism must be positioned horizontal when weighing the patient.
- The mattress and the mattress tray should contact to the internal wall when weighing is completed.

3.3.18. SAFETY INSTRUCTIONS FOR ACCESSORIES

WARNINGS

- Using incompatible accessories may result in medical device failure and increase the risk of patient injury or property damage.
- Ertunç Özcan recommends using Magic Loggia Ultimate only with the compatible accessories listed in Section 4.8, the compatibility of which has been tested by Ertunç Özcan in accordance with the relevant standards.
- Single-use components or accessories should not be used if packaging is damaged.
- Since disposable products are designed for one-time use only, reusing, reprocessing or sterilizing them may cause a failure of the device or patient injury.
- For installing the accessories instructions given in Section 4.8 should be followed otherwise it may lead to device failure.

- There should be a safe connection between the accessory and the device. Otherwise, incorrect installation of accessories may lead to endanger the hygienic safety.
- Appropriate accessories should be chosen from the Accessory List given in Section 4.8 regarding of the patient's birth-weights.
- The installation of the cover to the mattress shall be checked before each use and reusing after cleaning.
- Instructions given in Section 12 should be followed for the cleaning and reprocessing of reusable accessories.

3.3.19. CYBERSECURITY PRECAUTIONS

WARNINGS

- Default passwords must be changed immediately.
- Software and firmware should be kept up to date.
- The infant incubator should be monitored regularly for unusual activity.
- All related intended users should be trained about cybersecurity risks.
- Caution with unsolicited communications should be exercised.
- Any suspicious activity should be reported to Ertunç Özcan Technical Service Department immediately.

3.3.20. PRECAUTIONS FOR VOLATILE ORGANIC COMPOUNDS (VOCs)

WARNINGS

- In order to remove contaminants from interior of the incubator, an effective ventilation system should be used to increase air circulation inside the incubator.
- Air purifiers with HEPA filters which are particularly effective at removing VOCs and other contaminants should be used to improve interior air quality of incubator.
- The incubator should be cleaned regularly with low VOC cleaning materials and solutions.
- After cleaning, the incubator should be well ventilated and dried before reuse. This can help reduce VOC levels in the incubator.
- The use of products containing formaldehyde, cyclohexanone or other VOCs in or near the incubator should be avoided. This will provide a safer environment for the patient.

NOTE
The main material of the Magic Loggia Ultimate infant incubator is SABIC CYCOLOY FR RESINS C6200, which is FDA approved and VOC free.

3.4. TARGET GROUPS FOR MAGIC LOGGIA ULTİMATE

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

TARGET GROUP	TASK	COMPETENCY
Physicians and Nurses	Use of the product in accordance with the intended use	Physicians and nurses who have medical knowledge in neonatology or in the use of device
Reprocessing Personnel	Cleaning and Reprocessing	Biomedical Engineers who have knowledge in the reprocessing of medical devices

Technical Service Personnel	• Installation • Maintenance • Inspection • Repair	• Biomedical Engineers experienced in the servicing of medical devices • If complex service is required, special knowledge in electrical engineering and mechanics

3.5. TRAINING

- The 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 user manual gives instructions about the usage, cleaning, maintenance, and troubleshooting of the Ertunç Özcan Brand Magic Loggia Ultimate Model Infant Incubators. The manufacturer is not responsible for improper performance of the incubator if the user does not operate the unit in accordance with the instructions, does not follow the maintenance recommendations in Chapter 12 of this manual, or repairs with unauthorized parts. Calibration and repair should only be done by qualified service personnel.
This user manual must be read and clearly understood by the ones who are going to use the incubator.
This user manual must be kept somewhere easily accessible by the ones who will be using the incubator.
In case of further clarification needs regarding any stated information in this manual, please contact with relevant ERTUNÇ ÖZCAN personal.

4.2. EXPLANATION

The air circulation system of the incubator provides; a determined temperature control, proper temperature spread, humidity, affective protection of the patient from dirt carried by the air and controls the oxygen concentrations.

Access to the patient shall be conducted by means of access panels. When the access panel is open; hot air flows from under the front part of the mattress towards above the access panel, this air minimizes the temperature of the canopy environment to decrease.

The incubator is manufactured to operate in normal temperature environments between 20˚ and 30˚C under normal conditions.

In Magic Loggia Ultimate Model Infant Incubators, skin or air temperature control is chosen from the control module.

4.3. INTENDED USE OF THE DEVICE

The Magic Loggia Ultimate is an incubator 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)

Infant incubators are used to provide a controlled and supportive environment for infants or newborns with medical conditions that require temperature regulation; especially temperature control in neonatal hypothermia, prevention of body temperature drop shortly after birth, pre-operative and post-operative intensive care in neonatal surgery, humidity control and protection from infection. The primary goal is to create an environment that mimics the conditions in the mother's womb, facilitating the patient's growth and development while providing necessary medical care.
Therapy system for infants and neonates is up to a body weight of 10 kg or a body length of 55 cm.

4.4. TWINS IN MAGIC LOGGIA ULTIMATE

Twins can take therapy simultaneously by placing them in a single Magic Loggia Ultimate infant incubator, if there are no medical objections. For the therapy of twins, the total body weight is limited to 10 kg. During the treatment of twins together, Magic Loggia Ultimate shall be operated in Air Control Mode.

Post-natal separation trauma can be prevented by treating twins together in a single incubator. Additionally, direct skin contact between them can have positive effects on the therapy of both. The risk of overheating shall be considered due to warming mutually each other by physical contact and if necessary, the incubator air temperature may have to be reduced.

While operating in air temperature mode, the first patient can be monitored by Skin 1 Probe and the second patient can be monitored by Skin 2 probe.

WARNING

- The patients could have danger of hypothermia or overheating due to warming mutually each other by physical contact. For twins, the air temperature control mode shall be used.
- For X-Ray imaging, the appropriate protective precautions should be taken and instructions of physicians should be followed. It is recommended that one of twins be removed from the incubator to avoid high dose exposure during X-Ray imaging.

CAUTION

- There is a possible cross infection risk for twins when treating them in a single incubator.
- The risk of confusing the patients during administering medicines or foods should be paid attention.
- If different ambient temperature or air with different oxygen or humidity saturation levels is required by twins, twins should be treated in two separate incubators.

4.5. ENVIRONMENT OF USE

The usage of Ertunç Özcan Magic Loggia Ultimate incubator 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.
Magic Loggia Ultimate is not intended for home use.

4.6. INDICATIONS, CONTRAINDICATIONS, SIDE EFFECTS AND WARNINGS

Magic Loggia Ultimate incubator is generally indicated for thermoregulation and controlling oxygen, and humidity.

4.6.1. INDICATIONS

- The infants who are at risk for excessive temperature loss.
- Premature or low birth weight infants who require a controlled environment to maintain body temperature and reduce the risk of hypothermia.

- Neonates with specific medical conditions, such as jaundice, where phototherapy can be integrated into the incubator design.
- Infants with respiratory distress or breathing difficulties who may benefit from the warm and humidified air provided by the incubator.
- Infants needing protection from infections or other environmental factors, such as noise and excessive handling.
- The neonates or infants who have a severe disease and requires close observation.
- The neonates or infants who are unable to complete gestational period.
- The neonates or infants who have heart failure or symptomatic arrhythmia.
- The neonates or infants who have sepsis with signs of systemic infection.

4.6.2. CONTRAINDICATIONS

- Congenital anomalies incompatible with life
- Premature without viability (< 400 g and < 23 weeks of gestation)
- Infants with unstable vital signs or severe medical conditions that require immediate, intensive intervention and monitoring in a specialized intensive care unit.
- Infants with conditions that necessitate continuous or frequent access for medical interventions, as incubators can limit easy access to the patient.

4.6.3. SIDE EFFECTS

- The patient may be disturbed by the noise from the incubator.
- The patient may have irregular oxygen source.
- Prolonged exposure to humidity and heat in the incubator can cause to skin breakdown or pressure sores if the patient's skin is not properly cared for.
- Excessive heat and humidity in the incubator can lead to increased fluid loss through sweating, which can cause dehydration in premature infants.
- The closed environment of the incubator can be a breeding ground for bacteria if not properly disinfected, potentially leading to infection.
- Infants can become overheated if the incubator temperature is not properly regulated, leading to dehydration and other complications. Conversely, if the incubator is not set to the proper temperature, infants may become too cold, increasing the risk of hypothermia.
- Retinopathy of prematurity (ROP) is a condition that can occur in premature infants, especially those who require oxygen therapy while in the incubator. The use of oxygen must be carefully monitored to minimize the risk of ROP.

4.6.4. ADVERSE EFFECTS

- Separating the patient from the mother where it is more difficult to maintain patient’s body temperature constant may have an adverse effect of the building attachment between the mother and the patient, and on the breastfeeding the patient by the mother.

4.7. FEATURES

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

The use of the inlet panels or other equipment the incubator that can change the pattern of air flow may affect the temperature pattern, temperature variation, the relationship between the incubator temperature relative to the core cushion temperature, and the patient’s skin temperature.

4.7.1. CLASSIFICATION OF DEVICE

CLASSIFICATIONS	Class II b

4.7.2. STANDARDS

Designed in accordance with the requirements below stated standards	
EN 60601-1:2006	Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance
EN 60601-1-2:2015	Medical Electrical Equipment – Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Disturbances – Requirements and Tests
EN 60601-1-6:2010	Medical Electrical Equipment – Part 1-6: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Usability
EN 60601-1-8:2007	Medical Electrical Equipment – Part 1-8: General Requirements for Basic Safety and Essential Performance – Collateral Standard: General Requirements, Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems
EN 60601-1-10:2008	Medical Electrical Equipment – Part 1-10: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Requirements for the Development of Physiological Closed-Loop Controllers
EN 60601-2-19:2021	Medical Electrical Equipment – Part 2-19: Particular Requirements for the Safety of Infant Incubators
EN 60601-2-19- A11:2021	Medical Electrical Equipment – Part 2-19: Particular Requirements for the Basic Safety and Essential Performance of Infant Incubators
EN 62366-1:2015	Application of Usability Engineering to Medical Devices
EN 10993-1:2020	Biological Evaluation of Medical Devices-Part 1-Evaluation and Testing
EN ISO 14971:2019	Medical Devices-Application of Risk Management to Medical Devices
EN 62304:2006	Medical Device Software-Software Life-Cycle Processes
EN62304:2006/A1:2015	Medical Device Software-Software Life-Cycle Processes
EN 1041+A1:2013	Information Supplied by the Manufacturer with Medical Devices
EN ISO 80601-2-56:2017	Medical electrical equipment - Part 2-56: Particular requirements for basic safety and essential performance of clinical thermometers for body temperature

4.7.3. ELECTRICAL FEATURES

Power Requirements	230 (±10%) VAC, 50/60 Hz, 800 W, max 5 Amp
	110 (±10%) VAC, 50/60 Hz, 800 W, max 10 Amp

4.7.4. BATTERY FEATURES

Battery Type	Li-ion 18650
Battery Capacity	3.7 V, 2200 mAh
Full Charge Time	48 hrs
Device Operating Time When Fully Loaded	45 min
Low Battery Alarm and the Remaining Operating Time of the Device After Alarming	35% low battery level The device can work for 15 min in a low battery.

4.7.5. INCUBATOR FEATURES

Incubator External Dimensions	141 (H) x 104 (W) x 64 (D) cm (±2cm)
Incubator Weight	~100 kg
Panel Input	85 (W) x 34 (H) cm (±1cm)
Patient Tray	80 (W) x 40 (H) cm (±1cm)
Weighing Capacity	10 kg
The Mattress Curve (Trendelenburg)	Between 0˚ and 12˚
The Pulling Out Length of The Mattress	24 cm
Noise Level in The Canopy Environment	≤49 dBA
(In an environment noise below 39 dBA and 10 cm above the center of the patient's mattress, typically less than 42 dBA)	
Noise Level in The Canopy Environment with Oxygen	≤50 dBA
Servo oxygen system operates at 65% oxygen, under ambient noise less than 39 dBA and above the center of the patient mattress, typically less than 50 dBA.	
Cable and Grommets	10 pcs
QT Windows	6 with lids (iris)
Air Filter	<0,5 µ
In-Cab Air Flow Rate	<10 cm/sec

4.7.6. CONTROL OF AIR TEMPERATURE AND SKIN TEMPERATURE

Air Mode Range	20°C – 37°C
	37°C – 39°C exceed mode
Air Temperature Sensor Measurement Accuracy	±0.4°C
Air Temperature Sensor Control Accuracy	±0.5°C
Air Temperature Sensor Measurement Range	17°C - 47 °C
Skin Mode Range	34°C – 37°C
	37°C – 38°C exceed mode
Indication Sensitivity	0.1°C
Skin Temperature Sensor Measurement Accuracy	±0.1°C
Skin Temperature Sensor Control Accuracy	±0.3°C
Skin Temperature Sensor Measurement Range	17°C - 47 °C
Short Cut Set Buttons for Air Mode	30°C, 32°C, 34°C, 36°C
Short Cut Set Buttons for Skin Mode	34°C, 35°C, 36°C, 37°C
Stage Setting	0.1°C / 1°C
Warm-up Time	22 min

4.7.7. SERVO CONTROLLED OXYGEN MODULE (OPTIONAL) FEATURES

Oxygen Function Range	21% –65%
Oxygen Indication Sensitivity	1%
Short Cut Set Button for Oxygen	35%, 45%, 55%
Accuracy of Oxygen Control	± 5%, 21% Cal
Oxygen Measurement Range	15% - 99%
Inlet Pressure Range	4-6 bar (60-90 psi)
O_2 Sensor Operational Temperature Range	20°C - 41°C
Stage Setting	1% / 5 %

4.7.8. SERVO CONTROLLED HUMIDITY UNIT (OPTIONAL) FEATURES

Humidity Control Range	20% –95% (Display range on screen: 15%-99%)
Sensitivity of Humidity Indication	1%
Short Cut Set Button for Humidity	40%, 60%, 80%
Accuracy of Humidity Control	±10% RH
Accuracy of Humidity Measurement	± 3% RH
Maximum Humidity	>90% (when the set temperature inside the incubator is 39° C)
RH Sensor Operating Temperature Range	20°C – 41°C (68°F - 106°F)
Capacity of the Humidity Reservoir	1000 mL (0.26 gal)
Stage Setting	1% / 10%

4.7.9. CARBONDIOXIDE LEVEL

Maximum CO_2 Concentration	≤ 0.5 %

4.7.10. SCALE (OPTIONAL) FEATURES

Scale Weighing Range	0 – 9999 gr
Scale Sensitivity	1 gr
Accuracy of the Scale	500 gr ± 20 gr
	2000 gr ± 30 gr

4.7.11. HEIGHT ADJUSTMENT (OPTIONAL) FEATURES

Incubator Height	141 cm ± 2 cm
Height Adjustment Range	Lowest canopy 132cm (±1cm)
	Highest canopy 152cm (±1cm)
	Lowest with a side monitor 162 cm (±1cm)
	Highest with a side monitor 182 cm (±1cm)

4.7.12. ENVIRONMENTAL OPERATION TERMS

Operating Temperature Range	Environment between +20˚C and +30˚C
Storage Temperature Range	Environment between -20˚C and +60˚C
Operating Humidity Range	Between 5% and 85% Relative Humidity Non-condensable
Storage Humidity Range	Between 5% and 85% Relative Humidity Non-condensable

4.7.13. IP PROTECTION CLASS

IPX0	It is not protected against water and dust.

4.7.14. SOFTWARE FEATURES

Languages	Turkish, English

4.7.15. DISPLAY PANEL SCREEN FEATURES

Parameters monitored on 10” TFT Touch screen indicators:

- Temperature Value of The Set Operating Mode
- Measured Air Temperature
- Measured Skin1 Temperature
- Measured Skin2 Temperature - Optional
- Set Humidity Rate - Optional
- Measured Humidity Rate - Optional
- Set Oxygen Rate – Optional

Graphical and Numerical:

- Measured Oxygen Rate – Optional
- Menu Settings
- Alarm
- Error Messages
- Time and Date
- Weighing Results – Optional
- Memory – Trend Information – Optional
- Notes

4.7.16. MEMORY (TREND) FEATURES (OPTIONAL)

Graphically and/or numerically monitored parameters in the memory:

- Air
- Set
- Skin1 Temperature
- Skin2 Temperature
- Humidity Range
- Oxygen Range
- Scale
- Heater

4.7.17. SYSTEM CONTROL

- Microprocessor Control and Automatic Self-Test Feature
- Alarm Indicator Light Control Module
- Alarm Silence

4.7.18. STANDARD FEATURES

- 79 cm x 39 cm Wipeable and Waterproof Mattress
- Reusable Skin Temperature Probe
- Antibacterial Air Microfilter
- X-Ray Tray
- Air Curtain That Activates When the Access Panel is Opened
- Sterilizable / Autoclavable Water Reservoir in Humidifier
- Auto For Accessory Use in The Cabin Closable Inputs

- Double Wall
- Front and rear cover that can be opened 180 ° downwards

4.7.19. OPTIONAL FEATURES AND ACCESSORIES

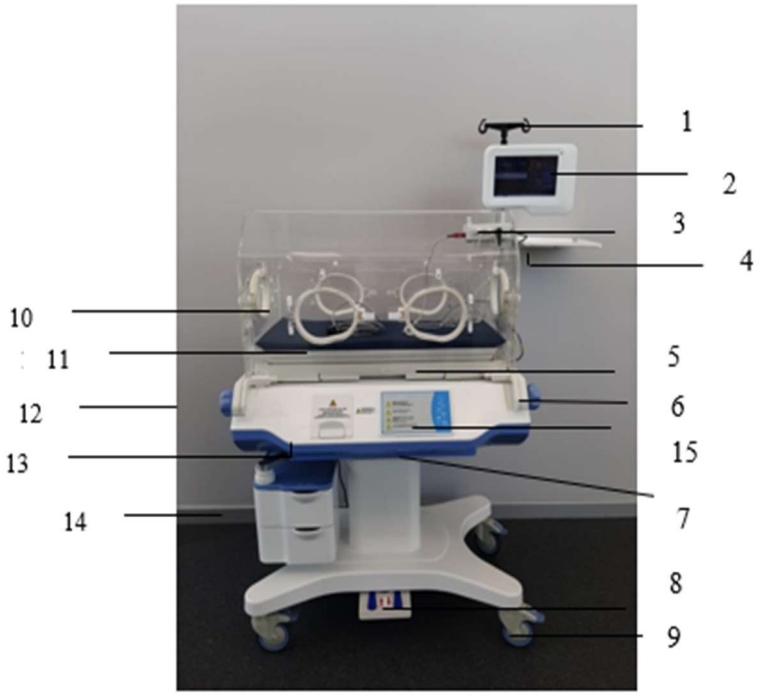
OPTIONAL FEATURES

- Digital balance
- Height adjustment
- Aspiration unit
- Flowmeter unit
- Servo controlled oxygen system
- 360º rotatable drawer (1/2/4 Drawer options are optional) (Right and / or left side)
- Movable resistance
- Condensation system that transfers the water vapor formed in the device under high temperature and humidity to the jar outside the system
- Automatic Humidity Mode
- Audible and light alarm in case the incubator covers are left open

ACCESSORIES

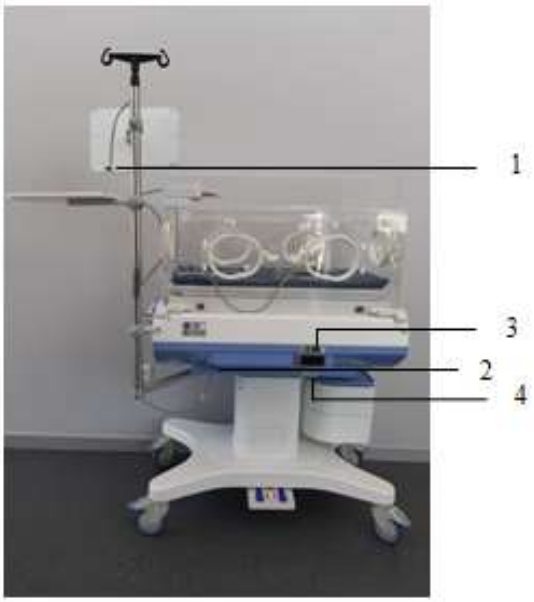
- Oxygen sensor
- Reusable skin temperature probe
- Disposable skin temperature probe
- Air filter

Figure 1: Magic Loggia Ultimate Model Infant Incubator



No	Explanation
1	IV Pole
2	Display Panel
3	Sensor Module
4	Monitor Tray
5	X-Ray Tray
6	Canopy Handle
7	On/Off Key
8	Height Adjustment Pedals
9	Wheels
10	QT Window
11	Mattress
12	Trendelenburg Handle
13	Humidifier
14	360º Rotating Drawer
15	Control Module

Figure 2: Magic Loggia Ultimate Model Front Side



No	Explanation
1	Data Cable Display Panel Input
2	Data Cable Incubator Input
3	Electric Power Group
4	Oxygen Input

Figure 3: Magic Loggia Ultimate Model Back Side

4.8. ACCESSORIES LIST

TYPE	MAKE / MODEL	PATIENT CATEGORY
Reusable Skin Probe	Tarry Medical Products Model Number: T-20970	For target patient population
Disposable Skin Probe	Tarry Medical Products Model Number: T-100	For target patient population
Oxygen Sensor	Analytical Industries Inc. Part Number: PSR-11-917-MH1	For target patient population
Air Filter	Air Safety Ltd.	For target patient population
Foam Mattress Textile	Gentuğ Textile	For target patient population

5. INSTALLATION AND CONTROL OF THE SYSTEM

WARNING

- Before using the incubator make sure to read this user manual. Using the incubator without understanding the whole user manual may cause injury of the patient or the user.
- When unpacking the equipment, be careful not to damage or scratch the sensitive unprotected surfaces. Personal injury or equipment damage may occur.

5.1. MECHANIC CONTROL

For the control process, the steps mentioned below should be followed;

- Unplug the power cable.
- Check if the power cable has any damages. If there is a damage, change the cable.
- Check all the parts of the installation. Make sure that there are no missing or damaged parts.
- Check the wheel movements. Make sure that the incubator is balanced and stable when the wheel lock is activated and can steer without any trouble when the wheel lock is deactivated.
- To check whether the wheels are loose or not, lift each end of the incubator and check every wheel with your hand. This checking action must be done with two people. There is a risk of the incubator falling over if the wheels are loose. The incubator shall not be used unless the loose wheels are changed.
- Make sure that the access panels (front and rear) are working properly.
- Make sure that the access panels (front and rear) are closed.
- Check the QT Windows and open by pressing the latch down. The access panel should be opening by itself. Close the QT windows and make sure that the latches close the panels safely.
- Make sure the Trendelenburg mechanism is working safely and the mattress is stabled when this mechanism is in use.
- Put water into the water reservoir of humidifier for breaking and cracking. Check if water reservoir removes easily or not.
- Check 360º Rotatable Drawers. Comply with the maximum weight value specified in the drawer.

5.2. CONTROL OF THE MEASURING MODULE

For the control process, the steps mentioned below should be followed;

- Make sure the power cable is connected to the switch and the device.
- Check the connections of the measuring module.
- Connect the skin probe to the skin-1 entry of the measuring module.
- Operate the device by using the On/Off buttons. After turning on the device, the system controls itself by its own self-test therefore you have to wait for the test to be completed.
- Make sure that the skin probe is working properly, to do this heat the skin probe with your hand and watch the alteration of the skin temperature showing on the screen.

5.3. CONTROL OF THE ACCESSORIES

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

6. FUNCTIONAL EXPLANATION

6.1. GENERAL

This chapter contains a general explanation about the Magic Loggia Ultimate Model incubators.

6.2. FUNCTION EXPLANATION

The concentration of temperature, humidity and oxygen is controlled by a forced air circulation system. Peripheral air is drawn into the system by a motor-driven fan through an air absorption filter. At the same time, some of this air, which has been driven into the canopy, flows over the heater by being absorbed by a fan. The air enters the canopy through channels in the main frame. It then passes through the front and rear inner walls.
When the access panels are open, a warm heat wave is created and continues to flow upwards through the open panel. This wave minimizes the air temperature when the front and/or back of the incubator is cooled. Air or skin temperature can be selected by the user to control the temperature of the incubator.

6.3. AIR CIRCULATION SYSTEM

The air circulation system of the incubator provides; a determined temperature control, proper temperature spread, humidity, affective protection of the patient from dirt carried by the air and controls the concentrations.

Access to the patient shall be conducted via access panels. When the access panel is open; hot air flows from under the front part of the mattress towards above the access panel, this air minimizes the temperature of the canopy environment to decrease.

The incubator is manufactured to operate in normal temperature environments between 20˚ and 30˚C under normal conditions.

6.4. TEMPERATURE REGULATION

Temperature is regulated by using either incubator air temperature or patient’s skin temperature.

The front panel keys enable the user to select the desired mode. In any mode of operation, the heater output is proportional to the amount of heat required to maintain the desired temperature.

The temperature in the incubator can be controlled using one of two modes: **Air Mode** or **Skin Mode**.
The incubator has double walls to maintain the patient's thermoregulation.

6.4.1. AIR CONTROL MODE

In Air Control Mode, the incubator air temperature is controlled to maintain the desired patient temperature. The air temperature is then adjusted based on the patient's needs and clinical status.

The Air Temperature panel is activated by pressing the Air indicator on the main page. The air temperature panel contains temperature settings, one-touch set points, and buttons to turn air mode on and off. In air mode, the air temperature can be maintained between 20°C and 37°C. In temperature override mode, the temperature can be maintained between 37°C and 39°C.

The incubator air temperature is monitored by a temperature sensor located in the sensor module and compared to the set air temperature. The information from this temperature sensor is fed to the heater control circuit which regulates the heater output to maintain the air temperature set point. The actual air temperature is displayed on the air temperature panel, which is activated by pressing the air indicator located on the main screen. A second thermistor in the air temperature sensor acts as a backup to limit the maximum incubator temperature. When the high temperature limit is reached, the heater shuts off.

WARNING

- Thermoregulation for low birth weight (less than 2.500 g), very low birth weight (less than 1.500g), extremely low birth weight (less than 1.000 g) who are highly vulnerable due to their underdeveloped organ systems and preterm (less than 37 completed weeks) who encompass a wide range of gestational ages and weights, but generally share characteristics of being underdeveloped and at risk of thermal instability require extreme precision and control. The incubator cannot differentiate between an increase in the core temperature and cold skin (fever) and low core temperature (hypothermia). Therefore; the risk groups of neonates mentioned above and infant's core temperature shall be monitored with a separate calibrated thermometer. Otherwise, the neonate / infant could be injured.

CAUTION

- The gestational age and weight of the patient should be considered when setting the incubator air temperature. Preterm infants may have different thermal needs depending on their stage of development.
- Disinfection methods mentioned in Section 12 shall be implemented to prevent the spread of pathogens within the incubator. Regular cleaning and disinfection of the incubator and its components can help reduce the risk of hospital-acquired infections.

6.4.2. SKIN CONTROL MODE

Pressing the skin indicator located on the main page will open the skin temperature panel. Temperature settings, one touch set values and switch to skin mode buttons are found on the skin temperature panel. In skin mode, the controller is used to set the skin temperature at 34°C to 37°C. In temperature override mode, the temperature can be selected at 37°C to 38°C. A skin temperature probe is attached directly to the skin of the patient. The information from the probe is supplied to the heater control circuitry, which proportions the heater output to maintain the skin set temperature. The air temperature is still shown in skin temperature mode, but for information purposes only. If the air temperature mode is selected while the skin temperature probe remains connected, the skin temperature parameter continues to display the actual skin temperature. However, it does not control the incubator temperature. The sensor module is equipped to accept 2 skin temperature probes.

WARNING

- The low birth weight (less than 2.500 g), very low birth weight (less than 1.500 g), extremely low birth weight (less than 1.000 g) and preterm (less than 37 completed weeks) / infant's core temperature shall be monitored with a separate calibrated thermometer. Otherwise, the neonate / infant could be injured.
- The skin temperature sensor is not a clinical thermometer, so check the neonate / infant's core temperature regularly using an independent thermometer.
- If the skin temperature sensors are wet, the patient may become too hot or too cold. Only dry skin temperature sensors shall be used.
- The skin temperature sensor shall not be used as a rectal temperature sensor. If the rectal temperature is measured with the skin temperature sensors, the device displays incorrect values or regulates the temperature based on incorrect values.

CAUTION

- It is important to ensure that the skin temperature sensors are positioned correctly on the patient's skin to ensure accurate measurements. Incorrect placement could result in inaccurate temperature readings and affect the incubator's temperature control response.
- The patient's skin should be monitored for any signs of irritation, redness, or pressure points resulting from the placement of the sensors. Sensors should be repositioned periodically to prevent skin damage.

6.5. UTILIZATION OF SCALE (OPTIONAL)

A built-in scale which can be monitored from the display panel can be attached to the incubator.
Select the scale mode from the function button.
Push "Tare Function" button to take tare.
For further information see Section 9.2.6.3.

IMPORTANT

The calibration process must be repeated for every cleaning procedure.
The calibration process must be repeated for every patient.

WARNING

- During the weighing process the mattress and the mattress tray should not be contacted to the internal wall of the hood.
- The Trendelenburg mechanism must be horizontal and at the lowest level during weighing procedure.

6.6. USE OF THE VERTICAL HEIGHT ADJUSTMENT (OPTIONAL)

Height adjustment feature can be added to the incubator.

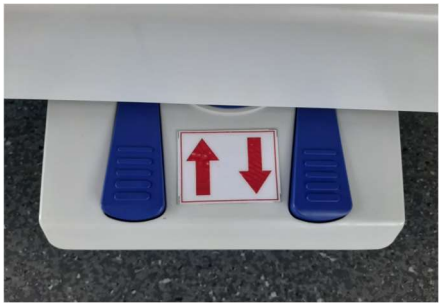


Figure 4: Vertical Height Adjustment Pedals

To raise the height of the incubator, press onto the up arrow. To lower down the height of the incubator, press onto the down arrow.

WARNING

- Adjust the height of the incubator before using it. Otherwise, it may cause injury to the patient or the user.

7. USAGE OF THE MAGIC LOGGIA ULTİMATE DISPLAY PANEL

7.1. DISPLAY PANEL INTERFACE

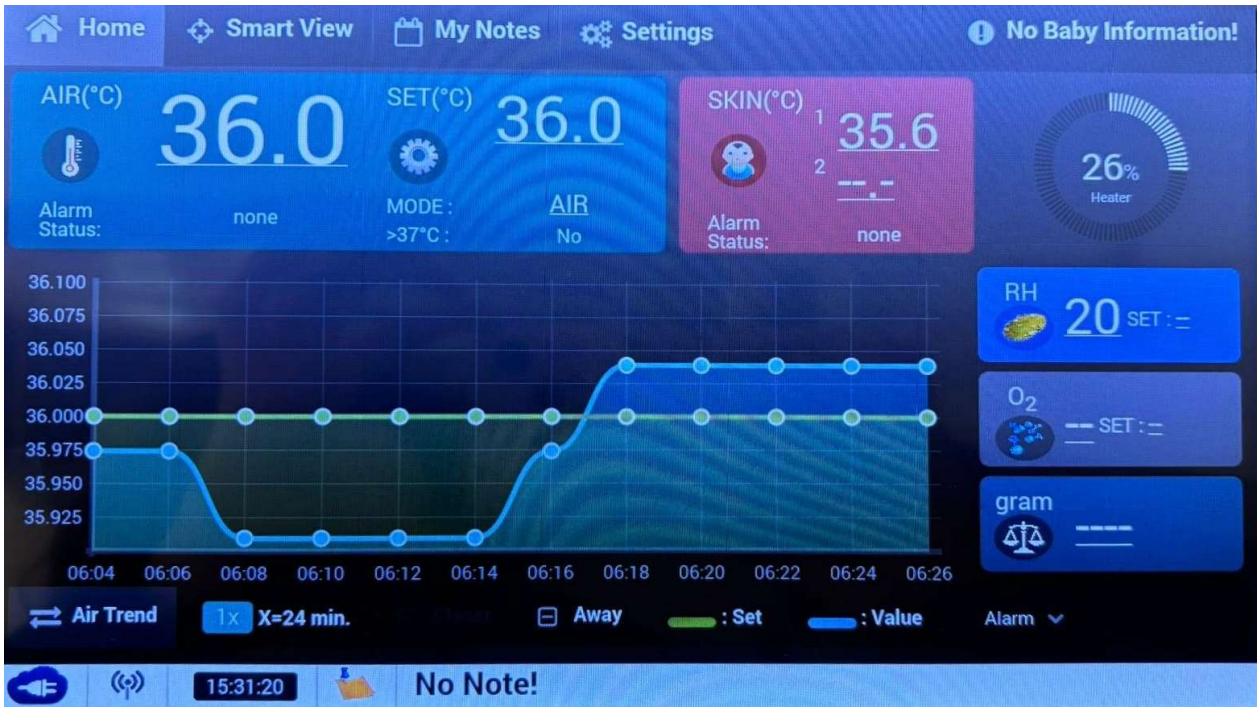


Figure 5: Front View of the Electronic Display Panel

The display panel provides all the incubator settings and their monitoring. Functions are explained in detail, in Section 9.

7.2. ELECTRIC POWER ASSEMBLY

Figure 6: Electric Power Assembly

Equipotential grounding tip to be used in the incubator, 1 AC power input, 2 AC power outlets, two fuse holders are as shown in Figure 6. Two 5A fuses can be easily replaced by pushing out of the notch part of the 250 V 5A fuse holder.

7.3. SENSOR MODULE ENTRY

Figure 7: Sensor Module Entry

To connect the sensor module to the control module, connect the module cable to the sensor module entry. When inserting the cable, place it according to the arrow mark on the connector. (Figure 7)

7.4. THE VIEW OF SENSOR MODULE

Figure 8: The View of the Sensor Module and Sensor Inputs

Air/Humidity Probe: Probe that measures the amount of air and humidity in the incubator.

Skin-1: Shows the connection point for the Skin 1 Probe.

Skin-2: Shows the connection point for the Skin 2 Probe

Skin-1 and Skin-2 Probe: To measure the patient's skin temperature, skin probes must be connected. For the incubator to operate in skin mode, the Skin 1 probe must be connected.
To measure the second patient's skin temperature, the Skin 2 probe must be connected.
Skin mode will only operate when the Skin 1 probe is connected. Skin mode will not operate if Skin 1 probe is not attached and Skin 2 probe is attached and it will activate ''Connect to Skin-1 probe input'' alarm.

Alarm Sensor: In case of alarm situation, a red light will illuminate on the light indicator located on the sensor module. The light is turned off by the system when the problem is resolved.

Scale: Shows the connection port for the scale module.

Scale Module Input: To measure the patient's weight, the scale and sensor module must be connected. If the connection is not made, the scale function keys will not be active. If the connection is not made, a "No Weight Sensor" warning is activated when the scale function key is pressed.

8. OPERATION OF THE CONTROL MODULE

8.1. OPERATION

To operate the device, the power cable should be plugged through power port on the electronic control panel and the socket.

IMPORTANT
Make sure the electrical features are provided as stated in product features.

It should be ensured that the supplied accessories are connected to the locations shown in Figure 8. The device is operated by pressing the On/Off key located on the control module (Figure 9) and on the power supply unit (Figure 6).

Figure 9: On / Off Key of Control Module

When first activated, the screen will be as shown in Figure 10 upon completion of the self-test.

Figure 10: Screen View After Activation

The device is designed to display all the data on one screen. Set values, read outs, trend data, all the alarm lists and menus can be seen on one screen.

8.2. IN CASE OF POWER FAILURE

In case of a power failure, the battery of the device will be activated.
An audible alarm will sound and the information line will display ''POWER FAIL''. The audible alarm can be turned off by pressing the alarm silencing button. If the alarm condition continues, after 15 minutes, the audible and visual power failure alarm is activated again and warns the user. The written notice will stay on the screen until the power is back again. In this case, it is possible to follow the measured values without using the keys and can keep the device under control for 45 minutes just for monitorizing. The alarm which has been turned off will later be shown under the alarm title.

Measurements recorded prior to the power cut will not be deleted during the power failure and these measurements will keep being recorded. When the device gets the power again the ‘‘POWER FAIL’’ warning will disappear and the normal activation functions of the device will start again.

The device keeps the set values during the operating time of the battery that is activated after the power failure, but when the battery life ends, the device shuts down completely and when it is reconnected to the power supply, the device restarts at the default settings specified below.

System Configuration Menu Items	Setting Options	Default Settings
Humidity Option	Yes / No	No
Oxygen Option	Yes / No	No
Skin Control Mode	Yes / No	No
Air Control Mode	Yes / No	Yes
Skin Temperature Difference	Yes / No	No
Weight Units	Lbs / kg	kg
Temperature Units	°F / °C	°C
Air Set Temperature	20°C to 37°C (Increments of 0.1°C)	34°C
Altitude	0 ft to 12,000 ft (0 to 3657 m) (Increments of 2000 ft)	0 ft (0 m)
External Interface	Serial Data	No
Language	Turkish, English	Turkish
Display Color	Multi Color	Multi Color

CAUTION

- In case of power failure, check whether the set values are maintained while the device is running on battery.

NOTE

When the battery life is over and the device is completely turned off, the set values should be adjusted again after reconnecting to the power supply.

9. FUNCTION MENUS

9.1. LOGIN PAGE

Figure 11: Login Page

New Baby: This function button provides access to the page where the patient's name, date of birth and sex will be entered. The information entered is displayed on the right side of the main page.
Previous Baby: When the unit is turned off and on again, this function button returns the patient's name, date of birth, and sex information for the newborn being treated.
Skip This Step: This function button provides access to the main page, which displays the patient's name, date of birth, and gender. A ''No Baby Info!'' message is displayed at the top right of the main page.

9.2. MAIN PAGE

Figure 12: Main Page

Header information; provides the required indicators needed to set the main page, smart screen, notes and setting information.
Footer information; shows the power situation, Wi-Fi, time and note information.

9.2.1. AIR MODE

The Air Temperature panel is activated by pressing the Air indicator located on the Main Page (Figure 12). The air temperature panel has temperature settings, one-touch Set Values, and Go to Air Mode and Switch to Air Mode buttons.

In this mode, the air temperature is kept between 20°C and 37°C (Over Temperature Limit Mode between 37°C and 39°C).

The desired air temperatures are set from, temperature settings “0.1˚C+”, “1.0˚C+”, “1.0˚C- ”, “0.1˚C-”. One touch set values “30˚C”, “32˚C”, “34˚C”, “36˚C”.

Switching to “Set Air Mode” can be done by pressing the switch to air mode while the incubator is operating on skin mode. If the switch to “Set Air Mode” button is pressed while the incubator is operating on air mode it will appear as ‘‘ALREADY IN AIR MODE’’ notice.

r

Figure 13: Air Mode

If it is desired to go above 37˚C of the air mode, the ">37˚C" button (Figure 14) located on the air temperature panel must be pressed. Once the button is pressed, the temperature can be increased and the ">37˚C" button will disappear and a ">37˚C" display will appear in the footer (Figure 15).

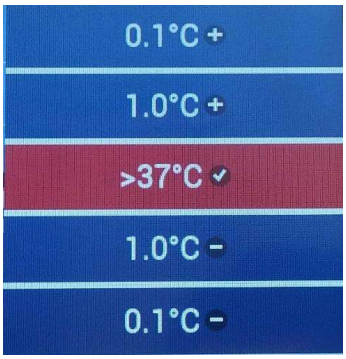


Figure 14: Override Rate 37˚C (99 °F)

Figure 15: Footer

9.2.2. SKIN MODE

Pressing the Skin button on the Main Page opens the Skin Temperature Panel (Figure 16).
Temperature settings, one-touch set values, and buttons for switching to skin mode are located on the Skin Temperature Panel.
In this mode, the skin temperature of the patient is kept between 34°C and 37°C (Over - Ride Temperature Limit Mode between 37°C and 38°C).

A temperature recognizing probe is attached directly to the patient's skin. The temperature of the patient read by the probe and the skin temperature that has been set up is shown together on the control mode screen. When the skin mode control is activated, the temperature value that has been set, does not control the air temperature, however the air temperature is still shown on the control module. When the air mode control is selected while the skin sensors are attached to the patient, the patient's skin temperature sensor will continue to show the actual skin temperature but it will not be able to control it.

The desired skin temperature can be set from temperature settings **"0.1˚C+", "1.0˚C+", "1.0˚C-**". One touch set values **"34˚C", "35˚C", "36˚C", "37˚C"**.
Switching to skin mode while the incubator is operating on air mode is done with the switch to "Set Skin Mode" button. If the switch to skin mode button is pressed while the incubator is operating on skin mode it gives a ''ALREADY IN SKIN MODE'' notice.
If the sensor is disconnected during the skin mode control, the patient skin temperature display will not show any value and the ''Skin-2 probe not connected'' alarm will be activated.

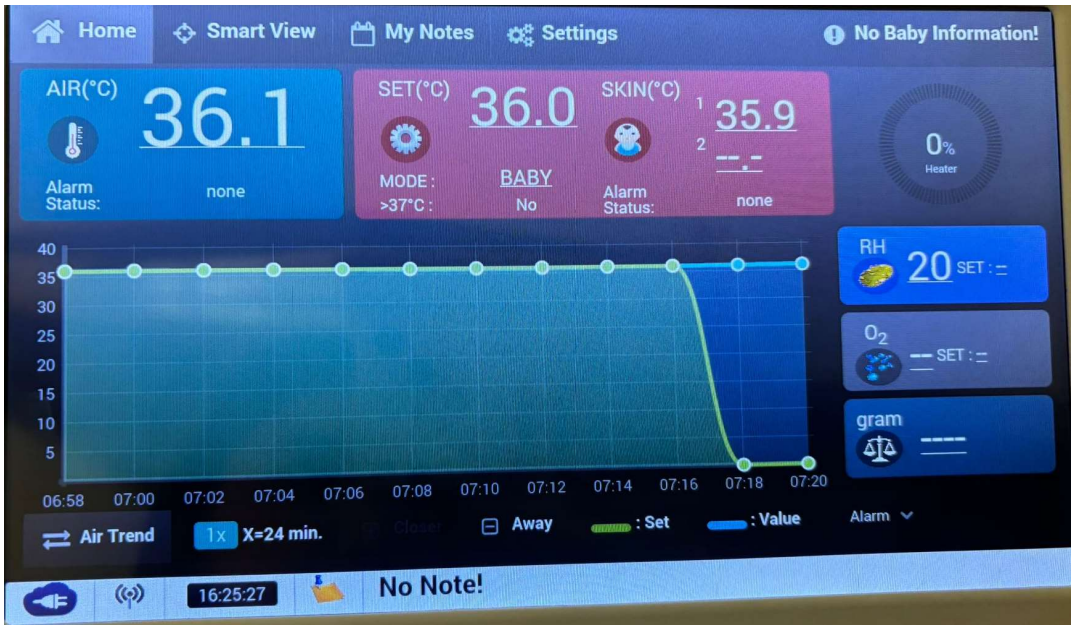


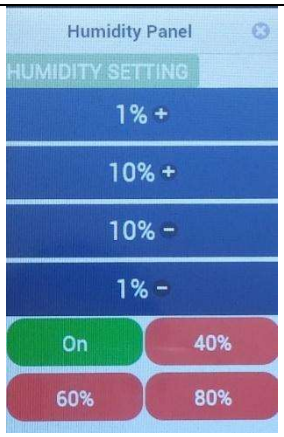
Figure 16: Skin Mode

9.2.3. SET MODE

Pressing the set button on the Main Page (Figure 12) opens the set temperature panel to set the temperature of the mode according to the mode in which the incubator is operating.
The desired temperatures are set from, temperature settings “0.1˚C+”, “1.0˚C+”, “1.0˚C-”, “0.1˚C-”.
Skin mode one touch set values are “34˚C”, “35˚C”, “36˚C”, “37˚C”.
Air mode one touch set values are “30˚C”, “32˚C”, “34˚C”, “36˚C”.
When in Air Mode, the Set Skin Mode button will activate, when in Skin Mode, the Set Air Mode button will activate.

9.2.4. HUMIDITY MODE (RH)

Pressing the Humidity button on the Main Page (Figure 12) accesses the Humidity panel for humidity-based settings.
Humidity settings; on/off, one touch set value buttons take place on the humidity panel.
In this mode, humidity is set between 20% and 95%.
Humidity mode can be switched on or off with one touch at ON/OFF button.
The desired humidity values are set with humidity settings “1%+”, “10%+”, “10%-”, “1%-”
One touch set values are “40%”, “60%”, “80%”.

Humidity values can be set to 1%+, 10%+, 10%-, 1%-, from the panel menu or set by one touch set values to 40%, 60% and 80%.	

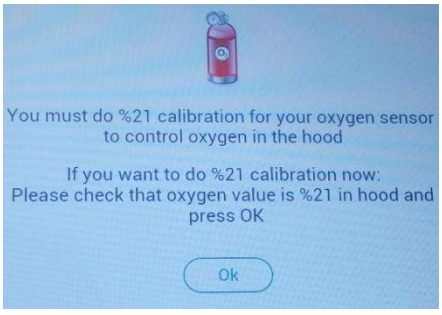
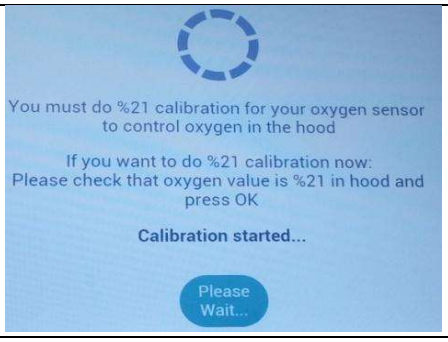
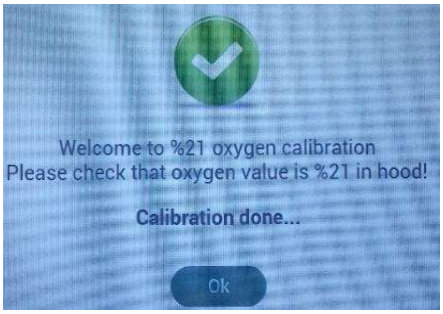
9.2.5. OXYGEN MODE

By pressing the O_2 indicator located on the Main Page (Figure 12), the oxygen panel is opened to access the oxygen settings.
Oxygen settings; On/Off, one touch set value buttons take place on the oxygen panel.
In this mode, oxygen is set between 21% and 65%.
Oxygen mode can be switched on or off with one touch at On/Off button.
The desired oxygen values are set with oxygen settings “1%+”, “5%+”, “5%-”, “1%-”
One touch set values are “35%”, “45%”, “55%”

Oxygen values can be set to “1%+”, “5%+”, “5%-”, “1%-”, from the oxygen panel menu or set by one touch set values to “35%”, “45%” and “55%”	

9.2.5.1. CALIBRATION OF OXYGEN VALUES

For 21% Calibration, press the “21% Calibration” button and complete the calibration process by following mentioned steps below;

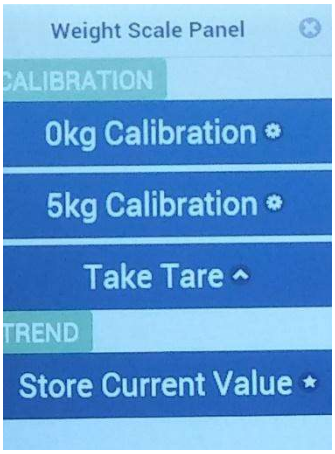
1st Step	
2nd Step	
3rd Step	

NOTE

100% Calibration is processed by Ertunç Özcan Technical Service during maintenance.

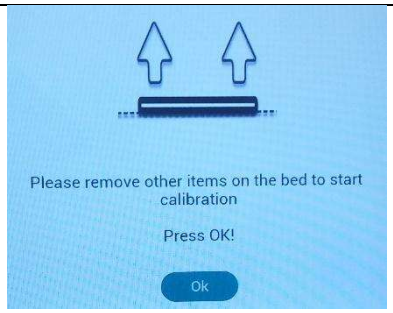
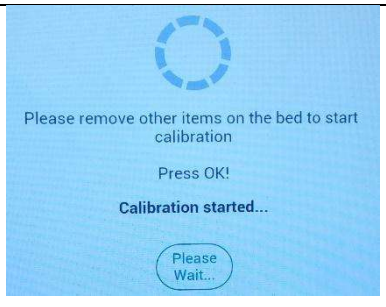
9.2.6. WEIGHT

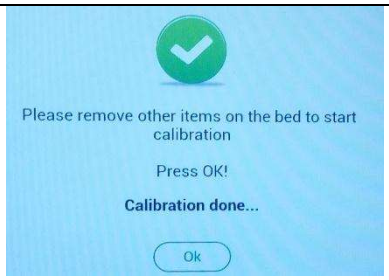
Pressing the weight indicator on the Main Page (Figure 12) opens the Weight Scale Panel to access the patient's weight readings. It has calibration, tare and trend functions.

0 kg Calibration, 5 kg Calibration, Tare and Record Existing Value functions are provided by the Weight Scale Panel menu.	

9.2.6.1. 0 KG CALIBRATION

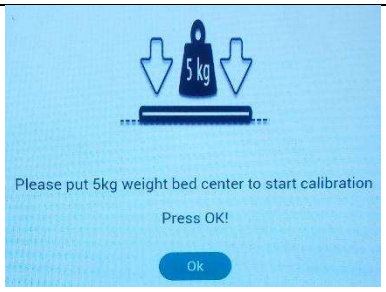
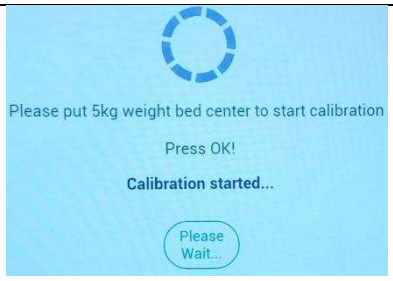
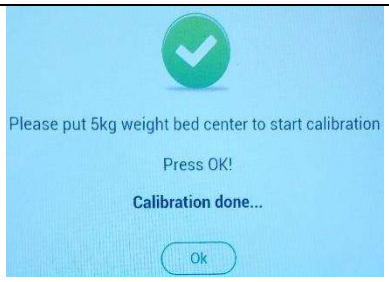
For 0 kg calibration, press the "0 kg Calibration" button by opening the scale panel, and complete the calibration procedure by following the steps indicated.

1st Step	
2nd Step	
3rd Step	

4th Step	

9.2.6.2. 5 KG CALIBRATION

For 5 kg calibration, press the "5 kg Calibration" button by opening the scale panel, and complete the calibration procedure by following the steps indicated.

1st Step	
2nd Step	
3rd Step	
4th Step	

9.2.6.3. TAKING TARE FUNCTION

To be able to tare, press the "Take Tare" button by opening the Weight Scale Panel and complete the calibration procedure by following the steps indicated.

1st Step	
2nd Step	

9.2.6.4. TREND FUNCTION

When the "Store Current Value" button is pressed, the measured weight is added to the trend as data.

Figure 17: Record Error

9.3. ALARMS

As all the alarms can be seen on the Main Page (Figure 12), the desired function alarm can be chosen as well. The selected alarm, the alarms date-time information, situation information, revision information is stated on the Main Page.
Alternatives of alarms are given below;

- All Alarm
- Active Alarm
- Air Alarm
- Skin Alarm
- Humidity Alarm
- O_2 Alarm
- Weight Alarm
- Other Alarms

Alarm table has Author, Alarm, Date-time, Status, Renewal information.
Author: Shows alarm author.
Alarm: Alarm lists given in Section 10.2
Date - Time: Shows alarm date and time.
Status: Gives information about alarm status. Give the information “done”, when the alarm condition is resolved, give the information “muted” when the alarm is muted.
Renewal: The renewal information is shown as a percentage will increase from 1% to 100% when the alarm is silenced. When mute alarm becomes active again at renewal shown 100%.

9.4. TRENDS

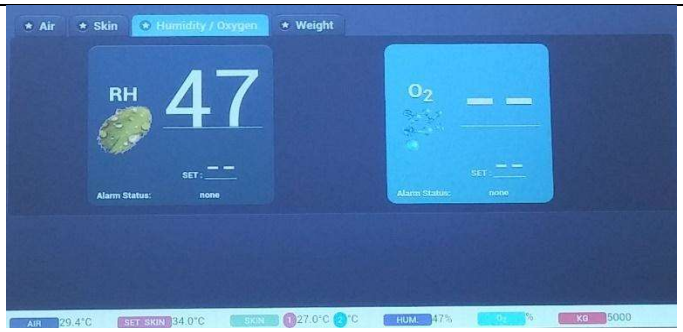
The recorded trends can be monitored on the main page by pressing the trend function button located on the Main Page (Figure 12).

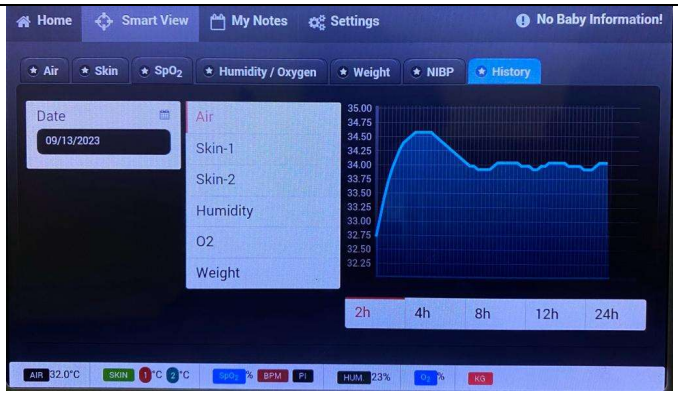
Function with recorded trend features,

Air Trend	24min, 48min, 96min, 3hr, 6hr, 12hr, 24hr, 48hr, 96hr, 8day, 16day, 32day
Set Trend	24min, 48min, 96min, 3hr, 6hr, 12hr, 24hr, 48hr, 96hr, 8day, 16day, 32day
Skin-1 Trend	24min, 48min, 96min, 3hr, 6hr, 12hr, 24hr, 48hr, 96hr, 8day, 16day, 32day
Skin-2 Trend	24min, 48min, 96min, 3hr, 6hr, 12hr, 24hr, 48hr, 96hr, 8day, 16day, 32day
Humidity Trend	24min, 48min, 96min, 3hr, 6hr, 12hr, 24hr, 48hr, 96hr, 8day, 16day, 32day
Oxygen Trend	24min, 48min, 96min, 3hr, 6hr, 12hr, 24hr, 48hr, 96hr, 8day, 16day, 32day
Weight Trend	As much as recorded in the limit of 32 days
Heater Trend	24min, 48min, 96min, 3hr, 6hr, 12hr, 24hr, 48hr, 96hr, 8day, 16day, 32day

9.5. SMART SCREEN

The Smart Screen on the Main Page (Figure 12) is designed to monitor Air, Skin, Humidity/Oxygen and Scale values. While monitoring the desired function and its set of values, other functions can be monitored as a footer with the Smart Screen alternative. This allows all function values to be monitored on the same screen.

AIR	
SKIN	
HUMIDITY / OXYGEN	
WEIGHT	

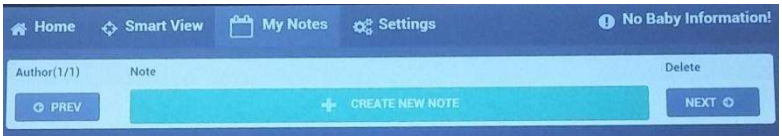
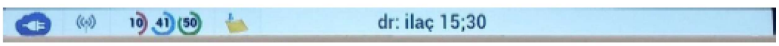
PAST	

9.6. NOTES

Pressing the “My Notes” button (Figure 31) on the Main Page (Figure 12) opens the Notes screen. This feature allows the end user to leave a note about the infant being treated or for the upcoming medical team to take over the shift.

Figure 18: Notes

To record or delete a note please follow the steps stated below.

1st Step Pressing the "Create New Note" button starts the recording process.	
2nd Step Enter your name and note information and press Save.	
The recorded note moves down to the information line and appears as a note.	
The number of recorded notes is shown on the notes icon.	
3rd Step To delete the record, press the "Delete" button.	

9.7. SETTINGS

The settings of; incubator language, heat unit, weight unit, date and time, wireless and service by pressing the settings display (Figure 32) located on the Main Page (Figure 12).

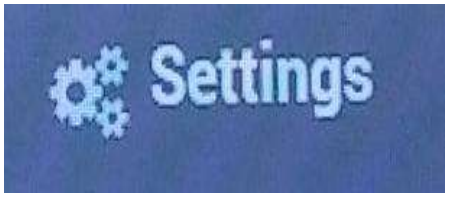
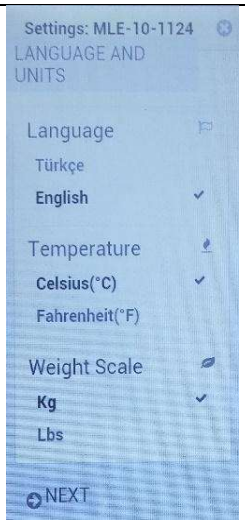
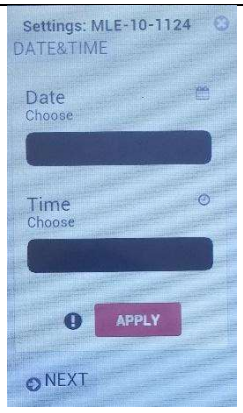
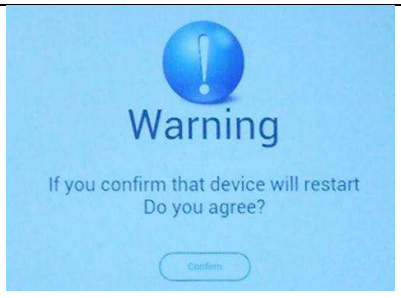
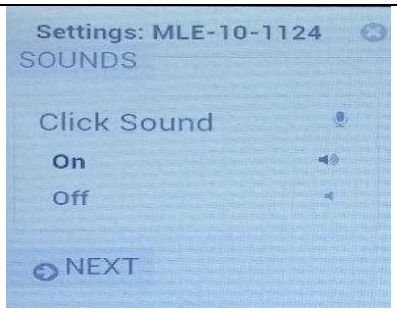
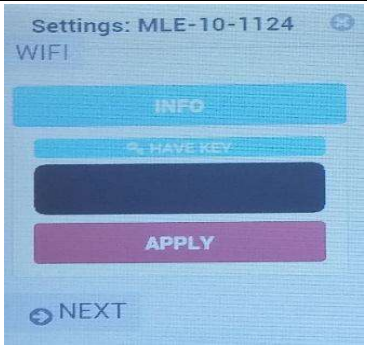
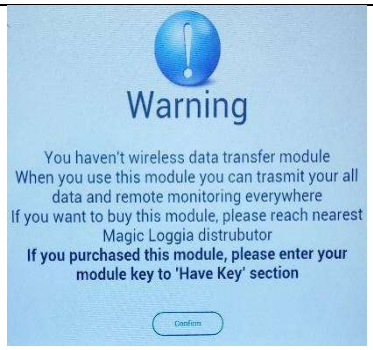
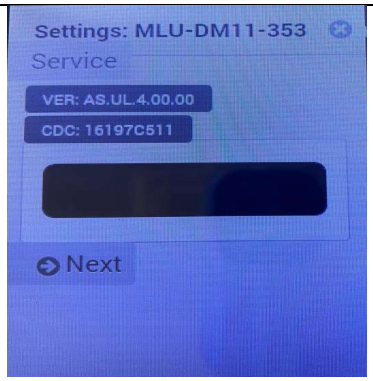


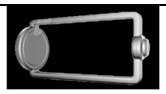
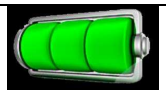
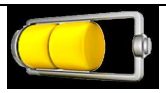
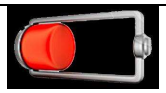
Figure 19: Settings

The language, heat unit and weight unit of the incubator can be set in the LANGUAGE AND UNITS section. Language: Turkish, English Temperature: Celsius (˚C), Fahrenheit (˚F) Weight: Kg, lbs	
The incubators date and time can be set in the DATE&TIME section. After setting the time and date, press the Apply button (Red).	
Press the “Confirm” button to apply the date and time.	

SOUND section, provides to turn the sound keys On or Off once appears, when the display panel is in use. Turning off the key sounds does not affect the alarm sounds in any case.	
The WIRELESS part is activated and provides the possibility of monitoring the data. **WARNING** ➢ In order to access Wireless password, please contact Ertunç Özcan Technical Service.	
WIRELESS provides information.	
SERVICE is only valid for the use of Ertunç Özcan Technical Service.	

9.8. OTHER ICONS

Other icons on the Main Page (Figure 12) are given below;

Power cable on and powered.	
If a note has not been entered, a "No Note!" message is displayed. If a note has been entered, the note is displayed as a sliding format in front of the icon.	
Battery empty	
Battery full	
Battery half full	
Low battery	

10. WARNINGS, ALARMS, ERRORS

10.1. WARNINGS

Plug Skin Sensor to Skin-1 Connector	This warning is displayed when the skin probe is connected to skin-2 or the skin probe is unplugged and the skin mode is requested to be activated.
Please unplug the Skin 2 sensor to pass Skin Mode	Skin Mode cannot be accessed if the Skin-1 and Skin-2 probes are connected at the same time, and the warning message "Please unplug Skin-2 sensor to pass Skin Mode" appears on the screen.
Skin Sensor Removed	This warning appears if the skin sensor is removed while the device is in skin mode.
Volume-2 Installed	This warning appears if the Skin 2 sensor is attached while the device is in Skin mode.

10.2. ALARMS

High Temperature	Activated when the incubator temperature shows 40˚C or over 40˚C.
High Air Temp	A written and audible alarm sounds when the air temperature value exceeds the set value by 1.5˚C.
Low Air Temp	A written and audible alarm sounds when the air temperature value falls 1.5˚C below the set point.
High Skin Temp	A written and audible alarm sounds when the skin temperature value exceeds the set value by 1˚C.
Low Skin Temp	A written and audible alarm sounds when the skin temperature value falls 1˚C below the set point.
High Skin-1 Temperature (>40˚C)	Skin-1 temperature is activated at 40˚C or when it exceeds 40˚C.
High Skin-2 Temperature (>40˚C)	Skin-2 temperature is activated at 40˚C or when it exceeds 40˚C.
No Skin-1 Sensor	A written and audible alarm is given when the Skin-1 sensor is unplugged in Skin mode.
High Humidity Value	A written and audible alarm is given when the humidity rate exceeds the set value by 10%.
Low Humidity Value	A written and audible alarm is given when the humidity rate falls 10% below the set value.
No Oxygen Sensor	A written and audible alarm is given when the oxygen sensor is not connected with sensor module.
High Oxygen Value	A written and audible alarm is given when the oxygen rate exceeds the set values high alarm limit.
Low Oxygen Value	A written and audible alarm is given when the Oxygen Set Point falls below the Low Alarm Set Point.
No Water in the Water	A written and audible alarm is given when the humidity parameter is set

Reservoir	and there is no water in the water reservoir of humidifier.
Low Battery	A written and audible alarm is given when the device has an external power failure and is using its own battery, but the battery is low.
No Sensor Module – Restart	If the sensor module is not connected to the device, a written and audible alarm is given, in which case no process can be performed on the device being used unless the sensor module is connected.
EO4 Connection Error	A written alarm is given if there is an error in the data stream between the control module and the display panel.
Error Press Here	If the display is not opened and the USB port is not plugged in, a written alarm is generated.
No Sensor Module	If the sensor module is not connected to the device, a written and audible alarm is given and no action can be taken until the sensor module is installed.
Battery Done, Turn Off Device	It gives an audible alarm when the battery runs out.

10.3. SILENCE / RESET OF ALARMS

Turn off: If the alarm is on, it can be turned off by pressing the silencing button. When the audible alarm is silenced, the alarm can be monitored continuously from the display panel. Pressing this button silences the audible temperature alarm for 15 minutes. If another alarm is triggered during this time, the silenced alarm will automatically be deactivated.
The same button can be used to silence the Audible Power Alarm for 2 minutes.

Reset: The alarm turns off automatically when the alarm situation is resolved.

10.4. ERRORS

ERRORS	EXPLANATIONS
Skin-1 Sensor Out of Order	If there is an error on the Skin-1 sensor, a written and audible alarm sounds.
Skin-2 Sensor Out of Order	If there is an error on the Skin-2 sensor, a written and audible alarm sounds.
Humidity Sensor Out of Order	If there is an error in the humidity sensor, a written and audible alarm sounds.
Oxygen-1 Sensor Out of Order	If there is an error in the oxygen sensor-1, a written and audible alarm sounds.
Oxygen-2 Sensor Out of Order	If there is an error in the oxygen sensor-2, a written and audible alarm sounds.

Power Fail	If the external power fails, a written and audible alarm sounds and the device continues to operate on its internal battery. Monitoring and data recording continues for approximately 45 minutes in battery mode.
Fan Error	A written and audible alarm sounds if the fan mode is not operating or if the airflow in the cabin is unbalanced.
System Error	Activated when there is an error in the electronic part located inside the device.
Air Circulation Error	Activated when there is a problem in the air circulation.
Skin Sensor Removed	Activated if the skin sensor is removed while the device is operating in skin mode.
Skin -2 Installed	When the device is in Skin mode, it is activated when the Skin-2 sensor is inserted.
No Scale Sensor	Activated when the balance module is not connected to the sensor module.
Heater System Malfunction	Activated when the heating system is not working.
Oxygen Sensor Malfunction	If the oxygen sensor fails, a written and audible alarm sounds.
Air Temperature Sensor Malfunction	If the air temperature sensor fails, a written and audible alarm sounds.

10.5. SYSTEM ERROR CODES

ERROR CODE	REASON	PROCESS
System Failure-1	Memory / Memory Failure	Please contact service
System Failure-2	Memory / RAM Failure	Please contact service
System Failure-3	Sensor Module Communication Malfunction	Please contact service
System Failure-4	Sensor Memory / Sensor RAM Failure	Please contact service
System Failure-5	Software Memory / Software Memory Failure	Please contact service
System Failure-6	Main Heater Thermocouple Malfunction	Check the connections, if the problem continues, please contact service.
System Failure-7	Humidity Heater Thermocouple Failure	Check the connections, if the problem continues, please contact service.
System Failure-8	Improper or Uncalibrated Component	Please contact service
System Failure-10	Improper or Uncalibrated Component	Please contact service
System Failure-14	Control Module Off or No Power	Check the connections, if the problem continues, please contact service.
System Failure-15	Display Module Connection Failure	Check the connections, if the problem continues, please contact service.

11. USAGE OF THE INCUBATOR

11.1. GENERAL USE

The following steps must be followed to use the incubator.

1. Check that the wheels are locked.

WARNING
- Before placing the patient into the incubator, the wheels must be always locked.

2. Connect the incubator's power cable to the switch that meets the electrical requirements of the specified technical features.
3. If an extension cable is to be used, connect the power cable to the extension cord and plug the extension cable into the switch.
4. Activate the incubator using the On/Off buttons on the control module and the power supply unit.
5. When the device is first activated a self-test will be done by the control circuit.

IMPORTANT
Self-test must be done every day.

WARNING
- Heat the incubator before placing the patient in it.

6. Select Air or Skin Temperature Control Mode. See Section 6.4.1 and 6.4.2 for more information.

IMPORTANT
The temperature control mode and temperature settings must be determined by the attending physician. The patient’s rectal and/or forearm temperature must be measured regularly as directed by the attending physician or nurse.

NOTE
The low temperature alarm may automatically activate after the incubator is turned on or until the temperature reaches the set temperature. This alarm can be disabled.

7. Place the patient on the mattress.
8. Place the skin probe on the patient's skin. Place the probe according to the patient's lying position. Make sure the patient's skin is dry and clean before applying the probe. Situations that may be caused by the skin probe are listed below. These situations can cause the patient to be overheated or underheated.

WARNING

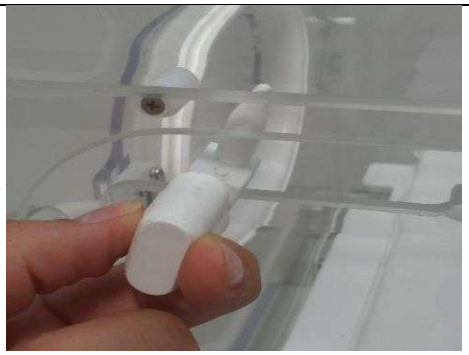
- Do not place the probe between the patient and the mattress. The measurements may be incorrect.
- Do not pull on the probe wires. Disconnect the probe from the skin by carefully pulling off the sticky part. Disconnect the probe from the measuring module by holding the measuring module.
- Check regularly that the probe is connected. If the probe is not in contact with the patient's skin, the measurements may be incorrect.
- When phototherapy lamps are on, do not place the probe directly on the heat source of the lamps. Place the probe where the light from the lamps will not reach. Phototherapy lamps may increase the patient's skin temperature.
- Do not open the probe package unless you need to use it. Replace damaged probe.

9. There are 10 grommets on the incubator panel (Figure 33). Probes and patient circuits, which are used for patient treatment and monitoring, must be inserted through these grommets to prevent temperature loss.

Figure 20: Grommets

11.2. ACCESS TO THE PATIENT

There are two opening access panels on the front and back of the canopy for easy access to the interior. The panels can be opened and locked by turning the latches located on the top left and right of these access panels. The ability to open the panel and pull the mattress toward you provides easy access to the patient for intervention.

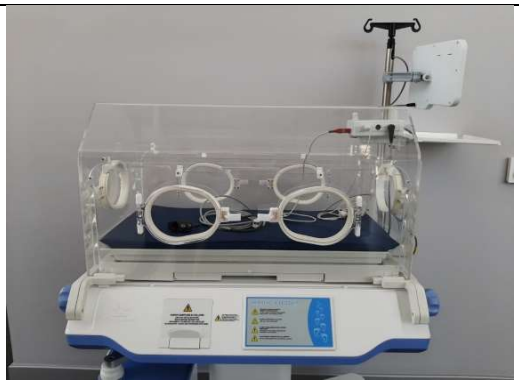
Turn the latches of the access panels.	
Open access panel.	
Pull the mattress tray towards you.	

The patient can also be accessed through the QT windows. There are 6 QT windows on the canopy. To prevent germs from getting on your hands, the QT windows can be easily opened by pressing the latches on the access windows with your elbows.

WARNING

- For patient safety, keep the QT windows closed while the incubator is in use.
- Warm the incubator before placing the infant in it.
- Do not leave the patient unattended when the access panels or QT windows are open.

11.3. LIFTING AND LOWERING OF THE CANOPY

Rotate the display panel before removing the canopies to prevent the canopy from coming down.	
Open the canopy lock by pulling the lock towards yourself.	
To lift the canopy, pull the canopy handles upward.	
When the canopy is fully raised, it forms a 45° angle. **WARNING** When the canopy is fully raised, it should not be released without control. Otherwise, it may result in personal injury or equipment damage.	

There is approximately a 12 cm gap between the canopy and the surface when the canopy locking mechanism is activated.

WARNING

- When the canopy is fully raised, it should not be released without control. Otherwise, it may result in personal injury or equipment damage.

WARNING

- Do not lift the canopy while the infant is in the incubator. Lift the canopy only for cleaning or disassembly.

11.4. TRENDELENBURG MECHANISM

Trendelenburg mechanism is used to tilt the mattress in between 0˚ to 12˚ in order to provide a trendelenburg position (head is slightly lower than the feet) or a reverse trendelenburg position (head is slightly upper than the feet).

For the neonates and infants in the incubators a reverse trendelenburg position where the patient's head is slightly upper than the feet is recommended since a reverse trendelenburg position helps facilitate optimal respiratory function for patients by keeping the airways open, allowing for better ventilation and oxygenation, digestive comfort by reducing the occurrence of gastroesophageal reflux (GER) in patients and reduce the risk of respiratory issues or infections by prevent the aspiration of fluids, such as milk or saliva, into the respiratory tract.

WARNING

- The Trendelenburg mechanism should be used in order just to provide a reverse trendelenburg position for patient. Otherwise, the positioning of the patient's body where the head is lower than the feet is generally not recommended for patients in an incubator due to the following risks and complications;
  - ✓ Increased Intracranial Pressure
  - ✓ Impaired Respiratory Function
  - ✓ Cardiovascular Changes
  - ✓ Gastroesophageal Reflux
  - ✓ Disruption of Body Temperature Regulation
  - ✓ Skin Integrity Issues
- It's important to note that medical professionals will assess each individual situation and consider the potential benefits and risks before making any positioning decisions for infants in an incubator. Always consult with a physician for specific advice and guidance regarding the care of infants in an incubator.
- Before placing the mattress in the Trendelenburg or Reverse Trendelenburg position, ensure that the patient's extremities are not pinched between the mattress layer and the valve wall. Failure to comply could result in death or serious injury.
- Before moving the incubator, always make sure that the mattress is in a linear position. Failure to comply could result in death or serious injury.

There are two mechanism handles on the left and right hand sides of the Trendelenburg mechanism. The Trendelenburg mechanism of the mattress can be performed by turning of these handles.

WARNING

- To put the mattress in the Trendelenburg or reverse Trendelenburg position, always tilt one end of the mattress and keep the other end in the lowest position. It is not recommended to lift both ends at the same time. Failure to comply could result in death or serious injury.
- Do not lift the canopy when the mattress is raised.

NOTE

These trendelenburg mechanism are imposed so that the infant can be positioned in reverse trendelenburg position. Do not lift both sides of the mattress at once unless the possible use of the enlargement radiography process. Do not leave infant unattended when both of knobs are raised.

Figure 21: Trendelenburg Handles

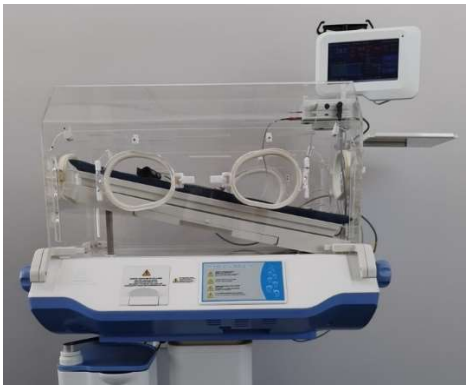


Figure 22: Trendelenburg Position

Figure 23: Reverse Trendelenburg Position

11.5. X-RAY TRAY USAGE

X-Ray Tray is used to perform X-Ray imaging of the neonates and infants accurately and efficiently without the need to disturb or move the patients from the incubator by allowing for convenient and secure placement of the X-Ray cassette. Placing the X-Ray cassette on a dedicated tray within the incubator helps to ensure the safety and stability of the patient during the imaging process. It provides a secure surface for the cassette, minimizing the risk of accidental movement or displacement that could potentially harm the patient. In addition, X-Ray Tray minimizes temperature and humidity fluctuations that may occur if the patient is temporarily moved outside the incubator for imaging. X-Ray Tray, which provides X-Ray imaging to be performed without lifting the premature, especially helps to prevent infections on low-birth-weight patients by reducing unnecessary contact between the premature and X-Ray detector.
Usage instruction of X-Ray Tray is given below;

- Open the front access panel.
- Pull the X-Ray tray, which is placed under the mattress, toward yourself (Figure 37).
- Place the film cartridge in the tray which is placed under the patient without moving the patient.

WARNING

- X-Ray tray shall not be used as writing support or mattress for the patient. Nothing shall be stored on tray and nobody shall be leaned on the tray.
- The X-Ray tray shall be fully inserted. Otherwise, there is a danger of interruption of the hot air duct. The result may be excessive cooling or overheating of the patient.
- The risk of incorrect diagnosis due to a translucent shadow of the hood on the X-Ray during taking X-Ray through the hood should be paid attention.
- For X-Ray imaging, the appropriate protective precautions should be taken and instructions of physicians should be followed. It is recommended that one of twins be removed from the incubator to avoid high dose exposure during X-Ray imaging.
- The incubator shall not be exposed to excessive humidity in order not to affect the imaging.
- The patient shall not be unattended when access panels are open. The patient could fall which may result in death or serious injury.

CAUTION

- Low battery charge can cause the system to shut down prematurely. Therefore, before imaging process battery level should be checked.

NOTE

Although the X-Ray tray itself does not directly influence the radiation dose received by the patient, the X-Ray tray's design and features may facilitate precise positioning of the patient within the incubator, ensuring that the body part of patient is aligned correctly with the X-Ray beam. Accurate positioning helps in obtaining diagnostically useful images with minimal need for repeat exposures, thus reducing the overall radiation dose.

Figure 24: X-Ray Tray

11.6. USAGE OF THE HUMIDIFIER

The infant incubator humidifier consists of a water reservoir and humidifier tray.

Figure 25: Humidifier and Tray

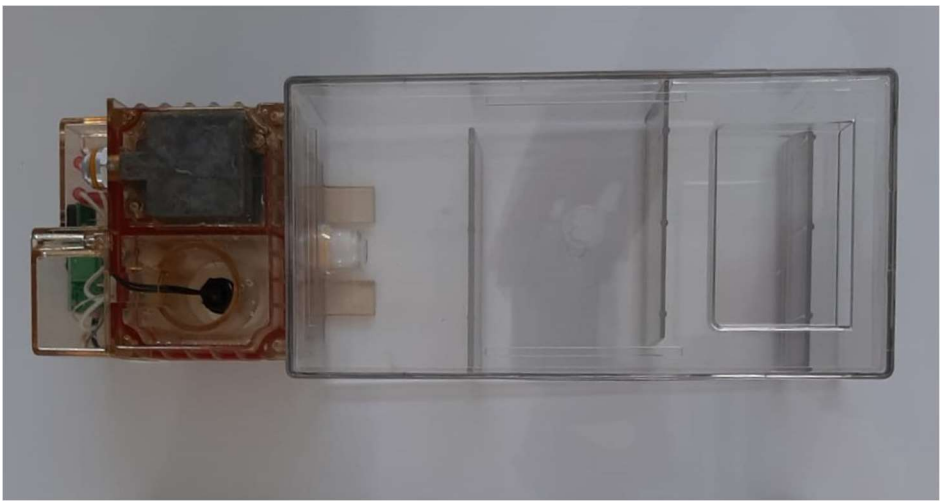


Figure 26: Water Reservoir

NOTE

The relative humidity level reached inside the incubator will be affected by the humidity level of the working environment.

WARNING

- Higher relative humidity decreases evaporative water loss and may cause an increase in patient's temperature. This effect is greatest in premature neonates of very low birth-weight. Therefore, the patient's temperature should be monitored routinely and the temperature control mode, temperature and humidity setting should be prescribed by the relevant physician.
- All access panels should be closed and grommets should be connected to the hood, otherwise, any open gaps in the hood may reduce the internal relative humidity of the incubator.

NOTE

If the environment temperature inside of the canopy is low, the air steam in the incubator may concentrate inside of the hood walls making it difficult to see inside. This concentration will not adversely affect the operating condition of the incubator.

11.6.1. REMOVING AND FILLING OF WATER RESERVOIR OF HUMIDIFIER

a) If an additional humidification is prescribed by the relevant physician fill the water reservoir of humidifier (Figure 39) with 1300 mL of sterile demineralized water.

b) To remove the humidifier, the handle should be pushed down and pulled toward you.

Figure 27: Removing the Humidifier

WARNING

- If humidity has been in use but is no longer needed, the water reservoir should be emptied and dried to avoid bacterial contamination. Then it should be reinstalled assembly in the incubator.
- The water reservoir must be emptied and refilled every day and only distilled water shall be used.
- When removing the water reservoir, it should be ensured that the water reservoir is hold from underneath to prevent it from falling
- Liquid in the collection bottle can contain patient fluids. Collection bottles and fluids should be handled according to hospital guidelines.
- The water reservoir should be filled to the maximum filling limit line (1300 mL). In order to prevent water spillage or personal injury, the water reservoir shall not be overfilled.
- If any liquids spill or leak around the device, the area should be dried in order to decrease the risk of injury.
- Using an incomplete humidifier can prevent the system from operating correctly, it should be ensured that the water reservoir lid is installed.

IMPORTANT

The humidity reservoir may be hot when removed from the device, so it should be cleaned after keeping it at room temperature for 15-20 minutes.

11.6.2. STERILIZATION OF WATER RESERVOIR OF HUMIDIFIER

The water reservoir of the humidifier (Figure 39) can be autoclaved at 121°C. The humidifier tray (Figure 38) of the humidifier can be sterilized with disinfectant sled.

11.7. AIR INTAKE MICROFILTER

a) Remove the air intake microfilter cover by removing the two screws as shown in Figure 41.
b) Check the microfilter. The microfilter needs to be replaced if it appears dirty.

CAUTION

- Dirty air may affect the oxygen concentration of the air intake microfilter and/or cause carbon dioxide to be produced. The filter must be checked regularly and changed at least quarterly.

Figure 28: Removing the Filter Lid

c) Watch the level in the canopy and check the air/oxygen system to see if the level has reached the point of the filter cover after verifying that the oxygen flow through the optional oxygen inlet valve is 8 L per minute.

11.8. OXYGEN

Oxygen can be supplied from a hospital line or an oxygen cylinder.

WARNING

- The misuse of additional oxygen can lead to severe side effects including blindness, cerebral damage and death. The dangers may vary according to the patient. The method of oxygen treatment, concentration and practice time shall be decided by the attending physician.
- When a high oxygen environment is required, arterial gas levels should be analyzed repeatedly in order to maintain the oxygen concentration in the incubator at a desired level. Physician's instructions in measuring the oxygen concentration shall be followed because the risk of retinopathy of premature may increase by ignoring the essential requirements.
- Physician shall be contacted immediately in case of an emergency where an oxygen treatment is needed.
- The oxygen flow rates cannot be used as a right scale of the oxygen concentration in the incubator. The oxygen concentrations shall be measured with a calibrated oxygen analyzer regularly as stated by the physician.
- Expired air filter, may increase the oxygen concentration and cause carbon dioxide. The air filters shall be changed regularly.
- The oxygen treatment may increase the noise level of the hood.
- The incubator should be disconnected from the hospital oxygen source when oxygen is not in use.
- In patient compartment, only electrical devices approved for use in an oxygen-enriched atmosphere shall be used.
- Auxiliary equipment which has a potential to spark shall not be placed in or beside of the infant incubator.
- It should be noted that oxygen delivered to the patient is not humidified.
- It should be ensured that grommets are properly installed and access panels are closed, otherwise

any open gaps in the hood may result in reduce the incubator internal oxygen.

- Oxygen sensors is a sealed sensor which contains potassium hydroxide electrolyte. Therefore, in order to prevent death or serious injury, the following instructions shall be complied;
  - ✓ If there is a leak in the sensor, it should be discarded immediately.
  - ✓ Only Ertunç Özcan recommended oxygen sensors should be used.
  - ✓ If the oxygen sensor is contacted with the skin or clothing, the affected area should be rinsed with a large quantity of water.
  - ✓ If the oxygen sensor is contacted with eyes, minimum 15 minutes the eyes should be flushed holding the eyes open and the physician should be called immediately.
- Using poorly maintained oxygen components raises the likelihood of fire hazards and may result in severe injuries or fatalities. To ensure safety;
  - ✓ Gas/oxygen components should be regularly inspected during preventive maintenance intervals to check for corrosion or damage.
  - ✓ Oxygen cells should be examined routinely for any signs of degradation or leakage, and replace them as needed.
- It should be ensured that oxygen supplier system pressured should be 4-6 bar.
- Oxygen use may increase the risk of fire. Materials that are compatible with oxygen and not flammable should be used with an oxygen system.
- The oxygen sensor shall not be touched while utilizing the trendelenburg mechanism.
- When oxygen is administered, an oxygen monitor should be used.

CAUTION

- The oxygen concentrations must be measured separately to see if the prescribed oxygen concentration is given.

Figure 29: Oxygen Inlet Valve

Allow 30 minutes for concentration to settle after changing oxygen flow settings.

11.9. 360º ROTATABLE DRAWERS (OPTIONAL)

Figure 30: 360º Rotatable Drawers

The drawer serves as a compartment or storage area for users to store essential medical supplies, equipment, and accessories needed for the care of the patient. 360º Rotating feature provides easy access to the drawers from any angle.

WARNING

- The maximum weight the drawer tables can carry is 1.2 kg.
- The maximum weight the drawers can carry is 2.5 kg.
- To prevent personal injury and equipment damage close the surface and drawers after use.
- To prevent personal injury and equipment damage do not put anything above the maximum weight capacity of the surface and drawers.

11.10. CONTROL COMPLETE

If the incubator is to be used, set the control to Air Mode and leave it running until it is ready for use. When not in use, turn off the incubator and unplug the power cable from the switch.

11.10.1. OPERATING IN USE

IMPORTANT

The incubator should not be used until the control of the system (Installation and Control of The System- Section 5) have been completed.

Incubator must be ventilated and must go under pre-heating process under the air mode control until the stated prescribed temperature by the relevant physician is reached.

CAUTION

- The incubator must not be activated during the pre-heating phase if the water reservoir is not filled with water.

NOTE

When the access panel is open, air curtains are automatically activated to prevent heat loss inside the canopy. However, it should be ensured to prevent this type of airflow from reaching the interior of the incubator to maintain thermoregulation.

12. CLEANING AND REPROCESSING, MAINTENANCE, REPAIRING

This section contains instructions for the cleaning, maintenance, repairing and reprocessing of the Magic Loggia Ultimate and its accessories.

WARNING

- The position of the incubator should not be changed without removing all accessories.
- It should be ensured that all oxygen supply units are closed and disconnected from the incubator before cleaning or preparing.
- The power cable should be unplugged to disconnect the power before performing service or maintenance.
- The air microfilter cannot be sterilized, cleaned or washed. Change the microfilter every 3 months.
- The weight capacity of the optional scale is ≤10kg.
- If more than 10 kg of weight is placed on the scale during cleaning, maintenance, and repair of the equipment, be careful not to place more than the specified weight on the scale, as this may damage the operating mechanism of the scale.
- There is a higher risk of fire in oxygen-enriched environments.
- Thoroughly air dry the Magic Loggia Ultimate after cleaning it with flammable agents. Small amounts of flammable agents, such as ether, alcohol or similar cleaning solvents left in the incubator can cause a fire.
- The cleanliness can be maintained by using various methods. However, to avoid damage or contamination, the following recommended methods should be used.
- The incubator should be thoroughly cleaned and disinfected after each infant is discharged and before being used again. If the same patient is left in an incubator for more than 7 days without cleaning or disinfecting, the patient may get an infection.

12.1. GENERAL

This section contains cleaning and maintenance instructions.

IMPORTANT

Except as described in this section, maintenance should only be performed by qualified Ertunç Özcan Service Personnel.

Calibration should be performed every 12 months.

Repair should only be done by Ertunç Özcan Technical Service under warranty.

Do not use the instrument if you think it is defective.

12.1.1. DEFINITIONS OF SERVICE TERMINOLOGY

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

12.2. MAINTENANCE

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

The recommended maintenance intervals are listed below.

Weekly or After Each Patient

- Disinfect the humidifier
- Clean and disinfect the incubator
- Check the air filter
- Sterilize the humidifier water reservoir after each patient especially after use on patients with infectious diseases or no more than once a week while the same patient is being treated

Quarterly

- Replace the air microfilter
- Check whether the thermal paste inside the resistance is dry or not; if the device is under warranty, obtain the paste from Ertunç Özcan Company, otherwise contact Ertunç Özcan Technical Service

NOTE
The period indicated above is the minimum replacement interval for the filter. The filter should be replaced when it appears dirty.

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

COMPONENT	INTERVAL	TARGET GROUP
Air Filter	Quarterly or when needed	User
Incubator Mattress	When needed	User
Grommet, QT window seals, QT window sleeve	When needed	User
Skin Probe (Disposable)	Weekly	User
Skin Probe (Reusable)	Yearly	User
Oxygen Sensor	Yearly or when needed	User
Control Module Battery	Yearly	Technical Service Personnel
Z tab/Latch, Inner wall hinge, Qt window latch and hinge	2 years	Technical Service Personnel
Oxygen solenoid valve	2 years	Technical Service Personnel
Fan Motor Kit	3 years	Technical Service Personnel
Water Reservoir	2 years	Technical Service Personnel
Humidifier	2 years	Technical Service Personnel
Heating Resistance/Thermostat	3 years	Technical Service Personnel
Heater Iron Block	5 years	Technical Service Personnel
Canopy/Hood	5 years	Technical Service Personnel
Incubator Upper Unit/Lower Unit	5 years	Technical Service Personnel
Trendelenburg	2 years	Technical Service Personnel
Scale Loadcell/Weighing Module	5 years	Technical Service Personnel
QT Window	5 years	Technical Service Personnel
Hoses/Connection connectors	3 years	Technical Service Personnel
Device Service and Maintenance	Yearly	Technical Service Personnel
Oxygen Sensor	Weekly	User
Scale Module	After each cleaning and when needed	User

WARNING

- Replace if materials become brittle, sticky, torn, dirty, or if strips of material peel off.
- There are lifetimes of the products specified in the table above along with their terms. Products must be changed at the specified times. Otherwise, problems may occur in the efficient operation of the device. Ertunç Özcan Company is not responsible for the problems that may occur and are not covered by the warranty.
- The products are not covered by the warranty due to the deformation that may occur when certain products are exposed to cleaning. Information on cleaning the product is detailed below. (Section 12.4)
- The incubator materials in the table above must be used in accordance with the instructions in the user manual, otherwise the product is not covered by the warranty in case of any user error that may occur within the specified period or years.
- Our company is not responsible for any parts other than those installed on the device by Ertunç Özcan Technical Service Personnel. These products are out of warranty.

12.2.1. MAINTENANCE KITS

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

- **Annual Maintenance Kit:** Thermal paste, Oxygen sensor, Skin Probe, Air filter, Grommet, QT Window seal, QT window sleeve
- **2-Years Maintenance Kit:** Z Tab/Latch, Inner Wall Hinge, Oxygen Solenoid Valve, Humidifier, Water Reservoir, Trendelenburg, Thermal Paste, Skin Probe, Air Filter, Grommet, QT Window Seal, QT Window Sleeve, QT Window Latch and Hinge, Control Module Interval Battery
- **3-Years Maintenance Kit:** Fan Motor Kit, Heating Resistance/Thermostat, Heating Iron Block, Water Collector/Hoses/Connection Connectors, Z Tab/Latch, Inner Wall Hinge, Oxygen Solenoid Valve, Humidifier, Water Reservoir, Trendelenburg, Thermal Paste, Skin Probe, Air Filter, Grommet, QT Window Seal, QT Window Sleeve, QT Window Latch and Hinge, Control Module Interval Battery
- **5-Years Maintenance Kit:** Incubator Upper/Lower Unit, Canopy, Fan Motor Kit, Heating Resistance/Thermostat, Heating Iron Block, Water Collecting Tank/Hoses/Connectors, Z Tab/Latch, Inner Wall Hinge, Oxygen Solenoid Valve, Humidifier, Water Reservoir, Trendelenburg, Thermal Paste, Skin Probe, Air Filter, Grommet, Window Seal, QT Window Sleeve, QT Window, QT Window Latch and Hinge, Control Module Battery

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

COMPONENT/ PART NO.	TYPE/ MODEL NO.	INTERVAL
Battery (Li-ion)	18650	In storage +30°C max During discharge -25°C ~ +60°C Heat above 90°C or incinerate. Deform, mutilate, crush, pierce, disassemble. Short circuit. Prolonged exposure to humid conditions.
Connector	2EDGVC-5.08-04P-12-00AH	Operating Temperature: -40°C~+105°C
Filter (EMI/RFI)	FN 9260B-6-06	Temperature Range (Operation and Storage): -25 °C to +85 °C
Relay (Solid State)	CPC1966Y	Storage Temperature -40°C to +125 °C
Power Supply (Internal) (Brick) (Direct Plug-in)	RPS-60-5	Working Temp: -20°C ~ +70°C (Refer to "Derating Curve") Working Humidity: 20% ~ 90% RH non-condensing Storage Temp-Humidity: -40°C ~ +85°C, 10% ~ 95% RH 3 years warranty
Switch (Power)	C1550AB	Electrical life (Operations) >10k, many >50k Storage temp. (1 year period) <125°C (<257°C) -Some discoloration of terminals may occur
Wire	0,25/0,50/0,75 Cable	-
DC-DC Converter Voltage Regulator	MEJ2S0505SC	Storage life (Standard: JEDEC JESD22-A103, Condition A) 125°C +10/-0°C for ≥1000 hours.
Selenoid Valve	RHF204H500	The valves have a service life of more than 100 million cycles when used with inert gas
Fuse	0217005.HXP	Operating Temperature: –55°C to +125°C Humidity: MIL-STD-202, Method 103, Test Condition A. high RH (95%) and elevated temperature (40°C) for 240 hours
Board	MX-5 OEM CIRCUIT BOARD	-
Shrink Tubing	RSFR-H (600 V)	Temperature: -45°C to 125°C Shrink Temperature:120°C
Crimp Connectors	FFD2638	Operating temperature: 75°C 600V
Temperature Sensor (Air)	SHT11	HTSL = High Temperature Storage Lifetime: 125°C, 1000 hours
Thermistor	PS302J2 (3K NTC)	-90 days warranty

		-Elevated Temperature Extended Life Test for Thermistor: 100°C Soak Aging >10 years
Reusable Temperature Sensor (Skin)	T-20970	-
Disposable Temperature Sensor (Skin)	T-100	-
Power Cable	Longwell-P	-
Wire	0,25/1,50/2,0/2,50 Cable	-
Resistance for (Humidity Chamber and Main Heater)	220W	-
Fan Motor	AC	-
Float Sensor (for Humidity Chamber)	59630-1-T-02-A	Temperature: Operating Normally Open: -40°C to + 40°C Normally Open High Voltage: -20°C to +105°C Change Over: -40 to +105°C Normally Closed: -40 to +105°C
Air Filter	3000/04, 6500/01, 6888/01, 8222/01, 8444/01, 4000/01	-

The use case data has been collected from Magic Loggia Ultimate that is currently available in the market and has been used for many years. Information such as frequency of use, cleaning period, and maintenance period of the devices that have been used in the market for 10 years are recorded in the form by the users. In the collected data, different maintenance and cleaning periods were applied to the devices. There is no negative effect on the performance of these devices due to the cleaning and disinfection cycles. The devices from which the data is collected maintain their performance from the first time they are used. Therefore, the information that the lifetime of our device is 10 years is supported by these forms.

Maintenance periods are defined in the Section 12.2.

12.3. REPAIRING

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

12.4. CLEANING & REPROCESSING

Follow the national infection prevention policies and reprocessing regulations.
Follow the infection prevention policies and reprocessing regulations of the healthcare facility (e.g., concerning the reprocessing cycles).

12.4.1. CLASSIFICATION OF MEDICAL DEVICES

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

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

12.4.2. CLASSIFICATION OF DEVICE-SPECIFIC COMPONENTS

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

CLASSIFICATION	EXPLANATION
Non critical	Grommets, Monitor tray, Pillar, Tank support link Sensor module (exterior surface), Canopy general (exterior surface) Inner wall (Canopy), QT window, Heater block (radiator), Fan blower Oxygen system inlet cover, Heater / block fixing latch, Hose holder, Main body (Base Unit), Drawers, Trendelenburg top tray (Mattress tray), Ventilation tray, Mattress, Scales module, X-Ray Tray, L profile, Water reservoir
Semi-critical	None
Critical	None

12.4.3. OVERVIEW OF THE REPROCESSING PROCEDURES OF THE COMPONENTS

Components	Surface Disinfection With Cleaning (Low Level Disinfection)	Machine Cleaning with Steam Sterilization	Description Of the Procedure
Grommets	Yes	No	Surface disinfection with cleaning
Control module	Yes	No	Surface disinfection with cleaning
Monitor tray, Pillar, Tank support link	Yes	No	Surface disinfection with cleaning

Sensor module (exterior surface)	Yes	No	Surface disinfection with cleaning
Canopy general (exterior surface)	Yes	No	Surface disinfection with cleaning
Inner wall (Canopy)	Yes	No	Surface disinfection with cleaning
QT window	Yes	No	Surface disinfection with cleaning
Heater block (radiator)	Yes	No	Surface disinfection with cleaning
Fan blower	Yes	No	Surface disinfection with cleaning
Oxygen system inlet cover	Yes	No	Surface disinfection with cleaning
Heater / block fixing latch	Yes	No	Surface disinfection with cleaning
Hose holder	Yes	No	Surface disinfection with cleaning
Main body (Base Unit)	Yes	No	Surface disinfection with cleaning
360º Rotating Drawer	Yes	No	Surface disinfection with cleaning
Trendelenburg top tray (Mattress tray)	Yes	No	Surface disinfection with cleaning
Mattress	Yes	No	Surface disinfection with cleaning
Scales Module	Yes	No	Surface disinfection with cleaning
X-Ray Tray	Yes	No	Surface disinfection with cleaning
L profile	Yes	No	Surface disinfection with cleaning
Water Reservoir	Yes	No	Surface disinfection with cleaning
Humidifier	No	Yes	Machine cleaning with steam sterilization

12.4.4. METHODS OF CLEANING

The recommended methods mentioned below should be used to clean the device to prevent damage or contamination.

CAUTION

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

NOTE

For off gassing of the incubator, before placing the patient in a new or recently cleaned incubator, ensure proper ventilation of the device. This can be achieved by running the incubator in a well-ventilated area for an extended period of time, ideally with the access panels open.

12.4.5. CLEANING AND DISINFECTING INDIVIDUAL COMPONENTS

12.4.5.1. CANOPY AND INNER WALL

- Keep the exterior clean and free of dust, dirt, and residual fluids.
- Clean with a slightly wet cloth using non-alcoholic hand soap and warm water.
- After cleaning, wipe with a damp cloth and rinse. Be sure to rinse thoroughly.

WARNING

- Before cleaning, turn off the Magic Loggia Ultimate and unplug the device from the AC power source and remove all accessories. Do not immerse the device in water or spill liquids on the modules.
- Do not use alcohol to clean the canopy. Alcohol can damage the outer surface of the canopy.
- Do not clean canopy and inner wall by steam sterilization.

12.4.5.2. SENSOR MODULE, SCALE MODULE AND 360º ROTATING DRAWER

- Keep the exterior clean and free of dust, dirt, and residual fluids.
- Clean with a slightly damp cloth using non-alcoholic hand soap and warm water or hospital-approved non-abrasive solutions.
- After cleaning, wipe with a damp cloth and rinse. Be sure to rinse thoroughly.

WARNING

- Before cleaning, turn off the Magic Loggia Ultimate and unplug the device from the AC power source and remove all accessories.
- Do not spill liquids into the modules when cleaning them. Failure to do so may result in personal injury or equipment damage.
- Use special care when cleaning sensitive screen surfaces. Clean with a soft, dry cloth.
- Do not clean sensor module, scale module and 360° rotating drawer by steam sterilization.

12.4.5.3. HUMIDIFICATION MECHANISM

- Keep the inside of the humidifier clean of dust, dirt and residual fluid.
- Use hospital-approved mild, non-alcohol soap, water and non-abrasive solutions and wipe with a damp cloth.
- Remove the humidifier. Clean the interior with a mild detergent/disinfectant solution.
- Rinse parts and dry thoroughly before reassembly.
- The humidifier can be disinfected with recommended solutions. The humidifier can also be disinfected by steam sterilization.
- The following solutions can be used to disinfect the humidifier:

Trademark	Trademark Owner	Certification
Oxycide	Ecolab USA	EPA Reg. No. 1677-237
Dismozon	BODE Chemie	CE

WARNING

- Do not remove and clean the humidifier during operation.
- The humidifier should be cleaned daily and the water reservoir should also be changed daily.
- Do not use peroxide solutions to clean the water reservoir.
- Do not use alcohol, chlorine, alkaline acid, sodium hypochlorite (bleach) aqueous solution, or aldehyde chemicals to clean.

12.4.5.3.1. STEAM STERILIZATION OF WATER RESERVOIR

- It is recommended that sterilization be performed using FDA-approved sterilizers and accessories.
- Thoroughly clean and dry the humidifier before beginning steam sterilization. Steam sterilization of the water reservoir is performed at 121°C for 30 minutes.
- Many repeated sterilization cycles may cause damage (small hairline cracks) in some areas that may weaken the reservoir and eventually require replacement.

Method of Sterilization	Traditional Sterilization Process
Type of Cycle	Gravity-Displacement Steam Sterilization Cycles
Exposure Time	30 min /sec
Temperature	121.0°C
Drying Time	30 min /sec

12.4.5.4. DISPOSABLE/ REUSABLE SKIN TEMPERATURE PROBES

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

WARNING

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

12.4.5.5. ELECTRONIC HARDWARE SURFACE CLEANING DISINFECTION PROCESS

- Use a low or medium strength disinfectant to clean all surfaces. Thoroughly clean and dry the device, including the electronics, and allow to dry.
- Be sure to clean all holes and recesses, then dry with a clean microfiber cloth or clean paper towel and allow to dry.

WARNING

- When cleaning and disinfecting the surfaces around the Control Module, Sensor Module, Display Module, Scale Module, Lift System buttons, LCD screen, Membrane Assembly, and On/Off buttons, do not spray the cleaning solution directly onto the surface of the device, but wipe with a damp cloth.
- Cleaning with steam sterilization is not possible.

12.4.5.6. CLEANING PROCESS OF HEATER BLOCK (RADIATOR) AND FAN BLOWER

- Before cleaning, remove the heater block using thermal gloves.
- Wipe the block with the recommended disinfectant.

CAUTION

- Do not forget to apply heat transfer compound (thermal paste) inside the heater block after cleaning.

- Remove the fan blower for cleaning.
- Wipe/wash the blower with water or disinfectant.
- After cleaning, replace the blower in the fan shaft.

CAUTION

- Since the heating block may be hot during operation, it may cause injury. Therefore, wait at least 45 minutes after turning the power off until the heater block cools down before handling this part.

WARNING

- Failure to clean and properly reassemble the heater block and fan BLOWER after cleaning may result in injury to the user and product. Use in this manner may result in reduced airflow, low airflow affecting temperature control and creating high oxygen levels in the incubator.
- Do not clean the inner channel heating surface of the heater block and do not wipe thermal paste. If there is not enough thermal paste on the inner surface of the heater block, add more.
- If there is a risk of infection in the incubator, clean the thermal paste and replace the thermal paste after disinfection.
- Autoclaving may damage equipment or impair functional integrity.
- Do not steam sterilize parts when disassembling for cleaning.
- Do not immerse the heater assembly in liquid.
- If liquid comes in contact with the inside of the body where the heater and fan are located, the motor and heater may be damaged.
- Prevent liquids from entering the motor shaft and heater while the heater block is cleaning the fan blower.
- Do not clean the heater block and fan blower by steam sterilization.

12.4.5.7. CLEANING PROCESS OF THE AIR INLET FILTER CHAMBER AND COVER

- Clean the filter compartment and cover.
- Install a new air inlet filter.
- Replace the air filter every 3 months.

CAUTION

- Make sure that the filter is routinely checked by an Ertunç Özcan Technical Service.
- The filter may need to be replaced sooner than 3 months, especially if the unit is used in an unusually dusty environment.

WARNING

- A dirty air inlet filter can affect performance or cause carbon dioxide (CO_2) build-up.
- Do not clean the air inlet filter chamber and cover by steam sterilization.

WARNING

- Before cleaning the incubator, unplug the power cable.
- The control module heater can be hot enough to burn if touched; do not disassemble the control board until at least 45 minutes after the unit has been turned off. Do not touch the heater.
- The incubator should be thoroughly cleaned and disinfected after each patient change, but at least once a week. For the most effective cleaning, disassemble the device parts prior to cleaning. The steps for disassembling the device parts are described in Section 12.4.6.

12.4.6. DISASSEMBLY STEPS

1. Before disassembly, the locking mechanisms of the four wheels of the incubator should be activated for safety. To lock the wheels, press the latch on the wheel and move the latch to the position shown in Figure 45.

Figure 31: Wheels unlocked

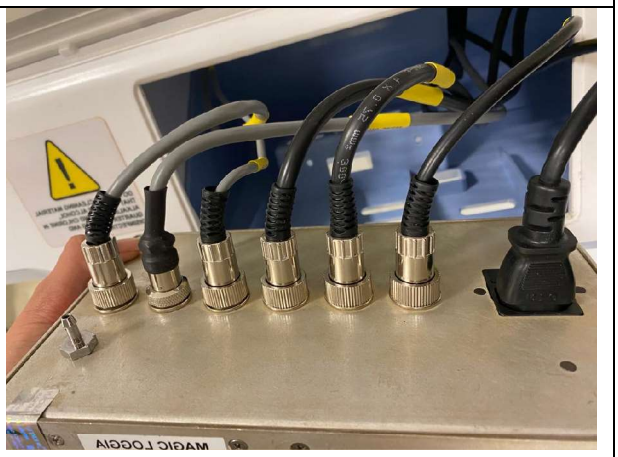
Figure 32: Wheels locked

2. Make sure the incubator power cable is unplugged.
3. Press the Power key to turn off the display panel.
4. Follow the steps below to disassemble the sensor module.

Disassemble the skin and scale probes.	
Slide the sensor module backward to remove it.	
Remove the analyzer module by pulling it toward you. **WARNING:** Do not spray liquid on the surface of the sensor module. When cleaning, wipe the surface with a soft, wet cloth only.	

Disconnect the sensor module cable of the analyzer.	

5. Follow the steps below to disassemble the control module

Turn the thumbscrews while holding the panel, then slide the panel out of the slot.	
Remove the module from the incubator.	
Remove the socket and DIN type connector.	

6. Rub the surface of the module with a wet cloth or disinfectant. Please follow the manufacturer's instructions regarding the use of recommended cleaning agents.
7. Lift the canopy as shown in Section 11.3 and clean the surfaces underneath by rubbing the surfaces of the heater with a damp soft cloth or disinfectant. Follow the manufacturer's instructions regarding the use of recommended cleaning agents.
8. To clean the radiographic surface, first lift the canopy and then pull out the radiographic surface.

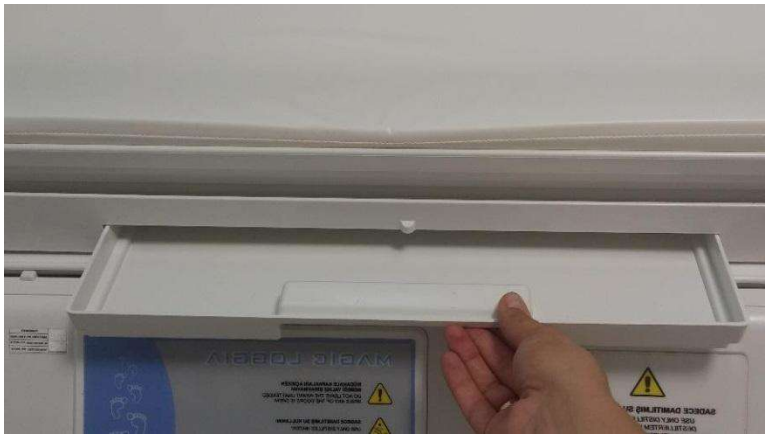


Figure 33: Disassembling the X-Ray Tray

9. When the canopy is raised, pull the patient mattress tray toward you. Remove the patient mattress and tray by lifting them.

Figure 34: Disassembling Patient Mattress and Tray

WARNING

- The weight capacity of the optional scale is ≤10 kg.
- If more than 10 kg of weight is placed on the scale during cleaning, maintenance, and repair of the device, be careful not to place more than the specified weight on the scale, as the scale's operating mechanism may be damaged.

10. After removing the patient mattress and tray, slide the lower tray back into place. When it is back in place, lift it from both sides to disassemble.

Figure 35: Disassembling the Lower Tray

10. Remove the handles of the Trendelenburg mechanism by pulling the handles upward.

Figure 36: Disassembling the Trendelenburg Mechanism Lifters

11. To remove the bottom tray, lift it by holding it through the channels located on the right and left sides of the incubator.

Figure 37: Disassembling the Lower Tray

12. Remove the fan and heater top plate by pulling them toward you.

WARNING

- Since the heating block may be hot during operation, it may cause injury. Therefore, wait at least 45 minutes after turning the power off until the heater block cools down before handling this part.

Figure 38: Disassembling the Top Plate

13. Remove the fan and heater by pulling them up. Remove the fan as shown in Figure 52 using the needle-nose pliers to remove the clamp holding the fan.

Figure 39: Removing the Fan

Figure 40: Removing the Heater

Figure 41: Remaining Surface After Removing the Fan and the Heater

14. Wipe down all surfaces after removing the fan and the heater.

CAUTION

- If materials such as injector caps, gauze, and tape fall into the area where the blower and heater are located due to use of the device, be sure to clean these materials from the area. The absence of these materials will reduce the performance of the device (air flow obstruction, heating problem, odor problem), so make sure the area where the heater and blower are located is clean when cleaning.
- White thermal paste on the heater provides heat transfer. Do not wipe when cleaning. In case of deletion, contact Ertunç Özcan Technical Service.
- Check whether the thermal paste inside the resistance is dry or not; if the device is under warranty, obtain the paste from Ertunç Özcan Company, otherwise contact Ertunç Özcan Technical Service.

15. Carefully reinstall the fan and heater, making sure they are properly seated.
16. Replace the top plate.
17. To open the inner walls of the canopy, follow the instructions shown in Figure 55.

Figure 42: Opening Inner Walls

18. To remove the QT window covers, pull them back.

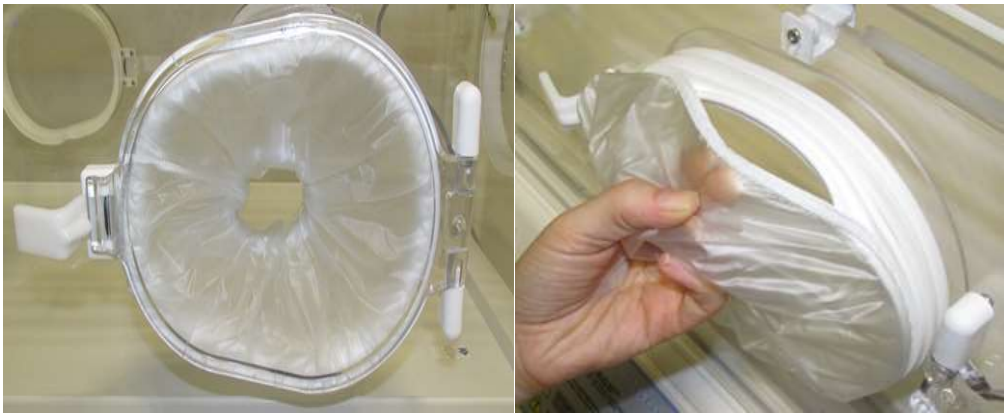


Figure 43: Disassembling the Covers

19. Remove the air inlet microfilter by loosening the screws on each side.

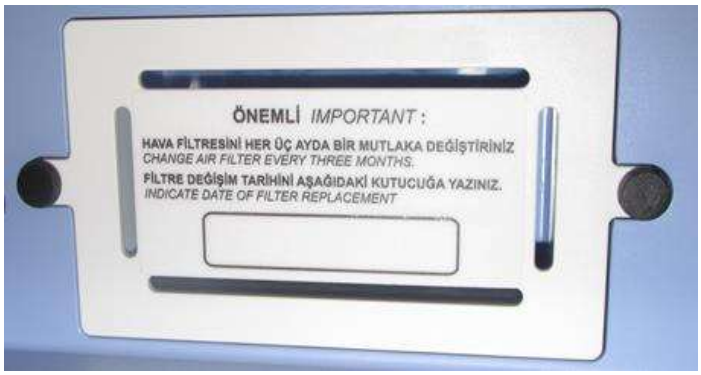


Figure 44: Disassembling the Air Inlet Microfilter

20. Reassemble the incubator and put the display panel back into the case when it is completely dry.
21. Disassemble the water reservoir as shown in Figure 39. Sterilization can be performed as desired.

WARNING

- Do not spray liquid on the surface of the sensor module. When cleaning, only wipe the surface with a soft, wet cloth.

12.4.7. CLEANING, DISINFECTION AND DRYING OPERATION PROCEDURES

12.4.7.1. CLEANING PROCEDURES

Product specific cleaning procedures should be followed. The Magic Loggia Ultimate and its accessories should be cleaned and cared for according to the instructions in this procedure. The Magic Loggia Ultimate requires proper maintenance and preventive care. This will ensure reliable performance and support the high level of performance required.

Cleaning, Disinfection and Drying Operation Procedure;

1. Remove dirt immediately. Use a cloth dampened with disinfectant to remove dirt and debris. Do not spray cleaning solution directly on the surface of the device.
2. Disinfect the surface of the component/device. Wipe the device thoroughly 3 times. Follow the contact time and mixing percentages recommended by the disinfectant manufacturer.
3. Remove residue after the product has been exposed to the disinfectant for the specified contact time.
4. Wipe with a microfiber cloth dampened with water (preferably drinking water quality). Allow to dry thoroughly.
5. Check the product for visible dirt. Repeat steps 1 to 5 as needed.
6. Check and ensure the product for visible damage and replace if necessary.

WARNING

- Perform cleaning when the device is not in use. Make sure that the power cable is unplugged and not working. Perform the cleaning procedure with the device turned off and cold.
- Be careful when assembling and disassembling devices with heater, fan motor, humidification, and condensation systems.
- Do not clean the inner duct heater surface of the heater block and do not wipe the thermal paste. If there is insufficient thermal paste on the inner surface of the heater block, add more.
- If there is a risk of infection in the incubator, clean the thermal paste and replace the thermal paste after disinfection.
- If liquid has dripped on the bottom surface of the body, dry the surface with a clean microfiber cloth or paper towel dampened with a cleaning solution and disinfectant to dry the surfaces.

12.4.7.2. DISINFECTANTS

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

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

WARNING

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

12.4.8. INSPECTION BEFORE USE

12.4.8.1. VISUAL INSPECTION

CHECKED ITEM	DESCRIPTION
Appearance	The main body and canopy must not be broken or deformed. (Otherwise, the patient and/or the user may be injured due to breakage, etc.)
Mechanical Connecting Parts	The canopy should be securely attached to the main body with the mechanical connectors. (Otherwise, the canopy may fall down.)
QT Window	Armhole connections should be made to QT window seals and covers.
Grommets	Make sure grommets are installed on both sides of the covers.
Sensor Module	It should not be broken or deformed. (Failure to do so may result in unsatisfactory control due to incorrect detection by the sensors.)
Access Panel Control Button	Each button should be held securely. It should safely open and close the access panel. (Otherwise, the patient may fall out.)
Trendelenburg Mechanism	It should operate smoothly. (Otherwise, it may not work.)
Power Switch	It should turn the power on and off safely. (Otherwise, it may not function).
Wheel	Each wheel should turn smoothly. (Otherwise, it will not move easily).

Filter	It should be clean. (Otherwise, the air circulation may not be controlled properly.)
Skin Temperature Probe	When the skin temperature probe is connected and the probe tip is in place, an appropriate temperature should be displayed.
Skin Temperature Probe Connecting Port	There should be no breaks or dirt in the area around the connection port.
Power Cable Inlet	The cable inlet should be clean without medical fluid.
Power Cable	The plug must not be deformed. The cable must not be damaged.
Height Adjustment	It should run smoothly, without noise.

12.4.9. CONTROL AFTER CLEANING AND DISINFECTION

12.4.9.1. ASSEMBLY OF INCUBATOR SUBCOMPONENTS / EQUIPMENT

WARNING

- Failure to install or properly install the device after electronic and mechanical equipment, hardware connections, cleaning, or maintenance may affect the basic performance and safety of the device.

1. Install the device according to the User Manual.
2. Check all cleaned and reassembled components for breakage or cracks.

WARNING

- Check that the canopy is securely attached to the body and that all connections are made properly.

3. Make sure the heater block fixing pin connection is made to maintain the distance under the cover before attempting to install the oval cover. Maintain the distance between the heater block and the oval cover in devices without a heater block fixing pin.
4. Install the oval cover.
5. Place the L profile arms.
6. Place the patient tray and the X-Ray tray inside.
7. Install the balance module.
8. If the patient mattress is not suitable for visual and physical examination, replace it.

WARNING

- If the cables and sockets of electronic equipment are not installed after cleaning or maintenance, the performance and safety of the device may be compromised.

IMPORTANT
Make sure the patient tray is inserted before reuse.

9. Make armhole connections to QT window seals and covers.
10. Make sure grommets are installed on both sides of the covers. Make sure the sensor module slot grommet is inserted. If the grommets are crooked or torn, replace them.
11. Check the hardware on the canopy, including the window latch, cover lock, and pin, and make sure they are working.
12. Replace the air inlet filter if it is damaged, visibly dirty, or more than 3 months old.
13. Install the air inlet filter cover and tighten the two thumbscrews.
14. Make sure the humidification module is connected to the water tank. Verify that there is no leak or leakage in the humidification system by adding distilled water to the water tank. If there is no leakage or spillage, place the humidification system in its housing on the body over the slide and lock the slide latch.
15. If necessary, reinstall any accessories previously removed from the device.

12.4.9.2. PREPARATIONS BEFORE REUSE

1. Assemble and prepare the device ready for use.
2. Check whether it is ready for operation.

12.4.9.3. PUTTING INTO SERVICE (MAKING AVAILABLE)

Safety Information

WARNING
- If the device is not properly cleaned, disinfected, or installed, it may become contaminated with infectious agents.

CAUTION
- The use of alcohol while cleaning the device may cause minor stress on the device, causing ultraviolet radiation to crack and / or puncture. Do not use alcohol, chlorine, alkaline acid, sodium hypochlorite (bleach) aqueous solution, aldehyde-containing chemicals for cleaning.
- Do not expose clear acrylics to direct radiation from germicidal lights.

IMPORTANT
Before starting technical service intervention or maintenance / repair operations, clean and disinfect the device.

12.4.10. RISK CONTROL OF CLEANING PROCESS

Elimination of risks arising from cleaning is indicated in the risk control table below.

POTENTIAL RISK	POTENTIAL HARM	RISK CONTROL
Failure to clean or disinfect the incubator	Biological- Infection	When the patient is discharged, or at least once a week, the incubator should be thoroughly cleaned and disinfected.
Failure to clean the heating surfaces according to the instructions	Biological- Infection	Disinfectant etc. Wipe the heater surfaces with a soft wet cloth. Always follow the cleaning solution manufacturer's instructions for use.
The incubator is connected to the power supply during cleaning.	Electromagnetic/ Electrical Energy- Electrical Shock	Do not clean the device while it is operating. Make sure the power cable is unplugged and inoperative. Perform the cleaning procedure with the device turned off.
Disassembling the control module heater without waiting for it to cool enough	Thermal Energy- Skin Burn	The control module heater can be hot enough to burn if touched; do not disassemble the control board until at least 45 minutes after the unit has been turned off. Do not touch the heater.
Cleaning the incubator with organic solvents scratching compounds, strong acids, or strong bases.	Non-life-threatening change in clinical status- Chemical – Damage to parts of device	Disinfectants recommended by the manufacturer should be used during cleaning.
Spraying the cleaning solution directly on the surface of the device.	Non-life-threatening change in clinical status – Damage to functionality of the device	Cleaning process recommended by the manufacturer should be used during cleaning.
Using alcohol, chlorine, alkaline acid, sodium hypochlorite (bleach) aqueous solution, aldehyde-containing chemicals (materials with abrasive properties) when cleaning the incubator	Damage to functionality of the device -Minor stress to the incubator and cracking and/or puncturing due to ultraviolet radiation	Cleaning process recommended by the manufacturer should be used during cleaning process of canopy and inner wall

13. TROUBLESHOOTING

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

SIGN	PROBABLE CAUSE	SOLUTION
The system is not powered on and the power failure alarm does not work.	The main power switch of the incubator may not be turned on.	Turn on the power switch.
Power failure alarm is on.	The power cable is not plugged into the switch (no UPS system).	Make sure the power cable is plugged in to the switch.
	Power cable is not connected to incubator (no UPS system).	Make sure the power cable is connected to the incubator.
	Battery is not charging. (UPS system present)	Contact with Ertunç Özcan Technical Service in order to change the battery.
Low temperature alarm is activated	Access panels or QT windows are open	Close access panels or QT windows.
	Skin probe is not stabilized properly (only in Skin Active mode)	Check the skin probe connection
Low skin temperature alarm is activated	Skin probe is not properly attached to skin (only in Skin Active mode)	Check the skin probe connection
Low oxygen concentrations	Access panels or QT windows are open	Close access panels or QT windows.
	Access panel cloths are open or not attached properly	Check the cloths attachment.
	Grommets are not attached properly.	Check and attach the grommets attachment.
	Canopy is not attached properly.	Make sure the canopy is attached properly.
	Air inlet microfilter cover is not properly secured	Check the air inlet microfilter cover and stable it.
	Air inlet microfilter is blocked	Check the air inlet microfilter and replace if necessary.
	The inner tube is not attached.	Turn off the incubator and do not operate it.
High oxygen concentrations	Filter is not installed	Check and install it if necessary.
	Air inlet microfilter is dirty	Change the filter
	Air inlet pipe is not adjusted	Connect the air inlet pipe
	Dirty fan is forced	Check the fan

	Not enough air flow inside the incubator	Check that the fan is attached. If it is attached, turn off the incubator and do not operate it.
High temperature and/or high set temperature alarm	Canopy hinge is not properly attached.	Make sure the hinges are attached properly by checking their attachments.
Low humidity rate alarm is on	Water reservoir of humidifier is empty	Fill the water reservoir. If the alarm is still active, turn off the incubator and do not operate it.
No water in the water reservoir of humidifier	Water reservoir of humidifier is empty	Fill the water reservoir. If the alarm is still active, turn off the incubator and do not operate it.
No sensor module alarm is on	Sensor module is not installed.	Check the installation of the sensor module.
Air flow alarm	Fan error	Change the motor fan.
	Filter lid or the controllers are not attached properly.	Check and stable it.
Fan error	Error in the motor fan	Call the authorized service.
	Air filter is dirty	Change the air filter
	Motor fan is dusty	Clean the motor fan
Measuring wrong temperature values	Air circuit has been blocked	Remove equipment that is blocking the normal air flow.
	The mattress or the mattress tray is not positioned correctly.	Check the positioning of the mattress and the mattress tray

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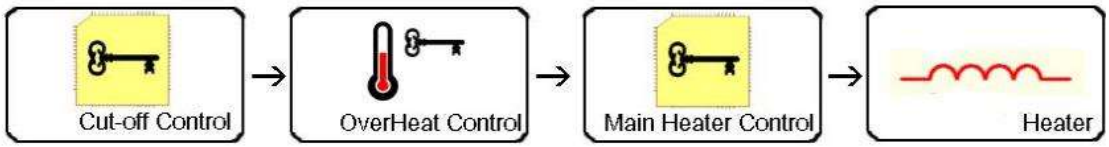
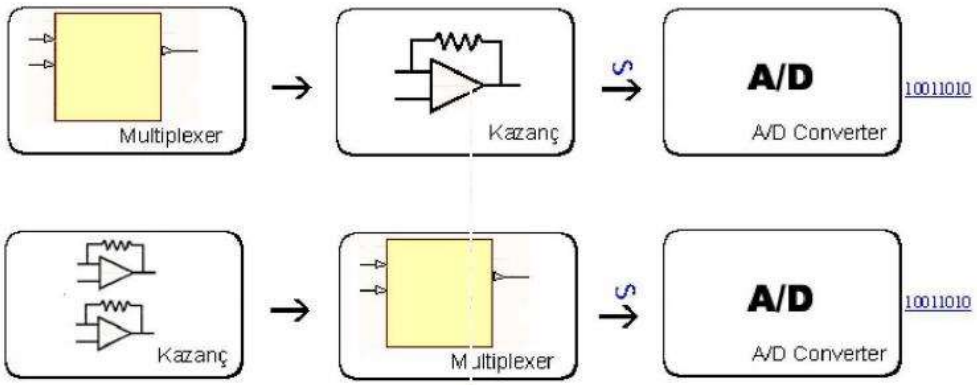
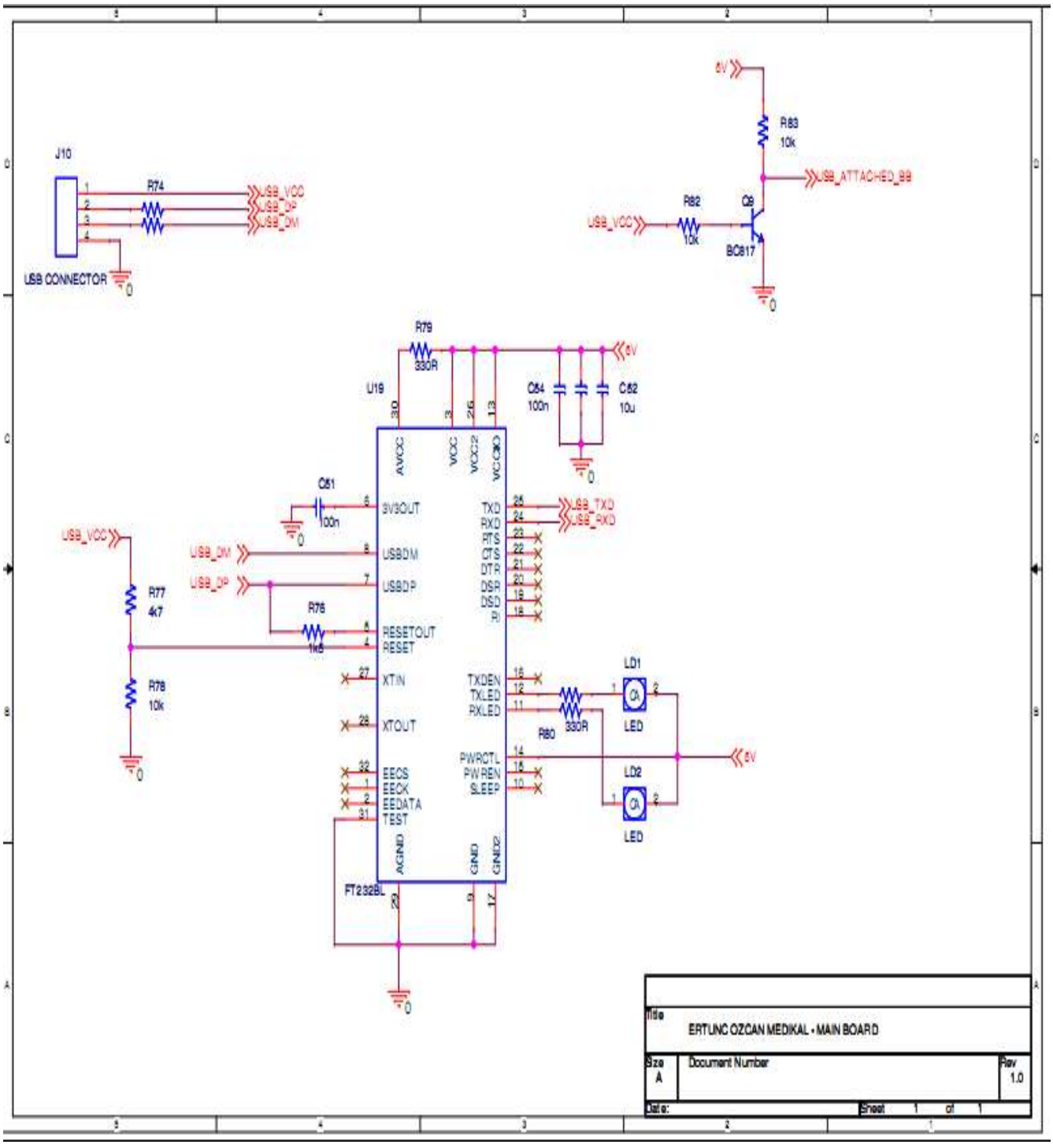
14. ELECTRONIC CIRCUIT SCHEMATICS

SENSORS

There are 3 sensors on the device, these are; 1 air temperature sensors, 2 skin temperature sensor. There is also an optional second skin temperature sensor that can be used for twins.






J10
R74
USB_VCC
USB_DP
USB_DM
USB CONNECTOR
6V
R83
10k
USB_ATTACHED_BB
R82
10k
Q8
BC817
USB_VCC
R79
330R
U19
C54
100n
C52
10u
C51
100n
3VOUT
USBDM
USBDP
RESETOUT
RESET
XTIN
XTOUT
EECS
EECK
EEDATA
TEST
AVCC
VCC
VCC2
VCC3IO
AGND
GND
GND2
FT232BL
TXD
RXD
RTS
CTS
DTR
DSR
DSD
RI
USB_TXD
USB_RXD
TXDEN
TXLED
RXLED
PWRCTL
PWREN
SLEEP
R77
4k7
R76
1k5
R78
10k
R80
330R
LD1
LED
LD2
LED
Title
ERTUNC OZCAN MEDIKAL - MAIN BOARD
Size
A
Document Number
Rev
1.0
Date:
Sheet 1 of 1

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

ANNEX A - ELECTROMAGNETIC SUITABILITY

ELECTROMAGNETIC SUITABILITY (EMC) GUIDE

Safety standards: IEC 60601-1, IEC 60601-2-19

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.
- Portable and mobile RF communication devices may affect the electrical medical devices. Be careful when using these devices around electrical medical devices.
- This device/system is designed to be used only by a professional health officer. This device/system may cause radio interferences and may cause disorder to the working order of the devices close by. Precautions to reduce negative effects may include; the air can be secured or the place of the device/system can be changed orientation can be carried out again.

Electromagnetic Suitability and Tests

Magic Loggia incubator 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

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

Guide and Manufacturers Declaration on Electromagnetic Immunity

Magic Loggia infant incubator is aimed to be used in the below stated electromagnetic environment. The customer or user of the Magic Loggia infant incubator, must guarantee to use this device in these environments.			
Immunity Tests	**IEC 60601-1-2 Test Level**	**Suitability Level**	**Electromagnetic Environment-Guide Information**
Electrostatic discharge (ESD) IEC 61000-4-2:2009	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	The site where the Magic Loggia infant incubator is located must be, wooden, concrete or ceramic tiled. If these sites are covered with a synthetic material, the relative humidity rate must at least be 30%.
Electrical fast transient burst/explosion IEC 61000-4-4:2012	For ± 2 kV power supply feeding line For ± 0.5 kV, ±1 kV, ±2 kV, ±4kV input/output line	100 kHz Implementation Time: ≥ 60s	The capacity of the power network must be at the capacity of the ones used in typical commercial environment or a hospital.
Sudden impact IEC 61000-4-5:2014/A1:2017	Line-to-line, ±0.5 kV, ±1 kV differential mode Line-to-ground, ±0.5 kV, ±1 kV, ±2 kV differential mode Phase angles 0, 90, 180, 270	Repetition rate 1 min It fits the circumstances.	The capacity of the power network must be at the capacity of the ones used in typical commercial environment or a hospital.
Voltage dips of the power source input lines, short interruptions and voltage variations IEC 61000-4-11:2004/A1:2017	For the voltage pit 0% Ut (for 0.5 cycles, 10 ms duration, angles: 0,45,90,135,135,180,225,270, 315) 0% Ut (For 1 cycle, in 20 ms time, angles: 0 70% Ut (For 25 cycles, 500 ms duration, angles: 0 0% Ut (For 250 cycles, 5000 ms duration, angles: -	12V, 0,5 cycle 12V, 1 cycle 168V, 25 cycle 12V, 5 second It fits the circumstances.	The capacity of the power network must be at the capacity of the ones used in typical commercial environment or a hospital. If the user of the Magic Loggia infant incubator needs to keep working in a main supply shortage situation it is suggested that the device is feed by continuous power supply or a battery.
Network frequencies (50/60 Hz) magnetic field IEC 61000-4-8:2010	30 A/m	30 A/m It fits the circumstances.	Magnetic field network frequencies must be at the level used in typical commercial environment or a hospital.
Note- Ut, is the main voltage before the test levels are applied.			

Guide and Manufacturers Declaration on Electromagnetic Protection

Magic Loggia infant incubator is aimed to be used in the below stated electromagnetic environment. The customer or user of the Magic Loggia infant incubator, must guarantee to use this device in these environments.

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

Note 1- On 80MHz and 800MHz, a higher frequency gap is applied.
Note 2- This manual 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 2.7 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 Magic Loggia infant incubator is used goes over the, above stated. Applicable RF suitability level the Magic Loggia infant incubator 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 Magic Loggia infant incubator 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 Magic Loggia Infant Incubator

Frequency Feeder	**150 kHz and 80 MHz**	**150 kHz and 800 MHz**	**800 MHz and 2,7 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 applied in all situations. Buildings, objects and people can affect the electromagnetic radiation to be reflected or absorbed.			
Electromagnetic Immunity Magic Loggia infant incubator is aimed to be used in the below stated electromagnetic environment. The customer or user of the Magic Loggia infant incubator, must guaranty to use this device in these environments			

Immunity Test	**IEC 60601-1-2 Test Level**	**Suitability Level**	**Electromagnetic Environment-Guide Information**
Immunity to conducted disturbances induced by RF fields EN 61000-4-6:2014	3 Vrms 150 kHz and 80MHz	3 Vrms	Magic Loggia Ultimate infant incubator 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.
Radiated, radiofrequency, electromagnetic field immunity EN 61000-4-3:2006/A2:2010	3V/m 80 MHz and 2.7 GHz	3 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 Magic Loggia infant incubator is used goes over the, above stated. Applicable RF suitability level the Magic Loggia infant incubator must be investigated to make sure it is operating normally.

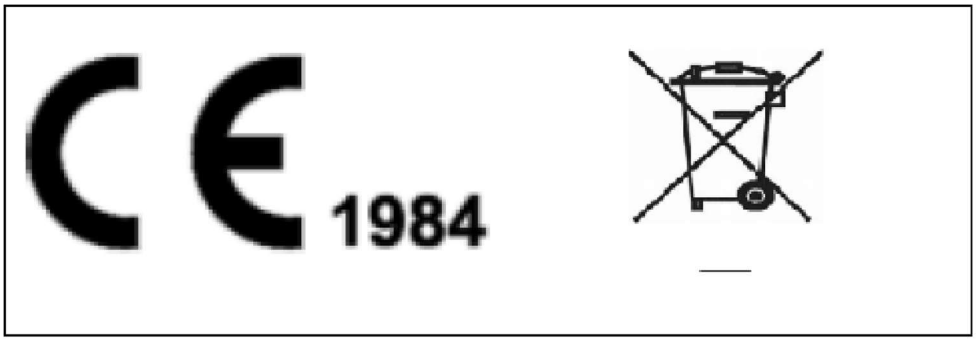
Note 1- This guide information can be applied in every situation. Buildings, objects and people can affect the electromagnetic radiation to be reflected or absorbed.

Note 2- For the actual isolation efficiency and the isolated surface filter attenuation to supply the lowest feature, it must be approved.

Electrostatic Discharge

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

ANNEX B -INFORMATION OF COMPLIANCE OF STANDARDS AND DIRECTIVES



Ertunç Özcan approves that; the usage, maintenance and service procedures are 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.

ANNEX C – CYBERSECURITY INSTRUCTIONS

Cybersecurity is critical throughout the lifecycle of a medical device, including the post-market phase.

The following is a description of all the interfaces and communication protocols that are available on the device.

Interfaces and Communication Protocols:

1. **Wi-Fi Connectivity:** Devices have Wi-Fi connectivity for data monitoring, remote access, and software updates.
2. **Serial Port (UART):** Serial port available for communication with external devices or for debugging purposes.

Please refer to Section 9.19 Settings for connecting to and using the Wi-Fi network on the device.

Cybersecurity Instructions:

Once an infant incubator is deployed and in use, ongoing cybersecurity measures are required to monitor, assess, and address potential vulnerabilities and threats. Below are instructions on the cybersecurity measures that should be taken in the post-market phase for the Magic Loggia Ultimate.

a) Firmware/Software Update Instruction

The following instructions for securing the cybersecurity of the device and updating the firmware/software are performed on the device.

These instructions provide a general framework for securing an infant incubator.

1. Default credentials are in a changeable format: Default usernames and passwords for all interfaces, especially web interfaces and remote access accounts, are not fixed. You can request your password from the web page.
2. Strong authentication application available on Wi-Fi connection for remote access.
3. Firewall configuration is available to restrict incoming and outgoing network traffic to essential services only.
4. The device firmware and software are kept up to date. Patches and updates are also released frequently to address security vulnerabilities.
5. Periodic vulnerability scans are performed at least annually to identify and remediate potential vulnerabilities in the device's software and configuration.
6. Train employees on cybersecurity best practices, including avoiding cyberattacks and recognizing suspicious activity.
7. A cybersecurity management plan is in place to quickly address any security incidents that may occur.
8. Only authorized personnel have physical access to the device.
9. Security experts are regularly engaged to perform penetration tests and security assessments of the device.

b) Instructions On Security Actions

Safety is paramount in the use of infant incubators to protect the health and well-being of patients. The following are precautions that should be taken and followed by the user or user facility to ensure the safe use of an infant incubator:

1. **Read and Understand The Instruction Manual:**
   - Begin by thoroughly reading and understanding this manual.
   - The manual contains critical information about the specific model of incubator and its safe operation.
2. **Setup and Adjustment:**
   - Place the device on a stable, level surface and make sure it is not near a heat source, direct sunlight or drafts.
   - Ensure that the neonatal device on which you are operating the device is properly grounded.
   - Ensure that all electrical connections are secure and meet local electrical safety standards.
3. **Daily Inspection:**
   - Visually inspect the device daily for loose or damaged parts, frayed cables, or signs of wear and tear.
   - Make sure the device is clean and free of debris or spills.
4. **Performance Check:**
   - Monitor and maintain the temperature and humidity levels provided by the device within the prescribed range for the patient's specific medical condition.
   - Calibrate and check the accuracy of the device's sensors regularly during maintenance periods.
5. **Patient Safety:**
   - Place the patient securely in the incubator to prevent accidental falls or movement.
   - Ensure that all accessories are properly secured and do not pose a risk to the patient
6. **Access and Visibility:**
   - Keep access to the incubator clear at all times so that medical staff can easily assess the patient.
   - Ensure that the viewing window is clear and unobstructed.
7. **Alarms and Monitoring:**
   - Familiarize yourself with the incubator alarm system and make sure it is working properly. Be trained in the use of the equipment provided by us.
   - Respond immediately to any alarms and follow the troubleshooting instructions in Section 13.
8. **Electrical Safety:**
   - Keep electrical cords and cables away from moving parts of the equipment to prevent pinching or damage.
   - Do not overload receptacles by installing additional equipment.
9. **Cleaning and Disinfection:**
   - Follow the recommended cleaning and disinfection procedures in Section 12.
   - Use approved disinfectants that are safe for infants.

10. **Maintenance and Service:**
    - Schedule regular maintenance checks according to the manufacturer's recommendations or local regulations.
    - Ensure that only authorized personnel repair or service the incubator.
11. **Training:**
    - Ensure that all personnel operating the equipment are properly trained in its use, maintenance, and safety procedures.
12. **Documentation:**
    - Maintain accurate records of temperature and humidity readings, alarm events, and any maintenance or service performed on the incubator.
13. **Recalls and Safety Alerts:**
    - Familiarize yourself with any recalls, safety alerts, or updates to the product. If necessary, take immediate action to address identified safety concerns.
14. **Local Compliance:**
    - Follow all local, state and national regulations and guidelines regarding the use of infant incubators.

Remember that the safety of the patient is the first priority when using an infant incubator. If you have any questions or concerns about the safe operation of the infant incubator, contact us for assistance.

c) Potential Cybersecurity Incidents

The device is protected against the cybersecurity events listed below and, in this context, the requirement verification test, static and dynamic code analysis, malformed input (fuzz) testing, vulnerability scanning and penetration testing activities were carried out by independent third parties.

Please contact Ertunç Özcan Technical Service when the following cybersecurity incidents occur:

1. **Unauthorized Access Attempts:** Unauthorized access to the network or control interface of the infant incubator.
2. **Malware Infection:** The incubator's cybersecurity measures can monitor for signs of malware infection, such as unexpected changes to system files or unusual network traffic patterns.
3. **Data Breach:** An unauthorized access or attempted infiltration of patient data or medical records stored on the infant incubator's system.
4. **Software Vulnerabilities:** The infant incubator cybersecurity system can monitor for known vulnerabilities in the device's software or operating system, and unpatched vulnerabilities may occur.
5. **Network Intrusion:** Unusual network traffic, unexpected connections in the incubator, or anomalies in network communications can cause a network intrusion.
6. **Security Configuration Changes:** Changes to security settings or configurations (e.g. firewall rules, user privileges) without proper authorization.

d) Notification of Cybersecurity Incidents to Users

In order to inform users about cybersecurity incidents and take necessary precautions, a product security information document has been shared on the website to reduce potential risks to patient safety and data security. In addition, customer security procedures were shared with the user on the website user access platform to enable users to address cybersecurity threats in the healthcare environment and take necessary measures.

e) Incident Response Plan

Incident Response Plan for Infant Incubator Users:

1. **Recognize the Event:**
    a. Be alert for unusual or suspicious device behavior, including unexpected alerts, system errors, or unauthorized access attempts.
2. **Isolate the Device:**
    a. If you suspect a cybersecurity incident, immediately disconnect the device from the network, if available, to prevent further potential danger. This step will help contain the incident and protect patient safety.
3. **Notify Relevant Personnel:**
    a. Notify your immediate supervisor or the person responsible for IT support at your healthcare facility about the suspected incident. Follow your facility's established communication protocol for reporting cybersecurity incidents.
4. **Document the Incident:**
    a. Keep detailed records of the incident, including date, time, and any observable symptoms or behaviors exhibited by the device. Documentation is crucial for later analysis and reporting.
5. **Contact Technical Support or IT Department:**
    a. Contact your healthcare facility's IT department/technical support team and Ertunç Özcan technical service immediately to report the incident and receive guidance on containment and resolution.
6. **Assist with the Investigation:**
    a. Collaborate with IT staff or incident responders during the investigation process. Provide any information or records that may help determine the root cause of the incident.
7. **Communicate with Healthcare Providers:**
    a. If the incident affects patient care, communicate with healthcare providers responsible for incubated infants to ensure patient safety.
8. **Return to Normal Operation:**
    a. Once the incident has been properly investigated and mitigated, work with IT staff to restore normal operation of the incubator. Ensure that it is securely reconnected to the network.
9. **Change Passwords and Access Credentials:**
    a. If the incident involves unauthorized access, contact Ertunç Özcan Technical service team to change all relevant passwords and access credentials associated with the device.
10. **Train Staff:**
    a. Share information about the incident (while maintaining patient privacy) with relevant staff members to raise awareness and help prevent future incidents.
11. **Review and Update Incident Response Plan:**
    a. After the incident is resolved, conduct a review and evaluation of the incident response process. Identify lessons learned and, if necessary, update the incident response plan to improve the handling of future incidents.

12. **Reporting to Authorities:**
    a. If required by regulations or law, report the incident to the relevant authorities, such as the healthcare regulator or data protection authority.
13. **Protect Confidentiality:**
    a. Strictly maintain confidentiality about the incident to protect patient privacy and comply with applicable laws and regulations.
14. **Test the Incident Response Plan Regularly:**
    a. Conduct regular tabletop exercises or simulations to test the effectiveness and readiness of the incident response plan.
15. **Keep Informed:**
    a. Stay informed about emerging cybersecurity threats and vulnerabilities related to medical devices and proactively update your cybersecurity measures accordingly.

Remember that responding to a cybersecurity incident is a coordinated effort involving IT professionals, healthcare providers and authorized personnel. Effective communication, documentation and collaboration are key elements of a successful incident response. Always prioritize patient safety and data security during incident response.

By taking these post-marketing cybersecurity actions, healthcare facilities can help ensure the ongoing safety and security of infant incubators and protect both patient data and the well-being of infants in their care. Continuous vigilance and proactive measures are essential to addressing evolving cybersecurity threats in healthcare settings.