ERTUNÇ ÖZCAN

BABYNEST H-100 MODEL TRANSPORT BABY INCUBATOR USER MANUAL

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INTRODUCTION

ERTUNÇ ÖZCAN company established by Ertunç Özcan in 1968 has been in service as a private company in the fields of importation, exportation, manufacturing and technical service on the purpose of selling medical devices and equipments besides hospital and laboratory supplies in Turkey. Since 2002, Ertunç Özcan has been manufacturing medical devices in its facility.

For further information about our company and products you can contact us from the contact information mentioned below;

HEADQUARTERS, DESIGN AND MANUFACTURING FACILITY

This facility covers the design, manufacture, distribution, sales and technical service activities of Phototherapy and Incubator Devices and their accessories within the scope of IS0 9001:2015, ISO 13485:2016 Standards and MDD 93/42/EEC.

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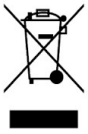
DEFINITIONS AND ICONS

NOTE, IMPORTANT, CAUTION AND WARNING

NOTE: Is used under the circumstances where clarification is need 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.
CAUTION: The term CAUTION is used in situations where there is a possibility of damaging the equipment.

WARNING: The term WARNING is used in situations where there is a possibility of injuring the patient or the user

TABLE OF ICONS

	**Caution: See the Relevant Annexes**		**Caution: Danger of Electrical Shock**
	**See the User Manual**		**Type BF Implementation Part**
	Power On (connect to a wall power switch)		**Caution: Hot Surface**
	**Power Off (disconnect from the wall power switch)**		**Manufacturer**
	Alternative Flow		**Do not throw out**
	**WARNING information**		**European Conformity**
MAX.	**Maximum**		**Serial Number**
	**Weight Limit**		**Keep Dry**
	**Frangible**		

This manual determines all the functions and usage instructions of the Ertunç Özcan brand Babynest H-100 model transport incubator.

NOTE : The explanations about the device which is stated in the user guide will be shown from Babynest H-100 model.

PURPOSE OF USAGE

The BabyNest H-100 model transport baby incubator is a baby transport incubator that is transported by a transport vehicle and designed to provide a suitable thermal environment for newborns and premature babies.

It is designed for the transport of newborns and babies in high risk group with serious illness and low weight babies to hospital.

The ambient temperature in the incubator where the baby is located and the skin temperature of the baby can be continuously monitored on the incubator screen.

RESPONSIBILITIES OF THE MANUFACTURER

The assembly, repair-maintenance and calibration activities of all incubator devices that our company has manufactured and sold are carried out with authorized technical personnel and equipment in accordance with standards. Ertunc Ozcan company is responsible for the reliability, safety and performance of devices.

Our company is not responsible for incorrect performance and failure to comply with maintenance recommendations as a result of not using the transport incubator according to the instructions for use. The device can only be repaired and calibrated by an authorized service staff.

All the users who operates the device must read and understand this user guide. When the transport incubator is not in use it must be stored with its user guide.

For further or detailed information please contact to the manufacturer.

CAUTION: During the warranty period if the transport incubator is interfered by unauthorized people, the warranty will be invalid.

The lifetime of the device you have purchased is 10 (ten) years. This is the period of availability of spare parts necessary for the device to function as described.

BABYNEST H-100 MODEL TRANSPORT INCUBATOR

OPERATION PRECAUTIONS

WARNINGS

- Misuse of the transport incubator can injure the baby. The transport incubators must be used only by the appropriately trained personnel under the supervision of a qualified medical personnel.
- The transport incubator shall not be used if it is not operating properly. Technical service must be given by an authorized and qualified staff.
- If the access panels are left open, the temperature inside the transport incubator will be affected by the working ambient temperature, so the preset temperature level may not be achieved. For this reason, do not leave the access panels open more than necessary. The value on the temperature display may not be reliable when the access panel is open. The baby must be kept away from this warm air flow, so as to prevent possible injuries.
- For the safety of the baby, do not leave the baby alone when the access panel and emergency response windows are open.
- When the access panels are open, warm air flows from under the front edge of the cushion to the top of the intake panel. This air temperature is normally higher than the air temperature inside the transport incubator. The baby must be kept away from this warm air flow, so as to prevent possible injuries.
- To prevent the baby from overheating the skin temperature must be monitored and checked in skin or air mode. The skin temperature must not be checked through rectal.
- It should be kept in mind that direct sunlight or phototherapy device and similar heat generating devices located very close to the transport incubator may affect the canopy temperature of the transport incubator unit and thus the air temperature in the transport incubator and the skin temperature of the baby.
- Spark generating auxiliary equipment should not be placed inside the baby transport incubator.
- Make sure that the attached parts of the transport incubator should not exceed the maximum weight capacity of the transport incubator.
- The skin temperature sensor should not be used as a rectal temperature sensor.
- The canopy should not be lifted while the baby is in the transport incubator. The baby should always be reached through the front cover or the side cover.
- In the transport incubator, auxiliary equipments (baby seats, headgear etc.) that may affect or even change the air flow should not be used. Otherwise, the temperature in the incubator will change and homogeneity will be disturbed, as a result, the baby's skin temperature will be adversely affected under these circumstances.
- When moving the transport incubator, at least two people are required for adequate control. Movements that can cause concussions should be avoided while the baby is inside.
- Make sure the bed is covered with cotton flannel type textile before putting the new-born to the bed.
- Please turn off the device with the on/off button when not in use.
- After the treatment is completed, turn off the device with the on/off button and unplug the power cord of the device until it can be used again for safety reasons.
- Special care must be taken to ensure that baby-worn devices and probes (type b applied parts) where the baby cannot be isolated from the ground are electrically safe. Medical electrical devices and equipment connected to the baby must be grounded.

ELECTRICAL PRECAUTIONS

WARNINGS

- To ensure grounding safety, connect the power cord only to properly grounded, hospital type power outlets. Do not operate the device if the grounding connection is suspected.
- The technical service of the device should always be performed by a qualified and authorized technical personnel due to the danger of electric shock.
- It should be ensured that the electrical properties specified in the device specifications are provided. Otherwise, personal injury or equipment damage may occur.
- Some chemical cleaning substances may be conductive. Please do not allow these cleaning substances to contact the electrical parts and do not spray these cleaning substances on surfaces. Otherwise, personal injury or equipment damage may occur.
- The control module of the device should not be cleaned by spraying or in a similar way. Cleaning agents that can be conductive can cause personal injury or equipment damage.
- Electrical equipments has a potential risk of electric shock. In this regard, please train your staff about the risks associated with electrical equipment.

EXPLOSION PRECAUTIONS

WARNINGS

- Please do not use the incubator in environments where easily flammable substances and gases (such as anesthetic gases) are present. Otherwise, personal injury or equipment damage may occur.
- The incubator should not be cleaned with flammable materials such as ether and alcohol, since it may cause fire even if a small amount of flammable materials left in the baby incubator comes into contact with oxygen.
- During cleaning and maintenance, turn off the oxygen supply of the incubator and cut off the oxygen flow of the incubator. When cleaning and/or maintaining is performed in oxygen-enriched environment, it presents a flammable and explosion hazard.
- Please keep all ignition sources such as matches, smouldering cigarettes, electric stoves and similar sources away from the incubator. Textiles, oil and other inflammable materials can ignite easily and burn violently in oxygen-enriched air.

HUMIDITY PRECAUTIONS

WARNINGS

- Please wet the humidifying sponge with water and place the sponge in its compartment.
- Please make sure all access covers are closed and pipe connection points are properly attached. Since open covers reduce the relative humidity inside the incubator, personal injury or equipment damage may occur.

OXYGEN PRECAUTIONS

WARNINGS

- The ignorant use of supplemental oxygen can lead to serious side effects, including blindness, brain damage, and death. Hazards may vary depending on the baby. The method, concentration and duration of oxygen therapy should be determined by the treating physician.
- In an emergency case where an oxygen treatment is needed, the physician should be informed immediately.
- The oxygen concentration that the baby inhales does not determine the oxygen partial pressure (SpO_2) in the blood. If deemed appropriate by the physician, blood SpO_2 value should be measured using appropriate clinical techniques.
- Oxygen flow rates cannot be used as an accurate indicator of oxygen concentrations in a transport incubator. Oxygen concentrations should be measured with a calibrated oxygen analyzer at intervals specified by the physician.
- Since a polluted air inlet filter can increase oxygen concentrations and lead to the formation of carbon dioxide, air filters should be changed regularly.
- Oxygen therapy can increase the noise level in the baby compartment.

SAFETY PRECAUTIONS

WARNINGS

- This guide should be read carefully and understood before using the transport incubator. Otherwise, it may cause injury.
- The misuse of the transport incubator may injure the new-born.
- Only properly trained personnel should use the transport incubator in the direction of a qualified physician aware of the currently known risks and benefits.
- Do not open the canopy while the new born baby is in the transport incubator. Access the baby through the access panels. Otherwise, it may cause personal injury or equipment damage.
- For the safety of the baby, do not leave the baby alone when the access panel is open. Otherwise, it may cause personal injury.
- Airflow passages should be kept open for patient safety and transport incubator performance during use.
- In order to prevent the new born baby overheat, please do not place the transport incubator out of direct sunlight or under a source of radiant heat.
- Do not place a surgical cover or a blanket on the new-born. It may lead to heat-related injuries and burns.

- Only authorized personnel can intervene in the section where the batteries (batteries) are located, due to the risk of chemical leakage.
- In order to place the new born baby into the transport incubator, please use access panels. Canopy should not be opened for placement.
- Always activate the wheel breaks before placing the baby into the incubator.
- Electrosurgical units or other devices that can emit electromagnetic waves may cause the skin temperature probe to detect a different temperature due to the electrical energy absorbed.
- In order to prevent the new-born from getting injury, the baby t's clothes, hoses, cables etc. must be kept in the boundaries of the bed when opening or closing the access panels or intervention windows.
- Please check all patient connecting hoses and cables before moving, removing, raising or lifting the bed to avoid injuring the baby.

PART 1
OVERVIEW

1.1. INTRODUCTION

This guide provides instructions for operation, cleaning, maintenance and troubleshooting of the Ertunc Özcan Babynest Model H-100 Baby Transport incubators. The manufacturer is not responsible for improper performance of the transport incubator if the user does not operate the unit in accordance with the instructions, does not follow the maintenance recommendations in Chapter 9 of this guide, or repairs are made with parts that are not approved for use. Calibration and repair should only be done by qualified service personnel.

This guide must be read and well understood by all persons who will operate the transport incubator.

This manual should be kept in a place that is easily accessible by the people who will use it.

If you do not understand something, please contact ERTUNC ÖZCAN Company for further information.

1.2. DESCRIPTION

The air circulation system of the transport incubator ensures stable temperature control, uniform temperature distribution, humidification, effective isolation of baby from airborne contaminants and control of oxygen concentrations.

Access to baby is provided by access panels. When the access panel is open, warm air flows from under the front edge of the cushion to the top of the access panel outlet; this minimizes the temperature drop in the air canopy environment.

The transport incubator is designed to be used at ambient operating temperatures between 20˚ and 30˚C under normal conditions.

In Babynest Model H-100 Baby Transport Incubators, skin or air temperature control is selected with the control module.

1.3. FEATURES

Features of the transport incubator are presented in Table 1. All features can be changed by the manufacturer without notice.

The use of access panels that can change the air flow pattern or other equipment and devices in the transport incubator can affect temperature regulation, temperature variability, transport incubator's temperature relation and baby's skin temperature depending on central pad temperature.

TABLE 1. FEATURES

CLASSIFICATION

Device Classification	Class IIb
Electrical Classification	I
Type	BF

STANDARDS

Designed in accordance with the requirements of below stated standards
(93/42/EEC) Medical Device Directive Council Decision
TS EN60601-1: 2009
TS EN60601-2: 2016
TS EN60601-2-19: 2021
TS EN60601-2-19-A11: 2021

ELECTRICAL FEATURES

Power Requirements	110 / 220-240 VAC (±%10) VAC
Frequency	50-60 Hz
Power Consumption	75 W
Extrernal DC Battery	12 VDC
Battery	12 VDC 26AH lead acid gel type

INCUBATOR FEATURES

Incubator Outside Dimensions	50.6 (Y) x 53.0 (G) x 102.0 (D) cm
Incubator Weight	40.0 Kg
New-born Bed Tray Size	63 (G) x 31.5 (Y) cm (±1cm)
Bed Capacity	10 Kg
The Pulling Out Level Of The Bed	20 cm
Noise Level Of The Canopy Environment	<49 dB
Cable And Hose Entrances (Grommets)	5 pcs.
Intervention Windows	5 pcs.
Air Filter	<0,5 µ

CONTROL OF AIR TEMPERATURE AND SKIN TEMPERATURE

Air Mode Control Range	17°C – 38.9°C
Skin Mode Control Range	17°C – 38.9°C
Measurement Sensitivity	0,1°C
Warm-up Time	22 min

OXYGEN MEASUREMENT RANGE (OPTIONAL)

Oxygen Indication Sensitivity	1%
Accuracy of Oxygen Control	± 5%, 21% Cal
Oxygen Measurement Range	15% – 99%
Inlet Pressure Range	4– 4,8 bar flow: 1-15 LPM (O_2 must be checked with an analyzer)
O_2 Sensor Operational Temperature Range	20°C – 41°C

PULSEOXIMETER FEATURE (OPTIONAL)

Parameters monitored by pulse oximetry: • Oxygen saturation of baby's blood • Pulse of baby	
SpO_2 Measurement Range	0%~100%
SpO_2 Screen Resolution	1%
Accuracy of SpO_2 Control	2% (70%~100%); below 70% is not defined
Heart Rate Measurement Range	15-300 bpm
Accuracy of Heartbeat Screening	1 bpm

CARBONDIOXIDE LEVEL

Carbondioxide (CO_2) Level	< 3 %

PROTECTION CLASSES AGAINST WATER AND FOREIGN PARTICLES: IPX0 and IP0X

ENVIRONMENTAL OPERATING CONDITIONS

Temperature

Operating Range	-15 ° C - +40 ° C environment (only during transport)
Storing Range	-25 ° C - +60 ° C

Humidity:

Operating Humidity	Between 0% and 95% Relative Humidity Non-condensable
Storing Humidity	Between 0% and 85% Relative Humidity Noncondensable

SOFTWARE FEATURES

Languages	Turkish and English

Control Panel Screen:

Parameters monitored on LCD screens:

- The heat value set in the operating mode
- Setted air tempature
- Measured air tempature
- Measured skin tempature
- Measured oxygen rate (optional)
- Setted oxygen rate (optional)
- Measured SpO_2 rate (optional)
- Setted SpO_2 rate (optional)
- Battery Level
- Menu settings
- Alarm

Standard Features:

- Skin temperature probe
- Air filter
- Passive humidifying sponge
- Serum holder
- Iris port
- Power cable
- Transport Trolley
- Baby seat belt

Optional Features:

- Masimo SpO_2 probe
- Ambulance strecher
- Oxygen sensor
- Monitor shelf
- Oxygen tank
- Flowmeter
- Disposable skin probe
- Examination lamp

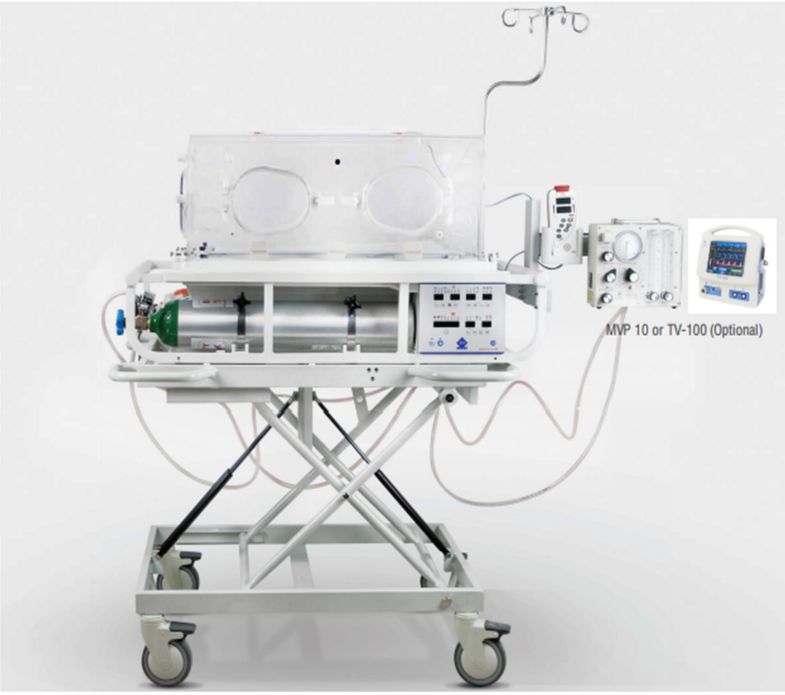


Figure1: Babynest H-100 Model Transport Incubator

PART 2
SETUP AND CONTROL OF THE SYSTEM

CAUTION: Please read this manual carefully before using the transport incubator. This transport incubator may cause injury to the patient or the user if used without understanding its entire operation.

Be careful not to damage the equipment and unprotected sensitive surfaces when unpacking. Otherwise, personal injury or equipment damage may occur.

2.1. MECHANICAL CONTROL

Follow the steps below for mechanical checking;

- Unplug the power cable.
- Check for any damage to the power cable. Replace the cable if damaged.
- Check all the parts for setup. Make sure that there is no missing or damaged part.
- Check the movement of the stretcher wheels. Make sure that the incubator is stable on the stretcher. Make sure that the incubator stand is stable when the wheels are locked and the wheels move freely when the wheel are not locked.
- Manually check whether each stretcher wheel is loose or not by lifting each corner of the transport incubator. This check must be done by two people. When using a loose wheel, there is a danger of the incubator tipping over. The transport incubator must not be placed on the stretcher until the loose wheels have been replaced.
- Make sure that the access panels (front, back and side) open and close properly. Make sure the access panels are closed.
- Check the interventionwindows. Open the intervention windows by pressing the latch. The lid must open automatically. Close the intervention windows and make sure the latches hold the lid.

2.2. CHECKING THE MEASUREMENT MODULE

Follow the steps below for checking the measurement module;

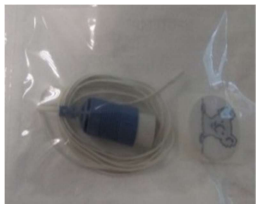
- Make sure the power cable is connected to the plug and the device.
- Check for the connections of the measurement module.
- Turn on the device from the On/Off buttons.
- At startup, the device performs system control with self-test. Wait for this test to complete.
- Make sure that the skin probe and SpO_2 probe are working. To do this, follow the variation of the skin temperature on the screen by heating the skin probe with your hand.

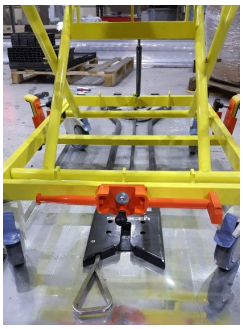
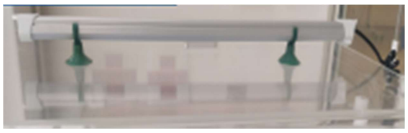
CAUTION: Using alternative methods, you can test if the SpO_2 probe works correctly or not. If you observe that it is not working properly depending on the test result, contact the technical service.

2.3. CHECKING THE ACCESSORIES

The accessories for the device are listed in Table 2.

TABLE 2. ACCESSORIES

	**SpO_2 Probe:** It measures the amount of oxygen molecules in the patient's blood by the hemoglobin molecules (SpO_2) and thus calculates the pulse.
	**Reusable Skin Probe:** Measures the patient's skin temperature.
	**Power Cable:** It allows the device to be supplied from the mains voltage.
	**Monitor Shelf (optional):** It has a capacity of 5 kg and is used to place documents on the device or a system/device with a maximum weight of 5 kg.
	**Disposable Skin Probe:** Measures the patient's skin temperature.
	**Serum Holder:** Allows the serum fluid to be transported.
	**Iris Port:** It is used to keep the stable ambient conditions inside the device stable during the intervention from the cover. (disposable)

	**Oxygen Sensor:** Measures the amount of oxygen given to the patient.
	**Air Filter:** Used to filter intake air.
	**Transport trolley:** It is used to move the incubator and change the height of the incubator. System should be fitted on a transport trolley in two or three levels, four-wheeled at least four brakes.
	**Stretcher Locking Mechanism:** It has four wheels and a brake mechanism; The adjustable system at two or three different height levels is mounted on the transport trolley.
	**Oxygen and Air Tank:** It provides oxygen and air to the system. (Optional)
	**Examination Lamp:** The lighting system provides to baby comfortable conditions.
	**Flowmeter:** It is used to measure of oxygen ratio. (Optional)

- Check all the accessories. Make sure that they are not missing or damaged.
- Make sure all accessories are securely mounted.

CAUTION: DISINFECT THE INCUBATOR BEFORE USE.

PART 3
FUNCTIONAL DESCRIPTION

3.1. GENERAL

This section includes a general description on the functions of the Babynest Model H-100 incubator.

3.2. FUNCTION

The temperature, humidity and oxygen concentration are controlled by the force-air circulation system. The ambient air is passed through the air suction filter by an engine-driven fan in a controlled manner and taken into the system. Part of this air which is directed into the canopy at the same time is again sucked by the fan and passed through the heater. The air enters the canopy through the guiding devices on the main body. The air then passes through the front, rear and side inner walls.

When the front and/or rear and/or side access panels are open, a hot air curtain is created and the air continues to flow upward through the opened panel. This curtain minimizes the air temperature drop in the incubator when the front and/or rear and/or side intake curtain is open..

Temperature of the transport incubator is regulated using the air or skin temperature. The user sets the air or skin mode.

The location of the incubator can be easily changed with the transport trolley. Our system is mounted on a three-stage collapsible trolley with four wheels, at least two of which have brakes. Trolley Spencer, EMS etc. used in 112 Emergency Aid Ambulances in the inventory of the Ministry of Health. It can be fixed to the floor of brand stretcher platforms, is compatible with all of them and can be easily placed without requiring any tools and without removing or installing parts in ambulance replacements.

The inside of the incubator is adequately illuminated with the examination lamp.

3.2.1 CHECKING THE TEMPERATURE

Temperature of the Babynest Model H-100 transport incubator is controlled by using the internal temperature of the transport incubator or baby’s skin temperature. The desired mode can be selected with a control module key and the operating mode can be monitored from the screen. Actual temperature values can be monitored simultaneously on two independent displays on the control module.

3.2.2 AIR CONTROL MODE

The transport incubator’s air temperature is monitored through the control module. Air is supplied to the heater control circuit, which controls the heater output, in order to keep the transport incubator’s temperature at the set value.

3.2.3 SKIN CONTROL MODE

A temperature sensing sensor connects directly to baby skin. After the skin temperature is set to the desired value in the control module, the skin temperature read from the baby's sensor is monitored on the control module screen.

During the skin mode control, if the sensor is removed from its socket, the baby skin temperature indicator will not show any value. Device automatically returns to air mode.

3.2.4 SpO_2 CONTROL MODE (OPTIONAL)

A SpO_2 sensor is attached directly to the baby's finger. After the SpO_2 is set to the desired value on the control module, the SpO_2 value read from the baby sensor is monitored on the control module screen.

During SpO_2 mode control, the SpO_2 indicator of the baby does not show any value if the sensor is separated from the part touching the baby.

In this mode, the BPM value is kept between 25 BPM and 240 BPM and the SpO_2 value between 2% and 100%.

3.2.5 OXYGEN MEASUREMENT MODE (OPTIONAL)

The internal atmosphere of the incubator can be enriched with oxygen. Oxygen for the baby can be supplied from a pressurized oxygen cylinder with a pressure reducing valve and a flowmeter, or from a hospital central system with a flowmeter.

CAUTION: Knowing that an oxygen concentration of more than 40% is harmful to the baby, the use of oxygen in the incubator should only be recommended and supervised by experienced medical personnel.

CAUTION: When oxygen is supplied to the incubator, the oxygen concentration must always be measured with an oxygen analyzer.

PART 4
USING THE BABYNEST H-100 CONTROL PANEL

4.1. ELECTRONIC CONTROL MODULE

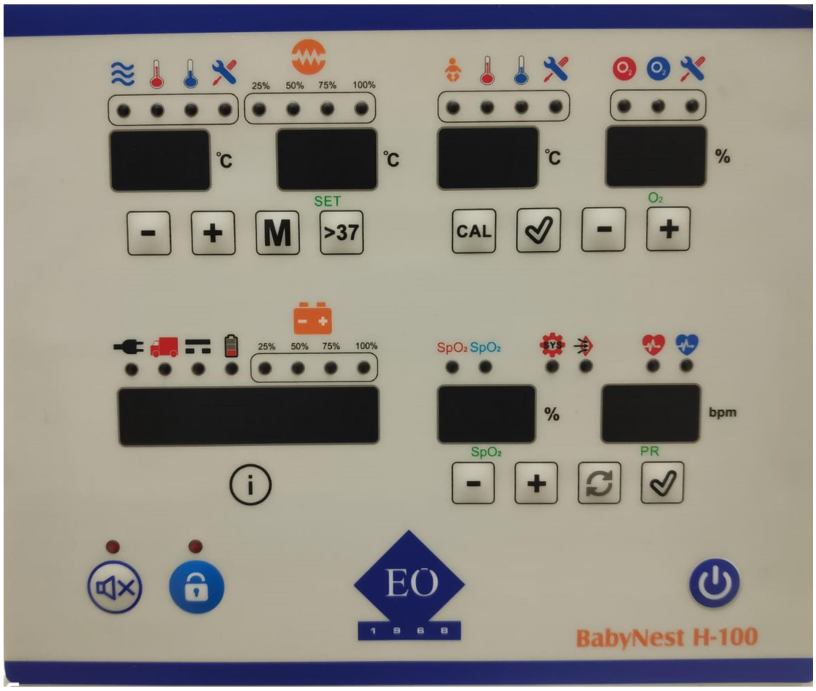


Figure 2. Front View of Electronic Control Panel

The control module keypad allows all settings of the transport incubator to be made and monitored. Keypad functions are described in detail in Section 4.3.

Figure 3. Control module On/Off key

4.2. SENSOR ACCESS / POWER MODULE

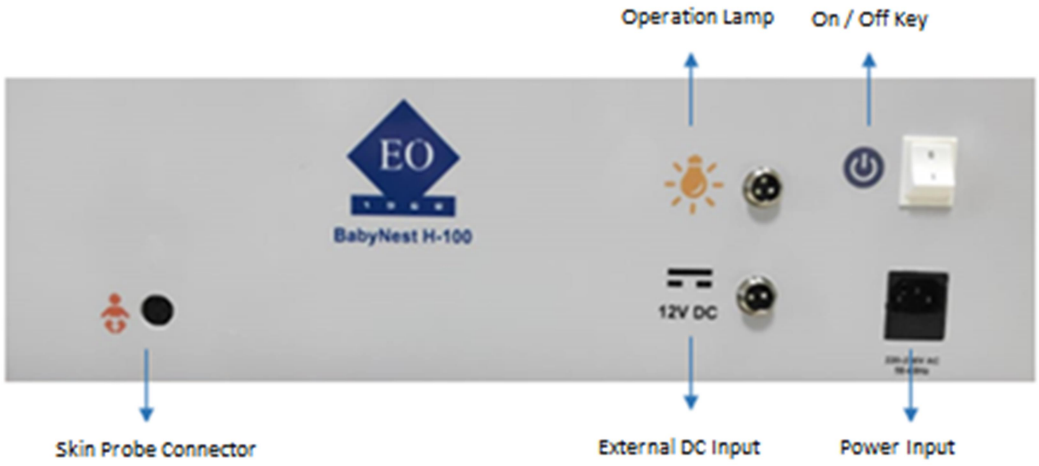


Figure 4. Sensory Access / Power Module

1 Masimo Rainbow SpO_2 Connector, 1 Oxygen Sensor Connector, 1 Skin Temperature Probe Connector, 1 External DC-Inlet, 1 ON/OFF Switch, 1 Operation Lamp, 1 Power-In of the transport incubator are as shown in Figure 4.

4.3. CONTROL MODULE KEYPAD

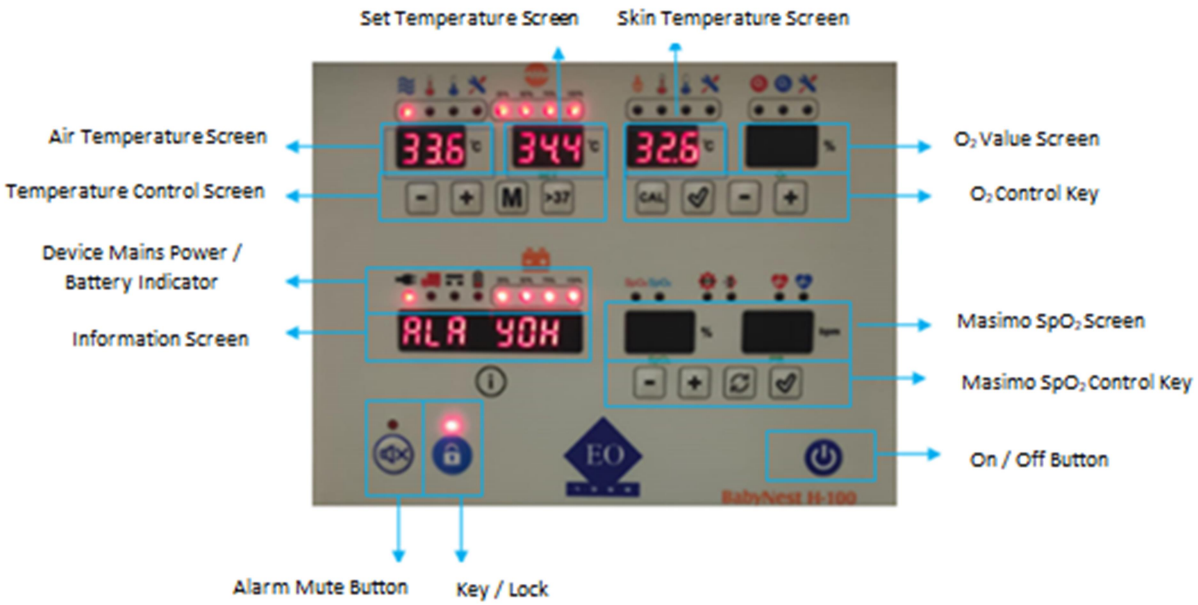


Figure 5. Membrane Keypad

1. **Device Mains Power/Battery Indicator:** The mains power is activated if the device is powered from the mains. If the power is interrupted or the plug is pulled out internal battery indicator is automatically activated. While an external battery is in use, the current status of the battery can be monitored in % on the control module. When power is restored or plugged in, the system shall automatically start from the mains / DC voltage and the internal battery can be charged while the device is operating from mains voltage.

2. **Baby Skin Temperature Indicator:** It displays baby's skin temperature in ℃. It tries to keep the baby's skin temperature constant at the value set by the user.

3. **Air Skin Temperature Indicator:** It indicates the internal temperature of the canopy in ℃. It tries to keep the internal air temperature constant at the value set by the user.

4. **Device Lock Key:** If no key is pressed on the control module, the device locks itself up within 20 seconds.

5. **Alarm Key:** If an alarm condition has occurred, the indicator flashes yellow and becomes active with a visual and audible alarm. If the reported alarm is a muteable alarm, pressing it deactivates it unless a new alarm condition occurs. The alarm is canceled by the system as soon as the muted alarm condition disappears.

6. **Oxygen Indicator:** It indicates the oxygen concentration.

7. **SpO_2 Indicator:** It indicates the SpO_2 value.

8. **On/Off Key:** It enables the device to turn on and start running, and when the same button is pressed again while the device is running, it enables the device to be turned off completely.

PART 5
OPERATING THE CONTROL MODULE

5.1. OPERATION

To operate the device, first connect the power cable to the power socket in the power group and to the mains plug.

CAUTION: It should be ensured that the electrical features specified in the product features are provided.

Make sure you attach the accessories supplied with the device to the places shown in Figure 4. Operate the device by pressing the On / Off switches on the control module (Figure 2) and the power input (Figure 3).

Figure 6: View Of The Screen After Turning On The Device

The device is designed in such a way that all data can be displayed on a single screen.

If the set values appear as "---", then that parameter is not in use in the cabinet and it means that it is turned off by the user. When the parameter is turned off, if there are alarm conditions related to the parameter, they will also be eliminated.

5.2. THE CASE OF POWER FAILURE

If the power to the device is interrupted, the device is supplied by the rechargeable battery.

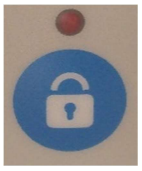
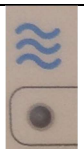
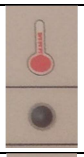
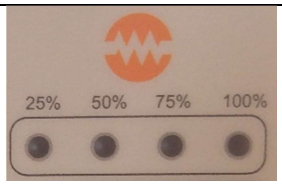
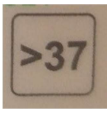
An audible alarm will occur. The audible alarm can be mutedd by the alarm muting key if desired.

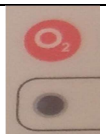
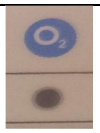
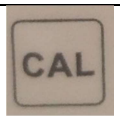
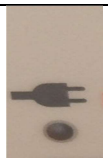
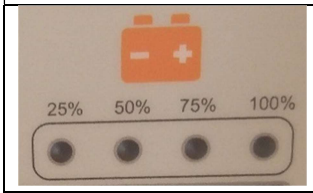
Measurements recorded before power failure will not be lost with power failure, and these values will continue to be recorded at the same time. When the power to the device is restored, the power failure fault will be eliminated and your device will return to its normal operating functions.

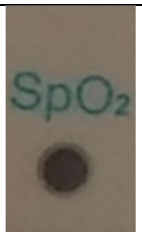
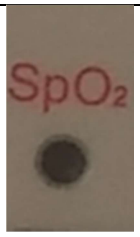
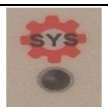
PART 6
MENUS

6.1. SYMBOLS USED ON THE SCREEN (FUNCTION KEYPADS)

TABLE 3. SYMBOLS

	**On/Off Button:** It is the button that enables the device control panel to be opened and closed.
	**Device Lock Key**: Locks or unlocks the use of all keys. If no key is pressed for 15-20 seconds, the system detects this and enters the automatic key lock mode.
	**Alarm Mute Button**: If an alarm condition has occurred, the indicator flashes with a red light and is activated by giving a visual and audible alarm. If the reported alarm is a muteable alarm, when pressed, it deactivates the alarm sound for 15 minutes unless a new alarm condition occurs. However, the presence of an alarm can be detected from the alarm indicator on the screen and the alarm status light indicator on the membrane keypad. The alarm is canceled by the system as soon as the silenced alarm condition disappears.
	**Air Mode Indicator**: Indicates that the device is operating in air mode.
	**High Temperature Indicator**: It is a light indicator that activates when a high air temperature alarm occurs for air mode, and a high skin temperature alarm occurs for skin mode.
	**Low Temperature Indicator**: It is a light indicator that activates when a low air temperature alarm for air mode and a low skin temperature alarm occurs for skin mode.
	**Fault Indicator:** It is a light indicator that activates if failure occurs when air mode is in use, skin mode is in use or during oxygenation.
	**Heater Power Indicator:** Indicates the operating power of the heater.
	**">37" Indicator:** This indicator becomes active when the temperature set value (in air mode and skin mode) is desired to be set above 37˚ C. In order to set the temperature higher than 37˚C, it is necessary to press the function key indicating >37˚.

	**Mode Switch Key:** It switches from air mode to skin mode or from skin mode to air mode.
	**Value Increase/Decrease Key:** "+" expression is used to increase the set value, and "-" expression is used to decrease the set value.
	**Skin Mode Indicator:** Indicates that the device is operating in skin mode.
	**High Oxygen Value Indicator:** If the oxygen value read from the module is 5% higher than the set oxygen value, a high oxygen value alarm occurs. This is the light indicator that is activated when an alarm occurs.
	**Low Oxygen Value Indicator:** If the oxygen value read from the module is 5% lower than the set oxygen value, a low oxygen value alarm occurs. This is the light indicator that is activated when an alarm occurs.
	**Oxygen Calibration Key:** It is the key to be used when oxygen calibration is desired.
	**Confirmation Key:** It is the key that allows the approval of the setted oxygen or SpO_2 value.
	**Mains Power Indicator**: Indicates that the device is operating at mains voltage.
	**Ambulance Mode**: It means that the device is fed from the battery in the ambulance. (12 VDC-14 VDC)
	**DC Power Mode:** Indicates that the device is running from battery with 12 VDC power.
	**Low Battery Indicator:** It is an illuminated LED indicator that activates when the device is running on battery and the battery capacity is low.
	**Battery Power Indicator:** Indicates at what power the device is running when running from the battery.

	**Low SpO_2 Value:** This is the led indicator that is activated when the SpO_2 value is lower than the setted high SpO_2 limit.
	**High SpO_2 Value:** This is the led indicator that is activated when the SpO_2 value is higher than the setted high SpO_2 limit.
	**Low PR Value:** It is the led indicator that is activated when the PR value is lower than the setted high PR limit.
	**High PR Value:** It is the led indicator that is activated when the PR value is higher than the setted high PR limit.
	**Function Switch Key**: It is used to switch between SpO_2 and PR modes.
	**System Failure Indicator:** It is the LED indicator that activates when there is any failure in the control module.
	**Air Circulation Failure Indicator**: It is the led indicator that activates "air flow failure" when there is any problem in air circulation.

6.1 FUNCTIONAL MENU

Functional menu is the menu where parameter settings, changes and records are made. Transitions between these menus are made with the function changing key. The functions of the icons in these menus related to the keys are given under the heading "6.1 Symbols Used on the Screen".

PART 7
WARNINGS, ALARMS, ERRORS AND OBSTRUCTIONS

7.1. ALARM TABLE

TABLE 4. ALARMS

BabyNest H-100 Alarm Table				
Alarm	**Symbol**	**Alarm Type**	**Info Screen**	**Cause of Alarm**
Low Air Temperature		Standard Alarm	LO AIR	The air temperature in air mode is 3.0°C below the set temperature after the temperature has been attained or if no operation is carried out for 1 hour.
High Air Temperature		Standard Alarm	HI AIR	The air temperature in air mode is 1.5°C above the set temperature after the temperature has been attained or if no operation is carried out for 1 hour.
High Air Temperature		Alarm cannot be muted	HI AIR	If the air temperature is >40, the heater is disabled and the system is turned off.
Faulty Air Sensor		Alarm cannot be muted	DFC AIR	If the Air Temperature Sensor is faulty
Low Skin Temperature		Standard Alarm	LO SKIN	The skin temperature in skin mode is 1.0°C below the set temperature after the temperature equilibrium has been reached or if no operation is carried out for 1 hour.
High Skin Temperature		Standard Alarm	HI SKIN	The skin temperature in skin mode is 1.0°C above the set temperature after the temperature equilibrium has been reached or if no operation is carried out for 1 hour.
High Skin Temperature		Alarm cannot be muted	HI SKIN	The skin temperature is >40°C,
Faulty Skin Sensor Error		Alarm cannot be muted	DFC SKIN	If the Skin Temperature Sensor has an error
Removed Skin Sensor		Warning Alarm	NO SKIN	The skin sensor is removed during skin mode operation.

Low Oxygen Value		Standard Alarm	LO O2	The measured oxygen level is 5 units below the set oxygen value after reaching the oxygen steady state or after 30 minutes of inactivity.
High Oxygen Value		Standard Alarm	HI O2	The measured oxygen level is 5 units above the set oxygen value after reaching the oxygen steady state or after 30 minutes of inactivity.
No Oxygen Sensor		Warning Alarm	NO O2	No oxygen sensor connected to the incubator
Oxygen Sensor Error		Warning Alarm	DFC O2	If the oxygen sensor has an error
Low SpO_2 Value		Warning Alarm	LO SPO2	If the SpO_2 value is higher than SpO_2 highest limit set by the operator
High SpO_2 Value		Warning Alarm	HI SPO2	If the SpO_2 value is higher than SpO_2 highest limit set by the operator
Low PR Value		Warning Alarm	LO PR	If the PR value is lower than highest PR limit set by the operator
High PR Value		Warning Alarm	HI PR	If the PR value is higher than highest PR limit set by the operator
Low Battery		Warning Alarm	LO BAT	If the battery level is low
System Error		Alarm cannot be muted	SYS ERR	The error is associated with Software or Hardware parts.

7.2. MUTE/RESET OF ALARMS

Mute: In case of an alarm, the alarm can be muted by pressing the mute button. As long as the audible alarm system is disabled, the alarm can be continuously monitored from the illuminated display on the control module. It is muted by pressing this key. If another alarm occurs during this time, the alarm muting feature is automatically disabled.

Reset: It cancels the alarm if the alarm condition is disappeared.

7.3. ERRORS

TABLE 5. ERRORS

Power Failure	If the external power is cut off, it gives an audible alarm and the device starts to work with its internal battery.
System Error	It is an audible and unmuted alarm that occurs when there is a malfunction in the control module. Contact the technical service unit.
Air Circulation Failure	It is an audible and unmuted alarm that occurs when there is a problem in air circulation. Contact the technical service unit.
Fan Failure	It gives a written and audible alarm when the fan motor does not work or the air flow balance in the cabin is disturbed. Contact the technical service unit.
Power Failure	If external power is interrupted, the alarm is written and audible, and the device starts to work with the battery. In battery mode, the device operates for 4 hours.

PART 8
BABYNEST H-100 THE TRANSPORT INCUBATOR USE

8.1. GENERAL USE

The following steps should be carried out for the use of the transport incubator.

CAUTION: Always lock the wheel brakes before placing the baby in the transport incubator.

1. Connect the power cable of the transport incubator in accordance with the electrical requirements specified in the technical features.
2. If an extension cable is used, attach the power cable of the incubator to the extension cable and extension cable to the plug.
3. Operate the transport incubator through the On/Off buttons on the power unit and on the control panel.
4. When the device is first turned on, the control circuit performs a self-test. During the self test, all leds on the control panel blink once at the same time. During the self-test, audio and visual alarms are tested.

CAUTION: Heat the incubator before laying baby down into the transport incubator.

5. Select air or skin temperature mode control.

IMPORTANT: The temperature control mode and temperature settings must be set by the related physician. Baby's rectal and/or axillary temperature must be monitored regularly according to the instructions of the related physician or nurse.

6. Lay the baby down on the pad.
7. Attach the SpO_2 probe to the baby’s finger. Make sure that the sensors in the probe are attached correctly to the finger of the baby, otherwise measurement is not possible as a result of the sensors not detecting it.
8. Place the skin probe on the baby’s skin. Place the probe according to the baby's lying position. Before placing the probe, make sure that the baby's skin is dry and clean. Below are the possible conditions that can occur with the skin probe. If these conditions occur, it may cause the baby over or under heated.

    - Do not place the probe between the baby and the pad. Otherwise it may cause incorrect measurement.
    - Do not pull the probe wires. Separate the probe from the skin by carefully pulling off the adhesive part. Remove the probe from the measuring module by holding the module.
    - Check periodically that the probe is connected. If the probe is not in contact with the skin, it may cause incorrect measurements.
    - When phototherapy lamps are used, the probe must not be located directly on the temperature path the lamp is emitting. Place the probe somewhere protected from the light of the lamp. The phototherapy lamp can increase the temperature of the baby's skin.
    - Do not open the probe prouch unless necessary for use. Replace the damaged probe.

9. There are a total of 5 hose inlets on the incubator panel (Figure 7). The cables and hoses to be used for baby's treatment and control are passed through these entrances to prevent heat loss.

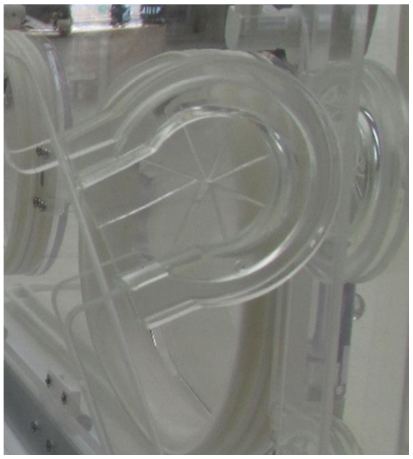
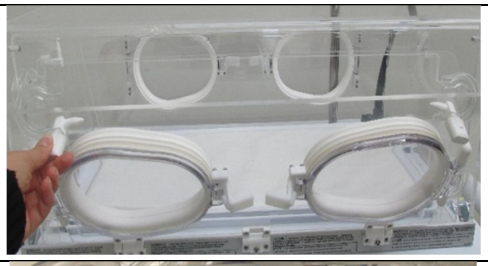
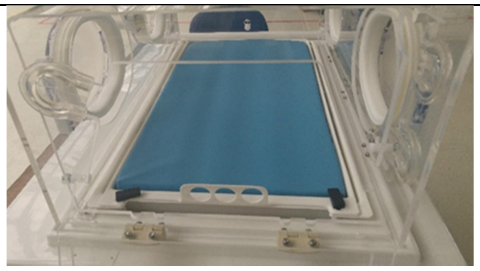
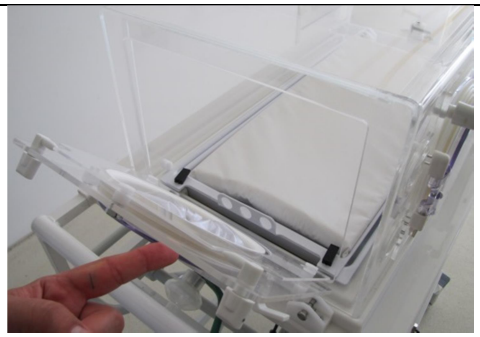
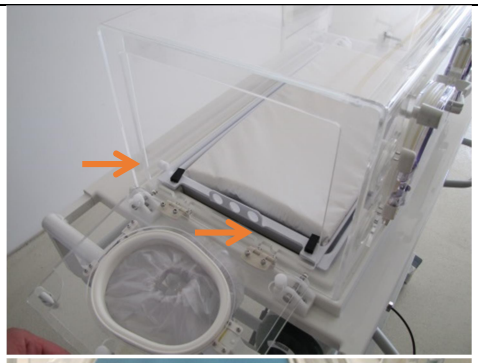
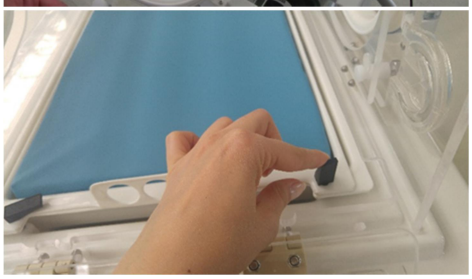
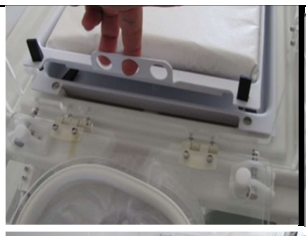
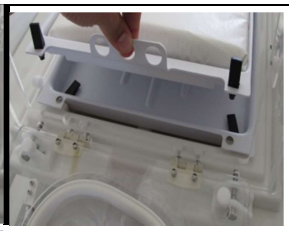
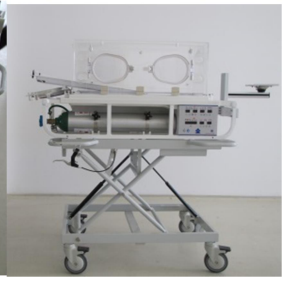
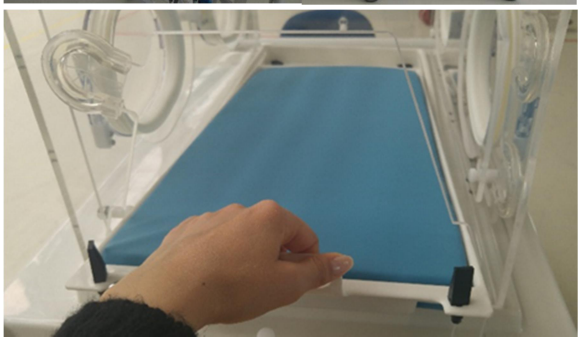


Figure 7. Hose inlets

8.2. ACCESS TO NEWBORN BABY

There are two access panels on the front and rear of the canopy, which open to allow easy access to the inside. The lid can be opened and locked by rotating the latches on the right and left upper corners of these access panels. After opening the lid, taking out the pad by sliding the pad forward allows easier intervention to the baby.

Rotate the latches of the access panels.	
Open the acces panels.	
Open the side window to take out the pad from the canopy.	

	
To take out the pad from the locked part, open the locks on the corners.	 
Hold the pad from the handle on the side of the pad and pull it towards yourself.	    

The baby is also intervened by using emergency response windows. There are 5 emergency response windows on the canopy. The emergency response window can be opened easily by pushing the latch on the top with the elbow to prevent microbial contamination.

CAUTION: Keep the emergency response windows closed for baby's safety when using the transport incubator.

CAUTION: Heat the incubator before putting baby into the transport incubator.

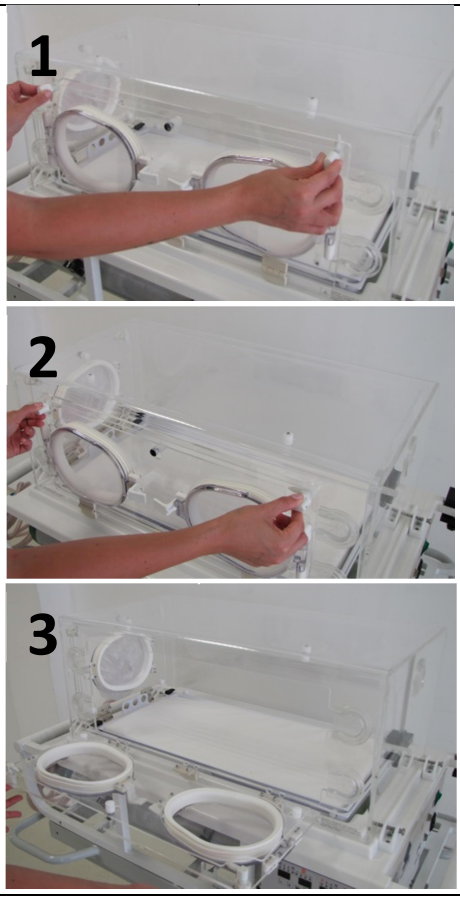
CAUTION: Do not leave the baby alone in the transport incubator while access panels or emergency response windows are open.

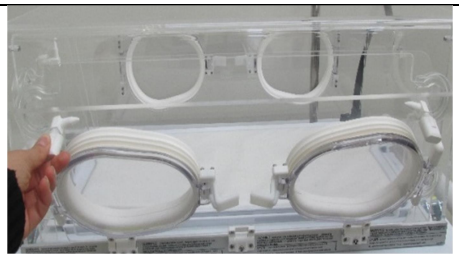
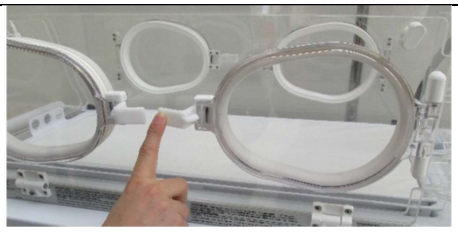
8.3. LIFTING AND LOWERING OF THE CANOPY

CAUTION: When there is a baby in the transport incubator, do not lift the canopy. Lift the canopy only for cleaning and disassembly.

CAUTION: Turn off the control panel before lifting the canopy.

While opening the canopy window, tilt it towards you by turning it from the hatches.



	
Open the access panels	
You can intervene with the baby from the window entrances by pressing the opening part on the canopy window.	

8.4. THE USE OF THE PASSIVE HUMIDIFIER SPONGE

To humidify the air circulation in the transport incubator, first humidify the sponge under the pad holder. If attention is paid to the amount of water absorbed by the pad, it is seen that the humidification is high. The passive humidifier sponge is shown in Figure 8.

Figure 8. The passive humidifier sponge

⚠ **CAUTION:** Use distilled sterilized water to avoid bacterial contamination. Replace the sponge each time the incubator is cleaned or disinfect it to leave no chemical residue.

⚠ **CAUTION:** Humidify the sponge out of the incubator. It is not advisable to pour water directly into the incubator, because the water may pass through the air conduction section and affect the control system.

8.5. AIR INLET MICROFILTER

Stone filter is used at the inlet of oxygen. It should be replaced if it appears dirty.

CAUTION: Dirty air inlet microfilter can affect oxygen concentrations and/or lead to the formation of carbon dioxide. The filter should be checked regularly and replaced at least **every three months**.

8.6. AIR and OXYGEN

Oxygen inlet valve filter cartridge should be checked every four months and should be replaced if the edges are greyed or darkened. Contact a qualified service personnel for this.

Figure 9. Oxygen Inlet and Oxygen Inlet Valve Filter Cartridge

Oxygen can be supplied through a wall source, through an oxygen cylinder, or through a flowmeter. Oxygen Concentration Guide is shown in Table 6.

TABLE 6. OXYGEN CONCENTRATION GUIDE

Oxygen Input	Normal Range
2 Lpm	25-30
4 Lpm	29-35
6 Lpm	33-41
8 Lpm	38-52
10 Lpm	45-75
12 Lpm	65-95

CAUTION:

- In order to confirm that the predicted oxygen concentration is given, the oxygen concentrations must always be measured separately.
- Unconscious use of supplemental oxygen can lead to serious side complications including blindness, brain injury and death. Hazards may vary by baby. The method, concentration and duration of treatment should be determined by the relevant physician.
- Oxygen therapy can increase the level of noise in the incubator.

- If oxygen is needed in an emergency, the doctor should be notified immediately.
- The oxygen concentration inhaled by the baby does not determine the oxygen partial pressure (SpO_2) of the blood. When deemed appropriate by the relevant physician, the blood SpO_2 value should be measured by accepted clinical techniques.

After each change of the oxygen flow setting, allow 30 minutes for the concentrations.

8.7. PRE-USE CHECK OF THE DEVICE

If a transport incubator is to be used, keep the incubator running until it is ready for use by putting it under air mode control. If the transport incubator is not to be used, turn it off and remove the power cable from the plug.

OPERATION DURING USE

IMPORTANT: The incubator should not be put into service until the general operational and functional checks (Section 8) have been carried out.

The transport incubator should be ventilated and in the air mode, it must be subjected to pre-heating process up to the temperature prescribed by the relevant physician, or up to the temperature specified by the department.

The incubator should be operated without wetting passive humidifier sponge during preheating step.

NOTE: The air vents that are functioning when the access panel of the transport incubator is open may be adversely affected by air flow, fan or ventilation. Take precautions to keep the incubator away from such air currents.

PART 9
CLEANING, MAINTENANCE & REPAIR

CAUTION: Do not displace the incubator without removing all accessories from the incubator. Before cleaning or maintaining, ensure that all oxygen supply units connected to the incubator are closed and dismantled. There is a risk of fire hazard in environments enriched with oxygen.

Unplug the power cable to disconnect electricity before service or maintenance procedures are applied.

Residues from ether, alcohol, or similar cleaning solutions may cause fire.

The air microfilter cannot be sterilized or cleaned by a process such as washing. Change the air microfilter every 3 months.

9.1. GENERAL

This part includes cleaning and maintenance instructions. Dismantling instructions are also included when necessary. Except as described in this section, maintenance should only be performed by a qualified service personnel. Cleaning should be carried out by a qualified personnel after every use and in any case necessary.

Calibrations should be performed at 12 months intervals.

Repairs must only be performed by the Ertunc Ozcan Technical Service under warranty. Do not use the device that you think is defective.

9.2. MAINTENANCE

The recommended maintenance periods are shown below. Always follow hospital and local regulations for the required intervals.

Weekly or after each patient

If used, disinfect the humidifier. Clean the incubator and check the air filter. Disinfect the incubator if necessary, or after use on patients with infectious diseases.

Once every three months

Change the air microfilter.

Note: This is the minimum change interval of the filter. The filter should be changed when it looks dirty.

Annually periodical maintenance

It is recommended that the internal battery, which allows monitoring of the current data in the control panel during power cut, should be checked by Ertunç Özcan technical personnel and changed if necessary.

Under normal conditions (20°C), the battery life is 5 years. If the battery needs to be changed, the device should be unplugged, necessary safety precautions should be taken, and the disassembly process should be started from the negative pole first and then the positive pole should be removed. When installing a new battery, connections should be made in the opposite order.

Figure 10. Internal Battery

9.2.1 PERIODIC MAINTENANCE PLAN

The device operator must check the following items to ensure the correct functioning of the transport incubator.

TABLE 7. PERIODIC MANTENANCE PLAN

EXAMINED PARTIES	MAINTENANCE PERIOD	EXECUTION
Skin Probe	Every time you use the equipment	User
Examination Lamp	Every 2 months	Technical
Qt Window Locks	Every 2 months	Technical
Qt Window	Every 2 months	Technical
Physical State Of The Mattress	Every time you use the equipment	User
Lockable Rail Bed System	Every 2 months	Technical
Internal Battery Charge Level	Before removal of each patient	User
Incubator Hood Fixing System	Every time you use the equipment	User
Passive Humidifier Sponge	Every 6 months	User
Oxygen and Humidity Hoses	Every 12 Months	User / Technical
Rings Oring's Oxygen and Humidity	Every 12 Months	Technical
Air filter	Every 3 months	User
Resistance	Every 12 Months	Technical
Cable and Hose Entries (Grommets)	Every 3 months	User / Technical
Fan Motor/Blower	Every 12 Months	Technical
Hood	Every 12 Months	Technical
Air and Oxygen inlet	Every 6 months	User / Technical

Note: Spare parts approved by authorized service or medical device manufacturer should be used. Persons who do not have a training approved by the authorized service should not interfere with the device.

9.2.2 PART REPLACEMENT

It is recommended that replacement of some parts suffering wear and tear should be done in the periods described below. Replacements should be done by trained technical personnel. Please always use authorized service parts.

TABLE 8. PART REPLACEMENT

PART REPLACEMENT	PERIOD	PERFORMER
Examination lamp	12 months or when needed	Technical
Internal Battery	18 months or when needed	Technical
High-Pressure Hose	12 months or when needed	User
Hood Fixing Parts / Mechanism	24 months	Technical
Air filter	3 months	User / Technical
Filter Retaining Particles	3 months	User
Oring's Rings Of Oxygen Valves	12 months	Technical
QT Window	24 months	Technical
QT Window Cuff	6 months	Technical
Mattress	12 months	User
Passive Humidifier Sponge	6 months or when needed	User
Iris Port	3 months	Technical

9.3. CLEANING

The incubator should be thoroughly cleaned and disinfected when the baby is discharged or at least once a week. Cleaning by disassembling the parts is the most effective way. The disassembly steps are described below.

CAUTION: Unplug the power cable before cleaning the transport incubator.

1. Before disassembly, the locking mechanisms of the four wheels of the incubator should be engaged in order to ensure safety. To lock the wheels, the latch should be in the lock position by pressing the latch on the wheel.
2. Make sure the incubator's power cord is unplugged.
3. Turn off the control panel using the On/Off button.
4. Wipe the surface of the heater with a soft cloth soaked with disinfectant etc. Always follow the instructions of the cleaning solution manufacturer for use.
5. Pull the canopy latches towards you so that it opens. Carefully lift the canopy and wipe the surface of the heater with a soft cloth soaked with disinfectant etc. for each step as you perform the following sections. Always follow the cleaning solution manufacturer's instructions for use.

6. After the canopy is opened, pull the baby pad tray towards you. Lift and remove the baby pad and tray.
7. Once you have taken out the baby pad and the tray, bring the bottom tray back to its original position. While in this position, hold it from both sides and lift it up.
8. Take out the base tray by opening the lock mechanism on the right and left side of the incubator.
9. Remove the fan and heater top plate.

⚠ **CAUTION:** Do not dismantle the heater without cooling the heater. At least 45 minutes should be waited for a cooled incubator. A non-cooled heater can cause burns.

10. Pull out the fan and heater and clean all surfaces.
11. Place the heater and fan in place, paying attention to what you install correctly.
12. Place the top plate in its place.
13. Pull out the emergency window ports. (Do not use again as it is disposable.)

Figure 11. Removal of Iris Ports

14. Unscrew and remove the screws on both sides of the air inlet microfilter.
15. Reinstall the incubator and make sure that it is completely dry, and finally install the control panel.

9.3.1 CLEANING THE PATIENT PROBE

Check that the patient probe are disposable or reusable. Disposable skin temperature probes should not be cleaned and used.

⚠ **CAUTION:** Disposable skin probes are not designed and approved for reuse. Reuse can affect measurement accuracy and system performance or cause malfunction due to product cleaning, disinfection, resterilization or physical damage.

The user should ensure that this product is not damaged or contaminated between uses in the same patient.

Reusable skin probes and the SpO_2 probe should be carefully wiped clean with a soft, damp cloth applied with disinfection material that can be used safely in probe materials. Make sure all cleaning materials are cleaned and dried.

9.3.2 CLEANING AGENTS

An iodophor or quaternary disinfecting detergent should be used, but only after the incubator has been emptied and disassembled as described in paragraph 9.2.1. Follow the manufacturer's instructions for use while using any antiseptic agent.

CAUTION: Do not clean the incubator with organic solvents, stripping compounds, strong acids or strong bases. These compounds can damage the parts.

Do not immerse the parts in the cleaning solution. Dry by wiping the cleaning solutions on the parts.

Do not allow cleaning solutions to leak between plastic parts in any way and remain without drying.

PART 10
TROUBLESHOOTING

Troubleshooting for the transport incubator is shown in Table 8. If the trouble cannot be determined from the tables, the unit should be taken out of service and should get technical service by a qualified service technician trained by manufacturer. If the incubator cannot be operated, contact the technical service.

TABLE 9. TROUBLESHOOTING

INDICATION	POSSIBLE CAUSE	SOLUTION
The system has no power and the Power Fail Alarm is not running.	The main power switch of the incubator is off.	Turn on the Power Switch.
Power Fail Alarm is active	The power cable is not plugged. (There is no UPS)	Make sure the power cable of the incubator is connected to the plug.
	The power cable is not connected to the incubator. (There is no UPS)	Make sure the power cable of the incubator is connected.
	Batteries are not charging. (There is a UPS)	
Low temperature alarm is active	Access lids or iris ports are open	Close all the lids and ports.
	The skin probe is not firmly fixed to the skin (only in SKIN operating mode)	Check the connection of the skin probe.
Low skin temperature is active	The skin probe is not firmly fixed to the skin (only in SKIN operating mode)	Check the connection of the skin probe.
Low Oxygen Concentrations	Access lids or iris ports are open	Close all the lids and ports.
	Iris entry ports glands are open or not connected properly	Check the connection of the port glands.
	Hose inlet holes are not properly connected.	Check the connection of hose inlet holes.
	Main Platform is not properly installed.	Make sure that the platform is properly installed.
	Air inlet microfilter cover is not properly fixed.	Check and fix the air inlet microfilter cover.
	Air inlet microfilter is not installed.	Check the air inlet microfilter and install if it is necessary.
	The internal pipe is not installed.	Turn off the incubator and take out of service.
High Oxygen Concentrations	Filter is not installed	Check it and install when necessary.
	Air inlet microfilter is dirty.	Replace the filter
	Air inlet pipe is not installed	Install the air inlet pipe
	Dirty fan does not function properly	Check the fan
	Air circulation inside the incubator is insufficient	Make sure fan is installed. If it is installed, turn off the incubator and take out of service.

High Temperature and/or High Set Temperature Alarm	The main platform or canopy sealing is not installed properly	Check the sealing and install it properly.
Incorrect temperature reading	Prevention of air circulation	Remove the materials that prevent regular air circulation.
	Pad or pad tray is in incorrect position	Check the position of the pad or pad tray

PART 11
INFORMATION OF NOTIFIED BODY

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

In case of functional impairment or stress recorded in the features or performance of the device, which may cause death or serious deterioration in the patient's or user's health condition, and lacks that have the same adverse effects in this instruction, please contact our authorized representative within the European community or our center in other places immediately and take the device out of service temporarily. According to the problem of the device, on-site repair or repair will be carried out in our center and nonconformity will be eliminated.

MDD (93/42/EEC)

APPROVED ORGANIZATION INFORMATION

Organization Name	KIWA BELGELENDİRME HİZMETLERİ A.Ş.
Address	ESKİ ANKARA ASFALTI ITOSB 9.CAD. NO:15 TEPEÖREN, TUZLA/İST.
Organization No.	1984

ANNEX A - Electromagnetic Compatibility

ELECTROMAGNETIC COMPATIBILITY (EMC) GUIDE

Safety standards: IEC 60601-1, IEC 60601-2-20

EMC Standards: IEC 60601-1-2

WARNING

Electrical medical devices require special precautions regarding EMC and should be installed and put into use in accordance with the EMC information given below.

WARNING

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

WARNING

This device/system is designed to be used only by a professional health officer. This device / system may cause radio interference or disrupt the operation of nearby devices. It may be necessary to take precautions to mitigate the negative effects by protecting the area or relocating or reorienting the device / system.

Electromagnetic Compatibility and Tests

BabyNest H-100 transport incubator has been tested and has fulfilled the conditions of the TS EN 60601-1-2:2011 Electromagnetic campatibility.

Guide and Manufacturers Declaration on Electromagnetic Emissions

<table>
<tr><td colspan="3">Babynest H-100 transport incubator is aimed to be used in the below stated electromagnetic environment. The customer or user of the Babynest H-100 transport incubator must warrant that this device will be used in this type of environment.</td></tr>
<tr><td>Emission Tests</td><td>Compatibility</td><td>Electromagnetic environment-Guide Information</td></tr>
<tr><td>Terminal breakdown voltage
TS EN 55011/A1</td><td>In accordance with the terms</td><td>Electromagnetic energy is used for the Babynest H-100 transport incubator to serve its aimed function. The electronic devices around it may be affected.</td></tr>
<tr><td>Emission breakdown
TS EN 55011/A1</td><td>In accordance with the terms</td><td rowspan="3">Babynest H-100 transport 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.</td></tr>
<tr><td>Harmonic emissions TS EN 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage waves /flicker emissions
TS EN 61000-3-3</td><td>In accordance with the terms</td></tr>
</table>

uide and Manufacturers Declaration on Electromagnetic Immunity

Babynest H-100 transport incubator is aimed to be used in the electromagnetic environment below stated. The customer or user of the Babynest H-100 transport incubator, must warrant that this device will be used in this type of environment.

Immunity Tests	**IEC 60601-1-2 Test Level**	**Compatibility Level**	**Electromagnetic Environment-Guide Information**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact discharge voltage ±2 kV, ±4 kV, ±8 kV, ± 15 kV air discharge voltage	In accordance with the terms	The Babynest H-100 baby incubator locations should be wood, concrete or ceramic bricked. If these locations are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient burst/explosion IEC 61000-4-4	For ± 2 kV power supply feeding line For ± 2 kV input/output line	In accordance with the terms	Power network quality should be that of a typical commercial or hospital environment.
Sudden impact IEC 61000-4-5	±0,5 kV, ±1 kV from line to line ±0,5 kV, ±1 kV, ±2 kV from line to ground	In accordance with the terms	Power network quality should be that of a typical commercial or hospital environment.
Voltage dips, short cuts and voltage fluctuations on power supply input lines TS EN 61000-4-11	%0 Ut 0.5 turn,10 ms @ 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° %0 Ut 1 turn,20 ms @ 0° %70 Ut 25 turn, 500ms @ 0° Short Cuts %0 Ut 250 turn, 5000ms	%0 Ut 0.5 turn,10 ms @ 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° %0 Ut 1 turn,20 ms @ 0° %70 Ut 25 turn, 500ms @ 0° Short Cuts %0 Ut 250 turn, 5000ms	Power network quality should be that of a typical commercial or hospital environment. If the user of the Babynest H-100 transport incubator needs to keep working under a main supply shortage conditions it is suggested that the device is fed by continual power supply or a battery.
Network frequencies (50/60Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Magnetic field network frequencies must be at the level used in typical commercial environment or a hospital.

Note- Ut is the mains voltage before the test levels are applied.

Guide and Manufacturers Declaration on Electromagnetic Protection

Babynest H-100 transport incubator is aimed to be used in the electromagnetic environment below stated. The customer or user of the Babynest H-100 transport incubator, should warrant that this device will be used in this type of environment.

Immunity Test	**IEC 60601-1-2 Test Level**	**Suitability Level**	**Electromagnetic Environment-Guide Information**
Against conducted disturbances induced by RF fields TS EN 61000-4-6	3 V and 6 V 150 kHz with 80MHz	3 V ve 6 V	Portable and mobile RF communications equipment should be no closer to any part of the Babynest H100 baby incubator, including cables, than the recommended separate stopping distance calculated from the equation applicable to the frequency of the transmitter. **Suggested stand apart distance**
Radiant, radio frequency, electromagnetic field TS EN 61000-4-3	3V/m 80 MHz with 2.7 GHz	3 V/m	d =$[\frac{3,5}{V1}]\sqrt{P}$ d =$[\frac{3,5}{E1}]\sqrt{P}$ 80 MHz ile 800 MHz d =$[\frac{7}{E1}]\sqrt{P}$ 800 MHz ile 2.7 GHz
TS EN 60601-2-20	3 V/m 26 MHZ with 1 GHz 10 V/m 26 MHz with 1 GHz	3V/m Work regularly 10 V/m No Danger	Here, according to the manufacturer of the P transmitter; W kind transmitter is the biggest output power and d meter kind is the suggested stay apart distance. A carried out electromagnetic field research states that the field strength spread form stable RF transmitters must be smaller than the suitability level of each frequency gap. The interference can be seen on the device with the icon shown below. 

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

- ISM (industrial, scientific and medical) bands between 150kHz and 80MHz; 6.765 MHz and 6.795 MHz; 13.553 MHZ and 13.567 MHz, 26.957 MHz and 27.283 MHz and 40.66 MHz and 40.70 MHz
- The suitability levels of ISM frequencies between 150kHz 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 Babynest H-100 transport incubator is used goes over the, above stated. Applicable RF suitability level the Babynest H-100 transport incubator must be investigated to make sure it is operating properly. If an abnormal situation is seen in the performance, additional measure may be needed for the Babynest H-100 transport 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 Babynest H-100 transport 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

Babynest H-100 transport incubator is aimed to be used in the below stated electromagnetic environment.

The customer or user of the Babynest H-100 transport incubator, must guarantie to use this device in these environments

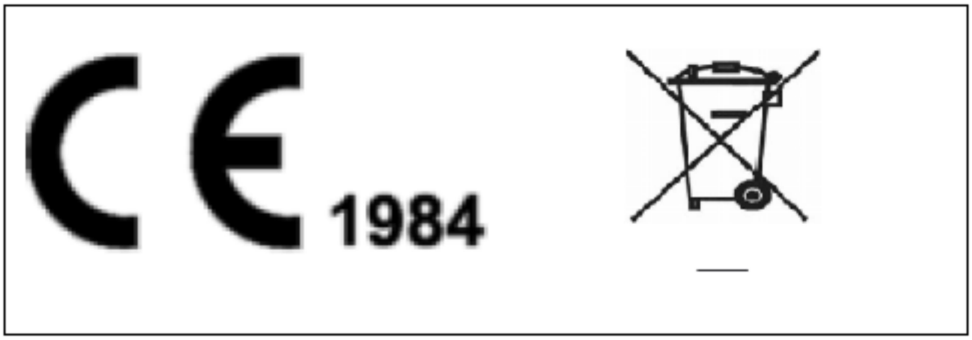
Immunity Test	**IEC 60601-1-2 Test Level**	**Compatibility level**	**Electromagnetic environment-Guide Information**
Against conducted disturbances induced by RF fields TS EN 61000-4-6 Radiant, radio frequency, electromagnetic field TS EN 61000-4-3	3 Vrms and 6 Vrms 150 kHz and 80MHz 3V/m 80 MHz and 2.7 GHz	3 Vrms and 6 Vrms 3 V/m	Babynest H-100 transport 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. 

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 Babynest H-100 transport incubator is used goes over the, above stated. Applicable RF suitability level the Babynest H-100 transport incubator must be investigated to make sure it is operating properly.

Note 1- These guidelines may not apply in all locations. Electromagnetic radiation is affected by reflection and absorption from structures, objects and people.
Note 2- Actual insulation effectiveness and filter attenuation of the isolated location must be validated to ensure that it meets the lowest specification.

Electrostatic Discharge
The equipment are in accordance with the TS EN 60601-1-2 requirements and Electrostatic Discharge Connection lightning.

Annex B - COMPLIANCE WITH STANDARDS AND DIRECTIVES



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

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

⚠	**The labels on The Device, CE label, User Guide and/or Service Guide will be translated into the language of the country that the device is being dispatched to.**