



OKM 730 INFANT RADIANT WARMER USER MANUAL

About Manufacturer

Manufacturer: Okuman Medikal Sistemler Anonim Sirketi Product Name: Infant Radiant Warmer Model: OKM 730 Adress HQ: Zübeyde Hanım Mahallesi Kazım Karabekir Caddesi 95 / 95 06060 İskitler, Ankara, TURKIYE Factory: İvedik Organize San. Bölgesi Arı Sanayi Sitesi 1.Etap 1417 Sok. No:51 Yenimahalle, Ankara, TURKIYE Document No: OKM 730-UM-007-112022-EN **Release Date:** 05.10.2018 Date/ Rev.: 11.11.2022/007 Notified Body: Kiwa Belgelendirme Hizmetleri A.Ş. İstanbul Tuzla Organize Sanayi Bölgesi (İTOSB) 9. Cad. No:15, 34957 Tepeören, Tuzla, İstanbul/TURKIYE Phone: +90 (216) 593 25 75 Fax: +90 (216) 593 25 74 Web: www.kiwa.com.tr E-mail: posta@kiwa.com.tr

CE₁₉₈₄

Read this user manual to use this medical device correctly.

Intellectual Property Statement

Okuman Medikal Sistemler Anonim Sirketi owns the intellectual property rights to this Okuman product and this manual. This manual may refer to information protected by copyright or patents and does not convey any license under the patent rights or copyright of Okuman, or of others. Okuman intends to maintain the contents of this manual as confidential information. Disclosure of the information in this manual in any manner whatsoever without the written permission of Okuman is strictly forbidden.

Publication, modification, reproduction, distribution, rental, adaptation, translation or any act involving any modification of this user manual is strictly prohibited without the written permission of Okuman Medikal Systems Anonim Şirketi.

Responsibility on the Manufacturer Party

Contents of this manual are subject to change without prior notice.

All information contained in this manual is believed to be correct. Okuman shall not be liable for errors contained herein or for incidental or consequential damages in connection with the furnishing, performance, or use of this manual.

Okuman is responsible for the effects on safety, reliability and performance of this product, only if:

• All installation operations, expansions, changes, modifications and repairs of this product are conducted by Okuman authorized personnel;

• The electrical installation of the relevant room complies with the applicable national and local requirements; and

• The product is used in accordance with the instructions for use.

WARNING!

• This equipment must be operated by skilled/trained clinical professionals.

• It is important for the hospital or organization that employs this equipment to carry out a reasonable service/maintenance plan. Neglect of this may result in machine breakdown or personal injury.

Warranty

In case of use of all new devices by Okuman Medikal Sistemleri Anonim Şirketi, a service warranty is given against defects in workmanship and materials and for a period of two (1) years from the date of delivery, and this warranty is non-transferable. In addition, there is a guarantee of supply for all parts for a period of 10 years. The service life of the device is 10 years.

This warranty does not cover parts breakage/deterioration as a result of consumables (eg LED lamps, plexiglass, etc.) or misuse. The only sanction of this warranty; It is the replacement or repair of damaged products during the warranty period. Warranty will not be valid for product modifications made without the written approval of Okuman Medikal Sistemleri Anonim Şirketi. No modifications should be made to the device by the user. Broken or deteriorated components should be replaced by Okuman Medikal Sistemleri Anonim Şirketi. In case of intervention by the customer, the seller will not be liable for direct or indirect damages and injuries.

After Sale Technical Support

Repair of devices under warranty should be carried out at authorized repair centers. Local Distributors or Okuman Technical Service can be contacted by the customer when necessary. In order to receive service support, the model name and serial number of the device must be reported.

Manufacturer: Okuman Medikal Sistemler Anonim Sirketi

HQ Address: Kazim Karabekir Caddesi 95/95 Iskitler, 06060, Ankara / TURKIYE

Factory Address: Ivedik OSB Ari Sanayi Sitesi 1417 Sk. No:51 Yenimahalle, Ankara / TURKIYE

Website: www.okuman.com.tr

E-mail: info@okuman.com.tr

Tel: +90 312 384 0520

Fax: +90 312 384 1975

Preface

Purpose of Manual

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

This manual is based on the base configuration and therefore some contents may not apply to your product. If you have any question, please contact us.

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

Intended Audience

This manual is geared for trained technical personnel who are expected to have a working knowledge of electrical and mechanical practices and terminology.

Illustrations

All illustrations in this manual serve as examples only. They may not necessarily reflect the setup or data displayed on your equipment.

Conventions

- Italic text is used in this manual to quote the referenced chapters or sections.
- [] is used to enclose screen texts.
- \rightarrow is used to indicate operational procedures.

Password

Technical service password may be needed to reach particular menus.

CONTENTS

1.INTRODUCTION	.1
1.1.Safety Information	. 1
1.1.1.Danger	. 1
1.1.2.Warnings	. 1
1.1.3.Warnings For Use Regarding Patient Health	. 2
1.1.4.Warnings Regarding The Use Of Equipment	. 2
1.2.Risks - Precautions - Warnings	. 3
1.2.1.Electrical Precautions	. 3
1.2.2.Risk Areas	. 3
1.3.Applied Standards	. 3
1.4.Equipment Symbols	. 4
2.GENERAL INTRODUCTION	.6
2.1. Product Intended Use	. 6
2.2.Contraindications	. 6
2.3.Indication	. 6
2.4.Side Effects	.7
2.5.General View of Device	.7
2.6.Heater Unit	.9
2.7.Control Unit	. 10
2.8.Bed Unit and X-Ray tray	. 11
2.9. The Monitor Shelf and IV Pole	. 12
2.10.Height Adjustment	. 12
2.11.Examination Lamps	. 13
2.12.Hands-Free Sensor (Optional)	. 14
2.13.Phototherapy Units (Optional)	. 15
2.14.Baby Scale (Optional)	. 15
2.15.Suction/Aspiration Unit (Optional)	. 15
2.16.Infant T-Piece Resuscitator Unit (Optional)	. 16
2.17.O2/Air Blender Module (Optional)	. 16
2.18.Manual/ Electronic Trendelenburg (Optional)	. 17

3.USING THE RADIANT WARMER	.18
3.1.Control Panel	. 18
3.2.Before the Operation	. 19
3.3.Powering On the Device	. 20
3.4. Warmer Modes	. 21
3.4.1.Using the Warmer Modes	. 21
3.4.1.1.Using the Pre-Warming Mode	. 22
3.4.1.2.Using Baby Mode	. 22
3.4.1.3.Using Manual Mode	. 25
3.5.Using APGAR Timer	. 27
3.6.Using CPR Timer	. 28
3.7.Checking Control Module Functions	. 29
3.7.1.Checking Power On Alarm	. 29
3.7.2.Checking APGAR Timer	. 29
3.7.3.Checking Examination Lamp	. 29
3.7.4.Checking Power Failure Alarm Function	. 29
3.7.5.Checking Temperature Accuracy	. 30
3.7.6.Checking temperature deviation alarm	. 30
3.7.7.Checking Over Temperature Alarm	. 30
3.7.8.Checking Sensor Failure Alarm	. 30
3.7.9.Memory Function	. 30
3.8.Alarm Messages	. 30
3.8.1.Deviation alarm	. 31
3.8.2.Power failure alarm	. 31
3.8.3.System failure alarm	. 31
3.8.4.Hi temp alarm	. 31
3.8.5.Probe alarm	. 31
4.USING ELECTRONIC TRENDELENBURG (OPTIONAL)	.32
4.1.Positive Tilt	. 32
4.2.Negative Tilt	. 33
4.3.Auto Untilt Function	. 33

4.4.Storing the Bed Tilt Angles to Memory	
4.5.Recalling the Bed Tilt Angles	
5.USING THE OKM 160 BABY SCALE (OPTIONAL)	35
5.1.Scale Process	
5.2.Automated Tare Process	
5.3.Weighing in the Inclined Position	
5.4.Taring	
5.5.Storing Weight Values	
5.6.Date and Time Adjustment	39
6.USING THE OKM 150 RESUSCITATION UNIT (OPTIONAL	
6.1.Specifications	41
6.2.Using The Module	
6.3.Working Explanation	
7.USING THE ASPIRATOR UNIT (OPTIONAL)	45
8.USING THE OKM 1001 PHOTOTERAPY UNIT (OPTIONAL	
8.1.General View of OKM 1001 Phototherapy Module	
8.2.The Control Panel	47
8.2.1.Powering the module	
8.2.2.Starting/stopping(or pausing) the phototherapy	
8.2.3.Setting/clearing phototherapy time	
8.2.4.Adjusting phototherapy light intensity	51
8.2.5.Displaying lamp life	
9.CLEANING AND DISINFECTION	52
9.1.Disassemble Before Cleaning	
9.2.Sterilization/ Cleaning	
9.3.Montage After Cleaning	
10.MAINTENANCE	53
10.1.Technical Assistance Maintenance	
10.2.Systematic Maintenance	
10.2.1. Rechargeable Battery Maintenance	
10.2.2. Replacing The Heater Unit	

10.2.3.Transfusion Soft Port (Silicon Grommets)	54
10.2.4. Fuse replacement	54
11.TROUBLESHOOTING	55
11.1.Errors	55
12.DEVICE SPECIFICATION	56
12.1.Label Information	56
12.2. Technical Specification	57

1. INTRODUCTION

OKM 730 Radiant Warmer is a trademark of Okuman and it has been designed to be used in Neonatology and Newborn Clinics for a part of treatment. The user is responsible for the consequences of using the device outside of its intended use.

1.1. Safety Information

DANGER

Indicates an imminent hazard that, if not avoided, will result in death or serious injury.

WARNING

Indicates a potential hazard or unsafe practice that, if not avoided, could result in death or serious injury.

CAUTION

Indicates a potential hazard or unsafe practice that, if not avoided, could result in minor personal injury or product/property damage.

NOTE

Provides application tips or other useful information to ensure that you get the most from your product.

1.1.1. Danger

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

1.1.2. Warnings

• Privacy Information: Intellectual Property Rights regarding all kinds of information presented in this User Guide belongs to Okuman. This manual cannot be reproduced in any form without the permission of the Okuman.

• Maintenance and Repair: Maintenance and repair of OKM 730 device shall be serviced by Okuman. Okuman is not responsible for injuries and damages that occur in maintenance works, which are not conducted by Okuman, and if this takes place, the equipment shall be out of the warranty.

• User Responsibility: Using the device without completely and thoroughly understanding the device specifications can cause injury to the treated baby. For this reason, the user manual must be read carefully before using the device.

• OKM 730 Radiant Warmer devices should only be used by suitably trained personnel under the supervision of qualified medical personnel who are familiar with their risks and advantages. Any user of Infant radiant warmer must be trained and familiar with the contents of the user manual before using the device. For this reason, it must be that the instruction manual is kept in a safe environment that can be reached when necessary.

1.1.3. Warnings For Use Regarding Patient Health

• During the phototherapy treatment, in order not to damage the baby's eyes, the eye protection band must be used.

• The blue light can damage the eyes when stayed too much around the patient.

• The bilirubin level of the patient should be measured continuously.

• There may be maculation's during the phototherapy due to the high rate of jaundice on the skin of infants.

• Blue light can inhibit the clinical observation of skin discolorations such as cyanosis (skin bruising).

• There may be toxic effect of bilirubinin and photoizormers during treatment.

• If the operator remains for a long time in the environment where the phototherapy device operates, may be exposed to some effects due to the phototherapy rays. That is, the blue light emitted by the lamps in the phototherapy may inhibit the clinical observations such as cyanosis by masking the skin discolorations. Also, blue light; may cause headache, nausea, eye problems and fluid loss.

• During the phototherapy treatment, there may be acceleration in the peripheral blood flow, water loss, eye damage and damage in the intestinal passages.

• The skin temperature of the baby should be constantly monitored for the possibility that its body temperature may rise.

The use of reflective foil can cause a dangerous increase in body temperatures.

• Necessary precautions should be taken so that the baby does not fall while the bed is being pulled.

1.1.4. Warnings Regarding The Use Of Equipment

• The power cable should only be connected to the city network and the grounded plug.

• If there is no grounded socket line, a grounding connection must be provided between the grounded metal surface using the grounding node on the device chassis and the interconnection cable.

• If you can not be sure that some parts of the device are working properly, the device should not be used and the technical service should be called immediately in such case.

• Always the original lamp should be used. The use of different lamps can change the light and temperature conditions.

• Okuman is not responsible for any damage that may occur if parts other than the accessories recommended by Okuman are used together with the device. Only accessories recommended by Okuman should be used.

• Device must not be used with flammable anesthetic gases or cleaning materials.

• The device must be switched off before moving.

• The device has 4 wheels with brake. It must be locked at least 2 brake of wheels while using.

• Liquid infusions and medicines should not be stored in the area of radiation.

• Radiation can damage the device. For example, the device should not be exposed to sunlight.

• Protect against electromagnetic waves. Some tools that are located next to device may

affect its operation. (For example, surgical blades, defibrillators ...). Keep such tools away from device.

• No products, such as drops or medicines, should be in the area of radiation.

• The device should not be used in the environments where there are gases facilitating imflammation (example: oxygen, nitrous oxide, anesthetic agents). Treatment should be started after these gases are removed.

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

• The weight that the rack can carry is max 20 kg.

• Plexi materials around the baby's bed which is situated in the device prevents the baby from getting out of the active treatment area. Therefore, plexi materials have to be re- inserted after the cleaning, etc. procedures and have to be checked for correct insertion.

• Ambient temperatures and the heat and light energy from different sources of radiation (sunlight, air conditioning, etc.) can cause to temperature increase in the cabinet of the phototherapy unit. Users are responsible for any problems that may occur in the baby if proper operating conditions can not be provided.

1.2. Risks - Precautions - Warnings

1.2.1. Electrical Precautions

The appliance must be connected to the mains according to the characteristic values stated on the product label.

1.2.2. Risk Areas

The device is not intended for use in areas which have explosion risk.

1.3. Applied Standards

OKM 730 Radiant Warmer applies the standards below:

- TS EN 60601-1
- TS EN 60601-2-21
- IEC 60601-1-2
- TS EN 61000
- ISO 13485
- ISO 9001
- ISO 14971

1.4. Equipment Symbols

X	Type BF device	
Ŷ	Universal serial bus (USB) port	
	Manufacturer	
	Read user manual first	
CE	CE symbol	
	Electrical products shall be treated according to relevant laws and regulations.	
	Warn sign	
	High voltage	

	Grounding
	Hot surface
	Eye protection band
~	Skin Temperature Probe

2. GENERAL INTRODUCTION

OKM 730 Radiant Warmer is used to care infants and do pediatric operations. This Infant Radiant Warmer adopts anti-blast infrared-tube made of microcrystal quartz as heat source, which has high radiant efficiency and is heated quickly. The advanced microprocessor control temperature system makes the operation more rational. The warmer has Pre-warm, Auto-warm (controlled by infant's skin temperature) and manual warm modes, which can meet with different needs. The Warmer has APGAR timer, separately display set temperature and real temperature. In order to insure the infant's safety during first aid, treatment, and nursing, this warmer has the alarm functions as sensor failure, power failure, and temperature deviation and over temperature alarm.

2.1. Product Intended Use

Radiant warmers are special life support devices with heaters and electronic equipment designed to allow monitoring of premature or low birth weight babies, maintaining body temperature, care and first interventions, and comfortable application of treatment. It can be used in areas such as newborn, infant care, neonatal and neonatal care hospital department, various NICUs. Radiant warmers are devices designed for therapeutic purposes.

The device is not intended for domestic use.

This device should only be used by suitably trained personnel and under the direction of qualified medical personnel.

2.2. Contraindications

Exposure of the newborn to cold causes a decrease in arterial oxygen and an increase in metabolic acidosis.

Radiant Warmers are contraindicated under the following conditions;

- Burns,
- Hypothermia,
- Hyperthermia.

2.3. Indication

Radiant Warmers are indicated for the following conditions;

- The need for short-term intubation and assisted respiratory support,
- Severe respiratory failure requiring assisted respiratory support,
- Recurrent apnea requiring positive pressure ventilation support,
- Low birth weight,

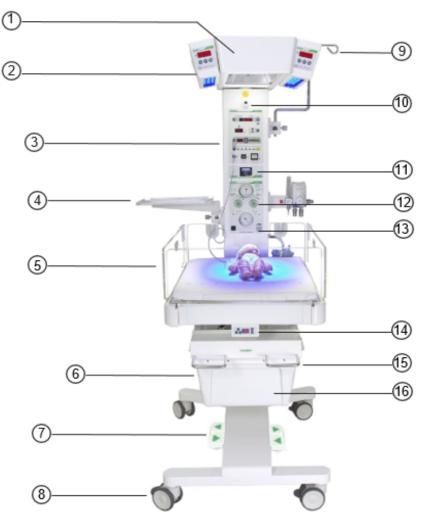
6

- 32-36. gestational weeks premature babies,
- Persistent cyanosis despite oxygen therapy,
- Conginatrial heart disease,
- Suspicion of metabolic disease,
- Serious congenital anomalies,
- <30 weeks and <1000 g of prematurity,

- Other conditions that require intensive care and complex treatment (metabolic disease, intracranial bleeding...)

2.4. Side Effects

In case of non-compliance with the hygiene rules, inter-patient contamination may occur. Skin probes must be disinfected before use.



2.5. General View of Device

Figure 2-1. General view of the device

No	Explanation	
1	Heater Unit	
2	OKM 1001 Phototherapy units (Optional)	
3	Control Module	
4	Rack	
5	Baby Bed	
6	Tank Holder	
7	Lift Pedals (Optional)	

8	Wheels (with brake), Ø 100 mm
9	IV Pole
10	Hands Free Sensor (Optional)
11	OKM 160 Baby Scale (Optional)
12	OKM 150 Resusitation Unit (Optional)
13	Aspirator Unit (Optional)
14	Electronic Trendelenburg (Optional)
15	Push Handles
16	Drawers

Manual The OKM 730 infant warmer has following basic modules and optional modules:

Basic Modules	Optional Modules
Heater Unit	Hands Free Sensor
Control Unit	Phototherapy Units
Bed Unit	Baby Scale
Monitor Tray	Suction Unit
IV Pole	Integrated Resuscitation Unit
Examination Lamps	O2/Air Blender Unit
Manual Trendelenburg	Electronic Trendelenburg
	Height Adjustment

The distribution of OKM 730 Radiant Heater according to its configurations is given below.

Features/	OKM	OKM	OKM	OKM
Configurations	730-Eco	730-Standard	730-Advanced	730-Full
X-Ray Tray	~	~	~	~
IV Pole	~	~	~	~
Monitor Shelf	~	~	~	~
Two-Sided Drawer		~	~	~
Aspirator Unit		~	~	~
Baby Scale with LCD Color Display			~	~
T-piece Resuscitation Unit			~	~
Electric Tilt Adjustment with Auto-Reset			~	~
Hands-Free Alarm Silence			~	~
Air/Oxygen Blender				~
Phototherapy Unit				~
E-base Electric Height Adjustment				~

Function of the modules are briefly described in following text.

2.6. Heater Unit

Heater unit includes a 500 W heater, reflector and examination light provided lighting for bed tray area. Heater unit could rotate two sides, the heater continues to heat when unit is rotated. Heater unit can be rotated on two sides in $\pm 45^{\circ}$ stepless. This angle is changeable, optionally. This option is used when taking X-Ray measurements.

The focus point of the examination lamps is not fixed. Operator is able to change the focus of the lamps by pressing front or back metal frames of lamps.

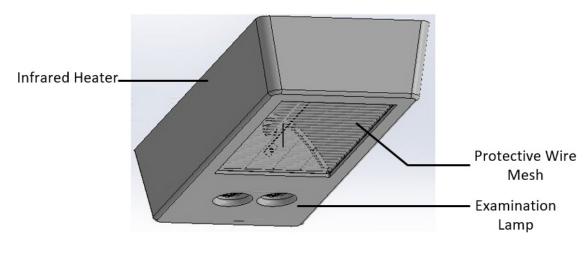


Figure 2-2. Heater Unit

2.7. Control Unit

Control unit controls the heater by three mode: Pre-warm mode, Manual mode, Baby mode (servo skin temperature control). This unit has a skin probe connector, alarm leds, buzzer, displays, ON/OFF switch and user buttons, APGAR and CPR timer features also.

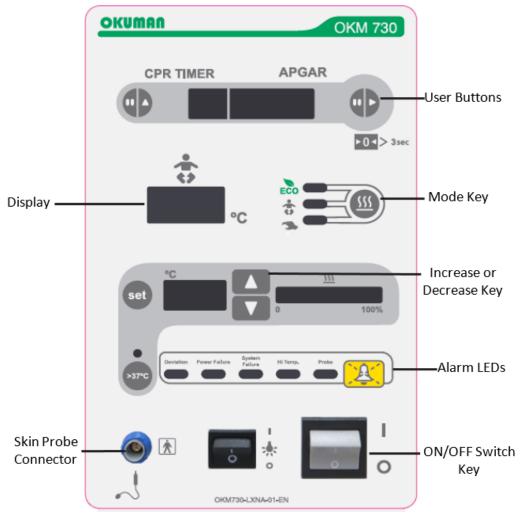
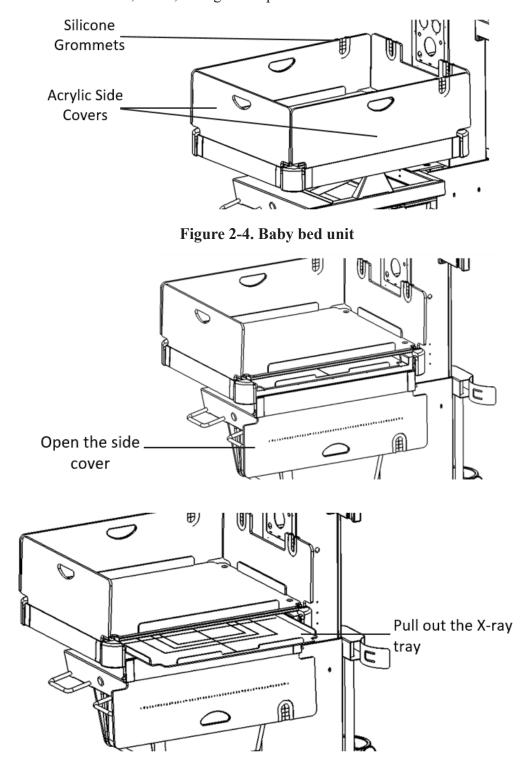


Figure 2-3. Control Unit Screen

2.8. Bed Unit and X-Ray tray

The design of bed body achieved multifunction and practicability, provided good assist for nurse baby. Dimensions of the bed is 70x55 cm. The bed has surrounded by acrylic side covers and has tilt option with -15° to $+15^{\circ}$ by electronic or manual trendelenburg. Bed body has height adjustment option and there is a section in the bed used for pull out X-ray tray. The bed unit includes a mattress made by a material flame retardant, washable, antibacterial and resistant to: corrosion, water, detergent soap.



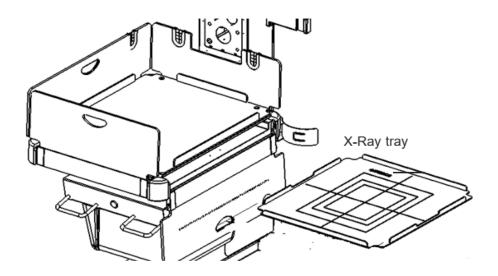


Figure 2-5. Placing the X-Ray tray

2.9. The Monitor Shelf and IV Pole

The device has a monitor shelf and various medical accessories can be placed IV pole is used as serum hanger for transfusion bottles.

Warning: The maximum loading is 20 Kg for the monitor shelf and 2 Kg for the IV pole.



Figure 2-6. Monitor shelf and IV pole

2.10. Height Adjustment

12

OKM 730 has lift unit which providing 30 cm height adjustment of baby bed. The minimum height of the baby bed is 80 cm and maximum height of the bed is 110 cm. Height adjustment can be done by pressing the pedals located at each bottom side of the device.

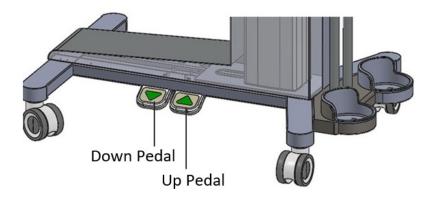


Figure 2-7. Height adjustment pedals

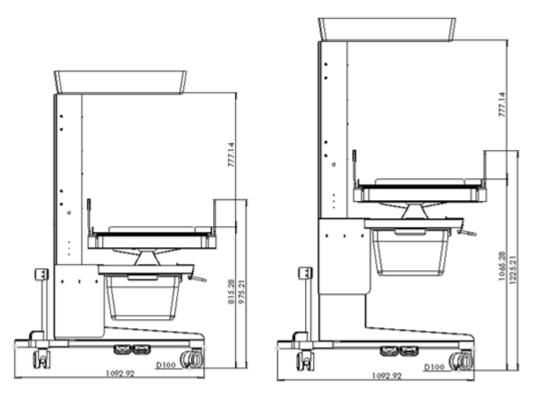


Figure 2-8. General dimensions of the device. Left: without lift. Right: with lift.

2.11. Examination Lamps

The OKM 730 has an examination LED lamp located on heater control unit. Optionally, a dimmer examination LED switch can be added (as on the right).

Dimmer LED lamps have 2 dim levels as %50 and %100. To switch on the lamps use examination lamp switch on control unit. User can select the dim level by switching the button to I or II positions. Please use the exam lamp only if you need. The examination lamps can be rotated by $\pm 30^{\circ}$ approximately.

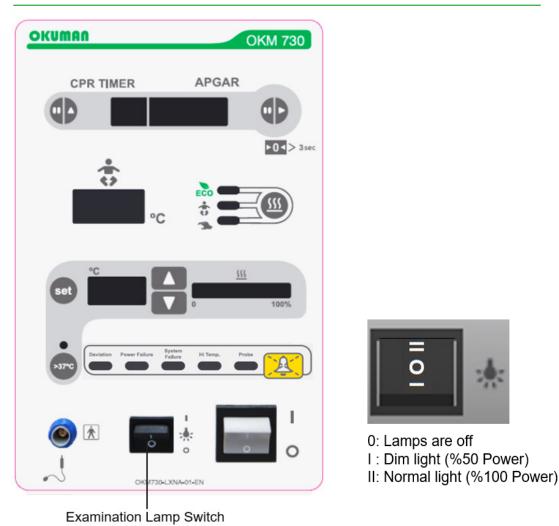
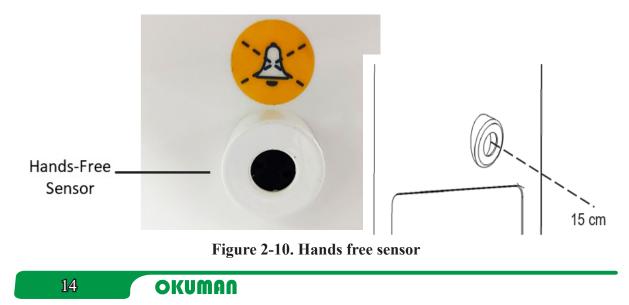


Figure 2-9. Examination lamp switch (left); optional dimmer examination lamp switch (right).

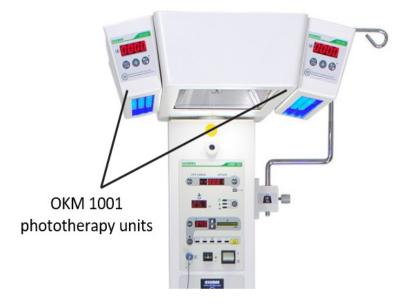
2.12. Hands-Free Sensor (Optional)

Hands free sensor provides easy access to silence the audible alarms. The sensor operates according to photocell mechanism. Detection distance of the sensor is max 15 cm. Putting the hands close to the sensor is enough to silence the alarm in baby check mode.



2.13. Phototherapy Units (Optional)

OKM 730 can be used with 2 OKM 1001 phototherapy units. Phototherapy units can be placed on the sides of heater unit.





2.14. Baby Scale (Optional)

The OKM 160 Baby Scale is very precise baby scale is able to weigh 1 gr to 10 kg with automatic tare and automatic zero-positioning on taring (when the bed is tilted) function.

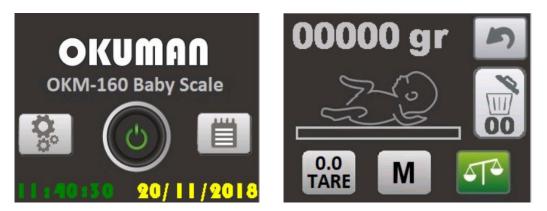


Figure 2-12. User interface of OKM-160 baby scale

2.15. Suction/Aspiration Unit (Optional)

OKM 730 can be combined with suction unit. Suction unit is used for cleaning the respiratory tracts of newborn.

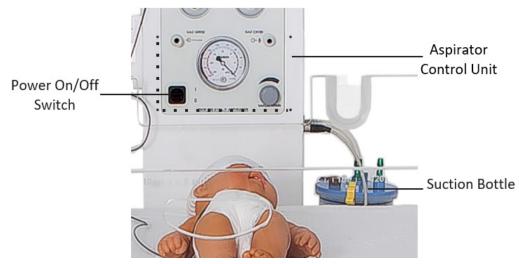


Figure 2-13. Aspirator unit

2.16. Infant T-Piece Resuscitator Unit (Optional)

OKM 730 can be combined with OKM 150 Resuscitation device. This unit provides manual respiratory support for newborn. The Resuscitation Unit is designed to arrange, balance and mechanically deliver the baby's postnatal breathing if necessary. It also applies the desired air gas mixture to the patient at the specified pressure limits by the help of Air/Oxygen blender (Optional).

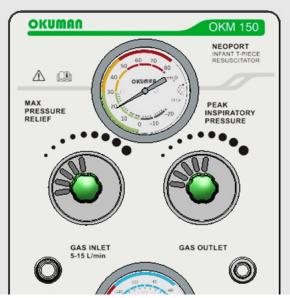


Figure 2-14. Infant T-Piece Resuscitator Unit

2.17. O2/Air Blender Module (Optional)

The OKM 730 can be combined with O2/air blender module. This module is used to provide air-oxygen mixture at %21 to %100 proportions. This module can be used with resuscitation module.

Note: Model of the O2/air blender module can varies in some configurations depends on customer's order. Refer to the operating manual of the blender module for use of the module.



Figure 2-15. O2/air blender module

2.18. Manual/ Electronic Trendelenburg (Optional)

There are two options for trendelenburg modules: Which are manual trendelenburg and electronic trendelenburg. Each modules provides ± 15 o tilt angle. Electronic trendelenburg has superior properties such as auto zeroing, displaying tilt degree and working compatible with baby scale.





Figure 2.16- Bed with electronic trendelenburg (left) and manual trendelenburg (right)

Rotate the trendelenburg wheel to right or left to give positive or negative angle tilt between -15 and +15 degree. The usage of the electronic trendelenburg will be described in next sections.





Figure 2-17. Manual trendelenburg

3. USING THE RADIANT WARMER

This section provides the information about use of the OKM 730 infant radiant warmer.

3.1. Control Panel

The control panel provides the user interface for the operation of APGAR and CPR timer control, switching on/off the device, selecting the working mode, setting the heater set value, audiovisual presentation of the alarm conditions, controlling the inspection lamps and displaying the skin temperature values. The control panel has one skin temperature probe input and RS232 communication port. Control panel interface and descriptions are given in following figure.

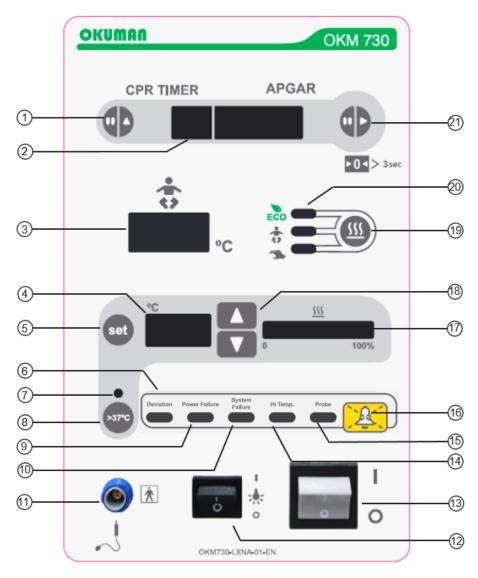


Figure 3-1. Scheme of control panel

No	Function explanation
1	CPR timer increasing and stop button
2	CPR Time (60 minutes) and APGAR(59 minutes 59 seconds) time display screen
3	Baby temperature display screen
4	Set temperature display (Optional environment temperature display)
5	Set key, press set key, the screen flash, and then press $\Delta \nabla$ key to adjust set temperature
6	Deviation alarm indicator
7	> 37 °C set key indicator
8	> 37 °C set key, press this key before set temperature over 37 °C
9	Power failure alarm indicator
10	System failure, head misplacement alarm (Optional)
11	Skin temperature sensor jack
12	Examination lamp switch,
13	Power switch
14	Over temperature alarm indicator
15	Sensor alarm indicator
16	Silence key, press silence key to make alarm silence for 10 minutes
17	Heat power indicator, indicate the heat power percentage
18	$\Delta \nabla$ keys, increase or decrease set temperature by 0.1 °C steps (in baby mode), increase or decrease heating power by %5 steps (in manual mode)
19	Mod key, choose heat mode
20	Warning mode indicator
21	Start / Stop button, this button is pressed to start or stop the time, when pressed for more than 3 seconds, APGAR timer "Reset" feature is activated.

3.2. Before the Operation

Check the warmer:

- Make sure the equipment has been sterilized.
- Make sure the acrylic side covers has been assemble firmly.
- Make sure the acrylic side covers has no crack and edged.

- Make sure the bed tilt suitable and lock well.
- Make sure the power cable connected well and the installation is safe.
- Make sure the wheel brakes locked.
- Skin probe is plugged
- Device is functioning properly

Note: Make sure the supply power accord with the require power in electric nameplate. In order to make the equipment earth well, must connect the power wire to single-phase three wire mains jack, do not use extension cord.

3.3. Powering On the Device

Connect the power cable to a grounded power jack. Then switch on the control module. When the device powered on all the displays flash and skin probe input is checked. If skin probe is not connected the module gives the probe error.

Note: Power system of the device is not affected by voltage fluctuations up to \pm %30 of rated input

Note: The F5A 5 ampere glass fuse protection to ensure that the device is not damaged by electrical interruptions or malfunctions. This fuse is at the bottom of the power input connector. In the event of a blow out, it is necessary for the authorized personnel to replace it with the new one.

Note: The control panel is supplied with a 9V rechargable battery which provides working time up to 15 minutes when power is failured. In this case module works normally, by performing the measurement and displaying tasks except for heating function.



Figure 3-3. Grounding cable

In cases where there is no grounded socket line, grounding should be made between the grounding node on the device chassis and the metal surface connected to the ground using the cable shown in the figure.

3.4. Warmer Modes

The OKM 730 infant warmer has three working modes:

- Pre-warming (ECO) mode
- Baby mode
- Manual mode

These modes can be selected by pressing mode select button.

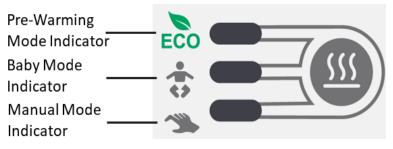


Figure 3-4. Mode selection

Selected mode is indicated by the lighting of the led lamp next to it. The system starts in Prewarming (Eco) mode by default when the device powered on. This mode uses heating power between %30 and %50.

In Baby (Servo) mode, the controller adjust the heating power through set value of the skin probe temperature and measure temperature from skin sensor in order to keep the temperature stable. The skin temperature will be provided close to the set temperature, by heating according to the temperature deviation which the baby needs.

In manual mode, the heating power is adjustable from 0 to 100% by 5% steps. Because of that the warmer heats according to the adjusted heating power, if heating power is set to high values, temperature of the environment of the baby may be extremely high. Therefore, in manual mode the device gives audible alarm in every 10 minutes to checking the safety of the baby. When getting an alarm by pressing silence key the alarm could be silenced for 10 minutes. For these reasons, it is strongly recommended to use the device in baby mode.

3.4.1. Using the Warmer Modes

In this section working with the warmer modes is described. Before using the device don't forget to connect the skin probe.

Note

If reuse the warmer after the power was disconnected, maintain or cleaning purposes, please follow pre-check steps to be sure the device working properly.

IMPORTANT: Heat mode and temperature values should be determined by a clinician.

WARNING

- Please read the operating precautions this manual before using the device.
- Please do not use the warmer if it does not pass checking, and refer to qualified service personnel.
- The operator must not leave alone the baby within the warmer.
- Baby's condition and skin temperature should be checked regularly.
- The baby may remain dehydrated throughout the long treatment period, sufficient water support should be provided by the nurse.
- In order to not to be affected by electricity shortages in the electrical network, please use the UPS line that is exist in the hospital. If the UPS system is not existing, please supply min 3KVA pure sinewave UPS device and use with the device.

3.4.1.1. Using the Pre-Warming Mode

The pre-warming mode is the automatic mode which allows the bed to reach the proper temperature before the baby is put into bed. This mode uses heating power between %10 and %30. In this mode, the power is %20 by default, and %10 upper and %10 lower power levels can be selected by user. To activate the pre-warming mode, press the mod select button untill led lamp of ECO mode is activated

Note: This mode should be changed to baby mode after the infant is placed on the warmer.

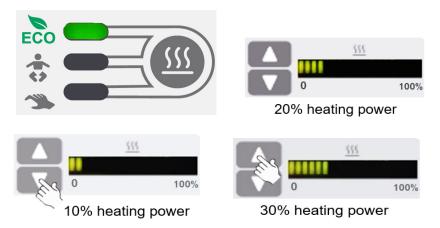
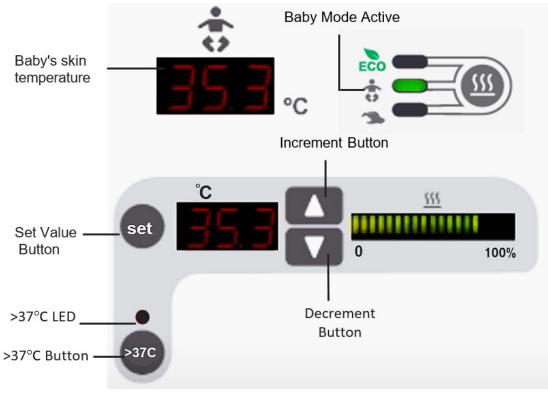


Figure 3-5. Pre-Warming mode is selected. Heating power can be decreased and increased by user limited up to %10 and %30 with %5 steps.

3.4.1.2. Using Baby Mode

In baby mode, the heater device uses a control algorithm to keep the baby's skin temperature at the desired setpoint. The set point can be selected between 25°C and 38°C. For this purpose, the heater power is increased or decreased according to the value of the skin temperature measured by the skin probe. Increment or decrement ratios of the power is depend on the temperature deviation between the set value and baby's skin temperature.



To activate the baby mode, press the mod select button untill led lamp of baby mode is activated.

Figure 3-6. Controls of baby mode

Note

The operator should choose the set temperature according to clinical requirement and baby's situation.

Connect the skin sensor probe to infant skin surface.

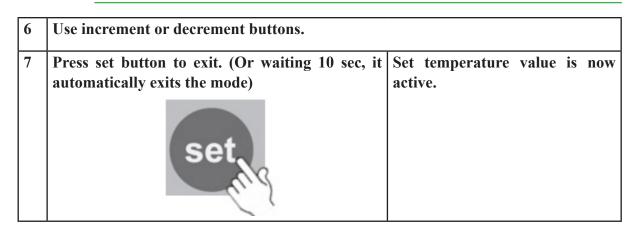
If baby lying on the bed, put the sensor between abdomen xiphoid and navel except liver area.

If baby prostrate on the bed, put the sensor on baby back, it would be better at kidney area. To make sure the sensor contact to baby skin well, it should have fixed the sensor by medicine tape. For lying on side baby, the place for put sensor should be confirmed by attending physician.

Follow the steps to adjust skin temperature set value in baby mode:

1	Press the mode select button to select Baby mode	be ON
2	Press the set button untill set display blinks	Set display will blink. Now you can enter the set value.
3	Press increment button to increment the set temperature value by 0.1°C	
4	Press increment button to increment the set temperature value by 0.1°C	
5	To increment the set value higher than 37°C, press >37°C button.	The yellow led will be ON to indicate, >37°C input is active.

OKUMAN





Even though the warmer is servo controled in baby mode, the operator should not leave away, in order to avoid baby without monitor and get accident.

The operator usually thinks that a baby's temperature is rectum temperature. Okuman also provides optional rectal probes when required for the OKM 730 infant radiant warmer.

WARNING

Do not use this mode if baby shock or fever.

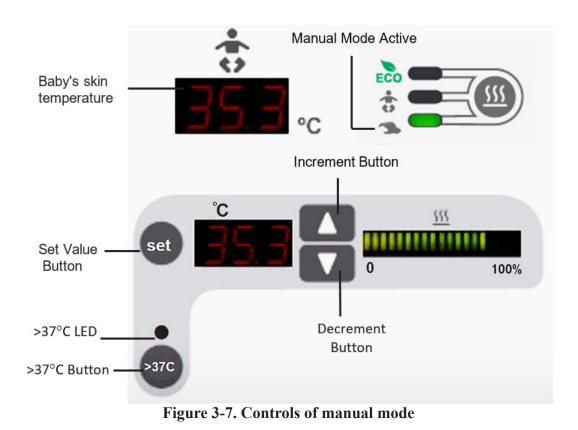
Do not use baby mode if baby in a shock. Because baby skin temperature was lower than usual when baby in a shock. If you use baby mode, it will make baby skin temperature too high.

Do not use baby mode while baby have a fever. Because baby skin temperature was higher than usual when baby have fever, if you use baby mode, it will make baby skin temperature too low.

3.4.1.3. Using Manual Mode

In manual mode, the warmer heat according to set heat power. Skin temperature of baby is not considered. This mode can be used for short time nursing, first aid or increasing low skin temperature.

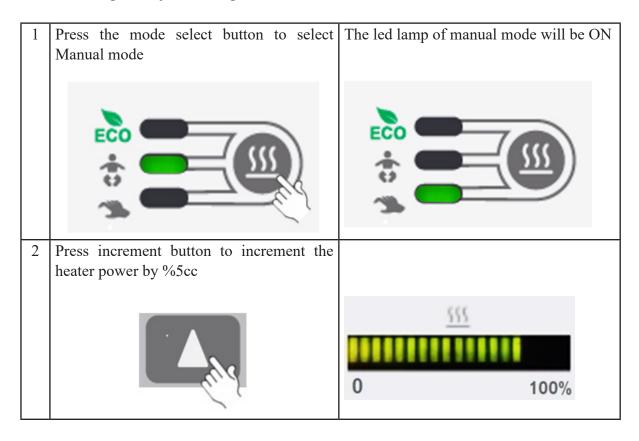
In manual mode, the temperature display shows the measured skin temperature. Set temperature display do not display any value. The operator should control the heat power by following clinician's directives.

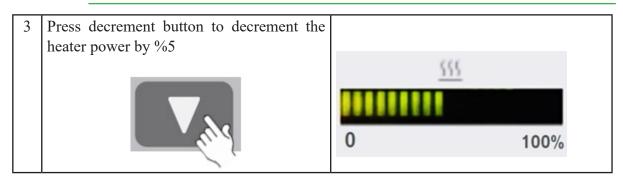


NOTE: The operator should choose and adjust suitable heat power accord with clinical requirement.

Follow the steps to adjust heater power level in manual mode:

OKUMAN





NOTES

In manual mode:

1. The heat power is steady, and doesn't change by measured skin temperature, so operator must pay attention to baby's temperature.

2. The baby check function is activated for the safety of the baby. The device will alarm at every 15 minutes for the operator to come and check the baby's condition.

3. After the device works 15 minutes with over 25% heat power, in order for infant safety, the device automatically decrease the heat power by 25%.

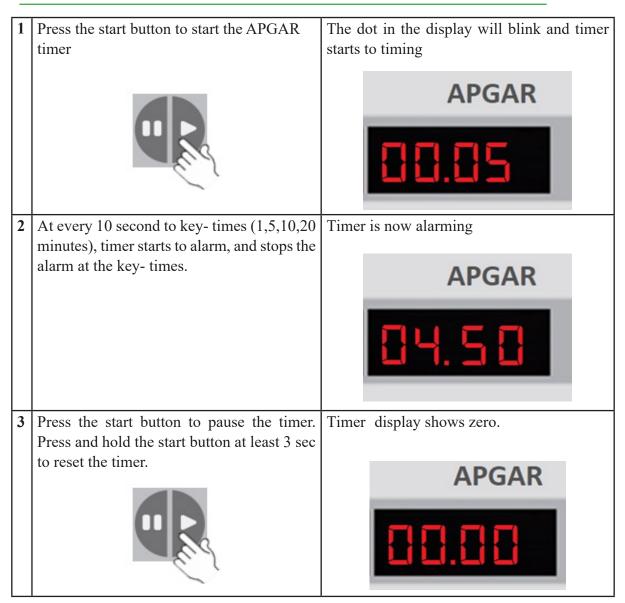
3.5. Using APGAR Timer

It takes the name from Dr. Virginia Apgar. After baby born, make class and grade accord with Appearance (Skin color), Pulse (Heart rate), Grimace response (Reflexes), Activity (Muscle tone) and Respiration (Breathing rate and effort). It offers the functions of three periods alarming indication: 1min, 5 min, and 10 min for clinical treatment.

APGAR function of OKM 730 provides forward timing function 0 to 20 minutes, reset and pausing the timing functions. APGAR timer alarms at 1 minute, 5 minutes, 10 minutes and 20 minutes by period of 10 seconds.



Figure 3-8. APGAR timer interface



3.6. Using CPR Timer

OKM 730 has a CPR timing module from 0 to 60 minutes. CPR timer counts down from adjusted time to zero. Before reaching to zero timer gives alarm and display blinks. CPR timer can be used drug injection, baby check as well as CPR intervention.

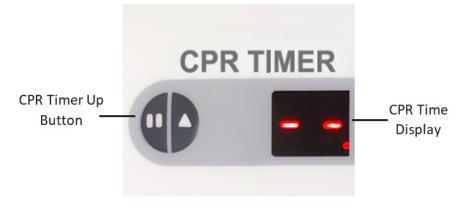


Figure 3-9. CPR timer interface

To use CPR timer follow these steps:

1	Press the up button to set the CPR time and start the CPR timer	The dot in the display will blink and timer starts to counting down
		CPR TIME
2	When the timer reachs to zero, display automatically closed. In last 10 sec to reach to zero timer gives alarm	CDD TIME

3.7. Checking Control Module Functions

To be sure that the device working properly, it is recommended to follow the pre-checking steps

3.7.1. Checking Power On Alarm

If connect the power, the system will self-test after turn on, and then come into pre-warm mode. The system will alarm if system has failure.

3.7.2. Checking APGAR Timer

APGAR timer displays six zero. Press Start/Stop key to start time, the timer will alarm with audible between 50 seconds to 1 minute, 4 minutes 50 seconds to 5 minutes, 9 minutes 50 seconds to 10 minutes, 19 minutes 50 seconds to 20 minutes.

3.7.3. Checking Examination Lamp

Turn on the examination lamp by using examination lamp switch.

3.7.4. Checking Power Failure Alarm Function

When the control module's power switch is ON, disconnect the power cable, then power failure alarm supposed to be actived and power failure alarm indicator must lights up and buzzer must sounds. Connect the power cable after check.

IMPORTANT: Make sure that the rechargeable battery is not depleted. If the battery is not charged, the alarm will not sound even if the alarm is activated. If the battery is well charged and the alarm does not sound while the alarm is active, the heater must be serviced.

3.7.5. Checking Temperature Accuracy

Put the skin sensor and a mercury-in-glass thermometer in the cup which fill $30^{\circ}C \pm 5^{\circ}C$ water, make the sensor probe close to thermometer mercurypool, after stirred, read the thermometer, contrast with controller display temperature, the deviation should be in $0.5^{\circ}C$.

NOTE: If the test temperature is over the allow deviation temperature, please test again, if it is over the allow deviation temperature again, please refer to professional service person.

3.7.6. Checking temperature deviation alarm

In baby mode, set the temperature at 34°C, after the display temperature arrive to 34°C and stable, put the skin sensor in the cup which fill 36°C water, the deviation alarm active with indicator lighting and intermittently audible alarm when the display temperature exceed 35°C, turn off the heat power indicator and cut off the power, the alarm will stop when the display temperature deviation in the range ± 1 °C, the deviation alarm active with indicator lighting and intermittently audible alarm when the display temperature below 33°C, the heat power indicator alarm when the display temperature below 33°C, the heat power indicator also display.

3.7.7. Checking Over Temperature Alarm

If the set temperature is between 34°C to 37°C, put the skin sensor in the cup which fill 40°C water, the over temperature alarm active with indicator lighting and audible alarm when the display temperature exceed 38°C, If the set temperature is >37°C, the over temperature alarm active with indicator lighting and audible alarm when the display temperature exceed 39°C. The heat power indicator will be turn off and the power will be cut off.

3.7.8. Checking Sensor Failure Alarm

In baby mode, disconnect the sensor, the sensor alarm active with indicator lighting and audible alarm, the heat power indicator will be turn off and the power will be cut off. The alarm will be stop if connect the sensor.

3.7.9. Memory Function

In normal working, if power cut off suddenly, power regain in 10 minutes, the control mode and the set value would not be changed.

Each time the device is swiched off, it would begin on Pre-warming (ECO Mode) Mode when it is swiched on.

3.8. Alarm Messages

The OKM 730 uses a alarm display and buzzer to provide 5 alarm conditions. Some of the alarm can be silenced but for CPR and APGAR timer's alarm can not be silenced through alarm silence button or hands free. For these both timer's alarm will be deactivated automically after

OKUMAN

30

Alarm Indicator LEDs Alarm Silence Button Deviation Failure System Failure Hi Temp. Probe

ten seconds. The alarm panel of the OKM 730 is shown below.



3.8.1. Deviation alarm

Deviation alarm occurs when the temperature deviation between baby's skin temperature and set temperature is higher than $\pm 1^{\circ}$ C, in baby mode. Audible and visual alarm is activated and heating power is switched off (heating power indicator will be off). Whenever the deviation falls below $\pm 1^{\circ}$ C alarm is silenced and heating power is switched on. This alarm can be silenced with alarm silence button.

3.8.2. Power failure alarm

When the power cable is disconnected or electricity outage happens, the power failure alarm will be active. This alarm cannot be silenced with alarm silence button.

3.8.3. System failure alarm

This alarm type is for optional functions (e.g. heater unit displacement). This alarm can be silenced with alarm silence button.

3.8.4. Hi temp alarm

This alarm will be active when skin temperature exceeds 38°C while set temperature is below 37°C and active when skin temperature exceeds 39°C while set temperature is higher than 37°C. Audible and visual alarm is activated and heating power is switched off (heating power indicator will be off).

3.8.5. Probe alarm

This alarm occurs in baby mode, when the skin probe is disconnected. This alarm can be silenced with alarm silence button.

Note

The alarm silence button silences the alarms for 10 minutes. After 10 minutes audible alarm is re-activated. However, alarm indicator led continues to show alarm situation.

OKUMAN

4. USING ELECTRONIC TRENDELENBURG (OPTIONAL)

Bed has electronic Trendelenburg feature with two memories and auto untilt function. Use up and down button to tilt the bed among the angles -15 and +15 degree.



Figure 4-1. Electronic trendelenburg control panel



Figure 4-2. Electronic trendelenburg user panel

4.1. **Positive Tilt**

To give positive incline to bed touch the positive incline button. This gives positive incline between 1 to 15 degree.



Figure 4-3. Setting up the positive incline.

4.2. Negative Tilt

To give negative incline to bed touch the negative incline button. This gives negative incline between -1 to -15 degree.

Figure 4-4. Setting up the negative incline.

4.3. Auto Untilt Function

Setting the bed to zero level position press "untilt" button. The bed automatically zeroes the position.



Figure 4-5. Untilting the bed

4.4. Storing the Bed Tilt Angles to Memory

To store any position of the bed press and hold "Zero" button and "Store" buttons together until the display blinks. For example, Figure 4-6 shows saving the bed position to memory M1 when the position is -10 degree. Same process can be applied for M2 memory.

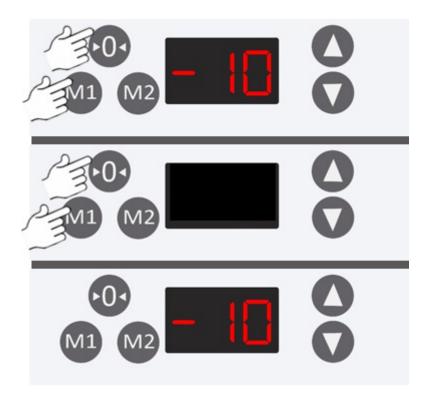


Figure 4-6. Storing the bed position to memory M1

4.5. Recalling the Bed Tilt Angles

To recall saved position of the bed press and hold memory button until bed movement finish. For example Fig 4-7 shows recalling the previously saved bed position (-10 degree) from memory M1. The same process can be followed for memory M2.

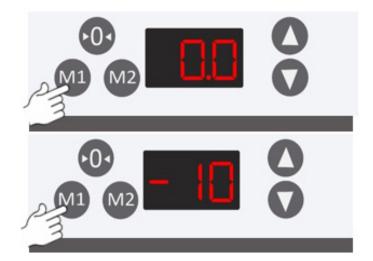


Figure 4-7. Recalling the bed position from memory M1.

5. USING THE OKM 160 BABY SCALE (OPTIONAL)

The OKM 160 Baby Scale has the properties

- Automatic / manual tare (zeroing),
- Automatic / manual weighing, up to $10 \text{ kg with} \pm 1 \text{ gr accuracy}$
- Memorizing the results up to 10 measurements
- Date/time adjustment.

The OKM 160 can also measure and tare when the bed position is inclined, and can automatically reset the bed position (for only the models with Electronic Trendelenburg) for accurate measurement. Taring is important in the sense that if there are additional weights on the bed. They will also increase the measurement accuracy by taking the tightness.



Figure 5-1. OKM-160 Baby Scale Module

The OKM 730 radiant warmer integrated with OKM 160 baby scale opening screen is shown in Fig. 5.1.



Figure 5-2. a) On/Off Button b) Back to the Main Screen Button

OKM 730 User Manual

While the main screen is on the display, touch the on / off button and touch the scale screen (Figure 5.2.a), and move to the RTC (real time clock / date) setting screen by touching the set button. The back button should be touched to return to the main screen (Figure 5.2b).

5.1. Scale Process

OKM 160 baby scale has automatic weighing feature. When the instrument is on the weighing screen, the measurement result is displayed automatically within 3-5 seconds. Thus, changes in the weight of the baby can be easily monitored.

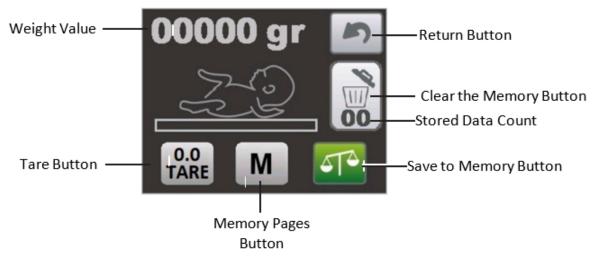


Figure 5-3. Weighing display

5.2. Automated Tare Process

If the measurement result is lower than the tare value, "ERROR" caption appears on the display and 3 measurement times are waited. If the measured value at the end of 3 measurement times is lower than the tare value, the automatic tare function is activated and the bed is narrowed (Figure 5-4). Note: The baby should not be in bed during taring.

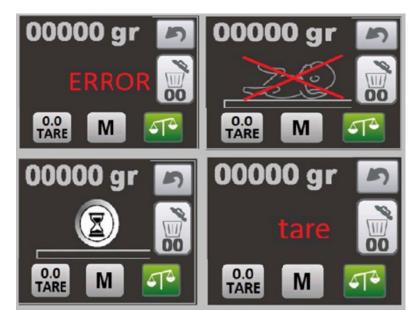


Figure 5-4. Automatical Taring Display

5.3. Weighing in the Inclined Position

When the bed is inclined, it does not take measurement and the user is informed by continuous visualization on the screen (Figure 5-5).



Figure 5-5. Inclined position warning screen

5.4. Taring

When the Tare button is touched, the bed position is checked and if it is not parallel, the bed is automatically made parallel. After it becomes parallel, TARE is displayed on the screen and bed resetting is carried out. This may take 10-15 seconds depending on the bearing vibration. If the tare operation is unsuccessful, the user will have to press the tare button again (Fig. 5-6).

Note: The baby should not be in bed during taring.

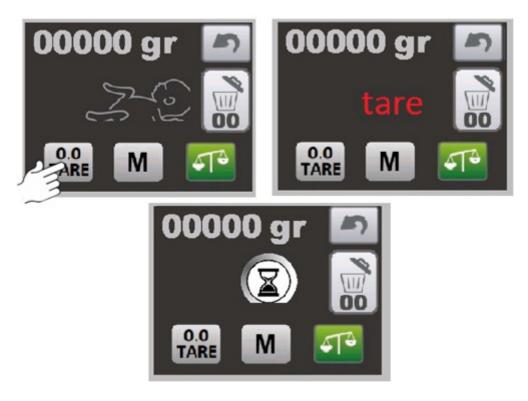


Figure 5-6. Taring Screen

5.5. Storing Weight Values

The baby scale has memory capacity for storing up to last 10 measurement. To store any weight measurement to data memory, press the memory button. Whenever user pressed the memory button, last data is stored to memory and number of the stored data is updated on trash can icon. If user saves the data more than 10 data, data is shifted and the previous ones will be deleted. The first 5 measurement is stored in page 1, and others in page 2.



Figure 5-7. Weighing screen and storing data

To recall the saved data press memory page button. The stored data saved as 2 page which storing the 5 values. To avigate between the pages press P1 or P2 button. To screen the stored data press M1 to M5 buttons on the active page.



Figure 5-8. Recalling the saved data

027 (50) g 0.0

To clear the memory press the clear button. All saved data is cleared.

Figure 5-9. Clearing the memory

TARE

N

5.6. **Date and Time Adjustment**

0.0

TARE

On the home screen, touch the set button to go to the RTC (real time date and time) setting screen. In this screen user can adjust the date and time in DD/MM/YY and HH/MM format.

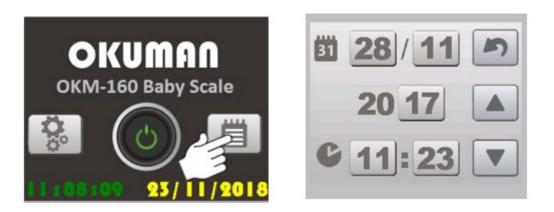


Figure 5-10. Date and Time Settings menu

By touching the field, the field to be changed is selected. The selected field will appear as black (Figure 5-11).

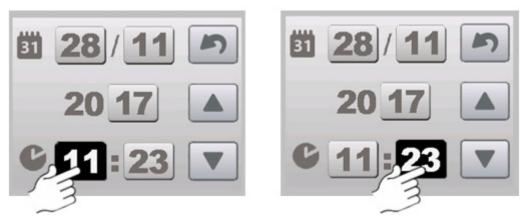


Figure 5-11. Selecting the field to be changed

39

Touch the up and down buttons to increase or decrease the value (Figure 5-12).



Figure 5-12. Incrementing and decrementing the values

Touch the return button to return to the main screen (Figure 5-13).



Figure 5-13. Return to the main menu

6. USING THE OKM 150 RESUSCITATION UNIT (OPTIONAL)

The Resuscitation Unit is designed to arrange, balance and mechanically deliver the baby's postnatal breathing if necessary. It also applies the desired air gas mixture to the patient at the specified pressure limits. These pressure limits are realized via the safety valve and peak valve setting knobs located on the unit. During the application, the part located on the upper part of the T-piece peep valve is closed while the transition to the inspration. It is opened for the expiration so that the gas flow at the desired limits is provided to the baby.

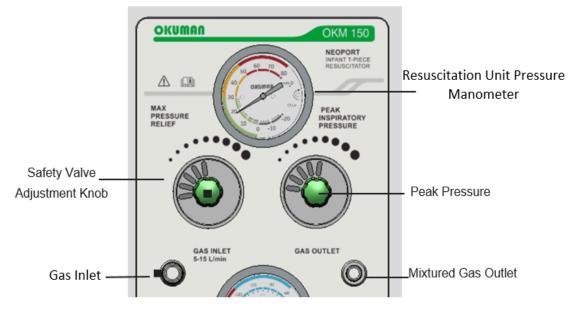


Figure 6-1. Control Unit Panel

6.1. Specifications

Following table gives the technical specifications of the OKM 150 Resuscitation Unit

OKM 150 SPECIFICATIONS		
Gas Inlet	0-15L/min	
Pressure Range	0~80cmH2O	
Manometer Measure Range	-20~80cmH2O	
Working Temperature	18 °C~30 °C	
Storage Temperature	- 40 °C~+ 55 °C	
Working Humidity	%30~ %75 RH	
Storage Humidity	≤ %93 RH	
Transport and Storage Pressure Range	500 hPa~1060 hPa	
Working Pressure Range	700 hPa~1060 hPa	
Flow rate	\leq 0,3 m/s	
Flow accuracy	±2 L/min	

6.2. Using The Module

• Connect the required supply hose to the gas inlet of the resuscitation unit. Put the T-Pieces

Circuit (1) and Gas Supply Line (2) as seen in the figure.

• Connect the patient feed hose with T-piece Peep Valve to the device as shown in figure. Connect Gas Supply Line (2) to the one of the O2 sources (Blender, O2 Cylinder or Hospital O2 Circuit)

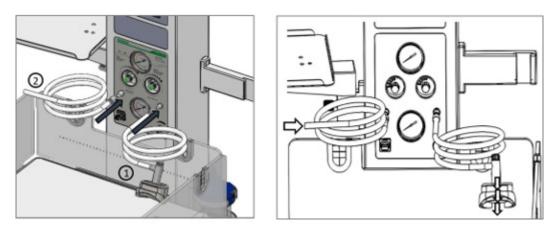


Figure 6-2. T piece Peep Valve Connections

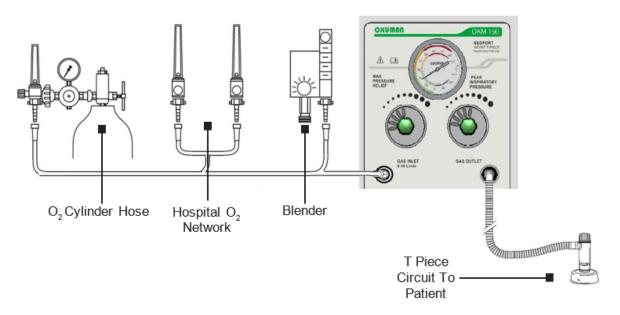


Figure 6-3. O2 source and T-piece peep valve connection

Note

42

The device must be used by qualified personnel with sufficient training and knowledge and experience.

PEEP: Positive End Expiration Pressure PIP: Peak Inspiratory Presssure

6.3. Working Explanation

Resuscitation Unit Pressure Manometer: Indicates the amount of air pressure on the baby.

Safety Valve Adjustment Button: During the operation, the amount of air pressure to be applied to the baby must not exceed certain values. The safety valve is used to keep this value constant and not to exceed it. Adjustable between 0-80 cmH2O. NOTE: This value can be a risk when it is over 30 cmH2O.

Peak Inspiratory Pressure (PIP) Adjustment Knob: It is used to set the peak value below the limit value set by the safety valve.

Mixture Gas Entry: Used to transfer the oxygen and air mixture into the device. The gas inlet pressure value should not exceed 4 bar.

Mixture Gas Output: The mixture gas at the set pressure value is transferred to the baby via the T part patient circuit.

Vacuum Manometer: Provides the monitoring of the set negative pressure value. **Vacuum Adjustment Knob:** Used to set the desired negative pressure value.

1. To resuscitate:

- Adjust gas supply to the desired flowrate
- Fit patient T-piece to resuscitation mask and place over the baby's mount or nose. Or

• Resuscitate by placing and removing your thumb over the PEEP cap to allow inspiration and expiration.

2. Set-Up:

• **Connect gas supply:** Connect oxygen or blended oxygen/air supply to gas inlet port using gas supply line.

• **Connect patient supply line:** Connect patient supply line and patient T-piece to the gas outlet port. Connect test lung to patient T-piece.

3. Check Settings:

Adjust gas supply to desired flowrate between 5 and 15LPM. To check maximum pressure:

• Occlude PEEP cap and turn PIP control fully clockwise.

• Adjust maximum pressure control knob clockwise or counter clockwise to set desired maximum pressure.

To set PIP:

• While the PEEP cap is occluded, turn the PIP knob counter clockwise until the desired peak inspiratory pressure is set.

To set PEEP:

- Adjust PEEP cab to the desired PEEP level.
- Turn off gas supply and remove test lung from patient T-piece.

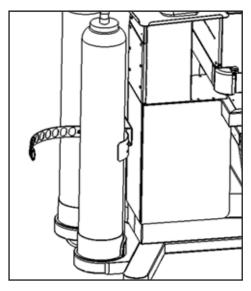


Figure 6-4. Fasten the rubber belt to fix the cylinders



Please read the operating instructions in this manual before using the appliance.

• Avoid unauthorized intervention of the device. Unless otherwise stated, the electromechanical and pneumatic system should not be intervened.

• Disposable accessories supplied with the device should not be used in other infants. Reusable patient circuits can be reused by being sterilized under appropriate condi- tions. The control of the appropriate conditions is responsibility of the user. The ma- nufacturer regards the mistakes originating from these situations as user error. The manufacturer is not responsible for problems caused by user errors.

• The operator must not leave the device during operation.

7. USING THE ASPIRATOR UNIT (OPTIONAL)

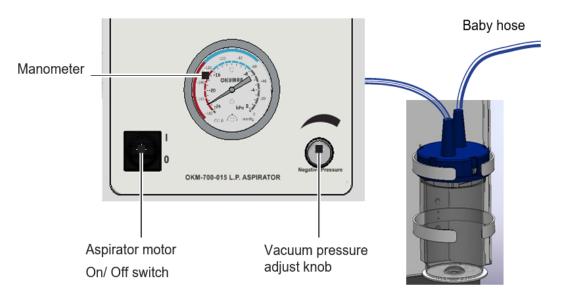
OKM 730 can be combined with the aspirator unit. Depending on the configuration aspirator unit and resisuation unit can be combined in the same frame together. Aspirator unit is used for cleaning the respiratory and rectal tracts of newborn. Using steps of the aspirator:

• Clean and sterilize suction bottle

• Make connections of suction bottle tube. One port should be connected to the motor input, other port should be used for suction purpose.

- Turn on suction,
- Seal up delivery tube,
- Screw down the pressure regulator valve gradually,

if the suction pressure increase gradually, it means gas circuit airproof well. Adjust the pressure regulator valve to clinical pressure value [pressure adjust range: 0 - 22Kp (0 - 165 mmHg) stepless] to do the suction for baby.



Suction bottle Figure 7-1. Aspirator unit and bottle connection

8. USING THE OKM 1001 PHOTOTERAPY UNIT (OPTIONAL)

OKM 730 infant radiant can be used with two OKM 1001 phototherapy modules. For the use of the OKM 1001 phototherapy modules, if the modules are not connected, it is necessary to make power connection to the heater module first, as shown in the service manual. The side angles of the heater module focuses the area of the OKM 1001 modules on the baby bed. When the OKM 1001 modules are installed, the device appears as follows.



Figure 8-1. OKM 730 with OKM 1001 phototherapy modules

OKM 1001 Technical Specifications		
Power Input	220 VAC 50/60 Hz	
Power	25W, 24Vdc, 1.5A	
Phototherapy lamps	54 pcs LED (18x3 array), 20000h life, max intensity 65 μ w/cm2	
Dim levels	4 levels (25, 50, 75, 100 %)	
Timer	Forward and backward timer (100 hours max)	
Alarm	Yes (when treatment finished)	
Auto stop	Yes (when treatment finished)	
Dimensions	47 x 10 x 13 (cm)	
Working conditions	-20°C ~+70°C	

8.1. General View of OKM 1001 Phototherapy Module

General view of the OKM 1001 phototherapy module is shown in figure. The module has a power switch (a),phototherapy lamp panel (b), control panel (c), and assembly part (d).

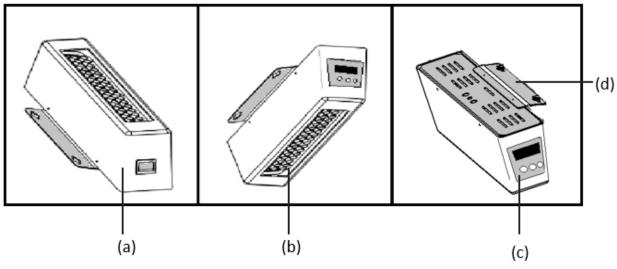


Figure 8-2. General view of OKM 1001 module

8.2. The Control Panel

OKM 1001 control panel is shown in figure. Control panel has three buttons, 4 digit 7 segment display and indicator red led lamp. Explanation of panel components are given in table below.

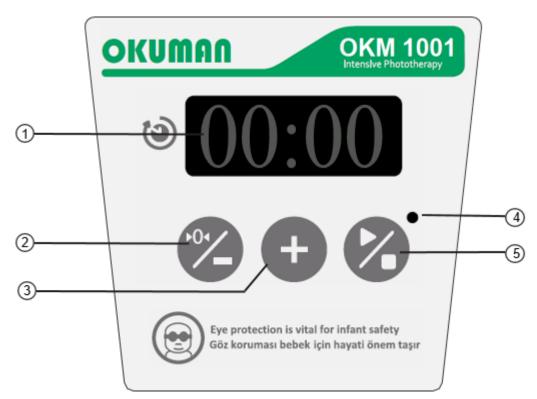


Figure 8-3. View of Control Panel

No	Explanation	Function
1	7 Segment display	Shows phototherapy time, dim level, remai- ning lamp life.

2	Reset button/Lamp life button	Clears the therapy time when therapy stop- ped. Shows remaining lamp life when therapy continues.
3	Increment button	Adjust phototherapy time by increasing the value by 1 minute increments. Also adjust phototherapy intensity by %25 increments.
4	Indicator led lamp	Powered on when phototheapy started. Powered off when phototheapy stopped.
5	Start/Stop phototherapy button	Starts/stops the phototherapy when pressed.

8.2.1. Powering the module

When the module is powered up, led display shows remaining lamp life and then switches to time display mode. When the module is first powered up, lamp life 20000 hours is shown by sliding to the left from right.

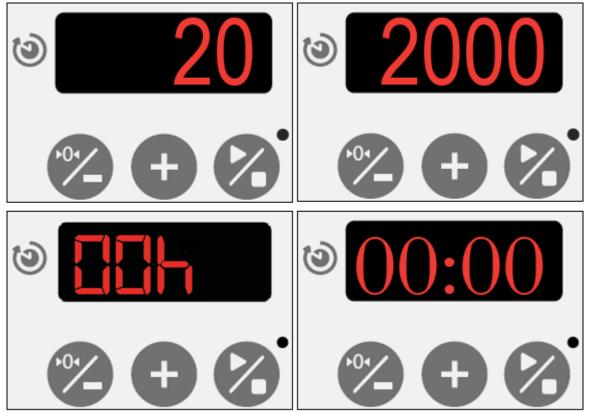


Figure 8-4. Power up display of the module

In this situation time display is clear and indicator led is off. This means that the module is ready for treatment

8.2.2. Starting/stopping(or pausing) the phototherapy

To start the phototherapy, press the start button of the control panel. When pressed to the start button, active light intensity is appears for a short time, then phototherapy lamps are activated.

48



Figure 8-5. Press the start button to start the phototherapy

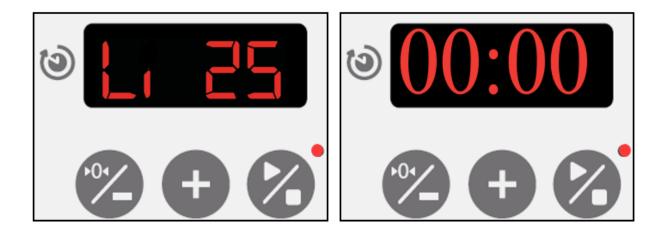


Figure 8-6. Display shows the light intensity and indicator led is ON (left). Then, display shows the phototherapy time and dots blink.

Default value of the light intensity is %25 for starting. User can change the light intensity anytime while phototherapy session is active. The display shows the phototherapy forward time (or backward time) now. To stop (or pause) phototherapy press the start button again.

49

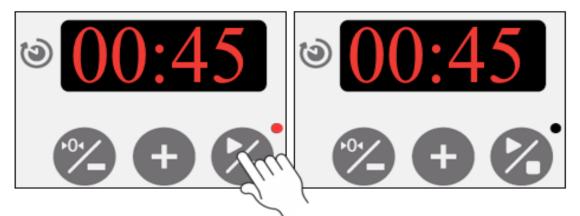


Figure 8-7. To stop or pause the phototherapy, press the start button again. The time will be paused, phototherapy lamps will be powered down and indicator led will be off.

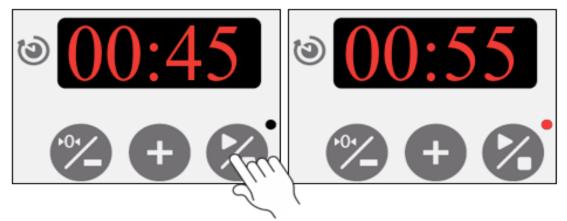


Figure 8-8. To resume the phototherapy press the start button again. The timing continues from the last value.

8.2.3. Setting/clearing phototherapy time

Resetting the time: User can reset the timer by pressing the reset button. After the reset, forward or backward time value is cleared. Then display shows the cleared time value.

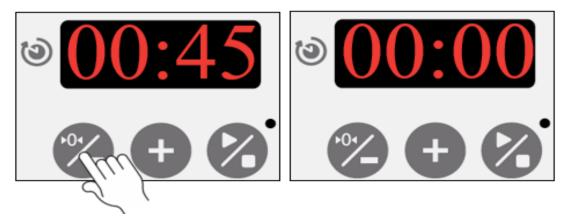


Figure 8-9. To reset the phototherapy timer press the reset button. Display shows the cleared time value.

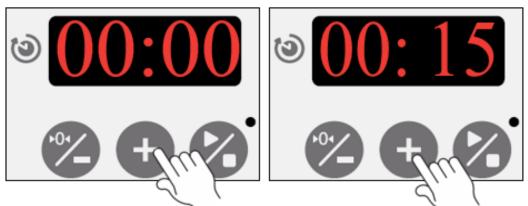


Figure 8-10. Function of the increment button is increment when phototherapy is not active. Press this button to increment the phototherapy duration in minute. For adjus- ting longer times keep this button pressed.

Note: Time decrement function is not available. instead of this, to correct the incorrect input values you should use reset time button and re-adjust the correct phototherapy duration time value by pressing increment button.

Note: The reset and increment functions of the buttons is active only when phototherapy is not active.

8.2.4. Adjusting phototherapy light intensity

To adjust the phototherapy light intensity, use increment button. The function of this button is adjustment of the dim levels of the led lamps while phototherapy led lamps are switched on. Light intensity can be selected as four levels by %25 increments.

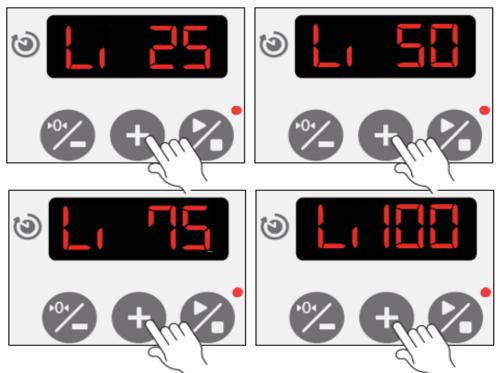


Figure 8-11. Light intensity can be selected as 25, 50, 75 and 100 % by pressing the increment button when phototherapy lamps are powered on.

Light intensity	Corresponding microwatt values
25 %	16.25 μW/cm ² /nm
50 %	32.5 µW/cm ² /nm
75 %	48.75 μW/cm ² /nm
100 %	$65 \mu\text{W/cm}^2/\text{nm}$

Light intensities corresspond to the microwatts values are given in following table:

8.2.5. Displaying lamp life

When pressing the reset button while phototherapy led lamps are powered on, the remaining lamp life of the module will be displayed as hour. The total life time of the lamps is 20000h. After this period, phototherapy led lamps must be changed with new one.

9. CLEANING AND DISINFECTION

• If use the warmer at first time, or finished a baby rescue/nurse, or use continuous for one week, the equipment must cleaning and sterilize.

• After stop warmer and disassembly , used the registered medium concentration (killed Mycobacterium tuberculosis) detergent/ disinfectant to clean. Used Kleenaseptic ® Detergents or 2% glutaraldehyde solution, or in accordance with the provisions of the manufacturer label to diluted disinfectant. Before cleaning, remove all the solid debris and dirt of disassembly parts



Must disconnect supply power and close all power switch before cleaning.

• Radiant box must cooling for 30 minutes before cleaning and sterilize.

• OKM 730 Radiant Warmer must be disinfected after use with the correct methods, otherwise it can cause allergic risk for the user. Therefore devices have been manufactured from a material that can be disinfected.

9.1. Disassemble Before Cleaning

NOTE: It needn't dissamble all of the parts for daily cleaning. Make sure the warmer was empty when cleaning, and do the cleaning after dissamble and clean part.

- 1. Disconnect main power plug and all gas tube.
- 2. Remove all auxiliary equipment.
- 3. Remove transfusion soft port (silicon grommets).
- 4. Remove shelf and other accessory.

9.2. Sterilization/ Cleaning

1. Clean surface of all parts, clean the obvious smutch by cloth with detergent, clean the surface by disinfectant, dry by cleaning cloth after sterilization.

2. Transfusion soft port (silicon grommets), make up sterilize liquid in sterilize vessel, steep the soft port in sterilize liquid for a set time, wash by water and dry.

3. Temperature sensor, cleaning surface by detergent carefully, do not put sensor plug and probe into detergent or water. Dry by cloth after cleaning.

4. Clean main machine after disassemble, clean all surface of equipment by detergent, dry by cloth or paper.

5. Clean reusable bottles, used the registered detergent/ disinfectant like glutaraldehyde class low temperature disinfectant and quaternary ammonium compounds disinfectant to clean all surfaces thoroughly, make sure cleaning all holes and grooves.

Note

• Do not use ultraviolet radiation, alcohol, acetone or other organic solution to sterili- zed the acrylic glass, in order to avoid damaged acrylic glass.

• Do not use lube, alcohol or other things to make device surface lubricating.

• It should avoid to let the liquid into device inner through heat yield hole when clean the warmer.

• Do not leave inflammables after cleaning and assemble.

9.3. Montage After Cleaning

Install all parts that are cleaned by following the removal order. Check each part by running it for several hours without a baby in the device. Put the necessary accessories in the right places. Perform the checks specified in Section 3.2

Note

Before inserting the parts into the radiant heater, please carefully inspect each part and see if they are broken. Replace such parts immediately.

10. MAINTENANCE

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

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

10.1. Technical Assistance Maintenance

We recommend you to buy Okuman Technical Assistance maintenance contract.

10.2. Systematic Maintenance

10.2.1. Rechargeable Battery Maintenance

Please check the condition of the build-in rechargeable battery before the first use of device or in the alternation of device using.

- Operate the unit for a period of 12 to 24 hours.
- Trigger a power failure alarm by disconnecting the AC power cord.
- The power failure alarm should activate and continue to alarm for at least 15 minutes.
- Reconnect the unit to the AC line and recharge the battery.
- If the power failure alarm cannot last more than 15 minutes, please replace the rechargeable

battery. For this battery, it should be replaced by qualified service personnel.

10.2.2. Replacing The Heater Unit

In order to ensure the effect of the infrared radiant, when the heater passes the lifetime, it must be replaced although it can work normally. The reason is:

• The electromagnetism spectrum infrared radiance of the heater will be reduced with the working time passing. Then the device will not achieve the standard. Thereby it is lack of the effect when the doctor uses it to keep warm to the patient.

• For the heater's replacing, it should be replaced by authorized and qualified service personnel.

10.2.3. Transfusion Soft Port (Silicon Grommets)

It must change soft port if the material has brittleness or glutinosity.

10.2.4. Fuse replacement

Unscrew the fuse cover, replace the fuse.

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

11. TROUBLESHOOTING

Troubleshooting of the infant radiant warmer is presented in the following table. If the fault cannot be localized from the table, the unit should be removed from service and servicing should be referred to our company or authorized and qualified service personnel.

11.1. Errors

Some error situations that may be encountered and the actions to be taken to resolve them are given below.

SYMPTOM	POSSIBLE CAUSE	REMEDY
	Skin sensor not inserted	Insert skin sensor
	Skin sensor disconnect	Check plug and connect situation
Sensor Failure Alarm	Skin sensor damaged	Replace skin sensor
Alaliii	Skin sensor do not connect to infant skin	Connect skin sensor to infant skin
	Skin sensor do not at right place	Put skin sensor at right place
Over Temperature	Electric circuit failure	Replace electric circuit component
Over Temperature Alarm	Solid relay damaged	Replace the relay
Temperature	The deviation over allow value between measured temperature and set temperature	If measured skin temperature below set temperature, check the skin sensor whether right; if measured skin temperature above set temperature, check baby skin temperature, adjust set temperature according to
Deviation Alarm	Skin sensor disconnect from baby skin and drop down	Connect skin sensor to baby skin
	Sharp change of environment temperature	Check the temperature of ambient
	Heating source beside	Remove the source far away from the Incubator
Visible And	Power cord disconnected	Connect the power cord
Audible Power	Power off	Switch off the power
Failure Alarm	Fuse fail	Replace Fuse

	Poor connection	Reseat the connector
	Broken panel	Replace the panel
Device doesnt	The gas supply inlet of the	Connect the appropriate gas supply to
supply air	device may not be connected	the gas supply line
to the baby	Tubes may be finished	Make new tube connection
	Flow meter may be off	Control Flowmeters
	The blender may be faulty	Check the Blender output
	Safety valve may be fully open	Check the safety valve

12. DEVICE SPECIFICATION

12.1. Label Information

Label includes serial number, rated power/voltage/current and frequency values, production year, usage and storage conditions, HQ and factory addresses, CE mark informations.

OK	UMAN	MEDİKAL SİSTEMLER ANO	NİM ŞİRKETİ
Name Model SN	: Radiant Warm : OKM 730 : 730XXXXXXX : 2022	Voltage	: 700W : 220 VAC : 4A : 50 - 60 Hz
HQ Fac	tory : lvedik Organize San, Bö	esi Kazım Karabekir Caddesi 95 / 95 06060 İski Igesi Arı Sanayi Sitesi 1.Etap 1417 Sok. No:51 Y www.okuman.com.tr	'eniMahalle, Ankara, Turkey 720 7207 7207 7207 7207 7207 7207 7207

12.2. Technical Specification

This equipment belongs to Class I, Type BF, continuous operation common equipment.		
Power	700 W	
Input Voltage	220~240 VAC ±10% , 50 Hz ±10%	
Current	4 A	
TEMPERATURE CONTROL R	ANGE AND RELATIVE SPECIFICATION	
Control modes	Pre-warm mode, manual mode, baby mode	
Temperature control range	25°C ~37°C,for set temperature≤37 37°C ~38°C ,for set temperature >37	
Skin temperature sensor measure range	10 °C ~ 45 °C	
Deviation between sensor measure temperature and control temperature	≤ 0.5 °C	
Skin Sensor Precision	≤ 0.3 °C	
Bed surface temperature Uniformity	≤ 1 °C	
Temperature Rise Time	≤ 30 min	
Trendelenburg feature	±15° adjustable (manual or electronic)	
ENVIRONMENT TEMPERATURE (It is a suggestion that please do not use outside of the allow environment)		
Operate temperature range	10 °C ~ 40 °C	
Store temperature range	0 °C ~+ 50 °C	
ENVIRONMENT HUMIDITY		
Operate humidity range	%15 ~ %90 RH	

Store humidity range	%15 ~ %90 RH	
ATMOSPHERIC PRESSURE		
Transport and Store atmospheric pressure range	500 hPa ~ 1060 hPa	
Operate atmospheric pressure range	700 hPa ~ 1060 hPa	
STREAM VELOCITY		
Environmental stream velocity	\leq 0,3 m/s	
ALARMS		
Sensor failure alarm	Alarm with audible and visual when sensor open circuit, short circuit or disconnect, cut off power.	
Over temperature alarm	Alarm with audible and visual when displayed temperature was approach 38°C for set temperature \leq 37, or approach 39°C for set temperature $>$ 37°C, cut off power.	
Deviation alarm	After temperature equilibrium, alarm with audible and visual when displayed temperature was 1°C above or below control temperature, cut off power if above 1°C.	
Power failure alarm	Alarm with audible and visual when power failure	
APGAR Time	Alarm with audible and visual when run between 50 seconds to 1 minute, 4 minutes 50 seconds to 5 minutes, 9 minutes 50 seconds to 10 minutes and 19 minutes 50 seconds to 20 minutes.	
System failure alarm	Alarm with audible and visual when occured an electronic failure (when done movement of the head as an optional left or right)	

12.3. EMC TEST REPORT

		ECLARATIONS – ELECTROMAGNETIC	
GUIDANCE AND MANUFACTURER DECLARATIONS – ELECTROMAGNETIC EMISSIONS			
This OKM 730 Radiant Warmer has been developed for use in the following environment. The customer or user must ensure that the OKM 730 Radiant Warmer is used in the speci- fied type of environment.			
Emission Test	Compli-	Electromagnetic Environment - Guidan-	
	ance	ce	
RF (radio frequence emissions)	1. Group	RF energy OKM 730 Radiant War-	
CISPR 11		mer is used only for internal operation.	
		For this reason, RF emissions are very	
		low and it is unlikely to interfere (in-	
		terfere) with nearby electronic devices.	
RF (radio frequence emissions)	A Class	OKM 730 Radiant Warmer is suitab-	
CISPR 11		le for use in all types of facilities, except	
Harmonic emissions	-	for those directly connected to low-vol-	
TS EN 61000–3–2		tage public networks that provide electri-	
Voltage surges/ flicker emissions	-	city for domestic and domestic purposes.	
TS EN 61000-3-3			

GUIDANCE AND MANUFACTURER DECLARATIONS - ELECTROMAGNETIC IMMUNITY

This OKM 730 Radiant Warmer has been developed for use in the following environment. The customer or user must ensure that the OKM 730 Radiant Warmer is used in the specified type of environment.

Immunity Test	TS EN 60601 test	Compliance	Electromagnetic			
	level	level	Environment—Guidance			
Electrostatic disc-	±6 kV contact	±6 kV contact	The floors should be wood,			
harge (ESB)	±8 kV air	±8 kV air	concrete, or ceramic tile. If			
TS EN 61000-4-2			floors are covered with synt-			
			hetic, the relative humidity			
			should be at least 10%.			
Electrical fast	± 2 kV for power	± 2 kV for	Mains power quality should			
transient burst	supply lines ± 1	power supply	be that of a typical commer-			
immunity TS EN	kV for input/output	lines $\pm 1 \text{ kV}$	cial or hospital environment.			
61000-4-4	lines	for input/output				
		lines				
Surge	\pm 1 kV in differenti-	\pm 1 kV in diffe-	Mains power quality should			
TS EN 61000-4-5	al mode	rential mode	be that of a typical commer-			
	± 2 kV in common	± 2 kV in com-	cial or hospital environment.			
	mode	mon mode				
For sudden vol-	In 0,5 cycle <5%	In 0,5 cycle $<5\%$	Mains power quality should be			
tage dips, short	UT (Drop in UT	UT (Drop in UT	that of a typical commercial or			
droupouts and	>95%) In 5 cyc-	>95%) In 5 cycle	hospital environment. In case			
voltage changes in	le 40% UT (Drop	40% UT (Drop	the user has to use the incuba-			
electrical supply	in UT = 60%) In	in $UT = 60\%$)	tor If the user needs to use the			
input lines	25 cycle 7%0 UT	In 25 cycle 7%0	incubator in such a way that			
TS EN 61000-	(Drop in UT is 30%)	UT (Drop in UT	he or she is exposed to power			
4-11	In 5 seconds < 5%	is 30%) In 5 se-	interruptions, it is recommen-			
	UT (Drop in UT >	conds $< 5\%$ UT	ded that the power be supplied			
	95%)	(Drop in UT >	from the uninterruptible power			
		95%)	supply or from the battery.			
Electrical frequ-	3 A/m electrical	3 A/m electrical	1 1 2			
ency	frequency	frequency	that of a typical commercial or			
(50/60 Hz) mag-			hospital environment.			
netic field TS EN						
61000-4-8						
Note: Alternative current prior to UT test level application is mains voltage.						

GUIDANCEANDMANUFACTURERDECLARATIONS-ELECTROMAGNETICIMMUNITY

This OKM 730 Radiant Warmer has been developed for use in the following environment. The customer or user must ensure that the OKM 730 Radiant Warmer is used in the specified type of environment.

Immunity Test	TS EN 60601 test	Compliance	Electromagnetic	
	level	level	Environment—Guidance	
Conducted RF TS EN 61000-4-6 Sprawling RF TS EN 61000-4-3	level 150 kHz to 80 MHz apart from 3 average square root volts of EBT bands Out of 10 average square root volts of EBT bands 150 kHz to 80 MHz 10 V/m 80 MHz to 2,5 GHz	3 average square root volts 10 average squa- re root volts	Environment—Guidance Portable and mobile RF communications equipment should be separated from the incubator, including its cab- les, by no less than the re- commended distances. Recommended separation distance: $d = 1,2 \sqrt{P}$ $d = 1,2 \sqrt{P}$ 80 MHz to 800 MHz $d = 2,3 \sqrt{P}$ 800 MHz to 2,5 GHz Here; P is the maximum rated output power of the transmitter in watts (W) ac- cording to the manufacturer; d is the recommended sepa- ration distance in meters (m) b field strengths arising from the fixed RF transmitter de- termined by an electromag- netic field survey c carried out should be less than the compatibility level of each frequency range. Interferen- ce may occur near equipment carrying the symbol below.	
			(((●)))	

NOTE 1: Higher frequency from in between 80 MHz to 800 MHz shall be applied. **NOTE 2:** These general information may not be applicable in all circumstances. Electromagnetic propagation is affected by absorption and reflections caused by structures, objects and people. a. EBT (industrial, scientific and medical) bands between 150 kHz a

nd 80 MHz from 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

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

c. Field strengths from fixed transmitters such as cordless telephone base stations (cellular / wireless) and terrestrial mobile radios, amateur radios, AM and FM radio broadcasts and TV broadcasts cannot be predicted theoretically precisely. The results of the electromagnetic field survey conducted to evaluate the electromagnetic environment caused by fixed RF transmitters should be taken into consideration. If the field intensity measured at the location where the radiant warmer is used exceeds the applicable RF compliance level stated above, it should be checked if the radiant warmer is operating normally. In the event of an abnormality in his work, additional measures may be required, such as changing the orientation or location of the radiant warmer.

d. Field strengths above the frequency range of 150 KHz to 80 MHz should be less than 3 V $/\,m.$

RECOMMENDED SEPERATION DISTANCES BETWEEN PORTABLE AND MOBILE RF COMMUNICATION EQUIPMENTS AND RADIANT WARMER

This OKM 730 Radiant Warmer is designed for use in electromagnetic environments where RF emission disturbances are kept under control. In order to contribute to the prevention of electromagnetic interference, the customer or user should maintain a minimum distance between the OKM 730 Radiant Warmer and the portable and mobile communication devices (transmitters), which are determined according to the maximum output power of these devices, as follows.

Maximum rated Seperation distance according to the frequency of the transmitter output power of (m)

	()				
the transmitter (W)	150 kHz to 80 Mhz d = 1.2 \sqrt{P} except			800 MHz to 2,5 GHz	
	EBT bands	bands	WIIIZ U – 1,2 VI	$d = 2,3 \sqrt{P}$	
0,01	0,12	0,12	0,12	0,23	
0,1	0,38	0,38	0,38	0,73	
1	1,2	1,2	1,2	2,3	
10	3,8	3,8	3,8	7,3	
100	12	12	12	23	

The maximum rated output power can be determined by using the equation for the frequency of the transmitter (d), the recommended separation distance in meters (m) for transmitters not specified above. Here; According to the manufacturer P is the maximum rated output power, in watts (W), of the transmitter. NOTE 1: The higher frequency range of 80 MHz to 800 MHz is applied.

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

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

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

© 2022 OKUMAN Medikal Sistemler A.S. All rights reserved.

Technical specifications are subject to change by OKUMAN without prior notice.



OKUMAN Medikal Sistemler A.S.

OKUMAN

HQ OFFICE

Kazım Karabekir Caddesi 95/95 06060 Iskitler Ankara/TURKEY **T:** +90 312 384 05 20 **F:** +90 312 384 19 75 **info@okuman.com.tr www.okuman.com.tr**

FACTORY

Ivedik OSB, Ari Sanayi Sitesi 1417 Sk, No: 51 Yenimahalle, Ankara / TURKEY **T:** +90 312 394 00 37 **info@okuman.com.tr** www.okuman.com.tr

Document No: OKM 730-UM-007-112022-EN