KR-1000

Baby Radiant Warmer

User Manual

WARNING

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Repair/Modifications:

Repairs on this device shall only be carried out by NOVOS or Factory Authorized Service Centers. Information on repairs can be obtained from NOVOS or Authorized Resellers. NOVOS shall not assume any responsibility for any injury to persons or damage to property arising directly or indirectly from unauthorized repair or modification of this device. In addition, any unauthorized repair or modification shall void any warranty provided by NOVOS. This document is provided for information purposes only. It cannot be changed or updated at will.

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About This Manual

Scope:

This manual contains a detailed description of all sub-components, use and care details of the KR-1000 Baby Radiant Warmer System.

Target Users:

This device should only be used by medical personnel trained in the operation of the device who are aware of all the risks and benefits of the operation of such devices.

The intended users of this guide are end users of the device, healthcare providers in delivery rooms and neonatal intensive care units, and hospitals' biomedical and clinical engineering services.

The product is intended for professional use.

Aim:

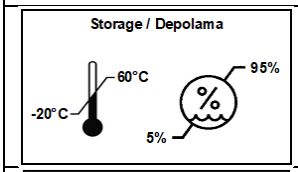
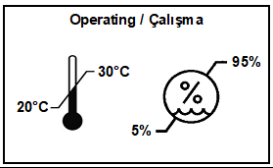
This manual is a guide to the following items of the KR-1000 Baby Radiant Warmer System:

- Installation
- Usage
- Maintenance

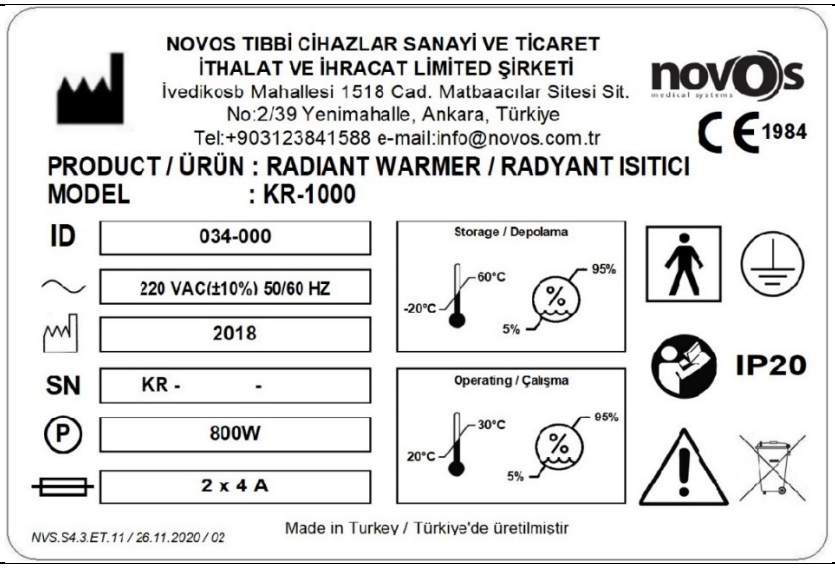
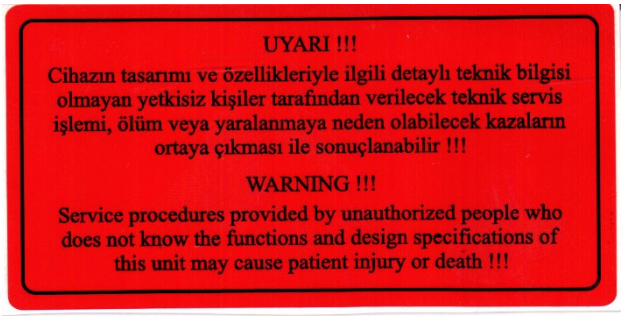
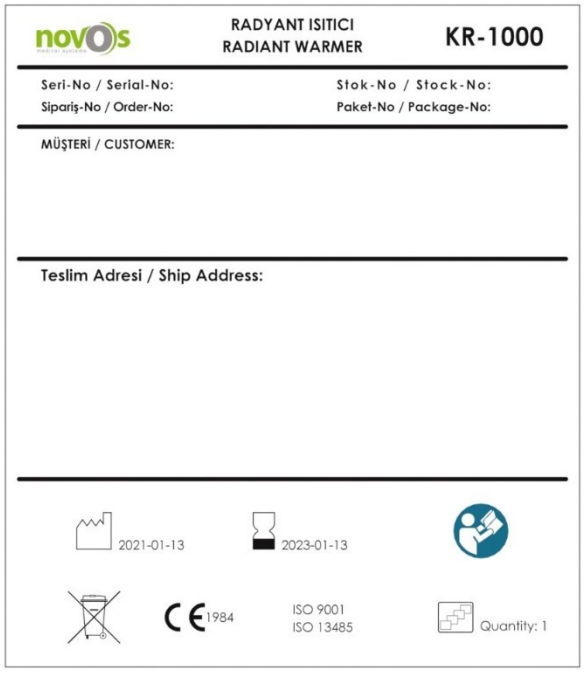
All features and technical information of the device are listed considering the user benefit in order to facilitate the efficient use of the device.

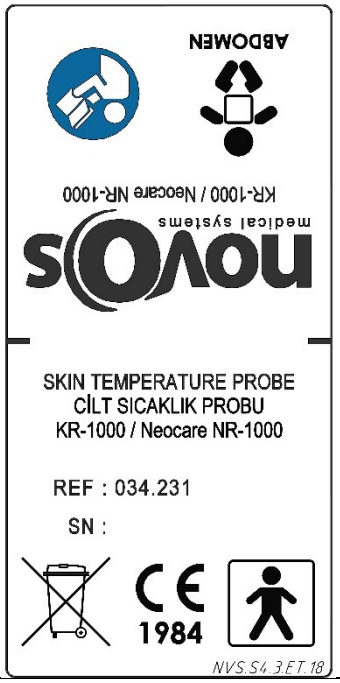
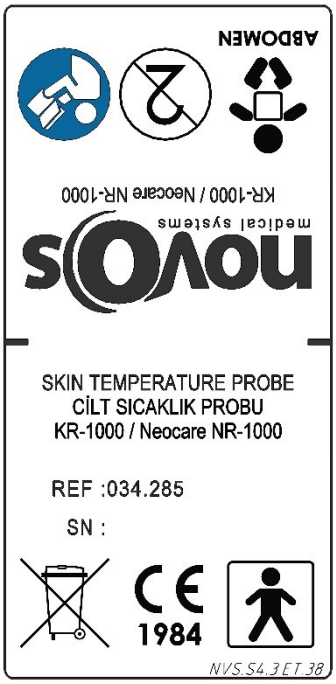
Symbols

	This symbol means "Attention, see relevant documentation" and may appear on any hardware component of the device.
	This symbol means the device is in the BF class.
	This symbol is used to warn the users of the device against possible risk or injury. Warnings are instructions that, if not followed, could result in fatal or serious injury to a user, engineer, patient, or other person, or could result in improper treatment.
ATTENTION	These are the guidances that may damage the system as described in this manual, if the attention notes are not followed.
NOTE:	NOTE is used where additional information on the subject is given.
	Hot Surface
	AC power available
	AC power not available
	Celsius/Fahrenheit switch
	Remote alarm silencer
	Alarm silencer button
	Setting button for target temperature above 37 °C
	Examination light on/off button
	Numpad light on/off button
	Save/delete button
	Weight records difference button
	Reset Trendelenburg button
	First save button for Trendelenburg
	Second save button for Trendelenburg

	Trendelenburg position button
	Reverse Trendelenburg position button
ID	Product ID.
	Manufacturer.
	Input voltage.
	Date of Manufacture.
	Electrical and electronic equipment waste should not be disposed of in general municipal waste, but should be collected separately.
SN	Serial number.
	Power.
	Fuse Box
	CE mark Authorized body
	Storage temperature and moisture
	Operation temperature and moisture

Labels on the Device

	Product Identity
	Technical Service Warning
	Outer Box Label

	Reusable Skin Probes
	Disposable Skin Probe

1. Safety Information

1.1. User Obligations for Patient Safety

ATTENTION	**Strictly follow this guide. Any use of the product requires thorough understanding and strict observation of all sections of these instructions. This equipment should only be used for the purpose specified in article "Intended Use". Follow all WARNING and ATTENTION notes stated in this manual and on the label on the device.**

The design of this equipment takes into account the relevant literature and labeling on the equipment, the purchase and use of this equipment is restricted to trained professionals and the specific features of the device are known to the trained operator. Therefore, instructions, warnings and cautions are mainly limited to the features of the NOVOS design. This document does not contain references to various hazards open to the consequences of misuse of the product by a medical professional and the operator of this device, and to potential side effects that may occur in patients with abnormal conditions. Modification or misuse of the product can be dangerous. NOVOS Tıbbi Cihazlar disclaims any responsibility for the results of product changes or modifications, and the results that may result from the combination of this product with other products from NOVOS or other manufacturers, unless such combination is approved by NOVOS.

	The use of this device requires continuous observation of the baby by trained medical personnel in order to provide immediate corrective action in situations involving risk of injury to the patient.

1.1.1. Patient Monitoring

Operators of this Radiant Warmer system should recognize their responsibilities in selecting appropriate safety monitoring that provides adequate information on equipment performance and patient condition. Patient safety can be achieved through a wide range of different tools, from electronic monitoring of equipment performance and patient status to simple and direct observation of clinical findings. The responsibility for selecting the best patient monitoring level rests solely with the operator of the equipment.

1.2. Limitation of Liabilities

NOVOS has liabilities in the production, sale (activities), installation, promotion, use, application and product production guarantee of goods etc. These liabilities are subject to and are limited to the specific terms described in this manual. Circumstances that void the warranty, negligence that may occur independently of NOVOS, product violation, etc. limit the liability of NOVOS regardless of whether it was the fault of NOVOS and regardless of the manner in which the fault occurred. NOVOS shall not assume any liability for compensation for damages arising from or related to the products and for the buyer's liabilities to third parties; the buyer shall not have any right to claim compensation for these damages.

1.3. Usage Restrictions

Before using this device, it is important to know, understand and correctly apply the safety measures to be applied. The precautions mentioned below are intended to prevent a possible risk of injury to the patient or the device operator who will be treated with the Radiant warmer, and to guarantee efficient use of the device.

1.3.1.Operating

- Read the entire user manual thoroughly before using the device.
- As with all other medical devices, interventions without understanding how to operate this product can cause injury to the patient or the user.
- This device should only be used by healthcare professionals trained in the operation of such devices.
- Before starting to operate the device, confirm that the device can be operated properly by following the steps in the “Pre-Start Check” checklist.

NOTE: If any step of the Pre-Start Checklist fails, the device must be taken out of service and the authorized Novos dealer must be contacted for repair.

1.3.2.Power Supply

- In case the electricity supplied to the device is cut, the device will give a "Power Failure" alarm.

NOTE: During the power failure, the "Power Failure" alarm is activated with a continuous beep sound. This alarm cannot be silenced until power supply is restored.

- Before any service, maintenance and cleaning procedures, make sure that the power plug is disconnected the from the socket. Supply power to the device only where you need to operate the device within the scope of service and maintenance procedures.

1.3.3.Servicing

- Servicing should only be carried out by persons who have been authorized by Novos to repair this device, in accordance with the procedures specified in the service manual.
- Information on extensive repair operations has been included in the service manual for service officers trained by Novos to provide accurate information to users and to demonstrate the equipment and the test equipment.

1.3.4.Cleaning and Maintenance

- The device should not be used in environments with anesthetic substances. Otherwise there is a danger of explosion.
- All necessary additional measures are mentioned in the cleaning and maintenance unit of this document.

1.3.5.Warnings on Indications, Contraindications, Side Effects, Adverse Effects and Possible Physiological Effects

Indications:

KR-1000 Baby Radiant Warmer is an open incubator system designed to assist the various needs of newborn infants such as thermoregulation, resuscitation (optional) and weight tracking (optional). It has the features to apply resuscitation and warming therapies to newborns in the most effective way to be used in delivery rooms, emergency services and neonatal intensive care units.

Contraindications:

The KR-1000 Baby Radiant Warmer is not designed for domestic use.

There are no known contraindications.

Side Effects:

If the skin probe is not connected, it may cause hyperthermia in infants with high fever.

Excessive use of oxygen level can cause eye damage.

May cause body dehydration, skin rash or irritation.

Adverse effect:

No adverse effects detected.

Warnings on Possible Physiological Effects:

	**Potential Risks** There are potential risks such as skin redness and rash in the use of all radiant warmers. Monitor the patient closely during thermal therapy, taking into account any signs of these risks.
	**Dehydration and Insensible Fluid Loss** Radiant energy generated in the warmer may increase the insensible fluid loss in the patient. Necessary measures should be taken to maintain fluid balance during thermotherapy.
	**Intravenous Tubing Systems** Radiant energy emitted by the device may adversely affect some components in the blood. When using intravenous tubing systems to transfer blood components to an infant undergoing thermal therapy on the device, make sure that these tubing are covered with aluminum foil.
	**Urine Tests and Weight Measurements** Radiant energy emitted by the device can cause urine to evaporate faster. In this case, urinalysis and weight measurements may be erroneous. It is recommended to change diapers frequently.
	**Skin temperature** In cases where the skin probe is not connected to the patient, the use of the device carries the risk of hyperthermia in babies with high fever.

1.3.6. Warnings for the Use of the Device

	**Operating Mode Selection** Avoid using manual mode if not specifically specified. Using manual mode requires constant patient supervision. In manual mode, it is the user's responsibility to control the factors such as ambient air flow, direct sunlight, phototherapy use and to determine the percentage of warming power accordingly. On the other hand, the warmer power percentage is determined automatically by the device in baby mode. Baby mode minimizes the need to control the baby and change the set temperature.
	**Reflective Tapes** In order for the skin temperature to be measured accurately, the skin probe should be fixed to the skin with reflective fixing tapes.
	**Number of Patients** It is recommended to use KR-1000 for only one patient at a time.
	**Fixing the Device** Always lock the wheels of the device before placing a baby.
	**Usage with Phototherapy Device** Phototherapy devices can cause the patient's skin temperature to increase. Monitor skin temperature continuously with the help of a skin probe. It is recommended to use baby mode during phototherapy application.
	**Long Term Use** If the device warmers will be used for a long time, the baby mode should be preferred. If any alarm is silenced while operating the device in this mode, supervision of patient closely is recommended.
	**Accompanied Devices** • All devices to be used with KR-1000 must comply with the IEC 60601 standard. • Do not use any unapproved accessories with the KR-1000. Do not connect such a device to the accessory mounting arm. • KR-1000 is not recommended to be used with an extra thermoregulation device.

	• Any device or combination of devices that do not comply with the conditions specified in this manual may adversely affect the functionality of the KR-1000. See the relevant document and the use of attached devices before using the medical device.
	**Plexiglass Protection Panels** • To open the plexiglass protective panels on the front and both sides of the device, push the panel in the direction of the arrow mark to release it from its locked hinge and pull it towards yourself to open the panel to the outside. • It is risky to leave the baby unattended when the plexiglass protective panels are in the open position or the rear plexiglass panel is completely removed. • Make sure the plexiglass protective panels are locked in the closed position.
	**Warmer Head** Do not hang any objects on the Warmer head.
	**Distance Between Bed and Warmer Head** The distance of 74 cm between the bed and the warmer head should be maintained. Otherwise, there may be negative effects on device performance or patient health.
	**Warming Performance** No object should be placed in the route of heat energy emitted from the warmer (between the bed and the warmer head). These objects will adversely affect the performance of the device by absorbing the emitted heat energy.
	Examination Lamps If the examination lamps will be used for a long time, the eyes of the patient should be covered with a protective eye patch. Otherwise, prolonged exposure to the light intensity provided by the device may damage the patient's eyes.
	**Patient Monitoring** It is recommended that you take the following precautions during thermal therapy. • Do not leave the patient unattended while using the device. • During thermal therapy, following the patient's instructions, symptoms such as skin rash, a sense of warmth to be felt by touching, diaphoresis or a rapid heartbeat should be checked frequently. • If phototherapy is continuing along with thermal therapy, take a break from phototherapy for accurate assessment while checking the patient's condition and skin color. • In addition to the skin temperature measured by the device from the abdominal area, take temperature measurements at least every two hours using an independent thermometer from remote points such as the armpits or ears. • Follow standard procedures to monitor the patient's body temperature and fluid balance. • There is no integrated oxygen monitor on the device. When using the Easypuff T-Piece resuscitator, it is recommended to monitor the set oxygen concentration with an independent oxygen monitor.

Line all electronic devices, the KR-1000 Baby Radiant Warmer system should be handled with care to prevent damage. Consider the following measures.

1.3.7.Bearing Capacity

	**Bed Weight Capacity** The maximum capacity of the baby bed is 10 kg.

1.3.8.EMC Restrictions

ATTENTION

- This device must be operated in accordance with the EMC information provided in this manual.
- Mobile and portable RF communication equipment can interfere with Medical Electrical Equipment.
- When using this device alongside other devices, it is important to verify normal operation in the configuration in which it is used.
- The use of electrosurgical devices or other devices that emit high electric fields may adversely affect the operation of the KR-1000. In this case, the skin probe cable should be kept as far away from these devices as possible. The excess part of the power cord should not be placed on the baby bed. The use of such devices may cause inaccurate measurement (display of temperatures above normal) on the KR-1000 skin probe due to the electrical energy they emit. In such cases, it is recommended to use the KR-1000 in "Manual" mode and to have the skin probe fixed to the device and the baby so that the skin temperature can be monitored.

1.3.9.Restrictions of the Environment in which the Device will be Used

	Do not use the device in the presence of flammable anesthetics or gases to avoid any risk of explosion.
	Environmental conditions such as airflow can affect the patient's thermal balance.

ATTENTION

- The device should be used in ideal environmental conditions between 20 °C and 30 °C. Unsuitable, low or high ambient temperature may disrupt the patient's thermal balance.

1.3.10.Electrical Safety Restrictions

	Wrap excess cable around the cable shield at the back of the column to prevent the power cable from tripping.
	This device is to be used only in rooms with line power installations that comply with national safety standards for hospital patient rooms (e.g., IEC / EN 60601.1 "Safety of Medical Devices "220 VAC and 50 - 60 Hz). To maintain ground integrity, connect only to a "hospital grade" plug socket.
	The power cord plug must be fixed to the power input in the wall or bank, as required by rules of low voltage directive. An extension cord or multiple sockets should never be used.
	If there is no suitable grounding system, the device should not be used.
	The total current drawn from the KR-1000's auxiliary power socket must not exceed the upper limit of 6A.
	The total electrical current leakage of all items supplied from the auxiliary electrical outlet should be less than 500 µA for 230V AC systems. Noncompliance could result in death or serious injury.

	Any device to be connected to the KR-1000 must comply with the following standards. • IEC 60601-1 (EN 60601-1) Medical Electrical Equipment Part 1: General Safety Requirements • IEC 60601-1 (EN 60601-1) Medical Electrical Equipment Part 1-2: General Requirements for Basic Safety and Basic Performance Guarantee Standard: Electromagnetic Compatibility; Requirements and Tests
	Use only auxiliary electro-medical device that complies with national safety standards for hospital patient rooms (e.g. IEC / EN 60601-1, "Safety of Medical Equipment", UL 544). Always observe the total leakage current and current consumption limits when using the integrated power strip to connect auxiliary devices! Auxiliary power socket for any type of device can lead to reduced safety in the system.
	The energy provided by the auxiliary power socket is not monitored! Do not connect life support devices that do not have their own power failure alarm to the auxiliary power outlet.

1.3.11. Transportation Restrictions

	Be careful when moving the device on its wheels on uneven surfaces, pavement descents/exits, while entering/exiting the elevator, as the wheels may be damaged or dislodged.
	Make sure that the wheels of the device are not locked during transportation.
	During transport, only move the device using the handles on the back of the device. Attempts to carry the device by holding it by plexiglass protectors may damage the device.

1.4. Warranty

All NOVOS products are warranted against manufacturing, workmanship and assembly defects for 12 months from the date of invoice. The conditions for this warranty are listed below;

1. Tax and import expenses of the shipped product are not covered by the warranty.
2. Repair, modification and changes made within the warranty period cannot be used to extend the specified warranty period.
3. The defect must have been caused by workmanship or material.
4. Only for problems caused by workmanship or materials, the parts replacement, reimbursement or repair of the product by NOVOS Tıbbi Cihazlar are possible. NOVOS Tıbbi Cihazlar reserves the right to apply one of the methods specified above, that is deemed appropriate based on the warranty claim.
5. NOVOS Tıbbi Cihazlar cannot be held responsible for the following conditions;
    a. Deterioration, wear or abuse of any component of the product
    b. Alteration, misuse, damage in transit, or modifications not approved by NOVOS Tıbbi Cihazlar or an authorized representative.
    c. Malfunctions arising from force majeure circumstances and other circumstances for which the manufacturer is not responsible.
    d. Malfunctions caused by voltage fluctuation.
    e. Malfunctions caused by inadequate or, if necessary, never provided customer service and maintenance.
    f. Normal wear and tear of working parts.
6. As for the warranty claim for the recovery of damage during transportation;
    a. The package/case should always be checked for any signs of damage.
    b. If any traces of damage are found, necessary records should be kept for proof of the damage.
    c. The carrier should be warned and the damaged product warranty claim form should be filled.
7. In any case, NOVOS Tıbbi Cihazlar is not liable for more than the original selling price.
8. The buyer guarantees that all services and maintenance are carried out in a timely manner by qualified personnel according to NOVOS service guidelines.

If these liabilities are not fulfilled, all warranty liabilities will expire.

Warranty applications depend on the following:

1. If any malfunction occurs in the device or its parts, NOVOS or its authorized representative must be notified in writing immediately.
2. Defective devices and parts must be returned to NOVOS or an authorized factory center in accordance with the instructions of NOVOS service personnel.
3. As a result of evaluations, NOVOS or the authorized factory center must confirm that the warranty conditions cover this defect.
4. Written notice of the failure of the device or part must be received by NOVOS or authorized factory center 2 weeks before the end of the warranty period.

The above provisions belong to the sole warranty which is applicable and provided by NOVOS. It cannot be aimed to describe or explain the warranty status in any other way.

Dealers and representatives of NOVOS are not authorized to change these warranty conditions.

NOVOS Tıbbi Cihazlar.

2. Product Description

2.1. Usage Purpose

KR-1000 is a combined open bed system with a radiant warmer designed for different needs of term and preterm newborns, especially thermoregulation, resuscitation (optional), weight monitoring (optional) in delivery rooms, emergency and neonatal intensive care units of hospitals.

2.2. Patient Population

As the information is given below, mature, premature and post-term infants constitute the patient population:

Normally born babies between 37 and 42 weeks are mature. Babies born before the 37th week are considered premature and those born after the 42nd week are considered as postmature newborns.

2.3. Life Cycle

Factors affecting the life cycle are listed below;

- Capacitance values may change due to the fact that the insulating liquids contained in the capacitors used in electronic cards decrease with heat and humidity factors after a certain period of time.
- The silicon structure of semiconductor materials (integrated, diode, etc.) on electronic cards may deteriorate over time and cause the semiconductor material to become partially or completely dysfunctional.
- Connectors of sensor-like parts on the device may oxidize over time or plastic parts may deform.
- Deformation or deterioration may occur in the body and silicon seals of the device over time as a result of cleaning these parts with disinfectant.
- The rechargeable battery on the motherboard should be changed due to its charge/discharge status over time.
- The membrane key panels on the device may deform over time.
- warming elements may lose their efficiency over time.

Conclusion:

The above-mentioned failures or breakdowns partially limit the life of the device. However, with the intervention of the authorized technical service, the device can be used functionally for an average of 10 years without being scrapped.

2.4. Main Functions

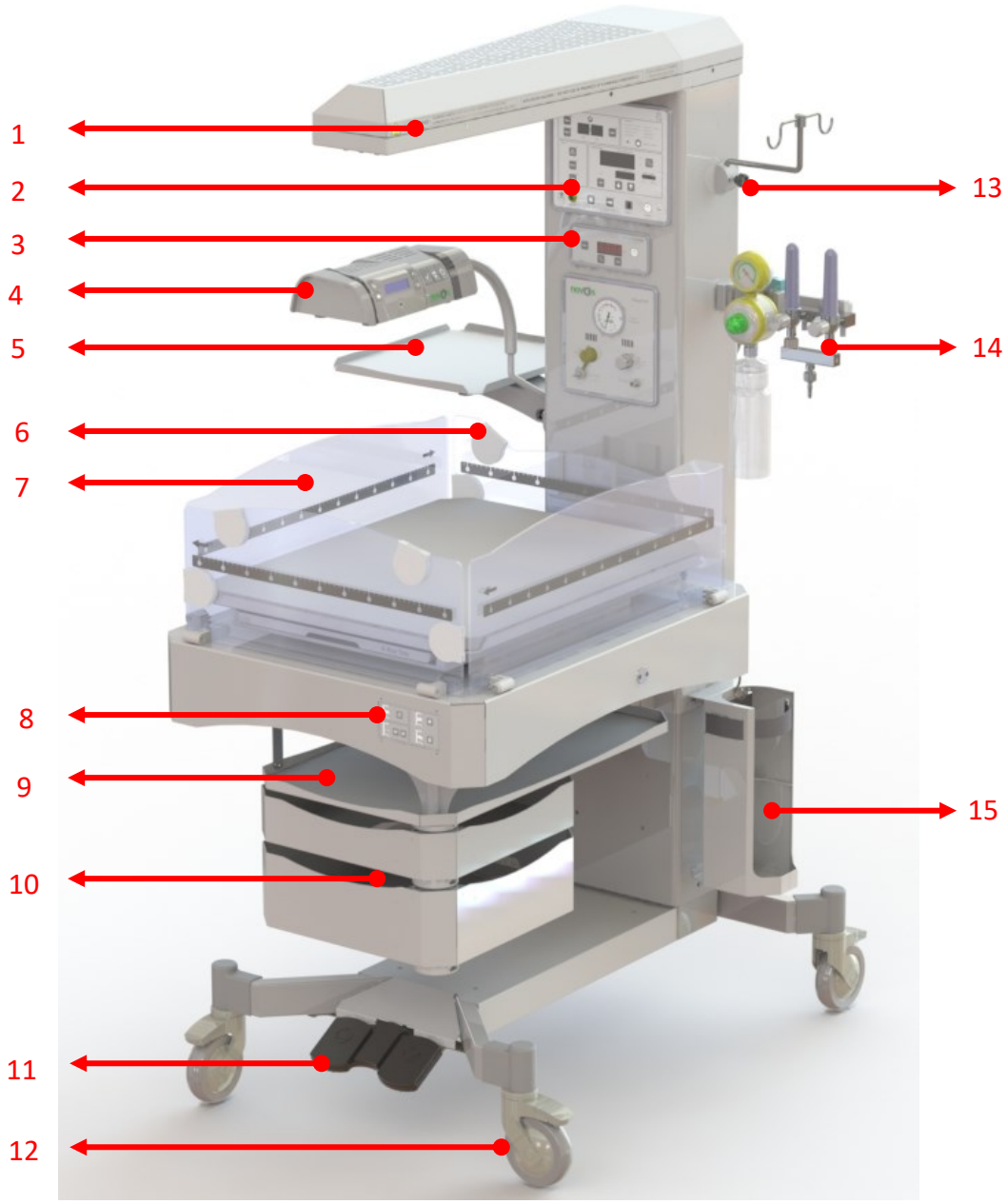
- With the help of modules and features that can be added optionally, different needs of newborns such as thermoregulation, resuscitation (optional), weight tracking (optional) are met, while the user can easily access the newborn for any kind of intervention.
- The patient can be easily intervened thanks to the foldable side plexiglass protectors.
- The KR-1000 Baby Radiant Warmer has an intelligent microprocessor control unit to provide optimum warming support for newborns and easy use for users.
- The warmer module, which contains ceramic warmer elements, ensures that the temperature is distributed evenly over the bed, ensuring that the whole body of the newborn is heated homogeneously.
- In pre-warming mode (Pre-Warming), the patient is pre-warmed without triggering any alarm before the patient is placed on the bed.

- In manual mode, warming is provided according to the warmer power percentage to be determined by the user.
- In infant mode (servo-controlled mode), for optimal temperature regulation, the KR-1000 measures the newborn's skin temperature using a double thermistor probe. In order to maximize the safety and accuracy of warming during operation, the newborn skin temperature is read with the help of the dual thermistors in the skin probe and these values are verified at every measurement. For maximum patient safety, the system checks itself and stops warming and warns the user by giving an alarm in case of prolonged operation at 100% power (such as the possibility of accidentally disconnection of the skin probe).
- At the touch of a button, the baby bed can be given a trendelenburg and reverse trendelenburg position and the bed can be returned to a horizontal position.
- With the help of the wide X-Ray tray and the ± 140° rotating warming head, the patient's X-ray can be taken without leaving the bed and without interrupting the treatment.
- The user is warned in order to determine the Apgar score with the help of the Apgar timer, which can be adjusted in 1, 5, 10, 20 minutes periods.
- Thanks to the directional examination lamps, the baby bed is illuminated and optimum vision is provided.
- Automatically activated control panel key lock prevents the device from being turned off accidentally.
- With the remote alarm silencing feature, the disinfection of the user's hands is maintained during the operation.

Besides, optionally;

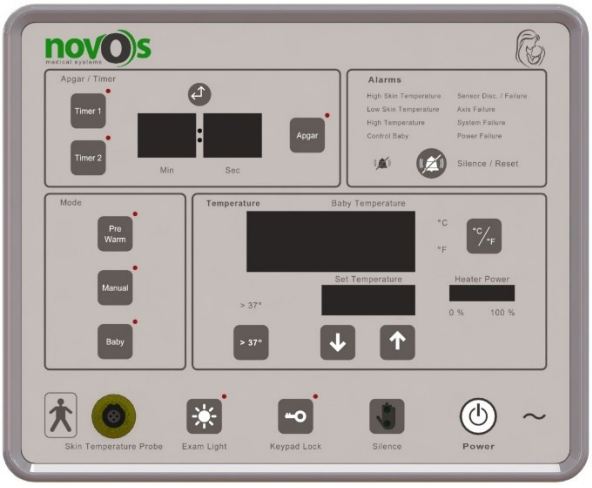
- The 360° rotatable baby bed allows the user to reach different parts of the baby without moving during the operation.
- With Easypuff, an integrated resuscitation device, the resuscitation process is easily completed, if required.
    - There are E-Cylinder slots on both sides of the device to provide the Easypuff with medical grade air and oxygen.
    - With the Air/Oxygen mixer or flow meter system that can be mounted on the accessory arm, the flow-controlled air/oxygen mixture required for Easypuff operation is provided.
- Oral, tracheal and nasal tracts can be cleaned with the pediatric vacuum unit.
- Thanks to the smart weighing feature, weight tracking can be done without taking the baby to an external scale.
- Thanks to its height adjustment feature, the device rises by +20 cm and offers an ergonomic use for different user profiles.
- Thanks to the 360° rotatable drawers, the patient's diapers etc. can be stored and easily accessed if needed.
- Neonatal jaundice treatment is provided with the help of the integrated Bililed Mini+ phototherapy system.

2.5. Controls and Gauges



1	Warmer Head	6	Grommet	11	Height Adjustment Pedals
2	Control Panel	7	Side Protector	12	Wheel
3	Balance Control Unit	8	Trendelenburg Control Unit	13	IV Pole
4	Phototherapy Unit	9	Auxiliary Tray	14	Accessory Mounting Arm + Vacuum Unit + Air/Oxygen Flow Meter System
5	Monitor Tray	10	Drawer	15	Cylinder Slot

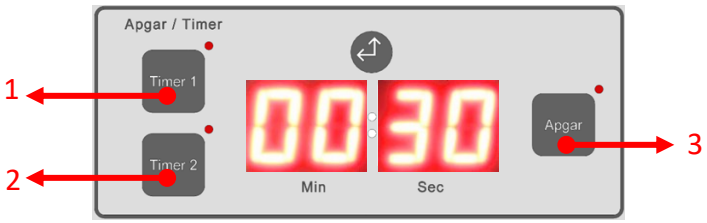
2.5.1.Overview to Control Panel



The control panel can be divided into 5 different zones.

1. Timers
2. Usage modes
3. Alarms
4. Temperature settings
5. Lower buttons group

2.5.1.1. *Timers*



1	**Timer 1 set/start button:** The first timer value is set by holding down and when the button is released the timer starts counting.
2	**Timer 2 set/start button:** The second timer value is set by holding down and when the button is released the timer starts counting.
3	**Apgar timer 1 set/start button:** The Apgar timer value is set between the values between 1,5,10,20 by holding down and when the button is released the timer starts counting.

At the end of all timer sessions, the device alerts the user with an audible signal.

To activate Timer 1 and Timer 2;

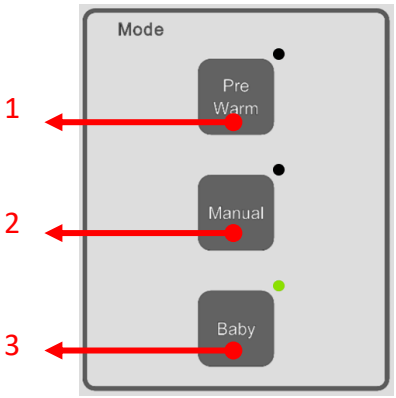
- Press and hold down the corresponding timer button.
- Incremental minute values will appear on the timer screen.
- When the target minute value appears on the screen, release the button.

To activate the Apgar timer;

- Press and hold down the Apgar timer button.

The timer has presets for 1,5,10,20 minutes. When the target minute value appears on the screen, release the button.

2.5.1.2. *Usage modes*



Green LED indicators in the upper right corner of the usage modes buttons indicate the active usage mode.

1	**Pre-warming mode button:** Used to activate pre-warming mode.
2	**Manual stop button:** Used to activate manual mode.
3	**Baby mode button:** Used to activate baby mode.

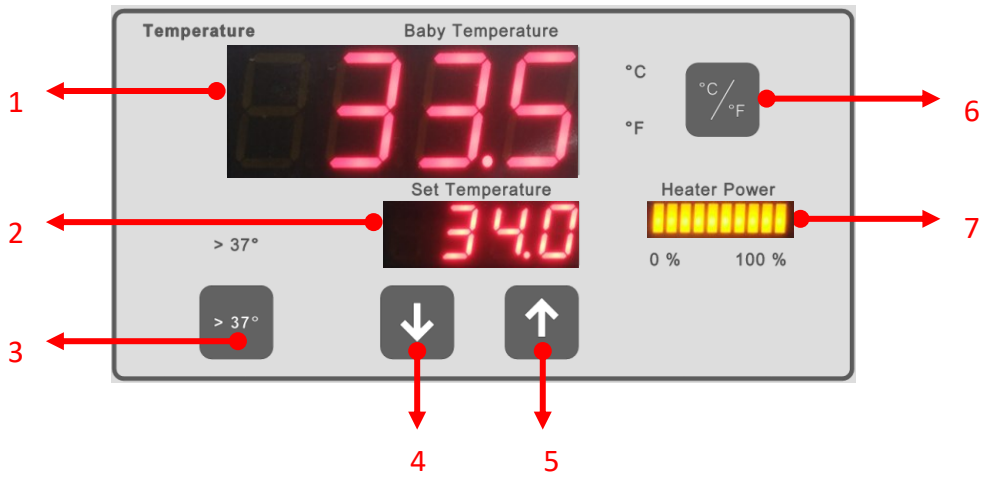
Details of the usage modes are given in the operating procedure section of the manual.

2.5.1.3. *Alarms*

1	High skin temperature alarm indicator	6	Sensor disconnection/fault alarm indicator
2	Low skin temperature alarm indicator	7	Axis failure alarm indicator
3	High temperature alarm indicator	8	System failure alarm indicator
4	Control baby alarm indicator	9	Power failure alarm indicator
5	Alarm silencing indicator	10	Alarm silencer button

Details of the alarms are given in the operating procedure section of the manual.

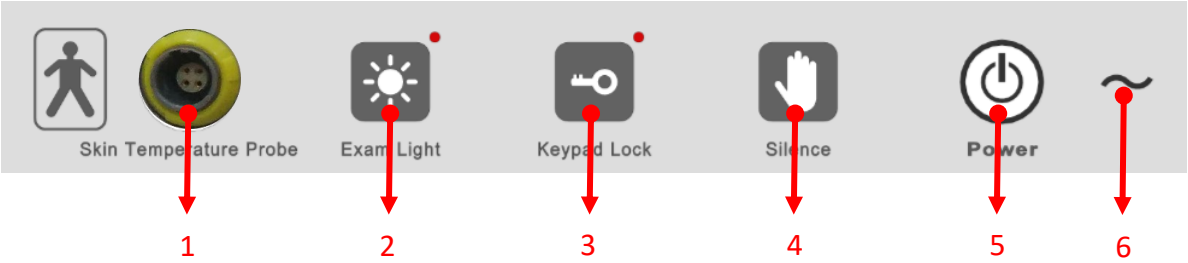
2.5.1.4. *Temperature settings*



1	**Current temperature display:** The current temperature measured is displayed on this display.

2	**Target temperature setting:** The target temperature in baby mode or the warmer power percentage determined in manual mode is displayed on this indicator.
3	**Set temperature>37 button:** If a skin temperature above 37 °C is targeted in Baby mode, the selection is confirmed by pressing this button.
4	**Down arrow button:** This is used to decrease the target temperature in baby mode or the percentage of warmer power in manual mode.
5	**Up arrow button:** This is used to increase the target temperature in baby mode or the percentage of warmer power in manual mode.
6	**Temperature unit change button:** This is used to set the temperature unit as °C or °F. If it is held down, the display will show the ambient temperature after AAA. After a while, “SSS” appears and the measured skin temperature keeps showing again.
7	**Warmer power indicator:** Warmer power percentage between 0% and 100% is displayed in 10% increments.

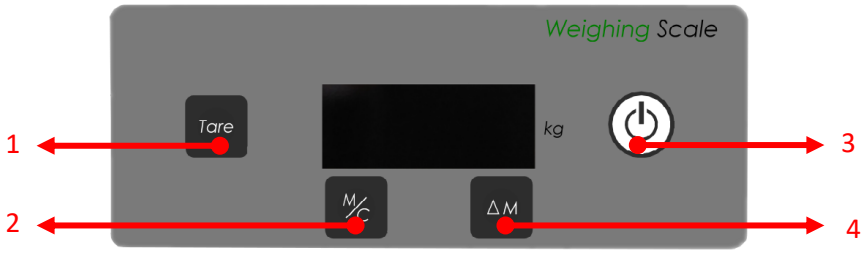
2.5.1.5. *Lower buttons group*



1	**Skin probe socket:** The skin probe used to measure the skin temperature is connected to the control panel via this socket.
2	**Examination lamp on/off button:** This is used to turn on/off the examination lamps in the warmer head.
3	**Key lock on/off button:** This is used to unlock or manually activate the key lock which is activated automatically after 1 minute in the absence of any user input.
4	**Hands-free alarm silencer:** This is used to silence audible alarms without touching any button. This is sufficient to keep your hand in front of the silencer area for 1 second.
5	**Power button:** This is used to turn on/off the control panel.
6	**AC power indicator:** This is an indicator that indicates whether AC energy is supplied to the device.

2.5.2.Balance Control Unit

KR-1000 has an optional balance unit that allows it to measure the baby's weight and store up to 6 records. This unit can also show the difference between consecutive recordings.



1	**Tare button:** This is used to measure tare weight manually.
2	**Save/Clear button:** This is used to save the measured value and clear old records. Press the M/C button once to save the value. To clear all saved values, hold down the M/C button until “Clr” appears.
3	**Balance unit on/off button:** This is used to turn on/off the balance control unit.
4	**Weight difference button:** This is used to display the difference between measurements.

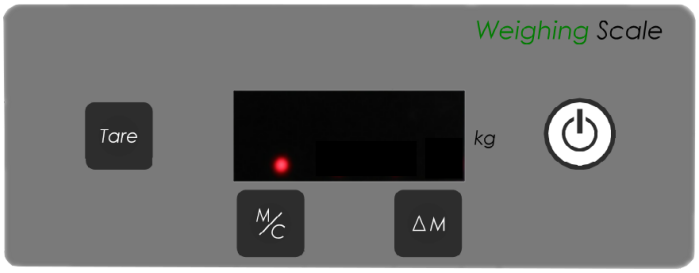
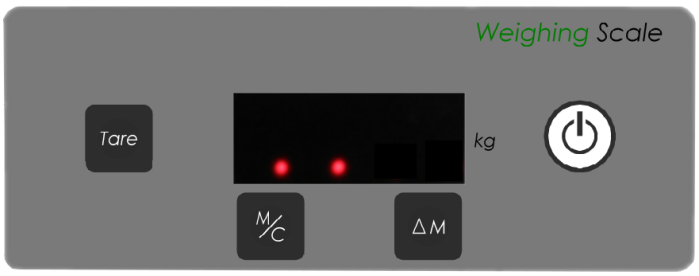
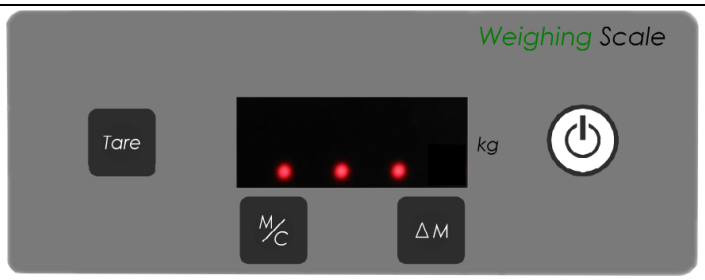
2.5.2.1. *Smart Tare Feature*

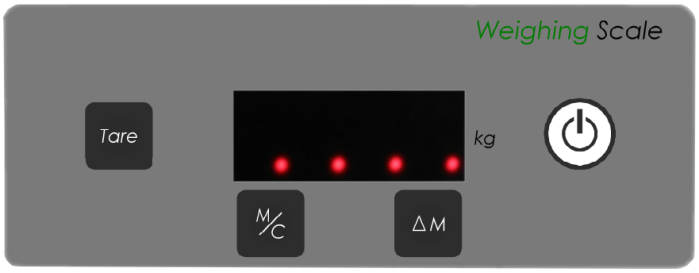
KR-1000 has a smart tare feature that facilitates the weighing process. With the help of the smart tare feature, taring can be done without user intervention. If there is a 200g (or more) load on the cradle, the smart tare feature will work automatically when this load is removed from the cradle. In this way, the tare process is completed without taking the baby to another bed.

⚠	Beware of situations where an object weighing 200g or more is removed from the cradle, otherwise the balance unit will start the tare process even if the baby is still in the cradle. This may cause inaccurate measurement. Use smart tare by lifting the baby each time before weighing the baby.
⚠	The maximum weight capacity of the balance unit is 10 kg. Do not place any objects that exceed the maximum weight capacity of the cradle on the baby bed.

2.5.2.2. *Weighing Process*

⚠	Make sure that the user is not in physical contact with the cradle during the weighing process and that the cradle is in a horizontal position.
⚠	Remove all unnecessary objects from the cradle.

• Press the balance unit's on/off button.	
• Wait for the weighing unit to start. The weighing unit performs self taring at every start. **NOTE:** An increasing number of points appear on the screen, indicating that taring is in progress. **WARNING:** Do not place or touch the cradle during the taring process.	  

	
If the baby is not in the cradle; • Press the taring button and wait until the process is finished. If the baby is in the cradle; • Take the baby out of the cradle and tare automatically and wait for the Smart Tare process.	

• Put the baby in the cradle and wait until the measured value stabilizes on the display.
• After measuring, you can store it as described in the following section.

2.5.2.3. *Weight Measurement Records*

The KR-1000 balance unit can store up to 6 measurements in memory and can show the difference between these records.

• After a fixed value appears on the screen, press the Save/Clear button to store the measured weight value.	
• The weighing unit saves the measurement value in the first available row.	
• After the 6th recording, the new measurements are overwritten and the display shows 6.rEC for each new record.	

The weighing unit also shows the difference between previously taken records.

For example, assume the 6 measurements are as follows;

1. 1.200 kg
2. 1.260 kg
3. 1.300 kg
4. 1.320 kg
5. 1.380 kg
6. 1.575 kg

In this case, the measurement differences are calculated as follows

1. rEC: 1.575 – 1.380 = 0.195 kg
2. rEC: 1.380 – 1.320 = 0.060 kg
3. rEC: 1.320 – 1.300 = 0.020 kg
4. rEC: 1.300 – 1.260 = 0.040 kg
5. rEC: 1.260 – 1.200 = 0.060 kg

<table>
<tr>
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- Press the ΔM button and see the weight difference as described above.

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- Press and hold the Save/Clear button to delete previously saved data.

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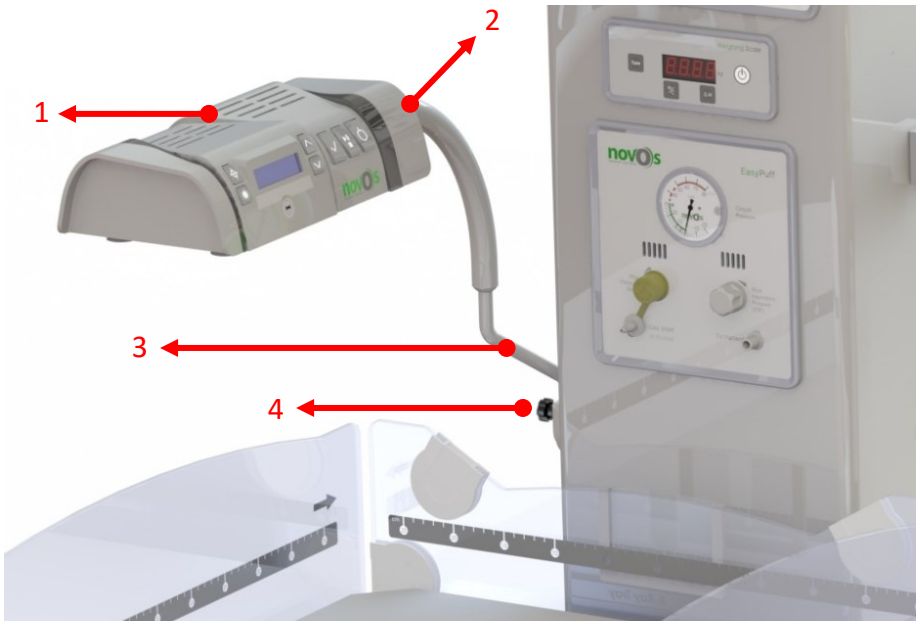
2.5.3.Easypuff Resuscitation Device (Optional)

1	**Manometer:** Displays the air pressure at the gas outlet in cmH_2O.
2	**Max pressure relief cover and control:** This is the control where the maximum gas pressure is determined.
3	**Gas inlet connection:** This is the gas entry point where the air / oxygen mixture is delivered to Easypuff.
4	**Manometer calibration hole:** The manometer reset setting is made through this control.
5	**PIP setting control:** Peak inspiratory pressure is set with the help of this control. The pressure is increased by turning it clockwise and decreased by turning it counter clockwise.
6	**T-piece patient circulation connection:** The patient circuit is connected to this connector.

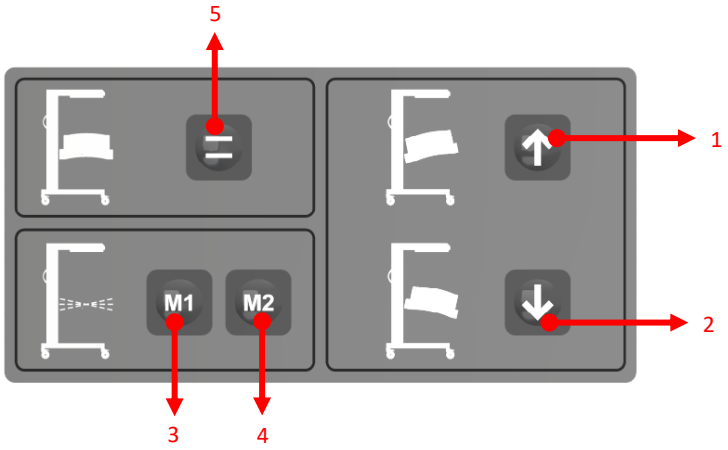
2.5.4.Bililed Mini+ Phototherapy (Optional)



1	**Bililed Mini+ Light Source:** For phototherapy lamp operation, see the Operating Device section.
2	**Light Source Joint Body Kit:** Allows the light source to be fixed to the spiral arm.
3	**Spiral Arm:** This is used to flexibly position the Bililed Mini+ light source.
4	**Spiral Arm Fixing Screw:** Allows the spiral arm to be fixed to the KR-1000 body.

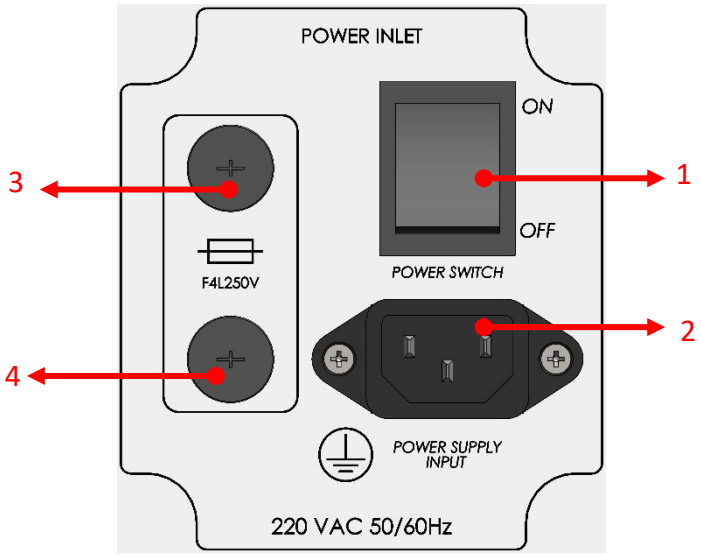
⚠	It is important to position the Bililed Mini+ light source so that it is not affected by the heat source. Otherwise, the warmer light source may cause permanent damage to the device.

2.5.5.Trendelenburg Control Unit



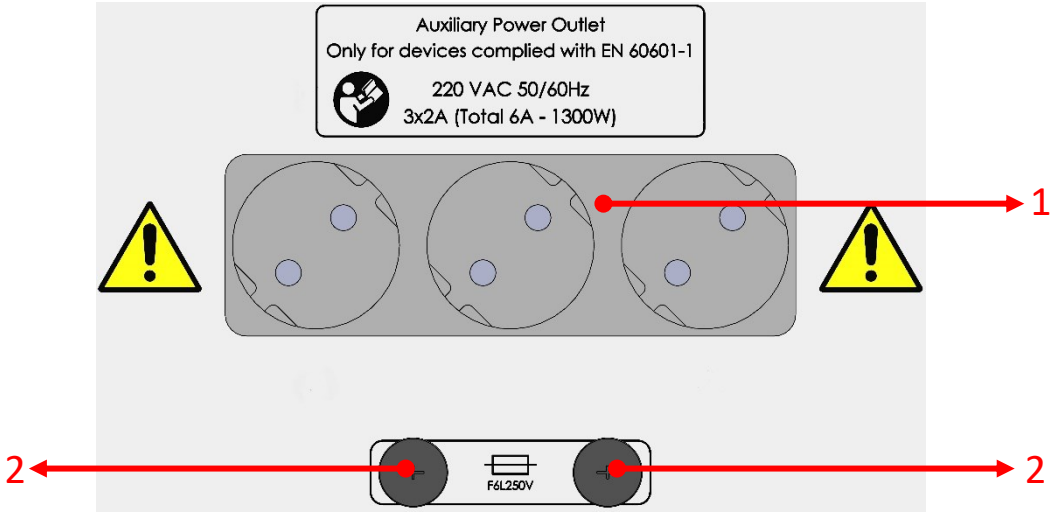
1	**Up arrow button:** Raises the foot end of the bed to give it a trendelenburg position.
2	**Down arrow button:** Raises the head-end of the bed to give it a reverse trendelenburg position.
3	**M1 first memory button:** When held down, it allows any position to be stored in memory. When pressed once, the bed moves to the previously saved position.
4	**M2 second memory button:** When held down, it allows any position to be stored in memory. When pressed once, the bed moves to the previously saved position.
5	**Bed alignment button:** Allows the bed to be brought to a horizontal position.

2.5.6.Power Input



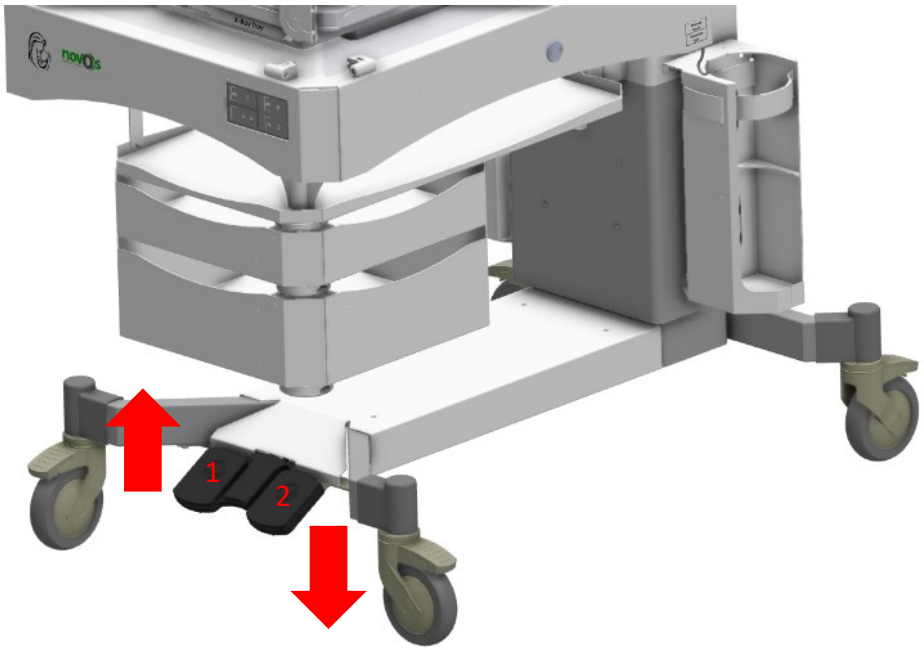
1	**Primary power switch:** This is the primary on/off switch that energizes the electronic components of the device such as the control panel, height adjustment motor, and scale control unit.
2	**AC power input:** This is the connector where the AC power is supplied to the device.
3	**Power input first fuse slot:** This is the slot where the first power input fuse of 4A is located.
4	**Power input second fuse slot:** This is the slot where the second power input fuse of 4A is located.

2.5.7.Auxiliary Power Socket



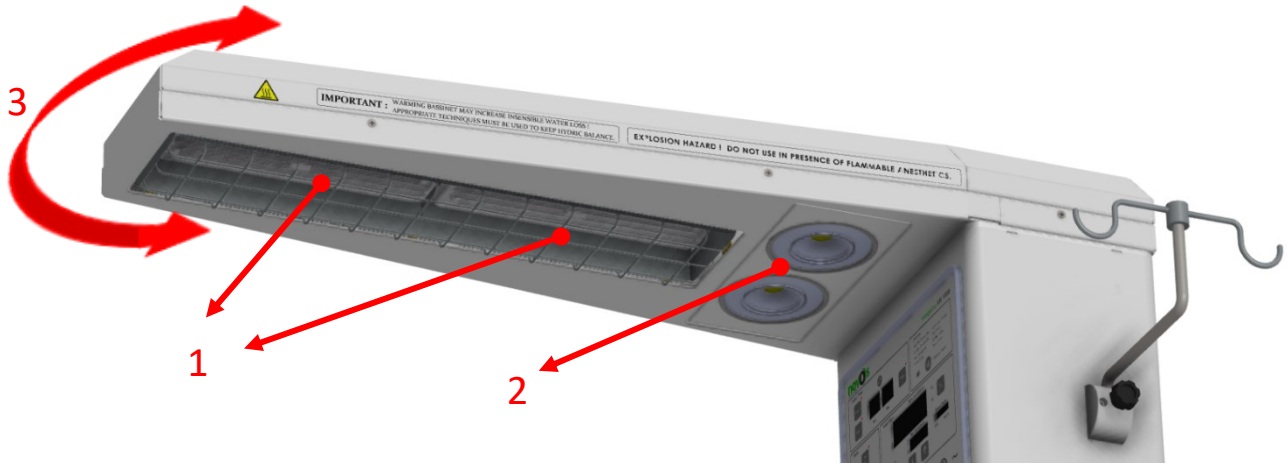
1	**Auxiliary Power Socket:** This is used to meet the energy needs of external devices.
2	**Auxiliary power input first fuse slot:** This is the slot where the first auxiliary power input fuse of 6A is located.
3	**Auxiliary power input second fuse slot:** This is the slot where the second auxiliary power input fuse of 6A is located.

2.5.8.Height Adjustment Pedals (Optional)



1	**Lifting Pedal:** Press the pedal lightly to increase the device height.
2	**Lowering Pedal:** Press the pedal lightly to decrease the device height.

2.6. Other Mechanical Components



2.7. Warmer Head

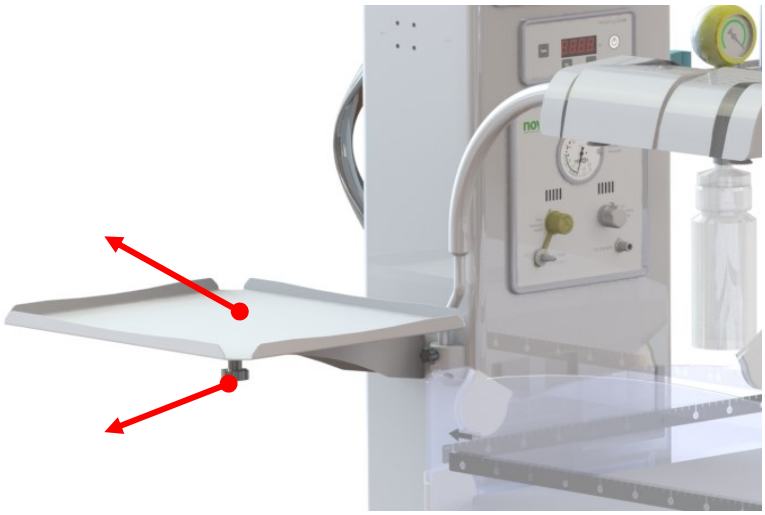
1	**Ceramic resistances:** Ceramic warmers with 400W power provide homogeneous warming on the baby bed surface.
2	**LED examination lamps:** 5W power embedded examination lamps can be positioned by applying light force to their front or rear ends.
3	**Rotating head:** The warmer head can rotate ±140° around the vertical axis.

2.7.1.IV Pole (Optional)

1	**Fixing Screw:** To position the double hook IV pole, loosen the fixing screw. Once the positioning process is complete, make sure the component is secured by turning the screw clockwise to fix its movement around the primary rotation axis.
2	**Secondary Rotation Axis:** IV pole offers a flexible use with its secondary rotation axis.

⚠	IV pole has a maximum load bearing capacity of 5 kg.

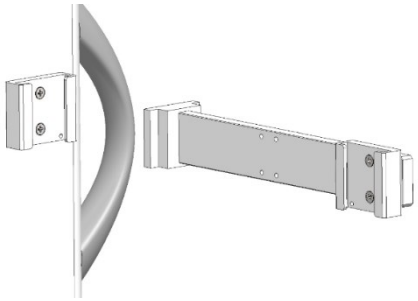
2.7.2.Monitor Tray (Optional)



1	**Monitor Tray:** The 33cm x 37cm rotating monitor tray can be used to place devices such as patient monitor SpO2 monitor.
2	**Monitor Tray Fixing Screw:** Loosen the fixing screw to adjust the position of the monitor tray. After the desired position is adjusted, tighten the screw clockwise to fix the monitor tray.

⚠	Monitor tray has a maximum load bearing capacity of 10 kg.

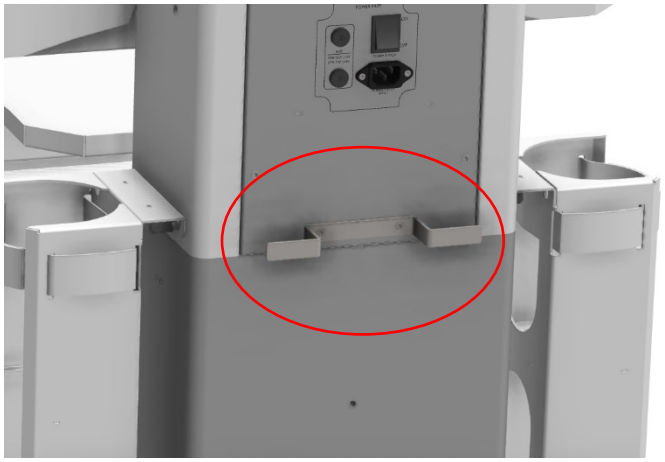
2.7.3.Accessory Mounting Rail (Optional)



Allows optional accessories such as flow meter system, air / oxygen mixer and vacuum unit to be connected to the device. The accessory mounting rail can be removed from its seat by lifting it upwards.

⚠	Accessory mounting rail has a maximum load bearing capacity of 10 kg.

2.7.4.Power Cable Coil



1	**Cable Coil:** The remaining part of the device's power cable can be wrapped around this coil.

2.7.5.Acrylic Protective Panels

There are acrylic protective panels surrounding all sides of the baby bed. The front, right and left panels can be folded down by gently pushing in the direction of the arrow. The rear protective panel can be removed by lifting it up.

There are rulers on all protective panels intended to follow up the development of the baby.

There are in total 8 grommets, 4 for each, for fixing the patient circuit, drainage and sensor cables on the front and back side guards.

2.7.6.Rotating Bed (Optional)

The KR-1000 has optional 360^{o} rotating bed.

To rotate the bed;

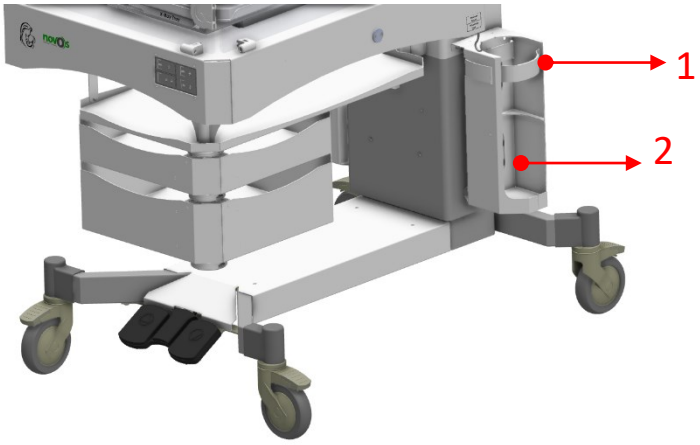
- Open all folding protective panels (left, right and front).
- Remove the rear acrylic protective panel.
- Rotate the bed.

2.7.7.X-Ray Tray

Maximum 14x14 '' X-Ray cassette can be placed on the X-Ray tray of the KR-1000.

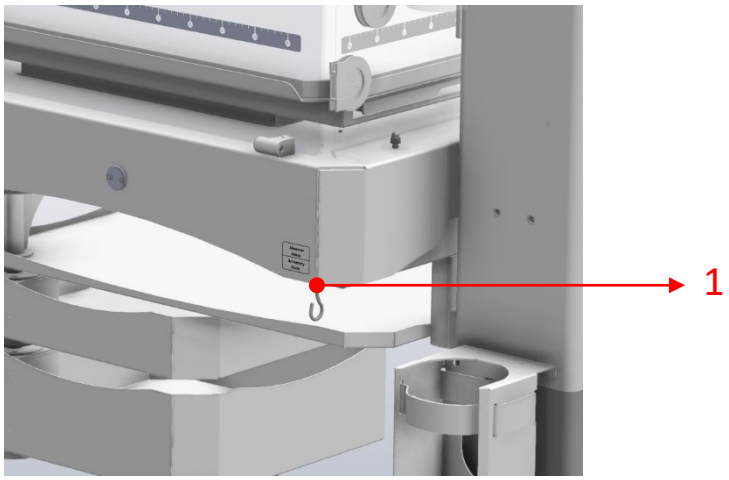
- Open the front protective panel by pushing it in the direction of the arrow.
- Pull out the X-Ray tray to insert the cassette.
- Push the X-Ray tray all the way in until you feel it click into the middle position.

2.7.8.E Cylinder Slots (Optional)



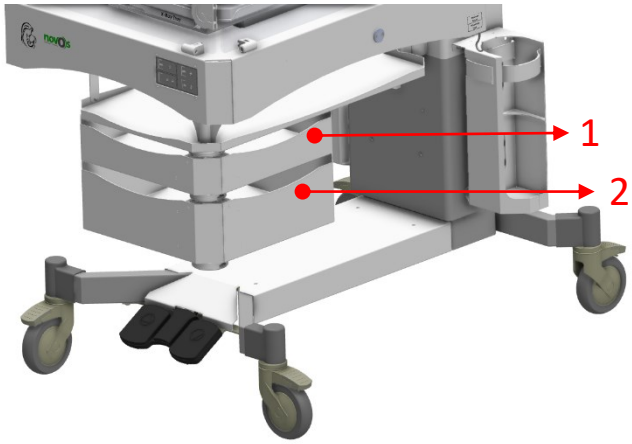
1	**Fastening belt:** After placing the E cylinders, the cylinders are fastened with the fastening belt.
2	**E Cylinder Slot:** There is one slot for air and oxygen cylinders on both sides of the device.

2.7.9.Accessory Hanger



1	**Accessory Hanger:** There is an accessory hanger that can rotate around itself at the back of the baby bed.

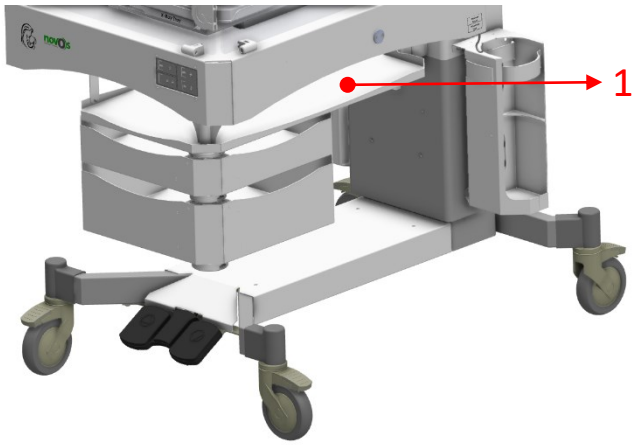
2.7.10.Rotating Drawer (Optional)



1	**Upper rotating drawer:**	Rotating drawers can be opened by rotating freely 360 °
2	**Lower rotating drawer:**	

⚠	Each of the rotating drawers has a maximum load bearing capacity of 5 kg.

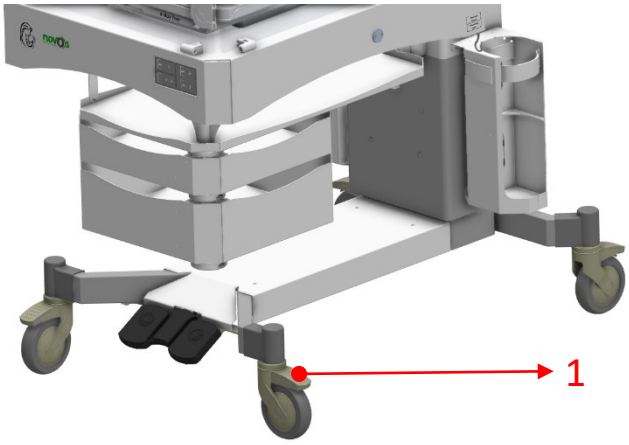
2.7.11.Auxiliary Tray (Optional)



1	**Auxiliary Tray:** There is an auxiliary tray on the top of the rotating drawers.

⚠	Auxiliary tray has a maximum load bearing capacity of 10 kg.

2.7.12.Wheel Locks

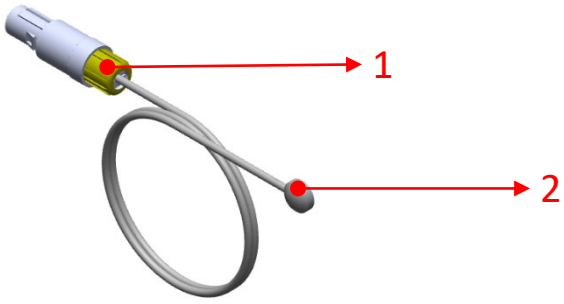


1	**Wheel Locks:** The wheels can be locked by lightly pressing the end of the lock pedal. Use opposite force to unlock.

2.8. Temperature Sensors

2.8.1.Skin Probe

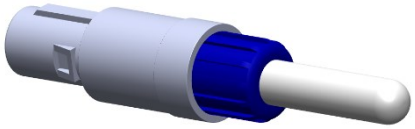
Allows the device to measure baby's skin temperature.



1	**Skin Probe Connector:** This is a one-way connector that allows the skin probe to be connected to the control panel.
2	**Skin Temperature Sensor:** It contains two thermistors to measure skin temperature. Its surface in contact with the skin is flat and its surface to be fixed with metallic reflective tape is flat and plastic.

2.8.2.Air Probe

Allows the device to measure the ambient air temperature.



3.Operating Procedure

Follow the steps below to ensure the most effective use of the KR-1000 Baby Radiant Warmer System.

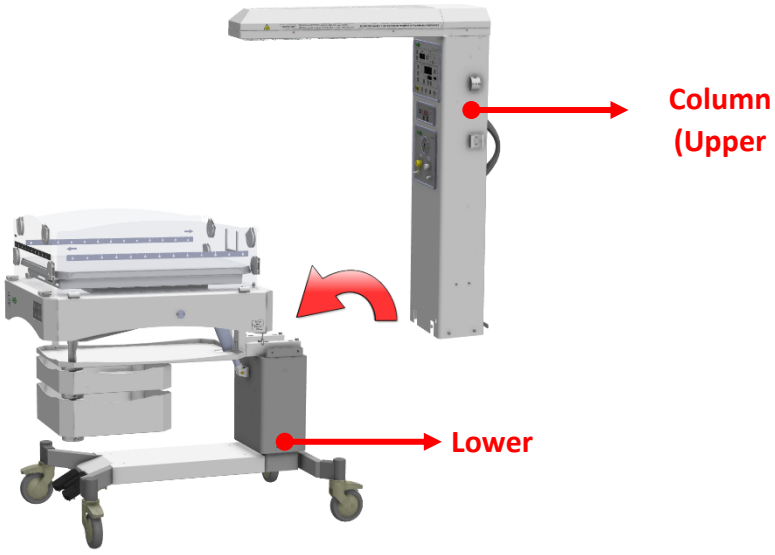
- Read all the information in this manual carefully.
- Note the WARNING and CAUTION statements in this manual.
- Read the “About This Manual” section.
- Keep this manual for reference when needed.

3.1. Installation

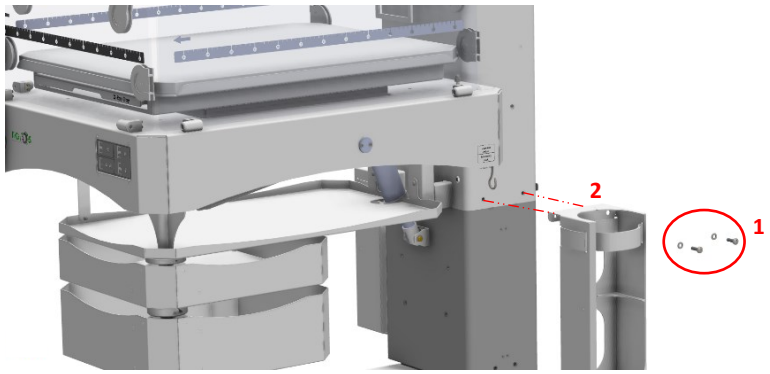
The KR-1000 is packaged in three main parts: the column (upper body), the main body (lower frame) and the accessory box containing all the accessories including the baby bed.

After receiving the device, follow the steps below to complete the installation.

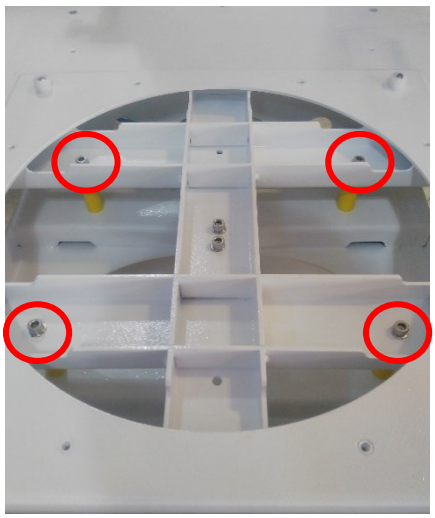
1. Unpack the device and take out the main body.
2. Lock the wheels.
3. Move the column out of the main body’s contact area and hold it.
4. If the device has an optional height adjustment feature, make the connector (*) connections under the column and on the column containing the height adjustment motor of the lower body.
5. Place the column on the lower body.



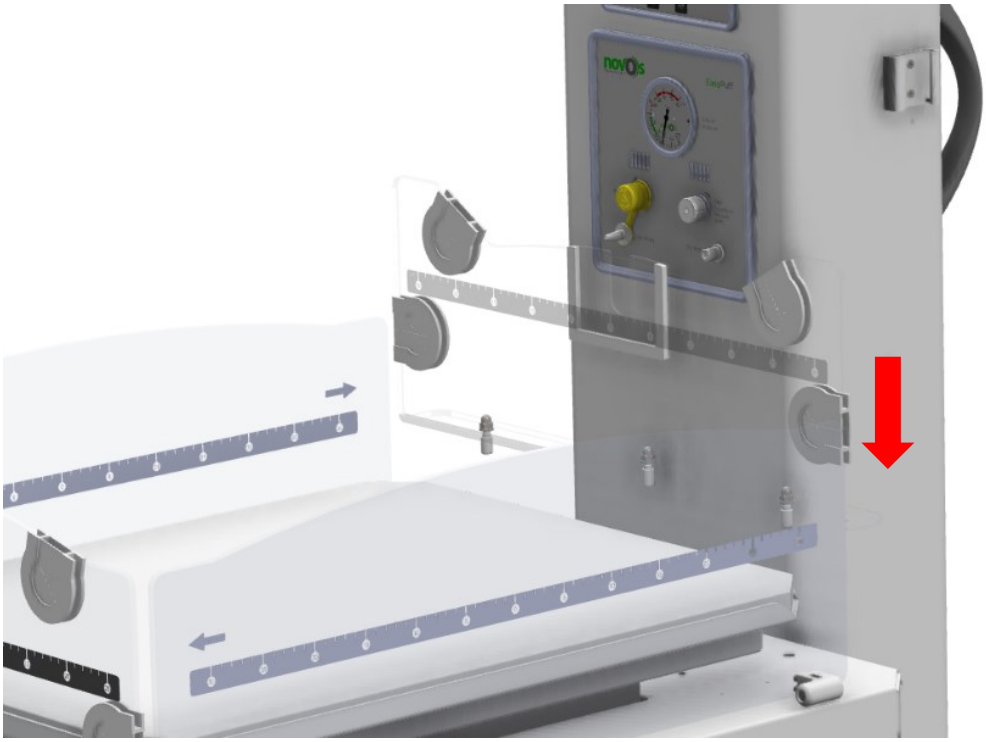
6. Fasten 4 x M6x20 cross-head screws (1), located on either side of the column, with the optional e-cylinder slots (2). If the E cylinder slots are not included in the system, fix the lower body and the column directly.



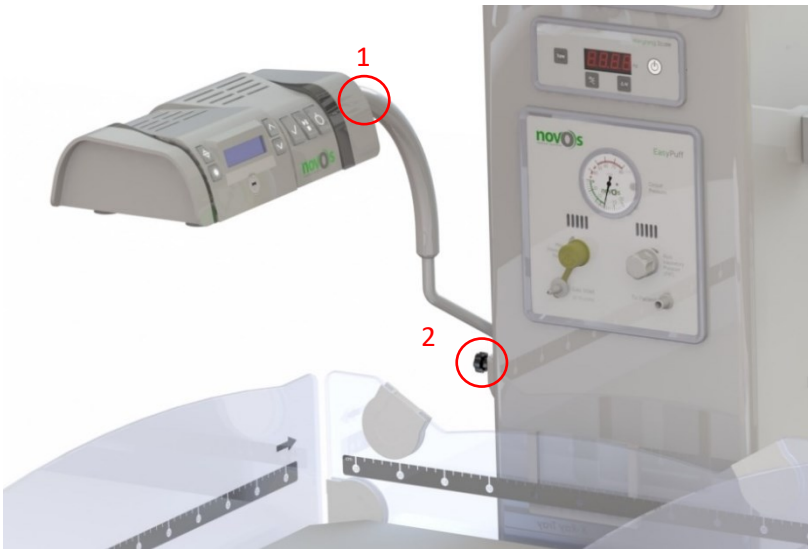
7. Connect the black balance and gray Trendelenburg unit cables under the cradle to the column.
8. Lift the baby bed with the bed tray and remove the cylindrical shaped load protectors on the balance module (optional) by unscrewing the 4 hex screws shown below. Then put the bed back in place.



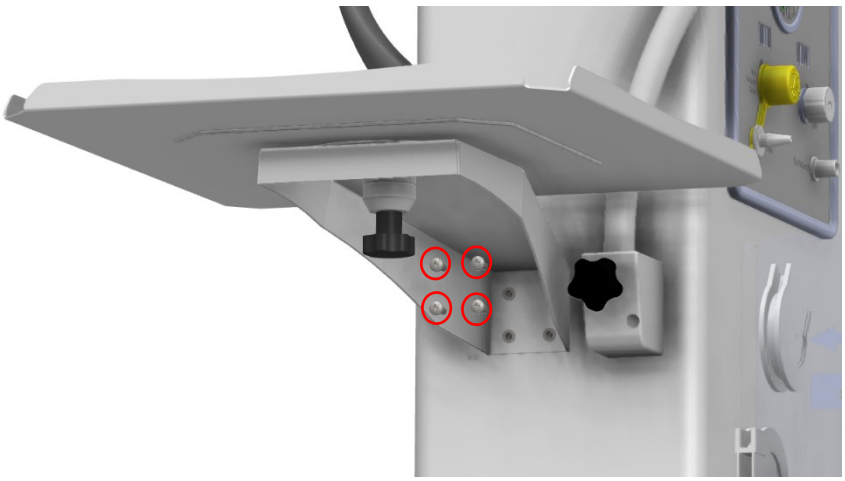
9. Place the rear protective panel in its position in the cradle.



10. Fix the phototherapy unit to the spiral mounting arm (1) and the spiral mounting arm to the KR-1000 (2). (Optional)

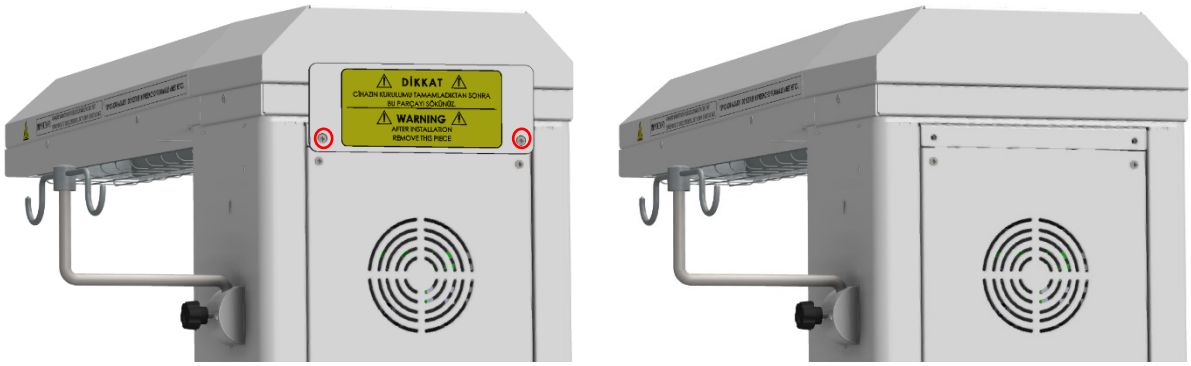


11. Fix the monitor tray with 4 screws. (Optional)

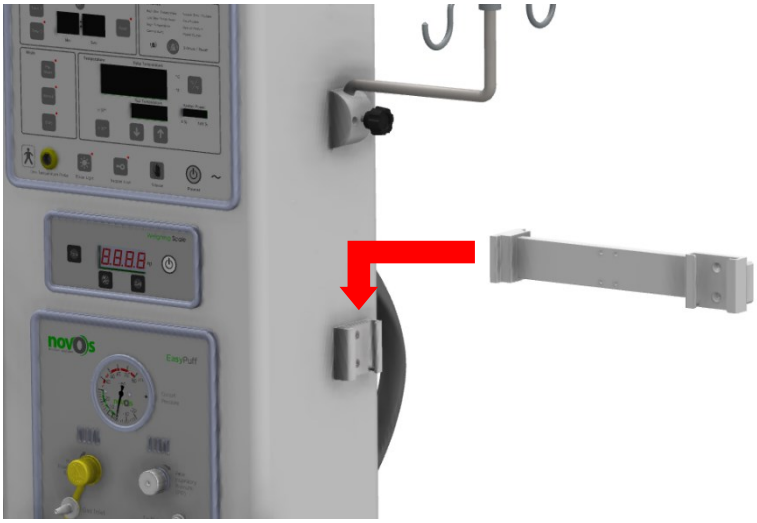


12. Place and secure the IV pole. (Optional)

13. Remove the 2 screws that hold the warmer head fixing plate on the back of the appliance and the plate.



14. Place the accessory mounting arm in its slot in the device column. (Optional)



15. Place the vacuum unit and flow meter systems.

3.2. Pre-Start Check

After the installation of the device, any maintenance / repair or modification, follow the steps below to confirm the normal operation of the device.

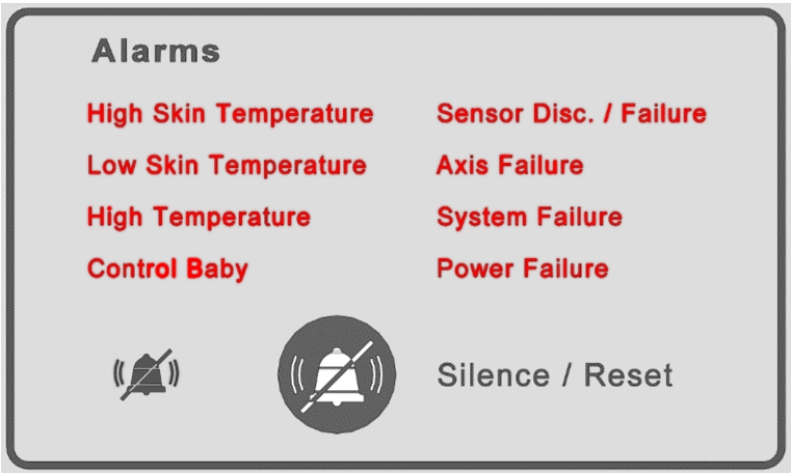
3.2.1.Alarm System Check

Before you begin, make sure that:

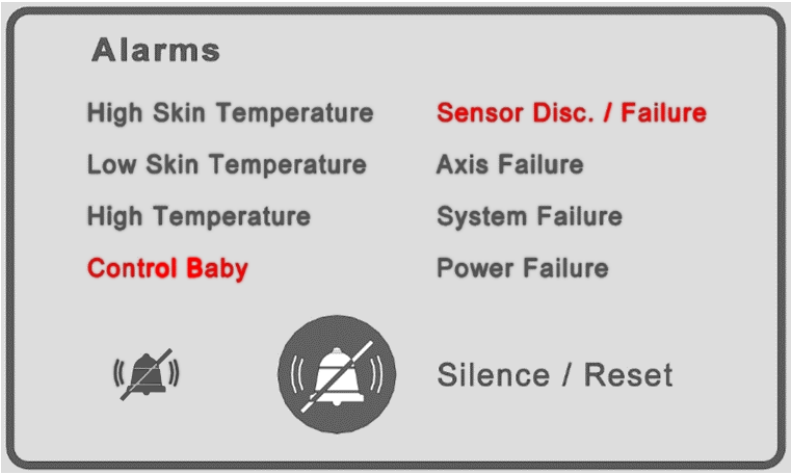
- No baby in the warmer.
- Skin sensor plugged in front panel socket.
- The power cord is plugged into a suitable wall outlet.
- Primary power switch is in the ON position.

The following procedure can be used to check the operation of audible and visual alarms.

1. Press the power button on the control panel
2. Make sure the audible alert is activated.
3. Make sure that all alarm indicator lights are temporarily illuminated immediately after the device is turned on.

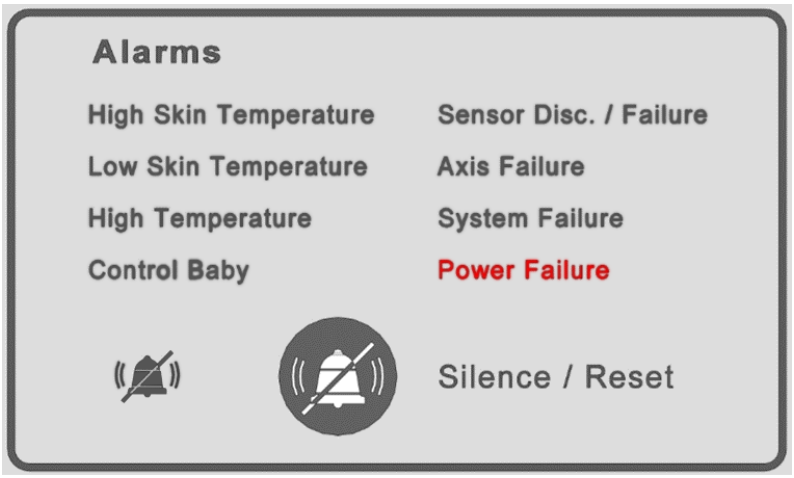


4. After starting, check the baby on the alarm panel and make sure the sensor connection failure / malfunction alarms are active.

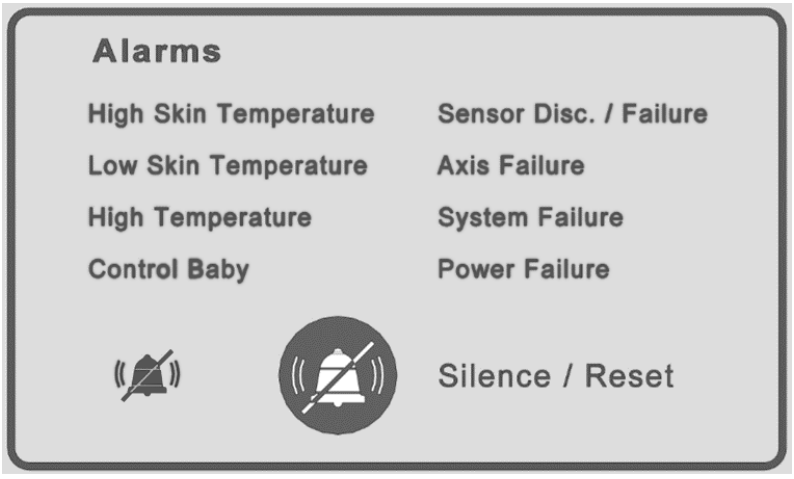


5. Turn on pre-warming mode
6. Unplug the power cord.

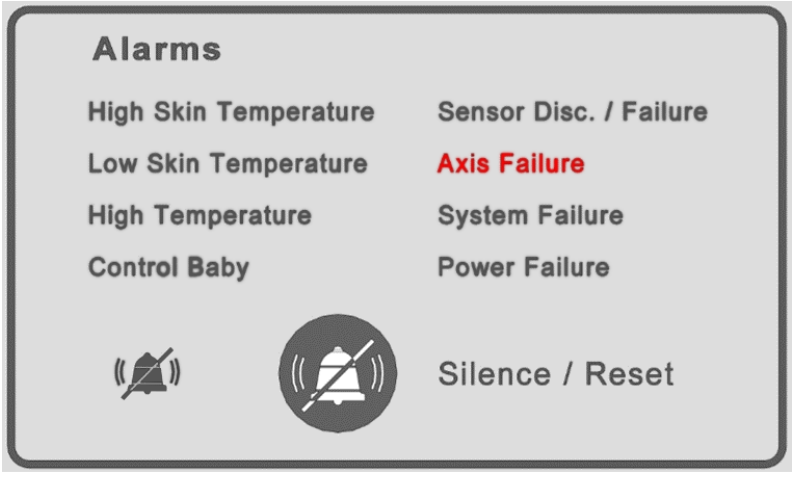
7. Check if the power failure indicator light flashes and audible alarm sounds.



8. Plug in the power cord.
9. Check the restart of the warmer.
10. Connect the skin probe and make sure there is no alarm on the alarm indicator.



11. Make sure the skin temperature sensor measurement appears on the control panel.
12. Turn the warmer head right or left.
13. See the axis fault alarm on the alarm display panel.



14. Press the power button to turn off the control panel.
15. Turn the primary power switch to the off position.

If any of the above steps do not give the desired result, please call service.

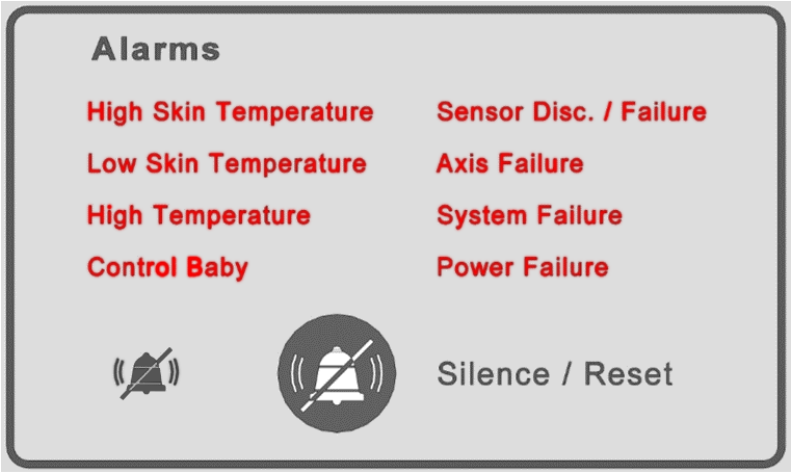
3.2.2.Control Panel Check

Before you begin, make sure that:

- No baby in the warmer.
- Skin sensor is plugged in front panel socket.
- The power cord is plugged into a suitable wall outlet.
- Primary power switch is in the ON position.

The following procedure can be used to verify that the electronic systems of the KR-1000 are working.

1. Press the power button on the control panel.
2. Make sure the audible start alert is activated.
3. Verify that the alarm indicator lights turn on temporarily immediately after the device is turned on.



4. Activate the pre-warming mode.
5. Verify that the device is operating with 30% or 40% warming power (This value depends on the ambient temperature.)
6. Open manual mode.
7. Set the warmer power to 100%.
8. Place your hand under the warmer and observe the rise in temperature.
9. Set the warmer power to 0%.
10. Switch to baby mode.
11. Set the target skin temperature to 34 °C.
12. Increase the temperature measured by the skin probe by rubbing the metal surface on the skin probe and observe that the warmer power is automatically adjusted as the measured temperature approaches the target value.
13. Set the target skin temperature to 37°C.
14. Press the >37 button.
15. Set the target skin temperature to 38°C.
16. Press the °C/°F button.
17. Observe the change in temperature unit on the baby temperature screen.
18. Press and hold the °C/°F button until you see AAA on the baby temperature screen.
19. Watch the measured ambient temperature shown on the baby temperature screen for a few seconds.
20. See SSS on the baby temperature screen.
21. Press and hold the timer 1 button.
22. Observe the change in the target minute value.

23. Release the timer 1 button to set any target value.
24. Observe the counting process on the timer screen.
25. 21-24 for timer 2. Repeat the steps.
26. Press and hold down the Apgar timer button.
27. Observe the preset timer times (1,5,10,20 min.).
28. Release the Apgar button to set any target value.
29. Observe the countdown process on the timer screen.
30. Press the examination lamp button.
31. Observe that the LEDs under the warmer head are lit.
32. If the indicator light next to it is not lit, press the key lock button (key lock not active).
33. Observe that the key lock indicator light turns on and all keys except key lock are no longer functional.
34. Press the key lock key again to disable the key lock function.
35. Keep your palm in front of the hands-free alarm silencer sensor.
36. Make sure the audible alarm silencer indicator is lit.
37. Hold your palm next to the detector again.
38. Observe that the audible alarm silencer indicator is off.

	If an error is encountered in any of the steps mentioned, contact the authorized service and do not use the device.

3.3. Preparation

After completing the pre-use checks, follow the steps below to use the device in the most effective way.

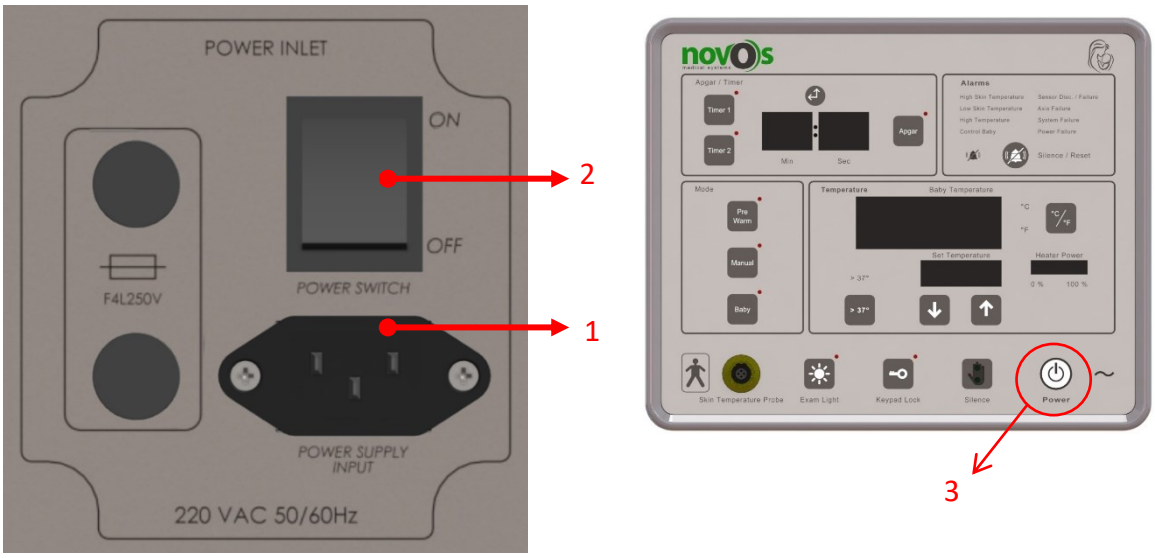
	Before placing the patient on the device, attach all accessories to be used, make the necessary adjustments, or complete the removal of unused accessories.
	Make sure the wheels are locked before the patient is placed on the device.
	Before starting the treatment, a biocompatible disposable cover should be placed on the baby bed.
	Do not leave the patient unattended while using the device.
	Make sure that there is no high air flow in the environment where the device will be used. This may adversely affect device performance.
	For patient comfort and safety, monitor skin temperature with the help of an independent thermometer. If the device warmers will be used for a long time, the baby mode should be preferred. If any alarm is silenced while operating the device in this mode, supervision of patient closely is recommended.
	The use of electrosurgical devices or other devices that emit high electric fields may adversely affect the operation of the KR-1000. In this case, the skin probe cable should be kept as far away from these devices as possible. The excess part of the power cord should not be placed on the baby bed. The use of such devices may cause inaccurate measurement (display of temperatures above normal) on the KR-1000 skin probe due to the electrical energy they emit. In such cases, it is recommended to use the KR-1000 in "Manual" mode and to have the skin probe fixed to the device and the baby so that the skin temperature can be monitored.

	Phototherapy devices can cause the patient's skin temperature to increase. Monitor skin temperature continuously with the help of a skin probe. It is recommended to use baby mode during phototherapy application.
	Radiant energy generated in the warmer may increase the insensible fluid loss in the patient. Necessary measures should be taken to maintain fluid balance during thermotherapy.
	The use of heated blankets, beds, and phototherapy devices may increase patient temperature. Monitor patient skin temperature with the help of a skin probe.
	Radiant energy emitted by the device may adversely affect some components in the blood. When using intravenous tubing systems to transfer blood components to an infant undergoing thermal therapy on the device, make sure that these tubing are covered with aluminum foil.
	Avoid using manual mode if not specifically specified. Using manual mode requires constant patient supervision. In manual mode, it is the user's responsibility to control the factors such as ambient air flow, direct sunlight, phototherapy use and to determine the percentage of warming power accordingly. On the other hand, the warmer power percentage is determined automatically by the device in baby mode. Baby mode minimizes the need to control the baby and change the set temperature.
	It is risky to leave the baby unattended when the acrylic protective panels are in the open position or the rear plexiglass panel is completely removed.
	Make sure the acrylic protective panels are locked in the closed position.
	The distance of 74 cm between the bed and the warmer head should be maintained. Otherwise, there may be negative effects on device performance or patient health.
	No object should be placed in the route of heat energy emitted from the warmer (between the bed and the warmer head). These objects will adversely affect the performance of the device by absorbing the emitted heat energy.
	Do not hang any objects on the Warmer head.
	During transport, only move the device using the handles on the back of the device. Attempts to carry the device by holding it by plexiglass protectors may damage the device.
	Make sure that the wheels of the device are not locked during transportation.
	The maximum capacity of the baby bed is 10 kg. Make sure there is no load heavier than the bearing capacity.
	Do not touch the protective grid underneath or above the radiant warmer. These surfaces may be hot, and burn may occur.

3.4. Essential Use

In this section, essential usage procedure of KR-1000 Baby Radiant Warmer System will be explained.

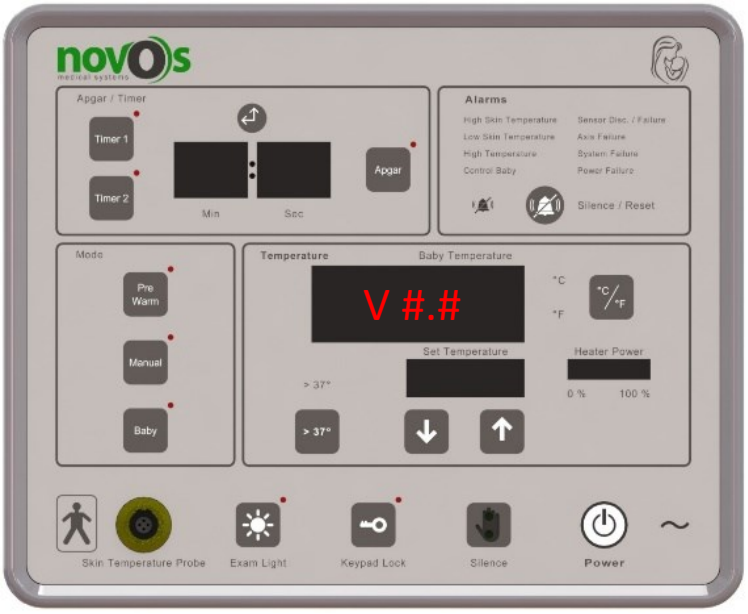
3.4.1.Operating Device



1. Connect the power cord to a properly grounded socket and the power input socket (1).

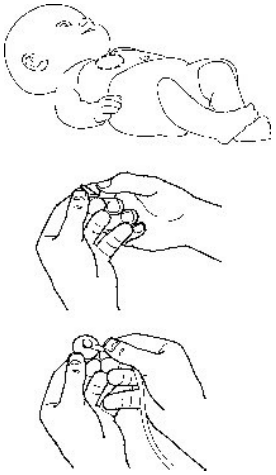
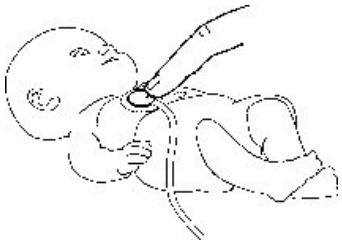
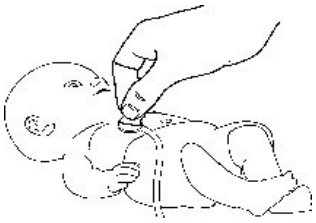
NOTE: Make sure that the power cord does not restrict the freedom of movement within the clinic.

2. Turn the primary power switch ON.
3. Press the control panel power button (3).
4. During startup, the software version of the device is displayed on the current temperature screen.



NOTE: As a safety precaution, the device works in baby mode at every startup.

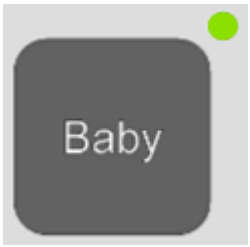
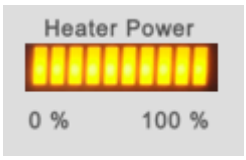
3.4.2.Placing/Removing Skin Probe

Placing Skin Probe 	• Gently clean and dry the skin in the area where you intend to stick the skin sensor. • Remove the paper behind the sensor retaining washer. • Place the white plastic side of the skin sensor in the center of the adhesive side of the sensor cover as shown.
	• Place the skin sensor with the help of the retaining washer with the metal side in contact with the baby's skin. • Gently press the edges of the retaining washer and hold for a short time to make the hydrogel glue stick to the baby's skin.
 **Removing Skin Probe**	• Gently pry the edge of the retaining washer. If necessary, moisten the retaining washer edges with sterile water and a moist cotton swab. • Gently lift the fixing washer and skin sensor from the skin surface. Avoid pulling from by holding the skin sensor cable directly.

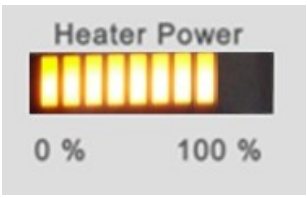
3.4.3.Operation Modes

3.4.3.1. *Baby Mode*

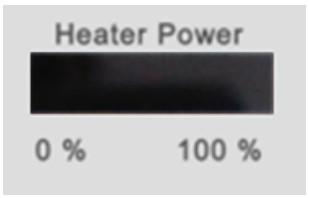
In baby mode, the KR-1000 keeps the baby's skin temperature constant by automatically adjusting the warmer power to compensate for heat loss caused by changing physiological and environmental conditions.

• Press the baby mode button on the control panel.	
• The active mode indicator LED in the upper right corner of the baby mode button will turn green.	
• Set the temperature using the up and down arrows.	
• The microcontroller automatically adjusts the warmer power.	

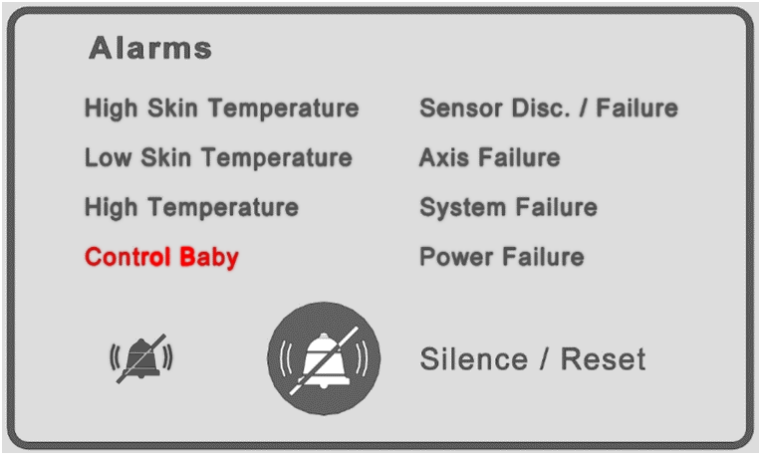
⚠	If the device is operating with a power above 80% in baby mode, the power will be completely cut off after 15 minutes as a safety measure.



After 15 minutes



- After the warmer's power automatically drops to 0%, the “control baby alarm” is triggered.

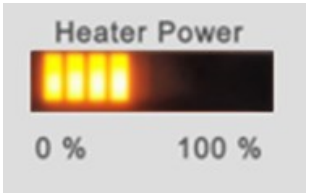
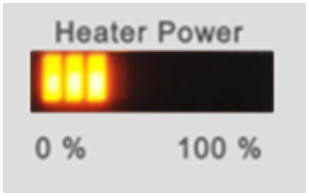


- Press the Baby Mode button again to continue warming in baby mode after a power failure.

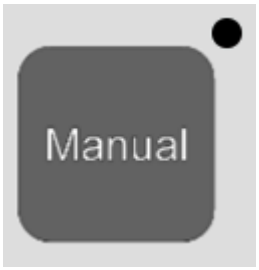
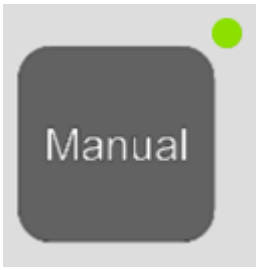
3.4.3.2. *Pre-Warming Mode*

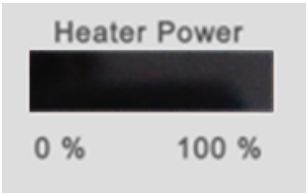
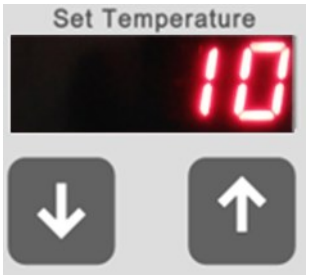
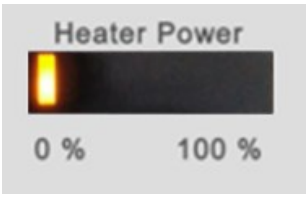
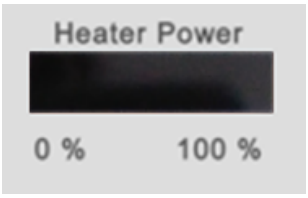
Turn on the KR-1000 at least 15 minutes before placing the baby on the device and switch to pre-warming mode so that the baby does not lie on a cold surface.

- Press the pre-warming button on the control panel.

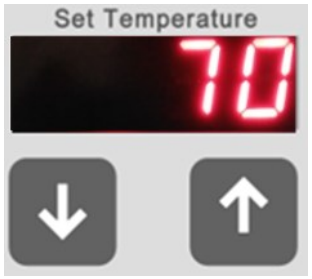
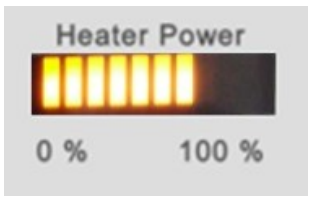
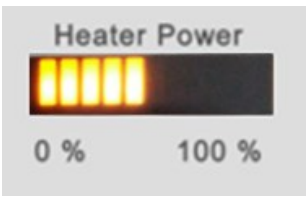
• The active mode indicator LED in the upper right corner of the pre-warming button will turn green.	
• If the air temperature is below 25 °C, the microcontroller adjusts the warmer power to 40%.	
• Or if the air temperature is above 25 °C, the microcontroller adjusts the warmer power to 30%.	
NOTE: The device works continuously in pre-warming mode without interruption.	

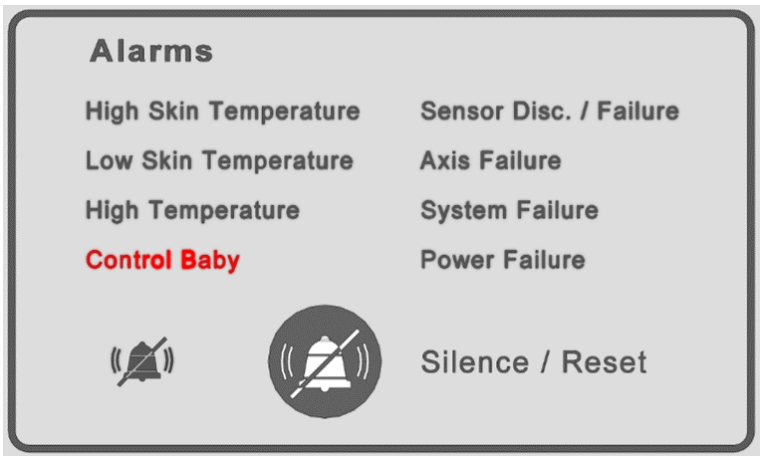
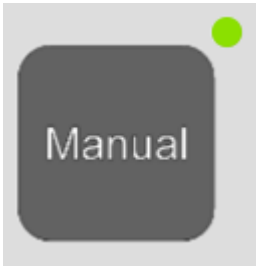
3.4.3.3. *Manual Mode*

• Press the manual button on the control panel.	
• The active mode indicator LED in the upper right corner of the Manual button will turn green.	

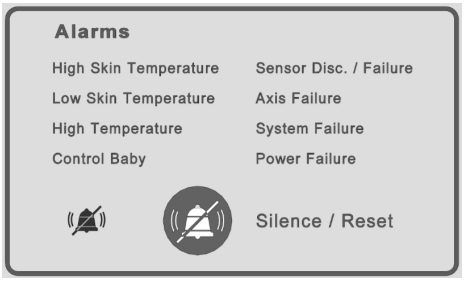
• In manual mode, the warmer power is adjusted by the user with the up and down arrows in the temperature settings section of the control panel.		
• Press the up arrow to increase the warmer power percentage.		
• Press the down arrow to decrease the warmer power percentage.		

	If the device is working with a power above 50%, the power level will automatically drop to 50% after 15 minutes as a safety measure.

	**After 15 minutes**	
		

• After the warmer's power automatically drops to 50%, the “control baby alarm” is triggered.	
• Press the Manual button again to reset the previous warmer percentage level.	

3.5. Alarms



Alarm	Mode	Cause	Action	Alarm silencer function
Control Baby	Baby	More than 80% energy has been given to the warmer for 15 minutes.	Warmer power drops to zero.	Bypasses the audible alarm only
	Manual	More than 50% energy has been given to the warmer for 15 minutes.	Warmer power drops to 50%.	N/A
	Pre-warmer	N/A	N/A	N/A
High Skin Temperature	Baby	The actual temperature is 0.5 °C above the set temperature.	Warmer power is automatically reduced.	Bypasses the audible alarm only
	Manual	Bypasses the audible alarm only	Warmer power drops to zero.	Bypasses the audible alarm only
	Pre-warmer	Actual temperature is above 38 °C	Warmer power drops to zero.	Bypasses the audible alarm only
Low Skin Temperature*	Baby	The actual temperature is 0.5 °C below the set temperature.	Warmer power is automatically increased.	Bypasses the audible alarm only
	Manual	N/A	N/A	N/A
	Pre-warmer	N/A	N/A	N/A
High Temperature	Baby	Actual temperature is above 39 °C	Warmer power drops to zero.	Bypasses the audible alarm only
	Manual	Actual temperature is above 38 °C	Warmer power drops to zero.	Bypasses the audible alarm only
	Pre-warmer			

Sensor Failure	Baby	Skin probe is faulty or disconnected	Warmer power drops to zero.	Bypasses the audible alarm only
	Manual	N/A	N/A	N/A
	Pre-warmer	N/A	N/A	N/A
Axis Failure (Axis Failure)	All modes	Warmer head not aligned	Warmer power drops to zero.	Bypasses the audible alarm only
Power failure (Power Failure)	All modes	Power cut	Warmer power drops to zero.	-

Low skin temperature*: If the baby's skin temperature is lower than the temperature set in baby mode, the Low Skin Temperature alarm will be disabled for 15 minutes or until the baby's skin temperature reaches the set temperature.

The 15-minute warming period ensures that the baby is safely warmed without the disturbance of audible alarms.

4.Troubleshooting

4.1. Fast Troubleshooting Guide

The troubleshooting tables provide the user with general conditions, possible causes, and recommendations. If, in special cases, these tables cannot help solve the problem, the warmer should be sent to the authorized service.

Problem	Potential Cause	Solution
Stable control of baby's skin temperature cannot be achieved.	The skin sensor and/or retaining washer may be poorly sticked on the baby.	Correctly re-stick the skin sensor and retaining washer.
	There may be an object blocking heat energy in the heat route between the baby and the warmer element.	Remove the object in the heat route.
	The warmer may be operating in Manual mode or Pre-warming mode.	• Put it in baby mode and adjust the set temperature as desired. • In manual mode, adjust the warmer power in a way to achieve the desired baby skin temperature.
Baby's skin temperature readings do not look correct.	Skin sensor is defective.	Check the performance of the skin sensor and replace it if it is defective.
	The skin sensor and/or retaining washer is poorly sticked on the baby.	Re-stick the skin sensor and retaining washer appropriately.
The System Failure light is on and the audible alarm sounds.	A software error may have occurred.	Send the warmer in for service.
	A hardware error may have occurred.	
The Power Failure light is on and the audible alarm sounds.	The power supply to the warmer is turned off.	Turn on the power supply.
	Internal fuses, power cord or internal cables may be faulty.	Send the warmer in for service.

5.Routine Cleaning and Maintenance

5.1. General Cleaning

The KR-1000 Baby Radiant Warmer System should be cleaned at intervals specified in the hospital protocol. Consider the following items for cleaning.

	Before cleaning, always disconnect the appliance from the power supply and wait for one hour to make sure that the warmer's components have cooled.
	If the UPS is attached, make sure it is turned off before cleaning. Do not remove the UPS shroud during the cleaning process. Make sure that no part of the UPS has been immersed in any cleaning product.
	Make sure all oxygen and air supplies are turned off and removed from the warmer before cleaning operations. When cleaning in an oxygen-rich environment, there may be an explosion and fire hazard.
	Remove and dispose of all disposable products using the recommended method for disposal before cleaning.
	Before starting any maintenance or sending the device and its parts for maintenance and repair, clean the device and its accessories in accordance with hospital protocol in order to avoid the risk of infection.
	After cleaning, verify that the device is completely dry before use.
	Prevent liquid (disinfectant or liquid detergent) from entering or collecting into any component of the device.
	Do not disinfect any part of the device by immersing in any liquid.
	Using an excessive amount of cleaning solution will cause the risk of liquid getting into the device. Be cautious about the amount of cleaning solution you will apply to the cleaning cloth.
	NOVOS recommends the use of quaternary ammonium components that do not have any harmful effects on the materials used in the device, that clean the surfaces and fight bacteria.
	Do not use cleaning materials containing: • caustic substances, • corrosive substances, • sodium hypochlorite, • iodine solutions, • strong acids, • strong alkalis, • bleaching solutions Such substances can damage the device.
	Solutions containing phenol components should not be used for cleaning.

ATTENTION

- Use only NOVOS approved cleaning solutions. Liquid solutions can be used for cleaning purposes. For example, hospital disinfectants and microbactericides.
- Remove dust from all plastic surfaces with a clean damp soft cloth.
- Remove dust from all accessible metal surfaces with a clean soft cloth.
- Clean all surfaces except acrylic protective panels in the cradle with alcohol or detergent or soap solution (maximum 2% in water), follow the manufacturer's instructions for use of the cleaning agent.
- Clean all parts of the warmer and accessories at normal room temperature (around 23 ° C).
- Do not spray cleaning solutions directly on the device. Instead, continue with the solutions sprayed on a clean cloth.
- Dry the surfaces with a clean, damp disposable cloth to prevent scratches.
- Except for the collection container of the optional venturi vacuum unit, any component of the system **is not suitable** for autoclave or gas sterilization.

5.1.1.Cleaning Skin Probe

Clean reusable (reusable) skin probes with alcohol or detergent or soap solution (maximum 2% in water) in line with the manufacturer's instructions on the use of cleaning agent. Apply the cleaning solution with a clean cloth or sponge and dry all surfaces after cleaning with a clean soft cloth.

	The skin probe is not suitable for autoclave or gas sterilization.
	During cleaning, take care not to damage the connector and cable parts of the skin probe.
	Make sure that the skin probe is removed from the control panel by holding only the gray connector part. Make sure that there is no excess voltage on the skin probe cable during use, cleaning or inspection.

5.1.2.Cleaning of Baby Bed

- Clean the bed with a disinfectant-detergent solution that is approved and diluted correctly to follow the manufacturer's cleaning agent usage instructions.
- Apply the cleaning solution with a clean cloth or sponge, and dry all surfaces with a clean, soft cloth after cleaning.

	The baby bed is not suitable for autoclave or gas sterilization.

5.1.3.Approved Solutions

Solution	Maximum Concentration Rate
Hydrogen peroxide	6%
Glutaraldehyde	2%
Sodium hypochlorite	0.5% Aqueous Solution
Iodophor	0.27%

5.1.4.After Cleaning

Make sure that pre-start checks can be carried out without any problems after the cleaning process is complete.

5.2. Maintenance

In order to achieve maximum performance and efficiency, this device should be maintained and serviced every 1 year. Records must be kept during these protective services. A technical services contract with NOVOS is recommended for a continuous service in line with the rules and standards.

It is recommended to contact the NOVOS Technical Service Department for maintenance and repair of the KR-1000 Baby Radiant Warmer System.

	Technical service and maintenance services should only be provided by technically qualified persons.
	To avoid the risk of electric shock, unplug the power cord of the device before maintenance and repair.
	For better performance and device safety, use only original NOVOS spare parts.
	If there is physical damage on the device or if all / some of the functions of the device do not function properly, do not use the device, contact NOVOS Technical Service Department for maintenance and repair of the device.
	Make sure all oxygen and air supplies are turned off and removed from the warmer before maintenance operations. There may be a risk of explosion or fire when servicing in an oxygen-rich environment.
	Make sure that the warmer is unplugged from the power supply and that the warmer parts have cooled down for one hour to avoid the possibility of burns during maintenance.

5.2.1.General Maintenance

After the maintenance is complete, make sure that the device is working correctly according to the published performance specifications.

- Follow the steps in the Alarm System Control section.
- Follow the steps in the Control Panel Control section.
- Make sure that only approved parts are used during service and maintenance.
- For service information, please refer to the KR-1000 Baby Warmer Service Manual.
- Contact authorized NOVOS representative for any further service or maintenance assistance.

5.2.1.1. *Maintenance Steps*

The cradle must be checked annually for safe operation.

The following actions must be performed by Technical Service personnel responsible for maintenance and authorized by Novos:

- The correct functioning of each acrylic protective panel on the cradle and the accuracy of the locking mechanism are checked.
- Check that the x-ray tray can move freely and that the x-ray cassette can be properly placed.

- The functionality of the membrane buttons of the control panel, trendelenburg control unit and optional balance control units is checked.
- 0 kg and 5 kg calibrations of the balance unit are performed.
- Trendelenburg and reverse trendelenburg movements are checked for compliance.
- It is checked whether all connector connections (skin probe, trendelenburg, optional balance unit) that can be accessed from the outside of the device are intact.
- The optional height adjustment unit is checked.
- It is checked that the wheels rotate freely and that the wheel brakes are working correctly.
- Make sure that the warmer head shaft nut is locked in place. The freedom of rotation of the warmer head and whether centering can be felt is controlled.
- The rechargeable battery in the control panel is changed.

6. Easypuff T-Piece Resuscitation (Optional)

6.1. Usage Purpose

The Easypuff T-Piece Resuscitator is an easy-to-use, manually operated, gas-powered resuscitator that provides controlled and accurate resuscitation of newborn babies in delivery rooms and neonatal intensive care units.

Easypuff is a baby resuscitator where the user can determine the exact pressure of the air / oxygen mixture that will be delivered to the baby's lungs.

Unlike manual resuscitation, the risk of barotrauma is minimized with the help of Easypuff, as the highest pressure applied to the lungs during inhalation is known.

	This device may only be used by appropriately trained personnel under the supervision of qualified medical personnel who are aware of the known risks and benefits of using resuscitator.

6.2. User's Responsibilities for Patient Safety

Since the device is used in emergencies, it is strongly recommended that medical personnel is well trained and confident to perform these tasks. Ensure that anyone using this device is adequately trained in resuscitation techniques.

Easypuff T-Piece Resuscitator should only be used after making sure that the correct pressures are applied to the baby.

Check the parts of the device and make sure they are not physically damaged. Never use the Easypuff T-Piece Resuscitator if it has damaged parts or is not working properly. Contact the authorized technical service of NOVOS.

An alternative resuscitation method (Ambu) should be available.

6.3. Usage Restrictions

The EasyPuff T-Piece Resuscitator can only be connected to a flow-regulated oxygen or oxygen / air mixture supplied by a mixer (blender or flow meter system) with flow meter output.

	Never use the device with flow values exceeding the 15 L/min limit.

The device is designed for use with babies with a maximum weight of 10 kg.

The allowable inlet gas flow rate is 5-15 L/min only for connection to the flow-regulated oxygen or oxygen/air mixture. However, the recommended operating flow is 8 L / min. Input current ranges are circuit specific, see User Instructions for Circuit.

Maximum Pressure Relief can be set up to a nominal 80 cmH2O [mbar] and should only be performed by persons trained in infant resuscitation in exceptional cases. Do not attempt to set the maximum pressure discharge above 80 cmH2O (mbar).

NOVOS cannot guarantee or approve the safety performance of third party accessories. Use only original parts and accessories of NOVOS. The use of unauthorized parts or accessories may cause serious damage to the patient and the device.

While the device is in use, users should ensure that the following are not available in the environment:

- Naked flame
- Flammable anesthetics
- Flammable gases
- Cleaning agents that can cause flame
- Sources of ignition

6.4. Preparation

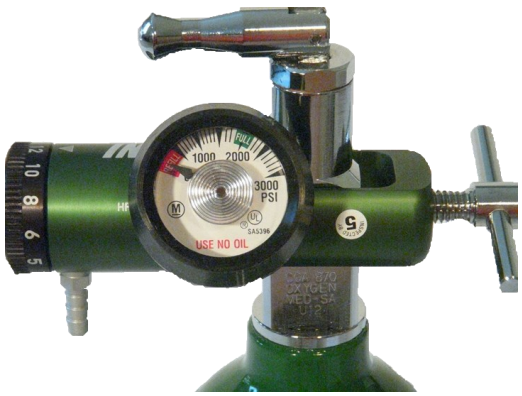
To make sure that the device works correctly, the following operations should be done before each use of Easypuff.

1. Check the manometer.

The manometer should show zero, indicating that there is no gas flow. If not, the manometer needs to be calibrated (See Service Manual).

2. Connect to a gas source:

Gas source examples are shown below;

Oxygen Sources	
	
Oxygen Tube with Flow Meter	Wall Mounted Oxygen Flow Meter
Sources of Air / Oxygen Mixture	

	
Flowmeter System	Air/Oxygen Mixer

It is recommended to set the total current outlet to 8 lpm. If a flowmeter system is to be used, make sure that the total flow output of the air / oxygen mixture does not exceed 15 lpm. For example, setting both oxygen and air flow to 4 lpm will provide a total flow of 8 lpm.

	Never use the device with flow values exceeding the 15 L/min limit.

The table below shows the flow rate that must be adjusted to achieve the desired oxygen concentration with a flow meter system.

Total Flow L/min.	Oxygen concentration								
	21%	30%	40%	50%	60%	70%	80%	90%	100%
1	Air - 1 O_2 - 0	Air - 0.87 O_2 - 0.12	Air - 0.75 O_2 - 0.25	Air - 0.62 O_2 - 0.37	Air - 0.5 O_2 - 0.5	Air - 0.37 O_2 - 0.62	Air - 0.25 O_2 - 0.75	Air - 0.12 O_2 - 0.87	Air - 0 O_2 - 1
2	Air - 2 O_2 - 0	Air - 1.75 O_2 - 0.25	Air - 1.5 O_2 - 0.5	Air - 1.25 O_2 - 0.75	Air - 1 O_2 - 1	Air - 0.75 O_2 - 1.25	Air - 0.5 O_2 - 1.5	Air - 0.25 O_2 - 1.75	Air - 0 O_2 - 2
3	Air - 3 O_2 - 0	Air - 2.62 O_2 - 0.37	Air - 2.25 O_2 - 0.75	Air - 1.87 O_2 - 1.12	Air - 1.5 O_2 - 1.5	Air - 1.12 O_2 - 1.87	Air - 0.75 O_2 - 2.25	Air - 0.37 O_2 - 2.62	Air - 0 O_2 - 3
4	Air - 4 O_2 - 0	Air - 3.5 O_2 - 0.5	Air - 3 O_2 - 1	Air - 2.5 O_2 - 1.5	Air - 2 O_2 - 2	Air - 1.5 O_2 - 2.5	Air - 1 O_2 - 3	Air - 0.5 O_2 - 3.5	Air - 0 O_2 - 4
5	Air - 5 O_2 - 0	Air - 4.37 O_2 - 0.62	Air - 3.75 O_2 - 1.25	Air - 3.12 O_2 - 1.87	Air - 2.5 O_2 - 2.5	Air - 1.87 O_2 - 3.12	Air - 1.25 O_2 - 3.75	Air - 0.62 O_2 - 4.37	Air - 0 O_2 - 5
6	Air - 6 O_2 - 0	Air - 5.25 O_2 - 0.75	Air - 4.5 O_2 - 1.5	Air - 3.75 O_2 - 2.25	Air - 3 O_2 - 3	Air - 2.25 O_2 - 3.75	Air - 1.5 O_2 - 4.5	Air - 0.75 O_2 - 5.25	Air - 0 O_2 - 6
7	Air - 7 O_2 - 0	Air - 6.12 O_2 - 0.87	Air - 5.25 O_2 - 1.75	Air - 4.37 O_2 - 2.62	Air - 3.5 O_2 - 3.5	Air - 2.62 O_2 - 4.37	Air - 1.75 O_2 - 5.25	Air - 0.87 O_2 - 6.12	Air - 0 O_2 - 7
8	Air - 8 O_2 - 0	Air - 7 O_2 - 1	Air - 6 O_2 - 2	Air - 5 O_2 - 3	Air - 4 O_2 - 4	Air - 3 O_2 - 5	Air - 2 O_2 - 6	Air - 1 O_2 - 7	Air - 0 O_2 - 8
9	Air - 9 O_2 - 0	Air - 7.87 O_2 - 1.12	Air - 6.75 O_2 - 2.25	Air - 5.62 O_2 - 3.37	Air - 4.5 O_2 - 4.5	Air - 3.37 O_2 - 5.62	Air - 2.25 O_2 - 6.75	Air - 1.12 O_2 - 7.87	Air - 0 O_2 - 9
10	Air - 10 O_2 - 0	Air - 8.75 O_2 - 1.25	Air - 7.5 O_2 - 2.5	Air - 6.25 O_2 - 3.75	Air - 5 O_2 - 5	Air - 3.75 O_2 - 6.25	Air - 2.5 O_2 - 7.5	Air - 1.25 O_2 - 8.75	Air - 0 O_2 - 10
11		Air - 9.62 O_2 - 1.37	Air - 8.25 O_2 - 2.75	Air - 6.87 O_2 - 4.12	Air - 5.5 O_2 - 5.5	Air - 4.12 O_2 - 6.87	Air - 2.75 O_2 - 8.25	Air - 1.37 O_2 - 9.62	
12			Air - 9 O_2 - 3	Air - 7.5 O_2 - 4.5	Air - 6 O_2 - 6	Air - 4.5 O_2 - 7.5	Air - 3 O_2 - 9		
13			Air - 9.75 O_2 - 3.25	Air - 8.12 O_2 - 4.87	Air - 6.5 O_2 - 6.5	Air - 4.87 O_2 - 8.12	Air - 3.25 O_2 - 9.75		
14				Air - 8.74 O_2 - 5.24	Air - 7 O_2 - 7	Air - 5.24 O_2 - 8.74			
15				Air - 9.36 O_2 - 5.61	Air - 7.5 O_2 - 7.5	Air - 5.61 O_2 - 9.36			

3. Connect the T-Piece patient circuit.

⚠	Please be careful not to damage the gas inlet when connecting the gas supply to Easypuff. A gentle force will be sufficient for the connector probe.

- Connect the test balloon to the T-Piece circuit, then connect the circuit to the gas outlet port.
- Connect the test lung to the T-Piece circuit (before use, observe the Test Lung for signs of damage such as discoloration)

4. Check flow settings.

- Adjust the gas outlet to the desired flow rate between 5-15 lpm.
- Recommended flow rate is 8 lpm.

NOTE: Make sure the oxygen concentration of an oxygen / air source is monitored using an oxygen analyzer, or is preset using oxygen / air flow rate graphs.

5. Check the maximum pressure.

PEEP Head

- Close the *PEEP head using your thumb and turn the PIP control clockwise all the way

*PEEP: Positive End Expiratory Pressure **PIP: Peak Inspiratory Pressure

- Remove the protective cap and adjust the maximum pressure control to the desired maximum pressure.

NOTE:

- The factory setting for the Maximum Pressure Output is 40 cmH2O [mbar].
- The Maximum Pressure Outlet valve serves as a general limit on the attainable circuit pressure. Resuscitation cannot be performed above 40 cmH2O [mbar] unless the Maximum Pressure Outlet valve is adjusted.

6. Set PIP Value

- While closing the PEEP cap with your thumb, turn the PIP control counterclockwise until the desired peak inspiratory pressure is set.

7. Set PEEP Value

- Take your thumb off the PEEP cap and adjust the PEEP value by turning the PEEP cap.

6.5. Operating

1. Adjust the gas flow to the desired flow rate (5-15 lpm) and oxygen concentration.

2. Select an appropriately sized neonatal resuscitation mask and connect the T-piece to the circuit. Place the mask over the baby's mouth and nose or connect the T-piece to the endotracheal tube.
3. Resuscitate by closing/opening the PEEP cap with your thumb to allow for inspiration and expiration.

6.6. Cleaning and Maintenance

- Clean the outer surfaces of Easypuff Baby Resuscitator with a damp cloth and mild soap or isopropyl alcohol.
- After cleaning, dry all surfaces using a clean, soft cloth or paper towel.
- When Easypuff is used under normal conditions, it requires minimal service or maintenance.

7. Bililed Mini+ Phototherapy Unit (Optional)

7.1. Usage Purpose

Bililed Mini+ is used routinely in the treatment of newborn jaundice. The baby is exposed to concentrated radiation of the blue spectrum of visible light for a period determined by a doctor, depending on the clinical condition.

Functions:

- 5-Level adjustable light intensity
- Therapy time information
- Lamp usage time information
- Focusing light

7.2. User's Responsibilities for Patient Safety

	Bililed Mini+ may only be used by appropriately trained personnel under the supervision of qualified medical personnel who are aware of the known risks and benefits of using phototherapy.
	Use of this device requires constant supervision of the baby by trained nursing personnel to provide immediate corrective action in situations where there is a risk of patient injury.
	The eyes of the patient who is applied phototherapy should be protected with an eye protector.
	The fluid balance of the patient may change depending on the use of phototherapy.
	Serum bilirubin levels of the patient should be measured regularly.
	Newborns receiving phototherapy with the Bililed Mini+ need adequate fluid supply and eye protection during treatment, as well as routine nursing and medical assistance, as in other types of phototherapies.
	Never cover the phototherapy unit with cloth, blanket, aluminum foil or other materials in order to increase the therapeutic effect. This may cause an increase in temperature as well as prevent the radiation of the therapy light.
	NOVOS cannot guarantee or support the safe performance of third-party accessories for use with Bililed Mini+ phototherapy device. Use only original NOVOS accessories.
	During phototherapy, the baby's temperature should be monitored with special care. Absorption of light through the baby's skin can cause a temperature shift to the patient, which increases the core temperature.

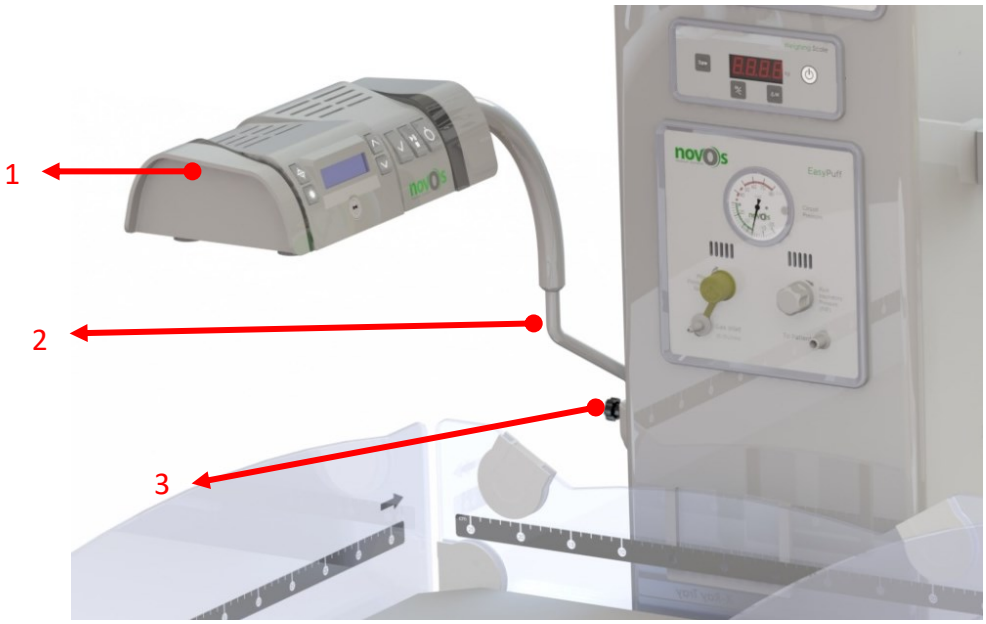
7.3. Use Restrictions

⚠	The Bililed Mini+ is not designed for use inside incubators and should not be directly exposed to heat from the radiant warmer. This possibility contains the risk of burning and explosion due to oxygen.
⚠	The NOVOS medical device complies with the requirements for interference immunity specified product-specific standards or EN 60601-1-2 (IEC 60601-1-2). However, depending on the design and use of a cell phone, the field exceeds the values generated near cell phones, causes field strengths, interferences, and failures.
⚠	Do not use the Bililed Mini+ if any part of the power supply is in direct contact with the baby's body! The power supply may become hot, and this over-warming could cause burns to the patient's skin.
⚠	HAZARD! There is a risk of explosion if used in the presence of flammable anesthetics. This device is not approved and licensed for use in places where explosive or flammable gas mixtures are likely to be existing.

7.4. Preparation

7.4.1. Placement of the Bililed Mini+

⚠	When used with a Bililed Mini+ radiant warmer, care must be taken to angle the light and not to direct it into the heat source. The light source should be placed at least 35 cm away from the baby and outside the route of the radiant warmer's heat source.
1	**Bililed Mini+ Light Source:** For phototherapy lamp operation, see the Operating Device section.
2	**Spiral Arm:** This is used to flexibly position the Bililed Mini+ light source.
3	**Spiral Arm Fixing Screw:** Allows the spiral arm to be fixed to the KR-1000 body.



1. Loosen **Spiral Arm Fixing Screw** and connect ***Spiral Arm***.
2. Tighten **Spiral Arm Fixing Screw** and fix ***Spiral Arm***.
3. Place the ***Bililed Mini+*** as followings;
    a. Not to be exposed to direct heat
    b. That distance between Bililed Mini+ and baby is at least 35 cm.

7.4.2.Power Supply Connection

	Make sure that the power cable is properly connected to the device and that all necessary measures have been taken against disconnection.
	If there is no suitable grounding system, the device should not be used. Do not use extension cords or multiple sockets.

7.5. Operating

7.5.1.Phototherapy Operation

<table>
<tr><td>

- Connect the power adapter (12V 0.7A) to Bililed Mini+ and plug it in.

.

- Turn on the device by pressing the "***Power***" button.

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- Flashing green LEDs indicate that the device has started.

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<tr><td rowspan="2">

- Wait for the device to boot up. During booting, the device model, software version, and immediately after, the total therapy time (LED Working Time) will be displayed.

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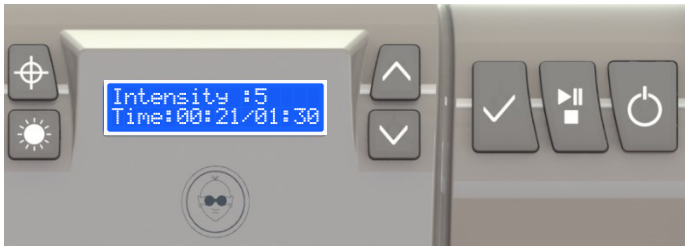
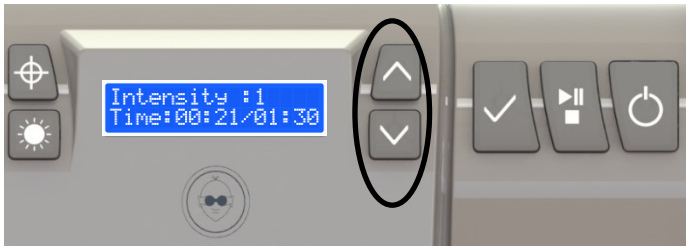
- When the startup is complete, the main screen will appear as shown in the figure.

</td><td> 
</td></tr>
</table>

Bililed Mini+ must be properly positioned and operated before therapy is initiated.

<table>
<tr><td rowspan="2">

- There are 5 preset therapy light intensity levels in total.
- Adjust the light intensity of the blue therapy LEDs using the "***Up and Down***" arrow buttons.

</td><td> 
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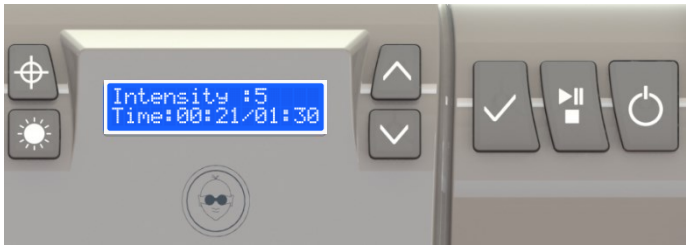
<tr><td> 
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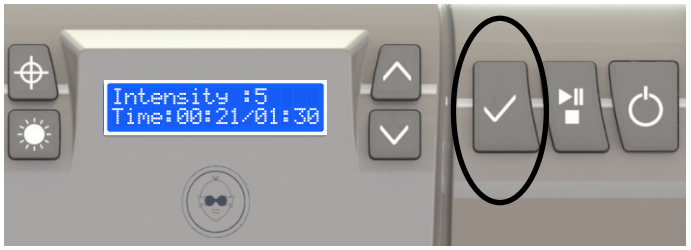
- The target therapy time can be set between 00:00 and 99:59.
- Enter the menu by pressing the "***Confirm***" button.

</td><td> 
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<tr><td>

- Go to "***Therapy Time***" option in the menu by pressing the "***Down***" arrow button.

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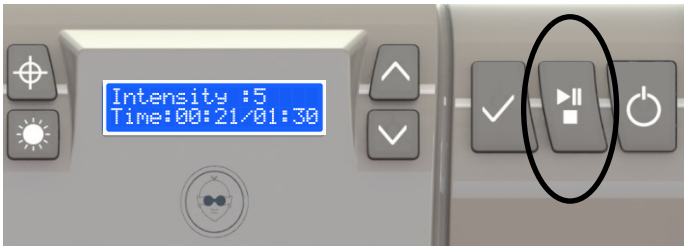
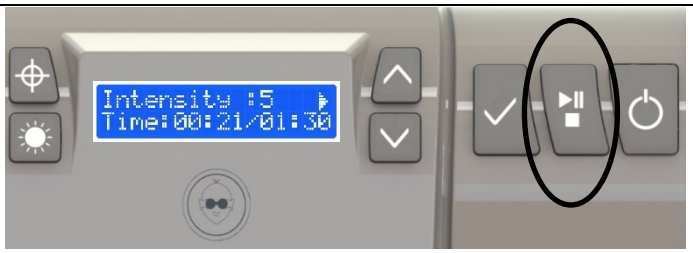
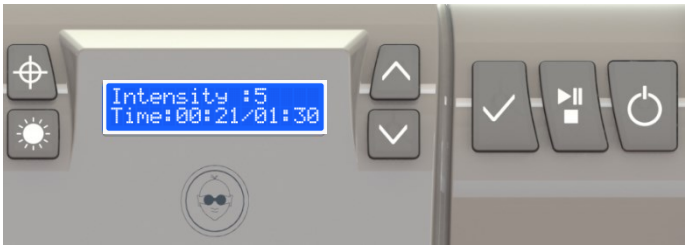
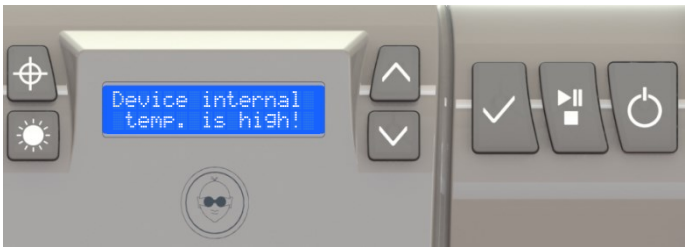
- Enter the "***Therapy Time Setting***" mode by pressing the "***Confirm***" button.

</td><td> 
</td></tr>
</table>

• Set the target therapy hour digit using the "***Up***" and "***Down***" arrow buttons.	
• Press the "***Confirm***" button.	
• Set the target therapy minute digit using the "***Up***" and "***Down***" arrow buttons.	
• Return to the menu by pressing the "***Confirm***" button.	
• Go to "***Exit***" option by pressing the "***Down***" arrow button twice.	

• Press the "***confirm***" button to exit the menu and return to the main screen.	
• Wear an appropriately sized eye mask so that the baby's eyes are completely covered.	
• Press the "***Therapy Start/Pause/Stop***" button.	
• Blue phototherapy and status LEDs will be lit. • The therapy time counter will flash. • The therapy started icon will be displayed in the upper right corner of the screen. • Pause therapy by pressing the "***Therapy Start/Pause/Stop***" button.	
• Therapy time counter will be fixed. • The therapy paused icon will be displayed in the upper right corner of the screen. • The status LED will turn green. • Resume therapy by pressing the "***Therapy Start/Pause/Stop***" button.	

• Stop therapy by holding down the "***Therapy Start/Pause/Stop***" for 3 seconds.	

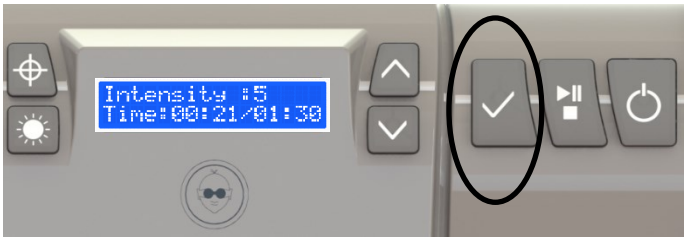
• A long beep will be heard. • Blue phototherapy and status LEDs will turn green. • The therapy started icon in the upper right corner of the screen will disappear. • The therapy time counter reverts to the target therapy time.	
• As a safety precaution, when the temperature inside the device is higher than 60 °C, the therapy is paused and the "High temperature inside the device" warning is displayed on the screen and a warning sound is heard. . When the temperature inside the device falls below 60 °C, the therapy continues from where it left off.	

WARNING!
If the temperature inside the device exceeds 60 °C, it means that the ambient temperature is high. Make sure the ambient temperature is between 20 °C and 30 °C.

WARNING!

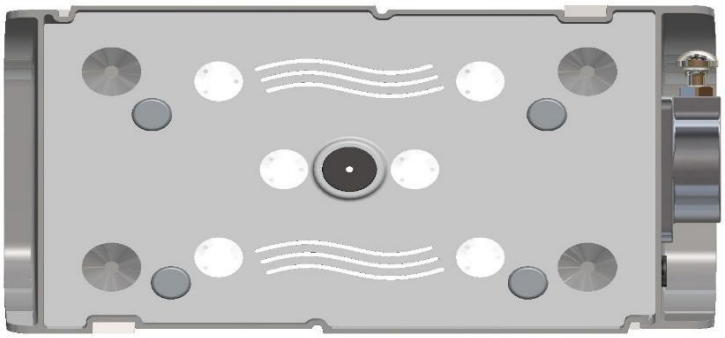
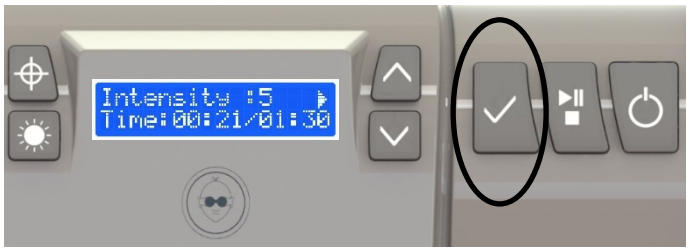
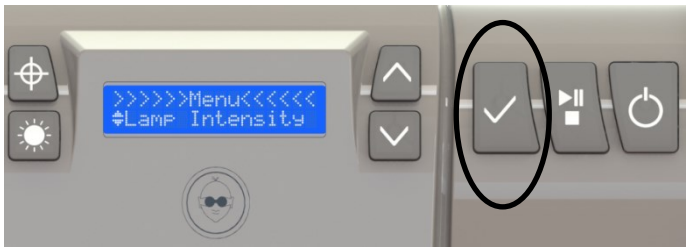
When the temperature inside the device drops below 60 °C, the therapy continues from where it left off, however, if the ambient temperature is not low enough, the "high temperature inside the device!" warning can be seen again.

To manually see the temperature inside the device, press and hold the ***Confirm*** button for 3 seconds while the device is turned off and the status indicator LED is red. • The internal temperature of the device will be displayed on the screen.	

To return to the therapy screen • Press the confirmation button 3 times, waiting for transition times between menus. • Finally, the therapy screen will be displayed. .	

When the targeted therapy time is reached, the message "Therapy Ended" will be displayed on the screen and this message will remain on the screen until any button is pressed.

7.5.2.Use of Examination Lamps

• Bililed Mini+ has 4 white examination LEDs. .	
• ***Press "Examination lamp"*** button.	
• Enter the menu by pressing the "***Confirm***" button.	
• Go to "***Lamp Intensity***" option in the menu by pressing the "***Down***" arrow button twice.	
• Enter the "***Lamp Intensity Setting***" mode by pressing the "***Confirm***" button.	

<table>
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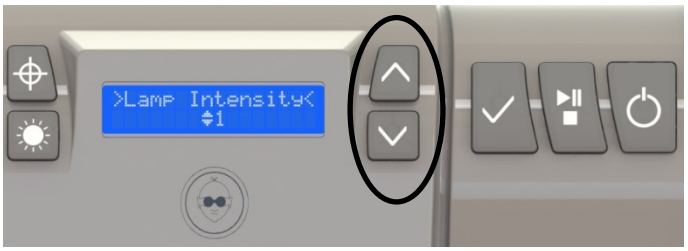
- There are 5 different preset levels for the examination lamp’s light intensity.
- Set the appropriate light intensity level for the white inspection LEDs using the "***Up and Down***" arrow buttons.

</td><td> 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<tr><td>

- Return to the menu by pressing the "***Confirm***" button.

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- Go to "***Exit***" option by pressing the "***Down***" arrow button.

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- Press the "***confirm***" button to exit the menu and return to the main screen.

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</table>

7.6. Cleaning and Maintenance

7.6.1.Cleaning

Bililed Mini+ should be cleaned and disinfected at the intervals specified in the approved hospital protocol.

WARNING!

Before cleaning and disinfection, disconnect the device from the electricity by unplugging the power plug.

- Remove visible dirt with a disposable cloth and detergent.
- Disinfect surfaces of the device by wiping.
- After spraying the antiseptic spray, wait for the time specified on the spray label for the effect (See manufacturer's instructions for declared exposure time).
- Wipe the surfaces with a clean, damp, disposable cloth, then dry (dry all surfaces with a dry cloth).

WARNING!

Avoid humidity (disinfectant and liquid detergent) from entering into the light source.

WARNING!

Do not disinfect any part of the device by immersing in liquid.

WARNING!

The LED Module included lenses, should only be wiped with a soft damp cloth.

WARNING!

Do not touch the lens with your fingers. Dirt, body oil, perfume or such ingredients on the finger can damage the optical properties.

WARNING!

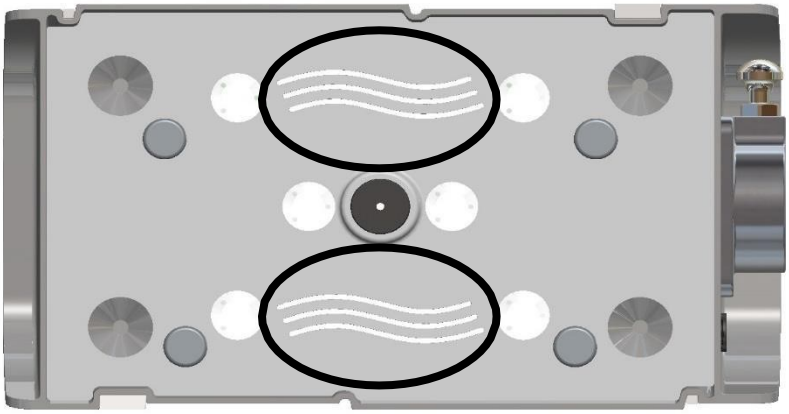
Do not use caustic, corrosive substances or disinfectants containing sodium hypochloride or alcohol. Such disinfectants can damage the phototherapy unit.

WARNING!

NOVOS recommends the use of Ammonia Quaternary components that do not have any harmful effects on the materials used in the device, that clean the surfaces and fight bacteria.

Cleaning of Air Channels

Air channels should be protected from dust for effective use of the device and long-lasting operation of the LED module. Clogged cooling channels due to dust cause the internal temperature of the device to increase, and this can lead to damage to electronic components.



7.6.2.Maintenance

This device should be maintained and serviced every 1 year. Records must be kept during these protective services. A technical services contract with NOVOS is recommended for a continuous service in line with the rules and standards.

It is recommended to contact the NOVOS Technical Service Department for repair of the Bililed Mini+ Phototherapy device.

WARNING!

Technical service and maintenance services should only be provided by technically qualified persons.

WARNING!

To avoid the risk of electric shock, unplug the power adapter of the device before maintenance and repair.

WARNING!

For better performance and device safety, use only original NOVOS spare parts.

Light Intensity Control

The LEDs used have an average lifespan of 50,000 hours. Actions such as carelessness during the use of LEDs, transportation of the device before the LEDs cool down, or touching the LEDs, shorten the lifespan. In order to accurately detect and evaluate the glow intensity of the LEDs, it is recommended to monitor the irradiance at regular intervals with a radiometer. When the radiant intensity falls 25% or less of the value stated in the lamp manufacturer's catalog, it should be changed.

LED Module Replacement

In order to maintain phototherapy efficiency, the Bililed Mini+ LED module must be replaced when the working hour (total therapy time) reaches 49,800 hours.

Please contact NOVOS Technical Service Department for LED Module replacement.

8. Venturi Vacuum Unit (Optional)

8.1. Usage Purpose

The venturi vacuum unit is used to create, adjust and measure a suction from a compressed gas source at the wall or a cylinder (oxygen or medical air). It allows suction of liquid or mucus in the absence of a vacuum pipeline network. The venturi vacuum unit must be connected directly to a compressed gas source using a probe or a cylinder that has a quick release connection from a rail mounting system or a pressure regulator in the wall. Venturi vacuum unit must be connected with a collection jar and suction hose.

8.2. User's Responsibilities for Patient Safety

	The Venturi Vacuum Unit should only be used by qualified medical personnel.
	Check the pressure from the gas supply. This will affect the maximum negative pressure to be applied. Maximum vacuum levels and suction flow rates are generated only when the supply line pressure is 4.5 bar or higher.
	Always check if the device is working before use.
	If the device falls down, it is necessary to check the pressure gauge accuracy and the collecting canister tightness.
	Never obstruct the air outlet of the device.
	Make sure the manometer needle points to zero when the device is not in use.
	Make sure that an antibacterial filter is always installed in the suction circuit of the device.
	The length of the tube is likely to affect suction performance.
	The measurement tolerances of the vacuum level gauge increase when the device is used outside the specified ambient temperature and pressure range.
	Do not throw antibacterial filters in the household waste bin.
	When the supply gas is oxygen, using lubricants that are incompatible with the gas may result in fire or explosion.
	When the supply gas is oxygen, make sure that the environment where the venturi vacuum unit is used is adequately ventilated.
	Never disassemble the device while it is connected to a compressed gas source.

	The venturi vacuum unit is not suitable for use in the MRI environment.

8.3. Operating

1. Make sure the device is not damaged and the connector is compatible with the supply connection.
2. Make sure the adjustment knob is in the closed position (turn fully clockwise).
3. Connect the device to the gas supply outlet of the network (air or oxygen).
4. Connect the outlet (nozzle) of the device to the collection vessel using a suction tube with a min 6.3 mm diameter.
5. Turn the adjustment knob on the front of the device counterclockwise and adjust the vacuum level with the patient circuit closed.
6. To stop suction, turn the adjustment knob to the off position.

Attaching the Collection Container:

- Attach the collection container under the venturi vacuum unit and turn it: Match the mark on the cover of the collection container with the mark on the edge of the bottom of the venturi vacuum unit body.

Detaching the Collection Container:

- Turn the collection container counterclockwise.
- Match the mark on the cover of the collection container with the mark on the edge of the bottom of the venturi vacuum unit body, then pull the container downwards.

Attaching the Plastic Filter:

- Push it in completely until it clicks into place.

Detaching the Plastic Filter:

- Pull and turn at the same time.
- Dispose of the filter by taking appropriate measures.

8.4. Cleaning and Maintenance

Under normal conditions of use, the Venturi Vacuum Unit does not require disinfection because the collection containers are protected by the filter in front of the device. Change the filter after every patient.

8.4.1. Venturi Vacuum Unit

Use a disinfectant cleaner appropriate for medical devices. Let the device dry before using it.

	• When using decontamination products, make sure they are compatible with plastic. • Do not use a surface decontamination product. • Do not spray the disinfectant directly on the device. Use a washcloth or disposable wipe. • Do not immerse any product in water.

8.4.2. Collection Container

There is no need to sterilize as the collection container is protected by an inlet filter in front of the device: Remove the filter after each patient or, if the device has been used for a patient for a long time, replace it as necessary, depending on the degree of contamination. However, if the liquid accidentally overflows or the filter is punctured, the collection jar should be disinfected or sterilized as follows.

1. Remove the collection container and unscrew the lid from the container.
2. Immerse the parts of the collection container (following the manufacturer's instructions for soaking, rinsing and drying times) in a disinfectant solution.
3. Clean, rinse thoroughly, soak in clean water for 1 minute, and then rinse.
4. Sterilize or disinfect in accordance with the instructions given by the manufacturer of the product used.
5. Reassemble each part and reattach the collection container.

	The collection container can withstand 30 disinfection or sterilization cycles.
	The collection container can be autoclaved at temperatures up to 134°C.

8.5. Technical Specifications

- Complies with ISO 10079-3.
- Manometer unit: mmHg and kPa.
- Imaging range: From 0 to -200 mmHg (0 to 25 kPa)
- Measurement precision: ±1.6% of the entire scale
- Vacuum gauge can rotate 90° (-45° to +45°)
- Collection container can rotate 90° (-45° to +45°)
- Antibacterial filter in front of the device has 99.97% efficiency for 0.3µm particles.
- If the exhaust is blocked, a safety valve is installed to protect the device.
- Working pressure supply: 3-6 bars.
- Maximum flow rate at 4.5 bar: 40 L / min. with safety container
- Maximum gas consumption at 4.5 bar: 60 L/min
- Noise level with safety container at maximum suction flow rate: 52dB.
- Ambient temperatures for use: 10-40°C.
- Atmospheric air pressure for storage and use: 800-1060 hPa.
- Relative humidity levels for storage and use: 0 – 100%

9.Annexes

9.1. Technical Specifications

9.1.1.Environmental Properties

Operating Temperature	20°C-30°C
Operating Humidity	5-95% RH, non-condensing
Storing Temperature	-20°C - 60°C
Storing Humidity	5-95% RH, non-condensing

9.1.2.Mechanical Properties

Height	177 cm
Height (Adjustable, optional)	197 cm
Bed Height	93 cm
Bed Height (Adjustable, optional)	113 cm
Width	90 cm
Depth	110 cm
Bed Dimensions	70 x 55 cm
Trendelenburg limits	±12°
Trendelenburg mechanism	Electronic
Distance between warmer and bed	74 cm
Warmer-Head Rotation Angle Range	±140°
Wheels	4 x Ø125 mm with brakes
Baby bad max. load capacity	10 kg
Monitor tray max. load capacity	10 kg
Accessory mounting rail max. load capacity	10 kg
Rotating drawers max. load capacity	2x5 kg / Upper (Auxiliary) tray: 10 kg
Maximum Total Weight	98,5 kg
Standard Model Weight	75,5 kg
IP Class	IP 20

9.1.3.Characteristic Properties

Supply Voltage	220V AC, (±10%)
Auxiliary Power Socket; Each socket max.	Each socket max 2A. For medical devices only (IEC 60601-1)
Supply Frequency	50 – 60 Hz
Nominal Power Consumption	800 W
Warmer power	2 x 400 W
Maximum Radiation on Bed:	22 mW/cm2
Mattress Liquid Permeability and Non-Flammability	It is 100% liquid proof, not fireproof.
Inspection LED power	2 x 5 W
Inspection Lamp Lighting Intensity	>1000 Lux (Above Bed)
Baby Mode Target Temperature Setting	34 – 38 °C, (in 0,1 °C intervals)
Heater Power Percentage	0-100%, (in 10% intervals)
Heater Service Life	20,000 operating hours (Under appropriate

	conditions)
Skin Temperature Display Range	10 – 50 °C
Temperature Measurement Accuracy	0,1 °C
Fuse	2x4A
Skin Temperature Sensor Resolution	0,1 °C
Touchless Alarm Silence	10 min.
Preheat Mode Heater Power Percentage	40% at temperatures below 25°C, otherwise 30%
Maximum Noise Level	45 dBA
Interface Languages	English

9.1.4.Other Properties

Resuscitation (Easypuff) T-piece resuscitation unit (Optional)

Peak Inspiratory Pressure (PIP)	5-70 cmH2O @ 8 lpm
Positive-end Expiratory Pressure (PEEP)	1-10 cmH_2O @ 8 lpm
Primary pressure Limit (Pre-set)	40 cmH_2O
Flow Capacity	5L/min (minimum) – 15L/min (maximum)
Airway Pressure Manometer Range	(-20) – 80 cmH_2O

Air/O_2 Blender (Optional)

Range	21-100% O_2
Precision	±3% at Full Scale
Flowmeter Range	0-15 lpm

Air/Oxygen Mixing System (Optional)

Pendant Pressure	3-5 bar
Tube Pressure	3-5 bar
Patient Circuit Flow Range	0-15 lpm

Vacuum Unit

Venturi (O2 supplied) **or normal type** (vacuum regulator)
Collection Container Capacity: 500 mL

Scale (Optional)

Weight Limit	0 – 10,000 g
Weight Display Resolution	1 g
Scale Sensitivity	±1 g
Scale Accuracy	±4 g

LED Phototherapy (Optional)

Light Intensity	(Measured from 35 m distance.) 5. Level: >40 µW/cm^2/nm – 2 mW/cm^2 – 2000 µW/cm^2 4. Level: >30 µW/cm^2/nm – 1.5 mW/cm^2 – 1500 µW/cm^2 3. Level: >25 µW/cm^2/nm – 1.25 mW/cm^2 – 1250 µW/cm^2

	2. Level: >20 µW/cm^2/nm – 1 mW/cm^2 – 1000 µW/cm^2 1. Level: >15 µW/cm^2/nm – 0.75 mW/cm^2 – 750 µW/cm^2
Wavelength	440 – 460 nm
Lamp Life	50,000 hours
Maximum Noise Level	<10 dBA

Software

Version: 3.x

9.1.5.Accessories and Consumables

- Reusable Skin Probe
- Disposable Skin Probe
- Skin Probe Retaining Washer
- Air Temperature Sensor
- Baby Bed Cover
- Vacuum Unit
- Single-use T-Piece Patient Circuit
- Infant Mask numbered 0 and 1
- Test Balloon
- Blender (Air/O_2 Mixer)
- Flowmeter System
- O_2 Hood
- E Cylinder Slots
- Adapter Housing
- IV Pole
- Monitor Tray
- Phototherapy Unit
- Eye Protection Band

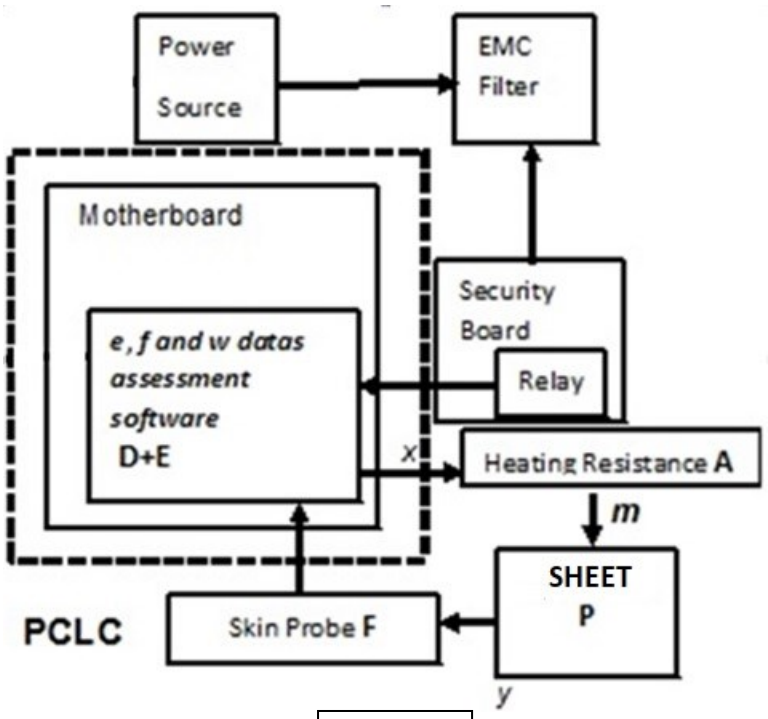


Figure-1

9.2. Compatibility

NOVOS baby warmers and accessories are designed to meet the requirements of:

IEC 60601-2-21	Safety requirements for baby radiant warmers
IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and basic performance
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and basic performance
ISO 8382	Resuscitators intended for human use
IEC 60601-2-50	Medical electrical equipment - Part 2-50: Special rules for basic safety and basic performance of baby phototherapy devices
EN 980	European standard for symbols used by medical device manufacturers
BS EN 10079-3	Medical suction device Part 3: Suction device powered by vacuum or pressure source
BS EN 13220	Flow meters for connection to terminal units of medical gas pipeline systems
BS EN 739	Low pressure tube assemblies for use with medical gases
BS EN 837-1	Pressure gauges. Bourdon tube pressure gauges. Dimensions, metrology, requirements, and testing
BS EN 738-1	Pressure regulators for use with medical gases. Pressure regulators and pressure regulators with flow meter

CE 1984

9.3. Guidance and Manufacturer's Declaration of Electromagnetic Compatibility

This document is the Guideline and Manufacturer's Declaration prepared with reference to the Electromagnetic Compatibility requirements of the Electrical Medical Device according to EN 60601-1-2.

EMC compatibility has been evaluated with original components. The use of incompatible components may result in increased emissions and decreased immunity.

This device is designed for use in below conditions and environments.

9.3.1. Electromagnetic Environment

KR-1000 is intended for use in the electromagnetic environment specified below. The customer or user of the KR-1000 must guarantee that the device will be used in such an environment.

Emission experiments	Compatibility	Electromagnetic Environment
RF Emissions ING 11	Group 1	KR-1000 uses RF energy only for its internal function. Therefore, it has very low RF emissions and is unlikely to interfere with nearby electronic devices.
	Class B	KR-1000 is suitable for use in local facilities, including buildings directly connected to the public low voltage power grid that supplies energy to buildings used for their purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions (IEC 61000-3-3)	Class A	

9.3.2.Electromagnetic Immunity

KR-1000 is intended for use in the electromagnetic environment specified below. The customer or user of the KR-1000 must guarantee that the device will be used in such an environment.

Immunity Test	IEC 60601 experiment level	Compatibility level	Electromagnetic Environment
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Places, in which KR-1000 will be used, should be wood, concrete, or ceramic brick. If these places are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst EFT IEC 61000-4-4	± 2 kV Mains ± 1 kV Inputs/Outputs	± 2 kV Grid Not applicable	The quality of mains power should be same of a typical commercial or hospital environment.
Impulse IEC 61000-4-5	± 1 kV Differential	± 1 kV Differential	The quality of mains power should be same of a typical commercial or hospital environment.
Mains frequency magnetic field (50/60 Hz) IEC 61000-4-8	3 A/m	3 A/m	Mains frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Immunity Test	IEC 60601 test level	Compatibility level	Electromagnetic Environment
Voltage Dips/Breaks IEC 61000-4-11	95% drop for 0.5 cycles 60% drop for 5 cycles 30% drop for 25 cycles	95% drop for 0.5 cycles 60% drop for 5 cycles 30% drop for 25 cycles	Main power quality should be in typical commercial quality or suitable for hospital environment. If the user of the KR-1000 needs to continue operating the device while there is a power cut in the power grid, it is recommended that the device be powered from an uninterruptible power supply or battery.
Conveyed RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	V_1=3 Vrms	Portable and mobile RF communications equipment should be kept away from any part of the KR-1000, including cables, no closer than the distance calculated in the equation applicable to the transmitter frequency. **Recommended Separation Distance** D = 1,167$\sqrt{P}$

Immunity Test	IEC 60601 experiment level	Compatibility level	Electromagnetic Environment
Propagated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	Portable and mobile RF communications equipment should not be closer to any part of the KR-1000, including cables, than the recommended distance calculated with the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ 80 MHz ilâ 800MHz $d = 2.3\sqrt{P}$ 800 MHz ilâ 2,5 GHz Whereas P is the maximum output power of the transmitter in W according to the transmitter manufacturer, and d is the recommended separation distance in meters. When determined by an electromagnetic site survey, radiated field strengths from fixed RF transmitters[1)] should be less than the compliance level in each frequency range[2)]. The interference can be found at the device site marked with the symbol below. 

[1)] The field strengths broadcasted from fixed transmitters, such as base stations for radio telephones (cellular / cordless) and terrestrial mobile radios, amateur radio AM and FM radio broadcast, and TV broadcast may not be predicted theoretically with accuracy. To evaluate the electromagnetic environment due to RF transmitters, electromagnetic site survey should be considered. If the measured field strength in the location in which the KR-1000 is used exceeds the applicable RF compliance level above, the KR-1000 should be observed to verify normal operation. If an

abnormality is observed in performance, additional measurements such as reorientation or repositioning may be required.

[2)] In the frequency range from 150 kHz to 80 MHz, field strengths should be lower than [V1] V/m.

9.3.3.Recommended Separation Distance

Recommended separation distance between portable and mobile RF communications equipment and the KR-1000			
The KR-1000 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the KR-1000 can prevent electromagnetic interference by maintaining the smallest distance between portable and mobile RF communications equipment (transmitters) and the KR-1000 as recommended below according to the maximum output power of the communications equipment.			
Transmitter's highest rated output power (W)	**Distance (m) 150 kHz to 80 MHz** $\mathbf{d = 1.2\sqrt{P}}$	**Distance (m) 80 MHz to 800 MHz** $\mathbf{d = 1.2\sqrt{P}}$	**Distance (m) 800 MHz to 2.5 GHz** $\mathbf{d = 2.3\sqrt{P}}$
0.01	0.12 m	0.12 m	0.23 m
0.1	0.37 m	0.38 m	0.73 m
1	1.17 m	1.2 m	2.3 m
10	3.69 m	3.8 m	7.3 m
100	11.67 m	12 m	23 m

9.4. Equipment Classifications

Class I

B type with BF type applied part

Continuous operation

IP Class IP20

Not suitable for use in the presence of flammable anesthetics

9.5. Trademark Registrations

KR-1000™, Easypuff™, Bililed Mini+™ models are Novos branded commercial products of Novos Tıbbi Cihazlar Sanayi ve Ticaret İthalat ve İhracat Limited Şirketi.

9.6. Manufacturer

Novos Tıbbi Cihazlar Sanayi ve Ticaret İthalat ve İhracat Limited Şirketi

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