KR-1000 Infant Warmer

User Manual

Version 1.0

Software Version 3.0

Revisions

Version	Date of Publish	Sections Changed
1.0	April 2017	-

NOTICE

Proprietary Information:

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Repairs/Modifications:

Repairs on this device shall be performed only by NOVOS or Factory Authorized Service Centers. Information about repairs can be obtained from NOVOS or Authorized Dealers. NOVOS will not be responsible for injury to persons or damage to property arising directly or indirectly from unauthorized repairs or modifications to this device. Furthermore, any unauthorized repairs or modifications void any warranty extended by NOVOS. This document is provided for your information only. It is not changed or updated without request.

Definitions:

WARNING!

Warnings are directions which, if they are not followed, can cause fatal or serious injuries to a user, engineer, patient or any other person or can lead to a mistreatment.

CAUTION!

Cautions are directions which, if they are not followed, can cause damage to the system described in this manual.

Contents

1.Safety Information

1.1. Symbols

	BF Type Equipment
	AC Power Available
	AC Power Not Available
	Celsius/Fahrenheit Switch Button
	Remote Alarm Silencer
	Alarm Silencer Button
	Set Target Temperature Over 37°C Button
	Examination Light On/Off Button
	Keypad Lock/Unlock Button
	Memory/Clear Button
	Weight Records Difference Button
	Reset Trendelenburg Button
	First Memory Button for Trendelenburg
	Second Memory Button for Trendelenburg
	Trendelenburg Position Button
	Reverse Trendelenburg Position Button

1.2. Operator's Responsibility for Patient Safety

WARNING!
Strictly follow this User Manual. Any use of the product requires full understanding and strict observation of all portions of these instructions. This equipment is only to be used for the purpose specified under "Intended Use". Observe all WARNINGS and CAUTIONS as rendered throughout this manual and on labels on the equipment.

The design of this equipment, the accompanying literature, and the labeling on the equipment take into consideration that the purchase and use of this equipment are restricted to trained professionals, and that certain inherent characteristics of the equipment are known to the trained operator. Instructions, warnings, and caution statements are limited, therefore, largely to the specifics of the Novos design. This publication excludes references to various hazards which are obvious to a medical professional and operator of this equipment, to the consequences of product misuse, and to potentially adverse effects in patients with abnormal conditions. Product modification or misuse can be dangerous. NOVOS Medical Systems disclaims all liability for the consequences of product alterations or modifications, as well as for the consequences which might result from the combination of this product with other products whether supplied by Novos or by other manufacturers if such a combination is not endorsed by NOVOS Medical Systems

1.3. Patient Monitoring

The operators of this infant incubator system must recognize their responsibility for choosing appropriate safety monitoring that supplies adequate information on equipment performance and patient condition. Patient safety may be achieved through a wide variety of different means ranging from electronic surveillance of equipment performance and patient condition to simple, direct observation of clinical signs. Responsibility for the selection of the best level of patient monitoring lies solely with the equipment operator.

1.4. Limitation of Liability

NOVOS Medical Systems' liability, whether arising out of or related to manufacture and sale of the goods, their installation, demonstration, sales representation, use, performance, or otherwise, including any liability based upon NOVOS Medical Systems' Product Warranty, is subject to and limited to the exclusive terms and conditions as set forth, whether based upon breach of warranty or any other cause of action whatsoever, regardless of any fault attributable to NOVOS Medical Systems and regardless of the form of action (including, without limitation, breach of warranty, negligence, strict liability, or otherwise).

NOVOS Medical Systems shall not be liable for, nor shall buyer be entitled to recover any special incidental, or consequential damages or for any liability incurred by buyer to any third party in any way arising out of or relating to the goods.

1.5. Warranty

All Novos products are guaranteed to be free of defects for a period of one year from date of delivery. The following are exceptions to this warranty:

1. The defect shall be a result of workmanship or material. Defects caused by misuse, mishandling, tampering, or by modifications not authorized by NOVOS Medical Systems or its representatives are not covered.
2. Rubber and plastic components and materials are warranted to be free of defects at time of delivery. Any product which proves to be defective in workmanship or material will be replaced, credited, or repaired with NOVOS Medical Systems holding the option. NOVOS Medical Systems is not responsible for deterioration, wear, or abuse. In any case, NOVOS Medical Systems will not be liable beyond the original selling price.
3. Failure caused by force-majeure events and others where the manufacturer cannot be liable.
4. Failures due to the voltage difference
5. Lack of or insufficient service and maintenance by the customer.
6. Normal wear and tear of operating parts.
7. Misuse of the machine and its equipment
8. The buyer assures that all service & maintenance intervals are observed and protocoled by qualified personnel according to the NOVOS service manuals. All warranty liabilities expire should these obligations not be met.

Application of this warranty is subject to the following conditions:

1. NOVOS Medical Systems or its authorized representative must be promptly notified, in writing, upon detection of the defective material or equipment.
2. Defective material or equipment must be returned, shipping prepaid, to Novos or its factory authorized service center.
3. Examination by Novos or its factory authorized service center must confirm that the defect is covered by the terms of this warranty.
4. Notification in writing, of defective material or equipment must be received by Novos or its factory authorized service center no later than two (2) weeks following expiration of this warranty.

The above is the sole warranty provided by NOVOS Medical Systems No other warranty expressed or implied is intended. Representatives of Novos are not authorized to modify the terms of this warranty.

NOVOS Medical Systems

2.Intended Use

2.1. Applications

WARNING!
The use of this device requires continuous supervision of the infant by trained nursing personnel in order to avoid immediate corrective action in situations with a risk of patient injury.

The NOVOS infant radiant warmers are specifically designed to provide a controlled source of warmth to babies in the first few weeks of life. The warmers can provide complete care for the newborn baby in delivery through to the critically ill baby in neonatal intensive care.

The KR-1000 Infant Warmer combines an integrated bassinet with optional accessories to suit your own particular warming needs.

KR-1000 has three different operating modes which are prewarm Mode, manual Mode and baby mode.

- In baby mode KR-1000 provides the stable control of baby's skin temperature by automatically adjusting the heater power to compensate the heat loss due to varying physiological and environmental conditions. This is achieved by using a microprocessor which reads the skin temperature of the baby and updates the heater power with a frequency of 100ms (1/10 of a second).
- In manual mode, KR-1000 provides user adjustable heater power and the option to monitor the baby's skin temperature using the skin sensor if desired.
- In prewarm mode, KR-1000 provides a prewarm cycle of the heater. This mode can be used to prepare the warmer just before using it with an infant.

2.2. Restrictions of Use

WARNING!
This device is designed to be used only in rooms with line power installations complying with national safety standards for hospital patient rooms (e.g., IEC/EN 601.1, "Safety of Medical Equipment"). To maintain grounding integrity, connect only to a "hospital grade" receptacle. Always disconnect supply before servicing.

WARNING!
DANGER, risk of explosion if used in the presence of flammable anesthetics. This device is neither approved nor certified for use in areas where combustible or explosive gas mixtures are likely.

WARNING!
The use of this device requires continuous supervision of the infant by trained nursing personnel in order to avoid immediate corrective action in situations with a risk of patient injury.

WARNING!
Mobile telephones must not be used within 10 meters (33 feet) of the incubator. Mobile telephones can interfere with the function of electro medical equipment and therefore endanger the patient!

Novos medical equipment conforms to the interference immunity requirements laid down in product-specific standards or in EN 60601-1-2 (IEC 60601-1-2). However, depending on the design of a mobile phone and the use situation, field strengths exceeding the values laid down in the specified standards may be generated in the immediate vicinity of mobile phones, thereby causing interference and malfunctions.

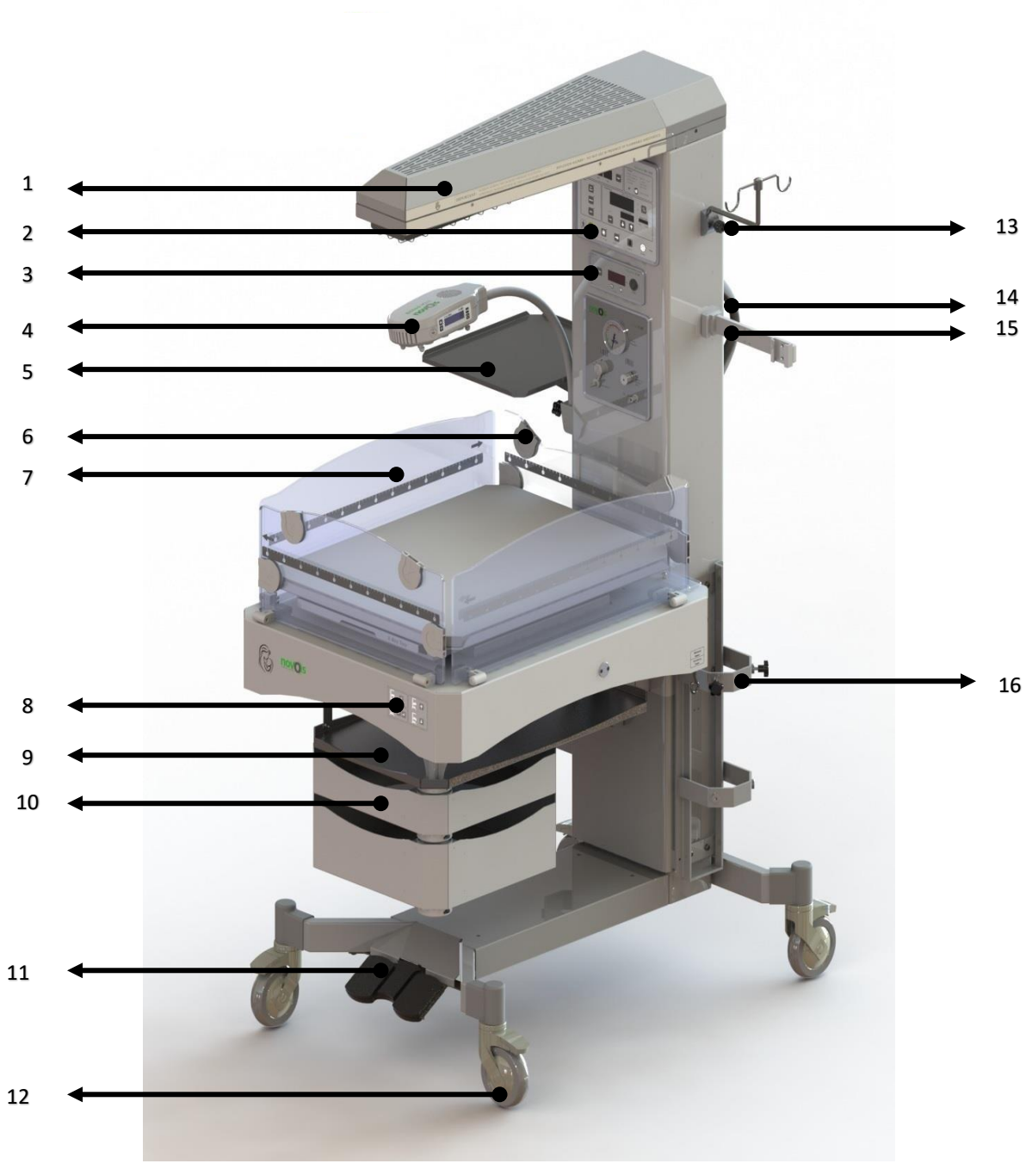
WARNING!
Maximum bassinet loading is 10 kg. Do not exceed maximum side load limits. Maximum side loads for the KR-1000 infant warmer are: 10 kg max up to 130 cm from floor 5 kg max from 130 to 160 cm from floor 1 kg max above 160 cm from floor.

WARNING!
Ensure all mounting accessories are securely fastened in the column mounting slot before items are placed or attached to each accessory.

WARNING!
Do not exceed the maximum total storage drawer and storage tray loading of 7 kg. The maximum total accessory weight on a KR-1000 should not exceed 65kg

3. Parts and Controls

3.1. Isometric View



1	Warmer Head	5	Monitor Tray	9	Tray	13	IV Pole
2	Control Panel	6	Grommet	10	Drawer	14	Handle
3	Scale Control Unit	7	Side Protector	11	Height Adjustment Footswitch	15	Extension Bar
4	Phototherapy Unit	8	Trendelenburg Control Unit	12	Wheel	16	Cylinder Racks

(3) Scale Control Unit (Optional): KR-1000 optional weighing system can be controlled with the scale control unit.

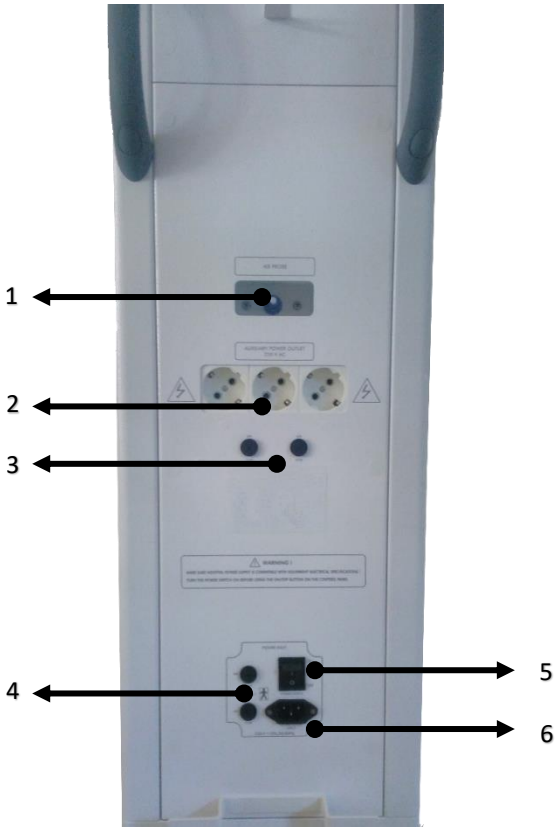
(7) Side Protector: KR-1000 has 3 foldable side protectors and a rear side protector which is completely extractable.

(8) Trendelenburg Control Unit: KR-1000 has the electronic trendelenburg with 2 memory option. The whole bassinet can be tilted up to ±12^{o} and can easily be aligned horizontally by reset function.

(11) Height Adjustment Footswitch (Optional): Mattress height of the KR-1000 can be adjusted with footswitches. It can be elevated up to 20cm.

(15) Extension Bar (Optional): A suction unit and air/oxygen blender options can be attached via extension bar of KR-1000.

3.2. Rear View

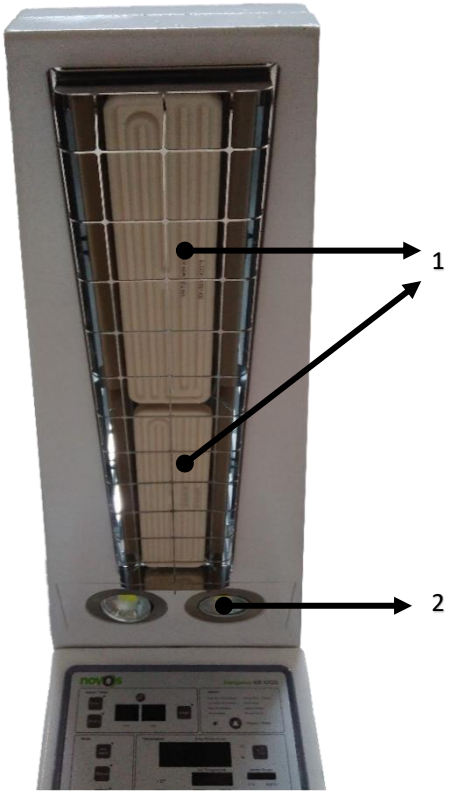


1	Air Probe	5	Power Switch
2	Multiway Plug	6	Power Input
3	Multiway Plug Fuses		
4	Main Fuses		

(1) Air Probe: The air probe measuring the environment air temperature is embedded at the rear of the device.

(2) Multiway Plug: KR-1000 provides a multiway plug for the power requirement of the third party devices such as phototherapy unit and patient monitor.

3.3. Warmer Head



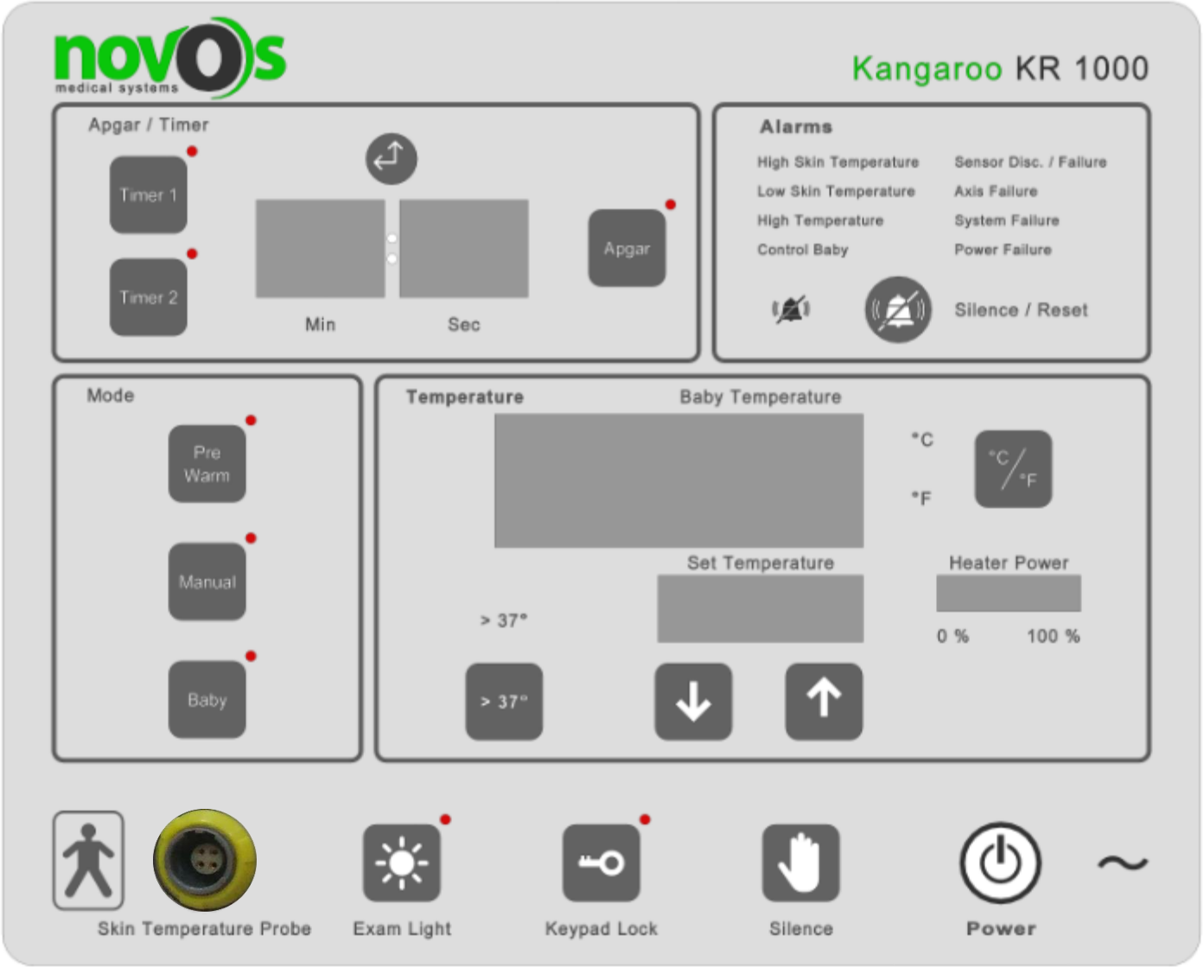
1	Ceramic Resistances
2	Examination LED

±140^{o} rotatable warmer head hosts the resistances and examination LEDs.

(1) Ceramic Resistances: KR-1000 regulates the air temperature above the mattress via 2 * 400W ceramic resistances.

(2) Examination LEDs: Rotatable examination LEDs helps to illuminate the mattress area.

3.4. Control Panel

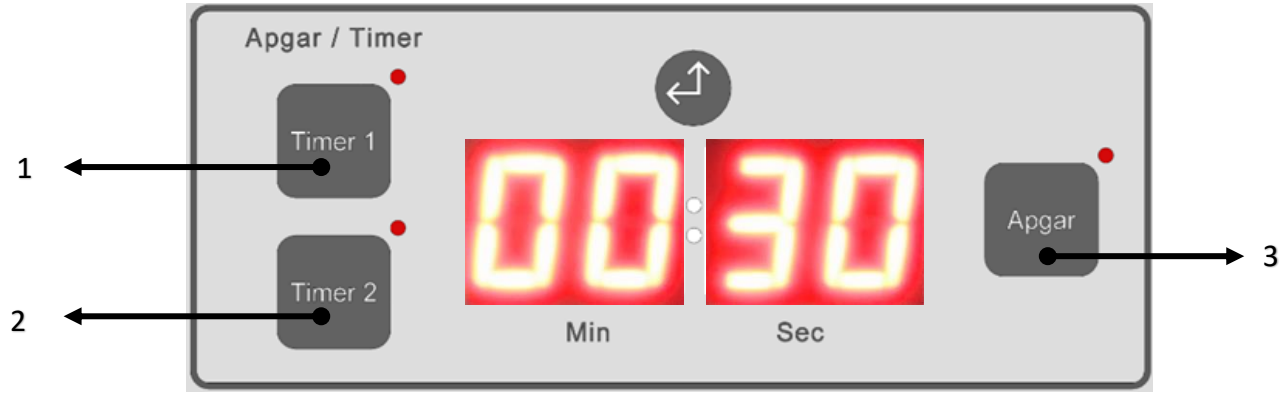


Control Panel can be divided into 5 different region.

1. Timers
2. Operating Modes
3. Alarms
4. Temperature Settings
5. Lower Button Group

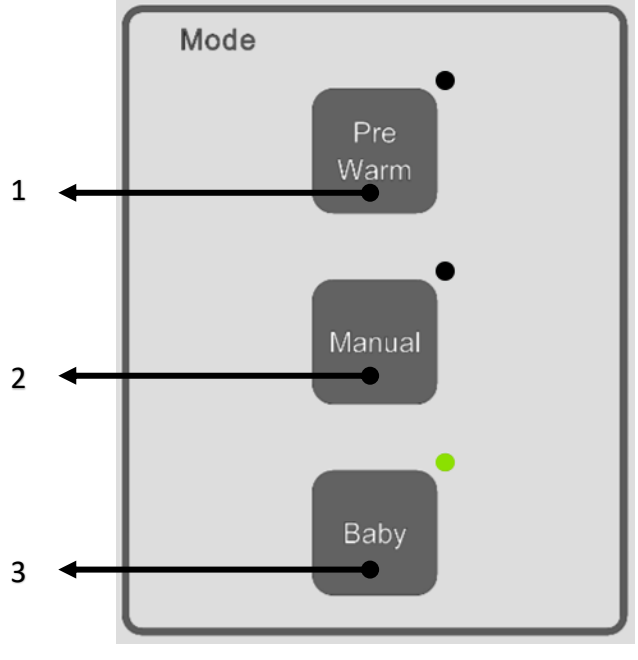
Function of each control will be explained in chapter 5.2 Control Panel Operation

3.4.1.Timers



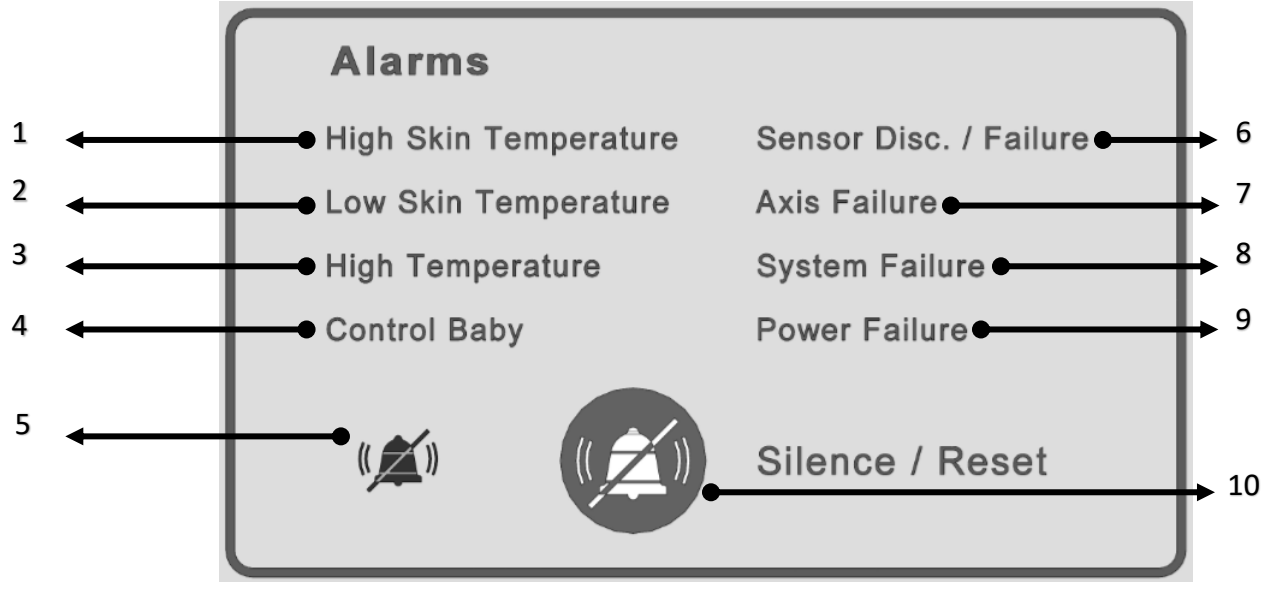
1	Timer 1 Set/Start Button	3	Apgar Timer Set/Start Button
2	Timer 2 Set/Start Button		

3.4.2.Operating Modes



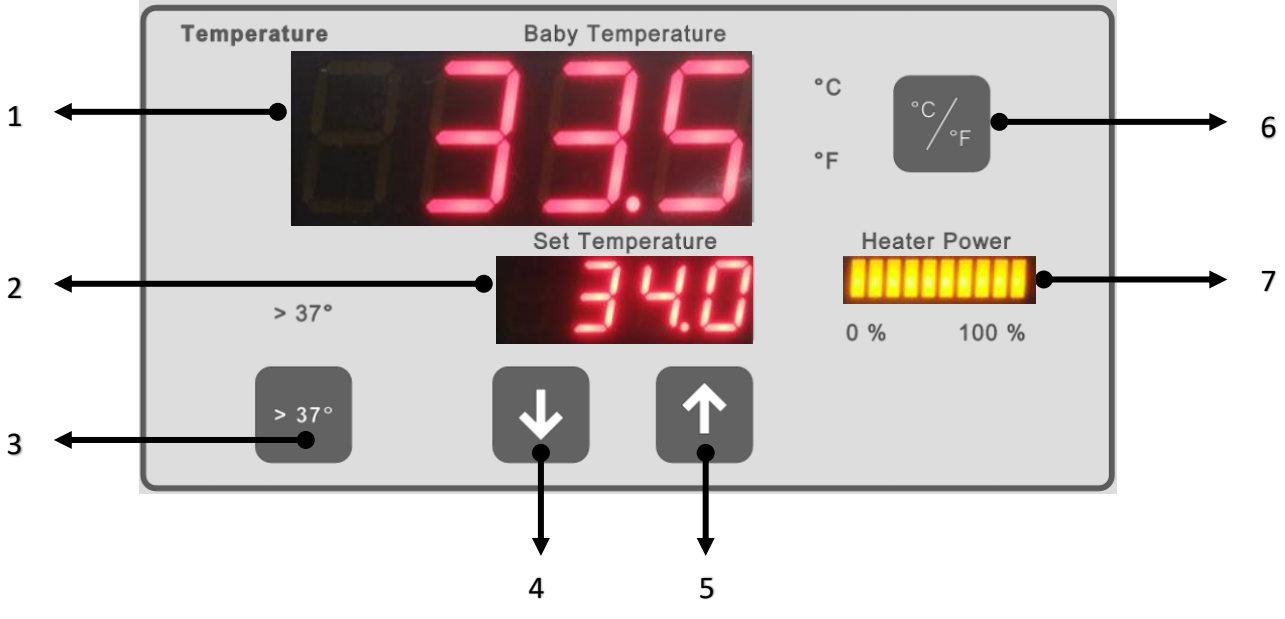
1	Pre-Warm Mode Button
2	Manual Mode Button
3	Baby Mode Button

3.4.3.Alarms



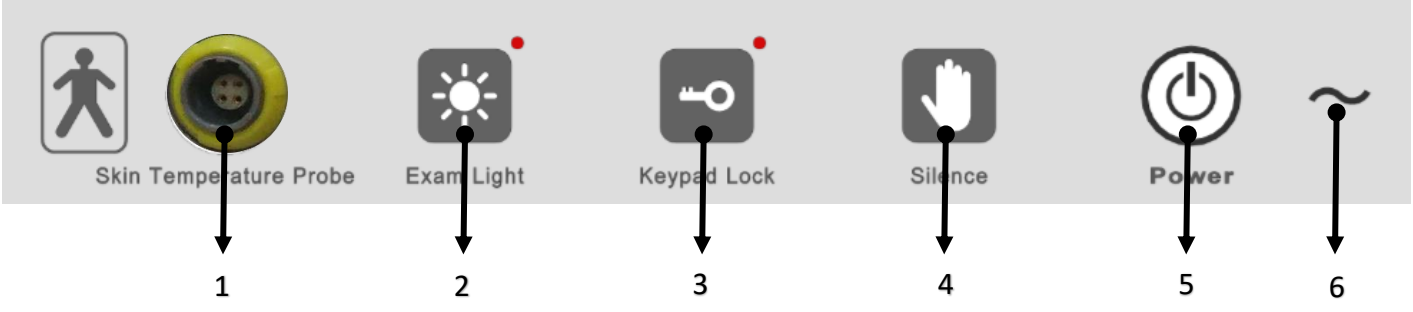
1	High Skin Temperature Alarm Indicator	6	Sensor Disconnection/Failure Alarm Indicator
2	Low Skin Temperature Alarm Indicator	7	Axis Failure Alarm Indicator
3	High Temperature Alarm Indicator	8	System Failure Alarm Indicator
4	Control Baby Alarm Indicator	9	Power Failure Alarm Indicator
5	Alarm Silenced Indicator	10	Alarm Silencer Button

3.4.4.Temperature Settings



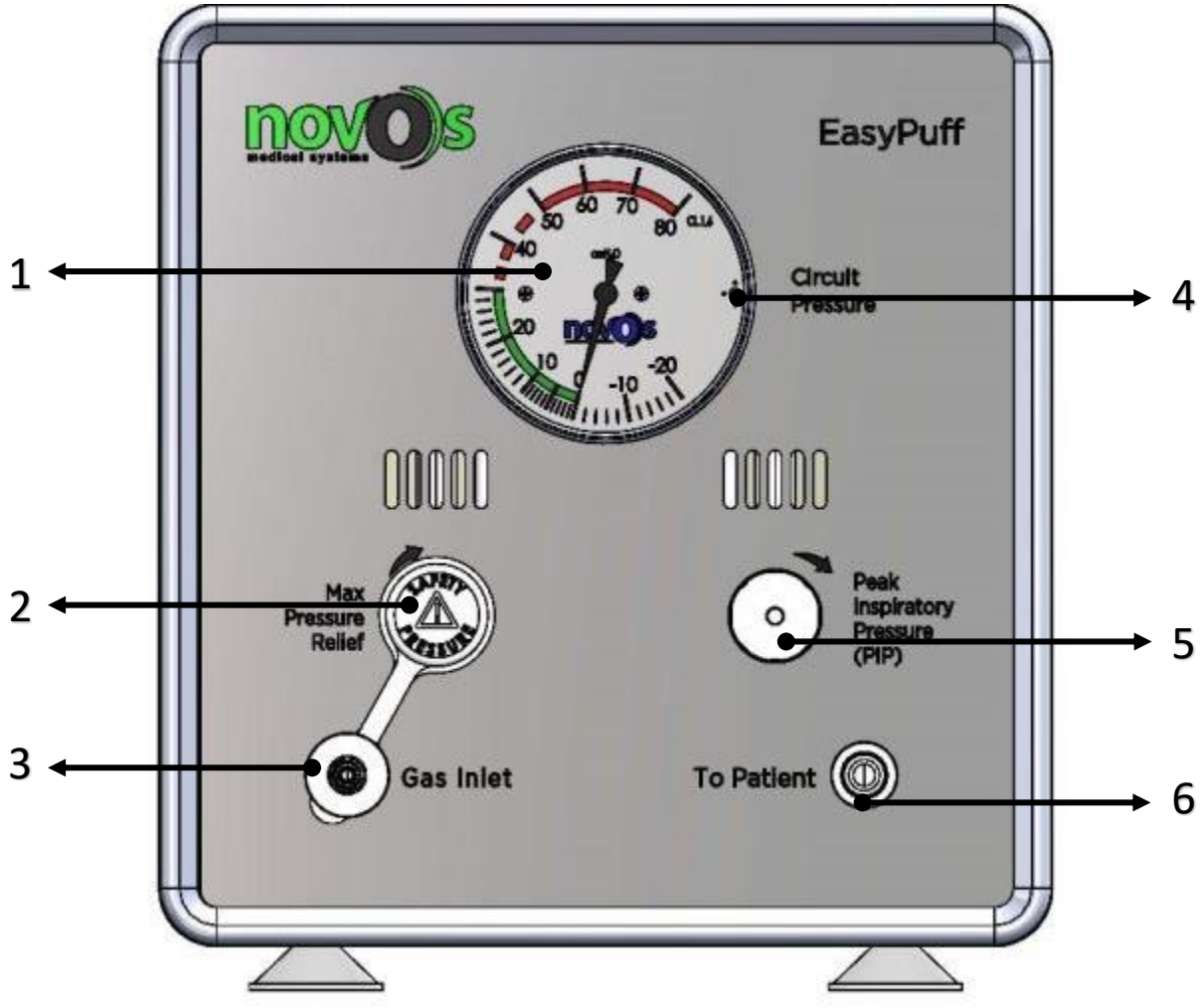
1	Instantaneous Temperature Display	5	Up Arrow
2	Set Temperature Display	6	Unit Switch Button
3	Set Temperature >37 Button	7	Heater Power Indicator
4	Down Arrow		

3.4.5.Lower Button Group



1	Skin Temperature Probe Socket	5	Handsfree Alarm Silencer
2	Examination Light On/Off Button	6	Power Button
3	Keypad Lock/Unlock Button	7	AC Power Indicator

3.5. Easypuff T-Piece Resuscitator (Optional)



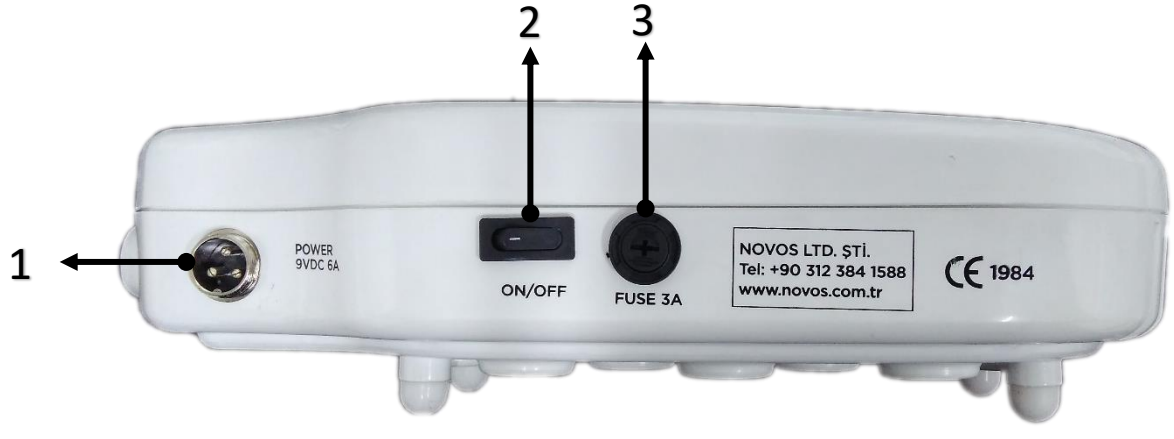
1	Manometer	4	Manometer Calibration Hole
2	Max. Pressure Relief Cap & Knob	5	PIP Setting Knob
3	Gas Inlet Connector	6	T-Piece Patient Circuit Connector

3.6. Bililed Mini Phototherapy Unit (Optional)

3.6.1.Front View

1	Light Intensity Button	3	Start/Pause Button
2	Focus Button	4	Reset Button

3.6.2.Rear View

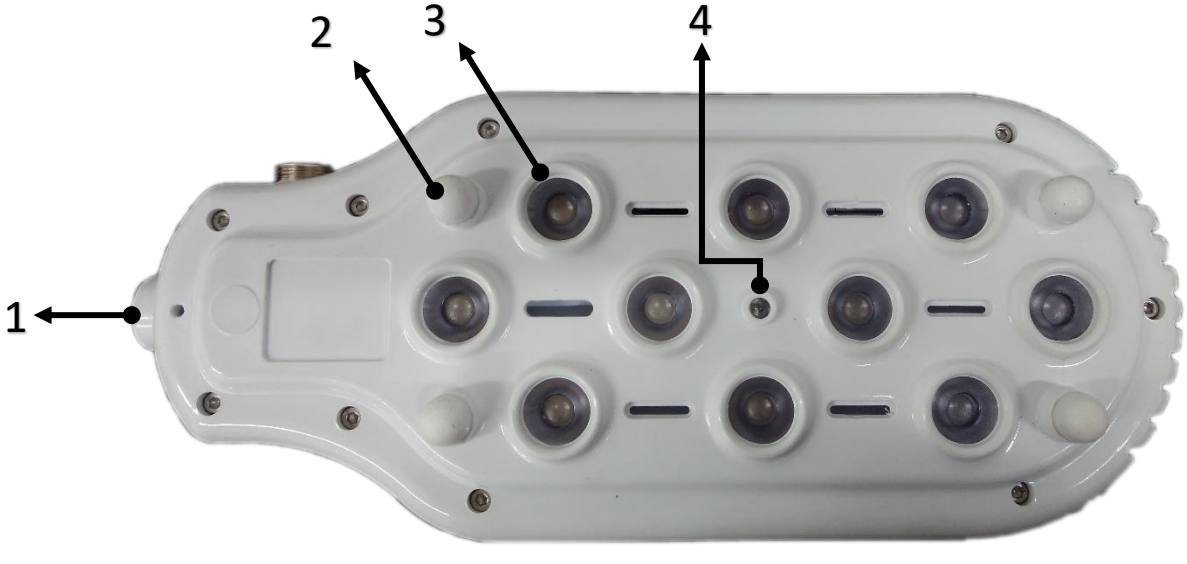


1	Power Input	3	Fuse Holder
2	On/Off Button		

3.6.3.Top View

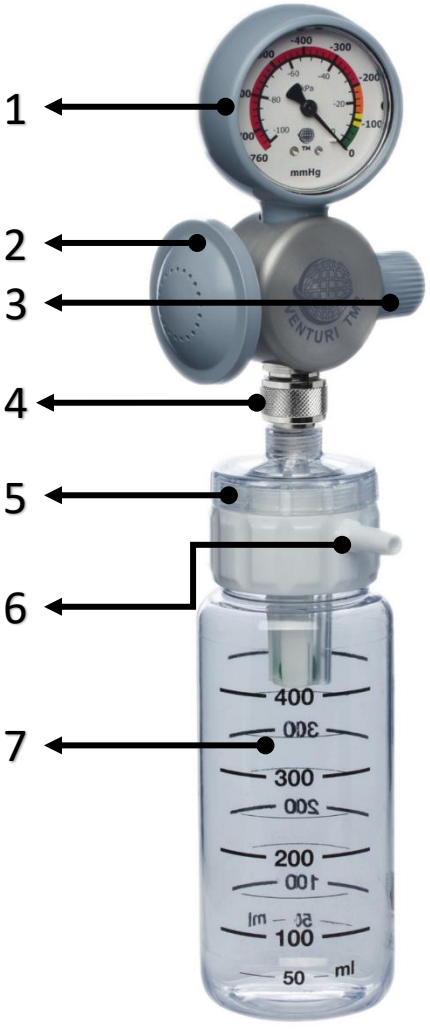
1	Vent

3.6.4.Bottom View



1	Spiral Extension Bar Mount	3	Blue Phototherapy LED
2	Plastic Stand	4	Focus LED

3.7. Venturi TM2 Suction Unit



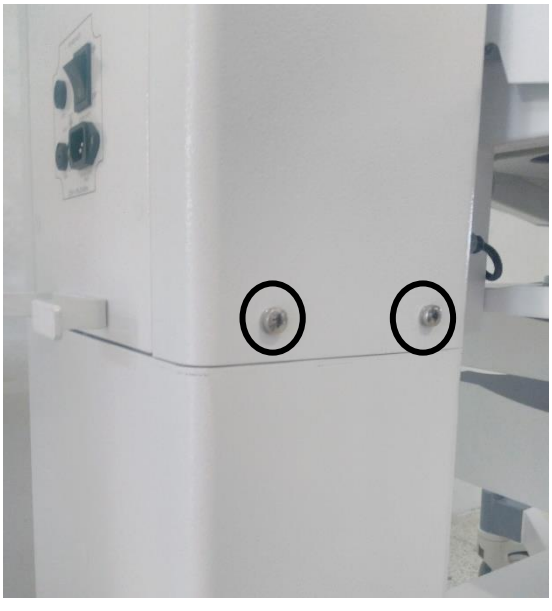
1	Vacuum Gauge Display
2	Silencer
3	Vacuum Regulation Knob
4	Skirt Connector
5	Paper Filter Holder
6	Nipple Outlet
7	Safety Jar (500mL)

4.Preparation

4.1. Unpacking and Assembly

KR-1000 is packed as three main parts, which are the column (upper frame), the main body (lower frame) and the accessories box containing the infant bed and all the accessories.
Upon receiving the device follow the steps below to complete the installation.

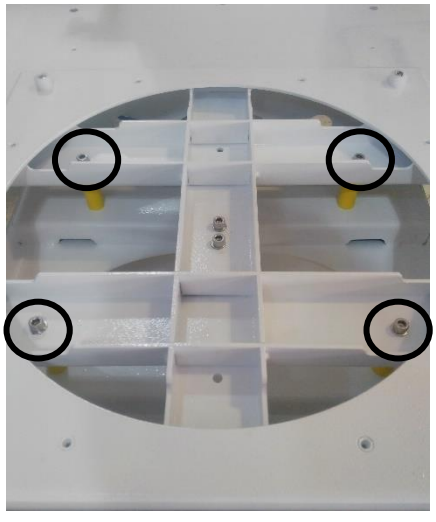
1. Unpack the device and move the main body aside.
2. Lock the wheels.
3. Lift and hold the column over main body contact region.
4. Connect the blue connectors if device has height adjustment feature.(optional)
5. Insert the column on main body.
6. Fix 4 M6x20 Philips Cylindrical Head Screws located at both sides of the column



7. Remove the warmer head fixing plate located at the back.

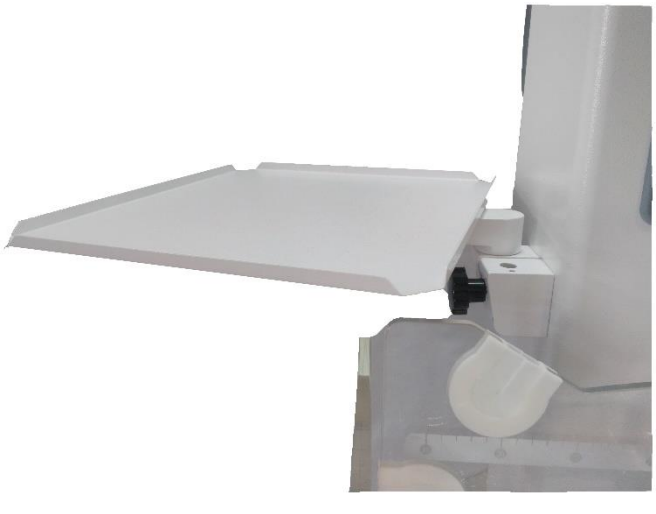
8. Connect scale (black) and trendelenburg (gray) cables to the column.

9. Remove the yellow loadcell protectors located on bassinet by unscrewing the 4 screws indicated below and locate the infant bed on its place.(optional)

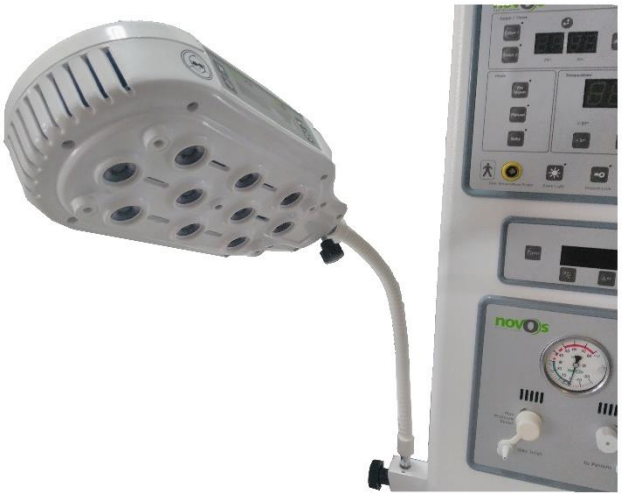


10. Insert the rear side protector

8. Unfold the side protectors.
9. Mount the monitor tray and IV Pole on their location.(optional)



10. Mount the spiral extension bar for phototherapy unit. Fix it with the plastic head screws located at the both end sides.(optional)



11. Mount the extension kit for blender and suction unit. (optional)

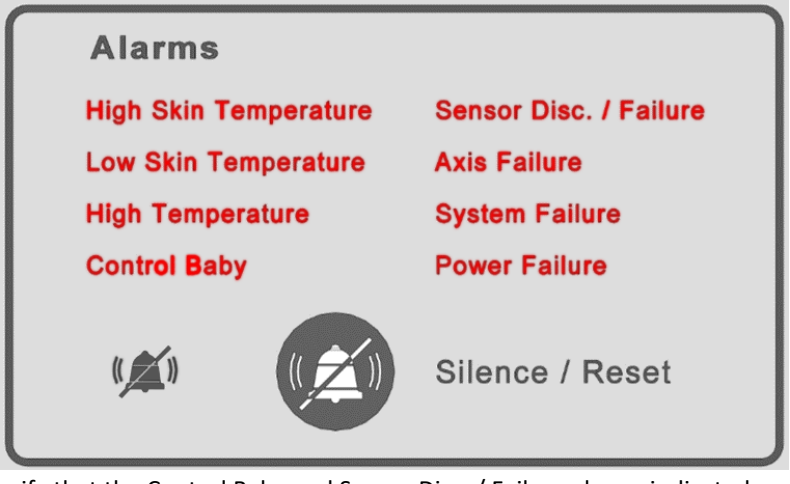
4.2. Alarm System Checkout

Before commencing ensure:

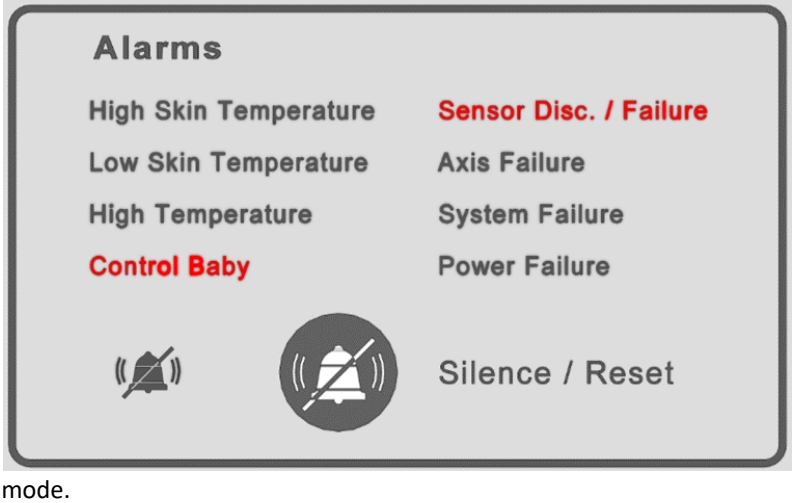
- A baby is not present on the warmer.
- There is no skin sensor connected into the front panel socket.
- The power cord is plugged into an appropriate wall supply outlet.
- The main ON/OFF switch is in ON position.

The following procedure can be used to verify the operation of auditory and visual alarms.

1. Press the Power button on Control Panel.
2. Verify the power-on audible warning sound.
3. Verify that all the alarm indicator lights are temporarily illuminated right after the device is switched on.

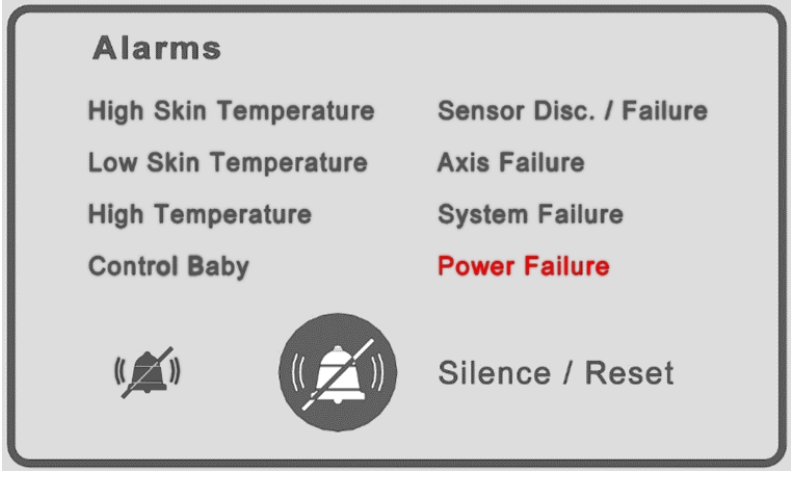


4. After initialization verify that the Control Baby and Sensor Disc. / Failure alarms indicated on Alarms Panel.

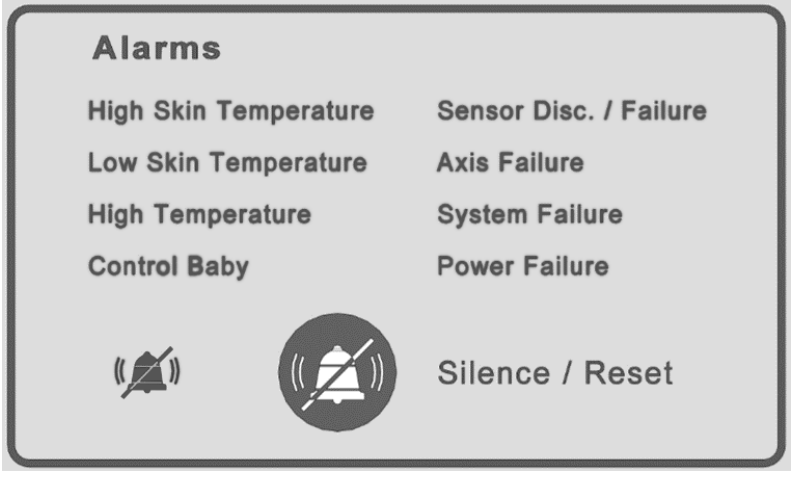


5. Switch to Prewarm mode.
6. Unplug the power cord from the wall supply.

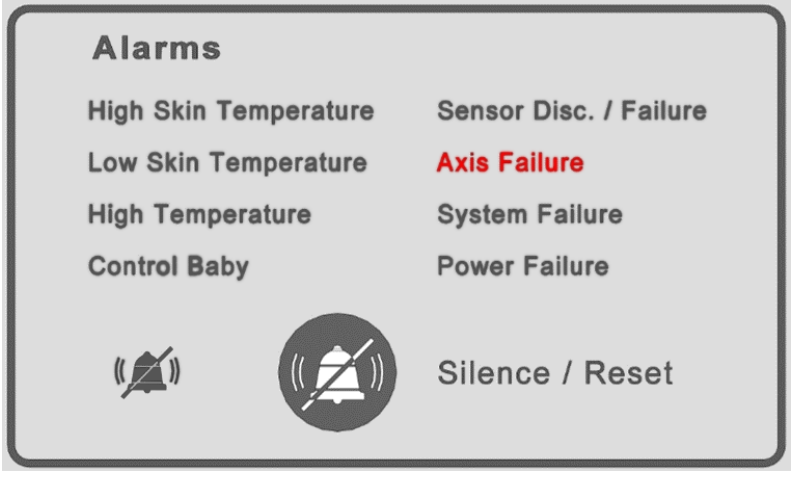
7. Check the Power Failure indicator light flashes and audible alarm sounds.



8. Plug the power cord into the wall supply outlet.
9. Check the warmer re-starts correctly.
10. Connect the skin probe and observe there is no alarm on the alarms display.



11. Verify that skin temperature sensor measurement seen on the control panel.
12. Move the warmer head to any side.
13. Observe the Axis Failure alarm on the alarm indicator display.



14. Press on the Power button to turn off the control panel.
15. Press the Power On/Off switch to the Off position.

If any of the steps does not produce the desired results, please call for service.

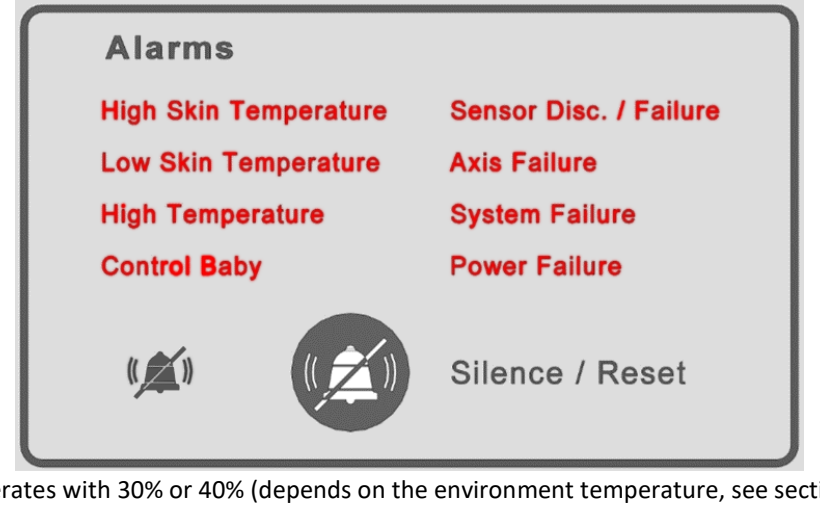
4.3. Control Panel Checkout

Before commencing ensure:

- A baby is not present on the warmer.
- Skin temperature sensor connected into the front panel socket.
- The power cord is plugged into an appropriate wall supply outlet.
- The main ON/OFF switch is in ON position.

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

1. Press the Power button on Control Panel.
2. Verify the power-on audible warning sound.
3. Verify that all the alarm indicator lights are temporarily illuminated right after the device is switched on.
4. Activate the prewarm mode.



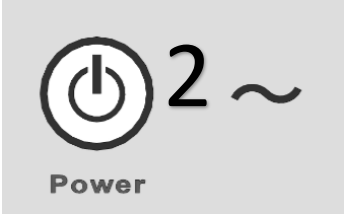
5. Verify that device operates with 30% or 40% (depends on the environment temperature, see section 5.4.1. Operation in Prewarm Mode) heater power.
6. Switch to Manual Mode.
7. Set heater power to 100%.
8. Observe the increase in the heat by positioning your hand under the heaters.
9. Set heater power to 0%.
10. Switch to baby mode.
11. Set target skin temperature to 34°C.
12. Increase the temperature measured by skin probe by rubbing the metal part and observe the auto adjustment of heater power while the measured temperature approaching to the target value.
13. Set target skin temperature to 37°C.
14. Press on >37 button.
15. Set target skin temperature to 38°C.
16. Press on °C/°F button.
17. Observe the temperature unit change in baby temperature display.
18. Press and hold on °C/°F button until you observe AAA on the Baby Temperature display.
19. Observe the measured ambient temperature shown on the Baby Temperature display for a few seconds.
20. Observe SSS on the Baby Temperature display.
21. Press and hold the Timer 1 button.
22. Observe the change in target minute value.

23. Release the Timer 1 button on any target value.
24. Observe the counting process on the timer display.
25. Repeat the steps 21-24 for the Timer 2.
26. Press and hold the Apgar button.
27. Observe the preset timer durations (1, 5, 10, 20 minutes).
28. Release the Apgar button on any target value.
29. Observe the countdown process on the timer display.
30. Press on the Exam Light button.
31. Observe the illuminated examination LEDs positioned under warmer head.
32. Press on Keypad Lock button if the indicator light next to it is not illuminated. (Keypad Lock is not active)
33. Observe the Keypad Lock indicator light is illuminated and all the buttons except that the Keypad Lock do not function anymore.
34. Press on Keypad Lock button again for disabling the Keypad Lock.
35. Position your hand palm near the hands-free alarm silencer detector.
36. Observe the alarm silencer indicator is illuminated.
37. Again position your hand palm near the detector.
38. Observe the alarm silencer indicator turned off.

If any of the steps does not produce the desired results, please call for service.

5.Operation

5.1. Switching KR-1000 On



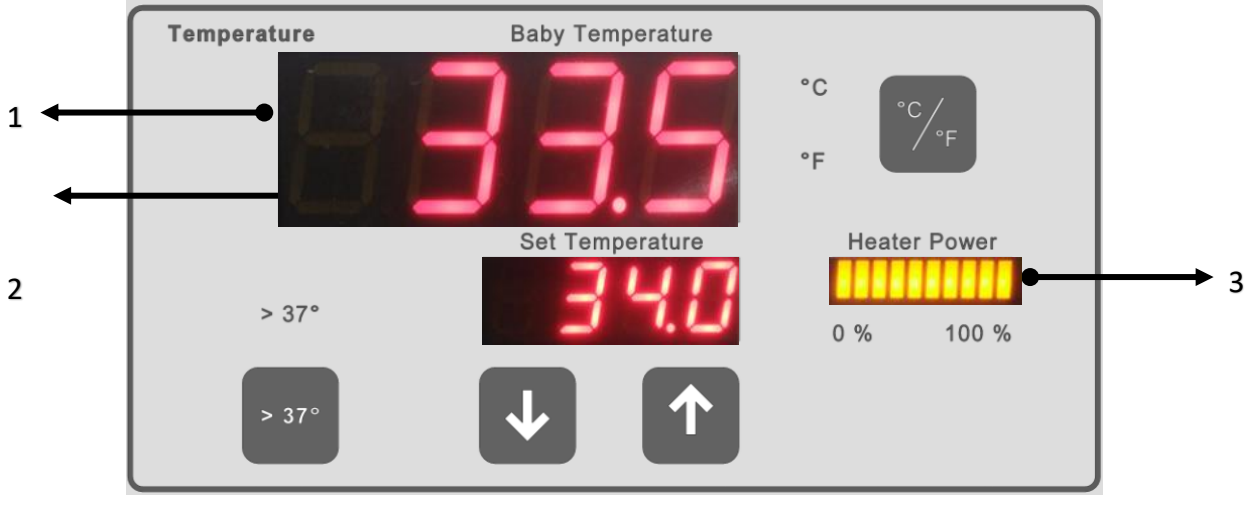
- Plug the power cable.
- Power on the device by using power switch (1).
- Press on the power button (2) located at the lower right corner of the control panel
- A long beep sounds during self-check indicates that the device is powered on properly.

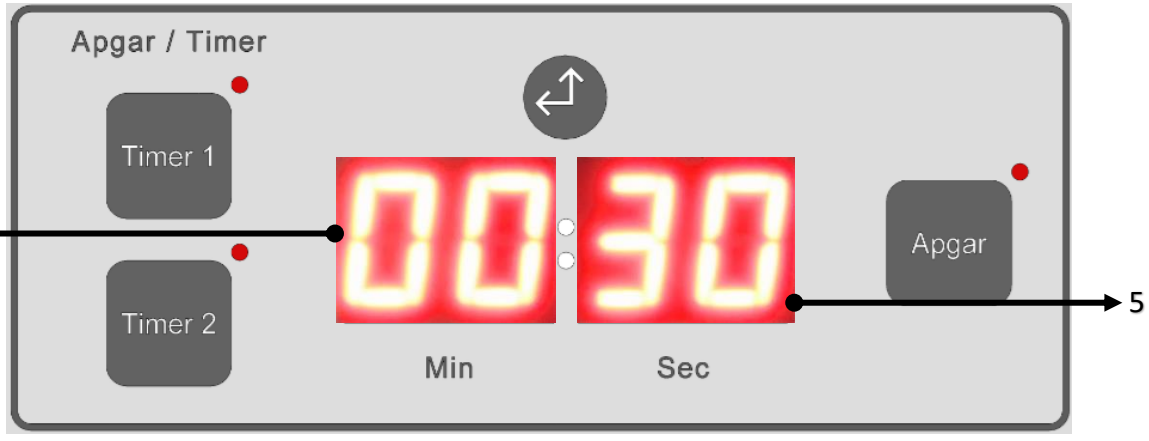
5.2. Control Panel Operation

5.2.1.Displays

There are four displays on the KR-1000 control panel;

1. Baby Temperature
2. Set Temperature
3. Heater Power Percentage
4. Timer Minute
5. Timer Second





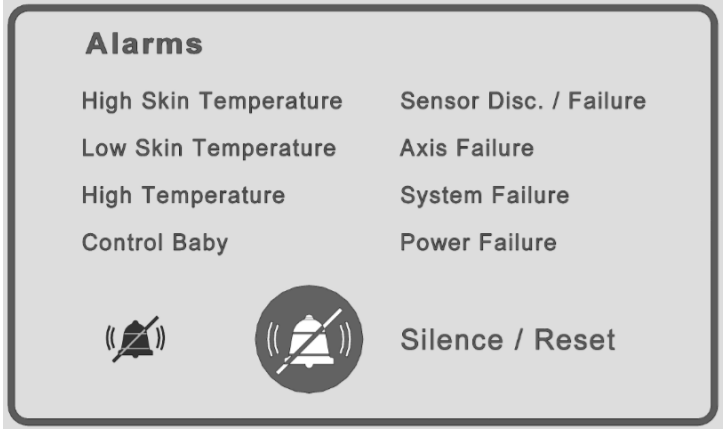
1. **Baby temperature:** shows the measured instantaneous skin temperature of the baby.

   If unit switch button  is pressed.until AAA is seen on the display

   - The ambient temperature is temporarily displayed.
   - A few seconds later SSS is shown on display and measured skin temperature returns.

2. **Set temperature:** Display the target skin temperature in baby mode, and heater power percentage (0-100%) in prewarm and manual modes.
3. **Heater Power Percentage:** Shows the power percentage of maximum power transferred to the ceramic heaters in 10% increments.
4. **Timer Minute and Second:** Shows the set and instantaneous minute, second values respectively.

5.2.2.Alarms



Alarm	Mode	Cause	Action	Alarm Silencer Function
Control Baby	Baby	Heater is energized over 80% for 15 continuous minutes.	Heater power drops to zero.	Bypasses the audible alarm only.
	Manual	N/A	N/A	N/A
	Prewarm	N/A	N/A	N/A
High Skin Temp	Baby	Actual temperature is 0.5°C above the set temperature.	Heater power is decreased automatically.	Bypasses the audible alarm only.
	Manual	Actual temperature is over 38°C	Heater power drops to zero.	Bypasses the audible alarm only.
	Prewarm	Actual temperature is over 38°C	Heater power drops to zero.	Bypasses the audible alarm only.
Low Skin Temp*	Baby	Actual temperature is 0.5°C below the set temperature.	Heater power is increased automatically.	Bypasses the audible alarm only.
	Manual	N/A	N/A	N/A
	Prewarm	N/A	N/A	N/A
High Temp	Baby	Actual temperature is above 39°C	Heater power drops to zero.	Bypasses the audible alarm only.
	Manual	Actual temperature is above 38°C	Heater power drops to zero.	Bypasses the audible alarm only.
	Prewarm			
Sensor Disconnect	Baby	Skin probe is faulty or disconnected.	Heater power drops to zero.	Bypasses the audible alarm only.
	Manual	N/A	N/A	N/A
	Prewarm	N/A	N/A	N/A
Axis Failure	All Modes	Warmer Head is not aligned.	Heater power drops to zero.	Bypasses the audible alarm only.
Power Failure	All Modes	Lack of input power.	Heater power drops to zero.	-

Low Skin Temp*: If the baby's skin temperature is less than the set temperature in Baby mode, the Low Skin Temperature alarm is disabled for 15 minutes or until the baby skin temperature is warmed up to the set temperature.

The 15 minute warm-up period enables safe continuous warming of the baby without nuisance due to audible alarms.

5.2.3.Examination Light

KR-1000 has two angle adjustable examination LEDs which can be activated/deactivated by the Exam Light  button located at the lower button group of control panel.

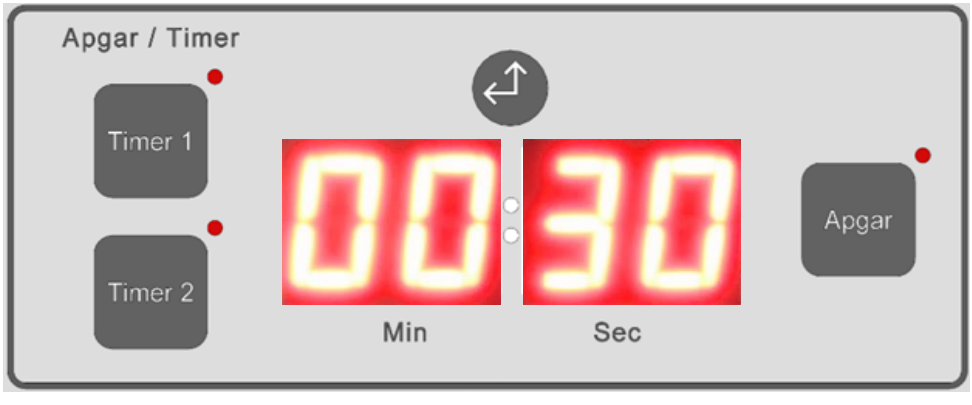
5.2.4.Keypad Lock

If there is no any user input, KR-1000 automatically locks the control panel in order to avoid undesired user input in a 60 seconds of time.

In order to activate/deactivate the keypad lock, press on Keypad Lock button. 

5.2.5.Timers

KR-1000 has three different timers;



- Timer 1: Count-up timer
- Timer 2: Count-up timer for twins.
- Apgar: Countdown timer for evaluating Apgar score of a newborn.

At the end of all timer sessions the device will warn the user with an audible sign.

In order to activate Timer 1 or Timer 2;

- Press and hold on the corresponding timer's button.
- Increasing minute values will be observed on the timer display.
- Release the button when the target minute value is observed on the display.

In order to activate the Apgar timer;

- Press and hold on the Apgar button.
- Apgar timer has presets of 1 5 10 20 minutes. Release the button when target minute value is observed on the display.

5.3. Sensors

5.3.1.Temperature Sensors

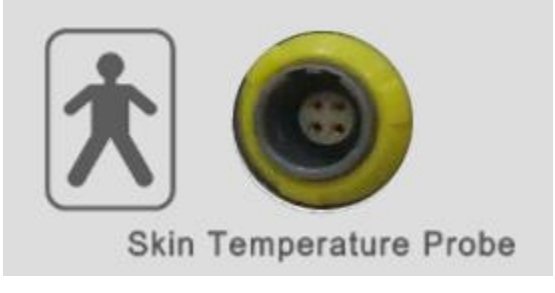
There are one air temperature sensor located at the back of the device and one double thermistor skin temperature sensor available in KR-1000.

Skin and Air Temperature Probes

Yellow Skin Probe containing two NTCs must be connected to the control panel in order to adjust the power of the heater resistance when the baby mode is activated. KR-1000 controls the baby's skin temperature with respect to the temperature value returned from this sensor in baby mode.

Skin probe must be attached to the abdomen region of the infant.

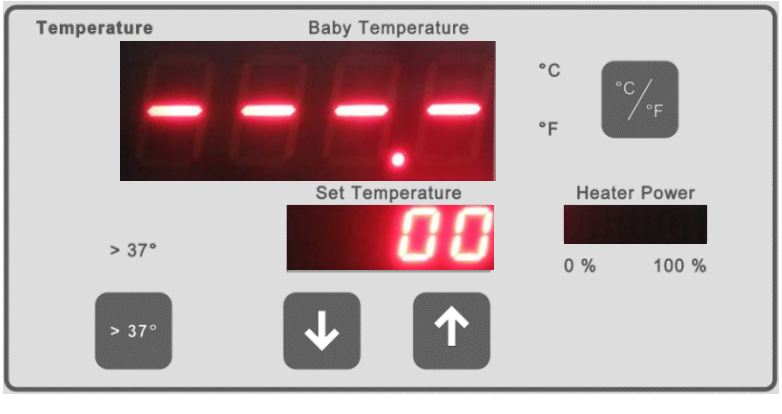
Skin probe must be connected to control panel when the device is being operated on Baby Mode.



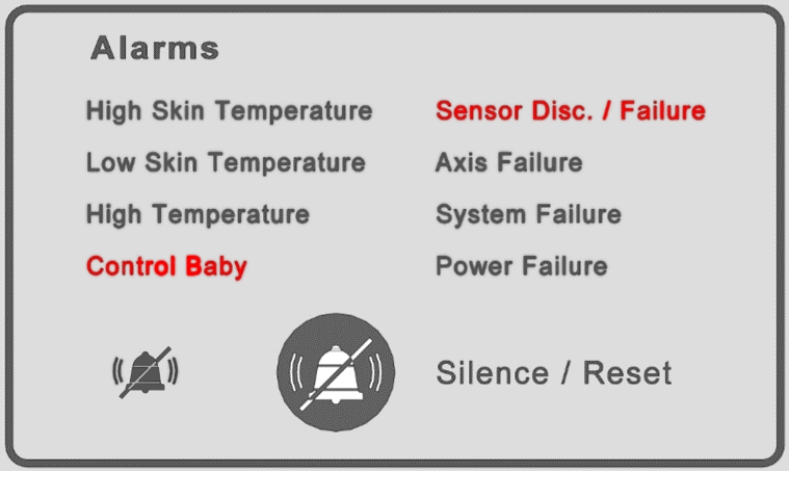
WARNING!
Avoid applying excessive force to the skin temperature probe socket during mounting/dismounting processes.

If a skin probe is not connected to the control panel;

- A dashed line will be seen on the instantaneous temperature display.

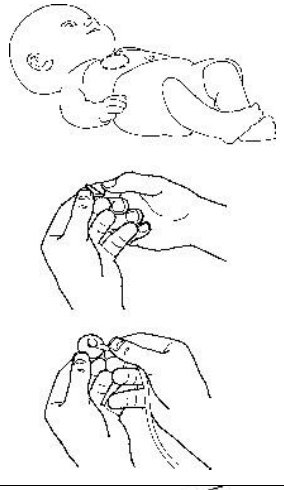
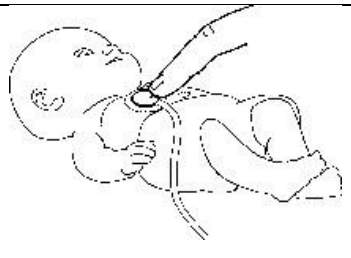
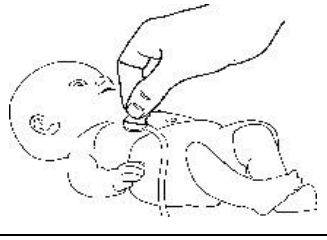


- Sensor Disc. & Control Baby Alarms are triggered.



The Air Probe must be connected at the back of control panel to measure the air temperature. Unlike the skin probe, the air probe must be in its position regardless of the operating mode.

5.3.2.Attachment/Detachment of Skin Probe

Attachment of Skin Probe 	• Gently clean and dry the baby's skin where you intend to place the skin sensor. • Remove the backing paper from the sensor cover. • 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 and sensor cover by keeping the metal side in contact with the baby's skin. • Gently press and hold the edges of the sensor cover to allow the hydrogel adhesive to adhere to the baby's skin
Detachment of Skin Probe 	• Gently lift up the edge of the sensor cover. If required moisten the edges of the sensor cover using sterile water and dampened cotton swab. • Gently peel the sensor cover and skin sensor from the skin surface. Take care not to pull directly on the skin sensor wire.

5.4. Operating Modes

WARNING!
Strictly follow this User Manual. Any use of the product requires full understanding and strict observation of all portions of these instructions. This equipment is only to be used for the purpose specified under "Intended Use". Observe all WARNINGS and CAUTIONS as rendered throughout this manual and on labels on the equipment.

WARNING!
The use of this device requires continuous supervision of the infant by trained nursing personnel in order to avoid immediate corrective action in situations with a risk of patient injury.

WARNING!
Use of electrosurgical units or other electrical field radiating equipment can affect the operation of the Warmer. Keep the patient probe lead as far away as possible from electrosurgical cables. Do not allow excess electrical cables to be laid on the bed platform. Use of electrosurgical units or other instruments which radiate electrical fields can cause indirect heating, by several tenths of a degree of the skin temperature probe due to absorbed electrical energy. When using these devices near the radiant warmer, operate the Warmer in manual mode for maximum safety.

WARNING!
The use of phototherapy equipment may raise the patient's temperature.

WARNING!
Radiant warmers increase an infant's insensible water loss. Take appropriate measures to maintain the patient's fluid balance while caring for them in a radiant warmer.

WARNING!
Do not use the Warmer in the presence of flammable anesthetics; a possible explosion hazard exists under these conditions.

WARNING!
Radiant energy can adversely affect blood components. When using intravenous tubing systems for delivery of blood components to patients occupying a warmer, shield any tubing with aluminum foil.

WARNING!
When using a radiant warmer, change the patient's diapers frequently. Radiant energy causes more rapid urine evaporation, and may lead to inaccurate urine diagnosis test analysis and inaccurate weight measurements.

WARNING!
Do not touch the protective grill under the radiant heater or the top of the heater assembly. These surfaces may be hot and a burn could result

WARNING!
Always set the caster brakes before placing a patient in the warmer.

5.4.1.Operation in Baby Mode

KR-1000 starts operation in Baby mode on each startup. In baby mode KR-1000 provides the stable control of baby's skin temperature by automatically adjusting the heater power to compensate the heat loss due to varying physiological and environmental conditions.

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

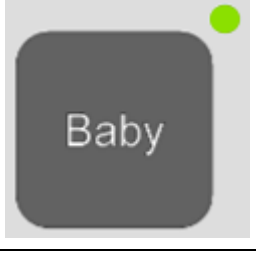
- Attach the skin probe to the infant's skin as shown in Section Attachment/Detachment of Skin Probe.

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

- Press on the Baby button on Control Panel.

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

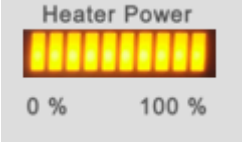
- Active mode indicator LED on the upper right corner of Baby button will turn green.

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

- Adjust the set temperature by using the up & down arrows.

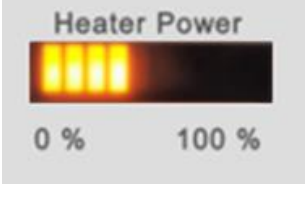
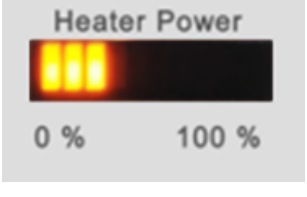
</td><td> 
</td></tr>
<tr><td>

- Microcontroller sets the heater power automatically.

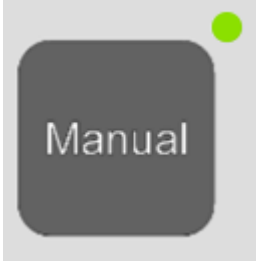
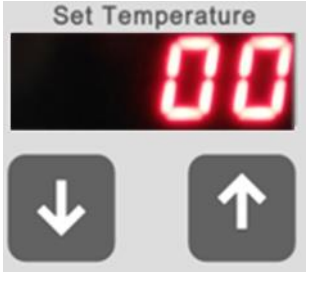
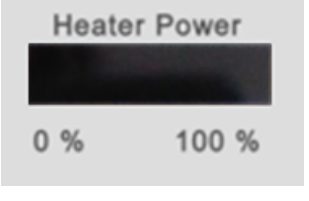
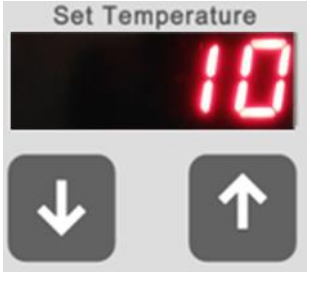
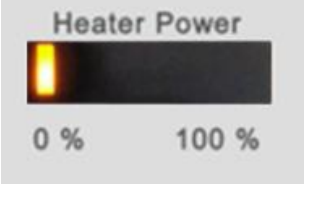
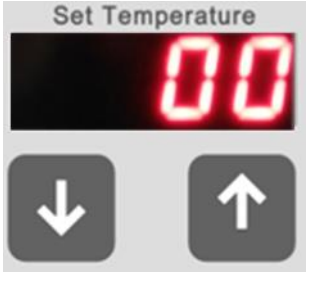
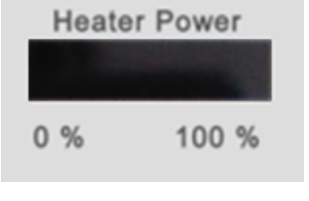
</td><td> 
</td></tr>
</table>

5.4.2.Operation in Prewarm Mode

If it is known beforehand that a baby is to arrive in the NICU, turn on KR-1000 at least 15 minutes before placing the baby and switch it to prewarm mode so that the baby does not lie on a cold surface initially.

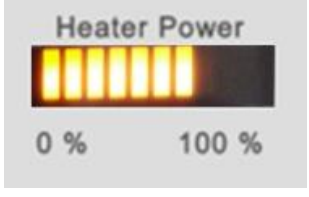
• Press on the Pre Warm button on Control Panel.	
• Active mode indicator LED on the upper right corner of Pre Warm button will turn green.	
• Microcontroller sets the heater power to 40% if the air temperature is lower than 25°C.	
• Or microcontroller sets the heater power to 30% if the air temperature is higher than 25°C.	
• The device works continuosly without any interrupt in Prewarm Mode.	

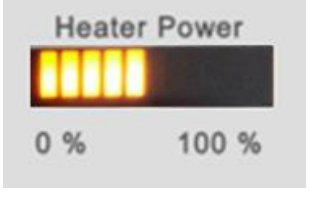
5.4.3.Operation in Manual Mode

• Press on the Manual button on Control Panel.		
• Active mode indicator LED on the upper right corner of Manual button will turn green.		
• In Manual Mode the heater power is set by the user via up & down arrows on Temperature Settings section of Control Panel.		
• Press on Up arrow to increase the heater power percentage.		
• Press on Down arrow to decrease the heater power percentage.		

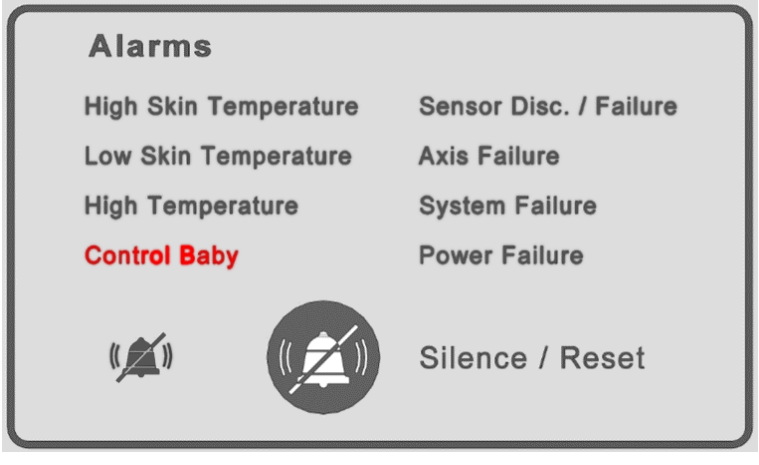
WARNING!
If the device is working with a power percentage over 50%, the power level will automatically be dropped to 50% after 15minutes as a safety precaution.

After 15 minutes

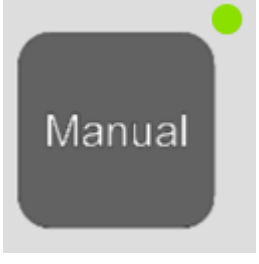




- After the heater power automatically drops to 50%, Control Baby Alarm is triggered.



- Press on Manual button again to reset the previous heater percentage level.



5.5. Bassinet

The bassinet of KR-1000 provides a comfortable thermo-insulated environment for the infants. Infant bed and an X-Ray tray is located above bassinet.

5.5.1.Side Protectors

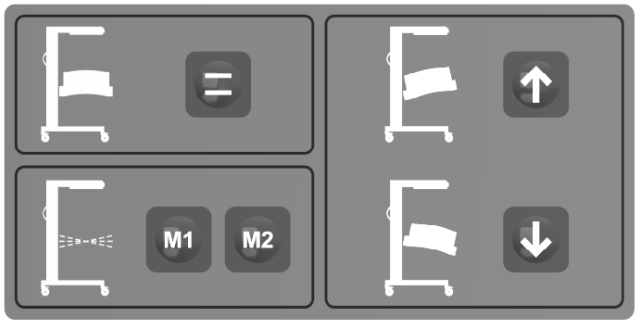
KR-1000 has 3 foldable side protectors and 1 rear protector with name tag. All these side protectors hosts a ruler for measuring the infant development. Front and rear side protectors have totally 8 grommets for tubing and sensor cables.

In order to open the side protectors;

- Slightly push the protector in the arrow direction
- Fold it down slowly.

5.5.2.Trendelenburg

KR-1000 has the electronic trendelenburg with 2 memory option. The whole bassinet can be tilted up to ±12^{o} and can easily be aligned horizontally by reset function.



- Press and hold on up arrow for applying trendelenburg position.
- Press and hold on M1 button to save the desired position to the memory 1 slot.
- Press on down arrow for applying the reverse trendelenburg position.
- Press and hold on M2 button to save the desired position to the memory 2 slot.
- Press on reset button to align the bassinet horizontally.

5.5.3.Rotational Bed (Optional)

KR-1000 features the 360^{o} rotational bed as an option.

In order to rotate the bed;

- Open all foldable side protectors (left, right and front).
- Extract the rear side protector.
- Rotate the mattress as desired.

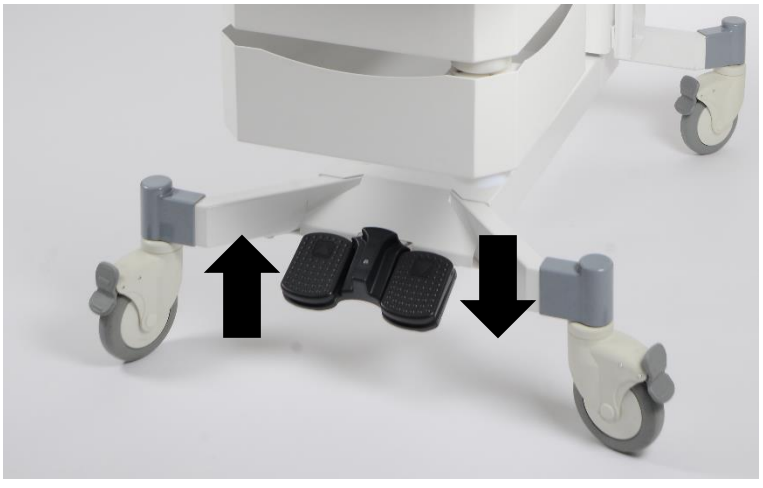
5.5.4.X-Ray Tray

X-Ray cassettes with a size of 14x14” max. can be placed into X-Ray Tray of KR-1000.

- Open the front side protector.
- Pull the X-Ray tray to place the cassette.
- Push the X-Ray Tray all the way in until you sense that it is settled on its middle position.

WARNING!
Please make sure that the X-Ray tray is settled to its position properly in order to avoid undesired movements during trendelenburg.

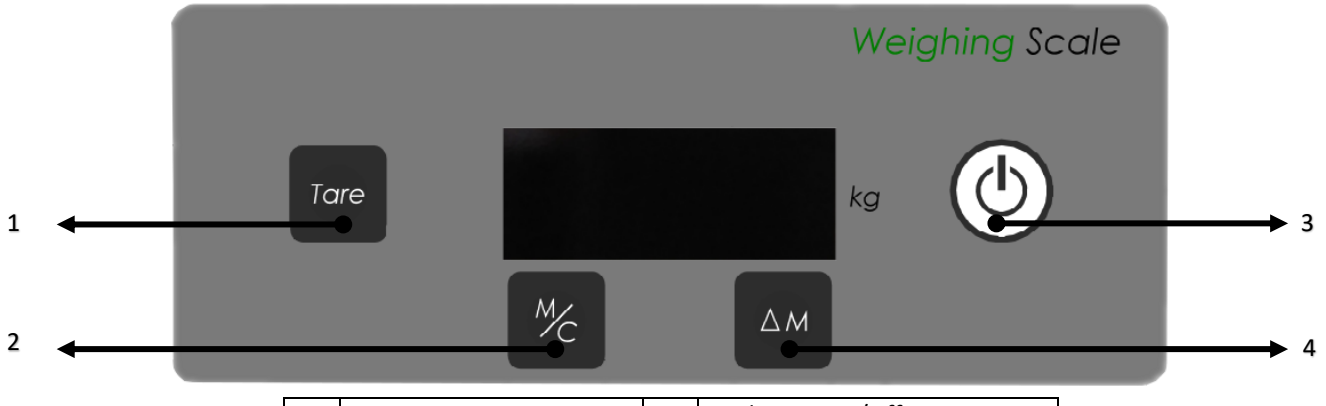
5.5.5.Height Adjustment (Optional)



- Press and hold on footswitch at the left side to increase the height.
- Press and hold on to footswitch at right side to decrease the height.

5.6. Scale Control Unit (Optional)

KR-1000 has an optional scale by which the baby weight can be measured and be saved up to 6 records. Weighing Scale can also show the difference between consecutive records.



1	Tare Button	3	Scale Unit On/Off Button
2	Memory/Clear Button		Weight Difference Button

Smart Tare Feature: KR-1000 Scale Control Unit has *Smart Tare* feature which makes taring be an easy process. By the help of *Smart Tare*, taring process can be done without any user interrupt. If a load of 200g (or above) is lift from the bassinet, *Smart Tare* process starts automatically.

WARNING!
Pay attention if an object having a weight of 200g or above is lifted from bassinet, then Scale Unit starts the tare process even the baby is still on the bassinet. This may result in wrong measurements.

Before weighing the baby use *Smart Tare* by lifting the baby for each time.

WARNING!
The maximum weight capacity of the scale unit is 10kg.
Do not place any object exceeding the maximum weight limit over bassinet.

5.6.1.Weighing Process

WARNING!
During the weighing process pay attention there is no physical contact to the bassinet from the user and make sure that the bassinet is in horizontal position.

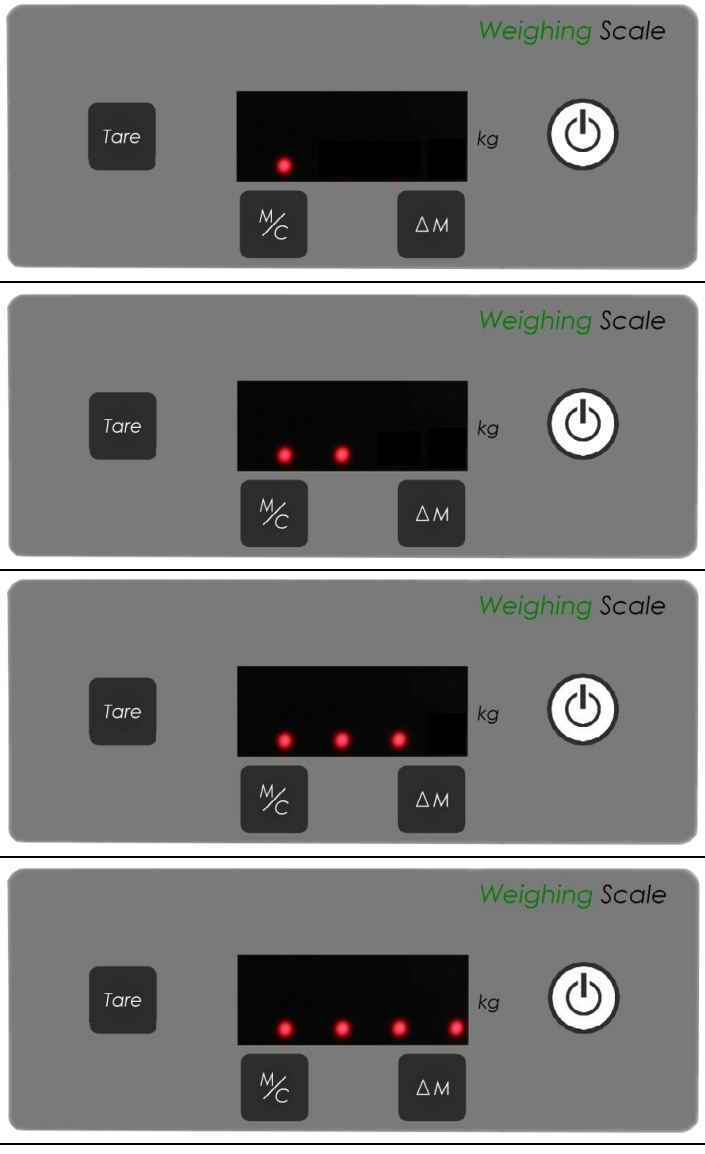
WARNING!
Remove all unnecessary objects placed on the bassinet.

- Press on Scale Unit On/Off Button.

- Wait for Scale Unit initialization.
  Scale Unit starts by self-taring on each startup.

  Note: Increasing number of dots mean that the taring is in progress.

WARNING!
Do not touch or place anything to the bassinet during the taring process.



If the baby is not placed on the bassinet; 1. Press on Tare button and wait for taring process to be finished. If the baby is on the bassinet; 2. Lift the baby from the bassinet and wait for *Smart Tare* handling the tare process automatically.	
3. Locate the baby on the bassinet and wait for the measurement value seen on display is stabilized.	
4. After the measurment has been done you may save it by following the steps described in section below.	

5.6.2. Weight Measurement Records

KR-1000 Scale Unit can save up to 6 measurements and show the differences between these records.

5. After a stable value is observed on the display, press on Memory/Clear button once to save the measured weight value.	
6. Scale unit saves the measurement data to the first available slot.	
7. After 6th record new measurements are overwritten to the last slot and 6. rEC is shown on the display for each new records.	

Scale unit also provides the differences between previously taken records.

Let the 6 measurements be 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

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

8. Press on ΔM button and observe the weight differences as explained above.	 
9. Press and hold on Memory/Clear button to erase previously saved data.	

5.6.3.Scale Calibration

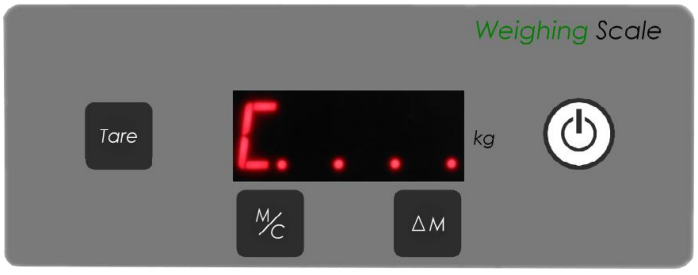
KR-1000 needs to be calibrated at the first installation or when the “CAL” warning is seen on the scale display.

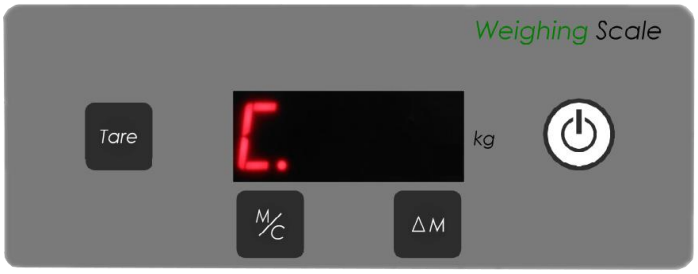
Calibration process is composed of two steps which are 0 kg and 5 kg calibration. Therefore a calibrated 5kg weight is needed to complete calibration process successfully.

WARNING!
During the calibration process pay attention there is no physical contact to the bassinet from the user and make sure that the bassinet is in horizontal position.

WARNING!
Remove all unnecessary objects placed on the bassinet and the mattress.

10. Press and hold the “Tare” button for 3 seconds.	

11. Observe C0 zero calibration indicator on the display.	
12. Press the “Tare” button to start the zero calibration and see the increasing number of dots next to character ‘C’.	   
13. After zero calibration is finished. See “C 5” 5kg calibration indicator on the scale display	

14. Put a calibrated 5kg weight on the center of the mattress.	
15. Press the “Tare” button to start the 5kg calibration	
16. Observe the increasing number of dots next to character ‘C’.	   
17. After 5kg calibration 5.000 kg ±1g is shown on the display. This means that the calibration is completed successfully.	

6. Easypuff™ T-Piece Resuscitator (Optional)

6.1. Application

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

Easypuff is an infant resuscitator in which the user can specify the exact amount of pressure of the air/oxygen mixture to be transferred to the infant's lung.

On the contrary of manual resuscitation with BVM, since the highest pressure applied to lungs during inhalation is known, risk of barotrauma is minimized by the help of Easypuff.

WARNING!
This device may only be used by properly trained personnel under the supervision of qualified medical personnel familiar with the currently known risks and benefits of using a resuscitator.

6.2. Operator's Responsibility for Patient Safety

Since the device is used in urgent situations, it is strongly recommended that the medical personnel must be well trained and have the confidence in their ability to handle these tasks. It has to be guaranteed that all users of this device have been sufficiently trained in resuscitation techniques.

Easypuff T-Piece Resuscitator must only be used after checking that correct pressures will be delivered to the baby.

Inspect the parts of equipment and ensure it has not physical damage. Never operate Easypuff T-Piece Resuscitator if it has damaged part or does not seem to operate properly. Contact authorized technical service of NOVOS.

An alternative means of resuscitation (bagging) must be available.

6.3. Restrictions of Use

EasyPuff T-Piece Resuscitator can only be connected to flow-regulated oxygen or oxygen/air mixture supplied by a blender with flowmeter output.

WARNING!
Never use the device with a flow rate exceeding the 15L/min limit.

The device is designed to be used on infants with a maximum weight of 10kg.

For connection to flow-regulated oxygen or oxygen/air mixture only, the allowable input gas flow rate is 5-15 L/min. But the recommended operating flow is 8 L/min. Input flow ranges are circuit specific, refer to circuit User Instructions.

The Max Pressure Relief can be adjusted up to a nominal 80 cmH2O [mbar], and should only be done in exceptional circumstances by persons trained in infant resuscitation. Do not attempt to set the Max Pressure Relief above 80 cmH_2O [mbar]

NOVOS cannot warrant or endorse the safe performance of third party accessories. Only use NOVOS original parts and accessories. Serious harm to the patient and device may result from the use of unauthorized parts or accessories

When the device is in use, users should ensure that;

- Naked flames
- Flammable anesthetics
- Combustible gases
- Cleaning substances that may cause combustion
- Sources of ignition are not present in the environment.

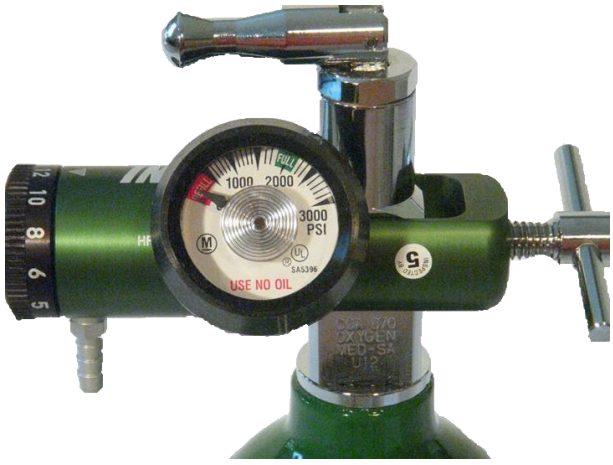
6.4. Preparation

The following procedure should be carried out prior to every use of the Easypuff to ensure that the device is functioning correctly.

1. Check Manometer

Manometer should reveal zero with no gas flow. If not, the manometer requires calibration (Refer to Service Manual)

2. Connect a Gas Supply:
Examples of gas supplies are shown below;

Oxygen Supplies	
	
Flow Regulated Oxygen Cylinder	Wall Type Oxygen Flowmeter

Air/Oxygen Mixture Supplies	
	
Flowmeter System	Air/Oxygen Blender

It is recommended to set the total flow output as 8 lpm. If a flowmeter system is used then beware of the total flow output of air/oxygen mixture does not exceed the 15 lpm. For example, setting both the oxygen and air flows to 4 lpm will give you a flow rate of 8 lpm in total.

WARNING!
Never use the device with a flow rate exceeding the 15L/min limit.

Below table indicates the flow ratio that should be set to obtain the desired oxygen concentration with a flowmeter system.

Total Flow LPM	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			

WARNING!
Please pay attention not to harm the gas inlet while connecting the gas supply to Easypuff. A gentle force will be enough to fit the connector properly.

3. Connect T-Piece Circuit

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

4. Check Flow Settings

- Adjust the gas supply to desired flow rate between 5-15 lpm.
- 8 lpm is the recommended flow rate.

Note: Ensure the oxygen concentration of an oxygen/air supply is either monitored using an oxygen analyzer or preset using oxygen/air flow rate graphs.

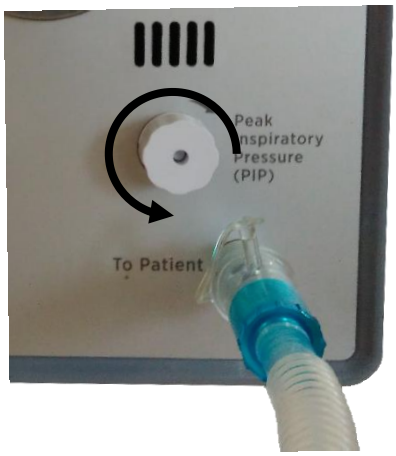
5. Check Max Pressure

- Occlude PEEP* cap using your thumb and turn PIP** control fully clockwise, until the knob does not turn anymore.

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

- Remove the protective cap and adjust maximum pressure control knob to set the desired maximum pressure.
  Note:
  - The factory setting of the Max Pressure Relief is 40 cmH2O [mbar].
  - The Max Pressure Relief valve acts as an overall limit on the achievable circuit pressure. Resuscitation above 40 cmH2O [mbar] cannot be achieved unless the Max Pressure Relief valve is adjusted.

6. Set PIP Value



While occluding the PEEP cap, turn PIP control knob counter-clockwise until the desired peak inspiratory pressure is set.

7. Set the PEEP

Remove your thumb from the PEEP cap and adjust the PEEP value by rotating the PEEP cap.

6.5. Operation

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

WARNING!
Never use the device with a flow rate exceeding the 15L/min limit.

2. Choose an appropriate sized neonatal resuscitation mask and connect it to T-Piece circuit. Place the mask over the baby's mouth and nose. **or** fit T-Piece to the endotracheal tube.

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

6.6. Cleaning and Maintenance

- Clean external surfaces of the Easypuff Infant Resuscitator using a damp cloth and mild soapy water or Isopropyl Alcohol.
- Dry all surfaces after cleaning with a clean soft cloth or paper towel.
- The Easypuff should require minimal servicing or maintenance when used under normal conditions.

7. Bililed Mini™ Phototherapy Unit (Optional)

7.1. Application

BILILED MINI is routinely used in treatment of neonatal hyperbilirubinemia, where the patient is submitted to an exposure of concentrated radiation in the blue spectrum of visible light during a time to be determined by the attending physician depending on the case.

Functions:

- Hour and date info
- 5 levels adjustable intensity
- Therapy time info
- Lamp usage time info
- Focusing light

7.2. Operator's Responsibility for Patient Safety

WARNING!
BILILED MINI should only be used by properly trained personnel under the supervision of qualified medical personnel familiar with the currently known risks and benefits of using a phototherapy device.

WARNING!
The use of this device requires continuous supervision of the infant by trained nursing personnel in order to provide immediate corrective action in situations with a risk of patient injury.

WARNING!
Eyes of the patient lie down near the phototherapy must be protected by using an eye protector.

WARNING!
The fluid balance of the patient may be altered due to the use of phototherapy.

WARNING!
Patient's serum levels of bilirubin should be regularly measured.

WARNING!
Newborns submitted to NOVOS BILILED MINI as to any other type of phototherapy, will require an adequate fluid supply and eyes protection during treatment, in addition to the routine nursing and medical assistance.

WARNING!
Never cover phototherapy unit with cloths, blanket, aluminum foil or other materials with the intention to boost the phototherapeutic effect. It may cause to temperature rising and/or obstruct to irradiance of light.

WARNING!
NOVOS cannot warrant or endorse the safe performance of third party accessories for use with BILILED MINI™ phototherapy. Only use original NOVOS accessories and parts with BILILED MINI™ phototherapy.

WARNING!
Infant temperature must be monitored with particular care during phototherapy. Absorption of light through the infant's skin will supply heat to the patient which may increase central temperature.

7.3. Restrictions of Use

WARNING!
BILILED MINI has not been established for using inside of incubators and it should not be exposed directly heat coming from radiant warmer.

Risk of burn! Risk of explosion upon O2!

WARNING!
NOVOS medical equipment conforms to the interference immunity requirements laid down in product-specific standards or in EN 60601-1-2(IEC 60601-1-2). However, depending on the design of a mobile phone and the use situation, field strengths exceeding the values generated in the immediate vicinity of mobile phones, thereby causing interference and malfunctions.

WARNING!
If any part of power supply is directly in contact with the baby's body, do not use BILILED MINI! Power supply of operating unit may heat up and this overheating may cause burn of patient skin.

WARNING!
DANGER! Risk of explosion if used in the presence of flammable anesthetics. This device is neither approved nor certified for use in areas where combustible or explosive gas mixtures are likely to be found.

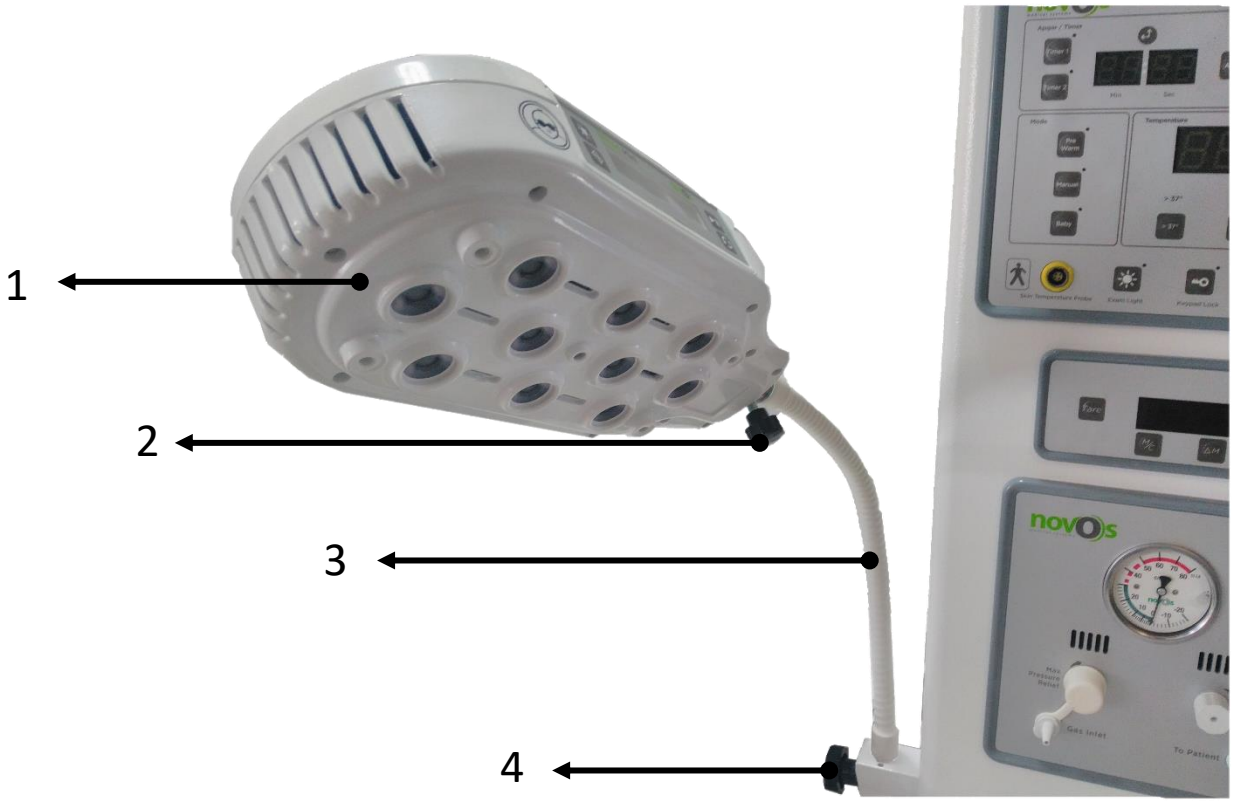
7.4. Preparation

7.4.1.Positioning of Bililed Mini

WARNING!
BILILED MINI has not been established for using inside of incubators and it should not be exposed directly heat coming from radiant warmer.

Risk of burn! Risk of explosion upon O2!

WARNING!
When used with a radiant warmer, care must be taken to angle the light and position it to the side of the heat source. The enclosure must be placed no further than 30 cm from the baby and out of the path of the radiant heat source.



1	Bililed Mini
2	Plastic Headed Screw No1
3	Spiral Extension Bar
4	Plastic Headed Screw No 2

1. Loosen the ***Plastic Headed Screw No 2*** and mount the ***Spiral Extension Bar***.
2. Tighten the ***Plastic Headed Screw No 2*** and fix the ***Spiral Extension Bar***.
3. Loosen the ***Plastic Headed Screw No 1*** and mount the ***Bililed Mini***.
4. Tighten the ***Plastic Headed Screw No 1*** and fix the ***Bililed Mini***.
5. Position the ***Bililed Mini*** so that;
    a. It is not exposed by the direct heat.
    b. The distance between the ***Bililed Mini*** and the infant is at most 30cm.

7.4.2.Connection of Power Supply

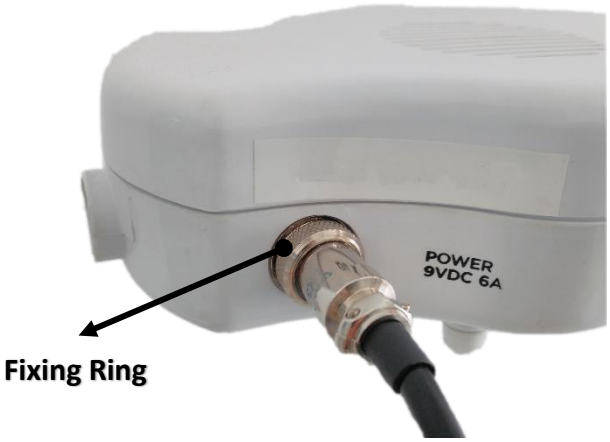
WARNING!
If any part of power supply is directly in contact with the baby's body, do not use BILILED MINI! Power supply of operating unit may heat up and this overheating may cause burn of patient skin.

WARNING!
Verify that power cord is connected properly to the device and all necessary measurements are supplied against disconnection.

WARNING!
If a proper grounding system is not available, the equipment should not be used. Do not use extension cord or multiple plugs.

Bililed Mini Power Adapter has a holder for attaching it to the back of the KR-1000.

- Plug the AC cable to the adapter
- Place the adapter to its holder
- Hang the adapter holder on its location.
- Plug the DC Power cable to the Bililed Mini and lock the connector by turning the fixing ring clockwise.



7.5. Operation

7.5.1.Normal Operation

<table>
<tr><td>18. Switch on the device by using the On/Off button located at the rear side.</td><td> 
</td></tr>
<tr><td rowspan="3">19. Wait for device initialization.</td><td> 
</td></tr>
<tr><td> 
</td></tr>
<tr><td> 
</td></tr>
<tr><td>20. Press on the Light Intensity Button to switch between intenstiy levels.
21. Set the desired intensity level from 1-5.</td><td>  </td></tr>
<tr><td>22. Press and hold on the Focus Button and position the device while as described in Positioning of Bililed Mini section.</td><td>  </td></tr>
<tr><td>23. Press on Start/Pause Button to start the therapy.</td><td>  </td></tr>
</table>

<table>
<tr><td>24. Therapy time can be monitored from the upper right corner of the screen.</td><td> 
</td></tr>
<tr><td rowspan="2">25. Press on Start/Pause Button to pause the therapy.
26. Press on the same button resume the therapy.</td><td>  </td></tr>
<tr><td> 
</td></tr>
<tr><td>27. Press on Reset Button to terminate the therapy and reset the therapy timer.</td><td>  </td></tr>
</table>

7.5.2.Adjusting the Date/Time Settings

28. Switch on the device by using the On/Off button located at the rear side.	
29. Press on both ***Light Intensity*** and ***Focus*** buttons simultaneously.	
Button **Function**  Increase the selected value.  Decrease the selected value  Switch to next position.	
30. After setting the minute value press on ***Reset Button*** one more time to return to main screen.	

7.6. Cleaning and Maintenance

7.6.1.Cleaning

BILILED MINI™ must be thoroughly cleaned and disinfected periodically according to approved hospital protocols.

WARNING!
Always disconnect power supply before cleaning and disinfection.

- Remove visible soiling with a disposable cloth and detergent.
- Wipe-disinfect the surfaces.
- After allowing disinfectant to take effect (see manufacturer's directions for prescribed exposure times), wipe surfaces with a clean, damp, disposable cloth, then rub dry.

WARNING!
Do not allow any moisture (disinfectant and liquid detergent) enter the unit, control panel and lens.

Do not disinfect control panel by immersion or spraying.

WARNING!
Do not disinfect unit, control panel and any parts of unit by immersion.

WARNING!
Led module including the lenses should be cleaned with a soft, damp cloth.

WARNING!
Do not touch lens by finger. The dirt, body oil, perfume or such ingredients available on finger may damage the optical property.

WARNING!
Do not use organic solvents sometimes used for cleaning and disinfecting (e.g., alcohols, phenols, halogen releasing compounds, oxygen releasing compounds, strong organic acids, etc.) Exposure to such substances may cause damage of equipment and parts.

WARNING!
We recommend using Ammonia Quaternary.

WARNING!
Do not allow any moisture (disinfectant and liquid) enter the unit.

Cleaning of Vent

For effective operation of the device and long-lasting use of LED module, vent must be free of dust. Blocked cooling channels because of dust may cause inside temperature increase and shut off the LEDs. Therefore each three months cooling channels on the top should be cleaned by using brush or low pressurized air

7.6.2.Maintenance

This equipment must be inspected and serviced at regular 1 year intervals. A record must be kept on this preventive maintenance. We recommend obtaining a service contract with NOVOS Service through your vendor.

For repairs of BILILED MINI phototherapy we recommend that you contact NOVOS Service.

Intensity Control:

Expected life of LED module is about 20.000 hours. However it is recommended to follow up the irradiance with a radiation monitor to assure a better evaluation of the actual efficacy of the LEDs. LED module should be replaced when there is a loss of 25% of the irradiance.

Replacement of LED Module:

We recommend replacing LED module when LED usage time is 20.000 hours. For replacement of LED module contact NOVOS technical service or authorized local service in your region.

8. VENTURI TM2™ Suction Unit (Optional)

8.1. Application

The VENTURI TM2™ ejector is used to create, to adjust and to measure a suction from a source of pressured gas on the wall or from a cylinder (oxygen or medical air). It enables to suck in liquids or mucus in the absence of vacuum pipeline network. The VENTURI TM2™ ejector should be connected either to a source of pressured gas on the wall, using a direct probe or a rail mounting system, or a cylinder through a pressure regulator fitted with a quick-release connector. The VENTURI TM2™ ejector should be associated with a collection jar and a suction hose.

8.2. Operator's Responsibility for Patient Safety

WARNING!
The VENTURI TM2 should only be used by qualified medical personnel.

WARNING!
Check the pressure delivered by the gas supply. This has an impact on the maximum vacuum level generated. The maximum vacuum levels and suction flow rates are only generated when the supply line pressure is 4.5 bar or greater.

WARNING!
Always test the operation of the device prior to use.

WARNING!
If the device is dropped, always make arrangements for the display accuracy to be checked.

WARNING!
Never obstruct the device's air exhaust.

WARNING!
Make sure that the needle indicates 0 when the device is not being used.

WARNING!
Make sure that the device is always fitted with an antibacterial filter in the suction circuit.

WARNING!
The length of the tubing may have an impact on suction performance.

WARNING!
The measurement tolerances of the vacuum level display increases when the device is being used outside its specified ranges of ambient temperature and pressure.

WARNING!
Do not dispose of the antibacterial filters in a bin for domestic waste.

WARNING!
When the source gas is oxygen, the use of lubricants that are not compatible with gas may cause fire or explosion.

WARNING!
When the source gas is oxygen, make sure that adequate ventilation of the room in which the VENTURI TM2 is used.

WARNING!
Never dismantle the device when it is connected to a pressurized gas source.

WARNING!
VENTURI TM2 is not compatible to use in an MRI environment.

8.3. Operation

1. Make sure that the device is undamaged and that the connector is compatible with the supply connection.
2. Make sure that the regulation knob is in its closed position. (Turn it clockwise completely.)
3. Connect the device to the network's gas supply outlet. (Air or O_2)
4. Connect the device's outlet (nipple) to the collection jar using a suction tube with a minimum diameter of 6.3mm.
5. Turn the regulation knob on the front of the device counter-clockwise and set the vacuum level with the patient circuit closed off.
6. To stop the suction, set the regulation knob to its closed position.

Fitting the Safety Jar:

- Insert and twist under VENTURI TM2: Line up the mark on the cover of the safety jar with the mark on the skirt under the body of the VENTURI TM2.

Removing the Safety Jar:

- Turn the safety jar counter-clockwise.
- Line up the mark on the cover of the safety jar with that on the skirt under the body of the VENTURI TM2 then pull the jar downwards.

Fitting the Plastic Filter:

- Push in fully until it clicks into place.

Removing the Plastic Filter:

- Pull and twist at the same time.
- Dispose of the filter by observing the appropriate precautions.

8.4. Cleaning and Maintenance

Under normal conditions of use, the VENTURI TM2, does not require disinfection since the safety jar is protected by the filter on the front of the device. Change the filter after each patient.

VENTURI TM2:

Use a disinfectant cleaner for medical devices. Leave to dry before using the device.

WARNING!

- **When using decontaminant products, make sure that they are compatible with plastic.**
- **Do not use surface decontaminants.**
- **Do not spray disinfectant directly onto the device. Use a cloth or disposable wipe.**
- **Do not immerse the device in any product.**

Safety Jar:

Since the safety jar is protected by an upstream filter on the front of the device, there is no need to sterilize it: simply replace the filter after each patient or, if the patient is admitted for a long period, replace as necessary after inspecting the filter to check the degree of fouling. However, if the liquid accidentally overflows or if the filter perforates, then the safety jar must be disinfected or sterilized as follows.

1. Remove the safety jar and disassemble the cover from the jar.
2. Immerse safety jar parts in a pre-disinfecting solution (respecting the manufacturer's instructions concerning soaking, rinsing and drying times.)
3. Clean, rinse thoroughly, soak for 1 minute in clean water and then dry.
4. Sterilize or disinfect in compliance with the instructions provided by the manufacturer of the particular product used.
5. Reassemble each part and refit the safety jar.

WARNING!
The safety jar can withstand 30 disinfection or sterilization cycles.

WARNING!
The safety jar can be autoclaved at temperature of up to 134°C.

8.5. Technical Specifications

- Complies with: ISO 10079-3: 2014
- Display Unit: mmHg and kPa.
- Display range: 0 to -200mmHg (0 to -25 kPa)
- Measurement accuracy: ±1.6% of full scale.
- Vacuum gauge can swivel through 90° (from -45° to 45°)
- Safety jar can swivel through 90° (from -45° to 45°)
- Antibacterial filter on front of the device: 99.97% efficiency for 0.3µm particles.
- Safety valve fitted to protect the device if the exhaust becomes obstructed.
- Operation pressure supply: 3-6 bar.
- Maximum flow rate at 4.5 bar: 40 L/min with safety jar.
- Maximum gas consumption at 4.5 bar: 60 L/min.
- Noise level with safety jar at maximum suction flow rate: 52dB.

- Ambient temperatures for use: 10-40^{o}C.
- Atmospheric air pressure for storage and use: 800-1060 hPa.
- Relative humidity levels for storage and use: 0 to 100%.

9. Routine Cleaning and Maintenance

9.1. General Cleaning

WARNING!
To avoid the possibility of burns when performing cleaning procedures, ensure the warmer is disconnected from the power supply and the heater element is allowed to cool for one hour.

WARNING!
To avoid the possibility of electric shock hazard when performing cleaning procedures, ensure the warmer is disconnected from the power supply.

WARNING!
If UPS is installed ensure it is turned off prior to cleaning. Do not remove the UPS shroud during cleaning procedures. Ensure no part of the UPS is immersed in any cleaning agent.

WARNING!
Do not allow liquids to seep into electrical housings.

WARNING!
Do not allow liquids to collect or enter into any oxygen or air fittings or inlets.

WARNING!
Ensure all oxygen and air supplies are turned off and disconnected from the warmer before performing cleaning procedures. Explosion and fire hazards can exist when performing cleaning procedures in an oxygen-enriched environment

WARNING!
Do not use solvents or abrasive cleaning solutions for cleaning surfaces of the warmer.

Always follow hospital and local guidelines for cleaning frequencies.

Clean the warmer and accessories either weekly or between babies using the following cleaning procedures:

- Before cleaning, remove and discard all used disposable products using the recommended method of disposal.
- Dust all plastic surfaces with a clean damp soft cloth.
- Dust all accessible metal surfaces with a clean soft cloth or paper towel.
- Clean all surfaces except the bassinet sides with alcohol, or detergent or soap solution (maximum 2% in water), ensuring the manufacturer's directions for use of the cleaning agent are followed.
- Clean the bassinet sides only with detergent or soap solution (maximum 2% in water), ensuring the manufacturer's directions for use of the cleaning agent are followed.
- Ensure no part of the warmer or accessories are immersed in any cleaning agent.
- Apply the cleaning solution with a clean cloth or sponge.
- Clean all parts of the warmer and accessories at normal room temperature (around 23°C).
- Dry all surfaces after cleaning with a clean soft cloth or paper towel.

CAUTION!
Do not clean the radiant heating element.

CAUTION!
Do not allow excess cleaning solution to seep in between plastic parts where it is difficult to wipe.

9.1.1.Cleaning of Skin Temperature Sensor

Clean the NOVOS skin sensor with alcohol, or detergent or soap solution (maximum 2% in water), ensuring the manufacturer's directions for use of the cleaning agent are followed. Apply the cleaning solution with a clean cloth or sponge, and dry all surfaces after cleaning with a clean soft cloth or paper towel.

CAUTION!
Do not autoclave or gas sterilize the NOVOS skin sensor.

CAUTION!
Do not pull on the sensor cup or sensor plug during cleaning or drying as the skin sensor may be damaged.

CAUTION!
Ensure the skin sensor is only removed from the controller by grasping the plug at the front panel. Ensure excessive strain is not placed on the sensor lead either during use, cleaning or inspection.

9.1.2.Cleaning of Mattress

- Clean the mattress with an approved and correctly diluted disinfectant-detergent solution, ensuring the manufacturer's directions for use of the cleaning agent are followed.
- Apply the cleaning solution with a clean cloth or sponge, and dry all surfaces after cleaning with a clean soft cloth or paper towel.

CAUTION!
Do not autoclave the mattress.

9.1.3.After Cleaning

CAUTION!
Ensure all warmer parts and accessories are checked before returning the device to service. Refer to relevant sections of this operating manual for directions

9.2. Maintenance

WARNING!
Only qualified personnel should carry out service and maintenance procedures.

WARNING!
To avoid the possibility of burns when performing maintenance procedures, ensure the warmer is disconnected from the power supply and the heater element is allowed to cool for one hour.

WARNING!
To avoid the possibility of electric shock hazard when performing maintenance procedures, ensure the warmer is disconnected from the power supply.

WARNING!
Ensure all oxygen and air supplies are turned off and disconnected from the warmer before performing maintenance procedures. Explosion and fire hazards can exist when performing maintenance procedures in an oxygen-enriched environment

9.2.1.General Maintenance

After any maintenance is completed, ensure the equipment is functioning correctly in accordance with the published performance specifications.

- Refer to Alarm System Checkout section.
- Refer to Control Panel Checkout section.
- Ensure only approved replacement parts are used during service and maintenance procedures.
- Please refer to the KR-1000 Infant Warmer Service Manual for servicing information.
- Please contact an authorized NOVOS representative for further assistance with any servicing or maintenance requirement.

9.2.2.Bassinet and X-Ray Tray Maintenance

The bassinet should be checked annually to ensure reliable operation.

The following procedure should be used by your technician:

- Check each bassinet side panel for smooth operation and correct latching. Replace if defective.
- Check x-ray tray module for smooth operation and correct placement of x-ray cassette. Replace if defective.

9.2.3.Main Body Maintenance

The main body should be checked at least annually to ensure reliable operation. The following procedure should be used by your technician:

- Check all main body fittings are secure. Please refer to KR-1000 Infant Warmer Service Manual for adjustment information.
- Check the operation and electrical connections of the electric elevator if fitted.
- Check castors rotate freely and castor brakes operate correctly

9.2.4.Warmer Head Maintenance

- At least annually check the warmer head swivel is secure.
- Ensure the warmer head pivot nut is locked/glued in place. Check the swivel movement of warmer head is free and that the central détente can be felt.

10. Troubleshooting

The troubleshooting charts provide the user with general situations, possible causes and suggested actions. If these charts cannot assist in solving the particular situation, the warmer should be sent for servicing.

Situation	Possible Cause	Remedy
Unable to provide stable control of the baby's skin temperature.	Skin sensor and/or sensor cover poorly attached to the baby.	Correctly re-attach the skin sensor and sensor cover.
	Heat path between the baby and heater element is obstructed.	Remove heat path obstruction.
	Warmer is operating in Manual or Prewarm mode.	• Change to Baby mode, and adjust set temperature as desired. • In Manual mode, and adjust heater power to achieve desired baby's skin temperature.
Baby's skin temperature readings do not appear correct	Skin sensor is faulty.	Check skin sensor performance and replace if defective.
	Skin sensor or sensor cover poorly attached to the baby.	Correctly re-attach the skin sensor and sensor cover
The System Failure light is illuminated or flashing and the audible alarm is sounding.	A software fault has been detected.	Send warmer for servicing.
	A hardware fault has been detected.	
The Power Fail light is illuminated and the audible alarm is sounding	The wall power supply to the warmer has been switched off.	Switch on the wall supply.
	The internal fuses, power cord or internal wiring may be defective.	Send warmer for servicing.

11. Appendices

11.1. Technical Specifications

11.1.1.Mechanical Specifications

Height	177 cm up to 197 cm max. (with adjustable height feature)
Width	68 cm (standard device), 92 (with accessories)
Depth	110 cm
Distance Between The Heater And Mattress	74 cm
Warmer Head Swivel Angle Range	±140^{o}
Mattress Height	93 cm up to 113 cm max. (with adjustable height feature)
Mattress Size	70 x 55 cm
Trendelenburg and Reverse Trendelenburg Angle Limits	±12^{o}
Castors	4 x Ø125mm with brakes
Maximum Load Capacity	Bassinet: 10 kg
	Monitor Tray: 5 kg
	Extension Bar for Accessories: 5 kg

11.1.2.Electrical Specifications

Supply Voltage and Current	230V AC ±20V, 5A max. (standard device), 10A max. (with accessories)
	110V AC ±10V, 10A max. (standard device), 20A max. (with accessories)
Auxiliary Power Outlet	2A max. for medical rated devices only (IEC60601-1)
Supply Frequency	50-60Hz
Nominal Power Consumption	850W
Maximum Power Rating	2300W (with accessories)
Heater Power	2 x 400W
Maximum Irradiance over Mattress	22mW/cm^{2}
Examination LED Power	2 x 5W
Maximum Light Intensity	600 lux
Skin Temperature Sensor Resolution	0.1^{o}C
Temperature Display Range	18^{o}C to 40^{o}C
Sensor Accuracy	0.1^{o}C

11.2. Compliance

The NOVOS infant warmers and accessories are designed to conform to requirements of:

IEC 60601-2-21	The safety requirements for infant radiant warmers
IEC 60601-1	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance
ISO 8382	Resuscitators intended for use with humans
IEC60601-2-50	Medical electrical equipment - Part 2-50: Particular requirements for the basic safety and essential performance of infant phototherapy equipment
EN980:2003	The European standard for symbols used by medical device manufacturers.
BS EN10079-3:2000	Medical suction equipment Part 3: Suction equipment powered from vacuum or pressure source.
BS EN 13220:1999	Flow-metering devices for connection to terminal units of medical gas pipeline systems
BS EN739:1998	Low-pressure hose assemblies for use with medical gases
BS EN837-1:1998	Pressure gauges. Bourdon tube pressure gauges. Dimensions, metrology, requirements and testing
BS EN738-1:1997	Pressure regulators for use with medical gases. Pressure regulators and pressure regulators with flow metering

CE 1984

11.3. Equipment Classifications

Class I

Type B with Type BF applied part

Continuous Operation

Not classified against ingress of liquids

Not suitable for use in presence of flammable anesthetics

11.4. Trademarks

KR-1000™, Easypuff™ Bililed Mini™ are trademarks of **Novos Tıbbi Cihazlar Sanayi ve Ticaret İthalat ve İhracat Limited Şirketi.**

VENTURI TM2™ is a trademark of **Technologie Medicale SAS.**

11.5. Manufacturer

Novos Tıbbi Cihazlar Sanayi ve Ticaret İthalat ve İhracat Limited Şirketi

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