KI 1000

User Manual

NVS.S9.KK01/Rev.06/06.04.2021

WARNING

Registered Information:

This document contains information on which NOVOS assumes the property rights. The information may not be reproduced in whole or in part unless authorized in writing by NOVOS. These information are the property of NOVOS, for its intended use only.

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.

Table of Contents

About This Manual

Scope:

This manual contains a detailed description of all sub-components, use and care details of the KI 1000 infant incubator.

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:

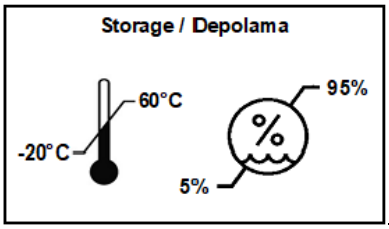
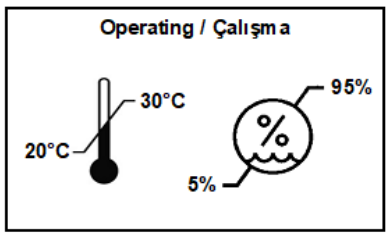
This guide is a guide to:

- Installation
- Usage
- Maintenance

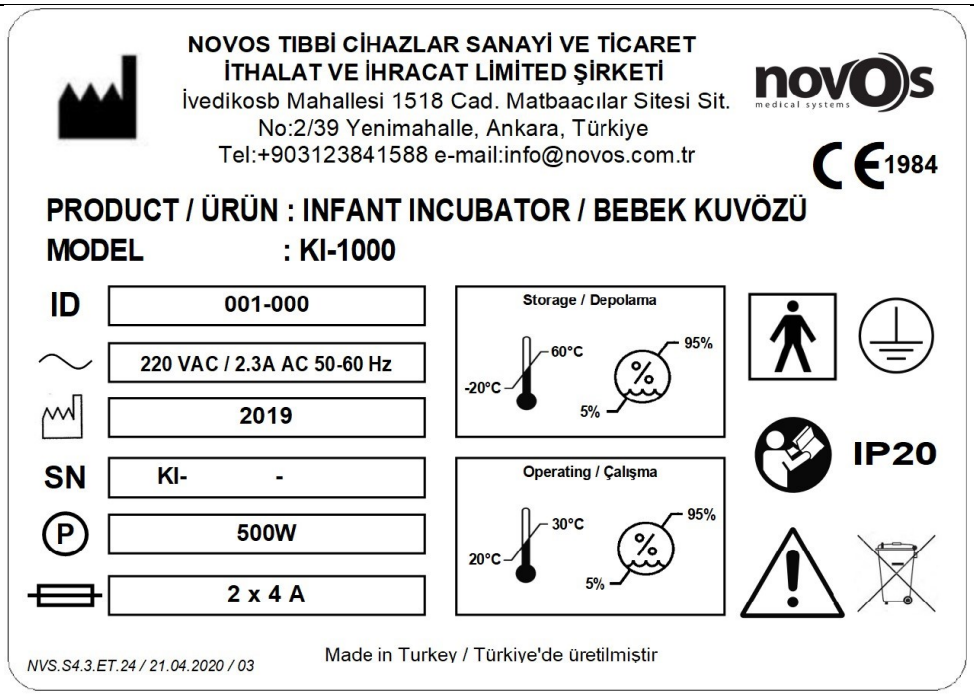
of the KI 1000 infant incubator. All features and technical information of the device are listed considering the user benefit in order to facilitate the efficient use of the device.

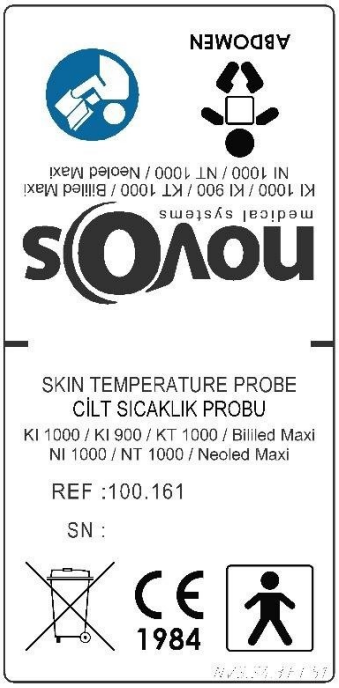
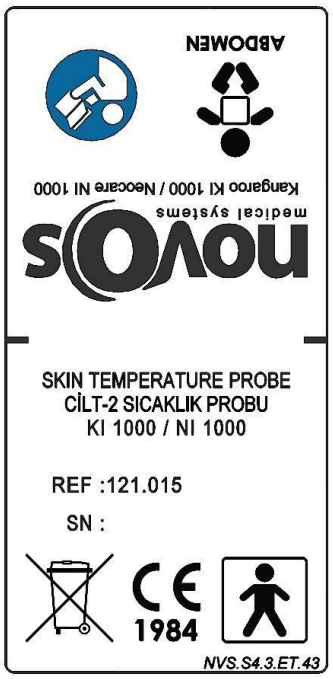
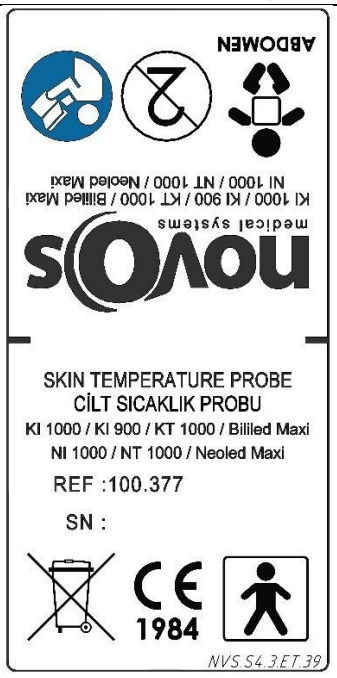
Symbols:

	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.
IP20	Protected against solid objects larger than 12.5 mm.
	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.
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
	See User Manual
	Protective Grounding
	Alternative Current
	This sign on the label indicates that the package should stand upright.
	This sign on the label indicates that the contents of the package are fragile and should be handled with care.
	This sign on the label indicates that the package must be protected from moisture and rain.
	Storage temperature and moisture
	Operation temperature and moisture

Label Information:

	Product Identity
	Technical Service Warning
	Outer Box Label

 	Reusable Skin Probe Label
	Disposable Skin Probe Label

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 incubator 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 heater, and to guarantee efficient use of the device.

	NOVOS does not approve the use of non-original spare parts and accessories with KI1000 Incubator systems. The use of non-original spare parts and accessories can adversely affect device safety and performance, and can also seriously harm patient health. Use only spare parts and accessories recommended by NOVOS.

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 Regarding Indications, Contraindications, Possible Physiological Effects

1.3.5.1. *Indications:*

- Baby's inability to maintain its own warmth despite being dressed and cuddled
- The baby’s being severely ill and requires close supervision
- Risk of excessive heat loss in the baby
- The baby’s having a known infection or developing sepsis
- Inability to complete the pregnancy period

1.3.5.2. *Counter Indications:*

- There are no known contraindications.

1.3.5.3. *Side effects:*

- The noise of the incubator disturbs the baby
- Irregular oxygen supply

1.3.5.4. *Adverse effects:*

- The general routine of separating the mother from the baby, where it is more difficult to keep the baby's body temperature constant, has an adverse effect on the mother's bond with the baby and the mother's breastfeeding.

	Always consider the physiological risks and fire hazards associated with the use of high O_2 concentrations.
	Considering the physiological effects from OO_2, it is mandatory to use the integrated O_2 measurement and control system or an independent OO_2 analyzer and to continuously monitor the O_2 concentration for O_2 management.
	Cross infections should be considered when treating twin babies.

1.3.6. Warnings for the Use of the Device

	**Risk of Injury** Never leave the baby unattended when the canopy, double wall, access hatches or oval windows are open, the bed is pulled out, or the grommets are removed. There is a risk of injury for the patient. Baby can fall from the incubator.
	**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.

Incubator and skin temperature

- Allow sufficient time for the incubator to reach target temperature before use.
- Additional external heat sources such as direct sunlight, spotlights, and electric pads or blankets should be avoided. These can cause the air temperature inside the incubator to rise uncontrollably.
- Since the KI 1000 controls the skin temperature of only one baby, the skin temperature control mode should not be used in twins. Otherwise, there is a risk of hypothermia or overheating for the baby to which the secondary skin probe is attached. For the care of twins, always the air temperature control mode should be used.
- It is the responsibility of the physician to infer from the measured skin temperature.
- The skin temperature control mode should not be used for babies in shock, as their skin temperatures are much lower than normal. In this case, controlling skin temperature increases the incubator's air temperature too much, which poses a risk of overheating to the baby. In such cases, it is recommended to use KI 1000 in air temperature control mode.
- Do not use the skin temperature control mode in babies with fever, as the skin temperature is higher than normal. In this case, skin temperature control may lower the incubator air temperature more than necessary, causing a risk of hypothermia.
- The place of the skin sensor probe on the baby's body should not be confused! The yellow skin temperature sensor (T1) is used for skin temperature control. Improper positioning of this sensor can cause the baby to overheat.
- No blankets or covers should be placed in the warm air duct. Otherwise, the temperature control system may be damaged and if the air from the warm air duct is directed directly to the baby, there may be a risk of overheating or burning.
- When treating older babies, their higher calorie output may cause the air temperature to rise in KI 1000. In this case, the double wall should be removed.
- For proper temperature control of the incubator, the room temperature should be at least 3 °C lower than the incubator's target temperature.

	• Medicated aerosol and similar substances should not create fog in the baby capsule. The fumes of these substances may adversely affect the incubator's operability.
	**Fixing the Device** Always lock the wheels of the device before placing a baby.
	**Usage with Phototherapy Device** • Never cover the phototherapy lamp or incubator canopy with fabric, aluminum foil or other materials to increase the phototherapy effect. The potential build-up of heat will likely result in the danger of overheating the baby because the incubator cannot be sufficiently cooled with ambient air under these conditions. • Always wear eye protection for the baby when using phototherapy. • During phototherapy, fluid supplementation should be increased to the baby to compensate for increased dehydration, e.g. parenteral infusion. • Baby temperature should be monitored with special care during phototherapy. Absorption of light through the baby's skin will provide the patient with heat that can increase their core temperature. For this reason - Decrease the incubator air temperature setting by about 2 °C at least 15 minutes before starting phototherapy. - Decrease the humidity value. - Room temperature should be at least 3 °C lower than KI 1000 air temperature. - When using phototherapy devices that do not have a built-in fan, the air temperature of the incubator may rise more significantly.
	**Accompanied Devices** • All devices to be used with KI 1000 must comply with the IEC 60601 standard. • Do not use any unapproved accessories with the KI 1000. • Any device or combination of devices that do not comply with the conditions specified in this manual may adversely affect the functionality of the KI 1000. See the relevant document and the use of attached devices before using the medical device. • Make sure all hoses and cables are routed correctly and securely without obstructions! Otherwise, be careful against extubation and disconnection hazards. • All devices and accessories to be used with KI 1000 are under the responsibility of the operator.
	**Patient Monitoring.** • Do not leave the patient unattended while using the device. • 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. • Never cover the sensor module gaps or never hang anything from the slots in the sensor module. Remove any dirt from the slots of the sensor.
	**Fire and other hazards caused by oxygen** • Do not approach with fire or cigarette! Fabrics, plastics and oils can easily ignite in an oxygen-rich atmosphere and burn with great intensity. • Slowly open the valves on the O_2 cylinders. • Do not operate the KI 1000 in an environment where flammable anesthetic agents or disinfectants are present. Otherwise there is a risk of explosion. • Do not use or store flammable liquids such as alcohol, ether or acetone inside the KI 1000 incubator. • Do not use electrical components inside the canopy that are clearly not designed for use in potentially explosive environments. • Use only the original KI 1000 air filter and oxygen sensor.

Warnings regarding parts of the device

- **Access covers:** Make sure the patient is not lying in the closing path when closing the access covers. When opening and closing covers, make sure hoses and cables are not caught in the moving double wall.
  Canopy: The canopy should not be used as a shelf for clothes, tools, etc. Before moving the canopy, make sure that nothing is placed on it, such as a phototherapy device. Hold the incubator canopy securely while tilting it. The canopy hinge lock should be locking itself. When it is locked, do not try to tilt the canopy further back. Do not tilt the canopy forward. When closed, make sure the canopy is securely in place
- **Side Oval Windows:** When opening and closing side oval windows, make sure hoses and cables are securely routed and do not come into contact with any obstructions.

1.3.7. Bearing Capacity

	The maximum load bearing capacity of the baby bed is 10 kg. Total body weight should not exceed 10 kg for twin babies to be treated.
	Maximum load bearing capacity of pulled out baby bed is 5kg. Do not lean on or apply weight on the bed when the bed is pulled out.

1.3.8. EMC Restrictions

ATTENTION

- This device must be operated in accordance with the EMC information provided in this manual.
- Cell phones should not be used within 20 m2 of the incubator. Cell phones may impair the functions of the electromedical device and thus patient safety may be compromised
- When using this device alongside other devices, it is important to verify normal operation in the configuration in which it is used.

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

ATTENTION

The device should be used in ideal environmental conditions between 20 °C and 30 °C. Unsuitable, low or high ambient temperature may affect optimum operation of the device and disrupt the patient's thermal balance. It should not be used in front of windows that receive direct sunlight etc.

1.3.10. Electrical Safety Restrictions

	The power cord plug must be connected to the power input on the wall or pendant in accordance with the rules of low voltage directive.
	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" 200-240VAC and 50 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.
	Some electrical equipment to be connected to the triple socket outlet on the KI 1000 may negatively affect the medical device, which will cause a decrease in safety.
	The total power of the equipment to be connected to the triple socket outlet on the KI 1000 must comply with the electrical requirements specified on the socket label.

	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 KI 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.
	Transportation operations while the device is in the box should be carried out by at least two people.

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 thereof.
    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 intended 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

The KI 1000 is an infant incubator system that provides a controlled temperature, humidity and environment with a high concentration of O_2, manufactured for infants up to 5 kg (11 lbs) body weight or 55 cm (22 inches) body length. The KI 1000 is designed for use in clinical settings where premature babies or sick babies who need to be in a temperature controlled environment are treated. It is used for the following purposes:

*In cases where a properly isolated air and temperature environment is required for the newborn,
*Transparent canopy when the newborn needs good supervision
*In cases where a suitable heated environment and proper air circulation is needed for the newborn
* When oxygen is needed in different concentrations
*When micro-controlled humidification is needed
*When other optional features are needed, when non-invasive O_2 ratio or other monitoring systems are needed
*In cases where the weight of the newborn should be followed up and monitored continuously

2.2. Patient Population

- Premature babies (less than 35 weeks)
- Babies born smaller than they normally should
- Babies with respiratory distress
- Babies with a heart rhythm disorder
- Babies who have not developed sucking reflex
- Babies with various genetic conditions
- Babies born by cesarean section may not be able to discharge the fluid in the lungs comfortably unlike normal birth.
  This can cause breathing difficulties.
- Those who cannot keep the body temperature at a certain level.

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 touch screen on the device can lose its sensitivity 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

- Applies convective heat therapy by controlling air or newborn skin temperature.
- Humidifies the air inside the canopy.
- Provides oxygen therapy by increasing the oxygen concentration in the canopy in a controlled manner.
- Facilitates newborn care and intervention thanks to oval windows and wide front / rear access doors.
- Provides Trendelenburg/Reverse Trendelenburg positioning by raising and lowering the newborn head position with its "Smart Tilting" feature.
- Enables critical alarms to be triggered and hence to warn medical personnel regardless of the operating mode, thanks to its "TTSS (Target Temperature Surveillance System)" feature.

Besides, **optionally**;

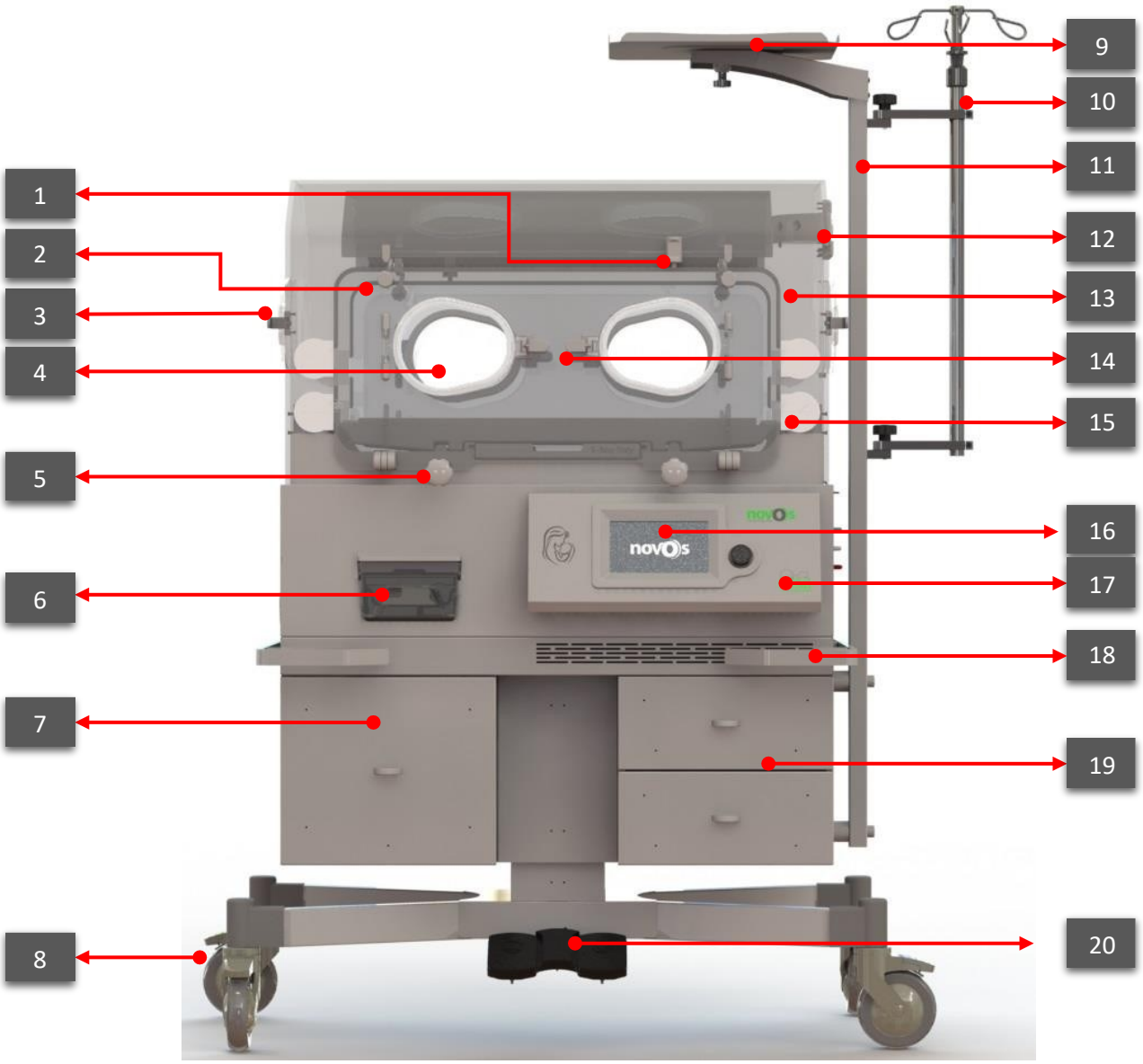
- Keeps the baby in the incubator thanks to its "Smart Weigh" feature, and allows the weighing process to be carried out after the automatic tare process without interrupting the heating therapy.
- Allows the operator to follow the baby more effectively with its height adjustment feature.

The parameters that can be monitored always from the KI 1000 main display are listed below.

- Measured and targeted air temperature
- Measured primary and secondary skin temperature and targeted skin temperature.
- Measured and targeted relative humidity ratio
- Measured and targeted oxygen concentration
- Weight information of the last balance measurement

2.5. Product Parts and Controls

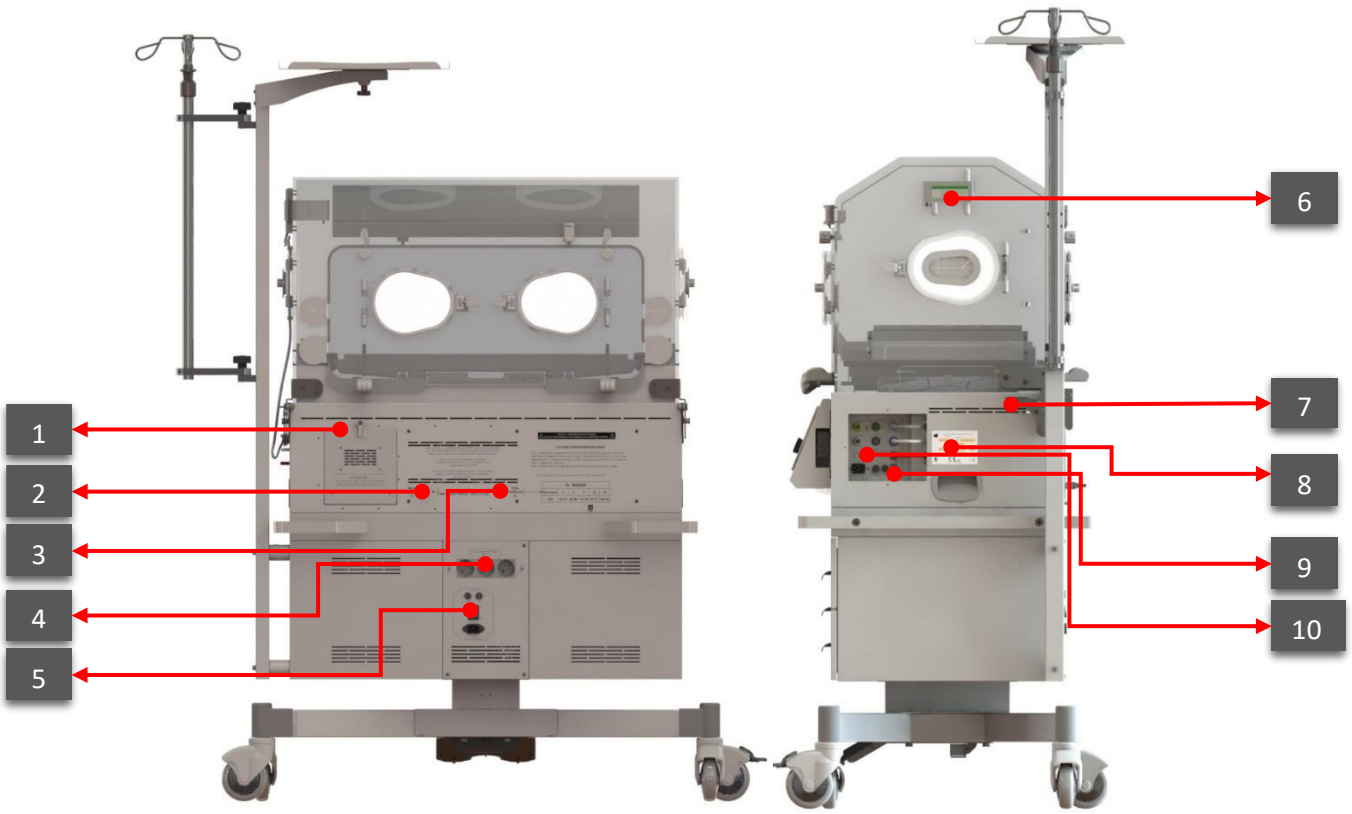
2.5.1. Front View



1	Secondary Cover Lock
2	Primary Cover Lock
3	Side Window with Grommet
4	Oval Window
5	Trendelenburg Adjustment Head
6	Water Reservoir
7	Cabinet
8	Braked Wheel
9	Monitor Tray
10	IV Pole

11	Monitor Tray / IV Pole
12	Oxygen/Humidity Sensor Box
13	Canopy
14	Oval Window Lock
15	Grommet
16	Touchscreen
17	Control Panel
18	Transport Holder
19	Drawer
20	Height Adjustment Pedals

2.5.2. Side and Rear View

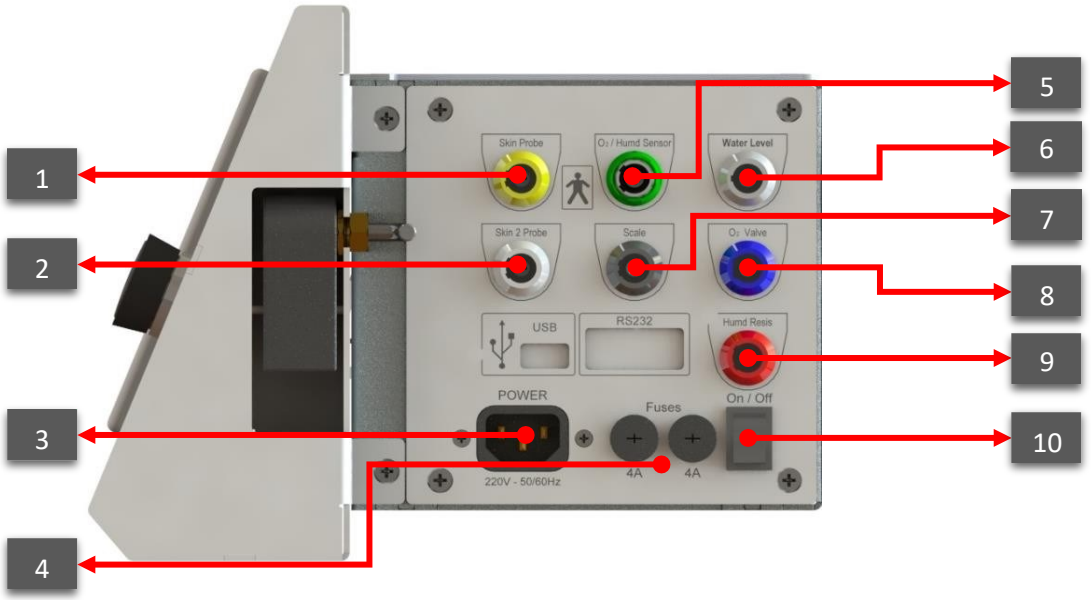


1	Air Filter Housing
2	Servo O_2 Inlet
3	Manual Flow Controlled O_2 Inlet
4	Internal triple socket
5	Power Supply and Height Adjustment Control On/Off

6	Oxygen/Humidity Sensor Module
7	Lockable Canopy Hinge
8	Product ID Label
9	Control Panel On/Off Switch
10	Connector Plate

2.5.3. Control Panel Connections

All sensors, balance, servo oxygen valves and humidity resistance are connected to the control panel via the connector plate on the right side of the device.



1	Primary Skin Probe
2	Secondary Skin Probe
3	Power Input
4	Fuses
5	Oxygen/Humidity Sensor Box

6	Water Level Sensor
7	Scale
8	Oxygen Valve
9	Humidity Resistance
10	On/Off Switch

3. General Overview

3.1. Control Panel

The KI 1000 has a fully removable control panel that houses almost all electronic components. .
This makes service & maintenance procedures for the KI 1000 very easy.

The control panel includes a 7” colored, touchscreen LCD display. Active screen display and button functions change according to the menu used. Only buttons relevant to the active menu are displayed on the screen. This helps to ensure that users are not confused. When a button is pressed, its function is activated and the corresponding menu is displayed on the screen.

Knob Button:

Along with the LCD, there is a knob button that can control the device in case of a touch screen failure.

To make a selection / setting with just one control;

- Turn the knob to select. The selected area is marked with a green rectangle.
- Press the knob button to confirm the selection.

3.2. Sensors

3.2.1. Temperature Sensors

3.2.1.1. *Skin Probes*

KI 1000 has an air temperature sensor located behind the control panel and measuring the temperature of the air returning from the canopy, and also 2 skin temperature sensors.
. (Secondary skin probe is an optional feature.)

Primary and Secondary Skin

The yellow Skin1 Probe must be connected to the control panel to regulate the air temperature inside the canopy when in skin mode or when TTSS (Target Temperature Surveillance System) is active. In the KI 1000 skin mode, it controls the air temperature inside the canopy according to the temperature value coming from this sensor.

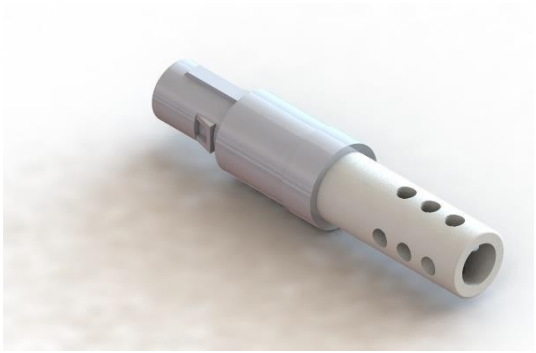
The white-colored Skin2 Probe (optional) is used for skin temperature monitoring of twin babies.

⚠	When the KI 1000 is operating in skin mode, the air temperature is controlled solely by the skin temperature measured by the yellow Skin1 probe. The skin temperature measured by the Skin2 probe is ignored.

The skin probe should be sticked to the baby's abdomen with the help of a reflective tape.

3.2.1.2. *Air Probe*

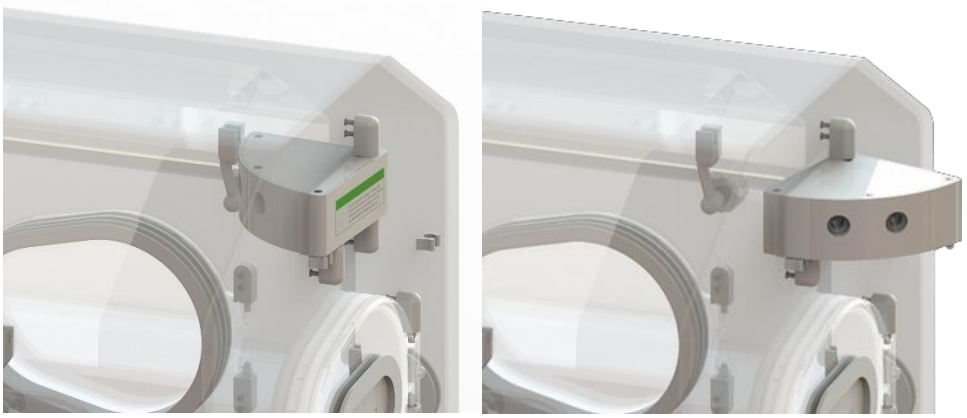
The Air Probe should be attached to the back of the control panel to measure the air temperature. Unlike the skin probe, the air probe must always be connected to the control panel, regardless of the operating mode.



Air Probe

3.2.2. Oxygen/Humidity Sensor Module

Oxygen and moisture sensors are located in the oxygen/humidity sensor module in the upper right corner of the incubator canopy. The module contains two identical oxygen sensors and a humidity sensor. This module should be kept closed during use. Otherwise, moisture and oxygen control features will be disabled.



⚠	Optional devices without Servo-oxygen feature have black plastic caps that cover the oxygen cell holes on the sensor box. Do not remove these caps!

3.3. TTSS (Target Temperature Surveillance System)

The KI 1000 offers the TTSS feature that informs you of the target air and target skin temperatures regardless of the operating mode (air mode or skin mode). In other words, although the control parameter can only be air or skin temperature in operating mode, the KI 1000 informs you about the deviation from both skin and air temperature and offers an extra safe patient monitoring.

For example, the user can set a target skin temperature in air mode so that the KI-1000 adjusts the heater power to the air temperature inside the canopy, while also monitoring the baby's skin temperature and triggering an additional High / Low Skin Temperature alarm for values that exceed user-preferred alarm limits.

The numerical values given in the table below can give you an idea of how TTSS works in air and skin mode.

Active Mode	Adjusted Air Temperature	Measured Air Temperature	TTSS Skin Temperature	Measured Skin Temperature	Alarm Limit	Alarm Status
Air Mode	38	38	37	37.6	±0.5°C	High Skin Temperature alarm is displayed.
Air Mode	37	37	37	36.4	±0.5°C	Low Skin Temperature alarm is displayed.

Active Mode	Adjusted Skin Temperature	Measured Skin Temperature	TTSS Air Temperature	Measured Air Temperature	Alarm Limit	Alarm Status
Skin Mode	37	37	35	35.6	±0.5°C	High Air Temperature alarm is displayed.
Skin Mode	37	37	37	36.4	±0.5°C	Low Air Temperature alarm is displayed.

3.4. Canopy

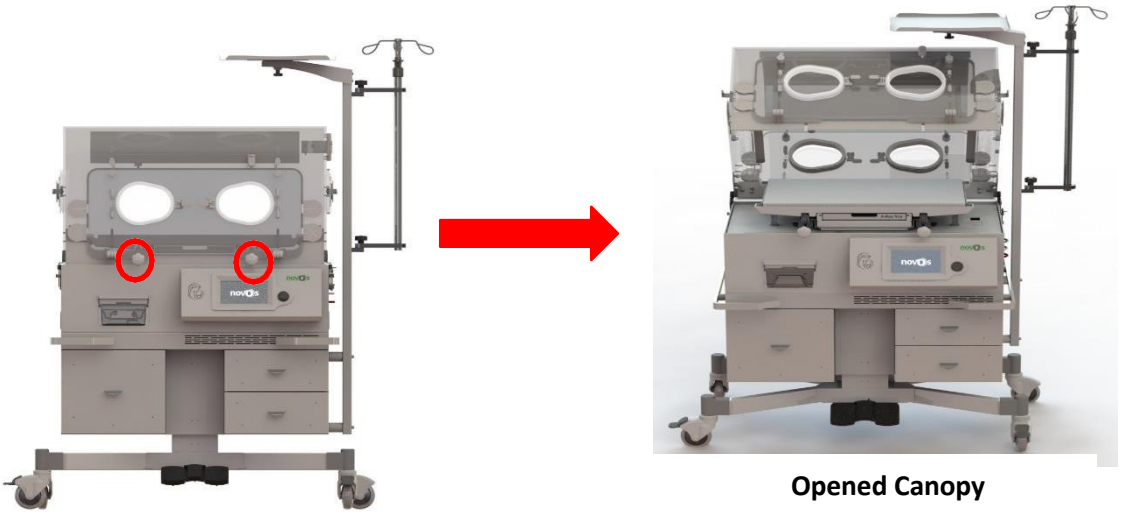
The KI 1000 has a canopy that can be opened for easy cleaning and disinfection.

The canopy can be tilted back. Lockable hinges do not allow the canopy to tilt beyond the specified point.

⚠	Don't apply too much force backward to activate the canopy lock!

To open the canopy;

- Lift the canopy by holding the white plastic cover hinges near the Trendelenburg adjustment head (See circled area on the image below).

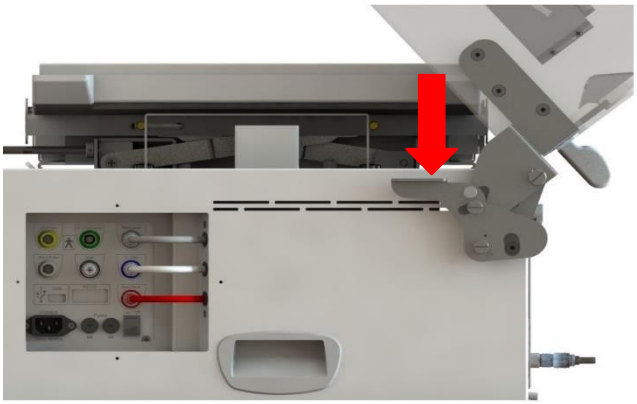


Opened Canopy

- Tilt the canopy backward until the canopy lock is

attached. Closing the canopy;

- Press the hinge lock in the direction of the arrow and hold the canopy by the cover hinges and seat it in a controlled manner to its original position.



Locked Canopy

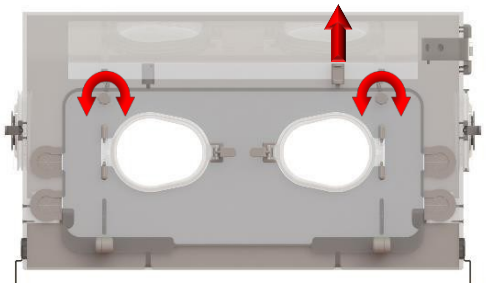
⚠	When handling the canopy, always make sure that the sensor inside the incubator is not damaged!

3.4.1.Front/Rear Access Covers

The KI 1000 has two wide access covers to reach the baby from both the front and the rear.

To open the cover;

- Turn the two primary locks inward so that they are in a horizontal position.
- Lift the secondary lock up and hold it like that.
- Open the cover by pulling it slightly towards you.



Primary and Secondary Cover Locks

Opened Cover

⚠	When opening and closing covers, prevent hoses or cables from getting caught in the double wall.

To close the cover;

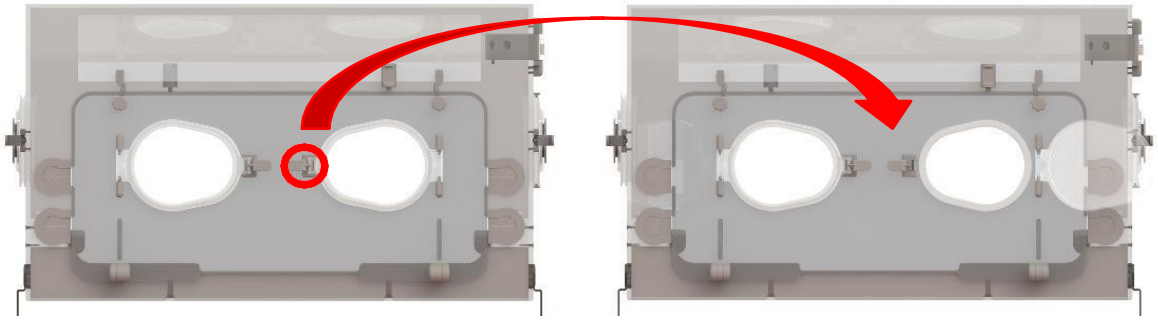
- Make sure the primary locks are in a horizontal position.
- Lift the cover and push it to its initial position.
- Flip up to activate primary locks.

3.4.2.Oval Windows

KI 1000 has a total of 6 oval windows that allow medical staff to use the contamination-preventing elbow method. Thus, possible risk of infection is avoided.

To open the oval window;

- Slightly press the window lock with your elbow.
- The corresponding oval window sash opens.



Oval Window Lock **Opened Oval**

⚠	During normal operation, never leave the baby unattended with the caps or oval windows open to avoid the risk of the baby falling out of the incubator.

To close the oval window, push the oval window back into place until the safety lock engages.

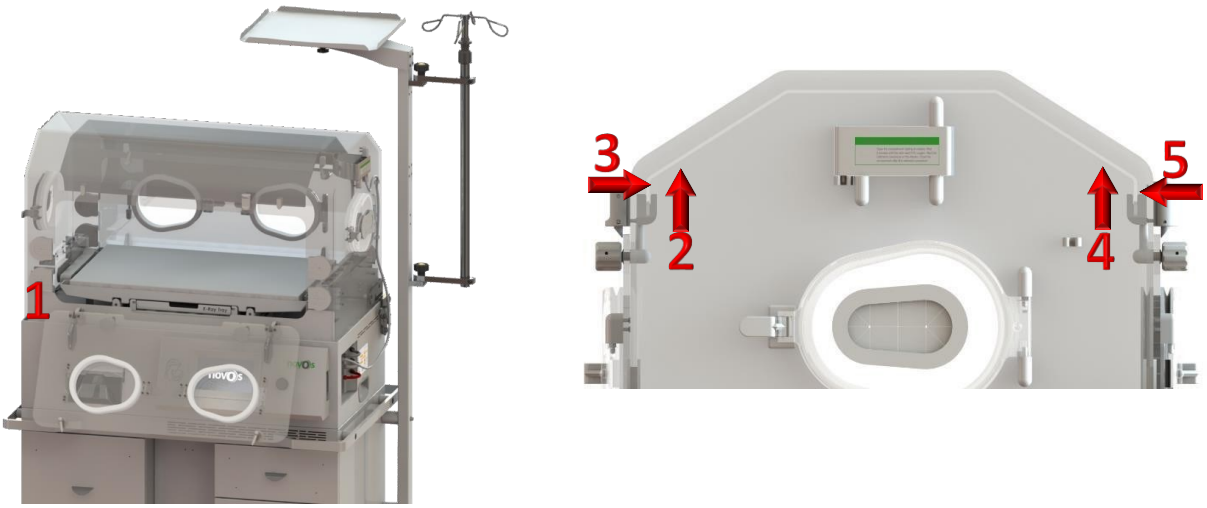
3.4.3.Double Wall

The KI 1000 has a double wall at the top of the canopy as standard. In addition, double walls surrounding the front and rear covers can be optionally added.

.

To remove upper double wall:

1. Open the front cover.
2. First, slightly lift up the double wall.
3. Gently push from outside to inside to free the upper double wall from its seat.
4. Lift the other side of the double wall up.
5. Pull it in, to release it from its seat.
6. Pull the double wall out of the canopy.



Removing Upper Double Wall

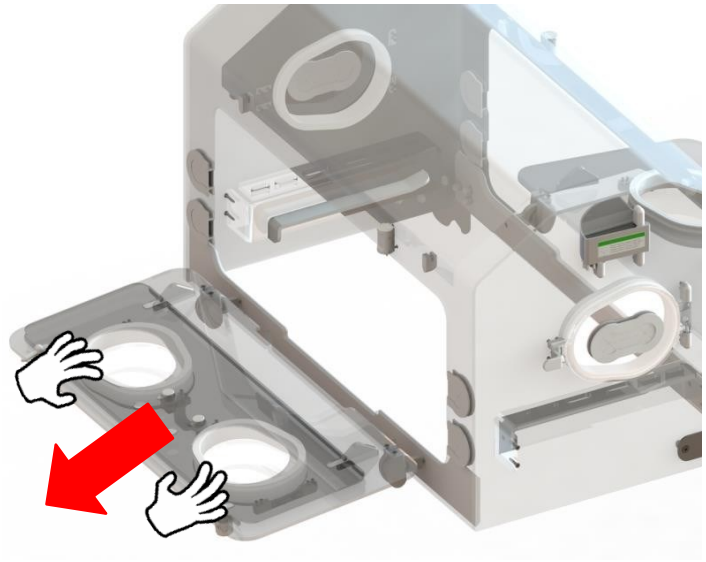
To attach upper double wall:

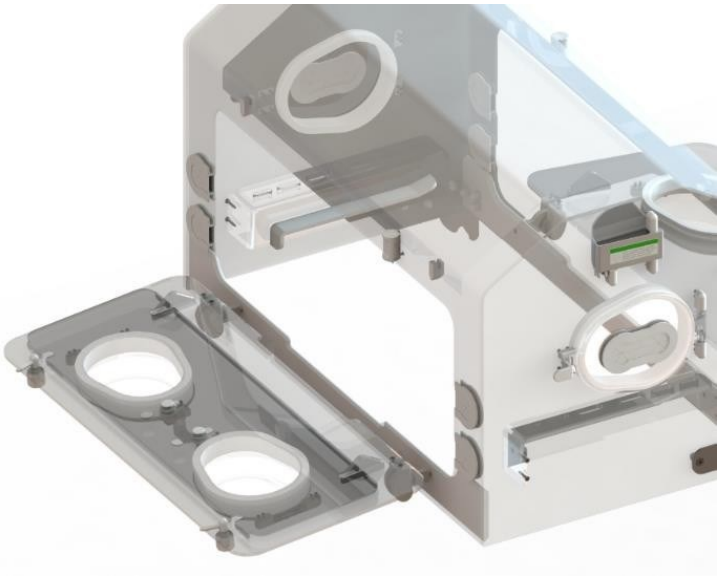
- Tuck the double wall inside the canopy.
- Tuck the double wall slightly inward from one side and insert the clamps of the canopy into their respective holes in the double wall.
- All clamps of the canopy must fit into the holes of the double skin.

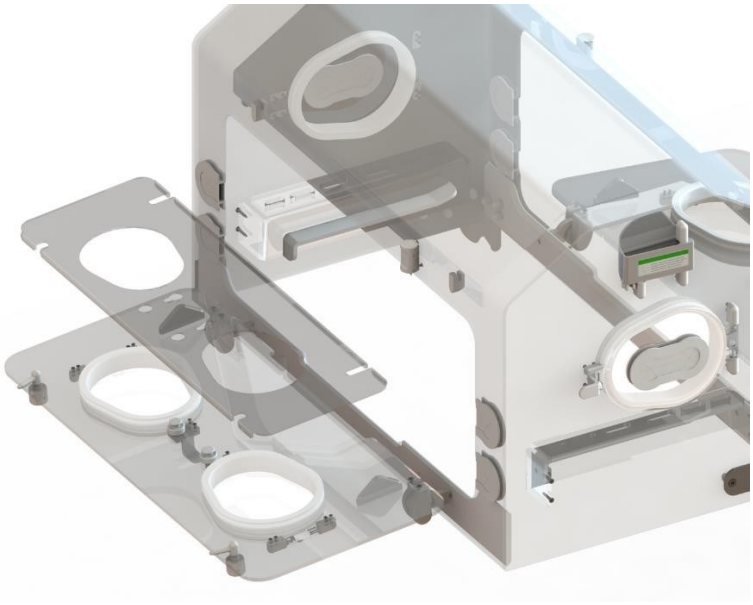
To remove the front/rear double wall (optional);

- Open the cover.

- Grab the double wall by the upper edge of the oval window clearance and pull it in the direction shown below.



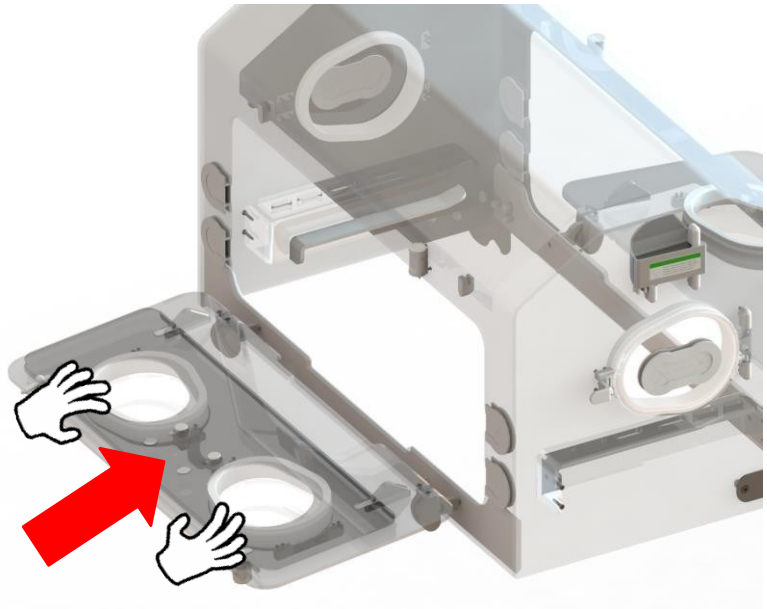




- Lift the double wall and detach it from the cover.

To install the double wall of front/rear cover (optional);

- Place the double wall in its seat.
- Slide the double wall in the direction shown below to lock it.



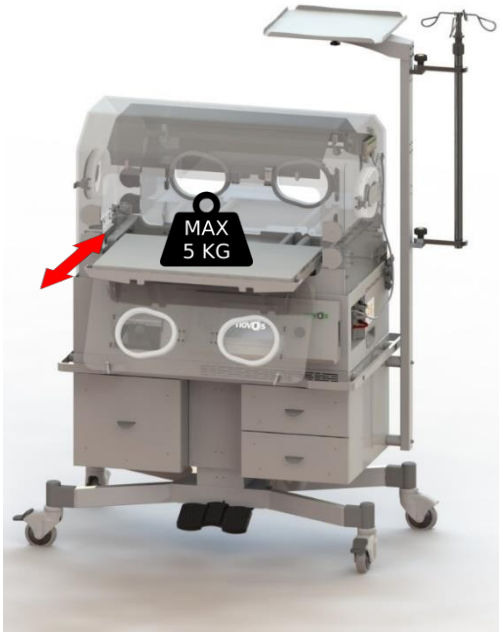
3.4.4.Grommets

KI 1000 has a total of 12 grommets, 4 on the front/rear walls of the canopy and 2 on the side oval windows.

These grommets provide access for patient circuits and other sensor cables while maintaining the thermal insulation of the canopy.

3.5. Baby Bed

KI 1000 has a sliding baby bed to provide parental bonding when necessary. The baby bed can be opened from front to back so that 3/4 of its total width remains outside.



Sliding bed

To open the sliding baby bed;

- Open the front cover and fold it down.
- Pull the bed out as far as it will come.

⚠	When the bed is pulled out, never leave the baby unattended to avoid the risk of the baby falling from the incubator.
⚠	Do not lean on the bed when the bed is pulled out. This situation poses a risk of patient injury and equipment damage.

To close the baby bed after the baby care process is completed;

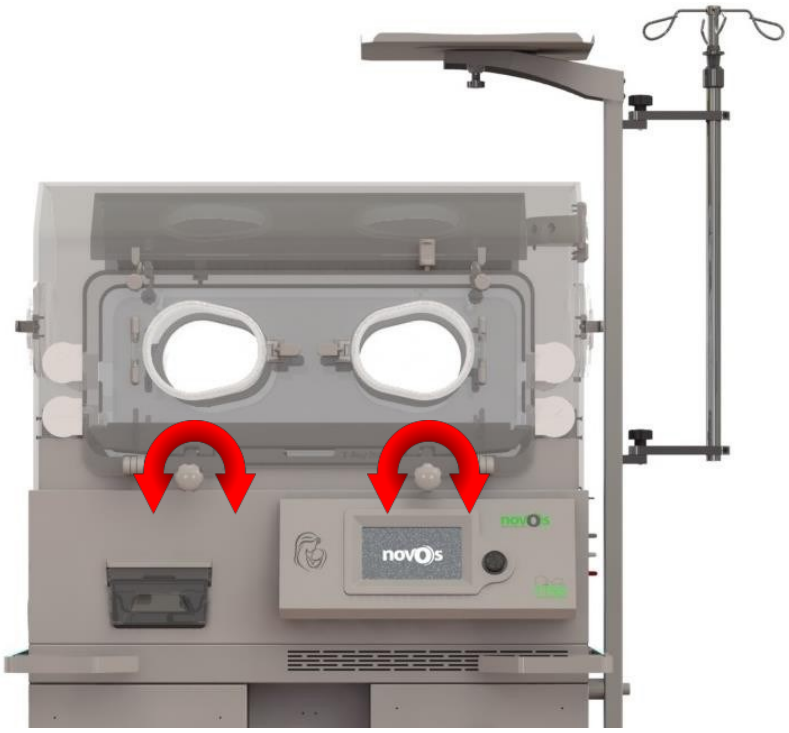
- Push the baby bed until it stops in its original position.

⚠	The white triangular pieces inside the canopy have a stopper function for the baby bed. Make sure the bed is centered without interrupting air circulation.
⚠	Make sure the bed is fully closed! Otherwise, the channeled hot air flow may be blocked and overheating/cooling may occur.

- Close the front cover.

3.5.1. Tilt Mechanism (Trendelenburg / Reverse Trendelenburg)

The smooth tilt mechanism of the KI 1000 provides Trendelenburg/Reverse Trendelenburg positioning at angles of ±12°.



- Turn the adjustment knob counterclockwise to tilt up the relevant side and apply the Trendelenburg / Reverse Trendelenburg position.
  For example, to increase the height of the left side of the bed, turn the left tilt adjustment head counterclockwise.
- To lower the relevant side, turn the adjusting knob clockwise.

3.6. X-Ray Tray

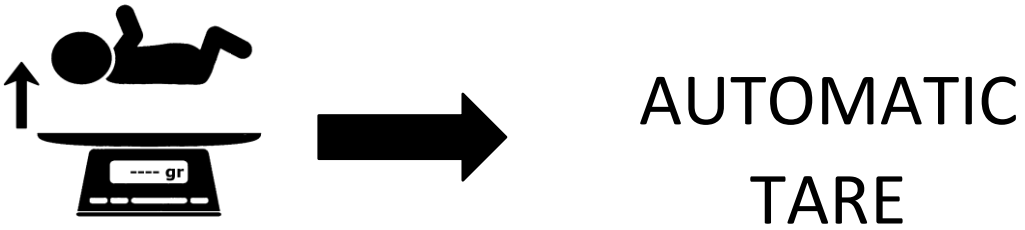
KI 1000 has an X-Ray tray of which dimensions are 396 mm x 256 mm. For this reason, while the baby is treated in a canopy, the x-ray procedure can be completed without any intervention.

X-The rail tray can be accessed by opening the front/rear access covers.

⚠	Always make sure that the X-ray tray is pushed in completely. Otherwise, the channeled hot air flow may be blocked.

3.7. Smart Weighing System (Optional)

The smart weighing system of the KI 1000 offers the ability to follow the developmental trend of the baby being treated. In addition, KI 1000 detects the baby being lifted out of bed and automatically initiates tare measuring. This feature allows medical staff to measure the tare of the baby without pressing any button while keeping the baby in the canopy.



3.8. Drawers and Cabinet

In KI 1000, there are two drawers and a cabinet to store the necessary items for care or treatment.

Transport Trolley
With Cabinets and Drawers

To open the drawer;

- Hold the drawer from its handle and pull it out as far as it can go.

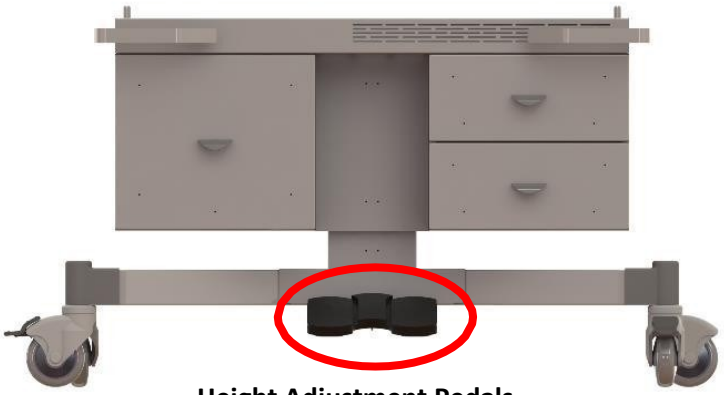
To open the cabinet;

- Hold the cabinet from its handle and pull it out as far as it can go.

The drawers and cabinet can be closed by being pushed inwards.

3.9. Height Adjustment System (Optional)

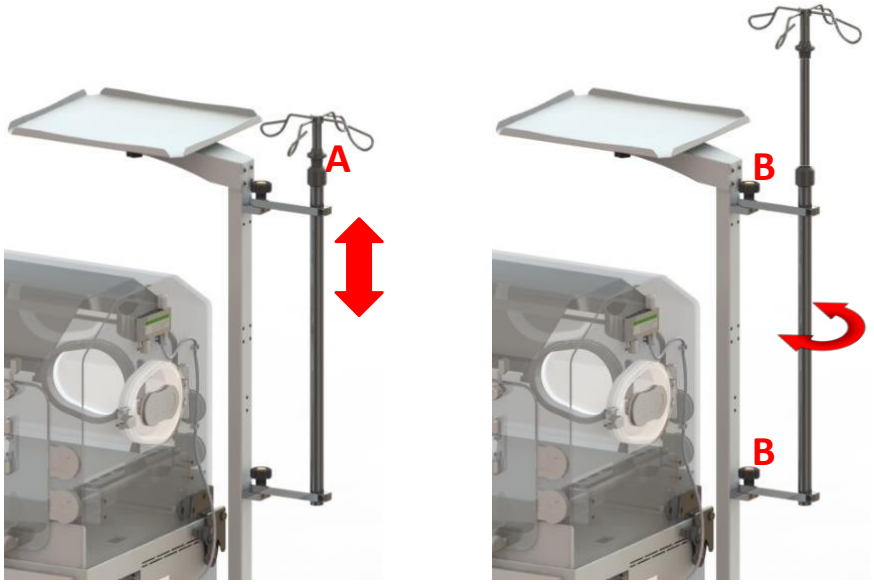
KI 1000 has an optional height adjustment system that can lift the incubator body up to 20 cm. In this way, the incubator height can be adjusted for different medical staff and all controls can be accessed without difficulty.



Height Adjustment Pedals

3.10. IV Pole (Optional)

The KI 1000 has an IV pole whose height and position around the vertical axis can be easily adjusted.



A	IV Pole latch
B	IV pole fixing screws

To increase the height of the IV pole;

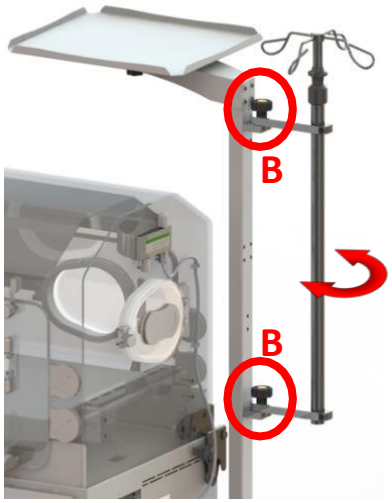
- Lift the IV pole latch up slightly with your thumb and index finger and simultaneously raise the IV pole.

To decrease the height of the IV pole;

- Lift the IV pole latch up slightly with your thumb and index finger and simultaneously lower the IV pole.

To adjust the position of IV pole around the vertical axis;

- Slightly loosen the 2 black plastic head screws (B).



- After adjusting the position, tighten the black plastic head screws (B)

3.11. Wheel Brakes

The KI 1000 has two lockable wheels at the front.

To activate the wheel brake;

- Press the outer edge of the brake pedal.

Wheel Brakes

To release the brake;

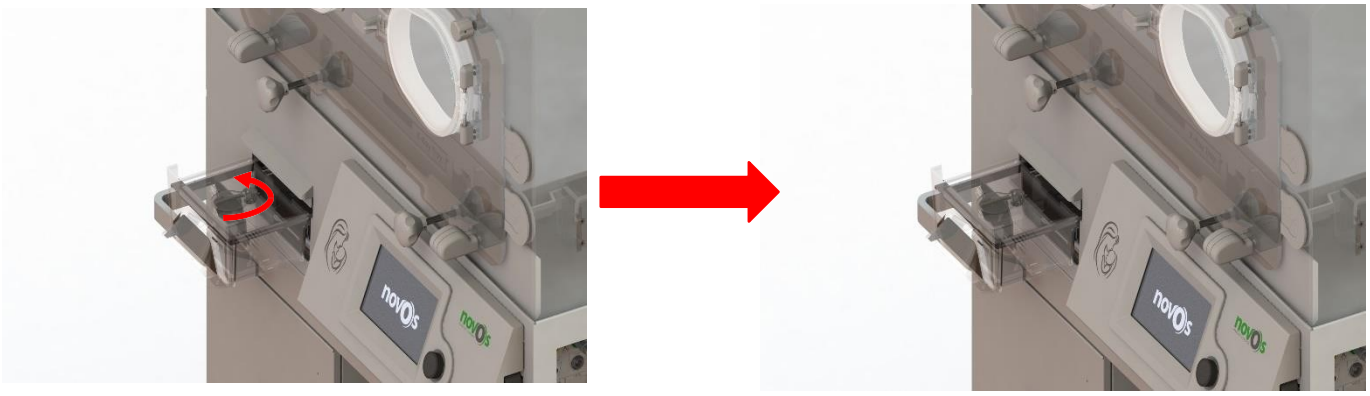
- Press the inner edge of the brake pedal.

⚠	Do not force the KI 1000 to move when the wheels locked.

3.12. Humidification System

3.12.1. Filling the Water Reservoir

- Disinfect your hands.
- Pull out the water reservoir drawer and turn the top cover in the direction of the arrow.



- Fill the water reservoir with distilled water until the water level reaches MAX. Note that the water reservoir capacity is 1.7L.

.

- Close the water reservoir cover and drawer.
- Check that the water reservoir is completely closed. If it is not closed, press the button under the chamber, and then close it.

⚠	Do not use any additives in water to moisten the incubator.
⚠	Use only unopened original packs containing pure and sterile distilled water. Water packs intended for moistening should not be mixed with infusion solutions.

3.13. O_2 System

Along with manual flow-controlled oxygen coming from an external flowmeter and directly released into the canopy, the KI 1000 also offers an optional servo oxygen system.

3.13.1. Oxygen Inlet Connection

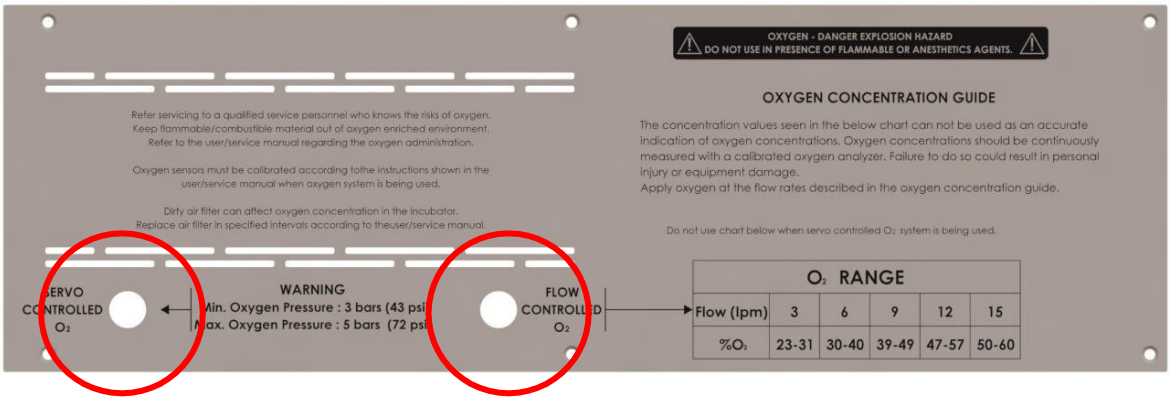
KI 1000 has two oxygen inlets. These are servo controlled O_2 (High Pressure) and manual flow controlled O_2 (Low Pressure).

⚠	Take all precautions against fire hazards caused by oxygen

- Connect the high pressure O_2 supply tubing to the Servo O_2 port on the left side of the back of the incubator.
- Make sure the oxygen jack is securely connected.
- Connect the quick connection probe to the outlet end of your medical O_2 gas pipeline.

ATTENTION!

The permissible gas pressure for servo controlled O_2 is between 300 and 500 kPa.



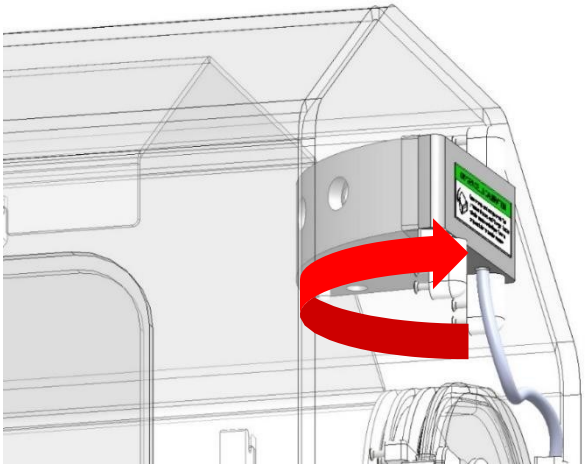
Oxygen Connection Points

For detailed information on oxygen therapy, refer to sections 5.6.1. Setting the O_2 Concentration on a Manual Flow Controlled O_2 System and 5.6.2 Setting the Oxygen Target Point on a Servo Controlled Oxygen System.

3.13.2. Changing Oxygen Cells

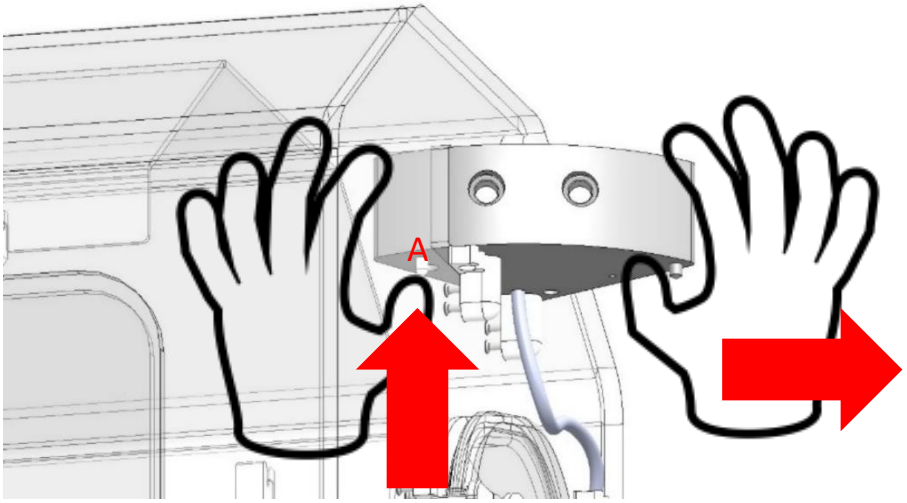
Oxygen cells must be replaced annually to maintain stable measurement of oxygen concentration. The oxygen/humidity sensor module must first be removed from the canopy to replace the oxygen cells;

1. Disconnect the oxygen/humidity sensor module cable from the control panel.

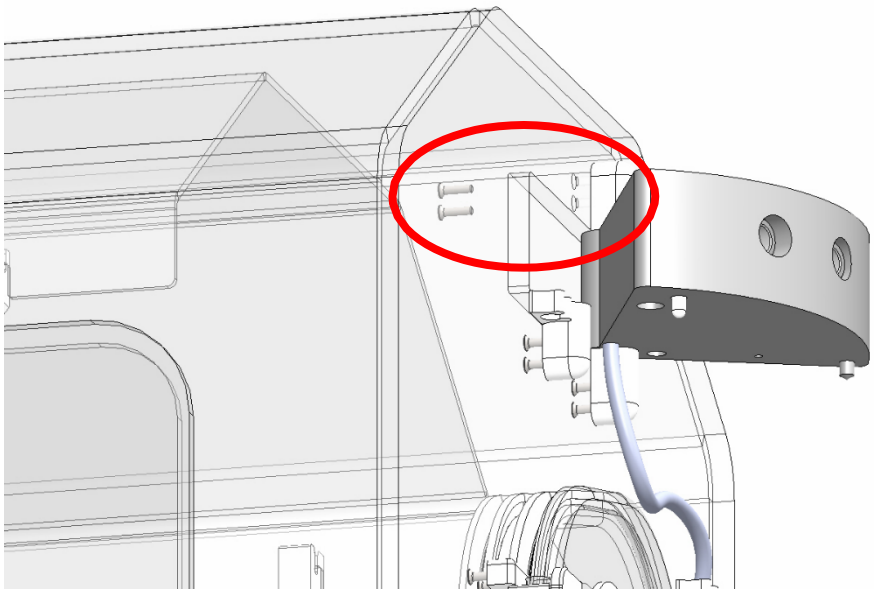


2. Turn on the oxygen/humidity sensor module.

3. Place your left hand inside the canopy. Using your left thumb, push in pin (A) and pull out the sensor box with your right hand.

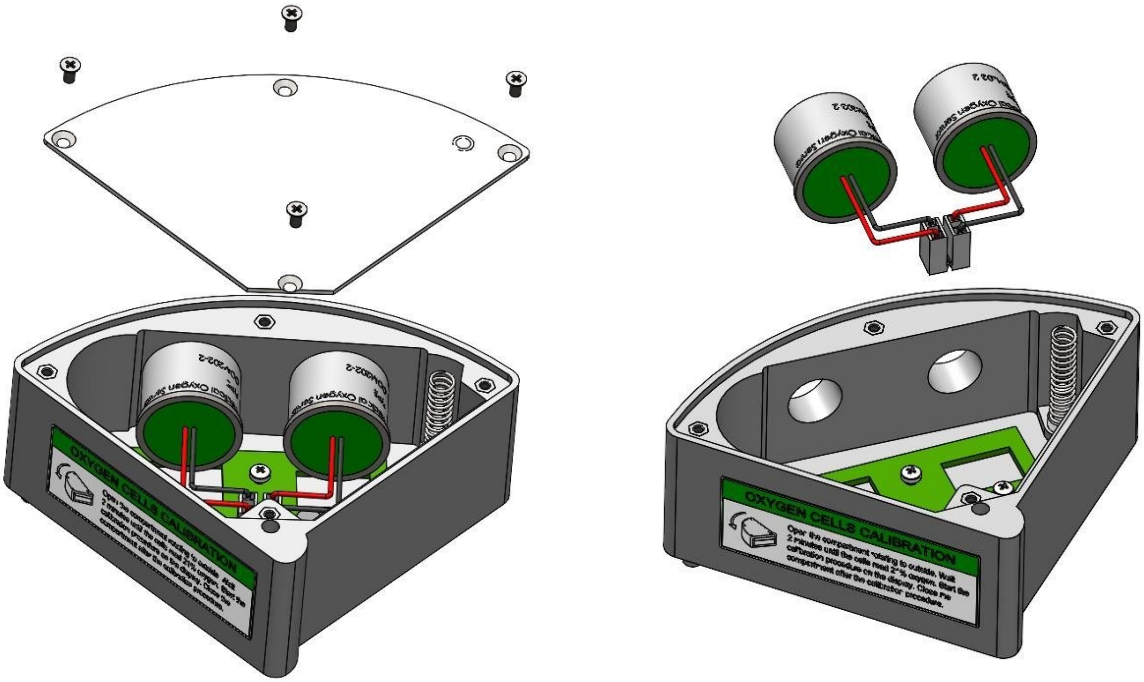


4. Unscrew the two screws of the sensor module top hinge and lift the sensor module upwards.



After the oxygen/humidity sensor module is removed from the canopy, the sensor module cover must be opened.

1. Unscrew the 4 screws of the sensor box cover.
2. Unscrew the screw of the cell holder plate (A).
3. Remove the cell holder plate (B).
4. Disconnect the jacks of the oxygen cells.
5. Remove the oxygen cells.



6. Follow the reverse procedure to reattach the oxygen/humidity sensor box into the canopy after replacing the oxygen cells.

4. Preparation

4.1. Unpacking and First Installation

KI 1000 can be grouped into six main parts;

1. Main Body
2. Transport Trolley
3. Monitor Tray / IV Pole
4. Monitor Tray
5. IV Pole
6. Oval Window Seals and Grommets

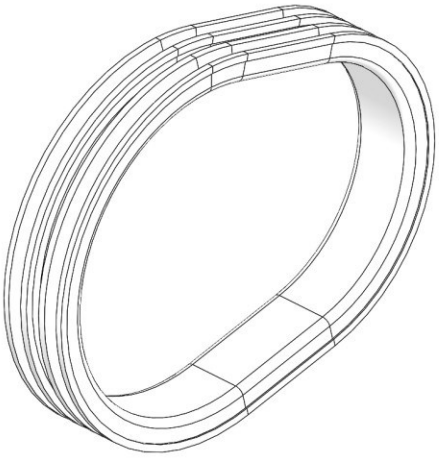
					
1	**2**	**3**	**4**	**5**	**6**

Before starting to assembly;

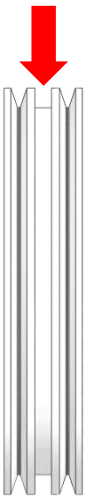
1. Check that all packing materials have been completely removed.
2. Check that the mains voltage is compatible with the specification on the product identification label. (The product identification tag is located on the right side of the device.)

Follow the steps below to complete the assembly;

1. Install 6 oval window seals as described in the picture below.



Oval Window Gasket

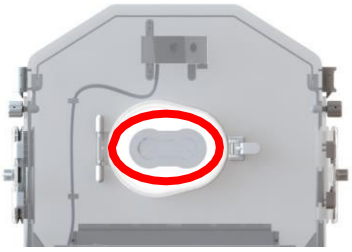


Side View of the Oval Window Gasket

There are 3 grooves on the oval window. Use the middle groove to fix the gasket to the canopy.

2. Attach 2 adjacent grommets on each lateral oval window.

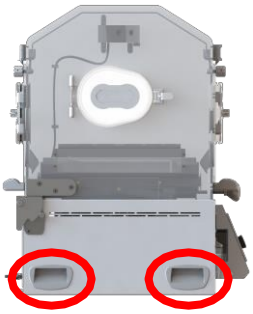
Grommet



3. Attach 8 grommets to the front and rear walls of the canopy.

4. Lock all the brakes of the transport trolley.

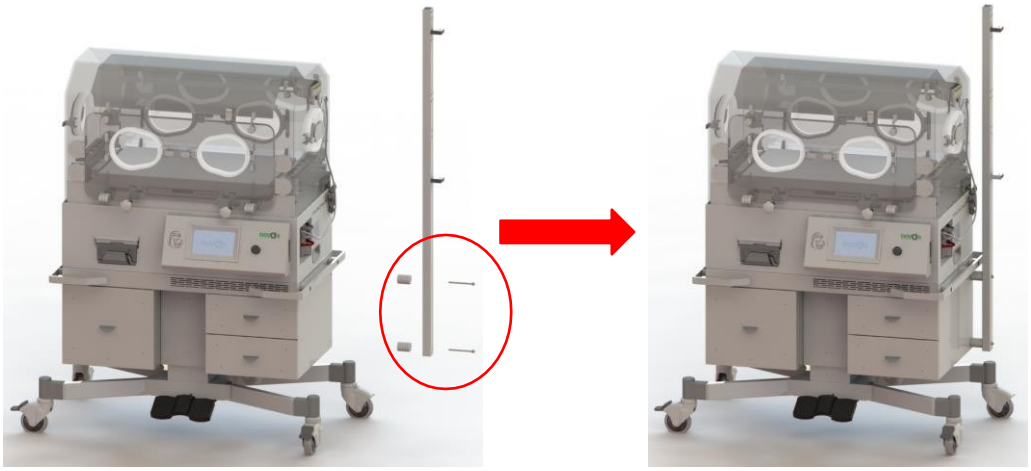
5. Hold the main body by the handles on both sides.



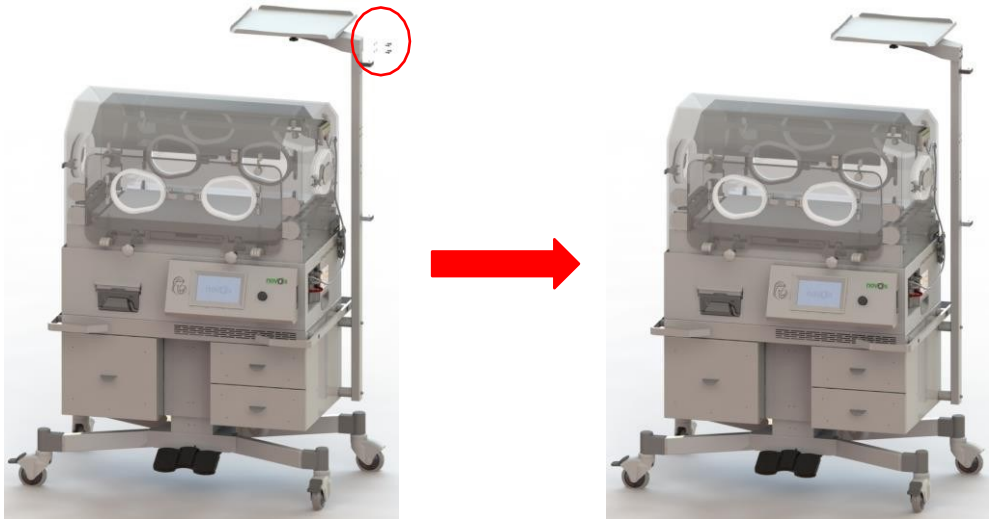
⚠	This stage of the installation must be done by at least two technical personnel. Never try to hold and lift the main body alone.

6. Lift the main body of the incubator and place it on the transport trolley.

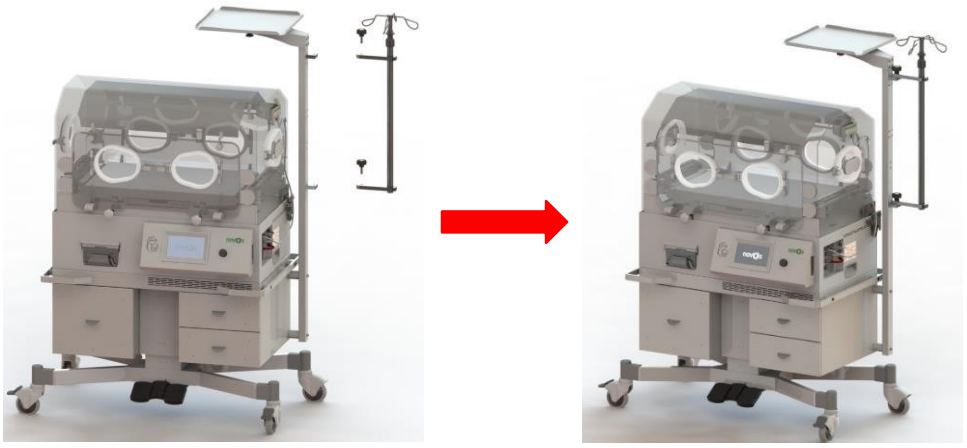
7. Secure the monitor tray and IV pole post to the incubator with two hex screws.



8. Place the monitor tray on the pole and fix it with 4 Phillips screws.



9. Attach the IV pole and fix it with plastic-headed clamping screws.



4.2. Pre-Start Check

Follow the instructions below before each use.

- Check that the equipment is disinfected according to an approved hospital protocol.
- Check that there is sufficient gas supply for the oxygen system.
- Check that all necessary accessories and auxiliary therapy equipment are at hand and in correct working condition.

Use only correctly processed components. Check that auxiliary equipment is ready for operation according to the relevant operating instructions.

- Check that there are no cracks or sharp, chipped edges on the incubator canopy.
- Check that there are no traces of rust on the incubator body.
- Check that the hinges, locks and tabs on the canopy are working correctly.
- Check that all cables and hoses are routed correctly and securely.
- Make sure the openings in the sensor module inside the canopy are not clogged with dirt.

4.2.1. Primary and Secondary Cover Locks and Hinges

Check that primary and secondary cover locks and hinges operate safety.

Perform the following test on the front and rear covers:

- Turn both primary locks down until they are released in a horizontal position.
- Lift the secondary lock slightly up and hold it like that.
- Fully open the front/rear cover by pulling on the primary locking heads.
- Confirm that the cover hinges are working properly.
- Make sure the primary locks are still free in a horizontal position.
- Lift the cover up and push it back into its closed position.

⚠	Before closing the access cover, always make sure that the primary locks are released in a horizontal position. Otherwise, access covers will not be closed while locks are in vertical position.

- Put the primary locks in a vertical position.
- Pull the cover and make sure it doesn't open.
- Put the primary locks in a horizontal position.
- Pull the access cover towards you and confirm that it cannot be opened due to the secondary lock.

If the primary and secondary locks cannot stay attached or the access cover's movement is not normal;

- Take the device out of service.

⚠	Always make sure the locks of the access covers are active to avoid the risk of the baby falling out of the incubator.

4.2.2. Oval Window Locks

Check that the oval window is working safely.

For each of the 6 oval windows:

- Press the lock to open the oval window.
- Push the oval window until the window lock is activated and then and shut it.
- Pull the edge of the oval window towards you and confirm that it cannot be opened.

If oval window locks do not remained attached properly;

- Take the device out of service.

4.2.3. Double Wall

The upper double wall should be placed in the 4 slots on the canopy wall.

- Check that the top wall is well in place.
- Check that the double walls of the access covers (optional) are securely fastened.

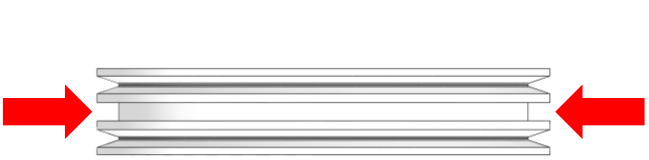
If the double wall or its slots in the canopy appear damaged;

- Take the device out of service.

4.2.4. Grommets and Oval Window Seals

- Check that all grommets and lateral oval windows on the front/rear covers are securely in place.
- Check that all 6 oval windows are in the right place.

⚠	Always make sure that oval window gaskets are installed from the center channel only. Otherwise, the thermal insulation of the canopy may be adversely affected.



Oval Window Gasket's Middle Channel

4.2.5. Baby Bed

⚠	A disposable cover should be placed on the baby bed before starting treatment.

The baby bed should be able to be opened easily without any obstacles.

- Open the front cover and fold it down.
- Pull the bed forward as far as it will go.
- Push the bed back to its original position.

	The white triangular pieces inside the canopy have a stopper function for the baby bed. Make sure the bed is centered without interrupting air circulation.

- Close the front cover.

If the bed cannot be pulled out or pushed in;

- Take the device out of service.

Check that the Trendelenburg mechanism works properly.

	Make sure the bed is fully closed! Otherwise, the channeled hot air flow may be blocked and overheating/cooling may occur.

- Turn the left adjusting head counterclockwise to see the left side of the baby bed tilts up.
- Turn the right adjusting head counterclockwise to see right left side of the baby bed tilts up.

If the tilt mechanism of the baby bed is not working properly;

- Take the device out of service.

4.2.6. X-Ray Tray

X-Verify that the rail tray is in place and does not obstruct the airway channels.

4.2.7. Smart Weighing System (Optional)

Check that the balance module latches are properly seated.

4.2.8. Height Adjustment System (Optional)

Check that the height adjustment system works normally.

- Press the left pedal to increase the height.
- Press the right pedal to decrease the height.

If the height adjustment system does not work properly;

- Take the device out of service.

4.2.9. Wheel Locks

Check that the brakes are working
normally. For each break;

- Press the outer edge of the brake pedal.
- Try to move the device and confirm the operability of the brake.

If the wheel brakes do not work properly;

- Take the device out of service.

4.2.10. Humidification System

Check that the water reservoir is full.

4.2.11. Oxygen/Humidity Sensor Module

For devices with optional servo oxygen system, the Oxygen/Humidity sensor module must remain steady in its off position.

- Check that the opening/closing movement of the oxygen/humidity sensor module is normal.
- Check that the sensor module lock on the outer wall of the canopy is engaged when the module is turned off.
- Check that the high pressure oxygen source is connected to the inlet port named “Servo Controlled O_2”. If the sensor module movement is not smooth, the module lock does not work properly, or a high pressure oxygen source is not connected to the device;

- Take the device out of service.

5.Use of Device

5.1. Operating KI 1000

Plug the device to the power supply.

⚠	Do not use extension cords for the power supply on the KI 1000 incubator! Plugging the incubator via an extension cord may result in a risk of electric shock to the patient in the event of a fault in the protective earth conductor, and may cause leakage currents to exceed the allowable limits.

To turn on the device;

- Press the On/Off switch located on the right side of the control panel.

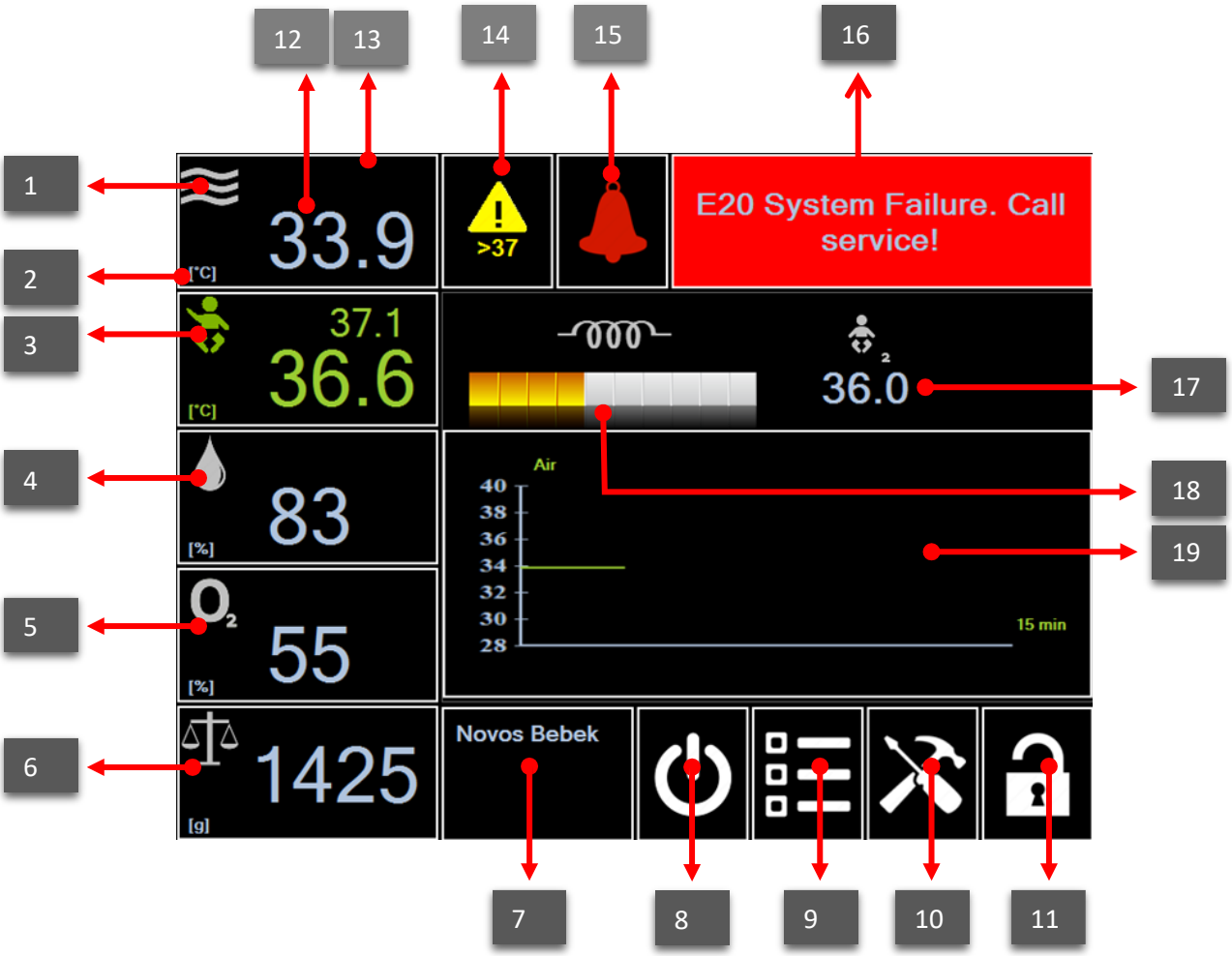
- An audible alarm will be heard. If there is no alarm, call service.
- The Novos Medical Systems Logo appears on the opening screen.

The incubator performs a "self-test" at each power-up. It is the operator's responsibility to verify the LCD Display, Knob LEDs and audible alarm functionality.

5.2. Main Display

After “Self-test”;

- Main screen appears.
- The main screen includes the following parameters;

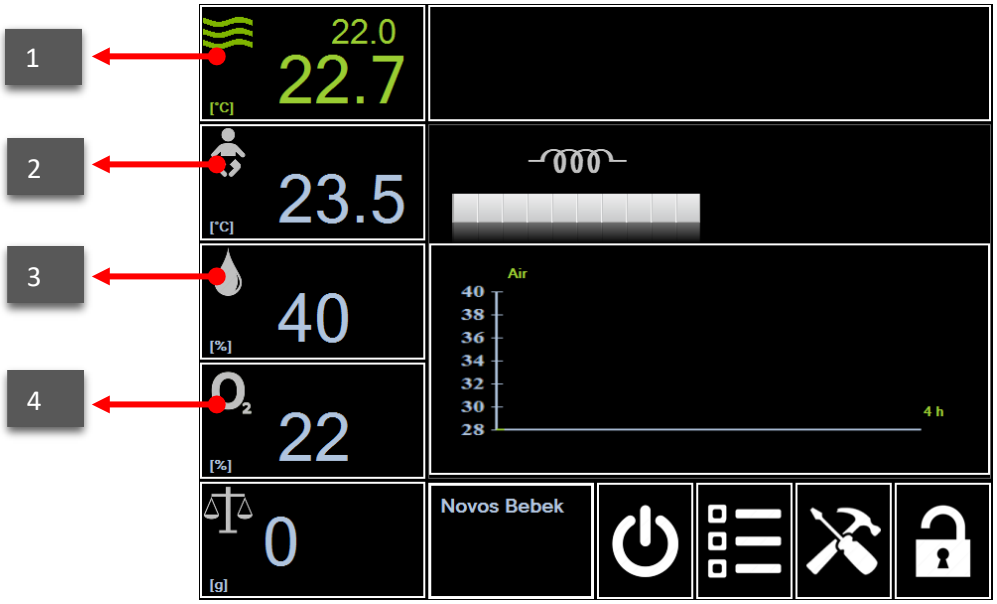


1	Active Mode Indicator (Green Highlight)	11	Key-lock
2	Unit Indicator	12	Measured Air Temperature
3	Skin Mode Control Box	13	Adjusted Air Temperature
4	Humidity Mode Control Box	14	37 ° Exceeded Indicator
5	Oxygen Mode Control Box	15	Alarm Silencer
6	Balance Mode Control Box	16	Alarms and Warnings Screen
7	Patient History Button	17	Secondary Skin Temperature
8	Standby Mode Button	18	Warmer Level Indicator
9	List of Accessible Modes	19	Trend Indicator
10	Settings Button		

5.2.1. Control Boxes

The main screen includes 4 control boxes that provide access to target value setting screens for air, skin temperature, humidity and oxygen controls.

The green highlighted animation in the upper left corner of the control box indicates that the related mode is active.



Except for the scale control box, all other control boxes contain the status indicator in the upper left corner, the instantaneous value in the center and the target value in the upper right corner.

	Mode	Active	Passive
1	Air		
2	Skin		
3	Moisture		
4	Oxygen		

The last measured value is displayed in the center of the balance control box.

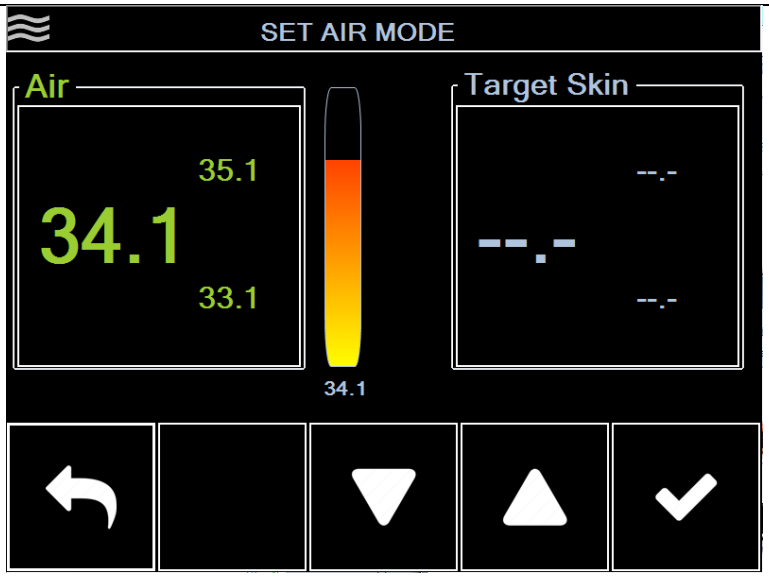
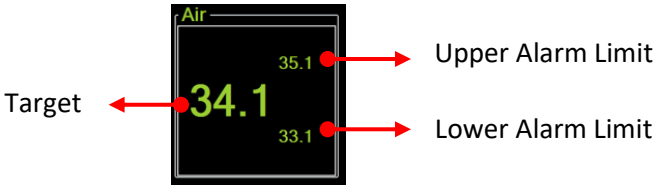
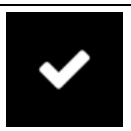
NOTE: In air temperature control mode, the device takes about 30 minutes to warm up. During this time, the "**Low Air Temperature**" alarm is suppressed not to be triggered.

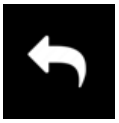
5.3. Use in Air Mode

⚠	Regularly measure baby's skin temperature! Do not leave the canopy open for any course of time, otherwise the air temperature inside the incubator will drop and this may cause hypothermia.

5.3.1. Setting the Air Temperature Target Value

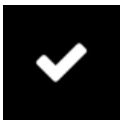
⚠	The target point must be at least 3 °C above the ambient temperature. In low ambient temperature conditions, high settings (39 °C) may not be fully achieved.

• To set the target point, press the air mode check box in the main screen.	
• The air mode screen appears.	
• Press the air area.	
• Turn the knob clockwise or press the up arrow to increase the target point.	
• Turn the knob counterclockwise or press the down arrow to decrease the target point.	
• Press the knob or the confirm icon to confirm the new setting.	

If you do not want to change the settings; • Press the return icon. New settings will be canceled. Main screen appears. Previous target point is preserved.	

5.3.2. Setting TTSS Target Skin Temperature

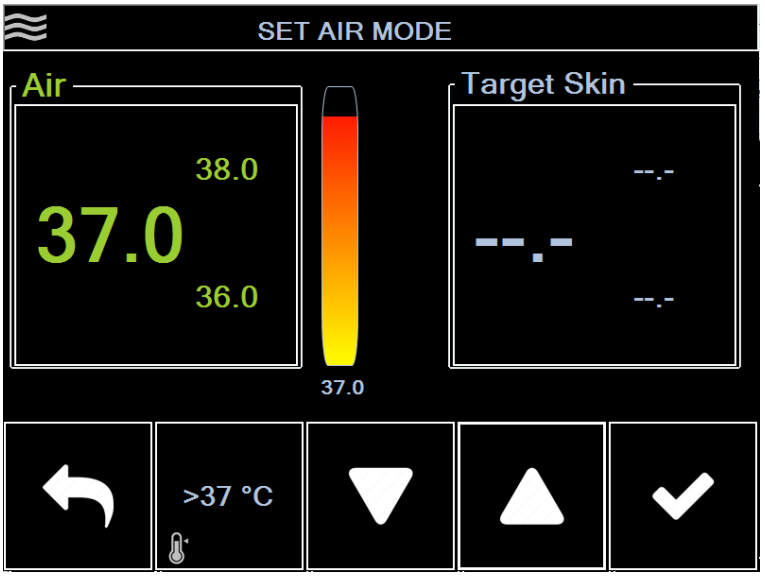
The "TTSS Target Skin" feature can also be activated on this screen.

To activate the target skin feature; • Select the target skin area.	
• Set the TTSS target skin temperature with the up and down arrows or the knob.	
• TTSS Press the approval icon to set the target skin temperature.	

Note that in order to use the skin temperature feature, the Skin1 probe must be sticked to the baby's body and is connected to the incubator.

5.3.3. Setting Extended Air Temperature Target Point

⚠	When the expanded target point for air temperature is set, special attention should be paid to monitor the baby's temperature.

If the standard target point range (20 °C-37 °C) is exceeded; • The "> 37 ° C warning icon" will appear next to the back button.	
• Press the> 37 ° C icon to activate target temperature setting above 37 ° C.	
• Set the air temperature with the up and down arrows or the knob (The air temperature can be raised up to a maximum of 39 °C).	
• Press the approval icon to save the new temperature.	
• > 37 °C icon will appear on the main screen.	

5.3.4. Reducing Air Temperature Inside the Canopy

The cooling rate is determined by the incubator design and can be increased in the following cases.

- By removing the double wall.
- By decreasing the external temperature (if possible).
- By lowering the moisture target point and opening the incubator canopy fully.

NOTE: Cooling is not accelerated by lowering the required air temperature below the originally intended value.

In case of **urgent** need for cooling; Open the canopy, wide access covers, side covers or oval windows.

⚠	Monitor the baby constantly to make sure the baby cannot fall out of the incubator while the canopy, covers, or oval windows are open.

5.3.5. Air Mode Alarms

In air mode, alarm thresholds can be set as ±0.5 °C, ±1 °C or ±1.5 °C. While

setting the device values, alarm limits should be taken into consideration.

If the deviation between the target and measured air temperature values exceeds the alarm threshold values;

- A red alarm message appears on the screen; "**Low Air Temperature**" or "**High Air Temperature**".
- An intermittent audible alarm sound.
- The central alarm indicator behind the knob illuminates.
- The measured value starts to flash.

The intermittent audible alarm can be silenced for 15 minutes. To silence the auditory alarm, press the  button.

- The visual warning message remains on the screen.
- The intermittent alarm sound is silenced for 15 minutes.

When the measured value returns within the specified range;

- The warning message disappears.
- The intermittent alarm sound is silenced.
- The measured value remains constant on the screen.

If the air probe is not connected;

- A warning message appears on the screen; **“Air sensor error. Call the Service”**

In this case;

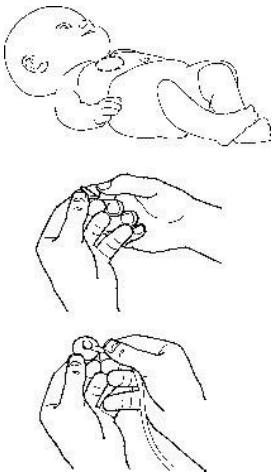
- If present, attach the air probe to the back of the control panel. For

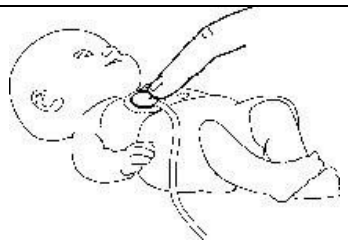
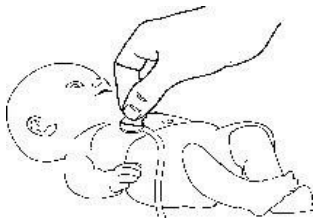
other alarms, see the "Alarms and Warnings" section.

5.4. Use in Skin Mode

	Before using the skin probe, always verify that it is the original NOVOS KI 1000 accessory.

5.4.1. Attaching/Detaching the Skin Probe

Attaching the Skin Probe 	• Gently clean and dry the place where the skin sensor will be placed on baby's skin. • Remove the backing paper of the sensor cover. • Place the white plastic side of the skin sensor on the adhesive side in the center of the sensor cover as shown.

	• Place the skin sensor and sensor cover, 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.
 **Detaching the Skin Probe**	• Gently lift the edge of the sensor cover. If necessary, moisten the edges of the sensor cover using sterile water and a moistened cotton swab. • Gently peel the sensor cover and skin sensor off the skin surface. Be careful not to pull the skin sensor cable directly.

5.4.2. Checking the Function of the Temperature Sensors

KI 1000 has two skin temperature sensors, Skin1 and Skin2. The skin temperature sensor is used to control the baby's skin temperature. However, the Skin2 temperature sensor allows to monitor the twins' skin temperature.

Just before using the skin temperature sensors, connect the sensors individually to their respective sockets (yellow or white) and wait for the measured value to appear on the screen.

- The measurement value obtained from the yellow skin temperature sensor is observed in the skin temperature control box.

- The measurement signal from the white skin2 temperature sensor is observed under the Alarms and Warnings section on the main screen.

If there is no measured value displayed, the corresponding sensor must be replaced.

Use of skin temperature measurement in air or skin temperature control modes.

Connect temperature sensors for measurement of skin1 and skin2 temperature;

- Plug the yellow skin probe connector into the yellow socket on the control panel (Skin Probe).

NOTE: When using skin mode, servo control takes place only with the help of temperature data from the yellow skin temperature sensor.

- Plug the white skin2 probe connector into the white socket on the control panel (Skin2 Probe)
- Route the sensor cable through one of the flexible grommets.
- Place the skin probe on the reflective tape.
- Using the adhesive pad, secure the sensor tip to the appropriate part of the baby's skin.

Positioning the skin temperature sensor (yellow)

If the baby is lying on its back;

- Fix the yellow sensor on the abdomen, near the

liver. If the baby is lying face down;

- Fix the yellow sensor on its back, preferably near the kidneys.

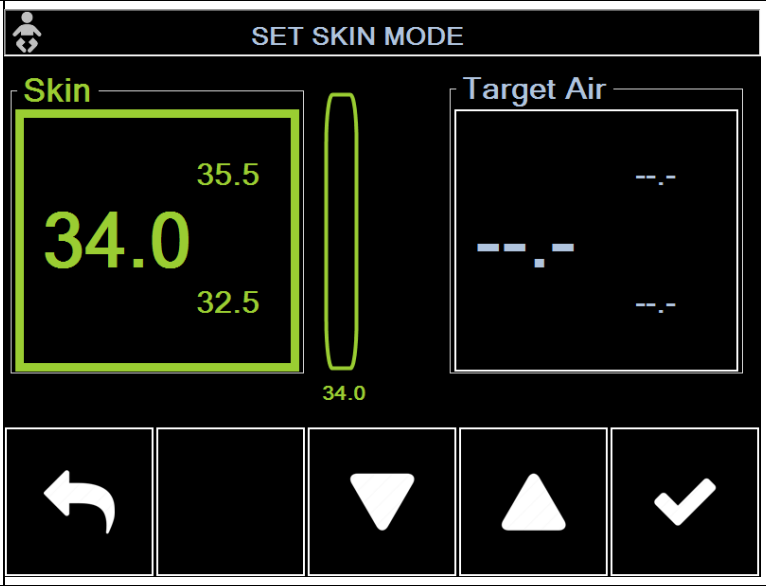
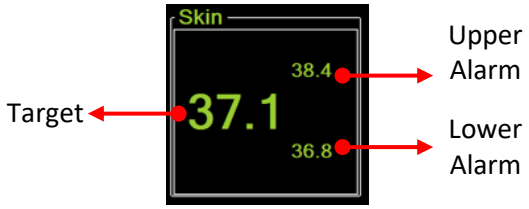
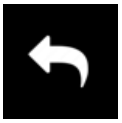
Positioning the skin temperature sensor (white)

- Fix the white sensor to the twin sibling as described above according to the lying position.

NOTE: When the skin probe is fixed, the measured skin temperature is displayed even if the incubator is in air mode. However, in this case the incubator temperature is not controlled as a function of the skin temperature. If the TTSS Target Skin feature is activated in conjunction with the air mode, the incubator will only trigger alarms related to skin temperature when the measured skin temperature is outside the alarm limits.

	Do not use skin temperature sensors to measure rectal (central) temperature! Do not place the sensor under the baby, otherwise measurement and control will be based on baby's core temperature instead of skin temperature.
	Regularly check that the skin temperature sensor is properly fixed on the baby's skin! Falling of the skin probe measures the air temperature, which imposes the risk of overheating the baby.
	Do not use the skin temperature control mode for shocked babies because in this case the skin temperature is much lower than normal. In this case, the incubator operating in skin mode increases the air temperature too much, which imposes the risk of overheating the baby. When dealing with patients in such situations, it is recommended to operate the KI 1000 incubator in air mode.
	Do not use the skin temperature control mode in babies with fever, as the skin temperature is higher than normal. In this case, the incubator operating in the skin mode decreases the air temperature too much, which imposes the risk of hypothermia.
	The skin temperature control mode should not be used in twins, as the KI 1000 only controls the baby's temperature based on temperature information from the primary skin probe. Otherwise, there is a risk of hypothermia or overheating. Always use the air temperature control mode when dealing with twins.
	Improper positioning of the primary skin probe may lead to overheating of the baby or insufficient warming therapy.
	Regularly measure baby's temperature! Do not leave the canopy open for a long time, otherwise the air temperature inside the incubator will drop quickly.

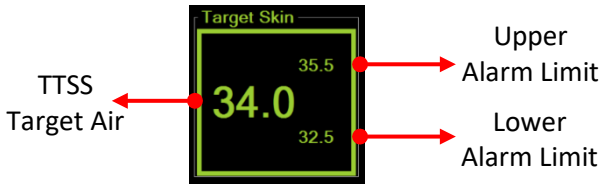
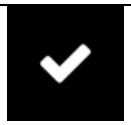
5.4.3. Setting the Skin Temperature Target Value

• To set the target point, press the skin mode check box in the main screen.	
• The skin mode screen appears.	
• Press the skin area.	
• Turn the knob clockwise or press the up arrow to increase the target point.	
• Turn the knob counterclockwise or press the down arrow to decrease the target	
• Press the knob or the confirm icon to confirm the new setting.	
If you do not want to change the settings; • Press the return icon. New settings will be canceled. Main screen appears. Previous target point is preserved.	

5.4.4. Setting TTSS Target Air Temperature

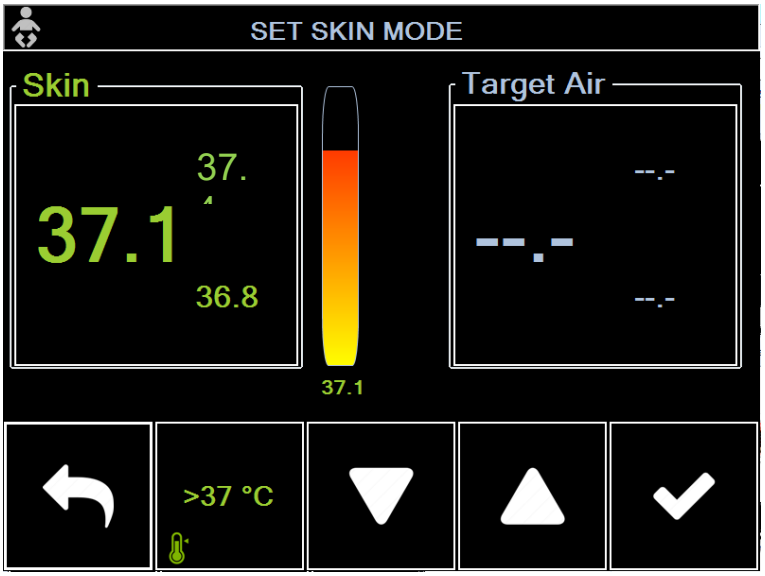
The “TTSS Target Air" feature can also be activated on this screen.

To activate the target air feature;

• Select the target air area.	
• Set the target air temperature with the up and down arrows or the knob.	
• Press the approval icon to set the target air temperature.	

5.4.5. Setting Extended Skin Temperature Target Point

	When the expanded target point for skin temperature is set, special attention should be paid to monitor the baby’s temperature.

If the standard target point range (34 - 37 °C) is exceeded; • >37 °C warning icon appears.	
• Press the >37 °C icon to activate the extended range.	
• Set the target skin temperature with the up and down arrows or the knob (The skin temperature can be raised up to 38 °C).	
• Press the approval icon to save the new target temperature.	

• > 37 °C icon will appear on the main screen.	

5.4.6. Skin Mode Alarms

In skin mode, alarm thresholds can be set as ±0,3 °C, ±0.5 °C or ±1.0 °C.

If the difference between the set and measured skin temperature exceeds the alarm limit;

- A red alarm message appears on the screen; "**Low Skin Temperature**" or "**High Skin Temperature**".
- An intermittent alarm sounds.
- The central alarm indicator behind the knob illuminates.
- The measured value starts to flash.

The intermittent audible alarm can be silenced for 5 minutes. To silence the auditory alarm, press the  button.

- The visual warning message remains on the screen.
- The intermittent alarm sound is silenced for 5 minutes.

When the measured value returns within the desired range;

- The warning message disappears.
- The intermittent alarm sound is silenced.
- The measured value remains constant on the screen.

If the skin probe is not connected or is defective;

- 3 dashes are displayed instead of the measured value.
- The warning message "Skin1 Sensor Error" is displayed on the screen.
- An intermittent audible alarm sounds.
- The central alarm indicator behind the knob illuminates.
- The measured value starts to flash.
- The red alarm LED starts to flash.

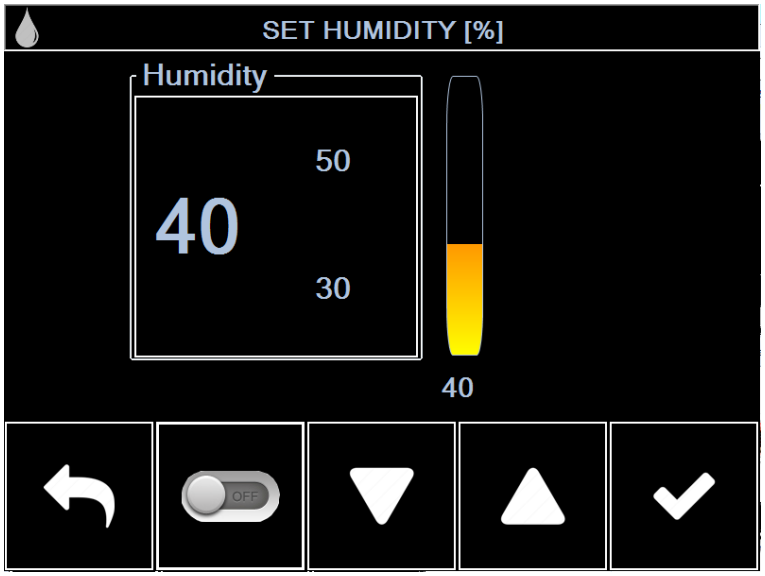
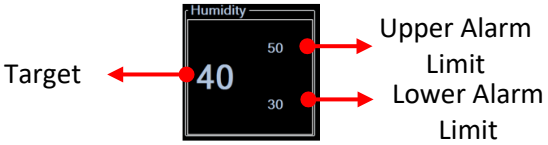
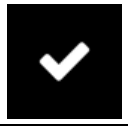
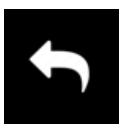
In this case, if there is an intact skin probe;

- Immediately plug it into the corresponding socket on the control panel.

For other alarms, see the "Alarms and Warnings" section.

5.5. Use of Servo Humidity

5.5.1. Setting Humidity Target Point

• To set the target point, press the humidity mode check box in the main screen.	
• The Set humidity [%] screen is displayed.	
• Press the humidity area.	
• Turn the knob clockwise or press the up arrow to increase the target point.	
• Turn the knob counterclockwise or press the down arrow to decrease the target point.	
• Use the On/Off button to activate the servo humidity control.	
• Press the knob or the confirm icon to confirm the new setting.	
If you do not want to change the settings; • Press the return icon. New settings will be canceled. Main screen appears. The previous target point and activation mode are preserved.	

5.5.2. Humidity Mode Alarms

Alarm threshold values for humidity control can be set as ± 5%, ± 10% or ± 15%.

If the deviation between the target and measured humidity values exceeds the alarm threshold values;

- A yellow alarm message appears on the screen; "**Low Humidity Temperature**" or "**High Humidity Temperature**".
- An intermittent audible alarm sound.
- The central alarm indicator behind the knob illuminates.
- The measured value starts to flash.

The intermittent audible alarm can be silenced for 30 minutes. To silence the auditory alarm, press the  button.

- The visual warning message remains on the screen.
- The intermittent alarm sound is silenced for 30 minutes.

When the measured value returns within the specified range;

- The warning message disappears.
- The intermittent alarm sound is silenced.
- The measured value remains constant on the screen.

If the humidity sensor is defective;

- The warning message **"Humidity sensor error. Humidity system has been shut down"** is displayed on the screen highlighting in red.
- An intermittent audible alarm sound.
- The central alarm indicator behind the knob illuminates.

In this case;

- Call technical service.

If the humidity sensor cable is not connected;

- The warning message **"Insert the O_2/Humidity module connector"** appears on the screen highlighted in red.
- An intermittent audible alarm sound.
- The central alarm indicator behind the knob illuminates.

In this case;

- Immediately plug the O_2/Humidity connector into the right side of the control panel.

If the water level drops to a minimum in the water reservoir;

- A red alarm message appears on the screen; **"Low Water Level. Humidity System has been Shut Down"**.
- An intermittent audible alarm sound.
- The central alarm indicator behind the knob illuminates.
- After refilling the water reservoir, the humidity system must be restarted.

When the water level sensor is malfunctioned;

- A red alarm message appears on the screen; "**Water level sensor error. Humidity system has been shut down**".
- An intermittent audible alarm sound.
- The central alarm indicator behind the knob illuminates.

In this case;

- Call technical service.

If the O_2/Humidity Sensor Module is turned on;

- A red alarm message appears on the screen; **"Turn off the O_2/Humidity Sensor Module".**
- An intermittent audible alarm sound.
- The central alarm indicator behind the knob illuminates.
- The Humidity System is shut down.

When the O_2/Humidity Sensor Module is turned off;

- The warning message disappears.
- An intermittent audible alarm sound.
- Since the humidity system was previously shut down, it must be restarted from the humidity control box.

For other alarms, see the "Alarms and Warnings" section.

5.6. Use of Servo O_2

The KI 1000 can apply both servo control and passive oxygen therapy to the baby. Both systems have their own unique oxygen inlet at the back of the device. Please check the "Oxygen Inlet Connection" section.

⚠	Oxygen supply may increase the noise inside the baby room and cause personal injury.
⚠	An oxygen analyzer must be used whenever the oxygen reaches the baby.

5.6.1. Setting O_2 Concentration in Manual Flow Controlled O_2 System

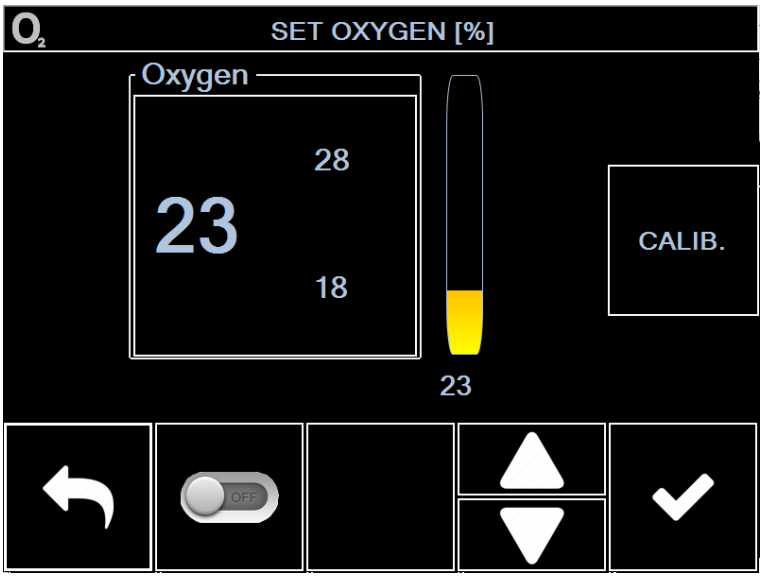
The system in which the applied oxygen concentration is controlled by the flow rate of the entering oxygen is referred to as the passive oxygen system. The table below shows the oxygen concentration values that can be obtained for different flow rates. These values should not be used as an accurate indicator of oxygen concentrations. Oxygen concentration should be measured continuously with a calibrated oxygen analyzer. Failure to do so may result in personal injury or equipment damage.

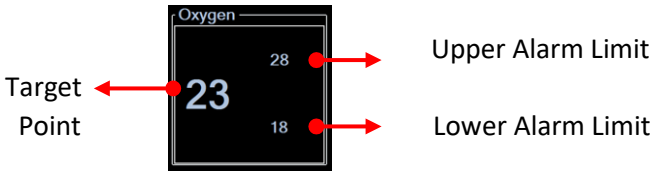
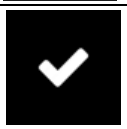
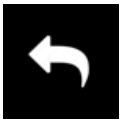
Flow (lpm)	**3**	**6**	**9**	**12**	**15**
O_2%	23-31	30-40	39-49	47-57	50-60

5.6.2. Setting the Oxygen Target Point on the Servo Controlled Oxygen System

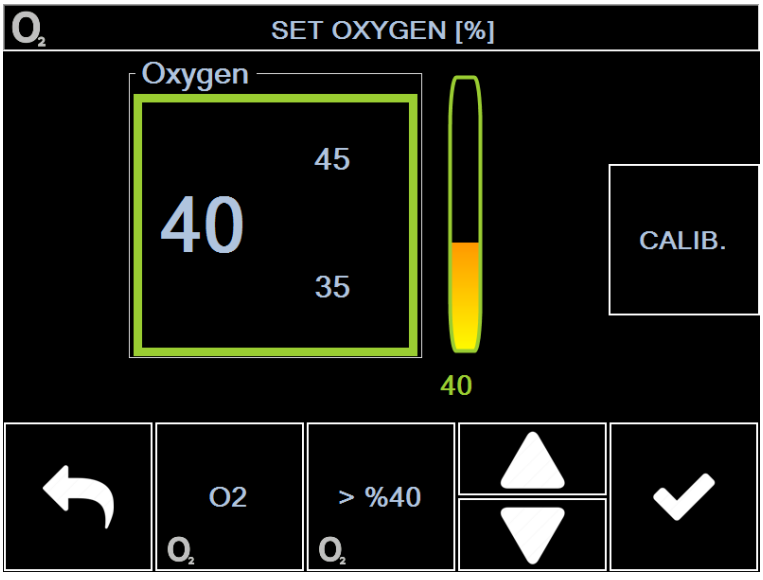
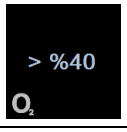
The standard target O_2 concentration range is defined as 21 – 40%. The expanded target concentration range is between 40.1% and 65%.

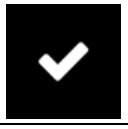
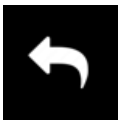
⚠	Always consider the physiological risks and fire hazards associated with the use of high O_2 concentrations.

• To set the target point, press the oxygen mode check box in the main screen.	
• The Set Oxygen [%] screen appears.	

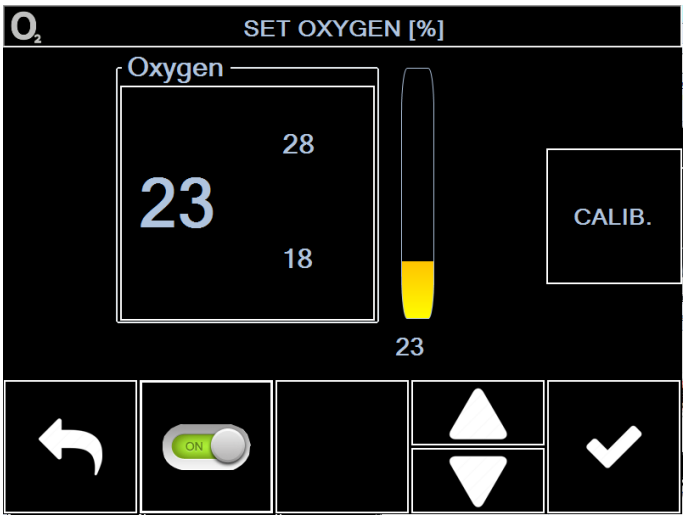
• Press the oxygen area.	
• Turn the knob clockwise or press the up arrow to increase the target point.	
• Turn the knob counterclockwise or press the down arrow to decrease the target point.	
• Use the On/Off button to activate the servo oxygen control.	
• Press the knob or the confirm icon to confirm the new setting.	
If you do not want to change the settings; • Press the return icon. New settings will be canceled. Main screen appears. The previous target point and activation mode are preserved.	

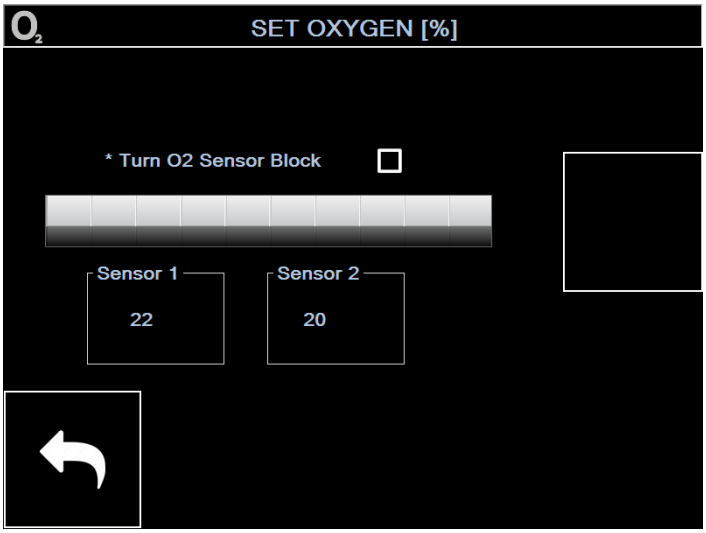
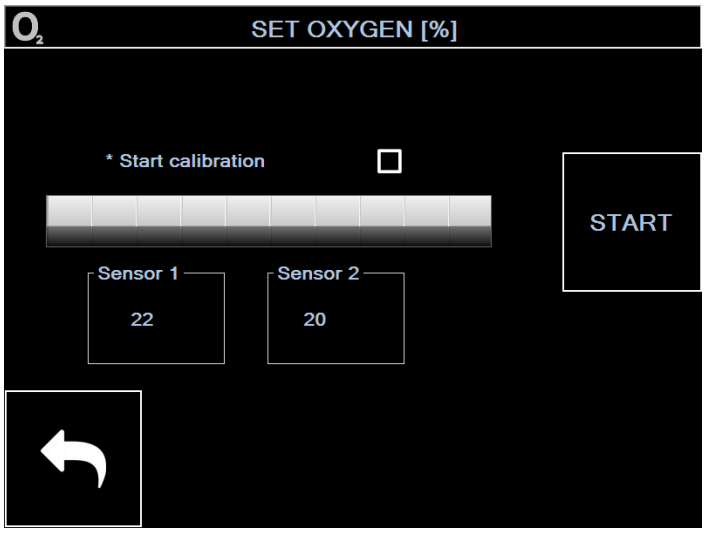
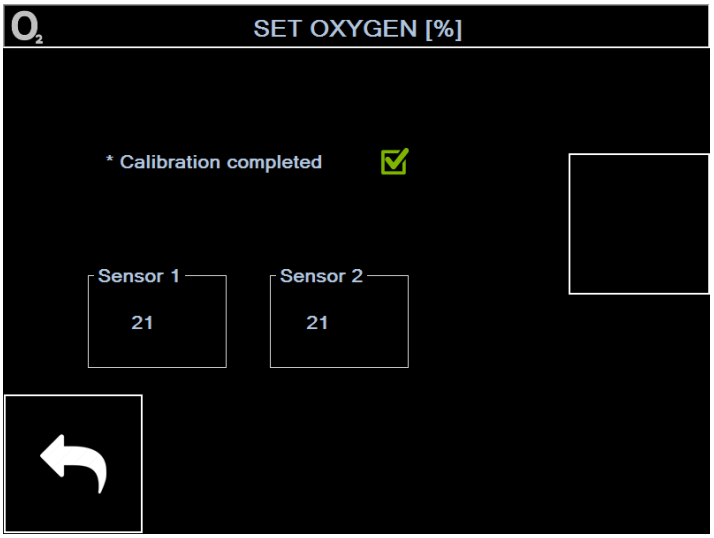
5.6.3. Setting the Expanded Oxygen Concentration Target Point

If the standard target point range (21 – 40%) is exceeded; • > 40% Warning icon will be displayed.	
• Press the >40% icon to activate the extended range.	

• Turn the knob clockwise or press the up arrow to continue increasing the target point after 40% (Oxygen concentration can be increased up to 65%).	
• Turn the knob counterclockwise or press the down arrow to decrease the target point.	
• Press the approval icon to save the new target value.	
If you do not want to change the settings; • Press the return icon. New settings will be canceled. Main screen appears. The previous target point and activation mode are preserved.	

5.6.4. Calibration of Oxygen Sensors

If "Calibrate Oxygen Sensors" warning message is received; • Press CALIB. button.	

• Turn the O_2 Sensor module located on the top right of the canopy.	
• Press the start button.	
• The device will calibrate the oxygen sensors and will automatically return to the main screen after calibration is complete.	

5.6.5. Oxygen Mode Alarms

Oxygen mode alarm thresholds can be set to ± 3% and ± 5%.

If the deviation between the target and measured oxygen concentration value exceeds the alarm threshold values;

- A red alarm message appears on the screen; "**Low Oxygen Temperature**" or "**High Oxygen Temperature**".
- An intermittent audible alarm sounds.
- The central alarm indicator behind the knob illuminates.
- The measured value starts to flash.

The intermittent audible alarm can be silenced for 5 minutes. To silence the auditory alarm, press the  button.

- The visual warning message remains on the screen.
- The intermittent alarm sound is silenced for 5 minutes.

When the targeted value returns within the specified range;

- The warning message disappears.
- The intermittent alarm sound is silenced.
- The measured value is fixed on the screen.

If any of the oxygen sensors is malfunctioned;

- The warning message **"O_2 sensor error. O_2 system has been shut down"** is displayed on the screen.
- An intermittent audible alarm sound.
- The central alarm indicator behind the knob illuminates.

In this case;

- Call technical service.

If the oxygen sensor block cable is not connected;

- The warning message **"Insert the O_2/Humidity module connector"** appears on the screen in red.
- An intermittent audible alarm sound.
- The central alarm indicator behind the knob illuminates.

In this case;

- Immediately plug the O_2/Humidity Sensor connector into the corresponding socket located on the right side of the control panel. If the O_2/Humidity Sensor Module is turned on;
- The warning message **"Turn off the O_2/Humidity sensor module"** appears on the screen in red.
- An intermittent audible alarm sound.
- The central alarm indicator behind the knob illuminates.
- The Oxygen System is shut down.

When the O_2/Humidity Sensor Module is turned off;

- The warning message disappears.
- The intermittent alarm sound is silenced.
- The servo oxygen must be reactivated, as the oxygen system was previously shut down for safety.

For other alarms, see the "Alarms and Warnings" section.

5.7. Use of Smart Weighing Option

KI 1000 balance module is located just below the bed and the x-ray tray. In the weighing process, the whole bed is weighed with the baby, together with the x-ray tray and the items placed on it. Thereafter, the weight of the items on the bed, the bed module and the x-ray tray is then subtracted from the total weight in order to determine the exact weight after the baby is removed from the bed. Before weighing, check that the bed is fully pushed in and is in a horizontal position. The balance module should be calibrated with regularly calibrated test weights. The sensor accuracy stated in the technical data is only obtained on the condition that balance calibration is carried out after installation.

During the weighing process, please make sure that:

- The KI 1000 is not subjected to any vibration,
- Nothing is placed on the bed surface.

5.7.1. Starting the Weighing Procedure

<table>
<tr><td>

- Press the Balance Control button on the main screen

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

Balance Screen will appear. If the baby is out of the incubator;

- Press the tare button to start taring.

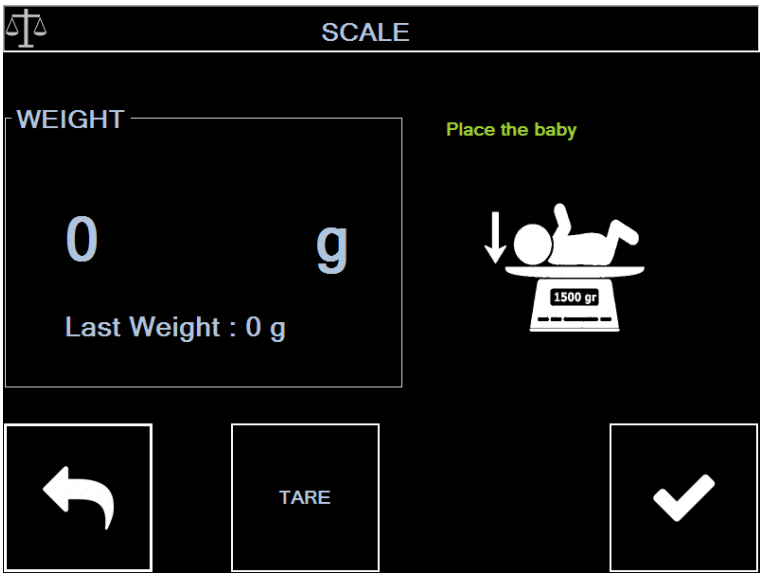
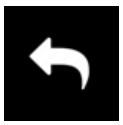
If the baby is already in the incubator;

- Gently lift the baby to start automatic taring.

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

- Wait a few seconds for taring to complete.

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

After the taring process is completed; • Place the baby to start the weighing process.	
• Press the approval icon to save the measured weight.	
If you do not want to save the weight; • Press the return icon. It returns to the main screen without saving the last measured value.	

5.8. Alarms and Warnings

The KI 1000 has 19 different alarms divided into two groups as Red Alarms and Yellow Alarms. The table below shows the alarm list. Here you can also find the background color of the alarm messages expressing the alarm priority.

Alarm settings can only be changed by authorized personnel!

When an alarm is triggered, the corresponding Alarm Silencer button (Red, Yellow) is displayed next to the Alarms and Warnings section.

Alarm Message	Alarm Priority	Alarm Silencer Button's Function
Air Sensor Error	High Priority	Audible alarm is activated.
Turn off the O2/Humidity Sensor module.	High Priority	Audible alarm is silenced for 5 minutes.
Connect O_2/Humidity Module Cable	High Priority	Alarm type turns into white. Audible alarm is permanently silenced. The alarm message changes to the corresponding warning message.
O_2 Sensor Error Oxygen System has been shut down.	High Priority	Alarm type turns into white. Audible alarm is permanently silenced. The alarm message changes to the corresponding warning message.
Humidity Sensor Error Humidity System has been shut down.	Medium Priority	Alarm type turns into white. Audible alarm is permanently silenced. The alarm message changes to the corresponding warning message.
Calibrate oxygen sensors	Medium Priority	Alarm type turns into white. Audible alarm is permanently silenced. The alarm message changes to the corresponding warning message.

Skin1 Sensor Error	High Priority	Audible alarm is silenced for 5 minutes.
Skin2 Sensor Error	High Priority	Audible alarm is silenced for 5 minutes.
Auxiliary Sensor Error	High Priority	Audible alarm is silenced for 5 minutes.
Low Water Level Humidity System has been shut down.	High Priority	Alarm is reset.
Water level Sensor Error Humidity System has been shut down.	High Priority	Alarm type turns into white. Audible alarm is permanently silenced. The alarm message changes to the corresponding warning message.
High Oxygen	High Priority	Audible alarm is silenced for 5 minutes.
Low Oxygen	High Priority	Audible alarm is silenced for 5 minutes.
High skin temperature	High Priority	Audible alarm is silenced for 5 minutes.
High air temperature	High Priority	Audible alarm is silenced for 15 minutes.
Low skin temperature	High Priority	Audible alarm is silenced for 5 minutes.
Low air temperature	High Priority	Audible alarm is silenced for 15 minutes.

Alarm Message	Alarm Priority	Alarm Silencer Button's Function
High Humidity	Medium Priority	The audible alarm is silenced for 30 minutes.
Low Humidity	Medium Priority	The audible alarm is silenced for 30 minutes.
Replace the air filter!	Medium Priority	-

	While the alarm silencing is active, the incubator's operator and medical personnel are fully responsible for patient care and safety. Failure to identify alarm conditions and to take corrective action could result in patient injury.

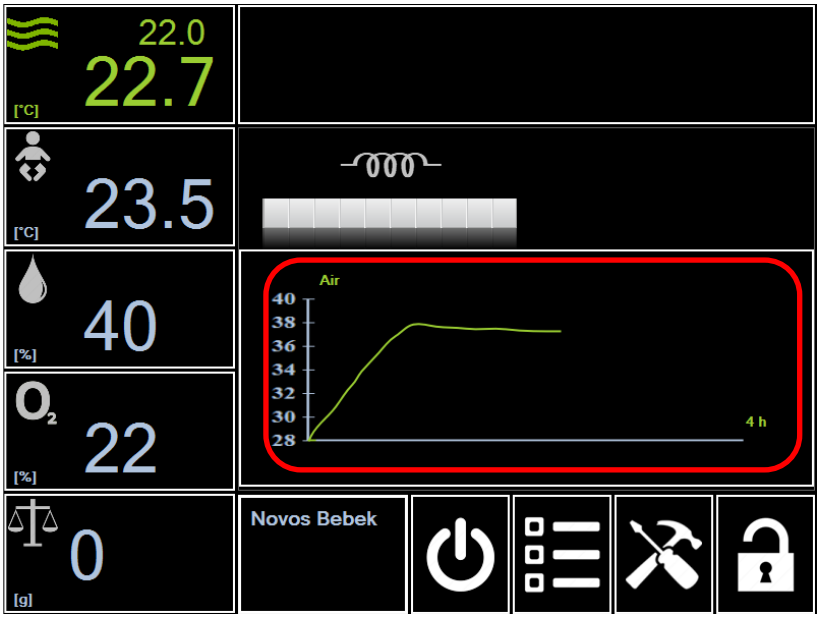
In addition to the alarms, there are 5 different warning messages regarding humidity and oxygen modes. Warning messages appear when their respective modes are not active. Otherwise, the corresponding alarms specified on the Alarms and Warnings screen will be triggered.

Warning Messages
Connect O_2/Humidity Module Cable
O_2 Sensor Error Oxygen monitoring has been shut down.
Humidity Sensor Error Humidity monitoring has been shut down.
Calibrate oxygen sensors
Water level sensor error

Warning messages are displayed with a white background and the white alarm silencing button has no function for alerts.

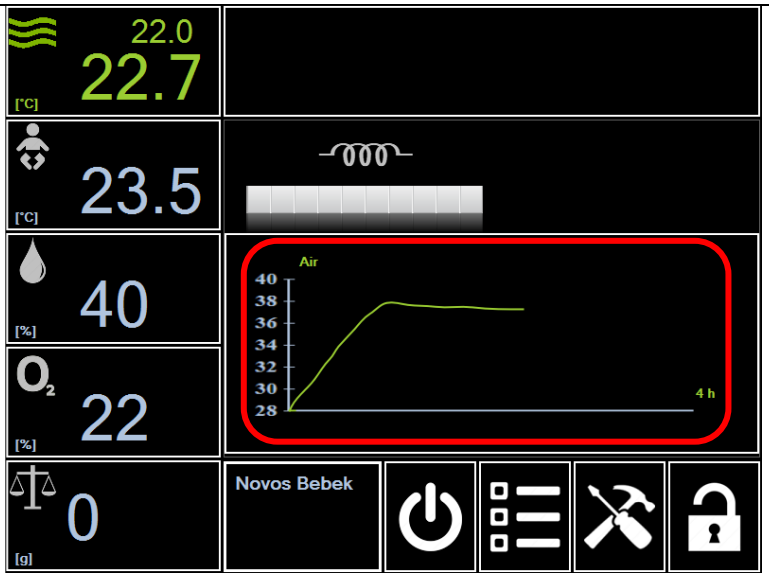
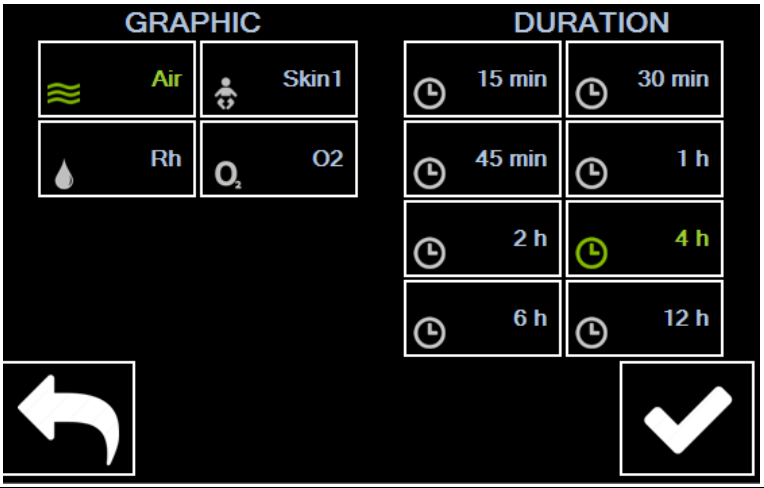
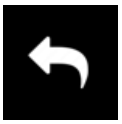
5.9. Trend Indication

Trends show graphically measured/recorded parameters. The data window shows the most recent data in the selected time period. The trend is shown on the main screen, so that both instant and previous values can be observed on the same screen.



The example shows the trend of the air temperature over the last 4 hours.

5.9.1. Setting the Graphic Type and Duration (Zoom)

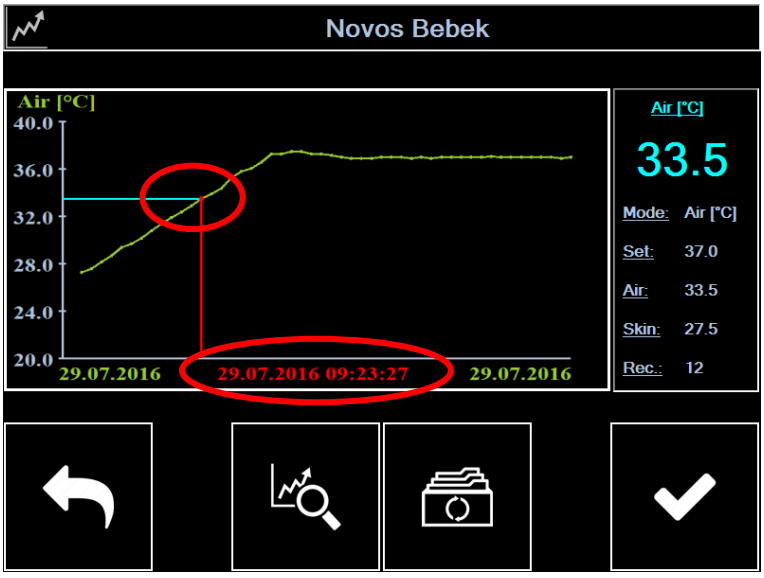
• Press the area where the Trend image is located on the main screen.	
• Select the desired trend image from the drop down list; ○ Air temperature ○ Primary Skin temperature ○ Moisture ○ Oxygen concentration • Set the time you want it to display, starting from the last 15 minutes, up to the last 12 hours.	
• Press the confirm key to save the selections.	
If you do not want to save the changes; • Press the return icon. Returns to the home screen without applying image changes.	

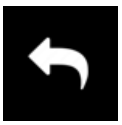
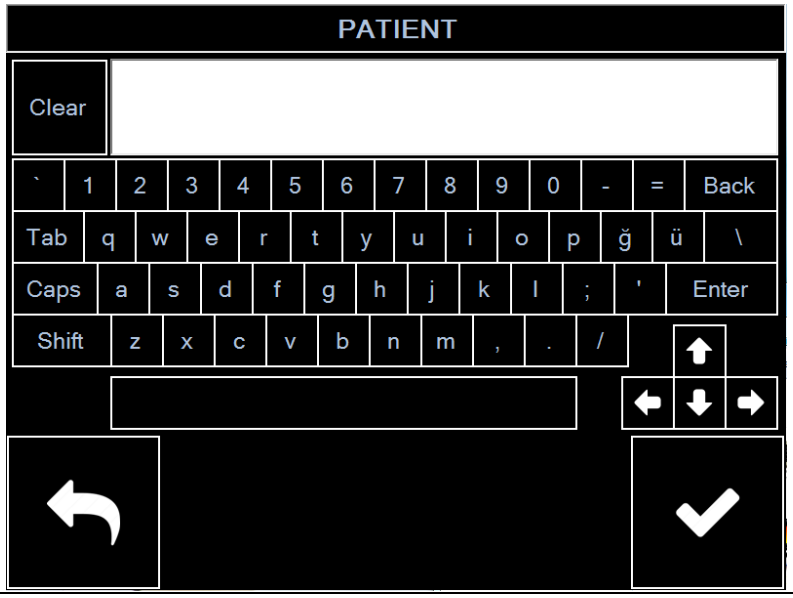
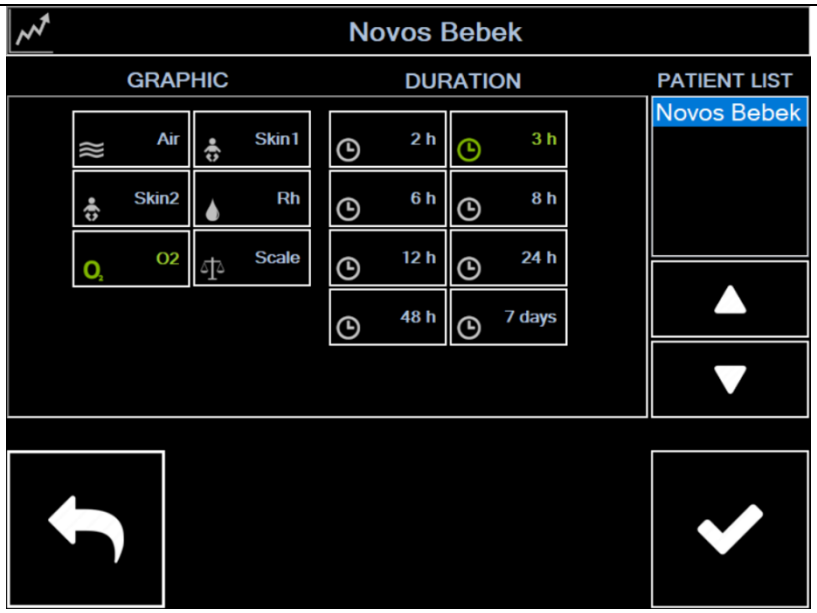
5.10. Patient History Records

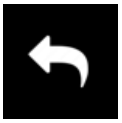
The KI 1000 can store data of 5 different patients. Recorded parameters are;

- Air temperature
- Primary Skin temperature
- Secondary Skin Temperature
- Humidity Ratio
- Oxygen concentration
- Weighing Results.

5.10.1. Viewing Patient History

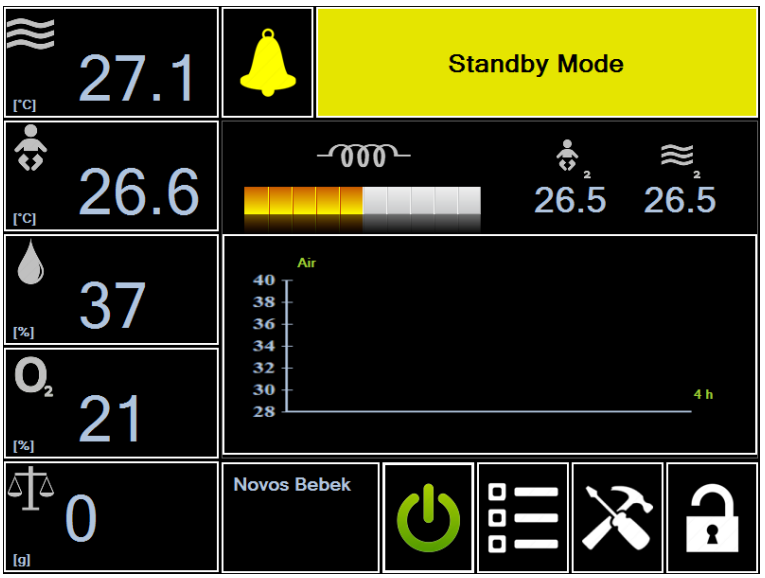
The last patient's name is displayed above the patient records button on the main screen. • Press patient records	
Patient history will be shown on the screen. In this example, air temperature records for "Novos Baby" are shown in the graph. Horizontal axis represents recording date/time and vertical axis represents air temperature. The time data highlighted in red on the horizontal axis indicates the date/time the selected recording was taken. On the right, other parameters belonging to the selected data point are listed. These parameters are archived periodically for each patient. These parameters are; • Operating Mode • Target Temperature • Air temperature • Skin temperature • Record Number. Use the knob or press the point of interest directly to switch between different data points.	

If you want to return to the main screen; • Press the return icon.	
To register a patient when a new baby is placed in the incubator; • Press the new patient button.	
• Enter the patient's name and press the confirm button to save the new patient. • Or press the return button to cancel changes.	
To select a different patient data or chart type, or to change the time interval to be displayed; • Press the Patient Record Parameters button.	
• Select the chart type to be monitored, from the chart type menu. You can select between the following parameters; ○ Air temperature ○ Primary Skin temperature ○ Secondary Skin Temperature ○ Humidity Ratio ○ Oxygen concentration ○ Weighing results • Select the time period to be displayed from the time section. Select the patient from the patient list by pressing the patient's name directly or using the up and down arrows.	
Press the Confirm button to save changes and return to the previous screen.	

If you do not want to save the changes; Press the return icon. Returns to the home screen without applying image changes.	

5.11. Standby Mode

KI 1000 has a standby mode feature. This mode is used when access covers need to remain open for supply, etc. When the standby mode is activated, all alarms are silenced.

To activate the standby mode; • Press the Standby Mode button on the home screen.	
• The yellow warning message displayed in the Alarms and Warnings section of the screen indicates that Standby Mode has been activated.	

KI 1000 adjusts the warmer level to 50% to compensate for heat loss caused by opened access covers. All audible alarms are silenced in standby mode. The main purpose in the standby mode is to maintain the previous conditions in the canopy so that the baby does not feel discomfort when the warming therapy is resumed.

	Never leave the baby unattended while the standby mode is active.

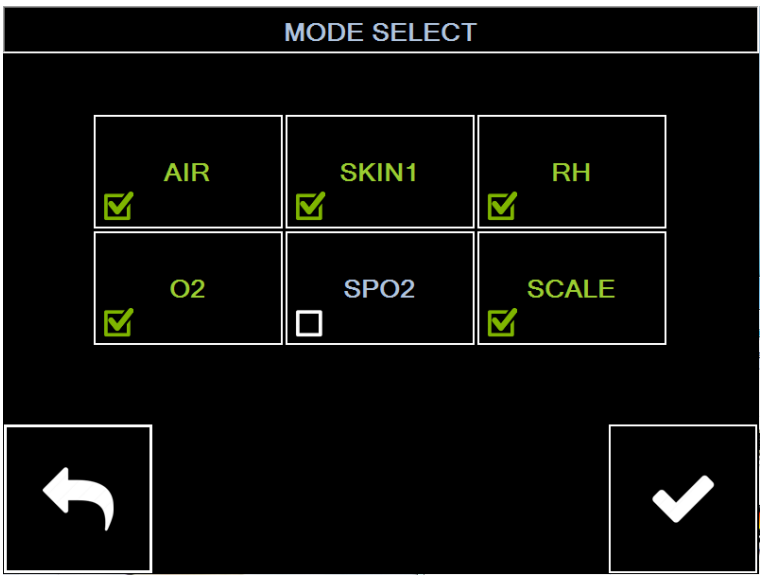
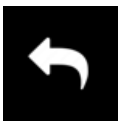
The KI 1000 switches to air mode in the background regardless of the previous operating mode. Therefore, the baby's skin temperature is no longer considered in standby mode. Standby mode should only be used when access covers need to be opened and heat therapy discontinued.

When the standby mode is deactivated by pressing the standby mode button one more time;

- The previous mode is activated with the same target points.

5.12. Selecting Accessible Modes

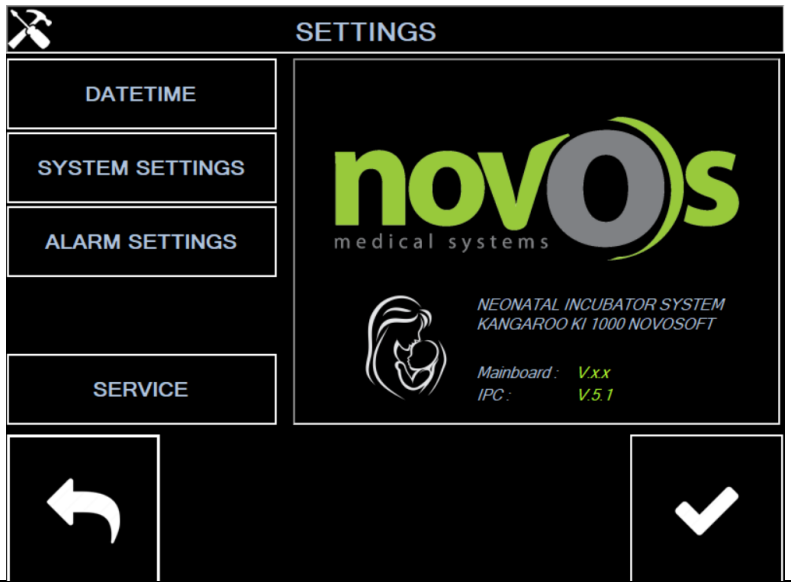
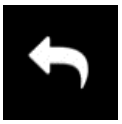
The modes (control boxes) desired to be displayed on the main screen of the KI 1000 can be selected separately.

To change active control boxes on the left of the screen • Press the Accessible Modes button on the home screen.	
The list of accessible modes will be displayed. To activate/deactivate any control box; • Activate/deactivate the relevant checkbox.	
• Press the Confirm button to save changes and return to the previous screen.	
If you do not want to save the changes; • Press the return icon. Returns to the home screen without applying image changes.	

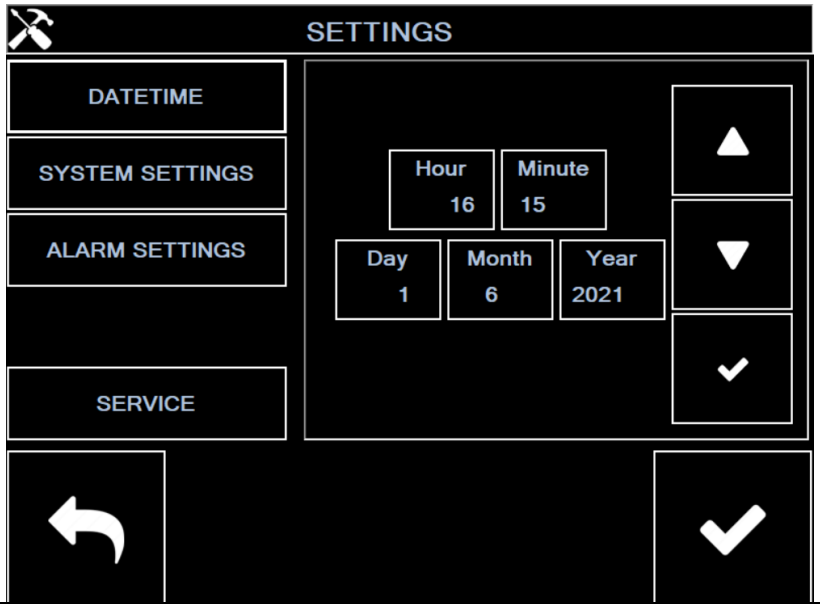
	SpO_2 feature is listed among active modes. But it has not been implemented in the system yet.

5.13. Settings

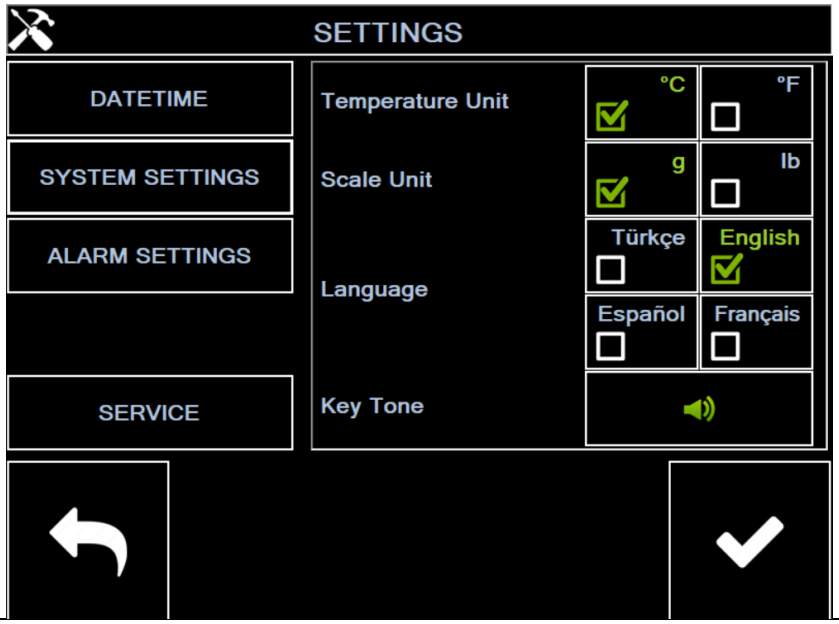
KI 1000 can be easily configured through the Settings menu.

To access the settings menu; • Press the Settings button.	
• The settings menu will be displayed on the screen.	
• Press the Confirm icon to save changes and return to the previous screen.	
If you do not want to save the changes; • Press the return icon. Returns to the home screen without applying image changes.	

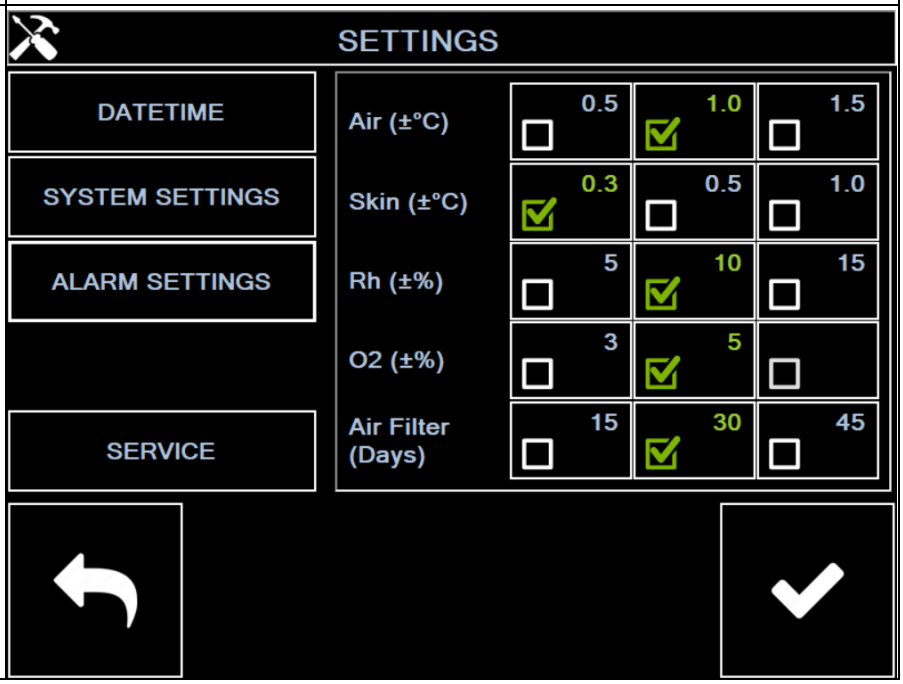
5.13.1. Configuring Date/Time Settings

To change date/time settings; • Press the DATE/TIME button.	
• Tap the relevant field to change. . • Use the Up Down arrows to change the value.	
• Press the DATE/TIME Confirm button to save the new date/time settings.	

5.13.2. Configuring System Settings

To change the temperature and weight units, key tone or interface language; • Press “SYSTEM SETTINGS” button.	
On this screen; • You can set the temperature unit in Celsius or Fahrenheit, • the unit of weight in grams or pounds, • and the interface language in Turkish, English, French or Spanish. • You can Activate / Deactivate the key tones.	

5.13.3. Configuring Alarm Settings

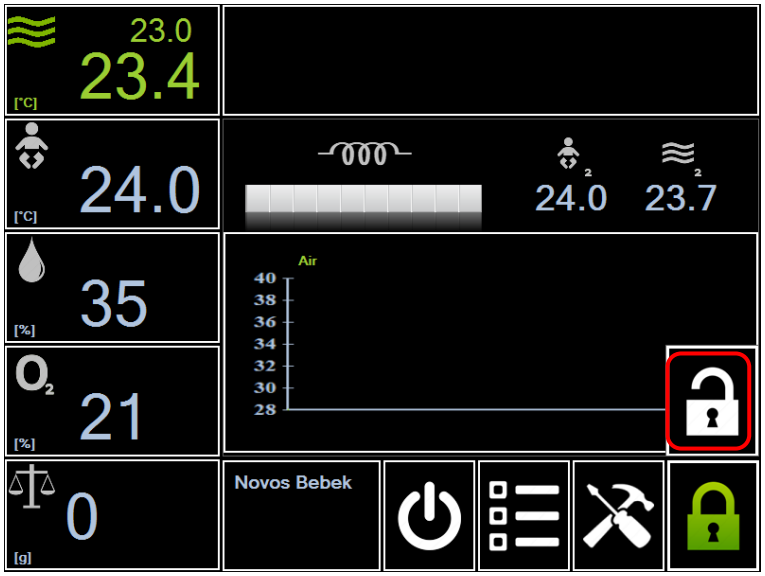
To change the alarm limits for different modes; • Press “ALARM SETTINGS” button.	
On this screen, you can set; • Air temperature • Skin temperature • Humidity Ratio • Oxygen concentration • Air filter replacement counter Alarm limits.	

5.13.4. Service Settings

Service settings can only be accessed with the service password provided to authorized technical personnel. To avoid equipment damage, please do not attempt to access or change device settings.

5.14. Screen Lock

If there is no user login, KI 1000 will automatically lock the screen within a minute.

<table>
<tr><td>To manually lock the screen;
• Press the green lock button.</td><td>  </td></tr>
<tr><td>• To unlock the screen, press the unlock button.</td><td> 
</td></tr>
</table>

5.15. Height Adjustment

To use the height adjustment feature; • Connect the AC power cord to the device from the AC input located on the back of the device. • Switch on the height adjustment motor using the On/Off switch.	
To raise the body; • Press the foot pedal with the up arrow figure. To lower the body; • Press the foot pedal with the down arrow figure.	

5.16. Shutting Down KI 1000

To shut down the device;

- Press the On/Off switch located on the right side of the control panel.

If the O_2 hose is connected to the source;

- Disconnect the hose jack from the source-end.

6.Routine Cleaning and Maintenance

6.1. Cleaning and Disinfection

6.1.1. Measures

The KI 1000 incubator system must be thoroughly cleaned and disinfected after each patient, according to approved hospital protocols. Follow the additional instructions that follow along with the specified hospital protocols.

	Always follow approved hospital protocols for handling equipment contaminated with body fluids.

	Always disconnect the device from power before cleaning and disinfecting.

	Risk of burns due to warmer! When the incubator is turned off, the warmer is hot enough to cause severe burns long after it has been turned off. (70 °C = 158 °F after 1 hour).

ATTENTION!

Do not allow moisture to enter the control panel. Do not disinfect the control panel by dipping or spraying. It may cause equipment damage.

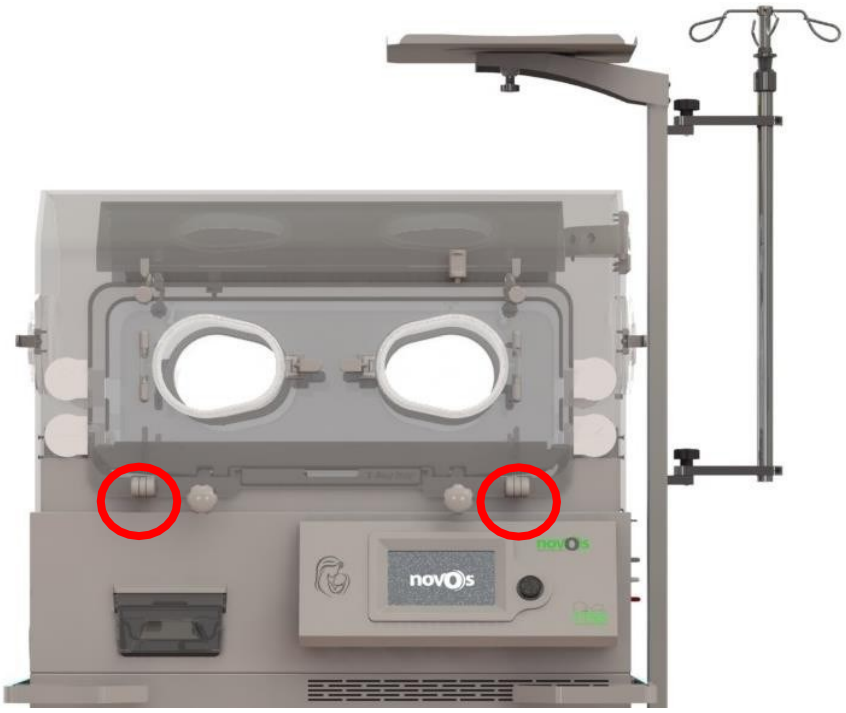
ATTENTION!

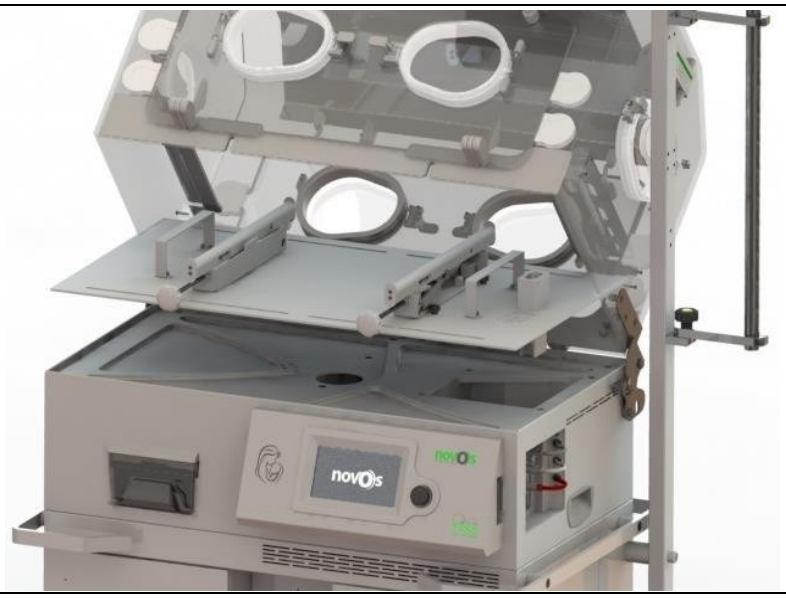
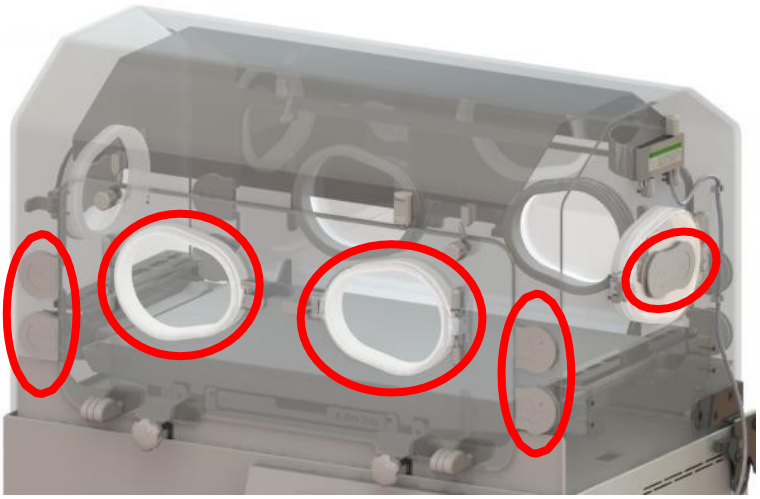
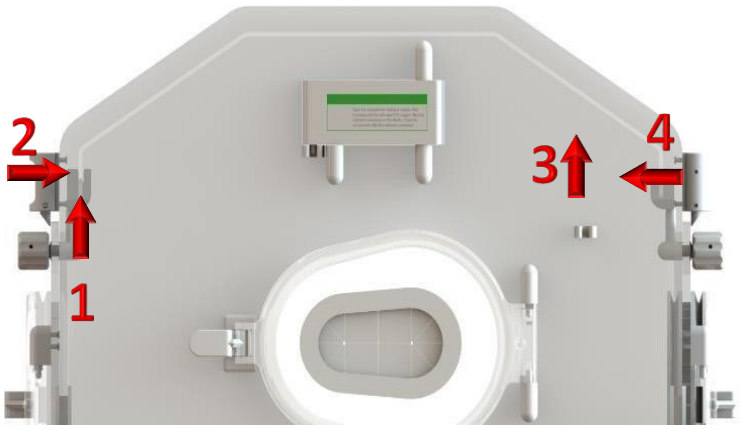
Make sure that only recommended cleaning agents and disinfectants are used! Cracks may occur on the product if acrylic and macrocolon material, other substances such as alcohol are used. Do not use UV radiation on incubators. This can also cause cracks in acrylic parts.

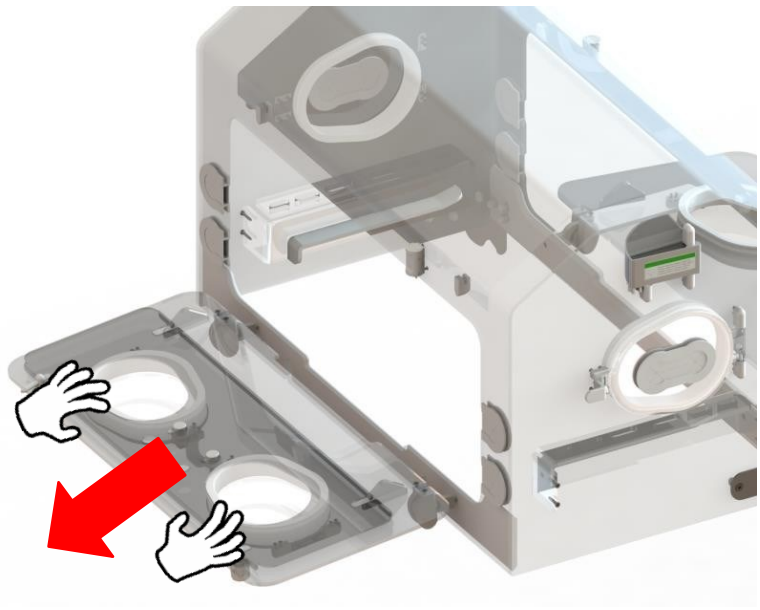
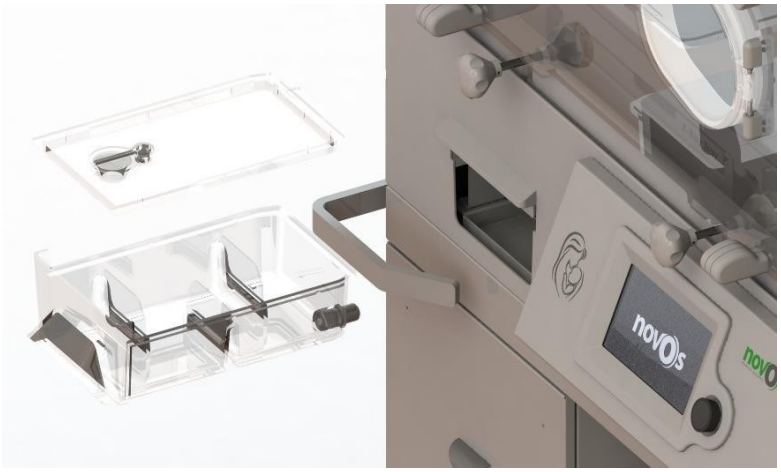
For cleaning and disinfecting accessories, follow the relevant operating instructions.

6.1.2. Removal of Incubator Components for Cleaning Purposes

Remove any installed auxiliary equipment, if any (refer to the specific operating instructions of the relevant equipment for maintenance instructions).

• Turn off the device and open the canopy by pulling up on both plastic hinges.	
• Move the bed tray and mattress out of the canopy. X-Remove the rail tray and balance; • Pull out the X-Ray tray and balance without damaging the balance cable. **Note:** If the balance option is not available, there is an X-Ray tray holder on the device instead of a balance unit.	

Remove the canopy base; • Loosen 4 black headed plastic screws and remove canopy base After removing the canopy base, the air ducts are accessible for cleaning and disinfection.	
Remove all grommets and window seals from the canopy. In total; • 12 grommets (4 on the front cover + 4 on the rear cover + 2 on the right oval window + 2 on the left oval window) • 6 oval window seals exist.	
Remove the upper double wall; • First, slightly lift up the double wall. • Gently push from outside to inside to free the upper double wall from its seat. • Lift the other side of the double wall up. • Pull it in, to release it from its seat. • Pull the double wall out of the canopy.	

Remove the front/rear double wall; • Grab the upper edge of the oval window area and pull in the direction of the arrow indicated in red.	
Remove the Water Reservoir • Completely remove the water reservoir drawer. • Remove the top cover and drain the water. • Send the entire water tank to the autoclave.	
• Hold the control panel by bringing the black handles on either side to a horizontal position and lift it out of the incubator's body.	

6.1.3. Cleaning and Disinfection Procedure

Use a non-detergent or alcohol-free disinfectant and a disposable cloth to clean the acrylic parts of the canopy.

- Open all the hatches and oval windows respectively.
- Remove visible dirt.
- Wipe and disinfect surfaces.
- After the penetration time of the disinfectant (see manufacturer's instructions for anticipated exposure time),

wipe the surfaces with a clean, damp disposable cloth, then dry.

- Clean any possible contamination near the sensor unit openings.
- Clean all grommets and oval window seals with a disinfectant solution.
- Use the disinfectant material according to the manufacturer's instructions.

ATTENTION!

Grommets and oval window seals should not be autoclaved.

- Remove the mattress from the bed.

ATTENTION!

Take care not to damage the sensor unit when removing the patient bed.

- Wipe and disinfect the mattress.
- After the penetration time of the disinfectant (refer to the manufacturer's instructions for anticipated exposure time), wipe the surfaces with a clean, damp disposable cloth, then dry.
- Sterilize the water reservoir for 10-15 minutes at 121 °C.
- Pull the control panel out of the unit by lifting the handles on both sides.
- Remove visible dirt with a disposable cloth and detergent.
- Wipe and disinfect surfaces.
- Wipe the fan blades lightly (Try not to move the fan off its axis)
- After the penetration time of the disinfectant (refer to the manufacturer's instructions for anticipated exposure time), wipe the surfaces with a clean, damp disposable cloth, then dry.

6.1.4. Changing Air Filter

The air filter should be changed every 90 days. In some cases, depending on the environment, the air filter needs to be changed sooner if it is visually dirty or damaged. For this purpose, the KI 1000 software can alert you every 15, 30 or 45 days for filter status check. This warning period, in other words the filter timer, can be specified in the KI 1000 software's Alarm Settings menu.

To install a new filter;

- Open the filter holder cover by turning the lock latch.

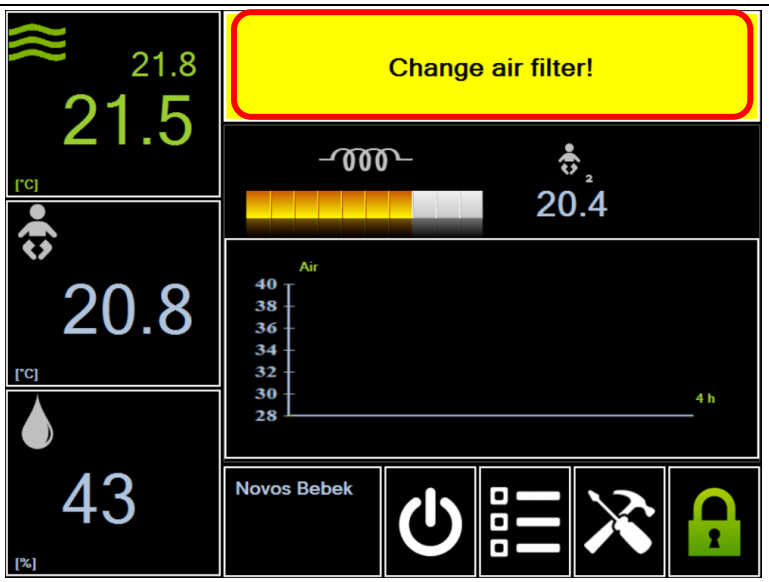
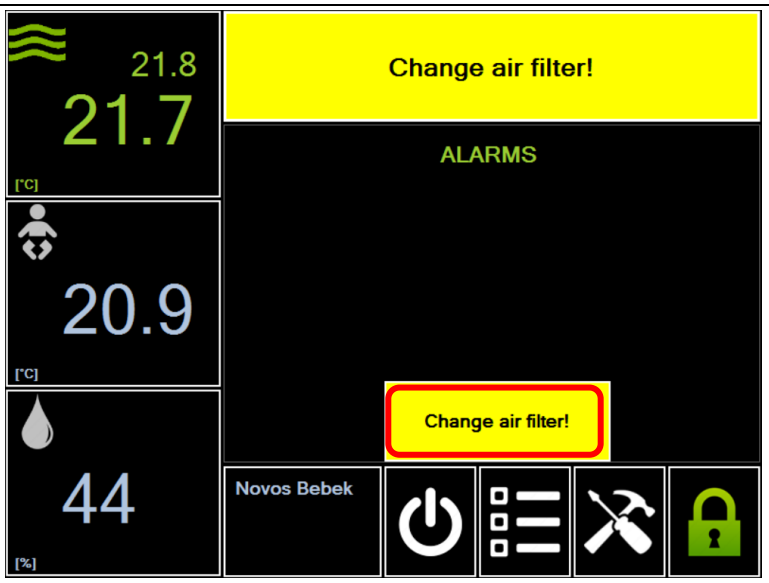
- Install the air filter.
- Close the filter holder.
- Note the installation date of the new filter on the label and stick this label to the filter holder.

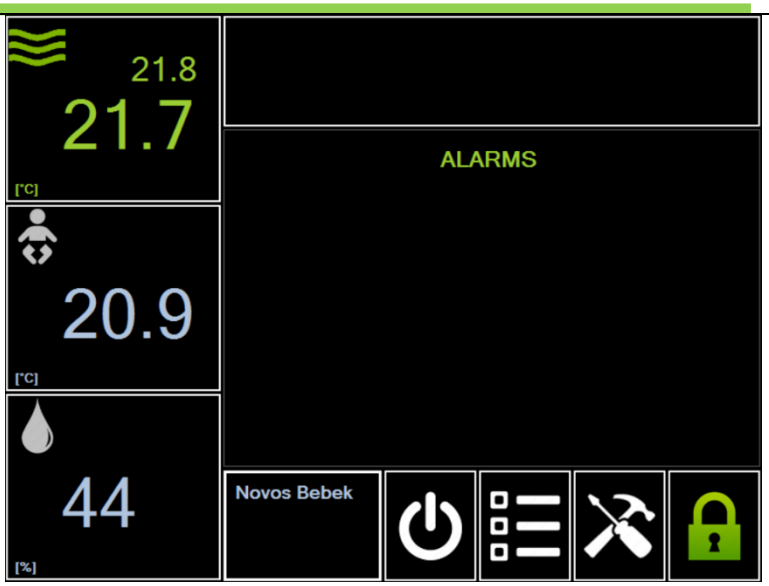
If the filter is already installed:

- Check if the filter is visibly dirty or damaged.

- Check the installation date, if already specified.
- If it is more than 90 days, replace the filter.

After replacing the filter, reset the filter time counter in the software.

• **Change the air filter** on your home screen! Press the warning indicator.	
• ***Replace the air filter!*** Press the button.	

• After pressing the button, the warning "Change air filter" will disappear from the list of alarms and warnings.	

6.1.5. 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.

6.2. Maintenance List

Component	Maintenance Interval	Deletion	Autoclave 121 °C
Water Reservoir	Patient change/weekly	-	Yes (4)
Canopy	Patient change/weekly	Yes (2)	-
Double Wall	Patient change/weekly	Yes (2)	-
Front Cover	Patient change/weekly	Yes (2)	-
Side Covers	Patient change/weekly	Yes (2)	-
U-Grommets, Seals	Patient change/weekly	-	-
Bearing	Patient change/weekly	Yes (1)	-
Mattress	Patient change/weekly	Yes (1)	-
X-Ray Tray	Patient change/weekly	Yes (1)	-
Air Guide Channel	Patient change/weekly	Yes (1)	-
Fan Blades	Patient change/weekly	Yes (1)	-
Main Body	Patient change/weekly	Yes (1)	-
Control Panel	Patient change/weekly	Yes (1)	-
Air Filter	Change every 90 days (3)	-	-

1. **Use surface disinfectants based on aldehydes and quaternary ammonium compounds.**
2. **Use detergent only. Do not use disinfectants that release alkaline or chlorine. Corrosion risk!**
3. **Use only original KI 1000 air filter! Fire danger!**
4. **Sterilize the water reservoir for 10-15 minutes at 121 °C**

Replaceable Parts	Intervals					Personnel in Charge
	When Required	Weekly	Every 3 months	Every 6 months	Annually	
Air Filter	-	-	X (1)	-	-	User and Service Personnel
Grommets, Seals, etc.	X (2)	-	-	-	-	User and Service Personnel
Skin Temperatur	X	-	-	-	-	User
Mattress	X	-	-	-	-	User
9V Rechargeable	-	-	-	-	X	Service Personnel
O_2 Sensors	-	-	-	-	X	Service Personnel
Maintenanc						
Preventive	-	-	-	-	X	Service Personnel
Calibration						
O_2 Sensors	X	-	-	-	-	User and Technical Personnel
Scale Unit	X (3)	-	-	-	X	Technical Personnel
LCD Display	X	-	-	-	-	User

1. **Use only original NOVOS air filter!**
2. **Replace if material becomes fragile or tacky or material strips break.**
3. **Measurement accuracy depends on local geological and geographical conditions. The specified sensor accuracy for the balance is only applicable if the scale has been calibrated at the installation site.**

	To avoid any risk of infection, clean and disinfect the incubator and accessories prior to maintenance according to established hospital protocols. This also applies to units and parts that are returned to service for repair.

	To avoid the risk of electric shock, disconnect the power supply before starting any maintenance.

	If physical damage is observed or the device is found to be malfunctioning, immediately take the KI 1000 incubator out of service. For maintenance service of the KI 1000 incubator, contact the NOVOS Technical Service Department.

ATTENTION!

The device should be regularly inspected and maintained at 1-year intervals. Records must be kept in this preventive maintenance.

We recommend a service contract with the NOVOS service through your dealer. For repairs of the KI 1000 incubator, we recommend that you contact NOVOS service.

6.3. Disposal of the Incubator

6.3.1. Disposal of the Air Filter

- It can be disposed of with household waste.

6.3.2. Disposal of the O_2 Sensors

	As for O_2 sensors • Do not throw it into the fire! • Do not force it to open! O_2 sensors contain corrosive acid that can cause caustic burns. Otherwise there is a risk of explosion.

ATTENTION!

Follow all local regulations for the disposal of O_2 sensors in an environmentally friendly manner.

The necessary information can be obtained from local environmental and public health authorities or approved waste disposal companies.

6.3.3. Disposal of the Incubator

At the end of its life cycle:

- Dispose of the incubator according to local waste disposal regulations; or
- Send the incubator to an approved waste disposal company for disposal.

More information can be obtained from local environmental and public health authorities.

7.Troubleshooting

7.1. Error Messages

Mess	Cause	Solution	Audible Alarm
E0 System Error CALL SERVICE!	• Faulty Driver Microprocessor	Contact authorized technical support personnel in your area.	Uninterrupted auditory alarm cannot be silenced.
E2 System Error CALL SERVICE!	• Defective Air Probe		
E3 System Error CALL SERVICE!	• Defective Fan Probe Error		
E4 System Error CALL SERVICE!	• Blocked Fan • Defective fan motor		
E6 System Error CALL SERVICE!	• Defective Water Level Sensor • Defective Thermostat		
E8 System Error CALL SERVICE!	• Defective solenoid oxygen valve		
E10 System Error CALL SERVICE!	• Excessive temperature	Check the cause of the high temperature. Air ducts may be blocked by a mattress or other	

8.Annexes

8.1. Technical Specifications

8.1.1. Device Classification

Protection class	Class 1, Type BF
Classification in compliance with 93/42/EEC	IIb
Protection against water and solid objects	IP20

8.1.2. Environmental Requirements

Operating Temperature	20 - 30 °C
Operating Humidity	5 - 95% RH, uncondensed
Storage Temperature	(-20) – 60 °C
Storage Humidity	5 - 95% RH, uncondensed

8.1.3. Electrical Properties

Supply Voltage and Current	220 VAC / 2.3A AC
Sections Applied	Type BF
Protection class	Class 1
Fuse	2 x 5A (standard) and 2 x 6A (If Height Adjustment Available)
Supply Frequency	50 - 60 Hz
Maximum Power Value	500 W
Noise Level	<47 dBA
Control Panel Resistance Type	Ø20 mm Flanged Cartridge Resistance
C. Panel Resistance Power Value	400 W
Humidity Resistance Type	Ø10 mm Cartridge Resistance
Humidity Resistance Power Value	150 W
Leakage Current Value	<100 µA

8.1.4. Mechanical Properties

Height	1376 mm + 200 mm
Monitor Tray / IV Pole and Height	1626 mm + 200 mm / 1686 mm + 400 mm
Bed Height	993 mm + 200 mm
Width	1051 mm
Depth	639 mm
Bed Dimensions	387 x 630 x 30 mm
Bed Weight Capacity	10 kg
Canopy Height	500 mm
Canopy Width (inner)	840 mm
Canopy Depth (inner)	458 mm
Trendelenburg Limits	±12°
Trendelenburg Mechanism	Mechanical
Screen Type and Size	7” Touchscreen LCD
Openable Bed Platform	It can be opened outwards by 3/4.
Number of Windows	4 side oval windows on the front/back covers and 2 grommets
Number of Access Covers	2
Openable and Lockable Canopy	Yes
Air Filter Type and Pore Size	Disposable, 0.5 µm

Transport Trolley	1 large drawer and 2 small drawers, optional height adjustable (+ 20 cm)
Wheels	In total 4 wheels with brakes
Wheel Diameter	125 mm
X-Ray Tray Dimensions	396 x 256 mm
Maximum Total Weight	137,5 kg
Standard Model Weight	127,5 kg

8.1.5. Sensor Features

Skin Temperature	Skin Probe Type	Single NTC
	Skin Temperature Measurement Range	18,2 – 45 °C
	Skin Temperature Display Range	18,2 – 45 °C
	Skin Temperature Display Resolution	0.1 °C
	Skin Temperature Measurement	±0.2 °C
	Target Skin Temperature Range	34 – 38 °C
	Secondary Skin Probe	Yes
Air Temperature	Air Probe Type	Double NTC
	Air Temperature Measurement Range	18,2 – 50 °C
	Air Temperature Display Range	18,2 – 50 °C
	Air Temperature Display Resolution	0.1 °C
	Air Temperature Measurement Accuracy	±0.2 °C
	Target Air Temperature Range	20 – 39 °C
Moisture	Humidity Sensor Type	Humidity sensor located in the oxygen/humidity sensor box located in the upper right corner of the cabinet
	Humidity Sensor Measurement Range	0 – 100%
	Relative Humidity Display Range	18 – 95%
	Relative Humidity Display Resolution	1%
	Humidity Sensor Measurement Accuracy	±1.8%
	Target Humidity Range	30 – 95%
Oxygen	Oxygen Sensor Probe Type	2 oxygen sensors in the oxygen/humidity sensor box located in the upper right corner of the cabinet
	Oxygen Sensor Measurement Range	0 – 100%
	Oxygen Concentration Display Range	18 – 100%
	Oxygen Concentration Display Resolution	1%
	Oxygen Sensor Accuracy	±3%
	Target Oxygen Range	21 – 65%
Scale	Scale Sensor Type	X- 4 pieces under the rail tray 7.5 kg, Planar Loadcell
	Scale System Weight Display Range	0 - 10 kg
	Weight Display Resolution	0.001 kg
	Scale Sensor Accuracy	5 g
	Scale System Capacity	30 kg (Bed Weight Capacity = 10 kg)

8.1.6. Servo Humidity Features

The Type of Water Used for Humidification	Distilled water
Water Reservoir Capacity	1,8 L
Insufficient Water Level Indicator	Yes
Water Reservoir Autoclave Feature	Yes

8.1.7. Alarm Features

Current Alarms	**Auditory Alarm Silence Button Function**
Air Sensor Error	The auditory alarm cannot be silenced.
Turn off the O_2/Humidity Sensor module.	The auditory alarm is silenced for 5 minutes.
Connect O_2/Humidity Sensor Module Cable	The auditory alarm is silenced.
O_2 Sensor Error Servo Oxygen System is shut down.	The auditory alarm is silenced.
Humidity Sensor Error Servo Humidity System is shut	The auditory alarm is silenced.
Oxygen calibration	The auditory alarm is silenced.
Skin 1 Sensor Error	The auditory alarm is silenced for 5 minutes.
Skin 2 Sensor Error	The auditory alarm is silenced for 5 minutes.
Low Water Level Servo Humidity System is shut down.	The auditory alarm is silenced.
Water level Sensor Error Servo Humidity System is	The auditory alarm is silenced.
High Oxygen	The auditory alarm is silenced for 5 minutes.
Low Oxygen	The auditory alarm is silenced for 5 minutes.
High skin temperature	The auditory alarm is silenced for 5 minutes.
High air temperature	The auditory alarm is silenced for 15 minutes.
Low skin temperature	The auditory alarm is silenced for 5 minutes.
Low air temperature	The auditory alarm is silenced for 15 minutes.
High Humidity	The auditory alarm is silenced for 30 minutes.
Low Humidity	The auditory alarm is silenced for 30 minutes.
Replace the air filter	-
Air Circulation Alarm (E4)	-
Air Temperature Alarm Limits	±0,5 °C, ±1,0 °C, ±1,5 °C
Skin Temperature Alarm Limits	±0,3 °C, ±0,5 °C, ±1,0 °C
Servo Humidity Alarm Limits	±5%, ±10%, ±15%
Servo Oxygen Alarm Limits	±3%, ±5%

8.1.8. Other Properties

User Interface	Touch Screen and Rotary Knob
Software Version	V5.1
Parameters Allowing Trends	Air, Skin1, Humidity, Oxygen
Trend Ranges	15 min - 7 days
Recordable Patient Data	Skin1, Skin2, Air, Moisture, Oxygen, Scale
Record Display Ranges	2h, 3h, 6h, 8h, 12h, 24h, 48h, 7 days
TTSS (Target Temperature Surveillance System)	Yes
Intelligent Weighing System	Yes

Error History	Sensor information recorded at the time of the error can be used for troubleshooting.
Standby Mode	Yes
Displaying Heater Power Percentage	In 10% increments
Warm Up Time	<35 minutes from 22 °C to 33 °C (at 22 °C ambient temperature)
Air Flow Rate	<0,1 m/s, <10cm/s
Servo Controlled O_2 Inlet Pressure	min. 300 kPa, max. 500 kPa
Max CO_2 Concentration	<0,5 vol%
Air Inlet Flowrate	<=30 L/dk
O_2 Concentration Rise	<10 min from 21% to 60%
> 37 ° C Confirm Button	Yes

8.2. Compatibility

Publishing Body	Date of	Document Name / Title
TSE	11-02-2009	TS EN 60601-1 / Electrical medical equipment-Part 1: General rules for basic safety and required performance
TSE	23-03-2016	TS EN 60601-1-2 / Electrical medical equipment-Part 1-2: General rules for basic safety and required performance - Supplementary standard: Electromagnetic disturbances - Features and experiments
TSE	12-04-2012	TS EN 60601-2-19 / Electrical medical equipment-Part 2-19: Specific features for the basic safety and required performance of baby incubators
TSE	09-12-2016	TS EN ISO 15223-1 / Medical devices - Symbols to be used in medical device labels, labeling and information to be conveyed- Part 1: General
TSE	17-12-2013	TS EN ISO 14971 / Medical devices - Application of risk management to medical
TSE	11-02-2009	TS EN 60601-1-10 / Electrical medical equipment-Part 1-10: General features for basic safety and required performance - Auxiliary standard: Features for the development of physiological closed-circuit controllers
TSE	29-03-2011	TS EN ISO 10993-1 / Biological evaluation of medical devices - Part 1: Evaluation and testing in a risk management process
TSE	23-03-2016	TS EN 62304 / A1 / Medical device software - Software life cycle processes
TSE	23-10-2015	TS EN 62366-1 / Medical devices - Part 1: Application of usability technique to medical devices
TSE	29-04-2008	TS EN 60601-1-8 / Electrical medical equipment-Part 1-8: General rules for basic safety and required performance - Auxiliary standard: General characteristics, experiments and guidance for warning systems in electrical medical equipment and electrical medical systems
TSE	18-12-2017	TS EN ISO 80601-2-56 / Electrical medical equipment-Part 2-56: Specific features for basic safety and essential performance of clinical thermometers for body temperature measurement
European Commission	06.2016	MEDDEV 2.7.1 / Clinical evaluation: Guide for manufacturers and notified bodies
European Commission	01.2013	MEDDEV 2.12.1 / Guidelines on a Medical Devices Vigilance System
European Commission	01.2012	MEDDEV 2.12.2 / Post Market Clinical Follow-up studies

8.2.1. Compliance Directive:

Council Directive 93/42/EEC of 14 June 1993 on medical devices (1993-07-12 OJ L L 169/1)

The Medical Devices Directive (Council Directive 93/42/EEC of 14 June 1993 on medical devices, OJ L 169/1 of 1993-07-12 [1]) aims to harmonize the laws related to medical devices within the European Union. The MD Directive is the 'A New Approach' Directive, in order for a manufacturer to legally place a legal medical device on the European market, the requirements of the MD Directive must be fulfilled. Manufacturers' products meeting the 'harmonized standards' [2] have the presumption of conformity with the Directive. Products that comply with the MD Directive must bear the CE mark. The Directive was last revised by a review according to 2007/47/EC. Compliance with the revised directive became mandatory on 21 March 2010.

CE 1984

8.2.2. Guidance and Manufacturer's declaration - Electromagnetic Emissions

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.

KI 1000 is designed for use in below conditions and environments.

8.2.2.1. *Electromagnetic Environment*

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

Emission experiments	**Compatibility**	**Electromagnetic Environment**
RF Emissions ING 11	Group 1	The KI 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.
RF Emissions CISPR 11	Class B	The KI 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	

8.2.2.2. *Electromagnetic Immunity*

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

Immunity Test	**IEC 60601 test level**	**Compatibility level**	**Electromagnetic Environment**
Voltage drops, short interruptions and voltage variations on power supply lines IEC 61000-4-11	95% drop for 0.5 cycles, 40% 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, 95% drop for 5 seconds	
	95% drop for 5 seconds		
Mains frequency magnetic field (50/60 Hz) IEC 61000-4-8	30 A/m	30 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 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 KI 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 Grid	± 2 kV Grid	
	± 1 kV Inputs/Outputs	Not applicable	
Impulse IEC 61000-4-5	± 1 kV Differential ±2 kV Common Mode	± 1 kV Differential ±2 kV Common Mode	

Immunity Test	IEC 60601 experiment	Compatibility level	Electromagnetic Environment
Conveyed RF IEC 61000-4-6	3Vrms out of ISM band 6Vrms in ISM band 150kHz to 80MHz.	$V_1=3V_{rms}$ $V_2=6V_{rms}$	**Recommended Separation Distance** D = 1,2√
Propagated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz .	3 V/m	$d = 1.2\sqrt{P}$ 800 MHz to 1000 MHz $d = 2.3\sqrt{P}$ 1000 MHz to 2.5 GHz

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: This document may not be applicable in all cases. Electromagnetic propagation is affected by absorption and reflection from buildings, people and objects.

a) Fixed transmitted field strengths such as base stations for radio (cellular/ cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast cannot be predicted theoretically with accuracy.
To assess the electromagnetic field in the area due to fixed RF transmitters, an electromagnetic field survey should be considered. If the measured field strength in the location in which the KI1000 is used exceeds the applicable RF compliance level above, the KI1000 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be required, such as reorienting or relocating the KI1000.

b) Over the frequency range 150kHz to 80MHz, field strengths should be less than 3 V / m.

8.2.2.3. *Recommended Separation Distance*

Transmitter's highest rated output power (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $\mathbf{d = 1.2\sqrt{P}}$	**80 MHz to 800 MHz** $\mathbf{d = 1.2\sqrt{P}}$	**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	0.38 m	0.38 m	0.73 m
1.0	1.2 m	1.2 m	2.3 m
10	3.8 m	3.8 m	7.3 m
100	12 m	12 m	23 m

For the rated transmitter at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter. Whereas, P is the maximum output power of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: This document may not be applicable in all cases. Electromagnetic propagation is affected by absorption and reflection from buildings, people and objects.

8.3. Trademark Registrations

Novos KI 1000™ model is a Novos branded commercial product of Novos Tıbbi Cihazlar Sanayi ve Ticaret İthalat ve İhracat Limited Şirketi.

8.4. Manufacturer

Novos Tıbbi Cihazlar Sanayi ve Ticaret İthalat ve İhracat Limited Şirketi

Address: İvedikosb Mahallesi 1518 Cad. Matbaacılar Sitesi Sit. No:2/39
Yenimahalle, Ankara, Türkiye

Phone: +90.312.384 15 88
Fax: +90.312.384 15 98
E-mail: info@novos.com.tr