Bilisphere 360 LED

User Manual

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.

WARNING!
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!

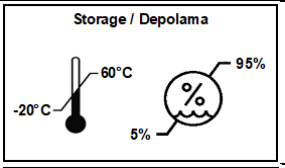
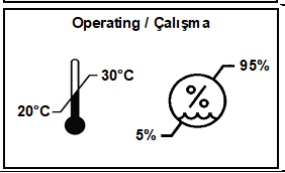
These are the guidance that may damage the system as described in this manual, if the attention notes are not followed.

Table of Contents

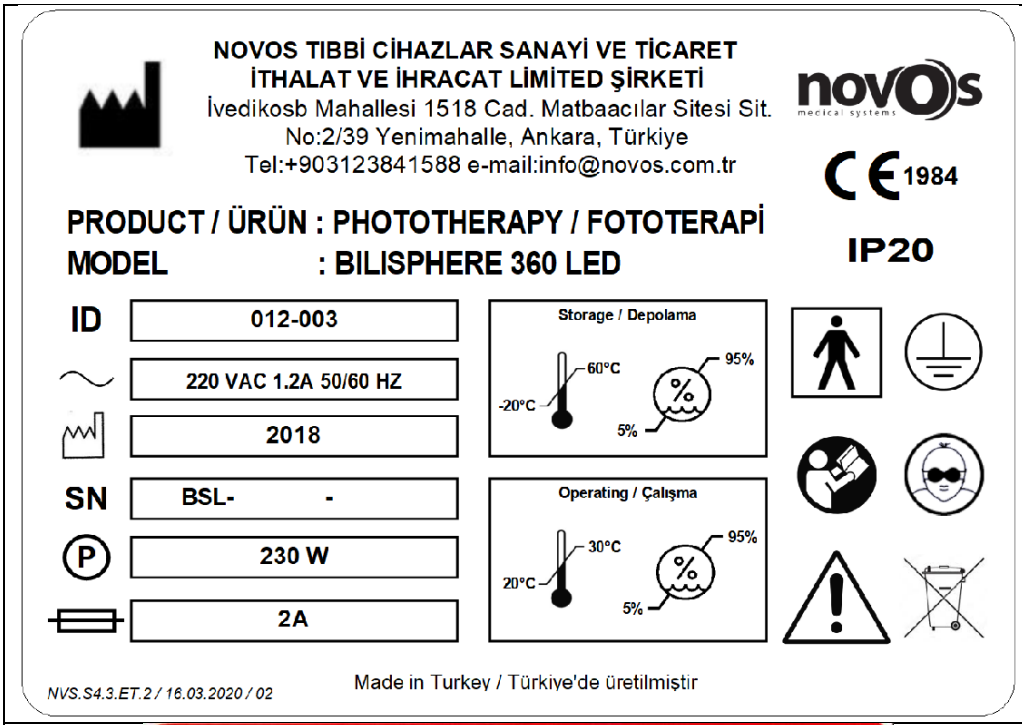
1.Safety Information

1.1. Symbols

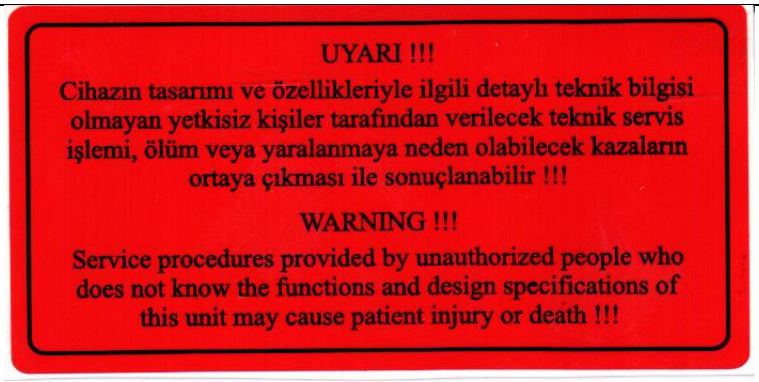
I	Device is ON.
O	Device is OFF.
IP20	Protected against solid objects larger than 12.5 mm.
	This symbol means the device is in the BF class.
	This symbol is used to warn the users of the device against possible risk or injury. Warnings are instructions that, if not followed, could result in fatal or serious injury to a user, engineer, patient, or other person, or could result in improper treatment.
ATTENTION	These are the guidance 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.
	Do not place hand here!
	Attention: There is a risk of electric shock
	Wear eye patch!
ID	Product ID.
	Manufacturer.

	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.
	Fuse Box
	Grounding
	CE mark Authorized body
	See User Manual
	Alternative Current
	Power
	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.
	Specifies the lower and upper temperature / humidity limits for storage.
	Specifies the lower and upper temperature / humidity limits for operation.

1.2. Label Information



Product Identity



Technical Service Warning

	Outer Box Label
	Reusable Skin Probe Label

1.3. User Obligations for Patient Safety

WARNING!
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.

1.4. Patient Monitoring

Operators of this phototherapy 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.

1.5 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.

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

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

Warranty applications depend on the following:

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

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

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

NOVOS Tıbbi Cihazlar

2. Usage Purpose

2.1. Applications

BİLİSPHERE 360 LED™ is routinely used in the treatment of neonatal hyperbilirubinemia, where concentrated radiation of the blue spectrum of visible light is applied for a period to be decided by the physician based on the patient's condition.

During jaundice treatment, the patient needs a thermotherapy device and is placed in a heated baby bed or incubator depending on its clinical condition. Considering these situations, NOVOS developed the BİLİSPHERE 360 phototherapy. The aim is to provide maximum patient comfort and shorten the treatment time during treatment.

BİLİSPHERE 360 LED is a versatile phototherapy, especially recommended for rapid decrease in serum bilirubin level, thus reducing the need for blood exchange and treatment time.

The expected lifetime of the Bilisphere 360 LED™ device is 10 years.

2.2. 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.

2.3. Patient Population

Bilisphere 360 LED is used in the treatment of babies between 0-28 days postnatal and for preterm babies whose adjusted age is 52 weeks.

2.4. Usage limitations

WARNING!
HAZARD! There is a risk of explosion if used in the presence of flammable anesthetics. This device has not been approved or documented for use in areas where flammable or explosive gas mixtures are likely.

WARNING!
This device is designed for use only in rooms with line powered installations that comply with national safety standards for hospital patient rooms (eg IEC / EN 60601-1, "Safety of Medical Devices"). To maintain ground integrity, connect only to a "hospital grade" plug socket.

WARNING!
Use of this device requires constant supervision of the baby by trained nursing personnel to provide immediate corrective action in situations where there is a risk of patient injury.

WARNING!
Cell phones should not be used at 10 meters near the incubator. Cell phones may impair the functions of the electromedical device and thus patient safety may be compromised

WARNING!
Side plexiglass protectors of Bilisphere 360 LED should always be installed in normal operating condition. Otherwise, there is a risk of injury for the patient during manual height adjustment.

WARNING!
NOVOS medical equipment conforms to the requirements for interference immunity specified in product specific standards or EN 60601-1-2 (IEC 60601-1-2). However, depending on the design and use of the mobile phone, field strengths exceeding the specified standard values may be generated near the phone. Thus, it can cause interference and malfunctions.

WARNING!
BİLİSPHERE 360 LED intensive phototherapy does not replace an incubator and / or any warmer.

WARNING!
BİLISPHERE 360 LED will be ready to work only when all the controls are successfully implemented.

WARNING!
NOVOS cannot guarantee or approve the safety performance of third-party accessories used with BİLİSPHERE 360 LED phototherapy. Use only original NOVOS accessories and parts with the BİLİSPHERE 360 LED™. Unauthorized use of parts and accessories may result in serious harm to the patient.

2.4.1.Warnings Regarding Indications, Contraindications, Possible Physiological Effects

- **Indications**

Hyperbilirubinaemia treatment

Kernicterus prevention

Patients with light sensitivity disorders (e.g. congenital erythropoietic porphyria)

- **Counterindications**

Bronze baby syndrome

Dehydration

Hyperthermia

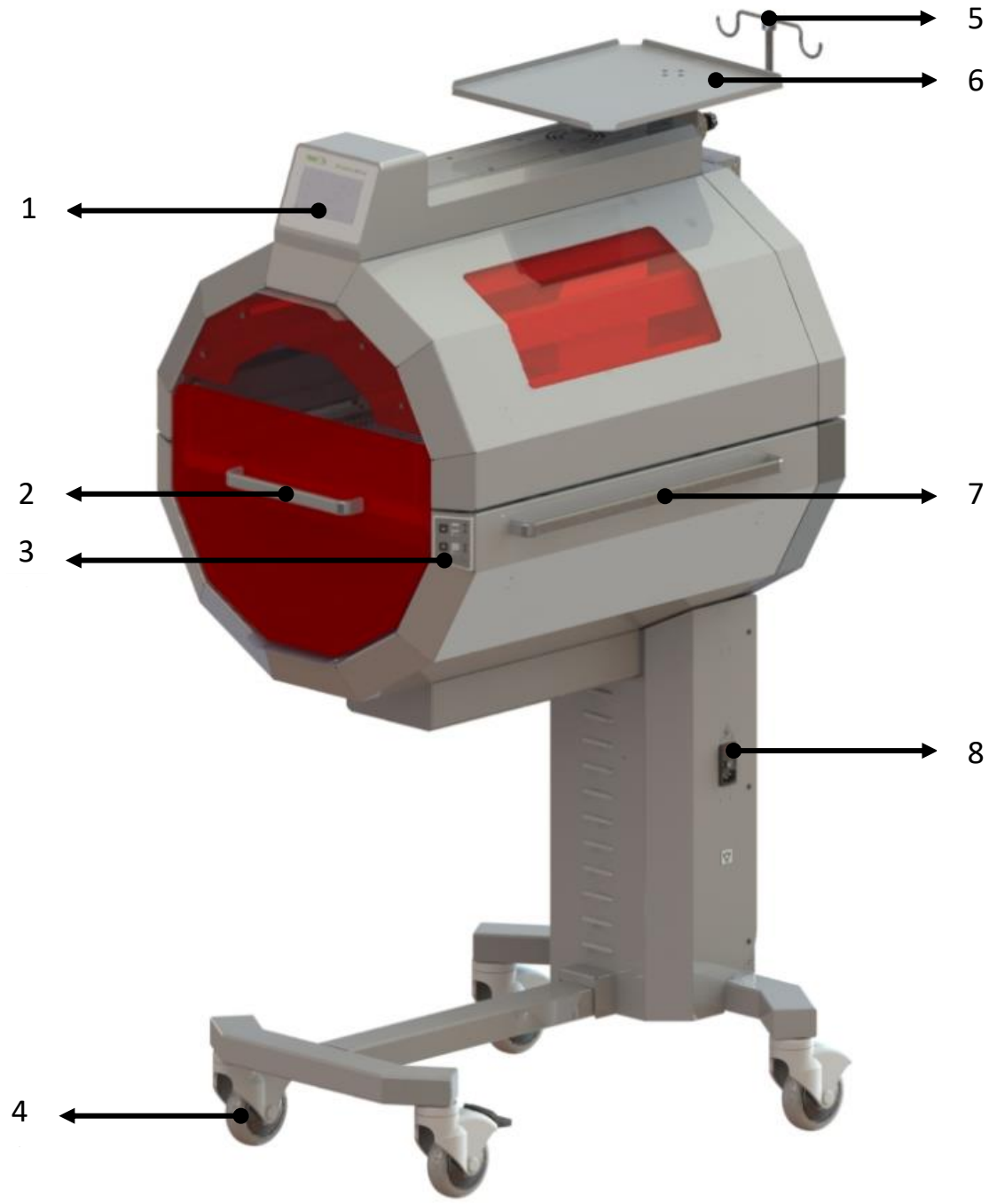
Temporary skin redness

- **Warnings on Possible Physiological Effects**

	The eyes of the doctor and nurse, who stay with the patient for a long time, may be damaged by the radiation. Therefore, avoid looking directly at the LEDs.
	The amount of bilirubin in the patient's blood should be measured continuously at regular intervals.
	The use of reflectors is not suitable! Because it can cause the patient's body temperature to increase to dangerous levels.
	As with all phototherapy treatments applied to babies, sufficient fluid should be given to the patient in phototherapy treatment with BS360 LED and a protective path should be worn on the eyes throughout the therapy. In addition, the patient's condition should be checked routinely by nurses and medical assistants.
	During therapy, the toxic effect of bilirubin can be seen.
	The hydraulic balance of the patient may vary depending on the phototherapy application.
	Bilirubin photo isomers can cause toxic effect during therapy.
	Drugs, serum and liquid infusions should not be stored or kept in the radiation field.
	In newborns with jaundice on their skin, whiteness may occur in the illuminated area within a few hours after treatment with the BS 360 LED device, and this area may become brighter. This is due to the intense effect of light on the bilirubin pigment deposited on the skin.

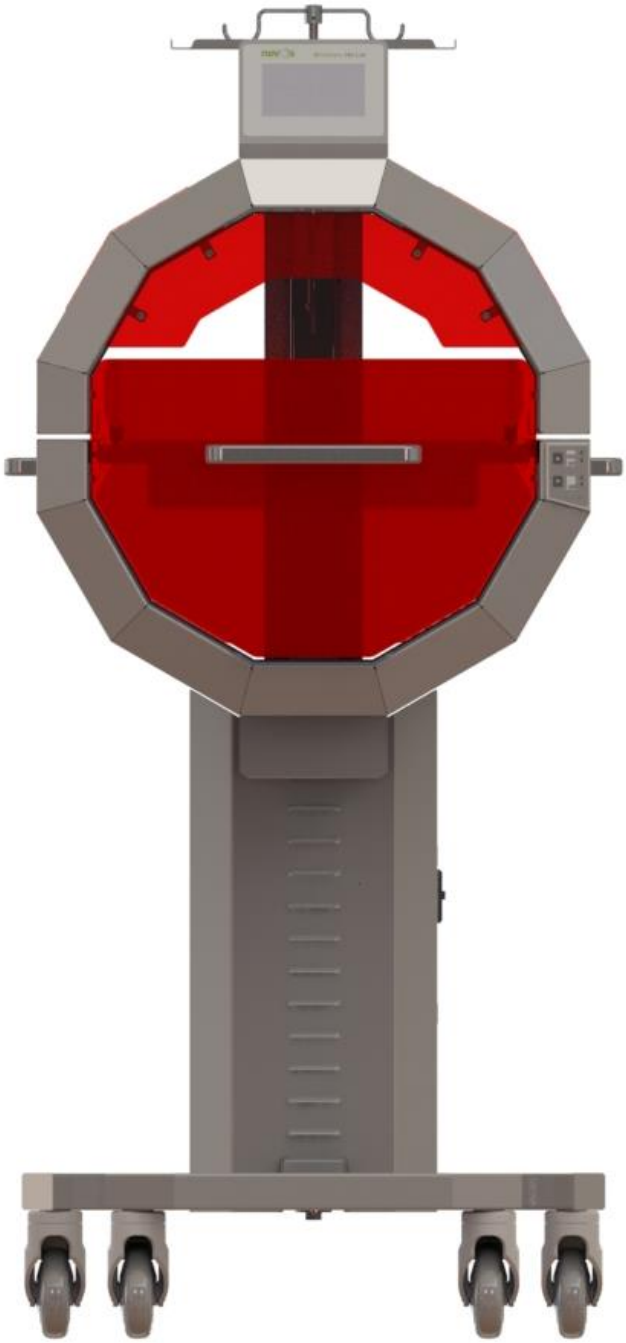
3.Parts and Controls

3.1. Isometric View



1	Control Panel	5	IV Pole (Optional)
2	Baby Bed Handle	6	Monitor Tray
3	Height Adjustment Membrane Switch	7	Side Handle
4	Wheels with brake	8	Power Input, Fuse Holder, On/Off Switch

3.2. Front View



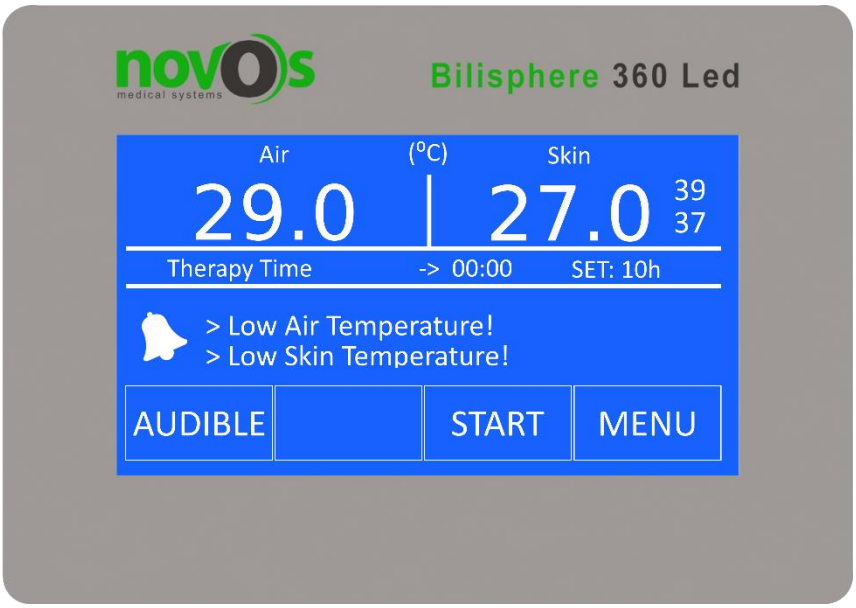
3.3. Side View

3.4. Control Panel

3.4.1.Main Display

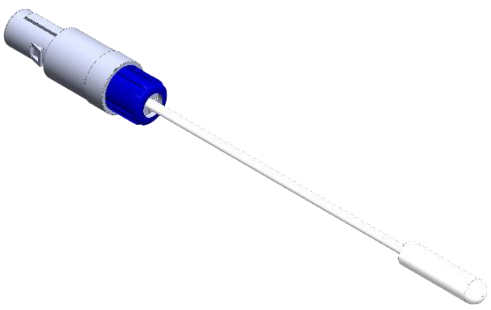
Bilisphere 360 LED has a 5.1” single-color touch screen. On this screen;

- Air temperature
- Skin temperature
- Therapy Time
- Set Therapy Time
- Fan Conditions
- Upper and Lower Skin Temperature Limits
- Alarms can be seen simultaneously.



3.5. Temperature Sensors

Air and skin temperatures are measured with the corresponding sensors shown below.

1) Skin Temperature Probe	2) Air Temperature Probe
	

4.Preparation

4.1. Unpacking and Installation

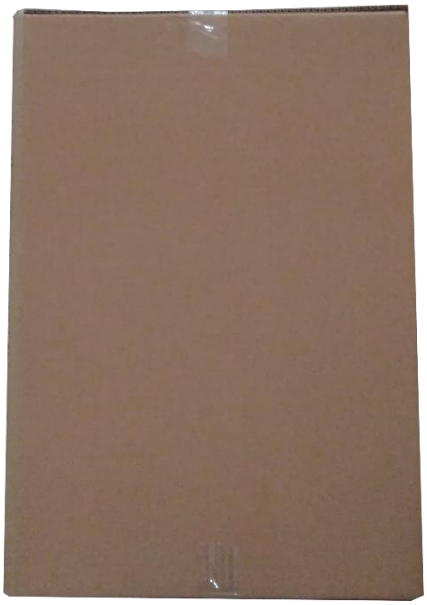
Bilisphere 360 LED is packaged in two main groups as main body and accessories. It includes accessory box, hammock, monitor tray, power cord, IV pole (optional) and eye protection mask. After you receive the package, complete the installation by following the steps below.

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

- Unpack and set the main body aside.

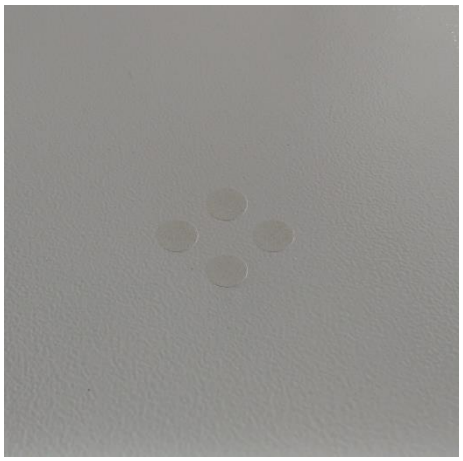
</td></tr>
<tr><td>

- Open the accessories box.
  Set aside the following:
  - monitor tray
  - power cord
  - IV Pole (Optional)
  - eye protection patches

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

- Align the monitor tray in place.

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

• Install 4 pieces of M4x12 YHB screws.	
• Install the white screw caps.	
• Slide and open the baby bed drawer.	

• Place the hammock.	
• Place the IV pole in place and tighten the plastic head screw to secure it in the desired position.	

4.2. Electronic Operation Control

Before start, make sure that:

- The cabin is empty,
- The air and skin temperature sensors are **NOT** connected to their sockets,
- The power cord is plugged into a suitable wall outlet.

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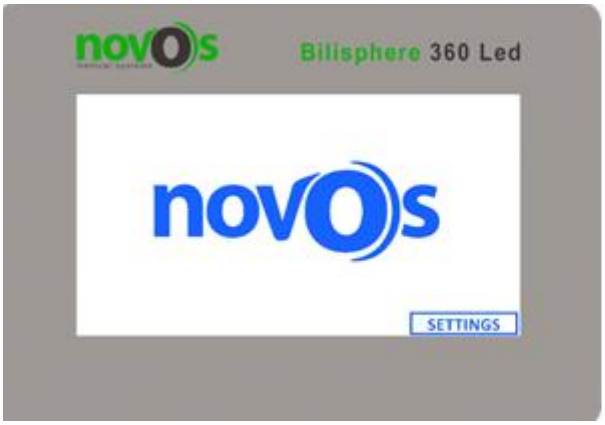
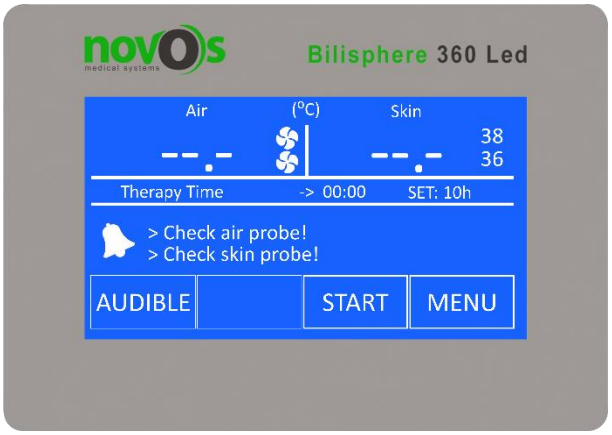
The following procedure can be used to verify the electronic operation of the Bilisphere 360 LED.

1. Press the On/Off switch located on the right side of the device.
2. Wait for start-up.

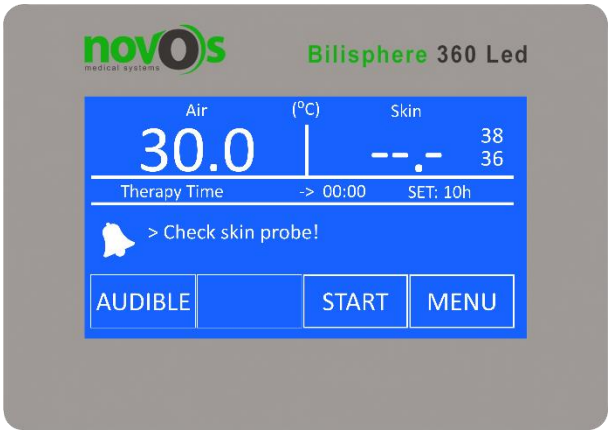


3. Watch for 2 alarms for air and skin probes on the main screen.

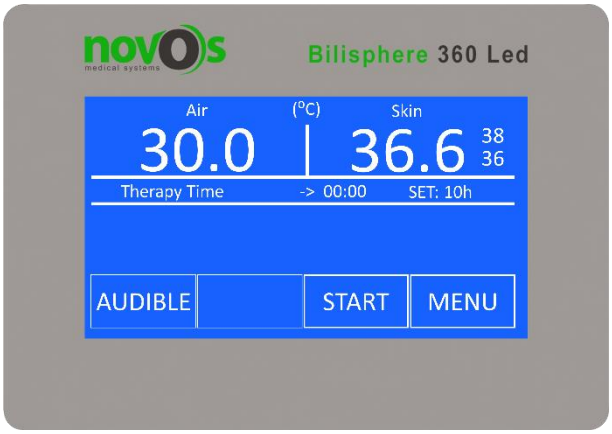


4. Plug the air probe into its socket.

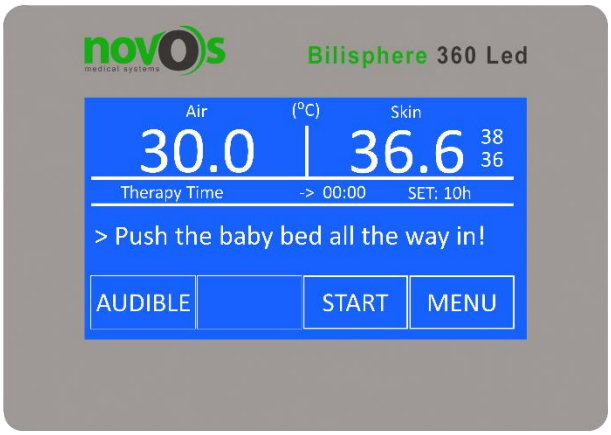
5. Observe that the warning message for the air probe not attached has cleared and the air temperature measured by the air probe appears in the upper left of the display.



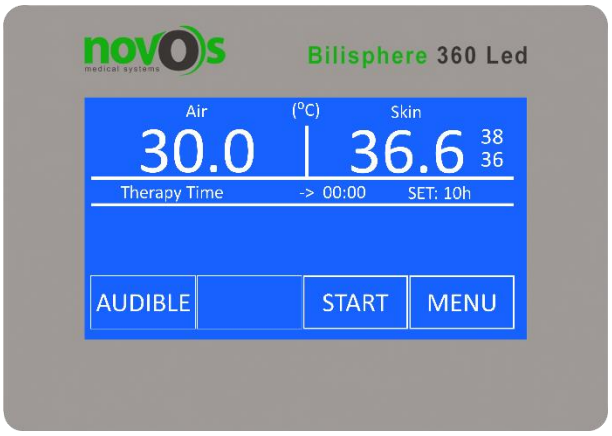
6. Plug the skin probe into its socket.
7. Observe that the warning message for the skin probe not attached has cleared and the skin temperature measured by the air probe appears in the upper right of the display.



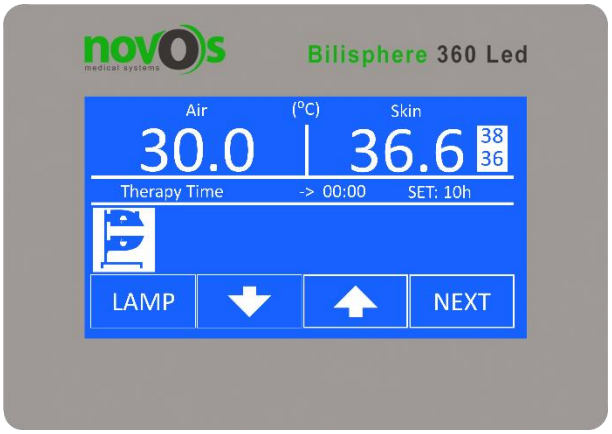
8. Slide the baby bed's drawer outwards.
9. Observe the warning message for the opened bed.



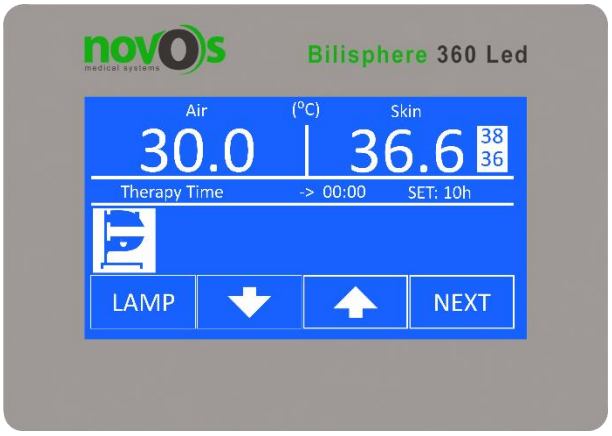
10. Push the baby-bed drawer completely into the device.
11. Observe that the warning message is cleared for the opened bed.



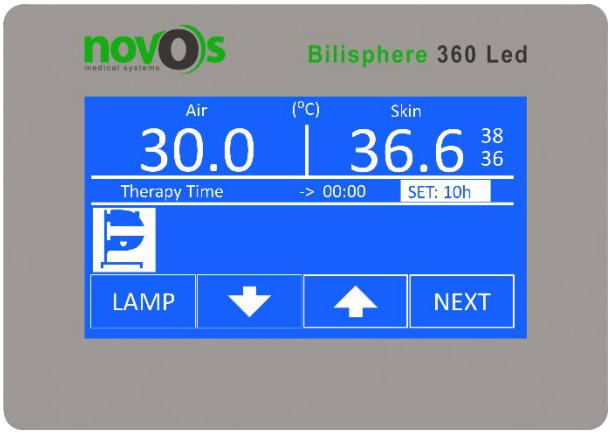
12. Press MENU button.



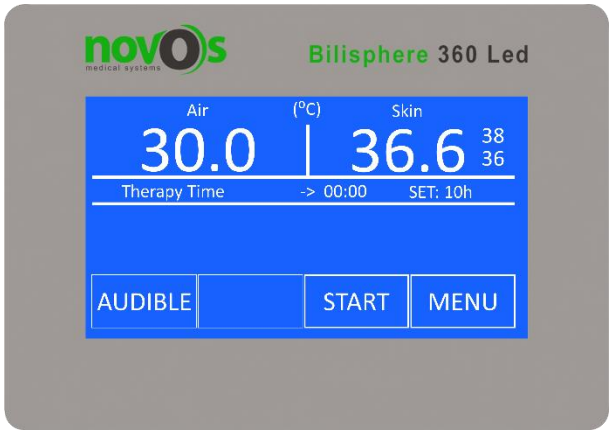
13. Press the LAMP button to turn on the lower lamp group.



14. Press the CONTINUE button to switch to the target therapy time settings.



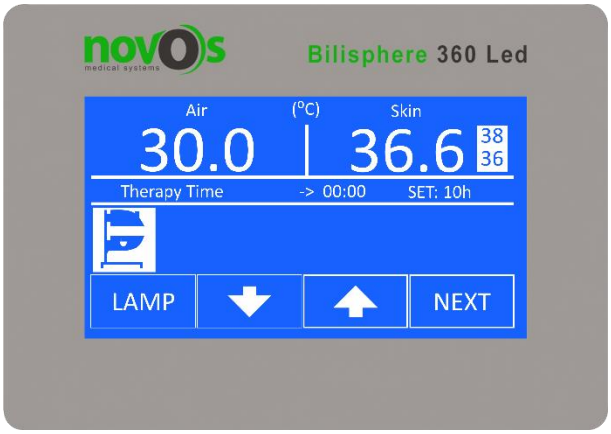
15. Press the CONTINUE button to exit the menu.



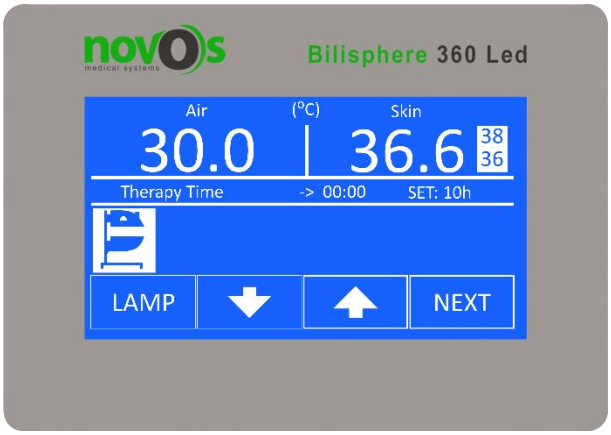
16. Press the START button to start therapy with only the lower groups of lamps as set in the menu.

17. Check that all 8 lamps of the lower lamp group work properly.
18. Press the STOP button and observe that the therapy is terminated.

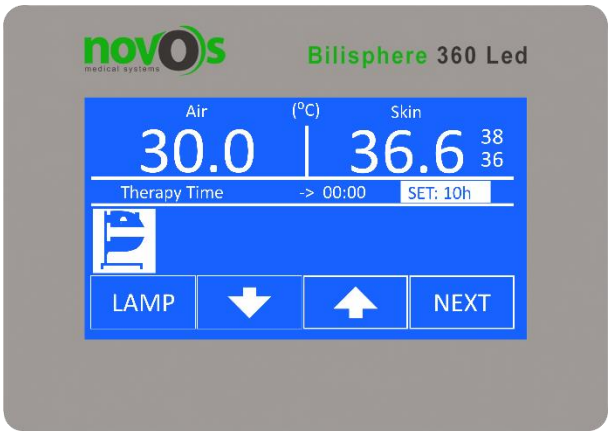
19. Press MENU button.



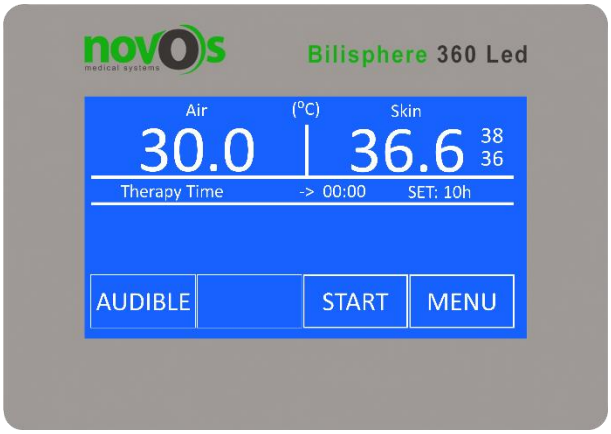
20. Press the LAMP button to turn on the upper lamp group.



21. Press the CONTINUE button to switch to the target therapy time settings.



22. Press the CONTINUE button to exit the menu.



23. Press the START button to start therapy with only the upper groups of lamps as set in the menu.

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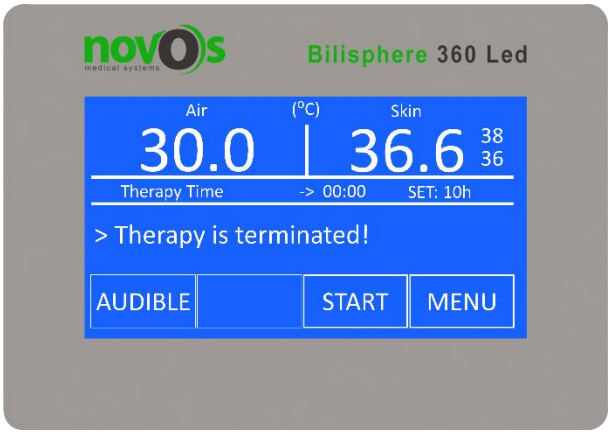
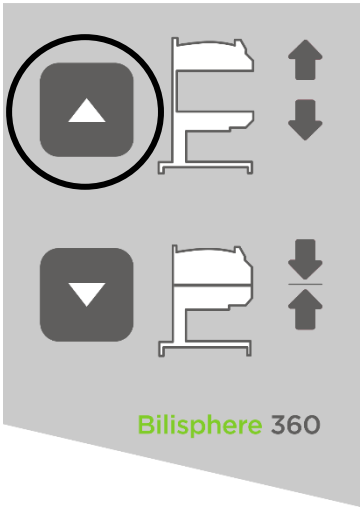
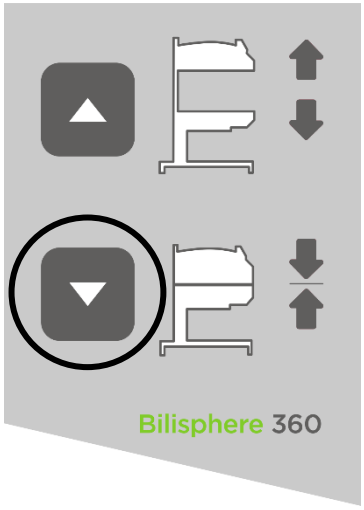


24. Check that all 8 lamps of the upper lamp group work properly.
25. Press the STOP button and observe that the therapy is terminated.

26. Press Up Arrow and observe the height increase in the upper part.



27. Press Down Arrow and observe the height decrease in the upper part.



WARNING!
Side plexiglass protectors of Bilisphere 360 LED should always be installed in normal operating condition. Otherwise, there is a risk of injury for the patient during manual height adjustment.

5. Use of Device

5.1. Turning On Bilisphere 360 LED

<table>
<tr><td>

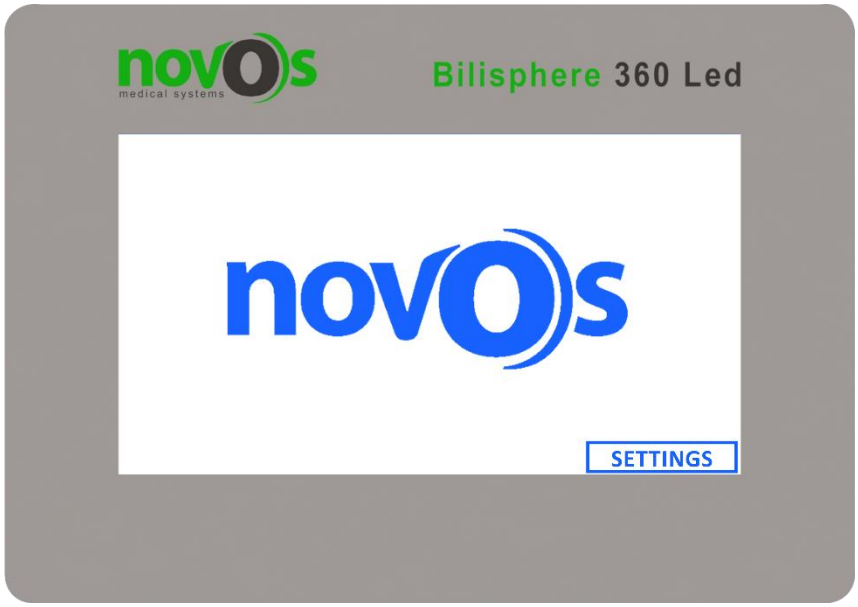
- Plug the power cord into the Power Input Socket located on the right side of the device. (1)

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

- Switch the device on by turning the On / Off switch to the I position. (2)

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

- Wait for the device to boot.

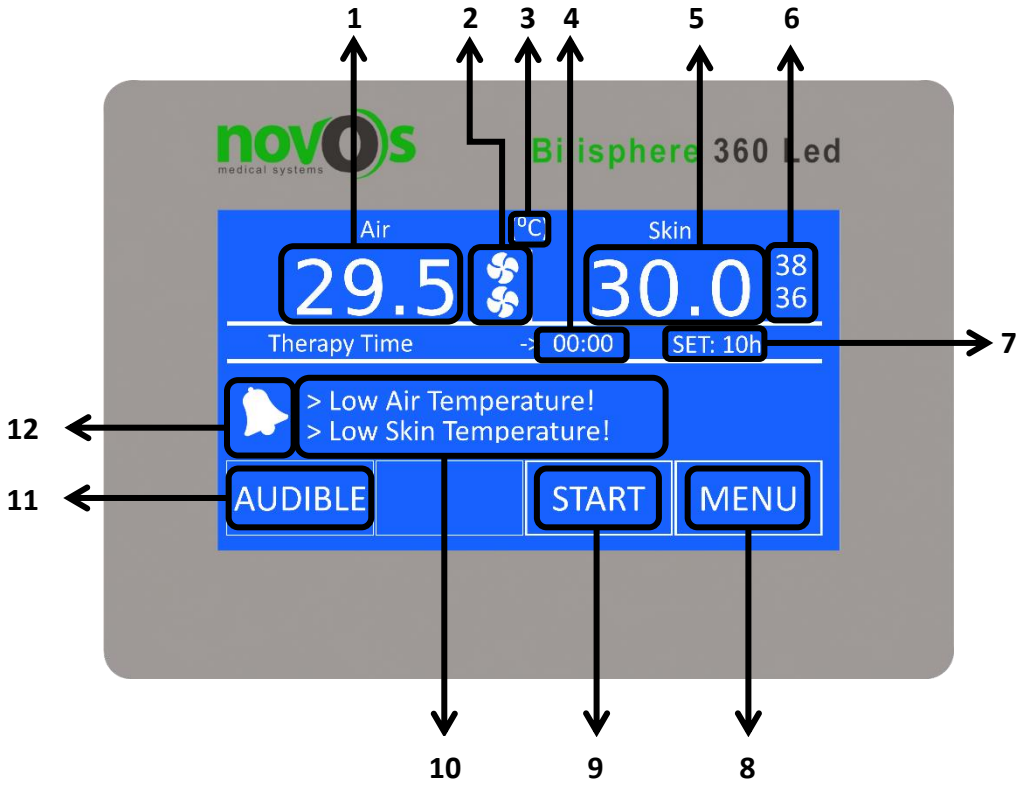
</td><td> 
</td></tr>
</table>

• Wait for the device to boot.	
• The Main Screen appears as seen in the image.	

5.2. Use of Control Panel

Bilisphere 360 LED has a control panel that houses the motherboard and a 5.1" LCD Touch screen. Except for manual height adjustment, all user inputs are transferred and processed through the control panel.

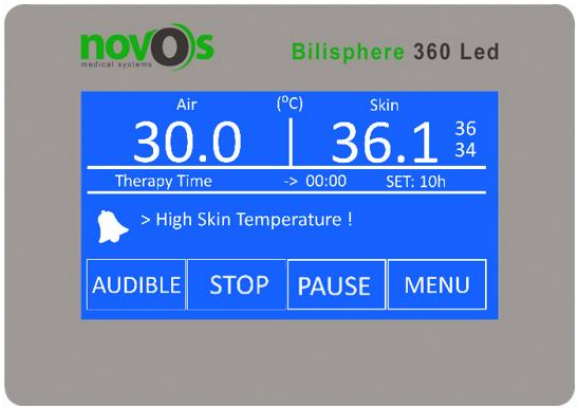
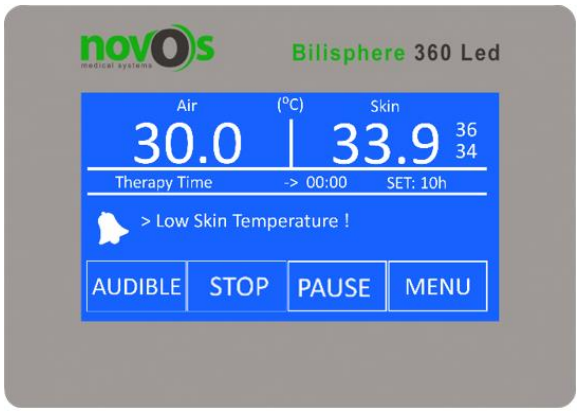
5.2.1.Main Display

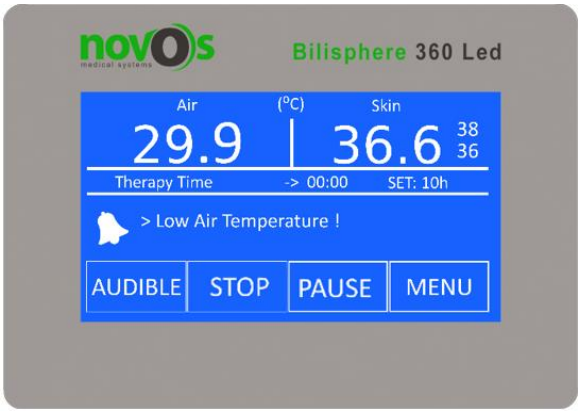
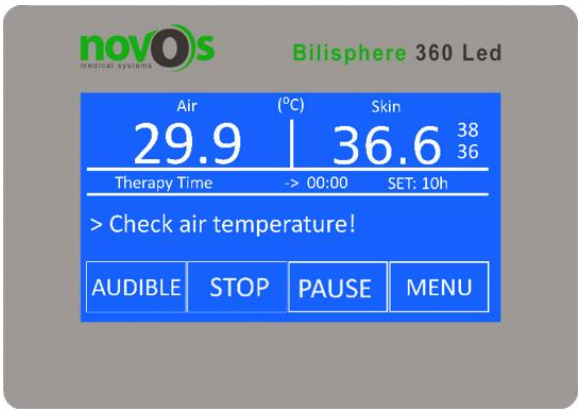
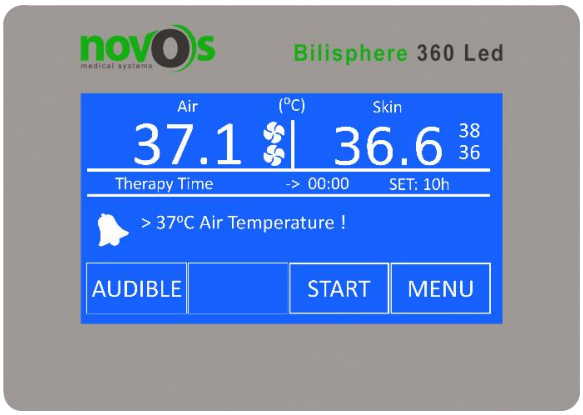
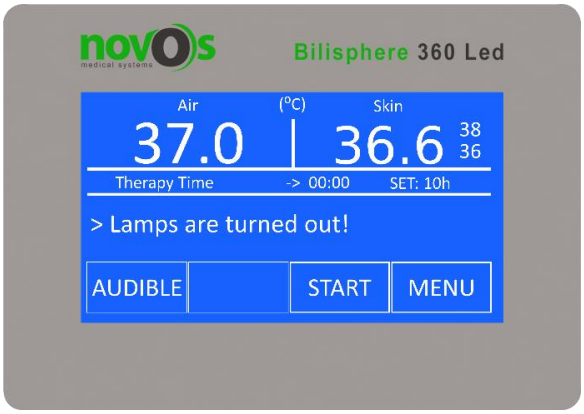


1	Air temperature	The air temperature inside the cabin is measured.
2	Fan Condition	Working condition of upper and lower fans.
3	Temperature Unit	Displayed temperature unit.
4	Therapy Counter	Time elapsed in phototherapy.
5	Skin temperature	The skin temperature measured by the skin probe.
6	Upper and Lower Alarm Limits of Skin Temperature	The range desired for skin temperature. If the measured value is not within this range, the audible alarm will be triggered.
7	Target Therapy Time	The period of time the phototherapy will be automatically terminated
8	***MENU*** Button	Menu access key.
9	***START*** Button	Phototherapy start button.
10	Alarms and Alerts	The area where various alarm and alerts are displayed.
11	***AUDIBLE*** Button	Audible alarms on / off button.
12	Audible Alarms Indicator	Audible alarm active / disabled indicator.

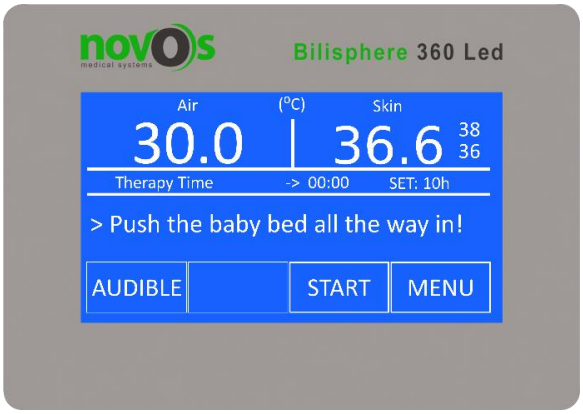
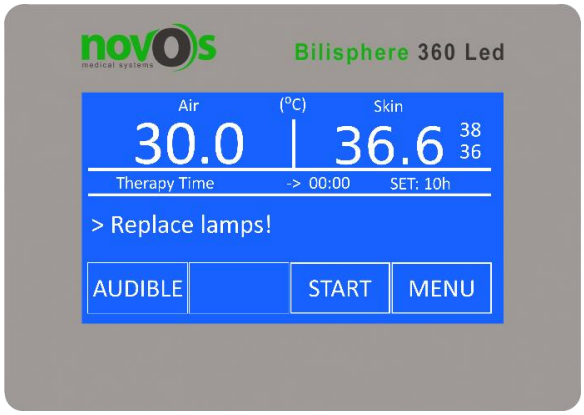
5.2.2.Alarms and Warnings

Alarm settings can only be changed by authorized personnel!

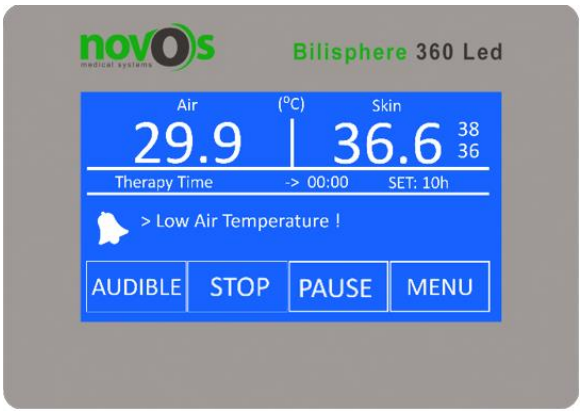
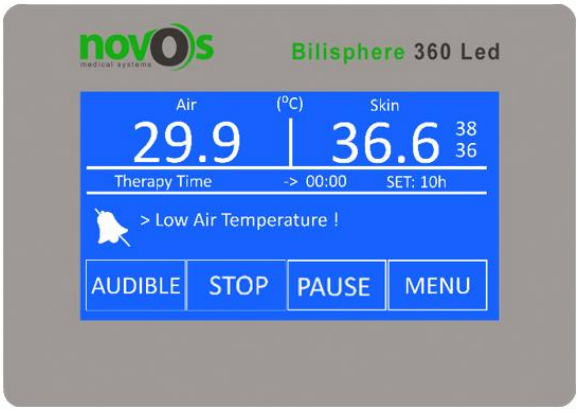
<table>
<tr><td colspan="2">High Skin Temperature: The measured skin temperature is not within the specified limits.</td></tr>
<tr><td>Alarm Message</td><td>Warning Messages</td></tr>
<tr><td> 
</td><td> 
</td></tr>
<tr><td colspan="2">Low Skin Temperature: The measured skin temperature is not within the specified limits.
High Priority</td></tr>
<tr><td>Alarm Message</td><td>Warning Messages</td></tr>
<tr><td> 
</td><td> 
</td></tr>
</table>

<table>
<tr><td colspan="2">Low Air Temperature: The measured air temperature is below 30 °C.
High Priority</td></tr>
<tr><td>Alarm Message</td><td>Warning Messages</td></tr>
<tr><td> 
</td><td> 
</td></tr>
<tr><td colspan="2">37°C Air Temperature: The measured air temperature is beyond 37 °C.
High Priority</td></tr>
<tr><td>Alarm Message</td><td>Warning Messages</td></tr>
<tr><td> 
</td><td> 
</td></tr>
</table>

5.2.2.1. *Alerts*

Push the baby bed all the way down: Baby bed drawer open, close completely.

Change the lamps: The service life of the lamps is over. (Working Time> 20,000 hours)

Upper piece rises: The height of the upper cover is increased by thermo-elevation.

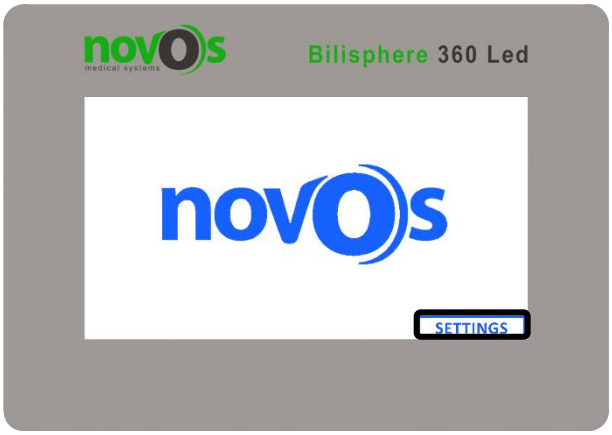

5.2.2.2. *Audible Alarms Activation / Deactivation*

• To silence the auditory alarm, press the ***AUDIBLE*** button.	
• The audible alarm will be silenced for 5 minutes.	

5.2.3.Settings Menu

From the settings menu, screen language selection, lamp life monitoring, temperature unit selection and touch screen calibration can be performed.

To access the settings menu, follow the steps below;

• Press the ***SETTINGS*** button while the startup is in progress. **Note:** If the ***SETTINGS*** button is not visible at this stage, it means the device has been switched off during an ongoing therapy. Please end therapy and restart the device.	
• The settings screen will be shown in 5 main tabs.	

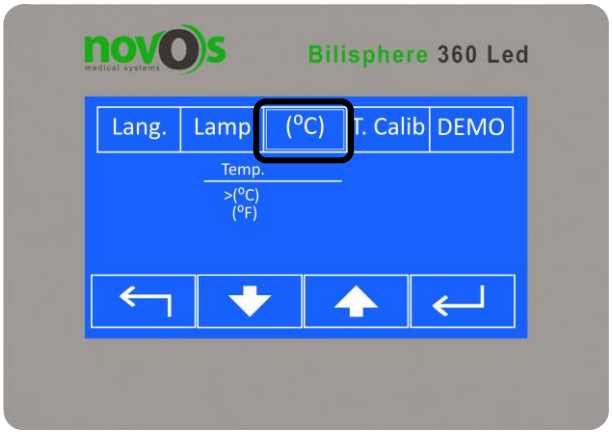
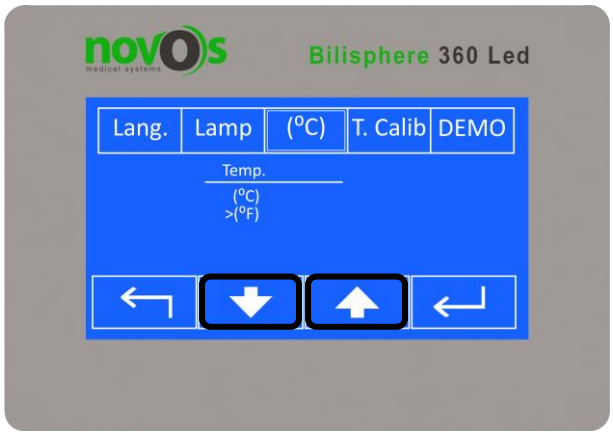
5.2.3.1. *Changing Display Language*

The first tab available in the settings menu is the Language tab. • Press the ***UP*** or ***DOWN*** keys to select the desired language among Turkish, English, French and Spanish options.	

5.2.3.2. *Total Lamp Usage Time*

• Press the ***Lamp*** tab to view the total usage time of the lamps.	

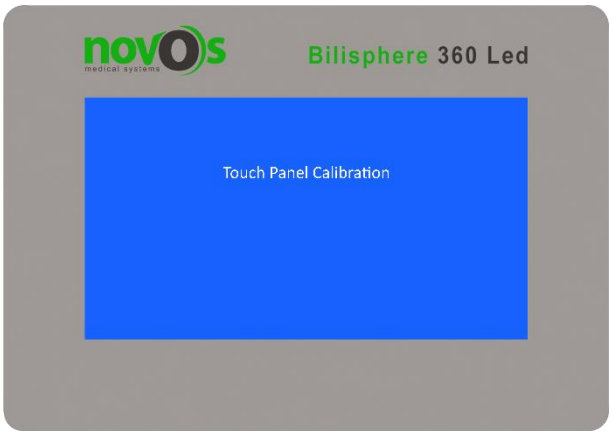
5.2.3.3. *Changing the Temperature Unit*

• Press the ***(°C)*** or ***(°F)*** tab key.	
• Press ***UP*** or ***DOWN*** to switch between Celsius and Fahrenheit temperature units.	

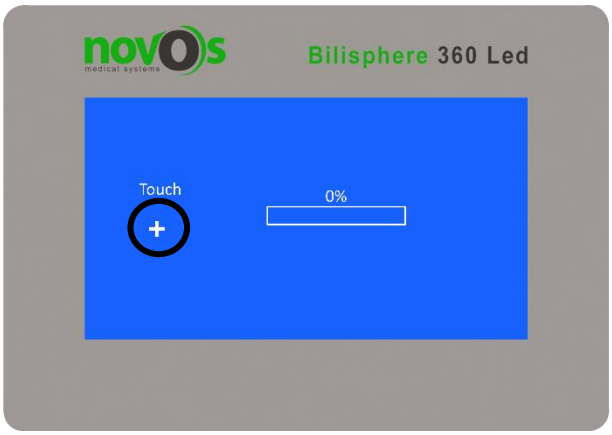
5.2.3.4. *Touch Screen Calibration*

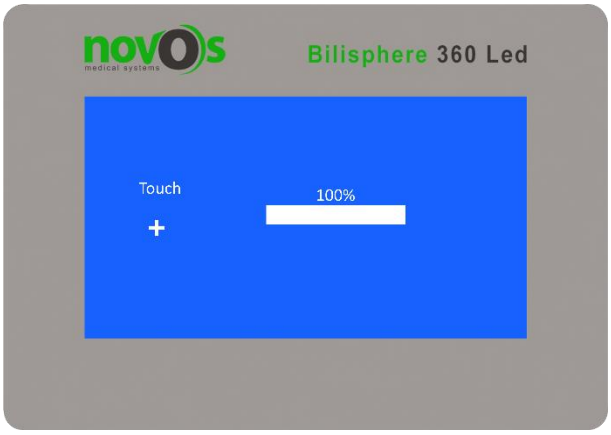
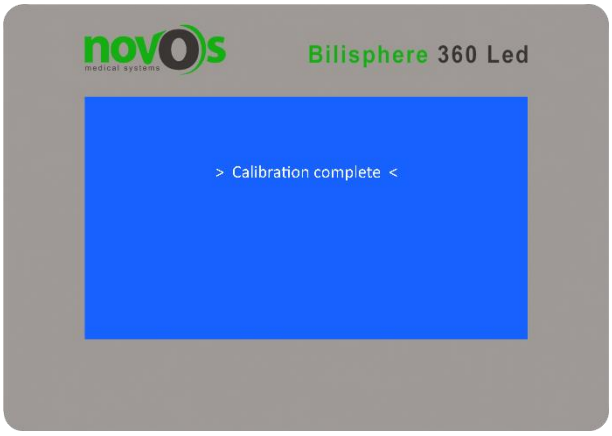
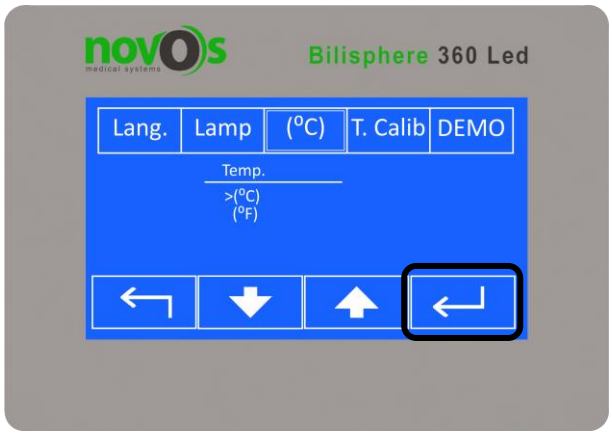
<table>
<tr>
<td rowspan="2">

- Press ***TS Calib***.

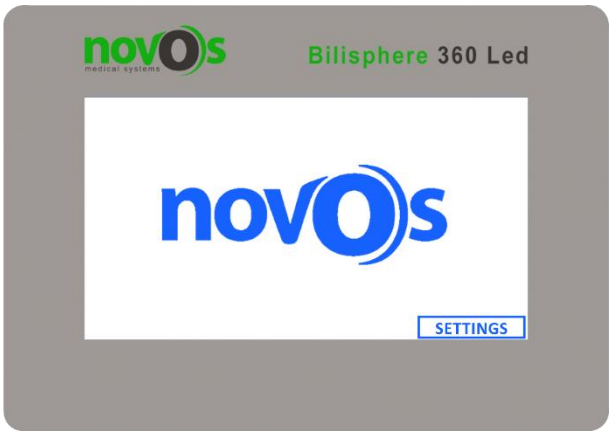
</td>
<td> 
</td>
</tr>
<tr>
<td> 
</td>
</tr>
<tr>
<td>

- Press and hold the point indicated by a cross.

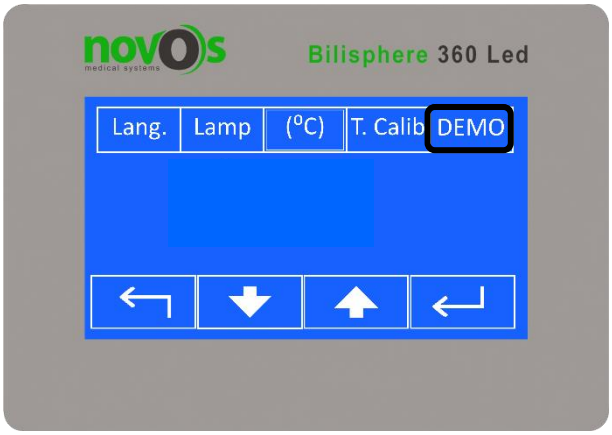
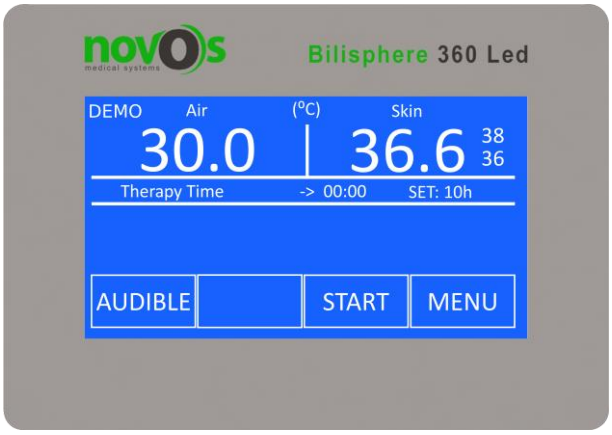
</td>
<td> 
</td>
</tr>
</table>

• When the progress bar shows 100%, remove your finger. • Repeat the same procedure for a total of 3 different points.	
• After the identification of the third point, the message "***Calibration completed***" appears, indicating that the calibration has been done successfully.	
• Press the ***CONFIRM*** to apply the changes.	

5.2.3.5. *DEMO Mode*

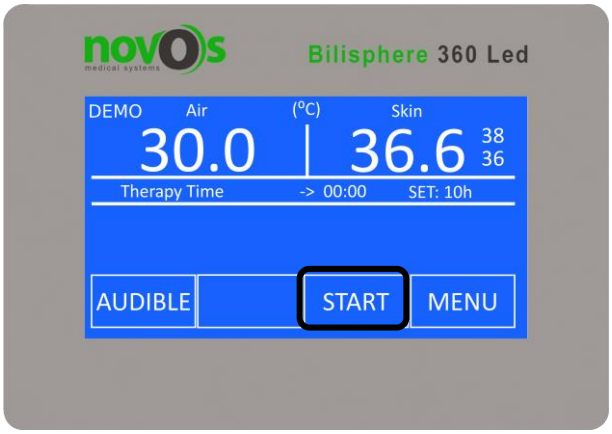
To operate the device in ***DEMO*** mode; • Press the On/Off switch located on the right side of the device. • Press the ***SETTINGS*** button displayed on the opening screen.	

WARNING!
Demo mode can only be accessed when the SETTINGS tab is pressed when the device is

• Press ***DEMO*** button.	
• After pressing the DEMO button in the settings menu, the device restarts in DEMO mode. • The DEMO sign will appear in the upper left corner of the screen.	

In DEMO Mode;

- The device simulates the air temperature to better understand the Thermo-Elevation feature.
- At the beginning of the demo mode, the air temperature is simulated as 30 °C.
- The air temperature will be automatically raised to 37 °C.
- When the air temperature reaches 32 °C, the upper fan group will be activated.
- When the air temperature reaches 34°C, the lower fan group will be activated.
- When the air temperature reaches 35 °C, the upper part will be raised by 10 cm.
- When the air temperature reaches 36°C, the upper part will be raised 10 cm more.
- When the air temperature reaches 37 °C, the demo will be terminated.
- After the demo is finished, the air temperature is simulated again to 30 °C, the fans stop and the lamps go out.
- At the end of the demo, the top cover will remain raised.
- To start a new demo session or to turn the device back on to administer therapy, the top cover must first be manually lowered completely.

• Press the ***START*** tab to start a new ***DEMO*** mode after manually lowering the top cover.	

To switch from DEMO mode to therapy screen, it is necessary to exit the DEMO mode.

- For this, after manually lowering the raised top cover at the end of the DEMO mode, turn the device off by pressing the On / Off switch and turn it on again.
- Follow the instructions in 5.3 Starting Therapy.

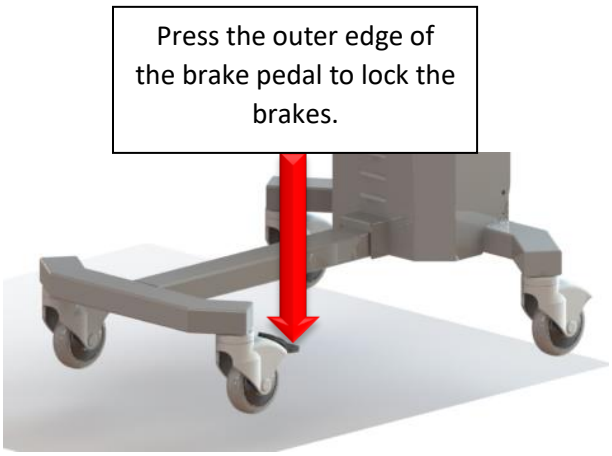
5.3. Starting Therapy

Before starting therapy, the Bilisphere 360 LED phototherapy device must be properly positioned.

<table>
<tr><td>

- Lock the brakes of the wheels to avoid unwanted movement of the equipment.

</td><td>



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

- Open the baby bed’s drawer and place the baby.

</td><td>

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

- Place the skin probe as described in 5.4.1 Placing/Removing the Skin Probe.

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

- Put an appropriately sized eye protection for the baby's eyes.

</td><td>

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

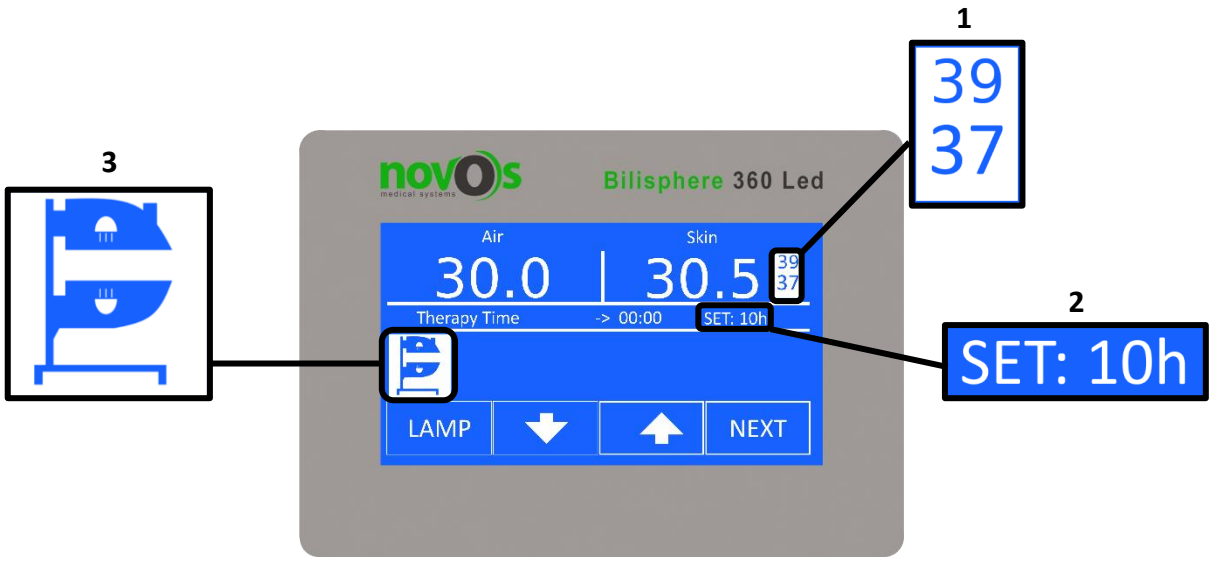
<table>
<tr>
<td>

- Push the bed drawer completely into the cabinet.

Note: During therapy, the baby bed drawer should be in the closed position.

</td>
<td>  </td>
</tr>
<tr>
<td colspan="2">Turn on the device as described in section 5.1 Starting Bilisphere 360 LED.</td>
</tr>
</table>

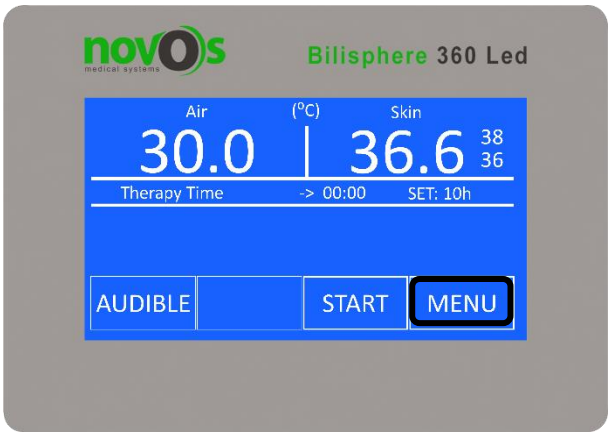
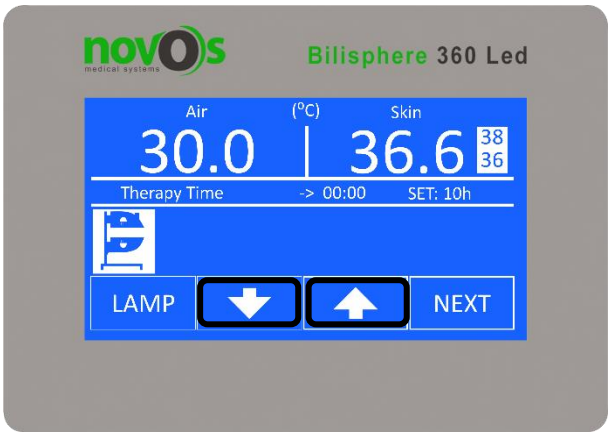
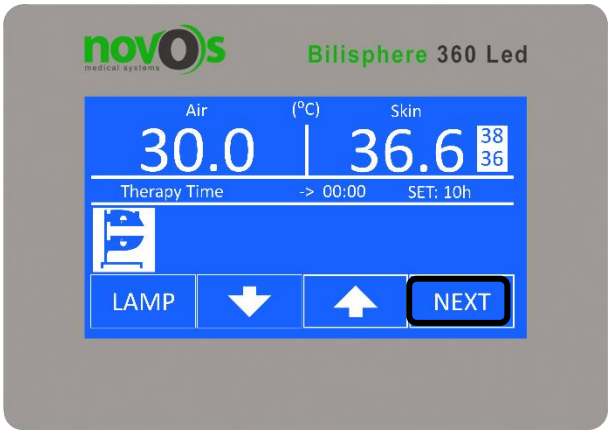
There are 3 parameters to be set before starting phototherapy.

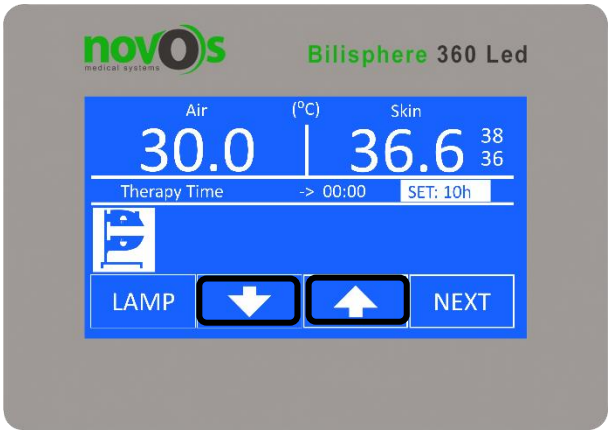
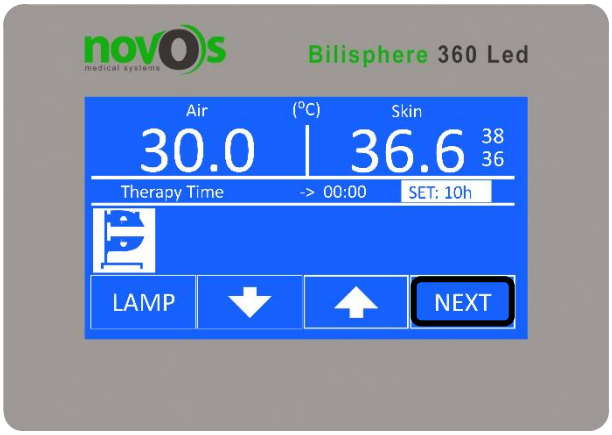


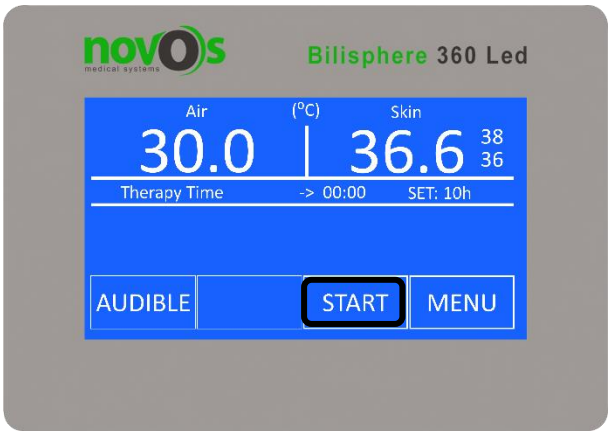
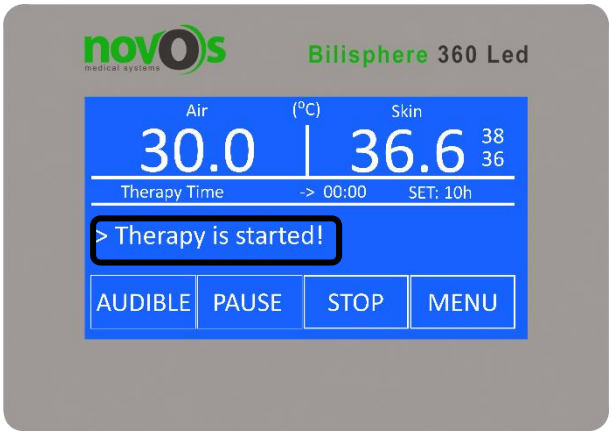
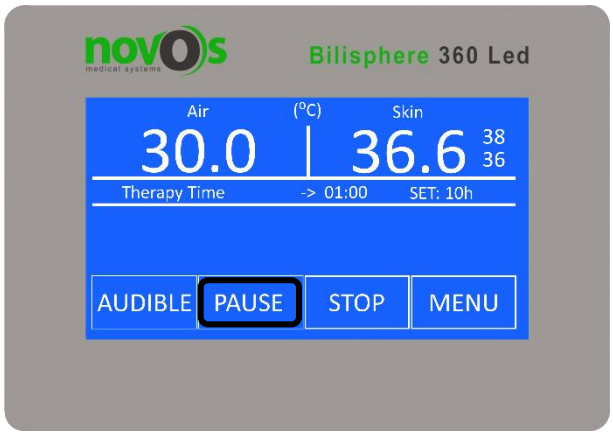
1. Upper and lower alarm limits for skin temperature.
2. Target Therapy Time
3. Active lamp groups.

All these parameters should be set according to the clinical condition of the baby.

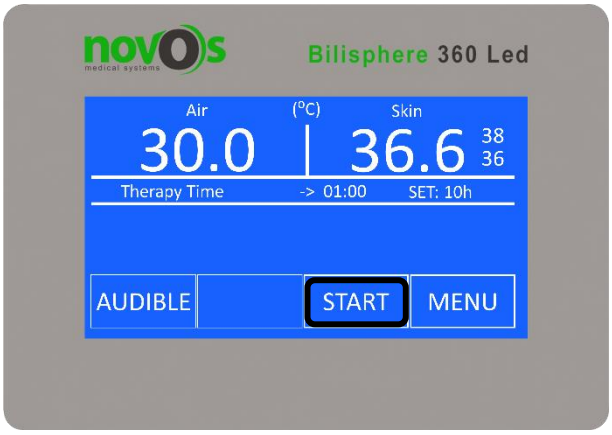
The following procedure explains how to start phototherapy.

• Press ***MENU*** button.	
• Press the ***UP*** or ***DOWN*** arrows to change between pre-defined alarm limits. (31-33, 32-34, 33-35, 34-36, 35-37, 36-38, 37-39).	
• Press the ***CONTINUE*** key to proceed to the ***Target Therapy Time*** parameter.	

• Press the ***UP*** or ***DOWN*** arrows to set the target therapy time.	
• Press the ***LAMP*** button to switch between the following lamp groups. ○ Use only the lower lamp groups. ○ Use only the upper lamp groups. ○ Use both the upper and lower lamp groups.	
• Press the ***NEXT*** button to exit the menu.	

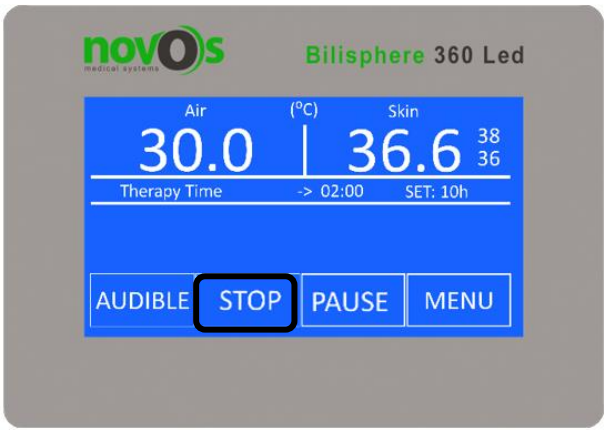
• Press the ***START*** to start therapy.	
• Watch for the **"Therapy started"** alert.	
• Press the ***PAUSE*** to pause therapy. The therapy counter will pause until it is resumed.	

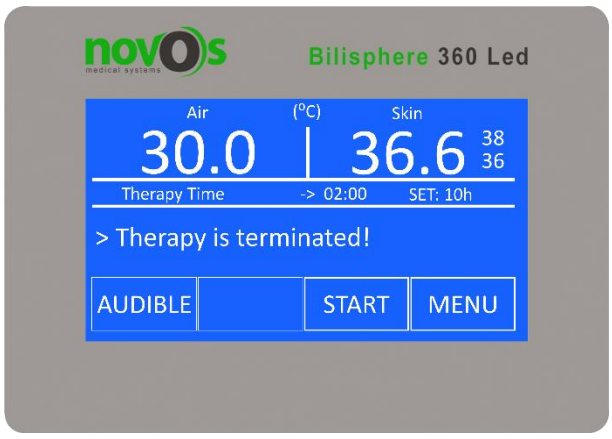
- Press the ***START*** to resume therapy.



- Press the ***STOP*** to stop therapy.

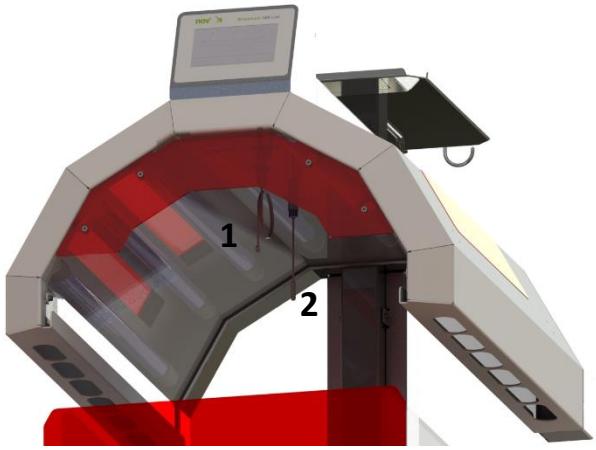
Note: Bilisphere 360 LED will automatically end the therapy after the target therapy time has passed. The therapy ended message will be displayed until any button is pressed.

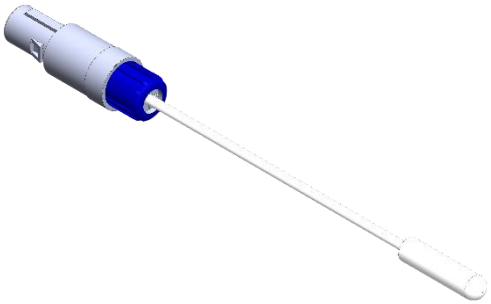




5.4. Temperature Sensors

There is one air and one skin temperature sensor placed on the ceiling of the Bilisphere 360 LED cabinet.

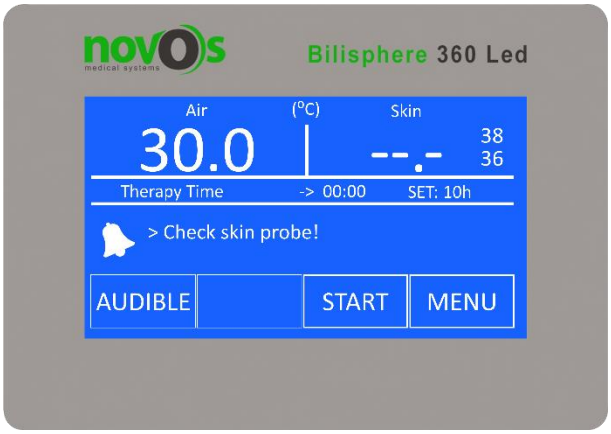


1) Skin Temperature Probe	2) Air Temperature Probe
	

WARNING!
Avoid applying excessive force to sensor sockets during attaching and detaching.

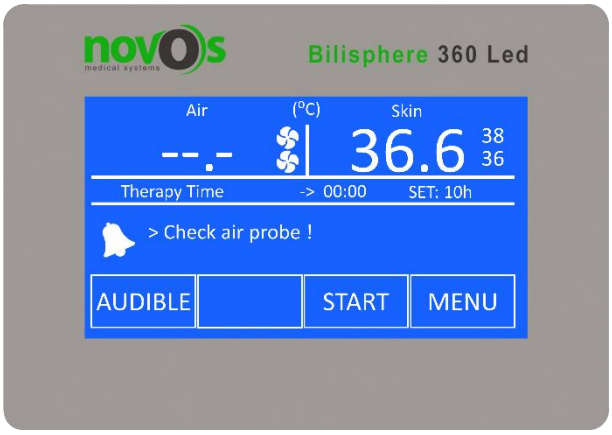
If the skin probe is not connected to the device;

- A dashed line will appear in the relevant part of the main screen.
- ***"Check the skin probe!"*** alarm will be triggered.

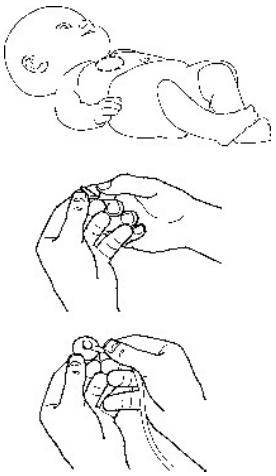
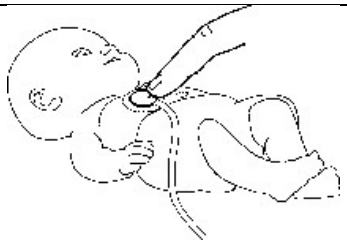
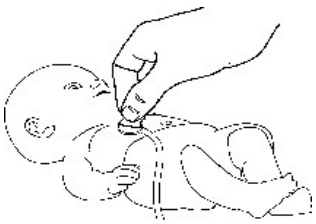


If the air probe is not connected to the device;

- A dashed line will appear in the relevant part of the main screen.
- ***"Check the air probe!"*** alarm will be triggered.
- The therapy will not be started.

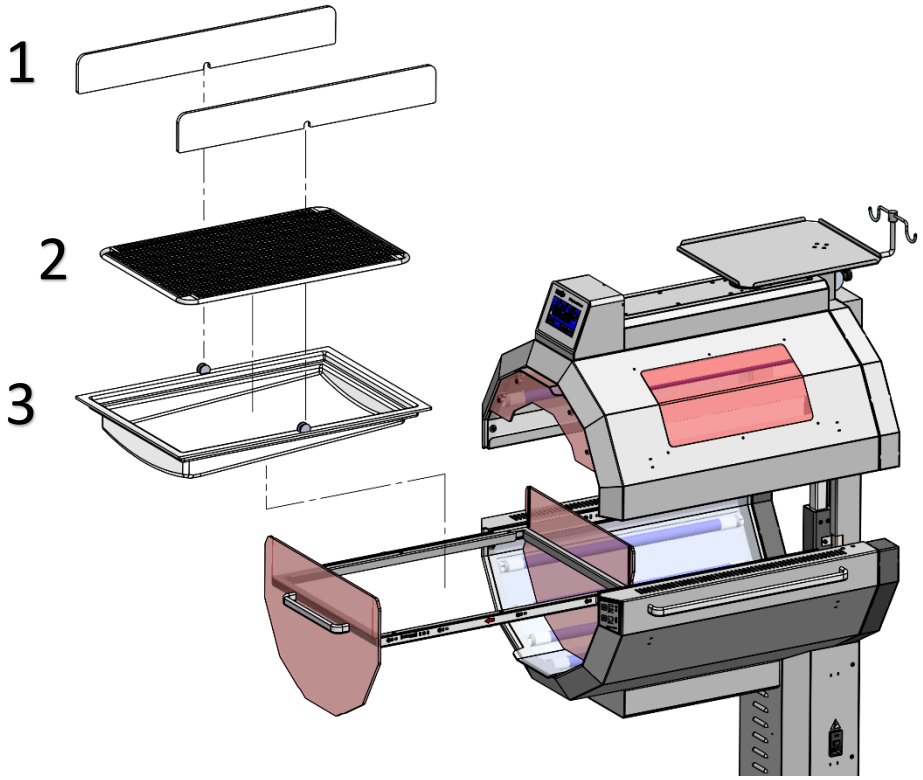


5.4.1.Placing/Removing the Skin Probe

Placing 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.
 **Removing 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.

5.5. Baby Bed

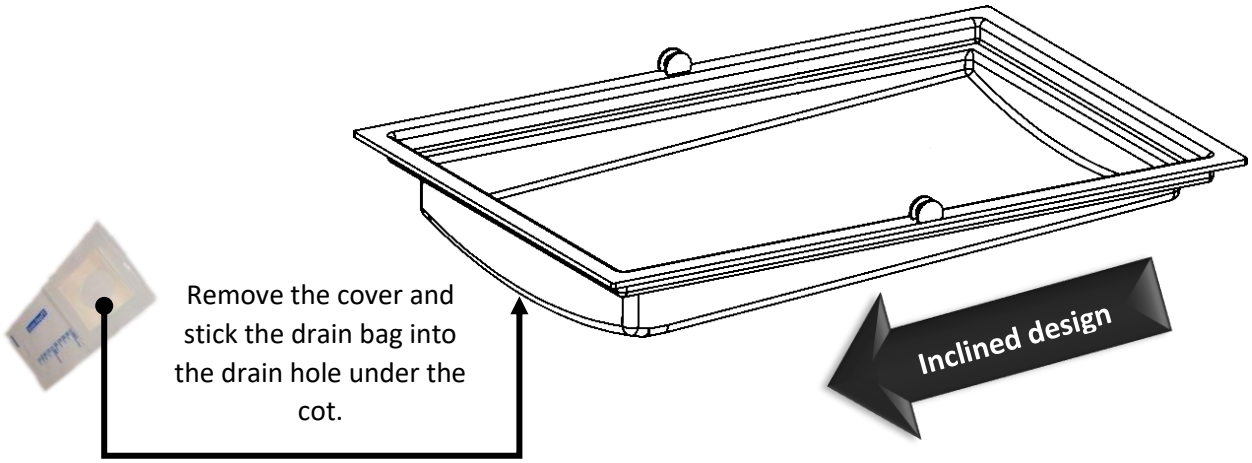
The baby bed of Bilisphere 360 LED consists of side plexiglass protectors (1), a hammock (2) and a baby cot with drainage (3). All these components can be removed from the device for disinfection



purposes.

5.5.1.Baby Cot with Drainage

Bilisphere 360 LED's baby cot has a special drain hole that can transfer liquid waste to the baby drainage bag with the help of its inclined design.



5.5.2.Hammock

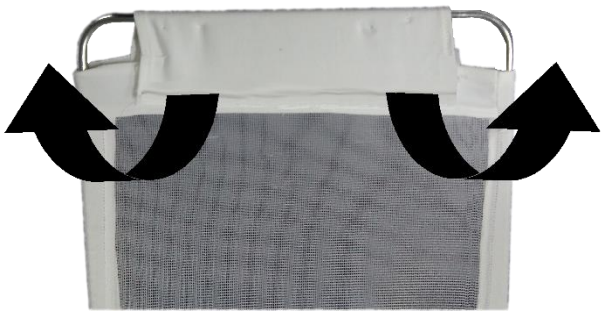
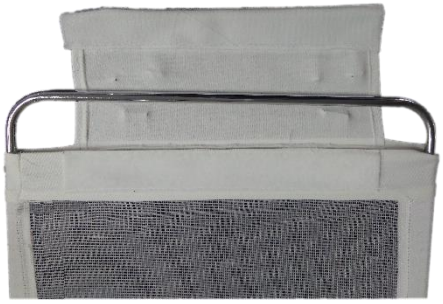
The hammock of Bilisphere 360 LED provides a comfortable surface while allowing the necessary blue light interference.

For disinfection purposes, the hammock can be washed by hand with mild detergent and water and can be replaced again.

5.5.2.1. *Hammock Replacement*

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

- Remove the hammock from the bed drawer.
- Release the hook-and-loop edge of the hammock.
- Pull the metal hammock frame and slide it out.

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

- Reverse the process to reattach the hammock to its frame.

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

- Before each use, visually check for damage and replace the hammock if necessary.

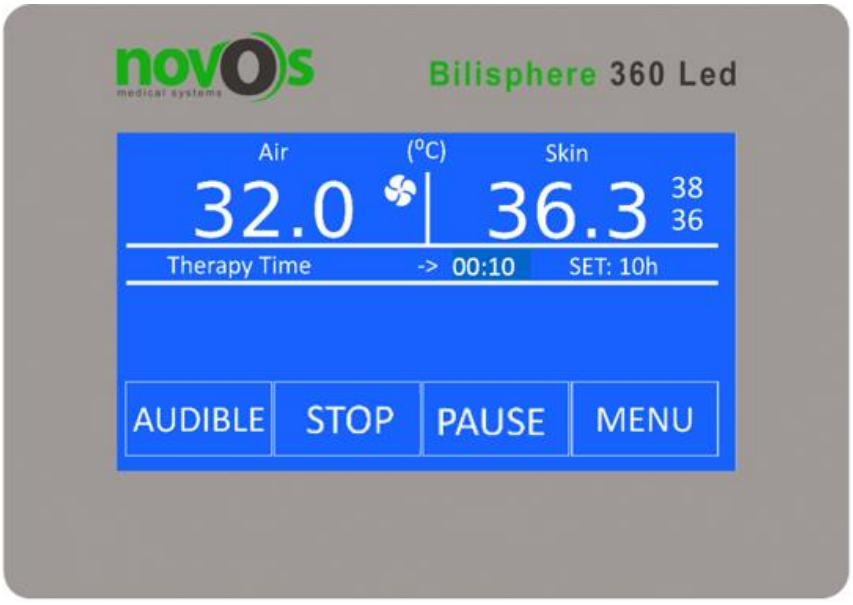
</td></tr>
</table>

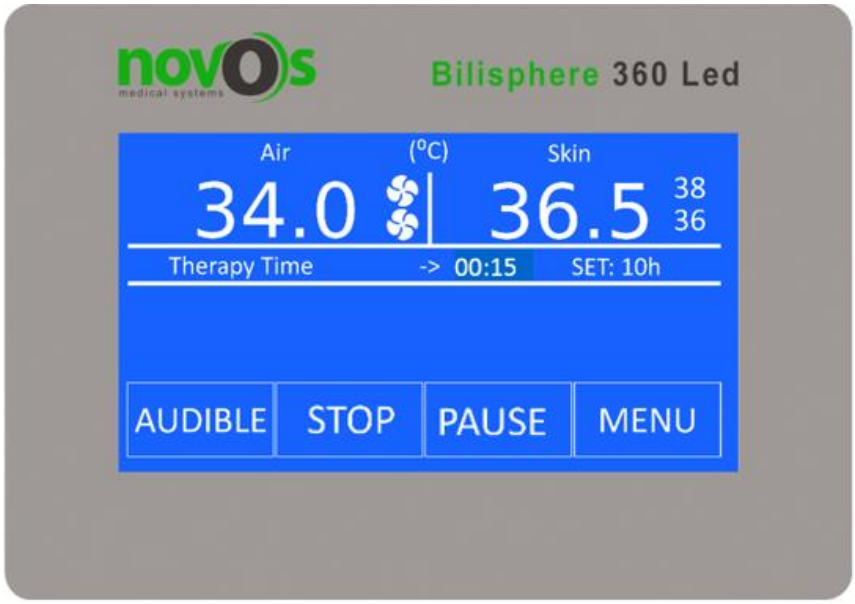
5.6. Thermo-Elevation

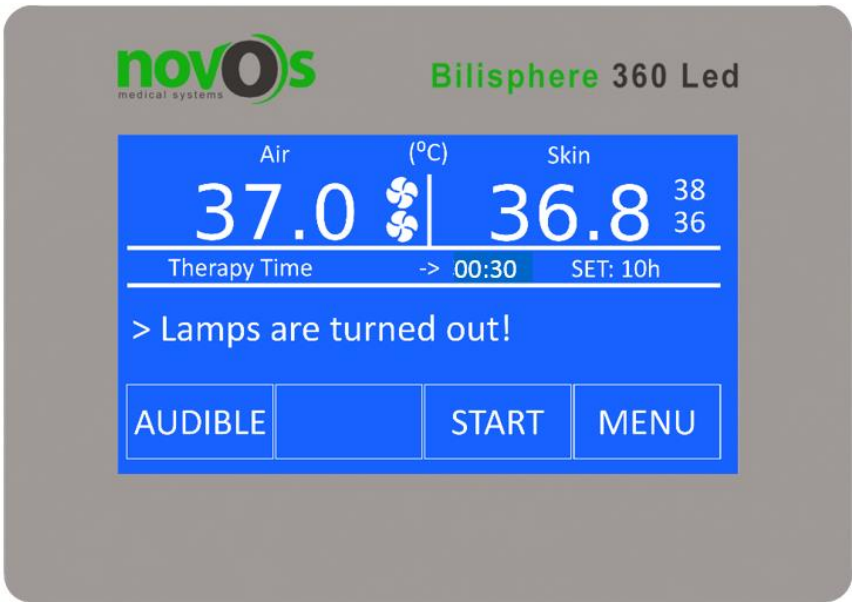
With the help of the Thermo-Elevation feature, unwanted temperature increase in the cabin is prevented. Therefore, the risk of hyperthermia, dehydration, tissue and cell damage is prevented.

5.6.1.Operation Principle

The microcontroller of Bilisphere 360 LED continuously measures the air temperature inside the cabinet and increases the height of the upper part to provide the necessary fresh air circulation. By doing this, the temperature inside the cabinet is kept within a safe range and unwanted increases are prevented.

<table>
<tr>
<td>1</td>
<td>Assume the therapy is started with an air temperature of 30.0°C.</td>
<td> 
</td>
</tr>
<tr>
<td rowspan="2">2</td>
<td rowspan="2">Air Temperature = 32.0 °C</td>
<td>Upper FAN starts to work.</td>
</tr>
<tr>
<td> 
</td>
</tr>
</table>

3	Air Temperature = 34.0 °C	**Lower FAN starts to work.** 
4	Air Temperature = 35.0 °C	**The upper part is raised 10 cm higher.** 

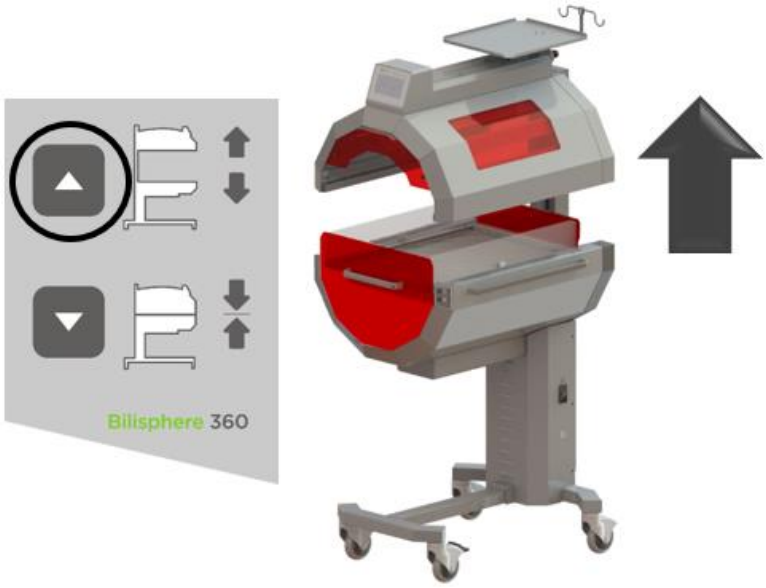
5	Air Temperature = 36.0 °C	**The upper part is raised 10 cm more higher.** 
6	Air Temperature = 37 °C	**Therapy will be ended.** 

5.7. Manual Height Adjustment for the Upper Part

If the measured air temperature is below 35 °C, the upper part height can also be adjusted manually. Regulation of the air temperature in the cabin can be supported by manual height adjustment. Temperature values between 30-35 °C can be obtained by changing the height of the upper part. The more space between the parts, the more fresh air flows through the cabinet, preventing unwanted temperature rise.

WARNING!
If the upper body height is increased by thermo-elevation, it cannot be lowered manually unless the air temperature drops below 35 °C.

Press and hold the Up Arrow to increase the height of the upper body.



Press and hold Down Arrow to decrease the height of the upper body

WARNING!
Side plexiglass protectors of Bilisphere 360 LED should always be installed in normal operating condition. Otherwise, there is a risk of injury for the patient during manual height adjustment.

6. Routine Cleaning and Maintenance

6.1. General Cleaning

Bilisphere 360 LED should be cleaned prior to each patient use.

The following process should be followed for cleaning and disinfection of the equipment:

- Lift the upper part 20 cm-25 cm higher.
- Disconnect the power supply.
- Remove accumulated dirt from surfaces using a soft brush and/or dry cloth/flannel.
- Using a mild detergent solution and warm water, clean the entire surface.
- Dry the entire surface using a dry flannel.

Disinfect the entire surface using an antiseptic spray. The antiseptic spray should not contain alcohol.

- Allow sufficient time for drying. (Follow the directions on the label on the antiseptic spray to ensure complete asepsis.)

The following process should be followed for cleaning the hammock:

- Remove the hammock from its frame.
- Wash the hammock by hand with a mild detergent and warm water solution.
- Rinse thoroughly in lukewarm water.
- Check if the hammock is excessively worn or damaged. If necessary, replace it with a new hammock.
- Let the hammock dry before repositioning.

6.2. 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.

6.3. Maintenance

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

The average lifespan of LED lamps is 20,000 hours, however, it is recommended to monitor the irradiance with a continuous radiometer to allow a better evaluation of the actual effectiveness of the lamps. When the radiant intensity falls 25% or less of the value stated in the lamp manufacturer's catalog, it should be changed.

WARNING! **Technical service and maintenance services should only be provided by technically qualified persons.**
WARNING! **Make sure that the Bilisphere 360 LED is not connected to the power supply during maintenance procedures to avoid the possibility of electrical shock.**
WARNING! **For better performance and device safety, use only original NOVOS spare parts.**

6.3.1.Lamp Replacement

When the total time counter reaches 19,800 hours, Novosoft gives an information message.

Please contact NOVOS Technical Service Department for LED lamps replacement.

6.3.2.Hammock Replacement

Over time, the hammock can wear out, so regularly inspect the hammock for excess wear or damage. Replace if necessary.

WARNING! **Make sure that the Bilisphere 360 LED is not connected to the power supply during cleaning procedures to avoid the possibility of electrical shock.**
WARNING! **Before cleaning and disinfecting, raise the upper part 20-25 cm.**
WARNING! **If the UPS is installed, make sure it is turned off before cleaning, and if there is, keep the UPS cover on the UPS during cleaning. Make sure that no part of the UPS has been immersed in any cleaning substance.**
WARNING! **Do not spray antiseptic to the lamps and do not allow liquids to seep into equipment.**
WARNING! **Do not use abrasive cleaning solutions, sodium hypochlorite or alcohol to clean the surfaces of Bilisphere 360 LED.**
WARNING! **Do not immerse any part of the equipment and lamps in liquid cleaning products.**

7.Troubleshooting

7.1. Fast Troubleshooting Guide

Failure Case	Cause	Solution Recommendation
Device does not start up.	Power supply failure.	Connect the power cord to a suitable outlet.
	The main on / off switch is in the off position.	Turn the switch to the I (on) position.
	Defective fuse.	Contact an authorized NOVOS Technical Service.
	Internal electrical problem.	
Display does not show up.	Internal electrical problem.	Contact an authorized NOVOS Technical Service.
The touchscreen is not working properly.	Touchscreen calibration is missing.	Restart the device and re-calibrate the touch screen from the settings menu.
The therapy does not start.	Air probe is not connected.	Connect the air probe.
	The baby-bed drawer may not be placed correctly.	Close the baby-bed drawer completely.
	Faulty Software.	Contact an authorized NOVOS Technical Service.
Lamps do not light up.	Air temperature is above 37 °C.	Wait for the air temperature of the compartment to drop below 37°C.
	Internal electrical problem.	Contact an authorized NOVOS Technical Service.
Upper piece does not rise.	Faulty motor.	Contact an authorized NOVOS Technical Service.
	Faulty Software.	
	Blown fuse on motor driver board.	
Fan does not work.	Faulty fan.	Contact an authorized NOVOS Technical Service.
	Faulty Software.	

8.Annexes

8.1. Technical Specifications

8.1.1.Environmental Conditions

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

8.1.2.Mechanical Properties

Height	1460mm- 1660mm
Width	685mm
Depth	815mm
Weight	66 kg
Screen Type	Monochrome LCD
Screen Dimensions	5.1"
Hammock Dimensions	58 cm x 38 cm

8.1.3.Electrical Properties

Supply Voltage and Current	220V AC , 1,2 A
Sections Applied	Class 1 Type BF
Fuses	2A
Supply Frequency	50Hz-60Hz
Maximum Power Value	230W
Noise Level	<55dBA
Air and Skin Temperature Sensor Resolution	0.1^{o}C
Sensor Sensitivity	0.1^{o}C

8.1.4.Radiation Properties

Number of LEDs	16 LED Tubes
Therapy Lamp Light Intensity Level	1
LED Current Value	0.052A
Spectral Radiation - Level 5	>100µW/cm^2/nm or >5mW/cm^2
Dominant Wavelength Range	440nm-460 nm
LED Life Cycle	20,000 hours

8.1.5.Other Properties

Software Version	V3.2
Resettable LED Life Counter	Yes
Focusing LEDs	No
Transport Trolley	No
Wheels	4 wheels in total, 2 with brakes
Fan	2 pcs.
Target Therapy Time	Adjustable between 0-99 hours in 1 hour intervals.
Upper Limit of Skin Temperature Alarm	Adjustable between 33 °C - 39 °C in 1 ° C intervals.
Lower Limit of Skin Temperature Alarm	Adjustable between 31°C - 37°C in 1 ° C intervals.
Skin Probe Failure Alarm	Yes
Therapy Ended Alarm	Yes
LED Life Warning	Yes
High Air Temperature Alert	>37°C
Low Air Temperature Alert	<28°C
Air Temperature Display Setting	0°C- 51°C
Skin Temperature Display Setting	0°C- 51°C
Eye Protection Patch	Prevents the passage of UV light of of 450 nm.
Interface Languages	Turkish, English, French, Spanish
Monitor Tray (Optional)	30,5x35,5x9cm – Capacity: 6 kgs
IV Pole (Optional)	Height: 146cm- 166cm- Capacity: 2kg

8.2. Compatibility

NOVOS Bilisphere 360 LED phototherapy system has been designed to comply with the requirements of the following standards:

IEC 60601-1 Medical electrical equipment - Part 1: General requirements for basic safety and basic performance

IEC60601-2-50 Medical electrical equipment - Part 2-50: Special rules for basic safety and basic performance of baby phototherapy devices

ISO 13485 specifies the requirements for a quality management system that an organization must demonstrate its ability to provide medical devices and related services that consistently meet the customer requirements and regulatory requirements applicable to medical devices and related services.

The main purpose of ISO 13485 is to facilitate harmonized medical device regulatory requirements for quality management systems. In conclusion, it contains some specific requirements for medical devices and excludes some of the ISO 9001 requirements that are not suitable as regulatory requirements. Due to these exceptions, organizations of which quality management systems comply with international standards cannot claim compliance with ISO 9001 unless their quality management systems comply with all requirements of ISO 9001.

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.

Bilisphere 360 LED is designed for use in below conditions and environments.

8.2.2.1. *Electromagnetic Environment*

Bilisphere 360 LED is intended for use in the electromagnetic environment specified below. The customer or user of the Bilisphere 360 LED must guarantee that the device will be used in such an environment.

Emission experiments	Compatibility	Electromagnetic Environment
RF Emissions CISPR 11	Group 1	Bilisphere 360 LED uses RF energy only for its internal function. Therefore, it has very low RF emissions and is unlikely to interfere with nearby electronic devices.
	Class A	Bilisphere 360 LED is suitable for use in local facilities, except for 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)	Compliant.	

8.2.2.2. *Electromagnetic Immunity*

Bilisphere 360 LED is intended for use in the electromagnetic environment specified below. The customer or user of the Bilisphere 360 LED must guarantee that the device will be used in such an environment.

Immunity Test	IEC 60601 experiment level	Compatibility level	Electromagnetic Environment
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Places, in which Bilisphere 360 LED will be used, should be wood, concrete or ceramic brick. If these places are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst EFT IEC 61000-4-4	± 2 kV Mains ± 1 kV Inputs/Outputs	± 2 kV Grid Not applicable	The quality of mains power should be same of a typical commercial or hospital environment.
Impulse IEC 61000-4-5	± 1 kV Differential ± 2 kV common	± 1 kV Differential ± 2 kV common	The quality of mains power should be same of a typical commercial or hospital environment.
Mains frequency magnetic field (50/60 Hz) IEC 61000-4-8	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 test level	Compatibility level	Electromagnetic Environment
Voltage Dips/Breaks IEC 61000-4-11	100% drop for 0,5 cycle, at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 100% drop for 1 cycles, at 0° 30% drop for 25 cycles, at 0° 100% drop for 250 cycles	100% drop for 0,5 cycle, at 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 100% drop for 1 cycles, at 0° 30% drop for 25 cycles, at 0° 100% drop for 250 cycles	Main power quality should be in typical commercial quality or suitable for hospital environment. If the user of the Bilisphere 360 LED needs to continue operating the device while there is a power cut in the power grid, it is recommended that the device be powered from an uninterruptible power supply or battery.
Conveyed RF IEC 61000-4-6	3 V (outside ISM band) 6 V (inside ISM band) 150 kHz to 80 MHz	V_1=3 V V_2=6 V	Portable and mobile RF communications equipment should be kept away from any part of the Bilisphere 360 LED, including cables, no closer than the distance calculated in the equation applicable to the transmitter frequency. **Recommended Separation Distance** D = 1,167$\sqrt{P}$

Immunity Test	IEC 60601 experiment	Compatibility level	Electromagnetic Environment
Propagated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	3 V/m	Portable and mobile RF communications equipment should not be closer to any part of the Bilisphere 360 LED, including cables, than the recommended distance calculated with the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ 80 MHz ilâ 800MHz $d = 2.3\sqrt{P}$ 800 MHz ilâ 2,5 GHz Whereas P is the maximum output power of the transmitter in W according to the transmitter manufacturer, and d is the recommended separation distance in meters. When determined by an electromagnetic site survey, radiated field strengths from fixed RF transmitters[1)] should be less than the compliance level in each frequency range[2)]. The interference can be found at the device site marked with the symbol below. 

[1)] The field strengths broadcasted from fixed transmitters, such as base stations for radio telephones (cellular / cordless) and terrestrial mobile radios, amateur radio AM and FM radio broadcast, and TV broadcast may not be predicted theoretically with accuracy. To evaluate the electromagnetic environment due to RF transmitters, electromagnetic site survey should be considered. If the measured field strength in the location in which the Bilisphere 360 LED is used exceeds the applicable RF compliance level above, the Bilisphere 360 LED should be observed to verify normal operation. If an abnormality is observed in performance, additional measurements such as reorientation or repositioning may be required.

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

8.2.2.3. *Recommended Separation Distance*

Recommended separation distance between portable and mobile RF communications equipment and the Bilisphere 360 LED			
The Bilisphere 360 LED is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Bilisphere 360 LED can prevent electromagnetic interference by maintaining the smallest distance between portable and mobile RF communications equipment (transmitters) and the Bilisphere 360 LED as recommended below according to the maximum output power of the communications equipment.			
Transmitter's highest rated output power (W)	**Distance (m) 150 kHz to 80 MHz** $\mathbf{d = 1.167\sqrt{P}}$	**Distance (m) 80 MHz to 800MHz** $\mathbf{d = 1.2\sqrt{P}}$	**Distance (m) 800 MHz to 2.5 GHz** $\mathbf{d = 2.3\sqrt{P}}$
0.01	0.12 m	0.12 m	0.23 m
0.1	0.37 m	0.38 m	0.73 m
1	1.17 m	1.2 m	2.3 m
10	3.69 m	3.8 m	7.3 m
100	11.67 m	12 m	23 m

8.3. Trademark Registrations

Bilisphere 360 LED™ model is a Novos branded commercial product of Novos Tıbbi Cihazlar Sanayi ve Ticaret İthalat ve İhracat Limited Şirketi.

8.1. Manufacturer

Novos Tıbbi Cihazlar Sanayi ve Ticaret İthalat ve İhracat Limited Şirketi

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