Bililed Maxi+

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. This 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.

Definitions:

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!

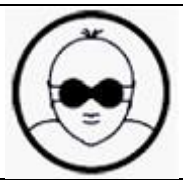
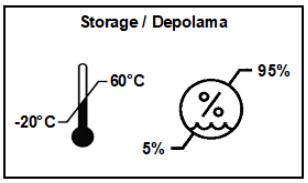
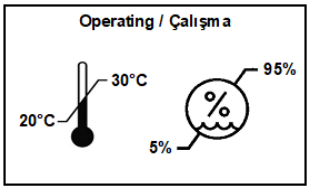
These are the guidance that may damage the system as described in this manual if the attention notes are not followed.

Table of Contents

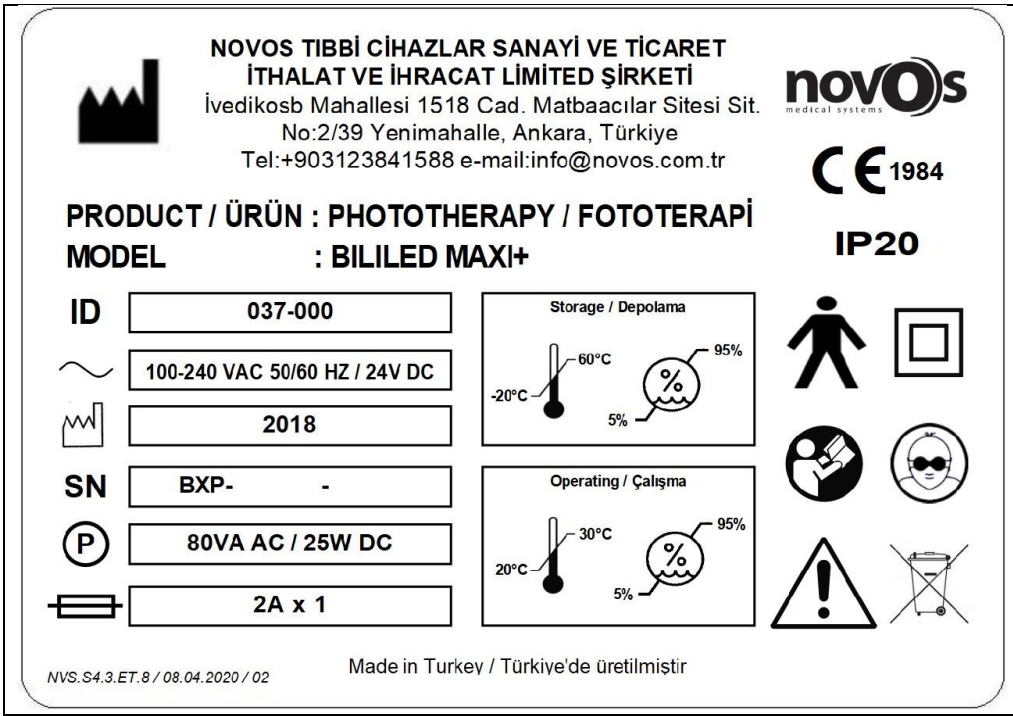
1.Safety Information

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 B 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.
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.
	Power
SN	Serial number

	Fuse Box
CE 1984	CE mark Authorized body
	See User Manual
	Class II Device
	Alternative Current
	Use eye protection band
	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

1.3. 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.

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

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

Warranty applications depend on the following:

1. If any malfunction occurs in the device or its parts, NOVOS or its authorized representative must be notified in writing immediately.
2. Defective devices and parts must be returned to NOVOS or an authorized factory center in accordance with the instructions of NOVOS service personnel.
3. As a result of evaluations, NOVOS or the authorized factory center must confirm that the warranty conditions cover this defect.
4. Written notification of the failure of the device or any part thereof must be received by NOVOS or authorized factory center no later than 2 weeks before the end of the warranty period.
    .

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

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

NOVOS Tıbbi Cihazlar.

2. Product Description

2.1. About This Manual

2.1.1. Scope

This manual contains a detailed description of all sub-components, use and care details of the Bililed Maxi+ phototherapy device.

This guide is a guide to

- Installation
- Usage
- Maintenance

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

2.1.2. 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.

2.2. Applications

2.2.1. Usage Purpose

Bililed Maxi+ 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 according to the patient's condition.

During jaundice treatment, the patient is placed in a heated baby bed or incubator depending on its clinical condition. Bililed Maxi+ is designed for jaundice treatment in hospitals.

2.2.2. Patient Population

Bililed Maxi+ is used in the treatment of babies between 0-28 days postnatal and for preterm babies whose adjusted age is 52 weeks.

2.2.3. Life Cycle

Factors affecting the life cycle are listed below;

- 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 buttons on the device may lose their functionality over time.

Conclusion:

The 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.

2.3. 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 receive phototherapy with Bililed Maxi+, and to guarantee efficient use of the device.

2.3.1. 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 the device, make sure that all checks have been made successfully.

NOTE: If it is determined that any function cannot be performed during the inspections performed, take the device out of service and call the authorized Novos service for repair.

2.3.2. Power Supply

	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.

2.3.3. 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.
- Use only original spare parts and accessories of NOVOS. The use of unauthorized parts may harm patient health and the device.

2.3.4. Cleaning and Maintenance

- All necessary additional measures are mentioned in the cleaning and maintenance unit of this document.

2.3.5. Warnings Regarding Indications, Contraindications, Possible Physiological Effects

2.3.5.1. Indications:

- Hyperbilirubinemia treatment
- Kernicterus prevention
- Patients with light sensitivity disorders (e.g., congenital erythropoietic porphyria)

2.3.5.2. Counter Indications:

- Bronze baby syndrome
- Dehydration
- Hyperthermia
- Temporary skin redness

2.3.5.3. 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 Bililed Maxi+ and a protective path should be worn on the eyes throughout the therapy. In addition, the patient's condition should be checked routinely by
	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 Bililed Maxi+ device, and this area may become brighter. This is due to the intense effect of light on the bilirubin pigment deposited on the skin.

2.3.6. Warnings for the Use of the Device

	**Fixing the Device** During the use of the device, the wheels of the device must be fixed in order for the treatment to continue correctly.
	**Patient Monitoring.** • Do not leave the patient unattended while using the device. • Blue light can prevent observation of the skin discoloration such as cyanosis (bruising)! The patient should be observed very carefully. • Thermotherapy devices (heated cradles, incubators, radiant heaters etc.) can cause the patient's body temperature to reach dangerous limits when used with the Bililed Maxi+. For this reason, the temperature of the baby should be continuously monitored with the help of a stand-alone thermometer throughout the use of the device from distant areas
	Do not cover the phototherapy unit or the device it is used with, with materials such as cloth or towel. This may cause an increase in temperature and / or prevent light emission. This can pose a danger to the patient and device.
	**Accompanied Devices** • All devices to be used with Bililed Maxi+ must comply with the IEC 60601 standard. • Hospital guidelines and medical protocol must be followed when using the Bililed Maxi+ with other devices.

	• Any device or combination of devices that do not comply with the conditions specified in this manual may adversely affect the functionality of the Bililed Maxi+. See the relevant document and the use of attached devices before using the medical device. • All devices and accessories to be used with Bililed Maxi+ are under the responsibility of the operator.
	In order to guarantee the minimum luminous value of 3.5 mW/cm2, the light intensity of the lamp should be measured at regular intervals using a light intensity measurement monitor or similar radiometers.
	The eyes of other babies lying close to the phototherapy device should be protected by taking precautions such as protective glasses and light barrier.
	The device should not be used in environments with substances that support combustion (oxygen, anesthetic agents, etc.). Otherwise, there is a danger of explosion.
	It is recommended that the distance of the Bililed Maxi+ phototherapy device to the baby is approximately 30 cm.

2.3.7. 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 this device. 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.

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

	The device should be used in ideal environmental conditions between 20 °C and 30 °C. Unsuitable ambient temperature, low or high ambient temperature may disrupt the patient's thermal balance.
	It should not be used in front of windows that receive direct sunlight etc.
NOTE:	This is a mobile device that can be operated 24 hours a day.

2.3.9. 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" 200VAC-240VAC and 50 Hz). To maintain ground integrity, connect only to a "hospital grade" plug socket.
	e 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.
	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.

2.3.10. Transportation Restrictions

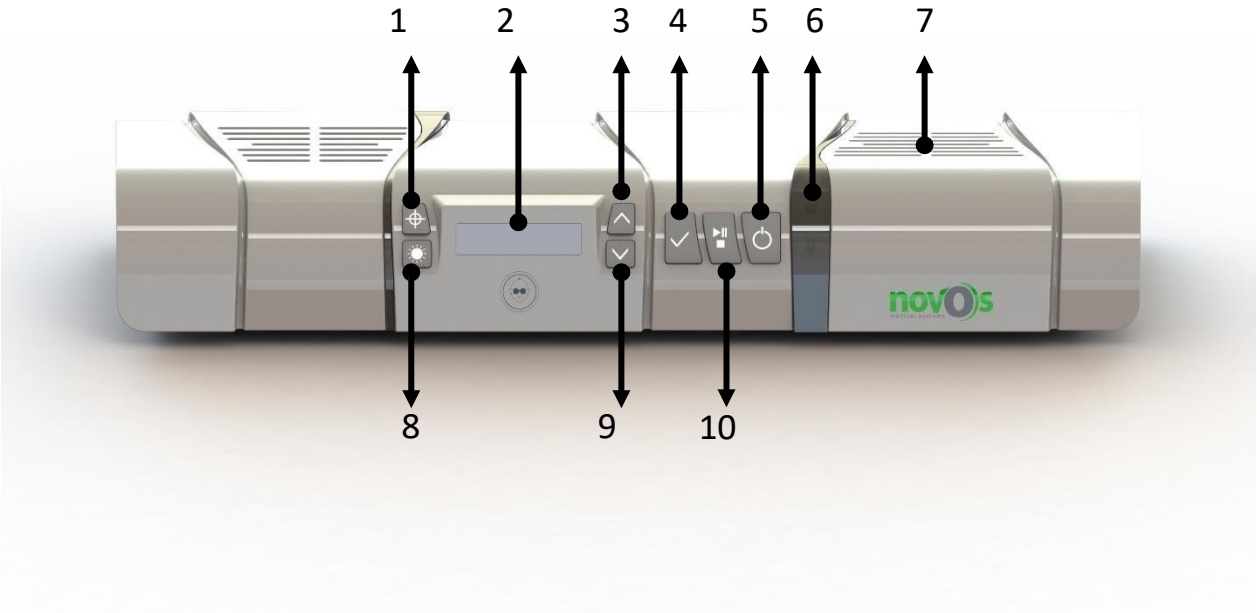
	Be careful when moving the device on its wheels on uneven surfaces, pavement descents/exits, while entering/exiting the elevator, as the wheels may be damaged or dislodged.
	Make sure that the wheels of the device are not locked during transportation.

3.Parts and Controls

3.1. Isometric View

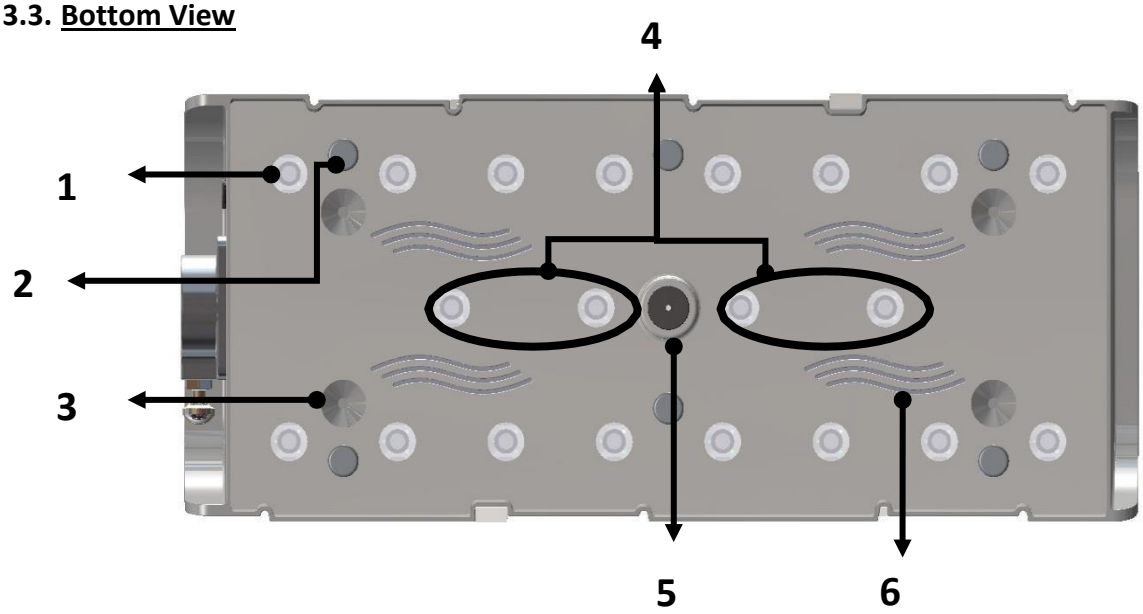
1	Bililed Maxi+ Light Source	4	Trolley
2	Safety Lock	5	Wheels
3	Height Adjustment Screw		

3.2. Front View



1	Focus Button	6	Status Indicator LED
2	2x16 LCD Display	7	Air Ducts
3	Up Arrow Button	8	Examination Lamp Button
4	Confirm Button	9	Down Arrow Button
5	Power Switch	10	Therapy Start / Pause / Stop Button

3.3. Bottom View



1	Blue Phototherapy LED (16 in total)	4	White Phototherapy LED (4 in total)
2	Plastic Screw Head	5	Focusing LED
3	Ventouse	6	Air Ducts

4. Preparation

4.1. Unpacking and Installation

Bililed Maxi+ and transport trolley thereof are included in one package. This package contains:

- Bililed Maxi+ Light Source
- Power Adapter (24V, 1.1A)
- Trolley
- Eye protection masks in 3 different sizes.

After you receive the package, complete the installation by following the steps below.

<table>
<tr><td colspan="2">• Unpack and set the trolley parts aside.</td></tr>
<tr><td rowspan="2">• Fix the trolley's right and left feet to the baseplate.</td><td>  </td></tr>
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<tr><td colspan="2">

- Unpack the Bililed Maxi+ light source.

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<tr><td rowspan="2">

- After locking the wheels of the trolley, secure the light source to the trolley (you will hear a locking sound when the light source is fixed to the mounting kit) and make sure the device is locked into the trolley.

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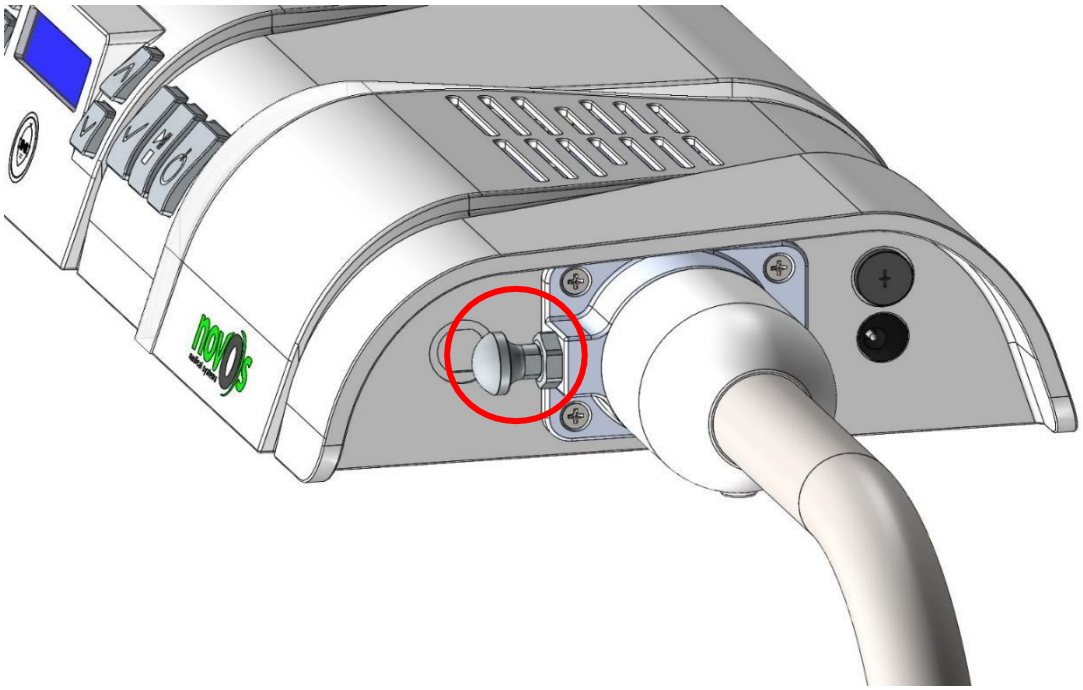
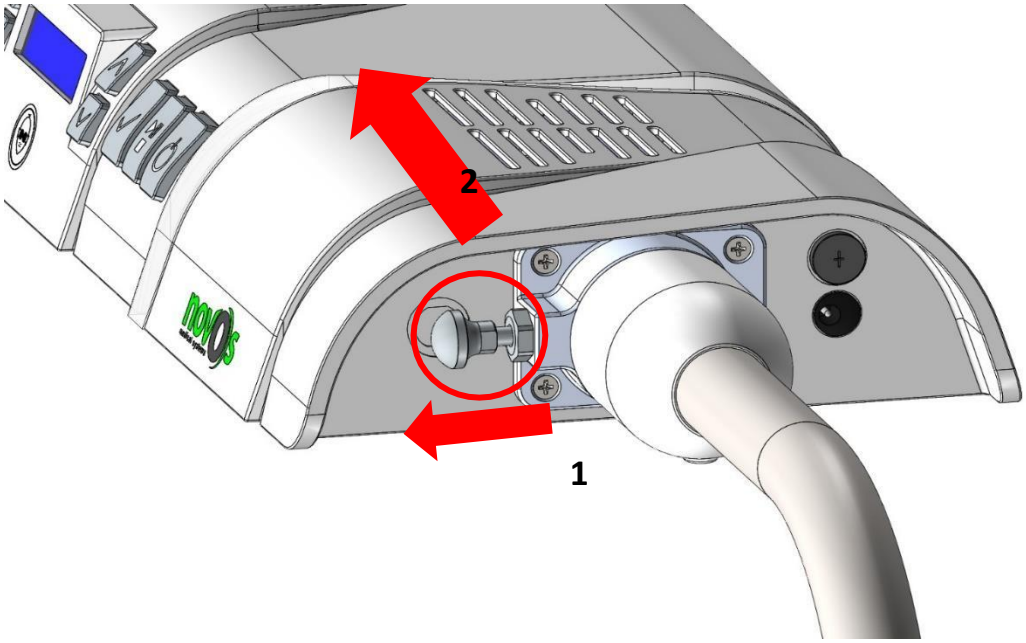
While the light source is attached to the trolley, the position of the safety lock is as shown in the figure below.



To detach the light source from the trolley, pull the safety lock towards you and then simultaneously pull the device out.



4.2. Electronic Operation Control

Please apply the Electronic Operation Check after installation and notify the NOVOS Technical Service Department when you find that any of the following steps could not be implemented successfully.

Before start:

- Make sure the power adapter is connected to the device and to a suitable outlet.

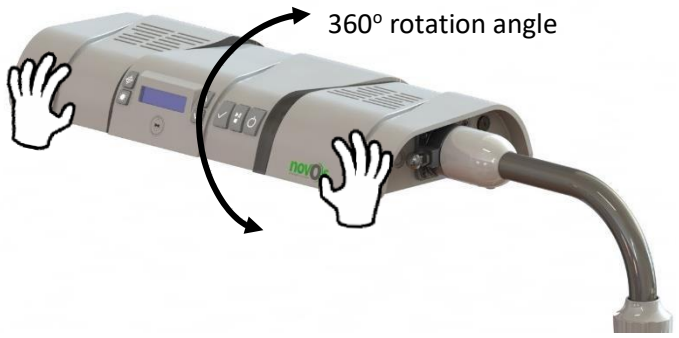
The following steps should be followed to verify the electronic operation of the Bililed Maxi+™.

1. Observe if the Status Indicator LED is flashing red.
2. Press the ***"Power"*** switch located on the right side of the device.
3. Wait for the device to boot until the home screen appears.
4. Observe if the Status Indicator LED is flashing green.
5. Switch between the therapy light intensity levels with the "***Down***" and "***Up***" arrow buttons.
6. Press the "***Focus***" button and observe that the red focus LED lights up.
7. Enter the menu by pressing the "***Confirm***" button.
8. Go to "***Therapy Time***" option by pressing the "***Down***" arrow button once.
9. Enter the "***Therapy Time Setting***" mode by pressing the "***Confirm***" button.
10. Set the target therapy hour digit using the "***Up***" and "***Down***" arrow buttons.
11. Press the "***Confirm***" button.
12. Set the target therapy minute digit using the "***Up***" and "***Down***" arrow buttons.
13. Set the target therapy time by pressing the "***Confirm***" button.
14. Go to "***Lamp Intensity***" option by pressing the "***Down***" arrow button once.
15. Enter the "***Lamp Intensity Setting***" mode by pressing the "***Confirm***" button.
16. Activate the examination lamp by pressing the "***Examination Lamp***" button.
17. Adjust the examination lamp brightness using the "***Up***" and "***Down***" arrow buttons.
18. Save the set inspection lamp intensity by pressing the "***Confirm***" button.
19. Go to "***Exit***" option by pressing the "***Down***" arrow button once.
20. Return to the main screen by pressing the "***Confirm***" button.
21. Start therapy by pressing the "***Therapy Start/Pause/Stop***" button.
22. Observe if the Status Indicator LED is flashing blue.
23. Wait for a minute and confirm that the countdown timer is working properly.
24. Pause therapy by pressing the "***Therapy Start/Pause/Stop***" button.
25. Observe if the Status Indicator LED is flashing green.
26. Resume therapy by pressing the "***Therapy Start/Pause/Stop***" button again.
27. Observe if the Status Indicator LED is flashing blue.
28. Stop therapy by holding down the "***Therapy Start/Pause/Stop***".
29. Observe if the Status Indicator LED is flashing green.

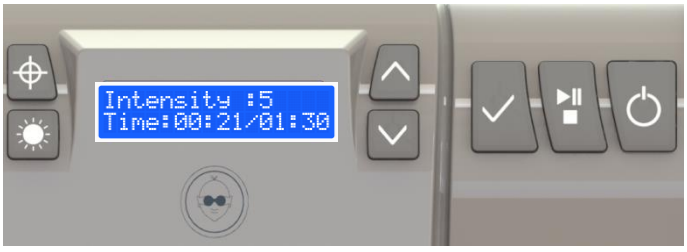
5. Use of Device

5.1. Positioning

Bililed Maxi+ can be rotated around the vertical and horizontal axis.

• After inserting the light source into the holder and making sure it is locked, you can position it by rotating it around the horizontal axis. • Once positioned, the device will stay in this position until you change it.	
• Loosen the height adjustment screw while holding the horizontal profile tube of the carrier. • Adjust the angle the device makes with the vertical plane. • Adjust the height of the device. • After the adjustments are complete, tighten the height adjustment screw.	
• Activate the trolley's brake by pressing the outer edge of the brake pedals.	

5.2. Starting Bililed Maxi+

• Connect the power adapter (24V, 1.1A) to the wall socket and device. • Turn on the device by pressing the "***Power***" button.	
• Flashing green LEDs indicate that the device has started.	
• During booting, the device model, software version, and immediately after, the total therapy time (LED Working Time) is displayed.	 
• When the boot is completed, the main screen will appear.	

5.3. Starting Therapy

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

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

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

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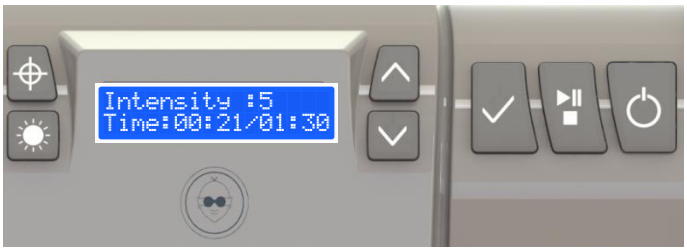
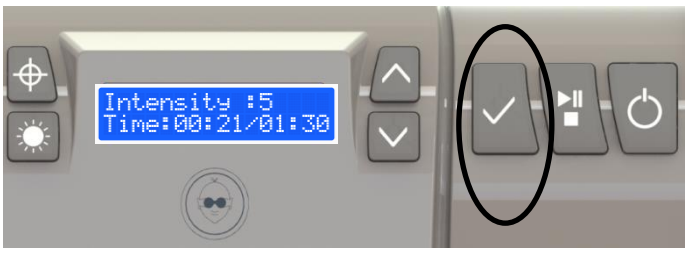
<tr><td> 
</td></tr>
<tr><td>

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

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

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

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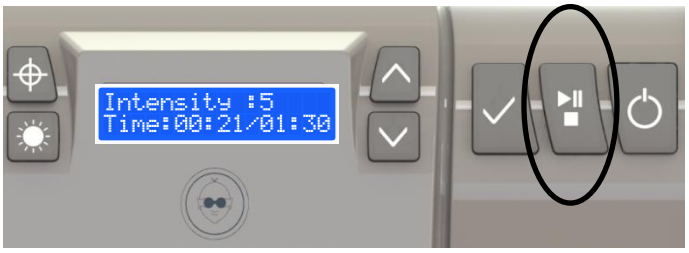
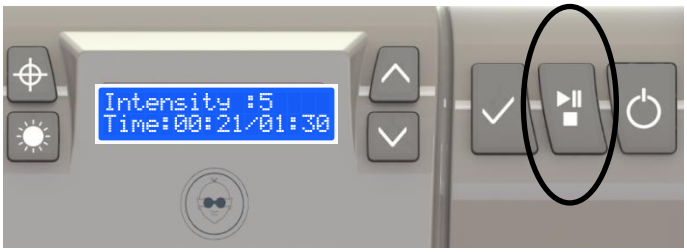
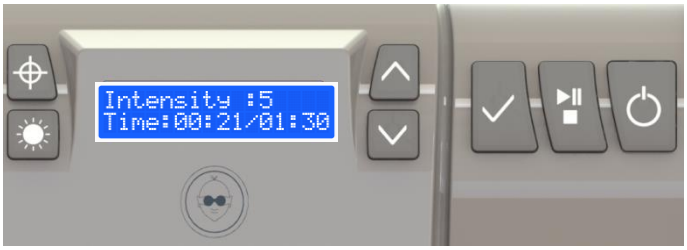
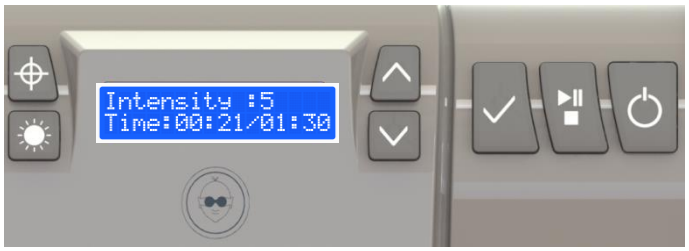
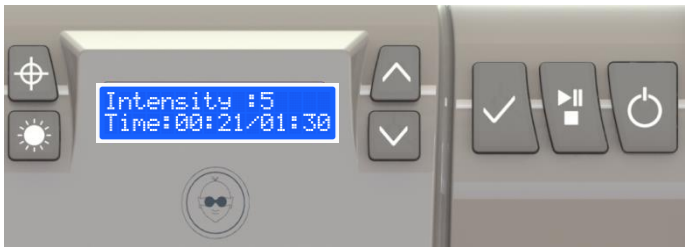
<tr><td>

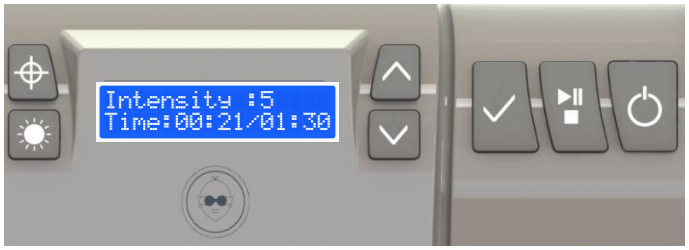
- Enter the "***Therapy Time Setting***" mode by pressing the "***Confirm***" button.

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

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

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

• Stop therapy by holding down the "***Therapy Start/Pause/Stop***" for 3 seconds.	
• A long beep will be heard. • Blue phototherapy LED and status LED will turn green. • The therapy started icon in the upper right corner of the screen will disappear. • The therapy time counter reverts to the target therapy time.	
• As a safety precaution, when the temperature inside the device is higher than 60 °C, the therapy is paused and the "High temperature inside the device" warning is displayed on the screen and a warning sound is heard. When the temperature inside the device falls below 60 °C, the therapy continues from where it left off.	
To manually see the temperature inside the device, press and hold the confirmation button for 3 seconds while the device is turned off and the status indicator LED is red. • The internal temperature of the device will be displayed on the screen.	

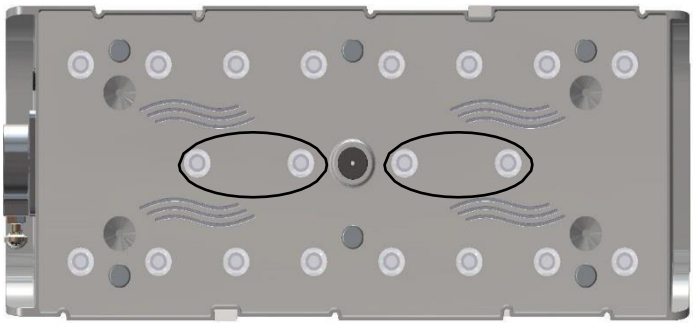
To return to the therapy screen • Press the confirmation button 3 times, waiting for transition times between menus. • Finally, the therapy screen will be displayed.	

⚠	If the temperature inside the device exceeds 60 °C, it means that the ambient temperature is high. Make sure the ambient temperature is within 20 °C-30 °C.
⚠	When the temperature inside the device drops below 60 °C, the therapy continues from where it left off, however, if the ambient temperature is not low enough, the "high temperature inside the device!" warning can be seen again. Pay attention to the ambient temperature for the efficient operation of the device.

5.4. End of Therapy

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

5.5. Use of Examination Lamps

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

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- There are 5 different levels for the examination lamp’s light intensity.
- Adjust the light intensity of the white therapy LEDs using the "***Up and Down***" arrow buttons.

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

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

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

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5.6. Alarms and Warnings

Alarm settings can only be changed by authorized personnel!

Alarm Message	Alarm Priority	Description
High temperature inside the device	High Priority	If the temperature inside the device exceeds 60 °C, it means that the ambient temperature is high. The therapy will be terminated. When the temperature inside the device drops below 60 °C, the therapy continues from where it left off, however, if the ambient temperature is not low enough, the "high temperature inside the device!" warning can be seen again.
LED life expired.	High Priority	LED will not work. Therapy will be terminated. LEDs need to be replaced.
Therapy-End Warning	Medium Priority	Indicates that the therapy ended.

6.Routine Cleaning and Maintenance

6.1. General Cleaning

Bililed Maxi+ should be cleaned at the intervals specified in the hospital protocol.

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

- Remove visible dirt with a disposable cloth and detergent.
- Disinfect surfaces of the device by wiping.
- After the antiseptic spray has been sprayed, wait for the time specified on the spray label for the effect.
- Wipe the surfaces with a clean, damp, disposable cloth, then dry (dry all surfaces with a dry cloth).

	Avoid humidity (disinfectant and liquid detergent) from entering into the light source.
	Do not disinfect any part of the device by immersing in liquid.
	The LED Module should only be wiped with a soft damp cloth.
	Do not touch the lens with your fingers. Dirt, body oil, perfume or such ingredients on the finger can damage the optical properties.
	Do not use caustic, corrosive substances or disinfectants containing sodium hypochloride or alcohol. Such disinfectants can damage the phototherapy unit.
	NOVOS recommends the use of Ammonia Quaternary components that do not have any harmful effects on the materials used in the device, that clean the surfaces and fight bacteria.

6.2. Maintenance

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

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

	Technical service and maintenance services should only be provided by technically qualified persons.
	To avoid the risk of electric shock, unplug the power adapter of the device before maintenance and repair.
	For better performance and device safety, use only original NOVOS spare parts.

6.2.1. Light Intensity Control

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

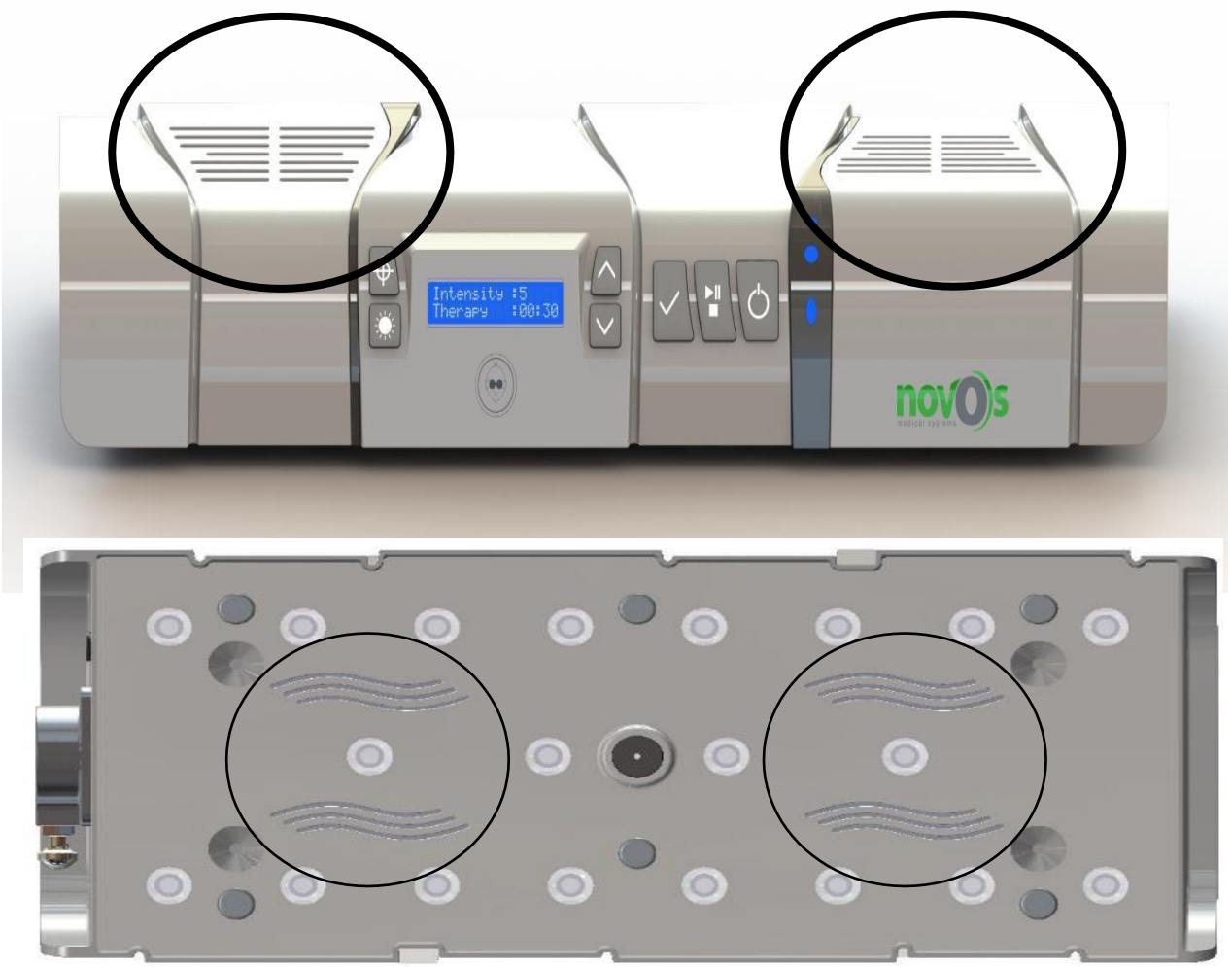
6.2.2. LED Module Replacement

In order to maintain phototherapy efficiency, the Bililed Maxi+ LED module must be replaced when the working hour (total therapy time) reaches 49,800 hours. When replacing the LEDs, all of them must be replaced at the same time. It is important that the radiation of all LEDs be homogeneous and equal in order to spread the treatment more effectively and homogeneously throughout the body.

Please contact NOVOS Technical Service Department for LED Module replacement.

6.2.3. Cleaning of Air Channels

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



7.Troubleshooting

7.1. Fast Troubleshooting Guide

Failure Case	Cause	Solution Recommendation
Device does not start up.	Power supply failure.	Connect the power adapter to a suitable outlet.
	Defective fuse.	Contact an authorized NOVOS Technical Service.
	Internal electrical problem.	
"Power Failure" message received during the boot.	Incorrect power adapter connection.	Connect the original Bililed Maxi+ power adapter. (24V, 1.1A)
	Internal electrical problem.	Contact an authorized NOVOS Technical Service.
Display does not work.	Internal electrical problem.	Contact an authorized NOVOS Technical Service.

8. Annexes

8.1. Technical Specifications

8.1.1. Mechanical Properties

Protection against water and solid objects	IP20
Height	82 mm – (with Transport Trolley: 1106 mm)
Width	528.5 mm – (with Transport Trolley: 1064 mm)
Depth	224 mm – (with Transport Trolley: 504 mm)
Trolley Height	1008 mm- 1721 mm
Trolley Wheels	Total 4 wheels, of which 2 are with brakes (Ø50)
Weight (Light Source)	2,07 kg
Transport Trolley Weight	15 kg

8.1.2. Electrical Properties

Supply Voltage and Current	100V-240V AC, 0.65 A AC
Supply Adapter Output	24V DC, 1.1A DC
Sections Applied	Type B, Class 2
Fuses	2A x 1
Supply Frequency	50Hz-60Hz
Maximum Power Consumption	80VA AC/ 25W DC
Noise Level	<50dbA

8.1.3. Environmental Conditions

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

8.1.4. Radiation Properties

Number of LEDs	16 Blue LEDs
Spectral Radiation - Level 5	>70µW/cm^2/nm
Dominant Wavelength Range	440nm-460nm
LED Life Cycle	50,000 hours
Effective Therapy Area	54 cm x 32 cm

8.1.5. Miscellaneous Properties

Software Version	V3.2
LED Module Runtime Reset	Yes
Focusing LED	Yes
Inspection LEDs	4 white LEDs
Inspection Lamp Light Intensity Level	5
Phototherapy Lamp Light Intensity Level	5
Trolley	Yes (Height Adjustable)
Screen Type	Monochrome LCD
Screen Dimensions	2x16 LCD

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	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 requirements
TSE	17-12-2013	TS EN ISO 14971 / Medical devices - Application of risk management to medical devices
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	6/5/2012	TS EN 60601-2-50 / Electrical medical equipment-Part 2-50 Specific features for basic safety and essential performance of infant phototherapy equipment
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 of Electromagnetic Compatibility

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

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

Bililed Maxi+ is designed for use in below conditions and environments.

8.2.2.1. Electromagnetic Environment

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

Emission experiments	**Compatibility**	**Electromagnetic Environment**
RF Emissions CISPR 11	Group 1	Bililed Maxi+ 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	Bililed Maxi+ 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	

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.

8.2.2.2. Electromagnetic Immunity

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

Immunity Test	IEC 60601 experiment	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 Bililed Maxi+ 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 level	Compatibility level	Electromagnetic Environment
Conveyed RF IEC 61000-4-6	3Vrms outside ISM, 6Vmrs inside 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 Bililed Maxi+ is used exceeds the applicable RF compliance level above, the Bililed Maxi+ should be observed to verify normal operation. If abnormal performance is observed, additional measures may be required, such as reorienting or relocating the Bililed Maxi+.

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 highest rated output power (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80 MHz $\mathbf{d = 1.\overline{2}\sqrt{P}}$	**80 MHz to 800 MHz** $\mathbf{d = 1.\overline{2}\sqrt{P}}$	**800 MHz to 2.5 GHz** $\mathbf{d = 2.\overline{3}\sqrt{P}}$
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

Bililed Maxi+™ 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

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