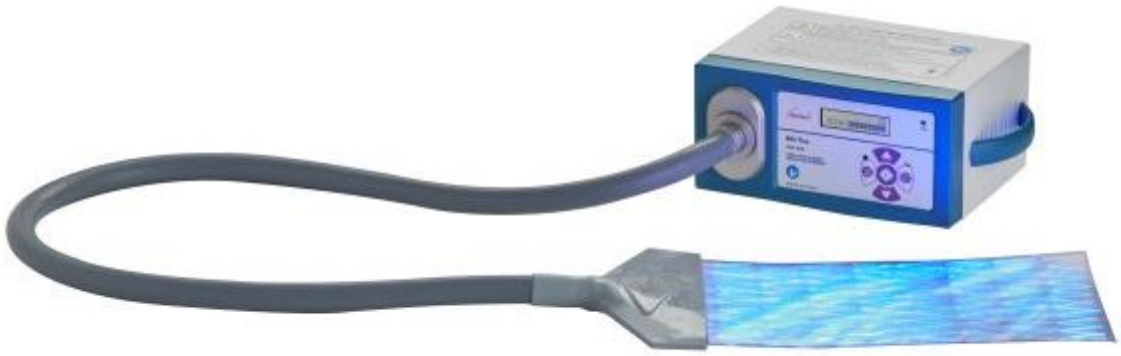
nice Neötech Medical Systems Pvt. Ltd.

nice 4060

Fibre Optic Blanket Infant Phototherapy



OPERATING/INSTALLATION MANUAL

This operating manual provides all the information necessary for the user to safely set up and operate this equipment. It is the responsibility of the user to follow the instructions and recommendations provided.

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Rev.00

Dt. 28/07/2021

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nice Neötech Medical Systems Pvt. Ltd.

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User Responsibility / Operator Profile

This product will perform in conformity with the description thereof contained in this operating manual and accompanying labels and/or inserts, assembled, operated, maintained and repaired in accordance with the instructions provided. Operator is positioned about 50cm approx. from the front panel of the device. The device should be placed leaving space up to 1m from the wall to access the device backside easily. This Product must be checked periodically. A defective Product should not be used. Parts that are broken, missing, plainly worn, distorted or contaminated should be replaced immediately. When such repair or replacement become necessary, nice Neötech recommends a telephone or written request for service advice to the nearest dealer.

This Product or any of its parts should not be repaired other than in accordance with written instructions provided by nice Neötech and by nice Neötech trained personnel. The user of this Product shall have the sole responsibility for any malfunction which results from improper use, improper faulty maintenance, repair, damage, or alteration by anyone other than nice Neötech.

Before using the device, read this entire manual. Attempting to use this device without a thorough understanding of its operation may result in patient or user injury. This device should only be operated by personnel trained in its operation and under the direction of qualified medical personnel familiar with the benefits and risks of this type of device.

Declaration for Languages

User Manual and label will be provided in the appropriate language to ensure that the user understands. Language validation will be done for the language of the user manual, Label and corresponding documents when nice Neötech Medical Systems Private Limited supplies to EU countries

Model Description

The Fibre Optic Blanket Infant Phototherapy uses blue light emitting diodes (LEDs) to convert bilirubin and helps to excrete them as waste, thus reducing the bilirubin level in the blood. The control system uses a microcontroller. The Illuminator device sends light through a fibre optic cable to the entire area of the panel. The panel is inserted into a protective cover. The wrap which is soft and comfortable allows the therapeutic light to be emitted towards the baby. With the use of the Fibre Optic Blanket Infant Phototherapy, the baby can be held and fed and enjoy the healing comfort of parents while treatment is administered. Additionally, when the Fibre Optic Blanket Infant Phototherapy is properly used with the fibre optic panel, the baby's eyes need not be protected as with conventional phototherapy.

Definitions

Timer: Displays the total usage hours.

Brightness: Intensity of the LED Light

Fan Fail: Error message for Cooling fan fail.

Sensor Fail: Error message for Temperature sensor fail.

Temperature: Displays temperature of the light source.

Definition of Warning indication

Three levels of Warning indication are used throughout this manual and on the unit. They are defined as follows,

A **DANGER** notice indicates an immediately hazardous situation which, if not avoided, will result in death or serious injury, serious damage to property such as total loss of equipment, and a fire.

A **WARNING** notice indicates an indirectly (Potentially) hazardous situation which if not avoided, will result in death or Serious injury, serious damage to property such as total loss of equipment, and a fire.

A **CAUTION** notice indicates a hazardous situation which, if not avoided can result in minor or moderate injury, partial damage to property and loss of data stored in computers.

Section A: Warnings

Warning: Before using the nice Neötech Fibre Optic Blanket Infant Phototherapy, read this entire manual. Attempting to use this device without a thorough understanding of its operation may result in patient or user injury. This device should only be operated by personnel trained in its operation and under the direction of qualified medical personnel familiar with the risks and benefits of this type of device.

Warning: Fibre optic Blanket Infant Phototherapy is intended for use by a qualified practitioner under the direction of qualified physician. Personnel operating the Fibre optic Blanket Infant Phototherapy must become thoroughly familiar with the instruction manual prior to using the baby Fibre Optic Blanket Infant Phototherapy with the patients.

Warning: Only facility-authorized personnel should troubleshoot the Model nice 4060 - Fibre Optic Blanket Infant Phototherapy. Troubleshooting by unauthorized personnel could result in Personal injury or equipment damage.

Warning: Do not use the Fibre Optic Blanket Infant Phototherapy if it fails to function as described. Personal injury or equipment damage could occur.

Warning: If therapy is interrupted for any reason, resume therapy as soon as possible and contact nice Neötech Medical Systems Pvt. Ltd.

Warning: Carefully place the panel cable to avoid entanglement.

Warning: To prevent personal injury, particular care must be taken to ensure that the additional equipment connected to the baby is electrically safe.

Warning: Follow the product manufacturer's instructions. Failure to do so could result in personal injury or equipment damage.

Warning: Position the Illuminator device on a stable surface, preferably lower than the infant.

Warning: Do not place the illuminator device, power supply in a Fibre Optic Blanket Infant Phototherapy or Infant Radiant Warmer.

Warning: Do not place a temperature sensor of the infant warmer under the fibre optic panel.

Warning: Do not obstruct the air vent slot; it may cause overheating the equipment.

Warning: Only facility-authorized personnel should perform preventive maintenance on the Model nice 4060 - Fibre Optic Blanket Infant Phototherapy. Preventive maintenance performed by unauthorized personnel could result in personal injury or equipment damage.

Warning: During phototherapy, the baby's water balance may become disturbed. Before and during phototherapy, make sure the baby is properly hydrated and that his or her body temperature is maintained.

Warning: After treatment has begun, the baby's bilirubin level should be measured to make sure therapy is effective.

Warning: The fibre optic panel must not be covered by anything except with the cover provided. Any other type of cover will cause a reduction in light intensity. The setup instructions must be followed exactly.

Warning: There is a possibility of electromagnetic interference or other interference causes from other external equipment, the Fibre Optic Blanket Infant Phototherapy may get in operation. Use EMC compliance Equipment to avoid the interference.

Warning: Don't misalign the EMI shielding and the beads as it may cause the EMI interference to the equipment.

Warning: The Fibre Optic Blanket Infant Phototherapy may cause radio interference: in this case adequate measurement may be required to prevent interference.

Warning: nice 4060 - Fibre Optic Blanket Infant Phototherapy compliance with EN/IEC 60601-1-2, 2014, the use of accessories, sensors and cables other than specified may result in increased emission/or create invalid output.

Shock Hazard: Ensure that the building power source is compatible with the electrical specifications shown on the right side of the Fibre Optic Blanket Infant Phototherapy and the variable height adjustable pedestal stand. For proper grounding reliability, connect the power cord only to a properly marked, three-wire, hospital-grade or hospital-use receptacle. Do not use extension cords.

Shock Hazard: Unplug the power cord from the controller assembly. Failure to do so could result in Personal injury or equipment damage.

Shock Hazard: Do not expose the unit to extensive moisture. Personal injury or equipment damage may occur.

Section B: Cautions

Caution: Do not use harsh cleansers, such as scouring pads or heavy-duty grease removers or solvents, such as acetone. Equipment damage could occur.

Caution: Some chemical cleaning agents may be conductive and/or leave a residue that may enable a built-up of conductive dust or dirt. Do not permit cleaning agents to contact electrical components. Do not spray cleaning solutions onto any of these surfaces. Equipment damage could occur.

Caution: Do not use silicone-based lubricants. Equipment damage could occur.

Caution: Keep the unit away from any heated surface

Caution: do not place sharp or heavy items on the panel, this can damage the panel and affect its light output.

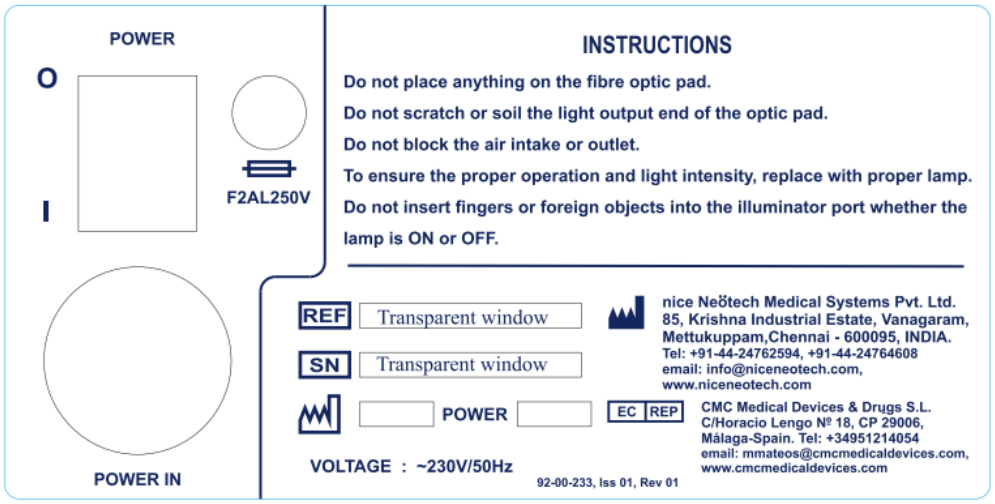
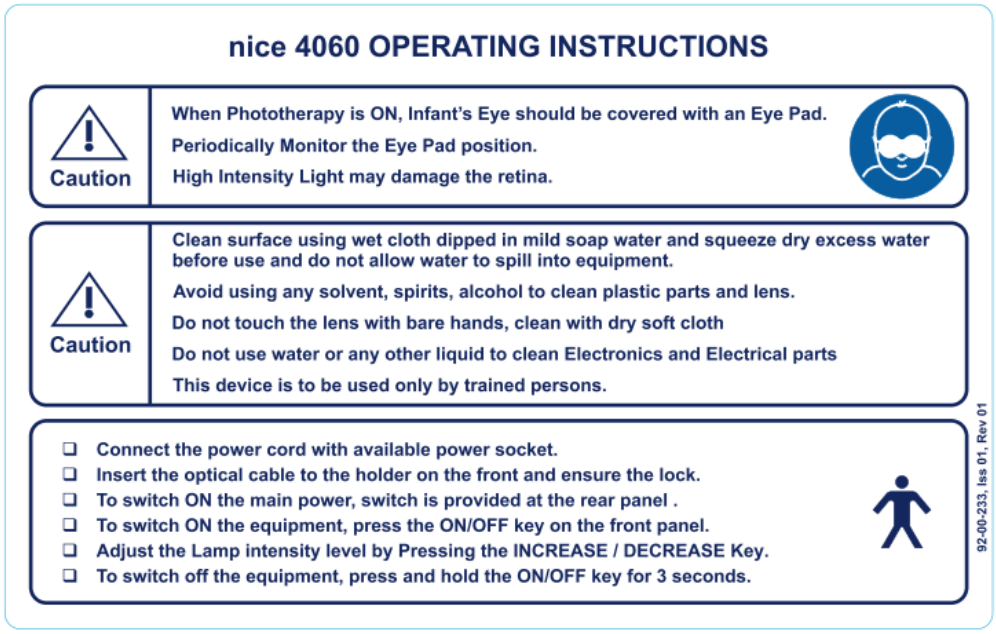
Caution: Use of nonstandard components: Consult the manufacturers for repair and replacements of components. Use of incorrect component can adversely affect safety, performance and/or damage the equipment performance.

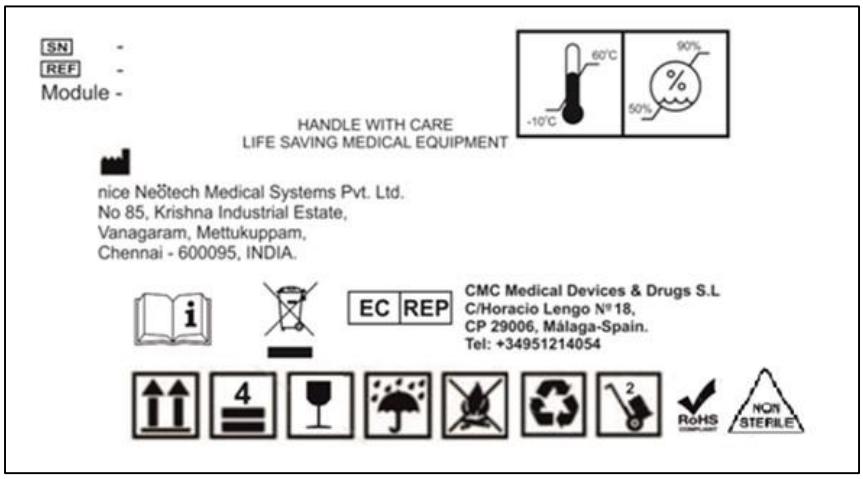
Section C: Symbols & Labels

Mark	Indication
	Warning
	Caution
	Alternating current
	Off (Power: disconnection from main)
	On (Power: connection to the main)
	Protective Earth (Ground)
	Type BF Equipment
	Refer Instruction for use
	Serial number
	Authorized Representative in the European community
	Date of Manufacture
	Manufacturer
	Model number
	Increase key
	Decrease key

	Audio paused key
	ON/OFF key

Labels

Label	Description
	Label, Front Panel
	Label, Switch, Information and Reference & Serial no.
	Label, Information

	Packing Label

Section 1: Description

1.1 Intended Use

The model nice 4060 Fibre Optic Blanket Infant Phototherapy is a device with a LED fibre optic light source intended to treat hyperbilirubinemia.

1.2 Indication

Fibre Optic Blanket Infant Phototherapy is used for Pre-mature babies in the treatment of neonatal hyperbilirubinemia.

1.3 Contraindication

Congenital erythropoietic porphyria, or a family history of porphyria.

1.4 Side Effects

Phototherapy may affect insensible water loss.

1.5 Target Population

Premature and Neonates.

1.6 Working Principle

Fibre optic phototherapy has a place in the management of neonatal hyperbilirubinemia. It is probably a safe alternative to conventional phototherapy in term infants with physiological jaundice. Blanket phototherapy represents advanced technology in phototherapy treatment given either in the hospital or at home. A Bili blanket is a phototherapy home treatment that consists of a portable illuminator and fibre optic pad. This therapy lowers the serum bilirubin level in the blood. A pad of woven fibre is used to transport light from a light source to the baby. The fibre optic cable is used to transfer the light from LED light to the end of the blanket. The Bili blanket releases waves of blue light, when these are absorbed in the skin, bilirubin breaks down and is eliminated from the baby's blood stream. The Blanket system can be used 24 hours a day to provide continuous treatment if prescribed by your physician or healthcare professional.

1.7 Product Description

nice 4060 Fibre Optic Blanket Infant Phototherapy uses blue light emitting diodes (LEDs) to convert bilirubin to waste products that are mostly excreted through urine and stool, thus reducing the bilirubin level in the blood.

nice 4060 Fibre Optic Blanket Infant Phototherapy provides a manual controlled source of light. The control system uses a microcontroller. The brightness level can be adjusted by the select key. The fibre optic cable is used to transfer the light from LED Light to the end of the blanket.

The Illuminator device sends light through a fibre optic cable to the entire area of the panel. The panel is inserted into a protective cover. This wrap is soft and comfortable which allows the therapeutic light to be emitted towards the baby. When the fibre optic cable is detached from the device, the Blue LED goes OFF automatically. Additionally, when the Fibre Optic Blanket Infant Phototherapy system is properly used with the fibre optic panel the baby's eyes need not to be protected as with conventional phototherapy.

1.8 Control Unit

The control unit contains the electronic circuits and controls used to operate the Fibre Optic Blanket Infant Phototherapy. The control unit performs regular self-checks during its operation including failure diagnostics. The control system is used to vary the light intensity 10% to 100% by 10 increments.

Section 2: Installation

2.1 Setup

After removal from the shipping containers, inspect the nice Neötech Fibre Optic Blanket Infant Phototherapy and all accessory items for any signs of damage which may have occurred during shipment. File a damage claim with the shipping carrier if damage has occurred. Also confirm the presence of all accessory items or factory installed options as listed on the packing slip.

2.2 Installation of Fibre Optic Blanket Infant Phototherapy

1. Place the Illuminator device on a hard, flat surface.

2. Insert the metal end of the light panel cable called the ferrule, into the opening end of the unit. Push the ferrule in and rotate to lock in. The light will not turn ON if the cable is not inserted in the illuminator device.

3. Connect the power cord end to the rear side of the appliance coupler.

4. Plug the Illuminator device into an electrical outlet. The power button will flash.

5. Press the Therapy ON/OFF button to turn the Illuminator device on and begin phototherapy.

6. To turn OFF the device when therapy is complete, press and hold the Therapy ON/OFF button for 3 seconds.

- Do not block any of the air vents on the Illuminator device.

2.3 Pre-use Checkout Procedures

2.3.1 Mechanical Checkout Procedures

- Before using the nice Neötech Fibre Optic Blanket Infant Phototherapy, read this entire manual. Attempting to use this device without a thorough Understanding of its operation may result in patient or user injury.

- Do not perform the Checkout Procedures (Mechanical and Control Unit) with patients.

- Read the “Checkout Procedures” section of this manual before putting the unit into operation. If the Fibre Optic Blanket Infant Phototherapy fails any portion of the checkout procedures it must be removed from use and repaired.

2.3.1.1 Overall Appearance

Disconnect the power cord from the AC power source for the mechanical checks portion of this procedure. Check the overall appearance of the Device. There should be no obvious damage.

2.3.1.2 Fibre Optic Cable Lock

Picture 1

- The fibre optic cable is inserted in the slot given in the device which is locked in by cable lock mechanism.
- The LED light will not turn ON if the fibre optic cable is not properly inserted in the fibre optic blanket phototherapy device.
- Check the locking function of the cable holder by applying nominal force to pull the cable, cable should not come out.
- To release the lock, push the ferrule inwards and check if the LED light turns OFF immediately after the fibre optic cable is released from the device.

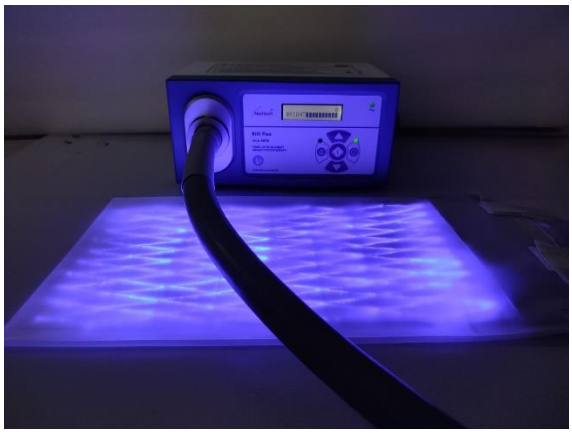
- Regularly inspect the fibre optical cable locking mechanism which fails the fibre optic cable will be come out.

2.3.1.3 Setup – Wrap – Around Blanket

The fibre optic panel must not be covered by anything except with the cover provided. Any other type of cover could cause a reduction in light intensity. The setup instructions must be followed exactly:

Picture 2

- This fibre optic pad provides full coverage around the baby's torso.
- Place a disposable cover onto the fibre optic pad with the light emitting side of the fibre optic pad facing the sheer side of the cover.
- Place the covered fibre optic pad under the baby's torso, positioning it, so it is under the baby's armpits.
- Wrap the fibre optic pad around the baby. Use the tape or hook and loop tabs to secure the fibre optic pad around the baby.
- The disposable cover is recommended for one time use for the infants, after the treatment gets over the cover should be disposed safely.



Picture 3

- The light intensity adjustment made on the device is transferred to the pad and the light is distributed evenly to the patient through unique diamond shaped fibre optic pad.

Picture 4

- The Blue LED cuts OFF as the fibre optic cable is detached.

2.3.2 Control Unit Checkout Procedure

Warning

- Do not perform the Checkout Procedures (Mechanical and Control Unit) while a patient occupies the Fibre Optic Blanket Infant Phototherapy.
- Read the “Checkout Procedures” section of this manual before putting the unit into operation. If the Fibre Optic Blanket Infant Phototherapy fails any portion of the checkout procedures it must be removed from use and repaired.

2.3.2.1 Control Unit Check

1. Connect the Fibre Optic Blanket Infant Phototherapy power cord to a proper grounded power source. Refer to the rating label on the Fibre Optic Blanket Infant Phototherapy for the proper voltage needed. Switch ON the power and verify the following on the Control Panel.

2. When the power is switched ON the controller performs self-test functions.

3. The LCD display shows the % of Light intensity by denoting the bar.

4. Adjust the light intensity with increase or decrease key.

2.3.2.2 ON/OFF Key functional check

1. Press ON/OFF key once to turn ON the equipment.
2. Press & Hold the ON/OFF key for 3 second and the equipment will turn OFF.

2.3.2.3 Select Key functional check

1. Increase key will increase the value; the decrease key will decrease the value.
2. The keys are used to adjust the intensity level of the light source.

Section 3: Operation

3.1 Control Panel Operation

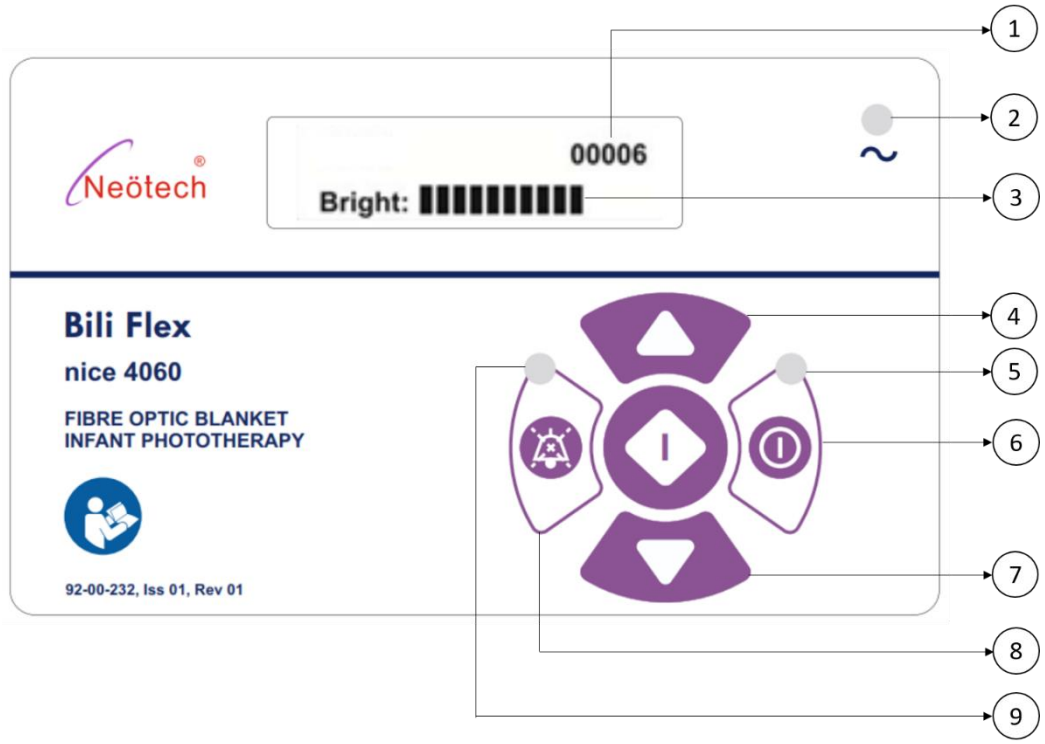


Figure 1

nice 4060 control panel

1	Total usage hours	6	ON/OFF key
2	AC IN indication	7	Decrease key
3	Intensity Level	8	Audio paused key
4	Increase key	9	Audio paused indicator
5	Power ON Indication		

3.1.1 Displays

- **Total Usage Hours:** The display indicates the total lamp usage hour.
- **AC IN Indicator:** The AC IN indicator lights when AC voltage is available.
- **Intensity Level:** The display indicates the intensity level of LED Light.
- **Power ON Indicator:** The Power ON LED indicator is lit when the equipment is ON.
- **Audio paused indicator:** The Audio paused LED indicator is lit when the equipment is ON.

3.1.2 Keys

- **ON/OFF Key:** This key is used to turn ON/OFF the equipment.
- **Increase Key:** The increase key is used to increase the intensity of the light.
- **Decrease Key:** The decrease key is used to decrease the intensity of the light.
- **Audio paused key:** The audio paused key is used to silent the indications.

3.1.3 Audio and Visual Indications

- **Fan failure indication:** This indication occurs when the fan stops working.
- **Sensor failure indication:** This indication occurs when temperature sensor gets open or short.
- **Over Temperature indication:** This indication occurs when the LED Light source heat sink gets over heated above 80°C.

3.1.4 Increase/Decrease the % of Intensity

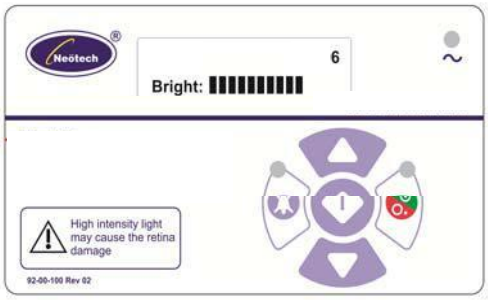


Figure 2

- To Increase the Intensity from 0-100%, press the increase key in increments of 10.
- To decrease the Intensity from 100-0% press decrease key in increments of 10.

Section 4: Cleaning & Maintenance

4.1 General

- ❑ Always switch off the equipment while cleaning.
- ❑ This Section Provides Cleaning and Maintenance Instructions. Where necessary, disassembly instructions are provided.
- ❑ Routinely inspect patient compartment for signs of breakage and replace assemblies before placing Fibre Optic Blanket Infant Phototherapy into service.

- Periodically check the insulation and the connection of the cable it may cause fire because of poor insulation and short circuits due to aging.
- Make sure the Fibre Optic Blanket Infant Phototherapy is disconnected from the power cord when performing cleaning and Maintenance procedures; a fire and explosion hazard exists when performing cleaning and/or Maintenance procedures in an oxygen-enriched environment.
- Switch off the equipment and disconnect the Power cord from the mains before take in to cleaning.
- Don't pour the water for cleaning, it may enter into the electronics circuits it cause short circuit and get shock.
- Disconnect power to the Fibre Optic Blanket Infant Phototherapy and allow the compressor/motor to cool before cleaning to avoid the possibility of a burn.

- Don't keep the metal surface in wet condition it may cause corrosion and damage the part.
- Use the cleaning solution sparingly on a cloth when cleaning the Fibre Optic Blanket Infant Phototherapy. Do not saturate the unit - excessive solution causes damage to internal components.
- **Use of nonstandard components:** Consult the manufacturer for repair and replacement of components. Use of incorrect component can adversely affect Safety, performance and/or damage the equipment performance.

4.1.1 Disassembly for Cleaning

- ❑ It is recommended that after every usage, or at least once a week, to thoroughly clean and disinfect the Fibre optic cable.
- ❑ The most effective way to clean is to first disassemble in categories according to the method of cleaning required.

- Do not scratch or soil the light output end of the optic cable.
- Periodically check the insulation and the connection of the cable it may cause fire because of poor insulation and short circuits due to aging.
- Switch off the equipment and disconnect the Power cord from the mains before take into cleaning

- Don’t pour the water for cleaning it may enter into the electronics circuits it cause short circuit and get shock.
- Disconnect power from the device and allow the Light to cool before cleaning to avoid the possibility of a burn.
- Wiring instruction and training should be provided, please follow the service procedure carefully given in this manual.

- Don’t keep the metal surface in wet condition it may cause corrosion and damage the part.
- Use the cleaning solution sparingly on a cloth when cleaning the device. Do not saturate the unit - excessive solution causes damage to internal component.

  Use of nonstandard components: Consult the manufacturer for repair and replacement of components. Use of incorrect component can adversely affect Safety, performance and/or damage the equipment performance.

4.1.2 Cleaning the Illuminator Device and Fibre Optic Panel

During cleaning the Fibre Optic Blanket Infant Phototherapy, the processing shall comply with EN ISO 17664:2017 for reusable of the device:

1. Clean the equipment with damped cloth using soap (e.g. liquid dish soap) and clean water.
2. Rinse the equipment completely with water damped cloth.
3. Disinfect the equipment by using 2% Glutaraldehyde to inactivate any remaining pathogens.

   ❑ When the equipment is not in use, all approachable external surfaces should be cleaned daily with an antiseptic solution like 2% Glutaraldehyde. Every seventh day, after shifting the baby to another cot, the equipment should be cleaned thoroughly, first by mild detergent solution and then by antiseptic solution for **3 minutes**. All detachable assemblies, are to be treated similarly

4. Rinse with damped cloth using sterile or clean water (i.e. water boiled for 5 minutes and cooled). Sterile water is preferred for rinsing off residual liquid chemical disinfectant from Fibre Optic Blanket Infant Phototherapy that has been chemically disinfected for reuse, because tap or distilled water may harbour microorganisms. However, when rinsing with sterile water is not feasible, instead, rinse with tap water or filtered water (i.e. water passed through a 0.2 µ filter).
5. Dry Fibre Optic Blanket Infant Phototherapy using dry towel or cloth and wipe down the fibre optic cable and pad cover.

- Use of cleaning/disinfecting solutions containing chemicals that are not listed above (i.e. alcohol, acetone, etc.), or chemicals in greater concentrations than those listed above, may damage the patient probe or other material being cleaned. .

4.2 Lifetime of product

Since the product is classified under programmable medical electrical system and in case of unavailability of microcontroller the life time of the product can be considered as minimum five years.

Section 5: Specifications

Electrical	
Input supply	~230V, 50 Hz
Power rating	40 W
Fuse	F2AL
Variable Intensity	0 to 100 % continuous (10 increments)
Light source	Blue LED, 9 W
Optical cable	1.42 m x Ø 20 mm
Blanket size	330 x 196 mm
Display parameters	% of intensity, usage hours
Temperature	
Operating Range	+ 15ºC to 35ºC environment
Storage Range	-10ºC to 60ºC environment
Humidity	
Operating Range	15% to 95% RH Non-Condensing
Storage Range	50% to 95% RH Non-Condensing
Dimensions/Weight	
Overall length	280mm, +/- 5mm
Overall width	200mm, +/- 5mm
Overall height	130 mm, +/- 5mm
Total weight	3.5 Kg, +/- 100 gram
Electrical Requirements	
Type of protection against electric shock	Class I Product
Degree of protection against electric shock	Type BF
Degree of protection against Ingress of water	IPX0
Mode of Operation	continuous
Quality Test Approval	
Quality Management System	ISO 13485:2016
Electrical Safety	IEC 60601-1 IEC 60601-2-50 IEC 60601-1-2
ISO Standards	ISO 10993-5 ISO 10993-10

Section 6: Warranty

6.1 Conditions

1. The warranty is confined to the first purchaser of the product only and is not transferrable.
2. Repairs under warranty period shall be carried out by the company authorized personnel only.
3. In the event of repairs of any part/s of the unit, this warranty will thereafter continue and remain in force only for the unexpired period of the warranty. The time taken for repair and in transit whether under the warranty or otherwise shall not be excluded from the warranty period.
4. In case of any damage to the product/misuse detected by the authorized service personnel the warranty conditions are not applicable and repairs will be done subject to availability of parts and on a chargeable basis only.
5. Wear and tear, and defects caused by manipulation or unsuitable treatment are not included under the warranty.
6. Temperature sensor & battery carry only 3 months warranty. Lamps do not carry any warranty.
7. We warranty this unit for 12 months from the date of installation. Warranty includes the repair and replacement of faulty components.
8. Defects caused by improper use, and defects due to causes beyond control like lightning, abnormal voltage, acts of god, and also defects caused by rats, cockroaches or any other insects will not be covered under warranty.
9. Warranty is not applicable if the equipment is not purchased from Neötech/authorized Neötech dealer.
10. Warranty is not applicable if the warranty card is not filled and sent back to Neötech.
11. Equipment has an expected shelf life of 5 years and service life of 6 years.

Customer Details cum Warranty Card

Date: _____

Hospital Name & Address: _____

_____

Contact Person & Telephone/Fax No_____

Email _____

Department: NICU / PICU / OT / Gynaecology / Causality / Others _____

Equipment Name: _____

Model No: _____ Sl. No. _____

Date of Purchase: _____ Date of Installation _____

Name of Authorized Dealer: _____

Customer Signature & Date
(I accept the terms & conditions of Warranty)

Dealer Signature with seal

Kindly fill the above and send the same

From _____
_____
_____

To:
The Service In-charge
nice Neötech Medical Systems Pvt. Ltd.
No.85, Krishna Industrial Estate,
Vanagaram, Mettukuppam,
Chennai-600095. Tamil Nadu, INDIA.
Ph: 91-44-24762594, 24764608
Email: service@niceneotech.com, info@niceneotech.com
Web: www.niceneotech.com
Toll Free No. 1800-425-2594 (India only)

Section 7: Trouble Shooting

7.1 General System Failure

s.no	Problem	Cause	Remedy
1.	AC IN indication LED is not turned on.	Power Failure	Check the unit is Plugged in to Main supply
			Check the mains are switched ON.
			Contact nice Neötech.

7.2 System Fault Fibre Optic Blanket Infant Phototherapy

s.no	Problem	Remedy
1.	Light not being emitted from the fibre optic panel	Check A/C Supply Voltage
		Check if Power Cord is disconnected
		Check panel is locked into illuminator correctly.
		Contact nice Neötech
2.	Illuminator LED Lamp is not turned ON	Check A/C Supply Voltage
		Check if Power Cord is disconnected
		Contact nice Neötech
3.	Illuminator LED Lamp is on but intensity is less	Check the percentage of intensity
		Replace Lamp
		Contact nice Neötech
4.	Fibre optic cable comes out	Check the locking mechanism
		Contact nice Neötech

7.3 Maintenance levels

- ❑ Always disinfect and clean the unit and accessories before any maintenance – even when returning the unit to the supplier for repair.
- ❑ Always disconnect power supply before any maintenance.
- ❑ Use only nice Neötech's original parts for maintenance.

- Periodically check the insulation and the connection of the cable it may cause fire because of poor insulation and short circuits due to aging.
- Don't misalign the EMI Shielding and the beads it may cause EMI interference to the equipment

7.4 Disposing of the Unit

- At the end of its Service life Dispose of the equipment in accordance with National waste
- Disposal Regulations or ask a suitable Disposal contractor for the disposal of the unit.
- The local Environmental agency can give further details.

Section 8: Spare Parts List

Sl. no	Part Name	Qty	Unit
1	PCB Assembly	1	No.
2	LED Engine Assembly	1	No.
3	Front panel Assembly	1	No.
4	Rear Panel Assembly	1	No.
5	Illuminator Lens	1	No.
6	Fibre Optic Cable	1	No.
7	Blue LED - 15W	1	No.
8	Power Cord 3Pin	1	No.
9	SMPS 12V DC	1	No.
10	Fuse – F2AL	1	No.

Service contact:

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No. 85, Krishna Industrial Estate, Vanagaram,
Mettukuppam Chennai-600095. Tamil Nadu, INDIA.
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Web: www.niceneotech.com

EU Authorised Representative:
Amstermed B.V
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www.amstermed.nl
SRN: NL-AR-000001971

Section 9: Manufacturer's EMC Declaration

Guidance and manufacturer's declaration – electromagnetic emissions		
The Phototherapy Unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Phototherapy Unit should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Class A	Phototherapy is used in professional hospital environment
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

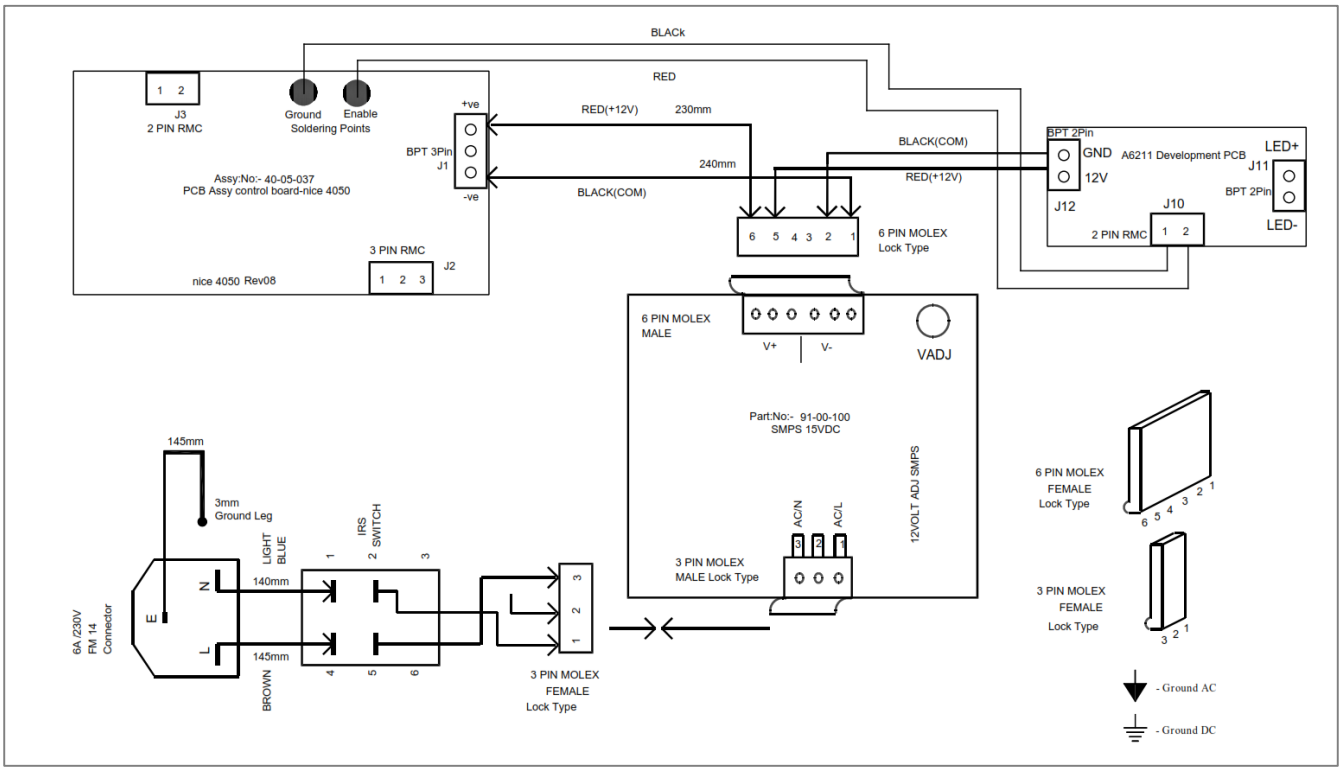
Guidance and manufacturer's declaration – electromagnetic immunity			
The Phototherapy Unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Phototherapy Unit should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	Criteria C	Floors should be wood, concrete or ceramic tile. If floors are covered with Synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient. IEC 61000-4-4	± 2 kV for power supply lines	Criteria A	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Criteria B	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	70% dips for 25 cycles 0% of dips for 0.5 0% short interruption for 5 Sec	Criteria B	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Phototherapy Unit requires continued operation during power mains interruptions, it is recommended that the Phototherapy Unit be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	Criteria A	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

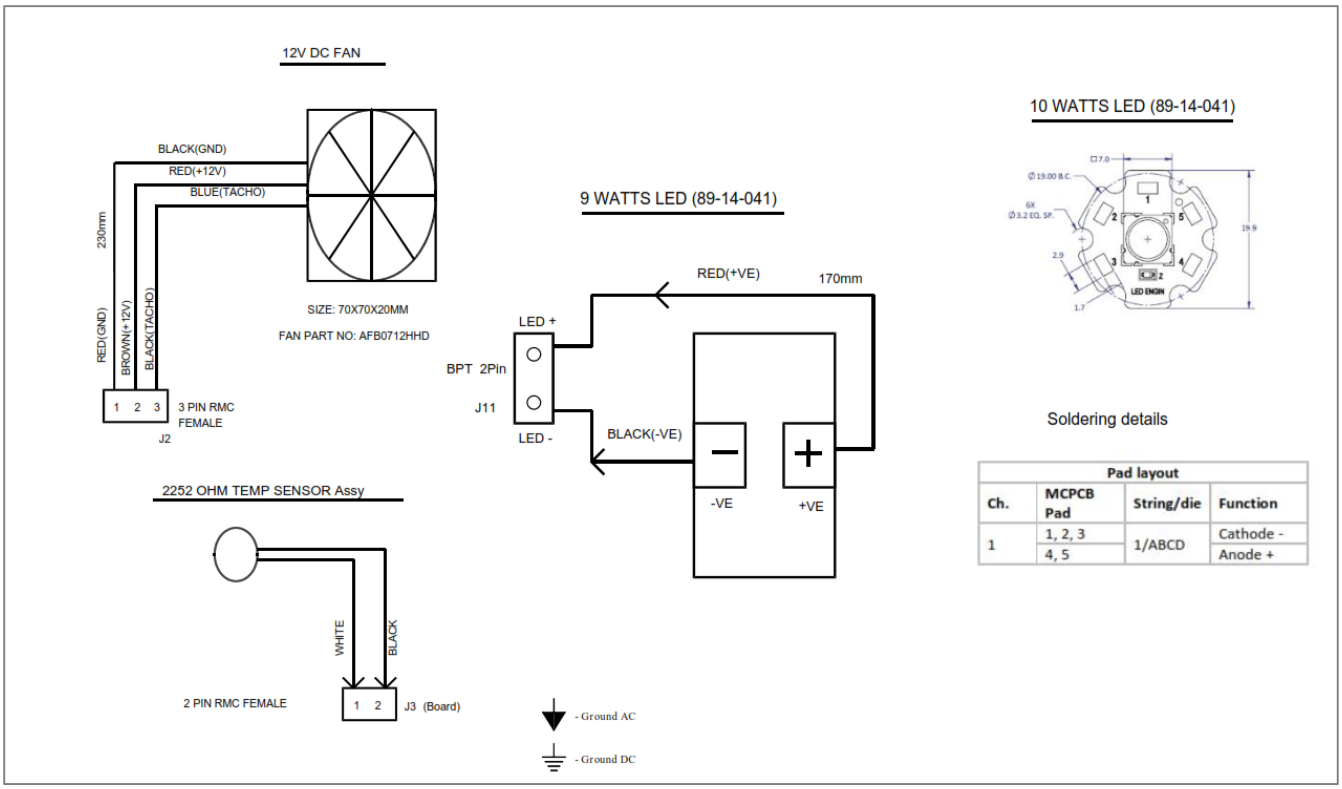
Guidance and manufacturer's declaration – electromagnetic immunity			
The Phototherapy Unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Phototherapy Unit should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bandsa 6 Vrms 150 kHz to 80 MHz in ISM bandsa	Criteria A	Floors should be wood, concrete or ceramic tile. If floors are covered with Synthetic material, the relative humidity should be at least 30 %.
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Acceptance criteria:

Performance criteria	Description
A	Normal performance within limits specified by nice Neötech
B	Temporary loss of function or degradation of performance which ceases after the disturbance ceases, and from which the equipment under test recovers its normal performance, without operator intervention
C	Temporary loss of function or degradation of performance, the correction of which requires operator intervention
D	Loss of function or degradation, which is not recoverable, owing damage to hardware or software, or loss of data

Section 10: Wiring Diagram





Section 11: For Complaints/Adverse Events/Comments/Feedback

			Date:		
Hospital Name & Address:					
Contact Person & Contact No. & Email:					
Department:	NICU / PICU / OT / Casualty / Others _____				
Equipment name:			Model no.:		
UDI / Serial No.:		Date of purchase:		Date of Installation:	
Pick one:	☐Complaints ☐ Adverse Events ☐Comments ☐Feedback				

In case of adverse events, fill the below details:

Incident happened to: (Patient / User)	
Details of incident happened person: (Name/Age/type of incident)	
Severity of the event (Minor injury / Major injury / Death)	
Brief description of the event	

For comments:

For Complaints:

For Feedbacks:

Kindly fill the above and send the same

From:

_____

_____

_____

To:
The Marketing In-charge
nice Neotech Medical Systems Pvt. Ltd.
No, 85. Krishna Industrial Estate,
Vanagaram, Mettukuppam,
Chennai-600095. Tamil Nadu,
INDIA.
Ph: 91-44-24762594, 24764608
Email: marketing@niceneotech.com
Toll Free No. 1800-425-2594 (India only)

NOTE: In case of serious/adverse events, report the incident to nice Neotech, European Authorized Representative and the competent authority of the Member State by filling and sending the below form as letter post or email.

Service Contact	EU Authorized Representative	Competent Authority
nice Neötech Medical Systems Pvt. Ltd. No. 85, Krishna Industrial Estate, Vanagaram, Mettukuppam Chennai-600095. Tamil Nadu, INDIA. Ph: 91-44-2476 4608 Telefax: 91-44-2476 2594 E-mail: service@niceneotech.com /info@niceneotech.com Web: www.niceneotech.com	**Amstermed B.V** Located in Saturnusstraat 46-62, Unit 032, 2132 HB Hoofddorp, The Netherlands. Mr. Mike Vermin Tel: +31 23 565 6337 info@amstermed.nl www.amstermed.nl SRN: NL-AR-000001971	**Ministerie van Volksgezondheid, Welzijn en Sport** Address:P.O. Box, 20350, The Hague, Netherlands Country:Netherlands Email: medicaldevices@minvws.nl Tel:+31 70 340 79 11