SEEFAR & SAPPHIRE

Neötech®

Infant Phototherapy

nice 4000 SPOT & nice 4000 LED

User manual

This user 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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nice 4000 LED

nice 4000 SPOT

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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, when assembled, operated, maintained and repaired in accordance with the instructions provided. This Product must be checked periodically. Operator is positioned near to the front panel of the device. User not to position infant phototherapy to make it difficult to operate / remove / disconnect the mains plug from mains socket. The device should be placed leaving space up to 1m from the wall to access the device back side easily. A defective Product should not be used. Parts that are broken, missing, plainly worn, distorted or contaminated should be replaced immediately, should such repair or replacement become necessary, nice Neötech recommends that a telephone or written request for service advice be made 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, faulty maintenance, improper repair, damage, or alteration by anyone other than nice Neötech.

Before using the nice Neötech 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 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, Corresponding documents, when nice Neötech Medical Systems Private Limited supplies to EU countries

Declaration for RoHS

RoHS electronic components are used for production of the devices and complies with Annex I categories of the RoHS Directive 2011 65 EU

Model Descriptions

The model **nice 4000 LED** is phototherapy with Light emitting diode lamp free standing model. The light source consists of a light weight plastic enclosure with 9 Blue LEDs, which is mounted on a stand. The light source can be tilted.

The model **nice 4000 SPOT** is phototherapy with Light emitting diode lamp free standing model. The light source consists of a light weight plastic enclosure with 24 Blue LED, which is mounted on a stand. The light source can be tilted.

Definitions

PHOTOTHERAPY UNIT

Phototherapy was discovered by chance when a nurse in a hospital nursery noticed that the infants placed closer to the windows were less "yellow" than those who were not. This observation led to the application of phototherapy in the treatment of neonatal hyperbilirubinemia.

New Born Jaundice:

The build-up of bilirubin in the blood is called hyperbilirubinemia or new born jaundice. Because bilirubin has a pigment or colouring, it causes a yellowing of the baby's skin and tissues. Before birth bilirubin is removed efficiently by the placenta. Immediately after birth the relatively immature neonatal liver provides the sole excretory pathway and is easily overwhelmed. This condition can be treated with phototherapy.

Some chemical substances react to light. When a new born with jaundice is exposed to phototherapy, the bilirubin absorbs light and changes form, it breaks down and become water soluble, it is then excreted mainly in the bile and to some extent in the urine.

When light is used therapeutically three specifications are of importance – Wavelength, Irradiance and Duration of Exposure.

- **Wavelength** - Solar irradiance that reaches the earth's surface consists of ultraviolet irradiation from 290 – 380nm (the ozone layer of the earth's atmosphere filters out ultraviolet of less than 290nm), the visible spectrum between 380 – 770nm and the near infrared from 770 – 1000nm. At midday sunlight has peak intensity in the blue-green region 450-500 nm.

- **Irradiance** is a measure of radiant flux impinging on a unit area or flux density. Irradiance is expressed as watts per square meter or milli watts per square centimetre. Irradiance is measured by a spectro radiometer.

- **Duration of Exposure:** The product of duration of exposure and irradiance will give a measure of the total radiant energy to which the subject has been exposed.

a. Points to note:

LED Light source – Bilirubin absorbs light of 460 nm, so it is good to have LED's with an Irradiance level between 450 to 465 nm.

Manoeuvrability – The phototherapy unit should be positioned easily over cots, Incubator, radiant heat cradles. This requires more mobility and easy adjustment of height and tilt of the lamp source.

b. Explanation of Terminology

This manual presents three types of precautionary information. The three types of statements carry equal weight; that is, they are of equal importance to the safe and effective use of the light. Each statement is categorized by using an introductory word in boldface as follows:

Identifies conditions or practices that might present danger for possible injury to the patient and/or user

Important: An instruction provided to help ensure correct clinical results and provide quality assurance to the phototherapy procedures.

An instruction that, if not followed, can result in a condition that could affect the performance of the phototherapy unit.

Other explanatory information is highlighted with the word Note. Information in this category is not considered precautionary.

Note: Background information is provided to clarify a particular step or procedure.

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 use 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 use 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.

General Safety Information:

Before administering phototherapy, read all sections of this manual carefully.

Observe all precautions to ensure the safety of the patient and those near the instrument. In addition, please refer to your hospital policy and procedure for phototherapy administration.

Section A: Warning

- Infant phototherapy is intended for use by a qualified practitioner under the direction of qualified physician. Personnel operating the Infant phototherapy must become thoroughly familiar with the instruction manual prior to using the Infant phototherapy with the patients.
- Incorrect use of the light, or the use of parts that are not manufactured or supplied by Neötech, can damage the light, and may cause injury to the patient and/or user.
- Don't use unspecified component.
- Do not use the light if any parts appear damaged or if there is any reason to believe that it is not functioning properly. Contact Neötech Medical Technical Service or our authorized service provider.
- When placing light enclosure directly on Phototherapy unit, care must be taken to ensure a safe operating environment
- Do not perform the service or maintenance activity while in use with the patient in infant phototherapy
- To avoid the risk of electric shock, Infant Phototherapy must only be connected to a supply mains with protective earth.
- **Eye Protection:** Do not look directly into the LED Lamp. During treatment, always protect the baby's eyes with eye patches or equivalent. Periodically and/or per your hospital protocol, verify that the baby's eyes are protected and free of infection. Patients adjacent to the light may also need to be protected with eye patches or equivalent.
- **Skin Temperature:** The use of skin-controlled mode of the incubator or radiant warmer is recommended. In addition, use of reflective foils may cause hazardous body temperatures. Monitor the infant's skin temperature as per your hospital policy during phototherapy usages to avoid fluctuations in body temperature.
- **Heat Supply:** The phototherapy light may impact the heat supply in thermotherapy devices (incubator units, radiant warmers, or heated mattresses) and the patient's body temperature.
- **Ambient Conditions:** Varying ambient conditions, such as the ambient temperature and/or different radiation sources, may adversely affect the patient temperature. Monitor the Patient Temperature periodically; please refer to your hospital phototherapy policy and procedure regarding appropriate ambient conditions.
- **Operator Safety:** Sensitive individuals may experience headache, nausea or mild vertigo if he/she stays too long in the irradiated area. Using the Neötech LED Phototherapy Unit in a well-lighted area or wearing glasses with yellow lenses can alleviate potential effects.
- **Photo isomers:** Bilirubin Photo isomers may cause toxic effects.
- **Diffuser:** Do not use the light if the diffuser is missing or damaged. The diffuser panel is a plastic shield that provides more uniform illumination. The diffuser panel also protects the baby and the unit from incidental debris or fluids.
- **Photosensitive drugs:** The light generated can degrade photosensitive medications. Do not place or store any drugs near or in the illuminated area.
- **Flammable agents:** Even Small quantity of flammable agents such as ether and alcohol, left in the Infant Phototherapy it can cause fire in connection with oxygen

- **Disconnect electrical power:** Always switch off the power and disconnect the power cord when cleaning the Phototherapy unit.

- The Infant Phototherapy should not be used near active high-frequency equipment, MRI machines, high-frequency ventilators, defibrillators or strong RF sources such as mobile phones and wireless communication systems. Exposure to high electromagnetic disturbances may cause inaccurate monitoring, unexpected device behaviour, or malfunction. Proper shielding and there must be a separation distance of at least 1.0m (3.3 ft) between this device and wireless communication device/ systems.

- The Infant Phototherapy should not be used adjacent to or stacked with other equipment, as this may lead to improper operation. If such use is unavoidable, both the Phototherapy and the other equipment must be carefully monitored to ensure they are functioning correctly. Failure to do so may result in device malfunction, inaccurate performance, or potential safety risks.

- Use of nice Neotech cables only. Use of cables other than those specified or provided by the nice Neotech of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

- The Infant Phototherapy is a Class A equipment (CISPR 11, Group 1 Classification) make it suitable for use in hospitals. Use in a residential environment may cause radio-frequency interference, as CISPR 11 Class B is normally required for such settings. To prevent potential disruptions to communication services, users should take mitigation measures, such as reloacating or re-orienting the equipment if interference occurs.

- **Important: Use of nonstandard components:** Consult the manufacturer for repair and replacement of LED. Use of incorrect LED can adversely affect safety, performance and/or damage the Phototherapy unit.

- **Important:** Maintain a distance of 20 - 40cm between the light enclosure and the infant to achieve optimal light intensity.

- Do not keep any unwanted objects over the source unit

- Eye pad (optional accessory) should be disposed after single use.

- Packing materials should be disposed after single use.

- Periodically check the irradiance level of lamp for effective therapy.

- The phototherapy unit should not be inclined above 10°.

- Any modification or alteration should not be done in the equipment.

Section B: Caution

- **Other equipment**: Do not attach other equipment to the Neötech Phototherapy or place anything on top of it. The pedestal stand and light unit are not designed to support additional equipment.
- Voltage fluctuation may damage the lamps. Use voltage stabilizer for stable voltage.
- The use of eye shields on the patient will possibly avoid Retinal Damage possible due to the intensity of the phototherapy lamps.
- Do not use flammable agent when using phototherapy equipment.
- Keep the patient in the effective area, monitor periodically failing which, patient may move away from the effective area.
- Continuous exposure of phototherapy treatment may cause water loss of the patient.
- Sensitive individuals may experience headache, nausea or mild vertigo if he/she stays too long in the irradiated area
- Continuous Exposure of phototherapy may cause increase in the skin temperature. Periodically monitor the patient skin temperature
- Isolation from the Supply mains is separable by a Plug provided.
- The equipment may get affected while using the defebulator.
- Clean surface using wet cloth dipped in mild soap water and squeeze dry excess water before use.
- Do not allow water to spill into source unit.
- Avoid using any solvent, spirits, alcohol to clean plastic parts and lens.
- Do not touch the lens with bare hands clean with dry soft clothes.
- Do not use water or any other liquid to clean electronic and electrical parts.
- For source unit tilting using hand, turn the source unit clock wise or anti-clock wise to the required angle and leave the source unit.
- For height adjustment – hold the ellipse pipe firmly and unscrew the knob to lift or lower to bring the source unit to the desired level from infant and screw the Knob.
- Do not lean (or) rest your hand on any part of the device, if done the device may overbalance.
- Pre-use check should be done before using the equipment.

Important: Before assembling and administering phototherapy, read all sections of this manual carefully. There are safety considerations that should be read and understood before use.

Section C: Symbols & Labels

Mark	Description
Manufacturer	
	Manufacturer – Indicates the medical device manufacturer
	Date of Manufacture – Indicates the date when the medical device was manufactured.
	Country of manufacture – To identify the country of manufacture of products
	Authorized representative in the European Community/ European Union – Indicates the authorized representative in the European Community/ European Union
	Catalogue number – Indicates the manufacturer's catalogue number so that the medical device can be identified.
	Serial Number – Indicates the manufacturer's serial number so that a specific medical device can be identified.
	Batch code – Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Use-by date – Indicates the date after which the medical device is not to be used.
	CE Mark European Conformity - Signifies European conformity (CE) mark Indicates manufacturer declaration that the product complies with applicable European regulations
Sterility	
	Non-sterile – Indicates a medical device that has not been subjected to a sterilization process.
Storage	
	Fragile, handle with care - Indicates a medical device that can be broken or damaged if not handled carefully.
	Keep dry - Indicates a medical device that needs to be protected from moisture.
	Temperature limit - Indicates the temperature limits to which the medical device can be safely exposed.
	Humidity limitation - Indicates the range of humidity to which the medical device can be safely exposed.

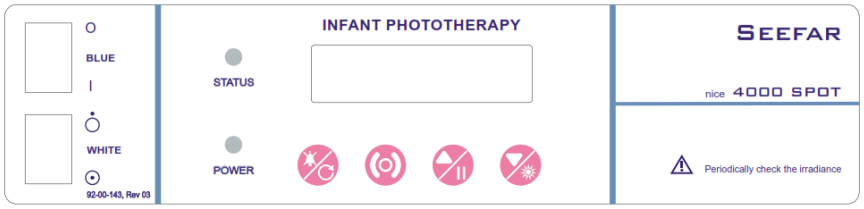
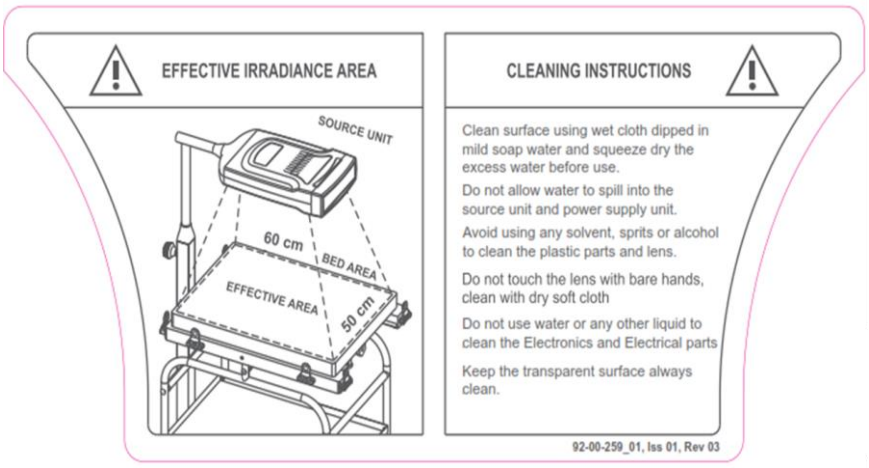
	Do not keep near fire – Do not keep the package near fire
	Maximum stackable limit – Pay attention to numbers on the stacked boxes icon. Some stacks will have top boxes marked with an X (number)
	This way up – For the duration/ delivery, the carton should face upright.
Safe use	
	Warning - indicates 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 use of equipment, and a fire.
	Caution - Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
	Refer Instruction for use – Indicates the need for the user to refer instructions for use given by the manufacturer
	Do not re-use - Indicates a medical device that is intended for one single use only
	Consult instructions for use or consult electronic instructions for use - Indicates the need for the user to consult the instructions for use.
On Device	
	General Prohibition sign
	Do not step on surface
	General mandatory action
	Alternating current
	Direct Current
	Off (Power: disconnection from main)
	On (Power: connection to the main)
	“Off” (only for a part of Equipment)

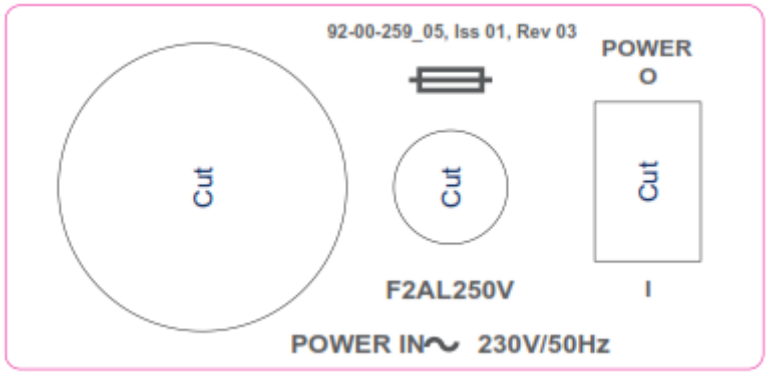
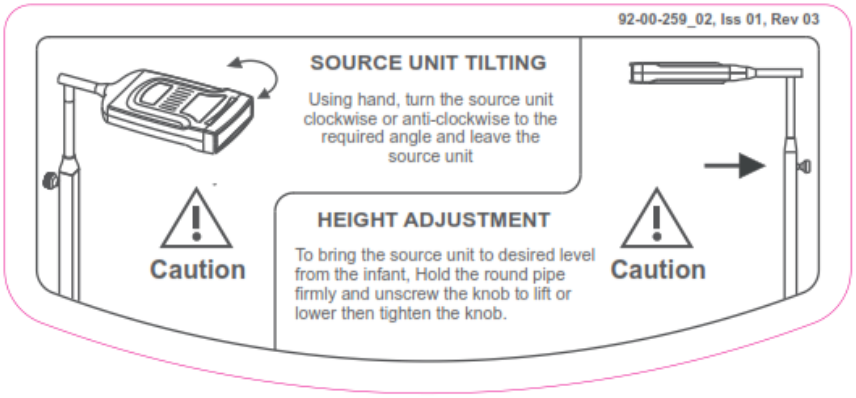
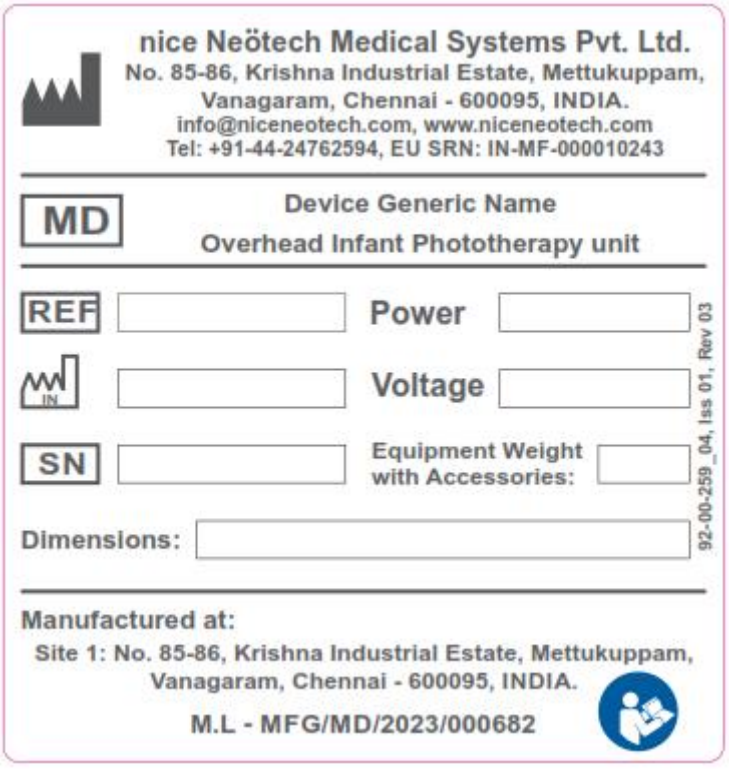
	“On” (only for a part of Equipment)
	Fuse
	Caution, Infant’s eyes should be covered with eye mask
	Audio Paused / Reset Key – nice 4000 LED
	Set Key – nice 4000 LED
	Increase/Pause Key – nice 4000 LED
	Decrease Key – nice 4000 LED
	Audio Paused / Reset Key – nice 4000 SPOT
	Set Key – nice 4000 SPOT
	Increase/Pause Key – nice 4000 SPOT
	Decrease Key – nice 4000 SPOT
Others	
	Medical Device - Indicates the item is a medical device
	WEEE Complaint - The symbol indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling. The WEEE marking must appear on any electrical and electronic equipment placed on the EU market.
	Recyclable Package – The product can be recycled or it was made from recycled materials.
	Use trolley for transportation – Used for heavy products that are difficult to carry by hand, even if you have multiple people.
	RoHS Complaint – RoHS (Restriction of Hazardous Substances) Indicates that no hazardous substances have been used in the product

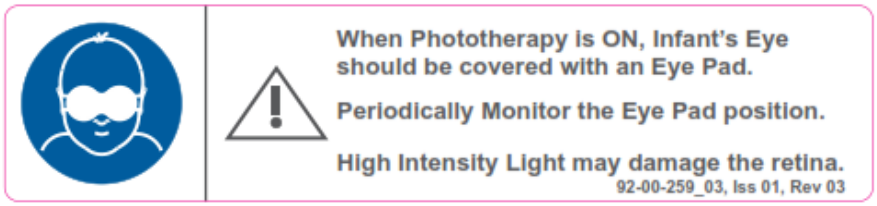
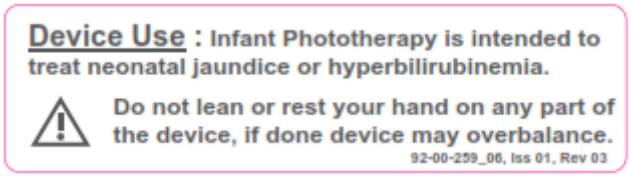
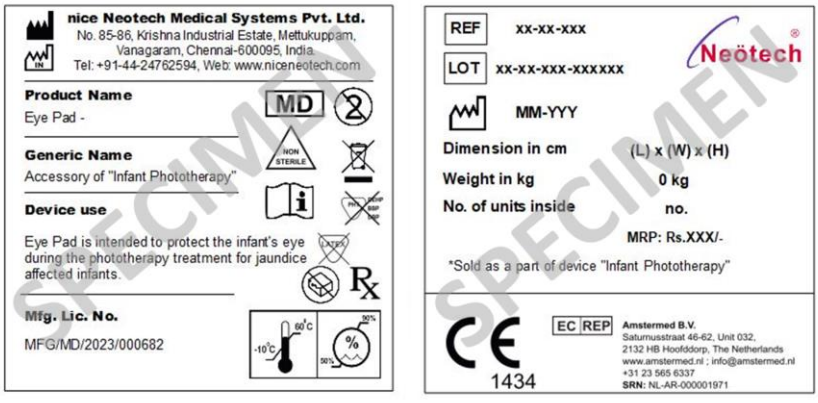
UDI	Unique device identifier - Indicates a carrier that contains unique device identifier information

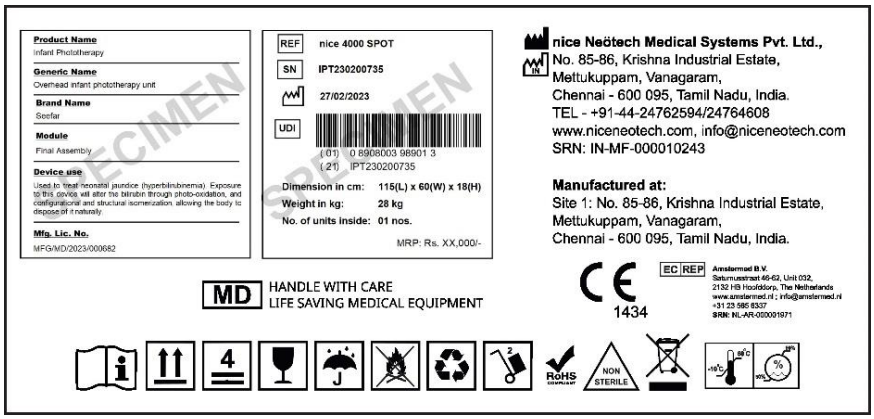
Labels

nice 4000 SPOT:

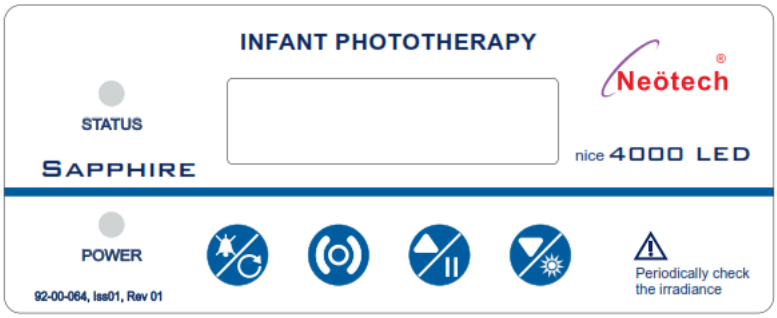
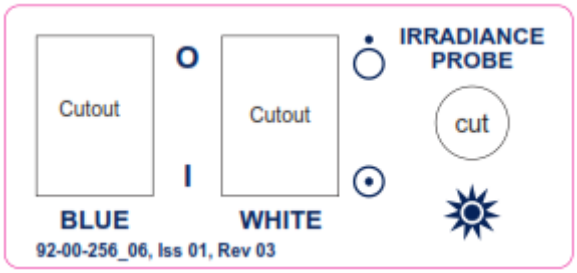
S. No	Label	Part Number	Label Description
1.		92-00-259	Safety sign, Do not step on Surface
2.		92-00-002	Neotech Logo
3.		92-00-143	Front panel
4.		92-00-259_01	Effective area and cleaning instructions

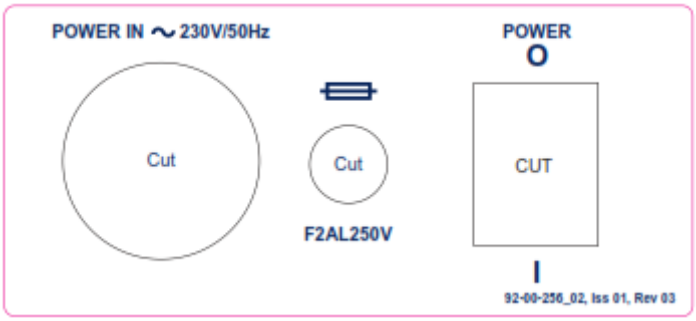
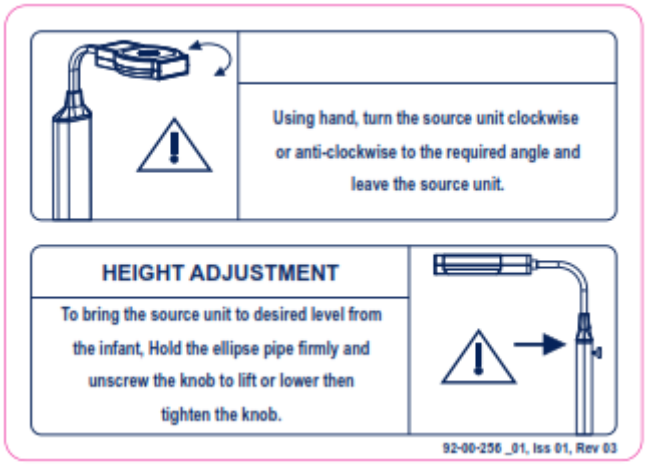
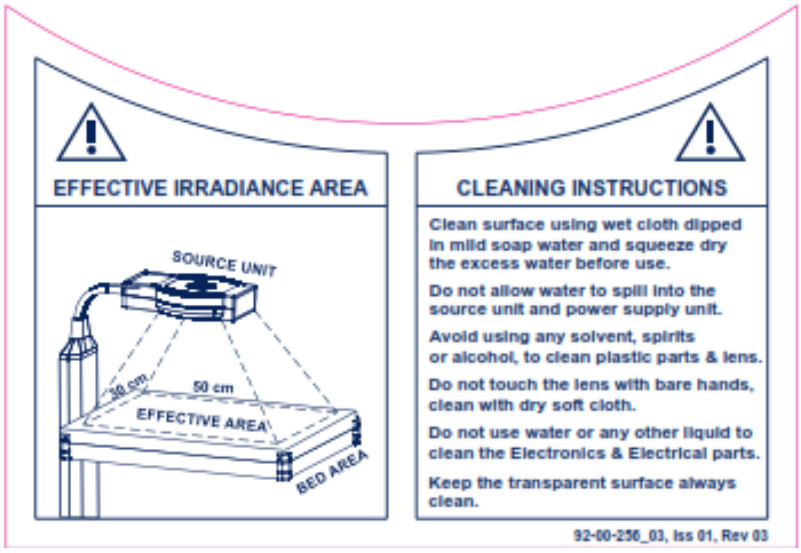
5.		92-00-259_05	Power Switch & fuse
6.		92-00-259_02	Tilting & Height adjustment
7.		92-00-259_04	Marking Plate

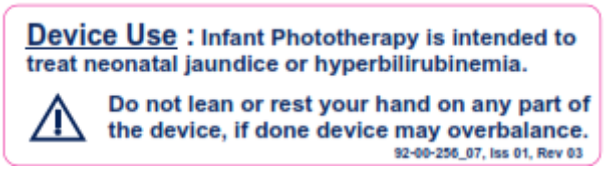
8.		92-00-259_03	Caution: Eye pad Instruction
9.		92-00-259_06	Device use
10.		--	UDI label
11.		99-00-259_07	CE Mark & EC REP details
12.		--	Packing label - Eye Pad

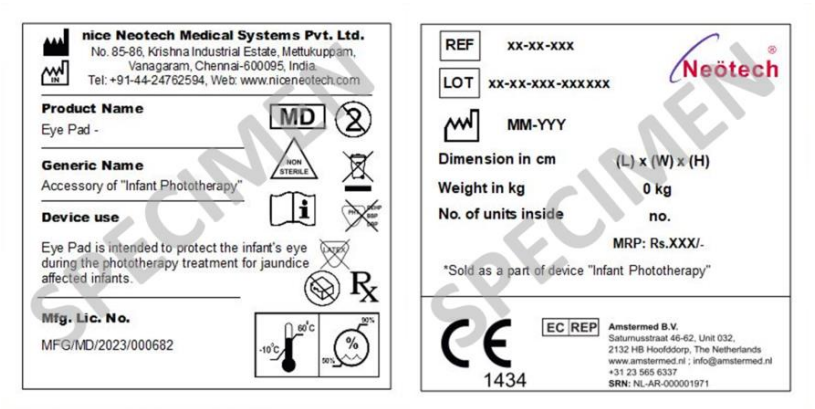
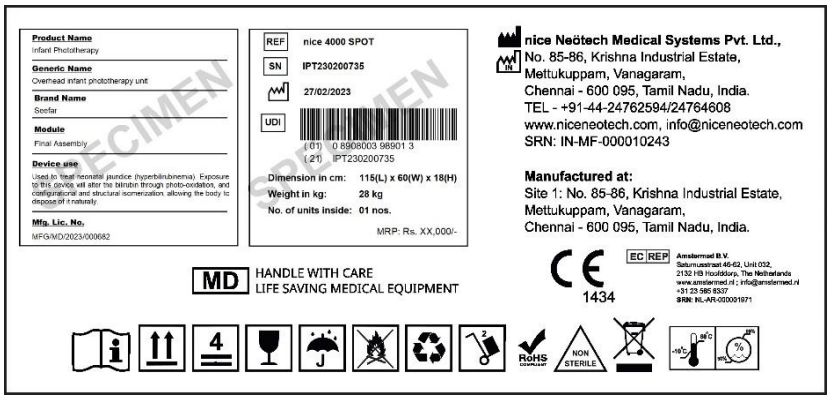
13.		--	Packaging, transport and storage Instruction

nice 4000 LED:

S. No	Label	Part Number	Label Description
		92-00-256	Safety sign, Do not step on Surface
		92-00-002	Neotech Logo
3.		92-00-064	Front panel
4.		92-00-256_06	LED Switch

5.		92-00-256_02	LED power Switch & fuse
6.		92-00-256_01	Height adjustment & source unit tilting instruction
7.		92-00-256_04	CAUTION : Eye pad Instruction
8.		92-00-256_03	Effective area and cleaning instructions

9.		92-00-256_05	Marking plate
10.		92-00-256_07	Device use instruction
11.		--	UDI Label
12.		92-00-256_08	CE Mark & EC REP details label

13.		--	Packing label - Eye Pad
14.		--	Packaging , transport and storage Instruction

Section 1: Description

1.1 Intended Use

The Phototherapy light is intended for the treatment of neonatal hyperbilirubinemia. The light can be used for infants in a bassinet, Incubator unit, open bed, or radiant warmer.

1.2 Medical Indications/Condition

Infant Phototherapy is intended for the treatment of neonatal unconjugated hyperbilirubinemia.

1.3 Contraindication

- Conjugated Hyperbilirubinemia

1.4 Side – effects

Phototherapy may cause insensible water loss, retinal damage, rashes.

1.5 Intended Patient Population

Premature, Neonates and Infants (upto 10 Kg body weight)

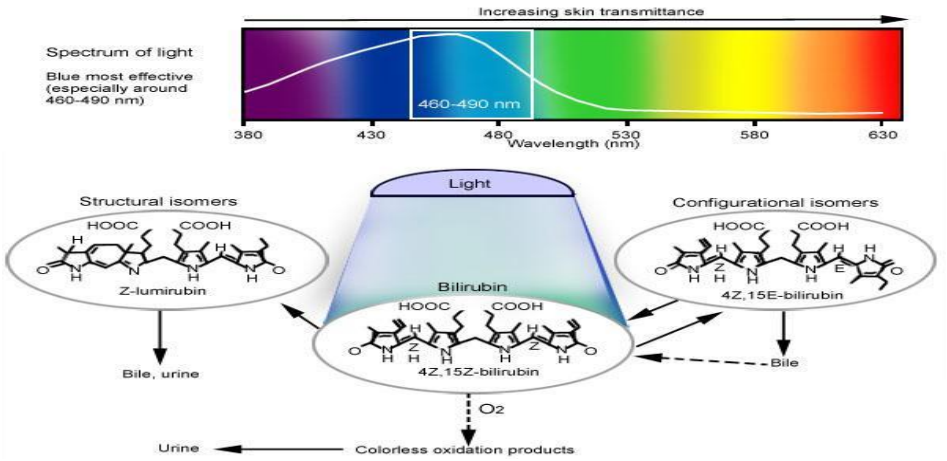
1.6 Device Intended User

Neonatologist and Healthcare Professionals.

1.7 Working principle

Some “normal” jaundice will disappear within a week or two without treatment. Other babies will require treatment because of the severity of the jaundice, the cause of the jaundice, or how old the baby is when jaundice appears.

Light in the blue region of the spectrum, near 460 nm, is most strongly absorbed by bilirubin. However, only light that penetrates the skin and is absorbed by bilirubin provides the needed photochemical effect. Tissue penetration increases as the wavelength of the light increases. Thus, one must balance the use of a higher wavelength of light, which more readily penetrates tissue, with the use of a wavelength that is more readily absorbed by bilirubin, which may penetrate less deeply. With this in mind, light in the 450-465 nm wavelength is used phototherapy.



Spectral irradiance is measured in watts per centimeter, or microwatts per square centimeter per nanometer (mW/cm2 per nm) over a wavelength band. Spectral power increases as the amount of skin exposed to phototherapy increases. Infants receiving phototherapy should be left only in their diaper, allowing adequate surface area exposure for phototherapy.

The dose of phototherapy, in mW/cm2 per nm, should be measured during phototherapy using a radiometer. These devices typically measure the spectral irradiance of phototherapy in the 425-475 or 400-480nm band wavelength. Measurements of spectral irradiance can differ greatly depending on where on the infant the measurement is made, taking several measures in different locations on the infant and averaging the values is important.

1.8 Device Description

General Description

- For over 30 years, phototherapy treatment in the hospital has been provided by a row of lights or LED suspended at a distance form a baby. This would provide light shining directly on an undressed baby (with diaper on) whose eyes would need protection from the light with soft eye pad. Advancements in technology have led to a LED phototherapy system which gives effective treatment without the inconveniences of conventional phototherapy treatment.

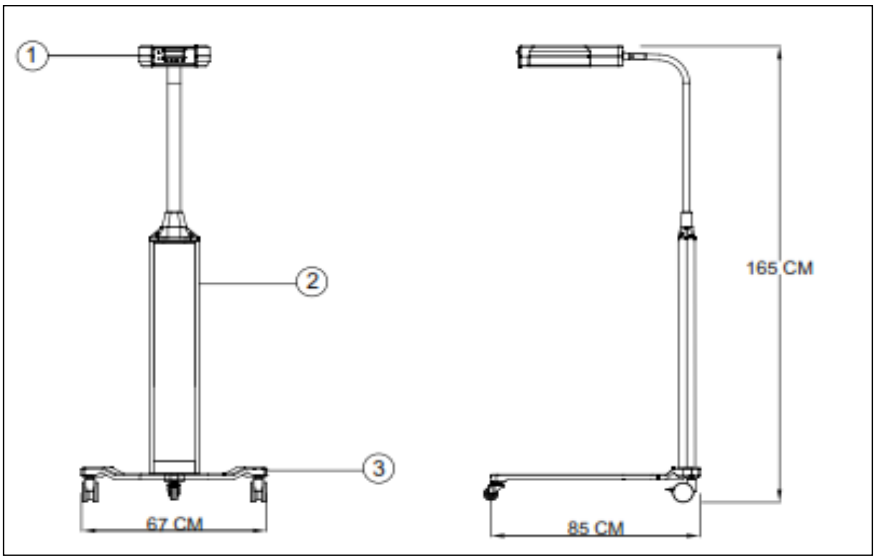
- nice Neötech Phototherapy System is a floor-standing equipment that delivers high-intensity blue light via LED Blue Lights to provide treatment for neonatal hyperbilirubinemia. A mains electricity (AC-powered) device designed to emit a blue light, the light output is optimized to provide an intensity of >45 µW/cm2/nm for nice 4000 LED and nice 4000 SPOT at maximum setting to treat neonatal jaundice (hyperbilirubinemia).

- A diffuser lens provides a more uniform illumination pattern and also protects the light from incidental debris or fluid exposure. Blue LED emits light in the range of 450 – 465 nm (peak wavelength 460 nm). This range corresponds to the spectral absorption of light by bilirubin, and is thus considered to be the most effective for the degradation of bilirubin.

- It consists of an overhead lamp consisting of several, daylight, blue LEDs and LED itself does not emit ultraviolet (UV) radiation. In addition, blue LED lamp does not emit significant energy in the infrared (IR) region of the spectrum, so there is no concern about IR exposure and excessive warming of the infant. As with all phototherapy lights, protective eyeshades must be used to protect the infant's eyes from excessive light exposure.

nice 4000 LED

The model nice 4000 LED is phototherapy with Light emitting diode lamp free standing model. The light source consists of a light weight plastic enclosure with 9 Blue LEDs of 5 Watt and 4 High bright white LED of 1 Watt for observation which is mounted on a stand. The light source can be tilted. In nice 4000 LED, the LED light intensity can be varied from 25% to 100%.

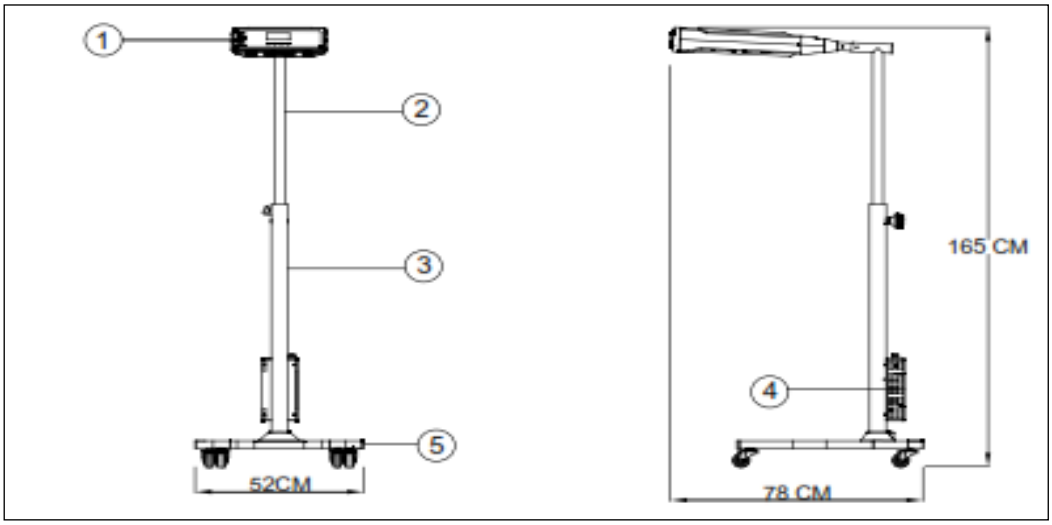


1.	Source unit assembly – 4000 LED
2.	Pillar assembly - 4000 LED
3.	Base assembly - 4000 LED

The Phototherapy system features nine high-power LEDs to effectively cover the bed area, ensuring optimal treatment for neonates. The absence of ultraviolet rays minimizes UV exposure, No infrared rays helps minimize water loss. The unit offers adjustable height, allowing users to control irradiance levels based on the neonate's needs and the type of cradle used. Convenient tilting, one-handed height adjustment, and smooth maneuvering with castors provide flexibility in system placement. The treatment timer ensures automatic cut-off after the set time, and features like lamp usage hour monitoring and replacement alerts contribute to minimal downtime. With lamp usage hours exceeding 20,000 hours, frequent lamp changes are not required, enhancing the system's efficiency and reliability.

nice 4000 SPOT

The model nice 4000 SPOT is phototherapy with Light emitting diode lamp free standing model. The light source consists of a light weight plastic enclosure with 24 High bright Blue LED of 1 Watt and 3 High Bright White LED of 1 Watt for observation which is mounted on a stand. The light source can be tilted. In nice 4000 SPOT, the LED light intensity can be varied high or low.



1.	Source unit assembly – 4000 SPOT
2.	L-pipe assembly - 4000 SPOT
3.	Pillar assembly - 4000 SPOT
4.	SMPS – 4000 SPOT
5.	Base assembly - 4000 SPOT

The phototherapy system is equipped with 24 high-power LEDs to effectively cover the bed area for phototherapy treatment. The absence of ultraviolet rays minimizes UV exposure, No infrared rays helps reduce water loss. The system offers adjustable height, allowing users to control irradiance levels for neonates and different cradle types. With convenient tilting, single-hand height adjustment, and smooth maneuvering castors, the source unit can be easily placed in various positions to suit user preferences. A built-in treatment timer ensures automatic cutoff at the set time, and features like lamp usage hour monitoring and replacement alerts contribute to minimal downtime in service. The impressive lamp usage hours exceeding 20,000 eliminate the need for frequent lamp changes, providing a reliable and efficient phototherapy solution.

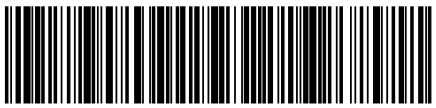
Seefar and Sapphire Infant Phototherapy with Accessories comprises the below assemblies

Phototherapy Eye Pad – Elastic: A phototherapy eye pad is used as an accessories to protect the baby's eye from blue light during phototherapy treatment.

1.9 UDI Carrier

This UDI system consists of Device Identifier (DI) and Production Identifier (PI). The same is incorporated and followed throughout the device life cycle. The UDI is placed on the device itself or on the packaging labels (for all packaging levels) as applicable.

Model No	UDI-DI	UDI-PI (For Example)
nice 4000 LED	08908003989006	IPTYYMMXXXXX IPT- Product Code YY – year MM – Month XXXXX – serial No
nice 4000 SPOT	08908003989013	IPTYYMMXXXXX IPT- Product Code YY – year MM – Month XXXXX – serial No

UDI Label
 (01) 0 8908003 98901 3 (21) IPT230700686

Section 2: Installation

2.1 nice 4000 LED

2.1.1 Unpacking and Inspection

- Remove the equipment from shipping containers and unpack all the assemblies and accessories of nice 4000 LED Infant Phototherapy.
- After removal from the shipping containers, inspect the nice 4000 LED infant phototherapy and all accessory items for any signs of damage which may have occurred during shipment.
- Also confirm the presence of all accessory items or factory installed options as listed on the packing slip.

Note: File a damage claim with the shipping carrier if damage is found in any of the assemblies or accessories in the container.

Do not use the equipment, if it appears or is suspected to be damaged.

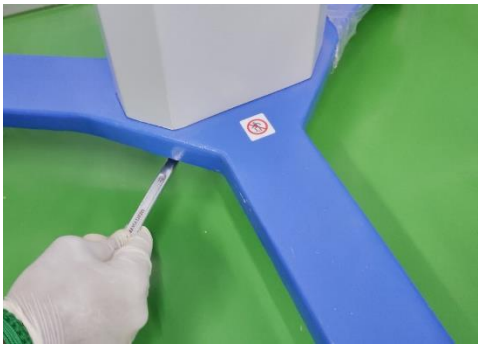
2.1.2 Setup

Combustible gases: Do not use the light in the presence of gases that support combustion (for example, oxygen, nitrous oxide, or other anaesthetic agents).

This section provides assembly procedures for the Base, pedestal stand and Source unit. When removing the equipment from the cartons, take care so that the phototherapy does not get damaged. After removal from the shipping containers, inspect the nice Neötech Phototherapy unit and all items for any signs of damage which may have occurred during shipment. File a damage claim with the shipping carrier if damage has occurred.

2.1.3 Installation of Equipment

2.1.3.1 Assembling Base and Pedestal stand



Picture 1

- The base unit consists of three castors for easy mobility, which allows convenient manoeuvring, to position the equipment easily under cots, incubator units and radiant heat cradles.
- The T-Shaped base is designed to prevent tip edge when the phototherapy unit is at any angle or distance. Base fits under the standard incubator units to allow easy placement.
- Assemble the base with the pedestal stand using 8x25 hexagonal bolt 6nos (front).

2.1.3.2 Pedestal Stand height adjustment: Vertical frame with Ellipse Pipe

Picture 2

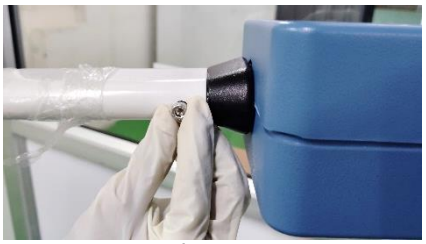
- First loosen the adjustment knob by holding the ellipse pipe, then adjust the height of the light source, and finally tighten the knob to lock the height.
- The plastic guided bush is positioned on the pillar at the intersection between the vertical frame and the ellipse pipe
- This unit helps in easy adjustment of height.

2.1.3.3 Assembling of Pedestal Stand and Light source

a. Light source (LED)

Picture 3

Picture 4



Picture 5

- The source unit consists of display, LED, lens, fan, heat sink and mounting holder.
- Initially connect the light source supply from SMPS by using wago connectors and mount the source unit holder inside the ellipse pipe as shown in the image.
- Finally fix by M5 (5x10) Allen bolt (SS) on both sides of the ellipse pipe.

b. Light Source Tilting:

Picture 6

- The light source can be tilted by gripping the device on either side and rotating it to the desired angle, allowing for an adjustment of up to 180 degrees.

2.1.3.4 Input Supply of 230V AC Power Connection

Picture 7

- The light is 230VAC mains-power operated. The power cord is fitted into the power supply module in the rear bottom of the pedestal stand.

Note: When lifting and Handling the Equipment follow the Cautions, Warnings & Instructions

2.1.4 Mechanical Pre-use Check Instructions

- Before using the nice Neötech LED Phototherapy unit, 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 Pre-use Check Instructions (Mechanical and Light source Unit) while a patient occupies the Phototherapy unit.
- Complete the “Pre-use Check Instructions” section of this manual before putting the unit into operation. If the Phototherapy unit fails in any portion of the Pre-use Check Instructions it must be removed from use and repaired.

2.1.3.1 Overall Appearance

1. Disconnect the power cord from the AC power source for the Mechanical check procedures.
2. Check the overall appearance of the Phototherapy unit. There should be no obvious damage.

Setup and Pre-use Check Instructions

- For units with castors, check that all castors are in firm contact with the floor and that the Phototherapy unit is stable and moves freely.
- Lock the two rear castors and check that the LED Phototherapy unit is held in place.
- Examine the power cord whether it is intact with the socket. Replace the power cord if damage is evident. The Power cord is replaced by only the trained service personnel.

Do not place items on top of the Light source. Items placed on top of the Light source can fall and injure the patient and may pose a fire hazard.

2.1.3.2 Mechanical Checks

I. Light Source

Picture 8

- Check the light source can be tilted by gripping the device on either side and rotating it to the desired angle, allowing for an adjustment of up to 180 degrees.

II. Height Adjustment

Picture 9

- This knob allows adjusting the height of the light Source.
- First, loosen the knob, then adjust the height of the light source by holding the ellipse pipe, and finally, tighten the knob to set the desired height.

III. Locking Castors (3 nos.)

Picture 10

- Position the device in the intended location, once the light is in place for phototherapy, these castors should be locked to prevent the machine from rolling around freely.
- The casters allow the unit to move with ease in any direction, actuate the brakes with slight foot pressure on locking lever.

IV. Check the Protective Cover:

- Check the external acrylic lens, it should be clear and clean.

Caution

Do not touch the lens with bare hand. Use soft cloth for cleaning.

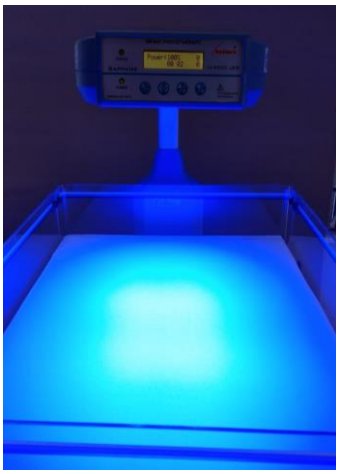
2.1.4 Light Source Pre-use Check Instructions

2.1.4.1 Check the Tilting of the light source

Picture 11

- Check the source unit whether it can be tilted by gripping the device on either side and rotating it to the desired angle, allowing for an adjustment of up to 180 degrees.

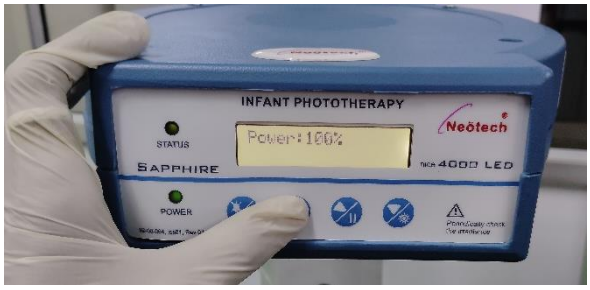
2.1.4.2 Check the Working of light source.



Picture 12

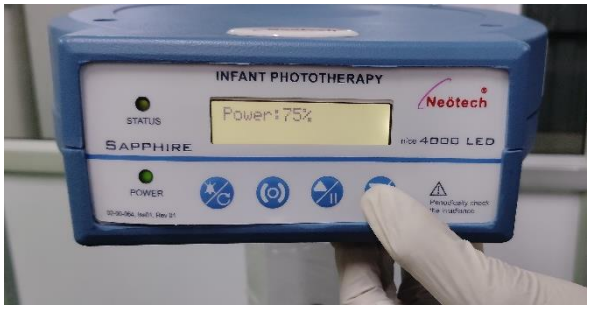
- Check four keys on the front panel, they should not be damaged and/or struck.
- Check the AC input line; the main switch should be ON at rear of the pedestal stand.
- Check the DC power input cable in the source unit, should be plugged into the socket.
- Check the light source ON / OFF switch, should be ON at the side of the light source.

2.1.4.2.1 Check the irradiance adjustment



Picture 13

- Check the irradiance by pressing the set key to show “POWER” parameter on the LCD display.



Picture 14

Picture 15

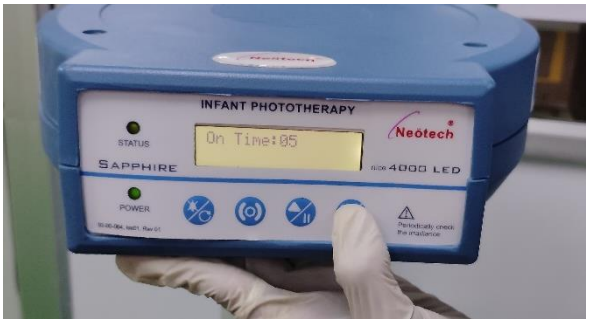
- Check the value as 25%, 50%, 75% or 100% as desired by using the Increase/Decrease key.

2.1.4.2.2 Check the Phototherapy Timer Setting

Picture 16

- Check the phototherapy timer by pressing the set key twice to show the "TIMER" parameter on the LCD display.
- To change the timer "on or off", utilize the increase/decrease key.

Picture 17



Picture 18

- Check the Increase/Decrease key to vary the timer setting up to 09 hours.

2.1.4.2.3 Check the Lamp Usage Hours Display

Picture 19

- Lamp usage hour is shown on the top right corner of the LCD display panel.
- Usage hour is automatically updated every hour.

2.1.4.2.4 Check the Treatment Hours Display

Picture 20

- Treatment hour is shown on the bottom right corner of the LCD display panel.
- Treatment hour is automatically updated every hour.
- Set time is shown left and next to colon, it indicates the remaining time from the set duration.

2.1.4.2.5 Check the Status Indication LED

Picture 21

- The status light is shown on the left side of the front panel.
- The green color indicates that lamp usage hour is less than 15,000.
- The Amber color indicates that lamp usage hour is greater than 15,000 and the red color with audio indication, indicates that the lamp usage hour is greater than 20,000.

2.1.4.2.6 Check the Power Indication LED

Picture 22

- The Power indication LED shows that the equipment is ON.

2.2 nice 4000 SPOT

2.2.1 Unpacking and Inspection

- Remove the equipment from shipping containers and unpack all the assemblies and accessories of nice 4000 SPOT Infant Phototherapy.
- After removal from the shipping containers, inspect the nice Neötech nice 4000 SPOT Infant Phototherapy and all accessory items for any signs of damage which may have occurred during shipment.
- Also confirm the presence of all accessory items or factory installed options as listed on the packing slip.

Note: File a damage claim with the shipping carrier if damage is found in any of the assemblies or accessories in the container.

Do not use the equipment, if damage is found.

2.2.2 Installation of Phototherapy

2.2.2.1 Assembling Base and pedestal stand

Base Unit

- The base unit consists of four castors (with 2 brakes, without 2 brakes) for easy mobility, which allows convenient manoeuvring, to position the equipment easily under cots, incubator units and radiant heat cradles.
- Base fits under the standard incubator units to allow easy placement.
- Assemble the base with the pedestal stand using 8x35 hex bolt.

Picture 23

2.2.2.2 Pedestal Stand height adjustment: Vertical frame with Ellipse Pipe

- This unit helps in easy adjustment of height of source unit.
- The plastic guided bush is placed at the junction between the vertical frame and ellipse pipe.
- First, loosen the adjustment knob by rotating it , while holding the ellipse pipe with your hand. Then, adjust the height as needed, and finally, tighten the knob to lock the desired height in place.

Picture 24

2.2.2.3 Assembling of Pedestal Stand and Light source.

IV. Light source (LED)

Picture 25

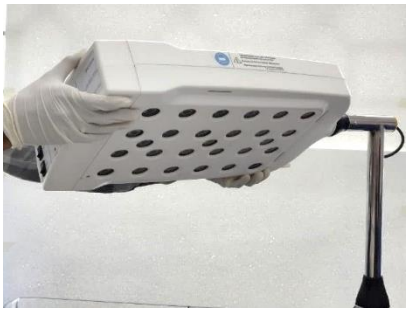
Picture 26

- The source unit consists of LED, lens, fan, heat sink and mounting holder.
- Before securing the source unit into the pillar assembly, link the connection from the SMPS to the source unit by connecting the Wago connector, make sure to connect the Wago connector from the source unit to the pillar. Ensure that the connections are properly made.

Picture 27

- After ensuring a proper connection, proceed to fix the source unit to the pillar pipe assembly. Secure it using 4x8 stainless steel button head fixed by M4 Allen bolts on both sides of the round pipe.

V. Light Source Tilting:



Picture 28

- Check the source unit whether it can be tilted by gripping the device on either side and rotating it to the desired angle, allowing for an adjustment of up to 180 degrees.

2.2.2.4 Input Supply of 230V AC Power Connection

Picture 29

- The light is 230VAC mains-power operated.
- The power cord is fitted into the power supply module in the rear bottom of the pedestal stand.

Note: When lifting and Handling the Equipment follow the Cautions, Warnings & Instructions.

2.2.3 Mechanical Checkout Procedure

Before using the nice Neötech LED Phototherapy unit, 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 Light source Unit) while a patient occupies the Phototherapy unit.

Complete the “Checkout Procedures” section of this manual before putting the unit into operation. If the Phototherapy unit fails in any portion of the checkout procedures it must be removed from use and repaired.

2.2.3.1 Overall Appearance

1. Disconnect the power cord from the AC power source for the Mechanical check procedures.
2. Check the overall appearance of the Phototherapy unit. There should be no obvious damage.

Setup and Checkout Procedures

- For units with castors, check that all castors are in firm contact with the floor and that the Phototherapy unit is stable and moves freely.
- Lock the two rear castors and check that the LED Phototherapy unit is held in place.
- Examine the power cord whether it is intact with the socket. Replace the power cord if damage is evident.

Do not place items on top of the Light source. Items placed on top of the Light source can fall and injure the patient and may pose a fire hazard.

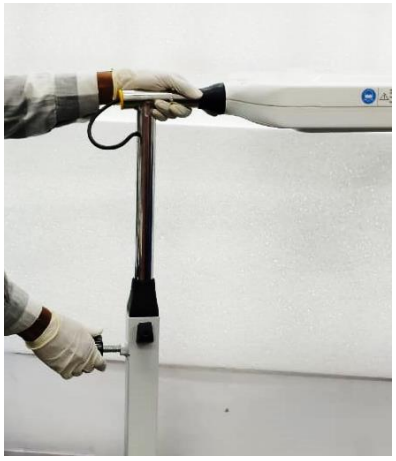
2.2.3.2 Mechanical Checks

I. Light Source

Picture 30

- Check the source unit whether it can be tilted by gripping the device on either side and rotating it to the desired angle, allowing for an adjustment of up to 180 degrees.

II. Height Adjustment



Picture 31

- This knob allows adjusting the height of the light Source.
- First, loosen the adjustment knob by rotating it, while holding the ellipse pipe with hand. Then, adjust the height as needed, and finally, tighten the knob to lock the desired height in place.

III. Locking Castors (2 nos.)

Picture 32

- Check whether the light Source can be tilted by gripping the device on either side or rotating to desired angle.
- Once the light is in place for phototherapy, these castors should be locked to prevent the light from rolling around freely.
- Castors lock and unlock with slight foot pressure on the locking lever.

IV. Check the Protective Cover

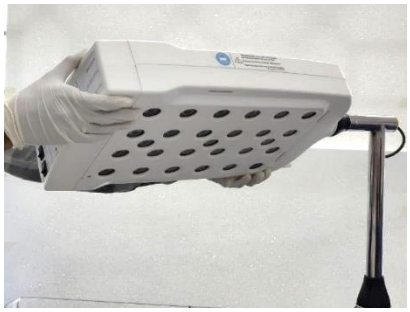
- Check the external acrylic lens, it should be clear and clean.

Caution

Do not touch the lens with bare hand. Use soft cloth for cleaning.

2.2.4 Light Source Checkout Procedure

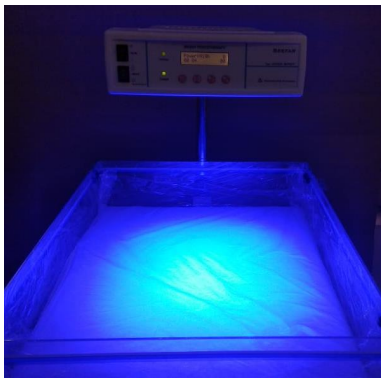
2.2.4.1 Check the Tilting of the light source



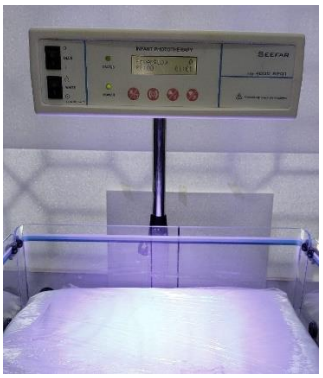
Picture 33

- Check the source unit whether it can be tilted by gripping the device on either side and rotating it to the desired angle, allowing for an adjustment of up to 180 degrees.

2.2.4.2 Check the Working of light source.



Picture 34



Picture 35

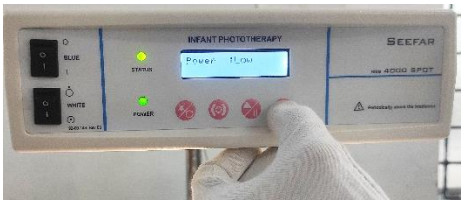
- Check the four keys on the front panel, they should not be damaged and/or struck.
- Check the AC input line; the main switch should be ON at the rear of the pedestal stand.
- Check the light source ON / OFF switch for treatment light (Blue LED) and observation light (White LED), should be ON at the front panel of the light source.

2.2.4.2.1 Check the irradiance adjustment

Picture 36

- Check the irradiance by pressing the set key to show “POWER” parameter on the LCD display.

Picture 37



Picture 38

- Verify the value, whether it is set to low or high, by utilizing the Increase/Decrease key.

2.2.4.2.2 Check the Phototherapy Timer Setting

Picture 39

- Check the phototherapy timer by pressing the set key twice to show the “TIMER” parameter on the LCD display.
- To change the timer “on or off”, utilize the increase/decrease key.

Picture 40

Picture 41

- Check the Increase/Decrease key to vary the timer setting up to 09 Hours

2.2.4.2.3 Check the Lamp Usage Hours Display

Picture 42

- Lamp usage hour is shown on the top right corner of the LCD display panel.
- Usage hour is automatically updated every hour.

2.2.4.2.4 Check the Treatment Hours Display

Picture 43

- Treatment hour is shown on the bottom right corner of the LCD display panel.
- Treatment hour is automatically updated every hour. Set time is shown left and next to colon, it indicates the remaining time from the set duration.

2.2.4.2.5 Check the Status Indication LED

Picture 44

- The status light is shown on the left side of the front panel.
- The green color indicates that lamp usage hour is less than 15,000.
- The Amber color indicates that lamp usage hour is greater than 15,000 and the red color with Audio and Visual Indications indicates that the lamp usage hour is greater than 20,000.

2.2.4.2.6 Check the Power Indication LED

Picture 45

- The Power indication LED shows that the equipment is ON.

Section 3: Operation

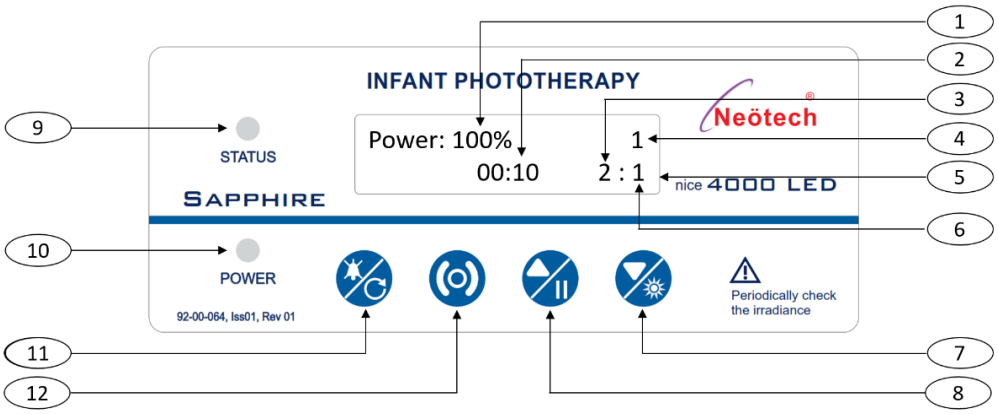
3.1 nice 4000 LED
3.2 nice 4000 SPOT
3.3 Accessories

Note: Check intensity - Before use, check the intensity of the light using a radiometer as per your institution's procedure.

Caution

Do not use flammable agent while using phototherapy equipment.

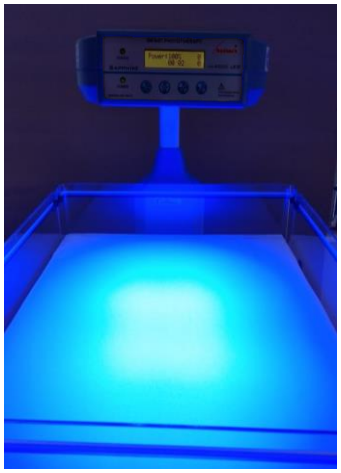
3.1 nice 4000 LED



1	Irradiance level Indication	7	Decrement Key
2	Equipment running time	8	Increment/Pause Key
3	Set treatment time	9	LED life time Status Indication
4	LED total life time	10	Power ON Indication
5	16 x 2 LCD Display	11	Mute Key
6	Remaining treatment time	12	Set Key

3.1.1 Light Source

3.1.1.1 Treatment Light



Picture 46

High bright 9 Blue LED Lamps - The light provides an intensity of >60 µW/cm²/nm fat distance of 30 cm. The High power LED cover the bed area for effective Phototherapy treatment.

The figure below shows that the infant phototherapy light distribution at maximum intensity control settings.

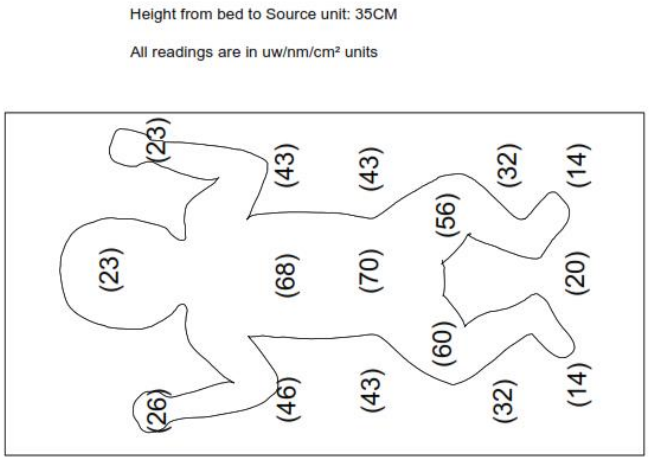


Figure 2

Note: The irradiance is measured by using an international ILT74 Hyperbilirubinemia light meter.

Note: Intensity can vary according to the requirement in the LED Phototherapy.

Warning

- The intensity of the lamps will decrease with usage of the lamps.
- Use of phototherapy may increase baby's skin temperature.
- To be used only on infants for whom phototherapy has been prescribed
- Cover infant's eyes with protective eye shields designed for use during phototherapy.
- **Eye Protection:** Do not look directly into the LED during treatment. Always protect the baby's eyes with eye patches or equivalent. Periodically and/or as per your hospital protocol, verify that the baby's eyes are protected and free of infection.

Caution

- A distance of more than 40cm between the light source and the baby may result in inadequate intensity.
- Continuous exposure of phototherapy treatment may cause water loss to the patient.
- Position the phototherapy light source over infant. Position the face of the light source not closer than 10 cm from the infant.
- Continuous Exposure of phototherapy may cause increase in the skin temperature. Periodically monitor the patient's skin temperature.
- Separable plug provided for isolation from the supply mains.
- Prepare the infant for overhead phototherapy - Infant may lie in an open crib, a bassinet, an incubator, or under a radiant warmer.

- Continuous exposure of phototherapy treatment may cause water loss of the patient

3.1.1.2 Light source height Adjustment

Picture 47

- This knob allows adjusting the height of the light Source.
- First, loosen the knob, then adjust the height of the light source by holding the ellipse pipe, and finally, tighten the knob to set the desired height.

Important: Maintain a distance of 20-40 cm between the light source and the infant to achieve optimal light intensity.

3.1.1.3 LED Light Source tilting

Picture 48

- The source unit can be tilted by gripping the device on either side and rotating it to the desired angle, allowing for an adjustment of up to 180 degrees.
- Even when the baby is in the incubator or warmer effective phototherapy treatment can be given by tilting the light source to the required angle (±90º).

Note: Tilt or Position the light source unit to center the light over the infant.

3.1.1.4 Switches

Picture 49

- Two switches are available on the source unit—one for Blue light operation, switching it "ON" /"OFF," and another for White light operation, controlling it similarly "ON" and "OFF.

Picture 50

- To switch ON the equipment, use the power switch at the rear side of the pedestal stand and to switch ON the Light source, use the power switch on the right side of the Light source.

Caution

Operator Safety: Sensitive individuals may experience headache, nausea or mild vertigo if he/she stays too long in the irradiated area. Using the Neötech Phototherapy in a well-lighted area or wearing glasses with yellow lenses can alleviate potential effects.

3.1.2 Front Panel

Picture 51

There are four keys in the front panel of the light source.

	Mute Key/ Reset Key	To mute the Audio indication and LED lamp status from OFF to ON if treatment time elapsed and To reset the running time
	Set Key	To Select the percentage of irradiance and timer.
	Increase/Pause Key	To increase the percentage of irradiance and timer and pausing treatment time.
	Decrease/irradiance Key	To decrease the percentage of irradiance, timer and real time/date and showing the irradiance value(optional)

There are two LED indications on the front panel of the light source

STATUS	Status Indicator	**Status Tri Colour LED:** Status of total usage hours of the lamp: ➢ The green colour indicates that lamp usage hour is less than 15,000. ➢ The Amber colour indicates that lamp usage hour is greater than 15,000. ➢ The red colour indicates that lamp usage hour is greater than 20,000.
POWER	Power Indicator	**The Power Green LED** shows that the equipment is ON.

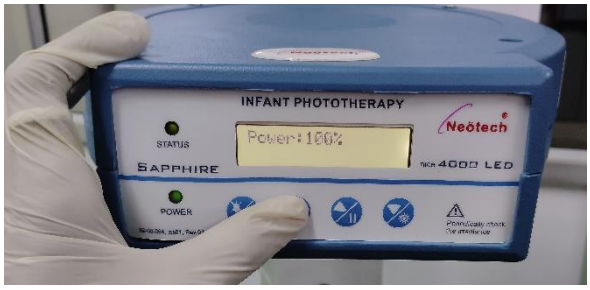
Warning

➢ Monitor the patient during treatment.

➢ Regular monitoring during treatment is recommended. Use the following guidelines:

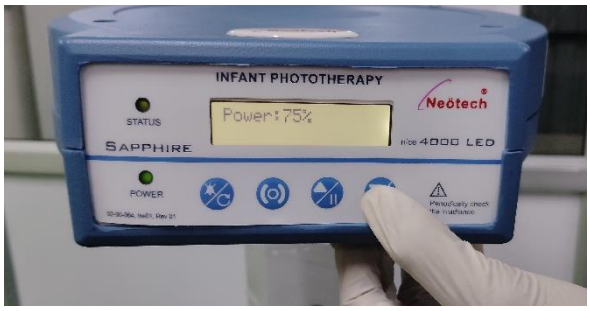
- Measure the patient's bilirubin level periodically during treatment as per your institution's procedures.
- Turn off the light when checking the baby's condition and visualizing skin color.
- Monitor patient temperature and fluid status as per your institution's procedures.
- Verify that the baby's eyes are protected and free of infection as per your institution's procedures.
- When treatment is finished, switch OFF the power and remove phototherapy from the therapy area.

3.1.2.1 Irradiance adjustment



Picture 52

➢ Press the set key to view the current % Irradiance output value



Picture 53

Picture 54

- Press the Increase/Decrease key to set the value as 25%, 50%, 75% or 100% as desired.

Note: To continue the next set parameter, press set key again. To exit from the operation wait for seven seconds - the equipment works in continuous mode & not in timer mode.

3.1.2.2. Phototherapy Timer Setting

Picture 55

- Press the set key twice to view the current timer setting.
- Use Increase/Decrease to ON or OFF the timer.
- Press the set key again to set ON or OFF the timer.

Picture 56

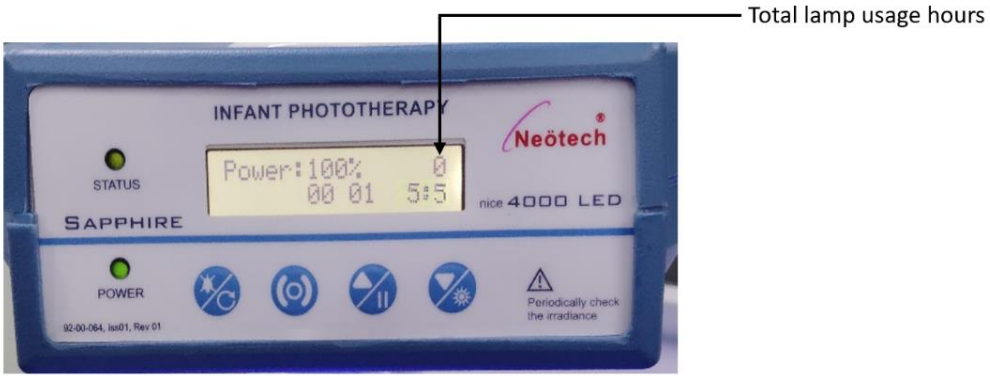
Picture 57

- Press the Increase/Decrease key to vary the timer setting up to 09 hours.

Note: To continue the next set parameter, press set key again. To exit from the operation wait for seven seconds - the equipment works in continuous mode & not in timer mode.

3.1.2.3 Total Lamp Usage Hours Display

Lamp usage hour is shown on the right top side of the LCD display panel. Usage hour is automatically updated every hour.



Picture 58

3.1.2.4 Treatment Hours Display – Timer Mode

Treatment hour is shown on the right bottom side of the LCD display panel. Treatment hour is automatically updated every hour.

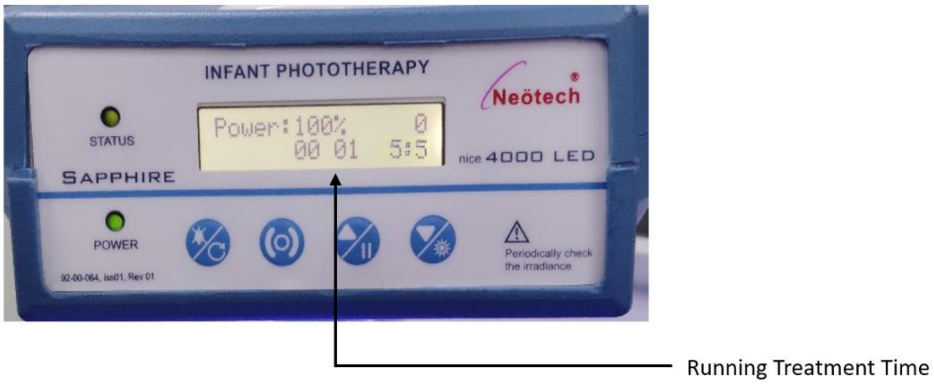
Picture 59

3.1.2.5 Running Hours Display

Running hour is shown on the Left bottom side of the LCD display panel. Timer is ON/OFF the running time is automatically updated every Minute.

Phototherapy Blue lamps are switched off when the pause key is pressed and the pause indication blinks in the LCD, for switching on, again press the pause key, the blue lamp is ON.

To reset the running time, press the reset key once.



Picture 60

3.1.3 Side Panel Control

- The ON/OFF switch is located on the right side of source unit as shown in the image.

Air Vents: Air vents are provided on top of the light Source to minimize the temperature inside the light source.

Caution

Do not cover or place any object over the air vents in order to avoid overheating of the light source.

Important: Maintain a distance of 20-40cm between the light Source and the infant to achieve optimal light intensity.

3.1.3 Effective Area / Normalized Spectra of the Blue LED

Caution

Keep the patient in the effective area, monitor periodically failing which patient falling off from the effective area.

The following graph shows the normalized spectrum of blue lamp and the spectral sensitivity of the spectrophotometer.

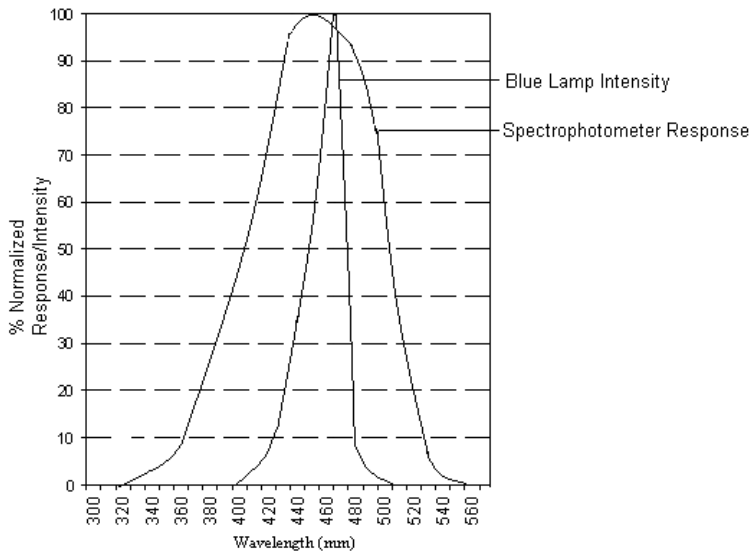


Figure 4
Calibration Curve of Radiometer Probe (International Light – SCD 144)

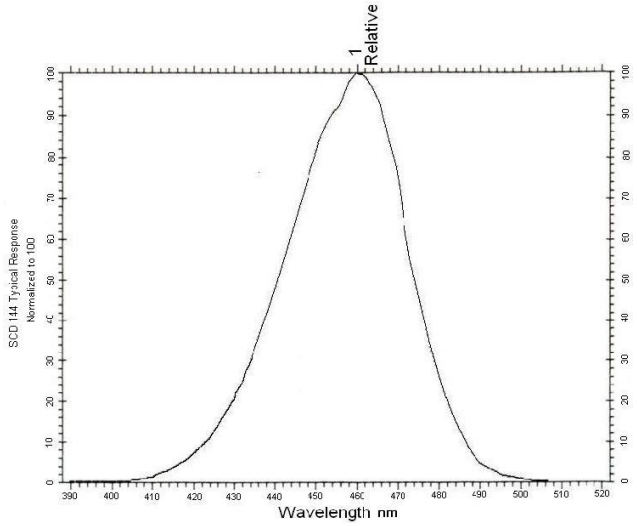


Figure 5

3.1.4 Audio and Visual Indication

Indication	Indication on front panel	Description
Time elapsed	To Continue Press -> MUTE	After time elapsed “To Continue Press -> MUTE” will displayed on the LCD screen with audio indication.
Lamp replacement	Red status LED	The lamp usage hour is greater than 20,000 hours red status LED will appear.
Over temperature	Over Temperature	If light source get overheat (> 70°C) “Over Temperature” will displayed on the LCD screen with audio indication.
Fan fail	Fan Failure	If fan gets fail or fan sensor disconnected, “Fan Failure” will displayed on the LCD screen with audio indication.
Sensor fail	Sensor Fail	If heater sensor gets fail or disconnected, “Sensor Fail” will displayed on the LCD screen with audio indication.

3.1.5 Controller Indication

Timer elapsed : After elapsing the set time it can be mute.

Lamp Replacement : > 20,000 hours it can be mute.

Over temperature : If light source get overheat (> 70°C) it can be mute (nice 4000 LED).

Fan Fail : If the fan gets fail it can be mute (nice 4000 LED).

Sensor fail : If heater sensor gets fail it can be mute (nice 4000 LED).

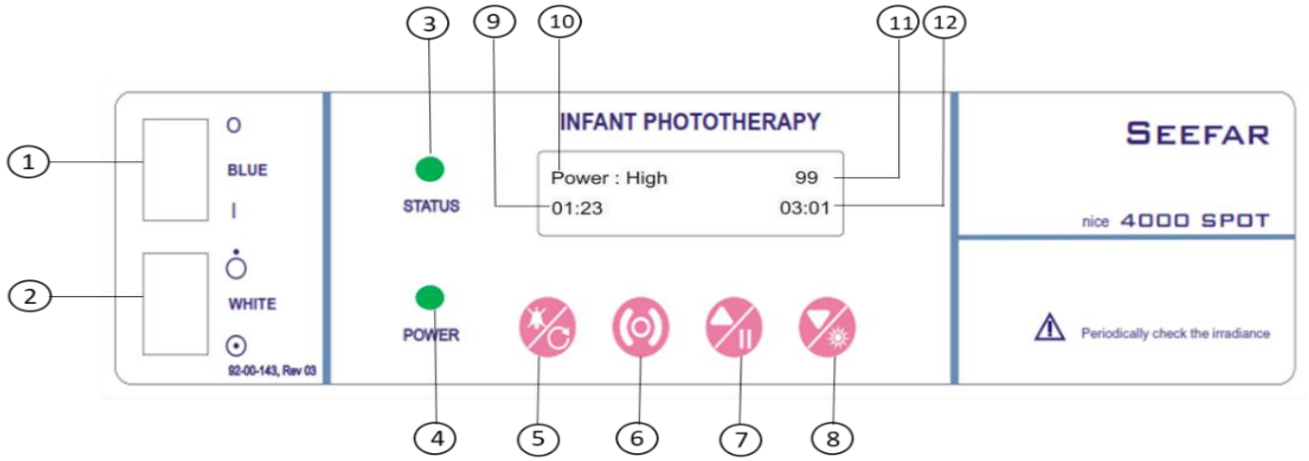
3.1.6 Shut Down procedure

- Remove the infant from the Infant phototherapy.
- Switch OFF the blue lamp by switch provided in the side panel.
- Switch OFF the main switch provided in the rear side of the infant phototherapy.

3.1.7 Transport/Movement details

- Check that all castors are in fine contact with the floor and that the Infant Phototherapy unit is stable & moves freely.
- Lock the brakes in antistatic castors to hold the phototherapy unit in static position.
- Unlock the brakes in antistatic castors to move the phototherapy unit again.

3.2. nice 4000 SPOT

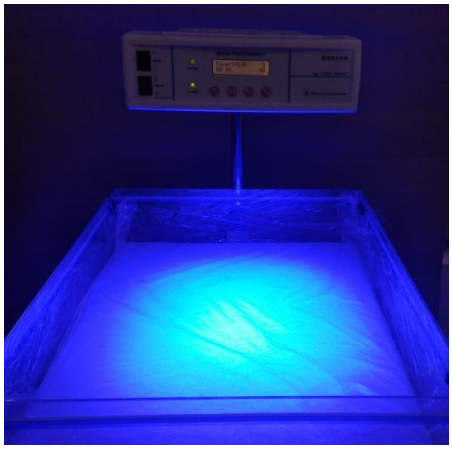


Front Panel Button and Indicators

1	Blue Lamp ON/OFF Switch	7	Increase / Pause Key
2	White Lamp ON/OFF Switch	8	Decrease / Irradiance Key
3	Status Indication	9	Running Hours
4	Power ON Indication	10	Intensity High/Low
5	Mute / Reset Key	11	Total Lamp Usages Hours
6	Set Key	12	Treatment Timer

3.2.1 Light Source

3.2.1.1 Treatment Light



Picture 61

High bright 24 Blue LED Lamps - The light provides an average intensity of >50-70 μW/cm²/nm at a distance of 40cm from the baby.

Note: Intensity can vary according to the requirement in the LED Phototherapy.

Warning

- The intensity of the lamps will decrease with usage of the lamps.
- Use of phototherapy may increase baby's skin temperature.
- To be used only on infants for whom phototherapy has been prescribed

- Cover infant's eyes with protective eye shields designed for use during phototherapy.
- **Eye Protection:** Do not look directly into the LED during treatment. Always protect the baby's eyes with eye patches or equivalent. Periodically and/or as per your hospital protocol, verify that the baby's eyes are protected and free of infection.

Caution

- A distance of more than 40cm between the light source and the baby may result in inadequate intensity.
- Continuous exposure of phototherapy treatment may cause water loss to the patient.
- Position the phototherapy light source over infant. Position the face of the light source not closer than 10 cm from the infant.
- Continuous Exposure of phototherapy may cause increase in the skin temperature. Periodically monitor the patient's skin temperature.
- Separable plug provided for isolation from the supply mains.
- Periodically check the irradiance of the Lamp for effective therapy.

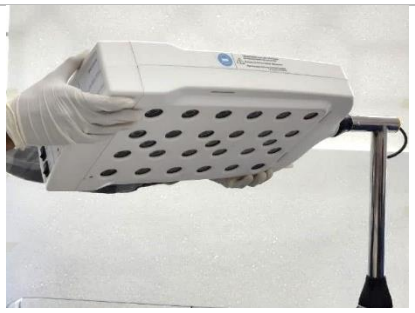
3.2.1.2 Light source height Adjustment

Picture 62

- This knob allows adjusting the height of the light Source.
- First loosen the knob, then adjust the height of the light Source by holding the ellipse pipe, and finally tighten the knob to lock the height.

Important: Maintain a distance of 20-40 cm between the light source and the infant to achieve optimal light intensity.

3.2.1.3 LED Light Source tilting



Picture 63

- LED Light Source can be tilted by grasping the device on either side and torqueing to desired angle.
- Even when the baby is in the incubator or warmer effective phototherapy treatment can be given by tilting the light source to the required angle (±90º).

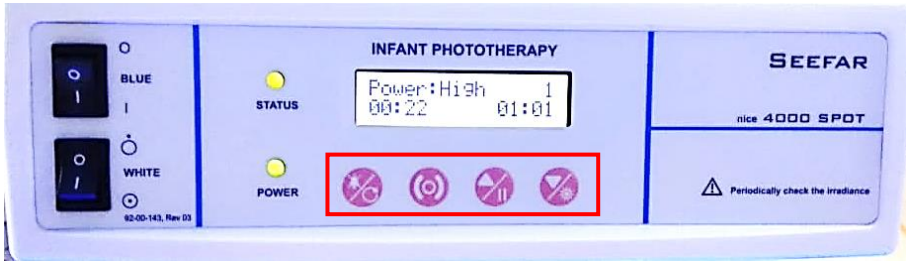
Note: Tilt or Position the light source unit to centre the light over the infant.

3.2.1.4 Switches

 Picture 64	➢ Two switches are provided in the equipment, one for Main Power ON/OFF and another for light source ON/OFF.
 Picture 65	➢ To switch ON the equipment, use the power switch at the rear side of the pedestal stand and to switch ON the Light source(Blue and white), use the power switch on the front side of the Light source.

Operator Safety: Sensitive individuals may experience headache, nausea or mild vertigo if he/she stays too long in the irradiated area. Using the Neötech Phototherapy in a well-lighted area or wearing glasses with yellow lenses can alleviate potential effects.

3.2.2 Front Panel Control



Picture 66

There are four keys in the front panel of the light source.

	Mute Key/ Reset Key	To mute the Audio and Visual Indications and To reset the running time.
	Set Key	To Set the intensity level, irradiance and timer.
	Increase/Pause Key	To increase the intensity level, irradiance and timer and to Pause the display.
	Decrease/irradiance Key	To decrease the intensity level, irradiance and timer.

There are two LED indications on the front panel of the light source:

STATUS	Status Indicator	**Status Tri Colour LED:** Status of total usage hours of the lamp: • The green colour indicates that lamp usage hour is less than 15,000. • The Amber colour indicates that lamp usage hour is greater than 15,000. • The red colour indicates that lamp usage hour is greater than 20,000.
POWER	Power Indicator	**The Power Green LED** shows that the equipment is ON.

Warning **Monitor the patient during treatment**

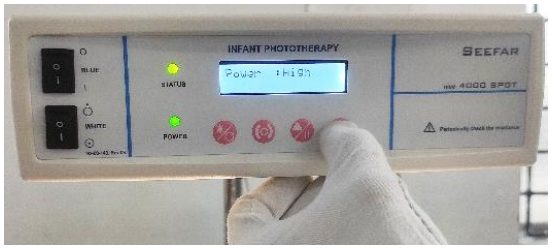
Regular monitoring during treatment is recommended. Use the following guidelines:

- Measure the patient's bilirubin level periodically during treatment as per your institution's procedures.
- Turn off the light when checking the baby's condition and visualizing skin colour.
- Monitor patient temperature and fluid status as per your institution's procedures.
- Verify that the baby's eyes are protected and free of infection as per your institution's procedures.
- When treatment is finished, switch OFF the power and remove phototherapy from the therapy area.

3.2.2.1 Irradiance adjustment

Picture 67

➢ Press the set key to view the current output range of Irradiance and the display shows "POWER".



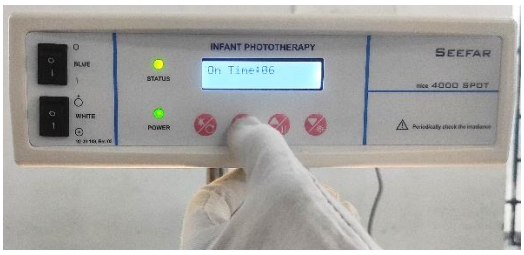
Picture 68

Picture 69

- Using the Increase/Decrease key set low or high rang as desired.

Note: To continue the next set parameter, press set key again and to exit from the operation and return to Main Menu, just wait for seven seconds, do not press any key,

3.2.2.2. Phototherapy Timer Setting



Picture 70

- Press the set key twice and the display shows “TIMER”.
- Use the Increase/Decrease key to set the timer ON or OFF.

Picture 71

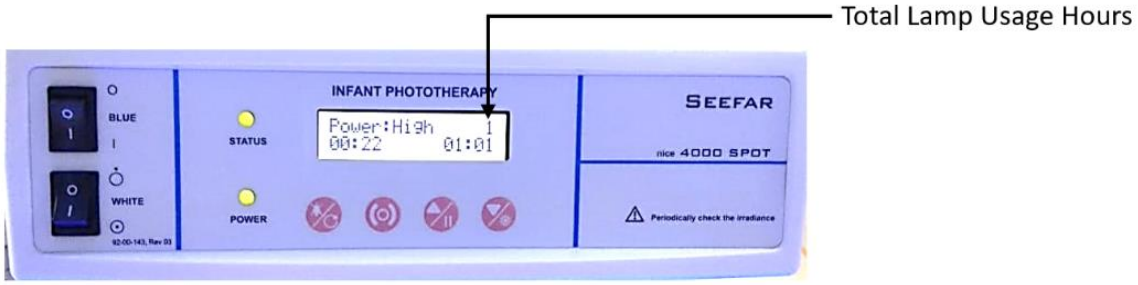
Picture 72

- Use the Increase/Decrease key to vary the timer setting up 1 to 9 hours.

Note: To continue the next set parameter, press set key again. To exit from the operation just wait for seven seconds without pressing any key. The Phototherapy works with the continuous mode if the timer is OFF.

3.2.2.3 Total Lamp Usage Hours Display

Lamp usage hour is shown on the right top side of the LCD display panel. Usage hour is automatically updated every hour.



Picture 73

3.2.2.4 Treatment Hours Display – Timer Mode

Treatment hour is shown on the right bottom side of the LCD display panel. Treatment hour is automatically updated every hour.

Picture 74

3.2.2.5 Running Hours Display

Running hour is shown on the Left bottom side of the LCD display panel. Timer is ON/OFF the running time is automatically updated every Minute.

Phototherapy Blue lamps are switched off when the pause key is pressed and the pause indication blinks in the LCD, for switching on, again press the pause key, the blue lamp is ON.

To reset the running time, press the reset key once.

Picture 75

Air Vents: Air vents are provided on top of the light Source to minimize the temperature inside the light source.

Caution: Do not cover or place any object over the air vents in order to avoid overheating of the light source,

Important: Maintain a distance of 20-40cm between the light Source and the infant to achieve optimal light intensity.

3.2.3 Effective Area /Normalized Spectra of the Blue LED

Caution: Keep the patient in the effective area, monitor periodically to avoid patient falling off from the effective area.

The following graph shows the normalized spectrum of blue lamp and the spectral sensitivity of the spectrophotometer.

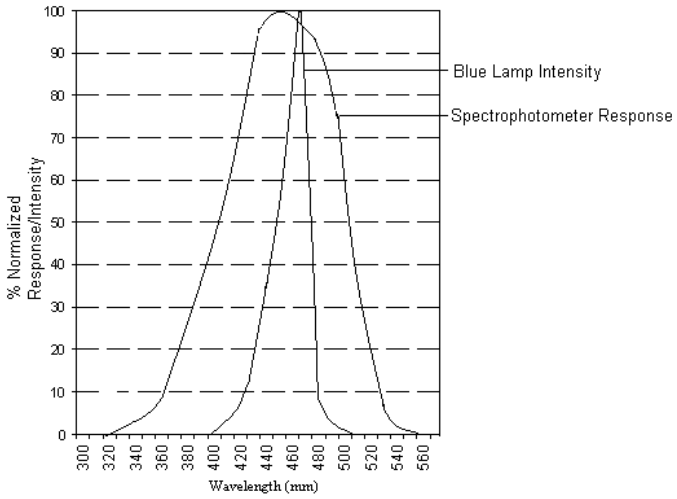


Figure 6

Calibration Curve of Radiometer Probe (International Light – SCD 144)

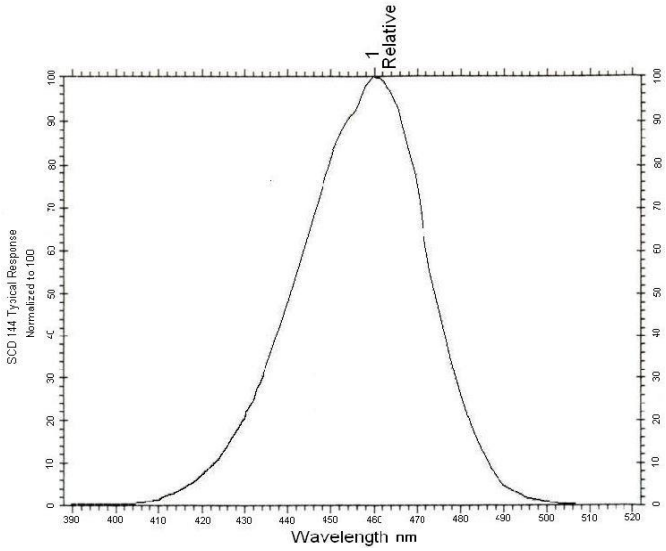


Figure 7

3.2.4 Audio and Visual Indications

Indication	Indication on front panel	Description
Time elapsed	--	After time elapsed audio indication is enabled.
Lamp replacement	Red status LED	The lamp usage hour is greater than 20,000 hours red status LED will appear.

3.2.5 Controller Audio and Visual Indications

Timer elapsed : After elapsing the set time it can be mute.
Lamp Replacement : > 20,000 hours it can be mute

3.1.6 Shut Down procedure

- Remove the infant from the Infant phototherapy.
- Switch OFF the blue lamp by switch provided in the front panel.
- Switch OFF the main switch provided in the rear side of the infant phototherapy.

3.1.7 Transport/Movement details

- Check that all castors are in fine contact with the floor and that the Infant Phototherapy unit is stable & moves freely.
- Lock the brakes in antistatic castors to hold the phototherapy unit in static position.
- Unlock the brakes in antistatic castors to move the phototherapy unit again.

3.3 Accessories

3.3.1 List of Accessories used with Infant Phototherapy

S.No.	Accessory Name	Single use / Reuse	Part no.	Intended use	Picture
1	Phototherapy Eye pad	Single-use, non-sterile	76-00-030 76-00-031 76-00-032	Intended to protect the baby's eye during phototherapy	

3.3.2 Instruction to use Phototherapy Eye pad

S. No.	Picture	Size	Instruction
1.		Small Medium Large	➢ Select the appropriate size of Eye pad for the baby
2.		➢ Place the Black fabric part of eye pad over the baby's eye.	
3.		➢ Lift the baby's head slightly and wear the elastic strap of eye pad to the back side of baby's head as shown in the image.	

4.		Ensure the eye pad is covered fully over the baby's eye.

Section 4: Cleaning and Maintenance

4.1 General
4.2 Cleaning and Disinfection of Infant Phototherapy
4.3 Life time of product

4.1 General:

- This Section Provides Cleaning and Maintenance Instructions where necessary, disassembly instructions are provided.
- Routinely inspect the height adjustment, lamp protective shield and Light source cover for signs of breakage and replace assemblies before placing Phototherapy into service.
- The service period for this equipment is six years.

- Incorrect use of the Phototherapy, or the use of parts that are not manufactured or supplied by Neötech, can damage the Phototherapy, and may cause injury to the patient and/or user.
- Do not use the Phototherapy if any parts appear damaged or if there is any reason to believe that it is not functioning properly. Contact Neötech Medical Technical Service or Neötech authorized service provider.
- This light may cause radio interference, in which case adequate measures may be required to prevent interference.
- Periodically check the insulation and the connections of the cable as it may cause fire because of poor insulation and short circuits due to ageing.
- Don’t pour the water for cleaning, it may enter into the electronics circuits it cause short circuit and get shock.
- Don’t misalign the EMI Shielding and the beads; it may cause the EMI interference to the equipment.

- 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 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.

4.2 Cleaning and Disinfection of Infant Phototherapy

During cleaning the Infant Phototherapy and its accessories, the processing shall comply with ISO 17664-1:2021 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 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 filtered water (i.e. water passed through a 0.2 µ filter).
5. Dry Infant Phototherapy using dry towel or cloth. Make sure that the unit is completely dry before using it.
6. Do not autoclave or gas sterilize the machine.

Switch off the equipment and disconnect the Power cord from the mains before cleaning.

Don’t pour water for cleaning; it may enter into the Lamp unit and Power supply unit. It will cause short circuit and get shock.

Don’t use flammable agents for cleaning.

Don’t keep the metal surface in wet condition, it may cause corrosion and damage the metal part.

4.2.1 Cleaning and disinfection of Lamp protective shield, light source and pedestal stand:

1. Physically clean the lamp protective shield, light source and pedestal stand with soft cloth, removing all visible contaminants by wiping using water general cleaning.
2. Clean the lamp protective shield, light source and pedestal stand with water damped cloth.
3. Disinfect the lamp protective shield, light source and pedestal stand by using 2% Glutaraldehyde to inactivate any remaining pathogens and leave it for 3 minutes.
4. Then rinse the lamp protective shield, light source and pedestal stand by wiping using water damped cloth
5. Dry lamp protective shield, light source and pedestal stand using dry towel or cloth

Some Chemicals cleaning agents may be Conductive and/or leave a residue which may permit a built-up of dust or dirt which may be Conductive. Do not permit cleaning agents to contact electrical components. Do not spray cleaning Solutions onto any of these Surfaces.

When cleaning the light source protective cover, care must be taken to prevent liquids from entering the Electrical circuit.

Irradiance Measurement: Measure with light meter designed to measure light in the 400-520nm with the central wave length of 460nm and a bandwidth of 60nm. Light meters with other bandwidth or center frequencies may yield different light output value.

Disconnect the power cord of Phototherapy from AC power before cleaning.

Alcohol can cause crazing of the Clear Acrylic. Do not Use alcohol for Cleaning.
Important: Perform a complete functional checkout (refer section 2) before returning the unit to service.

4.3 Life time of product

The lifetime of the LED lamps are 20,000 hours and it can be replaced if necessary to extend the lifetime of Infant Phototherapy and 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 five years and Service life of the device is extendable up to 1 years considering the replacement of spares and faulty components. So, the service life of the device is six years (5 years of lifetime + 1 year service life).

Section 5: Specifications

nice 4000 LED

Voltage supply	~230V/50Hz
Power Rating	60VA Max
Lamp wattage	5 Watts Blue LED, 1 Watts White LED
Fuse	F2AL/250V
Light Source	9 High Bright Blue LED, 4 High Bright White LED
Wavelength	Range 450 to 465nm, Peak 460nm.
Irradiance	9 High bright Blue LED, 60 µW/cm^2/nm at a distance of 30 cm. (Irradiance can be variable)
Effective Surface Area	500mm X 300mm.
Stabilization Period	0.5 hour
Height Adjustability	125–155cm from the floor
Light Source Tilting	-90º to +90° continuous (180°)
Lamp Usage Hours	>20000 Hours
Controls and Display	
Irradiance Output variable	25 – 100% increment of 25 %
Total Lamp Usage Hours	1 – 20000 hours (non-resettable).
Set Timer	1-9 hours
Treatment Time	Resettable.
Status Indication	Tri Color LED.
Thermostat	70±5°C, NC, Auto reset.
Controller Indications	
Timer elapsed	After elapsing the set time.
Lamp Replacement	> 20,000 hours.
Over temperature	If light source get overheat >70°C.
Audible noise	< 50 dB
MDD – Product Classification	Class IIa
IEC 60601-1 Specifications	
Type of Protection against electric shock	Class 1
Degree of Protection against electric shock	No applied part

Mode of Operation	Continuous
Protection against hazardous of explosion	Not protected
Protection against ingress of liquid	IP 20
Pollution degree	2
Operating Conditions	
Temperature range	10°C to 30°C
Humidity range	15 – 90% RH, non-condensing
Altitude	Sea level to 1.9 miles (3Kms)
Atmospheric Pressure	50 - 106 kPa
Transport and Storage conditions	
Temperature range	-10°C to 60 °C
Humidity range	50% - 90% RH, non-condensing
Dimension & Weight	
Equipment Dimension	(125-155) cm (H) X 67cm (W) X 85cm (L)
Equipment Weight	17kg
Mobility	3” castors with brake 2nos and 2”castor without brake 1no
Quality and Test approval	
Quality	ISO 13485:2016
Electrical & Product Safety	IEC 60601-1 & IEC 60601-1-2 IEC 60601-2-50
Graphical Symbols	ISO 15223-1

nice 4000 SPOT

Voltage supply	~230V/50Hz
Power Rating	70VA Max
Lamp wattage	1 Watt
Fuses	F2AL/250V
Light Source	24 High bright Blue LED 3 High Bright White LED
Wavelength	Range 450 to 465nm, Peak 460nm.
White light Luminous flux	130-140 lm for White LED.
White light color temperature	6000-6500K
Irradiance at a distance of 40 cm. (Irradiance can be variable)	24 High bright Blue LED, 50 - 55µW/cm^2/nm
Effective Surface Area	600mm X 500mm.

Stabilization period	0.5 hour
Height Adjustability	110–160cm from the floor.
Light Source Tilting	-90º to +90° continuous (180°)
Lamp Usage Hours	>20000 Hours.
Controls and Display	
Irradiance Output variable	High setting / Low setting
Total Lamp Usage Hours	1 – 20000 hours (non-resettable).
Set Timer	1-9 hours
Treatment Time	Resettable.
Status Indication	Tri Color LED.
Thermostat	70±5°C, NC, Auto reset.
Controller Indications	
Timer elapsed	After elapsing the set time.
Lamp Replacement	> 20,000 hours.
Over temperature	If light source get overheat >70°C.
Audible noise	< 50 dB
MDD - Product Classification	Class II a
IEC 60601-1 Specifications	
Type of Protection against electric shock	Class 1
Degree of Protection against electric shock	No applied part
Mode of Operation	Continuous
Protection against hazardous of explosion	Not protected
Protection against ingress of liquid	Not protected
Pollution degree	2
Operating Conditions	
Temperature range	10ºC to 30ºC
Humidity range	15 – 90% RH, non-condensing
Altitude	Sea level to 1.9 miles (3Kms)
Atmospheric Pressure	50 - 106 kPa
Quality Test Approval	
Quality Management System	ISO 13485:2016
Electrical Safety Standard & Particular standard	IEC 60601-1 & IEC 60601-1-2 IEC 60601-2-50
Graphical Symbols	ISO 15223-1: 2021
Transport and Storage conditions	
Temperature range	-10°C to 60 °C
Humidity range	50% - 90% RH, non-condensing
Physical Dimensions and weight	

Equipment Dimension	77cm (L) x57 cm (W) x110-160 cm (H)
Equipment Weight	14 Kg
Mobility	4 nos. 2” castors 2 with brake and 2 without brake

Note

1. The irradiance is measured by using an international ILT74 Hyperbilirubinemia light meter.

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. 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. Life time of the product is five years and Service life of the device is extendable up to 1 years so, the service life of the device is six years (5 years of lifetime + 1 year service life).

Customer Details cum Warranty Card

Date: _____

Hospital Name & Address: _____

_____

Contact Person & Telephone/Fax No_____

Email _____

Department: NICU / PICU / OT / Gynecology / 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 sent the same

From _____
_____
_____

To:
The Service In-charge
nice Neotech Medical Systems Pvt. Ltd.
No, 85-86 Krishna Industrial Estate,
Mettukuppam, Vannagaram,
Channai-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 Equipment Failure

S. No.	Problem	Cause	Remedy
1.	Equipment not functioning	Power Failure.	Check the unit if Plugged in to Main supply
		Switch is not turned ON	Check the mains are switched ON.
			Otherwise Contact nice Neotech
2.	Equipment not functioning, Power is ON.	Internal wire may be disconnected	Contact nice Neotech.
3.	Equipment is not functioning Main power is ON	12V DC power cable may be disconnected in the source unit	Check the unit if Plugged in to DC supply
			Check the light source is switched ON.
			Otherwise Contact nice Neotech
4.	Over temperature (nice 4000 LED only)	If heat sink temperature is > 70°C	Contact Neotech
5.	FAN failure (nice 4000 LED only)	Fan may be disconnected or defected	Contact Neotech
6.	All blue LEDs are OFF and alarm occurs	Timer may be time up after set time.	Reset the timer by pressing mute key.

7.2 Phototherapy Failure

nice 4000 LED and nice 4000 SPOT

S. No.	Problem	Cause	Remedy
1.	Lamps are not ON (LED)	Power Failure	Check the Power
		Power Cord disconnection	Re-connect the power cord.
		Defective D.C. Power cord	Contact Neötech
		LED may be defective	Contact Neötech
		Fuse blown	Replace Fuses
2.	Lamps are frequently fluctuating(LED)	Power Fluctuation	Use Stabilizer

3.	Height cannot be adjusted	Knob may be over tightened	Unscrew the height adjustment knob and adjust required level
			Contact Neötech
4.	Can't move the machine	Brakes may be applied on the castors.	Release the brake.
		Castors damaged	Change the Castors
			Contact Neötech
5.	Unable to tilt the source unit	Source module may be struck	Slightly shake and rotate the source module
			Contact Neötech
6.	Lamp usage Hours display is not working	LCD may be damaged	Contact Neötech
		Microprocessor may be defective	
7.	Irradiance level not adjustable	LCD may be damaged	Contact Neötech
		Microprocessor may be defective	
		Keys may be defective	
8.	LED Lamps are turned ON but the fan is OFF.	Fan is jammed due to debris	Clean the fan.
		Defective fan	Contact Neötech
		Defective wiring	
9.	Some LED's are not lit	LED may be defective	Contact Neötech

7.3 Maintenance Intervals

Periodically check the insulation and the connection of the cable; it may cause fire because of poor insulation and short circuits due to ageing.

Don't misalign the EMI Shielding and the beads; it may cause the EMI interference to the equipment

1. The equipment requires no maintenance between routine usage period other than a functional test each time the nice 4000 LED, nice 4000 SPOT is put into usage, and an irradiance check at least once a month.

2. At least once every six months the equipment should be examined by qualified Service Engineer to ensure operational safety.

3. Check the time totalizer reading and compare with the pre ageing hours of the lamp (as per section 1.6). If the hours are elapsed, replace all the lamps.

4. If the equipment is dropped or damaged or becomes excessively wet, take it out of service immediately for examination by a qualified Service Engineer to ensure safety and operational integrity.

5. A Service Manual enabling qualified technical personnel to carry on routine service schedules, fault finding and repairs is available from nice Neötech. nice Neötech can accept no responsibility for any deterioration in the safety, reliability or performance of equipment that has been modified, adjusted or repaired by persons other than representatives of nice Neötech.

6. The service life of the device is six years (5 years of lifetime + 1 year service life).

Light Intensity at 25%

nice 4000 LED : 9 High Blue LED 60 µW/cm2/nm at a distance of 30 cm (Irradiance can be variable)

nice 4000 SPOT : 24 High Blue LED >45 µW/cm2/nm at a distance of 30 cm (Irradiance can be variable)

The light intensity may be reduced to 25% of its total irradiance due to ageing/different height from mattress to light source. Check the light source with radio meter, if the irradiance is not at specified level replace all the Lamp (LED) or adjust the height of the light source.

7.3.1 Checking the Light Intensity

1. It is recommended that the intensity of the light be checked before each use, and at least every six months.

Note: The intensity of the light will be adversely affected if the LED Blue lamps burn out. Have a qualified technician to replace the lamps, if required.

- Only qualified personnel should perform service and repair. Take extreme care when working with exposed circuitry.
- Adjusting the Light Intensity: If the intensity of light falls to less than the desired extent, all Lamps (LED Lamps) need to be replaced.
- If the unit is not functionally and/or operationally reliable, it must be repaired or the operator should inform the concern of the danger arising from the use of the unit

7.3.2 Lamp Failure

1. If a single lamp fails, replace the same at the earliest opportunity.

2. If a lamp unit fails when Phototherapy is switched ON, check whether the relevant power cable is connected and that phototherapy fuses are in good condition.

3. If a lamp unit fails during use, suspect either a fuse failure or overheating which has caused the thermal cutout.

7.3.3 Lamp Replacement

To replace a lamp and clean the interior of the lamp housing necessitates opening the Phototherapy Unit and should be carried out by a qualified Service Engineer.

Take the machine out of usages before replacing a lamp.

If lamp has failed, then switch OFF the equipment, disconnect the power cord and allow the unit to cool down.

For lamp replacement, contact nice Neötech. Only use lamps approved by nice Neötech for replacement, as using unauthorized lamps may alter the unit's performance characteristics, potentially compromising patient safety.

Burn in time: After replacing the Lamp, the equipment should be put in ON for a minimum of 0.5 -3 hours for burn in test, to verify the functions of phototherapy unit

Before the unit is put into usages check that the Phototherapy functions correctly.

7.3.4 Fuse Replacement

If a lamp unit fails during use, suspect either a fuse failure or overheating which has caused the thermal cutout.

1. Switch OFF the equipment and disconnect the power supply by removing the power cord from AC supply.
2. Remove the fuse holders and check the fuses for continuity.
3. If necessary, fit a new fuse of the type and rating specified.

   DO NOT FIT A FUSE WITH A HIGHER CURRENT RATING
4. If the lamps still fail to light or the fuses blow again, take the equipment out of service for examination by a qualified Service Engineer.

Note:

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

Inspection & Maintenance: Yearly by trained Service Personnel.

Safety Checks:

The following must be performed on this unit at least every 6 months by persons who are capable of carrying out these safety tests in a proper way on the basis of their training. Knowledge and practical experience and who do not have to be instructed in this work.

Visual checks of the unit for mechanical damage affecting functions:

- Clarity of Acrylic protective lens. In the event of wear or poor clarity replace the same.

- Check the Height Adjustment.
- Check the Light source tilting.
- Check Safety Warning notices for ‘Legibility’.
- Check equipment fuse links for rated current and fusing characteristic.
- Perform functional check according to operating instructions (section 3)
- Check the power supply cord.

7.4 Disposing of the Unit

At the end of its usage life

- Dispose of the equipment in accordance with National Waste Disposal Regulations

or

- Ask a suitable Disposal contractor to dispose of the unit.
- Dispose the single use eye pad in accordance with National Waste Disposal Regulations or as per hospital waste disposal protocol.

The local Environmental agency can supply further details.

Section 8: Spare Parts List

nice 4000 LED

Sl. No.	Part No.	Part Name	Qty	Unit
1	93-00-030	Castor 3" with Brake (Double Wheel)	2.00	No
2	93-00-025	Castor 2" without Brake	1.00	NO
3	40-05-032	PCB Assembly	1.00	No
4	90-00-040	Power Cord	1.00	No
5	91-00-221	SMPS 12V DC (RPS)	1.00	No
6	91-00-173	Fan 12V DC	1.00	No
7	89-14-038	Blue LED 5 Watts (nice 4000 LED)	9.00	No
8	89-14-022	White High Power 1 watts	4.00	No
8	89-14-039	Lens 45° diffuser (nice 4000 LED)	13.00	No
9	91-00-084	Thermostat 70 ±5°C, NC	1.00	No
10	89-16-032	Fuse 2 amps	1.00	No

nice 4000 SPOT

S. No.	Part No.	Part Name	Qty	Unit
1.	93-00-024	Castor 2" with Brake	2.00	No
2.	93-00-025	Castor 2" without Brake	2.00	No
3.	40-05-057	PCB Assembly	1.00	No
4.	90-00-040	Power Cord	1.00	No
5.	91-00-221	SMPS 12V DC (RPS)	1.00	No
6.	91-00-173	Fan 12V DC	1.00	No
7.	89-14-021	Blue LED 1 Watt	24.00	No
8.	89-14-022	White LED 1 Watt	3.00	No
9.	89-14-039	Lens 45° (nice 4000 SPOT)	27.00	No
10.	91-00-084	Thermostat 70 ±5°C, NC	1.00	No
11.	89-16-032	Fuse 2 amps	1.00	No

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.			

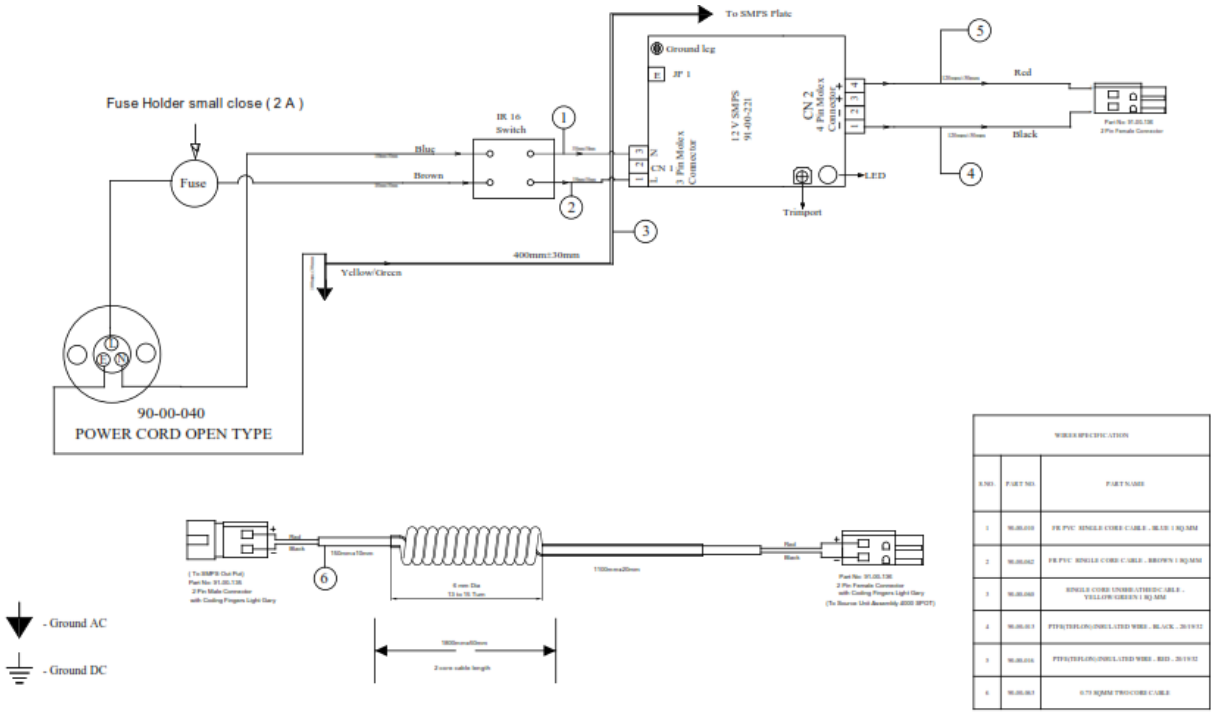
Guidance and manufacturer's declaration – electromagnetic immunity			
The Phototherapy Unit is intended for use in the electromagnetic environment specified below. The customer or the user of the Phototherapy Unit should assure that it is used in such an environment.			
IMMUNITY test	**IEC 60601 test 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:

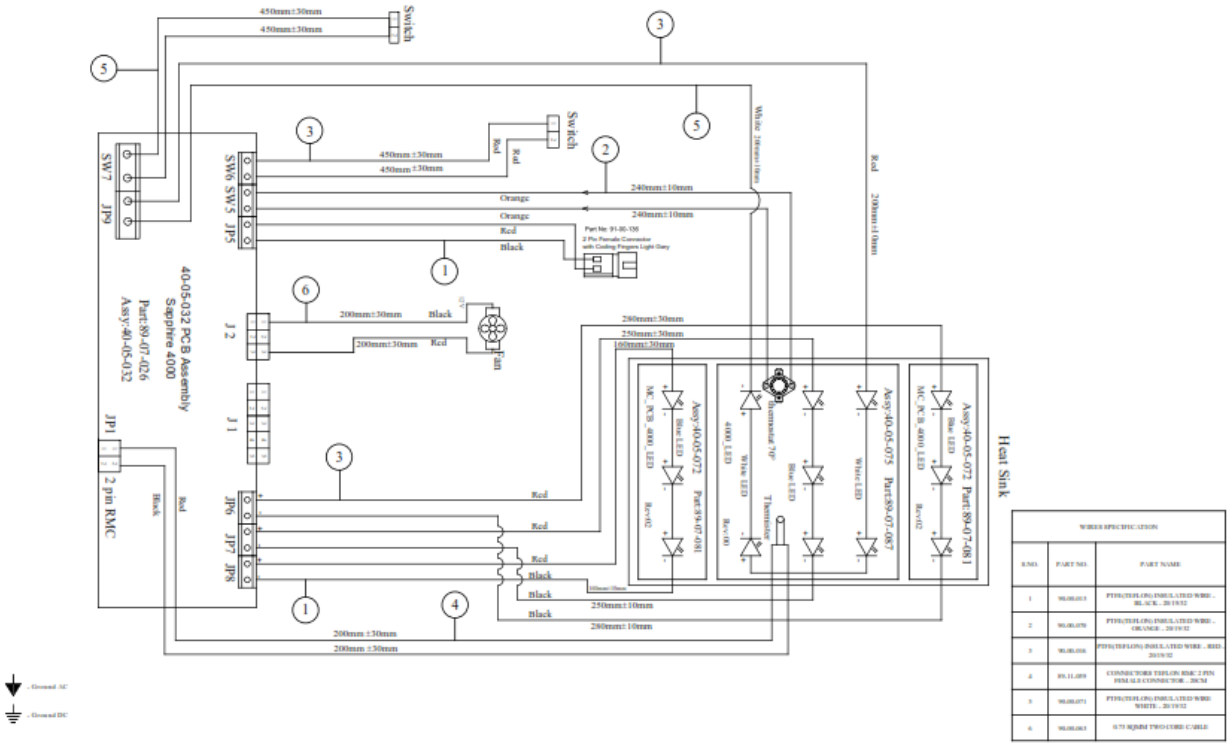
Performance criteria	Description
A	Normal performance within limits specified by nice Neotech
B	Temporary loss of function or degradation of performance which ceases after the disturbance ceases, and from which the equipment under test recovers its normal performance, without operator intervention
C	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 Drawing

1. nice 4000 LED

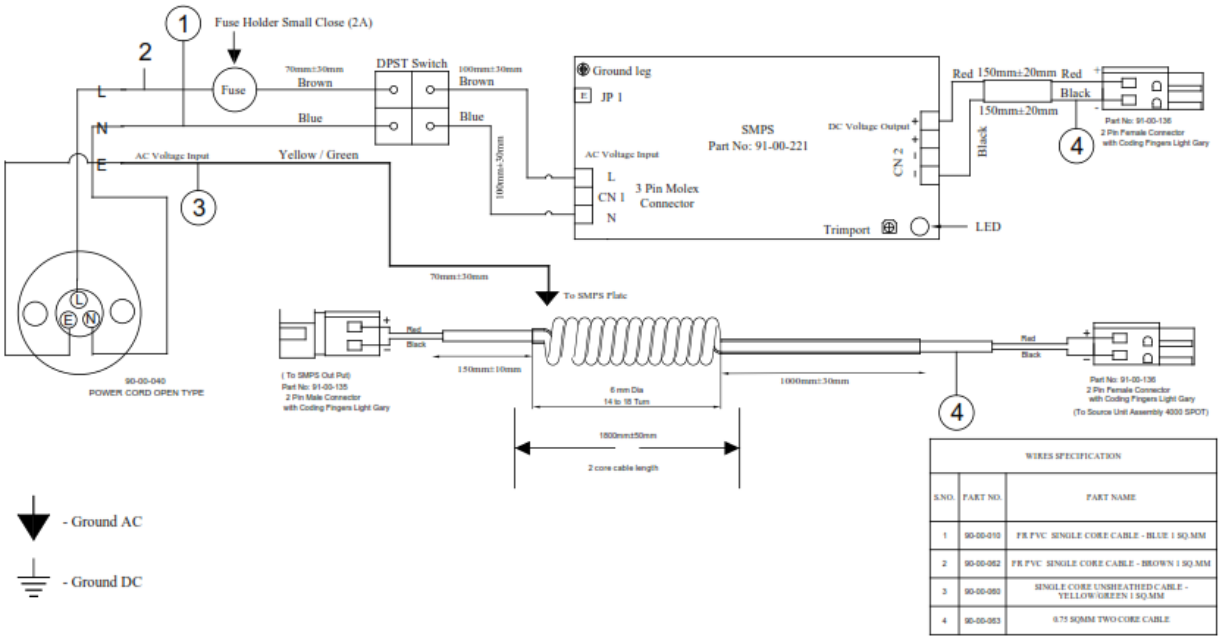


Pillar Assembly



Source unit assembly

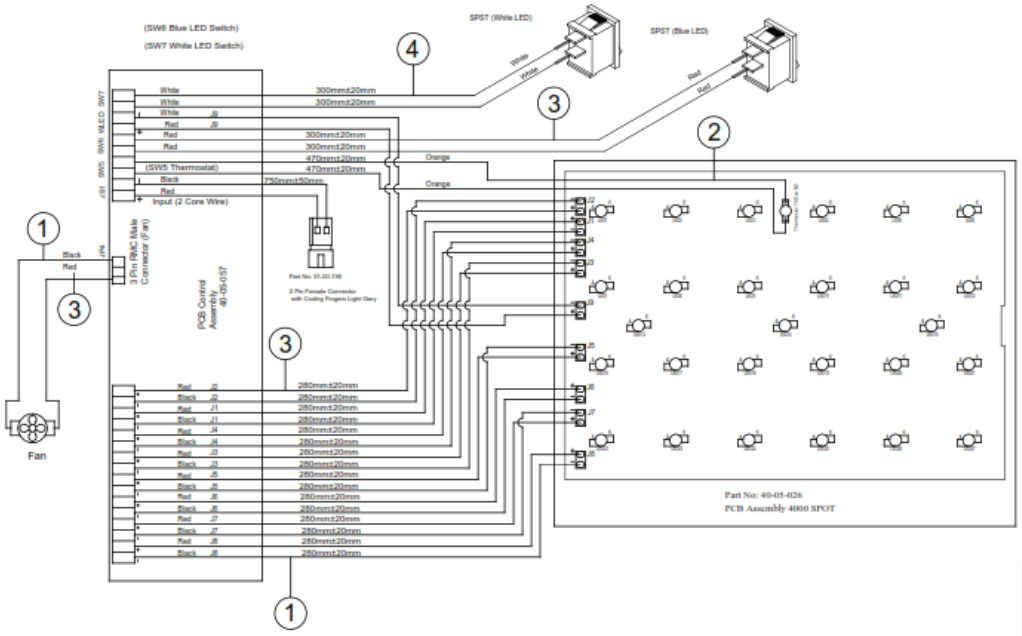
2. nice 4000 SPOT



WIRES SPECIFICATION

S.NO.	PART NO.	PART NAME
1	90-00-010	FR PVC SINGLE CORE CABLE - BLUE 1 SQ.MM
2	90-00-062	FR PVC SINGLE CORE CABLE - BROWN 1 SQ.MM
3	90-00-060	SINGLE CORE UNSHEATHED CABLE - YELLOW/GREEN 1 SQ.MM
4	90-00-063	0.75 SQMM TWO CORE CABLE

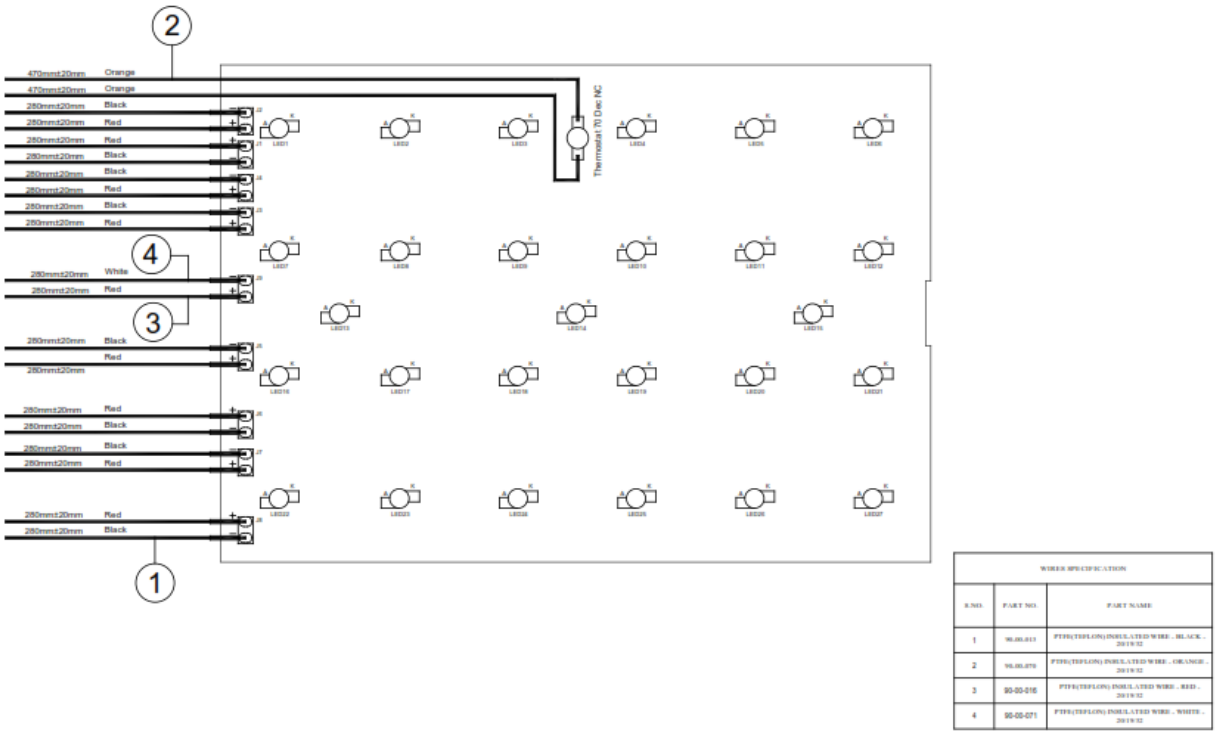
Pillar Assembly



WIRES SPECIFICATION

S.NO.	PART NO.	PART NAME
1	90-00-013	PTFE(TEFLON) INSULATED WIRE - BLACK - 20/0.32
2	90-00-070	PTFE(TEFLON) INSULATED WIRE - ORANGE - 20/0.32
3	90-00-076	PTFE(TEFLON) INSULATED WIRE - RED - 20/0.32
4	90-00-071	PTFE(TEFLON) INSULATED WIRE - WHITE - 20/0.32

Source Unit Assembly



WIRES SPECIFICATION		
S.NO.	PART NO.	PART NAME
1	90-00-013	PTFE(TEFLON) INSULATED WIRE , BLACK , 20/0/32
2	90-00-070	PTFE(TEFLON) INSULATED WIRE , ORANGE , 20/0/32
3	90-00-016	PTFE(TEFLON) INSULATED WIRE , RED , 20/0/32
4	90-00-071	PTFE(TEFLON) INSULATED WIRE , WHITE , 20/0/32

PCB Assembly

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, 85-86. Krishna Industrial Estate,
Mettukuppam, Vanagaram,
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. 85-86, Krishna Industrial Estate, Mettukuppam, Vanagaram, 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

Section 12: EC certificate notified body

Name:

PCBC – POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A.

Notified body number:

1434

Address:

02-844 Warsaw,
469 Pulawska Street,
Poland.

Ph: +48 22 46 45 200
email:pcbc@pcbc.gov.pl