

## Infant Phototherapy

# nice 4000 SPOT, nice 4005 SPOT

## 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 SPOT**



**nice 4005 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.



### Warning

- 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

nice Neötech Infant Phototherapy unit provide a light source of Blue light for infants and paediatric patients.

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.

The model nice 4005 SPOT is an undersurface phototherapy which can be used with observation trolley having a transparent bed area. The light source consists of a light weight plastic enclosure with 24 Blue LED, which can be placed on a surface.

## 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 LEDs 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:



**Warning**

- 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.



**Caution**

- 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



### 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 Neotech, can damage the light, and may cause injury to the patient and/or user.
- 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 Neotech Medical Technical Service or our authorized service provider.
- This light may cause radio interference, in which case adequate measures may be required to prevent interference.
- 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 Neotech 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.
- **Combustible gases:** Do not use the light in the presence of gases that support combustion (for example, oxygen, nitrous oxide, or other anaesthetic agents).

- **Disconnect electrical power:** Always switch off the power and disconnect the power cord when cleaning the Phototherapy unit.
- There is a possibility of electromagnetic interference or other interference causes from other external equipment and the phototherapy may get affected. Use EMC compliance Equipment to avoid the interference.
- The Phototherapy may cause radio interference, in which case adequate measures may be required to prevent interference.
- **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°.

## Section B: Caution



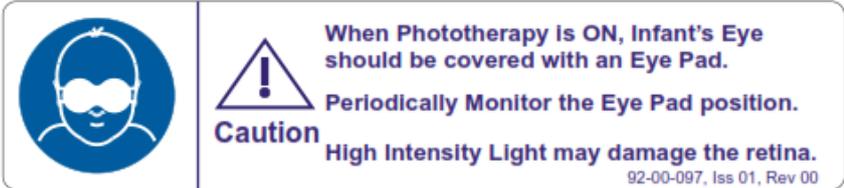
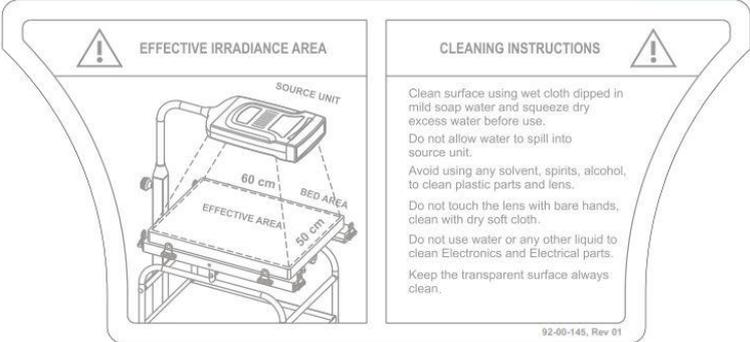
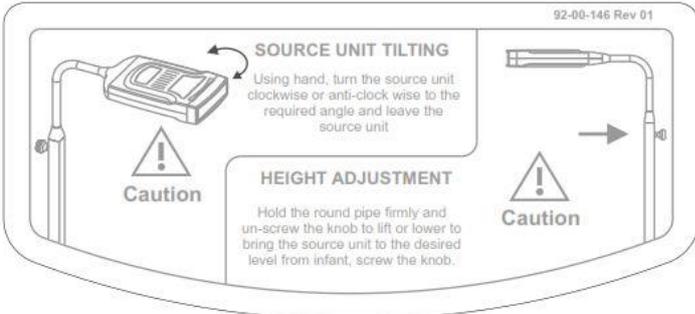
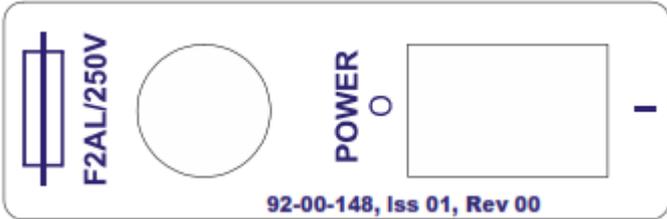
- **Other equipment:** Do not attach other equipment to the Neötech Phototherapy or place anything on top of it. The pedestal stand and light unit are not designed to support additional equipment.
- Voltage fluctuation may damage the lamps. Use voltage stabilizer for stable voltage.
- The use of eye 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 defibrillator.
- 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.

## Section C: Symbols & Labels

Mark	Indication
	Caution
	Warning
	Caution, ignition (Indicates possible ignition under certain condition)
	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
	Serial Number
	Authorized Representative in European Community
	Date of Manufacture

	Manufacturer
	Model Number
	Refer Instruction for use
	Audio Paused / Reset Key
	Set Key
	Increase/Pause Key
	Decrease Key
	Non-sterile
	Eye pad-Single use

Labels

S.No.	Label	Description
1.		Label, Eye mask
2.		Label, Toll free
3.		Label, 4000 SPOT irradiance area
4.		Label, 4000 SPOT tilting & Height adjustment
5.		Label, nice 4000 SPOT power Switch & fuse

<p>6.</p>		<p>Label, nice 4000 SPOT Infant Phototherapy</p>
<p>7.</p>		<p>Label, nice 4005 SPOT Infant Phototherapy</p>
<p>8.</p>		<p>Label, 4000 SPOT No stepping on surface</p>
<p>9.</p>		<p>Label – Marking plate</p>
<p>10.</p>		<p>Label – Packaging, Transportation and storage Instruction</p>

<p>11.</p>	 <p>nice Neötech Medical Systems Pvt. Ltd. No.85, Krishna Industrial Estate, Vanagaram, Mettukuppam, Chennai - 600 095, India. Tel:+91-44-24782594, Web: www.niceneotech.com</p> <p><b>REF</b> 76-00-032</p> <p>Product Name: Eye Pad Large</p> <p><b>LOT</b> LOT 76-00-032-20100700</p> <p>Single Use Only</p> <p>03-2019 CE 1434 02-2024</p>	<p>Eye Pad</p>
<p>12.</p>		<p>nice Neötech – Brand Logo</p>
<p>13.</p>		<p>Label – CE Mark</p>

## Section 1: Description

### 1.1 Intended Use

The model **nice 4000 SPOT** 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.

The model **nice 4005 SPOT** Phototherapy light is intended for the treatment of neonatal hyperbilirubinemia. The light can be used for infants in a bassinet or radiant warmer.

**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.

### 1.2 Indication

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

### 1.3 Contraindication

Infant Phototherapy is contradicted for elevated direct (conjugated) serum bilirubin; Phototherapy in these infants may cause the skin to turn grayish-brown, a phenomenon termed bronze baby syndrome. If skin discoloration does occur, it will fade with time.

### 1.4 Side – effects

Phototherapy may affect insensible water loss, retinal damage, mother and infant separation, rashes.

### 1.5 Target Population:

Premature and Neonates

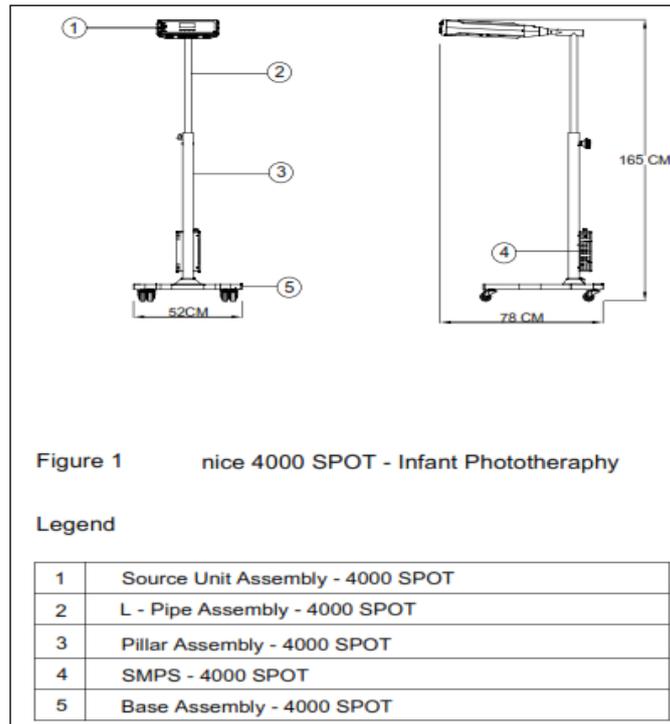
### 1.6. Working principle

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.

Phototherapy (light treatment) is the process of using light to eliminate bilirubin in the blood. Baby's skin and blood absorb these light waves. These light waves are absorbed by baby's skin and blood and change bilirubin into products, which can pass through their system.

For over 30 years, phototherapy treatment in the hospital has been provided by a row of lights or LED suspended at a distance from 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.

## 1.7 Product description



- A mains electricity (AC-powered) device designed to emit a blue light, the light output is optimized to provide an intensity of  $>50-55 \mu\text{W}/\text{cm}^2/\text{nm}$  for nice 4000 SPOT 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.
- Exposure to this device will alter the bilirubin through photo-oxidation, and configurational and structural isomerization, allowing the body to dispose of it naturally. It will typically have a built-in timer, but some may have a separate timer unit connected.
- LED light intensity can be varied from 25% to 100%
- The Stand is designed to hold source unit with a base designed to accommodate the weight distribution of the light enclosure at any height or angle
- The light Source consists of a lightweight plastic enclosure with 24 High Bright Blue LED for nice 4000 SPOT, which is mounted on a stand. The light source can be tilted.

## Section 2: Installation

### 2.1 nice 4000 SPOT

#### 2.1.1 Unpacking and Inspection

- Remove the equipment from shipping containers and unpack all the assemblies and accessories of Infant Radiant Warmer.
- After removal from the shipping containers, inspect the nice Neötech Infant Radiant Warmer 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.



**Warning**

- Do not use the equipment, if damage is found.

#### 2.1.2 Installation of Phototherapy

##### 2.1.2.1 Assembling Base and pedestal stand

###### Base Unit



Picture 1

- 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.

##### 2.1.2.2 Pedestal Stand height adjustment: Vertical frame with Round Pipe



Picture 2

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

### 2.1.2.3 Assembling of Pedestal Stand and Light source.

#### I. Light source (LED)



Picture 3



Picture 4



Picture 5

- The source unit consists of 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 round pipe.
- 4x8 SS Button head is fixed by M4 Allen bolt on both sides of the round pipe.

#### II. Light Source Tilting:



Picture 6

- The light Source can be tilted by grasping the device on either side and torqueing to desired angle up to 180 degrees.

### 2.1.2.4 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.



**Warning**

- Do not move the LED Phototherapy by pushing or pulling on the bed side panels. This action may lead to the deterioration and breakage of the components which form a safety barrier around the infant.

### 2.1.3 Mechanical Checkout Procedure



**Warning**

- 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.

#### 2.1.3.1 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 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.



**Warning**

- 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 whether the light Source can be tilted by grasping the device on either side or torquing to desired angle.

## 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 round pipe, and tighten the knob to lock the height.

## III. Locking Castors (2 nos.)



Picture 10

- Check whether the light Source can be tilted by grasping the device on either side or torquing 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.



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

## 2.1.4 Light Source Checkout Procedure

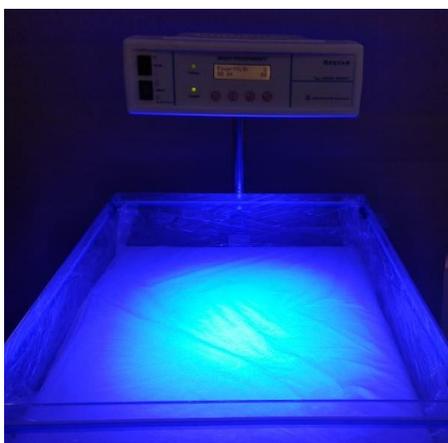
### 2.1.4.1 Check the Tilting of the light source



Picture 11

- Check the light Source whether it can be tilted by grasping the device on either side and torqueing to the desired angle up to 180 degrees.

### 2.1.4.2 Check the Working of light source.



Picture 12

- 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, should be ON at the side of the light source.

#### 2.1.4.2.1 Check the irradiance adjustment



Picture 13



Picture 14

- Press the set key and the display shows "POWER".
- Using the Increase/Decrease key set the value as low or high as desired.

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

#### 2.1.4.2.2 Check the Phototherapy Timer Setting



Picture 15



Picture 16

- Press the set key twice and the display shows “TIMER”.
- Use the Increase/Decrease key to vary the timer setting up to 22 hours.

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

#### 2.1.4.2.3 Check the Lamp Usage Hours Display



Picture 17

- 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 18

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

#### 2.1.4.2.5 Check the Status Indication LED



Picture 19

- 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.

#### 2.1.4.2.6 Check the Power Indication LED



Picture 20

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

## 2.2 nice 4005 SPOT

### 2.2.1 Unpacking and Inspection

- Remove the equipment from shipping containers and unpack all the assemblies and accessories of Infant Radiant Warmer.
- After removal from the shipping containers, inspect the nice Neötech Infant Radiant Warmer 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.



**Warning**

- Do not use the equipment, if damage is found.

### 2.2.2 Installation of Phototherapy

#### 2.2.2.1 Installing the observation trolley with the source unit



Picture 21

- The observation trolley consists of castors, side panels, storage tray to hold phototherapy. It is fixed using the appropriate screws and nuts.
- The phototherapy source unit is now placed on the storage tray provided for the placement of light source.

### 2.2.3 Mechanical Checkout Procedure



**Warning**

- Before using the nice Neotech 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.

**Warning:** 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

##### 2.2.3.2.1 Check the Angle of the light source

Check the light Source, can be tilted by grasping the device on either side and torquing to desired angle up to 180 degrees.

### 2.2.3.2.2 Locking Castors (2 nos.)



Picture 22

- Once the light source is in placed on the storage tray 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.

### Check the Protective Cover

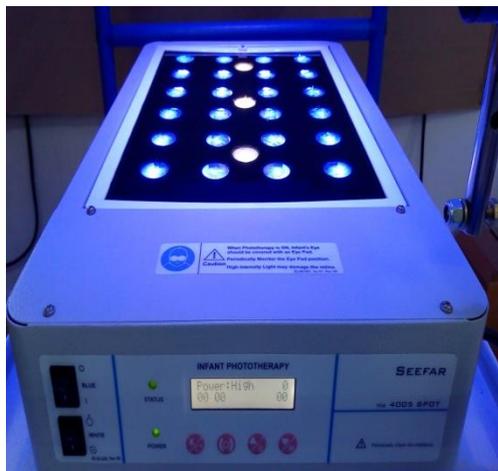
- ❖ Check the external acrylic lens, it should be clear and clean.



- 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 Working of light source.



Picture 23

- 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 rear of the pedestal stand.
- Check the light source ON / OFF switch, should be ON at the side of the light source.

#### 2.2.4.1.1 Check the irradiance adjustment



Picture 24

- Press the set key and the display shows "POWER".
- Using the Increase/Decrease key set the value as low or high as desired.

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

#### 2.2.4.1.2 Check the Phototherapy Timer Setting

Press the set key twice and the display shows "TIMER". Use the Increase/Decrease key to vary the timer setting up to 22 hours.

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

#### 2.2.4.1.3 Check the 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.

#### 2.2.4.1.4 Check the Treatment Hours Display

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

#### 2.2.4.1.5 Check the Status Indication LED

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.

#### 2.2.4.1.6 Check the Power Indication LED

The Power indication LED shows that the equipment is ON.

## Section 3: Operation

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



- Do not use flammable agent while using phototherapy equipment.

### 3.1 Control Panel Operation (nice 4000 SPOT & nice 4005 SPOT)

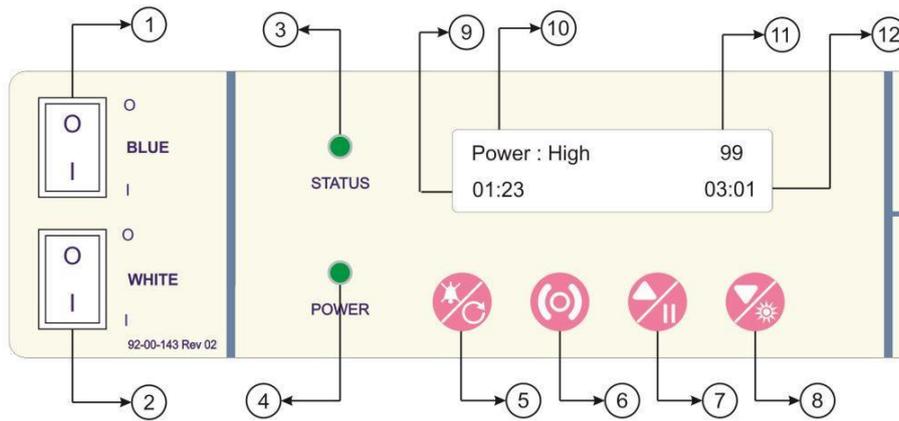


Fig 1

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

#### 3.1.1 Light Source

##### 3.1.1.1 Treatment Light



Picture 25

**High bright 24 Blue LED Lamps** - The light provides an average intensity of  $>50-55 \mu\text{W}/\text{cm}^2/\text{nm}$  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.

### 3.1.1.2 Light source height Adjustment



Picture 26

- I. This knob allows adjusting the height of the light Source.
- II. 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.

### 3.1.1.3 LED Light Source tilting



Picture 27

- LED Light Source can be tilted by grasping the device on either side and torquing 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 ( $\pm 90^\circ$ )

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

### 3.1.1.4 Switches



Picture 28



Picture 29

- Three switches are provided in the equipment, one for Main Power ON/OFF and another two for blue and white LED source ON/OFF.
- 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 right side of the Light source.



**Warning**

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

### 3.1.2 Front Panel Control



Picture 30

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

- Mute Key

- Set Key
- Increase Key
- Decrease Key

1. **Mute Key:** To mute the Audio and Visual Indications.
2. **Set Key:** To Select the percentage of irradiance, timer and real time/date.
3. **Increase Key:** To increase the percentage of irradiance, timer and real time/date.
4. **Decrease Key:** To decrease the percentage of irradiance, timer and real time/date.

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

- Status Tri Colour LED
- Power Green Colour LED

1. **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 with Audio and Visual Indications indicates that lamp usage hour is greater than 20,000.
2. **The Power Green LED** shows that the equipment is ON.



- **Monitor the patient during treatment**

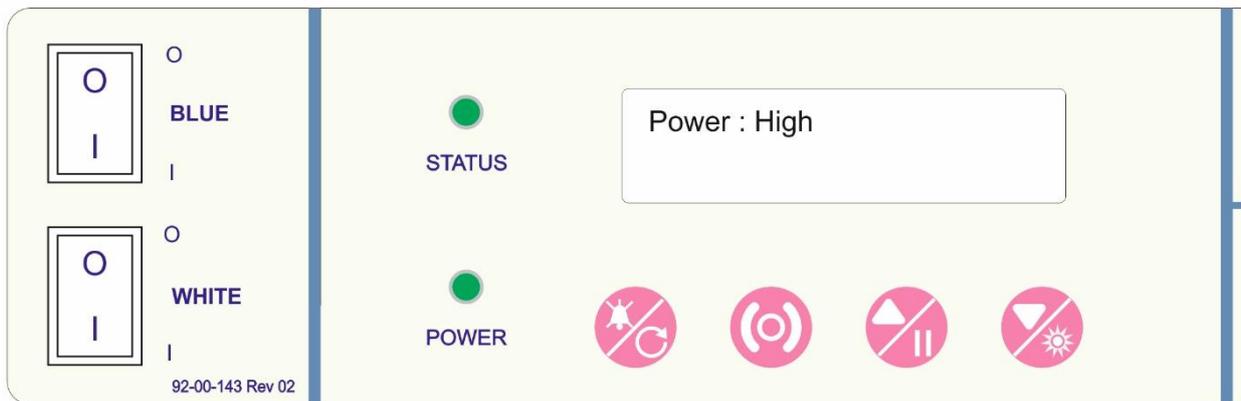
Regular monitoring during treatment is recommended. Use the following guidelines:

- 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.

### 3.1.2.1 Irradiance adjustment



1. Press the set key to view the current output range of Irradiance.



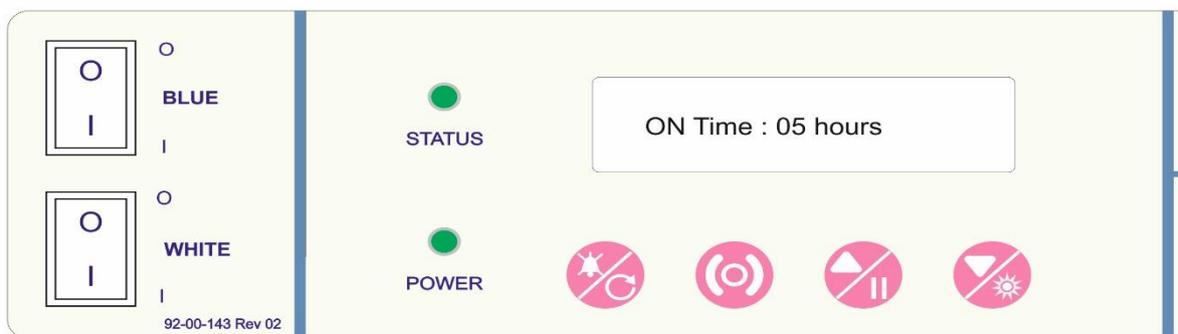
2. Press the Increase/Decrease key to set Low or High range as desired.

**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,

### 3.1.2.2. Phototherapy Timer Setting



1. Press the set key twice to view the On/Off current timer setting

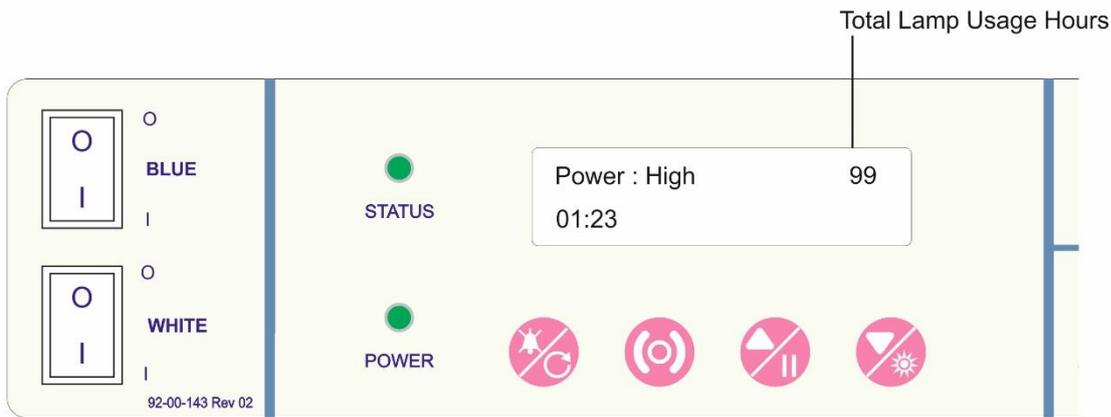


2. Press the Increase/Decrease key to ON or OFF Phototherapy Timer, after timer is ON, press increase/decrease key, to vary the timer setting up to 1 to 9 hours.

**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.

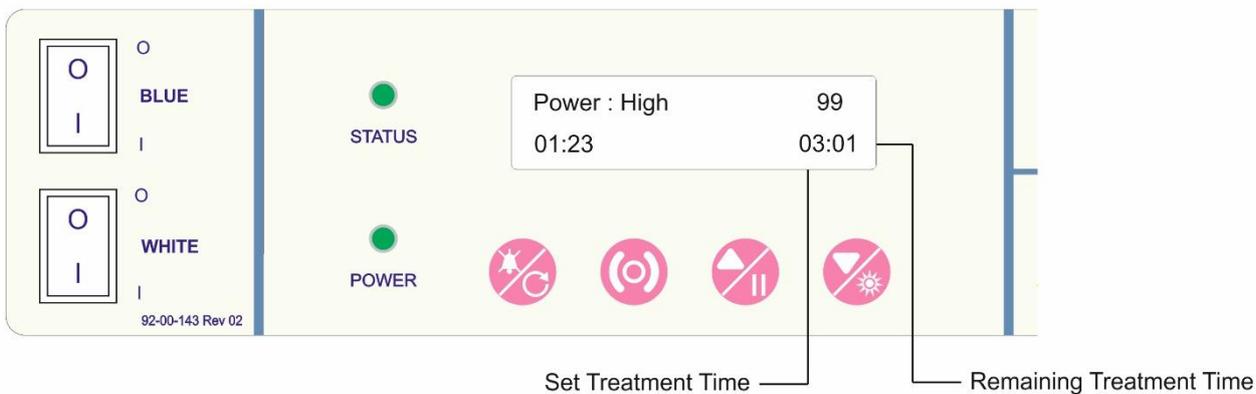
### 3.1.2.3 Total Lamp Usage Hours Display

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



### 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.

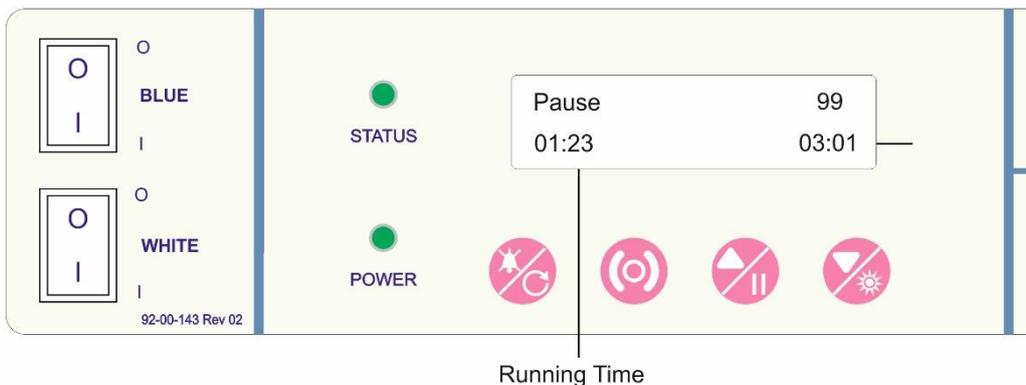


### 3.1.2.5 Running Hours Display

Running hour is shown on the Left bottom side of the LCD display panel. 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.



**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 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.

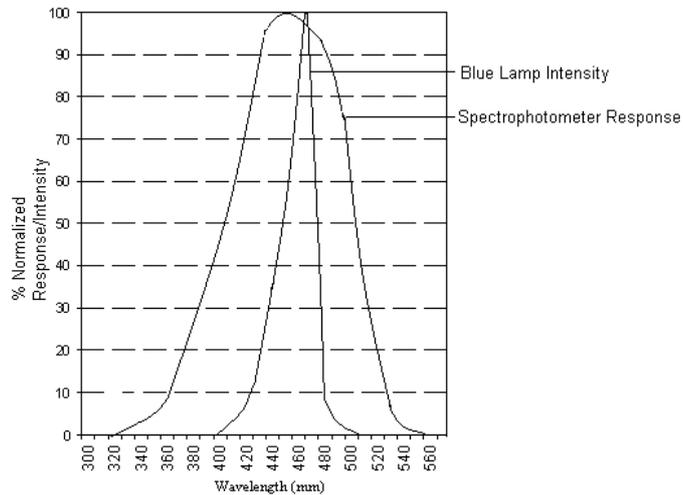


Fig: 2

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

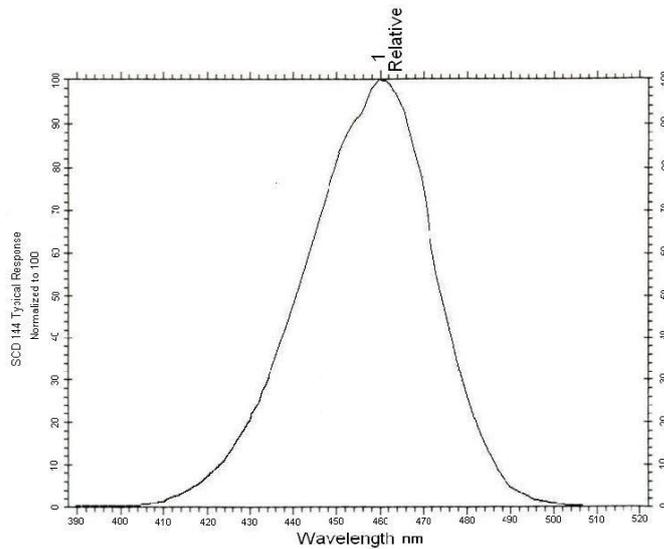


Fig: 3

### 3.1.4 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

## Section 4: Cleaning and Maintenance

### 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.



#### Warning

- Incorrect use of the Phototherapy, or the use of parts that are not manufactured or supplied by Neotech, 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 Neotech Medical Technical Service or Neotech 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 misalign the EMI Shielding and the beads; it may cause the EMI interference to the equipment.



#### Caution

- 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 EN ISO 17664:2017 for reusable of the device

1. Clean the equipment with dampened cloth using soap (e.g., liquid dish soap) and clean water.
  2. Rinse the equipment completely with water dampened 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 dampened 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 tap water or filtered water (i.e., water passed through a 0.2  $\mu$  filter).

5. Dry Infant Phototherapy using dry towel or cloth.



**Warning**

- 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.



**Caution**

- 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. Rinse 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



**Caution**

- 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.



**Warning**

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



**Caution**

- 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 lifetime of the product can be considered as five years and Service life as six years by replacement of spares.

## Section 5: Specifications

### nice 4000 SPOT

Voltage supply	~230V/50Hz
Power Rating	70VA Max
Lamp wattage	1 Watt
Fuses	F1AL/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 - 55 $\mu$ W/cm <sup>2</sup> /nm
Effective Surface Area	600mm X 500mm.
Stabilization period	0.5 hour
Height Adjustability	110–160cm from the floor.
Light Source Tilting	-90° to +90° continuous (180°)
Lamp Usage Hours	>20000 Hours.
<b>Controls and Display</b>	
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 $\pm$ 5°C, NC, Auto reset.
<b>Controller Indications</b>	
Timer elapsed	After elapsing the set time.
Lamp Replacement	> 20,000 hours.
Over temperature	If light source get overheat >64°C.
Audible noise	< 50 dB
<b>MDD - Product Classification</b>	Class II a
<b>IEC 60601-1 Specifications</b>	
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

<b>Operating Conditions</b>	
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
<b>Quality Test Approval</b>	
Quality Management System	ISO 13485:2016
Electrical Safety Standard	IEC 60601-1 & IEC 60601-1-2 IEC 60601-2-50
Graphical Symbols	ISO 7010
<b>Transport and Storage conditions</b>	
Temperature range	-10°C to 60 °C
Humidity range	50% - 90% RH, non-condensing
<b>Physical Dimensions and weight</b>	
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

## nice 4005 SPOT

Power Rating	~ 230 V / 50Hz /70V Light Source
Light source	24 Blue LED, 3 White LED
Mattress Tilting	± 15° on both sides
Mattress Tray	Transparent Acrylic
Side Panels	4 nos Acrylic Irradiance
Irradiance	>45 µW/cm <sup>2</sup> /nm at a distance of 30 cm
Irradiance Adjustment	Low & High
Lower setting of irradiance	>30 µW/cm <sup>2</sup> /nm a distance of 30 cm
Distance from mattress to source	95 cms
Effective Area	60 cm X 50 cm (3000 cm)
<b>Time totalizer</b>	
Total Lamp Usage Hours	Total Usage Hours of Lamp (non-resettable)
Treatment Hours	Continuous (resettable)
Castors	4" castor 4 nos. (2 with brake & 2 without brake)
Audible noise	< 25db
Equipment Dimension	77 cm (L) X 57 cm (W) X 110 cm (H)
Weight	22 kg
<b>Operating Conditions</b>	
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
<b>Quality/Test Approval</b>	
Quality	ISO 13485:2016
Electrical &Product Safety	IEC 60601-1 & IEC 60601-1-2, IEC 60601-2-50
<b>Optional Accessories</b>	
Eye Pad (single use non-sterile)	Pack containing 25nos.

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

**List of accessories**

Optional: Phototherapy eye pad (Single-use, non-sterile)

## 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. The expected service life of the equipment is six years and the shelf life of the equipment is 5 years.

#### 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 Neötech Medical Systems Pvt. Ltd.  
No, 85. Krishna Industrial Estate,  
Vannagaram, Mettukuppam,  
Chennai-600095. Tamil Nadu, INDIA  
Ph: 91-44-24762594, 24764608  
Email: [service@niceneotech.com](mailto:service@niceneotech.com),  
[info@niceneotech.com](mailto:info@niceneotech.com)  
Web: [www.niceneotech.com](http://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 Neötech
2.	Equipment not functioning, Power is ON.	Internal wire may be disconnected	Contact nice Neötech.
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 Neötech
4.	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

Sl. 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
4	Height cannot be adjusted	Knob may be over tightened	Unscrew the height adjustment knob and adjust required level
			Contact Neötech
5	Can't move the machine	Brakes may be applied on the castors.	Release the brake.
		Castors damaged	Change the Castors
			Contact Neötech

6	Unable to tilt the source unit	Source module may be struck	Slightly shake and rotate the source module
			Contact Neötech
7	Lamp usage Hour's display is not working	LCD may be damaged	Contact Neötech
		Microprocessor may be defective	
8	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 LEDs 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 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 all equipment is six years

#### Light Intensity at 25%

nice 4000 SPOT : 24 High Blue LED 50-55  $\mu\text{W}/\text{cm}^2/\text{nm}$  at a distance of 40 cm  
(Irradiance can be variable)



Caution

- 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.



Caution

- Only qualified personnel should perform service and repair. Take extreme care when working with exposed circuitry.
2. Adjusting the Light Intensity: If the intensity of light falls to less than the desired extent, all Lamps (LED Lamps) need to be replaced.
3. 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



Caution

- 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.
- **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.
- Take the nice 4000 SPOT out of usages before replacing a lamp.

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

1. To open the lamp housing, remove the six screws and washers securing the top of the light source.
2. To remove the failed lamp, de-solder the connection and peel.



Caution

- For replacement, use only Lamps approved by nice Neotech or the performance characteristics of the unit may change and patient safety may be impaired.
3. To fit a new lamp, solder the new lamp and paste it.
  4. Remove any dust from inside the lamp housing using a soft brush.
  5. Close the lamp cover and fit the six screws and washers and connect the power cable again.



- 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 Neotech'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

S. No.	Part No.	Part Name	Qty	Unit of measurement
1.	93-00-017	Castor 3"	3.00	No
2.	93-00-018	Castor 2"	1.00	No
3.	40-05-032	PCB Assembly	1.00	No
4.	90-00-040	Power Cord	1.00	No
5.	91-00-110	SMPS 12V DC	1.00	No
6.	91-00-060	Fan 3" 12V DC	1.00	No
7.	89-14-021	Blue LED 1 Watt (nice 4000 SPOT)	24.00	No
8.	89-14-022	White LED 1 Watt (nice 4000 SPOT)	3.00	No
9.	89-14-029	Lens 45° (nice 4000 SPOT)	27.00	No
10.	91-00-084	Thermostat 70 ±5°C, NC	1.00	No

## Section 9: Manufacturer's EMC Declaration.

<b>Guidance and manufacturer's declaration – electromagnetic emissions</b>		
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	

<b>Guidance and manufacturer's declaration – electromagnetic immunity</b>			
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 bands 6 Vrms 150 kHz to 80 MHz in ISM bands	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 %.

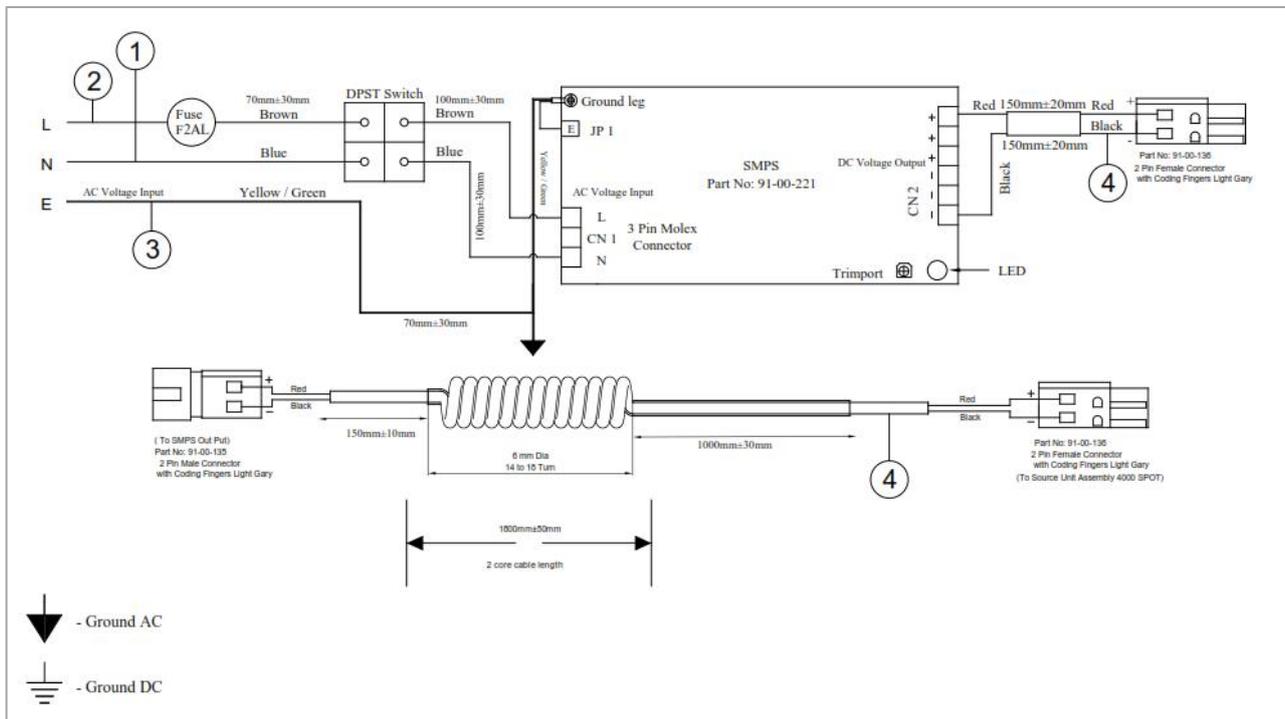
NOTE UT is the a.c. mains voltage prior to application of the test level.

### Acceptance criteria:

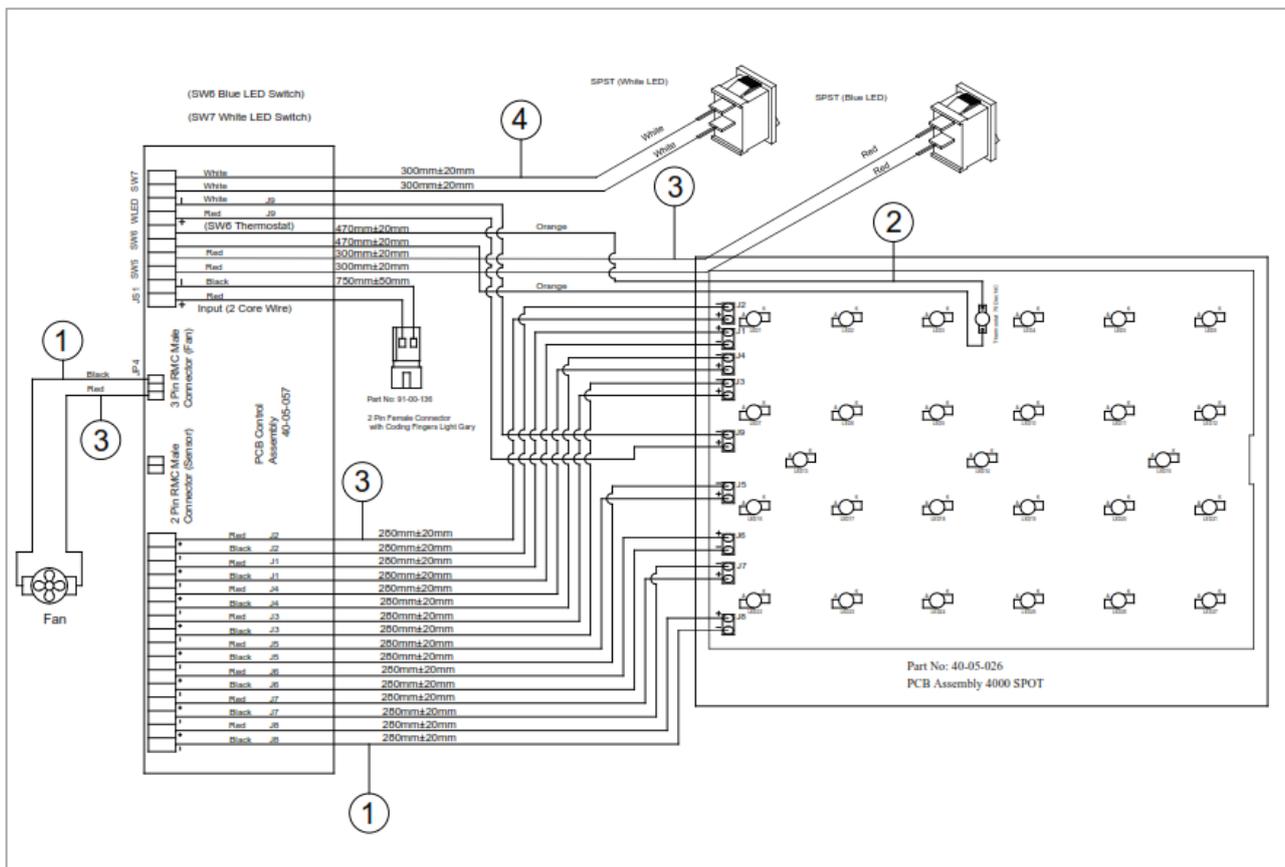
Performance criteria	Description
A	Normal performance within limits specified by nice Neótech
B	Temporary loss of function or degradation of performance which ceases after the disturbance ceases, and from which the equipment under test recovers its normal performance, without operator intervention
C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

## Section 10: Wiring Diagram

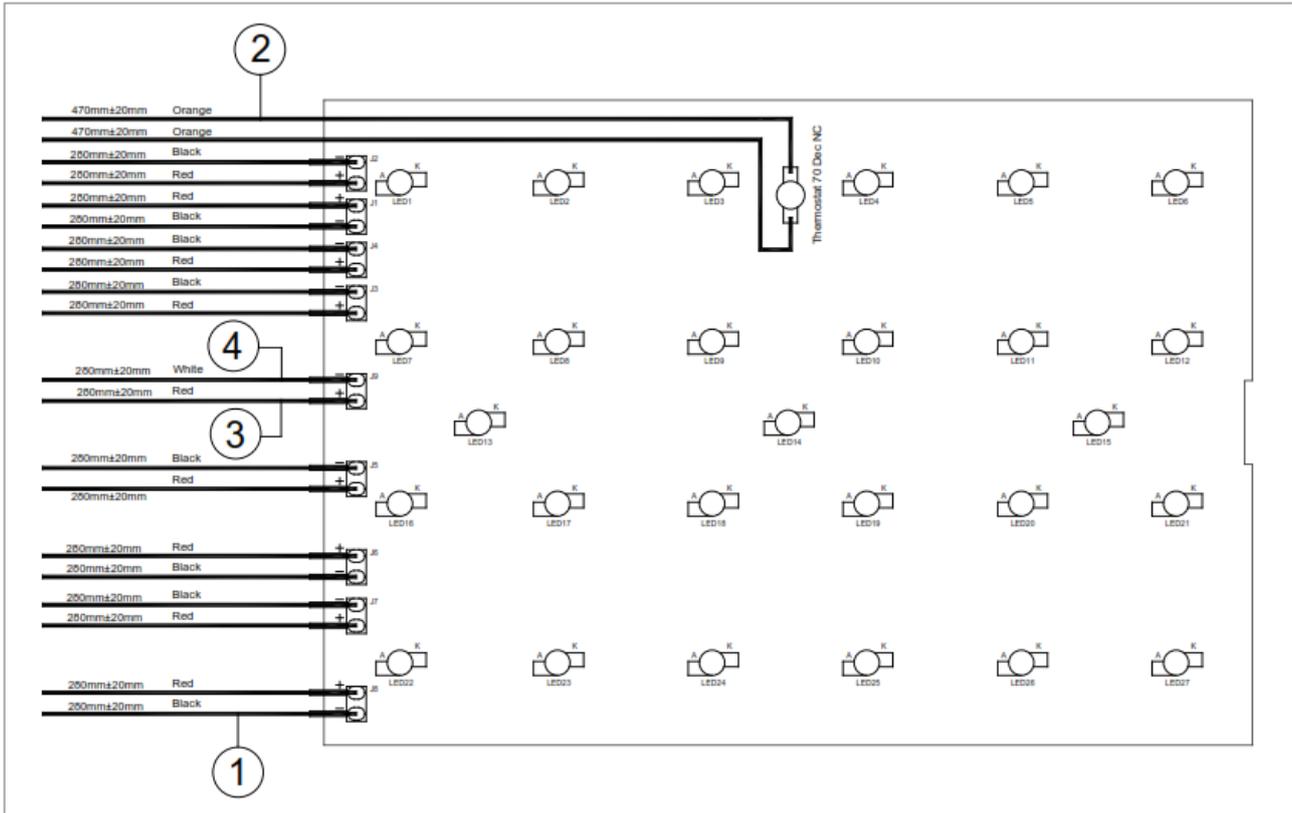
### 1. nice 4000 SPOT



Pillar Assembly

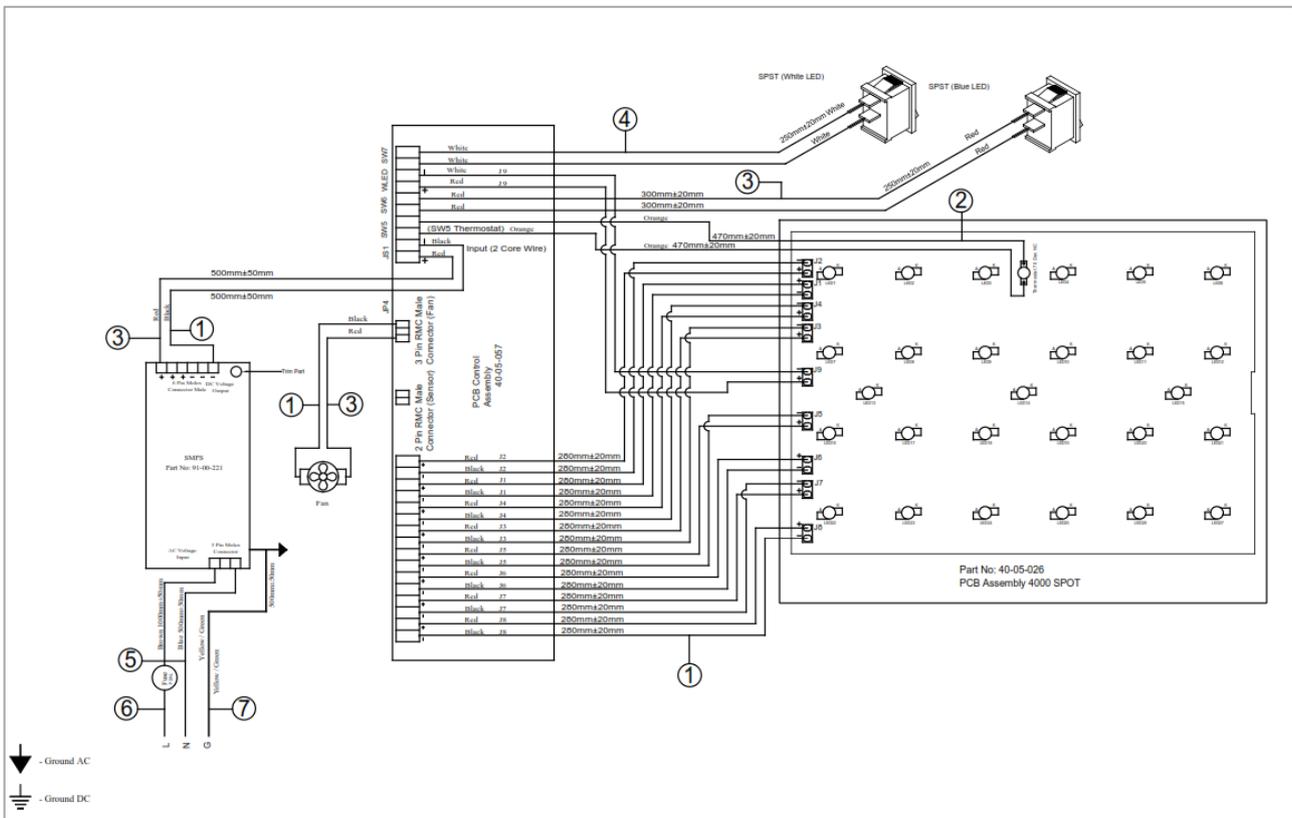


Source Unit Assembly



PCB Assembly

## 2. nice 4005 SPOT



Source Unit 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:		<input type="checkbox"/> Complaints <input type="checkbox"/> Adverse Events <input type="checkbox"/> Comments <input type="checkbox"/> 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:

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 Kindly fill the above and send the same

From:

\_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

To:

The Marketing In-charge  
 nice Neotech Medical Systems Pvt. Ltd.  
 No, 85, Krishna Industrial Estate,  
 Vanagaram, Mettukuppam,  
 Chennai-600095, Tamil Nadu,  
 INDIA.  
 Ph: 91-44-24762594, 24764608  
 Email: [marketing@niceneotech.com](mailto: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
<p><b>nice Neotech Medical Systems Pvt. Ltd.</b>            No. 85, Krishna Industrial Estate, Vanagaram, Mettukuppam Chennai-600095. Tamil Nadu, INDIA.            Ph: 91-44-2476 4608 Telefax: 91-44-2476 2594            E-mail: <a href="mailto:service@niceneotech.com">service@niceneotech.com</a> /<a href="mailto:info@niceneotech.com">info@niceneotech.com</a>            Web: <a href="http://www.niceneotech.com">www.niceneotech.com</a>            SRN: IN-MF-000010243</p>	<p><b>Amstermed B.V</b>            Located in Saturnusstraat 46-62, Unit 032, 2132 HB Hoofddorp, The Netherlands.            Mr. Mike Vermin            Tel: +31 23 565 6337  <a href="mailto:info@amstermed.nl">info@amstermed.nl</a>  <a href="http://www.amstermed.nl">www.amstermed.nl</a>            SRN: NL-AR-000001971</p>	<p><b>Ministerie van Volksgezondheid, Welzijn Sport</b>            Address:P.O. Box, 20350, The Hague, Netherlands            Country:Netherlands            Email: <a href="mailto:medicaldevices@minvws.nl">medicaldevices@minvws.nl</a>            Tel:+31 70 340 79 11</p>

## Section 12: EC certificate Notified Body

**Name:**

PCBC – POLSKIE CENTRUM BADANI CERTYFIKACJI

**Notified body number:**

1434

**Address:**

02-844 Warsaw,  
469 Pulawska Street,  
Poland.

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