

# nice Neötech Medical Systems Pvt. Ltd.

nice 4020

## Phototherapy Radiometer



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### OPERATING/INSTALLATION MANUAL

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

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nice Neötech Medical Systems Pvt. Ltd.

85. Krishna Industrial Estate, Vanagaram, Mettukuppam Chennai – 95

Ph: 91-44-24764608

E-mail: [info@niceneotech.com](mailto:info@niceneotech.com) / [marketing@niceneotech.com](mailto:marketing@niceneotech.com) / [service@niceneotech.com](mailto:service@niceneotech.com)

Web: [www.niceneotech.com](http://www.niceneotech.com)

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## User Responsibility / Operator Profile

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

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



**Warning**

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

## Declaration for Languages

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

## Model Description

This model of the nice 4020 Phototherapy Radio meter provides the irradiance value of light output from the Phototherapy Radiometer by using the microprocessor.

## Definitions

**Irradiance:** It is the radiant flux (power) received by a surface per unit area. It is also the distance between the light source and the skin to be treated.

**Photodiode:** A photodiode is a semiconductor p-n junction device that converts light into an electrical current. The current is generated when photons are absorbed in the photodiode. The exact measurement of the intensity of light is obtained.

**$\mu\text{W}/\text{cm}^2/\text{nm}$ :** Intensity, measured as microwatts per square centimeter per nanometer ( $\mu\text{W}/\text{cm}^2/\text{nm}$ ), is dependent upon the power of light source and its distance from the infant.

**$\mu\text{W}/\text{cm}^2$ :** Power density is defined as power per unit area. It can be expressed in terms of microwatts per square centimeter  $\mu\text{W}/\text{cm}^2$ . 1  $\mu\text{W}$  equals 0.000001 watt.

## Definition of Warning indication

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

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

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

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

## Section A: Warnings



### Warning

- Before using the nice 4020 Phototherapy Radio meter, read this entire manual. Attempting to use this device without a thorough understanding of its operation may result in patient or user injury. This device should only be operated by personnel trained in its operation and under the direction of qualified medical personnel familiar with the risks and benefits of this type of device.
- In a dust free area, keep hands clean and then install the equipment.
- Do not perform the Checkout Procedures (Mechanical and Control Unit) with a patient.
- Complete the “Checkout Procedures” section of this manual before putting the unit into operation. If the nice 4020 Phototherapy Radio meter fails any portion of the checkout procedures it must be removed from use and repaired.
- There is a possibility of electromagnetic interference or other interference causes from other external equipment, the may get in operation. Use EMC compliance Equipment to avoid the interference.
- Phototherapy Radio meter may cause radio interference, in which case adequate measure may be required to prevent interference.







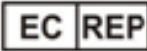






## Section B: Cautions




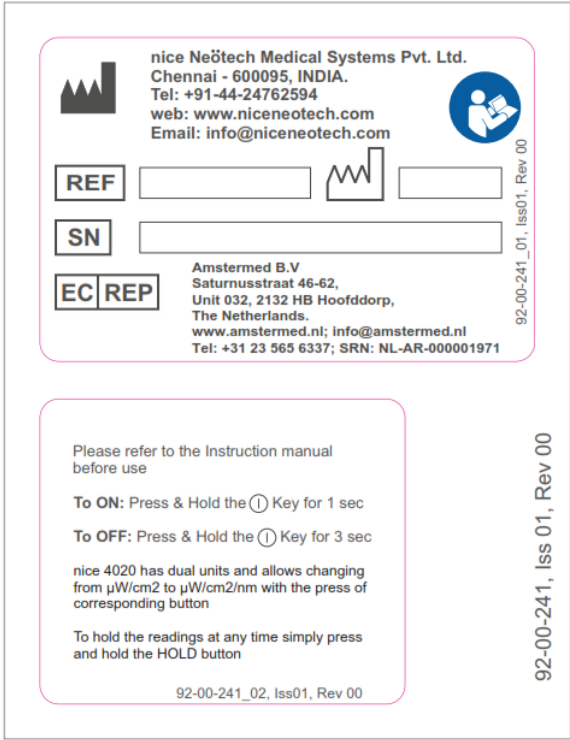
Caution



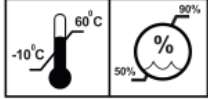











- Don't keep the metal surface in wet condition it may cause corrosion and damage the part.
- Use the cleaning solution sparingly on a cloth when cleaning the Phototherapy Radiometer. Do not saturate the unit - excessive solution causes damage to internal components.
- Use of nonstandard components: Consult the manufacturer for repair and replacement of components. Use of incorrect component can adversely affect Safety, performance and/or damage the equipment performance.
- Use of cleaning/disinfecting solutions containing chemicals (i.e. alcohol, acetone, etc.), or chemicals in greater concentrations, may damage the patient probe or other material being cleaned.

## Section C: Symbols & Labels

Mark	Indication
	Warning
	Caution
	Protective Earth (Ground)
	Type BF Equipment
	Refer Instruction for use
	Serial number
	Authorized Representative in the European community
	Date of Manufacture
	Manufacturer
	Model number
	Increase key
	Decrease key
	ON/OFF switch

# Labels

S.No.	Label	Description
1.		Label, Front Panel
2.		Label, Information and Reference & Serial no.

<b>3.</b>	<p>HANDLE WITH CARE LIFE SAVING MEDICAL EQUIPMENT</p>	 8 19 08 00 3 1 9 8 9 X X I
	<p>SN - REF - Module - UDI -</p>	
	<p> <b>nice Neotech Medical Systems Pvt. Ltd.,</b> No. 85, Krishna Industrial Estate, Vanagram, Mettukuppam, Chennai - 600 095, India. SRN: IN-MF-000010243</p>	<p> -10°C 60°C 80% 50%</p>
	<p><b>EC REP</b></p>	<p><b>Amstermed B.V.</b> Saturnusstraat 46-62, Unit 032, 2132 HB Hoofddorp, The Netherlands www.amstermed.nl ; info@amstermed.nl +31 23 565 6337 SRN: NL-AR-000001971</p>
	<p> </p>	
	<p>        </p>	

Packing Label

## Section 1: Description

### 1.1 Intended Use

nice 4020 Phototherapy Radiometer is intended to measure the blue spectrum of the phototherapy light which is for treatment of neonatal hyperbilirubinemia.

### 1.2 Indication

It is used in direct measurement of irradiance in phototherapy.

### 1.3 Contraindication

There are no such contradictions with the use of Phototherapy Radiometer.

### 1.4 Working Principle

The radiometer reading is taken with the level of the infant's chest or taken at the level of the phototherapy with the photodiode placed in the path of the incident light. The measurement is taken under the same test condition, to maintain consistency. The optimum irradiance of the radiometer provides consistent readings. If the power density of energy in the blue region is increased at the level of infant, the magnitude of this increase would be reflected in the measurement. Irradiance is represented in either of two units of measurements ( $\mu\text{W}/\text{cm}^2$  &  $\mu\text{W}/\text{cm}^2/\text{nm}$ ).

### 1.5 Product Description

This model of the nice Neötech Phototherapy Radiometer provides the accurate irradiance level of the blue light from the Phototherapy Radiometer. The control system uses a microprocessor and provides the irradiance value. A complete visual system is included on the control panel.

### 1.6 Control Unit

The control unit contains the electronic circuits and controls used to operate the Radiometer. It performs regular self-checks during its operation including failure diagnostics etc. Two units can be used for measuring the irradiance which are  $\mu\text{W}/\text{cm}^2$  &  $\mu\text{W}/\text{cm}^2/\text{nm}$ .

## Section 2: Installation

### 2.1 Setup

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

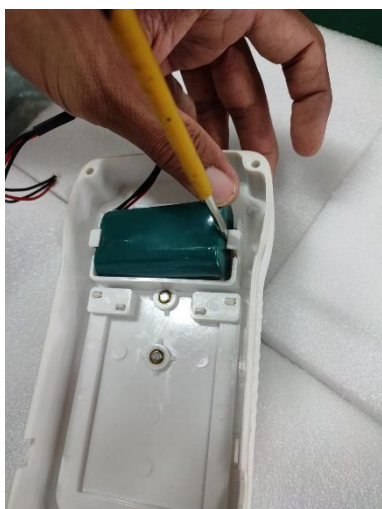
**Note:** The nice 4020 Phototherapy Radiometer battery has to be charged for 12- hours before the initial usage.

### 2.2 Installation of Phototherapy Radiometer



Picture 1

- The nice 4020 Phototherapy Radiometer comprises of a DC charger and with the irradiance value measuring probe.



Picture 2

- Remove the rear housing of the Phototherapy Radiometer.
- Place the battery in its slot with its flat side facing the housing.



Picture 3

- Connect the Molex pin from the battery to the RMC connector in the circuit. Now the front and rear housing are joined and tightened with the help of screws.

## 2.3 Pre-use Checkout Procedures

### 2.3.1 Mechanical Checkout Procedures



#### Warning

- Before using the nice Neötech Phototherapy Radiometer, read this entire manual. Attempting to use this device without a thorough Understanding of its operation may result in patient or user injury.
- Do not perform the Checkout Procedures (Mechanical and Control Unit) with patients.
- Read the “Checkout Procedures” section of this manual before putting the unit into operation. If the Phototherapy Radiometer fails any portion of the checkout procedures it must be removed from use and repaired.

#### 2.3.1.1 Overall Appearance

Check the overall appearance of the Device. There should be no obvious damage.

## 2.3.2 Control Unit Checkout Procedure



- Do not perform the Checkout Procedures (Mechanical and Control Unit) when the Phototherapy Radiometer is in use.
- Read the “Checkout Procedures” section of this manual before putting the unit into operation. If the Phototherapy Radiometer fails any portion of the checkout procedures it must be removed from use and repaired.

### 2.3.2.1 Control Unit Check

1. When the device is switched ON the controller performs self-test functions.
2. The LCD display shows the irradiance value of the phototherapy light source.
3. Check the value can be measured in both  $\mu\text{W}/\text{cm}^2$  &  $\mu\text{W}/\text{cm}^2/\text{nm}$ .

### 2.3.2.2 ON/OFF Key functional check

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

### 2.3.2.3 Select Key functional check

1. Press the Hold key, it freezes the measured irradiance value of the light source.
2. When  $\mu\text{W}/\text{cm}^2$  key is pressed, it should display the irradiance value in  $\mu\text{W}/\text{cm}^2$  unit.
3. When  $\mu\text{W}/\text{cm}^2/\text{nm}$  key is pressed, it should display the irradiance value in  $\mu\text{W}/\text{cm}^2/\text{nm}$  unit.

## Section 3: Operation

### 3.1 Control Panel Operation

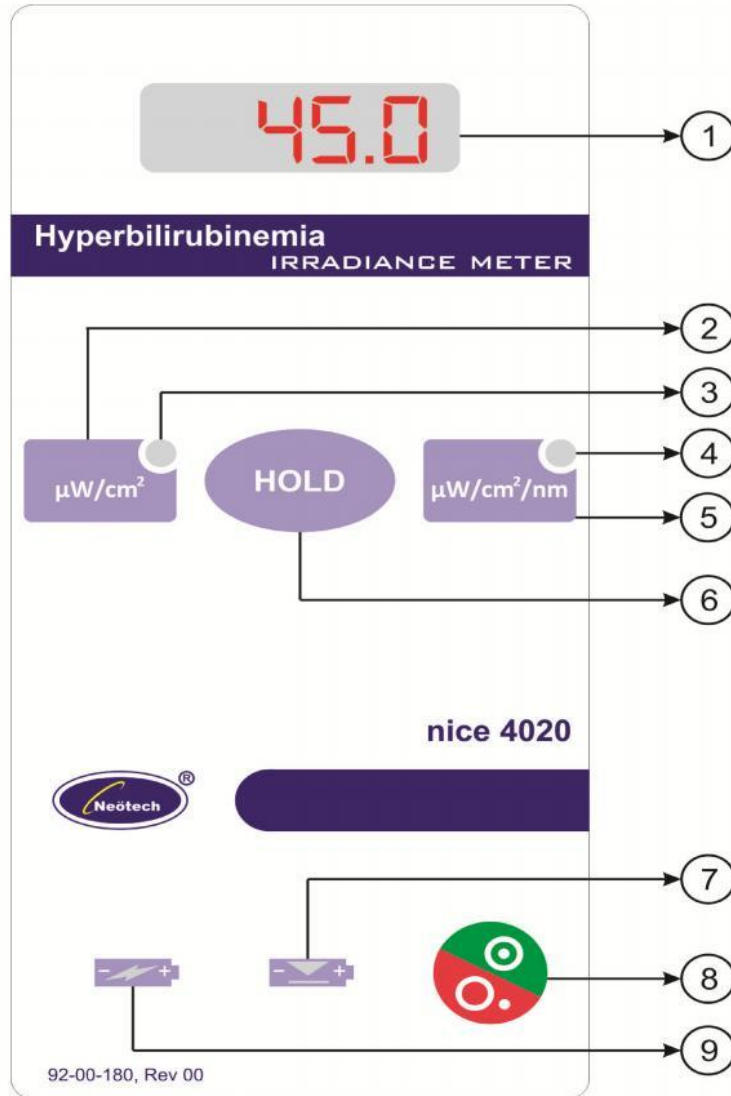


Figure 1

nice 4020 control panel

1	Irradiance display	6	Hold button
2	μW/cm² button	7	Battery indicator
3	μW/cm² indicator	8	ON/OFF button
4	μW/cm²/nm button	9	Battery charging indication
5	μW/cm²/nm indicator		

### 3.1.1 Displays & Keys

- ❖ **Irradiance value Display:** It will display the irradiance value.
- ❖  **$\mu\text{W}/\text{cm}^2$  key:** It displays the value in  $\mu\text{W}/\text{cm}^2$
- ❖ **Hold key:** It is use to hold the displayed irradiance value.
- ❖  **$\mu\text{W}/\text{cm}^2/\text{nm}$  key:** It displays the value in  $\mu\text{W}/\text{cm}^2/\text{nm}$ .
- ❖ **ON/ OFF key:** To switch ON/OFF the device.

### 3.1.2 Indications

- ❖ **Battery Charging Indication:** It indicates that the battery is getting charged.
- ❖ **Battery low indicator:** It indicates the low status of the battery.

## 3.2 Operating modes

### 3.2.1 Working mode

The device is switched on by pressing the power key in the front panel.



### 3.2.2 Charging the Radiometer

The charging of the nice 4020 is done by connecting a 10.5V AC charger in the charger port of the meter.



### 3.2.3 Irradiance Value Measurement

The output value of the nice 4020 Phototherapy Radiometer can be measured by  $\mu\text{W}/\text{cm}^2$  key or  $\mu\text{W}/\text{cm}^2/\text{nm}$  key available in the front panel.

### 3.2.4 Charging Time

The time taken to charge the radiometer is about 90 minutes.

### 3.2.5 Low Battery indication

The low battery indication is known by the blinking of red LED in the front panel.

## Section 4: Cleaning & Maintenance

### 4.1 General

- Always switch off the equipment while cleaning.
- This section provides cleaning and maintenance instructions. Where necessary, disassembly instructions are provided.
- Routinely inspect patient compartment for signs of breakage and replace assemblies before placing Phototherapy Radiometer into service.



- Periodically check the insulation and the connection of the cable it may cause fire because of poor insulation and short circuits due to aging.
- Make sure the Phototherapy Radiometer is switched OFF when performing cleaning and Maintenance procedures; a fire and explosion hazard might occur.
- Switch off the device before taking into cleaning.
- Do not scratch or soil the sensing part of the photodiode.
- Don't pour the water cleaning, it may enter into the electronics circuits it cause short circuit and get shock.
- Disconnect power to the Phototherapy Radiometer and allow the compressor/motor to cool before cleaning to avoid the possibility of a burn.
- Wiring instruction and training should be provided, please follow the service procedure carefully given in this manual.



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

#### 4.1.1 Disassembly for Cleaning

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

#### 4.1.2 Cleaning the Phototherapy Radiometer and Photodiode

During cleaning the Phototherapy Radiometer, 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 Phototherapy Radiometer that has been chemically disinfected for reuse, because tap or distilled water may harbour microorganisms. However, when rinsing with sterile water is not feasible, instead, rinse with tap water or filtered water (i.e. water passed through a 0.2 µ filter).
5. Dry Phototherapy Radiometer using dry towel or cloth and wipe down the fibre optic cable and pad cover.



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

## 4.2 Lifetime of product

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

## Section 5: Specifications

<b>Electrical</b>	
Operating Voltage	5V
Reference Voltage	2.5V
Operating Temperature	0- 60° C
Brightness Level	200 $\mu\text{W}/\text{cm}^2/\text{nm}$ (Max)
Display Windows	Irradiance Level Display
Audio & Visual Indication	Continuous & Interrupt
Individual Identities LED	$\mu\text{W}/\text{cm}^2$ Unit Indication
	$\mu\text{W}/\text{cm}^2/\text{nm}$ Unit Indication
	Charging Indication
	Power Indication
	Battery Low Indication
Individual Selection Key	Unit 1 ( $\mu\text{W}/\text{cm}^2$ ) selection key
	Unit 2 ( $\mu\text{W}/\text{cm}^2/\text{nm}$ ) selection key
	Power ON/OFF Key
	Hold Key
<b>Audio and Visual Indication</b>	
High Irradiance	If the irradiance level exceeds peak rating then display will indicate as "OvLd" (Over Load) with continuous beep
<b>Temperature</b>	
Operating Range	+ 15°C to 35°C environment
Storage Range	-10°C to 60°C environment
<b>Humidity</b>	
Operating Range	15% to 95% RH Non-Condensing
Storage Range	50% to 95% RH Non-Condensing
Altitude	Sea level to 1.9 miles 3 km
<b>IEC 60601-1 Specifications</b>	
Type of protection against electric shock	Class I Product
Degree of protection against electric shock	NA
Degree of protection against Ingress of water	IPX1
Protection against hazardous of explosion	Not protected
Mode of Operation	Continuous
Product Classification	Class I
<b>Quality Test Approval</b>	
Quality Management System	ISO 13485:2016

## Section 6: Warranty

### 6.1 Conditions

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

#### Customer Details cum Warranty Card

Date: \_\_\_\_\_

Hospital Name & Address: \_\_\_\_\_

\_\_\_\_\_

Contact Person & Telephone/Fax No \_\_\_\_\_

Email \_\_\_\_\_

Department: NICU / PICU / OT / Gynaecology / Causality / Others \_\_\_\_\_

Equipment Name: \_\_\_\_\_

Model No: \_\_\_\_\_ Sl. No. \_\_\_\_\_

Date of Purchase: \_\_\_\_\_ Date of Installation \_\_\_\_\_

Name of Authorized Dealer: \_\_\_\_\_

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

Dealer Signature with seal

Kindly fill the above and send the same

From \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

To:  
The Service In-charge  
nice Neotech Medical Systems Pvt. Ltd.  
No.85, Krishna Industrial Estate,  
Vanagaram, Mettukuppam,  
Chennai-600095. Tamil Nadu, INDIA.  
Ph: 91-44-24762594, 24764608  
Email: [service@niceneotech.com](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 System Failure

S.no.	Problem	Cause	Remedy
1.	Monitor does not work	No batteries fitted	Fit new batteries
		Batteries fitted incorrectly	Check that the batteries have been fitted as indicated in the battery compartment.
		Batteries discharged	Recharge / Fit new batteries
2.	No display	Battery expired	Check/recharge the battery
		Bad battery connection	Check battery connections
		Charger defects	Replace the charger
3.	Keys inoperable/ cannot turn unit off	Electronics component failure	Remove the rear panel & disconnect the battery

### 7.2 Maintenance levels

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



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

### 7.3 Disposing of the Unit

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

## Section 8: Spare Parts List

S. No.	Part No.	Part Name	Qty	Unit
1.	40-05-069	PCB Assembly 4020 Radiometer	1	No.
2.	40-20-019	Cosine filter	1	No.
3.	89-12-010	Photodiode –S6428,400 TO 54nm	1	No.
4.	89-14-034	Bandpass optical fibre	1	No.
5.	90-00-074	Spiral wire-2 core	1	No.
6.	91-00-137	Rechargeable li-ion battery- 7.2V 2200 AH	1	No.
7.	91-00-138	Wall mount switching power supply	1	No.
8.	99-00-072	Switch button PCB	3	No.

## Section 9: Manufacturer's EMC Declaration

Guidance and manufacturer's declaration – electromagnetic emissions		
The Phototherapy Radiometer is intended for use in the electromagnetic environment specified below. The customer or the user of the Phototherapy Radiometer 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 Radiometer is intended for use in the electromagnetic environment specified below. The customer or the user of the Phototherapy Radiometer 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 Radiometer requires continued operation during power mains interruptions, it is recommended that the Phototherapy Radiometer 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 Radiometer is intended for use in the electromagnetic environment specified below. The customer or the user of the Phototherapy Radiometer should assure that it is used in such an environment.

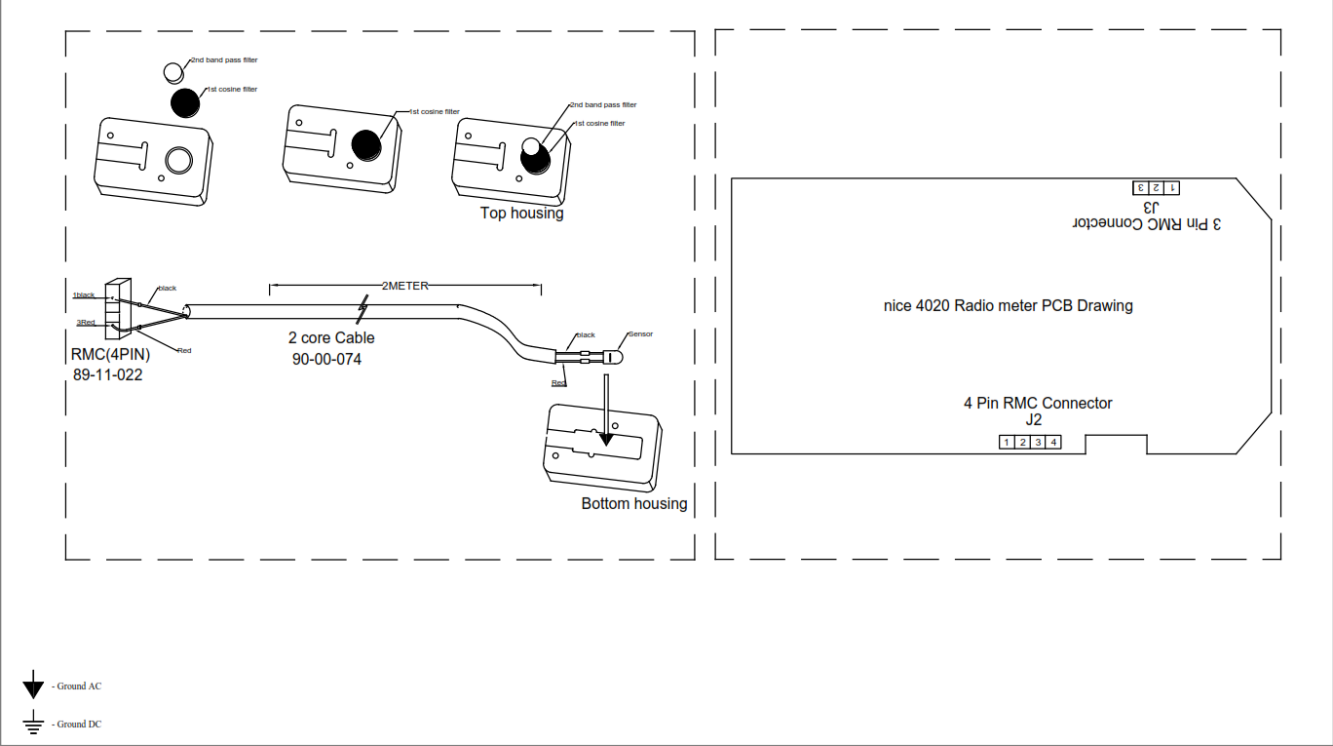
IMMUNITY test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz outside ISM bands 6 Vrms 150 kHz to 80 MHz in ISM bands	Criteria A	Floors should be wood, concrete or ceramic tile. If floors are covered with Synthetic material, 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 Neötech
B	Temporary loss of function or degradation of performance which ceases after the disturbance ceases, and from which the equipment under test recovers its normal performance, without operator intervention
C	Temporary loss of function or degradation of performance, the correction of which requires operator intervention
D	Loss of function or degradation, which is not recoverable, owing damage to hardware or software, or loss of data

# Section 10: Wiring Diagram



nice 4020 internal wiring

## 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:

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></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 en 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>