

nice Neotech Medical Systems Pvt. Ltd.

Model: nice 4050 Transilluminator



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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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. 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 Neotech recommends that a telephone or written request for service advice be made to the nearest nice Neotech Regional Service Center.

This Product or any of its parts should not be repaired other than in accordance with written instructions provided by nice Neotech and by nice Neotech trained personnel. The Product must not be altered without the prior written approval of nice Neotech's Quality Assurance Department. 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 Neotech.

Warning: Before using the nice Neotech Transilluminator, 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 Neotech Medical Systems Private Limited supplies to EU countries.

Model Descriptions:

The nice Neotech Transilluminator consists of a one meter fiber optic cable, connected to a LED light source. The light source is dimmable and delivers sufficient visible light through the body tissue to assist in the diagnosis of pneumothorax in the neonate.

nice 4050 FONT – Fiber Optic Neonatal Transilluminator – Table Top

nice 4050M – FONT – Fiber Optic Neonatal Transilluminator – Hand Held

Definitions:

Timer: To turnoff the LED automatically after elapsed the set time.

Brightness: Intensity of the LED Light

Self Test: Booting the equipment to check the internal peripheral.

Fan Fail: Error message for Cooling fan fail.

Sensor Fail: Error message for Temperature sensor fail.

Over Temperature: Error message for High Temperature.

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.

Section A: Warnings

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

Warning: Do not use the Transilluminator in the presence of flammable anesthetics; a possible explosion hazard exists under these conditions.

Warning: Disconnect the Transilluminator power cord and allow the unit to cool before replacing the LED Lamp.

Warning: In a dust free area, keep hands clean and then install the equipment.

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

Warning: Do not place items on top of the Transilluminator.

Warning: Do not perform the Checkout Procedures (Mechanical and Control Unit) with a patient.

Warning: Complete the "Checkout Procedures" section of this manual before putting the unit into operation. If the Transilluminator fails any portion of the checkout procedures it must be removed from use and repaired.

Warning: Regularly inspect the fiber optical cable locking mechanism which fails the fiber optic cable will be come out.

Warning: Do not make short bend of fiber optic cable.

Warning: Do not place anything on the Fiber Optic Cable.

Warning: Do not scratch or soil the light output end of the optic cable.

Warning: To ensure the proper operation and light intensity, replace with proper lamp.

Warning: Do not insert fingers or foreign objects into the illuminator port whether the lamp is ON or OFF

Warning: Use only the nice Neotech Fiber Optic Cable. Use of other manufacturer's fiber optic cable may affect the intensity.

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

Warning: The Transilluminator may cause radio interference, in which case adequate measure may be required to prevent interference

Warning: even Small quantity of flammable agents such as ether and alcohol, left in the Transilluminator it can cause fire in connection with oxygen.

Warning: Do not see the light output directly it may cause retina damage.

Section B: Cautions

Caution: Isolation from the supply mains is Detachable Power cord provided

Caution: Use cleaning solution sparingly on a cloth when cleaning the Transilluminator. Do not saturate the unit - excessive solution causes damage to internal components.

Caution: Do not autoclave or gas sterilize the Fiber Optic Cable. Do not immerse the cable in liquid cleaner. Avoid placing excessive strain on the cable tip. Always remove the cable by grasping and pulling at the panel.

Caution: Only competent individuals trained in the repair of this equipment should attempt to service it as detailed in the service manual. The Service Manual provides detailed information solely for use by individuals having proper knowledge, tools and test equipment, and for service representatives trained by nice Neotech.

Caution: The equipment may affect while using the defebulator.

Caution: 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.

Caution: Clean surface using wet cloth dipped in mild soap water and squeeze dry excess water before use.











Caution: Do not allow water to spill into equipment.












Caution: Avoid using any solvent, spirits, alcohol to clean plastic parts and lens.

Caution: Do not touch the lens with bare hands, clean with dry soft cloth.

Caution: Do not use water or any other liquid to clean Electronics and Electrical parts.

Section C: Symbols

Mark	Indication
	Attention, consult ACCOMPANYING DOCUMENTS
	Caution, ignition (Indicates possible ignition under certain condition)
	Caution, electric shock
	Caution, Pinched finger or hand
	Warning
	Warning, Do not touch
	Warning, Don't use fire
	Protective Earth (ground)
	Alternating current
	On/OFF

Mark	Indication
	Alarm silencer
	Serial Number
	Authorized Representative in European Community
	Date of Manufacture
	Manufacturer
	Model Number
	Refer Instruction for use
	Type B Equipment
	Increase Key
	Decrease Key
	Mode Key

Section 1: Description

1.1 Intended Use

1.2 General

1.3 Control unit

1.1 Intended Use

The Transilluminator is a device with a LED light source intended to deliver sufficient visible light through the body tissue to assist in the placement of IV's in pediatric and neonatal patients in less than a minute. It also assists in the diagnosis of pneumothorax in the neonate.

1.2 General

The Neotech Transilluminator provides a manual controlled source of Light. The control system uses a microprocessor. The audio and visual alarm system is included on the front panel. The brightness level can be adjusted by the select key. The fiber optic cable is used to transfer the light from LED Light to the end of the cable tip.

1.3 Control Unit

The control unit contains the electronic circuits and controls used to operate the Transilluminator. The control unit performs regular self checks during its operation including failure diagnostics. The control system is used to vary the light intensity 10% to 100%.

Section 2: Installation

- 2.1 Setup
- 2.2 Installation of Transilluminator
- 2.3 Mechanical Checkout Procedure
- 2.4 Control Unit Checkout Procedure

2.1 Setup

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

2.2 Installation of Transilluminator



Picture 1

- Connect the optical Cable lock end to the front side of the equipment.



Picture 2

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

Warning: Wiring instruction and training should be provided, please follow the operation procedure carefully given in this manual,

2.3 Mechanical Checkout Procedure

Warning: Before using the nice Neotech Transilluminator, read this entire manual. Attempting to use this device without a thorough Understanding of its operation may result in patient or user injury.

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

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

2.3.1 Overall Appearance

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

2.3.2 Fiber Optic Cable Lock



Picture 3

- Check the Locking function of the Cable Holder, Cable should not be comes out when apply nominal force to pull, it should be completely gone in

Warning: Regularly inspect the fiber optical cable locking mechanism which fails the fiber optic cable will be come out.

2.4 Control Unit Checkout Procedure

Warning: Do not perform the Checkout Procedures (Mechanical and Control Unit) while a patient occupies the Transilluminator.

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

2.4.1 Control Unit Check

- Connect the Transilluminator power cord to a proper grounded power source. Refer to the rating label on the Transilluminator for the proper voltage needed. Switch the power ON and verify the following on the Control Panel (Fig)
- When the power is switch ON the controller performs self test functions. If the controller detects a failure, the alarm stays on and service is required.
- The LCD display shows the % of Light intensity by denoting the bar.
- Adjust the intensity with the select key to increase or decrease the light intensity.

2.4.2 ON/OFF Key functional check

- Press ON/OFF key once the equipment will be turn ON
- Press & Hold the ON/OFF key for 3 second the equipment will be turn OFF.

2.4.3 Mute Key functional check

- The alarm can be mute for 2 minutes.

2.4.4 Select Key functional check

- Increase key will increase the value, the decrease key will decrease the value.
- Presses the select key for enter the value/menu.

2.4.5 Mode Key functional check

- The mode key is use to select a particular parameter.

Section 3: Operation

3.1 Control Panel Operation

3.2 Setting of ON time duration

3.3 View the Total Lamp usage hours.

3.4 Exit from the SET menu

3.5 Increase/decrease the % of Intensity

3.1 Control Panel Operation (See Figure 1)

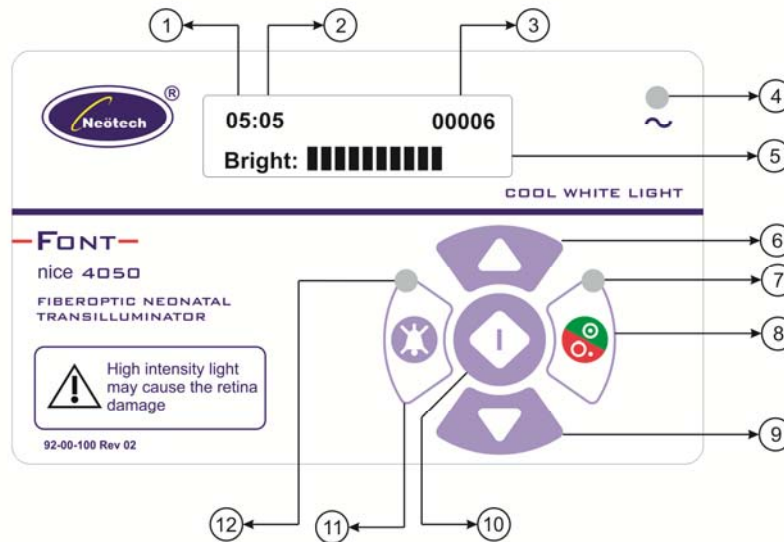


Figure 1

Front Panel Button and Indicators

1	Set Time in Minutes	7	Power ON Indication
2	Elapsed Time in Minutes	8	ON/OFF Key
3	Total Usages Hours	9	Decrease key
4	AC IN Indication	10	Select/Enter Key
5	Intensity Level	11	Mute ON/off key
6	Increase key	12	Mute On indicator

3.1.1 Displays

- ❖ **Set Time:** The display indicates the set required time (5/10 minutes).
- ❖ **Elapsed Time:** The display indicates the elapsed set time.
- ❖ **Total Usage Hours:** The display indicates the total lamp usage hour.
- ❖ **Intensity Level:** the display indicates the intensity level of LED Light.

3.1.2. Indicator Lights

- ❖ **AC IN Indicator:** The AC IN indicator lights when AC voltage is available.
- ❖ **Mute ON Indicator:** The Mute ON indicator lights when the alarm is in Mute.
- ❖ **Power ON Indicator:** The Power ON indicator lights when the equipment is in ON.

Caution: Isolation from the supply mains is Detachable Power cord provided

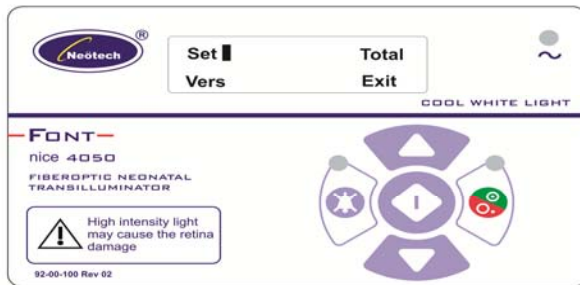
3.1.3. Keys

- ❖ **ON/OFF Key:** This key is used to ON/OFF the equipment.
- ❖ **Mute Key:** This key is used to mute the alarm.
- ❖ **Mode/Enter Key:** this key is used to select and enter the value/menu.
- ❖ **Increase Key:** The increase key is used to increase the intensity of the light.
- ❖ **Decrease Key:** The increase key is used to decrease the intensity of the light.

3.1.4. Alarms

- ❖ **Fan Failure Alarm:** The fan failure alarm is only active if the fan gets fail.
- ❖ **Sensor Failure Alarm:** The sensor failure alarm is only active if the sensor gets open/short.
- ❖ **Over Temperature Alarm:** The over temperature alarm is only activate when the LED Light source heat sink gets over heated.

3.2 Setting of ON time Duration



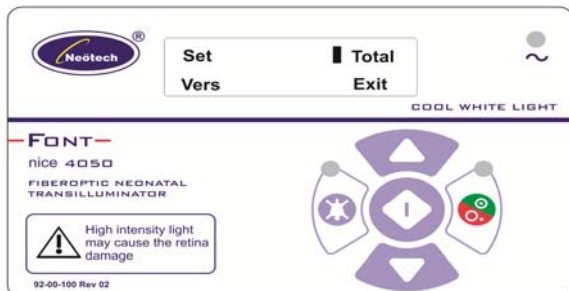
To enter into the SET mode press the Mode key.

To select the ON time, move the cursor into SET by using increase/decrease key and press the mode key.



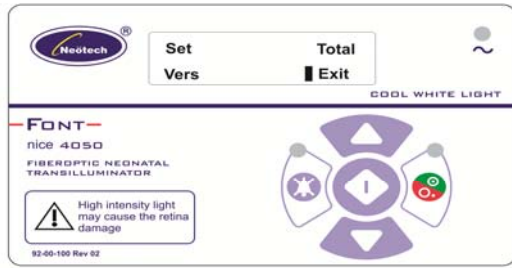
To change the ON time duration, use increase/decrease key for selecting 5 or 10 minutes.

3.3 View the Total Lamp Usage Hours.



To view the Total Lamp usage hour, move the cursor by using increase/decrease key to the TOTAL and press mode/enter key.

3.4 Exit from SET Mode.



To exit from the SET mode, move the cursor by using increase/decrease key into EXIT and press enter/mode key.

3.5 Increase/Decrease the % of Intensity



To Increase the Intensity from 5-100%, press the increase key.

To decrease the intensity from 100-5%, press the decrease key.

Section 4: Cleaning & Maintenance

4.1 Disassembly for cleaning

4.2 Lifetime of the product

4.1 Disassembly for Cleaning

- ❑ It is recommended that every usage, clean and disinfect the Fiber optic cable. The most effective way to clean is to first disassemble the parts.

Warning: Do not scratch or soil the light output end of the optic cable.

Warning: Periodically check the insulation and the connection of the cable it may cause fire because of poor insulation and short circuits due to aging.

Warning: Switch off the equipment and disconnect the Power cord from the mains before take in to cleaning

Warning: Don't pour the water for cleaning it may enter into the electronics circuits it cause short circuit and get shock.

Caution: Don't keep the metal surface in wet condition it may cause corrosion and damage the part

Warning: Disconnect power to the Transilluminator and allow the Lamp to cool before cleaning to avoid the possibility of a burn.

Warning: Wiring instruction and training should be provided, please follow the operation procedure carefully given in this manual,

Caution: Use the cleaning solution sparingly on a cloth when cleaning the Transilluminator. Do not saturate the unit - excessive solution causes damage to internal components.

Caution: 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

The following lists recommended cleaning solutions that may be used safely.

Generic Formulation	Max Concentration level
Hydrogen peroxide	6%
Sodium hypochlorite compound	0.5 % Aqueous Solution
Quaternary ammonium	0.2 %
Iodophors	50 mg/liter
Glutaraldehyde	2%

Caution: 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 Fiber optic cable or other material being cleaned.

Caution: Do not autoclave or gas sterilize the Fiber optic cable and the equipment.

4.2 Lifetime of product

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

Section 5: Specifications

Electrical connection
Input Voltage : ~230V, 50 Hz. 2A (400W)
Variable Intensity : 0 to 100% continues.
Light source : LED Cool White, Hi power White LED, 50W,
Optical Cable : 6mm Diameter & 1m Length.
On time : 5min & 10min selectable.
Display parameters : % of intensity, usage hours & timer
Alarm indication : Fan fail, Temperature Sensor fail, Light source over temperature.

Temperature:
Operating Range : + 15°C to 35°C environment
Storage Range : -10°C to 60°C environment

Humidity:
Operating Range : 15% to 95% RH Non-Condensing
Storage Range : 50% to 95% RH Non-Condensing
Dimensions/Weight
Overall length : 280mm, +/- 5mm
Overall width : 220mm, +/- 5mm
Overall height from the floor : 130 mm, +/- 5mm
Total Weight : 3.5 Kg, +/- 100 gram

Quality Test Approval
Quality : ISO 9001:2008
: ISO 13485:2003
Electrical Safety : IEC 60601-1
Optional Accessories : Roll Stand
Classification : Class I Product

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 Probe & Battery carry only 3 months warranty. Lamps do not carry any warranty.
7. We warrant 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. Expected Service life of the equipment is six 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 Neotech Medical Systems Pvt. Ltd.
No, 85. Krishna Industrial Estate,
Vannagaram, Mettukuppam,
Chennai-600095. Tamil Nadu,INDIA
Ph: 91-44-24762594, 24764608
Tele Fax: 91-44-24766920 – Ext: 203
Email: service@niceneotech.com, info@niceneotech.com
Web: www.niceneotech.com
Toll Free No. 1800-425-2594 (India only)

Section 7: Trouble Shooting

- 7.1 General System Failure
- 7.2 System Fault Transilluminator
- 7.3 Maintenance interval
- 7.4 Disposing of the equipment.

7.1 General System Failure

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

7.2 System Fault Transilluminator

Sl. No	Problems	Possible Causes and Remedy
1	No Display on the LCD.	Check A/C Supply Voltage
		Check if Power Cord is disconnected
		Check Fuse in the Rear side
		Other wise, Contact nice Neotech
2	Transilluminator LED Lamp is not turned on.	Check A/C Supply Voltage
		Check if Power Cord is disconnected
		Other wise Contact nice Neotech
3	Transilluminator LED Lamp is on but intensity is less	Check the percentage of intensity
		Replace Lamp
		Otherwise Contact nice Neotech
4	Fiber optic cable comes out	Check the locking mechanism
		Otherwise Contact nice Neotech

7.3 Maintenance Intervals:

- 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 Neotech's original parts for maintenance.

Warning: Periodically check the insulation and the connection of the cable it may cause fire because of poor insulation and short circuits due to aging.

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

7.6 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 disposal of the unit. The local Environmental agency can give further details.

Section 8: Spare Parts List

Sl. no	Part No	Part Name	Qty	Unit
1	40-05-037	PCB Assembly	1	No.
2	40-05-038	LED Engine Assembly	1	No.
3	40-05-045	Front panel Assembly	1	No.
4	40-05-046	Rear Panel Assembly	1	No.
5	87-00-062	Transilluminator Lens	1	No.
6	87-00-063	Fiber Optic Cable	1	No.
7	89-14-017	Hi Power White LED - 50W	1	No.
8	90-00-029	Power Cord 3Pin	1	No.
9	91-00-102	SMPS 36V DC	1	No.

Service contact:

nice Neotech Medical Systems Pvt. Ltd.

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Fax: +34952330100

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For Complaints/Comments/Suggestions or Feedbacks

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 _____

Complaints _____

Comments: _____

Suggestions: _____

Feed back: _____

Kindly fill the above and sent the same

From: _____

To:
The Marketing In-charge
nice Neotech Medical Systems Pvt. Ltd.
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Vannagaram, Mettukuppam,
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