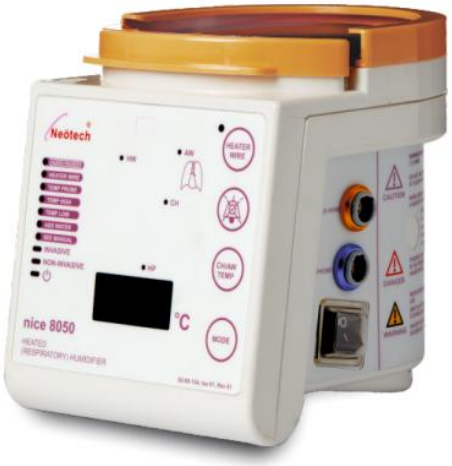
iSmart

Neötech®
HEALTH CARE EXCELLENCE

Heated (Respiratory) Humidifier



nice 8050 & 8010 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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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 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.

- Before using the nice Neotech Heated (Respiratory) Humidifier, 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:

Heated (Respiratory) Humidifier is designed to heat and humidify respiratory gases delivered to the patient via endotracheal tubes or face masks. Optimal humidity is achieved in nice 8050 and nice 8010 through the use of a temperature probe, heater wire adaptor, chamber and breathing circuit.

nice 8050 Servo Control Heated (Respiratory) Humidifier:
This model is intended to operate for Category 1 (Invasive therapy), Category 2 (Non-invasive therapy) and Category 3 (High flow therapy)

nice 8010 Heated (Respiratory) Humidifier:
This model is intended to operate for Category 2 (Non-invasive therapy) only.

Definitions:

a. **Respiratory Gases**	Gases breathed in by the patient.
b. **Humidification Chamber**	Tubing which carries respiratory gases from the chamber to the patient. Vessels containing water in which gas is heated and humidified by passing it over the heated water.
c. **Temperature / Flow Probe**	Sensor assembly for measuring temperature and flow of respiratory gases traveling through breathing circuit. Consists of a chamber sensor, flow sensor and airway sensor
d. **Airway Probe**	The Sensor assembly for measuring gas temperature at the end of the inspiratory limb
e. **Chamber Probe**	The Sensor assembly for measuring gas flow and temperature at the outlet of the humidification chamber
f. **Thermistor**	A temperature sensitive resistor placed inside the chamber and airway probes.
g. **Ambient Sensor**	A thermistor located in the temperature probe adaptor that allows the humidifier to monitor the ambient temperature.
h. **Chamber Set Point**	The temperature that the humidifier attempts to maintain at the chamber probe port
i. **Airway Set Point**	The temperature that the humidifier attempts to maintain at the airway probe port
j. **Heater Wire Adapter**	Electrical connector between the breathing circuit and the humidifier
k. **Breathing Circuit**	Tubing that carries respiratory gases to and from the patient
l. **Dual Heated Breathing Circuit**	A breathing circuit that is heated by means of heater wires, in both the expiratory and inspiratory limbs
m. **Single Heated Breathing Circuit**	A breathing circuit that is heated by means of a heater wire, in only the inspiratory limb
n. **PCB**	Printed Circuit Board.
o. **Heater Wire**	Wire inside the breathing circuit which heats the respiratory gases to minimize the condensation.
p. **Inspiratory Limb**	The section of the breathing circuit that takes the inspired gases to the patient.
q. **Expiratory Limb**	The section of the breathing circuit that takes the expired gases from the patient

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

Caution

- Before using the nice Neotech Heated (Respiratory) Humidifier, 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.
- Do not use the Heated (Respiratory) Humidifier in the presence of flammable anesthetics; a possible explosion hazard exists under these conditions.
- Switch OFF Heated (Respiratory) Humidifier if gas flow is stopped or changed considerably.
- Heater plate hot surface may exceed 90°C.
- To avoid the risk of electric shock, Heated Humidifier must only be connected to a supply main with protective earth.
- 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 Heated (Respiratory) Humidifier fails any portion of the checkout procedures it must be removed from use and repaired.
- Use of nice Neotech temperature probe, heater wire adaptor and cables only. Use of accessories such as temperature probes, heater wire adaptor and cables other than those specified or provided by the nice Neotech of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
- The nice 8010 and nice 8050 should not be used near active high-frequency equipment, MRI machines, high-frequency ventilators, defibrillators or strong RF sources such as mobile phones and wireless communication systems. Exposure to high electromagnetic disturbances may cause inaccurate monitoring, unexpected device behavior, or malfunction. Proper shielding and there must be a separation distance of at least 1.0m (3.3 ft) between this device and wireless communication device/ systems.
- The nice 8010 and nice 8050 should not be used adjacent to or stacked with other equipment, as this may lead to improper operation. If such use is unavoidable, both the nice 8010/ nice 8050 and the other equipment must be carefully monitored to ensure they are functioning correctly. Failure to do so may result in device malfunction, inaccurate performance, or potential safety risks.
- The nice 8010 and nice 8050 is a Class A equipment (CISPR 11, Group 1 Classification) make it suitable for use in hospitals. Use in a residential environment may cause radio-frequency interference, as CISPR 11 Class B is normally required for such settings. To prevent potential disruptions to communication services, users should take mitigation measures, such as reloacating or re-orienting the equipment if interference occurs.
- Even Small quantity of flammable agents such as ether and alcohol, left in the Heated (Respiratory) Humidifier it can cause fire in connection with oxygen.
- Ensure that invasive mode is set for patients that have bypassed airways.
- The use of breathing circuits, chambers or other accessories which are not approved by nice Neotech may impair performance or compromise safety.
- Ensure that both temperature probe sensors are correctly and securely fitted. Failure to do so may result in temperatures in excess of 41 °C being delivered to the patient.

Caution

- Ensure maintenance of grounding integrity by connection to a "hospital grade" receptacle. Always disconnect supply before servicing.
- When mounting a humidifier adjacent to a patient ensure that the humidifier is always positioned lower than the patient.
- The operation of high frequency surgical apparatus, shortwave or microwave equipment in the vicinity of the humidifier may adversely affect its function. If this occurs, the humidifier should be removed from the vicinity of such devices.
- Do not touch the glass tip of the chamber temperature probe during use. Keep black connectors dry at all times.
- Visually inspect accessories for damage before use.
- Normal operation cannot be guaranteed if powered from a source other than a pure sine wave, such as a square wave inverter.
- All applicable symbols are provided for live part on the equipment
- Heated (Respiratory) Humidifier is intended to be used in combination of medical respiratory devices such as CPAP, Bubble CPAP, Ventilator, Flow therapy, Resuscitator, etc.,
- All the combination of medical respiratory devices used with Heated (Respiratory) Humidifier to perform its intended use, should comply with the applicable safety standards.
- Single use marked product like breathing circuits, chambers should not be re-used as it may lead to cross contamination or infection or any health hazard on re-use.
- Do not add any attachments or accessories to the humidifier that are not listed in the instruction for use of the humidifier or accessory or the humidifier might not function correctly affecting the quality of the therapy or injuring the patient.
- Do not use the humidifier at an altitude above [3000 m] or outside a temperature of 18 to 26^{o}C using the humidifier outside of this temperature range or above this altitude can affect the quality of the therapy or injure the patient
- Covering breathing tubes with a blanket or heating them in an incubator or with an overhead heater can affect the quality of the therapy or injure the patient
- If the recommended flow range, gas pathway resistance, gas pathway compliance is not followed, it may affect the accuracy of set and monitored temperature of delivered gas.
- The performance of the HUMIDIFIER when exposed to, for example, electrocautery, electrosurgery, defibrillation, X-ray (gamma radiation), infrared radiation, conducted transient magnetic fields including magnetic resonance imaging (MRI), and radiofrequency interference may adversely affect its function.
- To prevent disconnection of the tubing or tubing system during use, especially during ambulatory use, only tubes in compliance with ISO 5367 or ISO 80601-2-74 should be used.
- The responsible organization should ensure the compatibility of the humidifier and all of the parts and accessories used to connect to the patient or other equipment before use.
- Modification or alteration should not be done in the equipment by the user
- Use or change the Disposable Circuit as per the Disposable circuit Manufacturer guidelines.
- Equipment connected to the serial port must comply with the safety standard IEC 60950 for personal computers.
- This product intended for use for a maximum of 7 days

Caution

- Read and understand the contents of this manual and demonstrate proficiency in the application of this device prior to use on a human.
- The product is intended for use by medical personnel trained in pulmonary ventilation and advanced cardiac life support techniques.
- The device has not been tested for use during Magnetic resonance imaging (MRI). However this device doesn't contain any ferrous material.
- Do not stretch or milk the tubing
- If the gas flow is interrupted turn the humidifier off.
- While mounting the humidifier adjacent to the patient ensure that the humidifier is positioned lower than the patient.
- Do not fill the chamber with water in excess of 37ºC.
- Do not touch the heater plate or chamber base. Surface may exceed more than 85ºC.
- The disposable breathing circuit is intended to be used with single infant.
- Covering breathing tubes with a blanket or heating them in an incubator or with an overhead heater can affect the quality of the therapy or injure the patient.
- Excessive liquid output could cause PATIENT injury and an accumulation of water in the breathing tube**.**
- Non – detachable power cord should be placed by the service personnel
- The HUMIDIFIER shall not be used with nitric oxide. Such use might cause the HUMIDIFIER to not function correctly causing serious deterioration of health.
- Do not use steam, gamma, or other methods – may damage the circuit/ interfaces and compromise patient safety.
- Check the gas flow and maintain it according to patient requirements.
- Breathing circuits/ Chamber: Avoid contact with chemicals, cleaning agents, or hand sanitizers, as they may pose a fire hazard.
- The used circuit/ interfaces should be properly disposed according to the local legislations.
- Do not use if circuit/ interfaces beyond the date of expiry.
- Do not pull, twist, or kink the circuit. Improper handling may impair functionality and patient safety.

Danger: Possible explosion hazard if used in the presence of flammable anesthetics.

Section B: Cautions

- Isolation from the supply mains is non detachable power cord provided.
- Use cleaning solution sparingly on a cloth when cleaning the Heated (Respiratory) Humidifier. Do not saturate the unit - excessive solution causes damage to internal components.
- Do not autoclave or gas sterilize the Heated (Respiratory) Humidifier & sensor. Do not immerse the device & sensor in liquid cleaner.
- 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.
- The equipment may affect while using the defibrillator.
- **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 distilled water/ water for injection in the chamber, using impure water or other liquid may cause adverse effects.
- Clean surface using wet cloth dipped in mild soap water and squeeze dry excess water before use.
- Do not allow water to spill into equipment.
- Avoid using any solvent, spirits, alcohol to clean plastic parts.
- Do not use water or any other liquid to clean Electronics and Electrical parts.
- If operating outside the recommended ambient temperature range, consult your local nice Neotech representative.
- Although the display is not illuminated, the unit may still be energized. Be sure to disconnect power from the humidifier before servicing.
- DO NOT immerse the black electrical connector plug in disinfectant.
- DO NOT autoclave probes.
- DO NOT use dishwashing detergents or solvents.
- Maintain minimum water level of at least 20ml in the chamber. Maximum water level is marked in the chamber.
- Oxygen concentration be measured at the point of delivery to the PATIENT with an Oxygen Analyzer
- Oxygen concentration can be affected by a partial obstruction downstream of the HUMIDIFIER, eg., when using Accessory equipment.
- When used without a heater wire, a water trap should be used.
- Do not use without a heater wire at flow rate less than 5 LPM.
- Minimum heater wire resistance 7.5 Ohms.

Caution

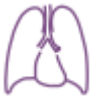
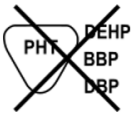
- Use only approved chambers, temperature probes and accessories.
- Disconnect the power supply before servicing.
- Always monitor and adjust proximal airway temperature as instructed in the heated humidifier instructions for use manual.
- Reversing the Inspiratory and expiratory circuits will result in elevated pressure being delivered to the nasal prong
- Back pressure created at the nasal prong in the expiratory circuits of the device varies with gas flow. Use of this device at gas flow> 12 LPM will result in higher back pressures.
- Do not use if the package has been opened or if any component is damaged.
- Ensure all parts are assembled correctly and are free from obstruction before applying to patient.
- Breathing circuit/ Chambers are supplied as non-sterile.
- Breathing circuits/ Chambers must be sterilized prior to use.
- Breathing circuits/ Chambers compatible with EO sterilization only.
- Breathing circuits/ Chambers sterilization process shall be performed by the end-user according to their validated hospital protocol.
- Do not use if breathing circuits/ Chambers packaging is not sealed.
- Do not use this circuit/ Chambers in case of any contamination or if it is damaged.
- Use in accordance with the manufacturer's instructions.

Section C: Symbols & Labels

Symbols:

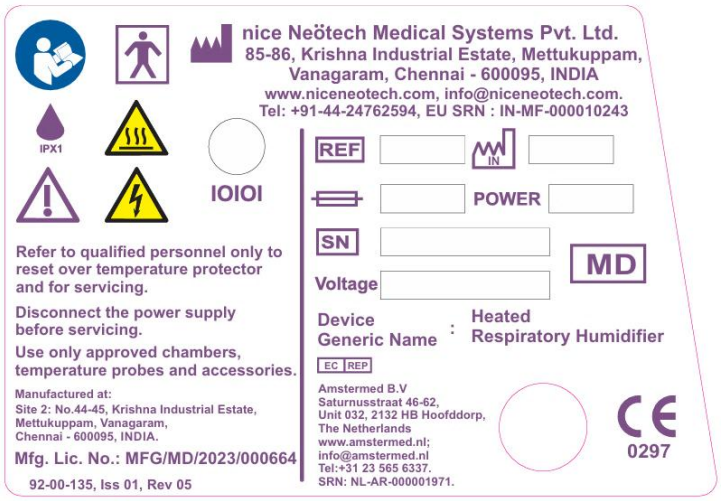
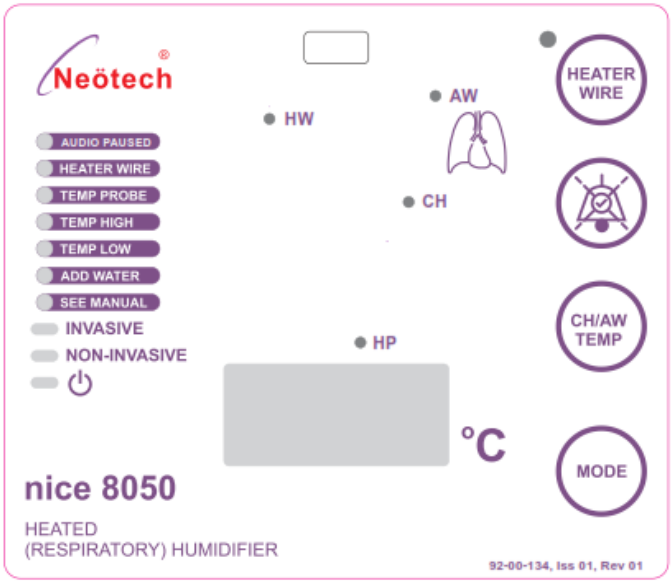
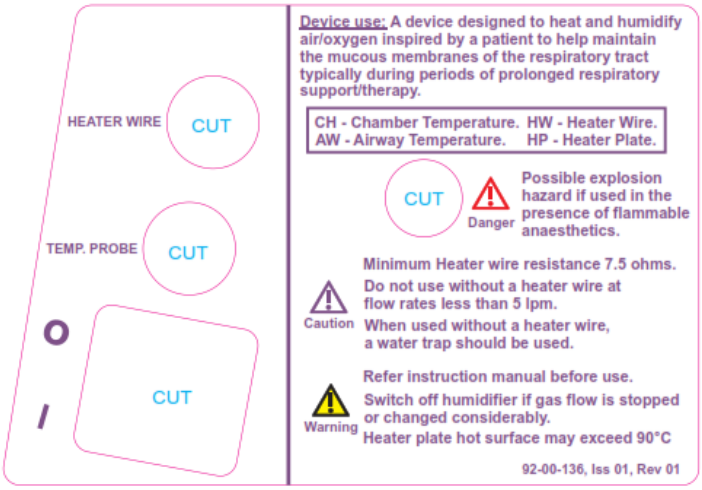
Mark	Title
Manufacturer	
	Manufacturer – Indicates the medical device manufacturer
	Date of Manufacture – Indicates the date when the medical device was manufactured.
	Country of manufacture – To identify the country of manufacture of products
	Authorized representative in the European Community/ European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

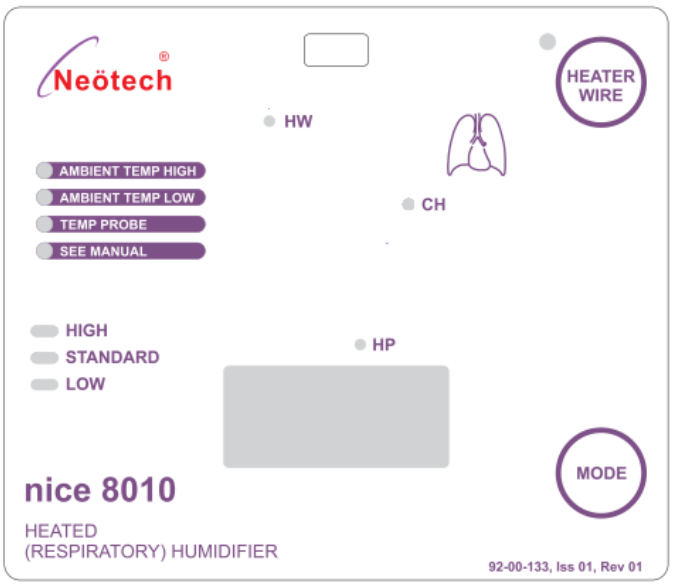
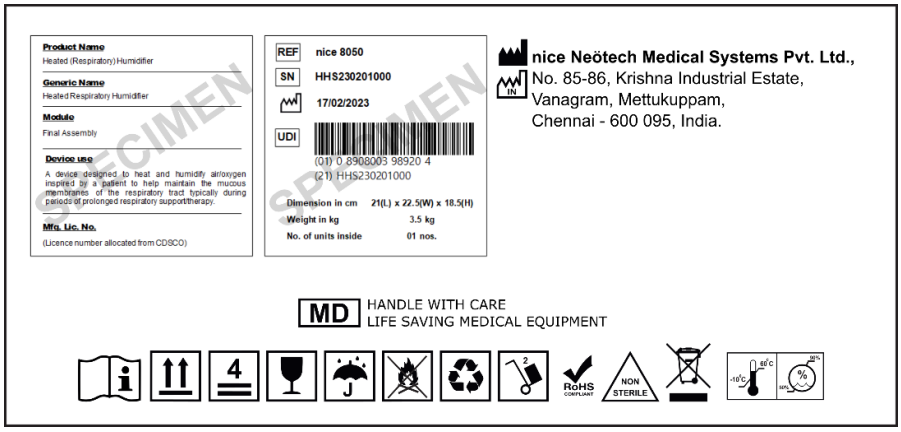
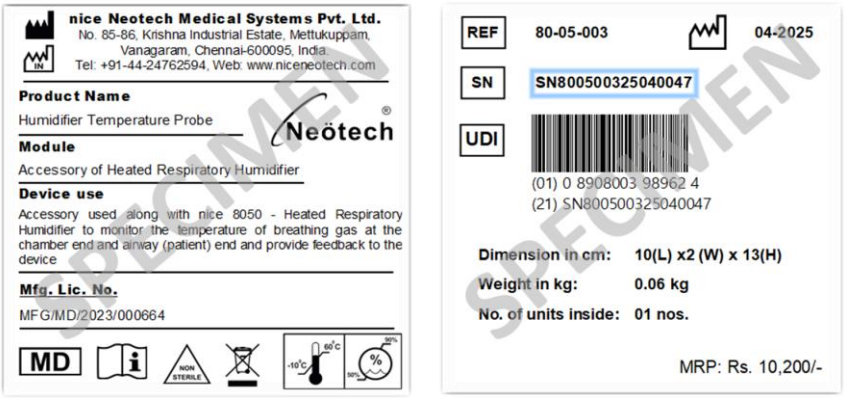
	Do not keep near fire – Do not keep the package near fire
	Maximum stackable limit – Pay attention to numbers on the stacked boxes icon. Some stacks will have top boxes marked with an X (number)
	This way up – For the duration/ delivery, the carton should face upright.
Safe use	
	Warning - indicates an indirectly (Potentially) hazardous situation which if not avoided, will result in death or Serious injury, serious damage to property such as total loss of use of equipment, and a fire.
	Caution - Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences
	The "Warning - Hot Surface" symbol indicates that a surface is hot and can cause burns or other injuries if touched. This warning is used to alert individuals to exercise caution and avoid direct contact with the surface.
	Cautions, Electric shock
	Danger
	Refer Instruction for use – Indicates the need for the user to refer instructions for use given by the manufacturer
	Do not re-use - Indicates a medical device that is intended for one single use only
	Consult instructions for use or consult electronic instructions for use - Indicates the need for the user to consult the instructions for use.
On Device	
nice 8050	
	ON/OFF key
	Heater wire key
	Timed Acknowledged key
	Chamber/Airway temperature key

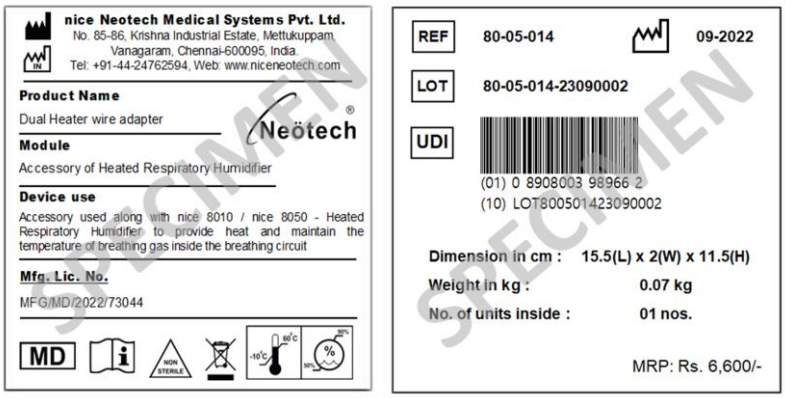
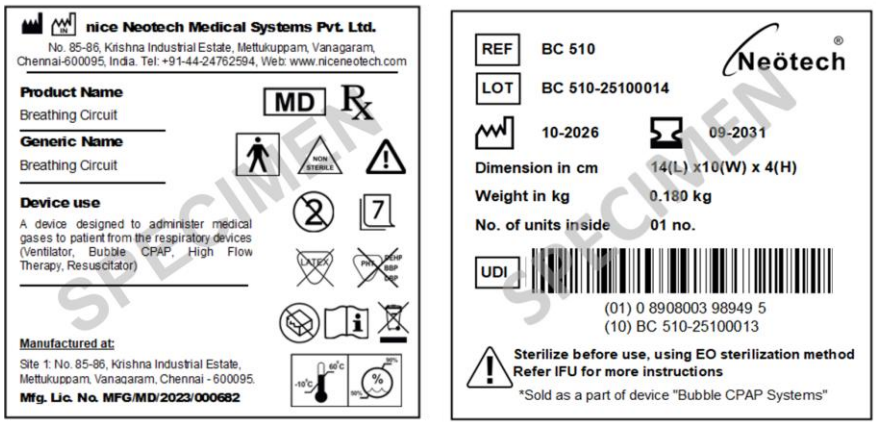
	Mode Key (Invasive /Non-Invasive)
	Standby
	Airway indication symbol
nice 8010	
	Mode Key (Low/Standard/High)
	Heater wire key
nice 8050 and nice 8010	
	Fuse
	IPX1 symbol indicates that a device has an Ingress Protection (IP) rating of IPX1, which refers to its resistance to water ingress.
	Serial interface – To identify a connector for a serial data connection.
Others	
	Medical Device - Indicates the item is a medical device
	Type BF Equipment – Indicates that the applied part is electrically connected to patient but not directly to heart.
	WEEE Complaint - The symbol indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling. The WEEE marking must appear on any electrical and electronic equipment placed on the EU market.
	Recyclable Package – The product can be recycled or it was made from recycled materials.
	Phthalate free – Indicates that the product does not contain the phthalate plasticizers DEHP, BBP and DBP.
	Indicates the absence of dry natural rubber or natural rubber latex as a material of construction within the medical device or the packaging of a medical device
	Use trolley for transportation – Used for heavy products that are difficult to carry by hand, even if you have multiple people.

	RoHS Complaint – RoHS (Restriction of Hazardous Substances) Indicates that no hazardous substances have been used in the product
	Unique device identifier - Indicates a carrier that contains unique device identifier information

Labels:

S.NO	Label	Part No.	Description
1.		92-00-135	Label – Marking plate – Heated (Respiratory) Humidifier
3.		92-00-134	Label – Front panel - nice 8050 Heated Humidifier
4.		92-00-136	Label – Instruction – Heated Humidifier

5.		92-00-133	Label – Front panel nice 8010
6.		92-00-016	Label – Probe tag
7.		--	Packaging label of Heated (Respiratory) Humidifier
8.			Packaging label of Humidifier Temperature Probe

9.		--	**Packaging label of Dual Heater wire adapter**
10.			**Packaging label of Breathing circuit**
11.		--	**UDI Label (nice 8050)**
12.		--	**UDI Label (nice 8010)**

Section 1: Description

1.1 Intended Use

nice 8050:

The model **nice 8050** is a Heated (Respiratory) Humidifier designed for use in hospital intensive care units. It is used to provide optimum humidity to respiratory gases delivered to patients via endotracheal tubes or face masks.

nice 8010:

The model **nice 8010** is a Heated (Respiratory) Humidifier designed for use in hospital intensive care units. It is used to provide optimum humidity to respiratory gases delivered to patients via endotracheal tubes or face masks.

1.2 Medical Indication/Conditions

Heated (Respiratory) Humidifier (nice 8010 & nice 8050) is used in Respiratory conjunction with dryness.

1.3 Contraindication:

No known contraindication, because air/oxygen/blended gas need humidification before delivering to all patient.

1.4 Side Effect:

No known side effects due to Heated (Respiratory) Humidifier

1.5 Target population:

Premature babies, Neonates, Infants, Pediatrics and Adults

1.6 Device Intended User:

Neonatologist, Anaesthetist and Healthcare Professionals

1.7 Working Principle

Respiratory humidification is a method of artificial warming and humidifying of respiratory gas to prevent drying of airways, support mucociliary function and improve gas exchange. The term respiratory gas conditioning stands for warming and humidification as well as purification of respiratory gas.

A heated respiratory humidifier operates based on the principle of warming and humidifying respiratory gases (air or oxygen) before they are delivered to the patient's airway. The respiratory humidifier receives dry medical gases (oxygen or air) from a ventilator or oxygen supply system. The humidification chamber contains a reservoir of sterile or distilled water, which is heated by a heater plate to promote evaporation, creating optimal humidity.

To ensure safe and effective delivery, the humidifier monitors and regulates gas temperature and humidity levels. Temperature probes measure gas temperature at various points, such as:

- Chamber temperature
- Airway temperature (near the patient)

These measurements allow the humidifier to adjust heater output for optimal performance. The warmed and humidified air is then delivered to the patient through the breathing circuit.

Heated humidifiers are active systems that independently add water vapor and heat to the inspiratory air from temperature-regulated reservoirs. Typically connected to the inspiratory end of breathing circuits, these humidifiers are often microprocessor-controlled, using sensors to maintain set humidity and temperature levels. In conjunction with a servo controller and heated breathing circuits, they can reduce condensation in the breathing circuit.

The design of the nice 8010 and nice 8050 humidifiers makes them ideal for various settings, including:

- Bubble CPAP System
- Infant T-Piece Resuscitator
- Adult and infant ventilators
- High Flow Oxygen therapy for adults, paediatric, and neonatal care

This process helps maintain respiratory mucosal function, prevent airway damage, and enhance patient comfort during mechanical ventilation or oxygen therapy.

1.8 Product Description

nice 8010:
The nice 8010 is a Heated (Respiratory) Humidifier designed for use in hospital intensive care units. It is used to provide optimum humidity to respiratory gases delivered to patients via Patient Interface like nasal Prongs , nasal cannula.

The Heated (Respiratory) Humidifier has two heating systems. The first is a heater plate, which heats the water contained in the humidification chamber, humidifying the air passing through it. The humidifier monitors the temperature of the gas at the chamber outlet with the chamber probe, and controls the amount of power delivered to the heater plate based on the selected mode (High/Medium/Low).

The second is a Heater wire, Humidified gas from the chamber travels through the inspiratory limb, where its temperature must be maintained in order to prevent the generated humidity from condensing. This is achieved with a heater wire encapsulated within the inspiratory limb and the amount of power delivered to the heater wire based on the feedback from environment temperature sensor.

nice 8050:
The nice 8050 is a Heated (Respiratory) Humidifier designed for use in hospital intensive care units. It is used to provide optimum humidity to respiratory gases delivered to patients via endotracheal tubes or face masks.

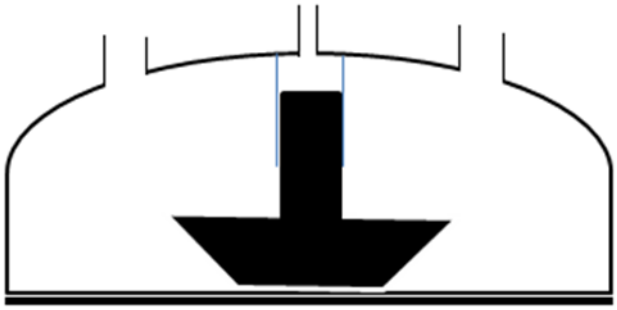
The Heated (Respiratory) Humidifier has two heating systems. The first is a heater plate, which heats the water contained in the humidification chamber, humidifying the air passing through it. The humidifier monitors the

temperature of the gas at the chamber outlet with the chamber probe, and controls the amount of power delivered to the heater plate, in order to maintain the chamber, set point. Under normal conditions the gas is heated to 37 °C in the invasive mode, 31 °C for the non- invasive mode.

The second is a Heater wire, the humidified gas from the chamber travels through the inspiratory limb, where its temperature must be maintained in order to prevent the generated humidity from condensing, and this is achieved with a heater wire encapsulated within the inspiratory limb. The humidifier maintains the temperature along the inspiratory limb by monitoring the temperature at the airway probe and controlling the power delivered to the heater wire. Under normal conditions the gas is heated to 40 °C in the invasive mode, 34 °C for the non-invasive mode. The humidifier is designed with **S10** Technology with the help of three sensors: Current Sensor, Flow Sensor and Temperature Sensor.

Humidification Chamber

The chamber fitted with a tube for refilling water. Humidifier chamber sits on top of the heater plate. The chamber designed with a metal bottom which transfers the heat fast and balanced. Water to be filled up to the mark. A mechanical float closes the water inlet port once the level reaches full. Humidified blended mixture passes through the out vent.

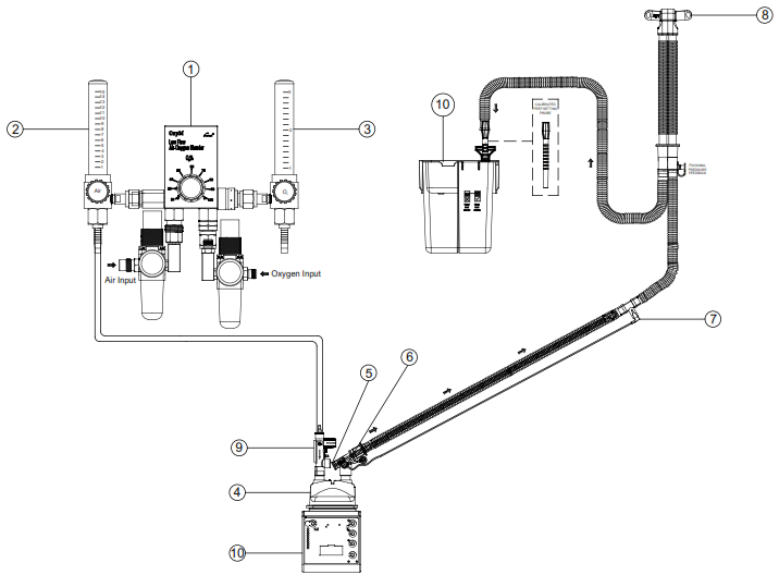


1.9 Intended combination devices:

- nice 5060 series Bubble CPAP System and other similar devices
- nice 5020 series Infant T-piece Resuscitator and other similar devices
- Infant/Paediatric/Adult Ventilator Systems

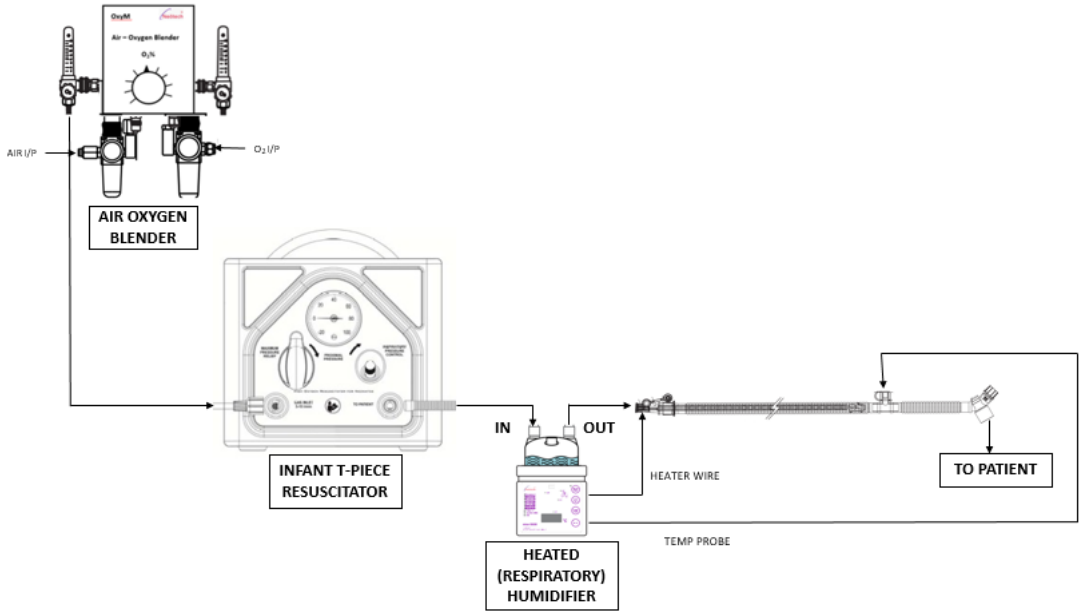
Connection descriptions:

- **Bubble CPAP System:**

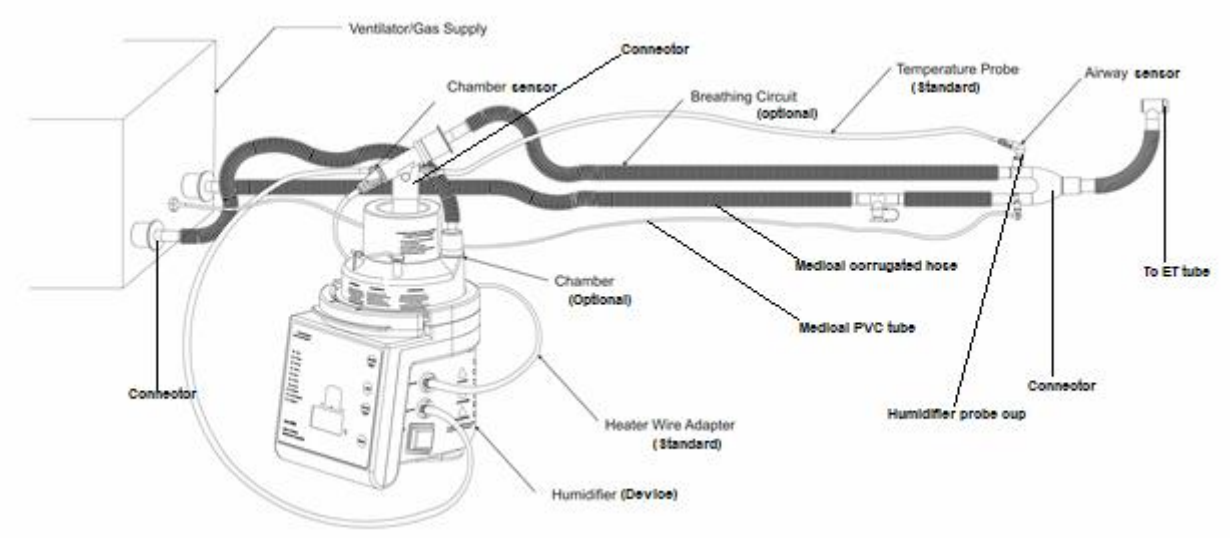


1	Low Flow Air - Oxygen Blender	6	Temperature Probe - Chamber Side
2	Flow Meter - 0 - 15 LPM	7	Temperature Probe - Air Way Side
3	Flow Meter - 0 - 3 LPM	8	Nasal Prongs
4	Humidity Chamber	9	Pressure Relief Device
5	Heater Wire Adaptor	10	Bubble Generator

- **Infant T-Piece Resuscitator with flowmeter, blender and humidifier**



- **Ventilator and other similar devices:**



1.10 Unique Device Identification (UDI Carrier)

The UDI identifies Heated (Respiratory) Humidifier with accessories throughout distribution and product life. The UDI appears on the Heated (Respiratory) Humidifier with Accessories label and it contains two parts i.e., device identifier (DI) and production identifier (PI). The UDI is established as per the requirements Chapter III and Annex VI of Regulations (EU) 2017/745.

#	Device Variant	Device Identifier (DI)	Production Identifier (PI)
1.	nice 8010	8908003989211	HRHXXXXXXXXX HRH- Product code YY – Year MM – Month XXXXX - serial number
2.	nice 8050	8908003989204	

Draft UDI label:

UDI label
UDI (01) 0 8908003 98920 4 (21) HHS240300851
nice 8050
UDI (01) 0 8908003 98921 1 (21) HHS230600070
nice 8010

Section 2: Installation

2.1 nice 8050

2.1 nice 8050

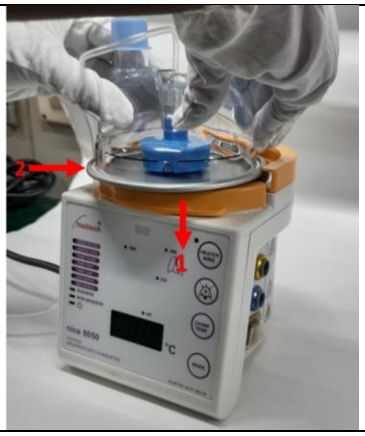
2.1.1 Unpacking and Inspection

- Remove the equipment from shipping containers and unpack all the assemblies and accessories of iSmart.
- After removal from the shipping containers, inspect the nice Neötech Heated Respiratory Humidifier and all accessory items for any signs of damage which may have occurred during shipment.

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

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

2.1.2 Fix the Humidifier Chamber (optional)

	➢ Slide the humidification chamber into the heater plate until you hear a click; this sound indicates that the chamber is securely fixed in place.
Picture 1	

2.1.3 Connect the Temperature Probe

	➢ Connect the blue plug to the blue socket. This socket is color-coded and keyed to the plug. Turn the plug until it slides in easily, it should click into place. ➢ This adapter has a blue plug and is used to measure the temperature and flow of a gas at the chamber and temperature of gas delivered to the patient. This information helps the humidifier, control the chamber output temperature and the breathing circuit temperature to ensure optimal humidity delivery.
Picture 2	

2.1.4 Connect the Heater Wire Adapter

	➢ Connect the heater wire adapter plug to the yellow socket on the humidifier base until an audible click is heard. ➢ Connect the other end(s) 'cloverleaf ' plug the heater wire adapter to the breathing circuit connector.
Picture 3	

Note: The humidification system is now set up and ready for use. After power on, the humidifier will default to invasive mode.

2.1.5 Pre-use Check Instructions

2.1.5.1 Mechanical Pre-use check Instructions

Ensure that the equipment is properly supported with mounting clamps, is free of defects, and is stable to prevent any operational issues. This applies to all combination devices used with humidifiers, including Bubble CPAP units and ventilators, to maintain their safe and effective performance.

Warning	• Before using the nice Neötech Humidifier, read this entire manual. Attempting to use this device without a thorough understanding of its operation may result in patient or user injury. • Do not perform the Pre-use Check Instructions (Mechanical and Light source Unit) while a patient occupies the Humidifier. If the Humidifier fails in any portion of the Pre-use Check Instructions it must be removed from use and repaired. • Examine the power cord whether it is intact with the socket. Replace the power cord if damage is evident. The Power cord is replaced by only the trained service personal

2.1.5.1.1 Overall Appearance

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

2.1.5.2 Control Unit Pre-Use Check Instructions

- Examine the power cord whether it is intact with the socket. Replace the power cord if damage is evident. The Power cord is replaced by only the trained service personal. Refer to the rating label on the Heated Respiratory Humidifier for the proper voltage needed.
- Switch the power on and verify the following on the Control Panel (Fig).
- The audible indication and all indicators are lit for approximately two seconds.

Note: During this time the controller also performs self-internal check functions.

The invasive mode indicator lit will be ON, which is the default mode.

2.1.5.2.1 Alarm verification Procedure

a) Heater wire Failure: By removing heater wire adapter from yellow socket this alarm occurs. This can be verified at any time, when the equipment is in Heater wire mode operation.

b) Temperature Probe Failure: By removing temperature probe from blue socket this alarm occurs. This can be verified at any time.

2.1.5.3 Accessory Checks

- Perform these checks if they are applicable.
- Check that all accessories provided with the Humidifier are damage free.
- Check that all gas accessories are operating properly.
- Where applicable, perform the pre-use check instructions detailed in the operation and maintenance manuals for the accessories.

2.1.5.4 Disposable chamber (optional) Pre-use Check Instructions

- Check whether the base of the chamber is locked properly to the humidifier unit.
- Water should be feed as per the instruction provided in Section 3.16.
- Check there is no leaks in the chamber and also in the connections.

2.2 nice 8010

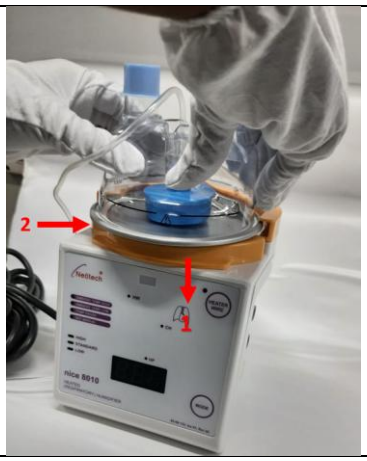
2.2.1 Unpacking and Inspection

- Remove the equipment from shipping containers and unpack all the assemblies and accessories of iSmart.
- After removal from the shipping containers, inspect the nice Neötech Heated Respiratory Humidifier and all accessory items for any signs of damage which may have occurred during shipment.

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

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

2.2.2 Fix the Humidifier Chamber (optional)

	➢ Slide the humidification chamber into the heater plate until you hear a click; this sound indicates that the chamber is securely fixed in place.
Picture 1	

2.2.3 Connect the Temperature Probe

	➢ Connect the blue plug to the blue socket. This socket is color-coded and keyed to the plug. Turn the plug until it slides in easily, it should click into place. ➢ This adapter has a blue plug and is used to measure the ambient temperature. This information helps the humidifier, control the chamber output temperature and the breathing circuit temperature to ensure optimal humidity delivery.
Picture 2	

2.2.4 Connect the Heater Wire Adapter

	➢ Connect the heater wire adapter plug to the yellow socket on the humidifier base until an audible click is heard. ➢ Connect the other end(s) 'cloverleaf ' plug the heater wire adapter to the breathing circuit connector.
Picture 3	

2.2.5 Pre-use Check Instructions

2.2.5.1 Mechanical Pre-use check Instructions

Ensure that the equipment is properly supported with mounting clamps, is free of defects, and is stable to prevent any operational issues. This applies to all combination devices used with humidifiers, including Bubble CPAP units and ventilators, to maintain their safe and effective performance.

Warning	• Before using the nice Neötech Humidifier, read this entire manual. Attempting to use this device without a thorough understanding of its operation may result in patient or user injury. • Do not perform the Pre-use Check Instructions (Mechanical and Light source Unit) while a patient occupies the Humidifier. If the Humidifier fails in any portion of the Pre-use Check Instructions it must be removed from use and repaired. • Examine the power cord whether it is intact with the socket. Replace the power cord if damage is evident. The Power cord is replaced by only the trained service personal

2.2.5.1.1 Overall Appearance

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

2.2.5.2 Control Unit Pre-Use Check Instructions

➢ Examine the power cord whether it is intact with the socket. Replace the power cord if damage is evident. The Power cord is replaced by only the trained service personal. Refer to the rating label on the Heated Respiratory Humidifier for the proper voltage needed.

➢ Switch the power on and verify the following on the Control Panel (Fig).

➢ The audible indication and all indicators are lit for approximately two seconds.

Note: During this time the controller also performs self-internal check functions.

The Previous mode indicator lit will be ON, whether it is low, high or standard.

2.2.5.2.1 Alarm verification Procedure

a) Heater wire Failure: By removing heater wire adapter from yellow socket this alarm occurs. This can be verified at any time, when the equipment is in Heater wire mode operation.

b) Temperature Probe Failure: By removing temperature probe from blue socket this alarm occurs. This can be verified at any time.

2.2.5.3 Accessory Checks

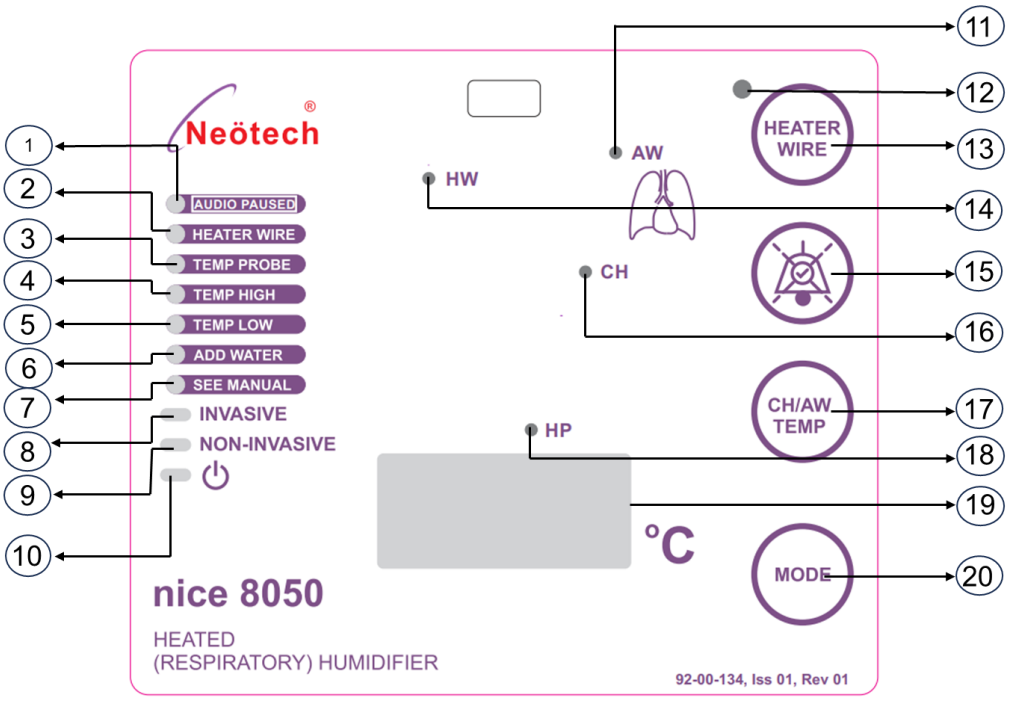
- Perform these checks if they are applicable.
- Check that all accessories provided with the Humidifier are damage free.
- Check that all gas accessories are operating properly.
- Where applicable, perform the pre-use check instructions detailed in the operation and maintenance manuals for the accessories.

2.2.5.4 Disposable chamber (optional) Pre-use Check Instructions

- Check whether the base of the chamber is locked properly to the humidifier unit.
- Water should be feed as per the instruction provided in Section 3.16.
- Check there is no leaks in the chamber and also in the connections.

Section 3: Operation

3.1 Control Panel Operation (nice 8050)



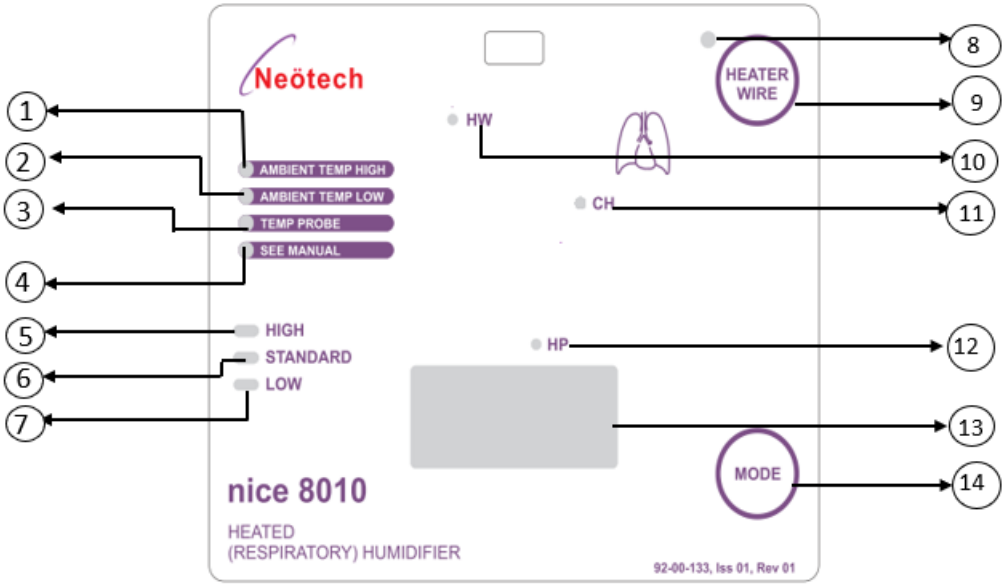
Picture 4

Front Panel Button and Indicators

1. Timed Acknowledged indication	11. Airway Sensor indication
2. Heater Wire Fail indication	12. Heater Wire Mode indication
3. Temperature Probe Fail indication	13. Heater Wire Mode Key
4. Temperature High indication	14. Heater Wire indication
5. Temperature Low indication	15. Timed Acknowledged key
6. Add Water indication	16. Chamber Sensor indication
7. See Manual indication	17. Chamber/ Airway Temperature Set key
8. Invasive Mode indication	18. Heater indication
9. Non-invasive Mode indication	19. Temperature display

10. Standby indication	20. Mode key

3.2 Control Panel Operation (nice 8010)

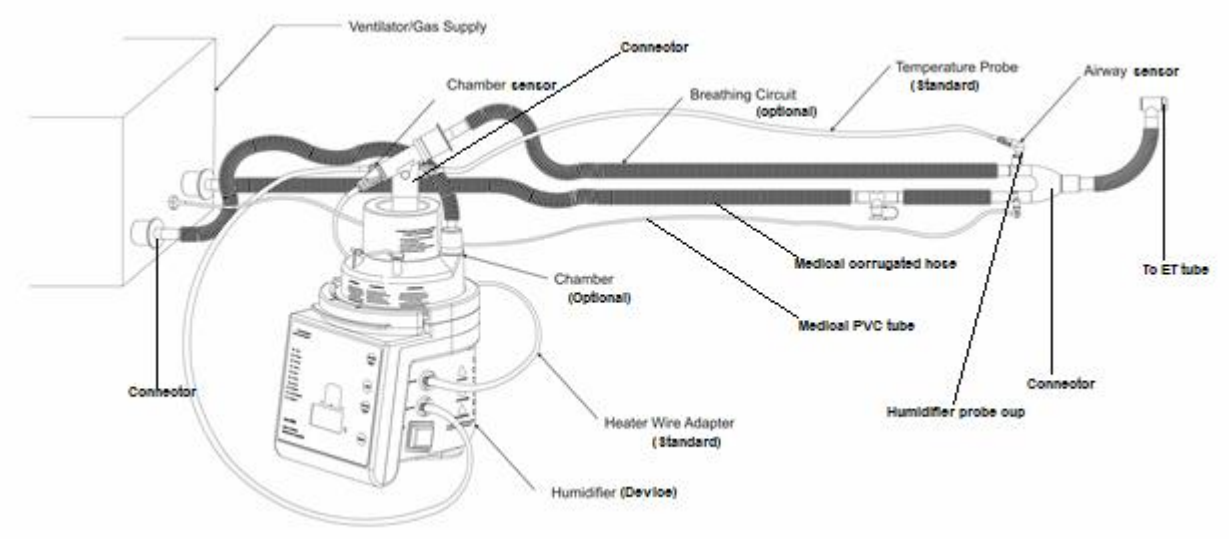


Front Panel Button and Indicators

1	Ambient Temperature High Indication	9	Heater Wire Key
2	Ambient Temperature Low Indication	10	Heater Wire Indication
3	Temperature Probe Fail Indication	11	Chamber Sensor Indication
4	See Manual Indication	12	Heater Indication
5	High Mode Indication	13	Mode Display
6	Standard Mode Indication	14	Mode Key
7	Low Mode Indication		
8	Heater Wire Mode Indication		

3.3 Heater Wire Operation (nice 8050 & nice 8010)

(Breathing circuit and Humidification chamber is optional)

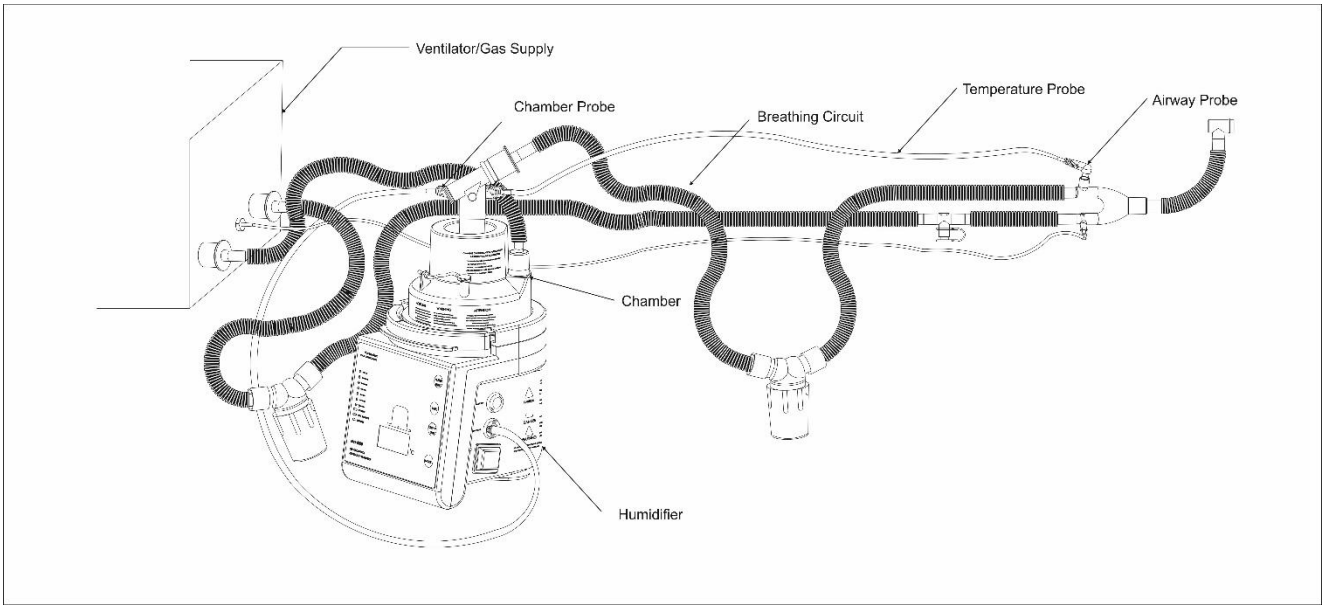


Picture 5

Humidified gas from the chamber pass through the inspiratory limb, where its temperature must be maintained in order to prevent the generated humidity from condensing. This is achieved with a heater wire encapsulated within the inspiratory limb. The humidifier maintains the temperature along the inspiratory limb by monitoring the temperature at the airway probe and controlling the voltage delivered to the heater wire. Under normal conditions the gas is heated to 40 °C in the invasive mode, 34 °C for the non-invasive mode.

Note: An optional, second heater wire, located in the expiratory limb, minimizes condensate in this limb.

3.4 Non-Heater Wire Operation (nice 8050 & nice 8010)



Picture 6

Heated (Respiratory) Humidifier maintains the airway temperature at the desired set point (invasive 37 °C or non-invasive 31 °C) by heating the chamber of water through the heater plate. As the gas cools considerably down the unheated circuit, a water trap circuit must be used to collect the resulting condensate.

3.5 Automatic Humidity Compensation (nice 8050)

nice 8050 Heated (Respiratory) Humidifier calculates the power required to adequately humidify the gas flow through the chamber. If the minimum power level is not met, then the chamber set point will automatically be increased in 0.5 °C steps until the minimum power is achieved. The maximum amount of compensation applied is either 3 to 5 °C depending on the mode (Invasive/Non-invasive)

If humidification is improved and too much power is being applied, then the humidifier will automatically reduce the chamber set temperature.

3.6 Flow Detection State (nice 8010)

At power-on the nice 8010 controls the heater plate to a fixed temperature dependent on the setting (40 °C at Low, 50 °C at Standard and 50 °C at High). The humidifier monitors the power required by the heater plate to maintain this temperature. Once the system is stable (about half an hour), the humidifier estimates the gas flow rate based on the power required. The humidifier then initiates the normal control state.

The humidifier delivers the power to the heater-wire circuit dependent on the environment temperature and the mode selected.

3.7 Normal Control State (nice 8010)

Once the flow has been identified, the humidifier controls the heater plate to a fixed temperature based on the flow. The humidifier then continues to monitor the heater plate temperature and heater voltage. Any significant power change (due to a change in flow, chamber run out of water etc.), will cause the humidifier to switch back to the flow detection state. Small power changes will cause the humidifier to step the heater plate temperature up or down to compensate.

3.8 Mains Voltage Compensation (nice 8010)

The humidifier automatically compensates for fluctuations in mains voltage to accurately control the power being delivered to the heater-wire and heater plate. Compensation is limited to ± 10 % of rated operating voltage.

3.9 Ambient Temperature Compensation (nice 8010)

Humidity compensation can be done manually, by noting that is environmental conditions change by ambient sensor then it might be necessary to re-adjust this setting. For example, a fall in room temperature could produce a buildup of unwanted condensate in the delivery circuit. A reduction in this setting may stop further buildups.

In the heater-wire mode of operation, cold ambient temperatures will cause the humidifier to automatically increase the heater-wire power, minimizing the condensate in the breathing circuit. Conversely for high ambient temperatures the heater-wire power is automatically reduced. Ambient temperature compensation is limited to between 18 and 30 °C, effectively limiting the maximum effect due to ambient temperature compensation.

Note:
Manual adjustment is needed when environmental conditions change significantly, such as a sudden drop in room temperature.
Heater-wire mode automatically compensates for ambient temperature changes to minimize condensation within a defined temperature range.

3.10 Display & Controls (nice 8050)

3.10.1 Power Switch

<table>
<tr><td rowspan="4">  </td><td colspan="2">The humidifier will power ON and OFF by the rocker switch is provided in the right side of the humidifier.</td></tr>
<tr><td colspan="2">After power-on the humidifier starts self-test for the followings:</td></tr>
<tr><td colspan="2">Power Sequence</td></tr>
<tr><td><u>Internal checks</u>:
1. Test presence of heater wire
2. Test presence of heater connection
3. Test integrity of temperature probe
4. Test correct operation of protection relays</td><td><u>Visual or audio checks</u>:
1. Display shows software version number 1.2 followed by audio tone for 2 second.
2. Temperature display self test and Indicator LED’s turn ON
3. If everything is working correctly, normal control is initiated.</td></tr>
</table>

Caution: Although the display is not illuminated, the unit may still be energized. Be sure to disconnect power from the humidifier before servicing.

3.10.2 Temperature Display

	The front panel display window shows the saturated gas temperature delivered to the patient. This display will normally show the temperature. This temperature gives an indication of the dew point (in °C) of the gas that is being supplied to the patient. The dew point of a gas is the best indication of both its humidity and energy content.

3.10.2.1 Chamber and Airway Temperature

Both the chamber and airway temperature can be displayed by pressing the CH/AW key for 1 second. The temperature is displayed in the following sequence:

1. The display compares the chamber and airway temperatures, showing the lower one first. To view the higher temperature range, press the CH/AW key. After displaying the higher temperature for 5 seconds, it will blink and then revert to showing the lower temperature.
2. Chamber and airway indicators “CH” and “AW” will also light up to show which temperature is being displayed.

3.10.3 Mode Key

	Long press the mode key, select humidifier to toggle Invasive & Non-Invasive. The Mode indicator LED shows the user which mode is selected Note: Invasive is the default mode on power up of the humidifier.

3.10.4.1 Invasive Mode

Invasive mode is for use with patients whose upper airways have been bypassed by either a tracheostomy or endotracheal tube. In this mode of operation, the humidifier attempts to deliver optimal humidity to the patient (37 °C, 100 % RH).

The humidifier normally controls the chamber outlet temperature to 37 °C, and the airway temperature to 40 °C, maintaining a +3 °C temperature gradient along the inspiratory limb. If however this temperature gradient is not maintained, the chamber set point is reduced in 0.5°C steps (minimum

setting of 35.5 °C), in order to reduce condensate buildup in the breathing circuit. If the chamber set point is less than 37 °C and sufficient temperature gradient has been maintained along the inspiratory limb, then the chamber set point is increased back up to 37 °C in 0.5°C steps.

3.10.4.2 Non-Invasive Mode

Non-Invasive mode is suitable only for patients whose natural humidification system (i.e. upper airways) has not been bypassed, but are receiving gas via a facemask or similar. The humidifier normally controls the chamber outlet temperature to 31°C, and the airway temperature to 34°C, maintaining a +3°C temperature gradient along the inspiratory limb.

3.10.5 Standby Mode

If the humidifier detects a problem with its setup or operation it will alarm. Depending on the severity of the alarm condition, the humidifier will either remove all power from the heating systems, or enter stand-by. The humidifier will also enter stand-by if the gas flow through the breathing circuit has stopped.

- Heater wire power is set at 15%.
- Control of chamber temperature is attempted, within the following limits:
- Heater plate temperature is limited to 50°C.
- Heater Plate power is limited to 20%

The humidifier will also enter stand-by and see manual indication, if there is no gas flow and no water in chamber after 15 mins with audible alarm indications.

3.10.4 Timed Acknowledged key

	This key is used to Pause the audible indication for 2 minutes temporarily. It Pauses indications except the sensor open, temperature probe failure and heater failure. The Timed Acknowledged indication key glows in yellow color when in use.

3.10.5 Heater Wire

	By pressing heater wire key, select humidifier to toggle heater wire ON or OFF. 1 When power ON, default heater wire operation will be ON. 2 To off the heater wire operation Press timed acknowledged key and heater wire key simultaneously.

3.10.6 CH/AW Temp Key

	By press CH/AW Temp key to shows the Chamber Actual Temperature and Airway Actual Temperature.

3.11 Displays & Controls (nice 8010)

3.11.1 Power Switch

	The humidifier will power ON and OFF by the rocker switch is provided in the right side of the humidifier.
	After power-on the humidifier starts self-test for the followings:

	Power Sequence	
	Internal checks: 5. Test presence of heater wire 6. Test presence of heater connection 7. Test integrity of temperature probe 8. Test correct operation of protection relays	Visual or audio checks: Display shows software version 1.6 number followed by audio tone for 1 second. Temperature display self test and Indicator LED's turn ON Normal display

Caution: Although the display is not illuminated, the unit may still be energized. Be sure to disconnect power from the humidifier before servicing.

3.11.2 Display

	The front panel display window shows the selected Mode (LO/STD/HI).

3.11.3 Mode Key

	By press mode key select humidifier to toggle Low, Standard & High mode. The indicator LED shows the user which mode is selected.

3.11.3.1 Low

- **Heater Plate Temperature**: The temperature is lower compared to the other modes.
- **Temperature Ranges**:
  45°C without heater wire
  40°C with heater wire

This mode is used when a lower temperature is needed for the operation, ensuring that the air or gas delivered is not too warm.

In environments where the ambient temperature is already warm, the low mode prevents the air or gas from becoming too hot, avoiding discomfort or harm.

3.11.3.2 Standard

- **Heater Plate Temperature**: The temperature is standardized.
- **Temperature Ranges**:

  60°C without heater wire
  50°C with heater wire

This is the default or normal mode where the temperature is set to a standard level, providing a balance between warmth and safety.

3.11.2.3 High

The temperature ranges from,

- 70°C (without heater wire)
- 50°C (with heater wire)

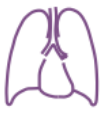
The heater plate temperature gets high when compared with other modes

3.11.4 Heater Wire Key

HEATER WIRE	❖ **When Enabled:** • **Heater Wire Probe Connection:** If the heater wire probe is not connected, the "H-W" (Heater Wire) LED will light up. ❖ **For Disabled:** • Long press the heater wire key, no alarms will be initiated, meaning the system will not generate any alerts related to heater wire operation.

3.12 Indicators (nice 8050)

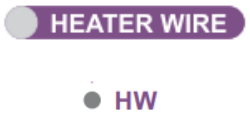
Humidifier indicators placed on the left of the front panel, are intended to aid the user in identifying problems with the incorrect setup of the device and its accessories.

HEATER WIRE HW	**Heater wire indicator:** Heater wire indicator and “HW” - LED glow if the heater wire in the breathing circuit has not been connected correctly, or if the heater wire or heater wire adaptor is faulty or disconnected. An intermittent connection or excessive current (total current in all limbs > 3.5 A) in the heater wires will also produce this alarm. The humidifier will disconnect the power from the heating systems if this alarm is active.
TEMP PROBE	**Temperature/ Flow probe indicator:** Temperature Probe indicator will glow if the temperature probe is not correctly plugged in, or the probe used is faulty and “S-O” will be displayed. The humidifier tests for the following probe fault conditions: ➢ Temperature probe disconnected ➢ Chamber thermistor open or short circuit ➢ Airway thermistor open or short circuit ➢ One thermistor shorted to another A medium priority alarm will be generated if any of the above faults are found, and the humidifier will disconnect the power from all heating systems.
AW  CH	**Chamber Probe & Airway Probe Indicator:** These indicators are used to show that either the chamber (CH) or airway (AW) temperature is being displayed.
ADD WATER	**Add water indicator:** This indicator alerts the user every 4 hours to check the humidification chamber.
TEMP HIGH TEMP LOW	**Temperature high and temperature low:** The indicator will light up if the displayed temperature is too high, or if the delivered temperature has been low for a period of time. The detailed conditions given in Section 3.4.2.
SEE MANUAL	**See manual indicator:** This indicates a serious hardware fault. Please refer to section 7, "Troubleshooting".

	The audio pause indicator will light up when we pause the alarm using the audio acknowledge key.
	When the temperature of the heater plate (HP) rises too high, the voltage will cut off, and the heater plate indicator will light up.
	The mode indicator lights up when the user selects either invasive or non-invasive mode, and the standby indicator lights up when the humidifier enters standby mode.
	Displays airway and chamber temperature and “S-O” when temperature probe is fault, “H-F” when heater fails.

3.13 Indicators (nice 8010)

Humidifier indicators placed on the left of the front panel, are intended to aid the user in identifying problems with the incorrect setup of the device and its accessories.

	**Heater wire indicator:** Heater wire indicator and “HW” - LED glow if the heater wire in the breathing circuit has not been connected correctly, or if the heater wire or heater wire adaptor is faulty or disconnected. An intermittent connection or excessive current (total current in all limbs > 3.0 A) in the heater wires will also produce this alarm. The humidifier will disconnect the power from the heating systems if this alarm is active.
	**Temperature Probe Indicator** Temperature Probe indicator will glow if the temperature probe is not correctly plugged in, or the probe used is faulty. The humidifier tests for the following probe fault conditions: ➢ Temperature probe disconnected ➢ Chamber/environment thermistor open or short circuit ➢ One thermistor shorted to another A visual alarm will be generated if any of the above faults are found, and the humidifier will disconnect the power from all heating systems.
	**See manual indicator:** This indicates a serious hardware fault. Please refer to section 7, "Troubleshooting".
	The high, standard and low indicator lights up when the user selects either high, standard and low.
	**Chamber Probe & Airway Probe Indicator:** These indicators are used to show that either the chamber (CH) or airway (AW) temperature is being displayed.
	When the temperature of the heater plate (HP) rises too high, the voltage will cut off, and the heater plate indicator will light up.

3.14 Operational Alarms (nice 8050)

These alarms are generated if problems occur with the operation of the humidifier

3.14.1 Heater Wire Operation – Invasive

These alarms are activated immediately if problems occur with the operation of the humidifier.

This alarm will occur if the displayed temperature is too high, or if the delivered temperature (Invasive mode only) has been low for a period of time.

High temperature:

The humidifier will immediately alarm if at any time the displayed temperature exceeds 40 °C, or if the airway temperature exceeds 41 °C. If either of these high temperature alarms occurs, the humidifier will immediately cutoff the heater wire and heater plate voltage.

Low Temperature:

The low temperature warning (visual only) and alarm (visual and audible) are active only when the humidifier is in Invasive mode & Non-Invasive Mode. Both are disabled during warm-up conditions. The warning alerts the user that low temperature is being delivered to the patient. The alarm alerts the user that a low level has been delivered to a patient for too long.

The low temperature warning and alarm activate by monitoring the displayed temperature. If the displayed temperature is below 35.5 °C for 25 seconds, the temperature indicator will light, and act as a warning to the user. If the temperature remains below this level for 20 minutes then a Temperature Alarm is activated.

The low temperature warning and alarm can be caused by cold or drafty ambient conditions, or can result from using gas flow rates outside the specification of the breathing circuit, chamber or humidifier.

NOTE: The low temperature alarm is disabled in stand-by mode.

3.14.2 Heater Wire Operation – non-invasive

High temperature:

The humidifier will immediately alarm if at any time the displayed temperature exceeds 40 °C, or if the airway temperature exceeds 41 °C. If either of these high temperature alarms occurs, the humidifier will immediately cutoff the heater wire and heater plate voltage.

Low Temperature

In addition, the airway temperature must reach 26.5 °C in non-invasive mode within 10 minutes, otherwise a visible and audible low temperature alarm will be activated, and the heater plate voltage will be cutoff. This will occur if the airway probe has not been inserted into the breathing circuit.

NOTE: The low temperature alarm is disabled in stand-by mode.

3.14.3 Non-Heater Wire Operation - Invasive

High Temperature

When the airway temperature exceeds 41 °C, the heater plate voltage is cutoff, and an immediate visible and audible high temperature alarm is activated.

Low Temperature

In invasive mode, the low temperature warning and alarm is identical for the heater wire mode (see above) after warm-up.

In addition, the airway temperature must reach 29.5 °C in invasive mode within 15 minutes, otherwise a visible and audible low temperature alarm will be activated, and the heater plate voltage will be cutoff. This will occur if the airway probe has not been inserted into the breathing circuit.

After warm-up, if the airway temperature drops below 29.5 °C, a visible and audible low temperature alarm will be activated, and the heater plate voltage will be cutoff.

NOTE: The low temperature alarm is disabled in stand-by mode.

3.14.4 Non-Heater Wire Operation – non-invasive

High Temperature

When the airway temperature exceeds 41 °C, the heater plate voltage is cutoff, and an immediate visible and audible high temperature alarm is activated.

Low Temperature

In non-invasive mode, the low temperature warning and alarm is identical for the heater wire mode (see above) after warm-up.

In addition, the airway temperature must reach 26 °C in non-invasive mode within 15 minutes, otherwise a visible and audible low temperature alarm will be activated, and the heater plate voltage will be cutoff. This will occur if the airway probe has not been inserted into the breathing circuit.

After warm-up, if the airway temperature drops below 26 °C, a visible and audible low temperature alarm will be activated, and the heater plate voltage will be cutoff.
NOTE: The low temperature alarm is disabled in stand-by mode.

3.14.5 Summary of Alarm Types, Conditions

Note: The below operational alarms may be caused by incorrect setup, faulty accessories or a faulty humidifier. User must ensure the alarm system after the installation or repair.

S. No	Type of Alarms	Actuated at	Priority Alarms	Alarm System verification	Remarks
1	Heater Failure	When heater fails (Displays – “H-F”)	Medium Priority	By removing heater connector from PCB “H-F” occurs. This alarm can be verified on self-test condition.	Audio cannot be paused
2	Heater wire failure	When heater wire is disconnected	Medium Priority	By removing heater wire adapter from yellow socket this alarm occurs. This can be verified at any time, when the equipment is in Heater wire mode operation.	Audio can be paused
3	Temperature probe failure	When Temperature probe is disconnected	Medium Priority	By removing temperature probe from blue socket this alarm occurs. This can be verified at any time.	Audio can not be paused
4	Temperature high	When it reaches the high temperature – (42deg) in Air way	Medium Priority	Keep the airway sensor in hot surface area up to 42deg and the high alarm occurs. This can be verified at any time.	Audio can be paused
5	Temperature low	After 10 minutes @ 26.0°C an audible and visible alarm is generated (after warm up period)	Medium Priority	After warm-up period keep the airway sensor in cold surface area up to 26° and the low alarm occurs.	Audio can be paused
6	Add water	A reminder alarms every 4 hours, to add water	Medium Priority	Keep the equipment in invasive heater wire mode and monitor after 4 hours this alarm occurs.	Audio can be paused
7	Sensor open	When Temperature probe is disconnected (Displays - “S-O”)	Medium Priority	By removing temperature probe from blue socket this alarm occurs. This can be verified at any time.	Audio cannot be paused

8	No flow	If there is no gas flow is detected, airway sensor indicator is lit.	Medium Priority	After warm up period stop the gas flow for 5 minutes this alarm occurs.	Audio can be paused

Statistics of alarm systems delay

S. No	Type of Alarms	Alarm condition delay	Alarm signal generation delay
1	Heater Failure	10 seconds	Alarm condition delay + 1 second
2	Heater wire failure	10 seconds	Alarm condition delay + 1 second
3	Temperature probe failure	Less than 5 seconds	Alarm condition delay + 1 second
4	Temperature high	Less than 5 seconds	Alarm condition delay + 1 second
5	Temperature low	10 minutes	Alarm condition delay + 1 second
6	Add water	4 hours once	Alarm condition delay + 1 second
7	Sensor open	Less than 5 seconds	Alarm condition delay + 1 second
8	No flow	10 minutes	Alarm condition delay + 1 second

3.15 Operational Alarms (nice 8010)

3.15.1.1 Temperature Probe Indicator

This alarm will occur if the temperature probe is open or short.

3.15.1.2 Ambient Temperature High

The humidifier will immediately visual alarm if at any time the environment temperature exceeds 42 °C

3.15.1.3 Ambient Temperature Low

The humidifier will immediately visual alarm if at any time the environment temperature below 18 °C

3.15.1.12 Heater Failure Alarm

The humidifier will immediately alarm with ”HF” indication if the Heater is defected or disconnected. This alarm will be activated in the non-heater wire mode also.

These alarms are activated if problems occur with the operation of the humidifier.

S. No	Type of Alarms	Actuated at	Priority Alarms
1	Heater Failure	When heater fails (Displays “HF”)	Medium Priority
2	Heater wire failure	When heater wire is disconnected	Medium Priority
3	Sensor open	When Temperature probe is disconnected (Displays “S-O”)	Medium Priority

3.16 Setup instructions

i) Insert Humidification Chamber

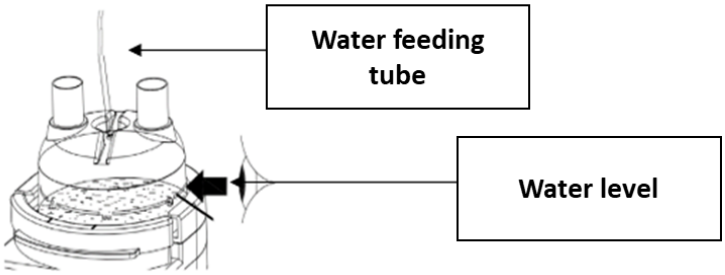
Caution

Discard the chamber if the seals are not intact when received.

- ➔ Slide the chamber on to the humidifier base.
- ➔ Remove the blue caps.

ii) Connect Water feeding tube with humidification chamber

Auto feed Humidification Chamber:



- ➔ Initially the chamber is fixed with the humidifier
- ➔ The chamber consists of a float assembly which regulates the water level in the chamber.
- ➔ The water inlet port is connected with the water feeding tube. Use only sterile/ distilled water.
- ➔ The water feeding tube from the chamber is connected to the water container
- ➔ The required amount of water is taken from the container whenever the level of water in the chamber gets lowered from its set level. This is achieved by dual float mechanism, one float acting as a backup to prevent the chamber from flooding should damage occur to the primary float mechanism.
- ➔ Check the humidification chamber for water flow from the bag.
- ➔ If no water is visible in the chamber or water consumption is low, check that the bag is spiked properly and that the feed tube is not kinked or blocked. Try gently squeezing the bag to promote water flow. Ensure that the height of the water bag is at least 50 cm higher than the humidification chamber. If in doubt replace the chamber.

Caution

- Do NOT use saline or other medicated fluids for filling humidification chamber.
- Do NOT add other substances to the water.
- Discard the chamber if the water level exceeds the maximum water level line.

Manual filling Humidification Chamber:

- ➔ Ensure the humidification chamber is cleaned as per hospital protocols before use.
- ➔ If the humidification chamber is connected to the bubble CPAP system/ ventilator or other respiratory devices, carefully disconnect it to avoid any damage or contamination.
- ➔ Use only sterile or distilled water to prevent mineral build-up and contamination. Avoid using tap or bottled water as these may contain impurities.
- ➔ Open the cap or designated inlet of the humidification chamber. Slowly pour the sterile or distilled water into the inlet port of chamber, ensuring it reaches the recommended water level indicated on the chamber (typically marked as a fill line). If using water feed port on the chamber, attach the appropriate water container or tubing to the feed port and fill the chamber to the recommended water level. Do not overfill the chamber, as this can lead to water spillage or incorrect functioning of the humidifier.
- ➔ Once filled, securely close the cap or inlet to prevent water leakage during operation.
- ➔ Reconnect the humidification chamber to the Bubble CPAP System/ ventilator or other respiratory equipment, ensuring all connections are tight and secure.
- ➔ Regularly check the water level during using to ensure it remains within the recommended range. Refill if necessary.
- ➔ Empty and clean the chamber at regular intervals as per the hospital protocols, especially between patient uses.

- Ensure that water is filled only to the level line indicated on the humidification chamber. Don't fill the chamber below or above the water level line.

3.17 Shutdown Procedure (nice 8050 & nice 8010)

- Switch OFF the Heated humidifier by the main switch provided in the side panel.
- Remove the temperature probe from the breathing circuit.
- Remove the heater wire adapter from the breathing circuit if exists.
- Remove the breathing circuit and breathing chamber from the Heated humidifier.

Note: Before Switch OFF the Heated humidifier Ensure the patient's therapy status.

3.18 Directions for Use (Breathing Circuit optional)

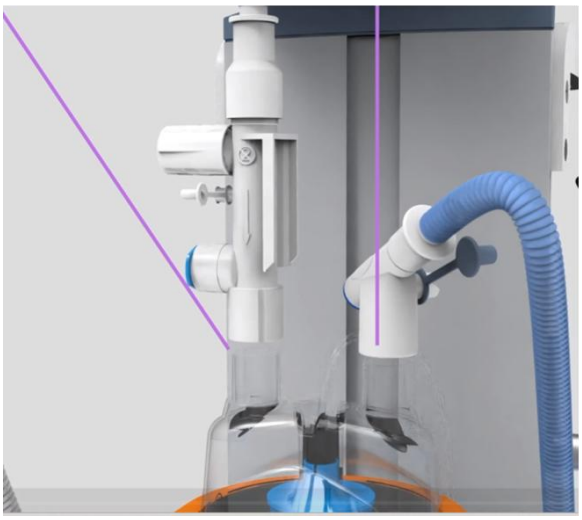
3.18.1 Connect Preset pressure manifold and Breathing Circuit

- ➔ Connect the gas supply line tubing between the pressure manifold and the flow source.
- ➔ Connect the pressure manifold to the chamber inlet port.
- ➔ Connect the blue inspiratory tube to the remaining chamber port.
- ➔ Remove the blue caps from the inspiratory tube and install the temperature probe ports and heater-wire adapter.

Ensure that the heater-wire (inside tube) is evenly distributed along the circuit length and is not bunched or kinked.

Connect the output of the Oxypap to the humidifier using a breathing circuit connected to a pressure manifold

The other end is connected to the inspiratory limb of the breathing circuit

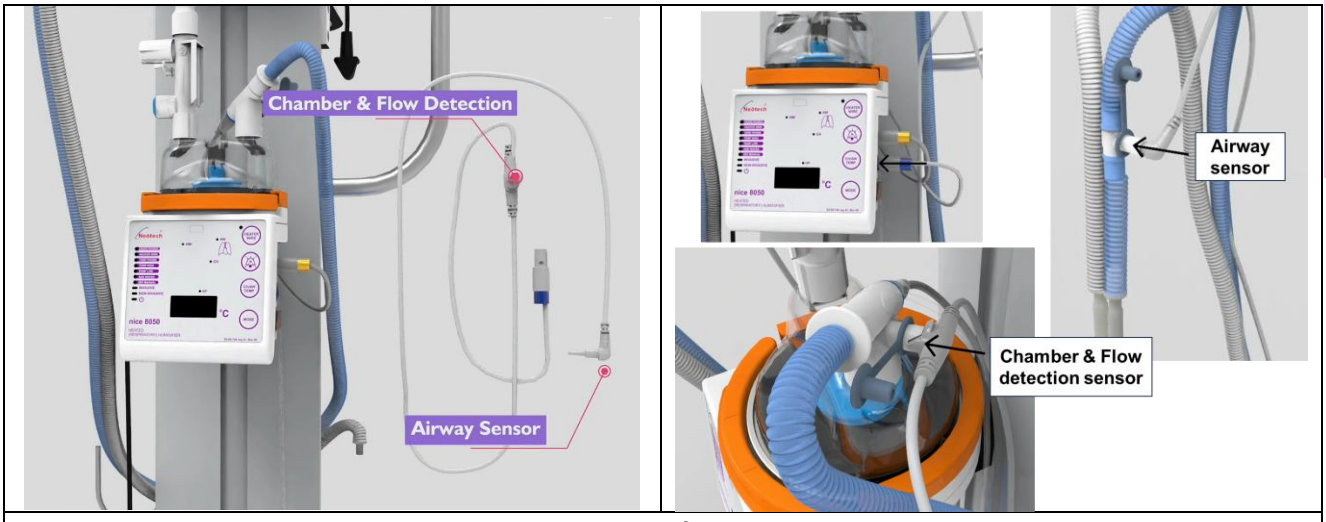


Set up the Inspiratory Limb:

- Start with the humidifier turned off.
- Connect the **heater wire adapter** to both humidifier and inspiratory limb and provides energy to power the heater wire in the limb. The humidifier adjusts the power delivered to the wire to maintain humidity and reduce condensate in the inspiratory limb.
- Insert the yellow plug into the yellow socket. The socket is color-coded and keyed to the plug. Turn the plug until it slides in easily, it should click into place.
- Connect the other end of the adapter shaped like a cloverleaf to the white socket at the back of the elbow connector on the inspiratory limb.

Heater Wire adapter connection

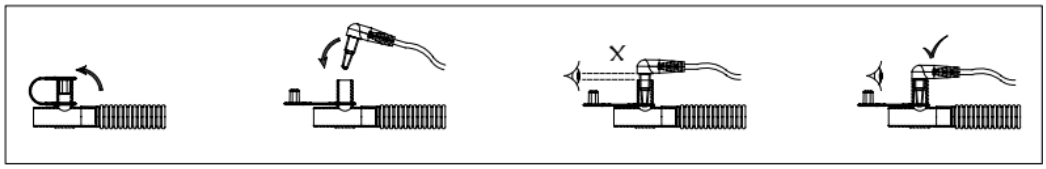
- Connect the temperature probe to the humidifier. This adapter has a blue plug and is used to measure the temperature and flow of a gas at the chamber and temperature of gas delivered to the patient. This information helps the humidifier, control the chamber output temperature and the breathing circuit temperature to ensure optimal humidity delivery.
- Connect the blue plug to the blue socket. This socket is color-coded and keyed to the plug. Turn the plug until it slides in easily, it should click into place.
- Connect the **temperature and flow probe** to the port in the side of the elbow connector. The probe port includes a V-shaped notch corresponding to a V-shape on the probe line. Push the probe firmly into place for correct operation of the humidification system. Fully insert the temperature probe (patient end probe) into the temperature probe port of inspiratory limb.



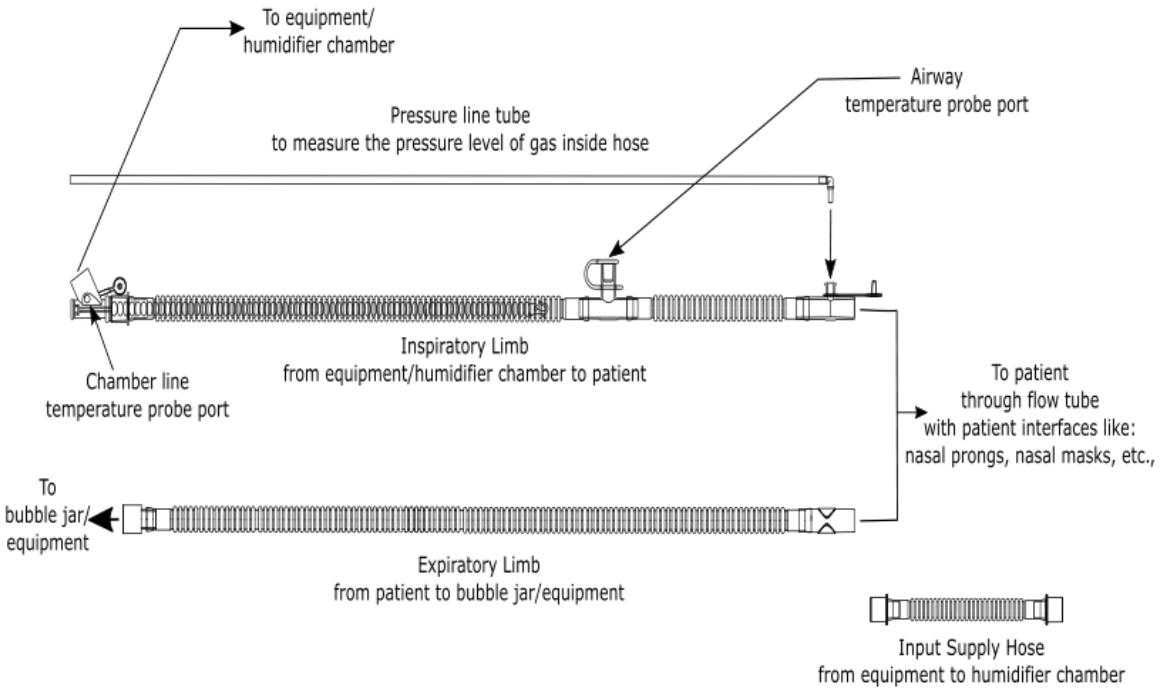
Temperature Probe connection

Caution

- Ensure the heater wire adapter and temperature probe is firmly seated against the chamber port and temperature probe port of the inspiratory limb. Failure to do so may result in gas temperature in excess of 41°C being delivered to the patient.



- To decrease possible bacterial contamination, do not reuse the breathing circuit.



3.18.2 Compatibility Guide for Breathing Circuits, Heater Wire Adaptors, and Chambers

1.Compatible Breathing Circuits with Heater Wire Adaptor:

- The heater wire adaptor (3-pin) can be used with the following breathing circuits: BC 510, BC 515, BC 520, BC 525, BC 530, BC 535, BC 540, BC 545, BC 550, BC 555, BC 570, BC 575, BC 580, BC 585, BC 610, BC 620, BC 625, BC 630, BC 635, BC 645, BC 650, BC 710, BC 720, BC 725, BC 730, BC 740, BC 745, and 50-05-150.
- The heater wire adaptor (2-pin) and dual heater wire adaptor can be used with the following breathing circuits: BC 520, BC 540, BC 620, BC 645, BC 720, BC 740.

2.Compatible chamber with heated (Respiratory) humidifier

Auto feed	Manual feed
Infant/Neonatal (80-05-015)	Infant/Neonatal nice 8020
Paediatric/Adult (80-05-016)	Paediatric/Adult nice 8030

3.19 Instructions for draining water from the Bubble Generator and Humidification Chamber:

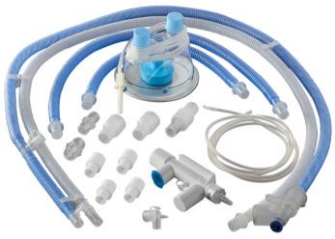
Humidification Chamber

- Ensure that the respiratory device (i.e., Bubble CPAP system and ventilator) is turned off and humidifier is turned off and disconnected from the power source to avoid any risks.
- Don't take the chamber after power off the humidifier, ensure the heat in the humidifier reduced.
- Carefully disconnect the humidification chamber from the breathing circuit and preset pressure manifold and from the humidifier by push down the finger guard and take off the chamber.
- Pour out the water from the chamber. Ensure the water is disposed of in accordance with the facility's guidelines.
- After draining the water, clean the chamber thoroughly with an appropriate disinfectant, following the cleaning instructions in Section 0.0. Rinse with sterile water if needed and ensure that all parts are completely dried.
- Store the cleaned and dried chamber in a clean, dry environment until it is ready to be used again.

3.20 Standard accessories (Reusable)

#	Accessory Name	Single-use / Reusable	Part no.	Intended use	Picture
1.	Temperature probe	Reusable	80-05-003	Temperature probe is intended for measuring chamber temperature and airway temperature.	
2.	Heater wire adapter	Reusable	80-05-014	Heater wire adapter is intended to interlink the Humidifier and breathing circuit heater wire.	

3.21 Optional Accessories

#	Accessory Name	Single-use / Reusable	Part no.	Intended use	Picture
1.	Single heated wire breathing circuit with Humidification Chamber and Pressure manifold	Non-sterile & Single-use only	BC 570	Breathing circuit is intended to direct the flow of medical gas(Air/oxygen) with optimum humidity to the patients	

Section 4: Cleaning & Maintenance of Heated (Respiratory) Humidifier

4.1 General

- ❑ Always switch off the equipment while cleaning.
- ❑ This section provides cleaning and maintenance instructions. where necessary, disassembly instructions are provided.
- ❑ Dry all surfaces after cleaning with a clean soft cloth or paper towel At least once every six months the equipment should be examined by a qualified Service Engineer to ensure safety and operational integrity.
- ❑ If any part of the equipment is damaged or fails to operate correctly, take it out of service immediately and contact a qualified Service Engineer to ensure operational safety.
- ❑ A Service Manual enabling qualified technical personnel to carry out routine service schedules, fault finding and repairs is available from nice Neötech.
- ❑ Always carry out a functional test after cleaning or maintenance to ensure safety and operational integrity.
- ❑ Periodically check the insulation and the connection of the power cord, Temperature probe cable and Heater wire adapter it may cause fire because of poor insulation and short circuits due to aging.
- ❑ Don't pour the water for cleaning it may enter into the electronics circuits it cause short circuit and get shock

Important - nice Neötech have 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 our company.

- 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 Heated (Respiratory) Humidifier. 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.
- Electrical shock and flammability hazard: Before cleaning, always turn off the device and disconnect from any power source.
- 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 Plastic enclosure being cleaned.

- Do not autoclave or gas sterilize the Heated (Respiratory) Humidifier & sensor. Do not immerse the device & sensor in liquid cleaner.

4.1.1 Cleaning and Disinfection of Heated (Respiratory) Humidifier

During cleaning the Heated (Respiratory) Humidifier, the processing shall comply with ISO 17664-1:2021 for reusable of the device

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

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

4. Rinse with damped cloth using sterile or clean water (i.e. water boiled for 5 minutes and cooled). Sterile water is preferred for rinsing off residual liquid chemical disinfectant from Heated (Respiratory) Humidifier 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 Heated (Respiratory) Humidifier using dry towel or cloth.

Disconnect the power cord from AC power before cleaning.

Note:

- Follow the manufacturer's instructions carefully.
- Use the correct dilution of the disinfectant.
- DO NOT immerse the humidifier in any liquid.

- 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 sensor or other material being cleaned.
- Do not autoclave or gas sterilize the humidifier.

4.1.2 Cleaning of Temperature Probe and Heater wire adapter

The cleaning methods listed below and do not affect the integrity or performance of the probe. It is the user's responsibility to qualify any deviations from these procedures, both for disinfecting efficacy and physical effect on the probe.

1. Physically clean the temperature probe and heater wire adapter with soft cloth, removing all visible contaminants by wiping using water general cleaning.
2. When the equipment is not in use, temperature probe and heater wire adapter cable surfaces should be cleaned daily with an antiseptic solution like 2% glutaraldehyde and leave for 3 minutes.
3. Then rinse the temperature probe and heater wire adapter by wiping using water damped cloth

4. Dry temperature probe and heater wire adapter using dry towel or cloth

Caution

DO NOT immerse the black electrical connector plug in disinfectant.
DO NOT autoclave probes.
DO NOT use dishwater detergents or solvents.

Note: Follow the manufacturer's instructions carefully. Use the correct dilution of the disinfectant.

4.1.3 Checking the Humidifier (Maintenance)

Warning

Annually

a. Check nice 8050 / nice 8010 for physical damage:

- Check the mains cable for damage, replace if necessary.
- Check the heater plate for deep scratching etc., replace if necessary.
- Check the heater wire adaptor for kinks, abrasions and damaged connectors. Check that the plugs couple with the sockets on the humidifier.

b. Carry out a full performance test.

4.1.4 Checking the Temperature Probe

Every Six months

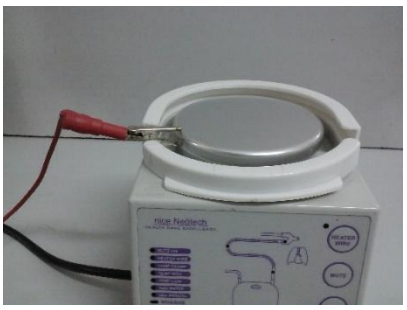
a. Visually check the humidifier probes for physical damage:
Check that the chamber probe's glass thermistor has not been damaged. Replace probe if required.
Inspect the chamber probe's glass thermistor for deposits or foreign material. Clean probe as required.
Check the probe cable for kinks and abrasions etc.
Check that the probe connectors couple with the humidifier sockets.

b. A temperature accuracy check and flow accuracy check should be performed on the nice 8050 temperature probe.

4.2 Safety Check

The unit should be tested to the current medical electrical standards for in-house testing for each specific country.

Note: The correct ground test point location is on the heater plate front underside edge, as shown in Picture 6 where the insulating anodizing layer has been removed.



Picture 6 showing the correct location of ground test point on the heater plate

4.3 Lifetime of product

The Life time of the product is five years considering the availability of components, which can be replaced, if necessary, without affecting the primary use of the device or does not degrade the property other critical components Thereby, Life time of the product is five years considering the availability of microcontroller.

Service life of the device is extendable up to 1 years so, the service life of the device is six years (5 years of lifetime + 1 year service life) considering the replacement of SMPS & microcontroller after 5 years.

4.4 Do's and Don'ts

DO

- Read all of the directions before using for the first time
- Visually inspect the Temperature Probe & Heater wire Adapter before each use.
- Make sure the Temperature Probe & Heater wire adapters are properly attached.
- Clean the case with isopropyl alcohol or soft detergent only
- Use only Neotech specified Temperature Probe, Heater wire

DON'T

- Use this humidifier if you suspect any malfunction.
- Use the device in the presence of flammable gases.
- Autoclave or freeze the temperature probe, heater wire adapter or device.
- Immerse the unit, temperature and heater wire adapter in any liquid.
- Expose the unit to devices that produce high levels of radio, short wave, microwave, x-ray, or high frequency interference.
- Place the unit itself in a water vapor-saturated environment.
- Expose the unit to a condensing water environment such as a mist tent.

Section 5: Specifications

nice 8010:

Supply Voltage	230V AC ± 10%
Supply Current	0.9 A
Supply Frequency	50 Hz Sine wave
Power rating	210W
Main Fuse	0.5A
Supply Voltage for Heater Plate	230V AC
Heater Plate Power	150W
Heater wire Impedance	7.5Ω
Fuse Heater Plate	2A
Supply Voltage for Heater wire	22V AC ± 5V
Supply Current for Heater wire	2.72 A
Heater Wire Power	60 W
Fuse Heater Wire	5A
Mode	Low, Standard & High (nice 8010)
Heater Plate over Temperature Cutoff	95°C
Heater Plate Thermal Cutout	118 ± 6°C
Display Temperature Range	15 to 70°C
Maximum Heater Wire Load	10.0 Ω (nice 8010)
Accuracy	± 0.3 °C (in 25 to 45 °C temperature range)
Measured gas temperature accuracy	± 2.0 °C
Recommended Gas Flow Range	up to 120 LPM (Minimum flow, gas pathway resistance and gas pathway compliance refer to breathing circuit specification)(nice 8010)
Pressure drop (variation may happen due to humidifying chamber with and tubing system)	Less than 0.3 cm H20 / meter of respiratory tube (22mm tubing system humidifying chamber)

Temperature control Pre-set

Mode	Setting	Constant Flow range (L/min)	Delivered patient temperature (°C)
Heater wire Mode	Low	5 to 60	28 to 32
	Standard	5 to 60	29 to 33
	High	5 to 30	32 to 35
Non-heater wire Mode	Low	5 to 60	24 to 26
	Standard	5 to 40	26 to 29
	High	5 to 30	27 to 31

Humidification Output	>12mg/L @ 5 to 60L/min
Maximum Operating Pressure	Refer to chamber and breathing circuit specification
Warm-up time	less than 30 minutes.
Maximum System Operating Pressure	20 kPa,
Gas leakage at max. Pressure	<100 mL/minute

Note 1: Performance results with Heater wire Adult BC610 and Neonatal - BC515 breathing circuit, Non-heater Wire - Adult – 615, Neonatal – 505

Note 2: For compatibility of Heated (Respiratory) Humidifier with breathing circuits and breathing chamber refer Manufacturer's Specification provided in User manual of breathing circuit and breathing chamber.

Visual and Audio Alarm

Humidifier Medium Priority Alarms	-Heater failure -Heater wire failure -Temperature probe failure -No flow -Temperature high -Temperature low -Add water
Alarm Pause Time Without user Intervention	120 seconds

High Temp alarm: Airway	43°C ±2°C
Low Temp alarm: Airway	<26°C ±2°C
Temp Probe Alarm	Disconnected or Damaged
Heater Wire Alarm	Disconnected or Damaged
Heater Plate alarm	Disconnected or Damaged
Algorithm of alarm: **Medium Priority** Pulse Frequency – 386.2 Hz, Number of Harmonics – 9, 3 Pulse burst, Pulse spacing: 231.2ms, 234.6ms Sound pressure Level - 58.8 db	
Dimensions **Without Chamber fitted** Dimensions : 13.5cm (L) X 16.5cm (D) X 15.5cm (H) Weight : 3Kgs Weight with chamber filled with water : 3.620 Kgs	

nice 8050:

Supply Voltage	230V AC ± 10%
Supply Current	0.9 A
Supply Frequency	50 Hz Sine wave
Power rating	210W
Main Fuse	0.5A
Supply Voltage for Heater Plate	230V AC
Heater Plate Power	150W
Heater wire Impedance	7.5Ω
Fuse Heater Plate	2A
Supply Voltage for Heater wire	22V AC ± 5V
Supply Current for Heater wire	2.72 A
Heater Wire Power	60 W
Fuse Heater Wire	5A
Mode	Invasive & Non-Invasive
Heater Plate over Temperature Cutoff	95°C
Heater Plate Thermal Cutout	118 ± 6°C
Display Temperature Range	15 to 70°C
Maximum Heater Wire Load	7.5 Ω
Accuracy	± 0.3 °C (in 25 to 45 °C temperature range)
Measured gas temperature accuracy	± 2.0 °C
Recommended Gas Flow Range	up to 60 LPM Invasive Mod up to 120 LPM non Invasive Mode (Minimum flow, gas pathway resistance and gas pathway compliance
Pressure drop (variation may happen due to humidifying chamber with and tubing system)	Less than 0.3 cm H20 / meter of respiratory tube (22mm tubing system humidifying chamber)
Temperature control Pre-set	
Heater wire mode – Invasive mode	
Chamber Set Point	36 to 40 °C
Airway Set Point	35 to 40°C
Heater wire mode – Non-invasive mode	
Chamber Set Point	32 to 36 °C
Airway Set Point	31 to 35 °C
Non-Heater wire mode – Invasive mode	
Airway Set point	37 °C (chamber temperature limited to 66 °C)
Non-Heater wire mode – Non-invasive mode	
Airway Set point	31 °C (chamber temperature limited to 66 °C)
Humidification Output	
Invasive mode	>33mg/L

Non-invasive mode	>12mg/L
Maximum Operating Pressure	Refer to chamber and breathing circuit specification
Warm-up time	less than 30 minutes.
Maximum System Operating Pressure	20 kPa,
Gas leakage at max. Pressure	<100 mL/minute.
Note 1: Performance results with Heater wire Adult BC610 and Neonatal - BC515 breathing circuit, Non heater Wire - Adult – 615, Neonatal – 505	
Note 2: For compatibility of Heated (Respiratory) Humidifier with breathing circuits and breathing chamber refer section 3.18.3	
Note 3: The set point of chamber and airway is set automatically inline with the specified ranges, to maintain the humidity compensation. This may vary based on the environment, gas flow, breathing circuit and breathing chamber.	
Visual and Audio Alarm	
Humidifier Medium Priority Alarms	-Heater failure -Heater wire failure -Temperature probe failure -No flow -Temperature high -Temperature low -Add water
Alarm Pause Time Without user Intervention	120 seconds
High Temp alarm: Airway	43°C ±2°C
Low Temp alarm: Airway	<26°C ±2°C
Temp Probe Alarm	Disconnected or Damaged
Heater Wire Alarm	Disconnected or Damaged
Heater Plate alarm	Disconnected or Damaged

Temperature Alarm

After warm up period if the airway temperature exceeds ± 2^0C from the airway set temperature, temperature high/low alarm will be activated.

	With Heater Wire	**Without Heater Wire**
Invasive Mode	After 10 minutes @ 29.5°C causes an audible and visible alarm. After 20 minutes @ 34°C causes an audible and visible alarm if at any time visible alarm at a airway temperature of 40 °C & audible alarm of 41°C	Airway temperature < 29°C causes an audible and visible alarm
Non-Invasive Mode	After 10 minutes @ 26.5 °C causes an audible and visible alarm.	Airway temperature < 26.0 °C causes an audible and visible alarm

Algorithm of alarm:
Medium Priority
Pulse Frequency – 515.7 Hz, Number of Harmonics – 9, 3 Pulse burst, Pulse spacing: 231.3ms, 235.8ms
Sound pressure Level - 58.8 db.

Dimensions
<u>Without Chamber fitted</u>

Dimensions	: 13.5cm (L) X 16.5cm (D) X 15.5cm (H)
Weight	: 3Kgs
Weight with chamber filled with water	: 3.620 Kgs

Common Specifications:

MDR Product classification	Class IIa
Electrical Safety Classification	
Type of Protection against Electric Shock	Class 1
Applied Part	BF (Breathing Circuit)

Mode of Operation	Continuous
Protection against hazardous Explosion	Not Protected
Ingress Protection	IPX1
Pollution Degree	II
Operating conditions	
Temperature	18°C to 26°C (To achieve best performance of humidifier)
Humidity	15–90% RH, non-condensing
altitude	Sea level to 1.9 miles (3Kms)
Atmospheric Pressure	50 to 106 kpa
Transport & storage conditions	
Temperature	-10°C to +60°C
Humidity	50 to 90% RH, non-condensing

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. We warranty this unit for 12 months from the date of Installation. Warranty includes the repair and replacement of faulty components.
7. 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.
8. Warranty is not applicable if the equipment is not purchased from Neotech/authorized Neotech Dealer
9. Warranty is not applicable if the warranty card is not filled and sent back to Neotech.
10. Expected Service life of the equipment is for six years and Shelf life is five 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,
Channai-600095. Tamil Nadu,INDIA
Ph: 91-44-24762594, 24764608
Email: service@niceneotech.com, info@niceneotech.com
Web: www.niceneotech.com / Toll Free No. 1800-425-2594 (India only)

Section 7: Trouble Shooting

7.1 General System Failure

Sl. No	Problem	Cause	Remedy
1	Add water indicator flashes, accompanied by an audible alarm.	Water in the chamber may be empty.	Check that there is sufficient water in the chamber. Refill or replace chamber as necessary. Check that the water bag is not empty, and the delivery tube is not kinked or occluded. Check that the water level in the chamber is not above the marked line. Replace chamber if the water is above this line. Check that the gas flow rate is within specification of the humidifier and accessories being used. Adjust as necessary. Has condensate formed on the chamber probe? Dry Probe and re-insert. Temperature probe faulty. Replace probe as required. Humidifier faulty. Service humidifier as required.
2	Chamber Probe alarm flashes accompanied by an audible alarm	Chamber probe may be defect	Check that the chamber probe is inserted into the breathing circuit correctly, and that the breathing circuit is set up correctly. Check that there is sufficient water in the chamber. Refill as necessary. Check that the water bag and delivery tube are not kinked or occluded. Ensure correct chamber is being used (refer Operating Manual) Check that the gas flow rate is within specification of the humidifier and accessories being used. Adjust as necessary. Has condensate formed on the chamber probe? Dry probe and re-insert. Temperature probe or humidifier faulty. Replace probe or service humidifier as required.
3	Heater wire fail alarm flashes, accompanied by an audible alarm	Heater wire may be failed	Check that the heater wire adaptor is correctly plugged into the humidifier along with the breathing circuit. Replace breathing circuit, and re-test.

			Replace heater wire adaptor, and check for intermittent connections. Re-test. Humidifier faulty. Replace PCBs.
4	Heater wire fail alarm not working	Heater wire mode not selected	Non-heater wire mode has been selected, connect a heated wire circuit or disable this mode by pressing the heater wire key.
5	Airway Probe fail alarm flashes along with an audible alarm	Airway Temperature Probe may be disconnected/Fail	Check that the airway probe is inserted into the breathing circuit correctly, the breathing circuit assembled correctly, and that there is water in the chamber. Check that the circuit is connected correctly to the ventilator – gas flow could be reversed through the humidifier. Check that the gas flow rate is within specification of the humidifier and type of accessories being used. Adjust as necessary. Check for excessive condensate build up. Excessively cold or drafty ambient conditions may cause this alarm to occur. Ensure there are no strong drafts around the breathing circuit. Replace probe as necessary. Humidifier faulty. Replace PCBs.
6	Temperature / Flow Probe fail alarm with airway or chamber indicators flashing	Temperature Probe may be disconnected/Fail	If the Temperature / Flow Probe alarm occurs with chamber or airway indicators also flashing, the temperature probe is faulty. Complete a probe accuracy check, and replace probe if required.
7	Temperature Indicator flashes, with audible alarm, coupled with a low temperature (< 35.5 °C) displayed	Sensor may be removed from the breathing circuit	The humidifier has been unable to maintain temperature over a period of time. Gas flow has been disconnected from the humidifier either reconnect gas flow or turn the humidifier off. Check that the gas flow rate is within specification of the humidifier and accessories being used. Check for drafts around the breathing circuit. This can be caused by fans or room air conditioning. If this is found to be the cause, the breathing circuit should be shielded from the ambient airflow. Check that the circuit is connected correctly to the ventilator – gas flow could be reversed through the humidifier. **WARNING: Never cover the breathing circuit.** Check for excessive condensate pooling in the breathing circuit. Drain circuit if necessary.

			Humidifier or probe faulty? Replace probe or service humidifier as required. Check that there is sufficient water in the chamber. Refill as necessary. Check that the water bag and delivery tube are not occluded.
8	Temperature indicator flashes, with audible alarm, and a high temperature is shown	Sensor may be near to the heat source/Heater is not cutoff	The gas flow rate may have suddenly changed. Monitor the displayed temperature, if the temperature does not fall rapidly then remove humidifier from patient, and complete a performance test on the humidifier, and temperature / flow probe. Replace probe or service humidifier as required

7.2 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.

- Don't misaligned the EMI Shielding and the beads it may cause the EMI interference to the equipment

7.3 Disposing of the Circuit and Unit

- At the end of its Service life Dispose of the breathing circuit and equipment in accordance with National waste Disposal Regulations or ask a suitable Disposal contractor to dispose of the breathing circuit and unit. The local Environmental agency can supply further details.

Section 8: Spare Parts List

Sl. no	Part No	Part Name	Qty	Unit
1	80-05-001	PCB – controller	1	No.
2	80-05-002	PCB - Power supply	1	No.
3	80-05-003	Temperature Probe	1	No.
4	80-05-010	Heater Wire Adapter	1	No.
5	89-11-071	Connector – 6 pin	1	No.
6	89-11-072	Connector – 4 pin	1	No.
7	91-00-131	Heater	1	No.
8	91-00-142	Transformer	1	No.

Service contact:

nice Neötech Medical Systems Pvt. Ltd.
No. 85, Krishna Industrial Estate, Vanagaram,
Mettukuppam Chennai-600095. Tamil Nadu, INDIA.
Ph: 91-44-2476 4608
Toll Free No. 1800-425-2594 (India only)
E-mail: service@niceneotech.com /info@niceneotech.com
Web: www.niceneotech.com
SRN: IN-MF-000010243

EU Authorised Representative
Amstermed B.V
Located in Saturnusstraat 46-62, Unit 032,
2132 HB Hoofddorp, The Netherlands.
Mr. Mike Vermin
Tel: +31 23 565 6337
info@amstermed.nl
www.amstermed.nl
SRN: NL-AR-000001971

Section 9: Manufacturer EMC Declaration

Guidance and manufacturer's declaration – electromagnetic emissions		
The Humidifier is intended for use in the electromagnetic environment specified below. The customer or the user of the Humidifier should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Class A	The Heated (Respiratory) Humidifier is suitable for use 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 Humidifier is intended for use in the electromagnetic environment specified below. The customer or the user of the Heated (Respiratory) Humidifier 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 A	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 A	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 & 1.0 cycles 0% short interruption for 250 cycles	Criteria A	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Humidifier requires continued operation during power mains interruptions, it is recommended that the Humidifier 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 Humidifier is intended for use in the electromagnetic environment specified below. The customer or the user of the Humidifier 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	10 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 Neotech
B	Temporary loss of function or degradation of performance which ceases after the disturbance ceases, and from which the equipment under test recovers its normal performance, without operator intervention
C	Temporary loss of function or degradation of performance, the correction of which requires operator intervention
D	Loss of function or degradation, which is not recoverable, owing damage to hardware or software, or loss of data

Section 10: Serial Port

The intended use of Heated humidifier serial port module is sending the following serial data for electronic health record management system through serial communication. nice 8050 is continuously sending data for every 1 second, until stop command is imitated. While transferring the data no security specifications are involved such as password.

Start/Stop serial communication	
Byte No.	**Data**
Byte 0	Start Of Message(0x65)
Byte 1	Init(0x01)
Byte 2	Start(0x01) / Stop(0x02)
Byte 3	Checksum
Byte 4	End Of Message(0x66)

Common parameters Package	
Byte No.	**Data**
Byte 0	Start Of Message(0x65)
Byte 1	Temperature Data(0x01)
Byte 2	Chamber temperature
Byte 3	Chamber temperature
Byte 4	Chamber set value
Byte 5	Chamber set value
Byte 6	Airway temperature
Byte 7	Airway temperature
Byte 8	Airway set point – heated wire mode
Byte 9	Airway set point – heated wire mode
Byte 10	Airway set point - non heated wire mode
Byte 11	Airway set point – non heated wire mode
Byte 12	Mode
Byte 13	Checksum
Byte 14	End Of Message(0x66)

Alarm parameters package	
Byte No.	**Data**
Byte 0	Start Of Message(0x65)
Byte 1	Alarm parameter(0x02)
Byte 2	Heater status
Byte 3	Heater wire status
Byte 4	Heater Wire Mode
Byte 5	Sensor short
Byte 6	Sensor open

Byte 7	Airway Probe Out
Byte 8	Chamber Probe Out
Byte 9	Airway Temp High
Byte 10	Chamber Temp High
Byte 11	Airway Temp Low
Byte 12	Add Water
Byte 13	Checksum
Byte 14	End Of Message(0x66)

Serial Port Characteristics and Configuration

Protocol - RS 232

Baud rate - 9600 bps.

Data bits - 8.

Stop bit - 1.

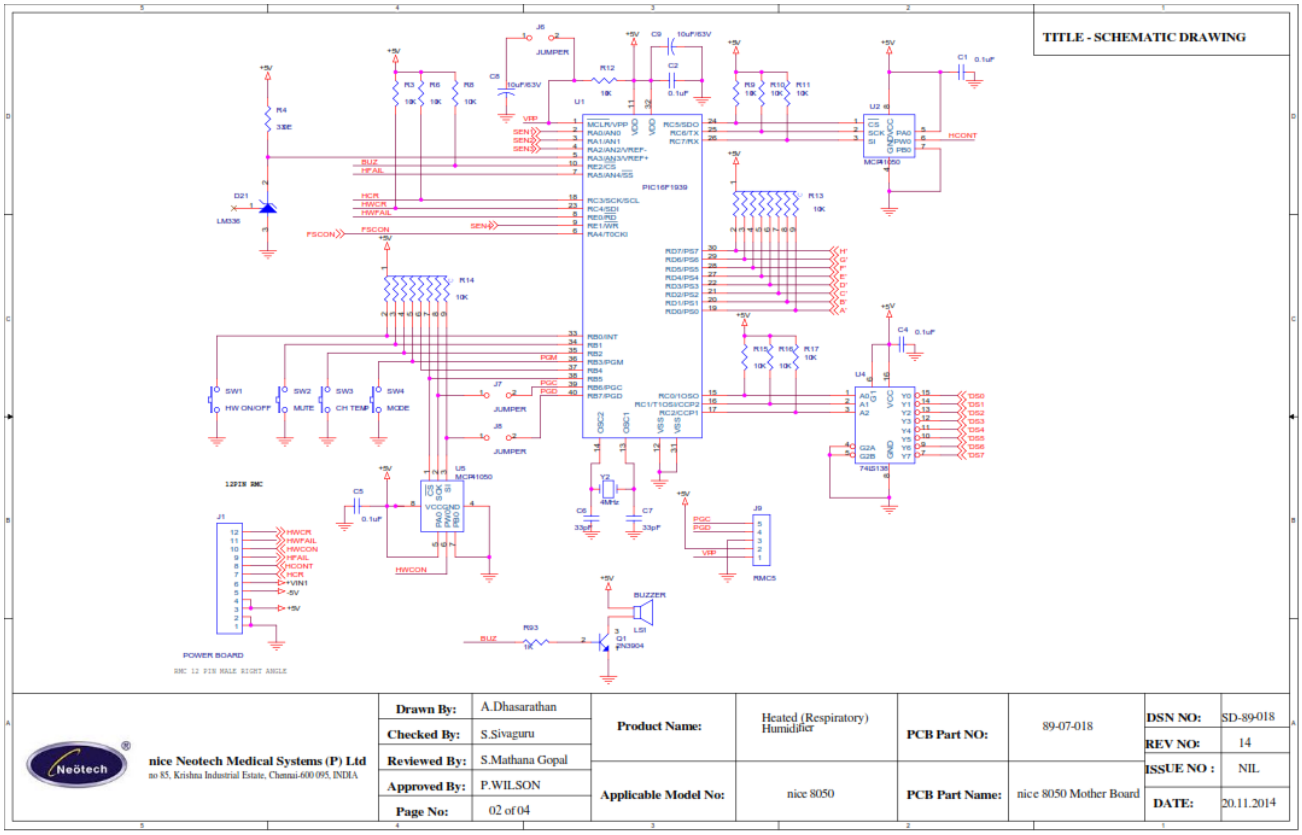
Parity - None.

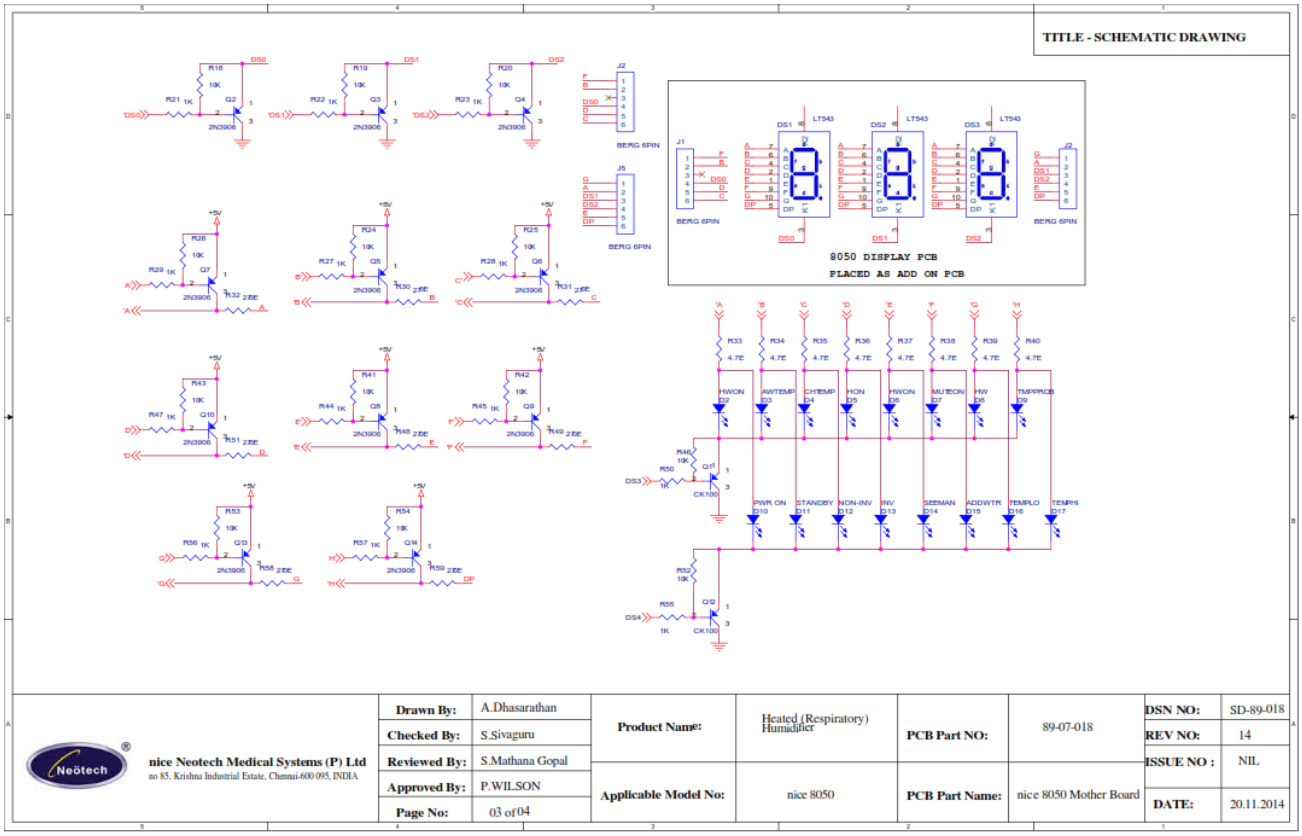
Hand Shaking - None.

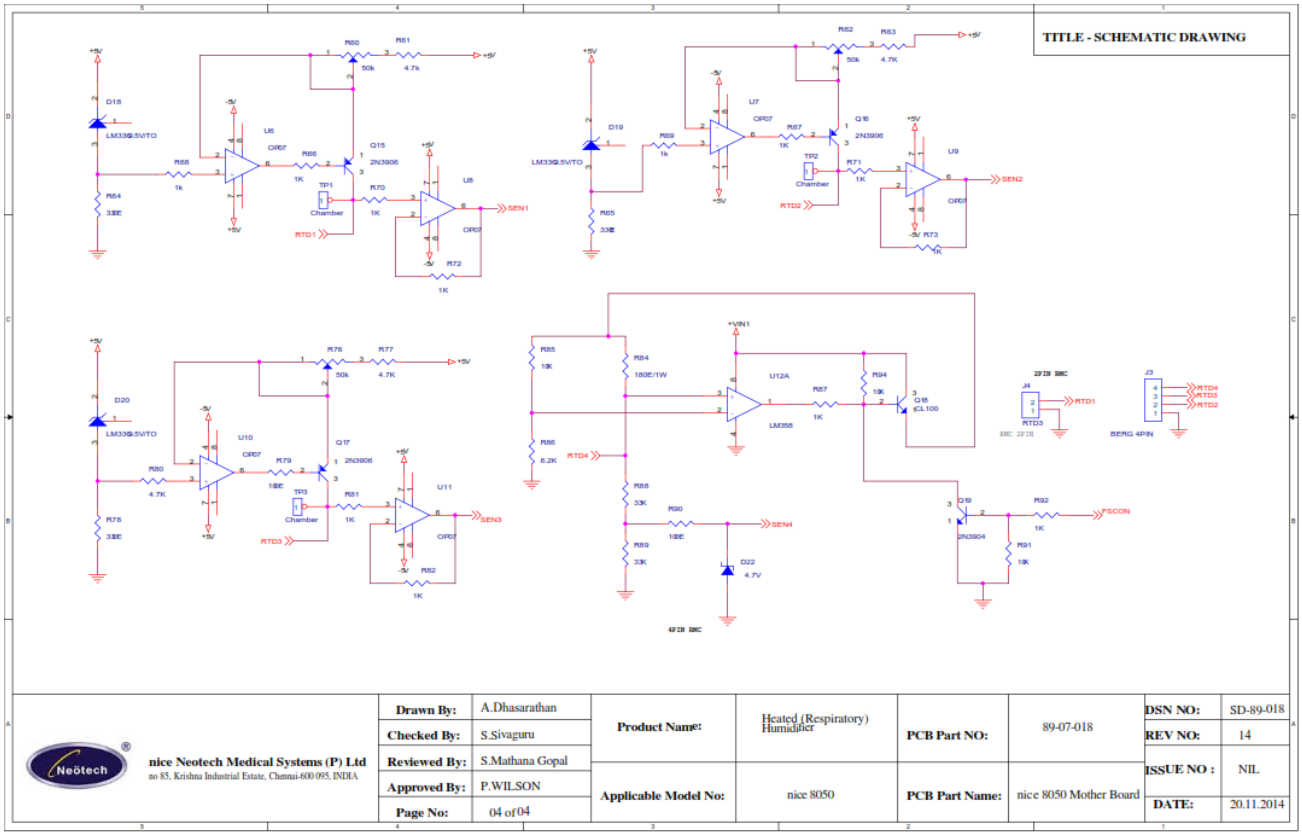
1.Equipment connected to the serial port must comply with the safety standard IE C 60950 for personal computers.
2.The serial port must not be used when the humidifier is in patient use.

Instructions:
1. Connection of the nice 8050 to electronic health record may result previously unidentified risks to the patients, operator or other third parties.
2.The responsible organization should identify, analyze, evaluate and control the previously unidentified risks.
3.Subsequent changes to the network/data coupling could introduce new risks and require additional analysis.
4.Changes to the IT network include configuration, connection of additional items, disconnecting items, update and upgrade of equipment connected to the network

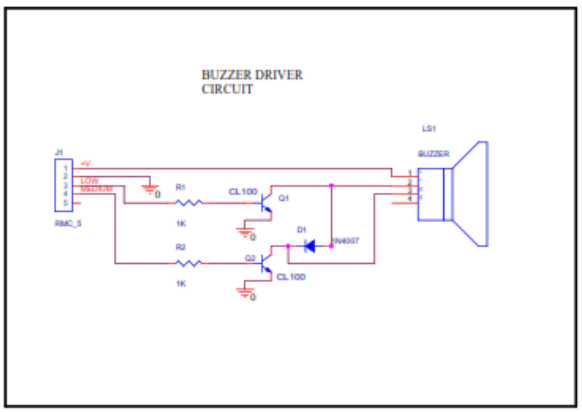
Section 11: Schematic Diagram



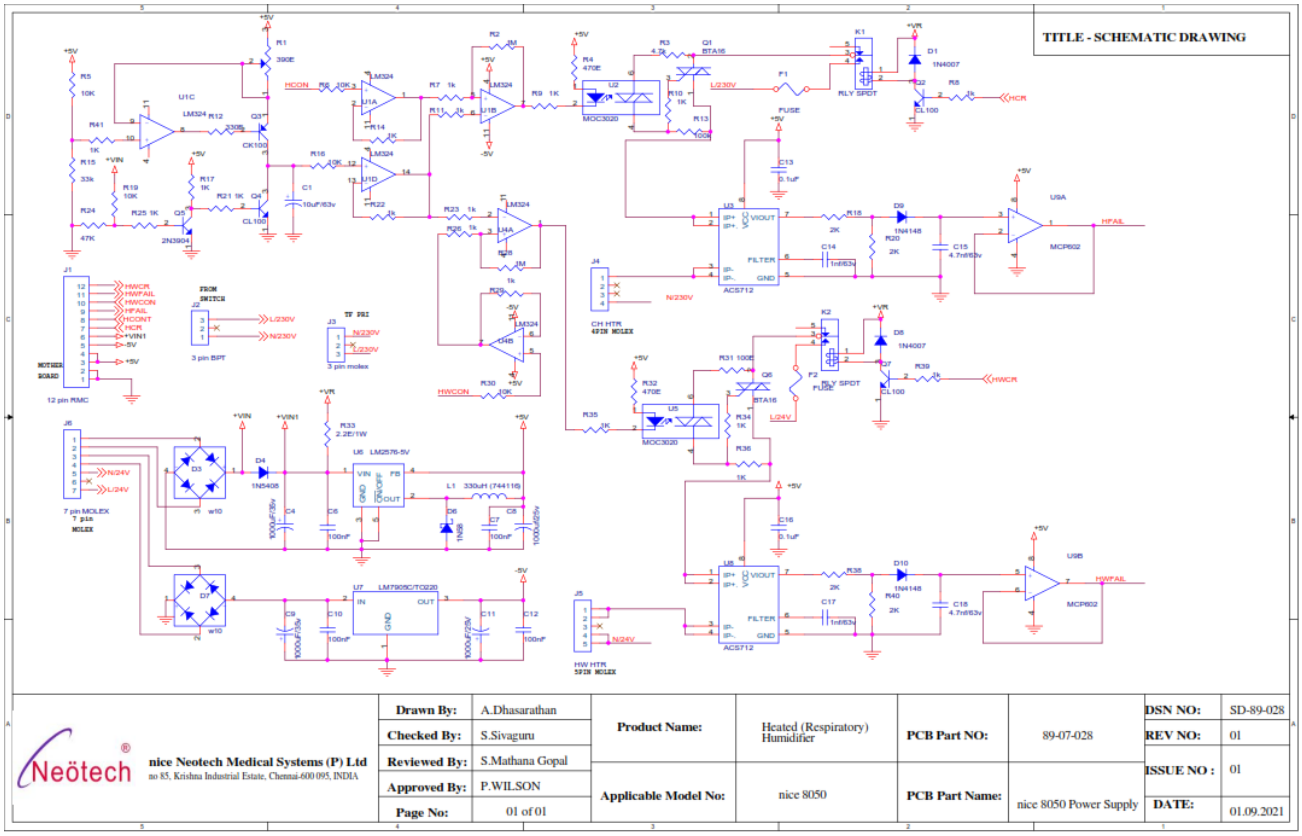




nice Neotech Medical Systems (P) Ltd no 85, Krishna Industrial Estate, Chennai-600 095, INDIA	Drawn By:	A.Dhasarathan	Product Name:	Heated (Respiratory) Humidifier	PCB Part NO:	89-07-018	DSN NO:	SD-89-018
	Checked By:	S.Sivaguru					REV NO:	14
	Reviewed By:	S.Mathana Gopal					ISSUE NO :	NIL
	Approved By:	P.WILSON	Applicable Model No:	nice 8050	PCB Part Name:	nice 8050 Mother Board	DATE:	20.11.2014
	Page No:	04 of 04						

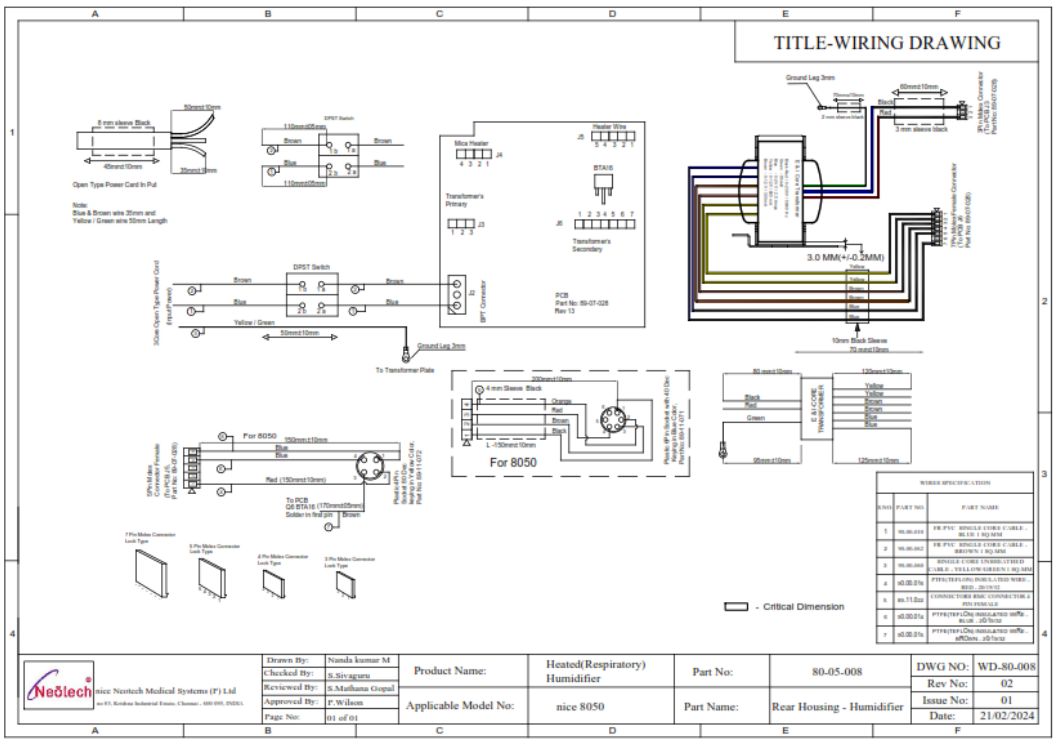


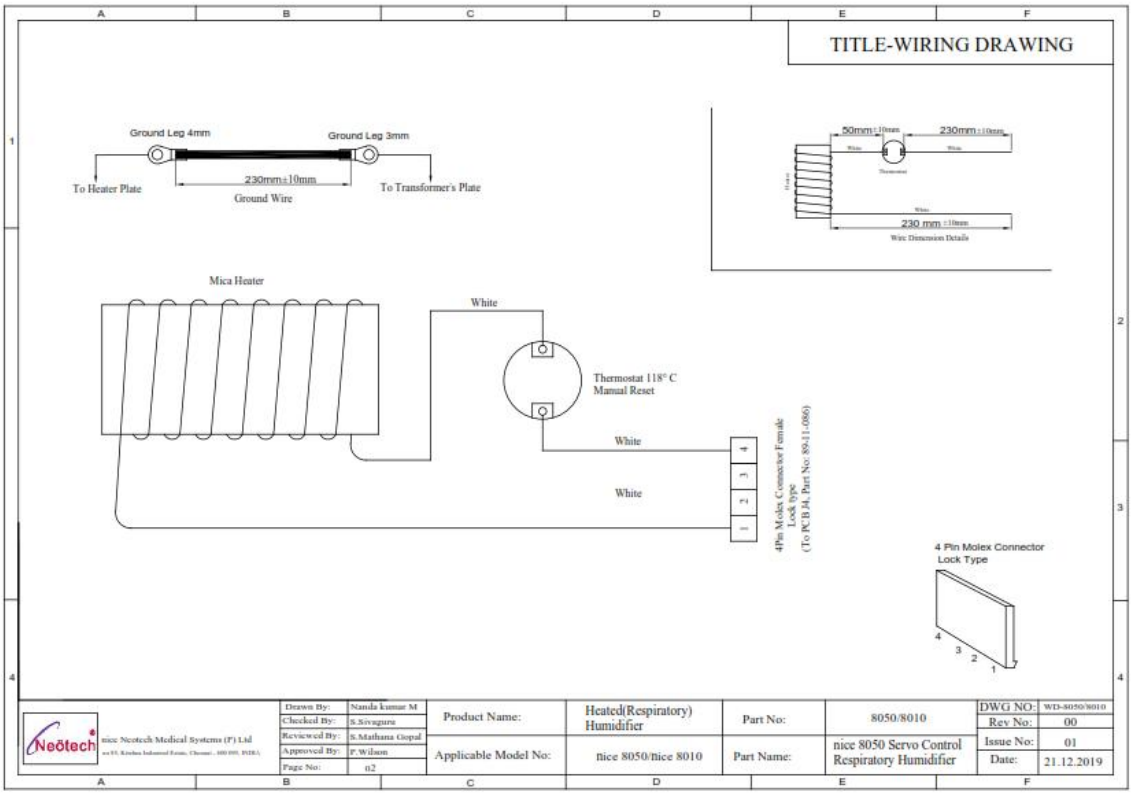
nice Neotech Medical Systems (P) Ltd no 85, Krishna Industrial Estate, Chennai-600 095, INDIA	Drawn By:	M.Lingaperumal	Product Name:	Heated (Respiratory) Humdifier	PCB Part NO:	89-07-018	DSN NO:	WD-89-018
	Checked By:	S.Sivaguru					REV NO:	13
	Reviewed By:	S.Mathana Gopal						
	Approved By:	P.Wilson	Applicable Model No:	nice 8050	PCB Part Name:	Mother Board	DATE:	06-09-2017
	Page No:	04 of 05						


TITLE - SCHEMATIC DRAWING
Neötech
nice Neotech Medical Systems (P) Ltd
no 85, Krishna Industrial Estate, Chennai-600 095, INDIA
Drawn By: A.Dhasarathan
Checked By: S.Sivaguru
Reviewed By: S.Mathana Gopal
Approved By: P.WILSON
Page No: 01 of 01
Product Name: Heated (Respiratory) Humidifier
Applicable Model No: nice 8050
PCB Part NO: 89-07-028
PCB Part Name: nice 8050 Power Supply
DSN NO: SD-89-028
REV NO: 01
ISSUE NO : 01
DATE: 01.09.2021

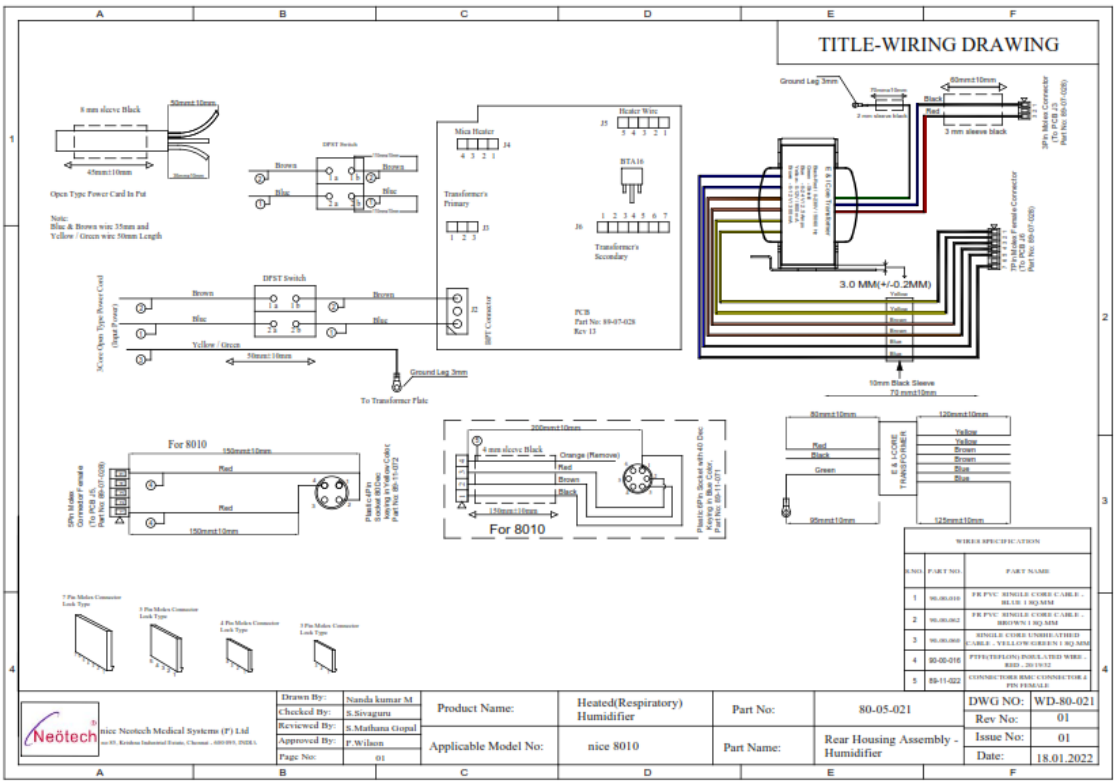
Section 12: Wiring Diagram

nice 8050





nice 8010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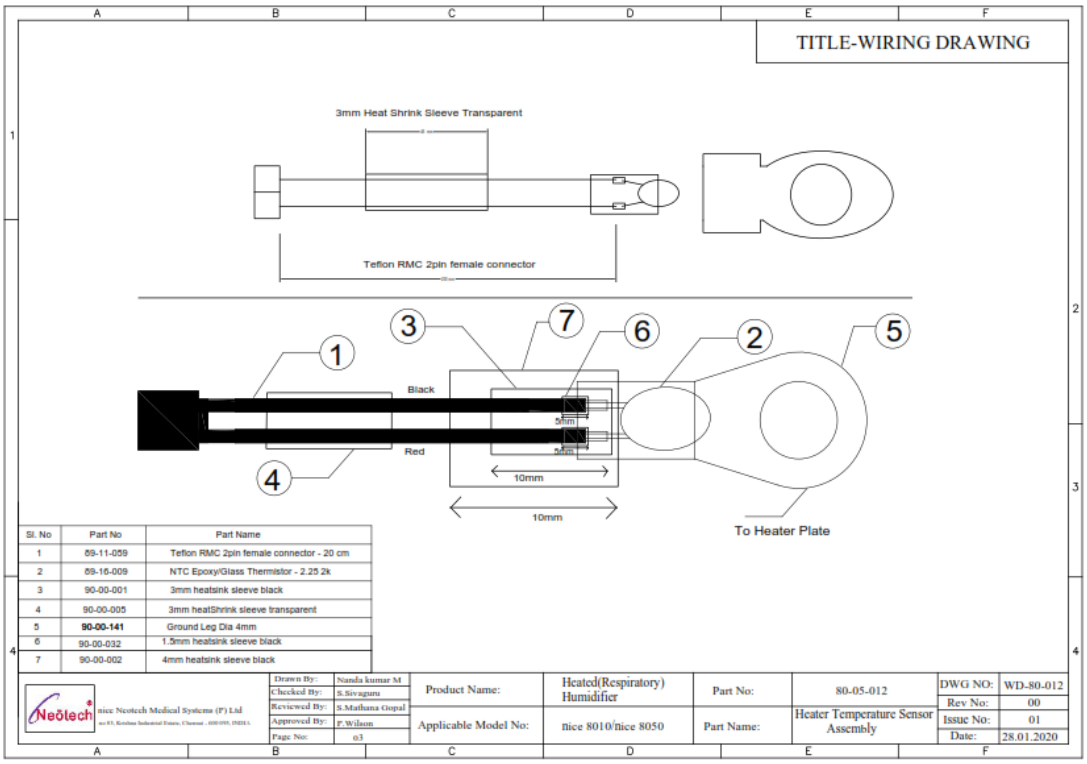
Product Name: Heated(Respiratory) Humidifier
Part No: 80-05-021
Applicable Model No: nice 8010
Part Name: Rear Housing Assembly - Humidifier
DWG NO: WD-80-021
Rev No: 01
Issue No: 01
Date: 18.01.2022
Drawn By: Nanda kumar M
Checked By: S.Sivaguru
Reviewed By: S.Mathana Gopal
Approved By: P.Wilson
Page No: 01
nice Neotech Medical Systems (P) Ltd
For 8010
3.0 MM(+/-0.2MM)
To Transformer Plate
Ground Leg 3mm


TITLE-WIRING DRAWING
3mm Heat Shrink Sleeve Transparent
Teflon RMC 2pin female connector
Black
Red
10mm
To Heater Plate
Sl. No | Part No | Part Name
1 | 89-11-059 | Teflon RMC 2pin female connector - 20 cm
2 | 89-16-009 | NTC Epoxy/Glass Thermistor - 2.25 2k
3 | 90-00-001 | 3mm heatsink sleeve black
4 | 90-00-005 | 3mm heatShrink sleeve transparent
5 | 90-00-141 | Ground Leg Dia 4mm
6 | 90-00-032 | 1.5mm heatsink sleeve black
7 | 90-00-002 | 4mm heatsink sleeve black
Product Name: Heated(Respiratory) Humidifier
Part No: 80-05-012
Applicable Model No: nice 8010/nice 8050
Part Name: Heater Temperature Sensor Assembly
DWG NO: WD-80-012
Rev No: 00
Issue No: 01
Date: 28.01.2020
Drawn By: Nanda kumar M
Checked By: S.Sivaguru
Reviewed By: S.Mathana Gopal
Approved By: P.Wilson
Page No: 03
nice Neotech Medical Systems (P) Ltd

Section 13: Servicing procedure

- Consult the manufacturer for repair and replacement of components. Spare parts are replaced only by the trained service personnel.

Precautions:

- Even if the nice8050 is switched off with the switch provided in power source, the unit is still energized. Disconnect the nice8050 from the power supply before servicing.
- After servicing the nice8050 should be performance tested to ensure correct operation.
- Ensure the case screws are correctly fitted to the product after assembly.

- The nice8050 contains electrostatically sensitive components. Ensure antistatic procedures are followed when servicing.

1. Removing the PCB, Ensure mains plug has been disconnected from the wall socket. Open the case and removes the PCB.
2. Ensure the correct type and rating fuses before replacing, Fuse ratings mentioned in section 5.
3. Before replacing the Heater, allow the heater to cool before attempting to replace.

Section 14: For Complaints/Adverse Events/Comments/Feedback

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

In case of adverse events, fill the below details:

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

For comments:

For Complaints:

For Feedbacks:

Kindly fill the above and send the same

From:

_____

_____

_____

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

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

EU Authorized Representative	Competent Authority	Notified Body
Amstermed B.V Located in Saturnusstraat 46-62, Unit 032, 2132 HB Hoofddorp, The Netherlands. Mr. Mike Vermin Tel: +31 23 565 6337 info@amstermed.nl www.amstermed.nl SRN: NL-AR-000001971	**Refer to the contact points in the below web address:** https://health.ec.europa.eu/medical-devices-sector/new-regulations/contacts_en	**DQS Medizinprodukte GmbH** August-Schanz-Straße 21 60433 FRANKFURT AM MAIN Country : Germany Phone : +49 69 95427 300 Fax : +49 69 95427 388 Email : medizinprodukte@dqs-med.de Website : www.dqs-med.de Notified Body number : 0297

Section 15: EC certificate notified body

Name:

DQS Medizinprodukte GmbH

Notified body number:

0297

Address:

August-Schanz-Straße 21
60433 FRANKFURT AM MAIN
Country : Germany

Phone : +49 69 95427 300
Fax : +49 69 95427 388

Email : medizinprodukte@dqs-med.de
Website : www.dqs-med.de