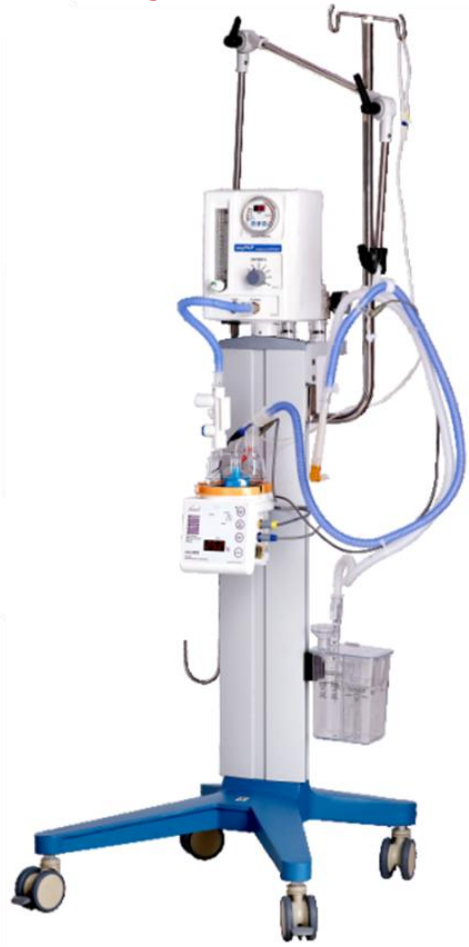
OxyPAP

Neötech®
HEALTH CARE EXCELLENCE

Bubble CPAP System with Accessories



OPERATING/ INSTALLATION MANUAL

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

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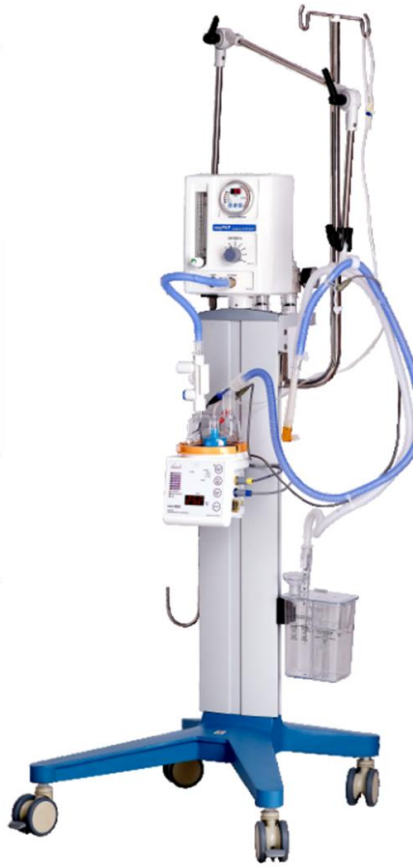
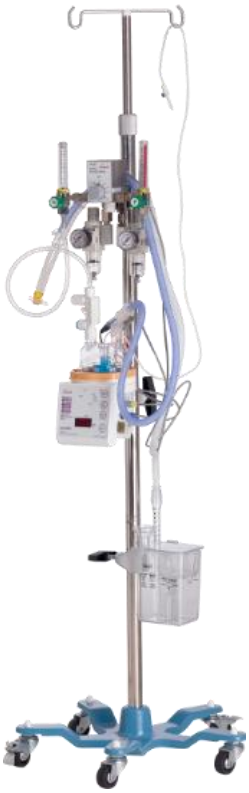
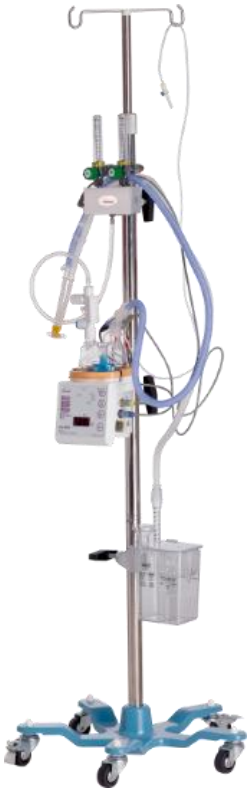


nice 5060 Bubble CPAP System



nice 5060 S Bubble CPAP System



nice 5060 F Bubble CPAP System

Table of Contents

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

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

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

Declaration for Languages

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

Model Descriptions:

nice 5060 - Bubble CPAP with internal Air/O2 Blender, Servo control humidifier (nice 8050), Disposable Humidification chamber with Auto feed, one set disposable circuit & Different size Nasal Prongs/ CPAP masks & Head Bonnet, bubble generator, Aluminum Stand & Patient circuit Arm, Preset pressure manifold.

nice 5060S - Air Oxygen Blender, Servo control humidifier (nice8050), Disposable humidification chamber with Auto feed, one set disposable circuit & Different size Nasal Prongs/ CPAP masks & Head Bonnet, Bubble Generator & SS Stand, Preset pressure manifold

nice 5060F - Air and Oxygen Flow meter manifold, Servo control humidifier (nice 8050), Disposable Humidification chamber with Auto feed, one set disposable circuit & Different size Nasal Prongs/ CPAP masks & Head Bonnet, Bubble generator & SS Stand, Preset pressure manifold

Definitions for heated (respiratory) humidifier and breathing circuits:

Humidification Chamber	Device that allows gas to be heated and humidified by passing it over heated water
Temperature / Flow Probe	Sensor assembly for measuring temperature and flow of respiratory gases traveling through breathing circuit. Consists of a chamber and airway probe
Airway Probe	The Sensor assembly for measuring gas temperature at the end of the inspiratory limb
Chamber Probe	The Sensor assembly for measuring gas flow and temperature at the outlet of the humidification chamber
Thermistor	A temperature sensitive resistor placed inside the chamber and airway probes.
Chamber Set Point	The temperature that the humidifier attempts to maintain at the chamber probe port
Airway Set Point	The temperature that the humidifier attempts to maintain at the airway probe port
Heater Wire Adapter	Electrical connector between the breathing circuit and the humidifier
Breathing Circuit	Tubing that carries respiratory gases to and from the patient
Dual Heated Breathing Circuit	A breathing circuit that is heated by means of heater wires, in both the expiratory and inspiratory limbs
Single Heated Breathing Circuit	A breathing circuit that is heated by means of a heater wire, in only the inspiratory limb
PCB	Printed Circuit Board.
Heater Wire	Wire inside the breathing circuit which heats the respiratory gases
Inspiratory Limb	The section of the breathing circuit that takes the inspired gases to the patient.
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.

General Safety Information:

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

Section A: Warnings

- nice 5060, 5060F, 5060S Bubble CPAP System is intended to be used by qualified medical personnel trained in pulmonary ventilation and advanced cardiac life-support techniques
- It is the responsibility of the purchaser to ensure that all users of this device have been adequately trained in product techniques.
- The Bubble CPAP must only be used after checking that correct pressures will be delivered to the baby.
- 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
- For connection to flow regulated oxygen or oxygen/air mixture only.
- Recommended operating gas flow range is 5 to 10 L/min.
- Do not attempt to use a higher flow than 10 L/min.
- The Maximum Pressure Relief valve is fixed inside the module, the maximum pressure is 40 cmH2O
- Do not attempt to set the Maximum Pressure Relief above 40 cmH2O.
- Use only nice Neötech's Respiratory Humidifier, Air oxygen blenders, patient circuits or approved equivalent.
- Ensure all oxygen and air supplies are turned off and disconnected from the nice 5060 before performing cleaning procedures. Explosion and fire hazards can exist when performing cleaning procedures in an oxygen enriched environment.
- Never oil or grease oxygen equipment. Oils and grease oxidize readily, and in the presence of oxygen, will burn violently.
- Oxygen concentrations higher than 40% can increase the risk of retrolental fibroplasia (retinopathy or prematurity). It is probable that even concentrations of 40% or less oxygen (formerly considered safe) could be dangerous to some infants. Therefore, arterial blood gas measurements are extremely important for regulation of the concentration of inspired oxygen when an oxygen-enriched environment is considered necessary. (See current edition of "Standards and Recommendations for Hospital Care of Newborn Infants" prepared by the Committee of Fetus and Newborn of the Academy of Pediatrics.)
- Periodically monitor the oxygen concentration with a calibrated oxygen measuring unit.
- The use of oxygen increases the danger of fire and the auxiliary equipment producing spark shall not be placed in the equipment.
- Even Small quantity of flammable agents such as ether and alcohol, left in the bubble CPAP it can cause fire in connection with oxygen.
- Ensure that invasive mode is set for patients that have bypassed airways.
- 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.

- 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 Bubble CPAP System 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 Bubble CPAP System 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 Bubble CPAP System 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 Bubble CPAP System 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.

- 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.

- 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.

- Always monitor, maintain and verify PAP level with a Digital PEEP monitor that measures proximal airway pressure.

- This Bubble CPAP System has not been tested for use during Magnetic Resonance Imaging (MRI). However, this device does not contain any ferrous material. The use of this device during MRI procedures may result in the failure of the device, blurring of the image, or misinterpretation of the image.

- Do not attempt to disassemble the Valve as it will damage the components.

- Adequate oxygen related trainings and knowledge on oxygen related risk is necessary for operators to handle oxygen.

- 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.

- Do not re-use the Single use CPAP Breathing circuit, Nasal Prong, Nasal mask, Head bonnet, and Mini flow. Reuse may result in transmission of infectious substances, interruption to treatment, serious harm or death.

- Breathing Circuit and interfaces is intended for use for a maximum of 7 days
- The CPAP unit should not be inclined above 10°.
- Do not obstruct the Bleed.
- Use only the nice Neötech Temperature probe and Breathing Circuit. Use of other manufacturer's probes may affect the accuracy of operation and the electrical safety of the patient.
- Check power supply of the Heated (Respiratory) Humidifier if front panel display is off.
- Periodically check the patient nasal area so that excess pressure is avoided.
- Do not use nasal prongs when nasal septum is injured to the patient, use nasal masks in such cases.
- Check the SpO2 level of hypo ventilating patient to prevent from hypercapnia.
- Always use pressure monitoring to verify that the patient is receiving the prescribed CPAP level.
- Remove any sources of ignition, such as cigarettes or open flames.
- Ensure any unused ports have their caps and/ or plugs in place before use.
- Do not use an in-line nebulizer between the pressure relief manifold and the dry side of the humidification chamber.
- Do not bypass the pressure relief valve as this may cause damage/ injury.
- Always use preset pressure relief manifold to prevent high pressure entering the patient.
- To prevent disconnection of the breathing circuit during use, only circuits in compliance with ISO 5367 or ISO 80601-2-74 should be used.
- Ensure the oxygen supply is turned on and functioning correctly before placing a patient into the unit for ventilation process. Failure to verify the oxygen flow can result in insufficient oxygen delivery, leading to severe hypoxia or death. Continuous monitoring of the oxygen supply is essential throughout the process.
- 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/ interfaces: 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.

Section B Cautions

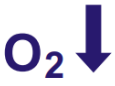
- **Use of nonstandard components:** Consult the manufacturer for repair and replacement of components. Use of incorrect component can adversely affect Safety, performance and/or damage the equipment performance
- For shipping and Storage, Place the removed P.C.board in an antistatic protective bag Equipment damage could occur.
- Do not use silicone-based lubricants. Equipment damage could occur.
- When removing the equipment from the cartons, take care not to scratch or otherwise damage unprotected surfaces.
- Isolation from the supply mains is provided by non-detachable power cord.
- Use a cleaning solution sparingly on a cloth when cleaning the Respiratory Humidifier. Do not saturate the unit, as excessive solution causes damage to internal components.
- Do not autoclave or gas sterilize the 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.
- 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, and 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 Neötech 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 dish wash detergents or solvents.
- Evaporation or condensation of water may occur during operation of this device. Always monitor water level and adjust as required pressure or water.
- 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.
- If the transport position of the Bubble CPAP System is more than 10°, over balance may occur.

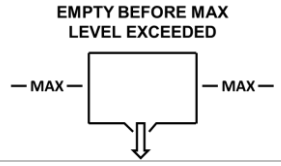
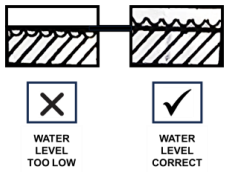
- When used without a heater wire, a water trap should be used.
- Do not use without a heater wire at flow rate less than 5 LPM.
- Minimum heater wire resistance 7.5 Ohms.
- Use only approved chambers, temperature probes and accessories.
- Always monitor and adjust proximal airway temperature as instructed 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.
- Do not stretch or milk the tubing
- Do not soak, wash, sterilize, or re-use this product. Avoid contact with hand sanitizers, chemicals or cleaning agents.
- If the gas flow is interrupted turn the humidifier off.
- Inlet pressure hoses for the gas mixer to comply with ISO 5359 standard requirements
- Use only nice Neotech Bubble CPAP Breathing circuit models (BC 510, BC 525, BC 530, BC 555, BC 570, BC 575, BC 560).
- Breathing circuit/ interfaces are supplied as non-sterile.
- Breathing circuits/ interfaces must be sterilized prior to use.
- Breathing circuits/ interfaces compatible with EO sterilization only.
- Breathing circuits/ interfaces sterilization process shall be performed by the end-user according to their validated hospital protocol.
- Do not use if breathing circuits/ interfaces packaging is not sealed.
- Do not use this circuit/ interfaces in case of any contamination or if it is damaged.
- Use in accordance with the manufacturer's instructions.

Section C: Symbols & Labels

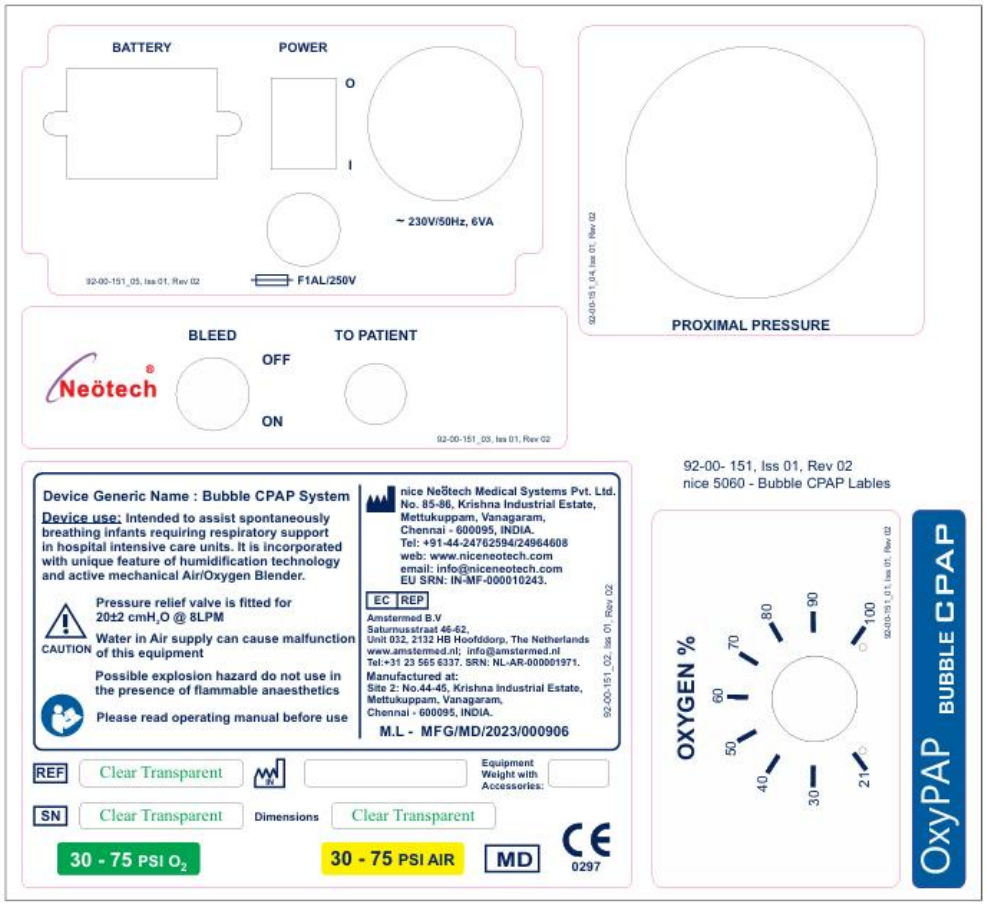
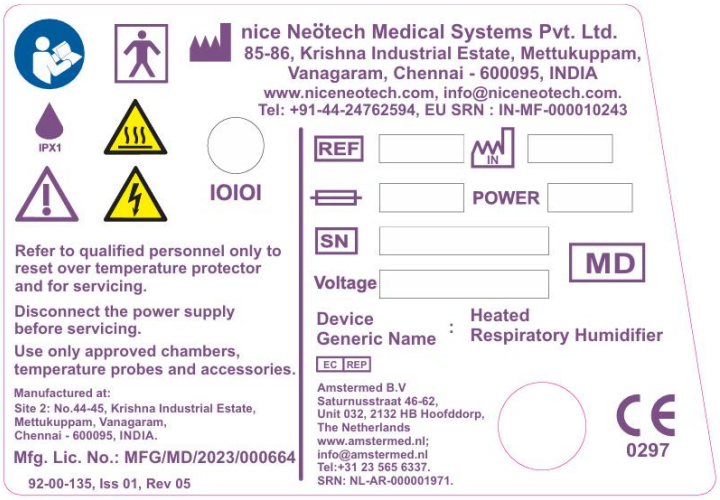
Mark	Title
Manufacturer	
	Manufacturer – Indicates the medical device manufacturer
	Date of Manufacture – Indicates the date when the medical device was manufactured.
	Country of manufacture – To identify the country of manufacture of products
	Authorized representative in the European Community/ European 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.
	Batch code – Indicates the manufacturer's batch code so that the batch or lot can be identified.
	Use-by date – Indicates the date after which the medical device is not to be used.
	CE Mark European Conformity - Signifies European conformity (CE) mark Indicates manufacturer declaration that the product complies with applicable European regulations.
Sterility	
	Non-sterile – Indicates a medical device that has not been subjected to a sterilization process.
	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.

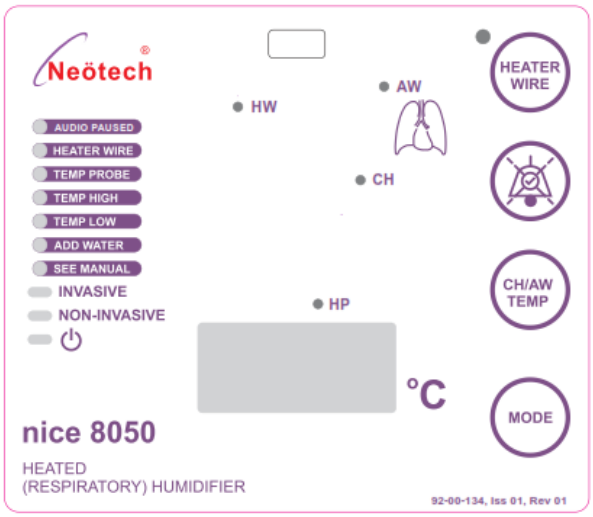
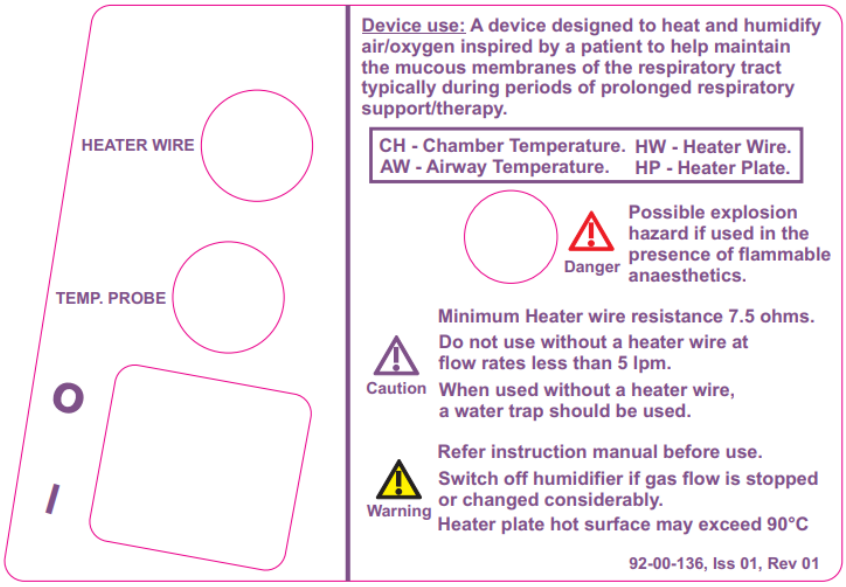
	Temperature limit - Indicates the temperature limits to which the medical device can be safely exposed.
	Humidity limitation - Indicates the range of humidity to which the medical device can be safely exposed.
	Do not keep near fire – Do not keep the package near fire
	Maximum stackable limit – Pay attention 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
	Danger - indicates the presence of a potentially hazardous or dangerous condition. It serves as a warning to alert individuals to take necessary precautions to avoid harm.
	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.
	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	
	Use no oil
	Fuse
	Off (Power: disconnection from main)
	On (Power: connection to the main)

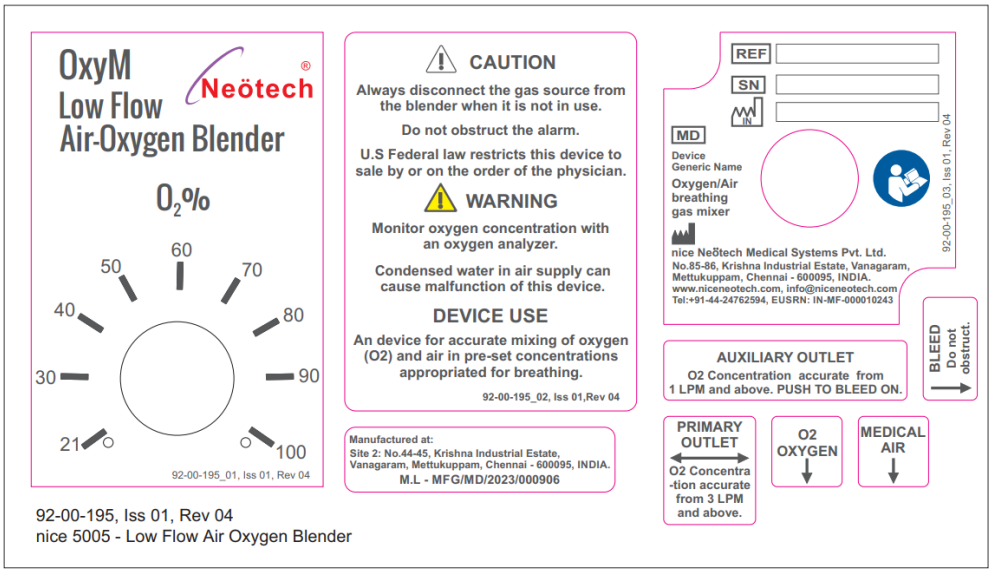
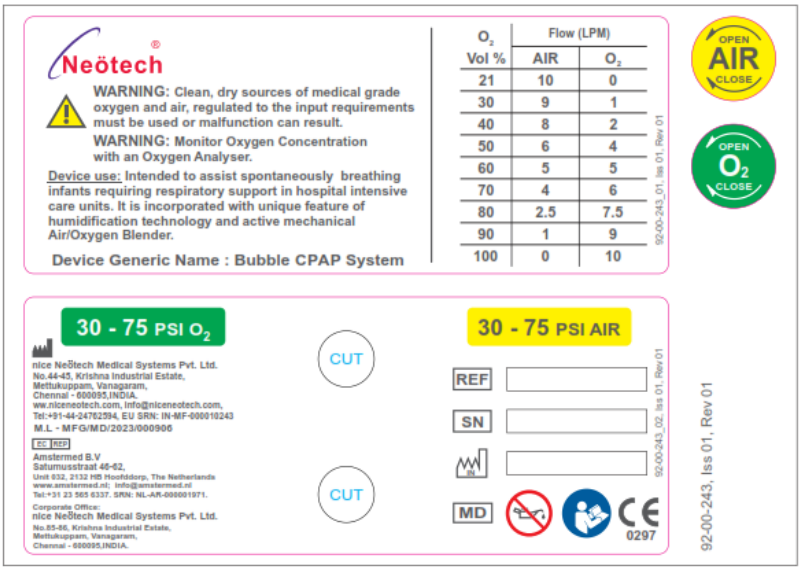
	PEEP Increase Key
	PEEP Decrease Key
	Set key/ Mute key
	Power failure
	Oxygen low
	Air low
	PEEP high
	PEEP low
	Main switch
	ON/OFF key
	Timed Acknowledged key
	Standby
	Serial interface – To identify a connector for a serial data connection.
	IPX1 symbol indicates that a device has an Ingress Protection (IP) rating of IPX1, which refers to its resistance to water ingress.
MAX	MAX (In Disposable Humidification chamber) - “MAX” mark represents the maximum water level limit. This is the highest level to which water can be safely added to the chamber.

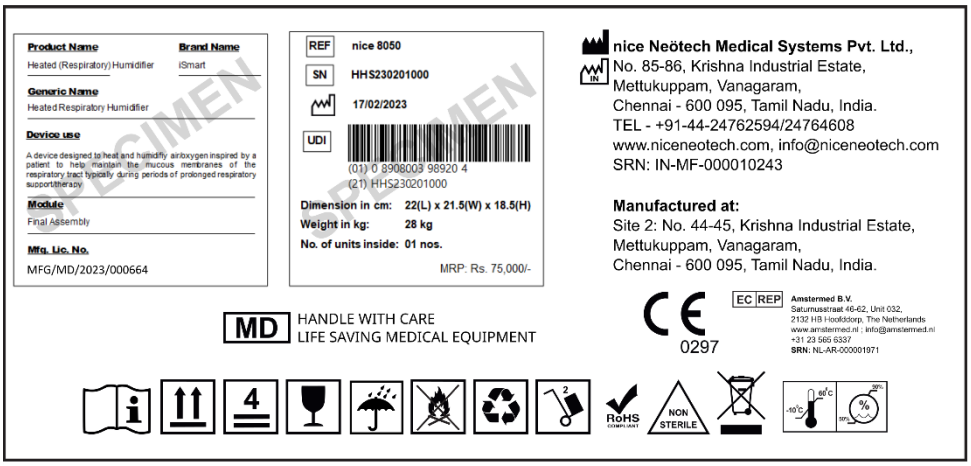
	Water level line (In Manual filling humidification chamber) – represents the recommended water level in the chamber. Don't fill the chamber below or above the water level line.
	Overflow Water Level Symbol (In Bubble generator) – indicates that the water in the bubble generator should be emptied or maintained so that it never surpasses the maximum level indicated by the "MAX" mark.
	Bubble Generator Water Level Symbol (In Bubble generator) Water level too low – indicates insufficient water, leading to reduced efficiency in treatment. Refill required immediately. Water level correct – indicates optimal water level, ensuring efficient, safe operation and effective humidification. No action needed.
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.
	"Rx" symbol indicates that the device is a prescription device, meaning it can only be used or dispensed on the order of a licensed healthcare professional.
	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

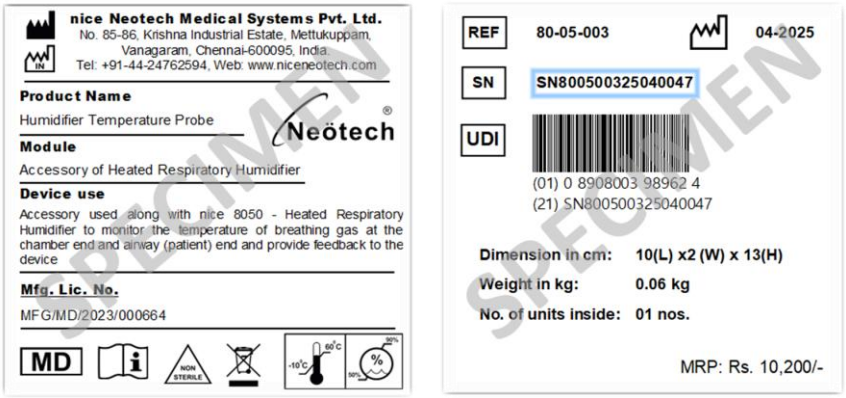
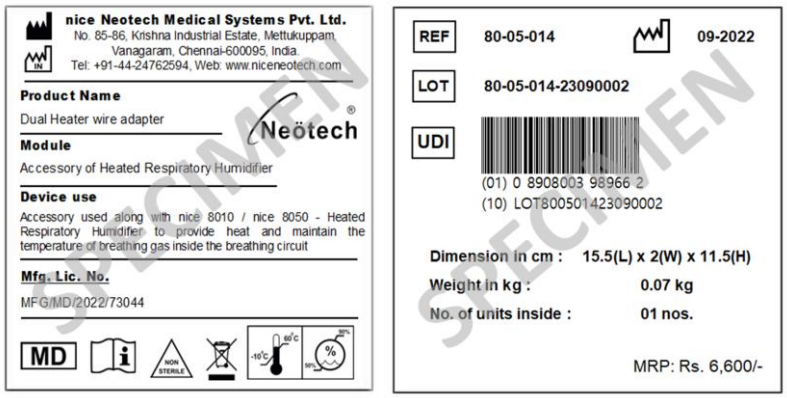
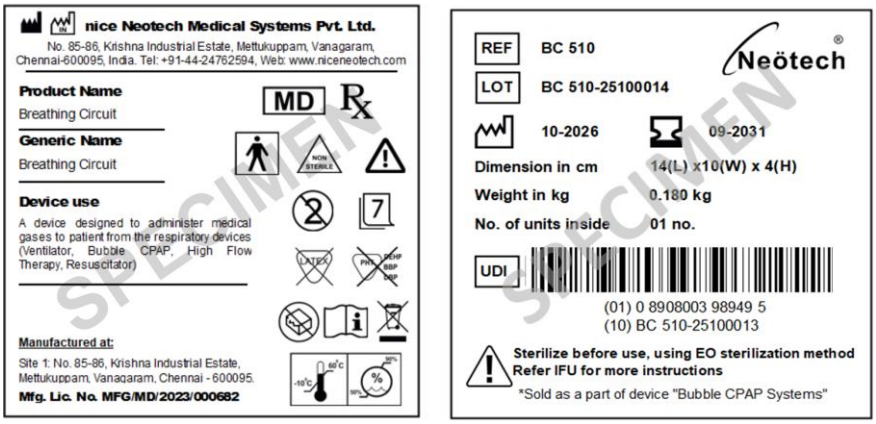
Labels:

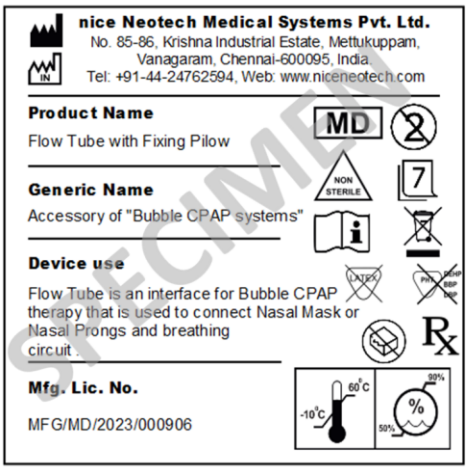
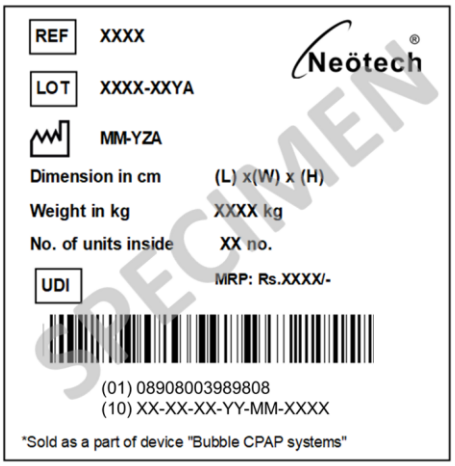
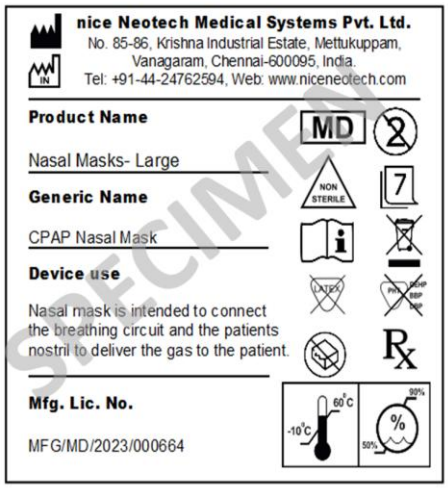
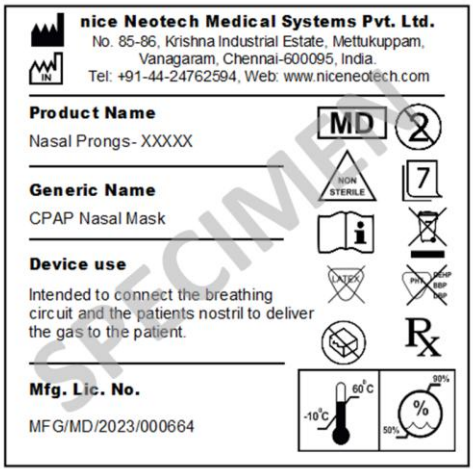
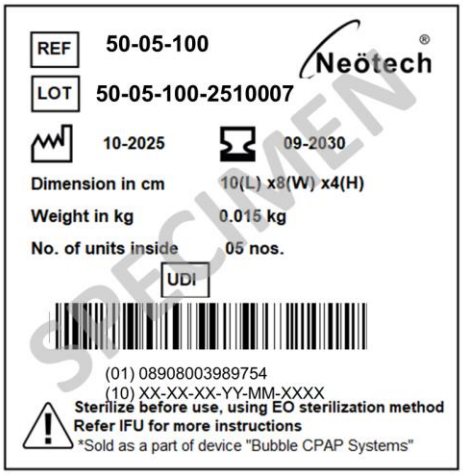
S.No.	Label	Description
1.		**Label – nice 5060 Bubble CPAP** **(nice 5060)**
2.		**Label – Marking plate – Heated (Respiratory) Humidifier**

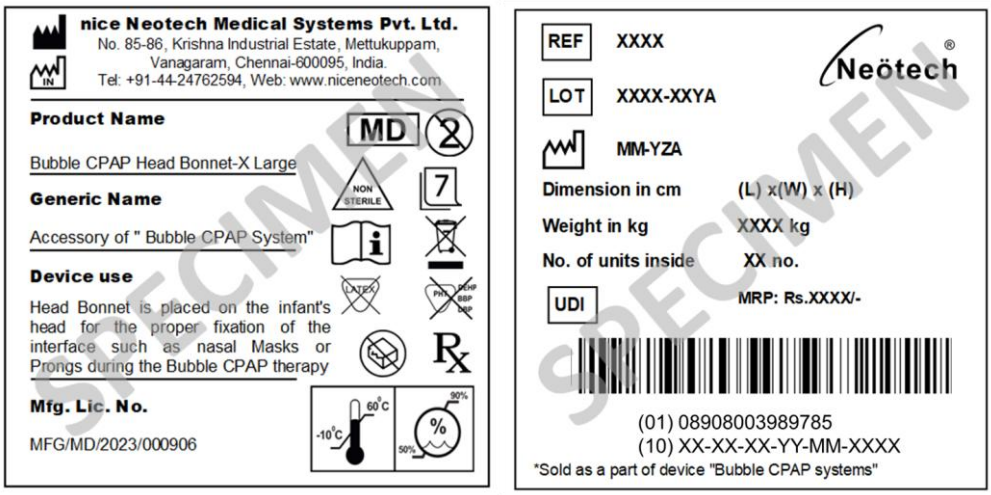
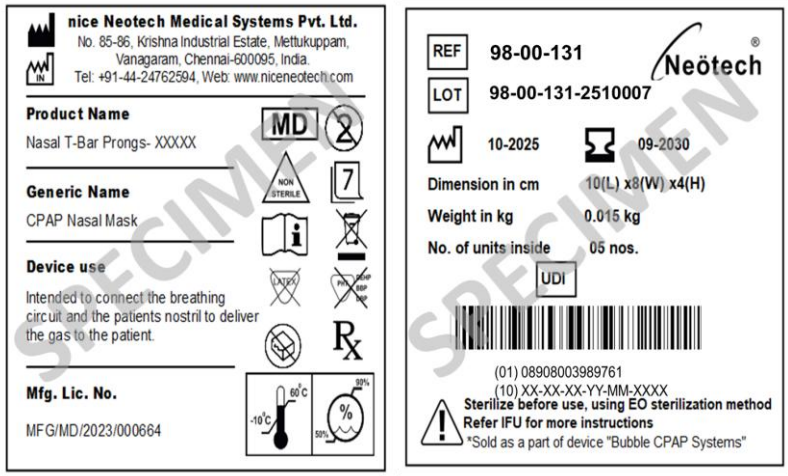
S.No.	Label	Description
3.		Label – Front panel nice 8050
4.		Label – Instruction – Heated (Respiratory) Humidifier
5.		Label – Probe tag for Temperature probe and Heated wire adapter

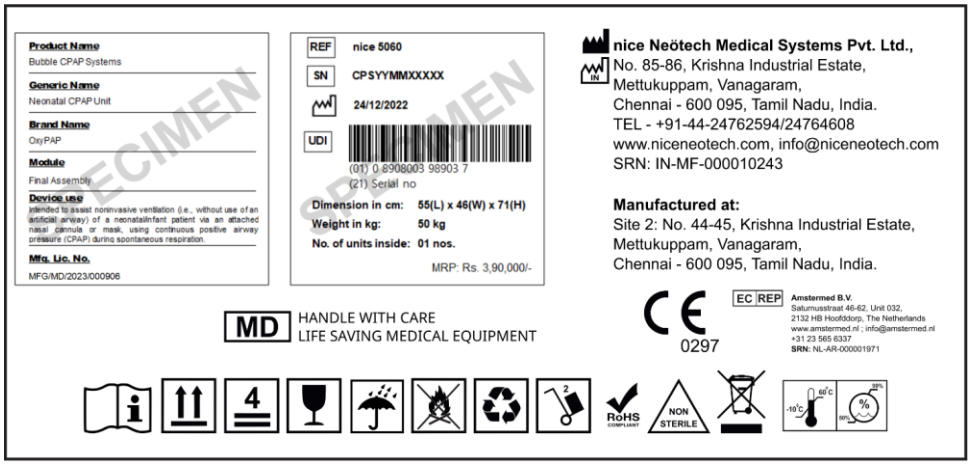
S.No.	Label	Description
6.	 92-00-195, Iss 01, Rev 04 nice 5005 - Low Flow Air Oxygen Blender	**Label – nice 5005 –Low flow Air Oxygen Blender (For nice 5060 S)**
7.		**Label – nice 5060 F – Bubble CPAP** **(For nice 5060 F)**

S.No.	Label	Description
8.	Device Generic Name : Bubble CPAP System Device use: Intended to assist spontaneously breathing infants requiring respiratory support in hospital intensive care units. It is incorporated with unique feature of humidification technology and active mechanical Air/Oxygen Blender.	Label Device Use nice 5060S - BUBBLE CPAP
9.	Amstermed B.V EC REP Saturnusstraat 46-62, Unit 032, 2132 HB Hoofddorp, The Netherlands www.amstermed.nl; info@amstermed.nl Tel:+31 23 565 6337. SRN: NL-AR-000001971. CE 0297 92-00-277 Iss 01, Rev 00	Label - CE & EC Rep
10.		Safety sign- Do not step on surface
11.		Max weight 1.5 Kg
12.		Packaging label of Heated (Respiratory) Humidifier

S.No.	Label	Description
13.		**Packaging label of Humidifier Temperature Probe**
14.		**Packaging label of Dual Heater wire adapter**
15.		**EC Rep and CE Label for Interfaces and Breathing circuit**
16.		**Packaging label of Breathing circuit**

S.No.	Label	Description
17.	 	Packing label of Flow tube
18.	 	Packing label of Nasal mask
19.	 	Packing label of Nasal prongs

S.No.	Label	Description
20.		**Packing label of Head bonnet**
21.		**Packing label of CPAP Nasal T-bar prongs (optional accessories)**
22.		**Draft UDI Label (nice 5060, nice 5060 S, nice 5060 F)**

S.No.	Label	Description
23.		Packaging label of Bubble CPAP System

Section 1: Description

1.1 Intended Use

Bubble CPAP Systems - nice 5060:

The nice 5060 Bubble CPAP System for use with spontaneously breathing infants requiring respiratory support in hospital intensive care units. It is incorporating with unique feature of humidification technology and active mechanical Air/Oxygen Blender.

Bubble CPAP Systems - nice 5060 S:

The nice 5060S Bubble CPAP System for use with spontaneously breathing infants requiring respiratory support in hospital intensive care units. It is incorporating with unique feature of humidification technology and active mechanical Air/Oxygen Blender.

Bubble CPAP Systems - nice 5060 F:

The **nice 5060F** Bubble CPAP System for use with spontaneously breathing infants requiring respiratory support in hospital intensive care units. It is incorporating with unique feature of humidification technology and passive Air/Oxygen blender.

1.2 Medical Indication/ Condition:

Bubble CPAP System (nice 5060, nice 5060 S & nice 5060 F) is used during:

- Respiratory Distress Syndrome.
- Post extubation in preterm very low birth weight babies.

1.3 Contraindication:

- Reduced consciousness and inability to protect their airway
- Unstable cardiorespiratory status or respiratory arrest
- Air leak syndrome (pneumothorax with bronchopleural fistula)
- Non-spontaneously breathing patients

1.4 Side Effect:

- Skin rashes
- Skin injury
- Nasal septal injury

1.5 Intended Patient population:

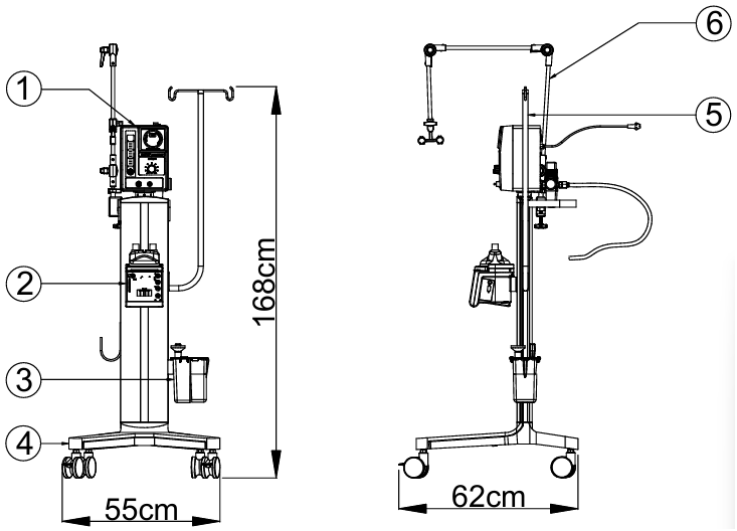
Premature, Neonates and Infants up to 10 kg.

1.6 Device Intended User:

- Neonatologist
- Healthcare Professionals

1.7 Product Description and Working Principle

Mechanical Layout



nice 5060 Bubble CPAP Sysytem	
S/NO	DESCRIPTION
1	CPAP Unit Assembly
2	Humidifier Assembly
3	Bubble generator
4	Base Assembly
5	IV Pole
6	Patient Circuit Arm

Bubble CPAP requires gas flow from the mechanical blender (Air / Oxygen) or passive blender (Air flowmeter + Oxygen flowmeter). Oxygen percentage from 21% to 100% of the blended gas can be set and it is delivered to the Respiratory humidifier to humidify and maintain the temperature the inspired gas to the patient. The CPAP works with pneumatic gas supply of Oxygen / Air Gas supply from the Hospital's gas pipeline. The gas pressure is regulated at 60 psi. The pressure regulated gas (Oxygen and Air) is connected with the Bubble CPAP device (nice 5060, nice 5060 S and nice 5060 F).

The Bubble CPAP has the flowmeter and the Digital PEEP monitoring with in-built air oxygen blender for monitoring the delivered gas pressure to the patient. Flowmeter is helped to set the required flow rate to the patient. Presetted pressure manifold is connected with the input of Humidification chamber. Output of the humidification chamber is connected to heated wire breathing circuit. The humidifier has the provision to fix the humidification chamber on the heater plate and also has the provision for fixing the temperature probe and heater wire adapter.

The temperature has two sensors: 1. Chamber sensor 2. Airway sensor. The heater wire adapter is used to interlink the humidifier and heater wire of the breathing circuit. The breathing circuit has two ports to fix the temperature probe. The port which is available in the humidification chamber is for fixing chamber sensor and the port near to patient end is to fix airway sensor. Breathing circuit has two limbs (tubes): 1. Inspiratory limb 2. Expiratory limb.

Both the limbs are connected with the flow tube. In the end of flow tube, it is connected with nasal prongs, nasal mask or nasal cannula, these are called patient interfaces. Miniflow and nasal prongs are connected to the patient with the help of head bonnet by the hookable fabric with the loops (tie) of head bonnet. It is easy to remove and

fix. The expiratory limb of the breathing circuit is connected to the calibrated PEEP setting probe. This probe is fixed in the bubble generator.

The bubble generator has water container and overflow container with the port of pressure probe fixing. By adjusting the pressure, it can set the desired PEEP level from 3 cmH2O to 10 cmH2O at flow rate of 8 LPM. The delivered PEEP can be monitored by using the Digital PEEP monitor provided. If any tube is disconnected, the inline Digital PEEP monitor helps to monitor the pressure drop in the breathing circuit.

Note: Active mechanical blender is not available in nice 5060 F.

Standard accessories:
For the models: nice 5060, nice 5060 S and nice 5060 F
Temperature probe (Reusable):

Temperature probe is intended for measuring chamber temperature and airway temperature in the humidifier.

Heater wire adapter (Reusable):

Heater wire adapter is intended to interlink the Humidifier and breathing circuit heater wire.

Breathing circuits (Single-use only):

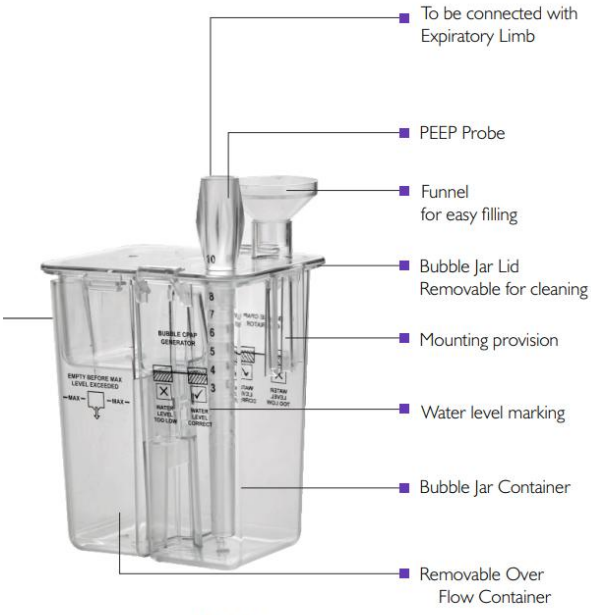
The nice Neötech **Infant/neonatal single-use Bubble CPAP breathing circuits** are used to direct the flow of medical gas (Air/oxygen) with optimum humidity to the patients.

Humidification chamber (Single-use only):

Humidification chamber is intended to hold the water and to direct the humidified gas.

Bubble generator

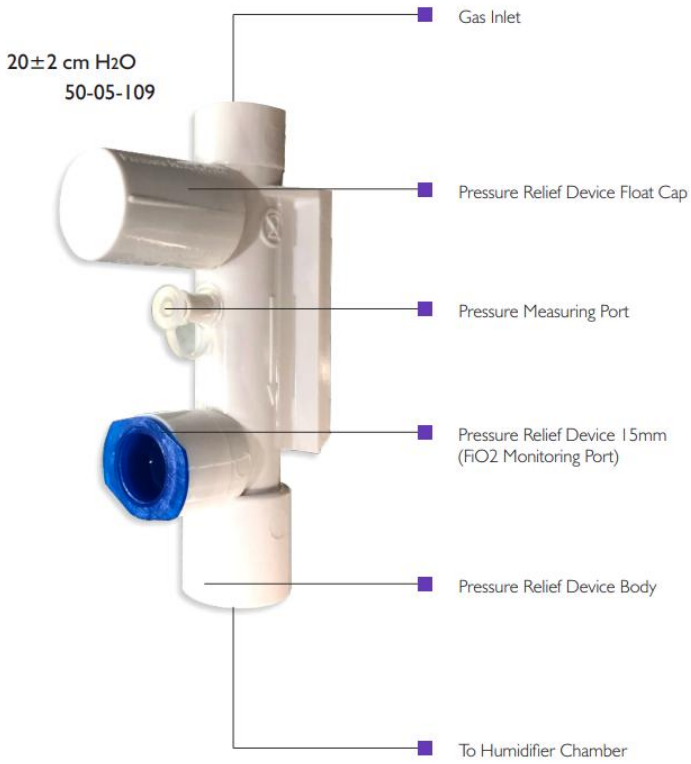
Bubble generator is intended to generate bubbles (pressure oscillations) and maintain the water level and control the set PEEP. It is capable of producing CPAP levels from 3-10 cmH2O. The Bubble generator is made up of three major components; the Bubble Jar container, an Overflow container and a PEEP probe. The mean CPAP level remains constant due to the generator's "Auto-level" mechanism.



50-05-079

Preset pressure manifold (Single-use only):

The Pressure manifold incorporates a pressure relief valve which activates automatically when the inspiratory pressure is 20±2 cmH_2O to prevent high pressure entering the patient. The Pressure manifold also provides additional ports to allow connection of external pressure monitoring devices and air/ oxygen analyzers.



Nasal prongs (Single-use only):

Nasal prongs is intended to connect the breathing circuit and the patient's nostril to deliver the gas to the patient. Available in 7 different sizes of Nasal septum.

Nasal mask (Single-use only):

Nasal mask is intended to connect the breathing circuit and the patient's nostril to deliver the gas to the patient. Available in 4 different sizes of Nose.

Head bonnet (Single-use only):

Head bonnet is intended to hold the breathing circuit with nasal prongs / nasal mask / nasal cannula connected to the nasal septum.

Product model	nice 5060	nice 5060S	nice 5060F
 Digital PEEP monitoring with in-built air oxygen blender and Alarm	✓		
 Heated (Respiratory) Humidifier	✓	✓	✓

 Air-oxygen Blender		✓	
 Air and Oxygen Flow meter manifold			✓
 Humidification Chamber	✓	✓	✓
 Bubble Generator	✓	✓	✓
 Preset pressure manifold	✓	✓	✓
 Bubble CPAP Breathing circuit	✓	✓	✓

 Head bonnet and flow tube	✓	✓	✓
 Nasal masks, Nasal prongs and Nasal T-bar prongs	✓	✓	✓

Working:

Bubble CPAP is a constant flow variable pressure system that incorporates a standard nasal prongs or mask interface attached to a dual-limb heated and humidified circuit. It is the least expensive system, is commonly used in level 2 and 3 neonatal care units, and is easy to initiate in the delivery room. Inspiratory flow is provided from a blended gas source while the expiratory side of the circuit is submersed into a water column. These low flows prevent buildup of back pressure in the system making it a safe application for neonates. The desired level of CPAP in cmH2O is determined by not only the depth of the tubing within the water column but also the amount of flow powering the system. Continuous bubbling requires a base flow rate of 4 to 8 L per minute depending on the type of system used. Bubble CPAP system characteristics vary, both the depth and the flow are important factors to consider. CPAP pressure is measured with a pressure Digital PEEP monitor to determine the actual pressure delivered. Gas flow is responsible for bubbling in the circuit and produces mini oscillations generated within the chest that can equate to nearly 5 to 20 Hz at average CPAP levels.

CPAP works by maintaining positive pressure in the airway during spontaneous breathing, thereby increasing functional residual capacity and improving oxygenation in infants with RDS. CPAP does this by stabilizing airspaces that have a tendency to collapse during expiration due to surfactant deficiency. A variety of mechanisms of action of nasal CPAP have been proposed. These include:

- Increase transpulmonary pressure
- Increase functional residual capacity
- Prevent alveolar collapse
- Decrease intrapulmonary shunting
- Increase lung compliance
- Conserve surfactant
- Increase airway diameter
- Splint the airway
- Splint the diaphragm
- Stimulate lung growth
- High frequency ventilatory effect (with bubble nasal CPAP)

Precaution

This equipment is intended for use only by properly trained personnel as directed by an appropriately qualified attending physician aware of currently known hazards and benefits.

If the equipment is damaged or fails to operate correctly, take it out of service immediately for examination by a qualified Service Engineer to ensure operational safety.

Always carry out a functional test before use to ensure safety and operational integrity.

Oxygen vigorously supports combustion. Exclude any source of ignition in the presence or oxygen and do not use oil or grease on oxygen equipment or spontaneous combustion may occur.

Oxygen is a drug and should be prescribed only by a physician.

Exposing an infant to an elevated oxygen concentration can result in retrolental fibroplasia (RLF) and brain damage.

Ensure that the operating instructions and recommendations contained in this book are thoroughly understood before using the equipment that the book is always accessible for reference and is stored with the equipment.

1.8 Control Unit (nice 8050)

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.

1.9 UDI Carrier

The UDI identifies Bubble CPAP System with Accessories throughout distribution and product life. The UDI appears on the Bubble CPAP System 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 5060	8908003989037	CPSYYMMXXXXX CPS- Product Code YY – year MM – Month XXXXX – serial No
2.	nice 5060S	8908003989044	
3.	nice 5060F	8908003989051	

UDI label:

nice 5060

UDI  (01) 0 8908003 98904 4 (21) CPS240900073
nice 5060 S
UDI  (01) 0 8908003 98905 1 (21) CPS240900070
nice 5060 F

Section 2: Installation

2.1 nice 5060

2.1.1 Setup

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

2.1.2 Installation of nice 5060 Bubble CPAP

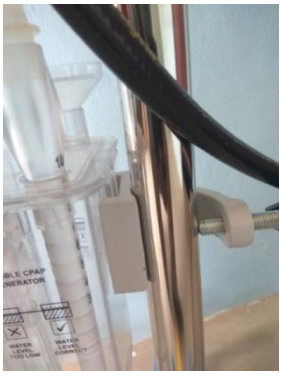
- Insert the Humidifier mounting bracket from the bottom side of the pillar with dovetail is located at front side of the pillar and tighten the screw. position the bracket should be higher than the Bubble generator bracket

- Fix the pillar with M5 Allan cap screw, ensure the tightening.

- Loose the curb screws below the module fix it with the top of the pillar & tighten the screw.

- Unscrew the knob, fix with handle and tighten the knob.

- Fix the humidifier with humidifier mounting bracket.



- Fix the Bubble Generator with Bubble Generator mounting bracket.

- Connect the Air Gases pipe line or concern sources.

- Connect the Oxygen Gases pipe line or concern sources.
- Connect the breathing circuits as per the picture given below. (refer Section 2.1.5)

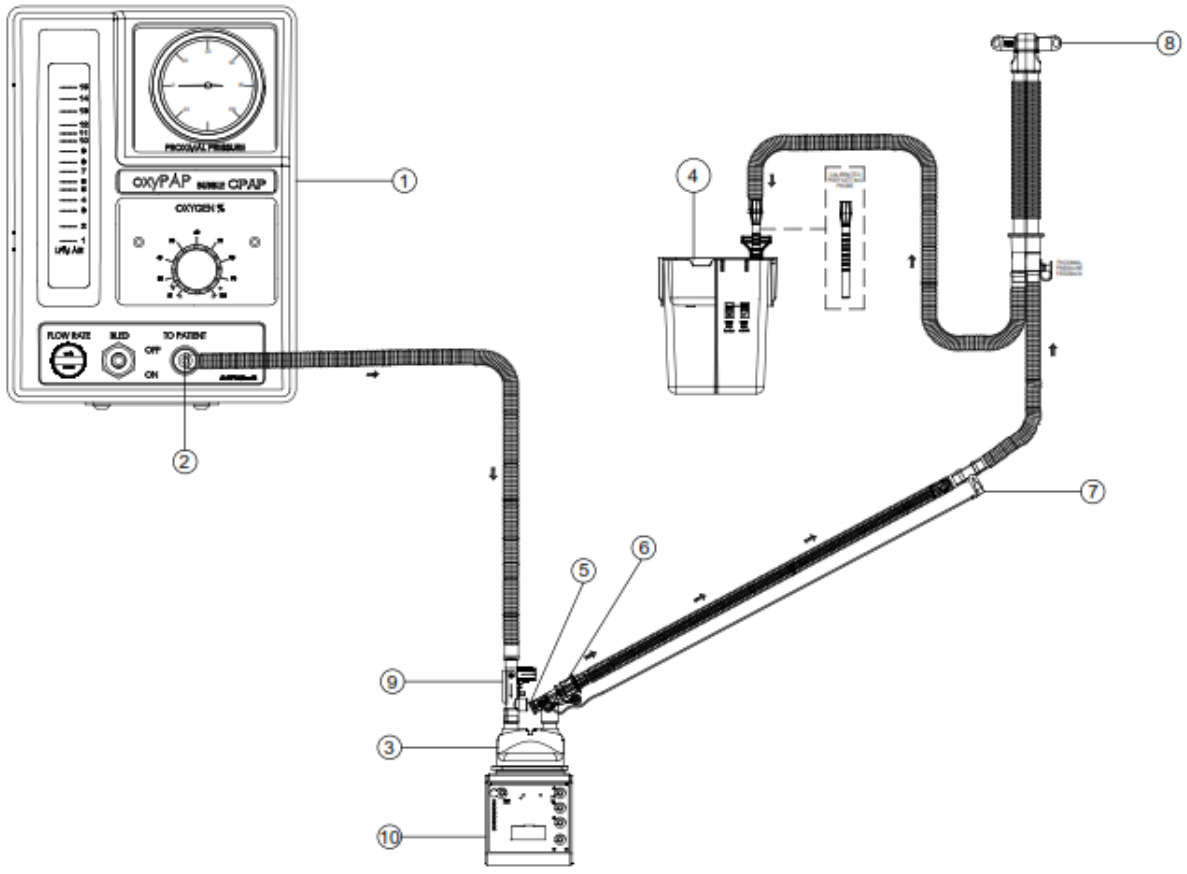
2.1.3 Setting of Bubble CPAP

- Set the flow rate at 5 LPM in the flow meter.
- Set the required FIO2 percentage.
- Fill the water in the Bubble generator.
- Fill the water in the humidifier chamber.
- Set the PEEP at 4cm H2O in the Bubble generator.
- Set the humidifier to the required mode by using mode key.
- Select the heater wire function ON.
- Connect the breathing circuits.
- Connect Air and oxygen to gas inlet port using gas supply line.

2.1.4 Check the Bubble CPAP Function.

- Check Digital PEEP monitor reads zero in the PEEP indicator with no gas flow.
- Adjust gas supply to desired flow rate at 5 LPM.
- Occlude the flow tube port & ensure the PEEP indicator reading should be 4 cmH2O.
- Ensure the humidifier mode of operation.

2.1.5 Patient Circuit Connection Details



1	Bubble CPAP	6	Temperature Probe – Chamber Side
2	To Patient Connector	7	Temperature Probe – Air Way Side
3	Humidification Chamber	8	Nasal prongs
4	Bubble Jar	9	Preset pressure manifold
5	Heater wire line	10	Heated (Respiratory) Humidifier

2.2 nice 5060F

2.2.1 Setup

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

2.2.2 Installation of nice 5060F Bubble CPAP

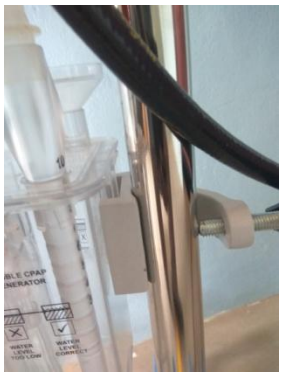
- Fix the Bubble generator pole mounting bracket on the pillar and tighten the screw, position the bracket lower the humidifier bracket.

- Fix Humidifier Pole mounting bracket on the pillar and tighten the screw. position the bracket should be higher than the Bubble generator bracket.

- Fix the pillar with M10 Hex Nut, ensure the tighten.

- Loose the curb screws below the module fix it with the top of the pillar & tighten the screw.

- Fix the humidifier with humidifier mounting bracket.



- Fix the Bubble Generator with Bubble Generator mounting bracket.

- Connect the Air Gases pipe line or concern sources.

- Connect the Oxygen Gases pipe line or concern sources.
- Connect the breathing circuits as per the picture given below. (refer Section 2.2.5)

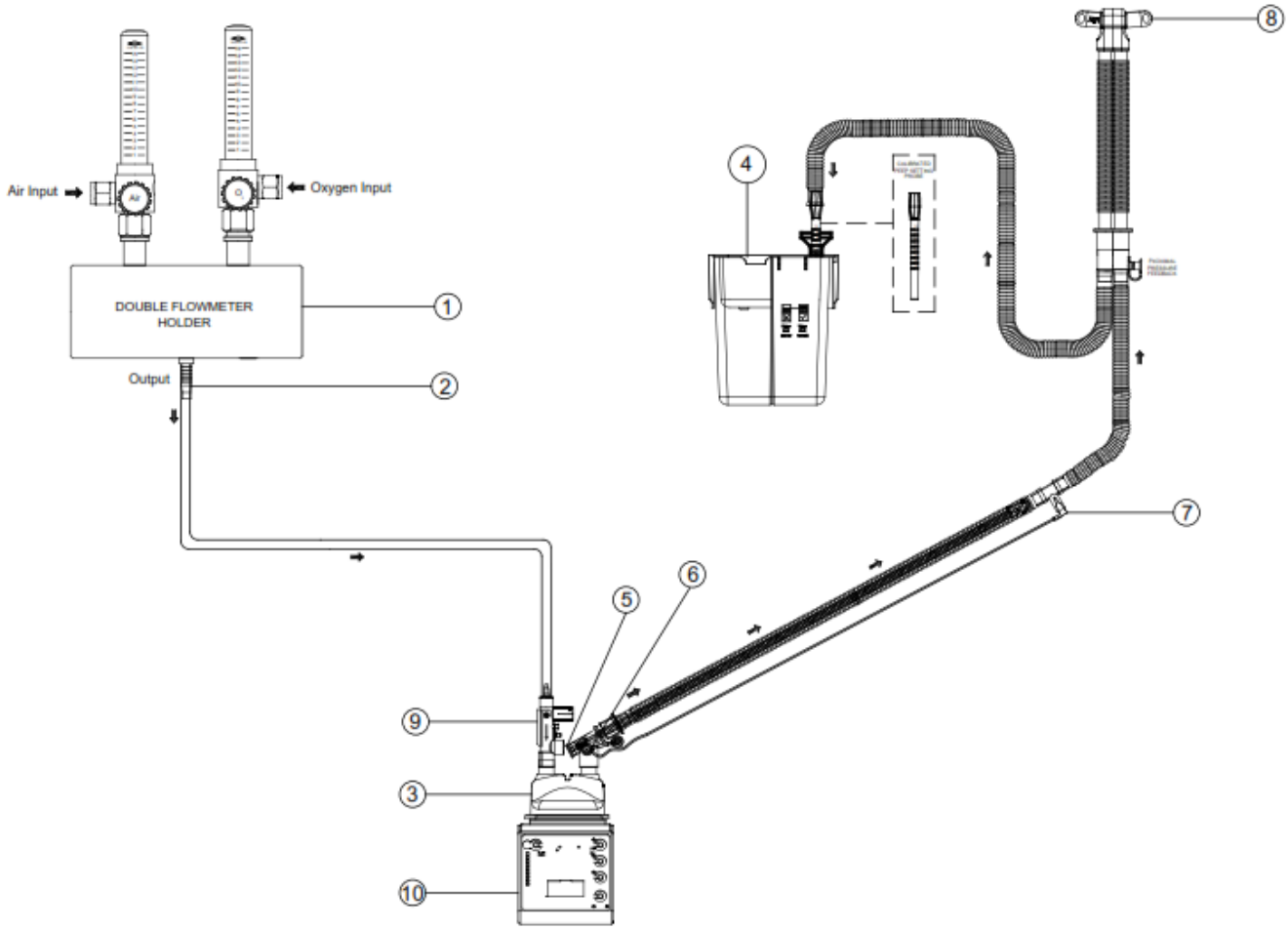
2.2.3 Setting of Bubble CPAP

- Set the flow rate at 5 LPM in the flow meter.
- Set the required FIO2 percentage.
- Fill the water in the Bubble generator.
- Fill the water in the humidifier chamber.
- Set the PEEP at 4cm H2O in the Bubble generator.
- Set the humidifier to the required mode by using mode key.
- Select the heater wire function ON.
- Connect the breathing circuits.
- Connect Air and oxygen to gas inlet port of using gas supply line.

2.2.4 Check the Bubble CPAP Function.

- Check Digital PEEP monitor reads zero in PEEP indicator with no gas flow.
- Adjust gas supply to desired flow rate at 5 LPM.
- Occlude the flow tube port & ensure the PEEP indicator reading should be 4 cmH2O.
- Ensure the humidifier mode of operation.

2.2.5 Patient Circuit Connection Details



1	Double Flowmeter holder	6	Temperature Probe – Chamber Side
2	Blended gas output	7	Temperature Probe – Air Way Side
3	Humidification Chamber	8	Nasal prongs
4	Bubble Jar	9	Preset pressure manifold
5	Heater wire line	10	Heated (Respiratory) Humidifier

2.3 nice 5060S

2.3.1 Setup

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

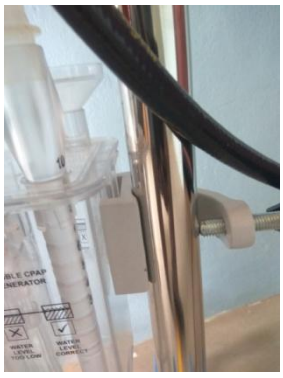
2.3.2 Installation of nice 5060S Bubble CPAP

- Fix Humidifier Pole mounting bracket on the pillar and tighten the screw. Position the bracket should be higher than the Bubble Generator bracket.

- Fix the on the pillar and tighten the screw, position the bracket lower the humidifier bracket.

- Fix the pillar with M10 Hex Nut, ensure the tighten.

- Fix the humidifier with humidifier mounting bracket.



- Fix the Bubble Generator with Bubble Generator mounting bracket.

- Connect the Air Gases pipe line or concern sources.

- Connect the Oxygen Gases pipe line or concern sources.
- Connect the breathing circuits as per the picture given below. (refer Section 2.3.5)

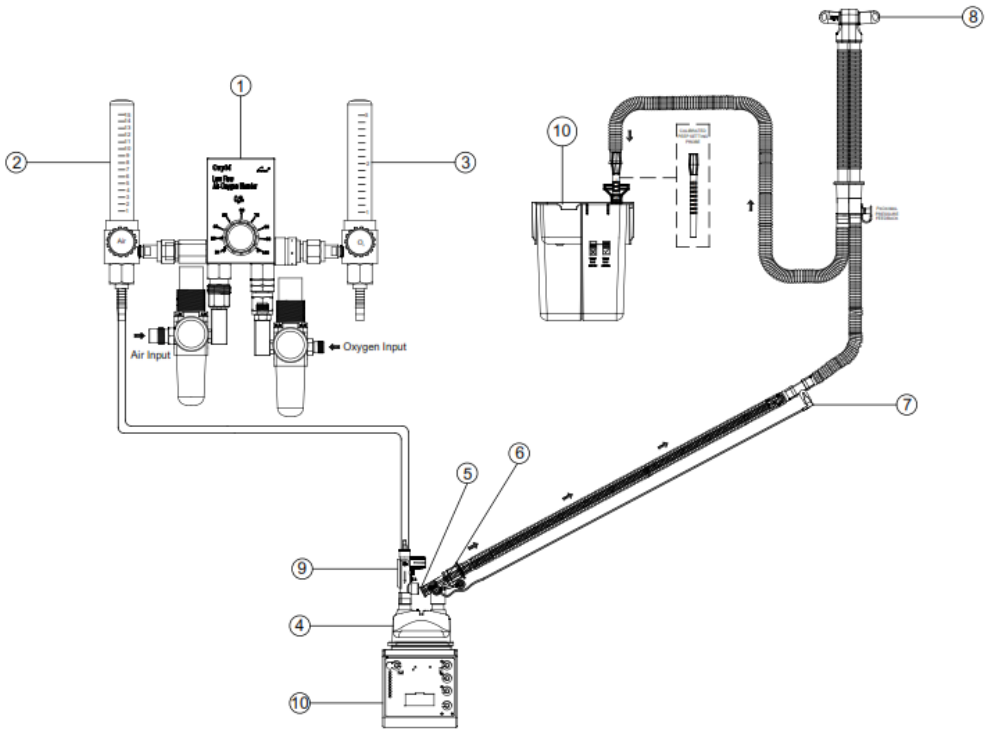
2.3.3Setting of Bubble CPAP

- Set the flow rate at 5 LPM in the flow meter.
- Set the required FIO2 percentage.
- Fill the water in the Bubble Generator.
- Fill the water in the humidifier chamber.
- Set the PEEP at 4cm H2O in the Bubble Generator.
- Set the humidifier to the required mode by using mode key.
- Select the heater wire function ON.
- Connect the breathing circuits.
- Connect Air and oxygen to gas inlet port using gas supply line.

2.3.4 Check the Bubble CPAP Function.

- Adjust gas supply to desired flow rate at 5 LPM.
- Ensure the humidifier mode of operation.
- The output of the flow meter is connected directly to the input of pressure relief device.

2.3.5 Patient Circuit Connection Details



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	Humidification Chamber	9	Preset pressure manifold
5	Heater Wire Adaptor	10	Bubble Generator

2.4 Installation of Heated (Respiratory) Humidifier (nice 8050)

2.4.1 Setup

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

2.4.2 Fix the Humidifier Chamber

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

2.4.3 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.

2.4.4 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) of the heater wire adapter to the breathing circuit socket(s).

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

2.5 Pre-use Check Instructions

- Before using the nice Neötech Bubble CPAP System, 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 while a patient occupies the Bubble CPAP System.
- Complete the “Pre-use Check Instructions” section of this manual before putting the unit into operation. If the Bubble CPAP System fails in any portion of the Pre-use Check Instructions it must be removed from use and repaired.

2.5.1 Overall System Check

- Ensure the entire system is stable and all components are securely mounted or positioned.
- Check that any movable parts, such as adjustable arms or stands, operate smoothly without excessive force or resistance.
- Confirm that all mechanical components are clean and free from dust or debris that could interfere with operation.

2.5.2 Mechanical Checks

Digital PEEP monitoring with in-built air oxygen blender:

- Inspect the power cord for any fraying, cuts, or damage. Ensure the power cord whether it is intact with the socket. Replace the power cord if damage is evident. The Power cord is replaced only by the trained service personal.
- Ensure the air and oxygen inlet ports are securely fitted to the rear of the CPAP unit, and the patient outlet port is securely fitted to the front.

Heated (Respiratory) Humidifier:

- Inspect the power cord for any fraying, cuts, or damage. Ensure the power cord whether it is intact with the socket. Replace the power cord if damage is evident. The Power cord is replaced only by the trained service personal.
- Ensure the heater plate is clean and free of any residue or deposits. Verify that it heats evenly and to the correct temperature.

Disposable Humidification Chamber:

- Ensure the water chamber fits securely into the humidifier base.
- Water should be feed as per the instruction provided in Section 3.18.
- Check there is no leaks in the chamber and also in the connections.

Bubble generator:

- Inspect the bubble chamber for any signs of wear, cracks, or leaks.
- Ensure all seals and gaskets are intact and provide a tight seal to prevent water or air leaks.

Bubble CPAP circuit:

- Check the tubing for any kinks, cracks, or wear that could obstruct airflow or cause leaks.
- Ensure all connectors are secure and free from damage. Verify that they fit tightly without any air leaks.

Nasal prongs/ Nasal Masks:

- Check the nasal prongs/mask for any tears, discoloration, or signs of wear.
- Verify that the nasal prongs/mask create a proper seal without excessive pressure points.

Mounting clamps:

- Check whether the mounting clamps are damage free and it is held firmly to the stand in the Bubble CPAP System.

Locking Castors (5 nos.):

- Once the Bubble CPAP System is in place, these castors should be locked to prevent the unit from rolling around freely.
- Castors lock and unlock with slight foot pressure on the locking lever.

Patient circuit arm:

- Ensure the stainless-steel patient circuit arm moves smoothly to various angles and securely locks in place using the turning knob, confirming it can hold larger weights without sagging.

2.5.3 Pre-use check of Digital PEEP monitoring with in-built air oxygen blender:

- **Power Fail:**
  - Remove the power cord and then switch on the equipment.
  - Power Fail LED is lit (9v non-rechargeable battery is provided).

2.5.4 Alarm Checks:

Bubble CPAP unit:

- **Power Failure Alarm:** Verify that the alarm sounds when the power supply is disconnected or fails.
- **Oxygen Supply Low Alarm:** Confirm that the alarm activates when the oxygen supply pressure drops to 30 psi.
- **Air Supply Low Alarm:** Ensure the alarm triggers when the air supply pressure falls to 30 psi.
- **PEEP High Alarm:** Check that the alarm sounds if the PEEP increases by 0.5 cmH2O above the set level.
- **PEEP Low Alarm:** Verify that the alarm activates if the PEEP decreases by 0.5 cmH2O below the set level.

Heated (Respiratory) Humidfier:

- **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.

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

2.5.5 Alarm and Reverse gas flow test for Air oxygen blender

Alarm Test:

- Step 1: Connect the Air-Oxygen Blender to air and oxygen source, pressurize the Blender and turn “ON” the flowmeter.
- Step 2: Set Oxygen Concentration Dial to 60% FIO2.
- Step 3: Disconnect or turn “OFF” the air supply to the Air-Oxygen Blender. The Blender should alarm with a loud whistle noise. The whistle indicates the alarm is operating correctly.

- Step 4: Reconnect and activate the air supply line to the Blender, the alarm should stop whistling.
- Step 5: Disconnect or turn “OFF” the oxygen supply line to the Blender. The whistle indicates the alarm is operating correctly.
- Step 6: Reconnect and activate the oxygen supply line to the Blender, the alarm should stop whistling.
- Step 7: If alarm fails to function properly, DO NOT USE.

Reverse gas flow Test:

- Step 1: Disconnect the oxygen hose from the gas source. Remove all outlet connections from the Blender to ensure that there is no outlet flow.
- Step 2: While gradually increasing the air supply pressure from 30-75 psi (2.07-5.17 bar) check for leakage past the oxygen inlet check valve.
- Step 3: Replace the Duckbill Check Valve in the oxygen inlet if leakage is > 100 ml/min (alarm condition).
- Step 4: Repeat steps 1-3 to check for leakage past the air inlet check valve.

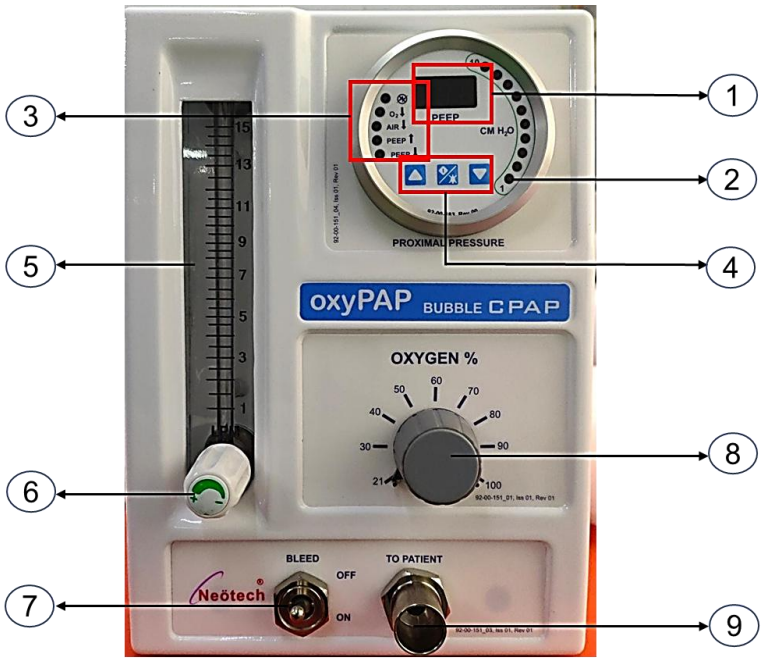
2.5.6 Accessory Checks

- Perform these checks if they are applicable.
- Check that all accessories provided with the bubble CPAP are mounted securely and that the load limits are not exceeded.
- Check that all gas accessories are installed and operating properly.
- Where applicable, perform the Pre-use Check Instructions detailed in the Operation and Maintenance Manuals for the accessories.

Section 3: Operation

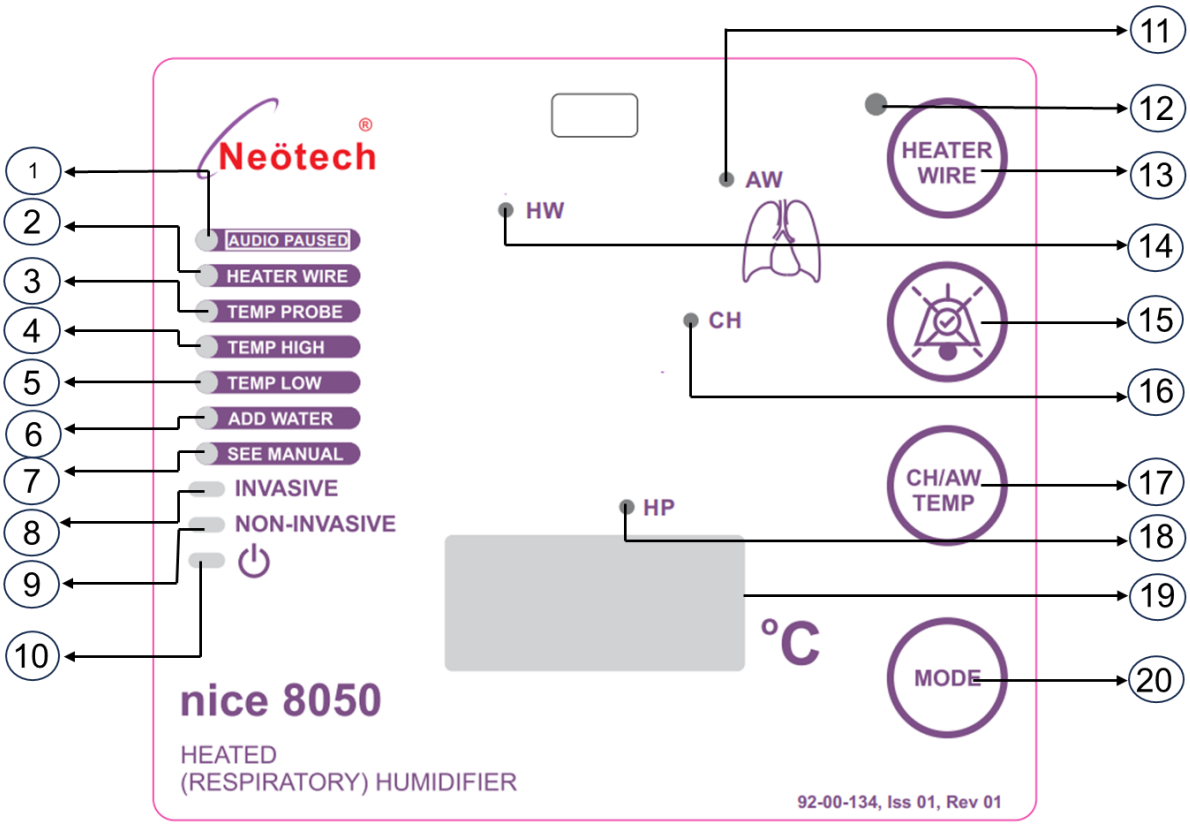
3.1 Control unit

3.1.1 Digital PEEP monitoring with in-built air oxygen blender:



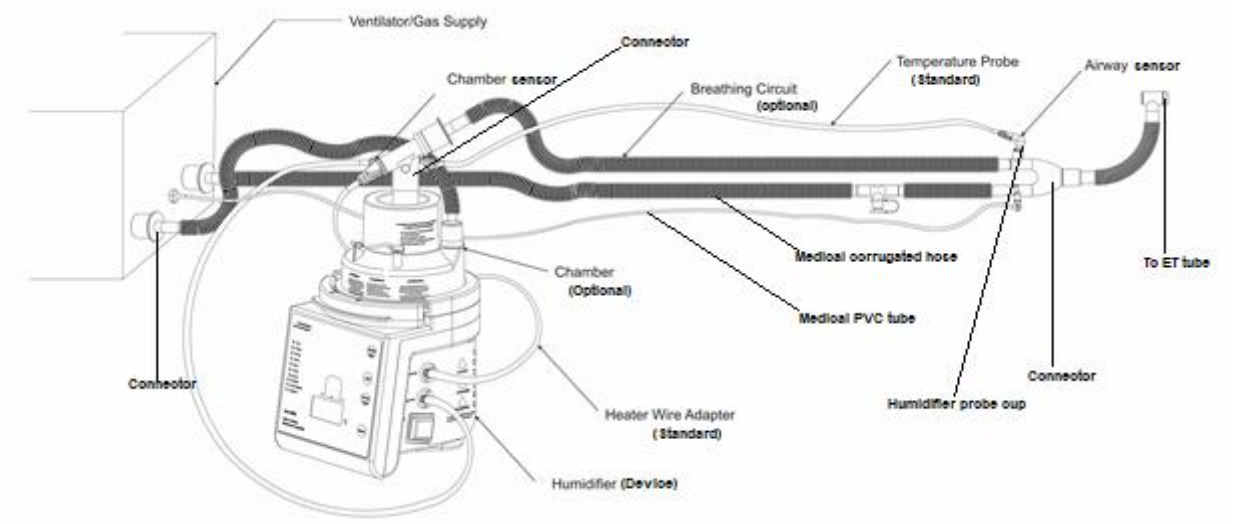
1. PEEP pressure display	6. Flow control knob
2. PEEP indicator	7. Bleed ON/ OFF switch
3. Visual indicators	8. FiO2 control knob
4. Control Keys	9. To patient connection port
5. Flow meter (0-15 LPM)	

3.1.2 Heated (Respiratory) Humidifier:



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

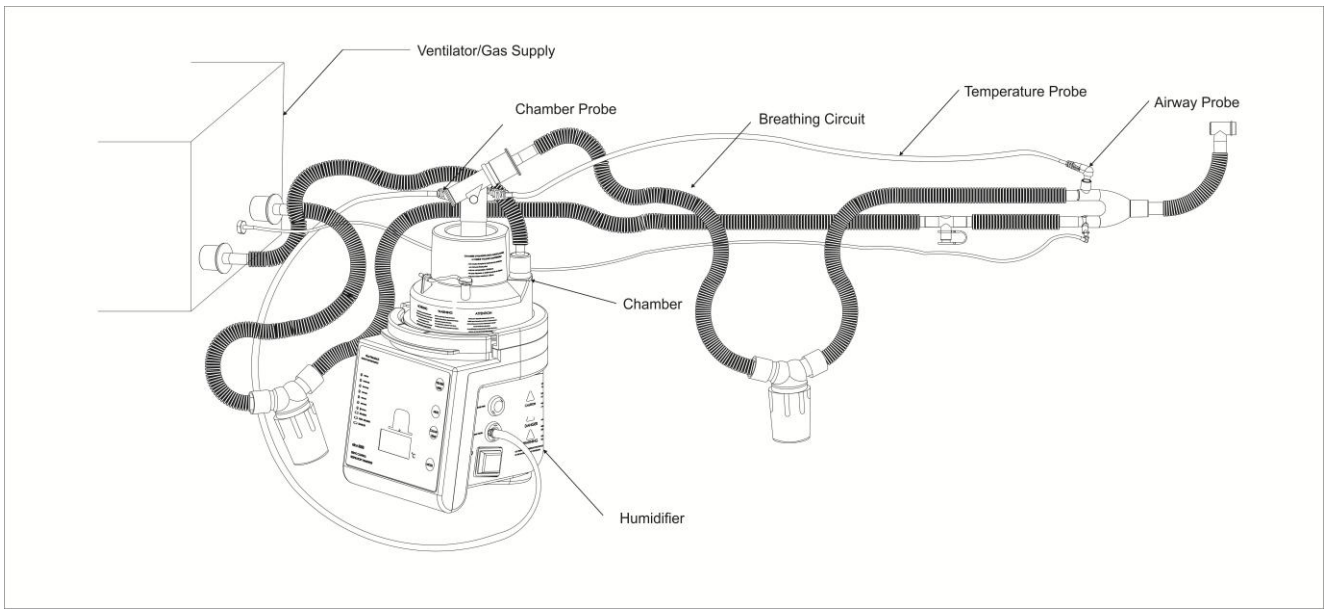
3.1.2.1 Heater Wire Operation (nice 8050)



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.

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

3.1.2.2 Non-Heater Wire Operation (nice 8050)



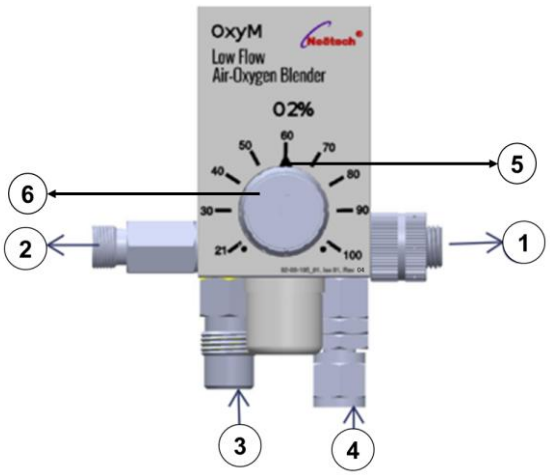
Heated (Respiratory) Humidifier maintains the airway temperature at the desired set point (invasive 37 °C or non-invasive 31 °C) by heating the chamber of water through the heater plate. As the gas cools considerably down the unheated circuit, a water trap circuit must be used to collect the resulting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

3.1.2.3 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.

3.1.3 Air Oxygen Blender:



1)	Auxiliary outlet
2)	Primary outlet
3)	Air inlet
4)	Oxygen inlet
5)	Pointer
6)	FiO2 control knob

The OxyM Air-Oxygen Blender provides selection of oxygen concentrations by means of a single control knob located on the front of the unit. Oxygen concentrations ranging from 21 to 100% are available.

	Output	**Flow Range**	**Bleed Flow**
Low Flow Blender	Primary, Left Side	0- 30 LPM	No Bleed Flow
	Auxiliary, Right Side	0-30 LPM	2.5-3.5 LPM

3.2 Switches & Keys

Digital PEEP monitoring with in-built air oxygen blender:

	**Main switch** - This switch is used to switch ON/OFF the device placed on the rear side of the device.
	**PEEP limit Increase/ Decrease Key** – This key is used to set the set PEEP alarm limits.
	Set key/ Mute key: **Set key** - Pressing the Set key for the first time allows the user to increase the PEEP value, pressing it a second time allows the user to decrease the PEEP value, and pressing it a third time returns the system to normal mode. **Mute key** – This key is used to mute the audio alarm. Mute all alarms except power failure alarm and in-built blender pressure difference alarm.
	**Bleed toggle switch** – This bleed switch is used to turn the bleed function ON or OFF, enabling accuracy in blending air and oxygen at low flow rates (<3LPM).

Heated (Respiratory) Humidifier:

<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
If everything is working correctly, normal control is initiated.</td></tr>
<tr><td>  </td><td colspan="2">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.</td></tr>
<tr><td>  </td><td colspan="2">This key is used to Pause the audible indication for 2 minutes temporarily. It Pauses indications except in the case of temperature probe failure and heater failure. The Timed Acknowledged indication key glows in yellow color when in use.</td></tr>
<tr><td>  </td><td colspan="2">By press CH/AW Temp key to shows the Chamber Actual Temperature and Airway Actual Temperature.</td></tr>
<tr><td>  </td><td colspan="2">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 when power up of the humidifier.</td></tr>
</table>

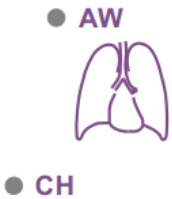
3.3 Indicators & Displays

Digital PEEP monitoring with in-built air oxygen blender:

	**Power Fail indication**	The power failure indicator LED lit when there is a power failure.
	**Oxygen pressure low indication**	The oxygen supply low indicator LED lit when oxygen supply pressure drops to 30 psi.
	**Air pressure low indication**	The air supply low indicator LED lit when air supply pressure drops to 30 psi.
	**PEEP High indication**	The PEEP high indicator LED lit when the PEEP limit increases above the set level in the PEEP probe.
	**PEEP Low indication**	The PEEP low indicator LED lit when the PEEP limit decreases below the set level in the PEEP probe.
	**PEEP display**	To display PEEP value and alarm description.

	**PEEP indicator**	PEEP indicator contains series of LEDs – illuminates according to the PEEP value maintained.

Heated (Respiratory) Humidifier:

	**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.
	**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.
	**Chamber Probe & Airway Probe Indicator:** These indicators are used to show that either the chamber probe (CH) or airway probe (AW) is not inserted into the breathing circuit correctly. If the humidifier finds that either probe is not inserted into the breathing circuit, an alarm will be generated. During this alarm the humidifier will initiate a probe out test periodically, or a test will be initiated immediately after Audio Paused Key has been pressed. During periods of low or zero gas flow, the airway probe out alarm is disabled. As soon as flow is detected however, an airway probe test is initiated.
	**Add water indicator:** This indicator alerts the user every 4 hours to check the humidification chamber.
	**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 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.

3.4 Operational Alarms

3.4.1 Digital PEEP monitoring with in-built air oxygen blender:

	**Power Failure**	activates when the power supply is disconnected or fails.
	**Oxygen pressure Low**	activates when the oxygen supply pressure drops to 30 psi.
	**Air pressure Low**	activates when the air supply pressure drops to 30 psi
	**PEEP High**	activates when the PEEP limit increases above the set level in the probe.
	**PEEP Low**	activates when the PEEP limit decreases below the set level in the probe.
In-built Air oxygen blender	**Pressure difference alarm**	Activates audible alarm if source pressures differ by 20 ±2 PSI

3.4.2 Heated (Respiratory) Humidifier:

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

3.4.2.1 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.

3.4.2.2 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.

3.4.2.3 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.

3.4.2.4 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.

3.4.2.5 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

3.4.3 Air Oxygen Blender Alarm/ Bypass:

The alarm feature provides for an audible alarm if source pressures differ by 20 ±2 PSI or more. The primary purpose of the alarm is to audibly warn the operator of an excessive pressure drop or depletion of either source gas. The alarm will also activate when there is reduce of either source gas resulting in a 20 ±2 PSI difference. Should both gas pressures (oxygen or medical air) increase or decrease simultaneously, and a 20 ±2 PSI differential is not seen, there will not be an audible alarm.

If either source gas pressure drops, the output pressure of the blender will drop similarly, since the source gases are always balanced to that of the lower pressure. The bypass function operates in unison with the alarm. The alarm bypass poppet communicates directly with the air supply on one end and the oxygen supply on the other. When the two source gases are near equal in pressure, the alarm bypass poppet is positioned over the bypass channel, blocking the flow of both gases. The poppet will remain seated for unequal pressures up to 20 ±2 PSI. Once a 20 ±2 PSI difference occurs, the higher gas pressure will overcome the spring force and pressure of the poppet at its opposite end, thus creating a path (air or oxygen) to flow into the alarm channel.

The gas with the higher pressure will also flow directly to the blender outlet port bypassing the Balance and Proportioning Modules. The gas is also directed to the bottom of the unit to the reed alarm, thus creating an audible warning. The oxygen concentration will be that of the gas at the higher pressure. The blender in the alarm/bypass mode will deliver the oxygen (100%) or medical air (21%) until the pressure has been restored to a differential of approximately 6 PSI. If the blender is set at 21% and the OXYGEN source pressure is reduced enough to produce a 20 ±2 PSI or greater differential, the unit may not alarm because it will continue to deliver 21% concentration according to the setting. If the control is moved slightly from the 21% setting, the alarm will sound. Similarly, if the blender is set to deliver 100% concentration and AIR source pressure is reduced or lost, the unit may not alarm because it will continue to deliver the selected 100% concentration.

If the blender is left connected to source gases but is not being used (i.e., no output flow or bleed flow) the unit will not alarm if a 20 ±2 PSI or greater pressure differential develops. If the blender is not in use, an alarm under these conditions will be an unnecessary distraction or nuisance.

3.5 Setup instructions

i) Insert Humidification Chamber

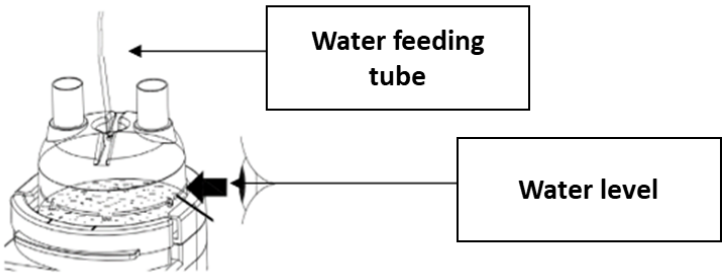
Caution

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.

Warning

- 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.

iii) Fill Bubble CPAP Generator

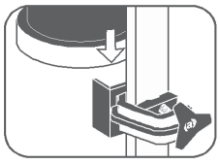
- ➔ Using the funnel provided, fill the CPAP generator with sterile/ distilled water until water flows into the overflow container.

➔ Set the CPAP probe to 10 cmH2 O, ready for the leak test.

Caution

- Ensure that the fill-funnel remains on the Bubble CPAP generator.
- Ensure that the humidifier and Bubble CPAP generator are mounted below the patient.
- Do NOT use saline or other medicated fluids in the Bubble Generator.
- Use of this device at gas flow rates of greater than 12 LPM may result in higher end expiratory pressures being delivered.

To attach the Bubble generator to a mounting clamp



Slide the equipment mount into the corresponding equipment mount holder. Use of this type of mounting system will assure that the device remains in the upright (vertical) position.

Note: This device includes an integral equipment mount that is intended to mate with an ISO 19054:2005/ Amd 1: 2016 compliant equipment mount holder.

Monitoring airway pressure

During use, continuously monitor airway pressure with an accurate pressure monitoring device.

Warning

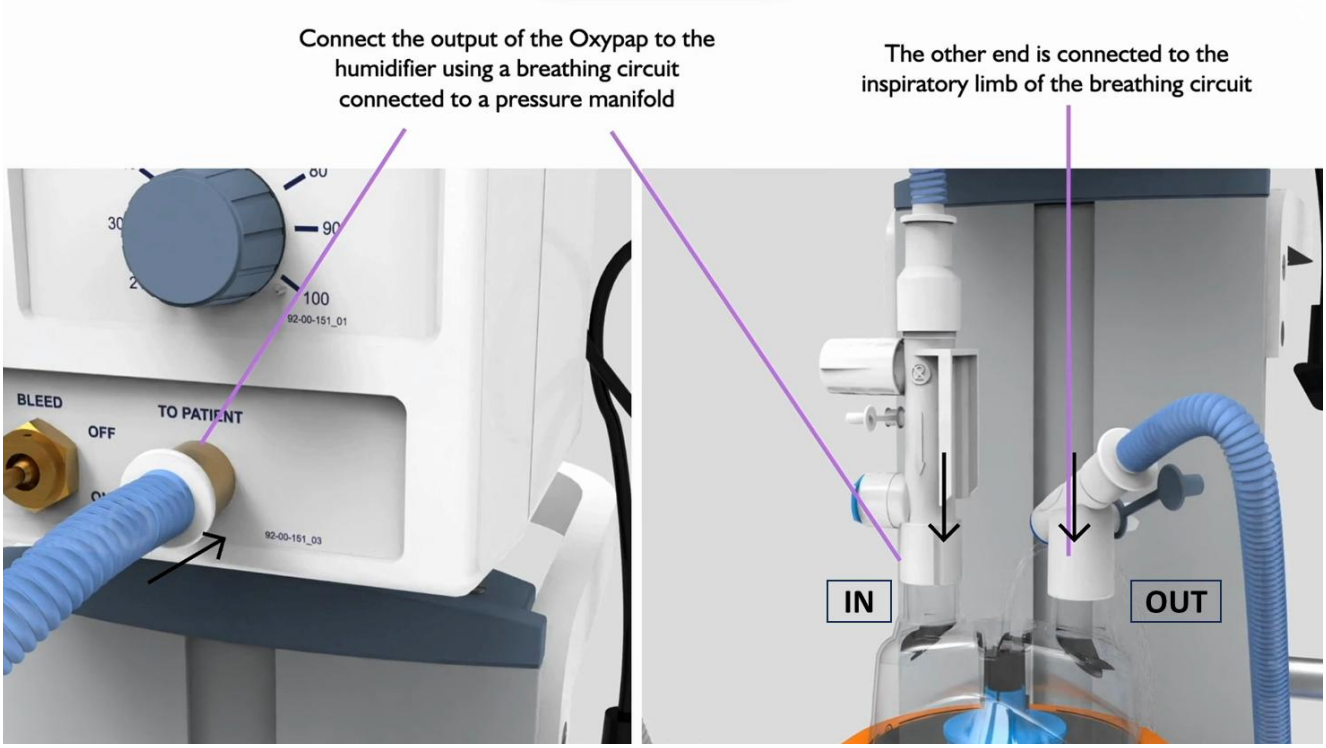
- Always monitor, maintain and verify PAP level with a Digital PEEP monitor that measures proximal airway pressure.

iv) 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.

Caution

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



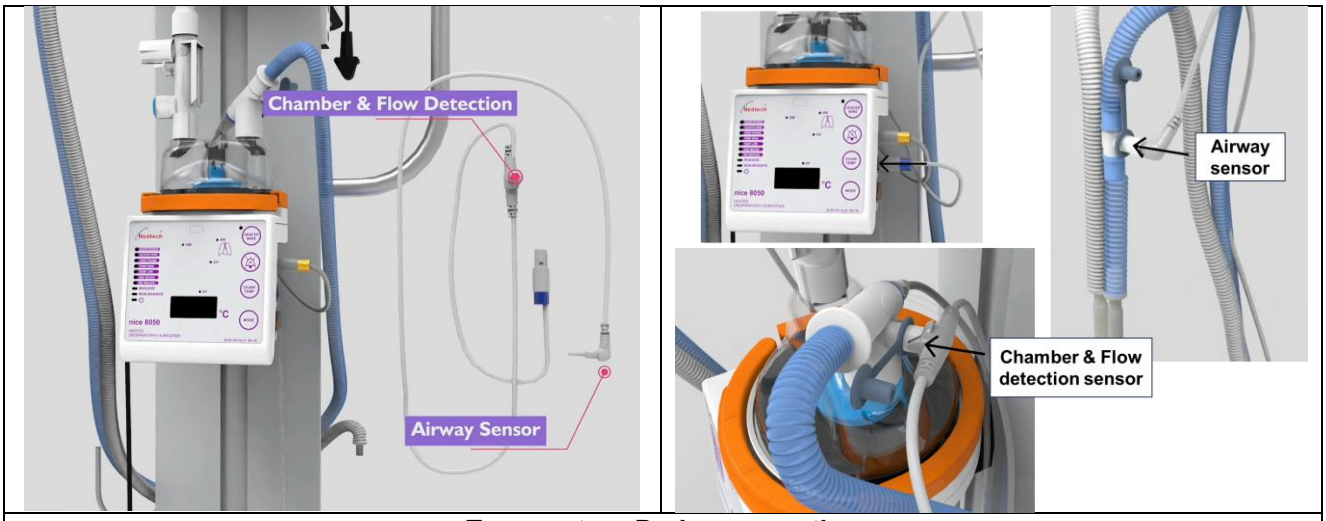
Set up the Inspiratory Limb:

- 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

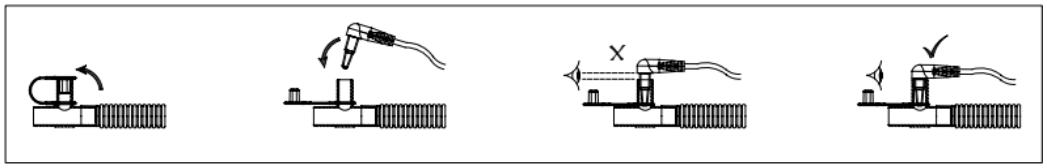
probe port includes a V-shaped notch corresponding to a V-shape on the probe line. Push the probe firmly into place for correct operation of the humidification system. Fully insert the temperature probe (patient end probe) into the temperature probe port of inspiratory limb.



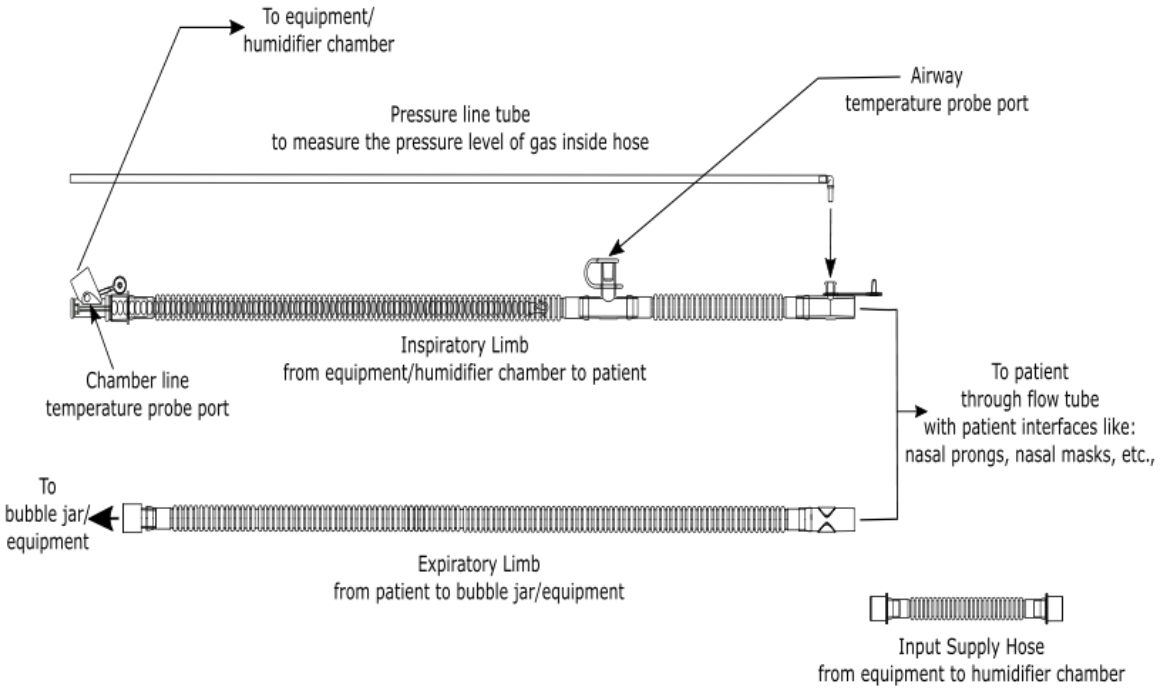
Temperature Probe connection

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.



Set up the Expiratory Limb:

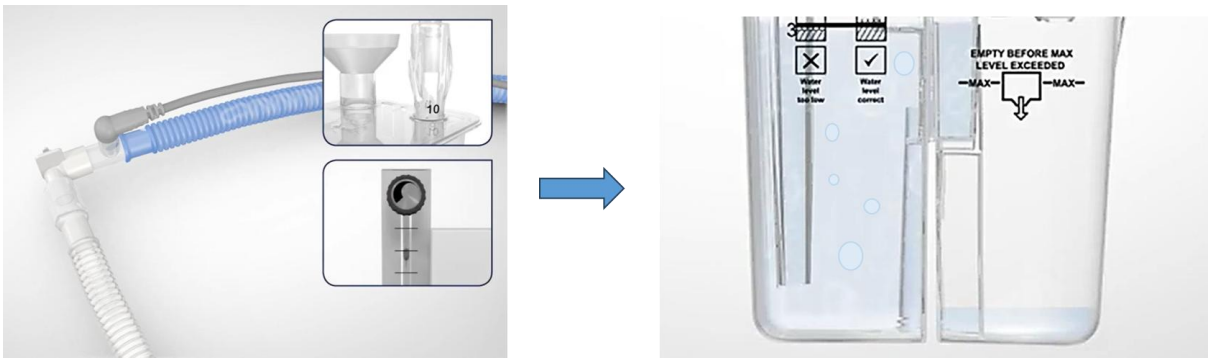
- Connect the clear expiratory tubing to the top of the PEEP probe and set the desired CPAP pressure by pulling out or pushing in the probe.

v) Perform the Leak Test

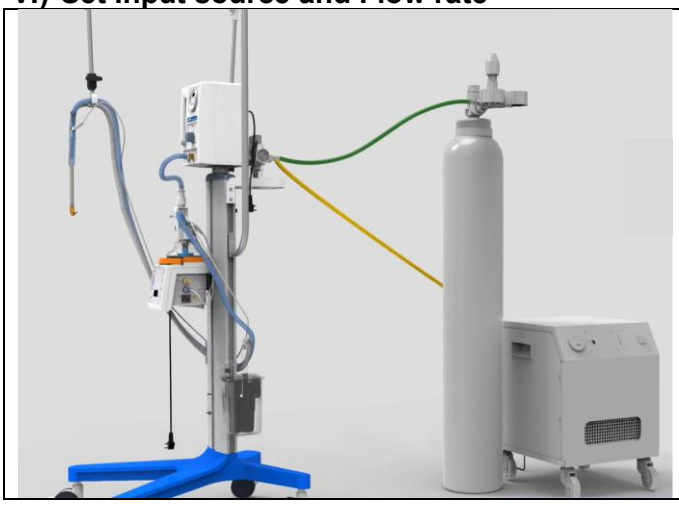
Caution

Check all connections are tight before use.

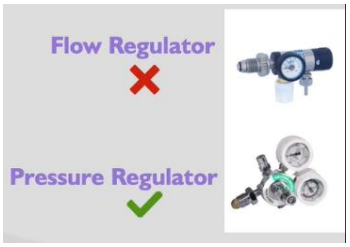
- ➔ Connect the test flow elbow white connector to the inspiratory and expiratory limbs to obtain a closed system for checking air leaks.
- ➔ Once the elbow is in place, set the CPAP probe to 10 cmH2 O and the input flow rate to 1 L/min.
- ➔ Observe the CPAP generator. Gentle, audible bubbling is acceptable; no bubbling means unacceptable leakage.
- ➔ If no bubbling is observed, check the entire system.



vi) Set Input source and Flow rate



Input Source for the Bubble CPAP through Oxygen Cylinder & Air Compressor



NOTE: When the oxygen source to the device is going to be from a cylinder, use a pressure regulator in combination with the cylinder. Using a flow regulator as an alternative can cause serious risks.

➔ Set the input flow rate at 5 LPM or required in the flow meter and maintain the input air and oxygen pressure 30-75 psi.
➔ Recommended flow rate: 5 to 10 L/min.
➔ Allowable flow range: 0 to 15 L/min.

Set the FiO2 percentage – nice 5060

- Set the required FIO_2 percentage on the dial knob (21% to 100%) of the Bubble CPAP unit.

Warning

The oxygen Concentration must be monitored with a calibrated oxygen measuring unit.

Set the FiO2 percentage – nice 5060S

- Set the required FIO_2 percentage on the dial knob (21% to 100%) of the Air-Oxygen Blender.

Warning

The oxygen Concentration must be monitored with a calibrated oxygen measuring unit.

Set the FiO2 percentage – nice 5060S

- Set the required FIO_2 percentage on the Air and O_2 knob with the following setting of Air and Oxygen Flow Meter Manifold.

Oxygen %	Oxygen Flow (LPM)	Air Flow (LPM)
30	1	9
40	2	8
50	4	6
60	5	5
70	6	4
80	7.5	2.5
90	9	1

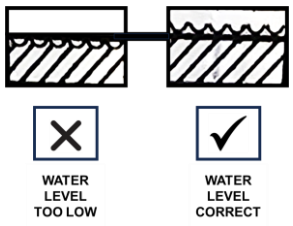
	Warning The oxygen Concentration must be monitored with a calibrated oxygen measuring unit.

vii) Set CPAP Level in the Bubble Generator

➔ The number on the CPAP probe above the lid indicates the CPAP pressure in cmH_2O. As an example, the illustration shows CPAP setting of 6 cmH_2O.

➔ Set the CPAP probe at the prescribed level (3 to 10 cmH_2O).

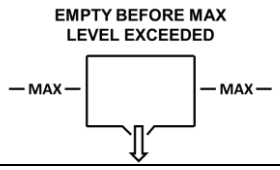
NOTE:



Bubble Generator water level symbol

✓	**denotes correct water level -** indicates insufficient water, leading to reduced efficiency in treatment. Refill required immediately.
✗	**denotes water level too low -** indicates optimal water level, ensuring efficient, safe operation and effective humidification. No action needed.

Refill the Bubble generator if the water level falls below the minimum water level line.



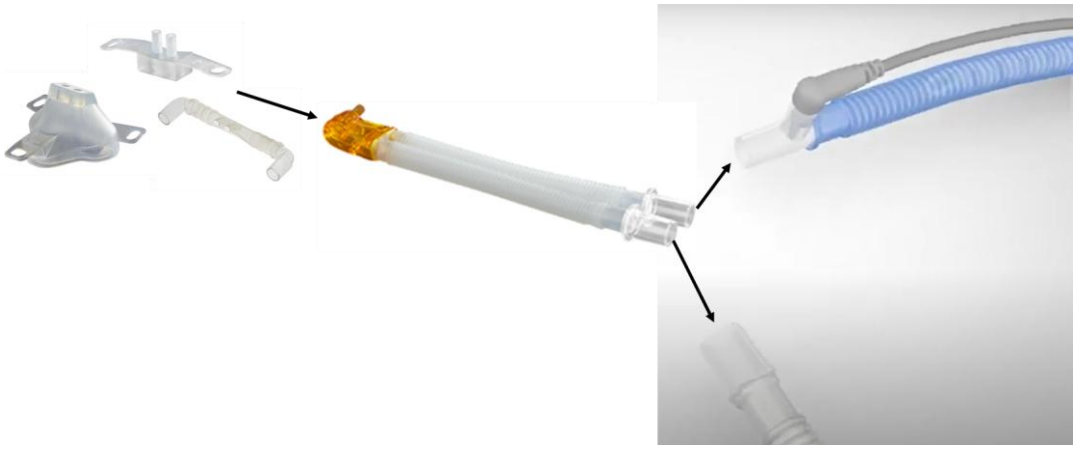
Overflow Water Level Symbol

Check and empty the overflow container once every 8 hours.

To remove, lift and then slide overflow container out.

viii) Connect Bubble CPAP Circuit to Patient Interface

➔ Remove the flow test elbow and connect the circuits to the Infant Interface via Flow tube.



➔ nice Neotech provides various models for Bubble CPAP Breathing circuit (BC 510, BC 525, BC 530, BC 555, BC 570, BC 575, BC 560). Detailed instructions provided in the Section 3.9

ix) Set the Humidifier

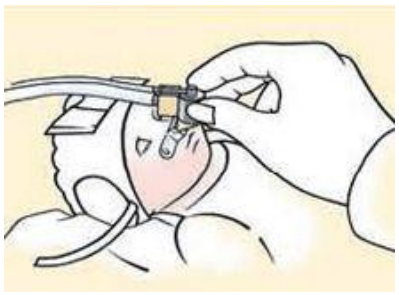
Caution

Ensure there is air flow present before turning on the humidifier.

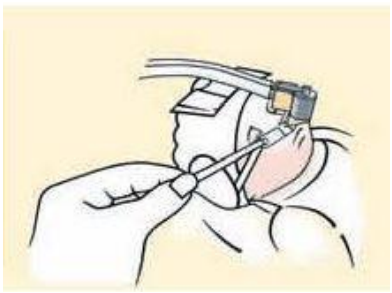
➔ Turn on the humidifier.
- If using the nice 8050, ensure it is on Invasive mode (37 °C).
- If using the nice 8010, set the temperature to 40 °C.

x) Attach Interface to Infant

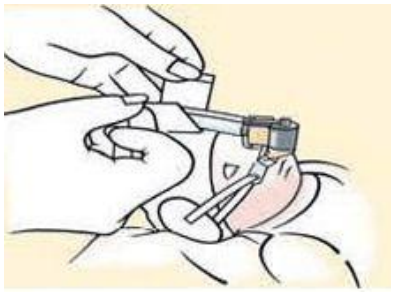
➔ Connect the interface (nasal prongs/ nasal masks) to the infant. Detailed information provided in Section 3.10.



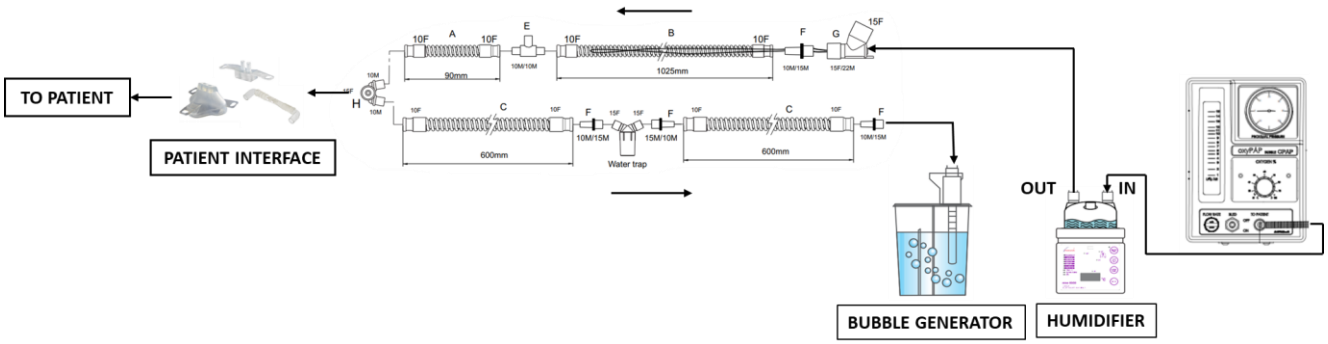
Fixing Head Bonnet



Fixing Nasal Prongs



Fixing Flow Tube



3.6 Checks during Operation

- Regularly observe that the water is feeding into the humidification chamber.
- Should the water level exceed the maximum level marked on the humidification chamber, the chamber should be replaced.
- Check all connections are tight before use and after adjustment.
- Ensure air flow is presence at all times. If air flow is interrupted, turn off the humidifier.
- Regularly observe the circuit for condensate, drain as required
- Regularly observed the Bubble generator for bubbling. If bubbling is not observed check for a minimize air leaks in the system and at the patient end. If air leaks have been minimized, air flow may be increased to achieve continues bubbling.
- Regularly observe the water level in the Bubble generator refill the Bubble generator if the water level drops below minimum water level line. **Check and empty the overflow container once every 8 hours.**
- Monitor the Patient oxygen level.
- Always use pressure monitoring to verify that the patient is receiving the prescribed CPAP level.

3.7 Shutdown procedure

i) Assess the patient:
- Ensure the patient is stable and can breathe independently.

ii) Disconnect the patient:
- Gently remove the patient interface (nasal prongs or mask) from the patient.
- Secure the interface to prevent contamination.

iii) Turn Off the Gas flow source:
- nice 5060 - Reduce the FiO_2% gradually to prevent abrupt cessation. Turn off the gas flow source from the bubble CPAP unit.
- nice 5060S – Reduce the FiO_2% gradually to prevent abrupt cessation. Turn off the Air-Oxygen Blender.
- nice 5060F - Reduce the Air and oxygen flow manifold gradually to prevent abrupt cessation. Turn off the Air-oxygen Flow meter manifold.

iv) Shut down the Heated (Respiratory) Humidifier:
- Decrease the temperature setting on the heated respiratory humidifier.
- Turn off the humidifier and allow it to cool down.

v) Disconnect the Breathing circuit:
- Carefully disconnect the breathing circuit from the patient interface.
- Dispose of single-use components according to the Section 7.2

vi) Turn Off the CPAP unit:
- Power down the CPAP unit and unplug the unit from the power source.

vii) Drain the Humidifier Chamber and Bubble generator:
- Remove and empty the water from the humidifier chamber and bubble generator according to the section 3.9.
- Clean and dry the chamber and bubble generator if it's reusable, or dispose of it if it's single-use.

viii) Clean and store the equipment:
- Clean all reusable components.
- Store the equipment in a clean, dry place.

ix) Perform a final check:

- Ensure that all equipment is properly shut down, cleaned, and stored.
- Check again that all castors are in the fine contact with the floor and that the CPAP unit is stable & moves freely.

3.8 Compatible Bubble CPAP circuits used in the Bubble CPAP System

BC 510	Infant/Neonatal Heater wire Breathing Circuit for Bubble CPAP
BC 525	Infant/Neonatal Heater wire Breathing Circuit for Bubble CPAP (T-Bar Prongs type)
BC 530	Infant/Neonatal Heater wire Breathing Circuit for Bubble CPAP with Humidification Chamber (T-Bar Prongs type)
BC 555	Infant/Neonatal Heater wire Breathing Circuit for Bubble CPAP with Humidification Chamber
BC 570	Bubble CPAP Breathing circuit (Combo kit)
BC 575	Bubble CPAP Breathing circuit with Bubble Generator (Combo kit)
BC 560	Silicone Infant/Neonatal Breathing Circuit with Heated Wire for Bubble CPAP

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

Bubble Generator

- Ensure that the Bubble CPAP system is turned off and disconnected from the patient.
- Disconnect the expiratory limb connected to the top of the bubble generator.
- Remove the bubble jar lid by lifting it off carefully to access the inside of the container.
- Gently lift the bubble jar container from its mounting provision to separate it from the rest of the system.
- Carefully pour out the water from the bubble jar container. Ensure that the water is disposed of properly, following the facility's guidelines for disposal of medical waste.
- If the overflow container has collected any excess water, remove it and pour out the water. Clean and dry the overflow container before reattaching it.
- After draining the water, clean the bubble jar container, lid, PEEP probe, and overflow contained according to Section 0.0. This includes rinsing, disinfecting and drying all parts thoroughly.
- Once all components are cleaned and dried, reassemble the bubble generator by placing the bubble jar container back into its mounting provision, reattaching the bubble jar lid.
- Store the bubble generator in a clean and dry environment until its next use.

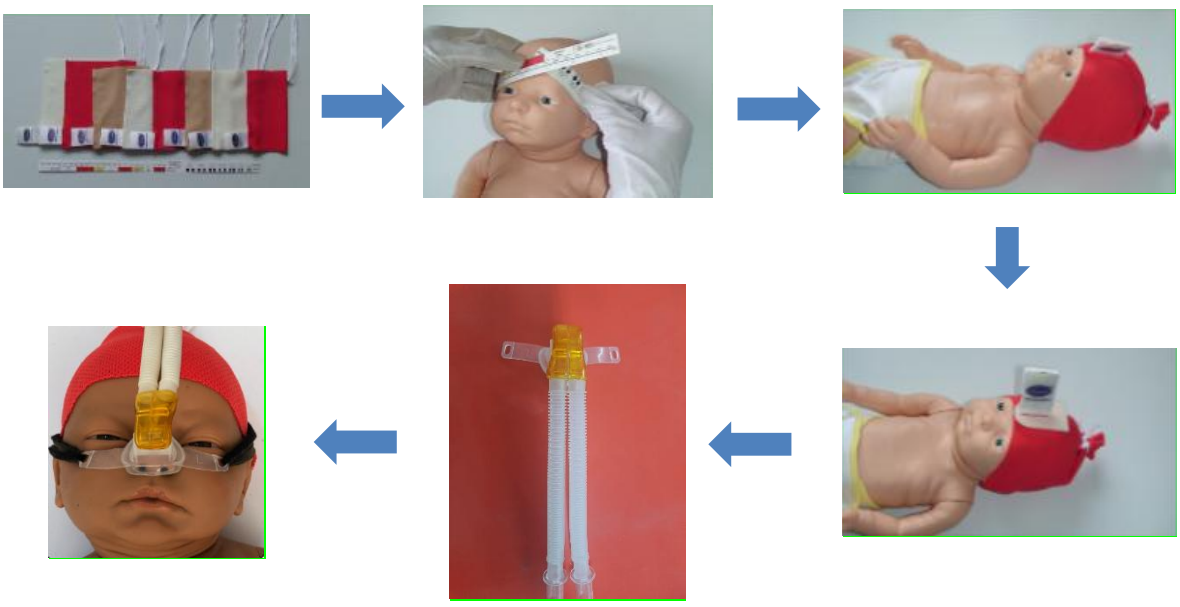
Humidification Chamber

- Ensure that the Bubble CPAP system 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.

3.10 Instructions for using Patient Interface (Nasal Mask, Nasal prongs and T-bar Prongs)

Nasal Mask

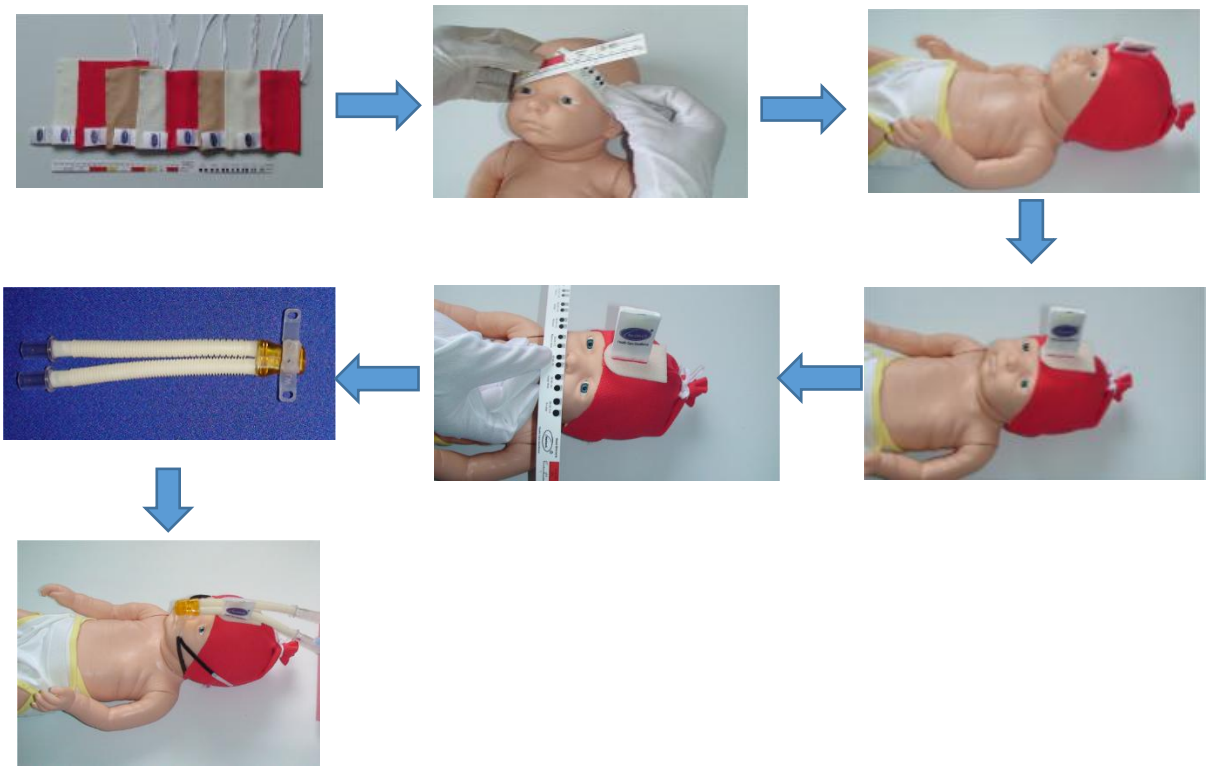
A – To be connected to flow tube
B – Anatomical Curve to fit Patient Nose
C – Provision to connect Head Bonnet
D – Soft Layer to be placed around the nose



1. An infant's head size is measured using a measuring tape.
2. Choose the correct size of head bonnet according to the infant's head size.
3. Fix the bonnet onto the baby's head, completely covering the ears. with the back edge of the bonnet at the base of the neck. The front edge of the bonnet should be just above the eyebrows.
4. The nasal mask is fixed to the flow tube.
5. The flow tube is placed over the fixing pillow. Then fixing pillow for the flow tube is placed on the Velcro of the head bonnet.
6. The mask covers the perimeter of the infant's nose.
7. The mask sits midway between the nose and upper lip.
8. The flow tube is connected to the breathing circuit.

Nasal Prongs

A – To Patient Nares
B – To be connected to head bonnet
C – To be connected with flow tube

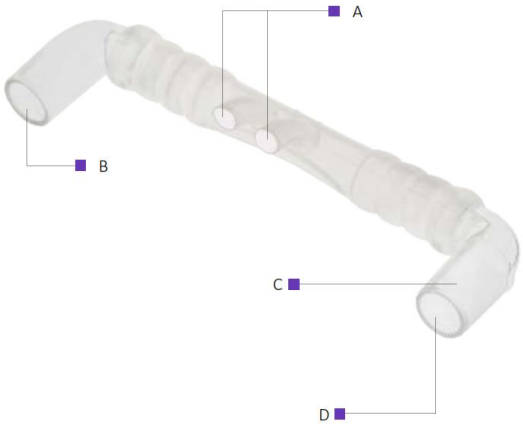


1. An infant's head size is measured using a measuring tape.
2. Choose the correct size of head bonnet according to the infant's head size.
3. Fix the bonnet onto the baby's head, completely covering the ears with the back edge of the bonnet at the base of the neck. The front edge of the bonnet should be just above the eyebrows.
4. Select the nasal prongs by measuring the nasal by using the measuring tape, then fix the nasal prongs to the flow tube.
5. The flow tube is placed over the fixing pillow. The fixing pillow for the flow tube is placed on the Velcro of the head bonnet.
6. Prongs covers the perimeter of the infant's nose.
7. The Prongs sits midway between the nose and upper lip.
8. The flow tube is connected to the breathing circuit.

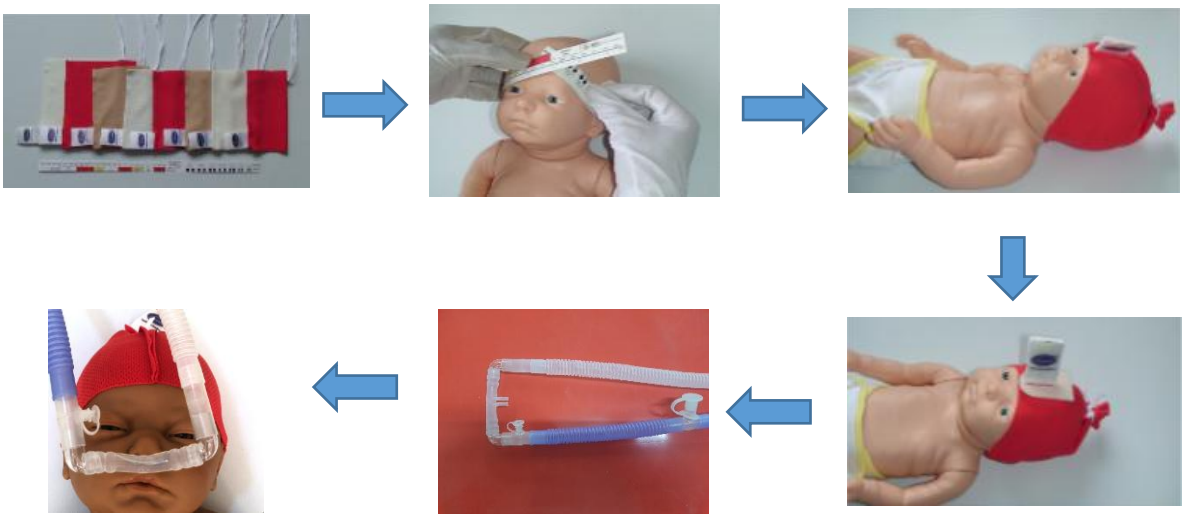
Caution

Over-tightening or inserting the prongs too deep may lead to pressure sores or nasal dilation.

Nasal T-Bar prongs:



A – To Patient Nares
B – Exhalation Port
C – 'L' Connector for connecting to breathing circuit
D – Inhalation Port



1. Measure the baby's head circumference with a head bonnet selection guide. Choose the correct size bonnet.
2. Slip the bonnet onto the baby's head completely covering the ears, with the back edge of the bonnet at the base of the neck and the front edge of the bonnet should be just above or on the eyebrows.
3. Choose the appropriate size of nasal T-bar prongs connect the breathing circuit for respiratory therapy to the patient nostrils.

Caution

Use the correct nasal prong size. Prongs that are too large cause nares blanching. If the prongs are too small, they may go too far up the nose and press up against the septum.

3.11 Standard accessories

#	Accessory Name	Single use / Reusable	Part no.	Intended use	Picture
1.	Single heated wire breathing circuit with Humidification Chamber, Bubble Generator and Pressure manifold	Non-sterile & Single-use only	BC 575	Breathing circuit is intended to direct the flow of medical gases (Air/Oxygen) with optimum humidity to the patients	
2.	Temperature probe	Reusable	80-05-003	Temperature probe is intended for measuring chamber temperature and airway temperature.	
3.	Heater wire adapter for 3 pin disposable circuit	Reusable	80-05-010	Heater wire adapter is intended to interlink the humidifier and breathing circuit heater wire.	
4.	CPAP Nasal prongs/Nasal Mask	Non-sterile & Single-use only	98-00-110 to 116 98-00-133 to 136	Nasal prongs/Nasal Mask is intended to connect the breathing circuit and the patient's nostril to deliver the gas to the patient. Available in 7 different sizes of Nasal septum. Nasal masks are available in 4 different sizes.	
5.	Flow Tube	Non-sterile & Single-use only	50-05-076	Flow Tube is intended to connect breathing circuit and patient interface	
6.	CPAP Head bonnet	Non-sterile & Single-use only	76-00-003 to 012	Head bonnet is intended to hold the breathing circuit with nasal prongs / nasal mask connected to the nasal septum. Head Bonnet is available is 8 different sizes.	

7.	Mounting bracket	Reusable	50-05-096 (Patient circuit arm) 50-05-140 (Air oxygen blender) 50-05-097 (Humidifier)	Mounting brackets for blenders and humidifiers holds and lock the devices to be used on the roll assembly, or on rails or walls in hospitals	

3.12 Optional accessories

#	Accessory Name	Single-use / Reusable	Part no.	Intended use	Picture
1.	CPAP Nasal T-bar prongs	Non-sterile & Single-use only	98-00-129 98-00-130 98-00-131 98-00-132	Nasal T-bar prongs is intended to connect the breathing circuit and the patient's nostril to deliver the gas to the patient. Available in 4 different sizes of Nasal septum	
2.	Medical Air Hose	Reusable	50-20-171	Inlet hose for Air from centralized line or compressor to respiratory care devices.	
3.	Medical Oxygen Hose	Reusable	30-05-067	Inlet hose for Oxygen from centralized line or compressor to respiratory care devices.	

Section 4: Cleaning and Maintenance

4.1 General

- ❑ Always switch off the equipment while cleaning
- ❑ Clean external surfaces of the Bubble CPAP System and Gas Supply line using a damp cloth
- ❑ Dry all surfaces after cleaning with a clean soft cloth or paper towel.
- ❑ The Bubble CPAP System should require minimal servicing or maintenance when used under normal conditions.
- ❑ 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.
- ❑ Switch off the equipment and disconnect the Power cord from the mains before take in to cleaning
- ❑ 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.

4.2 Dismantling Bubble CPAP

- ❑ Disconnect Patient breathing Circuit form Bubble CPAP setup.
- ❑ Remove the humidifier chamber from the humidifier.

4.3 Cleaning and disinfection of Bubble CPAP Systems

During cleaning the Bubble CPAP System, the processing shall comply with ISO 17664:2021 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 Bubble CPAP System that has been chemically disinfected for reuse, because tap or distilled water may harbour microorganisms. However, when rinsing with sterile water is not feasible, instead, rinse with filtered water (i.e. water passed through a 0.2 µ filter).

5. Dry Bubble CPAP System using dry towel or cloth.

- Disconnect the Bubble CPAP System from any main supply.

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

4.4 Cleaning and disinfection of Standard accessories –Temperature Probe, Heater wire adapter, IV Pole, mounting bracket; Optional accessories Air/ Oxygen input hoses

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 Heated (Respiratory) Humidifier, Temperature Probe, Heater wire adapter, IV Pole, mounting bracket with soft cloth, removing all visible contaminants by wiping using water general cleaning.

2. When the equipment is not in use, Heated (Respiratory) Humidifier, Temperature Probe, Heater wire adapter, IV Pole, mounting bracket should be cleaned daily with an antiseptic solution like 2% glutaraldehyde and leave for 3 minutes.

3. Then rinse the Heated (Respiratory) Humidifier, Temperature Probe, Heater wire adapter, IV Pole, mounting bracket by wiping using water damped cloth

4. Dry Heated (Respiratory) Humidifier, Temperature Probe, Heater wire adapter, IV Pole, mounting bracket using dry towel or cloth

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.

4.5 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 Neötech's original parts for maintenance.

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

4.5.1 Checking the Humidifier (Maintenance)

Annually

a. Check nice 8050 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.

4.5.2 Checking the Temperature Probe

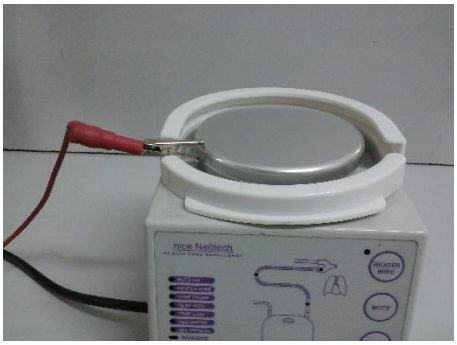
Every Six months

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.

4.5.3 Safety Check

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



The above image showing the correct location of ground test point on the heater plate and the insulating anodizing layer has been removed.

4.5.4 Replacement of Power failure Battery in the Digital PEEP monitoring with in-built air oxygen blender

- Only service personnel should replace the battery. Remove the 9V Dry Battery from the battery connector by pulling from the back side of the pillar. Replace new battery by pressing the cap. Always use Hi Watt branded battery to minimize the down time.

Note: Do not use rechargeable battery. Ensure there is no wrong polarity when battery is connected to the cap.

4.5.5 Air oxygen blender - maintenance

Air Oxygen Blender should be calibrated every 6 months or as per hospital protocol.

Applicable parts used in the Blender have been cleaned and de-greased for oxygen service. All lubricants used during assembly are designed for use in an oxygen enriched environment. Use only oxygen compatible lubricants when servicing this device. Elastomer components, such as diaphragms and O-rings, are designed to function satisfactorily for a minimum of two years. The need for cleaning and replacement depends on gas line conditions and is indicated by the Blender not meeting its specified performance

4.6 Lifetime of product

Since the product is classified under programmable medical electrical system and incase of unavailability of microcontroller the life time of the product can be considered as five years and service life of the device is extendable up to 1 years so, the service life of the device is six years (5 years of lifetime + 1 year service life)

4.7 Do's and Don'ts of humidifier

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.
- Use only Neötech 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.
- Clean the case with isopropyl alcohol or soft detergent only

4.8 Transport /movement details

Before transporting the Bubble CPAP:

1. Remove the baby from Bubble CPAP.
2. Remove the water reservoir from the IV stand.
3. Remove the water from the humidification chamber.
4. Release all the brakes in castors and then move the equipment safely.

- If the transport position of the Bubble CPAP System is more than 10°, over balance may occur.

Section 5: Specification

Specification/s	5060	5060S	5060F
General Specifications			
FiO_2 Concentration Range	21% to 100%	21% to 100%	21% to 100%
FiO_2 accuracy	± 3% O_2	± 3% O_2	± 3% O_2
Supply pressure	30 to 75 PSIG (206.85 to 517.10 Kpa) / 2.1-5.3 kg/cm2	30 to 75 PSIG (206.85 to 517.10 Kpa) / 2.1-5.3 kg/cm2	30 to 75 PSIG (206.85 to 517.10 Kpa) / 2.1-5.3 kg/cm2
Indication activation bypass	When supply pressures differ by 20 ± 2 PSI (137.90 Kpa)	When supply pressures differ by 20 ± 2 PSI (137.90 Kpa)	N/A
Overall flow range	0 to 30 LPM (Low Flow)	0 to 30 LPM (Low Flow)	N/A
Flow Meter			
Flow Range	0 to 15 LPM	0 to 15 LPM	N/A
Auxiliary Flow	N/A	0 to 3 LPM	N/A
Air Flow Range	N/A	N/A	0 to 15 LPM
*Oxy*gen Flow Range	N/A	N/A	0 to 15LPM
PEEP pressure display			
PEEP indicator cmH_2O	1 to 10 cmH_2O	N/A	N/A
Alarms	• Power failure • Oxygen supply low • Air supply low • PEEP high • PEEP low	N/A	N/A
Bubble Generator			
PEEP Adjustable Range	3 to 10 cmH_2O	3 to 10 cmH_2O	3 to 10 cmH_2O
Accuracy	±1 cmH_2O	±1 cmH_2O	±1 cmH_2O
Gas Flow Range	4 to 15 LPM	4 to 15 LPM	4 to 15 LPM
Connector	Swivel type 22mm Male/15mm Female Complies to ISO 5356-1	Swivel type 22mm Male/15mm Female Complies to ISO 5356-1	Swivel type 22mm Male/15mm Female Complies to ISO 5356-1
Mounting Type	Integrated as per ISO	Integrated as per ISO	Integrated as per ISO
Preset Pressure Manifold	20 ±2 cmH_2O	20 ±2 cmH_2O	20 ±2 cmH_2O
Mounting & Weight of CPAP			
Mounting Provision	Circuit Arm, Humidifier, Bubble Generator & CPAP Assembly	Humidifier, Bubble Generator & Blender	Humidifier & Bubble Generator
Dimension	55cm (L) X 62cm (D) X 168 cm(H)	55cm (L) X 62cm (D) X 168 cm(H)	55cm (L) X 62cm (D) X 168 cm(H)
Weight	33 Kgs	28 Kgs	28 Kgs
Roll Stand	Aluminium/Stainless Steel	Stainless Steel	Stainless Steel
Caster wheels	3” X 4# / 2” X 5#	2” X 5#	2” X 5#
Brake	Yes	Yes	Yes
IV Pole	Max Load 1.5 Kgs	Max Load 1.5 Kgs	Max Load 1.5 Kgs
Heated Humidifier			
Supply Voltage	230V AC ± 10%	230V AC ± 10%	230V AC ± 10%
Frequency	50Hz	50Hz	50Hz
Supply Current	0.9A	0.9A	0.9A
Power	210W	210W	210W
Main Fuse	0.5A	0.5A	0.5A
Heater Plate Rated Voltage	230V AC	230V AC	230V AC
Heater Power Rating	150W	150W	150W
Heater wire Impedance	7.5Ω	7.5Ω	7.5Ω
Fuse Heater Plate	2A	0.5A	0.5A
Heater Wire Rated Voltage	22V AC ±5V AC	22V AC ±5V AC	22V AC ±5V AC
Supply Current Heater Wire	2.72A	2.72A	2.72A
Power Rating Heater Wire	60W	60W	60W
Fuse Heater Wire	5A	5A	5A
Heater Plate cut-off Temperature	95°C	95°C	95°C
Heater Plate Thermal relay (Manual Reset) Safety Cut-	118°C ±6°C	118°C ±6°C	118°C ±6°C

Specification/s	5060	5060S	5060F
off Temperature			
Display Temperature Range	15 to 70°C	15 to 70°C	15 to 70°C
Accuracy Display Range	± 0.3 °C (in 25 to 45 °C temperature range)	± 0.3 °C (in 25 to 45 °C temperature range)	± 0.3 °C (in 25 to 45 °C temperature range)
Measured Gas Temperature Accuracy	±2°C	±2°C	±2°C
Recommended Gas Flow Range*	Up to 120 LPM	Up to 120 LPM	Up to 120 LPM
Pressure Drop**	Less than 0.3 cmH_2O @ 22mm male tubing connector at humidifier chamber	Less than 0.3 cmH_2O @ 22mm male tubing connector at humidifier chamber	Less than 0.3 cmH_2O @ 22mm male tubing connector at humidifier chamber
Temperature Control Pre-set set Point Values			
Heater wire mode. Chamber Set Point	32°C to 36°C	32°C to 36°C	32°C to 36°C
Heater wire mode. Airway Set Point	31°C to 35°C	31°C to 35°C	31°C to 35°C
Non-Heater Wire Mode. Airway Set Point	31°C (Chamber Temperature limited to 66°C)	31°C (Chamber Temperature limited to 66°C)	31°C (Chamber Temperature limited to 66°C)
Humidification Output			
Output	>12mg/L	>12mg/L	>12mg/L
Maximum Operating Pressure	8 kpa	8 kpa	8 kpa
Warm up Time	Less than 30 minutes	Less than 30 minutes	Less than 30 minutes
Maximum System Operating Pressure	20 kpa	20 kpa	20 kpa
Gas Leakage @ Maximum Pressure	<100 ml/min	<100 ml/min	<100 ml/min
Visual and Audio Alarm			
Humidifier Medium Priority Alarms	-Heater failure -Heater wire failure -Temperature probe failure -No flow -Temperature high -Temperature low -Add water	-Heater failure -Heater wire failure -Temperature probe failure -No flow -Temperature high -Temperature low -Add water	-Heater failure -Heater wire failure -Temperature probe failure -No flow -Temperature high -Temperature low -Add water
Alarm Pause Time Without user Intervention	120 seconds	120 seconds	120 seconds
High Temp alarm: Airway	43°C ±2°C	43°C ±2°C	43°C ±2°C
Low Temp alarm: Airway	<26°C ±2°C	<26°C ±2°C	<26°C ±2°C
Temp Probe Alarm	Disconnected or Damaged	Disconnected or Damaged	Disconnected or Damaged
Heater Wire Alarm	Disconnected or Damaged	Disconnected or Damaged	Disconnected or Damaged
Heater Plate alarm	Disconnected or Damaged	Disconnected or Damaged	Disconnected or Damaged
Alarm Frequency	975 Hz	975 Hz	975 Hz
Pulse Width	4 pulse burst, Pulse Spacing: 0.2s, 0.2s repeat time: 7.5s	4 pulse burst, Pulse Spacing: 0.2s, 0.2s repeat time: 7.5s	4 pulse burst, Pulse Spacing: 0.2s, 0.2s repeat time: 7.5s
Sound Level	59 dB	59 dB	59 dB
Electrical Safety Classification			
Type of Protection against Electric Shock	Class 1	Class 1	Class 1
Applied Part	BF (Breathing Circuit)	BF (Breathing Circuit)	BF (Breathing Circuit)
Mode of Operation	Continuous	Continuous	Continuous
Protection against hazardous Explosion	Not Protected	Not Protected	Not Protected
Ingress Protection	IPX1	IPX1	IPX1
Pollution Degree	II	II	II
Product Classification	IIb	IIb	IIb
Environmental Specifications: Operation			
Temperature	18°C to 26°C (To achieve best performance of humidifier)	18°C to 26°C (To achieve best performance of humidifier)	18°C to 26°C (To achieve best performance of humidifier)

Specification/s	5060	5060S	5060F
Humidity	15–90% RH, non-condensing	15–90% RH, non-condensing	15–90% RH, non-condensing
altitude	Sea level to 1.9 miles (3Kms)	Sea level to 1.9 miles (3Kms)	Sea level to 1.9 miles (3Kms)
Atmospheric Pressure	50 to 106 kpa	50 to 106 kpa	50 to 106 kpa
Environmental Specifications: Transport & Storage			
Temperature	-10°C to +60°C	-10°C to +60°C	-10°C to +60°C
Humidity	50 to 90% RH, non-condensing	50 to 90% RH, non-condensing	50 to 90% RH, non-condensing
Breathing Circuit			
Disposable with heated wire & Chamber	Standard	Standard	Standard
Nasal Prong	Small, Medium, Medium wide & Large	Small, Medium, Medium wide & Large	Small, Medium, Medium wide & Large
Head Bonnet	Medium, Large, X Large & XX Large	Medium, Large, X Large & XX Large	Medium, Large, X Large & XX Large
Interface Connectors	Conical Connector Comply with ISO 5356-1	Conical Connector Comply with ISO 5356-1	Conical Connector Comply with ISO 5356-1
Resistance to flow	2 Cm H_2O @ 13 LPM	2 Cm H_2O @ 13 LPM	2 Cm H_2O @ 13 LPM
Maximum chamber operating Pressure	8 kpa	8 kpa	8 kpa
Maximum Circuit Gas Leakage Rate	50 ml/min @ 60±3cmH2O	50 ml/min @ 60±3cmH2O	50 ml/min @ 60±3cmH2O
Maximum Working Temperature	50°C	50°C	50°C
Circuit Length	1.5 mts	1.5 mts	1.5 mts
Maximum Flow	25 LPM (Neonatal)	25 LPM (Neonatal)	25 LPM (Neonatal)
Gate Pathway Resistance	2cm H20 @ 10 LPM (Neonatal)	2cm H20 @ 10 LPM (Neonatal)	2cm H20 @ 10 LPM (Neonatal)
Gate pathway Compliance	1ml/cmH20 (Neonatal)	1ml/cmH20 (Neonatal)	1ml/cmH20 (Neonatal)
Dimension	BC 575 model Inspiratory - 1.25m / Expiratory – 1.30m	BC 575 model Inspiratory - 1.25m / Expiratory – 1.30m	BC 575 model Inspiratory - 1.25m / Expiratory – 1.30m
Gas Temperature form Heated Humidifier	45°C	45°C	45°C
Usage period of interfaces and Breathing circuit	Single patient use, For a maximum of seven days	Single patient use, For a maximum of seven days	Single patient use, For a maximum of seven days

* Minimum flow, gas pathway resistance and gas pathway compliance. Refer to breathing circuit specification.

**Variation may happen due to humidifying chamber and tubing system.

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. High pressure gauge damage is not included under the warranty if the applied input pressure is greater than 60 PSI
7. We warranty this unit for 12 months from the date of Installation. Warranty includes the repair and replacement of faulty components.
8. Defects caused by improper use, and defects due to causes beyond control like lightning, abnormal voltage, acts of god, and also defects caused by rats, cockroaches or any other insects will not be covered under warranty.
9. Warranty is not applicable if the equipment is not purchased from Neötech/authorized Neötech Dealer
10. Warranty is not applicable if the warranty card is not filled and sent back to Neötech.

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 send the same

From _____
_____
_____

To:
The Service In-charge
nice Neötech Medical Systems Pvt. Ltd.
No, 85-86, Krishna Industrial Estate,
Mettukuppam, Vanagaram,
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 System Failure

Sl. No	Problem	Cause	Remedy
1.	PEEP pressure is not shown in pressure gauge	No gas supply. Patient circuit is dis-connected.	Check the gas supply
			Check the patient circuit is intact.
			Otherwise Contact nice Neötech
2	PEEP is not achieved/ Bubbling is absent	No gas supply. Bubble generator may be damaged. Water level reduced.	Check the gas supply
			Replace the PEEP Knob
			Refill Water in Bubble Jar if level is low
			Inspect the entire gas pathways for leak
			Otherwise Contact nice Neötech
3	Oxygen concentration discrepancy between Blender settings and Output (analyzer).	Analyzer out of calibration	Calibrate the analyzer
		Flow requirements are below the specified LPM range.	Correct the flow. Verify that the correct outlet port is being used. Each outlet port has a different flow range.
		Gas supply is contaminated	Correct the contaminated gas supply. If repair is needed, contact nice Neötech
		Blender is out of calibration	Contact nice Neötech for repair.
		Bleed filter is obstructed, causing reduction of bleed	Contact nice Neötech
4	Water Out indicator Accompanied by an audible Indication	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 disposable chamber is not above the marked line. If the water is above this line	Replace chamber
		Check that the gas flowrate 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.	Complete at temperature and flow accuracy test on the probe.

			Replace probe as required
		Humidifier faulty.	Complete a performance test.
			Service humidifier as required
5	Chamber Probe Indication accompanied by an audible Indication	Check that the chamber probe is inserted into the breathing circuit correctly	The breathing circuit is setup 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	Replace Chamber
		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.	Complete performance tests.
			Replace probe or service humidifier as required
6	Heater wire Connector Indication accompanied by an audible Indication	Check that the heater wire adaptor is correctly plugged into the humidifier along with the breathing circuit.	Replace breathing circuit, and re-rest
			Replace heater wire adaptor and check for intermittent connections. Re-test
		Humidifier faulty.	Replace PCBs
7	Heater wire Indication Not working	Non-heater wire mode has been activated,	Connect a heated wire circuit or disable this mode by pressing heater wire key
8	Airway Probe Indication along with an audible Indication	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 bubble CPAP	Connect the circuit correctly
		Gas flow could be reversed through the humidifier	Correct the gas flow
		Check that the gas flowrate is within specification of the humidifier and type of accessories being used.	Adjust as necessary
		Check for excessive condensate buildup.	Excessively cold or drafty ambient conditions may cause this Indication to occur. Ensure there are no strong drafts around the breathing circuit
		Complete a probe accuracy check.	Replace probe as necessary
		Humidifier faulty.	Replace PCBs
9	Temperature probe Connector indicator flashes, accompanied by an	The humidifier has been unable to maintain temperature over a period of time. Gas flow has been disconnected from the humidifier.	Reconnect gas flow or turn the humidifier off.

	audible Indication	Check that the gas flowrate is within specification of the humidifier and accessories being used	Adjust as necessary
		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 air flow
		Check that the circuit is connected correctly to the bubble CPAP	Connect the circuit correctly
		Gas flow could be reversed through the humidifier  • **Never cover the breathing circuit**	Correct the gas flow
		Check for excessive condensate pooling in the breathing circuit.	Drain circuit if necessary
		Humidifier or probe faulty	Complete humidifier & probe performance test.
			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
10	Temperature is shown on the humidifier's display, with no audible Indication	Make sure the humidifier has had time to warm up and that there is sufficient gas flow through the breathing circuit	Complete humidifier and probe performance test. Replace probe or service humidifier as required
		The humidifier cannot maintain temperature. If the temperature indicator is also on then an Indication will occur eventually	
		Humidifier or probe faulty.	
11	High displayed Temperature no temperature Indication	Flow has recently been changed	Allow30minutesfor temperature to stabilize
			Humidity compensation is active
12	Temperature indicator flashes, With audible Indication, and a high temperature is shown.	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.
13	Alarm sounding	Inlet pressure difference greater than 20 PSI.	Correct the pressure difference
		Alarm module is not calibrated properly	Contact nice Neotech for repair.

		Inlet gas contamination, alarm module malfunction	Contact nice Neotech for repair.
14	Blender in bypass – no alarm.	sounder plate improperly installed or damaged	Contact nice Neotech for repair.
15	Blender is accurate only when inlet gas pressures are equal.	Balance module not functioning properly	Contact nice Neotech for repair
		Both air and oxygen gas sources are below 30 PSIG.	Correct the low-pressure condition

7.2 Disposing of the Unit

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

Section 8: Spare Parts List

Sl.No.	Part No.	Description	Qty	Unit
1	78-00-036	Bubble generator	1	No
2	78-00-035	Disposable Patient Circuit	1	No
3	50-05-108	Digital Pressure monitor CPAP unit assembly	1	No
4	78-00-032	Head Bonnet	1	No
5	78-00-031	Nasal Prongs	1	No
6	78-00-029	Mini Flow	1	No
8	80-05-010	Heater wire Adapter	1	No
9	80-05-003	Temperature Probe	1	No
10	50-05-089	PCB Pressure monitor assembly	1	No
11	50-05-088	Pressure monitor power supply assembly	1	No
12	80-05-001	PCB - controller	1	No.
13	80-05-002	PCB - Power supply	1	No.
14	80-05-003	Temperature Probe	1	No.
15	80-05-010	Heater Wire Adapter	1	No.
16	89-11-071	Connector – 6 pin	1	No.
17	89-11-072	Connector – 4 pin	1	No.
18	91-00-131	Heater	1	No.
19	91-00-142	Transformer	1	No.

Service contact:

nice Neötech Medical Systems Pvt. Ltd.
No. 85-86, Krishna Industrial Estate, Mettukuppam,
Vanagaram, 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

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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 Digital PEEP monitoring with in-built air oxygen blender and Humidifier is intended for use in the electromagnetic environment specified below. The customer or the user of the Digital PEEP monitoring with in-built air oxygen blender and Humidifier should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Class A	The Bubble CPAP System contains Respiratory Humidifier and Air Oxygen blender, Only Digital PEEP monitoring with in-built air oxygen blender and Respiratory Humidifier is electrically operated device and the whole unit is used in the 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 Digital PEEP monitoring with in-built air oxygen blender and 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**
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 Criteria B	Mains power quality should be that of a typical commercial or hospital environment. If the user of the Bubble CPAP System requires continued operation during power mains interruptions, it is recommended that the Bubble CPAP System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field	30 A/m	Criteria A	Power frequency magnetic fields should be at levels characteristic of

IEC 61000-4-8			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 Bubble CPAP System is intended for use in the electromagnetic environment specified below. The customer or the user of the Bubble CPAP System 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, 2006	3 Vrms 150 kHz to 80 MHz outside ISM bandsa 10 Vrms 150 kHz to 80 MHz in ISM bandsa	Criteria A Criteria C	Floors should be wood, concrete or ceramic tile. If floors are covered with Synthetic material, the relative humidity should be at least 30 %.
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 (Respiratory) 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.

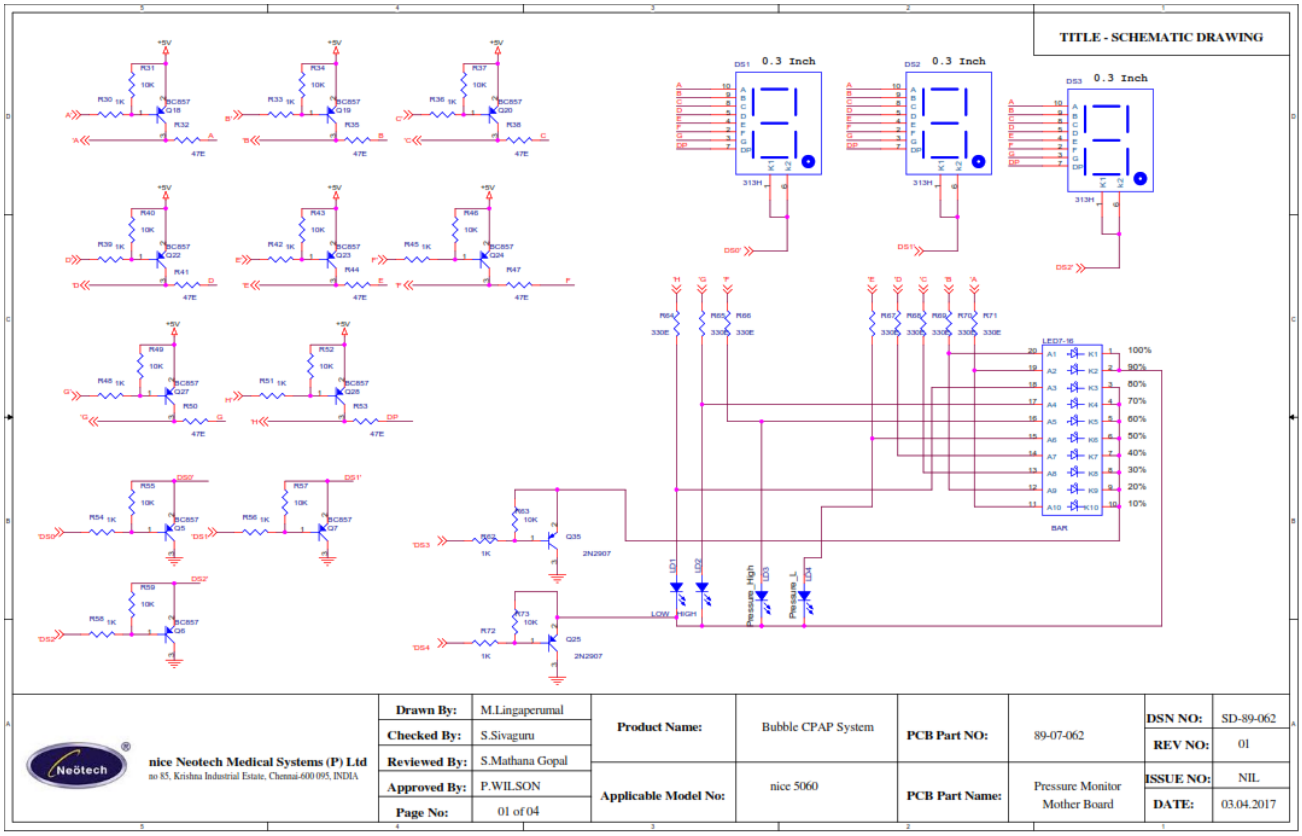
1. Equipment connected to the serial port must comply with the safety standard IEC 60950 for personal computers.
2. The serial port must not be used when the humidifier is in patient use.

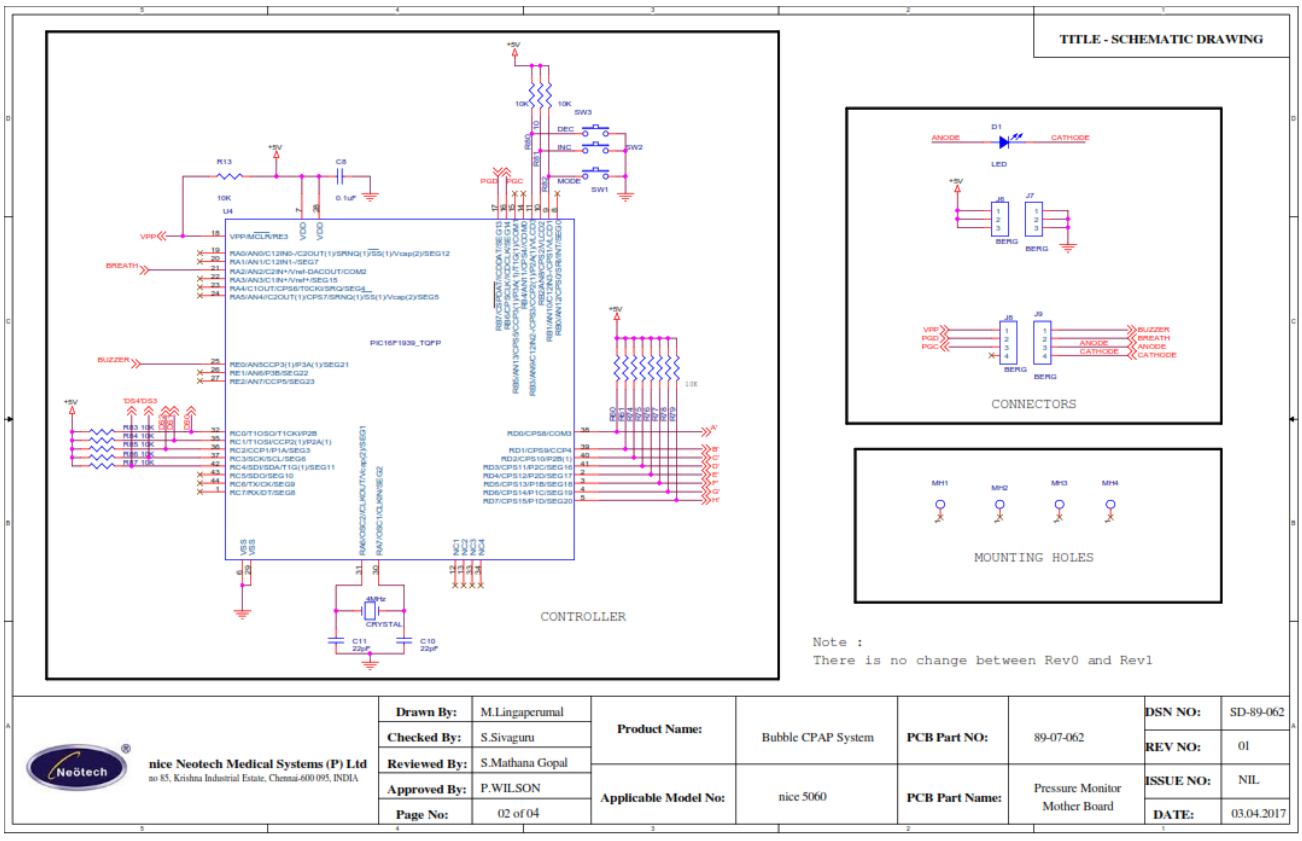
Instructions:

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

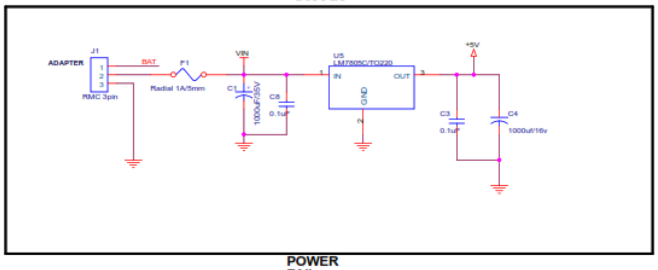
Schematic Diagram – nice 5060



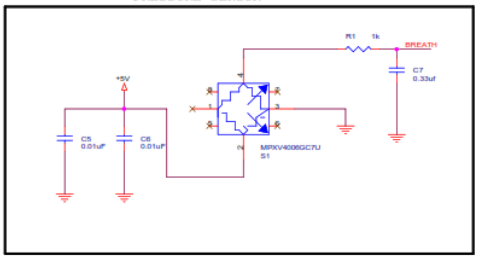


TITLE - SCHEMATIC DRAWING

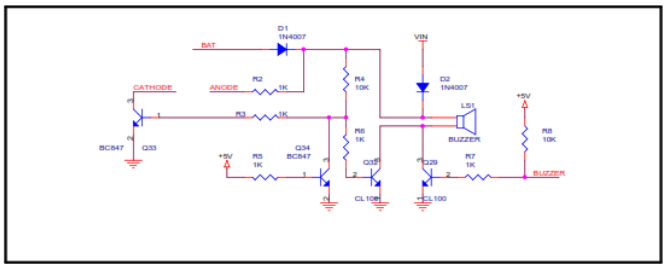
SUPPLY



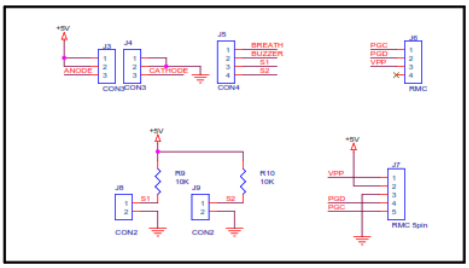
PRESSURE SENSOR



POWER FAIL

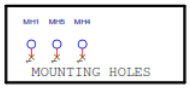


CONNECTORS



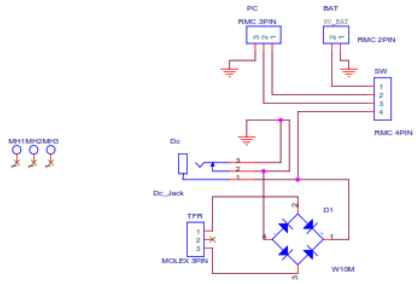
Note :

There is no Cicuit correction between Rev0 and Rev1, only position of some components are altered
Resistor R1 through hole changed to SMD
J8 and J9 connector position are adjusted



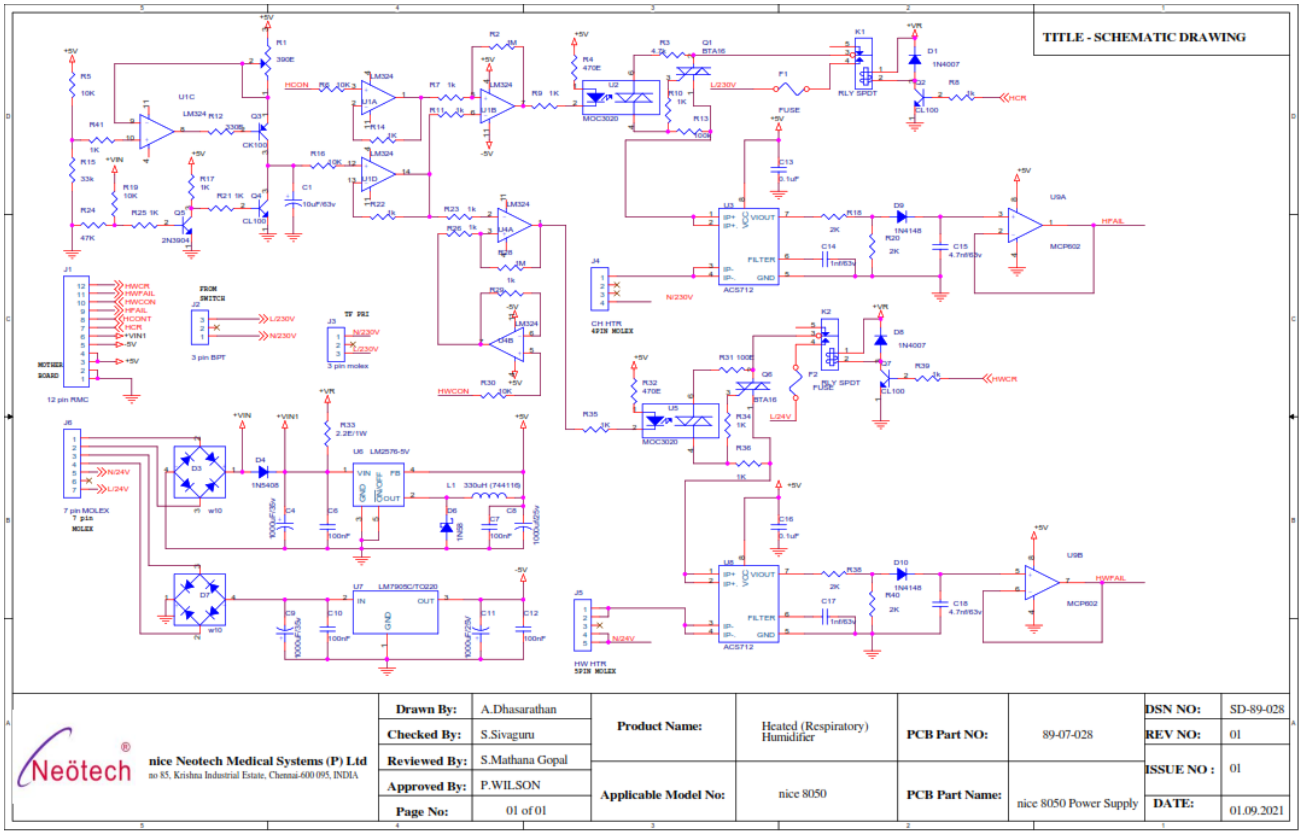
nice Neotech Medical Systems (P) Ltd no 85, Krishna Industrial Estate, Chennai-600 095, INDIA	Drawn By:	M.Lingaperumal	Product Name:	Bubble CPAP System	PCB Part NO:	89-07-063	DSN NO: SD-89-063
	Checked By:	S.Sivaguru					REV NO: 01
	Reviewed By:	S.Mathana Gopal					
	Approved By:	P.WILSON	Applicable Model No:	nice 5060	PCB Part Name:	Pressure Monitor Power Supply	ISSUE NO: NIL
	Page No:	03 of 04					DATE: 03.04.2017

TITLE - SCHEMATIC DRAWING

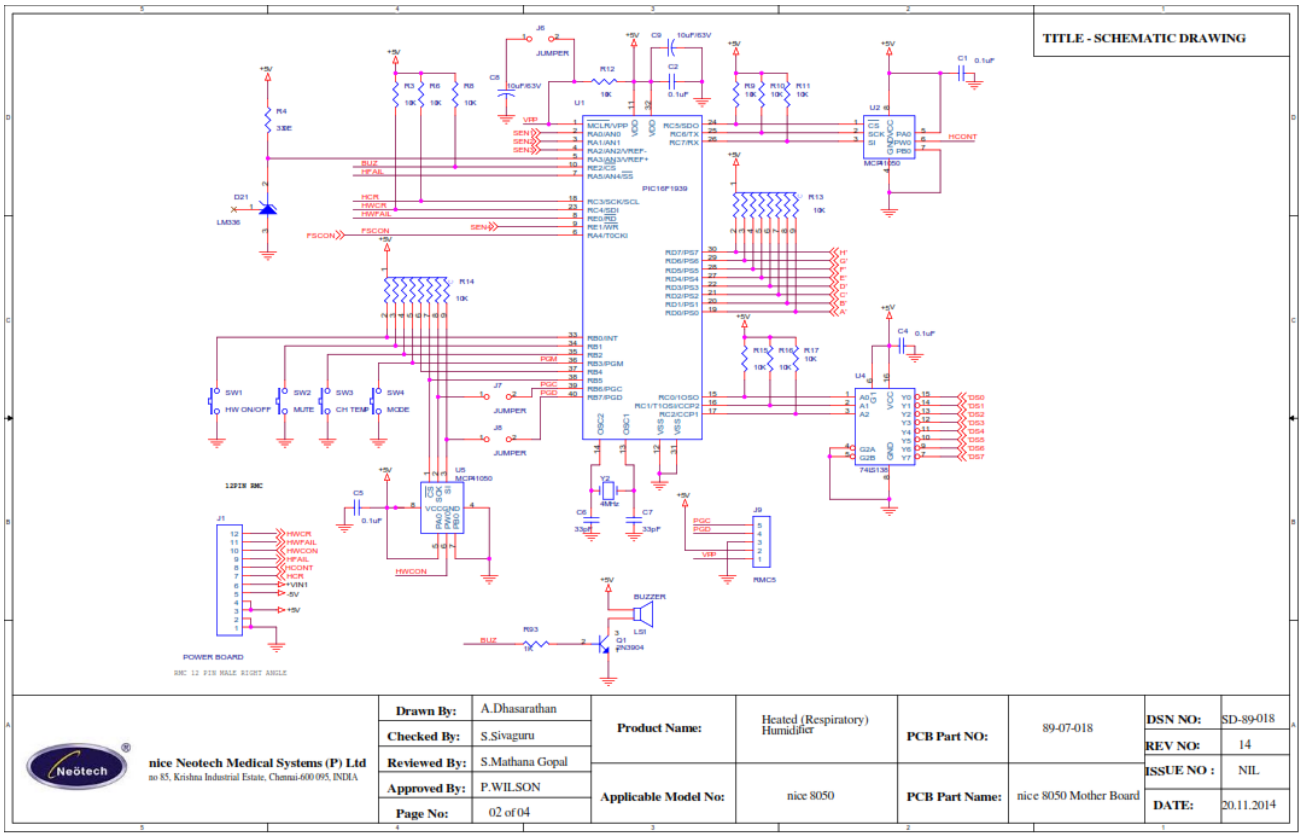


nice Neotech Medical Systems (P) Ltd no 85, Krishna Industrial Estate, Chennai-600 095, INDIA	Drawn By:	M.Lingaperumal	Product Name:	Bubble CPAP System	PCB Part NO:	89-07-061	DSN NO: SD-89-061
	Checked By:	S.Sivaguru					REV NO: 02
	Reviewed By:	S.Mathana Gopal					
	Approved By:	P.WILSON	Applicable Model No:	5060	PCB Part Name:	nice 5060 S Power Connector	ISSUE NO: NIL
	Page No:	04 of 04					DATE: 06.04.2017

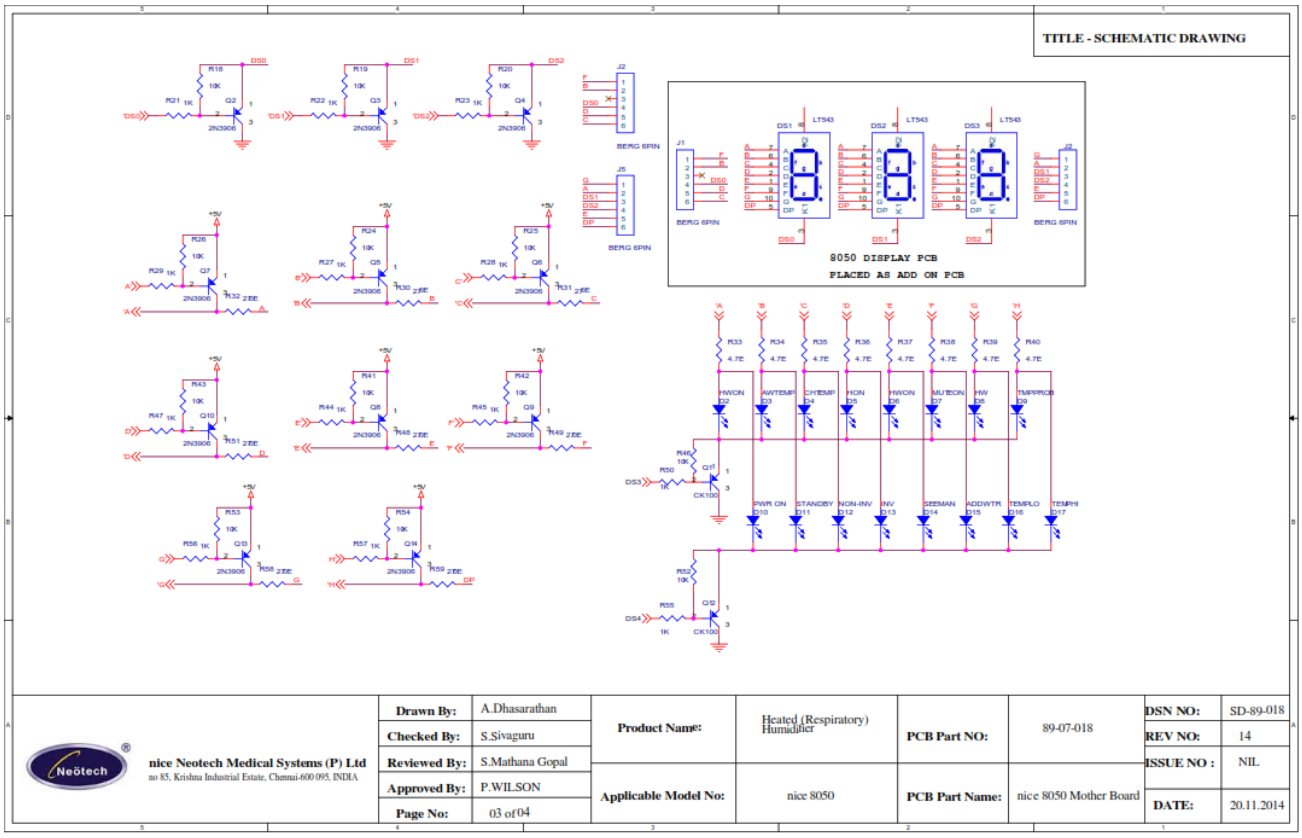
Schematic Diagram – nice 8050



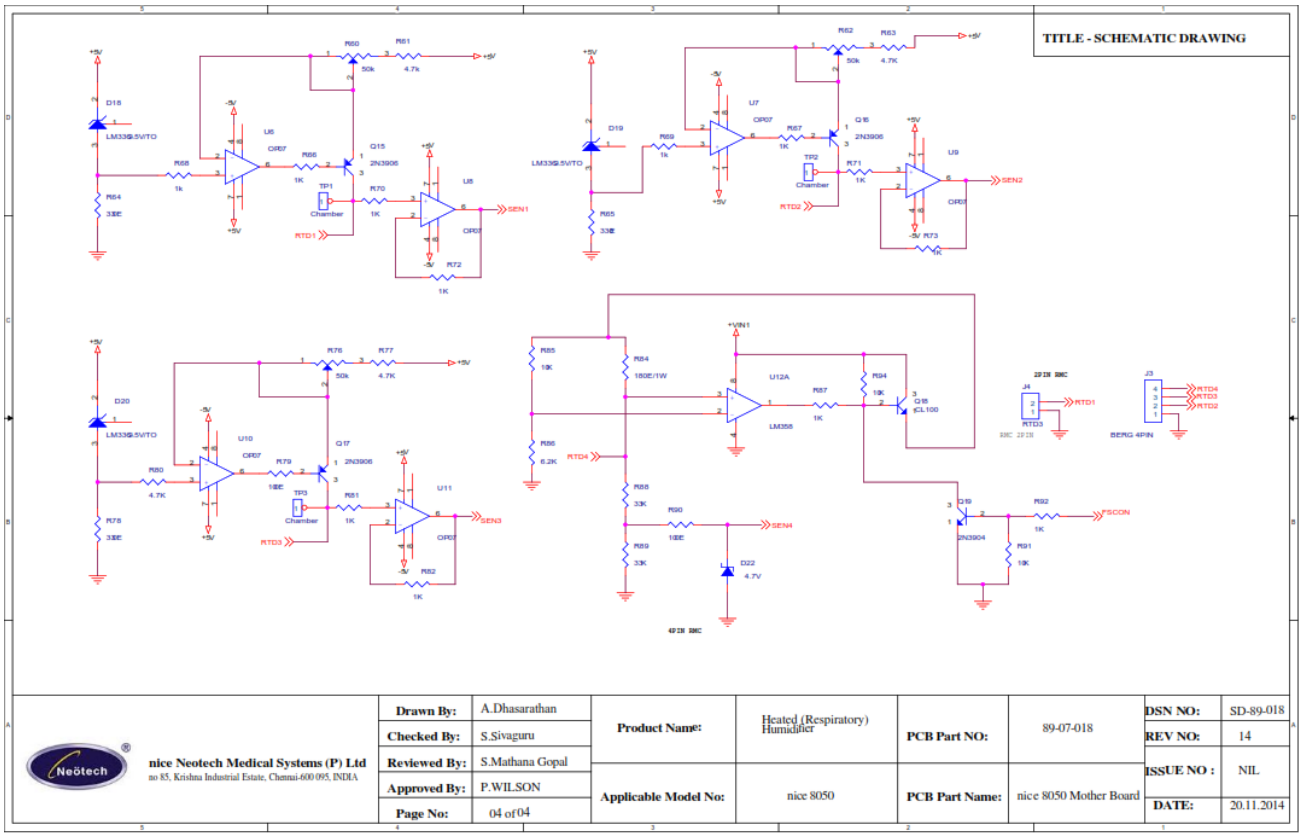
nice Neotech Medical Systems (P) Ltd no 85, Krishna Industrial Estate, Chennai-600 095, INDIA	Drawn By:	A.Dhasarathan	Product Name:	Heated (Respiratory) Humidifier	PCB Part NO:	89-07-028	DSN NO:	SD-89-028
	Checked By:	S.Sivaguru					REV NO:	01
	Reviewed By:	S.Mathana Gopal					ISSUE NO :	01
	Approved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



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:	02 of 04						



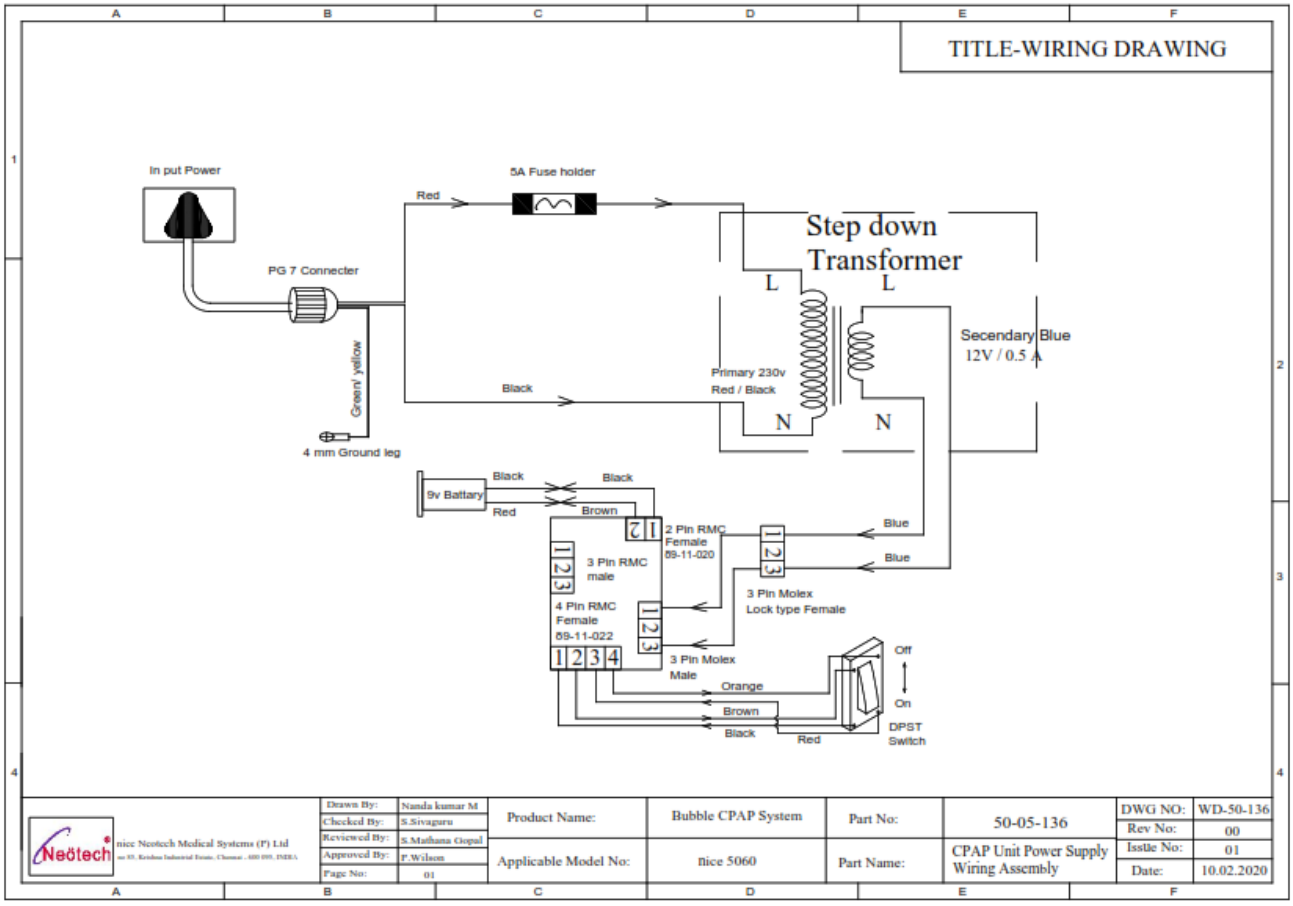
nice Neotech Medical Systems (P) Ltd no 85, Krishna Industrial Estate, Chennai-600 095, INDIA	Drawn By:	A.Dhasarathan	Product Name:	Heated (Respiratory) Humidifier	PCB Part NO:	89-07-018	DSN NO:	SD-89-018
	Checked By:	S.Sivaguru					REV NO:	14
	Reviewed By:	S.Mathana Gopal					ISSUE NO :	NIL
	Approved By:	P.WILSON	Applicable Model No:	nice 8050	PCB Part Name:	nice 8050 Mother Board	DATE:	20.11.2014
	Page No:	03 of 04						



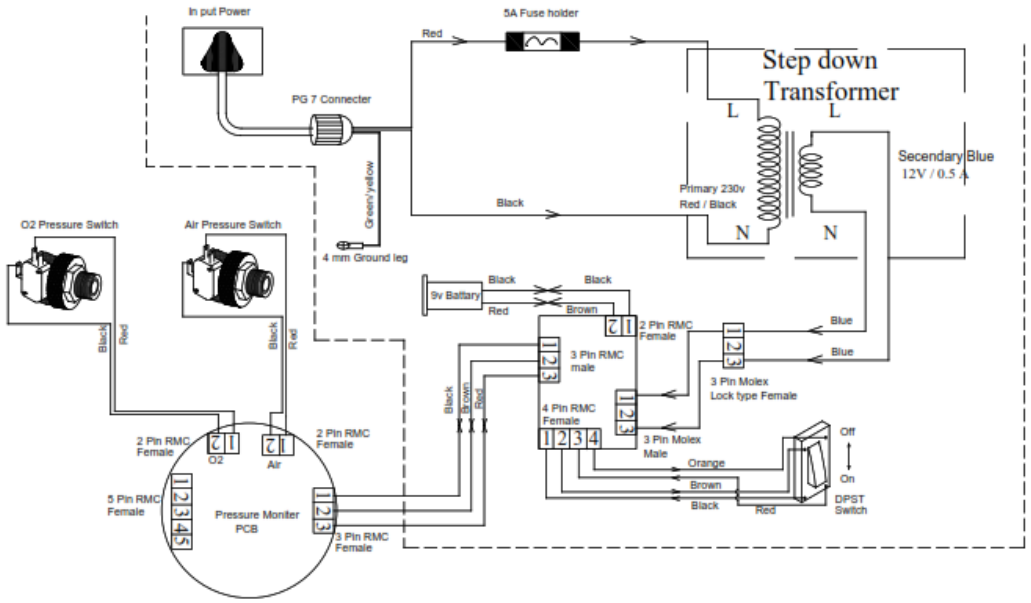
nice Neotech Medical Systems (P) Ltd no 85, Krishna Industrial Estate, Chennai-600 095, INDIA	Drawn By:	A.Dhasarathan	Product Name:	Heated (Respiratory) Humidifier	PCB Part NO:	89-07-018	DSN NO:	SD-89-018
	Checked By:	S.Sivaguru					REV NO:	14
	Reviewed By:	S.Mathana Gopal					ISSUE NO :	NIL
	Approved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

Section 12: Wiring Diagram

Wiring Diagram – nice 5060

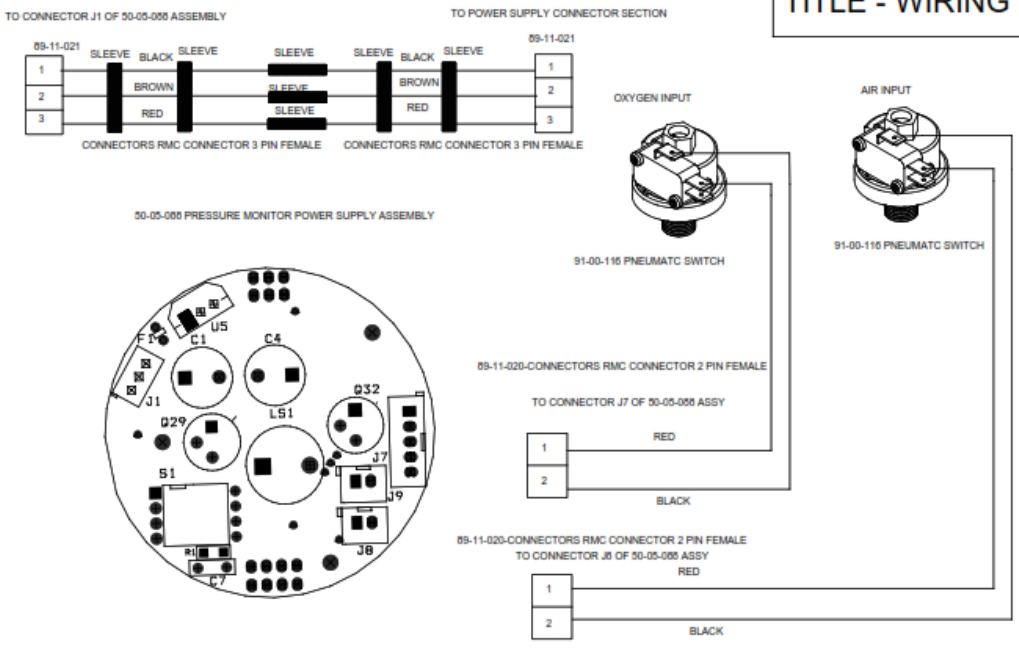


TITLE-WIRING DRAWING



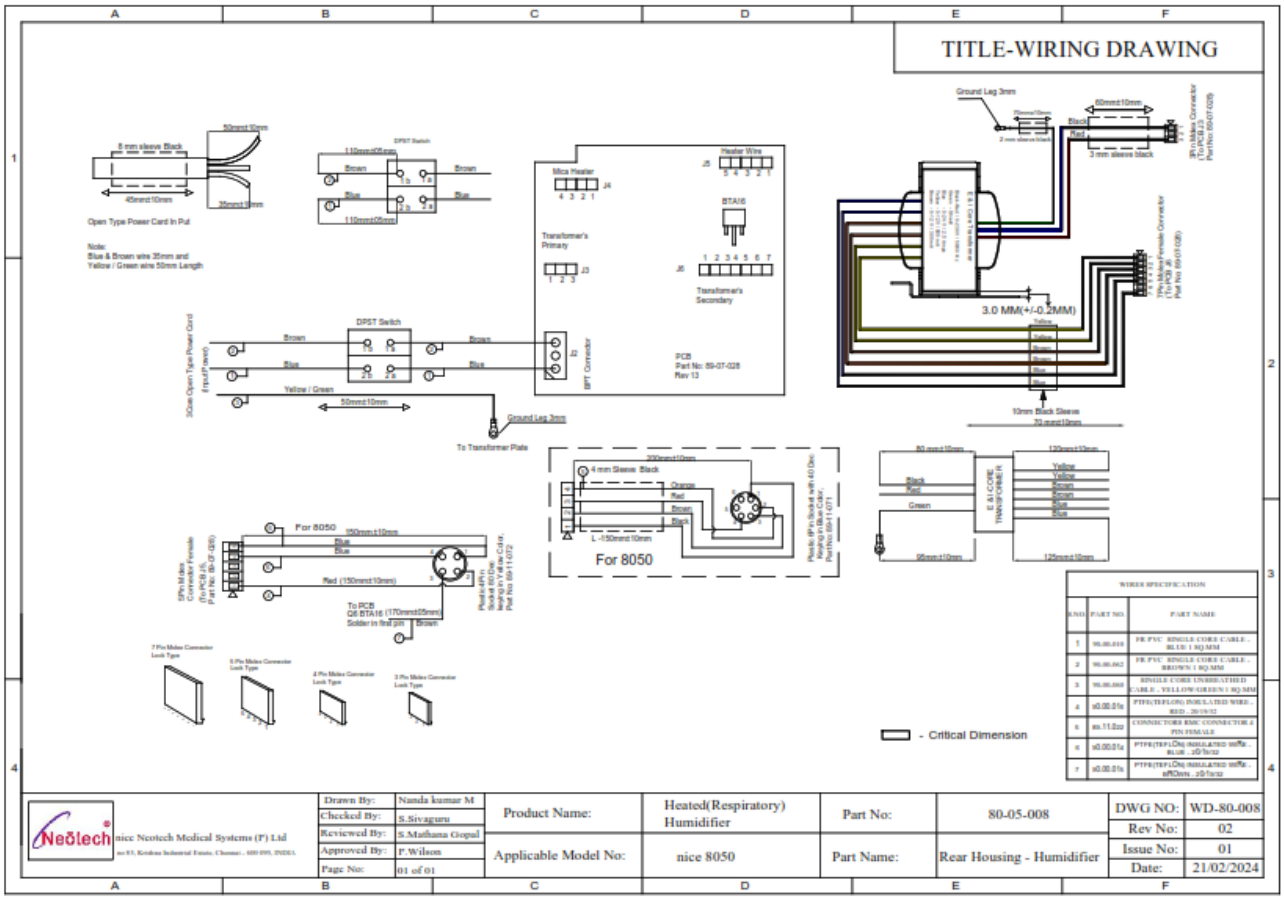
nice Neotech Medical Systems (P) Ltd	Drawn By:	S.Sivaguru	Product Name:	Bubble CPAP System	Part No:	50-05-108	DWG NO:	WD-50-108
	Checked By:	V.Senthilkumar					Rev No:	00
	Reviewed By:	S.Mathana Gopal	Applicable Model No:	nice 5060	Part Name:	5060 Pressure Monitor CPAP Unit	Issue No:	Nil
	Approved By:	P.Wilson					Date:	28.08.2019
	Page No:	01 of 01						

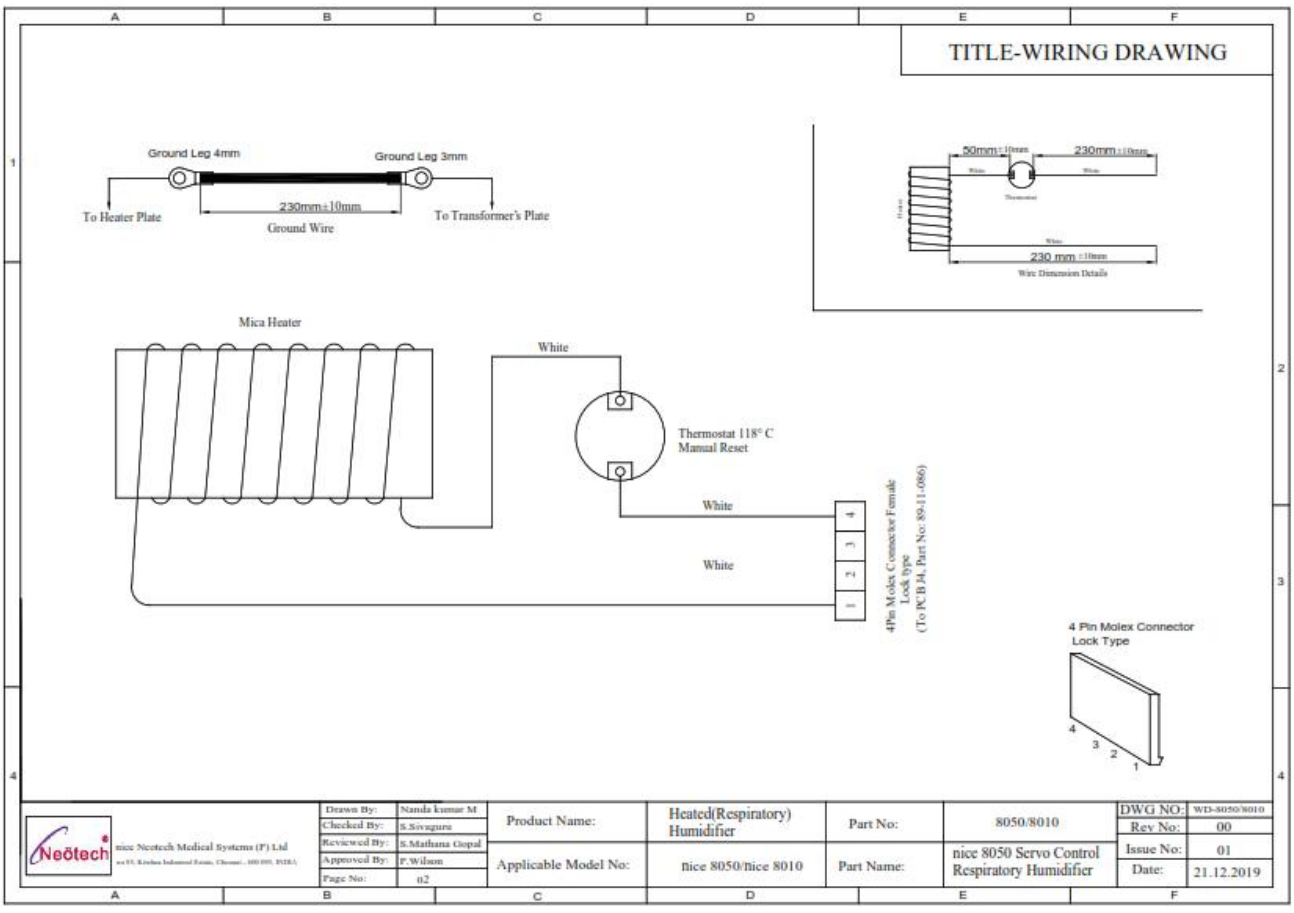
TITLE - WIRING DRAWING



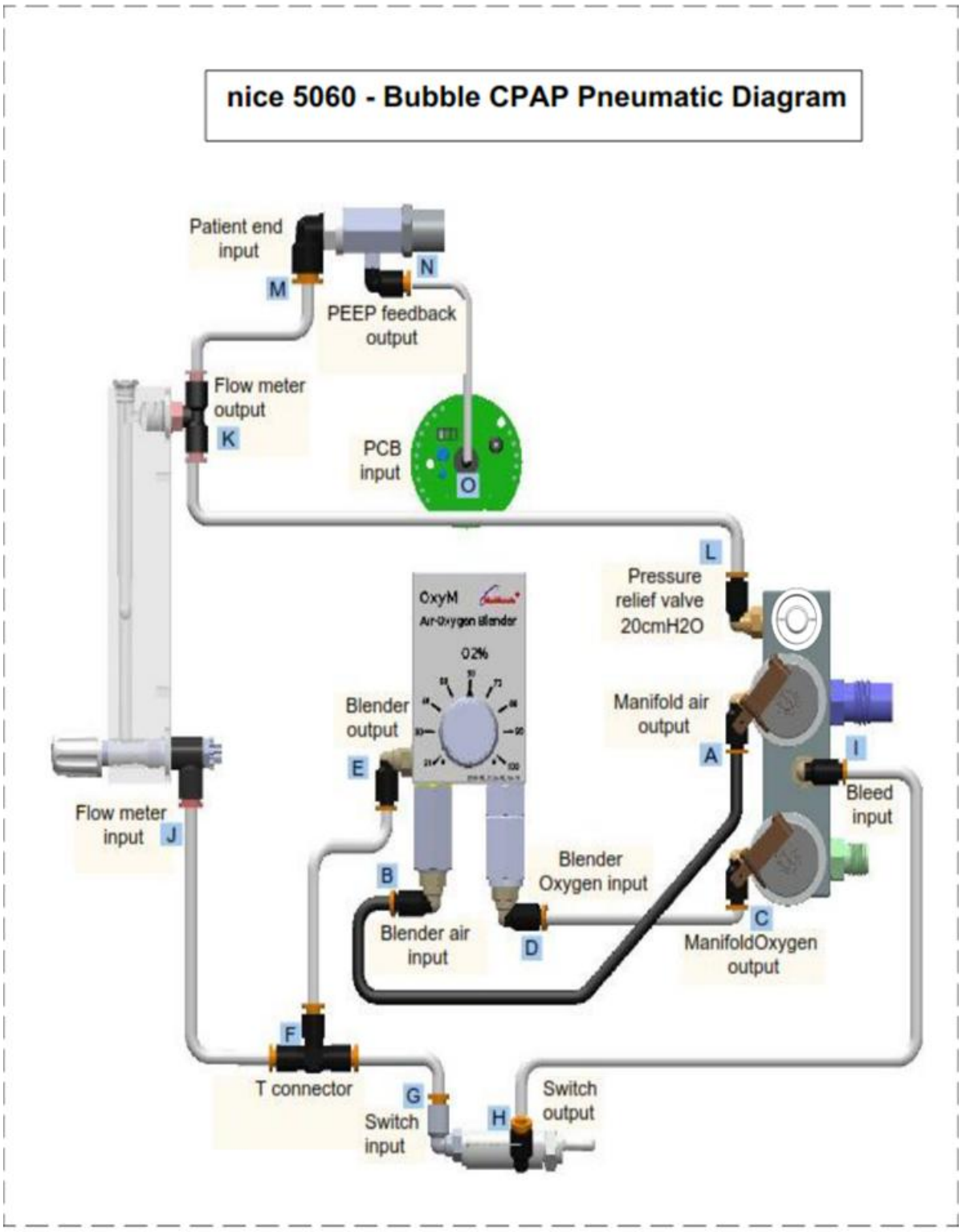
nice Neotech Medical Systems (P) Ltd	Drawn By:	S.Sivaguru	Product Name:	BUBBLE CPAP	PART NO:	50-05-107	DWG NO:	WD-50-107
	Checked By:	G.Kulasekarapandiyan					REV NO:	00
	Reviewed By:	P.Wilson	Applicable Model No:	nice 5060	PART NAME:	CPAP DIGITAL PRESSURE MONITOR ASSEMBLY	Issue NO:	01
	Approved By:						DATE:	10/03/2023
	Page No:	01						

Wiring Diagram – nice 8050

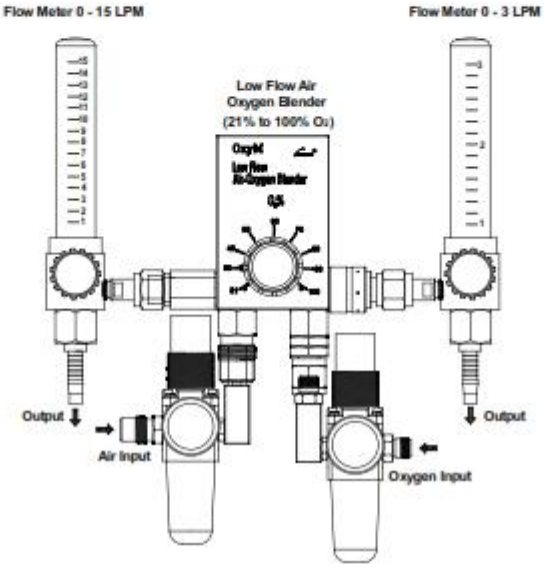


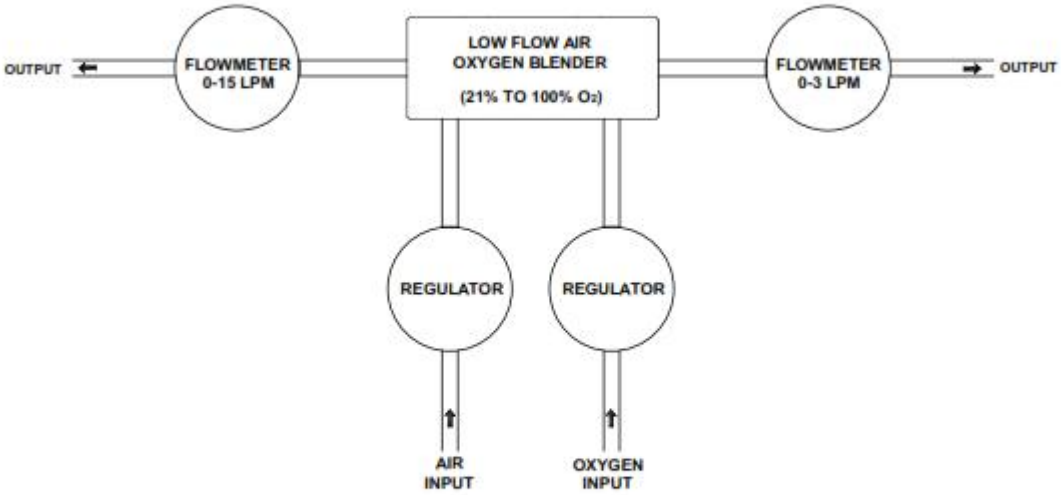


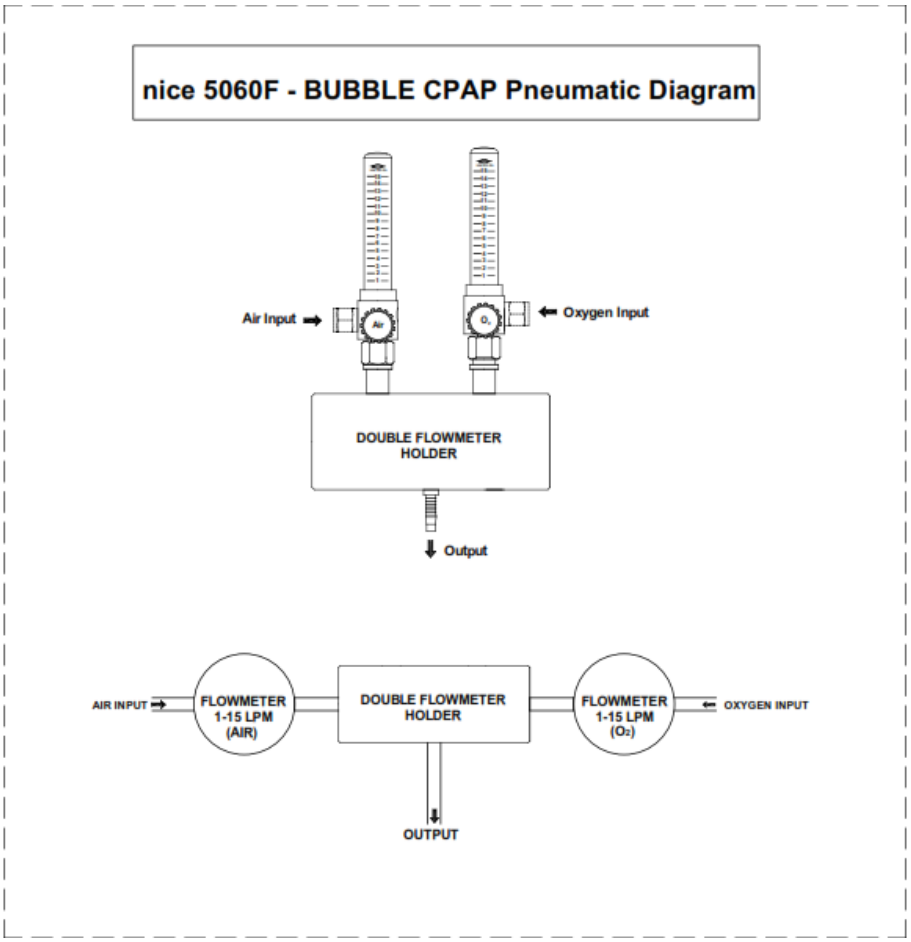
Section 13: Pneumatic diagram



nice 5060S - Bubble CPAP Pneumatic Diagram






nice 5060F - BUBBLE CPAP Pneumatic Diagram
Air Input
Oxygen Input
DOUBLE FLOWMETER HOLDER
Output
AIR INPUT
FLOWMETER 1-15 LPM (AIR)
DOUBLE FLOWMETER HOLDER
FLOWMETER 1-15 LPM (O2)
OXYGEN INPUT
OUTPUT

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 Neötech Medical Systems Pvt. Ltd.
No, 85-86, Krishna Industrial Estate,
Mettukuppam, Vanagaram,
Chennai-600095. Tamil Nadu, INDIA.
Ph: 91-44-24762594, 24764608
Email: marketing@niceneotech.com
Toll Free No. 1800-425-2594 (India only)

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

Service Contact	EU Authorized Representative	Competent Authority
nice Neötech Medical Systems Pvt. Ltd. No. 85-86, Krishna Industrial Estate,Mettukuppam, Vanagaram, Chennai-600095. Tamil Nadu, INDIA. Ph: 91-44-2476 4608 Telefax: 91-44-2476 2594 E-mail: service@niceneotech.com /info@niceneotech.com Web: www.niceneotech.com SRN: IN-MF-000010243	**Amstermed BV** Located in Saturnusstraat 46-62, Unit 032, 2132 HB Hoofddorp, The Netherlands. Mr. Mike Vermin Tel: +31 23 565 6337 info@amstermed.nl www.amstermed.nl SRN: NL-AR-000001971	**Ministerie van Volksgezondheid, Welzijn en Sport** Address:P.O. Box, 20350, The Hague, Netherlands Country:Netherlands Email: medicaldevices@minvws.nl Tel:+31 70 340 79 11

Section 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