HORNPUFF

Neötech®

Infant T-Piece Resuscitator

nice 5020

User manual

This user manual provides all the information necessary for the user to safely set up and operate this equipment.

It is the responsibility of the user to follow the instructions and recommendations provided.

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nice Neotech Medical Systems Pvt. Ltd.
85-86, Krishna Industrial Estate, Mettukuppam, Vanagaram Chennai-600095,
Tamil Nadu, INDIA.

Ph: 91-44-24764608 ; Web: www.niceneotech.com
E-mail: info@niceneotech.com / marketing@niceneotech.com / service@niceneotech.com

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User Responsibility/Operator profile

This Product will perform in conformity with the description thereof contained in this operating manual and accompanying labels and/or inserts, when assembled, operated, maintained and repaired in accordance with the instructions provided. This Product must be checked periodically. A defective Product should not be used. Parts that are broken, missing, plainly worn, distorted or contaminated should be replaced immediately. Should such repair or replacement become necessary, nice 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 nice Neötech Infant-Piece Resuscitator, read this entire manual. Attempting to use this device without a thorough understanding of its operation may result in patient or user injury. This device should only be operated by personnel trained in its operation and under the direction of qualified medical personnel familiar with the benefits and risks of this type of device.

Declaration for Languages

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

Declaration for RoHS

RoHS components are used for production of the devices and complies with Annex I categories of the RoHS Directive 2011 65 EU.

Model Descriptions

All models of the nice Neötech Infant T piece Resuscitator provide a controlled oxygen based Manual resuscitation facilities necessary in helping the new born baby with breathing difficulties survive the immediate post- natal period. The model nice 5020 Infant T piece Resuscitator is a resuscitation unit.

Definitions

RESUSCITATOR

Infant T-piece Resuscitator is used to inflate the lungs of the infants to survive the immediate post-natal period using Peak Inspiratory Pressure (PIP) and Positive End Expiratory Pressure (PEEP) controls manually with the use of test lung and mask. Breaths are delivered to the infant by occluding and opening in the T-piece PEEP cap with a finger or thumb. This technique can be performed by healthcare personnel trained in handling resuscitator in the emergency care.

Peak Inspiratory Pressure (PIP): It is the maximum inspiratory pressure required to improve oxygenation without causing adverse events. Delivering a controlled PIP is important as uncontrolled PIP that is too high may lead to lung injury, while under-inflating the lungs may not provide adequate gas exchange. The PIP can be adjusted by occluding the PEEP knob and turning the PIP knob on the device.

Positive End-Expiratory Pressure (PEEP): Positive End-Expiratory Pressure (PEEP) is the maintenance of positive pressure within the lungs at the end of expiration. The PEEP pressure ensures that the lungs do not collapse and reduces the work of breathing by the recruitment of the alveoli. The PEEP can be easily adjusted using the knob provided on the T-Piece circuit.

Maximum Pressure Relief: The maximum pressure valve relieves the excess pressure in the system, if any, for safety to the baby. The maximum permissible pressure in the system is to be set by occluding the PEEP knob, turning the PIP knob fully clockwise and adjusting the maximum pressure control knob clockwise or counterclockwise to set desired maximum pressure.

Manometer: Manometer is a medical device that is used to measure the pressure of a fluid or gas at a particular location close to the point of interest, typically near the patient or the proximal end of the medical device. It is commonly used in various medical applications, such as in respiratory therapy, where it can measure the airway pressure in patients during mechanical ventilation.

Functional Residual Capacity: FRC is a respiratory term used to describe the volume of air that remains in the lungs after a normal exhalation. Plays a crucial role in maintaining gas exchange efficiency in the lungs. It helps keep the alveoli (tiny air sacs in the lungs) open, ensuring a continuous supply of oxygen and removal of carbon dioxide during the respiratory cycle.

Test lung: The test lung is designed to be used for setting or demonstrating resuscitators and ventilators at positive pressure less than 100cmH_2O. The test lung is made up of silicon and latex free.

Retrolental Fibroplasia: Retrolental fibroplasia, also known as retinopathy of prematurity (ROP), is a serious eye condition that primarily affects premature infants. It occurs when abnormal blood vessels develop in the retina, the light-sensitive tissue lining the back of the eye. ROP typically develops in the neonatal intensive care unit (NICU) when the baby's retina is not fully developed at birth and is exposed to high levels of oxygen therapy.

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.

Unique Device Identifier: A UDI consists of a unique combination of numbers and letters that provide specific information about the medical device, such as the device's manufacturer, model and production information. The UDI system was implemented to improve patient safety, enhance device traceability, and facilitate post-market surveillance of medical devices.

Device Identifier: The Device Identifier is a fixed portion of the UDI and does not change for different units of the same device model. It is intended to uniquely identify the type and variant of the medical device, allowing healthcare providers, patients, and regulatory authorities to access specific information about that particular device.

Production identifier: It provides specific information about the manufacturing and production of a particular unit of the device and it is a variable portion of the UDI and can vary from one unit of the device to another within the same model. It includes details such as the lot or batch number, serial number, expiration date, or manufacturing date, depending on the type of device and the UDI standard used.

CE: CE stands for **conformité européenne** (European Conformity). Packages that carry this symbol need to comply with European health and safety standards. Using the CE logo without permission can land you in legal trouble.

RESPIRATORY DISTRESS SYNDROME

Respiratory distress syndrome is caused by pulmonary surfactant deficiency in the lungs of neonates.

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.

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

Section A: Warnings

- Please read and understand the instructions fully before using the nice 5020 infant resuscitator and related accessories. The nice 5020 infant resuscitator should not handle or used by untrained person.
- It is the responsibility of the purchaser to ensure that all users of this device have been adequately trained in resuscitation techniques.
- The nice 5020 resuscitator must only be used after checking that correct pressures will be delivered to the baby.
- For connection to flow regulated oxygen or oxygen/air mixture only.
- Recommended operating gas flow range is 5 to 15 L/min.
- Do not attempt to use a higher flow than 15 L/min.
- The Maximum Pressure Relief can be adjusted up to a nominal 74 cmH2O, and should only be done in exceptional circumstances by persons trained in infant resuscitation.
- Do not attempt to set the Maximum Pressure Relief (80 cmH2O (mbar)).
- Use only a nice Neötech Accessories for Infant T-Piece Resuscitator.
- Use only a nice Neötech Gas Supply Line or approved equivalent.
- Ensure all oxygen and air supplies are turned off and disconnected from the nice 5020 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.)
- The oxygen Concentration must be monitored with a calibrated oxygen measuring unit the ahead of the patient.
- Make sure that the oxygen supply to the infant resuscitator is turned off and that the resuscitator is disconnected from the oxygen supply when performing cleaning procedures.
- A fire and explosion hazard when cleaning in an oxygen-enriched environment, 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 infant resuscitator it can cause fire in connection with oxygen.
- High pressure may cause damage to the device. So operate the device under controlled pressure.
- Don’t keep unwanted material over the device.
- Periodically check PIP/ PEEP value with calibrated pressure gauge.

- Sterilize resuscitation accessories using Ethylene Oxide (EO) only prior to clinical use.
- Do not use steam, gamma, or other sterilization methods, as they may damage the circuit and compromise safety.
- Do not use the resuscitation accessories until aeration is complete.
- Ensure adequate aeration before patient contact.
- Do not use the accessories beyond the expiry date. Material degradation may compromise safety and performance.

Section B: Cautions

- **Use of non-standard 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.
- 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.
- This equipment is intended for use only by 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 so that the book is always accessible for reference and is stored with the equipment.
- The test lung should be monitored for signs of wear and material degradation and replaced as required.
- Do not attempt to resterilise resuscitation accessories after use.
- Ensure proper handling to avoid contamination after EO sterilization of resuscitation accessories.

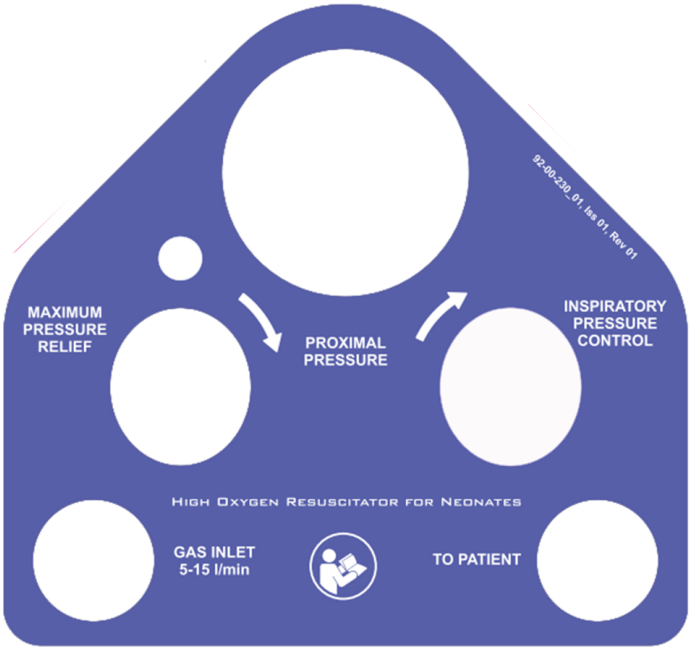
Section C: Symbols & Labels

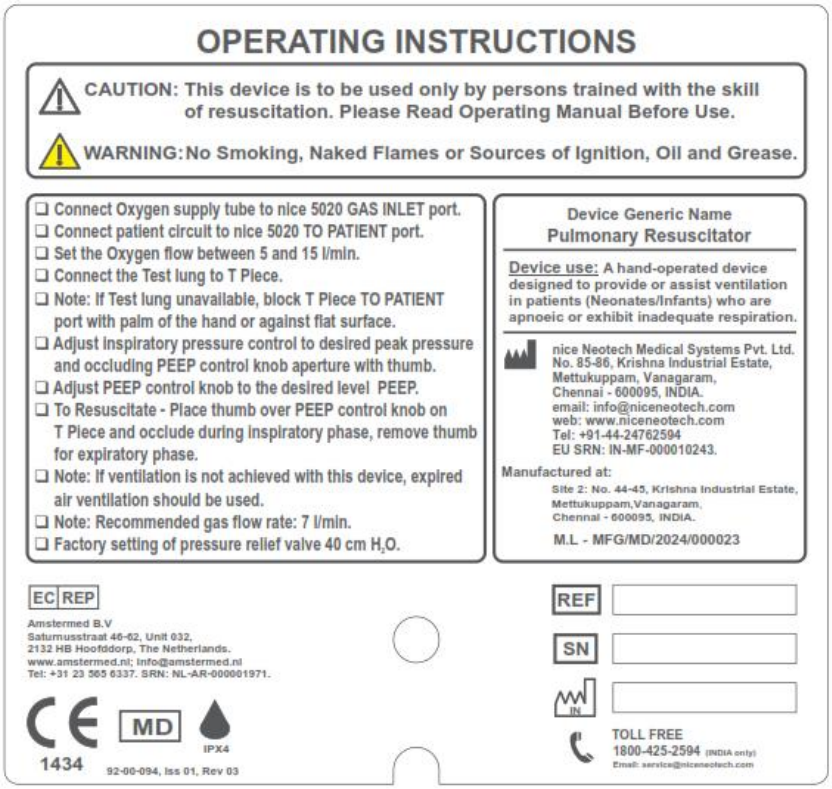
Mark	Title
Manufacturer	
	Manufacturer – Indicates the medical device manufacturer
	Date of Manufacture – Indicates the date when the medical device was manufactured.
	Country of manufacture – To identify the country of manufacture of products
	Authorized representative in the European Community/ European 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.
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.

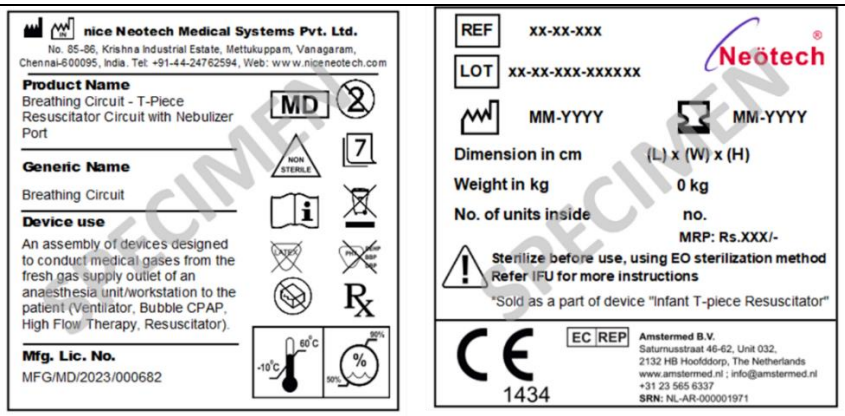
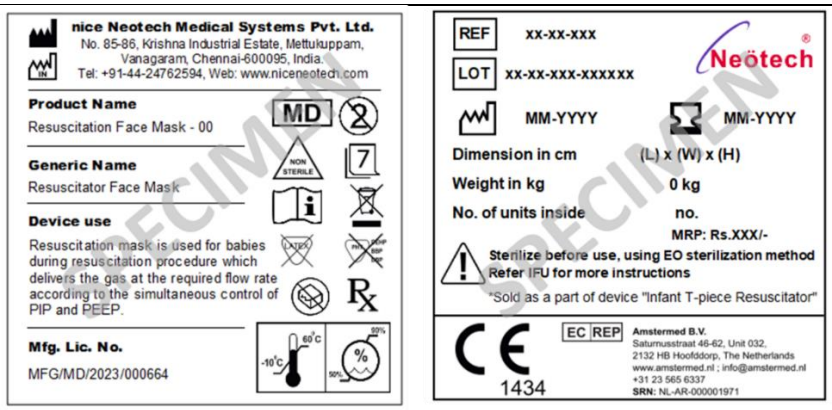
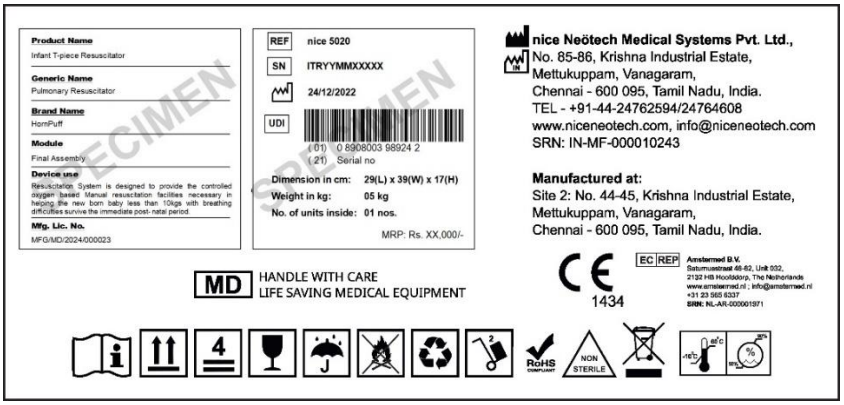
	Do not keep near fire – Do not keep the package near fire
	Maximum stackable limit – Pay attention to numbers on the stacked boxes icon. Some stacks will have top boxes marked with an X (number)
	This way up – For the duration/ delivery, the carton should face upright.
Safe use	
	Warning - indicates 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
	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.
Others	
	Medical Device - Indicates the item is a medical device
	Date - Indicates the date that information was entered or a medical procedure took place
	Type BF Equipment – Indicates that the applied part is electrically connected to patient but not directly to heart.
	Drip proof protection to IPX4 – Indicates that the product is resistant to water splashes from any direction.
	WEEE Complaint - The symbol indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling. The WEEE marking must appear on any electrical and electronic equipment placed on the EU market.
	Recyclable Package – The product can be recycled or it was made from recycled materials.
	Phthalate free – Indicates that the product does not contain the phthalate plasticizers DEHP, BBP and DBP.

	Indicates the absence of dry natural rubber or natural rubber latex as a material of construction within the medical device or the packaging of a medical device
	Use trolley for transportation – Used for heavy products that are difficult to carry by hand, even if you have multiple people.
	RoHS Complaint – RoHS (Restriction of Hazardous Substances) Indicates that no hazardous substances have been used in the product
	Unique device identifier - Indicates a carrier that contains unique device identifier information

Labels

S. No	Label	Part Number	Label Description
1.		92-00-230_01	Front Panel
2.		92-00-230_02	nice 5020 Brand label

3.		92-00-230_03	Neotech logo
4.		92-00-094	Operating instructions
5.		--	UDI Label

6.		--	Packing label – Resuscitation Accessories (T-Piece Resuscitator circuit)
7.		--	Packing label – Resuscitation Accessories (Resuscitation face mask)
8.		--	Packing box –Transport and Storage instruction

Section 1: Description

1.1 Intended Use

The Model nice 5020 Resuscitation System is intended to provide the controlled oxygen-based manual resuscitation facilities necessary for helping the new born baby less than 10kgs with breathing difficulties to survive the immediate post- natal period.

1.2 Medical Indications/Conditions

- Breathing difficulties
- Respiratory distress with matured lung.

1.3 Contraindication

- Patient with lung immaturity.

1.4 Side Effects

- Risk to ribs/ lungs/ liver/ heart
- Rashes/ Skin irritation

1.5 Intended Patient Population

Premature, Neonates and Infants (up to 10 Kg body weight).

1.6 Device Intended User

Neonatologist and Healthcare Professionals.

1.7 Working Principle

T-Piece Resuscitators are typically gas powered, and capable of delivering a pre-set, consistent and controlled peak inspiratory pressure (PIP) and positive end-expiratory pressure (PEEP), helping to protect the lungs from injury and also establish and maintain functional residual capacity (FRC). FRC is the volume of air that remains in the lungs following a typical expiratory phase. The T-Piece connects to a face mask or other interface to deliver a flow regulated, pressure limited gas supply to the infant, enabling application of controlled initial inflation breaths. PIP is the maximum inspiratory pressure required to improve oxygenation without causing adverse effects. Delivering a controlled PIP is important as uncontrolled PIP that is too high may lead to lung injury, while under-inflating the lungs may not provide adequate gas exchange. PEEP is the pressure in the lungs above atmospheric pressure (the pressure outside the body) that exists at the end of the expiration and is used to optimize oxygenation by preventing alveolar collapse.

A device consists of a maximum pressure relief valve, an inspiratory pressure control valve, and a manometer connected to an external gas (O2 cylinder flow meter/air O2 blender flow meter/centralised oxygen flow meter). The required PIP can be adjusted and set using the PIP valve from -20cmH_2O to 80cmH_2O. The

PEEP can be adjusted and set on the breathing circuit exhalation port knob of PEEP knob. The factory setting of Maximum Pressure Relief is 40 cmH_2O and can be adjusted from 5-74 cmH_2O. A manometer is provided to monitor the delivered PIP and PEEP. A flow rate of 5–15 LPM is given to the patient from the gas source. Depending on the set input pressure level in the external supply gas (50-60 psi), pressure gets expelled when it exceeds the set pressure level. The PEEP knob is used for varying the PEEP for say, from 1 to 10 cmH2O at 7 LPM input flow, and it helps in the inspiration (1 to 66 cmH_2O) and expiration cycles of gas to the neonates by using the thumb operation.

1.8 Device Description

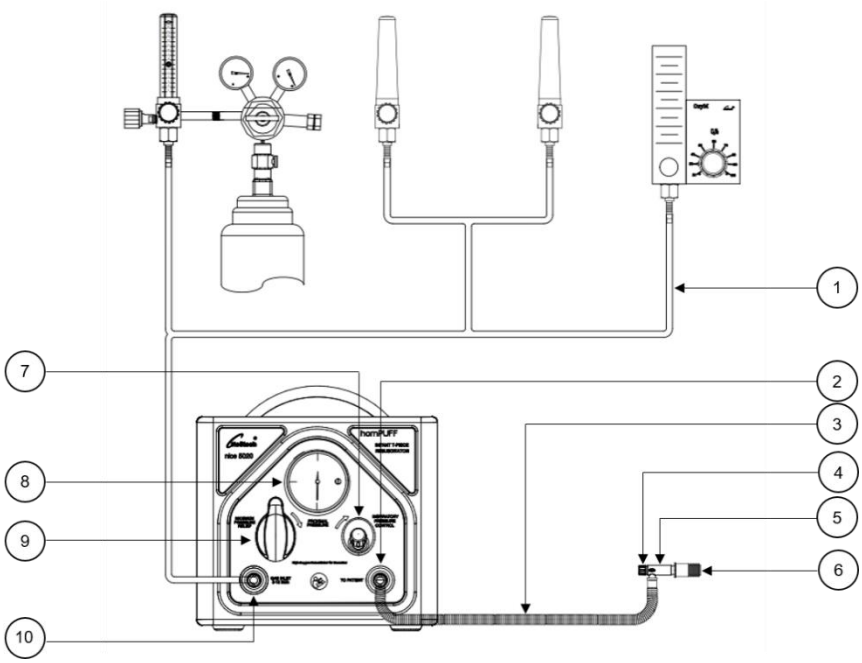


Figure 1

1.	Gas inlet hose	6.	Test lung
2.	To patient port	7.	Inspiratory pressure control knob
3.	T-Piece patient circuit	8.	Manometer
4.	PEEP knob	9.	Maximum pressure relief
5.	T-Piece	10.	Gas inlet port (5-15 LPM)

Infant T-piece Resuscitator or Emergency Resuscitator is used to inflate the lungs of the infants less than 10 kgs to survive the immediate post-natal period and in the treatment of Respiratory distress syndrome using Peak Inspiratory Pressure (PIP) and Positive End Expiratory Pressure (PEEP) controls manually with the use of test lung and treat the patient via mask. This technique can be performed by healthcare personnel trained in handling resuscitator at the emergency care.

Compared to self-inflating and flow-inflating bags, T-Piece resuscitators like the Horn Puff deliver a more controlled and consistent Peak Inspiratory Pressure (PIP) and Positive end-expiratory pressure (PEEP), which helps to protect the new-born's lungs, maintain functional residual capacity (FRC). Various manual ventilation devices in neonatal resuscitation include a technically more difficult setup, more time required to adjust pressures during resuscitation, a larger mask leak and less ability to detect changes in compliance. The nice 5020 T-Piece Resuscitation system is designed in such a manner to overcome the above drawbacks.

The infant resuscitator is a device that consists of a maximum pressure relief valve, an inspiratory pressure control knob, and a manometer connected to an external gas (O2 cylinder flow meter/air O2 blender flow meter/centralised oxygen flow meter). The required PIP can be adjusted and set using the Inspiratory Pressure

control. The PEEP can be adjusted and set on the breathing circuit exhalation port knob of PEEP knob. A manometer is provided to monitor the delivered PIP and PEEP.

HornPuff Infant T-Piece Resuscitator with Accessories comprises the below assemblies

- T-Piece Resuscitator circuit (Disposable): T-Piece Resuscitator circuit is used to deliver the respiratory gases from the equipment to the patient. nice Neötech offers two types of T-Piece circuits – T-Piece Resuscitation circuit with Nebulizer port and T-Piece Resuscitator circuit with heated wire with Nebulizer port (optional) which can be connected to a mask or an endotracheal tube.

- Resuscitation face mask: Resuscitation face mask is used for babies during Resuscitation procedure which delivers the gas at the required flow rate according to the simultaneous control of PIP and PEEP. Precise design of masks helps fit the contour of infant's nasal area and mouth. nice Neötech resuscitation masks for neonates and infants are available in different sizes to fit a range of patients. Sizes are 00, 0 and 1.

- Input hose (Gas supply line): Gas input hose transports gases from the oxygen cylinder/ Air-oxygen blender to the device.

1.9 UDI Carrier

The UDI identifies Infant T-piece Resuscitator with Accessories throughout distribution and product life. The UDI appears on the Infant T-piece Resuscitator 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)
nice 5020	08908003989242	ITRYYMMXXXXX (3 digit Product code + YY + MM + 5 digit serial number)

UDI label


Section 2: Installation

2.1 Unpacking and Inspection

- Remove the equipment from shipping containers and unpack all the assemblies and accessories of Horn puff.
- After removal from the shipping containers, inspect the nice Neötech Infant T piece Resuscitator and all accessory items for any signs of damage which may have occurred during shipment.
- Also confirm the presence of all accessory items or factory installed options as listed on the packing slip.

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

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

2.2 Installation of Infant T piece Resuscitator

Picture 1

➢ Connect the input gas hose with the gas inlet connector.

Picture 2

➢ Connect the other end of input gas hose with flow meter connected with oxygen cylinder/central oxygen pipe line/Air, O2 blended output.

Picture 3

- Connect the patient circuit with the patient limp connector.

Picture 4

- Connect the test lung with the T-Piece of the patient circuit

Note:

- Check that an Oxygen Cylinder is fitted for their emergency standby user operation as applicable.
- Check that adequate supplies of sterile Endotracheal Adaptors, Oxygen Tubing, T - piece Connectors, etc., are available for use.
- If the elapsed time from start of resuscitation is to be recorded, check that a suitable Clock or Timer is available, and that it is operational in accordance with the Manufacturer's instructions.
- Carry out a Functional Test to ensure operational integrity before using the nice 5020 infant resuscitator.

2.3 Pre-use check instructions

Before using the nice Neötech Infant T piece Resuscitator, 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 Infant T piece Resuscitator.

Complete the “Pre-use Check Instructions” section of this manual before putting the unit into operation. If the Infant T piece Resuscitator fails any portion of the Pre-use Check Instructions it must be removed from use and repaired.

2.3.1 Overall Appearance

- Check the overall appearance of the Infant T piece Resuscitator. There should be no obvious damage.

Setup and Pre-use Check Instructions

- Check the manometer needle is in zero.
- Check the knobs for damage in adjusting.
- Check the connector ports (gas inlet connector and patient limp connector) on the front panel.

2.3.2 Accessory Checks

- Examine the inlet gas hose for damage.
- Examine the patient circuit for damage.
- Check the test lung for damage.
- Check the Resuscitation face mask for damage.

2.3.2.1 Sterilization Instructions

2.3.2.1.1 Preparation

- Visually inspect the breathing circuit and Resuscitation face mask. Do not use if it is damaged.
- Do not remove circuit from package prior to sterilization.
- Place an EO indicator tape on the outside of each sterilization pack.
- Ensure labeling and lot tracking are applied according to hospital or facility policy.

- Sterilize using Ethylene Oxide (EO) only prior to clinical use.
- Do not use steam, gamma, or other sterilization methods, as they may damage the circuit and compromise safety.

2.3.2.1.2 Sterilization Process

Use a validated EO sterilization cycle appropriate for your equipment and load configuration. A general guideline is as follows:

Parameter	Recommended Range
EO Concentration	450 to 1200 mg/l
Temperature	40 to 60◦C
Chamber Humidity	60 to 80%
EO Exposure time	1 to 6 hours

- Avoid overloading the chamber.
- Ensure adequate space for EO circulation.

2.3.2.1.3 Aeration (EO Residual removal)

To reduce EO residuals, perform aeration immediately after sterilization as given general guidelines below or follow facility's validated aeration protocol.

Method	Aeration conditions
Heated Aeration	12–24 hours at 50–55 °C in a dedicated aeration cabinet
Ambient Aeration	7 days at room temperature (≥20 °C)

- Do not use the product until aeration is complete.
- Ensure adequate aeration before patient contact.

2.3.2.1.4 Post-Aeration Release

- Verify package integrity and indicator color change.
- Ensure the sterilization cycle was completed successfully (review cycle records).
- Do not use the product if:
  - Packaging is compromised
  - Indicator fails to show sterilization
  - Required aeration has not been performed

- Do not attempt to resterilize after use.
- Ensure proper handling to avoid contamination after EO sterilization.

2.3.3 Functional test of Infant Resuscitator

Varying PIP and Maximum Pressure relief knob:

Step 1: Set the Flow Rate

- Adjust the Flow Rate on the Flow Meter to 7 LPM (Liters Per Minute).

Step 2: Maximum Pressure Relief and PIP Knob Adjustment

- After fixing the flow rate at 7 LPM, set both the Maximum Pressure Relief knob and the Peak Inspiratory Pressure (PIP) knob on the resuscitator to their maximum or full condition (closed condition).

Step 3: Occlude the PEEP Knob

- After adjusting the knob to full condition on the resuscitator, locate the PEEP knob on the circuit and close or occlude it.

Step 4: Check Manometer Gauge

- Verify the pressure on the manometer gauge in the resuscitator. It should read between 62-68 cmH_2O. Ensure the pressure falls within the specified range.

Maximum Pressure Relief Adjustment:

Step 1: Set the Peak Inspiratory Pressure (PIP) Knob

- Turn the Peak Inspiratory Pressure (PIP) knob to its fully closed condition. Means adjusting it to its maximum setting.

Step 2: Adjust Maximum Pressure Relief Knob

- While keeping the PIP knob fully closed, gradually vary the Maximum Pressure Relief knob. Adjust it incrementally until the pressure on the manometer reaches up to 40 cmH2O.

Step 3: Occlude the PEEP Knob

- Close or occlude the PEEP (Positive End-Expiratory Pressure) knob in the circuit.

Step 4: Monitor Manometer Pressure

- In the pressure manometer gauge, ensure that the pressure falls within the specified range of 38-40 cmH2O with the PEEP knob occluded.

PIP Adjustment:

Step 1: Occlude the PEEP Knob

- Close or occlude the PEEP (Positive End-Expiratory Pressure) knob on the circuit.

Step 2: Vary and Adjust Peak Inspiratory Pressure (PIP) Knob

- While the PEEP knob is occluded, vary and adjust the Peak Inspiratory Pressure (PIP) knob. Set it at 30 cmH2O as indicated on the manometer gauge.

Step 3: Fix the PIP Setting

- After adjusting the PIP knob to 30 cmH2O, fix or secure this setting.

Step 4: Occlude PEEP Knob Again

- Close or occlude the PEEP knob on the circuit once more.

Step 5: Monitor Manometer Pressure

- Once the PIP is fixed, check the Peak Inspiratory Pressure on the manometer gauge. Ensure that the pressure falls within the specified range of 28-30 cmH2O.

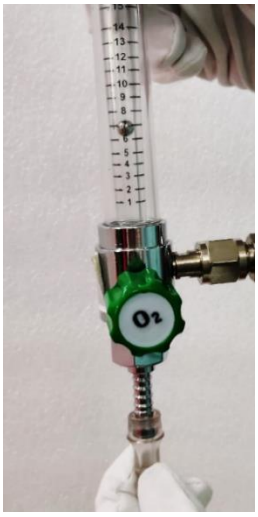
2.3.3 Check the Manual Ventilation System

- Check manometer reads zero with no gas flow.
- Connect oxygen or blended oxygen/air supply to gas inlet port using gas supply line.
- Connect patient supply line and patient T-piece to the gas outlet port.
- Connect test lung to patient T-piece (before use, inspect test lung for signs of damage such as discoloration, perishing or cracking)
- Adjust gas supply to desired flow rate between 5-15 LPM.
- To check Maximum Pressure, Occlude PEEP knob on the circuit and turn PIP control fully clockwise adjust maximum pressure control knob clockwise or counterclockwise to set desired maximum pressure.
- To set PIP, while still occluding the PEEP knob, turn PIP control knob counter-clockwise until the desired peak inspiratory pressure is set.
- To set PEEP, adjust PEEP knob to the desired PEEP level.
- Occlude the PEEP knob and, this will limit the Peak Inspiratory pressure achieved between set PIP Value.
- Turn off gas supply and remove test lung from patient T-piece.
- Ensure that the rigid plastic connector of the test lung is also removed from the T-piece before. Attempting to connect a mask or endotracheal tube. Failing to do so may cause unacceptable delays during patient resuscitation.

Note: Market available Disposable or reusable Patient circuit, Mask & Endotracheal tube can be used.

Section 3: Operation

3.1 Gas Supply Flow rate



Picture 5

- Set the Flow rate at 5-15 LPM in the Flow Meter.

3.2 Setting the Maximum Pressure

Picture 6

- Occlude PEEP knob provided in the circuit.

Picture 7

Picture 8

- Lift the cap of maximum pressure relief
- Turn PIP control fully clockwise adjust maximum pressure relief control knob clockwise or counterclockwise to set desired maximum pressure from 0 to 80 CmH_2O.

Note: The factory default range for maximum pressure is 40 CmH_2O.

3.3 Setting the Peak Inspiratory Pressure (PIP)

Picture 9

- Occlude the PEEP knob, turn PIP control knob counter-clockwise until the desired peak inspiratory pressure is set.

3.4 Setting the Positive End Expiratory Pressure (PEEP)

Picture 10

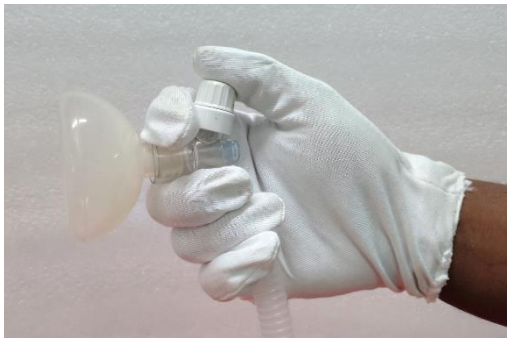
Picture 11

- Adjust PEEP knob clockwise (increase) or anti-clockwise (decrease) to the desired PEEP level.

3.5 Resuscitate with nice 5020 Infant Resuscitator

Picture 12

- Adjust gas supply to the desired flow rate. Fit patient T-piece to neonatal resuscitation mask and place over the baby's mouth and/or nose. Fit patient T-piece to the endotracheal tube.



Picture 13

Picture 14

- Resuscitate by placing and removing thumb over the PEEP knob to allow inspiration and expiration.

3.6 Infant T-Piece Resuscitator

3.6.1 Infant T-Piece Resuscitator with flow meter and blender

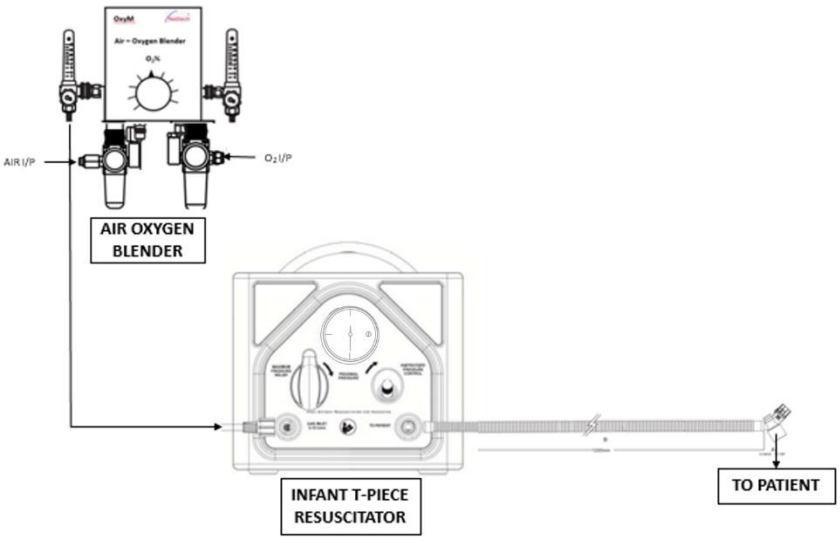


Figure 2

3.6.2 Infant T-Piece Resuscitator with flow meter, blender and humidifier

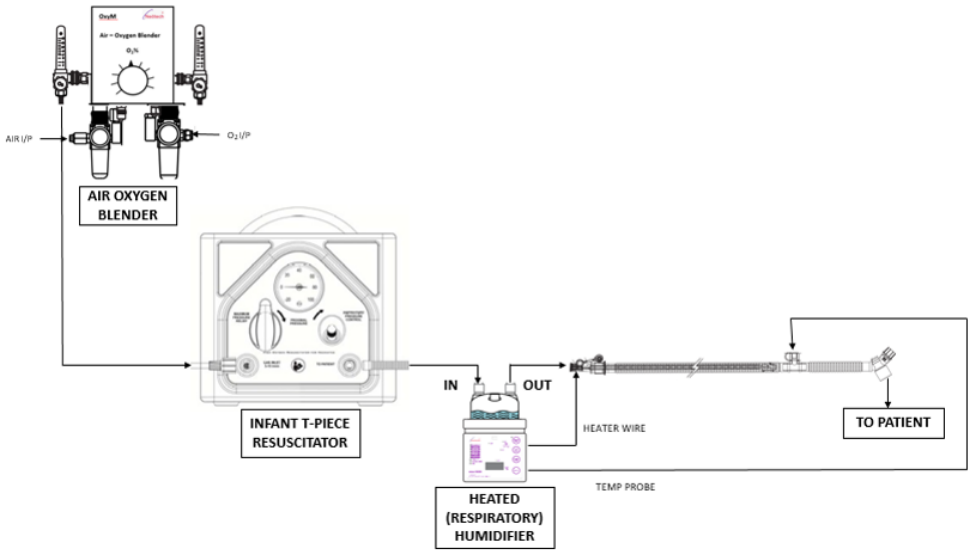
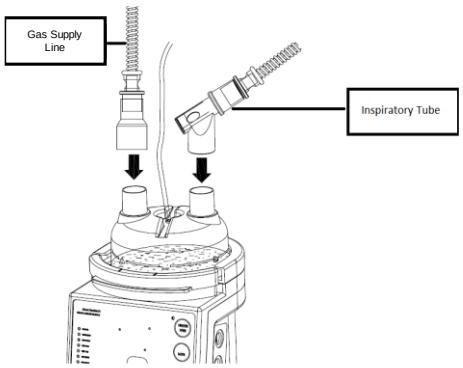
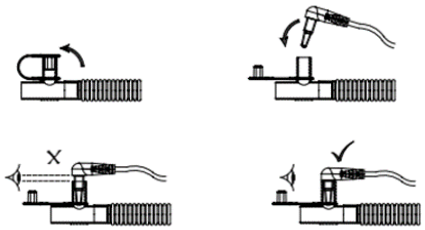
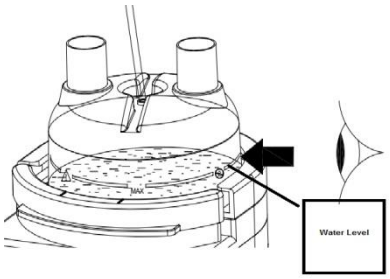


Figure 3

3.6.3 Mode of Action

I. Set-Up The following procedure should be carried out prior to every use of the Horn Puff to ensure that the device is functioning correctly.	
Step 1:	**Check manometer reads zero with no gas flow**.
Step 2:	**Connect gas supply** • Connect an oxygen or blended oxygen/air supply to the gas inlet port using the Gas Supply Line.
Step 3:	**Connect T-Piece Circuit** • Connect the T-Piece Circuit to the gas outlet port and connect test lung to the circuit. Before use, inspect test lung for signs of damage such as discoloration, perishing or cracking.
Step 4:	**Check Settings** • Adjust the gas supply to desired flow rate between 5 and 15 LPM. Note: Ensure the oxygen concentration of an oxygen/air supply is monitored using an oxygen analyzer.
Step 5:	**To Check Maximum pressure** • Occlude PEEP knob and turn PIP control fully clockwise, until the knob doesn't turn anymore and adjust maximum pressure control knob clockwise or counterclockwise to set desired maximum pressure.
Step 6:	**To Set PIP** • While still occluding the PEEP knob, turn PIP control knob counterclockwise until the desired peak inspiratory pressure is set.
Step 7:	**To Set PEEP** • Adjust PEEP knob to the desired PEEP level. Turn off gas supply and remove test lung from T-Piece. Ensure that the connector of the test lung is also removed from the T-Piece before attempting to connect a mask or endotracheal tube. Failing to do so may cause unacceptable delays during patient resuscitation.
II. To Resuscitate	
Step 8:	• Adjust gas supply to the desired flow rate.
Step 9:	• Fit T-Piece to neonatal resuscitation mask and place over the baby's mouth and nose. • Resuscitate by placing and removing finger or thumb over the PEEP knob to allow inspiration and expiration.

3.6.4 Directions for Use (T-Piece Resuscitator Breathing circuit)

	➢ Remove the product from the package and inspect for damage. If present, or if the package has been opened, do not use the product. ➢ Insert the gas supply line and inspiratory tube in the humidifier chamber connector as shown in the image.
	➢ Insert the airway probe in the airway sensor port of the breathing circuit
	➢ Water levels to be ensured as per the markings provided in the humidifier chamber

Note: To decrease possible bacterial contamination, do not reuse the breathing circuit

3.7. After use

- Switch OFF the Timer if applicable and record the finish time.
- Check the Oxygen Cylinder pressure on the Cylinder Pressure Gauge if used and then close the cylinder valve.
- Disconnect the Oxygen Supply Hose from the pipeline outlet terminal if applicable.

Note:

- Ensure the oxygen concentration of oxygen / air supply is either monitored using an oxygen analyzer, or preset using oxygen/air flow rate graphs.
- The factory setting of the Maximum Pressure Relief is 40 cm H2O.
- The Maximum Pressure Relief valve acts as an overall limit on the achievable circuit pressure. Resuscitation above 40 cm H2O cannot be achieved unless the Maximum Pressure Relief valve is adjusted.
- The nice 5020 infant resuscitator can be used with either reusable or single-use patient supply lines.
- Single-use patient supply lines can eliminate the possibility of cross-patient infection without requiring time consuming and expensive cleaning and sterilization procedures.

3.8. Accessories

Standard Accessories

S.No.	Accessory Name	Type of use	Part no.	Intended use	Picture
1	T-Piece Resuscitator circuit with nebulizer port	Single use	50-05-154	Used to deliver the respiratory gases from the equipment to the patient.	
2	Resuscitation face mask	Single use	Size 00 – 98-00-124 Size 0 – 98-00-125 Size 1 – 98-00-126	Used for babies during resuscitation procedure which delivers the gas at the required flow rate according to the control of PIP and PEEP.	
3	Input hose (Gas supply line)	Single use	50-05-260	Connect an oxygen or blended oxygen/air supply to the gas inlet port using the Gas Supply Line.	

Optional Accessories

S.No.	Accessory Name	Type of use	Part no.	Intended use	Picture
1	T-Piece Resuscitator circuit with heater wire and nebulizer port	Single use	50-05-150	Used to deliver the respiratory gases from the equipment to the patient.	

Section 4: Cleaning and Maintenance

4.1 General

During cleaning the Infant T-Piece Resuscitator, the processing shall comply with ISO 17664-1:2021 for reusable of the device:

1. Clean the equipment with damped cloth using soap (e.g. liquid dish soap) and clean water.
2. Clean the equipment completely with water damped cloth.
3. Disinfect the equipment by using 2% Glutaraldehyde to inactivate any remaining pathogens.
4. 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, 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.
5. 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 Infant T-Piece Resuscitator 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).
6. Use of cleaning/disinfecting solutions containing chemicals that are not listed above (i.e. alcohol, acetone, etc.), or chemicals in greater concentrations than those listed above, may damage the patient sensor or other material being cleaned.
7. Do not autoclave or gas sterilize the resuscitator monitor.
8. Cleaning shall be performed at ambient condition.

4.2 Dismantling Infant T-Piece Resuscitator

- Disconnect Patient Circuit form nice 5020 infant resuscitator.
- Before cleaning, remove and discard all used disposable products/Accessories.

Take care not to lose the Tubing Adaptor Stems. These should not normally have to be removed.

4.3 Cleaning of Infant T-Piece Resuscitator

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

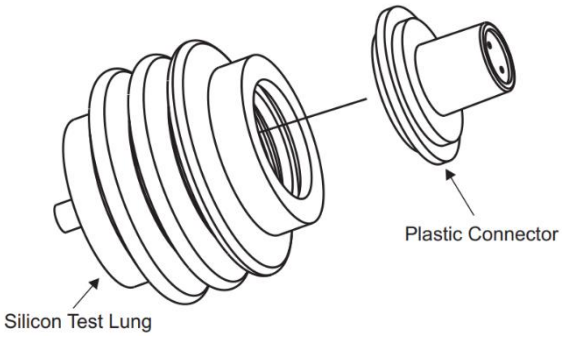
1. Physically clean the components/parts with soft cloth, removing all visible contaminants by wiping using water general cleaning.
2. Don't keep the metal surface in wet condition it may cause corrosion and damage the part
3. Clean the components/parts with water damped cloth.

4. Disinfect the components/parts by using 2% Glutaraldehyde to inactivate any remaining pathogens and leave it for 3 minutes.
5. Then clean the components/parts by wiping using water damped cloth
6. Dry components/parts using dry towel or cloth.

4.4 Cleaning of Test Lung

- The test lung is a consumable item. The test lung should regularly be inspected for signs of damage such as discoloration, perishing or cracking. Replace the test lung if damage is observed.
- Test lung must be cleaned before every use or in accordance with hospital cleaning procedure.

Ensure the silicon test lung and plastic connector are both removed from the T-Piece before use on a patient.



The test lung consists of two parts, the flexible silicon test lung and a rigid plastic connector. The two parts of the parts of the test lung may be disassembled for disinfection. The test lung can be cleaned using disinfectants containing either peracetic or orthopthaldehyde. Other disinfection method can damage the test lung and are not recommended.

4.5 Maintenance

- Always disinfect and clean the unit and accessories before any maintenance – even when returning the unit to the supplier for repair.
- Always disconnect the accessories before any maintenance.
- Use only nice Neötech's original parts for maintenance.
- Perform functional tests to ensure that the T-piece Resuscitator unit operates correctly.
- Manometer should be checked at regular intervals, particularly after cleaning and servicing, and always before each use. Periodic checks help identify any potential issues, such as calibration errors or damage.

Inspect the entire circuit for any visible damages, such as cracks, breaks, or leaks while connecting to the T-piece Resuscitator unit it may cause inaccurate flow of oxygen.

4.6 Life time of product

Since the Infant T-Piece Resuscitator is classified under gas powered medical devices due to the mechanical components ageing or wear and tear the life time of the product can be considered as five years and Service life of the device is extendable up to 1 years considering the replacement of spares and faulty components. So, the service life of the device is six years (5 years of lifetime + 1 year service life). The Shelf life of the product is nil and the resuscitation accessories is 1.5 years (18 months) from the date of manufacture.

Section 5: Specification

Parameters	Specifications
Gas inlet flow range	5LPM (min) to 15LPM (max) If the gas Inlet flow rate increases from 5 to15LPM, the peak inspiratory pressure may be increased approximately 8cm H2O
Manometer Range	-20 to 80 cmH2O
Flow Accuracy	0 – 10 LPM ± 1 LPM, 11 – 15 ± 2 LPM
Manometer Accuracy	+/- 2.0% of Full Scale deflection
Maximum pressure relief	@7LPM 1 to 66 cm H2O Factory Set @ 40 cm H2O
Peak inspiratory pressure	@5 LPM 1 to 64 cmH2O @7 LPM 1 to 66 cmH2O @10 LPM 1 to 68 cmH2O @15 LPM 1 to 70 cmH2O
Positive end-expiratory Pressure	@5LPM 1 to 6 cmH2O @7LPM 1 to 10 cmH2O @10LPM 2 to 20 cmH2O @15LPM 4 to 40 cmH2O
Delivered oxygen concentration	up to 100% depending on gas supply
Gas supply system complying with ISO 10651, duration (400L Cylinder)	@4 LPM, 1 Hour 40 Minutes @8 LPM, 50 Minutes @12 LPM, 33 Minutes
Recommended Baby Weight	up to 10Kg
Gas cylinder valve	The gas cylinder valve fitted to the gas cylinder is as per the ISO 10297
Flow Regulator	Pressure Regulator as per ISO 10524-1 or ISO 10524-3
Inlet Pressure	1000 Pa
Standard Accessories	
Disposable Patient circuit	1set; Length – 1.2m; ID – 12mm
	Inspiratory and Expiratory resistance - 1cm H2O @ 3 and 6 LPM
Face Mask	3 nos. different sizes
Low flow oxygen hose	1no.
Environment	
Operating Temperature	10 °C to 30°C
Operating Relative Humidity	15 – 90% RH, non-condensing
Storage Ambient Temperature	-10° C to 60 °C
Storage Relative Humidity	50 - 90% RH, non-condensing
Altitude	Sea level to 1.9 miles (3 Km)
IEC 60601-1 Specification	
Mode of Operation	Continuous

Types of protection against electric shock	N/A
Degree of protection against electric shock	N/A
Protection against hazardous of explosion	Not protected
Protection against increase of liquid	IPX4
Resuscitator Dimension	
Dimension	22.86 cm (H) x 12.7 cm (W) x 26.67 cm (L)
Weight	2.5kg
Quality Test Approval	
Quality standard	ISO 13485:2016
Particular Standard	ISO 10651-5:2006
Graphical Symbol	ISO 15223-1:2021

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
5. Warranty conditions are not applicable and repairs will be done subject to availability of parts and on a Chargeable basis only 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 50 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 abnormal, Acts of god, and also defects caused by rats, cockroaches or any other insects will not be Covered under warranty.
9. Warranty is not applicable if the equipment is not purchased from Neötech/authorized Neötech Dealer
10. Warranty is not applicable if the warranty card is not filled and sent back to Neötech.
11. Life time of the product is 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).

Customer Details cum Warranty Card

Hospital Name & Address: _____

_____

Contact Person & Telephone/Fax No_____

Email _____

Department: NICU / PICU / OT / Gynecology / Causality / Others _____

Equipment Name: _____

Model No: _____ Sl. No. _____

Date of Purchase: _____ Date of Installation _____

Name of Authorized Dealer: _____

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

Dealer Signature with seal

Kindly fill the above and sent the same

From _____
_____
_____

To:
The Service In-charge
nice Neötech Medical Systems Pvt. Ltd.
No.85-86, Krishna Industrial Estate,
Mettukuppam, Vanagaram,
Chennai-600095. Tamil Nadu ,INDIA
Ph: 91-44-24762594, 24764608
Email: service@niceneotech.com, info@niceneotech.com
Web: www.niceneotech.com
Toll Free No. 1800-425-2594 (India only)

Section 7: Trouble Shooting

7.1 General

S.no.	Problem	Remedy
1.	Unable to achieve the PIP and PEEP Pressure during the setup procedure	Check that the gas flow rate is set to 5-15L/min.
		Inspect the test lung for sign of damage.
		Ensure firm Connection between the gas supply, resuscitator, connectors and T-Piece circuit.
		Ensure the test lung is firmly connected to the T-Piece circuit.
		Confirm that the manometer shows zero with no gas flow.
		Check the maximum pressure relief is set correctly.
2.	The infant chest and upper abdomen are not rising during the inspiratory cycle	Confirm the good seal between the mask and infants face has been achieved.

7.2 Proactive Instruction

- Adhere to the manufacturer's guidelines and recommendations for maintenance routine checks.
- Maintenance and Cleaning Procedures for T-piece Resuscitator Must be conducted by Qualified Personnel.
- Oxygen Supports Combustion - Strictly Avoid Ignition Sources and Refrain from Using Oil or Grease on Oxygen Equipment to Prevent Spontaneous Combustion.
- 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.

7.3 Disposing of the Unit

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

Section 8: Spare Parts List

S.No.	Part No.	Description	Qty	Unit
1	50-05-047	Test Lung	1	No.
2	50-05-051	Inspiratory Pressure regulator Assembly	1	No.
3	50-05-154	Disposable Patient Circuit – 5020	1	No.
5	88-00-231	Proximal Meter/Manometer	1	No.
6	98-00-124	Resuscitation Mask, Size 00	1	No.
7	98-00-125	Resuscitation Mask, Size 0	1	No.
8	98-00-126	Resuscitation Mask, Size 01	1	No.

Service contact:

nice Neötech Medical Systems Pvt. Ltd.
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

EU Authorised Representative

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

CE 1434

Section 9: For Complaints/Adverse Events/Comments/Feedback

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

In case of adverse events, fill the below details:

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

For comments:

For Complaints:

For Feedbacks:

Kindly fill the above and send the same

From:

_____

_____

_____

To:
The Marketing In-charge
nice Neotech Medical Systems Pvt. Ltd.
No, 85-86. 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 Neotech, European Authorized Representative and the competent authority of the Member State by filling and sending the below form as letter post or email.

Service Contact	EU Authorized Representative	Competent Authority
nice Neötech Medical Systems Pvt. Ltd. No. 85, Krishna Industrial Estate, Vanagaram, Mettukuppam 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	**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	**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 10: EC certificate notified body

Name:

PCBC – POLSKIE CENTRUM BADAN I CERTYFIKACJI S.A.

Notified body number:

1434

Address:

02-844 Warsaw,
469 Pulawska Street,
Poland.

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