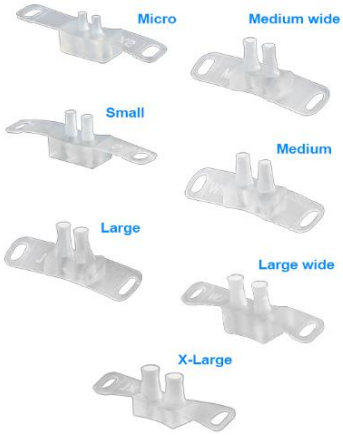
nice Neötech Medical Systems Pvt. Ltd.

Patient Interfaces

Nasal cannula



Nasal prongs

Nasal mask

Nasal t bar prongs

Flow tube

Resuscitation face mask

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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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 in accordance with the instructions provided. 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.

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 Patient Interface, 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:

Nasal cannula	Nasal cannula is intended to connect the breathing circuit and the patient's nostril to deliver the gas to the patient.
Nasal prongs	Nasal prongs is intended to connect the breathing circuit and the patient's nostril to deliver the gas to the patient.
Nasal mask	Nasal mask is intended to connect the breathing circuit and the patient's nostril to deliver the gas to the patient.
Nasal T Bar prongs	The CPAP Nasal T bar Prong seals and delivers air inside the nares or nasal openings of your nose. It is held in place by head bonnet/ headgear that is worn on the crown of the head using hook able laces. This style of CPAP prong is nonrestrictive and lightweight.
Resuscitation face mask	Resuscitation 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.
Flow tube	Flow Tube is intended to deliver the gas with Low flow resistance. Made of flexible, soft and biocompatible material, it act as an interface for CPAP therapy.

Definition

CPAP	Continuous positive airway pressure (CPAP) is delivered to spontaneously breathing newborn to maintain lung volume during expiration. This procedure involves blended and humidified air to be supplied to infants through nasal mask or prongs.
PEEP	Continuous positive airway pressure maintained during respiratory therapy which is called Positive End expiratory Pressure by using Bubble Generator
PIP	The peak inspiratory pressure (PIP) is the highest pressure measured during the respiratory cycle and is a function of both the resistance of the airways and the compliance of the respiratory system.

Definition of Warning indication:

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

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

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

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

Section A: Warnings

- For single patient use only. Reuse may result in transmission of infectious substances. Attempting to reprocess will result in degradation of materials and render the product defective.
- Appropriate patient monitoring must be used at all times. Failure to monitor the patient may result in loss of therapy, serious injury Follow physician’s instruction.
- Ensure that the patient does not lie on the tube fixation. This can lead to redness of or injury to the skin.
- If the patient has any adverse reactions such as skin redness, chest tightness, dyspnea, gastric distension, severe headache, lacrimation, snivel and so on, please contact the medical and nursing professional.
- The supply tubes must be positioned appropriately and tightly attached to the patient interface.
- When therapy is on hold, please place the patient interface in an environment that is clean and free of debris. The performance can be compromised by dirt, and it can also contaminate.

Section B: Cautions

- Failure to use the set-up described can compromise performance and affect patient safety
- Before connecting the interface, check for adequate gas flow and ensure that the system has warmed up.
- Do not use if packaging is not sealed.
- DO NOT soak, wash, sterilize, or reuse this product.
- Choose the appropriate size of nasal mask, nasal prongs, nasal T-bar prongs which cannot cause blockage of nostrils. Re-evaluating the interface size is an important part of routine patient assessments.
- Over-tightening or inserting the prongs too deep may lead to pressure sores or nasal dilation.
- 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.
- Prongs that are too small may lead a clinician to over-tighten the fixating laces to eliminate a leak.
- If the base of the prongs is not sitting properly on the Flow Tube. Remove the interface and reapply it while ensuring the interface is evenly seated.
- Make sure the Cannula does not form a seal, leave some space in the nares.A clear gap must be visible around each cannula.
- The Head Bonnet is placed correctly on the head, above or below eyebrows and not over the eyes.
- The head bonnet is positioned too far back on the forehead, causing the prongs to kink

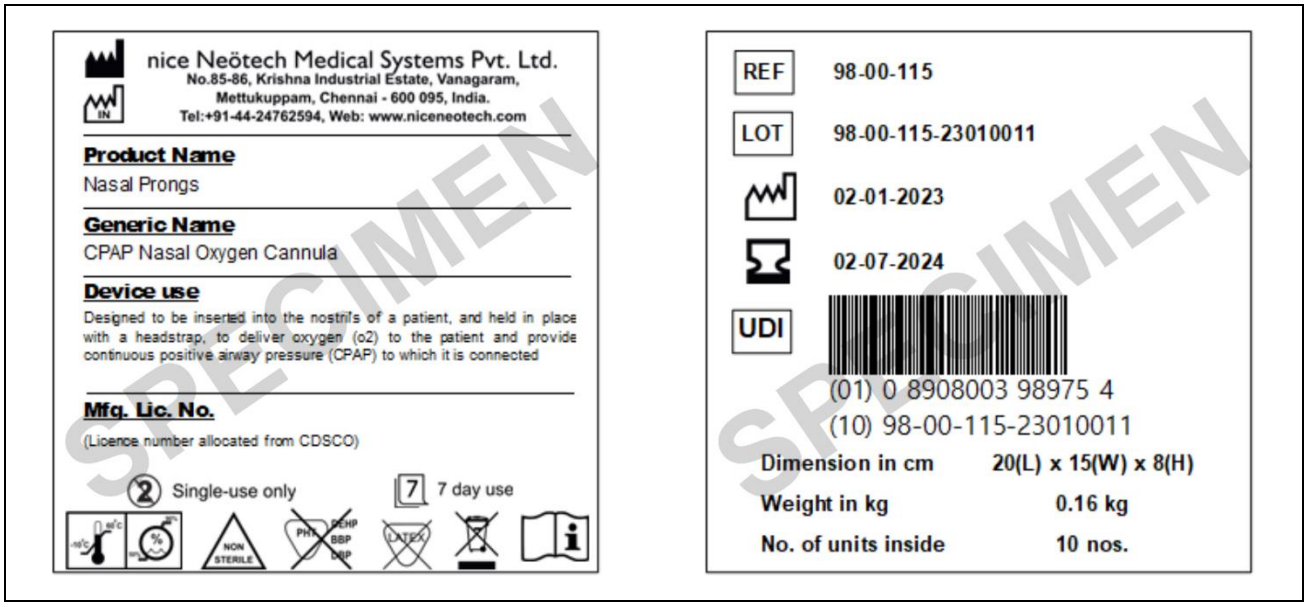
Section C: Symbols & Labels

Symbols

Mark	Indication
	Medical Device
	Type BF Equipment
	Do not re-use
	Serial Number
	Unique Device Identifier (Device Identifier + Product Identifier)
	Authorized Representative in European Community
	Date of Manufacture
	Manufacturer
	Country Code of Manufacturer
	Model Number
	Refer Instruction for use
	Batch Date
	Use-by Date
	7 Day use

	Disposal of waste
	Non sterile
	Non-Phthalate
	Temperature Limit
	Humidity Limit

List of Labels



Section 1: Description

1.1 Intended Use

Patient interfaces (Nasal cannula, Nasal prongs, Nasal mask and Nasal t bar prongs and Head bonnet, Flow tube, Resuscitation face mask) are used during respiratory support along with respiratory care devices.

1.2 Indication:

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

1.3 Contraindication:

- Blocked nasal passages.
- Unstable cardiorespiratory status or respiratory arrest.
- Surgery to nasopharynx.

1.4 Side Effect:

May cause skin irritation, redness or mask pressure on their bridge of their nose respectively.

1.5 Target population:

Neonates, Infants, Pediatrics and Adults

1.6 Device Intended User:

Anaesthetist & Neonatologist

1.7 Working Principle

Patient Interface delivers the gas during CPAP, High Flow Oxygen Therapy and other Respiratory Therapy System, by placing the patient interface like nasal prongs, nasal mask, nasal cannula, Nasal T-bar prongs which are placed over the baby nasal area. When the baby have low surfactant, the lungs collapse and it make difficult to breathe. This leads less *Oxy*gen supply to internal organs. The best method to treat these infant's to provide a non-invasive ventilation strategy by delivering continuous positive airway pressure (CPAP) to a spontaneously breathing new born infant's to maintain lung volume during expiration. Blended and humidified *Oxy*gen is delivered through short binasal prongs or a nasal mask.

Patient interfaces plays a vital role in maintaining the PEEP level of the patient. Patient interfaces include, Flow tube and Nasal prongs /mask. Flow tube is the interlink between the breathing circuit and nasal prongs/mask. Whereas head bonnet helps to hold the nasal prongs/mask to the patient's nostril position firmly until the treatment. Nasal prongs or mask shall be used at the final patient end to deliver the gas from the device. Nasal prongs are fitted directly into the patient nares. Nasal mask will cover the entire nose region.

1.8 Product Description

Patient interfaces comprises the below assemblies

Nasal cannula
Nasal prongs
Nasal mask
Nasal T bar prongs
Resuscitation face mask
Flow tube

Patient Interface used during the CPAP therapy and Ventilator treatment. The components such as Nasal Masks, Nasal Prongs, Nasal T- Bar Prongs (optional), Flow Tube and Flow Tube Fixing Pillow, The patient and the medical device is connected using the Patient Interface.

- **Nasal Mask**

  Nasal mask is intended to connect the breathing circuit and the patient's nostril to deliver the gas to the patient. CPAP Nasal Mask for use in delivering gases during bubble CPAP treatment which are placed over the baby nasal area. They made anatomically fit for infant's nares with size designation and having slots for fixing flow tube. A Bubble CPAP nasal mask is triangular in shape and sits on the face around the nose. It's held in place by head gear/head bonnet (stretchy laces that go around the nose) using hookable laces. The mask is made of non-reactive silicone and is disposable.

  Available in 4 different sizes of Nasal Mask - small, medium, large and X-large.

- **Nasal Prongs**

  Nasal prongs is intended to connect the breathing circuit and the patient's nostril to deliver the gas to the patient. CPAP Nasal Prongs has a pair of short tubes positioned directly in the infant's nares to deliver the prescribed CPAP level. High Profile design and appropriate prongs length allows comfortable supply of required gases.

  Available in 8 different sizes of Nasal Prongs - Micro, small, medium, medium wide, large, large wide, X large.

- **Nasal Cannula**

  Nasal cannula is intended to connect the breathing circuit and the patient's nostril to deliver the gas to the patient. Available in different sizes of Nasal septum that fits all populations-neonates, premature, pediatrics, infant and adult.

  1. Max flow Nasal Cannula - premature, neonates, infants, pediatrics
  2. Adult Max Flow Nasal Cannula - small, medium, large

3. Hiflex Nasal Cannula - premature, neonates, infants, pediatrics

The Nasal Cannula is intended to use during High flow Oxygen Therapy to infants requiring high levels of oxygen for respiration. High flow oxygen therapy (HFOT) is a form of respiratory support used in the hospital where oxygen, often in conjunction with compressed air and humidification, is delivered to a patient at rates of flow higher than that delivered traditionally in oxygen therapy. High flows of an air/oxygen blend can be administered via a nasal cannula to accurately deliver high volume of oxygen during oxygen therapy.

- **Nasal T-Bar Prongs**

  The CPAP Nasal T bar Prong seals and delivers air inside the nares or nasal openings of your nose. It is held in place by head bonnet/ headgear that is worn on the crown of the head using hook able laces. This style of CPAP prong is non-restrictive and lightweight.

  The Bubble CPAP Nasal T bar prong is intended to use during CPAP treatment in different sizes according to baby. Continuous positive airway pressure (CPAP) is a form of positive airway pressure ventilator, which applies mild air pressure on a continuous basis to keep the airways continuously open in people who are not able to breathe spontaneously on their own. Nasal T bar prongs are used as the nasal interface between the circuit and the infant's airway.

Available in 5 different sizes of Nasal T-Bar Prongs - size 0, size 1, size 2, size 3, and size 4

- **Nasal prongs for the Ventilator**

  CPAP Nasal Prongs has a pair of short tubes positioned directly in the infant's nares to deliver the prescribed gas flow from the ventilator (CPAP mode).

  Available in three different sizes based on baby's weight: Large, Small and X-Small.

- **Flow Tube**

  Flow tube is an interface for the bubble CPAP therapy that is used to connect nasal masks or nasal prongs and breathing circuit. Flow tube fixing pillow prevents the compressions caused by flow tube on the sensitive skin of the newborn as they cushion the head.

- **Resuscitation mask**

  Resuscitation 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. Available in 3 different sizes (size 00, size 0, and size 01).

1.10 Unique Device Identification (UDI Carrier)

#	Device Variant	Device Identifier (DI)	Production Identifier (PI)
1.	CPAP Nasal prongs	(01) 08908003989754	(10) XX-XX-XX-XX-XX-XXXX (Product code + YY + MM + 4 digit serial number)

Draft UDI label:

Section 2: Installation

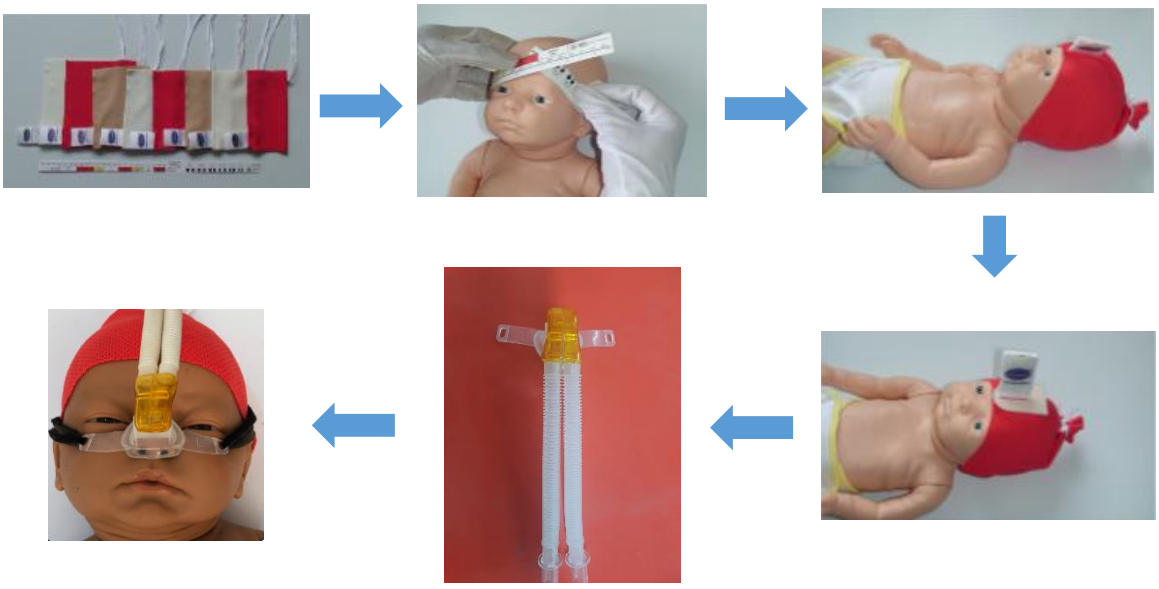
2.1 Set Up

After removal from the shipping carton, inspect the Patient Interface for any signs of damage which may have occurred during shipment. File a damage claim with the shipping carrier if damage has occurred.

2.2 Patient Interface Connection

2.2.1 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

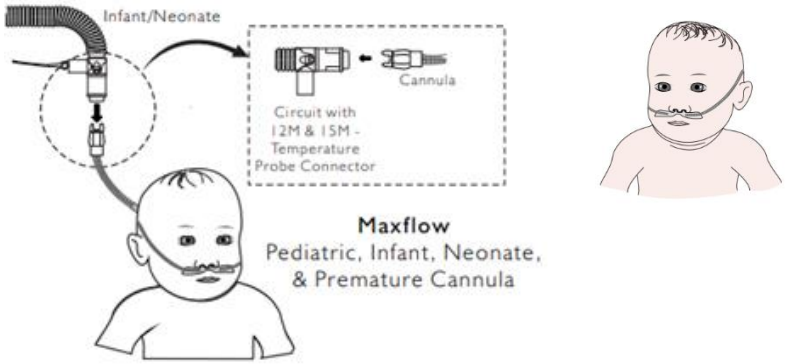


1. An infant's head size is measured using a measuring tape.

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.

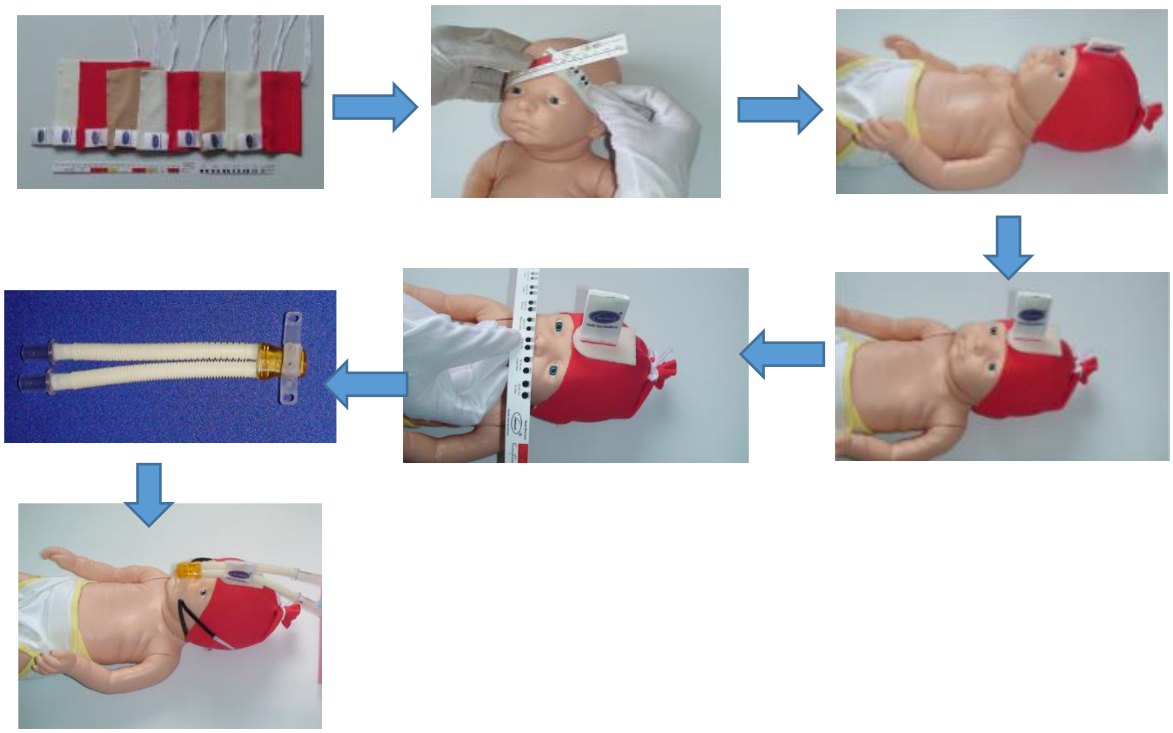
2.2.2 Nasal Cannula

1. The adhesive stickers on the Wang pads are removed.
2. The Wang pads must be stuck properly on the cheeks of infant.
3. The nasal cannula are carefully placed in both nares & on the Wang pads.
4. The cannula should be placed in a way such that there are no leaks.
5. If adhesion is lost, replace the Wang pads.
6. Make sure the cannula are not kinked or folded over.
7. Connect the Swivel connection tightly into the breathing circuit.



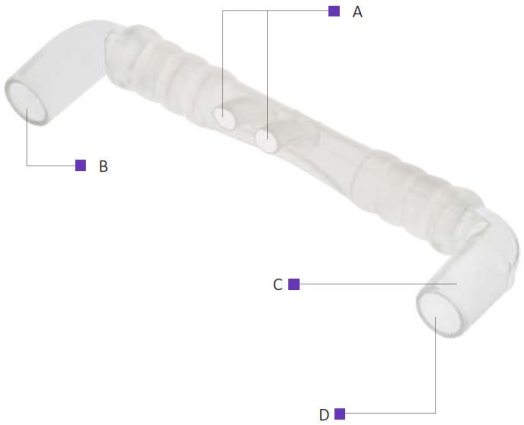
2.2.3 Nasal Prongs

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

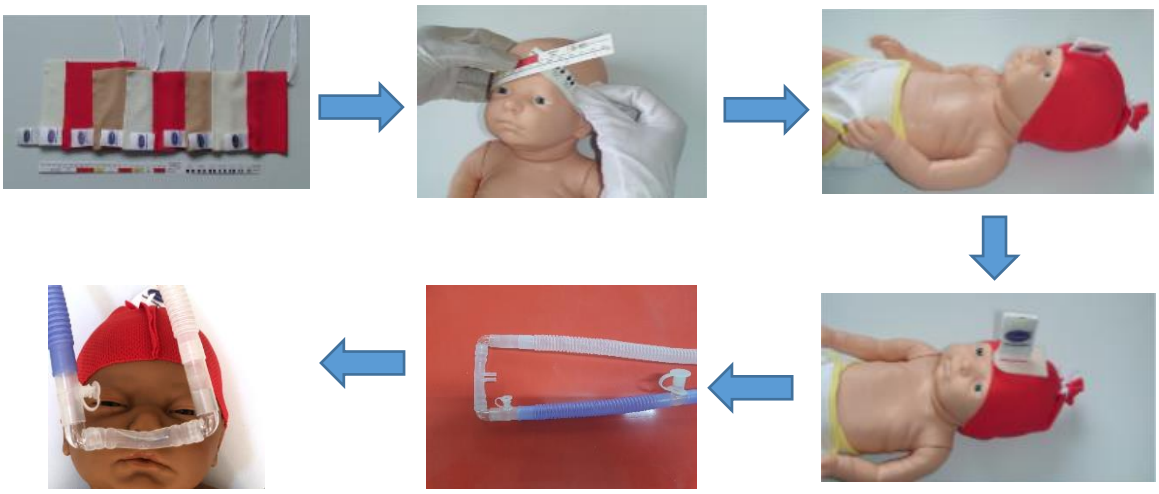


1. An infant's head size is measured using a measuring tape.
2. Choose the correct size of head bonnet according to the infant's head size.
3. Fix the bonnet onto the baby's head, completely covering the ears with the back edge of the bonnet at the base of the neck. The front edge of the bonnet should 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.

2.2.4 Nasal T-bar Prongs



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



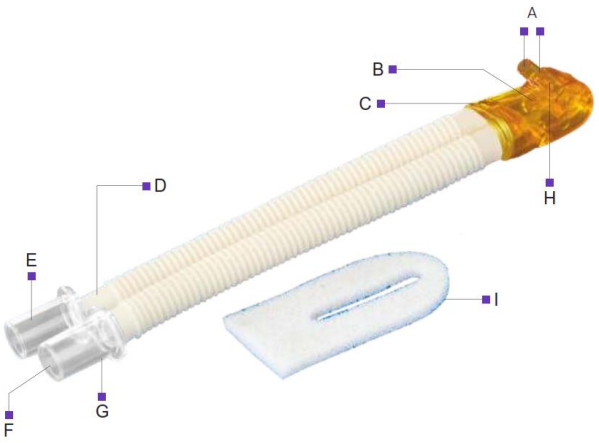
1. Measure the baby's head circumference with a head bonnet selection guide. Choose the correct size bonnet.
2. Slip the bonnet onto the baby's head completely covering the ears, with the back edge of the bonnet at the base of the neck and the front edge of the bonnet should be just above or on the eyebrows.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

2.2.4 Nasal Prongs for Ventilator

A- To patient nares.
B - To be connected to head bonnet.
C - To be connected to breathing circuit

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 prongs which cannot cause blockage of nostrils.
4. Connect CPAP nasal prong to heated humidified gas source and ventilator via breathing circuit.
5. Gently insert CPAP nasal prong in infant's nares.
6. Nasal prong orientation should be nearly perpendicular to the horizontal plane to prevent excessive pressure on the nose. Be careful that the unit does not distort shape of the nose. Gradually increase system pressure until prescribed pressure is achieved. Check for sufficient flow from the gas source and leaks.

2.2.5 Flow Tube



A –To Nasal Prongs/Nasal M
B –Inhalation & Exhalation gas flow divider
C – Rigid Body
D – Non-Kinkable tube
E – To Expiratory limb
F –Connector 10M
G –To Inspiratory Limb
H – Flexible Connector
I – Flow tube fixing pillow

- Flow Tube is taken and Nasal Prongs/Masks are attached to the Nasal Prong Holder.
- After the placement of Head Bonnets, the Flow Tube fixing pillow is placed inserted in the Velcro strip of the Bonnet.
- The Flow Tube is placed over the fixing pillow that is helpful in relieving the compressions on the Infant's head.
- After fixing the flow Tube in a V-shaped manner, the breathing circuits are connected to the Flow Tube Holder.
- The fittings between the Flow Tube and Breathing Circuit should be sealed tight and without leaks.
- The Breathing Circuit is placed lower from the level of Flow Tube in order to minimize the condensation

2.3 Pre-use Check Instructions

- Before using the nice Neötech Patient Interface, read this entire manual. Attempting to use this without a thorough understanding of its operation may result in patient or user injury.
- Do not perform the Pre-use Check Instructions (Mechanical) while a patient occupies the Patient Interface.
- Complete the "Pre-use Check Instructions" section of this manual before putting into operation. If the Patient Interfaces in any portion of the Pre-use Check Instructions it must be removed from use.

2.3.1 Overall Appearance

Check the overall appearance of the Patient Interfaces. There should be no obvious damage and color change

Section 3: Operation

3.1 Principle of Operation

Patient Interface deliver the gas during CPAP, High Flow Oxygen Therapy and other Respiratory Therapy System, by placing the patient interface like nasal prongs, nasal mask, nasal cannula ,Nasal T-bar prongs which are placed over the baby nasal area. When the baby have low surfactant, the lungs collapse and it make difficult to breathe. This leads less Oxygen supply to internal organs
A Bubble CPAP nasal mask is triangular in shape and sits on the face around the nose. It's held in place by head gear/head bonnet (stretchy laces that go around the nose) using hookable laces during the CPAP treatment in different sizes with respect to baby.

According to the infant, the patient interface is selected to deliver the gas effectively. During the respiratory therapy, the patient interface will be connected according to selection of interface which is lightweight to connect to patient nostril. It will deliver the supplemental oxygen mixture at selected flow rate according to the respiratory need. Patient interfaces plays a vital role in maintaining the PEEP level of the patient. Patient interfaces include, Flow tube and Nasal prongs /mask. Flow tube is the interlink between the breathing circuit and nasal prongs/mask. Whereas head bonnet helps to hold the nasal prongs/mask to the patient's nostril position firmly until the treatment. Nasal prongs or mask shall be used at the final patient end to deliver the gas from the device. Nasal prongs are fitted directly into the patient nares. Nasal mask will cover the entire nose region.

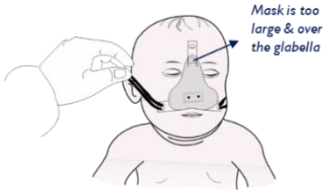
3.2 Measures to be noted while using Patient interfaces

3.2.1 Nasal Masks

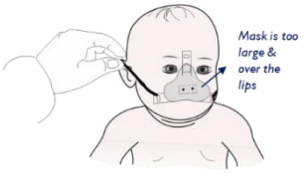
1. The clinician must select the correct size of mask for the infant.
2. Check the tension on the hook able laces. If they are too tight, they collapse the mask.
3. After the Interface is initially set-up, continue to monitor and assess it throughout the treatment.
4. Some infants may be on CPAP therapy for several weeks, and the correct size of the interface may change.
5. Re-evaluating the interface size is an important part of routine patient assessments.
6. Attention to this detail reduces the potential for skin/septal injury and ensures that the prescribed CPAP level is achieved and maintained for optimal therapy.

Improper mask size

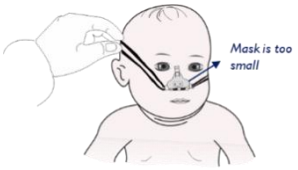
a) The mask is too large if the top of the mask rests on the glabella, the area between the eyebrows.



b) The mask is too large if the bottom of the mask covers the infant's lips.



c) The mask is too small if the mask does not cover the perimeter of the nose and the bottom of the mask occludes nares.



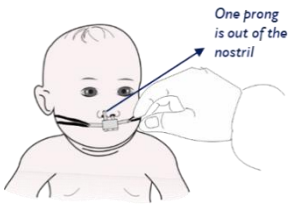
3.2.2 Nasal Prongs

1. The clinician must select the correct size of prongs for the infant.
2. Ensure the hookable lace tension is not too tight. If they are too tight, they collapse the prongs.
3. After the Interface is initially set-up, continue to monitor and assess it throughout the treatment.
4. Some infants may be on CPAP therapy for several weeks, and the correct size of the interface may change.
5. Prongs that are too small may lead a clinician to over-tighten the fixating laces to eliminate a leak.
6. Over-tightening or inserting the prongs too deep may lead to pressure sores or nasal dilation.
7. 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.

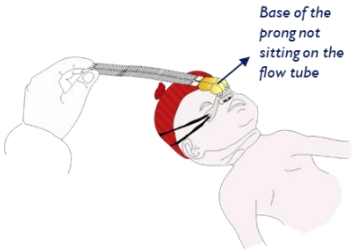
For CPAP Nasal prongs

1) Incorrect nasal prong position

a) One prong is not in the nostril.
Corrective action: Remove the prongs and reinsert the prong tips into each nostril.



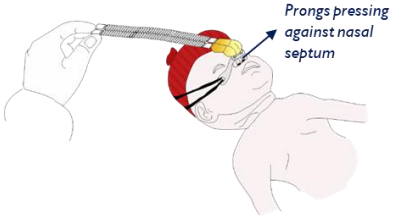
b) The base of the prongs is not sitting properly on the Flow Tube.
Corrective action: Remove the interface and reapply it while ensuring the interface is evenly seated.



2) Hook able laces are too tight.

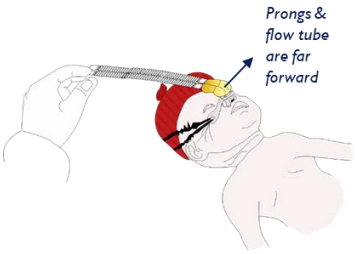
c) The base of the interface is resting on the apex, and the prongs are pressing against the nasal septum.

Corrective action: Only the upper portion of the prongs should be in the nares. Ensure the flow tube is properly positioned over the nares.



3) Improper flow tube alignment with the infant's nose

d) The nasal prong and flow tube placement are too far forward, causing the prongs to collapse.



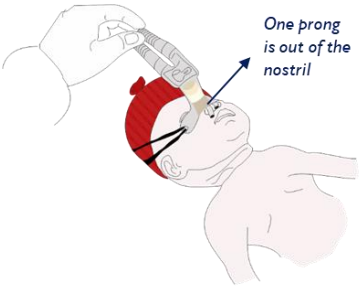
e) The head bonnet is positioned too far back on the forehead, causing the prongs to kink.

Corrective action: If the flow tube is positioned in front of the nose, the prongs bend. Loosen the securing lace on the support block and reposition the flow tube and nasal prongs over the infant's nares. If the flow tube is positioned incorrectly, it affects the angle of the prongs and causes them to bend or collapse. Ensure the head bonnet is properly placed above the brow line. Loosen the hookable lace and slide the flow tube forward until the flow tube head is perpendicular to the apex of the infant's nose.

For Ventilator Prongs

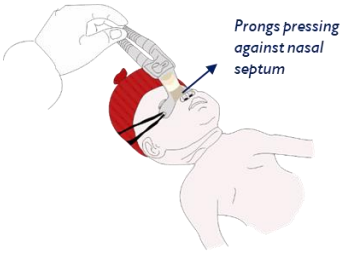
1) **Incorrect nasal prong position**
a) One prong is not in the nostril.

Corrective action: Remove the prongs and reinsert the prong tips into each nostril.

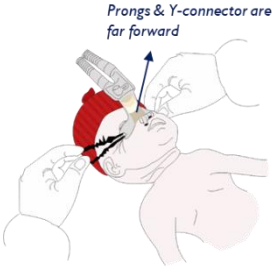


2) **Hookable laces are too tight**
b) The base of the interface is resting on the apex, and the prongs are pressing against the nasal septum.

Corrective action: Only the upper portion of the prongs should be in the nares. Ensure the Y-connector is properly positioned over the nares.



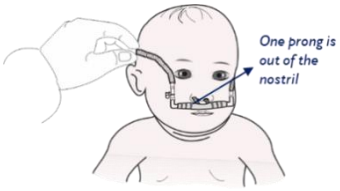
3) **Improper Y-connector alignment with the infant's nose**
c) The nasal prong and flow tube placement are too far forward, causing the prongs to collapse



3.2.3 Nasal T-bar prongs

1. The clinician must select the correct size of the T bar prongs for the infant.
2. After the Interface is initially set-up, continue to monitor and assess it throughout the treatment.
3. Some infants may be on CPAP therapy for several weeks, and the correct size of the interface may change.
4. Prongs that are too small may lead a clinician to over-tighten the breathing circuit to eliminate a leak.
5. Over-tightening or inserting the prongs too deep may lead to pressure sores or nasal dilation.
6. Use the correct nasal T bar prong size. Prongs that are too large cause nares blanching.
7. If the prongs are too small, they may go too far up the nose and press up against the septum.
8. Ensure the prong tension is not too tight.
9. Place the breathing circuit according to the nasal T bar prong placement.

1) Incorrect Nasal T Prong position
   a) One prong is not in the nostril.
   Corrective action: Remove the prongs and reinsert the prong tips into each nostril.



2) Improper Breathing Circuit alignment
   b) The Nasal T bar Prong and Breathing circuit placement are too far forward, causing the T bar prongs to collapse.
   Corrective action: If the breathing circuit is positioned on one side and is leaning, the prongs bend. Loosen the L-tube on the cheeks and nasal prongs over the infant's nares. Place the breathing circuit evenly on both sides.

3.2.4 Flow Tube

1. Ensure that the Flow Tube and its connector called the Flow Tube Holder is without any damages.
2. Check the connections of the Flow Tube with the Prongs or Masks and Breathing Circuits.
3. Make sure the Flow Tube is inserted properly in the velcro strip and is seated evenly over the fixing pillow.
4. After the Interface is initially set-up, continue to monitor and assess it throughout the treatment.
5. The Flow Tube is placed correctly on the head and not over the eyes.
6. Follow the steps that are given in the Interface Setup Guide.

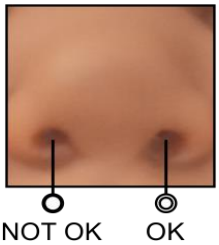
3.2.5 Head Bonnet

1. The clinician must select the correct size of Head Bonnet for the infant according to the head measuring tape.

2. Check the tension on the hookable laces. If they are too tight, they will collapse the mask.
3. After the Interface is initially set-up, continue to monitor and assess it throughout the treatment.
4. Some infants may be on CPAP therapy for several weeks, and the correct size of the interface may change.
5. Ensure the Flow Tube is inserted properly in the Nasal Masks or Prongs and is fixed properly on the head bonnet using Flow Tube Fixing Pillow.
6. The Head Bonnet is placed correctly on the head, above or below eyebrows and not over the eyes.
7. Follow the steps that is given in the Interface Setup Guide.

3.2.6 Nasal Cannula

1. Make sure the Cannula does not form a seal, leave some space in the nares.
2. A clear gap must be visible around each cannula.
3. See that the cannula fits the baby and use accordingly.
4. Cannula can become unattached if not used with the Wang pads (only for Maxflow kids and Hiflex kids).
5. Ensure that the Cannula is connected with the breathing circuit correctly.



3.3 Disposing of the Patient Interfaces

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

Section 4: Specification

Nasal Cannula	
Maxflow/Hiflex Kids (Pediatric, Infant, Neonate & Premature Cannula)	
Flow range	
Premature	4 to 9 LPM
Neonates	4 to 10 LPM
Infants	4 to 15 LPM
Pediatrics	4 to 15 LPM
Maxflow adult nasal cannula	
Flow range	
Small	10 to 40 LPM
Medium	10 to 60 LPM
Large	10 to 60 LPM
Inspiratory resistance at 60 LPM	>13 cmH2O
Leakage at 60 LPM	>9 LPM
Nasal Prongs	
CPAP Nasal Prong size	
Micro	Baby Weight Up to 500 grams
Small	Baby Weight Up to 500-1000 grams
Medium	Baby Weight Up to 1000-1500 grams
Medium Wide	Baby Weight Up to 1000-1500 grams
Large	Baby Weight Up to 1500-2200 grams
Large Wide	Baby Weight Up to 1500-2200 grams
X-Large	Baby Weight Up to 2200-3000 grams
Nasal T-Bar Prongs	
Size 0	Baby Weight Up to <700 grams
Size 1	Baby Weight Up to <700 grams
Size 2	Baby Weight Up to 700-1250 grams
Size 3	Baby Weight Up to 1250-2000 grams
Size 4	Baby Weight Up to 2000-3000 grams
Nasal Mask – Component Weight	
Small	2.0 Grams
Medium	2.4 Grams
Large	2.6 Grams
X-Large	3.5 Grams
Flow Tube	
Flow Tube	7 mm ID corrugated tube
Environment	
Operating Temperature	15^{o}C to 35^{o}C
Operating Humidity	50% to 90%
Quality Standard Adherence	
Quality Management System	ISO 13485:2016
Biological evaluation of medical devices	ISO 10993-1:2018 ISO 10993-10:2021

Section 5: For Complaints/Adverse Events/Comments/Feedback

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

In case of adverse events, fill the below details:

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

For comments:

For Complaints:

For Feedbacks:

Kindly fill the above and send the same

From:

_____

_____

_____

To:
The Marketing In-charge
nice Neotech Medical Systems Pvt. Ltd.
No, 85. Krishna Industrial Estate,
Vanagaram, Mettukuppam,
Chennai-600095. Tamil Nadu, INDIA.
Ph: 91-44-24762594, 24764608

Email: marketing@niceneotech.com
Toll Free No. 1800-425-2594 (India only)

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

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