nice Neötech Medical Systems Pvt. Ltd.

Breathing Circuits

Infant/Neonatal Breathing Circuit

Adult Breathing Circuit

Pediatric Breathing Circuit

T-piece Breathing Circuit

OPERATING/INSTALLATION MANUAL

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

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nice Neotech Medical Systems Pvt. Ltd.

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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 and repaired 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.

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

Declaration for Languages

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

Declaration for RoHS

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

Model Descriptions:
1. Infant & Neonatal Breathing Circuit

BC 510	Infant/Neonatal Heated wire Breathing Circuit for Bubble CPAP
BC 515	Infant/Neonatal Heated wire Breathing circuit for Ventilator with expiratory limb water trap
BC 520	Infant/Neonatal Dual Heated wire Breathing circuit for Ventilator
BC 525	Infant/Neonatal Heated wire Breathing circuit for CPAP T bar prong
BC 530	Infant/Neonatal Heated wire Breathing circuit for CPAP T bar prong with chamber
BC 535	Infant/Neonatal Heated wire Breathing circuit for Ventilator with chamber and expiratory limb water trap
BC 540	Infant/Neonatal Dual Heated wire Breathing circuit for Ventilator with chamber
BC 545	Infant/Neonatal Heated wire Breathing circuit for SLE Ventilator with expiratory limb water trap
BC 550	Infant/Neonatal Heated wire Breathing circuit for Ventilator with chamber and expiratory limb water trap
BC 555	Infant/Neonatal Heated wire Breathing Circuit for Bubble CPAP with chamber
BC 570	Bubble CPAP Combo Kit

BC 575	Bubble CPAP Combo Kit with Bubble Generator
BC 580	High flow oxygen therapy breathing circuit
BC 585	High Flow Oxygen Therapy combo kit

2. Adult Breathing Circuit

BC 610	Adult Single heated heater wire breathing circuit, and water trap
BC 615	Adult Dual limb on non-heated disposable breathing circuit with inspiratory and expiratory water trap
BC 620	Adult Dual heated wire breathing circuit with water trap
BC 625	Adult Single limb single heated wire breathing circuit
BC 630	High Flow Oxygen Therapy combo kit
BC 635	Adult Breathing Circuit for Ventilator with Heated Wire, Exhalation Limb Water Trap and Humidification chamber
BC 640	Adult Breathing Circuit for Ventilator with Dual Limb Water Trap and Humidification chamber
BC 645	Adult Breathing Circuit for Ventilator with dual heated wire and Humidification chamber
BC 650	Adult Single Limb Breathing Circuit with Heated Wire and Humidification chamber

3. Pediatric Breathing Circuit

BC 710	Pediatric Single heated wire breathing circuit, and water trap
BC 715	Pediatric w/o heated wire breathing circuit and water trap
BC 720	Pediatric Dual heated disposable breathing circuit with water trap
BC 725	Pediatric Single limb heated wire breathing circuit
BC 730	Pediatric Breathing Circuit for Ventilator with Heated Wire, Exhalation Limb Water Trap and Humidification chamber
BC 735	Pediatric Breathing Circuit for Ventilator with Dual Limb Water Trap and Humidification chamber
BC 740	Pediatric Breathing Circuit for Ventilator with dual heated wire and Humidification chamber
BC 745	Pediatric Single Limb Breathing Circuit with Heated Wire and Humidification chamber

4. T-Piece Resuscitator Circuit

50-05-154	T-Piece Resuscitator Circuit with Nebulizer Port
50-05-150	T-Piece Resuscitator Circuit with Heated wire and Nebulizer Port.

Definition

Breathing Circuit	Tubing that carries respiratory gases to and from the patient
Heater Wire	Wire inside the breathing circuit which heats the respiratory gases
Bubble CPAP	Bubble CPAP System for use with spontaneously breathing infants requiring respiratory support in hospital intensive care units.
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

Chamber	Device that allows gas to be heated and humidified by passing it over heated water
Component	A breathing circuit that uses connectors between two joints to transport respiratory gases to and from the patient.
Bubble Generator	Bubble generator is intended to generate bubbles and maintain the water level and control the set PEEP.
Nasal T-Bar Prongs	Nasal T-bar prongs is intended to connect the breathing circuit and the patient's nostril to deliver the gas to the patient.
Dual Heated Breathing Circuit	A breathing circuit that is heated by means of heater wires, in both the expiratory and inspiratory limbs
Single Heated Breathing Circuit	A breathing circuit that is heated by means of a heater wire, in only the inspiratory limb
Exhalation Limb Water Trap	A water trap in the expiratory limb reduces possible leaks and water condensation

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

- The disposable breathing circuit is intended to be used with single Patient.
- Breathing Circuit is intended to use for a maximum of 7 days.
- Choose the breathing circuit after checking the patient group. Observe your doctor's instructions.
- The used breathing circuit should be properly disposed of according to local legislations.
- No alterations are permitted in breathing circuit.
- Do not crush the circuit tube.
- Monitor the gas flow and keep it at the proper level for the patient.
- Avoid inserting additional heating wire within the tubing.
- Avoid pulling, twisting, or kinking the tube.
- Do not cover the circuit with materials such as blankets, towels or bed linen.
- Regularly observe that the water is feeding into the humidification chamber.
- Check all connections are tight before use and after adjustment
- Regularly observe the water level in the Bubble generator and refill the Bubble generator if the water level drops below minimum water level line.

Section B: Cautions

- Do not use this circuit in the event of contamination or if it is damaged.
- Check the patient's breathing circuit and artificial airway for leaks and/or disconnection.
- Check the gas flow and maintain them according to patient requirements
- Make sure that the interfaces are fitted properly in the breathing circuit.
- After the breathing circuits are connected in the corresponding ports, check whether the connections are not loose and that they are intact.
- After the breathing circuits are connected in the corresponding ports, check whether the connections are not loose and that they are intact.
- Use in accordance with the manufacturer's instructions.
- If the product has passed its expiration date, do not use it.
- Regularly check the water traps and the Breathing circuit hoses for water accumulation. Empty as required.
- Regularly observe the Bubble generator for bubbling. If bubbling is not observed check for a minimize air leaks in the system and at the patient end.

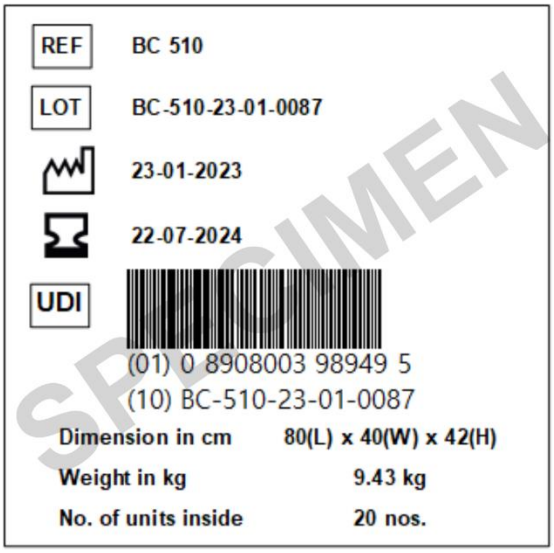
Section C: Symbols & Label

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

Breathing circuits are intended to direct the flow of medical gas (Air/Oxygen) with optimum humidity from the respiratory devices to the patients.

1.2 Indication

Used along with CPAP System, Ventilator and High Flow Oxygen Therapy and other respiratory therapy Equipments.

1.3 Contraindication

No Side Effects

1.4 Side effects

Prolonged use of breathing circuits beyond its expiration time, may cause skin damage

1.5 Target Population

Premature, Neonates, Infants, Pediatric and Adults.

1.6 Device Intended User

Anaesthetist & Neonatologist

1.7 Working Principle

An arrangement of components known as a breathing circuit connects the patient's airway to a medical device that controls the composition of the gas mixture to create an artificial environment for the patient to breathe into and out of. There are various breathing circuit designs, each with a unique mechanism for providing a source of fresh gas flow, a length of breathing tubing for the gas to go through, and Pressure relief valve that release the excess pressure from input supply gas, thus ensuring safety to the patient during respiratory therapy. Inspiratory and expiratory limbs that transport respiratory gases to and from the patient are included in breathing circuits. It has heater wire to prevent condensation and can be used as a humidifier in both invasive and non-invasive modes. In the case of a ventilator, the inspiratory limb is connected to the humidifier, and the expiratory limb is connected to the expiratory port of the ventilator. According to the needs of the patient, either a single heated wire, a dual heated wire, or a non-heated wire is used.

1.8 Product Description

The breathing circuit comprises of single heated wire breathing circuit and dual heated wire breathing circuits along with humidification chamber, preset pressure manifold and bubble generator.

The Breathing Circuit is intended to use during CPAP, Ventilator and High Flow Oxygen Therapy as an interface between Nasal Masks/Prongs, Nasal Cannula and the device used. Assembly of components which connects the patient's airway to Bubble CPAP, Ventilator, or High Flow Oxygen Therapy creating an artificial atmosphere, from and into which the patient breathes.

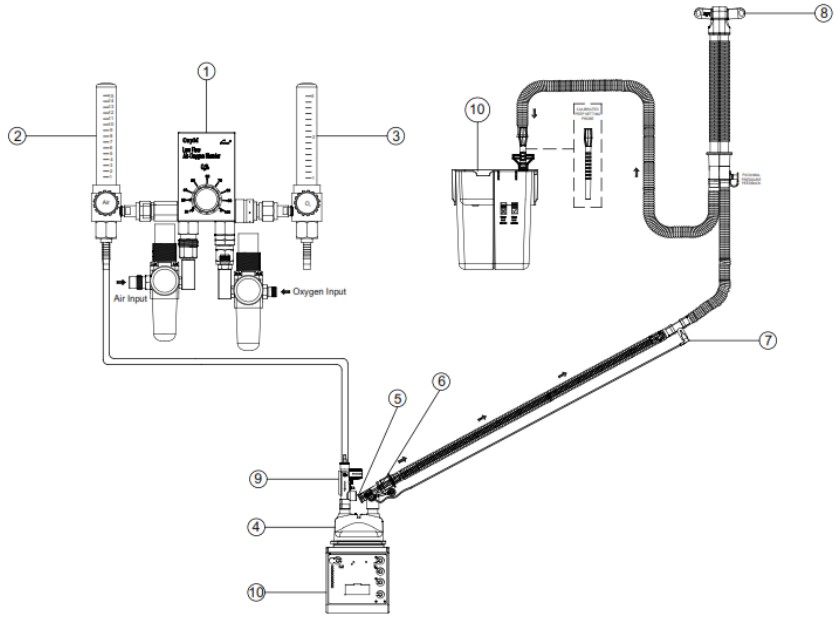
The Inspiratory limb delivers the fresh gas from the machine to the patient and the Expiratory limb carries expired gas from the patient and vents it to the atmosphere through the expiratory valve/port during Ventilation or is connected to a Bubble Generator during CPAP. In High Flow Oxygen Therapy, only the inspiratory limb is connected to the patient.

The gas supply tube comes from the blender output and flow meter with control to the humidification chamber. Inspiratory tube with heater wire from Humidifier chamber output goes to the patient.

1.9 Intended combination devices:

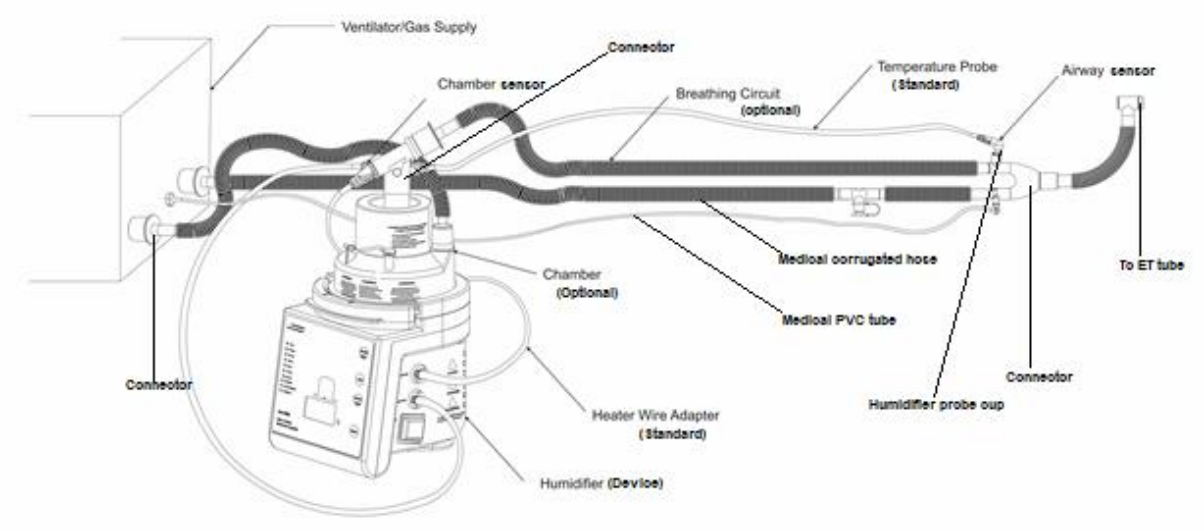
- nice 5060 series Bubble CPAP System and other similar devices
- nice 5020 series Infant T-piece Resuscitator and other similar devices
- Infant/Pediatric/Adult Ventilator Systems

Connection descriptions:



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

- **Ventilator and other similar devices:**



1.10 Unique Device Identification (UDI Carrier)

#	Device Variant	Device Identifier (DI)	Production Identifier (PI)
1.	BC 510	(01) 08908003989495	(10) BC-XXX-XX-XX-XXXX (Product code + YY + MM + 4 digit serial number)

Draft UDI label:

Section 2: Installation

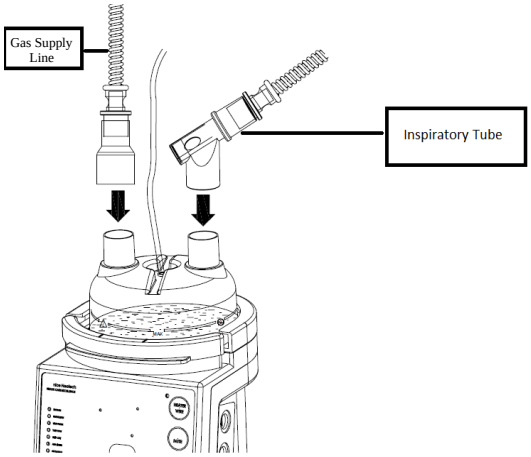
2.1 Set Up

After removal from the shipping carton, inspect the Breathing Circuit and all necessary connectors, for any signs of damage which may have occurred during shipment. File a damage claim with the shipping carrier if damage has occurred.

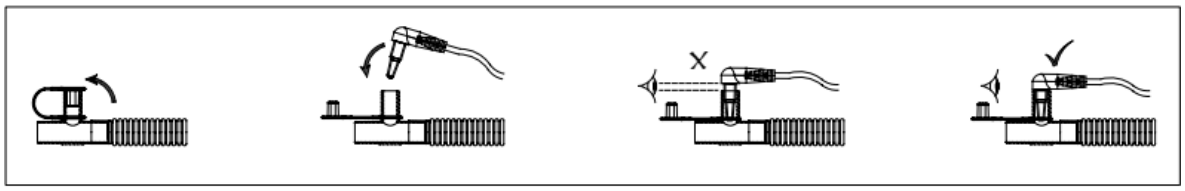
2.2 Breathing Circuit Connection

- **Directions for Use (Breathing Circuit)**

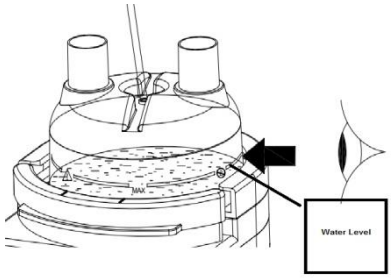
1. Remove the product from the package and inspect for damage. If present, or if the package has been opened, do not use the product.
2. Insert the expiratory and inspiratory tube (picture 1) in the humidifier chamber connector as per the picture 4.
3. Insert the airway probe in the airway sensor port of the breathing circuit (refer picture 2).
4. To decrease possible bacterial contamination, do not reuse the breathing circuit.
5. Water levels to be ensured as per the markings provided in the humidifier chamber (refer picture 3).



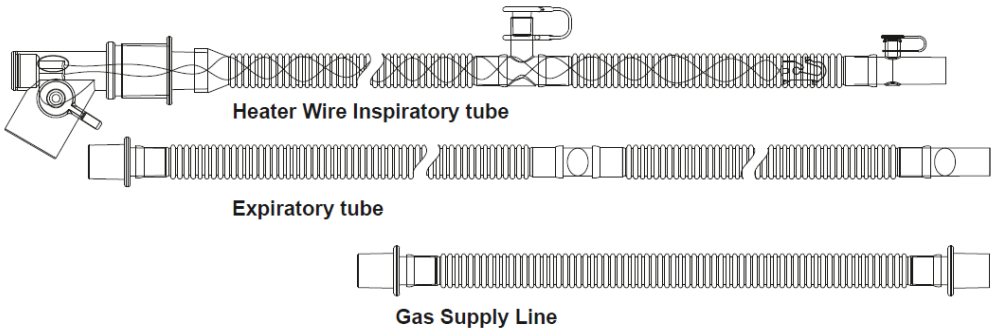
Picture 1



Picture 2



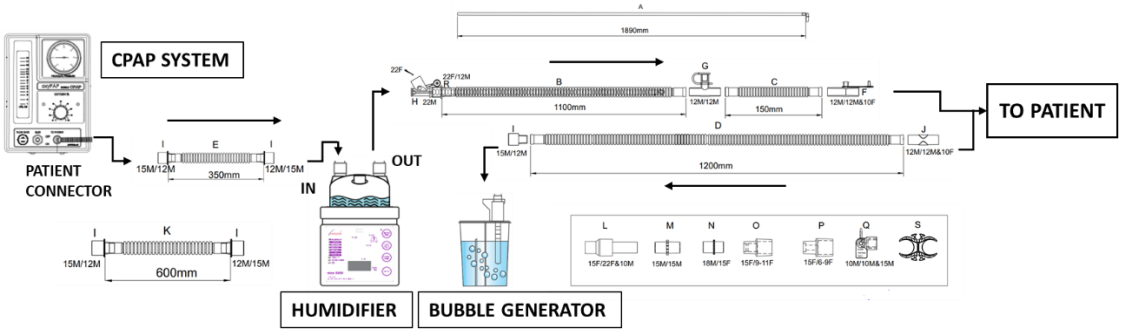
Picture 3



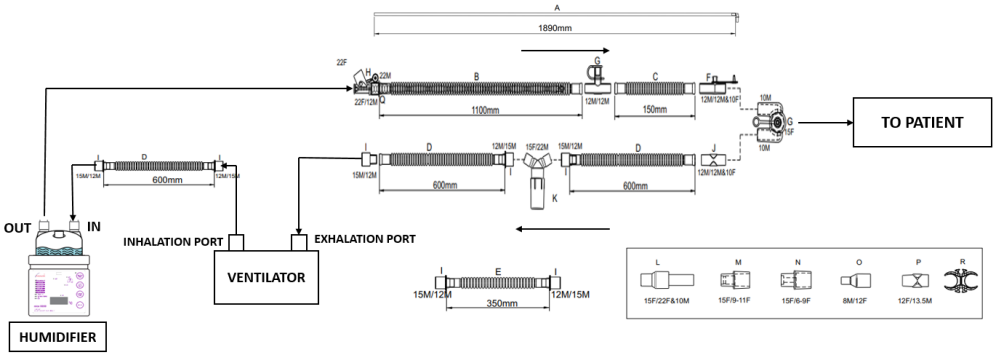
Picture 4

2.2.1 Infant/Neonatal Breathing Circuit

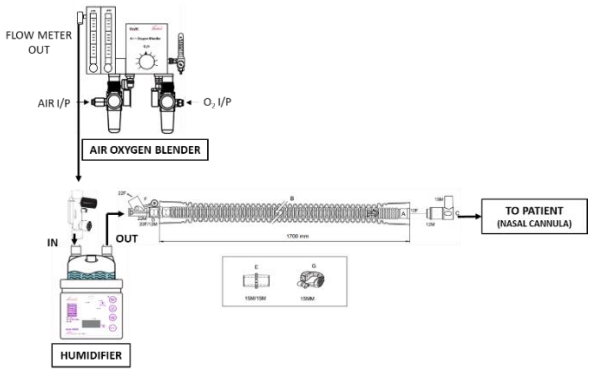
- **Bubble CPAP BC ->BC 510,BC 525,BC 530,BC 555,BC 570,BC 575**



- **Ventilator BC ->BC 515,BC 520,BC 535,BC 540,BC 545,BC 550**

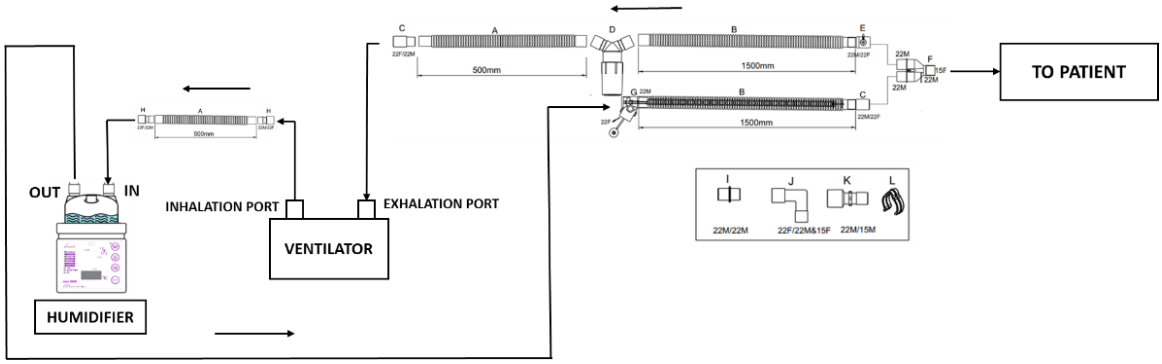


- **High Flow Oxygen Therapy BC ->BC 580,BC 585**

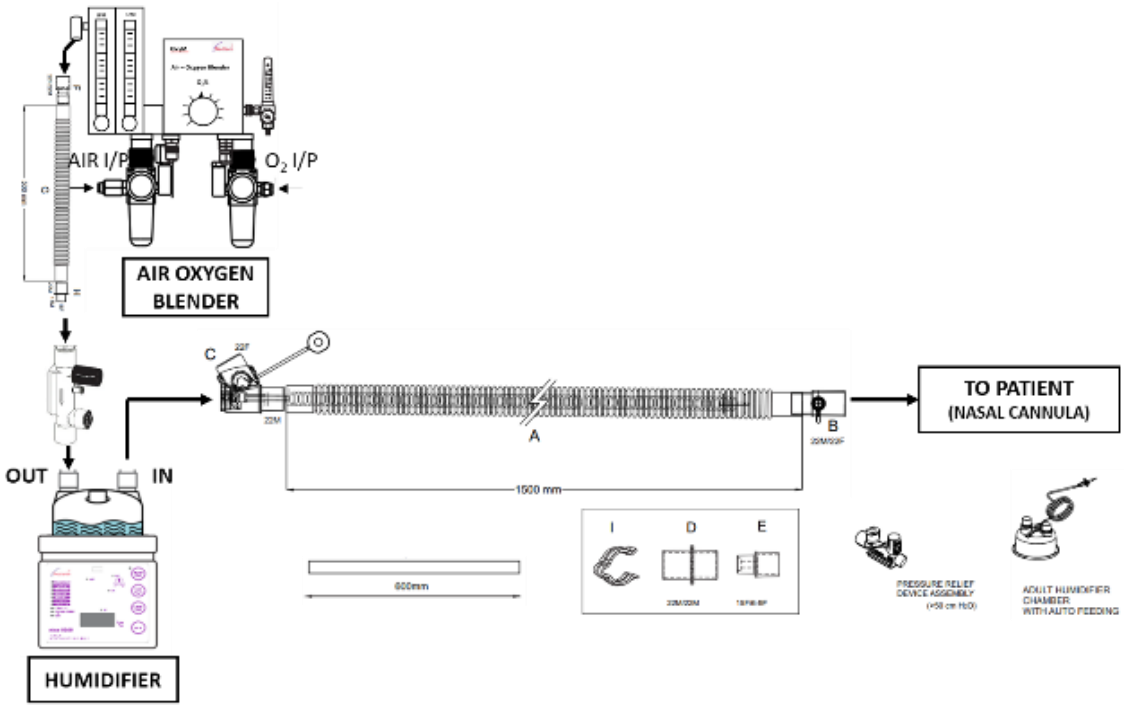


2.2.2. Adult Breathing Circuits

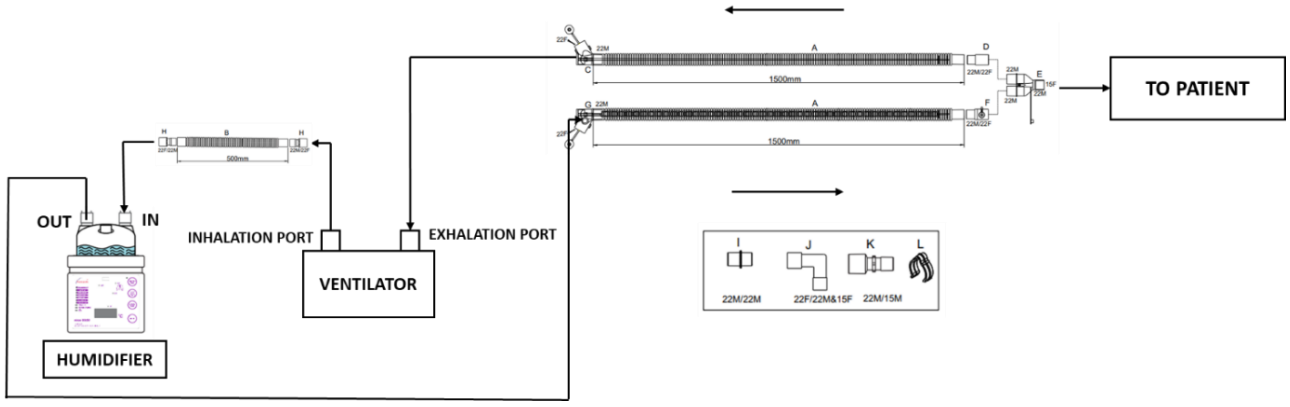
- **Ventilator BC ->BC 610,BC 615,BC 620,BC 635,BC 640,BC 645**



- **High Flow Oxygen Therapy BC ->BC 630**

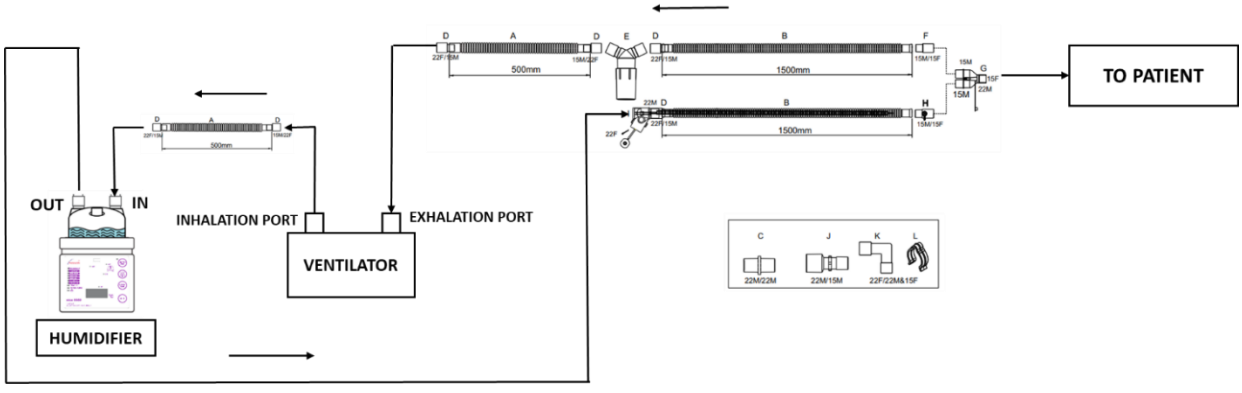


- **Adult BC ->BC 650,BC 625**

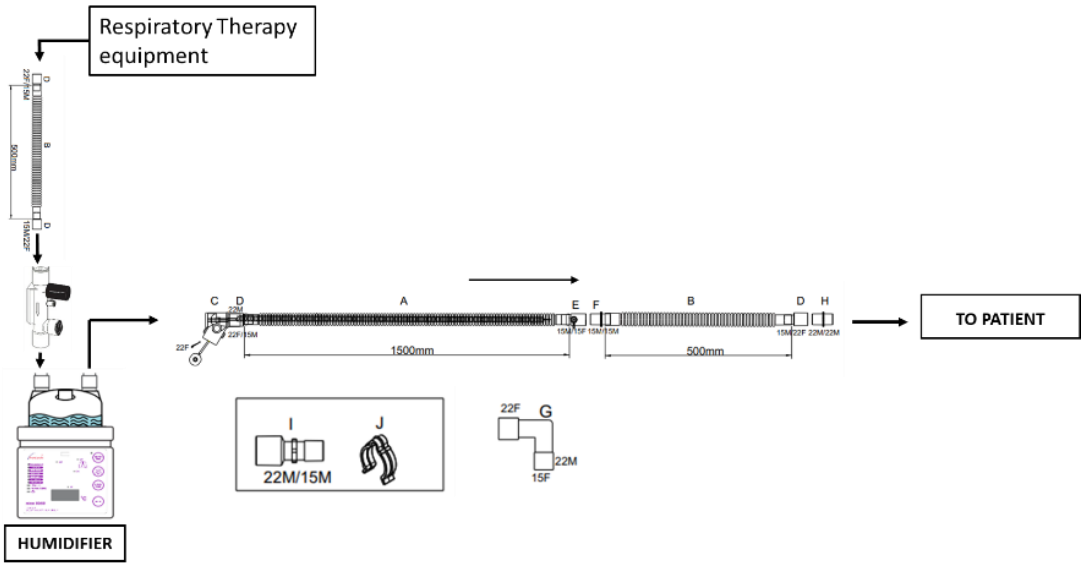


2.2.3. Pediatric Breathing Circuit

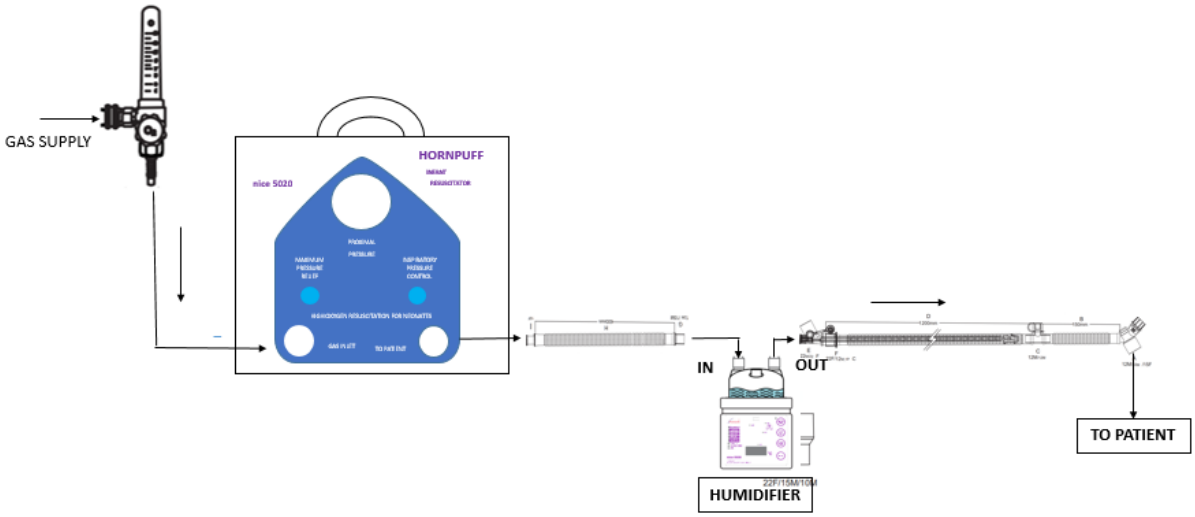
- **Ventilator BC ->BC 710,BC 715,BC 720,BC 730,BC 735,BC 740**



- **Pediatric BC ->BC 725,BC 745**



2.2.4 T-Piece Resuscitator Circuit
50-05-150, 50-05-154



2.3 Pre-use Check Instructions

Warning

- Before using the nice Neötech Breathing Circuit, 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 Breathing Circuit.
- Complete the “Pre-use Check Instructions” section of this manual before putting into operation. If the Breathing Circuit fails 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 Breathing Circuit. There should be no obvious damage.

2.3.2 Disposable chamber Pre-use Check Instructions

- Check whether the base of the chamber is locked properly to the humidifier unit.
- Water should be feed as per the instruction provided in Section 3.2
- Check there is no leaks in the chamber and also in the connections

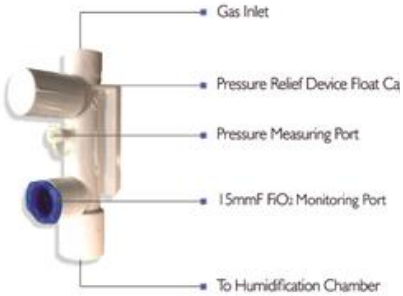
Section 3: Operation

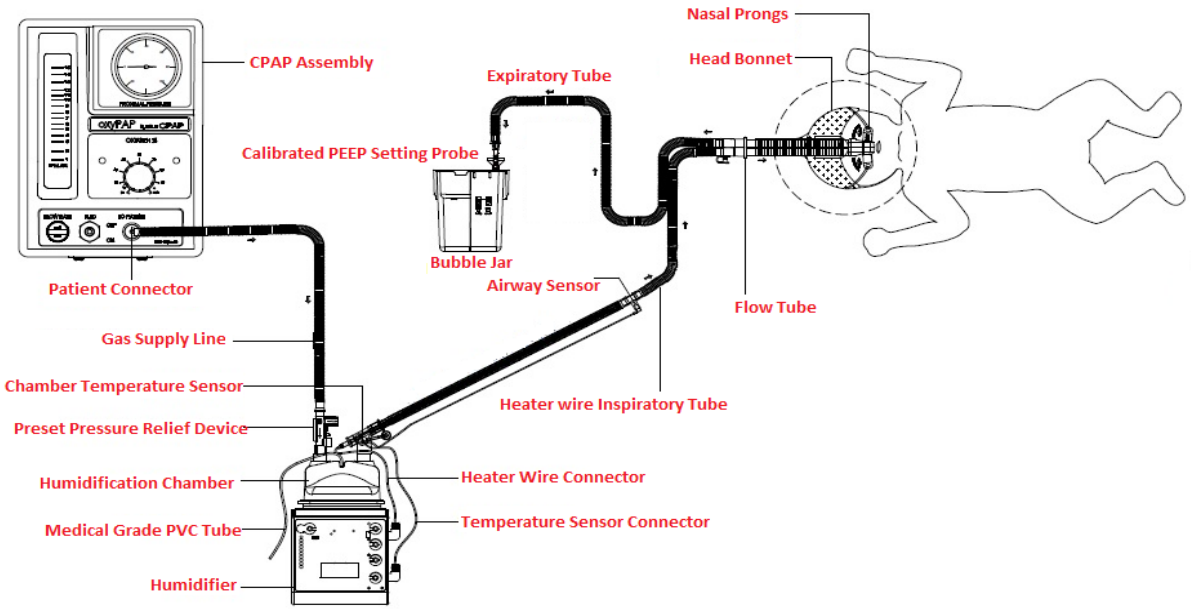
3.1 Principle of Operation

When a patient is receiving CPAP, ventilation therapy, or high flow oxygen therapy, a breathing system, also known as a breathing circuit, is utilized to give oxygen to the patient. To provide a source of fresh gas flow, a length of breathing tubing to route the gas, and an adjustable pressure relief valve to control pressure within the system, numerous breathing system types are in clinical use.

The breathing circuits are designed for Infants/Neonates, Pediatric, Adult. It have two limb expiratory limb and inspiratory limb which will be connected with the patient Interfaces. Additionally offered are a present pressure manifold, a bubble generator, a humidification chamber. The usage of a preset pressure manifold, which is connected to a humidification chamber, allows for the maintenance of the inspiratory preset gas pressure provided to the patient. Depending on the patient population, the pressure limiting relief can be set at 20 cm of water, 40 cm of water, or 50 cm of water. The humidifier chamber sits on top of the heater plate. The chamber is designed with a Aluminium base plate, which transfers the heat and hold the temperature inside the chamber. Water to be filled up to the mark when water level is decreased from the legible water line. A mechanical float closes the water inlet port once the level reaches full and the output of the humidification chamber is connected with Breathing circuit (Inspiratory Limb).The bubble generator maintains the positive end expiratory pressure (PEEP). The exhalation port of bubble generator shall be fixed at the desired positive airway pressure value between 3cm H2O and 10 cm H2O.

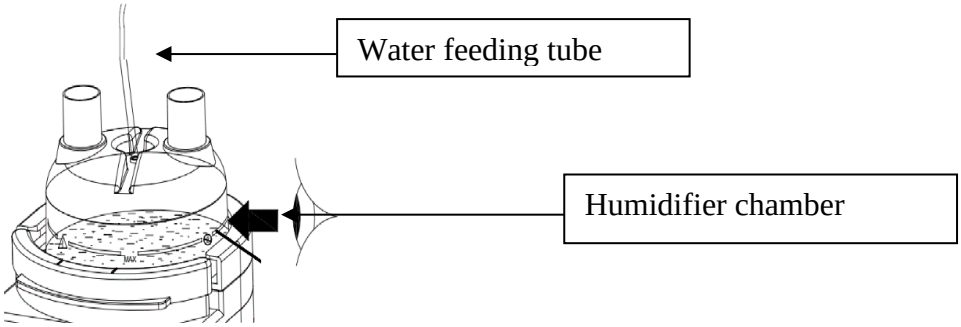
According to the intended use of the patient, either a single heated wire, a dual heated wire, or a non-heated wire are used. In a single-heated circuit, the inspiratory limb of this circuit has a heater wire that works with a respiratory humidifier to maintain the temperature and prevent the generated humidity from condensing, and a water trap is provided in the expiratory limb to collect the condensate water if there is no heater wire in the expiratory limb. A water trap in the expiratory limb reduces possible leaks and water condensation.

		
Bubble Generator	Over pressure Relief Valve	Humidification chamber



3.2 Instructions for Water filling (Chamber and Bubble Generator)

3.2.1 Humidification Chamber



- Initially the chamber is fixed in the humidifier
- The chamber consists of a float assembly which regulates the water level in the chamber.
- The water inlet port is connected with the water feeding tube,
- The water feeding tube from the chamber is connected to the water container
- The required amount of water is taken t from the container whenever the level of water in the chamber gets lowered from its set level.

3.2.2 Bubble Generator

Remove the lid from the jar.
Fill the jar to the mean fill line with sterile water.

Note: To assure consistency, water level must be between minimum and maximum lines without the drop tube beneath the surface of the water.

Note: The Bubble generator reference marks indicate PAP level at the mean water line at 6 LPM.

3.3 Breathing Circuit Position and Guidelines

After selecting the breathing circuit according to the patient population, assemble the circuit for the intended use. Position the breathing circuit properly for the patient so that the circuit will not be pushed, pulled, or kinked as a result of patient movement, transport, or other activities, including bed operations.

Ensure there is no undue stress placed on any tubing or cables.

3.3.1 Benefit of Careful Position of Breathing Circuit

Positioning the breathing circuit components as described can help minimize the following:
• Drag on the patient interface
• Tension on the patient interface

3.4 Measures to be noted while using Breathing Circuits

- During Respiratory ensure the breathing circuit doesn't get kinked –this will obstruct gas flow to the patient and should doesn't get twisted – this will twist the endotracheal tube and could damage the patient's trachea
- After the breathing circuits are connected in the corresponding ports, check whether the connections are not loose and that they are intact.
- The circuits should be properly inserted in the respective ports. By not doing so, the patient is at high risk.
- Check the gas flow and maintain them according to patient requirements.
- The heater wire adaptor and temperature probe connections are to be ensured. Make sure that the interfaces are fitted properly in the breathing circuit.
- Inspect the connections of chamber and breathing circuits and the adaptors that is fixed in the tubes of the circuits.

3.5 Disposing of the Circuit

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

Section 4: Specification

Gas Pathway Resistance	0.04 cmH_2O/l/min	
Gas Pathway Compliance	<1.5ml/cmH_2O	
Gas Leakage	30ml/min@ 60±cmH_2O	
Length and diameter	(Ins)1100+150 mm, (Exp)1200mm and 12 mm (Dia) ->BC 520	
Inspiratory tube Heater wire resistance	22 – 23 Ohms	
Expiratory tube Heater wire resistance	24 – 25 Ohms	
Raw material	Hose – LDPE+PP+TPE, Connectors – PC+PP	
Storage Environment:		
Temperature	-10 ºC to 60 ºC	
Relative Humidity	50% to 90%	
Operating Environment:		
Temperature	15 ºC to 35 ºC	
Relative Humidity	15% to 90%	
Bubble Generator		
PEEP Adjustable Range	3 to 10 cmH_2O	
Accuracy	±1 cmH_2O	
Gas Flow Range	4 to 15 LPM	
Connector	Swivel type 22mm Male/15mm Female Complies to ISO 5356-1	
Mounting Type	Integrated as per ISO	
Preset Pressure Manifold		
Infants/Neonates	20 ±2 cmH2O	
Pediatrics	40 ±2 cmH2O	
Adult	50 ±2 cmH2O	
Humidification Chamber		
	Infant/Neonatal (80-05-015)	**Pediatric/Adult (80-05-016)**
Type	Auto feed	Auto feed
Inlet & Outlet Port	22mm Male	22mm Male
Compressible Volume	360 ml	720 ml
Maximum Water Capacity	130 ml	130 ml
Maximum Peak Flow	180 LPM	180 LPM
Material	PC,AL,nitrile,Si,PVC	PC,AL,nitrile,Si,PVC
Quality Standard Adherence		
Quality Management System	ISO 13485:2016	
Anesthetic and respiratory equipment	ISO 5367:2014	
Biocompatibility evaluation	ISO 18562-4:2017	
Biological evaluation of medical devices	ISO 10993-1:2018 ISO 10993-5:2009 ISO 10993-10:2010	

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