

OxyM



Air-Oxygen Blender with Accessories



nice 5005
Low Flow Air Oxygen Blender



nice 5010
High/Low Flow Air Oxygen Blender

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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Dt. 19/06/2024



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

This Product or any of its parts should not be repaired other than in accordance with written instructions provided by nice Neotech and by nice Neotech trained personnel. The Product must not be altered without the prior written approval of nice Neotech's Quality Assurance Department. The user of this Product shall have the sole responsibility for any malfunction which results from improper use, faulty maintenance, improper repair, damage, or alteration by anyone other than nice Neotech.



Warning

- Before using the nice Neotech Air Oxygen Blender, 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 Neotech Medical Systems Private Limited supplies to EU countries.

Model Descriptions

nice 5010 High/Low Air Oxygen Blender

nice 5010 High/ Low Flow Air Oxygen Blender is used in delivering precise blend of compressed medical Air and USP O₂ gases at a output flow rate of up to 2-120 LPM via outlet ports connected to Bubble CPAP, Ventilator or High Flow Therapy which is provided with a flow meter.

nice 5005 Low Flow Air Oxygen Blender

nice 5005 Low Flow Air Oxygen Blender is used in delivering precise blend of compressed medical Air and USP O₂ gases at a output flow rate of up to 0-30 LPM via outlet ports connected to Bubble CPAP, Ventilator or High Flow Therapy which is provided with a flow meter.

Explanation of Abbreviations

O₂: Medical Oxygen Gas.

Air: Medical Air.

PSI: Pound per Square Inches (Unit of Pressure for Air/O₂).

LPM: Liter per Minute (Unit of Flow for Air/O₂).

FIO₂: Fractional Concentration of Inspired Oxygen.

USP: United States Pharmacopeia.

NIST: Non-Interchangeable Screw Thread.

DISS: Diameter Indexed Safety System.

Definition of Warning indication

Three levels of warning indication are used throughout this manual and on the device. 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, could 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 may result in minor or moderate injury, partial damage to property.

Section A: Warnings



Warning

- Before using the nice Neotech OxyM Air/O₂ Blender, read this entire manual. Attempting to use this device without a thorough understanding of its operation may result in patient or user injury. This device should only be operated by personnel trained in its operation and under the direction of qualified medical personnel familiar with the risks and benefits of this type of device.
- Do not use the OxyM Air/O₂ Blender in the presence of flammable anesthetics; a possible explosion hazard exists under these conditions.
- In a dust free area, keep hands clean and then install the equipment.
- Do not perform the Checkout Procedures (Mechanical and Control Unit) with a patient.
- Complete the “Checkout Procedures” section of this manual before putting the unit into operation. If the OxyM Air/O₂ Blender any portion of the checkout procedures it must be removed from use and repaired.
- Even small quantity of flammable agents such as ether, alcohol, grease and oil left in the OxyM Air/O₂ Blender it can cause fire in connection with oxygen.
- If either the air or oxygen gas source fails, the OxyM Air/O₂ Blender alarm sounds, alerting the clinician that a condition has occurred that may significantly alter the FiO₂ and flow output from the OxyM Air/O₂ Blender.
- Do not position blender under any excessive heat sources outside the specified operating temperatures.
- Turn OFF bleed when blender is not in use or using above 3 l/min or 15 l/min to decrease gas waste and to decrease ignition risk.
- If either the air or oxygen gas source pressure is reduced or increased creating a pressure differential of 20 ±2 PSI, the OxyM Air/O₂ Blender alarm sounds. This condition significantly alters the FiO₂ and flow output from the OxyM Air/O₂ Blender.
- Store the Air-Oxygen Blender in a clean, dry area when not in use.
- Always operate the OxyM Air/O₂ Blender with clean and dry medical grade gases.
- Air Inlet Filter/Water Trap is recommended for use with the OxyM Air/O₂ Blender.
- The blended gas delivered to patient must be monitored with an oxygen analyzer.
- Due to rapid alarm response, continuous supervision by a qualified operator is mandatory during use.
- DO NOT steam clean, autoclave, or otherwise subject the OxyM Air/O₂ Blender to temperatures above 145°F (62°C)
- DO NOT immerse the assembled OxyM Air/O₂ Blender in liquid decontamination agents.
- Consult a physician for appropriate FiO₂ setting.
- DO NOT tape, obstruct, or remove the reed alarm outlet at any time.
- Consult instructions for use
- NEVER leave a ventilator patient unattended.
- Do not clean with aromatic hydrocarbons.

- Disconnect the Air-Oxygen Blender from all connections prior to disassembly.
- When reassembling the Blender, do not pressurize the system until the retaining screw of the Proportioning Module has been fully tightened. The Proportioning Module can be forcefully ejected by gas pressure if not sufficiently tightened.
- Missing or illegible labels must be replaced, contact nice Neotech.
- Condensed water in air supply can cause malfunction of this device.
- DO NOT occlude or obstruct the bleed port or muffler on the bottom of the OxyM Air/O₂ Blender.
- Adjustment of the oxygen concentration must be verified using an oxygen analyzer.
- Use this Air-Oxygen Blender only for its Intended Use as described in this manual.
- The Air-Oxygen Blender shall be serviced by a qualified service technician.
- Accuracy of oxygen concentration will be affected if bleed is not activated at flow settings below 15 l/min for the High Flow Blender, and 3 l/min for the Low Flow Blender.
- DO NOT use Blender when alarm is sounding.
- Oxygen Concentration Dial does not rotate 360 degrees. Rotating the dial less than 21% or over 100% oxygen will damage the Blender.
- The blender is designed to operate ideally at 50 psig (345 kPa) source of air and Oxygen.
- The factory installed air and oxygen gas supply fittings, which contain essential check valves and filters, must not be substituted with any other parts not approved by nice Neotech. Doing so may cause gas supply contamination due to back flow.
- nice Neotech's Air Oxygen Blender is not suitable for use with Oxygen 93.
- Bleed oxygen flow can cause ignition.
- There is a risk of hypercapnia during the treatment using Air Oxygen Blender. So, SpO₂ level of the patient should be monitored regularly.















Section B: Cautions














- Do not autoclave or gas sterilize the Air oxygen Blender. Do not immerse the device in liquid cleaner.
- Only competent individuals trained in the repair of this equipment should attempt to service it as detailed in the service manual. The Service Manual provides detailed information solely for use by individuals having proper knowledge, tools and test equipment, and for service representatives trained by nice Neotech.
- Use of nonstandard components: Consult the manufacturer for repair and replacement of components. Use of incorrect component can adversely affect Safety, performance and/or damage the equipment performance.
- Clean surface using wet cloth dipped in mild soap water and squeeze dry excess water before use.
- Do not allow water to spill into equipment.
- Avoid using any solvent, spirits, alcohol to clean plastic parts.
- Always operate air/ oxygen blenders with clean and dry medical grade gases. Contaminant or moisture can cause defective operation. Air used for medical purposes must meet USP compressed air and/or ANSI Z86.1-1973 grade F, and water vapor content must not exceed a blender's dew point of 10°F (-12.22°C) below the lowest ambient temperature to which the delivery system is exposed.
- Water vapor content of medical air or O₂ supply to the OxyM Air/O₂ Blender must not exceed 5.63 grams H₂O per cubic meter of non-condensable gas.
- The oxygen should be "medical oxygen" that is, at least 99.0% pure. Both gases must contain <37.5 milligrams of water per cubic meter of gas (mg/Nm³) or (<50 ppm H₂O).
- When using a bottled high pressure gas source, always use a pressure reducing regulator set within 30-75 psi (2.1-5.2 bar).
- Ensure all connections are tight and leak free.
- When pressurizing the Blender inlets, avoid pressure surges greater than 100 psi (6.9 bar).
- Do not smoke in an area where oxygen is administered.
- All nice Neotech blenders are tested for backflow at the factory. However, the Reverse gas flow test is verified as per ISO 11195 requirements and no leakage is found in both inlets. It is recommended that when not in use, either the blender supply gases should be detached from the blender or the blender bleed function should be left on, to prevent any chance of cross contamination.
- Before use on a patient, the oxygen concentration of the delivered gas should be checked at setting intended for use. A separate, calibrated oxygen analyzer should be used whenever the blender is used on a patient.
- Inlet pressure hoses for the gas mixer to comply with ISO 5359 standard requirements.
- Improper orientation of the Air-Oxygen blender may compromise its performance and safety. Ensure that the blender is positioned exactly as specified in the user manual. Failure to adhere to the correct orientation can lead to malfunction, inaccurate gas mixing, or potential safety hazards.

Section C: Symbols & Label

Symbols:

Mark	Title
Manufacturer	
	Manufacturer – Indicates the medical device manufacturer
	Date of Manufacture – Indicates the date when the medical device was manufactured.
	Country of manufacture – To identify the country of manufacture of products
	Authorized representative in the European Community/ European Union – Indicates the authorized representative in the European Community/ European Union
	Catalogue number – Indicates the manufacturer’s catalogue number so that the medical device can be identified.
	Serial Number – Indicates the manufacturer’s serial number so that a specific medical device can be identified.
	CE Mark European Conformity - Signifies European conformity (CE) mark Indicates manufacturer declaration that the product complies with applicable European regulations.
Sterility	
	Non-sterile – Indicates a medical device that has not been subjected to a sterilization process.
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)

	<p>This way up – For the duration/ delivery, the carton should face upright.</p>
<p>Safe use</p>	
	<p>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.</p>
	<p>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</p>
	<p>Refer Instruction for use – Indicates the need for the user to refer instructions for use given by the manufacturer</p>
	<p>Consult instructions for use or consult electronic instructions for use - Indicates the need for the user to consult the instructions for use.</p>
<p>Others</p>	
	<p>Medical Device - Indicates the item is a medical device</p>
	<p>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.</p>
	<p>Recyclable Package – The product can be recycled or it was made from recycled materials.</p>
	<p>Use trolley for transportation – Used for heavy products that are difficult to carry by hand, even if you have multiple people.</p>
	<p>RoHS Complaint – RoHS (Restriction of Hazardous Substances) Indicates that no hazardous substances have been used in the product</p>
	<p>Unique device identifier - Indicates a carrier that contains unique device identifier information</p>

List of Labels:

OxyM **Neotech**
Air-Oxygen Blender

O₂%

50 60 70
40 80
30 90
21 100

Cut

92-00-194_D1, Iss 01, Rev 04

92-00-194, Iss 01, Rev 04
nice 5010 - Air Oxygen Blender

92-00-194

Labels – nice 5010 Air Oxygen Blender

CAUTION

Always disconnect the gas source from the blender when it is not in use.
Do not obstruct the alarm.

U.S Federal law restricts this device to sale by or on the order of the physician.

WARNING

Monitor oxygen concentration with an oxygen analyzer.

Condensed water in air supply can cause malfunction of this device.

DEVICE USE

An device for accurate mixing of oxygen (O₂) and air in pre-set concentrations appropriated for breathing.

92-00-194_02, Iss 01, Rev 04

Manufactured at:
Site 2: No.44-45, Krishna Industrial Estate,
Vanagaram, Mettukuppam, Chennai - 600095, INDIA.
M.L - MFG/MD/2023/000906

REF

SN

MD

Device Generic Name
Oxygen/Air breathing gas mixer

Cut

nice Neotech Medical Systems Pvt. Ltd.
No.85-86, Krishna Industrial Estate, Vanagaram,
Mettukuppam, Chennai - 600095, INDIA.
www.niceneotech.com, info@niceneotech.com
Tel: +91-44-24762594, EUSRN: IN-MF-000010243

92-00-194_03, Iss 01, Rev 04

AUXILIARY OUTLET
O₂ Concentration accurate from 2 LPM and above. PUSH TO BLEED ON.

BLEED
Do not obstruct.

PRIMARY OUTLET
O₂ Concentration accurate from 15 LPM and above.

O₂ OXYGEN

MEDICAL AIR

OxyM **Neotech**
Low Flow Air-Oxygen Blender

O₂%

50 60 70
40 80
30 90
21 100

Cut

92-00-195_01, Iss 01, Rev 04

92-00-195, Iss 01, Rev 04
nice 5005 - Low Flow Air Oxygen Blender

92-00-195

Labels – nice 5005 Low Flow Air Oxygen Blender

CAUTION

Always disconnect the gas source from the blender when it is not in use.
Do not obstruct the alarm.

U.S Federal law restricts this device to sale by or on the order of the physician.

WARNING

Monitor oxygen concentration with an oxygen analyzer.

Condensed water in air supply can cause malfunction of this device.

DEVICE USE

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





AUXILIARY OUTLET
O₂ Concentration accurate from 1 LPM and above. PUSH TO BLEED ON.

BLEED
Do not obstruct.

PRIMARY OUTLET
O₂ Concentration accurate from 3 LPM and above.

O₂ OXYGEN

MEDICAL AIR

<p>Amstermed B.V Saturnusstraat 46-62, Unit 032, 2132 HB Hoofddorp, The Netherlands www.amstermed.nl; info@amstermed.nl Tel:+31 23 565 6337. SRN: NL-AR-000001971.</p> <p style="text-align: center;">EC REP</p> <div style="border: 1px solid black; border-radius: 15px; padding: 10px; display: inline-block;">  </div> <p style="text-align: center;">92-00-277 Iss 01, Rev 00</p>	<p>92-00-277</p>	<p>Label - CE & EC Rep</p>			
<div style="text-align: center;">   <p>DRAFT</p> <p>(01)0 8908003 98923 5 (21) AOB220712345 nice 5010</p>   <p>DRAFT</p> <p>(01) 0 8908003 98922 8 (21) AOB240600123 nice 5005</p> </div>	<p>---</p>	<p>Draft UDI Label (nice 5005, nice 5010)</p>			
<div style="border: 1px solid black; padding: 5px;"> <table border="0" style="width: 100%;"> <tr> <td style="width: 25%; vertical-align: top;"> <p>Product Name Air Oxygen Blender</p> <p>Generic Name Oxygen/Air breathing gas mixer</p> <p>Brand Name OxyM</p> <p>Module Final Assembly</p> <p>Device Use An device designed for accurate mixing of oxygen (O2) and air in pre-set concentrations appropriated for breathing.</p> <p>Mfg. Lic. No. MFG/MD/2023/000906</p> </td> <td style="width: 25%; vertical-align: top;"> <p>REF nice 5010</p> <p>SN AOBYYMMXXXXX</p> <p>MW 24/12/2022</p> <p>UDI  (01) 0 8908003 98923 5 (21) Serial no</p> <p>Dimension in cm: 55(L) x 46(W) x 71(H) Weight in kg: 50 kg No. of units inside: 01 nos.</p> <p style="text-align: right;">MRP: Rs. 1,12,000/-</p> </td> <td style="width: 50%; vertical-align: top;"> <p> nice Neotech Medical Systems Pvt. Ltd., No. 85-86, Krishna Industrial Estate, Mettukuppam, Vanagaram, Chennai - 600 095, Tamil Nadu, India. TEL - +91-44-24762594/24764608 www.niceneotech.com, info@niceneotech.com SRN: IN-MF-000010243</p> <p>Manufactured at: Site 2: No. 44-45, Krishna Industrial Estate, Mettukuppam, Vanagaram, Chennai - 600 095, Tamil Nadu, India.</p> </td> </tr> </table> <div style="text-align: center; margin-top: 10px;"> <p>MD HANDLE WITH CARE LIFE SAVING MEDICAL EQUIPMENT</p> <div style="display: flex; justify-content: space-around; align-items: center;">  <div style="border: 1px solid black; padding: 2px; font-size: 8px;"> EC REP Amstermed B.V. Saturnusstraat 46-62, Unit 032, 2132 HB Hoofddorp, The Netherlands www.amstermed.nl; info@amstermed.nl +31 23 565 6337 SRN: NL-AR-000001971 </div> </div> <div style="display: flex; justify-content: space-between; margin-top: 10px;"> <div style="display: flex; gap: 5px;">         </div> <div style="display: flex; gap: 5px;">      </div> </div> </div> </div>	<p>Product Name Air Oxygen Blender</p> <p>Generic Name Oxygen/Air breathing gas mixer</p> <p>Brand Name OxyM</p> <p>Module Final Assembly</p> <p>Device Use An device designed for accurate mixing of oxygen (O2) and air in pre-set concentrations appropriated for breathing.</p> <p>Mfg. Lic. No. MFG/MD/2023/000906</p>	<p>REF nice 5010</p> <p>SN AOBYYMMXXXXX</p> <p>MW 24/12/2022</p> <p>UDI  (01) 0 8908003 98923 5 (21) Serial no</p> <p>Dimension in cm: 55(L) x 46(W) x 71(H) Weight in kg: 50 kg No. of units inside: 01 nos.</p> <p style="text-align: right;">MRP: Rs. 1,12,000/-</p>	<p> nice Neotech Medical Systems Pvt. Ltd., No. 85-86, Krishna Industrial Estate, Mettukuppam, Vanagaram, Chennai - 600 095, Tamil Nadu, India. TEL - +91-44-24762594/24764608 www.niceneotech.com, info@niceneotech.com SRN: IN-MF-000010243</p> <p>Manufactured at: Site 2: No. 44-45, Krishna Industrial Estate, Mettukuppam, Vanagaram, Chennai - 600 095, Tamil Nadu, India.</p>	<p>---</p>	<p>Packing label</p>
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Section 1: Description

- 1.1 Intended Use
- 1.2 Indication
- 1.3 Contraindication
- 1.4 Side effects
- 1.5 Target population
- 1.6 Device Intended User
- 1.7 Product description
- 1.8 Working principle
- 1.9 Intended Combination Devices
- 1.10 Unique Device Identification (UDI Carrier)

1.1 Intended Use

The **nice 5005 Low flow Air/Oxygen Blender** is perfect for NICU and Newborn Nursery or for a flow of 30 lpm or less. Increased accuracy at even the lowest flow range. It dispenses a continuous and precise blend of medical air and USP oxygen via outlet ports to patients. The exact Fractional Concentration of Inspired Oxygen (FIO₂) blend of gases corresponds to the dialled in FIO₂ setting indicated by the control knob.

The **nice 5010 High/Low flow Air/Oxygen Blender** is versatile dual range blender. Ideal for equipment needing flows from 2 -120 lpm, yet also capable of increased accuracy even at a low flow range. It dispenses a continuous and precise blend of medical air and USP oxygen via outlet ports to infant, pediatric and adult patients. The exact Fractional Concentration of Inspired Oxygen (FIO₂) blend of gases corresponds to the dialled in FIO₂ setting indicated by the control knob.

1.2 Indication:

- Respiratory distress syndrome
- Low SPO₂

1.3 Contraindication:

No known contraindications.

1.4 Side Effects:

No known side effects

1.5 Target Population:

Premature babies, Neonates, infants, Paediatrics & Adults

1.6 Device Intended User:

Anaesthetist, Neonatologist and Healthcare Professionals.

1.7 Product Description

The OxyM line of blenders is a medical device used to mix Medical Grade Air and Oxygen to a concentration ranging from 21% to 100%. The inlet gas connections are standard DISS or NIST. The outlets from the blender delivers accurate FIO₂ mixtures from either one or two outlet ports and has an overall standard flow range of 2 - 120 LPM for nice 5010 and 0-30 LPM for nice 5005. They can be used with ventilators, High Flow Oxygen Therapy, Anaesthesia Machine, Bubble CPAP and resuscitation device, among others.

The OxyM Air/Oxygen Blender is a precision proportioning device for mixing medical grade air and oxygen to any concentration from 21% to 100% oxygen and delivering it to a variety of respiratory care devices. The blender uses source air and oxygen at a pressure of 50 psi connected to two D.I.S.S. fittings on the bottom of the blender. Each fitting has a built-in 30 micron particulate filter. The gas source then passes through a duckbill check valve, which prevents reverse gas flows from either source.

1.8 Working Principle:

OxyM is an independent mechanical device designed for accurate mixing of air and oxygen (O₂) with O₂ concentrations ranging from 21% to 100% (oxygen/air proportioner) that are appropriated for breathing in patients who need a concentration of O₂ above the normal concentration in air. The mixer receives air and oxygen from either the hospital gas pipeline or from compressed gas cylinders; it may include a pressure-regulating mechanism to supply a pressure of 50 psi connected to two D.I.S.S fittings on the bottom of the blender. Each fitting has a built-in 30 micron particulate filter. The gas source then passes through a duckbill check valve, which prevents reverse gas flow from either source.

The blender uses a two-stage balancing system with the gas entering into each stage to equalize the operating pressure of the gas sources before entering the proportioning stage.

The gases then flow into the proportioning stage where they are mixed to the percentage dialled-in on the front panel knob ranging 21% to 100%. This stage has a double-ended valve with valve seats on either end. Each one of these valve seats controls the passage of the air or oxygen to the outlet of the blender.

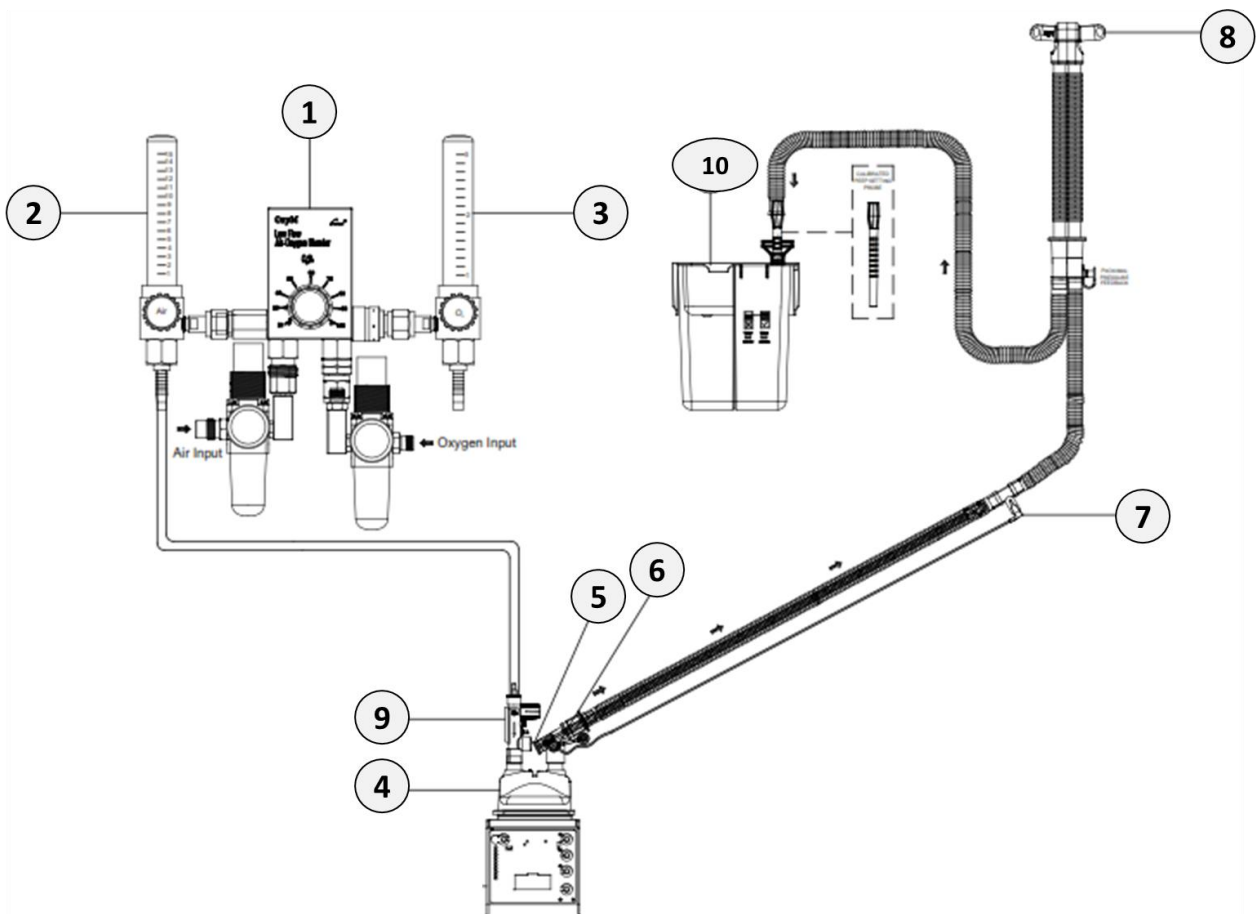
The mixer may deliver the gas to the patient through devices such as ventilators, tracheostomy tubes, endotracheal (ET) tubes, oxygen tents, bubble CPAP, resuscitation device and/or masks.

1.9 Intended combination devices:

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

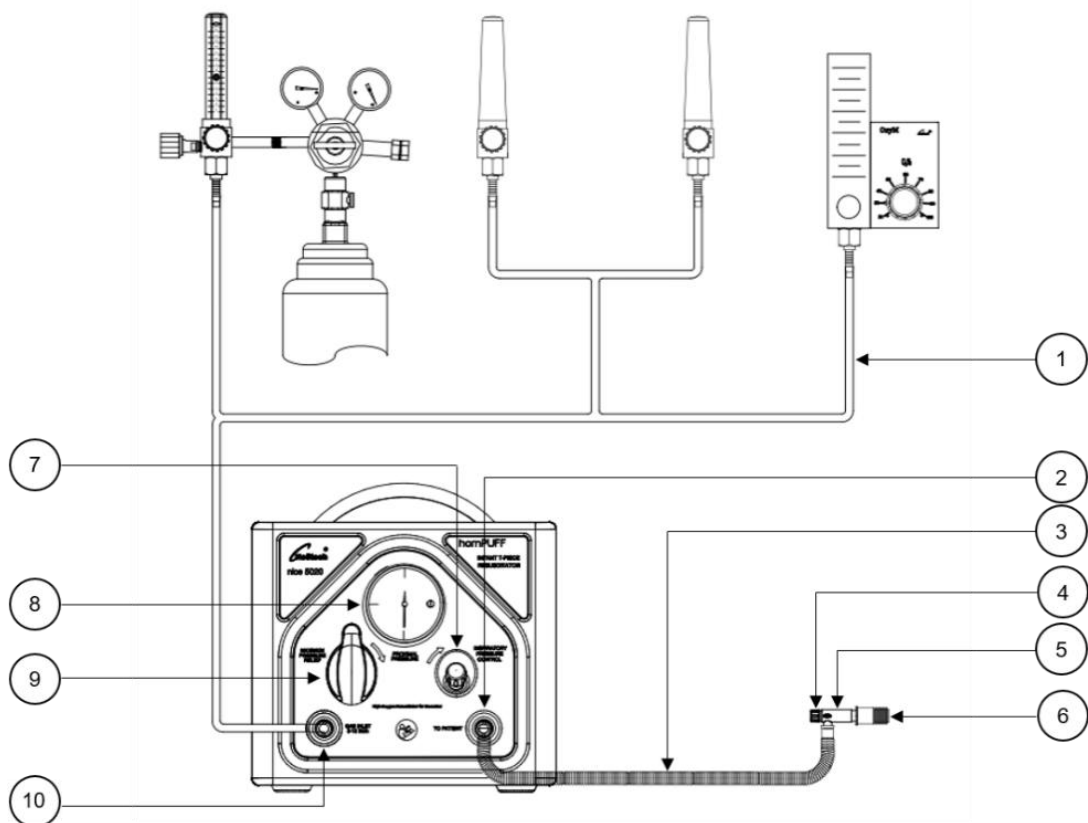
Connection descriptions:

- **Bubble CPAP System:**



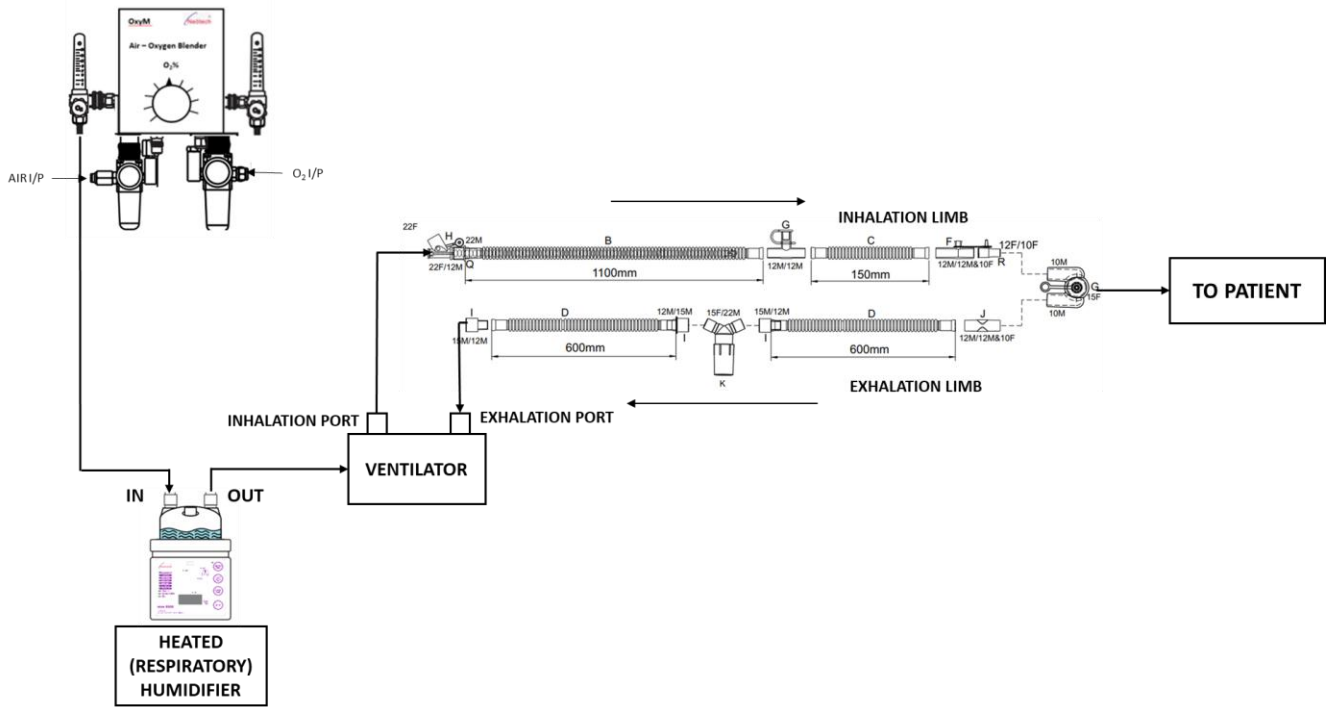
1	Low Flow Air - Oxygen Blender	6	Temperature Probe - Chamber Side
2	Flow Meter - 0 - 15 LPM	7	Temperature Probe - Air Way Side
3	Flow Meter - 0 - 3 LPM	8	Nasal Prongs
4	Humidity Chamber	9	Pressure Relief Device
5	Heater Wire Adaptor	10	Bubble Generator

• **Infant T-piece Resuscitator:**



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)

• **Ventilator Systems:**



1.10 Unique Device Identification (UDI Carrier)

#	Device Variant	Device Identifier (DI)	Production Identifier (PI)
1.	nice 5005	8908003989228	AOBYMMXXXXX
2.	nice 5010	8908003989235	AOB- Product Code YY – year MM – Month XXXXX – serial No

Draft UDI label:

<div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 0 auto;">UDI</div> <p style="text-align: center;">DRAFT</p> <p style="text-align: center;">(01) 0 8908003 98922 8 (21) AOB240600123</p> <p style="text-align: center;">nice 5005</p>	<div style="border: 1px solid black; padding: 5px; width: fit-content; margin: 0 auto;">UDI</div> <p style="text-align: center;">DRAFT</p> <p style="text-align: center;">(01)0 8908003 98923 5 (21) AOB220712345</p> <p style="text-align: center;">nice 5010</p>
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Section 2: Installation

2.1 nice 5005

- 2.1.1 Unpacking and Inspection
- 2.1.2 Installation of Blender
- 2.1.3 Fixing of Air & Oxygen Inlet Hose [Optional accessory]
- 2.1.4 Fixing of Flow meter (0-3 LPM), (0-15LPM) [Optional accessory]
- 2.1.5 Fixing of Output Hose

2.2 nice 5010

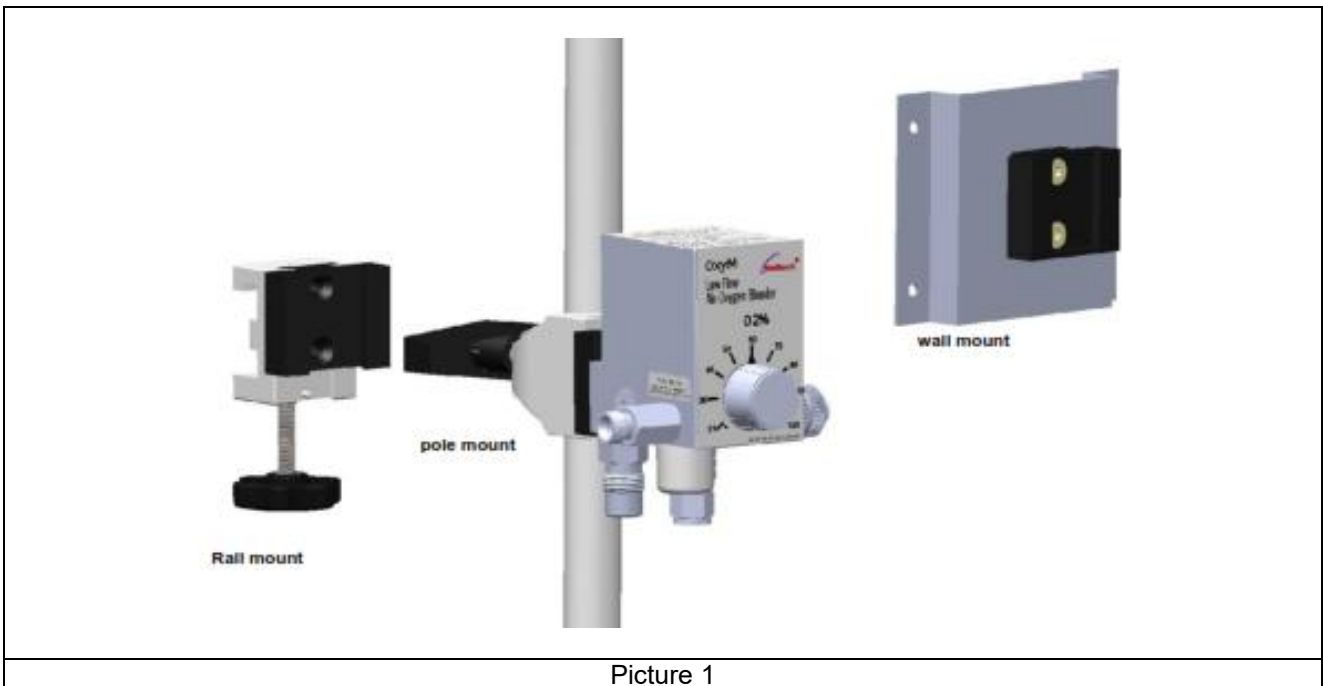
- 2.2.1 Unpacking and Inspection
- 2.2.2 Installation of Blender
- 2.2.3 Fixing of Air & Oxygen Inlet Hose [Optional accessory]
- 2.2.4 Fixing of Flow meter (0-3 LPM), (0-15LPM) [Optional accessory]
- 2.2.5 Fixing of Output Hose

2.1 nice 5005

2.1.1 Unpacking and Inspection

After removal from the shipping containers, inspect the Air-Oxygen Blender and all accessory items for any signs of damage which may have occurred during shipment. File a damage claim with the shipping carrier if damage has occurred.

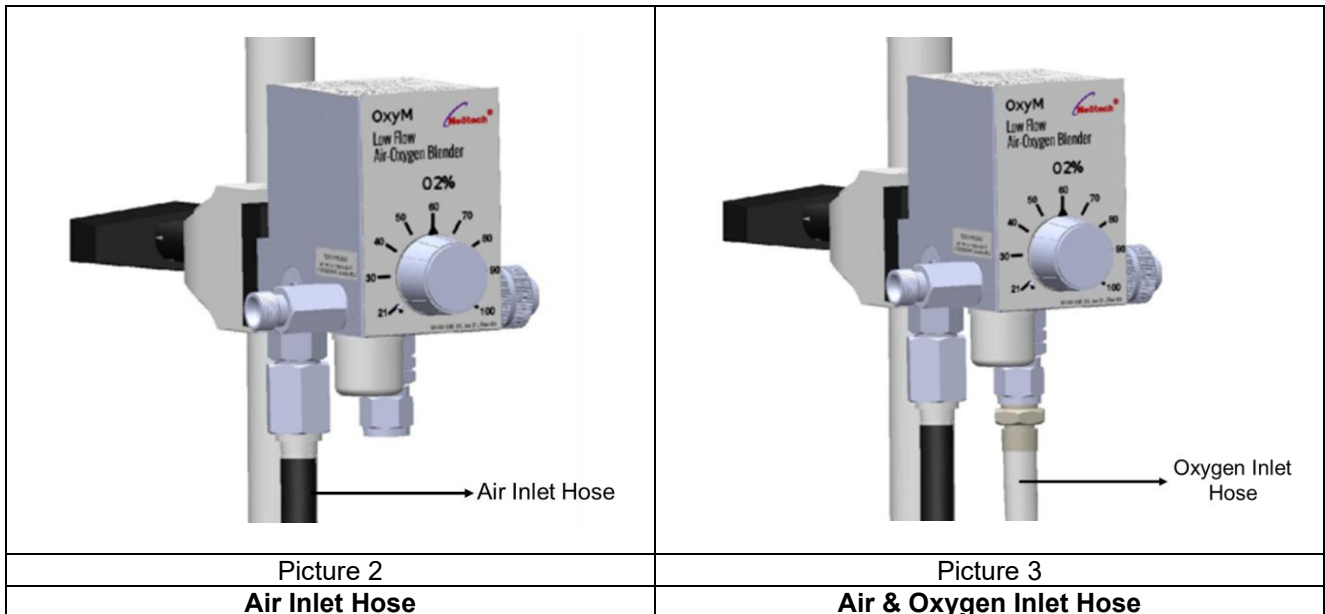
2.1.2 Installation of Blender



Picture 1

The blender can be either pole, wall, or rail-mounted for easy use and for any desired application

2.1.3 Fixing of Air & Oxygen Inlet Hose [Optional Accessory]



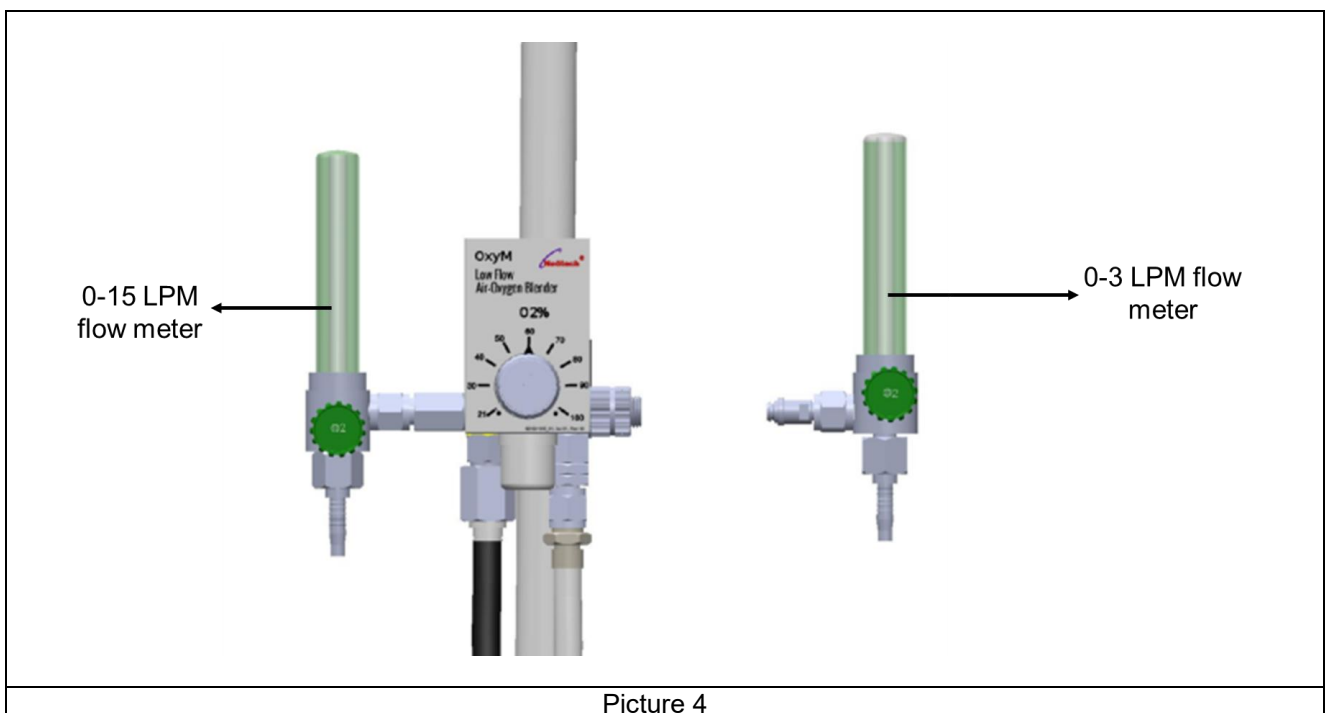
The inlet fittings are located on the bottom of the blender and conform to Diameter Index Safety System (D.I.S.S.) and air and oxygen connections cannot be interchangeable. Connect an air high pressure hose to the air fitting (Picture 2) and an oxygen high pressure hose to the oxygen fitting (Picture 3) on the bottom of the blender. To prevent moisture from entering the blender, it is recommended that an air inlet water trap be used between the air hose and inlet fitting.

NOTE:

	ISO standard color coding	American standard color coding
Air	Black	Yellow
Oxygen	white	Green

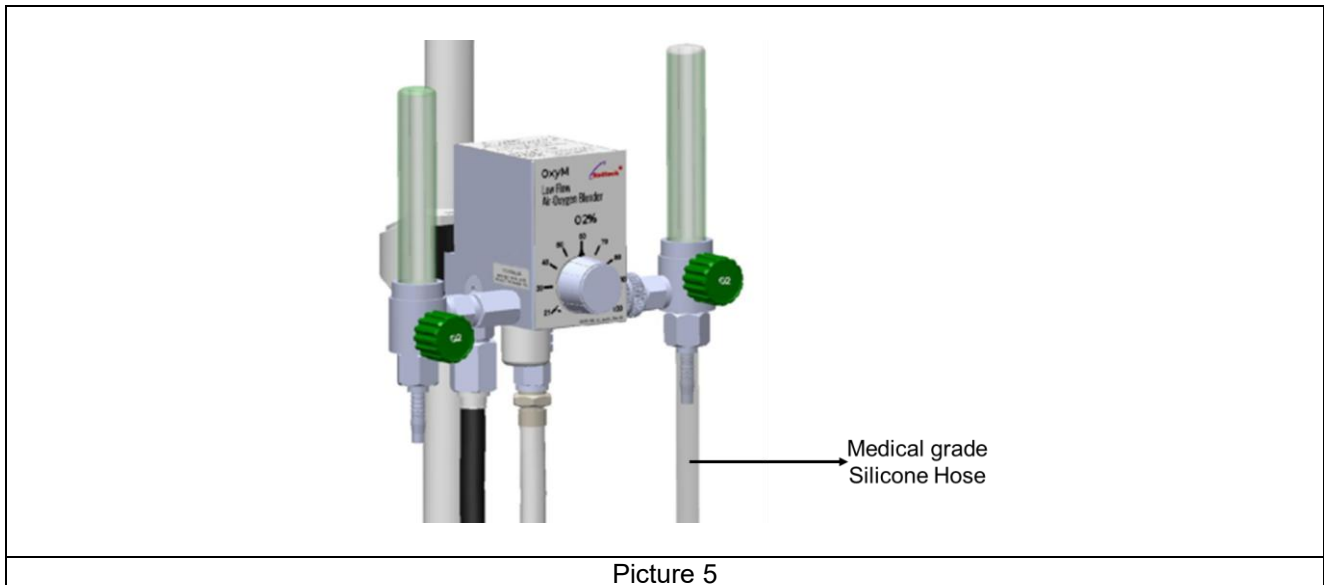
NOTE: Ensure the input hose connectors are properly connected; the high-pressure gases may cause the tube to fly around causing hazard to users and patients.

2.1.4 Fixing of Flow meter (0-3 LPM), (0-15LPM) [Optional Accessory]



Flow Meter (0-3 LPM) connect to the auxiliary output of blender and (0-15 LPM) primary output. DISS fitting is provided for connect the flow meters to blender, NIST fitting is optional.

2.1.5 Fixing of Output hoses



Picture 5

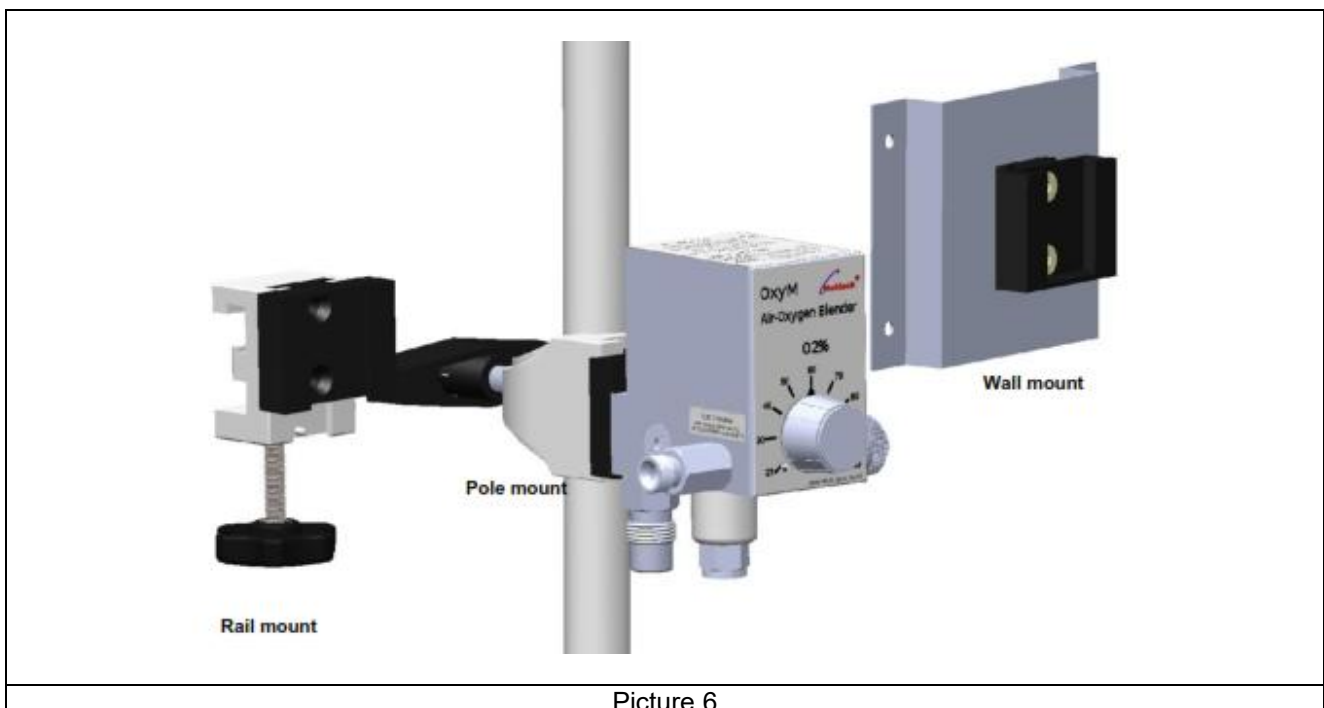
Medical grade silicone hose connects the output of flow meter. If Right & Left outlets are used simultaneously, neither one will deliver its maximum flow. Rotate the flow meter knob as get the required outlet flow.

2.2 nice 5010

2.2.1 Unpacking and Inspection

After removal from the shipping containers, inspect the Air-Oxygen Blender and all accessory items for any signs of damage which may have occurred during shipment. File a damage claim with the shipping carrier if damage has occurred.

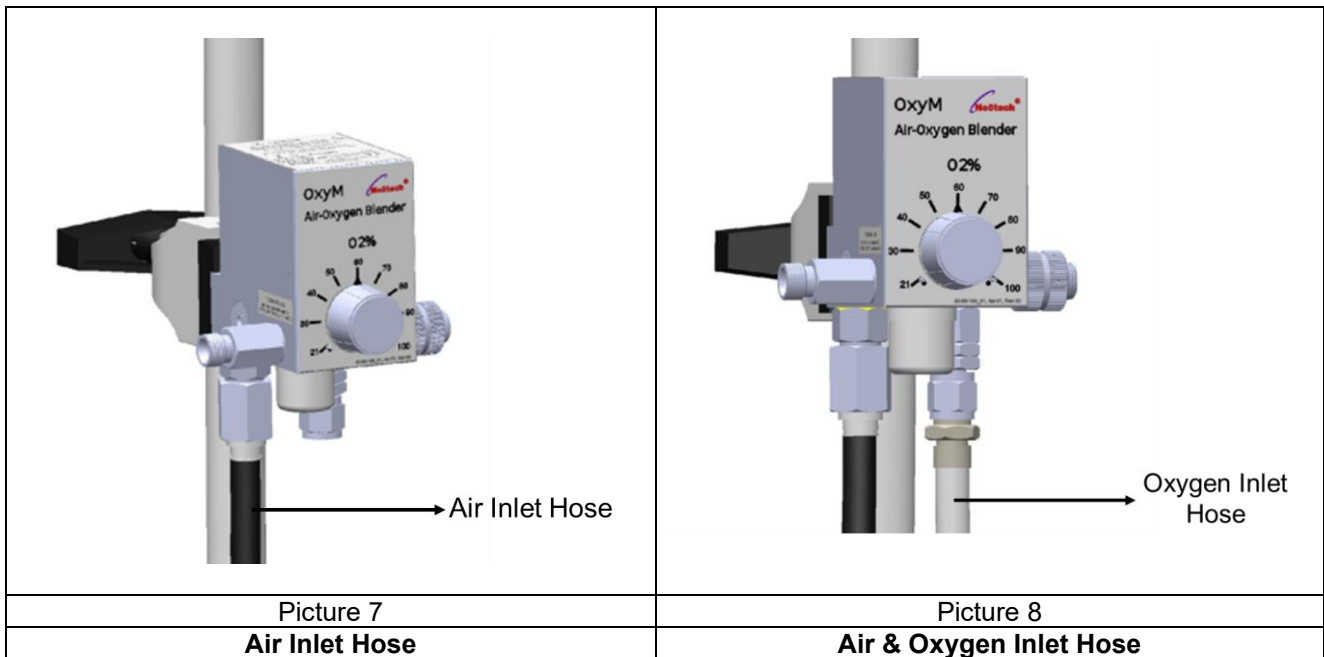
2.2.2 Installation of Blender



Picture 6

The blender can be either pole, wall, or rail-mounted for easy use and for any desired application

2.2.3 Fixing of Air & Oxygen Inlet Hose [Optional Accessory]



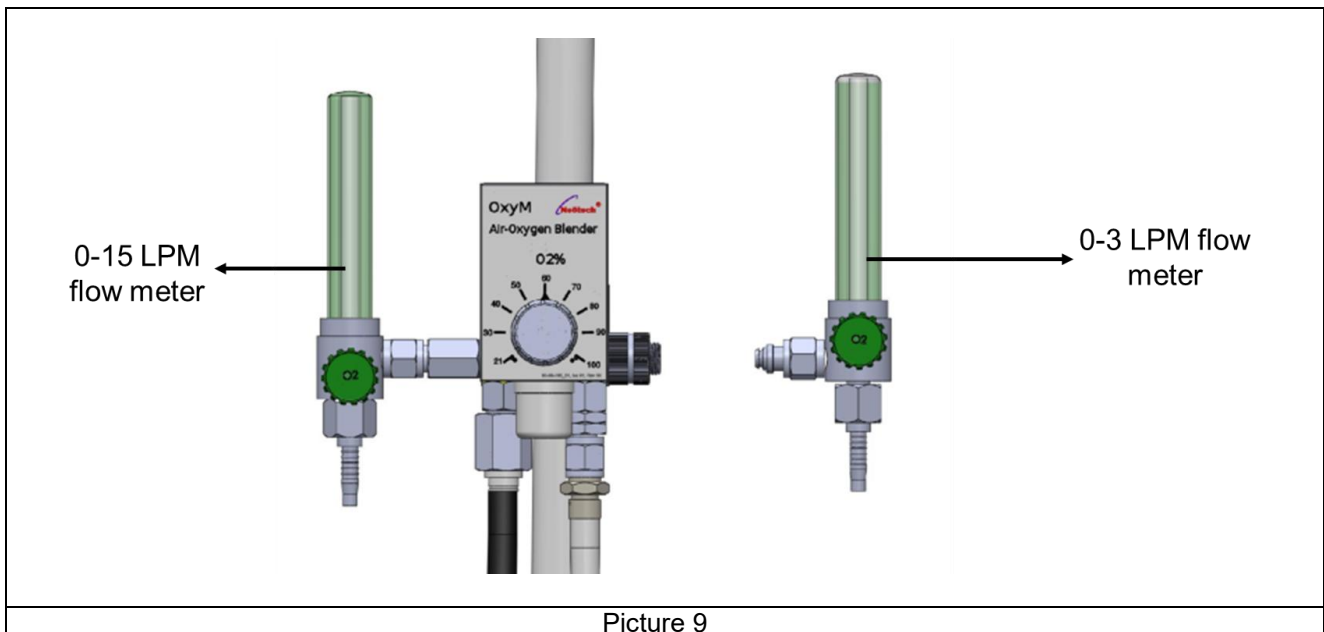
The inlet fittings are located on the bottom of the blender and conform to Diameter Index Safety System (D.I.S.S.) and air and oxygen connections cannot be interchange. Connect an air high pressure hose to the air fitting (Picture 7) and an oxygen high pressure hose to the oxygen fitting (Picture 8) on the bottom of the blender. To prevent moisture from entering the blender, it is recommended that an air inlet water trap be used between the air hose and inlet fitting.

NOTE:

	ISO standard color coding	American standard color coding
Air	Black	Yellow
Oxygen	white	Green

NOTE: Ensure the input hose connectors are properly connected; the high-pressure gases may cause the tube to fly around causing hazard to users and patients.

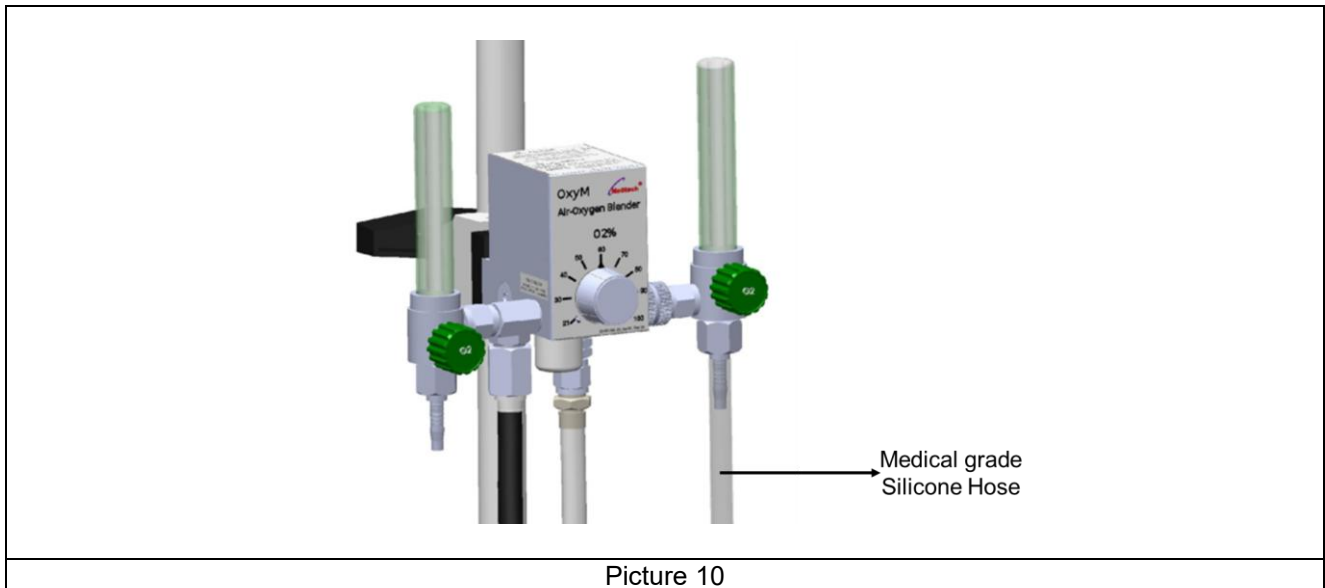
2.2.4 Fixing of Flow meter (0-3 LPM), (0-15LPM) [Optional Accessory]



Picture 9

Flow Meter (0-3 LPM) connect to the auxiliary output of blender and (0-15 LPM) primary output. DISS fitting is provided for connect the flow meters to blender, NIST fitting is optional.

2.2.5 Fixing of Output hoses



Medical grade silicone hose connects the output of flow meter. If Right & Left outlets are used simultaneously, neither one will deliver its maximum flow. Rotate the flow meter knob as get the required outlet flow.

Section 3: Operation

3.1 nice 5005

- 3.1.1 Pneumatic diagram
- 3.1.2 Control Panel Operation
- 3.1.3 Connection Ports
- 3.1.4 Operation Overview
- 3.1.5 Functions
 - 3.1.5.1 Gas Inlet Ports
 - 3.1.5.2 Balance chamber
 - 3.1.5.3 Proportioning Module
 - 3.1.5.4 Alarm/Bypass
 - 3.1.5.5 Outlet Ports
 - 3.1.5.6 Bleed Outlet
 - 3.1.5.7 Auxiliary Bleed Switch
- 3.1.6 Pre-Use Testing consists of:
 - 3.1.6.1 Alarm Test
 - 3.1.6.2 Reverse Gas Flow Procedure
 - 3.1.6.3 Oxygen concentration Checking Procedure
 - 3.1.6.4 Output Flow checking Procedure
- 3.1.7 Operating Instructions

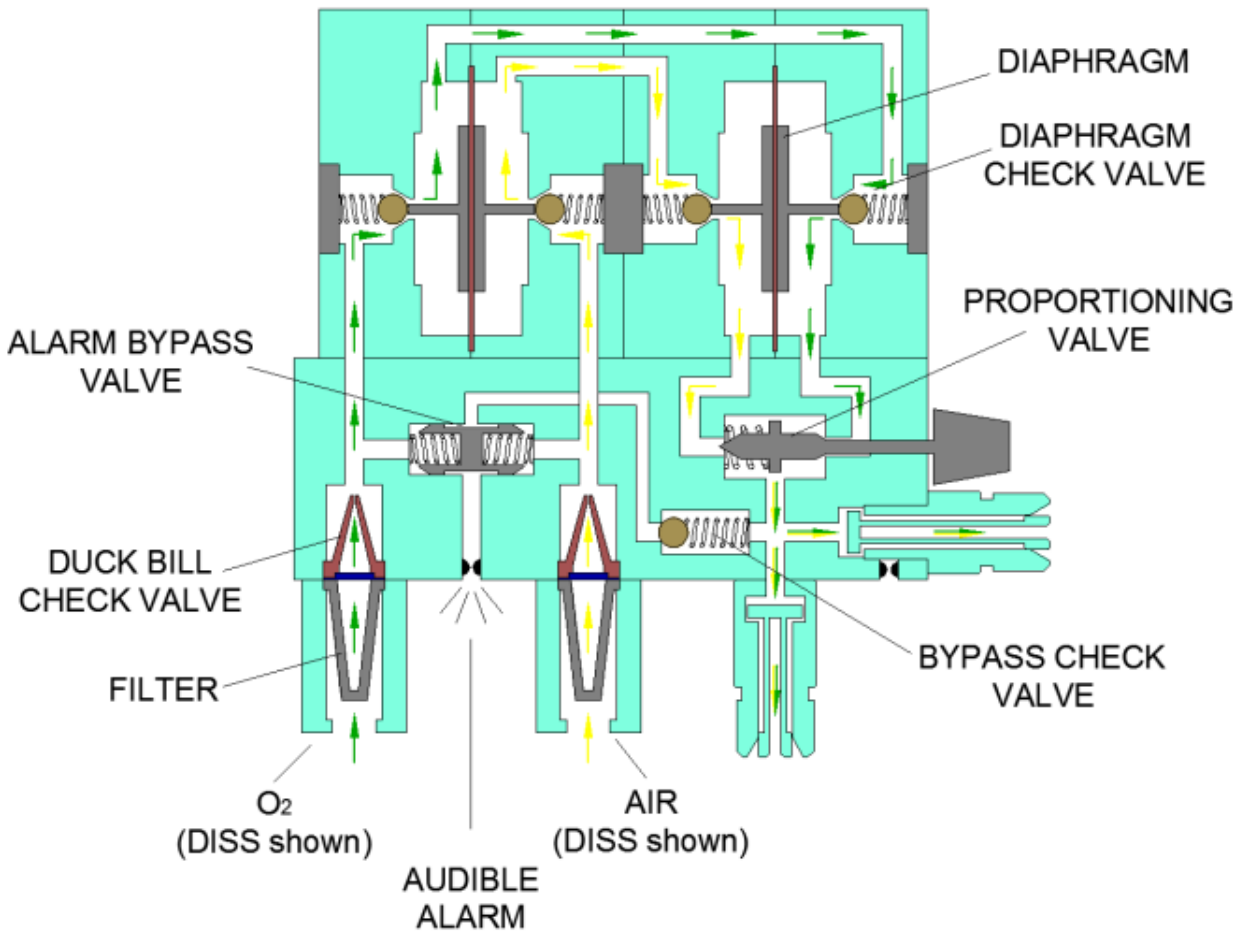
3.2 nice 5010

- 3.2.1 Pneumatic diagram
- 3.2.2 Control Panel Operation
- 3.2.3 Connection Ports
- 3.2.4 Operation Overview
- 3.2.5 Functions
 - 3.2.5.1 Gas Inlet Ports
 - 3.2.5.2 Balance chamber
 - 3.2.5.3 Proportioning Module
 - 3.2.5.4 Alarm/Bypass
 - 3.2.5.5 Outlet Ports
 - 3.2.5.6 Bleed Outlet
 - 3.2.5.7 Auxiliary Bleed Switch
- 3.2.6 Pre-Use Testing consists of:
 - 3.2.6.1 Alarm Test
 - 3.2.6.2 Reverse Gas Flow Procedure
 - 3.2.6.3 Oxygen concentration Checking Procedure
 - 3.2.6.4 Output Flow checking Procedure
- 3.2.7 Operating Instructions

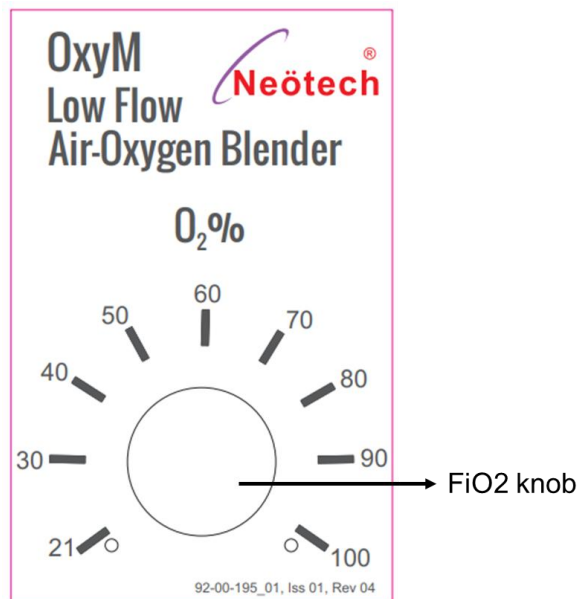
3.3 Accessories (Optional)

3.1 nice 5005

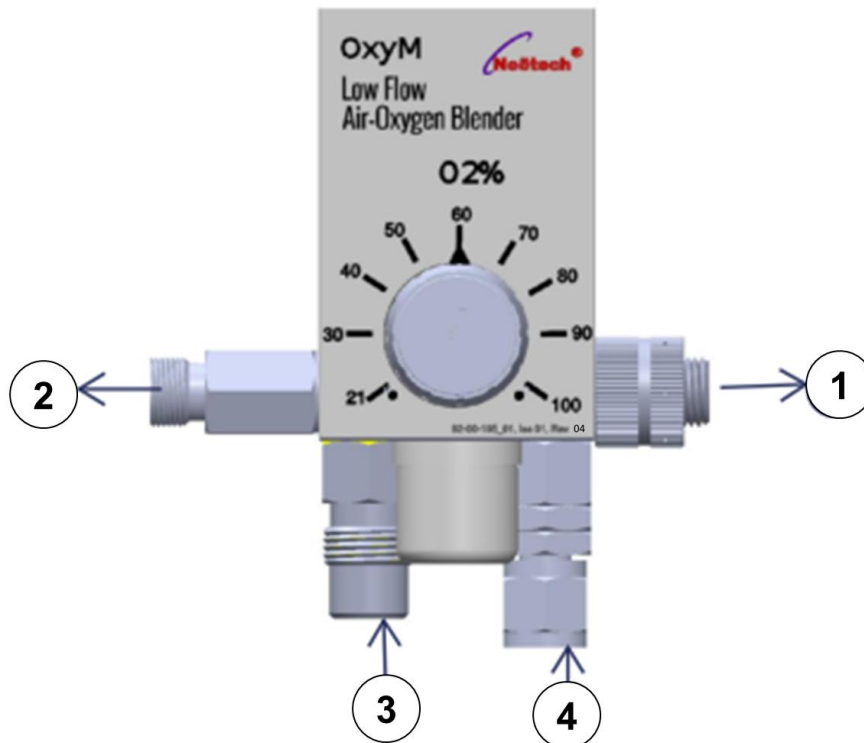
3.1.1 Pneumatic diagram



3.1.2 Control Panel Operation



3.1.3 Connection Ports



1	Auxiliary outlet
2	Primary outlet
3	Air inlet
4	Oxygen inlet

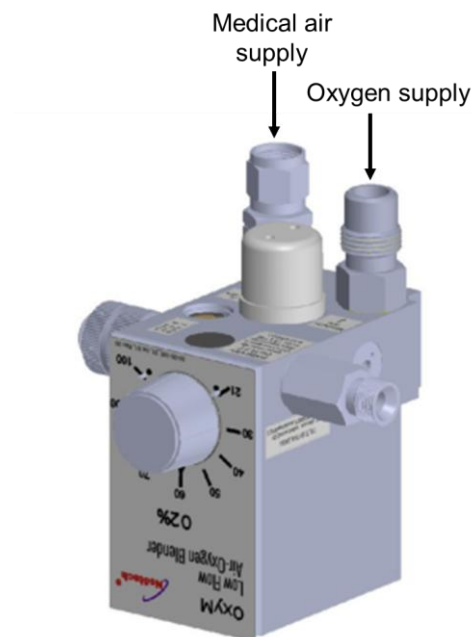
3.1.4 Operation Overview

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

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

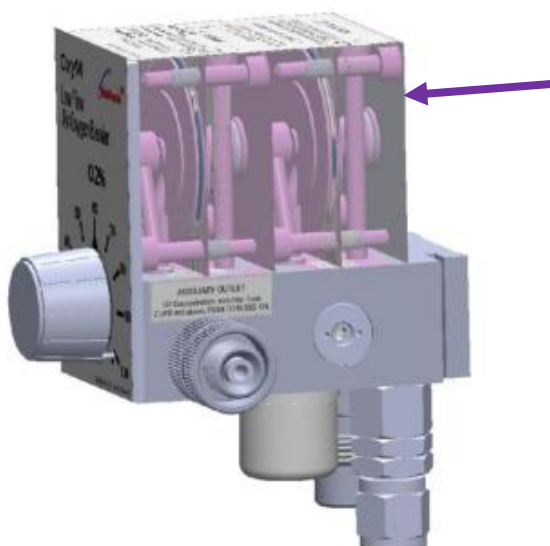
3.1.5 Functions

3.1.5.1 Gas Inlet Ports



The ports located on either side of the unit allow flexibility for the clinician. The OxyM Air-Oxygen Blender operates by using two 30–75 PSI gas sources that enter the device through DISS connectors located on the bottom of the unit. Each inlet connector incorporates a 30 micron particulate filter. After passing through the filter, the gases travel through duckbill check valves that prevent reverse gas flow from either the air or oxygen supply systems. The OxyM Air-Oxygen Blender is tested for compliance with ISO 11195 (2018), clause 9, regarding reverse-gas flow as delivered.

3.1.5.2 Balancing chamber



The gases then enter the two-stage pressure diaphragm balance modules, which equalize the operating pressures of the air and oxygen before entering the proportioning module. The diaphragm in the balance chamber responds to a difference in pressure and directs the movement (stroke) of each ball valve needle depend upon position of control knob. The movement of each ball valve needle adjusts the amount of gas flowing through the balance chamber, equalizing the air and oxygen pressures to the lower of the two pressures.

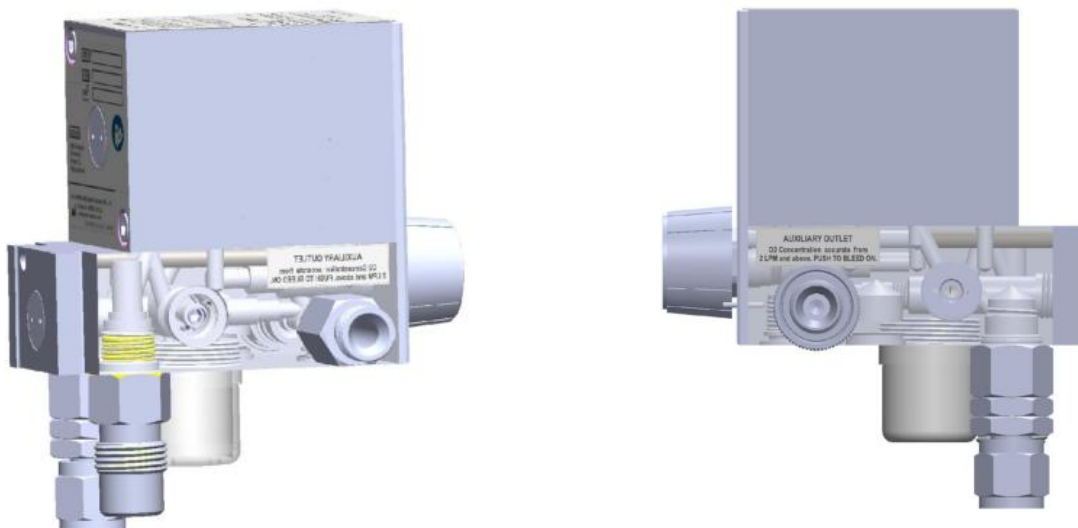
3.1.5.3 Proportioning Module



From the balance module, the gases flow into the proportioning module and mix according to the oxygen percentage selected with the OxyM Air-Oxygen Blender control knob. This module consists of a double shaft positioned between two valve seats. One valve seat controls the passage of air and the other valve seat controls the passage of oxygen into the OxyM Air-Oxygen Blender outlets. At this point, the two gases have been blended according to the oxygen percentage selected by the control knob.

When the Oxygen Concentration Knob is at the full counterclockwise position (21%), the double ended valve will completely close off the flow of oxygen, allowing only the air to flow. When the Oxygen Concentration Knob is adjusted to the full clockwise position (100%), the flow of air is blocked, permitting only the flow of oxygen through the Blender outlet.

3.1.5.4 Alarm/Bypass



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

If either source gas pressure drops, the output pressure of the blender will drop similarly, since the source gases are always balanced to that of the lower pressure. The bypass function operates in unison with the alarm. The alarm bypass poppet communicates directly with the air supply on one end and the oxygen supply on the other. When the two source gases are near equal in pressure, the alarm bypass poppet is positioned over the bypass

channel, blocking the flow of both gases. The poppet will remain seated for unequal pressures up to 20 ± 2 PSI. Once a 20 ± 2 PSI difference occurs, the higher gas pressure will overcome the spring force and pressure of the poppet at its opposite end, thus creating a path (air or oxygen) to flow into the alarm channel.

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

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

3.1.5.5 Outlet Ports



The primary and auxiliary outlets are DISS male adapters with check valves. On the Low Flow OxyM Air-Oxygen Blender, two outlet ports are located on the right and left sides of the Blender and allow ranges from 0-30 LPM with bleed and 0-30 LPM without bleed respectively.

3.1.5.6 Bleed Outlet

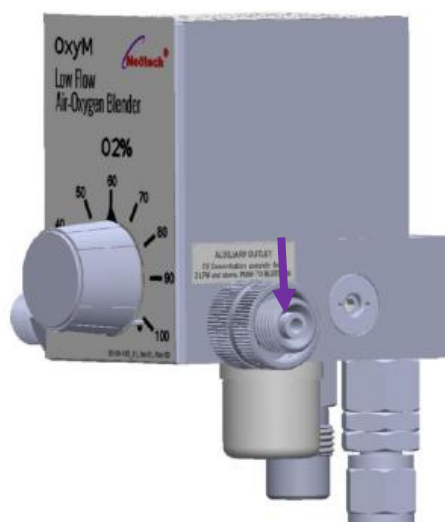


For the Low Flow OxyM Air-Oxygen Blender, when a connection is made to the right-side outlet port, for example, when a flow meter is attached, a bleed flow of 2.5-3.5 LPM is achieved. The Blender bleed flow exits the unit through a bleed port on the bleed switch.

A male DISS oxygen fitting with check valve that delivers flow when connected to a flow regulating device, such as flowmeter. This outlet is equipped with a bleed valve that allows the user to control if the bleed is ON or OFF. With the bleed in the ON position delivers accurate oxygen concentration from 1LPM and above at the right-side outlet port of blender.

Note: Only the auxiliary output facilitates the usage of bleed.

3.1.5.7 Auxiliary Bleed Switch



The switch is used to engage and disengage the bleed. The bleed is necessary to maintain accurate FiO_2 Concentration (2.5-3.5) l/min for the Low Flow. To activate the bleed, slide and rotate (if applicable) the knurled Knob back until it contacts the cover. To deactivate the bleed, pull and rotate (if applicable) knob away from cover until it reaches a positive stop.

3.1.6 Pre-Use Testing consists of:

- Alarm Test
- Reverse Gas Flow Procedure

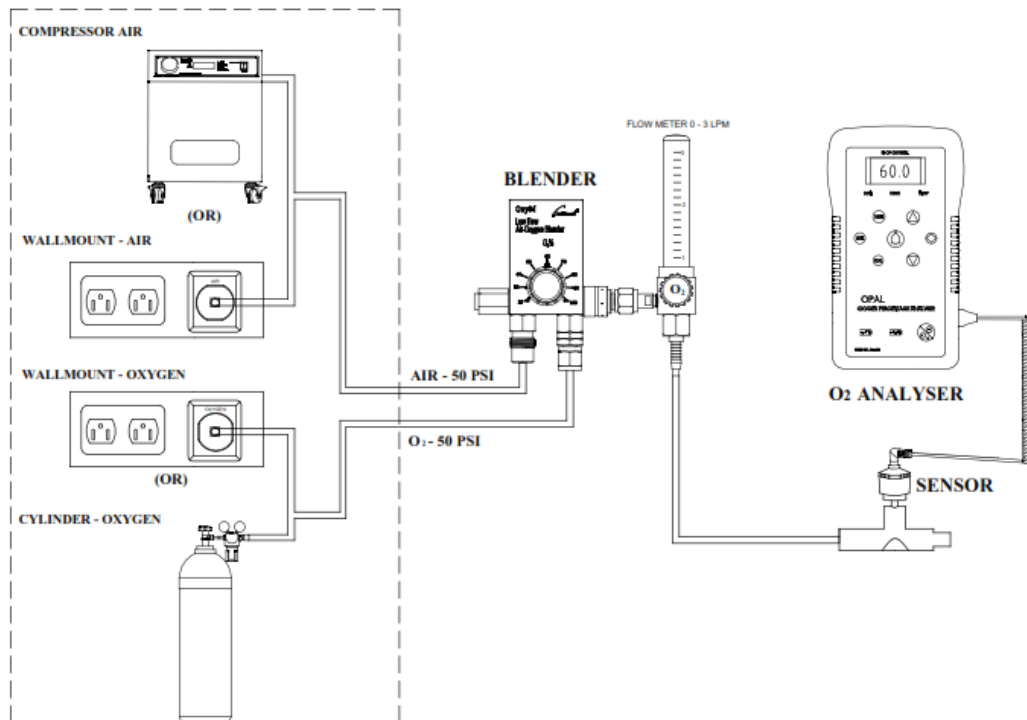
3.1.6.1 Alarm Test

- Step 1: Connect the Air-Oxygen Blender to air and oxygen source, pressurize the Blender and turn "ON" the flowmeter.
- Step 2: Set Oxygen Concentration Dial to 60% FIO_2 .
- Step 3: Disconnect or turn "OFF" the air supply to the Air-Oxygen Blender. The Blender should alarm with a loud whistle noise. The whistle indicates the alarm is operating correctly.
- Step 4: Reconnect and activate the air supply line to the Blender, the alarm should stop whistling.
- Step 5: Disconnect or turn "OFF" the oxygen supply line to the Blender. The whistle indicates the alarm is operating correctly.
- Step 6: Reconnect and activate the oxygen supply line to the Blender, the alarm should stop whistling.
- Step 7: If alarm fails to function properly, DO NOT USE.

3.1.6.2 Reverse Gas Flow Procedure

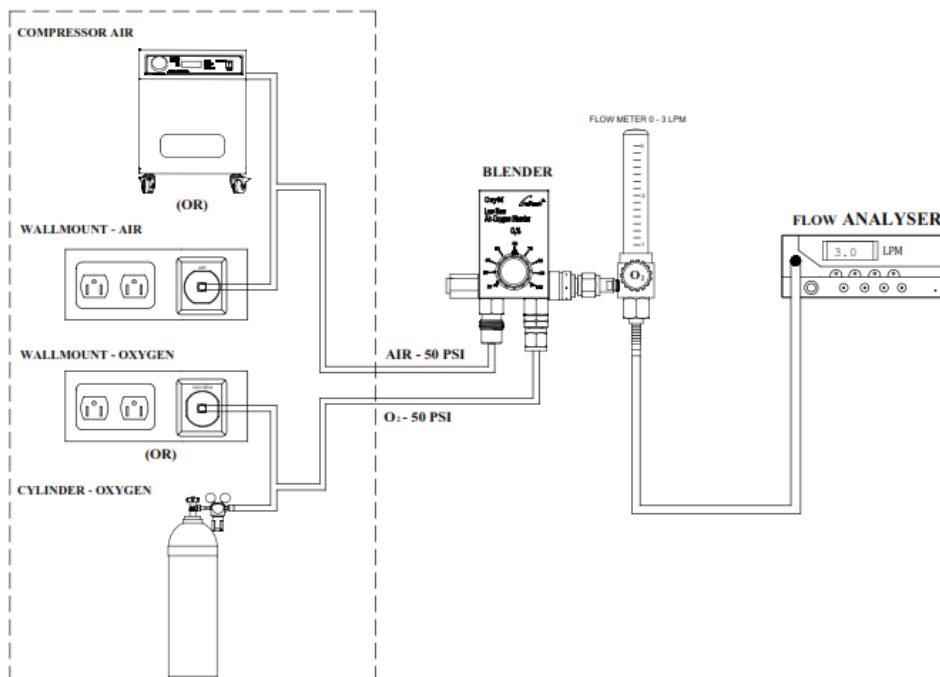
- Step 1: Disconnect the oxygen hose from the gas source. Remove all outlet connections from the Blender to ensure that there is no outlet flow.
- Step 2: While gradually increasing the air supply pressure from 30-75 psi (2.07-5.17 bar) check for leakage past the oxygen inlet check valve.
- Step 3: Replace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

3.1.6.3 Oxygen concentration checking Procedure



- The output of gas (air and oxygen) mixture is passed through the flow meter and connected to the T-Piece of the Oxygen Analyzer or Monitor.
- The oxygen sensor is connected to the oxygen sensor port of the T-Piece, to monitor the Oxygen concentration.

3.1.6.4 Output Flow checking Procedure



- The flow of blended gas is shown in the flow meter connected in the outlet connector of the Air Oxygen Blender.
- The flow can be increased or decreased as required by rotating the flow meter knob counterclockwise or clockwise respectively.

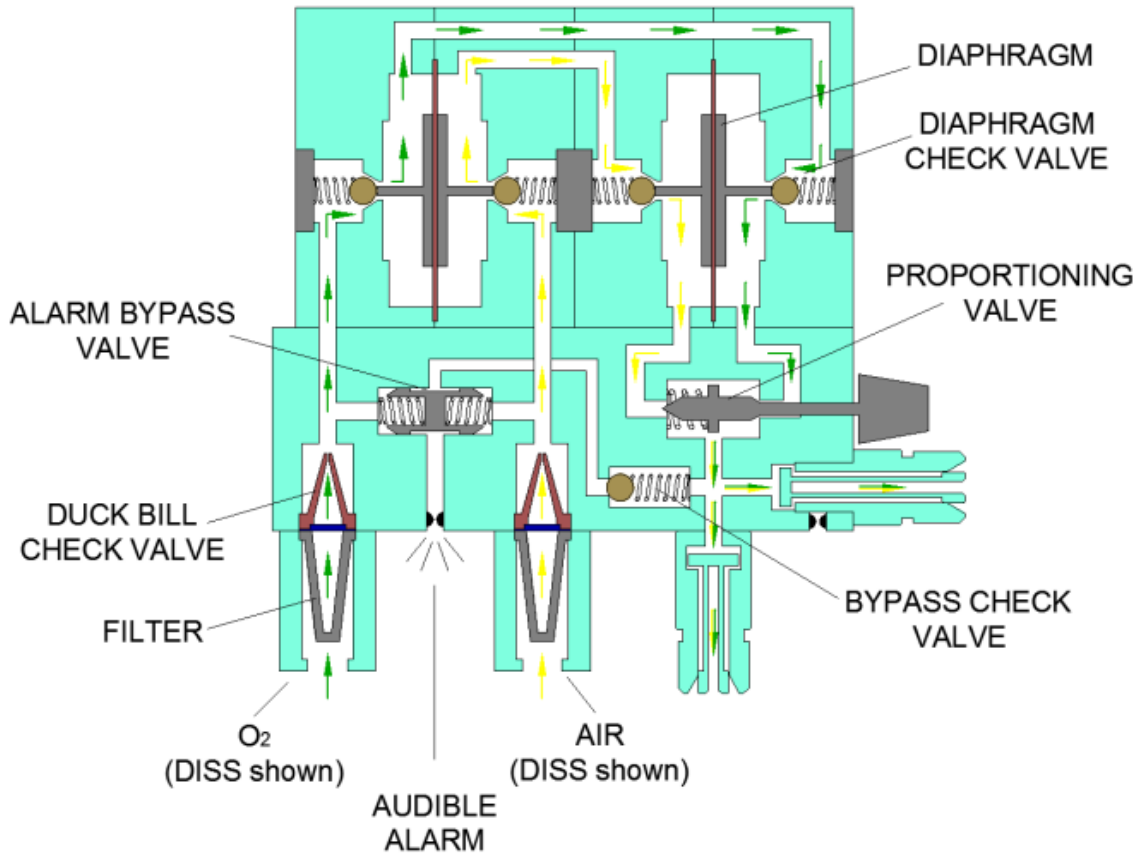
3.1.7 Operating Instructions

- Connect Air and Oxygen supply lines to blender either wall or cylinder mount.
- Connect flowmeter to Blender outlet.
- Adjust the Oxygen Concentration Dial to the prescribed concentration.
NOTE: The Oxygen Concentration Dial does not rotate 360°. DO NOT force dial less than 21% or over 100% oxygen, this will damage the Blender.
- Confirm the flow of air and/or oxygen mixture to the patient.
- Confirm the concentration of air/oxygen with an Oxygen Analyzer/Monitor. If necessary, activate bleed flow valve to maintain FIO₂ accuracy.
- To activate the bleed, turn and rotate the knurled collar back until it contacts the cover.
- To deactivate the bleed, pull and rotate the collar away from the cover until bleed flow valve is closed.
- Turn "OFF" gas supplies when Air-Oxygen Blender is not in use.

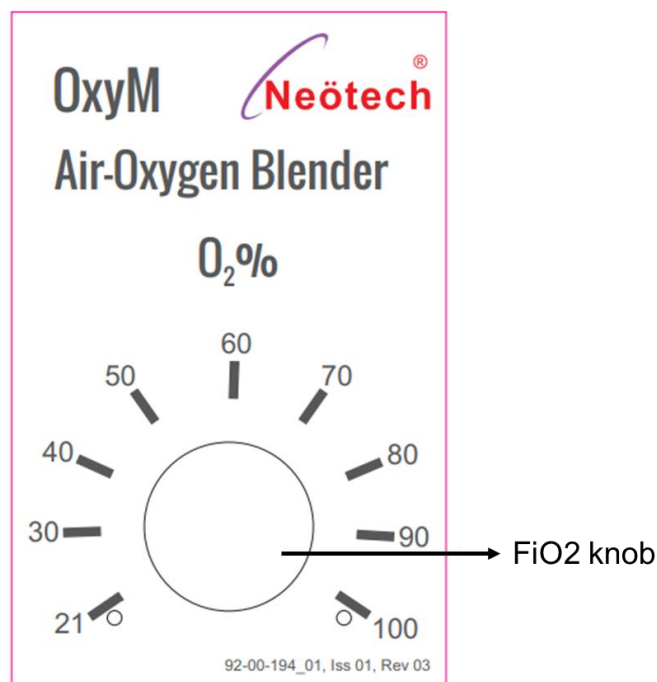
Note: Use pressure regulators for Air and Oxygen input for safe and effective blending.

3.2 nice 5010

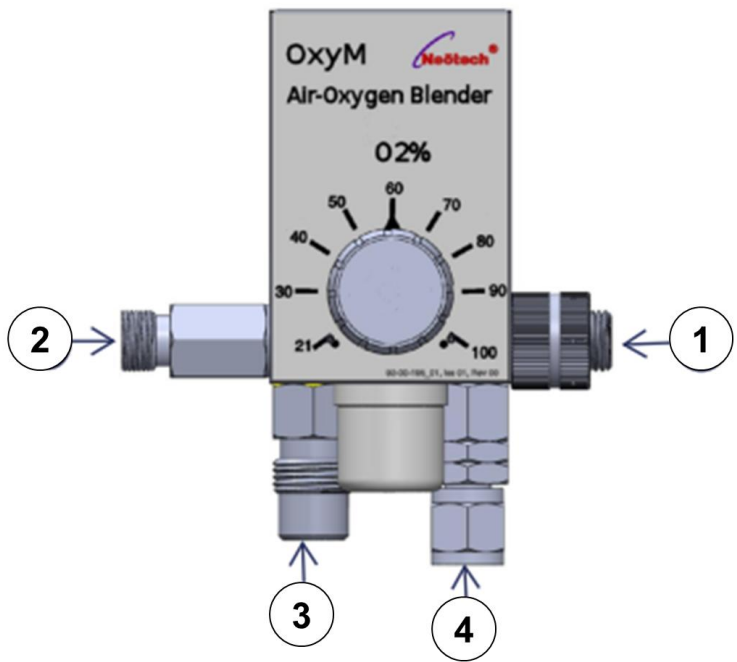
3.2.1 Pneumatic diagram



3.2.2 Control Panel Operation



3.2.3 Connection Ports



1	Auxiliary outlet
2	Primary outlet
3	Air inlet
4	Oxygen inlet

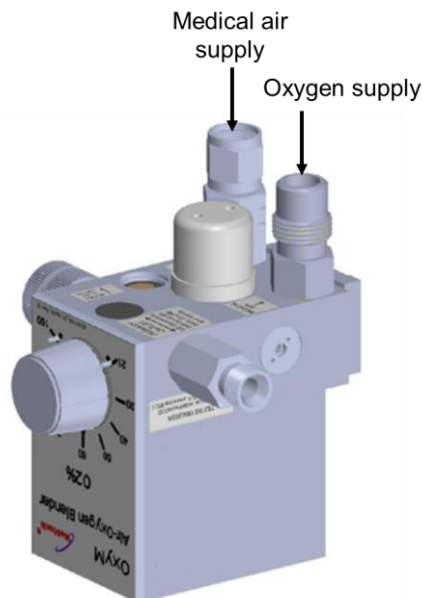
3.2.4 Operation Overview

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

	Output	Flow Range	Bleed Flow
High/Low Flow Blender	Primary, Left side	2-120 LPM	No Bleed Flow
	Auxiliary, Right Side	2-120 LPM	10-12 LPM

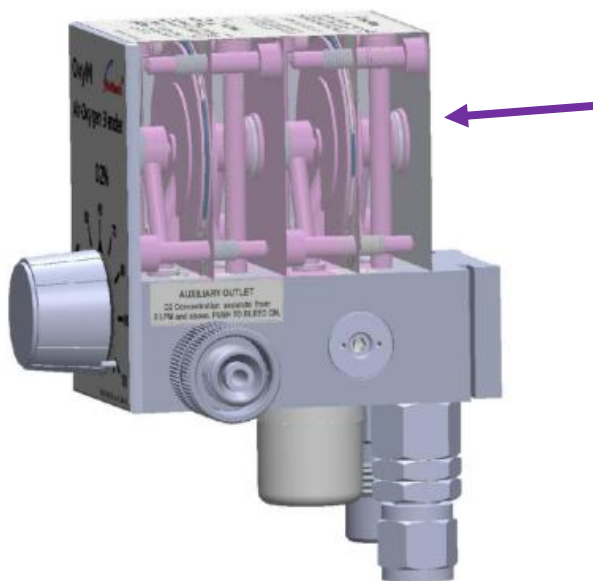
3.2.5 Functions

3.2.5.1 Gas Inlet Ports



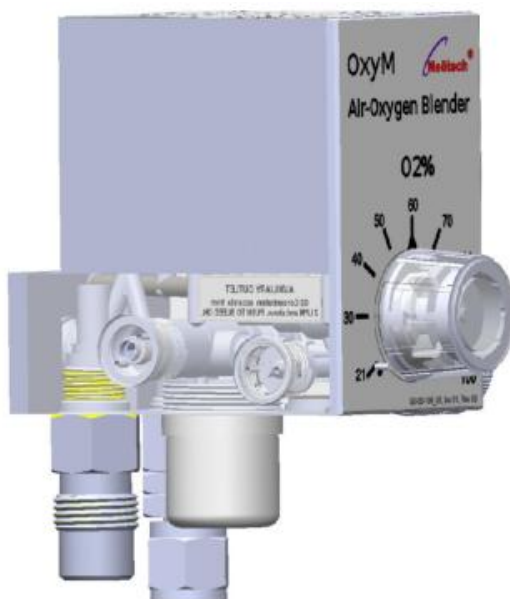
The ports located on either side of the unit allow flexibility for the clinician. The OxyM Air-Oxygen Blender operates by using two 30–75 PSI gas sources that enter the device through DISS connectors located on the bottom of the unit. Each inlet connector incorporates a 30-micron particulate filter. After passing through the filter, the gases travel through duckbill check valves that prevent reverse gas flow from either the air or oxygen supply systems. The OxyM Air-Oxygen Blender is tested for compliance with ISO 11195 (2018), clause 9, regarding reverse-gas flow as delivered.

3.2.5.2 Balancing chamber



The gases then enter the two-stage pressure diaphragm balance modules, which equalize the operating pressures of the air and oxygen before entering the proportioning module. The diaphragm in the balance chamber responds to a difference in pressure and directs the movement (stroke) of each ball valve needle depend upon position of control knob. The movement of each ball valve needle adjusts the amount of gas flowing through the balance chamber, equalizing the air and oxygen pressures to the lower of the two pressures.

3.2.5.3 Proportioning Module



From the balance module, the gases flow into the proportioning module and mix according to the oxygen percentage selected with the OxyM Air-Oxygen Blender control knob. This module consists of a double shaft positioned between two valve seats. One valve seat controls the passage of air and the other valve seat controls the passage of oxygen into the OxyM Air-Oxygen Blender outlets. At this point, the two gases have been blended according to the oxygen percentage selected by the control knob.

When the Oxygen Concentration Knob is at the full counterclockwise position (21%), the double ended valve will completely close off the flow of oxygen, allowing only the air to flow. When the Oxygen Concentration Knob is adjusted to the full clockwise position (100%), the flow of air is blocked, permitting only the flow of oxygen through the Blender outlet.

3.2.5.4 Alarm/Bypass



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

If either source gas pressure drops, the output pressure of the blender will drop similarly, since the source gases are always balanced to that of the lower pressure. The bypass function operates in unison with the alarm. The alarm bypass poppet communicates directly with the air supply on one end and the oxygen supply on the other.

When the two source gases are near equal in pressure, the alarm bypass poppet is positioned over the bypass channel, blocking the flow of both gases. The poppet will remain seated for unequal pressures up to 20 ± 2 PSI. Once a 20 ± 2 PSI difference occurs, the higher gas pressure will overcome the spring force and pressure of the poppet at its opposite end, thus creating a path (air or oxygen) to flow into the alarm channel.

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

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

3.2.5.5 Outlet Ports



The primary and auxiliary outlets are DISS male adapters with check valves. On the High Flow OxyM Air-Oxygen Blender, the primary outlet port is located on the left side of the Blender, and the auxiliary outlet is located on the right side of the Blender, allowing ranges up to 2-120 LPM with bleed and 2-120 LPM without bleed respectively.

3.2.5.6 Bleed Outlet



For the High/Low Flow OxyM Air-Oxygen Blender, when a connection is made to the right side outlet port, for example, when a flow meter is attached, a bleed flow 10-12 LPM is achieved. The Blender bleed flow exits the unit through a bleed port on the bleed switch.

A male DISS oxygen fitting with check valve that delivers flow when connected to a flow regulating device, such as flowmeter. This outlet is equipped with a bleed valve that allows the user to control if the bleed is ON or OFF. With the bleed in the ON position delivers accurate oxygen concentration from 5LPM and above at the right-side outlet port of blender.

For a high flow air-oxygen blender, the additional bleed should be activated if the total flow delivered to the patient is less than 15 LPM.

Note: Only the auxiliary output facilitates the usage of bleed.

3.2.5.7 Auxiliary Bleed Switch



The switch is used to engage and disengage the bleed. The bleed is necessary to maintain accurate FiO_2 Concentration (10-12) l/min for the High Flow. To activate the bleed, slide and rotate (if applicable) the knurled Knob back until it contacts the cover. To deactivate the bleed, pull and rotate (if applicable) knob away from cover until it reaches a positive stop.

3.2.6 Pre-Use Testing consists of:

- Alarm Test
- Reverse Gas Flow Procedure

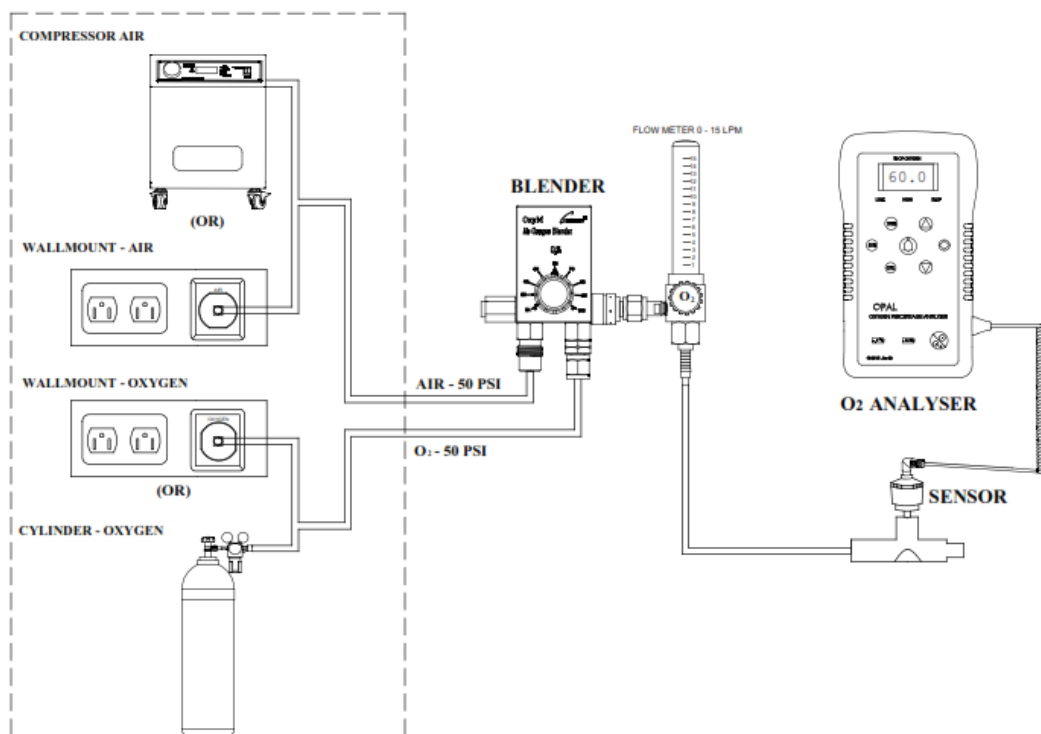
3.2.6.1 Alarm Test

- Step 1: Connect the Air-Oxygen Blender to air and oxygen source, pressurize the Blender and turn "ON" the flowmeter.
- Step 2: Set Oxygen Concentration Dial to 60% FiO_2 .
- Step 3: Disconnect or turn "OFF" the air supply to the Air-Oxygen Blender. The Blender should alarm with a loud whistle noise. The whistle indicates the alarm is operating correctly.
- Step 4: Reconnect and activate the air supply line to the Blender, the alarm should stop whistling.
- Step 5: Disconnect or turn "OFF" the oxygen supply line to the Blender. The whistle indicates the alarm is operating correctly.
- Step 6: Reconnect and activate the oxygen supply line to the Blender, the alarm should stop whistling.
- Step 7: If alarm fails to function properly, DO NOT USE.

3.2.6.2 Reverse Gas Flow Procedure

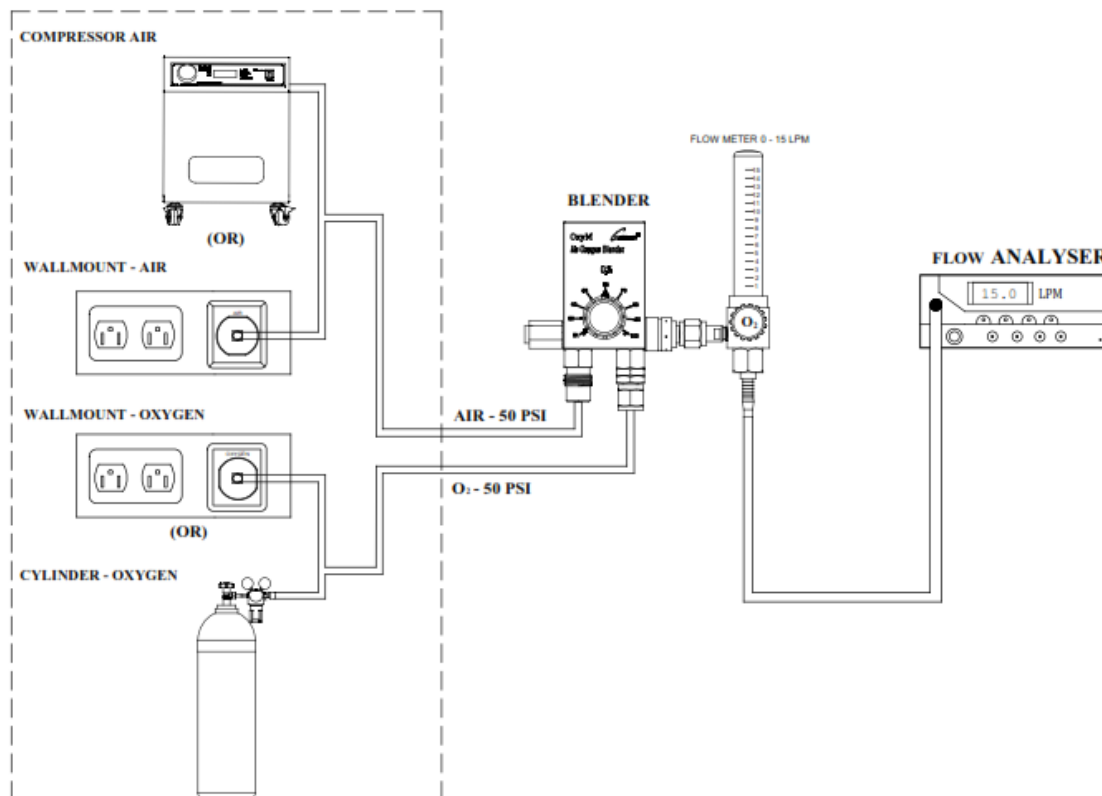
- Step 1: Disconnect the oxygen hose from the gas source. Remove all outlet connections from the Blender to ensure that there is no outlet flow.
- Step 2: While gradually increasing the air supply pressure from 30-75 psi (2.07-5.17 bar) check for leakage past the oxygen inlet check valve.
- Step 3: Replace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

3.2.6.3 Oxygen concentration checking Procedure



- The output of gas (air and oxygen) mixture is passed through the flow meter and connected to the T-Piece of the Oxygen Analyzer or Monitor.
- The oxygen sensor is connected to the oxygen sensor port of the T-Piece, to monitor the Oxygen concentration.

3.2.6.4 Output Flow checking Procedure



- The flow of blended gas is shown in the flow meter connected in the outlet connector of the Air Oxygen Blender.
- The flow can be increased or decreased as required by rotating the flow meter knob counterclockwise or clockwise respectively.

3.2.7 Operating Instructions

- Connect Air and Oxygen supply lines to blender either wall or cylinder mount.
- Connect flow meter to Blender outlet.
- Adjust the Oxygen Concentration Dial to the prescribed concentration.
- NOTE: The Oxygen Concentration Dial does not rotate 360°. DO NOT force dial less than 21% or over 100% oxygen, this will damage the Blender.
- Confirm the flow of air and/or oxygen mixture to the patient.
- Confirm the concentration of air/oxygen with an Oxygen Analyzer/Monitor. If necessary, activate bleed flow valve to maintain FIO₂ accuracy.
- To activate the bleed, turn and rotate the knurled collar back until it contacts the cover.
- To deactivate the bleed, pull and rotate the collar away from the cover until bleed flow valve is closed.
- Turn "OFF" gas supplies when Air-Oxygen Blender is not in use.

Note: Use pressure regulators for Air and Oxygen input for safe and effective blending.

3.3 Accessories (Optional)

#	Accessory Name	Type of use	Part no.	Intended use	Picture
1.	Flow meter 0 to 15LPM	Reusable	88-00-105	The flowmeter accurately controls gas flow rates with $\pm 5\%$ full-scale accuracy, featuring a rotary pin valve and available in various outputs like 3 LPM and 15 LPM. It is compatible with Air Oxygen Blenders, using DISS fittings per CGA V-5:2008.	
2.	Flow meter 0 to 3LPM	Reusable	88-00-139		
3.	Medical Air Hose	Reusable	50-20-171	Inlet hose for Air from centralized line or compressor to respiratory care devices.	
4.	Medical Oxygen Hose	Reusable	30-05-067	Inlet hose for Oxygen from centralized line or compressor to respiratory care devices.	
5.	Mounting Bracket	Reusable	Rail- 50-05-140 Pole – 50-05-129 Wall – 50-05-127	Mounting brackets for air-oxygen blenders provide secure positioning on rails, poles, or walls, ensuring stability and easy access for medical use. They support safe and convenient placement, keeping the blender securely in place during operation.	
6.	Air Oxygen Regulator	Reusable	50-05-130 50-05-131	Controls pressure up to 150 kg/cm ² for air-oxygen blenders, filters irritants, and prevents cross-connection with non-interchangeable connectors.	

Section 4: Cleaning & Maintenance (nice 5005 and nice 5010)

- 4.1 Cleaning the Air Oxygen Blender
- 4.2 Cleaning of Air/Oxygen Flowmeters and Air/Oxygen input hose (Optional accessory)
- 4.3 Maintenance
- 4.4 Recommended maintenance schedule
- 4.5 Performance Check
 - 4.5.1 Low Flow Blender Alarm / Bypass Check Reverse Flow Check
 - 4.5.2 High Flow Blender Alarm / Bypass Check
 - 4.5.3 Methods of Measurement of flow, pressure and Oxygen Concentration of delivered gas

4.1 Cleaning the Air Oxygen Blender

During cleaning the Air-Oxygen Blender, the processing shall comply with ISO 17664-1:2021 for reusable of the device

1. Clean external surfaces of the nice 5005 / nice 5010 Air Oxygen Blender and Gas Supply line with damp cloth using soap (e.g. liquid dish soap) and clean water.
2. Rinse the equipment completely with water damp cloth.
3. Disinfect the equipment by using 2% Glutaraldehyde to inactivate any remaining pathogens.
- When the equipment is not in use, all approachable external surfaces should be cleaned daily with an antiseptic solution like 2% glutaraldehyde. Every seventh day, the equipment should be cleaned thoroughly, first by mild detergent solution and then by antiseptic solution for 3 minutes. All detachable assemblies, are to be treated similarly
4. Rinse with damp 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 Air Oxygen Blender that has been chemically disinfected for reuse, because tap or distilled water may harbour microorganisms. However, when rinsing with sterile water is not feasible, instead, rinse with tap water or filtered water (i.e. water passed through a 0.2 μ filter).
5. Dry all surfaces after cleaning using dry towel or cloth.

Note: Follow the manufacturer's instructions carefully.
Use the correct dilution of the disinfectant.
DO NOT immerse the blender in any liquid.



Warning

- Disconnect all gas connections and equipment before cleaning
- Do not immerse the assembled Low Flow blender in liquid decontamination agents.
- Do not use any strong solvent cleaners on labels or markings.



Caution

- **Use of nonstandard components:** Consult the manufacturer for repair and replacement of components. Use of incorrect component can adversely affect Safety, performance and/or damage the equipment performance
- Use of cleaning/disinfecting solutions containing chemicals that are not listed above (i.e. alcohol, acetone, etc.), or chemicals in greater concentrations than those listed above, may damage the Plastic knob being cleaned.

- Do not autoclave or gas sterilize the Air Oxygen Blender. Do not immerse the device in liquid cleaner.

4.2 Cleaning of Air/Oxygen Flowmeters and Air/Oxygen input hose (Optional accessory)

- The cleaning methods listed below and do not affect the integrity or performance of the flowmeter and input hoses. It is the user's responsibility to qualify any deviations from these procedures, both for disinfecting efficacy and physical effect on the flowmeter and input hoses.
- Physically clean the flowmeter and input hoses with soft cloth, removing all visible contaminants by wiping using DM water general cleaning.
- Rinse the flowmeter and input hoses surfaces completely with water damped cloth.
- Disinfect the flowmeter and input hoses surfaces by using 2% Glutaraldehyde to inactivate any remaining pathogens
- Rinse the flowmeter and input hoses surfaces completely with water damped cloth.
- Dry all surfaces after cleaning using dry towel or cloth.



Caution

DO NOT autoclave flowmeter.
DO NOT use dishwasher detergents or solvents.

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

4.3 Maintenance

The following maintenance on the Air-Oxygen Blender must be performed by a trained service technician:

- The alarm should be tested prior to being placed into clinical service and periodically there after every year conduct the Performance Check or as per the hospital protocol.
- Check that the blending accuracy of oxygen stays within the tolerance of $\pm 3\%$ as the routine maintenance check.

4.4 Recommended Maintenance Schedule

OxyM Air-Oxygen Blender is designed to provide the maximum amount of utilization with a minimum amount of maintenance. When determining the desired frequency of complete overhaul intervals, three variables must be considered:

- Frequency of use
- Cleanliness of compressed air source
- Use of an air inlet filter/water trap

The Blender, like other pieces of health care equipment, will require routine maintenance over a period of time. Before to placing the Blender into clinical use, follow the performance-check as described below. When using the Blender with a compressed air source, an air inlet filter/water trap is recommended. Contaminants from hospital air lines may compromise the function of the Blender.



Caution

- Applicable parts used in the Blender have been cleaned and de-greased for oxygen service. All lubricants used during assembly are designed for use in an oxygen enriched environment. Use only oxygen compatible lubricants when servicing this device. Elastomer components, such as diaphragms and o-

rings, are designed to function satisfactorily for a minimum of two years. The need for cleaning and replacement depends on gas line conditions and is indicated by the Blender not meeting its specified performance.

4.5 Performance Check

Before placing the Blender into clinical use, perform the following performance checks.



Warning

- If the OxyM Air-Oxygen Blender does not function as described below, contact nice Neotech (refer to the company information at the beginning of this manual).
- DO NOT use the OxyM Air-Oxygen Blender until correct performance is verified.

4.5.1 Low Flow Blender Alarm / Bypass Check Reverse Flow Check

SL. No.	Adjustment	Response
1	Applying 30 -75 PSIG air/oxygen source gas. Adjust the control knob to 60%	Alarm/By pass* should not activate (if gases are within 20 PSI of each other).
2	Disconnect the 50 PSIG air source from the Blender.	Audible alarm, by pass* gas flow starts.
3	Reconnect the 50 PSIG** air source to the Blender.	Audible alarm stops; by pass* gas flow stops flowing.
4	Disconnect the 50 PSIG** oxygen source from the Blender.	Audible alarm, by pass* gas flow starts.
5	Reconnect the 50 PSIG** oxygen source to the Blender.	Audible alarm stops; by pass* gas flow stops flowing.
6	Connect a flow meter and an oxygen analyzer to either outlet port; with the Blender control knob set at 60%, adjust the outlet flow rate to 6 – 8 LPM.	Oxygen analyzer should read 60 ±5% when measured from the flow meter outlet.

* Bypass flow should occur whenever the alarm sounds, but this condition can only be verified by measuring O₂ concentrations with an oxygen analyzer.

** Gas supply pressures of 50 PSIG provide optimal performance.

4.5.2 High Flow Blender Alarm / Bypass Check

SL. No.	Adjustment	Response
1	Connect the 50 ±5 PSIG (3.52 ± 0.35 kg/cm ²) air/ oxygen source gases. Adjust the control knob to 60%. Connect the flow meter to the auxiliary outlet and set the flow to 2 LPM.	Alarm/Bypass should not activate.
2	Connect an oxygen flow meter to the auxiliary outlet to activate the auxiliary bleed and disconnect the 50 PSIG (3.52 kg/cm ²) air source from Blender. NOTE: The Blender must be flowing gas for the alarm to activate.	Audible alarm.
3	Reconnect the 50 PSIG (3.52 kg/cm ²) air source to the Blender.	Audible alarm stops. Verify oxygen concentration with an oxygen analyzer.
4	Disconnect the 50 PSIG (3.52 kg/cm ²) oxygen sources from the Blender.	Audible alarm.

5	Reconnect the 50 PSIG (3.52 kg/cm ²) air source to the Blender.	Audible alarm stops. Verify oxygen concentration (57% to 63%) with an oxygen analyzer.
6	Verify that the oxygen flow meter is set at 2 LPM.	Oxygen analyzer should read 57 to 63% when measured from the flow meter outlet

4.5.3 Methods of Measurement of flow, pressure and Oxygen Concentration of delivered gas

1. Flow: The flow of blended gas is shown in the flow meter connected in the outlet connector of the Air Oxygen Blender.
2. Pressure: Remove the flow meter from the outlet connector and insert pressure gauge or pressure monitor to measure the output pressure.
3. Oxygen concentration: The output of gas (air and oxygen) mixture is passed through the flow meter. Connect the oxygen analyzer in the T-piece which is connected to the output of flow meter to measure the oxygen concentration.

NOTE:

- Air Oxygen Blender should be calibrated every 6 months or as per hospital protocol.
- Accuracy of Air Oxygen Blender should be confirmed every week or as per hospital protocol.

4.6 Lifetime of product

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).

Section 5: Specifications

5.1 nice 5005

Parameter	Specification
Gas Inlet Supply Pressure	30 – 75 psig. Output flow rate will be diminished if either supply pressure is below 50 psig; output flow will increase if both supply pressures are above 50 psig.
Oxygen Concentration Control	21 to 100%
Auxiliary Outlet Flow Range	Right Side Outlet 0 to 30 LPM (Bleed 2.5 to 3.5 LPM)
Primary Outlet Flow Range	Left Side Outlet 0 to 30 LPM (No Bleed)
Fittings	DISS Fitting (NIST fitting is also available)
Accuracy	The accuracy is $\pm 3\%$ FIO ₂ at any set-point, provided the inlet supply pressures are between 30 and 75 psig and the difference between them does not exceed 10 psi.
Stability	O ₂ concentration shall not vary from a set-point by more than $\pm 5\%$ if either the inlet supply pressure or the output flow rate is changed within its range specified herein.
Alarm/Bypass Activation	When inlet gas pressures differ by 20 ± 2 psi.
Alarm Sound Generator	Reed Alarm
Alarm Sound Intensity	80.3 dB minimum at 1 foot
Alarm / Bypass Reset	When inlet gas pressure differential is 10 PSI or less
Pressure Drop	Less than 6 PSI at 50 PSIG inlet pressures and 10 LPM flow rate
No. of output ports	Two DISS output ports (NIST fitting is also available)
Weight	1 .25kg (without flow meter)
Dimensions	Height: 14.8 cm Width: 11.5 cm Depth: 11.3 cm
Medical Air input hose (optional accessory)	3 meters length, Black & White colored, Female DISS 1160
Medical Oxygen Hose (optional accessory)	3 meters length, White colored, Female DISS 1240
Auxiliary flow meter (optional accessory)	0 to 3 LPM, DISS fitting
Primary Flow Meter (optional accessory)	0 to 15 LPM, DISS fitting

5.2 nice 5010

Parameter	Specification
Gas Inlet Supply Pressure	30 to 75 psig. Output flow rate will be diminished if either supply pressure is below 50 psig; output flow will increase if both supply pressures are above 50 psig.
Oxygen Concentration Control	21 to 100%
Auxiliary Outlet Flow Range	Right Side Outlet 2 to 120 LPM (Bleed 10 to 12 LPM)
Primary Outlet Flow Range	Left Side Outlet 2 to 120 LPM (No Bleed)
Fittings	DISS Fitting (NIST fitting is also available)
Accuracy	The accuracy is $\pm 3\%$ FIO ₂ at any set-point, provided the inlet supply pressures are between 30 and 75 psig and the difference between them does not exceed 10 psi.
Stability	O ₂ concentration shall not vary from a set-point by more than $\pm 5\%$ if either the inlet supply pressure or the output flow rate is changed within its range specified herein.
Alarm/Bypass Activation	When inlet gas pressures differ by 20 ± 2 psi.
Alarm Sound Generator	Reed Alarm
Alarm Sound Intensity	80.2 dB minimum at 1 foot
Alarm / Bypass Reset	When inlet gas pressure differential is 10 PSI or less

Pressure Drop	Less than 6 PSI at 50 PSIG inlet pressures and 40 LPM flow rate
No. of output ports	Two DISS output ports (NIST fitting is also available)
Weight	1 .25kg (without flow meter)
Dimensions	Height: 14.8 cm Width: 11.5 cm Depth: 11.3 cm
Medical Air input hose (optional accessory)	3 meters length, Black & White colored, Female DISS 1160. The detachable air inlet pressure hoses supplied with this Air-Oxygen Blender meet the requirements of ISO 5359.
Medical Oxygen Hose (optional accessory)	3 meters length, White colored, Female DISS 1240. The detachable oxygen inlet pressure hoses supplied with this Air-Oxygen Blender meet the requirements of ISO 5359.
Auxillary flow meter (optional accessory)	0 to 3 LPM, DISS fitting
Primary flow meter (optional accessory)	0 to 15 LPM, DISS fitting

Dryness and Composition for inlet gases:

Air	Medical Air supply should meet the requirements of ANSI Z86.1 – 1973 commodity specification for Air, type 1 grade D or better.
Oxygen:	Oxygen supply must meet all requirements of Medical Grade Oxygen.
Dew Point	Both inlets should remain 10°F (-12.22°C) or more below the lowest temperature to which the air distribution system equipment is exposed. At a temperature of 25°F (-3.9°C) and a pressure of 90 psi (6.33 kg/cm ²) this equates to 2000 mg/m ³

Environmental Conditions	
Operating Temperature	10 to 30°C
Operating Humidity	15 to 90% RH, non-condensing
Storage Temperature	-10 to 60°C
Storage Humidity	50 to 90% RH, non-condensing

Quality Standard	
QMS	ISO 13485:2016
Particular ISO standard	ISO 11195:2018
Graphical Symbols	ISO 15223-1:2021

Section 6: Warranty

Conditions

1. The warranty is confined to the first purchaser of the product only and is not transferrable.
2. Repairs under warranty period shall be carried out by the company authorized personnel only.
3. In the event of repairs of any part/s of the unit, this warranty will thereafter continue and remain in force only for the unexpired period of the warranty. The time taken for repair and in transit whether under the warranty or otherwise shall not be excluded from the warranty period.
4. In case of any damage to the product/misuse detected by the Authorized service personnel the warranty conditions are not applicable and repairs will be done subject to availability of parts and on a chargeable basis only
5. Wear and Tear, and defects caused by manipulation or unsuitable treatment are not included under the warranty.
6. We warranty this unit for 12 months from the date of Installation. Warranty includes the repair and replacement of faulty components.
7. Defects caused by improper use, and defects due to causes beyond control like lightning, acts of god, and also defects caused by rats, cockroaches or any other insects will not be covered under warranty.
8. Warranty is not applicable if the equipment is not purchased from Neotech/authorized Neotech Dealer
9. Warranty is not applicable if the warranty card is not filled and sent back to Neotech.
10. 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

Date: _____

Hospital Name & Address: _____

Contact Person & Telephone/Fax No _____

Email _____

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

Equipment Name: _____

Model No: _____ Sl. No. _____

Date of Purchase: _____ Date of Installation _____

Name of Authorized Dealer: _____

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

Dealer Signature with seal

Kindly fill the above and send the same

From

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

7.2 Disposing of the equipment.

7.1 System Failure

SI. No	Problem	Cause	Remedy
1	Oxygen concentration discrepancy between Blender settings and analyzer.	Analyzer out of calibration	Calibrate the analyzer
		Flow requirements are below the specified LPM range.	Correct the flow. Verify that the correct outlet port is being used. Each outlet port has a different flow range.
		Gas supply is contaminated	Correct the contaminated gas supply. If repair is needed, contact nice Neotech
		Blender is out of calibration	Contact nice Neotech for calibration.
		Bleed is obstructed, causing reduction of bleed	Contact nice Neotech
2	Alarm at constant activation	Inlet pressure difference greater than 20 PSI.	Correct the pressure difference
		Alarm module is not calibrated properly	Contact nice Neotech for repair.
		Inlet gas contamination, alarm module malfunction	Contact nice Neotech for repair.
3	Blender in bypass – no alarm.	sounder plate improperly installed or damaged	Contact nice Neotech for repair.
4	Blender is accurate only when inlet gas pressures are equal.	Balance module not functioning properly	Contact nice Neotech for repair
		Both air and oxygen gas sources are below 30 PSIG.	Correct the low-pressure condition
5	Blender produces no alarm when air/ oxygen input supply is cut off.	Alarm mechanism disturbed or damaged.	Contact nice Neotech

7.2 Disposing of the Unit

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

Section 8: Spare Parts List (optional accessories)

Sl. no	Part No	Part Name	Qty	Unit
1	50-05-129	Blender pole mounting bracket	1	No.
2	50-05-127	Blender wall mounting bracket	1	No.
3	50-05-140	Blender rail mounting bracket	1	No.
4	30-20-067	Oxygen Supply Hose, 3 meter	1	No.
5	50-20-171	Air Supply Hose, 3 meter.	1	No.
6	50-05-083	Service O-ring Kit	1	No.
7	88-00-105	Flow meter (0 to 15LPM)	1	No.
8	88-00-139	Flow meter (0 to 3LPM)	1	No.

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:	<input type="checkbox"/> Complaints <input type="checkbox"/> Adverse Events <input type="checkbox"/> Comments <input type="checkbox"/> 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
<p>nice Neotech Medical Systems Pvt. Ltd. No. 85-86, Krishna Industrial Estate, Mettukuppam, Vanagaram, Chennai-600095. Tamil Nadu, INDIA. Ph: 91-44-2476 4608 Telefax: 91-44-2476 2594 E-mail: service@niceneotech.com /info@niceneotech.com Web: www.niceneotech.com SRN: IN-MF-000010243</p>	<p>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</p>	<p>Refer to the contact points in the below web address: https://health.ec.europa.eu/medical-devices-sector/new-regulations/contacts_en</p>

Section 10: EC certificate notified body

Name:

DQS Medizinprodukte GmbH

Notified body number:

0297

Address:

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

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

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