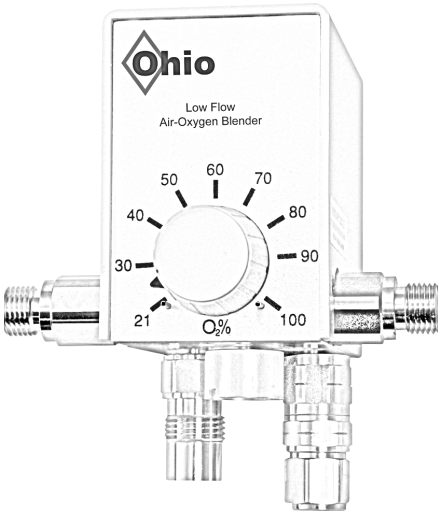
Ohio® Medical

Air/Oxygen Blenders

Instructions For Use



Rx Only

6700-0494-200 (Rev. 7) 03/2021

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Model Identifier

LOW FLOW BLENDERS		
NEO_2 Blend With Unique Bleed Switch 6750-0018-9XX	Blender With On/Off Knob 6750-0019-9XX 6750-0022-9XX	Standard Low Flow 6750-0020-9XX
		
unique on/off bleed switch blender with 2 assembled flowmeters	blender equipped with on/off bleed knob	versatile blender with left, right ports
HIGH/LOW FLOW BLENDERS		
High/Low With Attached Flowmeter 6750-0027-9XX	3 Ports 6750-0025-9XX	Standard High/Low Flow 6750-0024-9XX
		
high/low blender with 1 assembled flowmeter	high/low blender with left, right, bottom ports	versatile blender with right, bottom ports

Addendum 1

Bleed Knob Models: 6750-0019-9XX/6750-0022-9XX
Low Flow with Bleed Knob Blender model 6750-0019-9XX AND 6750-0022-9XX have a bleed knob that has been installed in lieu of the right side output port. This enables the user to maintain accurate concentrations when using the bottom or left outputs for all flows within the specification of the blender with a simple turn of the knob.

A label attached to the side of the blender indicates how to position the knob for accurate concentrations at settings less than or greater than the flow rate indicated. The knob must be pushed in prior to turning.

Addendum 2

Low Flow with Bleed Switch (NEO_2 Blend) Models: 6750-0018-9XX (Right and Left Flowmeter)
High-Low with Bleed Switch Blender 6750-0026-9XX (Right Flowmeter)
Blender models 6750-0018-9XX and 6750-0026-9XX are always offered with assembled flowmeters. The flowmeter on the right side is mounted to a uniquely designed rotating bleed switch that is used in the same manner as the knob described in Addendum 1. Any time these blenders are used in a flow range requiring the bleed to be active (see the Flow Table in Section 4), rotating this flowmeter as described below will activate the bleed as well as the flowmeter. Even if the flowmeter is not to be used, positioning it vertically so the bleed is active allows the blender to be used with its lower flows. The flow rate for these flowmeters should be set using the center of the ball.

RIGHT SIDE FLOWMETER
The right side flowmeter and the blender bleed are inactive when the flowmeter is angled towards the front of the blender. To activate the flowmeter and initiate the required bleed for lower flows, push the flowmeter in towards the side of the blender and then rotate it clockwise (towards the back) to its vertical position. The internal bleed will now be active and the flow rate may be set using the knob on the flowmeter. As long as the flowmeter is in this position, any output port can be used for low flows even if the flowmeter itself is not being used. To return the flowmeter and bleed to its off (inactive) state, return it to its angled position by pushing it in and rotating it counterclockwise (towards the front).

LEFT SIDE FLOWMETER (IF PRESENT)
CAUTION: The flowmeter on the left side is stationary. Do not try to turn it.

If the flowmeter on the left side is to be used for flows requiring a bleed for accuracy (see the Flow Table in Section 4), be sure the knob (see Addendum 1) or right-side flowmeter (see above) is set properly.

This flowmeter is meant for flows above 3 L/min. It may, however, be used below 3 L/min with the following consideration; when set below 3 L/min, turn on the required bleed by setting the right side flowmeter to its vertical position following the procedure as described above. Even though the flowmeter on the right is not being used, having it in the vertical position activates the internal bleed thereby guaranteeing O_2 accuracy while using the left side flowmeter at flows below 3 L/min.

Receiving/Inspection

Remove the Ohio Medical LLC Air/Oxygen Blender from the packaging and inspect for damage. If there is any damage, DO NOT USE and contact your dealer or service representative.

Read All Instructions Before Using

This instruction manual is provided for your safety and to prevent damage to the Air/Oxygen Blender. This manual instructs a professional to install and operate the Air/Oxygen Blender. If you do not understand this manual, DO NOT USE the Air/Oxygen Blender and contact your dealer or service representative.

Device Description

The Ohio Medical LLC Air/Oxygen Blender is a restricted medical device intended for use by qualified and trained personnel under the direction of a physician in institutional environments where delivery of air/oxygen mixtures is required.

Intended Use

The Ohio Medical LLC Air/Oxygen Blender is designed to dispense a continuous blend of Medical Air and Oxygen via outlet ports to infant, pediatric and adult patients.

Warnings & Cautions

WARNINGS

If the pressure of the oxygen or air gas source increases or decreases, resulting in a 20 psi (138 kPa) difference, the alarm will sound. This will affect the blender's output flow and oxygen concentration.

The blender alarm will sound if the air or oxygen gas source fails. This indicates to the user that the oxygen concentration or flow may not be accurate. A physician must determine the correct FIO_2 setting.

The blender MUST NOT be exposed to extremely high temperatures, as in the case of steam autoclaving (which could reach 145°F/62°C).

DO NOT autoclave.

The alarm should not be obstructed, removed or tampered with.

The blender is designed to operate from a 50 psig (345 kPa) source of air and oxygen.

Before use on a patient, the oxygen concentration of the delivered gas should be checked at the setting intended for use. A separate, calibrated oxygen analyzer (complying with ISO 7767) should be used whenever the blender is used on a patient.

The bleed port on the bottom of the blender must not be covered at any time.

NEVER leave a ventilator patient unattended.

Some special order blenders may not have a bleed when using the right side outlet. When this is the case, the flow specifications for "flow without bleed" apply to the auxiliary outlet.

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 Ohio Medical LLC. Doing so may cause gas supply contamination due to back flow.

CAUTIONS

Moisture or dirt can affect the operation of the blender.

A clean dry gas source must be used at all times.

The air must meet "USP grade" compressed air (standard formerly ANSI Z86.1-1973 grade F) and at 75 PSI (517 kPa) water vapor content cannot exceed a dew point of 5°F (2.8°C) below the lowest ambient temperature to which the blender and accessories are exposed.

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).

A water trap assembly and filter must be used to avoid malfunction should water accidentally getting into the gas supply sources.

Do not use in a MRI room unless the blender has been built to be used for such an environment. This will be indicated by “MRI” on the blender.

The flowmeter on the left side of the NEO2 blender is stationary. Do not try to turn it.

If the blender does not pass the performance test, do not place the unit into service; call your dealer or service representative

Note: This blender has been degreased for oxygen service prior to delivery. The upper flow limit is the total flow that the blender will pass, not the limit per port.

Symbols Explained

	Refer to manual for proper method of operation		Date of Manufacture		
	Refer to manual for proper method of operation		Manufacturer		Country of Manufacture
	Warning: Condensed water in air supply can cause malfunction of this device		Warning: Do not obstruct alarm or bleed holes in the bottom of this device		
	Product should be kept dry	SN	Serial Number	MD	Medical Device
EC REP	Authorized Representative in the European Community	REF	Catalog Number	UDI	Unique Device Identifier
Rx Only	Caution: Federal (USA) Law restricts this device to sale by or on the order of a licensed healthcare provider.				
CE 2797	The CE Mark displayed on this product signifies that this device is in compliance with the European Medical Devices Directive (Council Directive 93/42/EEC). As a prerequisite for the CE mark, Bio-Med Devices operates under an ISO 13485 compliant quality system (covering the design and manufacture of medical devices).The four-digit code underlying the CE mark (2797) pertains to Bio-Med's Notified Body, the British Standards Institute, whose function is to investigate and attest to the validity of CE-mark claims.				

Specifications

Configurations available deliver accurate FIO_2 mixtures from one (1) up to three (3) outlet ports allowing the blender to power three items at once. Several flow ranges are available. They can be used with ventilators, nasal cannulas, mask CPAP and resuscitation bags. The Low Flow version of the blender provides flows from 3 to 30 L/min with no gas bleed. The high/low blender provides flow from 15-20 L/min with no gas bleed. MRI conditional versions that are made entirely of non-magnetic materials are also available.

Device-Specific Standards	Complies with ISO 11195 : 1995
Oxygen % Range	21 to 100%
Oxygen % Accuracy	±3% of full scale
Supply Pressure	Both supplies within range of 30-75 PSI (207-517 kPa) and Air & oxygen must be within 10 psi (69 kPa) of each other. Do not use on a patient or with a ventilator outside of this range.*
Maximum Flow	≥120 L/min High/Low Flow Blender (≥30 L/min, Low Flow Blender) at 60% setting & 50 PSI (345 kPa) inlet pressures
Pressure Drop	<6 psi (42 kPa) at 50 psi (345 kPa) inlet pressure and 40 L/min flow (10 L/min, Low Flow blender)

Alarm/Bypass Reset	When inlet gas pressure differential is ≥6 psi (42 kPa)
Alarm Intensity	80 dB at 1 foot
Input Fittings	Oxygen Female DISS, Air Male DISS (NIST available)
Output Fitting(s)	Oxygen Male DISS
Dimensions	3.5" (8.9 cm) H × 2.25" (5.7 cm) W × 2.9" (7.3 cm) D
Weight	2.35 lbs (1.07 kg) basic low flow model with plastic chamber plates 3.15 lbs (1.43 kg) basic low flow model with aluminum chamber plates
Reverse Gas Flow	From either gas inlet to the other is zero (complies with clause 6 of ISO 11195)

*Blender performance with supply pressures below range (0-30 PSI/0-207 kPa) cannot be predicted. Due to low output pressure, it will not be able to adequately drive a ventilator. Not for patient use. Blender performance with supply pressures above range (75-112.5 PSI/517-775 kPa) with supplies balanced, available output flows and oxygen percentages will remain consistent with specification. Output pressures will be proportionally higher and may damage the ventilator. Not for patient use.

Introduction & Operation

This 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 (345 kPa) connected to two DISS fittings on the bottom of the blender. Each fitting has a built-in 30 micron particulate filter. The gas source passes through a duckbill check valve which prevents reverse gas flows from either source.

The blender uses a double stage balancing system with the gas entering into the first 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 dialed in on the front panel knob. 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.

Many different configurations of blenders and output ports are available. The model number can be found on the back of the blender. See 'Model Identifier' on page 2 or use the front of the blender to identify which row to use in the table below to determine its flow range. The blender will be Low Flow or High/Low Flow. The flow limitations listed below apply, regardless of what is attached to the port. If the bleed is active, the "flows with bleed" applies to all output ports. Conversely, if the bleed is inactive, the "flows without bleed" applies to all ports.

Note: The upper flow limit is the total flow that the blender will pass, not the limit per port. As an example, if 30 L/min is passing through any one port on a Low Flow blender, then no other port should be used as 30 L/min is the upper flow limit for this blender.

The bleed referred to in the table and elsewhere in this manual is activated in one of three ways depending on what is on the right side of the blender. If there is a DISS fitting, attaching a device to this fitting will turn on the bleed. If there is a knob, setting it to the "<" position will turn on the bleed (see Addendum 1). If there is a flowmeter on a switch mounted here, rotating it to its vertical position will turn on the bleed (see Addendum 2). If none of these options are available on the right side, then the bleed cannot be turned on and off.

Flow Range Table

Model	Flow Range *without* Bleed	Flow Range *with* Bleed
Low Flow	3-30 L/min	0-30 L/min (3 L/min Bleed)
High/Low Flow	15-120 L/min (No Bleed)	2-108 L/min (10-12 L/min Bleed)

WARNING Some special order blenders may not have a bleed when using the right DISS outlet.

When this is the case, the flow specifications for without bleed apply.

Note: The NEO_2 Blend conforms to the Low Flow configuration with flow limited by the flowmeters. Refer to Addendum 2 in the beginning of this manual.

The blender has an audible built in alarm which detects if either of the gas sources changed by more than 20 psi (138 kPa) from the other. The alarm will warn the user that they are running out of one of the gas sources or that there is a severe pressure drop in one source. If both gas sources drop or increase together such that a 20 psi (138 kPa) difference cannot be detected, no alarm will sound. If the blender is connected but not being used and a 20 psi (138 kPa) difference in gas sources develops, the blender will not alarm.

The blender alarm/bypass function will provide > 90 L/min (the full 30 L/min, Low Flow Blender) upon the loss of air or oxygen, if the remaining gas is at 50 psi (345 kPa)

Setting Up The Blender

The blender can be either pole, wall, or rail-mounted for easy use and for any desired application. The inlet fittings are located on the bottom of the blender and conform to Diameter Index Safety System (DISS) and air and oxygen connections cannot be reversed. Connect an air high pressure hose to the air fitting and an oxygen high pressure hose to the oxygen fitting on the bottom of the blender. It is recommended that an air inlet water trap be used between the air hose and inlet fitting to prevent moisture from entering the blender.

The primary outlet (see Addendum 1) on the bottom of the standard high flow blender is appropriate for high flow situations, as with most ventilators requiring flows up to 120 L/min. Flows of less than 15 L/min (3 L/min, Low Flow blender) require the right side outlet (bleed knob or bleed switch). If both outlets are used simultaneously, neither one will deliver its maximum flow.

Testing The Blender

The following checks should be performed before placing the blender into service. Note: If the blender does not pass these checks do not place the unit into service; call your dealer or service representative.

- Connect the 50 psi (345 kPa) air and oxygen sources to the appropriate fittings and set the blender to 60% (the alarm should not activate).
- Check to ensure that the oxygen concentration is actually 60% by using a calibrated oxygen analyzer (conforming with ISO 7767).
- Disconnect the oxygen source from the blender and listen for the audible alarm. Once it alarms, reconnect the oxygen to stop the alarm.
- Verify the oxygen concentration again.
- Disconnect the air source from the blender and listen for the audible alarm
- Once it alarms, reconnect the air and verify the oxygen concentration again.

Using The Blender

- Connect the gas outlet of the blender either directly or via a high pressure hose to the ventilator or other equipment with which it is being used.
- Set the control on the front panel to the desired oxygen concentration.
- Turn on the 50 psi (345 kPa) air and oxygen sources.
- Set the controls on the ventilator or equipment being used.
- Use a calibrated oxygen analyzer to check the accuracy of the patient gas.
- When changing oxygen concentration, wait sixty seconds (equilibration time) before checking it against the analyzer.

- To use the standard high flow blender for low flow applications, connect a flowmeter to the secondary outlet (refer to Addendum 1 and 2 at the beginning of this manual), and set the concentration with the knob on the front panel.
- Turn on the source gases, set the flowmeter, and check the output with a calibrated oxygen monitor.

Troubleshooting Guide

Problem	Possible Cause	Possible Solution
Oxygen analyzer doesn't agree with setting of blender	Analyzer out of calibration	Calibrate oxygen analyzer
	Blender out of calibration	Call Service Department
	Dirty gas supply	Call Service Department
	Bleed on bottom of blender is restricted	Call Service Department
	Air is flowing into piece of equipment being used and diluting concentration	Correct situation by stopping the flow of air
Blender alarming	Air and oxygen source pressures have greater than 20 psi (138 kpa) differential	Bring the source pressures within the 20 psi (138 kpa) range
	Alarm system is out of calibration	Call Service Department
	Dirty gas is contaminating alarm system	Call Service Department
The only time the blender is accurate is when the source pressures are exactly the same	Pressure balance chamber not working properly	Call Service Department

Cleaning Instructions

The blender should only be cleaned by wiping the outside surfaces with alcohol applied to a tissue or cloth. These blenders should never be sprayed with or immersed in any other liquid. Be sure not to allow ingress of any appreciable quantity of alcohol into any alarm or vent holes. Never insert anything into the holes in the alarm cover.

Service Recommendations

Periodic preventive maintenance should be performed to ensure continued proper operation of the blender. The frequency of preventative maintenance is determined by many factors, some of which are:

- Frequence and length of use
- Quality of the compressed gas source(s)
- Environmental conditions

Interval	Recommended Procedures
Prior to each use	Performance test
Every year between PM's	Calibration certification
Every two years	Major overhaul, cleaning and calibration **Recommend return to factory for this service**

Training Recommendations

Upon receipt of the blender, the qualified medical professional should at a minimum read the manual in its entirety, and follow their own facility's training guidelines for new equipment.

Device End-Of-Life Disposal

To decommission the blender, the user may send it back to Bio-Med Devices for proper disposal and recycling of all applicable components. If this is not practical, the user may dissemble the device and recycle components using local recycling resources. It is recommended to separate out the brass, aluminum, and other metals for recycling. Elastomers should be discarded. There are no internal batteries or electronics. Please consider these potential hazards before attempting disassembly of the blender:

- Do not attempt disassembly with gas sources attached.
- Beware sharp corners of metal parts, which could cut one's hands.

This device and its packaging contain no hazardous materials. No special precautions need to be taken when disposing of the device and/or its packaging.

Blender Warranty

The warranty lasts for one year from date of purchase. This warranty covers parts and labor. Shipping costs are covered up to six months from the date of purchase. This warranty is limited to defects in parts and workmanship and does not cover incidents due to misuse or abuse of the product. All service must be performed by authorized service personnel. The manufacturer will not be held responsible for unauthorized service work on any blender.

EC REP

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