

AIR/OXYGEN BLENDER

INSTRUCTION MANUAL

CATALOG #2122
REV 010606



TABLE OF CONTENTS

ADDENDUM 1- Low Flow Selector Knob	1
ADDENDUM 2- Special Dual Flowmeter Low Flow Blender	1
1. WARNINGS, CAUTIONS AND NOTES	2
2. EXPLANATION OF SYMBOLS	3
3. SPECIFICATIONS.....	3
4. INTRODUCTION AND OPERATION	5
5. SETTING UP THE BLENDER.....	6
6. TESTING THE BLENDER.....	6
7. USING THE BLENDER.....	6
8. TROUBLE SHOOTING GUIDE	7
9. BLENDER WARRANTY	8
10. CLEANING INSTRUCTIONS	8

ADDENDUM 1- Low Flow Selector Knob

A low flow selector knob has been installed on some blenders as an option in lieu of the auxiliary side port. This enables the user to maintain accurate concentrations using the single primary output for both high and low flows 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 of 15 LPM and greater and for flows of less than 15 LPM. The markings are ">15 LPM" for 15 LPM and greater and "<15 LPM" for less than 15 LPM. The knob must be pushed in prior to turning.

ADDENDUM 2- Special Dual Flowmeter Low Flow Blender

Some special low flow blenders may have two flowmeters mounted to them, one on each side, with the one to the right having two positions, upright or angled forward. This can be identified by an On/Off label of the flowmeter. Any time this blender is used below 3 lpm, an internal bleed is required to maintain the accuracy of the O₂ concentration being delivered. If the flowmeter on the right side has a label instructing the user to push it in to turn it on, this bleed is automatically activated when the flowmeter on the right is set to the "ON" position as described below. Do not try to turn the flowmeter unless instructed to do so by this label. To conserve gas, this bleed may be turned off when this flowmeter is not in use. The flowmeter on the right side is for delivering flows below 3 lpm. The left flowmeter is generally used for flows above 3 lpm, but may be used below 3 lpm as explained below.

The flow rate for these flowmeters should be set using the center of the ball.

RIGHT SIDE FLOWMETER

The right side flowmeter and corresponding bleed is inactive when it is angled towards the front of the blender. To activate it and initiate the required bleed, 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. 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

CAUTION: The flowmeter on the left side is stationary. Do not try to turn it.

This flowmeter is meant for flows above 3 lpm. It may, however, be used below 3 lpm with the following consideration; when set below 3 lpm, 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 O₂ accuracy while using the left side flowmeter at flows below 3 lpm.

1. WARNINGS, CAUTIONS AND NOTES

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 FIO₂ setting.

The blender must not be exposed to extremely high temperatures, as in the case of steam autoclaving (which could reach 145°F / 63°C).

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

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, or without remote monitoring.

Some special order blenders may not have a bleed when using the auxiliary outlet. When this is the case, the flow specifications for the primary outlet apply to the auxiliary outlet.

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" per FDA terminology, that is, at least 99.0% pure. Both gases must contain <37.5 milligrams of water per cubic meter of gas ($\frac{\text{mg}}{\text{Nm}^3}$) or (<50 ppm H₂O).

A water trap assembly and filter must be used to avoid malfunction should water accidentally get 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 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.

NOTES

This blender has been degreased for oxygen service prior to delivery.

2. EXPLANATION OF SYMBOLS



Attention, See instructions for Use



Date of Manufacture

SN

Serial Number

REF

Catalog Number



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, the manufacturer operates under an ISO 13485 compliant quality system (covering the design and manufacture of medical devices). The four-digit code underlying the CE mark (0086) pertains to the Notified Body, the British Standards Institute, whose function is to investigate and attest to the validity of CE-mark claims.

3. SPECIFICATIONS

The High/Low Flow line of blenders delivers accurate FIO₂ mixtures from either one or two outlet ports and has an overall standard flow range of 2 - 120 LPM. They can be used with ventilators, nasal cannulas, mask CPAP and resuscitation bags. By adding an additional side port to the standard two-port model, three outlet ports are able to provide combined flows from 2 - 100 LPM, allowing it to power three items at once. The Low Flow version of the blender provides flows from 3 to 30 LPM with no gas bleed. A MRI compatible version is also available that is made entirely of non-magnetic materials.

CAUTION: 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.

Device-Specific Standards: Complies with ISO 11195 : 1995.

Oxygen % Range: 21 to 100%

Oxygen % Accuracy: $\pm 3\%$ 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.

*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.

Maximum Flow: ≥ 120 LPM (≥ 50 LPM, 0-50 Flow blender; ≥ 30 LPM, Low Flow blender) @ 60% setting & 50 psi (345 kPa) inlet pressures.

Standard Flow Ranges: refer to table in Section 4.

Custom Configuration Flow Ranges: refer to addendums and table in Section 4.

Pressure Drop: < 6 psi (42 kPa) at 50 psi (345 kPa) inlet pressure and 40 LPM flow (10 LPM, Low Flow blender).

Low Supply Alarm: as described in Section 4.

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.

Output Fitting(s): Male DISS, oxygen type.

Dimensions: Height 3 1/2" (8.9 cm)
 Width 2 1/4" (5.7 cm)
 Depth 2 7/8" (7.3 cm)

Weight: 2 3/4 lbs (1.25 kg).

No electronics incorporated.

Reverse Gas Flow: From either gas inlet to the other is zero (complies with clause 6 of ISO 11195).

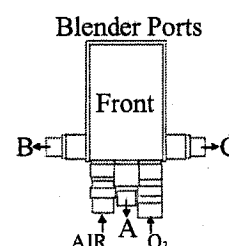
4. INTRODUCTION AND OPERATION

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 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.

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.

Depending on the model, there may be up to three gas outlets on the blender as outlined in the table below. The model number can be found on the back of the blender. Use the first four digits to identify the configuration. Under certain custom configurations, some ports may not be present. The flow limitations listed below apply, regardless of what is attached to the indicated port.



Model	Ports	Flow Range Port A	Flow Range Port B	Flow Range Port C
2000K	A, Knob @C	6-50 lpm (No Bleed) 0-50 lpm (6 lpm Bleed)	N/A N/A	Knob Set >6 Knob Set < 6
2001	A, C	15-120 lpm (No Bleed)	N/A	2-108 lpm (10-12 lpm Bleed)
2001K	A, Knob @C	15-120 lpm (No Bleed) 2-108 lpm (10-12 lpm Bleed)	N/A N/A	Knob Set >15 Knob Set < 15
2002	A	15-120 lpm (No Bleed)	N/A	N/A
2003	B, C	N/A	3-30 lpm (No Bleed)	0-30 lpm (3 lpm Bleed)
2004	A, B, C	15-120 lpm (No Bleed)	15-120 lpm (No Bleed)	2-108 lpm (10-12 Bleed)

WARNING: Some special order blenders may not have a bleed when using the auxiliary outlet. When this is the case, the flow specifications for the primary outlet apply to the auxiliary outlet.

NOTE: The low flow blender with two flowmeters conforms to the model #2003 configuration with flow limited by the flowmeters. Refer to Addendum 2 in the beginning of this manual.

The blender has an audible alarm built in to detect if either of the gas sources changes by

more than 20 psi (138 kPa) from the other. This 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, then 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 LPM (the full 30 LPM, Low Flow Blender) upon the loss of air or oxygen, if the remaining gas is at 50 psi (345 kPa)

5. SETTING UP THE BLENDER

The blender can be either pole-, wall-, or rail-mounted for easy use for any desired application. The inlet fittings are located on the bottom of the blender and conform to Diameter Index Safety System (D.I.S.S.) so that 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 LPM. Flows of less than 15 LPM (3 LPM, Low Flow blender) require the auxiliary outlet (side port). If both outlets are used simultaneously, neither one will deliver its maximum flow.

6. TESTING THE BLENDER

The following checks should be performed before first 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.

First, 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 see 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 and verify the oxygen concentration again. Next 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.

7. 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 and 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 (see Addendum 1), and set the concentration with the knob on the front panel. Then turn on the source gases, set the flowmeter and check the output with a calibrated oxygen analyzer.

8. TROUBLE SHOOTING GUIDE

PROBLEM	CAUSE OF PROBLEM	TO SOLVE PROBLEM
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

9. 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.

10. 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.