AIR/OXYGEN BLENDER

INSTRUCTION MANUAL

CATALOG #2122
REV 111308

CE
0086

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ADDENDUM 1- Low Flow Selector Knob

A low flow selector knob has been installed on blenders 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- Flowmeters

Several blenders are offered with flowmeters mounted on the right side of the blender. In most cases, this flowmeter is mounted to a uniquely designed rotating 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 is inactive when the flowmeter is angled towards the front of the blender. To activate it 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

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.

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 right side outlet. When this is the case, the flow specifications for "flow without bleed" 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 ($^{mg}/_{Nm^3}$) or (<50 ppm H_2O).

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.

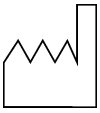
NOTES

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

The upper flow limit is the total flow that the blender will pass, not the limit per port.

2. EXPLANATION OF SYMBOLS

Attention, See instructions for Use



Date of Manufacture

SN Serial Number

REF Catalog Number

CE
0086

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

Configurations available deliver accurate FIO_2 mixtures from one to up to three 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 0-50 LPM Blender is a perfect compromise between the High Flow and Low Flow blenders as it requires less of a bleed for accuracies below 6 LPM than the High Flow while allowing

greater maximum flow than the Low Flow Blender. The Low Flow version of the blender provides flows from 3 to 30 LPM with no gas bleed. MRI compatible versions that are made entirely of non-magnetic materials are also available.

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: ±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. (NIST available)

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.

Many different configurations of blenders and output ports are available. The model number can be found on the back of the blender. 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, 0-50 LPM, High 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 LPM is passing through any one port on a Low Flow blender, then no other port should be used as 30 LPM 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[1]. 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. It will either always or never be present. The latter is the case for the High Flow, which has no bleed available.

[1] **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.***

Flow Table

Model	Flow Range without Bleed	Flow Range with Bleed
Low Flow	3-30 lpm	0-30 lpm (3 lpm Bleed)
Mid Flow (0-50 LPM)	15-120 lpm	0-50 lpm (6 lpm Bleed)
High Flow	15-120 lpm (No Bleed)	N/A
High/Low Flow	15-120 lpm (No Bleed)	2-108 lpm (10-12 Bleed)

NOTE: The low flow blender with two flowmeters 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 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 right side outlet (knob or switching flowmeter). 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 Addendums 1 & 2), 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.