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ADDENDUM
Low Flow Selector Knob
A low flow selector knob has been installed on some of the Bio-Med Devices Blenders, Catalog #2001, as an option (standard on units mounted on the Crossvent ventilators) 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.
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 (*30 psi [207 kPa] in the case of overseas devices and those manufactured for Air-Shields). 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 degrees F).

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.

An oxygen analyzer should be used to verify the initial patient gas concentration and when making any adjustments to the concentration (Bio-Med Devices' M-2 Oxygen / Temperature Monitor or M-10 ten-function Ventilation Monitor may be used in this capacity).

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.

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 compressed air and ANSI Z86.1-1973 grade F and water vapor content cannot exceed a dew point of 5 degrees F. below the lowest ambient temperature to which the blender and accessories are exposed.

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 by Bio-Med Devices to be used for such an environment. This will be indicated by “MRI” on the face plate.

NOTES
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.

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

The Bio-Med 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.

There are two gas outlets on the Bio-Med Devices blender (see addendum): the main outlet is located on the bottom and is used for applications requiring flows in the range of 15 to 120 liters per minute (3 to 30 LPM, Low Flow blender). The secondary outlet is located on the right side and is used for applications requiring flows under 15 LPM (3 LPM, Low Flow blender). When the secondary outlet is used, a bleed of 10 to 12 LPM (2.5 to 3.5 LPM, Low Flow Blender) exits the bottom of the blender.

**NOTE:** 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.

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.

*(30 psi [207 kPa] in the case of overseas devices and those manufactured for Hill Rom Air-Shields)

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).
3. SETTING UP THE BLENDER

The Bio-Med Devices 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. Bio-Med Devices recommends 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) on the bottom of the standard 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.

4. 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 Bio-Med Devices Service Department at (203) 458-0202.*

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. 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.

5. USING THE BLENDER

Connect the gas outlet on the bottom 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 blender for low flow applications, connect a flowmeter to the secondary outlet (see addendum), 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.
6. TROUBLE SHOOTING GUIDE

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*(30 psi [207 kPa] in the case of overseas devices and those manufactured for Hill Rom Air-Shields)*
7. BLENDER WARRANTY

The Bio-Med Devices, Inc. warranty lasts for one year from date of purchase. This warranty covers parts and labor. Shipping costs are covered up to six months from date of purchase. This warranty is limited to defects in parts and workmanship; Bio-Med Devices will not be held responsible for misuse or abuse of the product.

All service must be done by Bio-Med Devices or an authorized service representative of Bio-Med Devices. Bio-Med Devices will not be held responsible for unauthorized service work on any blender.

8. 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, Bio-Med Devices operates under an ISO 9001 and EN46001 compliant quality system (covering the design and manufacture of medical devices). The four-digit code underlying the CE mark (0086) 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.
9. SPECIFICATIONS

Bio-Med Devices’ 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 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. Bio-Med Devices also offers an MRI compatible version that is made entirely of non-magnetic materials.

CAUTION: Do not use in a MRI room unless the blender has been built by Bio-Med Devices to be used for such an environment. This will be indicated by “MRI” on the face plate.

Oxygen % Range: 21 to 100%

Oxygen % Accuracy: ±3% of full scale

Supply Pressure: 30-75 psi (207-517 kPa) Air & oxygen must be within 10 psi (69 kPa) of each other.

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

Flow Range, primary outlet, no bleed: 15-120 LPM (3-30 LPM Low Flow blender)

Flow Range (see addendum), auxiliary outlet*, with bleed: 2-90 LPM (0-30 LPM, Low Flow blender)
*See Notes (Section 1)

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

Alarm/Bypass Reset: when inlet gas pressure differential is ≥6 psi (42 kPa).

Alarm Intensity: 80 dB at 1 foot

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).
10. CLEANING INSTRUCTIONS

Bio-Med Devices' line of blenders 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.
APPENDIX

European Agent

Bio-Med Devices' Official Agent in Europe is:

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