Inspiration HEALTHCARE

BIO-MED DEVICES

AIR/OXYGEN BLENDER

INSTRUCTION MANUAL

CATALOG # 2120 REV 100605

CE 0086

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ADDENDUM 1- Low Flow Selector Knob

A low flow selector knob has been installed on some of the Bio-Med Devices Blenders (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 less than or greater than the flow rate indicated. The knob must be pushed in prior to turning.

ADDENDUM 2- NEO_2 BLEND Blender

The NEO_2 BLEND is a low flow blender with two flowmeters mounted to it, one on each side. Any time this blender is used below 3 lpm, an internal bleed is required to maintain

the accuracy of the O_2 concentration being delivered. Due to the unique design of the NEO_2 BLEND, this bleed is automatically activated when the flowmeter on the right is set to the "ON" position as described below. 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.

<u>The flow rate for these flowmeters should be set using the center of the ball.</u>

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 O_2 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 (*30 psi [207 kPa] in the case of overseas devices and those manufactured for Draeger / Hill Rom / Air-Shields), 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 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.

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 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 blender.

The flowmeter on the left side of the NEO_2 BLEND 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
The NEO_2 BLEND 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.

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, 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 (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.

3. SPECIFICATIONS

Bio-Med Devices' line of blenders delivers accurate FIO_2 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 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. Bio-Med Devices also offers MRI compatible versions that are 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 blender.

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 (≥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 2

Custom Configuration Flow Ranges: refer to addendums and table in Section 2

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).

4. 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.

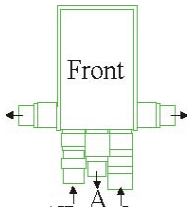
Depending on the model, there may be up to three gas outlets on the Bio-Med Devices blender as outlined in the table below. The model number can be found on the back of the blender. Use the first four digits to identify the configuration[1]. Under certain custom configurations, some ports may not be present. The flow limitations listed below apply, regardless of what is attached to the indicated port.

Note 1. For 2002K2 with 0-50 LPM on the front of the blender, use 2000K for its configuration.

Blender Ports

B

AIR O



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

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 NEO₂ BLEND 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.

*(30 psi [207 kPa] in the case of overseas devices and those manufactured for Draeger / 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).

5. 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 Addendum1) 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 (6 LPM, 0-50 LPM blender; 3 LPM, Low Flow blender) require the auxiliary outlet (side port or knob). 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 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.

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 at the beginning of this manual), 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 BLENDER OUT OF CALIBRATION	CALIBRATE OXYGEN ANALYZER CALL BIO-MED SERVICE DEPARTMENT
	DIRTY GAS SUPPLY	CALL BIO-MED SERVICE DEPARTMENT
	BLEED ON BOTTOM OF BLENDER IS RESTRICTED	CALL BIO-MED 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 BIO-MED SERVICE DEPARTMENT
	DIRTY GAS IS CONTAMINATING ALARM SYSTEM	CALL BIO-MED SERVICE DEPARTMENT
THE ONLY TIME THE BLENDER IS ACCURATE IS WHEN THE SOURCE PRESSURES ARE	PRESSURE BALANCE CHAMBER NOT WORKING PROPERLY	CALL BIO-MED SERVICE DEPARTMENT

EXACTLY THE SAME		

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

9. 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.

10. 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.

11. SERVICE RECOMMENDATIONS

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

Frequency & length of use
Quality of the compressed gas source(s)
Environmental conditions

Recommended Maintenance Schedule

Interval	Recommended Procedures
Prior to each use	Performance test
Every year between PM's	Calibration certification
Every 2 years	Major overhaul, cleaning and calibration **Recommend return to factory for this service**

APPENDIX European Agent

Bio-Med Devices' Official Agent in Europe is:

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