



CATALOG #2121 REV 040821

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TABLE OF CONTENTS

ADDENDUM 1- LOW FLOW SELECTOR KNOB	<u> </u>
ADDENDUM 2- NEO ₂ BLEND BLENDER	1
1. INTRODUCTION AND OPERATION	2
2. WARNINGS, CAUTIONS AND NOTES	6
3. PREVENTIVE MAINTANENCE	8
4. TOOLS	8
5. DISASSEMBLY & REASSEMBLY	9
6. CALIBRATION & TEST PROCEDURE	17
7. PERFORMANCE CHECK	23
8. TROUBLE SHOOTING GUIDE	24
9. PARTS	25
10. BLENDER WARRANTY	29
11. CE MARK	30
12. SPECIFICATIONS	31

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- NEO₂ BLEND Blender

The NEO₂ 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 O₂ concentration being delivered. Due to the unique design of the NEO₂ 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.

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 rotate 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. INTRODUCTION AND OPERATION

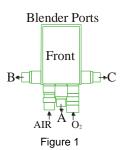
The Bio-Med Air/Oxygen Blender is a precision proportioning device for mixing medical grade air and oxygen to any concentration from 21% to 100% oxygen and delivering it to a variety of respiratory care devices. The blender uses source air and oxygen at a pressure of 50 psi connected to two D.I.S.S. 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.

WARNING: 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 Bio-Med Devices. Doing so may cause gas supply contamination due to back-flow.

The blender uses a two-stage balancing system with the gas entering into each 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 up to three gas outlets on the Bio-Med Devices blender depending on the model. Figure 1 indicates the various standard configurations.



Model	Ports	Flow Range - Port "A"	Flow Range - Port "B"	Flow Range - Port "C" ³
2000K 2002K2 ¹	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 2002K ²	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	А	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)

Note 1. Mounted on Crossvent 2 ventilator.

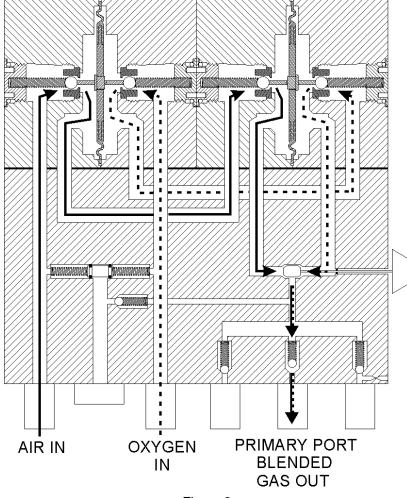
Note 2. Mounted on Crossvent 3 & 4 ventilators

Note 3. Some special order blenders may not have a bleed in this port. For these blenders, the output range would be the same as for those flows indicated with no bleed.

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.

1.1. PRIMARY OUTLET

Figure 2 illustrates the flow pattern when air and oxygen are provided to the inputs under normal conditions using the primary outlet for the exiting of blended gas. The gas sources enter the lower section of the blender where they pass by a shuttle spool. This spool is used for the alarm and remains balanced in this instance, thus blocking passage of gas to the alarm. The gases continue into the first stage of a two-stage balancing chamber. Here, the diaphragm reacts to any difference in source pressures and helps equalize these pressures. From here, the gases continue into the second stage of the balancing chamber where again, a diaphragm adjusts to equalize any remaining difference in pressure. The gases are metered to the proper proportions resulting in the concentration as set by the knob on the front of the blender. From the valve, the now blended gas exits the blender through the primary outlet. Each outlet has a check valve that prevents gas from passing through it unless a hose or other device is threaded onto it.

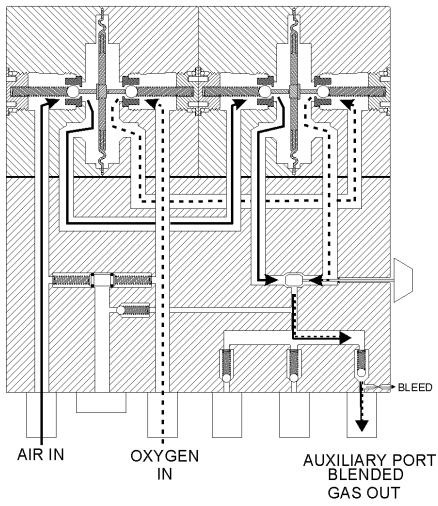


THEORETICAL REPRESENTATION

Figure 2

1.2. AUXILIARY OUTLET

Figure 3 illustrates the same conditions as Figure 2, but with the blended gas exiting the low flow auxiliary port. Use of this port induces a bleed to atmosphere which is necessary to maintain accurate concentrations when using the blender at flows of less than 15 lpm (3 lpm in the Low Flow Blender, 6 lpm in the 0-50 LPM Blender).



THEORETICAL REPRESENTATION

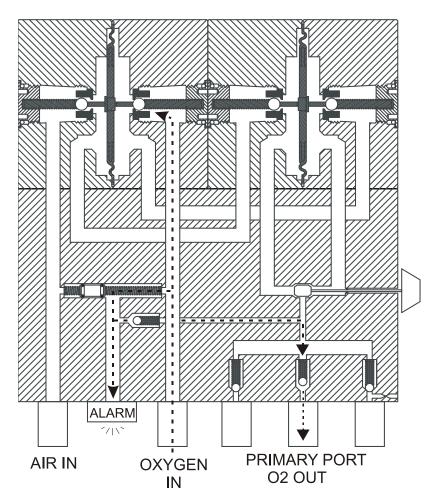


1.3. ALARM CONDITION

The blender has an audible alarm built in to detect if either of the gas sources changes by more than 20 psi (30 psi for units sold overseas) 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 (30 psi for units sold overseas) difference cannot be detected, then no alarm will sound. If the blender is connected but not being used and a 20 psi (30 psi for units sold overseas) difference in gas sources develops, the blender will not alarm.

The blender alarm/bypass function will provide > 90 LPM (\geq 30 LPM capability in the Low Flow Blender, \geq 50 in the 0-50 LPM Blender) upon the loss of air or oxygen, if the remaining gas is at

50 psi. Fig. 4 illustrates the flow pattern when the air source is lost and only oxygen is provided to the input using the primary outlet for the exiting of gas. Notice two major events occurred relative to the previous figures. First, the alarm shuttle has shifted to the air side due to the absence of pressure on this side. This now exposes the passage to the alarm and the bypass to the outlet. Second, the diaphragm in the first stage of the balancing chamber has shifted due to the imbalance of pressure and has closed the oxygen side.



THEORETICAL REPRESENTATION

Figure 4

2. WARNINGS, CAUTIONS AND NOTES

WARNINGS:

Never leave a ventilator patient unattended, or without remote monitoring.

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° 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 monitor (complying with ISO 80601-2-55) must 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.

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 right side 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 Bio-Med Devices. Doing so may cause gas supply contamination due to back-flow.

This blender is not suitable for use with Oxygen 93.

Bleed oxygen flow can cause ignitions.

Only qualified, trained service technicians should attempt repairs and service when needed.

Be certain all components are properly installed prior to pressurizing the blender. Parts improperly installed may be ejected.

Bio-Med Devices cannot be held responsible for any failure to adhere to the recommendations set forth in this manual.

Because this is a CE marked device, it must never be modified without prior expressed written consent from Bio-Med Devices.

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 ($\frac{mg}{Nm^3}$) 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 an 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 front plate, and an MR-conditional label on the case.

The flowmeter on the left side of the NEO₂ 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.

The blender should be checked by a qualified technician at the intervals specified in Section 11.

All Bio-Med Devices blenders are tested for backflow at the factory. However, some level of backflow (10 ml./hr.) is acceptable per the ISO standard 11195. It is recommended that when not in use, either the blender supply gases should be detached from the blender (or turned off by installing on/off valves) or the blender bleed function should be left on, to prevent any chance of cross contamination.

Always apply pressure to the blender slowly.

NOTES: 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.

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.

This device has no latex content.

3. PREVENTIVE MAINTANENCE

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:

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

Gas Inlet Filter

The filter element in the air and oxygen supply inlet fittings should be replaced during major overhauls or whenever they become contaminated.

Preventive Maintenance Parts Kit

Part Number 2008 - All BMD Blenders

Included in the kits are the following parts: Filters, O-rings, check valve ball, balancing chamber balls, duck bill check valves, bleed muffler and retainer, diaphragms, spring, label. This kit is subject to change without notice.

4. TOOLS

Adjustable Spanner Spanner wrench (BMD P/N TOOL076) 5/32" Hex Wrench 1/8" Hex Wrench 3⁄4" Open End Wrench 11/16" Open End Wrench Adjustable Wrench Needle Nose Pliers #1 Phillips Screw Driver Grease- Dupont Krytox GPL-207 or equivalent Alcohol

5. DISASSEMBLY & REASSEMBLY

Note: Be sure the work area is clean and free from any materials or particles that may contaminate parts during the disassembly and reassembly of the blender.

Note: Calibration procedures must be performed following servicing of the blender.

Note: The primary focus of these instructions is for the standard Hi-Low Flow Blenders. Procedures for other models are essentially the same, but some parts may differ.

Note: Input and output fittings on OEM blenders may differ from what is represented here.

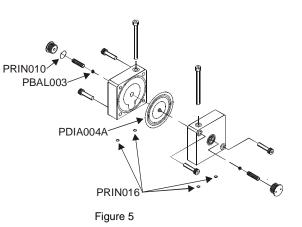
Note: Plug configurations may differ from what is represented here.

5.1. Cover

5.1.1. Remove the Blender Outer Cover, if present, by removing the Philips screws (2 per side). Earlier style covers may also require any side output fittings to be removed using a ³/₄" wrench (refer to 5.9).

5.2. Balancing Chambers

- 5.2.1. Using a 5/32" hex wrench, remove the four screws from the top of the Balancing Chambers and separate the two chambers from the lower block of the blender.
- 5.2.2. NOTE: Spring and ball will be loose when cap is removed. Using a spanner wrench, remove the caps from each side of one of the chamber assemblies.
- 5.2.3. Remove the ball and spring from each side and set aside.



- 5.2.4. Remove the o-rings from the caps and also the o-rings from the bottom of the chamber halves and dispose of these.
- 5.2.5. Using the 5/32" hex wrench again, remove the two screws from both sides of the chamber, separate the two halves and remove and discard the diaphragm.
- 5.2.6. Clean the chamber halves with alcohol, paying particular attention to the ball seats.
- 5.2.7. To reassemble, lay one of the halves down on a flat surface with the diaphragm cavity facing up. Place the new diaphragm on top and center it within the cavity.
- 5.2.8. Place the other half on top of the first half, diaphragm cavity down.
- 5.2.9. Thread two screws into the side facing you far enough to hold the pieces together, but not so tight as to capture the diaphragm. The diaphragm will need to be further aligned.
- 5.2.10. With the chamber assembly input/output orifices facing you, take the bottom half of the blender, lay it on its side and hold the chamber assembly firmly against it so as to align the bottoms of the two chamber halves in a flat plane (see Figure 6).



Figure 6

- 5.2.11. While holding in this position, reach in with a small tool and move the
- diaphragm by pushing on the pin until the pin is centered in the hole.

- 5.2.12. Tighten the two screws firmly while taking care to maintain the position of the two halves against the blender bottom and the location of the diaphragm in the center of the hole.
- 5.2.13. Turn the assembly over and install the other two screws.
- 5.2.14. If balancing chamber material is aluminum then torque all four screws to 47 in-lb using a calibrated 5/32" hex wrench.
- 5.2.15. If balancing chamber material is plastic then torque all four screws to 30 in-lb using a calibrated 5/32" hex wrench.
- 5.2.16. Lay the assembly down and place a new ball in the seat over the diaphragm pin. Be sure the ball is clean prior to installing.
- 5.2.17. Lightly grease the new o-ring and place over the threads of the cap.
- 5.2.18. Place a small amount of grease on one end of the spring and insert this end into the hole in the cap. The grease is there to help hold the spring in the hole while assembling the cap to the chamber.
- 5.2.19. Thread the cap into the chamber with the spring over the ball.
- 5.2.20. Turn over and repeat the ball, o-ring, spring and cap installation on this side.
- 5.2.21. Lightly grease four new o-rings and install them in the appropriate holes in the bottom of the assembly.
- 5.2.22. Set the assembly aside and repeat this entire process for the second balancing chamber assembly.

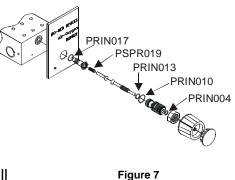
LOWER BLOCK

The lower block may only be thoroughly cleaned internally after complete disassembly. Follow the disassembly instructions below, saving the reassembly of each section until all parts have been removed from the block and it has been cleaned and thoroughly dried. It may be cleaned with alcohol. Once the block is dry, go back to each section and follow the instructions for reassembly of each part into the block.

5.3. PROPORTIONING VALVE

Note: This describes the proportioning valve in the Hi-Low Flow Blender. For the Low Flow Blender, use the methods as described here while referring to the exploded view in the PARTS sections of this manual.

- 5.3.1. Carefully pry off the end cap on the concentration-setting knob, loosen the nut underneath and remove the knob.
- 5.3.2. Using a 5/8" wrench, remove the front seat lock nut and remove the front plate.
- 5.3.3. With an appropriate spanner, unscrew and remove the front half of the proportioning valve.
- 5.3.4. Tip the block assembly forward and the rear valve shaft with spring should fall out.

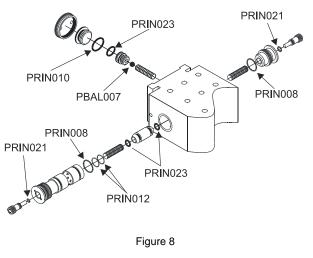


- 5.3.5. Insert a 1/8" hex wrench into the center of the rear seat within the block, unscrew and remove it from the block.
- 5.3.6. Unscrew the valve shaft from the front seat and remove all o-rings from all parts. Do not overlook the small o-ring inside the front valve seat in the spanner hole end.
- 5.3.7. Clean and carefully inspect all parts, paying particular attention to the valve seat areas where the valve shaft tapers make contact with the seats. Replace if they show any signs of wear or nicks.

- 5.3.8. Lightly lubricate and reinstall all o-rings. Do not overlook the small o-ring inside the front valve seat at the spanner hole end.
- 5.3.9. Install the rear seat using the 1/8" hex wrench.
- 5.3.10. Place just enough grease on the end of the new spring to keep it from falling out of the rear valve shaft. Insert the spring into the end of the shaft and install the shaft into the rear seat, spring end first.
- 5.3.11. Lubricate the threads on the front valve shaft and thread it into the front valve seat just far enough so the taper touches the seat.
- 5.3.12. Thread the front seat into the block just far enough that the outer most o-ring is within the block.

5.4. ALARM SPOOL & BYPASS VALVE

- 5.4.1. Using a spanner, remove the cap from the left side of the block and then tip the block on its side to remove the spring which is inside.
- 5.4.2. Using a 1/8" hex wrench, remove the alarm adjusting screw from the center of the cap.
- 5.4.3. From the opposite side, remove the spool assembly with the same spanner. Remove the adjusting screw from the center of the spool and remove the spring through the adjusting screw opening.



- 5.4.4. Using an appropriate tool, push the shuttle valve out of the spool by inserting the tool through the opening for the adjusting screw and pushing on the end of the valve. Take extreme care not to mar the inner surface of the spool.
- 5.4.5. Remove all o-rings and thoroughly clean all parts.
- 5.4.6. Lightly lubricate new o-rings and replace per diagram.
- 5.4.7. Insert the shuttle valve back into the spool and push it all the way into the opposite end. Reinstall the spring through the opening for the adjuster screw and reinstall the adjuster, threading it so it is flush with the end of the spool.
- 5.4.8. Install the other adjuster screw into the cap and set the spool assembly, cap with adjuster and second spring to the side.
- 5.4.9. Remove the cap from the back of the block, located in the center of the integral mounting flange. Earlier blenders will have an alarm reed behind this cap. If so, remove it, making note of which side of the reed plate is facing the cap just removed.
- 5.4.10. Remove the second cap that is within this cavity.
- 5.4.11. Looking deep into this cavity now, beyond the area where the alarm spool would normally be, the seat for the bypass valve may be seen. Using a 5/32" hex wrench, unscrew and remove this seat. If it does not come out attached to the wrench, tip the block so as to expel it. Watch for a ball and spring to follow it.
- 5.4.12. If the seat came out with the wrench then now tip the block so as to expel the ball and spring located in the bottom of this opening.
- 5.4.13. Remove all o-rings from the parts just removed, clean the parts thoroughly and replace the o-rings with new ones, lubricating lightly before installing.
- 5.4.14. Place the spring back into the bottom of the cavity and then drop the new ball

in on top of it.

- 5.4.15. Place the seat on the end of the 5/32" hex wrench and carefully lower it into place above the ball. Screw it down and tighten.
- 5.4.16. Reinstall the cap, reed (if present) and end cap. Be sure to reinstall the reed in the same orientation as previously noted.
- 5.4.17. Reinstall the spool assembly from the left side of the block and screw down snugly.
- 5.4.18. Turn the block over and drop in the second spring so that it is within the cavity in the end of the shuttle valve within the spool.
- 5.4.19. Install the cap with adjuster into this opening making sure the tip of it is properly positioned within the center of the spring and tighten snugly.

5.5. ALARM (bottom mounted)

- 5.5.1. With a $\frac{3}{4}$ " wrench, remove the O₂ supply fitting from the bottom of the block. <u>This is a left hand thread so turn it clockwise to remove</u>. Set it aside.
- 5.5.2. Use the same ³/₄" wrench to remove the air fitting and set it aside. Remove the filter and duckbill check valve from within the cavity of the air supply fitting.
- 5.5.3. Using soft jaw pliers, remove the alarm housing from the bottom of the block.
- 5.5.4. Remove the o-ring from the housing and discard.
- 5.5.5. Lightly grease the new o-ring and install on the alarm housing.
- 5.5.6. Reinstall the housing into the block.

5.6. OXYGEN SUPPLY FITTING with FILTER AND CHECK VALVE

Note: These check valves are to prevent one gas supply from contaminating the other gas supply due to back-flow. It is important that the proper operation of the check valves is verified whenever this fitting is disturbed. Refer to the Calibration & Test Procedure section.

- 5.6.1. Remove the O_2 supply fitting (refer to 5.5.1).
- 5.6.2. Using two ³/₄" wrenches, separate the two halves of the fitting. <u>This is a left hand thread so turn it clockwise to separate.</u>
- 5.6.3. Remove the filter, spacer and duckbill check valve that is under the filter and discard.
- 5.6.4. Take the half with the free turning nut on it and insert a 1/8" hex wrench into the nipple within the nut. Hold the other end with a ³/₄" wrench and unscrew the nipple. This thread has a thread lock on it so it may require a little effort.
- 5.6.5. Remove all o-rings from all parts and clean the parts thoroughly. Be sure to properly clean the thread lock from the nipple.
- 5.6.6. Lightly grease new o-rings and install on the nipple. Insert the nipple through the nut and place a small amount of thread lock on its threads.
- PVAL031 PSPA009 f the se to PFIL008 PFIL008 PFIL008 PRIN011 at is parts from PRIN023

- PRIN011



- 5.6.7. Screw the nipple into the hex fitting and tighten. Check for any excess thread lock between the nut and hex that may have flowed out from the threads and clean off, if present.
- 5.6.8. Lightly grease and install new o-rings over the threads of the two halves.
- 5.6.9. Assemble the duckbill check valve, spacer and filter into the fitting as illustrated in the diagram. If the spacer is black, the duckbill fits into the recessed area of the spacer.

5.6.10. Reassemble the two halves and reinstall into the block where it is labeled "OXYGEN". It is a left thread so it must be turned counterclockwise to install.

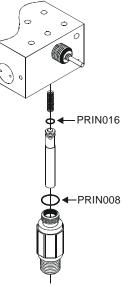
5.7. AIR SUPPLY FITTING AND FILTER AND CHECK VALVE

Note: These check values are to prevent one gas supply from contaminating the other gas supply due to back-flow. It is important that the proper operation of the check values is verified whenever this fitting is disturbed. Refer to the Calibration & Test Procedure section

- 5.7.1. Remove the Air supply fitting from the block (refer to 5.5.2).
- 5.7.2. Remove and replace the filter, spacer and duckbill check valve. If the spacer is black, the duckbill fits into the recessed area of the spacer.
- 5.7.3. Remove and discard the o-ring from the Air fitting. Clean the fitting.
- 5.7.4. Lightly grease a new o-ring and replace it over threads of fitting.
- 5.7.5. Install the fitting over the filter in the block.

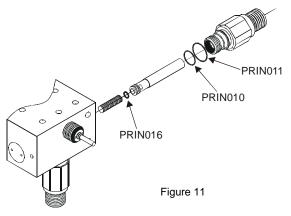
5.8. PRIMARY OUTLET FITTING

- 5.8.1. Using a ³/₄" wrench, remove the primary outlet fitting from the bottom of the block. <u>Once it is removed, there will be a loose spring</u> inside the cavity.
- 5.8.2. Remove the check valve plunger that is inside the fitting.
- 5.8.3. Remove all o-rings and clean the plunger and fitting.
- 5.8.4. Lightly grease new o-rings and install them on the plunger and fitting.
- 5.8.5. Place the spring, if removed, into the primary outlet cavity so it is seated in the recess in the center of the bottom of the cavity.
- 5.8.6. Hold the plunger over the spring so that the shoulder on the o-ring end is centered in the spring and lower the fitting over the plunger. Screw the fitting into the block and tighten with the wrench.



5.9. AUXILIARY OUTLET FITTING

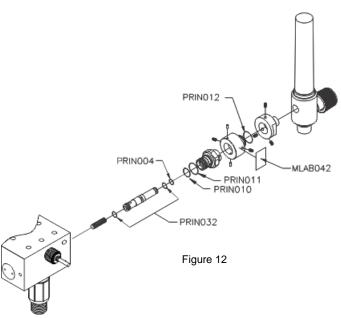
- 5.9.1. If there is a flowmeter here, go to Step 5.10. If there is a knob here, go to Step 5.11.
- 5.9.2. Using a ³/₄" wrench, unscrew the auxiliary outlet fitting from the side of the block. <u>Once it is removed, there will be a loose spring inside the cavity.</u>
- 5.9.3. Remove the check valve plunger that is inside the fitting.
- 5.9.4. Remove all o-rings and clean the plunger and fitting.
- 5.9.5. Lightly grease new o-rings and install them on the plunger and fitting.
- 5.9.6. If the blender has an outside cover, then finish this procedure after the cover has been reinstalled (refer to 5.14). Place the spring, if removed, into the auxiliary outlet cavity so it is seated in the opening in the center of the cavity.



5.9.7. Hold the plunger over the spring so that the shoulder on the o-ring end is centered in the spring and lower the fitting over the plunger. Screw the fitting into the block and tighten with the wrench.

5.10. AUXILIARY FLOWMETER WITH ON/OFF

- 5.10.1. This step only applies to blenders with a flowmeter in this position that can be pushed in and turned.
- 5.10.2. Set the flowmeter to the OFF position as instructed by the label on the flowmeter mount.
- 5.10.3. Remove the GAS ON/GAS OFF label.
- 5.10.4. Using a 1/16" hex wrench, loosen the two setscrews closest to the flowmeter and pull off the flowmeter.
- 5.10.5. Using the same hex wrench, loosen the outer setscrews on the remaining half of the flowmeter mount and pull this part off. <u>Do not disturb the</u> <u>other setscrews.</u>



- 5.10.6. Using a ³/₄" wrench, remove the remaining ON/OFF valve. <u>Once it is removed,</u> there will be a loose spring inside the cavity.
- 5.10.7. Remove the valve stem from the valve bushing.
- 5.10.8. Remove all the o-rings and clean the parts.
- 5.10.9. Lightly grease the new o-rings and install all but <u>PRIN032*</u> according to the illustration. This one will be installed during reassembly.
- 5.10.10. Insert the valve stem into the bushing from the threaded end, leading with the end of the stem with no o-ring installed.
- 5.10.11. With the spring properly positioned in the bottom of the cavity in the blender manifold, reinstall the valve assembly and tighten it with the ³/₄" wrench. Press in on the valve stem and verify it moves smoothly against the spring.
- 5.10.12. Slip the first half of the flowmeter mount (with the pins protruding within the inner diameter) over the valve stem and engage the pins within the slots in the valve bushing. Push it all the way against the bushing so that the o-ring groove on the end of the valve stem is exposed.
- 5.10.13. Lightly grease the remaining PRIN032 that was left off previously and install it on the end of the valve stem.
- 5.10.14. Now slide this mount back out over the o-ring just installed until the end of it is flush with the end of the valve stem. Tighten the setscrews in this position. Test the actuation of the ON/OFF valve by pushing in, turning and releasing the mount. It should move without binding.
- 5.10.15. With the valve in the ON position (pushed in and turned clockwise), install the flowmeter onto the valve so that it is upright (parallel to the front of the blender) and tighten the setscrews.
- 5.10.16. Push in and turn the flowmeter to the OFF position. It should be angled to the front. Adhere the ON/OFF label onto the flowmeter mount so that in the OFF position, the "GAS ON" portion of the label is facing forward. When the

flowmeter is in the ON position, the "GAS OFF" portion of the label should rotate and now face forward.

5.11. HIGH/LOW FLOW KNOB

- 5.11.1. This step only applies to blenders with a knob in this position that can be pushed in and turned.
- 5.11.2. Set the knob to the "greater than (>)" position as instructed by the label on the side of the blender.
- 5.11.3. Using a 1/16" hex wrench, loosen the two setscrews closest to the outside edge of the knob and pull off the knob. <u>Do not disturb the</u> <u>other setscrews.</u>
- 5.11.4. Using a ³/₄" wrench, remove the ON/OFF valve bushing with the slots in it. <u>Once it is removed, there will be a loose spring inside the cavity.</u>

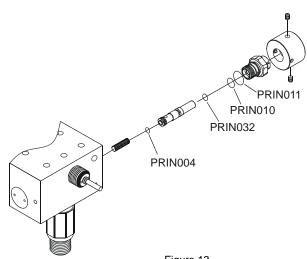


Figure 13

- 5.11.5. Remove the valve stem from the bushing.
- 5.11.6. Remove all the o-rings and clean the parts.
- 5.11.7. Lightly grease the new o-rings.
- 5.11.8. Insert the valve stem into the bushing from the threaded end as in the illustration.
- 5.11.9. With the spring properly positioned in the bottom of the cavity within the blender manifold, reinstall the valve assembly and tighten it with the ³/₄" wrench. Press in on the valve stem and verify it moves smoothly in and out against the spring.
- 5.11.10. With the indicator line on the end of the knob pointing upwards and somewhat left of center, slip the knob over the valve bushing and shaft, engaging the two pins in the knob with the slots in the bushing. Continue to slide the knob onto the shaft just to the point that it bottoms out on the shaft and you can feel it just starting to push against the spring tension of the shaft. Tighten the knob to the shaft in this position by tightening the two outside setscrews. It is important this is done properly or maximum flow may not be achieved when the knob is in the "less than (<)" position.
- 5.11.11. Test the actuation of the knob by pushing in, turning and releasing it. It should move without binding.

5.12. SIDE PORT CAP

- 5.12.1. Using the appropriate spanner, remove the cap on the side port(s).
- 5.12.2. Remove the o-ring and clean the cap.
- 5.12.3. Lightly grease the new o-ring and replace over the threads of the cap.
- 5.12.4. Screw the cap back into the block and tighten with the wrench.

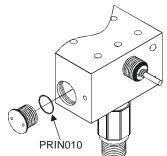
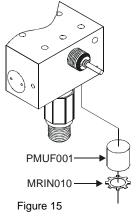


Figure14

5.13. MUFFLER

- 5.13.1. From the underside of the block, carefully pry out the retaining star clip and remove the foam muffler.
- 5.13.2. Insert the new muffler into the cavity and press the star clip back into place. Note that the clip has a slightly concave form to it. This is to aid insertion and retention.



5.14. FINAL ASSEMBLY

- 5.14.1. Once the block has been completely reassembled, reinstall the two balancing chambers to the top of the block. Be sure the o-rings are properly fitted into the orifices in the bottom of the chambers.
- 5.14.2. If balancing chamber material is aluminum then tighten & torque the four chamber screws to 47 in-lb using a calibrated 5/32" hex wrench.
- 5.14.3. If balancing chamber material is plastic then tighten & torque the four chamber screws to 30 in-lb using a calibrated 5/32" hex wrench.
- 5.14.4. Reinstall the front plate and retaining nut. Leave the nut loose and the knob off for the calibration procedure to follow.
- 5.14.5. Reinstall the outer cover and then any side output ports removed. Refer to 5.9.

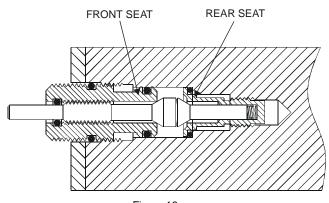
6. CALIBRATION & TEST PROCEDURE

Tools required:

1/8" hex wrench
Adjustable Spanner
9/32" nut driver
5/8" wrench
11/16" wrench
0 to >120 lpm flow valve or flowmeter
Flow measurement device
Oxygen analyzer

Minimum supply pressures required are Oxygen- 50 psi, Air- 50 psi. Oxygen analyzer should be capable of displaying concentrations in at least tenths.

6.1. PROPORTIONING VALVE- HI/LOW FLOW BLENDER (Refer to 6.2 for Low Flow & 0-50 LPM models)



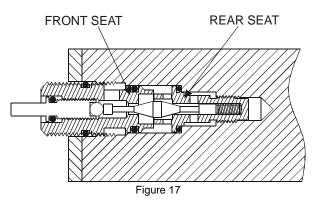


<u>Objective:</u> When the knob is set to 21%, the front seat is closed due to the taper of the front shaft being seated into the front seat orifice. The rear seat is fully open and allows only air to pass. As the knob is then turned to 100%, the shaft moves back thus progressively opening the front seat while at the same time progressively closing the rear seat until the knob reaches 100% and the rear seat is closed. The rear taper must seal the orifice in the rear seat and the knob must reach the 100% stop pin simultaneously. In order to do this, the distance between the front and rear seat is critical. The following procedure will establish this distance by positioning the front seat, which can be moved, relative to the rear seat, which is fixed.

- 6.1.1. If the blender has not been disassembled and only its calibration is to be verified, go directly to 6.3. Otherwise, proceed with 6.1.2.
- 6.1.2. If the knob is on, remove it by removing the cap on the front and loosening the nut underneath. Pull off the knob.
- 6.1.3. Rotate the shaft counterclockwise until the valve just seats. A slight resistance should be felt. <u>Do not force</u>.
- 6.1.4. Taking care not to move the shaft, carefully replace the knob and position the needle against the 21% stop.
- 6.1.5. Tighten the nut on the knob collet. When doing this, be sure the knob is far enough away from the locking nut underneath it so that as it is turned to 100%, it does not bottom out on the nut before reaching the 100% position.
- 6.1.6. Turn the knob clockwise until a slight resistance is felt or until the knob

reaches the 100% stop pin. Ultimately, these should occur simultaneously. Do not force. Once resistance is felt, this means the rear shaft is seating in the rear seat and turning the shaft beyond this point may damage the seat. If the shaft seats prior to the knob reaching the stop pin, then go to the next step. If the knob reaches the stop pin prior to the shaft seating, then go to step 6.1.8.

- 6.1.7. If the shaft seated before the knob reached the stop, then the front seat is threaded into the block too far. Make a mental note of how far away from the stop pin the knob pointer is and then turn the knob back to the 21% stop. Remove the knob by loosening the nut on the knob collet and pull the knob off the shaft. Loosen the locking nut on the front seat and using a spanner turn the seat and shaft together as one counterclockwise, approximating the distance the knob was away from the stop as previously noted. Go back to step 6.1.4 and repeat. These steps may have to be repeated several times until the proper relationship between the front and rear seats is obtained. Once this is done, then lock the front seat in place by tightening the locking nut, taking care not to move the seat in the process.
- 6.1.8. If the knob reached the stop pin before the shaft seated in the rear seat, then the front seat is not threaded into the block far enough. Hold the knob in position to prevent the shaft from turning. Remove the knob by loosening the nut on the knob collet and pull the knob off the shaft. Loosen the locking nut on the front seat and turn the seat and shaft clockwise together as one until slight resistance is felt indicating the shaft has seated into the rear seat. Be careful that the shaft does not turn within the front seat while doing this. Once the shaft has seated, hold the front seat in this position and tighten the locking nut. Taking care not to turn the shaft, replace the knob so that it is against the 100% stop pin.
- 6.1.9. Performing the preceding steps should have properly positioned the front seat relative to the rear seat and the end points of the scale (21% and 100%) should now be calibrated. Then check 30%, 60% and 90% as well. Repeat these steps as many times as necessary until all points are within 3% full scale.
- 6.2. PROPORTIONING VALVE- LOW FLOW & 0-50 LPM BLENDERS (Refer to 6.1 for High/Low Flow model)

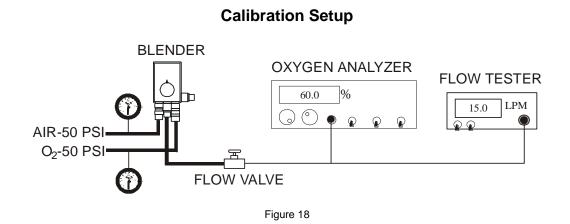


<u>Objective:</u> When the knob is set to 21%, the front seat is closed due to the taper of the front of the shaft being seated into the front seat orifice. The rear seat is fully open and allows only air to pass. As the knob is then turned to 100%, the shaft moves back thus progressively opening the front seat while at the same time progressively closing the rear seat until the knob reaches 100% and the rear seat is closed. The rear taper must seal the

orifice in the rear seat and the knob must reach the 100% stop pin simultaneously. In order to do this, the distance between the front and rear seat is critical. The following procedure will establish this distance by positioning the front seat, which can be moved, relative to the rear seat, which is fixed.

- 6.2.1. Connect 50 PSI Air and Oxygen supplies to their respective inputs on the blender. Tee into each of these supply lines a pressure gauge so that pressures can be accurately set and monitored.
- 6.2.2. Connect the primary blender output to a flow valve capable of >50 lpm, a flow measurement device, and an oxygen analyzer per the manufacturer's instructions. Refer to Figure 18.
- 6.2.3. Turn on both supply pressures simultaneously and fully open the flow valve connected to the blender output.
- 6.2.4. Remove the knob on the blender, if it is not already removed. Turn the shaft clockwise or counterclockwise as required until the o-ring that is on the shaft can just be seen and then turn it clockwise so that the o-ring is just inside the front seat and no longer visible.
- 6.2.5. Loosen the locking nut for the front seat and turn the seat with the shaft clockwise until a flow of approximately 40 lpm (80 lpm for 0-50 blenders) is obtained as indicated by the flow measurement device.
- 6.2.6. Lock the seat in this position by tightening the nut.
- 6.2.7. Turn the shaft clockwise until a slight resistance is felt and 98% 100% concentration is indicated on the analyzer.
- 6.2.8. Taking care not to disturb the position of the shaft, place the knob on the end of the shaft such that it against the 100% stop pin and tighten the collet nut.
- 6.2.9. Using the flow valve connected to the output in the test setup, adjust the flow to 30 lpm (50 lpm for 0-50 LPM blenders).
- 6.2.10. Turn the concentration knob to 21% against the stop and verify the concentration is 21% 22%.
- 6.2.11. If it is 21% at the stop, then slowly turn the knob away from the stop, being sure to give the analyzer enough time to react, and watch the analyzer for the point at which the concentration begins to increase. If this occurs just as the knob is moved away from the 21% position, then the seat is properly adjusted. If, however, the knob must be moved away from the stop by some distance in order to get a change in concentration, then the seat is too far in so go to step 6.2.13.
- 6.2.12. If it is higher than 22% when against the stop, then observe the actual concentration as indicated by the analyzer. Loosen the knob on the shaft and without turning the shaft, position the knob pointer approximately where it would be to give the observed concentration if it was properly calibrated. Make a mental note of how far away from the stop pin the knob pointer is in this position. This represents approximately how far the seat needs to be turned to correct the error. Remove the knob, loosen the seat's locking nut and slowly turn the seat clockwise by this predetermined amount. Taking care not to disturb the seat, relock the seat, turn the shaft to the 100% position and replace the knob against the 100% stop pin. Recheck 21% and 100%. Then check 30%, 60% and 90% as well. Repeat these steps as many times as necessary until all points are within 3% full scale.
- 6.2.13. If, as described in step 6.1.11, it is still 21% when the knob is away from the 21% position, then turn the knob to the point where the concentration begins to rise. Make a mental note of how far away from the stop pin the knob is at this point. Then, without changing its position, remove the knob, loosen the seat locking nut and turn the seat and shaft together counterclockwise by an amount

corresponding to approximately ½ the distance the knob was noted to be from the stop pin. Lock the seat with the nut, turn the shaft to 100% and replace the knob. Recheck 21% and 100%. Then check 30%, 60% and 90% as well. Repeat these steps as many times as necessary until all points are within 3% full scale.



6.3. CALIBRATION VERIFICATION

- 6.3.1. Connect 50 PSI Air and Oxygen supplies to their respective inputs on the blender. Tee into each of these supply lines a pressure gauge so that pressures can be accurately set and monitored.
- 6.3.2. Connect the blender output to a flow valve capable of passing more than120 lpm, a flow measurement device, and an oxygen analyzer per the manufacturer's instructions.
- 6.3.3. Turn on supply pressures simultaneously.
- 6.3.4. Set the knob to 21% and 100% and verify the concentrations as indicated by the analyzer are 20.8% 23% and 98% 100% respectively. If these conditions are not met, then it may be possible to make minor adjustments by repositioning the knob on the shaft. To do this, remove the knob, turn the shaft to meet the specification in question and replace the knob on the shaft against the stop-pin. Be aware that any change in the knob/shaft relationship will affect both ends of the scale. If it is not possible to bring both ends into specifications by this method, then it will be necessary to perform the calibration steps in the sections preceding this one. The aforementioned steps should be done with the blender set up with air and oxygen supplies connected as it is here, however, so rather than just feeling for the shaft to meet the seat as described in Steps 6.1 or 6.2, actual concentrations can be observed as the shaft and/or front seat are repositioned.
- 6.3.5. Once the 21% and 100% have been calibrated, then verify the full range of concentrations as indicated in the following tables.

KNOB %	O2 SUPPLY	AIR SUPPLY	FLOW	CONCENTRATION	
	PRESSURE	PRESSURE	LPM	%	
21	50	50	15 ¹	20.8 - 23	
30	50	50	15 ¹	27 – 33	
60	50	50	15 ¹	57 – 63	
90	50	50	15 ¹	87 – 93	
100	50	50	15 ¹	98 - 100	
KNOB %	O2 SUPPLY	AIR SUPPLY	FLOW	CONCENTRATION	
	PRESSURE	PRESSURE	LPM	%	
21	50	50	MAXIMUM ²	20.8 - 23	
30	50	50	MAXIMUM ²	27 – 33	
60	50	50	MAXIMUM ²	57 – 63	
90	50	50	MAXIMUM ²	87 – 93	
100	50	50	MAXIMUM ²	98 - 100	

Note 1: 3 lpm for low-flow blender, 6 lpm for 0-50 LPM blender

Note 2: Maximum means flow valve fully open, 30 lpm for low-flow blender, 50 lpm for 0-50 LPM blender

6.3.6. If any of these specifications are not met, return to 6.1.

- 6.3.7. <u>Note: Some special order blenders may not have a bleed in the auxiliary output. This is by design. If your blender does not have this bleed, then skip this step.</u> If the blender has an auxiliary output with a bleed on the side, then remove the calibration setup from the primary output and connect it to the auxiliary output. Set the flow to 2 lpm. Using tubing with an appropriate fitting on one end that will cover the bleed port on the bottom of the blender, position this snugly over the bleed port and connect the other end to a flow measurement device. Verify a bleed flow rate of 10–12 lpm (2.5-4.0 lpm at 50 psi gas pressure and set to 60% Oxygen for low-flow blenders, 5.5-6.5 lpm for 0-50 LPM blenders). If it is not within this specification, inspect the bleed orifice under the muffler (see Figure 15) or the bleed orifice in the auxiliary output fitting for occlusion.
- 6.3.8. Verify the concentrations delivered from the auxiliary output as indicated in the following table.

KNOB %	O2 SUPPLY	AIR SUPPLY	FLOW	CONCENTRATION
	PRESSURE	PRESSURE	LPM	%
60	50	50	MAXIMUM ¹	57 – 63
60	50	50	2 ²	57 – 63
60	50	60	2 ²	57 – 63
60	50	40	2 ²	57 – 63

Note 1: Maximum means flow valve fully open, 30 lpm for low-flow blender, 50 lpm for 0-50 LPM blenders Note 2: If this blender has no bleed in the auxiliary output, then this number should be the lower of the two numbers in the flow range with no bleed as indicated in the table on page 2.

6.3.9. If any of these specifications are not met, re-verify bleed (step 6.3.7).

6.4. ALARM

IMPORTANT: The following instructions assume supply pressures of 50 psi as is standard in the United States. Due to the differences in supply pressures used internationally, the alarm should be calibrated using the pressures at which the blender will be used. Units sold overseas alarm at a pressure differential of 30 psi (206.8 kPa). This value rather than 20 psi should be used in the instruction below.

- 6.4.1. Refer to 6.3.1 6.3.3 for setup. Use supply pressures that are standard for the area in which the blender will be used.
- 6.4.2. Lower the air supply pressure until the alarm sounds. Air supply pressure should be 20 \pm 2 psi below the oxygen supply pressure at this point, i.e. 30 psi if O₂ is 50 psi. If the pressure is not within this range at the point of alarm, then proceed with the next step.
- 6.4.3. If the blender has a cover, it must be removed to access the alarm adjustments. Remove the four cover screws, two on each side, and remove the cover. With older covers, the auxiliary output must also be removed, if present, in order to remove the cover.
- 6.4.4. The alarm adjustment is located on the side of the blender closest to the supply that failed, in this case the air side. If the alarm sounded at a pressure higher than the specification in 6.4.2, i.e. 40 psi if O₂ was 50 psi, then turn the hex screw in (clockwise) ½ turn and return to 6.4.2. If the pressure was lower than the specification in 6.4.2, i.e. 20 psi if O₂ was 50 psi, turn the adjuster out (counterclockwise) ½ turn and return to 6.4.2. Continue adjusting the alarm in smaller and smaller increments until lowering the air pressure causes the alarm to operate properly.
- 6.4.5. With the alarm now sounding, slowly raise the air pressure. The alarm should stop before the pressure reaches 15 psi above the properly calibrated pressure as described in step 6.4.2.
- 6.4.6. Repeat for the oxygen supply pressure.

6.5. DUCK BILL CHECK VALVE

WARNING: 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 Bio-Med Devices. Doing so may cause gas supply contamination due to back-flow.

- 6.5.1. Remove anything previously connected to all blender outputs.
- 6.5.2. Leave the air supply connected to the supply source and to the blender.
- 6.5.3. Disconnect the oxygen supply hose from the supply source, but leave the other end connected to the blender.
- 6.5.4. Turn on the air supply source.
- 6.5.5. The reverse flow of gas from the gas inlet should not exceed 10 ml/h (0,01667 l/min). If the reverse flow exceeds this rate, then replace the oxygen fitting check valve (refer to 5.6).
- 6.5.6. Repeat for the air supply side. If the air supply side fails, then replace the air fitting check valve (refer to 5.7)

7. PERFORMANCE CHECK

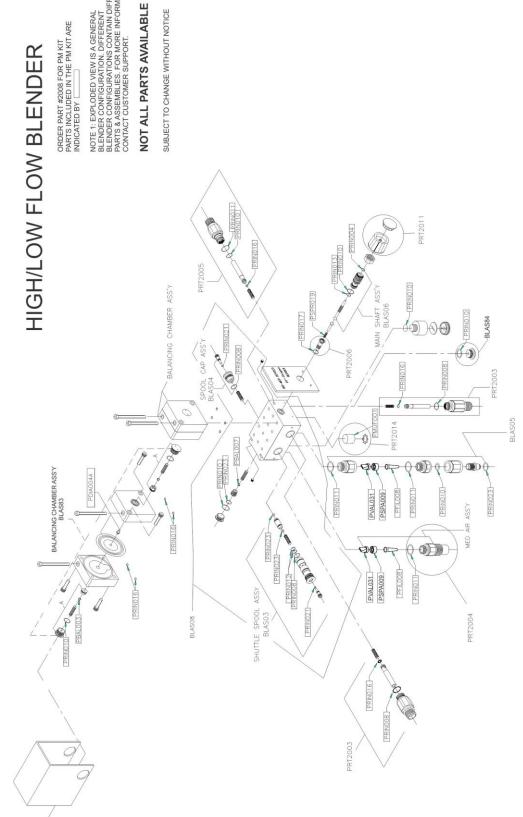
Before placing the blender into service, the following should be checked for proper operation. When taking readings from the analyzer, be sure to wait long enough for it to stabilize.

- 7.1. Connect 50 PSI O_2 gas supply to the O_2 supply fitting (and no supply to the air fitting). Turn on the O_2 supply. The reverse flow of gas from the air inlet fitting should not exceed 10 ml/h (0,01667 l/min). Perform the same procedure with air to the air fitting (and no supply to the O_2 fitting).
- 7.2. Set up as in Figure 18. Set the blender to 60%.
- 7.3. With both air and oxygen supply pressures equal and flow coming from the blender, the blender should not alarm.
- 7.4. With the flow set to 15 lpm, turn off the air supply pressure. The blender should alarm and 100% oxygen should be observed on the analyzer.
- 7.5. Turn the air supply back on. The alarm should stop and 57% 63% should be observed on the analyzer.
- 7.6. With the flow set to 15 lpm, turn off the oxygen supply pressure. The blender should alarm and 21% (air) should be observed on the analyzer.
- 7.7. Turn the oxygen supply back on. The alarm should stop and 57% -63% should be observed on the analyzer.
- 7.8. With 15 lpm, set the blender to 21% and verify 20.8% 23% concentration.
- 7.9. With 15 lpm, set the blender to 100% and verify 98% 100% concentration.
- 7.10. If the blender has an auxiliary outlet, connect the flow valve, analyzer and flow measurement device to it, set the flow to 2 lpm and repeat steps 7.3 7.8 using this lower flow.
- 7.11. If there is a knob on the side of the blender, leave the set up as in Figure 18. Set the knob to the "less than (<)" indication, adjust the flow to 2.0 lpm and repeat 7.3 7.8 using this lower flow.

8. TROUBLE SHOOTING GUIDE

PROBLEM	CAUSE OF PROBLEM	TO SOLVE PROBLEM
OXYGEN ANALYZER DOESN'T AGREE WITH SETTING OF	ANALYZER OUT OF CALIBRATION	CALIBRATE OXYGEN ANALYZER
BLENDER	BLENDER OUT OF CALIBRATION	CALIBRATE ACCORDING TO INSTRUCTIONS
	BLEED ON BOTTOM OF BLENDER IS RESTRICTED	CLEAN BLEED ORIFICE IN AUXILIARY PORT
	AIR IS BEING INTRODUCED INTO THE SYSTEM AFTER THE BLENDER AND DILUTING CONCENTRATION	CORRECT SITUATION BY FINDING AND REMOVING THE FLOW OF AIR
BLENDER ALARMING	AIR AND OXYGEN SOURCE PRESSURES HAVE GREATER THAN 20 PSI* DIFFERENTIAL	BRING THE SOURCE PRESSURES WITHIN THE 20 PSI* RANGE
	ALARM SYSTEM IS OUT OF CALIBRATION	CALIBRATE ALARMS PER INSTRUCTIONS
	DIRTY GAS IS CONTAMINATING ALARM SYSTEM	CLEAN AND CALIBRATE BLENDER- CORRECT DIRTY GAS SOURCE
THE ONLY TIME THE BLENDER IS ACCURATE IS WHEN THE SOURCE PRESSURES ARE EXACTLY THE SAME	PRESSURE BALANCE CHAMBER NOT WORKING PROPERLY	SERVICE BALANCING CHAMBERS

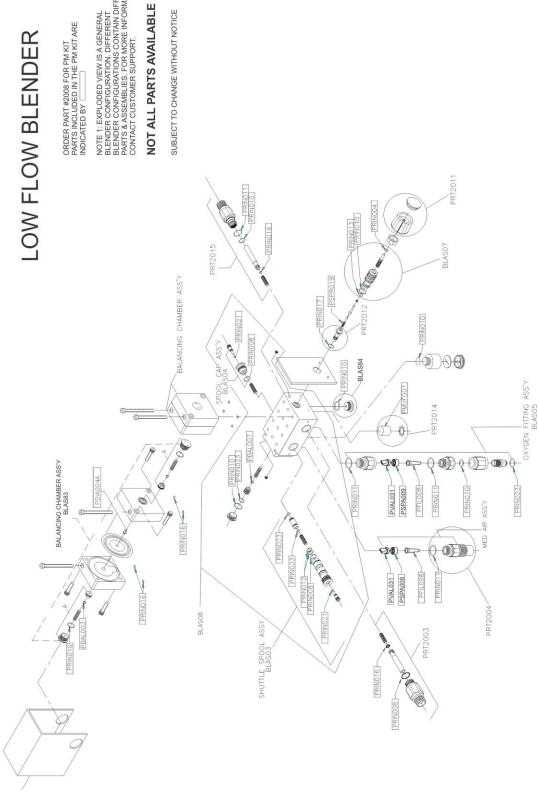
*30 psi (206.8 kPa) for units sold overseas



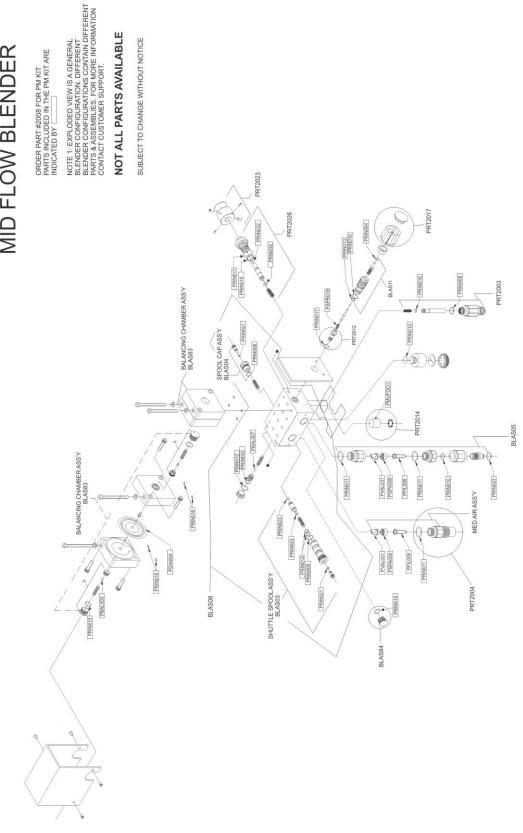
NOTE 1: EXPLODED VIEW IS A GENERAL BLENDER CONFIGURATION. DIFFERENT BLENDER CONFIGURATIONS CONTAIN DIFFERENT PARTS & ASSEMBLIES. FOR MORE INFORMATION CONTACT CUSTOMER SUPPORT.

SUBJECT TO CHANGE WITHOUT NOTICE

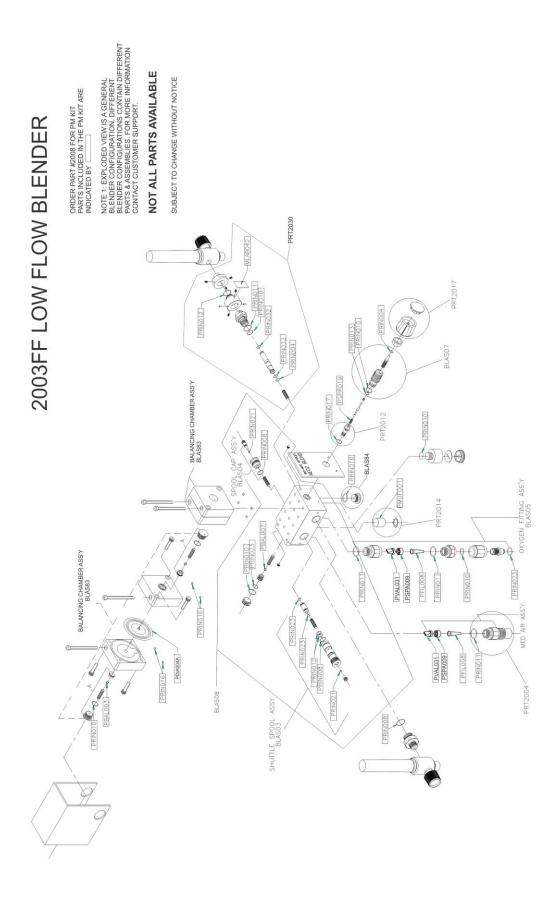
9. PARTS



NOTE 1: EXPLODED VIEW IS A GENERAL BLENDER CONFIGURATION. DIFFERENT BLENDER CONFIGURATIONS CONTAIN DIFFERENT PARTS & ASSEMBLIES. FOR MORE INFORMATION CONTACT CUSTOMER SUPPORT.



MID FLOW BLENDER



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. CE MARK

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.

Warning: Because this is a CE marked device, it must never be modified without prior expressed written consent from Bio-Med Devices.

12. SPECIFICATIONS

Bio-Med Devices' line of blenders delivers accurate FIO₂ mixtures from one to up to three outlet ports, allowing it 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. Bio-Med Devices also offers MR-conditional versions that are made entirely of non-magnetic materials.

CAUTION: Do not use in an 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 front plate, and an MR-Conditional label on the case.

Device-Specific Standards: Complies with ISO 11195.

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.

*<u>Blender performance with supply pressures below range (0-30 PSI / 0-207 kPa)</u> 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: 2.35 lbs (1.07 kg)

No electronics incorporated.

Reverse Gas Flow: From either gas inlet to the other, complies with clause 9 of ISO 11195.

Operating Temperature: 41° to 104° F (5° to 40° C)

Ambient Humidity: 5 to 90% non-condensing