GENTEC®

Medical Air/Oxygen Blender
Service Manual

Model No.GMX30U-AIR/O2
GMX120U-AIR/O2

Please read this user manual carefully and thoroughly before servicing the blender.
Keep for future reference.

Contents

1. Product Description

The GENTEC **Air/Oxygen** Blender is a medical device used to mix Medical Grade Air and Oxygen to a concentration ranging from 21% - 100% oxygen. The inlet gas connections are standard DISS or NIST. The inlets are clearly marked and labeled on the bottom of the Blender. The outlets are standard DISS male oxygen connections. A concentration adjustment knob is located on the front panel of the Blender to set the specific F_{IO_2} blend desired.

2. Warnings and Precautions

⚠ **WARNING** Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

⚠ **CAUTION** Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury.

⚠ WARNING
• The Air/Oxygen Blender should be operated by qualified medical personnel under direct supervision of a licensed physician. • Prior to disassembly, disconnect all connections from the blender. • Only use clean and dry Medical Air and Medical Oxygen to avoid contamination. • The air must meet USP compressed air and ANSI Z86.1-1973 grade F and water vapor content must not exceed a dew point of 5 degrees F. • The Medical Air/Oxygen Blender should be serviced by a qualified service technician. • Oxygen concentrations must be verified by an oxygen analyzer. • When reassembling the Blender, ensure all components are properly installed before pressurizing the unit. Failure to do so may result in ejected components. • Always follow ANSI and CGA standards for Medical Gas Products, Flowmeters and Oxygen Handling. • International/relevant local laws and Directive 93/42/EEC servicing requirements must be followed for CE marked devices. • **DO NOT** tape, obstruct, or remove the alarm. • **Oxygen Concentration Knob does not rotate 360 degrees.** Rotating the Knob less than 21% or over 100% oxygen will damage the Blender.

⚠ WARNING
• This Service Manual is provided for your safety • It is essential to read and understand this entire manual before attempting to service the Medical Air/Oxygen Blender. • If you have any questions regarding the installation, setup, operation, and/or maintenance of the Medical Air/Oxygen Blender, consult GENTEC.

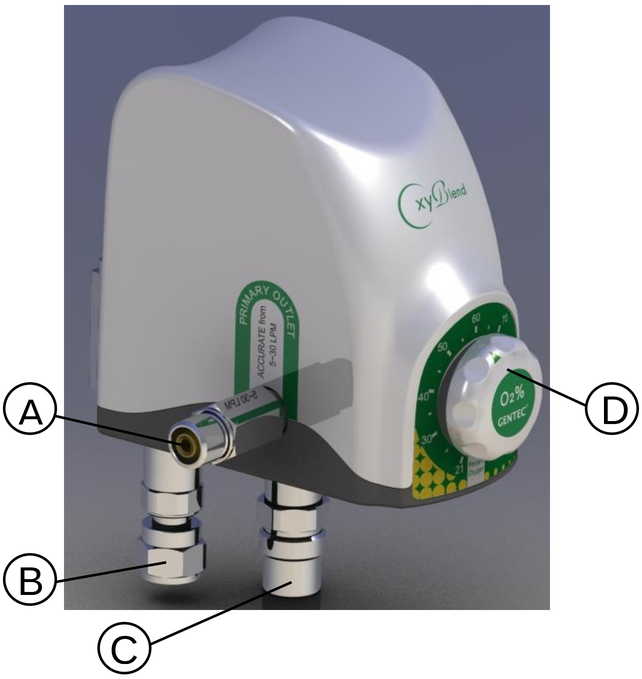
⚠CAUTION

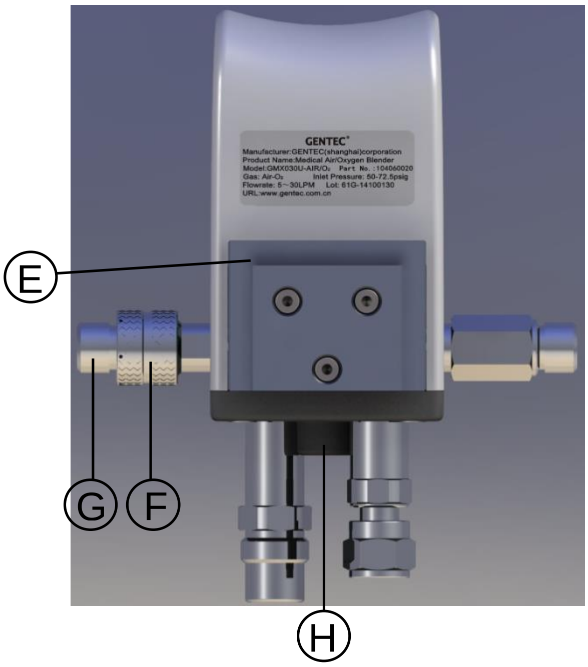
- Use recommended lubricants sparingly as lubricant may migrate to other areas and cause the Blender to malfunction.
- When pressurizing the Blender inlets, avoid pressure surges greater than 100 psi (6.9 bar) .
- Be sure all connections are tight and leak free before returning to service.
- Store Blender in a clean, dry area when not in use.
- Consult a physician for appropriate FiO2 setting.
- **DO NOT** steam clean or autoclave or otherwise subject blender to temperatures above 145°F (62°C)
- **DO NOT** gas sterilize with (ETO) Ethylene Oxide.
- **DO NOT** immerse Medical Air/Oxygen Blender into any liquid.
- **DO NOT** use if dirt or contaminants are present on or around the Blender or connecting devices.
- **DO NOT** clean with aromatic hydrocarbons.

3. Explanation of Abbreviation

FIO_2	Fractional Concentration of Inspired Oxygen
DISS	Diameter Indexed Safety System
NIST	Non-Interchangeable Screw Thread
lpm	Liters Per Minute
psi	Pounds Per Square Inch
Nm	Newton meter

4. Blender Diagrams





ITEM	COMPONENT DESCRIPTIONS in Blender Diagrams
A	**Primary Outlet Port** A male DISS oxygen fitting with check valve that delivers flow when connected to a flow regulating device, such as a flowmeter.
B	**Oxygen Inlet Fitting** A female DISS or NIST oxygen fitting with one way valve for connection to an oxygen supply hose assembly.
C	**Air Inlet Fitting** A male DISS or NIST air fitting with one way valve for connection to an air supply hose assembly.
D	**Oxygen Concentration Knob** A Knob used for selecting oxygen concentrations between 21%-100%. **This Knob does not rotate 360°.** The Knob starts at 21% and ends at 100%. The F_{IO_2} scale is used for reference only.
E	**Rear Slide Mount** for mounting.
F	**Auxiliary Bleed Sleeve** The sleeve is used to engage and disengage the bleed. The bleed is necessary to maintain accurate F_{IO_2} Concentration below 15 lpm for the High Flow and 5 lpm for the Low Flow. To activate the bleed, slide and rotate (if applicable) the knurled sleeve back until it contacts the cover. To deactivate the bleed, pull and rotate (if applicable) sleeve away from cover until it reaches a positive stop.
G	**Auxiliary Outlet Port** A male DISS oxygen fitting with check valve that delivers flow when connected to a flow regulating device, such as a flowmeter. This outlet is equipped with a bleed valve that allows the user to control if the bleed is ON or OFF. With the bleed in the ON position, this outlet delivers accurate oxygen concentrations in the following flows: **Model** **Flow Range** High Flow 5 – 120 lpm Low Flow 0 – 30 lpm
H	**Alarm** An audible alarm that sounds due to an excessive pressure drop or deletion of either gas supply.

5. Description of Components

5.1 Gas Inlet Connections

Oxygen inlet and Air inlet fittings are located at the bottom of the blender. The air and oxygen source gas enters through these gas specific fittings. Each inlet connector contains a particulate filter and duckbill check valves to prevent reverse gas flow from either the air or oxygen supply systems.

5.2 Diaphragm Balance Module

The two gases then enter the two-stage pressure Diaphragm Balance Module. In this module, the pressures of both gas sources are equalized prior to entering the Proportioning Module. The pressure is equalized at the lower pressure. The diaphragm within the module responds to the difference in pressure and directs the movement of each check valve assembly contained within the air and oxygen chambers. The movement of each ball adjusts the amount of gas flowing through the Diaphragm Balance Module, equalizing the air and oxygen pressures to the lower pressure.

5.3 Proportioning Module

From the Diaphragm Balance Module, the gases flow into the Proportioning Module and mix according to the oxygen percentage selected on the Oxygen Concentration Knob. The Proportioning Module consists of a double ended valve positioned between the two valve seats.

One seat controls the passage of air and the other valve seat controls the passage of oxygen into the outlets. At this point, the two gases have been blended according to the oxygen percentage selected on the Oxygen Concentration Knob.

When the Oxygen Concentration Knob is at the full counterclockwise position (21%), the double ended valve will completely close off the flow of oxygen, allowing only the air to flow.

When the Oxygen Concentration Knob is adjusted to the full clockwise position (100%), the flow of air is blocked, permitting only the flow of oxygen through the Blender outlet.

5.4 Alarm/Bypass

An audible alarm signals when the difference in pressure between the two inlet gasses exceeds 15 ±2 PSI or more. The alarm condition serves as an audible warning to the operator of an excessive pressure drop or depletion of either source gas. The alarm also activates when there is an elevation of either source gas resulting in a 15 ±2 PSI difference.

When the two source gases are near equal in pressure, the alarm bypass poppet is positioned over the bypass channel, blocking the flow of both gases. The poppet will remain seated for unequal pressures up to 15 ±2 psi (1.06 kg/cm_2). Once a 15 psi ±2 (1.06 kg/cm_2) difference is sensed by the poppet, the higher gas pressure will overcome the spring force and pressure will overcome the

spring force and pressure at its opposite end, thus creating a path for gas (air or oxygen) to flow into the alarm channel.
The gas with the higher pressure will also flow directly to the Blender outlet port by passing the Balance and Proportioning Modules. The gas is also directed to the bottom of the unit to the reed alarm, thus creating and audible warning. The oxygen concentration will be that of the gas at the higher pressure. The Blender in the alarm/bypass mode will deliver the oxygen (100%) or air (21%) until the bypass mechanism resets when the source gas pressure is restored to a differential of approximately 6 psi (0.42 kg/cm_2).

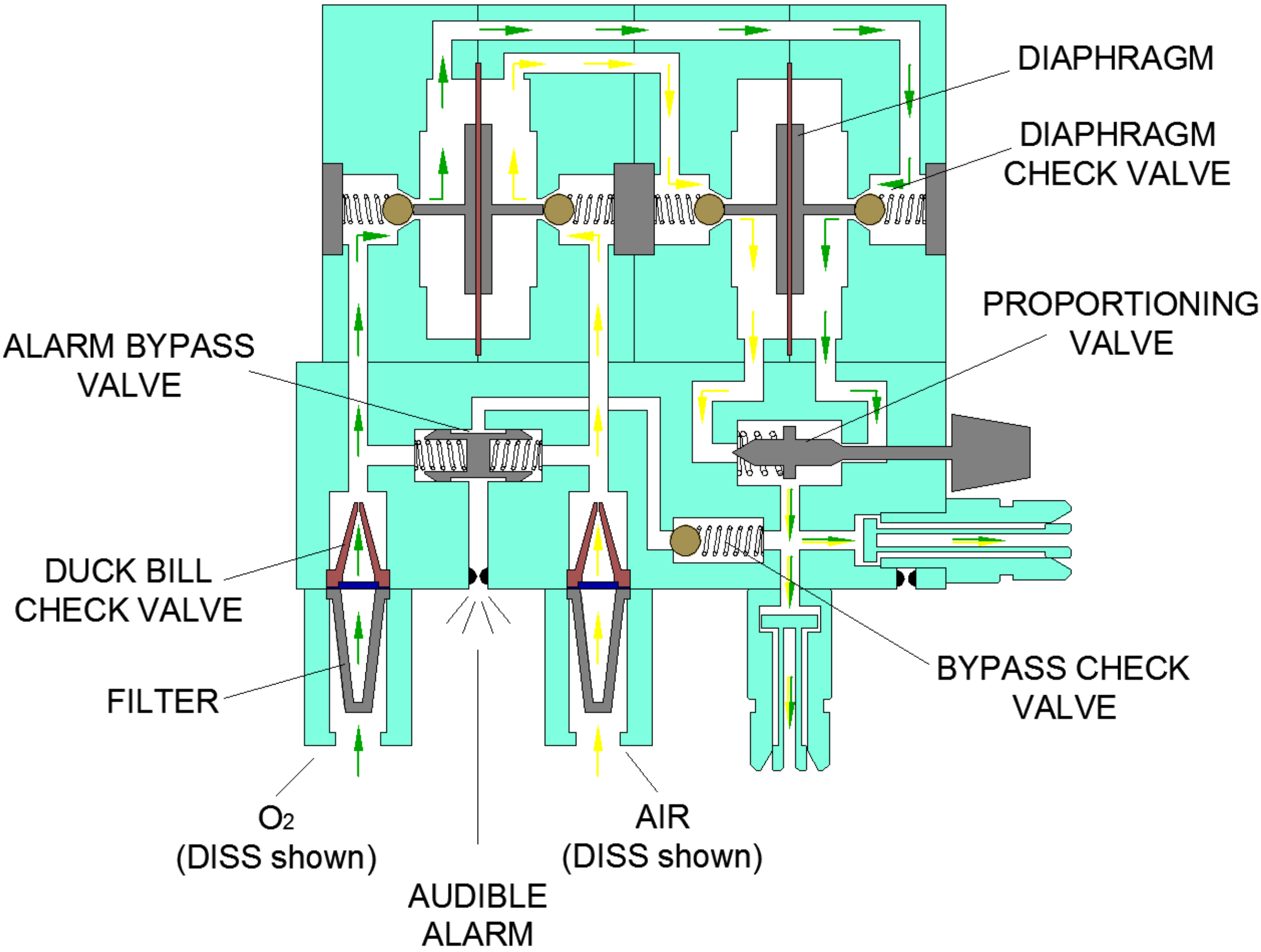
If the Blender is set at 21% and the OXYGEN source pressure is reduced enough to produce a 15 ±2 PSI (1.06 kg/cm_2) or greater differential, the unit will not alarm because it will continue to deliver 21% concentration according to the setting. If the control is moved slightly from the 21% setting, the alarm will sound.

Similarly, if the Blender is set to deliver 100% oxygen concentration and AIR source pressure is reduced or lost, the unit will not alarm because it will continue to deliver the selected 100% concentration. **The alarm will not function when there is no flow to the Blender.**

5.5 Gas Outlets

The Primary and Auxiliary Outlets are DISS male adapters with check valves.
On the Low Flow Air/Oxygen Blender, two outlet ports are located on the right and left sides of the Air/Oxygen Blender and allow low ranges from 0-30 LPM with bleed valve and 3 - 30 LPM without bleed respectively. On the High Flow Air/Oxygen Blender, two outlet ports are also located on the right and left sides of the Air/Oxygen Blender and allow low ranges from 0-120 LPM with bleed valve and 15 - 120 LPM without bleed respectively.

6. Air / Oxygen Flow Path Indication Diagram



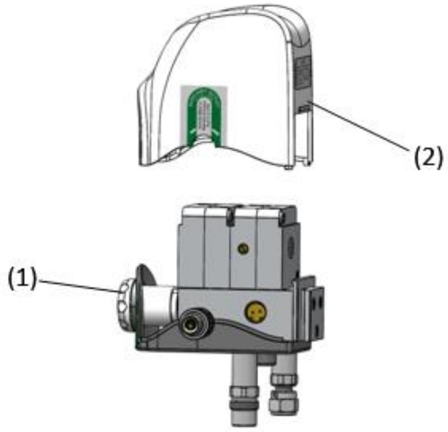
7. Maintenance Procedures, Repair and Calibration

7.1 Disassembly

Tools Required

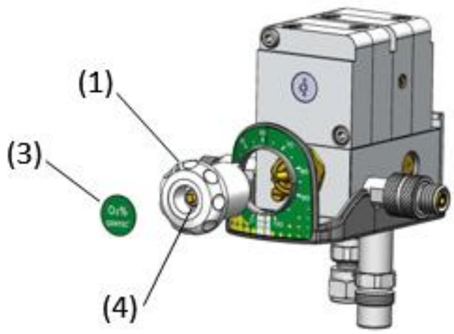
Phillips screwdriver, flathead screwdriver
12mm, 16mm, 17mm, 19mm, and 24mm open-end wrench
8mm socket drive
Snap Ring Plier
3mm, 4mm Allen wrench

Figure A



1. Turn the oxygen concentration knob (1) to point towards 21% concentration.
2. Above the Rear Slide Mount, push in the top cover (2) to detach the hook before pulling upwards to remove the top cover.
   Note: It may be easier to detach the hook with the oxygen concentration knob facing down while using your thumb to push down to detach the hook

Figure B



3. Remove the sticker label (3).
4. Use the 8mm socket drive to loosen the nut (4) and remove the knob (1).

Figure C

5. Use a 17mm open-end wrench and turn clockwise to loosen the oxygen inlet assembly (5)
6. Use a 19 mm open-end wrench and turn counterclockwise to loosen the air inlet assembly (6).
7. Use a Phillips screwdriver to remove the four screws (7) at the bottom.
8. Remove the bottom cover (8).
9. Remove the spring (9) and reed disc (10)

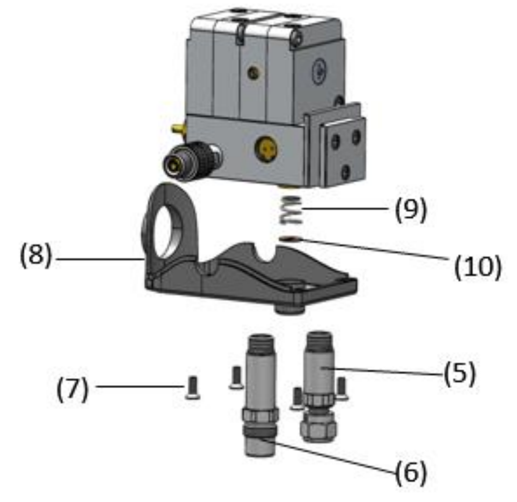


Figure D

10. Use a 12mm open-end wrench to loosen the auxiliary outlet port (11)
11. Use a 16mm open-end wrench to loosen the primary outlet port (12)
12. Use snap ring pliers (or special tool) to loosen the alarm assembly (13)

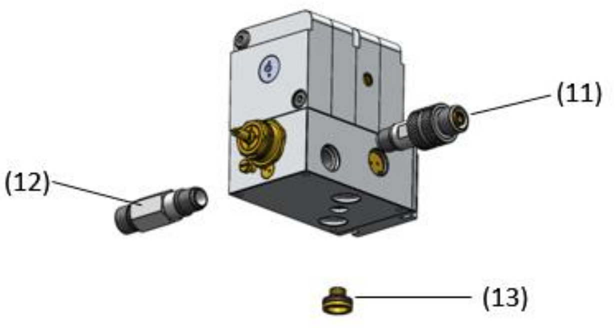
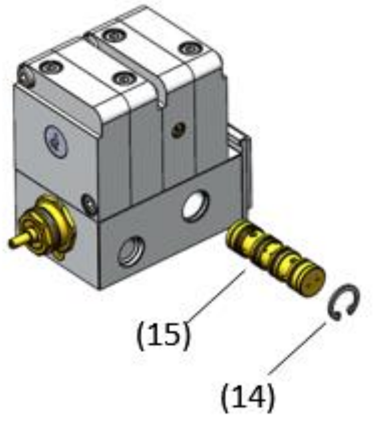


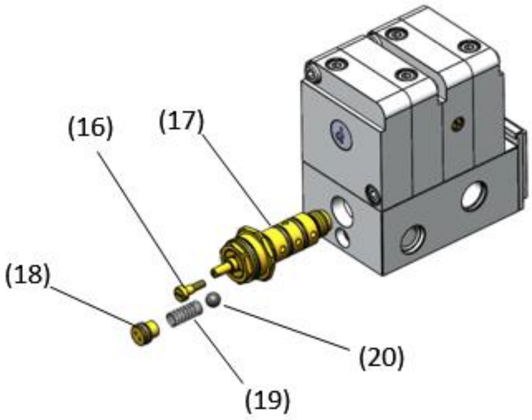
Figure E

13. Use snap ring pliers to remove the retainer ring (14).
14. Remove the shuttle valve assembly (15).



15. Use a flat screwdriver to loosen the screw(16)
16. Use a 24mm open-end wrench to remove the proportional valve assembly (17).
17. Remove the plug (18), spring (19), and rubber ball (20).

Figure F



18. Use a 4 mm hex wrench to remove the 4 screws (21).
19. Separate the two balancing chambers from the lower block of the blender. (22), (23).
    Note: O-rings may become loose during this process.

Figure G

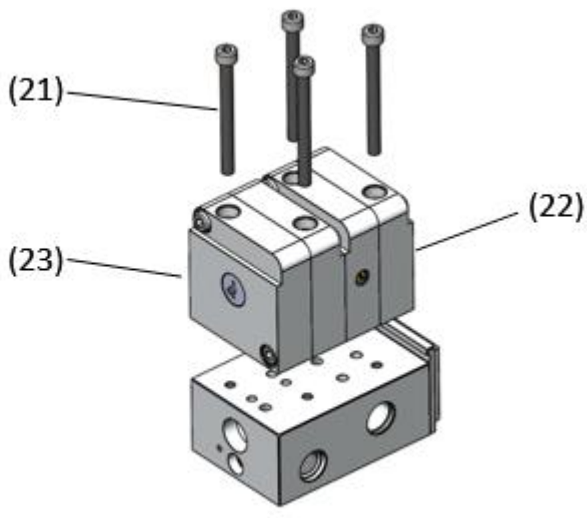


Figure H

20. Use a 3mm wrench to loosen the screws from the slide mount (24).
21. Remove the slide mount from the lower block (25)
22. Use a flat screwdriver to loosen the screws (26) and remove the O-ring (27)

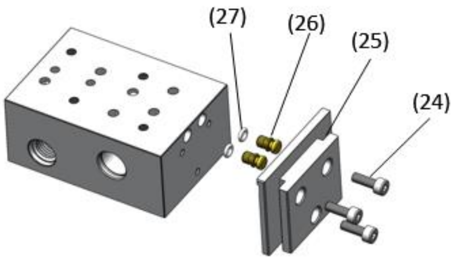
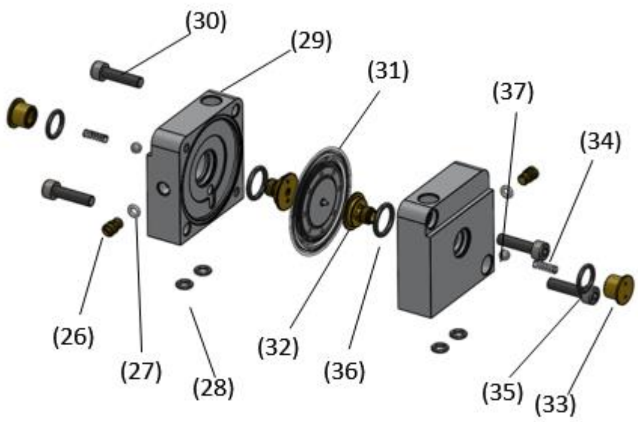


Figure I

23. To disassemble the balancing chamber, separate the two end caps (29) and the four O-rings at the bottom (28)
    Note: the O-rings may have become loose during step 19.
24. Use the 4mm hex wrench to remove four screws (30)
25. Remove the regulator diaphragm (31)
26. Use a flat screwdriver to remove the plug (26) and O-ring (27)
27. Use two snap ring pliers to loosen the seat (32) and cap screw (33)
28. Remove the O-ring (35), (36), spring (34) and ball (37)
    Note: Only one balancing chamber contains the plug (26) and O-ring (27), all other components are the same.



29. Make sure all O-rings have been removed from diaphragm housings and check valves.
30. Disassembly is complete.
31. Manifold block and diaphragm housing may be ultrasonically cleaned.

7.2 Cleaning

GENTEC recommends using an ultrasonic cleaner for cleaning all non-elastometric and non-metallic components. When ultrasonic cleaner is not available, an all-purpose liquid cleaner may be substituted. Rinse with clean warm water after using an all-purpose liquid cleaner. All passages must be blow dried before reassembly.

7.3 Assembly

Tools Required

Tools Required

Phillips screwdriver, flathead screwdriver

12mm, 16mm, 17mm, 19mm, and 24mm open-end wrench

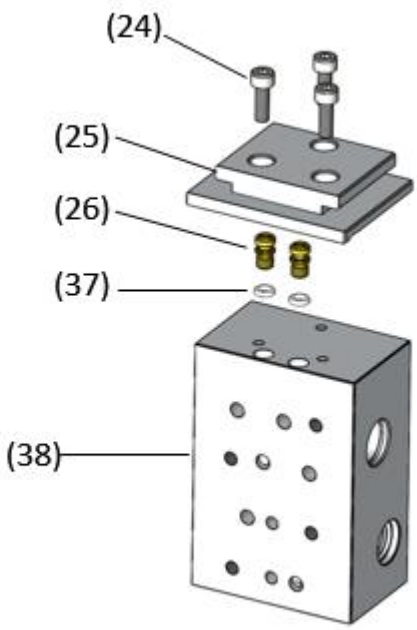
8mm socket drive

Snap Ring Pliers

3mm, 4mm Allen wrench

Krytox GPL-207, Kyrtox GPL-106 or equivalent

Figure J



1. Lay the lower block as shown in Figure J (38) on a flat surface and insert the two O-rings(37) into the plugs(26)
2. Use a flathead screwdriver to screw the plugs(26) into the lower manifold block (38)
3. Use a 3mm hex wrench to tighten the screws (24) and slide mount (25) into the lower block (38).

Figure K

4. Replace O-ring (35) on plug (33)
5. Replace O-ring (36) on seat (32)
6. Replace O-ring (27) onto plug (26)
7. Use a flathead screwdriver to screw the plug (26) onto the module (29)
8. Assemble the ball (37), spring (34) with plug (33) and insert the assembly to match with the seat (32). Use snap ring pliers to tighten seat (32)

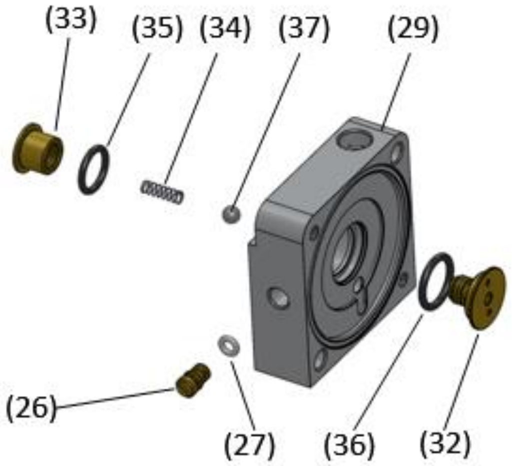


Figure L

9. Place the diaphragm (31) into the chamber module (29). Be sure the diaphragm sits properly in the groove. Tighten the four screws (30) to enclose the diaphragm in the chamber.
10. Using the four long hex screws (21), insert them into the balancing chambers. At the bottom of the balancing chambers (29), replace the O-rings (29) at the flow path holes. Attach both balancing chambers onto the lower block (38) and tighten the long hex screws (21).

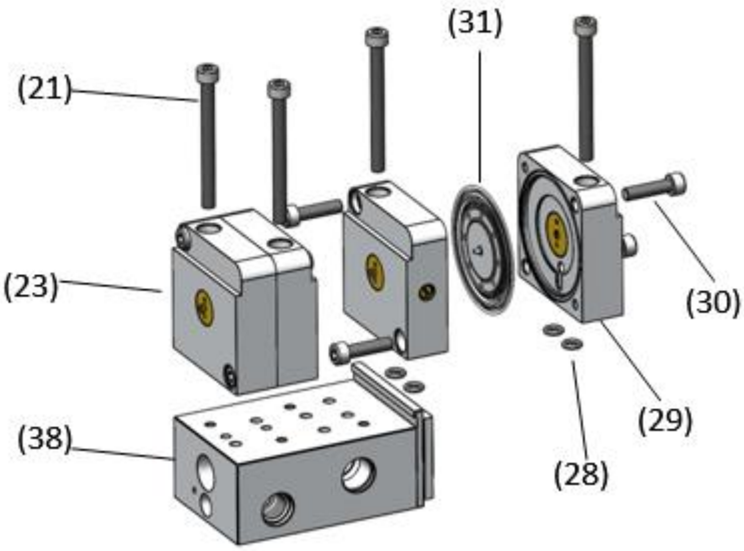


Figure M

11. Insert shuttle valve assembly (15) into the lower block. Use snap right pliers to clip the retaining clip (14) into place.
12. At the front end of the lower block, assemble the ball (20), spring (19), and plug (18) into the body.
13. Screw in the proportional valve assembly (17) into the lower block. Use a 24 mm open wrench to tighten.
14. Use a flat head screwdriver to tighten the screw (16).

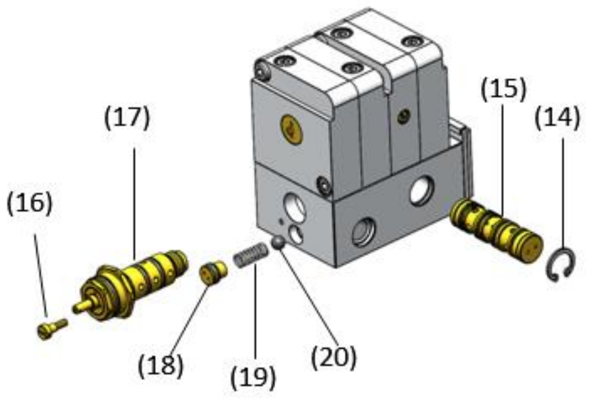


Figure N

15. Install the alarm assembly (13) into the lower block with snap ring pliers.
16. Install the auxiliary (11) and primary (12) outlet assemblies into the body.

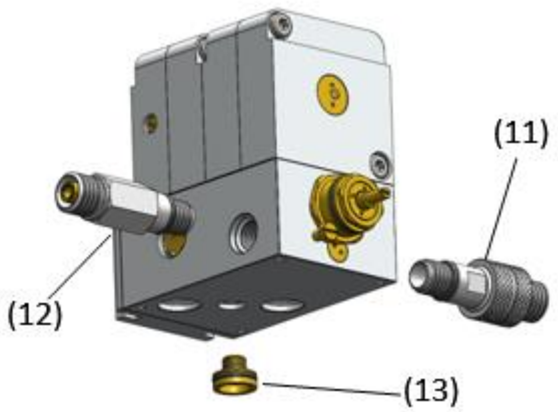


Figure O

17. Install the spring (9) and reed disc (10) into the body. Note the reed disc should be installed facing up, the flush surface should be facing the bottom cover.
18. Attach the bottom cover (8) to the body and tighten the screws (7) with a Philips screwdriver.
19. Attached the oxygen (5) and air inlet (6) assembly. Oxygen inlet assembly has left handed threads. [torque both to 10 ft-lbs (13.6 Nm)]

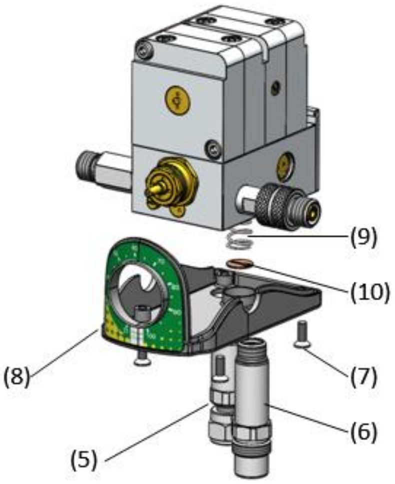
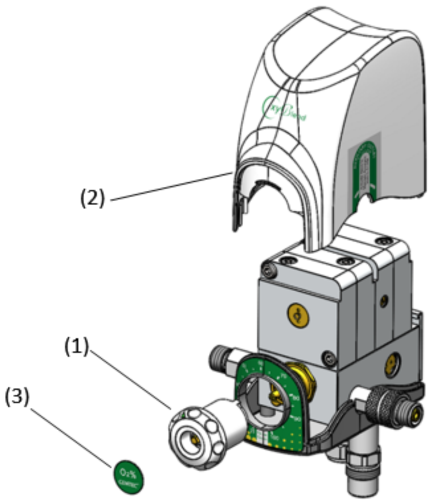


Figure P

20. Calibrate the proportional valve assembly according to test procedures below. Use an oxygen analyzer to adjust the valve to 60% oxygen concentration.
21. Once calibrated to 60% concentration, fix the concentration knob (1) onto the valve assembly and tighten with an 8mm socket drive.
22. Replace the knob label (3) and carefully re-attached the top cover (2).



7.4 Test

7.4.1 Equipment and Tools

7.4.1.1 Equipment Required

Medical Air Supply

Medical Oxygen Supply

Calibrated Oxygen Analyzer/Monitor

Calibrated Air or Oxygen flow monitor 0 to 70 lpm or greater

Flowmeter 0 to 70 lpm or greater

Calibrated Pressure Gauges 0 to 100 psi

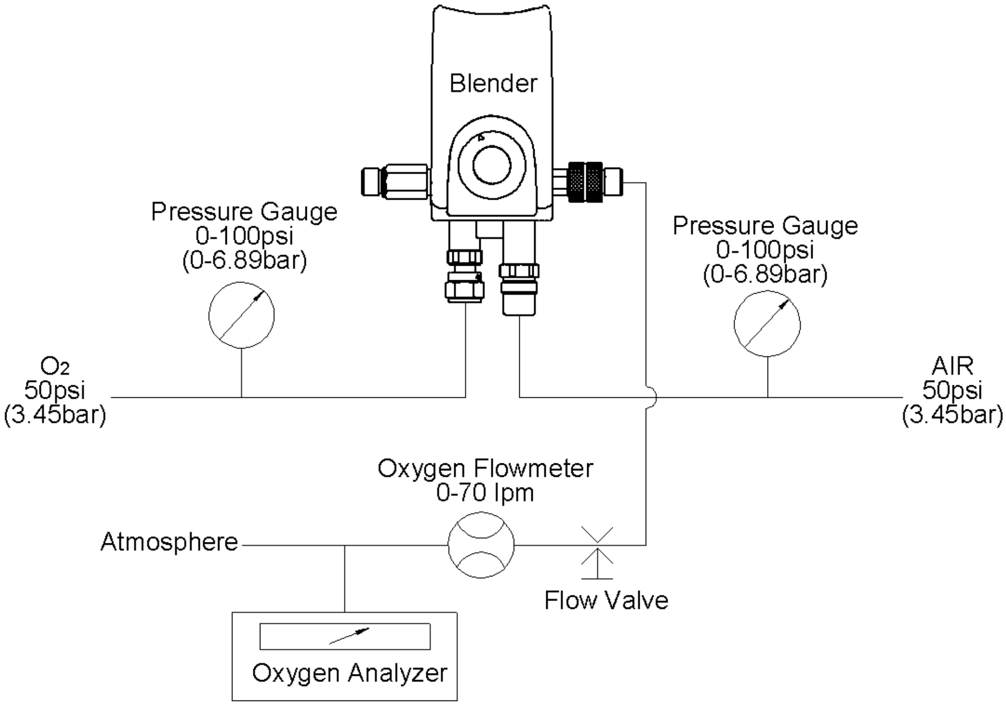
Oxygen (0-80 psig) and Air Regulator (0-80 psig) with Tubing / Hoses

7.4.1.2 Tools Required

Phillips Screwdriver

Torque Driver capable of 10 in-lbs
Adjustable Wrench
Retaining Ring Pliers
Nut Driver

Typical Test Configuration Diagram



7.4.2 Air and Oxygen Supply Setup

The Gas supplies shall be clean and dry and have a range of 0-100 psig (6.89bar). Make sure the gas lines are purged clean before attaching to system.

7.4.3 Blender Setup

1. Mount the Blender in an upright position onto a secure bracket on a wall or pole.
2. Secure the air and oxygen inlet hoses to the corresponding Blender inlets located at the bottom of the blender. A condensation trap is recommended to be installed before the Blender air inlet.
3. Install a flow valve after the auxiliary outlet port and then a 0-70 lpm flowmeter.
4. At the outlet of the flowmeter, install a 3 way tee valve to connect to the Oxygen Analyzer and Atmosphere.
5. The system is now ready for an initial performance test.

7.4.4 Initial Performance Test

1. Ensure the Oxygen Analyzer/Monitor is calibrated according to the manufacturer's instructions prior to testing the Blender.
2. Set Air & Oxygen pressures to 50 psi (3.45 bar). Set flow to 15 lpm, the blender alarm should not alarm.
3. Adjust the proportional valve stem until the oxygen analyzer displays a value of 60% ± 0.3%.

4. An initial pressure drop may occur, no further drop in pressure should occur.
5. If a continuous pressure drop is observed, troubleshoot by using a commercial leak detector to find source of leak and refer to Section 4: TROUBLESHOOTING for further instructions.
6. Use a lint free dry cloth to wipe Blender clean of commercial leak detector.
7. Ensure both inlet pressures are at 50 psi and flowrate is set at 15 lpm.
8. Turn off the air supply pressure. The blender alarm should activate and the oxygen analyzer should display 100% oxygen concentration.
9. Turn the air supply back on and the alarm should deactivate when the oxygen analyzer range is between 57%~63%.
10. Turn off the oxygen supply pressure. The blender alarm should activate and the oxygen analyzer should display 21% oxygen
11. Adjust the inlet pressures to verify the concentration value does not exceed ± 3%:
    a. Set the air inlet pressure to 50 psi (3.45 bar) and the oxygen inlet pressure to 42 psi (2.9 bar). Verify concentration reading.
    b. Set the air inlet pressure to 42 psi (2.9 bar) and the oxygen inlet pressure to 50 psi (3.45 bar). Verify concentration reading
12. If the margin of error is within acceptable range, fix the concentration knob in place. If the margin of error is above ± 3% repeat the steps above. When it is determined the accuracy is not within range, then replace one or both of the balancing chambers.

7.4.5 Reverse Gas Flow Procedure

1. Disconnect the oxygen hose from the gas source and remove all outlet connections from the Blender. Ensure there is no outlet flow.
2. With the oxygen hose attached to a pressure regulator, perform a hose leak test by placing the free end of the oxygen supply hose under water. Gradually increase the supply pressure from 30 – 72.5 psi (2.07 - 5 bar), check for leakage past the oxygen inlet check valve. A presence of bubbles indicates a leakage on the check valve.
3. Replace the Duckbill Check Valve in the oxygen inlet if bubbles indicate leakage.
4. Ensure Air hose is connected to the air pressure regulator and repeat steps 1-3 to check for leakage past the air inlet check valve.
5. Reconnect the inlet hoses and adjust both supply pressures back to standard inlet pressure.

7.4.6 Verification Test

Complete Operation Verification Procedure as per the test table. Record test results in the test table. When Verification Test is complete, replace top cover.

NOTE: Operation Verification Procedure should be performed at least once a year.

LOW FLOW Operation Verification Procedure

(50psi/3.45bar MODELS)

NO	FUNCTION TEST	KNOB SET Oxygen (%)	OXYGEN INLET PRESSURE ±1		AIR INLET PRESSURE ±1		FLOWMETER SET TO lpm ±0.2	AUXILIARY BLEED	TARGET VALUE	ACTUAL VALUE
			psi	bar	psi	bar				
1	leak	60	50	3.45	50	3.45	closed	closed	＜2psi/2min	
2	back flow	60	72.5	5	0	0	0	closed	＜100ml/min	
3	back flow	60	0	0	72.5	5	0	closed	＜100ml/min	
4	set point	21	50	3.45	50	3.45	5	open	18%-24%	
5	set point	40	50	3.45	50	3.45	5	open	37%-43%	
6	set point	60	50	3.45	50	3.45	5	open	57%-63%	
7	set point	80	50	3.45	50	3.45	5	open	77%-83%	
8	set point	100	50	3.45	50	3.45	5	open	97%-103%	
9	set point	60	50	3.45	50	3.45	1.5	open	57%-63%	
10	set point	60	50	3.45	42	2.9	1.5	open	57%-63%	
11	set point	60	42	2.9	50	3.45	1.5	open	57%-63%	
12	Alarm ON	60	50	3.45	Slowly reduce to 30	Slowly reduce to 2.07	5	closed	30±2psi	
13	Alarm OFF	60	50	3.45	Slowly Increase until alarm shuts off		5	closed	45psi MAX	
14	Alarm ON	60	Slowly reduce to 30	Slowly reduce to 2.07	50	3.45	5	closed	30±2psi	
15	Alarm OFF	60	Slowly Increase until alarm shuts off		50	3.45	5	closed	45psi MAX	
16	flow rate	60	50	3.45	50	3.45	MAX	closed	30lpm MIN	
17	flow rate	60	50	3.45	0		MAX	closed	30lpm MIN	
18	flow rate	60	0		50	3.45	MAX	closed	30lpm MIN	
19	flow rate	60	50	3.45	50	3.45	MAX	open	30lpm MIN	

HIGH FLOW Operation Verification Procedure

(50psi/3.45bar MODELS)

NO	FUNCTION TEST	KNOB SET Oxygen (%)	OXYGEN INLET PRESSURE ±1		AIR INLET PRESSURE ±1		FLOWMETER SET TO lpm ±0.2	AUXILIARY BLEED	TARGET VALUE	ACTUAL VALUE
			psi	bar	psi	bar				
1	leak	60	50	3.45	50	3.45	closed	closed	＜2psi/2min	
2	back flow	60	72.5	5	0	0	0	closed	＜100ml/min	
3	back flow	60	0	0	72.5	5	0	closed	＜100ml/min	
4	set point	21	50	3.45	50	3.45	15	open	18%-24%	
5	set point	40	50	3.45	50	3.45	15	open	37%-43%	
6	set point	60	50	3.45	50	3.45	15	open	57%-63%	
7	set point	80	50	3.45	50	3.45	15	open	77%-83%	
8	set point	100	50	3.45	50	3.45	15	open	97%-103%	
9	set point	60	50	3.45	50	3.45	3	open	57%-63%	
10	set point	60	50	3.45	42	2.9	3	open	57%-63%	
11	set point	60	42	2.9	50	3.45	3	open	57%-63%	
12	Alarm ON	60	50	3.45	Slowly reduce to 30	Slowly reduce to 2.07	15	closed	30±5psi	
13	Alarm OFF	60	50	3.45	Slowly Increase until alarm shuts off		15	closed	45psi MAX	
14	Alarm ON	60	Slowly reduce to 30	Slowly reduce to 2.07	50	3.45	15	closed	30±5psi	
15	Alarm OFF	60	Slowly Increase until alarm shuts off		50	3.45	15	closed	45psi MAX	
16	flow rate	60	50	3.45	50	3.45	MAX	closed	120lpm MIN	
17	flow rate	60	50	3.45	0		MAX	closed	80lpm MIN	
18	flow rate	60	0		50	3.45	MAX	closed	80lpm MIN	
19	flow rate	60	50	3.45	50	3.45	MAX	open	120lpm MIN	

8. Troubleshooting

No.	Problem	Probable Cause	Solution
1	Oxygen concentration discrepancy between blender setting and analyzer	Flow requirements are below the specified range. Bleed valve not open or may be blocked.	Adjust flow; Open the bleed valve
		Malfunctioning balancing module	Replace the balancing module.
		Loose adjustment knob	Recalibrate the control knob
		Analyzer out of calibration	Calibrate analyzer
		Gas supply is contaminated	Rectify gas source
2	Alarm sound is abnormal.	Buzzer orifice clogged	Clean the orifice
		Reed damaged	Replace reed
3	Cannot connect to the inlet hose	Wrong connection	Choose the suitable hose in accordance with ISO 5359-2008.
4	Leakage from the inlet connections	Damaged O-rings or loose connections	Replace the O-rings or tighten the connections
5	Alarm	Inlet pressure difference greater than 10 PSI	Correct the pressure difference
		Inlet filter is obstructed.	Replace the filter.
		Loss of pressure from one gas source	Check the gas source and the connection
6	Insufficient outlet flow	Insufficient gas supply	Raise the supply pressure.
		The desired flow is above the specified range.	Reduce the quantity of downstream equipment
7	Unsteady outlet flow	Large fluctuation of supply pressure	Use steady gas supply source.

Kit Diagram (LOW 104060020/HIGH 104060110)