



Air / Oxygen Gas Mixer

USER'S MANUAL



Sechrist Industries, Inc.
4225 E. La Palma Avenue • Anaheim, CA 92807 • USA
(USA & Canada): 1-800-SECHRIST (732-4747)
Phone: 714-579-8400 • Fax: 714-579-0814
Website: www.SechristUSA.com
E-mail: info@SechristUSA.com

FEDERAL LAW (USA) RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.



Table of Contents

INTRODUCTION 3

USER / OWNER RESPONSIBILITY 3

WARNINGS & CAUTIONS 3

EXPLANATION OF ABBREVIATIONS..... 5

EXPLANATION OF SYMBOLS..... 5

DEVICE DESCRIPTION 6

INTENDED USERS 6

INTENDED PURPOSE 7

INDICATIONS FOR USE 7

INTENDED USE ENVIRONMENT 7

CONTRAINDICATIONS 7

SPECIFICATIONS 7

SETTING UP THE GAS MIXER..... 8

OPERATING INSTRUCTIONS 8

USING THE GAS MIXER WITH OTHER EQUIPMENT 8

PERFORMANCE VERIFICATION 8

 Prior to Each Use..... 8

 Monthly..... 9

ROUTINE MAINTENANCE 10

FACTORY OVERHAUL..... 12

LIFETIME OF DEVICE..... 12

TROUBLESHOOTING..... 12

Sechrist Industries, Inc. thanks you for choosing a Sechrist Air/Oxygen gas mixer. We also caution you that before attempting to use the gas mixer in a patient care setting, you must make yourself thoroughly familiar with the instructions in this manual and any product labeling. Throughout this manual, warnings, cautions and notes will be utilized to bring your attention to particularly important matters.

INTRODUCTION

The gas mixer is a precision proportioning device for mixing medical grade air and oxygen to any concentration from .21 to 1.0 FiO₂ and delivering it to a variety of respiratory care devices. The gas mixer uses medical grade air and oxygen at a pressure of 50 psig (345 kPa) connected to two D.I.S.S. fittings. The gas mixer uses a double stage balancing system with the gas entering 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 oxygen concentration set using the gas mixer control 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 gas mixer.

The gas mixers are available in low flow or high flow configurations. The gas mixers also are available in various configurations for the input/output connectors.

USER / OWNER RESPONSIBILITY

WARNING: It is the responsibility of the procuring organization to ensure they have the tooling, equipment and training necessary to perform the tasks they are procuring components or kits for.

WARNING: Hospitals or users who perform certain repairs and/or periodic service without undergoing training by Sechrist Industries assumes sole responsibility for any malfunction, which results from improper usage, faulty maintenance, improper or unauthorized repairs, damage or alteration performed.

The Sechrist gas mixer will perform in accordance with the specifications and descriptions contained within this manual and accompanying labeling when the gas mixer is operated and maintained in accordance with the instructions contained within this manual and other accompanying documentation. Do not attempt to operate this equipment before reading and thoroughly understanding these instructions. The gas mixer shall be checked periodically as specified within this manual (see Routine Maintenance Section). A defective product shall never be used in a clinical setting. Any necessary repair shall be provided at the Sechrist home offices in Anaheim, CA or by an individual trained and authorized by Sechrist Industries. However, Sechrist recognizes that some hospitals and other users maintain their own service groups (biomedical engineers and technicians) who perform certain repairs and/or periodic service. Given this, Sechrist does provide spare components and kits for such effort.

WARNING: Serious incidents, deaths, and malfunctions that have occurred in relation to the device must be reported by the user to Sechrist and the Competent Authority of the Member State in which the user and/or patient is established.

WARNINGS & CAUTIONS

WARNING: indicates the possibility of personal injury or death to the patient and/or operator of the device.

WARNING: The Sechrist Air/Oxygen Gas Mixer models identified in this manual are not standalone devices. These gas mixers are designed to mix medical grade air and medical grade oxygen for delivery to various respiratory care and heart-lung bypass equipment.

WARNING: It is the responsibility of the procuring organization to assure them they have the tooling, equipment, and training necessary to perform the tasks they are procuring components or kits for.

WARNING: No modification of this equipment is allowed. Do not modify this equipment without authorization from the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of the equipment.

WARNING: The gas mixer is designed to mix medical grade air and medical grade oxygen (O₂), only; do not modify the inlets to accommodate any other source gases.

WARNING: Hospitals or users who perform certain repairs and/or periodic service without undergoing training by Sechrist Industries assumes sole responsibility for any malfunction, which results from improper usage, faulty maintenance, improper or unauthorized repairs, damage or alteration performed.

WARNING: The user of the Sechrist Air/Oxygen Gas Mixer shall have sole responsibility for any malfunction, which results from improper usage, faulty maintenance, improper and/or unauthorized repairs, damage or alteration performed by anyone other than Sechrist Industries.

WARNING: Do not use Sechrist high flow gas mixers for neonate and pediatric patients.

WARNING: Alarm/bypass conditions must be corrected swiftly, as the selected oxygen concentration will not be delivered during a bypass situation. The pressure differential between the air and oxygen inlet gas sources must be kept within 20 psig (138 kPa).

WARNING: Liquid water or other contaminants in either inlet gas, particularly in the air inlet, will cause malfunction of this equipment and any attached equipment. Inlet gases shall meet gas dryness of .0045 mg water per cubic centimeter of gas.

WARNING: Oxygen concentration must be monitored downstream from the gas mixer with a suitable, calibrated oxygen analyzer, equipped with alarms that can be set for high and low FiO_2 ($\text{O}_2\%$). FiO_2 ($\text{O}_2\%$) shall then be adjusted to maintain appropriate blood gas concentrations.

WARNING: Oxygen vigorously accelerates combustion. To avoid explosion hazard, do not expose the gas mixer to any instruments or other equipment that may have been contaminated by oil or grease. Gas supplied to the gas mixer must be extremely clean (no more than 25 parts per million (ppm) of gaseous hydrocarbons is allowed.) A high concentration of hydrocarbons in the gas inlet is a fire hazard.

WARNING: The gas mixer audible alarm may not function when both air and oxygen inlet pressures are less than the minimum specified inlet pressure of 30 psig (207 kPa).

WARNING: The outlets have the capability of providing gas pressures equal to the inlet pressures. Therefore, any equipment attached must provide safety relief protection to prevent excessive pressures being delivered to patients.

WARNING: Whenever a patient is attached to respiratory care equipment, constant attendance is required by qualified personnel. The use of alarm or monitoring systems does not provide absolute assurance of a warning for every possible system malfunction. In addition, some problems may require immediate attention.

WARNING: Inlet pressures ≤ 30 psig (207 kPa) or ≥ 70 psig (483 kPa) may result in gas mixer damage or malfunction. Use of a suitable inlet gas regulation system is necessary.

WARNING: The Sechrist Air/Oxygen gas mixer is a sophisticated medical device designed for use by qualified personnel under the direction of a qualified physician.

WARNING: This product shall only be maintained and repaired by a Sechrist Industries factory-trained technician or by written instructions from Sechrist Industries. This product shall not be modified in any way, except with prior written approval of Sechrist Industries. Unapproved modifications can result in death or serious injury.

WARNING: The gas mixer does not contain gas sterilizing filters and will inlet the same quality of gas supplied from the gas sources. Use of appropriate gas purity and gas line filters is the responsibility of the user.

WARNING: When the gas mixer is used to supplement respiratory equipment, the user must refer to and follow the instructions provided by the manufacturer of the respiratory equipment.

WARNING: Do not obstruct the alarm. Do not tamper with the alarm.

WARNING: Do not use gas mixer when the alarm is sounding.

WARNING: The gas mixer is not suitable for use with oxygen concentrators.

WARNING: The gas mixer bleeds air/oxygen gas mixture. Do not expose gas mixer to ignition sources.

WARNING: When both supplies are within range of 30-70 psig (207-483 kPa), the gas mixer will maintain the delivered oxygen concentration within 1% of the selected concentration with small fluctuations of the inlet pressure. The additional 2% error results from the readability of the set point and scale error. Do not use on a patient or with respiratory and heart-lung bypass equipment outside of gas mixer pressure specification.

WARNING: Overhaul gas mixer every two (2) years from the Date of Manufacture.

WARNING: Visually inspect gas mixer upon receipt. Do not use gas mixer if there is any damage and contact provider.

WARNING: Do not use gas mixer if bubbles are detected during the reverse gas flow test.

WARNING: This precision gas-mixing device may become nonfunctional or damaged if used without the watertrap assembly and filters provided.

WARNING: Periodically replace the air water trap/inlet filter (Sechrist P/N 3529E in Figure 4) at least every 6 months or as needed.

WARNING: Replace the internal sintered stainless-steel filters (Sechrist P/N 3522K in Figure 3) at least every 6 months or as needed.

WARNING: The gas mixer is not MRI compatible.

WARNING: Do not autoclave and/or sterilize.

CAUTION: Do not immerse the gas mixer in any solution.

CAUTION: Before using this gas mixer, verify that the performance verification procedure has been performed by a qualified individual.

CAUTION: The outlet pressure of the gas mixer will always be slightly lower than the lower of the two inlet pressures. Some respiratory equipment attached to the gas mixer may require closer tolerance; if so, consult with the manufacturer of that equipment.

CAUTION: The bleed flow is located on the bottom of the proportioning module and is necessary to maintain the oxygen concentration accuracy at very low flow settings.

CAUTION: The alarm/bypass will activate when the first gas is connected. The alarm will reset upon the connection to the second gas inlet.

CAUTION: The Air/Oxygen Gas mixer gas pathway has been flushed with oxygen prior to delivery.

CAUTION: indicates the potential of damage to equipment and/or other property if the caution is ignored.







CAUTION: call attention to statements that are intended to supplement or emphasize basic instructions contained within this manual.

CAUTION: Sechrist air/oxygen gas mixers are not intended to be single-use devices. They are non-invasive, non-implantable devices.


EXPLANATION OF ABBREVIATIONS

DISS	Diameter Index Safety System
NIST	Non-Interchangeable Screw Thread
PSIG	Pound Per Square Inch Gauge
LPM	Liters Per Minute
Air/O ₂	Air/Oxygen
O ₂ %	Oxygen Percent
FiO ₂	Oxygen Concentration of delivered gas mixture

EXPLANATION OF SYMBOLS

SYMBOL	MEANING
	Caution
	Manufacturer
	Date of Manufacture
	Reference/Model Number
	Serial Number
	User/operator to refer to instruction manual

SYMBOL	MEANING
	Warning, prohibition, or mandatory action
	Authorized Representative in the European Community
	Medical Device
	EU Importer
	Do not use if package is damaged
	Country of origin

 DANGER
This product is not intended as a life-sustaining or life-supporting device.
Remove the gas mixer from the packaging and inspect for damage. If there is any damage, DO NOT USE and contact provider.
No electronics are incorporated in the gas mixer.

DEVICE DESCRIPTION

- The Sechrist Air/Oxygen Gas Mixer is a precision pressure regulation and proportioning device which is designed to accurately mix medical breathing air (medical grade) and medical breathing oxygen (medical grade) to any selected $\text{O}_2\%$ oxygen concentration from .21 to 1.0 FiO_2 (21% and 100%), for delivery to various respiratory care and heart-lung bypass equipment. The gas mixer receives medical grade air and medical grade oxygen (O_2) at a nominal 50 psig via D.I.S.S., or other inlet connections meeting appropriate international standards. The unit will operate as intended with inlet pressures of 30 to 70 psig providing that the pressures are within 20 psig of one another. It should be noted that the outlet pressure of the mixer will be slightly lower than the lower of the two inlet pressures. Various outlets for the mixed gas are provided depending upon the model requirements. The outlets may be used for the convenient connection of a flowmeter(s) or other respiratory equipment requiring a controlled oxygen concentration.
- The Sechrist Air/Oxygen Gas Mixer is a reusable device which is sold non-sterile and does not require sterilization/re-sterilization.
- The Sechrist Air/Oxygen Gas Mixers are designed with two configurations:
 - Low Flow:
 - At least 40 LPM @ FiO_2 of 0.60 with inlet pressures of 344 kPa (50 psig), Inlet range of 30-70 psig produces an output flow range of 29-60 LPM.
 - High Flow:
 - At least 100 LPM @ FiO_2 of 0.60 with inlet pressures of 344 kPa (50 psig), Inlet range of 30-70 psig produces an output flow range of 70-150 LPM.

KEY FEATURES

The Sechrist Air/Oxygen Mixer has the following main features.

- FiO_2 knob: The FiO_2 knob allows the qualified personnel to mix medical grade Air and medical grade Oxygen, at operator selected ratios (FiO_2), for delivery to patients through various types of respiratory care equipment and heart bypass oxygenation equipment. The qualified personnel can select from FiO_2 's of .21% to 1.0% for delivery.
 - FiO_2 knob (P/N 3538A) has no direct contact with humans or contact with substances.
- Flowmeter knob: The flowmeter knob allows the qualified personnel to adjust the flow rate from 100-1000ml/min.
 - Flowmeters (P/N 43664, 0-10 LPM) and (P/N 43785, 0-1000mL) have no direct contact with humans. Flowmeters come in contact only with medical grade Air and medical grade Oxygen to control flow.
- Alarm module: The pressure differential between the (air and oxygen) gas inlet supplies is within 20 psig (138 kPa). An alarm activates if the pressure differential between the (air and oxygen) gas inlet supplies is above 20 psig.
- Filters: Ensures particulates do not enter the gas pathways.
 - Filters (P/N 3529E) & (P/N 3522K) have no direct contact with humans. Filters come in contact with medical grade air or medical grade oxygen.
- Water trap: The water trap is intended to trap and drain water that collects during respiratory therapy.

INTENDED USERS

Medical professionals with the appropriate training and experience and who are qualified to mix medical grade air and medical grade oxygen at operator selected ratios, for delivery to patients through various types of respiratory care and heart-lung bypass equipment.

The Sechrist Air/Oxygen Gas Mixer is not designed for use by lay persons.

INTENDED PURPOSE

The Sechrist Air/Oxygen Gas Mixers are designed to mix medical grade air and medical grade oxygen, at operator selected ratios, for delivery to patients receiving respiratory care through various respiratory care and heart-lung bypass equipment.

The Sechrist Air/Oxygen gas mixer is a precision pressure regulation and proportioning device, which is designed to accurately mix medical grade air and medical grade oxygen. The gas mixer can provide FiO₂ concentrations of .21 to 1.0 for delivery to a variety of respiratory devices and heart-lung bypass equipment.

INDICATIONS FOR USE

The Sechrist Air/Oxygen gas mixers may be indicated whenever precise concentrations of oxygen are required for clinical applications. Use of the gas mixer in its appropriate configuration may be found throughout the healthcare environment. The Sechrist air/oxygen mixer is a precision pressure regulation and proportioning device, which is designed to accurately mix medical grade air and medical grade oxygen (O₂). The mixer can provide FiO₂'s of .21 to 1.0 for delivery to a variety of respiratory devices.

- Intended Patient Population: Do not use high flow gas mixers for neonate and pediatric patients.
- Medical Condition to be Treated: Patients who need supplemental oxygen therapy ranging from .21 to 1.0 FiO₂, (21% to 100% O₂) through various types of respiratory care and heart-lung bypass equipment.
- Principle of Operation/Mode of Action: The Sechrist Air/Oxygen Mixer is a precision pressure regulation and proportioning device which is designed to accurately mix medical grade air and medical grade oxygen to any selected O₂% oxygen concentrations between 21% and 100%, for delivery to a variety of respiratory care and heart-lung bypass equipment.
- Key Performance and Safety Claims: Sechrist Air/Oxygen Mixer is designed to mix medical grade air and medical grade oxygen.

INTENDED USE ENVIRONMENT

Device is designed for hospital and clinic use only for delivery of precise oxygen concentrations directly to the patient or delivery of precise FiO₂'s to other equipment, such as a ventilator and/or heart-lung bypass equipment.

CONTRAINDICATIONS

While supplemental oxygen therapy is not without possible side effects, such as absorption atelectasis and oxygen toxicity, the detrimental effects of oxygen shall never prevent its use when indicated ¹.

¹ Donald F. Eagan, MD, Eagan's Fundamentals of Respiratory Care, Fifth Edition 1999

SPECIFICATIONS

Multiple configurations are available, with and without attached flowmeter(s). All models utilize the same gas mixer and therefore the following specifications apply to all configurations.

Specifications	High Flow	Low Flow
Outlet Flow Range	at least 100 lpm @ at 60% oxygen with inlet pressures of 50 psig (345 kPa). Inlet range of 30 (+1. -0) psig – 70 (+0. -1) psig produces an output flow within a range of 70-150 lpm	at least 40 lpm @ at 60% oxygen with inlet pressures of 50 psig (345 kPa). Inlet range of 30 (+1. -0) psig – 70 (+0. -1) psig produces an output flow within a range of 29-60 lpm
Maximum Inlet Flow (psig)	Maximum inlet flow (psig) is equal to maximum outlet flow (psig) plus maximum bleed flow (psig)	
**Bleed Flow	8.0-10.0 lpm @ 16 lpm flow rate at 50 psig	2.5-4.5 lpm @ 8 lpm flow rate at 50 psig
Bypass Alarm Activation	50 psig (345 Kpa)	50 psig (345 Kpa)
	24-28 psig (165-193 Kpa)	24-28 psig (165-193 Kpa)
Alarm/Bypass De-activation: psig	Inlet gas pressure differential is ≥10 psig (69 kPa).	
Alarm Sound Level:	Minimum of 60 db at 1 ft (0.3 m)	
Oxygen Concentration Adjustment Range	FiO ₂ 0.21 to 1.0 (21% - 100% O ₂)	
Gas Inlet Pressure	50 psig (345 kPa) ± 20 psig (138 kPa) (at 4.0 standard cubic feet per minute (SCFM) min. flow)	
Accuracy of Oxygen Concentration of Delivered Gas (O ₂ %)	± 3% of full scale	
Connection Types:	Input Fittings: Oxygen female DISS, Air male DISS (NIST available)	
	Low flow — Oxygen male Barb Fitting	
	Output Fittings: High flow — Oxygen DISS Fitting	
Water Trap Filtration	A 0.01-micron water trap/ filter is provided for the air inlet connection	

Inlet filtration	Each Air/Oxygen inlet fitting has a 5-micron particulate filter.
Reverse Gas Flow	Reverse gas flow from either gas inlet is prevented by inlet check valves.
Service Life	Two (2) years
Lifetime of Device	The lifetime of Sechrist gas mixers is 20 years provided they are overhauled using Sechrist supplied components and Sechrist certified technicians once every 2 years.
Optional Accessories	The following operator detachable inlet pressure hoses comply with Compressed Gas Association (CGA) V-1, V-5, and G-4.1: <ul style="list-style-type: none"> Ref. IV 308 14-foot (4.27 m) Air Inlet Hose (Not available in Europe) Ref. IV 309 14-foot (4.27 m) Oxygen Inlet Hose (Not available in Europe) Mounting pole
Optional flowmeters	1 – 10 lpm ± 3% of full scale 1 – 15 lpm ± 3% of full scale 100 - 1000 ml/min..... ± 3% of full scale
Inlet gases shall meet gas dryness of .0045 mg water per cubic centimeter of gas.	
Air:	Medical Air inlet should be USP grade or equivalent.
Oxygen:	The oxygen should be USP medical grade oxygen or equivalent.
Dimensions (without flowmeters)	
Depth:	≅ 3.94 inches (without watertrap attached)
Width:	≅ 2.40 inches
Height:	≅ 5.16 inches
Weight	≅ 4.7 lbs.
Shipping Weight:	≅ 12 lbs.
Operating Temperature Range:	80°F ±15°F

SETTING UP THE GAS MIXER

The gas mixer can be either pole or wall mounted. The inlet fittings of the gas mixer conform to Diameter Index Safety System (D.I.S.S.) * and 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. It is recommended that an air inlet water trap be used between the air hose and inlet fitting to prevent moisture from entering the gas mixer.

*The gas mixer is available with inlet NIST fittings and outlet Barb fittings upon request.

OPERATING INSTRUCTIONS

- ◆ Before using the gas mixer, verify that performance verification has been completed.
- ◆ If applicable, connect the gas mixer outlet to the inlet device that will deliver the oxygen concentration to the patient.
- ◆ From reliable pressure regulated gas sources, connect both medical grade air and medical grade oxygen to the gas mixer inlets utilizing appropriate gas hoses (P/N IV 308 air inlet hose and P/N IV 309 oxygen inlet hose). **NOTE:** P/N IV 308 and IV 309 are not CE marked.
- ◆ Using the gas mixer FiO₂ control knob, select the desired oxygen concentration FIO₂ from .21 to 1.0.
- ◆ If the configuration includes a flowmeter/s, initiate gas flow through the flowmeter(s) by turning the knob(s) on the flowmeter(s) counterclockwise to the desired flow setting.
- ◆ Begin the operation of the attached delivery unit, if applicable.
- ◆ After the selected gas mixture has washed out the room air from the delivery unit, analyze and monitor the delivered gas concentration with a calibrated oxygen analyzer. Appropriately set the high and low alarm limits on the analyzer.
- ◆ Periodically observe the water trap assembly for the accumulation of moisture. Moisture shall be removed from the water trap assembly by depressing the valve at the bottom of the water trap bowl.
- ◆ Periodically observe the oxygen analyzer and evaluate the delivered FIO₂.

USING THE GAS MIXER WITH OTHER EQUIPMENT

- ❖ Connect the gas outlet of the gas mixer either directly or via a high-pressure hose to the equipment with which it is being used.
- ❖ Set the control on the front panel to the desired oxygen concentration.
- ❖ Turn on the 50 psig (345 kPa) air and oxygen sources.
- ❖ Use a calibrated oxygen analyzer to check the accuracy of the delivered gas.

PERFORMANCE VERIFICATION

Prior to Each Use

Prior to each clinical usage, the user shall perform the following tests:

- Bypass/alarm system test
 - The user shall briefly disconnect one inlet gas to assure that the bypass/alarm system is functioning. With a single inlet gas disconnected, the audible alarm shall sound and the analyzed O₂% shall indicate the O₂% of the single inlet gas, i.e., 21% if the oxygen was disconnected and 100% if the air inlet was disconnected.
- Accuracy of Oxygen Concentration of Delivered Gas
 - With an accurately calibrated oxygen analyzer, the user shall analyze the O₂% at the following settings: 21%, 30%, 40%, 50%, 60%, 70%, 80%, 90% and 100%.
- Reverse Gas Flow Procedure
 - Reverse gas flow is inspected by supplying pressure to one of the gas supply inlets while a test hose is connected to the other inlet with the free end submerged in clean water. If bubbles are detected, do not use the gas mixer.

Monthly

The following more extensive procedure shall be performed at least once a month, or more frequently as indicated or desired.

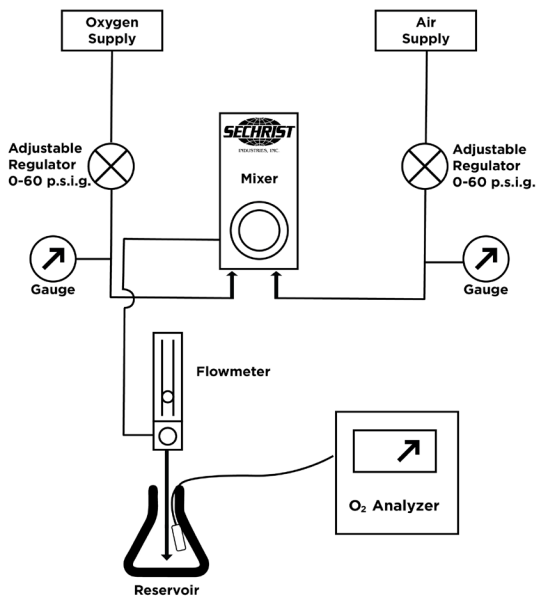
This procedure provides a means of determining if the gas mixer is functioning in accordance with the design specifications. This verification is intended to be performed in the health care setting by qualified personnel.

The procedure shall be followed exactly as outlined. If the gas mixer fails to meet the established standards, it shall be removed from clinical application until calibration and/or service is accomplished (see troubleshooting section or service manual)

CAUTION: Personnel responsible for daily and monthly performance verification testing shall keep accurate records of testing activities.

The performance verification process requires a simple configuration as diagramed below.

Figure 2



- ❖ Connect the gas mixer to the inlet gases with independently adjustable pressure regulators (0 – 60 psig).
- ❖ Connect a flowmeter to the gas mixer outlet (for models 3600 and 3601 only).
- ❖ Direct the flow from the flowmeter to a reservoir (e.g., a bottle or tube) making sure that no room air is being entrained to dilute the mixture.
- ❖ Place a calibrated O₂ analyzer probe within the reservoir.

Test for overall accuracy

- ❖ Set both inlet pressures to 50 psig (344 kPa).
- ❖ Set the flowmeter to 8 lpm for configurations with the following flowmeters: 0 – 10 lpm and 100-1000 ml/min, 1 – 15 lpm, 0 – 16 lpm.
- ❖ Set the flowmeter to 15 lpm for configurations with the following flowmeters: 2 – 20 lpm, 2 – 32 lpm, and 3 – 30 lpm.
- ❖ Compare the O₂ analyzer readings at the following settings: 21%, 30%, 40%, 50%, 60%, 70%, 80%, 90% and 100%. Since the gas mixer has an overall accuracy of $\pm 3\%$ full scale and if the analyzer accuracy is within $\pm 1\%$, the FiO₂ comparisons shall agree within $\pm 4\%$ points.

Test for accuracy with varying inlet pressures.

- ❖ Set the O₂% to 60% with the inlet pressures at 50 psig (345 kPa).
- ❖ Verify the setting accuracy comparing the setting with the analyzed value.
- ❖ Set the O₂ pressure to 40 psig (276 kPa) leaving the air inlet at 60 psig (414 kPa).
- ❖ Note the analyzer reading.
- ❖ Set the O₂ pressure to 60 psig (414 kPa) and the air inlet to 40 psig (276 kPa)
- ❖ Note the analyzer reading.
- ❖ Analyzed O₂ concentrations shall vary by no more than 2% with the above pressure changes.

Test the alarm module function.

- ❖ Set inlet pressures to 50 psig (344 kPa).
- ❖ Set the O₂% to 60%.
- ❖ Reduce the air inlet pressure to 24 psig. (166 kPa).
- ❖ The audible alarm shall sound within the following pressure range of 24-28 psig, and the O₂ analyzer shall read greater than 97%.
- ❖ Slowly increase the air inlet pressure to 50 psig (345 kPa). The alarm shall cease and reset prior to obtaining a inlet pressure of 40 psig. (276 kPa).
- ❖ Reduce the O₂ inlet pressure to 24 psig (165 kPa).
- ❖ The audible alarm shall sound within the following pressure range of 24-28 psig, and the O₂ analyzer shall read less than 25%.
- ❖ Slowly increase the O₂ inlet pressure to 50 psig (345 kPa). The alarm shall cease and reset prior to obtaining a inlet pressure of 40 psig (276 kPa)

Check the inlet filters.

- ❖ To test the flow through the water trap filter and air inlet filter assemblies, a small test port has been provided on the rear of the gas mixer just above the air inlet.
- ❖ Turn both inlet gases off and allow the gases to cease flowing. With a ¼ inch hex nut driver, remove the plug from the test port and install a 10-32 threaded nipple.
- ❖ Connect an accurate pressure gauge (0-60 psig) (0-414 kPa) to the nipple.
- ❖ Turn the inlet gases.
- ❖ Set the gas mixer FiO₂ control to .21.
- ❖ Observe the pressure registered by the gauge connected to the test port.
 - ❖ The difference between the test gauge pressure and the inlet pressure shall vary by no more than 5 psig (34 kPa).
 - ❖ If the pressure differential is > 5 psig (34 kPa), replace the inlet filters as outlined in the routine maintenance section.

ROUTINE MAINTENANCE

NOTE: The manufacturer will make available on request circuit diagrams, component part lists, descriptions, calibration instructions, or other information that will assist trained service personnel to repair those parts of medical equipment that are designated by the manufacturer as repairable by service personnel.

Routine maintenance of the gas mixer is limited to periodic performance verification, replacement of the inlet filters and cleaning of the exterior surfaces. A gas mixer in need of calibration or service shall not be used until the necessary procedures are performed and the equipment has been tested to determine that it is functioning properly. Calibration and servicing may only be accomplished by personnel trained and authorized to do so by Sechrist Industries. Routine maintenance, as defined in this manual, may be performed by a competent individual having experience in the maintenance of devices of this nature. Parts designated within this manual shall be replaced only with parts manufactured or sold by Sechrist Industries.

- ❖ Inlet filters
 - Periodically replace the air water trap/inlet filter (Sechrist P/N 3529E in Figure 4) at least every 6 months or as needed.
 - Replace the internal sintered stainless-steel filters (Sechrist P/N 3522K in Figure 3) at least every 6 months or as needed.
- ❖ Cleaning
 - Exterior surfaces of the gas mixer may be wiped clean with a mild soap solution or a liquid disinfectant solution. Do not use cleaning agents that contain abrasives.

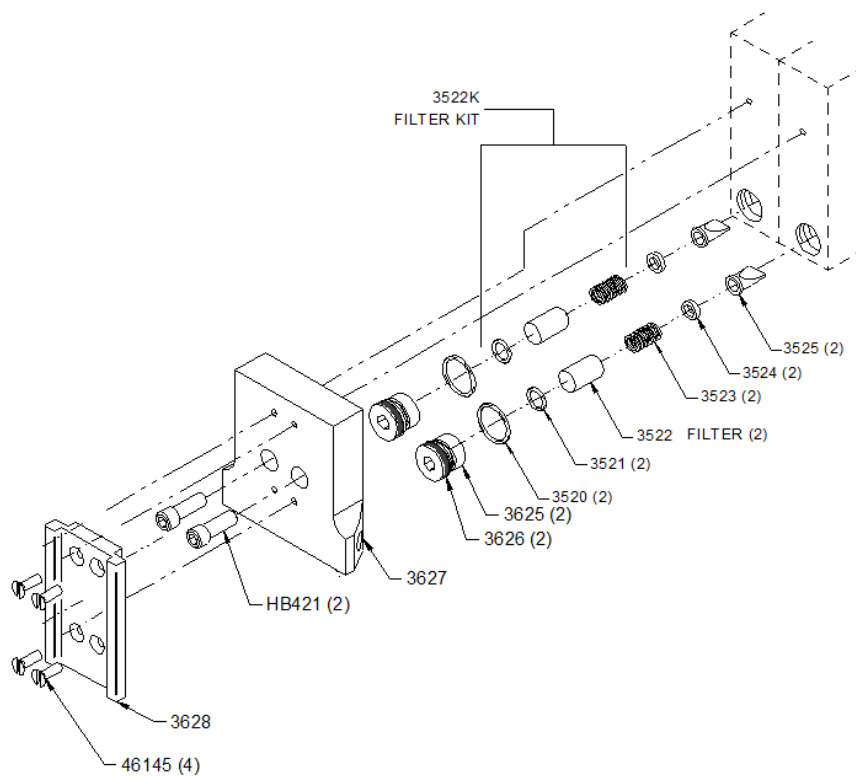


Figure 3

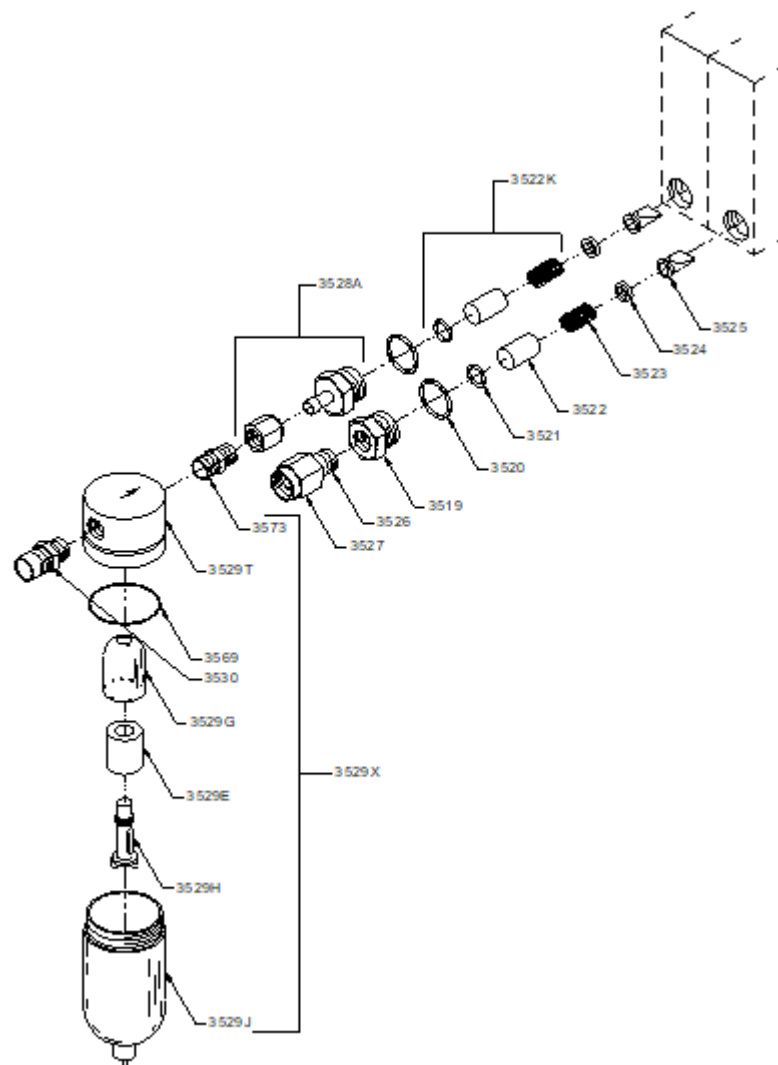


Figure 4

FACTORY OVERHAUL

To ensure proper function and accuracy, the Sechrist Air/Oxygen Gas Mixers must be thoroughly overhauled every two (2) years. To maintain the product warranty, the overhaul must be performed by Sechrist Industries or by Sechrist authorized personnel.

LIFETIME OF DEVICE

The lifetime of Sechrist Air/Oxygen Gas Mixers is twenty (20) years provided they are overhauled using Sechrist supplied components and Sechrist certified technicians once every two (2) years.

TROUBLESHOOTING

Problem	Possible Cause	Correction
Inaccurate O ₂ %	O ₂ analyzer out of calibration (most common problem).	Recalibrate O ₂ analyzer.
	Improper purity of inlet gases.	Check/verify inlet gas purity.
	Incorrect gas supplied to inlet.	Assure that outlets and hoses are connected correctly.
	Front and rear seats are worn.	Recalibrate gas mixer (shall be performed only by Sechrist Industries or by Sechrist authorized personnel).
	Incorrect calibration of proportioning module.	
	Malfunctioning balancing module.	Recalibrate the balancing module (shall be performed only by Sechrist Industries or by Sechrist authorized personnel).
O ₂ % control knob is difficult to turn.	Faceplate has shifted.	Reposition faceplate.
	Bent adjustment shaft.	Replace shaft and recalibrate (shall be performed only by Sechrist Industries or by Sechrist authorized personnel).
O ₂ % change > 1% when testing.	Air or O ₂ inlet filter may be dirty causing a > 20 psig (138 kPa) difference.	Replace inlet filter.
	Regulator needle out of calibration.	Recalibrate gas mixer (shall be performed only by Sechrist Industries or by Sechrist authorized personnel).
Continuous alarm with both inlet pressures equal.	Dirty inlet filter(s).	Replace filter(s).
	Bypass check ball leaking.	Clean check ball and seat (shall be performed only by Sechrist Industries or by Sechrist authorized personnel).
	Alarm module out of calibration.	Recalibrate (shall be performed only by Sechrist Industries or by Sechrist authorized personnel).
Alarm not sounding with the loss of pressure from one source gas.	Defective alarm reed.	Replace alarm reed (shall be performed only by Sechrist Industries or by Sechrist authorized personnel).
	Alarm module out of calibration.	Recalibrate gas mixer (shall be performed only by Sechrist Industries or by Sechrist authorized personnel).
	Alarm poppets stuck.	Clean, lubricate poppets and recalibrate as outlined in the service manual (shall be performed only by Sechrist Industries or by Sechrist authorized personnel).

CAUTION: If the problem or concern continues after taking the appropriate correction, consult an authorized Sechrist service representative or contact Sechrist Industries Technical Support.