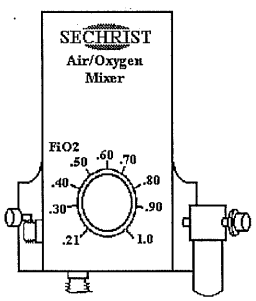
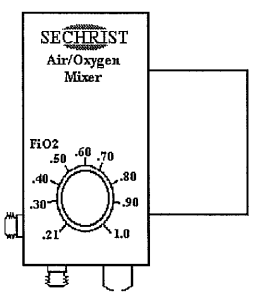
SECHRIST INDUSTRIES, INC.

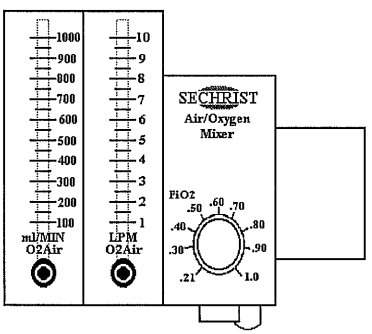
3500 / 3500HL Series

Air / Oxygen Mixer

USER'S MANUAL







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

SECHRIST

INDUSTRIES, INC.

EC DECLARATION OF CONFORMITY

Sechrist Industries, Inc.
4225 E. La Palma Avenue
Anaheim, CA 92807 USA

Declaration that the medical devices described hereafter:

Model 3500/3500HL Series Air-Oxygen Mixers and Accessories, including the following catalog numbers:

20099	20155	3500B	3500CP-M1
20112	20457	3500CP-G	3600
20121	20459	3500CP-M	3601

are in conformity with the essential requirements and provisions of Council Directive 93/42/EEC, Annex II. Conformity has been achieved under the supervision of Notified Body Number 0120, SGS United Kingdom, Ltd, Unit 202B Worle Parkway, Weston super Mare, North Somerset BS22 OWA, United Kingdom.

9/13/05
Date

Greg Godfrey
Vice President, Quality Assurance &
Regulatory Affairs

CE 0120
93/42/EEC
P/N 49277 REV. 1

Doc. # 180043 Rev. 1

WARRANTY

SECHRIST INDUSTRIES, INC. warrants this product to meet the published specifications and to be free from defects in material and workmanship under normal use for a period of one (1) year from the date of original installation. THE FOREGOING IS IN LIEU OF ANY OTHER WARRANTY, EXPRESS, IMPLIED OR STATUTORY, INCLUDING WITHOUT LIMITATION ANY WARRANTY OF MERCHANTABILITY. The sole liability of SECHRIST under this warranty is limited to replacing, repairing, or issuing credit at the discretion of SECHRIST for the products, equipment or parts which fail to meet the published specifications or which become defective during the warranty period and which are upon examination by SECHRIST found not to meet the published specifications or to be defective in material or workmanship. SECHRIST will not be liable under this warranty unless the following provisions are strictly complied with: (a) SECHRIST is promptly notified, in writing, upon discovery of the failure of said product or equipment to meet the published specifications or of defects in material or workmanship, (b) the defective product, equipment or part thereof is returned to SECHRIST, transportation charges prepaid by the buyer, (c) the defective part is received by SECHRIST for examination no later than one (1) month following the expiration of the warranty period and provided (d) that examination by SECHRIST of said product, equipment or part shall disclose to SECHRIST'S satisfaction that such defect has not been caused by improper usage, accident, neglect, alteration, abuse, improper installation or unauthorized repair. Products, equipment or parts replaced under this warranty are warranted only through the terms of the original warranty. SECHRIST neither assumes nor authorizes any other person or entity to assume for it any other warranty, obligation or liability in connection with its products or equipment whatsoever, and this warranty can only be changed in writing by a duly authorized representative of SECHRIST. SECHRIST makes no representations or warranties whatsoever as to the fitness or usefulness of the products or equipment manufactured by it for any medical treatment, physical condition or other purpose whatsoever. In no event shall SECHRIST be liable for personal injury, property damage or any special or consequential damage to any buyer, user or any other person whomsoever, including, but not limited to, loss of profits, loss of use of the product or equipment, or for damages of any other kind whatsoever based on a claim for breach of warranty other than a refund of the purchase price of any defective product or equipment. Any authorization for repair or alteration by buyer must be in writing from SECHRIST to prevent the voiding of this warranty. In the event SECHRIST or its representatives render any technical advice or service of any kind to buyer or anyone else in connection with the equipment or products covered by this warranty, the buyer hereby releases SECHRIST from all liability of any kind whatsoever as a result thereof; and the warranty as hereinbefore set forth shall not be enlarged or affected by said action by SECHRIST.

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MDD 93/42/EEC
EU Authorized Representative
AR-MED, Ltd (Company 3154742)
Runnymede Malthouse
Egham, Surrey TW20 9BD
United Kingdom

P/N 100001 Rev. 7

INTRODUCTION

We at Sechrist Industries, Inc. thank you for choosing a Sechrist air/oxygen mixer. We also caution you that before attempting to use the 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.

USER / OWNER RESPONSIBILITY

The Sechrist mixer will perform in accordance with the specifications and descriptions contained within this manual and accompanying labeling when the 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 mixer should be checked periodically as specified within this manual (see Routine Maintenance section). A defective product should never be used in a clinical setting. Any necessary repair must be provided at the Sechrist home offices in Anaheim, CA or by an individual trained and authorized by Sechrist Industries.

WARNINGS & CAUTIONS

WARNINGS indicate the possibility of personal injury or death to the patient and/or operator of the device.

CAUTIONS indicate the potential of damage to equipment and/or other property if the caution is ignored.

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

WARNING

Alarm/bypass conditions must be corrected swiftly, as the selected oxygen concentration, will not be delivered during a bypass situation.

WARNING

Liquid water or other contaminants in either supply gas, particularly in the air supply, will cause malfunction of this equipment and any attached equipment. Supply gases should meet gas dryness of .0045 mg water per cubic centimeter of gas.

WARNING

Oxygen concentration must be monitored downstream from the mixer with a suitable, calibrated oxygen analyzer, equipped with alarms that can be set for high and low FIO_2's. FIO_2's should then be adjusted to maintain appropriate blood gas concentrations.

WARNING

The mixer is designed to mix air and O_2 only; do not modify the inlets to accommodate any other source gases.

WARNING

Oxygen vigorously accelerates combustion. To avoid explosion hazard, do not expose the mixer to any instruments or other equipment that may have been contaminated by oil or grease. Gas supplied to the 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 supply is a fire hazard.

WARNING

The mixer audible alarm may not function when both air and O_2 supply pressures are less than the minimum specified inlet pressure.

WARNING

The outlets have the capability of providing gas pressures equal to the inlet pressures. Therefore, any attached equipment must provide safety relief protection in order to prevent excessive pressures from 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

Excessive supply pressures (> 70 psi, 482 kPa) may result in mixer damage or malfunction. Use of a suitable supply gas regulation system is necessary.

WARNING

A 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 should only be maintained and repaired by a Sechrist Industries factory-trained technician or by written instructions from Sechrist Industries. This product should 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 mixer does not contain gas-sterilizing filters and will supply 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 Sechrist mixer is used to supplement respiratory equipment, the user must refer to and follow the instructions provided by the manufacturer of the respiratory equipment.

CAUTION

Do not immerse the mixer in any solution. Do not sterilize.

CAUTION

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

CAUTION

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

INDICATIONS FOR USE

Intended Use

The purpose of the device is to enable qualified personnel to mix medical-grade air and medical-grade oxygen, at operator selected ratios, for delivery to patients through various types of respiratory care equipment.

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 (O_2). The mixer can provide for FIO_2's of .21 to 1.0 for delivery to a variety of respiratory devices. The mixer receives air and oxygen via diameter index safety system (D.I.S.S.) inlet connections at a nominal pressure of 50 psi. (344 kPa). The unit will operate satisfactorily with inlet pressures of 30 – 70 psi (207 - 482 kPa) providing that the pressures are within 20 psi (138 kPa) of one another. The Sechrist air/oxygen mixers may be indicated whenever precise concentrations of oxygen are required for clinical applications. Use of the mixer in its appropriate configuration, may be found throughout the healthcare environment. Uses include but may not be limited to bedside delivery of precise oxygen concentrations directly to the patient or delivery of precise FIO_2's to other equipment, such as a ventilator, isollettes, or resuscitation equipment.

CONTRAINDICATIONS

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

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

OPERATING INSTRUCTIONS

- Before using the mixer, verify that performance verification has been completed.
- If applicable, connect the mixer outlet to the inlet device that will be delivering the oxygen concentration to the patient.
- From reliable, pressure regulated gas sources, connect both medical grade air and medical grade oxygen to the mixer inlets utilizing appropriate gas hoses (P/N IV 308 air supply hose and P/N IV 309 oxygen supply hose). **NOTE:** The alarm/bypass will activate when the first gas is connected. The alarm will reset upon the connection to the second gas supply.
- Using the calibrated control knob, select the desired oxygen concentration (FIO_2) from .21 to 1.0.
- If the configuration includes a flowmeter/s, initiate gas flow through the flowmeter(s) by tuning the knob(s) on the flowmeter(s) counter clockwise 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 watertrap assembly for the accumulation of moisture. Moisture should be removed from the water trap assembly by depressing the valve at the bottom of the watertrap bowl.
- Periodically observe the oxygen analyzer and evaluate the delivered FIO_2.

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.

FIO_2	.21 +.01 to 1.0 –0.1
Accuracy *	± 3%
(high flow configurations)	at least 100 lpm @ an FIO_2 of .60 with inlet pressures of 50 psi (344 kPa). Supply range of 30-70 psi produces an output flow within a range of 70-150 lpm
(low flow configurations)	at least 40 lpm @ an FIO_2 of .60 with inlet pressures of 50 psi (344 kPa). Supply range of 30-70 psi produces an output flow within a range of 29-60 lpm
Supply Pressures **	
Nominal	50 psi (344 kPa)± 10 psi (68 kPa) (@ 4.0 standard cubic feet per minute (SCFM) min. flow)
Minimum	30 psi (207 kPa)
Maximum	70 psi (482 kPa)
Bleed Flow***	
(high flow configurations)	8.0 to 10.0 lpm @ 16 lpm flow setting
(low flow configurations)	2.5 to 4.5 lpm @ 8 lpm flow setting
Dimensions (without flow meters)	
Height	6 inches (15.24 cm)
Width	6 inches (15.24 cm) (pole mount) 6 ½ inches (16.51 cm) (wall mount)
Depth	6 inches (15.24 cm) (pole mount) 5 ½ inches (13.97 cm) (wall mount)
Weight	6 lbs. (2.73 kg)

Optional flowmeters

1 – 10 lpm	± 3% of full scale
1 – 15 lpm	± 3% of full scale
0 – 16 lpm	± 3% of full scale
2 - 20 lpm	± 3% of full scale
2 – 32 lpm	± 3% of full scale
3 – 30 lpm	± 3% of full scale
100 - 1000 ml/min	± 3% of full scale

*NOTE: The mixer will maintain the delivered FIO_2 within ± 1% of the selected concentration with small fluctuations of the supply pressure. The additional 2% error results from the readability of the set point and scale error.

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

***NOTE: The bleed flow is located on the bottom of the proportioning module and is necessary in order to maintain FIO_2 accuracy at very low flow settings.

Optional Accessories

The following operator detachable inlet pressure hoses comply with Compressed Gas Association (CGA) V-1, V-5, and G-4.1:

Ref. IV 308 14 foot (.6614 m) Air Supply Hose
Ref. IV 309 14 foot (.6614 m) Oxygen Supply Hose

PERFORMANCE VERIFICATION

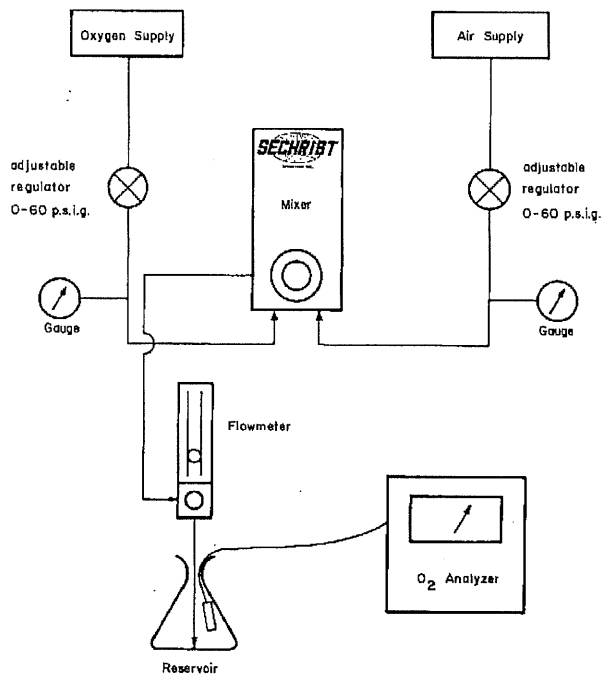
Prior to each clinical usage, the user should perform an alarm test and analyze the full FIO_2 range. With an accurately calibrated oxygen analyzer, the user should analyze the FIO_2 at the following settings; 21%, 40%, 60%, 80%, and 100%. Additionally, the user should briefly disconnect one supply gas to assure that the bypass/alarm system is functioning. With a single supply gas disconnected, the audible alarm should sound and the analyzed FIO_2 should indicate the FIO_2 of the single supply gas; i.e. 21% if the oxygen was disconnected and 100% if the air supply was disconnected.

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

This procedure provides a means of determining if the 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 should be followed exactly as outlined. If the mixer fails to meet the established standards, it should be removed from clinical application until calibration and/or service is accomplished (see troubleshooting section or service manual)

NOTE: It is strongly recommended that personnel responsible for performance verification testing keep accurate records of testing activities.

The performance verification process requires a simple configuration as diagramed below. (Figure 1)



- Connect the mixer to the supply gases with independently adjustable pressure regulators.
- Connect a flowmeter to the mixer outlet.
- 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 O_2 analyzer probe within the reservoir.

Test for overall accuracy

- Set both supply pressures to 50 psi(344 kPa)

- Set the flowmeter to 8 lpm for configurations with the following flowmeters; 0 – 10 lpm, 1 –15 lpm, 0 – 16 lpm, and 100 – 1000 ml.
- Set the flowmeter to 15 lpm for configurations with the following flowmeters; 2 – 20 lpm, 2 – 32 lpm, and 3 – 30 lpm.
- Compare the O_2 analyzer readings at the following settings. Since the mixer has an overall accuracy of ± 3% and if the analyzer accuracy is within ± 1%, the following comparisons should agree within ± 4% points.
    - .21
    - .40
    - .60
    - .80
    - 1.0

Test for accuracy with varying inlet pressures.

- Set the FIO_2 to .60 with the inlet pressures at 50 psi (344 kPa).
- Verify the setting accuracy comparing the setting with the analyzed value.
- Set the O_2 pressure to 40 psi (276 kPa) leaving the air supply at 60 psi (414 kPa).
- Note the analyzer reading.
- Set the O_2 pressure to 60 psi (414 kPa) and the air supply to 40 psi (276 kPa)
- Note the analyzer reading.
- Analyzed O_2 concentrations should vary by no more that 2% with the above pressure changes.

Test the alarm module function.

- Set supply pressures to 50 psi (34 kPa).
- Set the FIO_2 to .60.
- Reduce the air supply pressure to 24 psi. (166 kPa).
- The audible alarm should sound within the following pressure range of 24-28 psig, and the O_2 analyzer should read 100%.

- Slowly increase the air supply pressure to 50 psi (344 kPa). The alarm should cease and reset prior to obtaining a supply pressure of 40 p.s.i. (276 kPa).
- Reduce the O_2 supply pressure to 24 psi (166 kPa).
- The audible alarm should sound within the following pressure range of 24-28 psig, and the O_2 analyzer should read 21%.
- Slowly increase the O_2 supply pressure to 50 psi (344 kPa). The alarm should cease and reset prior to obtaining a supply pressure of 40 psi (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 mixer just above the air inlet.
- Turn both supply 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 psi) (0-414 kPa) to the nipple.
- Turn the supply gases on and set the flow to 16 lpm.
- Set the mixer FIO_2 control to .21.
- Observe the pressure registered by the gauge connected to the test port.
- The difference between the test gauge pressure and the supply pressure should vary by no more than 5 psi (34 kPa).
    - If the pressure differential is > 5 psi (34 kPa) replace the inlet filters as outlined in the routine maintenance section.

THEORY OF OPERATION

The Sechrist air-oxygen mixer is a precision pressure regulation and proportioning device which is designed to accurately mix medical-grade Air (air) and medical-grade Oxygen (O_2) to any selected FIO_2 between 21% and 100% for delivery to various types of respiratory care equipment. To accomplish this task, the Sechrist mixer is composed of three major components or modules. The balancing module, the proportioning module, and the alarm/bypass module.

Gas is delivered to the balancing module where inlet pressures are equalized. Supply pressures that do not meet the minimum specified pressure, may result in the device not functioning to the specification. Supply pressures that exceed the maximum specified pressure, may result in device damage or malfunction. Duckbill valves,

positioned between the diaphragm and inlet filters, prevent reverse gas flow. Gas then travels to the proportioning module where the gases are mixed to the user- defined concentration. A continual flow of gas supports the alarm/bypass module, which provides an audible alarm in the event of either a significant loss of supply gas pressure or a loss of a single supply gas.

Filters are incorporated in both of the gas inlet connections. One-way check valves are also located in both of the gas inlet connections to prevent the cross-contamination of one gas supply to the other source.

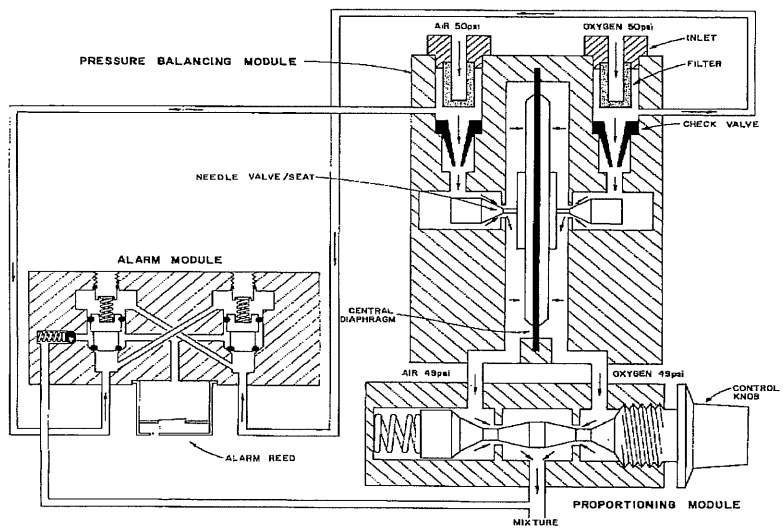


Figure 2

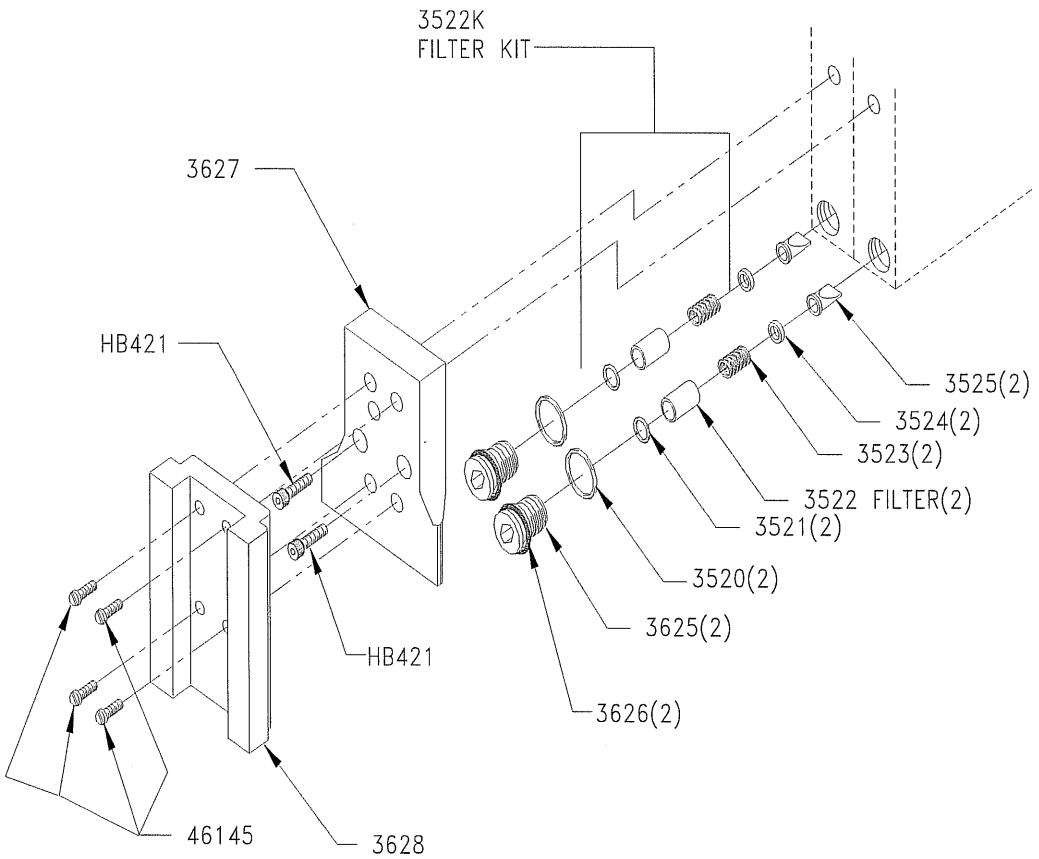
ROUTINE MAINTENANCE

Routine maintenance of the mixer is limited to periodic performance verification, replacement of the inlet filters and cleaning of the exterior surfaces. A mixer in need of calibration or service should 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 should be replaced only with parts manufactured or sold by Sechrist Industries.

Routine maintenance procedure

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

CAUTION
Do not immerse the mixer in any solution. Do not attempt to sterilize.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HB421
HB421
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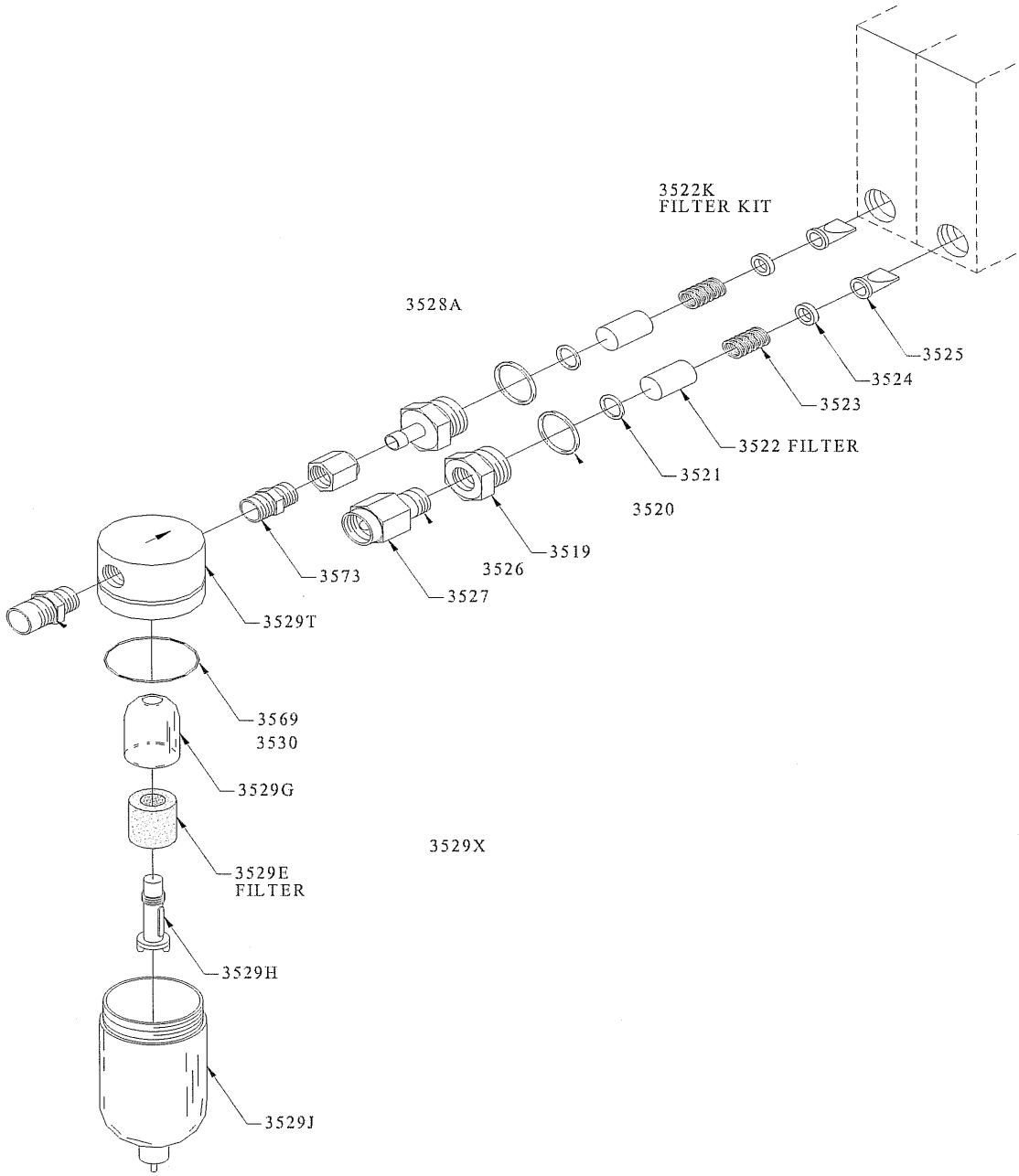
3525(2)

Figure 3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3573
3529T
3569
3530
3529G
3529X
3529E
FILTER
3529H
3529J

Figure 4

Factory overhaul

In order to assure proper function and accuracy, the Sechrist air/oxygen mixers must be thoroughly overhauled every two- (2) years. To maintain the product warranty, this overhaul must be performed by Sechrist Industries or by Sechrist authorized personnel.

TROUBLESHOOTING

Problem	Possible Cause	Corrective Action
Inaccurate FIO_2	O_2 analyzer out of calibration (most common problem).	Recalibrate O_2 analyzer.
	Improper purity of supply gases.	Check/verify supply gas purity.
	Incorrect gas supplied to inlet.	Assure that outlets and hoses are connected correctly.
	Front and rear seats are worn.	**Clean or replace seats.
	Incorrect calibration of proportioning module.	**Recalibrate mixer as outlined in the service manual.
	Malfunctioning balancing module.	**Recalibrate the balancing module as outlined in the service manual.
FIO_2 control knob is difficult to turn.	Faceplate has shifted.	Reposition faceplate.
	Bent adjustment shaft.	** Replace shaft and recalibrate as outlined in the service manual.
FIO_2 change > 1% when testing.	Air or O_2 inlet filter may be dirty causing a > 20 psi (138 kPa) difference.	Replace inlet filter.

Problem	Possible Cause	Corrective Action
	Regulator needle out of calibration.	**Recalibrate mixer as outlined in the service manual.
Continuous alarm with both inlet pressures equal.	Dirty inlet filter(s). Bypass check ball leaking. Alarm module out of calibration.	Replace filter(s). **Clean check ball and seat. **Recalibrate as outlined in the service manual.
Alarm not sounding with the loss of pressure from one source gas.	Defective alarm reed. Alarm module out of calibration. Alarm poppets stuck.	**Replace alarm reed. **Recalibrate as outlined in the service manual. **Clean, lubricate poppets and recalibrate as outlined in the service manual.

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

**** To be performed only by authorized personnel.**