

# MEDICAL DEVICE INFORMATION

Oxygen PSA generator for medical use

Document responsible: DH

Document no: TF-MDD 02

Last update: 6 May 2022

Reviewer/approver: AHL/SAT

Revision: 02

First revision: 7 April 2022



## WARNINGS AND IMPORTANT INFORMATION READ BEFORE USE!

The following information covers only:

Oxygen PSA generators CE marked as MD (Medical Device) and produced by OXYMAT – Slovakia, s.r.o. before May 4, 2022 (see product nameplate): O10; O20; O40; O60; O70; O100; O190; O280; O430; O640; O880; O1250; O1500, O880 X2; O1250 X2; O1500 X2

and

Oxygen PSA generators CE marked as Medical Oxygen Generator and produced by OXYMAT A/S (see product nameplate): O20-1, O20-2, O20-3, O20-4, O20-5, O20-6; O200-1, O200-2, O200-3, O200-4, O200-5, O200-6 O200-3 X2, O200-4 X2, O200-4 X3, O200-4 X4, O200-4 X5, O200-4 X6 O20-1 (pallet), O40-1 (pallet), O60-1 (pallet), O20-2 (pallet), O40-2 (pallet), O60-2 (pallet), O20-3 (pallet), O40-3 (pallet), O60-3 (pallet) O20 (Half Pallet), O40 (Half pallet), O60 (Half pallet)



**Warning:** OXYMAT PSA oxygen generator system is sold for use in industrial applications and for medical use. When PSA (pressure swing adsorption) generator is used for medical purpose, it must be stated in declaration of conformity and refer to 93/42/EC MDD (medical device directive). If you have ordered medical oxygen generator system, you must follow procedures for service and maintenance of medical optional devices\*\*. In case PSA oxygen generator is used for clinical purposes, it should be signed “exclusively for clinical investigations”.



**Important:** Upon receiving your OXYMAT PSA oxygen generator system, inspect the unit thoroughly for signs of damage. Any signs of damage, either external or internal, should be noted on the delivery receipt, and also reported immediately to both the freight company and OXYMAT. Contact OXYMAT at Tel +45 4879 7811 or Tel +421 32 779 0123



**Important:** The owner of the OXYMAT PSA oxygen generator system is responsible of keeping all the equipment in safe working order. Parts and units must be replaced if they are no longer in safe working condition. Installation of equipment and assembling to other equipment must be done in compliance with current local regulations and directions.



**Important:** The operator of the OXYMAT PSA oxygen generator system must always use safe working methods in compliance with current local safety regulations and directions. In case of difference between directions in the manual and local regulations the strictest must be followed.



**Warning:** Use only hoses and pipes of correct size and suitable for operating pressure and fluid. Never use hoses which are frayed, damaged or worn. Always use the correct type and size of connections. Make sure hoses are depressurized before disconnecting.



**Warning:** All tubes, hoses and piping used for oxygen must be compatible with oxygen and cleaned for oxygen service.

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**Warning:** Lifting lugs on columns, if present, are only for handling of the columns if they are detached from the PSA generator unit. The PSA oxygen generator unit is not to be lifted by the lifting lugs on columns or by the pipes. The PSA oxygen generator must be lifted by the skid, with a suitable lifting device operated by a certified or trained operator. Take the necessary precautions to avoid units tipping over during handling. Anchor all parts to the concrete floor by means of anchor bolts or like.



**Warning:** Exhaust gas from the oxygen PSA oxygen generator contains only 8-21 % oxygen. Exhaust gas must be led by piping or ducts out of the room to outdoor atmospheric air. Failure to do this may cause serious damage, injury or death. The room where the PSA generator is located must always be well ventilated.



**Warning:** Safety valve outlets from PSA and product tank must be connected by piping out of the room to safe area (outdoor atmospheric air). Failure to do so may cause serious damage, injury or death.



**Warning:** Make sure that your back-up/emergency oxygen supply is installed with an oxygen pressure regulator. The pressure must not exceed the design pressure stated in the Design Review Certificate. Check valves must be fitted at both oxygen delivery outlet from product tank and backup oxygen outlet.



**Warning:** Always vent oxygen to outdoor atmospheric air. While venting oxygen, make sure there is no smoking or open flame. Do not allow venting oxygen to come in contact with clothing or hydrocarbon materials.



**Warning:** Oxygen is a powerful oxidizing agent. It can cause fire or explosion. Observe strict cleanliness procedures when fabricating and connecting the oxygen piping. It is imperative that oxygen systems be properly cleaned and inspected to ensure that no combustible materials remain in the connecting piping and fittings. Do not allow the free flow of oxygen from the oxygen PSA oxygen generator or from product tank.



**Warning:** The interior of the cabinet contains electrical parts that may produce electrical hazard if not handled properly. To prevent electrical shock, care must be taken when servicing this equipment. In general, electrical installation and servicing is to be performed by trained or authorized personnel only.



**Warning:** Do not attempt to open the inspection hatch or similar unless the unit cycle pressure gauge reads zero and the rubber hose from the filter elements is disconnected to release pressure. PSA oxygen generator columns can contain hazardous substances. Handle only with proper protective clothing, gloves and eyewear and according to local environment and work environment regulations. In general, mechanical and piping installation and servicing is to be performed by trained or authorized personnel only.



**Warning:** Improper behaviour as a result of inadequate qualification and knowledge can lead to substantial injury to person and property. Therefore don't allow any activities to be performed by other than appropriately qualified personnel.

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**Warning:** Tanks must be depressurized and purged thorough with air to remove all oxygen before service or inspection. Always vent oxygen to outdoor atmospheric air. Make sure there is no smoking or open flame.



**Warning:** When servicing control valves only use lubricant suitable for oxygen service.

Use Klüber Klubertemp 92-302 or similar. Never use oil, grease or other lubricant not designed for oxygen. Such lubricants can self-ignite or explode in contact with oxygen.



**Important:** For safety, installation and operating etc. of compressor, air dryer unit or other auxiliary equipment refer to the concerned manuals of the equipment.



**Warning:** The compressor, air tank or other feed air supply and pressurized equipment must be fitted with adequate protective devices to protect against exceeding allowable limits of the concerned equipment e.g. safety relief valves. Feed air supply must be protected against exceeding the maximum allowable pressure for OXYMAT PSA oxygen generators. The safety relief valves on PSA generator columns and product tank (if supplied) are solely for the protection of these components.



**Warning:** The following will cause damage not covered under the manufacturer's warranty. Feed air temperature T(O) above 40°C or below 5°C. Water, oil, rust, scale and/or other foreign objects carryover in the feed air due to damaged filter elements and/or plugged drains. The feed air quality must comply with specifications to ISO/EN 8573.1: 2010 class 2.4.1, unless otherwise stated.



**Caution:** OXYMAT prefilter 1µm and microfilter 0,01µm elements have been selected based upon their ability to function in severe operating conditions. Filters has to be chosen according OXYMAT recommendation, otherwise OXYMAT cannot guarantee product gas quality. Use prefilter and microfilter to reach feed air quality to comply with ISO specification 8573-1:2010 class 2.4.1.



**Caution:** The "oxygen compatible" lubricants Klüber Klubertemp 92-302 used in process valves is safe up to 60°C as mentioned on product sheet and MSDS (material safety data sheet) by manufacturer. In case of combustion, CO, Hydrocarbons, and traces of fluorinated products will be released.



**Caution:** We recommend maintenance and greasing once a year on all process valves.



**Warning:** OXYMAT PSA oxygen generator cannot be disconnected from the power supply for the period longer than 6 months. It could cause PLC data loss. This period begins to count from the date of final operation test mentioned in Design Review Certificate. This type of certificate is always part of the delivery - unique for each serial number of PSA oxygen generator.



**Warning:** In case of generator for medical use, do not forget to use recommended filters to comply with MDD. Coal tower with microfilter has to be used. After product tank use particle filter and bacterial sterile filter. Otherwise, the performance will not be the same as it was during the testing. Recommended bacterial sterile filter - this filtration system provides particle removal down to 0.01 micron and DOP efficiency of more than

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**99.9999%. Sterile filter meets requirements of HTM2022 medical gas pipeline systems specification.**



**Warning:** If PSA ordered without product analysis, customer takes full responsibility if product purity out of specification.



**Important:** PSA oxygen generator for medical use must be installed according to EN ISO 7396-1:2016.



**Important:** PSA oxygen generator for medical use must be equipped with:

1. OMED (medical upgrade kit) consisting of:

- Coal tower
- 0.01-micron filter
- 0.01-micron filter (on product tank)
- Bacterial filter (on product tank)

2. Oxygen analyzer

3. Purity control

4. CO, CO2 analyzer

Otherwise MDD declaration of conformity is not valid.



**Important:** Air compressor shall be connected to an emergency electrical supply.



**Important:** Air compressor shall not be used as source of medical air.

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## Action in case of danger and accident:

- Store first-aid box and fire extinguishers close-at-hand
- Familiarise personnel with the inside emergency plan
- Emergency stop has to be activated
- Take first-aid measures in accordance with the inside emergency plan

## Pictograms and labels on equipment

Symbol	Symbol description/ <i>Placed</i>	Explanation
	<b>S9/17 Keep equipment in a well-ventilated area and gases away from combustible material</b>  <i>On front of a PSA generator</i>	Warning: Oxidizing gas. Keep equipment in a well-ventilated area and gases away from combustible material. See WARNINGS AND IMPORTANT INFORMATION
	<b>WARNING</b>  <b>Equipment must be placed in a well-ventilated area. Avoid inhalation of gases</b>  <i>On exhaust silencer</i>	Warning: Equipment must be placed in a well-ventilated area. Avoid inhalation of gases.  See WARNINGS AND IMPORTANT INFORMATION concerning exhaust gases

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Symbol	Symbol description/Placed	Explanation
 <b>WARNING</b>  <b>VOLTAGE</b> Turn off power and disconnect before service  <b>PRESSURE</b> Depressurize equipment before service  <b>MANUAL</b> See manual before service	<p><i>On skid plate</i></p>	<p>Warning: See WARNINGS AND IMPORTANT INFORMATION.</p> <p>Voltage - Turn off power and disconnect power supply before service or repair.</p> <p>Pressure - Depressurize before service or repairs.</p> <p>Manual - See manual before service or repair.</p>
	<p><b>S9/17 Keep equipment in a well-ventilated area and gases away from combustible material</b></p> <p><i>On product tank near oxygen outlet</i></p>	<p>Warning: Oxidizing gas. Keep equipment in a well-ventilated area and gases away from combustible material. See WARNINGS AND IMPORTANT INFORMATION.</p>
	<p><b>WARNING</b></p> <p><b>Do not lift PSA generator unit by lifting lugs or by pipes</b></p> <p><i>On top of a PSA generator</i></p>	<p>Warning: Do not lift PSA generator unit by the lifting lugs or by pipes. See WARNINGS AND IMPORTANT INFORMATION.</p>

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Symbol	Symbol description/ <i>Placed</i>	Explanation
	-  <i>On outside of (upper) control cabinet</i>	Warning: Voltage. See WARNINGS AND IMPORTANT INFORMATION.
	-  <i>On front of a tank / column</i>	Warning: Tip over hazard. See WARNINGS AND IMPORTANT INFORMATION.
	<b>HOT SURFACE</b>  <b>Do not touch until cool</b>  <i>Inside lower control cabinet on zirconium probe (if fitted)</i>	Warning: Hot surface. Do not touch until cool. Allow for a cooling down of Zirconium probe module if present.