MEDICAL FLUID DISTRIBUTION NETWORK (MGPS) INSTRUCTIONS FOR USE

Revision: 08/2023

CE 0476

1. WHAT IS MGPS AND WHAT IT IS USED FOR

MGPS is a medical device class IIb for Medical gas distribution network (MGDN) and class IIa for anesthesia gas suction system (AGSS) according to Article 51 of Regulation (EU)2017/745.

It is intended for the following applications:

- the distribution of medical gases and vacuum (MGDN)
  - MGDN-O2 (UDI-DI: 05430003250006; REF : ALMB P&ID_STD LLL-GGG)
  - MGDN-N2O-Kalinox (UDI-DI: 05430003250013; REF : ALMB P&ID_STD LLL-GGG)
  - MGDN-CO2 (UDI-DI: 05430003250020; REF : ALMB P&ID_STD LLL-GGG)
  - MGDN-Air (UDI-DI: 05430003250037; REF: ALMB P&ID_STD COMPR MEDICAL AIR)
  - MGDN-Vacuum (UDI-DI: 05430003250044 ; REF: ALMB P&ID_STD VACUUM)
- the extraction of anesthetic gases (AGSS) (UDI-DI: 05430003250051)

Please read the entire instruction manual carefully before using this tool as it contains important information for you. Do you have any questions or doubts? Then contact your supplier.

2. IMPORTANT INFORMATION FOR USING MGPS

Precautions

Instructions for use for specific materials are included in the customer file upon delivery of the installation.

The gases are continuously available at the required service pressure as long as there is sufficient pressure at the source. Regularly check the levels of the gas sources.

By connecting to a take-off point, the supply of the desired gas starts. Each off-take point is specific to the gas supplied and cannot be used for other types of gases thanks to a gas-specific connection (EN ISO 7396). It is sufficient to use flexible hoses or other materials for connection to discharge valves sold by specialized manufacturers. It is recommended to follow the recommendations of these manufacturers regarding this equipment.

The network is intended for use in patient care (MDR 2017/745).

Shut off valves at the beginning of a zone, located in a sealed or lockable box, make it possible to isolate parts of the network in an emergency. (cf. EN ISO 7396).

Care areas (operating room, anesthesia induction room, recovery room, anesthesia room, intensive care, cardiac monitoring, neonatology, ...) are equipped with an emergency alarm system (cf. EN ISO 7396). Which will generate an alarm when the network pressure exceeds the threshold values.

Electromagnetic compatibility (EMC) is the ability of electrical equipment and systems to function acceptably in their electromagnetic environment by limiting the unintended generation, dissemination and reception of electromagnetic energy that can cause undesirable effects. The EMC conformity certificate can be found in the customer file for the relevant components. (cf. EN 60601-1-2:2017)

The network must be maintained by authorized and trained personnel authorized by the supplier/installer or the head of the facility (cf. ISO 9001).

Restrict access to the installation to authorized persons only .

Wear a helmet and hearing protection and keep a sufficient distance when the pipe is being purged.

Warnings

In operation steps of the alarm

The alarm system is activated in the event of a pressure drop or increase when the defined extremes are exceeded. Care personnel must be trained to use the alarm system according to the manufacturer's recommendations to cover the risk of gas supply interruption.

The owner must draw up emergency procedures (cf. Royal Decree 06/11/1979), in particular:

- communication procedures, through which any emergency situation can be immediately communicated to all potentially affected areas of the institution. This communication should include the following:
  - the nature of the emergency;
    - details of the procedures for the protective measures to be applied to the gas supply;
  - the probable duration of the emergency and the remedial measures to be taken.

  It is advisable to appoint experienced persons in each zone to coordinate the actions and make the necessary announcements.

- procedures including protective measures that ensure that gas consumption from the network(s) is reduced to an appropriate level and, if necessary, the involvement of emergency services.
- procedures through which remedial measures can be taken. These measures should remedy the gas supply interruption. They can demonstrate the need to isolate other initially unaffected areas in order to allow the repair work to take place.

The owner must ensure that the personnel are trained in these procedures and that this training is maintained by means of emergency procedure initiation exercises (cf. Royal Decree 06/11/1979).

Fire

The safety instructions must be communicated to the staff and regularly reminded. Attention should be drawn to:

- the prohibition of greasing the supply and use parts;
- the ban on bringing oxygen and nitrous oxide into contact with fats of any origin;
- the prohibition to smoke in the vicinity of the treatment devices and to use flames and devices that contain glowing parts or parts that can generate sparks.
- the obligation to use components compatible with oxygen and with anesthetic gases in the case of SEGA

The owner must draw up an intervention plan in the event of a fire that clarifies the role of the acting persons who are appointed to carry out the following actions:

- Isolation of the zones that are seen as the cause
  - Disable these zones.
  - Emergency supply of gas and medical vacuum.

Power cut

In the event of a power cut, the gas supply will not be affected. Supply from a mechanical source and alarm systems should be provided with an emergency power source to ensure continuity of power supply and supervision

Overflow of the vacuum network

The suction system connected to the vacuum relief valves must include a protection system against the overflow of the canisters.

In case of blockage or reduced flow of one or more vacuum pressure relief valves, it is strongly recommended to have the network checked by a specialist.

Shocks on the pipes

- **Risk of leakage**
  Any shock or blow to the pipes must be declared, and their condition must then be checked by a specialist.

- **Danger of suspended pipes coming down**
  Same as before.

Close and open the taps

- **Risk of poor accessibility**
  It is advisable to keep access to the taps free at all times and to ensure that no objects are placed on them that could prevent access.

- **Supply interruption**
  After a repair, the taps, which are protected by a sealed box, must not be manipulated under any circumstances, as clearly indicated on the affixed label.

Risks associated with interventions on the network

Reporting these risks is the **responsibility of the person performing the intervention** .

- **External cleaning of the network**
  - **Risk of damage to the pipes**

It is recommended NOT to clean the piping externally with chemicals or with detergents common to the hospital environment.

  - **Risk of damage to the alarm system and the triggers**

The cabinets of the alarm system and of the releases must be cleaned in accordance with the manufacturer's instructions.

  - **Risk of network disconnection**

The seal of the cabinets must not be broken during cleaning. Cleaning must be done by experienced personnel.

  - **Risk of clogging of the discharge valves**

The discharge valves and the bed beams should be cleaned in accordance with the manufacturer's instructions

- **Painting the network**
  - **Risk of damage to the pipes**

It is recommended to apply the paint using a brush. Applying paint using an oxidative spray is strictly prohibited.
Pipes are always identified by pipe stickers as described in the EN ISO 7396 standard . Painting the pipe network is therefore not required.

- **Maintenance of the network**
  - **Risk of gas supply interruption**

Servicing the check valves or regulators and tightness checks may require an interruption of the gas supply to the check valves being worked on. The interruption of the compressed air supply may stop operation or result in a reduction in the flow rate of the SEGA.

It is recommended that the person carrying out the work obtains prior permission from the care staff and that an interruption of the gas supply to the patients is avoided.

  - **Danger of infection**

There is a risk of soiling at the vacuum check valves. The maintenance man takes care of taking all necessary precautions to avoid infection. It is advisable to use disposable gloves for this operation.

  - **Fire hazard**

It is forbidden to use lubricants other than those recommended by Air Liquide Medical. The use of parts suitable for use with oxygen or with anesthetic gases is mandatory as appropriate.

- **repairs**

It is advisable to call a specialist for any intervention resulting from an error in the network or any part of it.

  - **Risk of gas supply interruption**

It may be necessary to shut off the gas supply during repair work. It is advisable to make sure before any intervention whether or not the gas supply must be interrupted. If the gas supply has to be interrupted, it is strongly recommended to draw up an interruption plan.

  - **Risk of reduced performance**

The parts or elements of the network that are replaced during an intervention must be those recommended by the manufacturer.

- **Physical damage to the supply sources**

- **Fire hazard**

Damaged sources of oxidizing gas can cause a catastrophic fire. Personnel should be trained to handle compressed gas cylinders and secure areas for cylinder delivery or cryogenic liquid filling.

Risks associated with activities in the vicinity of the network

Changes in the immediate environment of the network (maintenance and furnishing of premises, etc.) may entail certain risks. These potential risks are classified by situation in order to facilitate the awareness of the intervention personnel.
Preventing these risks is the **owner's responsibility.**

- **Maintenance work**

  - **Electromagnetic compatibility**

It is the customer's responsibility to assess the risks associated with (maintenance) work and changes in the vicinity of the MGPS network.

  - **Danger of the pipes coming down**

The network is attached to the walls or ceiling with brackets . However, the pipes are not designed to support the weight of, for example, a ladder placed against them or any object suspended from them, or to serve as a support for other techniques.

  - **Electrocution hazard**

The gas pipes and electrical supplies must either circulate in separate compartments or be more than 50 mm apart.

  - **Risk of loss of identification of the gases**

The medical gases flowing through the network are identified by labels. However, it is recommended not to cover them with paint or make them invisible with solid objects. The same applies to taps, cabinets and all other identification carriers.

  - **Fire hazard**

The use of lubricants other than those prescribed by Air Liquide Medical is prohibited. The use of components suitable for use with oxygen and or with anesthetic gases, as appropriate, is mandatory.

  - **Supply interruption**

Shutting off a tap can result in an interruption of the supply of medical fluids. The interruption of the compressed air supply can lead to stoppage of operation or reduced flow of the SEGA

It is sufficient for the intervening party to intervene only after authorization from the care staff and to avoid an interruption of the gas supply to the patient

- **Renovation work**

The risks associated with the aforementioned maintenance work also apply here.

This file becomes null and void in case of changes in the arrangement of the premises mentioned in this file due to lifting, destroying or moving partitions.

The renovation of the premises through which the network runs can entail the following risks:

  - **Electromagnetic compatibility**

It is the customer's responsibility to assess the risks associated with (maintenance) work and changes in the vicinity of the MGPS network.

- **Electrocution and explosion hazard**

The installed network takes into account the existing electricity and oxidizing gas network at the time of delivery. It is recommended to ensure that the passage of new electrical cables is at a minimum distance of 50 mm from all pipes and that the passage of oxidative gases is at a minimum distance of 1 meter from the medical gas pipes (cf. KB 06/11/1979).

- **Fire hazard**

The pipes that run through the risk areas are protected (cf. Royal Decree 06/11/1979) and their route takes into account the safety regulations in force. It is recommended to ensure that the premises are not used for purposes other than those provided for in this file.

- **Risk of puncture**

The network is indicated by identification labels for the gases on the passages through walls and partitions and on the external path.

It is recommended to avoid drilling and trenching in the vicinity of the network, and to take the external route of the pipes into account when excavating.

- **Risk of entrapment of the gases**

When installing the network, the layout of the rooms at the time of delivery has been taken into account. The installation of lowered ceilings must not entail any entrapment of gases in the event of leakage. It is therefore necessary to provide the lowered ceilings with ventilation or to install a duct around the pipes (cf Royal Decree 06/11/1979). It is advisable to consult the manufacturer in this regard.

- **Electrocution hazard**

The network must not be used to ground electrical equipment (cf. EN ISO 7396).

- **Risk of corrosion**

The network must not come into contact with corrosive materials (cf. EN ISO 7396)

3. HOW DO YOU USE THIS PRODUCT?

Connection to an outlet starts the supply of the desired fluid. Each connection is specific to the supplied fluid and is not compatible with other types due to a gas-specific connection . Hoses or connection material for the outlets, sold by specialized manufacturers, must be used in accordance with the instructions of these manufacturers.

4. HOW DO YOU MAINTENANCE THIS PRODUCT?

The maintenance of the network must be carried out by a trained and competent person. If the maintenance is the responsibility of the owner, the evidence must be kept.

The service life of this medical device is lifelong given that the maintenance of each component is carried out according to the maintenance plan.

CE-marked parts must be replaced by materials that have an equal CE-marking.

The parts in contact with gases must conform to the norm EN ISO 15001 concerning the presence of grease and particles

Pipelines

The pipelines for pressurized gas do not require any special intervention. However, an annual check of its condition is recommended.

This check concerns the appearance of the pipes and the identification of the gases (marking at least every 10 metres, at every branch, change of direction and passage of a wall). Any deformation due to impact must be checked by a specialist of the manufacturer. The newly affixed labels must comply with standard EN ISO 7396.

To check the general condition of the network, a leak test can be carried out using a leak detector with bubbles compatible with oxygen and the network, or via the tightness test of the self-check (cf. EN ISO 7396).

In case of leakage, the intervention of a specialist from the manufacturer is recommended.

Pressure regulators

The pressure regulators have to be checked yearly according to the instructions of the manufacturer

The control of the operating pressure at the pressure regulators can be carried out annually.

In case of deviations, the intervention of a specialist of the manufacturer is recommended.

Medical gas outlets

The maintenance of the gas outlets needs to be performed according the instructions of the manufacturer

The gas outlets in the critical service areas must be maintained annually in accordance with the requirements in force in Belgium and the manufacturer's instructions.

The round sealing rings may only be lubricated with the product recommended by the manufacturer .

It is recommended to continue to monitor the good condition of the valve (locking) and, in case of wear of one of the withdrawal valves, to request its replacement from Air Liquide Medical.

Alarm system

The check of the good functioning of the alarm system has tob e performed conform the instructions of the manufacturer and EN ISO 7396-1& 2

In the event of malfunctioning of the alarm system, the intervention of an Air Liquide Medical specialist is recommended.

Central High Pressure

The maintenance and yearly check of the good functioning of the central needs to be performed according to the instructions of the manufacturer.

Assembly, disassembly and maintenance must be performed by technicians trained in accordance with the procedures described in the service manual.

It is necessary to regularly check the cleanliness of the installation and use original spare parts.

Control closing boxes

The yearly maintenance and check of the good functioning of the control closing boxes needs to be performed according to the instructions of the manufacturer.

Regular cleaning of the closing boxes ensures a better and longer life of the product. The display is cleaned with a cloth and mild detergent. It is forbidden to use cleaning solvents, water, etc. inside the enclosures, in order not to damage the electronics and some sensitive parts.

Bed beams

The bed beams are provided with a "medical" CE marking (MDR 2017/745). It is necessary to regularly carry out the cleanliness and maintenance of the discharge valves (see above "Medical gas discharge valves") in accordance with the instructions of the manufacturer.

Medical pendants

Every 5 years the following checks need to be performed according to the instructions of the manufacturer:

- *a check of the arm system for signs of wear, abrasion, correct fastening, and correct position of movable parts and bearings personnel*
- *A check of the lifting system and greasing of the spindle*

Every 10 years, the compressed gas, vacuum hoses need to be replaced

Symbols	Description
	Name, registered trademark, address of the manufacturer
	Production date
REF	Catalog reference number
LOT	lot number

	Expiration date
	Consult the user instructions
	Warning
	Medical Device
	Not sterile
	UDI
	In accordance with the requirements of European Directives
	Reading the instructions is mandatory (EN ISO 7010)

 MANUFACTURER

Air Liquide Medical
Avenue Bourget 44 / 5
B-1130 Brussels, Belgium


Production date :
Lot number :
Expiry Date - EXP:

See lot number label