EEG

MEDICAL

IFU: Instructions For Use

Medical Gas Pipeline Systems

Client

ProjectName

Content

1 Introduction

Thank you for choosing EEG NV - EEG Medical as the manufacturer of your Medical Gas Pipeline System.

This document, the instructions for use, is a part of the accompanying information of a medical device. It has been made with the purpose to inform the persons accountable for the use, maintenance, decommissioning and disposal of the medical device, particularly regarding safe use.

This document is regarded to be a part of the medical device.

The Medical Gas Pipeline System (later named MGPS) is an assembly of components which can be supplied by one or several different manufacturers. To inform you in the best possible way, reference may be made to the instructions for use of the various manufacturers.

To make sure that you have mastered all the functions of your new unit, please read the manual in its entirety. Keep the manual within easy reach as a convenient reference.

2 Document information

Document name: DOC_QHSE_015_EN

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Revision: 05

Although the context of this document is fixed, it is possibly that due to client feedback some information (e.g. documentation from manufacturers of used components is added before approval of the specific IFU for the MGPS. To be able to identify these versions an index is used.

Index	Date	History of changes
A	DD/MM/YYYY	Not applicable – first release of IFU for project
B	DD/MM/YYYY	/
C	DD/MM/YYYY	/
D	DD/MM/YYYY	/
E	DD/MM/YYYY	/

3 General information

3.1 Contact information

3.1.1 Responsible manufacturer

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Notified Body number: 0044

4 Identity of the medical device

4.1 Description of the medical device

A MGPS is a complete system which comprises a supply system, a monitoring and alarm system and a distribution system with terminal units at the points where medical gases or vacuum are required. The scope of a MGPS is distributing (channelling) medicinal gases or medical device gases or vacuum.

The terminal units installed in the vicinity of the patient (e.g. patient bed, medical room, …) are the endpoint of a MGPS. They are the main connection points for other devices to bridge the gap between the MGPS and the patient. The connected devices are responsible to administer the correct amount of gas (e.g. mixtures, pressure, flow, …) to the patient. The MGPS doesn't have any direct contact with the human being.

The product MGPS can be either a complete system or a part/extension of an existing system.

The size of the MGPS is project specific.

4.2 Commercial product name

MGPS: Medical Gas Pipeline System

4.3 Medical device family name

Referring to the European Medical Device Nomenclature (EMDN): Z120309 - Medical/medicinal gas pipeline systems and related accessories

5 Symbols and signs

Consult instructions for use.

Indicates the medical device manufacturer and can be found on the label of the device. The symbol is accompanied by the name and address of the manufacturer.

Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.

Indicates the manufacturer’s serial number so that a specific medical device can be identified. The serial number can be found on the product label adjacent to the symbol.

Indicates the item is a medical device.

The explanation of other symbols and signs found on specific components of the MGPS can be found in the instructions for use of the manufacturer of the components. As the MGPS is a project specific medical device these components can be different for each MGPS. The instructions for use of the used components from other manufacturers can be found in the annexes of this IFU.

6 Use specification

6.1 Intended use

The MGPS is a medical device and can be seen as an assembly of parts that is designed to:

- Channel a continuous supply of the appropriate compressed medicinal gas and/or medical device gas and or vacuum to areas where they are used in patient care or to power equipment in such a way that the safety of the patient and/or end user is ensured.
- remove anaesthetic gases and vapours (AGSS – Anaesthetic Gas Scavenging disposal System) to reduce occupational exposure to anaesthetic gases and vapours.

The intended purpose is achieved by connecting other medical devices via the terminal units to the MGPS.

6.2 Intended users

The product is to be operated exclusively by qualified personnel, on the basis of which the use by laymen is prohibited. The qualified personnel shall be an adult, authorized and competent healthcare professionals (such as medical officers, doctors, nurses,…) which are aware of the possible hazards.

6.3 Intended patient population

The MGPS channels medical gases on demand to patients to whom gasses must be administered according to the evaluation of a healthcare practitioner.

6.4 Use environment

The MGPS is intended to be used in healthcare facilities, both public and private, such as hospitals, clinics or similar facilities that provides patients with their healthcare needs. It applies to all facilities providing healthcare services regardless of type, size, location or range of services.

6.5 Indications

Since the product medical gas pipe system is not applied directly to the patient, the consideration of the indications for the product is not applicable.

6.6 Contra-indications

Since the product medical gas pipe system is not applied directly to the patient, the contraindications for the listed product components is not applicable.

6.7 Operating principle

Gases and vacuum, either produced on-site or connected to the MGPS (cryogenic tanks, cylinders, …) are channelled throughout the pipeline system. The transfer of the gas from the source to the terminal unit is possible thanks to the energy the gas possesses (pressure difference).
Medical compressed gases and vacuum are provided in areas of healthcare facilities where it is used in patient care or to operate devices such as ventilators and surgical tools.

The MGPS doesn't have any direct contact with the human being.

The intended purpose of the installation is continuous operation.

7 Information for safety

7.1 Performance and readiness for safe us as intended

7.1.1 Product validation before first use

After installation a validation test is performed for each MGPS which is placed on the market. Before first use the user must verify if the MGPS has passed the validation test successfully. Once this has been acknowledged, the MGPS is ready to perform safely and as intended.

The proper assembly must be recorded in a written acceptance protocol. That Acceptance protocol documents all tests prescribed in accordance with the EN ISO 7396-1 standard that are to be carried out for the respective product configuration.

7.1.2 Product/technical specifications – Performance

After the onsite assembly/installation activities a device called 'MGPS' is born.
There are no two equal devices in terms of size, composition, … .The device is always project specific and installed on-site (although some parts can be prefabricated in the workshop located on the manufacturer's premises to facilitate the on-site installation).

The MGPS is made to distribute the following gases (non-exhaustive list):

- Oxygen
- Nitrous oxide
- Medical air
- Carbon dioxide
- Oxygen/nitrous oxide mixtures
- Helium/oxygen mixtures
- Oxygen 93
- Gases and gas mixtures classified as medical device, gases delivered to medical devices or intended for medical purposes or gases and gas mixtures for medicinal use not specified above
- Air for driving surgical tools
- Nitrogen for driving surgical tools
- Vacuum

And/or can contain one or more of the following:

- An AGSS (Anesthetic Gas Scavenging disposal System) to remove (excess) anesthetic gases and vapors.
- Exhaust pipes (e.g. pressure-relief, disposal of air or nitrogen for driving surgical tools)

It is designed to distribute the above mentioned gases under the following conditions:

- Compressed medical gases other than air or nitrogen for driving surgical tools:
  - min 4 barg – max 5 barg
- Air or nitrogen for driving surgical tools (also known as Air motor or Air 800):
  - Min 7 barg – max 10 barg
- Vacuum: -0.6 barg (not less than -0.6 barg)
- AGSS:
  - operating pressure: 5 barg
  - Flow in accordance with EN ISO 7396-2

After installation the MGPS must adhere to all the applicable (technical) requirements mentioned in the standard EN ISO 7396-1 and/or EN ISO 7396-2.

8 Your medical device

Your device has been classified as a 'class IIb' medical device according to the medical device regulation (MDR) 2017/745.

The identification number/serial number of your device can be found on the EU Declaration of Conformity.

☐	Cylinders and/or a cylinder bundle which are filled with medical gas under pressure (200 bar)(1)
☐	Cryogenic vessels which are filled with cryogenic gas under low pressure(2)
☐	Air compressor system (one or more compressors)
☐	Vacuum delivery system (vacuum pumps)
☐	Supply systems
☐	Second stage pressure regulators (in a two-stage MGPS)
☐	Area shut-off valves
☐	Electric insulator according to technical notice T013
☐	Copper tubes
☐	Piping for AGSS in copper or PVC
☐	Gas outlets
☐	Safety devices such as pressure relief valves
☐	Alarm panels
☐	Installation for gas detection
☐	Medical supply units (e.g. ceiling pendants, bedhead unit, booms, ...)
☐	Low-pressure hose assemblies

(1) The cylinders or cylinder bundles are supplied by other companies and are outside the responsibility of this installation.

(2) The cryogenic installation is not the responsibility of EEG NV - EEG Medical, it is only connected to the MGPS of EEG NV - EEG Medical.

The size of the MGPS (e.g. number of components) is project specific.

The high pressure is reduced to a lower pressure by means of a pressure reducer before it reaches the user.

Each system has a pressure regulator so that a constant pressure can be supplied to the pipe network up to the points of consumption (gas outlets). For the vacuum system, the vacuum pumps ensure a constant negative pressure.
A supply system consists of a system of automatic or manual switchover, safety valves and alarms. Thanks to these systems, this installation guarantees a continuous and safe distribution of the medical gas.

8.1 Operating instructions

No deviations from the manufacturer's requirements. Reference is made to the instructions for use supplied by the manufacturers of the various components.

8.1.1 Start-up or shutdown procedure

The intended purpose of the installation is continuous operation.

The installation must be switched on and off at the request of, and under the supervision of, the healthcare institution. The safety of the patient and the users should always be considered.

The safety instructions for switching on and off must take into account the EN ISO 7396-1 and/or EN ISO 7396-2 standard.

Specific start-up or shutdown instructions of supply systems such as (non-exhaustive list) compressor units or vacuum pumps can be found in the instructions for use of the manufacturer which can be found in the annex of this document.

8.1.2 Procedure for commissioning or periodic testing of the MGPS

If tests are carried out, it is important that they are carried out by trained and educated personnel. Tests must always be carried out in accordance with the requirements of standard EN ISO 7396-1 and/or EN ISO 7396-2.

8.1.2.1 Periodic testing

For healthcare facilities located in Belgium it is required according the Royal Decree of the 6th November 1979 to perform periodic inspection.

- Annual visual inspection of the installation (this inspection includes checking the protection and control device).
- Once every 3 years: leakage test at (at least the) nominal distribution pressure for oxidizing gases (>22 % oxygen percentage such as e.g. oxygen, nitrous oxide, other gas mixtures with a content of >22% oxygen)

These inspections are to be performed by a qualified organisation or an organization equipped for that purpose.
These periodic tests shall be used as input to the preventive maintenance plan of the healthcare organisation in order to check aged components and thus to detect and counteract unsafe conditions or reduced device performance in good time.

8.1.3 Risks related to usability hazards

See 10.4 Operating the system

8.2 Service or maintenance

Some activities are carried out on the pipeline systems and their components at regular intervals, in particular on the supply systems; typically the replacement of cylinders or cylinder bundles and the preventive (planned) maintenance. During preventive maintenance on one source of supply (or during replacement of cylinder or cylinder bundles), that source is unable to supply the pipeline system. If the continuity of supply is an absolute requirement, in case of failure of a second source of supply there is the third which can supply the pipeline system. Where the continuity of supply is not required (e.g. in facilities where the service is not continuous or the service provided is not considered to be life supporting) and therefore the preventive maintenance or other activities resulting in the interruption of the supply may be carried out when the supply system is not functioning, two sources of supply are sufficient. This situation has already been recognized for the supply systems for air and nitrogen for driving surgical tools: three sources of supply are not necessary; two are sufficient.

8.2.1 Service or maintenance in relation to the lifetime of the device

The lifetime of the medical device MGPS, 15 years, can only be reached by implementing a preventive maintenance plan. It is thus obligatory for the safe use of the device. This plan shall take into account the expiry date for medical devices or components which are subject to degradation over time, anticipated material degradation, … .. This

information is part of the instructions for use of the different components which can be found in the annex (e.g. periodic change of rubber seals in gas outlets, membranes of pressure regulators, ...).

9 Risk Management

9.1 General

For a MGPS it is necessary to make a full risk assessment of the entire system.

After the risk assessment (i.e. the combination of severity and probability of occurrence of harm), the design should focus on minimizing the risks by applying procedures in the following order of priority:

1. Inherent safe design
2. Protective measures in the medical device itself or during its manufacturing/instalment
   a. Where point 1 is not possible, safeguards shall be incorporated
   b. Where the above point is not possible, alarms circuits are installed
3. Safety information
   a. Where the above is not possible, the user shall be warned separately

Always apply the following hierarchy

1. Elimination of risk 'at the source' (work at the root cause)
2. Collective measures that protect everyone, then
3. Organizational measures, then
4. Personal Protective Equipment (PPE) and in addition
5. Always give instructions about the risks

Table F.1 of the EN ISO 7396-1 standard can be used to manage risks. This table contains a list of common safety objectives, underlying causes, hazardous situations and appropriate risk control measures to mitigate the risk to acceptable levels.

The table also indicates which organizations is responsible for taking action.

9.2 Residual risk

No residual risk (risk remaining after risk control measures have been implemented) was identified during the risk analysis of this medical device.

10 General description of components

10.1 Cylinders and cylinder bundles

A high-pressure cylinder is a cylinder intended to contain gas. Depending on its physical properties, this gas may be contained in the cylinder under high pressure or in liquid form.

It is also important that the cylinders are painted with the colours according to the legislation (EN 1089-3).

10.2 High-pressure coils for the connection of cylinders and high-pressure hoses for cylinder packs (frames)

10.2.1 High-pressure coils

These coils are the fixed spiral pipes that form the connection between the cylinders and the supply system

10.2.2 High-pressure hoses

These hoses are the connection between the cylinder bundle or cylinder and the supply system.

10.3 High-pressure manifold

Installed downstream of the supply system. Designed to connect multiple cylinders to one side of the supply system. Each connection has a non-return valve and must be connected with a coil or hose to the cylinder.

10.4 Compressor

The compressors make compressed air. They can be placed per 2, 3, 4 or more. The number depends on the needs of the customer and the choice of the different sources.

10.5 Treatment system

The treatment system serves to purify the compressed air. Small dust particles, oil, water, … can be eliminated in this way. By installing the correct treatment system compressed air can be filtered to fulfil the requirements of medical air.

10.6 Adsorption dryer

An adsorption dryer eliminates the moisture content of the air through adsorption.

10.7 Second stage pressure regulator

This device controls the second stage pressure of the pipeline system. It reduces the pressure from high to low. The pressure of the gas is readable upstream and/or downstream of the device.

Each bed space/patient space shall be supplied from at least two permanently fitted (line) pressure regulators to ensure continuity of supply.

In order to ensure continuity of supply the two line pressure regulators should not be in use at the same time. If in use at the same time they may both fail.

10.8 Shut-off valve

Shut-off valves are provided to isolate sections of MGPS for maintenance, repair, planned future extensions and to facilitate periodic testing.

The location of the shut-off valves must be known and can be found on the “As-built” drawings of the MGPS.

10.9 Alarm panel

The alarm panel is designed to monitor the presence (pressure) of the medical gases. In case of failure, a specific alarm is activated.

10.10Pipelines

The purpose of the installed pipelines is to transport the medical gas to the various outlets. The pipes comply with the EN 13448 standard and after installation are provided with the necessary marking as described in the EN ISO 7396-1 standard.

10.11Exhaust pipes

Pipes installed for e.g. pressure-relief, disposal of air or nitrogen for driving surgical tools)

10.12Gas outlets

The gas outlets are quick access points to the medical gases. Each gas has a specific connection (impossible to create an inversion). They are designed and marked CE according to the ISO 9170-1 and/or EN ISO 9170-2 standard.

A gas 'outlet' can also be an AGSS (Anaesthetic Gas Scavenging disposal System) to remove (excess) anaesthetic gases and vapours.

10.13 Reading of measured values

The parts that have a measuring function are arranged in such a way that they can be easily read. The pressure is indicated in bar. These are checked during commissioning and maintenance and adjusted if necessary.

11 Maintenance instructions

Maintenance instructions of the MGPS (including information about calibration, if applicable) can be found in the technical data sheets and instructions for use of the separate components.

See the technical data sheets and IFU of the components in annex.

Just like installation and commissioning tasks, maintenance must be performed by a qualified and trained person.

Again, lubricants or oil may never be used unless stated otherwise (and compatible with the gas). See chapter Safety guidelines.

12 Operational management

Once installed, dangerous situations can still occur. Technical errors and management errors can lead to problems or incidents during the use of the installation. In order to reduce these risks, the healthcare institution must take risk control measures. One of the risk control measures is to set up an operational management.

If there is no operational management, it may happen that a certain safety aspect is not performed and only visual checks are performed.

The application of an operational management aims to maintain the installation in terms of:

- safety and reliability;
- patient safety;
- efficiency of operation;
- continuity of the installation and the gases.

The requirements for the operational management of a MGPS should be described in an operational management document.

Guidelines for operational management are included in the appendix G of the latest standard EN ISO 7396-1 and can be used by the healthcare institution to create a document for operational management.

The operational management document should contain documented procedures for the following (non-exhaustive list):

- Management of documents and registers;
- Training and communication;
- Emergency management;
- Change management;
- Work permits;
- Preventive maintenance;
- Repairs;
- Management of resources;
- Storage and processing of cylinders;
- Purchase of medical equipment;

- Management of contractors.

13 Safety guidelines

- Respect the maintenance recommendations
- Never work on a device or pipe/hose which is under pression
- It is strictly forbidden to remove the CE marking
- Respect the requirements mentioned in the standard EN ISO 7396-1 concerning testing, commissioning and certification
- Make sure that the used material is in good condition and of good quality
- Only use material that is compatible with the nature of the gas, the pressure and the desired flow rate. The use of non-recommended material can lead to risks of fire and/or explosion.
- Do not use grease at the various connections. The fatty substance may ignite in the presence of oxygen. If the use of lubricant is required during construction, modification or maintenance of the installation, use only oxygen compatible lubricants.
- The device may only be used for medical activities. There shall be no connection for any other application, this to avoid all possible contamination.
- Various accessories may complete the installation. In this way, a MGPS is set up. However, it is required that each accessory complies with the legislation imposed on medical installations and has a CE identification where possible.
- Make sure that the personnel are properly trained. As a supplier, we provide the hospital's staff with the necessary knowledge for each extension. Also make sure that staff is used to the use of medical gases.
- Appoint a person responsible for the use of the gas and material. It is therefore also important to respect the necessary safety rules.
- The device must be built and maintained by an installer who is in possession of a valid quality management system for medical devices (e.g. EN ISO 13485).
- Copper brazing must be performed by a trained person with a valid EN ISO 13585 certificate for the application and by using filler material according to EN ISO 17672.
- The operational management system must address the need for training the personnel who carries out work on the device/installation. This to safeguard the optimal and safe operation of the device/installation.
- Examine and give the necessary training about the safety signs which are present in the vicinity of the installation.
- Safeguard the tightness of the installation. Note that no modifications may be made to an installation bearing a CE marking without having carried out all the necessary tests demonstrating the conformity of the installation.
- The testing of the installation must be carried out by a competent person. E.g. an authorized person to test medical gas installations of a company certified according to EN ISO 13485 by a notified body.
- It must be ensured that bottles, bottle packs or storage tanks are secured on a flat, horizontal surface. Any risk of falling must be excluded.
- Provide safety equipment that avoids the risks of overpressure or regression of a product.
- Make sure that all bottles, bottle packs or storage tanks are located in well-ventilated areas and away from any source of heat.
- Gently and gradually open the taps on the bottles or bottle packs, as well as any other tap.
- Respect the cleanliness of the material. The presence of small particles due to different actions can be the basis of breakdowns. Upon delivery of the material, the entrances and exits are blocked or the material is packed. The removal of these elements is only done during installation.
- Never try to change the technical characteristics of the installation. These modifications can significantly alter the operation of the installation, which can make it dangerous for everyone's safety (including that of the patient).
- The person who modifies the intended use or the medical device without the manufacturer's consent is considered to be the manufacturer of the modified medical device.

- The person responsible for the quality of the gas is the hospital pharmacist. It is therefore recommended that the quality of the transported gases be checked at regular intervals.
- Basic hygiene procedures should be observed when working on terminal units, plant and pipelines (that is, covering of all lesions with waterproof dressings; washing of hands after carrying out the work; abstaining from eating, drinking or smoking when carrying out the work; and taking remedial action). In case accidental wounds occur during the work. Only in extreme cases (for example known serious pathogenic contamination of the system) would further actions be required. In such cases, the advice of the infection control officer of the healthcare facility should be sought.

14 Risk control measures

Once commissioned the product itself is considered to be a safe product without residual risk. But the safety of the device can be greatly influenced by how the product, connected components, gas supplies, … are managed by the healthcare facility. Therefor the following risk control measures must be evaluated upon their applicability for the MGPS in the healthcare facility. When deemed applicable they shall be incorporated into the operational management of the healthcare facility in order to safeguard the use of the MGPS.

14.1 Safeguarding the continuity of the gases

- Ensure that reserve and emergency resources are included in the capacity and location of the resources
- Set up an inventory management system
- Set up a preventive maintenance system for each source
- Establish operational procedures for supplying cylinders for emergencies to ensure continuity of supply
- Establish procedures to minimize the use of gases in emergency situations
- Routinely test the backup and emergency sources to ensure they work when the primary and secondary sources fail
- Routine testing of the alarm system
- Set up a document for operational management in case the supply fails. Also consider pipeline supply problems (pipeline burst, failure of hoses, …).
- Protect pipelines in high-risk areas
- Insert a work permit system for work on the installation
- Set up one or more contingency plans for areas with highly dependent patients
- Use the facilities for connecting local emergency sources adjacent to the collection points
- Use the emergency connections near zone valves
- Work with a gas supplier that applies the principles of risk management
- Choose the correct dimensions of the storage tank
- Use telemetry on the storage tanks
- Set up an adequate system for stock management and re-ordering
- Provide an adequate number of cylinders on site
- Provide a suitable location for cylinder storage rooms and maintain them in an orderly condition
- Train personnel in replacing cylinders on manifolds
- Draw up a contingency plan that provides for problems with supply from the gas supplier (e.g. due to force majeure)
- Routine assessment of the delivery schedule
- Routine assessment of the source's inventory
- Create an operational management document on supply problems
- Ensure that the distances between sources (continue to) comply with local regulations/guidelines

- Ensure that the plant rooms and rooms with collectors have adequate temperature control and ventilation. Assess the temperature control of the room in order to prevent the segregation of gas mixtures
- Provide adequate physical protection against mechanical damage where necessary
- Provide clear signs to keep unloading areas clear
- Establish procedures to maintain access to the sources
- Routinely assess the delivery system to ensure the system remains safe
- Assess the risks associated with the presence of two sources in different locations.
- Draw up an operational management document on actions to be taken in the event of an alarm or alarm system failure.
- UPS (uninterruptible power supply) must be present to ensure the continuity of the electrical system
- Emergency power generator with sufficient power to run the gas production system on site, so that the supply is maintained
- Monitor the capacity of the emergency power supply
- Routinely test the emergency power supply
- Create an operational management document that deals with power outage issues
- Establish procedures to ensure that all components are working again after power is restored
- Verify that spare sources of compressors or oxygen concentrators can keep the gas supply going in the event of a power outage.
- Provide a preventive maintenance plan for critical components
- Identify high-risk areas (e.g. areas with highly dependent patients)
- Require that the second or third source maintain supply to the pipeline system until the on-site gas production system can be repaired/replaced (such as compressed air system, valves, control panel, analysers).

14.2 Safeguarding the system performance

- Draw up an operational management document on
  - periodic usage checks
  - periodic testing and maintenance of safety valves
  - periodic checks for the alarm of high pressure
  - periodic checks for low pressure alarm
  - periodic inspection and maintenance of pressure valves
  - Capacity checks of equipment connected to the installation
  - periodic inspection periodic maintenance of pressure reducing valves
  - periodic checks of the installation, layout and accessibility of the sources
  - periodic checks to assess the capacity of the source
  - Periodic checks for leakage of the installation
  - Periodic maintenance of the installation
- Perform commissioning checks after installation

14.3 Safeguarding the quality of the gas

- Make proper contractual arrangements with the gas supplier
- Document pharmacist/quality control responsibilities in an operational management document
- Establish proper maintenance procedures for on-site gas production
- Operational management document describes correct cleaning procedures and test requirements
- Operational Management document describes correct maintenance procedures for gas compressors/vacuum pumps/oxygen boosters
- Operational Management document describes correct test procedures for potential contaminants in medical air
- Use components that meet the purity criteria of EN ISO 15001.

- Correct location of connection to compressed air system(s)
- Correct functioning of air purifier/filter unit
- Operational Management document describes the correct procedure for cleaning/replacing filters and the testing requirements for MGPS filters.
- Operational Management document describes the correct procedure for cleaning/replacing filters and test requirements for filters for medical equipment connected to the MGPS.
- Operational management document describes correct filter maintenance procedures
- Commissioning checks to demonstrate the performance of any backflow protection devices or differential pressure settings
- Operational Management document describes correct test and maintenance procedures of backflow protection devices and differential pressure settings
- Ensuring that there is no backflow in medical equipment connected to MGPS
- Operational management document prohibits the use of adapters
- Commissioning of the MGPS to demonstrate that there are no cross-links
- Operational management document deals with the control of cross-contamination in case of system change/expansion
- Establishing and monitoring the responsibility of the pharmacist (or director) of health care institution
- Operational Management document identifies correct on-site gas production testing procedures
- Provide emergency training for all involved employees/users of the on-site gas production system
- The operational management document specifies the need for an assessment of the competence of all involved employees/users of the on-site gas production emergency system and specifies the requirements for further training and registration of the training.
- Define emergency training requirements for all involved employees/users of the on-site gas production system
- Define the correct procedures for operating the system to produce gas on site in an emergency situation

14.4 Operating the system

- Define the correct procedures in the operational management document for each part / each component of the MGPS
- Define responsibilities for all employees/users involved in the MGPS
- Define training requirements for all employees/users involved in the MGPS
- Ensure all zone valves, control panels and alarm panels are in the correct location and properly labelled
- Provide training to all employees/users involved in the MGPS
- Operational Management document specifies the need for a competence assessment of all employees/users involved in MGPS and specifies the requirements for in-service training and training registration
- Assess personnel requirements for safe management of the MGPS (during and outside working hours)
- Operational management document specifies the need to regularly assess staffing requirements
- Defining the correct procedures for operating the MGPS in an emergency situation
- Define training requirements for emergency situations for all employees/users involved in the MGPS
- Provide emergency training for all employees/users involved in the MGPS
- Operational Management document specifies the need for an assessment of the competence of all employees/users involved in operating the MGPS in emergency situations and specifies the requirements for refresher training and registration of the training.
- Availability of external maintenance services for both preventive and corrective maintenance of the installation
- The operational management document specifies the need to regularly assess staffing requirements
- Assess personnel requirements for safe management of the on-site gas production system (during and outside normal working hours)

- The operational management document defines the appropriate preventive maintenance system to ensure the reliability of the installation
- Define responsibilities for all involved employees/users of the on-site gas production system
- Define training requirements for all involved employees/users of the on-site gas production system.
- Ensure that all zone valves, control panels and alarm panels are in the correct location and properly labelled
- Train all involved employees/users of the on-site gas production system
- The operational management document specifies the need for an assessment of the competence of all employees / users of the on-site gas production system involved and specifies the requirements for further training; registration of the training.

15 Compatibility

15.1 Connected medical device/general purpose equipment

The medical device of EEG NV - EEG Medical covered by these instructions for use can be a complete MGPS or a part/extensions/... of an existing MGPS. To achieve the intended purpose of the device, other devices must be connected to the MGPS.

To be able to connect other medical devices/(general-purpose) equipment to the MGPS, the MGPS has been installed according to the European standard for medical gas pipeline systems, EN ISO 7396-1 and/or EN ISO 7396-2.

The most common connection to be made is connecting devices to the terminal units of the MGPS. All terminal connections are according to EN ISO 9170-1 and/or EN ISO 9170-2. In order to obtain a safe combination between gas outlet and connected device, the connection must be restricted to the correct gas connections insert probes according the beforementioned standard. Information about the used gas outlets used within this MGPS can be found in the technical data sheet/instructions of the specific components, .which can be found in the annex of this document.

There it can be consulted which specific standard is used e.g. DIN, AFNOR, British Standard, ... in order to safely connect the devices.

15.2 Gas compatibility limitations

The MGPS channels gas through separate pipeline for each gas. These pipelines are individually labelled, purged, filled and tested. In the validation report and as-built drawings the identification of the gases delivered by the pipeline has been verified and validated. Any change in relation to these documents results in the loss of validity of these documents.

This paragraph is not applicable for a change of gas supplier (e.g. switching from supplier A for medical oxygen to supplier B for medical oxygen) if the same standards and requirements apply to these gases. This quality check is the responsibility of the client.

16 Emergency procedure

In order to be able to prepare an emergency procedure, we provide "As-built" drawings with our MGPS.

- Up-to-date "As-built" drawings of the entire MGPS
- Up-to-date "As-built" oversight scheme of the entire MGPS to provide a fast insight of the installation.

See the annex "As-built" drawings to update your emergency procedure with the provided information.

As a manufacturer of MGPS, EEG NV - EEG Medical is of the opinion that an emergency procedure can only be drawn up correctly if you have up-to-date drawings of the complete installation.

17 Materiovigilance – incident reporting

17.1 Instruction to report

As a manufacturer we instruct the user and the patient to report any serious incident that has occurred in relation to our medical device to ourselves, the manufacturer, and the competent authority having jurisdiction in the country where the device is in use.

Please report every incident to the competent authority and to the responsible manufacturer, see contact details.

17.2 Purpose of reporting

The purpose of materiovigilance is to study and follow incidents that might result from using medical devices. It enables dangerous devices to be withdrawn from the market and to eliminate faults in medical devices with the intention of constantly improving the quality of devices and providing patients and users with increased safety.

17.3 What should be reported

What to report?

- any dysfunction or any change of the characteristics and/or performance of a device, and any inadequacy in the labelling or instructions, which might lead to or have led to death or serious relapse in the state of health of a patient, a user or a third party.
- any technical or medical reason related to the characteristics or performance of a device for reasons shown in the previous paragraph and having led to the systematic withdrawal from the market by a manufacturer of devices of the same type.

As soon as ~~Heyer Benelux~~ EEG Medical gets informed about any malfunction or deterioration in the characteristics and/or performance of a device, as well as any inadequacy in the labelling or the instructions for use which, directly or indirectly, might lead to or might have led to the death of a patient, or USER or of other persons or to a serious deterioration in their state of health, our vigilance procedure is initiated.

The purpose of the procedure is to ensure or improve the health and safety of patients, users and others by reducing the likelihood of reoccurrence of the incident elsewhere.

See contact details.

For quality issues related to the medical device you can contact ~~quality@heyer.be~~ quality.medical@eeg.be.

18 Decommissioning / disposal

18.1 Decommissioning

Should a decommissioning of the medical device be planned, we are happy to offer our customers the necessary support during the decommissioning. This way we safeguard the safe disconnection of (a part of) the pipeline system from parts which remain in service.

18.2 Disposal

When used correctly it should not be necessary to follow a special disposal procedure of the medical device due to absence of toxic or hazardous substances. Individual materials / materials used (e.g. copper) are also recyclable.

However care must be taken with medical vacuum pipeline systems.

Warning!

The vacuum system must be considered potentially contaminated and you must take the precautions listed below.

18.2.1 Infection or microbial hazards

18.2.1.1 Disposal of medical vacuum systems

Suction controllers are fitted with integral filters and floats to prevent aspirated fluids from passing into the vacuum system pipework. Additionally, fluid drainage jars are fitted with floats and are often used in conjunction with an anti-foaming agent to prevent carryover.

Drainage jar-to-suction controller tubing is frequently protected by the addition of a hydrophobic filter, which will effectively seal the tube should the filter become wet.

Contamination of the medical vacuum distribution system may result, however, if one or more of these features is omitted or compromised in some way.

Repetitive induction of fluids can cause a blockage of the pipeline as transported and dissolved solids dry out. It is important that an authorised person within the healthcare facility is notified immediately of any incident involving contamination of the pipeline. Medical staff should be aware of their responsibilities in this respect, and infection control should also be advised of any contamination incident

However, if a pipework or plant to be removed is known to have been contaminated by aspirated blood, body fluids or toxic agents, the advice of the infection control officer should be sought.

Waste oil and condensate from vacuum pumps and exhaust traps should be disposed of as “hazardous waste” in accordance with hospital procedures.

Disposal of (parts) of a MGPS which includes a vacuum network.

Annex 1 EU Declaration of Conformity

Annex 2 As-built drawing

Annex 3 Validation reports

Annex 4 CE and ISO certificates

Annex 5 Technical data sheets and IFU of used components

Annex 6 Other certificates

Such as start-up certificates (e.g. compressor supply systems, vacuum pumps, alarm systems, ...), warranty certificates, ...