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#### 1.1. General Information

This technical documentation is not liable to any obligations on the part of the manufacturer. The manufacturer **MBRAUN GmbH** reserves the right for technical and optical modifications as well as functional modifications on the systems or system's components described therein. Any duplication of this documentation, even in form of excerpts, is only permitted after having obtained the manufacturer's information and concession.

Title: Operating Instructions for MBRAUN – Systems
Standard Operating Instructions

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#### 1.2. Liability

The manufacturer will not take any liability of object, personal or secondary damage caused by improper use or ignoring of safety instructions as well as caused by the owner's manual due to missing updates after the system or its software have been modified, nor will the manufacturer take any liability of damages due to loss of data. In addition, the terms of business that are part of the order/contract will apply.

Our products are continuously modified and improved due to innovation, legal requirements and standards. Consequently, the information given in this documentation may not accurately reflect every detail of the system actually delivered. Please contact the manufacturer in cases of uncertainty.

Products mentioned in this manual are eventually trademarks and are used for identification purposes only.

#### 1.3. Warranty

We guarantee the equipment as stated in the order/contract.

This warranty will expire in case of:

- Interference into or modification and relocation of the system without prior consent of the manufacturer;
- Improper use of the system;
- Insufficient maintenance of the system;
- Inappropriate operation of the system;
- Negligence of correct supply requirements;
- Application of third-part components to the system without prior consent of the manufacturer;
- Alteration of program or configuration write-ups without manufacturer's consent.



This applies to a single unit and multi-unit system types.

1.4.	Entries Referring to the System	Entries Referring to the System		
	This documentation is part of the system:			
	Designation / Type:			
	Serial number (s):			
	Person(s) in charge of the system:			
	Space left for notes on system settings, instructions for maintenance etc.			
1.5.	Service Address			
	MBRAUN GmbH – Inert Gas Systems Dieselstrasse 31 85748 Garching Germany			
	Tel:+49 (0)89 32669-230 Fax:+49 (0)89 32669-235	E-mail: <u>service@mbraun.de</u> Internet: <u>www.mbraun.com</u>		

## 1.6. Intended Use

The purpose of the **MBRAUN** gas purification system, together with a glove box, is for the enabling and maintaining a pure inert gas atmosphere inside a hermetically sealed enclosure. Materials that are sensitive to moisture and/or oxygen are handled by using the attached gloves or additionally specially designed handling systems. The system is intended for professional use only.

# **▲** NOTICE

The system will require certain modification for working with delicate or dangerous materials.

**Examples of such cases include:** 

- pharmaceutical or nuclear applications
- working with substances that will lead to dangerous situations if exposed to air in case of a failure of the system
- very expensive materials that might be destroyed if exposed to air in case of a failure of the system

These application types must be discussed with MBRAUN prior to operating the system.

## 1.7. Safety Instructions

#### 1.7.1. General Information

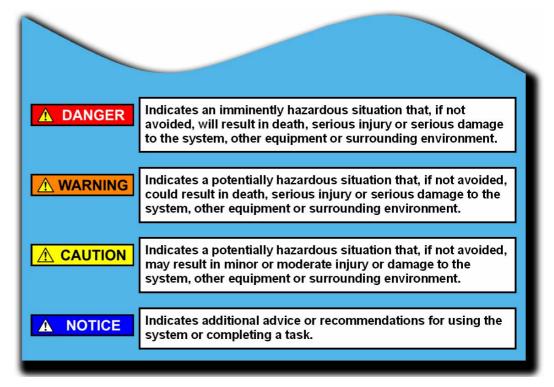
Prior to installation, initialization and operation of the system, this manual should be read in its entirety and be located in a suitable area near the system to allow for easy reference. Any persons charged with the transport, storing, installation, commissioning, operating, maintenance and/or service of this system must be familiar with the entire contents of this manual.

To ensure safe operation of the system and to maintain a safe working environment, the information contained within this chapter must be adhered to by all users of the system. Advice contained in this chapter is intended to supplement, not supersede, the safety advice given in other chapters of this manual and the general safety regulations and guidelines prevailing in the user's workplace.

In addition to the guidelines and information contained within this manual all internal, local health, safety and environmental guidelines should be followed.

Safety instructions plus pertinent information is marked in the following manner:

Table 1.1: Signal Words – Definition



Please consider all instructions, in particular safety instructions, in order to achieve safe operation of the system.

## 1.7.2. Operation Guidelines

MBRAUN Glove box systems are operated using inert gas enabling the user to handle substances that are sensitive to oxygen and/or moisture. It is the responsibility of the user to follow all local health, safety and environmental guidelines with regards to the handling and disposing of substances that may be injurious to health. This also applies to the disposal of vacuum pump oil and all components and filtering devices that come in contact with the gas flow.

# **A** DANGER

There is a risk of suffocation when working with high inert gas concentrations.

On request, **MBRAUN** can recommend a personal measuring instrument that alerts the operator to a reduction of oxygen content in the ambient air.

The following general safety guidelines must be considered when working with inert gas concentrations:

- The selected location should have a "room" volume that is significantly larger than the glove box interior volume.
- The system should be located in a well ventilated area. This is especially important during a purging procedure or when opening an active system (i.e. antechambers, etc.).
- All exhaust fumes should be vented through an adequate disposal/ventilation system.

# **A** NOTICE

Contact MBRAUN prior to the acquisition of the system if it is not possible to adhere to all the above recommendations. This way the system can be equipped with additional safety devices.

 Prior to performing maintenance or service inside an active system, remove one glove to allow a slow equalization of the glove box interior atmosphere with the ambient room air.

# **⚠** CAUTION

To better avoid the risk of suffocation, it is necessary for the glove box atmosphere to be completely replaced with ambient room air prior to servicing the interior of an active glove box.

# **MARNING**

Standard MBRAUN glove box systems are not designed for the use of strongly poisonous or radioactive substances. The system can be designed to meet these applications; however this must be discussed with MBRAUN prior to the acquisition of a system.

#### 1.7.3. Safety Instructions: General Hazards

This system has been designed and manufactured considering all relevant safety regulations. Improper use or operation by persons not qualified accordingly may result in danger to the:

- Life and health of the operator;
- System itself;
- · Surroundings of the user;
- Performance and efficiency of the system.

General hazards of the system may arise in the following ways:

- Mechanical hazard caused by squeezing, shearing and cutting, catching and winding, stretching or by freely moving parts;
- Thrust caused by kinetic energy of moving mass;
- · Sharp corners and edges;
- · Electrical hazard caused by touching live parts (directly or indirectly);
- Thermal hazard causing burns;
- Chemical hazard causing poisoning, corrosion and explosion;
- · Toxic hazard due to inhalation of vapours and gases;
- · Gases under pressure;
- · Liquids under pressure;
- · Combination of hazards caused by:
  - faulty installation
  - incorrect loading
  - breakdown of power or media supply
  - breakdown and/or incorrect arrangement of preventive measures
  - combination of escaping media
- Hazards caused by:
  - human misconduct
  - noise
  - allergies, excitations of mucous membrane, unknown effects caused by media
  - ejection of parts
  - disturbance / malfunction of control system
  - leaking of hoses or pipes
  - combination of atmospheres or vapours
  - fire hazard
  - natural hazards e.g. lightning, flooding, environmental catastrophes etc.

## 1.7.4. Over and under pressure safety of the box

Under normal operation condition the box may be operated between – 15 mbar and + 15 mbar (corresponding to – 1500 Pa to + 1500 Pa).

However in the unlikely case of a failure of a valve the box may be exposed to extreme pressures.

The standard safety feature to prevent dangerous situation arising from this malfunction is provided by the glove itself. The fixture of the glove has been designed in a way that the glove will be dismounted before any damage is caused to the box.



For standard systems always ensure that at least one glove port remains in normal operation. That means glove fixed and glove port not sealed with an inner or outer glove port cover.

The intended use of the inner glove port cover that is available as an option from MBRAUN is for sealing a glove port during exchange of a glove.

The intended use of the outer glove port cover that is available as an option from MBRAUN is for temporarily sealing a glove port.

Additional safety measures are required if the application requires that all glove ports be sealed simultaneously or to ensure that the inner box atmosphere remains protected from exposure to ambient air in the event of a valve malfunction. Please contact <a href="MBRAUN">MBRAUN</a> <a href="MBRAUN">Service Department</a> for further assistance.

This remark also applies to each section of multi-box systems with individual compartments, separated by an antechamber or an intermediate door, as well as for gas purification systems that have a multi-box operation-mode.

## 1.7.5. Safety Instructions: Mechanical



Freely moving parts may cause squeezing, shearing and cutting, catching and winding, stretching of extremities. Extreme caution should be taken to avoid touching any moving parts of the system during operation.

When handling materials with mechanical, pneumatic or vacuum systems it is possible that materials may be ejected. Extreme caution should be taken to avoid any possible contact with the ejected materials without proper protection.

Only genuine parts supplied by **MBRAUN** should be used in the operation of the system. These parts are constructed in conformance with applicable safety regulations. No liability will be taken by **MBRAUN** in the event of installation of parts manufactured by companies other than **MBRAUN**, which may result in additional and unknown hazards.

Simultaneous operation of the system by two or more persons is not recommended as this may cause hazards based on misconduct or mutual misunderstanding. In case of the system being operated by two or more persons, operation should be conducted in such a way as to ensure each individual's respective task does not influence other tasks in any way.

Safety covers, panels, panes, windows or doors may not be removed at any time, unless there is a need for service. The system may not be opened (i.e. antechambers, etc.) during processing or power failures. In the case of any safety deficiencies, the system must be decommissioned and the service personnel informed accordingly. During decommissioning compliance with all local health, safety and environmental guidelines must be followed.

#### 1.7.6. Safety Instructions: Electrical

This system operates under high voltage. Risk of injury caused by high voltages exists anytime the system is connected to the power supply, this includes when the system is powered off. Capacitors within the system may be charged when the system is switched off and disconnected from main power supply.



Interchange of current bearing wires can result in electrical hazards such as shock, involuntary muscle reaction, muscle paralysis, burnt tissues and organs, or death.

Connection to the main power supply must be performed by a qualified electrician according to local area guidelines. All neutral and ground wires must be connected accordingly.

Opening the system or removing parts when the system is powered on, may result in exposure to live electrical connectors. Extreme caution should be taken to avoid directly or indirectly touching live connectors to avoid possible electric shock.

# **⚠** CAUTION

Prior to performing any electrical service work on the system, ensure the system is powered off and disconnected from the power supply.

Service required while the system is in operation should only be performed only by qualified personnel trained in the knowledge and prevention of all potentially dangerous and hazardous situations.

The system must be grounded/earthed at all times. Do not remove or cut off any ground wire for the system or its components. In case of insufficient grounding or damaged ground conductor ensure the system will be inoperable and secure it against unauthorized or unintentional operation.

# **▲** DANGER

Insufficient grounding can cause electrostatic charging of plastic parts, hoses or pipes, wiring and/or the system as a whole, which could cause solvents and process chemicals to ignite when not within an Inert Gas atmosphere.

Replacement of fuses should be of the same type and current rating.



Makeshift fuses and/or short circuit fuse holders should never be used in the operation of the system.

## 1.7.7. Safety Instructions: Handling of Electronic Components

Electrostatic discharges can cause damage to parts. When handling electronic components the following precautions should be observed:

- a) Wear a grounded wrist strap or work on a grounded static-dissipating work surface. If this not possible touch an adjacent earth ground (i.e. central heaters or water pipes) before handling electronic components or printed circuit boards.
- b) Leave electronic components and printed circuit boards in their original packaging until final installation.
- c) Handle electronic components by their body or case, avoid touching of leads.
- d) Keep electronic components and printed circuit boards away from such static generating materials as vinyl, plastic bags, etc.



Maintenance and repair work required, but not listed in this manual, should only be carried out by MBRAUN service or by persons of equivalent qualification.

## 1.7.8. Safety Instructions: Chemicals and Gases

Chemicals used in the system are not supplied by **MBRAUN**. Chemicals are provided and applied by the system user.

Proper handling of chemicals, corrosives and solvents is the user's responsibility. Materials used may be flammable, explosive, toxic.

Below are some guidelines to refer to when handling chemical substances:

- Ensure the all relevant Control of Substance Hazardous to Health (COSHH) guidelines are followed;
- Observe relevant safety regulations as well as material safety data sheets (MSDS) and additional advice provided by the supplier;
- Wear proper protective safety masks, gloves and eyewear whenever working with chemicals, corrosives or solvents;
- Mark all containers and supply lines of chemicals (i.e. containers of media and waste) with appropriate labels and warning signs;
- Ensure proper ventilation and exhaustion of vapours;
- · Keep away from ignition sources;
- Do not smoke;



Released chemicals may react with each other, leading to unwanted and/or unknown substances, which may cause additional risks.

Proper handling of gases is the user's responsibility. Gases used may be flammable, explosive, toxic. Below are some guidelines to refer to when handling gaseous materials:

- Do not inhale the gas to avoid risk of suffocation.
- Prevent electrostatic charging and beware of ignition sources.
- · Do not smoke.



When using corrosive, gassing or noxious materials, the safety of all employees must be ensured by whatever means necessary. Specifically, all employees must be trained in the safe handling of the materials to be used.

## 1.7.9. Safety Instructions: Symbols Used on System

The following symbols refer to **MBRAUN** components and parts. However, components and parts of sub-suppliers may show other symbols, not expressly mentioned or referred to in this manual. The following caution and command symbols may be seen on the system:

Table 1.2: Safety Symbols



General hazard



Electrical hazard



Pressurised gas hazard



Wear safety mask



Wear safety goggles



Wear protective gloves

# **M** NOTICE

The owner of the system is responsible to place adequate danger signals and labels in suitable places. This applies in particular to signals and labels concerning process chemicals used. Regardless of the number of caution symbols and information placed on or around the system, all safety instructions of this manual must be observed!

## 1.7.10. Safety Instructions: Emergencies

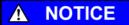
In case of an emergency, please observe the following instructions:

- 1. Immediately shutdown the system using the main power switch.
- 2. Disconnect the system from all gas supplies.
- 3. Refer to the material safety data sheets for information on treating the emergency. Contact the appropriate emergency response personnel in the area and/or listed on the material safety data sheets.



Do not disconnect the water supply for systems containing components requiring a cooling water source.

Prior to restarting, the system must be fully checked for safety, contact the **MBRAUN** Service Department after the emergency has been rectified.



In addition to the information contained in this manual all local health, safety and environmental guidelines must be followed.

## 1.7.11. Additional Safety Information

The system is considered unsafe for operation if:

- · there is any visible damage;
- it fails to perform according to specification;
- it has been subject to prolonged storage under unfavourable conditions;
- it has been subjected to severe transport stress.

If the system meets any or all of the above:

- make it inoperable;
- secure it against any unauthorized or unintentional operation;
- contact the MBRAUN Service Department.



Do not perform any service or repair of the system or its components other than described in this manual.



Maintenance, repair and service other than described in this manual may only be performed by MBRAUN service personnel or properly trained/qualified individuals.

#### 1.8. Transport, Storage and Site Location

Prior to installation and operation of the system, the Operating Instructions must be read and observed. Contact the MBRAUN Service Department with any questions.

#### 1.8.1. Transport

Preparations for transporting an MBRAUN system should be carried out by an MBRAUN technician only. The transport of the system or any part of a multi-unit system should be performed by a forwarding agency offering specialized transportation services.



The system is extremely heavy and awkward, if not handled properly tipping or overturning may occur. Use extreme caution when transporting a system and ensure all parts are securely fastened prior to relocation.

#### 1.8.2. Storage

The system can be stored safely under the following conditions:

- Free of liquids or substances (e.g. process chemicals, etc.);
- Room temperature between +10°C and +40°C with a relative humidity ≤80% and no condensation;
- Protected from dust and contamination.

# **▲** NOTICE

After moving the system from storage conditions to final site location allow sufficient time for the system to adapt to the current environment.

#### 1.8.3. Site Location

Selecting the site for an **MBRAUN** system or any part of a multi-unit system should be carried out by **MBRAUN** technicians only.

#### Prerequisites:

Table 1.3: Prerequisites

Room:	<ul> <li>Dry atmosphere with a temperature between +15 °C and +30 °C;</li> <li>Well ventilated.</li> </ul>
Surface Conditions:	Firmly structured floor;     Level positioning.
Clearance:	<ul> <li>Minimum distance of 600 mm from surrounding walls</li> <li>Allow sufficient working area where glove ports, antechambers, etc. require access.</li> </ul>

#### 1.9. Modifications

Changes and/or modifications of any kind to **MBRAUN** systems should be made by **MBRAUN** technicians only. Any unauthorised change or modification to the system will cause the warranty to expire. However, exceptions can be made with prior written confirmation from **MBRAUN** (Refer to section 1.3 Warranty for additional information).

#### 1.10. Standards, CE Conformity

This system corresponds in its technical design to various international and national standards listed below, as well as other standards, directions and regulations.

All MBRAUN Standard Systems are covered exclusively by the EC Directive 73/23/EEC, because the risks are mainly of electrical origin.

# **A** NOTICE

A complete listing of all applied harmonized norms are available upon request from MBRAUN Service Department

#### 1.10.1. Electrical safety

• **Directive 73/23/EEC** 19 February 1973 on the harmonisation of the laws of

Member States relating to electrical equipment designed for use within certain voltage limits as last amended by

Directive 93/68/EEC

EN 60204-1:1997 Safety of machinery:

Electrical equipment of machines. Part 1: General requirements.

■ ISO 13849-1:1999 Safety of machinery:

Safety-related parts of control systems. Part 1: General principles for design

#### 1.10.2. Electromagnetic Compatibility

• **Directive 89/336/EEC** 3 May 1989 on the approximation of the laws of the

Member States relating to electromagnetic compatibility

1.10.3. Safety of Machinery

• **Directive 98/37/EC** 22 June 1998 on the approximation of the laws of the

Member States relating to machinery

1.10.4. Noise Emissions

• Sound Pressure The A-weighted sound pressure level at the system does

not exceed 70 dB(A).

## 1.10.5. EC declaration of conformity



The system complies with all the essential health and safety requirements of the applicable EC harmonized technical directives.

The EC declaration of conformity is forwarded to the user. The system bears the CE marking.