Technical opinion

on the subject of

"Specifications for mobile glove boxes for crisis intervention in situations of extraordinary biological hazard"

Issued by:

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Contents

1 Preface

Mobile glove boxes (MGBs) are technical devices designed to protect employees in crisis intervention in situations of exceptional biological hazard. This general opinion covers specifications for mobile glove boxes in accordance with norms for cutting edge technology, such as DIN EN 12469 and DIN 12980.

Given that activity using mobile glove boxes in accordance with customary specifications for a class 3 conventional microbiological safety workbench is often not feasible for crisis intervention in situations of extraordinary biological hazard due to practical reasons, the issue of special recommendations for usage is appropriate.

In accordance with the Biological Agents Ordinance (BioStoffV), mobile glove boxes must be designed in such a way that the propagation of aerosols outside of the glove box is reduced, prevented or excluded and that employees do not come into contact with these, (as with class 3 microbiological safety workbenches).

For the correct assignment of activities using a mobile glove box, the employee must carry out a risk assessment prior to carrying out their work.

For reasons pertaining to organisation and practicality, it is not possible to carry out a commissioning audit (test type 3), which is a requirement in stationary laboratories, in most cases. An expert service technician is not normally available on the operation site. An independent audit and certification should therefore be carried out on the MGB by an accredited body (such as the TÜV) based on this technical opinion. The manufacturer must be able to provide proof of a certified quality assurance system (e.g. ISO 9000ff).

The requirement for a regular (normally annual) routine check (test type 4) at the point of use may also be waived, given that the device is intended for use over a restricted period of time (e.g. of three to five weeks).

The use of mobile glove boxes as an alternative to microbiological safety workbenches of class 1, 2 or 3 in a laboratory environment is not permitted.

2 Scope

Molecular-biological diagnostics play a decisive role in intervention in the case of an outbreak of an unknown disease or to support containment measures in epidemics caused by dangerous infectious agents such as viral haemorrhagic fevers (such as the Ebola virus) for the following activities:

- in identifying the triggering agent,
- in identifying infected persons to take quarantine measures.

The devices can be used for sample preparation and for initial diagnosis in patients or on samples carrying unknown pathogen types, in the context of non-targeted activities.

Disease outbreaks caused by hazardous infectious agents often occur in regions where resources are limited and where the infrastructural conditions required for this kind of diagnosis (and therefore any effective countermeasures) are not available.

Mobile diagnostic elements, which can be quickly transported to the operation site, can provide a solution to this issue. These elements must be operated as closely as possible to the source of infection to keep the so-called turnaround time (i.e. the

period of time between taking the patient sample and receiving the results) as short as possible. The mobile diagnostic device must also be designed to be able to follow moving or changing sources of infection throughout the course of an outbreak.

A stationary laboratory at protection level 3 or 4 does not meet specifications such as mobility for quick deployment in areas that are difficult to access. The same applies to the class 3 microbiological safety workbenches available on the market for use in stationary operation, which fail to meet the specifications outlined above in any case due to their weight. With diagnostic elements however, appropriate occupational health and safety measures must be taken in order to reach the protection target without compromising the operation and its purpose.

At choosing which procedure to implement, it already must be ensured that risks are minimised, as outlined in the risk assessment. Therefore, molecular biology diagnostics are the focus of these diagnostic devices, while enrichment cultures in pathogens capable of multiplication should be avoided. This reduces the necessary number of high-risk activities to the inactivation of pathogens that are potentially contained in the patient sample. Qualified personnel must also have undertaken the appropriate educational and training measures to enable them to safely carry out the diagnosis procedure and minimise risks as far as possible in accordance with the risk assessment.

Health and safety conditions must be met when inactivating samples as part of non-targeted diagnosis procedures under field conditions in order to prevent putting the personnel at risk of accidental release of living pathogens. In principle, there are two possibilities for this happening:

- Working openly with infectious samples in an enclosed space where pathogens may be released. Protective measure: Wearing personal protective equipment (PPE) with respiratory protection.
- Working with infectious samples in a mobile glove box. Inactivating samples in a mobile glove box enables outward transfer and further processing of samples that are no longer infectious.

Previous field experience using both of these two variants has demonstrated that the use of mobile glove boxes is preferable. Wearing PPE involves more requirements in terms of infrastructure (an enclosed laboratory space is required). Wearing PPE also puts a significantly higher strain on personnel; particularly those working in warm climatic conditions, and require shift work and therefore a significantly larger workforce. Trained personnel are one of the most limited resources in the case of disease outbreaks.

Mobile glove boxes, on the other hand, into which samples can be inserted and inactivated, proved very useful during the Ebola outbreak in West Africa in 2014/2015, as well as in other cases. This protective measure removes the need to wear PPE with respiratory protection.

Criteria for using a mobile glove box:

The use of a mobile glove box for sample inactivation in the context of non-targeted medical diagnostic activities using samples which may contain pathogens from risk group 3 or 4 is considered an adequate occupational safety measure in accordance with BioStoffV for the following indications:

- Outbreak of an unknown disease and/or epidemic caused by an infectious biological agent from risk group category 3 or 4 and
- Outbreak in an area where infrastructure is limited: No stationary diagnostic facility with a minimum protection level of 3 is accessible within 4 hours or the capacity of the stationary diagnostic facilities available is not sufficient.

3 Definitions

3.1 Mobile glove box (MGB)

Enclosed protective device with negative pressure and (turbulent) interior air current. The operating personnel have access to the inside of the box via the point of access. Supply air is filtered by one filter and exhaust air by two filters connected in a series.

3.2 Personal protection

Retention capacity that prevents any aerosols that might constitute a hazard to the operating personnel from leaking out of the MGB into the environment.

Note:
When using an MGB, the protection outlined above can be achieved by using sealed housing with a defined leak rate, maintaining negative pressure, as well as using the glove system and appropriate transfer equipment.

3.3 Point of access

Components for carrying out processes and handling products and devices within the MGB.

3.4 Gloves

This point of access component allows the operator to access the interior of the MGB with their hands, while maintaining an effective barrier.

3.5 Glove opening

Glove connection point (arm port).

3.6 Multi-component glove system

Multi-component access system, consisting of a one-piece arm protection made up of a glove system, connecting elements (sleeve), and the glove itself.

3.7 Gauntlet

One-piece glove system to cover the whole arm.

3.8 Transfer system

Air locks, that enable transport of materials into and out of the MGB while reducing the release of unwanted aerosols to a minimum.

3.9 Situations of extraordinary biological hazard

If an outbreak displays infectious medical, microbiological or epidemiological characteristics that deviate from what is considered 'normal', the outbreak is classed as 'extraordinary'. A 'normal' outbreak is one that displays characteristics of an endemic infectious disease corresponding to the known geographical, seasonal and

demographic distribution of the area and the expected corresponding epidemiological characteristics.

3.10 Diagnostic samples

Excreta, secretions, blood and blood components, tissue and tissue fluids from humans and animals, which are used for the purposes of clinical laboratory testing.

3.11 Test type

3.11.1 Test type 1

A single, comprehensive test (type test/examination) on an MGB carried out by the manufacturer or an independent/neutral third party (e.g. TÜV).

3.11.2 Test type 2

Tests (routine tests) carried out by the manufacturer on all MGBs during or at the end of production and before delivery.

3.11.3 Test type 3

Commissioning tests comprise any controls carried out before the device is deployed, which should be carried out by the operator once the MGB has been set up or following any changes to the installation or environment.

In the case of **(3)** there are normally designated tests for stationary laboratories, however, in the case of MGBs, these cannot be carried out for practical reasons (see preface).

4 Safety and protection objectives

MGBs must protect the operator and environment from the harmful effects of biological agents inside the MGB (personal protection).

Note:
MGBs must not pose any risk to the operator (e.g. mechanical or electrical risks).

5 Structure

MGBs must be contained on the front side by a viewing panel with point(s) of access. Materials can only be transferred into the interior of the device via the transfer system.

MGBs must have an air supply flowing into the interior of the device. The air that enters the device must be filtered with a HEPA filter of class H 13 or equivalent filtering system (e.g. P3 respiratory apparatus filters). The exhaust air must be filtered by at least two filters connected in a series and the supply air must be filtered by a HEPA filter of class H 13 or an equivalent filtering system. In normal operation, a negative pressure of at least -50 Pa should be applied (in comparison to the working environment).

6 Construction and design

6.1 Materials

6.1.1 Specifications

Generally speaking, all MGB components should be resistant to water, the corrosive properties of any gases or liquids used inside the device as well as any suitable cleaning and disinfectants used to clean the device. Smooth materials should be used for the interior work surface. These materials should be resistant to abrasion and corrosion.

The materials used for the external surfaces should also be smooth and resistant to abrasion and corrosion. Any coating should be applied in such a way that avoids the formation of cracks and chips.

6.1.2 Test

Test: Inspection and verification of certification (manufacturer's certificate(s)).

Test type: 1

6.2 Ventilation technology

6.2.1 Activation/deactivation

The ventilation system of an MGB can only be switched on and off by the operator using a special tool, key, swipe card or by entering a code.

Test: Inspection, ventilation, activation and deactivation.

Test type: 1, 2, 3

6.2.2 Ventilator

The ventilator motor must run automatically while the device is in operation, even during a power failure.

Test: Inspection of the circuit layout, performance test.

Test type: 1, 2, 3

6.2.3 Aspiration and exhaust ports

When the MGB is in operation, the aspiration and exhaust ports must not be covered.

Test: Inspection, operating instructions, quick start operating instructions.

Test type: 1, 2, 3

6.2.4 Air flow volume

The volume of air flowing through the supply air filter should be at least 180m^3/h per m^3 of MGB volume.

Test: Measuring.

Test type: 1, 2, (3)

6.2.5 Intake air flow

The volume of air intake should correspond to the minimum value outlined in section 6.3.3 when the glove is removed.

Test: Measuring.

Test type: 1, 2, (3)

6.3 Points of access

6.3.1 Gloves and gauntlets

Gloves or multi-part glove systems used at the point of access must meet the specifications for category III PPE (complex PPE) in accordance with EC Directive 89/686/EEC and any future applicable EU directives on personal protection equipment (PPE).

Gloves and gauntlets must be tested, in particular for resistance to permeation and penetration. These tests must be carried out in accordance with DIN EN 374-1, DIN EN 374-2, ASTM F1671 and DIN EN 16523-1 (gloves) or DIN EN 14605 (gauntlets) as appropriate.

MGB manufacturers must set appropriate change intervals.

Test: Inspection and certification for type examination, declaration of conformity and operating instructions.

Test type: 1

6.3.2 Changing point of access

The construction of the MGB must ensure that the point of access/glove can be changed in a way that ensures low risk of contamination.

Test: Evaluation of glove/point of access changes by carrying out a trial in accordance with manufacturer specifications; additional pressure test.

Test type: 1, 2, (3)

Note:
Possible suitable procedures are listed in VDI 2083 sheet 16.1:2010-08.

Once the point of access components have been changed, the airtightness of the point of access must be checked.

Each time the gloves are changed, a visual inspection must be carried out to check the gloves, and the connection between the gloves and the gauntlet.

Test: Visual inspection.

Test type: 3

A pressure test must be carried out at the point of access at least once each working day in accordance with manufacturer specifications or other valid procedures conforming to VDI 2083 sheet 16.

Test: Pressure test.

Test type: (3)

6.3.3 Personal protection in the case of glove tear-off

In accordance with DIN EN 12469:2000-09, C.2. Specifying the testing procedure depending on the design of the MGB. Possible set-up:

- Fully remove the gloves/glove system prior to testing.
- To position the nebuliser: Ensure the spray axis is at the same height as the upper edge of the point of access. Distance from front panel: 100 mm, no stainless steel cylinder.
- Liquid sampler (LS), positioning: Two LS at the same height as the upper edge of the point of access, two LS at the height of the centre of the point of access, two LS at the height of the lower edge of the point of access; horizontal gap as stipulated in DIN EN 12469.
- two channel samplers, positioning: Horizontal level of the air inlets at the height of the lower edge of the point of access, horizontal gap between air inlets and outer vertical edges of the point of access: 200 mm, vertical axis of the inlet 150 mm from the front panel.
- Carry out positive control.
- Three tests should be carried out on each point of access.
- Only the point of access to be tested should be open.

Test: Microbiological test. Designation and documentation of the incoming flow velocity; visualisation using smoke.

Test type: 1

Test: Test for incoming flow velocity value, visualisation using smoke.

Test type: 2, (3)

6.4 Disinfectability and cleanability

6.4.1 Routine operation

The surfaces of the MGB must be resistant to the cleaning and disinfectants used. A disinfectant suitable for a wide range of applications should be used. The interior surfaces of the MGB should be as even as possible to facilitate cleaning and disinfection processes. All interior surfaces attached to the material locks, including airlock doors, must be easy to clean and disinfect. All external surfaces of materials to be used within an airlock environment must be easy to clean and disinfect. The use of UV rays should be avoided as these are known to have a limited effect.

Test: Inspection, inspection of operating instructions, material certification.

Test type: 1

6.4.2 Final disinfection

Disposable MGBs (that can be disposed of after mobile use) should be used where possible. All surfaces (interior and exterior) should be cleaned and disinfected before disposal. Thermal disinfection is then carried out on the hermetically sealed MGB, normally through complete incineration of the device. National specifications regarding this process should also be adhered to.

Test: Inspection, inspection of operating instructions.

Test type: 1

6.5 Transfer systems

The possibility of accidental opening of the transfer system must be excluded. Openings should be interlocking to prevent the possibility of potentially infectious biological agents from being released.

Test: Visual inspection and performance test.

Test type: 1, 2

6.6 Filter technology

6.6.1 Filter types

As a minimum a HEPA filter should be used to filter air in accordance with DIN EN 1822-1 of filter class H 13 or equivalent.

Test: Manufacturer's works certificate.

Test type: 1

6.6.2 Airtightness and leak tightness

The air filters must be permanently airtight and leaktight. The air filters must not show any signs of leaks (e.g. as a result of transport damage), even after installation. The airtightness of the filters must be ensured by using permanent, flexible seals.

Test: In accordance with VDI 2083 sheet 3 or DIN EN ISO 14644-3.

Test type: 1, 2, (3)

6.6.3 Protection

All filters must be protected against mechanical damage.

Test: Visual inspection to check for protection devices.

Test type: 1, 2, 3

6.6.4 Filter change

The MGB must be designed so that the contaminated filters can be changed in a way that ensures low risk of contamination, e.g.

- using the Ohlmeyer procedure or
- modular filter removal procedure. This ensures that the contaminated filter elements can be disposed of in commercial disposal containers adapted for the individual filter types, e.g. in 60 litre containers
- or separately in the case of modular filters, e.g. in two or three filter systems.

Test: Evaluation of filter change by carrying out a trial.

Test type: 1

6.6.5 Protection against liquids

Filters in certain areas, e.g. underneath segmented and/or perforated work surfaces should be protected from liquid spills and droplets.

Test: Spill simulation (provocation test with UV tracer). Method: A 250 ml measuring cylinder (plastic) conforming to DIN 12681 specifications is filled to nominal capacity with a 2% fluorescein sodium solution. The cylinder is then placed in the middle of the work surface and tipped over to the left or right (whichever represents the most unfavourable situation). Once the liquid has been carefully removed from the work surface, it can be disposed of. The filters are examined with a suitable UV light for any residue of the spilt liquid. No residue should be visible on the filters.

Test type: 1

6.7 Leak tightness – housing

The leak tightness of the housing must conform to class 4 of the ISO 10648-2:1994-12 standard, table 1. The test pressure should correspond to four times the amount of internal pressure inside the device under normal working conditions, however this should be equivalent to at least -250 Pa (negative pressure). The acceptance criterion corresponds to a leak rate of 10% of the total volume per hour.

Test type: 1, 2

The housing and transfer system of the MGB should be tested at least once a week while the device is in operation according to its intended purpose. The acceptance criterion is a leak rate of 10% of the total volume per hour under a pressure level of at least two times higher than the target pressure level range for normal working conditions.

Test type: (3)

Note:
For the airtightness test, a constant pressure test is used. In a constant pressure test, leak rate is determined by the current of exhaust air.

Test: In accordance with ISO 10648-2.

6.8 Stability/sturdiness

MGBs should conform to the stability specifications outlined in EN 61010-1. MGBs should be designed to be suitably stable and slip-resistant when set up on the floor or on a table. In particular, the tilt stability of mobile constructions, hinged front panels and service hoods, etc. should be tested. The device should also be checked to ensure it cannot be knocked or tipped over.

Test: In accordance with DIN EN 61010-1 and visual inspection of operating instructions.

Test type: 1

6.9 Viewing panels

Any viewing panels built into the device must be made from plastic materials that are resistant to disinfectants.

Test: Verification of certification (manufacturer's certificate(s)).

Test type: 1

6.10 Noise levels

The maximum noise levels emitted by an MGB at the airflow velocity/flow rate recommended by the manufacturer and measured at a height of 0.7m from the lower edge of the device and at a centre distance of 0.5m from the viewing panel must not exceed 60 dB(A).

Test: Measuring.

Test type: 1

6.11 Lighting

The average nominal illuminance of the work surface in accordance with DIN EN 12665 should be at least 750lx.

Test: Measuring.

Test type: 1

6.12 Ergonomics

The general ergonomic specifications outlined in DIN EN ISO 14738 should be adhered to.

Test: Inspection; measuring if applicable.

Test type: 1

6.13 Control and display elements

Control and display elements must not be positioned in the contaminated workspace.

Note:
Measuring devices must be protected from the workspace using protection filters against germs.

Test: Visual inspection and operating instructions.

Test type: 1

6.14 Monitoring devices

Differential pressure should be constantly measured and monitored as the basis of the vacuum monitoring procedure and importantly, for monitoring the barrier function.

It is important to ensure that no biological agents can be released. To this end, negative pressure level of at least 50 Pa must be maintained.

The display device must be easily visible to the operator from the main working position (e.g. from a sitting position).

To display the internal pressure of the MGB, a manometer suitable for taking measurements between -500 and +500 Pa must be used.

If the device is operating outside of the safe operating limits, a visual warning signal (red control light) will be displayed and an audible warning signal should be heard.

There should be no setting off for the visual warning signal when the device is in operation (i.e. an off switch). Audible warning signals can be set off (be switched off). If the audible warning signal has been switched off once (1st error warning), the monitoring device must be reset so that the audible warning signal will be indicated

for any further warnings. This should be done no later than five minutes after the signal is initially switched off.

When the MGB is started up, an audible signal should sound until conditions are safe for operating the device.

Test: The monitoring devices can be tested by intentionally setting the device to pressure levels outside of the target range for operation in accordance with DIN EN 842 and DIN EN ISO 7731.

Test type: 1

Test: Test by setting device to levels outside of target state operation.

Test type: 2, 3

6.15 UV-C lamp

The use of ultraviolet (UV) rays is not recommended in MGBs.

6.16 Emergency power supply connection

An emergency power supply must be provided for safe operation of the MGB.

Test: Instruction manual.

Test type: 1

7 Test

Scope and details of MGB tests can be found in table 1 of DIN EN 12469 and DIN 12980.

7.1 Protocol

The test and subsequent results must be unambiguous and reproducible. This includes (among other things) measuring equipment, customer; test item, tester, location; time, specification; comparison of target/actual results, etc.

7.2 Scope

Table 1: Tests to be carried out on MGBs in accordance with DIN EN 12469 and DIN 12980

Specifications	**Test type**			
	1	**2**	**3**	**(3)**
	Liability			
	Manufacturer		**Operator**	
Materials	x	-	-	-
Stability/sturdiness	x	-	-	-
Viewing panels	x	-	-	-
Noise levels	x	-	-	-
Lighting	x	-	-	-
Ergonomics	x	-	-	-
Control and display elements	x	-	-	-
Monitoring devices	x	x	x	-
Emergency power supply	x	-	-	-
Labelling	x	x	x	-
Accompanying documents	x	x	x	-
Ventilation technology				
Activation/deactivation	x	x	x	-
Ventilator	x	x	x	-
Aspiration and exhaust ports	x	x	x	-
Air flow volume	x	x	-	x
Intake air flow	x	x	-	x
Points of access				
Gloves and gauntlets	x	-	-	-
Changing point of access	x	x	-	x
Visual inspection and pressure test	-	-	-	x
Microbiological personal protection test in case of glove tear-off	x	-	-	-
Incoming flow velocity and visualisation in case of glove tear-off	x	x	-	x
Disinfectability and cleanability				
Routine operation	x	-	-	-
Final disinfection	x	-	-	-
Transfer systems				
Visual inspection and performance test	x	x	-	-
Filter technology				
Filter type	x	-	-	-
Airtightness and leak tightness	x	x	-	x
Protection against mechanical damage	x	x	x	-
Filter change	x	-	-	-
Protection against liquids	x	-	-	-
Leak tightness – housing				
Pressure test (4x target level of negative pressure)	x	x	-	-
Pressure test (2x target level of negative pressure)	-	-	-	x

Test types: *1 type test; 2 routine testing; 3 commissioning test - visual inspection and performance test; (3) commissioning tests cannot normally be carried out, although these are customary for stationary installations.*

8 Labelling

8.1 Identification label

MGBs should carry an identification label positioned in an area that is visible when the device is in operation. The following information should be displayed as a minimum requirement using abrasion-resistant materials:

- Manufacturer/supplier; information in accordance with § 6 ProdSG [German Product Safety Act] specifications (name, street, number, postcode, location within the EEA); minimum size 9 pt (3.2 mm);
- Nominal data (supply voltage, power and frequency, total power consumption);
- Year of manufacture;
- Type/model description;
- Serial number;
- MGB conforming to technical opinion for MGB, ABAS decision 9/2016
- Negative pressure levels for operation;
- Intake air flow velocity;
- Air flow volume;
- Weight;
- PPE required for operation (gloves, gauntlets);
- Filters required.

8.2 Warning label

Above the point of access on the MGB, warning label W009 'Biohazard' must be displayed with the corresponding DIN EN ISO 7010.

8.3 Quick start instruction manual

A quick start instruction manual should be affixed to the MGB, outlining the most important information regarding safe operation and disposal.

Test: Verification of labels referred to in point 8 should be carried out by means of an inspection.

Test type: 1, 2, 3

9 Accompanying documents

Operating instructions should be provided with the MGB in German in accordance with DIN EN 82079-1 (VDE 0039-1):2013-06. These must include, among other information, all specifications required for tests carried out prior to initial commissioning of the device (test type 3).

Specifications for maintenance and test intervals must also be provided.

The operating instructions must include the following information:

a) A declaration or certificate of conformity;
b) Assembly instructions with information on how to connect the MGB to an electrical power supply;

c) Description of proper use and foreseeable forms of misuse;
d) Specifications for maintenance and procedure for changing the filter to avoid contamination as well as disposal specification;
e) For MGBs, specifications for the maintenance and changing of the point of access as well as any associated tests and disposal specifications;
f) Specifications for disinfection and cleaning including suitable disinfectants and procedures;
g) Any manufacturer's specifications for safe operation including requalification and monitoring measures, e.g.
   - average air flow volume through the air filter;
   - average intake air flow velocity when gloves are removed;
   - negative operating pressure compared with the working environment in normal operating conditions.

Test: Maintenance by means of visual inspection.

Test type: 1

Verification of availability of operating instructions.

Test type: 2, 3

Note:
As a basic principle, the operating instructions must be written in German. Provision of the operating instructions in any other language are to be arranged between the manufacturer and operator.

10 Summary

This technical opinion defines the minimum specifications for mobile glove boxes (MGBs) for crisis intervention in situations of extraordinary biological hazard. These devices are usually used for limited periods of time or e.g. for one period of several weeks.

The manufacturer of the MGB must be able to provide proof that all specifications within the scope of a type test have been met and audited by an accredited body (e.g. TÜV). The manufacturer should also have a certified quality assurance system in place to ensure that minimum quality specifications are met.

A comprehensive commissioning test carried out by the operator at the operation site is often not feasible for practical reasons. This justifies stricter specifications for the manufacturer in the form of testing and certification.

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