Technical Specification

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# Patient compartment of negative pressure ambulance — Technical specifications

*Compartiment patient pour ambulance à pression négative — Spécifications techniques*



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# Foreword

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This document was prepared by Technical Committee ISO/TC 22, *Road vehicles*, Subcommittee SC 40, *Specific aspects for light and heavy commercial vehicles, busses and trailers.*

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# Introduction

According to the data from World Health Organization, there have been large-scale outbreaks of respiratory infectious diseases in the past decades, such as SARS, bird flu, H1N1, MERS, CoVID-19, etc., posing a huge challenge to the public health system. In the fight against respiratory diseases, the concept of negative pressure ambulances was initiated by public health and epidemic experts. For the establishment and improvement of the public health emergency rescue system, we have studied the negative pressure ambulance products with global experts.

A negative pressure ambulance is defined as an ambulance fitted with negative pressure and sterilization equipment, used for the care, monitoring and transportation for respiratory disease patients. It provides treatment for patients, isolates sources of transmission and prevents cross infection effectively. Due to the highly contagious nature of respiratory viruses, conventional ambulances are not up to the task of transporting. Compared with conventional ambulances, negative pressure ambulances can effectively block airborne transmission, greatly reduce the risk of infection for medical and public personnel, as well as the contamination of the surrounding environment, effectively ensuring the safe transport of respiratory infection patients.

As a special type of ambulance, the difference between a negative pressure ambulance and any other conventional ambulance mainly lies in the patient compartment, which has functions such as blocking the source of infection, disinfecting and sterilizing, preventing cross-infection and many others. In the state of the art, there are no special, systematic and unified technical requirements for negative pressure ambulances globally. During the production and use phase, the absence of unified regulations and unbalanced standards for the negative pressure ambulance, especially for its patient compartment, causes great trouble to the production and leading the risk of use. For the safe use of negative pressure ambulances, it is of great significance to develop a technical specification for the patient compartment of negative pressure ambulances in the ISO system as a global reference in line with their differences and characteristics. This document mainly involves the special requirements and test methods of the patient compartment, including sealing and isolation, negative pressure, ventilation rate, directional airflow, sterilization system, filtration, and sterilization device of the negative pressure system. Relative technical standards and test methods are fully in accordance with the needs of the medical and health industry, to improve the technical level of the products and provide safer services in the transfer of patients, and promote effective and timely treatment of patients in the epidemic environment.

In summary, forming a set of global, unified, formal negative pressure ambulance technical specifications of patient compartments could have a positive impact on controlling infectious respiratory diseases around the world, reduce the risk of transmission and can better protect medical workers and the surrounding environment.

# Patient compartment of negative pressure ambulance — Technical specifications

## 1 Scope

This document specifies the relevant terms and definitions, technical requirements and test methods for the patient compartment of negative pressure ambulances.

This document is applicable to ambulances equipped with negative pressure systems.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all their content constitutes the requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 12219-1, *Interior air of road vehicles — Part 1: Whole vehicle test chamber — Specification and method for the determination of volatile organic compounds in cabin interiors*

EN 1789:2020, *Medical vehicles and their equipment — Road ambulances*

## 3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

ISO and IEC maintain terminology databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at https://www.electropedia.org/

**3.1**
**ambulance**
vehicle used to treat, monitor and transfer at least one patient, and is equipped with at least two seats for trained personnel

**3.2**
**negative pressure ambulance**
type of medical emergency vehicle equipped with negative pressure and disinfection facilities with the purpose to cure, monitor and transfer persons with respiratory infectious diseases

**3.3**
**negative pressure system**
device that achieves an air pressure below a specified value of atmospheric pressure in a medical compartment and has the function of targeted collection and disinfection of exhaled air from patients with respiratory infectious diseases

Note 1 to entry: It usually consists of a negative pressure fan, a filtration device, a disinfection device and a gas collection device.

**3.4**
**patient compartment**
internal area of the *negative pressure ambulance* (3.2) which is equipped with a *negative pressure system* (3.3) and used for transporting and/or treating patients with respiratory infectious diseases

# 4 General requirements for patient compartment

The patient compartment of the negative pressure ambulance shall meet the requirements of the type-B or type-C ambulance in EN 1789:2020, 4.4.

# 5 Special requirements for patient compartment

## 5.1 Sealing and isolation requirements

The patient compartment shall be separated and sealed from the driver's compartment, or an independent square compartment shall be used as the patient compartment to prevent the air in the patient compartment from spreading to the external environment.

When the vehicle is stationary, close all the doors and windows of the patient compartment, turn on the negative pressure system after activating the vehicle, and adjust the flow rate of the air outlet of the negative pressure system to (240 ± 5) $m^3/h$, and the negative pressure value in the patient compartment shall be below -18 Pa.

The patient compartment shall be independent of the ventilation system of the driver’s compartment.

## 5.2 Requirements for performance of negative pressure

When the vehicle is stationary, close all the doors and windows of the patient compartment, activate the vehicle and turn on the negative pressure system. After the system is turned on for 3 min, the negative pressure value in the patient compartment shall be between (-30 Pa and -15 Pa), and the fluctuation range of the negative pressure value after stabilization shall be less than ±3 Pa.

## 5.3 Ventilation frequency requirements

When the vehicle is stationary, close all the doors and windows of the patient compartment, activate the vehicle and turn on the negative pressure system. After the system is turned on for 3 min, the air change rate of the patient compartment shall not be less than 20 times per hour.

## 5.4 Air directional collection efficiency requirements

The vehicle shall have the function of directional air collection. When the vehicle is stationary, close all the doors and windows of the patient compartment, activate the vehicle and turn on the negative pressure system. After the system is turned on for 3 min, the air flow in the patient compartment shall be directed towards the collection port near the patient's head. The air in the patient compartment flows into the negative pressure system through the air collection device and shall only be discharged to the outside of the vehicle after filtration. The efficiency of the directional air collection shall be ≥90 %.

The gas collection device shall be able to isolate the gas exhaled by the patient in a relatively independent space. The air collection device shall facilitate medical staff to take care of patients in real-time during transportation, such as first aid, monitoring, medication, etc., without affecting the convenience of patient movement.

## 5.5 Requirements for disinfection system

The patient compartment shall be equipped with disinfection systems. The device shall have a timing function and be able to finish disinfection without personnel intervention.

As for spray method for disinfection, the atomized liquid shall meet the non-toxic requirements in terms of oral, inhalation, eye irritation/corrosion and skin irritation/corrosion, etc. The disinfection effect of spray method shall achieve a microbial killing logarithm greater than or equal to 3,00.

As for other methods for sterilization, there can be local medical and health regulations related to the disinfection products.

## 5.6 Requirements for filtration equipment of negative pressure system

The negative pressure system shall efficiently filter all the air discharged from the vehicle to achieve the biological safety protection of the surrounding environment.

When filtering the particles with a diameter of ≥0,3 μm, the filtration performance of the built-in filter material in the negative pressure disinfection system shall reach the filtration efficiency of ≥99,7 %. The filter material shall be easy to replace.

According to ISO 29463-1, the built-in air filter of the negative pressure system is tested under the condition of no less than the actual air volume, and its filtration performance shall meet ISO 30E or above.

The filter shall be easy to install and replace in a sealed manner, and shall not be loosened or damaged during vehicle operation.

The filter shall not be damaged after repeated disinfection with various common disinfectants, and the filtration performance shall not be weakened.

## 5.7 Requirements for disinfection device of negative pressure system

If ozone sterilization is used as a built-in disinfection device in the negative pressure system, it shall be able to offer an ozone concentration of ≥60 mg/m$^3$ inside the negative pressure system. The disinfection device shall have the function of timing, which can carry out the timing disinfection treatment for 60 min and above without personnel intervention. As for other disinfection methods, there can be air disinfection regulations or local medical regulations related to the corresponding device. After setting the ozone timing disinfection function, personnel shall immediately evacuate from the patient compartment and close all the doors and windows.

# 6 Marking

Negative pressure ambulances shall be equipped with markings, which shall be fixed by bolts, rivets, adhesives, etc. according to the body structure. The markings shall be firm, reliable and easy to detect and identify. The style of the label is shown in Figure 1. The background colour of the marking shall be yellow, the symbol shall be black, and the side length of the label shall not be less than 130 mm. A label shall be placed on both sides of the patient compartment.


NOTE The upper part is the sign indicating a biological hazard warning with reference number IS0 7010-W009. The lower part indicates that the marking applies to negative pressure ambulances.

**Figure 1 — Negative pressure ambulance marking**

# 7 Manual

The product manual of negative pressure ambulance should at least include the following contents:

— instruction for use case of negative pressure ambulance: when performing tasks, turn on the negative pressure system and keep the patient compartment sealed throughout the process. When the vehicle enters the decontamination area and is ready for decontamination, the negative pressure system is allowed to be turned off and the decontamination shall be started immediately;

— replacement intervals and steps for filter cartridges for negative pressure systems;

— use of negative pressure system and disinfection system in negative pressure patient compartment.

# 8 Test methods

## 8.1 Sealing performance test

When the vehicle is stationary, close all doors and windows of the negative pressure patient compartment, install an air flow meter at the air outlet of the negative pressure system, turn on the negative pressure system after activating the vehicle, and adjust the flow rate of the air outlet of the negative pressure system to (240 ± 5) $m^3/h$, use a negative pressure detector to measure the negative pressure value in the negative pressure patient compartment every 2 min, and take 3 measurements and record the average value as the negative pressure value.

## 8.2 Negative pressure performance test

When the vehicle is stationary, close all the doors and windows of the negative pressure patient compartment, activate the vehicle and turn on the negative pressure system. After the system runs for 3 min, measure the negative pressure value every 10 s, record the arithmetic mean of three measurements as negative pressure value. Compare the fluctuation range of three measurements to determine whether it meets the negative pressure stability requirements.

## 8.3 Ventilation rate test

In the stationary state of the vehicle, close all doors and windows of the patient compartment, install the air flow meter at the outlet of the negative pressure system and turn on the negative pressure system after activating the vehicle. After the system runs for 3 min, measure the air flow value at the outlet of the negative pressure system every 2 min, and measure it 3 times. Calculate the average of three measurements as the flow rate $Q_{ave}$. Then calculate the one-hour ventilation volume of the patient compartment using Formula (1) below:

$$V_{\text{total flow rate}}=Q_{ave}*t \quad (1)$$

where

$V_{\text{total flow rate}}$ is the ventilation volume of the patient compartment in one-hour ($m^3$);

$Q_{ave}$ is the air flow at the outlet of the negative pressure system ($m^3/s$);

$t$ is 3 600 s.

Calculate the ratio between the ventilation volume and the volume of the compartment to determine whether the ventilation rate requirement is met.

## 8.4 Air directional collection efficiency requirements

### 8.4.1 Test equipment and facilities

The test equipment and facilities are comprised of the following:

— vehicle VOC detection chamber, which shall meet the environmental requirements in ISO 12219-1;

— gas mixture dilution input device, able to dilute n-hexane gas to a given concentration and ensure gas outflow at a flow rate of 10 l/min, with a minimum duration of 20 min;

— gas sampling device, able to sample gas at a flow rate of (100-200) ml/min, with a sampling time of at least 15 min and a class 1,0 flow accuracy);

— 6 mm PTFE tube (for simulating gas influx and sampling gas export);

— TENAX sampling tube;

— thermal desorption gas chromatography-mass spectrometry instrument;

— pure nitrogen gas (99,99 %), high-concentration n-hexane gas or pure n-hexane solution.

### 8.4.2 Test procedures

#### 8.4.2.1 Preparation before the test

The vehicle shall be parked in the vehicle VOC detection chamber. In the stationary state of the vehicle, close all doors and windows of the patient compartment, and turn on the negative pressure system after activating the vehicle. If the gas collection device on patient's head is equipped, the test shall be started after installation.

Three sampling points shall be set in the compartment: at the front, at the middle, and at the rear seats for medical staff. The sampling points shall be located at the height of the seat headrest. Connect each sampling point to the specific gas sampling device outside the vehicle using a sampling tube without restricting opening and closing the doors. Install a gas mixing and dilution input device at the patient's breathing position on the stretcher, which is connected to the outside of the vehicle. Connect the negative pressure system exhaust outlet to the outside of the vehicle VOC detection chamber through a pipeline.

#### 8.4.2.2 Background group test

During the test, the environmental conditions in the chamber shall be set as follows: temperature of (25 ± 2) °C, humidity of 50 % ± 10 % RH.

The vehicle doors and windows shall be opened for ventilation for 1 h. After 1 h, TENAX tubes shall be connected to the three sampling points respectively, and the doors of the vehicle shall be closed. The gas collection device shall be turned on for 15 min for blank sampling inside the vehicle.

#### 8.4.2.3 Sample group test

After the blank sampling is completed, the doors and windows of the vehicle shall be opened for ventilation for 30 min. TENAX tubes shall be connected to the three sampling points respectively, then the doors of the vehicle shall be closed. The air conditioner in the patient compartment shall be turned on and adjusted to the maximum air flow rate. Then, turn on the negative pressure system and the gas mixing and dilution input device. A simulant gas with a set concentration shall be continuously input at a flow rate of 10 l/min, and the gas collection device shall be turned on simultaneously for 15 min. After the sampling is completed, the gas mixing and dilution input device and the gas collection device shall be turned off.