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General Technical Requirements of Modular Isolation Units for Emergency Medical Use

应急医用模块化隔离单元通用技术要求

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General Technical Requirements of Modular Isolation Units for Emergency Medical Use

1 Scope

This Standard specifies the requirements, inspection and testing, marking, packaging, transportation and storage of modular isolation units for emergency medical use.

This Standard is applicable to modular isolation units for emergency medical use, and is not applicable to medical isolation warehouses for the isolation and transfer of infectious patients.

2 Normative References

The following documents are essential to the application of this document. For the dated documents, only the versions with the dates indicated are applicable to this document; for the undated documents, only the latest version (including all the amendments) are applicable to this document.

GB/T 5338 Series 1 Freight Containers - Specification and Testing - Part 1: General Cargo Containers for General Purposes

GB 5749 Sanitary Standard for Drinking Water

GB/T 7106 Graduation and Test Method for Wind Resistance Performance of Windows

GB 18466 Discharge Standard of Water Pollutants for Medical Organization

GB 18582 Limit of Harmful Substances of Architectural Wall Coatings

GB/T 20145 Photobiological Safety of Lamps and Lamp Systems

GB/T 29468 Cleanroom and Associated Controlled Environments - Guidelines of Partition Sandwich Panel Application Technology

GB/T 35248-2017 Consumer Product Safety - Guidelines for Suppliers

GB/T 36372-2018 Cleanrooms and Associated Controlled Environments - General

Technical Requirements of Combined Envelope Structure

GB 50009 Load Code for the Design of Building Structures

GB 50057 Design Code for Protection of Structures against Lightning

GB 50068 Unified Standard Reliability Design of Building Structures

GB 50242 Code for Acceptance of Construction Quality of Water Supply Drainage and Heating Works

GB 50312-2016 Code for Engineering Acceptance of Generic Cabling System

GB 50303 Code for Acceptance of Construction Quality of Building Electrical Engineering

GB 50325 Code for Indoor Environmental Pollution Control of Civil Building Engineering

GB 50343 Technical Code for Protection of Building Electronic Information System against Lightning

GB 50346-2011 Architectural and Technical Code for Biosafety Laboratories

GB 50591-2010 Code for Construction and Acceptance of Cleanroom

GB 50686-2011 Code for Construction and Acceptance of Infectious Diseases Hospitals

GB 50849-2014 Code for Design of Infectious Diseases Hospital

GB 51039-2014 Code for Design of General Hospital

WS/T 367 Regulation of Disinfection Technique in Healthcare Settings

3 Terms and Definitions

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

3.1 Isolation area

Modular space that is used to block the transmission route of patients or suspected patients who are and may be infectious through the air. Ventilation is adopted to make the static air pressure lower than the atmospheric pressure and that of the adjacent and connecting areas, and to effectively control the exhaust gas and prevent the virus from spreading out.

4.2.2 Isolation channel

4.2.2.1 The clear width shall be no less than 1.4m.

4.2.2.2 There shall be conditions for medical staff to wear and take off protective clothing in accordance with the prescribed medical procedures.

4.2.2.3 Pressure display devices, non-manual faucet sinks, lighting facilities and storage cabinets for medical supplies shall be provided for easy observation.

4.2.2.4 In application, the unit door and the isolation area door shall be interlocked; and the unit door may only be opened after the isolation area door is closed for 1 min.

4.2.2.5 Reliable measures shall be taken to prevent unauthorized personnel from entering.

4.2.3 Pass-through box

4.2.3.1 The size shall meet the requirements of relevant standards and meet the transmission requirements.

4.2.3.2 Double-sided windows and doors shall be airtight and interlocked, and equipped with safe and reliable disinfection devices.

4.2.4 Isolation area

4.2.4.1 The indoor height shall be no less than 2.4m; and the plane size shall be no less than 3.0m×2.8m.

4.2.4.2 The isolation area door shall be a side-hung door, which shall open to the isolation channel. There shall be an observation window on the door, and the door shall be equipped with a door closer and an emergency unlocking switch. The door width shall be no less than 1.1m.

4.2.4.3 Medical equipment belts shall be equipped, and the installation height shall be 1.35m~1.45m above the ground.

4.2.4.4 Hospital beds, lockers, network interfaces, power sockets, lighting equipment, etc. shall be equipped.

4.2.4.5 The windows of the isolation area shall conform to above Level-6 (including Level-6) sealing windows specified in the standard of GB/T 7106; and shall be at least double-glass. The glass shall be impact-resistant and shatter-resistant. A curtain is arranged between the two layers of glass, which is controlled by the patient or medical staff to open.

4.2.4.6 The height of the built-in bathroom shall be no less than 2.1 m, the width of the

heat insulation, sound insulation, vibration resistance, impact resistance, insect resistance, corrosion resistance, fire prevention and airtightness. Materials with few joints and tight joints should be selected.

4.4.2 External envelop door and window materials should meet the requirements of 4.3.5 in GB 50686-2011, with the following features such as long life, corrosion resistance, non-shedding, easy maintenance, light weight, high strength, non-fading, and good sealing performance. Closed windows rather than the wooden doors and windows should be used; and the glass shall be resistant to impact and breakage.

4.4.3 Unit doors and equipment room doors shall meet the requirements of impact resistance, corrosion resistance, waterproof, fireproof and airtightness.

4.5 Envelop structure

4.5.1 Sealing measures shall be adopted for all types of wall-piercing pipelines. In addition, there shall be no cracks, holes, openings, etc. penetrating the structure.

4.5.2 Non-combustible materials of at least Class-B1 shall be selected for interior trim panels, which shall conform to the relevant provisions of GB/T 29468. The surface shall be resistant to weak acid and alkali corrosion, able to withstand the cleaning agents and disinfectants recommended by the manufacturer, and have certain impact resistance and weather resistance.

4.5.3 The ceiling, floor, and wall shall be easy to clean or wash, and the yin and yang angles shall be circular and reliably sealed. Skirting boards and wall skirts shall be level with the wall. The ground shall be leak-proof, seamless, smooth and non-slip.

4.5.4 The partition wall should reach the top, and the gap of the floor shall be filled and sealed.

4.5.5 There must be no hazardous substances in the materials, and they shall conform to the relevant provisions of GB 50325 and GB 18582.

4.6 Electrical and intelligent systems

4.6.1 It shall be designed, installed and used in accordance with GB 51039-2014 and GB 50849-2014.

4.6.2 The lighting design shall use high energy efficiency, high color rendering light source. The lighting fixture shall adopt diffuse reflection type. When using LED lamps, the photobiological safety (no blue light hazard and ultraviolet light hazard) shall be tested according to the requirements of GB/T 20145, and reach the "non-hazardous" standard.

4.6.3 A network interface shall be provided in the unit, and a wireless network shall be

b) Ordinary fan coil units shall not be used.

NOTE: When it is difficult to use a fresh air system due to the limit of the external environment, it should use the partial circulating air after the user has a clear understanding of the operating principle and proposes a safe and reliable unit application process.

4.8.2 The indoor airflow organization shall be conducive to the flow of airflow from the space with low risk of contamination to the space with high risk of contamination, minimizing indoor backflow and eddy currents, and the method of upper delivery and lower discharge should be adopted.

4.8.3 The supply air of the ventilation system shall be sent into the room after three-stage filtration at coarse, medium and sub-high efficiency.

4.8.4 The fresh air inlet of the ventilation system shall take effective rainproof measures, install a protective net that is easy to disassemble; and it shall be more than 2.3m above the outdoor ground and far away from pollution sources.

4.8.5 The exhaust air shall be filtered by a high-efficiency filter and then discharged. The exhaust high-efficiency filter shall be installed at the exhaust outlet of the isolation area, and it shall be possible to perform leak detection and disinfection in situ.

4.8.6 The height of the indoor exhaust (return) air outlet of the isolation area shall be conducive to the discharge of pollutants and avoid rolling up dust on the ground. The lower edge of the indoor exhaust (return) air outlet shall be 0.1m higher than the ground, and the upper edge should not be 0.6m higher than the ground. The wind speed at the exhaust outlet should be no greater than 1.5m/s.

4.8.7 The isolation channel and the entrance of the isolation area should be equipped with an indoor static pressure difference real-time monitoring display device and an environmental parameter display device.

4.8.8 Pressure difference detection devices shall be installed before and after each level of air filter. The measuring tube shall be unblocked and installed tightly.

4.8.9 The supply and exhaust fans of the ventilation system shall be reliably interlocked to ensure the indoor negative pressure requirements. When starting up, turn on the exhaust fan first and then turn on the supply fan. The order is reversed when shutting down. A spare exhaust fan should be equipped.

4.8.10 The air duct of the ventilation system shall be made of corrosion-resistant, aging-resistant, non-absorbent, and easily disinfected materials, and the air duct tightness shall comply with the relevant provisions of GB 50591.

and visual observation.

5.5.2 The lighting shall be confirmed through drawing review, visual observation, on-site testing, and product documentation review.

5.5.3 The network system shall be confirmed through drawing review and on-site testing.

5.5.4 The call intercom system shall be confirmed through drawing review, visual observation, and on-site testing.

5.5.5 The broadcasting system shall be confirmed through drawing review, visual observation, and on-site testing.

5.5.6 The monitoring system shall be confirmed through drawing review, visual observation, and on-site testing.

5.5.7 The closed-circuit television facility system shall be confirmed through drawing review, visual observation, and on-site testing.

5.5.8 The intelligent access control system shall be confirmed through drawing review, visual observation, and on-site testing.

5.5.9 Lightning protection shall be confirmed through drawing review, visual observation, and on-site testing.

5.5.10 The electrical system construction shall be inspected in accordance with the provisions of 7.4 in GB 50686-2011 and GB 50303.

5.6 Water supply and drainage system

5.6.1 The material selection for pipes and pipe fittings of the water supply and drainage system shall be confirmed through drawing review, product documentation review, and visual observation.

5.6.2 The pipeline and valve configuration of the water supply and drainage system shall be confirmed through drawing review, and visual observation.

5.6.3 Sewage discharge shall be confirmed through drawing review, and on-site inspection.

5.6.4 The construction of the water supply and drainage system shall be inspected in accordance with 5.4 of GB 50686-2011. The part involving concealed works shall be performed water pressure test on the pressure-bearing pipeline, and perform water filling and water passing tests on the non-pressure-bearing pipeline in accordance with GB 50242.

5.7.11 Reliable interlocking of the supply and exhaust fans shall be confirmed through visual observation at the opening/closing test site, or judged based on the absolute pressure change of the unit. There shall be no absolute pressure reversal during the entire opening/closing process.

5.7.12 The air duct material shall be confirmed through drawing review, product information and on-site visual observation; and the air duct tightness shall be confirmed by on-site testing. The test method conforms to the provisions of GB 50591-2010.

5.7.13 The redundant backup measures for the exhaust fan of the ventilation system may be confirmed through drawing review, visual observation and on-site test. During the on-site test, artificially simulate the failure of the main exhaust fan, the system shall automatically switch to the standby exhaust fan to operate, and maintain the orderly pressure gradient of the unit.

6 Marking, Packaging, Transportation and Storage

6.1 The product nameplate shall be placed on an obvious place, indicating the manufacturer, product model, production date, production serial number, outline size, weight and other information. The safety-use warning label and the inspection-qualified label shall be pasted in a conspicuous position.

6.2 Packing protection shall be carried out according to the needs before leaving the factory to ensure that it is waterproof, moisture-proof, not damaged, deformed, or contaminated during storage and transportation.

6.3 The transportation shall take into account the ship, road conditions and restrictions. It shall be firmly fixed during transportation, and measures shall be taken to prevent damage during transportation.

6.4 During storage, the storage site shall be flat, and featured by hard ground, slightly elevated, and unobstructed drainage.

7 Settlement and Evacuation Requirements

7.1 Technical data

The unit supplier shall provide an on-site installation operation manual to clarify the operation methods and precautions for connection with the foundation, on-site hoisting, pipeline and medical pipeline connection.

7.2 Basic requirements

7.2.1 The foundation axis, supporting surface elevation, levelness, anchor bolts, etc.

Appendix A

(Normative)

Use Requirements of the Unit

The use of the unit meets the following requirements:

a) Before accepting patient, make sure that all water, electricity and pipelines in the unit are properly connected and that the equipment in each area is operating normally. If there is any abnormality, notify the relevant maintenance personnel in time.

b) It shall be ensured that the interlock function and emergency unlock function of the unit door and the ward door are normal.

c) Avoid sharp objects piercing or hitting the inner decorative surfaces (walls, roofs, floors, doors and windows) to ensure the integrity and airtightness of the internal envelop structure.

d) Before entering the isolation area, medical personnel shall check the pressure display device, and the relevant maintenance personnel shall be notified in time if the pressure value is abnormal.

e) Medical staff shall reduce the frequency of entering and exiting the isolation area, and various items shall be delivered through the pass-through box as far as possible.

f) When the door on one side of the pass-through box is opened, do not force open the door on the other side to avoid damage to the interlocking device. The pass-through box can only store materials or sundries for a short time. When the interlocking device of the sundries fails to work normally, the maintenance personnel shall be notified in time for repair.

g) The disinfection of the unit is carried out in accordance with WS/T 367 and the relevant disinfection plan for special viruses.

h) Before the unit is disinfected, close the doors and windows and the airtight valves of the air supply and exhaust pipes; and open and ventilate after disinfection.

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