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**WS**

**INDUSTRY STANDARD OF THE  
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**WS/T 656-2019**

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**Safety management for anaesthetic machine  
(English Translation)**

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## Foreword

This standard was drafted in accordance with the rules given in GB/T 1.1-2009.

This standard was drafted. Chinese People's Liberation Army General Hospital, Chinese Medical Equipment Association, Eastern Theater General Hospital, Chinese People's Liberation Army the General Instrument and Equipment Inspection and Supervision Station

of the Joint Logistics Support Army, Nanjing Hospital (Nanjing First Hospital) affiliated to Nanjing Medical University, Nanjing Medical University Nanjing Drum Tower Hospital Affiliated to the College.

## 1 Scope

This standard specifies the acceptance, personnel, use environment, and safety of anesthesia machines used by medical institutions before and during clinical use.

Performance and maintenance related management and technical requirements.

This standard applies to the safety management of anesthesia machines used clinically by medical institutions.

This standard does not apply to anesthesia machines and portable anesthesia machines that use flammable anesthetics such as cyclopropane and ether.

## 2 Normative references

The following documents are essential for the application of this document. For dated references, only the dated version applies to this document.

For undated references, the latest version (including all amendments) applies to this document.

GB 9706.29 Medical electrical equipment. Part 2. Particular requirements for the safety and basic performance of anesthesia systems  
GB 15982 Sanitary Standards for Hospital Disinfection  
JJF 1234 Ventilator Calibration Specification  
WS/T 367 Medical Institution Disinfection Technical Specification  
WS 392 ventilator clinical application

## 3 Terms and definitions

GB 9706.29, JJF 1234 and the following terms and definitions apply to this standard.

Anesthesia machine

Equipment that distributes and delivers various medical and anaesthetic gases and vapors to the respiratory system.

Anaesthetic ventilator A ventilator designed for use during anesthesia.

Anaesthetic vaporizer A device capable of providing volatile pharmaceutical vapors in a controlled concentration manner.

Common gas outlet

Port for anesthetic gas and vapor output from anesthesia machine.

Manager of clinical anaesthetic machines the personnel who manage the anesthesia

machine equipped in the anesthesia machine use department of the medical institution.

#### **4.1 Management organization**

Anesthesia machine security is composed of the head of the medical institution, the medical business management department, the medical device management department and the anesthesia machine use department.

Full management organization.

#### **4.2 Management responsibilities**

##### **4.2.1**

The leaders of medical institutions shall perform the following duties.

- a) Have leadership responsibility for the safety control of the anesthesia machine;
- b) Responsible for coordinating the deployment of medical device managers, medical engineering technicians and related testing equipment needed for the safety management of anesthesia machines.

##### **4.2.2**

The medical service management department shall perform the following duties.

- a) Coordinate and manage key links and activities in the safety control of anesthesia machines;
- b) organize the development of anesthesia machine safety control plan and management system and supervise implementation;
- c) Develop an emergency deployment system for anesthesia machines.

##### **4.2.3**

The medical device management department shall perform the following duties.

- a) Formulate safe operating procedures for anesthesia machines;
- b) organize the acceptance testing, periodic testing, maintenance, repair and post-repair testing of the anesthesia machine;
- c) Train the department and operator of anesthesia machine on the safe operation procedures of anesthesia machine;
- d) Collect the safety information of the anesthesia machine, conduct the annual safety control evaluation, submit the evaluation report to the safety management organization of the anesthesia machine and propose improvements Comments.

#### **4.2.4**

The user department shall perform the following duties.

- a) Organize personnel in this department to study and implement the safety control plan and management system of anesthesia machine;
- b) organize the operators to receive training and assessment of the operating procedures of the anesthesia machine;
- c) Equipped with clinical anesthesia machine management personnel (can work part-time).

### **4.3 Management System**

#### **4.3.1**

Anesthesia machine safety management system should include. acceptance system, use registration system, emergency deployment system, maintenance system, cycle Inspection system, archive management system, etc.

#### **4.3.2**

The acceptance system should include the following.

- a) Check the qualifications of production enterprises and distributors;
- b) check the factory test report or certificate and its validity period;
- c) check the instruction manual and maintenance manual;
- d) check incidental services;
- e) Carry out the acceptance test of the anesthesia machine, record it, and keep it on file.

#### **4.3.3**

The use registration system should include the following.

- a) Each anesthesia machine should be provided with a use register;
- b) The use register should contain the equipment's name, model, serial number, storage location, date of use, etc .;
- c) When using anesthesia machines, the use date and start and end time, the user's name, the pre-use status and post-use status of the safety confirmation item should be registered;
- d) Safety confirmation records before use. For sample records, see Table A.1 in Appendix A.

#### **4.3.4**

The emergency deployment system should include the following.

- a) the person responsible for emergency deployment;