

ICS 11.020
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**INDUSTRY STANDARD OF THE
PEOPLE'S REPUBLIC OF CHINA**

WS/T 657-2019

**Safety management for infusion pump and syringe pump
(English Translation)**

Issued on: October 18, 2019

Implemented on: May 1, 2020

Issued by: National Health Commission

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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. Xuanwu Hospital of Capital Medical University, Shanghai Renji Hospital, Beijing Shunyi District Hospital, China Medical Equipment Association, Institute of Hospital Management, National Health and Health Commission.

1 Scope

This standard specifies the use of medical infusion pumps and syringe pumps (hereinafter referred to as infusion equipment) in medical institutions before clinical use and use.

During the use of safety and performance testing management requirements.

This standard applies to the safety management of medical infusion pumps and syringe pumps used clinically by various medical institutions.

2 Normative references

The following documents are essential for the application of this document. For dated references, only the dated version applies to this article Pieces. For undated references, the latest version (including all amendments) applies to this document.

GB 9706.1 Medical electrical equipment. Part 1. General requirements for safety GB 9706.27 Medical electrical equipment Part 2-24. Particular requirements for the safety of infusion pumps and controllers JJF 1259 Calibration Specifications for Medical Syringe Pumps and Infusion Pumps YY 0505 Medical electrical equipment. Part 1-2. General requirements for safety. Collateral standard. EMC requirements and tests

3 Terms and definitions

The terms and definitions defined in GB 9706.1, GB 9706.27, YY 0505 and JJF 1259, as well as the following terms, apply to this document.

Infusion pump

Devices that are intended to control the flow of fluid into a patient by the positive pressure generated by a pump.

Infusion pump

Through one or more single-acting syringes or similar containers, the operator sets the flow rate per unit time to control the injection into the patient Device for fluid flow in the body.

Supporting materials Pump infusion lines and syringes for use with infusion equipment.

4.1 Management organization

Headed by the head of the medical institution, medical business management department, medical device management department, medical device use department and logistics support department Together form an infusion equipment safety management organization.

4.2 Management responsibilities

4.2.1

The leaders of medical institutions shall perform the following duties.

- a) Responsible for the safety management of infusion equipment;
- b) Resource allocation to ensure the safe management of infusion equipment.

4.2.2

The medical service management department shall perform the following duties.

- a) Organize the development of safety control plans and management systems for infusion equipment and supervise their implementation;
- b) Coordinate the safety management of infusion equipment of various departments.

4.2.3

The medical device management department (including medical engineering department, equipment department, equipment department, equipment department, etc.) shall perform the following duties.

- a) Fully responsible for the technical work of safety management of infusion equipment;
- b) Formulate technical operation specifications for safety control of infusion equipment;
- c) Training and assessment of the users and operating personnel in 4.2.3 b);
- d) Responsible for maintenance, repair and performance testing of infusion equipment;
- e) Formulate emergency backup plan and emergency deployment system for infusion equipment;
- f) Collect safety management information of infusion equipment, conduct annual safety control evaluation, and submit evaluation reports to the safety management organization of medical institutions and put forward suggestions for improvement.

4.2.4

The user department shall perform the following duties.

- a) Organize personnel in this department to study and implement safety management system for infusion equipment;
- b) organize the operators to receive training in technical operation specifications, and operate only after passing the assessment;
- c) responsible for routine maintenance of infusion equipment;
- d) Report any problems with the infusion equipment to the medical device management department and record them in a timely manner;
- e) There should be full-time or part-time safety management personnel who are responsible for the daily management of the infusion equipment of the department.

4.2.5

The logistics support department shall provide power supply that meets the requirements of the infusion equipment.

4.3 Management System

4.3.1

A safety management system for infusion equipment should be established and publicized for implementation.

4.3.2

The safety management system of infusion equipment shall include inspection and inspection system, maintenance system, failure report system, emergency plan (emergency Deployment) system and training evaluation system.

4.3.3

The inspection system includes the following.

- a) Duties of inspectors;
- b) inspection cycle;
- c) content requirements for inspections;
- d) Inspection requirements;
- e) Disposition of violations.

4.3.4

The maintenance system shall include the following.

- a) the person in charge of maintenance;
- b) maintenance intervals and requirements;
- c) procedures and requirements for hidden dangers and failures;
- d) Management of maintenance files.

4.3.5

The fault reporting system should include the following.

- a) fault reporting procedures;
- b) troubleshooting procedures;
- c) Failure report, failure reason and processing record.

4.3.6

The emergency plan system should include the following.

- a) Duties of the person responsible for the emergency plan;
- b) emergency procedures;