

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

WS/T 658-2019

**Safety management of baby incubator
(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, Renji Hospital of Shanghai Jiaotong University, China Medical Equipment Association, National Health Institute of Hospital Management, Health Commission.

1 Scope

This standard specifies the management, safety, performance testing and management of infant incubators configured for use by medical institutions before and during clinical use.

Inspection, cleaning, disinfection and sterilization requirements.

This standard applies to the safety management of infant incubators used by 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. 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 11243 Medical electrical equipment Part 2. Particular requirements for the safety of infant incubators GB 15981 Evaluation methods and standards for disinfection and sterilization effects GB 15982 Sanitary Standards for Hospital Disinfection JJF 1260 Incubator Calibration Specification WS/T 313 Hand hygiene regulations for medical staff WS/T 367 Medical Institution Disinfection Technical Specification

3 Terms and definitions

The terms and definitions defined in GB 9706.1, GB 11243, GB 15982, GB 15981, and JJF 1260, as well as the following terms, apply to this file. For ease of use, some terms and definitions in GB 11243 and JJF 1260 are repeatedly listed below.

Incubator

A device having a baby cabin that controls the specific environment of a baby by heated air.

[GB 11243-2008, definition 2.1.101] 3.2 Baby compartment an environmentally-controllable enclosure for holding a baby and having a portion where the baby can be observed.

[GB 11243-2008, definition 2.1.102] 3.3 Air controlled incubator the air temperature in the baby incubator is automatically controlled by the air temperature sensor to a value set by the user.

[GB 11243-2008, definition 2.1.103] 3.4 Baby controlled incubator an air temperature-controlled baby incubator has an additional function that can automatically control the air temperature of the incubator to make the baby's skin temperature the temperature measured by the degree sensor is close to the temperature set by the user.

[GB 11243-2008, definition 2.1.104] 3.5 Incubator temperature Measured air temperature (temperature at point A in Figure 1 of this document) above the center of the mat surface in

the infant cabin.

[JJF 1260-2010, definition 3.3] 3.6 Average incubator temperature the average value of the incubator temperature read at even time intervals when the temperature is stable.

[GB 11243-2008, definition 2.9.109] 3.7 Steady temperature condition the state when the temperature of the incubator does not change more than 1 ° C within a 1-hour interval.

[GB 11243-2008, definition 2.10.101] 3.8 Medical engineering technicians in medical institutions, a person with a medical engineering background and engaged in medical device management, technical support and protection.

4.1 Management organization

Under the leadership of the medical institution, the medical business management department, the medical device management department, the baby incubator use department, and the logistics support the departments together form an infant incubator safety management organization.

4.2 Management responsibilities

4.2.1

The leaders of medical institutions shall perform the following duties.

- a) Responsible for the leadership of clinical safety management of infant incubators;
- b) The resources for ensuring the safe management of clinical use of infant incubators.

4.2.2

The medical service management department shall perform the following duties.

- a) Responsible for the safety management of medical services in the clinical use of infant incubators;
- b) Responsible for the coordination of the departments involved in the safety management of infant incubators.

4.2.3

The medical device management department shall perform the following duties.

- a) Fully responsible for the safety management of clinical use of infant incubators;
- b) Develop safety control plans and management systems for infant incubators;
- c) Formulate technical operation specifications for quality control of infant incubators;
- d) Responsible for the training and assessment of relevant technical specifications and management systems for the use departments and operators;

- e) Responsible for organizing routine inspections and spot checks of safety and quality control, and handling issues related to safety and quality control;
- f) arrange specialized medical engineering technicians to be responsible for the maintenance, repair and performance testing of the baby incubator;
- g) responsible for the measurement and management of infant incubators;
- h) Develop emergency plans and emergency deployment systems for infant incubators;
- i) Collect safety and quality control information of infant incubators, conduct safety and quality control evaluations, Use safety management organizations and medical institution leaders to submit evaluation reports and suggest improvements.

4.2.4

The user department shall perform the following duties.

- a) Organize the personnel in this department to study and implement the safety management system of the baby incubator;
- b) organize operators to receive training in technical operation specifications and operate strictly in accordance with technical specifications;
- c) Responsible for the daily maintenance and safety management of the baby incubator;
- d) Any problems with the incubator should be reported to the medical device management department and recorded in a timely manner to ensure medical safety;
- e) Set up full-time or part-time management personnel to be responsible for the daily management of the baby incubator in this department;
- f) Cooperate with the supervision of the medical device management department to ensure the safe and effective use of baby incubators;
- g) Carry out monitoring, evaluation and reporting of adverse and safety events in infant incubators.

4.2.5

The logistics support department shall perform the following duties.

- a) the working environment required to ensure the safe use of the baby incubator;
- b) equip the baby incubator with dual power or backup power;
- c) Provide an uninterrupted supply of oxygen to the incubator.

4.3 Management System