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

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**Safety Management for cardiac defibrillator
(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. The Central Military Commission Logistics Department Ministry of Health Bureau of Pharmaceutical Instruments, the People's Liberation Army No. 307 Hospital, China the First Affiliated Hospital of the People's Liberation Army General Hospital, the China Medical Equipment Association, and the Chinese People's Armed Police General Hospital.

1 Scope

This standard specifies the personnel, environment, safety performance of the cardiac defibrillator used by medical institutions before and during clinical use.

Management and technical requirements related to maintenance.

This standard applies to the safe management of cardiac defibrillators used in clinical settings in medical institutions. Cardiac defibrillator monitor, cardiac defibrillation pacing monitor the safety management can be carried out with reference to this standard.

2 Normative references

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

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

Medical electrical equipment - Part 2-4. Safety requirements for cardiac defibrillators JJF 1149 Cardiac Defibrillator Calibration Specification YY/T 0841 Medical electrical equipment Medical electrical equipment periodic test and post-repair test

3 Terms and definitions

The following terms and definitions apply to this document.

Cardiac defibrillator cardiac defibrillator Applying electrical pulses to the patient's skin (external electrodes) or exposed hearts (in vivo electrodes) through the electrodes to normalize the heart rhythm Medical electrical equipment.

Manual defibrillator manual defibrillator the cardiac defibrillator is manually selected by the operator for energy, charging, and discharging.

Automatic external defibrillator automated external defibrillator, AED Once the operator is activated, the defibrillator automatically analyzes the ECG signal (ECG) obtained by placing the electrodes on the chest surface to identify the heart.

Rhythm, a defibrillator that performs a charging operation on its own when a heart rhythm is detected.

Periodic test recurrent test Full performance testing of specified items at time intervals as specified by national verification procedures or as recommended by calibration specifications.

Testing during use

The detection performed during two periodic tests.

4.1 Management Organization

4.1.1

There should be medical care consisting of the head of the medical institution, the medical business management department, the medical device management department and the clinical use department.

Device Safety Management Organization.

4.1.2

The safety management of cardiac defibrillators should be incorporated into the medical device safety management system.

4.2 Management responsibilities

4.2.1

The head of the medical institution shall perform the following duties.

- a) Fully responsible for the safety management of cardiac defibrillators;
- b) resource allocation to ensure safe management of cardiac defibrillators;
- c) organize the development of a safety management system for cardiac defibrillators;
- d) Regularly organize the safety evaluation of cardiac defibrillators.

4.2.2

The medical business management department shall perform the following duties.

- a) the implementation of safety management plans and regulations for organizing cardiac defibrillators;
- b) supervise and check the implementation of safety management plans and regulations for cardiac defibrillators;
- c) develop emergency plans for the safety management of cardiac defibrillators and organize drills on a regular basis;
- d) Coordinate the safety management aspects of the defibrillator.

4.2.3

The medical device management department shall perform the following duties.

- a) is fully responsible for the safety management techniques of the cardiac defibrillator;
- b) develop safe operating procedures;
- c) develop technical specifications for the safety management testing of cardiac defibrillators;

- d) implement safety management related technology testing activities;
- e) Responsible for relevant technical training for users;
- f) undertake maintenance work on the cardiac defibrillator;
- g) Collect safety management information for cardiac defibrillators, submit evaluation reports to medical device safety management organizations, and propose improvements;
- h) Responsible for the establishment of equipment files, including equipment model, serial (number), use department, safety management records, etc., all files the information should be kept for 5 years after the device is terminated.

4.2.4

The clinical use department shall perform the following duties.

- a) Organize personnel in this department to learn and implement the safety management system for cardiac defibrillators;
- b) organize the personnel to receive training and assessment of the operating procedures;
- c) designate the department's safety management supervisor;
- d) Once the fault is found, ensure that the emergency plan is implemented and repaired in accordance with the fault repair system;
- e) responsible for the maintenance of the cardiac defibrillator to ensure the integrity of the cardiac defibrillator;
- f) Establish a daily safety confirmation record for the cardiac defibrillator (should include whether the accessory is complete, the appearance is intact, the function is normal, Inspector, date of inspection, use registration record (should include date of use, user, patient name and medical record number, technique) Operating parameters, equipment status, etc.) and maintenance records (should include maintenance content, maintenance date, maintenance personnel).

4.3 Management System

4.3.1

The safety management of cardiac defibrillators should be throughout the life cycle of the equipment, covering acceptance, clinical use, maintenance, periodic testing, Emergency deployment, personnel training, file management and other processes.

4.3.2

The safety management system, plan, applicable standards, operational procedures, etc. of the defibrillator should be established and documented to relevant departments and phases.