

ICS 11.020
CCS C 05

WS

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

WS/T 602-2018

**Safety management for high frequency surgical unit
(English Translation)**

Issued on: August 17, 2018

Implemented on: August 1, 2019

Issued by: National Health Commission

Table of Contents

- Foreword
- 1 Scope
- 2 Normative references
- 3 Terms and definitions
- 4 Management requirements
 - 4.1 Management Organization
 - 4.2 Management responsibilities
 - 4.3 Management System
 - 4.4 File Management
- 5 High frequency electric knife safety technical requirements
 - 5.1 Appearance and functional requirements
 - 5.2 Test conditions
 - 5.3 Testing items
 - 5.4 Testing methods and requirements

Foreword

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

This standard was drafted. Peking University Third Hospital, China Medical Equipment Association, China Institute of Metrology, Beijing Medical Devices Inspection Institute, General Logistics Department, Ministry of Health, Institute of Pharmaceutical Instruments.

Drafters of this standard. Xu Feng, Tian Jin, Xu Heng, Liu Wenli, Shao Haiming, Sun Jingsheng, Meng Jianguo, Jia Jiange, Li Ming, Wang Dong, Li Yi Lin, Liu Xiaohua.

High-frequency electric knife safety management

1 Scope

This standard specifies the safety management requirements and safety technical requirements for high-frequency electrosurgical instruments used in medical institutions before and during clinical use.

And safety detection cycle.

This standard applies to the safety management of high frequency electric knives for clinical use in medical institutions.

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.

GB 9706.1 Medical electrical equipment - Part 1. General requirements for safety
GB 9706.4 Medical electrical equipment - Part 2-2. Particular requirements for safety of high-frequency surgical equipment
JJF 1217 high frequency electric knife calibration specification

3 Terms and definitions

The following terms and definitions as defined in GB 9706.1 and GB 9706.4 apply to this document.

High frequency leakage current the non-functional current of the output electrode of the high-frequency electric knife to the ground.

Protective earth impedance A device with a power input jack between the protective earth connection point in the socket and all accessible metal parts of the protected ground Impedance; or equipment with a non-removable power cord, protective grounding pin in the network power plug and all accessible metal with protective grounding the impedance between the parts.

4.1 Management Organization

4.1.1

There should be the head of the medical institution, the medical business management department, the medical device management department, the high-frequency electric knife use department, and the logistics guarantee.

A medical device safety management organization composed of a barrier department.

4.1.2

Safety management of high frequency electric knives should be included in the medical device safety management system.

4.2 Management responsibilities

4.2.1

The person in charge of the medical institution shall perform the following duties.

a) has leadership responsibility for the safety management of high-frequency electric

knives;

- b) Determine the level of safety responsibility, organize the implementation of the management system and safe operating procedures;
- c) Guarantee the right amount of medical engineering and technical staff.

4.2.2

The medical business management department shall perform the following duties.

- a) Organize the implementation of safety management plans and regulations for high-frequency electrosurgical knives;
- b) Coordinate the safety management of high-frequency electric knives.

4.2.3

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

- a) Fully responsible for the safety technical work of high frequency electric knives;
- b) Formulate safety management systems and plans for high-frequency electric knives;
- c) develop operational specifications for the safety of high-frequency electric knives;
- d) Train the use department and operators on the contents of items b) and c), and operate the high-frequency electric knife after passing the examination;
- e) organize regular safety inspections and spot checks to address safety related issues;
- f) Responsible for the maintenance and regular inspection of high frequency electric knives;
- g) develop an emergency plan;
- h) Collect high-frequency electric knife safety management information, conduct annual safety evaluation, and submit to the hospital safety management organization and the head of the medical institution Evaluation report and suggestions for improvement.

4.2.4

The use department shall perform the following duties.

- a) Study and implement the safety management system for high-frequency electric knives;
- b) Organize the operator to receive the training of the operation specification and operate after passing the examination to ensure that the operator meets the requirements of the operation specification.

begging;

- c) responsible for the daily maintenance of high frequency electric knives;

- d) It is found that the high-frequency electric knife is reported in time and the emergency plan is implemented when necessary to ensure medical safety;
- e) Establish registration records and maintenance records for the daily use of high-frequency electric knives;
- f) Collaborate with the medical device management department to ensure the high-frequency electric knife's integrity.

4.2.5

The logistics management department shall perform the following duties.

- a) provide electricity;
- b) Guarantee the qualified environmental conditions required for high frequency electric knives.

4.3 Management System

4.3.1

The hospital shall, in conjunction with the characteristics of the unit's high-frequency electrosurgical unit, establish and improve the safety management system for high-frequency electric knives and publish them.

4.3.2

The safety management system for high-frequency electric knives should include inspection system, maintenance and maintenance system, emergency response system, and training assessment.

System, new high-frequency electric knife pre-use acceptance system, adverse event reporting system and archival data management system.

4.3.3

The inspection system should include the following.

- a) inspection personnel;
- b) inspection cycle;
- c) inspection contents, such as usage records, maintenance records and equipment status;
- d) inspection records;
- e) Disposal of violations.

4.3.4

The repair and maintenance system shall include the following.

- a) maintenance person in charge;