

ICS 11.040.60
CCS C42

YY

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

YY/T 0860-2024

Replacing YY/T 0860-2011

Radio frequency ablation instrument for cardiac application

心脏射频消融治疗设备

Issued on: September 29, 2024

Implemented on: October 15, 2025

Issued by: National Medical Products Administration

Table of Contents

1 Scope	1
2 Normative references	1
3 Terms and Definitions	1
4 Categories	1
5 Requirement	2
4 References	7

Foreword

This document is in accordance with the provisions of GB/T 1.1-2020 "Guidelines for standardization work Part

1. Structure and drafting rules for standardization documents" Drafting. This document replaces YY/T 0860-2011 "Cardiac Radiofrequency Ablation Therapy Equipment". Compared with YY/T 0860-2011, except for the structural adjustment In addition to editorial changes, the main technical changes are as follows:

- Changed the description of the scope (see Chapter 1, Chapter 1 of the.2011 edition).
- Changed the definition of cardiac radiofrequency ablation therapy equipment (see 3.1, 3.1 of the.2011 edition);
- Deleted the terms and definitions of temperature control and power control (see 3.3 of the.2011 edition);
- Added classification (see Chapter 4);
- Deleted the composition (see Chapter 4 of the.2011 edition);
- Deleted working conditions (see 5.1 of the.2011 edition);
- Changed the operating frequency requirements (see 5.1.1, 5.2.1 of the.2011 edition);
- Changed the requirements and test methods for RF output power (see 5.1.2, 6.2.2, 5.2.2,

1 Scope

YY/T 0860 is the product standard for the cardiac radiofrequency ablation system, the generator and accessories used to destroy the tissue that sustains an arrhythmia. It specifies the classification and requirements for cardiac RF ablation treatment equipment and its accessories, and describes the corresponding test methods. RF ablation is a controlled burn inside a beating heart: the output power, the impedance and temperature feedback that modulate it, and the behaviour of the system when a catheter loses contact are what separate an effective lesion from a perforation. It is standardised together with its accessories because the generator and the catheter behave as one system. For a manufacturer or an importer of cardiac ablation systems seeking Chinese registration, this is the standard the type testing follows.

This document specifies the classification and requirements of cardiac radiofrequency ablation equipment (hereinafter referred to as equipment) and its accessories, and describes the corresponding test method. This document applies to cardiac radiofrequency ablation treatment equipment and its accessories. This type of equipment is used for cardiac interventional radiofrequency ablation surgery or heart/chest Surgical radiofrequency ablation procedure.

2 Normative references

The contents of the following documents constitute essential clauses of this document through normative references in this document. For referenced documents without a date, only the version corresponding to that date applies to this document; for referenced documents without a date, the latest version (including all amendments) applies to This document.

GB 9706.1 Medical electrical equipment Part

3 Terms and definitions

The terms and definitions defined in GB 9706.1, GB 9706.202 and YY 0650 and the following terms and definitions apply to this document.

3.1 Used in conjunction with cardiac radiofrequency ablation surgery accessories, it uses the thermal effect of high-frequency current to ablate target cardiac tissue. Technical equipment.

4 Categories

Cardiac radiofrequency ablation treatment equipment is divided into cardiac interventional radiofrequency ablation equipment and cardiac surgical radiofrequency ablation equipment. Cardiac interventional radiofrequency ablation equipment is used in conjunction with

cardiac radiofrequency ablation catheters. During cardiac interventional surgery, the ablation catheter enters the heart through the blood vessels. The device uses the thermal effect of high-frequency current to ablate the target cardiac tissue from the inside of the heart. Some devices are also used in conjunction with perfusion pumps. Cardiac surgery radiofrequency ablation equipment is used in conjunction with cardiac surgery radiofrequency ablation forceps/pen and other surgical accessories.

7 Ethylene oxide sterilization residues

YY 0650 General technical requirements for radiofrequency ablation treatment equipment

YY 0778 Radiofrequency ablation catheter

YY/T 1057 General technical requirements for medical foot switches