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



# YY 9706.108-2021

**Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems**

医用电气设备 第1-8部分：基本安全和基本性能的通用要求 并列标准：通用要求、测试和指南 医用电气设备和医用电气系统中的报警系统

**Issued on: March 9, 2021** **Implemented on: May 1, 2023**

**Issued by: National Medical Products Administration**

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## Foreword

All technical contents (requirements) of this Part are mandatory. The serial standards of Medical Electrical Equipment can be divided into two parts.

1.General and Collateral Requirements;

2.Particular Requirements. This Part is Part 1-8. This Part was drafted as per the rules specified in GB/T 1.1-2009. This Part replaced YY 0709-2009 Medical Electrical Equipment - Part 1-

8.General Requirements for Safety - Collateral Standard. General Requirements, Tests and Guidance for Alarm Systems in Medical Electrical Equipment and Medical Electrical Systems. Compared with YY 0709-2009, the major technical changes of this Part are as follows besides the editorial modifications.

--- Update the structure of this Part according to the standard structure of IEC 60601-1.2005+A1.2012;

--- Add the term "acknowledged" (see

3.37 of this Edition);

--- Add the general requirements (see Clause 4 of this Edition);

--- Added ME equipment identification, marking and documents (see Clause 5 of this Edition);

--- Add the operator adjustable sound pressure level (see

6.3.3.3 of this Edition);

--- Add the DISTRIBUTED ALARM SYSTEM intended for confirmed delivery of ALARM CONDITIONS (see 6.11.2.2.1 of this Edition);

--- Add the DISTRIBUTED ALARM SYSTEM not intended for confirmed delivery of ALARM

CONDITIONS (see 6.11.2.2.2 of this Edition);

--- Add the technical requirements for the provision of ME equipment with a global AUDIO OFF in a DISTRIBUTED ALARM SYSTEM (see 6.11.2.2.3 of this Edition);

## 1 Scope, Object and Related Standards

YY 9706.108 is the collateral standard governing alarms in medical electrical equipment. It exists because alarms fail as a system rather than as individual devices: a bedside surrounded by monitors each alarming in its own way, at its own priority and with its own sound, produces alarm fatigue, and the alarm that matters is the one that gets silenced. This standard imposes a common grammar, covering how alarm conditions are assigned priority, what the audible and visual signals for each priority must be, how alarms may be paused or silenced and for how long, and what the equipment must log. Alarm safety is a recognised patient safety priority worldwide. Being a YY standard without the /T suffix, compliance is compulsory in China. It took effect in May 2023.

The object of this Part is to specify BASIC SAFETY and ESSENTIAL PERFORMANCE requirements and tests for ALARM SYSTEMS in ME EQUIPMENT and ME SYSTEMS and to provide guidance for their application. A requirement in a particular standard takes priority over the corresponding requirement in this Part.



## 2 Normative References

The following documents are essential to the application of this Document. For the dated documents, only the versions with the dates indicated are applicable to this Document; for the undated documents, only the latest version (including all the amendments) is applicable to this Document.

## 3 Terms and Definitions

For the purposes of this Document, the terms and definitions given in GB 9706.1-2020 and YY/T 1474, and the following apply.

## 4 General Requirements

If the MANUFACTURER chooses as a means of RISK CONTROL to have the ME EQUIPMENT or ME SYSTEM notify the OPERATOR that a HAZARDOUS SITUATION can exist, then the ME EQUIPMENT or ME SYSTEM shall include an ALARM SYSTEM complying with this collateral standard for that purpose.

## 5 ME EQUIPMENT Identification, Marking and Documents

NOTE. Additional requirements on ACCOMPANYING DOCUMENTS are specified in this

collateral standard, together with the technical requirements, giving rise to requirements on ACCOMPANYING DOCUMENTS. These requirements are also listed in Table B.2.

## 6 ALARM SYSTEMS

When applicable, the MANUFACTURER shall address in the RISK MANAGEMENT PROCESS the RISKS associated with verbal ALARM SIGNALS. Compliance is checked by inspection of the RISK MANAGEMENT FILE.