

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

YY/T 0841-2023

**Medical electrical equipment - Recurrent test and test after
repair of medical electrical equipment
(English Translation)**

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Foreword

This document is drafted in accordance with the rules provided in GB/T 1.1-2020

Directives for standardization - Part 1.Rules for the structure and drafting of standardizing documents.

This document replaces YY/T 0841-2011 Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment. Compared with YY/T 0841-2011, in addition to structural adjustment and editorial modification, the main technical revisions are as follows.

-- Add the definitions of "configuration" and "line-to-earth voltage" (see 3.8 and

3.17);

- Add some terms in GB 9706.1-2020 (see 3.28, 3.31, 3.33, 3.35);
- Delete the definition of "normal condition" (see 3.26 of the 2011 edition);
- Change the measuring of protective earth resistance to adapt to the test of ME systems in GB 9706.1-2020 (see 5.3.2; 5.3.2 of the 2011 edition);
- Add the measurement of insulation resistance (see 5.3.3);
- Add the method of measuring the equipment leakage currents, and explain the relevant contents (see 5.3.4.1);
- Add some required values (see Table 2).

This document adopts IEC 62353.2014 Medical electrical equipment - Recurrent test and test after repair of medical electrical equipment by modification.

The technical differences between this document and IEC 62353.2014 and their reasons are as follows.

- Use the normatively referenced GB 9706.1 to replace IEC 60601-1.2005 and IEC 60601-1.2005+AMD 1.2012 to adapt to our country's technical conditions;
- Use the normatively referenced GB 4793.1 to replace IEC 61010-1 (see Annex C) to adapt to our country's technical conditions;
- Use the normatively referenced GB 4793.5 to replace IEC 61010-031 (see Annex C) to adapt to our country's technical conditions;
- Use the normatively referenced GB/T 17045 to replace IEC 61140 (see 6.2) to adapt to our country's technical conditions;
- Use the normatively referenced GB/T 18216.1 to replace IEC 61557-1 (see Annex C) to adapt to our country's technical conditions;
- Use the normatively referenced GB/T 18216.2 to replace IEC 61557-2 (see Annex C) to adapt to our country's technical conditions;
- Use the normatively referenced GB/T 18216.4 to replace IEC 61557-4 (see Annex C) to adapt to our country's technical conditions.

The following editorial changes have also been made to this document.

- Delete some explanatory content in the Scope and move it to the Introduction;
- Move the general requirements for testing from the Scope to 4.1;
- Use the informatively referenced GB/T 5465.2 to replace IEC 60417 (see 3.45, 3.46, 3.47, Annex A);
- Add some notes.

1 Scope

This document specifies testing of medical electrical equipment and medical electrical system (hereafter referred to as ME equipment and ME systems) or parts of such equipment or systems, which comply with GB 9706.1, before putting into service, during maintenance, during inspection, after repair and in other services, or on occasion of recurrent tests.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

GB 4793.1, Safety requirements for electrical equipment for measurement, control and laboratory use - Part 1. General requirements (GB 4793.1-2007, IEC 61010-1:2001, IDT)

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply. Some of the definitions are necessarily different from those in GB 9706.1, as different measuring methods are used.

4 Requirements

The responsible party may omit certain tests based on manufacturers' written information or accompanying documents.

ME systems shall be visually inspected to determine whether the ME system

configuration is still the same as at the time of the last inspection, or whether any equipment making up the ME system has been exchanged, added or removed.

5 Tests

For Class I ME equipment, it shall be demonstrated that the protective earth conductor connects all accessible conductive parts, which may become live in case of a fault, in a proper and safe way to either the protective earth terminal of the mains plug for plugged-in equipment or to the protective earth point for permanently installed equipment.

ME equipment is separated from mains, and the equipment leakage current is measured according to Figure 6.

6 Results of test and evaluation

The evaluation of safety of ME equipment or ME system shall be performed by electrically skilled persons (as defined in GB 17045) who have the appropriate training for testing the equipment under test. If using the measurement equipment listed in Annex C, measurement uncertainties do not need to be taken into consideration for the limits.

Annex A

(Informative)

General guidance and rationale

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