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STANDARD

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**Medical electrical equipment—
Part 1 : General requirements
for safety—
1. Collateral standard :
Safety requirements for
medical electrical systems**

ICS 11.040.01

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safety

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Foreword

This translation has been made based on the original Japanese Industrial Standard established by the Minister of International Trade and Industry and the Minister of Health and Welfare through deliberations at the Japanese Industrial Standards Committee in accordance with the Industrial Standardization Law:

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Safety requirements for
medical electrical systems**

Introduction This Japanese Industrial Standard has been prepared based on IEC 60601-1-1 *Medical electrical equipment—Part 1 : General requirements for safety—1. Collateral standard : Safety requirements for medical electrical systems* published in 1992 as the first edition and the Amendment 1 (1995) without any modification in the technical contents.

The mark * located on the upper left side of the subclause number means that the rough statement or explanation is given in Annex AAA (informative).

In this Standard, the portions underlined with dots mean the matter not stated in the original International Standard.

Section One—General

1 Scope and object

***1.201 Scope** This Standard applies to the safety of MEDICAL ELECTRICAL SYSTEMS. It describes the safety requirements for MEDICAL ELECTRICAL SYSTEMS to provide protection for the PATIENT, the OPERATOR and surroundings.

NOTE — It is presumed that the party assembling or modifying the MEDICAL ELECTRICAL SYSTEMS will take the necessary steps to assure compliance with this Standard.

2 Terminology and definitions Where the terms “voltage” and “current” are used, they mean the r.m.s. values of an alternating, direct or composite voltage or current.

For the purpose of this Standard the following additional definitions apply:

2.201 COUPLING All functional connections between different items of equipment.

2.202 INDIRECT CONTACT Contact of persons or livestock with exposed conductive parts which have become live under fault conditions (IEV 826-03-06).

***2.203 MEDICAL ELECTRICAL SYSTEM** (hereafter referred to as “SYSTEM”) Combination of either more than one item of MEDICAL ELECTRICAL EQUIPMENT or MEDICAL ELECTRICAL EQUIPMENT and other non-medical electrical equipment having a specified function and inter-connected by:

— COUPLING, and/or

— a MULTIPLE PORTABLE SOCKET OUTLET.

NOTE — The SYSTEM includes those accessories which are needed for operating the SYSTEM and are to be specified by the manufacturer. (See also examples given in Annexes BBB and FFF.)

***2.204 PATIENT ENVIRONMENT** Any volume in which intentional or unintentional contact between PATIENT and parts of the SYSTEM or some other persons touching parts of the SYSTEM can occur (see Fig. 201).

2.205 SEPARATION DEVICE A component or arrangement of components with a SIGNAL INPUT PART and SIGNAL OUTPUT PART that prevents for safety reasons a transfer of unwanted voltage or current between parts of a SYSTEM.

***2.206 MULTIPLE PORTABLE SOCKET-OUTLET** A combination of two or more socket-outlets intended to be connected to, or integral with, flexible cables or cords, and which can easily be moved from one place to another while connected to the supply.

3 General requirements

3.201 General requirements for the SYSTEM A SYSTEM after installation or subsequent modification shall not cause a SAFETY HAZARD for the PATIENT, the OPERATOR or surroundings.

A SYSTEM as a whole shall provide:

- within the PATIENT ENVIRONMENT the same level of safety as MEDICAL ELECTRICAL EQUIPMENT complying with JIS T 0601-1, IEC 60601-1, and relevant detail specifications, and
- outside the PATIENT ENVIRONMENT the level of safety appropriate for non-medical electrical equipment complying with other **IEC** or **ISO** safety standards.

Non-medical electrical equipment outside the PATIENT ENVIRONMENT may be such that it complies with the relevant JIS, technical standard stated in the Electrical Appliance and Material Control Law or it provides equivalent safety thereto.

(Test) Compliance is considered to exist if the requirements of subclauses **3.201.1**, **3.201.2** and **3.201.3** are met.

3.201.1 MEDICAL ELECTRICAL EQUIPMENT shall comply with the general safety requirements according to JIS T 0601-1, IEC 60601-1 and its relevant particular standards. The equipment may be the one which complies with JIS T 1001, JIS T 1002 and relevant detail specification.

(Test) Compliance is checked by inspection of appropriate documents or certificates.

***3.201.2** Non-medical electrical equipment shall comply with **IEC** and **ISO** safety standards that are relevant for the equipment in question. See also Annex DDD: Bibliography.

Equipment of class 0 shall not be used in a SYSTEM. However equipment of class 0 or class 0I may be used, if the equipment is combined with means which ensure safety, for example, an isolating transformer (DOUBLE INSULATION or REINFORCED INSULATION).

(Test) Compliance is checked by inspection of appropriate documents or certificates.

***3.201.3** COUPLING of equipment in a SYSTEM shall not result in a safety level for the PATIENT that is inferior to the level given in **JIS T 0601-1**.

3.201.4 A SYSTEM using equipment, components or forms of construction different from those detailed in relevant standards as mentioned in subclauses **3.201.1** and **3.201.2** shall be accepted if it can be demonstrated that an equivalent degree of safety is obtained.

4 General requirements for tests

***4.201 General requirements for tests for the SYSTEM** After installation or subsequent modification the SYSTEM shall be in compliance with the requirements of this Standard.

(Test) Compliance is checked by inspection, by testing or by analysis, as specified in the relevant subclause.

- Only hazards arising from the interconnection of different equipment to constitute a SYSTEM shall be considered.
- Safety tests, on individual equipment of the SYSTEM, already carried out to the relevant standards used, shall not be repeated.
- Tests shall be carried out:
 - in NORMAL CONDITION unless otherwise specified in this Standard, and
 - under operating conditions as specified by the manufacturer of the SYSTEM.

6 Identification, marking and documents

6.1.201 Marking Where in the ACCOMPANYING DOCUMENTS a warning is given related to a particular SAFETY HAZARD from a non-medical electrical equipment, symbol 14, Table D1, Annex D of **JIS T 0601-1** (see Fig. 202) shall be provided on that particular non-medical electrical equipment or on a particular part of that equipment.

NOTE — The party assembling or modifying the SYSTEM should calculate the power consumption of the SYSTEM, make sure that this consumption is consistent with the power that the MULTIPLE PORTABLE SOCKET-OUTLET(S) can support and document it.

(Test) Compliance is checked by inspection.

***6.8.201 Accompanying documents** A SYSTEM (including a modified SYSTEM) shall be accompanied by documents containing all the data necessary for safe and reliable use.

NOTE — It is the responsibility of the assembler of a SYSTEM (including a modified SYSTEM), that it is accompanied by documents containing all the data necessary for safe and reliable use.

These documents shall include:

- a) The ACCOMPANYING DOCUMENTS for each item of MEDICAL ELECTRICAL EQUIPMENT (see **6.8** of **JIS T 0601-1**).
- b) The accompanying documents for each item of non-medical electrical equipment.

c) The following information:

- instructions for cleaning and, where applicable, sterilizing and disinfecting each item of equipment forming part of the SYSTEM;
- additional safety measures which should be applied, during installation of the SYSTEM;
- which parts of the SYSTEM are suitable for use within the PATIENT ENVIRONMENT;
- additional measures which should be applied during preventive maintenance;
- a warning that MULTIPLE PORTABLE SOCKET-OUTLETS shall not be placed on the floor;
- the maximum permitted load for any MULTIPLE PORTABLE SOCKET-OUTLET(S);
- an instruction that MULTIPLE PORTABLE SOCKET-OUTLETS provided with the SYSTEM shall only be used for powering equipment which forms part of the SYSTEM;
- an explanation of the risks of connecting a non-medical electrical equipment, which has been supplied as a part of the SYSTEM, directly to the wall outlet when the SYSTEM is supplied via a MULTIPLE PORTABLE SOCKET-OUTLET with a separating transformer;
- an explanation of the risks of connecting electrical equipment which has not been supplied as a part of the SYSTEM, to the MULTIPLE PORTABLE SOCKET-OUTLET.

(Test) Compliance is checked by inspection.

Section Two—Environmental conditions

Section Three—Protection against electric shock hazards

16 ENCLOSURES and PROTECTIVE COVERS

16.201 ENCLOSURES Within the PATIENT ENVIRONMENT parts of non-medical electrical equipment which, after removal of covers, connectors, etc. without the use of a TOOL, may be contacted by the OPERATOR during routine maintenance, calibration, etc. shall operate at a voltage not exceeding 25 V a.c. or 60 V d.c. or peak value supplied from a source which is separated from the SUPPLY MAINS by one of the methods described in subclauses 17 g) 1) to 5) of JIS T 0601-1.

Additionally the instructions for use shall instruct the OPERATOR not to touch such a part and the PATIENT simultaneously.

(Test) Compliance is checked by inspection.

17 Separation

***17.201 Electrical separation** If the allowable values of LEAKAGE CURRENTS can be exceeded—caused by conductive connections between different items of equipment of a SYSTEM and other systems, e.g. a luminous call system or a data processing system—then safety measures incorporating a SEPARATION DEVICE shall be applied.

Such safety measures provide suitable electrical separation between the equipment.

NOTE — SEPARATION DEVICES may be insulating or may be voltage or current limiting. If safety measures incorporating an insulating SEPARATION DEVICE are applied, such a SEPARATION DEVICE will have the dielectric strength, CREEPAGE DISTANCES and AIR CLEARANCES appropriate to the highest voltage occurring during a fault at the point of electrical separation.

(Test) For the SEPARATION DEVICES involved, compliance with the requirements of this subclause shall be checked as follows:

The insulating SEPARATION DEVICES shall withstand a dielectric strength test according to clause 20 of JIS T 0601-1 between their SIGNAL INPUT PART and their SIGNAL OUTPUT PART. The terminals of each of these parts are connected together during the test.

The test voltage is chosen from clause 20, Table 5 of JIS T 0601-1, for BASIC INSULATION.

The reference voltage (U) is the highest RATED supply voltage or, for polyphase equipment, the phase to neutral supply voltage. For INTERNALLY POWERED EQUIPMENT, U is 250 V.

19 Continuous LEAKAGE CURRENTS and PATIENT AUXILIARY CURRENTS

*19.201 LEAKAGE CURRENTS

19.201.1 ENCLOSURE LEAKAGE CURRENT In NORMAL CONDITION the allowable ENCLOSURE LEAKAGE CURRENT from or between parts of the SYSTEM within the PATIENT ENVIRONMENT shall not exceed 0.1 mA.

In the event of the interruption of any non-permanently installed protective earth conductor the allowable ENCLOSURE LEAKAGE CURRENT from or between parts of a SYSTEM within the PATIENT ENVIRONMENT shall not exceed 0.5 mA.

If the SYSTEM includes a MULTIPLE PORTABLE SOCKET-OUTLET the ENCLOSURE LEAKAGE CURRENT shall also be measured from parts which are in NORMAL CONDITION protectively earthed.

19.201.2 PATIENT LEAKAGE CURRENT In NORMAL CONDITION the PATIENT LEAKAGE CURRENT shall not exceed 0.1 mA for TYPE B and BF EQUIPMENT and 0.01 mA for TYPE CF EQUIPMENT.

(Test) Compliance with the requirements of subclauses 19.201.1 and 19.201.2 is checked by inspection and measurement of LEAKAGE CURRENTS using a device according to JIS T 0601-1, subclause 19.4 e).

19.201.3 Connection of SIGNAL INPUT PARTS or SIGNAL OUTPUT PARTS (see also Annex BBB) If compliance of the MEDICAL ELECTRICAL EQUIPMENT with subclause 19.2 b) first dash and/or 19.2 c) of JIS T 0601-1 is achieved by specifying that the SIGNAL INPUT PART and/or SIGNAL OUTPUT PART is for exclusive connection to equipment as specified in the ACCOMPANYING DOCUMENTS, then the SIGNAL INPUT PART and/or SIGNAL OUTPUT PART shall be connected: