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(JIPT/JSA)

**Medical electrical equipment —
Particular requirements for the safety
of short-wave therapy equipment**

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Foreword

This translation has been made based on the original Japanese Industrial Standard established by the Minister of Health, Labour and Welfare and the Minister of Economy, Trade and Industry through deliberations at the Japanese Industrial Standards Committee according to the proposal of establishing a Japanese Industrial Standard from Japan Industries Association of Physical Therapy Device (JIPT)/Japanese Standards Association (JSA), with a draft of Industrial Standard based on the provision of Article 12 Clause 1 of the Industrial Standardization Law.

This Standard has been made based on IEC 60601-2-3 *Medical electrical equipment—Part 2 : Particular requirements for the safety of short-wave therapy equipment* for the purposes of making it easier to compare this Standard with International Standard; to prepare Japanese Industrial Standard conforming with International Standard; and to propose a draft of an International Standard which is based on Japanese Industrial Standard.

Attention is drawn to the possibility that some parts of this Standard may conflict with a patent right, application for a patent after opening to the public, utility model right or application for registration of utility model after opening to the public which have technical properties. The relevant Ministers and the Japanese Industrial Standards Committee are not responsible for identifying the patent right, application for a patent after opening to the public, utility model right or application for registration of utility model after opening to the public which have the said technical properties.

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the original JIS is to be the final authority.

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Medical electrical equipment—Particular requirements for the safety of short-wave therapy equipment

Introduction This Japanese Industrial Standard has been prepared based on the second edition of IEC 60601-2-3 *Medical electrical equipment—Part 2: Particular requirements for the safety of short-wave therapy equipment* published in 1991 and Amendment 1:1998 with some modifications of the technical contents.

The portions given sidelines or dotted underlines are the matters modified from the original International Standard. The list of modifications with the explanations is given in Annex 1 (informative).

This particular Standard is developed based on JIS T 0601-1 *Medical electrical equipment—Part 1: General requirements for the safety* and shall be applied along with it.

The requirements of this Standard take priority over those of JIS T 0601-1.

Subclauses or figures which are additional to those of JIS T 0601-1 are numbered starting from 101; additional Annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

This Standard specifies the requirements for the safety of short-wave therapy equipment and their test methods. In addition, this will modify and supplement IEC 60601-1 : 1988 (second edition) (hereafter referred to as “general rules”) including Amendment 1 and Amendment 2. This Standard refers to JIS T 0601-1-2.

The purpose of this Standard is to update the publications mentioned above and materials.

A rationale for the more important requirements, where appropriate, is given in Annex AA (informative). It is considered that a knowledge of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However this Annex AA (informative) does not form part of the requirements of this Standard.

The subclauses which have corresponding rationale statements in Annex AA (informative) are marked with an asterisk (*) before their numbers. Terms defined in clause 2 of this Standard or of JIS T 0601-1 are bold faced.

Section 1 General

1 Scope and object This clause of JIS T 0601-1 applies except as follows:

Addition:

This particular Standard specifies the requirements for the safety of **short-wave therapy equipment** as defined in 2.1.101, hereafter referred to as **equipment** having a rated output power not exceeding 500 W.

Information : The term “short-wave” in the original International Standard means “TANPA” in Japanese in engineering classification. However, in the field of physical therapy equipment, there is a history that this equipment has been familiar as TYÔTANPA-RYÔHÔ-KIKI for a long period. If this expression is changed, there is a fear to cause confusion, and so the term “short-wave” is translated as “TYÔTANPA”.

Low power equipment defined in 2.2.101 is exempted from certain requirements of this Standard. Such equipment is called **low power equipment**.

Remarks : The International Standard corresponding to this Standard is as follows:

In addition, symbols which denote the degree of correspondence in the contents between the relevant International Standard and JIS are IDT (identical), MOD (modified) and NEQ (not equivalent) according to ISO/IEC Guide 21.

IEC 60601-2-3:1991 *Medical electrical equipment—Part 2: Particular requirements for the safety of short-wave therapy equipment* and Amendment 1 (1998) (MOD).

1.5 Collateral standards

Addition:

The following collateral standards apply.

JIS T 0601-1-1 *Medical electrical equipment—Part 1: General requirements for safety*
—1. *Collateral standard: Safety requirements for medical electrical systems*

Remarks : IEC 60601-1-1:1992 *Medical electrical equipment—Part 1: General requirements for safety—1. Collateral standard: Safety requirements for medical electrical systems* and Amendment 1 (1995) are equivalent to the said standard.

JIS T 0601-1-2 *Medical electrical equipment—Part 1: General requirements for safety—2. Collateral standard: Electromagnetic compatibility—Requirements and tests*

Remarks : IEC 60601-1-2:1993 *Medical electrical equipment—Part 1: General requirements for safety—2. Collateral standard: Electromagnetic compatibility—Requirements and tests* is identical with the said standard.

IEC 60601-1-4: 1996 *Medical electrical equipment—Part 1: General requirements for safety*
—4. *Collateral standard: Programmable electrical medical systems*

2 Terminology and definitions

Clause 2 of JIS T 0601-1 applies except as follows:

*2.1.5 Applied part

Addition:

Accessible parts of **applicators**

Additional definitions:

2.1.101 short-wave therapy equipment equipment for the treatment of the **patient** by exposure to electric or magnetic fields produced by the operation of the **equipment** with frequencies between 3 MHz and 45 MHz

2.1.102 output circuit all conductive parts used to couple radio-frequency power from the generator to the **applicators**, including conductive (inaccessible) parts of the **applicators** and their connecting cables

2.1.103 applicator an accessory or part of the **equipment** intended to be used to couple the r.f. power to the **patient**, but excluding the associated connecting cables

2.2.101 low power equipment equipment having a **rated output power** not exceeding 10 W

***2.12.101 rated output power** maximum radio-frequency power assigned by the manufacturer, averaged over a period of 1 s, which can be delivered to the load specified in clause 50.

3 General requirements Clause 3 of JIS T 0601-1 applies except as follows:

3.6 Addition to the list of single fault conditions:

aa) failure of the insulation between the **applied parts** and live parts of the output circuit

4 General requirements for tests

Clause 4 of JIS T 0601-1 applies except as follows:

4.11 Sequence

Amendment:

The tests called for in 20.2 shall be performed immediately after the compliance test of 42.3 (clause C20 of Annex C of JIS T 0601-1).

Addition:

4.101 Routine tests The testing during manufacture (see Rationale in 4.1 of JIS T 0601-1) should include:

a) Measurement of the operating frequency with the **equipment** operating under the conditions specified in item b) below.