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**Medical suction equipment—Part 1:
Electrically powered suction
equipment—Safety requirements**

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Contents

	Page
Introduction	1
1 Scope	1
2 Normative references.....	3
3 Terms and definitions.....	4
4 General requirements and general requirements for tests	7
5 Classification	7
6 Identification, marking and documents.....	7
7 Power input	10
8 Environmental conditions.....	10
8.1 Basic safety categories.....	10
8.2 Removable protective means	10
8.3 Environmental conditions.....	10
8.4 Special measures with respect to safety	10
9 Protection against electric shock hazards	10
9.1 General	10
9.2 Requirements related to classification	10
9.3 Limitation of voltage and/or energy.....	10
9.4 Enclosures and protective covers.....	10
9.5 Separation	11
9.6 Protective earthing, functional earthing and potential equalization	11
9.7 Continuous leakage currents and patient auxiliary currents	11
9.8 Dielectric strength.....	11
10 Protection against mechanical hazards	11
10.1 Mechanical strength	11
10.2 Moving parts.....	12
10.3 Surfaces, corners and edges.....	12
10.4 Stability in normal use	12
10.5 Expelled parts.....	12
10.6 Vibration and noise.....	12
10.7 Pneumatic and hydraulic power	13
10.8 Suspended masses	13
11 Protection against hazards from unwanted or excessive radiation.....	13
11.1 X-radiation.....	13
11.2 Alpha, beta, gamma, neutron radiation and other particle radiation	13
11.3 Microwave radiation.....	13

11.4	Light radiation (including lasers)	13
11.5	Infra-red radiation	13
11.6	Ultraviolet radiation	13
11.7	Acoustical energy (including ultra-sonics)	13
11.8	Electromagnetic compatibility	13
12	Protection against hazards of ignition of flammable anaesthetic mixtures	13
12.1	Locations and basic requirements	13
12.2	Marking, accompanying documents	13
12.3	Common requirement for Category AP and Category APG equipment	14
12.4	Requirement and tests for Category AP equipment, parts and components thereof	14
12.5	Requirement and tests for Category APG equipment, parts and components thereof	14
13	Protection against excessive temperatures and other safety hazards	14
13.1	Excessive temperatures	14
13.2	Fire prevention	14
13.3	Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compliance	14
13.4	Pressure vessels and parts subject to pressure	18
13.5	Human errors	18
13.6	Electrostatics charges	19
13.7	Biocompatibility	19
13.8	Interruption of the power supply	19
14	Accuracy of operating data and protection against hazardous output	20
14.1	Accuracy of operating data	20
14.2	Protection against hazardous output	20
15	Abnormal operation and fault conditions: environmental tests	20
15.1	Abnormal operation and fault conditions	20
15.2	Environmental tests	21
16	Constructional requirements	22
16.1	General requirements	22
16.2	Enclosures and covers	22
16.3	Components and general assembly	22
16.4	Mains parts : components and layout	26
16.5	Protective earth : terminals and connection	26
16.6	Construction and layout	26
	Annexes A to L	32
	Annex M (informative) Rationale statement	33
	Annex N (informative) Typical ranges of volume for collection containers for specific uses	34

Annex O (informative)	Lumen (passageway) size and its effects on flow.....	35
Annex JA (informative)	Comparison table between JIS and corresponding International Standard.....	36

Foreword

This translation has been made based on the original Japanese Industrial Standard established by the Minister of Health, Labour and Welfare through deliberations at the Japanese Industrial Standards Committee according to the proposal of establishing a Japanese Industrial Standard from Japan Association of Medical Devices Industries (JAMDI), Japanese Society of Anesthesiologists (JSA) and Japanese Standards Association (JSA) with a draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law.

Consequently JIS T 7327 : 1989 has been withdrawn and replaced with this Standard.

This JIS document is protected by the Copyright Law.

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, or utility model right. The relevant Minister and the Japanese Industrial Standards Committee are not responsible for identifying the patent right, application for a patent after opening to the public and the utility model right.

JIS T 7208 series consists of the following 2 parts under the general title “*Medical suction equipment*”:

Part 1 : Electrically powered suction equipment—Safety requirements

Part 2 : Manually powered suction equipment

Medical suction equipment—Part 1: Electrically powered suction equipment—Safety requirements

Introduction

This Japanese Industrial Standard has been prepared based on the second edition of ISO 10079-1 published in 1999 with some modifications of the technical contents in order to correspond to the actual conditions in Japan, such as addition of test method of **equipment**, for interruption and restoration of the power source, whose setting returns to the initial status when the power supply is reconnected, and alteration of an inside diameter of **inlets of collection containers** from 6 mm or larger to 5 mm or larger.

The portions with dotted underlines in this Standard are the matters in which the contents of the corresponding International Standard have been modified. A list of modifications with explanations is given in Annex JA.

NOTE : In this Standard, the bold characters in the text mean terms defined in this Standard and JIS T 0601-1 : 1999. If not indicated in boldface type, the terms defined in the standards mentioned above shall be interpreted in context without applying the definition.

1 Scope

This Standard specifies minimum safety and performance requirements for medical and surgical suction equipment for health care facilities such as hospitals, for domiciliary care of patients and for field and transport use (see figure 1).

Although such equipment may be driven by centrally powered piped vacuum systems, compressed gases and electricity, or be manually powered for a variety of applications, this Standard addresses only **mains** electricity- and battery-powered suction equipment.

NOTE 1 See also Annex M in this Standard.

NOTE 2 Transportation means to transfer **patients**, not to move **patients** to another place in medical facilities.

NOTE 3 The International Standard corresponding to this Standard and the symbol of degree of correspondence are as follows.

ISO 10079-1 : 1999 *Medical suction equipment—Part 1: Electrically powered suction equipment—Safety requirements* (MOD)

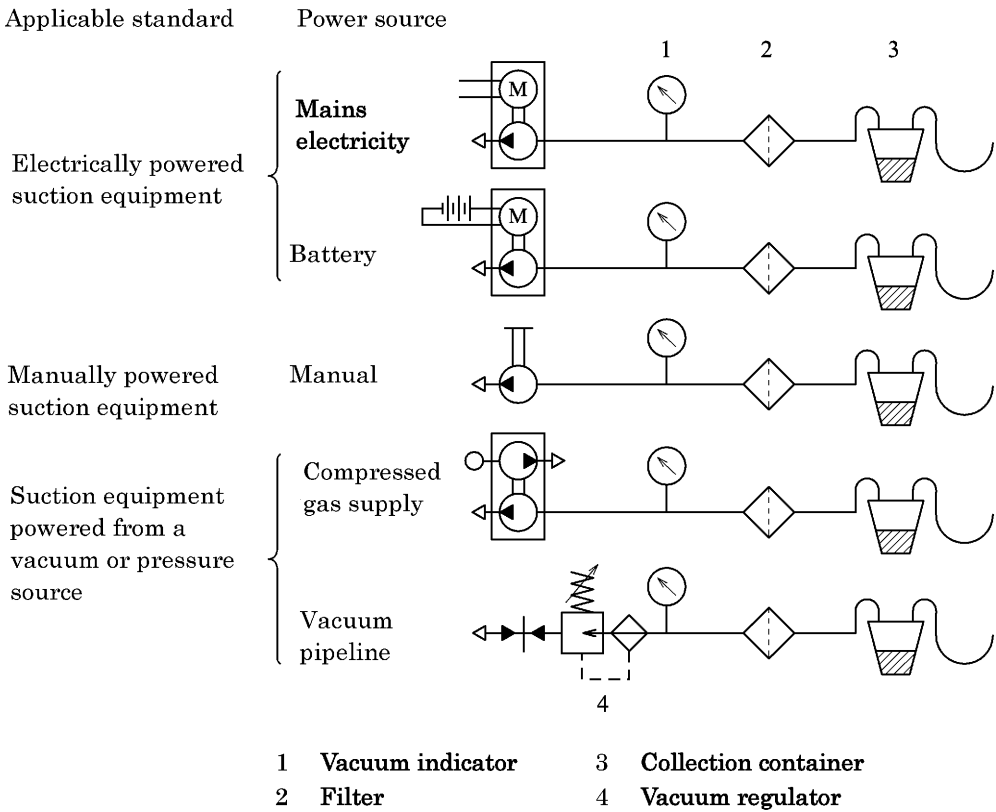
In addition, symbols, which denote the degree of correspondence in the contents between the relevant International Standard and JIS, are IDT (identical), MOD (modified), and NEQ (not equivalent) according to ISO/IEC Guide 21-1.

This Standard is referred to as a “Particular Standard” of JIS T 0601-1. The requirements of this Standard take precedence over those of JIS T 0601-1.

The scope and object given in clause 1 of JIS T 0601-1 apply, except that 1.1 of JIS T 0601-1 is replaced by the following.

This Standard is not applicable to:

- a) central power supply (by vacuum/compressed air generation), piping systems of vehicles and buildings, and wall connectors;
- b) catheter tubes, drains, curettes and suction tips;
- c) syringes;
- d) dental suction equipment;
- e) waste gas scavenging systems;
- f) laboratory suction;
- g) autotransfusion systems;
- h) passive urinary drainage;
- i) closed systems for wound **drainage**;
- j) gravity gastric **drainage**;
- k) orally operated mucous extractors;
- l) suction equipment where the **collection container** is downstream of the **vacuum pump**;
- m) equipment marked as suction unit for permanent tracheostomy;
- n) ventouse (obstetric) equipment;
- o) neonatal mucous extractors;
- p) suction equipment marked for endoscopic use only.



NOTE 1 Components illustrated are not necessarily required by this Standard.
NOTE 2 Actual systems may consist of other arrangements and components not illustrated.

Figure 1 Schematic drawing of suction equipment

2 Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this Standard. For standards with the year indication, only the edition of the indicated year shall apply but the revisions (including amendments) made thereafter shall not apply.

- JIS C 0920:2003 *Degrees of protection provided by enclosures (IP Code)*
NOTE : Corresponding International Standards : IEC 60529:2001 *Degrees of protection provided by enclosures (IP Code)* (IDT)
- JIS C 1509-1:2005 *Electroacoustics—Sound level meters—Part 1: Specifications*
NOTE : Corresponding International Standard : IEC 61672-1:2002 *Electroacoustics—Sound level meters—Part 1: Specifications* (IDT)

JIS C 60695-11-5:2007 *Fire hazard testing—Part 11-5 : Test flames—Needle-flame test method—Apparatus, confirmatory test arrangement and guidance*

NOTE : Corresponding International Standards : IEC 60695-11-5:2004 *Fire hazard testing—Part 11-5 : Test flames—Needle-flame test method—Apparatus, confirmatory test arrangement and guidance* (IDT)

JIS T 0601-1:1999 *Medical electrical equipment—Part 1: General requirements for safety*

NOTE : Corresponding International Standards : IEC 60601-1:1988 *Medical electrical equipment—Part 1: General requirements for safety*, Amendment 1:1991 and Amendment 2:1995 (MOD)

JIS T 3251:2005 *Suction catheters for use in the respiratory tract*

NOTE : Corresponding International Standards : ISO 8836:1997 *Suction catheters for use in the respiratory tract* (MOD)

JIS T 7201-2-1:1999 *Inhalational anaesthesia systems—Anaesthetic and respiratory equipment—Conical connectors—Part 2-1 Cones and sockets*

NOTE : Corresponding International Standards : ISO 5356-1:1996 *Anaesthetic and respiratory equipment—Conical connectors—Part 1: Cones and sockets* (MOD)

JIS Z 8733:2000 *Acoustics—Determination of sound power levels of noise sources using sound pressure—Engineering method in an essentially free field over a reflecting plane*

NOTE : Corresponding International Standards : ISO 3744:1994 *Acoustics—Determination of sound power levels of noise sources using sound pressure—Engineering method in an essentially free field over a reflecting plane* (MOD)

IEC 60079-4:1975 *Electrical apparatus for explosive gas atmospheres. Part 4: Method of test for ignition temperature.*

3 Terms and definitions

For the purposes of this Standard, the terms and definitions given in clause 2 of JIS T 0601-1 apply, except that the definition given in 2.1.5 shall be replaced by the following:

2.1.5 applied part

all parts in the liquid pathway

Add to definition 2.4.3 the following:

2.4.3 SELV (safety extra-low voltage)

electrical sources which are isolated (e.g. car battery) and do not require a separate transformer or converter with separate windings

For the purposes of this Standard, the following additional terms and definitions also apply.

3.1 breast pump

vacuum pump for the collection of breast milk

3.2 collection container

container in which liquids and solid particles are collected

3.3 collection container assembly

collection container and its closure with connectors for **suction**

3.4 drainage

removal by **suction** of fluids from a body cavity or wound

3.5 end-piece

that part of the suction equipment applied to the **patient** which begins at the site that where material is drawn in and ends at the first detachable connection

NOTE : Examples of commonly used **end-pieces** are a Yanker sucker and a suction catheter.

3.6 exhaust opening

port or ports through which exhaust is discharged

3.7 filter

device for retention of particulate matter

3.8 free air flow

unrestricted flow of air through a designated **inlet**

3.9 high flow suction

suction which produces a **free air flow** of 20 L/min or more

3.10 high vacuum

vacuum of 60 kPa or more below atmospheric pressure

NOTE : 1 kPa = 7.5 mmHg = 10.2 cmH₂O = 10 hPa

3.11 inlet

port of a component through which fluids and/or solid particles enter

3.12 intermediate tubing

tubing between the **collection container** and the vacuum source

3.13 intermittent suction

type of suction in which the negative pressure applied to the **end-piece** is automatically and periodically returned to atmospheric pressure

3.14 low flow suction

suction which produces a **free air flow** less than 20 L/min

3.15 low vacuum

vacuum of not more than 20 kPa below atmospheric pressure

3.16 medium vacuum

vacuum of more than 20 kPa but less than 60 kPa below atmospheric pressure

3.17 outlet

port of vacuum source of a component through which fluids and/or solid particles exit

3.18 overflow protection device

system intended to prevent liquid or solid particles from entering the **intermediate tubing**

3.19 suction

application of **vacuum** to remove fluids and/or solid particles

3.20 suction tubing

tubing for conduction of fluids and/or solid particles between the **end-piece** and the **collection container**

3.21 thoracic drainage

drainage by application of **suction** to the thoracic cavity of the **patient**

NOTE : For the purposes of this Standard, all **thoracic drainage** is considered to be active.

3.22 vacuum

pressure less than atmospheric pressure

NOTE : In this Standard, **vacuum** is expressed as a difference from atmospheric pressure.

3.23 vacuum indicator

device for displaying the level of **vacuum**

3.24 vacuum pump

powered device for generating **vacuum**

3.25 vacuum regulator

device for controlling the maximum **vacuum** applied to the **patient**

4 General requirements and general requirements for tests

The requirements given in clauses 3 and 4 of JIS T 0601-1 apply, together with the following additional item:

- 4.6 f) Where reference is made in test methods to tubing, the tubing which is supplied or recommended by the marketing authorization holder (MAH) shall be used.

5 Classification

The classification given in clause 5 of JIS T 0601-1 applies.

6 Identification, marking and documents

The requirements given in 6.1 of JIS T 0601-1 apply, with the following additions and modifications:

6.1 e) Marking of manufactures

Replace by the following.

The name and address of the MAH responsible for securing that the **equipment** complies with this Standard.

NOTE : In the corresponding International Standard, also the device and detachable components are required to be identified. However, in this Standard, the corresponding parts are excluded, in view of the state of distribution of the equipment in Japan.

6.1 f) Type name

Add the following.

The **equipment** shall be marked with a batch or serial number and also year of manufacture.

6.1 p) Power

Replace by the following.

- 1) All **equipment** generating **suction** shall be marked with words indicating **suction**, and with an indication of the available level of **vacuum** as determined by the MAH. This marking shall be visible in the normal working position.

NOTE : Suction equipment including vacuum should be marked with the designation: “**high vacuum/high flow**”, “**high vacuum/low flow**”, “**medium vacuum/high flow**”, “**medium vacuum/low flow**”, “**low vacuum/high flow**” or “**low vacuum/low flow**”, as appropriate.

- 2) **Low vacuum** equipment with a level of **vacuum** which is not adjustable by the user shall be marked either with the level of **vacuum** which can be attained or with words indicating by **low vacuum**.
- 3) Intermittent suction equipment shall be marked with words indicating **intermittent suction**. Equipment which can provide both continuous and **intermittent suction** shall have the mode control clearly marked.
- 4) If there is a single **exhaust opening**, it shall be marked with words indicating **exhaust opening**.
- 5) Suction equipment intended for **thoracic drainage** and complying with **59.8** shall be marked as such.
- 6) The **inlet** connection to the **collection container** shall be identified unless misconnection is prevented by a design feature.
- 7) If the suction equipment is intended for use in the field and/or transport and does not comply with **53.1**, it shall be marked on the equipment case as not suitable for use at temperatures below ... °C or above ... °C with the appropriate limiting temperatures marked. If no case is provided, the statement shall be marked on the equipment.

Add the following additional items:

- aa) Suction equipment containing a **filter** which is intended to be cleaned or changed by the user shall have wording clearly marked on the equipment, or on the **filter** unit, to the effect that the **filter** should be cleaned or changed in accordance with the MAH's recommendations.
- ab) **The capacity of the collection container**

6.3 c) Add the following.

If a progressive variation in the degree of **vacuum** is available, the direction of adjustment to increase **vacuum** shall be clearly and permanently marked.

6.8.1 General matters

Add the following.

The **collection container** capacity shall be stated in the **accompanying documents**.

6.8.2 a) General information

Add the following.

The instructions for use shall additionally include the following information:

- 1) instructions for operating the **vacuum** regulator, if supplied, and for setting the required **vacuum**;
- 2) the size and type of **suction tubing** recommended for use with the suction equipment and its means of connection to the **collection container**;

- 3) recommended methods for cleaning and disinfection or sterilization of all **applied parts**;
- 4) the method for removing the **collection container** for emptying;
- 5) details of the operation of any **overflow protection device** fitted to the **collection container assembly**

NOTE : In the corresponding International Standard, the usable capacity of the **collection container** in all the recommended inclined planes of operation shall be described. However, in this Standard, it is not recommend that the **collection container** is used in the inclined plane of operation, and therefore the corresponding parts are excluded.

- 6) if applicable, the method of controlling frothing in the **collection container**;
- 7) instructions, if applicable, for the replacement or cleaning of air **filters**, and for cleaning and sterilization or disinfection of the **filter housing**;
- 8) on performance as either
 - 8.1) the type of equipment (e.g. medical suction, **high vacuum** and high flow)
 - 8.2) the level of **vacuum** and flow obtainable
 - 8.3) the **vacuum** and air flow characteristics obtainable from the equipment as required by 6.1 p) 1), 2) or 3), as appropriate.
- 9) instructions to inspect **suction tubing**, **collection containers** and any other components that are subject to wear or damage;
- 10) a statement advising removal and servicing of the equipment if liquid or solid has been drawn into the **vacuum pump**;

NOTE : In some cases, this may require servicing by the manufacturer or his authorized agent.

- 11) if applicable, a statement that **suction** ceases when the **overflow protection device** operates, and the method of correcting this situation,

If an **overflow protection device** is not applicable, a precaution that the equipment shall be used so that liquid or solid suctioned does not overflow the **collection container**;

- 12) recommendations for cleaning and/or disinfection of the outer casing;
- 13) instructions for cleaning and sterilization or disinfection of reusable **suction tubing**;
- 14) instructions or cleaning and sterilizing or disinfecting any part of a **filter assembly** which is reusable;