

JIS

JAPANESE
INDUSTRIAL
STANDARD

Translated and Published by
Japanese Standards Association

JIS T 7208-2 : 2005
(JAMEI/JSA/JSA)

**Medical suction equipment—
Part 2:Manually powered suction
equipment**

ICS 11.040.20

Reference number : JIS T 7208-2 : 2005 (E)

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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 through deliberations at the Japanese Industrial Standards Committee according to the proposal of establishing a Japanese Industrial Standard from Japan Association of Medical Equipment Industries (JAMEI)/Japanese Society of Anesthesiologists (JSA)/Japanese Standards Association (JSA), with a draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law.

This Standard has been made based on **ISO 10079-2 : 1999 *Medical suction equipment—Part 2: Manually powered suction 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 Minister 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.

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

Part 1: Electrically powered suction equipment—Safety requirements (to be established)

Part 2: Manually powered suction equipment

Part 3: Suction equipment powered from a vacuum or pressure source (to be established)

Date of Establishment: 2005-03-25

Date of Public Notice in Official Gazette: 2005-03-25

Investigated by: Japanese Industrial Standards Committee

Standards Board

Technical Committee on Medical Equipment

JIS T 7208-2 : 2005, First English edition published in 2006-08

Translated and published by: Japanese Standards Association
4-1-24, Akasaka, Minato-ku, Tokyo, 107-8440 JAPAN

In the event of any doubts arising as to the contents,
the original JIS is to be the final authority.

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Printed in Japan

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Contents

	Page
Introduction	1
1 Scope	1
2 Normative references.....	3
3 Terms and definitions	3
3.1 manually powered vacuum, manually generated vacuum	3
3.2 transportable equipment	3
4 Cleaning and sterilization	3
5 Design requirements.....	3
5.1 Connectors	4
5.2 Suction tubing.....	4
5.3 End-pieces.....	4
6 Operational requirements	4
6.1 Ease of operation	4
6.2 Dismantling and reassembly	4
6.3 Mechanical shock.....	4
6.4 Immersion in water	5
6.5 Stability	5
6.6 Overfill protection devices	5
6.7 Vacuum indicators	5
7 Physical requirements	6
7.1 Dimensions	6
7.2 Mass.....	6
7.3 Collection container	6
8 Performance requirements for vacuum and flowrate	7
8.1 Vacuum	7
8.2 Flowrate.....	7
8.3 Free air flow.....	7
8.4 Packaging	7
9 Resistance to environment	7
9.1 Operating conditions	7
9.2 Storage.....	7
10 Marking	7
11 Information to be supplied by manufacturer.....	7

Annex A (normative) Test methods.....	9
Annex B (informative) Table of typical ranges of volume for collection containers for specific uses.....	14
Annex C (informative) Rationale statement.....	15
Annex 1 (informative) Comparison table between JIS and corresponding International Standard.....	16

Medical suction equipment—Part 2: Manually powered suction equipment

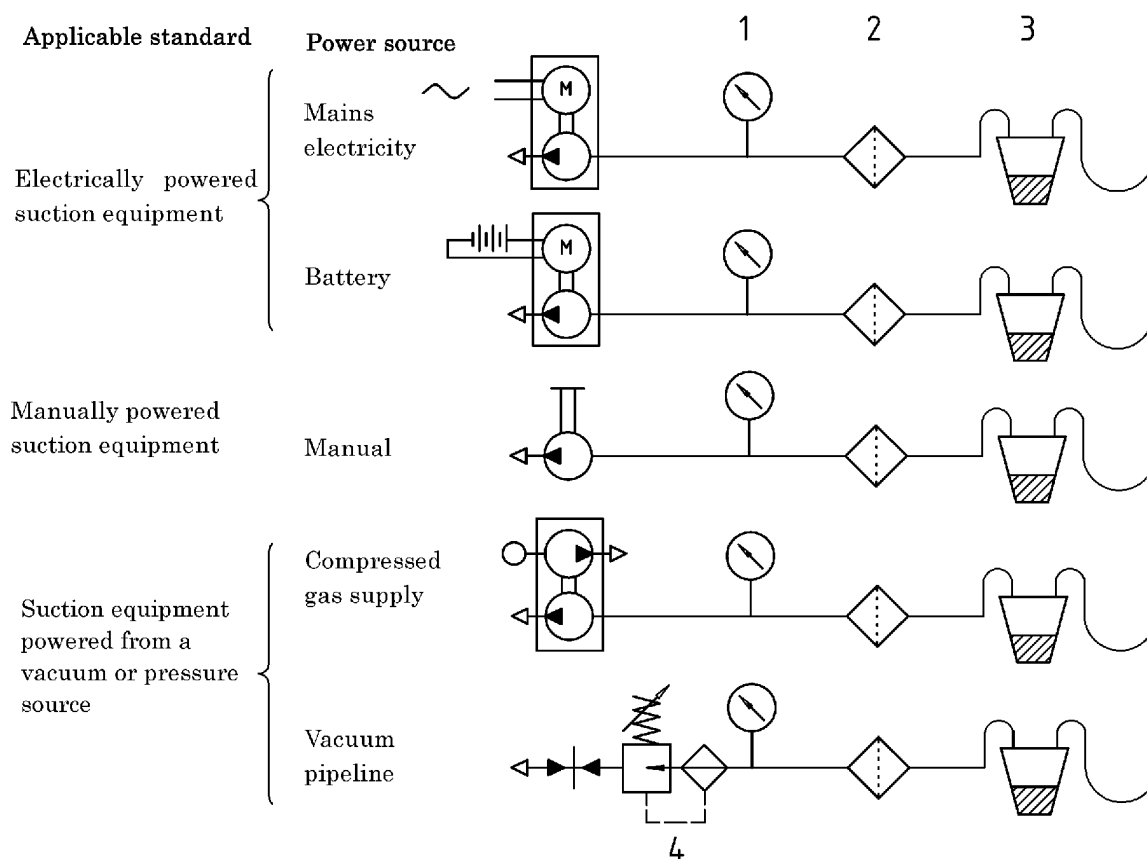
Introduction This Japanese Industrial Standard has been prepared based on the first edition of **ISO 10079-2** *Medical suction equipment—Part 2: Manually powered suction equipment* published in 1999 with some modifications of the technical contents.

Portions underlined with dots are the matters in which the contents of the original International Standard have been modified. A list of modifications with the explanations is given in Annex 1(informative).

1 Scope This part of **JIS T 7208** specifies safety and performance requirements for manually powered medical suction equipment intended for oro-pharyngeal suction. It covers equipment operated by foot or by hand or both (see figure 1). Non-electrical suction equipment which may be integrated with electrical equipment is also included in the scope of this part of **JIS T 7208**. This part of **JIS T 7208** does not apply to electrically powered suction equipment, nor to suction equipment powered from a vacuum or pressure source, nor to the following:

- a) medical gas piping systems (by vacuum/compressed air generation) 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) breast pumps;
- q) liposuction;

- r) uterine aspiration;
- s) thoracic drainage.



NOTES 1 Components illustrated are not necessarily required by this part of JIS T 7208.

2 Actual systems may consist of other arrangements and components which are not illustrated.

Figure 1 Diagrammatic illustration of suction equipment

Remarks : The International Standard corresponding to this part of JIS T 7208 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.

ISO 10079-2:1999 *Medical suction equipment—Part 2: Manually powered suction equipment* (MOD)

2 Normative references The following standards contain provisions which, through reference in this text, constitute provisions of this part of **JIS T 7208**. If the indication of the year of coming into effect/publication is given to these referred standards, only the edition of indicated year constitutes the provision of this part of **JIS T 7208** but the revision and amendment made thereafter do not apply.

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

Remarks : ISO 8836:1997 *Suction catheters for use in the respiratory tract* is equivalent to the said standard.

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

Remarks : ISO 5356-1:1996 *Anaesthetic and respiratory equipment—Conical connectors —Part 1: Cones and sockets* is identical with the said standard.

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

3 Terms and definitions For the purposes of this part of **JIS T 7208**, the terms and definitions given in **ISO 10079-1:1999** and the following apply.

3.1 manually powered vacuum, manually generated vacuum generation of vacuum by human effort with a hand or foot or both

3.2 transportable equipment equipment which is intended to be easily moved from one place to another, whether or not connected to the vacuum supply, without an appreciable restriction of range

4 Cleaning and sterilization

4.1 The suction equipment shall meet the requirements given in **8.1** to **8.3** after those components which are subject to contamination and which are intended for re-use have been submitted to 30 cycles of cleaning, disinfection and/or sterilization as recommended by the manufacturer.

4.2 Any filters installed shall either be of the disposable type or be capable of being cleaned, disinfected and/or sterilized for re-use in accordance with **4.1**.

4.3 Suction equipment incorporating a re-usable collection container assembly shall comply with the requirements given in **8.1** to **8.3**, before and after the collection container assembly has been subjected to 30 cycles of cleaning, disinfection and/or sterilization as recommended by the manufacturer.

4.4 Suction tubing shall either be for single use or be capable of being cleaned, disinfected and/or sterilized as recommended by the manufacturer.

5 Design requirements

NOTE : The constructional requirements may deviate from those detailed in this part of **JIS T 7208** if the equivalent level of safety is obtained.

5.1 Connectors

5.1.1 Collection container connectors The connectors for the suction tubing and the intermediate tubing to the vacuum source shall be designed to facilitate correct assembly or marked to indicate correct assembly when all parts are mated. Compliance shall be checked by inspection.

The construction of the connections has frequently been a source of spillover into a vacuum pump. The use of mechanical fittings so as to ensure correct attachment is highly desirable.

5.1.2 Inside diameter of suction tubing connection The inside diameter of the suction tubing connection (inlet port) shall be equal to or larger than the inside diameter of the largest tubing size recommended by the manufacturer.

5.1.3 Exhaust opening It shall not be possible to connect suction tubing to the exhaust opening.

5.2 Suction tubing

5.2.1 General If supplied, suction tubing shall have an inside diameter of not less than 5 mm. Suction performance may be markedly affected by the length, diameter and degree of collapse of the suction tubing. When tested in accordance with **A.2** of Annex A, the degree of collapse of the suction tubing supplied with the equipment shall be less than 0.5 throughout its entire length.

5.2.2 Length of suction tubing for foot-operated suction equipment When the foot-operated vacuum pump is on the floor in the operating position, the length of suction tubing, if supplied, shall be such that the end-piece can be positioned at least 1.3 m above the floor.

NOTE : See also Annex C (informative).

5.3 End-pieces Suction catheters, if supplied or recommended by the manufacturer, shall comply with **JIS T 3251**.

6 Operational requirements

6.1 Ease of operation The suction equipment shall be designed to be operated by one person unaided.

6.2 Dismantling and reassembly Suction equipment intended to be dismantled by the user (for example, for cleaning) shall be designed to facilitate correct assembly or marked to indicate correct reassembly when all parts are mated. After dismantling, reassembly and testing in accordance with the manufacturer's instructions, the suction equipment shall meet the requirements given in **8.1 to 8.3**, as appropriate.

6.3 Mechanical shock After suction equipment intended for field or transport use or both has been drop-tested in accordance with clause **A.3** of Annex A, it shall meet the requirements given in **8.1 to 8.3**, as appropriate.

If the suction equipment can be operated outside its carrying case, it shall meet the requirements given in **8.1 to 8.3**, as appropriate, after the individual parts of the