



JAPANESE
INDUSTRIAL
STANDARD

Translated and Published by
Japanese Standards Association

JIS T 7209 : 2007

(JAMEI/JSA/JSA)

**Oxygen concentrators for medical use
— Safety requirements**

ICS 11.040.10

Reference number : JIS T 7209 : 2007 (E)

PROTECTED BY COPYRIGHT

T 7209 : 2007

Date of Establishment: 2007-01-25

Date of Public Notice in Official Gazette: 2007-01-25

Investigated by: Japanese Industrial Standards Committee
Standards Board

Technical Committee on Medical Equipment

JIS T 7209 : 2007, First English edition published in 2007-05

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.

© JSA 2007

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from the publisher.

Printed in Japan

PROTECTED BY COPYRIGHT

Contents

	Page
Introduction	1
Section 1: General	1
1 Scope and object.....	1
1A Normative references.....	2
2 Terms and definitions	3
3 General requirements.....	4
4 General requirements for tests.....	4
5 Classification	4
6 Identification, marking and documents.....	4
7 Power input	6
Section 2 : Environmental conditions	6
8 Basic safety categories.....	6
9 Removable protective means	7
10 Environmental conditions.....	7
Section 3 : Protection against electric shock hazards	7
13 General	7
14 Requirements related to classification	7
15 Limitation of voltage and/or energy.....	7
16 Enclosures and protective covers.....	7
17 Separation	7
18 Protective earthing, functional earthing and potential equalization	7
19 Continuous leakage currents and patient auxiliary currents	7
20 Dielectric strength	7
Section 4 : Protection against mechanical hazards.....	7
21 Mechanical strength	7
22 Moving parts.....	8
23 Surfaces, corners and edges.....	8
24 Stability in normal use	8

25	Expelled parts	8
26	Vibration and noise	8
27	Pneumatic and hydraulic power.....	8
28	Suspended masses.....	8
Section 5 : Protection against hazards from unwanted or excessive radiation		9
29	X-Radiation	9
30	Alpha, beta, gamma, neutron radiation and other particle radiation.....	9
31	Microwave radiation	9
32	Light radiation (including lasers)	9
33	Infrared radiation	9
34	Ultraviolet radiation	9
35	Acoustical energy (including ultrasonics)	9
36	Electromagnetic compatibility	9
Section 6 : Protection against hazards of ignition of flammable anaesthetic agent		9
37	Locations and basic requirements.....	9
38	Marking, accompanying documents.....	9
39	Common requirements for category AP and category APG equipment.....	9
40	Requirements and tests for category AP equipment, parts and components thereof	10
41	Requirements and tests for category APG equipment, parts and components thereof	10
Section 7 : Protection against excessive temperatures and other safety hazards		10
42	Excessive temperatures	10
43	Fire prevention.....	11
44	Overflow, spillage, leakage, humidity, ingress of liquids, cleaning, sterilization, disinfection and compatibility.....	11
45	Pressure vessels and parts subject to pressure.....	11
46	Human errors.....	11
47	Electrostatic charges	11
48	Biocompatibility	11
49	Interruption of the power supply	11

Section 8 : Accuracy of operating data and protection against hazardous output	12
50 Accuracy of operating data	12
50.3 Flow indicator.....	12
50.4 Oxygen concentration	12
50.5 Mean oxygen concentration	13
50.6 Tolerance on flowrate.....	13
50.7 Backpressure effect	13
50.8 Outlet pressure.....	14
51 Protection against hazardous output.....	14
51.1 Flow control device	14
51.2 Filter.....	14
51.5 Oxygen concentration status indicator.....	14
Section 9 : Abnormal operation and fault conditions; environmental tests	15
52 Abnormal operation and fault conditions	15
53 Environmental tests	15
Section 10 : Constructional requirements.....	15
54 General	15
55 Enclosures and covers.....	15
56 Components and general assembly	15
57 Mains parts, components and layout.....	16
58 Protective earthing : Terminals and connections	16
59 Construction and layout	16
Section 11 : Additional clauses.....	16
60 Auditory indicators	16
61 Indication of loss of mains power.....	16
Annex N (normative) Test apparatus	17
Annex P (informative) Rationale statement.....	18
Annex Q (informative) Bibliography	22
Annex JA (informative) Comparison table between JIS and corresponding International Standard.....	23

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 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 **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, 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.

Oxygen concentrators for medical use—Safety requirements

Introduction

This Japanese Industrial Standard has been prepared based on the second edition of ISO 8359 published in 1996 with some modifications of the technical contents.

Oxygen concentrators provide a safe source of oxygen-enriched air for patients in need. These devices raise the level of inspired oxygen by separating nitrogen or oxygen from ambient air.

Oxygen concentrators fall into two main classes according to the means whereby gas separation is effected, namely:

- a) oxygen concentrators in which oxygen selectively permeates or transports through a membrane or lattice,
- b) pressure swing absorbers (PSA) in which air is exposed at a certain pressure to molecular sieve material which selectively retains nitrogen and other components until they are subsequently released when the pressure is reduced.

Details of the arrangement of test apparatus for carrying out a number of the tests to check compliance with certain requirements are given in Annex N.

A rationale for the most important requirements is given in Annex P. It is considered that a knowledge of the reasons for the requirements will not only facilitate the proper application of this Standard, but will expedite any subsequent revision. Test methods other than those specified in this Standard, but of equal or greater accuracy, may be used to verify compliance with the given requirements. However, in the event of a dispute, the methods specified in this Standard are to be used as the reference methods.

Portions underlined with dots in this Standard are the matters different from the corresponding International Standard. A list of modifications with the explanations is given in Annex JA.

Section 1 : General

1 Scope and object

This Standard is Japanese Industrial Standard based on JIS T 0601-1. In JIS T 0601-1, this type of Standard is referred to as a “Particular standard”. As stated in 1.3 of JIS T 0601-1, the requirements of this Standard take precedence over those of JIS T 0601-1. The scope given in clause 1 of JIS T 0601-1 apply, except that 1.1 shall be replaced by the following:

This Standard specifies safety requirements for continuous-flow oxygen concentrators, as defined in 2.0.8. However, this Standard does not apply to oxygen concentrators intended to supply gas to several patients via a piped medical gas installation or to those intended for use in the presence of flammable anaesthetic and/or cleaning agents.

The scope of this Standard is not restricted to membrane oxygen concentrators and pressure swing absorbers (PSA), as alternative methods of concentrating oxygen may become available in future. It is not intended that this Standard should restrict future developments of new methods of concentrating oxygen. For rationale statement, refer to Annex P.

NOTE : The corresponding International Standard of this Standard and the symbol which denotes the degree of correspondence are as follows.

ISO-8359 : 1996 *Oxygen concentrators for medical use—Safety requirements* (MOD)

In addition, a symbol which denotes the degree of correspondence (MOD) means modifications according to ISO/IEC Guide 21.

1A Normative references

The following standards contain provisions which, through reference in this text, constitute provisions of this Standard. The most recent editions of the standards (including amendments) indicated below shall be applied.

JIS C 1509-1 *Electroacoustics—Sound level meters—Part 1: Specifications*

NOTE : The corresponding International Standard : IEC 60651: 1979 *Precision sound level meters* was already withdrawn. The subsequent IEC 61672-1: 2002 *Electroacoustics—Sound level meters—Part 1: Specifications* is identical with the said standard.

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

NOTE : The corresponding International Standard : IEC 60601-1 *Medical electrical equipment—Part 1: General requirements for basic safety and essential performance* (MOD)

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

NOTE : The corresponding International Standard : IEC 60601-1-2 :1993 *Medical electrical equipment—Part 1-2: General requirements for safety—Collateral standard : Electromagnetic compatibility—Requirements and tests* (IDT)

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

NOTE : The corresponding International Standard : 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)

ISO 9703-1 *Anaesthesia and respiratory care alarm signals—Part 1: Visual alarm signals*

ISO 9703-2 *Anaesthesia and respiratory care alarm signals—Part 2 : Auditory alarm signals*

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

2 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 oxygen concentrator outlet

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

2.0.1

administration accessories all accessories for conducting the product gas from the oxygen concentrator outlet to the patient, but excluding any fixed tubing extensions

2.0.2

oxygen concentrator outlet port of the oxygen concentrator from which the product gas flows

2.0.3

flow control device device which controls the flow of the product gas

2.0.4

flow indicator device which shows the volume of product gas passing through the oxygen concentrator in a specified unit of time

2.0.5

operator control control to enable the user, without the need for tools, to cause the oxygen concentrator to perform its intended function

2.0.6

outlet pressure gauge pressure at the oxygen concentrator outlet under the test flow conditions

2.0.7

oxygen analyzer device which measures and quantitatively indicates the concentration of oxygen present in a gaseous mixture

2.0.8

oxygen concentrator device which, by selective removal of constituents of ambient air, increases the concentration of oxygen in the product gas

2.0.9

product gas output from the oxygen concentrator consisting of respirable oxygen-enriched air

2.0.10

oxygen concentration status indicator device which indicates when the proportion of oxygen in the product gas is at an abnormal level

3 General requirements

The requirements given in clause 3 of JIS T 0601-1 apply.

4 General requirements for tests

The requirements given in clause 4 of JIS T 0601-1 apply.

5 Classification

The classification given in clause 5 of JIS T 0601-1 applies, except for the following deletions.

- Delete 5.5.
- In 5.6 delete all except for “continuous operation (running) equipment” and “intermittent operation (running) equipment”.

6 Identification, marking and documents

The requirements given in clause 6 of JIS T 0601-1 apply, except for the following additions and modifications.

- The following additional general requirement also applies.

All markings pertaining to the operation of the oxygen concentrator shall be legible to an operator having visual acuity, corrected if necessary, of at least 1.0 and seated or standing 1 m from the oxygen concentrator flooded with illuminance of 215 lux.

NOTE : All markings should have a luminance contrast of at least 50 % when compared with the surrounding background material.

- In 6.1 e) add the following.

The oxygen concentrator shall be marked with its country of origin plus the address of the manufacturer.

- Delete 6.1 r).
- To 6.1 add the following additional items.

aa) The marking on the outside shall additionally include the following:

- 1) a warning against removal of the cover by unauthorized persons;
- 2) a warning “NO SMOKING OR NAKED FLAMES”;
- 3) the nominal concentration of oxygen in the product gas, expressed as a percent volume fraction (%), at a flowrate of 2 L/min or at the recommended maximum flowrate;
- 4) the statement “USE NO OIL OR GREASE”;
- 5) on the flow indicator, the output (e.g. output, gas flow, etc.).