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Heat exchanger for heart-lung bypass

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Contents

	Page
Introduction	1
1 Scope	1
2 Normative references	1
3 Terms and definitions	2
4 Requirements	4
4.1 Biological characteristics	4
4.2 Physical characteristics	4
4.3 Performance characteristics	4
5 Tests and measurements to determine compliance with this Standard	5
5.1 General	5
5.2 Biological characteristics	5
5.3 Physical characteristics	5
5.4 Performance characteristics	6
6 Information supplied by the manufacturer	8
6.1 Information on the heat exchanger	8
6.2 Information on the packaging	8
6.3 Information in the accompanying documents	9
6.4 Information in the accompanying documents in a prominent form	10
7 Packaging	10
7.1 Unit container	10
7.2 Shipping container	10
Annex A (informative) Examples of connectors, gauges and reference steel fittings	13
Annex JA (informative) Comparison table between JIS and corresponding International Standard	21

Foreword

This Japanese Industrial Standard has been revised by the Minister of Health, Labour and Welfare through deliberations at the Japanese Industrial Standards Committee as the result of proposal for revision of Japanese Industrial Standard submitted by Medical Technology Association of Japan (MTJAPAN)/Japanese Standards Association (JSA) with a draft being attached, based on the provision of Article 12, paragraph (1) of the Industrial Standardization Act applied mutatis mutandis pursuant to the provision of Article 16 of the said Act. This edition replaces the previous edition (**JIS T 1704** : 2008), which has been technically revised.

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Heat exchanger for heart-lung bypass

Introduction

This Japanese Industrial Standard has been prepared based on **ISO 7199** : 2016, Edition 3, and its Amendment 1 : 2020 with some modifications of the technical contents to reflect the local conditions in Japan. The amendment to the said International Standard has been incorporated into this Standard.

The vertical lines on both sides and dotted underlines indicate changes from the corresponding International Standard. A list of modifications with the explanations is given in Annex JA.

1 Scope

This Standard specifies requirements for sterile, single-use, extracorporeal (i.e. for heart-lung bypass) heat exchangers intended for heat exchange of blood or myocardial protection fluid (hereafter referred to as heat exchangers). This Standard does not apply to

- implanted oxygenators (vascular intima oxygenators),
- extracorporeal blood-gas exchangers (oxygenators),
- liquid oxygenators,
- extracorporeal circuits (blood tubing), and
- separate ancillary devices.

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

ISO 7199 : 2016 *Cardiovascular implants and artificial organs — Blood-gas exchangers (oxygenators)*+Amendment 1 : 2020 (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**.

The previous edition of this Standard, JIS T 1704 : 2008, remains valid for three years from the date of public notice of the revision of this Standard.

2 Normative references

Part or all of the provisions of the following standards, 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 T 0993-1 *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

NOTE Normative reference in the corresponding International Standard: ISO 10993-1 *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

JIS T 3250 *Haemodialysers, haemodiafilters, haemofilters and haemoconcentrators*

ISO 10993-11 *Biological evaluation of medical devices — Part 11: Tests for systemic toxicity*

ISO 80369-7 *Small-bore connectors for liquids and gases in healthcare applications — Part 7: Connectors for intravascular or hypodermic applications*

3 Terms and definitions

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

3.1

blood pathway

paths of the heat exchanger containing blood or myocardial protection fluid during intended clinical use

3.2

test blood

whole blood obtained by anticoagulating the blood taken from human, bovine or porcine, used with or without dilution with saline solution

3.3

heat exchanger

component that is intended to control the temperature of the circulating blood or myocardial protection fluid

3.4

heat exchanger performance factor, R

ratio of the difference between the temperature of blood at the inlet of the heat exchanger and the temperature of blood at the outlet of the heat exchanger to the difference between the temperature of the water at the inlet of the heat exchanger and the temperature of blood at the inlet of the heat exchanger

Note 1 to entry The heat exchanger performance factor is calculated by the following formula:

$$R = \frac{B_{To} - B_{Ti}}{W_{Ti} - B_{Ti}}$$

where, R : heat exchanger performance factor

B_{To} : temperature of blood at the outlet of the heat exchanger (°C)

B_{Ti} : temperature of blood at the inlet of the heat exchanger (°C)

W_{Ti} : temperature of water at the inlet of the heat exchanger (°C)

3.5

integral part

part that is connected to the heat exchanger and cannot normally be separated by the user

3.6

operating variables

settings of controls that affect the function of the device

3.7

platelet reduction

percentage reduction of platelets contained in a circuit incorporating a heat exchanger, as a function of time

3.8

plasma-free haemoglobin level

concentration of plasma-free haemoglobin in a circuit incorporating a heat exchanger, as a function of time

3.9

normalized index of hemolysis, NIH

grams of plasma-free hemoglobin released after pumping 100 L of blood

Note 1 to entry The normalized index of hemolysis is calculated by the following formula:

$$\text{NIH}(\text{g}/100 \text{ L}) = \Delta f_{\text{Hb}} \times V \times \frac{100 - \text{Hct}}{100} \times \frac{100}{Q \times t}$$

where, Δf_{Hb} : increase of plasma free hemoglobin concentration (g/L) over the sampling time interval

V : circuit volume (L)

Q : flow rate (L/min)

Hct : hematocrit (%)

t : sampling time interval (min)

3.10

white blood cell reduction

percentage reduction of white blood cells contained in a circuit incorporating a heat exchanger, as a function of time

3.11

residual blood volume

difference between the priming volume of the unit and the blood volume that can be extracted

4 Requirements

4.1 Biological characteristics

4.1.1 Sterility and non-pyrogenicity

The blood pathway shall be sterile and non-pyrogenic. Compliance shall be verified in accordance with **5.2.1**.

4.1.2 Biocompatibility

All parts of the blood pathway shall be biocompatible with respect to their intended use. Compliance shall be verified in accordance with **5.2.2**.

4.2 Physical characteristics

4.2.1 Blood pathway integrity

When tested in accordance with **5.3.1**, the blood pathway shall not leak.

4.2.2 Heat exchanger fluid pathway integrity

When tested in accordance with **5.3.2**, the heat exchanger fluid pathway shall not leak.

4.2.3 Blood volumes

When tested in accordance with **5.3.3**, the volume of the blood pathway shall be within the tolerances specified by the manufacturer (see **6.3**).

4.2.4 Connectors

Connectors for connection to the blood pathway shall, when tested in accordance with **5.3.4**, allow a secure connection (see Figures A.1 to A.11 for examples of connectors).

Connectors of a type that allows connection of tubes with an inner diameter of 4.8 mm, 6.3 mm, 9.5 mm or 12.7 mm, or a type that complies with **JIS T 3250**, Figure 1, or a type that complies with **ISO 80369-7**, have been found satisfactory.

Connectors, gauges and reference steel fittings with dimensions corresponding to Annex A are considered as one way to comply with this requirement.

Performance testing of connectors shall be carried out in accordance with Clause 6 of **ISO 80369-7**. The reference steel fittings specified in Annex A may be used for this testing.

Connectors for the heat exchanger fluid pathway shall be capable of being connected using fast couplings.

Connectors corresponding to Figure 2 of **JIS T 3250** can be used.

4.3 Performance characteristics

4.3.1 Heat exchanger performance factor

When determined in accordance with 5.4.1, the heat exchanger performance factors shall be within the range of values specified by the manufacturer (see 6.3).

4.3.2 Blood cell damage

When determined in accordance with 5.4.2, the increased concentration of plasma-free haemoglobin, platelet reduction and white blood cell reduction (positive or negative) shall be within the range of values specified by the manufacturer (see 6.3). The haemolysis results shall be reported as plasma-free haemoglobin level (mg/dl) and normalized index of hemolysis.

4.3.3 Shelf life

When the test specified in 5.4.3 is performed, the test results shall demonstrate the rated shelf life as specified by the manufacturer.

5 Tests and measurements to determine compliance with this Standard

5.1 General

5.1.1 Tests and measurements shall be performed with the device under test prepared according to the manufacturer's instructions for intended clinical use.

5.1.2 Operating variables shall be those specified by the manufacturer for intended clinical use, unless otherwise specified.

5.1.3 Unless otherwise stated, the temperature of test liquids shall be $37\text{ }^{\circ}\text{C} \pm 1\text{ }^{\circ}\text{C}$.

5.1.4 If the relationship between variables is nonlinear, sufficient determinations shall be made to permit valid interpolation between data points.

5.1.5 The test or measurement procedures are to be regarded as reference procedures. Other procedures can be accepted, provided that the alternative procedure has been shown to be of comparable precision and reproducibility.

5.2 Biological characteristics

5.2.1 Sterility and non-pyrogenicity

Sterility shall be guaranteed through verifying compliance with sterilization validation standard or other standard at least equivalent to this. Non-pyrogenicity shall be evaluated in accordance with **ISO 10993-11**.

NOTE The sterilization validation standard stipulated by the Ministry of Health, Labour and Welfare can be referred to.

5.2.2 Biocompatibility

Compliance to biocompatibility requirements shall be verified by testing in accordance with **JIS T 0993-1**.

5.3 Physical characteristics

5.3.1 Blood pathway integrity