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(MTJAPAN/JSA)

Hard-shell cardiectomy/venous reservoir
systems (with/without filter) and
soft venous reservoir bags

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In the event of any doubts arising as to the contents,
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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 3231** : 2011), which has been technically revised.

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Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags

Introduction

This Japanese Industrial Standard has been prepared based on **ISO 15674** : 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 hard-shell cardiotomy/venous reservoir systems and soft venous reservoir bags intended for use as a blood reservoir during cardiopulmonary bypass (CPB) surgery (hereafter referred to as the reservoirs).

This Standard applies only to the blood reservoir aspects for multifunctional systems which can have integral parts such as blood-gas exchangers (oxygenators), blood filters, defoamers, blood pumps, etc.

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

ISO 15674 : 2016 *Cardiovascular implants and artificial organs — Hard-shell cardiotomy/venous reservoir systems (with/without filter) and soft venous reservoir bags* + 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 3231** : 2011, 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

hard-shell cardiotomy reservoir

extracorporeal device consisting of rigid walls designed to collect, defoam and filter suctioned blood

3.2

hard-shell venous reservoir

extracorporeal device consisting of rigid walls designed to collect and defoam venous blood

3.3

soft-bag venous reservoir

extracorporeal device consisting of collapsible, pliable walls designed to collect venous blood

3.4

hard-shell cardiotomy/venous reservoir system

extracorporeal device designed to function simultaneously as both a venous reservoir and cardiotomy reservoir

3.5

blood-gas exchanger

extracorporeal device designed to supplement, or be a substitute for, the respiratory function of the lungs

3.6

integral part

part that is connected to the reservoir or is part of the reservoir system that cannot normally be separated by the user

3.7

operating variable

setting of controls which affects the function of the device

3.8

static volume

priming volume present in the device at zero flow

3.9

break-through volume

volume of fluid that, when added during the initial priming of the dry device (as received from the manufacturer), must be exceeded before fluid first exits the device

3.10

sealed hard-shell reservoir

hard-shell reservoir that may be operated at either positive or negative pressure

3.11

priming volume

amount of static fluid volume required prior to starting the operation of the device

3.12

dynamic priming volume

amount of fluid volume that is required for appropriate function of the device at a given flow rate within the range of flow rate specified by the manufacturer

Note 1 to entry The dynamic priming volume can be affected by negative pressure applied to a hard-shell reservoir.

Note 2 to entry For the soft bag reservoirs, this volume depends on the inflow pressure and the position of the compression mechanism.

3.13

platelet reduction

percentage reduction of platelets contained in a circuit as a function of time

3.14

plasma-free haemoglobin level

concentration of plasma-free haemoglobin in a circuit as a function of time

3.14.1

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)

3.15

white blood cell reduction

percentage reduction of white blood cells contained in a circuit as a function of time

3.16

predicate reservoir

similar reservoir to the test reservoir that has previously been approved and used for the same intended clinical use

3.17

filtration efficiency

ability of the filter to remove particles from the simulated blood suspension test fluid, expressed as a percentage

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 and 5.3.2, the blood pathway shall not leak.

4.2.2 Blood volumes

The volume of the blood pathway shall be within the tolerances specified by the manufacturer [see 6.3 k)].

4.2.3 Connectors

Connectors for connection to the blood pathway shall, when tested in accordance with **5.3.3**, allow a secure connection (see Figures B.1 to B.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 used.

Connectors, gauges and reference steel fittings with dimensions corresponding to Annex B 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 B may be used for this testing.

4.3 Performance characteristics

4.3.0 Guidance for testing is given in Annex A. Some of these tests can be combined and performed at the same time.

4.3.1 Blood cell damage

4.3.1.1 Plasma-free haemoglobin

When determined in accordance with **5.3.4**, the increased concentration of plasma-free haemoglobin shall be within the range of values specified by the manufacturer (see **6.3**). The hemolysis results shall be reported as plasma-free haemoglobin level (mg/dl) and normalized index of hemolysis.

4.3.1.2 Platelet reduction and white blood cell reduction

When determined in accordance with **5.3.4**, the percentage reduction of platelets and the percentage reduction of white blood cells shall be within the range of values specified by the manufacturer (see **6.3**).

4.3.2 Air-handling capacity

Testing to demonstrate the air-handling characteristics shall be conducted at various flow rates and the results shall be recorded [see **6.3 p**]. The test shall be conducted according to the manufacturer's protocols.

4.3.3 Priming volume of the reservoirs

The volume of the reservoir(s) shall be determined and the results presented in accordance with **6.3 o**). The test shall be conducted according to the manufacturer's protocols.

4.3.4 Defoaming characteristics

Where applicable, the defoaming characteristics shall be determined and the results shall be recorded [see **6.3 p**]. The test shall be conducted according to the manufacturer's protocols.

4.3.5 Volume calibration

Where applicable, the accuracy of the volume markings shall be measured and tolerances shall be presented as required in **6.3 n**). The test shall be conducted according