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Extracorporeal blood circuit

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Contents

	Page
Introduction	1
1 Scope	1
2 Normative references.....	2
3 Terms and definitions	2
4 Requirements.....	3
4.1 General	4
4.2 Biological safety	4
4.3 Sterility.....	4
4.4 Nonpyrogenicity.....	4
4.5 Mechanical characteristics	4
4.6 Expiration date	6
4.7 Tubing compliance	6
4.8 Requirements regarding fluid lines and cleaning set of fluid for dialysis	6
4.9 Requirements regarding extension tubing for aid of blood circuit	6
4.10 Requirements regarding monitoring set for blood circuit.....	6
5 Test methods.....	6
5.1 General	6
5.2 Biological safety.....	7
5.3 Sterility.....	7
5.4 Nonpyrogenicity.....	7
5.5 Mechanical characteristics	7
5.6 Expiration date	10
5.7 Tubing compliance	10
6 Packaging	10
6.1 Primary packaging	11
6.2 Secondary packaging	11
7 Labelling	11
7.1 Labelling on the device	11
7.2 Labelling on the primary package	11
7.3 Labelling on the secondary package	11
7.4 Accompanying documentation	12
7.5 Use of symbols	13
Annex JA (informative) Comparison table between JIS and corresponding International Standard	14

Foreword

This translation has been made based on the original Japanese Industrial Standard 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 Japan Medical Devices Manufacturers Association (JMED)/Japanese Standards Association (JSA) with the draft being attached, based on the provision of Article 12 Clause 1 of the Industrial Standardization Law applicable to the case of revision by the provision of Article 14.

Consequently **JIS T 3248 : 2011** is replaced with this Standard.

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Extracorporeal blood circuit

Introduction

This Japanese Industrial Standard has been prepared based on the third edition of ISO 8638 published in 2010 with some modifications of the technical contents in order to harmonize with the actual conditions in Japan.

The portions underlined with dots in this Standard are the matters modified from the corresponding International Standard. A list of modifications with the explanations is given in Annex JA. Annex JA is not included in the corresponding International Standard.

1 Scope

This Standard specifies extracorporeal blood circuits (hereafter referred to as “circuits”) which are intended to be used for extracorporeal blood circulation connected to haemodialysers, haemodiafilters or haemofilters.

In addition, this Standard applies to the following devices constructing the circuit:

- transducer protector;
- cleaning set of fluid for dialysis;
- extension tubing for aid of blood circuit;
- monitoring set for blood circuit.

This Standard is not applicable to

- haemodialysers, haemodiafilters or haemofilters,
- plasmafilters,
- haemoperfusion devices,
- vascular access devices,
- blood pumps,
- pressure monitors for the extracorporeal blood circuit,
- air detection devices,
- systems to prepare, maintain or monitor dialysing fluid,
- systems intended to perform haemofiltration or haemoconcentration.

NOTE 1 The requirements for haemodialysers, haemodiafilters and haemofilters are specified in JIS T 3250.

NOTE 2 The International Standard corresponding to this Standard and the symbol of degree of correspondence are as follows.

ISO 8638:2010 *Cardiovascular implants and extracorporeal systems—Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters* (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.

JIS T 3248: 2011 may be applied until September 30 in 2015.

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 any revisions (including amendments) made thereafter shall not apply.

JIS T 0307 : 2004 *Medical devices—Symbols to be used with medical device labels, labelling and information to be supplied*

JIS T 0993-1 : 2012 *Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process*

NOTE : Corresponding International Standard : ISO 10993-1 : 2009 *Biological evaluation of medical devices—Part 1: Evaluation and testing within a risk management process* (MOD)

JIS T 0993-7 : 2012 *Biological evaluation of medical devices—Part 7: Ethylene oxide sterilization residuals*

NOTE : Corresponding International Standard : ISO 10993-7 : 2008 *Biological evaluation of medical devices—Part 7: Ethylene oxide sterilization residuals* (IDT)

JIS T 3209 : 2011 *Sterile injection needles*

NOTE : Corresponding International Standard : ISO 7864 : 1993 *Sterile hypodermic needles for single use* (MOD)

JIS T 3211 : 2011 *Sterile infusion administration set*

ISO 594-2 : 1998 *Conical fittings with 6 % (Luer) taper for syringes, needles and certain other medical equipment—Part 2: Lock fittings*

ISO 10993-4 : 2002 *Biological evaluation of medical devices—Part 4 : Selection of tests for interactions with blood*

ISO 10993-11 : 2006 *Biological evaluation of medical devices—Part 11: Tests for systemic toxicity*

3 Terms and definitions

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

3.1 extracorporeal blood circuit

blood circuit which consists of tubing for blood pathway, tubing for attaching and connecting necessary components for pressure monitors in the circuit and haemodialysis (e.g. air-capture chambers and transducer protectors) and tubing for fluid lines

3.2 fluid pathway

part for passage of blood

3.3 labelling

written, printed, graphic or electronic matter that:

- is affixed to or printed on a medical device itself or any of its containers or wrappers, or
- accompanies a medical device and which is related to identification, attached document, technical description and use of the medical device but excluding shipping documents

3.4 pump segment

portion of the circuit that is acted upon by the blood pump

3.5 transducer protector

component of the circuit that is intended to provide an interconnection between the circuit and the haemodialysis machine while allowing the pressure within the circuit to be measured by the machine

It is also known as “pressure-transmitting sterile barrier”.

3.6 air capture chamber

component similar to a drip cylinder that is designed to remove air bubble from fluid

Air capture chambers are also known as drip chambers, bubble traps, and venous or arterial blood chambers.

3.7 access port

part of the circuit intended to infuse a drug into the circuit and to collect blood

3.8 cleaning set of fluid for dialysis

medical device intended to use for the cleaning or disposal of fluid in dialysis and circuit

3.9 extension tubing for aid of blood circuit

medical device intended to use for aids of extension of the circuit, etc.

3.10 monitoring set for blood circuit

medical device connecting blood circuit and blood pressure gauge intended to monitor blood pressure information during dialysis

4 Requirements

4.1 General

The requirements in 4.2 to 4.10 shall be satisfied.

4.2 Biological safety

The biological safety evaluation specified by 5.2 shall be performed for parts of the concerned device which makes a direct or indirect contact with blood.

NOTE : In Japan, the materials to be used for a device, which makes a direct or indirect contact with blood, shall be verified for biological safety in accordance with JIS T 0993-1.

4.3 Sterility

The blood pathway of the device shall be sterile. Compliance shall be verified in accordance with 5.3.

4.4 Nonpyrogenicity

The blood pathway of the device shall be nonpyrogenic. Compliance shall be verified in accordance with 5.4.

4.5 Mechanical characteristics

4.5.1 Structural integrity

No leakage shall occur at the circuit when it is tested in accordance with 5.5.1.

The concerned device is tested on the following condition.

- a) 1.5 times the specified maximum pressure
- b) 1.5 times the maximum negative pressure specified by the manufacturer (however, it shall not be less than -700 mmHg), or the maximum practicable negative pressure

4.5.2 Connectors to haemodialyser, haemodiafilter or haemofilter

4.5.2.1 The dimensions of the connectors made of rigid materials shall be as given in figure 1. Compliance shall be verified for the dimensions in accordance with 5.5.2.

4.5.2.2 Connectors made of semi-rigid materials shall be verified for the dimensions in accordance with figure 1, and comply with the performance requirements specified in ISO 594-2.

4.5.3 Connectors to vascular access device

The connector intended for connection between circuits and vascular access devices shall have Luer taper lock fitting specified by ISO 594-2 (see ISO 594-2). Compliance shall be verified in accordance with 5.5.3.

4.5.4 Connectors to ancillary components

All parts of the circuit intended for use with non-integral ancillary components, such as anticoagulant infusion lines, pressure-monitor lines, fluid lines and level-adjustment lines, shall terminate in fittings which meet the performance requirements of taper lock fittings specified in ISO 594-2. Compliance shall be verified in accordance with 5.5.4.