



JAPANESE  
INDUSTRIAL  
STANDARD

Translated and Published by  
Japanese Standards Association

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JIS T 3248 : 2022

(MTJAPAN/JSA)

**Extracorporeal blood circuit**

Date of Establishment: 2005-03-25

Date of Revision: 2022-03-01

Date of Public Notice in Official Gazette: 2022-03-01

Investigated by: Japanese Industrial Standards Committee  
Standards Board for ISO area  
Technical Committee on Medical Equipment

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JIS T 3248 : 2022, First English edition published in 2023-10

Translated and published by: Japanese Standards Association  
Mita MT Building, 3-13-12, Mita, Minato-ku, Tokyo, 108-0073 JAPAN

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In the event of any doubts arising as to the contents,  
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Printed in Japan

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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 3248** : 2012), which has been technically revised.

However, **JIS T 3248** : 2012 remains valid for three years from the date of public notice of the revision of this Standard.

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# Extracorporeal blood circuit

## Introduction

This Japanese Industrial Standard has been prepared based on **ISO 8637-2** : 2018, Edition 1, with some modifications of the technical contents for reflecting the local needs and situations in Japan.

The 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 extracorporeal blood circuits (hereafter referred to as circuits), which are intended to be used for extracorporeal blood circulation connected to haemodialysers, haemodiafilters and haemofilters.

This Standard applies to the following devices constructing the circuit :

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

This Standard does not apply 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 dialysis fluid;
- systems or equipment 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 8637-2 : 2018 *Extracorporeal systems for blood purification — Part 2 : Extracorporeal blood circuit for haemodialysers, haemodiafilters and haemofilters* (MOD)