

JIS

JAPANESE
INDUSTRIAL
STANDARD

Translated and Published by
Japanese Standards Association

JIS T 7329 : 2008

(JAMEI/JSA)

Washer sterilizers for medical use

ICS 11.080.10

Reference number : JIS T 7329 : 2008 (E)

PROTECTED BY COPYRIGHT

17 S

T 7329 : 2008

Date of Establishment: 2008-06-25

Date of Public Notice in Official Gazette: 2008-06-25

Investigated by: Japanese Industrial Standards Committee
Standards Board

Technical Committee on Medical Equipment

JIS T 7329: 2008, First English edition published in 2008-12

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 2008

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

MT

PROTECTED BY COPYRIGHT

Contents

	Page
1	Scope..... 1
2	Normative references..... 1
3	Terms and definitions..... 2
4	Requirement on a design 6
4.1	Design, structure, parts, and accessory of a washer sterilizer 6
4.2	Safety of a washer sterilizer 8
4.3	Process monitoring and control devices..... 8
4.4	Sterilization performance of a washer sterilizer 11
4.5	Deairing performance 11
4.6	Drying performance (if applicable) 11
4.7	Evaluation of detergency performance 11
4.8	Guarantee and record of performance of a washer sterilizer 11
5	Test and inspection..... 12
5.1	Design, structure, parts, and accessory of a washer sterilizer 12
5.2	Safety of a washer sterilizer 13
5.3	Process monitoring and control devices..... 13
5.4	Sterilization performance of a washer sterilizer 15
5.5	Deairing performance 20
5.6	Drying performance (if applicable) 22
5.7	Detergency performance 22
5.8	Guarantee and record of performance of a washer sterilizer 22
6	Marking 22
6.1	Identification marking..... 22
6.2	Caution mark..... 23
6.3	Accompanying documents..... 23
6.4	Accompanying documents specified in PAL 24
6.5	Other documents and information (repair/maintenance guide) 25
Annex A (informative)	The test soil preparation method and detergency performance evaluation test method for a washer sterilizer (complying with UFGS) 26

Foreword

This translation has been made based on the original Japanese Industrial Standard established by the Minister of Health, Labour and Welfare 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 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 Minister 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.

Washer sterilizers for medical use

1 Scope

This Japanese Industrial Standard specifies the basic requirement for a washer sterilizer that washes and sterilizes a used medical device (matters to be sterilized) polluted by organic matters, such as blood and necrotic cells, using the saturated vapour (that is directly available from the water in the chamber, or that is generated by a built-in steam generator, or that is available from an external steam source) in order to safely implement washing and post-processing of sterilization of a medical device for re-use. The washing methods include a hot-water immersion method, an ultrasonic irradiation method, a jet stream spray method, etc.

In addition, some sterilizers only sterilize a medical device (matters to be sterilized), using the saturated vapour, for the purpose of the secondary sterilization for re-use without washing a medical device.

A washer sterilizer covered in this Standard shall have a vessel²⁾ corresponding to the national pressure vessel structure standard¹⁾. However, this Standard excludes a washer sterilizer for biohazard and other types of sterilizers.

Notes¹⁾ It refers to the Safety Standard related to Construction Code for First Class Pressure Vessels specified by Industrial Safety and Health Law.

²⁾ It refers to First Class Pressure Vessel specified by Industrial Safety and Health Law, Enforcement Order, Article 1, Item 5.

2 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 B 7505 *Bourdon tube pressure gauges*

JIS C 1010-1 *Safety requirements for electrical equipment for measurement, control, and laboratory use—Part 1: General requirements*

JIS C 1806-1 *Electrical equipment for measurement, control and laboratory use—EMC requirements*

JIS Z 8737-2 *Acoustics—Noise emitted by machinery and equipment—Measurement of emission sound pressure levels at a work station and at other specified positions—Survey method in situ*

ISO 11138-1 *Sterilization of health care products—Biological indicators—Part 1 : General requirements*

ISO 11138-3 *Sterilization of health care products—Biological indicators—Part 3 : Biological indicators for moist heat sterilization processes*