



JAPANESE
INDUSTRIAL
STANDARD

Translated and Published by
Japanese Standards Association

JIS T 0601-2-208 : 2008

(JIPT/JSA)

**Medical electrical equipment —
Part 2-208: Particular requirements for
the safety of electric potential equipment**

ICS 11.040.60

Reference number : JIS T 0601-2-208 : 2008 (E)

PROTECTED BY COPYRIGHT



Documents

Document Sharing Hub

7 S

Date of Establishment: 2008-11-25

Date of Public Notice in Official Gazette: 2008-11-25

Investigated by: Japanese Industrial Standards Committee
Standards Board

Technical Committee on Medical Equipment

JIS T 0601-2-208 : 2008, First English edition published in 2009-04

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 2009

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
Introduction	1
Section 1 General	1
1 Scope and object.....	1
1A Normative references.....	2
2 Terms and definitions	2
3 General requirements.....	3
6 Identification, marking and documents.....	3
Section 2 Environmental conditions.....	3
Section 3 Protection against electric shock hazards.....	3
19 Continuous leakage currents and patient auxiliary currents	3
20 Dielectric strength	4
Section 4 Protection against mechanical hazards	5
Section 5 Protection against hazards from unwanted or excessive radiation	5
36 Electromagnetic compatibility	5
Section 6 Protection against hazards of ignition of flammable anaesthetic mixtures.....	5
Section 7 Protection against excessive temperatures and other harms	5
Section 8 Accuracy of operating data and protection against hazardous output	5
50 Accuracy of operating data	5
51 Protection against hazardous output.....	6
Section 9 Abnormal operation and fault conditions; environmental tests	7
Section 10 Constructional requirements	7

Foreword

This translation has been made based on the original Japanese Industrial Standard established by the Minister of Health, Labour and Welfare and the Minister of Economy, Trade and Industry through deliberations at the Japanese Industrial Standards Committee according to the proposal of establishing a Japanese Industrial Standard from Japan Industries Association of Physical Therapy Device (JIPT)/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 Ministers 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.