This is a free page sample. Access the full version online.

NSAI Standards

Irish Standard
I.S. EN 80601-2-59:2009

Medical electrical equipment -- Part 2 -59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening (IEC 80601-2-59:2008 (EQV) + corrigendum Apr. 2009 (EQV))

© NSAI 2009 No copying without NSAI permission except as permitted by copyright law.

This is a free page sample. Access the full version online.

I.S. EN 80601-2-59:2009

Incorporating amendments/corrigenda issued since publication:

The National Standards Authority of Ireland (NSAI) produces the following categories of formal documents:

I.S. xxx: Irish Standard – national specification based on the consensus of an expert panel and subject to public consultation.

S.R. xxx: Standard Recommendation - recommendation based on the consensus of an expert panel and subject to public consultation.

SWiFT xxx: A rapidly developed recommendatory document based on the consensus of the participants of an NSAI workshop.

This document replaces:	*This document is based on:* EN 80601-2-59:2009	*Published:* 23 December, 2009

This document was published under the authority of the NSAI and comes into effect on: 5 July, 2010	ICS number: 11.040.55

NSAI
1 Swift Square,
Northwood, Santry
Dublin 9

T +353 1 807 3800
F +353 1 807 3838
E standards@nsai.ie

W **NSAI.ie**

Sales:
T +353 1 857 6730
F +353 1 857 6729
W standards.ie

Údarás um Chaighdeáin Náisiúnta na hÉireann

This is a free page sample. Access the full version online.

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 80601-2-59

December 2009

ICS 11.040.55

English version

Medical electrical equipment - Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening

(IEC 80601-2-59:2008 + corrigendum 2009)

Appareils électromédicaux - Partie 2-59: Exigences particulières pour la sécurité de base et les performances essentielles des imageurs thermiques pour le dépistage des humains fébriles (CEI 80601-2-59:2008 + corrigendum 2009)

Medizinische elektrische Geräte - Teil 2-59: Besondere Anforderungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Wärmebildkameras für Reihenuntersuchungen von Menschen auf Fieber (IEC 80601-2-59:2008 + Corrigendum 2009)

This European Standard was approved by CENELEC on 2009-11-17. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the Central Secretariat or to any CENELEC member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

Central Secretariat: Avenue Marnix 17, B - 1000 Brussels

© 2009 CENELEC - All rights of exploitation in any form and by any means reserved worldwide for CENELEC members.

Ref. No. EN 80601-2-59:2009 E

This is a free page sample. Access the full version online.

Foreword

The text of document 62D/697/FDIS, future edition 1 of IEC 80601-2-59, prepared by SC 62D, Electromedical equipment, of IEC TC 62, Electrical equipment in medical practice, and SC 3, Lung ventilators and related equipment, of ISO TC 121, Anaesthetic and respiratory equipment, was submitted to the IEC-CENELEC parallel vote and was approved by CENELEC as EN 80601-2-59 on 2009-11-17.

The following dates were fixed:

– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2010-09-01
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	2012-12-01

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive MDD (93/42/EEC). See Annex ZZ.

In this standard, the following print types are used:

– Requirements and definitions: roman type.

– *Test specifications: italic type.*

– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.

– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

– “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

− “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

− “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

− “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

This is a free page sample. Access the full version online.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

The text of the International Standard IEC 80601-2-59:2008 + corrigendum April 2009 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following note has to be added for the standard indicated:

ISO/IEC 17025 NOTE Harmonized as EN ISO/IEC 17025:2005 (not modified).

This is a free page sample. Access the full version online.

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

Annex ZA of EN 60601-1:2006 applies, except as follows:

Publication	Year	Title	EN/HD	Year
Addition:				
ISO/TR 13154	-[1)]	Medical electrical equipment - Deployment, implementation and operational guidelines for indentifying febrile humans using a screening thermograph	-	-
ASTM E1213-97	2002	Standard Test Method for Minimum Resolvable Temperature Difference for Thermal Imaging Systems	-	-

[1)] Undated reference.

This is a free page sample. Access the full version online.

Annex ZZ
(informative)

Coverage of Essential Requirements of EC Directives

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and within its scope the standard covers all relevant essential requirements as given in Annex I of the EC Directive 93/42/EEC with the exception of Essential Requirements 3 and 10.1.

Compliance with this standard provides one means of conformity with the specified essential requirements of the Directive concerned.

WARNING: Other requirements and other EC Directives may be applicable to the products falling within the scope of this standard.

This is a free page sample. Access the full version online.

This page is intentionally left BLANK.

This is a free page sample. Access the full version online.

CONTENTS

FOREWORD ... 3
INTRODUCTION ... 5
201.1 Scope, object and related standards ... 6
201.2 Normative references ... 7
201.3 Terms and definitions ... 8
201.4 General requirements ... 10
201.5 General requirements for testing of ME EQUIPMENT ... 10
201.6 Classification of ME EQUIPMENT and ME SYSTEMS ... 11
201.7 ME EQUIPMENT identification, marking and documents ... 11
201.8 Protection against electrical HAZARDS from ME EQUIPMENT ... 11
201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS ... 12
201.10 Protection against unwanted and excessive radiation HAZARDS ... 12
201.11 Protection against excessive temperatures and other HAZARDS ... 12
201.12 Accuracy of controls and instruments and protection against hazardous outputs ... 12
201.13 HAZARDOUS SITUATIONS and fault conditions ... 13
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) ... 13
201.15 Construction of ME EQUIPMENT ... 13
201.16 ME SYSTEMS ... 13
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS ... 13
201.101 Laboratory accuracy of a screening thermograph ... 14
201.102 Screening thermograph alarm conditions ... 17
Annexes ... 18
Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS ... 18
Annex AA (informative) Particular guidance and rationale ... 20
Annex BB (normative) CALIBRATION SOURCE ... 26
Annex CC (informative) Reference to the essential principles ... 27
Bibliography ... 29
Index of defined terms used in this particular standard ... 34

Figure AA.1 – Relative drift of 4 DETECTORS as a function of time ... 24

Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements ... 10
Table 201.C.101 – ACCOMPANYING DOCUMENTS, instructions for use of a SCREENING THERMOGRAPH ... 18
Table 201.C.102 – ACCOMPANYING DOCUMENTS, technical description of a SCREENING THERMOGRAPH ... 19
Table AA.1 – Example of relevant uncertainty terms for a SCREENING THERMOGRAPH ... 22
Table CC.1 – Correspondence between this particular standard and the essential principles ... 27

This is a free page sample. Access the full version online.

INTERNATIONAL ELECTROTECHNICAL COMMISSION

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC provides no marking procedure to indicate its approval and cannot be rendered responsible for any equipment declared to be in conformity with an IEC Publication.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International standard IEC 80601-2-59 has been prepared by a Joint Working Group of IEC subcommittee 62D: Electromedical equipment, of IEC technical committee 62: Electrical equipment in medical practice, and of ISO subcommittee SC3: Lung ventilators and related equipment, of ISO technical committee 121: Anaesthetic and respiratory equipment.

The text of this particular standard is based on the following documents:

FDIS	Report on voting
62D/697/FDIS	62D/720/RVD

Full information on the voting for the approval of this particular standard can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 12 P-members out of 15 having cast a vote.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

This is a free page sample. Access the full version online.

In this standard, the following print types are used:

– Requirements and definitions: roman type.
– *Test specifications: italic type.*
– Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type.
– TERMS DEFINED IN CLAUSE 3 OF THE GENERAL STANDARD, IN THIS PARTICULAR STANDARD OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this standard, the term

– “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);
– “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this particular standard are by number only.

In this standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

– “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;
– “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;
– “may” is used to describe a permissible way to achieve compliance with a requirement or test.

An asterisk (*) as the first character of a title or at the beginning of a paragraph or table title indicates that there is guidance or rationale related to that item in Annex AA.

A list of all parts of the IEC 60601 series, published under the general title: *Medical electrical equipment*, can be found on the IEC website

The committee has decided that the contents of this publication will remain unchanged until the maintenance result date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

The contents of the corrigendum of April 2009 have been included in this copy.

This is a free page sample. Access the full version online.

INTRODUCTION

The minimum safety requirements specified in this particular standard are considered to provide for a practical degree of safety in the operation of ME EQUIPMENT for human febrile temperature screening.

This document describes ME EQUIPMENT that uses infrared technology to detect naturally emitted heat at the skin surface of the FACE. Such ME EQUIPMENT can be useful at ports-of-entry or ports-of-exit and the entrances to buildings under indoor environmental conditions to separate febrile from afebrile individuals to help prevent the spread of communicable diseases. Care can be needed when evaluating individuals under changing environmental conditions, but the inner canthus of the eye has been demonstrated to be a robust measurement site and is supplied by the internal carotid artery. [40] [1)]

A body core temperature of 38 °C or above was used as the criterion to restrict traveling during the SARS (severe acute respiratory syndrome) epidemic (April 2003). [73] The US Center for Disease Control advises that SARS typically begins with a temperature above 38 °C, which is 1 °C higher than normal human body core temperature which averages around 37 °C. [29] It is hard to give an accurate assessment of how many people were checked by infrared temperature measurements in China during the SARS epidemic. There is official Chinese government data indicating that during a two-month period in the spring of 2003, 30 million travelers were screened in China. From this cohort, 9 292 travelers with elevated temperature were detected and 38 were suspected of being SARS carriers. SARS was diagnosed in 21 of these cases. All elevated temperatures were confirmed using traditional clinical temperature measurements of body temperature. Although it is hard to determine the human body's core temperature accurately by infrared measurement of SKIN TEMPERATURE, it is a potential method for screening for elevated temperature values. [36] [73] [75]

This particular standard amends and supplements IEC 60601-1 (third edition, 2005): Medical electrical equipment – Part 1: General requirements for safety and essential performance, hereinafter referred to as the General Standard (see 1.4).

The requirements are followed by specifications for the relevant tests.

A "General guidance and rationale" section giving some explanatory notes, where appropriate, about the more important requirements is included in annex AA. It is considered that knowledge of the reasons for these requirements will not only facilitate the proper application of the standard but will, in due course, expedite any revision necessitated by changes in clinical practice or as a result of developments in technology. However, this annex does not form part of the requirements of this standard.

---

1) Figures in square brackets refer to the Bibliography.

This is a free page sample. Access the full version online.

MEDICAL ELECTRICAL EQUIPMENT –

Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening

201.1 Scope, object and related standards

Clause 1 of the general standard[2)] applies, except as follows:

201.1.1 * Scope

Replacement:

This International Standard applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of SCREENING THERMOGRAPHS intended to be used for the individual non-invasive febrile temperature screening of humans under indoor environmental conditions, hereafter referred to as ME EQUIPMENT. This International Standard sets laboratory characterization test limits for the SCREENING THERMOGRAPH.

NOTE A SCREENING THERMOGRAPH is intended for screening and detection of human subjects with SKIN TEMPERATURES elevated above normal. An elevated SKIN TEMPERATURE needs to be followed up by a subsequent temperature measurement using a clinical thermometer (see IEC 80601-2-56).

If a clause or subclause is specifically intended to be applicable to ME EQUIPMENT only, or to ME SYSTEMS only, the title and content of that clause or subclause will say so. If that is not the case, the clause or subclause applies both to ME EQUIPMENT and to ME SYSTEMS, as relevant.

201.1.2 Object

Replacement:

The object of this particular standard is to establish particular BASIC SAFETY and ESSENTIAL PERFORMANCE requirements for SCREENING THERMOGRAPHS as defined in 201.3.209.

201.1.3 Collateral standards

Addition:

This particular standard refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 2 of this particular standard.

IEC 60601-1-3 does not apply. All other published collateral standards in the IEC 60601-1 series apply as published.

201.1.4 Particular standards

Replacement:

In the IEC 60601 series, particular standards may modify, replace or delete requirements contained in the general standard and collateral standards as appropriate for the particular

---

2) The general standard is IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance.*

This is a free page sample. Access the full version online.

ME EQUIPMENT under consideration, and may add other BASIC SAFETY and ESSENTIAL PERFORMANCE requirements.

A requirement of a particular standard takes priority over the general standard.

For brevity, IEC 60601-1 is referred to in this particular standard as the general standard. Collateral standards are referred to by their document number.

The numbering of sections, clauses and subclauses of this particular standard corresponds to that of the general standard with the prefix “201” (e.g. 201.1 in this standard addresses the content of Clause 1 of the general standard) or applicable collateral standard with the prefix “20x” where x is the final digit(s) of the collateral standard document number (e.g. 202.4 in this particular standard addresses the content of Clause 4 of the 60601-1-2 collateral standard, 203.4 in this particular standard addresses the content of Clause 4 of the 60601-1-3 collateral standard, etc.). The changes to the text of the general standard are specified by the use of the following words:

"Replacement" means that the clause or subclause of the general standard or applicable collateral standard is replaced completely by the text of this particular standard.

"Addition" means that the text of this particular standard is additional to the requirements of the general standard or applicable collateral standard.

"Amendment" means that the clause or subclause of the general standard or applicable collateral standard is amended as indicated by the text of this particular standard.

Subclauses or figures which are additional to those of the general standard are numbered starting from 201.101. However due to the fact that definitions in the general standard are numbered 3.1 through 3.139, additional definitions in this standard are numbered beginning from 201.3.201. Additional annexes are lettered AA, BB, etc., and additional items aa), bb), etc.

Subclauses or figures which are additional to those of a collateral standard are numbered starting from 20x, where “x” is the number of the collateral standard, e.g. 202 for IEC 60601-1-2, 203 for IEC 60601-1-3, etc.

The term "this standard" is used to make reference to the general standard, any applicable collateral standards and this particular standard taken together.

Where there is no corresponding clause or subclause in this particular standard, the clause or subclause of the general standard or applicable collateral standard, although possibly not relevant, applies without modification; where it is intended that any part of the general standard or applicable collateral standard, although possibly relevant, is not to be applied, a statement to that effect is given in this particular standard.

201.2 Normative references

NOTE Informative references are listed in the bibliography beginning on page 29.

Clause 2 of the general standard applies, except as follows:

Addition:

ISO/TR 13154, *Medical electrical equipment – Deployment, implementation and operational guidelines for identifying febrile humans using a screening thermograph*

SAI GLOBAL

This is a free preview. Purchase the entire publication at the link below:

Product Page

Looking for additional Standards? Visit Intertek Inform Infostore

Learn about LexConnect, All Jurisdictions, Standards referenced in Australian legislation