BS EN 80601-2-59:2017+A1:2023

BSI Standards Publication

Medical electrical equipment

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

bsi.

Documents
Document Sharing Hub

Full document details: BS EN 80601-2-59:2017+A1:2023

National foreword

This British Standard is the UK implementation of EN 80601-2-59:2019+A1:2023. It is identical to IEC 80601-2-59:2017, incorporating amendment 1:2023. It supersedes BS EN 80601-2-59:2009, which is withdrawn.

The start and finish of text introduced or altered by amendment is indicated in the text by tags. Tags indicating changes to IEC text carry the number of the IEC amendment. For example, text altered by IEC amendment 1 is indicated by ⟨A1⟩ ⟨A1⟩.

The UK participation in its preparation was entrusted to Technical Committee CH/62/4, Electromedical equipment.

A list of organizations represented on this committee can be obtained on request to its committee manager.

Contractual and legal considerations

This publication has been prepared in good faith, however no representation, warranty, assurance or undertaking (express or implied) is or will be made, and no responsibility or liability is or will be accepted by BSI in relation to the adequacy, accuracy, completeness or reasonableness of this publication. All and any such responsibility and liability is expressly disclaimed to the full extent permitted by the law.

This publication is provided as is, and is to be used at the recipient's own risk.

The recipient is advised to consider seeking professional guidance with respect to its use of this publication.

This publication is not intended to constitute a contract. Users are responsible for its correct application.

© The British Standards Institution 2023
Published by BSI Standards Limited 2023

ISBN 978 0 539 18788 5

ICS 11.040.55

Compliance with a British Standard cannot confer immunity from legal obligations.

This British Standard was published under the authority of the Standards Policy and Strategy Committee on 31 October 2019.

Amendments/corrigenda issued since publication

Date	Text affected
23 February 2023	Implementation of IEC amendment 1:2023 with CENELEC endorsement A1:2023

AVA Documents
Document Sharing Hub

Full document details: BS EN 80601-2-59:2017+A1:2023

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN IEC 80601-2-59+A1

February 2023

ICS 11.040.55

Supersedes EN 80601-2-59:2009 and all of its amendments and corrigenda (if any)

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 80601-2-59:2017)

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 (IEC 80601-2-59:2017)

Medizinische elektrische Geräte - Teil 2-59: Besondere Anforderungen für die Sicherheit einschließlich der wesentlichen Leistungsmerkmale von Wärmebildkameras für Reihenuntersuchungen von Menschen auf Fieber (IEC 80601-2-59:2017)

This European Standard was approved by CENELEC on 2017-10-24. 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 CEN-CENELEC Management Centre 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 CEN-CENELEC Management Centre has the same status as the official versions.

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

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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

© 2019 CENELEC All rights of exploitation in any form and by any means reserved worldwide for CENELEC Members.

Ref. No. EN IEC 80601-2-59:2019 E

Documents
Document Sharing Hub

Full document details: BS EN 80601-2-59:2017+A1:2023

European foreword

The text of document 62D/1501/FDIS, future edition 2 of IEC 80601-2-59, prepared by SC 62D "Electromedical equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 80601-2-59:2019.

The following dates are fixed:

- latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2020-04-11
- latest date by which the national standards conflicting with the document have to be withdrawn (dow) 2022-10-11

This document supersedes EN 80601-2-59:2009.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

Endorsement notice

The text of the International Standard IEC 80601-2-59:2017 was approved by CENELEC as a European Standard without any modification.

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

ISO 80601-2-56	NOTE	Harmonized as EN ISO 80601-2-56
IEC 60601-1-10	NOTE	Harmonized as EN 60601-1-10

Documents
Document Sharing Hub

Full document details: BS EN 80601-2-59:2017+A1:2023

European foreword to amendment 1

The text of document 62D/1892/CDV, future IEC 80601-2-59/AMD1, prepared by SC 62D "Electromedical equipment" of IEC/TC 62 "Electrical equipment in medical practice" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN IEC 80601-2-59:2019/A1:2023.

The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2023-08-22
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2026-02-22

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users' national committee. A complete listing of these bodies can be found on the CENELEC website.

Endorsement notice to amendment 1

The text of the International Standard IEC 80601-2-59:2017/AMD1:2023 was approved by CENELEC as a European Standard without any modification.

Documents
Document Sharing Hub

Full document details: BS EN 80601-2-59:2017+A1:2023

Annex ZA
(normative)

Normative references to international publications with their corresponding European publications

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements 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 1 Where an International Publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

NOTE 2 Up-to-date information on the latest versions of the European Standards listed in this annex is available here: www.cenelec.eu.

The Annex ZA of EN IEC 80601-2-59:2019 applies with the following changes:

Publication	Year	Title	EN/HD	Year
Replace the first four entries with the following:				
IEC 60601-1	2005	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance	EN 60601-1	2006
-	-		+ corrigendum Mar.	2010
+ 1	2012		+ A1	2013
-	-		+ A12	2014
+ 2	2020		+ A2	2021
IEC 60601-1-2	2014	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests	EN 60601-1-2	2015
+ 1	2020		+ 1	2021
IEC 60601-1-6	2010	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability	EN 60601-1-6	2010
+ 1	2013		+ 1	2015
+ 2	2020		+ 2	2021

Documents
Document Sharing Hub

Full document details: BS EN 80601-2-59:2017+A1:2023

IEC 60601-1-8	2006	Medical electrical equipment - Part 1-8: General requirements for basic safety and essential performance - Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems	EN 60601-1-8	2007
+ 1	2012		+ 1	2013
-	-		+ AC	2014
+ 2	2020		+ 2	2021

Documents
Document Sharing Hub

This page is left deliberately blank.

Documents
Document Sharing Hub

Full document details: BS EN 80601-2-59:2017+A1:2023

CONTENTS

FOREWORD 4
INTRODUCTION 7
201.1 Scope, object and related standards 8
201.2 Normative references 9
201.3 Terms and definitions 10
201.4 General requirements 12
201.5 General requirements for testing ME EQUIPMENT 13
201.6 Classification of ME EQUIPMENT and ME SYSTEMS 13
201.7 ME EQUIPMENT identification, marking and documents 13
201.8 Protection against electrical HAZARDS from ME EQUIPMENT 14
201.9 Protection against mechanical HAZARDS of ME EQUIPMENT and ME SYSTEMS 14
201.10 Protection against unwanted and excessive radiation HAZARDS 15
201.11 Protection against excessive temperatures and other HAZARDS 15
201.12 Accuracy of controls and instruments and protection against hazardous outputs 15
201.13 HAZARDOUS SITUATIONS and fault conditions for ME EQUIPMENT 16
201.14 PROGRAMMABLE ELECTRICAL MEDICAL SYSTEMS (PEMS) 16
201.15 Construction of ME EQUIPMENT 16
201.16 ME SYSTEMS 16
201.17 Electromagnetic compatibility of ME EQUIPMENT and ME SYSTEMS 16
201.101 LABORATORY ACCURACY of a SCREENING THERMOGRAPH 17
201.102 SCREENING THERMOGRAPH ALARM CONDITIONS 20
202 Electromagnetic disturbances – Requirements and tests 21
206 USABILITY 21
Annexes 23
Annex C (informative) Guide to marking and labelling requirements for ME EQUIPMENT and ME SYSTEMS 23
Annex AA (informative) Particular guidance and rationale 25
Annex BB (normative) CALIBRATION SOURCE 32
Annex CC (informative) Reference to the essential principles 33
Bibliography 36
Index of defined terms used in this document 40

Figure AA.1 – Illustration of TARGET in the visible spectrum 27
Figure AA.2 – Illustration of TARGET in the infrared spectrum 27
Figure AA.3 – Relative drift of 4 DETECTORS as a function of time 30

Table 201.101 – Distributed ESSENTIAL PERFORMANCE requirements 13
Table 201.C.101 – Marking on the outside of a SCREENING THERMOGRAPH or its parts 23
Table 201.C.102 – ACCOMPANYING DOCUMENTS, general of a SCREENING THERMOGRAPH 23
Table 201.C.103 – ACCOMPANYING DOCUMENTS, instructions for use of a SCREENING THERMOGRAPH 24

AVA Documents
Document Sharing Hub

Full document details: BS EN 80601-2-59:2017+A1:2023

Table 201.C.104 – ACCOMPANYING DOCUMENTS, technical description of a SCREENING THERMOGRAPH 24
Table AA.1 – Example of relevant uncertainty terms for a SCREENING THERMOGRAPH 28
Table CC.1 – Correspondence between this document and the essential principles 33

Documents
Document Sharing Hub
Full document details: BS EN 80601-2-59:2017+A1:2023

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 itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
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.

This second edition cancels and replaces the first edition published in 2008. This edition constitutes a technical revision.

This edition includes the following significant technical changes with respect to the previous edition:

a) updates of the normative references and the bibliography;
b) expansion of the applicability to pandemic infectious diseases in general.

Documents
Document Sharing Hub

Full document details: BS EN 80601-2-59:2017+A1:2023

The text of this document is based on the following documents:

FDIS	Report on voting
62D/1501/FDIS	62D/1515/RVD

Full information on the voting for the approval of this document can be found in the report on voting indicated in the above table.

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

In this document, 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 DOCUMENT OR AS NOTED: SMALL CAPITALS.

In referring to the structure of this document, 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 document are preceded by the term "Clause" followed by the clause number. References to subclauses within this particular document are by number only.

In this document, 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 document conform to usage described in Clause 7 of the ISO/IEC Directives, Part 2. For the purposes of this document, the auxiliary verb:

– "shall" means that compliance with a requirement or a test is mandatory for compliance with this document ;
– "should" means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this document ;
– "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.

Documents
Document Sharing Hub

Full document details: BS EN 80601-2-59:2017+A1:2023

The committee has decided that the contents of this publication will remain unchanged until the stability 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.

NOTE The attention of National Committees and Member Bodies is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committees that the content of this publication be adopted for implementation nationally not earlier than 3 years from the date of publication.

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

Documents
Document Sharing Hub

Full document details: BS EN 80601-2-59:2017+A1:2023

INTRODUCTION

The minimum safety requirements specified in this document 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 controlled 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 region medially adjacent to the inner canthus of the eye has been demonstrated to be a robust measurement site and is supplied by the internal carotid artery. [1][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). [2] The US Centers 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. [3] 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 travellers were screened in China. From this cohort, 9 292 travellers 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 can be used for screening for elevated temperature values. [2] [4] [5] Improved rates of detection may result from improved techniques.[6]

International travellers were screened during the 2009 H1N1 influenza outbreak. [7] [8] The pandemic potential of other influenzas such as H7N9 [9] is of concern to the World Health Organization (WHO). [10]

Middle East Respiratory Syndrome Coronavirus (MERS-CoV) was first reported in Saudi Arabia in 2012, and a total of 1 026 laboratory-confirmed cases resulting in at least 376 deaths (36,7%) have been confirmed by the World Health Organization (WHO) as of 25 February 2015. [11] Most identified cases have had fever, although some mild and/or asymptomatic cases have been reported. [11] [12] [13] [14] The possibility of widespread dissemination of MERS-CoV during religious pilgrimage [11] and other regional travel has been investigated, but appears to be under control [15], although WHO continues to express concern. [13] [14] Fever screening at airports has also been employed during outbreaks of Dengue in Taiwan. [16] [17]

The 2014 Ebola outbreak originating in West Africa has brought issues of the potential for global pandemic to the forefront. [18] [19] [20] [21] Controversy has arisen over the effectiveness of thermography for fever screening at airports and other checkpoints [22] [23], while empirical data has demonstrated the effectiveness of this technology when used in compliance with appropriate international standards [24] [25] [26] [27] and WHO guidance. [10] [20] [21]

This document is intended to be applicable for thermographic fever screening devices for the above-mentioned and any other fever-producing infectious diseases. [10] [15] [28] [29].

---

1 Figures in square brackets refer to the Bibliography

Documents
Document Sharing Hub

Full document details: BS EN 80601-2-59:2017+A1:2023

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 part of IEC 80601 applies to the BASIC SAFETY and ESSENTIAL PERFORMANCE of SCREENING THERMOGRAPHS intended to be used for the individual non-invasive febrile temperature screening of a human under controlled environmental conditions, hereafter referred to as ME EQUIPMENT. This document sets laboratory characterization test limits for the SCREENING THERMOGRAPH.

NOTE 101 A SCREENING THERMOGRAPH is intended for screening of a human subject and detection of SKIN TEMPERATURE elevated above normal. An elevated SKIN TEMPERATURE needs to be followed up by a subsequent temperature measurement using a clinical thermometer (see ISO 80601-2-56 [30]).

NOTE 102 The main part of such equipment is commonly referred to as an infrared camera.

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 document 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 document refers to those applicable collateral standards that are listed in Clause 2 of the general standard and Clause 201.2 of this document.

〖A1〗 IEC 60601-1-2:2014, IEC 60601-1-2:2014/AMD1:2020, IEC 60601-1-6:2010, IEC 60601-1-6:2010/AMD1:2013 and IEC 60601-1-6:2010/AMD2:2020 apply as modified in Clauses 202 and 206 respectively. 〈A1〉

---

2 〖A1〗 The general standard is IEC 60601-1:2005, IEC 60601-1:2005/AMD1:2012 and IEC 60601-1:2005/AMD2:2020, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*. 〈A1〉

Documents
Document Sharing Hub
Full document details: BS EN 80601-2-59:2017+A1:2023