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BSI Standards Publication

Summary of requirements and tests to products in the scope of IEC 60601-2-66

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National foreword

This Published Document is the UK implementation of IEC TR 62809:2019. It supersedes PD IEC/TR 62809:2013, which is withdrawn.

The UK participation in its preparation was entrusted to Technical Committee EPL/29, Electroacoustics.

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

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TECHNICAL REPORT

Summary of requirements and tests to products in the scope of IEC 60601-2-66

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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SUMMARY OF REQUIREMENTS AND TESTS FOR PRODUCTS IN THE SCOPE OF IEC 60601-2-66

FOREWORD

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IEC 62809, which is a Technical Report, has been prepared by IEC technical committee 29: Electroacoustics.

This second edition cancels and replaces the first edition published in 2013. This edition constitutes a technical revision.

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

a) introduction of the term FITTED OSPL90 (FITTED MAXIMUM OUTPUT SOUND PRESSURE LEVEL) (201.3.206 of IEC 60601-2-66:2019);

b) the allowable maximum output sound pressure level is now based on FITTED MAXIMUM OUTPUT SOUND PRESSURE LEVEL (201.9.6 of IEC 60601-2-66:2019).

c) ESSENTIAL PERFORMANCE is based on risk analysis (201.4.3).

The text of this Technical Report is based on the following documents:

Draft TR	Report on voting
29/1015/DTR	29/1019/RVDTR

Full information on the voting for the approval of this Technical Report 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.

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

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.

A bilingual version of this publication may be issued at a later date.

INTRODUCTION

During the preparation of IEC 60601-2-66, members of the involved technical committee and working group voiced concerns about the complexity of the document and its structure as part of the IEC 60601 series. Members felt distracted from the technical content by this complexity during reviews of the document stages. There was also concern that groups in the hearing aid community would have problems to understand and apply the standard and that this could be an issue with its acceptability.

In order to have a broad consensus for the new standard, it was agreed that the standard should be supported by this Technical Report, which should enable members of the community and the industry to have a basic understanding of the requirements of the standard, without the need to study the complete standard document and the documents that are referenced in it.

IEC 60601-2-66 was published to address the specific requirements for safety of hearing aids, and it is entitled “Particular requirements for the basic safety and essential performance of hearing aids and hearing aid systems”. It was published because IEC 60601-1 is a general standard intended to address a wide range of medical electrical equipment – including large scale facilities such as MRI machines, for example – and thus has large sections that are not relevant to low-voltage, low power, subminiature hearing aids.

If IEC 60601-2-66 was not published, test and regulatory organizations would probably have difficulty applying IEC 60601-1, because it does not contain specific guidance for hearing aids. This Technical Report contains all the requirements from IEC 60601-2-66 which relate to hearing aids and reduces discussion with those that do not relate to hearing aids.

It includes specific references to the applicable requirements within IEC 60601-1, and it is suggested that hearing aid designers and manufacturers along with test and regulatory organizations read this Technical Report as an overview of IEC 60601-2-66.

SUMMARY OF REQUIREMENTS AND TESTS FOR PRODUCTS IN THE SCOPE OF IEC 60601-2-66

1 Scope

This document, which is a Technical Report, provides an overview of the requirements and tests of IEC 60601-2-66 in combination with the applicable sections of IEC 60601-1, and the collateral standards of the IEC 60601 series.

NOTE The IEC 60601 series consists of three levels of standards: IEC 60601-1, known as the general standard, several IEC 60601-1-X documents, known as the collateral standards, and a series of particular standards covering requirements for specific types of equipment (IEC 60601-2-X).

It is intended to assist various groups involved in the product lifecycles process – like designers and suppliers – to get an overview of the basic requirements without studying all involved standard documents in detail. The table includes not all but just the more common requirements and tests.

It is crucial to understand that the summary in this document cannot serve as an input for a product requirement specification or as a test plan without consulting IEC 60601-2-66 itself. This document alone cannot be used to establish or assess compliance to IEC 60601-2-66.

The summary in Table 1 below does not preclude the user from reading the referenced standards in their entirety for a thorough knowledge of the basic safety of hearing aids and hearing aid systems.

2 Normative references

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

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*
IEC 60601-1:2005/AMD1:2012

IEC 60601-2-66:2019, *Medical electrical equipment – Part 2-66: Particular requirements for the basic safety and essential performance of hearing aids and hearing aid systems*

3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

- IEC Electropedia: available at http://www.electropedia.org/
- ISO Online browsing platform: available at http://www.iso.org/obp