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TECHNICAL REPORT

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

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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.

The text of this technical report is based on the following documents:

Enquiry draft	Report on voting
29/776/DTR	29/791/RVC

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 standard, 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- withdrawn,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 instrument 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 instruments, and it is entitled “Particular requirements for the basic safety and essential performance of hearing instruments and hearing instruments 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 instruments.

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 instruments. This Technical Report contains all the requirements from IEC 60601-2-66 which relate to hearing instruments, and reduces discussion with those that do not relate to hearing instruments.

It includes specific references to the applicable requirements within IEC 60601-1, and it is suggested that hearing instrument 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 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 the standard document itself. This Technical Report alone cannot be used to establish or assess compliance to the standard.

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 instruments and hearing instrument 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 60601-2-66:2012, *Medical electrical equipment – Part 2-66: Particular requirements for the basic safety and essential performance of hearing instruments and hearing instrument systems*

3 Summary of requirements and tests

The reference column in Table 1 shows the clause number of IEC 60601-2-66:2012 and, if applicable the reference to IEC 60601-1:2005, or other documents. References to the particular standard, IEC 60601-2-66:2012 start with the number 201, while references to the general standard, IEC 60601-1:2005, start directly with the clause or subclause number.

Other documents will be referred to explicitly. Some detailed references, for example describing tools, are placed in the text instead of in the reference column.