

TECHNICAL REPORT

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

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

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

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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.

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- withdrawn,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

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

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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.