

INTERNATIONAL STANDARD

NORME INTERNATIONALE

**Electroacoustics – Audiometric equipment –
Part 7: Instruments for the measurement of auditory brainstem responses**

**Electroacoustique – Equipements audiométriques –
Partie 7: Instruments pour la mesure des réponses du tronc cérébral à une
stimulation auditive**



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INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

PRICE CODE
CODE PRIX

M

ICS 17.140.50

ISBN 2-8318-1038-4

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INTERNATIONAL ELECTROTECHNICAL COMMISSION

**ELECTROACOUSTICS –
AUDIOMETRIC EQUIPMENT –****Part 7: Instruments for the measurement
of auditory brainstem responses**

FOREWORD

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International Standard IEC 60645-7 has been prepared by IEC technical committee 29: Electroacoustics.

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

FDIS	Report on voting
29/674/FDIS	29/682/RVD

Full information on the voting for the approval of this standard 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.

The list of all the parts of the IEC 60645 series, under the general title *Electroacoustics – Audiometric 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- withdrawn;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.

INTRODUCTION

Developments in the field of diagnostic hearing measurement have resulted in a number of instruments designed to evaluate the auditory evoked potentials of the human hearing system which can be evoked by acoustic or vibratory signals having different spectral and temporal characteristics. The practical use of such instruments concerns the measurement of these electric potentials and their separation from electric signals emerging from other physiological or artificial sources.

ELECTROACOUSTICS – AUDIOMETRIC EQUIPMENT –

Part 7: Instruments for the measurement of auditory brainstem responses

1 Scope

This part of IEC 60645 applies to instruments designed for the measurement of auditory evoked potentials from the inner ear, the auditory nerve and the brainstem, evoked by acoustic and/or vibratory stimuli of short duration. This part of IEC 60645 defines the characteristics to be specified by the manufacturer, specifies performance requirements for two types of instrument, screening and diagnostic, and specifies the functions to be provided on these types.

The purpose of this part of IEC 60645 is to ensure that measurements made under comparable test conditions with different instruments complying with this standard will be consistent. This part of IEC 60645 is not intended to restrict development or incorporation of new features, nor to discourage innovative approaches.

The application of electric stimuli for special purposes is beyond the scope of this standard.

2 Normative references

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.

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

IEC 60645-1:2001, *Electroacoustics – Audiological equipment – Part 1: Pure-tone audiometers*

IEC 60645-3:2007, *Electroacoustics – Audiometric equipment – Part 3: Test signals of short duration*

ISO 389 (all parts), *Acoustics – Reference zero for the calibration of audiometric equipment*

ISO/IEC Guide 98-3, *Uncertainty of measurement – Part 3: Guide to the expression of uncertainty in measurement (GUM:1995)*

3 Terms and definitions

For the purposes of this document, the following terms and definitions apply.

3.1

auditory evoked potentials

AEP

electric potentials which can be evoked by acoustic or vibratory stimulation of the auditory system and recorded by means of electrodes