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INTERNATIONAL STANDARD

NORME INTERNATIONALE

Semiconductor devices – Part 14-10: Semiconductor sensors – Performance evaluation methods for wearable glucose sensors

Dispositifs à semiconducteurs – Partie 14-10: Capteurs à semiconducteurs – Méthodes d'évaluation des performances des capteurs de glucose implantables

IEC 60747-14-10:2019 (en-fr)

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SEMICONDUCTOR DEVICES –

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FOREWORD

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The text of this International Standard is based on the following documents:

FDIS	Report on voting
47E/679/FDIS	47E/686/RVD

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

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

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SEMICONDUCTOR DEVICES –

Part 14-10: Semiconductor sensors – Performance evaluation methods for wearable glucose sensors

1 Scope

This part of IEC 60747-14 specifies the terms, definitions, symbols, tests, and performance evaluation methods used to determine the performance characteristics of wearable electrochemical-glucose sensors for practical use. This document is applicable to all wearable electrochemical-glucose sensors for consumers and manufacturers, without any limitations on device technology and size.

2 Normative references

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.

ISO 15197:2013*, In vitro diagnostic test systems – Requirements for blood glucose monitoring systems for self-testing in managing diabetes mellitus*

3 Terms and definitions

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

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

3.1 General terms

3.1.1
electrochemical glucose sensor
sensor with which the glucose level is measured electrochemically using the redox of glucose through a three- or two-electrode system

Note 1 to entry: Figure 1 shows the basic principle of electrochemical reaction of glucose.

Note 2 to entry: Figure 2 shows several examples of the wearable glucose sensors and systems.