

INTERNATIONAL STANDARD

NORME INTERNATIONALE

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

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



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IEC Central Office
3, rue de Varembe
CH-1211 Geneva 20
Switzerland

Tel.: +41 22 919 02 11
info@iec.ch
www.iec.ch

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CONTENTS

FOREWORD.....	4
1 Scope.....	6
2 Normative references	6
3 Terms and definitions	6
3.1 General terms.....	6
3.2 Characteristic parameters	11
4 Essential ratings and characteristic parameters.....	13
4.1 Identification and type.....	13
4.2 Limiting values and operating conditions.....	13
4.3 Additional information	13
5 Test method	13
5.1 General.....	13
5.2 <i>In vitro</i> evaluation	15
5.2.1 Test procedure	15
5.2.2 Sensitivity.....	16
5.2.3 Selectivity.....	16
5.2.4 Response time.....	17
5.2.5 Linearity	17
5.2.6 Repeatability	18
5.2.7 Reliability.....	18
5.2.8 Limit of detection.....	19
5.2.9 Regression equation between output value and concentration	19
5.2.10 Matching data between output value and concentration	20
5.3 Preclinical investigation	21
5.3.1 Test protocol	21
5.3.2 Effectiveness of evaluation procedure	21
5.3.3 Analytical performance evaluation	22
5.4 Clinical evaluation.....	24
5.4.1 Test protocol.....	24
5.4.2 Clinical investigation procedure	24
5.4.3 Analytical performance evaluation	25
Annex A (informative) Possible interfering substances.....	26
A.1 Purpose.....	26
A.2 List of the possible interfering substances.....	26
Annex B (informative) Consensus error grid.....	27
B.1 Purpose	27
B.2 Graphs.....	27
B.3 Table	28
Annex C (informative) ISO 15197:2013 error grid.....	29
C.1 Purpose	29
C.2 Graphs.....	29
Bibliography.....	32
Figure 1 – Schematic of the electrochemical reaction of glucose.....	7
Figure 2 – Schematic of the wearable and wireless glucose sensor system	8
Figure 3 – Configuration of the three-electrode system	9

Figure 4 – Configuration of the two-electrode system.....	10
Figure 5 – Possible insertion location of the wearable glucose sensor	10
Figure 6 – <i>In vitro</i> test and evaluation set-up for the wearable electrochemical-glucose sensor	14
Figure 7 – Preclinical test and evaluation set-up for the wearable electrochemical-glucose sensor	14
Figure 8 – Clinical test and evaluation set-up for the wearable electrochemical-glucose sensor	15
Figure 9 – <i>In vitro</i> measurement procedure of the glucose sensor.....	15
Figure 10 – Sensitivity of the glucose sensor	16
Figure 11 – Selectivity of the glucose sensor	17
Figure 12 – Response time of the glucose sensor	17
Figure 13 – Linearity of the glucose sensor.....	18
Figure 14 – Repeatability of the glucose sensor.....	18
Figure 15 – Reliability of the glucose sensor.....	19
Figure 16 – Limit of detection of the glucose sensor	19
Figure 17 – Regression analysis between output value and reference glucose value	20
Figure 18 – Preclinical test procedure of glucose	21
Figure 19 – Glucose clinical test procedure.....	24
Figure B.1 – Consensus error grid (mmol/l).....	27
Figure B.2 – Consensus error grid (mg/dl)	28
Figure C.1 – Error grid adapted from ISO 15197:2013: Measured glucose value-concentration plot (mg/dl)	29
Figure C.2 – Error grid adapted from ISO 15197:2013: Measured glucose value-concentration plot (mmol/l).....	30
Figure C.3 – Error grid adapted from ISO 15197:2013: Difference-concentration plot (mg/dl)	30
Figure C.4 – Error grid adapted from ISO 15197:2013: Difference-concentration plot (mmol/l)	31
Table 1 – Table of specifications for the wearable electrochemical-glucose sensor.....	13
Table 2 – Matching table between output value and reference glucose value	20
Table 3 – Glucose concentration intervals for the measurement of repeatability, reliability, and accuracy	22
Table 4 – Glucose concentration of samples for accuracy evaluation	23
Table E.1 – Risk categories	28

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SEMICONDUCTOR DEVICES –

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

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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/>
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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 – Entry: Figure 1 shows the basic principle of electrochemical reaction of glucose.

Note 2 – Entry: Figure 2 shows several examples of the wearable glucose sensors and systems.