IEC 60747-14-10

Edition 1.0 2019-11

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 60747-14-10:2019-11(en-fr)

Documents
Document Sharing Hub

Full document details: IEC 60747-14-10-2019

THIS PUBLICATION IS COPYRIGHT PROTECTED
Copyright © 2019 IEC, Geneva, Switzerland

All rights reserved. Unless otherwise specified, no part of this publication may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm, without permission in writing from either IEC or IEC's member National Committee in the country of the requester. If you have any questions about IEC copyright or have an enquiry about obtaining additional rights to this publication, please contact the address below or your local IEC member National Committee for further information.

Droits de reproduction réservés. Sauf indication contraire, aucune partie de cette publication ne peut être reproduite ni utilisée sous quelque forme que ce soit et par aucun procédé, électronique ou mécanique, y compris la photocopie et les microfilms, sans l'accord écrit de l'IEC ou du Comité national de l'IEC du pays du demandeur. Si vous avez des questions sur le copyright de l'IEC ou si vous désirez obtenir des droits supplémentaires sur cette publication, utilisez les coordonnées ci-après ou contactez le Comité national de l'IEC de votre pays de résidence.

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

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

About the IEC
The International Electrotechnical Commission (IEC) is the leading global organization that prepares and publishes International Standards for all electrical, electronic and related technologies.

About IEC publications
The technical content of IEC publications is kept under constant review by the IEC. Please make sure that you have the latest edition, a corrigendum or an amendment might have been published.

IEC publications search - webstore.iec.ch/advsearchform
The advanced search enables to find IEC publications by a variety of criteria (reference number, text, technical committee,…). It also gives information on projects, replaced and withdrawn publications.

IEC Just Published - webstore.iec.ch/justpublished
Stay up to date on all new IEC publications. Just Published details all new publications released. Available online and once a month by email.

IEC Customer Service Centre - webstore.iec.ch/csc
If you wish to give us your feedback on this publication or need further assistance, please contact the Customer Service Centre: sales@iec.ch.

Electropedia - www.electropedia.org
The world's leading online dictionary on electrotechnology, containing more than 22 000 terminological entries in English and French, with equivalent terms in 16 additional languages. Also known as the International Electrotechnical Vocabulary (IEV) online.

IEC Glossary - std.iec.ch/glossary
67 000 electrotechnical terminology entries in English and French extracted from the Terms and Definitions clause of IEC publications issued since 2002. Some entries have been collected from earlier publications of IEC TC 37, 77, 86 and CISPR.

A propos de l'IEC
La Commission Electrotechnique Internationale (IEC) est la première organisation mondiale qui élabore et publie des Normes internationales pour tout ce qui a trait à l'électricité, à l'électronique et aux technologies apparentées.

A propos des publications IEC
Le contenu technique des publications IEC est constamment revu. Veuillez vous assurer que vous possédez l'édition la plus récente, un corrigendum ou amendement peut avoir été publié.

Recherche de publications IEC - webstore.iec.ch/advsearchform
La recherche avancée permet de trouver des publications IEC en utilisant différents critères (numéro de référence, texte, comité d'études,…). Elle donne aussi des informations sur les projets et les publications remplacées ou retirées.

IEC Just Published - webstore.iec.ch/justpublished
Restez informé sur les nouvelles publications IEC. Just Published détaille les nouvelles publications parues. Disponible en ligne et une fois par mois par email.

Service Clients - webstore.iec.ch/csc
Si vous désirez nous donner des commentaires sur cette publication ou si vous avez des questions contactez-nous: sales@iec.ch.

Electropedia - www.electropedia.org
Le premier dictionnaire d'électrotechnologie en ligne au monde, avec plus de 22 000 articles terminologiques en anglais et en français, ainsi que les termes équivalents dans 16 langues additionnelles. Egalement appelé Vocabulaire Electrotechnique International (IEV) en ligne.

Glossaire IEC - std.iec.ch/glossary
67 000 entrées terminologiques électrotechniques, en anglais et en français, extraites des articles Termes et Définitions des publications IEC parues depuis 2002. Plus certaines entrées antérieures extraites des publications des CE 37, 77, 86 et CISPR de l'IEC.

Documents
Document Sharing Hub

Full document details: IEC 60747-14-10-2019

IEC 60747-14-10

Edition 1.0 2019-11

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

INTERNATIONAL
ELECTROTECHNICAL
COMMISSION

COMMISSION
ELECTROTECHNIQUE
INTERNATIONALE

ICS 31.080.01

ISBN 978-2-8322-7564-1

Warning! Make sure that you obtained this publication from an authorized distributor.
Attention! Veuillez vous assurer que vous avez obtenu cette publication via un distributeur agréé.

® Registered trademark of the International Electrotechnical Commission
Marque déposée de la Commission Electrotechnique Internationale

Documents
Document Sharing Hub

Full document details: IEC 60747-14-10-2019

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 *In vitro* 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

AVA Documents
Document Sharing Hub

Full document details: IEC 60747-14-10-2019

Figure 4 – Configuration of the two-electrode system 10
Figure 5 – Possible insertion location of the wearable glucose sensor 10
Figure 6 – *In vitro* 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 – *In vitro* measurement procedure of the glucose sensor 15
Figure 10 – Sensitivity of the glucose sensor 16
Figure 11 – Selectivity of the glucose sensor 16
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 B.1 – Risk categories 28

Documents
Document Sharing Hub
Full document details: IEC 60747-14-10-2019

INTERNATIONAL ELECTROTECHNICAL COMMISSION

SEMICONDUCTOR DEVICES –

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

FOREWORD

1) The International Electrotechnical Commission (IEC) is a worldwide organization for standardization comprising all national electrotechnical committees (IEC National Committees). The object of IEC is to promote international co-operation on all questions concerning standardization in the electrical and electronic fields. To this end and in addition to other activities, IEC publishes International Standards, Technical Specifications, Technical Reports, Publicly Available Specifications (PAS) and Guides (hereafter referred to as "IEC Publication(s)"). Their preparation is entrusted to technical committees; any IEC National Committee interested in the subject dealt with may participate in this preparatory work. International, governmental and non-governmental organizations liaising with the IEC also participate in this preparation. IEC collaborates closely with the International Organization for Standardization (ISO) in accordance with conditions determined by agreement between the two organizations.
2) The formal decisions or agreements of IEC on technical matters express, as nearly as possible, an international consensus of opinion on the relevant subjects since each technical committee has representation from all interested IEC National Committees.
3) IEC Publications have the form of recommendations for international use and are accepted by IEC National Committees in that sense. While all reasonable efforts are made to ensure that the technical content of IEC Publications is accurate, IEC cannot be held responsible for the way in which they are used or for any misinterpretation by any end user.
4) In order to promote international uniformity, IEC National Committees undertake to apply IEC Publications transparently to the maximum extent possible in their national and regional publications. Any divergence between any IEC Publication and the corresponding national or regional publication shall be clearly indicated in the latter.
5) IEC itself does not provide any attestation of conformity. Independent certification bodies provide conformity assessment services and, in some areas, access to IEC marks of conformity. IEC is not responsible for any services carried out by independent certification bodies.
6) All users should ensure that they have the latest edition of this publication.
7) No liability shall attach to IEC or its directors, employees, servants or agents including individual experts and members of its technical committees and IEC National Committees for any personal injury, property damage or other damage of any nature whatsoever, whether direct or indirect, or for costs (including legal fees) and expenses arising out of the publication, use of, or reliance upon, this IEC Publication or any other IEC Publications.
8) Attention is drawn to the Normative references cited in this publication. Use of the referenced publications is indispensable for the correct application of this publication.
9) Attention is drawn to the possibility that some of the elements of this IEC Publication may be the subject of patent rights. IEC shall not be held responsible for identifying any or all such patent rights.

International Standard IEC 60747-14-10 has been prepared by subcommittee 47E: Discrete semiconductor devices, of IEC technical committee 47: Semiconductor devices.

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.

Documents
Document Sharing Hub

Full document details: IEC 60747-14-10-2019

A list of all parts of the IEC 60747 series, published under the general title *Semiconductor devices*, can be found on the IEC website.

The committee has decided that the contents of this document will remain unchanged until the stability date indicated on the IEC website under "http://webstore.iec.ch" in the data related to the specific document. At this date, the document will be

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

IMPORTANT – The 'colour inside' logo on the cover page of this publication indicates that it contains colours which are considered to be useful for the correct understanding of its contents. Users should therefore print this document using a colour printer.

Documents
Document Sharing Hub

Full document details: IEC 60747-14-10-2019

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.

Documents
Document Sharing Hub

Full document details: IEC 60747-14-10-2019

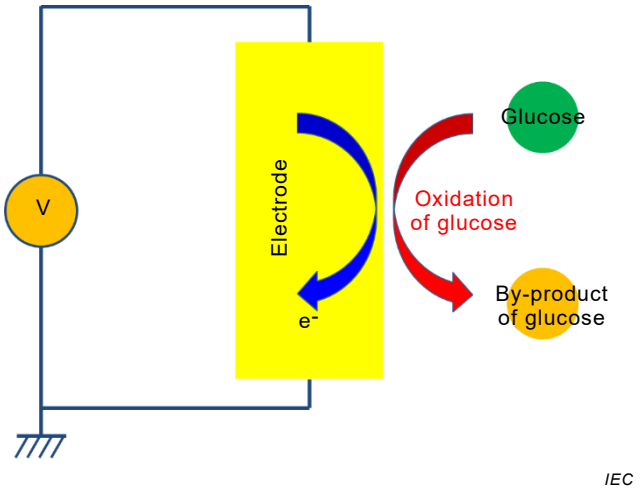
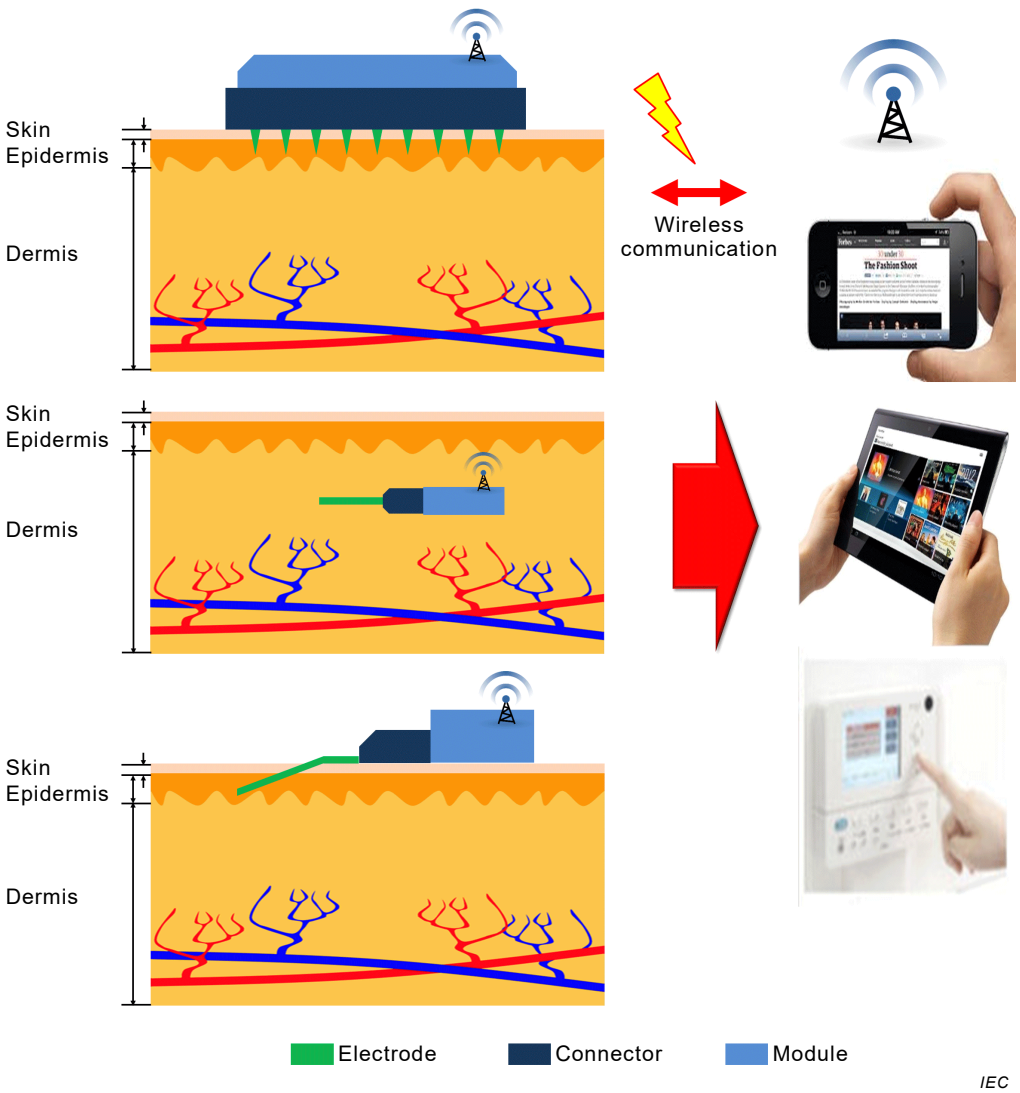


Figure 1 – Schematic of the electrochemical reaction of glucose

Documents
Document Sharing Hub
Full document details: IEC 60747-14-10-2019



Key

Components of the wearable and wireless glucose system

Electrode	Three electrodes of the glucose sensor that can measure and record glucose concentration from interstitial fluid or blood.	Connector	Intermediate between the sensor electrode and module.
Module	Includes a system with a convertor, signal processing circuit, wireless communication circuit, and bias circuit.		
Epidermis	Composed of the outermost layers of cells in the skin.	Dermis	The layer of skin between the epidermis (with which it makes up the cutis) and subcutaneous tissues that consists of connective tissue and cushions the body from stress and strain.

Figure 2 – Schematic of the wearable and wireless glucose sensor system

Documents
Document Sharing Hub
Full document details: IEC 60747-14-10-2019

3.1.2
working electrode
WE
electrode where the reaction of interest occurs in an electrochemical system

3.1.3
counter electrode
CE
electrode, also called auxiliary electrode, used in a three-electrode electrochemical cell for voltammetric analysis or other reactions in which an electrical current is expected to flow

3.1.4
reference electrode
RE
electrode that acts as a reference to measure and control the required working potential, regardless of current flow

3.1.5
three-electrode system
electrochemical system comprising a working electrode, counter electrode, and reference electrode

Note 1 to entry: Figure 3 describes the configuration of the three-electrode system in the electrochemical glucose measurement system.

Note 2 to entry: In the three-electrode system, the reference electrode is typically close to the working electrode so that it can accurately adjust its potential. Current does not flow into the reference electrode, but does flow into the counter electrode. The three-electrode system applies potential between the working and counter electrodes, and measures amperometric current flowing from the working electrode to the counter electrode. As the three-electrode system is able to apply stable and accurate potential through the reference electrode, it is used for the investigation of the mechanism of electrochemical reactions, electrochemical analysis, and to obtain various parameters.

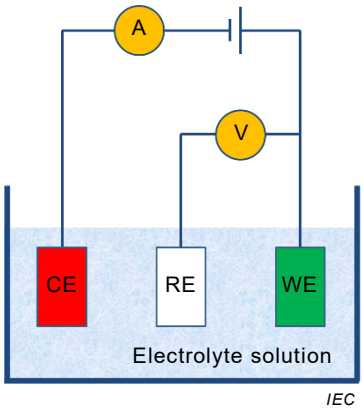


Figure 3 – Configuration of the three-electrode system

3.1.6
two-electrode system
electrochemical system comprising a working electrode and counter/reference electrode

Note 1 to entry: Figure 4 describes the configuration of the two-electrode system in the electrochemical glucose measurement system.

Documents
Document Sharing Hub
Full document details: IEC 60747-14-10-2019

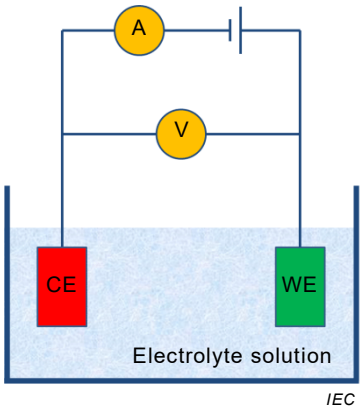


Figure 4 – Configuration of the two-electrode system

3.1.7
wearable glucose sensor
glucose sensor that is intended to be totally or partially introduced, surgically or medically, into the human body to measure glucose levels through the blood or interstitial fluid, and which is intended to remain in place following the procedure or mounted on human skin

Note 1 to entry: Figure 5 describes three types of wearable glucose sensors. Implant-type glucose sensors are located under the skin either in the epidermis, dermis, or other tissue. Patch-type glucose sensors are located on the skin, and are partially inserted and exposed.

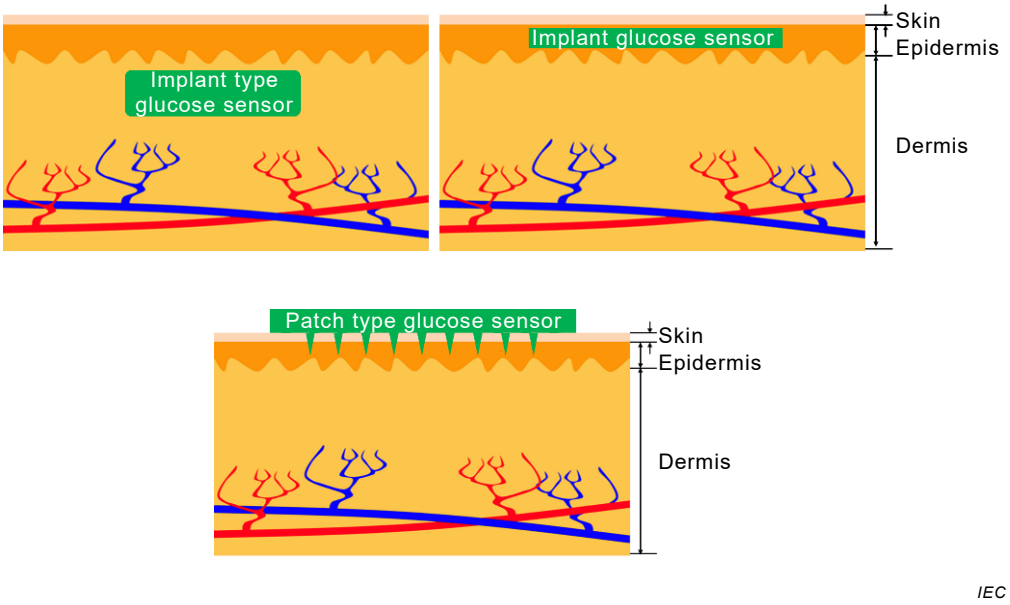


Figure 5 – Possible insertion location of the wearable glucose sensor

3.1.8
amperometric response
current response of the glucose sensor caused by a change in the glucose concentration under the working potential

3.1.9
working potential
optimal potential of the working electrode that maximizes the amperometric response of glucose and minimizes the amperometric response of interference

Documents
Document Sharing Hub
Full document details: IEC 60747-14-10-2019

3.1.10
interference
bio-reagents present in bio-fluids such as blood and interstitial fluid, which can indicate a larger amperometric response than that of glucose in the glucose sensor and can interfere with the measurement of glucose levels

Note 1 to entry: All interferences that affect the electrochemical response to glucose during measurement are listed in Annex A.

3.1.11
***in vitro* evaluation**
evaluation of glucose and other bio-reagents performed outside the animal or human body

3.1.12
preclinical evaluation
stage of research that begins before clinical evaluation (testing in humans), and during which important feasibility, iterative testing, and drug safety data are collected through safety and effectiveness evaluation

Note 1 to entry: "Preclinical investigation", "preclinical test", "preclinical development", or "preclinical study" are synonymous with "preclinical evaluation".

3.1.13
clinical evaluation
systematic investigation in one or more human subjects, undertaken to assess the safety or performance of a medical device

Note 1 to entry: ”Clinical investigation” “clinical test”, “clinical development”, or “clinical study” are synonymous with “clinical evaluation”.

[SOURCE: ISO 14155:2011, 3.6]

3.2 Characteristic parameters

3.2.1
sensitivity
quotient of the change in the glucose concentration of a measurement system and the corresponding change in the current being measured, which can be

$$sensitivity = \frac{\Delta I}{\Delta C} \quad \text{[A/mmol/l]} \tag{1}$$

where

I is current

C is concentration

Note 1 to entry: The sensitivity of a measurement system can depend on the value of the quantity being measured.

Note 2 to entry: The change in the value of the quantity being measured is larger compared with the resolution.

3.2.2
selectivity
parameter that can detect a certain analyte and not react with admixtures and contaminants such as interference from acetaminophen and ascorbic acid

Note 1 to entry: All interferences that affect the electrochemical response of glucose during measurement are listed in Annex A.

Documents
Document Sharing Hub
Full document details: IEC 60747-14-10-2019

3.2.3
response time
duration between the instant when the prior amperometric response is stable before the glucose concentration changes and the instant when the amperometric response reaches a final value following the change in glucose concentration

3.2.4
linearity
mathematical relationship or function that can be graphically represented as a straight line, as in the glucose concentration and electrochemical response that are directly proportional to each other

3.2.5
repeatability
measurement precision under a set of repeatability conditions that include the same measurement procedure, operators, measurement system, operating conditions, and location, and replicate measurements on the same or similar objects over a short period of time

Note 1 to entry: A condition of measurement is a repeatability condition only with respect to a specified set of repeatability conditions.

3.2.6
reliability
measurement precision under a set of reliability conditions that include the same measurement procedure, operators, measurement system, operating conditions, and location, and replicate measurements on the same or similar objects over a long period time

3.2.7
limit of detection
LOD
smallest reliable measurable quantity value, called resolution, that the glucose sensor is able to make

Note 1 to entry: This note applies to the French language only.

3.2.8
reproducibility
measurement precision under reproducibility conditions that include different locations, operators, measurement systems, and replicate measurements on the same or similar objects

Note 1 to entry: The different measurement systems use different measurement procedures.

Note 2 to entry: Specification gives the conditions changed and unchanged.

3.2.9
life-time
statistical measurement of how long the glucose sensor may work

3.2.10
accuracy
closeness of agreement between a measured quantity value of glucose concentration and a true quantity value of reference glucose concentration

Note 1 to entry: Accuracy is analyzed through error grid analysis.

Documents
Document Sharing Hub
Full document details: IEC 60747-14-10-2019

4 Essential ratings and characteristic parameters

4.1 Identification and type

The wearable electrochemical-glucose sensors shall be clearly and durably marked in the order given below:

a) year and week (or month) of manufacture;

b) manufacturer name or trade mark;

c) terminal identification (optional);

d) serial number;

e) factory identification code (optional).

4.2 Limiting values and operating conditions

The manufacturer shall clearly indicate the operating conditions and limitations for the use of the wearable glucose sensor. Table 1 shows a list of specifications for operating conditions and limitations.

Table 1 – Table of specifications for the wearable electrochemical-glucose sensor

Parameter[a]	Symbol[b]	Min.[c]	Max.[d]	Unit[e]	Measuring condition[f]

[a] Name of characteristic parameters

[b] Symbol of parameters

[c] Minimum value of parameters

[d] Maximum value of parameters

[e] Specified condition for evaluation

[f] Specified condition for evaluation

4.3 Additional information

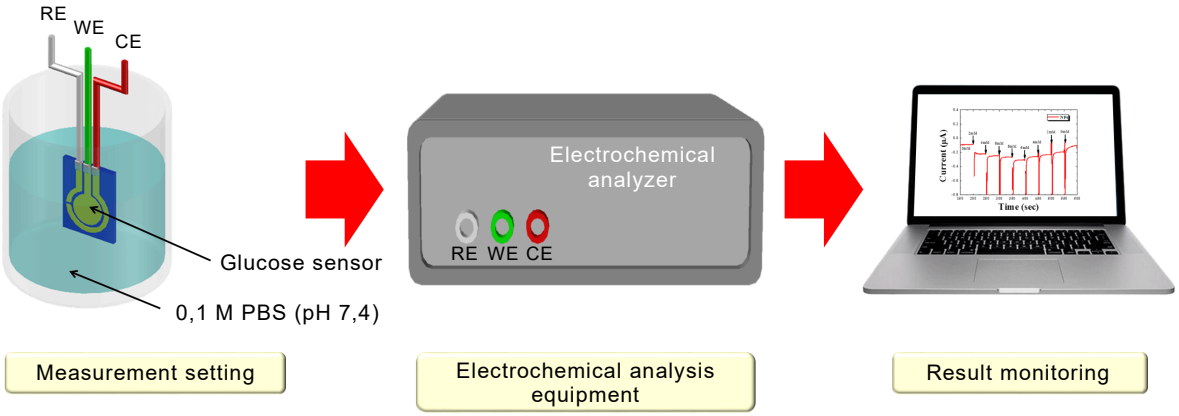
Some additional information should be given, such as operating conditions (e.g. operating temperature, storage temperature, input voltage, equivalent circuit, and power consumption, etc.), handling precautions, physical information (e.g. outline dimensions, terminals, etc.), accessories, installation guide, package information, PCB interface and mounting information, and any other relevant information.

5 Test method

5.1 General

The sequence of general test procedures for the wearable electrochemical-glucose sensors is shown in Figure 6, Figure 7, and Figure 8. After the glucose sensor has been mounted on the test module, the level of glucose is measured by applying potential with an electrochemical analyzer. The wearable electrochemical-glucose sensor is evaluated in the sequence of *in vitro*, preclinical, and clinical tests. For the preclinical and clinical tests, the wearable sensor is usually integrated and assembled with signal analysis circuitry and a communication module for wireless and continuous monitoring.

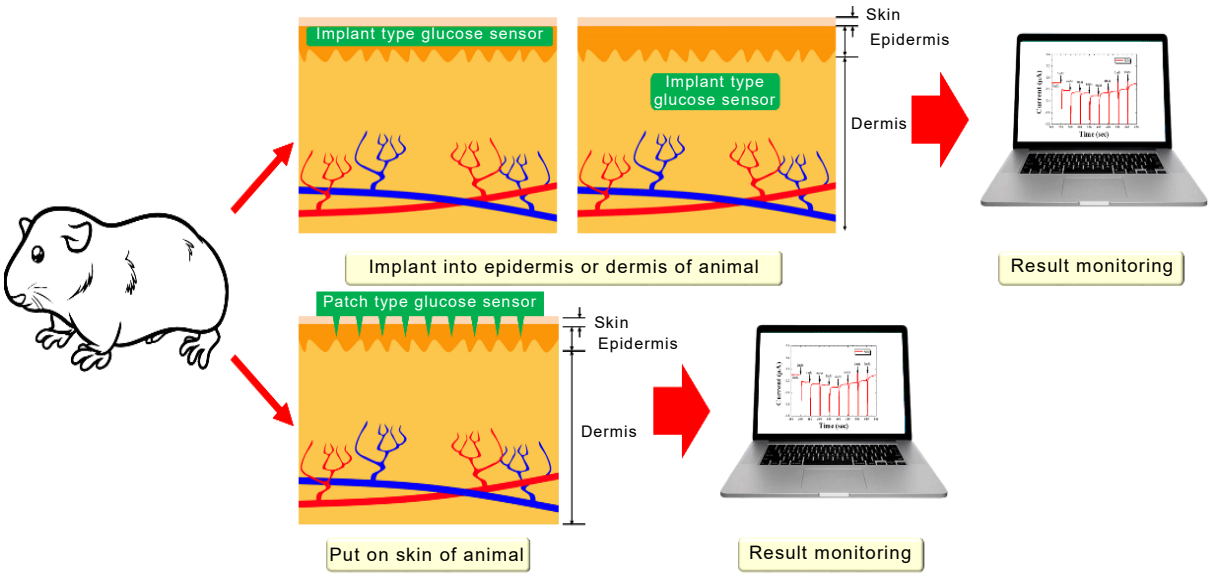
Documents
Document Sharing Hub
Full document details: IEC 60747-14-10-2019



IEC

NOTE In order to characterize the patch- and implant-type glucose sensors, each sensor is dipped into 0,1 M phosphate buffered saline (PBS) (pH 7,4), and potential, such as a constant or specific waveform, is applied to the glucose sensor. The investigator measures the change in the current response as the glucose concentration varies, and analyzes the parameters of sensitivity, selectivity, response time, repeatability, reproducibility, limit of detection, and life-time.

Figure 6 – *In vitro* test and evaluation set-up for the wearable electrochemical-glucose sensor



IEC

Figure 7 – Preclinical test and evaluation set-up for the wearable electrochemical-glucose sensor

Documents
Document Sharing Hub
Full document details: IEC 60747-14-10-2019

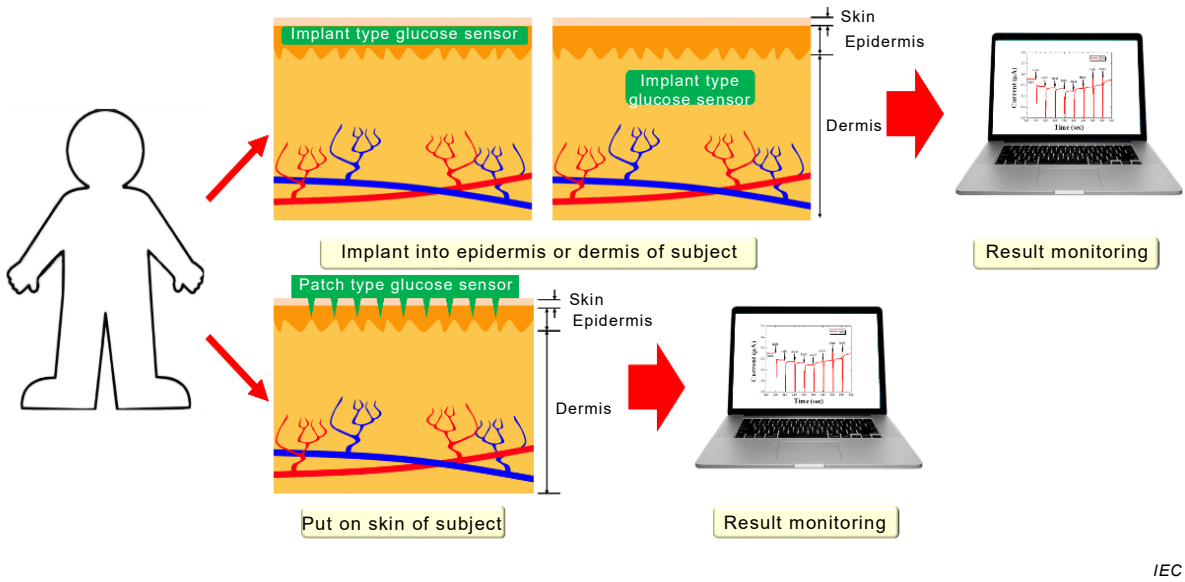


Figure 8 – Clinical test and evaluation set-up for the wearable electrochemical-glucose sensor

5.2 *In vitro* evaluation

5.2.1 Test procedure

In vitro evaluation shall be conducted as shown in Figure 9. The following test procedure is performed:

a) as shown in Figure 9, all the implements and reagents for evaluation of the glucose sensor are set up;

b) reagents for *in vitro* evaluation include 0,1 M PBS, glucose solution, interferences, electrochemical analyzer, and monitoring system. The 0,1 M PBS solution is the background solution for all *in vitro* evaluations;

c) sensitivity, selectivity, response time, linearity, repeatability, and reliability analyses are implemented;

d) evaluation of the glucose sensor is analyzed statistically or through the methods specified below.

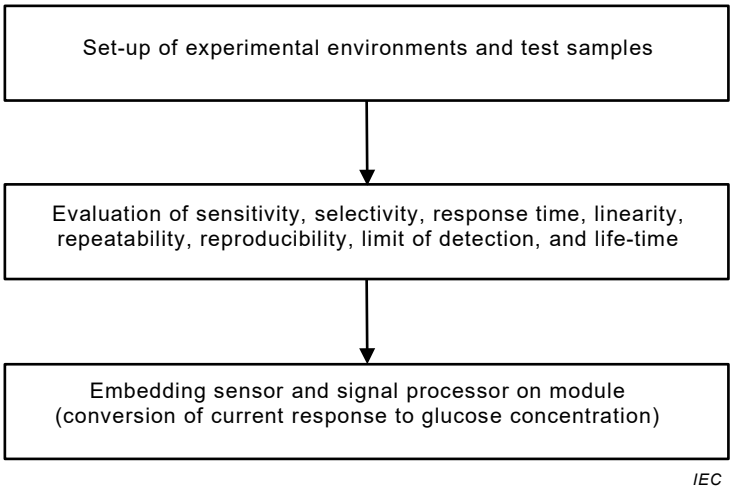


Figure 9 – *In vitro* measurement procedure of the glucose sensor

Documents
Document Sharing Hub
Full document details: IEC 60747-14-10-2019

5.2.2 Sensitivity

The current response of the glucose sensor during measurement, and the parameter that indicates how much current flows according to glucose concentration.

In order to investigate the sensitivity of the glucose sensor, the glucose concentration is progressively and gradually changed into specific values for a wide range of tests. Figure 10 shows a typical plotting of current versus glucose concentration. Sensitivity is defined as the quantity of current according to glucose concentration.

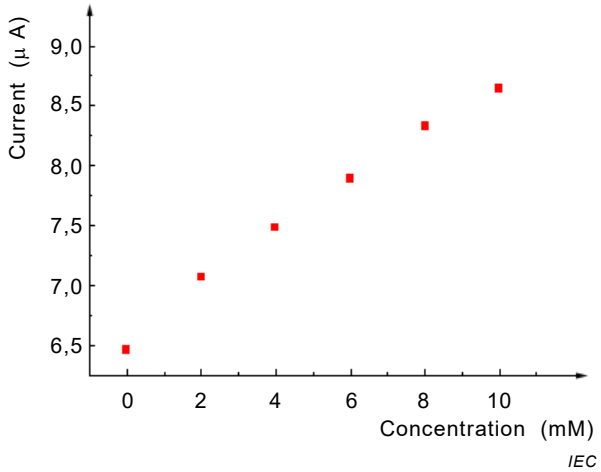


Figure 10 – Sensitivity of the glucose sensor

5.2.3 Selectivity

A parameter that reacts to one reagent with good selectivity means that the glucose sensor indicates a high current response to glucose only and a low current response to other substances.

Figure 11 shows the results of a selectivity test. In order to evaluate the selectivity of the glucose sensor, interferences such as ascorbic acid and acetaminophen are added to the 0,1 M PBS solution along with glucose at two specific concentrations.

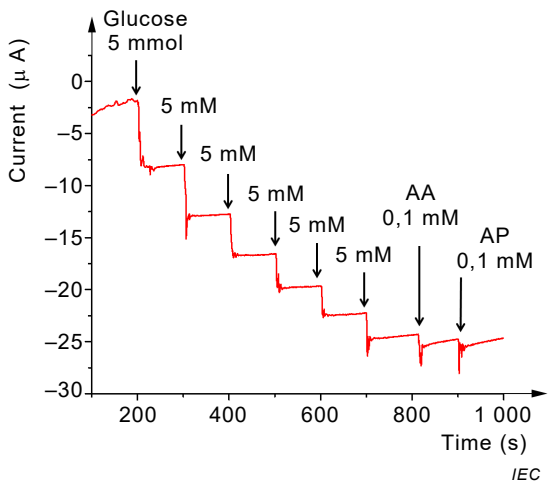


Figure 11 – Selectivity of the glucose sensor

Documents
Document Sharing Hub
Full document details: IEC 60747-14-10-2019

NOTE 1 All the interferences are listed in Annex A.

NOTE 2 The recommended concentrations of interferences are determined from the CLSI document EP07-A2: Interference Testing in Clinical Chemistry; Approved Guideline-Second Edition, see Bibliography.

NOTE 3 The concentrations of glucose in the 0,1 M PBS solution are intervals of 2,8 mmol/l to 5,5 mmol/l (50 mg/dl to 100 mg/dl) and intervals of 13,9 mmol/l to 19,4 mmol/l (250 mg/dl to 350 mg/dl).

5.2.4 Response time

This refers to the time taken for the amperometric response to reach a final value following a change in glucose concentration. Figure 12 shows an example of how to calculate the response time. The final value is defined as 90 % of the quantity of the current that reaches a stable value.

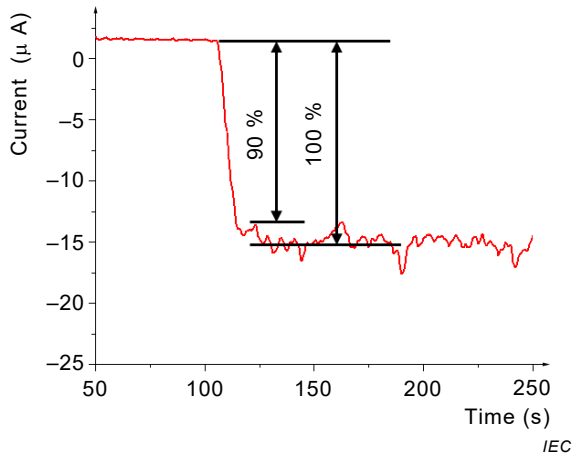
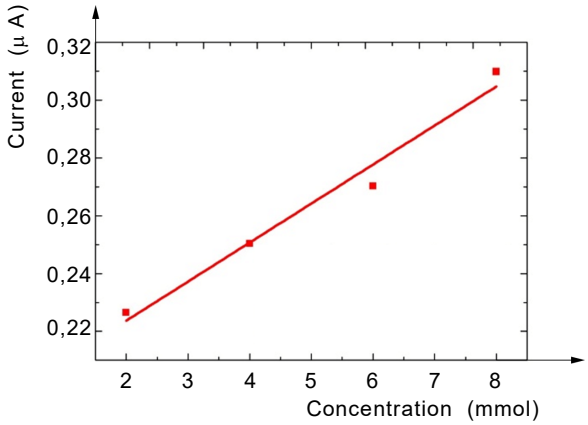


Figure 12 – Response time of the glucose sensor

5.2.5 Linearity

The parameter that indicates how much of the current response to the glucose level is linear, and how wide its range is. Figure 13 shows a plotting of current versus glucose concentration. The scattered dots are plotted on the graph and fitted through a linear function.

Documents
Document Sharing Hub
Full document details: IEC 60747-14-10-2019



Equation	$y = a + b * x$		
Adj. R-squ	0,964		
		Value	Standard Er
Current	Intercept	1,967E-3	8,199 39E-9
Current	Slope	1,35E-2	1,497E-9

IEC

Figure 13 – Linearity of the glucose sensor

5.2.6 Repeatability

The parameter that determines how stable the glucose sensor is in the short-term.

Figure 14 shows a graph to evaluate repeatability. In order to evaluate the repeatability of the glucose sensor, the amperometric response changed by repetition of the same test is measured and recorded using the same method and conditions over a period of time less than 24 h.

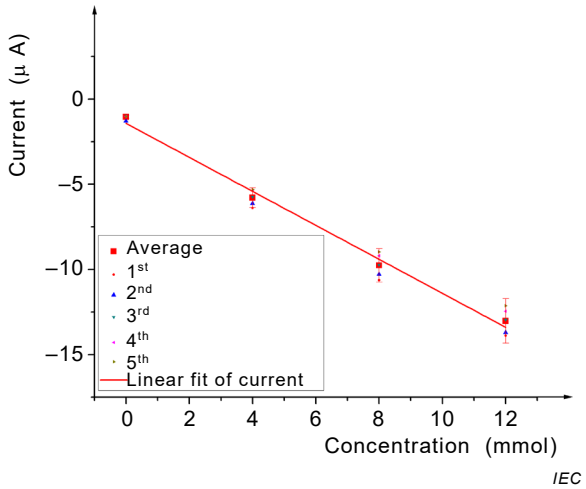


Figure 14 – Repeatability of the glucose sensor

5.2.7 Reliability

The parameter that determines how stable the glucose sensor is in the long-term (over a few days).

Documents
Document Sharing Hub
Full document details: IEC 60747-14-10-2019

Figure 15 shows a graph to evaluate the reliability. In order to evaluate the reliability of the glucose sensor, the amperometric response changed by repetition of the same test is measured and recorded using the same method conditions over a few days or longer.

During long-term measurement (over a few days), the investigators measure and compare the deviation in the current response of the glucose sensor.

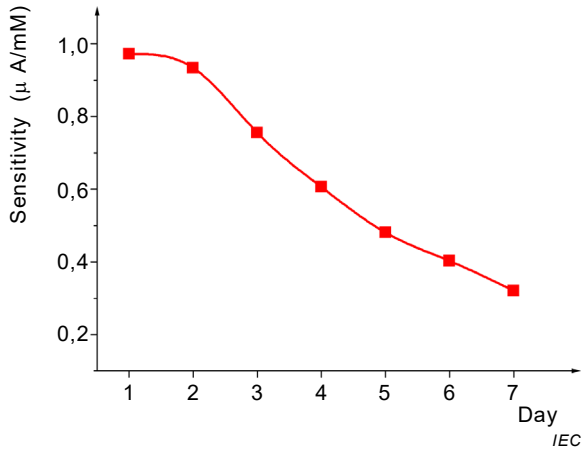


Figure 15 – Reliability of the glucose sensor

5.2.8 Limit of detection

This is the parameter that determines how low a concentration of glucose the glucose sensor can measure. The limit of detection test is performed by adding a small amount of glucose. Figure 16 shows the result of a limit of detection measurement as a small amount of the glucose is injected. Signal-to-noise ratio (SNR) shall be more than 3 where the glucose concentration is at the minimum limit of detection.

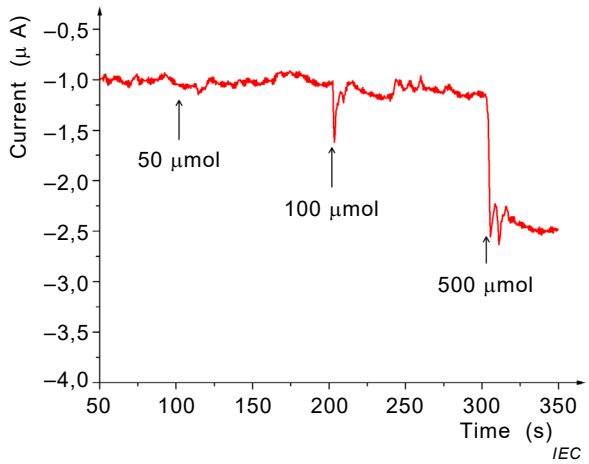


Figure 16 – Limit of detection of the glucose sensor

5.2.9 Regression equation between output value and concentration

This equation determines the specific relation between the output value (or any output value, such as current response, output voltage, and digit value) and the glucose value by regression analysis so that the unknown glucose value is able to be determined by comparing the glucose value (from the test device) to the reference. Figure 17 shows a graph to obtain the correlation between the reference glucose values and the output of the glucose sensor.

AVA Documents
Document Sharing Hub
Full document details: IEC 60747-14-10-2019