IEC 60747-14-10

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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

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SEMICONDUCTOR DEVICES –

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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.

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- withdrawn,
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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.

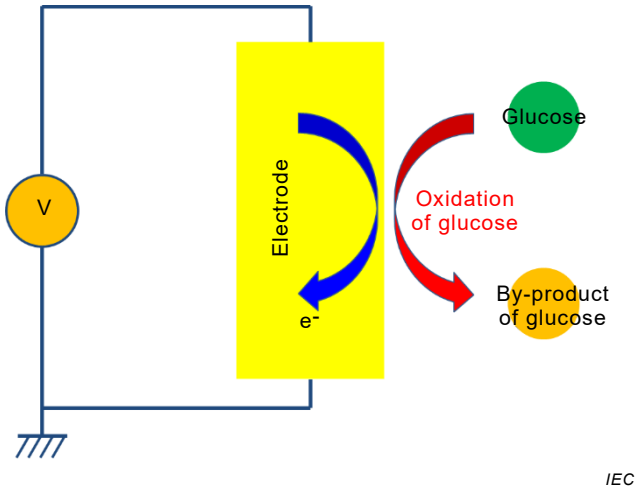
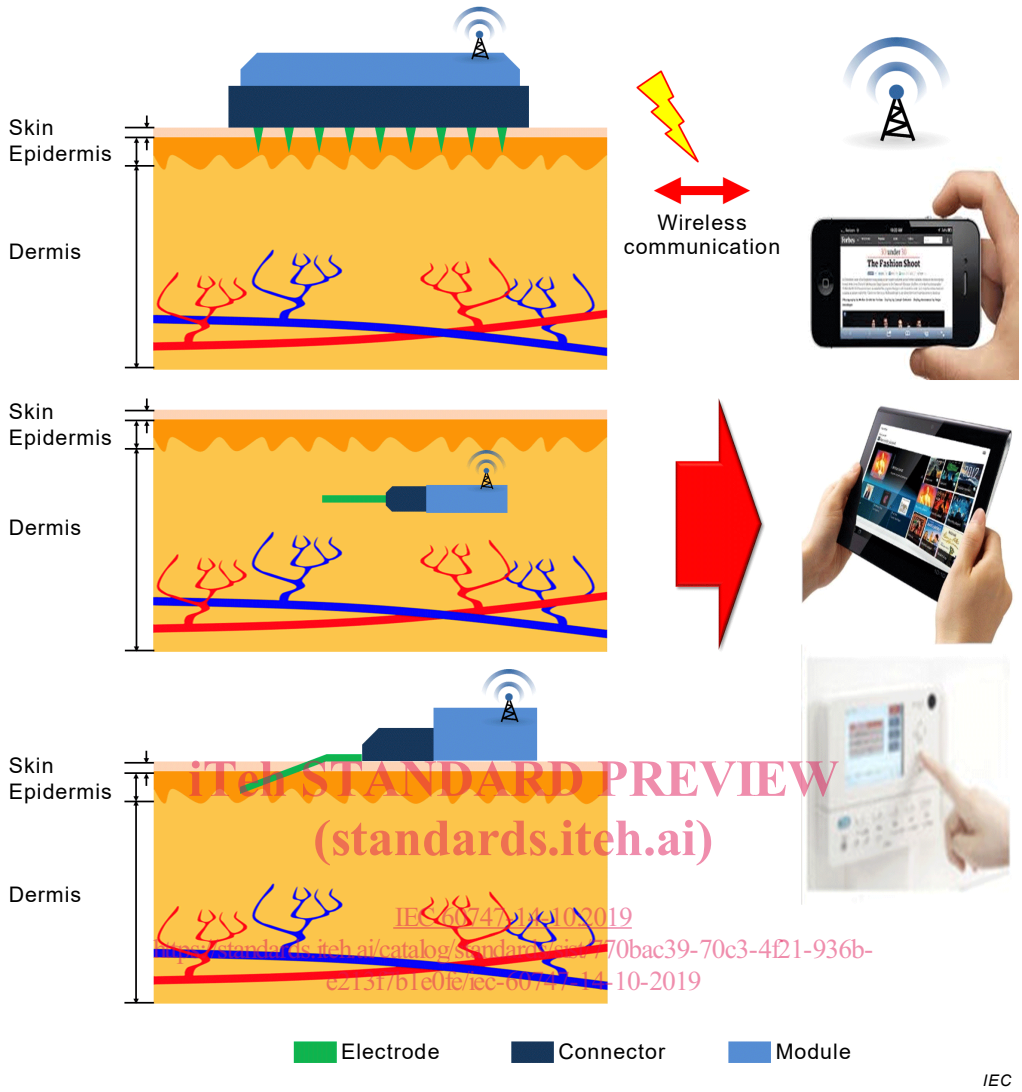


Figure 1 – Schematic of the electrochemical reaction of glucose



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

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.

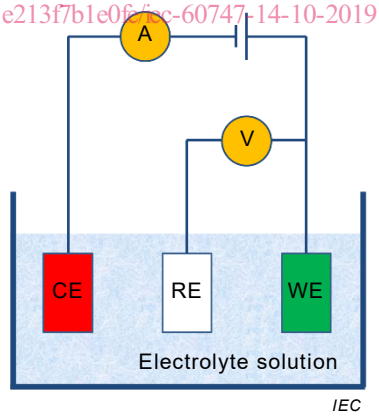


Figure 3 – Configuration of the three-electrode system

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.

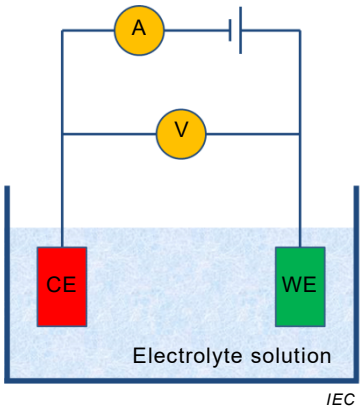


Figure 4 – Configuration of the two-electrode system

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.

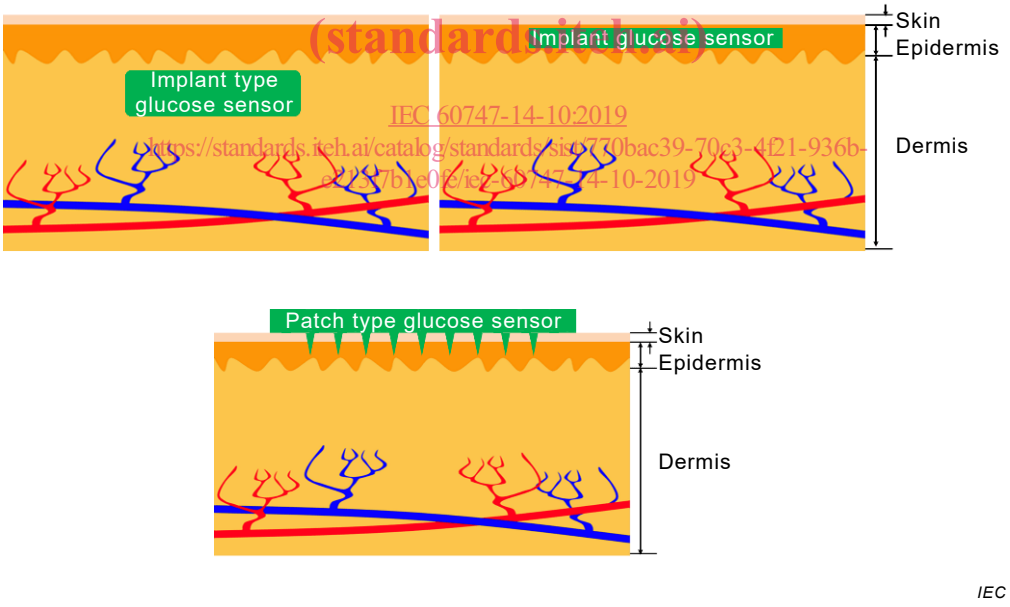


Figure 5 – Possible insertion location of the wearable glucose sensor

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

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.

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.

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.