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Implants for surgery — Measurements of open-circuit potential to assess corrosion behaviour of metallic implantable materials and medical devices over extended time periods

Implants chirurgicaux — Mesurages sur de longues périodes du potentiel en circuit ouvert pour l'évaluation du comportement à la corrosion des matériaux métalliques et dispositifs médicaux implantables

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 16429 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 1, *Materials*.

Introduction

This International Standard was developed because, in contrast to polarization measurements which are well described in ASTM G5 [6] and literature, there is no standard available on typical open-circuit potential measurements over extended time periods.

Relating to corrosion behaviour of implant materials and surgical implant devices, the long-term electrochemical behaviour in the body environment is of interest.

Metal surfaces undergo spontaneous changes at their interface with an electrolytic environment to reach a state of equilibrium. Depending on the conditions, the corresponding physico-chemical and electrochemical reactions can be highly active and corrosive, or very sluggish and passive. For passivating metals such as those usually used for surgical implants, the formation and stability of the passive film is an important prerequisite for corrosion resistance of these materials, under given conditions.

With the measurement of the open-circuit potential over a longer time period, the spontaneous reaction to the environment (electrolyte) in the form of passivation or activation, the formation of a steady state potential and its stability can be assessed. Regarding surgical implant materials and devices, the measurements of these properties is of interest because they help to characterize implant material systems and to optimize processing, surface treatments and properties. Furthermore, measurements of the long-term open-circuit potential in combination with mechanical loading give information on the effect of mechanical, dynamic conditions on the electrochemical potential, passivity and corrosion behaviour.

This International Standard specifies conditions for the measurement of the open-circuit potential over extended periods of time. Isotonic 0,9 % NaCl (see 3.5) is used as the electrolyte (testing solution). This solution is related to body fluid in that it contains approximately the same concentration of Cl ions, and Cl ions are the most likely species in this solution to cause metal corrosion due to their aggressivity. For more stringent testing conditions, solutions with higher concentrations of Cl ions are given in Annex A.

Implants for surgery — Measurements of open-circuit potential to assess corrosion behaviour of metallic implantable materials and medical devices over extended time periods

1 Scope

This International Standard specifies a test method for measurements over extended time periods of the open-circuit potential of implant materials and surgically implantable devices immersed in a test environment related to body fluid, using a standard corrosion test cell to study the electrochemical corrosion properties of the devices.

This method of monitoring the open-circuit potential can also be combined with mechanical static or dynamic loading tests.

This International Standard is applicable in particular to metallic materials which form passive layers with protective properties against corrosion, as typical for surgical implant materials.

This test method is intended for the investigation of single metallic materials or alloys. It is not applicable to dissimilar material combinations, which require particular considerations in measuring and interpreting the results.

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.

ISO 3696, *Water for analytical laboratory use — Specification and test methods*

ISO 16428, *Implants for surgery — Test solution and environmental conditions for static and dynamic corrosion and wear tests on implantable materials and medical devices*

3 Terms and definitions

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

3.1
corrosion potential
electrode potential of a metal in a given corrosion system

3.2
corrosion system
system consisting of one or more metals and those parts of the environment (including specimen, electrolyte, electrodes) that influence corrosion

3.3
environmental test conditions
conditions under which a sample (specimen) is tested, including temperature, aerating elements, pH, and identification, volume and exchange rate of the contacting fluid

3.4
free corrosion potential
corrosion potential in the absence of net (external) electrical current flowing to or from the metal surface

[ISO 8044]

3.5
isotonic NaCl solution
aqueous solution of NaCl (0,9 % mass fraction) which has the same surface tension as living tissues

NOTE In surgical applications it prevents the collapsing of tissues.

3.6
open-circuit potential
potential of an electrode measured with respect to a reference electrode or another electrode when no current flows to or from it

[ASTM G 15]

cf. **free corrosion potential** (3.4).

3.7
passive layer
surface layer on a metal that forms as result of the reaction with the environment, or spontaneously under given conditions, and has the capacity to protect the metal against corrosion

NOTE Passive layers are usually adherent and of submicroscopical thickness (see ISO 8044).

3.8
reference electrode
electrode having a stable and reproducible potential that is used as a reference in the measurement of electrode potentials

3.9
working electrode
test or working electrode in an electrochemical cell; the test specimen in the context of this standard

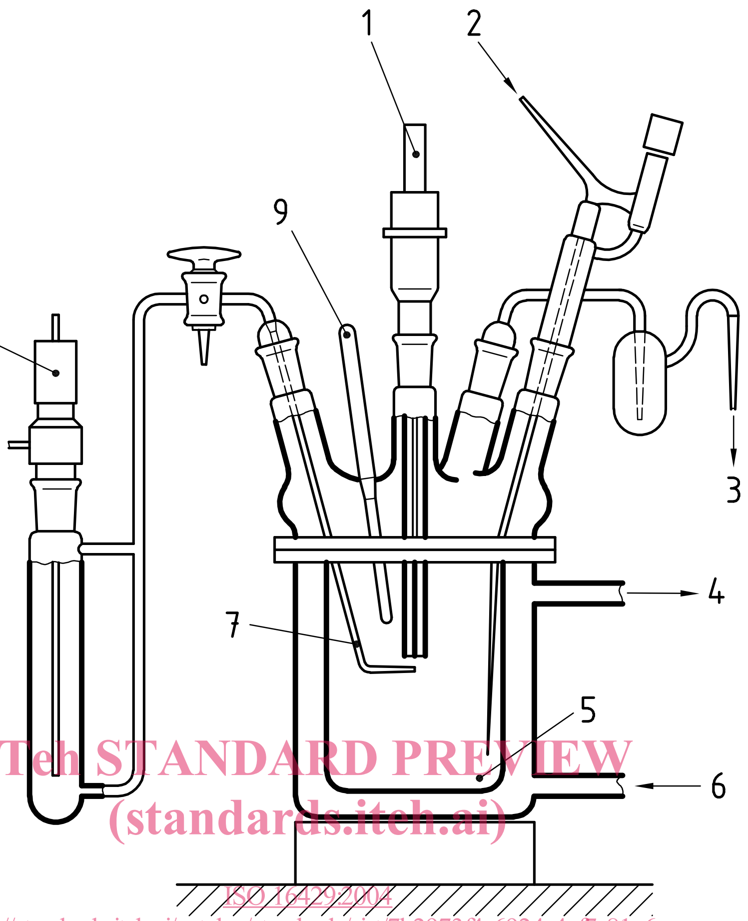
4 Significance and application

4.1 Principle

In this electrochemical test method, the test specimens (samples) are immersed in an isotonic test solution of NaCl[9], which relates to the physiological environment of the body as described in ISO 16428. Other test solutions and the other environmental conditions are also described in ISO 16428. For more stringent test conditions, more acidic test solutions (lower pH) are suggested in Annex A.

The tests are carried out in an electrochemical test cell similar to that described in the ASTM G 5[6]. The test cell provides access for the electrodes and other necessary equipment (Figure 1).

While the specimen is exposed to the environment for a specified period of time, the open-circuit potential is recorded continuously as a function of time. The specimen functions as the working electrode and its behaviour is measured against a reference electrode (Figure 2).



Key

1 working electrode (test specimen)
2 gas inlet
3 gas outlet
4 water outlet
5 test solution (electrolyte)
6 water inlet
7 Luggin probe
8 reference electrode
9 thermometer

Figure 1 — Example of electrochemical test cell[3]