
**Implants for surgery — Test solutions
and environmental conditions for static
and dynamic corrosion tests on
implantable materials and medical
devices**

*Implants chirurgicaux — Solutions d'essai et conditions
environnementales pour les essais statiques et dynamiques de
corrosion sur les matériaux 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.

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Introduction

In many instances testing of medical devices and materials in a physiological environment is highly desirable for scientific purposes and development work as well as for the assessment of the performance of surgical implants and devices. The application of original physiological fluids is often difficult because of the rapid deterioration of such media.

The application of artificial media is common, but there is the disadvantage that the compositions vary widely and testing results are often not comparable.

This International Standard specifies basic reproducible environmental conditions using a test fluid of isotonic sodium chloride (NaCl) solution. This solution is appropriate because it is used for injections and irrigation in surgery and has an ion content similar to that of human body fluids. Of particular importance are the chloride (Cl^-) ions because the corrosion resistance of most metals is very sensitive to them. Correspondingly, the isotonic NaCl solution is already widely used in the testing of medical devices.

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Implants for surgery — Test solutions and environmental conditions for static and dynamic corrosion tests on implantable materials and medical devices

1 Scope

This International Standard specifies standard environmental conditions for the testing of metallic materials intended for implantation, surgical implants, and medical devices. The test conditions described simulate physiological conditions in a simplified manner controlling the test solution, the temperature, the gaseous atmosphere and the proportions of sample size and volume of solution.

These environmental testing conditions can be employed where necessary in combination with various static or dynamic tests where the effect of the physiological environment is to be considered. Typical applications are corrosion fatigue tests and selected fretting and wear tests, as well as general electrochemical tests.

Typical articulating joint simulator tests and aspects particular to the dental field are not considered by this International Standard. Solutions that attempt to replicate the tribological properties of body fluids, such as those used in wear studies, are outside the scope of this International Standard.

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*

3 Terms and definitions

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

3.1

corrosion fatigue testing

assessment of corrosion fatigue behaviour where cyclic loading tests are carried out in an aqueous test solution which is related to the human physiological environment

NOTE The test solution may either cause visible corrosion effects and/or acceleration of the fatigue process.

3.2

environmental testing conditions

conditions under which a sample (specimen) is tested including the testing fluid, temperature, aeration, the pH, and the volume ratio and exchange of the fluid

3.3

isotonic sodium chloride solution

aqueous solution of sodium chloride (0,9 % NaCl mass fraction) which provides the same osmotic pressure in living tissues as the physiological fluid (blood serum)

NOTE In surgical applications, it prevents the collapse of tissues and serves as an infusion solution.