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**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.

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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.

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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<sup>-</sup>) 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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