

TECHNICAL REPORT

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Implants for surgery — Partial and total hip joint prostheses — Recommendations for simulators for evaluation of hip joint prostheses

*Implants chirurgicaux — Prothèses partielle et totale de hanche —
Recommandations concernant les simulateurs de marche destinés à l'évaluation des
prothèses de hanche*



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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.

The main task of ISO technical committees is to prepare International Standards. In exceptional circumstances a technical committee may propose the publication of a technical report of one of the following types :

- type 1, when the necessary support within the technical committee cannot be obtained for the publication of an International Standard, despite repeated efforts;
- type 2, when the subject is still under technical development requiring wider exposure;
- type 3, when a technical committee has collected data of a different kind from that which is normally published as an International Standard ("state of the art", for example).

Technical reports are accepted for publication directly by ISO Council. Technical reports of types 1 and 2 are subject to review within three years of publication, to decide whether they can be transformed into International Standard. Technical reports of type 3 do not necessarily have to be reviewed until the data they provide are considered to be no longer valid or useful.

ISO/TR 9325, which is a technical report of type 2, was prepared by Technical Committee ISO/TC 150, *Implants for surgery*.

Annexes A, B and C of this Technical Report are given for information only.

Introduction

These recommendations are concerned with the laboratory evaluation of wear, endurance and friction characteristics of hip joint prostheses and the conditions of loading and environment that approximate to those that are believed to prevail *in vivo* and under which, consequently, a prosthesis will be required to function effectively when implanted in the patient. The loading profile used may be developed from *in vivo* biotelemetry information, or from predictions from external dynamic measurements.

The application to a hip joint prosthesis, for a considerable period of time, of a rigidly controlled cyclic load of the correct magnitude and combination of directional components under accurate temperature control, and in a medium of liquid lubricant, necessitates the use of an apparatus (commonly referred to as a simulator) that is purpose-built, often by the establishment that is conducting the tests, and which will differ to some extent from an apparatus constructed by another centre of expertise. Indeed, a particular design of simulator may well be unique in the way in which the various design considerations have been met.

The present incomplete state of knowledge of the loading system generated in the hip during walking, the largely unproven correlations between conditions *in vivo* and the concepts and detail of apparatus design and test environment, coupled with the difficulties inherent in the precise and accurate determination of hip prosthesis performance and the fact that the quality of measurements can be no better than that of the weakest link in the experimental chain, do not allow the exact specification of the test apparatus or procedure.

For these reasons, it was decided to produce this Type 2 Technical Report which gives recommendations for the conditions that should appertain to a hip joint simulator and the test specimens, in order to improve comparability of results. It is hoped that these recommendations will be adopted by the various centres involved in testing hip joint prostheses and thereby facilitate the future preparation of International Standards dealing with simulators and the testing of hip joint prostheses.

The use or interpretation of experimental results obtained from simulators is not discussed.