

# CONSOLIDATED VERSION

# VERSION CONSOLIDÉE



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**Medical devices – Application of usability engineering to medical devices**

**Dispositifs médicaux – Application de l'ingénierie de l'aptitude à l'utilisation aux dispositifs médicaux**



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ELECTROTECHNICAL  
COMMISSION

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**Medical devices – Application of usability engineering to medical devices**

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APPLICATION OF USABILITY ENGINEERING  
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**This Consolidated version of IEC 62366 bears the edition number 1.1. It consists of the first edition (2007-10) [documents 62A/574/FDIS and 62A/579/RVD] and its amendment 1 (2014-01) [documents 62A/889/FDIS and 62A/897/RVD]. The technical content is identical to the base edition and its amendment.**

**In this Redline version, a vertical line in the margin shows where the technical content is modified by amendment 1. Additions and deletions are displayed in red, with deletions being struck through. A separate Final version with all changes accepted is available in this publication.**

**This publication has been prepared for user convenience.**



International Standard IEC 62366 has been prepared by a joint working group of subcommittee 62A: Common aspects of electrical medical equipment used in medical practice, of IEC technical committee 62: Electrical medical equipment in medical practice and technical committee ISO/TC 210: Quality management and corresponding general aspects for medical devices.

It is published as double logo standard.

This publication has been drafted in accordance with the ISO/IEC Directives, Part 2.

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Clause and subclauses for which a rationale is provided in informative Annex A are marked with an asterisk (\*).

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## INTRODUCTION

Medical practice is increasingly using MEDICAL DEVICES for observation and treatment of PATIENTS. USE ERRORS caused by inadequate MEDICAL DEVICE USABILITY have become an increasing cause for concern. Many of the MEDICAL DEVICES developed without applying a USABILITY ENGINEERING PROCESS are non-intuitive, difficult to learn and to use. As healthcare evolves, less skilled USERS including PATIENTS themselves are now using MEDICAL DEVICES and MEDICAL DEVICES are becoming more complicated. In simpler times, the USER of a MEDICAL DEVICE might be able to cope with an ambiguous, difficult-to-use USER INTERFACE. The design of a usable MEDICAL DEVICE is a challenging endeavour, yet many organizations treat it as if it were just “common sense”. The design of the USER INTERFACE to achieve adequate (safe) USABILITY requires a very different skill set than that of the technical implementation of that interface.

The USABILITY ENGINEERING PROCESS is intended to achieve reasonable USABILITY, which in turn is intended to minimise USE ERRORS and to minimise use-associated RISKS. Some, but not all, forms of incorrect use are amenable to control by the MANUFACTURER. The USABILITY ENGINEERING PROCESS is related to the RISK MANAGEMENT PROCESS as indicated in Figure A.1.

This International Standard describes a USABILITY ENGINEERING PROCESS, and provides guidance on how to implement and execute the PROCESS to provide SAFETY in MEDICAL DEVICES. It is intended to be useful not only for MANUFACTURERS of MEDICAL DEVICES, but also for technical committees responsible for the preparation of particular MEDICAL DEVICE standards.

Amendment 1 updates the standard to add urgently needed requirements to deal with legacy devices where the USER INTERFACE design is of unknown provenance.

## INTRODUCTION TO THE AMENDMENT

The first edition of IEC 62366 was published in 2007. This amendment is intended to add urgently needed requirements to deal with legacy devices for which the user interface design is of unknown provenance. Work is continuing in parallel to develop the second edition of IEC 62366.