IEC 62366

Edition 1.0 2014-01

INTERNATIONAL STANDARD

NORME INTERNATIONALE

AMENDMENT 1
AMENDEMENT 1

Medical devices – Application of usability engineering to medical devices

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

IEC 62366:2007-10/AMD1:2014-01(EN-FR)

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FOREWORD

This amendment 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.

The text of this amendment is based on the following documents:

FDIS	Report on voting
62A/889/FDIS	62A/897/RVD

Full information on the voting for the approval of this amendment can be found in the report on voting indicated in the above table. In ISO, the standard has been approved by 23 P-members out of 23 having cast a vote.

The committee has decided that the contents of this amendment and the base publication will remain unchanged until the stability date indicated on the IEC web site under "http://webstore.iec.ch" in the data related to the specific publication. At this date, the publication will be

- reconfirmed,
- withdrawn,
- replaced by a revised edition, or
- amended.

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.

FOREWORD

Add the following note at the end of the Foreword:

NOTE The attention of National Committees is drawn to the fact that equipment manufacturers and testing organizations may need a transitional period following publication of a new, amended or revised IEC or ISO publication in which to make products in accordance with the new requirements and to equip themselves for conducting new or revised tests. It is the recommendation of the committee that the content of this publication be adopted for mandatory implementation nationally not earlier than 3 years from the date of publication.

INTRODUCTION

Add after the last paragraph of the introduction the following paragraph:

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

2 Normative references

In the existing introductory paragraph, replace the first sentence with:

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application.

3 Terms and definitions

Add the following new definition:

3.27
USER INTERFACE OF UNKNOWN PROVENANCE
UOUP
USER INTERFACE or part of a USER INTERFACE of a MEDICAL DEVICE previously developed for which adequate RECORDS of the USABILITY ENGINEERING PROCESS of this standard are not available

5 USABILITY ENGINEERING PROCESS

Add the following new subclause:

5.10 * USER INTERFACE OF UNKNOWN PROVENANCE (UOUP)

Instead of all of the requirements of 5.1 through 5.9, UOUP may be evaluated according to Annex K.

Compliance is checked by application of Annex K.

Annex A – General guidance and rationale

A.2 Rationale for requirements in particular clauses and subclauses

Add, after the existing paragraph of the rationale for Clause 7, the following new rationale.

Subclause K.2.1 – Application specification

The application specification is the essential source used to identify the most important characteristics related to the use of a MEDICAL DEVICE. When evaluating a USER INTERFACE including UOUP, the ACCOMPANYING DOCUMENTS can provide a valuable source for retrospectively establishing the application specification.

Furthermore, the application specification needs to be consistent with the ACCOMPANYING DOCUMENTS. Therefore it is best practice to carefully review the ACCOMPANYING DOCUMENTS. Elements of the application specification which cannot be derived (determined) from the ACCOMPANYING DOCUMENTS need to be established using other sources.

Subclause K.2.3 – Review of post-production information

Available post-production information is reviewed to identify known problems with the MEDICAL DEVICE with UOUP that might have been caused by USABILITY problems in the USER INTERFACE.

Because the post-production information can be incomplete (e.g., due to under-reporting of adverse events and customer complaints) and the root cause of the problem can be difficult to identify, the MANUFACTURER should analyse the SEVERITY of the potential HARM associated with the identified problem rather than the number of event reports, customer complaints or product recalls.

Add, immediately following existing Annex J, the following new annex: