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- withdrawn,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:

Annex K
(normative)

Evaluation of a USER INTERFACE OF UNKNOWN PROVENANCE (UOUP)

K.1 General

Annex K was created in recognition of the fact that many MANUFACTURERS will be interested in applying the tools defined in this standard to USER INTERFACES or parts of USER INTERFACES that have already been commercialized prior to the publication of this standard. Such USER INTERFACES or parts of USER INTERFACES were not developed using the PROCESSES of IEC 62366 and as a result are of unknown provenance with respect to these PROCESSES. Since this standard focuses on USABILITY ENGINEERING as part of the product development PROCESS, it was determined that an appropriately scaled (as described in subclause 4.3 of this standard) and alternative PROCESS should be developed to cover these USER INTERFACES or parts of USER INTERFACES of unknown provenance.

The following represents such a PROCESS that relies, wherever possible, on existing documentation created during the development of a legacy USER INTERFACE or part of a USER INTERFACE. It also attempts to allow the PROCESS to be applied utilizing organizational resources as efficiently as possible. When completed, it will result in the creation of a USABILITY ENGINEERING FILE and assure that the RISK MANAGEMENT FILE identifies RISKS caused by USABILITY problems of the USER INTERFACE.

The PROCESS of this annex can be applied to UOUP for a USER INTERFACE or part of a USER INTERFACE for which adequate records of the development using the USABILITY ENGINEERING PROCESS of IEC 62366:2007 are not available. However, if any modifications are made to the USER INTERFACE or its parts, only the unchanged parts of the USER INTERFACE remain UOUP and the changed parts of the USER INTERFACE are subject to 5.1 to 5.9.

EXAMPLE 1 For an unchanged legacy USER INTERFACE that was designed and developed prior to the publication of IEC 62366:2007, the USER INTERFACE is evaluated using this annex for determining conformance to this standard.

EXAMPLE 2 A USER INTERFACE, without adequate records of development to IEC 62366:2007, is subsequently modified. The modified parts are evaluated using 5.1 to 5.9 for determining conformance to this standard. The unmodified parts of the USER INTERFACE are evaluated using this annex for determining conformance to this standard.

EXAMPLE 3 A USER INTERFACE that was designed and developed prior to the publication of IEC 62366:2007 is subsequently modified by adding a new software feature. The USER INTERFACE of the added software feature and all parts of the USER INTERFACE that are affected by the added software feature are evaluated using 5.1 to 5.9 for determining conformance to this standard. The unmodified parts of the original USER INTERFACE are evaluated using this annex for determining conformance to this standard.

EXAMPLE 4 An existing USER INTERFACE is changed to rely on a general purpose component for which no adequate records of the development using IEC 62366:2007 exist. Changes to the existing USER INTERFACE are needed to integrate the general purpose component into the MEDICAL DEVICE. The necessary changes of the USER INTERFACE caused by integrating the general purpose component are evaluated using 5.1 to 5.9 for determining conformance to this standard. The unmodified parts of the original USER INTERFACE are evaluated using this annex for determining conformance to this standard.

K.2 USABILITY ENGINEERING PROCESS for USER INTERFACE OF UNKNOWN PROVENANCE

K.2.1 * Application specification

The MANUFACTURER shall establish an application specification as required in 5.1. The MANUFACTURER shall record this application specification in the USABILITY ENGINEERING FILE.

Compliance is checked by inspection of the USABILITY ENGINEERING FILE.

K.2.2 PRIMARY OPERATING FUNCTIONS

The MANUFACTURER shall identify and record the PRIMARY OPERATING FUNCTIONS of the MEDICAL DEVICE with UOUP as required by 5.4.

Compliance is checked by inspection of the USABILITY ENGINEERING FILE.

K.2.3 * Review of post-production information

The MANUFACTURER of the MEDICAL DEVICE with UOUP shall review available post-production information including complaints and field reports for incidents or near incidents and including complaints associated with the use of the PRIMARY OPERATING FUNCTIONS.

All identified cases of USE ERROR that could result in a HAZARDOUS SITUATION or those cases where field information suggests HAZARDS or HAZARDOUS SITUATIONS that could have been caused by inadequate USABILITY shall be recorded in the USABILITY ENGINEERING FILE and addressed in K.2.4 and K.2.5.

Compliance is checked by inspection of the USABILITY ENGINEERING FILE.

K.2.4 HAZARDS AND HAZARDOUS SITUATIONS caused by USABILITY problems

The MANUFACTURER shall review the RISK ANALYSIS of the MEDICAL DEVICE with UOUP and ensure that the HAZARDS and HAZARDOUS SITUATIONS associated with USABILITY or with PRIMARY OPERATING FUNCTIONS have been identified and documented.

Compliance is checked by inspection of the USABILITY ENGINEERING FILE.

K.2.5 RISK CONTROL

The MANUFACTURER shall verify and document that adequate RISK CONTROL measures have been implemented for all identified HAZARDS and HAZARDOUS SITUATIONS identified in K.2.4 and that all RISKS are reduced to an acceptable level as indicated by the RISK ASSESSMENT.

If the MANUFACTURER determines that changes to any part of the USER INTERFACE are required to reduce RISK to an acceptable level, those changes shall not be considered UOUP and shall be subject to the requirements of 5.1 through 5.9.

Compliance is checked by inspection of the USABILITY ENGINEERING FILE.

K.2.6 RESIDUAL RISK evaluation

Based on any new information identified in performing steps K.2.4 and K.2.5, the MANUFACTURER shall re-evaluate the overall RESIDUAL RISK according to ISO 14971:2007, 6.4, and document the result in either the USABILITY ENGINEERING FILE or the RISK MANAGEMENT FILE.

Compliance is checked by inspection of the USABILITY ENGINEERING FILE or the RISK MANAGEMENT FILE.

K.2.7 ACCOMPANYING DOCUMENT

If the MANUFACTURER determines while establishing the application specification in K.2.1 that the ACCOMPANYING DOCUMENT of the MEDICAL DEVICE with UOUP does not contain an adequate summary of the application specification, the ACCOMPANYING DOCUMENT shall be updated to include that information.

Compliance is checked, where appropriate, by inspection of the ACCOMPANYING DOCUMENT.

Index of defined terms

Insert, following the term USER INTERFACE, the following defined term.

AVANT-PROPOS

Le présent amendement a été établi par un groupe de travail joint du sous-comité 62A: Aspects généraux des équipements électriques utilisés en pratique médicale, du comité d'études 62 de la CEI: Equipements électriques dans la pratique médicale, et du comité technique ISO/TC 210: Management de la qualité et aspects généraux correspondants des dispositifs médicaux.

Le texte de cet amendement est issu des documents suivants:

FDIS	Rapport de vote
62A/889/FDIS	62A/897/RVD

Le rapport de vote indiqué dans le tableau ci-dessus donne toute information sur le vote ayant abouti à l'approbation de cet amendement. A l'ISO, la norme a été approuvée par 23 membres P sur 23 ayant voté.

Le comité a décidé que le contenu de cet amendement et de la publication de base ne sera pas modifié avant la date de stabilité indiquée sur le site web de la CEI sous "http://webstore.iec.ch" dans les données relatives à la publication recherchée. A cette date, la publication sera

- reconduite,
- supprimée,
- remplacée par une édition révisée, ou
- amendée.

INTRODUCTION À L'AMENDEMENT

La première édition de la CEI 62366 a été publiée en 2007. Le présent amendement est destiné à ajouter des exigences indispensables traitant des dispositifs existants pour lesquels la conception de l'interface utilisateur est de provenance inconnue. Des travaux continuent en parallèle en vue d'élaborer la deuxième édition de la CEI 62366.

AVANT-PROPOS

Ajouter la note suivante à la fin de l'avant-propos:

NOTE L'attention des Comités Nationaux est attirée sur le fait que les fabricants d'appareils et les organismes d'essai peuvent avoir besoin d'une période transitoire après la publication d'une nouvelle publication CEI ou ISO, ou d'une publication amendée ou révisée, pour fabriquer des produits conformes aux nouvelles exigences et pour adapter leurs équipements aux nouveaux essais ou aux essais révisés Le comité recommande que le contenu de cette publication soit entériné au niveau national au plus tôt 3 ans après la date de publication.

INTRODUCTION

Ajouter, après le dernier alinéa de l'introduction, le nouvel alinéa suivant: