SLOVENSKI STANDARD
SIST EN 62366:2008/A1:2015

01-september-2015

Medicinske naprave – Izvedba tehnik uporabe pri medicinskih napravah - Dopolnilo A1

Medical devices - Application of usability engineering to medical devices

Medizinprodukte - Anwendung der Gebrauchstauglichkeit auf Medizinprodukte

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

Ta slovenski standard je istoveten z: **EN 62366:2008/A1:2015**

ICS:

11.040.01	Medicinska oprema na splošno	Medical equipment in general

SIST EN 62366:2008/A1:2015 **en**

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN 62366:2008/A1

May 2015

ICS 11.040

English Version

Medical devices - Application of usability engineering to medical devices (IEC 62366:2007/A1:2014)

Dispositifs médicaux - Application de l'ingénierie de l'aptitude à l'utilisation aux dispositifs médicaux (IEC 62366:2007/A1:2014)

Medizinprodukte - Anwendung der Gebrauchstauglichkeit auf Medizinprodukte (IEC 62366:2007/A1:2014)

This amendment A1 modifies the European Standard EN 62366:2008; it was approved by CENELEC on 2015-04-14. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this amendment the status of a national standard without any alteration.

Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CENELEC member.

This amendment exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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CENELEC

European Committee for Electrotechnical Standardization
Comité Européen de Normalisation Electrotechnique
Europäisches Komitee für Elektrotechnische Normung

CEN-CENELEC Management Centre: Avenue Marnix 17, B-1000 Brussels

Ref. No. EN 62366:2008/A1:2015 E

Foreword

The text of document 62A/889/FDIS, future IEC 62366:2007/A1, prepared by SC 62A "Common aspects of electrical equipment used in medical practice" of IEC/TC 62 "Electrical equipment in medical practice" and ISO/TC 210 "Quality management and corresponding general aspects for medical devices" was submitted to the IEC-CENELEC parallel vote and approved by CENELEC as EN 62366:2008/A1:2015.

The following dates are fixed:

• latest date by which the document has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	2016-01-14
• latest date by which the national standards conflicting with the document have to be withdrawn	(dow)	2018-04-14

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CENELEC [and/or CEN] shall not be held responsible for identifying any or all such patent rights.

This document has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association, and supports essential requirements of EU Directive.

For the relationship with EU Directive 93/42/EEC, see informative Annex ZZ, included in EN 62366:2008.

This standard covers the Principle Elements of the Safety Objectives for Electrical Equipment Designed for Use within Certain Voltage Limits (LVD - 2006/95/EC).

Endorsement notice

The text of the International Standard IEC 62366:2007/A1:2014 was approved by CENELEC as a European Standard without any modification.

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

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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.