ICS 11.040.01 SLOVENSKÁ TECHNICKÁ NORMA December 2015

STN	**Zdravotnícke pomôcky. Uplatnenie stanovenia použiteľnosti na zdravotnícke pomôcky. Zmena A1**	**STN EN 62366/A1** 36 4894

Medical devices.Application of usability engineering to medical devices

Táto norma obsahuje anglickú verziu európskej normy.
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 11/15

STN EN 62366 z mája 2010 sa bez zmeny A1 môže používať do 14. 04. 2018.

Obsahuje: EN 62366:2008/A1:2015, IEC 62366:2007/A1:2014

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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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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

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

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

IEC 62366

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INTERNATIONAL STANDARD

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AMENDMENT 1
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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

INTERNATIONAL
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ICS 11.040

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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.