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Medicintekniska produkter – Tillämpning av metoder för att säkerställa medicintekniska produkters användarvänlighet

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

Som svensk standard gäller europastandarden EN 62366:2008. Den svenska standarden innehåller den officiella engelska språkversionen av EN 62366:2008.

Nationellt förord

Europastandarden EN 62366:2008

består av:

- **europastandardens ikraftsättningsdokument**, utarbetat inom CENELEC
- **IEC 62366, First edition, 2007 - Medical devices - Application of usability engineering to medical devices**

utarbetad inom International Electrotechnical Commission, IEC.

ICS 11.040

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**Medical devices -
Application of usability engineering to medical devices
(IEC 62366:2007)**

Dispositifs médicaux -
Application de l'ingénierie de l'aptitude
à l'utilisation aux dispositifs médicaux
(CEI 62366:2007)

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

This European Standard was approved by CENELEC on 2007-12-01. CENELEC members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard 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 Central Secretariat or to any CENELEC member.

This European Standard 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 Central Secretariat has the same status as the official versions.

CENELEC members are the national electrotechnical committees of Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

CENELEC

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

Central Secretariat: rue de Stassart 35, B - 1050 Brussels

Foreword

The text of document 62A/574/FDIS, future edition 1 of IEC 62366, prepared by a joint working group of subcommittee 62A: Common aspects of electrical medical 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 was approved by CENELEC as EN 62366 on 2007-12-01.

The following dates were fixed:

- latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement (dop) 2008-09-01
- latest date by which the national standards conflicting with the EN have to be withdrawn (dow) 2010-12-01

This European Standard has been prepared under a mandate given to CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directives MDD (93/42/EEC) and IVD (98/79/EC). See Annex ZZ.

In this standard, the following print types are used:

- Requirements and definitions: roman type.
- *Means to assess compliance: italic type.*
- Informative material appearing outside of tables, such as notes, examples and references: in smaller type. Normative text of tables is also in a smaller type
- TERMS DEFINED IN CLAUSE 3 OR AS NOTED: SMALL CAPITALS.

Annexes ZA and ZZ have been added by CENELEC.

Endorsement notice

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

In the official version, for Bibliography, the following notes have to be added for the standards indicated:

IEC 60601-1	NOTE Harmonized as EN 60601-1:2006 (not modified).
IEC 60601-1-8	NOTE Harmonized as EN 60601-1-8:2007 (not modified).
ISO 9000	NOTE Harmonized as EN ISO 9000:2005 (not modified).
ISO 9001	NOTE Harmonized as EN ISO 9001:2000 (not modified).
ISO 9241-11	NOTE Harmonized as EN ISO 9241-11:1998 (not modified).
ISO 13485	NOTE Harmonized as EN ISO 13485:2003 (not modified).

Annex ZA
(normative)

**Normative references to international publications
with their corresponding European publications**

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE When an international publication has been modified by common modifications, indicated by (mod), the relevant EN/HD applies.

<u>Publication</u>	<u>Year</u>	<u>Title</u>	<u>EN/HD</u>	<u>Year</u>
ISO 14971	2007	Medical devices - Application of risk management to medical devices	EN ISO 14971	2007



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MEDICAL DEVICES – APPLICATION OF USABILITY ENGINEERING TO MEDICAL DEVICES

1 * Scope

This International Standard specifies a PROCESS for a MANUFACTURER to analyse, specify, design, VERIFY and VALIDATE USABILITY, as it relates to SAFETY of a MEDICAL DEVICE. This USABILITY ENGINEERING PROCESS assesses and mitigates RISKS caused by USABILITY problems associated with CORRECT USE and USE ERRORS, i.e. NORMAL USE. It can be used to identify but does not assess or mitigate RISKS associated with ABNORMAL USE.

NOTE For the purposes of this standard, USABILITY (see 3.17) is limited to characteristics of the USER INTERFACE.

If the USABILITY ENGINEERING PROCESS detailed in this International Standard has been complied with and the acceptance criteria documented in the USABILITY VALIDATION plan have been met (see 5.9), then the RESIDUAL RISKS, as defined in ISO 14971, associated with USABILITY of a MEDICAL DEVICE are presumed to be acceptable, unless there is OBJECTIVE EVIDENCE to the contrary (see 4.1.2).

This International Standard does not apply to clinical decision-making relating to the use of a MEDICAL DEVICE.

2 Normative references

The following referenced documents are indispensable for the application of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

NOTE Informative references are listed in the bibliography beginning on page 96.

ISO 14971:2007, *Medical devices – Application of risk management to medical devices*

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