

**KINGDOM OF SAUDI ARABIA  
SAUDI STANDARDS, METROLOGY AND QUALITY ORGANIZATION**

**SASO**

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**SAUDI STANDARD**

**DRAFT No19982 /2011**

**MEDICAL ELECTRICAL EQUIPMENT –**

**Part 1-6: General requirements for basic safety  
and essential performance –  
Collateral standard: Usability**

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**SAUDI STANDARDS, METROLOGY AND QUALITY ORGANIZATION**

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**INTRODUCTION**

The Saudi Standards ,Metrology and Quality Organization (SASO) has adopted the International Standard IEC 60601-1-6 /2010 “MEDICAL ELECTRICAL EQUIPMENT – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability” issued by the International Electro technical Commission (IEC). It has been adopted without any technical modifications with a view to its approval as a Saudi standard.

**MEDICAL ELECTRICAL EQUIPMENT –****Part 1-6: General requirements for basic safety  
and essential performance –  
Collateral standard: Usability****1 Scope, object and related standards****1.1 \* Scope**

This International Standard specifies a PROCESS for a MANUFACTURER to analyse, specify, design, VERIFY and VALIDATE USABILITY, as it relates to BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL ELECTRICAL EQUIPMENT, hereafter referred to as ME EQUIPMENT.

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.

If the USABILITY ENGINEERING PROCESS detailed in this collateral standard has been complied with and the acceptance criteria documented in the USABILITY VALIDATION plan have been met (see 5.9 of IEC 62366:2007), then the RESIDUAL RISKS, as defined in ISO 14971, associated with USABILITY of ME EQUIPMENT are presumed to be acceptable, unless there is OBJECTIVE EVIDENCE to the contrary (see 4.1.2 of IEC 62366:2007).

**1.2 Object**

The object of this collateral standard is to specify general requirements that are in addition to those of the general standard and to serve as the basis for particular standards.

**1.3 Related standards****1.3.1 IEC 60601-1**

For ME EQUIPMENT, this collateral standard complements IEC 60601-1.

When referring to IEC 60601-1 or to this collateral standard, either individually or in combination, the following conventions are used:

- "the general standard" designates IEC 60601-1 alone;
- "this collateral standard" designates IEC 60601-1-6 alone;
- "this standard" designates the combination of the general standard and this collateral standard.

**1.3.2 Particular standards**

A requirement in a particular standard takes priority over the corresponding requirement in this collateral standard.

**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 The way in which these referenced documents are cited determines the extent (in whole or in part) to which they apply.

IEC 60601-1:2005, *Medical electrical equipment – Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-8:2006, *Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*

IEC 62366:2007, *Medical devices – Application of usability engineering to medical devices*

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

### 3 Terms and definitions

For the purposes of this document, the terms and definitions given in IEC 60601-1:2005, IEC 60601-1-8:2006, IEC 62366:2007 and the following definitions apply.

NOTE An index of defined terms used with this collateral standard is found beginning on page 23.

#### 3.1

##### \* OPERATOR-EQUIPMENT INTERFACE

means by which the OPERATOR and the ME EQUIPMENT communicate

[ANSI/AAMI HE 74:2001, definition 3.24 modified]

NOTE The ACCOMPANYING DOCUMENTS are considered part of the ME EQUIPMENT and the OPERATOR-EQUIPMENT INTERFACE.

#### 3.2

##### OPERATOR PROFILE

summary of the mental, physical and demographic traits of the intended OPERATOR population, as well as any special characteristics that can have a bearing on design decisions, such as occupational skills and job requirements

### 4 General requirements

#### 4.1 \* Conditions for application to ME EQUIPMENT

The ME EQUIPMENT shall provide adequate USABILITY such that the RISKS resulting from NORMAL USE and USE ERROR are acceptable. See also 7.1.1 and 12.2 of the general standard.

*Compliance with this subclause is considered to exist when compliance with 4.2 and other clauses and subclauses of this collateral standard is demonstrated.*

#### 4.2 \* USABILITY ENGINEERING PROCESS FOR ME EQUIPMENT

A USABILITY ENGINEERING PROCESS complying with IEC 62366 shall be performed.

In applying IEC 62366, the terms in this collateral standard and those in IEC 60601-1:2005 shall be used as follows:

- The term “MEDICAL DEVICE” shall assume the same meaning as ME EQUIPMENT.
- The term “USER” shall assume the same meaning as OPERATOR.
- The term “PATIENT” shall include animals.

- The term "SAFETY" shall assume the same meaning as BASIC SAFETY and ESSENTIAL PERFORMANCE.
- The term "USER INTERFACE" shall assume the same meaning as OPERATOR-EQUIPMENT INTERFACE.
- The term "USER PROFILE" shall assume the same meaning as OPERATOR PROFILE.

*Compliance is checked by inspection of the USABILITY ENGINEERING FILE. Evidence of compliance with this clause and all requirements of this standard referring to inspection of the USABILITY ENGINEERING FILE are satisfied if the MANUFACTURER has:*

- *established a USABILITY ENGINEERING PROCESS;*
- *established acceptance criteria for USABILITY; and*  
*demonstrated that the acceptance criteria for USABILITY have been met.*

#### **4.3 \* REPLACEMENT OF REQUIREMENTS GIVEN IN IEC 62366**

In addition to requirements of IEC 62366 the following replacements shall apply:

*Replace the first two paragraphs including NOTES 1 and 2 of Clause 6 of IEC 62366:2007 by:*

The instructions for use shall include a brief description of the ME EQUIPMENT, its physical operating principles and significant physical and performance characteristics relevant to its USABILITY. The same information shall also be included in the technical description, if this is provided as a separate document.

NOTE An important purpose of this description is to help the OPERATOR to develop a correct mental model of the ME EQUIPMENT.

The instructions for use shall contain a summary of the application specification.

## **Annex A** (informative)

### **General guidance and rationale**

#### **A.1 General guidance**

This annex provides a concise rationale for the important requirements of this collateral standard. Its purpose is to promote effective application of the collateral standard by explaining the reasons for the requirements and provide additional guidance where appropriate.

#### **A.2 Rationale for particular clauses and subclauses**

The following are rationales for specific clauses and subclauses in this collateral standard, with clause and subclause numbers parallel to those in the body of the document.

##### **Subclause 1.1 – Scope**

This collateral standard focuses on the USABILITY of the OPERATOR-EQUIPMENT INTERFACE of ME EQUIPMENT. USABILITY, in general, includes attributes such as OPERATOR satisfaction and EFFICIENCY. These attributes might be related to the BASIC SAFETY or ESSENTIAL PERFORMANCE of the ME EQUIPMENT. A degradation of these attributes can increase the probability of USE ERROR. Examples of attributes that are not considered could include the aesthetics of the ME EQUIPMENT or the amount of supplies consumed.

##### **Definition 3.1 – OPERATOR-EQUIPMENT INTERFACE**

The OPERATOR-EQUIPMENT INTERFACE includes all means of communication between the ME EQUIPMENT to the OPERATOR and the OPERATOR to the ME EQUIPMENT. These means include, but are not limited to:

- markings and ACCOMPANYING DOCUMENTS;
- lights;
- video displays;
- push buttons;
- touch screens;
- auditory and visual INFORMATION SIGNALS;
- ALARM SIGNALS;
- vibratory signals;
- keyboard and mouse; and
- haptic controls.

##### **Subclause 4.1 – Conditions for application to ME EQUIPMENT**

This collateral standard specifies requirements addressing particular RISKS associated with USABILITY. When these requirements are complied with, the RESIDUAL RISKS associated with USABILITY are presumed to be acceptable unless there is OBJECTIVE EVIDENCE to the contrary. This follows from 4.2 of the general standard, which states “Where this standard or any of its collateral or particular standards specify verifiable requirements addressing particular RISKS, and these requirements are complied with, the RESIDUAL RISKS addressed by these

requirements shall be presumed to be acceptable unless there is OBJECTIVE EVIDENCE to the contrary.”

The criteria for judging RISK acceptability are established by the USABILITY VALIDATION plan, which specifies the criteria for determining successful VALIDATION of the USABILITY of the PRIMARY OPERATING FUNCTIONS.

#### **Subclause 4.2 – USABILITY ENGINEERING PROCESS for ME EQUIPMENT**

The first edition of this collateral standard was published in 2004, and introduced a USABILITY ENGINEERING PROCESS tailored to ME EQUIPMENT. The second edition was published in 2006 and was intended to align the collateral standard with the third edition of IEC 60601-1 — principally the inclusion in IEC 60601-1:2005 of the requirement to conduct a RISK MANAGEMENT PROCESS following ISO 14971. The USABILITY ENGINEERING PROCESS described in the second edition of IEC 60601-1-6 was little altered from that in the first edition.

Shortly after the publication of the 2004 edition of IEC 60601-1-6, IEC Subcommittee 62A formed a joint project with ISO Technical Committee 210 to develop a general USABILITY ENGINEERING PROCESS standard applicable to all MEDICAL DEVICES as defined in the ISO quality system standard, ISO 13485:2003. This project was similar in scope to the effort that took the RISK MANAGEMENT PROCESS described in IEC 60601-1-4 and generalized it to produce ISO 14971. The result of the joint IEC/SC 62A – ISO/TC 210 USABILITY standard project was IEC 62366:2007.

While the USABILITY ENGINEERING PROCESS described in IEC 62366 is more mature and refined than the PROCESS in the second edition of IEC 60601-1-6, it is fundamentally the same PROCESS involving the same elements.

As with the RISK MANAGEMENT PROCESS before it, the existence of a generalized standard for USABILITY ENGINEERING eliminates the need for much, but not all, of the content in the second edition of IEC 60601-1-6. For example, IEC 62366 defines the USER as the “person using, i.e. operating or handling, the MEDICAL DEVICE”. This definition includes those who clean, maintain or install the MEDICAL DEVICE. In IEC 60601-1:2005, persons performing those functions are described as SERVICE PERSONNEL. This subclause bridges between the general PROCESS requirement in IEC 62366 and the specific application to ME EQUIPMENT.

#### **Clause 4.3 – Replacement of requirements given in IEC 62366**

Clause 6 of IEC 62366:2007 specifies the general requirements for the material to be included in the ACCOMPANYING DOCUMENT, if such a document is provided. The ACCOMPANYING DOCUMENT is required to include a summary of the application specification (see 5.1 of IEC 62366). This replacement paragraph clarifies that for ME EQUIPMENT the summary is described in the same terms used in subclause 7.9.2.5 of IEC 60601-1:2005 to specify the ME EQUIPMENT description.

In IEC 60601-1, the ACCOMPANYING DOCUMENTS consist of the instructions for use and the technical description. IEC 62366, on the other hand, discusses the ACCOMPANYING DOCUMENT without specifically identifying any sub-parts. IEC 60601-1 anticipates that the instructions for use and the technical description can be provided as separate physical documents. If they are, then the summary of the application specification is required to appear in both documents.

**Annex B**  
(informative)

**Mapping between the elements of IEC 60601-1-6:2006 and  
the related elements in IEC 62366:2007**

This annex contains a mapping of the clauses and subclause of IEC 60601-1-6:2006 to the comparable clauses and subclauses in IEC 62366:2007. Table B.1 is intended to provide a tool to assist users of IEC 60601-1-6:2006 to trace requirements between that edition and their equivalent requirements in IEC 62366:2007.

**Table B.1 – Mapping between the elements of IEC 60601-1-6:2006  
and the related elements in IEC 62366:2007**

IEC 60601-1-6:2006		Related elements in IEC 62366:2007	
Clause	Title	Clause	Title
1	Scope, object and related standards	1	Scope NOTE IEC 62366:2007 applies to MEDICAL DEVICES as defined in 3.11. That definition is identical to that in ISO 13485:2003.
2	Normative references	2	Normative references
3	Terms and definitions	3	Terms and definitions
3.1	ABNORMAL USE	3.1	ABNORMAL USE
IEC 60601-1: 2005, 3.4	ACCOMPANYING DOCUMENT	3.2	ACCOMPANYING DOCUMENT
IEC 60601-1-8: 2006, 3.3	ALARM LIMIT	3.3	ALARM LIMIT
IEC 60601-1-8: 2006, 3.4	ALARM OFF	3.4	ALARM OFF
IEC 60601-1-8: 2006, 3.9	ALARM SIGNAL	3.5	ALARM SIGNAL
IEC 60601-1-8: 2006, 3.11	ALARM SYSTEM	3.6	ALARM SYSTEM
IEC 60601-1: 2005, 3.10	BASIC SAFETY	ISO 14971: 2007, 2.24	SAFETY NOTE SAFETY is used as defined term in IEC 62366.
IEC 60601-1: 2005, 3.27	ESSENTIAL PERFORMANCE		
		3.7	CORRECT USE NOTE This is a new term in IEC 62366, and is defined as "NORMAL USE without USE ERROR."
3.2	EFFECTIVENESS	3.8	EFFECTIVENESS
3.3	EFFICIENCY	3.9	EFFICIENCY
IEC 60601-1: 2005, 3.37	HAND-HELD		NOTE Not a defined term in IEC 62366.
IEC 60601-1: 2005, 3.38	HARM	ISO 14971: 2007, 2.2	HARM
IEC 60601-1: 2005, 3.39	HAZARD	ISO 14971: 2007, 2.3	HAZARD
IEC 60601-1: 2005, 3.40	HAZARDOUS SITUATION	ISO 14971: 2007, 2.4	HAZARDOUS SITUATION

Table B.1 (continued)

IEC 60601-1-6:2006		Related elements in IEC 62366:2007	
Clause	Title	Clause	Title
IEC 60601-1-8:2006, 3.23	INFORMATION SIGNAL	3.10	INFORMATION SIGNAL
IEC 60601-1:2005, 3.44	INTENDED USE	ISO 14971:2007, 2.5	INTENDED USE
IEC 60601-1:2005, 3.55	MANUFACTURER	ISO 14971:2007, 2.8	MANUFACTURER
IEC 60601-1:2005, 3.63	MEDICAL ELECTRICAL EQUIPMENT	3.11	MEDICAL DEVICE
IEC 60601-1:2005, 3.71	NORMAL USE	3.12	NORMAL USE NOTE The phrase, "or in accordance with generally accepted practice for those MEDICAL DEVICES provided without instructions for use" has been added to deal with MEDICAL DEVICES, such as simple surgical instruments, that are not accompanied by instructions for use.
IEC 60601-1:2005, 3.72	OBJECTIVE EVIDENCE	ISO 14971:2007, 2.10	OBJECTIVE EVIDENCE
IEC 60601-1:2005, 3.73	OPERATOR	3.23	USER NOTE In IEC 62366, the USER includes but is not limited to cleaners, maintainers and installers. In IEC 60601-1:2005, individuals who install, assemble, maintain or repair ME EQUIPMENT are described as "SERVICE PERSONNEL."
3.4	OPERATOR-EQUIPMENT INTERFACE	3.24	USER INTERFACE NOTE The word "communicate" was replaced by "interact".
3.5	OPERATOR PROFILE	3.25	USER PROFILE
IEC 60601-1:2005, 3.76	PATIENT	3.13	PATIENT NOTE "Animal" has been deleted from the IEC 60601-1 definition.
3.6	PRIMARY OPERATING FUNCTION	3.14	PRIMARY OPERATING FUNCTION
IEC 60601-1:2005, 3.89	PROCESS	ISO 14971:2007, 2.13	PROCESS
3.7	REASONABLY FORESEEABLE MISUSE		NOTE Not a defined term in IEC 62366.
IEC 60601-1-8:2006, 3.34	REMINDER SIGNAL	3.15	REMINDER SIGNAL
IEC 60601-1:2005, 3.100	RESIDUAL RISK	ISO 14971:2007, 2.15	RESIDUAL RISK
IEC 60601-1:2005, 3.101	RESPONSIBLE ORGANIZATION	3.16	RESPONSIBLE ORGANIZATION
IEC 60601-1:2005, 3.102	RISK	ISO 14971:2007, 2.16	RISK
IEC 60601-1:2005, 3.103	RISK ANALYSIS	ISO 14971:2007, 2.17	RISK ANALYSIS
IEC 60601-1:2005, 3.105	RISK CONTROL	ISO 14971:2007, 2.19	RISK CONTROL
IEC 60601-1:2005, 3.106	RISK EVALUATION	ISO 14971:2007, 2.21	RISK EVALUATION
IEC 60601-1:2005, 3.107	RISK MANAGEMENT	ISO 14971:2007, 2.22	RISK MANAGEMENT

Table B.1 (continued)

IEC 60601-1-6:2006		Related elements in IEC 62366:2007	
Clause	Title	Clause	Title
IEC 60601-1:2005, 3.108	RISK MANAGEMENT FILE	ISO 14971:2007, 2.23	RISK MANAGEMENT FILE
IEC 60601-1, 2005, 3.114	SEVERITY	ISO 14971:2007, 2.25	SEVERITY
3.8	TRAINING		NOTE Not a defined term in IEC 62366.
3.9	USE ERROR	3.21	USE ERROR
3.10	USE SCENARIO	3.22	USE SCENARIO NOTE The phrase "used to specify and test the USABILITY of the ME EQUIPMENT" is replaced by "as performed by a specified USER in a specified environment" to make the definition more general.
3.11	USABILITY	3.17	USABILITY NOTE 1 The phrase "of the USER INTERFACE" has been inserted into the definition.  NOTE 2 Impaired EFFICIENCY can also lead to USE ERRORS. The OPERATOR might be induced to take inappropriate short cuts if the ME EQUIPMENT does not meet their expectations.
3.12	USABILITY ENGINEERING	3.18	USABILITY ENGINEERING
3.13	USABILITY ENGINEERING FILE	3.19	USABILITY ENGINEERING FILE
3.14	USABILITY SPECIFICATION	3.20	USABILITY SPECIFICATION
3.15	VALIDATION	3.26	VALIDATION
IEC 60601-1:2005, 3.138	VERIFICATION	ISO 14971:2007, 2.28	VERIFICATION
4	General requirements	4	Principles
4.1	Conditions for application to ME EQUIPMENT	4.1.2	RESIDUAL RISK  This requirement is covered in 4.1 of this collateral standard as well as in 4.1.2 of IEC 62366.  NOTE This subclause in IEC 62366 mimics the statement in the fourth bullet of 4.2 of IEC 60601-1:2005 and closes the loop with respect to the acceptability of RESIDUAL RISKS associated with USABILITY when the process described in IEC 62366 has been complied with and the acceptance criteria document in the USABILITY VALIDATION plan have been met.

Table B.1 (continued)

IEC 60601-1-6:2006		Related elements in IEC 62366:2007	
Clause	Title	Clause	Title
4.2	RISK MANAGEMENT PROCESS for ME EQUIPMENT	5.3.1	<p>Identification of characteristics related to SAFETY</p> <p>NOTE In IEC 62366, the list of items to be considered in that part of the RISK ANALYSIS specified in ISO 14971:2007, 4.2 has been reduced to:</p> <ul style="list-style-type: none"> <li>– the application specification including the user profile(s); and</li> <li>– the frequently used functions.</li> </ul> <p>IEC 62366 explicitly requires the frequently used functions to be identified as an input to the RISK ANALYSIS. In IEC 60601-1-6:2006, this was implicit in the definition of PRIMARY OPERATING FUNCTION.</p>
		5.3.2	<p>Identification of known or foreseeable HAZARDS and HAZARDOUS SITUATIONS</p> <p>NOTE In IEC 62366, the list of items to be considered has been expanded from that in 4.2 of IEC 60601-1-6:2006. The list now includes:</p> <ul style="list-style-type: none"> <li>– preliminary USE SCENARIOS; and</li> <li>– if an incorrect mental model of the operation of the device can cause a USE ERROR resulting in a HAZARDOUS SITUATION.</li> </ul> <p>IEC 62366 requires that the SEVERITY of possible HARMS be recorded in USABILITY ENGINEERING FILE so that this information is available in case a RISK/benefit analysis is required in subclause 5.9 of IEC 62366:2007.</p>
5	ME EQUIPMENT identification, marking and documents		NOTE There is no equivalent heading in IEC 62366.
5.1	ACCOMPANYING DOCUMENTS	6	<p>ACCOMPANYING DOCUMENT</p> <p>NOTE IEC 62366 does not distinguish between the instructions for use and the technical description. It refers only to the ACCOMPANYING DOCUMENTS. This requirement to include a summary of the MEDICAL DEVICE application specification in the technical description, if this is provided as a separate document, is covered in Clause 4.3 of this collateral standard</p>
5.2	TRAINING and materials for TRAINING	7	<p>Training and materials for training</p> <p>NOTE The list of training options in IEC 62366 has been clarified to indicate that the MANUFACTURER is required to do at least one of the following:</p> <ul style="list-style-type: none"> <li>– provide the training materials;</li> <li>– ensure that the material are available; or</li> <li>– provide the training.</li> </ul> <p>In addition, IEC 62366 recommends that the ACCOMPANYING DOCUMENTS include the suggested duration and frequency of required training.</p>
6	USE ERROR and USABILITY		NOTE There is no equivalent heading in IEC 62366.

Table B.1 (continued)

IEC 60601-1-6:2006		Related elements in IEC 62366:2007	
Clause	Title	Clause	Title
6.1	Safety for the PATIENT, OPERATOR and other persons	4.1.1	USABILITY ENGINEERING PROCESS NOTE This subclause describes the requirement that a USABILITY ENGINEERING PROCESS be established to provide SAFETY for the PATIENT, USER and others related to USABILITY. IEC 62366 contains additional verbiage that states the PROCESS is to address USER interactions according to the ACCOMPANYING DOCUMENTS in situations ranging from transport and storage to final disposal.
6.2	USABILITY ENGINEERING PROCESS	5	USABILITY ENGINEERING PROCESS
6.2.1	General	4.2	USABILITY ENGINEERING FILE NOTE This subclause of IEC 62366 contains the requirements for the recording of results of the USABILITY ENGINEERING PROCESS in the USABILITY ENGINEERING FILE. The requirements are not substantially altered from those in the first paragraph of 6.2.1 of IEC 60601-1-6:2006.
		4.3	Scaling of the USABILITY ENGINEERING effort NOTE This subclause of IEC 62366 contains the permissive requirement that allow the USABILITY ENGINEERING PROCESS to be scaled-up or scaled-down based on the nature of the device or the significance of the modification. The requirement is not substantially altered from that in 6.2.1 of IEC 60601-1-6:2006.
6.2.2	Input for the USABILITY ENGINEERING PROCESS		NOTE There is no equivalent heading in IEC 62366.
6.2.2.1	ME EQUIPMENT application specification	5.1	Application specification NOTE The application specification now includes the device's operating principle. The operating principle is a description of the physical methods use to accomplish the INTENDED USE and the mechanisms by which it works. IEC 62366 speaks of the "intended medical indication" which IEC 60601-1-6:2006 describes as the "medical purpose."
X		5.2	Frequently used functions NOTE IEC 62366 contains a specific requirement to identify the frequently used functions that involve USER interaction. In IEC 60601-1-6:2006, this requirement is implicit in the definition of PRIMARY OPERATING FUNCTION.
6.2.2.2	PRIMARY OPERATING FUNCTIONS	5.4	PRIMARY OPERATING FUNCTIONS NOTE This subclause now explicitly identifies that the inputs to the PRIMARY OPERATING FUNCTIONS include the frequently used functions and those functions related to the SAFETY of the MEDICAL DEVICE.
6.2.2.3	Information for safety as a RISK CONTROL	4.1.3	Information for SAFETY NOTE The requirement to record the results of any RISK ANALYSIS is moved to 5.3.1 and 5.3.2.

Table B.1 (continued)

IEC 60601-1-6:2006		Related elements in IEC 62366:2007	
Clause	Title	Clause	Title
6.2.3	USABILITY SPECIFICATION	5.5	<p>USABILITY SPECIFICATION</p> <p>NOTE The description of the USABILITY SPECIFICATION has undergone substantial refinement. The USABILITY SPECIFICATION now includes:</p> <ul style="list-style-type: none"> <li>– testable requirements for USABILITY VERIFICATION; and</li> <li>– testable requirements for USABILITY of the PRIMARY OPERATING FUNCTIONS including criteria for determining the adequacy of the RISK CONTROL achieved by the USABILITY ENGINEERING PROCESS.</li> </ul> <p>A new informative annex (Annex G) has been added to provide guidance on how testable requirements, expressed as USABILITY goals, might be described.</p> <p>The inputs to the USABILITY SPECIFICATION focus on “known and foreseeable USE ERRORS” rather than describing them as “predictable USE ERRORS.”</p> <p>IEC 62366 does not require that all the USE SCENARIOS be described in the USABILITY SPECIFICATION. IEC 62366 only requires the frequent USE SCENARIOS and the reasonably foreseeable worst case USE SCENARIOS to be described.</p>
X		5.7	<p>USER INTERFACE design and implementation</p> <p>NOTE This is a new subclause in IEC 62366, and simply says that the USER INTERFACE described in the USABILITY SPECIFICATION is to be designed and implemented using appropriate USABILITY ENGINEERING methods and techniques.</p>
6.2.4	USABILITY VERIFICATION	5.8	<p>USABILITY VERIFICATION</p> <p>NOTE No substantive change in the requirement for USABILITY VERIFICATION.</p>
6.2.5	USABILITY VALIDATION plan	5.6	<p>USABILITY VALIDATION plan</p> <p>NOTE IEC 62366 focuses on the frequent USE SCENARIOS and reasonably foreseeable worst case USE SCENARIOS described in the USABILITY SPECIFICATION.</p>
6.2.6	USABILITY VALIDATION	5.9	<p>USABILITY VALIDATION</p> <p>NOTE IEC 62366 describes in more detail the actions to be taken if the acceptance criteria documented in the USABILITY VALIDATION plan are not met. This provides a connection back to the ISO 14971 RISK MANAGEMENT PROCESS. See IEC 62366:2007, Figure A.1. As a RISK/benefit analysis requires that RISK be assessed, it is necessary to understand the SEVERITY of the potential HARM. That is why subclause 5.3 requires that the SEVERITY of the potential HARM be recorded in the USABILITY ENGINEERING FILE.</p>

Table B.1 (continued)

IEC 60601-1-6:2006		Related elements in IEC 62366:2007	
Clause	Title	Clause	Title
Annexes		Annexes	NOTE The annexes in IEC 62366 have been revised and expanded. However, all the annexes remain informative.
Annex A	General guidance and rationale	Annex A	General guidance and rationale NOTE This annex has been revised to align with the normative text. An extensive section (Clause 5) and Figure A.1 were added to explain the relationship between IEC 62366 and ISO 14971.
Annex B	A taxonomy of OPERATOR action	Annex B	Categories of USER action NOTE This annex has been revised and Figure B.1 redrawn to improve the explanation of the relationship between terms such as NORMAL USE, CORRECT USE and USE ERROR.
Annex C	Examples of USE ERRORS, ABNORMAL USE and design flaws potentially leading to USE ERRORS	Annex C	Examples of USE ERROR, ABNORMAL USE and possible causes NOTE This annex has been only slightly modified to improve some of the examples.
Annex D	Guidance on the usability engineering process	Annex D	Guidance on the USABILITY ENGINEERING PROCESS NOTE This annex was revised only to the extent needed to align it with the normative requirements.
		Annex E	Questions that can be used to identify MEDICAL DEVICE characteristics associated with USABILITY that could impact on SAFETY NOTE This is a new annex which contains a list of questions that the MANUFACTURER can use as an aid memoir in identifying characteristics associate with USABILITY that could impact SAFETY. It is modelled on Annex C of ISO 14971:2007.
		Annex F	Examples of possible USABILITY related HAZARDOUS SITUATIONS NOTE This is a new annex containing examples that demonstrate the relationship of HAZARDS, scenarios, HARMS and RISK CONTROL measures related to USABILITY.
		Annex G	USABILITY goals: Illustrative example for a home parenteral infusion pump NOTE This is a new annex containing an example of USABILITY goals for a home parenteral infusion pump developed through a collaboration between MANUFACTURERS representatives and the US FDA's Center for Devices and Radiological Health.
Annex E	Sample USABILITY SPECIFICATION	Annex H	Sample USABILITY SPECIFICATION and its inputs NOTE This annex was revised only to the extent needed to align it with the normative requirements.
Annex F	Reference documents	Annex I	Recommended reading list NOTE No substantive change.
		Annex J	Reference to the essential principles NOTE This is a new annex that maps the requirements in IEC 62366 to the essential principles of SAFETY and performance of MEDICAL DEVICES in ISO/TR 16142.
Bibliography		Bibliography	NOTE No substantive change.

Index of defined terms used in this collateral standard	Index of defined terms
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## Annex C (informative)

### References to items of USABILITY provided in IEC 62366:2007 and their use in other standards

#### C.1 Introduction

This annex is intended to provide references to specific items of USABILITY as given in IEC 62366:2007 as source in comparison to those used in other standards, such as the ISO 9241 series and standards on software. The indicated references are considered as guidance.

#### C.2 General topics / limitations

IEC 62366 is a safety-related standard and requires a design and development process on USABILITY, and, where applicable, appropriate terms from the ISO 9241 series are used.

The ISO 9241 series does not specifically address safety issues. Furthermore, the ISO 9241 series started as a collection of ergonomic requirements for office work with visual display terminals. In 2006, the series was renamed "Ergonomics of human – system interaction". However, it is not yet clear if the series takes adequate account of all the contexts and situations that need to be considered for specific MEDICAL DEVICES, such as safe operation in the dark, when wet, when exposed to severe cold or heat, or without external electrical power.

Nevertheless, the ISO 9241 series provides valuable additional information about USABILITY methods, processes and requirements.

#### C.3 References to items of USABILITY in IEC 62366 and their use in other standards

Table C.1 provides references of specific items of USABILITY defined in IEC 62366:2007 in comparison to those used in other standards, e. g. the ISO 9241 series and certain software standards.

**Table C.1 – References to items of USABILITY in IEC 62366  
and their use in other standards**

IEC 62366:2007	ISO 9241 or other standards providing related information <sup>a</sup>
Definition 3.8 EFFECTIVENESS measure of accuracy and completeness with which USERS achieve specified goals [ISO 9241-11:1998, definition 3.2, modified]	Definition 3.2 effectiveness: Accuracy and completeness with which users achieve specified goals. ISO 9241-11 [2] <sup>1)</sup>
Definition 3.9 EFFICIENCY EFFECTIVENESS in relation to the resources expended	Definition 3.3 efficiency: Resources expended in relation to the accuracy and completeness with which users achieve goals. ISO 9241-11 [2]

<sup>1)</sup> Figures in square brackets refer to the Bibliography.



Table C.1 (continued)

IEC 62366:2007	ISO 9241 or other standards providing related information <sup>a</sup>
Definition 3.17 USABILITY characteristic of the USER INTERFACE that establishes EFFECTIVENESS, EFFICIENCY, ease of user learning and user satisfaction	Definition 3.1 usability: Extent to which a product can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use. NOTE See Annex D for other approaches to usability. ISO 9241-11 [2]
a) Definition 3.19 USABILITY ENGINEERING FILE set of records and other documents that are produced by the USABILITY ENGINEERING PROCESS b) USABILITY ENGINEERING FILE Clause 4.2 / Annex A subclause 4.2 c) Documenting the USABILITY ENGINEERING activities Annex D.3.3 d) Research protocols and informed consent Annex D.4.3.3	ISO/IEC 25062 [26] Intended to be used to report the measures obtained from a test of USABILITY as defined for the items effectiveness, efficiency and satisfaction in a specified context of use Section 5 Report Format Annex A Checklist Annex C Report Template Annex D Example Record of test results empirically identified.–
a) Definition 3.2 ACCOMPANYING DOCUMENT document accompanying a MEDICAL DEVICE and containing information for those accountable for the installation, use and maintenance of the MEDICAL DEVICE or the user, particularly regarding SAFETY [ISO 14971:2007, definition 2.1, modified], b) ACCOMPANYING DOCUMENT Clause 6 / Annex A, clause 6	ISO 9241 does not define an equivalent to accompanying document (accompanying document consist of more than the instructions for use)
See above	ISO/IEC 15910 [23]
See above	ISO/IEC 18019 [25]
See above	ISO 14598-6 [22]
Definition 3.20 USABILITY SPECIFICATION documentation defining the USER INTERFACE requirements related to USABILITY a) USABILITY SPECIFICATION subclause 5.5, Annex A subclause 5.5 b) USER research, Design concept development, (conceptual design) Design requirement/criteria development Annex D.2.3 – D.2.5 c) Design requirement/criteria development Annex D.4.4	No definition provided in ISO 9241-11 [2]  ISO 9241-11:1998 Clauses 5, 6, 7, Annex A

Table C.1 (continued)

IEC 62366:2007	ISO 9241 or other standards providing related information <sup>a</sup>
a) USER INTERFACE design and implementation Subclause 5.7, Annex A subclause 5.7 b) Design implementation and deployment Annex D.2.8 c) Design specifications Annex D.4.6	ISO 9241-20 [3] ISO 9241-110 [4] ISO 9241-171 [5] ISO 9241-300 [7] ISO 9241-302 [8] ISO 9241-303 [9] ISO 9241-400 [13] ISO 9241-410 [14]
Identification of known or foreseeable HAZARDS and HAZARDOUS SITUATIONS Annex A subclause 5.3.2 – task related requirements –	ISO 9241-2 [1]
Annex A subclause 5.3.2 – context of use –	ISO 9241-920 [15]
USABILITY VERIFICATION, USABILITY VALIDATION Subclauses 5.8, 5.9, Annex A subclauses 5.8, 5.9 Design evaluation Annex D.2.7 Design VERIFICATION Annex D.4.7.2 Production unit final VALIDATION Annex D.4.7.3	ISO 9241-304 [10] ISO 9241-305 [11] ISO 9241-307 [11] ISO/IEC 14598-1 [17] ISO/IEC 14598-2 [18] ISO/IEC 14598-3 [19] ISO/IEC 14598-4 [20] ISO/IEC 14598-5 [21] ISO/IEC 14598-6 [22]
The benefits of USABILITY ENGINEERING Annex D.1.2	ISO 13407 [16] Clause 4
Planning the USABILITY ENGINEERING PROCESS Annex D.3 A systematic approach Annex D.4.1	ISO 9241-210 [6]
Methods and techniques used in the USABILITY ENGINEERING PROCESS Annex D.5	ISO/TR 16982 [24]
USABILITY testing Annex D.5.15	ISO 9241-11 [2] (Annex) ISO/IEC 25062 [26]
Workload assessment Annex D.5.17	ISO 9241-2 [1]

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- [3] ISO 9241-20:2008, *Ergonomics of human-system interaction – Part 20: Accessibility guidelines for information/communication technology (ICT) equipment and services*
- [4] ISO 9241-110:2006, *Ergonomics of human-system interaction – Part 110: Dialogue principles*
- [5] ISO 9241-171:2008, *Ergonomics of human-system interaction – Part 171: Guidance on software accessibility*
- [6] ISO 9241-210:—<sup>2)</sup>, *Ergonomics of human-system interaction – Part 210: Human-centred design for interactive systems*
- [7] ISO 9241-300:2008, *Ergonomics of human-system interaction – Part 300: Introduction to electronic visual display requirements*
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- [9] ISO 9241-303:2008, *Ergonomics of human-system interaction – Part 303: Requirements for electronic visual displays*
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- [12] ISO 9241-307:2008, *Ergonomics of human-system interaction – Part 307: Analysis and compliance test methods for electronic visual displays*
- [13] ISO 9241-400:2007, *Ergonomics of human-system interaction – Part 400: Principles and requirements for physical input devices*
- [14] ISO 9241-410:2008, *Ergonomics of human-system interaction – Part 410: Design criteria for physical input devices*
- [15] ISO 9241-920:2009, *Ergonomics of human-system interaction – Part 920: Guidance on tactile and haptic interactions*
- [16] ISO 13407:1999, *Human-centred design processes for interactive systems*
- [17] ISO/IEC 14598-1:1999, *Information technology – Software product evaluation – Part 1: General overview*
- [18] ISO/IEC 14598-2:2000, *Software engineering – Product evaluation – Part 2: Planning and management*
- [19] ISO/IEC 14598-3:2000, *Software engineering – Product evaluation – Part 3: Process for developers*

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<sup>2)</sup> To be published.

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- [21] ISO/IEC 14598-5:1998, *Information technology – Software product evaluation – Part 5: Process for evaluators*
- [22] ISO/IEC 14598-6:2001, *Software engineering – Product evaluation – Part 6: Documentation of evaluation modules*
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- [25] ISO/IEC 18019:2004, *Software and system engineering – Guidelines for the design and preparation of user documentation for application software*
- [26] ISO/IEC 25062:2006, *Software engineering – Software product Quality Requirements and Evaluation (SQuaRE) – Common Industry Format (CIF) for usability test reports*
- [27] ANSI/AAMI HE 74:2001, *Human factors design process for medical devices*

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