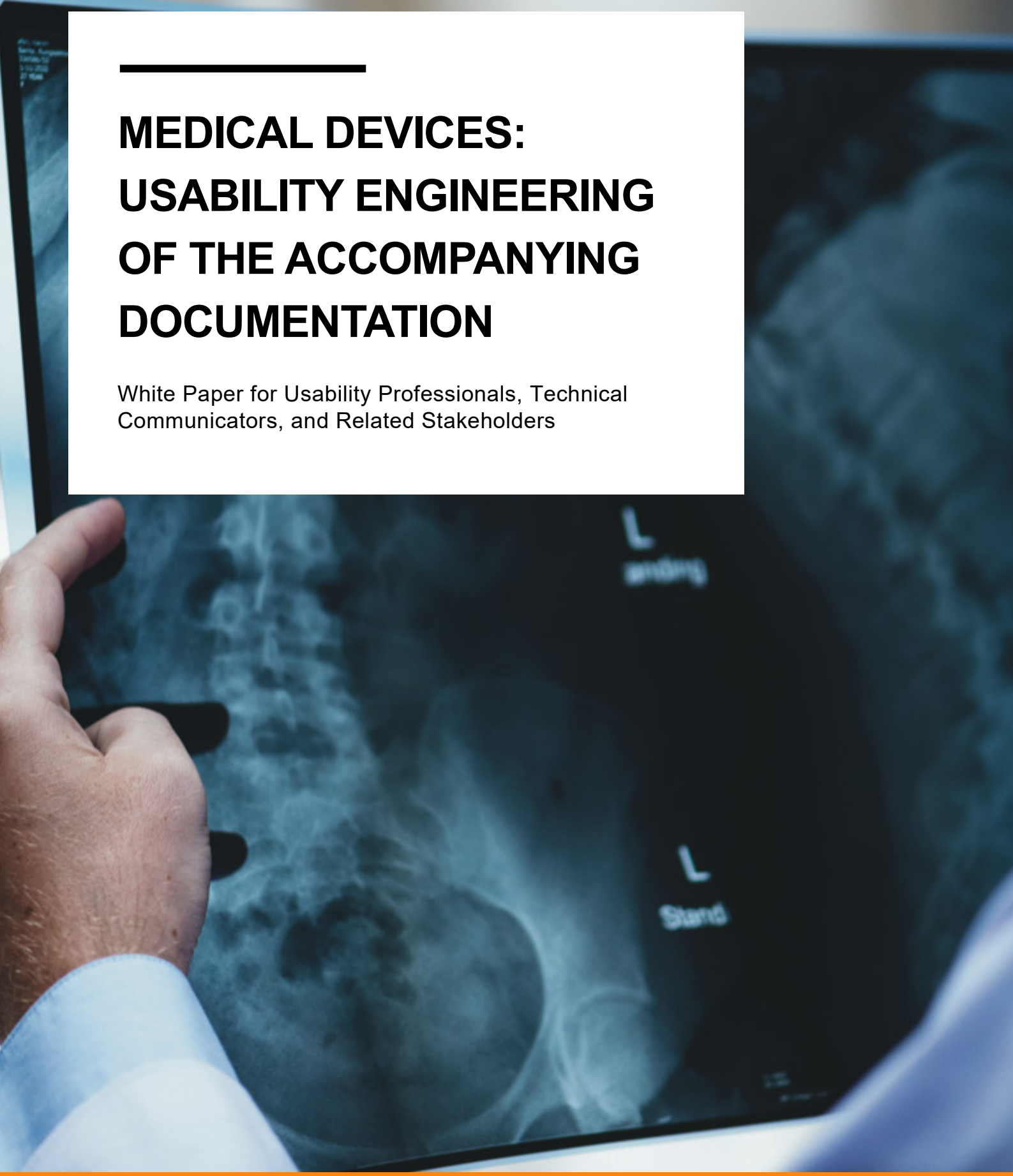
MEDICAL DEVICES: USABILITY ENGINEERING OF THE ACCOMPANYING DOCUMENTATION

White Paper for Usability Professionals, Technical Communicators, and Related Stakeholders



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Scope

Usability engineering and technical communication are two closely related professional communities. Goals we share are to enable users and to ensure safety. Yet in practice, professionals from the two communities do not cooperate as much as one might expect or wish.

This white paper deals primarily with the specific topic in its title: medical devices and the usability engineering of their accompanying documentation. Manufacturers of medical devices must take the safety of patients, users, and third parties into careful consideration. Safety is main concern of regulators. Therefore, applying usability engineering is mandatory for the development of medical devices.

Domain-specific aspects of medical devices aside, parts of this white paper apply to the usability engineering of information for use in general. On this meta level, we also wish to bridge the gap between usability professionals and technical communicators—a gap that should not be there in the first place.

We intend this white paper as the basis for a common understanding and collaboration among those involved in the usability engineering process:

- usability professionals
- technical communicators
- related stakeholders, such as
  - product managers
  - quality managers
  - regulatory affairs professionals
  - risk managers
  - software developers
  - development engineers
  - department heads
  - executives
  - others involved
- professionals working for
  - manufacturers
  - contractors
  - consultancies
- regulatory bodies
  - notified bodies in the EU
  - government authorities, such as the FDA

Table of Contents

1. Introduction: Common Ground

The usability engineering and technical communication communities share basic goals and a user-centered perspective. With their work, both communities enable users and ensure the safety of patients, users, and third parties. However, the two fields are surprisingly separated by gaps in approach, terminology, and collaboration. On top of that, the broader industry of medical devices has its own terminology, which is defined by regulations in many cases.

The following terms and concepts are at the intersection between usability engineering, technical communication, and medical devices. To get everyone on the same page, we recap and summarize the most essential terms and concepts.

1.1. Usability

Usability emerges when a user interacts with a system. The user's and the system's individual characteristics affect the interaction. The resulting usability is commonly defined as positive if the interaction is effective (users reach their goals), efficient (minimal resources are expended), and satisfactory (positive experience while interacting).

Additionally, for medical devices, the criterion of learnability (ability to learn command and control while using the system) is often used.

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Normative references on usability

The commonly accepted definition of usability is given in the horizontal standard ISO 9241-11 on human-system interaction:

> The extent to which an interactive system can be used by specified users to achieve specified goals with effectiveness, efficiency and satisfaction in a specified context of use.
>
> — ISO 9241-11:2018, Sec. 3.1.1

IEC 62366-1 specifically applies to usability engineering of medical devices. In its appendix, the criterion of learnability is explained as:

> The time needed to become acquainted with the MEDICAL DEVICE and its operation . . .
>
> — IEC 62366-1:2015, Appx. A.2, p. 22

The IEC 62366-1 standard's definition of usability (Sec. 3.16) is similar to the one in ISO 9241-11. Both refer to the three criteria: effectiveness, efficiency, and satisfaction.

1.2. Usability Engineering

We chose the standard IEC 62366-1:2015 on *Medical devices – Part 1: Application of usability engineering to medical devices* as our reference on usability engineering because it is the most current, most specific, and most relevant standard for developers of medical devices. It is used in the two most important world regions in terms of regulating medical devices: the European Union and the United States.

DEEP DIVE

Normative reference on usability engineering

IEC 62366-1 defines usability engineering as follows:

> application of knowledge about human behaviour, abilities, limitations, and other characteristics to the design of MEDICAL DEVICES (including software), systems and TASKS to achieve adequate USABILITY
>
> — IEC 62366-1:2015, Sec. 3.17

1.3. Accompanying Documentation

As a term, *instructions for use* is more commonly known and used than *accompanying documentation*. However, the latter is specific to medical devices and is used in the IEC 62366-1 standard. Therefore, we have decided to use the term *accompanying documentation* in this white paper. According to the IEC 62366-1 standard's definition, *instructions for use* are a subset of the *accompanying documentation*.

Terms and concepts in other sources from regulatory authorities vary and partially overlap with this definition, for example:

- *information supplied with the device*[1] or *by the manufacturer*[2], respectively
- *labeling*[3]
- *information for use*[4]
- *instructions for use*[5]
- *information for safety*[6]

[1] Current European regulations MDR 2017/745/EU & IVDR 2017/746/EU, both Annex I

[2] Previous European regulations MDD 93/42/EEC & IVDD 98/79/EC, both Annex I

[3] US regulation FFDCA, Section 201(m)

[4] International standard IEC/IEEE 82079-1:2019 on the preparation of information for use
When referring to the IEC 62366-1 standard or medical devices, we use the term *accompanying documentation*. In contrast, we may use *information for use* in a broader sense and in reference to the horizontal standard IEC/IEEE 82079-1:2019, the ISO 9241 series, or other such standards.

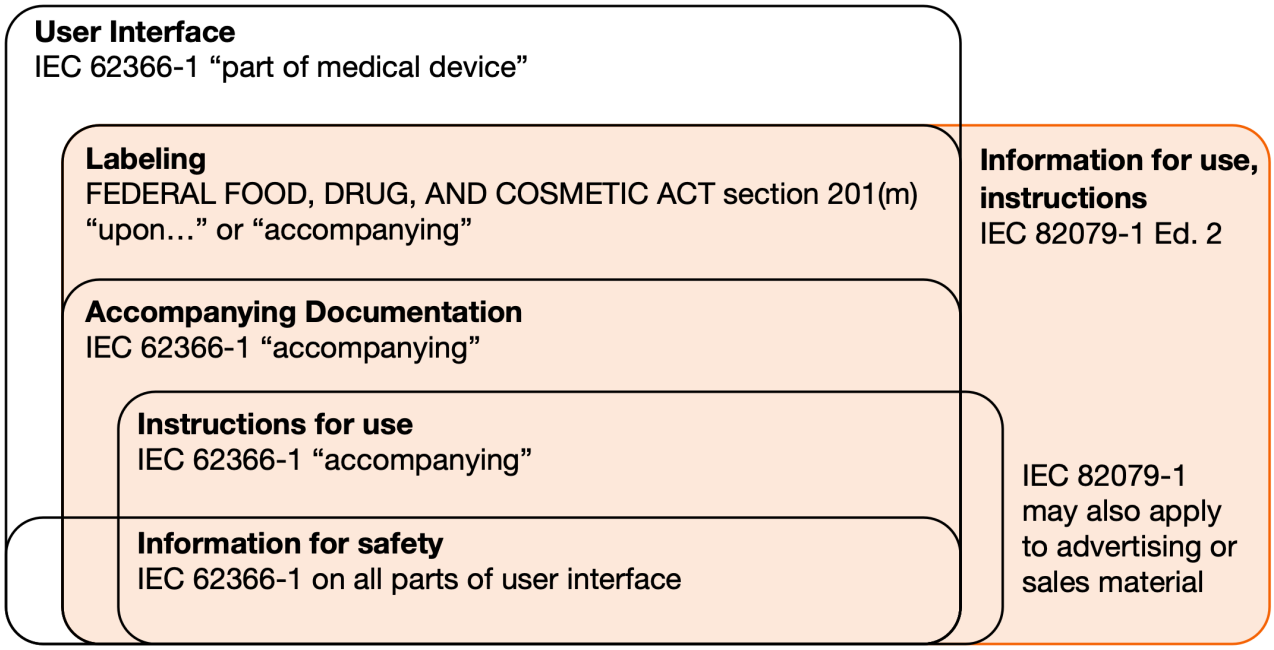
[5] MDR, IVDR, MDD, IVDD, & IEC/IEEE 82079-1:2019

[6] IEC 62366-1:2015, Sec. 4.1.3 & ISO 14971

- *label* (as distinguished from *labeling*)[7]

Torsten Gruchmann and Roland Schmeling have illustrated this overlap (not all terms included) in the Venn diagram in **Figure 1** below. Their distinctions are valid and worthwhile. For the purpose of this white paper, it would be going too far to elaborate on the differences. But we would like to raise awareness that such distinctions exist to avoid confusion.

Figure 1 Overlapping concepts related to accompanying documentation[8]



[7] MDR, IVDR, MDD, IVDD, FFDCA, & IEC/IEEE 82079-1:2019

[8] Figure 1 is adapted from a presentation by Gruchmann & Schmeling, 2018, p. 3, NORM01 available from https://tagungen.tekom.de/h18/, translated from German, included with their kind permission.

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Normative references on accompanying documentation

In the IEC 62366-1:2015 standard on usability engineering for medical devices, accompanying documentation is defined as to include any kind of information for the user and emphasizes safe use (Sec. 3.2). Notes to this entry explain that accompanying documentation can consist of a number of different information products, such as:

- instructions for use
- technical description
- installation manual
- quick reference guide, etc.

Accompanying documentation need not necessarily be supplied as printed media but may be provided in various forms, such as:

- auditory materials
- visual materials
- tactile materials
- multiple media types

The new draft standard on information to be provided by medical device manufacturers ISO/DIS 20417:2019 references IEC 62366-1:2015. EN ISO 20417 will replace the current harmonized European standard EN1041:2008+A1:2013. According to the draft of a European Implementing Decision from July 2019 (https://ec.europa.eu/docsroom/documents/36104), EN ISO 20417 will be harmonized under the European MDR and IVDR.

1.4. Information for Safety

Information for safety is any information on the user interface of a medical device that supports the correct use of the medical device and avoids harm from use. Information for safety should prevent the user from acting in an unsafe manner, e.g., applying the medical device in an inappropriate situation. Information for safety is explicitly part of mitigating the risks that arise from the application of medical devices.

Examples of information for safety include:

- warnings on the medical device
- describing improper use or possible hazards
- promoting the use of protective equipment
- information about measures to reduce harm
- specification of necessary maintenance intervals or maximum service life
- how to dispose of the medical device properly[9]

In addition, information for safety may be specified by certain safety standards for medical devices, in some cases including exact phrases or symbols to use.

[9] Based on ISO 14971

PRACTIONERS' INSIGHT

Conflicting requirements for information for safety

Certain safety standards for medical devices specify exact phrases to be used, for example, phrases for warning messages. To fully comply with this medical device standard, manufacturers have to include the specified phrases in their accompanying documentation. Unfortunately, in some, cases the specified phrases have been poorly authored and are easily misunderstood by the defined user group particularly in the intended context of use. In such cases, the requirements of certain medical device standards are in conflict with the requirements for usability engineering.

To comply with the usability engineering requirements, we strongly recommend testing such specified phrases of information for safety. To mitigate the issue of users misunderstanding or being confused by specified phrases, manufacturers can provide additional explanatory text that refers to the specified phrase. A revision of the additional text based on user feedback may be necessary. Therefore, manufacturers should evaluate the additional text with users early in the process in order to avoid having to repeat the summative usability evaluation.

One could make an argument for not using the specified phrases as they are but instead editing them to make them easier to understand. In general, the application of harmonized European standards is not mandatory. Manufacturers are principally free to apply the most suitable methods and technologies, which may not be reflected in the relevant harmonized standards. Whether or not this is a worthwhile argument, must be determined by subject-matter experts and stakeholders for each individual project.

1.5. Why Usability Engineering of the Accompanying Documentation?

Medical device manufacturers need to ensure an adequate risk-benefit profile of the medical devices they plan to market. Manufacturers therefore apply a systematic risk management process as described in ISO 14971. This process includes a list of specific steps how and in which order risks can be identified and may be mitigated:

> The manufacturer shall use one or more of the following risk control options in the priority order listed:
> a) inherent safety by design;
> b) protective measures in the medical device itself or in the manufacturing process;
> c) information for safety.
>
> — ISO 14971:2007, Sec. 6

This shows that options other than information for safety are preferred by regulators for mitigating risks. However, the mitigation of some risks will always lie in the hands of users; therefore, users need to be informed about risks. This means that information supplied by the manufacturer of the medical device needs to be adequate for users. Users must be able to perceive and understand the information, and the information must support the correct use of the medical device. On this basis, regulators mandate manufacturers to validate the adequacy of information for safety.

PRACTIONERS' INSIGHT

The accompanying documentation's usability can adversely affect a product's overall usability

During usability tests, we have, on occasion, seen users who were able to safely use a device – without the help of the accompanying documentation. But upon using a document, user made mistakes that they had not made before.

In such a case, the device's usability was in fact acceptable – until the user turned to the accompanying documentation. Only then, users were misled or confused by the information provided. Hence, the medical device's usability – in conjunction with the accompanying documentation – was worse and not sufficient to pass the summative usability evaluation.

This observation may seem surprising at first glance. But it is in fact reflected in a number of regulations and internations standards, for medical devices and in other industries. Namely, the user documentation of a product is commonly defined to be an integral part of the product itself.

Our observation offers anecdotal evidence in support of this definition that the accompanying documentation is an integral part of the product. Accordingly, poor usability of the accompanying documentation can have adverse effects on a product's overall usability.

This is no argument for minimizing the role accompanying documentation plays in summative usability studies. On the contrary, it is an argument in favor of testing the accompanying documentation early and repeatedly.

1.6. Regulatory References

The IEC 62366-1[10] standard is the primary, internationally accepted reference on usability engineering for medical devices. For technical communicators, the primary references are IEC/IEEE 82079-1P10F[11]P on the preparation of information for use and the series of standards on user documentation ISO/IEC/IEEE 26511, ISO/IEC/IEEE 26512, ISO/IEC/IEEE 26513, ISO/IEC/IEEE 26514, and ISO/IEC/IEEE 26515[12]. For the accompanying documentation of medical devices specifically, EN 1041[13] is the relevant standard. However, it is going to be replaced by the new EN ISO 20417[14], which is currently under development.

In Europe, EN 1041 and the outdated IEC 62366 are listed as harmonized European standards under the regulations MDD[15] and IVDD[16]. Under the new regulations MDR and IVDR, the upcoming EN ISO 20417 and the current IEC 62366-1 are expected to be listed as harmonized standards, according to a recently published draft standardization request from the European Commission[17].

For the United States, IEC 62366-1 is mirrored by the national organizations ANSI and AAMI as ANSI/AAMI/IEC 62366-1:2015.

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[10] IEC 62366-1:2015 Medical devices – Part 1: Application of usability engineering to medical devices

[11] IEC/IEEE 82079-1:2019 Edition 2.0 Preparation of information for use (instructions for use) of products – Part 1: Principles and general requirements

[12] ISO/IEC/IEEE 26511:2011 Systems and software engineering – Requirements for managers of user documentation, ISO/IEC/IEEE 26512:2011 Systems and software engineering – Requirements for acquirers and suppliers of user documentation, ISO/IEC/IEEE 26513:2009 Systems and software engineering – Requirements for testers and reviewers of user documentation, ISO/IEC/IEEE 26514:2008 Systems and software engineering – Requirements for designers and developers of user documentation, ISO/IEC/IEEE 26515:2011 Systems and software engineering – Developing user documentation in an agile environment

[13] EN 1041:2008+A1:2013 Information supplied by the manufacturer of medical devices

[14] ISO/DIS 20417:2019-03 *Medical devices – Information to be provided by the Manufacturer*, latest draft at the time of publication

[15] *Commission communication in the framework of the implementation of the Council Directive 93/42/EEC concerning medical devices* (https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices_en)

[16] *Commission communication in the framework of the implementation of the Directive 98/79/EC of the European Parliament and of the Council on in vitro diagnostic medical devices* (https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/iv-diagnostic-medical-devices_en)

[17] *Draft standardisation request as regards medical devices in support of Regulation (EU) 2017/745 and in vitro diagnostic medical devices in support of Regulation (EU) 2017/746*. July 26, 2019; retrieved from https://ec.europa.eu/docsroom/documents/36104

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Regulatory relevance on international standards not harmonized under European regulations

IEC/IEEE 82079-1 is currently not harmonized under any European regulation. It is designated internationally as a horizontal standard and applies to a broad range of information for use and products. As such, this standard is considered to reflect the *state of the art*. In the absence of a specific harmonized European standard, the state of the art is principally accepted by notified bodies as an alternative indicator of regulatory compliance.

In December 2016, the US Food and Drug Administration (FDA) has adopted IEC 62366-1:2015 as a "recognized consensus standard." Nonetheless, the FDA has its own guidance document titled "Applying Human Factors and Usability Engineering to Medical Devices." The usability engineering process and terminology described therein differ in part from IEC 62366-1:2015. However, both pursue the same goal: The reduction of use related risks.

For further resources, *see* Chapter 6 *References* on page 53.

2. Usability Engineering and Information Development: Matching Processes and Terms

For usability professionals and technical communicators to cooperate effectively, it is necessary to understand each other's processes and terminology.

Based on the context of use analysis, a project's lead technical communicator will plan and develop the accompanying documentation. Thereafter, technical authors and illustrators start to create the content.

Planning, developing, and creating the accompanying documentation can be viewed as a form of requirements engineering. Basic principles regarding accompanying documentation include, for example:

1. researching regulatory requirements, formulating objectives and constraints
2. defining testable criteria
3. producing a design solution, that is, a plan on how to implement the above
4. creating the content
5. iteratively evaluating (i.e., reviewing, testing, etc.) and refining drafts of the accompanying documentation

Requirements, objectives, and constraints can be derived, in part, from overlapping activities. For example, the user group profiles created as part of the usability engineering are equally relevant to technical communicators in terms of target audiences. Usually, such derived requirements, objectives, and constraints need to be reevaluated and clearly defined for the accompanying documentation.

If a product is part of a larger line of products or will be in the foreseeable future, interdependencies between products will affect the accompanying documentation's content. Terminology, content structure, illustration styles, and typography, for example, need to be kept consistent across all products of the line.

During a product's life cycle, the content of accompanying documentation will have to be changed and updated regularly, for example, to reflect technical modifications or new legal requirements. Such changes to the content are required by regulations to be traceable between publication versions[18]. Auditors may scrutinize any change's traceability. In contrast to changes to marketing materials, for example, changes to the accompanying documentation are often significantly less trivial. Therefore, future changes and updates to the content of accompanying documentation have to be factored in from the start.

Work during the initial planning and development of the accompanying documentation will lay foundations for its long-term maintainability and the cost-effectiveness of its maintenance. Changing certain decisions later on may prove difficult or costly.

'Producing a design solution' is a usability engineering term. Regarding accompanying documentation, the design solution can be understood to include, for example:

- the content model
- the document's layout
- decisions on standardization, such as terminology, spelling, writing style, illustration styles

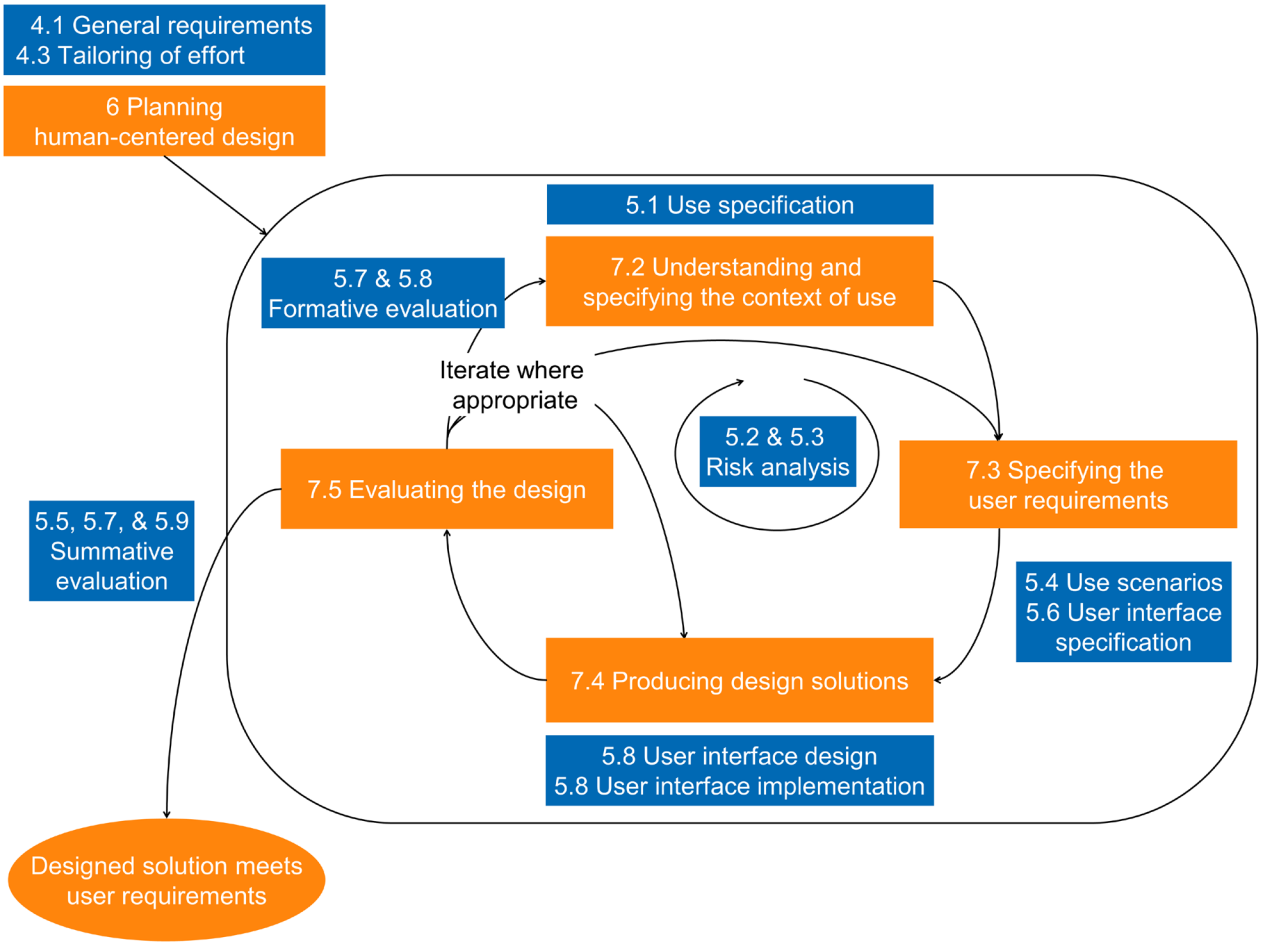
Some of the above can be implemented in software tools used by technical communicators. For example, the content model can be formulated as a Document Type Definition (DTD) intended for XML-based authoring tools. For any authoring tool, the layout will be implemented in a document template that supports the consistent use of formats, such as paragraph and character styles. Ultimately, all these aspects and decisions should be documented internally in the form of a style guide for future revisions of the accompanying documentation.

[18] E.g., see Title 21 of Code of Federal Regulations (CFR) §11.10(k)(2) https://www.ecfr.gov/cgi-bin/text-idx?SID=2bf7addb2daea82ea5da9207e08b4ce2&mc=true&node=se21.1.11_110&rgn=div8

2.1. Processes

To compare the usability engineering and information development processes, we chose to focus on individual projects. The larger perspective of entire organizationstakes business management processes into account additionally and is beyond our intended scope of this white paper.

Figure 2 Process visualization of the general usability engineering process (orange boxes refer to ISO 9241-210) and the medical device usability engineering process (grey boxes refer to IEC 62366-1).



Usability Engineering is always an iterative process in which feedback is sought using evaluations. Therefore, we chose the illustration above from the general usability engineering standard ISO 9241-210 and combined it with the specifics from IEC 62366-1, the usability engineering standard addressing medical devices. The numbers in the illustration refer to the chapters of the standards.

To ensure effective and efficient execution of the different activities a plan is necessary (see Sec. 6 *Planning Human-Centered Design*). Primarily, the plan helps ensure sufficient resources and personnel with appropriate skills and defining how much effort needs to be expended – very much depending on how much risk a particular medical device poses for patients, users, and third parties. In the planning phase of the usability engineering process, it is sensible to formulate quality objective that are human centered. Such objectives explicitly list the qualities that the project has to deliver to users, e.g., efficient use, particulars of the user experience, etc.

Once a plan exists, usability professionals analyze the context in which a medical device is used in order to understand it and to specify the contexts in which the device may be used (7.2 *Understanding and Specifying the Context of Use*). Aspects to take into consideration include researching characteristics of users, their tasks and goals, finding out in which environment the device will be used, and which resources users will need—all such aspects might play a role while developing a user interface.

With these insights, usability engineers develop user requirements (7.3 *Specifying the user requirements*) that define which goals the design solution is to achieve. These requirements drive the design solution and can be broken down to use scenarios and technical requirements for the system and user interface.

Then, some form of design solution is created (7.4 *Producing design solutions*). This can be a non-functional very early prototype up to the final user interface for the medical device which is going to be marketed. It includes defining the workflows for users, deciding about which user interface elements are used and selecting color schemes. This applies to industrial design as well as to user interface design.

Once a prototype exists, usability professionals evaluate it to ensure it meets the actual user requirements (7.5 *Evaluating the design*). This may be done through usability tests of the chosen system design, during which users are observed as they interact with the system, or through expert review. Formative evaluations are conducted during the development process and deliver input to the appropriate iterations as shown in **Figure 2** on page 17. At the end of the development cycle, the summative evaluation determines that the medical device is fit for its purpose and safe to use. This study is carried out by usability professionals who test workflows for critical tasks and identify potential use errors.

PRACTIONERS' INSIGHT

Claims from clinical evaluations and marketing

Even though usability engineering for medical devices has a strong focus on mitigating risks arising from the use, there are further aspects. Usability engineering might address some of the claims made in the clinical evaluation plan. A claim might be that patient compliance will be higher because of a better user experience or improved workflows.

Another aspect are marketing claims. These might be supported by usability engineering as well. Such a claim may be e.g. that the time needed to finish a particular treatment is shorter compared to other products.

These examples illustrate that summative usability testing results may contribute valueable data to other emprical studies.

In the **Table 1** on page 20, we present a comparison of corresponding sections in the four standards that we regard as the most relevant in relation to the processes for technical communicators and usability professionals:

- ISO 9241-210:2019 and IEC 62366-1:2015 on usability engineering
- IEC/IEEE 82079-1:2019 and ISO/IEC 26514:2008 on information development

Table 1 High-level comparison of processes: usability engineering and information development

Table line	Usability engineering process steps Paraphrased	Chapter in ISO 9241-210:2019	Chapter in IEC 62366-1:2015	Information development process steps Paraphrased	Chapter in IEC/IEEE 82079-1:2019	Chapter in ISO/IEC 26514:2008
1	Planning human-centered design	6	4.1, 4.3	Planning information management	5.4, 6.1, 6.2, 6.3.1	5
2	Understanding and specifying the context of use (users, user goals, resources, environment)	7.2	5.1	Gathering basic information; researching target audiences	6.2.1, 6.2.2, 6.3.2	6
3	Risk management	N/A	5.2, 5.3	Risk management	6.2.7	N/A
4	Specifying the user requirements	7.3	5.4, 5.6	Researching and formulating project requirements, goals, and constraints; defining testable criteria	6.2.1, 6.2.2, 6.3.2	6
5	Producing design solutions	7.4	5.8	Regarding accompanying documentation, the design solution can be understood to include, for example: the content model; the document's layout; decisions on standardization, such as terminology, spelling, writing style, illustration styles	6.3.2	7

Table line	Usability engineering process steps Paraphrased	Chapter in ISO 9241-210:2019	Chapter in IEC 62366-1:2015	Information development process steps Paraphrased	Chapter in IEC/IEEE 82079-1:2019	Chapter in ISO/IEC 26514:2008
6	Implementation of prototypes (software, hardware, and mechanics)	N/A	5.8	Creating written and visual content, refining concepts and content structures, implementing content, layout, and output media (e.g., print, digital, interactive, mobile) using appropriate authoring tools	6.3.2	8
7	Performing formative evaluation, i.e., an evaluation that is intended to improve the concept	7.5	5.7.2, 5.8	Performing review of draft (i.e., desk check; at least by editors or peers and by SMEs or the designated content owner), empirical evaluation of draft	6.3.3	8
8	Iteratively redesigning and reevaluating	7.2; 7.3; 7.4	5.1 to 5.8	Implementing review/evaluation feedback, further review/evaluation loops	6.3.2, 6.3.3	8
9	Implementation and final assembly of the system	N/A	5.8	Finalizing the content and producing final output media	6.4	9
10	Content freeze of the accompanying documentation's final version	N/A	N/A	Performing the final review for sign-off (i.e., desk check by SMEs or designated content owners)	6.2.12, 6.3.3	9.1, 9.2
11	Performing summative evaluation for compliance purposes This evaluation is intended to measure the usability of the system in conjunction with the accompanying documentation.	7.5	5.5, 5.7.3, 5.9	Formal sign-off by the respective executives after completion of the summative evaluation	6.2.12, 6.3.3	9.2

Note that the comparison in **Table 1** leaves room for interpretation because each of the four standards has a different perspective and focus on the matter.

For example, IEC 62366-1 has a strong focus on risk management and safety at the process level. The generally applicable ISO 9241-210 standard barely mentions risk management and safety. As another example, the ISO/IEC 26514 standard covers the information development process in greater detail than IEC/IEEE 82079-1.

With the comparison in **Table 1**, we want to provide a basic orientation and help start the conversation between professionals from different fields.

2.2. Terms

Identical terms may differ in meaning or do overlap only partly within the communities of usability engineering, technical communication, and other professions or industries.

We would like to point out and raise awareness that across fields terms may hold unexpected potential for misunderstandings.

2.3. Regulatory Conclusion

Should the summative user interface evaluation unexpectedly reveal new use errors, close calls, or use difficulties, the manufacturer is mandated to continue the usability engineering process. Use errors, close calls, and use difficulties include instances in which users did not find or understand information or did not use the device correctly according to the accompanying documentation.

If no use errors that pose unacceptable risks are found, the medical device is in compliance with IEC 62366-1. The usability engineering file documents this compliance. Once the summative user interface evaluation is successfully completed the manufacturer may initiate – from a usability engineering perspective – the regulatory clearance of the device. The regulatory clearance is the primary legal hurdle for bringing a medical device to market.

PRACTIONERS' INSIGHT

Cost factors for redesigns

The later a medical device needs redesign within the development lifecycle, the higher the project risks regarding schedule, effort, and cost are. Therefore, it is important to keep in mind that early user interface evaluations reduce the project risks related to usability engineering. We are painfully aware of the fact that sometimes summative user interface evaluations fail and a substantial redesign is required before a device can be marketed. The higher the risk arising from newly use errors found in a user interface evaluation is, the more likely it is that an expensive redesign of the medical device will be necessary. This, in turn, will adversely impact schedule, effort, and costs.

3. Making It Work: Collaborating Throughout the Project

After setting up a regulatory framework and establishing a common ground for technical communicators and usability professionals as well as other interested parties, we turn now to the practical application of our respective skills to accompanying documentation.

In this first *Making It Work* section, we look at how to get started with accompanying documentation. First, we consider the context of use analysis as a method for "getting to know" the users and their environment. Then, we look at planning and developing the accompanying documents.

In the second *Making It Work* section, we present appropriate methods specifically for evaluating the accompanying documentation. Each method is described with regards to its application as well as its outcomes and what they mean for both technical communicators and usability professionals.

The usability methods we have selected are appropriate for the usability engineering of both the accompanying documentation as well as the medical devices. Furthermore, these methods are also applicable to products in other industries, not only to the domain of medical devices.

We briefly introduce following selection of methods:

3.1. METHOD Context of Use Analysis

When to use

A context of use analysis is carried out at the beginning of development if intended users, their tasks and goals, intended use environment, and necessary resources are not sufficiently available or understood. Ideally the analysis is executed "in the context" meaning at the exact location where the anticipated interaction of potential users and device will take place. This ensures the most realistic knowledge acquisition in the actual context of use.

Why to use

The targeted user or patient groups and their context of use vary and are specific to each medical device. The analysis of these target audiences and the context of use is one fundamental basis for all aspects of product development, including usability engineering, information development, and marketing.

What you need

At the beginning of a development project of medical devices the project team including usability engineering need recent and accurate data in order to start and to base development on.

That is data on the context of use, including:

- users
- their tasks and goals
- environments of use
- resources needed when using.

This information can be gained by observing or interviewing users. One has to differentiate the approach for lay users (i.e., homecare products) or expert users (i.e., medical devices in hospitals).

What to do

A context analysis consists of collecting and analyzing detailed information about the intended users, their tasks, and the technical and environmental constraints. The data for a context of use analysis can be gathered using interviews, workshops, surveys, site visits, artifact analysis, focus groups, observational studies, or contextual inquiry.

The main goals are to:

- ensuring that all factors that relate to use of the system are identified before design work starts.
- providing insights on usage patterns that are unsafe to enable a new, safer design
- creating a basis for usability testing

The context of use analysis involves collecting and analyzing detailed information about:

- the intended users
- their tasks
- the tools that support the users' tasks
- the physical environment in which a medical device will be used
- the user's social and organizational environment
- the technical environment and associated technical constraints
- analysis of use errors, close calls, and use difficulties
- other contextual factors that will affect the user experience

This information about the context of use is an essential input to the problem definition, product goals, requirements, conceptual design, detailed design, and the planning of usability methods and input to the creation of accompanying documentation. Information about the context of use of a product are generally collected early in the product development and then refined as additional data are gathered from usability studies. When developing a successor device, one starts with and rechecks the initial context of use information of the predecessor.

What to keep in mind

The context of use analysis should also collect and analyze detailed information about:

- use of accompanying documentation by the users
- availability of accompanying documentation for the users
- possibility for users to refer to the accompanying documentation while performing a task
- knowledge about information for safety included in the accompanying documentation

What to expect as a result

Based on the user profiles and the context of use, technical communicators analyze the information provided with respect to the documentation’s content. The right content needs to be accessible by the users in the respective situations with the device, in a sensible medium and format.

Results by usability professionals	Results by technical communicators
• user groups and user group profiles, personas • tasks, task models, goals • as-is-scenarios, i.e., descriptions how problems are solved today For the use specification, the above are combined.	• target group analysis • task analysis

3.2. On Planning and Developing the Accompanying Documentation

Producing a design solution of a product or device is a creative process. Planning and developing accompanying documentation is a creative process, too. It is the technical communicators' contribution to producing the overall design solution. The diverse aspects of this stage are described by relevant standards on information development, as laid out in **Table 1** on page 20 above.

DEEP DIVE

Guidance on planning and developing accompanying documentation

ISO/IEC 26514 on user documentation lays out principles of researching and formulating requirements, objectives, and constraints with respect to the information development process.

IEC/IEEE 82079-1 on information for use is not as detailed with respect to the information development process. However, Chapter 6 includes an extensive list of aspects to take into account during this stage.

Noteworthy literature includes *Information Development: Managing Your Documentation Projects, Portfolio, and People* by JoAnn Hackos (2007, [32]) and *Usability of Products and Instructions in the Digital age: Manual for Developers, IT Specialists, and Technical Writers* by Gertrud Grünwied (2017, in German, [31]).

Such aspects of planning and developing accompanying documentation include, for example[19]:

- applicable regulations and standards affecting accompanying documentation
- further technical, organizational, and market-related properties or limitations
- identify required content, according to regulations and standards, context of use analysis/task analysis/target audience analysis
- number and type of information products
- target media, respective key parameters of layout, navigation, etc.
- target markets and required languages
- information types, content structure, standardization, content reuse
- types and key parameters of illustrations
- writing style, wording, etc.
- limiting aspects of production and distribution (e.g., maximum page count of print media limited by the product's packaging)

[19] See Chapter 6 of IEC/IEEE 82079-1:2019 on Preparation of information for use (instructions for use) of products – Part 1: Principles and general requirements

PRACTIONERS' INSIGHT

Planning and developing accompanying documentation

There is not one universal overarching methodology on how to pull together all the individual aspects of planning and developing accompanying documentation for any given project.

For example, information types and content structure greatly depend on the target audience and use scenarios. In certain use scenarios, users cannot work with digital media. Printed instructions for use are obligatory in such cases. Then again, the physical size and number of pages of printed instructions for use can be constrained by the size of the medical device's packaging. Limitations in size and number of pages will have implications for the overall design of the actual content. The size and number of pages not only affect the layout and illustrations but also the structure of written content, the writing style, etc.

The relevance of the aspects in this example and of each of the aspects listed above varies between projects.

What to expect as a result

Concluding this stage early in the process is usually not possible. The lead technical communicator will specify the subset of requirements, objectives, and constraints that is essential to start creating content. While the actual content creation progresses, the lead technical communicator will further specify and refine the characteristics of accompanying documentation.

At a later point in the process, the planning and development outcome should be properly recorded internally for implementing updates to the accompanying documentation and maintaining consistency. Such internal records may include, for example:

- document template
- content model (possibly XML based, incl. DTD, XML Schema, or else)
- style guide[20]

[20] For publicly available examples, see Apple Style Guide (http://help.apple.com/asg/) or Microsoft Style Guide (https://docs.microsoft.com/en-us/style-guide/welcome/). See also Annex A of ISO/IEC 26514.

- terminology database
- publishing workflows, scripts (e.g., for screenshots, illustration, PDF/HTML output)

Conclusion

For this stage in the information development process, technical communicators are typically trained to focus on objectives, such as efficiency, cost, and long-term maintainability of the accompanying documentation.

You should openly discuss the accompanying documentation's role in the overall usability of the medical device across teams.

For usability professionals	For technical communicators
In practice, the "design solution" for the accompanying documentation is often vaguer than for the medical device itself. Some aspects of the information development aim to increase efficiency and reduce costs. They may be at odds with the usability of accompanying documentation. Point out if you think so. But accept compromise, if necessary. When cooperating with technical communicator: discuss objectives and priorities, discuss what you can and cannot reasonably test in a usability test.	There is no one single method for doing this part of the information development process. This part is creative work. Discuss and define objectives and priorities with usability professionals and stakeholders. Prioritize aspects of the information design that are most relevant for the project at hand The results of this part of the information development process are the basis for starting to create content. Iteratively refine and improve the information design and the content.

4. Making It Work: Usability Evaluation Methods

Once you have begun developing your accompanying documentation, we strongly recommend that you also start testing it. This section presents a variety of methods that can be used at different times in the development cycle with more or less effort to evaluate your accompanying documentation.

While the methods are described in individual chapters here, this is for the sake of clarity only. Methods may be mixed-and-matched at will, with the exception of the summative usability test which has stricter rules. All other methods allow you to curate a test of your choice. Thus, you may choose to start with an expert review, but add in some reading comprehension questions. Or you may choose to perform a formative usability test and follow it up with a peer review.

These methods are described here in the context of medical devices, but they can be applied across domains. Each method includes insights into when you might want to apply it, how to plan it and what to do with the results, whether you are a usability professional or a technical communicator.

The usability methods we have selected are appropriate for the usability engineering of both the accompanying documentation as well as the medical devices. Furthermore, these methods are also applicable to products in other industries, not only to the domain of medical devices.

We briefly introduce following selection of methods:

4.1. METHOD Peer and Expert Review of Accompanying Documentation

Peer and expert reviewers evaluate a draft of the accompanying documentation according to certain criteria in the expert's area of expertise. To perform the review, the reviewers usually do not require access to the device or to a lab. Because reviewers can usually do this from their desk, this type of review is sometimes called "desk check."

Reviewers could be technical communicators, usability professionals or subject matter experts.

When to use

You can employ peer and expert reviews at almost any stage of a project to pursue different objectives. Peer and expert reviews are primarily performed formatively.

Preceding a revision's sign-off and publication, a final expert review is mandatory for regulatory and liability reasons.

Why to use

Peer and expert reviews are efficient in terms of required resources and achieved outcomes.

Formative reviews will inform the ongoing development and creation process, as do formative usability tests. Formative reviews can be equally worthwhile for early drafts, for individual chapters of an incomplete draft, or simply for selected criteria like those listed below.

Formative reviews are generally advisable preceding more elaborate methods, such as usability testing, to resolve efficiently the most obvious issues early on.

What you need

- A draft of the accompanying documentation or parts thereof, not necessarily completed yet

What to do

Distribute the accompanying documentation's draft to the reviewers including instructions on which criteria to evaluate. Below such criteria and who may evaluate it are given:

- editorial consistency, correctness, and conformance to organizational policies, for example, spelling, style, layout and typography, illustrations, etc.
  being evaluated by fellow technical authors, editors, terminologists, illustrators, and others having editorial content expertise
- technical accuracy
  being evaluated by subject-matter experts, such as development engineers and software developers, or by others with technical expertise, such as technical product managers, customer support specialists
- safety and security
  being evaluated by subject-matter experts who are involved with the risk assessment
- usability of accompanying documentation
  being evaluated by usability professionals
- legal accuracy, compliance, and liability
  being evaluated by regulatory and legal subject-matter experts, such as regulatory affairs managers or legal counsels
- translation and localization
  being evaluated by subject-matter experts who are native speakers, e.g., from national subsidiaries or contractors, or by a second expert translator

Note that not every expert mentioned above necessarily has to evaluate the entire document. For example, a legal counsel may very specifically review only a few certain parts with legal implications, such as the intended use. An engineer involved with the risk assessment, as another example, may only evaluate those parts related to information for safety.

Use of checklists, such as the ones provided in Annex E *Checklists for user documentation* of ISO/IEC 26514, can be helpful.

What to keep in mind

- Storage and sharing of review feedback
  Which software tool is the most suitable for this purpose depends

largely on the software used to create the accompanying documentation and on the mode of publication. For accompanying documentation intended to be printed, the commenting feature of PDF files is tried and tested. For other modes of publication, content-management systems usually provide integrated review and commenting features.
In any case, when you choose the software used to collect feedback, take its feature for archiving the feedback into account. Manufacturers are obligated by regulations to document the review and the resulting changes to the accompanying documentation.

- Project management and scheduling
  - Reviewing feedback is rarely a one-way, top-down channel of communication. Expect significant parts of the feedback to require reconciliation and clarification.
  - Include the technical authors in the scheduling along with the reviewers.
  - If you have many reviewers and large amounts of feedback, have a subject-matter expert first reconcile redundant or contradictory feedback before giving the feedback to technical authors.
  - Designate a content owner. A content owner has the authority to make final decisions about the accompanying documentation's content, for example, in matters of style
  - Plan for a mode of communication between technical authors and subject-matter experts to clarify feedback.
- Completeness of the review regarding the respective criteria above
  Each reviewer should be encouraged to fully evaluate their respective criteria. Ensuring and documenting this is not trivial and will often depend on soft factors, such as corporate culture or the relationships between individuals.

What to expect as a result

Following the review, the technical authors will implement the feedback and will clarify aspects with individual peers or experts if necessary. At one point in time depending on the overall project plan, the technical authors will create a new draft of the accompanying documentation. The new draft may be evaluated using another method, for example, formative usability testing.

For usability professionals	For technical communicators
Expect that technical authors will need to clarify parts of the review feedback with different subject-matter experts. Keep in mind that different stakeholders may direct requests at technical authors that are unrelated to usability. If unwanted effects of such changes to the draft become apparent at a later point, technical authors can trace back the changes to their source and help clarify the matter. Some feedback may be created using heuristic evaluation. In this cae, the result should include the connection to the evaluation criteria chosen.	The work necessary to implement the review feedback can vary significantly. One kind of feedback that is usually easy to implement are simple changes to the phrasing, for example, by an editor. Changing instructions or descriptions that are technically incorrect may require substantial effort on the part of the technical author to clarify the exact details with the respective subject-matter experts. Technical authors will often sift through the feedback before implementing it to identify parts that need clarification. Discerning which feedback is plausible and can be implemented and which feedback needs clarification, is the time-consuming part of a technical author's job as opposed to the actual implementation of the feedback. Clarifying feedback with more than one subject-matter expert or stakeholder in larger organizations may take more time than expected.

4.2. METHOD Formative Usability Testing

Formative usability testing is an evaluation rather early in the development process that involves users in contrast to the previous method "Peer and expert reviews." Users execute tasks and are observed by usability experts in order to gain feedback on the usability of the device or product with or without accompanying documentation. This feedback is used to check and guide further development.

In real life accompanying documentation is not always available or device and documentation are at different stages of the development process. It is possible to test a more advanced prototype of the device with more rudimentary instructions for use, or to test instructions for use independently of the medical device.

If applicable, a different method, independent of the actual medical device, such as formative usability testing of the accompanying documentation only or a reading comprehension test (see further below) may be used.

However accompanying documentation and device are brought together at the end of development and are tested in a summative usability test in order to gain market access.

PRACTIONERS' INSIGHT

Goals of formative usability testing concerning accompanying documentation

Formative usability tests may be employed to find design weaknesses in general, for example, missing page numbers or difficult to find information because of poor structuring. The tests may also aim to determine whether, for example, users can follow the steps contained in the instructions, even if the format has not yet been finalized. This latter test, in particular, demands a prototype of the product, but not necessarily the final product. In particular for devices for which users are expected to need the instructions for use (like many homecare products) formative tests should include both the accompanying documentation and the medical device prototype

When to use

As shown in **Figure 2** on page 17 of the human-centred design process, the evaluation takes place at the end of an iteration loop of development. Formative usability testing concentrates on how well users can execute tasks and what problems arise while carrying out tasks. The main objective is to find usability problems and ways to fix them. Meaning formative usability testing checks the principal understanding and structure of how the prototype of the device works (functional structure, naming of functions, interaction concept). The testing should be carried out as a combination of device and accompanying documentation. Thus, results may affect the device only, the documentation only or the combination of device and documentation. Formative usability testing should be carried out with participants of relevant user groups.

Why to use

Results of the formative usability testing are used to guide further development iterations and activities. They tell the development team if their intended concepts work for users or not. Once several iterations have been carried out and concept as well as medical device are adjusted according to user feedback the stage of summative usability testing is reached.

What you need

Usability testing means that usability professionals observe test participants while they try to solve test tasks with an interactive system. This interactive system consists of the medical device itself as well as all accompanying documentation including, for example, operation manuals and labelling.

Thus, in order to run a usability test - observing users solving tasks - one needs at least a visualization of parts of a system plus the relevant parts of instructions of use. This could be connected sketches of a few first conceptual screens of a command and control sequence, an early low-fidelity prototype, up to to a nearly final system generated with prototyping software, a high-fidelity prototype. The same is true for the instructions of use, they can also vary from a concept up to a near final stage. Apart from the system or visualized parts thereof and the fitting documentation one also needs a good set of relevant usability test tasks. Relevant means relevant for the users as well as intended use. In addition, tasks need to be set and phrased in order to deliver meaningful usability findings for the combination of medical device and documentation. For accompanying documentation this includes finding the correct information within the structure and understanding what to do. Similarly, issues with layout and font, font size etc. may be discovered.

What to do

The following procedure is commonly applied for formative usability testing:

- Preparation: make available prototypes of the product and copies of the accompanying documentation, set focus of the test, recruit relevant test participants, set relevant test tasks.
- Data collection: moderate test, ask a lot of open, explorative question, observe test participants while solving test tasks, record usability findings – positive as well as negative.

- Analysis: analyze and rate findings, report and discuss test results in order to plan future iterations or activities.

Above procedure means explicitly for accompanying documentation:

- Determine what aspects of the accompanying documentation are of interest and derive tasks to test these aspects.
- Observe how participants look for information, what they look at and what they do not look at, ask what they were looking for and expecting to find.
- Observe at which steps participant performed correctly and incorrectly with the accompanying documentation.
- Analyze how often participants found information and how often they did not.

What to keep in mind

Meaningful results are only gained if relevant test participants solve relevant test tasks. Therefore, test participants must be recruited along user profiles set up in the context of use or use specification phase of **Figure 2** page 17. Keep in mind that all prior activities and results must constantly be checked and confirmed or adjusted. In usability testing this means re-checking the validity of user group profiles, intended use and user requirements.

What to expect as a result

The main benefit of formative usability testing is feedback from actual users. Applied early in the development process one will collect feedback on the basic concepts and understanding of the system ideally in combination with the accompanying documentation. Based on the usability test results the development team can steer and decide on necessary iterations and development activities.

Results by usability professionals	Take-away for technical communicators
Usability findings may be positive or negative. How well users understand the underlying structure, workflows, and terms become apparent. Since context of use information is constantly rechecked possible gaps or misunderstandings in context of use description become apparent. The results of formative usability tests will substantiate a draft, or they will point out which parts of the structural concept of the device and which terms of the accompanying documentation lack understanding by the users. Results will give insight into which parts cause misunderstandings and may highlight how to resolve them.	Results and insights gained by usability professionals may affect various parts of the accompanying documentation, such as: • use of terms • phrasing • content structure • illustrations • relation between images and text

4.3. METHOD Reading Comprehension Test of Accompanying Documentation

When to use

Reading comprehension tests may be part of a summative or formative evaluation of the accompanying documentation. This method can be integrated into a test that includes the medical device, but this is unlikely to be a primary use case. Its purpose is to determine whether the information provided can be understood, though not necessarily applied. This is especially important for homecare products.

Why to use

Reading comprehension tests make sense when your wording, and ideally pictures, are set and you want feedback on how well readers will understand what you mean. This may be formative, while you still expect to be making a lot of changes to the text. It may also be summative, to ensure that the text is understandable, i.e., that the readers understand individual sentences.

Some guidance papers[21] call for documents to be written at a specific grade level (e.g., 4th grade or 8th grade) to ensure the readability for the intended users. This is especially the case for lay users. Some sources recommend reading level indices (e.g., Flesh-Kincaid) to determine the reading level. These indices calculate a grade level for a block of text based on the number of words per sentence and syllables per word. While they may help to predict readability, they are no guarantee thereof. Nor does a high reading level necessarily mean that users with less education will not be able to understand it, especially in the medical technology context, long words cannot and should not always be avoided. While such indices can provide additional insight, it is dangerous to rely on them alone.

What you need

Text and/or illustrations must be far enough along that you expect users to be able to understand them. Ideally a wide spectrum of users should be available to read. For homecare products it is particularly advantageous to include participants with lesser education levels or lower fluency in the language being tested to ensure comprehension across the target population.

What to do

During a reading comprehension test, participants are given the entire IFU, sections of the IFU or even single IFU phrases and asked to respond to questions. These questions may be open or closed, often they are multiple choice, including fill-in-the-blank. For example, if participants are presented with a warning detailing the necessary ambient conditions for operation, they may be asked in which of four situations they should not use the device. Or, they may be asked to determine what dosage of a medication a child of a certain age and weight requires based on a dosing table[22].

[21] FDA (2001) *Guidance on Medical Device Patient Labeling* and IEC 60601-1-11:2015 *Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare*

[22] Additional interesting examples are given in a guidance document by the FDA titled *Label Comprehension Studies for Nonprescription Drugs* (2010). This document is not of regulatory importance for medical device manufacturers in general, rather it may provide additional ideas for reading comprehension studies.

What to keep in mind

Which passages of the IFU are chosen for evaluation during a reading comprehension test determine the impact of the results. While in some cases specific passages, like warnings, may be of interest, in other cases generalizable passages like necessary steps may be the focal point.

- Generalizability is dependent upon the passages and participants included.
- Questions must be pre-tested iteratively.
- Tests may be remote or in person.
- Large sample sizes are advantageous.

What to expect as a result

Reading comprehension tests give you an overview of how well users are likely to be able to understand the information you are providing them with. You may find terminology to be revised or learn that your sentence structure needs simplification. While a reading comprehension test won't tell you that users can apply the information you are providing, it will let you know about basic barriers to understanding, a prerequisite for application.

Results by usability professionals	Take-away for technical communicators
• an overview of passages that users can or cannot understand • possible insight into why some passages are difficult to understand, e.g., certain words may repeatedly be misunderstood	Results may identify terms and phrases previously assumed to be easy to understand. Qualitative feedback will provide technical authors with insight into the target audiences and help guide revisions of the content. In addition, quantitative readability scores may provide estimates how well a text is suited for the education level of the target audience.

4.4. METHOD Usability Testing of Accompanying Documentation Only

This method is very similar to the section formative usability testing. There is a big difference though: Only the accompanying documentation is available. The medical device is not available for use during the usability test.

When to use

This method is used when the focus is completely on the IFU and the device is not available. Usability studies of the IFU only may encompass tasks that address how well participants understand information and the extent to which they are able to find information in the IFU. Because the device is not available, or only available to look at, such studies do not need to be completed in any particular environment.

This method makes sense when the IFU is rather far along and has a set form that is to be evaluated. Looking at the IFU only can also make sense if a master IFU is being tested.

Unlike a reading comprehension test, the focus of this test is not just on whether users can understand the words being used, but rather on whether they can transform the words into knowledge that they can apply. Where reading comprehension tests provide the participant with specific sections of the AD to look at, usability testing of the IFU does not, participants are required to find information on their own.

What you need

The IFU needs to be far enough along that users can realistically search for information. It must also be in the correct form, i.e., if it is intended to be used digitally, it should be available digitally. It is especially important here to precisely define what you want to learn, so that tasks can be developed to answer the corresponding questions.

Include technical writers in the preparations for the usability test. They may have certain parts of the accompanying documentation in mind worth checking. Technical writers can provide feedback to usability professionals on planned tasks of the usability test.

What to do

Tasks included in a study that looks at the IFU only can vary in nature, depending on the study's specific goals.

Tasks may focus on understanding the information in the IFU, this can encompass so-called *knowledge task data* - safety-relevant information from the IFU that cannot be tested in a simulated environment. To test the understandability, and to an extent the perceivability, of such information, scenarios in which fictitious users do something that requires the application of the IFU can be constructed. Questions based on these scenarios can then target specific information that users may or may not be able to identify. For example, an instrument tray's IFU may call for it to be used only with specific equipment. To test whether users recognize this information and understand it, a scenario could describe Nurse Alex reprocessing an endoscope using STERRAD in a plastic tray. After reading the scenario, participants would be asked whether Alex proceeded correctly.

The primary challenge with such scenarios is twofold: Including the right amount of information and phrasing questions so that they are understandable, without being on the nose. Both of these factors depend on the specific goals of each task. To determine whether information sticks out and is perceived as important, it may be necessary to include more "fluff" - superfluous information. To determine whether users understand specific information correctly, it can be more useful to phrase questions very precisely (e.g., in the example above, asking whether Alex used a permissible sterilization method).

Tasks might, however, also address how well information can be found. Such tasks can be simpler, for example, asking participants to find out which methods of sterilization a given instrument tray is compatible with. Thought participants may know the correct answer, the trick here is to get them to find the answer in the IFU.

What to keep in mind

During studies that utilize the methods described above, the facilitator should not only note that a question was answered incorrectly, but also what users answered, and, ideally, where they sought and found information in the IFU.

What information was found or not found and how participants proceeded can provide valuable input about the effectiveness of the IFU's format and how it draws attention to specific pieces of information. Incorrect responses can point out how information provided in the document may be misunderstood.

If these methods are used in a summative study, the data points described above may be used to derive and recognize root causes.

What to expect as a result

Testing the accompanying documentation separate from the product can produce similar kind of results as the formative usability test described in Section 4.2 on page 32.

4.5. METHOD Summative Usability Testing

When to use

Summative usability testing is conducted at the end of user interface development to validate the safe and effective use of the user interface and effectiveness of use-related risk mitigation measures (in accordance with IEC 62366-1:2015). The user interface, of course, includes the accompanying documents.

Why to use

Summative usability testing is the most accurate method by which to evaluate the usability of medical devices. It is intended to simulate actual use with intended users. Its focus is evaluating if the users can complete the tasks associated with hazard-related use scenarios without use errors. In case a device is to be marketed in the U.S. also close calls or difficulties need to be analyzed.

What you need

Hazard-related use scenarios which were selected for evaluation.

Representative context of use

- user groups: primary and secondary (as specified) and a sample size of n=5[23] for each distinct user group or n=15 as recommended by the FDA.
- environment: different levels of simulation possible to mimic the actual use environment (usability lab might be sufficient but in other cases a professional medical simulation room is needed)
- tasks: essential tasks and safety-critical tasks; ensure realistic task flow without too many interruptions by the test moderator
- situation (training/briefing, access to accompanying documentation)
- product and accessories (accompanying documentation, labeling, …)

A finalized user interface and the final version of the accompanying documentation is available. The accompanying documentation - as part of the user interface - should be available to the user during the summative usability test, as appropriate to simulate realistic use

[23] Five users per user group is the absolute minimum that notified bodies (e.g., TÜV SÜD) will accept. We do not recommend to use such a small sample size.

PRACTIONERS' INSIGHT

How do formative and summative usability tests differ?

The greatest difference between formative and summative usability studies lies in the fact that for summative studies the product and accessories MUST be production-equivalent. This means the medical device needs to be fully functional and look just like it is intended to look when it hits the market. It also means that the AD needs to be final - final wording, layout, pictures - and in its final format - paper size, font, binding, medium. Summative usability testing may be carried out in the design validation phase - but to keep in mind: if changes have to be made to the product that affect the user interface, these parts must be reevaluated.

However, it is not just the product that is different, the moderator's role is different, too. While formative tests are often conversational in nature, summative tests are not. The moderator's interactions with the participants are generally limited to asking questions to understand the root causes of use errors and difficulties, and, if necessary, clarifying tasks.

The context is different, as well. Formative tests do not need to be as realistic as summative test sessions, which should mimic the medical device's real-world application setting as well as possible.

Finally, the goal is different. A formative test wants to find weaknesses to improve the product and AD. A summative test wants to determine whether all risks have been adequately mitigated.

PRACTIONERS' INSIGHT

How to incorporate the Accompanying Documentation in a summative test

In planning a summative evaluation, you will need to decide how and when to incorporate the accompanying documentation. The usage of the accompanying documentation has to be representative for the specified context of use. If the users have access to the accompanying documentation in real use, they also may have during the test session. In our opinion, there are three possibilities for incorporation of the accompanying documentation in a summative usability test:

1. IN TRAINING SESSION If training is foreseen for the medical device being tested, users may interact with the accompanying documentation as part of this training. They may also be given the opportunity to read the AD during the period of time between training and test sessions or be permitted to look at the AD prior to beginning the first task of the test session (all depending on actual use conditions)
   We think that inclusion of the AD prior to the test session alone, is insufficient.
2. IN TEST SESSION Depending on the product being tested, users may turn to the accompanying documentation for help during the test session (in our experience this is more realistic for home care devices than for professional equipment in the OR). For example, they may look up how to perform novel tasks or to remind themselves how to perform trained tasks. In addition, the test moderator may ask test participants to look up certain things to evaluate the findability and understandability of information in the accompanying documentation in form of knowledge tasks.
3. IN POST-SESSION INTERVIEW Every summative test session should be followed by a post-session interview in which the participant is asked for comments on possibly found usability issues. In this phase of the summative usability evaluation the participant should be asked to read at least all safety instructions and report if anything is not legible or understandable. The information tested at this time often includes warnings that cannot realistically be tested during the test session (see "knowledge tasks" or IEC/TR 62366-2, Sec. 17.3.3.6).

What to do

At the start of a summative evaluation, a usability engineer must first select hazard-related use scenarios to be included in the study. All safety-critical tasks must be included. However, manufacturers may also choose to include all hazard-related use scenarios. Next, successful completion of the tasks related to these scenarios must be operationalized, that is, specific criteria for successful task completion must be defined. For AD in particular, this involves looking at where “information for safety” or “instructions for use” are listed as risk-mitigation factors and determining how this information can be assessed.

During the usability test, participants are observed while they perform tasks with a medical device. Depending on the context of use, the AD may or may not be available during all tasks (for possibilities for including the AD in a usability test, see the “practitioner’s insight” box above). If it is available, participants may refer to it at any time, how referring to the IFU is evaluated, is situation-dependent. For example, looking at an IFU to check a cleaning step for a homecare product is no more than an observation, however, running out of the room to check an IFU on a desktop computer in another room because of a high-priority alarm in a hospital is certainly a use error. In addition to documenting use of the AD during the regular test session, specific questions may also target the IFU in particular, seeking to capture how well participants understand specific information.

Testing involves recruiting targeted users as test participants and asking those users to complete a set of tasks. A test facilitator conducts the testing via a test protocol while the test sessions are typically recorded by a video. The results of the summative usability evaluation are documented in a test report. In addition, a root cause analysis has to be carried out to identify the potential consequences of all use errors that have occurred (see IEC 62366-1, Sec. 5.9).

Usability testing is conducted with participants who are representative of the real or potential users of the system. For some tests, users must have certain domain, product and application-specific knowledge and experience.

What to keep in mind

Apply the following general principles also to the AD:

- Enable realistic tasks in large aggregated tasks.
- Interrupt the test participant as few as possible.
- Do not use the think aloud technique.
- Do a pilot test.
- Attach a post-interview to the observation.

More specific points are:

- realistic access to accompanying documentation
- specifics which require using accompanying documentation
- knowledge tasks asking users for specific information regarding the safe use of the device

In general the goal of usability testing the AD is to assess use errors and use difficulties that occur in the context of AD use or disuse. To ensure that the accompanying documentation is adequately addressed in usability testing special tasks asking the user to work with the AD may be required. This is especially important to address information for safety. For example, users may be asked to perform cleaning based on the instructions for use.

The usability of the accompanying documentation, as evaluated during usability testing can be assessed along the following dimensions:

- effectiveness represented by success rates for use errors, close calls, use difficulties.
- efficiency showing how quickly is able users find information in the accompanying documentation.
- usage of the accompanying documentation throughout a test task e.g. using the IfU several times for one subtask or using the IfU at all.
- participant comments about the understandability of the accompanying documentation.

What to expect as a result

- tested user interface that is safe
- documentation for notified bodies and authorities.

Results by usability professionals	Results for by technical communicators
• measures as to the usability of the medical device, i.e., device in conjunction with the accompanying documentation • safety of use, incl. use difficulty, close calls, use errors • effectiveness • efficiency (optional) • user satisfaction (optional)	If nothing out of the ordinary is being discovered, the results from the summative user interface evaluation usually have no relevance for technical authors. Only in case new unacceptable risks have been found unexpectedly, the accompanying documentation may have to changed. Once changes have been incorporated, the manufacturer must determine whether an additional summative evaluation is necessary.

5. Conclusion

Manufacturers of medical devices need to comply to regulations for usability engineering to market their medical devices. A topic that is often neglected is that accompanying documentation is also part of the user interfaces and therefore needs to be evaluated within the usability engineering process to avoid hazard-related use errors.

To ensure a smooth development of the medical device it is ideal to start thinking about usability engineering as early as possible. But al-ready during the definition of user profiles and the use environment, as part of the use specification, aspects should be included needed by technical communicators. Examples are the users' reading ability or a description of the use environment informing technical communicators how accompanying documentation will be used by users.

It is best to align technical communicators and usability engineers very early on during the development of a medical device and to en-sure they keep working closely together. Ideally work products and feedback are exchanged early and often between the two disciplines. To avoid silos, technical communicators should be invited as observers to formative usability tests allowing them to experience issues with accompanying documentation at first hand. Ideally, the collaboration of usability engineers and technical communicators not only affects the accompanying documentation, but also the text placed on other parts of the user interface.

If both groups interact well, results will be better, and stress is avoided during the project because results are available at the right time. Additionally, if technical communicators and usability engineers coordinate well early on manufacturers avoid schedule overruns and additional costs caused by having to revise insufficient accompanying documentation, which failed during a summative user interface evaluation. A worst-case scenario which in most cases creates severe delays and costs because the medical device cannot be marketed. Instead technical communicators need to apply changes to the ac-companying documentation and usability engineers need to repeat parts of the summative user interface evaluation.

Keeping all the issues mentioned above in mind is important, but at the end what counts is that healthcare providers are enabled to deliver the best treatment for their patients. Correct and usable accompanying documentation can play an important role, but only if its quality is up to the task.

6. References

6.1. Short List of Primary References

This white paper is based primarily on the following references. These pertain specifically to the usability engineering of medical devices and their accompanying documentation.

International standards

[1] IEC 62366-1:2015 Medical devices – Part 1: Application of usability engineering to medical devices (mirrored as EN and ANSI/AAMI standards)

[2] IEC/IEEE 82079-1:2019 Edition 2.0 Preparation of information for use (instructions for use) of products – Part 1: Principles and general requirements

For the USA, FDA guidance documents

[3] Applying Human Factors and Usability Engineering to Medical Devices (FDA Guidance, Feb 2016) https://www.fda.gov/regulatory-information/search-fda-guidance-documents/applying-human-factors-and-usability-engineering-medical-devices

[4] Guidance on Medical Device Patient Labeling (FDA, Apr 2001) https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-medical-device-patient-labeling

6.2. Comprehensive List of References

Related references include standards, the underlying European and US regulations, and traditional publications. This list is intended as a starting point for readers to explore specific aspects.

International standards

[5] ANSI Z535.6-2011 (R2017) Product Safety Information in Product Manuals, Instructions, and Other Collateral Materials

[6] IEC 60601-1-11:2015 Medical electrical equipment – Part 1-11: General requirements for basic safety and essential performance – Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment (mirrored as EN and ANSI/AAMI standards)
[7] IEC TR 62366-2:2016 Medical devices – Part 2: Guidance on the application of usability engineering to medical devices
[8] ISO 9241-11:2018 Ergonomics of human-system interaction – Part 11: Usability: Definitions and concepts
[9] ISO 9241-13:1998 Ergonomic requirements for office work with visual display terminals (VDTs) – Part 13: User guidance
[10] ISO 9241-110:2006 Ergonomics of human-system interaction – Part 110: Dialogue principles
[11] ISO 9241-125:2017 Ergonomics of human-system interaction – Part 125: Guidance on visual presentation of information
[12] ISO 9241-210:2019 Ergonomics of human-system interaction – Part 210: Human-centred design for interactive systems
[13] ISO 14971:2019 Medical devices – Application of risk management to medical devices
[14] ISO/IEC/IEEE 26513:2017 Systems and software engineering – Requirements for testers and reviewers of information for users
[15] ISO/IEC/IEEE 26514:2008 Systems and software engineering – Requirements for designers and developers of user documentation

European regulations and standards

Current regulation, which came into effect in 2017:

[16] Medical Device Regulation 2017/745/EU (abbrev. MDR; specifically, Annex I, Chapter III). http://data.europa.eu/eli/reg/2017/745/oj
[17] *In vitro* Diagnostics Regulation 2017/746/EU (abbrev. IVDR; specifically Annex I, Chapter III). http://data.europa.eu/eli/reg/2017/746/oj
[18] Draft Commission Implementing Decision listing the standards that are planned to be harmonized under the current regulations above (July 2019, https://ec.europa.eu/docsroom/documents/36104)
[19] prEN ISO 20417:2019 Medical Devices – Information to be provided by the manufacturer (will replace EN 1041 [23])

Previous regulation, which is being phased out until 2024:

[20] Medical Device Directive 93/42/EEC (abbrev. MDD; specifically Annex I, Section 13.) https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices_en

[21] *In vitro* Diagnostics Directive 98/79/EC (abbrev. IVDD; specifically Annex I, Section 8.) https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/iv-diagnostic-medical-devices_en

[22] Active Implantable Medical Device Directive 90/385/EEC (abbrev. AIMDD; specifically Annex 1, Section 15.) https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/implantable-medical-devices_en

[23] EN 1041:2008+A1:2013 Information supplied by the manufacturer of medical devices (will be replaced by EN ISO 20417 [19])

US regulations, standards, and FDA guidance documents

[24] Device Advice: Comprehensive Regulatory Assistance (FDA) https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm

[25] Human Factors and Medical Devices (FDA) https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HumanFactors/default.htm

[26] List of Highest Priority Devices for Human Factors Review (FDA, Feb 2016) https://www.fda.gov/media/95804/download

[27] Introduction to Medical Device Labeling (FDA) https://www.fda.gov/medical-devices/overview-device-regulation/device-labeling

[28] ANSI/AAMI HE75:2009 (R2013) Human factors engineering – Design of medical devices

[29] Label Comprehension Studies for Nonprescription Drug Products (FDA, Aug 2010; intended for the labels of drug products as opposed to the accompanying documentation of medical devices, not mandatory regarding compliance of the latter but methodically worthwhile for reading comprehension tests) https://www.fda.gov/regulatory-information/search-fda-guidance-documents/label-comprehension-studies-nonprescription-drug-products

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[30] Bartell, S. & Traynor, B. (2017). ISO/IEC/IEEE Standard 26513 calls for early testing of user documentation. In technical communication, July. Retrieved from http://www.tcworld.info/e-magazine/technical-communication/article/isoiecieee-standard-26513-calls-for-early-testing-of-user-documentation/

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[32] Hackos, J.T. (2007). Information Development: Managing Your Documentation Projects, Portfolio, and People, 2nd ed. Indianapolis, IN: Wiley

[33] Heuer-James, J.-U. (2015). Fulfilling legal market requirements. In technical communication, September. Retrieved from http://www.tcworld.info/e-magazine/technical-communication/article/fulfilling-legal-market-requirements/

[34] Reilly, A. (2016). Standards for software documentation. In technical communication, April. Retrieved from http://www.tcworld.info/e-magazine/translation-and-localization/article/standards-for-software-documentation/

[35] Vermeulen, F. (2016). Creating compliant manuals for the US. In Communicator, Autumn. Retrieved from https://www.istc.org.uk/publications-and-resources/articles/creating-compliant-manuals-for-the-us/

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