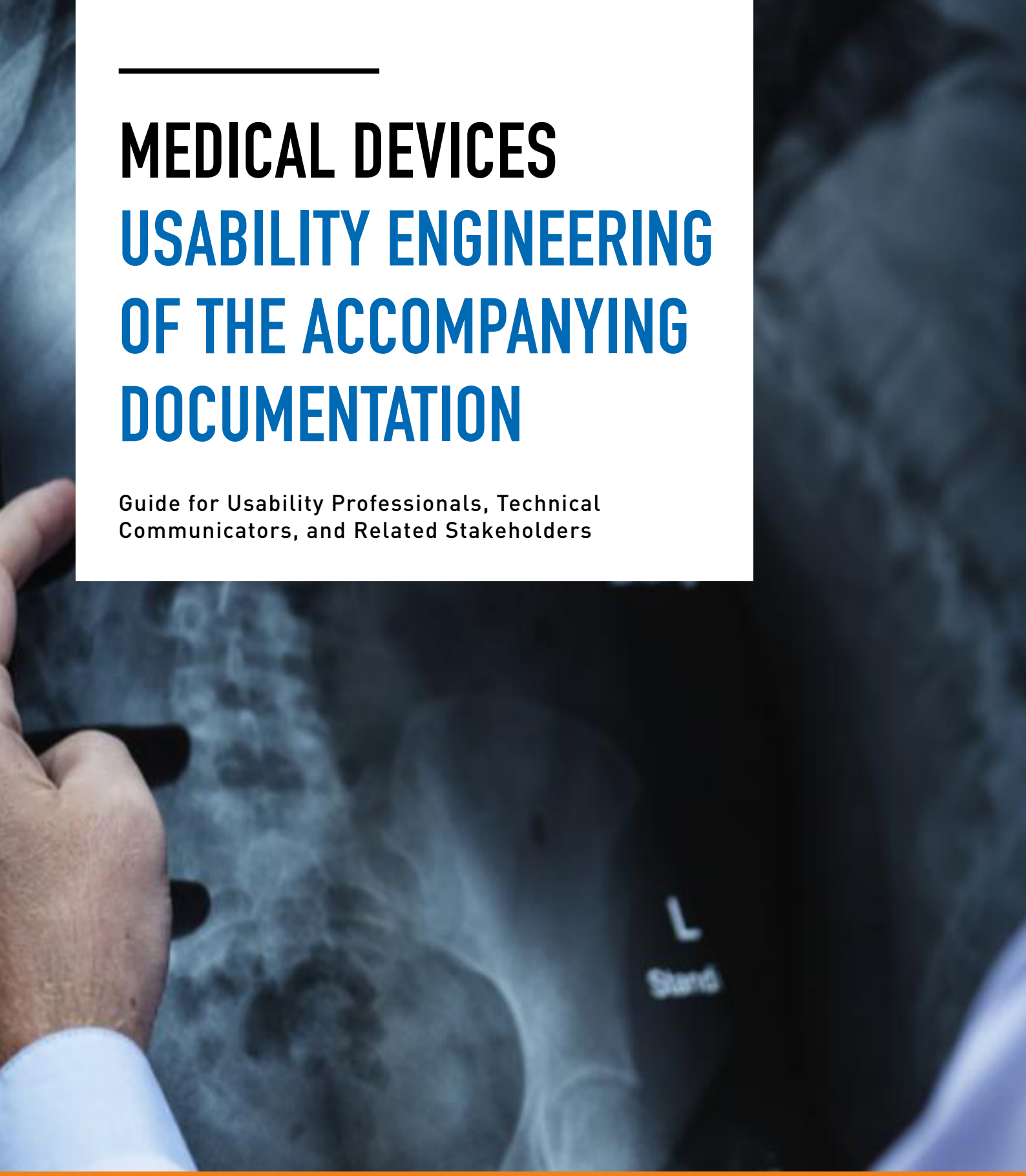


MEDICAL DEVICES
USABILITY ENGINEERING OF THE ACCOMPANYING DOCUMENTATION

Guide for Usability Professionals, Technical Communicators, and Related Stakeholders

GERMAN **UPA**
Berufsverband der Deutschen Usability und User Experience Professionals

Value Proposition

Adding value and cost benefits through well-designed accompanying documentation

Design accompanying documentation with love and care or just fulfil the bare minimum of requirements? This is a decision that medical device manufacturers must make for each product. Our advice is, of course: If you are going to do it (and you have to do it), then do it right, because it is worth it!

Accompanying documentation naturally represents a cost factor for the device's production and thus increased investments for purchasers. But at the same time, new value factors emerge when accompanying documentation is done right, and they must not be neglected in quality and investment decisions that are based on a holistic calculation of the real effects that an investment has on everyday operation. Manufacturers and purchasing departments alike must broaden their view on accompanying documentation.

For purchasing departments this means: Costs and values/benefits must be viewed from a cradle-to-the-grave perspective in order to promote everyday practice. The true and maybe invisible quality factors and unique selling propositions of medical products and services need to be identified and considered for a sustainable decision.

Old business models have had their day. Thus, one-to-one cost decisions, that is, simple feature comparisons or a comparison of two product offerings, are questionable. The entire service and application cycle must be included in the purchase decision.

New business models that are based on holistic and systemic views onto the daily operation are certainly on the rise. Instead of focusing purely on hardware features or on the obvious product perception, the accompanying documentation must not be seen as a pure add-on material or merely as a legally required appendage to the product but rather as an service and quality aspect equivalent to the whole usage ecosystem

of the product. This new and essential role of the accompanying documentation serves new aspects and benefit parameters for decision makers in the purchase role.

Breakdown of Costs and Sketching a New Business Perspective

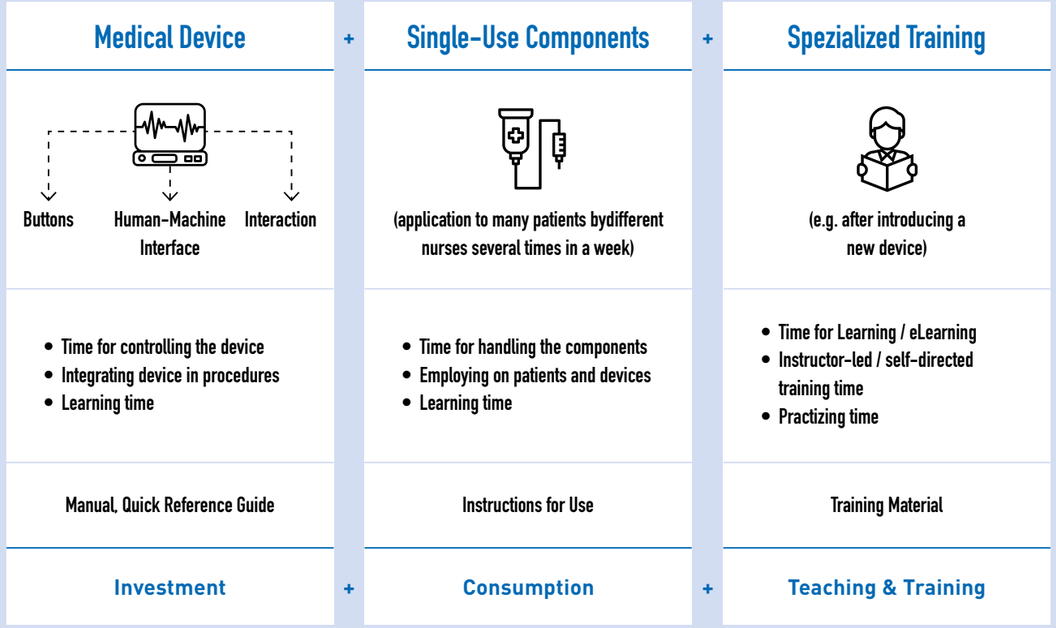
We find that there are at least two misleading thoughts regarding costs of a new medical device that is going to be purchased:

- Costs are a one-time investment that is mainly determined by the price of the medical device and its maintenance or all single-use components for the device. Thus, finding a more affordable device or cheaper single-use components will result in lower costs.

- Costs can be reduced by purchasing a medical device with a better usability because this will require lower effort and costs for staff training (e.g. in Matern 2013, p. 428).

Of course, these two thoughts do have a certain legitimacy. However, they are somewhat misleading with regards to the total investment that can be expected for the time the device will be in use in any healthcare facility. In fact, the total investment costs for the introduction of a new medical device feed on three components (see **Figure 1**):

Figure 1 Cost components of a medical device from a meta viewpoint.



- Medical device: costs for the medical device itself (hardware, Human Machine Interface, and software), operation and maintenance costs, and healthcare staff costs related to time, handling effort, and use errors during medical procedures.

- Single-use components: costs for all disposable components that are necessary to apply the medical device in the treatment of patients and healthcare staff costs related to time, handling effort, and use errors.

- Teaching and (re-)training: costs for the training offered by the manufacturers and healthcare staff costs related to time and effort for learning or practicing.

Applying these cost-components to an example: The costs for an injection pump comprise costs for the pump, costs for disposables, for example, syringes and catheter sets, costs for handling effort, and costs for training healthcare staff. Additional costs are associated with administrative tasks, maintenance, and handling all supplies.

In each component, parts of the accompanying documentation are involved. Yet the accompanying documentation is typically underestimated as a cost factor: Healthcare staff reads the user manual, for instance, to get a first impression of how to operate the new device or to check the meaning of a rarely-seen device status display. They read the handling instructions of single-use components if they are from a new manufacturer or if the design has been revised. They may also work through the training material or complete an exercise (again), for example, in the real (hospital) context, in case the training was based on e-learning.

This leads to our assumption that the formula 1 + 1 = 3 is true for the medical device industry.

Applying good design and usability engineering to accompanying documentation creates a new value that manufacturers should consider in their business models.

Unproductive or rather time-consuming support and training materials lead in many cases to higher losses and negative returns although the product itself initially appears to be cheaper compared to competitors' products with sufficient documentation.

A Simple Case Cost Calculation

In the following rough calculation, we want to examine the effect that well-designed accompanying documentation may have on costs. For the sake of argument, we assume that healthcare staff costs 1 Euro per hour. For the ease of calculation, we only look at the training component of the accompanying documentation.

Now looking at the design of a training: We know from experience that contextual micro-learning units are better for skill-based learning than standard learning concepts (see Gerstheimer et al. 2019). Micro-learning deals with providing relatively small learning units and to allow short-term (from a few seconds to 15 Min) learning activities in the context of knowledge application. The cognitive load of micro-learning units is low but the learning success is high (details see e.g. Hug 2007).

In the calculation, we are continuing the example of the injection pump that is going to be purchased for a hospital with 1.000 employees. The variable is the design of the training:

Table 1 Exemplary comparison of costs for a well or poorly designed training component for a medical device.

	Design variant 1	Design variant 2
Time for training	120 min	10 min
Costs per nurse	120 €	10 €
Costs hospital	120.000 €	10.000 €
Delta	**110.000 €**	

- **Design Variant 1:** Training consists of reading a manual and an instructor-led training unit in a training room. Reading the and the training take 60 Min each.
- **Design Variant 2:** Training consists of integrating contextual training units (as videos) in the context of use (the hospital). There are 5 training units, each spans 2 Min.

Looking at the calculation makes clear that a better designed training may reduce costs for introducing a new medical device in a hospital. There are even more savings possible when looking at the design of the other materials, for example, the instructions for use.

Further, any user of a medical device, for example, nurses, doctors, and other healthcare staff, invest time when applying the different materials. This is not only the case during training, but actually every time when any part of the accompanying documentation is consulted. This is the staff's time on the clock, which adds up. These costs can justify purchasing a device which has better accompanying documentation to offer, because a more expensive medical device or more expensive single-use components, do not necessarily result in the highest total investment costs.

The "Good Design" Advice

By good design we mean executing an integrated and user-oriented service approach across all user touch-points, from marketing material to user training to the instructions for use to maintenance and expert documentation. (e.g., see Privitera, 2019)

The cost and value formula of good design is universal and simple: Time is money! And time can be saved through good design. Contextual and user-oriented design of the accompanying documentation can pay off in incredible savings as time presents. On top a better user experience in everyday and frequent usage or in relevant operations is possible, especially when many stakeholders are involved.

Good design goes beyond only looking at the standard usability design criteria effectiveness, efficiency, and satisfaction. It is about providing particular information bits at the right moment and in the right context in a suitable modality and fitting media type. Considerable design aspects and keywords are for example: reading time, comprehensibility, international understandability / universal language, visualization, cross-media implementation, located/deposited information, and content modality. The micro-learning approach seems to be a good base to start with (see Gerstheimer et al. 2019). Experienced design professionals should be integrated in the design process (see Bailey 2020, p. 140).

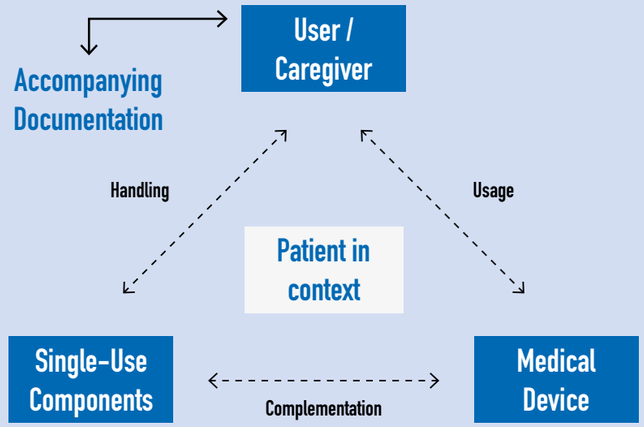
Conclusion

Truly good medical devices are only as good as their accompanying documentation including training materials, instructions for use, and other use-in-context instructions. The accompanying documentation is a facilitator and enables healthcare staff to fulfil their tasks with patients. Their tasks require using that medical device and handling related medical supplies. The accompanying documentation may accelerate or decelerate them, depending on their design and efficient support of users.

A holistic view of all elements involved in user interactions with the medical device for its specific use cases and context of use is necessary as the basis for design and usability engineering of the accompanying documentation (see Figure 2).

Usability engineering and design are related counterparts in this matter. In order to develop a good design of all elements, hardware, software, and accompanying documentation, must be brought to contextual knowledge and operational key results.

Figure 2 Holistic view on using accompanying documentation in context



Accompanying documentation should become a unique selling point for manufacturers in the future. Designing (user-oriented) materials with microlearning concepts has generated positive results in our experience. Therefore, our recommendations for manufacturers of medical devices include:

- Focus on usability as well as on good design when integrating the IEC 62366-1 process. You can save effort if you focus on both right from the beginning. The stakeholders are already involved. Thus, costs will not rise but the results will be much more valuable for the end-users. Do look at the market size for your device: The larger the market for the device is, the higher becomes the value of your well-designed accompanying documentation.
- Do not wear blinders. The IEC 62366-1 standard focuses on minimizing risks caused by insufficient usability. Other goals, such as a higher market success or market differentiation, are not primarily addressed. Thus, aim not only at compliance with regulations but also at good design thus enhancing your market success and differentiation. The larger the market the higher the value of your well-designed accompanying documentation can be.
- Do integrate design professionals in the development process of the accompanying documentation. Only then will the added value (through good design) bear fruits. The costs for developing well-designed accompanying documentation – which is short, contextual, and available – is lower than typically expected.

Working Group Medical Devices

The working group Medical Devices is one of 11 working groups of the German UPA, the German branch of the international UXPA.

There are some 20 active members in the working group working for medical device manufacturers either directly as employees or as consultants and contractors.

The working group's main objectives are:

- to integrate a human-centered design perspective with the highly regulated medical device development processes
- to provide a networking platform for experts from the medical device industry as well as usability engineering community
- to exchange experiences and on state-of-the-art processes and techniques
- to publish and contribute to conferences

We still have a lot to do. New members are always welcome.
Interested? Write us: ak-medizintechnik@germanupa.de

Find news and updates from the working group on:
www.germanupa.de/arbeitskreise/arbeitskreis-medizintechnik/

Scope

In this guide, we show in detail how to integrate processes of usability and technical communication. The two professional communities are closely related and share the common goal to enable users and ensure safety. Yet in practice, professionals from the two communities do not cooperate as much as one might expect.

We focus on the specific topic of medical devices and the usability engineering of their accompanying documentation. Medical device manufacturers must take the safety of patients, users, and third parties into careful consideration. Safety is the main concern of regulators. Therefore, applying usability engineering to the development of medical devices is mandated by international regulations.

Domain-specific aspects of medical devices aside, parts of this guide apply to the usability engineering of information for use in general. On a meta level, we wish to help bridge the gap between usability professionals and technical communicators — a gap that is larger in day-to-day practice than necessary.

We intend this guide to be the basis for a common understanding and collaboration among the diverse professionals and stakeholders involved in the usability engineering process:

TECHNICAL COMMUNICATORS
USABILITY PROFESSIONALS

RELATED STAKEHOLDERS:

PRODUCT MANAGERS
SOFTWARE DEVELOPERS
DEPARTMENT HEADS
QUALITY MANAGERS
DEVELOPMENT ENGINEERS
EXECUTIVES
RISK MANAGERS
REGULATORY AFFAIRS PROFESSIONALS
OTHERS INVOLVED

REGULATORY BODIES:

NOTIFIED BODIES IN THE EU
GOVERNMENT AUTHORITIES, SUCH AS THE FDA

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Chapter 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 medical device industry 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 all the most essential terms and concepts.

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).

DEEP DIVE

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 con text 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.

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

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)

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

[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 me dical 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

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

Torsten Gruchmann and Roland Schmeling have illustrated this overlap (not all terms included) in the Venn diagram in Figure 3. Their distinctions are valid and worthwhile.

For the purpose of this guide, 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 3 Overlapping concepts related to accompanying documentation[8]

[8] Figure 3 is adapted from a presentation by Gruchmann & Schmeling at the tekom annual conference 2018, available from https://www.use-lab.com/download/sonstiges/NORM01%20Gruchmann_Schmeling%20GA_Medizinprodukte.pdf, translated from German, included with their kind permission.

DEEP DIVE

NORMATIVE REFERENCES ON ACCOMPANYING DOCUMENTATION

In IEC 62366-1:2015 (Sec. 3.2) on usability engineering for medical devices, accompanying documentation is defined as to include any kind of information for the user and emphasizes safe use. The 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.

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
- description of improper use or possible hazards
- promotion of the use of protective equipment
- information about measures to reduce harm
- specification of necessary maintenance intervals or maximum service life
- ways 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

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

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.

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.

"Medicine used to be simple, ineffective, and relatively safe.

It is now complex, effective, and potentially dangerous."

(Sir Cyril Chantler)

Chapter 02

Usability Engineering and Information Development: Matching Processes and Terms

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

Information Development

Based on the context of use analysis, a project's lead technical communicator will plan and develop fundamental aspects of the accompanying documentation.
Thereafter, technical authors and illustrators can start to create the content. The first draft of the accompanying documentation will be evaluated formatively using one or multiple methods of those laid out below. Feedback and findings from formative evaluations are then used to iteratively revise and reevaluate the accompanying documentation.

Hence, compared on a high level, information development is similar to other development and engineering processes. 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. planning how to implement the above – or producing a design solution in usability terminology
4. creating the content or implementation
5. iteratively evaluating (i.e., by reviewing, testing, etc.) and revising drafts of the accompanying documentation.

Requirements, objectives, and constraints can be derived, in part, from overlapping activities with product development and usability engineering. For example, the user group profiles (included in the use specification) 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 further defined for the accompanying documentation.

Considering documentation-specific dependencies throughout a product's life cycle

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 [10]. Auditors may scrutinize any change's traceability. In contrast to changes to, for example, marketing materials, changes to the accompanying documentation are often significantly more complex. Factoring in future changes and updates to the accompanying documentation from the start will therefore help the entire project with respect to:

- staying on schedule
- improving the accompanying documentation's quality
- making use of synergies across hardware/software engineering, usability engineering, and information development

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.

Particular specifications of the accompanying documentation

In development processes, requirements, such as the ones introduced above, are satisfied by a set of specifications. Particular specifications of the accompanying documentation include, for example:

- the content model
- types of media and layout
- decisions on standardization, such as terminology, spelling, writing style, illustration styles

Specifications will then be used by individual technical authors, illustrators, and others to create the actual content. The creation of content corresponds to implementation in other engineering processes.

Note that content is not limited to text and illustrations but includes non-obvious aspects, such as a Document Type Definition (DTD) intended for XML-based authoring tools. A DTD is a common form of implementation of the content model specification. In authoring tools, the layout will be implemented in a document template that supports the consistent use of formats, such as paragraph and character styles.

At some point all of these aspects and decisions will be documented internally in the form of a style guide for future revisions of the accompanying documentation. Standardization of, for example, terminology, spelling, style, usage, typography, illustrations, etc., is part of the expertise of technical communicators.

Standardization reduces ambiguity, improves the long-term maintainability of the accompanying documentation, and facilitates the translation process. In addition, standardization can benefit any user-facing content, such as user interfaces, customer support content, or marketing content in terms of comprehensibility, maintainability, and translatability.

[10] 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

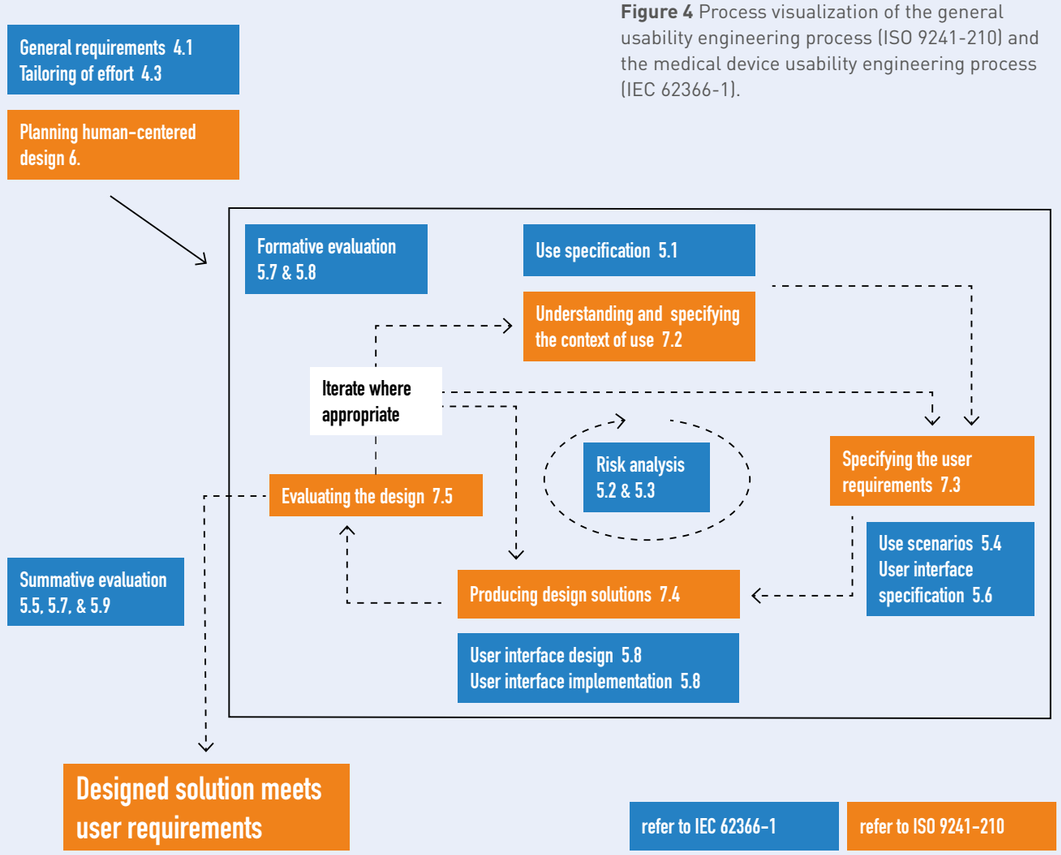


Figure 4 Process visualization of the general usability engineering process (ISO 9241-210) and the medical device usability engineering process (IEC 62366-1).

Comparing and aligning processes

To compare the usability engineering and information development processes, we chose to focus on the level of individual projects. The larger perspective of entire organizations takes business management processes into account and is beyond the intended scope of this guide.

An iterative process

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.

Plan

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 defines how much effort needs to be expended – very much dependent upon 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 objectives 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.

Research and analyze

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.

Develop requirements

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

Create the design solution

Then, a design solution is created in one form or another (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. Creating a design solution includes defining the workflows for users, deciding which user interface elements will be used and selecting color schemes. This applies to industrial as well as to user interface design.

Implementation done by specialists

The implementation is done by technical specialists, such as software developers, mechanical design engineers, or, in the case of accompanying documentation, by technical authors, technical illustrators, and others.

Evaluate

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 drive the appropriate iterations as shown in **Figure 4 on page 25**. At the end of the development cycle, the summative evaluation determines whether 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.

Comparison of relevant standards

In **Table 2 on page 28-29**, 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:

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

Note that the comparison in **Table 2** 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 2**, we want to provide a basic orientation and help start the conversation between professionals from different fields.

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 worth considering. Usability engineering might address some of the claims made in the clinical evaluation plan. A claim might be that patient adherence will be higher because of a better user experience or improved workflows.

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

Such examples illustrate that summative usability testing results may contribute valuable data to other empirical studies.

Table 2 High-level comparison of processes: usability engineering and information development.

	Usability engineering process steps Paraphrased	Information development process steps Paraphrased	Chapter in ISO 9241-210:2019	Chapter in IEC 62366-1:2015	Chapter in IEC/IEEE 82079-1:2019	Chapter in ISO/IEC 26514:2008
1	Planning human-centered design	Planning information management	6	4.1, 4.3	5.4, 6.1, 6.2, 6.3.1	5
2	Understanding and specifying the context of use (users, user goals, resources, environment)	Gathering basic information; researching target audiences	7.2	5.1	6.2.1, 6.2.2, 6.3.2	6
3	Risk management	Risk management	N/A	5.2, 5.3	6.2.7	N/A
4	Specifying the user requirements	Researching and formulating project requirements, goals, and constraints; defining testable criteria	7.3	5.4, 5.6	6.2.1, 6.2.2, 6.3.2	6
5	Producing design solutions	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	7.4	5.8	6.3.2	7
6	Implementation of prototypes (software, hardware, and mechanics)	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	N/A	5.8	6.3.2	8
7	Performing formative evaluation, i.e., an evaluation that is intended to improve the concept	Performing review of drafts (i.e., desk check; at least by editors or peers and by SMEs or the designated content owner), empirical evaluation of drafts	7.5	5.7.2, 5.8	6.3.3	8
8	Iteratively redesigning and reevaluating	Implementing review/evaluation feedback, additional review/evaluation loops	7.2, 7.3, 7.4	5.1 to 5.8	6.3.2, 6.3.3	8
9	Implementation and final assembly of the system	Finalizing the content and producing final output media	N/A	5.8	6.4	9
10	Content freeze of the accompanying documentation's final version	Performing the final review for sign-off (i.e., desk check by SMEs or designated content owners)	N/A	N/A		
11	Performing summative evaluation for compliance purposes This evaluation is intended to measure the usability of the system in conjunction with the accompanying documentation.	Formal sign-off by the respective executives after completion of the summative evaluation	7.5	5.5, 5.7.3, 5.9		

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 completed successfully, 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 new 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.

Chapter 03

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 now turn 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 documentation.

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 and for 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:

- **Context of Use Analysis**
- **Planning and Developing the Accompanying Documentation**

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.

Note that the intended user and patient group may be one and the same. However, as they may be distinct from each other, we reference them separately. Terminologically, technical communicators often refer to "user groups" as "target audiences."

Why to use

The intended user or patient groups and their context of use vary and are specific to each medical device. The analysis of user groups, their tasks and goals, as well as the use environment 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, usability professionals will collect the required data on the context of use. Such data may include:

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

This information can be gained by observing or interviewing users. In addition, other employees within a company who interact with users regularly are often a good source of information, for example, customer support representatives, service technicians, or marketing representatives.

The distinction between lay users (i.e., home-care products) and professional users (i.e., medical devices in hospitals) is an important one regarding user research and product design. Regarding lay users, one usually cannot assume that they have prior subject matter knowledge about a medical device. If they do, for example, possibly in case of patients with chronic conditions (e.g., diabetes), the user research should reflect this. Professional users can be assumed to have a certain understanding of general concepts, such as hygiene procedures, or specific concepts, for example, radiological protection in case of X-ray technicians.

What to do

A context of use 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:

- 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 the following aspects:

- 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 is generally collected early in the product development and then refined as additional data is 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

Specifically regarding the accompanying documentation, the context of use analysis should collect and analyze detailed information on the following aspects:

- 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

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 • use environment description • all of the above is comprised in the use specification	• target group analysis • task analysis

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.

On Planning and Developing the Accompanying Documentation

Producing the design solution for 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 2 on page 28-29**.

Such aspects of planning and developing accompanying documentation include, for example [11]:

- applicable regulations and standards affecting accompanying documentation
- further technical, organizational, and market-related properties or limitations
- 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)

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) and Usability of Products and Instructions in the Digital age: Manual for Developers, IT Specialists, and Technical Writers by Gertrud Grünwied (2017, in German).

[11] 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

What to expect as a result

Concluding this stage early in the process is usually not possible. In coordination with other team leads, the lead technical communicator will specify the subset of requirements, objectives, and constraints for the accompanying documentation as far as necessary 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 similar)
- style guide [12]
- terminology database
- publishing workflows, scripts (e.g., for screenshots, illustration, PDF/HTML output)

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.

[12] 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.

Conclusion

For this stage in the information development process, technical communicators often have stronger focus on such objectives 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 that for the medical device itself. Some aspects of the information development, e.g., content re-use strategies, aim to increase efficiency and reduce costs. Sometimes such aspects may negatively affect the usability of accompanying documentation. Such conflicts should be openly discussed across teams if they come up. When cooperating with technical communicators: discuss objectives and priorities from your point of view, discuss what you can and cannot reasonably test in a usability test.	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 early stage in the information development process should allow technical authors to start creating content. Iteratively refine and improve the information design and the content.

Chapter 04

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 of medical devices. Furthermore, these methods are also applicable to products in other industries, not only to the domain of medical devices.

We briefly introduce the following selection of methods:

- **Peer and Expert Review of Accompanying Documentation**
- **Formative Usability Testing**
- **Reading Comprehension Test of Accompanying Documentation**
- **Usability Testing of Accompanying Documentation Only**
- **Summative Usability Testing**

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".

Suitable reviewers include technical communicators, usability professionals, and 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.

Generally, formative reviews should precede more elaborate methods, such as usability testing, to efficiently resolve the most obvious issues early on.

What you need

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

In case of medical devices intended for international distribution, a translation of drafts may be necessary. For example, if translation into numerous target languages is foreseeable, it may be feasible to create the translation master in English even if the usability testing is not being done with English native speakers, because translators who translate from English into other languages are more readily available.

What to do

Distribute the accompanying documentation's draft to the reviewers, including instructions on which criteria to evaluate. The following is a selection of such criteria and who may evaluate it:

- editorial consistency, correctness, and conformance to organizational policies, for example, spelling, style, layout and typography, illustrations, etc.

- evaluated by fellow technical authors, editors, terminologists, illustrators, and others having editorial content expertise

- technical accuracy

- 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

- evaluated by subject matter experts who are involved with risk assessment

- usability of accompanying documentation

- evaluated by usability professionals

- legal accuracy, compliance, and liability

- evaluated by regulatory and legal subject matter experts, such as regulatory affairs managers or legal counsel

- translation and localization 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 certain parts with legal implications, such as the intended use. An engineer involved with the risk assessment, as another example, may only evaluate 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

Regarding 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 a software 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.

Regarding 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.

- Allow 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,

For usability professionals	For technical communicators
Expect that technical authors almost always have to clarify parts of the review feedback with subject matter experts. Allow for such a channel of communication. 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 methods. In this case, the result should include the details about the evaluation criteria used.	The effort 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.

if necessary. At some 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.

METHOD Formative Usability Testing

Formative usability testing is an evaluation rather early in the development process in order to gain feedback on the usability of the accompanying documentation and/or product, where:

- users execute tasks

- are observed by usability experts

PRACTIONERS' INSIGHT

GOALS OF FORMATIVE USABILITY TESTING CONCERNING ACCOMPANYING DOCUMENTATION

Formative usability tests may be employed to find design weaknesses, for example, difficulties finding information because of poor structuring, understanding of fundamental layout and whether users can follow steps contained in the instructions. This latter test demands a prototype of the medical product, not necessarily the final product. It is advisable to apply formative tests early in the development in particular for devices where instructions for use are expected to be used later on, such as homecare products.

The formative usability test is carried out either with

- accompanying documentation alone

- medical device or product alone

- both of the above (ideal situation)

The results of formative usability testing are used to check and guide further development.

When to use

As shown in **Figure 4 on page 25** of the human-centred design process, the evaluation takes place at the end of an iteration loop of development. At this stage of development the main objective is

- to find usability problems and understand why they occur

- to get user feedback on the concept of documentation and/or medical device

- guide further development and generate user input for the next iterative development step

Thus, results may affect the device only, the documentation only or the combination of device and documentation.

Why to use

Since results of formative usability testing are used to guide development steps it serves three purposes

- involving users in development for user-centred products

- increase usability and understanding of documentation, device or combination of both by feeding user feedback into development

- comply with regulatory requirements

What you need

Formative usability testing means that usability professionals observe test participants while they solve test tasks. Thus you need

- the documentation and/or product in a concept state, prototype state, or final state

- test participants

- moderation guideline including test tasks

Test participants are selected according to user groups of the medical product that documentation is to be tested. For example, a homecare blood glucose meter might have the following user groups:

- persons with type 1 diabetes

- persons with type 2 diabetes

- relatives

- diabetologists

- diabetes specialist nurses

Formative testing is a qualitative approach and tries to find out "what" is being understood and "why" or "why not." Thus, the usual number of participants ranges from 3 to 10 participants per user group. A helpful methodology for gaining additional qualitative data is the "think aloud" method. Here, test participants speak out "loud" and tell the test moderator what they perceive and see and why they are doing what they are doing.

The **moderation guideline** lays out the entire test procedure from start to end. It is used by the moderator during the test session itself and includes all test tasks. It needs to be archived since it contains all the information needed to understand the test at a later time.

The **test tasks** that participants are asked to complete need to be relevant to the respective user groups. Relevant means: They are chosen taking into respect what tasks and interactions the user group is expected to have with the device in the future.

In the above example, persons with diabetes would run through the procedure of gaining a blood sample [13], measuring the glucose level and reading it from the meter. Thus the test will evaluate the usability of the device and the usability of the documentation if it is needed in order to work the task.

If the primary goal is the use and understanding of the documentation, test tasks might be geared towards forcing use of the documentation.

What to do

The following procedure is commonly applied for formative usability testing:

- Plan:
  Set main questions to be answered by the test, consider time and budget available.

- Recruit:
  Choose relevant user groups. The user group profile will list personal characteristics as well as tasks and goals of that user group.

PRACTIONERS' INSIGHT

HOW MANY PARTICIPANTS ARE NEEDED FOR FORMATIVE TESTING

3 to 10 participants per user group will add up to a significant number of test sessions which often exceeds time and costs. Since the development is iterative, one usually concentrates on the user groups which are relevant for the main questions the test shall answer.

If the main purpose of the study is how users handle and use the device, in the example above, persons with type 1 or 2 diabetes would be invited to participate.

If your goal is to identify risks and evaluate mitigations, you would also invite the direct users (persons with diabetes and possibly caring relatives in the above example). Alternatively, you could also invite a risk-expert to review the document to identify optimization potential and follow this up with user testing in a later iterative step.

- Test preparation:
  Set test tasks according to overall test question and user group profile. Check that available prototypes of documentation and/or product support selected test tasks. Compile moderation guideline including pre and post questionnaire.

- Data collection:
  Moderate test, set tasks, observe test participants and apply the "think aloud" methodology. Protocol usability findings and other results.

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

For accompanying documentation, the procedure described above means:

- Determine what aspects of the accompanying documentation are of interest and set 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 what they were expecting to find.

- Observe at which steps participants performed as expected and unexpected with the accompanying documentation.

- Analyze how often participants found information, how often they did not, why not and what they looked for instead.

[13] Generally any step that would require using a needle on a person is only simulated, to avoid ethical concerns and the necessity for special ethics approval, e.g., through an institutional review board (IRB).

What to keep in mind

Clearly define the question you want the test to answer. If you are performing the test for a client or an in-house division require a clear question to be answered. Preparation, correct recruitment, possibly an adjustment of the moderation guideline and good moderation are also essential in getting meaningful results.

Formative testing is often applied early in the development. It may use paper and pencil prototypes even in a rough state. However, a short formative test with feedback from relevant future users will help direct development early on and thus potentially save time, money and effort in comparison to late user testing.

It is also a good opportunity to re-check if the context of use analysis is valid or has to be adjusted.

Formative testing with users helps to differentiate between perceived good interaction (development team thinks it knows what will work well for users) and actual good interaction (users show what works well for them and demonstrate what does not work well for them).

For usability professionals	For technical communicators
• As a usability tester, insist on a clearly defined question for the test to answer. • Always report positive as well as negative usability findings. Positive findings are to be kept and also increase the acceptance of the test results by the development team, since there good points as well as potential for optimization. • As a moderator be curious and let the users talk. • Constantly re-check the context of use description and adjust if necessary. • Formative testing will give valuable input early on in the development. Fast, lightweight testing is better than late or no testing. • Involve all stakeholders as early as possible.	Results and insights gained by usability professionals may affect various parts of the accompanying documentation, such as: • use of terms • phrasing • content structure, detail and depth • use of illustrations and graphics • relation between images and text

What to expect as a result

The main results of formative testing is feedback on the concept, structure and information of accompanying documentation and, if tested together, the medical product.

Due to the qualitative nature of formative testing, the results will tell the technical communicator and the development team what aspects of the concept work well, what aspects have to be improved and, if the test is run well, why the initial concept was not or poorly understood by users.

Based on these results the development team can steer and decide on necessary iterations and further development activities.

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 understand the intended meaning. 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. Reading comprehension tests may also be a useful method in the context of translations.

Some guidance papers...[14] 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 context of medical devices, long words cannot and should not always be avoided. While such indices can provide additional insight, it is dangerous to rely on them alone.

[14] 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

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. 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 instructions for use, sections of the instructions for use, or even single instructions for use phrases and asked to respond to questions. These questions may be open or closed, often they are multiple choice, including fill-in-the-blanks. 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...[15].

What to keep in mind

The selection of passages selected for evaluation during a reading comprehension test determines 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.

Results by usability professionals	Take-away for technical communicators
• An overview of passages that users can or cannot understand and that can be generalized • 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 f or the education level of the target audience.

[15] 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 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 that terminology needs to be revised or learn that your sentence structure needs simplification. While a reading comprehension test won't tell you whether or not users can apply the information in practice, it will let you know about basic barriers to understanding, a prerequisite for application.

METHOD Usability Testing of Accompanying Documentation Only

This method is very similar to the section on 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 instructions for use and the device is not available. Usability studies of the instructions for use only may encompass tasks that address how well participants understand information and the extent to which they are able to find information in the instructions for use. 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 instructions for use is rather far along and has a set form that is to be evaluated. Looking at the instructions for use only can also make sense if a master instructions for use 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 accompanying documentation to look at, usability testing of the instructions for use does not, participants are required to find information on their own.

What you need

The instructions for use need 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 that are worth checking. Technical writers can provide feedback to usability professionals on planned tasks for the usability test.

What to do

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

Tasks may focus on understanding the information in the instructions for use, this can encompass so-called knowledge task data (safety-relevant information from the instructions for use 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 instructions for use 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 instructions for use 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 the STERRAD sterilization method 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," that is, 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. Though participants may know the correct answer, the trick here is to get them to find the answer in the instructions for use.

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 instructions for use.

What information was found or not found and how participants proceeded can provide valuable input about the effectiveness of the 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 on **page 45**.

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 documentation.

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. If a device is to be marketed in the U.S. also close calls or difficulties need to be analyzed.

[15] This is in line with the FDA and IEC 62366-1:2015 by using concepts such as hazard-related use scenarios and critical tasks.

What you need

Hazard-related use scenarios which were selected for evaluation.

Representative context of use:

- user groups: primary and secondary (as specified)
- 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: focus on tasks that contribute to a medium or high level of risk [16]; 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, etc.)

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

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. For FDA compliant summative evaluations 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 test tasks must be defined.

During the usability test, participants are observed while they perform tasks with a medical device. Depending on the context of use, the accompanying documentation may or may not be available during all tasks. If it is available, participants may refer to it at any time; how referring to the accompanying documentation is evaluated, is situation-dependent. For example, looking at accompanying documentation t o check a cleaning step for a homecare product is no more than an observation, however, running out of the room to check the accompanying documentation 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 accompanying documentation during the regular test session, specific questions may also target the accompanying documentation 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.

For tasks involving accompanying documentation it is necessary to identify where "information for safety" or "instructions for use" are listed as risk control measures. Then it is necessary to decide how and when to incorporate the accompanying documentation into the summative evaluation. The use of the accompanying documentation has to be representative of the specified context of use. If the users have access to the accompanying documentation in real use, they also may have it during the test session. In our opinion, there are three possibilities for incorporating of the accompanying documentation in a summative usability test:

1. During test session

The test moderator may ask test participants to execute either knowledge tasks during which users need to demonstrate they remember or look up certain information regarding the safe use of a medical device.

Especially for homecare devices it might be necessary to create special test tasks which ask users to execute the task using the accompanying documentation actively. This might be necessary in order to show that information in the accompanying documentation is not presented in a confusing way.

For example, users may be asked to perform cleaning based on the instructions for use. This might involve choosing the right type of towel, the correct cleaning agent, and executing each step in a correct order, while explicitly using the accompanying documentation.

During test tasks users may also turn to the accompanying documentation for help during the test session (this is more realistic for certain use environments such as homecare devices than an operating room). For example, they may look up how to perform novel tasks or to remind themselves how to perform trained tasks. This can provide good insight into how well the accompanying documentation works.

2. During 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. During this phase or even in extra session afterward the summative usability test the participant should be asked to read at least information for safety identified in the risk analysis. The information tested at this time often includes warnings that cannot realistically be tested during the test session. To address all goals of IEC 62366-1:2015 the user should be asked for what to do in a certain case. Then the user has to do the following:

- a. Find the information within the accompanying documentation.
- b. Understand the information.
- c. Verbalize the correct action.

The verbalizating is a proxy for understanding the accompanying documentation and being able to act accordingly. This represents the bare minimum to fulfill the requirements of IEC 62366-1.

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 accompanying documentation during the period of time between training and test sessions or be permitted to look at the accompanying documentation prior to beginning the first task of the test session (all depending on actual use conditions). Inclusion of the accompanying documentation prior to the test session alone, is insufficient to show that the user interface is safe to use.

Some medical device standards prescribe exact wording for some information for safety. This might fail during summative user interface evaluation. For more information on this see the **practitioners' insight box "conflicting requirements for information for safety."**

What to keep in mind

Apply the following general principles to the accompanying documentation:

- Enable realistic tasks in large aggregated tasks.
- Interrupt the test participant as little as possible.
- Do not use the think aloud technique.
- Perform a pilot test.
- End with a post-interview.

More specific points are:

- realistic access to accompanying documentation
- specific test tasks that 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 accompanying documentation is also to assess use errors and use difficulties that occur in the context of accompanying documentation use or disuse.

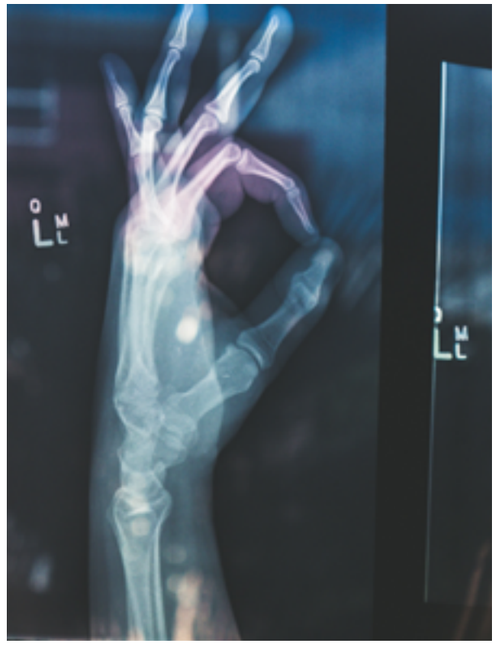
The usability of the accompanying documentation, as evaluated during usability testing can be assessed along the following dimensions:

- effectiveness represented by success rates of test tasks or no discovery of use errors, close calls, and use difficulties [17].
- efficiency showing how quickly users are able to find information in the accompanying documentation.
- use of the accompanying documentation throughout a test task e.g. using the accompanying documentation several times for one subtask or using the accompanying documentation at all.
- participant comments about the understandability of the accompanying documentation.

In case a use error, close call or use difficulty is discovered, a root cause analysis is necessary. Of great importance for this root cause analysis are the results of the post-interview with the test participant.

What to expect as a result

- user interface including accompanying documentation that is safe to use
- documentation for notified bodies and regulatory authorities.



Results by usability professionals	Take-away for 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 discovered, the results from the summative usability evaluation usually have no relevance for technical authors. • Only if new, unacceptable risks are found unexpectedly, will the accompanying documentation have to change. • Once changes have been incorporated, the manufacturer must determine whether an additional summative evaluation is necessary.

[17] As for writing this paper close calls and use difficulties are only relevant for FDA compliant usability tests.

Chapter 05

Conclusion

Manufacturers of medical devices have to comply with 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 interface and, therefore, has to be evaluated within the usability engineering process to avoid use errors.

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

It is best to align technical communicators and usability professionals very early on during the development of a medical device and to ensure they keep working closely together. Ideally, work products and feedback are exchanged early and often between the two disciplines. Technical communicators should be invited as observers to formative usability tests, allowing them to experience issues with accompanying documentation first hand. Ideally, the collaboration of usability professionals and technical communicators not only affects the accompanying documentation, but also the text placed in 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 professionals 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 accompanying documentation while usability professionals need to repeat parts of the summative user interface evaluation.

Keeping all the issues mentioned above in mind is important, but in 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.

Chapter 06

References

Short List of Primary References

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

International standards

- IEC 62366-1:2015+AMD1:2020 Medical devices – Part 1: Application of usability engineering to medical devices
- ISO 9241-210:2019 Ergonomics of human-system interaction – Part 210: Human-centred design for interactive systems
- IEC/IEEE 82079-1:2019 Edition 2.0 Preparation of information for use (instructions for use) of products – Part 1: Principles and general requirements
- ISO/IEC/IEEE 26514:2008 Systems and software engineering – Requirements for designers and developers of user documentation

For the USA, FDA guidance documents

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

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

- ANSI Z535.6-2011 (R2017) Product Safety Information in Product Manuals, Instructions, and Other Collateral Materials
- 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
- IEC/TR 62366-2:2016 Medical devices – Part 2: Guidance on the application of usability engineering to medical devices
- ISO 9241-11:2018 Ergonomics of human-system interaction – Part 11: Usability: Definitions and concepts
- ISO 9241-13:1998 Ergonomic requirements for office work with visual display terminals (VDTs) – Part 13: User guidance
- ISO 9241-110:2020 Ergonomics of human-system interaction – Part 110: Dialogue principles
- ISO 9241-125:2017 Ergonomics of human-system interaction – Part 125: Guidance on visual presentation of information
- ISO 14971:2019 Medical devices – Application of risk management to medical devices
- ISO/IEC/IEEE 26513:2017 Systems and software engineering – Requirements for testers and reviewers of information for users

European regulations and standards

- Current regulations, which came into effect in 2017:
- Medical Device Regulation 2017/745/EU (abbrev. MDR; specifically, Annex I, Chapter III). http://data.euro pa.eu/eli/reg/2017/745/
- In vitro Diagnostics Regulation 2017/746/EU (abbrev. IVDR; specifically Annex I, Chapter III). http://data.europa.eu/eli/reg/2017/746/
- ISO 20417:2020 Medical Devices – Information to be supplied by the manufacturer (will replace EN 1041 [23])
- Previous regulations, which are being phased out until 2024:
- 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
- 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
- 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
- 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

- Device Advice: Comprehensive Regulatory Assistance (FDA) https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm
- Human Factors and Medical Devices (FDA) https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HumanFactors/default.htm
- List of Highest Priority Devices for Human Factors Review (FDA, Feb 2016) https://www.fda.gov/regulatory-information/search-fda-guidance-documents/list-highest-priority-devices-human-factors-review
- Introduction to Medical Device Labeling (FDA) https://www.fda.gov/medical-devices/overview-device-regulation/device-labeling
- ANSI/AAMI HE75:2009 (R2018) Human factors engineering – Design of medical devices
- 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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Regulatory References

- The IEC 62366-1[18] standard is the primary, internationally accepted reference on usability engineering for medical devices. For technical communicators, the primary references are IEC/IEEE 82079-1[19] 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[20]. For the accompanying documentation of medical devices specifically, EN 1041[21] is the relevant standard. However, it is going to be replaced by the new ISO 20417[22], which is currently under development.
- In Europe, EN 1041 and the outdated IEC 62366 are listed as harmonized European standards under the regulations MDD[23] and IVDD[24]. Under the new regulations MDR and IVDR, the upcoming 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[25].
- For the United States, IEC 62366-1 is mirrored by the national organizations ANSI and AAMI as ANSI/AAMI/IEC 62366-1:2015.
- In December 2016, the US Food and Drug Administration (FDA) 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.

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

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

[20] 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

DEEP DIVE

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.

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

[22] ISO 20417:2020 *Medical devices – Information to be provided by the Manufacturer*, latest draft at the time of publication

[23] *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)

[24] *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)

[25] *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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German UPA

The German UPA is the professional association of German usability professionals. The association is a network by and for usability experts who want to contribute to the knowledge transfer and opinion formation of all topics related to usability. Within the German UPA, members collaborate in different working groups on specific subject matters.

Its members bring experience from various professional fields and work in diverse functions and positions across the industry and government. New members are always welcome.

You can find more information on the German UPA website.

www.germanupa.de

Imprint

Medical Devices: Usability Engineering of the Accompanying Documentation
Guide for Usability Professionals, Technical Communicators, and Related Stakeholders

Edition 1.0

Published by the German Usability Professionals Association

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Publisher
German UPA e.V.
Keplerstrasse 2
39104 Magdeburg
Germany

Publication date
2020

This publication is available from the working group's Web page:

www.germanupa.de/arbeitskreise/arbeitskreis-medizintechnik

German UPA e.V.
Keplerstraße 2, 39104 Magdeburg
www.germanupa.de

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