THE WHITEPAPER

UNDERSTANDING

USABILITY ENGINEERING IN MEDICAL DEVICES

A Guide to IEC 62366-1

CRAFTED BY

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CALL OUT

In most countries, regulatory requirements mandate that manufacturers establish, document, implement, and maintain a **usability engineering process** to ensure the safety and effectiveness of medical devices for patients, users, and other stakeholders. The most common standard is **IEC 62366-1** published in 2015 and meanwhile supplemented by a corrigendum COR1 in 2016 and an Amendment AMD1 in 2020).

INTENDED OUTCOME

The main goal of this whitepaper is to enable professionals to ensure the process complies with IEC 62366-1. In the following you will get detailed information on

- how **the process is structured**,
- which **deliverables are expected** of the usability professional and
- how to **fulfill the requirements** of each step of the process.

INTENDED AUDIENCE

This whitepaper was created for usability engineers, regulatory affairs specialists, and quality assurance professionals involved in the development and approval of medical devices. In details it is intended for:

Usability Engineers & Usability Professionals who are tasked with integrating usability practices into medical device development and ensuring that these practices comply with relevant standards.

Regulatory Affairs Specialists who need to ensure that all aspects of device development, including usability, meet regulatory requirements.

Quality Assurance Professionals who oversee the quality and safety of medical devices, focusing on the usability aspect to mitigate risks associated with device use.

MANAGEMENT SUMMARY

In the increasingly complex landscape of medical devices, ensuring **usability** is paramount not only for **user satisfaction and task efficiency but, more critically, for patient and user safety**. Inadequate usability can lead to **use errors**, which in turn can result in **hazardous situations and harm**. Recognizing this critical link, the International Electrotechnical Commission (IEC) has developed **IEC 62366-1**, a foundational standard that specifies a **usability engineering (also referred to as human factors engineering) process** for medical device manufacturers. By adhering to the principles and practices outlined in IEC 62366-1, manufacturers can systematically analyze, specify, design, and evaluate the usability of their medical devices, thereby **mitigating risks associated with normal use**. This process must address **all user interactions with the medical device** as described in the accompanying documentation, encompassing aspects from transport and storage to installation, operation, maintenance, repair, and disposal. It is crucial that **usability engineering activities are planned, executed, and documented by competent personnel** with the necessary education, training, skills, or experience.

The standard emphasizes a strong **link between the usability engineering process and the risk management process** outlined in **ISO 14971**. The usability engineering process serves as a vital input to risk analysis by identifying potential **hazards and hazardous situations arising from use errors**. Conversely, the risk management process informs the usability engineering effort by highlighting safety-critical aspects of the user interface. Where a documented product realization process exists (e.g., as per **ISO 13485**), the usability engineering process should be appropriately integrated or referenced within it. The **Usability Engineering File (UEF)** is a central element of this process, serving as a repository for **all records and documents produced throughout the usability engineering lifecycle**. Compliance with IEC 62366-1 is primarily verified through inspection of this file.

THE MEDICAL USABILITY ENGINEERING PROCESS ACCORDING TO IEC 62366-1 IN DETAIL

IEC 62366-1 defines 10 main steps involved in the usability engineering process:

1. Prepare use specification
2. Identify user interface characteristics related to safety and potential use errors
3. Identify known or foreseeable hazards and hazardous situations
4. Identify and describe hazard-related use scenarios
5. Select hazard-related use scenarios for summative evaluation
6. Establish user interface specification
7. Establish user interface evaluation plan
8. Perform user interface design, implementation and formative evaluation
9. Perform summative evaluation of the usability of the user interface
10. Evaluate overall residual risk related to use

It's important to understand that the ten steps of this process don't necessarily have to be in a fixed order. Rather, the process is iterative and may require a flexible sequence of steps, depending on the specific requirements and characteristics of the medical device and the results achieved during the development process. In the following, the steps are explained in detail.

1 PREPARE USE SPECIFICATION

The process begins with the preparation of a **use specification**, a critical document that serves to define the context in which the medical device will be used. It begins often with a preliminary phase that gathers available data before detailed usability activities commence. This preliminary specification might initially be as simple as a statement of intended use, outlining the medical indications, user groups, and use environments to be explored further. The process of refining the use specification is iterative, adapting as more information is obtained through user research, which could necessitate additional research activities. In detail, the standard asks to include the following aspects:

Intended medical indication
Generally speaking, the intended medical indication of the medical device serves as a basic input for all development activities. It specifies the condition(s) or disease(s) that the medical device is designed to screen, monitor, treat, diagnose, or prevent. This includes a clear definition of the medical purpose of the device.

Intended patient population
In this section, characteristics such as age group, weight range, health status, or specific conditions of the patients for whom the device is intended are specified.

Intended part of the body or type of tissue applied to or interacted with
Here, the specific anatomical location or tissue type involved in the device's use is specified.

Intended user profiles
The user profile documentation captures detailed characteristics of specific user groups, such as demographics, knowledge, skills, and limitations, including physical and cognitive impairments.

Intended use environment
The actual conditions and settings where users will interact with the device, including factors like lighting, noise, temperature, frequency of use, location (e.g., hospital, home), and social attributes (e.g., individual vs. team use, stress levels) are described in this section.

Operating principle
A high-level description of how the medical device functions. Specific tasks or actions that the device performs as part of its intended use.

Anticipated tasks (not mandatory)
Although not explicitly mentioned, outlining the anticipated tasks of users in the operation of the medical device can be valuable in supporting subsequent usability engineering activities.

The **use specification** serves as a fundamental input for identifying potential hazards and hazardous situations related to the user interface. It also forms the foundation for defining the **user interface specification**. Apart from that, it provides relevant input for the planning of **formative** and **summative user interface evaluations**.

2 IDENTIFY USER INTERFACE CHARACTERISTICS RELATED TO SAFETY AND POTENTIAL USE ERRORS

As part of the risk analysis process (according to ISO 14971), manufacturers are required to **identify user interface characteristics that could be related to safety and potential use errors**. This identification is typically performed by applying task analysis methods based on the previously mentioned anticipated tasks and involves usability professionals. By going through the human-product interaction step by step, corresponding user interface characteristics and potential use errors can be identified. A **use error** is referred to as an **action or lack of action** by a user during the use of a medical device that leads to a different outcome than intended by the manufacturer or expected by the user.

3 IDENTIFY KNOWN OR FORESEEABLE HAZARDS AND HAZARDOUS SITUATIONS

Building upon the identified user interface characteristics this step includes 2 major activities:

A

Identify **foreseeable hazards and hazardous situations** that could arise from the potential use errors identified in step 2.

B

Research **known hazards and hazardous situations** that have arisen from users interacting with the medical device to date. This can be done by conducting a corresponding literature or database search.

! It must be mentioned that the identification of known or foreseeable hazards and hazardous situations is a core component of the risk management process outlined in ISO 14971 but usually needs to be supported by usability engineering.

4 IDENTIFY AND DESCRIBE HAZARD-RELATED USE SCENARIOS

Once hazards and hazardous situations are identified, manufacturers need to **identify and describe hazard-related use scenarios.** A use scenario describes an interaction where a user from a specific user profile engages with the medical device to achieve a particular outcome within a defined use environment. Accordingly, a hazard-related use scenarios describes a sequence of events including potential use errors, that could lead to a hazardous situation. It is written from a user's perspective and in sufficient detail to understand the potential risks. We recommend defining all correct use scenarios before starting to create hazard-related use scenarios. This makes it much easier to follow the process.

5 SELECT HAZARD-RELATED USE SCENARIOS FOR SUMMATIVE EVALUATION

Not all identified hazard-related use scenarios may require summative evaluation. The standard presents 3 options to **select the hazard-related use scenarios that will be included in the summative evaluation**. All options require a clearly defined selection scheme and a rationale which is reasonable and well documented.

OPTION 1

Select all hazard-related use scenarios for SUMMATIVE EVALUATION. This option requires the least justification but the most evaluation effort.

OPTION 2

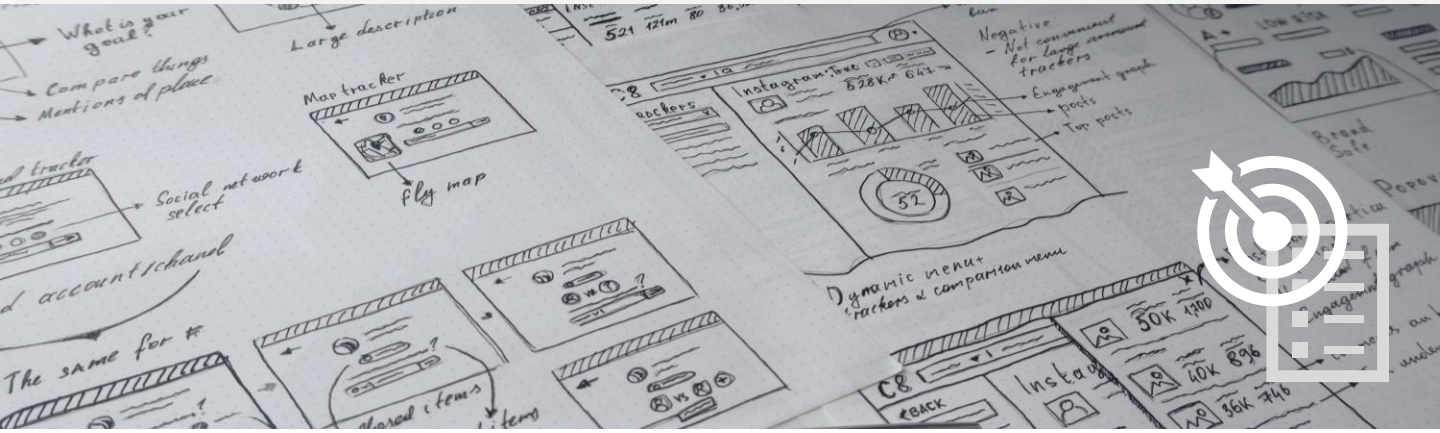
Select a subset of the hazard-related use scenarios based on the severity of the potential harm that could be caused by a certain use error. This option requires a selection scheme that clearly rates the severity level of harm resulting from each use error. Note that the relevant standard does not define a certain severity level as critical as other international guidelines do.

OPTION 3

Select a subset of the hazard-related use scenarios based on the severity and additional circumstances specific to the medical device and the manufacturer. This option offers a loophole for manufacturers that want to define a selection scheme not only based on the severity level of harm but on additional circumstances like the probability of harm. Note that this option should only be chosen if valid data are available, and the selection scheme and the rationale are well documented.

6 ESTABLISH USER INTERFACE SPECIFICATION

The **user interface specification** contains the specifications of the user interface requirements, which should ensure that the solution is well suited to the intended users. It is the design input for all user interface design activities. Therefore, it should be established early in the usability engineering process to provide valuable design inputs to the engineering team in relevant stages of the development. However, in iterative design methodologies, it may need to be updated and refined based on insights gained from **formative evaluations**. Within this section, the standard requires manufacturers to specify the user interface requirements of the medical device in detail so that the **design characteristics of the user interface are clearly defined**. Therefore, it should take into account the use specification, known or foreseeable hazards, potential use errors, and hazard-related use scenarios. Make sure that you write your **user interface specification** so that it includes **testable technical requirements** such as the coloring or size of user interface control elements. Also specify whether accompanying documentation or a specific training for your medical device is required.



7 ESTABLISH USER INTERFACE EVALUATION PLAN

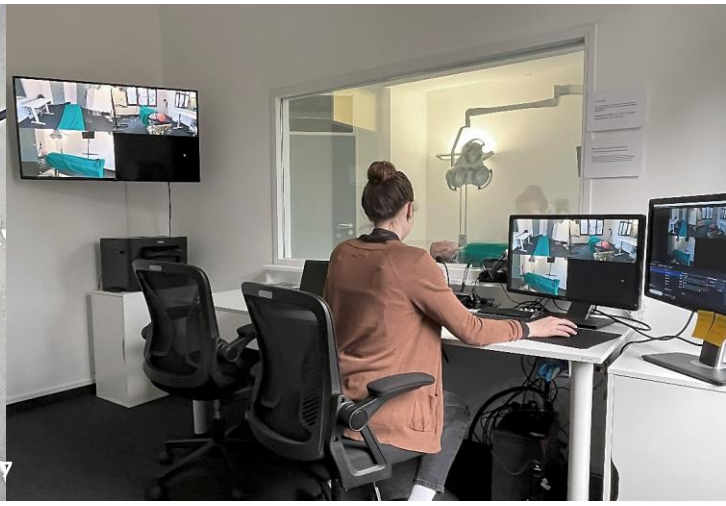
Detailed and frequent evaluation is a core element of the usability engineering process. Therefore, the standard requires manufacturers to establish a **user interface evaluation plan**, outlining the **objectives, methods, and criteria for all user interface evaluation activities including formative and summative evaluations**. Plainly said, this plan specifies how the user interface design will be evaluated throughout the development of the medical device. While simulated use usability tests are standard for **summative evaluations**, methods such as expert reviews and cognitive walkthroughs are also widely recognized for **formative evaluations**.

8 PERFORM USER INTERFACE DESIGN, IMPLEMENTATION AND FORMATIVE EVALUATION

This step involves the **design and implementation of the user interface** based on the user interface specification. An **iterative user interface design methodology** is strongly recommended, with formative evaluations conducted throughout the development process to gather user feedback and identify usability issues early on. **Formative evaluations** serve two main purposes:

- Gather input to improve the user interface while still under development **(design focus)**
- Identify previously unknown use errors that could lead to hazardous situations **(safety focus)**

A multidisciplinary team approach involving users, engineers, usability specialists, and other relevant stakeholders is essential. Formative evaluations aim to **explore and refine the design** and can employ various methods such as expert reviews, cognitive walkthroughs, and early-stage usability tests (simulated use). The results of formative evaluations should inform design revisions.



9 PERFORM SUMMATIVE EVALUATION OF THE USABILITY OF THE USER INTERFACE

Upon completion of the user interface design and implementation, usually a **summative evaluation** needs to be performed on the **final or production-equivalent user interface**. This evaluation aims to **validate the safety of the user interface** by assessing its effectiveness in the context of the selected hazard-related use scenarios.

Summative evaluation typically involves **usability tests (simulated use) with representative users** performing defined test tasks derived from the selected hazard-related use scenarios under conditions that simulate the intended use environment. A summative evaluation is not based on any rigid, technical test criteria but rather includes analyzing qualitative data collected during a usability test. For this evaluation to be successful, the collected data must enable the manufacturer to determine that no additional improvements to the user interface are needed, or that they are not feasible. Therefore, it is required that this data contains a **detailed description of all upcoming use-related problems (use errors, close calls and difficulties) and the associated root causes** of these problems. Summative usability tests are challenging activities involving a team of trained and experienced usability professionals.

The test personnel usually consists of two professionals, a test facilitator moderating the test tasks and a note-taker observing and documenting the human-product interaction in detail.

10 EVALUATE OVERALL RESIDUAL RISK RELATED TO USE

Upon completion of the summative evaluation, the results are transferred into the risk management process to **assess whether the residual risk related to the use of the medical device is acceptable**. This involves:

- **Reviewing the outcomes** of the usability engineering process and the data collected in the summative evaluation. This is usually done in workshops involving both usability and risk professionals.
- **Evaluating the residual risk** according to the risk management process based on ISO 14971. This is an activity performed by the corresponding risk responsible.

The standard requires that all identified use-related problems identified during summative evaluation must be reviewed during this step so make sure you address both use errors, close calls and difficulties. In case additional risk control measures are implemented based in the results of the summative evaluation, all design changes of the user interface must be reviewed to ensure they have not introduced new hazards or hazardous situations.

THE IMPORTANCE OF THE USABILITY ENGINEERING FILE

The **Usability Engineering File (UEF)** is the cornerstone of compliance with IEC 62366-1. It serves as the **central repository for all documentation generated throughout the usability engineering process**. This includes, but is not limited to:

- The **use specification**.
- Records of identified **user interface characteristics related to safety and potential use errors**.
- Records of **known or foreseeable hazards and hazardous situations** related to the user interface.
- Descriptions of **hazard-related use scenarios**.
- The rationale for **selecting hazard-related use scenarios** for summative evaluation.
- The **user interface specification**.
- The **user interface evaluation** plan.
- **Formative** evaluation protocols and reports.
- **Summative** evaluation protocol and report.
- Records of the overall **residual risk** evaluation related to use.
- **Justification** for any deviations or exclusions from the standard.

A well-maintained UEF **provides objective evidence of adherence to the usability engineering process** and facilitates regulatory review.

CONCLUSION

The medical usability engineering process as defined in IEC 62366-1 is an **indispensable element of medical device development.** By systematically applying the steps outlined in this standard, usability and quality professionals can ensure that medical devices are **safe and effective for their intended users and use environments**. The process, with its strong emphasis on **human-product interaction, risk mitigation, and thorough evaluation**, ultimately contributes to **reducing use errors and enhancing patient safety**.

Adherence to IEC 62366-1, supported by comprehensive documentation within the Usability Engineering File, is not merely a regulatory requirement but a fundamental commitment to producing medical devices that are both usable and safe for those who rely on them. The guidance provided in **IEC TR 62366-2** further supports the effective implementation of this critical process and contains additional, valuable information.

DISCLAIMER

This white paper is for informational purposes only and provides a general overview of the usability engineering processes according to the IEC 62366-1 standard. It is not intended as a comprehensive or exhaustive source for the standard itself and does not replace the official publications or the detailed reading of the IEC 62366-1 standard. Readers are strongly encouraged to refer directly to the complete texts of the standard issued by the International Electrotechnical Commission (IEC) to ensure they understand and comply with the latest and accurate requirements.

REFERENCES

IEC 62366-1:2015
Medical devices – Part 1: Application of usability engineering to medical devices. International Electrotechnical Commission, Geneva, Switzerland, 2015.

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