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Understanding Usability: Definition and Principles

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What is usability?

Characteristics of the user interface that facilitate use. This is, characteristics that make it easier for the user to perceive and understand the information presented by the user interface, and to make decisions based on that information. Also, **the characteristics that facilitate the interaction with the medical device** to achieve its specified goals in the intended use environments.

It is the responsibility of the manufacturer to establish, document, implement and maintain a usability engineering process to provide safety for the patient, user and others. These activities shall be planned, carried out, and documented by competent personnel on the basis of appropriate skills or experience.

Usability and Safety

Safety is defined as freedom from unacceptable risk. Unacceptable risk can arise from use error, which can lead to exposure to direct physical hazards or loss or degradation of clinical functionality.

The usability engineering process shall **analyze the interactions between the user and the device**, including, but not limited to those mentioned below.

Many of these factors can influence safety to various extents. This way, **the application of usability engineering as a process directed to identify and minimize use errors**, is able to reduce risks associated with normal use and identify risks associated with abnormal use.

Interactions between the user and the device:

Transport
Storage
Installation
Operation
Maintenance
Disposal

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Usability engineering for risk reduction

Use error

User action (or lack of) **that leads to a different result** than that intended by the manufacturer or expected by the user while using a medical device.

Abnormal use

Conscious, intentional act or omission that is contrary to or violates normal use and is also beyond any further reasonable means of user interface-related risk control by the manufacturer (such as reckless use or sabotage).

Some, but not all, forms of incorrect use are suited to control by the manufacturer. This way, the usability engineering is closely linked to the risk management process.

To reduce use-related risk, **the manufacturer shall use one or more of the following options**, in descending order of priority:

Inherent safety by design

Protective measures in the medical device itself or in the manufacturing process

Information for safety (perceivable, understandable, and supportive to correct use)

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Usability Engineering Process

The Usability Engineering Process is performed according to the following checklist:

1 Use Specification is prepared:

- Medical indication
- Patient population
- Part of the body or type of tissue interacted with
- User
- Use environment
- Operating principle

2 Identification of user interface characteristics that could be related to safety.

3 Identification of known or foreseeable hazards and hazardous situations:

- During the identification, additional information should be considered, such as information regarding similar devices and already identified use errors.

User Interface

All means of interaction between the medical device and the user (both hardware and software interfaces), such as:

- Elements that require manual manipulation
- Cables and tubing connections
- Accessories
- Handles
- Force required to move the weight
- Work surface height;
- Dimensions that affect reach requirements;
- Markings and accompanying documentation;
- Video displays
- Push buttons
- Touch screens
- Auditory, vibratory, tactile, and visual signals to inform users
- Voice recognition
- Keyboard and mouse
- Haptic controls

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4 Identification of Hazard-Related Use Scenarios

- The manufacturer must identify and describe the reasonably foreseeable hazard-related use scenarios linked to the associated hazards and hazardous situations identified in step 3. Each identified hazard-related use scenario should include a description of all tasks and their sequences, as well as the severity of the associated harm.

5 Selection of the hazard-related use scenarios for evaluation.

- Typically, either all of them, or a set of scenarios designated based on the severity of the potential harm.

6 Establishment of user interface specification.

7 Establishment of user interface evaluation plan.

8 Design and implementation of the user interface.

- Including accompanying documentation and training if needed.

9 Perform summative evaluation of the usability of the user interface.

Summative evaluation

User interface evaluation conducted at the end of the user interface development with the intent to obtain objective evidence that the user interface can be used safely.

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