Usability Engineering
IEC 62366-1:2015

In February 2015, IEC 62366-1 *Medical devices - Part 1: Application of usability engineering to medical devices* replaced the prior version, which is now obsolete. The new standard, and its US counterpart, are FDA-CDRH recognized consensus standards.

The new standard contains a large number of definitions, many of which have been revised from the previous version. In addition, the process flow underwent significant changes. As in the previous version, however, there is a strong reliance on the linkage to ISO 14971:2007.

An important concept is the Use Scenario, which means (to paraphrase the definition) the sequence of tasks a user performs and the response from the medical device. This is an important element, since it helps define the relationship between the user and the device as mediated by the interface. Figure 1 illustrates a Use Scenario.

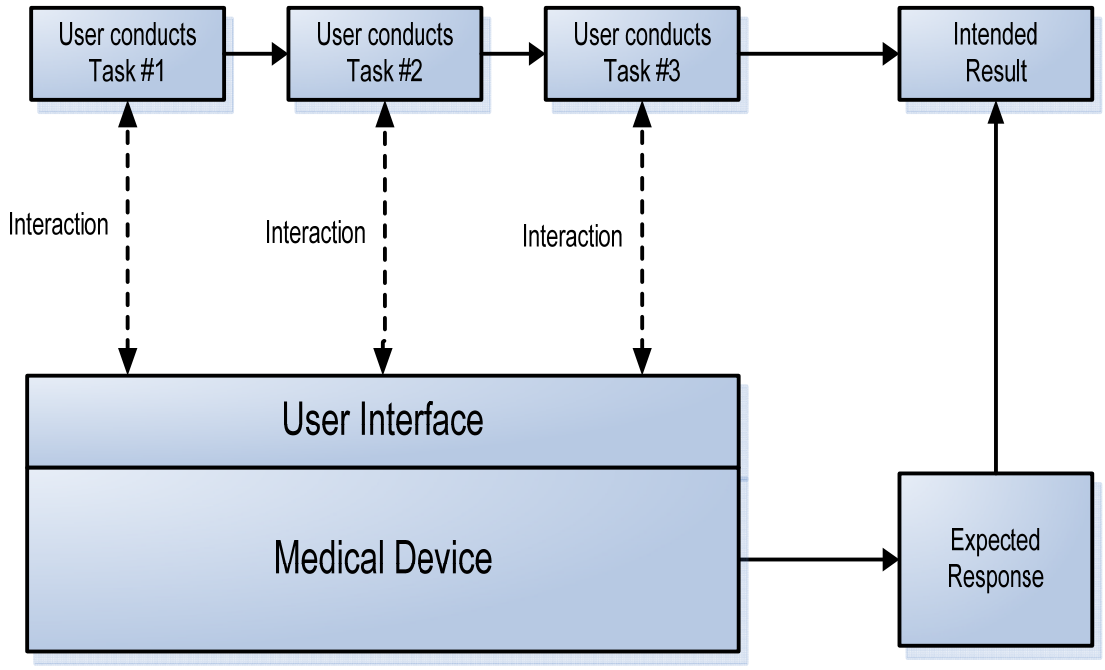

Figure 1 A Use Scenario

As the user uses the device there are a variety of possible outcomes. For example, as shown in Figure 1, the device responds as expected and the intended result occurs. However, the outcome could deviate from the intended result. Usually, this happens in one of three ways:

- The device does not operate correctly creating a hazardous situation. For example there could be a fault in the device.
- The user provides an incorrect input to the device and the device responds creating a hazardous situation. (The device operated as intended based on the received input.)
- The user makes an error in perception (misreading the device) or cognition (misinterpreting the device) and takes an action that creates a hazardous situation.

This situation naturally leads to a classification of types of use as illustrated in Figure 2. The types are defined in the standard and paraphrased as:

- *Normal Use* means operation, routine inspection, user adjustments, and stand-by, according to the instructions for use.

    - *Correct Use* means normal use without use error
    - *Use Error* means user action or lack of user action that leads to a result different than the intended use
- *Abnormal Use* means a conscious, intentional act or intentional omission contrary to normal use

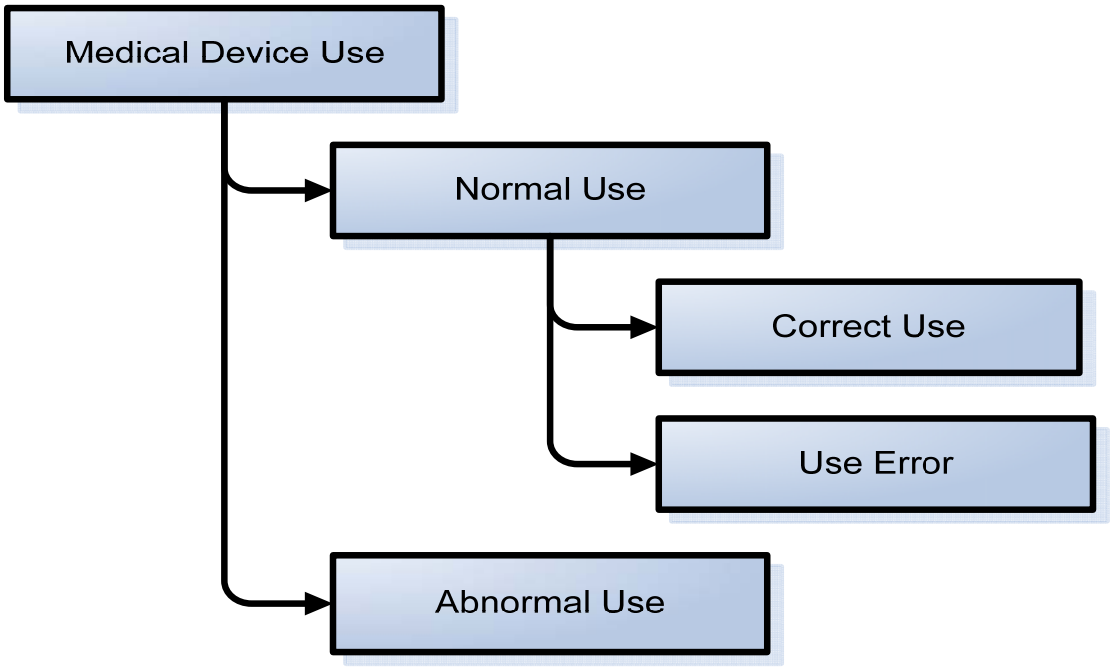

Figure 2 Types of Use

The standard has a very important caveat concerning abnormal use.

> **Conscious disregard of such information for safety by the user is considered to be an intentional act or intentional omission of an act that is counter to or violates normal use and is also beyond any further reasonable means of user interface-related risk control by the manufacturer (*i.e.,* abnormal use).**

This means that if the manufacturer provides adequate information for the user, who chooses to ignore it, there are no risk control measures the manufacturer can take.

The standard distinguishes among the three cases: Correct use, Use error, and Abnormal use. Since, in the risk management context, the manufacturer does not have control over abnormal use, there are two scenarios to consider.

This leads to Hazard-related Use Scenario, which is a Use Scenario that could lead to a hazardous situation or harm. The terms “hazardous situation” and “harm” follow the definitions in ISO 14971:2007. Figure 3 illustrates a Hazard-related Use Scenario.

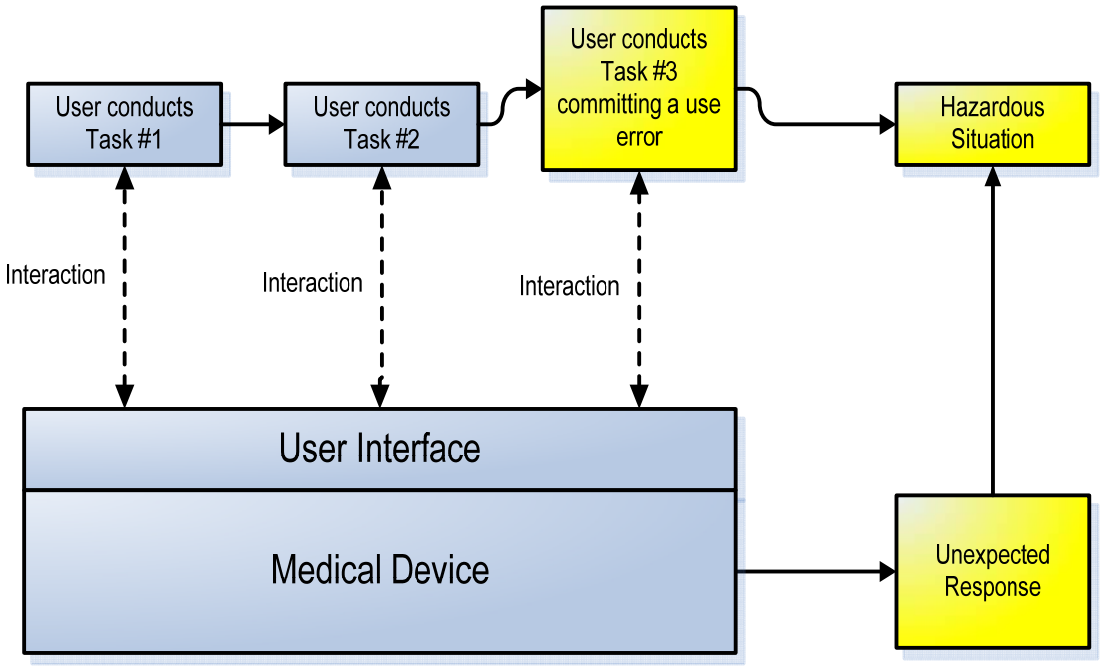

Figure 3 Hazard-related Use Scenario

The Usability Engineering Process

Figure 4 provides a view of the Usability Engineering Process. For simplicity, we divide the usability engineering process into segments that follow the flow of the standard.

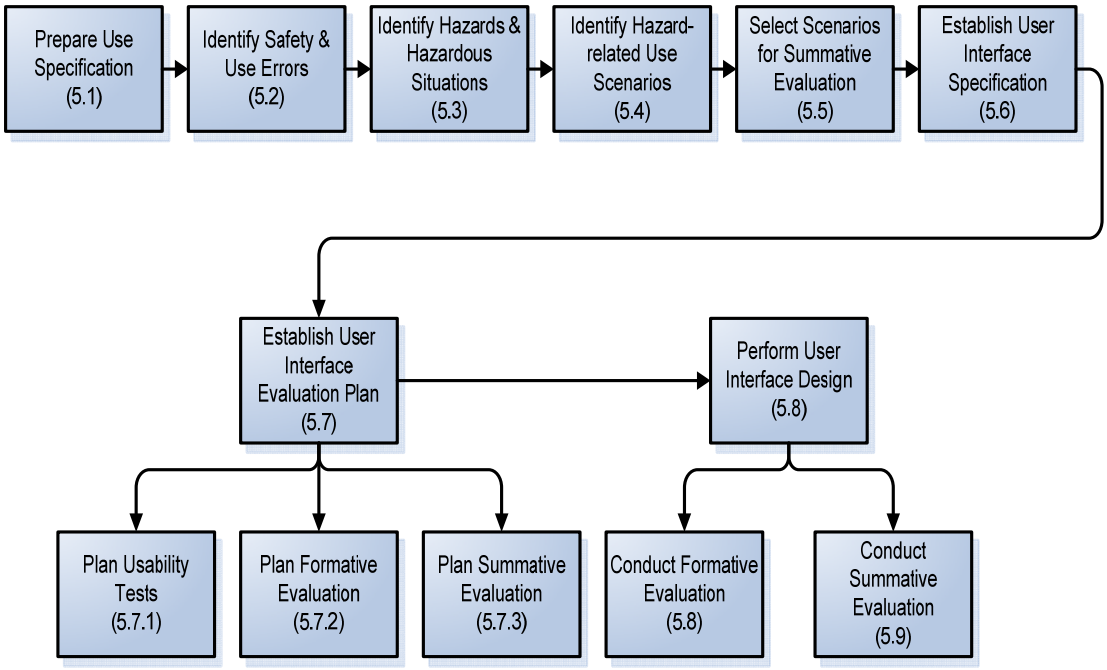

Figure 4 Usability Engineering Process

The User Interface Specification
The first segment results in a User Interface Specification. It accounts for a number of elements that affect the User Interface including:

- The use specification
    - intended medical indication
    - intended patient population
    - intended part of the body or type of tissue applied to or interacted with
    - intended user profile
    - use environment
- Hazard-related Use Scenarios

The design project designs the User Interface to comply with the User Interface Specification. In design control terms, it constitutes the design input.

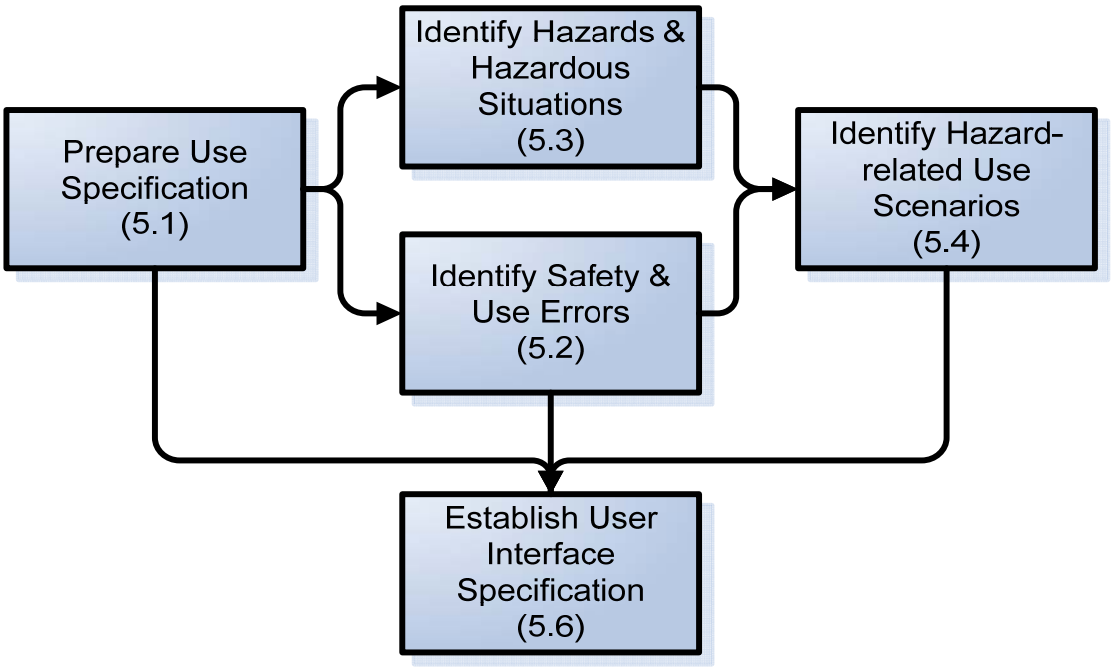

Figure 5 Developing the User Interface Specification

Plan Evaluations
Evaluations demonstrate that the user interface matches the specification and accounts for the Hazard-related Use Scenarios.

The evaluation plan is typically developed concurrently with the User Interface Specification and, as shown if Figure 6, has three components.

A *Usability Test* is a method for exploring or evaluating a user interface with intended users within a specified intended use environment. A usability test is optional but is almost always performed. The Usability Test Plan should include:

- The involvement of representative intended users and the user profile of each;
- The test environment and other conditions of use;
- Whether or not the accompanying documentation, the instructions for use, is provided during the test;
- Whether device specific training is provided prior to the test and, if so, the minimum elapsed time between the training and the start of the test.

Formative Evaluation means user interface evaluation conducted with the intent to explore user interface design strengths, weaknesses, and unanticipated use errors. The Formative Evaluation Plan should include:

- The evaluation methods being used;
- The parts of the user interface being evaluated; and
- When in the usability engineering process to perform each of the user interface evaluations.

Summative Evaluation means 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. The Summative Evaluation Plan should include:

- The evaluation method;
- A rationale that the method produces objective evidence;
- The parts of the user interface being evaluated;
- The criteria to determine if the information for SAFETY is perceivable, understandable, and supports correct use of the device;
- Whether or not the accompanying documentation, the instructions for use, is provided during the test;
- Whether device specific training is provided prior to the test and, if so, the minimum elapsed time between the training and the start of the test.

The Summative Evaluation Plan should look at all of the Hazard-related Use Cases. When this is not feasible, the plan could look at only a subset. Selection of the subset should be based on severity of the harm using the criteria developed as part of risk management, ISO 14971:2007.

In a great quotation that sums the issue Robert Stakes said, "When the cook tastes the soup, that's formative; when the guests taste the soup, that's summative."

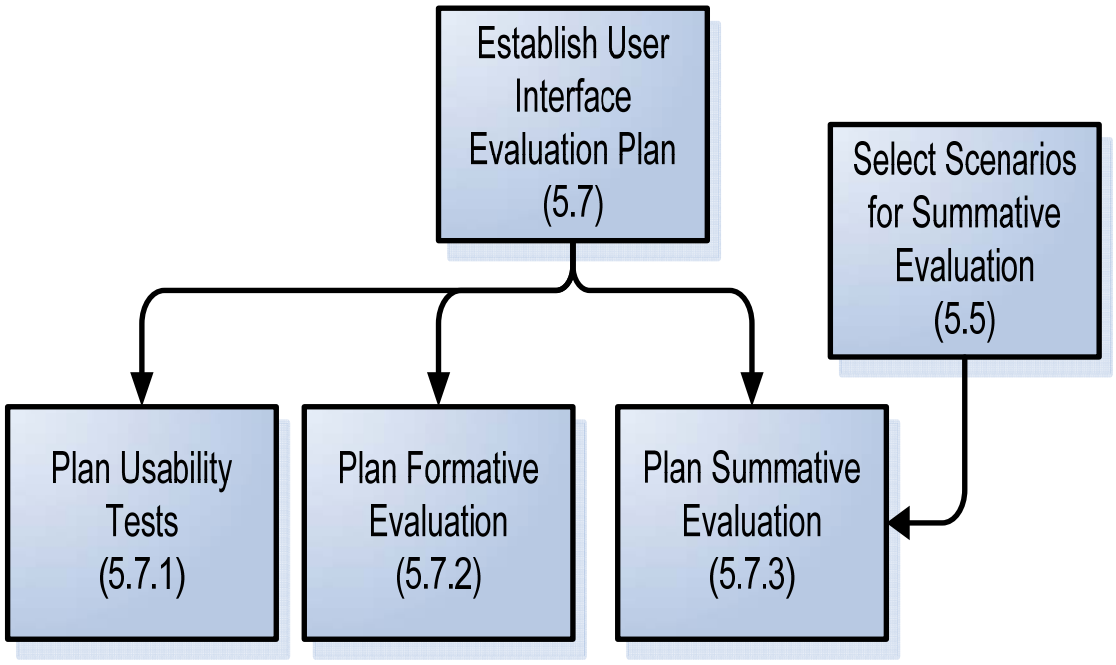

Figure 6 The Evaluation Plan

Interface Design
The design team will start to build the interface according to the User Interface Specification. As part of the process, the designated people will execute the Formative Evaluation Plan. (The cook tastes the soup.)

Conduct Evaluations
While the Formative Evaluation is conducted during the interface design, the Summative Evaluation uses the “final” design. There may be design changes required and parts to finish, but the design should be mature enough for representative users to evaluate. (The guests taste the soup.)

Follow the respective plans to conduct the evaluations and document the results.

For the Summative Evaluation, be sure to evaluate each of the identified hazard-related use scenario.

Analyze the results to identify any new use errors, hazards, hazardous situation, or hazard-related use scenario. If there any, cycle back through the process. If not, then identify the residual risk and evaluate it using the acceptability criteria established in ISO 14971:2007.

Documentation
The plans, results, reports, *etc*. become quality records and support the design. Ensure they are reviewed, approved, and maintained in the Usability Engineering File.