

# Guidance for Industry and FDA Premarket and Postmarket Review Staff

## **Device Use Safety: Incorporating Human Factors in Risk Management**

### *Draft Guidance – Not for Implementation*

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**U.S. Department of Health and Human Services  
Food and Drug Administration  
Center for Devices and Radiological Health**

**Division of Device User Programs and Systems Analysis  
Office of Health and Industry Programs**

## **Preface**

### **Public Comment:**

For 90 days following the date of publication in the Federal Register of the notice announcing the availability of this guidance, comments and suggestions regarding this document should be submitted to the Docket Number assigned to that notice, Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD 20852.

### **Additional Copies:**

Additional copies can be obtained from the Center for Devices and Radiological Health's (CDRH) World Wide Web site at <http://www.fda.gov/cdrh/HumanFactors.html> or CDRH's Facts-on-Demand at 1-800-899-0381 or 301-827-0111 (specify number 1497 when prompted for the document shelf number).

# Device Use Safety: Incorporating Human Factors in Risk Management

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# **Device Use Safety: Incorporating Human Factors in Risk Management<sup>1</sup>**

## **1.0 Introduction**

This guidance describes how hazards related to medical device use should be addressed as part of the risk management process during device development. Hazards related to device use are best identified and addressed using *human factors* techniques. Therefore, this guidance describes how human factors techniques should be integrated into risk management processes. The goal is to minimize hazards related to device use and assure that intended users are able to use medical devices safely and effectively, to facilitate review of new device submissions, and to address hazards related to device use throughout the product's life cycle. The content of this guidance applies to human factors processes for considerations for devices including the design of device user interface, how the device operates, who should use it, and under what conditions. Documentation of these decisions should demonstrate that the device manufacturer has undertaken efforts to control use-related hazards.

Addressing hazards related to device use must be undertaken within the context of a thorough understanding of how a device will be used. Essential components of this understanding include:

- Device users,
- Typical and atypical device use,
- Device characteristics,
- Characteristics of the environments in which the device will be used, and
- The interaction between users, devices and use environments.

Based on an understanding of these components, potential use scenarios that could lead to hazards should be identified and addressed. Testing prototype devices with users may identify other unanticipated use scenarios resulting in hazards. Following the identification of their probable causes and outcomes, problematic use scenarios are mitigated or controlled by modifying the user interface (e.g., control or display characteristics, logic of operation, labeling) of the device or the abilities (e.g., training, limiting use to qualified users) of users to use the device. The field of human factors provides a variety of techniques that are useful for these undertakings.

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<sup>1</sup> This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

This guidance does not focus on any specific kind of medical device, but applies to all medical devices and device-related components (e.g., packaging, labeling) that involve interaction by the user with the device or its components (e.g., thought, perception, decision-making, manipulation with hands, etc.). It is intended for medical device manufacturers, the Food and Drug Administration (FDA)'s Center for Devices and Radiological Health (CDRH) reviewers of pre-market submissions, and as a general reference for post-market surveillance activities associated with hazards related to device use. It is intended for readers who have some understanding of design controls and risk management. Some readers may find it helpful to review the documents referenced herein.

## **1.1 Hazards Related to Device Use**

A *hazard* is a potential source of harm. Hazards arise in the use of medical devices due to the inherent risk of medical treatment, from device malfunctions, and from the use of devices. This document addresses hazards associated with interactions between users and devices. It does not focus on hazards inherent to medical treatment or device malfunction.

Hazards associated with device use are a common and serious problem. Evidence from researchers (Cooper, Leape, and others) suggests that the frequency and consequence of hazards resulting from medical device use may far exceed those arising from malfunctions of the device. This means that ensuring that users can use the devices safely and effectively is essential if hazards are to be identified and addressed.

Designers usually consider how devices will be used; however, their analyses are too often inadequate and result in an inaccurate or incomplete understanding of device use. This prevents proper consideration of design issues that pertain to device use, and increases the likelihood of unexpected use scenarios that can result in hazards to users or patients.

Sources of hazards considered during medical device design include:

- Chemical hazards (e.g., toxic chemicals),
- Mechanical hazards (e.g., kinetic or potential energy from a moving object),
- Thermal hazards (e.g., high temperature components),
- Electrical hazards (e.g., electrical shock, electromagnetic interference (EMI)),
- Radiation hazards (e.g., ionizing and non-ionizing),
- Biological hazards (e.g., allergic reactions, bio-incompatibility, infection), and
- Diagnosis, monitoring, or treatment hazards (e.g., failure to identify disease, failure to detect important changes in medical conditions, ineffective or dangerous therapy).

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A large number of hazards associated with medical device use occur for one or more of these reasons:

- Devices are used in ways that were not anticipated;
- Devices are used in ways that were anticipated, but inadequately controlled for;
- Devices are used by users whose capabilities are inadequate;
- Device use is inconsistent with user's expectations or intuition about device operation;
- Device use requires physical, perceptual, or cognitive abilities that exceed those of the users;
- The use environment (Section 3.2.1) affects device operation and this effect is not understood by the user; or
- The use environment causes user's physical, perceptual, or cognitive capacity necessary to use the device to be exceeded.

### **1.2 Use Scenarios Resulting in Hazards**

Hazards related to use often occur as a result of a sequence or chain of events involving device use. For instance, a user may calibrate a device incorrectly and then proceed to use it incorrectly. This use scenario involves the ineffective calibration as well as the incorrect use of the device following the calibration. In this example, a hazard occurred due to how the device was used. When we refer to “use *scenarios* resulting in hazards” in this document, we are referring to the problematic use of the device in its entirety (i.e., not only the calibration or the use of the device after calibration).

## **2.0 Risk Management**

Risk management involves a systematic application of policies, procedures, and practices to the analysis, evaluation, and control of risks. It is a key component of quality management systems, and is a central requirement of the implementation of Design Controls in the Quality Systems Regulation § 820.30(g).

*Risk* for a given hazard is a function of the relative likelihood of its occurrence and its consequence. Risk management includes the identification and description of hazards, how they might occur, their expected consequences, and an estimation or assessment of their relative likelihood. Following the estimation of risk, risk management focuses on controlling or mitigating the risks.

Thorough consideration of use-related hazards in risk management processes should include the following tasks:

1. Identify and describe hazards related to device use through analysis of existing information (Section 5.3);
2. Apply empirical techniques (Section 5.4), using representative device users, to identify and describe hazards that do not lend themselves to identification through analytical techniques;
3. Estimate the likelihood and consequences (*risk*) of use scenarios resulting in hazards;
4. Develop strategies and controls to eliminate or reduce the likelihood or mitigate the consequences of use-related hazards scenarios;
5. Select and implement control strategies;
6. Ensure controls are appropriate and effective in reducing risk;
7. Determine if new hazards have been introduced as a result of implementing control strategies; and
8. Verify that functional and operational requirements are met and validate safe and effective device use.

This process will be explained in Section 5 in conjunction with human factors techniques.

## **3.0 Human Factors**

To understand hazards related to device use, it is necessary to have an accurate and complete understanding of *how* a device will be used. Understanding how people use and interact with technology is the subject of the science of human factors. How human factors considerations are applied to the development of medical devices will depend on the characteristics of the device technology, the device users, the environment within which the technology will be used, how dangerous device use is, and how critical the device is for patient care. An introduction to human factors in medical devices can be found in the FDA document, *Do It By Design* (<http://www.fda.gov/cdrh/humfac/doi.html>)

### **3.1 Human Factors in the Use of Medical Devices: Overall Considerations**

Several general human factors concepts should be considered before proceeding with a discussion of human factors techniques in the context of risk management.

#### **3.1.1 User Preference does not Necessarily Indicate Safety and Effectiveness**

A focus solely on user preference in the development of a design does not assure that safety and effectiveness have been adequately considered. Users generally prefer devices that are easy and satisfying to use and aesthetically pleasing. Too often, manufacturers and users emphasize these device characteristics at the expense of safety and effectiveness.

Although design features that assure safety and effectiveness may decrease user preference in some instances, they are necessary nevertheless. For instance, safety-related user interface design features such as shields over critical controls, mechanical or software-based interlocks, or verification requirements may slow down the use of a device or affect aesthetics.

#### **3.1.2 Use Scenarios with a Low Frequency of Occurrence that Result in Hazards Require Careful Consideration**

Rare or unusual use scenarios resulting in hazards (Section 1.2) with serious consequences often prove to be the greatest threat to safe and effective medical device use after a device becomes available for general use. Users are often not prepared for use scenarios of this kind and the situations are often not dealt with adequately in device design, training, or operating instructions. These scenarios are often difficult to identify through analytical processes typically employed to identify hazards and estimate risks. This underscores the importance of applying empirical techniques (Section 5.4) early in the design process.

#### **3.1.3 Direct Inspection or Paper-based Analyses of a Device may not Identify all Hazards**

Many hazards involving unsafe or ineffective device use can be complex and involve subtle interactions among aspects of the use environment, users (professional and patient users), and the device user interface (see Figure 1). They can also be rare, unusual, or non-intuitive to analysts who are familiar with the operation of the device. This makes them difficult to identify or envision through analytical processes (Section 5.2). Therefore, it is important to obtain information from the intended user population and test devices under actual or simulated use conditions (Section 5.4) to identify hazards that would not be detected using analytic techniques.

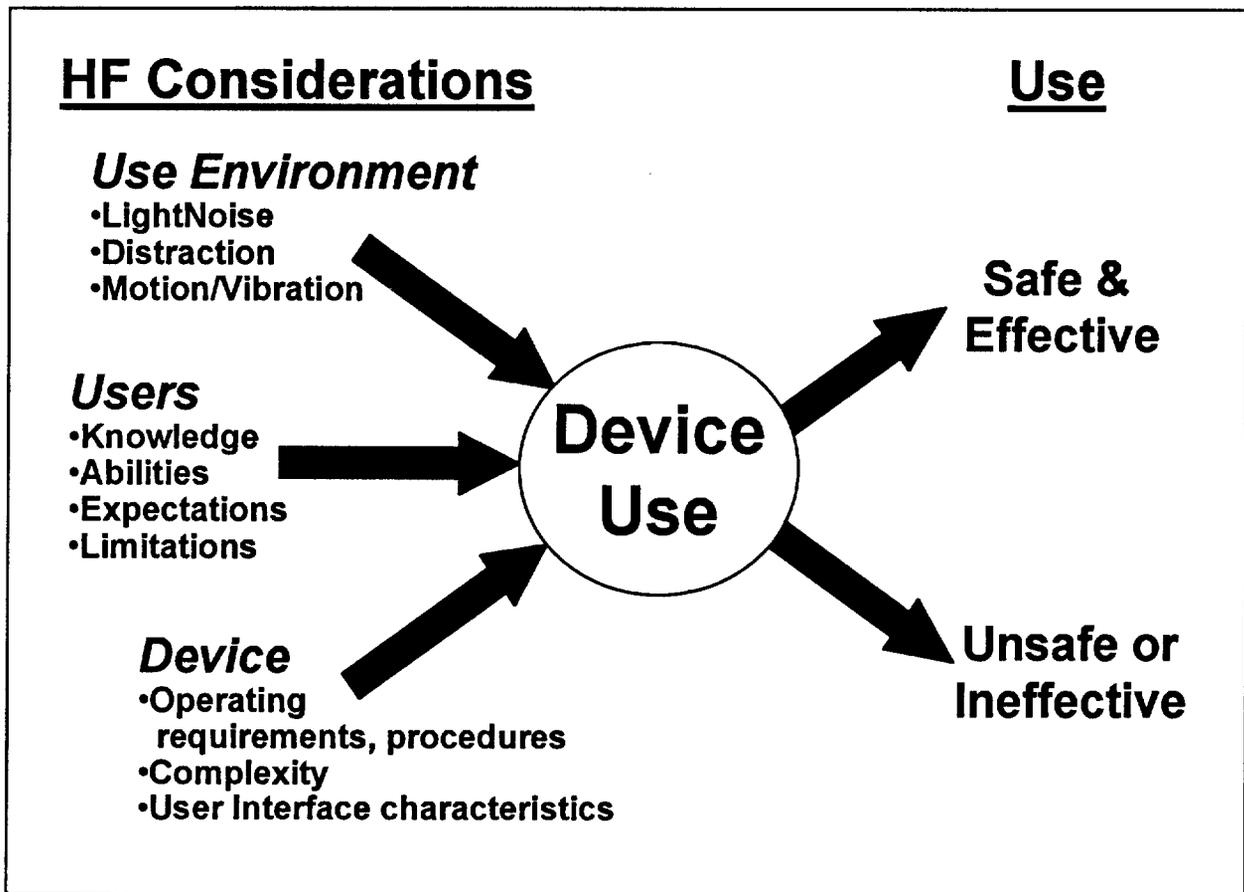


Figure 1. Interaction of HF considerations leading to (1) safe and effective use, or (2) unsafe or ineffective use

### 3.1.4 Human Factors Considerations for the Device-User System

Safe and effective use of medical devices can be determined by the following major components of the device-user system. These include characteristics of: (1) The use environment, (2) the users, and (3) the Device.

### 3.1.5 Use Environments

Use environments for medical devices can vary widely and can have major impacts on device use and use-related hazards. For instance, the amount of thinking and concentration a person exerts is called *mental workload*. The mental workload imposed on users by the environment in which they use devices can exceed their abilities to use devices properly. For instance, in an operating room, there may be too many alarms on different devices for a nurse to be able to identify the source of any single alarm. Mental workload is often used synonymously with mental “stress”. There can be a physical component to workload associated with medical device use (*physical workload*) that also adds to the stress experienced by the user. Devices that can be used safely under conditions of low stress (i.e., low workload) may be difficult or dangerous to use under high stress when the user may be distracted and will often have much less time to make important decisions or physically manipulate device components.

Use environments can also limit the effectiveness of visual and auditory displays (alarms and other signals) if they are not designed appropriately. If a device will be used in a noisy environment, the user may not be able to hear alarms if they are not sufficiently loud or distinct. If there are multiple alarms occurring for different devices or for the same device, the user may fail to make important distinctions between them. If the user cannot understand critically important information, an error is likely. Similarly, motion and vibration can affect the degree to which people are able to perform fine physical manipulations such as typing on the keyboard portion of a medical device. Motion and vibration can also affect the ability of users to read displayed information.

Important considerations for displays (including visual alarm indicators) and labeling affixed to the device include ambient light levels in which the device will be used, the angles from which the device might reasonably be viewed, and the presence of other devices in the use environment. If the device will be used in low light conditions, display scales or device status indicators might not be clear to the user. Some scales will be read inaccurately when viewed from an angle due to parallax or because part of the display may be blocked. Other display information can be lost in bright light conditions due to a lack of contrast. When certain types of equipment are used in close proximity to other equipment, the association of visual and auditory displays with the corresponding equipment can be lost, confused, or the displays may not be noticed at all.

### **3.1.6 User Characteristics**

A device that is easy for one person to use safely and effectively may present problems for another. Users need devices that they can use safely and effectively. To assure that these needs are met, it is necessary to understand user characteristics that might affect device use.

When considering users of medical devices, it is convenient to refer to the expected users of a device as a *user population*, and to describe it in terms of the abilities or limitations of its members that could affect device use. For any given device, the abilities of the user population may be relatively homogenous. On the other hand, the user population may contain sub-components that have very different abilities, for example, user populations that consist of young and old users, or home users and professional caregivers.

Important characteristics of user populations include:

- General health and mental state (stressed, relaxed, rested, tired, affected by medication or disease) when using the device,
- Physical size and strength,
- Sensory capabilities (vision, hearing, touch),
- Coordination (manual dexterity),
- Cognitive ability and memory,
- Knowledge about device operation and the associated medical condition,
- Previous experience with devices (particularly similar devices or device interfaces), and
- Expectations about how a device will operate.

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In general, highly trained user populations will be much more capable of operating complex devices but can still be confused by poorly designed user interfaces. Older users may have difficulty remembering specific sequences for operation, using their hands to do tasks that require fine manipulation, or sensing device outputs such as alarm sounds or displayed information. When considering risks with device use, it is important to consider components of the user population expected to have certain kinds of difficulties when using a device. With proper application of human factors techniques and considerations, the design of a device can often be made to compensate for limitations in user ability. For example, diabetics often suffer from some degree of retinopathy (degenerative disease of the retina) resulting in impaired eyesight. These users have difficulty reading the results of blood glucose test kits when the meter displays are very small. Blood glucose meters with small displays are not a good design for this user population. After this problem was understood, subsequent models with larger displays mitigated this risk. When design modifications are made to address certain user needs, the proposed new design should be tested with these users to assure that the changes are effective.

User experience and expectations are important considerations. Users will expect devices and device components to operate in ways that are consistent with their experience with other similar devices or device interface components. For example, users may expect that the amount of a given variable (such as gas or liquid flow rate) will increase by turning a control knob to the right. Hazards could result if a device operates in a different manner than users have reason to expect.

### **3.1.7 Device User Interface Characteristics**

Human factors considerations relate directly to the device *user interface* and responses of the device to user actions. From the perspective of many users, the device user interface is the most important aspect of the device. A well-designed user interface will not induce the user to take, or conversely fail to take, necessary actions and will prevent or discourage actions that could result in hazards.

The user interface of a device includes all components of a device with which users interact while using, maintaining, or preparing the device for use. It includes hardware features that control device operation such as switches, buttons, and knobs and device features that provide information to the user such as indicator lights, displays, auditory, and visual alarms. The size and configuration of the device are important parts of the user interface, particularly for hand-held devices. Device labeling, packaging, training materials, operating instructions and other reference materials are considered part of the user interface. An important aspect of these user interfaces is the extent to which the logic of information and control aspects of the interface is consistent with users' abilities and expectations.

An important concept related to the design and function of the user interface is *error tolerance*. Error tolerance is the quality of a user interface that prevents or mitigates dangerous or disastrous consequences when an error occurs. Humans make errors. Some kinds of error can be anticipated and are essentially unavoidable – such as inadvertently pressing an adjacent key on a multi-key keypad, or even bumping the keypad inadvertently while doing other tasks. Good application of human factors techniques to device design will assure that the design is tolerant of

errors that are likely to be made by users (e.g., the placement of a shield over an activation button, which initiates a beam of radiation, to prevent inadvertent activation of that button). The logic of device operation can also determine error tolerance. For example, some devices may include interlocks that request the user to verify a critical operation before proceeding.

## **4.0 Level of Effort for Device Use in Risk Management**

The type and extent of human factors and risk management efforts necessary to control risk effectively will vary. This variability results from the unique characteristics of the device, expected use, the user population, and the risks of use-related hazards. The central question to be answered in use-related hazard identification and control efforts is: “Can the users use the device safely and effectively?” For some devices, relatively small efforts may be adequate to answer the central question, while other devices will require greater effort.

The advantages of addressing hazards resulting from device use through application of human factors in risk management extend beyond improved safety. Device manufacturers have found competitive advantages from the application of human factors in the design of their products. Also, these efforts reduce the necessity for modifications during implementation and reduce costly updates. When human factors techniques are used in the design of devices, particularly if the perspective of users is obtained, the overall ease of use and aesthetics of a device can be improved with the same effort. Users appreciate devices that are easy to use, if they know the devices are safe. With increased safety, the likelihood of incurring expenses associated with recalls or liability is also reduced. For the process to be well integrated, personnel conducting human factors efforts should be part of the risk management team.

## **5.0 Applying Human Factors Techniques in the Risk Management Process**

This section provides an overview of how human factors considerations and techniques can be incorporated into the risk management processes. This should involve these central steps:

- Identify anticipated and unanticipated use-related hazards,
- Describe how use scenarios resulting in hazards occur,
- Develop strategies to control use-related hazards, and
- Demonstrate safe and effective device use (validation).

Human factors efforts are directed at the identification, description, and modification of use scenarios that result in hazards. Figure 2 shows the structure of a use scenario resulting in a hazard for a medical device. The figure shows how the use of a device is influenced by human factors characteristics that can be separated into the three broad human factors areas (Section 3.2): 1) Use Environment, 2) Users, and 3) Device. When they are identified, these influences can be described as the causes or contributing factors within the use scenario. Human factors techniques should be applied to identify use scenarios resulting in hazards and to understand the role of human factors causes and contributing factors.

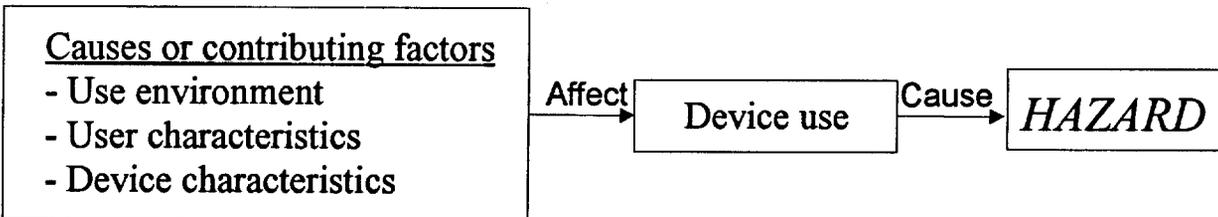


Figure 2. Use Scenario Resulting in a Hazard

Figure 3 shows the sequence of essential risk management activities keyed to the human factors techniques that support them. Human factors techniques are discussed in the sections that follow. Table 1 provides a cross-reference between risk management activities and the sections in which the relevant human factors techniques are discussed.

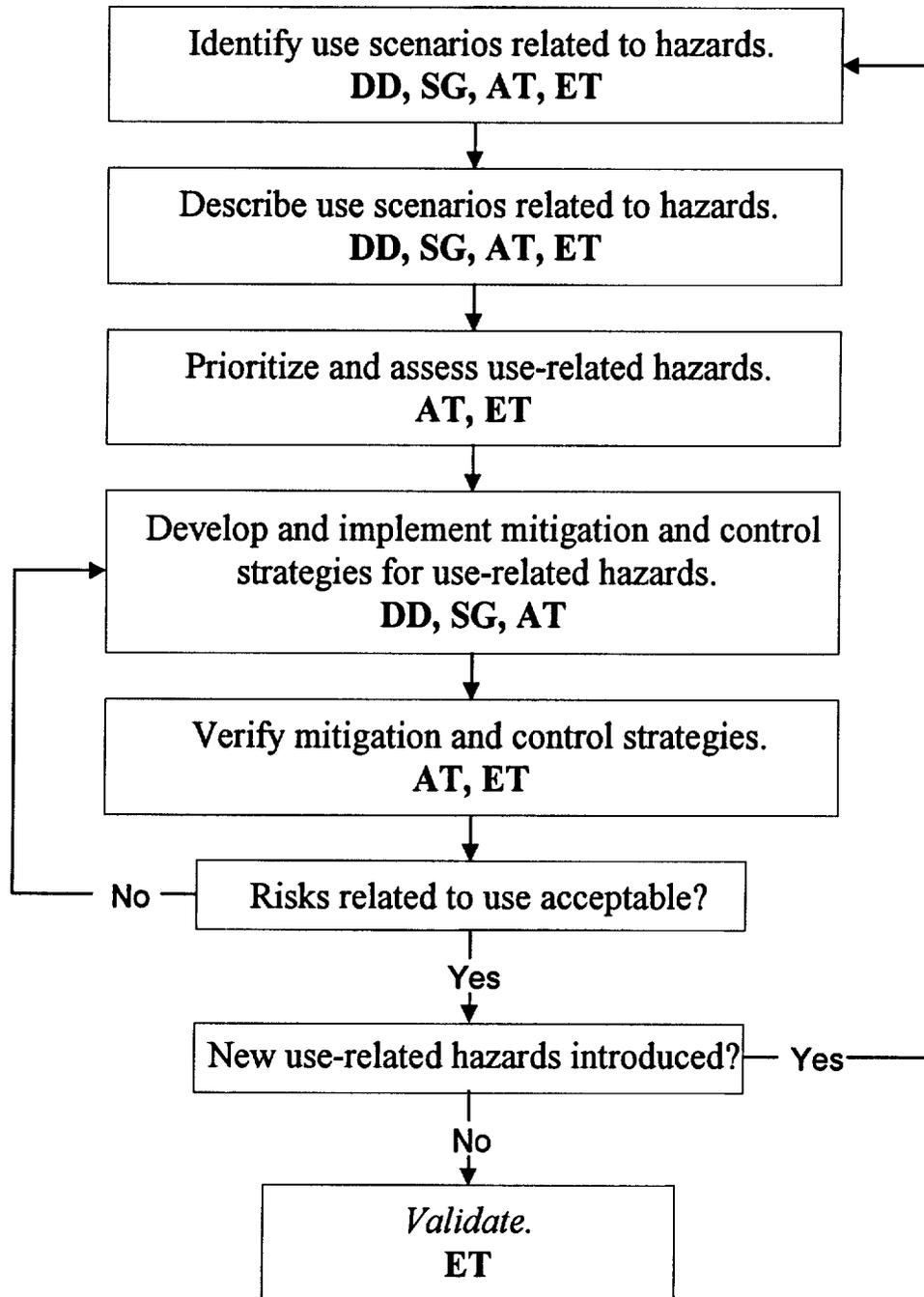
## 5.1 Device Use Description

A description of the anticipated use of a device is an essential initial step for accurately and completely understanding device use. The device use description should include the following information:

- User needs for successful device use and how they are met by the device,
- General use scenarios that describe how the device will be used,
- Design (or preliminary design) of the user interface,
- Overall device operation,
- Characteristics of the intended user population (particularly that which could affect device use), and
- Expected use environments.

The device use description may be developed from documents on device operation that do not necessarily focus on user interaction as long as they describe the intended use of the device. Input from design team personnel can be very useful at this stage, however, input from intended users should also be obtained.

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**Key**  
DD - Device Use Description  
SG - Standards and Guidelines  
AT - Analytical Techniques  
ET - Empirical Techniques

Figure 3. Use of Human Factors Techniques within the Risk Management Process

**Table 1**

<b>Risk Management Activity</b>	<b>Applicable Sections</b>
1 Identify use scenarios resulting in hazards.	Section 5.1: Device use Description Section 5.2: Standards and Guidelines Section 5.3: Analytic Techniques Section 5.4: Empirical Techniques
2. Describe use scenarios resulting in hazards.	Section 5.1: Device use Description Section 5.2: Standards and Guidelines Section 5.3: Analytic Techniques Section 5.4: Empirical Techniques
3. Prioritize and assess use-related hazards.	Section 5.3: Analytic Techniques Section 5.4: Empirical Techniques Section 5.5: Prioritization and Assessment
4. Develop and implement mitigation and control strategies for use-related hazards.	Section 5.1: Device use Description Section 5.2: Standards and Guidelines Section 5.3: Analytic Techniques Section 5.6: Mitigation and Control of Use-related Hazards.
5. Verify mitigation and control strategies.	Section 5.3: Analytic Techniques Section 5.4: Empirical Techniques Section 5.7: Verification and Validation
6. Determine if the risks resulting in device use are acceptable.	Section 5.1: Device use Description Section 5.2: Standards and Guidelines Section 5.3: Analytic Techniques
7. Determine if new hazards have been introduced.	Section 5.1: Device use Description Section 5.2: Standards and Guidelines Section 5.3: Analytic Techniques Section 5.4: Empirical Techniques
8. Validate safe and effective device use.	Section 5.4: Empirical Techniques Section 5.7: Verification and Validation

### **5.1.1 Known Use-related Hazards for Similar Devices and Interface Components**

Known use-related hazards associated with similar devices may be obtained from journals, manufacturer complaint files and customer feedback, FDA materials, and MDR (Medical Device Reporting) database reports. Important information should include reasons why design changes have been made on other products, manufacturer or FDA-initiated recalls, and descriptions of known problems with the use of specific user interface components such as audible alarms in a given environment when their use is critical. The level of detail of the device use description should be sufficient to support an understanding of user-device interactions (e.g., adjusting, reading, timing, applying sample).

Some hazards related to device use are evident from the device use description itself. Developing the device use description provides a basis for *analytical techniques* (Section 5.3), and is necessary for creating valid test scenarios for “usability testing” (Section 5.4). For example, if a device is intended to be used on emergency vehicles including helicopters, potential use-related hazards might involve failure to hear audible alarms (if present), or inability to perform device connections or manipulations if they require significant time, attention, or manual dexterity. These identified hazards would then be used in subsequent human factors activities. For instance, when developing scenarios for usability testing, the possible impact on use caused by noise and motion of a helicopter environment should be simulated (or an actual helicopter would be used in the testing).

## **5.2 User Interface Design Information in Standards and Guidelines**

The development of the device interface should include review and incorporation of relevant standards and guidelines that are applicable to the design. To facilitate pre-market review and assist manufacturers, FDA has published device-specific and general guidances, some of which contain specific recommendations for device user interface characteristics. For the same reasons, FDA has officially recognized device-specific and general standards published by standards bodies such as Association for the Advancement of Medical Instrumentation (AAMI) and International Electro-technical Commission (IEC). FDA general and specific guidances as well as standards recognized by FDA are listed on FDA’s home page ([www.fda.gov/cdrh](http://www.fda.gov/cdrh)).

Device-specific standards often contain some information for developing specific user interface features such as auditory alarms (preferred loudness and pitch), visual displays (size or brightness), printed or displayed text (size, color, and contrast), as well as the overall layout of the user interface. Some general standards also contain considerations applicable to the design of the user interface of some devices.

It is difficult for the developers of standards and guidelines to keep them current with developments in technology that influence interface design. When developing a new interface, carefully evaluate the applicability of existing standards and guidance to the new interface.

### **5.3 Analytical Techniques**

Analytical techniques involve the systematic breakdown of device use scenarios to identify safety-critical user actions, use-scenarios resulting in hazards, and an understanding of the contexts in which they can occur. During this process, information from the device use description is expanded upon and applied to typical, atypical, and worst-case use scenarios. Results of analytical techniques will allow some use scenarios resulting in hazards to be identified prior to or early in development of the user interface and operating logic.

There are a variety of analytical techniques that are used by human factors and systems engineers. Analytical techniques used for human factors application include function and task analysis, heuristic analysis, and expert reviews. These techniques can be applied within more comprehensive techniques such as Operational Analysis, Analysis of Similar Systems, Failure Modes Effects Analysis (FMEA), Fault Tree Analysis (FTA), Critical Incident Technique, Hazard and Operability Studies (HAZOP), and others. The choice of which to use depends on the complexity of the device, its development, and the anticipated needs of the overall human factors process.

Unfortunately, not all problems with device use can be identified or well-understood through analysis because analytical techniques do not involve actual users, the intended context for use, or realistic use environments. Empirical techniques (Section 5.4) allow problems to be understood in greater depth and for use scenarios not evident from analytical techniques to be identified. But empirical techniques require identification of the general use scenarios and possible problems associated with device use obtained from applying analytical techniques.

#### **5.3.1 Identifying and Describing Use Scenarios Resulting in Hazards**

Sources of information for identifying and describing use scenarios resulting in hazards include known problems with similar devices or similar user interface components and safety-critical tasks identified in *task analyses* (Section 5.3.2). With respect to the design process, use scenarios identified from this kind of analysis can be thought of as *anticipated* use scenarios. *Unanticipated* use scenarios that result in hazards should be identified and described through the application of empirical techniques such as *usability testing* (Section 5.4):

The extent of effort focused on the identification and description of use scenarios resulting in hazards should be determined by reasonable assessment of the likelihood of each scenario. In general, the set of scenarios to be considered should be kept manageable, although care should be taken not to dismiss scenarios involving atypical, unexpected, or unusual device use unless the likelihood of these scenarios occurring can be dismissed with near-certainty.

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Answering the following questions can help identify and describe use scenarios that may result in hazards (Note: This list is not necessarily exhaustive):

1. Why have problems occurred with the use of other similar products?
2. How might the user set the device up incorrectly and what effects would this have?
3. What are the critical steps in setting-up and operating the device, and can they be performed adequately by the expected users?
4. Is the user likely to operate the device differently than the instructions indicate?
5. Is the user likely to choose a patient population or clinical condition other than that intended by the manufacturer?
6. How might safety-critical tasks be performed incorrectly and what effects would this have?
7. How important is user training and will users be able to operate the device safely and effectively if they don't have it?
8. How important are recommendations for storage and maintenance for proper device function, and what might happen if they are not followed?
9. Do any aspects of using the device seem complex, and how can the operator become "confused" when using the device?
10. Are the auditory and visual warnings effective for all users and use environments?
11. To what extent will the user depend on device output or displayed instructions for adjusting medication or taking other health-critical actions?
12. What will happen if necessary device accessories are expired, damaged, missing, or otherwise different than recommended?
13. Is device operation reasonably resistant to everyday handling?
14. Can touching or handling the device harm the user or patient?
15. If the device fails, does it "fail safe" or give the user sufficient indication of the failure?
16. Could device use be affected if power is lost or disconnected (inadvertently or purposefully), is its battery is damaged, missing or dead?
17. Is the status of the device's connection to the patient apparent where necessary?

### **5.3.2 Function and Task Analyses**

Descriptions of *function* and *task* may vary among the variety of function and task analysis techniques available. These differences are not critical; the important contribution of applying these techniques is the systematic breakdown of the device-use process into discrete steps or sequences for the purposes of description and further analysis. With respect to safety, function and task analysis can contribute in four ways:

- Supporting general safety through the achievement of good design for human operation,
- Identifying hazards to device users,
- Providing a basis for analysis of use-related hazards, and
- Evaluating incidents, accidents, or use-scenarios associated with hazards to find out what went wrong, or what might go wrong.

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For example, using some hand-held blood glucose meters includes the following tasks:

1. Patient's finger is lanced with automatic lancing device (device +user)
2. Blood sample is placed on test strip (user)
3. Test strip is placed in device (user)
4. The sample is allowed to react with reagents in the test strip (device)
5. Blood glucose level in the sample is measured (device)
6. The resulting value is displayed (device)
7. The displayed value is read and interpreted (user)

Note: "User," "device," and "device + user" steps are included in this example.

Following the identification of functions and tasks, analysis includes relating these to what is known about the device and the human factors considerations involved. For instance, in Task 2 above, the user places a sample of blood on a test strip. Some initial considerations for this task include:

- Is any hazard-related use scenario particularly likely, and if so, what are its consequences?
- How difficult is it for users to use the device components and accessories to do this task correctly?
- How much effort is required by the user to apply a sample correctly?
- What characteristics of the user population might cause some users to have difficulty with this task?
- Where will the testing be done, and could ambient conditions affect the test results or the users ability to perform the task?
- Is the proper use of test strips evident to the user?

In early glucose monitors, the user had to perform Task #4 (The sample is allowed to react with reagents in the test strip). Users had difficulty doing this task well, and the accuracy of the results too often suffered. In subsequent models, this task is done automatically by the device. Modification in device design and operation removed that problematic use scenario.

Analyzing functions and tasks will allow identification of possible hazards associated with device use. Function and task analyses can provide a foundation for subsequent human factors efforts. For instance, *test scenarios* (Section 5.4.2) should be based on *use scenarios resulting in hazards* that involve tasks identified as critical or error-prone.

### 5.3.3 Heuristic Analysis

Heuristic analysis is an analytic process in which evaluators inspect the device to evaluate its use from the perspective of users. The object is to identify possible use-related hazards with a focus on the interaction of the user with the user interface and operating logic of the device. Design team members usually perform heuristic evaluation. This kind of analysis may involve the perspective of clinical or human factors experts or users as well. This technique is particularly useful for early identification of difficult or counter-intuitive aspects of the device user interface. Another benefit is the evaluation of candidate interface designs. The output of this process is

limited because evaluators typically do not represent real users, use scenarios considered may not be comprehensive, and the evaluation environment is not representative of actual use.

Heuristic analyses should consider generally accepted concepts for design and operation of the user interface, sometimes known as “de-facto” standards or “population stereotypes.” A simplistic example might be a switch oriented in a vertical direction being “on” when it is in the “up” position and “off” when in the “down position”. Other de-facto standards are specific to certain kinds, or families, of medical devices.

#### **5.3.4 Expert Review**

Expert review typically involves identification and recommendations for addressing scenarios resulting in hazards by clinical or human factors experts. The process used may be very similar to the heuristic analyses (Section 5.3.3). The difference is the degree of reliance on the knowledge and ability of experts. The success of the expert review depends on the expert’s knowledge of the device, its use, the intended users, and his or her ability to evaluate device use effectively. This kind of review can provide very useful information, particularly early in the design process, but may not be comprehensive since it does not include the review of actual device use and may not include the perspective of actual users.

### **5.4 Empirical Techniques (Use Studies)**

Empirical information on device use can be obtained through a variety of techniques that study the use of devices. Use studies are applicable to a number of risk management activities. These techniques can be used early in the design process to identify unanticipated use-related hazards. They can also be used to clarify suspected problems with device use, demonstrate that use-related hazards have been addressed, evaluate candidate design alternatives, and to validate safe and effective use by intended users. Beyond application to safety and effectiveness of device use, use studies provide a powerful means for creating effective labeling (including directions for use), and device designs that are user friendly, satisfying to use, and desirable to users.

Use studies will provide accurate results to the extent that the users involved in the testing represent actual device users, the test conditions represent actual use conditions, and the test is conducted well. Members of the device development team are not good participants for use studies since their knowledge of how the device operates will influence how they use it. If users have certain limitations in their abilities, one focus of the testing should be to establish whether these limitations affect device use. If so, further effort is required to determine whether potential use problems associated with user limitations can be mitigated by modifying the design of the device interface or the operation of the device.

#### **5.4.1 Walk-through**

A simple kind of study involving users is the *walk-through*. It is less time-consuming than more formal usability testing. In a walk-through, a user or small group of users are “walked” through the process of using a device. During the walk-through, participants are questioned and encouraged to provide feedback on difficulties they notice while using the device. This technique can provide valuable information but is limited due to the lack of realism. The walk-through is best used for evaluating design alternatives early in the development process.

#### **5.4.2 Usability Testing**

Usability testing (also called *user testing*), is a powerful technique used to determine how usable or unusable a product is. This technique can also be used to identify and understand previously unanticipated or poorly understood use scenarios resulting in hazards if care is taken to focus on the safety and effectiveness perspective. The central advantage of usability testing is that device use is realistic, and the results of the process are more representative of actual use than results obtained through analytical techniques only. If usability testing is employed early in the development process, it can identify many potential use-related hazards, and allow them to be modified with a minimum of effort.

Usability testing can be done in a variety of ways in various degrees of complexity and formality but should include these features:

- An overall goal of improving the usability including the safety and effectiveness of a product,
- Test participants represent intended users of the device,
- Test participants do real tasks, particularly tasks that best reflect whether safe and effective use is occurring,
- Testers observe and record important aspects of what test participants do and say (participants may also respond to questionnaires), and
- Resulting data are analyzed to identify use scenarios resulting in hazards and recommend specific actions to address them.

In addition to safety and effectiveness, usability testing is used extensively by manufacturers to enhance the functionality, aesthetics and hence the desirability and marketability of products. For medical devices, usability testing should enhance understanding of the hazards related to device use. Demonstrating how well users like using a product is not sufficient to do this. However, both safety *and* user preference data can be collected simultaneously in usability testing. When reviewing reference materials on usability testing, it is important to distinguish between methodologies that are oriented strongly toward testing of user preferences and those that focus on testing the safety and effectiveness of a device.

Usability testing involves systematic observation and collection of performance and subjective data from actual users using a device (or device component). Test coordinators should provide general and specific instructions on how to use the device as necessary, develop test scenarios for use, recruit and instruct test participants, and develop data collection and analysis methodologies.

Test scenarios guide the operation of devices by test participants. For usability testing to be valuable for ensuring safe and effective device use, test scenarios should be developed that focus the device use and evaluation on selected use scenarios known or suspected to result in hazards, (Sections 5.3.1, and 5.3.2). It may be necessary to prioritize the use scenarios prior to inclusion in test scenarios (Section 5.5).

In addition to focusing on known or suspected use scenarios resulting in hazards, the testing methodology should also allow for previously unanticipated use scenarios resulting in hazards to be identified and described. Testing can also focus on exploring details of how a use-related hazard scenario occurs with the expectation that this understanding will support controls to address the hazard.

Data collected from use studies may include objective measures such as the type and number of errors made, time required to do tasks, and requests for help. Subjective measures include descriptions of difficulties encountered while using the interface, good and bad use scenarios resulting in hazards, user preference for existing or possible modifications of the user interface or characteristics of device operation.

## **5.5 Prioritization and Assessment of Use-related Hazards**

Use-related hazards identified by analytical and empirical techniques should be assessed to determine their priority for subsequent risk control efforts. It may be necessary to prioritize use scenarios that need further examination with analytic or empirical techniques.

This process can involve obtaining and combining input from several individuals who provide perspective from a variety of areas of expertise. This process should also incorporate valid and useful information about likelihood and consequences (i.e., risk) of use-related hazards for similar devices when available.

Important perspectives include those from persons with expertise in:

- Clinical aspects of the underlying medical condition associated with the device use and the results of effective and ineffective use (*clinical expert*),
- Day-to-day use of the device or similar devices (*expert user*),
- The design and operation of the device (*engineer*), and
- Human factors analysis and testing (*human factors or usability specialist*).

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These individuals should then assess the likelihood of these hazards and their causes to estimate the risk for each. Within the general process described in this guidance, assessment of preliminary results through group consensus is most useful for:

- Identifying hazards for which mitigation is necessary,
- Ruling out hazards that have been successfully addressed,
- Developing strategies and controls to eliminate or reduce the likelihood of or mitigate the consequences of hazards related to use, and
- Verifying that controls are effective in reducing or eliminating hazards.

### **5.6 Mitigation and Control of Use-related Hazards**

Instructions, labeling, and training can influence users to use devices safely and effectively and are critical human factors considerations for device use. At the same time, these approaches are limited in their effectiveness. If device interface problems are serious, hazards related to device use will likely persist despite these measures. Therefore, serious design deficiencies should not be “patched up” with instruction, labeling or training, since they will likely not overcome serious design problems that could affect safety and effectiveness of device use.

To the extent possible, the device interface design should convey the concept for correct operation through its appearance or operation (“look and feel”) so that its operation is intuitive to users and reliance on instructions and labeling is minimized. When user interface design problems are identified during development, efforts should focus on improving its design. Early identification of interface design problems will reduce time and expense for any modifications necessary and reduce the need to rely on instructions, labeling, or training “patches.”

The following list presents the order of preference for applying strategies to control or mitigate risks of use-related hazards:

1. **Remove hazard causes through design:** The design should be developed to eliminate hazards to the extent possible. If hazards cannot be eliminated, the design should act to reduce their risk.
2. **Make design or operating logic error tolerant:** When specific errors on the part of the user are likely, such as pressing an adjacent key on a keypad, the operating logic of the device should preclude a hazardous outcome resulting from this kind of error. Safety mechanisms such as safety guards, shielded controls, or interlocks will make the design more tolerant of inadvertent errors made by users.

3. **Alert users:** When neither design nor safety features will effectively eliminate a use-related hazard or mitigate the consequences, the device should detect the condition and produce an adequate warning signal to alert users of the hazard.
4. **Develop written procedures and training for safe operation:** Where it is impractical to eliminate hazards through any of the previous strategies, written procedures and training for safe operation should be used.

## **5.7 Verification and Validation of User Interface Design**

Verification confirms that the specific functional and operational requirements for the design of a device user interface have been met. The process for verifying individual user interface requirements may require focused efforts for each. For instance, if it was determined that a device will be used by an elderly user population, a specification would likely be developed to assure that the device's alarm volume can be adjustable to a sufficient level to accommodate minor to moderate hearing loss. Verification would involve testing the device alarm with a small group of users with a range of hearing from normal to moderate hearing impairment. Whether users with moderate hearing loss can hear the alarm well enough to allow them to use the device safely and effectively is the essential component of this verification.

Validation establishes that the device meets the needs of the intended users. The ability to use it safely and effectively under the intended use conditions is the primary need of medical device users. An interface design is validated using usability techniques (Section 5.4.2). For the purpose of validation, it is particularly important to use a production version of the device, representative device users, actual or simulated use environments, and address all aspects of the intended use. It is not always necessary for validation to be extensive at the end of the design process if small-scale iterative testing of interface components was done adequately during development.

### **5.7.1 Clinical Trials**

Well-planned clinical trials can provide a useful vehicle for validating safe and effective device use. To do this, a methodology should be developed that provides a focus on anticipated use scenarios related to hazards, and allows for identification of unanticipated use-related hazards as well. The methodology should address the perspective of device users including their assessment of device use and their experience with inaccurate or undesired results (regardless of whether these have an impact on medical treatment during the clinical trial). The methodology should include a means for collecting, evaluating, summarizing and reporting this kind of information. Much of this information takes the form of verbal descriptions (e.g., confusion experienced by users when interpreting device output). For this reason, qualitative results in the form of verbal responses may be more useful and appropriate than strictly quantitative measures, although quantifying summaries of related verbal descriptions is very useful.

## **6.0 Device Use Documentation**

For the majority of devices subject to design controls, Quality Systems Regulations recommend that manufacturers develop and document a design control procedure that incorporates risk management. CDRH expects that the manufacturer will have already developed and begun the design control process before a submission for new-device approval is initiated. The submission of documentation associated with the design control process can streamline and facilitate that part of the pre-market review process concerned with *safe and effective device use*.

When information pertaining to device use safety is extensive, it is helpful to provide it in summary form that highlights the most important issues, considerations, resolutions, and conclusions. When portions of this information are presented in various parts of a submission a cross-reference should be provided.

The level of detail of device use documentation submitted should be consistent with the level of concern of use-related hazards for the device. The kinds of information that should be included with the device use documentation submitted are described below.

### **6.1 Device Overall**

- The purpose and operation of the device;
- The patient populations *on* whom the device will be used;
- The physical device, e.g., size, shape, weight, important components, and how powered;
- A comparison of device use with other devices currently in use that operate similarly or perform similar tasks; and
- A description of how the device addresses the needs of intended users.

### **6.2 Device User Interface**

- The physical characteristics of the user interface; and
- Existing or anticipated labeling materials that will be provided to the user with the device, e.g., labels on the device itself, packaging, operating instructions, and training materials.

### **6.3 Device Use**

- The logic of operation (user interaction with device interface);
- How the device is set up, operated, and maintained; and
- The primary tasks that the user is expected to perform

### **6.4 Device User Population**

- The intended population of device users;
- The characteristics of device user population that were considered during the design;
- The training and information tools that the user population will require to operate the device safely and effectively; and
- The population of users for which the device is not intended to be used.

## **6.5 Device Use Environments**

- Environments in which the device is intended to be used (e.g., home, hospital, medevac vehicles); and
- Environments in which the device is unsuited, or which may be expected to affect device performance.

## **6.6 Use-related Hazards**

- The use-related hazards that have occurred with similar, already marketed, devices;
- The processes used to identify and prioritize use-related hazards;
- The use-related hazards that have either been identified during development or have occurred with this device during early testing;
- How significant use-related hazards were mitigated or controlled during design and development; and
- Why strategies used to address use-related hazards are appropriate.

## **6.7 Verification and Validation**

- Testing and evaluation processes and results associated with determining whether device use design considerations have been achieved; and
- Testing and evaluation processes and results associated with determining whether intended device users can use the device safely and effectively in actual or simulated conditions.

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