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Draft Guidance for Industry and Food and Drug Administration Staff

Design Considerations for Devices Intended for Home Use

DRAFT GUIDANCE

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**Department of Health and Human Services
Food and Drug Administration**

Center for Devices and Radiological Health

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Preface

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Table of Contents

1. Introduction.....	4
1.1 Scope.....	5
1.2 Definitions.....	5
2. Background.....	6
2.1 Design Controls for Home Use Devices under the Quality System regulation.....	7
2.2 Overview of Factors to Consider for Home Use Devices.....	8
3. Environmental Considerations.....	9
4. User Considerations.....	11
5. Device Considerations.....	12
5.1 Lock-Out Mechanisms.....	12
5.2 Calibration.....	12
5.3 Mechanical Strength.....	13
5.4 Electrical Issues.....	13
5.5 Electromagnetic Compatibility (EMC).....	14
5.6 Wireless Technology.....	15
5.7 Alarm Systems.....	15
6. Human Factors.....	16
6.1 User Training and Certification.....	17
7. Labeling.....	17
7.1 Handling the Device in an Emergency.....	18
7.2 Disposal of Hazardous Waste Materials.....	19
7.3 Hygienic Maintenance.....	19
8. Postmarket Considerations.....	20
8.1 Customer Service.....	20
8.2 Medical Device Reporting.....	20
8.3 Selling or Purchasing Used Prescription Devices.....	21
9. Conclusion.....	21
10. Additional Resources.....	22

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1. Introduction

This draft guidance is intended to assist manufacturers in designing and developing home use devices that comply with applicable standards of safety and effectiveness and other regulatory requirements. Home use devices are associated with unique risks created by the interactions among the user (often a layperson), the use environment, and the device. This guidance identifies several factors that manufacturers of home use devices should consider, especially during device design and development, and provides recommendations for minimizing these unique risks.

Throughout this guidance the term “you” refers to manufacturers as defined in 21 CFR 820.3(o). For convenience the definition is restated here: *Manufacturer* means any person who designs, manufactures, fabricates, assembles, or processes a finished device. Manufacturer includes but is not limited to those who perform the functions of contract sterilization, installation, relabeling, remanufacturing, repacking, or specification development, and initial distributors of foreign entities performing these functions.

For additional information or questions about the FDA-recognized standards referenced in this guidance document, please contact CDRH's [Standards Program](http://www.fda.gov/StandardsProgram) (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards.default.htm>) or by calling 301-796-6574).

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1.1 Scope

This draft guidance provides recommendations for minimizing the risks associated with home use devices by considering the user, the use environment, the device or system, human factors, and labeling. This guidance applies to both prescription and over-the-counter medical devices that are intended for home use.¹ The recommendations in this document apply whenever you are designing or developing a home use device, as defined in subsection 1.2 below. This draft guidance also provides recommendations regarding postmarket considerations. These recommendations should also be considered when a manufacturer is designing a device that is likely to be used in the home, even if the device is not intended solely for home use.

1.2 Definitions

The following definitions apply for purposes of this guidance document:

A **home use device** is a medical device intended for users in any environment outside of a professional healthcare facility or clinical laboratory. The term includes devices intended for use in both professional healthcare facilities and homes.

A **user** is a lay person such as a patient (care recipient), caregiver, or family member who directly uses a device or provides assistance to the patient in using the device.

A **professional healthcare facility** is an environment where operators with medical training are continually available to use devices when patients are present. This includes but is not limited to hospitals, long-term care facilities, nursing homes, emergency medical services, clinics, and outpatient treatment facilities.

A **clinical laboratory** is a facility that (1) performs testing on materials derived from the human body for the purpose of providing information for the diagnosis, prevention, or treatment of any disease or impairment of, or assessment of the health of, human beings; and (2) has been certified to perform such testing under the Clinical Laboratory Improvement Amendments of 1988 (42 U.S.C. 263a) in accordance with 42 CFR part 493, or has met equivalent requirements as determined by the Center for Medicare and Medicaid Services in accordance with those provisions.

¹ Sponsors of home use in vitro diagnostic tests to diagnose HIV are advised to contact CBER to discuss issues related to those tests.

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A **qualified healthcare professional** is a licensed or non-licensed healthcare professional with sufficient skills and experience with the use of a device to aid or train someone to use and maintain the device.

A **home** is any environment other than a professional healthcare facility or clinical laboratory where a device may be used.

2. Background

For a variety of reasons, use of devices outside professional healthcare facilities or clinical laboratories is on the rise. First, the United States population is aging, and the elderly are more likely to live with chronic diseases that require daily medical care at home. Second, due to medical advancements, many individuals with chronic diseases are living longer, but are dependent on home medical care. Finally, an increasing focus on reducing healthcare costs for patients of all ages has spurred the growth of the home health care market. Integral to the home health care market are home use devices. Although home use devices provide significant benefits to patients and families, including quality of life improvements and cost savings, home use devices are also associated with unique risks. These risks result from interactions among the user, the use environment, and the device, and can greatly impact user and patient safety.

Due to the increasing prevalence of home use devices, minimizing the risks posed by such devices can greatly improve the public health. With this in mind, FDA developed the following considerations that can help manufacturers reduce or minimize common risks posed by home use devices. These risks are best addressed at the design stage. Failure to adequately consider certain factors during the design of home use devices may result in inappropriate use, use error, or incompatibilities between the use environment and the home use device. This may lead to hazardous situations or cause the device to malfunction, possibly contributing to death or serious injury.

When developing a new home use device, you should take the considerations in this guidance document into account and, to the greatest extent possible, reduce or minimize risk through device design, commonly referred to as “designing risk out of the device.” For any premarket submission to FDA, you should include summaries of the specific steps you took to ensure that the device is suitable for home use and explain in your premarket submission how you implemented the considerations in this guidance document. This can help FDA determine whether applicable safety and effectiveness requirements have been met.

Following the recommendations in this guidance can help you develop a device that is best suited to the home use environment, which should decrease the occurrence of adverse events by minimizing the risks to patient and user safety.

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2.1 Design Controls for Home Use Devices under the Quality System regulation

The Quality System regulation (QS regulation)² describes requirements intended to help ensure that finished medical devices have a reasonable assurance of safety and effectiveness. For example, it requires that you establish and maintain procedures to control the design of the device to ensure that specified design requirements are met. This guidance document provides recommendations on technical issues to consider during the design and development of home use devices. This section outlines certain aspects of design control that are particularly important for home use devices.

Under 21 CFR 820.30 -- Design Controls, a manufacturer must establish procedures to ensure that device design will translate into a device that performs properly according to its intended use and user needs.³ Design control requirements of the QS regulation apply to design and development of the device as well as its packaging and labeling (e.g., Instructions for Use), and its cleaning, disinfection, and sterilization procedures. When establishing design controls for home use devices, you should take into account considerations related to device performance and user needs in the home environment, which are discussed in detail below. For more information about creating and implementing design controls, we recommend you refer to [Design Control Guidance for Medical Device Manufacturers](http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm070627.htm), (<http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm070627.htm>). We also recommend that you refer to ANSI/AAMI HE74-2001, *Human Factors Design Process for Medical Devices*, for a process-oriented approach to user interface design, which is especially relevant in developing safe and effective home use devices.

You should consider developing a risk management plan. This risk management plan should describe the process for identifying hazards, estimating and evaluating the known risks, controlling the risks, and monitoring the effectiveness of the controls. In your risk analysis, special attention should be paid to the possible causes of use-related errors and failures, as home use devices are exposed to more hazards than are present in professional health care facilities, and present greater potential for harm caused by misuse (intentionally or not) on the part of the user.

Your risk management plan should also include elements to control risk that can enhance the ease of use for the intended user population based on human factors engineering methods (see Section 6). Methods to control risk and to enhance ease of use include designing the device to reduce or minimize risks, developing protective measures in the device itself (e.g., an automatic shutoff), or providing information for safety. You should strive for the highest level of risk mitigation possible by designing risk out of the system to the greatest extent possible. Most importantly, labeling alone generally does not offer sufficient risk control for the home use environment because warning labels, especially lengthy ones, can be ignored by

² 21 CFR Part 820.

³ See 21 CFR 820.30(g); see also 61 FR 52620 at 52616.

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or be confusing to the user. Accounting for the considerations described in this document will help mitigate risk and guide device design so that it is appropriate for the intended user and use environment.

Software plays a critical role in the operation of some devices. For these devices, you should focus on developing device and software architecture and algorithms for performance, error detection, control, and recovery. When developing a home use device, you should broaden your existing concept development and preliminary testing processes to account for the needs of home users and requirements for straightforward device operation, obvious interface layouts, and appropriate alarm methods. If software upgrades are required, you should consider how this will be performed in the home environment with the least burden on and lowest risk to the user.

For software in general, we recommend you review and use IEC 62304 First edition 2006-05, *Medical device software – Software lifecycle processes*, as well as FDA’s guidance [General Principles of Software Validation; Final Guidance for Industry and FDA Staff](http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm126955.pdf) (<http://www.fda.gov/downloads/RegulatoryInformation/Guidances/ucm126955.pdf>).

Please also refer to FDA’s [Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm) (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089543.htm>).

More information on human factor-specific design control, such as use error, hazards, human skills and abilities, environmental considerations, design elements, user interfaces and alarms, and testing, is available in ANSI/AAMI HE75:2009, *Human Factors Engineering - Design of Medical Devices*.

2.2 Overview of Factors to Consider for Home Use Devices

To increase the likelihood that home use devices will be used safely and effectively, you should account for risks in the following areas that are particularly important for these devices: the environment; the user; the device or system; human factors; and labeling. Although these same areas are relevant to devices used in healthcare facilities and clinical laboratories, there are aspects of these areas that are unique to the home environment.

The user should be considered throughout the design process and during the postmarket phase to improve future versions of the device. You should also consider how the device itself will interact with the environment in which it will be used to ensure that the device is compatible with the use environment. Human factors and labeling also should be considered during the design, testing, and postmarket phases across the complete product life cycle. These considerations are discussed in more detail below.

3. Environmental Considerations

When designing a home use device, you should account for the range of environments in which it may be used and the applicable environmental conditions noted below. The labeling of the device should include warnings against using the device in environmental conditions which would raise safety or effectiveness concerns; however, labeling should never be used to mitigate risks associated with device design flaws. FDA recommends you follow IEC 60601-1-11 Edition 1.0 2010-04, *Medical electrical equipment –Part 1-11: General requirements for basic safety and essential performance –Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment* for the appropriate environmental considerations in the design of home use devices, even if they do not involve electrical equipment. You should include in your premarket submissions a description of the efforts you took to account for the environmental considerations outlined below in your device design.

- **Location:** Home use device design should permit the device to operate in its intended use location(s) (e.g., urban/suburban/rural, school/office/retail environments, and train/plane/car). Consider where the device will be used and how these locations would impact the user and the device's ability to function and operate safely and effectively. You should also note possible sources of electromagnetic interference (EMI) for electric powered medical devices in the use location(s) that may be near or in contact with other objects that would interfere with their functioning, such as large electric motors or amateur radio transmitters, radio and TV transmitters, radar, and high tension power lines.
- **Physical location:** Home use device design should take into account the structures in which the device will be used. Your device design should permit the device to move in and out of the environment, as well as move from place to place within the environment (e.g., from room to room). Crowded use environments can interfere with device use and movement, present tripping hazards, or increase the likelihood that device parts will bump into or get tangled with objects in the environment. In addition, the device may not operate in a certain physical location if it relies on a wireless signal that may be unavailable.
- **Contaminants:** Home use device design should permit the device to be operated in a non-sterile environment. The risk that the device could be affected by contaminants such as vermin, pets, tobacco smoke, and household chemicals should be mitigated as much as possible by designing the device so that the ingress of fluids and air particles that would affect device operation is prevented.
- **Water supply:** You should specify the type of water that is required to properly operate and clean the home use device, e.g., well water versus distilled water. For

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additional information on keeping water safe, see [Center for Disease Control and Prevention's Web site \(http://www.bt.cdc.gov/disasters/foodwater/facts.asp\)](http://www.bt.cdc.gov/disasters/foodwater/facts.asp).

- **Temperature:** Home use device design should incorporate expectations for the anticipated temperature variability in the intended use environment, especially for devices that are portable and may be exposed to fluctuations and extremes in temperature.
- **Dampness and humidity:** Home use device design should incorporate expectations for the variability in humidity levels which are expected to be present in the intended use environment, especially for devices that are portable and may be exposed to fluctuations and extremes in humidity.
- **Atmospheric pressure changes:** Home use devices should be designed to operate properly within a range of atmospheric pressures such as lower pressures that occur in the mountains and during air travel, or higher pressures that exist below sea level.
- **Air flow:** Home use device design should ensure that air flow will be adequate for proper device operation.
- **Childproofing:** Home use devices should be childproof, even if they are not intended to be used by children. Devices should have a minimal number of parts that can be manipulated easily as well as a minimal number of detachable parts that could fall off the device, presenting an inhalation or swallowing hazard.
- **Tampering:** Home use devices should be resistant to tampering, including intentional or non-intentional misuse.
- **Travel and International Use:** Design of portable home use devices should anticipate that users will travel, locally or internationally, with their medical devices and may use a variety of transportation modes as they travel. For electrical home use devices, you should provide information in the labeling on the adaptability of the device to the electrical supplies and voltage rates of other countries, and whether an adaptor may be used to operate the device. Given that electrical power varies by country, electrical converters and battery back-up may be necessary to operate the device in a country outside the United States. Labeling should also include information on how users can get help if the device malfunctions while they are away from home.

In designing the device, you should also anticipate that users, including users of any body-worn medical devices, may be required to pass through security screening systems while traveling. These systems continue to evolve, but currently include backscatter X-ray and millimeter wave technologies. You should consider whether these systems can interfere with the operation of the device. In addition, if users must

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undergo a security pat-down to avoid the automated screening system, you should consider how the procedure might affect body-worn medical devices, such as a continuous blood glucose meter. In the instructions for use (IFU), consider referring the user to the [Transportation Security Administration \(TSA\) Web site](http://www.tsa.gov/travelers/airtravel/specialneeds/index.shtm) (<http://www.tsa.gov/travelers/airtravel/specialneeds/index.shtm>), which includes information about procedures for travel with medical equipment.

- **Fluid Exposure:** You should consider what the device can safely tolerate when it is subject to fluid spills or submersion, as well as the amount of fluid that the device can be exposed to without impacting its safe use.

4. User Considerations

The users of home use devices are different from the health care professionals who typically operate medical devices in a professional health care facility. Home users can have a large range of physical, sensory, cognitive, and emotional capabilities and disabilities that should be considered in your home use device design. If the home use device is not designed for ease of use and understanding, you increase the risk of misuse and non-use of the device.

We recommend you review:

- FDA's guidance on human factors, [Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094460.htm) (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094460.htm>)
- ANSI/AAMI/IEC 62366:2007, *Medical devices - Application of usability engineering to medical devices*
- ANSI/AAMI HE75:2009
- IEC 60601-1-11: 2010

The following personal characteristics can affect device use and should be considered in the design of the device. Note that some home use devices are designed to diagnose or treat medical conditions that can cause functional impairments; therefore, it is important to design those devices to be usable by individuals who have impairments. When a premarket submission is required, it should include a description of the efforts you took to account for these characteristics in your device design.

- **Physical:** You should design for users with a range of physical sizes, mobility, dexterity, coordination, flexibility, strength, and stamina.
- **Sensory/Perceptual:** You should design for users with a range of vision and hearing abilities and tactile sensitivities. In your home use device design, you should consider the visibility of the device interface under a variety of ambient lighting conditions, the visibility of any alarm signals and whether they will be differentiated from other sounds in the environment, the types of feedback mechanisms that will operate while

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the user is interacting with the device, and whether any perceptual issues might affect the user's ability to use the device properly, which could include handling the device and the manner in which it touches the user.

- **Cognitive:** You should design for users with a range of abilities to process information and literacy levels, and consider the potential that users might have some type of cognitive impairment that could affect how they interact with the home use device. Consider the amount of experience the users might have with a type of device and with similar devices, and how able and willing they might be to learn and adapt to using a new device.
- **Emotional:** You should consider that many home use device users may be providing care for a loved one who is unable to use the device unassisted. Whether a person is providing care to others or performing self-care, he or she can be dealing with a new diagnosis or condition along with the need to operate a medical device, which can be overwhelming and cause anxiety for the user.

5. Device Considerations

Home use devices should be simple for users to understand, operate, and maintain safely and effectively. Below are some of the device-specific considerations that you should take into account when designing a home use device.

5.1 Lock-Out Mechanisms

FDA recognizes that lockout mechanisms can be used for controlling access to certain device functions, such as preventing the patient from changing settings entered by the health care professional or caregiver. However, the safety of home use devices should not depend solely on such mechanisms. Before using a lock-out mechanism as the only mechanism to reduce or prevent patient harm, you should first rule out other design solutions. However, if a lock-out mechanism is the only mechanism available to reduce or prevent patient harm, it should be used.

5.2 Calibration

Home use devices should be designed without the need for calibration, but if that is not possible, the device should be designed to require minimal calibration by the user. Calibration instructions on the device display should be step-by-step and preferably provide the user with any feedback necessary to complete the calibration process. This should also include a visual indicator on the device that states when it was last calibrated and when the next calibration is needed.

The device should also discourage operation without calibration. However, when the performance of the device depends on the use of calibrators, the traceability of the values

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assigned to these calibrators should be assured through a quality management system. If the device calibration needs to be done by a trained professional, you should indicate whether the device can remain in the home or has to be calibrated in another location. You should refer to available consensus standards and FDA guidance documents particular to the type of device that you are designing to review specific calibration requirements.

5.3 Mechanical Strength

Because some home use devices are portable and will be moved around frequently, it is critical to test them to see how they function after impact with the ground or other objects.

IEC 60601-1-11:2010-04 includes information on mechanical strength for both transit operable and non-transit operable electrical medical devices. The medical device and its parts, including mounting and other accessories, should have adequate mechanical strength so that they can withstand stress caused by normal use that includes pushing, dropping, rough handling, freefall, vibration, and impact with the ground or another object. If the device will be used while the user is in transit, the device should have adequate mechanical strength and durability to withstand normal transport conditions on trains, road vehicles, cycles, ships, and aircraft. FDA recommends you follow IEC 60601-1-11:2010 for mechanical strength in the design of medical devices, including those devices that are not electrical equipment. For portable medical devices that are intended to be used only with a carrying case, the case should be tested along with the device.

5.4 Electrical Issues

Design of home use devices that use electricity should take into account that some use environments might have unreliable sources of electricity and poor electrical grounding. The General Standard ANSI/AAMI/ES 60601-1:2005, *Medical electrical equipment – Part I: General requirements for basic safety and essential performance* includes information regarding the following electrical issues related to medical devices:

- **Supply Mains:** If a device includes its own supply main you should follow the characteristics of the supply mains that are specified in IEC 60601-1-11:2010, which discusses additional information about interruption of the power supply/supply mains to medical equipment. Voltage limitations for both life-supporting and non-life supporting medical devices are covered by the standard.
- **Internal electrical power source:** If the safe performance of a device is dependent on an internal electrical power source (e.g., batteries), the IFU should describe the typical operation time or number of procedures and the typical service life of the power source. If the device uses a rechargeable power source, the IFU should explain whether the device can be used while it is charging. If the internal power source is replaceable, the IFU should explain the replacement process.

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- **Permanently installed devices:** If a device is to be permanently installed in a home, the labeling should include clear information and specifications about proper protective grounding and recommend that the installation should be performed by a qualified professional.
- **Outlets and Adaptors:** Because older buildings may have poor-quality outlets and/or a limited number of outlets, you should inform the user if the device should not share an outlet with another electrical device or be connected to an outlet controlled by a wall switch. You should also consider whether surge protectors, extension cords, or ground fault interrupters are appropriate for use with your device and inform the user accordingly. For example, if the device is life-sustaining, you should provide surge protection. As some plugs are not compatible with some outlets in the home (e.g., the home has two-pronged outlets but the device requires a three-pronged outlet), you should inform the user in the IFU whether and what type of adaptor can be used safely with the device.
- **Power outages:** If a device requires electricity to operate, it should be designed with back-up power options, such as a battery or generator. You should also provide instructions in the device labeling for emergency contact information in the event of a power outage (e.g., manufacturer, power supply company, or clinical care provider, as appropriate). If the device cannot operate without a backup power supply, this should be noted either on the device or in the warnings section of the IFU. The design of the device should include a way to continue to use the device in the event of a power outage. The IFU should disclose the continued device use time or number of procedures available following a loss or failure of the electrical power supply before needing to go to a backup power supply. The device should also be designed with a battery or other power backup supply to be used when the power is out for long periods of time. You should include in your IFU how long the user should expect the device to work on backup power.
- **Battery life:** If a device operates on battery power, you should inform the user how long he or she can expect the device to work on a fully charged battery.

5.5 Electromagnetic Compatibility (EMC)

Electromagnetic compatibility (EMC) is the ability of a device to operate properly in its intended use environment without introducing excessive electromagnetic disturbance into that environment. The FDA recognizes the standard, IEC 60601-1-2 Third edition 2007-03 , *Medical Electrical Equipment, Part 1-2: General Requirements for Basic Safety and Essential Performance – Collateral Standard: Electromagnetic Compatibility – Requirements and Tests*. This standard describes EMC testing and includes both tests for immunity of the device to outside electromagnetic disturbance and emissions from the device to the outside. In addition to evidence of compliance with this standard, you should provide summary information in your premarket submissions to FDA describing the testing that was

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conducted and how, the device functions and modes that were tested, the pass/fail criteria used, reference standards and any deviation or allowances that were taken, any device modification needed to pass the testing, and appropriate labeling. Device manufacturers should consider appropriate levels of testing in accordance with the risks presented by such environments in addition to the basic immunity testing described in standard IEC 60601-1-2:2007.

If your home use device contains any electrical components, information in your premarket submission to FDA should include a complete description of the EMC characteristics of the device, and the information to verify those characteristics.

Lay users should not be expected to understand how to avoid electrostatic discharge (ESD) or how to take proper ESD precautions. You should consider that the standard ESD test levels are often exceeded in the home environment and home use devices should be designed to reduce this increased risk to an acceptable level.

5.6 Wireless Technology

If a device incorporates radio frequency (RF) wireless technologies, the device description in the premarket submission should contain a complete description of the exact wireless technology used, its functions, including alarm conditions carried, characteristics, performance, and risk management. Compliance of RF wireless technologies with applicable technology standards and Federal Communications Commission (FCC) rules does not necessarily alleviate home use device safety and effectiveness concerns. Particular points to address include quality of service needed, data integrity, coexistence, security, and EMC of the wireless signals. Due to the increased use of RF wireless technology that operates in the same frequency range, you should carefully address RF wireless coexistence through testing the device with other common applications of RF wireless technology that can be expected to be present in the environment of use. If your device or system is expected to have two or more like devices operating wirelessly in close proximity to one another (e.g., mobile or body worn devices located in a waiting room or the same room of a home), the ability to so operate should also be tested.

5.7 Alarm Systems

Alarm systems are of particular concern for home use devices because noise both inside and outside the home can interfere with the users' ability to hear an alarm signal. Users can have hearing impairments, including the inability to hear specific frequencies. Device alarm systems with high or medium-priority alarm signals should be designed to be heard in uncontrolled noise environments typically found in the home. If the alarm system incorporates wired or wireless connections to other locations, the entire device system should be designed and tested to mitigate risks from loss or degradation of these connections.

FDA recommends you provide alarm signals for home use devices in at least two of the three following modes: visual, auditory, and tactile. This alarm signal could be localized to the

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area where the device is being operated or in another location, which is known as a distributed alarm system. For example, the alarm could sound in another room or in a remote location where it is being monitored. FDA recommends you follow IEC 60601-1-8 Second edition 2006-10, *Medical electrical equipment; Part 1-8; General requirements for basic safety and essential performance; Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems*, for the design of alarm systems, including distributed alarm systems.

6. Human Factors

To understand the hazards associated with the use of a medical device in the home, it is necessary to have an accurate and complete understanding of *how* a device will be used by the users. Understanding and optimizing how people use and interact with technology is the subject of human factors engineering.

Human factors engineering offers well-established methods to identify user interface design issues that could affect medical device safety and efficacy. In a typical “usability” test session, representative device users perform selected tasks under conditions of simulated (not actual) use in an appropriately realistic environment. Depending on the nature of the device and the goals of the test, the test environment could range from a conference room to a sophisticated, high-fidelity simulation of the expected use environment or an actual home. Testing early in the design process and then several more times as the design evolves is an effective way to prevent user interaction problems from persisting into the later stages of the design process, at which point effective solutions to problems may be more limited and more expensive to implement.⁴ Following the formative stage of design development, FDA recommends that you conduct a human factors validation study.⁵

We recommend that you consult FDA’s guidance, [Medical Device Use-Safety: Incorporating Human Factors Engineering into Risk Management](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094460.htm), (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094460.htm>). FDA also has draft guidance on this topic, [Applying Human Factors and Usability Engineering to Optimize Medical Device Design](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm259748.htm), (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm259748.htm>). Additionally, you may refer to relevant U.S. and international standards, e.g., ANSI/AAMI HE75:2009; ANSI/AAMI/IEC 62366:2007; and ISO 14971:2007.

⁴ Such testing may be subject to IDE requirements in section 520(g) of the FD&C Act and 21 CFR Part 812 and the human subject protection requirements in 21 CFR Parts 50 and 56 depending on the nature of the testing.

⁵ Such a study may also be subject to the IDE and human subject protection requirements referenced above.

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6.1 User Training and Certification

When designing devices, you should take into account that users may not understand multiple steps, may receive minimal training or teaching on how to operate these devices, and may not be able to understand multiple warnings and precautions. In addition, users may not understand the need to calibrate, clean, and maintain the device. User training may be critical for safe operation of home use devices.

We recommend that you consider the need for training as you determine the complexity of your home use device. The time needed for successful training depends on factors specific to the device. We also recommend that you consider testing the user's comprehension and retention of the training received through a return demonstration, written test, or both.

For many devices, the user may also need a partner to help operate the device safely and to provide monitoring of the patient while the device is being used. We recommend that you outline the responsibilities of the care partner, the caregiver, and the care recipient during the training sessions and provide instructions to users on emergency procedures, such as the procedures necessary if a serious adverse event occurs. We recommend that you provide guidance to the user on any retraining or recertification that is needed for safe operation of the device and indicate how frequently this needs to be done. You should also provide ways to verify that this retraining is taking place. We recommend that you provide checklists to the user to encourage safe operation through a validation of steps.

7. Labeling

Labeling for home use devices must address all applicable requirements in 21 CFR Part 801 and 809.10. For further assistance refer to the information addressed in FDA's [Guidance on Patient Labeling; Final Guidance for Industry and FDA Reviewers](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070782.htm) (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070782.htm>).

In general, the IFU for the user should be simple, concise, and easily understood. Instructions written for the user should be written in a narrative format and pictures may be helpful to explain instructional steps. Although instructions, labeling, and training can influence users to use devices safely and effectively, use of such material assumes that the user will remember or refer back to the information. These approaches are less effective than designing the user interface so that it is inherently apparent to users how to use the device. The device's labeling should include contraindications that clearly explain why any individuals should not use the device, and clear warnings of all hazards that cannot be designed out. Using the same terms throughout the labeling to identify the device avoids confusion for the user. In addition to the labeling requirements found in 21 CFR Part 801 and 809.10, information for developing labeling for home use devices can be obtained from the following documents:

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- [Labeling of Home-Use In Vitro Testing Products: Approved Guideline](http://www.clsi.org/source/orders/free/gp14-a.pdf), Clinical and Laboratory Standards Institute's CLSI GP-14, Vol. 16 No. 2 (June 1996) (<http://www.clsi.org/source/orders/free/gp14-a.pdf>).
- FDA's guidance [Establishing Safety and Compatibility of Passive Implants in the Magnetic Resonance \(MR\) Environment](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm107705.htm) (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm107705.htm>). FDA recommends that implanted devices include labeling that encourages patients to register the conditions under which the implant can be scanned safely with the [MedicAlert Foundation](http://www.medicalert.org) (<http://www.medicalert.org>) or equivalent organization.
- FDA's [Guidance on Medical Device Patient Labeling](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070782.htm) (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070782.htm>). This guidance discusses how the labeling should be written to address the needs of the patient in particular including risk statements, the descriptive portion of the device labeling, operating information, troubleshooting information, and ways to address warnings, appearance, precautions, and testing.
- FDA's [Guidance for Industry and FDA Staff: Investigational Device Exemptions \(IDE\) for Devices Indicated for Nocturnal Home Hemodialysis](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071138.htm) (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071138.htm>).
- ISO 15197 First edition 2003-05-01, *In vitro diagnostic test systems – Requirements for blood-glucose monitoring system for self-testing in managing diabetes mellitus*, Clause 5.

The IEC 60601-1-2:2007 standard contains specific labeling information based on the electromagnetic compatibility (EMC) test with recommendations for separation distances for radiating emitters to maintain the tested immunity levels. The standard also states that for devices incorporating wireless technology, the labeling should contain summary information about the exact wireless technology in the device, its capabilities, quality of service needs, wireless security and any EMC warnings or precautions. The information should include brief information about how to recognize and deal with electromagnetic interference (EMI) if it occurs.

7.1 Handling the Device in an Emergency

FDA recommends that manufacturers of life-supporting and life-sustaining care devices for the home have plans for providing emergency service and supplies during natural disasters and public health emergencies. You may refer to the booklet "[How to Prepare for and Handle Power Outages for Medical Devices that Require Electricity](#)"

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Draft - Not for Implementation

(www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/UCM252812.pdf). The booklet provides information that a user should have in the event of a power outage, including a contact telephone number for the manufacturer. The booklet advises the user that he or she keep all of his or her device information in one place that is readily accessible, such as on the refrigerator or on a device identification card that the user carries. The booklet recommends that users contact their local power companies and their local social services departments to be put on lists for special attention when public health or safety emergencies happen. The booklet also advises users to look for signs of damage to the device and how to identify the circumstances under which the device or its accessories should not be used.

Refer to the following sources for more pertinent information about handling the device in an emergency:

- Department of Homeland Security: [Prepare for Emergencies Now](http://www.ready.gov/sites/default/files/FEMA_Disabilities_R-6_web_june2012.pdf) (http://www.ready.gov/sites/default/files/FEMA_Disabilities_R-6_web_june2012.pdf)
- FDA's Web site for [Medical Device Safety in Emergencies](http://www.fda.gov/medicaldevices/safety/emergencysituations/ucm055987.htm) (<http://www.fda.gov/medicaldevices/safety/emergencysituations/ucm055987.htm>).

7.2 Disposal of Hazardous Waste Materials

For information on the proper disposal of medical waste in each state of the United States, see the [Environmental Protection Agency's Web site](http://www.epa.gov/osw/nonhaz/industrial/medical/programs.htm) (<http://www.epa.gov/osw/nonhaz/industrial/medical/programs.htm>).

The IFU should include information concerning the proper disposal of the device and its accessories. You should provide proper warnings and precautions regarding safe disposal of waste products when using the device in the home environment and help the user understand the difference between biological waste and regular waste. If the device or accessories require professional assistance to dispose of biological or biohazardous waste, the IFU should state that the user should make proper arrangements for safe waste disposal.

7.3 Hygienic Maintenance

Home users do not have easy access to the cleaning, disinfecting, and sterilization supplies that are readily available in professional health care facilities. Ideally, home use devices should be designed to be cleaned with readily available cleaning supplies and simple cleaning techniques.

However, if a home use device or its accessories require sterilization prior to use, FDA recommends that you describe in the labeling for your device or system the complete disinfection cycles and methods for sterilizing or disinfecting the system. FDA has draft guidance on this topic, [Processing/Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling](#)

Contains Nonbinding Recommendations

Draft - Not for Implementation

(<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm252999.htm>).

If a medical device or its accessories require professional hygienic maintenance prior to reuse, contact information for those services should be provided in the labeling and IFU. A technical description for hygienic maintenance requirements in the labeling and IFU should include methods to clean, disinfect, sterilize, rinse, dry, handle, and store the device before and after any type of service procedure, as well as indicate what steps are required if a device is transferred to another user. The IFU should also cover how to obtain consumable or disposable supplies.

For medical device reuse information written for the user, see: [FDA Offers Tips about Medical Devices and Hurricane Disasters – Reuse of Medical Devices](http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/BreastPumps/ucm055987.htm#reuse) (<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/BreastPumps/ucm055987.htm#reuse>).

For more information on hygienic maintenance information on reprocessed single-use devices, see FDA's [Guidance for Industry and FDA Staff - Medical Device User Fee and Modernization Act of 2002, Validation Data in Premarket Notification Submissions \(510\(k\)s\) for Reprocessed Single-Use Medical Devices](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071434) (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm071434>).

FDA also recommends that you refer to IEC 60601-1-11:2010 section 7.5.2, *Additional requirements for professional hygienic maintenance*, in the design of medical devices, including those devices that are not electrical equipment.

8. Postmarket Considerations

8.1 Customer Service

If you already have in place a toll-free technical assistance telephone number, email address, or Web site address for users regarding questions about problems with the device, or if the device is life-supporting or life-sustaining and you have a person available 24 hours a day to talk with users, it is important to keep these systems in place. Information obtained through technical assistance is valuable data to be captured for analysis within your quality system.

8.2 Medical Device Reporting

The Medical Device Reporting (MDR) regulation⁶ requires you to submit reports to the FDA whenever you become aware of information that reasonably suggests that a device you market may have caused or contributed to a reportable death or serious injury, or has

⁶ 21 CFR Part 803.

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malfunctioned and the malfunction would be likely to cause or contribute to a reportable death or serious injury should it recur.

For the FDA Form 3500A, instructions for completing specific items on the form, and the coding manual see [MedWatch: The FDA Safety Information and Adverse Event Reporting Program](http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/ucm149238.htm) (<http://www.fda.gov/Safety/MedWatch/HowToReport/DownloadForms/ucm149238.htm>).

For additional guidance on the MDR regulation and the reporting requirements refer to FDA's guidance [Medical Device Reporting for Manufacturers](http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094529.htm) (<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm094529.htm>).

FDA believes it is helpful to have the reporting number for product problems or adverse events in your labeling or on your device. FDA's reporting number is 1-800-332-1088.

8.3 Selling or Purchasing Used Prescription Devices

Prescription devices may only be sold or given to the person for whom the device is prescribed and may only be sold by or on the order of a health care professional legally allowed to prescribe devices. FDA maintains a web page for consumers interested in purchasing medical products (<http://www.fda.gov/MedicalDevices/ResourcesForYou/Consumers/default.htm>).

9. Conclusion

By taking into consideration the physical environment, the user, the device or systems, the labeling, and by utilizing human factors, you can produce devices that suit the home use environment, and are thereby more likely to have reasonable assurance of their safety and effectiveness for their intended use. By including descriptions of your efforts to take into account the various factors outlined in this guidance document in your premarket submissions, FDA can be better assured that your devices meet applicable safety and effectiveness requirements. Designing your home use device in this manner should result in a safer and easier-to-use device, minimize use error, and reduce the likelihood that adverse events will occur-- the preferred outcome of a well-designed medical device.

10. Additional Resources

1. Ad Hoc Committee on Health Literacy for the Council on Scientific Affairs, American Medical Association, “Health Literacy: Report of the Council on Scientific Affairs,” JAMA, February 10, 1999 — Vol 281, No 6.
2. Centers for Disease Control and Prevention (CDC), “Emergency Preparedness and Response” Web site: <http://www.bt.cdc.gov>
3. Center for Health Care Strategy (CHCS), Health Care Literacy Fact Sheet, http://www.chcs.org/usr_doc/Health_Literacy_Fact_Sheets.pdf.
4. CDRH Device Advice: “Comprehensive Regulatory Assistance”:
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>.
5. CDRH, “FDA offers tips about medical devices and hurricane disasters.”
<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/ConsumerProducts/BreastPumps/ucm055987.htm#reuse>.
6. CDRH Home Use Devices Web site:
<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/HomeHealthandConsumer/HomeUseDevices/default.htm>
7. CDRH Human Factors Web site:
<http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HumanFactors/default.htm>.
8. CDRH Medical Device Reporting Web site,
<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm>.
9. Global Harmonization Task Force document SG1/N41:2005 *Essential Principles of Safety and Performance of Medical Devices*.
10. Institute of Medicine of the National Academies, “Health Literacy: A Prescription to End Confusion” (2004) <http://www.iom.edu/Reports/2004/Health-Literacy-A-Prescription-to-End-Confusion.aspx>
11. Keay, S. et al. The safe use of infusion devices. Continuing Education in Anaesthesia, Critical Care & Pain (2004) 4 (3) 81-85.

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Draft - Not for Implementation

12. Kost, G J, ed. Principles & practices of point-of-care testing. Philadelphia: Lippincott Williams & Wilkins, 2002.
13. National Research Council. Health Care Comes Home: The Human Factors. Committee on the Role of Human Factors in Home Health Care, Board on Human-Systems Integration, Division of Behavioral and Social Sciences and Education. Washington, DC: The National Academies Press, 2011.
14. Transportation Security Administration (TSA), “Travelers with Disabilities and Medical Conditions”<http://www.tsa.gov/travelers/airtravel/specialneeds/index.shtm>.