Design Considerations and Pre-market Submission Recommendations for Interoperable Medical Devices

Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

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Preface

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Design Considerations and Premarket Submission Recommendations for Interoperable Medical Devices

Draft Guidance for Industry and Food and Drug Administration Staff

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I. Introduction

As electronic medical devices are increasingly connected to each other and to other technology, the ability of these connected systems to safely and effectively exchange and use the information that has been exchanged becomes increasingly important. Advancing the ability of medical devices to exchange and use information safely and effectively with other medical devices as well as other technology offers the potential to increase efficiency in patient care.

FDA intends to promote the development and availability of safe and effective interoperable medical devices. FDA is issuing this draft guidance to assist industry and FDA staff in identifying specific considerations related to the ability of electronic medical devices to safely and effectively exchange and use exchanged information. This document highlights considerations that should be included in the development and design of interoperable medical devices and provides recommendations for the content of premarket submissions and labeling for such devices.

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requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

The need and desire to connect medical devices to each other as well as other products, technologies and systems is growing in the healthcare community. This interconnectivity of various products or systems that may include medical devices has been characterized by many as "interoperability."[1] Interoperability in healthcare has the potential to encourage innovation and facilitate new models of health care delivery by promoting the availability and sharing of information across systems even when products from different manufacturers are used.

In this guidance we refer to interoperability as the ability of two or more products, technologies or systems to exchange information and to use the information that has been exchanged. By exchange of information we mean to include transmission, reception or both, that may be accomplished by means of wired or wireless methods that may exist on a local network, or through the internet. The use of the exchanged information can include various purposes such as displaying, storing, interpreting, analyzing and automatically acting or controlling another product. When medical devices are involved in an interoperable system (system of connected devices in which information is exchanged and used across the connections and which includes at least one medical device), safety is the most important consideration.

Systems that include interoperable medical devices may be composed of existing devices, products, or technologies acting together to achieve a function different from the individual medical device. Medical devices may be standalone, may broadcast data so anyone can access the data, may connect and exchange information with other medical devices, non-medical device technologies, and systems, or may be incorporated in a complex system of medical devices and/or non-medical device technologies. Increased use of interoperable medical devices has the potential to foster rapid innovation at lower cost. However, appropriate safety considerations including system level safety considerations that are not taken in to account in the device design can result in unforeseen safety and effectiveness issues for the device or for the system.

Medical device interoperability is not limited to unidirectional patient data but includes more complex interactions, such as exerting command and control over a medical device(s). Establishing and implementing appropriate functional, performance, and interface requirements for devices with such interactions is important. One way to achieve this is through use of standardized architectures and communication protocols. Another way is to specify non-standard interface requirements and characteristics in a

[1]See Institute of Electrical and Electronics Engineering (IEEE) Standard Computer Dictionary: A Compilation of IEEE Standard Computer Glossaries (New York, NY: 1990).

public manner such as labeling.

Device design elements that factor in interoperability considerations may improve data portability and patient safety. However, errors stemming from inadequate interoperability can occur, such as the transmission of weight in kilograms when the receiving medical device assumes the measurement is in pounds, and can lead to patient harm and even death.

The failure to establish and implement appropriate functional, performance, and interface requirements during product development may lead to the exchange of inaccurate, untimely, or misleading information, It may also lead to device malfunction, including the failure to operate, and can lead to patient injury and even death.

Device-specific information, such as UDI (unique device identifier), and patient-specific data, such as ECG waveforms, contained within a medical device can contribute importantly to patient care and improved patient outcomes. In addition, such information and data may be used to populate electronic health records and allow patients, their families, and health care providers to make better informed healthcare decisions. FDA has taken steps to facilitate the availability of medical device data and promote safe and effective interoperability. For example, FDA has recognized various consensus standards that support medical device interoperability while at the same time exercising enforcement discretion for medical device data systems (MDDS)[2] to make it easier to share and display data from medical devices.

This guidance is intended to highlight the following items that medical device manufacturers should consider to provide a reasonable assurance of safety and effectiveness of their interoperable medical devices: 1) designing systems with interoperability as an objective; 2) conducting appropriate performance testing and risk management activities; and 3) specifying the functional, performance, and interface characteristics in a public manner such as labeling.

III. Scope

This guidance provides manufacturers with design considerations when developing interoperable devices, and recommendations regarding information to include in pre-market submissions and device labeling.

[2] Medical Device Data Systems (MDDS) are hardware or software products that transfer, store, convert formats, and display medical device data. A MDDS does not modify the data, and it does not control the functions or parameters of any connected medical device. MDDS are not intended to be used in connection with active patient monitoring. For additional information on our regulation of MDDS, please see our guidance document: http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM401996.pdf. See also Federal RegisterNotice (80 FR 6996; 2/9/15) which states "Blood Establishment Computer Software (BECS) and accessories to BECS are not MDDS devices

This document does not address aspects of compatibility issues with the physical connection (e.g. the specifications of the physical connection between two electronic products such as USB, wireless connection, etc…) but rather focuses on the data schema which defines the information content of the data being exchanged over those physical connections.

This document is not intended to provide guidance on whether or not a specific product or modification to a product requires a pre-market submission. We intend this document to complement other FDA guidance documents.

The pre-market discussion within this guidance applies to the following premarket submissions for interoperable medical devices[3]:

- Premarket Notification (510(k)) including Traditional, Special, and Abbreviated 510(k) submissions;
- De novo requests;
- Premarket Approval Applications (PMAs);
- Product Development Protocols (PDPs);
- Humanitarian Device Exemption (HDE) submissions;
- Biologics License Applications (BLA).

IV. Definitions

Electronic Data Interface:

For purposes of this guidance, electronic data interface (EDI) is the medium by which independent systems interact and/or communicate with each other thereby allowing the exchange of information between systems. It includes both the physical connection (i.e. USB port, wireless connection, etc.) and the data schema which defines the information content. It is a medium by which a medical device exchanges and uses information.

Interoperable medical devices:

For purposes of this guidance, interoperable medical devices are devices as defined in Section 201(h) of the Federal Food, Drug, and Cosmetic Act that have the ability to exchange and use information through an electronic data interface with another medical device, product, technology, or system. Interoperable medical devices can be involved in simple unidirectional transmission of data to another device or product or in more complex interactions, such as exerting command and control over one or more medical devices.

[3] Manufacturers may also consider applying this guidance as appropriate to Investigational Device Exemption (IDE) submissions and to devices exempt from premarket review. For studies in which the primary purpose of the IDE study includes the interaction of two or more devices, the sponsor may wish to consider the recommendations within this guidance document.

V. Design Considerations for Interoperable Devices

Manufacturers can choose from many design solutions to create interoperable medical devices. The information model (data attributes), the functional model (role played within the interoperable system), and the architectural model (how the device is connected within the system) should be considered during the design and development of an interoperable device. Design inputs should include the desired functional, performance, and interface characteristics of the electronic data interface.

Manufacturers of interoperable medical devices should perform a risk analysis and conduct appropriate testing that considers the risks associated with interoperability, reasonably foreseeable misuse, and reasonably foreseeable combinations of events that can result in a hazardous situation.

As a general matter, one action manufacturers can take to mitigate risk and facilitate safe and effective interoperability is to clearly set forth in device labeling the functional, performance, and interface requirements of their electronic data interface. Providing these characteristics along with limitations of the interface or use of the device in an interoperable system can minimize the risk of failure to exchange and use data as intended.

As part of a comprehensive quality system under 21 CFR Part 820, medical device manufacturers must manage risks including those associated with an electronic data interface that is incorporated into the medical device. The following considerations should be appropriately tailored to the selected interface technology, and the intended use and use environments for the medical device.

1. ***Purpose of the Electronic Data Interface***: Device manufacturers should consider the purpose for each of the electronic data interfaces. This should include the types of data exchanges taking place (e.g. sending, receiving, issue command and control).

2. ***The Anticipated Users***: Manufacturers should determine the anticipated user(s) for each of the electronic data interfaces. Examples of users include: clinical user, biomedical engineers, IT professional, system integrator, system designers, and medical device designers.

3. ***Risk Management***: Manufacturers should consider ways to mitigate all risks identified in risk analysis, such as risks that arise from others connecting to the electronic data interface including the risk of inappropriate access to the device.

4. ***Verification and Validation:*** Manufacturers should establish, maintain, and implement appropriate verification and validation to ensure that their devices with electronic data interfaces work correctly prior to delivery, during the integration process, and continue to work while in use.

5. ***Labeling Considerations***: Manufacturers should include information that users may need to connect predictably and safely to the interface for its intended purpose

A. Purpose of the Electronic Data Interface

Manufacturers should, as part of their device design, clearly establish the purpose of electronic data interfaces that are included on a medical device and consider that purpose when they are both designing the device (including the electronic data interface) and developing the device instructions.

In designing a medical device's electronic data interface, manufacturers should consider the level of interoperability[4] needed to achieve the purpose of the interface, as well as the information necessary to describe the interface. The labeling should be in sufficient detail to allow any user to connect and use the medical device and interface as it is intended.

Elements to consider in the design of the device's electronic data interface include but are not limited to the following:

- Types of devices that it is meant to connect to;
- Type of data exchange taking place (e.g. sending, receiving, issue command and control);
- The use of standards (data format, transmission, interface standards, etc.);
- The need for time synchronization;
- Method of data transmission;
- The necessary timeliness and the reliability of information (e.g. sample rate, transmission rate, etc.);
- What the user should or should not do with the electronic data interface including contraindications, warnings and precautions on the use of the exchanged information;

[4] As a reference the concept of "Levels of interoperability" are described by others as follows

- Turnitsa, C.D. (2005). "Extending the Levels of Conceptual Interoperability Model". Proceedings IEEE Summer Computer Simulation Conference, IEEE CS Press
- Healthcare Information and Management System Society (HiMMS) Dictionary of Healthcare Information Technology Terms, Acronyms and Organizations, 2nd Edition, 2010, Appendix B, p190, original source: HIMSS Electronic Health Record Association

- Clinical context for the use of the information exchanged in the interface, such as an infusion pump used to deliver anesthesia to a sedated patient in the intensive care unit;
- Interoperability scenarios for the use of the interface, i.e., how the manufacturer anticipates the interface being used. For example an interface on a pulse oximeter is used to send data to a computer system in an eight hour study on neonates to assess sleep. The computer system is also gathering information from ECG. Therefore the information from the pulse oximeter and ECG need to have their times synchronized and data collected at a specific rate. Knowing the scenario would demonstrate the need for specific features.
- The functional and performance requirements of the device as a result of the exchanged information;
- Expected flow of information or exchange of information through an application programming interface (API) which may include considerations of acceptable and unacceptable commands on the interface and impact of such interface on the device safety and effectiveness.

B. Anticipated Users

It is important to identify not just the purpose of the electronic interface, but also the anticipated users of the electronic data interface. Determining the anticipated users will help in appropriately applying risk management strategies for activities such as developing appropriate instructions for use and setting limitations for use of the device, including contraindications, warnings and precautions. Manufacturers should identify the anticipated user(s) for their device and how the device is used in the target interoperable system. The manufacturer should make sufficient information available so that the anticipated user(s) can use the electronic data interface safely and effectively. Different types of users may need different information. For example:

- Users, operators, and, clinicians need to know the clinical uses and potential risks relevant to the use environment and the clinical task at hand.
- Maintainers and hospital clinical engineers need to know what actions to take to verify correct configuration and operation. They also need to assure that the system is performing as specified. The verification procedures should be considered as part of the design (i.e. sourced from the manufacturer or part of a standard).
- IT professionals need to understand the performance needs and security requirements of the devices connected to the networks they maintain and operate.
- System integrators, system designers, and medical device designers are responsible for the safe and effective operation of their systems or devices and need to know the capabilities of the components they use so that they can perform adequate risk management and validation.

Manufacturers should consider the different users when they are both designing the device (including the electronic data interface) and developing the device instructions. These considerations may influence whether the manufacturer places certain limitations on the users of the device or limitations on how the device may be used. Developing different instructions for different users may help to mitigate the risks.

Manufacturers' risk management strategies should address the risks associated with the anticipated users of the device, reasonably foreseeable misuse of the device, and reasonably foreseeable combinations of events that can result in a hazardous situation. However, FDA recognizes that a manufacturer cannot be responsible for all possible uses outside of the purpose of the interface. Based upon these risks, a manufacturer may want to change the design of the device, the intended interoperability scenarios, or include warnings, precautions or contraindications in device labeling to reduce risks to acceptable levels.

C. Security and Risk Management Considerations

Including an electronic data interface on a medical device may have an impact on the security and other risk management considerations for the medical device, the network, and other interfaced devices. Analysis of risks due to both the intended and unintended access of the medical device through the interface should be considered.

FDA recommends that manufacturers include in their risk management approach a particular focus on the potential hazards, safety concerns, and security issues introduced when including an electronic data interface. For example, as part of the evaluation and design process[5], manufacturers should consider the following:

- Whether implementation and use of the interface degrades the basic safety or risk controls of the device;
- Whether implementation and use of the interface/interfaces degrades the essential performance of the device;
- Whether the appropriate security features are included in the design;[6] and
- Whether the device has the ability to handle data that is corrupted or outside the appropriate parameters.

In addition, existing communication and interoperability standards can be useful in deciding what issues or concerns should be addressed in the risk analysis of an electronic data interface.

[5] This list is not intended to be a comprehensive list of the issues that a manufacturer should address for their individual device. Manufacturers should conduct their own assessment and address the issues identified during their risk management activities.

[6] Please see the FDA guidance, "Guidance for Industry - Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software," http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm077812.htm.

FDA believes that an interoperable system should maintain basic safety and essential performance during normal and fault conditions. A manufacturer should design an interoperable device that can mitigate risks associated with the following specific error scenarios:[7]

- Failures or malfunctions caused by direct or indirect connection of intended devices;
- Failures or malfunctions caused by invalid commands;
- Failures or malfunctions caused by receiving and processing erroneous data or commands; and
- Failures or malfunctions caused by not adhering to the non-functional requirements of the communication specification.

Medical devices that receive data from other sources should complete a risk assessment of their connection that considers reasonably foreseeable uses and misuses. The manufacturer should ensure that the risks are mitigated through the design of the device.

D. Verification and Validation Considerations

The verification and validation warranted will depend on the level of risks associated with the device, the purpose of the interface, the anticipated use of the device in the target system, and the intended use of the device.

Interoperable medical devices should undergo an appropriate level of testing to demonstrate that the interactions on the electronic data interface perform as intended. The medical device manufacturer should test the electronic data interface based upon the purpose of the interface and should make sure that it complies with the intended specifications. For devices meant to be used with a limited number of specific devices, appropriate testing demonstrating safe operation with those specific devices may be appropriate. For devices meant to work with many devices, it may be appropriate to test the device against the interface specification and with representative devices for verification. If the medical device is meant to be a part of a larger interoperable system, the manufacturer should conduct testing to reasonably assure that the medical device will continue to safely and effectively fulfill its intended use when it is assembled, installed, and maintained according to its instructions.

For example:

- Verify and validate that when data is corrupted that it can be detected and appropriately managed.

[7] See Section 5.4 of ASTM 2761-09 (2013), "Medical Devices and Medical Systems - Essential safety requirements for equipment comprising the patient-centric integrated clinical environment (ICE) - Part 1: General requirements and conceptual model."

- Perform testing to assure that the device continues to operate safely when data is received in a manner outside of the parameters specified. Determine how or if this can be detected and what impact this will have on the rest of the system.
- Implement a fault tolerant design and verify its performance.
- Establish and specify fail safe states for critical functions (e.g. delivering energy, real-time monitoring).
- If conforming to consensus standards, verify and validate that the design meets the intent and scope identified in the standards.
- Verify only authorized users (individuals, devices and systems) are allowed to exchange information with the interoperable medical device.
- Validate the user(s) interface. Determine that the user(s) are capable to correctly use the interface(s).

As part of the specification for an interoperable device, the manufacturer should also consider developing appropriate test scenarios which will allow a user to assess if the basic safety and effectiveness of the device is maintained when incorporated into the intended interoperable system.

E. Labeling Considerations

One way to mitigate risk and facilitate safe and effective medical device interoperability is to include in labeling the functional and performance requirements of the electronic data interface.

Even if a device is not subject to pre-market submission, the recommendations found in Section 6.4, which gives labeling recommendations for pre-market submissions, may be helpful to develop clear labeling and minimize risk.

F. Use of Consensus Standards

FDA recognizes the benefits of relying on the use of published consensus standards in the design of medical devices, in general, and in the development of interoperable medical devices, in particular. As such, FDA has recognized numerous consensus standards relevant to the development and design of interoperable medical devices and encourages their use. In many cases, the standards that support interoperability may be used by not only manufacturers of medical devices, but also many other stakeholders such as healthcare delivery organizations, including system integrators, system designers, and information technology professionals who work in health care settings.

Many of the currently available standards that support medical device interoperability are design standards. These standards may help manufacturers with design considerations identified in Section 5. For example, standards may specify data format, interoperability architecture design, or other aspects associated with interoperability. Conformance with

recognized consensus standards is voluntary for a medical device manufacturer. FDA recognition of design standards does not mean that FDA is recommending a particular design standard over another. FDA recognition of design standards that support interoperability are meant to encourage manufacturers, health care organizations, and others to implement interoperability in a standardized way. Alternatively, manufacturers may choose to use their own design preferences for their interface (in lieu of a published consensus standard) for their medical devices. In either case, problems or misuse of interoperable medical devices can be minimized by making the functional, performance, and interface requirements openly available to all users.

For current FDA recognition of any standards, please refer to the FDA Recognized Consensus Standards Database.[8]

VI. Recommendations for Contents of Pre-market Submissions

Not all interoperable medical devices may require premarket submission to the FDA. This section provides guidance for those interoperable medical devices that require a premarket submission.

When preparing a pre-market submission, consider any other appropriate FDA guidances or special controls applicable to the device. For a medical device that is intended to exchange and use information with or from another product, technology, or system, FDA recommends that sponsors provide basic information similar to what would normally be provided to support other functions or features on a medical device. Specifically, when considering the presence of an electronic data interface, we recommend considering the elements that were discussed in the "Design Considerations for Interoperable Devices" section of this document. As with any submission, when making a claim that a device exchanges and uses information with or from other devices, technologies, or products, the information submitted should be sufficient to support the claim.

A. Device Description

As part of the device description typically submitted in a pre-market submission, a sponsor should include a discussion of any electronic data interfaces found on the device,

[8] On August 6, 2013, the FDA recognized several standards that support interoperability of medical devices: http://www.gpo.gov/fdsys/pkg/FR-2013-08-06/pdf/2013-19020.pdf. The FDA continues to evaluate standards in this area for recognition. To see if the FDA recognizes a particular standard that supports interoperability, check the CDRH Recognized Consensus Standards Database at: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm

the purpose of each interface, and the anticipated users of the interfaces. Describe how each interface is meant to be used or the limitations of the use of the interfaces. If the interface is only meant to be used by the manufacturer, this should be clearly stated. If the interface is meant to be used with only specific devices, those devices should be clearly specified.

If the device is meant to exchange or use data with or from other medical devices, products, technologies, or systems, then the device description should include a description of the information exchanged, how it is exchanged, and the impact the exchanged information has on the device or other impacted devices. This may include some or all of the following elements based upon the claims of data exchange and use made for the medical device:

- Explain the purpose of the interface and the role the device plays within an interoperable system. This may be as simple as stating that the device is meant to deliver device data to a specific product, technology, or system architecture described in a standard.
- Specify if the interface is meant to transmit, receive, or exchange information.
- Specify any standards used including relevant version numbers and dates.
- Describe the requirements for timeliness and the integrity of the information (e.g. sample rate, transmission rate, etc.).
- Describe the communication format, rate, and transmission method.
- Discuss the limitations (what the user should not do), contraindications, precautions, warnings.
- Describe the functional and performance requirements as a result of the clinical context of the information.
- Describe the API (Application Programming Interface) if the device is software that can be used by other software, medical device or system.

Please note that the level of detail necessary may depend upon the intended interoperable scenario(s) in which the manufacturer expects the interoperable medical device to be used.

B. Risk Analysis

Manufacturers' risk analysis should consider the risks associated with interoperability, reasonably foreseeable misuse, and reasonably foreseeable combinations of events that can result in a hazardous situation. Based upon these risks, a manufacturer may want to change the design of the device, the intended interoperability scenarios, or include device limitations and/or warnings to reduce risks to acceptable levels. As discussed in ISO

14971, mitigations may not be necessary for risks that are broadly acceptable[9]; these decisions should be captured within the risk analysis documentation.

FDA emphasizes that the same process of defining hazardous situations, risks, and mitigations can be used when considering a system that contains more than one connected medical device. There may be additional hazardous situations that arise in these situations. The manufacturer should specify which mitigations are implemented and which are necessary for safe use but may require implementation by other parties, such as the party responsible for set-up or installation. These should be included in the risk analysis section of the submission.

For devices subject to the risk analysis in 21 CFR 820.30(g), FDA recommends including an analysis of the interface or interfaces on the devices, the intended connections, and any effects that the connection may have on the device performance. The normal risk analysis submitted should include hazards that were considered, the risks that may result, and how the hazards and risks were addressed. Your submitted analysis should address:

- Risks and the methods for reducing these risks to acceptable levels;
- Fault tolerant behavior, boundary conditions, and fail safe behavior such as how the device handles delays, corrupted data, data provided in the wrong format, and any other issues with the reception and transmission of data;
- Any security risks[10] that may be involved with the presence of an electronic data interface; and
- Risks arising from normal use as well as reasonably foreseeable misuse. For example, a manufacturer may want to include in the labeling an explicit warning against foreseeable uses that could result in harm.

It is important to note that there are a variety of methods including assurance cases that can be used to capture information on risk and how it is addressed in the design and implementation of a device. This document does not specify which method should be used; rather it emphasizes the need to capture this information.

C. Verification and Validation

As part of the device performance testing typically submitted in a pre-market submission,, a sponsor should include results of verification and validation testing for the electronic data interfaces on the device. The nature and extent of the validation depends

[9] ISO 14971:2007, "Medical devices -- Application of risk management to medical devices."
[10] For additional information on cybersecurity in medical devices, please see our guidance document, "Guidance for Industry - Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software," http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm077812.htm.

upon the risks associated with the device, the purpose of the interface, the anticipated use of the device in the target system, and the intended use of the device. Manufacturers should consider aspects highlighted in section 5.4 under design considerations.

For those devices that are only meant to be used with a limited number of specific devices, documentation demonstrating appropriate testing with those specific devices may be appropriate. For those devices meant to connect with a class of devices or to be used by any device or computer system, documentation demonstrating appropriate testing with a representative of that class of devices or within the context of the system may be more appropriate. Documentation which demonstrates the following performance testing should be included in the submission:

- Verify that the device interface meets its design specifications.
- Validate that the device interface performs as intended.
- Determine and verify the information that should be provided to a user to connect to the interface and to allow the user to ensure that the connection has been made correctly.
- Verify that the device will perform safely and within specification when used under normal and reasonably likely to occur abnormal conditions (e.g. receives data outside of specification, connected to an unintended device or system, does not lock up the system when the interface is exercised).

The degree of documentation can vary based upon the risks associated with the device, the purpose of the interface, the anticipated use of the device in the target system, and the intended use of the device. For those elements of the interface that use a standard, demonstrating conformance to that standard may be sufficient[11]. For example, if the purpose of the interface along with the intended scenarios for use of the interface do not add significant risk to the operation of the medical device, then test summaries may be sufficient.

The following examples describe situations in which different levels of documentation have been determined appropriate for submission to FDA; one in which it has been previously determined that a submission is necessary and when complete test reports should be submitted and another when only a testing summary should be submitted.

- If an infusion pump is intended to receive patient data from several devices (e.g. a pulse oximeter, ventilator, and blood pressure monitor) and use this data to change infusion pump settings, complete test reports should be provided to the FDA in the planned submission.

- If a non-invasive blood pressure monitor has an interface intended to

[11] To determine the appropriate amount of documentation to support conforming to a standard, see the guidance document, "Guidance for Industry and FDA Staff - Recognition and Use of Consensus Standards," http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm077274.htm.

allow historical data to be downloaded to a computer, then a summary of the testing performed on the interface may be sufficient.

D. Labeling

The following recommendations are intended to help prepare labeling that satisfies the requirements of 21 CFR Part 801 and 809, as appropriate.[12] For additional information on developing labeling, please consult FDA Guidance: Labeling - Regulatory Requirements for Medical Devices (FDA 89-4203) (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM095308.pdf) and "Alternative to Certain Prescription Device Labeling Requirements" (http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm072748.pdf).

Information regarding the electronic data interface on the device should be included in the labeling, so that the device can be used safely and effectively for its intended uses. This information should enable users to connect to the device in the specified manner, and should give proper instruction to use the connection to the device in the ways in which it was designed. Manufacturers should also include in labeling any limitations of the connection to discourage any misuse of the device. Precautions, warnings and contraindications should be included in device labeling as well. Validation of labeling should include human factors studies that include all identified potential users of the data interface.

If the device is meant to interact with only a few specific devices, the labeling should explicitly state that the medical device is meant to connect with the specific devices listed (including the version) and that it should not be used with other medical devices or non-medical device technologies. If the interface is only meant to be used by the manufacturer's technicians for software updates or diagnostics, this should be stated in the labeling in an appropriate way that prevents access by other users. For example, detailed specifications regarding use of the electronic data interface is not included in the patient and healthcare provider labeling (user manual). When appropriate, the labeling should include instructions that the electronic data interfaces found on the device are not meant for connecting to other medical devices or non-medical device technologies and that use of the electronic data interface is reserved for representatives of the manufacturers.

FDA recommends that the following information be included in the device labeling:

[12] Labeling must comply with the requirements of 21 CFR Parts 801 and 809, as appropriate, before a medical device is introduced into interstate commerce. Labeling recommendations in this guidance are consistent with the requirements of 21 CFR Parts 801 and 809.

679
680 • Specify the purpose of the interface including any devices, device types, or
681 software (including the version of the software) with which it is meant to
682 connect.
683 • Specify whether the data is meant for a specific purpose or user or whether the
684 data is meant for anyone to access.
685 • Specify whether the connection is meant to control the operations of another
686 device.
687 • Specifications for each interface, as well as the necessary performance and
688 functional requirements from the device related to the sending or receiving of
689 data/control.
690 • Summary of the testing performed on the interfaces to verify interoperability
691 claims and any activities required by the user to verify safe operation. In the
692 case where testing was performed to an interface specification and verified
693 with a representative device, please specify the representative device used.
694 • Reference relevant standards used.
695 • A description of any fault tolerance behavior, boundary condition testing, or
696 fail safe for critical functions (e.g., delivering energy, etc…) that will allow
697 the user to understand how to use the interface correctly.
698 • Specify any known limitations (what the user should not do),
699 contraindications, precautions and warnings.
700 • Specify recommended connections or architectures.
701 • Specify recommended settings, or configurations for the electronic data
702 interface.
703 • Instructions for IT personnel on how to connect or install and disconnect or
704 uninstall the device.
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