

1 **Design Considerations and Pre-**
2 **market Submission**
3 **Recommendations for Interoperable**
4 **Medical Devices**

6 **Draft Guidance for Industry and**
7 **Food and Drug Administration Staff**

10 ***DRAFT GUIDANCE***

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Preface

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95 **Design Considerations and Pre-**
96 **market Submission**
97 **Recommendations for**
98 **Interoperable Medical Devices**
99

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101 **Draft Guidance for Industry and**
102 **Food and Drug Administration Staff**
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104 *This draft guidance, when finalized, will represent the current thinking of the Food and*
105 *Drug Administration (FDA or Agency) on this topic. It does not establish any rights for*
106 *any person and is not binding on FDA or the public. You can use an alternative approach*
107 *if it satisfies the requirements of the applicable statutes and regulations. To discuss an*
108 *alternative approach, contact the FDA staff or Office responsible for this guidance as*
109 *listed on the title page.*

110 **I. Introduction**
111

112 As electronic medical devices are increasingly connected to each other and to other
113 technology, the ability of these connected systems to safely and effectively exchange and use
114 the information that has been exchanged becomes increasingly important. Advancing the
115 ability of medical devices to exchange and use information safely and effectively with other
116 medical devices as well as other technology offers the potential to increase efficiency in
117 patient care.
118

119 FDA intends to promote the development and availability of safe and effective interoperable
120 medical devices. FDA is issuing this draft guidance to assist industry and FDA staff in
121 identifying specific considerations related to the ability of electronic medical devices to
122 safely and effectively exchange and use exchanged information. This document highlights
123 considerations that should be included in the development and design of interoperable
124 medical devices and provides recommendations for the content of premarket submissions and
125 labeling for such devices.
126

127 FDA's guidance documents, including this guidance, do not establish legally enforceable
128 responsibilities. Instead, guidances describe the Agency's current thinking on a topic and
129 should be viewed only as recommendations, unless specific regulatory or statutory

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

132 **II. Background**

133
134 The need and desire to connect medical devices to each other as well as other products,
135 technologies and systems is growing in the healthcare community. This interconnectivity of
136 various products or systems that may include medical devices has been characterized by
137 many as “interoperability.”¹ Interoperability in healthcare has the potential to encourage
138 innovation and facilitate new models of health care delivery by promoting the availability
139 and sharing of information across systems even when products from different manufacturers
140 are used.

141
142 In this guidance we refer to interoperability as the ability of two or more products,
143 technologies or systems to exchange information and to use the information that has been
144 exchanged. By exchange of information we mean to include transmission, reception or both,
145 that may be accomplished by means of wired or wireless methods that may exist on a local
146 network, or through the internet. The use of the exchanged information can include various
147 purposes such as displaying, storing, interpreting, analyzing and automatically acting or
148 controlling another product. When medical devices are involved in an interoperable system
149 (system of connected devices in which information is exchanged and used across the
150 connections and which includes at least one medical device), safety is the most important
151 consideration.

152
153 Systems that include interoperable medical devices may be composed of existing devices,
154 products, or technologies acting together to achieve a function different from the
155 individual medical device. Medical devices may be standalone, may broadcast data so
156 anyone can access the data, may connect and exchange information with other medical
157 devices, non-medical device technologies, and systems, or may be incorporated in a
158 complex system of medical devices and/or non-medical device technologies. Increased
159 use of interoperable medical devices has the potential to foster rapid innovation at lower
160 cost. However, appropriate safety considerations including system level safety
161 considerations that are not taken in to account in the device design can result in
162 unforeseen safety and effectiveness issues for the device or for the system.

163
164 Medical device interoperability is not limited to unidirectional patient data but includes
165 more complex interactions, such as exerting command and control over a medical
166 device(s). Establishing and implementing appropriate functional, performance, and
167 interface requirements for devices with such interactions is important. One way to
168 achieve this is through use of standardized architectures and communication protocols.
169 Another way is to specify non-standard interface requirements and characteristics in a

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

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170 public manner such as labeling.

171

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

176

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

181

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

192

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

199

200 **III. Scope**

201

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

205

206 This document does not address aspects of compatibility issues with the physical connection
207 (e.g. the specifications of the physical connection between two electronic products such as

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 Register Notice (80 FR 6996; 2/9/15) which states “Blood Establishment Computer Software (BECS) and accessories to BECS are not MDDS devices

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208 USB, wireless connection, etc...) but rather focuses on the data schema which defines the
209 information content of the data being exchanged over those physical connections.

210

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

214

215 The pre-market discussion within this guidance applies to the following premarket
216 submissions for interoperable medical devices³:

- 217 • Premarket Notification (510(k)) including Traditional, Special, and Abbreviated
- 218 510(k) submissions;
- 219 • De novo requests;
- 220 • Premarket Approval Applications (PMAs);
- 221 • Product Development Protocols (PDPs);
- 222 • Humanitarian Device Exemption (HDE) submissions;
- 223 • Biologics License Applications (BLA).

224

225

226 **IV. Definitions**

227

228 **Electronic Data Interface:**

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

234

235 **Interoperable medical devices:**

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

242

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245

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.

246

247 **V. Design Considerations for Interoperable Devices**

248

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

255

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

260

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

266

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

272

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

277

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

282

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

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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

297

A. Purpose of the Electronic Data Interface

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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.

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308

In designing a medical device’s electronic data interface, manufacturers should consider the level of interoperability⁴ 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.

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

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- 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

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- 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.

341 **B. Anticipated Users**

342

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

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- 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.

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

373

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

381

382 **C. Security and Risk Management Considerations**

383

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

388

389 FDA recommends that manufacturers include in their risk management approach a particular
390 focus on the potential hazards, safety concerns, and security issues introduced when
391 including an electronic data interface. For example, as part of the evaluation and design
392 process⁵, manufacturers should consider the following:

393

- 394 • Whether implementation and use of the interface degrades the basic safety or
395 risk controls of the device;
- 396 • Whether implementation and use of the interface/interfaces degrades the
397 essential performance of the device;
- 398 • Whether the appropriate security features are included in the design;⁶ and
- 399 • Whether the device has the ability to handle data that is corrupted or outside
400 the appropriate parameters.

401

402 In addition, existing communication and interoperability standards can be useful in deciding
403 what issues or concerns should be addressed in the risk analysis of an electronic data
404 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>.

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

410

- 411 • Failures or malfunctions caused by direct or indirect connection of intended
- 412 devices;
- 413 • Failures or malfunctions caused by invalid commands;
- 414 • Failures or malfunctions caused by receiving and processing erroneous data or
- 415 commands; and
- 416 • Failures or malfunctions caused by not adhering to the non-functional
- 417 requirements of the communication specification.

418

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

422

423 **D. Verification and Validation Considerations**

424

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

428

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

440

441 For example:

442

- 443 • Verify and validate that when data is corrupted that it can be detected and
- 444 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.”

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

457
458 As part of the specification for an interoperable device, the manufacturer should also
459 consider developing appropriate test scenarios which will allow a user to assess if the basic
460 safety and effectiveness of the device is maintained when incorporated into the intended
461 interoperable system.

462

463 **E. Labeling Considerations**

464

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

468

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

472

473 **F. Use of Consensus Standards**

474

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

483

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

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

497
498 For current FDA recognition of any standards, please refer to the FDA Recognized
499 Consensus Standards Database.⁸
500
501

502 **VI. Recommendations for Contents of Pre-market** 503 **Submissions**

504
505 Not all interoperable medical devices may require premarket submission to the FDA. This
506 section provides guidance for those interoperable medical devices that require a premarket
507 submission.

508
509 When preparing a pre-market submission, consider any other appropriate FDA guidances
510 or special controls applicable to the device. For a medical device that is intended to
511 exchange and use information with or from another product, technology, or system, FDA
512 recommends that sponsors provide basic information similar to what would normally be
513 provided to support other functions or features on a medical device. Specifically, when
514 considering the presence of an electronic data interface, we recommend considering the
515 elements that were discussed in the “Design Considerations for Interoperable Devices”
516 section of this document. As with any submission, when making a claim that a device
517 exchanges and uses information with or from other devices, technologies, or products, the
518 information submitted should be sufficient to support the claim.
519

520 **A. Device Description**

521
522 As part of the device description typically submitted in a pre-market submission, a
523 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>

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

529

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

536

537 • Explain the purpose of the interface and the role the device plays within an
538 interoperable system. This may be as simple as stating that the device is
539 meant to deliver device data to a specific product, technology, or system
540 architecture described in a standard.

541 • Specify if the interface is meant to transmit, receive, or exchange
542 information.

543 • Specify any standards used including relevant version numbers and dates.

544 • Describe the requirements for timeliness and the integrity of the
545 information (e.g. sample rate, transmission rate, etc.).

546 • Describe the communication format, rate, and transmission method.

547 • Discuss the limitations (what the user should not do), contraindications,
548 precautions, warnings.

549 • Describe the functional and performance requirements as a result of the
550 clinical context of the information.

551 • Describe the API (Application Programming Interface) if the device is
552 software that can be used by other software, medical device or system.

553

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

557

558 **B. Risk Analysis**

559

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

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565 14971, mitigations may not be necessary for risks that are broadly acceptable⁹; these
566 decisions should be captured within the risk analysis documentation.

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

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

- 579 • Risks and the methods for reducing these risks to acceptable levels;
- 580 • Fault tolerant behavior, boundary conditions, and fail safe behavior such
581 as how the device handles delays, corrupted data, data provided in the
582 wrong format, and any other issues with the reception and transmission of
583 data;
- 584 • Any security risks¹⁰ that may be involved with the presence of an
585 electronic data interface; and
- 586 • Risks arising from normal use as well as reasonably foreseeable misuse.
587 For example, a manufacturer may want to include in the labeling an
588 explicit warning against foreseeable uses that could result in harm.
589

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

594

595 **C. Verification and Validation**

596

597 As part of the device performance testing typically submitted in a pre-market
598 submission,, a sponsor should include results of verification and validation testing for the
599 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>.

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

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

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

620
621 The degree of documentation can vary based upon the risks associated with the device,
622 the purpose of the interface, the anticipated use of the device in the target system, and the
623 intended use of the device. For those elements of the interface that use a standard,
624 demonstrating conformance to that standard may be sufficient¹¹. For example, if the
625 purpose of the interface along with the intended scenarios for use of the interface do not
626 add significant risk to the operation of the medical device, then test summaries may be
627 sufficient.

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

- 632 • If an infusion pump is intended to receive patient data from several
633 devices (e.g. a pulse oximeter, ventilator, and blood pressure monitor) and
634 use this data to change infusion pump settings, complete test reports
635 should be provided to the FDA in the planned submission.
- 636 • 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)," <http://www.fda.gov/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm077274.htm>.

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

639

640 **D. Labeling**

641

642 The following recommendations are intended to help prepare labeling that satisfies the
643 requirements of 21 CFR Part 801 and 809, as appropriate.¹² For additional information
644 on developing labeling, please consult [FDA Guidance: Labeling - Regulatory](#)
645 [Requirements for Medical Devices \(FDA 89-4203\)](#)
646 ([http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Guidanc
648 eDocuments/UCM095308.pdf](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Guidanc
647 eDocuments/UCM095308.pdf)) and “Alternative to Certain Prescription Device Labeling
649 Requirements”
649 ([http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Guidanc
650 eDocuments/ucm072748.pdf](http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/Guidanc
650 eDocuments/ucm072748.pdf)).

651

652

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

662

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

675

676 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.

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