

Medical Device Plug-and-Play (MD PnP) Program
Massachusetts General Hospital / Partners HealthCare System
Johns Hopkins Medicine
Kaiser Permanente

This document contains three sections:

1. Overview (this page)
2. Background and Clinical Context
3. Sample RFP, RFI, and Contract Language

Section 1: Overview

Medical Device "Free Interoperability Requirements for the Enterprise", or MD FIRE, is an open international collaborative project to improve patient safety through the adoption of fully interoperable medical devices and systems.

MD FIRE has two synergistic goals. The first is to promote the awareness and knowledge of medical device interoperability throughout the medical and healthcare community. To that end, MD FIRE has resulted in clinical societies (including the American Medical Association) and the FDA now endorsing the potential of medical device interoperability to lead to "improvements in patient safety and clinical efficiency." The second goal of MD FIRE is to enable healthcare delivery organizations to acquire and use interoperable medical devices. To that end, MD FIRE has created sample RFP and contracting language that may be re-used to aid in the purchase and maintenance of fully interoperable medical devices and systems in support of patient safety.

MD FIRE is a living document; updates to the MD FIRE contracting language are posted on the www.mdnp.org website. The MD FIRE document may be shared under the Creative Commons Attribution-Share Alike license. (*Note: This October 2011 Version 1.3 has not yet been posted to the web site.*)

We welcome your collaboration, endorsement, and proposals for changes or enhancements to the MD FIRE document. Please contact Julian M. Goldman, MD (jgoldman@mdnp.org).

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Endorsement and Authors:

The original MD FIRE documents were drafted by the CIMIT MD PnP Program "Interoperability Contracting Requirements Working Group," which convened interdisciplinary experts from The Massachusetts General Hospital, Partners HealthCare, Kaiser Permanente, and Johns Hopkins during 2008. Participants included clinical, materials management, biomedical engineering, and legal experts.

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Subsequent versions of MD FIRE reflect additional input following the original release. The current version reflects re-formatting and minor edits, but no changes to substance.

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Section 2: Background and Clinical Context

This section discusses the requirements for medical device interoperability in the modern healthcare environment. These requirements are changing the way in which we procure and use medical devices. Section 3 provides examples of sharable language for Requests for Proposal (RFPs), Requests for Information (RFIs), and contracts.

Background

Medical devices, essential for the practice of modern medicine, have been designed traditionally to operate independently using proprietary protocols and interfaces for integration into both the Healthcare Delivery Organization's (HDO's) existing medical devices and Systems (as defined below) and a vendor's products or Systems. With the increasing complexity of the healthcare environment, stand-alone and/or proprietary medical devices and Systems no longer provide an acceptable solution. To improve patient safety, medical devices and Systems of medical devices and other Information Technology (IT) products and Systems must easily integrate with other vendors' equipment, software and Systems that have been or will be installed at the HDO.

For purposes of this paper and the Appendix, "System" is defined as a collection of (i) multiple medical devices that are interconnected or (ii) one or more medical devices, which may or may not be directly interconnected, that are connected to other equipment. A System may be a newly created System, an HDO legacy System, or the combination of a new System and a legacy System.

Essential improvements in patient safety and healthcare efficiency in high-acuity clinical settings require system solutions that can be implemented using standardized, interoperable medical devices and Systems that are medical devices.^[1] Clinical societies (including the American Medical Association) and the FDA now endorse the potential of medical device interoperability to lead to "improvements in patient safety and clinical efficiency."^{[2][3]}

Our collaboration through the Medical Device Plug-and-Play (MD PnP) Interoperability program leads us to conclude that HDOs must lead a call to action for interoperability of medical devices with various HDO legacy or new Systems. One way that HDOs can effect this change is by including medical device interoperability as an essential element in the procurement process and in vendor selection criteria.

We HDOs intend to adopt and implement interoperability standards for medical device interconnectivity via our procurement actions. We also recognize that the necessary standards are not yet fully developed or widely implemented by medical equipment vendors. However, we believe that adoption of standards-compliant interoperable devices and associated Systems (i) will enable the development of innovative approaches to improve patient safety, healthcare quality, and provider efficiency for patient care; (ii) will improve the quality of medical devices; (iii) will increase the rate of adoption of new clinical technology and corresponding improvements in patient care; (iv) will release HDO resources now used to maintain customized interfaces; and (v) will enable the acquisition and analysis of more complete and more accurate patient and device data, which will support individual, institutional, and national goals for improved healthcare quality and outcomes.

Our goals are to (i) educate the medical community; (ii) facilitate compliance by medical device manufacturers; (iii) encourage the implementation of interoperability by compiling and presenting the evidence of present and projected clinical demand for the interoperability of medical devices; and (iv) encourage and facilitate the development and adoption of medical device interoperability standards and related technologies through HDO procurement actions.

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Clinical Context

Why is medical device interoperability necessary to improve patient safety? As an example, when taking an x-ray in the Intensive Care Unit, the ability to synchronize the x-ray with the patient's breathing cycle has been demonstrated to improve image quality.^[4] Similarly, a safety interlock that would stop the flow of opioid pain medication from an infusion pump and call the nurse if a patient showed signs of respiratory distress could save lives.^[5] There are numerous other examples whereby medical device interoperability and medical System integration, if available, will improve patient safety.^[6] ^[7] Unfortunately, the capability of interconnecting and synchronizing these medical devices is not available today.

Standards-based medical device interoperability can provide real-time comprehensive population of a patient's electronic medical record (EMR), and in the future will permit the creation of integrated error-resistant medical Systems that will support advanced capabilities such as (i) automated System readiness assessment; (ii) physiologic closed loop control of medication delivery, ventilation, and fluid delivery; (iii) decision support; (iv) safety interlocks; (v) monitoring of device performance; (vi) plug-and-play modularity to support "hot swapping" of replacement devices and selection of "best of breed" components from competitive sources; and (vii) other innovations to improve patient safety, treatment efficacy, and workflow efficiency.^[6]

Recommendations

We strongly encourage HDOs to adopt medical device interoperability as an essential element of their procurement process.

We have drafted sample medical device and Systems interoperability requirements and encourage HDOs and vendors to use such requirements in their procurement process, including their RFPs, RFIs and contracts for the procurement of medical devices, whether stand-alone or in Systems, and any associated services. Sample language is included as Section 3 of this document, and is also available at http://mdpnp.org/MD_FIRE.php. In addition, we have included text that describes the possible uses of those clauses and how they can be implemented by the HDO in an RFP, RFI, or contract. We also hope and expect that sample language regarding medical devices and Systems interoperability will evolve over time. For that reason, this document and the sample language are available under shareware license through the www.mdpnp.org web site.

We believe that changing the way in which HDOs procure medical devices, by including in those procurement actions the requirements for interoperability, will provide a way for all HDOs to ensure patient safety, improve healthcare quality, reduce healthcare costs, and provide for more comprehensive and secure management of health information.

Section 3: Sample RFP, RFI, and Contract Language

This section of the document provides examples of sharable language for Requests for Proposal (RFPs), Requests for Information (RFIs), and contracts. The language is to be used in an RFP or RFI that is an initial step in selecting vendors in a competitive bidding process. Include in the RFP the contract language examples below if it is the intention of the Healthcare Delivery Organization (HDO) to utilize them for the contract. It is anticipated that one or more of the sections below would be included as part of the Product specifications or other contract language in any contract that would be entered into by the HDO. Each of the sample sections below may be included in any combination in any document.

“Product” refers to the medical device(s) or Systems that will be acquired by the HDO’s procurement action.

“Company” refers to the supplier of the Product.

“System” is defined as a collection of (i) multiple medical devices that are interconnected or (ii) one or more medical devices, which may or may not be directly interconnected, that are connected to other equipment. A System may be a newly created System, an HDO legacy System, or the combination of a new System and a legacy System.

Sample language is included the examples below:

MD FIRE: RFP & RFI EXAMPLES

RFP Example A: Request for Specific Functionality and Interoperability Capabilities

Note: Requests a complete description of specific functionality and interoperability capabilities. The text shown is only an example and would have to be greatly expanded by the HDO in a detailed specification. This may be used if the HDO knows what interoperability capabilities it is seeking, what Product functions support that interoperability, and which standards are to be implemented. Language in square brackets [this or that] should be selected as appropriate by the Healthcare Delivery Organization (HDO).

- Current Interoperability Functionality: The Product must have the following capabilities:
 - Pulse oximeter sends % oxygen saturation and pulse rate data to other clinical Systems using standard XXXX.
 - Other Specifications.
- Future Interoperability Functionality: The Product must have the following capabilities within [18 months] [of standard XXXX being approved] [of these functions being included in applicable specifications published by the Health IT Standards Panel (HITSP)]:
 - Pulse oximeter sends clinical and technical (equipment) alarms, and upper and lower oxygen saturation and pulse rate alarm settings to other clinical Systems using standard [XXXX].
 - Pulse oximeter interfaces with clinical Systems and accepts data and control to set alarm limits (and averaging time and sensitivity mode, if applicable).
 - Other specifications.
- Performance testing: The ability of the Product to meet all specified operational and functional requirements will be verified in the HDO’s own test and operational environments in accordance with the mutually agreed-upon terms in the contract.
- Support: All Product functions must be included in the regular maintenance and support agreement, copies of which shall be provided along with the response to the RFP.

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RFP Example B: Complete Interoperability

Please include in the RFP response the approach and plans for interoperability of your Product(s), specifically:

- List all external interfaces for each Product, including interface and communication standards and terminology definitions (referred to collectively herein as “interfaces”). This includes listing any interface standards for a Product that Company does not intend to implement or conform to.

For each of these interfaces, describe:

- The unique identifier or name for the interface.
- The applicable standard or the Company’s own name for the interface. Examples include, but are not limited to: ANSI, ASTM, NEMA, ISO DICOM, IEEE, IHE, USB, WiFi, ZigBee, Bluetooth, HL7 (and which parts of HL7 you support), and Continua.
- The standard name and version if applicable, e.g., HL7 2.3.
- The domain, subset, and profile of the interface as applicable, e.g., IHE Radiology Profile.
- Whether its classification is “proprietary & closed”, “proprietary & open”, “standard” (i.e., HL7 or DICOM), “standard with a third party implementation guideline or profile” (e.g., IHE Radiology) or “standard with a third party implementation guideline and third party certification” (e.g., Continua or USB or WiFi).
- Whether it is currently in operational use at HDO sites, developed but not in use, in development, or planned for development.
- References to the interface’s specification – these could be external links to Standards Development Organizations or the Company’s own documentation, as applicable.
- A description of the Product functions supported by the interface.
- Disclosure of license fees, if any, to use the implemented standard.

To the extent possible at the RFP stage, the HDO should include detailed specifications for the Product and identify the other products and/or Systems with which the Product should be interoperable and/or integrated.

Note: If the HDO determines that it will contract for the item or items above after receiving the information in response to the above, that information should be included in the terms of the contract or the Product’s specifications.

A table illustrating the information required above is shown at the end of this document.

RFP Example C: Description of All Interoperability Current and Planned Capabilities and Related Functionality

Note: Requests a complete description of the Product’s “Current” (as defined below) interoperability capabilities, but does not call for any particular function or standard. This example also includes language anticipating the possibility that to the extent that a respondent must engage in Product development to satisfy the HDO’s requirements, some portion of that development work could be funded by the HDO. Any such funding by the HDO, however, would be only an option and not a requirement for the development of the Product.

Please include in the RFP response the approach and plans for interoperability of your Product(s), specifically:

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- All interoperable interface standards, technology standards, terminology standards, communication standards, and design guidelines that the Products will implement and comply with (including but not limited to USB, WiFi, ZigBee, Bluetooth, HL7, Continua). For each standard and guideline, describe:
 - The Current and proposed scope of compliance with each standard and guideline, including but not limited to the exact specifications and guideline versions.
 - A description of the Current and proposed Product functions that are interoperable and supported by the standards and guidelines.
 - An estimate of the [Not to Exceed or time and materials, estimated] cost and schedule to implement the proposed capabilities and standards listed above. If updates or compliance are included in the regular maintenance agreement, please describe those terms.

Note: this clause would be inserted only if the HDO intends to fund some or all of the Company's Product development work that is necessary to meet an RFP's Product requirements. However, this clause would not be included in any contract that also included Company-funded Product development.
- Describe the process for demonstration, acceptance testing, and certification and validation of the Product's interoperability for the standards listed above. If you propose to provide independent validation and verification of capability, the full price of that effort should be described.
- Describe the processes for Product maintenance and upgrades to accommodate new interface technology, new interface standards, updated interface standards, or new Product functionality.
- Describe the supported proprietary, customized, standards-based, and interoperable interfaces, electronic data interfaces, and data transfer functions supported by the Product.
- Describe the Product's Current and proposed functions that are available or fully functional only when (i) the System is interfacing with Company's Products or other products and Systems that would be provided by subcontractors to the Company or companies that are collaborating with, but are not under the control of the Company; and (ii) the Company would have systems integration responsibility for the Products and any legacy and other Systems.
- List the Product's Current and proposed interfaces that are fully supported only when interoperating with Company's Products or the products of companies that are collaborating with, but are not under the control of the Company.

"Current" means functions, features, and compliance that are currently marketed by Company and in use by its customers.

For all of the above items, please describe all the resources required from the HDO and third parties, including costs and dependencies, where known.

RFI Example D: Description of Technology Supporting Interoperability

Note: Requests a complete description of the Product technology. This should be used only if the HDO intends to evaluate the Product's technology and implementation.

Please describe Company's implementation of technology relevant to interoperability with other medical devices and Systems, including:

- Description of the current and proposed System architecture, including interfaces.
- Description of the current and proposed software architecture, including interfaces.

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- Description of the current and proposed hardware architecture, including interfaces.
- Description of the current and proposed application architecture, including interfaces.

RFI Example E: Description of Company's Past Support for Interoperability

Note: Requests a complete description of the Company's corporate activities related to interoperability, but not directly related to the Product itself. This should be used only if the HDO intends to evaluate a Company's past commitment and contributions to interoperability.

Please describe the efforts and contributions that Company has made to achieving medical device interoperability for your products in particular or the industry in general. The response may take any form, but as an example it could include:

- Company's participation in interoperability standards consortiums, societies, or other similar organizations developing or promoting interoperability.
- Any relevant public demonstrations, plug-fests, or product implementations that show the interoperability of Company's products.

MD FIRE: SAMPLE CONTRACT TERMS

Option 1: Complete Interoperability

Note: The purpose of this section is to provide an example of contract terms for a procurement action that seeks complete Product interoperability. Language in square brackets [this or that] should be selected as appropriate by the Healthcare Delivery Organization (HDO). The term "Supplier" refers to the vendor that is entering into the contract for a Product. All other terms mean the same as indicated in the prior section that addresses RFP and RFI clauses.

1. During the Term of the Agreement and any subsequent period during which HDO is purchasing support and maintenance services from Supplier for Products, Supplier will implement federally ratified interoperability standards and interoperability specifications for all interfaces described in paragraph X above as follows:
 - Applicable specifications published by the Health IT Standards Panel (HITSP).
 - Applicable certification criteria published by the Certification Commission for Health IT (CCHIT).
 - Applicable specifications recognized by the Secretary of US Health and Human Services and required under the federal contracting provisions of US Executive Order 13410.
 - Other interoperability standards and specifications recognized or required in applicable laws, rules, regulations, and legislation from the federal government and states and districts where HDO operates.

Note: This requirement would also need to be supported in the Agreement by (i) detailed descriptions of the timelines for implementation, (ii) the allocation of costs, (iii) the other product and System dependencies, and (iv) the consequences (i.e., potentially liquidated damages or other adverse consequences) that the Supplier will incur if those obligations are not met in a satisfactory manner.

Supplier will implement these standards and specifications [before the US Government and its agencies mandate compliance for any final specification] in accordance with HDO project timeline in Exhibit X.

As part of the HDO's acceptance testing process, Supplier shall demonstrate in the HDO's own test and operational environments that the Products successfully

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interoperate with the HDO's existing third party equipment and Systems in accordance with the requirements in this Exhibit and with the use cases [described in this Agreement, mutually agreed upon by the parties].

Note: There could be non-disclosure and other restrictions on the access to third party equipment and Systems that Supplier may need to address. Thus, there could be significant negotiations and additional contract language detailing how the tests will be run (including whether they will be run under "live" conditions, scheduling, access/use of the HDO's data, equipment and Systems), and how the costs will be allocated between the Supplier and the HDO for the acceptance tests and any remedial actions, as further described below. To the extent that any data or other output will result, it also should be made clear that the HDO will own it.

2. For any proprietary interfaces, Supplier shall provide to HDO and designated third party suppliers the information necessary for them to understand and test the Product's interface specifications that are in use by HDO and, where needed, a royalty-free license to use these proprietary interfaces with third party products that interoperate with Products in use by HDO.

In the event the Product fails to interoperate with third party products and Systems in accordance with the Product's integration and interoperability specifications set forth in this Agreement, then Supplier shall remediate the problem at Supplier's cost and shall reimburse HDO for its reasonable costs and expenses resulting from re-work, re-testing, re-certification, and re-validation of the product.

Note: Because it would seem that non-interoperability would not occur if both parties have properly performed their obligations under the contract, the remedial process needs to be fully described, including the number of attempts that the Supplier is permitted in order to correct the problem before the contract is terminated for cause. The inclusion of liquidated damages should be seriously considered.

3. For all of these terms, Supplier shall specify whether the capability is available in the proposed Product without a maintenance agreement. If any capability is available only with a maintenance or development agreement, the terms of that agreement shall be fully disclosed and described.

Note: Since the Supplier is normally expected to provide Product support, to the extent that the Product depends on software for its interoperability with other products or Systems, the HDO needs to determine how it would support the Product without the Supplier's support, e.g., availability of source code.

Option 2: Independent Lab Testing of Interfaces

Supplier agrees to have each interface tested and verified by an independent lab approved by Supplier and HDO.¹ All costs from the Supplier and other third parties for independent lab testing and certification shall be listed separately [and paid by Supplier]. Supplier also agrees to obtain any applicable consortia certification for Product interfaces, including without limitation, USB, WiFi, ZigBee, Bluetooth, HL7, and Continua.

¹ Such as the Medical Device Plug-and-Play Lab at the Center for Integration of Medicine and Innovative Technology (CIMIT) or the Kaiser Garfield Center

Option 3: Connectivity by Clinical Domain

Note: This section provides a means to add requirements by clinical domain. HDO should consider specifying domains as needed.

Product and all subsequent releases and replacement Products shall comply with applicable interoperability standards, guidelines, and certifications in the following domains:

- acute care documentation Systems
- physiological monitors
- ventilators
- patient care beds
- etc.

Option 4: Request for Conformance to Specific Standards

Note: This section provides a means to add conformance to specific standards if not required by other sections.

Product and all subsequent releases and replacement Products shall comply with the following standard:

- e.g., ASTM F2761-2009

Option 5: Commitment to Work towards Interoperability

Purpose: This section is to be used when the Supplier is expected to make commercially reasonable efforts to achieve interoperability and at the same time to inform the HDO of any issues, barriers, or problems with the current set of standards. However, it is preferable to have the contract establish some deadlines or other incentives for the Supplier's attainment of a specified level of interoperability, along with any allocation of costs among the parties and the consequences if the deadlines are not met by the Supplier.

At every release of a Product's software, either for implementation or maintenance, Supplier shall use *commercially reasonable efforts* to implement applicable [federally ratified] interoperability standards. Supplier and HDO shall meet quarterly [in-person or by teleconference by mutual agreement] to discuss Supplier's progress towards implementing and conforming to applicable standards. At each meeting, Supplier shall provide the following information:

1. For each interface, a description of the progress and accomplishments made towards conformance with standards
2. For each interface, a list of issues, objections, and problems encountered with the Supplier's Products, third party products, and the HDO's or standards' specifications that prevent or delay conformance

Option 6: Example of HDO Requirements Definition

Exhibit X

This is a placeholder for the HDO to define its own program/project timeline with respect to identifying the requirements for interoperable interfaces that would be referenced in the Agreement. To support this Agreement language, this Exhibit should at a minimum specify:

- When requirements will be delivered from the HDO to the Supplier
- When the Supplier is expected to complete development of interfaces

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- When the Supplier is expected to complete testing, validation, and certification of interoperable interfaces

The actual content of this exhibit should be created by the HDO.

Option 7: RFP Example for Implementation of a Specific Technical Standard

NTP: Request for Network Time Protocol Implementation

Note: Requests a complete description of specific functionality and interoperability capabilities. The text shown is only an example and would have to be greatly expanded by the HDO in a detailed specification.

- Current Interoperability Functionality: The Product must have the following capabilities:
 - A reliable system clock in UTC that includes a full implementation of either Network Time Protocol version 4 (NTPv4) or Simple Network Time Protocol version 4 (SNTPv4) as specified by IETF RFC 5905. See <http://www.ntp.org/rfc.html>.
 - If the product supports manual or automatic local time zones, then the local time shall be based on an algorithm that utilizes UTC.
 - If the product utilizes automatic or manual daylight savings time, then the local time shall be based on an algorithm that utilizes UTC.
 - The product shall use local time or UTC for all user and electronic interfaces.
 - If the product is unable to synchronize on UTC through the implementation of NTPv4 or SNTPv4, then the product will inform the user in an appropriate manner.

Option 8: RFP Examples for Conformance or Certification to Specific Industry Interoperability Profiles and Design Guidelines

Note: This section references external specification documents that may have changed since this document was originally approved and published.

- IHE Profile compliance. See Appendix H of the IHE User Handbook. http://www.ihe.net/Resources/upload/IHE_PCD_User_Handbook_2011_Edition.pdf

Please note that the IHE User Handbook states on page 31:

[The IHE RFP] Structure only solves one part of integration: a vendor could support an IHE profile (i.e., information is present and in the right order) but use terms that connected systems can't understand, requiring either the supplier or the facility to perform the translation. To identify cases in which a system under consideration does not support standardized nomenclature and terminologies, purchasers must ask suppliers to specify their level of terminology and nomenclature support when responding to an RFP.

Therefore MD FIRE users may want to supplement this material with other contract or RFP terms as appropriate and desired.

- Continua Health Alliance Design Guidelines version 1 http://www.continuaalliance.org/static/cms_workspace/External_Guidelines_Order_Form_2010.pdf

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Please note that only the version 1 Continua Design Guidelines are publicly available. At this time, compliance with a later version requires that the vendor become a member of the Continua Health Alliance in order to have access to those Design Guidelines.

Please note that the Continua Health Alliance Design Guidelines only apply to some healthcare use cases and are not universal.

Continua Health Alliance full compliance

Please note that there are several possible combinations of Continua Compliance. There are currently two Continua Interfaces (PAN and xHR), and two transport standards that are certified by USB and Bluetooth, respectively (and not by Continua). Please see http://www.continuaalliance.org/static/cms_workspace/Continua_Certification_Public.pdf for more information. Example compliance statements are below.

Example Continua Compliance terms:

- Vendor's product will be certified compliant by the Continua Health Alliance for the PAN interface.
- Vendor's product will be certified compliant by the Continua Health Alliance for the xHR interface.

Example Transport Standard Compliance terms:

- Vendor's product will fully comply and pass BlueTooth HDP/MCAP Self-Qualification tests.
- Vendor will be certified compliant by USB for the USB Interface transport standard. See <http://www.usb.org/developers/compliance/labs/> for more information.

This table contains **examples** of the expected level of detail to be provided by Supplier for its external interfaces.

Example Interface Standard Table								
Interface Name	Standard	Domain	Type	In use?	Scope of Conformance	Plans	Reference to Interface Specification	Functions Supported
Patient demographics	HL7 2.3	Demographics	Open standard, not validated	In operational use	Partial implementation	No plans to discontinue	www.hl7.org	Receive and display patient demographic data
Patient lab data	Proprietary	Laboratory	Proprietary, open	In operational use	Full	Will be maintained for existing products, but eventually replaced by CCHIT certification	Example: www.vendorname.com/productsupport/interfaces	Send patient lab data
Patient lab data	HL7 2.3	Laboratory	Open standard, CCHIT certification	Planned for development	Planned to be lab data	Will replace lab data interface within 12 months of ratification of the specification and adoption by the US government	www.hl7.org	Send patient lab data to the EMR
Patient weight	IEEE 11073 Continua V2 Guidelines	Disease Management	Open validated standard, Continua guidelines, Continua validation	No	Full & certified	Planned for delivery in 2011 Q4 products	http://www.continuaalliance.org/products/cert-process.html	Receive CHF patient's weight
Contrast injectors	CIA425, Part 2: Injector	CANOpen Application Profile for Medical Diagnostic, Add-on Modules, Part 2: Injectors	Standard	Yes	Full	No plans to change	http://www.can-cia.org	Connect injectors to CANOpen network for x-ray contrast injections
Pulse oximeter	IEEE P11073-10404(sm)	Pulse oximeter	Standard	Yes	Full	No plans to change	https://development.standards.ieee.org/pub/active-parts?n=12	Acquire pulse oximeter data
Integrated Clinical Environment (ICE) data logger	ASTM F2761 ICE Part II	ICE system data logging	In process	No	N/A	All products will conform	http://www.astm.org/Standards/F2761.htm	Continuously log data from patient-centric devices in the ICE
Disease taxonomy	ICD-11	All	Standard	No	None	Will implement within 18 months of ratification and publication by WHO	http://www.who.int/classifications/icd/revision/en/index.html	All functions support clinical documentation

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