

# Medical Device Interoperability: Standards Overview

Bridget Moorman

*"...A seamless flow of information between many disparate devices over a network and to/from intended recipients." Sounds great—where do I sign up?*

*It is our pleasure to once again bring Bridget Moorman, president of BMoorman Consulting, LLC, and her ideas to IT World. In this article, Bridget shines light on various medical device interoperability standards that attempt to interface biomedical device and clinical information systems.*

*This is one of those articles that's a "keeper"—one to cut out and save. Bridget has great ideas on how to keep track of these standards, especially tracking how your in-*

*stitution fares in device interoperability. Not only can this help with making quick technology assessments and aid future technology planning, it can help to produce a report to show the C-suite where you stand in terms of interoperability. Include information such as what you can and cannot connect with in an "interoperability tracking report." This article also is a great summary of these standards.*

Jeff Kabachinski  
IT World Columnist

In a previous article on medical device interoperability ("Biomedical Device Interfacing to Clinical Information Systems: a Primer," *BI&T*, May/June 2008), a sidebar briefly outlined the applicable standards for the biomedical device-clinical information systems interface. Through the efforts of several groups, there have been changes in the standards defining this interface. One could argue that the groups' overall goals are the same, however, their approach and perspectives differ. Additionally, each is carving out a specific domain within the device-clinical information system interface in which they are endeavoring to drive or build applicable standards. Each of these groups is using clinical use cases to define the actors, interfaces, and needed interactions between the different parts of the system. The groups name the actors differently; however, there are similarities in functionality. As a clinical engineer (CD) or biomedical equipment technician (BMET), and based on a healthcare organization's current and future models of care, following the standards development

and tracking how your devices adhere to them can make future biomedical device-clinical information system connectivity easier.

There are four main efforts, three international and one specific to the United States, defining standards for device interoperability:

- The Continua Alliance
- Integrating the Health Environment—Patient Care Devices Domain (IHE-PCD)
- American Society for Testing and Materials—Integrating the Clinical Environment (ASTM-ICE)
- The Health Information Technology Standards Panel (HITSP)

Remember, the ultimate goal of interoperability is a seamless flow of information between many *disparate* devices over a network to and from the intended recipients. The key word is *disparate* such that different vendors can communicate over different networks to different recipients. How does each of the organizations working on standards usage and development in this device interface arena determine how interoperable their construct is? To be truly interoperable, standards that are broadly written for wide application must be constrained by imposing additional requirements. Therefore each of the organizations has at times limited the variability in specific areas of the standards for adherence to their construct and to move towards the ultimate goal of interoperability.



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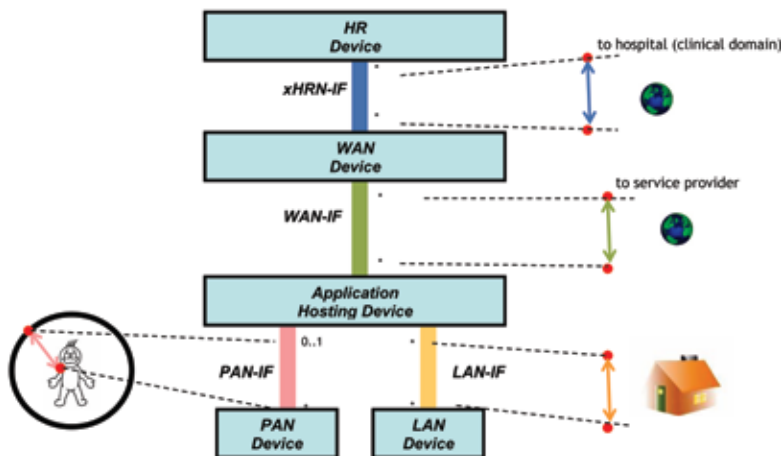


Figure 1. Continua's interoperability paradigm.

DEVICE/OTHER	STANDARD	STATUS
Pulse Oximeter	IEEE 11073-10404	Completed
Blood Pressure Monitor	IEEE 11073-10407	Completed
Thermometer	IEEE 11073-10408	Completed
Weighing Scale	IEEE 11073-10415	Completed
Glucose Meter	IEEE 11073-10417	Completed
Cardiovascular	IEEE 11073-10441	Completed
Strength	IEEE 11073-10442	Completed
Activity Hub	IEEE 11073-10471	Completed
Optimized Data Exchange	IEEE 11073-20601	Completed
Basic ECG	IEEE P11073-10406	Draft
INR – Blood Coagulation	IEEE P11073-10418	Draft
Insulin Pump	IEEE P11073-10419	Draft
Body Composition Analyzer	IEEE P11073-10420	Draft
Peak Flow	IEEE P11073-10421	Draft
Physical Activity Monitor	IEEE P11073-10443	Draft
Medication Monitor	IEEE P11073-10472	Completed
Technical Report-Overview	IEEE P11073-0103	Draft

Table 1. IEEE PHD standards and status.

## Continua

The Continua Health Alliance is a nonprofit industry coalition started in 2006. It has more than 180 member companies today. Continua's vision is to build a "system of interoperable personal health solutions." This is done by certifying and branding Continua-enabled products.

If a product has the Continua logo on it, then it is certified to work or be interoperable with any other Continua-branded product. Certification comes with rigorous independent testing to the selected Continua standards. The main thrust of Continua currently is the personal tele-health arena, which includes disease management, health and wellness, and aging independently. From a design standpoint, the members' products tend to be small and portable, which drives the engineering toward smaller messaging to keep battery life as long as possible. Additionally, the personal area network (PAN) emphasis for the devices

is on wireless protocols that also need to be energy or battery efficient.

Continua's actors in their interoperability paradigm are the PAN and local area networking (LAN) devices, an application hosting device (AHD), a wide area networking (WAN) device, and a health record (HR) device (Figure 1). The interfaces are defined as the PAN, LAN, WAN, and x (electronic or personal) health record network (xHRN).

As part of their effort to have interoperable products for Continua's V1 (which focused on the PAN and xHRN interfaces), several standards in the PAN and device data exchange have been selected and/or developed. Of particular note is the expansion of IEEE 11073 (formerly 1073 and colloquially called the Medical Information Bus or MIB) to the personal health device (PHD) arena. There are 14 IEEE 11073-104ZZ standards (see Table 1) that also rely upon the new IEEE 11073-20601 Optimized Data Exchange standard. Essentially, the specific instances of a personal health device along with a more constrained data exchange standard were written for use by the current consumer health device market. The standards are meant to be standalone and prescriptive. If a vendor wishes to produce one of the products, they only need to purchase IEEE 11073 and IEEE 11073-104ZZ. Before, IEEE 11073 had a reputation of being descriptive and not standalone. It is fair to say the 14 instances for personal health devices are simple scenarios and therefore a prescriptive approach will work. It remains to be seen if that simplicity can be extended to more complex devices and device systems. A diagram of how the standards are used in a hierarchical fashion for the PAN interface is shown in Figure 2. Continua has constrained the lower level protocol standards for com-

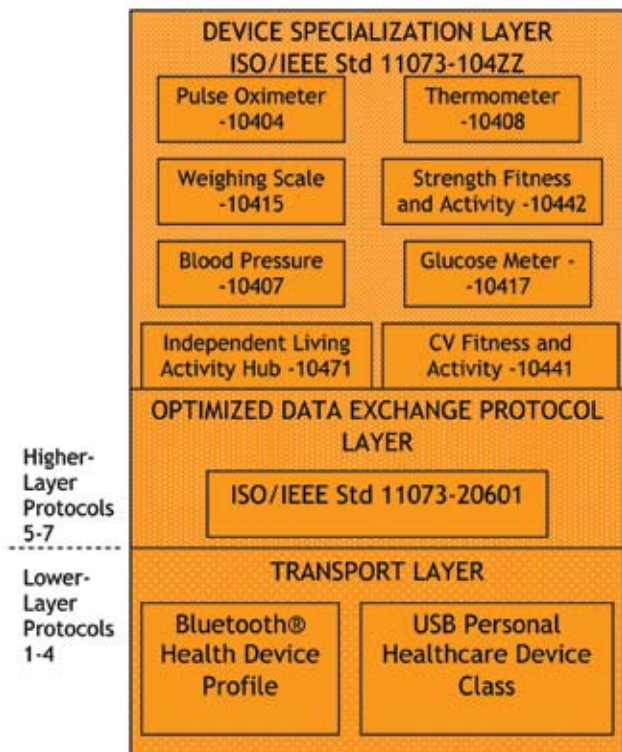


Figure 2. Continua OSI 7 layer model construct with applicable standards.

munication to USB and Bluetooth in order for a device to be considered Continua V1 certified. There are other lower-level protocols, such as serial, IrDA, and ZigBee, which Continua so far has decided not to support for Continua certification.

Similarly, standards are identified for Continua certification on the LAN and WAN interfaces. As in the PAN interface, the standards are chosen and then constrained to meet Continua guidelines for product certification.

### IHE-PCD

IHE-PCD Domain's charter states it is "concerned with Use Cases in which at least one actor is a regulated patient care device," which distinctly separates IHE-PCD's goals from Continua's goals. The PCD domain was started in 2005, and has built a technical framework of use cases which have defined profiles describing transactions (with interfaces) and actors. Each of the profiles represents an interface in which the actors are defined and a standard or standards identified for that specific interface and/or transaction. Table 2 shows the latest technical framework identifying the profiles (transactions) and actors.

PCD-01, as shown in Figure 3 is an example of an

IHE-PCD profile. Figure 3 shows the different actors and the interfaces. PCD-01 is the interface between the Device Observation Reporter (DOR) and the Data Observation Customer (DOC). IHE-PCD has identified IEEE 11073-10101 Domain Information Model (DIM) Medical Device Class (MDC) Attributes mapping to an HL7 2.6 message as the data/messaging standard used to communicate the device data from the DOR to the DOC. There is an implication that IEEE 11073-10201 is used to communicate from the device to the DOR with the DOR translating or mapping the information in the IEEE 11073-10101 message format to HL7 2.6. A Sample PCD-01 message is below:

```
MSH|^~&|INFO_SRC_PHILIPS^ACDE48234567ABCD^EUI64|||2006121515
3500||ORU^R01^ORU_R01|PMS116621490051|P|2.5|||NE|AL||8859/1
PID||AB60001^^^Philips Medical^PI||Brooks^Albert^^^^L||19610101|M
PV1|||UNIT_1^^Bed1
OBR|1|PMS116621490051^INFO_SRC_PHILIPS^ACDE48234567ABCD^EUI
-64|PMS116621490051^INFO_SRC_PHILIPS^ACDE48234567ABCD^EUI-64|
69837^MDC_DEV_METER_PHYSIO_MULTI_PARAM_MDS^MDC|||2006121
5153500
OBX|1|ST|184326^MDC_ECG_STAT_ECT^MDC|1.5130.1.184326|^|||||F
OBX|2|ST|184327^MDC_ECG_STAT_RHY^MDC|1.5130.1.184327|Sinus
Rhythm|||||F
OBX|3|NM|150456^MDC_PULS_OXIM_SAT_O2^MDC|1.5238.1.150456|99|2
62688^MDC_DIM_PERCENT^MDC|||||F
OBX|4|NM|147842^MDC_ECG_HEART_RATE^MDC|1.5130.1.147842|81|264
864^MDC_DIM_BEAT_PER_MIN^MDC|||||F
OBX|5|NM|150037^MDC_PRESS_BLD_ART_ABP_SYS^MDC|1.5190.1.1500
36|126|266016^MDC_DIM_MMHG^MDC|||||F
OBX|6|NM|150038^MDC_PRESS_BLD_ART_ABP_DIA^MDC|1.5190.1.1500
36|76|266016^MDC_DIM_MMHG^MDC|||||F
OBX|7|NM|150039^MDC_PRESS_BLD_ART_ABP_MEAN^MDC|1.5190.1.15
0036|92|266016^MDC_DIM_MMHG^MDC|||||F
```

In the message above, the IEEE 11073-10101 nomenclature is associated with each device observation (OBX). For example, in OBX 3 the pulse oximetry saturation of oxygen shows a value of 99 with dimensions of percentage. IHE-PCD has not constrained the PCD-01 DEC profile at the lower protocol layers as Continua has.

IHE-PCD showcased two other interesting developments at the Healthcare Information and Management Systems Society (HIMSS) Interoperability Showcase in 2009: the Alarm Communication Management (ACM) profile and the continuation of the Rosetta Terminology Mapping (RTM). In the ACM, five new actors are defined along with five new transactions. According to IHE-PCD, if a vendor conforms to the ACM profile, they meet the IEEE and U.S. Food and Drug Administration definitions for alarms. In the ACM profile, the alarm reporter can send a priority alarm message with a weighting of no/low/medium/high which when handled by the other actors will ensure proper dissemination and prioritization of alarm messages.

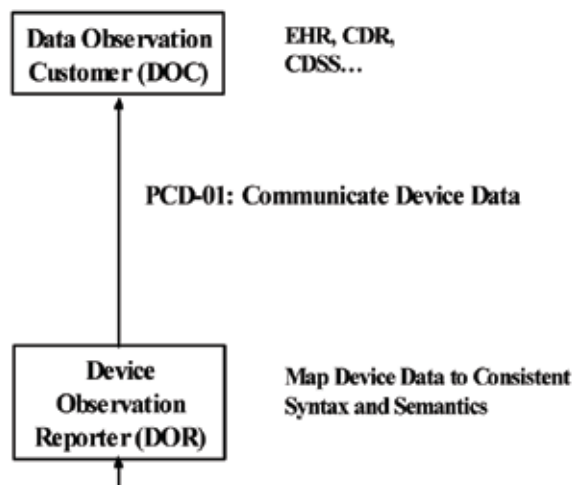


Figure 3. From IHE-PHD wiki at [http://wiki.ihe.net/index.php?title=PCD\\_Profile\\_Device\\_Enterprise\\_Communication](http://wiki.ihe.net/index.php?title=PCD_Profile_Device_Enterprise_Communication)

With the RTM profile, work has continued on developing a “Rosetta Stone” that correlates each vendors’ internal terms and units of measure for each of the IEEE 11073 defined reference identifications (example: MDC ECG HEART RATE is defined by HR by three different vendors and HTRT by another vendor). The end goal of this profile work is to generate a final set of terms, their units of measure, and enumerated values for testing purposes.

IHE-PCD holds Connect-a-thons to determine vendor conformance to the profiles. Conformance is not as strict as certification (as done by Continua). With a successful Connect-a-thon performance, vendors can then state in their literature that they conform to a particular profile. Some members of the IHE-PCD believe that once the RTM Profile is finalized, the quality and rigor of conformance offered by an IHE-PCD profile that uses the RTM could approach the implied performance “guarantee” for interoperability that certification offers. It remains to be seen if this can truly provide the functionality that certification would provide and relies upon all of the vendors complying.

### ASTM-ICE

Integrating the Clinical Environment (ICE) standard (ASTM F2671-2009) was chartered

by the American Society for Testing and Materials (ASTM) and is co-sponsored by the American Society for Anesthesiology (ASA). The definition of ICE on the ASTM website (<http://www.astm.org/Standards/F2761.htm>) is “a medical system designed to safely provide data acquisition, and integration and control of a heterogeneous combination of medical devices and other equipment in a high-acuity patient environment...(and) is intended to enable the creation of systems for innovation in patient safety, treatment efficacy, and workflow efficiency.” ICE is a patient safety standard which requires biomedical device integration at the point-of-care. The goal is to drive interoperability standards definition toward safety. The contention is that if there is not a bi-directional flow of data (technical closed loop without reliance on a human to close the loop), then safety is not being improved.

Current activity involves a gap analysis of existing communication standards to support ICE in which six clinical scenarios are analyzed to identify action not covered by existing standards that would affect a safe function of the device in the clinical scenarios. The first standard being

ID	Transaction Title	Profile	Source Actor	Receiving Actor	Notes
PCD-01	Communicate PCD Data	DEC	Device Observation Reporter (DOR)	Device Observation Consumer (DOC)	
PCD-02	Subscribe to PCD Data	SPD	Device Observation Consumer (DOC)	Device Observation Filter (DOF)	
PCD-03	Communicate Infusion Order	PIV	Infusion Order Programmer (IOP)	Infusion Order Consumer (IOC)	
PCD-04	Report Alarm	ACM	Alarm Reporter (AR)	Alarm Manager (AM)	Formerly ACM-01
PCD-05	Report Alarm Status	ACM	Alarm Manager (AM)	Alarm Reporter (AR)	Formerly ACM-02
PCD-06	Disseminate Alarm	ACM	Alarm Manager (AM)	Alarm Communicator (AC)	Formerly ACM-03
PCD-07	Report Dissemination Alarm Status	ACM	Alarm Communicator (AC)	Alarm Manager (AM)	Formerly ACM-04
PCD-08	Subscribe to Alarm	ACM	Alarm Archiver (AA)	Alarm Manager (AM)	Formerly ACM-06

Table 2. From the IHE PCD wiki at [http://wiki.ihe.net/index.php?title=PCD\\_Technical\\_Framework](http://wiki.ihe.net/index.php?title=PCD_Technical_Framework)

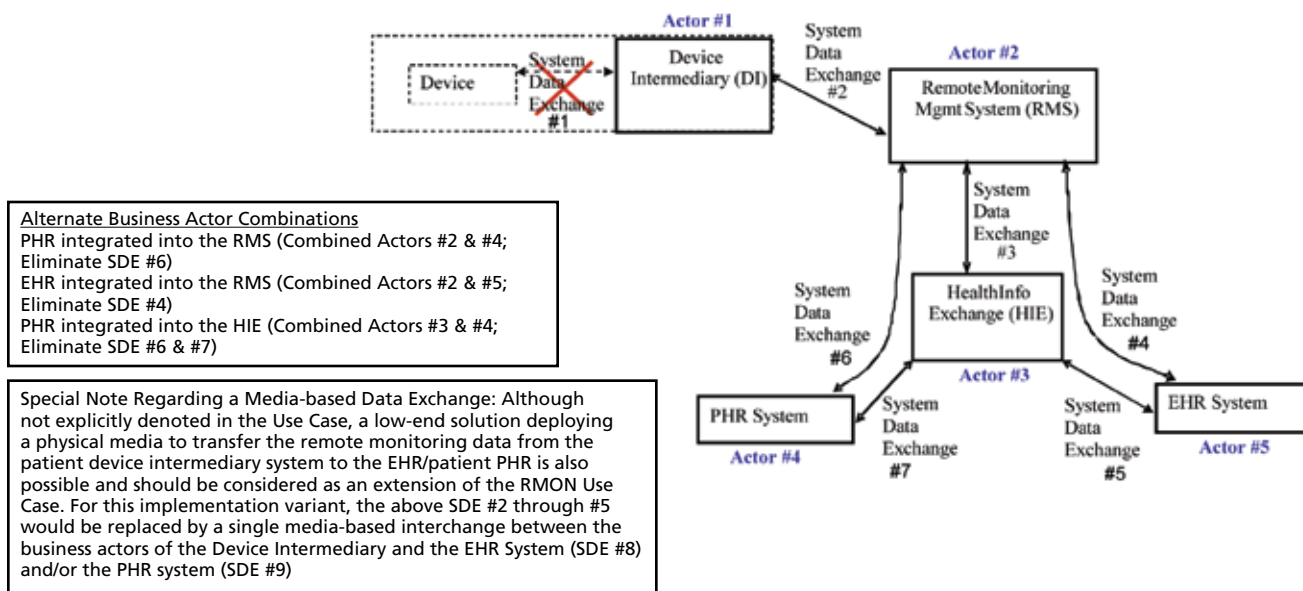


Figure 5. HITSP RMON diagram from HITSP Remote Monitoring Interoperability Specification IS 77 20081218 V1.0.

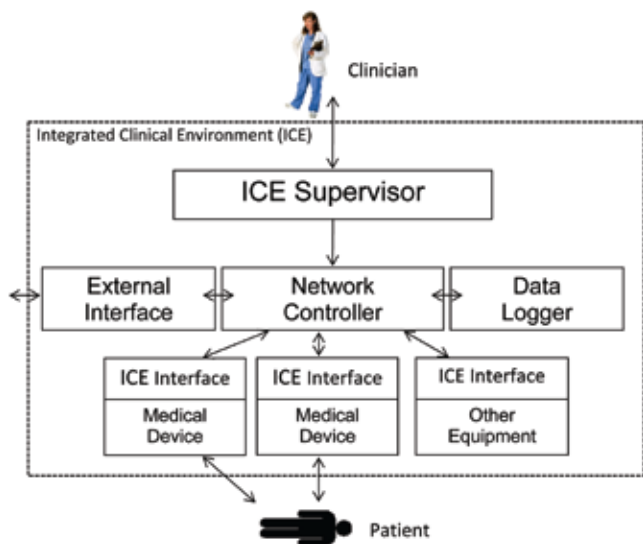


Figure 4. Functional Elements of the Integrated Clinical Environment – ASTM Standard F2671-2009 – used by permission of MD PnP.

compared to the clinical requirements workflow is IEEE 11073. This work is being done in conjunction with the IHE-PCD group. ICE has also begun interacting with HITSP.

The conceptual ICE system is shown in Figure 4.

The functional blocks described can be physically separate or collapsed into one or more physical entities. The ICE supervisor is the interface to the clinician and

is where safety interlocks and distribution of integrated alarms occur among other functions. The Network controller is the interface where plug and play occurs. The External Interface is the interface of the ICE outside of the clinical environment. According to the standard, this could be the facility backbone, public switched network, or Internet. The Data Logger is used to record everything within the ICE for future forensic activities, i.e. incident investigations and/or training scenarios.

### HITSP

HITSP was chartered by the U.S. Department of Health and Human Services to provide standards harmonization in the health information technology arena to meet the federal mandate for a universal electronic medical record. HITSP bases each of its interoperability specifications (IS) on use cases as promulgated by the National e-Health Collaborative (NeHC), formerly known as American Health Information Community (AHIC). The interoperability specifications are meant to be compulsory on any players in the healthcare realm who are contributing to an electronic medical record for a US citizen. Of particular interest to the clinical engineering community is HITSP I77 Remote Monitoring Interoperability Specification (RMON). The actors and interfaces in I77 are in Figure 5.

HITSP's actors for IS77 are the device intermediary (DI), remote monitoring management system (RMS), health information exchange (HIE), personal health re-

Device	Network capability: Yes-No	Wired - Wireless	Wired Physical: DB9, DB22, RJ45	Wireless: BlueTooth, ZigBee, 802.11Z, IrDA, other	Transport: RS232, TCP/IP, Serial	Data: Proprietary, 11073-10101/10201, 11073-104ZZ	Messaging: HL7 2.5/2.6, HL7 CCD, IHE XDR	Other: Continua Certified, IHE-PCD conformance to specific profile, part of medical network (monitor connected to central station), ICE compliant (ASTM F29.21)
Pulse Oximeter	Yes	Both	RJ45	Bluetooth	TCP/IP	11073-20601/10404	N/A	Continua V 1.0
Patient Monitor	Yes	Wired	RJ45	N/A	TCP/IP	11073-10101/10201	HL7 2.5	Connected to Patient Monitoring Central Station, IHE-PCD-01
Ventilator	Yes	Wired	DB9	N/A	RS232-Serial	Proprietary	N/A	None
Infusion Pump	Yes	Wireless	N/A	ZigBee	TCP/IP	Proprietary	N/A	Connected to Smart Pump Central Station

Table 3. Example of what and how to track interoperability in a medical equipment maintenance management system.

cord (PHR) system and electronic health record system (EHR). Between each of these systems is a numbered system data exchange (SDE) and, as noted in the diagram, actors can combine, collapsing some of the interfaces. HITSP calls out information exchange requirements (IERs) along each SDE (there could be more than one IER for each SDE). Each IER is also associated with data requests (DR). For example in the case of SDE No. 2, the DI has one IER with the RMS (IER 39). IER 39 consists of 23 DRs which are specific to the device. DR 80 is one of the DRs in IER 39 and is defined as data from a blood glucose system which will use the standard as specified by IEEE 11073-10417. The other DRs at this interface include those for temperature, blood pressure, pulse oximetry and weight, which specify the associated IEEE 11073-104ZZ standard.

As part of the American Recovery and Reinvestment Act (ARRA) of 2009 process for defining ‘meaningful use’ of an EHR, HITSP has recommended that remote monitoring medical device interoperability (IS77) be available by 2013 or 2015. Moreover, a document on the “Common Methods for Device Connectivity Technical Note – TN905” has been approved and published by HITSP. This technical note (TN) will cover the more complex medical device connectivity situations. This TN905 will also be folded into the HITSP definition of ‘meaningful use’ with a possible date for compliance as recommended for IS77.

A final note: Formal activity funding for HITSP

ended Jan. 31 and is continuing on a no-cost extension through April 30. It has yet to be determined if the harmonization and standards identification work will be as prolific as when there was an active U.S. government contract. Nonetheless, the standards identified in the Interface Specifications and Technical Notes are still valid and useful.

### Practical Uses

How can biomedical technology professionals use this information? As the organizations described above develop use cases and promulgate standards for interoperability, a CE or BMET can use the information to help prepare for a biomedical device-clinical information system interoperability project. By tracking interface features of an institution’s devices and systems, it will be easier to determine how interoperable a system is as well as plan for future interoperability projects. Table 3 gives a suggested list of information that could be tracked in a medical equipment maintenance system. By having this extra information in the system, queries could be made on an institution’s medical equipment systems to determine overall “networkability” or interoperability capability. Additionally, if an institution begins to replace equipment and systems, interoperability requirements could be specified, possibly even to patients’ homes.

### Conclusion

There has been significant progress in the biomedical

ORGANIZATION	DOMAIN	EXAMPLE ACTORS	EXAMPLE INTERFACES	EXAMPLE STANDARDS
Continua Note – has constrained lower-level protocol standards to USB and Bluetooth in V1.0 and requires certification <a href="http://www.continuaalliance.org/">http://www.continuaalliance.org/</a>	Personal Tele-Health	PAN-Device, AHD, HR	PAN, xHRN	Blue Tooth , USB, IEEE 11073 PHD standards, IHE XDR
IHE-PCD Note – has not constrained lower-level protocols and surmises that use of the RTM Profile could approach performance “guarantee” for interoperability that certification offers <a href="http://www.ihe.net/pcd/">http://www.ihe.net/pcd/</a>	Must have a regulated device	Device, DOR, DOC	PCD-O1 DEC	IEEE 10101/10201, HL7 2.6
ASTM Note – desires to drive interoperability standards towards safety. Contends that without bi-directional flow of data, safety is not improved <a href="http://www.astm.org/Standards/F2761.htm">http://www.astm.org/Standards/F2761.htm</a>	Integrated Clinical Environment (ICE)	Medical Device, ICE Network Controller, ICE Supervisor	ICE equipment interface, ICE manager	ASTM F2671-2009; mapping to IEEE 11073 standards currently
HITSP Note – is meant to be compulsory on any players in healthcare realm who are contributing to an EMR for a U.S. citizen. However, contracted work has ended and is yet to be seen if the work will be furthered. Have identified for meaningful use as having device interoperability by 2013-2015 <a href="http://www.hitsp.org/">http://www.hitsp.org/</a>	Any players in USA electronic medical environment – specifically Remote Monitoring (RMON) IS77 and Common Device Connectivity TN905	DI, RMS, HIE, EHR/PHR	SDE 2-7 which require IERs which identify DRs	For glucose monitor, IER 39 specifies DR 80 which specifies IEEE 11073-10417; other DRs like temp, BP, SPO2 specify associated IEEE 11073-104ZZ

Table 4. Summary comparison of standards and standards/promulgating organizations.

device interoperability standards arena. This work has been promulgated by four separate organizations driving standards definition and constraining broad standards to meet interoperability goals. Table 4 gives a summary comparison of the organizations, their domains, example actors, interfaces, and standards designations. Additionally, each of these groups needs volunteers, especially in the clinical and operational arena, to help drive standards selection and development to meet the needs of the users. Getting involved could help ensure the healthcare organizations’ needs are met with respect to interoperability. In the near future, truly seamless, manufacturer-independent biomedical device interoperability is possible. In the meantime, CEs and BMEs can track biomedical device and systems networking and interoperability capability in medical equipment management systems to enable a quick assessments and easier future technology planning. Being able to give your administration an “interoperability” report could be of tremendous value for future strategic planning. Additionally, tracking this information can create ties to your information technology (IT) department that are collaborative in nature. Lastly, knowing how your institution’s medical equipment is connected and can be in the future highlights your value to the administration. ■

### Acronym Glossary

ARRA—American Reinvestment and Recovery Act of 2009  
 ASA—American Society of Anesthesiology  
 ASTM—American Society for Testing and Materials - <http://www.astm.org/>  
 ICE—Integrating the Clinical Environment  
 Continua—[www.continuaalliance.org](http://www.continuaalliance.org)  
 AHD—Application Hosting Device  
 xHRN—x(electronic or personal) Health Record Network  
 LAN—Local Area Network  
 WAN—Wide Area Network  
 EHR—Electronic Health Record  
 EMR—Electronic Medical Record  
 HITSP—Health Information Technology Standards Panel—[www.hitsp.org](http://www.hitsp.org)  
 DI—Device Intermediary  
 DR—Date Requirement  
 HIE—Health Information Exchange  
 IER—Information Exchange Requirement  
 NeHN (formerly AHIC) – National e-Health Collaborative  
 SDE—System Data Exchange  
 HL7—Health Level 7 - <http://www.hl7.org/>  
 IEEE—Institute for Electrical and Electronic Engineers—<http://www.ieee.org/web/standards/home/index.html>  
 IHE-PCD—Integrating the Healthcare Environment – Patient Care Devices—<http://www.ihe.net/pcd/>  
 ACM—Alarm Communication Mapping  
 DOC—Device Observation Consumer  
 DOR—Device Observation Reporter  
 RTM—Rosetta Terminology Mapping