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HRS White Paper on Interoperability of Data from Cardiovascular Implantable Electronic Devices (CIEDs)

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HRS White Paper on Interoperability of Data from Cardiovascular Implantable Electronic Devices (CIEDs)

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Preamble

This HRS Needs Assessment is in the category of the Heart Rhythm Society (HRS) documents delineating a future direction of research, technology development, or health care policy and adheres to the following requirements set forth by the HRS:

1. There are no clinical practice recommendations.
2. The Chair and Vice-Chair of the document are free of any relationships with industry and other entities (RWIs).
3. The remainder of the writing committee may have RWIs, with no dollar limit, but may not have relevant stock, stock options, equity, or royalties or be employed by industry.
4. The writing committee is encouraged to gain information from advisors. Advisors must be physicians or health care providers who are not able to serve as writing committee members because they have

relevant stock, stock options, equity, or royalties. Advisors cannot be employed by industry and do not participate in writing.

5. The writing committee uses industry forums to engage representatives of industry, the U.S. Food and Drug Administration, or other third-party organizations in a dialogue to provide an exchange of information.

6. A full disclosure of RWIs for each writing committee member and each advisor is provided in an appendix

Background

Cardiac implantable electronic device (CIED) technologies have improved significantly over the past decade, and indications for these devices have expanded. This has led to an increasing number of patients being managed with CIEDs, resulting in an exponential quantity of data that needs to be sorted, interpreted, acted upon and stored. The basic settings, diagnostic and therapeutic capabilities of CIEDs are similar regardless of manufacturer. Each has developed proprietary nomenclature, technical standards and communication protocols to describe similar if not identical features and functionalities. Clinicians, primarily concerned with evaluating battery status, programmed parameters, arrhythmias and therapies delivered, must pull together data from multiple settings (hospital, office, remote monitoring) and multiple vendors in order to manage large numbers of CIED patients. Traditional electronic health records (EHR) used for both in-patient and out-patient care are not well suited to managing CIED data, and stand-alone products designed for this purpose struggle with mixed success to unlock the data from proprietary formats.

The Heart Rhythm Society (HRS) in partnership with CIED manufacturers and the EHR industry has been leading an effort since 2006 to overcome these challenges by developing a standard lexicon of CIED terminology[1] as well as a vendor-neutral platform for communicating CIED data across electronic systems[2]. Industry participants include Biotronik, Boston Scientific Corporation, Medtronic, Inc., Abbott (formerly St.

Jude Medical), EPIC, GE Healthcare, Geneva Health Solutions, Heartbase, Implicity™, Lille Corporation, LindaCare, MicroPort Scientific Corporation (formerly Sorin Group), MURJ, and NEXTGEN Healthcare.

A similar collaboration between American College of Radiology and the radiology vendor industry lead to the development of one of the most successful data standards in medicine: the Digital Imaging and Communications in Medicine (DICOM) standard. DICOM is used for storing, transmitting and archiving medical images and is now the universal standard for managing medical images.

In this document, we provide a brief overview of U.S. federal initiatives to promote interoperability of data, the requirements needed to communicate data between information technology (IT) systems in a way that permits the sending and receiving systems to understand and process the data, a summary of the work of HRS to date and finally strategies for clinicians seeking an environment in which they can manage their CIED patient data in a single IT system.

Brief Overview of HIT Interoperability Landscape

U.S. Federal Initiatives

From the outset, EHRs were heralded as tools that would simplify work for clinicians, improve quality by enabling timely access to data by health care provider, empower patients to take charge of their own data, and ultimately improve the quality and efficiency of health care. While almost all of healthcare has shifted from paper to electronic record keeping, the anticipated benefits have not materialized, with increased documentation and administrative burdens associated with EHRs directly contributing to the increased rates of physician burnout.[3, 4] One key contributor to the frustration of clinicians with present EHR systems is that they are not interoperable: data are siloed within separate systems, often even within an individual health system. Information transfer still requires transmission of hard copies (paper, facsimile) or another electronic medium (CD/DVD-ROM) that is subsequently converted to electronic format into another EHR, creating redundancy and the potential for human error. To address these challenges, a bipartisan majority of the U. S.

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Congress passed the 21st Century Cures Act of 2016 (The Cures Act) requiring the US Department of Health and Human Services (HHS) and the Office of the National Coordinator for Health Information Technology (ONC) to improve the interoperability of health information.[5] Broadly, the requirements fall into four categories:

1. Promoting patient, clinician, and payer access to clinical data via open and accessible application programming interfaces (APIs). APIs allow one software program to access the data and services provided by another software program.

2. Prohibition of information blocking. Information blocking is defined as impediments to the free and open (authorized) access to clinical information[6] The Cures Act seeks to confront this practice by prohibiting information blocking by health care providers, health IT developers, exchanges and networks, establishing disincentives and imposing penalties for information blocking.

3. Development of a Trusted Exchange Framework and Common Agreement to improve data sharing across disparate health information networks.[7] Currently there are over 100 health information exchanges, most organized at the state or regional level to facilitate secure sharing of health information between organizations and health care providers. The original vision was that individual health information exchanges would securely share information creating a nationwide network. This approach has been hindered primarily because of variability of participation agreements across exchanges. The Cures Act calls on ONC to develop or support a trusted exchange framework and common agreement to address this challenge, thereby enabling a provider, health system or patient who joins one regional health information exchange to also have access to data from all the other exchanges, providing access to a patient's medical record across all exchanges and across the country.

4. Reduction of clinician burden in the use of EHR systems, especially administrative and reporting burden.[8] This will be undertaken largely through another branch of Health and

Human Services, the Centers for Medicare & Medicaid Services (CMS). New Evaluation and Management codes, to be released at the end of 2019 aim to reduce the administrative burden of often unnecessary documentation.

In parallel, CMS has renamed the EHR Incentive Program for Electronic Health Records (also known as "Meaningful Use") to "Promoting Interoperability".[9] The work described herein supports these initiatives by identifying and specifying a common, shared lexicon for CIED management, a key requirement of data interoperability as outlined next.

Informatics of Interoperability

The Institute for Electrical and Electronics Engineering (IEEE) defines interoperability as the "ability of two or more systems or components to exchange information and to use the information that has been exchanged."[10]

There are two components required to achieve this:

1. The ability of two or more systems to **exchange** formatted information:
    - Syntactic interoperability refers to the format of data, such that sending and receiving systems can transmit and receive the data; in other words, syntax refers to the structure of the message.
2. The ability of those systems to understand and **use** the information that has been exchanged:
    - Semantic interoperability refers to the meaning of the message, such that the data exchanged are understood by both systems to have the same meaning. This requires use of a common data lexicon used by all parties, with common shared definitions and a controlled vocabulary.

When these two conditions are met, the communicating computer systems can transmit, receive, process, tabulate, calculate, analyze, and use the exchanged data. Otherwise, while the data can be stored

and retrieved generically, the data will have only limited use due to incompatible formats and / or differences in semantic meaning. Below are the four broad categories of requirements to achieve data interoperability.

1. Development of a controlled vocabulary

   A controlled vocabulary is a standardized set of words and phrases that define and describe concepts. Controlled vocabularies are used to organize information for subsequent retrieval and overcome the ambiguities of natural language.

2. Specification of data elements

   Each concept of a controlled vocabulary and its associated metadata must be clearly defined as data elements. Typically, this includes not only the name of the data element but also the allowed (permissible) values (also known as the "value set"), definitions of the allowed values, data format, data rules (range, cardinality, optional vs. required), reference resource information and (when it exists) the terminology binding (linkage of the concept to an existing information models such as Logical Observation Identifiers Names and Codes [LOINC] or Systematized Nomenclature of Medicine-Clinical Terms [SNOMED-CT]).

3. Agreement on data management framework

   Capture, transmission, and use of structured data necessitate technical data models (the framework for management of the data itself in database systems) as well as specification of data transmission "handshake" standards for communication between systems. This specification of the physical management of data and accompanying metadata in a consistent, validated, and testable manner is the keystone to enabling the use and dissemination of data as a resource.[11]

4. Structured Reporting

   Finally, the process for data capture and validation must be integrated into consistent clinical workflows. These best practice processes must be tuned to the specific context (e.g., CIED implantation or removal, in-person clinic follow-up, remote monitoring). The general principles of

structured reporting include the acquisition of information as data (rather than prose) by the individual closest to the data along with the use of the data for multiple purposes (e.g., procedure reporting, quality assessment, registry reporting).

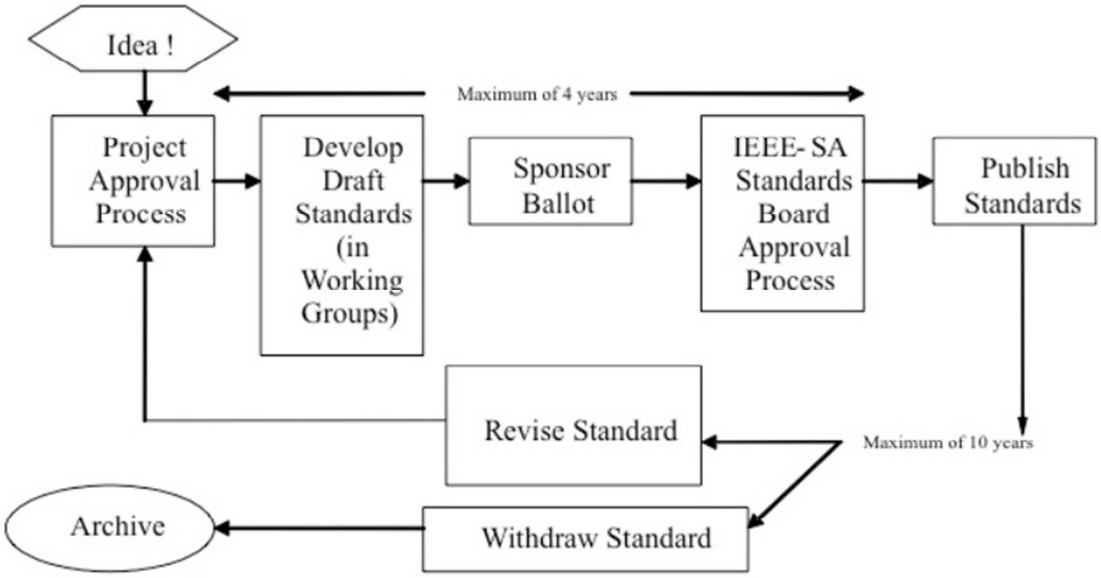
Given the incredible breadth of clinical medicine and the nuances of language, achieving interoperability is a daunting task that requires a coalition of clinicians, informaticians, industry, process engineers and EHR/HIT vendors. The circumscribed and definable parameters delineating CIED management seem a natural fit for accomplishing interoperability.

History of HRS Work on CIED Data Interoperability

In 2005, HRS accepted the invitation from the American College of Cardiology (ACC) to form a cardiac electrophysiology subcommittee of the Cardiology Domain of the Integrating the Healthcare Enterprise (IHE).[12]

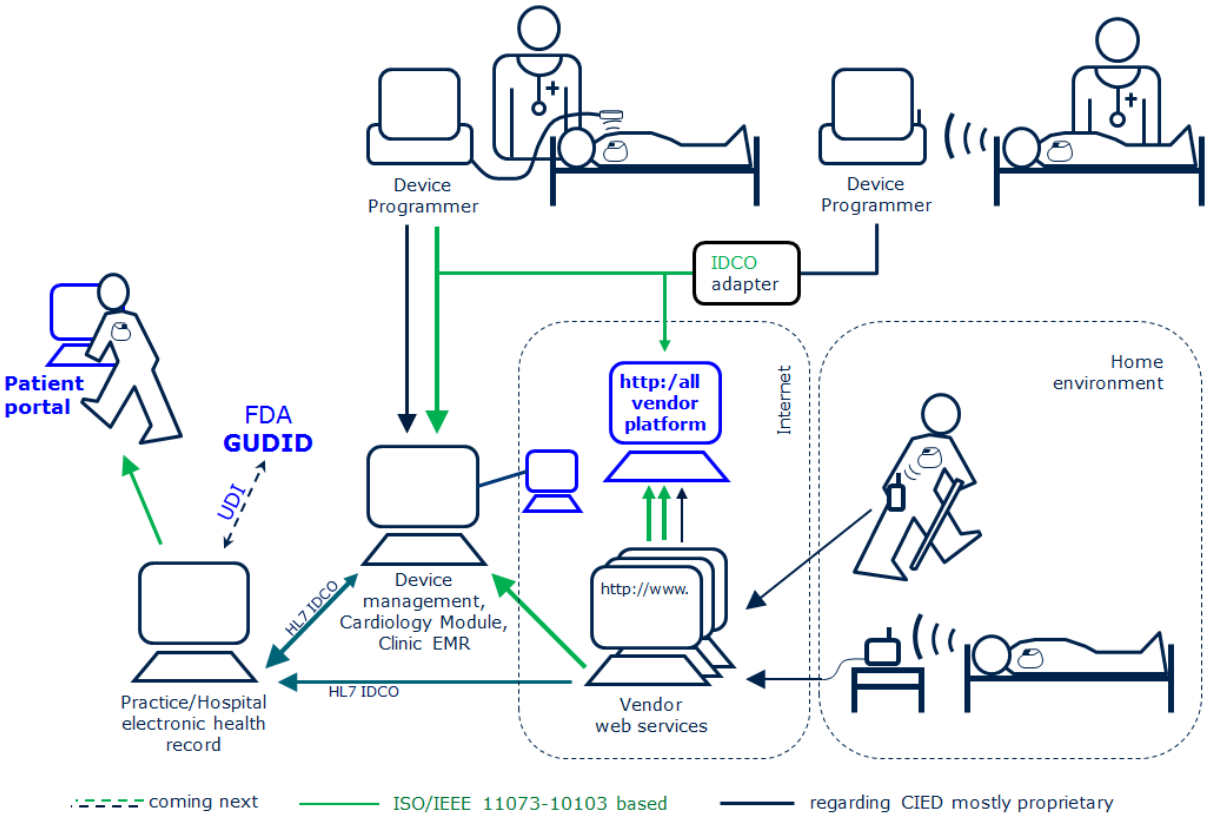
The first stage of the work required clinicians and engineers from the four major CIED manufacturers to identify the key concepts required to manage patients with these devices and then develop the CIED controlled vocabulary. Participants agreed upon the vocabulary and then specified the data elements and metadata of the nomenclature in a vendor neutral fashion. Once this was completed, the controlled vocabulary was brought to the IEEE, the standards development organization responsible for oversight of this domain of medical terminology. Per IEEE protocol, members of IEEE (engineers and clinicians) reviewed the proposed new nomenclature standard and voted on approval (Figure 1). IEEE approved the controlled vocabulary as an IEEE standard 11073-10103 on August 27th, 2012. Subsequently, it was approved as an international standard by the International Standards Organization (ISO) and recognized by the U.S. Food and Drug Administration. [1,13,14]

Figure 1: IEEE standards approval process[15]



Once the nomenclature was complete, clinicians and industry engineers turned their focus toward developing a standards-based IHE profile to specify CIED data transmission and communication across IT platforms while maintaining the relative structural arrangement of the data. IHE leverages existing standards (such as the IEEE 11073-10103 CIED controlled vocabulary and Health Care Level 7 (HL7)) to create "plug-and-play" healthcare equipment and electronic medical records that communicate with each other. The work product of this collaboration was the Implantable Device Cardiac Observation (IDCO) Profile.[2] Importantly for the vendors, both the IEEE nomenclature and IDCO Profile were constructed to allow vendor-specific features and functionalities to be included. Furthermore, reports maintain individual vendor characteristics and the standards anticipate ongoing improvements in proprietary diagnostic and therapeutic features.

Figure 2: Overview of Systems Involved in Managing CIED Data



Legend:

Green Arrows represent interfaces mostly relying on the IDCO nomenclature. The width of the arrows tries to emphasize the importance and relevance of the interface format today. Black Arrows represents proprietary interfaces or proprietary add-ons as a standard. GUDID = Global Unique Device Identification Database.

IHE Connectathon

An essential component of developing an IHE profile is the testing of systems at IHE Connectathon events leading to IHE certification. IHE Connectathons are cross-vendor, live, supervised and structured testing events to advance health IT interoperability where industry leaders test implementations of IHE Profiles. At a Connectathon, both sending and receiving vendors test their product to ensure that the profile has been implemented correctly and that the systems are able to send and/or receive the data accurately. All tests are evaluated on interoperability and conformance to IHE Profiles found in IHE's Technical Frameworks[16]. The test floor is overseen by IHE's technical project managers providing a safe, neutral test

environment and an unparalleled opportunity for industry collaboration and problem resolution. IHE Connectathons take place annually in the US, Europe and Asia. The IDCO Profile was first tested in draft version at a Connectathon in 2009, even before the final IEEE endorsement of the 11073-10103 nomenclature.

Following the IEEE approval of the vocabulary and IHE certification of the IDCO Profile, vendors began implementing support for both in commercially available products. However, as with many initial introductions of new standards, the IDCO profile failed to become widely implemented and used for several reasons. First, only CIED vendors implemented it. EHR vendors were preoccupied at the time with meeting the requirements of the EHR Incentive Program ("Meaningful Use") and reported that customers were not requesting support for the IDCO profile. EHR vendors saw no financial incentive to support the profile. In addition, EHR and CIED vendors received no requests from physicians for support of the profile which they interpreted as a lack of demand for data interoperability from the clinical community.

Work of the HRS Interoperability Workgroup

Following the implementation of the IDCO profile detailed above with the 2012 version of the ISO/IEEE 11073 Health informatics - Medical / health device communication standards[1] for CIEDs, deficiencies became apparent that necessitated revisions of the nomenclature. The most significant and unanticipated problem was that CIED manufacturers did not implement the full IEEE-approved controlled vocabulary. As a result, only a limited set of data could be transmitted in the IDCO profile. This led other industry partners and clinicians to believe that the IEEE nomenclature was insufficiently robust and unable to support clinical patient care. Additional challenges included ambiguities in the data element definitions and the introduction of new CIED technologies after the nomenclature was completed in 2012. In 2017, HRS convened the HRS Interoperability Workgroup to address these limitations. The workgroup was expanded to include HRS members, representatives from the ACC, the four major CIED vendors, EHR vendors, and remote monitoring IT vendors, along with participation by the U.S. Food and Drug Administration.

Workgroup Methodology

The HRS Interoperability Workgroup holds monthly calls to review the existing nomenclature, develop new data elements and define parameters for communicating notifications from remote monitoring servers to EHRs and remote monitoring vendors. After each monthly call, workgroup members vote electronically on the recommendations discussed during the call. Engineers from the vendors meet weekly to develop the technical standard based upon the outcome of the monthly calls and votes.

Mandatory vs Optional Data Elements

As noted previously, the most significant problem with the initial implementation of the IEEE vocabulary by industry was the selective and incomplete support of IEEE data elements. For example, battery status might be communicated in the IEEE nomenclature, but pacing capture thresholds might not be supported. To address this, the workgroup developed the concept of mandatory versus optional data elements per device class (PM, ICD, CRT) that a vendor must provide to be in compliance with proper implementation of the vocabulary.

Data elements required for quality clinical care, such as device type, serial number, lead sensing, impedances, capture thresholds, programmed settings, etc, were identified as being mandatory for reporting. If the data could be provided by the device but the relevant feature had been programmed "Off," this information must be communicated using the appropriate flag.

Data elements that were not essential for clinical care were labeled as optional. If an optional data element was not available, it could be eliminated from the interoperability message while not needing to be labeled "not available." Allowances were made to address different manufacturers providing similar but not identical information to describe the same concept.

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Figure 3, prepared by the Engineering in Medicine and Biology (EMB/11073/EMBS_WG) Working Group of the IEEE Engineering in Medicine and Biology Society/11073 Committee (EMB/11073), represents a sample of the nomenclature in a human readable report. On the figure, data elements that the workgroup deemed mandatory are presented in black, and data elements deemed optional are presented in grey. (See Appendix A for a full example)

Figure 3: Human Readable Report – Example

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Patient Name:	Doe, John
Date of Birth:	Jan 1, 1940
Gender:	Male

Interrogation Date, Type:	Oct 25, 2007 10:00 AM, Remote
Previous Interrogation Date, Type, Program:	Sep 25, 2007 10:00 AM, In-Clinic (Reprogrammed)
Clinician Name, Clinic:	Dr. Anderson, Main Heart Center New Jersey
Clinician Contact:	Phone: +1 12 345 6789, e-mail: follow-up-physician@clinic.org

Device Demographics

Device Type:	CRT-D
Device Manufacturer:	Manufacturer Name
Device Model:	Device Model Name
Device Serial Number:	5867463524
Device Implant Date:	May 1, 2005
Device Implanter, Facility:	Dr. Miller, Main Heart Center New York
Device Implanter Contact:	Phone: +1 12 345 6789

Lead Demographics

	Lead 1	**Lead 2**	**Lead 3**	...
Lead Location Chamber:	RA	RV	LV	
Lead Location Detail:	Appendage	Apex	Posterolateral	
Lead Implant Date:	05/01/2005	05/01/2005	05/01/2005	
Lead Manufacturer:	Vendor Name	Vendor Name	Vendor Name	
Lead Model:	SuperSense	SuperSense	SuperSense	
Lead Serial Number:	1234567812	1234567813	1234567814	
Lead Polarity Type:	Unipolar	Bipolar	Quadripolar	
Lead Connection Status:	Connected	Connected	Connected	
Lead Special Function:	Pressure Sensor			

Legend:

Black represents elements that the HRS Interoperability Workgroup deemed Mandatory

Grey represents elements that the HRS Interoperability Workgroup deemed Optional

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Example of Expanded Capabilities- Notifications

The workgroup is expanding the nomenclature to achieve more complete coverage of CIED content, to include the Universal Device Identification (UDI)[17] and it is addressing the recent technological advances, such as the broader use of remote monitoring, by including new features in the nomenclature. It is important to note that the nomenclature makes allowances for individual proprietary vendor features and it does not limits vendors from offering new and distinguishing diagnostic or therapeutic functions for their devices.

One goal of the IEEE nomenclature and IDCO profile is to allow clinicians to review and manage their CIED patient data on a single EHR or remote monitoring data management platform. As such, alert-related information for abnormal findings need to be communicated from the remote monitoring server to the EHR or remote monitoring platform. The notification information will be included in the revised nomenclature and are illustrated in the example below:

Scenario: The device indicates that a high ventricular rate during high atrial rates has been detected.

Two notifications in the IDCO message:

Notification 1:

- Type(s) (the coded categories which do apply for this notification):
  - High Atrial Rate
  - High Ventricular Rate
- Priority (equivalent to the alert levels or colors in the vendor systems): Medium
- Description (original vendor defined text): "Mean ventricular heart rate during mode switch mode or atrial burden high."

Notification 2:

- Type(s)
  - High Ventricular Rate
- Priority: Medium
- Description: "VT detected"

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Escalation Process

When technical issues arise that require harmonization of device characteristics amongst the CIED manufacturers, which is beyond the clinical scope and expertise of the workgroup, the workgroup escalates the request to the Association for Advancement of Medical Instrumentation (AAMI) Cardiac Rhythm Management Device (CRMD) Committee. AAMI is a nonprofit organization dedicated to the mission of developing and managing safe and effective health care technology. It is the primary source of consensus standards, both national and international, for the medical device industry. All of the CIED manufacturers are AAMI's members and have engineering representation at the Cardiac Rhythm Management Device Committee.

Example: There is tremendous variability in representing the battery longevity information among manufacturers. This information may also vary between pacemakers and defibrillators from a single vendor. (Table 2).

Table 2: Illustration of the Variation in Defining the Battery Status

	Battery Status	Battery Voltage	Battery Impedance	Battery Longevity	Battery percentage	Other
Vendor A						
PM	OK, Explant, Battery Capacity Depleted	N/A	N/A	Yes, years (if >= 1 year) or months (if < 1 year) remaining until Explant	Yes, percentage remaining until Explant	Charge remaining, power consumption, magnet rate
ICD/CRT-D	OK, Explant, Battery Capacity Depleted	N/A	N/A	Yes, years (if >= 1 year) or months (if < 1 year) remaining until Explant	Yes, percentage remaining until Explant	Charge remaining, power consumption
Vendor B						
PM	BOS, MOS, RRT, EOS, Unknown	Yes if available	N/A	For some, remaining longevity in months	Yes, percentage remaining until Explant	Battery RRT Trigger
ICD/CRT-D	BOS, MOS,	Yes if	N/A	For some,	Yes, percentage	Battery RRT Trigger

	RRT, EOS, Unknown	available		remaining longevity in months	remaining until Explant	
Vendor C						
PM	EOS or EOL, ERI or RRT,	Yes	For some	For some, remaining longevity in years/months		PM
ICD/CRT-D	EOS or EOL, ERI or RRT,	Yes	For some	For some, remaining longevity in years/months		
ILR	Good, RRT, EOS	No	No	No	No	
PM	EOS or EOL, ERI or RRT,	Yes	For some	For some, remaining longevity in years/months		
ICD/CRT-D	EOS or EOL, ERI or RRT,	Yes	For some	For some, remaining longevity in years/months		
Vendor D						
PM	BOS, ERI, EOS, OK for some	Yes	For some	For newer devices*, remaining longevity in years/months	For some	Bar graph
ICD/CRT-D	BOS, MOS 1, MOS 2**, ERI, EOS	Yes	No	Remaining service time after ERI detection only.	Yes	Bar graph
ILR	BOS, ERI, EOS	Yes	No	No	Yes	Bar graph
*** Availability may vary between remote monitoring and programmer** **** MOS1/MOS2 no longer present in future device generations**						

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284 ***Legend***:

BOS	Beginning of Service	**EOS**	End of Service
BOL	Beginning of Life	**EOL**	End of Life
MOS	Middle of Service	**OY**	One Year Remaining
RRT	Recommended Replacement Time	**OK**	Battery is OK
ERI	Elective Replacement Indicator	**Explant**	The battery is nearing depletion, generator replacement must be scheduled
Battery Capacity Depleted	Functionality is limited, therapies can no longer be guaranteed	**N/A**	Not available

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The lack of standardization is a barrier when implementing an interoperable nomenclature within the IEEE framework. The workgroup requested AAMI's assistance with this challenge. The AAMI CRMD Committee reviewed this request and agreed to develop a single consistent standard to express the battery longevity. This AAMI project is in its infancy and should be available in the coming years.

SUMMARY

These revisions and clarifications will expand the capabilities of the IDCO profile and ISO/IEEE-11073 nomenclature[1] making it less ambiguous to the clinicians, more specific for industry to implement thereby improving patient care, and expanding its use to more device and electrode types including leadless pacemakers, subcutaneous ICDs, and implantable loop recorders.

Next Steps

The current state of CIED data management and the variability across the industry in reporting basic device functions such as battery status adversely affects patient care and should not be accepted by patients or the EP community. Implementation of the ISO/IEEE 11073 nomenclature and IHE IDCO Profile will provide benefits for CIED developers/manufacturers, EHR developers, remote monitoring vendors, clinicians, clinical investigators and most importantly patients. Patients will benefit from more efficient care enabled by this work, allowing health care resources to focus on structured reporting and best practices for managing their devices. CIED manufacturers will have a tool for the transmission of data to end-users with confidence that the data are correctly understood and represented and will no longer need to partner with individual vendors to develop multiple custom integration profiles. For EHR developers, it ensures that device data will be received in an understandable syntax that can be formatted for display to clinicians and patients, again with confidence in the accuracy of interpretation. Consistent syntax coupled with automatically populated data

fields will assure data integrity by avoiding common sources of error in data transfer and entry. Clinicians will be able to review aggregated data across multiple CIEDs vendors displayed in a common format within a single EHR, minimizing or eliminating the need to access multiple software systems and web portals to manage data from multiple CIED vendors. The benefits for clinical investigators may be even greater than for clinicians. Present systems, due to the varying data encoding and display formats, make it impossible to directly aggregate device data across multiple vendors, a task more readily accomplished when device data are available in a common, public format and analytics tools can be developed and shared. Similar benefits accrue to regulatory agencies and registries seeking to aggregate device information across multiple vendors.

Going forward, vendors (both of CIEDs and of EHR systems and other software systems that utilize CIED data) must commit to the support of the ISO/IEEE 11073 nomenclature and IHE IDCO profile. This will require the assignment of resources both to support the current standard (including tools to convert device data from proprietary formats) and the development of tools for the retrieval and use of standardized data via device programmers and remote monitoring websites. Ideally, such data could be readily retrieved (albeit with the implementation of appropriate security measures to prevent unauthorized access) by end-users, including researchers and EHR vendors.

Similarly, EHR developers must commit to developing software that will utilize data transmitted in the standard format, and to presenting those data in a common format, thus enhancing the compatibility of EHR systems across the spectrum of CIED manufacturers.

The first step in measuring success will be to recognize vendors who demonstrate support for and compliance with the IEEE nomenclature and IDCO profile by participating in the IHE certification process. Hundreds of industry's top leaders gather to collaborate and test implementations of IHE Profiles and other world-class standards. This unique testing environment allows vendors to test, re-test, and debug their systems in minutes because participants are working toward a greater goal. For the IDCO profile, this would mean each CIED manufacturer would have the opportunity to test their implementation of the IDCO profile with any EHR or remote monitor vendor attending the Connectathon. Once a vendor has demonstrated

interoperability and compliance with the IHE technical framework, the vendor can market their product as being compliant with the IHE IDCO Profile.

The current data standard incorporates the wide spectrum of CIED parameters and capabilities available in CIEDs on the market today. However, new parameters and algorithms being incorporated into the next generation of CIED technologies will need to be defined and codified. For example, description of pacing systems that can include traditional right atrial and/right ventricular endocardial or epicardial leads needs to be supplanted with the recognition that modern pacing systems include pacing of multiple chambers. Accurate description of the pacing sequence (left ventricular pacing preceding right ventricular pacing, for example) will be required. Combining leadless pacing systems with implantable defibrillator that are separate, possibly cross-vendor, and yet with the capability to communicate will require new data description parameters. The data standard will need not only to describe these new developments but provide a mechanism for expansion for device capabilities not yet even in development or even conceived.

Electrophysiologists, allied professionals and administrators involved in the care and administration of health care resources for patients with CIEDs should have easy access to identify which CIED, EHR and remote monitor vendors have met the IHE IDCO Certification process and make purchasing decisions based upon this information.

Success will require clinicians and vendors to remain committed to the IHE process.

We hereby request that:

- Vendors (CIED manufacturers, EHR developers, and others) commit to support and adopt the current ISO/IEEE 11073 nomenclature and IHE IDCO Profile;
- Vendors gain IHE Certification of their products by participating in Connectathons to demonstrate implementation and compliance;

- HRS and vendors work together to educate the clinical community and health care infrastructure regarding the benefits of implementing products compliant with the IHE IDCO Profile;
- HRS create a resource for clinicians and health care administrators to use as a reference to identify vendors and products that have met the IHE certification process;
- Stakeholders including HRS, AAMI, CIED manufacturers, EHRs and remote monitor vendors continue to work together to further develop both the IEEE nomenclature and IDCO profile to incorporate new devices, new algorithms, and resolve unanticipated ambiguities.
- Patients should be able and encouraged to engage with the data from their CIEDs (via ONC's open API initiative) using smart phones or other internet-connected devices.[5]

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Appendix A- IEEE P11073-10103™ -Draft Standard for Health informatics - Point-of-care medical device communication - Nomenclature - Implantable device, cardiac

This example was prepared by the Engineering in Medicine and Biology (EMB/11073/EMBS_WG) Working Group of the IEEE Engineering in Medicine and Biology Society/11073 Committee (EMB/11073).

Legend:
Black represents elements that the HRS Interoperability Workgroup deemed Mandatory
Grey represents elements that the HRS Interoperability Workgroup deemed Optional

Patient Name:	Doe, John
Date of Birth:	Jan 1, 1940
Gender:	Male

Interrogation Date, Type:	Oct 25, 2007 10:00 AM, Remote
Previous Interrogation Date, Type, Program:	Sep 25, 2007 10:00 AM, In-Clinic (Reprogrammed)
Clinician Name, Clinic:	Dr. Anderson, Main Heart Center New Jersey
Clinician Contact:	Phone: +1 12 345 6789, e-mail: follow-up-physician@clinic.org

Device Demographics

Device Type:	CRT-D
Device Manufacturer:	Manufacturer Name
Device Model:	Device Model Name
Device Serial Number:	5867463524
Device Implant Date:	May 1, 2005
Device Implanter, Facility:	Dr. Miller, Main Heart Center New York
Device Implanter Contact:	Phone: +1 12 345 6789

438 **Lead Demographics**
439

	Lead 1	Lead 2	Lead 3	...
Lead Location Chamber:	RA	RV	LV	
Lead Location Detail:	Appendage	Apex	Posterolateral	
Lead Implant Date:	05/01/2005	05/01/2005	05/01/2005	
Lead Manufacturer:	Vendor Name	Vendor Name	Vendor Name	
Lead Model:	SuperSense	SuperSense	SuperSense	
Lead Serial Number:	1234567812	1234567813	1234567814	
Lead Polarity Type:	Unipolar	Bipolar	Quadripolar	
Lead Connection Status:	Connected	Connected	Connected	
Lead Special Function:	Pressure Sensor			

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442 **STATUS / MEASURMENTS**
443

Battery	08/25/2007	**Capacitor**	(most recent charging)
Battery Status:	MOS	**Charge Date:**	June 1, 2006 10:00 a.m.
Battery Voltage:	6.3 V	**Charge Time:**	8.1 sec
Battery Impedance:	2500 Ohm	**Charge Energy**:	36 J
Battery Remaining:	75 % 4 years 11 months	**Charge Type:**	Reformation
RRT (ERI) Trigger:	Battery voltage < 5.7 V / Cap. Charge time > 12 s		

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Lead Channel Measurements / Status					
Observation date/time (interval):	08/24/2007 2:00	07/24 - 08/24/2007 3:00		08/24/2007 2:00	
	RA	**RV**		**LV** [1)]	
Mean Intrinsic Amplitude:	-	4.7 mV	(BP)	3.5 mV	(BP)
Min Intrinsic Amplitude:	-	4.0 mV	(BP)	2.2 mV	(BP)
Impedance:	-	> 3000 Ω	(BP)	500 Ω	(BP)
Pacing Threshold:	-	0.6 V @ 0.5 ms	(UP)	0.6 V @ 0.5 ms	(BP)
Threshold Measurement Method:	-	Dev automatic		Progr automatic	
Lead Channel Status:	-	Check Lead		-	

446

Shock Lead Configuration and Measurement		
Cathode^{-} – Anode^{+}	**Impedance, Date/Time, Measurement-Type**	**Status**
RV Coil, RA Coil – Can	330 Ω, 10/03/2007, low-voltage pulse	Check lead

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Brady Statistics [1)]		
RA Pacing:	50 %	[3)]
RV Pacing:	30 %	[3)]
AP-VP:	10 %	
AS-VP:	20 %	
AP-VS:	40 %	
AS-VS:	60 %	

Mean Atr. Heart Rate [2)]:	72 bpm	
Mean Ven. Heart Rate [2)]:	72 bpm	

Atrial Tachy Statistics [3)]	
AT/AF Burden per day:	10 %
Max ModeSw-Epis Duration:	48.6 h
Time in ModeSw per day:	5 %
Number of ModeSw per day:	360

CRT Statistics [3)]	
LV Pacing:	95 %
CRT Pacing:	80 %

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452 **COUNTERS / EPISODES**

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Episode Counts		
Type	**Recent[1)]**	**Total[2)]**
VF	1	4
VT1	0	0
ModeSw	2	150
AT/AF	3	3
...	...	...

Therapy Counts		
Therapy	**Recent[1)]**	**Total[2)]**
Shocks delivered	1	5
Shocks aborted	0	0
ATPs	2	3

[1)] Since 09/27/2009 10:12 a.m. (last 3 weeks), [2)] Since Implantation (05/01/2005) or device reset

Episode List

ID	Date/Time	Type	Therapy applied / Details	Result	Atr./Ven. Rate [bpm] Detect	Term	Duration hh:mm:ss
1723	03/30/2009 02:00:16	Periodic IEGM	Monitoring only		- / -	- / -	-
...	...	...	...	...	...	...	...
7	10/27/2007 07:04:02	VT1	No therapies	-	80 / 140	101 / 103	00:00:17
6	10/27/2007 12:10:03	VT2	2 ATP, 5x 30J / 30J Shock ineffective	Unsuccessful	83 / 140	75 / 75	00:00:17
5	10/24/2007 23:00:04	ATR	10 ATP	Successful	200 / 60	60 / 60	43:00:13
4	10/11/2007 10:12:05	NST	- / Non sustained	-	95 / 158	75 / 75	00:00:30
3	08/09/2007 02:00:12	Periodic IEGM	Monitoring only	-	- / -	- / -	-
...	...	...	...	...	...	...	...
1	07/09/2007	VF (induced)	30J Shock	Successful	104 /	102 /	00:00:11

08:15:12	210	102

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455 **DEVICE SETTINGS**

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Brady Settings	
Brady Mode:	DDDR
Lower Rate:	60 bpm
Hysteresis Rate:	55 bpm
Night Rate:	55 bpm
Sensor Type:	Accelerometer
Max Tracking Rate:	130 bpm
Max Sensor Rate:	120 bpm
SAV Delay:	140..180 ms
PAV Delay:	110..150 ms

Atrial Tachyarrhythmia Settings	
AT Mode Switch Mode:	DDIR
AT Mode Switch Rate:	180 bpm

CRT Settings	
CRT Paced chambers:	BiV
LV-RV Delay:	-20 ms

Magnet Mode:	Detection and therapies temporarily suspended

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Tachyarrhythmia Zone Settings

Ventricular Therapy: ON **Atrial Therapy:** N/A

Zone	Limit bpm	Detection X of Y	ATP	Shocks	Details	Status
VF	195	12/18	1x Ramp	5x 30J		Active
VT1	165	9/12	5x Burst	1x 20J, 1x 30J, 5x 30J	SMART detection and redetection on	Active
FastVT	165	9/12	5x Ramp+Scan	1x 20J, 5x 30J	Progressive therapy	Active
VTMon	145	-	-	-		Active
AT/AF	200	12/15	-	-	Triggers Mode Switch	Inactive
Periodic IEGM	-	-	-	-	Every 30 days	Active

…	…	…	…	…	…	…

Lead Channel Settings			
	RA	**RV**	**LV**
Sensitivity:	0.8 mV (fixed)	1.3 mV (adaptive)	1 mV (fixed)
Sensing Polarity	Unipolar	Bipolar	Bipolar
Sensing Vector:	RA Tip – Can	RV Tip – RV Ring	LV Tip – LV Ring
Pacing Output:	1.8 V (fixed)	2.0 V (adaptive)	2.0 V (adaptive)
Pacing Pulse Width:	0.5 ms	0.5 ms	0.5 ms
Pacing Polarity:	Unipolar	Bipolar	Bipolar
Pacing Vector:	RA Ring – Can	RV Tip – RV Ring	LV Tip – RV Ring

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473 **Appendix B- HRS Interoperability Working Group- A collaboration between HRS, Industry Partners**

474 Roster (as of 2/20/2019)

475 **HRS Physician Advisory Group**

Robert L. Abraham, MD, CCDS Assistant Professor Vanderbilt Heart and Vascular Institute, Cardiology Nashville, Tennessee	**Sana M. Al-Khatib, MD, FHRS, CCDS** Associate Professor of Medicine Duke University Medical Center Durham, North Carolina
H. Vernon Anderson, MD Professor of Medicine Univ. of Texas McGovern Medical School Cardiology Division Houston, Texas *(Representative from the American College of Cardiology)*	**Deepak Bhakta MD FHRS CCDS FACP FACC FAHA** Associate Professor of Clinical Medicine Program Director, Cardiovascular Diseases Fellowship Indiana University School of Medicine Indiana University Health Physicians Indianapolis, Indiana
T. Jared Bunch, MD Physician Intermountain Heart Rhythm Specialists Murray, Utah	**Martha G. Ferrara, DNP, RN, CCDS, FHRS** Assistant Director of EP Services White Plains Hospital White Plains, New York
Richard A. Friedman, M.D., MBA Professor and Executive Vice Chairman Department of Pediatrics Hofstra-Northwell School of Medicine Director, Adult Congenital Heart Disease Program Cohen Children's Hospital New Hyde Park, New York	**Sanjaya Gupta, MD, FACC, FHRS** Saint Luke's Cardiovascular Consultants Asst. Professor of Medicine University of Missouri-Kansas City Lee's Summit, Missouri
Fred M. Kusumoto, MD, FHRS Director, Electrophysiology and Pacing Mayo Clinic Jacksonville Jacksonville, Florida	**Neal Lippman, MD, FHRS** Attending Electrophysiologist Arrhythmia Consultants of Connecticut, LLC Hartford, Connecticut
G. Stuart Mendenhall, MD, FHRS, FACC (Vice Chair) Cardiac Electrophysiologist Scripps Memorial Hospital - La Jolla La Jolla, California	**Michael J. Mirro, MD, CCDS, FHRS,FACC, FAHA,CCDS** Chief Academic Research Officer Parkview Mirro Center Fort Wayne, Indiana
Suneet Mittal, MD FHRS Director, Electrophysiology The Valley Hospital Paramus, New Jersey	**Gerald A. Serwer, MD, FHRS** (Chair) Professor University of Michigan Pediatric Cardiology Ann Arbor, Michigan

David J. Slotwiner, MD, FACC, FHRS (Immediate Past Chair) Chief, Division of Cardiology Assistant Professor of Medicine, School of Health Policy & Research New York Presbyterian Queens Flushing, New York	**Paul R. Steiner, MD, FHRS** Cardiac Electrophysiologist Dartmouth-Hitchcock Medical Center Lebanon, New Hampshire
James E. Tcheng, MD, FACC, FSCAI Professor of Medicine Professor of Community and Family Medicine (Informatics) Durham, North Carolina *(Representative from the American College of Cardiology)*	**Paul D. Varosy, MD** Director of Cardiac EP VAECHCS/University of Colorado Denver, Colorado
Bruce L. Wilkoff, MD, FHRS, CCDS Director of Cardiac Pacing and Tachyarrhythmia Devices, Cleveland Clinic Cleveland, Ohio	

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477 **Industry Partners**

Abbott Laboratories **Eileen Ong** Sr. Software Engineer Sunnyvale, California	**Boston Scientific Corporation** **Craig Reister** Fellow, Systems Engineer Externals Systems Engineering St. Paul, Minnesota
Biotronik **Alexander Kraus, PhD** Therapy Manager, Health Services Berlin, Germany	**Epic Systems Corporation** **Matt Caldwell** EDI Verona, Wisconsin **Ben Smalley** Cardiology Content Manager and Content Developer Madison, Wisconsin
Geneva Health Solutions **Jeff Marchese** Chief Technology Officer Pasadena, CA	**Heartbase, Inc.** **Nicholas J. Gawrit** President Chicago, Illinois

Manish Wadhwa, MD Co-Founder/Chief Medical Officer Pasadena, CA	
I**mplicity** **Louis Pinot de Villechenon** Director of Product Paris, France **Arnaud Rosier, MD, PhD** CEO Paris, France	**Lille Group** **Jordan Rosen** CEO Albany, New York
LindaCare **Miguel Maquiera** Chief Technology Officer Leuven, Belgium **Robert Lerman, MD** Chief Medical Officer & VP Clinical Operations New York, New York	**Medtronic, Inc.** **Steve Glinski** Principal Software Engineer Mounds View, MN **Kate Anderson** Sr. Principal system engineer and Technical Fellow Minneapolis, Minnesota **Laurie Green** Principal Systems Support Specialist, Released Product Engineering Minneapolis, Minnesota
Murj **Chris Irving** Co-Founder, CXO (Chief Experience Officer) Santa Cruz, California	

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481 **Appendix B- Disclosures**

Name	Employment	Honoraria/ Speaking/ Consulting	Speakers' bureau	Research*	Fellowship support*	Ownership/ Partnership/ Principal/Majority stockholder	Stock or stock options	Intellectual property/ Royalties	Other
Writing group members									
David Slotwiner, MD, FHRS (Chair)	New York-Presbyterian/Queens, New York, New York; Weill Cornell Medical College, Cardiology Division, New York, New York	None	None	None	None	None	None	None	None
Robert L. Abraham, MD, CCDS	Vanderbilt Heart and Vascular Institute, Cardiology, Nashville, Tennessee	None	None	None	None	None	None	None	None
Sana M. Al-Khatib, MD, FHRS, CCDS	Duke University Medical Center, Durham, North Carolina	None	None	None	None	None	None	None	None
H. Vernon Anderson, MD, FACC, FSCAI	University of Texas, Health Science Center at Houston, Houston, Texas	None	None	None	None	None	None	None	1; American College of Cardiology
T. Jared Bunch, MD, FHRS	Intermountain Heart Rhythm Specialists; Eccles Outpatient Care Center, Murray, Utah	None	None	3; Boston Scientific Corp 8; Boehringer Ingelheim	None	None	None	None	None
Martha G. Ferrara, DNP, FNP, FHRS, CCDS	White Plains Hospital, White Plains New York	None	0; Boston Scientific Corp.	None	None	None	None	None	None
Neal Lippman, MD, FHRS	Arrhythmia Consultants of Connecticut, LLC, Hartford, Connecticut	1; Boston Scientific 3; Abbott	None	None	None	None	None	None	None
Gerald A. Serwer, MD, FHRS	University of Michigan Congenital Heart Center, Ann Arbor, Michigan	None	None	None	None	None	None	None	None

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Paul R. Steiner, MD, FHRS	Dartmouth-Hitchcock Medical Center, Lebanon, New Hampshire	None	None	None	None	None	None	None	None
James E. Tcheng, MD	Duke University Medical Center, Durham, North Carolina	None	None	None	None	None	None	None	None
Niraj Varma, MD, PhD	Cleveland Clinic, Cleveland, Ohio	1; Biotronik, Medtronic, Inc.	None	3; Abbott	None	None	None	None	None
Bruce L. Wilkoff, MD, FHRS, CCDS	Cleveland Clinic, Cleveland, Ohio	1; Abbott Vascular 2; Medtronic, Inc.; Philips	None	None	None	None	None	None	None

Number value: **0** = $0; **1** = ≤ $10,000; **2** = > $10,000 to ≤ $25,000; **3** = > $25,000 to ≤ $50,000; **4** = > $50,000 to ≤ $100,000; **5** = > $100,000 to ≤ $200,000; **6** = > $200,000 to ≤ $300,000; **7** = > $300,000 to ≤ $400,000; **8** = > $400,000.

*Research and fellowship support are classed as programmatic support. Sources of programmatic support are disclosed but are not regarded as a relevant relationship with industry for writing group members, advisors, or reviewers.

Reviewer disclosure table

Peer reviewer	Employment	Honoraria/ Speaking/ Consulting	Speakers' bureau	Research*	Fellowship support*	Ownership/ Partnership /Principal/ Majority stockholder	Stock or stock options	Intellectual property/ Royalties	Other
Joseph E. Marine, MBA, MD, FHRS	Johns Hopkins University, Baltimore, Maryland	1; American College of Cardiology	None	None	None	None	None	1; Up to Date	None
Andrew D. Blaufox, MD, FHRS, CEPS-P	Cohen Children`s Medical Center, New York, New York	None	None	None	None	None	None	None	None

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Deepak Bhakta, MD, FHRS, CCDS	Indiana University School of Medicine, Indianapolis, Indiana	None	None	None	None	None	None	None	None
Michael J. Mirro, MD, FHRS, CCDS	Parkview Health, Fort Wayne, Indiana	None	None	None	None	None	None	None	None
Taya V. Glotzer, MD, FHRS	Electrophysiology Associates, Hackensack, New Jersey	1; Medtronic, Inc.; Abbott L Laboratories	None	None	None	None	None	None	None
Ralph J. Verdino, MD	Univ of Penn Health System, Philadelphia, Pennsylvania	1; St. Jude Medical 2; Zoll Medical Corporation	None	None	None	None	None	None	4; Lifewatch Corp (Membership on Advisory Committees) 5; Knowledge to Practice (Board Member)

Number value: **0** = $0; **1** = ≤ $10,000; **2** = > $10,000 to ≤ $25,000; **3** = > $25,000 to ≤ $50,000; **4** = > $50,000 to ≤ $100,000; **5** = > $100,000.

*Research and fellowship support are classed as programmatic support. Sources of programmatic support are disclosed but are not regarded as a relevant relationship with industry for writing group members or reviewers.

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