IHE Change Proposal

Tracking information:

IHE Domain	Patient Care Devices
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Person assigned:	John Rhoads

Change Proposal Summary information:

Editorial Update – Implantable, Manufacturer	
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Integration Profile(s) affected:	Implantable Device – Cardiac – Observation
Actor(s) affected:	None
IHE Technical Framework or Supplement modified:	IHE Patient Care Device (PCD) Technical Framework; Volume 1; Revision 1.0; August 12, 2011
Volume(s) and Section(s) affected:	Volume 1 (PCD TF-1); Section 6, Section 6.5
Rationale for Change: 1. This change request is to update wording in this section by adding the word "implantable" to be more specific that this profile deals with implantable devices only and not similar surface-mounted systems. 2. Also changing the word "vendor" to "manufacturer" to be specific about who is the IDC-Reporter providing this data to IDC-Consumers.	

Proposed Changes:

Replace Section 6 by the following:

6 Implantable Device – Cardiac – Observation (IDCO)

Cardiac physicians follow patients with implantable cardiac devices from multiple ~~vendor~~ manufacturers. These devices are categorized as implantable pacemakers, cardioverter defibrillators, cardiac resynchronization therapy, and implantable cardiac monitor devices. As part of patient follow-up an interrogation of an implanted cardiac device is performed (either in-clinic or remotely from a patient's residence). These initial device interrogations (solicited or unsolicited) are typically performed by manufacturer provided interrogation ~~vendor proprietary~~ equipment using manufacturer specific protocol. Information is collected regarding the system (attributes, settings and status), the patient (demographics and observations) and therapy (delivery and results).

To improve workflow efficiencies cardiology and electrophysiology practices require the management of “key” information in a central system such as an EHR or a device clinic management system.

To address this requirement, the Implantable Device – Cardiac – Observation (IDCO) Profile defines a standard-based translation and transfer of summary device interrogation information from the manufacturer provided interrogation ~~system~~ equipment to the information management system.

The IDCO profile specifies a mechanism for the translation, transmission, processing, and storage of discrete data elements and report attachments associated with cardiac device interrogations (observations).

Replace Section 6.5 by the following:

6.5 IDCO Patient Identification Considerations

This profile assumes a pre-coordinated association of identifiers across the two Patient Identifier Domains: the device ~~vendor~~ manufacturer systems providing the observations and the clinics receiving the observations.

Depending on local regulations each implantable cardiac device ~~vendor~~ manufacturer may be obligated to maintain a registry that maps a unique device identifier with the patient in which it is implanted. In some locales this mapping is the strict responsibility of the implanting or other organization. Specific patient identification information is typically not stored in the device but is made available in the registry or by other means. Consequently the Implantable Device – Cardiac – Reporter is only required to send this identifier which represents the patient to device relationship for an implanted device as part of the [PCD-09] transaction. This identifier by normative convention is the concatenation of a unique industry wide manufacturer id, unique manufacturer model number, and unique manufacturer serial number.

This profile specifies one actor, the Implantable Device – Cardiac – Consumer, as the endpoint for observation messages. The Implantable Device – Cardiac – Consumer will have pre-coordinated a cross-reference of patient identifiers across the two Patient Identifier Domains. This will be done by storing the unique device identifier within the patient’s record. This will typically be the patient’s unique identity but could be the patient’s location in emergency situations.

In some cases the Implantable Device – Cardiac – Reporter will have detailed patient identification information like name, address, etc. In these cases the Implantable Device – Cardiac – Reporter can send this information as part of the [PCD-09] transaction.