IHE Change Proposal

Tracking information:

IHE Domain	Patient Care Devices
Change Proposal ID:	CP-PCD-070-0
Change Proposal Status:	Submitted
Date of last update:	8-12-2011
Person assigned:	John Rhoads

Change Proposal Summary information:

Example Text Change	
Submitter's Name(s) and e-mail address(es):	Stephen Swanson (sswanson@sjm.com) Gene Hageman (gene.hageman@medtronic.com) Alexander Kraus (alexander.kraus@biotronik.com) Ken Hoyme (ken.hoyme@bsci.com)
Submission Date:	June 13, 2012
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 2; Revision 1.0; August 12, 2011
Volume(s) and Section(s) affected:	Volume 2 (PCD TF-2); Section 3.9.4.1.2.5
Rationale for Change: 1. There was confusion on what values should be contained in the OBX-5 fields when the Value Type (OBX-2) is Coded With Exceptions (CWE). The Change Proposal clarifies the intended use of this field.	

Proposed Changes:

Replace the text defining the use of OBX-~~5with~~ 3 with the following:

OBX-3.1 Observation Identifier, Identifier shall be <*Code*> [numeric] as defined in Annex C.3 'Expanded Terms' of IEEE 11073-10103 (see 3.9.3 Referenced Standards).

OBX-3.2 Observation Identifier, shall be <*Reference ID*> as defined in Annex C.3 'Expanded Terms' in IEEE 11073-10103 (see 3.9.3 Referenced Standards)

OBX-3.3 Observation Identifier, Name of Coding System shall be MDC to reference the group of medical device communication standards (IEEE 11073-xxxxx)

Replace the text defining the use of OBX-5 with the following:

OBX-5 Observation Value – This is the actual value of the observation.

If OBX-2 is of type CWE then

OBX-5.1 shall be <*Code*> [numeric] as defined in Annex D.3 ‘enumerations’ or Annex E.3 ‘vendor enumerations’ of IEEE 11073-10103 (see 3.9.3 Referenced Standards) .

OBX-5.2 shall be <*Enumerator Identifier*>_<*EnumerationCode [mnemonic]*> as defined in Annex D.3 ‘enumerations’ or Annex E.3 ‘vendor enumerations’ in IEEE 11073-10103 (see 3.9.3 Referenced Standards)

OBX-5.3 shall be MDC to reference the group of medical device communication standards (IEEE 11073-xxxxx)

OBX-5.9 can contain the according *Display Name* as defined in Annex D.3 ‘enumerations’ or Annex E.3 ‘vendor enumerations’ of IEEE 11073-10103 (see 3.9.3 Referenced Standard) or an equivalent (maybe more compact) localized display name. If the vendor has implemented vendor-specific extensions (per IEEE 11073-10103 Sections 8 and A.4) than OBX-5.9 is required. This display name should only be used by the receiving system as a reference or if the Identifier in OBX-5.1 is unknown to the receiver (e.g. for proprietary vendor content). Generation and localization of display names in the receiving system shall always be preferred.

~~OBX-5 Observation Value – This is the actual value of the observation.~~

~~If OBX-2 is of type CWE then~~

~~OBX-5.1 shall be an *enumeration code [mnemonic]* as defined in Annex D.3 ‘enumerations’ or Annex E.3 ‘vendor enumerations’ of IEEE 11073-10103 version 1.05.02 (10/04/2011) and OBX-5.2 can contain the according *display name* as defined in Annex D.3 ‘enumerations’ or Annex E.3 ‘vendor enumerations’ of IEEE 11073-10103 version 1.05.02 (10/04/2011) or an equivalent display name in another language~~.

IHE Change Proposal

Tracking information:

IHE Domain	Patient Care Devices
Change Proposal ID:	CP-DOM-xxx (assigned by Domain Technical Committee)
Change Proposal Status:	Submitted
Date of last update:	8-12-2011
Person assigned:	(assigned by Domain Technical Committee)

Change Proposal Summary information:

Editorial Update – Implantable, Manufacturer	
Submitter's Name(s) and e-mail address(es):	Stephen Swanson (sswanson@sjm.com) Gene Hageman (gene.hageman@medtronic.com) Alexander Kraus (alexander.kraus@biotronik.com) Ken Hoyme (ken.hoyme@bsci.com)
Submission Date:	May 30, 2012
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 2; Revision 1.0; August 12, 2011
Volume(s) and Section(s) affected:	Volume 2 (PCD TF-2); Section 3.9.4.1.2.7
Rationale for Change: 1. We need a means of associating a specific PDF in the message with an episode group, if that PDF contains only the captured waveform for that episode.	

Proposed Changes:

Add the Observation Sub-ID row to Table 3.9.4.1.2.7-1: OBX Segment as follows:

Name	Seq	DT	Len	Opt	Rep	Min	Max	Tbl	Fixed Value	Ex Val
Set ID - OBX	1	SI	4	R	False	0	1			
Value Type	2	ID	2	R	False	0	1	0125	Y	ED
Observation Identifier	3	CWE	478	R	False	1	1			
identifier	1	ST	20	R		1	1		Y	*18750-0*
Text	2	ST	199	R		0	1		Y	Cardiac Electrophysiology Report
name of coding system	3	ID	20	R		0	1	0396	Y	LN
Observation Sub-ID	4	ST	20	RE	False	0	1			1
Observation Value	5	ED	99999	R	True	0	*			Encapsulated PDF
source application	1	ST	10	RE		1	1		Y	Application
type of data	2	ST	10	RE		1	1		Y	PDF
Encoding	4	ST	10	RE		1	1		Y	Base64
Data	5	ED	*	RE		1	1		Y	*Encapsulated and Base64 binary encoded PDF File*
Observation Result Status	11	ID	1	R	False	1	1	0085		
Date/Time of the Observation	14	TS	26	RE	False	0	1			

Name	Seq	DT	Len	Opt	Rep	Min	Max	Tbl	Fixed Value	Ex Val
Time	1	DTM	24	R		1	1			20040328134623.1234+0300

Replace the text describing OBX field usage following Table 3.9.4.1.2.7-1 as follows:

OBX-2 If sending an encapsulated PDF the value will be ED. If referencing an external report the value will be RP.

OBX-3 Value is a report ID from the LOINC coding system, and will be set to `18750-0^Cardiac Electrophysiology Report^LN.`

OBX-4 If a value is provided here the embedded PDF will contain data related to a specific episode or EGM being referenced via grouping to other episode related data elements having the same Sub-ID in OBX-4 inside this message.

OBX-5 If referencing an external document the Observation Value will contain a reference pointer to the external document.

OBX-5.1 If sending an encapsulated PDF the Type of Data component will have the value "Application"

OBX-5.2 If sending an encapsulated PDF the Data Subtype component will have the value "PDF".

~~OBX-5.3 Not used for an encapsulated PDF.~~

OBX-5.3 will be empty.

OBX-5.4 If sending an encapsulated PDF the Encoding component will have the value "Base64".

OBX-5.5 If sending an encapsulated PDF the Data component contains the encapsulated Base64-encoded PDF/A document in accordance with ISO 19005-1.

Notes: 1. An actor participating in this transaction must support encapsulated data with a length beyond the nominal 65536 byte limit of the OBX-5.

2. The base64 encoded stream must not include CR/LF characters, which are forbidden within HL7 field text streams. Breaking a base64 encoded stream into lines of 76 characters or less is used for email in accordance with RFC 822, but is not applicable to encapsulated data in HL7.
The attached PDF or externally referenced report will contain in its content the device ID, patient ID and name if known, and the dates of the procedure and document.