

IEEE 1073 Meeting Notes

September

Wednesday, September 10, 2003

[Items in [blue text](#) were presented as slides; only brief notes were recorded]

Wed Q1

Intro, Roll-Call, Agenda (Cooper)

[\[IEEE_1073_Agenda_s003_Sep_rev1.ppt\]](#) 

Attendees	Wed	Thurs	Friday
Todd Cooper, Breakthrough Solutions	1234		
Joe Morrissey, Motorola	123		
Paul Schluter, GE Medical Systems <i>Information Technologies</i>	1234		
Eric Sundkvist, Siemens Medical Solutions	1234		
Laura Letellier, Baxter Healthcare Corp.	12		
Tim Shoemaker, Vigilance Medical Technologies	1234		
David Cypher, NIST	1234		
Nicolae Goga, Technical University of Eindhoven	1234		
Mary Brady, NIST	1234		
Rick Rivello, NIST	1234		
Masaaki Hirai, Nihon-Kohden	1234		
Michael Gardiner, VAMC, Washington, D.C.	1234		
Paul Morozoff, SpaceLabs Medical	1234		
Lars Steubesand, Philips	1234		

1/1073 Status

[See Todd's slides, '[IEEE 1073 Status Update r2 \(030910\).ppt](#)', dated September 10, 2003] 

- standards balloted
- PAR extended and approved
- formed ballot groups for 'Application Profiles' -20201 and -20202
- PAR status and 'actions'
- X73-20000 PAR [generally agreed to]
- X73-60101 Application Gateway - HL7, ORI PAR (Scope and Purpose) [generally agreed to]
- P1073.3.1 'Transport Profile - Connection Mode' PAR due to expire @ end 2003
- P1073.4.1 'Physical Layer Interface - Cable Connected' PAR due to expire @ end 2003
- IHC (Bill Hawley) over 60 beds, 500 devices, using 'classic' MIB (.3.1/.4.1)
- Coordination & Joint Working Groups
 - Point-of-Care Joint Working Group, focused on X73 ORI messaging
 - Key issues include unique identification of observations + HL7 versions and messaging methods
 - Another limitation of HL7 v2.4 used by POCT1 ORI is limited depth in representing parameter data.
 - Melvin Reynolds - heading up both efforts (from HL7 ORI and IEEE 1073 sides)
 - Major meeting in January - San Diego
 - ECG Joint Working Group
 - Focus on systematic names and term codes and X73 inclusion
 - Pacemaker term evaluations
 - Key objective: HL7 message profiles identifying the X73 ...
 - Persistent Object Joint Working Group
 - (in holding pattern for POC JWG progress and X73 strategic planning)
- Standard maintenance (Nomenclature)

- Awaiting update on IEEE Frame to Word converter project (due any day now ...)
- Developing proposal for “gold” nomenclature database.
- Integration of tool with profile registration and other terminology systems and support (e.g. HL7/LOINC or SNOMED)
- X73 Promotional/Coordination activities
 - U.S. HHS/NCVHS
 - Secretary Tommy Thompson makes public endorsement of key standards, including X73!
 - Term
 - US FDA/CDRH - Liaison Finalized (Carol Cary)
 - CHI Project (DOD, CDC, VA, ...) looking @ X36
 - ANSI Health Informatics Standards Board (HISB)
 - WG1 - Coordination and Issue Resolution between SDOs
 - “ANSI/HISB Stamp of Approval” - - - but, ANSI questions charter of HISB/WG1
 - has anyone drawn a chart showing all the medical connectivity SDO’s?
- EMBS updated
 - providing some financial support for X73 activities
 - 1 day X73 class @ annual EMBS meeting in Cancun next week
 - elevate IEEE 1073 visibility within other organizations
 - provide an update to the EMBS “board”
 - role of “sponsor” - report to IEEE Standards Board
- ISO TC215 Health Informatics Update
 - TC reorganization
 - Ventilator nomenclature issues: resolve in v 2.0 (missing terms; inappropriate systematic names)
 - HIMSS assumed TC Secretariat
- ITU & eHealth
 - ITU-T & -D eHealth Workshop - Geneva ‘03
 - Message from Melvin: Don’t reinvent the wheel!
 - Proposed use-case based integration projects
 - Establish a formal liaison between ITU and ISO
 - eHealth ‘Standardization Coordination Group’
 - [ITU-T eHealth Workshop Standards_bodies_letter-final-signed (from ITU).pdf]**
- Additional X73-related activities
 - Prototyping and demonstration project activities
 - completing Viasys Ventilator implementation for Demo II
 - Many hospitals have expressed interest in prototyping projects:
 - Vanderbilt, IHC, Texas Children’s, Duke, Mass General
- Strategic Planning Summits
 - Evaluate need for X73 for TODAY (vs. 20 years ago)
 - Include both technical and key business decision makers
 - Determine roadmap to meet those needs with X73
 - Discussion (Laura Letellier, Baxter)
 - we need to make strong business cases, work closely with marketing people
 - how do we justify the need for standards; strong business cases
 - *maybe we can continue this interesting and important discussion on Friday!*

Wed Q2

RF Transport Discussion Review (Cooper)

Discussion about RF wireless has been going on over the past two years, on an intermittent basis.

[Todd: par_request_form_1073-0-1-1.rtf]

- technologies include but not limited to IEEE 802.11 (WiFi) and 802.15 (Bluetooth).
- *shared RF transport infrastructure* to support medical device data as well as other clinical apps
- consider all use cases: in the hospital, at home, etc., what are the most appropriate technologies
- we should provide guidelines that hospital IT people can use to set up RF wireless infrastructure
- must operate in a ‘safe and effective manner’

-

[Todd: ITU-T 'Workshop on Standardization in E-health', 23-35 May 2003] slides ~28 to 31

- Laura: must make a clear distinction between 'real-time' IV pump alarms (e.g. fluid has run out) vs. lower-priority alarms.

X73 RF Wireless Guidelines Discussion (Morrissey)

[Joe: RF transport presentation.ppt] ☞

- medical data requirements (reliability, latency, priority, size, how often)
- wireless systems and technology protocols
- spectrum
- technology requirements
- security
- EMC and coexistence issues

Project scope -

Wireless Systems / Protocols -

- existing medical telemetry
 - 450 - 470 MHz
 - 2450 MHz
 - WMTS
 - ambulances may use transmitters > 50 W
 - new low power RF links (Medtronic 'pacemaker-C')
 - 802.11x (local area networks) 'b' widely used, 'g' deploying now, 'a' deploying now.
 - 802.15x (personal area networks)
- mobile phones
- radios
- 2-way pages (paging networks)
- Satellite (IRIDIUM, GlobalStar, etc.)
- Ultra wide band (UWB) (added during discussion)

Todd: who is using technology what where?

- Michael Gardiner @ VAMC using 802.11 technologies
- Laura Letellier: mostly 802.11 technologies, little Btooth in use
(let's say we have an infusion device that moves room to room, Btooth can't handle, 802.11 does)

Spectrum

- licensed communication bands
- unlicensed communication bands (915 MHz, 2450 MHz, 5.2 GHz)
- existing medical telemetry
- WMTS (**608-614 MHz**, 1395-1400 MHz and 1427-1432 MHz) -- works only in the US
see <http://wireless.fcc.gov/services/personal/medtelemetry/>

WMTS (see Joe's slides)

Technology Layers (see Joe's slides)

Other technology requirements (see Joe's slides)

- there are Btooth access points that can run 'class 1' at 1 Watt

Security

- HIPAA
- Encryption
- User Controls
-

Wed Q3

X73 RF Wireless Guidelines Discussion (Morrissey, Schluter, Cooper)

[\[latency.1073.2003-05-02.doc\]](#)

[\[Paul Schluter to update to include discussion, updated version latency.1073.2003-05-11.doc\]](#)

Issues regarding data rate (

- constant?
- access driven?
- dedicated?
- MTU?
- bursty?
- constant/intermittent?
- bit rate
- reliable / connectionless
- latency
 - peer-to-peer layer “delay”
 - application level end-to-end requirement

Guideline bullets (Morrissey)

[\[Joe Morrissey was drafting an outline, and should be included in the minutes\]](#)

- Overview
- Table of Medical Device Requirements
 - prioritized (requirements tradeoffs)
- Overview of RF Technology / system specifications
 - consider WiFi, Bluetooth, mobile phones ...
- Upper layer
 - discovery / connection
 - transient data
- Use-case topologies
- Failure analysis (of system / redundancy)
- QoS
- Security/HIPAA
- EMC, coexistence

Lars: who is legally responsible for an shared infrastructure used by multiple vendor devices?

- reply: endorsing a uniform standard (e.g. roaming, QoS, etc.) would encourage networking equipment vendors, safety and regulatory agencies (e.g. NIST, FDA) and others to participate.

Target audiences: Medical equipment users, medical equipment vendors, equipment vendors

Wed Q4

Conformance Testing (Mary Brady, NIST)

[\[get Mary's slides\]](#)

Basic Approach

- start with ventilators
- use XML to analyze data
- convert ASN.1 encoded PDUs into XML

ValidatePDU

- convert ASN.1 definitions to XML Schema; validate messages by validating XML messages v. Schema

Test generator

- test definitions, data type support and data value generation (with range limits, etc.)

ValidatePDU

- Goal: build an XML Schema that can be used to validate ventilator PDUs
- identified list of ventilator PDU's
- Convert from BER/MDER or ASN.1?

- Tried both, but to no avail!
- Break apart PDU's - try subsets for Association, ROSE, CMDIP, ...

ASN.1 tools

- IBM ASN.1 to XML (XER)
- OSS Nokalva
 - ASN.1 syntax checker (THIS WORKS)
 - ASN-1 Step (syntax + encodings)
 - Compilers
- Objective Systems
 - ASN2XSD - ASN.1 to XML Schema (THIS WORKS)
 - ASN1Viewer -view BER, DER encodings
 - XMLBinder - compiler for XML Schema
 - Compilers

ASN.1 -> XML Mapping

- BOOLEAN -> xsd:boolean (Excluded)
- INTEGER -> (Excluded, alternate types)
 - restricted by minInclusive, maxInclusive
 - ranges beyond "long" or "unsignedLong" are represented by "big integer"

ASN.1 -> XML Mapping

- BIT STRING, SIZED NAMED BITS
- OCTet string, sized (included)
- Character string types
- Time String Types (???)
- ENUMERATED
- NULL
- OBJECT IDENTIFIER (excluded)
- RELATIVE OID (???)
- REAL (FLOAT)
- SEQUENCE (restricted)
- OPTIONAL KEYWORD
- DEFAULT KEYWORD
- SET (use SEQUENCE)
- SEQUENCE OF ? SET OF (use SEQUENCE)
- OPEN
- Tagged types
- EXTERNAL and EmbeddedPDV Types (excluded)

ASN.1 Problems

- Uleed ASN.1 modules from 1073.2.1.1
- E.1.3.1 ASSOCIATION (asn1, xsd)
 - in EXTERNAL DEF, removed the word UNIVERSAL
 - used -1990 option due to EXTERNAL
- E.2.1 ROSE (asn1, xsd)
 - IMPORTS: -- didn't import anything
 - other errors, see Mary's slides

Discussion: BITS-32 vs. BIT-STRING (Mary, Lars and Todd)

Next Steps

- continue working out issues with ASN.1
- identify mechanism for combining schema def's into particular PDU's
- Data Type issues?
- Translate object def's to Schema
- Provide XML instance examples
- What else can we check?

Test Coverage and Select (Nico Goga)

[Handout, "Test selection & coverage"] paper copy, needs to be scanned

Thursday, September 11, 2003

Th Q1

ECG JWG

[Barry's slides: 'Status of AnnotatedECG.ppt'] ☞

- Review Progress Since May (Brown)
- Barry gave a quick overview of the FDA-HL7 Annotated ECG effort;
- March ballot passed, as an 'informative document'.
- August ballot as 'normative document' has passed, discussed a few of the negative comments.
- Next steps: submit for normative membership ballot in January 2004.
- Still investigating how to get a usable schema and message validation software.
- Work on an implementation guide has begun.
- A few early adopters: eResearch Technologies, Eli Lilly, AMPs viewer.

Discussion regarding how the IEEE annotated ECG nomenclature is referenced by the HL7-ECG project.
Referenced in XML with: codeSystem="2.16.840.1.113883.6.24" codeSystemName="MDC"
Balloting: 'informative' -> 'committee' (August 2003) -> 'membership' (January 2004, ~90% req'd)

MFER Update (Hirai)

[Masaki's MFER slides: 'HL7 2003 9.ppt'] ☞

- Japanese Society of Electrocardiology, Conference this week (Sept 8)
- MFER demo: Nihon Kohden, Fukuda Denshi, Suzuken, Medical storage (wireless LAN, 100/10BASE-T, memory card)
- International Conference on Harmonisation (November 2003, finalize spec in Osaka, Japan)
- MFER tutorial (Oct 16-17, 2003, at HL7 meeting in Korea)

Holter (using digital cassettes or memory, using MFER encoding) interoperability between scanners!

Also includes a standard to send Holter data records to HIS/EHR using MFER.

Plans to submit this as an ISO standard.

Looking at IEEE 1073 for 'real-time' transfer, but archived record in MFER format, to be done in future.

Systematic Names Overview and Discussion (Cooper)

Todd reviewed IEEE 11073-10101-D03 pg 103 (ventilator concepts)

[Todd's Nomenclature Model diagrams]

[Michael Kramer's table 'TableConstructionSystematicName (Kraemer).doc']

Systematic Names Strategy (Schluter)

Key issue: for 'synonymous' terms:

1. Should the 'systematic names' be the same? tentative 'yes', if concepts are the same.
2. Should the 'reference ID' be the same? **NO**, different 'reference IDs' are okay for same concept.
This allows concepts to be hierarchically grouped in different ways, which is useful for XML implementations where the 'reference ID', rather than 'code', is used.
3. Should the 'code' be the same? **YES**, the codes should be the same.
'Systematic name must match code.'
'Term codes must uniquely map to a single systematic name.'
=> suggests that we may need to go back and update existing systematic names to match.
'Synonymous' terms are considered synonymous at some level of generalization.
When transferring device data to an HL7 system, should still retain original device nomenclature as well as the more generalized term that would be used by the HL7 system. This allows bidirection transform.

Todd: to be discussed and summarized further, and presented to the group after Th lunch or Friday.
THC: "synonymous" is defined as either (a) the same systematic name, though different term code or reference ID; or (b) a shared generalization term also defines the level of synonymy. In a database implementation, synonyms are established by either a shared generalization / specialization term OR by a special relationship. **[THIS NEEDS TO BE EDITED OR DELETED]**

Final resolution regarding 'synonym' terms: For synonym terms defined in a 'new' partition, the *systematic name* and *reference ID* shall be different than the equivalent term in the 'base' partition (the numeric *code* is implicitly different since it is in the 'new' partition).

[see the file 'sys_names2a.doc']

Pacemaker Terms (Schluter)

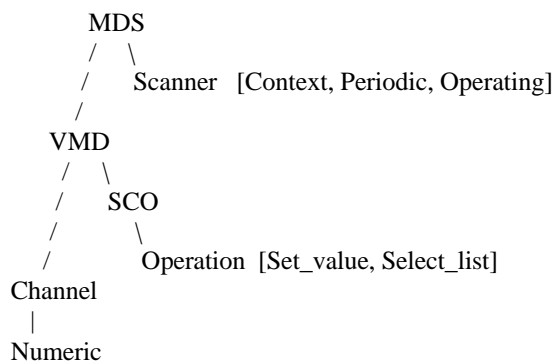
not discussed, since Linda Halvorsen and Doug Baird from Guidant were not present

Th Q2

Application Profile State Analysis (Goga)

[Nicu handed out a 29 page paper document]

Lars gave an overview of the remote control package:



Multiple operations may be invoked as a single 'atomic' operation.
For an infusion pump, operations can be executed at a later time.

Nicu continued on with his presentation.

Nicu posed two questions:

1. **Integrated state tables** -- can the state tables for the 'agent' and 'manager' be combined?
Lars: although a combined state table would be nice, it would be too unwieldy and complex.
It would be better to keep them separate to promote understandability.
2. Referring to pg 11, should show an integrated 'on-the-wire' diagram.

Action Item: Todd will create an email list for those interested in 'remote control' and Nicu's work.

Pacemaker POC JWG Discussion (Guidant)

Guidant was not able to attend our Friday session, and met briefly with us prior to lunch on Thursday. However, Guidant will perform a 'gap analysis' between the pacemaker codes they need versus the codes in the ECG annotation nomenclature, and contact Paul Schluter regarding their findings.

Th Q3

X73 Strategic Planning

[see Todd's slides 'Strategic Planning', ...]

- Key issues
 - Completion of all X73 component technologies
 - Standards
 - Supporting tools and resources
 - Usage of the standards by all stakeholders
 - Medical device and system vendors
 - Healthcare providers
 - Identification of stakeholder 'value propositions'
 - Participation by both technical and business decision makers in the planning process

Example issue: everyone says this would be great, but nobody wants to pay for it!

 - Establish 'roadmap to X73' plan for meeting stakeholder needs and providing full support.

Stakeholders:

VAMC
Premiere
Medical device vendors
System vendors
H/C providers
Biomedical engineers
Hospital IT staff
Hospital admin staff
Government agencies: FDA, TÜV

General discussion:

Medical device and system vendors:

- System vendors need *devices* supporting the standard, to build a business case and to validate.
- Device vendors need *systems* to implement first.
- System and device vendors need hospitals asking for it.

Healthcare providers

- VAMC:

Other impediments:

- 'Open b-bad' -- vendors say 'an open interface is bad for our largely proprietary solutions'.
- Standards are difficult to implement (at least for early adopters)
- IEEE 1073 is complicated; '*generalized protocols are more difficult to implement than narrow ones*'
- too many standards (e.g. nine waveform standards, existing and new ones being developed)
- staying with existing legacy protocols is easier

How standards help:

Medical device and system vendors:

- reduces integration costs (supporting multiple interfaces is costly)

Healthcare providers (and the patients they serve)

- improves patient safety
- automates clinical workflow

Other criteria:

- Should be as easy to implement as "legacy" or proprietary/targeted protocols.
- Once a standard is established, and supporting tools are available, then standards-based development really facilitates implementation. e.g. NIST provides conformance tools that vendors could use to validate their implementations.
- Establish clear tie-in with HL7 (e.g. JWG efforts, IEEE 1073 to HL7 gateway)

Solutions?

- Legislative edict
- Regulatory edict
- POC CIC style (resolves antitrust issues; focused standard development)
- Demo/Prototype projects (make it higher profile, e.g. Demo-2 at Duke)
- User demand

Technical solutions - how can we make implementation easier?

- Simplify implementation; OTS tools: use XML and related tools (widely available, lower cost, ...)
- Profiling/ICS
- 'Simple protocol for simple devices' --
 - e.g. canned messages, etc., simple polling mode sampling devices, X73-Irda 'Ultra'.
- get rid of all the technical hurdles that are major obstacles to first-time implementers
 - e.g. ACSE - use 'canned' sample code

More discussion -

- TÜV is far more interested in how protocols are implemented, and may be a better regulatory agency to promote and influence the use of standards than the FDA. The Japanese Ministry of Health would be another regulatory agency to be interested in the technical implementations and the use of standards.

Polling Mode Profile Review (-20201) (Cooper) *not discussed*

Baseline Mode Profile Review (-20202) (Cooper) *not discussed*

Th Q4

Synonym terms: Resolved how to represent 'synonym' terms for ECG annotation nomenclature extension [see notes for Thursday, Q3].

Protocol state tables: discussed best representation. Following the IrDA state table format appears to be the best approach, due to its compact format.

Framework and Overview Review (Cooper) *not discussed*

Friday, September 12, 2003

Fri Q1

X73 11073-10316 Dialysis Devices Update

[Todd presented a MS-Word document regarding dialysis devices]

- General semantics
 - Infusor
 - SpO2
 - BP
 - Temperature
 - Weight
 - Hemodynamic Calculator
 - Cardiac Output
- List of parameters required for dialysis, provided by Gambro from John Kellum, et.al., "The first international consensus conference on continuous renal replacement therapy", *Kidney International*, v 62 (2002), pp. 1855-1863.
- Proposed schedule
 - American Society of Nephrology 2003-011 San Diego
 - ISO/IEEE X73 Working Meetings 2004-01 San Diego
 - CRD 2004-02 San Diego
 - ISO/IEEE X73 Working Meetings 2004-04/5 San Antonio
 - ADQI-4 2004-05 Italy (may include a prototyping demonstration)

Framework and Overview Review IEEE P1073/D06 (Cooper)

[Todd: '11073-00000-d06a.doc']

- General discussion and review of this draft document.
- NCCLS POCT1-A included as ISO/IEEE 11073-90101.

Fri Q2

continuing discussion on 'Framework and Overview'

Action: Todd will contact NCCLS to obtain permission to use some of the NCCLS POCT1-A figures.

Paul: IEEE 1073.3.2 power options are important to cite in a 'top-level' conformance statement, to avoid the situation where a 'high-power' DCC is connected to a 'low-power' BCC (and thus no interoperability). That is, we need a clear way to express the presence (on a BCC) or requirement (by a DCC) for 'high-power' that is suitable for including a on customer bid specification or purchase order.

Paul: we need to define some mnemonics to describe the various options, so that they can be expressed on a purchase order, e.g. "IEEE 1073.3.2 BCC with **HI-PWR**, **LO-PWR**, or **NO-PWR** power options."

Action: Todd will create a use case for filling out the 'Implementation Conformance Statement'.

Polling Mode - Agent Side

AARQ ? no change
AARE ? no change
AARJ ? no change
ABRT ? no change
RelReq ? no change (could be removed?)
RelResp ? no change (could be removed?)

MDS create ? event time / no change
MDS create.response ? no change
 PollReq ? InvokeID, Poll #, obj/attr.group (TYPE)
 PollResponse ? InvokeID, Poll #, DataValues

other functions needed:

16-bit host to net.byte.order
MDIV IF converter
relative time
memcmp()

Follow-up discussions (Group)

None.

Action Item Review

As indicated in minutes (**red bold** font)

Agenda Topics for January Meetings (Cooper)

January meeting with HL7 in San Diego.

Plan to meet with LAPOCTSIG on Monday Q3,4 and Tuesday Q1,2

Topics -

- follow on with topics from this meeting
- RF (half-day)
- strategic plan and establishing a roadmap, including demos
- ECG (Michael Kraemer will review in Arhus meeting)
- NIST and conformance testing