

**CEN/TC 251 WG IV  
HEALTH INFORMATICS -  
Technology for Interoperability  
SECRETARIAT: MEGA**

***TITLE/  
SUBJECT:*** **1<sup>st</sup> Draft minutes for the 34<sup>th</sup> WG IV Meeting:**

Erasmus Expo & Congrescentrum  
Campus Woudestein  
Burgemeester Oudlaan 50  
3062 PA Rotterdam  
NETHERLANDS

**09:00 to 17:00 Monday 11<sup>th</sup> October and  
Wednesday 13<sup>rd</sup> October, 2010 and Open  
forum sessions on 10<sup>th</sup> October**

***SOURCE:*** **CEN/TC 251/WG IV Secretariat**

***ACTION  
REQUIRED:*** **For confirmation in the next meeting**

*Available for  
CEN members, CEN/TC 251 delegates, WG IV experts and observers.*

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**Sunday 10<sup>th</sup> October, 2010**

**Note different venue from WG meetings:**

Novotel Brainpark Rotterdam  
K.P. van der Mandelelaan 150  
3062 MB Rotterdam  
Tel (+31)10/2532532  
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<b>14:00-18:30</b>	<b>Joint Initiative Open Forum</b> <b>Open to all JWG attendees</b>
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**14:00-15:00**      **Joint work**

**15:00-15:45**      **Report from the Joint Initiative Harmonization track**

**15:45-16:00**      **Report from the JIC**

**16:00-16:30**      **Coffee break**

**16:00-18:30**      **Session on software as Medical Devices**

JIC JWG material will be available at the JIC web site: <http://www.jointinitiativecouncil.org/>

**18:30**              **Adjourn for day**

**Monday 11<sup>th</sup> October, 2010**

**9:00-10:00      The ISO/TC215 & CEN/TC251 Plenary meeting**

**10:00-17:00      TC215/WG7 & TC251/WGIV JWG**

10:30-10:45      *Coffee break*

12:15-13:15      *Lunch*

15:00-15:15      *Coffee break*

**1.      Welcome, Introductions and Apologies**

T Cooper, A Värri, A Holopainen

[T Cooper] welcomed joint working group.

[A Värri] welcomed joint working group with the new CEN/TC251/WGIV scope statement:

CEN/TC251/WG IV scope statement; accepted by resolution 1004/2010 taken by CEN/TC 251 on 2010-06-16.

Standardization in the application of information and communication technology (ICT) to physical (i.e. not stand alone software) medical devices for plug-and-play interoperability at the point of care and to medical imaging device interoperability, as well as facilitating the efficient exchange of device data in all health and social care environments including personal health devices.

In Attendance

Todd Cooper – Chair ISO/TC215/WG7 (US)

Alpo Värri – Chair CEN/TC251/WG4 (FI)

Arto Holopainen – Secretariat (FI)

Björn-Erik Erlandsson (SE)

Malcolm Clarke (UK)

Jeong Young-bok (KR)

Leighton Hansel (US)

Joe Lewelling (US)

Masaaki Hirai (JP)

Koichiro Matsumoto (JP)

Eiji Takahashi (JP)

Senghwan Lee (KR)

Byoung-Kee Yi (KR)

Melvin Reynolds (UK)

Anthony Maeder (AU)  
Stefan Sauermann (AT)  
Miguel Martínez de Espronceda (ES)  
Thomas Norgall (DE)  
Michael Krämer (DE)  
Charlie McCay (UK)  
Bob Kemp (NL)

Apologies

S Eagles (US)  
P Krantz (US)  
J Wittenber (US)

**2. Confirmation of the Agenda**

T Cooper

[T Cooper] updated that Dr. Maureen Baker / NHS will join JWG for item 11 to give update on draft TR 80001-2-x HDO implementation guidance.

William Goossen will join JWG for item 13 to give update on DCM - Medical Devices.

Stefan Sauerman will give update on draft TR 11073-00103 during item 15.

Group approved to proceed with these changes.

**3. Approve Minutes of the ISO/TC 215 WG7 meeting held in Rio de Janeiro, May 2010**

T Cooper

Approved.

**4. Approve Minutes of the CEN/TC 251 WGIV meeting held in Madrid, December 2009**

A Värri

Approved.

**5. Matters arising from the previous meeting Minutes**

T Cooper, A Värri

[T Cooper] noted that there should have been new IEEE PAR for Urianalysis PHD.

**Action:** [T Cooper] to remind Dr. Kwak and Sun Ki Lee about this.

[A Värri] went through actions from previous minutes.

**Action:** [T Norgall] will provide informative English publication/article that will give overview for the technical tradeoffs made between the Generic Bluetooth specification 2.1 and Medical Bluetooth specification MDP.

**6. ISO-IEEE Process Issue Update / Resolution**

T Cooper

[T Cooper] presented the issue with ISO CS-IEEE process. There has been a problem in transferring documents from IEEE 11073 to ISO/TC215 recently although the process worked rather well a couple of years ago.

ISO CS issue summary:

- Document renaming changes (inconsistent with IEEE & 11073)
- Document renumbering
- PSDO (Partner Standards Developing Organization) Agreement & “fastrack” Processing
- Document types supported: IS only? Presently the contract between ISO/TC215 and IEEE 11073 does not include the transfer of other types of documents than standards from 11073 to TC215.
- Mixed document types in single series are not allowed

*[See WG7 resolutions and more details on this from Rio Meeting presentation: “N0302\_ISO\_TC215\_2010\_Rio\_WG7\_Closing\_Plenary\_Report\_r2.pdf”]*

**7. Report of recent IEEE 11073 meetings**

T Cooper

[T Cooper] went through meeting held at Cambridge, US on 2010/OCT/04-2010/OCT/08. Meeting minutes are not yet available. Minutes will be placed to HL7 Health Care Devices document space (<http://www.hl7.org/Special/committees/healthcaredevices>) when ready.

*[See meeting agenda for more information*

*N0303d9\_Agenda\_of\_WG7\_meeting\_2010-10-Cambridge\_US.doc*

*and the link*

*[http://wiki.hl7.org/index.php?title=Health\\_Care\\_Devices\\_%28DEV%29\\_WG\\_MTG\\_2010-10\\_Cambridge](http://wiki.hl7.org/index.php?title=Health_Care_Devices_%28DEV%29_WG_MTG_2010-10_Cambridge)*

Short summary of the meeting (some items):

- HL7 international is in transition to move from US oriented to fully international organization
- Jan Wittenber presented Roadmap Model, how all pieces fit together (X73+DCM+IHE+...)
- NIST (National Institute of Standards and Technology) Medical Device Connectivity Test Tooling - Semantic Interoperability of Medical Devices

NIST IHE-PCD (HL7 v2) test tool can be found at:

<http://xreg2.nist.gov:8080/PCD-HL7WebCon/>

ICS generator tool can be found at:

[http://xw2k.nist.gov/medicaldevices/ICSGenerator/ics\\_index.html](http://xw2k.nist.gov/medicaldevices/ICSGenerator/ics_index.html)

*[See presentation N0307\_NIST\_HL7\_IEEE\_OCT2010.pdf]*

- **IEEE status report**

*[See Kathryn Bennett's (IEEE Liaison) status report*

*"N0308\_IEEE-SA Update.pdf"]*

[A Värri] asked if IEEE publication "11073-00101:2008: Guidelines for the use of RF wireless technology" could be used by health care organizations to identify possible issues with RF e.g. inside hospitals.

[M Reynolds] noted that the document includes lot of US-specific information (frequency bands etc.). Document should be updated with international content before it could be brought to ISO.

[T Cooper] noted that there is WG7/TR related to this. [ISO/TR 21730:2007 : Health informatics -- Use of mobile wireless communication and computing technology in healthcare facilities -- Recommendations for electromagnetic compatibility (management of unintentional electromagnetic interference) with medical devices]

- **IDC (Implantable Device Cardiac) update**

[S Sauermann] noted that there is iCardea-project ([www.srdc.com.tr/icardea/](http://www.srdc.com.tr/icardea/)) ongoing in Europe that is working with "An Intelligent Platform for Personalized Remote Monitoring of the Cardiac Patients with Electronic Implant Devices".

- **Telematics**

Intelligent car interfaces, how car could interface BT-sensors, safety, accident monitoring, orientation.

JWG had discussions on terminology mappings (LOINC, SNOMED, etc.) related to NIST work and RTMMS (Rosetta Terminology Mapping Management System). [T Norgall] suggested discuss with Clem McDonald to get development update. More information on LOINC development at: <http://loinc.org/background/loinc-development>

**Action:** [T Cooper] to initiate discussion with ISO/TC215/WG7 and HL7 health care devices group to define formally how RELMA/LOINC is able to share codes.

## 8. Report of recent IEEE 11073 PHD meetings

M Clarke

*[See separate IEEE11073 PHD update presentation  
“N0314\_2010-10-05-IEEE11073-PHD-Update.pdf”]*

[M Clarke] presented IEEE-11073-PHD update.

3D accelerometer has been moved from 11073-10443 (Physical activity monitor) to a revision of 11073-10441 (Cardio).

- [S Sauermann] noted that it could be good idea to have 3D accelerometer as separate specialization and not include it in other specializations. There would be use cases for separate 3D accelerometer specialization, e.g. in GAIT analyses.
- [M Reynolds] noted that one 3D accelerometer use case is also monitoring of Parkinson tremors. Cardio and fitness can be seen as complimentary to 3D accelerometer. Separate 3D accelerometer would be good.
- [S Sauermann] pointed out that the problem to work new specializations is the lack of resources.

[M Clarke] continued presentation.

IEEE Appeal panel has decided (related to appeals on 11073-10441 and 11073-10442) that real-time use cases are useful and requested PARs be filed to change the standards to support near real-time. If this is not feasible, PHD WG should evaluate the possibility for new standard.

11073-10472 (Medication Monitor) has been published. It was noted that specialization does not include any mechanism that would provide information about medications inside the device. Specialization; as it is; provides only simple information if medication has been taken or not.

[M Clarke] continued with lower layers report.

[See presentation X73\_Lower\_Layers\_Report\_2010-10-08\_CambridgeMA.ppt]

**9. Brief Report of general European 'eHealth' standards situation.**

M Reynolds

Proposal for eHealth-INTEROP Phase 2 has been submitted to the EU Commission. Response is expected before end of the year.

**10. Review of work plan (215/WG7 & 251/WGIV)**

T Cooper, A Värri

ISO/TC215/WG7 work programme was reviewed (T Cooper).

There was discussion about five-year review cycle. There are some ISO/IEEE standards that either ISO or IEEE has had lead for five-year review cycle.

**Action:** [T Cooper] to check with Patty Krantz how to coordinate five-year review cycle reaffirmation between IEEE-ISO/CS.

CEN/TC251/WGIV work programme was reviewed (A Värri).

Alert list from CEN/TC251 secretariat:

Reference	WG resolution / action
CEN/TS 15127-1:2005	<b>Resolution:</b> WGIV recognizes that this item is not in the scope of WGIV. WGIV suggest this item to be revised and moved to WGIII to support medical device directive activity. WGIII might also consider moving this to IEC.
EN 1064:2005+A1:2007	[T Norgall] pointed out that there has not been any indication that WGIV should revise this. However, when WGIV decides resolution for this, WGIV should first check the situation with OpenECG community (Franco Chiarugi) that is using this. <b>Action:</b> [A Värri] to contact Franco Chiarugi about this and update situation with JWG for decisions (if needed) during next meeting.

CEN should actively monitor ISO activity so that CEN can mirror relevant information soon as possible.

Potential merger of CEN/TC251/WG IV with another CEN/TC251 working group

- [S Sauermann] asked about the situation of potential merger with CEN/TC251/WGIV and another CEN/TC251 WG.
- [A Värri] told that the merger was discussed during the 64<sup>th</sup> CEN/TC 251 Meeting in Brussels, Belgium, 2010-06-16. NSBs are in favour of keeping the present working group structure as it is for now. However, it was discussed that an evaluation report about the possible consequences of merger (good – bad) should be prepared.

- [See documents “IV10-001.pdf” and “IV10-003.pdf” for query and results about possible merger]

Possible new work items from ambient assisted living ecosystem

- [T Norgall] introduced that PHD/Continua area fits also to AAL (Ambient Assisted Living, [www.aal-europe.eu](http://www.aal-europe.eu)) scope. There are active projects ongoing in Europe in this AAL area. [One example project was presented; see separate presentation “AAL Interoperability Requirements Rotterdam 101011.ppt”]. There might be interests from AAL projects to propose new work items to PHD and Continua area.
- JWG discussed how new work items can be introduced to 11073-PHD.
- [M Clarke] mentioned that it could be good idea to submit new proposals directly to IEEE. That way the standard, if successful, becomes international standard in any case. Surely new proposals can also be introduced to Continua.
- JWG decided to formulate two CEN/TC251/WGIV resolutions on this.
- **Resolution:** CEN/TC251/WG IV recognizes the need to establish a unified standard ecosystem that enables seamless solutions for personal health and ambient assisted living (AAL) applications. For this purpose WG IV invites all interested parties, in particular ongoing European and regional projects and industry to cooperate in developing related formal international standards.
- **Resolution:** CEN/TC251/WG IV recommends that future standards for seamless solutions for personal health and ambient assisted living (AAL) application shall be aligned with or integrated into the existing international standards system established by ISO, IEEE, CONTINUA, HL7, IHE, and others.
- **Action:** [T Norgall] to start discussions with AAL ecosystem (The EU Commission and interested AAL project-groups)

17:00

**Adjourn for day**

**Tuesday 12<sup>th</sup> October, 2010**

**09:00-10:30 TC215/WG7/WG4 & TC251/WGIV/WGIII JWG**

10:30-10:45 Coffee break

**11. Network Risk management ISO/IEC JW7 80001-X Update**

T Cooper

[T Cooper] gave overview of 80001-X status. [See presentation “TC215\_WG7\_2010-10-12\_80001\_Update\_Cooper-Eagles\_r1.ppt”]

Ballot has been completed on the FDIS 80001-1. Near Unanimous Approval (IEC: 100% Approval ~ ISO: single negative vote).

Three technical report NWIPs are being circulated (vote/comment active until 2011/JAN/07):

- IEC 80001-2-x Step by Step Risk Management of Medical IT-NETWORKS; Practical Applications and Examples
- IEC 80001-2-x Guidance for the communication of medical device security needs, risks and controls
- IEC 80001-2-x Guidance for wireless networks

Dr. Maureen Baker / NHS gave overview of another 80001-2-x technical report in progress:

- IEC 80001-2-x Health Delivery Organization (HDO) Implementation Guidance [See document draft: “HDO implementation guidance IEC80001 v13.1.pdf”]

Dr. Baker emphasized that the guidance have to be practical and useful for health care organizations. HODs have been in the lead of the preparation of this guidance.

Guidance covers small HDOs and large HDOs. Small and large HDOs have very different resources and processes in place.

Currently there is need to have more input from other HODs. Document will be circulated for comments as soon as copyright issues are resolved.

**Action:** TC215/WG7 will propose NWIP on 80001-2-x HDO Implementation Guidance when copyright issues are resolved.

**12. CLARISK (ISO/TS25238) review ballot**

T Cooper

Luuc Posthumus presented overview of ISO/TS 25238:2007 review ballot results.  
[see document: ISO\_TS\_25238\_SRballot\_results.zip]

Ballot result is not unambiguous.

- Total voting: 15
- Confirm with or without correct:7
- Revice/Amend:3
- Withdraw:5

JWG had discussion on the results. There were comments that the content of 25238 could be merged with one 80001-2-x TR.

JWG suggested that let the situation rest for now and wait new standards to arise.

ISO/TC215/WG4 to formulate resolution on this. ISO/TC215/WG7 will support this action in its report to TC.

<b>10:45-16:30</b>	<b>TC215/WG7 &amp; TC251/WGIV JWG</b>
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12:15-13:15	Lunch
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15:00-15:15	Coffee break
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**13. DCM - Medical Devices Update**

T Cooper

William Goossen presented DCM work in Netherlands.

Detailed Clinical Models provide a new way to structure medical information. It combines expert knowledge, data specification and terminology and enables various technical applications. (<http://www.detailedclinicalmodels.nl/dcm-en>)

Detailed Clinical Models for Medical Devices defines the main concepts of using medical device-related data safely and traceably for patient care.  
([http://wiki.hl7.org/index.php?title=Detailed\\_Clinical\\_Models\\_for\\_Medical\\_Devices](http://wiki.hl7.org/index.php?title=Detailed_Clinical_Models_for_Medical_Devices))

There are currently two DCM projects underway. HL7 is developing DCMs usable outside the HL7 domain. ISO/TC 215 is not focusing on actual DCM development, but rather on defining standard methods and best practices for building DCMs.

**14. MFER - New Work Items Review**

M Hirai

[K Matsumoto] presented overview on MFER status and ISO/TS 11073-92001 Medical waveform format encoding rules. *[See presentation: "MFER-ISO-TC215-Rotterdam.ppt"]*

2010 is a renewal year and MFER committee intends to obtain IS. NWIP is in process.

JWG discussed the harmonization of MFER with the other parts of 11073

- [T Cooper] asked how harmonization is planned to be done
- [M Hirai] explained the use of mapping table
- [M Clarke] asked how to make sure the terminology is aligned with other 11073 parts. It is not preferable, that parallel terminology is created.
- [M Hirai] explained that current 11073 terminology does not cover all the needed terms used in MFER. In this case, there is need to create new terms.

Current position of MFER:

- Currently Japanese Ministry of Health, Labor and Welfare has adopted MFER as recommended standard
- Japanese Society of Electrocardiology has adopted MFER as standard of electrocardiogram
- MFER committee receives many inquiries about adoption of MFER from around the world.

JWG had discussion on online data streaming

- [M Clarke] asked if MFER supports online data transfer
- [M Hirai] No, MFER is intended to be file-based format
- [M Clarke] asked about the differences between HL7 definitions
- [M Hirai] HL7 format can be more suitable for transferring through link but MFER provides better file-based approach. MFER can be converted to HL7.

[E Takahashi] presented overview of TS11073-92301 Electrocardiography.

[T Cooper] noted that there will be numbering changes in current MFER documents. After numbering changes, NWIPs are expected to be placed.

**Action:** [M Hirai] to propose NWIPs for re-numbered MFER documents to be handled during next meeting in Finland.

**15. 11073 Draft Standards review**

T Cooper

[T Cooper] gave an overview of 11073 standards review situation.

*[See presentation: X73\_11073\_POC\_Stds\_Planning\_2010-10-12A.ppt]*

11073-10201 DIM Revision. Clarifications to content, e.g. enhanced attribute descriptions. Context free pre-coordination of X73 terms (normative annex), e.g. how to define are we transferring settings or measurements.

Draft standards for ballot:

- 11073-20201 (Polling Mode)
- 11073-20202 (Baseline Asynchronous Mode)
- 11073-20301 (Remote Control Optional Package)

Draft standard ballot target end of NOV/2010.

[T Cooper] noted that if somebody has comments to changes, they need to be submitted within a couple of weeks.

**Status of 11073-00103 Draft Guide for Health informatics - Personal health device communication – Technical report – Overview**

- [S Sauermann] presented the work status with “11073-00103 Draft Guide for Health informatics - Personal health device communication – Technical report – Overview”. Next step is to submit PAR for one year extension.
- [M Reynolds] reminded that standard’s content should guide clearly without too much interpretation. Try to avoid words like “should” and “shall”.
- *[See document: tech\_report\_ieee-11073-00103-d06\_20101011.doc]*

**16. IHE ICE-PAC Rapid Device Configuration (RDC) Project Update**

T Cooper

[T Cooper] gave update on IHE Integrated Clinical Environment PCD Analysis Committee’s (ICE-PAC) Rapid Device Configuration (RDC) Project.

*[See presentation: ICE-PAC\_RDC\_Project\_Discussion\_r5.ppt]*

See more information:

- Medical Device Plug-and-Play (MD PnP) Interoperability program (<http://mdpnp.org>).
- Rapid Device Configuration (<http://wiki.ihe.net/index.php?title=RDC>)

Two example scenarios were presented and discussed:

- PACU -> ICU with ventilator and pumps
- Device failure in ICU

## 17. Update on FEF (ENV14271)

A Värri

Invited expert Bob Kemp joined the JWG.

[A Värri] presented the topic.

Background:

- the specification of a polygraphic data format was published in the EEG journal in 1992. This specification has been named EDF for European Data Format later (<http://www.edfplus.info> )
- the format was implemented by several manufacturers as it was easy to do. See list in <http://www.edfplus.info/companies/companies.html>
- it was proposed to make EDF as the formal CEN standard but CEN/TC251/WGIV experts of the 1990'ies found many ways to improve the specification and did not accept the proposal
- a format to satisfy the requirements of the experts sufficiently was specified and it became ENV 14271 File exchange format for Vital Signs, FEF in 2002-3
- less than five companies implemented FEF as it was already too extensive incorporating all the wishes
- ENV 14271 was removed from the work item list in June 2010
- expecting the formal removal to happen, a small number of experts decided to try again to formalize the so popular EDF and its year 2003 extension EDF+ as a CEN standard and began drafting it into the form of a standard document already in 2008. The goal has been not to introduce incompatibilities to the EDF specification so that most of the existing EDF software would be compliant with no or minor modifications and CEN/TC251 would have a standard that is actually used. The specification work has suffered from the lack of volunteers to type in the specification in the compatible manner and this is where we stand now

[A Värri] proposed steps to go forward:

- firstly prepare standard EDF with two profiles, basic (close to the original EDF) and extended (close to EDF+) because EDF(+) already has quite wide support in industry
- next step is to collect new feature requests from industry about properties which are perhaps missing from EDF and prepare a new work item direct after the first EDF release

JWG had discussion on EDF:

- [M Krämer] noted that most important concern is EDF's "closed world" approach. The EDF should be aligned with existing standards e.g. 11073. Interfacing should be simple and compatible. A Värri responded that ENV 14271 was a result to this request.
- [T Norgall] noted that this area is not in mass market. We realize the need for interoperability. Compromise would be to provide means for semantic interoperability. Also to provide easy way (motivation) that vendors are taking it to use.
- [T Cooper] There are similar formats in other areas that fulfil business needs but are not perhaps so elegant in specification.
- [S Sauermann] told that he has been discussing with the Austrian expert Alois Schloegl on this area and they have recognized several issues with EDF: 16 bit sample resolution is not enough, Annotations not sufficient (e.g. for sleep states).
  - [B Kemp] replied that annotations should not be used for sleep states. Different clinicians might use different annotations. 16-bit sample data has not been a problem with vendors.

[A Värri] raised question that should there be basic profile for EDF (easy to implement) and an extended profile EDF+ (more supported features, more implementation work) or just one.

- [B Kemp] Concern: if you offer only basic EDF without annotations (EDF+ supports annotations, EDF does not) you might be giving wrong information to manufacturers. Basically all EEG devices need to store data and annotations. There has to be a note that if annotations are used, the extended profile has to be used.

[T Cooper] asked how the proposed format supports complete care workflow processes like current CDA-based solutions. Should the proposed model include also report and summaries (e.g. HL7 GAS group is defining guide for Anesthetic Record using CDA)? This relates also to liability issues.

- [B Kemp] It should be understood that EDF is just one part of system. It contains the real raw data and it is not meant to contain e.g. report or summary. About liability, in Netherlands original data has to be stored 10 years and data has to be available for viewing in original format.
- [S Sauermann] We should engage with other groups e.g. GAS group to understand their solution. Is there standardized report format in EDF/EDF+ used systems? Is there need for one?
- [B Kemp] European sleep labs have adopted American standards that states what parameters should be reported.
- [T Cooper] There are obviously two phases in proposed work. One with the data format and other with reporting. Should we proceed also towards report side? When both are in place, we can see how it fits to reference system. I could engage e.g. Charlie McCay, vice-chair of HL7 technical steering committee, to check if somebody is already doing such work.

- [A Värr] noted that in this kind of exercise (report and summary) we might be defining medicine. Also there might be very different viewpoints in sleep labs.
- [A Sauermann] We have done similar thing with laboratory reports in Austria. It can be done.
- [T Cooper] perhaps it could be good idea to create superset of parameters that gives possibilities to many use cases.
- JWG decided action on this:  
**Action:** [T Cooper] to contact HL 7 in order to investigate the need to produce a standard for the structured report of polygraphic sleep studies.

[A Värr] proposed following for supported video-formats.

**Proposal:**

Two types of image and video formats are supported by EDF-SE

- Formats standardised by a standardisation body which makes the format specifications available for free or for a fee
- Freely publicly available format specifications

**JWG accepted this proposal.**

JWG continued with the discussions on draft document. *[See document: CEN\_TC251\_WGIV\_ElectronicDataFormatForSleepAndEEG\_EDF\_V06.doc]*

[B Kemp] we need to add note that if there is need to use annotations, extended format has to be used. Also note to scope about possibility to store sleep scores with extended format.

[M Clarke] noted that it could be good idea to use 11073-PHD codes in documents measurement table.

- [A Värr] defined EDF codes are already in wide use and some EDF viewer applications copies codes directly to display.
- [M Clarke] How about localization and support for different languages if codes are displayed to user as they are stored in data?
- [A Värr] there could be additional method (e.g. some information in header section) that gives the option to use codes instead of visual-strings in data.

[T Norgall] noted that we need to find somehow the acceptance for this new standard from the users.

**Action:** [A Värr] CEN/TC251/WG4 to continue the work with the ENV14271 replacement standard (EDF-SE) to present new work item proposal (NWIP).

**18. Current CEN/TC251/WGIV ballots for review**

A Holopainen

prEN ISO 12052 (DICOM): (UAP ballot between 2010-09-09 and 2011-02-09).

**19. Current ISO/TC215/WG7 ballots for review**

T Cooper

No items here.

**16:30                    *Adjourn for day***

**18:00-21:00        *Social event (separate registration)***

**Wednesday 13<sup>th</sup> October, 2010**

**09:00-12:15 TC215/WG7 & TC251/WGIV JWG**

10:30-10:45 Coffee break

12:15-13:15 Lunch

20. **Regulation of standalone software and the European Medical Device Directive**  
A Värri

[A Värri] presented the review of MDEG B&C guidance document.  
[See presentation: *MDD09090.PPT*]

One recognized problem with the guideline document is the lack of clear definition in examples whether the software is medical device or not.

[A Värri] recommended everybody interested to provide comments for document even though the formal comment circulation has passed.

[A Värri] There are quite few harmonized standards for the health care software development. It seems that current standards guide software development towards water fall model, which might not be the best model today. We should check also other software development standards and methods from other areas that might provide more flexible development.

- [T Cooper] mentioned that there is a project ongoing that handles this topic.
- **Action:** [T Cooper] to provide status update on the methods used in health care software development

[A Värri] mentioned that Finland has provided position paper related to guideline.  
[See document: *POSITION PAPER \_ FIN\_Qualification & Classification of sw.pdf*]

[S Sauermann] presented the COCIR's decision tree for qualification of software as medical device. This tree gives quick and fast way to do preliminary analysis whether software is regarded as medical device.

[See document: *Figure 1 - Decision tree MSW - final draft for COCIR MSW\_2010-07-23.pdf*]

[S Sauermann] noted that it is difficult to understand medical device relations to large software systems and processes that include e.g. the use of office tools. One way to address this is to apply risk management to every process and software.

21. **TC215 WG Resolutions**

T Cooper

WG7 recommendation to present Preliminary New Work Items for International Standards on the following IEEE items:

- 10419 Insulin pump
- 10420 Body composition analyser
- 10421 Peak expiratory
- 10418 INR analyzer
- 10413 Respiration rate
- 10443 Physical activity monitor

**Action:** [T Cooper] to resolve with Patty Krantz, Melvin Reynolds and TC215 secretariat how to handle ISO/IEEE documents when revised or reaffirmed in IEEE.

22. **Cooperation, and liaison possibilities, e.g. ISO/IEC JTC1/WG7 Sensor networks**

A Värri

[A Värri] noted that the working draft of ISO/IEC WD 29182-1, Information technology — Sensor Networks: Sensor Network Reference Architecture (SNRA) — Part 1: General overview and requirements, includes references to healthcare devices. WG should contact ISO/IEC JTC1/WG7 and investigate a possible cooperation need on this matter.

**Action:** [T Cooper] to contact Richard Dixon Hughes and Adrian Stokes on this matter.

Sensor networks relates also to the Ambient Assisted Living items discussed during the review of work plan (see item 10).

23. **Educational and primer materials**

A Värri

CEN/TC251/WGIV has web pages at [www.cs.tut.fi/sgn/wgiv](http://www.cs.tut.fi/sgn/wgiv).

[A Värri] is mastering web pages, so all material to web pages are updated by him. Additional links to educational and primer materials could be added to this site.

It was noted that links to HL7 (<http://www.hl7.org>) and IHE wiki (<http://wiki.ihe.net>) should be added to pages.

JWG discussed about possibilities to place draft standards to web pages. CEN allows draft standards to be circulated but IEEE does not.

**24. ~~Possible TR for Medical Device Informatics Standardization Roadmap~~**

~~J Wittenber~~

**Cambridge MA Meeting Updates: FDA, IHE PCD, NIST**

T Cooper

[T Cooper] presented summary of the meeting.

*[See presentations: “N0312\_FDA-update.pdf”, “IHEUpdate2010-10-04.pdf” and “N0307\_NIST\_HL7\_IEEE\_OCT2010.pdf”]*

**25. Any other relevant business**

T Cooper, A Värri, B-E Erlandsson, T Norgall

No items here.

**26. Resolutions**

A Holopainen

[T Cooper] formulates ISO/TC215/WG7 resolutions discussed during item 21.

CEN/TC251/WGIV resolutions:

Nbr	Reference	Resolution
1	CEN/TS 15127-1:2005	WGIV recognizes that this item is not in the scope of WGIV. WGIV suggest this item to be revised and moved to WGIII to support medical device directive activity. WGIII might also consider moving this to IEC.
2	AAL1	WG IV recognizes the need to establish a unified standard ecosystem that enables seamless solutions for personal health and ambient assisted living (AAL) applications. For this purpose WG IV invites all interested parties, in particular ongoing European and regional projects and industry to cooperate in developing related formal international standards.
3	AAL2	WG IV recommends that future standards for seamless solutions for personal health and ambient assisted living (AAL) application shall be aligned with or integrated into the existing international standards system established by ISO, IEEE, CONTINUA, HL7, IHE, and others.

27. **Date and Location of next Meetings**

T Cooper, A Värri

ISO/TC215 Plenary and joint Working Groups, 23-27 May 2011 Kuopio, Finland

There is also possibility for CEN/TC251/WGIV to meet during JAN/FEB/2011 if there is need. WG noted that telco could be also a preferable way to meet.

28. **Closing and WG resolution development**

T Cooper, A Värri

29. **Closing and non-resolution topics**

T Cooper, A Värri

<b>13:15-17:00</b> <b>Mini-Plenary</b>
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10:30-10:45 <i>Coffee break</i>
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**17:00**                      **Adjourn for day**

## Krantz, Patty

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**From:** Arto Holopainen [arto.holopainen@megaemg.com]  
**Sent:** Friday, October 29, 2010 7:38 AM  
**To:** 'Arto Holopainen'

**Attachments:** IV10-007\_Draft\_Minutes\_34th\_WGIV\_Meeting\_Rotterdamd\_2010.pdf



IV10-007\_Draft\_Minutes\_34th\_WG...

Dear CEN/TC251/WGIV members,

Please find attached ISO/TC215/WG7 & CEN/TC251/WGIV JWG Rotterdam 2010 meeting minutes 1st draft.

You will find original and attachments from livelink:

<http://cen.iso.org/livelink/livelink?func=ll&objId=1143578&objAction=browse&sort=name>

With Kind Regards,

Arto Holopainen  
Secretary  
CEN/TC251/WGIV  
[www.cs.tut.fi/sgn/wgiv/](http://www.cs.tut.fi/sgn/wgiv/)

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