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## **Connectivity Industry Consortium (CIC)**

The Universal Standard for Point of Care Connectivity

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### CIC EI MEDICA 2005 Meeting Summary

November 16<sup>th</sup>, 2005 Düsseldorf, Germany



This memo summarizes the essential details of the Point of Care Connectivity Industry Consortium - European Initiative MEDICA 2005 Meeting, held November 16<sup>th</sup> on the Roche boat "MS Viking Sky" in Düsseldorf.

## 1. EXECUTIVE SUMMARY

The European Initiative (EI) of the formerly US Connectivity Industry Consortium (CIC) held its sixth major briefing meeting for Point-of-Care organizations during MEDICA on November 16, 2005 in Düsseldorf, Germany. The meeting was held in conjunction with the MEDICA 2005 conference on one of the boats chartered by Roche Diagnostics. Forty-three individuals announced their interest in participating at the meeting. (Eight out of the forty-three weren't able to attend for technical reasons.) Thirty-five individuals representing twenty-four international point-of-care (POC) organizations and eleven countries attended the meeting in 2005.

During MEDICA 2000, the CIC launched a European Round Table (ERT) with the goal of involving European users and vendors in the development efforts and to internationalize the standard. In 2001 the ERT was renamed "European Initiative" (EI). By the end of the year the Connectivity Industry Consortium (CIC) achieved its goal of developing a standard for point-of-care (POC) connectivity based on existing IEEE and HL7 standards and on specifications developed by the CIC. The CLSI<sup>1</sup> (formerly NCCLS) updated and approved the originally proposed AUTO6-P draft standard. The standard was renamed 'POCT1-A' and referred to the standard published by CLSI.

Relevant HL7 and IEEE standard specifications correspond to POCT1-A. The ongoing process of adopting NCCLS POCT1-A as formal international ISO, CEN and IEEE standard is unparalleled in the history of standardization and hence still has to overcome some administrative obstacles. It is embedded in the current development of the CEN ISO IEEE 11073 family of standards which was enabled by the 2002 ISO/IEEE pilot process agreement. Results from POCT1-A-related NCCLS modification and extension efforts are reflected in the new standard draft POCT1-A2.

Having started with development of prototype or demonstration implementations of the CIC protocols at the second EI meeting in conjunction with the MEDICA 2001, the Fraunhofer Institute für Integrierte Schaltungen (Fraunhofer IIS) had presented a POCT-1A Demonstrator, implementing a complete POCT1-A Device Interface between POCT-Device and POCT Observation Reviewer, during the third EI meeting in conjunction with the MEDICA 2002. Meanwhile, the Fraunhofer IIS POCT1-A portfolio offers not only general support and services for POCT1-A interface development, but particularly a set of protocol simulators with related compatibility and interoperability testing services, which several industrial partners already successfully integrated in their product development processes.

Our sixth EI meeting in conjunction with the MEDICA 2005 received excellent feedback. Three diagnostic companies presented their experiences and the benefit of equipping point-of-care devices with POCT1-A compliant interfaces. Two cooperation partners out of the three gave a demonstration of interoperability among their devices using POCT1-A connectivity. One further company announced it would implement the standard in 2006. Moreover, the meeting provided information on the status quo of the update of the POCT1-A, which was renamed to POCT1-A2 in 2005. In addition, the presentations provided updates upon the standard internationalization and implementation process, the perspectives, projects and activities of the POC standard development in the US and in Europe. A representative of the CPOCT Industrial Liaison Committee (ILS) informed the members about the latest discussion at the AACC Meeting 2005 in Orlando, USA. Also new incentives for the standard implementation in Europe were introduced.

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<sup>1</sup> As of January 2005, the NCCLS changed its name to the "Clinical Laboratory and Standards Institute", CLSI.

Christina Rode-Schubert, CIC Secretary General, opened the meeting. She gave a brief review of CIC EI history and introduced new incentives from the healthcare market requiring standardization in the field of IT architecture. In addition to the Quality Assurance Guideline („RilIBAK“) issued by the German Medical Association (“GMA“) and introduced during last year’s meeting, she presented the topics “Integration Issue of the Health Care Reform” and “The Medical Record“. The reform of the German health care system establishes “Integrated Care” (Integrierte Versorgung) as well as “Medical Care Centers” (Medizinische Versorgungszentren). The latter are a kind of “Competence Center for Health Care“, where different medical disciplines cooperate to provide optimal medical treatment for patients. To enable this, common understanding and documentation of the course of disease, the target of treatment and the therapy is required. The “Medical Record“ is technically a server-based, smart card enabled service to provide patient-specific health data ubiquitously. The system requires a telematics infrastructure platform. A prototype shall be launched in January 2006. Intended quality of communication and documentation services requires an open system architecture and semantic interoperability standards like POCT1-A2. Remote POC devices have to communicate with the enterprise information network for data exchange, quality control and comprehensive documentation. Hence it is expected that especially the introduction of Medical Care Centers and the launch of the Medical Records will be further drivers for POCT1-A2 adoption and product development.

Thomas Norgall, Fraunhofer-Institut für Integrierte Schaltungen Erlangen, then updated attendees on the recent progress regarding formal approval of the standard by DIN, CEN and ISO (see above), industrial and user acceptance as well as related activities from a CIC European Initiative perspective. The institute offers not only general support and services for POCT1-A interface development, but particularly an independent service and related protocol simulator tools for POCT1-A compliance and interoperability testing. These were successfully used by several industrial partners in their product development processes, most recently in an ongoing cooperation with Roche.

Bob Uleski, leader of an initiative resulting from AACC 2004 conference considerations aiming at the development of common test vehicles for POCT1-A2 and representative of the EI cooperation partner CPOCT Industrial Liaison Committee (ILS), gave a comprehensive presentation on the US activities discussed during the Committee’s meeting in conjunction with the annual AACC congress in Orlando.

Andreas Staubert, Roche Diagnostics GmbH Mannheim, Germany and first representative of the Diagnostic Industry, opened the session “Industrial Experiences Implementing the POCT1-A“. He outlined the different POCT-1A implementation activities at Roche Diagnostics. Roche currently is implementing the standard in the new generation of NPT devices and Roche hospital IT products will provide full support for the POCT1-A standard. Launch of the first POCT1-A equipped device is announced for Q1/2006. Andreas Staubert presented a list of positive and negative experiences regarding the standard implementation as well as a “wish list“ covering the next steps.

This was followed by Andreas Moe from HemoCue AB Sweden who presented the experiences of HemoCue implementing the POCT1-A in the “HemoCue 201 DM System“, the blood glucose meter of the company. He explained the HemoCue device-specific workflow and the company’s POCT1-A implementation experiences. Furthermore, he introduced a list of missing issues regarding the standard’s functionality and he summarized “what the customers have asked for“.

Allan Soerensen from Radiometer Medical ApS Denmark, a cooperation partner of HemoCue, continued. He introduced the topic “RADIOMETER and CIC protocols“ reporting in particular on the POCT1-A ORI and DML experiences and data processing.

The cooperation partners HemoCue and Radiometer kindly gave a live demonstration on data exchange using POCT1-A interoperability. It included the HemoCue PC Software and RADIANCE (radiometer software), as well as a LIS simulator software installed on a laptop. When the HemoCue 201 DM Analyzer was docked, the results were sent from the Analyzer to the HemoCue PC Software using the POCT1-A protocol, which automatically forwarded the results to RADIANCE as well using the POCT1-A protocol, which in turn immediately sent the results to the LIS simulator (using ASTM protocol) where the results could be seen in clear text just seconds after the Analyzer was docked.

This highly interesting session was closed by Karl-Ludwig Dronka from Bayer Health Care Germany, who expressed strong interest on the part of his company to implement the standard in their POC devices. He announced a presentation of Bayer's experiences at our next MEDICA Meeting 2006.

The session led to a discussion among the representatives of the diagnostic industry on further detailed technical questions coming up during the implementation process. A "chatroom" infrastructure, ideally accessible via the CIC EI website, was regarded to be an expedient solution to provide a platform for discussing specific questions and to generate and disseminate "best practice" expertise.

H.G. Wahl, Hospital Laboratory Klinikum Lüdenscheid, introduced as Chair the POCT Working Group (POCT WG) of the German Association of Clinical Chemistry and Laboratory Medicine (DGKL). Their mission is to enable and promote the successful adoption of POC. The POC WG has been cooperation partner of the CIC EI since 2004 when it held its first event during MEDICA congress in Düsseldorf. The goal of this cooperation is to strengthen and promote the POC topic at future MEDICA events.

Peter Luppa, University Hospital Munich, Germany and member of the POCT WG, kindly represented the user side giving a presentation on "Benefit of a communication standard as the POCT1- A for a central laboratory in a university hospital". He outlined his experiences connecting POCT devices to the central laboratory of the University Hospital Munich.

Heiko Ziervogel, HCx Consulting Berlin, closed the session of the cooperation partner POCT WG presenting a very interesting contribution on a "Market Survey POCT". He focussed on the user perspectives in Germany, and his results emphasized the conclusion that successful POCT testing requires connectivity. As expected, this statement was confirmed by the auditorium.

Finally Thomas Norgall, CIC Europe Initiative Chairperson, led the meeting discussion. He reviewed, summarized and closed the sixth CIC EI MEDICA meeting.

Please find all presentations as attached and soon on our POC EI website ([www.poct.fraunhofer.de](http://www.poct.fraunhofer.de)).

In the discussion the attendees agreed again that there is still a lot of work left to be done at European and international levels to educate users in particular on how implementation of the POCT1-A standard can establish cost-effective multi-vendor connectivity. This issue was already part of the CIC sunset strategy and is recorded in the "Sunset Transition Plan". Funds are set aside to continue supporting the CIC EI.

In addition the discussion showed very positive feedback on the valuable "Industrial Experiences Session", which provided what was restated, that during the implementation process of the standard, technical questions arise, which need to be discussed and solved among the vendors.

To have a forum discussing these kind of questions (implementation and maintenances issues) continuously between the EI MEDICA Meetings, a BSCW ("Basic Support For Cooperative Work") server providing corresponding means for information exchange has already been set up by the Fraunhofer Institute. Recipients of this email will soon receive an invitation to register.

The CIC EI continues to be actively involved in the further development of global POCT standards. In this regard, its mission is to articulate the European users' perspective in particular. Emphasis is on motivating the different players in the POCT arena to bring in their expertise and resources and to co-ordinate their work towards common standards that fit well into the emerging system of international interoperability standards and frameworks. Hence EI does not completely restrict its focus to "pure" POCT device interoperability issues only, but also has to take into account the whole domain of medical device communication including ongoing "e-health" activities and related infrastructure deployment.

Furthermore, the EI endorses the POCT1-A(2) compatibility/interoperability testing and certification activities of the Fraunhofer Institute. The institute offers an independent testing service that enables companies to provide standard-compliant-proofed implementations. The task of the EI will be to promote the standard and supporting services among the diagnostic industry.

## 2. PRESENTATIONS

The following presentations will be available on the CIC EI website.

- Christina Rode-Schubert - BE Consult Heidelberg Germany, Secretary'General CIC Europe: A Brief CIC EI History - and a New Incentive for the POCT1-A in Europe
- Thomas Norgall - Fraunhofer-Institut für Integrierte Schaltungen IIS-A Erlangen Germany, CIC Europe Chairperson: Status Quo and Ongoing Work. The ongoing and successful European process of adopting NCCLS POCT1-A as a formal international ISO and CEN standard.
- Robert Uleski - Industrial Liaison Committee USA: The CIC EI ILC Cooperation: The CPOCT-ILC Committee at the AACC Meeting 2005.
- Andreas Staubert - Roche Diagnostics GmbH Mannheim Germany: Industrial Experience Implementing the POCT1-A communication standard I: Roche Diagnostics Mannheim
- Andreas Moe - HemoCue AB Ängelholm Sweden: Industrial Experience II - Implementing POCT1-A in HemoCue 201 DM System.
- Allan Soerensen - Radiometer Medical ApS Bronshoj Denmark: Industrial Experience III - RADIOMETER and CIC protocols.
- H.G. Wahl - Märkische Kliniken GmbH, Klinikum Lüdenscheid Germany: The POCT Working Group of the German Association of Clinical Chemistry and Laboratory Medicine - Introduction (*presentation material still missing*).
- Peter Lupp - University Hospital Munich Germany: Benefit of a communication standard as the POCT1- A for a central laboratory in a university hospital. Experiences connecting POCT devices with a central laboratory.
- Heiko Ziervogel - HCx Consulting Bad Saarow Germany: Market Survey POCT - User perspectives in Germany - Successful POCT Testing requires connectivity.

### 3. PARTICIPANTS

Thirty-five individuals representing twenty-four different organizations attended the meeting, as summarized in the following two tables.

**Table 1: Attendance, by Country**

| COUNTRY      | ATTENDEES |
|--------------|-----------|
| Austria      | 2         |
| Canada       | 1         |
| Denmark      | 3         |
| Finnland     | 2         |
| France       | 1         |
| Germany      | 19        |
| Italy        | 1         |
| UK           | 1         |
| USA          | 2         |
| Sweden       | 2         |
| Swiss        | 1         |
| <b>Total</b> | <b>35</b> |

Participants represented the in-vitro diagnostics industry, information technology vendors, point-of-care users, universities and research institutes, healthcare consultancies, and other point-of-care-related organizations. The following table summarizes the attendance by the type of organization represented.

**Table 2: Attendance, by Organization Type**

|                        | PARTICIPANTS | ORGANIZATIONS |
|------------------------|--------------|---------------|
| Diagnostics            | 20           | 10            |
| Information Technology | 4            | 4             |
| User                   | 2            | 2             |
| Consultant             | 3            | 3             |
| University & Institute | 3            | 3             |
| Others                 | 3            | 2             |
| <b>Total</b>           | <b>35</b>    | <b>24</b>     |

#### **4. NEXT STEPS EUROPE**

The former CIC website, taken over by the EI in 2003, is maintained by the Fraunhofer-Institut für Integrierte Schaltungen, Erlangen, and will be developed as a resource for meeting documentation and presentations, information updates, implementation aids, contacts and best practices.

The POCT1-A related services initiated by the EI provided by the Fraunhofer IIS and piloted in cooperation with Roche Diagnostics will be announced on the Internet page of the CIC EI.

The EI intends to provide through regular contact to the European diagnostic industry current information on available POCT1-A devices, developer and user experiences, available services and the status of standardization. In addition, technical questions arising from standard implementation efforts shall be documented and discussed - and hopefully sufficiently answered.

To set up the information exchange and the discussion among the POCT1-A community, the Fraunhofer Institute will invite registered CIC EI participants to register for the BSCW server.

Representatives of the EI continue to participate in an international initiative generating Common CIC EI / AACC ILC POCT1-A test and verification tools and possibly a related global certification infrastructure.

The CIC EI continuously works on the internationalization push by continued national and international standardization as well as marketing and outreach activities (e.g. coordinate articles, trade shows).

The CIC EI focuses on the POCT future in general and especially in conjunction with the MEDICA congress. The EI will again present innovative POCT development activities and incentives during MEDICA 2006.

The CIC EI strives for POCT to become a main topic at MEDICA in Düsseldorf, and is therefore searching for cooperation partners to strengthen the POCT topic at Medica. The first step towards this goal was the valuable cooperation between the CIC EI and the POCT Working Group of the German Society of Clinical Chemistry and Laboratory Medicine (DGKL) during MEDICA 2005 (see section 1). The cooperation partners activate synergies by bundling their activities. The events of the cooperation partners during MEDICA 2005 took place the same day. The same media will be used to jointly announce corresponding meetings before MEDICA 2006.

#### **5. THE CIC EI NETWORK**

A mailing list has been established to facilitate communication between individuals interested in European point-of-care connectivity standardization issues. If you are interested in being added to this mailing list, or would like to distribute information to the list, please contact the CIC European Initiative General Secretary, Christina Rode-Schubert, at the following e-mail address: [christina.rode-schubert@MBE.unisg.ch](mailto:christina.rode-schubert@MBE.unisg.ch)

#### **6. SOURCE OF SUPPLY THE STANDARD**

POCT1-A2 is an approved standard of the CLSI (former NCCLS - National Committee of Clinical Standards) and can be ordered as follows:

Document name: POCT1-A Point-of-Care Connectivity; Approved Standard (2001)  
*Note: The standard is distributed either on CD-ROM or (via web) as electronic document (PDF)*

Order by mail: Clinical and Laboratory Standards Institute  
 940 West Valley Road, Suite 1400  
 Wayne, PA 19087-1898, United States

Order by phone: USA (+01) 610 - 688 1100  
 or Toll Free ~ 1.877.447.1888 (US only)

Order by fax: USA (+01) 610 - 688 6400

Order by email: orders@clsi.org

Order via the web: [www.clsi.org](http://www.clsi.org)  
 (payment with credit card only)

Cost: CLSI Members: US \$ 100.- Non-members: US \$150.-  
 Plus shipping and handling (for CD-ROM)

## 7. ATTENDEES

Thirty-five individuals from twenty-four organizations registered to attend the CIC MEDICA 2004 Meeting. The following table provides a detailed list of attendees.

**Table 3: CIC MEDICA 2005 Attendees**

| Attendee         | Organization        | Country       |
|------------------|---------------------|---------------|
| Allan Soerensen  | Radiometer          | Denmark       |
| Andreas Kassner  | VHITG               | Germany       |
| Andreas Moe      | Hemocue             | Sweden        |
| Andreas Staubert | Roche Diagnostics   | Germany       |
| Andy Quintenz    | BIOSITE             | France        |
| Carmina Pascual  | Roche Diagnostics   | Swiss         |
| Chris Morgan     | PA Consulting Group | United Kindom |



|                         |                         |          |
|-------------------------|-------------------------|----------|
| Christian Heller        | A. Menarini Diagnostics | Germany  |
| Christina Rode-Schubert | BE Consult              | Germany  |
| Cyrille Timwo Monthe    | Stryker Navigation      | Germany  |
| Dirk Boecker            | Pelikan Technologies    | USA      |
| Eija Sandholm           | Orion Diagnostica       | Finnland |
| Fabrizio Mastrantonio   | A. Menarini Diagnostics | Italy    |
| Fraterman               | BNLD                    | Germany  |
| Georg Hoffmann          | Trillium                | Germany  |
| Hans Guenther Wahl      | Klinikum Lüdenscheid    | Germany  |
| Heiko Ziervogel         | HCx Consulting          | Germany  |
| Jürgen Feuerstein       | A. Menarini Diagnostics | Germany  |
| Jürgen Richter          | Roche Diagnostics       | Germany  |
| Karl-Lidwig Dronka      | Bayer Health Care       | Germany  |
| Kent H. Rokkjær         | Bang & Olufsen          | Denmark  |
| Kenth Svanberg          | Hemocue                 | Sweden   |
| Klaus Deuter            | LRE Medical             | Germany  |
| Mark Mattingley-Scott   | IBM                     | Germany  |
| Michael Groves          | Responsebio             | Canada   |
| Michael Hock            | Fresenius Kabi          | Germany  |
| Per Molgaard Pedersen   | Bang & Olufsen          | Denmark  |
| Peter Lupp              | TU München              | Germany  |
| Ralf Kleyer             | A. Menarini Diagnostics | Germany  |
| Robert Uleski           | ILC                     | USA      |
| Stefan Kreber           | Fresenius Kabi          | Germany  |
| Steve Miller            | Roche Diagnostics       | Austria  |
| Thomas Norgall          | Fraunhofer Institut     | Germany  |
| Timo Särme              | Orion Diagnostica       | Finnland |
| Wolfgang Janschitz      | Roche Diagnostics       | Austria  |