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

The Universal Standard for Point of Care Connectivity

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### **CIC MEDICA 2004 Meeting Summary**

November 25<sup>th</sup>, 2004 Düsseldorf, Germany



This memo summarizes the essential details of the Point of Care Connectivity Industry Consortium - European Initiative MEDICA 2004 Meeting, held November 25<sup>th</sup> on the Roche boat "MS Viking Sky" in Düsseldorf.

## 1. EXECUTIVE SUMMARY

The European Initiative of the further US Connectivity Industry Consortium (CIC) held its fifth major briefing meeting for Point-of-Care organizations during MEDICA on November 25, 2004 in Düsseldorf, Germany. The meeting was held in conjunction with the MEDICA 2004 conference on one of the boats chartered by Roche Diagnostics. Twenty-nine individuals representing twenty-one international point-of-care (POC) organizations attended this meeting.

During MEDICA 2000, the CIC launched a European Round Table (ERT) with the goal of involving European users and vendors in the developing efforts and to internationalize the standard.

In 2001 the ERT was renamed to "European Initiative" (EI). The EI reported during the second MEDICA meeting on its progress and solicited further input from international POC users. Also, Thomas Norgall investigated the possibility of involving the Fraunhofer Institute in developing prototype or demonstration implementations of the CIC protocols.

The Fraunhofer Institute realized their plan and presented a POCT-1A Demonstrator, showing communication between POCT-Device and POCT Observation Reviewer at the third EI meeting during MEDICA 2002.

In 2001 the Connectivity Industry Consortium (CIC) achieved its goal to develop a standard for point-of-care (POC) connectivity based on existing IEEE and HL7 standards and on specifications developed by the CIC.

The NCCLS has updated and approved the originally proposed AUTO6-P draft standard by the end of 2001. 'POCT1-A' refers to the standard published by NCCLS. HL7 and IEEE have published relevant corresponding specifications to POCT1-A in their own norms.

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 had to overcome by major 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. To speed up CEN ISO/IEEE adoption, the original POCT1-A standard will be published using a fast track process in ISO TC 215. First formal results are expected for early 2005. Results from ongoing POCT1-A-related NCCLS modification and extension efforts will be reflected in future revisions of the standard.

The EI meeting during MEDICA 2004 provided information upon the status quo of the POCT1-A standard internationalization and implementation process. Furthermore perspectives, projects and activities of the POC standard development in the US were presented during the workshop. Apart a new quality guideline of the German Medical Association was discussed as an important incentive for the standard implementation.

Christina Rode-Schubert, CIC Secretary General, opened the meeting. She gave a brief review on CIC EI history. And she introduced a new Quality Assurance Guideline („RiliBÄK") issued by the German Medical Association ("GMA"). The guideline aims at a high-level quality control for point-of-care testing devices. It is required that results from POC device measurements are subject to quality control and documentation procedures equivalent to related practices performed in clinical labs. To minimize costly human documentation and communication overhead, remote POC devices have to be connected to clinical networks for lab quality control as well as for comprehensive documentation. POCT1-A is the adequate and practicable connectivity standard to be used in such applications. Hence it is expected that this guideline will be a major driver for POCT1-A use and product implementation.

We would like to take this opportunity to thank Jeff DuBois from Nova Biomedical, representative of the NCCLS and a founding member of the CIC, for all his contributions to point-of-care connectivity through the years. It was with great regret that we heard at the 2004 Medica that this would be his last meeting. Please join us in thanking Jeff for all of his contributions to POC connectivity and wishing him the best in his future endeavours.

During this meeting, Jeff gave a short presentation on POCT in the US. He introduced the two new projects of the NCCLS and reported on the status of the proposed Joint Activities between the AACC ILC and the NCCLS.

Going forward, Dr. Lou Dunka will assume Jeff's role as chair of the NCCLS POCT Area Committee and as a member of the CIC EI. Please join us in welcoming Lou to these new roles, and to future Medica meetings.

On a related note, as of January 2005, the NCCLS changed its name to the "Clinical Laboratory and Standards Institute", CLSI.

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.

Next, Andreas Staubert, Roche Diagnostics GmbH Mannheim, represented the Diagnostic Industry. He draw a picture of the different POCT-1A implementation activities at Roche Diagnostics. Roche intends to implement the standard in the new generation of NPT devices and Roche hospital IT products will provide full support for the POCT1- A standard.

At the same time he brought up detailed technical questions who came up during the implementation process. He suggested that setting up a chat group on the CIC EI website to discuss specific questions and to generate and provide "best practice" would be an expedient solution.

Heiko Ziervogel, HCx Consulting Berlin, gave a speech on POC in Europe focusing on user needs. He introduced the POCT Working Group of the German Society of Clinical Chemistry (DGKL). Their mission is to enable and enhance the successful adoption for POC. The POC Working Group has held its first event during MEDICA 2004 and is going to establish a regulatory meeting at the Düsseldorf congress.

It was decided that the CIC European Initiative will cooperate with the German POC Working Group to strengthen and promote the topic POC at future MEDICA events in Düsseldorf.

Albrecht Bechmann, Cooperation of LEO-IMPACT CONSULTING GmbHx Berlin, made an effort to present the economical benefits of a POCT standard.

Georg Hoffmann, Trillium GmbH Grafrath, announced the POCT Communication Standard as "The first step towards the fourth generation of laboratory systems". The new generation will be network-based "boundary-less laboratories". He emphasized that this architecture demands an open and cost-efficient POCT standard.

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

Please find all presentations as attached and on the NEW 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 on European/international levels to educate especially users on how implementation of the POCT1-A standard can establish cost-effective multi-vendor connectivity. This issue was already part of the CIC sun-set strategy and is written down in the "Sunset Transition Plan". Funds are set aside to continue supporting the CIC EI.

In addition the discussion demonstrated, that through the implementation process of the standard technical questions arise, which need to be discussed and solved. Therefore, corresponding means for information exchange ("chat room") were considered to be set up on the CIC EI web page by the Fraunhofer Institute.

The CIC EI will keep actively involved in the further development of global POCT standards. In this regard, its mission is to particularly articulate the European users' perspective. 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 considerations.

In the US, Bob Uleski leads a new initiative resulting from AACC 2004 conference considerations aiming at the development of common test vehicles for POCT1-A. Representatives of the CIC EI are involved in the preparation process for such a development, which was agreed to preferably utilize already existing related implementations, and in particular the European work from Fraunhofer IIS which was already presented at the 2002 CIC EI MEDICA event.

## 2. PRESENTATIONS

The following presentations are available on the CIC EI website.

- Christina Rode-Schubert - BE Consult Heidelberg, Secretary General CIC Europe: A Brief CIC History - the US and European Movement. And the German „RiliBÄK“ Guideline - a new Incentive.
- Jeff DuBois - Nova Biomedical USA, NCCLS Representative: POCT in the US / NCCLS - New Projects and AACC ILC Proposed Joint Activities.
- Thomas Norgall - Fraunhofer-Institut für Integrierte Schaltungen IIS-A Erlangen, CIC Europe Chairperson: POCT1-A Approval in ISO, CEN, DIN - Status Quo - Obstacles and Drivers
- Andreas Staubert - Roche Diagnostics GmbH Mannheim: POCT-1A Activities at Roche Diagnostics.
- Heiko Ziervogel - HCx Consulting: POC In Germany - Implementation and Best Practice - the Perspective of the POCT working group of the German Society of Clinical Chemistry (DGKL).
- Albrecht Bechmann - Cooperation of LEO-IMPACT CONSULTING GmbH Berlin: Economic benefits of a POCT standard.

- Georg Hoffmann - Trillium GmbH Grafrath: POCT Communication Standard - The first step towards the fourth generation of laboratory systems.
- Thomas Norgall - Fraunhofer-Institut für Integrierte Schaltungen IIS-A, Erlangen, CIC Europe Chairperson, Next Steps Europe (Part of the Meeting Minutes).

### 3. PARTICIPANTS

Approximately thirty individuals representing twenty-one different organizations attended the meeting, as summarized in the following two tables.

**Table 1: Attendance, by Country**

COUNTRY	ATTENDEES
Australia	2
Denmark	1
Finland	4
Germany	15
Netherlands	2
Canada	1
UK	1
USA	3
<b>Total</b>	<b>29</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	14	8
Information Technology	1	1
User	4	3
Consultant	6	5
University & Institute	2	2
Others	2	2
<b>Total</b>	<b>29</b>	<b>21</b>

## 4. NEXT STEPS EUROPE

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

The Fraunhofer Institute will implement extensions of the CIC EI internet page to offer appropriate means for information exchange and to discuss technical requirements among the POCT1-A users ("chat room") ASAP. In addition technical questions arising from standard implementation efforts shall be discussed - and hopefully sufficiently answered - on the CIC EI website.

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

The CIC EI will continue 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 and presents ongoing and further POCT development activities during MEDICA 2005.

The CIC EI strives for POCT to become a main topic during MEDICA in Düsseldorf. First step to this goal is a cooperation between the CIC EI and the POCT Working Group of the German Society of Clinical Chemistry and Laboratory Medicine (DGKL) during MEDICA 2005. It is intended to use the same media to jointly announce corresponding meetings before MEDICA. These events will take place at the same day - presumably Thursday. And we'll try to bring the meeting locations closely together.

## 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-A is an approved standard of the 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.nccls.org](http://www.nccls.org)  
or  
[www.clsi.org](http://www.clsi.org)  
(payment with credit card only)

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

## 7. ATTENDEES

Twenty-nine individuals from twenty-one organizations registered to attend the CIC MEDICA 2004 Meeting. The following table provides a detailed list of direct and indirect attendees.

**Table 3: CIC MEDICA 2004 Attendees**

Attendee	Organization	Country
Albrecht Bechmann	Kooperationspartner der LEO IMPACT CONSULTING GmbH	Germany
Andreas Staubert	Roche Diagnostics GmbH	Germany
Bernd Schleimer	Radiometer Copenhagen	Germany
Chris Morgan	The Technology Partnership plc	UK
Christian Kargl	Roche Diagnostics GmbH	Austria
Christina Rode-Schubert	Business Engineering Consult	Germany
Doug Broadfoot	Response Biomedical Corp.	Canada
Dr. Fraterman	St. Bernward Krankenhaus Hildesheim	Germany
Eric Kamp	Balance	Netherlands
Eva Raschke	BRAHMS AG	Germany
Frank Thederahn	Alphagen GmbH	Germany
Georg Hoffmann	Trillium GmbH Grafrath	Germany

Gunter Freiherr von Leoprechting	LEO-IMPACT CONSULTING GmbH	Germany
Heiko Ziervogel	HCx Consulting Berlin	Germany
Jeff Dubois	NCCLS / Nova Biomedical Waltham MA	USA
Joanne Stephenson	Response Biomedical Corp.	Canada
Joni Wright	Response Biomedical Corp.	Canada
Joshua Guthermann	Boston Biomedical Consultants, Inc.	USA
Jurgen Lensvelt	Balance	Netherlands
Klaus Kjoller	Radiometer Copenhagen	Denmark
Laura Strandberg	Orion Diagnostica	Finland
Markku Roiha	GE Healthcare Clinical Systems Helsinki	Finland
Mathias M. Müller	Institute of Laboratory Diagnostics	Austria
Michael Hock	Fresenius Kabi Deutschland GmbH	Germany
Michaela Miller	Boston Biomedical Consultants, Inc.	USA
NN	Alphagen GmbH	Germany
Pekka Riepponen	Orion Diagnostica	Finland
Raimo Majuri	Orion Diagnostica	Finland
Thomas Norgall	Fraunhofer-Institute IIS-A Erlangen	Germany