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

The Universal Standard for Point of Care Connectivity

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### **CIC MEDICA 2003 Meeting Summary**

November 20<sup>th</sup>, 2003 Düsseldorf, Germany



This memo summarizes the essential details of the Point of Care Connectivity Industry Consortium (CIC) MEDICA 2003 Meeting, held November 20 on the Roche boat "MS Viking Sky" in Düsseldorf. Approximately thirty attendees from throughout Europe joined representatives of the CIC and European standardization organizations for this important meeting on Europe-specific issues involving point-of-care connectivity.

## 1. EXECUTIVE SUMMARY

The European Initiative of the further US Connectivity Industry Consortium (CIC) held its fourth major briefing meeting for Point-of-Care organizations during Medica on November 20, 2003 in Düsseldorf, Germany. The meeting was held in conjunction with the MEDICA 2003 conference on one of the boats chartered by Roche Diagnostics. Twenty-nine individuals representing twenty-three 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 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.

By the end of 2002 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 approved the standard last year. 'POCT1-A' refers to the standard published by NCCLS. HL7 and IEEE have published relevant components of the POCT1-A specification in their own norms. The ongoing process of adopting POCT1-A as formal international ISO and CEN standard is expected to provide first results soon.

The EI meeting during MEDICA 2003 provided these information upon the status quo of the POCT1-A standard internationalization and implementation. Furthermore perspectives and activities of the POC standard development in the US were discussed during the workshop.

Christina Rode-Schubert, CIC Secretary General, opened the meeting. She presented the objectives and the agenda of the meeting. Furthermore she gave a brief review on CIC history and introduced the next horizon for POC standard development.

Jeff DuBois from Nova Biomedical, Representative of the NCCLS and member of the CIC community was so kind to give a spontaneous presentation on the future of "Connectivity Standards for POC Testing" activities from the NCCLS perspective.

Thomas Norgall, Erlangen Fraunhofer-Institut für Integrierte Schaltungen, then updated attendees on the progress regarding user acceptance, approval process of the standard by DIN, CEN and ISO, and related activities according the CIC Europe perspective.

Next, Heiko Ziervogel, HCx Consulting, mirrored the user perspective, asking: "POCT in Europe - What matters most?". His answer illustrated the differences between the perspectives of vendors and users/customers, who have a focus on data filtering ("is it mission critical?") and presentation.

René Spronk from Ringholm Integration Consulting presented "IHE - Integrating the Healthcare Enterprise" focusing on "The IHE Lab Profile". Further lab- and POCT-related activities are on the IHE agenda for 2004.

Juan Fernandez from Roche Diagnostics Barcelona presented "The Hospital IT vision of Roche Diagnostics", announcing that Roche Diagnostics will be implementing the CIC standard.

Finally, Dr. Hilmar Luthe, University of Göttingen, presented "European Expectations and Experiences with the Integration of POCT Analysis Systems in LI Systems", where he emphasized the user perspective again.

Please find attached all presentations.

In the discussion the attendees agreed again that there is still a lot of work left to be done on the European/international level to educate especially users on how the implementation of the POCT1-A standard supports 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.

Furthermore the discussion showed that most important is to step into the future and mirror the next horizon for POC standard development.

The EI is deeply interested in participating 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, Sean Field, Roche Diagnostics, has succeeded Jeff Perry as the AACC POCT ILC chair for 2004. Sean's focus for 2004 will be implementation of the two main next-step initiatives identified in 2003:

1. Developing and releasing a common industry-wide test vehicle for the POCT1-A standard
2. Architecting and designing a plug-and-play implementation of POCT1-A

During the Medica Meeting 2004, progress toward these ILC initiatives will be presented to the EI members.

## 2. PRESENTATIONS

The following presentations are attached to the meeting minutes.

- Christina Rode-Schubert - BE Consult, Secretary'General CIC Europe: CIC History, Objectives (Action Items) and Agenda
- Jeff DuBois - Nova Biomedical and NCCLS Representative: Connectivity Standards of POC Testing
- Thomas Norgall - Fraunhofer-Institut für Integrierte Schaltungen IIS-A, Erlangen, CIC Europe Chairperson: CIC Europe - Status Quo of the Standard Approval in DIN, CEN and ISO
- Heiko Ziervogel - HCx Consulting: POC in Europe - What matters most? User Perspectives
- René Spronk - Ringholm Integration Consulting: IHE Integrating the Healthcare Enterprise - The IHE Lab Profile
- Juan Fernandez - Roche Diagnostics Barcelona: The Hospital IT vision of Roche Diagnostics
- Hilmar Luthe - University of Göttingen: European Expectations and Experiences with the Integration of POCT Analysis Systems in LIS
- Thomas Norgall - Fraunhofer-Institut für Integrierte Schaltungen IIS-A, Erlangen, CIC Europe Chairperson, Next Steps Europe and Closing

## 3. PARTICIPANTS

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

**Table 1: Attendance, by Country**

COUNTRY	ATTENDEES
Australia	1
Czech Republic	2
Denmark	1
Finland	3
France	1
Germany	13
Netherlands	2
Spain	1
Sweden	1

UK	2
USA	2
<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	9
Information Technology	3	3
User	4	3
Consultant	4	4
University & Institute	3	3
Others	1	1
<b>Total</b>	<b>29</b>	<b>23</b>

#### 4. NEXT STEPS EUROPE

The CIC EI will be renamed again. The new name - like Connectivity Initiative Europe (CIE) - will be promoted ASAP.

The former CIC website is taken over by the EI. It will be maintained as a resource for implementation aids, information updates, contacts and best practices.

The EI will continue the internationalization push by some world-wide marketing and outreach activities (e.g. coordinate articles, trade shows).

The EI focuses on the future and presents further POCT development activities during Medica 2004.

#### 5. THE CIC EI NETWORK

A mailing list has been established to facilitate communication between individuals interested in European issues surrounding standardization of point-of-care connectivity. 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

The POCT1-A is an approved standard of the NCCLS (National Committee of Clinical Standards) and can be ordered as follows.

Name: POCT1-A Point-of-Care Connectivity; Approved Standard (2001)  
*Note: The standard is distributed on CD-ROM*

Order by mail: **NCCLS**  
 940 West Valley Road, Suite 1400  
 Wayne, PA 19087-1898, United States

Order by phone: USA (+01) 610 - 688 1100

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

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

Cost: NCCLS Members: US\$ 65.- Non-members: US\$105.-  
*Plus shipping and handling*

## 7. ATTENDEES

Twenty-nine individuals from twenty-three organizations registered to attend the CIC Medica 2003 Meeting. The following table provides a detailed list of direct and indirect attendees.

**Table 3: CIC Medica 2003 Attendees**

Attendee	Organization	Country
Arno Fraterman	BNLD & Labormedizin Dortmund	Germany
Bayarse-Hamilton (?)	IMCOMEGE (?)	UK
Christina Rode-Schubert	Business Engineering Consult Heidelberg	Germany
Daniel Diesel	Roche Diagnostics Graz	Austria
Doug Hirst	Bradford Royal Infirmary	UK
Georg Hoffmann	Trillium GmbH Grafrath	Germany
H. Mollard	HC Consultant	France

Hans-Martin Lauer	B. Braun Medizinelektronik Puchheim	Germany
Harm Overbeek	Vital Scientific Spankeren	Netherlands
Heiko Ziervogel	HCx Consulting Berlin	Germany
Hilmar Luthe	University of Göttingen	Germany
Horst Merkle	Roche Diagnostics Mannheim	Germany
Jan L. S. Dols	Academic Medical Center / University of Amsterdam	Netherlands
Jeff DuBois	NCCLS / nova biomedical Waltham MA	USA
Jeff Perry	Philips Medical Systems	USA
Joachim Dudeck	GMDS Advisory Board Gießen	Germany
Juan Fernandez	Roche Diagnostics Barcelona	Spain
Klaus Kjoller	Radiometer Medical Copenhagen	Denmark
Laura Strandberg	Orion Diagnostica Espoo	Finland
Ludek Taborsky	Hospital Na Homolce / Dep. Of Clinical Biochemistry Prague	Czech Republic
Ossi Hiltunen	Orion Diagnostica Espoo	Finland
Paul Mundill	Orion Diagnostica Espoo	Finland
Rene J. Spronk	Ringholm Integration Consulting Essen	Germany
Reyninger	Hospital Na Homolce / Dep. Of Clinical Biochemistry Prague	Czech Republic
Roman Rosenkranz	Conwerx Technology Wildau	Germany
Rune Björkmann	Pharmacia Diagnostics Uppsala	Sweden
Stephan Letschert	HiM Health Information Management Bad Homburg	Germany
Thomas Norgall	Fraunhofer-Institute IIS-A Erlangen	Germany
Zlotan Takacs	Philips Medical Systems Boeblingen	Germany