

3rd International Symposium

IT Networks incorporating Medical Devices in Hospitals and Medical Facilities

Forum for Responsible Organizations and Medical Devices Manufacturers for
an interdisciplinary Dialogue of all Partners within the Healthcare Community

March, 17th-18th, 2011, Husa President Park Hotel,
Brussels, Belgium



Kindly supported by:

DGBMT

DKE
VDE DIN

-HKG-



Organizers:

VDE
INSTITUTE

PROSYSTEM AG
International Healthcare Consulting

Target audience

The Symposium is addressed to decision makers from hospitals and Healthcare Delivery Organizations (HDO's) like medical and administrative directors, CIO's and Quality Assurance Managers. It is also dedicated to R&D, Compliance- and Product Managers from Medical Device Manufacturers and providers of IT-Infrastructure and -Services.

Motivation and background

Collaboration between Medical Devices Manufacturers and HDO's is going to face dramatic changes. Backgrounds are basically four megatrends in the Healthcare Industry.

- increasing reliance on software to provide required functionality of Medical Devices
- integrated, user-assembled, medical electrical system.
- evolution of Health Information Technology (HIT) to a patient-centered system using information to improve efficiency, lower costs and deliver better outcomes for patient health.
- increasing use of interconnected medical devices in the homecare environment

All aspects require reliable connectivity and functionality within the HIT-System. Besides providing basic safety and essential performance, medical electrical systems need to incorporate privacy and security solutions that include reasonable administrative, technical and physical safeguards to ensure confidentiality, integrity and availability of patient data while preventing unauthorized or inappropriate access.

In the homecare application the devices need to communicate over public data networks to the healthcare provider's IT network. Remote Access to Medical Devices can exploit further potential to reduce cost of healthcare delivery.

To support the collaboration between HDO's and Manufacturers, on October 27th 2010, IEC the International Standardization Organisation published the International Standard IEC 80001-1 "Application of Risk-Management for IT-networks incorporating Medical Devices; Part 1: Roles, Responsibilities and activities".

After a preparation time of ~10 years, HDO's integrating Medical Devices from different manufacturers into one Medical IT-Network, can now rely on a well defined responsibility sharing with their suppliers. While proactive hospitals already implemented IEC 80001-1 requirements by running pilot projects, the wide majority of the responsible organizations is still in the process to get started now.

To give further guidance and to facilitate the practical implementation of IEC 80001-1, a set of new Technical Reports has been developed. They will be published in summer 2011 after a finalizing meeting in Best, Netherlands just days before the symposium. The outcome of this meeting will be introduced during the course of the symposium as well as the latest developments addressing:

- Step by Step Risk Management of Medical IT-Networks; Practical Applications and Examples
- Guidance for the communication of medical device security needs, risks and controls
- Guidance for wireless networks
- Health Delivery Organization Implementation Guidance (Draft status only!)

The 3rd International Symposium on "IT Networks incorporating Medical Devices in Hospitals and Medical Facilities" will be held on March, 17th-18th, 2011 in Brussels, Belgium at the renowned Huis President Park Hotel. Speakers will be key representatives from the EU-Commission, COCIR, EU hospitals, Medical Device Manufacturers and International Standardization Organizations.

All presentations will be held in English.

Host and Organizers

Organizers are the VDE Institute, a notified Body for Medical Devices and Quality Management Systems, in cooperation with PROSYSTEM AG, an established, international Consulting company for Medical Devices with focus on Risk Management and Software Security.

Program Day 1: March 17th, 2011

Registration open from 9:30 a.m.

10:30 a.m. **Welcome Coffee Break**

■ **Session I – Keynotes**

11:00 a.m. Welcome Address, Objectives and course of the Symposium
Michael Bothe, Oliver Christ

11:10 a.m. The new COCIR IT-Strategy and expectations from
International Standardization Bodies
Nicole Denjoy, COCIR

11:40 a.m. Trends and Objectives of European Regulation related to Medical Devices
& IT-Networks
Speaker from EU Commission (to be confirmed)

12:10 p.m. Demanding needs of General Hospitals – a Plug & Play Credo –
Julian Goldman, Massachusetts General Hospital

12:50 p.m. Question & Answers
Moderation: Oliver Christ

01:00 p.m. **Lunch Break**

■ **Session II – The new IEC 80001-1 Series**

02:15 p.m. The IEC 80001 series – “Go live” for pilot studies
Todd Cooper, Co-Convener JWG7

02:40 p.m. Medical IT Network Security- Guidance for the communication
of medical device security needs, risks and controls
Nick Mankovich, Philips Healthcare, USA

03:05 p.m. Wireless Connectivity for Medical Devices: Guidance & Best Practices
based on IEC TR 80001-2-x Wireless Wi-Fi Alliance White Paper
Phil Raymond, Wi-Fi Alliance

03:30 p.m. Benefits of an IEC 80001-1 compliant Medical IT-Network
Juergen Stettin; University of Applied Science HH

03:55 p.m. Question & Answers
Moderation: Michael Bothe

04:00 p.m. **Coffee Break**

■ **Session III – Risk-Management as a strategy**

04:30 p.m. Step by Step Risk-Management an IEC 80001-1 Guidance approach
Karen Delvecchio, GE

04:55 p.m. Managing Risk in Medical IT Networks: a Hospital perspective
to improve safety, security and effectiveness
Martin Janssen, Consultant,NL

05:20 p.m. Clinical Risk Management – seen from an service integrator's point of view
Martin Ellis, BT

05:45 p.m. Question & Answers
Summary of Day 1
Moderation: Oliver Christ

6:30 p.m. **Transfer to Diamant Building**

7:00 p.m. **Welcome Reception & Dinner at COCIR**

Program Day 2: March 18th, 2011

Registration open from 8:00 a.m.

■ Session IV – Economical Impacts & Healthcare

- 09:00 a.m. Welcome Address, Introduction of Day 2
Michael Bothe, Oliver Christ
- 09:10 a.m. Healthcare (IT, MD) as economical growth factor European & Worldwide – a commission viewpoint
COCIR/ EU-Commission (to be confirmed)
- 09:45 a.m. Medical Device Integrator - A new key competence in Hospitals
Michael Bothe, VDE-Institute
- 10:15 a.m. Medical IT Networks in Hospitals - The FDA position -
N.N.
- 10:40 a.m. Question & Answers
Moderation: Oliver Christ
-

10:45 a.m. **Coffee break**

■ Session V – Software as Medical Device

- 11:15 a.m. Strategic Up-date from the European SAMD Group
N.N.
- 11:40 a.m. Changes to IEC 62304 – software lifecycle processes – and up-coming new standards
Patty Krantz, Medtronic Inc., USA, Convener of JWG3
- 12:05 p.m. Inhouse-Solutions – practical experience with Software as Medical Device
Jochen Kaiser; Uni Erlangen
- 12:30 p.m. Software Medical Devices - Impact of Regulation
Dr. Georg Heidenreich, Siemens, COCIR (to be confirmed)
- 12:55 p.m. Question & Answers
Moderation: Michael Bothe
-

01:00 p.m. **Lunch break**

■ Plenum VI – Outlook & Future Perspectives

- 02:00 p.m. Outlook: Up-coming Technical Reports as Guidance for IEC 80001-1 implementation
Sherman Eagles
- 02:30 p.m. Why could safe & secure Medical IT-Networks enable an economical growth in the Healthcare Market 2012?
Oliver Christ
- 03:00 p.m. Closing Remarks - Mark your calendar
Michael Bothe
- 03:15 p.m. End of the Symposium

Location

The Symposium will take place in Brussels, Belgium at renowned HUSA President Park Hotel. The newly renovated Hotel is located in the brand new Rogier Convention District, just a stone throw away from the North Station and 2 kilometres away from the famous "Grand Place", UNESCO's universal patrimony.

Behind its sumptuous French-stone facade, guests will experience over 6 floors, a universe of brightness and comfort. The gorgeous garden at the back of the hotel makes this place a unique setting, an oasis of greenery in the heart of the Capital of Europe.



For participants of the symposium we have blocked superior single rooms at a discounted rate of € 99.00 per person and night including breakfast. Please make your own individual booking under the reference symposium2011 before Feb., 21st 2011 in advance to take benefit of the discount. The rooms offers new wooden floors and furniture, flat screen, mini bar, rain shower & WIFI.

Husa President Park Hotel
Boulevard du Roi Albert II, 44
B-1000 Brussels • BELGIUM
Tel.: +32 (0)2 203 20 20
Fax: +32 (0)2 203 24 40
info.president@husa.es
www.husapresidentpark.com

The following benefits are included in the participant package:



- Admission to all sessions
- Lunch for both days
- Reception and dinner at Diamant Building
- Beverages and snacks during breaks
- Proceedings in pdf. format from dedicated Server

Registration and Booking

The event is organized by VDE Testing and Certification Institute in cooperation with PROSYSTEM AG, Hamburg.

After receipt of the registration, participants will receive an invoice with the bank account details via mail. After receipt of payment, the participants will get a confirmation which has to be presented at the sign-in desk before the event starts.

In case a written cancellation will be sent 14 days prior to the event, the termination is free of charge. Thereafter the total fee is due. In case of not showing up or cancellation at the day of the event, the total fee is due. The registration can be delegated to another person at any time.

The organizer reserves the right to terminate the event before it has been started. In that case, paid fees will be reimbursed. Indemnification is excluded.

Please use our Internet-Portal for comfortable booking or credit card payment:

<http://www.vde-medtech.com/symposium2011>

or please fill out the form below and send it to one of the following contacts by E-Mail or Fax.

VDE Prüf- und Zertifizierungsinstitut GmbH

Testing and Certification Institute

Dipl.-Ing. Michael Bothe, MBA

Merianstraße 28

63069 Offenbach / Main

Tel.: +49 69 8306-220

Fax: +49 69 8306-777

michael.bothe@vde.com

PROSYSTEM AG

Sima Niknafs

Beim Strohhaus 27

20097 Hamburg

Tel.: +49 40 471036-19

Fax: +49 40 471036-20

sima.niknafs@prosystem-ag.com

I herewith make a binding registration for the Symposium on March 17th-18th, 2011

- € 1,249.00 per person € 2,498.00 3 persons (33% discount)
 € 3,747.00 5 persons (40% discount)
VDE members receive a discount of € 100.00 / participant Membership No. _____
- € 899.00 per person for representatives from hospitals, medical care centers, doctor's surgeries and universities

Name

Function

Company / Institution

Phone

Street Address

Fax

City

E-mail

Tax ID Number

Date

Signature

**Name Participant 2*

Function

**Name Participant 3*

Function

**Name Participant 4*

Function

**Name Participant 5*

Function

All prices are net and do not include 21% legal VAT.