

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/symposium2012>

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 Strohhouse 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 1st-2nd, 2012

- € 998.00 per person (Dinner included) € 1,798.00 3 persons (33% discount / Dinner included)
VDE members receive a discount of € 100.00 / participant Membership No. _____
- € 399.00 per person for representatives from hospitals, medical care centers, doctor's surgeries (Dinner excluded)
- € 199.00 for students / two days (Dinner excluded)
- € 99.00 for students / one day (Dinner excluded)

Additional Dinner Option:

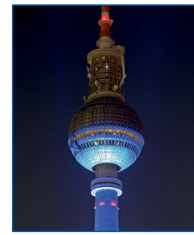
- € 99.00 for Welcome Reception at TV Tower Restaurant including entry fee, Dinner and complementary Beverages. Maximum of 2 Persons / Booking.
Limited seats available. Registrations will be accepted in rank order.

Name	Function
Company / Institution	Phone
Street Address	Fax
City	E-mail
Tax ID Number	
Date	Signature
*Name Participant 2	Function
*Name Participant 3	Function

All prices are net and do not include 7% legal VAT.

Location

The Symposium will take place in Berlin, Germany, at the Central Campus of Charité Hospital. Conveniently located in the heart of the city, the campus is within walking distance from Central Station and well serviced by express bus from Berlin Tegel Airport. The prestigious Charité is one of the biggest University Hospitals in Europe and with its charming merge of Tradition and innovation the perfect environment for this entire event.



This year's motto of the Welcome Reception and Dinner is "Wireless Networking – Technical and Interpersonal". No location in Berlin can be better to symbolize these two aspects than Berlin TV Tower at Alexanderplatz. Its Circulating Restaurant at 208 m above ground gives an ideal surrounding to enjoy the scenery of Germany's Capital City during sundown and do intense Networking within the community.

Accommodation

In order to allow the participants to make their own choice, accommodation is not included into the Symposium Fee. Please find below Hotel recommendations ranked by distance. The more distant options can be reached easily by public transport available within walking distance. Please make your individual arrangements with the hotel. An early booking is highly recommended to receive favorable rates.

Mikon Eastgate Hotel ***
A = 0,45 Km, B = 2,5 Km
Hessische Str. 10, 10115 Berlin (Mitte)
Fon: +49 (0) 30 40054090
Fax: +49 (0) 30 400 540 - 92
E-Mail: info@mikonhotels.com
Single Room starting at € 50,-

Best Western Hotel Berlin Mitte ***
A = 0,6 Km, B = 2,3 Km
Albrechtstr. 25, 10117 Berlin (Mitte)
Fon: +49 (0) 30 5268000
Fax: +49 (0) 30 52680099
E-Mail: info@berlin-mitte.bestwestern.de
Single Room starting at € 79,-

Mercure Hotel Berlin City ***
A = 0,6 Km, B = 2,5 Km
Invalidenstraße 38, 10115 Berlin (Mitte)
Fon: +49 (0) 30 308260
Fax: +49 (0) 30 826100
E-Mail: h5341@accor.com
Single Room starting at € 89,-

Ramada Hotel Berlin Mitte ****
A = 0,8 Km, B = 2,2 Km
Chausseestr. 118-120, 10115 Berlin (Mitte)
Fon: +49 (0) 30 2787550
Fax: +49 (0) 30 278755 - 550
E-Mail: berlin.mitte@ramada.de
Single Room starting at € 80,-

A = Distance Hotel/ Symposium, B = Distance Hotel/ TV-Tower Event

Benefits & Additional Values

Participants will benefit from the following values:

- Lunch, Snacks and Beverages on both days
- Symposium proceedings from dedicated server
- Great Network opportunity with international experts on MD & ICT Technologies
- Unique Dinner event at the Berlin Television Tower Restaurant (March 1st, optional)
- First-hand up-date information on the latest Requirements for Medical Device Software
- All relevant documents for a pilot implementation of IEC 80001-1
- FREE access to FOUR follow-up Workshops to support Pilot-projects during 2012

3rd International Symposium

IT Networks incorporating Medical Devices & Software

Key's to Success: Safety, Effectiveness and Data/System Security

March, 1st-2nd, 2012, Charité Central Campus,
Luisenstrasse 64, Berlin, Germany



Kindly supported by:

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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

The expectation of all modern societies around the globe is the availability of safe and effective health services. 80% of all upcoming Innovation in Health Information Technologies (HIT) and Medical Devices (MD) is related to:

- Software in Medical Devices
- Software as Medical Device or
- Software for IT-Networks incorporating Medical Devices

All aspects require reliable functionalities for an IT based communication. Devices for home healthcare markets furthermore need a capability to communicate even over (unreliable) public data networks in a safe, secure and effective way.

Besides providing Basic Safety and Essential performance (IEC 60601-1, 3rd ed.) Medical Electrical Systems need to incorporate privacy and security requirements to ensure confidentiality, integrity and availability of clinical data while preventing unauthorized or inappropriate access.

To support the collaboration between Hospitals (Responsible Organizations, HDO's), Medical Device Manufacturers and IT Providers, in October 2011 the International Standard IEC 80001-1 "Application of Risk-Management for IT-networks incorporating Medical Devices; Part 1: Roles, Responsibilities and activities" has been published as DIN EN 80001-1 / VDE 0756-1 in Germany and becomes therefore an generally accepted code of practice for hospitals. Similar publications have been adopted in U.S. and other EU Member States.

Today Hospitals integrate Software as well as Medical Devices from different vendors (Medical Device Manufacturers, IT Providers and others) into one Medical IT-Network. This can only work reliably, if responsibilities are carefully shared among different suppliers.

If you are excited to learn about

- the differences between Medical Device Software (IEC 62304) and Healthcare Software Systems (IEC 82304-1)?
- a Step by Step Risk Management Approach to implement IEC 80001-1 efficiently into Medical IT-Networks?
- about a practical guidance for the communication of medical device security needs?
- how wireless IT-Networks could be set-up to incorporate Medical Devices safe & effective ?
- which lessons were already learned from implemented Pilot-projects on IEC 80001-1?

then join us at the 3rd International Symposium on "IT-Networks incorporating Medical Devices & Software" on March 1st -2nd, 2012 at the Carit  Central Campus, Luisenstrasse 64 in Berlin, Germany. 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 1st, 2012

	Registration open from 9:30 a.m.
10:30 a.m.	Welcome Coffee
■	Key 1: Society Demands – Safe & effective Medical Devices
11:00 a.m.	Welcome Address, Objectives and course of the Symposium <i>Michael Bothe, Oliver Christ</i>
11:10 a.m.	Keynote I: Demanding needs of General Hospitals for a safe & effective Use of Medical Devices and Health Software <i>Julian Goldman, Massachusetts General Hospital</i>
12:00 p.m.	Keynote II: Interoperability & Security – Future Trends <i>Brian Fitzgerald, FDA, CDRH</i>
12:50 p.m.	Question & Answers <i>Moderation: Oliver Christ</i>
01:00 p.m.	Lunch Break
■	Key 2: IEC 80001-1 – Risk-Management as a strategy
02:15 p.m.	The IEC 80001 series – "Go live" for pilot studies <i>Todd Cooper, Co-Convener JWG7</i>
02:40 p.m.	Step by Step Risk-Management on IEC 80001-1 Guidance approach <i>Karen Delvecchio, GE</i>
03:05 p.m.	Practical Implementation Guideline to IEC 80001-1 by the German Hospital Federation <i>Markus Holzbrecher-Morys, DKG, Berlin</i>
03:30 p.m.	Clinical Risk Management – seen from an service integrator's point of view <i>Dr. Adrian Stavert-Dobson, BT</i>
03:55 p.m.	Question & Answers <i>Moderation: Michael Bothe</i>
04:00 p.m.	Coffee Break
■	Key 3: Medical IT-Networks – Trust by Data & System Security
04:30 p.m.	Benefits of an IEC 80001-1 compliant Medical IT-Network <i>Juergen Stettin, University of Applied Science HH</i>
04:55 p.m.	Medical IT-network Security – Guidance for security disclosure and communication. <i>Nick Mankovich, Philips</i>
05:20 p.m.	Wireless Connectivity for Medical Devices: Guidance & Best Practices based on IEC TR 80001-2-x Wireless Wi-Fi Alliance White Paper <i>Phil Raymond, Wi-Fi Alliance / Philips</i>
05:45 p.m.	Question & Answers Summary of Day 1 <i>Moderation: Oliver Christ</i>
	Networking Event:
6:00 p.m.	Transfer to the TV Tower, Alexanderplatz
6:30 p.m.	Grouping at TV Tower Entrance
7:00 p.m.	Welcome Reception and Dinner at TV Tower Restaurant, 208 m above ground

Program Day 2: March 2nd, 2012

	Registration open from 8:00 a.m.
■	Key 4: Regulatory Trends – Software as a Medical Device
09:00 a.m.	Welcome Address, Introduction of Day 2 <i>Michael Bothe, Oliver Christ</i>
09:10 a.m.	Trends and Objectives of European Regulation related to Medical Devices & Medical Device Software <i>EU Commission, to be confirmed</i>
09:40 a.m.	Regulatory Guidance for Software as a Medical Device – a Notified Body Recommendations – <i>Dr. Jomuna Choudhuri, VDE Institute</i>
10:15 a.m.	The new COCIR IT-Strategy and expectations from International Standardization Bodies <i>COCIR, to be confirmed</i>
10:40 a.m.	Question & Answers <i>Moderation: Oliver Christ</i>
10:45 a.m.	Coffee break
■	Key 5: Pilot Projects – IEC 62304 & IEC 80001-1 in practise
11:15 a.m.	International Regulatory Trends for Medical Software <i>Peter Linders, Philips Healthcare</i>
11:40 a.m.	Changes to IEC 62304 – software lifecycle processes – and up-coming new standards <i>Patty Krantz, Medtronic Convener of JWG3</i>
12:05 p.m.	Inhouse Solutions – practical experience with Risk Management of Medical Networks <i>Jochen Kaiser, Uni Erlangen</i>
12:30 p.m.	Applying IEC 80001-1 to Hospital Bed Communication Experiences from a Pilot Study in Krefeld, Germany <i>Peter Rings, Linak; Lukas Vogler, Prosystem AG / Mediarch</i>
12:55 p.m.	Question & Answers <i>Moderation: Michael Bothe</i>
01:00 p.m.	Lunch break
■	Key 6: Outlook & Solutions – Spirit of practical collaboration 2012
02:00 p.m.	How IEC 60601-1 + Amd1 can safeguard Clinical treatment by providing safe & effective Medical Systems <i>Michael Bothe, VDE-Institute</i>
02:30 p.m.	Up-coming new Technical Reports & Standards for Medical Software & MIT-Networks <i>Sherman Eagles</i>
03:00 p.m.	A new Spirit of Collaboration for 2012 How to implement a vision <i>Oliver P. Christ, PROSYSTEM</i>
03:15 p.m.	End of the Symposium