

2<sup>nd</sup> International Symposium

# IT Networks incorporating Medical Devices in Hospitals and Medical Facilities

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

Feb 25<sup>th</sup>-26<sup>th</sup>, 2010, Am Büsing Palais, Offenbach/Main



Kindly supported by:

**DGBMT**

-HKG-

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Quality Consulting Medical GmbH

**ITG** INFORMATION TECHNOLOGY  
SOCIETY WITHIN VDE

**DKE**  
VDE DIN

Organizers:

**VDE**  
INSTITUTE

**PROSYSTEM AG**  
International Healthcare Consulting

## Target audience

The primary target groups are decision makers and responsible managers from hospital operators and addresses assistant, medical and administrative directors as well as CIO's and Quality Assurance Managers. It is also dedicated to R&D, compliance and product managers from Medical Device Manufacturers for hospitals, Medical Care Centers and group practices. Finally it is interesting for suppliers and providers of IT Infrastructure and services.

## Motivation and background

On January 8<sup>th</sup>, 2010 the International Standard Organizations IEC and ISO approved the technical content of IEC 80001-1 "Application of Risk-Management for IT-networks incorporating Medical Devices; Part 1: Roles, Responsibilities and activities". The Standard will be finalized at a joint-International Standardization Meeting on February 22<sup>nd</sup>-24<sup>th</sup> in Offenbach, Germany. Directly following the meeting we would like to share the results with the participants of this symposium.

Motivated from positive feedback received from the participants of the 1<sup>st</sup> Symposium held in March 2009 in Frankfurt and the big interest from hospital operators of IT Networks to improve efficiency and reduce risks in patient treatment, the organizers decided to offer again a platform for exchange of ideas and transfer of knowledge. The coming event has its focus on IT Networks in hospitals from an operator's point of view and will be held on February 25<sup>th</sup>-26<sup>th</sup>, 2010 at the renowned Büsing-Palais in Offenbach/Main, Germany. The location is close to Frankfurt Airport and Central Station and can be conveniently reached by public transport. Speakers will be key representatives from hospitals, Medical Device Manufacturers and International Standardization.

Fostered by the growing integration of Medical Devices in IT Networks and the European Harmonization of International Standards, the philosophy of system responsibility has fundamentally changed. In future the operator of any system with networked Medical Devices will assume responsibility and liability, correspondingly. As a consequence of that, the operator has to envisage new tasks which include an upgrade and the further development of the established Quality and Risk Management System. New competences and job descriptions are required. In future system integration will become an indispensable core competence of a hospital and the basis for cost reduction and competitive advantage. To establish this new competence, a corresponding strategic planning and the establishment of special know-how is essential. The recruiting of qualified professionals in conjunction with tailored seminars and trainings, e.g. the Medical Device Integrator offered by the VDE-Institute, will give assistance to reach this objective. To better safeguard their own interests and in order to identify forward-looking technical and organizational trends in the healthcare sector, a successful mid-term strategy should also contain a higher level of contribution in standardization. To support this objective the organizers have the mission to foster the dialog between the interest groups and join experts from Medical Device Manufacturers, hospital operators and International Standardization.

The focus of the symposium is on Medical IT Networks from the operators point of view. Therefore, latest specifications, status reports and case studies will be comprehensively covered. With this information, decision makers will gain the necessary transparency and scope to successfully implement the requirements. As part of that the symposium serves as a platform for a continuous exchange of ideas with experts of all healthcare disciplines. 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 : February 25<sup>th</sup>, 2010

Registration open from 8:00 a.m.

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## ■ Plenum I – Keynotes

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- 9:00 a.m. Welcome Adress, Objectives and course of the Symposium, Organisational issues  
*Oliver Christ, Michael Bothe*
- 
- 9:10 a.m. Why some IT projects save money and lives and others do the opposite  
*Daniel Grandt*
- 
- 9:45 a.m. Trends and Objectives of European Regulation related to Medical IT-Networks  
*Matthias Neumann\**
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- 10:15 a.m. Plug & Play in Hospitals  
*Julian Goldman*
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## 10:45 a.m. Coffee Break

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## ■ Plenum II – IT-Networks : Status from Hospitals I

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- 11:00 a.m. IT-Networks in Anaesthesia, Status and Potential  
*Jan-Peter Jantzen*
- 
- 11:30 a.m. Challenges and Solutions for Medical IT-Networks in complex full service hospitals  
*Heikki Terioe*
- 
- 12:00 p.m. How to migrate an IT-network into a "Medical IT-Network" in a typical hospital  
*Jochen Kaiser*
- 
- 12:30 p.m. IT-Networks in Orthopedia  
*Joerg A. K. Ohnsorge*
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## 1:00 p.m. Lunch Break

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## ■ Plenum III – Regulatory and Normative Considerations

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- 2:00 p.m. Medical IT Network Security – Guidance for Security in Medical Device connection  
*Nick Mankovich*
- 
- 2:30 p.m. IT Networks in Hospitals – The FDA position  
*Brian Fitzgerald*
- 
- 3:00 p.m. Managing Risk in Medical IT Networks: a Hospital perspective to improve safety, security and effectiveness  
*Martin Janssen*
- 
- 3:30 p.m. Benefits of an IEC 80001-1 compliant Medical IT-Network  
*Juergen Stettin*
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## 4:00 p.m. Coffee Break

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## ■ Plenum IV – Industry Perspective

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- 4:00 p.m. Technology Integration in OR's – an Industry Perspective  
*Clemens Bulitta*
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- 4:30 p.m. Industry Cooperation to reduce risk in Medical IT-Networks  
*Karen Delvecchio*
- 
- 5:00 p.m. Importance of Beta- Testing IEC 80001 in pilot studies  
*Todd Cooper*
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- 5:30 p.m. Summary of the day  
*Oliver Christ, Michael Bothe*
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## 6:00 p.m. Transfer to Frankfurt Main Tower Restaurant

6:30 p.m. Far sight inspirations from the viewing terrace on the 56<sup>h</sup> floor

7:00 p.m. Reception & Dinner "Networking for 80001 pilots"

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\* not yet confirmed

## Program Day 2: February 26<sup>th</sup>, 2010

### ■ Plenum V – Status from Hospitals II

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8:30 a.m.	Introduction of Day 2 <i>Oliver Christ, Michael Bothe</i>
8:35 a.m.	Strategic Aspects of a Hospital Cluster IT-Network <i>Holger Strehlau</i>
9:05 a.m.	PACSystem Integration for a seamless IT Infrastructure in Hospitals <i>Stephan Zidowitz</i>
9:35 a.m.	Chances and Challenges in Health-IT from a users perspective <i>Bjoern Bergh</i>

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### 10:05 a.m. Coffee break

### ■ Plenum VII – Services for Healthcare Providers

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10:20 a.m.	Clinical Risk Management - seen from an service integrator's point of view <i>Martin Ellis</i>
10:50 a.m.	Surgical Cockpit <i>Mathias Hofer</i>
11:20 a.m.	Medical Device Integrator - A new key competence in Hospitals <i>Michael Bothe</i>
11:50 p.m.	Software Medical Devices - Impact of Regulation <i>Eva-Maria Reiter</i>

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### 12:20 p.m. Lunch break

### ■ Plenum VIII – Perspective and Outlook

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1:00 p.m.	How will IEC 80001 benefit Hospitals? <i>Sherman Eagles</i>
1:30 p.m.	IT-Networks in TeleMonitoring Applications <i>Joerg O. Schwab</i>
2:00 p.m.	How IHE Patient Care Devices Profiles complement IEC 80001 <i>Ken Fuchs</i>
2:30 p.m.	Why could safe & secure Medical IT-Networks enable an economical growth in the Healthcare Market 2012? <i>Oliver Christ</i>
3:00 p.m.	Closing Remarks - Mark your calender <i>Oliver Christ, Michael Bothe</i>

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End of the Symposium approx. 3:15 p.m.

### Special "Breakout sessions"

In parallel to the symposium Agenda, stakeholders from IT-Providers, Healthcare Delivery Organisations and Medical Device Manufacturers have the opportunity to create their own individual breakout session based on Topics such as Advanced Technology, Implementation Issues and pilot studies. For further details please contact the organizer.

## Location

The Symposium will take place at renowned Büsing-Palais, Offenbach/ Main, which is conveniently located in the heart of Offenbach and close to Frankfurt Airport and Central Station. Local attractions like the famous Leather Museum and the Main River with the spectacular skyline of downtown Frankfurt are within walking distance. 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 **symposium2010** before Jan., 31<sup>st</sup> 2010 in advance to take benefit of the discount.



Enjoy the tranquillity of the Sheraton Offenbach Hotel next to Büsing Park. It is a superb location with excellent connections to the trade fairs in Offenbach and Frankfurt, the highway and international airport. The 221 rooms, including one suite, are comfortably appointed in a contemporary design. Light-colored, modern furniture and welcoming color combinations convey an impression of warmth. Guests have DSL High-Speed Internet access. The Classic rooms feature adjustable air-conditioning, minibar, voicemail, cable TV, hotel video service, and a large desk.

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[www.sheraton.com/frankfurtoffenbach](http://www.sheraton.com/frankfurtoffenbach)

### The following benefits are included in the participant package:



- Admission to all sessions
- Lunch for both days
- Reception and dinner at spectacular 53<sup>th</sup> Floor Main Tower Restaurant
- Beverages and snacks during breaks
- Proceedings on CD-ROM

## Speakers Profiles



**Björn Bergh, Prof. Dr. med.**, University Hospital Heidelberg. After certification in Diagnostic Radiology, he acted as CIO of the University Hospital Frankfurt before he became Director of IT at the University Hospital Heidelberg. In 2004 appointed as Professor for Medical Information Systems, he was speaker of the German association of university hospitals CIOs and contributed to various funded projects.



**Michael Bothe, Dipl.-Ing., MBA, VDE Institute**, Offenbach. Studied Telecommunication at Technical University Braunschweig. Held various positions in technology-, quality- and innovation management. Since mid 2008 Head of Medical Systems / Processes.



**Clemens Bulitta, MD**, Siemens Healthcare, Erlangen, graduated at University of Heidelberg and worked as a resident at the University Hospitals of Essen and Mainz, as a Research Fellow at Harvard Medical School, Boston before he joined Siemens in 2001. Today he is Head of Clinical Marketing and IT Solutions Surgery in the Business Unit Special Systems.



**Oliver P. Christ, Dipl.-Ing.**, CEO Healthcare of PROSYSTEM AG, Hamburg. He studied Electronic Engineering at Technical University of Darmstadt. 10 years ago he founded PROSYSTEM AG together with his partner Prof. Dr. Juergen Stettin. He chairs various committees of DKE and DIN and worked in international standardization for more than 20 years.



**Todd H. Cooper**, Breakthrough Solutions Foundry Inc., Poway, CA. After graduation at University of Arizona he was a System Architect of Medical Devices. Since 2005 he is Managing Director of BTS. Convenor of various committees, int. al. ISO TC 215 WG7 Health Informatics - Devices.



**Karen Delvecchio, M.S.**, GE Healthcare, Milwaukee, WI, graduated in Electrical Engineering at Marquette University, Milwaukee. After working as a Software Engineer at Delco, she joined GE Healthcare in 1996. Recently she is Lead Systems Engineer for Patient Monitoring Networks developing system-level engineering requirements and member of IEC 62A / JWG7.



**Sherman Eagles, B.A.**, Minneapolis, MN, studied Physics at Macalester College and worked at Medtronic in Software Design. Since his retirement he is partner at SoftwareCPR. He is convenor of a number of committees, including Medical Software (IEC 62304) and IEC 80001.



**Martin Ellis**, BT Health, London, studied General Nursing and Risk Management at City University, London, before he joined London NHS Trust. Since 2007 he is Patient Safety Director at BT Health. His skills span Patient Safety, Audit and Risk Management, Governance and Assurance.



**Brian Fitzgerald**, FDA, Washington, DC studied Engineering in Cardiff, Wales. He worked as Lead Auditor, before he joined UL in 1992. In 2003 he changed to FDA and serves now as Deputy Director of the Electronic and Software Engineering Department.



**Ken Fuchs**, Draeger, Andover, MA, studied at Babson College and Rensselaer Polytechnic Institute. After various positions at Siemens and Draeger, today he is Director Systems and Clinical Engineering and Deputy Chairman of the IHE Group Operation Equipment.



**Julian M. Goldman, Ph.D., MD**, Partners HealthCare System, Boston. After receiving his Ph.D. he worked as a physician at University of Colorado. In 2002 he joined Harvard Medical School and founded the Medical Device "Plug-and-Play" Interoperability Program in 2004. Today he is Medical Director at Partners HealthCare System and chairs ISO TC 121 and Continua Use Case WG.



**Daniel Grandt, Prof., MD**, University of Essen-Duisburg, received his education at the Universities of Essen and UCLA, Los Angeles. Today he is Department Head and CEO of the Institute for Medication Safety, University Essen & Saarbruecken hospital. Consulting the Secretary of the Federal Ministry of Health he is an expert in prevention of medical errors and risk management.



**Mathias Hofer, MD**, University Hospital Leipzig, studied at the Universities of Leipzig and Barcelona. After receiving his Ph.D. in 2005, he worked at the Innovation Center Computer Assisted Surgery-ICCAS at the medical faculty of the University of Leipzig. Recently he is resident of the ENT-department at the University Hospital Leipzig.



**Martin Janssen, B.ASc**, Radboud University Nijmegen Medical Centre, Netherlands, studied Biomedical Engineering in Enschede, started his career in 1989 in Sydney, Australia and is currently consultant for clinical process improvements and innovations. He led the development of Risk Management applications for the Dutch Clinical Engineering Society (WIBAZ).



**Jan-Peter A.H. Jantzen, Prof., Dr., DEAA**, Hospital Hannover Nordstadt, worked after graduation at Johannes Gutenberg University, Mainz and University of Texas Southwestern Medical School, Dallas. Today he is chief physician at the Hospital of Anaesthesiology, Intensive care and pain therapy and member of Workgroups from DIN, CEN and ISO.



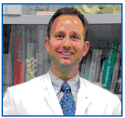
**Jochen Kaiser, Dipl.-Inf.**, University Hospital Erlangen, studied Informatics at University of Erlangen-Nuremberg. Since end 2005 he is IT Security Manager (CISO) and Technical Expert in DKE Standardization for Risk Management of networked Medical Devices (IEC ISO 80001).



**Nicholas J. Mankovich, Ph.D., M.S., CIPP**, Philips Healthcare, U.S.A. After graduation and doctorate in Biological Sciences at University of Illinois, he worked as a Professor in Radiology. Since 1995 he is with Philips Research, recently as Senior Director for Product Safety and Data Security.



**Matthias Neumann, Dr.**, Federal Ministry of Health, Berlin. After graduation and doctorate he started his career at the Federal Institute for Drugs and Medical Devices (BfArM), before he joined BMG in 2002. Today he is a Senior Executive, responsible for national and European regulation of Medical Devices.



**Joerg A. K. Ohnsorge, MD, Ph.D.**, University Hospital Aachen. After Studies at the Universities of Toulouse and Aachen, residencies in Koblenz, Aachen and Bremerhaven and fellowships at the Hospital of Special Surgery, New York in 2007 he became Professor of Orthopaedic Surgery & Traumatology at University Hospital Aachen. He is specialised in minimally invasive surgery.



**Eva-Maria Reiter, M.A.**, Siemens Healthcare, Erlangen. After graduation in German studies and History at the Bavarian Julius-Maximilians-University, Wuerzburg, she worked as a consultant in QMS implementation and regulatory affairs of Medical Devices. In 2001 she joined Siemens Healthcare, where she is today VP QM for RIS/PACS and chairs the ZVEI Working group MICS.



**Joerg O. Schwab, Prof., MD, FESC**, University Hospital Bonn, graduated at Justus-Liebig University, Giessen and received his education at the University Hospitals of Giessen and Bonn. Today he is in charge of Heart Failure and ICD-Department, Intensive Care Unit and Remote Monitoring and Member of the Nucleus "Tele-monitoring" of the German Society for Cardiology.



**Juergen Stettin, Prof., Prof. Dr. med., Dipl.-Phys.**, PROSYSTEM AG, has a degree in Physics and a degree in Medicine. Since 1999 he is Professor for Medical Engineering at University of Applied Sciences, Hamburg and is CEO of PROSYSTEM AG. He is involved in international standardization committees IEC 62304 and IEC 80001 for many years.



**Holger Strehlau, Dipl.-Kfm.**, Horst-Schmidt Hospitals, Wiesbaden studied Economics and worked as Head of Finance and administrative Director in various hospitals before he joined a Hospital Consulting company as a Managing Director. Today he is Chairman of the Board of Managers at Horst-Schmidt Hospitals and President of the Hessian Hospital Association.



**Heikki Terioe, Ph.D., M.Sc., CCE**, Karolinska University Hospital, Stockholm, acquired degrees in Applied Physics, Electrical Engineering and Biomedical Engineering from Linköping University of Technology. Today he heads R&D Biomedical Engineering Department. Since 1989 Board member of the Swedish Society for Medical Engineering and -Physics he serves as Secretary general at IFMBE / IUPESM.



**Stephan Zidowitz, Ph.D.**, Fraunhofer MEVIS, Bremen, studied Physics at the Technical University Braunschweig. After working in the IT industry he joined in 2002 Fraunhofer MEVIS - Institute for Medical Image Computing. Currently he is Head of Quality Assurance and senior research scientist in the field of medical image processing and computer assisted surgery.

## 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/symposium2010>

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

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### I herewith make a binding registration for the Symposium on February 25<sup>th</sup>-26<sup>th</sup>, 2010

€ 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 and doctor's surgeries

Special Breakout session (€ 3,000.00): proposed topic \_\_\_\_\_

additional guest(s) at Frankfurt Main Tower Restaurant    No. \_\_\_\_\_ (€ 100.00 per person)

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*\*Name Participant 5*

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*Function*

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