



IAMERS Newsletter

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Letter from the President

Dear Members,

While we continue to work through issues pertaining to pass codes and access to service software, we realize the need to have clinical people behind our actions with the FDA. As we meet and discuss our issues with FDA and Congress, we are often asked if hospitals experience the same problems. You will note on Page 5 that the Board of Directors has voted to allow clinical members to join IAMERS. We are doing this because we believe our efforts with FDA and other governmental agencies will be enhanced with clinical members.

The other pressing issue with FDA is the UDI regulations. We believe that the nature of large capital equipment for diagnostic imaging requires special consideration. At the suggestion of the UDI specialist at FDA, Jay Crowley, IAMERS is in the process of writing a White Paper to clarify our position on UDI and how it might be best approached within diagnostic imaging. Please note on Page 6 the elements of our White Paper. We welcome all comments or suggestions you may have. All members will be sent a copy of the final version of our White Paper.

As always the Newsletter takes a break in July and August. Of course we will keep you informed of any news in the meantime. The Newsletter will return in September.

We wish you a wonderful summer and hope to see many of you at the European Meeting in Munich in early September.

Please send us your comments and ideas on how you feel IAMERS can be improved. We welcome your input.

Cheers,



Happy 4th of July

IAMERS First Site Visit – Technische Universität München

During the IAMERS European Meeting in Munich, we will take our first ever site visit. Dr. Michael Friebe will be hosting us on a visit to the Technische Universität München (TUM). While there we will see some seriously interesting and nascent research.

IFL, a central research laboratory at the University, is open for joint projects of the medical and non-medical groups of the Technische Universität München. Its goal is consequently to encourage interdisciplinary work and discussion between Applied Sciences, Engineering and Medicine in close contact with physicians in order to generate new lines of applied research in Medical Technology and Computer-and Robot-Aided Medical Procedures.

A further goal of IFL is to be a show-room for current research in the area in order to keep both the medical personnel at the Klinikum rechts der Isar (means clinic on the right side of the Isar River), the teaching hospital at the university, and the scientific community informed of the latest results and thus obtain early feedback and encourage new collaborations.

Some of the current projects at IFL (and these are just my personal favorites) include:

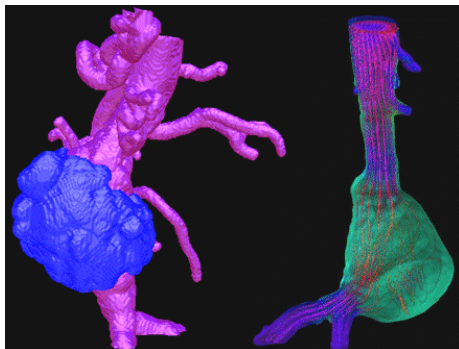
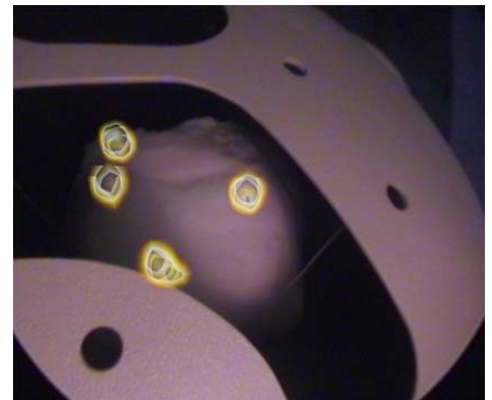


Augmented Reality Magic Mirror using the Kinect. What is that you ask? The Kinect allows tracking of users without additional markers. TUM has developed a magic mirror that generates an overlay of a video image with volume visualization from a CT volume. Such a system could be used for education of anatomy.

Another of the interesting research projects is **Freehand SPECT for Sentinel Lymph Node Localization.** And here's the explanation:

Nuclear medicine imaging modalities assist commonly in surgical guidance given their functional nature. However, when used in the operating room they present limitations. Pre-operative tomographic 3D imaging can only serve as a vague guidance intra-operatively, due to movement, deformation and changes in anatomy since the time of imaging, while standard intra-operative nuclear measurements are limited to 1D or (in some cases) 2D images with no depth information.

To resolve this problem, they propose the synchronized acquisition of position, orientation and readings of gamma probes intra-operatively to reconstruct a 3D activity volume. In contrast to conventional emission tomography, here, in a first proof-of-concept, the reconstruction succeeds without requiring symmetry in the positions and angles of acquisition, which allows greater flexibility and thus opens doors towards 3D intra-operative nuclear imaging.



Last, but not least, **Prediction of Rupture Risk for Abdominal Aortic Aneurysms.** Translation - An abdominal aortic aneurysm (AAA) describes an enlarged aortic diameter in the abdominal part of the body. Due to weakening rupture of the inner aortic wall layer, blood cells accumulate inside the wall layers and lead to a thrombus. In order to choose a suitable individual treatment, a prediction of rupture risk would be helpful. However, it is not possible to predict the rupture risk only with quantitative parameters extracted out of CT-images such as size and diameter. It is important to also include

qualitative predictors like characteristics of the aortic wall and fluid dynamics.

Together with their medical and academic partners, the University is interested in creating a model of the aorta and its thrombus in order to do certain calculations on wall stress and fluid dynamic computations. A further integration of other medical imaging devices such as PET/CT and IVUS into the geometrical model can provide more information about biochemical activities inside the aneurysmatic walls.

While at the University you will see a demonstration of the DeclipseSPECT, an intraoperative SPECT system developed by the university in a project with Surgiceye (www.surgiceye.com). Our own Dr. Friebe is the Chairman of the Advisory Board at Surgiceye.

Next we will visit the Nuclear Medicine Department to see the world's first PET/MRI system. The following statement was issued by Siemens this past November (2010):

“The department of nuclear medicine at the university hospital Klinikum rechts der Isar of the Munich Technical University today started clinical use testing with a world's first in medical is in the body,[first body/medical] but also its type and its activity. Moreover it may display technology, thereby opening up new perspectives for the diagnosis of diseases such as cancer or dementia. The combination of a magnetic resonance tomograph (MR) and a positron emission tomograph (PET) in one device allows doctors – for the first time – to simultaneously see the position of internal organs, how these are working, as well as their metabolism, all in a single image. This may help doctors to make a more accurate diagnoses by not only seeing where a tumor is, but also how the body reacts to medication administered to the patient.

The device, called the Biograph mMR*, has been developed by Siemens Healthcare and is a pioneering achievement in medical imaging. The Biograph mMR combines two technologies that normally would not be able to work next to each other: Magnetic resonance imaging uses a strong magnetic field and electromagnetic waves, while positron emission tomography uses low-dose radioactively charged radiopharmaceuticals, with which the patient is injected before the examination. These radiopharmaceuticals react with the body tissue and the resulting radiation is measured and finally converted into an image. According to physics applied in these imaging techniques, those two technologies should conflict with each other and make simultaneous imaging impossible. But the Biograph mMR is designed to overcome this physical hurdle. Thanks to funding of the Deutsche Forschungsgemeinschaft (DFG) the first systems will be installed in Germany.”



*The Biograph mMR system was 510(k) cleared by the FDA on June 10th 2011.



Michael Friebe holds more than 25 patents relating to diagnostic imaging and image guided therapy.

Michael will be our opening speaker at the IAMERS European meeting this September. He will lead the panel discussion on *Imaging's Evolution*, which will focus on Clinical, Technical and Industry Perspectives. Also participating in the panel will be Wayne Webster and Phil Jacobus.

Michael is an adjunct professor for medical imaging entrepreneurship at TUM, and a frequent contributing editor to the IAMERS Newsletter.

We are grateful for what will surely be a lively panel discussion and a fascinating trip to Technische Universität München.

IAMERS Members Pose for a Photo at German Radiology Conference



Dave Band – Platinum Medical, Oliver Lehmkuhler & Bastian Berkel – Tomovation, Rob Kerwin, Anders Jensen – Agito Medical

CAVEAT EMPTOR¹: KNOW YOUR INTERNATIONAL BUSINESS PARTNER Robert J. Kerwin, IAMERS General Counsel

With the worldwide rise in ferreting out bribery and global corruption, it is never more important to really know your business partner. The risk of ‘not’ knowing with whom you are dealing in business may include being exposed to situations potentially violative of the U.S. Foreign Corrupt Practices Act (“FCPA”). This admonition begs the question: how does one learn about your international business partner? The Bureau of Industry and Security of the U.S. Department of Commerce has a “Denied Party List” which provides a list of individuals who have been denied export privileges. See, www.bis.doc.gov/complianceand enforcement/listtocheck.htm. The U.S. Department of State, International Traffic in Arms Regulations site (“ITAR”) addresses the export of military products and technologies. The ITAR website contains a list compiled by the U.S. State Department of individuals who are barred from participating directly or indirectly in the export of potential defense goods, including technical data. See, www.pmdtc.state.gov.

Finally, the U.S. Treasury Department, Office of Foreign Assets Control has a site which identifies individuals or companies whose “property is blocked” for use on foreign transactions. See, www.treasury.gov/ofac/downloads/sdnlist.txt. While the above are hardly comprehensive, they are a starting point to learn more about the international partner with whom you may be dealing. You may also wish to make use of the ‘Gold Key Service’ of the U.S. Commercial Service. Their trade representatives may be helpful in finding you representation in a foreign country and the cost of taking advantage of the service is modest. See, www.buyusa.gov.

¹ Latin phrase: buyer beware.

IAMERS To Admit Clinical Members

At the last Board of Directors meeting, held in the Bahamas at the IAMERS' Annual Meeting, it was decided that we should allow clinical members into the association. The idea behind this decision is to help support our efforts with the FDA and lobbying. As we approach the FDA and Congressional representatives, we believe that our causes will be advanced if we have hospitals and imaging centers in support of our position.

There is no charge to be a clinical member. However, their membership does not entitle them to the same benefits that you have. To summarize:

- ▶ Clinical members cannot vote
- ▶ Clinical members cannot attend the RSNA or other IAMERS receptions without paying
- ▶ Clinical members will receive, by email, the information pertaining to our work in D.C.
- ▶ All clinical members must have sponsors
- ▶ Clinical members can attend IAMERS meetings, but must pay to do so

In order to qualify as a clinical member, they must work in a hospital or imaging center as a doctor, engineer, or administrator. This level of membership is not open to anyone outside of a clinical environment. It is also not open to a clinical individual who has a separate business interest in addition to their clinical responsibilities.

You can help us recruit clinical members. Our efforts with FDA, Congress, and other governmental bodies, will be enhanced if we can demonstrate that hospitals and clinics are in support of our efforts.

By regular mail you will receive a copy of the Clinical application form.

White Paper on UDI Implementation

IAMERS is in the process of writing a White Paper in an effort to state our position on how UDIs should be administered for pre-owned diagnostic imaging equipment. The implementation of UDI for Class II Devices (diagnostic imaging equipment is Class II) is still a few years away. We are, therefore, hoping that we have time to get it right.

Our concern is the complexity of certain equipment like CT and MRI. UDI has been likened to the VIN number on your car. We think that may be too simplistic a comparison for a MRI. We welcome any suggestions you have. Thanks to Jeff Fall and John Vartanian, below is a brief summary of IAMERS' idea of where the UDI should rest.

- UDI is the magnet for the whole system;
- If 510K approved sub-systems are exchanged in system - UDI remains the same;
- If 510K approved parts are exchanged in system – UDI remains the same;
- If Magnet is replaced then UDI is amended with a new UDI to account for all the sub-systems that make up the whole system;
- If MRI system is upgraded with any parts, sub-systems or software that will enhance the performance of the system then UDI is amended;
- Same rules apply to CT
Gantry is the UDI;
- Same rules apply for the Cath/Angio system. Gantry is the UDI;
- Same rule apply for Nuc Med
Gantry is the UDI;
- Same rules apply for Mammography
The main stand will act as the gantry;
- Same rules apply for RAD/R&F table will act as gantry;
- Same rules may apply for Ultrasound;
- Systems that are upgraded with other manufactures 510K approved sub-systems or parts must amend the UDI to reflect the changes.

Included in the White Paper will be IAMERS' view as to why it's better for all to establish these definitions before the full implementation for Class II devices.

Important Dates & IAMERS Events

AAMI • 25 – 28 June 2011

Exhibits 25th – 27th

Henry B. Gonzalez Convention Center

San Antonio, TX

IAMERS Booth # 628

AHRA • 15 – 19 October 2011

Dallas, TX

IAMERS European Meeting • 7 – 9 September 2011

Bayerischerhof Hotel

Munich, Germany

EANM • 15 – 19 October 2011

Birmingham, UK

MD Expo • 20 – 23 October 2011

Hilton in Walt Disney World Resort

Orlando, FL

RSNA • 27 November – 1 December 2011

Booth # TBA

IAMERS Member Meeting • Sunday 27 Nov 2011

5:30 – 6:30 PM • InterContinental Hotel

IAMERS Annual RSNA Reception ♣

Monday, 28 November 2011

6:30 PM - ? • InterContinental Hotel

MEMBERS & THEIR GUESTS ONLY

June 2011						
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29	30	31				

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31						

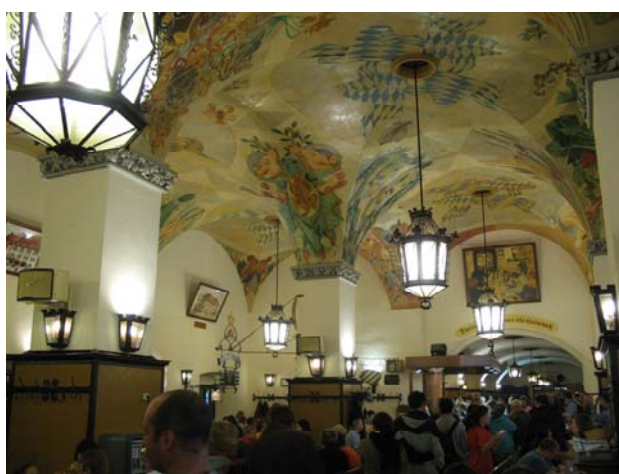
July 2011						
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September 2011						
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November 2011						
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Religious/US/world holidays

♣ Member tickets are allocated based on company size in case of RSNA & ECR. Companies with 15 employees or less receive 2 tickets. 15+ employees receive 4 tickets.



Going to the IAMERS meeting in Munich? While there have a beer and a brat at the famous Hofbräuhaus. It's a must-experience Munich event.

IAMERS News & Information

- If you would like to give us your ideas on UDI, we would appreciate it. We hope to have the White Paper completed in July.
- IAMERS has established a Washington DC working group. During these meetings we exchange ideas on all issues pertaining to FDA and our legislative agenda. The next meeting will be held in late summer. As always, the meetings are held in our lobbyist's office. All members are welcome to join in – but you must let me know ahead of time. We bring in lunch so as to maximize our meeting time. Over the next few meetings, we would like to formalize a permanent group.
- Please visit the IAMERS website. We want you to be satisfied with your listing; and we welcome any ideas of suggestions that you might have.
- Please tell us if you can help on a committee. There's plenty to do in areas such as marketing. The more members that can help, the more we can accomplish. If there is something specific you would like to do for the association, let us know.
- Let us know what you think about our articles and our direction. If you don't communicate with us, we'll never know how best to improve. This is your trade association.
- Tell us what's important to you. What do you need from IAMERS on behalf of your business? If you don't tell us, we may not know.
- Is there something you would like to put in the Newsletter? Some news about your company? Let us know. We're happy to include it.
- IAMERS is grateful for the contributions of its sponsors – for all events.

Comments and opinions are welcome.

Diana Upton

ISO Education for Members

If you are interested in an ISO course, please let us know. IAMERS feels strongly that ISO certification is an important credential. In order to not lose money, we need a minimum of 10 participants @ \$300 pp. The price includes lunch and runs about four (4) hours. The meeting will likely be Washington, DC.

If you would like to attend an ISO education seminar, please let us know.

2011/2012 IAMERS Board of Directors

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