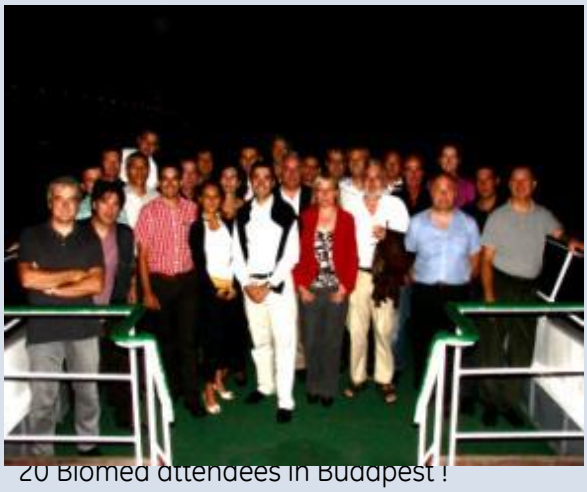
Biomedical Advisory Council

Budapest 14th Sept 2011

A very productive Biomed Advisory Council!

With the support and the logistics management of GE Healthcare, the annual session of the BAC (biomed advisory council) was held on September 14&15, 2011 in Budapest under the lead of Paolo Lago (Clinical Engineer Director - IRCCS Policlinico S.Matteo) who is the Chairman of the BAC.
The BAC was held in conjunction with the annual meeting EMBEC 2011 - 5th European Conference of the International federation for Medical and Biological Engineering.
The 5th meeting of the BAC has gathered 20 attendees representing more than 10 different nationalities.



20 Biomed attendees in Budapest !

Lot of things underway!

During GE's presentation, we covered two main topics focusing on the advanced healthcare IT evolution and on shared maintenance services. We started our day with the market trends and the impact on technological changes that modify the environment of clinical engineers. Then, we heard two testimonials from Mr. Torbjörn Johansson (biomedical engineer - Akademiska Sjukhuset Hospital - Sweden) and also Mr. Maurizio Rizzetto (Director Clinical Engineering and Informatics– Santa Maria Degli Angeli Hospital – Italy) on the collaboration between biomed and IT managers.
Then we had interactive sessions on Remote Connectivity, Shared Maintenance and Asset Management.

Testimonial from Sweden

The presentation from Mr. Torbjörn Johansson addressed the clinical engineer collaboration with IT staff and the main challenges he is facing within his hospital. The Akademiska Sjukhuset Hospital is one of the main structures in Sweden with more than 1100 beds and 8000 employees.
He described the pros and cons of separate IT and biomedical engineering departments. The main benefit is the distinction of expertise but the main drawbacks is that the IT staff may lack flexibility and do not always understand the medical issues that the clinical engineers face.
IT managers are sometimes more focussed on technical aspects rather than clinical patient data. Nevertheless Mr. Torbjörn Johansson is convinced that, as technology continues to require more and more from IT infrastructures, integration of the two areas has become critical to effective management and implementation of new technologies .

Mr. Torbjörn Johansson from Sweden

He also described which types of service contracts are running within his hospital and on which criteria he selects an OEM (Original Equipment Manufacturer) with his team. Cooperative maintenance contract is one of the 3 major contracts because it fits with his organization of 50 engineers who are in the front line with the end users and who can diagnose very quickly the troubleshooting (before calling an OEM service support).
Availability of the equipment has been discussed and described by Mr. Torbjörn Johansson as a significant point in a service contract. It has been challenged by himself and his team and they have developed a specific matrix to translate uptime into downtime. This matrix allows them to choose which contract is the most appropriate related to their needs.

Then, he outlined the process of procurement into his hospital with the combination of three departments: procurement, biomedical engineering and IT departments. This task is becoming more and more multi-disciplinary. These departments choose providers based on demands, functionality, service and cost efficiency.
Today, there are new demands for medical devices because the environment has changed, remote services are growing, and we observe the highest demand on suppliers regarding virus definition, patches, etc...
In a nutshell, Mr. Torbjörn Johansson drew a compelling view of what is the biomedical engineer's mission nowadays and the main challenge he is facing

Testimonial from Italy

Mr. Maurizio Rizzetto, who is leading the clinical engineering and the IT departments, described the inevitable collaboration between those departments and the complexity of the infrastructure technology.
He outlined the issue of the software in a daily practice. More and more medical equipments are running with software but it is still difficult to define them as medical devices. A few guidelines come out from the European regulation (COCIR) which allows categorizing several softwares such as PACS, but many others remain very complex to classify.

Mr. Maurizio Rizzetto from Italy

In the USA, clinical engineers benefit from specific guidelines and the literature is full of articles on that subject but it is still in progress in Europe.
In the USA, software as a stand-alone or information system can be classified as a medical device depending on the type of data exchanged or the risk to patients. We can distinguish three levels of classification for medical devices: class I (e.g. LIS); class II (e.g. PACS), class III (devices with high risk)
The way to manage software within a healthcare facility has unique characteristics compared with hardware. Therefore, software has to be produced with excellent reliability and high quality. The main concern in software is the safety, which involves good engineering practices, Mr. Rizzetto reminded us.
He also described the certification for a software which is based on the severity of
injury that a device could permit or inflict, either directly, on a patient or operator as a result of device failure or simply by not using the device for its intended use.

Therefore, the level of concern determines the classification of the devices (major, moderate or minor). Furthermore, softwares have specific peculiarities because they can fail without warning; it is subjected to inputs or a combination of inputs which are not always anticipated. As a consequence, software are more complex than hardware.

Another aspect is the protection of the medical information system against malicious software. In that case, users should use appropriate technical network defences , restrict physical access whenever possible, establish secure remote access for servicing, etc...

To conclude, Mr. Rizzetto said:

-device manufacturers need to share more information about design validation and risk, as well as newly discovered discrepancies and how they might impact safety.

-Clinical Engineers and IT staff need to share the specific knowledge they each have about the network and how medical devices are used, and how changes to their network may impact connected devices.

-Regulators need to monitor safety and risks, and provide appropriate guidance when needed to reduce risk.

Tamas Pados (GE Healthcare-Hungary)

What is Insite Exc?

Tamas Pados who is the service delivery leader in Eastern Europe explained to us what is InSite and what are the main benefits of this technology.
InSite is a service product designed by GE Healthcare which provides express connection to GE support. The support can be done through on-screen applications, proactive monitoring systems or direct break fix connections. This technology is a way to get instant access to an engineer and to reduce downtime.
Tamas Pados went through customer requirements to enable Insite Exc. First, GE Healthcare needs to know if the customers are able to access the internet and which network configuration they use. Then, GE establishes the list of specific of products which can support InSite. Later, customers can subscribe to it as a service contract option, knowing that InSite Exc features are included in the product warranty

Supported systems are pre-configured and only need IT network access to GE's secure Online Support Centre. At installation, and with the permission of the customer, the InSite service connection will be initiated. In any case, we advise customers to contact their GE service representative to get InSite ExC for capable existing systems.

Interactive workshops' sessions

During the afternoon, we had 2 workshops on shared services given that more and more hospitals perform the maintenance themselves. We split the group in 2 with various topics to debate. The "Buda's" group discussed trainings and what could be improved from a biomedical engineer standpoint. Many insights came out, for instance, the trainings certification for trainees, e-learnings to facilitate the delivery, IT/new technology's trainings for the biomed, partnership with OEM.... The "Pest's" group worked on spare parts. They have identified different ways of improvement to order parts through web access, with the part identification process including pictures and full description... They also discussed providing on line: PSDB/FAQ (Problem Solution DataBase), service manual, tracking order, end of product life...
It was a very productive session where everyone could express their needs and their expectations from an OEM.

Christian Rapin (GE Healthcare-EMEA)

News from Asset Management

Christian Rapin who is the sales & marketing leader of Asset Plus in Europe, described the new challenges in asset management within a hospital environment. He presented the concept of Asset Plus, which is a powerful tool addressed to all hospital administrators (biomed, IT manager, clinical staff and chief officers). This software has developed enterprise asset management functionalities and adapted them to the procedures and constraints of the hospital environment. Asset Plus tracks the full life-cycle of each and every asset, zooming in to identify, analyse and correct any equipment malfunctions. Having kept pace with regulatory changes, Asset Plus Reflex meets the very latest traceability and productivity demands. It is a modular and integrated software suite. The main benefits of that solution are:

- Quality of care (with more time for patient..)

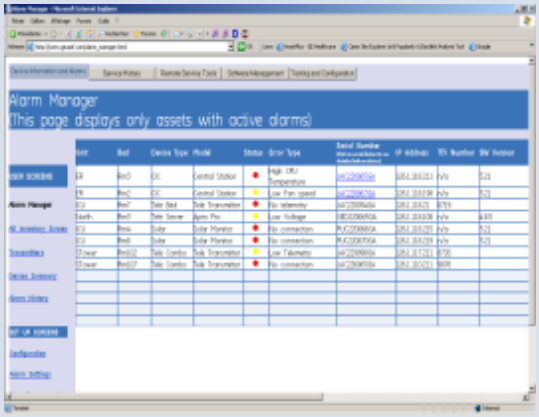
-Technical advantages (with update on regulation aspects, Optimized quantity of Assets...)

-Cost cutting (Reduced lost assets, reduced down time...)

Then, Christian Rapin proceeded to outline the main challenges in asset management, such as the implementation (owner identification, turnover in the team...); data analysis and data input (no time for collecting the data, manual process...); integration (low standardization, low technical integration...). To answer to these challenges, many solutions exist, such as dashboard and benchmarking, consultancy, cloud computing, RFID, etc. GE Healthcare asset management solutions help manage clinical and non-clinical assets throughout their life cycle.

DSSM a new tool for Biomed...

Finally, Christine Davis (Asset Management Marketing Manager USA) and Guillermo Reyes (Service Marketing Manager USA) presented an experimental model called Devices Service System Manager. The main function of the DSSM is to gather device client status information connected to the network and display it in a useful form for the biomed technician. This remote asset visibility tool shall provide a quick glance of all devices and their status. The main benefit is that the biomed quickly knows if there are any devices with a problem. The user shall be able to view all devices at a particular location, even if it consists of multiple networks within the hospital.



DSSM: Device System Service Manager

The system shall be as closely integrated to webmin as possible. Ideally, a user would see all the clients with alarms on the main alarm screen, and then he/she would be able to click on that device row and it would log on to that device, via webmin, to begin troubleshooting with this tool.
The system shall send automatic notifications of errors/warnings that are red or yellow, via an eMail and/or pager and/or pda. Customers shall be able to specify the method of delivery. The system should support at least 500 devices per site.
This new tool should be launched shortly in the USA and looks promising. Christine Davis and her team will keep us updated on the progress.

BAC Participants

Patrice Lacroix *(France)*; Rodolphe Triquet (*France)*; Mario Lugli *(Italy)*; Paolo Lago *(Italy);* Maurizio Rizzetto *(Italy);* Claudio Cecchini *(Italy);* Ana Cabrero López *(Spain)*; Antonio Boo Mecias *(Spain);* José Ramón Román Collado *(Spain);* Antonio Cobo *(Spain);* Isabel Brinca *(Portugal);* Arne Sørensen *(Denmark);* Pekka Erola *(Finland);* Hannelore Bardt *(Germany);* Christoph Katzek *(Germany);* Torbjorn Johannson *(Sweden);* Wolfgang Foessl *(Austria);* Eric Bider *(Switzerland);* Pavel Sirotkin *(Russia);* George Saatsakis *(Greece)*

Next steps

Following this meeting in Budapest, we have defined with Paolo Lago (BAC's chairman) and the BAC members to work on a publication in order to share best practices within the European biomed community. To that purpose, we should schedule different meetings and define a roadmap by the end of the year. The goal is to publish a whitepaper before the next BAC in 2012. The BAC members can be assured of the support of GE Healthcare in this initiative.

Special thank you to …

We would like to thank all who contributed to this event and specially Laura Carli (Executive Assistant – GE Healthcare Italy) who took us to Budapest!