

Biomedical/Clinical  
Engineering Association  
of Ireland



Aontas Bithleáis Innealtóireacht na hÉireann

# I 9<sup>th</sup> Annual Biomedical & Clinical Engineering Scientific Conference

**“The Domain of the Clinical Engineer:  
From Innovator to Equipment Manager ”**

**4th October 2014  
Stillorgan Park Hotel  
Dublin**





**4th October 2014**

Welcome to our members, speakers, visitors and exhibitors to this year's BEAI Annual Scientific Conference. Many thanks to all our sponsors for making this one of best networking opportunities for Clinical Engineers that has taken place in Ireland. We welcome too our student presenters who continue to raise the bar in bringing us up to date, research and development presentations, highlighting the science that underpins our working lives.

The general theme of our conference is:



### **The Domain of the Clinical Engineer: From Innovator to Equipment Manager**

The conference programme consists of oral presentations, posters, discussion and q&a sessions and prize-giving. Prizes will be presented for the best oral presentation, the best poster and the best article in the BEAI Spectrum in 2014.

I would like to thank the Executive Committee of the BEAI for their work throughout the year and in particular for their work to make today's meeting a success. In particular, I would especially like to thank Brian Kearney, Oleg Shrolik, Frank Kelly and Kieran Healy, for going above and beyond the call of duty in their work to ensure today is a success. I hope you will enjoy today's meeting as a scientific event, a networking event and socially. I hope you will meet old friends and make new ones.

Enjoy!

Meabh Smith  
BEAI Chairperson

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Aontas Bithleáis Innealtóireachta na hÉireann

## ***"The Domain of the Clinical Engineer: From Innovator to Equipment Manager"***

### **19<sup>th</sup> Annual Scientific Conference**

**Saturday 4<sup>th</sup> Oct 2014**

**Stillorgan Park Hotel, Co. Dublin**

### **Programme of Event**

<b>Time:</b>	<b>Presenter:</b>	<b>Topic:</b>
09:00 – 10:00	BEAI Executive Committee	Registration, Tea/Coffee and Networking
<b>Morning Session</b>		<b>Chair: Bernard Murphy</b>
10.00 – 10.05	Meabh Smith, BEAI Chair	Opening Address
10.05 – 10.30	Ronan Wright, Wassenburg	Endoscope Reprocessing from a Global Perspective
10.30 – 11.00	Martin McHugh, Dundalk IT	Software as a Medical Device – the Black, White and Grey
<b>11.00 – 11.30 Break - Tea / Coffee</b>		<b>Visit Stands / Networking</b>
<b>Mid – Morning Session</b>		<b>Chair: Ronnie McDermott</b>
11.30 – 11.50	Noel Murphy, HSE	Real Time Location Systems: Disruptive Innovation?
11.50 – 12.10	John Sandham, TBS	Medical Device Management
12.10 – 12.25	Student Session – Brian Kearney, TCD	Assessing Asymmetries in the Distribution of Attention across the Whole Visual Field in Unilateral Spatial Neglect
12.25 – 12.40	Student Session – Fiona Malone, GMIT	The evaluation and characterisation of thrombin-induced mammalian thrombi models for the investigation of vascular occlusion in acute ischemic stroke
12.40 – 12.55	Student Session – Darren Dawson, CIT	An Insight into the Development of a Biomechanical Model to analyse gait stability in Older Adults
12.55 – 13.00	Session Chair	Session Discussion
<b>13.00 – 14.00 Lunch</b>		<b>Visit Stands / Networking</b>
<b>Afternoon Session</b>		<b>Chair: Scott Barkley</b>
14.00 – 14.10	Alan Glass, AMNCH	Defibrillator Battery Management
14.10 – 14.40	Jim Davenport, OLCHC	CE Marking: 37 years in a Challenging yet Rewarding Environment
14.40 – 15.00	John Tiernan, Enable Ireland	Investigation of the provision of special seating services in Ireland: is there equity of service provision across regions?
15.00 – 15.10	Poster Presenters	Short Discussion
<b>15.10 – 15.30 Break - Tea / Coffee</b>		<b>Workshop plus Visit Stands / Networking</b>
15.30 – 15.45	Session Chair	Session Discussion and Prize Giving
15.45 – 15.50	Meabh Smith, BEAI Chair	Concluding Remarks
15.50 – 16.00	All	Final Exhibition Viewing / Networking

Accredited by:





Aontas Bithleáighis Innealtóireachta na hÉireann

## 19<sup>th</sup> Annual Scientific Conference

**Saturday 4<sup>th</sup> Oct 2014**

**Stillorgan Park Hotel, Dublin**

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# **Speakers**

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## **Endoscope Reprocessing from a Global Perspective**

### **Mr. Ronan Wright**

Global Business Development Director  
Wassenburg Medical



Mr Ronan Wright is Managing Director at Wassenburg Ireland Ltd as well as Business Development Director at Wassenburg Medical B.V. With 17 years of experience in endoscope reprocessing at a number of companies including, Hitachi, Johnson & Johnson & Pentax, he has been directly involved with Wassenburg products since their introduction on the Irish market in 2003. He has an active role in a number of Irish normalization committees on endoscope reprocessing.

### **Abstract**

In this presentation Ronan shares his long experience in Endoscope Reprocessing in Ireland and most recently his post as Worldwide Business Development Director for Wassenburg Medical. He will look at the reprocessing techniques we have developed in Ireland based on International standards in line with Local guideline policy's for AERs – Automated Endoscope Reprocessors & Drying and Storage Cabinets.

He will compare this to what our neighbouring countries UK & Europe see as best practice. Ronan will give examples from further afield in Middle East, Russia's, Asia Pacific and America markets. While benchmarking our techniques in comparison to the Global market.

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## Software as a Medical Device – the Black, White and Grey

### Dr. Martin McHugh

Martin Mc Hugh is a lecturer in software engineering at Dublin Institute of Technology. He received his B.Sc. in 2005 and his M.Sc. in 2009. Subsequently, he obtained a PhD specialising in the field of medical device software engineering. He is a leading international expert in the field of medical device regulation from both a manufacturer and healthcare provider perspective. He has over 20 peer-reviewed publications in this field and has presented his research internationally. Martin has provided consultancy services to a number of medical device manufacturers including Bluebridge Technologies and Portable Medical Technology. His current research focuses on the area of developing a clinical decision support system which can be implemented on a mobile device for use in a healthcare environment.



### Abstract

Unlike other fields, the medical device industry is bound by the regulatory constraints of the region in which the device is marketed for *use*. Historically, these regulations have been applicable to medical device manufacturers, however, the regulatory bodies have recognised the shift in changing technologies and now healthcare providers are being bound by these regulations. As a result, the recent European Medical Device Directive amendment (2007/47/EC) and the Food and Drug Administration (FDA) Medical Device Data System Rule directly refer to the role in which healthcare delivery organisations play in the safe and reliable performance of medical devices.

Of particular concern to regulatory bodies is the rise of mobile platforms used in healthcare environments. In and of themselves, these devices can act as e-readers containing medical text books which clinicians can refer to, however, a number of these devices connect to internal healthcare networks which could inadvertently cause conflicts on the network. The FDA has provided specific guidance which medical device mobile application developers can follow when producing regulatory compliant software. Despite this, confusion remains amongst application developers and healthcare providers as to where the liability resides.

Ireland is one of the largest medical device exporters in the world. The medical device markets are typically dominated by large medical device organisations such as GE and Siemens. These organisations suffer diseconomies of scale i.e. slow to react to change.

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## Real Time Location Systems: Disruptive Innovation?

### Mr. Noel Murphy

BEng, CEng, MIEI

Noel is a Senior Biomedical Engineer in Cork University Hospital. He is a chartered engineer with Engineers Ireland and was an executive member of the BEAI for a number of years. He has a keen interest in the introduction of new innovative technologies to the healthcare space and in the past year has been a member of the Health Innovation Hub, a demonstrator project based out of University College Cork which looks to support and accelerate the commercialisation of innovative healthcare solutions.



### Abstract

In 2013, Noel project managed the installation of a Real Time Location System (RTLS) in Cork University Hospital to investigate the merits of the technology in supporting the Clinical Engineering Department's role as Equipment Managers. In his presentation today Noel give an overview of RTLS technologies and give examples of how CUH is now utilising the technology.

A 'disruptive innovation' is an innovation that helps create a new market and value network, and eventually disrupts an existing market and value network displacing an earlier technology. The term is used in business and technology literature to describe innovations that improve a product or service in ways that the market does not expect, typically first by designing for a different set of consumers in a new market and later by lowering prices in the existing market. In recent times a lot of focus has been placed on the theory and its application in the healthcare setting. In his presentation today, Noel will review the concept behind the theory, give examples from the healthcare sector and investigate if RTLS meets the criteria to merit the technology being categorised as a 'disruptive innovation'.

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## Medical Device Management

**Dr. John Sandham IEng MIET MIHEEM**

Chief Executive Officer, TBS GB Ltd; EBME Ltd;  
Chairman, [www.ebme.co.uk](http://www.ebme.co.uk)



Over 25 year's medical devices managerial experience delivering innovation and cost saving improvements. Re-engineering of management processes to deliver systematic improvements at reduced costs.

John has been working in the field of medical devices for over 25 years. John has had over 120 educational articles published. He has been published in the Open University Science review, Engineering Technology Journal (IET), Clinical Services Journal, and [www.ebme.co.uk](http://www.ebme.co.uk). He is a recognised expert in his field of medical devices management, process analysis, and procurement with some of his papers being referenced by the NHS Library and World Health Organisation. John set up the website '[www.ebme.co.uk](http://www.ebme.co.uk)' with a colleague in 1999 to allow the sharing of knowledge to enable improvements in practice. John was awarded his Doctorate in Professional Studies for Compliance in Medical Devices Management Policy in May 2014.

### Abstract

Hospitals have always faced fundamental questions of patient safety, care, and budgetary concerns. There has been increasing recognition recently of the serious issue of medical devices management, covering the areas of procurement, training, maintenance, and governance. This issue, documented by the National Audit Office, National Patient Safety Agency, Medicines and Healthcare Products Regulatory Agency, National Health Service Litigation Authority, and World Health Organisation, impacts on healthcare costs and patient safety. It has led to new Health and Social Care Act Regulations, enforced by the Care Quality Commission.

As a result of my work in the field of medical devices management, I sought to improve medical devices management policy through participatory research conducted at an NHS Hospital in London. It took the form of a case study that specifically explored the core policy areas, but this time in collaboration with participants with expertise in one or more of the four interrelated policy areas of procurement, training, maintenance, and governance.

The action research informed changes in policy, especially around procurement, leading to improvements in practice. The overall outcome of the project was an organisationally approved best practice policy model for medical devices management within a governance framework that meets the needs of the external regulators, and the management of the organisation. More specifically it was discovered that the use, maintenance, and governance of medical equipment were all reliant on a central issue, namely procurement practice. Procurement conduct for the organisation was redefined within the Hospital policy, and is making training, maintenance, and governance easier to achieve, thereby reducing risk and cost. Moreover, it is anticipated that the model could be used at similar healthcare organisations, ultimately leading to a contribution to knowledge and practice which assists in patient safety and meeting budgets.

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## Assessing Asymmetries in the Distribution of Attention across the Whole Visual Field in Unilateral Spatial Neglect

**Mr. Brian Kearney**



Brian graduated from DIT Kevin Street in 2009 with a BEng (Hons) in Electrical/Electronic Engineering. In 2009, Brian commenced work as a clinical engineer in Naas General Hospital and is involved in medical equipment and clinical information system management, along with roles in project management and hospital services such as power generation systems. Brian is current secretary of the BEAI, national secretary of the Clinical Engineering Professional Vocational Group (CEPGV), an executive member of the biomedical engineering division of Engineers Ireland and an independent expert with ETCI TC10. Brian has recently completed an MSc in Bioengineering in Trinity College Dublin, with research interests focusing around electrophysiological signal analysis

### Abstract

Unilateral spatial neglect (USN) is defined as the impaired or lost ability to respond to sensory stimuli (auditory, visual, tactile and olfactory) presented in the contralesional hemisphere of a neurological patient. USN is caused by lesions, typically strokes, that can occur in both the left and right hemisphere of the brain, but with lesions in the right hemisphere typically causing the more severe and persistent deficits. USN is one of the single best predictors of poor functional recovery following stroke and despite the clinical significance of the condition, the underlying cognitive deficits are not well understood. In the absence of a biological marker for unilateral neglect, clinicians are reliant on paper and pencil tests (e.g. line bisection, cancellation tasks) that have limited diagnostic sensitivity and suffer from a number of methodological problems. The hypothesis of this study was that a prototypical random dot motion (RDM) direction discrimination task can be objectively used to accurately diagnose the presence and severity of USN in stroke patients. The main objective of this study was to obtain behavioural and electrophysiological data from a cohort of right hemisphere stroke patients and healthy control subjects using the RDM task, and compare the results to the gold standard paper & pen tests currently used to clinically assess unilateral spatial neglect. The main objective was achieved and the primary results indicated that the RDM could be used to objectively diagnose the presence of USN through the measure of detection accuracy. The measure of reaction time to targets was deemed unreliable due to a low number of valid trials. However, a relatively new decision signal, known as the centroparietal positive potential (CPP), was successfully evoked in the control group, indicating that the RDM task was capable of eliciting the required brain signals needed to objectively measure neglect. A future objective is to increase task compliance, primarily through decreasing the difficulty of the task, which should increase the number of valid trials available for analysis and thus pave the way for validating an objective measure for tracking the severity of USN.

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## **The evaluation and characterisation of thrombin-induced mammalian thrombi models for the investigation of vascular occlusion in acute ischemic stroke.**

### **Ms. Fiona Malone**



Fiona graduated from the UL in 2013 with a first class honours degree in Biomedical Engineering. Her Final Year Project won the Engineering & Mechanical Sciences Category as part of the 2014 Undergraduate Awards.

She has since commenced her postgraduate studies at GMIT, where she is investigating the intracranial haemodynamic factors that influence the rehabilitation of ischaemic stroke patients. Her work to date on the experimental monitoring of cerebral haemodynamics won first prize in the New Researcher Category at the 20th Annual Conference of the Bioengineering Section of the Royal Academy of Medicine in Ireland in January of this year.

### **Abstract**

A lack of blood supply to any part of the brain for an unknown period of time may lead to brain tissue necrosis, commonly known as stroke. Stroke remains the third most common cause of death worldwide and kills more than 2,000 people a year in Ireland. This is a higher death toll than those who die from breast cancer, prostate cancer and bowel cancer combined. Stroke is also the leading cause of acquired long-term disability and is almost twice as prevalent among women as men. Over 80% of all strokes are ischaemic that can result from a thrombus occlusion of a major cerebral artery.

Thrombosis is an important repair mechanism within the human body but also occurs if blood flow becomes stagnant. In vivo, erythrocyte rich thrombi are generally formed in relatively static, low flow-regions, as with arterial fibrillation. Animal thrombi models have played a unique role in understanding the pathophysiology, morphology and mechanical characteristics of thrombi underlying the vascular occlusion in acute ischemic stroke.

This project concerns the histological and mechanical examination and characterisation of thrombin induced, erythrocyte rich mammalian thrombi. Haematoxylin and Eosin stains were completed on ovine and bovine thrombi specimens at day 1 and day 33 (n=35). The presence of nuclei and erythrocytes correlated significantly with stained human thrombi samples reported from literature. Compositional differences were noticed in the thrombi after 33 days. Tensile and compression tests were conducted at varying strain rates. Initial results indicate a possible increase in elasticity with increase in thrombin concentration (NIH units/ml blood). There was also a decrease in stiffness of 33-day old thrombi compared to 1-day old thrombi.

The successful development of such thrombus models may provide a basis for the characterisation of post-operative thrombi removed from humans. Knowledge about the histological characteristics of thrombi may provide a means for improving current endovascular therapies and the development of new treatment strategies for revascularisation in patients with acute ischemic stroke. These findings could indicate that the composition of thrombi is a potential key variable regarding the selection of the appropriate treatment options for ischemic stroke patients and in predicting the performance of mechanical thrombectomy devices and thrombolytics.

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## An Insight into the Development of a Biomechanical Model to analyse gait stability in Older Adults

**Mr. Darren Dawson, Mr. Keith Bryan**



Graduated from CIT with a Bachelors in Engineering (Honours), in Biomedical Engineering in 2013. Awarded a Rísam PhD Scholarship from CIT in Biomedical Engineering. This presentation is based on part of the research and development of this PhD topic

### **Abstract**

According to the 2011 Census there are currently over 535,000 older adults living in Ireland. The World Health Organisation stated in 2004 that about 30% of people aged 65 and above suffer from falls each year. Applying this statistic to the total population of older people in Ireland, roughly 160,000 older adults fall each year. Furthermore 80% of those falls (128,000) are non-injurious and hence not reported to health professionals, leaving about 32,000 older people with potentially serious injuries each year. This has a large financial cost on the Irish economy. The total financial burden as a result of injuries from falls in Ireland is currently not known, however recent research using data from one hospital in Ireland, estimated the hospital costs of admissions due to falls among older people at €10.8 million.

Gait analysis is an important method of clinical evaluation of normal or pathological patterns of locomotion. In recent years many new models have been developed for use in motion analysis systems. Many models being developed are to analyse the gait of specific populations such as children with different pathologies such as cerebral palsy and myelomeningocele. Most of these models being developed are used to analyse only upper extremity kinematics and kinetics during assisted ambulation with a specific walking aid. However no biomechanical model currently exists which is designed to analyse the entire body during walking aid assisted gait for an older population.

A novel biomechanical model is currently under development for the gait analysis of stable and unstable older subjects. The model will be capable of analysing total body kinematics, and kinetics of the lower extremities, in subjects without a walking aid. The model will also (and more importantly) be capable of performing the additional task of upper extremity inverse dynamics during ambulation with a roller walker or cane walking aid.

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## Defibrillator Battery Maintenance

### Mr. Alan Glass

Principal Clinical Engineering Technician  
Medical Physics and Clinical Engineering Department  
The Adelaide and Meath Hospital, Tallaght, Dublin 24  
E-mail: alan.glass@amnch.ie



### Abstract

Ninety Five Defibrillator Batteries to change every two years.  
'OH NO, I DON'T BELIEVE IT'

Now it has to be done every year—but why?  
This presentation looks at the changes made to the testing of the 'Heartstart XL' battery.

Over the last two years changes in the battery manufacturing has caused reliability problems which led to this change in the cycle frequency of its replacement; however have all the problems gone away?

## Clinical Engineering: 37 years in a Challenging and Rewarding Environment

### Mr. Jim Davenport

Jim had a two week break after leaving Kevin Street College before starting on Our Lady's Children's Hospital Crumlin in 1977. He took a very pro-active interest in Intensive Care and kept Our Lady's at the forefront in emerging technologies and co-authored three papers published in Anaesthesia, the BJA and Acta Anaesthesiolica Scandinavica. He pioneered Paediatric Transport and Retrieval in Ireland. He is immensely proud of the other seven members of his skilled team. He has always considered himself lucky to be working in a job that he loves.



### Abstract

In this presentation Jim shares his long experience in Clinical Engineering in Our Lady's Children's Hospital Crumlin. He deals with three main issues, the critical Role of research, Patient Safety Issues and the Role of clinical Engineering in the development and design of biomedical equipment and accessories. He also reflects on 22 years Flying Solo and on then building a skilled and enthusiastic Clinical Engineering Team. In everything that the Clinical Engineering Department do, they must never lose sight of the fact that the care of the Patient and their Family is always the central focus.

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## **Investigation of the provision of special seating services in Ireland: is there equity of service provision across regions?**

**Mr. John Tiernan**

Seat Tech Service Co-ordinator and Senior Clinical Engineer  
Enable Ireland | Sandymount Avenue | Dublin 4 | Ireland  
Phone: +353 1 2615926 | Email: [jtihernan@enableireland.ie](mailto:jtihernan@enableireland.ie)



### **Abstract**

This paper is founded on original work from an academic healthcare study pertaining to the availability of wheelchair and special assistive seating technology across Ireland. The research provides Irish data on requirements for special seating services across the nation with focus on regional differences and funding availability.

The paper first outlines the objectives and explains the limitation of the research. The opening literature review identifies the number of Irish wheelchair users as being in the order of 40 thousand, with those requiring supplementary special supportive seating numbering up to 27 thousand people. The literature review places the Irish scenario in the context of normalised international data, identifying consistency in the data.

A custom-developed questionnaire provided to specialist healthcare providers is then discussed. This questionnaire collated the regional data, both quantitative and qualitative, using an un-blinded sampling approach. It was targeted at therapists and experts with specific training and experience in the provision of special seating services.

Finally, regional differences highlighting regional inequities in services and funding are presented, with significantly higher level of provision of special seating services to those who need them in areas closer to Dublin as compared to HSE regions in the West and South. There appears to be a correlation between adequacy of service provision and HSE regional spending practices. This trend is reinforced with qualitative data relating to various aspects of the services provided.

The findings that indicate regional inequities of service provision could serve as an input for planning purposes to develop future HSE budget-planning to improve provision in regions with immediate needs. A significant output of this paper is the availability of a comprehensive map of seating services in Ireland, which was not the case prior to the research. Budget spend in the context of a critical population mass to ensure optimization of service benefit based on population dispersion is proposed. This data could be used as a direct input to government/other department planning on healthcare spend for the future.

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# **Posters**

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## **“Cradle to Grave” Medical Equipment Management**

### **Mr. Declan Murray**

Declan Murray is currently the chief clinical engineer at St Vincent's University Hospital (SVUH). He has worked at SVUH for the past 11 years. To date he has accumulated 24 years experience in clinical engineering in the public health services of England and Ireland. He has qualified from the Medical College of St Bartholomew's Hospital, University of London, with a Masters of Science in Medical Electronics and Physics.



In his career thus far he has successfully implemented and coordinated numerous large scale Hospital development programmes. He endeavours to achieve the best patient outcomes with the application of appropriate technologies in line with best international practice. He strives to practice in a professional, dignified, caring and proficient manner.

Key specialities have included; medical equipment management, nephrology (encompassing research and development in the following, access recirculation, blood volume monitoring, heparin free dialysis and on line clearance), neurology, neonatology and accreditation.

### **Abstract**

#### **Aim**

To implement a sole equipment management database for St Vincent's University Hospital (SVUH). This is achieved using the ECRI-AIMS™ database which is a comprehensive system for managing all aspects of technology-based assets found in healthcare institutions. It is a web browser application, enabling the data stored centrally at the hospital to be accessed via a web browser connected to the hospital Intranet.

#### **Benefits**

Complete clinical asset management for medical equipment, from identifying the clinical requirement right through to equipment retirement i.e. “cradle to grave”, encompassing:

- Comprehensive asset management
- Complete in-house service management
- Full contract management
- Hazard safety notice management
- Medical Equipment Replacement Programme (MERP)
- Customisable reporting capabilities for SVUH senior management and relevant external parties

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## An Equipment Qualification Approach to Medical Device Introduction

**Mr. Dermot Hale, Mr. Enda F. Fallon**

*Centre for Occupational Health & Safety Engineering and Ergonomics, College of Engineering and Informatics,  
National University of Ireland Galway,  
d.hale2@nuigalway.ie & enda.fallon@nuigalway.ie*



Dermot Hale holds a primary degree and a research Masters in Industrial Engineering, both from NUI Galway. He is currently a Quality & Validation Engineer in the medical device manufacturing sector, where he is also responsible for the management of Environmental and Health & Safety systems. He is undertaking a PhD at NUI Galway (part-time), investigating the application of equipment qualification methods in healthcare.

### **Abstract**

Medical devices are associated with errors in two ways: through failure of the device (Dhillon, 2000), and through user misuse of the device (Money et al., 2011). Amoore and Ingram, (2002) in analysing adverse incidents involving medical equipment found that although adverse incidents are often ascribed to human factors, including users' inexperience, they are typically multifactorial in origin, with latent factors, faults, errors, and mistakes aligning together. Latent factors, aspects of the system predisposing threat or error (Helmreich, 2000), in particular have been identified as resulting in patient safety incidents (Adams et al., 2003).

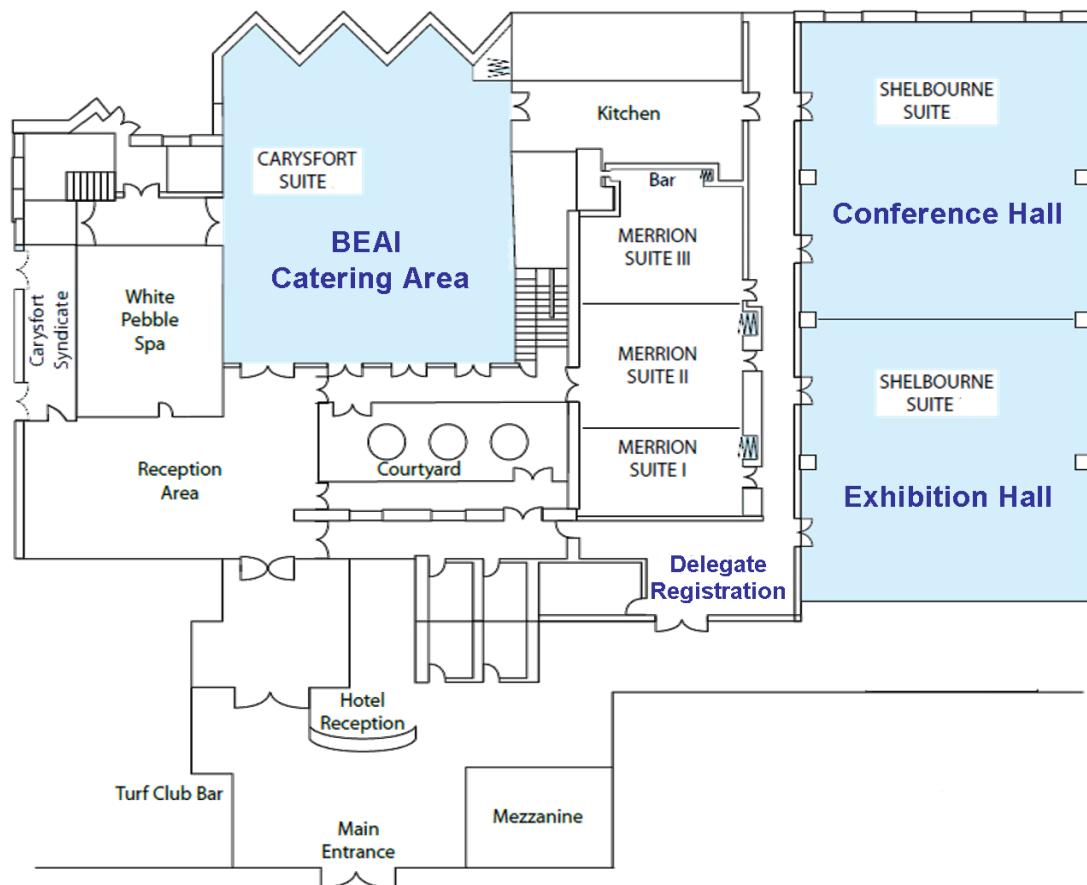
Equipment Qualification (EQ) is commonly used as a framework to guide the introduction of manufacturing equipment in the medical device and pharmaceutical industries. In these manufacturing industries, as in healthcare, quality and safety of processes is critical. The EQ process can pre-emptively identify latent quality and safety concerns and provide an auditable documentation record of adherence to best practice in the introduction of new medical devices. Equipment Qualification (EQ) is a formal quality assurance process which establishes confidence that specified equipment and ancillary systems are suitable for their intended use and are capable of consistently operating within established limits and tolerances. The EQ process includes four stages of qualification: Design Qualification (DQ), Installation Qualification (IQ), Operational Qualification (OP) and Performance Qualification (PQ).

This presentation seeks to demonstrate how the Equipment Qualification practices of high reliability manufacturing organisations can be utilised by healthcare; introducing the EQ framework, practices and protocols with a demonstration of tools, techniques and considerations for each stage. The presentation will also discuss current work in the development of a systems engineering reference architecture for the qualification of medical equipment in healthcare.

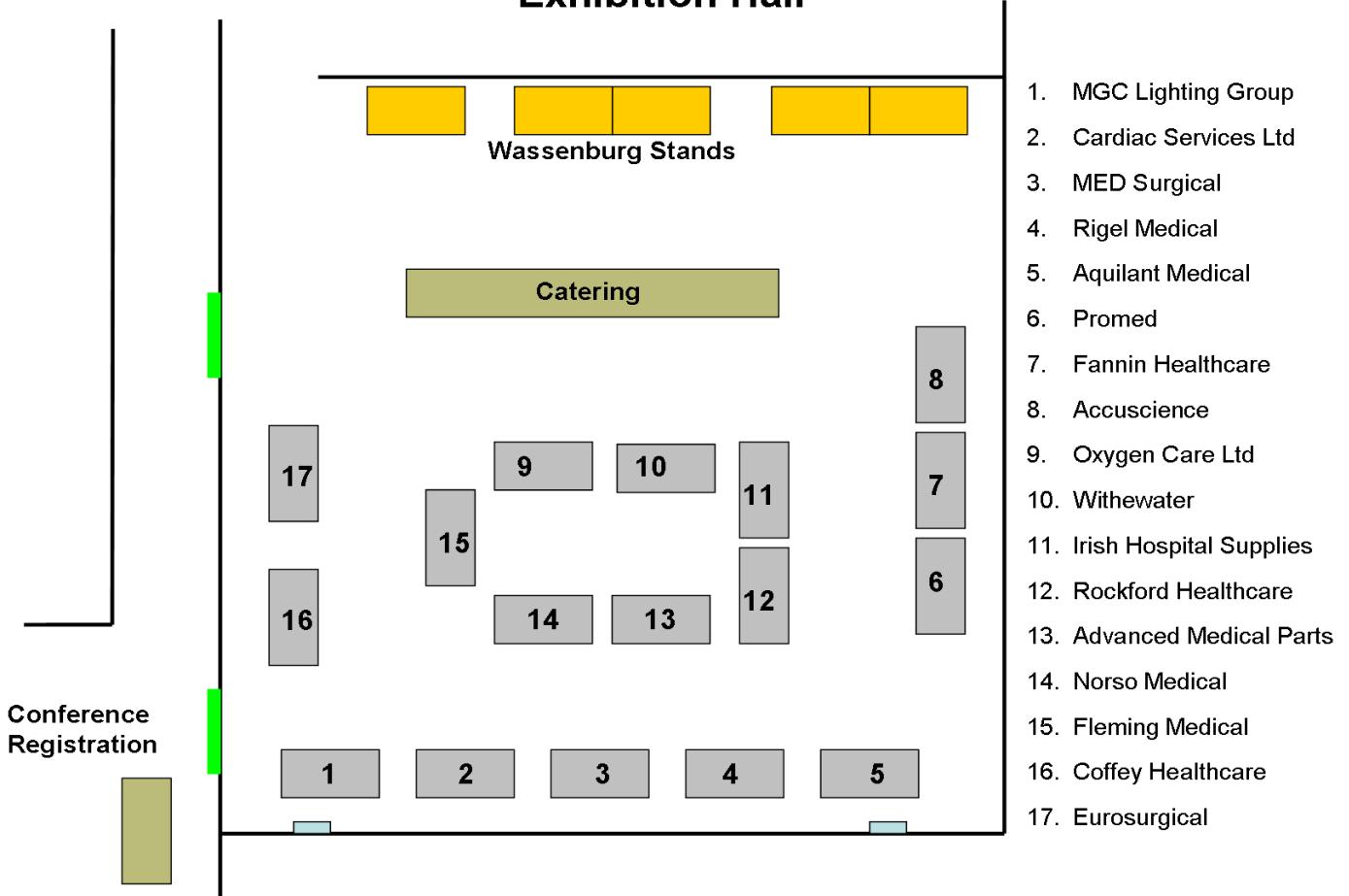
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# **Exhibitors**

# Conference and Exhibition Floor Plan



## Exhibition Hall



## DECONTAMINATION EXPERTS

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# **WASSENBURG**

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## medical

**ABOUT WASSENBURG GLOBAL:** Wassenburg Medical is a leading international company based in the Netherlands and specialized in the development and manufacture of innovative high-level washer disinfectors and drying/conditioning cabinets for flexible endoscopes. The company was established in 1984. For more than 30 years now it has developed into a highly-qualified specialist in all aspects of automated endoscope reprocessing. Wassenburg currently employ 250 people in head offices and manufacturing premises throughout the Netherlands, offices in the United Kingdom, Ireland, Belgium and France and an ultra-modern pre-assembly factory and customer service center in Vietnam, the full product range is distributed through an exclusive distribution network. As the leader in High-end Endoscope reprocessing, Wassenburg is passionate about creating the best innovative solutions for its customers.

**ABOUT WASSENBURG IRELAND:** Wassenburg Ireland is operational for 3 years now, **specializing in Endoscope reprocessing.** From our head office in Santry, Dublin, we offer sales, service and training support to the relevant stakeholders at Endoscopy Healthcare facilities throughout Ireland. Our service engineers are located in the East, West, Midlands and South of the country. We are not just equipment providers to healthcare facilities, but also function as consultants. Our team is on hand to deliver all aspects of support necessary from room design, transportation of the flexible endoscopes, to choices of PPE to be worn, the right chemicals to be utilized in the department and all the way to testing of the washers and dryers. We provide accredited training to nurses and certified training to engineers for front line support.

Almost 6 million endoscopes were processed through Wassenburg endoscope washers since first launched by Johnson & Johnson Ireland back in 2003. Wassenburg equipment has touched over 6 million patients where diagnostic endoscopy procedures have taken place. We understand the enormous responsibility we have to deliver a product that can reproduce and deliver the same performance for each patient every time. We believe in delivering quality products and most importantly a 1<sup>st</sup> class after sales service and support. Wassenburg equipment meets all international standards and local RIMD HSE requirements.

**HOYA COLLABORATION:** In November 2013 Wassenburg announced a joint venture with the HOYA corporation. With this strategic acquisition Wassenburg and HOYA, through its division PENTAX Medical, are now able to give its global customers complete access to a wider portfolio in the field of flexible endoscopy from endoscopes to automated endoscope reprocessors (AERs).

For more information contact : [info@wassenburg.ie](mailto:info@wassenburg.ie)

**NIHON KOHDEN**

### Life Scope G9

The genesis of monitoring



Two smaller images below show multiple monitors displaying vital signs and a close-up of the monitor screen.

**HEINEN + LÖWENSTEIN**



Two smaller images below show a close-up of the equipment and a hand interacting with it.

Patient Monitoring / Neurology / Cardiology

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The role of the Health Products Regulatory Authority (The HPRA) is to protect and enhance public and animal health by regulating medicines, medical devices and other health products. The HPRA is responsible for regulating a wide range of health products available in Ireland. This includes:

- Human and veterinary medicines;
- Clinical Trials;
- Medical Devices;
- Controlled Drugs;
- Blood and blood components;
- Tissues and cells;
- Cosmetic products;
- The protection of animals used for scientific purposes;
- Organs intended for transplantation.



The HPRA is the competent authority for medical devices in Ireland. As part of this role the HPRA;

- Maintains a register of all medical devices
- Examines and approve applications for clinical investigations
- Maintains a post market surveillance system
- Establishes and administers a vigilance system for adverse incident reporting
- Conducts post market surveillance audits
- Enforces the legislation where necessary
- Designates and monitors Notified Bodies
- Participates in international working groups for medical devices

The landscape of medical device regulation is evolving, with the need to reinforce the current regulatory system and the ongoing negotiations at a European level on proposed regulations. The Joint Plan for immediate action has highlighted the need for improved performance and oversight of notified bodies, reinforced market surveillance, enhanced cooperation and coordination and improved transparency and communication. The HPRA is further development its capabilities, systems and expertise for medical devices. The current focus is on a life-cycle approach to market surveillance, to meet expectations



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