IRISH MEDICINES BOARD

news LETTER

MEDICAL DEVICES

DECEMBER 2011 Vol. 1 No. 33

IRISH MEDICINES BOARD, KEVIN O'MALLEY HOUSE, EARLSFORT CENTRE, EARLSFORT TERRACE, DUBLIN 2 TEL: 01 676 4971 FAX: 01 634 4033 EMAIL: MEDICALDEVICES@IMB.IE

Letter from the Editor

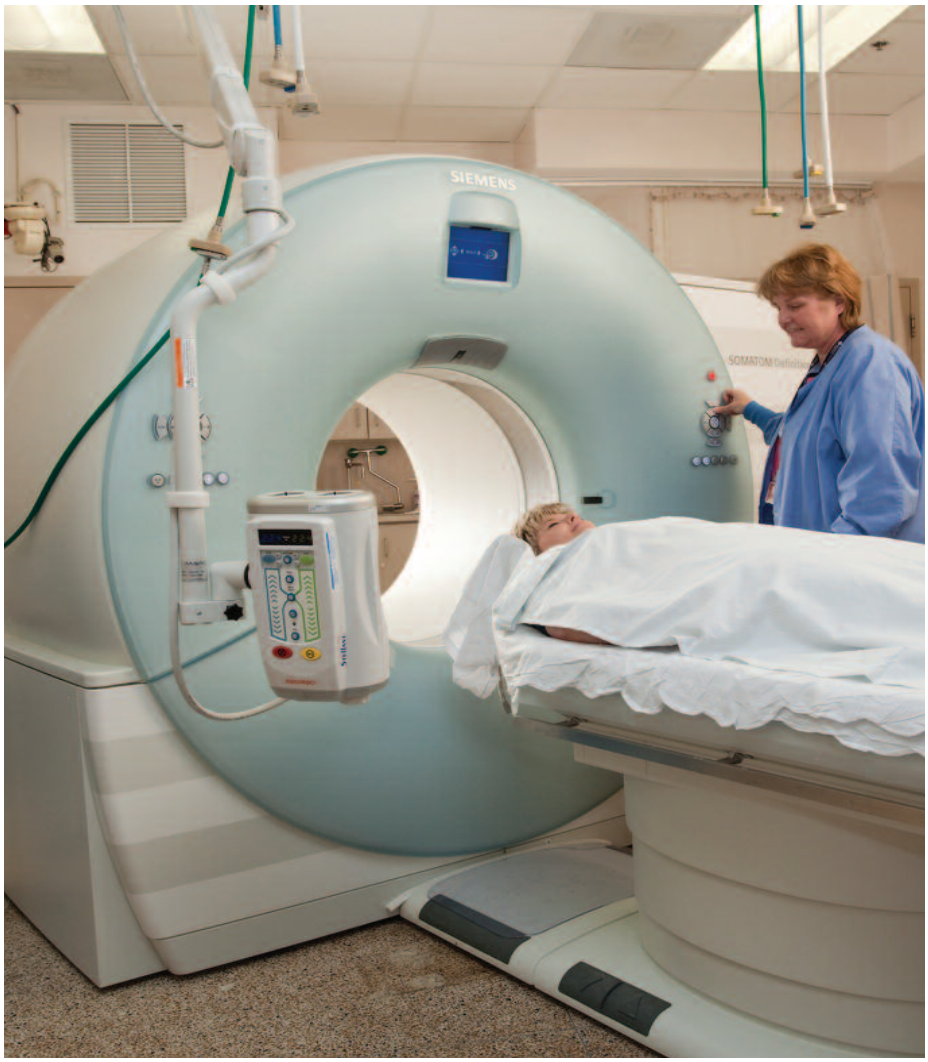
Welcome to the third and final edition of the medical devices newsletter for 2011.

In this edition, we are pleased to feature an article kindly provided by Prof. Richard Reilly and Dr. Ed Lalor of Trinity College. This article provides an overview of neural engineering and the research taking place in this field at Trinity College.

We also feature an article on the importance of safety information communicated by medical device manufacturers and an overview of a recently published IMB brochure on automated external defibrillators (AEDs). Updates on all recent European meetings attended by the IMB are also provided.

As always, readers are encouraged to provide feedback particularly in relation to articles that may be of interest by contacting us at medicaldevices@imb.ie.

Finally, we would like to wish all our readers a very happy and peaceful Christmas.



CONTENTS

Overview of Neural Engineering

PROF. RICHARD REILLY and DR. ED LALOR

The brain is a complex system, and its disorders include a wide spectrum of neurological diseases. It is estimated that 38% of the population in the European Union suffer from psychiatric disorders every year [1].

The medical, social and economic burdens of brain disorders are enormous. It has been recently estimated that the total cost of brain disorders in Europe during 2010 was €789 billion [2]. Due to increase in life expectancy in Europe, it is predicted that the cost of brain illness is only going to increase in future. Thus the research of today in understanding the brain and brain disorders is vital for the health challenges of the future. There is therefore unprecedented demand for treatments that delay, prevent and cure chronic neurological and psychiatric illnesses.

It is only recently that the term *Neural Engineering* or *Neuroengineering* has been used, in recognition that engineers, neuroscientists and clinicians are working together to address the problems associated with the complexity of the nervous system. The main goal of the new discipline of neural engineering is to develop solutions to neurological, neurosurgical, and rehabilitative problems. Neural engineering is in an early period of discovery where we are defining the limitations both technologically and biologically of how we can fundamentally alter the function of the nervous system. With its emphasis on quantitative methods applied to the nervous system, neural engineering has generated considerable excitement not only for the development of interfaces between the brain and computers but for its mostly untapped potential to develop treatment for patients with neurological disorders.

The recent success of this new, distinct discipline draws from advances in four specific areas. These include cognitive neuroscience where the tremendous growth in neuroscience knowledge has provided a much more detailed understanding of neurophysiology and neural systems, the basis of information processing. The development of new biocompatible materials that can exist within the body for long periods also has had a major impact. Advanced methods in signal processing and mathematical modelling of nonlinear and nonstatationary systems have been vital to describe the dynamics of neural signals and systems. Finally and critically, as the statistics above demonstrate, there are increased demands on the delivery of clinical interventions and for solutions to address neurodegenerative diseases.

The growth in neural engineering is also being driven by new technology advances in imaging of the brain in real-time, new biomarkers and imaging protocols for early diagnosis and disease monitoring, and the increased use of imaging & informatics in drug and device development. Neural engineering covers theoretical methods and applications areas: brain-machine interfaces, neural interfacing, neurotechnology, neuroelectronics, neuromodulation, neural prostheses, neural control neurorehabilitation, neuro-diagnostics, neurotherapeutics, neuromechanical systems, neurorobotics, neuroinformatics, neuroimaging, neural circuits: artificial and biological, neuromorphic engineering, neural tissue regeneration, neural signal processing, theoretical and computational neuroscience, systems neuroscience and also importantly translational neuroscience.

At the Trinity Centre for Bioengineering at Trinity College, neural engineering is one of five research strengths in bioengineering, where the emphasis is on harvesting information from signals acquired from excitable tissue (typically EEG and fMRI) and the development of novel neurological diagnostic methods and devices. Neural Engineering Research Group has two laboratories (led by Dr Ed Lalor and Prof. Richard Reilly) both composed of multidisciplinary teams of engineers, neurologists, neurophyscologists and neuropsychiatrists. Our mathematical neurodynamical modelling of brain function is focused on an improved quantitative understanding of human precognitive (perceptual) and cognitive abilities and the development of technologies for a quantum leap in the fields of neurorehabilitation.

Through active collaboration with clinical colleagues, the multidisciplinary research teams in the Neural Engineering Laboratories at Trinity College are developing new ***Functional Neuroimaging*** methods to simultaneously image brain function with the highest spatial and temporal resolution possible, as well as imaging the functional and structural connectivity of the brain. This has clincial impact for the understanding of neurological disorders, with current studies into dystonia [3], multiple sclerosis [4,5], acute brain injury and cognition function in older age[6]. One area where these new functional neuroimaging methods are applied is to the study of multisensory integration, investigating how the different sensory modalities, such as sight, sound, and motion perception, become integrated into a perceptual experience that is coherent and unified. Multisensory integration also investigates how different sense modalities interact and alter each other's processing. Multisensory integration is an essential aspect of human function that is, as yet, poorly understood. Poor functioning of multisensory integration is common in

several clinical populations: schizophrenia, autism and ageing. In Trinity College, we are developing new experimental methods to investigate the neurophysiological locations, levels and latencies at which multisensory interactions occur, and to probe to what extent and in what instances are multisensory interactions linear or non-linear. Recent results from clinical studies into multisensory processing in older people reflected at the behavioural and neural level, suggest specific impairments in switching between sensory modalities with age [7]. Probing these impairments may offset problems with multisensory processing such as physical instability and falls in older age.

Trinity neural engineering researchers are also investigating ***Brain Activity*** to improve the ability to decode brain signals across all levels of complexity from single neurons to the whole brain. Results have demonstrated that neurophysiologically interpretable mathematical models can be applied to individual neuroimaging data to infer the nature of synaptic deficits underpinning diseases such as schizophrenia [8]. Thus using models based on non-invasive neuroimaging methods such as EEG, the potential is there to investigate the influence of pharmacological manipulations on neurological diseases and opens up a new exciting dimension for drug discovery.

Trinity College neural engineers are developing new ***Active Implantable Devices*** to functionally interface to neural tissue in real time [9], [10]. Clinical application of electrical stimulation is a promising treatment for a range of neurological and psychiatric disorders. Deep brain stimulation in specific brain regions has provided remarkable therapeutic benefits for otherwise treatment-resistant movement and affective disorders such as Parkinson's disease, essential tremor, dystonia and chronic pain. The hope of many is that this technology may transform the treatment of neurological disorders the same way pacemakers and defibrillators impacted cardiology. Research in Trinity College is aimed at providing a new understanding on the role of such stimulation in specific clinical populations with the overall goal of developing targeted electrotherapies.

The future of this exciting new discipline of neural engineering will be determined by its success in improving human health and quality of life through its contribution to the understanding, restoration and enhancement of the function of the nervous system.

PROFESSOR RICHARD REILLY is Professor of Neural Engineering, a joint appointment in the School of Medicine and the School of Engineering at Trinity College Dublin.

DR. ED LALOR is the Ussher Lecturer in Active Implantable Devices in the School of Engineering at Trinity College Dublin.

1. Wittchen, H. U., Jacobi, F., Rehm, J., Gustavsson, A., Svensson, M., Jonsson, B., Olesen, J., Allgulander, C., Alonso, J., Faravelli, C., Fratiglioni, L., Jennum, P., Lieb, R., Maercker, A., Van Os, J., Preisig, M., Salvador-Carulla, L., Simon, R. & Steinhausen, H. C. 2011. The size and burden of mental disorders and other disorders of the brain in Europe 2010. Eur Neuropsychopharmacol, 21, 655-79.
2. Gustavsson, A., Svensson, M., Jacobi, F., Allgulander, C., Alonso, J., Beghi, E., Dodel, R., Ekman, M., Faravelli, C., Fratiglioni, L., Gannon, B., Jones, D. H., Jennum, P., Jordanova, A., Jönsson, L., Karampampa, K., Knapp, M., Kobelt, G., Kurth, T., Lieb, R., Linde, M., Ljungcrantz, C., Maercker, A., Melin, B., Moscarelli, M., Musayev, A., Norwood, F., Preisig, M., Pugliatti, M., Rehm, J., Salvador-Carulla, L., Schlehofer, B., Simon, R., Steinhausen, H.-C., Stovner, L. J., Vallat, J.-M., Den Bergh, P. V., Van Os, J., Vos, P., Xu, W., Wittchen, H.-U., Jönsson, B. & Olesen, J. 2011. Cost of disorders of the brain in Europe 2010. European Neuropsychopharmacology, 21, 718-779
3. Bradley, D., Whelan R., Kimmich O., O'Riordan S., Mulrooney N., Brady P., Walsh, R., **Reilly, R.B.**, Hutchinson, S., Molloy, F., & Hutchinson, M. Temporal discrimination thresholds in adult-onset primary torsion dystonia: an analysis by task type and by dystonia phenotype. *Journal of Neurology, June, 2011*
4. Kiiski, H., **Reilly, R.B.**, Lonergan, R., Kelly, S., O'Brien, M., Kinsella, K., Bramham, J., Burke, E.T., O'Donnchadha, S., Nolan, H., Hutchinson, M., Tubridy, N, & Whelan, R. Change in PASAT performance correlates with change in P3 ERP amplitude over a 12-month period in multiple sclerosis patients. *Journal of the Neurological Sciences*, 305, 45-52, 2011
5. Whelan R, Lonergan R, Kiiski H, Nolan H, Kinsella K, Hutchinson M, Tubridy N, **Reilly RB**. "Impaired information processing speed and attention allocation in multiple sclerosis patients versus controls: A high-density EEG study". *Journal of the Neurological Sciences*. Volume 293, Issues 1-2, 15 June 2010, Pages 45-50
6. Galli A., Garattini C., Burke N., Rapcan R., D'Arcy S., **Reilly R.B.**, Robertson I.H. "Cognitive function monitoring using temporal speech dynamics, *Proceedings of the International Association of Gerontology and Geriatrics-VII European Congress* Bologna, April 2011.
7. Setti A, Finnigan S., Sobolewski R., McLaren L., Robertson I.H., **Reilly R.B.**, Kenny R.A., Newell F.N., "Audiovisual temporal discrimination is less efficient with ageing: An ERP study", *NeuroReport*, Vol 22, Iss 11, 554-558, August 2011
8. Moran R., Kiebel S.J, Stephan K.E, Bombach N. O'Connor W.T., Murphy K.J. **Reilly R.B**, Friston K.J., "Bayesian estimation of synaptic physiology from the spectral responses of neural masses", *NeuroImage*. **Vol. 42, Issue 1**, pp *272-284*, August 2008
9. Tsanov M., Chah E, Vann S.D., **Reilly R.B**, Erichsen J.T., Aggleton J.P., O'Mara S.M., Theta-Modulated Head Direction Cells in the Rat Anterior Thalamus, *Journal of Neuroscience*, 31(26):9489-9502, June 2011.
10. Chah E, Hok V, Della-Chiesa A., Miller J.J.H, O'Mara S.M, **Reilly R.B.,** "Automated spike sorting algorithm based on laplacian eigenmaps and k-means clustering" Vol 8, No. 1, 2011.

Regulatory Updates

QUALIFICATION & CLASSIFICATION OF SOFTWARE WORKING GROUP

Two meetings of the Qualification and Classification of Software Working Group were held during September. The purpose of these meetings was to finalise the draft text of the guidelines which was endorsed at the recent Classification and Borderline Working Group and will now be tabled at the MDEG meeting in January 2012 for publication approval. In acknowledging the pace of innovation and change within the software industry it was recommended that the working group is continued to allow for future software developments and applications to be considered.

In its current format, the guidance document deals solely with qualification and classification of standalone software whilst also providing illustrative examples on how the criteria and rules are applied. Additionally, the use of software within the remit of the *In-vitro* Diagnostic (IVD) Medical Device Directive 98/79/EC is also considered. Software which is embedded in a medical device is, however, outside of the document's scope.

IVD TECHNICAL GROUP

A meeting of the IVD Technical Group (IVDTG) took place in September. An update was provided on the revision of the IVD Directive (98/79/EC). A draft impact assessment report was submitted to the impact assessment board for review in September 2011. The concept of a network of reference laboratories for

IVDs was discussed and a number of member states expressed interest in joining a group to explore this concept. Among the other items discussed were the revision of Meddev 2.14/1 Rev 1 (IVD Guidance: Borderline issues – A Guide for Manufacturers and Notified Bodies) and the draft guideline on qualification and classification of software. The Commission provided an update on the current status of the addition of vCJD to Annex II List A and advised that they are awaiting the amendment of the IVD Directive, which is expected shortly. An overview was provided on the GHTF activities with regards to clinical evidence for IVDs and the draft EMA guideline on the co-development of biomarkers and medicinal products.

COMPETENT AUTHORITY FOR MEDICAL DEVICES

The 28th Meeting of the Competent Authorities for Medical Devices (CAMD) was held in Krakow during October. Detailed discussions were held on the developing cooperation between the CAMD and the Heads of Medicines Agencies (HMA) networks and on the topic of developing new models for appropriately funding and resourcing the medical devices regulatory network in the future. The IMB is centrally involved in both of these initiatives. Discussions were also held at the meeting on control of advertising of medical devices, the role of national reference laboratories for in-vitro diagnostic medical devices and the future development of the Central Management Committee.

HEADS OF MEDICINES AGENCIES – COMPETENT AUTHORITY FOR MEDICAL DEVICES WORKSHOP

A second workshop to discuss and develop cooperation between the HMA and the Competent Authorities for Medical Devices (CAMD) networks took place in Vienna in September. This workshop allowed for detailed discussions on developing a formal cooperation between the two networks to improve coordination, management and harmonisation of the regulatory system for medical devices. The workshop also discussed developing proposals on future funding and resourcing of the regulatory network. The meeting also allowed opportunity for technical discussion on topics of joint interest such as regulation of drug-device combination products and clinical research. The European Commission updated the workshop on the revision to the medical devices legislation.

RECAST WORKING GROUP

The Recast Working Group met in September and again in October. This group allows for detailed discussions amongst Competent Authorities and with the European Commission on how specific proposals which may form part of the revision to the medical devices legislation could operate in practice and what specific legislative changes would be useful. The group has received submissions from several competent authorities and Commission working groups and has compiled a 'wish-list' for consideration by the European Commission. The group now intends to focus on specific policy areas and develop more detailed proposals/discussion documents which may be useful for the revision to the legislation.

CLINICAL INVESTIGATION & EVALUATION WORKING GROUP

The Clinical Investigation & Evaluation (CIE) Working Group met in October and finalised the revision to the Meddev guidance on post-market clinical follow up studies. This guidance document will now be tabled at the Medical Device Expert Group meeting in January for final endorsement and publication. Discussions also took place on the practical issues encountered with the implementation of the clinical investigation module on the European database, EUDAMED. An update was also provided on the proposed cooperation between the CIE Working Group and the Heads of Medicines Agency network to discuss topics relating to clinical research. The CIE Working Group also announced the launch of their webpage which can be found at **http://ec.europa.eu/health/medical-devices/dialogue-parties/working-groups/cie_wg_index_en.htm**

COMPLIANCE AND ENFORCEMENT WORKING GROUP (COEN)

A meeting of the COEN Working Group was held in Brussels in October 2011. Discussions continued among member states on enhancing cooperation between market surveillance authorities and customs authorities. The role of economic operators in the context of Regulation 768/2008 was also further discussed. Updates were provided by the European Commission on various items including the upcoming recast of the medical devices directive and discussion on harmonised standards. Details of specific market surveillance projects undertaken by member states and various issues of mutual interest were also discussed. The next meeting of the COEN group is scheduled for January 2012.

CENTRAL MANAGEMENT COMMITTEE

The Central Management Committee (CMC) met in Krakow during October. Discussions included the previous CMC decision on the standard address format for medical device manufacturers. This decision was again endorsed by CMC for implementation at national level during 2012. The CMC were updated on the proposals for designation, monitoring and for specific criteria for medical device notified bodies to harmonise performance. Other discussions took place on proposals on the readability of instructions for use and a proposal to revise the process for decision making on classification & borderline issues. The next CMC meeting is due to take place in March 2012.

NOTIFIED BODY OPERATIONS GROUP

The Notified Body Operations Groups (NBOG) held a workshop meeting in November to discuss and develop two key proposal documents relating to notified bodies for medical devices. The first is a proposal to significantly revise the process for designation and monitoring of notified bodies to ensure that all notified bodies are appointed and overseen in the same way and are performing at a consistently high level. The second document is a proposal to define and detail specific criteria and requirements for notified bodies. The IMB is acting as the lead on both of these documents on behalf of the NBOG and the Central Management Committee (CMC). It is hoped that the documents will be finalised and published in early 2012 and will be useful in the context of the revision of the devices legislation.

Safety Communications circulated regarding Medical Devices

The medical device safety communications that are circulated to healthcare professionals and medical device 'users' may be divided into two main groups:

1. Communications that are circulated by the manufacturer or his local agent.

2. Communications that are circulated by a regulatory agency.

The primary aim of these communications is to advise the user of the device, whether that is at home, in a hospital or in a community setting, of important information regarding the use of their medical device. This article will outline the purpose of the different communications and will also summarise the content that you should expect to see included in such communication.

MANUFACTURERS COMMUNICATIONS

Healthcare professionals receive many communications from distributors and manufacturers relating to medical devices, some of these communications relate to product improvements or product enhancements while others relate to product recalls or software updates. In this article we are concerned with those communications that have an impact on the safe use of the device. The guidelines on a medical devices vigilance system Meddev 2.12-1 rev 6, defines such safety related communications as a '**field safety notice**'.

A '**field safety notice**' **(FSN)** is the

communication format that a manufacturer must use to communicate such safety related issues to the customers and/or users of the device.

Examples of those actions that can be communicated via a FSN include:

- the return of a medical device to the supplier (recall);
- device modification;
- device exchange;
- device destruction;
- retrofit by purchaser of manufacturer's modification or design change;
- advice given by manufacturer regarding the use of the device (e.g. where the device is no longer on the market or has been withdrawn but could still possibly be in use e.g. implants or change in analytical sensitivity or specificity for diagnostic devices)

This is quite broad reaching as a device modification can include:

- permanent or temporary changes to the labelling or instructions for use;
- software upgrades including those carried out by remote access;
- modification to the clinical management of patients to address a risk of death or serious deterioration in state of health related specifically to the characteristics of the device.

The guidelines state that the FSN should be on a company letterhead, be written in the language(s) accepted by the national competent authority(s) and include the following:

1. A clear title, with "Urgent FIELD SAFETY NOTICE" followed by the commercial name of the affected product, an identifier (e.g. date) and the type of action.

2. Specific details to enable the affected product to be easily identified e.g. type of device, model name and number, batch/lot or serial numbers of affected devices and part or order number.

3. A factual statement explaining the reasons for the action, including description of the device deficiency or malfunction, clarification of the potential hazard associated with the continued use of the device and the associated risk to the patient, user or other person and any possible risks to patients associated with previous use of affected devices.

continued overleaf →

4. Advice on actions to be taken by the user. Include as appropriate:
   - identifying and quarantining the device,
   - method of recovery, disposal or modification of device
   - recommended review of patients previous results or patient follow up, e.g implants, IVD.
   - timelines.

5. A request to pass the field safety notice to all those who need to be aware of it within the organisation and to maintain awareness over an appropriate defined period.

6. If relevant, a request for the details of any affected devices that have been transferred to other organisations, to be given to the manufacturer and for a copy of the field safety notice to be passed on to the organisation to which the device has been transferred.

7. If relevant, a request that the recipient of the field safety notice alerts other organisations to which incorrect test results from the use of the devices have been sent. For example failure of diagnostic tests.

8. Confirmation that the relevant national competent authorities have been advised of the field safety corrective action.

9. Any comments and descriptions that attempt to
a) serve to play down the level of risk in an inappropriate manner
b) advertise products or services should be omitted.

10. Contact point for customers how and when to reach the designated person. An acknowledgment form for the receiver might also be included (especially useful for manufacturer's control purposes).

The manufacturer can send the FSN by post, email, fax or in some instances may hand deliver the notice. The manufacturer may address the FSN to the healthcare professionals impacted by the issues outlined in the communication e.g. theatre staff, clinical engineering, lab managers, specific clinical specialities or in some instances where the devices are used by multiple departments the manufacturer may address the notice to the CEO, the risk manager or the procurement department.

The manufacturer often includes an acknowledgement form / fax back form with the FSN which he requests the recipient to return. This form can request acknowledgment of the receipt of the letter and further details regarding the numbers of affected devices etc.

A monthly listing of field safety notices relating to actions that have impacted the Irish market is published on the IMB website.
http://www.imb.ie/EN/Publications/Publications.aspx?categoryid=78&year=&letter=

REGULATORY AGENCIES COMMUNICATION

The principal regulator communications that are circulated regarding medical devices are the safety notices that are published by the IMB and medical device alerts (MDA) that are published by the MHRA in the United Kingdom. These communications are competent authority communications which are circulated to highlight specific concerns or market actions. They are not issued in the place of a manufacturer communication (FSN) and in many instances only highlight or supplement a notice that has already been circulated by the manufacturer.

For example the IMB may circulate safety notices in the following instances:

- To highlight a serious public health issue.
- To highlight an issue that has already been communicated by a manufacturer via a field safety notice but where the manufacturer has indicated to the IMB that he has experienced difficulty reaching all customers or obtaining feedback from all customers.
- To highlight an issue when either the device manufacturer or Irish distributor no longer exist. For example where the manufacturer has gone into liquidation or where the manufacturer is not known e.g. counterfeit devices.
- To communicate concerning trends that the IMB has noted with particular product families.
- To communicate safety concerns that the IMB has noticed in monitoring vigilance issues e.g. equipment management issues, traceability issues.

The format of the IMB safety notices is standard, it provide details of the target audience, an outline of the issue, details regarding the background of the issue and concludes with the detail of the recommended actions.

The safety notices that are published by the IMB are posted on the IMB website and are circulated, at the time of publication, to healthcare professionals who have subscribed to our mailing list. The IMB also circulates, via email, a listing of IMB safety notices and MHRA medical device alerts at the end of each calendar month. All IMB safety notices can be found at
http://www.imb.ie/EN/SafetyQuality/Advisory,WarningRecallNotices/MedicalDevices.aspx

In practice, IMB safety notices and MHRA medical device alerts are only issued for a small percentage of the overall FSN's distributed in Ireland.

The recipient of the safety communication, (FSN, IMB safety notice or medical device alert) should ensure that

continued overleaf →

the communication reaches the most appropriate personnel within his organisation. He should also ensure that the issue outlined in the notice is considered, the risks assessed and the appropriate / recommended actions are completed.

In some instances, the recipient of the notice may not be the most appropriate person to deal with the issue, therefore a well defined, effective mechanism for managing the communications is necessary. Some organisations, hospitals and the community care setting have found that it is very beneficial to have one designated medical device vigilance contact, a local medical device vigilance team that meet to assess the issues that arise, local medical device vigilance procedures and a database to support the management of such communication. Such structures and defined responsibilities and processes help to ensure that the communications are dealt with in a timely manner. (See IMB medical devices newsletters *February 2004 Vol. 1 No. 7* and *December 2006 Vol. 1 No. 18* for more information).
http://www.imb.ie/EN/Publications/Publications.aspx?year=0&page=2&categoryid=54&letter=&q=&pagecategoryID=-1

Should you receive a FSN from a manufacturer that is not included on the IMB listing please let us know by email vigilance@imb.ie.

Central Management Committee (CMC) on Medical Devices – Decision on information to be provided in relation to the address of the manufacturer

The Central Management Committee (CMC) on medical devices was established at the end of 2010 following endorsement at the 26th Meeting of the Competent Authorities for Medical Devices in Liège. The key objective of the CMC is to improve the effectiveness of the regulatory system for medical devices through greater consistency in interpretation of the requirements of the legislation.

On the 7th June 7 2011, the CMC issued a decision that represents agreement between market surveillance authorities of the member states on a harmonised interpretation of what format of address a manufacturer (and when relevant an authorised representative) of medical devices shall put on the label and instructions for use to meet the requirements of the European medical device legislation.

The address shall be the address of the registered place of business of the legally responsible manufacturer and shall include the following details:

- street/road,
- number/house/floor,
- postal code
- city
- state/region and
- country

The same details shall be provided for the address of the authorised representative. Manufacturers based in countries which do not have specific elements of this required format e.g. postal codes, cannot and would not be expected to include them.

The Compliance and Enforcement Group (COEN), was asked to appropriately enforce the implementation of this decision. Competent Authorities within the medical device sector request that manufacturers implement the decision by September 2012.

The full text of the decision may be accessed at:
http://www.cmcmd.eu/mediapool/97/978504/data/Decision_3_COEN-1.pdf

Further information on CMC may be found at www.cmc-md.eu

Publication of IMB leaflet on safe use of Automated External Defibrillators

Approximately 5,000 sudden cardiac deaths occur in Ireland each year, one of the highest rates in Europe, with roughly 70% occurring outside of the hospital setting. Automated external defibrillators (AED) play an important role in reducing the time to response when out of hospital cardiac arrests occur. The number of AEDs in use in Ireland has increased as awareness of the associated benefits has grown and it is becoming more common for AEDs to be seen at locations such as sports facilities and shopping centres.

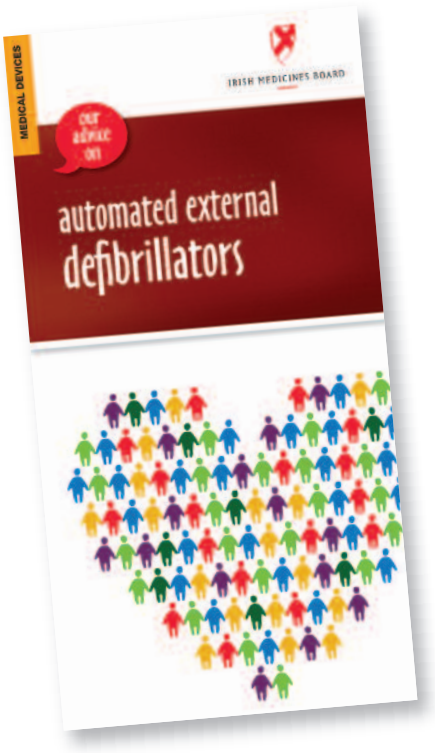
An AED can improve a person's survival chances following sudden cardiac arrest. Therefore, defibrillators need to be 'fit for use' at all times in the event that they are needed for an emergency situation. The IMB has received reports relating to safety problems with AEDs. Some of the issues can be corrected by the manufacturer (e.g. software upgrades) and others can be overcome with good maintenance and servicing practice.

The IMB has produced a leaflet to highlight to AED users in the community some of the important points to consider to ensure their AED is fit for use when needed. The leaflet provides guidance on what should be considered before an AED is purchased and after the AED has been purchased and put into use, including:

CE marking and traceability

- All medical devices must BY LAW display a CE mark.

continued overleaf →



- Accessories such as electrodes, used with a defibrillator to assess the patient and deliver therapy, are also medical devices. If supplied separately they must also bear the CE mark.

Defibrillator storage

- Inappropriate storage conditions can result in the defibrillator being unusable when needed and/or long term damage to the defibrillator and its accessories.
- Defibrillators and their accessories (pads, electrodes, battery, etc.) can be badly affected by the weather and other environmental conditions.
- Check the manual of the defibrillator and its accessories to identify the conditions that can affect its performance, such as:
  – Storage temperature
  – Exposure to moisture and damp (environmental humidity).

AED training

- All users of defibrillators should complete a recognised training course on their use.
- Ensure that the names of trained users and their contact details are displayed near the defibrillator and that all staff, facility members and users are aware of those who can use the device.

Servicing and maintenance

- A defibrillator, like all medical equipment, must be used and maintained in accordance with the guidance given by the manufacturer.
- A maintenance plan and schedule should be put in place and should include all accessories (pads, battery pack, electrodes, etc.) used with the defibrillator.

Defibrillator updates

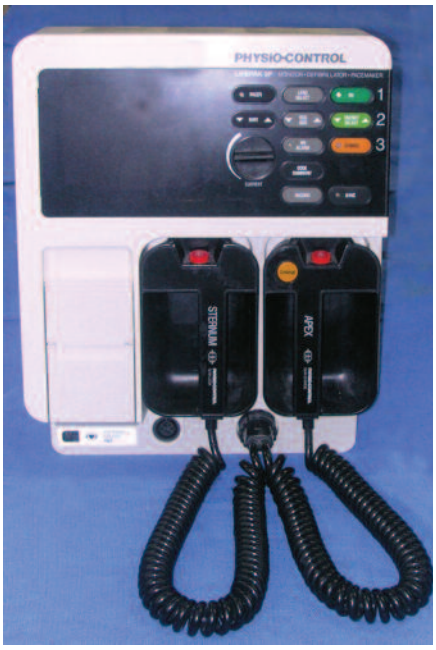
- A defibrillator may need to be updated (e.g. software) or changed during its time in use.
- To make sure that all necessary maintenance can be carried out on your defibrillator, it is important that it can be easily accessed at all times.

Status indicator

- Your defibrillator has a status indicator that shows its current status. This is usually a light on the defibrillator and there may also be a voice prompt.
- The maintenance schedule for your defibrillator should include a log to record when the status of the defibrillator is checked.

Periodic self tests

- Make sure you have a clear understanding of the service tests performed by your defibrillator.
- If your defibrillator indicates it has failed a test during maintenance



CHECK THE USER MANUAL IMMEDIATELY and take the appropriate steps to identify the cause of the failure. Contact your local distributor or the manufacturer as soon as possible.

External factors

- The performance of your defibrillator can be affected by other external factors including electromagnetic interference.
- Ensure the defibrillator is used away from any identified sources of interference.

The AED leaflet is not intended to be a guide on how to use a defibrillator nor does it replace or reduce the importance of your defibrillator manual and training.

The AED leaflet will be available in electronic format on the IMB website www.imb.ie and hard copies of the leaflet can also be requested from the IMB.

IRISH MEDICINES BOARD

The Medical Devices Newsletter is designed by Ashfield Press Publishing Services for

IRISH MEDICINES BOARD, KEVIN O'MALLEY HOUSE, EARLSFORT CENTRE, EARLSFORT TERRACE, DUBLIN 2
tel: +353 1 6764971 fax: +353 1 6344033 email: medicaldevices@imb.ie: http://www.imb.ie