MDET

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Medical Device Education and Training

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Hazards of Surgical Plume

New Children's Bed Standards: EN50637

Remote Teaching and on-line courses

T34 (v3) syringe driver battery performance white paper

NAMDET and HSIB statements on DERS

First WiFi DERS in chemo service for the UK

Safety update: mains fuses and plugtops

First ever ISO13485 for Max Fax and Rehab service

Biomedical Engineering in Ethiopia

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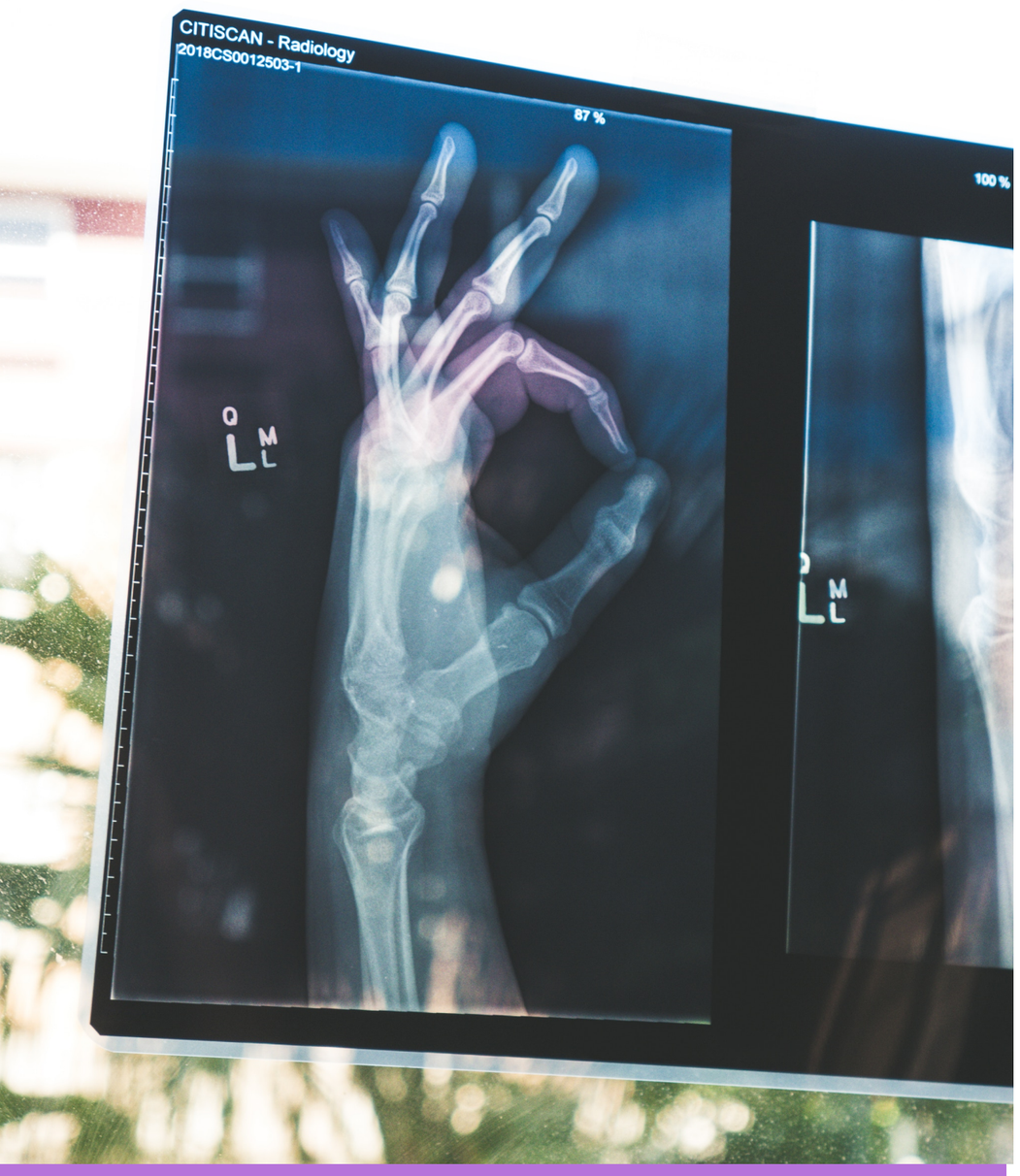


CONTENTS:

Words from the Editor...

Has it been over a year already since the covid pandemic hit and threw everything into disarray? How time flies '*tempus fugit*'. Those of us at the 'coal face' dealing with ever-changing plans, crisis followed by crisis, and the second wave planning the workload seemed never-ending. With work pressures increasing, we still managed to work our way through it, had colleagues on hand to support us, and people to turn to for guidance, and we will never forget their help and support going forward.

So many people lost loved ones; for our family, the sudden passing of our eldest brother brought into perspective the restrictions covid meant to us as a family. With limited attendance at the funeral, no wake to celebrate the short and eventful life of a loved one, choosing who will be allowed into the church and who will be left outside and no time to mourn and grieve has been a tough one to cope with. Our thoughts are with all families at this time who have lost loved ones too.

During 2020, I am truly amazed by all the effort and hard work shown in supporting our medical device colleagues right across the NHS and industry. Our efforts have proved that the role of the medical device educators and trainers is ever vital and a 'kingpin' role that should be supported and promoted right across the industry, NHS and healthcare. On top of already busy workloads, our members and writers have put together a great edition of MDET to share with you.

We look forward to the easing of lockdown and all your stories and article submissions for the next edition of MDET due in October.

For all article, editorial enquiries, advertising opportunities : please use the '*contact us*' page of the NAMDET website. www.namdet.org

Paul T. Lee: BA (Hons) RSci, MIPEM
Chairman NAMDET, MDET Editor

Jordan Lee: MA, BA (Hons)
Managing Editor MDET

NAMDET would like to thank BD Ltd. for their generous early commercial commitment, and ongoing support, which enabled this important journal to be first established.

HAZARDS OF SURGICAL PLUME

Electro Surgery Consultant Steve Veck provides an update on the hazards that exist from surgical plume

Some of you may remember our last Annual Conference in York 2019, which seems to be a foggy memory in the long distant past. During that conference I presented on Surgical Plume, which raised many questions. Some of those questions were in fact statements, suggesting that the removal of surgical plume should be the norm.

Sadly, it is still not the case and surgical plume evacuation is far from being the norm. Surgical Plume Evacuation is sporadic at best and still appears to be used selectively in many places. However, suddenly there appears to be a renewed interest in the subject, which has clearly been related to SARS-Cov2.

Healthcare staff not unreasonably are asking questions, as to their personal safety from contracting Covid -19 caused by inhaling Covid particulate matter. Not surprisingly, various queries have arisen and I personally have dealt with numerous questions, by phone, emails and social media.

It became clear that a great deal of interest was and is being shown regarding surgical plume, and this is evident by the increased number of publications during 2019-2021 in particular. From my perspective this is interesting, especially as I have been lecturing on this very subject for 30 plus years. Healthcare Staff have increased concerns as to what they could do to afford themselves protection. Some hospitals have taken up a voluntary position, in respect of providing their staff adequate and essential personal protection. Others have simply adopted the view that, until a policy is in place of a mandatory nature, they are not taking any action.

So here we are at another point in the Covid 19 pandemic, most would accept that the virus is here to stay! Despite the UK achieving excellent rollout of the vaccination programme, many have yet to be vaccinated, for a number of complex reasons.

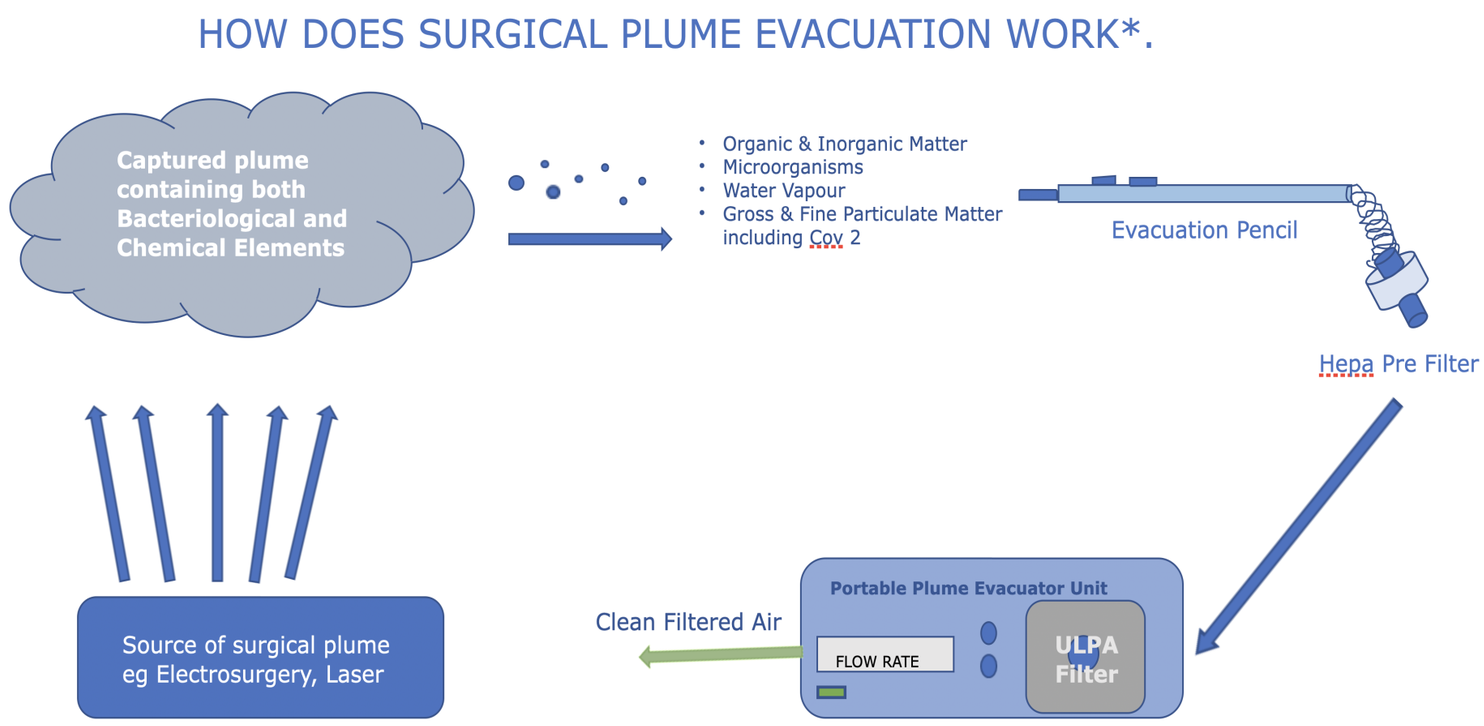
The potential of renewed activity with new Corona Virus cases is very much a real and present possibility. Meanwhile, our healthcare system will endure and meet the demand in treating patients. Some of these patients may well be Covid positive, especially acute or trauma cases. It is these patients that undoubtably present additional risk to healthcare professional. I say additional because, Covid-19 is in truth, an addition to all other hazardous risks, known to be associated with the emission of surgical plume.

By way of recap, here are some of the risks:

During approximately 95% of Surgery, in Endoscopic and Laparoscopic procedures, the use of various thermal medical devices, for example Laser, Ultrasonic and Electrosurgical Generators to name a few, are used. These devices are known to generate surgical plume, which will contain various types and sizes of particulate matter.

Indeed, the particulate matter generated can and does vary in size, depending on the energy source being used.

For example, Electrosurgery which is still widely used, produces very small particulate matter of approximately 0.07µ (microns). Laser produces larger matter of around 0.31µ Whenever tissue is disrupted, it produces surgical smoke plume. This is a good time to explain the difference between 'plume' and 'smoke'. To some it may be just a case of semantics, however Standards and mitigation policies are all based on risk assessment:



*Plume Evacuation can be performed from Central Pipeline Systems or Portable Evacuators and many other options also.

"Smoke is a component of the aerosols that when diffused from the surgical site, becomes airborne, and then transmit to breathing zones of persons present. This movement of airborne materials is plume, which becomes the risk for exposure to the hazard

Therefore, if the material does not disperse, it cannot be respirable – and it is not a hazard, nor does it present a risk. Smoke is not the hazard nor is it the risk".1

For the reasons mentioned previously, I prefer to use the words surgical plume, which can contain both chemical and biological particulate, also organic and inorganic matter.

Both particulate and matter present their own set of hazards and concerns. The content of this plume as mentioned earlier is both of a chemical and biological state and contains Carbons, Hydrocarbons, Blood, Faecal Matter, Bacteria, Virus's, Pathogens, Carcinogens, HPV, Hep B and HIV, all in all a very toxic mix with massive mutagenic potential.

Perhaps this is a good point to ask the question 'Why are our Healthcare Professionals still being exposed to surgical plume?' and that is indeed a very good question. Especially, when we have various statutory Acts to protect us...don't we?

Well, here is an expert from the **Health & Safety at Work Act 2015**:

"The **Act** places a general duty to *'ensure so far as reasonably practicable the **health**, **safety** and welfare at **work** of all of their employees'. Employers must comply with the **Act**. They must: provide and maintain **safety** equipment and **safe** systems of **work**."*

The main issue with this Act, is that it is perhaps too broad based and therefore does not invoke a need to bring about change. There is also an attitude, that surgery has been carried out for years, with surgical plume being present. There is no doubt a financial burden to be considered, in the provision of adequate surgical plume evacuation.

I recently presented on a Surgical Plume webinar along with Mr Steve Leung - a Renal Surgeon from Edinburgh, who understood the necessity in adequate surgical plume evacuation in theatres. He supported and participated in a drive to furnish all theatres with adequate equipment for surgeons and staff.

During my time, I have probably heard many of the arguments, for not using surgical plume evacuation. I recall a conversation with an Anaesthetist some years ago, who told me that "There was absolutely no evidence of nurses or surgeons becoming ill or contracting diseases or cancer as a result of inhaling surgical plume".

Actually, he is quite right, that indeed is the case. But he was missing the real point and that is, just because the evidence has not been researched, it does not necessarily mean that cases do not exist. My suspicion is that, as a research project it would be practically impossible to collate enough evidence, given that many of these conditions manifest in later life. Then there is the issue

of tracing the individuals and furthermore, ruling out environmental or genetic factors.

Some years ago, the widespread use of asbestos in the building trade was the norm. Asbestos was discovered as far back as 2400BC in Finland, with various pots, pans and other cooking items being made from asbestos. In 61 -112AD Pliny the Younger, an ancient roman scholar wrote that slaves who mined and used asbestos became seriously ill. Nearly 2,000 years later in 1930 Dr E R A Merewether, a famous researcher published his findings on asbestos production and use, showing clearly that it produced a latency in the development of disease. He went on to say 1 in 4 workers would develop Asbestosis.

In that same year Dr C W Price joined Dr Merewether in bringing about regulations, to protect production workers of Asbestos. This Regulation Act did not however, protect the construction industry. Leaping forward a further 30 years, in which time much was published (indeed some 200 articles) regarding the safe use of asbestos products and yet a regulation only came into being in 1969. It has taken many more years, to bring about real change to this hazardous material. Numerous claims have resulted in litigation, even though the disease has been of a latent onset.

"...there are several pieces of anecdotal evidence, that may suggest a correlation between surgical plume and health concerns."

We might well draw some parallels to surgical plume with this scenario. I appreciate that we cannot provide widespread evidence of surgical plume causing death or disease. However, there are several pieces of anecdotal evidence, that may suggest a correlation between surgical plume and health concerns. We simply do not know, how many retired healthcare professionals leave the Healthcare arena and then go on to develop issues that may well have been related to years of inhalation of surgical plume.

Here are some examples of anecdotal evidence:

Case 1: Mr Anthony Hedley – Retired Orthopaedic Surgeon who had in his career performed over 11,000 procedures and spent as much as 40,000+ hours exposed to surgical plume. He was diagnosed in his latter years with Idiopathic Pulmonary Fibrosis, which doctors could not rule out was caused by his exposure to surgical plume, especially as he was a non-smoker. He had a life saving double lung transplant and now takes every opportunity to warn other healthcare professionals.

Case 2: Dr P***** – Consultant Gynaecologist – Australia. This gentleman recently contacted me to discuss a keen interest he had in surgical plume. He went on to tell me he had been diagnosed with an OPSCC – Oropharyngeal Squamous Cell Carcinoma p16 positive oncogen. Interesting as this oncogene is more often associated with a low risk genital type. Then if I add that Dr P was an active Colposcopist, used to treating patients with a number of genital abnormalities, not least HPV (Human Papilloma Virus) oncogen 16 and 18. HPV 16 & 18 are HPV elements that may well go on to develop as cancers. Initially graded as CIN I, II, III then micro invasive cancer. This might leave at least a hypothesis of origin of his condition. Remember surgical plume can bring about mutagenic changes which in this case may well prove as strong evidence.

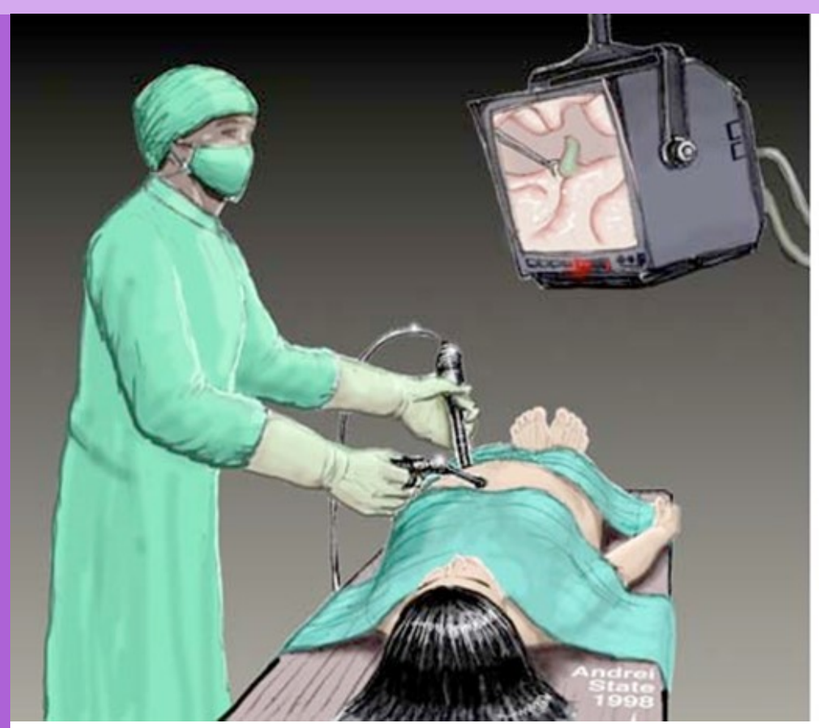
Case 3: Ms Angela Hohn – Registered Nurse Atlanta VA Healthcare. Angela had presented to her Primary Care Practitioner with a pain proximal to her ribcage. Her doctor dismissed it as a possible muscular injury and so did Angela. However, after months of pain she finally haad a CT scan which revealed a lesion in the right lung. Her Pulmonologist diagnosed a Stage IV Non-Small Cell Lung Cancer. Angela had been a Theatre Nurse in England in 1979, then in 1980's moved to work in the Operating Theatres in Jamaica then eventually in the USA. She had always kept fit, running and generally maintaining a healthy lifestyle and had never smoked nor had any members of her immediate family.

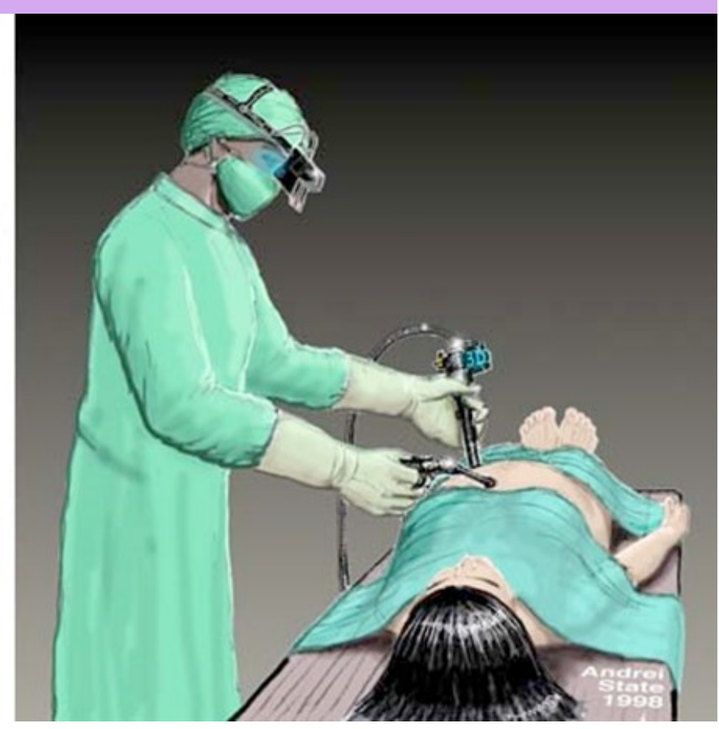
Case 4: Case 4: Dr B*** B*** - Consultant Gynaecologist, again a well renowned Colposcopist. I was on the same teaching faculty as this gentleman and he shared his concerns with me one day. He said that he was an avid amateur singer, but that he had persistent bouts of sore throats and infections. He sought advise and was diagnosed as having some polyps surrounding his vocal cords. He felt that this was a direct result of exposure to some levels of surgical plume, even though his Colposcopy Department had measures in place to eradicate surgical plume.

Conclusion:

What have we learned so far? We know that surgical plume can behave in a mutagenic way, we also know that particle size <5 microns can surpass the average theatre paper mask. We also know that particle size is important, in that small particles can reach the deepest parts of the alveoli, which can then be absorbed directly into the bloodstream.

Given the emerging evidence, which at the very least demonstrates a clear potential





for a serious hazard, surely now we must act swiftly in order to protect our healthcare professionals? Should we wait for a government directive? Considering the time taken by government to act on the subject of asbestos back in the 1930's we surely must take decisive action, even before any mandatory policies are issued.

I currently sit as a Council Member for British Standards Institute (BSI) and I am in the working group on Surgical Plume on the ISO16571:2019 document. Clearly, I am unable to divulge where that document is in terms of release. However, the document itself will not necessarily invoke a mandatory policy. We need to be engaging our relevant associations and colleges and insisting on bringing this subject to the forefront of all agendas. Government needs to be made aware of an urgent need for change, this is best approached through professional bodies. In addition to all of the existing risks associated with surgical plume, we now have an added risk of contracting Covid-19 virus.

References:

1. ICSP – International Council on Surgical Plume – Education Resource Material.

National Association of Medical Device Educators and Trainers

www.namdet.org

NAMDET Annual Conference (virtual) November 11, 2021

Save the date....

NEW CHILDREN'S BED STANDARDS EN50637:2017

Requirement for the basic safety and essential performance of medical beds for children

The safety of the child has the highest priority in every hospital. To ensure it, the new European Paediatric Standard 50637, which focuses on mechanical and electrical components, came into force on the 31st of August 2020. Any beds supplied / sold for use by children or adults with smaller anatomy after 31/8/2020 should comply with the new standard (but it is not law). Any existing beds in circulation supplied before 31/8/2020 do not need to meet the regulation – it is only for beds supplied after 31/8/2020.

The existing adult bed standard EN 60601-2-52 that most medical beds are CE marked to for typical sized adults, does not cover requirements for children and adults with smaller anatomies. The EN 50637:2017 standard seeks to ensure safety for young patients and adults who, because of their smaller body measurements and anatomies, have higher risks of being entrapped in medical beds and cots.

Definition of a Child Patient

A CHILD is defined in this context as a PATIENT having a physical size equal to or less than 155 cm and a mass equal to or less than 70 kg. Please note that the standards also cover adult users with atypical anatomy within this range.

What does this new standard cover?

Amongst other elements the new standard covers: lateral strength of siderails, secure storage and the lock out of controls/headsets, extra precautions against strangulation and entrapment such as sizes of feed tube holes or loose cables that could get wrapped around a child's neck, instructions and warning and revised labelling.

What or who does the EN 50637:2017 standard apply to?

It is not age related, so can include elderly dementia patients with smaller body anatomy. The limitation of 180 cm lying surface length is to reduce parents sharing beds with the child or the bed being used by an adult. However, if a bed can be used by both a child and an adult, e.g. length of 180 cm or 200 cm, then it will need to conform to both adult EN 60601-2-52 and the children's EN 50637 standard. The European standard seeks to ensure safety for young patients and adults who, because of their smaller body measurements and anatomies, have higher risks of being entrapped in ordinary medical beds and cots. The need to have a European Standard on this topic arose following incidents and casualties caused by medical beds with cot sides. The victims were children and adults with an atypical anatomy.

Summary of EN50637:2017

Summary of EN50637:2017

This Standard applies to;

1. BASIC SAFETY and ESSENTIAL PERFORMANCE of MEDICAL BEDS, intended for CHILDREN and ADULTS with atypical anatomy
2. Medical beds with nonadjustable and electrical / mechanical adjustable functions.
3. MEDICAL BEDS with an internal length of up to 180cm suitable to a body length of 155 cm.

NOTE : The limitation of 180 cm is in order to minimise the foreseeable misuse, of a parent sharing the bed with the child or that the bed will be used by an ADULT.

If a manufacturer wishes to make a bed that can be used by both a child and an ADULT, e.g. length of 180 cm or more, then it will fulfil both EN 60601-2-52 and this particular standard.

This Standard does not apply to;

1. MEDICAL BEDS intended for ADULTS
2. Incubators covered by EN 60601-2-19
3. Beds for children, covered by EN 716-1 and EN 716-2
4. Cribs and cradles covered by EN 1130 (all parts)
5. Bunk beds and high beds, covered by EN 747-1 and 747-2.

HAZARDS inherent in the intended physiological function of MEDICAL BED or ME SYSTEMS within the scope of this standard are not covered by specific requirements in this standard except in 7.2.13 and 8.4.1 of EN 60601-1:2006. NOTE 2 See also 4.2 of EN 60601-1:2006.

NOTE: Body length is measured from crown to sole.

The EN 50637:2017 standard contains updates to EN 60601-2-52, mainly:

*lateral strength of side rails

*secure storage & lockout of handset

*extra precautions against strangulation & entrapment such as sizes of feed tube holes or loose cables that could get wrapped around a child's neck

*labelling instructions & warnings

OLYMPUS

Launched in September 2020, the Olympus virtual hub offers free live and interactive educational seminars focusing on hot topics in medical technology in collaboration with faculty from the UK and Ireland.

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REMOTE TEACHING

Diane Irvine gives us some advice on how to maintain learning when you go to Virtual Training

In the rush to deliver remote teaching in “survival mode," did you really have time to consider the technical, scheduling and educational aspects of online training. Or did you believe you could continue to deliver training as before but on camera?

So, exactly how can we conventional instructors rapidly acquire the necessary technical skills and confidence to switch to an online approach? How do we adapt our training and what are our options?

With the online platforms currently available, live teaching can easily be scheduled in a virtual classroom, with greater certainty, inclusivity, and effectivness. Pre-recorded video and text-based online training are other remote options, and they have the advantage of being available on demand.

While it’s a mistake to underestimate the lost advantages of live teaching when learning “on-line, on-demand”, effectiveness is all about quality. As trainers, our focus must remain on the active learning.

So, what does it takes to deliver high quality live/virtual, and pre-recorded, video/text blended training, over the internet? There are two key factors for online training success:

- The technical skills you require
- The ability to adapt the structure and delivery of your content to digital media

CRUCIAL TO SUCCESS IS YOU!

CRUCIAL TO SUCCESS IS YOU

Whether face-to-face or virtual, crucial to the success of the training you provide is YOU. You need to feel confident, so learn how to set up your equipment, how to use it competently and how to trouble-shoot when things go wrong.

There are specific challenges with the virtual classroom, especially if your learners are reluctant to participate or are finding the content difficult to grasp. You also need to have additional skills to approach and engage all your learners without losing the attention of others in the group.

SYNCHRONOUS AND ASYNCHRONOUS

Online training falls into two main categories:

- **Synchronous**: a virtual classroom with tailored delivery of content, interaction and feedback, working in real-time.

- **Asynchronous**: pre-recorded video and/or text-based teaching materials which can be accessed by the learner, any time they want, but with no live interaction or feedback.

A virtual classroom is a real-time online simulation of face-to-face learning. There's plenty of scope for high-quality audio-visual interaction.

The use of break-out “rooms” for small-group collaborative work and tutorials enhances the learners’ experience, the same as it does in face-to-face teaching.

WHAT ARE THE CHALLENGES?

It can be difficult when your learners are based across different time-zones. Another challenge is that as numbers rise in the virtual classroom, interaction becomes more difficult.

Online learning that is on-demand can give a more limited learning experience, especially when the content is text-based because text-based learning offers few if any opportunities for interaction or feedback.

Studying alone with only a computer and text-based materials may not be the way your audience are able to learn. Video-based online training can be a reasonable compromise. A blend of video, audio and text resonates more with a much greater number of learners than mostly text-based courses.

WHAT ARE THE ADVANTAGES?

The key educational advantages of the live/virtual classroom are that they accommodate intensive individual coaching and interaction between trainers and delegates. Just like in real life, there’s the potential for effective learning to take place in real-time when the learner can stay focused, the I.T. is reliable and you get the delivery right. So which factors help you decide on the type of online training to use?

IN THE "CLASSROOM"

Start your course by explaining the housekeeping rules: a quiet room, mobile phones on silent and away from microphones to avoid feedback. Request that microphones are on mute during presentations and ask learners to un-mirror their video (so that simple hand-held visual aids are legible) and make sure everyone’s full name is are attached to their video feed.

Let your learners know that there’s a Q&A period at the end of each session, so while you’re happy to address urgent issues during your lesson, waiting until the appropriate time works best.

For bigger groups, suggest they put questions in the chatbox and consider addressing important issues in real time during your presentation if feasible.

Some platforms have a "hands-up" feature, displaying a visual indicator when a learner wants to speak. Other platforms have an integrated polling system which you can use to question larger audiences and boost engagement.

Technical difficulties, keeping track of timed activities, use of a polling system and white board functions are all better handled by a designated technical assistant.

It’s also useful on more complex courses to nominate one of your speakers to act as Moderator to keep the programme moving forward. They monitor overall time-management and make program changes to take account of any slippage. They also give the floor to speakers and attendees.

For more complex courses your various faculty members, techie and Moderator will all be working separately, so have a Whatsapp group set up for ease of communication, to use when you need to change the running order of presenters, for example.

TECHNICAL ELEMENTS

High sound quality is one of the few key elements worth investing in when recording and teaching online, so get a good microphone.

You don't need expensive professional equipment to film like a pro. It is possible to create good quality videos using your smartphone and laptop webcams. If using a smartphone, invest in a tripod to stabilize your image.

Choose a neutral backdrop that's easy on the eye. Wear clothing in neutral shades. Invest in lighting – it makes a significant difference to how you look when teaching. Film in landscape mode and stay on the left or right of the screen, so you have space to add text or keywords postproduction.

ANYTHING ELSE?

Have contact details for all participants, make sure learners know you work strictly to time – starting on the dot and re-starting promptly after breaks. Standardise any time zones. Email any pre-course materials and give instructions for materials needed.

Suggest that your learners ensure a secure internet connection (preferably hard-wired) for the duration of the course in your pre-course email.

Schedule frequent short breaks. Learning via platforms like Zoom, Webbex, Teams and Goto can be tiring for participants. Avoid scheduling live-virtual classroom sessions lasting longer than half a day. Time sequences lasting 45 to 60 minutes and individual or group activities of 15 -20 minutes work well. Include breaks of 5 to 10 minutes in every hour.

NUMBER ONE THING!

The story board! It's created to organise and develop the final video-recording or live/virtual course, and it's used to bring together all the materials and practical information needed to complete your project.

Detail the outcome for each sequence, what you want to say, what you want to show in the way of mages. Detail any sounds you want to add. Also, number your sequences according to the plan, and indicate their duration. There are virtual storyboard applications available, which save time and effort for more complex projects.

Putting big chunks of text on your PowerPoint slides will bore your learners to death! Adding visuals helps learners retain information far better than using audio alone. Use simple infographics, video clips, charts and diagrams whenever you can.

Always keep your eye on the prize, which is your lesson outcome. What do you want to teach? What do your learners want to learn?

QUESTIONS = CONTROL

Use questions to point the way forward, from one point to the next, towards their destination – the outcome you've set. In addition, though, questions encourage ownership of the knowledge you're providing because it helps them take it on board and remember it, then continue exploring for themselves.

Questionnaires are useful tools for evaluating the progress of your learners and validating their achievements. There are different types of questionnaire which you can easily mesh with your training material. Use them to check for gaps in knowledge, what outcomes your learners are seeking, and the retention of information between sessions.

The internet has transformed the way we deliver training, and within a short period of time, virtual classrooms have become the new gold-standard for teaching adult education worldwide.

GOOD LUCK!

Diane Irvine, Founder
Healthcare Skills Training International Ltd.)

Access our e-learning programmes on the e-LfH Hub

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e-Learning for Healthcare was formed in April 2007 to deliver a range of programmes, after a successful pilot with the Radiology-Integrated Training Initiative (R-ITI) which generated a model for the future delivery of generic and professional healthcare training. In 2013, e-LfH transitioned across to Health Education England and continues to work in partnership to develop e-learning programmes to support the health and care workforce.

e-LfH is now in the process of delivering or developing more than 400 e-learning programmes in collaboration with organisations including Royal Colleges, Department of Health and Social Care, NHS England and NHS Improvement and Public Health England.

NAMDET is pleased to help lead on the e-LfH 'Medical Devices' training and e-learning modules and looks forward to the development and delivery of new courses throughout 2021.

46+ million
e-learning sessions launched on the Hub

1.5+ million
registered users

25+ thousand
e-learning sessions available within 350+ programmes

Guidance for Teaching Online for Healthcare Educators

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NHS
Health Education England

CPD ECG COURSES

Cardinal Health's Medical Affairs launches ECG online courses

CardinalHealth

Essential to care™

Cardinal Health's Medical Affairs in collaboration with Charles Bloe Training, has launched two clinically based CPD ECG courses. Charles Bloe Training provide high quality training courses and clinical updates for all health and social care staff. Both courses have been authored by Charles G Bloe BJN UK Cardiovascular Nurse of the Year 2020.

The first course is a 12 Lead ECG Recording and ECG Rhythm Recording course; to access the course use this link. This short course aims to reduce variations in recording/interpreting ECGs by ensuring that members of staff that perform 12-lead ECG recording and ECG Rhythm Recording do so using evidence-based information based on national approved guidelines issued by The Society for Cardiological Science & Technology (SCST).

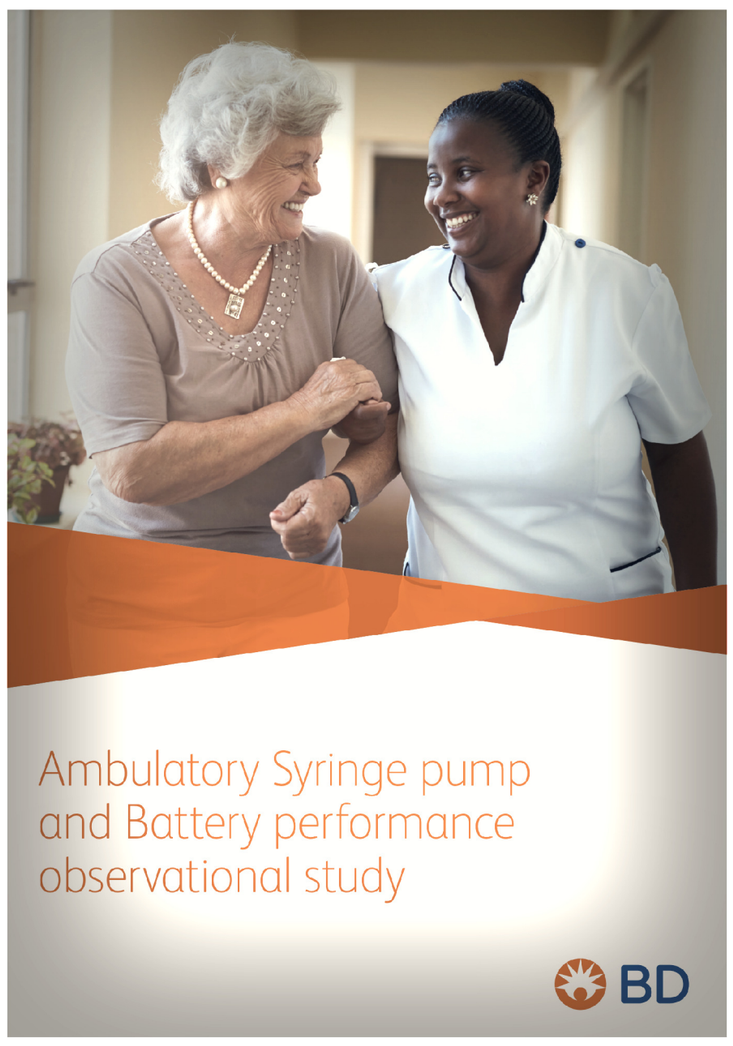
The second course is a 12 Lead ECG in Acute Coronary Syndrome (ACS) course; to access the course use this link. This programme provides an overview of the 12-lead ECGs seen in patients presenting with chest pain and Acute Coronary Syndrome (ACS). Participants of this course will understand ACS (pathology & implications), be able to identify ECGs in Acute Myocardia Ischaemia, STEMI and non-STEMI, amongst other principles.

A NEW REPORT ON BATTERIES FOR THE T34 SYRINGE DRIVERS

Historically, the CME **T34™** 2nd edition syringe driver could typically dispense fluid at 1ml/h for several days on a single 6LR61 9V battery. When the CME T34™ 3rd edition syringe driver was released, several software and hardware additions were made to add functionality to support backup alarms and other requirements in place with the latest standards.

The combination of changes caused a decrease in the performance at 1ml/h to 25h with a single 6LR61 9V battery. One of the goals for the launch of the BD BodyGuard™ T project was to improve the battery duration from the initial release of the 3rd edition syringe driver. Improvements were made to the software while keeping all the required updates in hardware to improve the battery duration while meeting the standards requirements.

Ask your local BD Representative for a copy of the battery 'performance and observational study' report



BD Battery assessment on the CME T34™ and BD BodyGuard™ T Syringe driver.

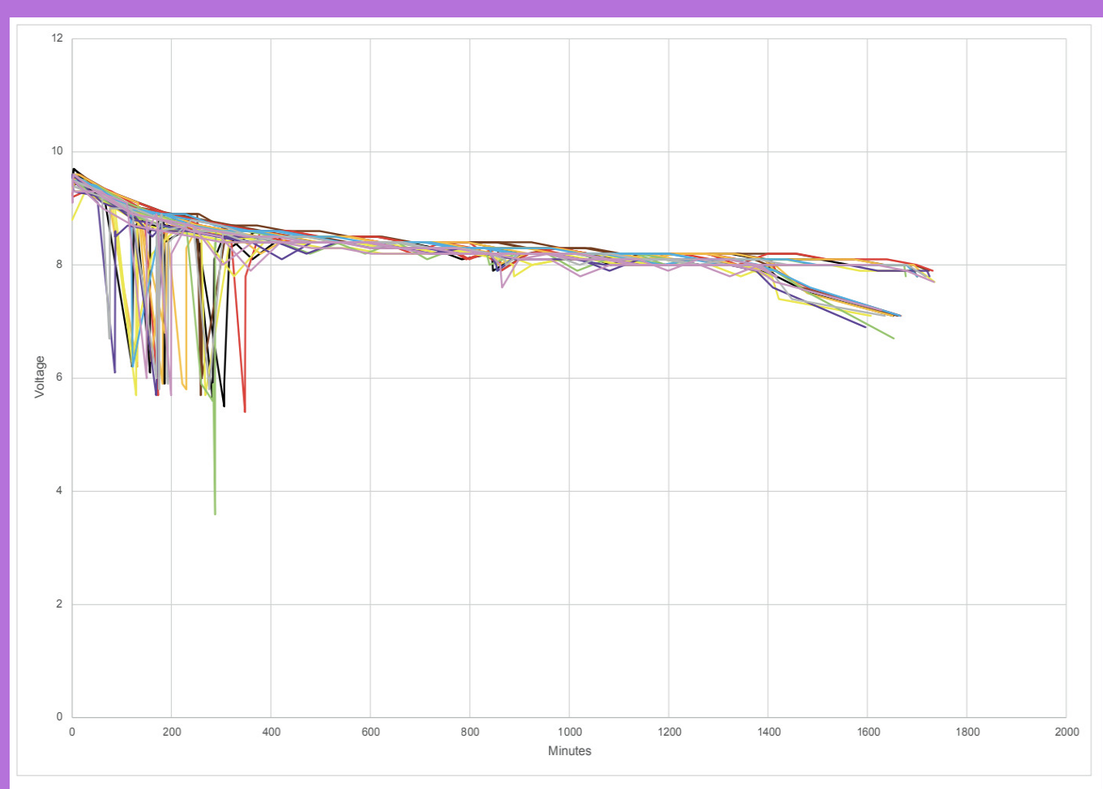
The CME T34™ syringe driver is susceptible to variations within the available consumer off-the-shelf 9V 6LR61 batteries. The current draw associated with syringe driver motor movement coupled with the internal resistance of the battery can cause situations where the battery voltage drops and triggers low/ end battery alarms or possible hardware shutdown. The issue is associated with pumps across 10+ years of the T34™; aspects of the T34™ design were assessed with no positive correlation with the unique aspects of this issue.

The battery impedance has been determined to have the best correlation to the voltage drops associated with early low/end battery alarms and pump shut down issues and other characteristic behaviours.

- **Higher battery impedance usually occurs in a battery**

voltage range from 9V to 8.4V. This has a correlation with early low/end battery alarms within the first 1-12 hours of a 24-hour infusion

- **Higher battery impedance correlates to larger voltage dips which are more likely to trigger alarms**
- **Battery brands with higher impedance are more likely to have early battery**



Graph showing Battery voltage from event logs. Resume as needed from early low/end battery alarms to finish ≥23-hour infusion.

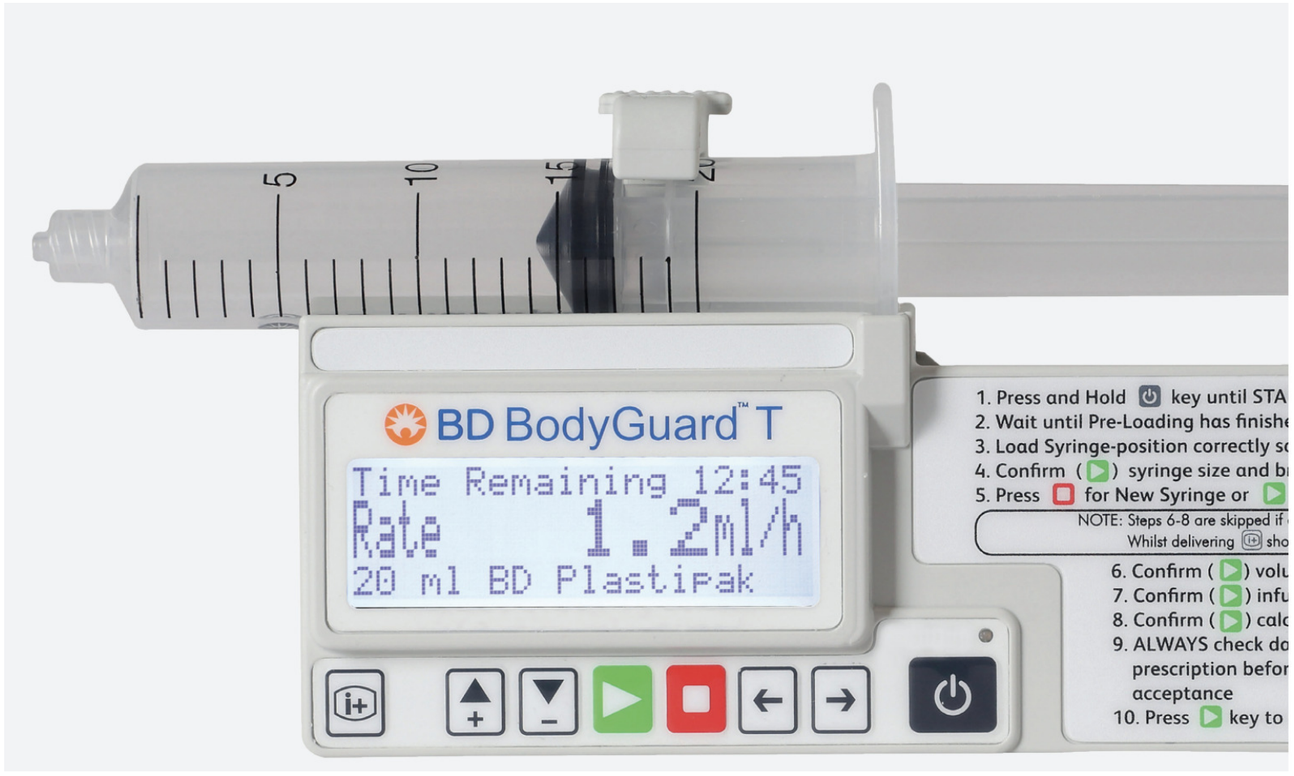
Battery Performance

The CME T34™and BD BodyGuard™ T Syringe driver performance varies when using different 9V alkaline 6LR61 battery brands. This study highlights the potential for a 9V alkaline battery to experience random voltage drop events when used with an ambulatory syringe driver alongside the variability potential across brands, models and, sometimes, production batches.

It also shows the BD BodyGuard™ T syringe driver battery duration performance across battery brands at nominal conditions. The aim is to provide biomedical, clinical, and procurement department-relevant information in terms of product performance when selecting a 9V 6LR61 battery.

Note: For the BD BodyGuard™ T syringe driver BD recommends to always use 6LR61 batteries but does not recommend any battery brands as BD does not control the manufacturing process of these batteries

The full report and white paper coving all the results is available from BD



Results

Consistancy of performace observed with T34™ syringe drivers	Battery Brand /Model (6LR61)	Sample size	Failure rate	Complaint indicator	*Impedance/ **Impedance Variability (ohms)
Good	Duracell Plus	90	0.00%	Low	1,83 to 2.7
Good	Panasonic Power line	120	0.00%	Low	2,52 to 2,66
Good	Varta Power One	90	0.00%	-	3,16 to 3,30
Marginal	Duracell Procell Intense	60	2.00%	Low	3.0
Marginal	Energizer Max	120	7.50%	Low	2,83 to 5,48
Less good	Varta Industrial Pro	30	10.00%	-	5.83
Less good	Duracell Ultra Power	30	0.00%	High	6.58
Less good	NX Power tech	27	11.00%	High	5.92
Less good	Duracel Procell	83	49.00%	High	4,26 to 5,26

Overall Conclusion

The studies indicate the range of performance of different battery brands and lots with regards to the syringe pump. These two studies are important to consider when selecting a suitable battery for your facility.

The performance of the CME T34™ and the BD BodyGuard™ T syringe pump can be impacted as a result of variability between different battery brands and lots.

The two observatinoal studies performed by BD provides data to biomedical, clinical, and procurement departments for consideration when selecting a 9V 6LR61 battery for their syringe pump.

BD recommends to always use 6LR61 batteries with the syringe pump.

NATIONAL DERS POSITION STATEMENT

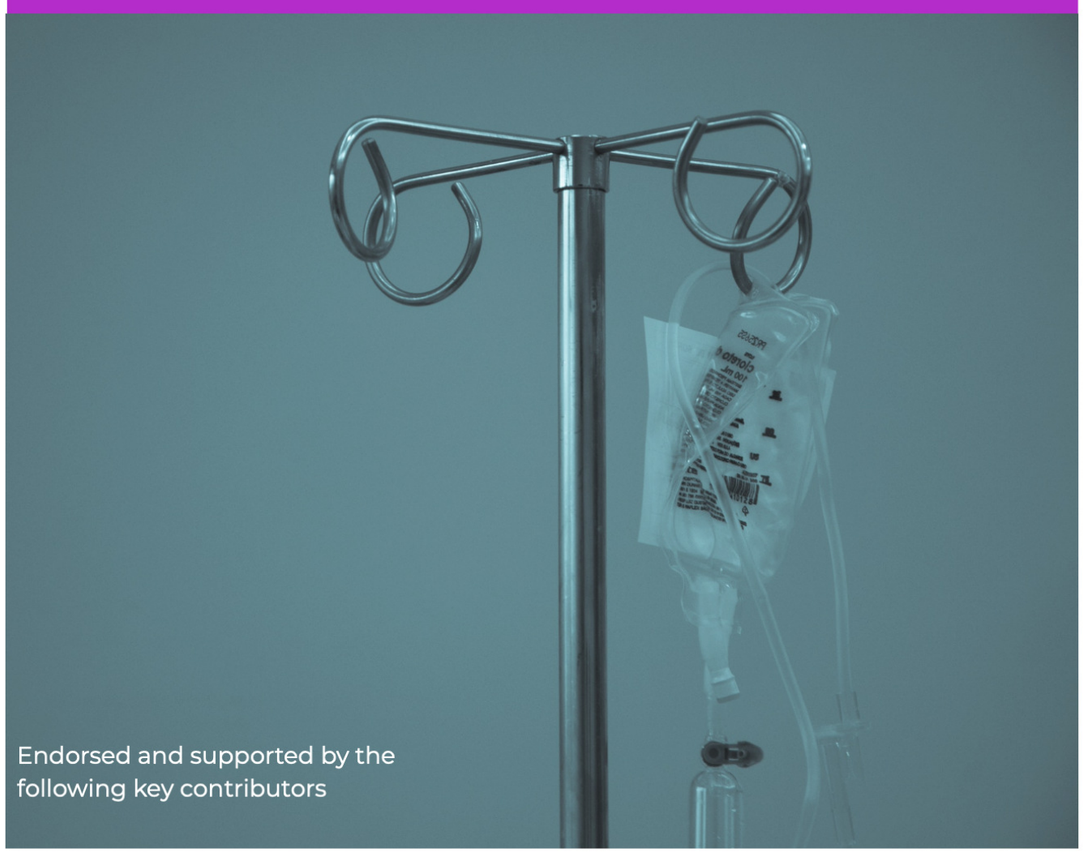
Many millions of intravenous (IV) infusions are administered to patients through infusion pumps each year in the UK. Despite many published papers outlining the advantages and benefits of using 'smart pumps' with dose error reduction software (DERS), its use in the UK is less than 30%, with most using no DERS at all.

In 2017, a national survey was issued by NHS Improvement looking at infusion pumps with DERS capability and asked questions around adoption, infrastructure, purchasing for safety, ongoing support and potential for mandating smart pump adoption in the UK. In 2018, a 2 year project was initiated and a number of leading infusion pump suppliers were invited to participate in a review project to look at the implementation of Dose Error Reduction Software (DERS) and smart infusion pumps across the UK, and to review six key position statements.

In November 2020, the report was published and summarises the final meeting and looks at each of the position statements discussed and the agreed outcomes. 5 major suppliers contributed towards the project via a non-restricted educational grant and NAMDET acknowledges and thanks these industry partners who have supported this project and without whom it would not have be possible.

National Association of Medical Device Educators and Trainers

National DERS and 'Smart pump' position statement group report 12th November 2020



Six key position statements were established for the project and helped focus the attention on some active and measurable outcomes.

Key Statements

1. Define what we mean by DERS.

2. Explore the evidence, where is it and make recommendations to suit.

3. Does DERS need additional infrastructure and support to allow its adoption?

4. Should DERS be mandated in the NHS?

5. What role should Arms Length Bodies (ALBs) play?

6.Can DERS be implemented easily in the UK?

In total, over 1/4 million infusions were shared from organisations that had DERS capability and reports. These were analysed for common drugs that cause issues, potential errors, and magnitude of potential harm.

Many thousands of 'DERS' events were reported with some worrying trends. In some instances potential drug errors of times 10, and even a hundred times overdose with lipids in a Neonatal Intensive Care Unit were identified and stopped.

This position statement will help hospitals who are not currently using smart pumps, to encourage them to review their safety practices and records, and act on them as needed. The power of local data should not be underestimated and Trusts/units are encouraged to use their own data – once collated - to raise any safety issues within their own organisation. Smart pumps can reduce any infusion-related errors, so this exercise can be a powerful tool to support the increased use of smart pump technology, and uncover poor local safety practices.

Common themes and known drugs where error has been seen to occur (i.e. potassium, insulin and heparin) should be prioritised and help those developing DERS datasets to start with a known list of high risk medications.

The position statement goes on to review each of the 6 key statements and review all the current published evidence around DERS, adoption, issues and ongoing management.

The report is freely available and can be downloaded via the NAMDET website or via this link.

8. Summary of Final Position Statements

Position Statement 1. Define what we mean by DERS

Smart pumps providing electronic infusion Dose Error Reduction Systems (DERS) are a suite of safety programmes designed to help reduce variation through standardised medication rates and concentrations from infusion pumps. This will take the form of a regularly updated library of drugs and built-in infusion pump safety software with safety limits intended to help reduce dosing errors, reduce variation in care and provide programmable alarms to help reduce patient harm.

Position Statement 2. Explore the evidence, where is it? And make recommendations to suit

A clear lack of central reporting on DERS breaches, trapped errors and CQI reporting means that the impact on patient safety and the potential benefits for DERS may be lost.

On balance, from published literature, we believe that appropriately implemented and used smart pumps (including but not limited to DERS) confer a benefit to patient safety.

Position Statement 3. Does DERS need additional infrastructure and support to allows its adoption?

The use of smart pumps are only part of a complex multidisciplinary system; successful implementation, via technology integration, together with continuous management and ongoing review, is required for sustainability, and continuous quality improvement

Position Statement 4. Should DERS be mandated by the NHS?

Health organisations with smart pump (DERS) capability who are not using it must review their own medication error incidences and report to the appropriate safety committee, governance teams and/or medication safety officer to ensure good governance and drive continuous quality improvement.

Position Statement 5. What role should Arms Lengths Bodies (ALBs) play?

We would recommend that the occurrence of serious incidents that involve pump technology (i.e. when DERS software captures potential dose or rate limit breaches or errors) are investigated by NHSE & NHSI/MHRA/HSIB/CQC [ie, Arm's Length Bodies (ALBs)/regulators] and the learning disseminated through national bodies to drive the increased use of smart pumps.

Position Statement 6. Can DERS be implemented easily in the UK?

When procuring smart pumps, include the expertise and people who will use the technology in the procurement process and future-proof purchases. This may include IT and network specialists, medical device management, MDSO, MSO, Clinical Governance and Risk, Clinical end users and the supplier/manufacturer.

HSIB 'SMART' INFUSION PUMP REPORT

The Healthcare Safety Investigation Branch (HSIB) published their full report in December 2020, and their investigations found that the implementation of smart pump functionality would benefit from the use of risk management practices. Existing NHS Clinical risk standards could provide a basis for both manufacturers and trusts to work together to manage risks. The investigation highlighted the main implementation challenges:

* No national consistency in drug libraries and that there is no agreed national drug library for use in NHS.
* No national guidelines or standards on how to implement the libraries and guidance documents often needed updating.
* Substantial IT infrastructure is needed to support the integration of smart pump technology.
* Software is needed to upload and download data logs (including any errors detected) and monitor the status of each smart pump. Maintaining the required IT infrastructure required specialist staff roles and often a new skill set.

The full report can be accessed via this link

GENESISCARE AND DERS

GenesisCare is the first in the UK to go live with a chemotherapy drug library over a wireless DERS system

GenesisCare is delighted to announce they are the first in the UK to go live with a chemotherapy drug library over a wireless DERS (Dose Error Reduction Software) system, that has so far been deployed from one server to 5 of our outpatient oncology centres, and will shortly be available at all 6 GenesisCare chemotherapy sites.

Further to our successful deployment at the centre in Milton Keynes, GenesisCare have now installed the ICU Medical Plum 360™ infusion pumps in combination with the ICU Medical MedNet™ enterprise-class IV medication management platform.

Adoption of the 'Best in KLAS' Plum 360 smart infusion pumps, with their unique cassette technology and medication safety capabilities, now allows GenesisCare to deliver two compatible medications at independent rates through a single line to patients with less air-in-line interruptions, helping to improve the efficiency of patient treatment.

Head of Nursing at GenesisCare, Richard Schorstein said "*I am excited that at GenesisCare we are leading the way in using new technologies to improve chemotherapy care. The new Plum 360 pumps, in combination with the MedNet medicines safety software, along with the iQemo integration, will bring huge benefits. It will provide improved safety in medicines management; nursing and pharmacy workflow efficiencies; and improved data capture. I would like to express my thanks to the GenesisCare Project Team and the ICU Medical Team for their support in delivering this project. I am really proud of our nursing and pharmacy teams, we wouldn't have been able to do this without their engagement, enthusiasm and hard work*".

The introduction of ICU Medical MedNet safety software, with Plum 360 smart pumps into GenesisCare, ensures safe administration of IV Systemic Anti-Cancer Therapy (SACT) and provides standardisation of treatment across all GenesisCare medical centres.

As GenesisCare's Head of Pharmacy, Titilayo Alagbe praised "This is an innovative development of the chemotherapy service to GenesisCare patients. The software provides performance data such as nurses time spent on medication administration and infusion time providing assurance of safe administration of SACTs.

I am proud of this project and it shows GenesisCare values being embraced such as partnership, integrity, and innovation".

An efficient and smooth installation has been possible thanks to ICU Medical's remote clinical training provision along with their cyber secure UL-2900 certified technologies. Ensuring secure and encrypted wireless deployment of a medication safety drug library across all GenesisCare sites from a single location, has helped to maintain compliance and further enhance patient safety and quality of care.

By Spring '21, the system will be integrated with iQemo across the GenesisCare network, giving a fully automated process for recording the administration of chemotherapy using barcoded technology to identify the patient, the drug, and the infusion device.

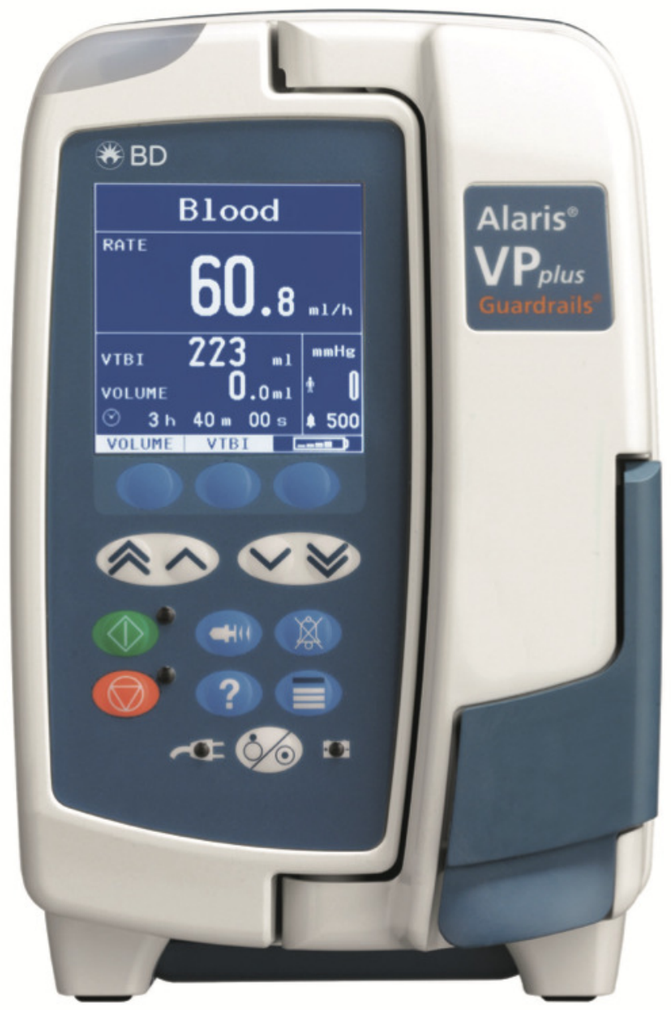
GenesisCare

Blood transfusions with BD Alaris™ pumps

Delivering safe patient care and work-flow efficiencies

With over 2.5 million blood transfusions happening every year in the UK alone[1], ensuring patient safety is paramount, but reducing the risk of complications can be challenging. Did you know that 8 out of 12 of the most serious errors were found during gravity administration?[2]

BD Alaris infusion pumps can help support your patients' blood transfusion needs and also help:



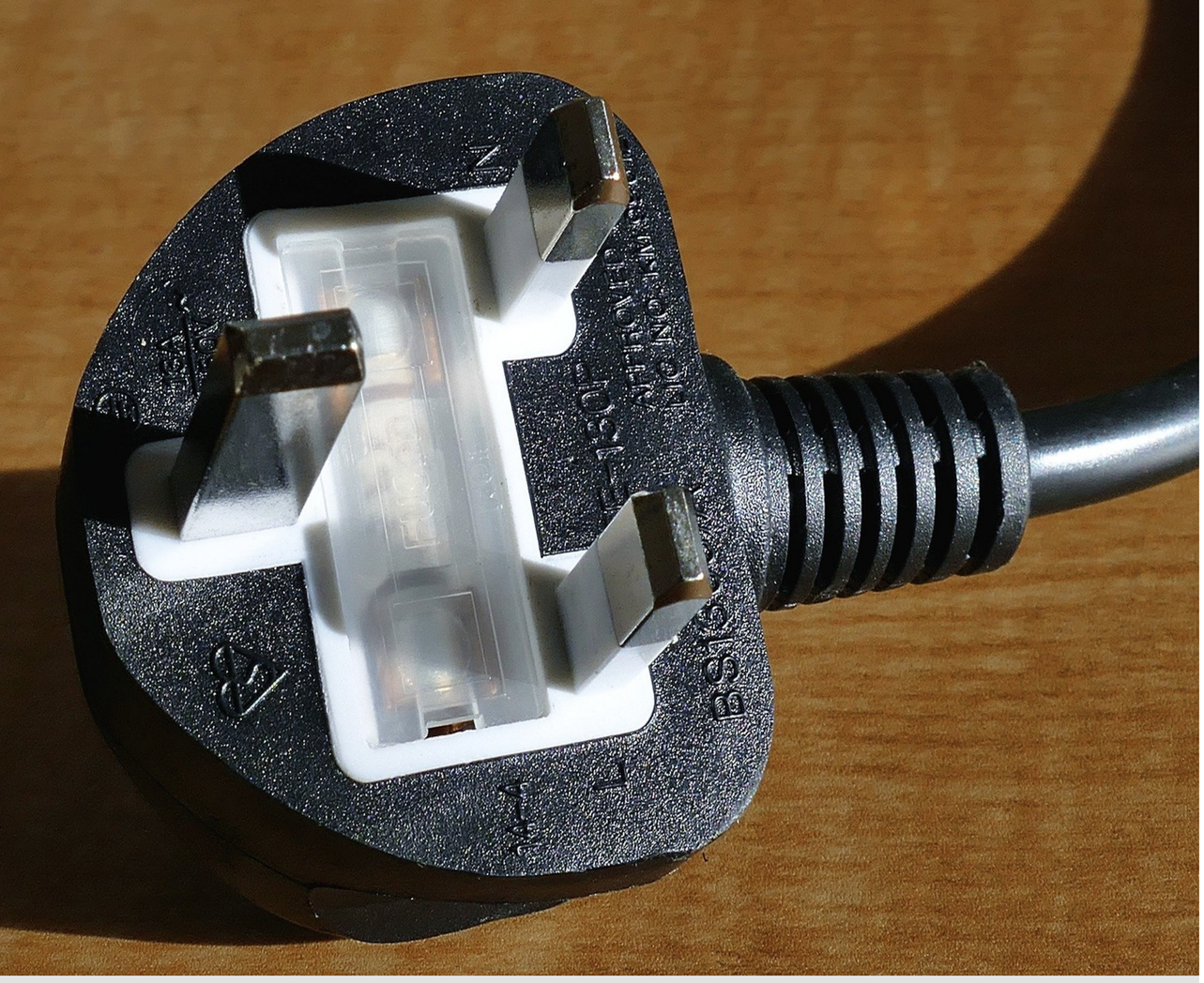
- Enhance compliance and safety[3,4]
- Decrease blood wastage and additional costs[3,5]
- Improve clinicians' efficiency[3]

To find out more visit: bd.com/uk/pumping-blood

0000CF04175 Issue 1 Date of Preparation February 2019

1. https://www.nhsbt.nhs.uk/what-we-do/blood-services/blood-transfusion/transfusion-faqs/. **2.** Blandford A, et al. BMJ Open 2016;6:e009777. **3.** Centrella-Nigro A, et al. Journal of Infusion Nursing. 2018 Nov 1;41(6):372-4. **4.** R Bissett IP, et al. Samoa Med J. 2010;2:25-8. **5.** Houck D, et al. 2007 Nov 1;30(6):341-4.

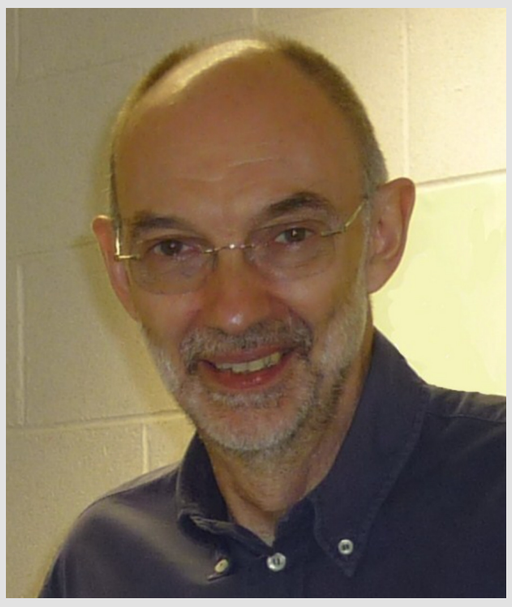
BD



PLUG-TOP FUSES FOR DETACHABLE AND NON-DETACHABLE MAINS LEADS

What fuse to use in the mains plug fitted to a detachable or non-detachable mains lead?

Justin McCarthy
BSc MSc CEng FIET FIPEM.
Clinical Scientist,
Consultant Clinical Engineer



A question that was raised by a delegate to a recent one day course on electrical safety and testing of medical equipment was, what rating of fuse should be used in the 13 A plug on a detachable mains lead?

This is a reasonable question to ask, and a common dilemma.

Definitions

The common UK terms used in this paper are given below. The equivalent defined terms used in IEC 60601-1:2005 + AMD1:2012 + AMD2:2020 are given in small capitals and the definitions from that Standard are used or adapted.

Mains lead (POWER SUPPLY CORD)
Flexible mains lead, fixed to or assembled with electrical equipment for connection to supply mains.

Detachable mains lead (DETACHABLE POWER SUPPLY CORD)
Flexible mains lead intended to be connected to electrical equipment by means of a suitable appliance coupler for mains supply purposes.

Appliance Coupler (APPLIANCE COUPLER)
Means enabling the connection of a flexible mains lead to electrical equipment without the use of a tool, consisting of two parts: a MAINS CONNECTOR and APPLIANCE INLET

Mains Connector (MAINS CONNECTOR)
Part of an appliance coupler integral with or intended to be attached to a flexible mains lead that is intended to be connected to the supply mains.
*Note - A MAINS CONNECTOR is intended to be inserted into the APPLIANCE INLET of electrical equipment

Appliance Inlet (APPLIANCE INLET)
Part of an appliance coupler either integrated in or fixed to electrical equipment for mains supply purposes.

Mains Plug (MAINS PLUG)
Part, integral with or intended to be attached to a mains lead of electrical equipment, to be inserted into a mains socket-outlet.

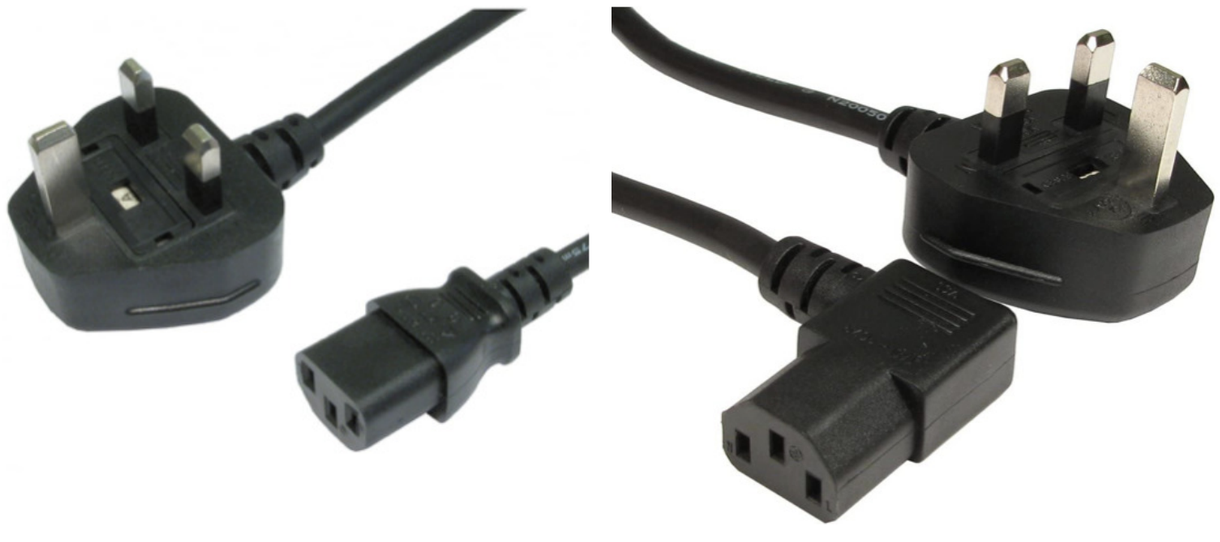
*NOTE 1: In the UK, often referred to as a '13 A plug' or a 'square pin plug'. Sometimes called a 'plug-top', often in the context of reference to the integral 'plug-top fuse'.
*NOTE 2: UK plugs, sockets and wiring systems are used in other countries, including in Ireland.

Plug-top fuse
The BS 1362 fuse that must be fitted into a BS 1363 UK mains plug.

Medical Electrical Equipment (MEE)
Equipment meeting the requirements of relevant parts of the IEC 60601 suite of Standards, in particular the general standard IEC 60601-1.

Discussion
In a large hospital, there are probably many hundreds of detachable mains leads available for use. In practice, it is impossibility to keep a particular lead with a specific item of equipment. This poses the problem of how best to manage and periodically test these mains leads.

The majority of these detachable mains leads are fitted with a BS 1363 or a BS 1363/A (1) plug at one end, and the very common type C13 mains connector, conforming to relevant parts of IEC 60320-1, at the other end.



Two illustrations of BS 1363 UK mains plugs wired to C13 type mains connectors

The mains connector plugs into the type C14 appliance inlet on the equipment. The C13/C14 appliance coupler combination is rated at 10 A.(2) This type of detachable mains lead must be wired with three core cable.

The question is, what rating plug-top fuse should be fitted to detachable mains leads with type C13 mains connector? This raises the question of the purpose of the plug-top fuse. An interesting Wikipedia article AC power plugs and sockets: British and related types gives a history of the development of the BS 1363 plug and socket system and also states that ... *the fuse is there to protect the flexible cord between the plug and the appliance under fault conditions*[50][51].

The references given in support of this are:
[50] Geoffrey Stokes (2008), *A Practical Guide to the Wiring Regulations*, John Wiley & Sons, p.65 (retrieved 24 February 2014 from Google Books)

[51] Cook, Paul, "Commentary on IEE Wiring Regulations 16th Edition (BS 7671:2001)", Cl 6.8, IET 2002 ISBN 0852962371

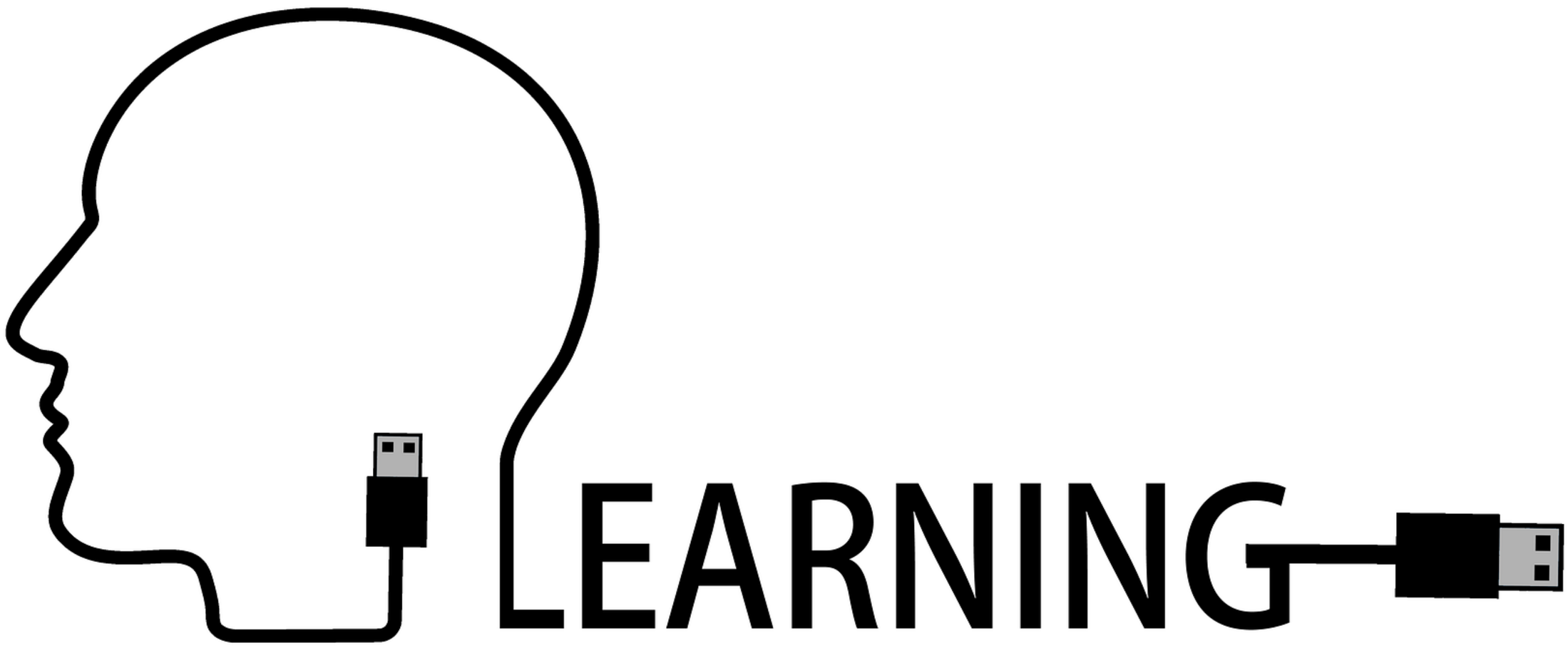
An internet search for possible suppliers of detachable leads as described, indicates that there is considerable variation in both cable size and fuse rating of available products, ranging from 0.5 mm^2 cable with 3 A fuse to 1.0 mm^2 cable with a 13 A fuse. Given the impossibility of keeping detachable mains leads with individual items of medical electrical equipment, there needs to be some standardisation of the leads.

The need for a plug-top fuse arises because, in accordance with BS 7671 (The Wiring Regulations), the installed supply circuit, if a ring circuit, is protected by a 32 A circuit breaker, or by a 20 A breaker if a radial circuit. Damage to a flexible mains cable, such as might occur if run-over with a patient bed could, without the plug-top fuse, cause a severe electrical fault and take out the whole supply circuit, affecting many other items of plugged in equipment.

BS1362 fuses are available in 1, 2, 3, 5, 7, 10 and 13 A ratings. The BS 1362 standard only specifies the detailed characteristics of the 3 A and 13 A types.

The extract from the reference given above (Cook P, 2002) states that ... *a 0.5 mm^2 plug flex is protected by a 3 A fuse whatever its length, and a 1.0 mm^2 p.v.c. flex is protected whatever its length by a 13 A fuse.*

Unlike in domestic premises, many supply circuits in healthcare premises are radial circuits, protected by a 20 A circuit breaker. Looking at the characteristics of the BS 1362 13 A fuse, serious damage to a detachable mains lead fitted with a 13 A fuse might trip a 20 A breaker before the plug-top



fuse blows (circuit breakers operate much faster than fuses). This would take out the supply circuit, to which other equipment may be connected. This would be very unlikely if a 10 A fuse is fitted to the plug-top, and this is inline with the 10 A rating of the C13 mains connector.

Medical electrical equipment (MEE) must meet relevant parts of IEC 60601 suite of Standards. There is a requirement in the general standard, IEC 60601-1, for the mains supply to MEE to be internally fused within the equipment. Thus, internal equipment faults are not relying on the plug-top fuse to protect them.

Therefore, the sensible policy would be to arrange for all detachable mains leads that are fitted with C13 mains connector to be wired with minimally 1.0 mm_2 cable, and fitted with a 10 A fuse. They should be periodically tested by visual inspection and an earth continuity test. For the purpose of testing the earth continuity end-to-end of the detachable mains lead, a Type E plug connector shown on the right (meeting IEC 60320-2-2) can be made up with only an earth connection accessible. Earth continuity should be less than or equal to 0.1 Ω.

When brand new, each detachable lead should be checked for polarity and for insulation. Polarity will not alter from the 'as new' situation. Insulation is only likely to be compromised by damage which which be checked by visual examination in-service. Any lead tested as part of an equipment test will be subjected to an in-service insulation test.

Type E plug connector

It is not a practical possibility to put each individual detachable mains lead on the inventory as an identifiable item, but each should be labelled with a 'Next test due' date.

If the suggested procedure is followed, then the risks from using any available detachable mains lead are minimised. All are to the same specification.

A 10 A fuse plug in the plug-top would allow for any item of equipment up to 2.4 kW to be supplied. Higher rated equipment should not be run off a C13 mains connector.

An alternative, larger C19/C20 appliance coupler combination, rated at 16 A is/should be used of a higher rated equipment. Such detachable mains leads should be wired with 1.5 mm_2 cable, and the plug-top fused at 13 A. They are much more likely to remain with the equipment they are designed for, but similar routine checks should be carried out on any not associated with a particular item of equipment.

Type C19 Mains Connector
By Sibaz - Own work, CC BY 3.0,
https://commons.wikimedia.org/w/index.php?curid=15510000

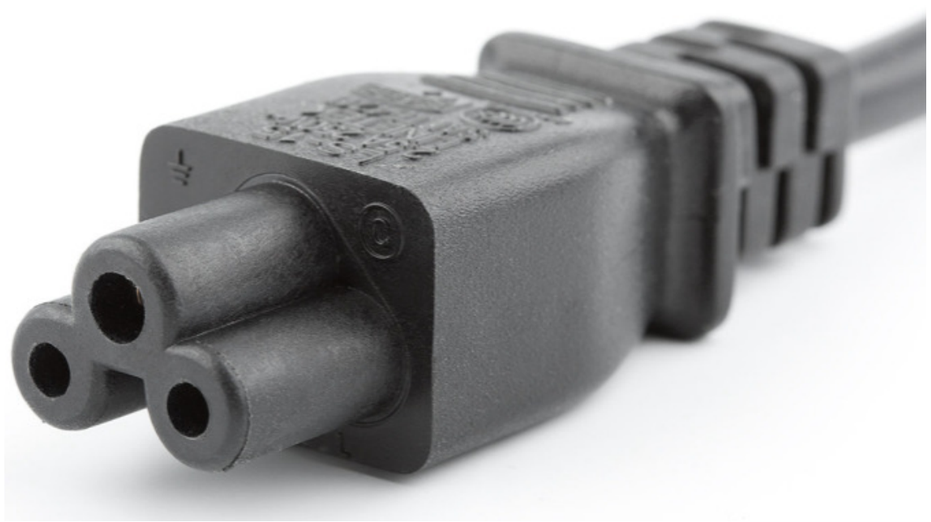
Other types of mains connectors

Two other types of mains connectors on detachable mains leads are in fairly common use, particularly with IT type equipments.

Low power Class II equipment often uses the C7 'figure of eight' mains connector shown below:

Type C7 mains connector
Sabergum at the English-language Wikipedia

The C5 mains 'clover leaf' connectors shown below, are often found on laptop switched-mode power supplies or other low power Class I equipment.



Type C5 Mains connector
https://commons.wikimedia.org/wiki/File:IEC_60320_C5_connector.jpg#/media/File:IEC_60320_C5_connector.jpg

Both C7 and C5 mains connectors are rated in the IEC 60320-1 Standard at 2.5 A and 250 V. United States version may carry a higher rating marking. The Standard does not allow rewireable versions. Mains leads using these are likely to use 0.75 mm^2 cable, but some may be only 0.5 mm^2. These cables should be fused in the plug-top with a 3 A, BS 1362 fuse. Routine visual inspection, earth conductor continuity checks for the C5 type, and labelling are all required.

Non-detachable mains leads

The basic principle that the plug-top fuse is there to protect the supply circuit in the case of a mains cable fault or damage is still applicable. However, some items of MEE are fitted with lighter duty, fixed mains cables.

The danger of having a 13 A plug-top fuse supplying a equipment wired with 0.75 mm^2 cable (rated at 6 A) is that serious cable damage could cause the cable to burn rather than the fuse to blow quickly. A 5 A plug-top fuse would be appropriate.

Other MEE with internal fuses greater than 6 A, and wired with non-detachable mains cables should have 1.0 mm^2 cable. It is acceptable to use a 10 A plug-top fuse, but there is no risk involved in using an appropriate lower rating.

Non-MEE with non-detachable mains leads and without internal fuses should be filled with a plug-top fuse either based on the manufacture's installation instructions or appropriate to the rating of the equipment, but taking account of any likely start-up in-rush current such as occurs with motor driven equipment. For example, desk lamps, wired with 0.75 mm^2 or lighter cable, may reasonable be fused at 1 A.

Summary Proposals

For medical electrical equipment (MEE):

- Detachable mains leads fitted with BS 1363 UK plugs and C13 mains connectors should be wired with minimally 1.0 mm^2 three-core cable, and fused at 10 A. They should be periodically tested for

protective earth conductor resistance ≤0.1 Ω and labelled with a ‘next test due’ date.

- Detachable mains leads wired with 0.75 mm_2 cable and fitted with C13 mains connector **should not be used or available**.

- Detachable mains leads fitted with a C19 mains connector should be wired with 1.5 mm_2 cable and the plug-top fused at 13 A and tested as above.

- Detachable mains leads fitted with BS 1363 plugs and C7 or C5 mains connectors should be fused with a 3 A plug-top fuse.

- For non-detachable mains leads, BS 1363 plugs fitted to 0.75 mm_2 cable should be fused in the plug-top with a 5 A fuse or lower, as recommended by the manufacturer.

- For non-detachable mains leads, BS 1363 UK plugs fitted to 1.0 mm_2 cable may be fused in the plug-top with a 10 A fuse, or lower as recommended by the manufacturer, but should not be fused at 13 A.

For Non-MEE

- As above, detachable mains leads fitted with BS 1363 UK plugs and C13 mains connectors should be wired with minimally 1.0 mm_2 three-core cable, and fused at 10 A.

- Detachable mains leads fitted with BS 1363 plugs and C7 or C5 mains connectors should be fused with a 3 A plug-top fuse.

- BS 1363 UK plugs fitted to 0.5 mm_2 non-detachable mains leads should be fused in the plug-top with a fuse not exceeding 3 A. A lower value may be appropriate for low power equipment.

- Non-detachable mains leads with BS 1363 UK plugs fitted to 0.75 mm_2 cable should be fused in the plug-top with a fuse not exceeding 5 A. A lower value may be appropriate for low power equipment.

- Non-detachable mains leads with BS 1363 UK plugs fitted to 1.0 mm_2 cable should be fused in the plug-top with a fuse appropriate to the power consumption of the equipment, but taking account of any likely inrush current.

Footnotes:

(1) According to BS 1363-1 : 2016+A1 : 2018, subclause 7.1c), mains plugs marked BS 1363/A are designated as 'rough use plugs'.

(2) The Wikipedia entry explaining IEC 60320-1 is useful. https://en.wikipedia.org/wiki/IED_60320 Most pictures are taken from this with attribution where required.

The author would be very interested to have comments and feedback on these suggestions at justin@clineng.co.uk.

JOURNEY TO JOINT QMS CERTIFICATION FOR MANUFACTURE OF MEDICAL DEVICES IN TWO NHS WALES SERVICES

GIG CYMRU NHS WALES
Bwrdd Iechyd Prifysgol Bae Abertawe
Swansea Bay University Health Board

Bofalu am ein gilydd cydweithio gwella bob amser
Caring for each other
Working together
Always improving
caring for each other working together always improving

Designing and providing medical device solutions bespoke to patients comes with specific risks and quality implications. Two specialist services in Swansea Bay University Health Board (SBUHB) have successfully worked together to put in place ISO certified Quality Management systems in their departments, an approach that would ensure they were compliant to Article 5.5 (in house manufacture and use of medical devices within the same health institution) of the EU Medical Device Regulations (EU MDR)*.

Both the Maxillofacial Laboratory (MFL) and the Rehabilitation Engineering Unit (REU) provide a supra regional tertiary service and are considered to manufacture medical devices, which they provide to patients under the care of SBUHB.

The Maxillofacial Laboratory (MFL), led by Peter Evans, provides a service to construct custom-made devices and appliances including facial and body prostheses surgical/surgical support devices, fixed and removable intra-oral prosthetics and orthodontic appliances and the Rehabilitation Engineering Unit (REU), led by Dr. Lorna Tasker, provides services to meet the complex needs of patients requiring engineering solutions for their wheelchair seating, mobility and pressure ulcer care across South West Wales. These services include Specialist Seating, Functional Electrical Stimulation and Pressure Ulcer Prevention and Intervention Service (PUPIS).

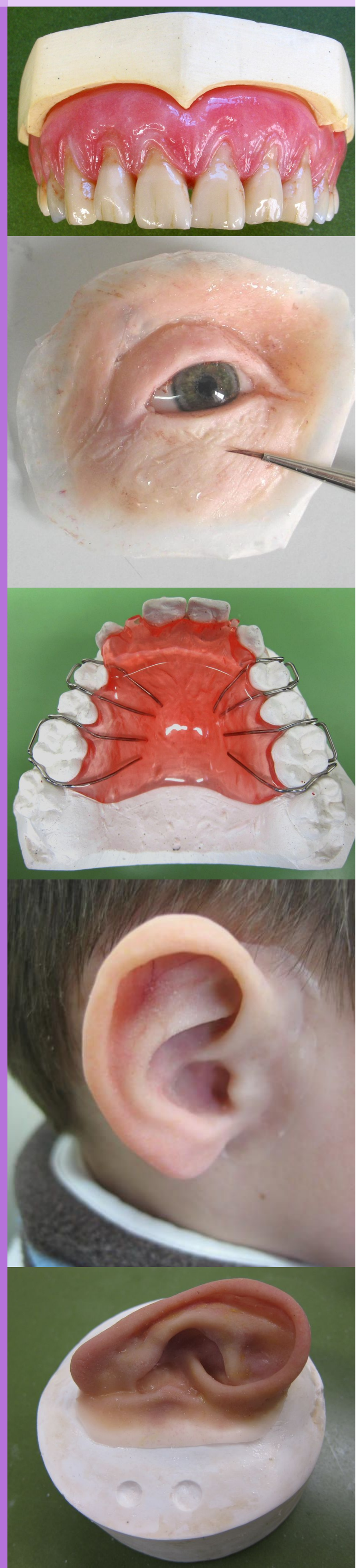
The services had previously undertaken some joint working, sharing of equipments and knowledge especially in the area of scanning and 3D design, but the idea to share resources was a novel approach. The approach was supported in an external review by Justin McCarthy, Consultant Clinical Engineer, who recommended establishing a joint Quality Management System which could satisfy Article 5.5 of the EU MDR. The teams recognised their limited experience and the requirement for support from either an external consultancy or the creation of a fixed term NHS post to lead implementation. After taking the advice, the latter was chosen and a business case was developed with funding being successfully secured for a specialist to project

manage the implementation of a joint ISO 13485-compliant QMS. Several ISO and commercial standards were considered, including ISO 9001, however ISO 13485 was selected as an internationally recognised standard specifically written as a framework for organisations involved in the design, production, installation and servicing of medical devices and related services, as well as being considered best practice (refer to Guidance for health institutions on in-house manufacture and use, IPEM 2021). Dr. Rebecca Nix joined REU and MFL as Quality Implementation Manager in September 2019 to commence the implementation of the joint QMS.

There followed 18 months of hard work to plan the approach, write documentation, implement new working practices and support cultural change. One of the major challenges was the different types of services and custom medical devices involved. The units are very different in their service delivery models but the joint working gave an excellent opportunity for efficiency, not least in cross auditing.

In February 2021, both units successfully completed their Stage 1 external assessment of the Joint QMS and two months later the REU and MFL's Joint QMS passed their Stage 2 external assessment with no nonconformities (one recommendation), and have subsequently received formal certification of their Joint QMS as compliant with ISO 13485.

The certificated Joint QMS is a significant team achievement for both services, and will be maintained via annual surveillance visits by the external certification body, and cyclic re-certification assessments, following the approach of continuous improvement. There are great positives for Services and Health Boards achieving such certification, including regarding patient safety and compliance toward evolving medical device legislation.



Peter Evans

Dr. Lorna Tasker

Dr. Rebecca Nix

"It is believed that Swansea Bay's Maxillofacial Laboratory is the first of its type in the UK to achieve this"

There are great positives for Services and Health Boards achieving such certification, including regarding patient safety and compliance toward evolving medical device legislation. It is believed that Swansea Bay's Maxillofacial Laboratory is the first of its type in the UK to achieve this.

Both services are grateful to the support and openness right the way through this process from internal services who had already developed ISO Certified systems such as Medical Equipment Management Services (MEMS) and externally from RE units in North Wales and Birmingham as well as nationally from NHS Wales.

The implications of EU MDR and the evolving UK legislation affects all services providing any medical device, including in house developed software. Thus, concurrently within SBUHB, a Task and Finish Group (chaired by Christine Morrell, Director of Therapies and Health Science) was established in 2019 to raise awareness and draw on the experiences within REU and MFL to support other Health Board services in their journey toward achieving compliance. Indeed, these implications have been recognised within the Principality with the creation of the Welsh Government Medical Device Regulation Implementation forum. Dr. Lorna Tasker, Peter Evans and Dr. Rebecca Nix have been active contributors to the forum in regard to their progress and experiences of achieving certification (as applicable for clinical services which undertake 'in house' manufacturing), as well as reaching out to their professional networks and contacts within the UK to share their experiences, knowledge and learning.

This level of quality assurance and the practices there-in provide substantial confidence to teams and patients alike. A formalised QMS also provides a reliable platform for service improvement and device innovation, which will continue to promote MFL and REU as exemplars of high standards in medical device provision, within NHS Wales, wider healthcare and industry.

*The postponement of the date of full application of the EU Medical Device Regulation (EU MDR) to May 2021, combined with the final exit of the UK from the EU on the 31st December 2020 has resulted in the EU MDR not becoming retained EU law within the United Kingdom. A 'Guidance for health institutions on in-house manufacture and use' document has been published via the Institute of Physics in Medicine (IPEM) to provide guidance on the regulatory issues and best practice involved in the manufacture, management and use of medical devices manufactured within health institutions and recommends that an appropriate QMS framework is in place.

Useful resources, including a General Safety and Performance Requirement Checklist developed in Swansea Bay, and the Guidance for Health Institutions on in-House Manufacture and Use, are also available from the IPEM website:

IPEM > Scientific Journals & Publications > Free Publications .

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THE CADD®- SOLIS V4 WIRELESS AMBULATORY INFUSION SYSTEM

Smiths Medical Announces the ECRI Evaluation Of The CADD®-Solis V4 Wireless Ambulatory Infusion System

CADD®-Solis v4 wireless ambulatory infusion system.

Smiths Medical, a leading medical device manufacturer, announces the release of the ECRI evaluation report for CADD®-Solis v4 with wireless communication Patient-Controlled Analgesic (PCA) and epidural infusion pump. ECRI is an independent non-profit organisation improving the safety, quality and cost-effectiveness of care across all healthcare settings worldwide (www.ecri.org). The report highlights ECRI's evaluation ratings, test results and purchasing recommendations for the CADD®-Solis pump.

The CADD®-Solis v4 system is a continuation of Smiths Medical's commitment to advance patient care and help improve patient outcomes through leading-edge technology.

The CADD®-Solis pump maintains the advantages of an ambulatory pump for patient mobility and provides a single system that effectively delivers IV PCA, epidural, peripheral nerve blocks and subcutaneous from pump to patient.

For the hospital, the CADD®-Solis system is designed to enhance patient safety through 'smart programming' (use of medication safety software) and reduce the risk of tubing misconnections, while providing a comprehensive and intuitive user experience for the healthcare provider.

Glen Johnson, NordUK Senior Marketing Manager at Smiths Medical, says: "Smiths Medical is committed to patient safety and adoption of smart infusion pumps. The wireless bi-directional communication sets the foundation for integrating pain management data delivery directly into the patient records in a hospital's Electronic Health Records (EHR auto-documentation), saving clinicians time charting and increasing documentation accuracy."

smiths medical

BIOMEDICAL ENGINEERING IN ETHIOPIA

David Morris, Betsi Cadwaladr University Health Board, tells us all about his time in Ethiopia

A small room in an outbuilding at the back of a hospital campus, not far from the mortuary and the emergency generator, has a sign on the door - Biomedical Engineering. It's the same in many many hospitals across the UK, and it seems also all over the world as this particular department is in the Nigist Eleni Mohammed Memorial General Hospital in Hosanna, southern Ethiopia.

It was my honour to join Biniam, Mokenen and Abiy, the Biomed team in Hosanna, for a week as part of the Glan Clwyd Hosanna Link. The partnership was set up in 2006 as part of an NHS-wide initiative encouraging links between health institutions in the UK and hospitals in developing countries.

I was keen to be more than an Amazon delivery man however, and after speaking to the people who run the Link we decided it was better for me to spend the time evaluating what exactly they needed so we could prioritise for future visits. Our budget, and the amount we could carry on the plane, could only stretch so far.

My first impressions of Ethiopia were firstly how developed the capital Addis Abiba was, then – as we travelled further out towards Hosanna – what a beautiful country it was. There were green rolling hills, colourful painted huts and smiling people everywhere.

When I was asked to join the team of doctors and nurses from Wales on the visit I was unsure at first what I could offer. So much of our work in the UK now is servicing rather than repair, and when we do need to fix things it's a case of finding which circuit board is faulty and replacing it – component level repairs are rarely cost effective. I was sure this wouldn't be the same in a remote corner of Africa. Speaking to two colleagues from Glan Clwyd hospital who'd been on previous visits reassured me that I'd be fine. It was a matter of every little helps.

As soon as the Hosanna team heard I was coming they set about compiling a shopping list of things I could bring with me. As I soon learned, the main issue they have is getting hold of spare parts, test equipment and tools.

Hosanna Hospital itself was much more established than I was expecting. It had an A&E department, intensive care, theatres, maternity, neonatal unit, pathology and radiology. With strong links to the nearby university it was also full of medical students.

Queues of people were to be found outside most units most mornings, with the eye clinic and maternity seeming to have most demand. It was interesting to see that there was accommodation provided for pregnant mothers so they could travel from villages far away and live at the hospital until they were ready to deliver. Most of the healthcare seemed to be provided free of charge.

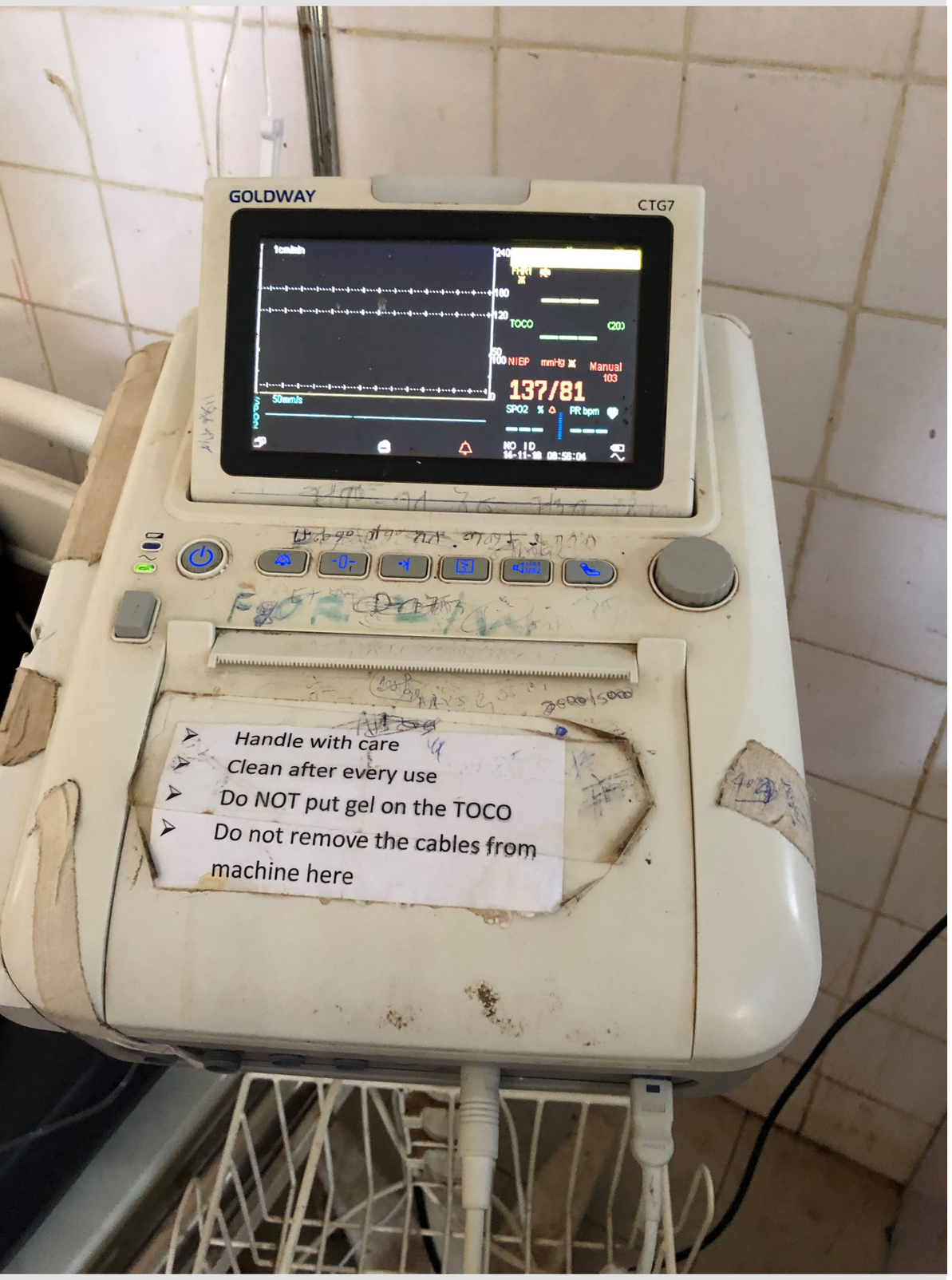
During the week I was there I spent my time looking around visiting pretty much every part of the hospital, helping with repairs, trainings clinical staffand giving advice on the future development of biomedical engineering.

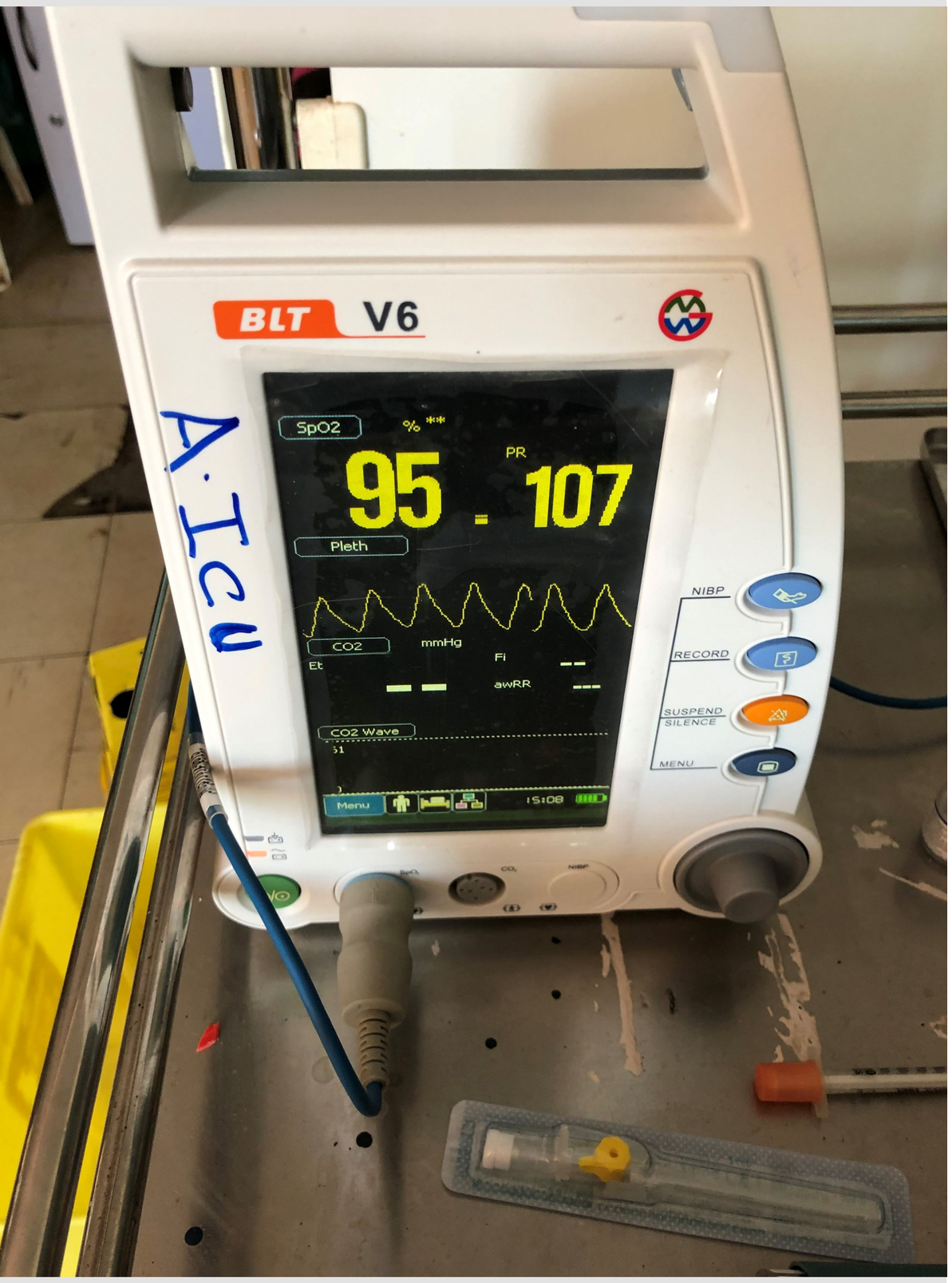
I found the hospital was reasonably well equipped, though quite a few pieces of equipment were out of action due to being faulty or requiring semi consumable items such as SpO2 probes and ECG leads. There seemed to be major issues with the fluctuating power supply and while surge protection was common, fuses were constantly blowing and tricky to get hold of.

Another key issue was that hospital management seemed to assume that an engineer was an engineer and so the very small team were constantly being asked to repair anything from printers to the hospital's ancient water pump as well as the medical equipment they should be spending their time on.

Many items of specialist equipment which would be covered by a service contract with the manufacturer back in the UK, such as pathology and radiology kit, were the responsibility of the three Biomed engineers in Hosanna.

I explained this to the Chief Executive, making the comparison of a paediatric surgeon expected to run the eye clinic as well as caring for her own patients, and he seemed to agree. I hope he will make some changes to help take some of the load off the team so they can concentrate on building their experience and knowledge on the medical devices they should be working on.





To my frustration I was never quite able to find a resolution to the issue of getting hold of spare parts. I think this will need the involvement of the hospital finance and procurement departments, such as they are.

It was impossible to do much in just a week but I hope I was able to give some useful advice, and I'm still in touch with the engineers out there. Sadly I just don't have the time at the moment to be more proactive but hopefully one day I'll return and continue the work I started. I also hope the Link are able to send more biomedical engineers out there – perhaps in small groups rather than individually as I think more could be done this way.

It was a fantastic, eye-opening experience which made me appreciate how lucky we are here in the UK, but also understand how similar the work we do is across the world, particularly the relationship between biomed engineers and the clinical staff we are there to support.

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Conferences and Webinars of Interest

Access the NAMDET website here; to see all registration details or click on the links to find out more.

29 June 2021

BSI/AAMI Conference on International Standards and Regulation

This is a wide-ranging free online event held over two consecutive afternoons during which invited healthcare subject experts, regulators, medical device manufacturers and standards-makers share their knowledge, insights and perspectives on the key issues affecting the medical device sector now and in the next couple of years. This year's conference will continue our emphasis on ...
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30 June 2021

EBME Expo 2 day event: 30th June to 1st July

The EBME Expo is an independent educational event bringing together healthcare professionals who are responsible for the management of medical equipment. These medical equipment healthcare professionals are involved in areas such as procurement, maintenance, user training, and managing inventories. Follow this link for event information

Find out more »

07 July 2021

MDSO Webex ; MDSI and Implants

The next Medical Device Safety Officer (MDSO) Webex from the team at MHRA will have an update of MDIS (Medical Device Information System) from NHS Digital and an open mic session on 'Implants' Please prepare your open mic question in advance. The usual will also be covered including; updates form the team at MHRA, NHSE ...
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Find out more »

19 July 2021

National MDSO Conference (Virtual)

Colleagues at the MHRA, NHSE and NHSI are planning the annual Conference for Medical Device Safety Officers (MDSO) for Monday 19th July 2021. Invited speakers will focus on patient safety and medical devices issues. Please follow this link to book a place

Find out more »

14 September 2021

NPAG Clinical Engineering Conference

National Performance Advisory Group (NPAG) are holding their Clinical Engineering Conference in the Midlands on 14th September 2021. See the NPAG newsletter (follow this link) for themes and content and for conference details please email marie.cherry@npag.eastamb.nhs.uk

Find out more »

21 September 2021

MPEC Conference (virtual)

NAMDET's colleagues at IPEM (Institute of Physics and Engineering in Medicine) are delighted to announce that the annual MPEC 2021 will again be held online from the 21st- 23rd September 2021. The event with the theme 'Breaking Through Barriers' will showcase all the best science and learning within the field, as well as offer opportunities ...
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Find out more »

11 November 2021

NAMDET Annual Conference (Virtual) Nov 11th 2021

NAMDET are pleased to announce that we are partnering with Olympus Medical and their 'virtual hub' to host our annual conference for 2021. The Conference team are meeting to discuss the main themes, invited speaker list and keynote speaker. Please reserve this date in your diary . More information to follow.....

Find out more »

Please checkout the NAMDET website as new posts, and events are added regularly. Sign up for free NAMDET membership and get email posts and automatic notification when each new post is added.

MEDICAL DEVICE NEWS

How Tests & Testing Kits for Coronavirus (Covid-19) Work

Medical Device Safety Information (MHRA)

Read about how the MHRA is accredited to publish National Patient Safety Alerts (NatPSA) for medical devices and medicines.

Medical Device Safety Alerts (MHRA)

Includes the latest Field Safety Notices (FSN) about contaminated consumables, giving sets and contaminated wipes for medical devices

Medical Device Information System (MDIS)

Regulations made under the MMD bill will facilitate the tracking of higher-risk implanted medical devices across the UK.

New MDSO resources page on NAMDET website.

NAMDET have developed a separate page for Medical Device Safety Officers and includes reading materials and background.

HSIB second report on Oxygen Issues during Covid

This second interim bulletin focuses on findings from the reference event and explores the role of the Medical Gas Committee (MGC) in NHS trusts.

New NRLS on its way

Lucie Mussett, Patient Safety Lead for 'developing the new digital system to support patient safety learning' talks about a replacement for NRLS.

National Patient Safety Alert:

Urgent assessment/treatment following ingestion of ‘super strong’ magnets.

FDA warns device makers of falsified records.

FDA has alerted medical device manufacturers to sterility issues and record falsification at two Steril Milano ethylene oxide sterilisation facilities dating back to 2016. Up to 97 manufacturers may be implicated.

Thank you to all our NAMDET members and supporters for their contributions towards this edition of MDET

National Association of Medical Device Educators and Trainers

NAMDET c/o 30 Aston End Road, Aston, Stevenage, London, SG2 7EU

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