MDET

Volume 3
Issue 2
October 2020

The official journal of NAMDET
Medical Device Education and Training

www.namdet.org

Contents:

Message from the NAMDET Chairman

Can it be October already ?

The Covid-19 pandemic and ever changing world has taken us all by surprise, but the way in which we have all risen to the challenge has been an amazing advert for the way the NHS, Industry, academia and private sector have all pulled together. We are still tackling what has to be the biggest challenge that I have ever faced in my 33 year NHS career to date, and I am so very proud to be part of this amazing joint effort.

This edition of MDET has some exciting new articles and some with a focus on Civid-19, sharing our esteemed colleagues' expertise and thoughts too. We have updates on T34 syringe driver battery, feedback from the NHS Nightingale hospitals, temperature measuring during Covid-19, Medical Device Directive updates and October's Global CE day to name just a few.

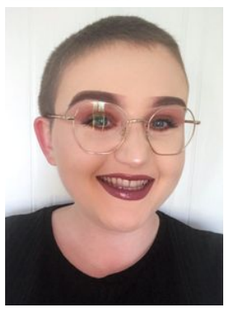
The new electronic format also allows you to save your own PDF copy, share for free to your colleagues and you can also link to a local printer and run off hard copies for your own bookshelf. All previous version of MDET are also free to download via the NAMDET website www.namdet.org

Please keep safe and we hope you enjoy the read.

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 established, and also maintained for 2020.

MDET

The official journal of NAMDET
Medical Device Education and Training

An interview with Mary Caddies, Barts Health NHS Trust

"No one falls because everyone supports each other."

I'm Mary Caddies, Trust Lead Medical Device Trainer and from April 2020, I was based at the Nightingale Hospital as part of the Clinical Engineering senior management team led by Dr Malcolm Birch, Director of Clinical Physics at Barts Health NHS Trust.

I trained as a nurse at Barts Hospital in 1984. My career path has included surgical High Dependency Unit (HDU) Nursing, Haemodialysis and I was then a renal ward sister at Royal London Hospital for ten years. I have been in my current role as a medical device trainer for the last 15 years but nothing in my career prepared me for the weeks and months ahead. My team and I work closely with the Education Academy, Practice Development Nurses (PDNs), Clinical Scientists, company trainers and national agencies e.g. MHRA (Medicines and Healthcare products Regulatory Agency), Healthcare Safety Investigation Branch (HSIB) and NAMDET. The Trust has five large sites and for a while, the London Nightingale was the sixth.

My team and I are all members of NAMDET (National Association of Medical Device Educators and Trainers) and we were delighted, thanks to our Trust communication team, to have been able to share our Barts Health medical device training pages with them and also with Health Education England (HEE) and e-learning for healthcare (e-LfH).

I was asked to join the Clinical Engineering senior management team at the Nightingale Hospital with very little notice. They have certainly been among the most challenging weeks of my career but I was privileged to have been able to support the clinical and education teams by providing regularly updated equipment training material, as well as the commissioning and deployment of medical devices for the critical care bay

I have never worked anywhere quite like it and I was in awe of the spirit of simply everyone involved. I definitely learnt more than I taught and if you'd asked me before I was deployed whether we'd be successfully treating patients on anaesthetic machines used as an ITU ventilator I wouldn't have believed it. I had so much support from clinicians in developing relevant and useful training resources.

Many were self-isolating and advising from home and others went above and beyond in patiently educating me to enable me to train others. We had very little notice of what equipment would arrive to equip the bed areas and the manufacturers were generally brilliant and responded quickly by providing on or off-site support.

I listened to feedback from staff following their first shifts on the ward and they would have liked a list of equipment that they would be expected to use in the bays and links to short learning materials. I quickly developed the list and constantly looked at ways of getting this sent to staff prior to starting at NGH. The ODPs, clinicians, army medics and education teams were also involved in delivering device training and I even jumped in the back of an ambulance to train paramedics on unfamiliar monitors and pumps prior to collecting a patient from another hospital.

NHS
Barts Health
NHS Trust

MDET

The official journal of NAMDET
Medical Device Education and Training

A simulation bay at the O2 arena and also beds in the NGH non-Covid ward areas were created to orientate staff to an unfamiliar work space prior to starting shifts. As most equipment was in clinical use it was very hard to provide hands on training and therefore videos and short user guides proved invaluable. They can be found here:

In one of the daily 4pm clinical meetings Dr Alan McGlennan, NGH Medical Director, shared this photo from a Spanish festival. It depicted how no one falls because everyone supports each other at the Nightingale Hospital and that is exactly how I've felt across all the Barts Health sites in recent times.

Reflecting on my experience at the Nightingale...
One thing that became apparent when we started at the Nightingale Hospital was that we had to have an approach that was built on continuous improvement and that everyone who came into the Nightingale Hospital came with that approach.

They came with a willingness to learn, to try new things, realising that we had never done this before but also quickly realising that we had a voice. If they had a suggestion on how this was to work better they could make those suggestions in an environment that was non-hierarchical and they had a voice that was listened to; and so when you have a rapidly changing brief and you've got a culture where everyone can contribute, it became a really dynamic atmosphere and one where we all felt we were contributing in making improvements that would help to save patients lives.

There is a lot of learning to be done as to why the Nightingale worked so successfully. It was refreshing and invigorating to feel part of one big team. Looking after each other and being kind was so important. Everybody had a single purpose and we all knew that the common purpose was to save as many lives as we could. When you have got that focus and a workforce that is engaging, welcoming and supporting and continuously trying to improve, then you see good outcomes.

Despite the challenges of the winter weeks and months ahead, the words of Sir Tom Moore, 'Tomorrow will be a good day', should resonate with us all.

simulation bed area

....we had a voice

Educating the Educators Workshop

A meeting report from Lisa Whitney, Medical Devices and Decontamination Lead,Quality and Safety Department Sussex Community NHS Foundation Trust. Brighton General Hospital. NAMDET London & South East

As Medical Device Educators we develop, implement and deliver strategies to educate medical device users, but do we have the essential skills required?

At the London and South East Regional NAMDET meeting in April 2019, the group identified a gap in the current educational portfolio: there are no national courses for Medical Device Educators.

It was recognised that new Medical Device Educators are often isolated in their roles and discussions ensued on how best to support our colleagues. Suggestions included: shadowing an experienced educator; mentor system; and use of the NAMDET forum.

The concept of running a workshop the afternoon prior to the annual NAMDET conference in York in November 2019 was born at this meeting. Two members of the group, one from the NHS and one from industry embraced the opportunity to facilitate the workshop with input from the group. Support from two other colleagues from the NHS, one of which is a NAMDET board member was offered. From these tentative discussions, several meetings were held with the workshop group and ideas for the workshop were formulated.

The NAMDET board agreed to support this venture and the workshop was promoted on the NAMDET website. Initially this was restricted to 20 delegates, but due to demand a larger room was sourced and the workshop was open to more delegates.

The 13th November dawned and the four facilitators, Marcus Berry (Fresenius Kabi), Mary Caddies (Barts Health NHS Trust), Lindsay Coleman and Lisa Whitney (Sussex Community NHS Foundation Trust) met at the Marriott Hotel and prepared for the workshop.

Education workshop meeting York, 13th November 2019

The aim of this workshop was to understand the myriad of roles undertaken by NAMDET members, review established education courses and to ascertain the appetite to provide a bespoke accredited Medical Device Educator course. The feedback from the workshop was extremely positive and a summary of the session was provided at the NAMDET conference. the following day

The workshop clearly identified the desire for NAMDET to introduce a nationally recognised accredited course. This would specifically address areas of the core identified elements. It is not intended to replace educational courses already available but would complement them with a bespoke modular medical device course. It is anticipated to use existing NAMDET member expertise and resources to provide this course.

NAMDET is looking to establish an Educational Professional Group and is supporting the London and South East Regional group to formulate an accredited course that is Approved by NAMDET, delivered by NAMDET for NAMDET.

The Chairman of NAMDET, Paul Lee, extended his thanks to the facilitators and praised the professionalism, planning and co-ordination of the workshop as a credit to our organisations and NAMDET. We look forward to the next stages and the development of a purpose built course by NAMDET for NAMDET in 2020/21.

Marcus Berry (Fresenius Kabi) summarises the main workshop feedback and outlines the next steps for NAMDET

Sarah Jennings: Patient Safety Clinical Lead (Medical Devices)
NHS England & NHS Improvement.

Demystifying humidifiers:

Human error when using a two-step process for oxygen delivery in humidification systems.

Humidification systems are designed to provide moisture to patients' oxygen treatment to help prevent dry secretions forming and to keep mucosa moist. Humidified air or oxygen is essential for patients with tracheostomies and laryngectomies, but also used where patients need over 4 litres per minute of oxygen for prolonged periods.

There are a variety of humidification systems. Some incorporate a 2-step process where a gauge on the device allows the percentage of inspired oxygen (FiO_2) to be varied, whilst receiving oxygen via the oxygen flowmeter. Both FiO_2 and litres per minute need to be set to give effective treatment.

NRLS review

A patient safety incident was reported to the National Reporting and Learning System (NRLS), where the oxygen delivery system for a COVID-19 patient was changed from being delivered via a nebuliser, to delivery through a humidification system. Whilst establishing the oxygen requirement on the humidification device at 40%, the wall flowmeter was not turned on. This was not noticed, and the patient received no oxygen despite staff believing the patient was on 40% via the flow control device on the humidification system.

"40% oxygen selected but oxygen flow not turned on"

Extract from incident report:
"I noted that the patient [device] was dialled to 40% however oxygen flow was not turned on. Last O2 source switch over was patient's nebs to [humidification device] with staff nurse this morning".

We searched the NRLS for reported incidents that occurred over a one-year period between 19 May 2019 and 18 May 2020, where a two-step process (gauge and flowmeter) is required to setup a humidification system, and where human error in understanding how the device works may lead to patient harm.

Key findings

Eight similar incidents were identified where device set up errors resulted in patients not receiving the required amount of oxygen, leading to deterioration and reduction of oxygen saturation. These reports suggest training to improve staff knowledge in the setting up and use of humidified systems may be required to mitigate these errors.

Between May 2019 and May 2020: 8 similar incidents were identified.

Although these humidification devices are indeed medical devices, they may be classified as consumables within organisations and therefore mapping training for such devices may fall between medical device trainers and educators, and respiratory teams.

Editor note: *Thanks to NHS England & NHS Improvement for sharing this useful summary. Since there is no apparent hard design fix to this issue, the request from the national patient safety team is to encourage NAMDET members to review what devices are used within their organisations and to ensure understanding and competency in their use.*

National Association of Medical Device Educators and Trainers

www.namdet.org

NAMDET 2020 Virtual Conference and Regional Meetings November 12th 2020 meetings happening between 10 a.m. & 2 p.m.

Safer Intravenous Fluid Delivery: The Monidrop® Infusion System

An article from the team at Pentland Medical

Intravenous fluid flow rate is calculated via the drop rate.[1] The drop factor is the number of drops it takes to make up one ml of fluid and relates to the size of each drop; this cannot be altered. There are two sizes; 20 drops per ml and 15 drops per ml, although 20 drops per ml is much more common with 15 drops per ml typically used for thicker fluids. When using electronic infusion controllers, the flow rate needs to be set. The rate is the volume (ml) divided by the duration in hours (mls/hour).

Issues in IV administration

Whether paper and pen or a calculator is used to calculate the volume and rate at which an intravenous drug is to be administered, the aim is to ensure that it is delivered safely and in accordance with the written prescription. Historically, this does not always happen. The National Institute for Health and Care Excellence (NICE),[2] cites a 1999 report, which showed a significant number of hospitalised patients dying as a result of infusion of too much or too little fluid. Further, NICE suggests that '...it is likely that as many as 1 in 5 patients on IV fluids and electrolytes suffer complications or morbidity due to their inappropriate administration.'2

Cousins et al's[3] study of intravenous drug administration found one error in dose or infusion volume and 132 (48% of nurses studied) errors in administration rate; errors in administration rate were also found by Taxis and Barber[4] and Tissot et al.[5]

Bruce and Wong[6] and Han et al[7] found that infusions were being administered slower than prescribed because nurses were not monitoring gravity infusion systems (i.e. no pump) nor were they readjusting the rate to take account of changes in gravity if the patient altered their position. Some studies indicate that some infusion rate errors are due to miscalculation of infusion rates. Calabrese et al.8 observed medication administration in five intensive care units and found 75 errors out of 187 were due to wrong infusion rates; at least three of these errors were due to miscalculation of the infusion rate required.

A systematic review of the UK literature by McLeod et al (2013),[9] found that medication administration errors were five times more likely in IV administration. In one study, including timing errors of ±30 min increased the error rate from 27% to 69% (320 IV doses).

Similarly, a Medicines and Healthcare Products Regulatory Agency report[10] found that of 1085 IV administration errors using an infusion pump, 21% were attributed to user error, with the most common issue being over-infusion. Early results from the ECLIPSE study[11] showed an 11.5% infusion error rate (n=2008), with gravity infusion giving the highest errors.

Volumetric Pumps

Currently, powered volumetric infusion pumps aim to provide an accurate flow of fluids over a prescribed period. These employ a linear peristaltic pumping mechanism applied to the infusion tubing ('giving set') to control the speed of infusion over a specified time.

However, these require specialist administration sets, which are more expensive than simple gravity administration sets where the infusion rate is calculated and set by the health care professional.

Additionally, shortages of pumps are common in many UK Hospitals – a problem that was exacerbated during the initial surge of COVID-19 infections early in 2020. The National Infusion and Vascular Access Society (NIVAS) published the COVID-19 Gravity Infusion and Bolus Admin Guidance earlier in 2020 in anticipation of increased pump shortages.[12]

Such studies, coupled with current guidance on IV infusion safety suggest that a simple but effective method of fluid delivery and monitoring is required both to save resources and improve patient safety.

Towards a solution

The Monidrop® (Monidor Finland) IV fluid Monitor allows for accurate delivery in infusion speed, target volume and speed and total volume infused. The system is portable, chargeable, and compatible with most commonly used drip sets (20 drops/ml). Additionally, when used in conjunction with the IV Screen remote monitoring software application, allows Nurses to remotely monitor details of several infusions in real-time on a computer or mobile device. The Monidrop®device attaches to the drip chamber and shows on the screen;

* Infusion speed
* Total volume
* Treatment duration

Flow rate can be adjusted by using the administration set's roller clamp - the infusion speed is shown on the system's screen (ml/h). Monidrop® monitors the infusion but does not adjust it. It has a series of built-in alarms which indicate if it is outside the measurement range of 6ml/h to 1200ml/h, or if the battery is low.

The wireless connection enables remote monitoring, thus allowing the system to be used in both acute and home care settings. The information obtained from the Monidrop device is transmitted wirelessly to the IV Screen and from there, Nursing staff can set target speeds for each patient by inputting the total volume of fluids they would like to infuse and over how long. If the infusion then starts to run too fast or too slow, this will flag up on the screen and prompt the Nurse to adjust the infusion speed. Trials are currently ongoing for COVID-19 patients in isolation with positive results showing a reduction in unnecessary patient contact to monitor infusion speed.

An initial study was undertaken in the Kuopio University Hospital, Finland to determine the benefits and performance of the Monidrop® device in the monitoring of intravenous infusion in the hospital wards. This was a comparative study against conventional clinical practice. The secondary aim was to establish if using the device could improve the accuracy of fluid therapy compared to visual assessment.

Thirty-one patients prescribed intravenous fluid therapy or drug infusion were recruited from the medical ward and the emergency department; 15 were randomised to the Monidrop® group, 16 to the control group. The momentary infusion rate of the Monidrop® device was measured at 30 minutes and six hours from the beginning of treatment, and the patient's total fluid intake and drugs administered were recorded. The alerts raised by the Monidrop® device were recorded, and the nurses were asked to assess the appropriateness of those alerts.

No adverse events or safety issues occurred during the trial. The Monidrop® device was used in for a total of 230 hours. A total of 53 alerts were recorded; twenty-three (43%) resulted from a variation in the flow rate. Three were evaluated as inappropriate, but no security-related concerns or observations were raised. The primary endpoint of the trial was reached; the device was safe and usable in a clinical environment. Almost all (92.9%) of the nurses found nothing of concern, and only one respondent had paid attention to a seemingly great variation in the readings of the device during the treatment. The final analysis of the differences between Monidrop® and the control groups is ongoing.

Cost savings

Currently, a commonly used volumetric pump set for blood and blood components costs £2.91 per unit when purchased through NHS supply chain. Capital outlay will also be required for the actual pump. In a typical 400-bed hospital which uses on average, 9039 blood administration sets, the cost would be £26,303.49 per annum. A theoretical reduction in use of these sets by 10%, 15%, 20% or 50% would result in savings of £2,630.35, £3,945.52, £5,260.70 and £13,151.75, respectively. A reduction in the use of volumetric pumps and associated costly administration sets could be realised using the Monidrop® system as it facilitates effective blood product administration, as well as other fluids and medications, using a standard administration set costing £0.61.

The purpose of Monidrop®is not to directly replace the function of volumetric pumps as they are a mandatory requirement for certain fluids and medications, and in certain scenarios. However, by increasing nurses' confidence to administer IV therapy with gravity and, as a result, increasing patient safety, the overall requirement for pumps is reduced, leading to cost-savings and other efficiencies.

The Future

Monidrop® plans in remote monitoring are already producing great results and will fit well with the NHS desire to adopt digital healthcare solutions. Other exciting developments include the addition of a dedicated low-cost dial infusion set designed to deliver stable, consistent, and accurate delivery volume for hours. This will be in the form of a dial-flow giving set, however, there will be no numbers printed on the dial and users will instead take the speed of infusion from the Monidrop®screen. Initial testing indicates a far greater consistency of infusion speed in comparison to traditional gravity sets with roller clamp control.

Conclusion

The Monidrop® system is simple yet effective. Early results from the three-month clinical trial suggest that using the system can prevent over/under delivery of IV fluid. Accurate administration will prevent complications and thus shorter hospital stay and reduced costs. Monidrop® also clearly offers significant advantages in patient safety and fits well with NHS plans to adopt digital solutions with remote monitoring functions.

References:

1. Royal College of Nursing (RCN). Clinical topics. Flow rate and IV drugs. 2018. Available at: https://www.rcn.org.uk/clinical-topics/safety-in-numbers/flow-rate-and-iv-drugs

2. National Institute for Health and Care Excellence. Intravenous fluid therapy in adults in hospital. Clinical guideline [CG174]. 2017 (Update). Available at: https://www.nice.org.uk/guidance/cg174

3. Cousins D, Sabatier B, Begue D, et al. Medication errors in intravenous drug preparation and administration: a multicentre audit in the UK, Germany and France. Quality and Safety in Health Care. 2005;(14):190–195

4. Taxis K, Barber N. Incidence and severity of intravenous drug errors in a German Hospital. European Journal and Clinical Pharmacology. 2004;59(11):815–817

5. Tissot E, Cornette Limat S, Mourand J, Becker M, et al. Observational study of potential risk factors to medication administration errors. Pharmacy World and Science. 2003:25(6):264–268

6. Bruce J, Wong I. Parenteral drug administration errors by nursing staff on an acute medical admissions ward during day duty. Drug Safety. 2001;24(11):855–862

7. Han P, Coombes I, Green B. Factors predictive of intravenous fluid administration errors in Australian surgical care wards. Quality and Safety in Health Care. 2005;14(3):179–184

8. Calabrese A, Erstad B, Brand K, et al. Medication errors in adult patients in the ICU. Intensive Care Medicine. 2001;27(10): 592–1598

9. McLeod MC, Barber N, Franklin BD. Methodological variations and their effects on reported medication administration error rates. BMJ Qual Saf. 2013 Apr;22(4):278-89. doi: 10.1136/bmjqs-2012-001330

10. Medicines and Healthcare Products Regulatory Agency. Infusion Pumps. 2013. Available at: https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/403420/Infusion_systems.pdf

11. Blandford A, Furniss D, Lyons I, et al. Exploring the Current Landscape of Intravenous Infusion Practices and Errors (ECLIPSE): protocol for a mixed-methods observational study. BMJ Open 2016;6:e009777. doi: 10.1136/bmjopen-2015-009777

12. COVID19; NIVAS Gravity infusion and Bolus IV drug administration guidance. Available at: *https://nivas.org.uk/contentimages/main/NIVAS-COVID19-Gravity-Infusion-Bolus-Admin-Giuidance-2-converted-SH.pdf*

For more information about Monidrop® please follow this link or click any of the images on this page

Choosing the right drip stand

A review of the guidelines and standards: Paul Lee, Medical Devices Training Manager, Swansea Bay University Health Board

The clamber for mobile drip (infusion) stands across the world has meant an unprecedented call for thousands of these devices for use in safe Intravenous (IV) therapy. Mobile drip stands are essential in the use of gravity (drip-rate) infusions and when using infusion pumps and syringe pumps. In addition, these are essential to allow patients to be mobile and get out of bed (if able). The simple drip stand must be able to help support the infusion devices, be height adjustable and have a safe and stable base.

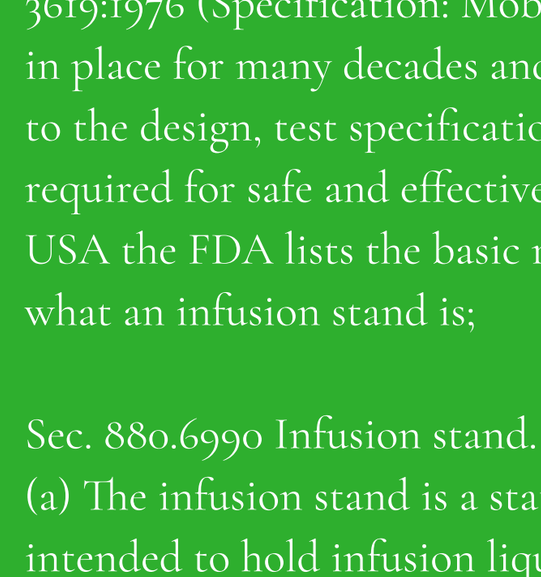
Covid field hospitals have been inundated with deliveries and procurement teams under huge pressures to meet orders, and of course manufacturers clambering to design and make drip stands, perhaps which they have not been involved in making before.

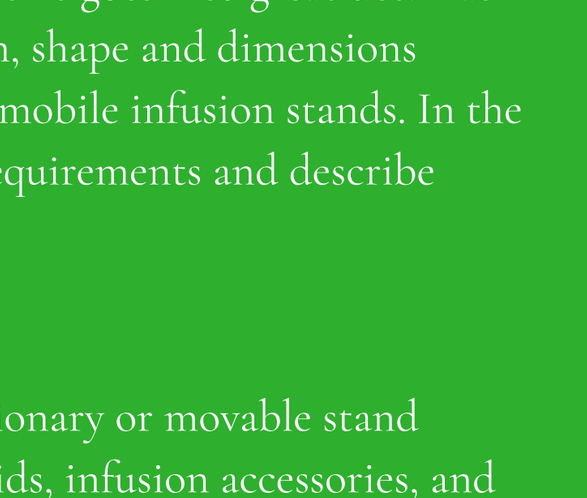
Nevertheless, in the UK, the MHRA have a system to control medical devices using CE classification marking (Class 1, 2, 3) that affords some sort of assurance that devices are safe and tested in accordance with agreed directives, protocols and UK and European standards.

In the UK, BS EN 60601-1 (sub clause 9) highlights that instability should be considered an 'unacceptable' risk for medical equipment and list basic test for safety (including a 10 degree angle tip test). In addition, a British Standard BS 3619:1976 (Specification: Mobile Infusion Stands) has been in place for many decades and this goes into great detail as to the design, test specification, shape and dimensions required for safe and effective mobile infusion stands. In the USA the FDA lists the basic requirements and describe what an infusion stand is;

Sec. 880.6990 Infusion stand.
(a) The infusion stand is a stationary or movable stand intended to hold infusion liquids, infusion accessories, and other medical devices.

(FDA Title 21: Subchapter H: Medical Devices, part 880, subpart G)



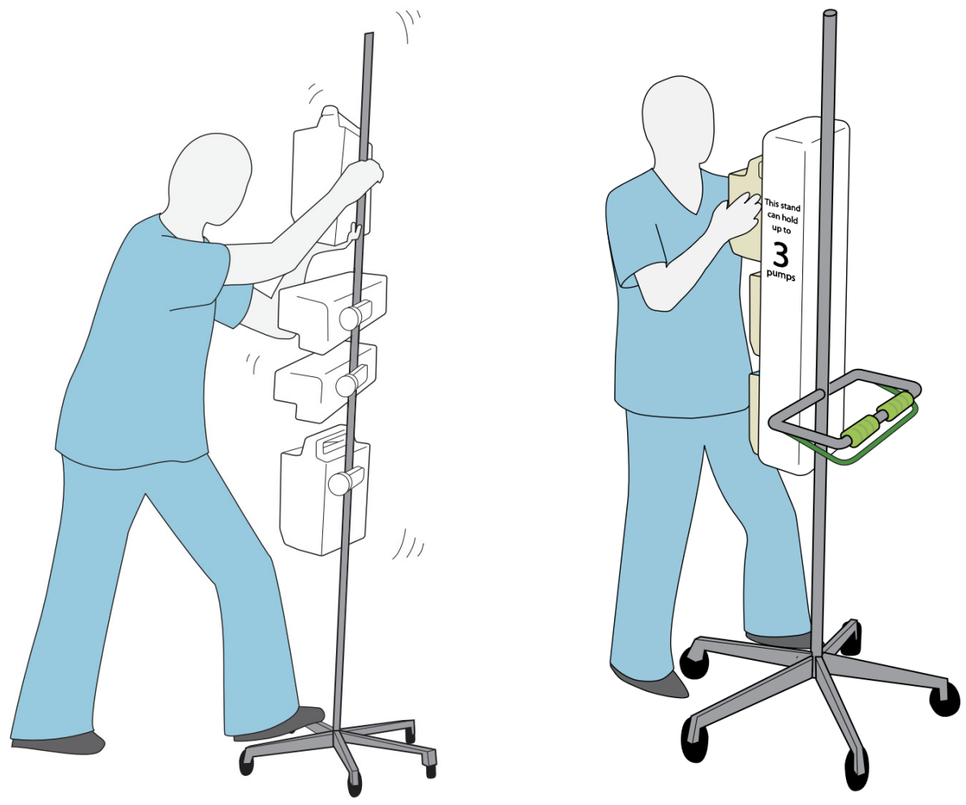


What the standards say_

The National Patient Safety Agency (NPSA) back in 2010 issued advice and guidance to manufacturers of infusion devices including listing some of the issues of safety around the use of infusion stands and are summarised below:

Issues:

- Gravity infusion stands are not designed to hold devices and can be unsteady and inclined to topple over.
- Consideration is not given to the manoeuvrability of the stands and movement is very awkward for patients.
- Base units can make stands heavy and cumbersome.
- Stands can be hard to clean.
- Stands can be hard to control during device attachment due to the lack of a braking mechanism.
- Some stand poles are too large to accept all types of infusion devices.
- Attaching devices to stands can be very cumbersome, particularly if there is more than one device already loaded onto the stands.
- Pole clamps may also be too small to fit around the stand.



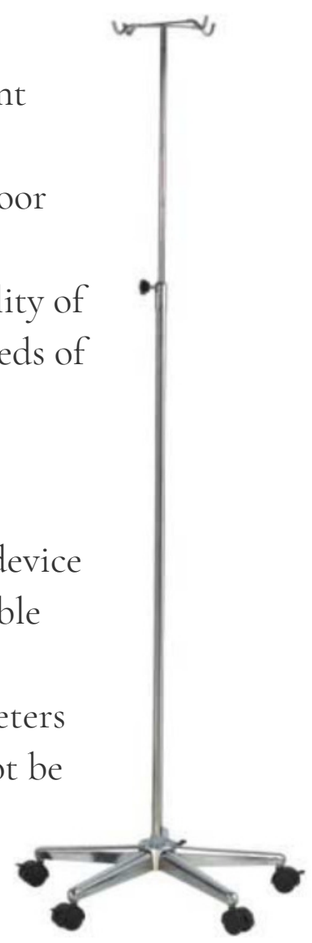
Images courtesy of Royal College of Art, NPSA and Helen Hamlyn centre (NPSA 2010)

The NPSA 2010 recommendations went on to advocate:

- Gravity infusion stands should not be used to mount infusion devices; equipment stands should be used instead.
- These should be designed to cater for the additional weight that devices add to the stand.
- They should also specify how many devices can safely be mounted.

Refer to the British Standards for guidelines on stability.(BS EN 60601-1 stability in normal use; see how some companies test devices)

- Equipment stands should have handles to aid patient movement.
- Larger wheels can also help navigate over uneven floor surfaces.
- Consideration should be given to the manoeuvrability of equipment stands, particularly with regard to the needs of mobile patients.
- Equipment stands should be designed taking into consideration the need for cleaning.
- Manufacturers should consider ways of aiding the device attachment process. Docking stations may be a suitable option, in addition to a parking brake.
- Device manufacturers typically cater for pole diameters of 15-40mm. Hence equipment stand poles should not be any larger than 40mm.



BS 3619:1976. Mobile Infusion Stands

Despite being over 40 years old, the BSI standard is still available and listed as 'current' via the BSI website and lists some important safety factors, features and considerations for manufacturers and purchaser. The following is a summary of the salient points to consider:

Materials

Section 4.1 Points out that the material for the upper pole should be stainless steel rod of approx 12mm (+/-1mm). The NPSA have previously pointed out that the dimensions are important as some medical devices are not able to be clamped to the lower part of the pole due to restrictions on the size of pole clamps on different infusion devices.

Section 4.2 Points out that the hooks themselves on the top of the pole should be strong and made from 8mm diameter bar. Their shape and dimensions are also listed: 105 mm from centre of the pole, 44mm high with 30mm drop and 14mm above the bar. This again affords safety and strength to support IV fluid bags (a 1,000 ml bag of sodium chloride can weigh as much as 1kg)

Section 4.3 Advocates a main outer bar diameter of approx 30mm and also outlines the minimum thickness of material too. Section 4.5 Relates to the base, and only states it should be made from a '*suitable material*' and have '*durability*' an additional note is listed: "***The design of the base has not been specified but the purchaser might wish to consider the geometry of the base best suited to his requirements***"

Note; there is no minimum or maximum number of wheels listed in the BSI standard, but *Appendix A* goes into some detail about the test required for stability.

Base dimensions:

The base should not exceed 660 mm

* Dimensions from centre of pole to centre of caster 205-255mm
* Height from floor to hooks - 1.75m to 2.75m

The pole.

The standard alludes to the pole being adjustable, marked for safety and the last 100mm being labelled to warn the user that you are approaching the last portion of the pole.

Castors.

Should be made from anti-static material and be at least 50mm in diameter. There is also a BS standard listed BS 2099-1 and BS2050-1978 for castors and their anti-static properties.

Stability Test. BS 3619:1976 (*Appendix A*)

Although the BSI 3619 standard does not list the minimum or maximum number of wheels, the 'stability test' in its *Appendix A* goes into detail as to how the mobile stand should be tested. The stand should be adjusted to its maximum heigh (i.e. 2.75m) and two (2) of its wheels placed against a stop strip. A 1,000ml bag of fluid (acting as a weight; equivalent to approx. 1 kg) and simulating the real case scenario is then hung on one of the hooks. The stand is then tilted at an angle of 9 degrees, and should remain stable and not tip over.

* Set to maxium height (i.e 2.75m)
* 1,000 ml bag (weight)
* A safe 'stop strip'
* 2 castors placed at the strip
* Tilted to 9 degrees
* Remain stable

Note: BS 3619:1976 suggests an angle of 9 degrees for stability test and BS EN 60601-1 suggests 10 degrees.

Summary

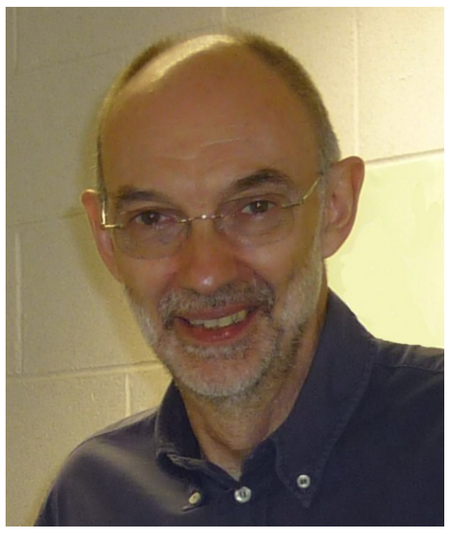
Both the MHRA guidance on Infusion Systems (archived) and Royal Colleague of Nursing (RCN) standards for infusion therapy outline many areas of safe IV practice and safe use of infusion pumps but neither have 'any' reference to safety or stability of mobile drip stands.

In a recent article published in SCOPE (IPEM: Institute of Physics & Engineering in Medicine) Dr. Scott Brown and Andrew Frost highlighted the flimsy nature of some drip stands purchased for the Nightingale Hospitals in the UK. Poorly designed bases make them unstable, raising patient safety issues if drip stands subsequently topple over. Any issues about stability, safety or design issues should be reported to the MHRA.

The NPSA guidance from 2010 goes some way to highlight the safety issues with mobile drip stands and infusion stands. Despite being over 4 decades old, the BSI standard (BS3619 :1976) is clear that to be CE marked, then a strict set of tests and criteria must be followed and passed. Purchasers and manufacturers may wish to visit this, and any other supporting standards, for drip stands, infusion stands and stands used for other medical devices.

Where are we with Medical Devices Regulation?

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



Context

A new EU Medical Devices Regulation, replacing the 1993 Medical Devices Directive (as amended) came into force in May 2017. The UK, through senior MHRA people, had played a very significant part in the negotiations that developed this regulation, starting in 2012.

The date of full application was originally intended to be 26 May 2020. On the date of full application of an EU Regulation, that regulation becomes direct law in all member states without further legislative process. This is not the case for an EU Directive which has to be put into national law through national processes and can to some extent be interpreted and 'tweaked' differently in each Member State.

The UK formally left the EU on 31 January 2020 but among other matters under the European Union (Withdrawal Agreement) Act 2020 which implemented the Brexit withdrawal agreement, this Act made provisions for changes to EU law to be legally binding in the UK during the implementation period (after the UK has left the EU). Therefore in May of 2020, the EU Medical Devices Regulation (EU MDR) would have automatically become retained EU law in the UK.

In March of 2020, the EU Commission made a proposal that the date of full application of the EU MDR should be postponed by one year. Ostensibly this was because of difficulties due to the Corona virus in setting up some new provisions and data bases required by the Regulation. Many commentators had previously voiced opinions that the original timescales for these were very over ambitious and perhaps the pandemic provided an acceptable reason for delay.

The Commission proposal was swiftly pushed through the tripartite procedure — the Commission proposes, Member States (the Council) and the European Parliament negotiate and all three come to a final agreement. An amending Regulation (EU) 2020/561 was agreed and came into force at the end of April 2020.

As far as the UK is concerned the net effect of this is that the EU MDR will not become UK law since the date of full application on 26 May 2021 is after the end of the withdrawal agreement transition period.

A further complication is that the existing UK medical devices regulations are based on the three Medical Devices Directives (for active implantable, general and in-vitro diagnostic devices) and are in the Medical Devices Regulations 2002 (S.I. 2002/618) as amended from time to time since.

This statutory instrument is made under powers in the European Communities Act 1972 which ceases to apply at the end of this year and with it the power to amend the UK MD regulations. For this reason a new Bill is going through Parliament, the Medicines and Medical Devices Bill, which will give power to make and amend regulations on these issues.

The way ahead

To date the only information or guidance we have on the possible shape of UK MD regulations is in this Government website post *https://www.gov.uk/guidance/regulating-medical-devices-from-1-january-2021*

You might be inclined to think that the issue is all about manufacturers making devices, CE marking or in the future, UKCA marking them, and the NHS ensuring that they buy only marked devices. What may not be widely appreciated is that certain activities that are undertaken within NHS health institutions are also manufacture. Devices that meet the definition of a medical device and are made and deployed within the same health institution are not 'placed on the market'.

Examples from Clinical Engineering would be one-off or small numbers of equipment which are not commercially available to meet the needs of a particular group of patients or a specialist surgical instrument made for a particular clinician. Software that meets the definition of a medical device and runs on a non-medical device platform e.g. a PC is also developed in-house. More widely, many professions make and issue custom-made devices; rehabilitation engineering, maxillo-facial, occupational therapy and podiatry departments are all examples.

Also, modifying a CE marked medical device in a way not intended by the original manufacturer or that significantly alters is intended use, performance or safety is also considered 'manufacture'. Use of a device not intended by the manufacturer without any modification ('*off-label*' use) is also considered 'manufacture'.

Such devices that are not '*placed on the market*' are not covered by the existing UK 2002 regulations (as amended). The above activity is not legislated for with the exception of certain in-vitro diagnostic devices. MHRA have provided some guidance on the legal situation regarding in-house manufacture of general MDs but no guidance on what would be best practice when this activity is carried out.

The EU MDR does cover such activity and provision was made in Article 5.5 for it to be legally continued without requiring full conformity assessment and CE marking, provide certain conditions were met.

Before the postponement, MHRA had been working on guidance for this so called 'health institution exemption', had issued a first draft and called for comments. They had got to a final draft which was then embargoed, though a few of us who had been actively working with them were allowed sight of it. This guidance has never been issued since the EU MDR will not be UK law.

In legal terms therefore, until the end of 2020, UK law regarding medical devices remains the 2002 Regulations as amended. Assuming the Medicines and Medical Devices Bill goes through all its stages by or before the end of the year, there will be powers given in that Act to make new or amend existing regulations. Naïvely, I assumed at first that these would closely follow the EU Regulations but I now think that pressure from politicians and probably from unelected political advisors may be driving for regulations in this area that do not align with or resemble the EU regulations.

Certainly the guidance linked to above says that CE marked devices i.e. meeting the EU MDR will not be allowed on the UK market from 1 July 2023, without also a UKCA mark i.e. meeting UK regulations also.

This is all of most direct concern to commercial manufacturers but it is likely to put up costs for purchasers.

What I have no hint about is the thinking around in-house manufacture and use and any possible health institution exemption. Although to the best of my knowledge there has never been any problem with in-house manufacture of devices, there has been with modification or off-label use, PP mesh for example. I think it is highly unlikely that the existing lack of any formal regulation will continue.

.....In legal terms therefore, until the end of 2020, UK law regarding medical devices remains the 2002 Regulations as amended.....

A possibility is that there might be no health institution exemption, therefore such activities as exampled above would require full conformity to whatever regulations are brought in. That would have some pretty profound effects including financial ones even for departments that make only low risk devices. Manufacture of on-off higher risk device would probably become prohibitively expensive to the detriment of certain patients.

It is to be hoped that provisos and conditions similar to those in Article 5.5 (which were heavily influenced by the UK during the negotiation stage) will be included. The engineering aspects of these fit in with generally considered best practice. The additional administrative burden (making a declaration, reporting etc.) is reasonable light.
The future situation at the time of writing this (early October 2020) is very uncertain. Of course it is possible that by the time of publication things become clearer.

In a role I had providing advice and some planning for NHS Wales on the possible implications of the MDR and then on the affect of the postponement I said this:

"We should not think that the work we have done and are doing on the health institution exemption has been a waste of time. The fundamental requirements; reference to the General Safety and Performance Requirements, a quality management system in place, good documentation, some element of clinical evaluation and post deployment clinical follow-up for in-house devices, will all continue to be required even if legally we have some extra time.

All of the above are in my opinion, best practice for medical device manufacture, whether a legal requirement or not. We should continue with this work."

I cannot be certain that they 'will be required' but I do think they will remain best practice.

Note: the opinions expressed are mine and do not represent those of nor are they endorsed by NAMDET.

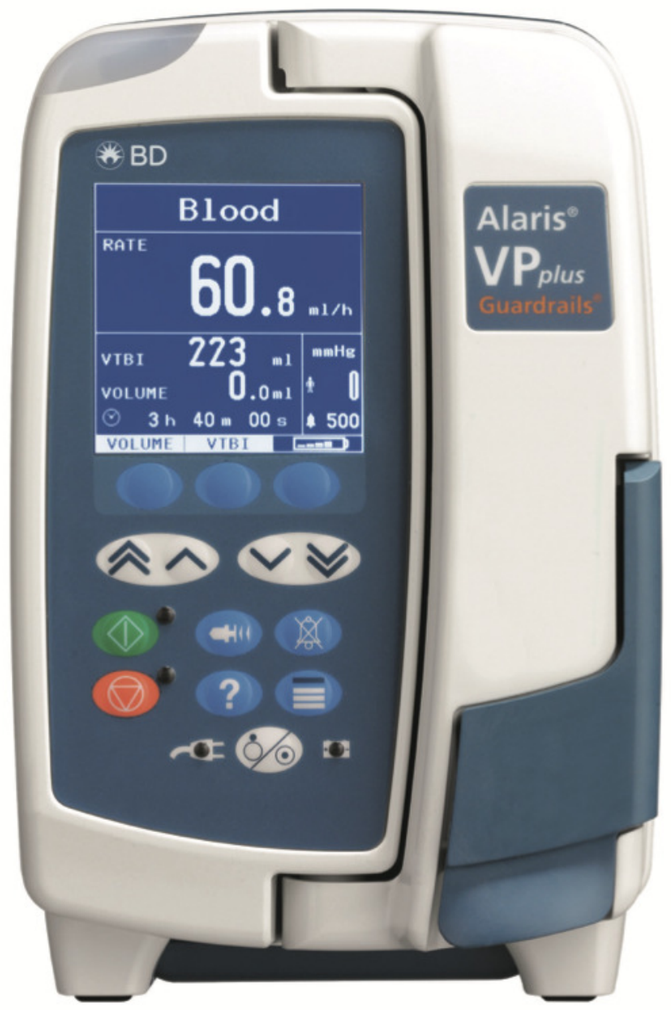
From 1 January 2021, there will be a number of changes to how medical devices are placed on the market in Great Britain. Check the Gov.UK website for updates and information .
https://www.gov.uk/guidance/regulating-medical-devices-from-1-january-2021

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

Finding a suitable battery for a T34 syringe driver.

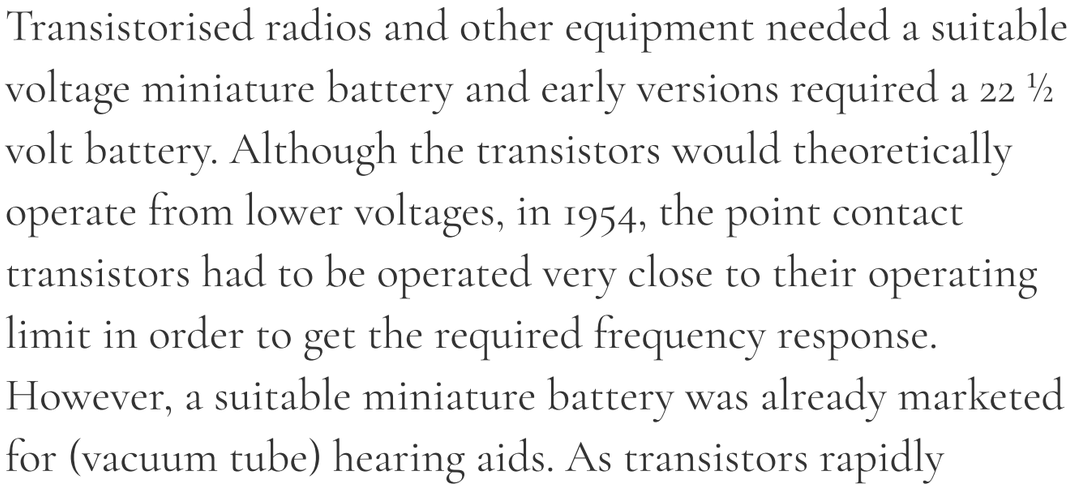
Paul T. Lee, Medical Devices Training Manager & Martin Ryan, Technical Officer: Swansea Bay University Health Board.

History

Transistorised radios and other equipment needed a suitable voltage miniature battery and early versions required a 22 ½ volt battery. Although the transistors would theoretically operate from lower voltages, in 1954, the point contact transistors had to be operated very close to their operating limit in order to get the required frequency response. However, a suitable miniature battery was already marketed for (vacuum tube) hearing aids. As transistors rapidly improved, particularly when alloy transistors were introduced, radios were able operate from lower voltages and the battery manufacturers introduced suitable batteries as the demand arose.

The PP3 appeared when portable transistor radios became common, and is still called a "transistor" battery by some manufacturers.

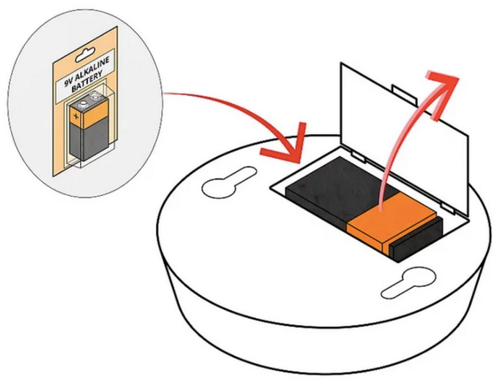
courtesy of wikipedia



1956: PP3 (Power Pack 3) 9 volt battery manufactured by EVER READY in the USA and used for transistor radios

Today, the 9 volt, PP3 sized battery (zinc carbon) is predominantly built to be used in a 'smoke detector'. Their characteristics, longevity and power drain are matched to this most common domestic application. Despite there being a range of 9 volt battery options available from suppliers (i.e. Power, Ultra, Super power etc.) there doesn't appear to be a dedicated 9 volt battery built specifically for use in medical devices. Users are expected to use a battery developed for domestic use in a medical device that has completely different characteristics, power output and power drain.

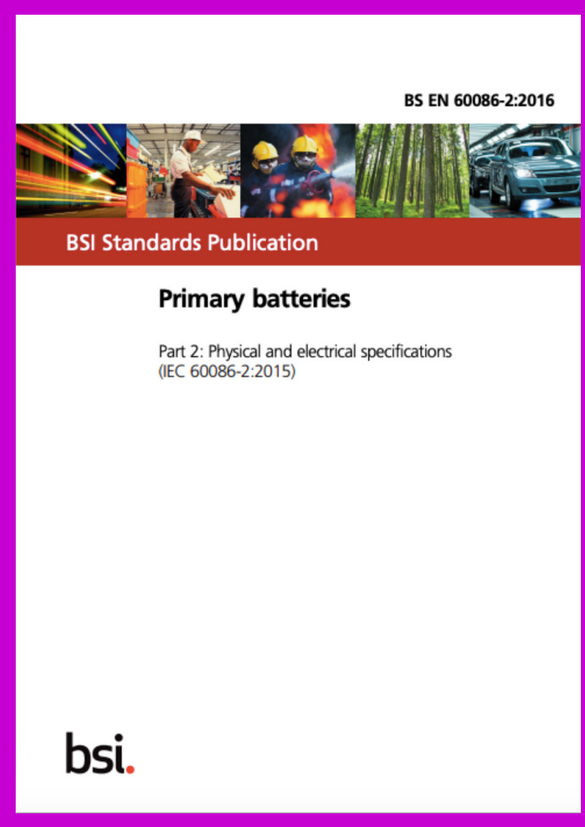
PP3, 9 volt battery mainly designed for use in domestic smoke detectors



Nowadays, there is a plethora of batteries, from a number of different suppliers, and a new set of part numbers that have replaced the original Every Ready numbers commonly known as PP3 and PP9 etc.

A BSI standard (BS EN 60086-2-2016: Primary Batteries) goes some way to outline battery characteristics, performance, test specifications and most importantly physical dimensions. For the T34 syringe driver a recent issue has highlighted these small variances in battery dimensions (i.e. +- 2mm) and in 2019 a safety alert recommending an adaption to the device where a small sponge has been mandated to be fitted inside the battery compartment to certain models to help ensure proper battery contact for the syringe driver.

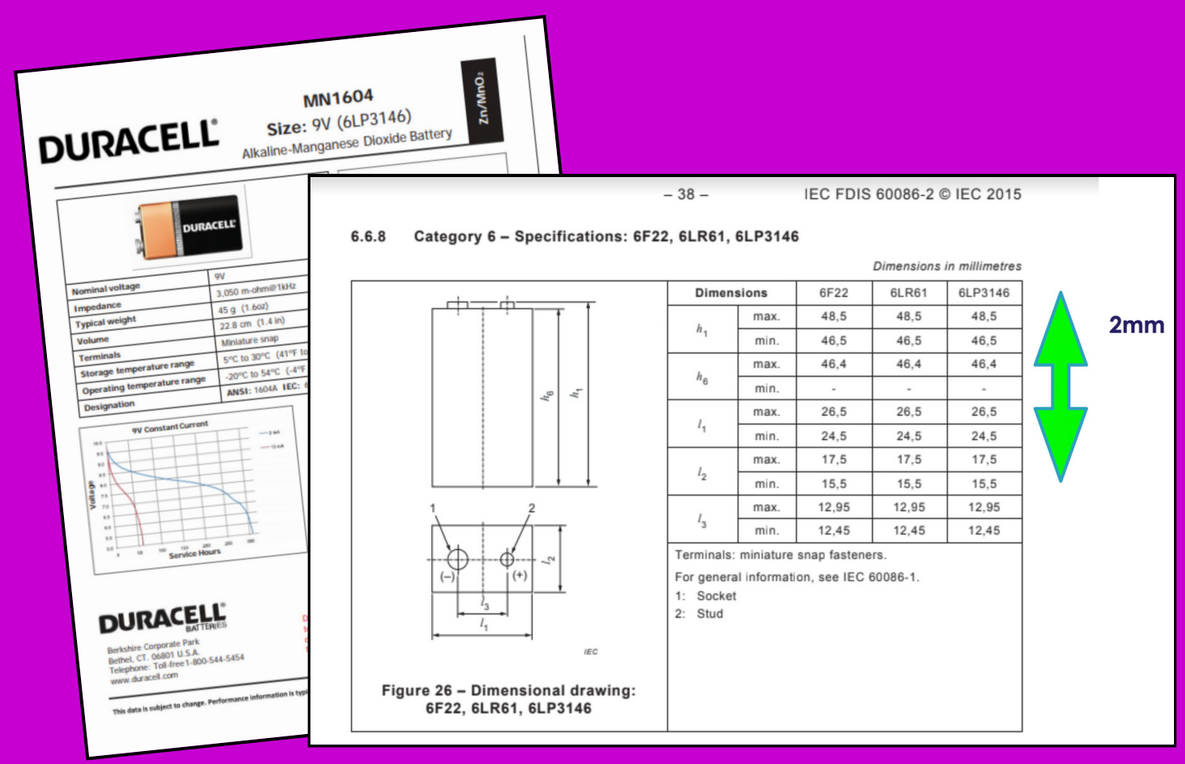
The BSI standard lists a number of new part numbers for 9 volt batteries including 6LR61 (alkaline) 6F22 (carbon zinc) and 6LP3146 (alkaline). These number variations seem to relate to the internal chemical make up and the type of internal cells used to make up the 9 volt battery.



The internal cells vary for different battery types.

The number 6 as a prefix denotes the actual number of cells used to make up the battery i.e. 6LR61 = 6 x LR61 cells. Manufacturers also supply a range of 'data sheets' that can help purchasers identify performance, characteristics and suitability for use in devices and machines. Discharge curves, average power, chemical make up and expected time to last are also listed on these data sheets.

When it comes to 9 volt batteries the variance of +-2mm for physical height is noted for the size of these devices and this variance can, and has caused issues in the past where loose or intermittent battery contact can affect the device's operation in clinical use.



Inside batteries

The internal make up of the 9 volt battery varies, and the part number can often be used to denote this variance.

The battery could be made up of flat, plate-like cells and from zinc, carbon or alkaline chemicals. The LR61 battery (similar to a AAAA sized battery) is an alkaline, cylindrical battery and 6 x 1.5 batteries are connected in series to make up the required voltage of 9 volts. This type of battery (6LR61) has been 'recommended' as the only battery type to use in aT34 syringe driver.

Internal cell structure varies from battery to battery type
courtesy of wikipedia

In total, 6 x LR61 battery cells are needed to make up the recommended battery for use in the T34 syringe driver. These battery types have shown in tests to be most suited to the performance and characteristics of use for this syringe driver.

LR61 battery (AAAA sized)

During 2020, a series of tests were performed on a number of different (6LR61) 9 volt batteries that were all available to NHS Wales hospitals via the internal stock ordering system. These batteries had been through a procurement and compliant route process to ensure cost-effective pricing and delivery options. However, at present, there is no actual battery performance, power characteristics test required, or carried out on these batteries as part of this process.

3 types of 6LR61 battery available to NHS Wales

Testing of new batteries for use in the V3: T34 syringe driver

A bench-top test was established to compare these 3 battery types for use in the T34 syringe driver (version 3)
1) Duracell ULTRA 2) Procell 3) NX Power Tech.

Battery Performance

In March 2020, reports of T34 (v2) failing in use (random low/end battery message) after just a few hours use were reported. In addition, the Medical Device Safety Officer's (MDSO) network and monthly WebEx meeting was also reporting similar issues across the rest of the UK.

The battery in question was identified as an NX POWER battery and the T34 event logs were shared showing a 'crash' of the battery voltage and devices failing after just a few short hours in clinical use. In direct response to this, a Duracell: Procell (9-volt) battery was supplied as an alternative for NHS Wales's stores.

These Procell (9 volt alkaline 6LR61) replacement batteries were also tested using the same test methodology and showed that they were performing well. However, just before Swansea Bay UHB was about to issue a new safety alert recommending these Procell batteries, they also began to show up in DATIX incident reports as failing after a few hours use (i.e. low battery message: similar circumstances as the previous NX POWER battery failings). These new replacement batteries had a slightly different dimension and were smaller than the previous batteries in stores.

Comparisons and Test T34 (version 3)

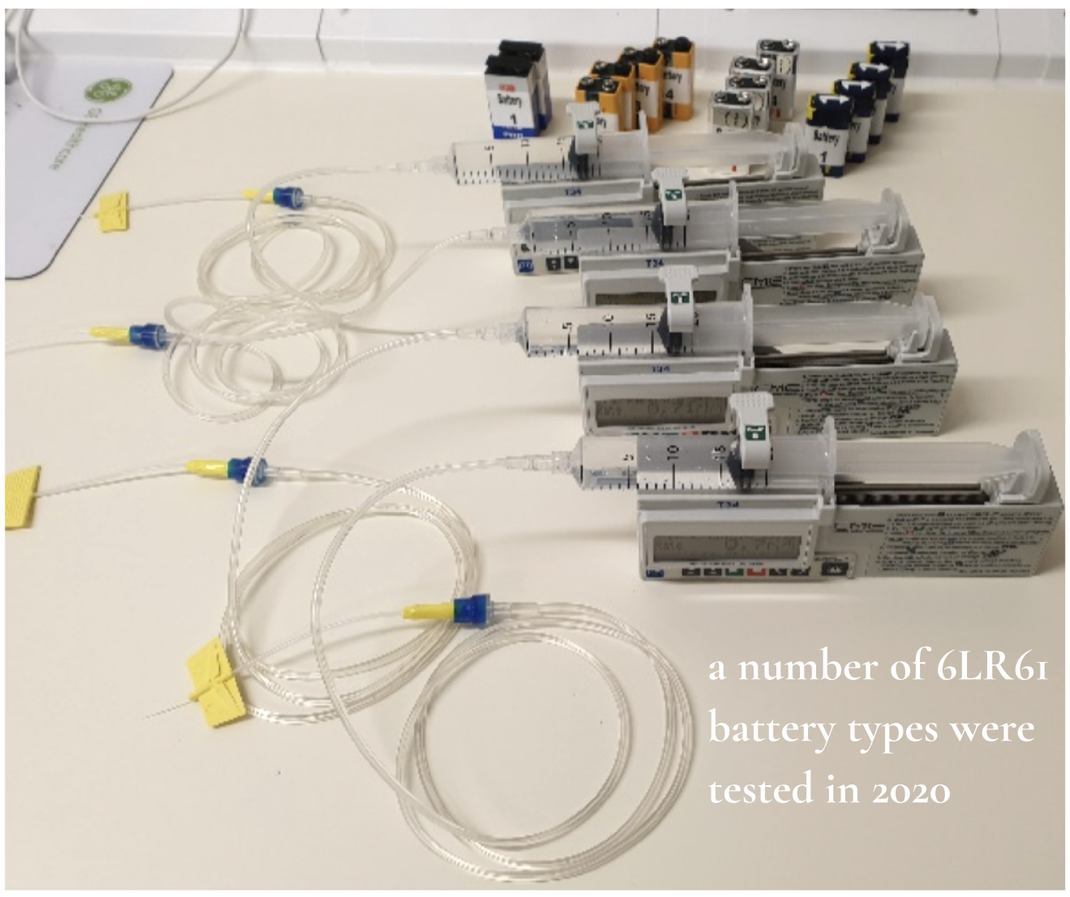
In an effort to compare battery performance and suitability for use, the T34 syringe drivers were set up and run for 24 hours, uninterrupted, then repeated as long as the batteries would last. Each v3 pump was run for 24 hours and the battery voltage recorded for each of the three battery types. The event log records the battery voltage at each hourly check (volts), however the pump's display shows battery life as a percentage (%) and it was difficult to compare these two measurements to give an accurate value and expected battery life.

Note: T34 Version 2
In addition, the batteries were also tested in a Version 2: T34 to ascertain if they also performed as expected and would be suitable for ongoing use with the established inventory of devices.

Methods.

New T34 syringe drivers (v3) were selected for test and set up using a range of syringes, lines and needles. Initial tests showed that the pressure/force required to infuse a syringe filled with sterile water was approx. twice that of using air, and therefore the devices were tested as close to clinical practice that was able using;

*** 9 volt alkaline battery**
*** sterile water for injection**
*** BD Plastipak 20ml Luer Lok™ syringes (300629)**
*** BD syringe extension set with anti-siphon valve (100-172SX)**
*** BD saf-T-intima™ sub cut safety needles (383318)**



a number of 6LR61 battery types were tested in 2020

Note: A larger syringe (30ml) and users accessing the front panel, reviewing the history/event log (that illuminates the screen using addition battery power) may impact further on battery capacity to perform over 24hrs.

The devices were tested over a 24 period and then restarted if the battery life allowed. The driver was allowed to run to 'low battery' and then continue until the 'end battery' message was seen. The event log was downloaded using the dedicated *Bodycomm* v3 software supplied by BD Ltd. The data files were then exported and analysed in Excel.

The **Procell** 9 volt batteries were only just performing for 24hrs when used in the v3 T34 syringe driver. Despite DATIX reports indicating random failings there were no indication of battery failings in the batches supplied for testing. However it's ongoing suitability for use in the T34 due to its variance in dimensions may need to be reviewed.

The **Duracell Ultra** operates for the full 24hrs in each case and then for additional infusion time (15 and 17hrs resp.) This battery also performed for 4 full days (24hrs) when used in a T34 version 2. However, the cost effectiveness of this battery needs to be considered due to its increase cost vs. alternative batteries available.

The new **NX Power Tech** batteries supplied for test performed for 40 and 48 hours (resp.) before any low battery alarm. In addition, they showed no indication of battery failings due to low battery issues as originally described. However, subsequent DATIX reports relating to batch numbers 113, 165 and 095 have since raised concern about this battery as a suitable alternative going forward.

Previous battery tests carried out in the department suggested the use of a **Varta (Industrial pro)** battery and this also showed good performance when tested in a version 2 and version 3 T34. Again, its cost effectiveness, physical dimensions also needs to be considered vs. performance of other batteries available.

October 2020 update.

A new Field Safety Notice (MMS-20-3887) has been issued by BD Ltd. relating to their own tests and a new battery has now been recommended for use. The **Duracell PLUS** 9-volt 6LR61 battery has shown to perform well in their test and is now the recommended battery (for T34:v2) going forward. Tests are ongoing and a decision is expected soon on their recommendation for a suitable battery for use in their latest version 3:T34 syringe driver.

Whether users move to this new style battery (and establish their internal ordering and procurement systems to match) or risk assess their current batteries and practice is for each institution to decide. The regulator in the UK (MHRA) is clear that this FSN is labelled as 'advisory' and not legal in law. However, a clear and concise risk assessment will be required to satisfy the advice in the Field Safety Notice and the recommendations made by the supplier.

NOTE:
If any 9 volt battery fails (i.e. low battery/end battery/power off) when used in a T34 syringe driver after just a few hours, then these should be retained for investigation: noting the batch number and any delivery information to help the investigation team focus their attention on possible corrective actions. In addition, the details about the syringe driver (v2 or v3) and any other supportive information should also be shared.

MHRA and Gov.Uk updates

1. Safety-critical alerts are changing at the MHRA

The MHRA will now issue all safety-critical alerts for medicines and medical devices that require action as ***National Patient Safety Alerts***

The Medicines and Healthcare products Regulatory Agency (MHRA) is changing the way it issues safety-critical alerts to healthcare providers.

From now on, all safety-critical alerts for medicines and medical devices that require action to be taken by healthcare organisations will be issued as National Patient Safety Alerts. These alerts follow criteria and a template agreed by the National Patient Safety Alerting Committee (NaPSAC).

This is to ensure that National Patient Safety alerts:

1. are only issued for safety-critical issues (those that have a risk of death or disability) that require organisations to act
2. explain risk clearly and effectively
3. have required actions that have been assessed for feasibility, safety, efficacy and cost-effectiveness
4. can be quickly recognised and actioned by senior personnel
5. have actions that are SMART (specific, measurable, achievable, realistic and timely)

Failure to take the actions required by any National Patient Safety Alert may lead to the Care Quality Commission (CQC) taking regulatory action in England.

All healthcare providers that currently receive medical device alerts and drug alerts should now ensure they subscribe to receive National Patient Safety Alerts.

In the short term, drug alerts and medicines safety communications that do not meet the NaPSAC criteria will continue to be issued using the current format and process while the MHRA consults with the health system and healthcare professionals to determine the best way for these to be issued going forward.

All healthcare providers that currently receive medical device alerts and drug alerts should now ensure they subscribe to receive National Patient Safety Alerts.

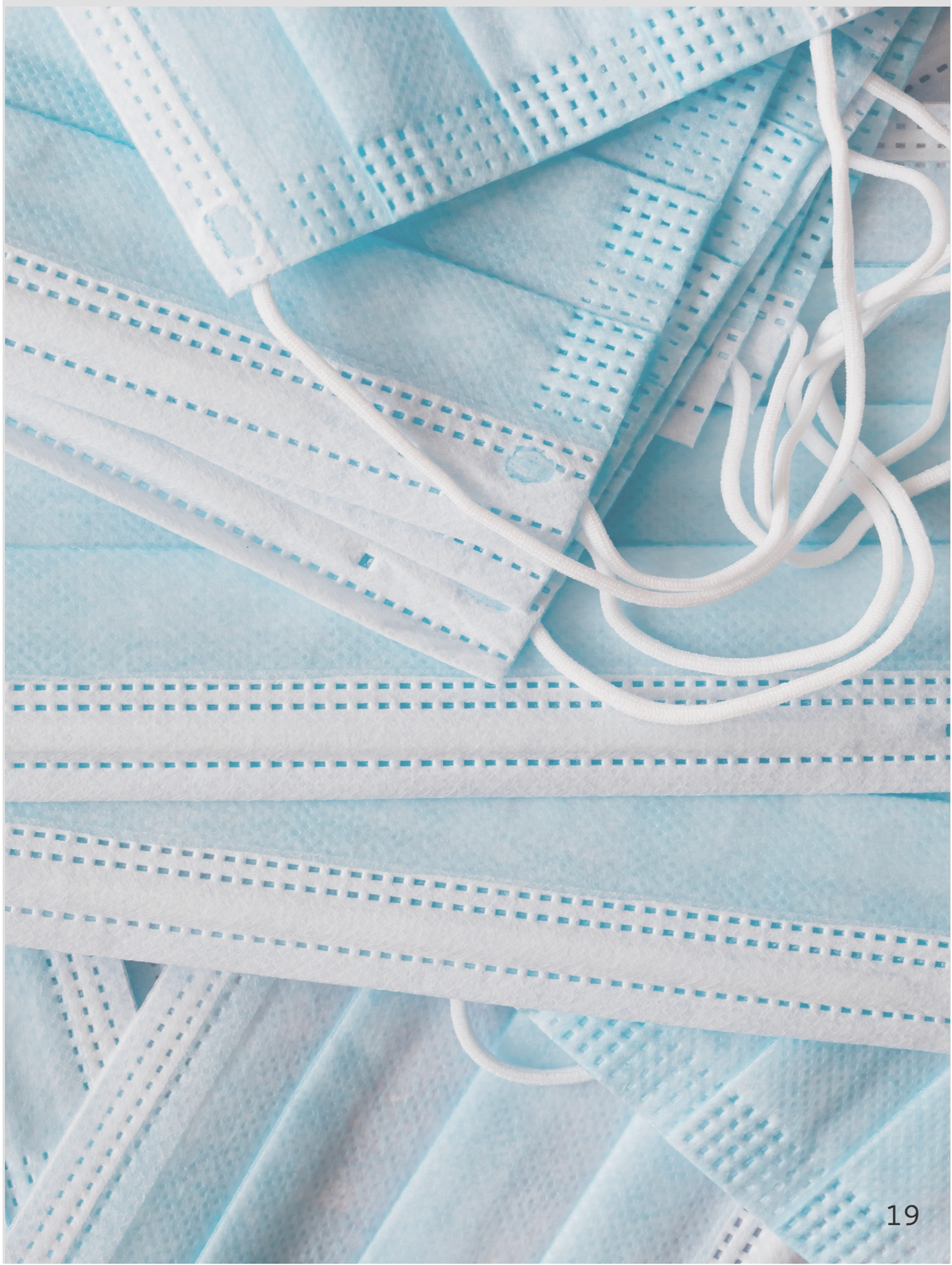
In the short term, drug alerts and medicines safety communications that do not meet the NaPSAC criteria will continue to be issued using the current format and process while the MHRA consults with the health system and healthcare professionals to determine the best way for these to be issued going forward.

Safety communications for medical devices that do not meet the NaPSAC criteria will change and these changes will be communicated in due course.

NaPSAC consists of representation from all organisations that issue safety information to the NHS. It was established to improve the effectiveness of safety-critical communications and to support providers to better implement the required actions to ensure patients are protected.

The MHRA is the second organisation to be accredited to issue these alerts, after NHS England and Improvement's National Patient Safety team.

For the full article and all links on National Patient Safety Alerts, please visit this link



2. Skin creams dried on fabric can lead to fire deaths. The MHRA reports.

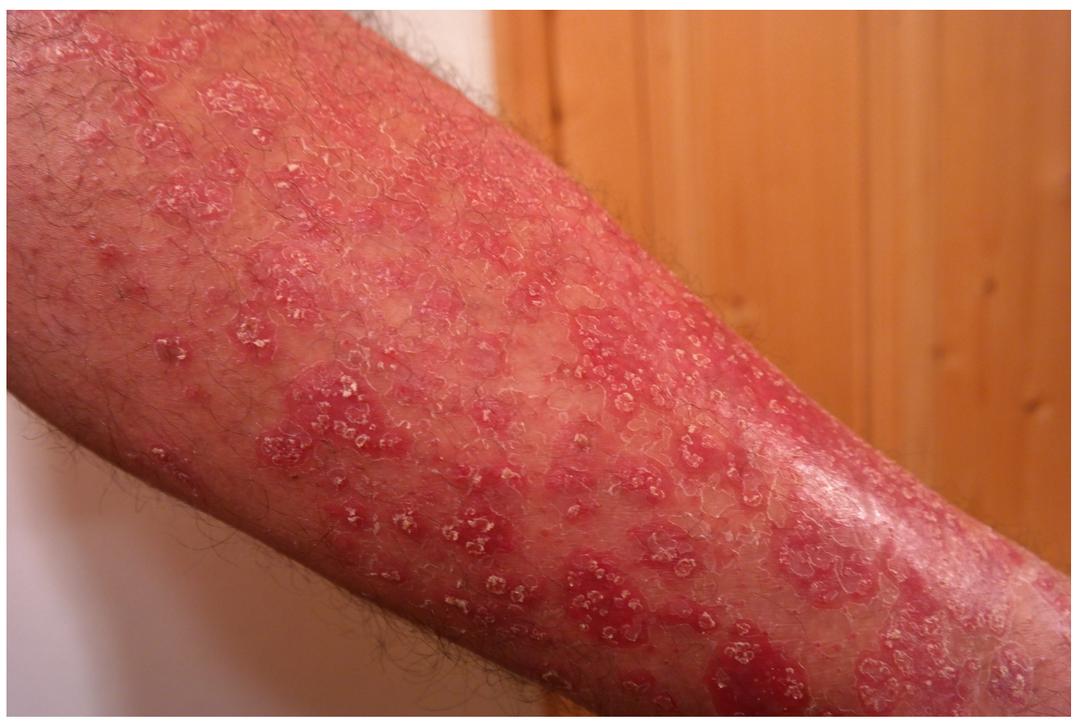
A new campaign to raise awareness of the fire risk and the precautions that need to be taken by users of skin creams has been launched

Some skin creams, when dried on to fabric, can create a highly flammable combination that can cause serious injury and death, the regulators warns. This follows research showing that the risk arises, even if the creams do not contain paraffin.

The Medicines and Healthcare products Regulatory Agency (MHRA) has partnered with the National Fire Chiefs Council (NFCC), Fire and Rescue Services and health charities in a new campaign to raise awareness of the fire risk and the precautions that need to be taken by users of skin creams.

Emollient skin creams are used by thousands of people every day to manage dry, itchy or scaly skin conditions such as eczema, psoriasis and ichthyosis. They are easily transferred from skin on to clothing and bedding. When fabric with dried-on cream comes into contact with a naked flame, the resulting fire burns quickly and intensely and can result in serious injury or death.

Since 2010, more than 50 deaths and serious injuries have been linked to the use of emollient skin creams.....



The risk increases with every application of the cream as it transfers, dries and builds up on the fabric. Some cream remains even when the items are washed, so it's important to minimise the risk in additional ways, such as removing long sleeved or loose clothing before cooking or using a safety lighter.

MHRA first took regulatory action on the issue in 2008, and since 2018 has recommended that labelling and product information for emollient products should include a warning about the fire hazard, with clear advice not to smoke or go near naked flames.

Since 2010, more than 50 deaths and serious injuries have been linked to the use of emollient skin creams. A review has shown that those most at risk tend to be over 60, smokers and have reduced mobility. The MHRA recommends anyone in this high-risk group, or their carers, should arrange a fire service assessment of their personal surroundings. They must exercise caution when close to naked flames or potential ignition sources (for example, lighting a cigarette).

Please see the full MHRA news report available via this link

3. One pharmacist's report helps safer use of inhalers in the UK

Reporting suspected side effects or incidents to the Yellow Card scheme supports the safe use of medical products for everyone

After a patient nearly choked when accidentally inhaling their lung medication capsule through the wrong part of their inhaler – Jazz, a concerned pharmacist, alerted the Medicines and Healthcare products Regulatory Agency (MHRA) of the potential risk.

Jazz, pharmacist and Yellow Card reporter, said:
I reported to Yellow Card because I thought if this happened to one person, it could happen to others, and I wanted to protect patient safety.

The MHRA did a detailed investigation and found there was potential for confusion when using the medicine and the device in combination. They then worked with the manufacturer to improve the safety information.

Now the products come with warnings about choking and clearer instructions on how to insert the capsule correctly into the device, including pictures that make it easy to understand.

The MHRA also alerted doctors, pharmacists and healthcare professionals across the UK about the safety risk.

It really goes to show that every piece of information is important and can make such a big difference to patient safety.

Mick Foy, Manager at the MHRA's Vigilance and Risk Management of Medicines Division, said:
Patient safety is at the heart of everything we do, and everyone has a role to play in the safe use of medicines.

The MHRA uses Yellow Card reports to strengthen our investigations and advice on how to use products safely to protect patients. Whether you've experienced a side effect, seen a faulty medical device, or observed a potential issue, your report to the Yellow Card scheme helps us take action to protect everyone.

Throughout the week of World Patient Safety Day, the MHRA is reminding the public to report safety concerns involving medicines and medical products using the Yellow Card scheme, and supports the focus of this year's World Patient Safety Day on healthcare worker safety. The MHRA commends the crucial role healthcare professionals play in reporting and flagging patient safety issues, including reporting through Yellow Card.

Anyone can use the Yellow Card scheme to report suspected side effects of medicines, incidents involving medical devices, and defective or fake medical products.

Reports can be made on the Yellow Card website, via the mobile app from the Google Play Store or Apple App Store, via freephone (0800 731 6789, 9am to 5pm Monday to Friday) or by reporting an issue to their healthcare team who can file a report on their behalf.

MHRA news reports and this article available via this link

4. Regulating medical devices from 1st January 2021

The UK has left the EU, and the transition period after Brexit comes to an end this year. What do you need to do to place a medical device on the Great Britain, Northern Ireland and European Union (EU) markets from 1 January 2021?

From 1 January 2021 the Medicines and Healthcare products Regulatory Agency (MHRA) will take on the responsibilities for the UK medical devices market that are currently undertaken through the EU system.

This on-line guidance provides information on how the UK system will operate, including for:

*** Getting your device certified**
*** Conformity marking your device**
*** Registering your device with the MHRA**

This guidance is divided into sections on the different rules that will apply in Great Britain, Northern Ireland and the EU. Great Britain is England, Wales and Scotland.

For Northern Ireland, different rules will apply to those in Great Britain after the transition period. For more information on the regulatory system for medical devices in Northern Ireland, please see 'Regulation of medical devices in Northern Ireland' This guidance does not cover other 'New Legislative Framework' products, which are subject to separate guidance.

The proposals outlined in this guidance notice will take effect through legislative changes that will be introduced later in 2020. They are still therefore subject to parliamentary approval.

This information is meant for guidance only. You should consider whether you need separate professional advice before making specific preparations. Speak to your solicitor or trade association if you are unsure which regulatory framework applies to your goods.

GOV.UK

Summary of key requirements for placing a device on the Great Britain market

From 1 January 2021, there will be a number of changes to how medical devices are placed on the market in Great Britain. These are:

CE marking will continue to be used and recognised until 30 June 2023. Certificates issued by European Economic Area (EEA)-based Notified Bodies will continue to be valid for the Great Britain market until 30 June 2023.

A new route to market and product marking will be available for manufacturers wishing to place a device on the Great Britain market from 1 January 2021.

From 1 January 2021, all medical devices and in vitro diagnostic medical devices (IVDs) placed on the UK market will need to be registered with the MHRA. There will be a grace period for registering:

4 months for Class IIIs and Class IIb implantables, and all active implantable medical devices

8 months for other Class IIb and all Class IIa devices

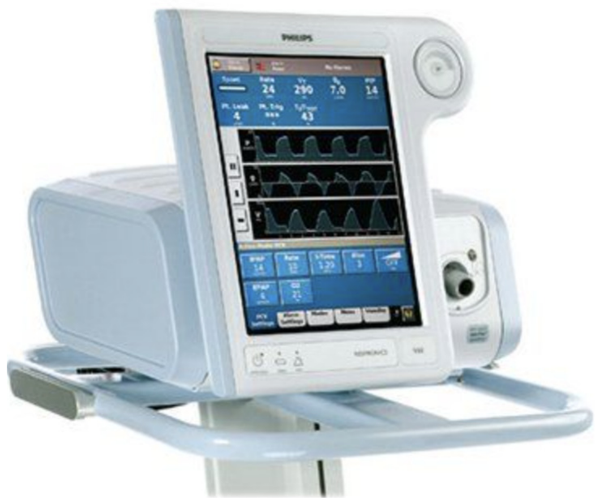
12 months for Class I devices

The above 12-month grace period will not apply to manufacturers of Class I devices and general IVDs that are currently required to register with the MHRA.

If you are a manufacturer based outside the UK and wish to place a device on the UK market, you will need to establish a UK Responsible Person who will take responsibility for the product in the UK. Further detail on the UK Responsible Person is set out on the Gov.uk website

Medical Device News

1. Philips Respironics V60 ventilator – actions to be taken to avoid potential unexpected shutdown leading to complete loss of ventilation.



There are 2 ways in which this shutdown can occur:

1. The first will sound a warning to alert the user that the machine is shutting down. This will let the user know they need to switch to an alternative source of ventilation.

2.The second failure mode will cause the device to shut down with no warning to the user.

Checkout the link above for the full details of the alert

National Patient Safety Alert

MHRA

Philips Respironics V60 ventilator – actions to be taken to avoid potential unexpected shutdown leading to complete loss of ventilation.

Date of Issue:	23-Sep-20	Reference No:	NatPSA/2020/007/MHRA

This alert is for action by: All hospital trusts and other healthcare providers using the affected ventilators.

This is a safety critical and complex National Patient Safety Alert. Implementation should be coordinated by an executive leader (or equivalent role in organisations without executive boards). Supported by their clinical lead for critical care and heads of procurement.

Explanation of identified safety issue:

In March 2020 Philips Health Systems released an FSN concerning a number of V60 ventilators. This FSN concerned a hardware fault in the device, which can result in an unexpected shutdown.

There are 2 ways in which this shutdown can occur:

The first will sound a warning to alert the user that the machine is shutting down. This will let the user know they need to switch to an alternative source of ventilation. There is a risk that the patient will be unventilated while this second source of ventilation is prepared.

The second failure mode will cause the device to shut down with no warning to the user. If a device fails in use and does not alarm, the patient will not be adequately ventilated and there is a potential risk of brain damage or death, depending on how long it takes clinicians to become aware of the situation and respond.

Actions required

Primary actions (1-7) to be completed by 7 October 2020

1.Identify and locate affected devices in your organisation.

2.Identify alternative ventilators available on site.

3.If no suitable alternative is available, and capacity is an issue currently or expected imminently, follow protocol for resource shortage escalation set out by your local governance.

4.Train all relevant staff on alternative ventilators and ensure training records are up to date.

5.When actions 1–4 are complete, remove affected V60s from use and quarantine until repaired by the manufacturer.

6.Place the alternative devices into service in place of the affected V60s

2. Safety critical alerts are changing at the MHRA

The Medicines and Healthcare products Regulatory Agency (MHRA) is now an accredited issuer of National Patient Safety Alerts. This means there will be some changes to what you receive from CAS as set out in this link. There are also some changes to the website and a reminder to organisations to register out of hours email addresses with us if you have them.

MHRA

National Patient Safety Alert

3. Foreign body aspiration can occur if loose items are unintentionally introduced into the airway during intubation, ventilation or advanced airway management. This can lead to partial or complete airway blockage or obstruction, and if the cause is not suspected, it can be fatal.

National Patient Safety Alert

NHS

Foreign body aspiration during intubation, advanced airway management or ventilation

Date of issue:	1 September 2020	Reference no:	NatPSA/2020/006/NHSPS

This alert is for action by: All acute, specialist and ambulance trusts, independent providers of NHS-funded surgical or critical care, and mental health trusts with electro-convulsive therapy (ECT) suites.

This is a safety critical and complex National Patient Safety Alert. Implementation should be co-ordinated by an executive lead (or equivalent role in organisations without executive boards) and supported by clinical leaders in anaesthetics and resuscitation.

Explanation of identified safety issue:

Loose items unintentionally introduced into the airway during intubation, ventilation or advanced airway management (known as foreign body aspiration [FBA]) can lead to partial or complete airway blockage or obstruction. If the cause is not suspected, this can be fatal.[1] Complications following FBA may not be immediately recognised due to sedation and anaesthesia and may be postoperatively misdiagnosed as asthma, chronic obstructive pulmonary disease (COPD), or stridor.[2]

An example incident reads:
"patient presented in ED following repeated GP attendance, 4 months post anaesthesia with worsening respiratory symptoms. Symptoms resolved after removal of ECG backing plastic [from the respiratory tract]."

Actions required

Actions to be completed by 1 June 2021

1. Amend current purchasing,[A] and introduce ongoing controls on purchasing, to ensure ECG/ECT electrodes have either large sheet backing for multiple electrodes or fully coloured or patterned individual backing in:
   a) all areas where intubation or advanced airway management regularly occurs (including theatres, emergency departments, ECT suites, and emergency ambulances).[B]
   b) all resuscitation trolleys/emergency response kits containing intubation or advanced airway equipment and containing ECG electrodes.[B]

2. Amend current purchasing,[A] and introduce

The most common types of foreign bodies identified in incident reports were transparent backing plastic from electrocardiogram (ECG) electrodes and plastic caps of unclear origin. The alert asks providers to reduce this risk by purchasing safer products without loose and small transparent parts. Providers are also asked to develop or amend local protocols to ensure pre-prepared intubation and advanced airway management devices are covered or protected until use; and that the ends of reusable breathing system hoses are closed between patient cases.

4. Philips sterilizable defibrillator internal paddles (specific models) – may fail to deliver therapy if pre-use checks are not followed;

Check all paddles between each usage, in accordance with the instructions for use, to confirm they are safe and ready for use. The checks include mechanical check, visual inspection, functional check and continuity check.

• If the device fails one or more of these checks, remove it from service and replace the paddles.

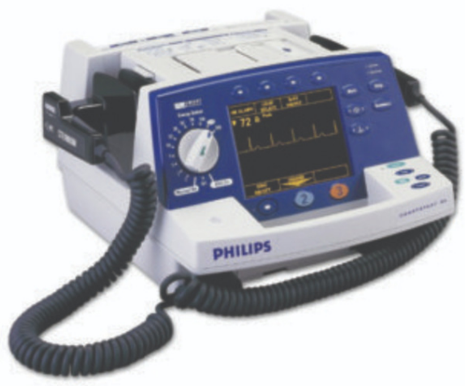
Philips sterilizable defibrillator internal paddles (specific models) – may fail to deliver therapy if pre-use checks are not followed (MDA/2020/022)

Manufactured by Philips – defibrillator internal paddles may wear over time and might fail to deliver therapy, so it is important to do routine operational checks between each usage.

Medical Device News

5. Philips HeartStart XL Defibrillator/Monitor – therapy selector switch may fail.

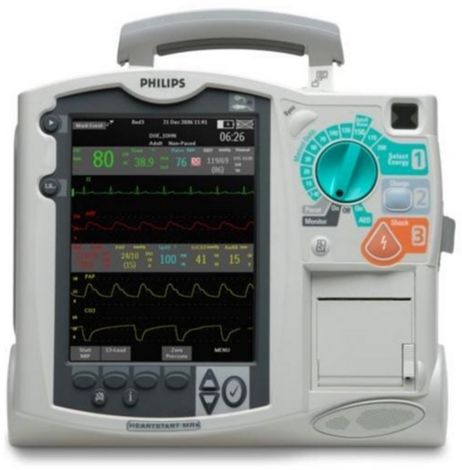
Manufactured by Philips – the rotary therapy selector switch may fail resulting in unexpected device behaviours which could lead to a delay or failure in delivering therapy.



6. Philips HeartStart MRx Monitor/Defibrillators

may fail to deliver therapy without alerting the user to a fault in the event of internal damage.

The Philips HeartStart MRx Monitor/Defibrillator MRx may fail to identify a fault and alert the user in the event of internal damage suffered during a drop or due to severe mechanical shock.



7. Risk of harm caused by the interruption of high flow nasal oxygen (HFNO) to babies,

children and adults in acute respiratory failure without hypercapnia during patient transfer.

This National Patient Safety Alert should be treated as a high priority as it may relate to care provided for Covid-19 patients. Some HFNO delivery devices have a transport mode, but most require mains power and will not deliver oxygen during transfer unless attached to a compatible uninterruptible power supply (UPS) device.

Providers are asked to add clear labels to these devices to make staff aware that even brief interruptions to mains power supply could lead to respiratory and cardiac arrest; and that HFNO in any emergency department or short stay unit must not be started without a plan for how to transfer the patient onwards.

Where a UPS is used, action must be taken on the storage and maintenance of UPS devices to ensure they are ready for use and staff know where to locate them.

8. Blood control safety cannula & needle thoracostomy for tension pneumothorax

The alert relates to the risk of harm from using 'blood control (closed system) intravenous cannulas' to decompress a pneumothorax, as they cannot be used for this purpose without additional equipment.

The alerts asks providers to provide and add labels to 'standard' cannulas to indicate they should be used for tension pneumothorax; and labels on cupboards, drawers etc. used to store 'closed system' cannulas to indicate they must not be used for tension pneumothorax.

National Patient Safety Alert

NHS

Blood control safety cannula & needle thoracostomy for tension pneumothorax

Date of issue:	02 April 2020	Reference no:	NatPSA/2020/003/NHSPS

This alert is for action by: Acute and specialist hospital providers (adult and children's) and ambulance trusts.

This is a safety critical and complex National Patient Safety Alert. Implementation should be co-ordinated by an executive lead (or equivalent role in organisations without executive boards) and supported by clinical leaders in paramedic response, emergency medicine, respiratory medicine, resuscitation, and theatres.

Explanation of identified safety issue:

Tension pneumothorax can occur following chest trauma, respiratory disease and infection, or during resuscitation requiring invasive or non-invasive ventilation. It is a life-threatening condition resulting from a collapsed lung when air trapped in the pleural cavity compromises cardiopulmonary function.[1,2]

Immediate temporary decompression is required to prevent cardiac arrest.[1,2,3,4,5] This is commonly done by inserting a needle and cannula, usually used for intravenous access, through the chest wall into the pleural cavity (needle thoracostomy) – see Note 1. The needle is withdrawn, and the cannula left in place to allow the trapped air to flow out.

New blood control (closed system) intravenous cannulas are increasingly used in the NHS; at least 130 trusts bought a total of three million of them in the last year (see Note 2 for suppliers). They look very similar to both traditional and standard safety cannula (with needle guard or shield) but have an extra integral septum which closes when the needle is withdrawn and stops free flow in or out of the cannula. Flow is only possible once an intravenous line or Luer-lock syringe is attached to the hub, which opens the septum

Actions required

Actions to be completed by 09/04/2020

1. Identify if your organisation purchases blood control (closed system) safety cannula
   - See Note 2.
2. If it does, for all clinical areas and teams likely to undertake needle thoracostomy, including ambulances, emergency departments (EDs), intensive care units, respiratory units or any unit providing invasive or non-invasive ventilation, including units for COVID-19 patients:
   a) Provide standard safety cannulas* for needle thoracostomy in appropriate trays, drawers, pockets, within emergency workspaces, emergency kit bags, and resuscitation trolleys, and clearly label *'For use in tension pneumothorax'.*
   b) Attach visible warnings/notices to cupboards, drawers, etc in these emergency workspaces, emergency kit bags, and resuscitation trolleys where blood control (closed system) cannula are stored stating: *'Do **not** use for tension pneumothorax'*, with a direction to where

9.Introducing patient safety specialists

Joan Russell, Head of Patient Safety Policy and Partnerships, and Wayne Robson, Head of Patient Safety Cross System Development, describe plans for designating and networking 'patient safety specialists'.

Giving everyone in the NHS a foundation level understanding of patient safety is critical, but we also need experts to lead on safety in their own organisations. Feedback from the consultation strongly supported the development of a network of patient safety specialists in local systems. These specialists should be recognised as key leaders within the safety system, visible to their organisations and others, able to support their organisations' safety work. In some ways the concept is similar to designating someone a Caldicott Guardian, Director of Infection Prevention and Control or Freedom to Speak Up Guardian. But in contrast to these designations we want the introduction of the patient safety specialist concept to develop existing people and roles rather than create new posts.

Medical Device News

10. Hillrom launches series of free educational webinars for medical device industry.

Medical device provider Hillrom has launched a new digital symposium called Completing the Picture Digital Festival, which aims to inspire, educate and share best practice for the healthcare technology and connected care sectors.

The free event builds on Hillrom's established Completing the Picture symposium, which has provided best practice and educational insight for the medical device industry for the past 18 years. Due to the COVID-19 pandemic, however, the symposium cannot physically go ahead this year. Instead, Hillrom has launched the Completing the Picture Digital Festival in its place this year, which will see the popular event take place online for free.

11. NICE proposes simplifying how medicines and medical devices are selected for evaluation.

NICE National Institute for Health and Care Excellence

As part of the work underway to review the methods and processes NICE uses to develop guidance on medicines, medical devices and diagnostics, NICE has launched a public consultation on proposals for changing how it selects the topics it will develop guidance on. The proposals clarify the criteria that would see a device or diagnostic selected for NICE guidance development. In particular, these include where the costs and impacts are expected to be significantly cost incurring or cost saving, or there is uncertainty about the likely cost or the impact it would have on the healthcare system.

12. GTMA and the UK medical manufacturing supply chain

The GTMA formed a cluster of member companies interested in working in the medical sector in March 2020, anticipating the need for an immediate response to the COVID-19 pandemic and ongoing medium/long-term growth in the global requirement for medical devices and other manufacture.

The UK is the third largest medical device market in Europe, and the sixth biggest globally. From an estimated value of £7 billion in 2015 it now exceeds £12 billion, reported by market analysts.

Initially 40 companies joined this initiative, but the number has grown steadily to over 90. Early activity of this cluster was in response to the demand generated by the UK ventilator call and specifically to provide a supply chain to make CPAP devices form UCL. Other projects have followed, and we expect growth of interest in this sector to continue. The GTMA are continuing to build up intelligence and connections into the UK medical manufacturing supply chain. For more information follow the link to the GTMA website

13. BSI update on the new UKCA and future UK regulation of medical devices and in vitro diagnostics.

CE UKCA

BSI would like to share with you a critical announcement regarding the new UK Conformity Assessed (UKCA) mark for medical devices. The Medicines and Healthcare products Regulatory Agency (MHRA) published new guidance on GOV.UK, which sets out how medical devices and IVDs will be regulated after the transition period with the EU has ended (from 1 January 2021). We are currently working through the details and preparing questions for the MHRA to gain clarity in several areas; at this time, we would like to highlight the publication and urge you to familiarise yourself the details.

MDET

The official journal of NAMDET
Medical Device Education and Training

Temperature Measurement in Hospitals to detect COVID-19

Professor Mark Tooley FREng
Specialist Scientific Advisor to the CSO team in NHS England, and also Clinical Digital Advisor to the West of England Academic Health Science Network. Founder member of the NBTMG, the national body temperature measurement group.

Dr Keith Ison, retired medical physicist Biography: Wide involvement in medical physics and clinical engineering, spent last 15 years of career as head of medical physics at Guy's and St Thomas' Hospital in London. Former IPEM President. Working with CSO England Office and Clinical Engineering Networks on COVID responses, networking and leadership.

Background

Measuring an individual's body temperature is not straightforward. How well do existing techniques cope when either screening for fever or when taking routine clinical observations?

Screening

One symptom of COVID-19 is an elevated body temperature (over 37.8°C). Fever has been reported in between 45% and 87% of patients with mild to moderate infections and in up to 99% of patients with severe disease.

However, a significant proportion of cases do not have a raised body temperature and some individuals may be taking anti-fever medication (1-4). Also, during the incubation phase of COVID-19, which can last between 2 and 14 days, someone may not show any symptoms at all but still be infectious (5-6). For these reasons, Public Health England (PHE) does not recommend the use of temperature checks to screen for possible COVID-19 cases at transport hubs, workplaces or in other non-clinical settings. Such checks identify less than 25% of infections at most (7).

Similarly, guidance for care homes advises the use of daily monitoring for COVID-19 symptoms amongst residents and staff, but does not include temperature screening of staff on arrival at work (8), because of the potential to provide false reassurance that an individual is not infected with COVID-19. Screening an individual's temperature also creates a duty-of-care for that individual (9).

Imprecise measurement

Non-contact infrared forehead thermometers (NCIFT) and Thermal Scanning Cameras have both been used as screening methods to try to identify individuals with fever, but often these devices are derived from industrial ones, and were never designed for clinical use. Other more clinically accepted methods of estimating core body temperature, such as oral and tympanic thermometers, are more accurate but less convenient. All non-contact infrared thermometry techniques – whether forehead thermometers, thermal imaging cameras or tympanic thermometers – pick up infrared radiation from the body and use an algorithm to convert this into an estimate of surface temperature. How well their displayed temperature correlates with an individual's core body temperature depends on multiple factors, including the environment in which they are used, where they are pointing and the distance between the thermometer and the forehead.

An IEC note describes ways to improve validity in thermal camera measurements (10) but expert comment is that an acceptable standard is rarely, if ever, achieved in practice (11).

Minimum requirements are that subjects must be screened individually, with their face unobstructed by masks, spectacles, headwear or cosmetics, and the environment must be carefully controlled to avoid temperature fluctuations.

A recent review reported that NCIFT is not accurate enough to replace other devices such as oral or tympanic thermometers (12). However, studies have shown poor correlation between temperatures obtained using forehead thermometers and those measured by tympanic and oral methods (13-14). Also, to limit errors, handheld infrared thermometers should be held less than 2 metres away from the person being measured, requiring PPE to be worn. Temperature screening using more accepted methods such as oral or tympanic thermometry may act as an additional precaution, but should not be used in the absence of other measures.

MDET

The official journal of NAMDET
Medical Device Education and Training

Use of non-contact temperature measurement for routine clinical observations

A recent shortage of tympanic thermometers has prompted the suggestion that NCIFTs be used instead, perhaps with a fall back option of carrying out a second measurement if any clinically-significant discrepancy is detected. This idea has a number of serious flaws, not least being the practical difficulty of finding and cross-calibrating different types of device.

The best practical options for routine temperature measurement remain oral and tympanic thermometers. Even though these two types of measurement can also have errors, the published evidence suggests that their accuracy is substantially better in practice than that of forehead measurement devices.

References

1. Michelen M, Jones N, Stavropoulou C. 2020. In patients of COVID-19, what are the symptoms and clinical features of mild and moderate cases. Centre for Evidence-Based Medicine. https://www.cebm.net/covid-19/in-patients-of-covid-19-what-are-the-symptoms-and-clinical-features-of-mild-and-moderate-case

2. Zhou F, Yu T, Du R, Fan G, Liu Y, et al. 2020. Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study. The Lancet 395:1054-62

3. Wang D, Hu B, Hu C, Zhu F, Liu X, et al. 2020. Clinical Characteristics of 138 Hospitalized Patients with 2019 Novel Coronavirus–Infected Pneumonia in Wuhan, China. JAMA 323:1061-9

4. Aronoff DM, Neilson EG. 2001. Antipyretics: mechanisms of action and clinical use in fever suppression. Am J Med 111:304-15

5. Yu P, Zhu J, Zhang Z, Han Y. 2020. A Familial Cluster of Infection Associated With the 2019 Novel Coronavirus Indicating Possible Person-to-Person Transmission During the Incubation Period. J Infect Dis 221:1757-61

6. Ogoina D. 2011. Fever, fever patterns and diseases called 'fever' – A review. Journal of Infection and Public Health 4:108-24

7. European Centre for Disease Control. 2014. Infection prevention and control measures for Ebola virus disease. 12/10/2014

8. DHSC P, NHS, CQC, CARE. 2020. Admission and Care of Residents in a Care Home during COVID-19.

References cont...

9. Zanfir-Fortuna G. 2020. Thermal Imaging as Pandemic Exit Strategy: Limitations, Use Cases and Privacy Implications. https://fpf.org/2020/06/03/thermal-imaging-as-pandemic-exit-strategy-limitations-use-cases-and-privacy-implications/

10. IEC. 2017. IEC 80601-2-59:2017 Medical electrical equipment — Part 2-59: Particular requirements for the basic safety and essential performance of screening thermographs for human febrile temperature screening

11. Howell K, Mercer J, Smith R. 2020. Infrared thermography for mass fever screening: repeating the mistakes of the past? Thermology International 30:5-6

12. Bolton S, Latimer E, Clark D. 2020. Temporal artery and non-contact infra-red thermometers: is there sufficient evidence to support their use in secondary care? Global Clinical Engineering Journal 2:8-16

13. Crawford, M., "Use of temporal artery or forehead thermometers is misleading", British Medical Journal, 351:h6125, 2015

14. Fletcher, T., Whittam, A., Simpson, R., Machin, G., "Comparison of non-contact infrared skin thermometers", J. Met, Eng & Technol. 2018 https://doi.org/10.1080/03091902.2017.1409818

MDET

The official journal of NAMDET
Medical Device Education and Training

Global CE Day 2020

What is Global CE Day?

Global Clinical Engineering Day was initiated as a celebration of the important contributions that clinical engineering professionals are making every day around the world.

By celebrating together we recognise contributions while promoting recognition for our profession and our roles in improving patient care outcomes.

Since 2016, the Clinical Engineering community has been celebrating Global CE Day and 2020 is no different. The pressures of COVID-19 have raised the importance of the CE community and workforce and 21st October sees UK focus on this branch of healthcare science and an opportunity for all Clinical Engineering departments to promote and advertise the fantastic work they do, and share their contributions over that past 12 months.

How to spread the word.

Want to spread the message about what we do daily?

If hosting an event is not possible, you can collaborate with Global CE Day by creating and sharing content that reflects the value of our profession.

You can write a paper, a blog entry, create a post for social media, an infographic, an image or even sit down with a healthcare stakeholder and interview them as a testimonial; showing how Clinical Engineers work with a healthcare stakeholder (director, manager, etc.) can make a huge difference! You can share this content on social media channels such as twitter, linkedin, facebook and youtube.

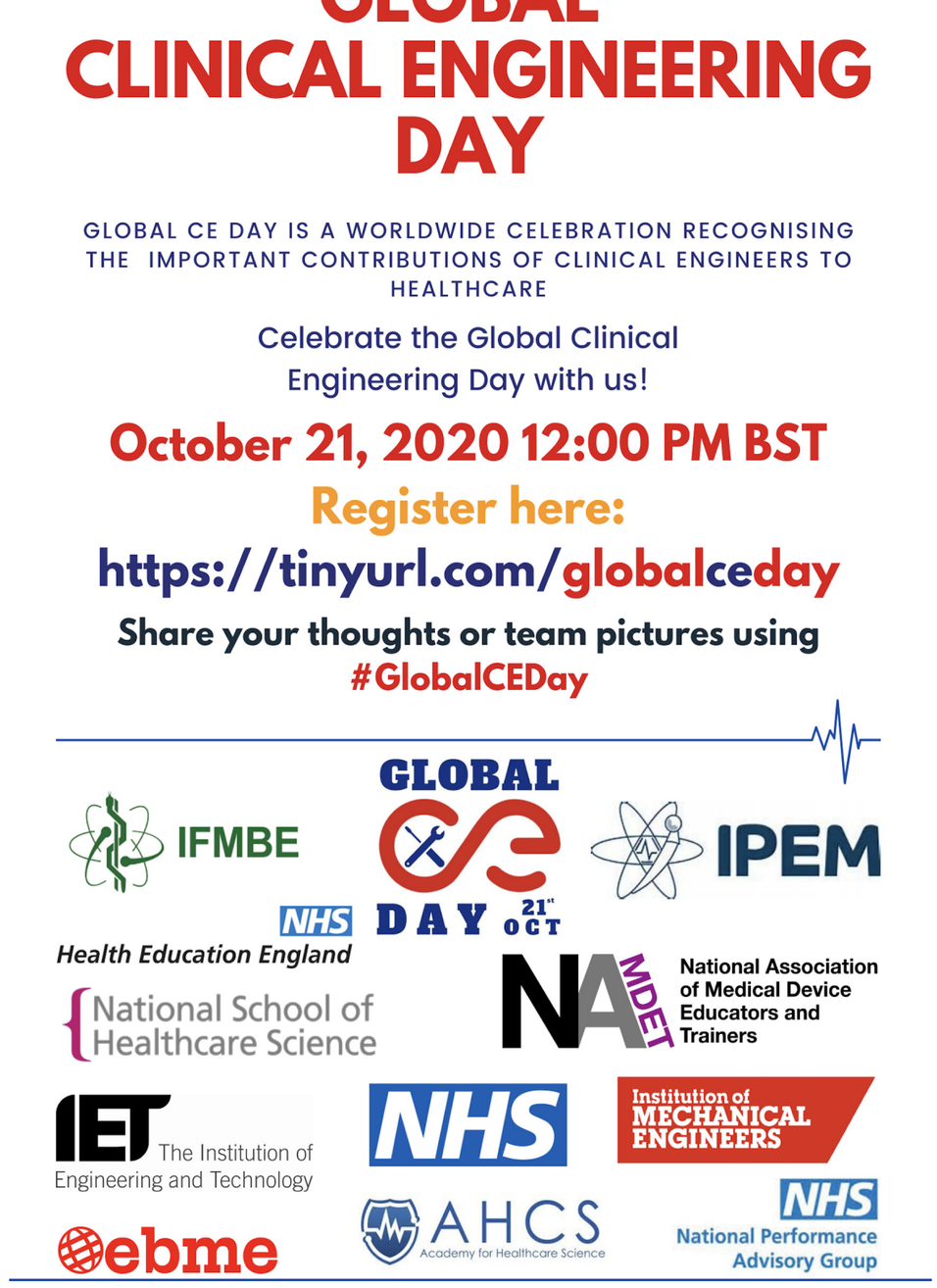
Why not invite your Chief Executive, Medical Director and Director of Therapies or Head of Science to visit your department (social distance of course) or say a few words on a blog or video message.

The UK contribution will be shared nationally on 21st October and this year we are linking in on the Sunday (October 25th) where the rest of the globe will be presenting a 24 hour celebration from all across the planet.

You can join the UK event for free by registering via the following link.

link to Global CE day

Join us in celebrating the Global Clinical Engineering Day. This fifth Global Clinical Engineering Day is a worldwide celebration recognising the important contributions of clinical engineers to healthcare. The theme this year is COVID-19.



Join in Celebrating the fifth

Global Clinical Engineering Day!

October 21, 2020

Global CE Day is a worldwide celebration recognising the important contributions of clinical engineers to healthcare

Suggested Activities

Celebrate: by sharing your team pictures using **#GlobalCEDay** on Twitter, LinkedIn, Facebook. **Network** across the globe!

Promote: the vital work you do & the contribution to patient care on local and public websites and social media.

Share: the innovation and new ways of working as a result of Covid-19 and into the recovery phase

Encourage: your Communications Department to spread the word on the intranet and social media

Organise: local awards, Invite Board members

Visit: IPEM website for info & resources

Get Involved/Question?

Basit Abdul

CE Division (IFMBE) Coordinator, England

Chair Global CE Day working group, UK

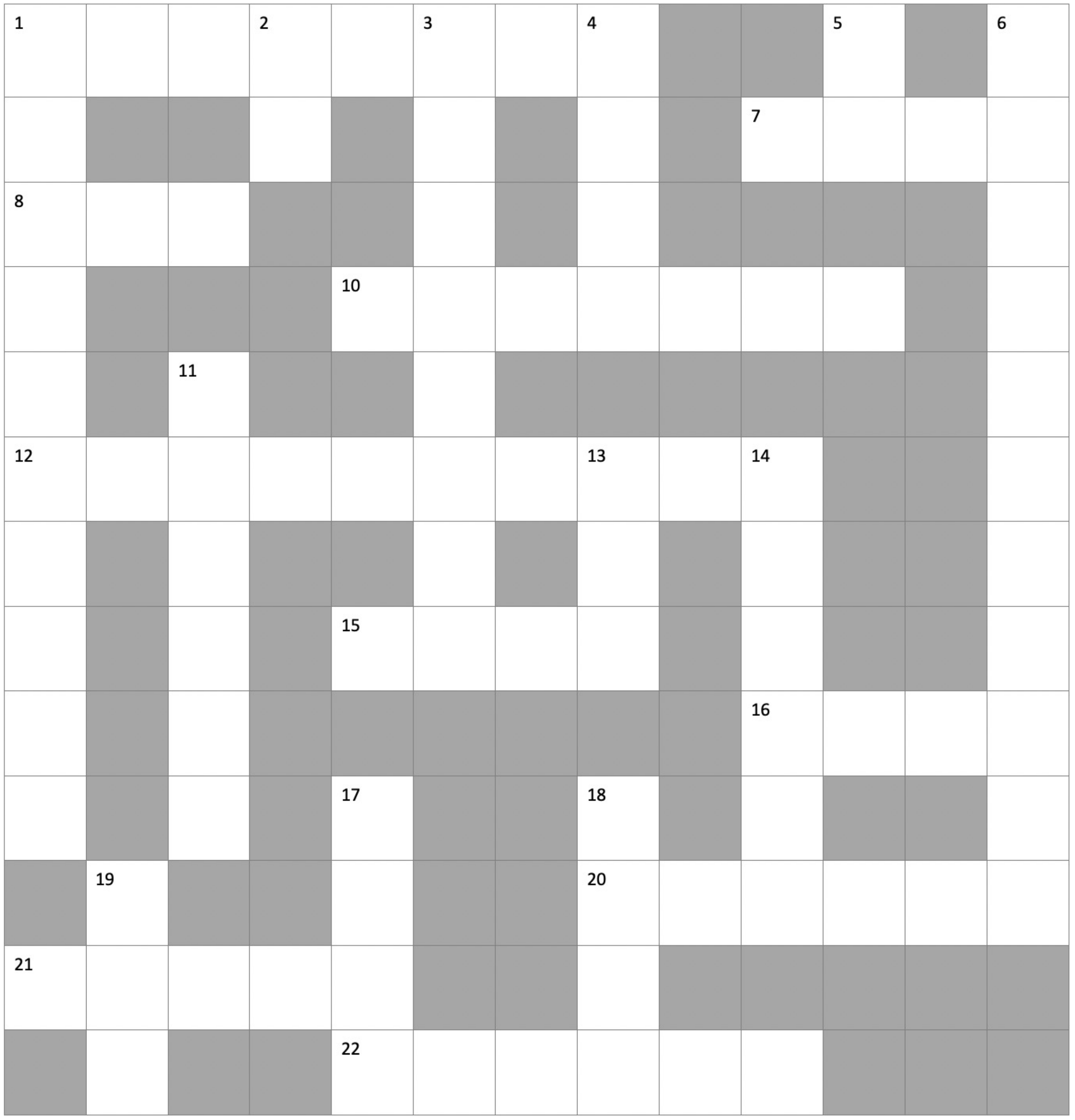
basit.abdul@england.nhs.uk

GLOBAL CE DAY 21st OCT

National Association of
Medical Device Educators
and Trainers

www.namdet.org

Medical Devices Crossword



Many thanks to Claire Johnson MSc, BSc (Hons), RGN, Governance Lead Medicines & Medical Devices, MHRA Medical Device Safety Officer. Nuffield Health for sharing this resource. Answers will be posted on the NAMDET website

Across:

1. BER is short for Beyond ..... Repair (8)

7. An implant that is placed into the eye, for example (4)

8. Can be 3 or 12 lead and monitors heart rhythm and electrical activity (3)

10. Essential to ensure safe operating standard for any medical device that uses electricity - See 1 down ..... Safety ..... (7)

12. MHRA stands for Medicines & Healthcare products ..... (10) See 11 down

15. A group of individuals working together to achieve their goal (4)

16. A .... Indemnity Form is required when you trial or borrow a piece of equipment (4)

20. Not a never, an ..... event (6)

21. ..... Safety Notice

22. This reporting mechanism is vital in helping the MHRA monitor the safety of all healthcare products in the UK to ensure they are acceptably safe for patients and those that use them. Yellow (see 14 down) ..... (6)

Down:

1. See 10 across (10)

2. .. (see 19 down) ™ devices to comply with NS/PSA/RE/2017/004 alert (2)

3. Risk level which can be used for devices whose failure or misuse would have a significant impact on patient care or temporary adverse health consequences, but would be unlikely to cause direct serious harm (8)

4. The amount of money needed to buy, do or make something (4)

5. .. marking is the current certification mark that indicates conformity with health, safety and environmental protection standards for products sold within the European Economic Area (EEA) (2)

6. Examples of these could be competency or risk (11)

11. See 12 across (6)

13. Acronym for Original Equipment Manufacturer (3)

14. See 22 across (4)

17. Compatible .... are required to ensure safe & effective defibrillation (4)

18. Safe medical device management support safe patient .... (4)

19. See 2 down (3)

Thank you from all of us at BD UK & Ireland

1030 Eskdale Rd, Winnersh Triangle, Wokingham, Berkshire, RG41 5TS

bd.com/en-uk