

# Medical Device Training

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# When I started (1986)





## **MDA response to Recommendation 11**

*If an alarm system fails on monitoring equipment, an untoward incident report should be filed and equipment serviced.*

- *‘devices should only be set up or operated by users who are **competent and confident** in their use’*
- *‘education and training are essential to ensure that users of devices with alarms have appropriate **knowledge and skill** to optimise their use of the device...’*
- *‘training should be **readily available** to all those using devices, including those who move into new care areas’*

**Clothier Report: 1995**

- ‘patient received a fatal dose because the apparatus had been **incorrectly programmed** by a member of the Anaesthetic Medical Staff’
- ‘This individual had in fact been **offered training** on this pump but had **declined**’
- ‘It is clearly the responsibility of the NHS Trust (i.e. the Employer), to ensure that all **Medical Staff** who come into contact with medical devices at the workplace are **fully trained and competent** in their use’ The word of a new doctor arriving is insufficient’



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## BBC NEWS

You are in: UK: Wales  
Friday, 9 March, 2001, 13:29 GMT

### Hospital to pay for fatal drugs error



Dr Basnyet gave 10 times the correct dose of painkiller  
A hospital trust has been ordered to pay almost £7,000 after a doctor it employed gave a patient a lethal overdose.

Carmarthenshire NHS Trust was fined £3,000 at Llanelli Magistrates Court and ordered to pay nearly £4,000 in costs after admitting failing to train a doctor in the use of medical equipment.

Anaesthetist Kala Basnyet wrongly programmed a machine dispensing painkiller - and consequently gave 10 times the correct amount of painkiller to a patient at Prince Philip Hospital, Llanelli.

**Relative Diane Taylor**  
"At least justice has been seen to be done"  
real 56k

**BBC Wales's Ashleigh Crowler**  
"In a statement the hospital apologised for the error"  
real 56k

# 1,400 killed and injured by faulty medical

ALMOST 1,400 patients were killed or seriously injured by faulty medical equipment last year – a rise of more than 100 per cent in just three years.

By Rachel Ellis

some being born faulty equipment for, nurses, in factories. But first in England will also be written to avoid in complaints.

Law firm Dr Susanne Lodge, Clinical Director at the MHRA, said: "More and more medical devices are being used at home for a number of reasons – people are being discharged from hospital earlier and more people are using medical equipment at home."

According to a report by the Medicines Division, the number of deaths and injuries from faulty medical equipment in England and Wales rose to 1,397 in 2014, up from 1,000 in 2011.

This compares with 440 serious injuries in 2011, but experts fear the number of deaths and injuries could rise to 1,600 products by 2015.

# Healthy baby died after he was put in 'broken' incubator

A 'PERFECT' baby boy died after he was placed in a broken incubator, his grieving parents claimed yesterday.

By Rebecca Evans and Sophie Holland

Way in Swansea's Singleton Hospital before being sent home. A week after the birth the mother and baby were re-admitted because she was suffering from a chest infection. She was being treated by doctors while the baby was put in the incubator. He died a week later.

The baby's mother yesterday said she was taking legal action against the hospital, as she believes a "long list of errors" led to his death. The mother of three believes that not enough has been done to ensure the same mistake are not repeated. She said: "There were more than 20 errors on the part of the hospital."



Unfortunate: A baby sleeps in a hospital incubator

**BBC NEWS ENGLAND**

10 March 2011 Last updated at 21:13

## Patient death caused by 'unapproved' medical technique

An unauthorised modification made to equipment used during keyhole knee surgery contributed to a man's death, a jury has ruled.

Father-of-three Luigi Beccuore, 49, from Warwickshire, agreed to take part in a stem-cell clinical trial.

He died in an operation in 2009 when a surgeon used an unauthorised modification to equipment used during keyhole knee surgery.



**BBC NEWS**

Open BBC News in video and audio

Last Updated: Wednesday, 20 December 2006, 15:20 GMT

E-mail this to a friend Portable version

## Baby died after injection error

A six-week-old boy died after air was mistakenly injected into his bloodstream during a routine operation, a Swansea inquest has heard.



Aaron Hayward, 6, died in April 2002 at the city's Singleton Hospital.

The inquest judge said the error was caused by a mistake by a nurse.

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## Pensioner's care at Wrexham hospital went 'drastically wrong'

© 10 December 2015 | News



Alan Walker with his widow, Irene

The family of a pensioner who died at a north Wales hospital said they were told something had gone "drastically wrong", an inquest has heard.

Alan Walker, 81, from Leeswood, near Mold in Flintshire, died at Wrexham Maelor Hospital in January 2014 after being admitted with an infected wound.



Trained and competent to use? <sup>6</sup>

## History

- Scotland (over 20 years ago)
- Wales (approx. 15)
- Some others..... (none)
- Suppliers; Reps and Clinical Trainers (external)
- Embedded trainers (contracted)
- Clinical Engineers, MEMS, EBME, Nurses and HCPs
- NAMDET (370 members: as of Sept 2016)

## Statutory Training

- Usually required by **law**
- Training on the basis of specific **legislation**
- Employer to ensure their staff have **the knowledge** to maintain a healthy and safe working environment for themselves and their colleagues

(Health and Safety at Work Act 1974; Management of Health and Safety at Work Regulations 1999)

See: RCN guidelines available at :

<https://www.rcn.org.uk/get-help/rcn-advice/training-statutory-and-mandatory>



## Mandatory Training

- **Compulsory training** that is determined essential by an organisation for the safe and efficient delivery of services.
- It is designed to reduce organisational **risks** and comply with local/national **policies & government guidelines.**



## Mandatory training might include:

- *blood transfusion processes*
- *incident reporting*
- *hand hygiene*
- *infection prevention*
- *personal protective equipment*
- *medicines handling and management*
- **medical devices**

See: RCN guidelines available at :

<https://www.rcn.org.uk/get-help/rcn-advice/training-statutory-and-mandatory>

**Provision & Use of Work Equipment Regulations**  
requires that **equipment provided for use at work** is:

- Suitable ; safe ; maintained ; inspected
- Used only by people who have received **adequate information, instruction and training**

PUWER 1998. <http://www.hse.gov.uk/work-equipment-machinery/puwer.htm>

- The **use of work equipment** is also very widely interpreted and means any activity involving work equipment and includes starting, stopping, programming, setting, transporting, repairing, modifying, maintaining, servicing and cleaning

PUWER 1998. <http://www.hse.gov.uk/work-equipment-machinery/puwer.htm>

## **HASAWA** (Health and Safety at Work Act) 1974. Section 2 (General Duties)

- (c) the provision of such information, instruction, **training** and supervision as is necessary to ensure, so far as is reasonably practicable, the health and safety at work of his employees;

<http://www.hse.gov.uk/legislation/hswa.htm>

## MHRA Managing Medical Devices Bulletin ; April 2015

### Section 6: Recommendations for Training

- **Policy** on training regarding the safe use of medical devices.
- All users supported in **attending** training.
- Trained in **adverse incident** reporting.
- Trained in the **safe operation** of medical devices.
- End users are given **appropriate training**
- **Contractors** are adequately trained and appropriately qualified.
- Independent contractors using medical devices have appropriate **risk management** systems in place.

[https://www.gov.uk/government/uploads/system/uploads/attachment\\_data/file/421028/Managing\\_medical\\_devices\\_-\\_Apr\\_2015.pdf](https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/421028/Managing_medical_devices_-_Apr_2015.pdf)



## Medical Device Trainers

- Job descriptions /scope
- Risk assessments
- Frequency of use vs. competency
- Workbooks
- Competency checklists
- Self assessments

National approval??

Transferable??

Doctors??

## National Association of Medical Device Educators and Trainers



### our objectives



**status & standing**  
Raise the status and standing of Medical Device Trainers and Educators



**mutual support**  
Provide a forum for mutual support and assistance between members



**represent**  
Represent the consensus view and opinions of members at regional and national level



**inform & improve**  
Inform and improve national policy and the regulatory landscape by communicating NAMDET member positions on issues of importance



**contribute**  
Positively contribute to reducing adverse medical device incidents

our 5 year strategy

## UK regions and groups

371 members

[www.namdet.org](http://www.namdet.org)

1,888 sessions

12,810 page views

(last 90 days)





Training for Safety  
**MDDL**  
MEDICAL DEVICE DRIVING LICENCE

Home Who We Are Contact eLearning Register Login

**Welcome & Thank You**

Congratulations and thank you for visiting the Medical Device Driving Licence website now owned and managed by NAMDET. We want to help you to provide certificated proof of your competence in using medical devices for your Personal Development Plan (PDP) and Continuing Professional Development (CPD). Successful completion of each session will generate a certificate for download to put into your own files and add a category to your own Licence. Certificates will then be stored within the secure database on this website.

[We have provided a short 8 minute presentation of the background to the Medical device Driving Licence. Just Click on the screen above to view this.](#)

To register for the course please [click here](#).

If you have already registered [please login](#).

**The Process**

1. User registers with the Medical Device Driving Licence (MDDL).
2. User is then issued a personalised unique login.
3. User undertakes the Devices in Practice module followed by a short assessment. If successful this is recorded on their licence.
4. User undertakes other modules as appropriate, along with their assessments. Successfully completed assessments are recorded on the licence.
5. Users can access their MDDL records and print a copy for their personal records and as evidence for their personal development plan (PDP), for their continued professional development (CPD) and to give to a prospective employer.
6. Where appropriate certain modules will expire and have to be renewed.
7. As the scheme develops employers define appropriate modules to be held by individual employees and applicants.
8. An employer will be able to demonstrate that employees have all completed medical device training to an appropriate level.
9. The employee will have ownership of their MDDL and it will travel with them from Trust to Trust. This will help to save time and costs on unnecessary retraining.

**NAMDET**

2016; NAMDET took over management and ownership of **MDDL**

- Established new Education Review Panel
- Test and update all eLearning modules and content
- Review national training needs and add new modules



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**Devices e-learning modules**

We have developed a number of modules that provide training to support the driving licence assessments. These modules are available to use for free on our website and cover topics related to our work and where we know there are reported incidents.

Click below to access the available modules

- [Devices In Practice](#)
- [Basic Observations](#)
- [Defibrillators](#)
- [Electrosurgery](#)
- [Anaesthetic Machines](#)
- [The Operating Table](#)



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**Basic observations**

This educational package has been produced as a helpful background and reminder on basic patient observations in the clinical workplace. The package covers:

- taking a pulse
- checking blood pressure
- measuring respiratory rate
- taking a temperature
- the Glasgow Coma Scale
- basic ECG monitoring
- urine output
- drain losses
- record keeping
- 'track and trigger' systems

The module is intended to be a reminder of best practice and will provide users with a better understanding of why procedures need to be followed, the value of record keeping and the possible pitfalls with cutting corners.

The module is aimed at all medical, nursing and allied healthcare professionals working in a healthcare setting. It is also for all community care workers in nursing and private healthcare settings and all FY1 and FY2 doctors and as a helpful reminder to more experienced doctors.

The module runs for approximately 45 minutes. You may require more time to re-read and review specific areas and to undertake the attached questions.

[Start the basic observations e-learning module](#)



## Training starts at Procurement

### Specification

- Human usability
- Who will use it and what are their needs
- Why is the device required
- Training programme built into the specification

### The selection

- Criteria assess training requirements
- Criteria assess training offered

MEC 2014 john.amoore@aapct.scot.nhs.uk



# Training is not a substitute

Paul T. Lee; ABMU Health Board  
MDSO Webex; Sept 7<sup>th</sup> 2016

Medical Devices  
'easy to use'  
'fail safe'  
'team effort'



