



HEALTH ESTATES

creating healing environments



DEVICE BULLETIN
DB(NI)2008/02
website only

ADVERSE INCIDENT
REPORTS 2007

Northern Ireland
Adverse Incident Centre (NIAIC)

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1 Introduction

This Device Bulletin provides an overview of medical device and estates related adverse incident reports received by the Northern Ireland Adverse Incident Centre (NIAIC) and Medical Device/Equipment Alerts (MDEAs) issued by NIAIC in 2007.

Comprehensive guidance on reporting adverse incidents and disseminating NIAIC safety guidance is given in DB(NI)2008/01 published in April 2008.

A list of NIAIC publications is provided in this report however please refer to our website (www.dhsspsni.gov.uk/niaic) for details of all our publications, which includes lists of Medical Device/Equipment Alerts and other guidance publications.

1.1 Background to NIAIC

A centre for providing safety guidance relating to medical devices, non-medical equipment, plant and building elements to the Health and Social Services in Northern Ireland has been established for over 30 years with adverse incident reports recorded, investigated and safety guidance issued since 1992. We are interested in any adverse event involving a medical device, non-medical equipment, plant or building element that may have implications for service-users, staff and others - not just when something has failed.

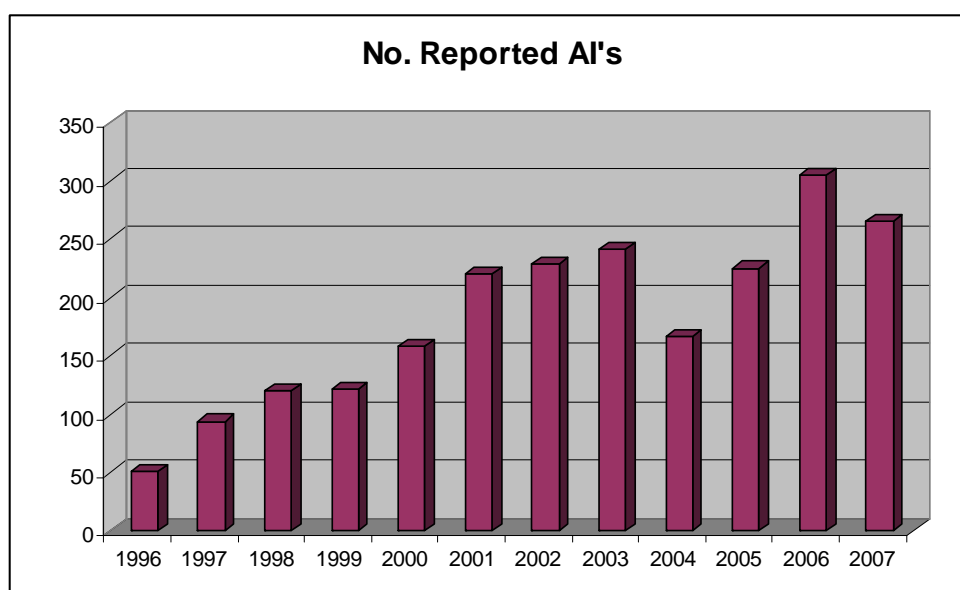
NIAIC has established collaborative working arrangements with other UK centers responsible for medical devices and estates safety. For medical device safety this is with the Medicines and Healthcare products Regulatory Agency in England (MHRA) and Incident Reporting and Investigation Centre, Health Facilities Scotland. For estates safety issues this is with NHS Estates & Facilities in England. For estates safety issues in Scotland, this is the responsibility of the Incident Reporting and Investigation Centre, Health Facilities Scotland.

The NIAIC is operated on behalf of the Department of Health Social Services and Public Safety by Health Estates Agency.

1.2 Adverse Incident Reports to NIAIC - 2007

In 2007 the total number of reported Adverse Incidents was 265, while this was a reduction on the previous year the overall trend in the volume of reports continues to show an upward rise. NIAIC has attributed the small drop in reported incidents this year to the continued change in the management structure within the new HSC Trusts caused by the review of Public Administration.

Whilst there is still an upward trend in the reporting of incidents, this does not imply that the health & social care environment is a more dangerous place, only that with a more open culture staff are more likely to report untoward events.



Description of reports	2007	
	Number of reports	%
Medical Device related reports	241	91%
Estates related reports	24	9%

In 2007, the Medicines and Healthcare products Regulatory Agency (MHRA) received 8,634 adverse incident reports (this includes medical device related reports received by NIAIC). Comparing the number of reports received by MHRA with the number reported to NIAIC in the same period, the number of reports to NIAIC reflected the level of reporting which would be expected for health and social services in Northern Ireland.

In 2007, MHRA medical device specialists completed 100 investigations of adverse incidents reported as involving a fatality. In 70 of these they were able to conclude that there was no established link between the fatality and the device(s) involved in the incidents.

However, the MHRA and NIAIC consider that there remains significant underreporting of medical device associated adverse incidents across the UK.

As a result of investigations by NIAIC and the reporting of outcomes to MHRA, on a UK wide basis this helped MHRA to take the following action:

- 113 Medical Device/Equipment Alerts (MDEAs) were issued
- 86 notifications were shared with Competent Authorities in EU member states
- 674 manufacturer's field safety corrective actions and 92 other manufacturer's field actions were undertaken
- 206 cases requiring the provision of advice on safer device use or improved staff training were identified
- 397 manufacturer undertakings to improve designs, manufacturing processes and quality systems.

1.3 National Patient Safety Agency (NPSA)

The NPSA's anonymised National Reporting and Learning System has been implemented across the NHS although agreement to capture HSC data has yet to be finalised. This system allows reporting of all failures, mistakes, errors and near misses, with the aim of ensuring that lessons for patient safety are both learned and shared throughout the health service.

Working relationships have yet to be agreed with NIAIC and NPSA, similar to those between NPSA and MHRA, to ensure that NIAIC works alongside the NPSA to ensure mutually beneficial development of our reporting systems, with the common goal of maximising our effectiveness in preventing harm arising from the use of medical devices and estates systems.

In the meantime, although incidents involving the use of a medical device that are reported to the NPSA may be shared with the MHRA, the anonymous and incomplete reporting allowed under the NPSA system hampers rapid action by the MHRA. Therefore the NPSA has agreed to encourage reporting of all medical device incidents directly to the MHRA and we envisage that this position will be reflected in Northern Ireland with NIAIC.

1.4 Safety Alert Broadcast System (SABS)

SABS(NI) is an electronic system developed by the Northern Ireland Adverse Incident Centre and is the primary method of distributing MDEAs to the healthcare environment across Northern Ireland. It incorporates a feedback mechanism to record acknowledgement of receipt and action taken by trusts following the release of alerts. The HSC SABS liaison officer ensures onward distribution of the alert as appropriate; updates and feedback on action taken is logged on the SABS website.

The NIAIC should be informed about a change of SABS contact on Tel :028 9052 3868 or E-mail: niaic@dhsspsni.gov.uk

NB. A similar SABS system is operated by the Department of Health, in England to administer safety information to all NHS Trusts and Primary Care Trusts in England & Wales and should not be confused with the system which operates within Northern Ireland. Since SABS went live in Jan 2008 **all** MDEAs have been distributed to the registered SABS liaison officer in all HSC Trusts. This allows the SABS liaison officers the opportunity to decide the relevance of the alert to their organisation.

We strongly suggest that all MDEAs should be checked for relevance within your organisation before onward distribution. A suggested distribution list is included in each MDEA.

1.5 NIAIC Medical Device Liaison Officers

HSC Trusts should all have designated a medical device liaison officer (MDLO). These MDLOs encourage and train staff and users to report adverse incidents. In many organisations the MDLO and the SABS contact is the same person carrying out all functions of reporting, disseminating and feedback. In organisations where this is not the case, both contacts should work closely together.

Local procedures for all MDLOs should ensure that:

- the appointed MDLO within HSC Trusts has the necessary authority to take responsibility for the reporting of medical device related adverse incidents
- all medical device related incidents are reported to the NIAIC
- appointed MDLO personally reports all medical device adverse incidents to the NIAIC **OR** other reporters within the trust provide the MDLO with copies of their reports to the NIAIC, and all subsequent related correspondence
- that the NIAIC is informed of changes to MDLO contact details as they occur
- a deputy NIAIC Liaison Officer is appointed and can carry out all duties allocated to the MDLO
- regular reviews are undertaken to ensure that local procedures are effective and are being followed

1.6 MHRA and other devolved administrations

The MHRA is the competent authority (CA) for the United Kingdom for medical device regulation. Ongoing arrangements between MHRA, Scotland and Northern Ireland have allowed delegation of certain report processing and incident investigation responsibilities to Scotland (through the Incident Reporting and Investigation Centre (IRIC)) and Northern Ireland (through the NIAIC).

NIAIC does however refer all medical device related incidents reports and the outcomes of the NIAIC investigations to the MHRA in order to ensure that all medical device related safety information

is considered on a UK wide basis. We also have an agreed working relationship with our colleagues in IRIC in Scotland for the exchange of safety information in respect to medical device and estates safety and with DH Estates & Facilities for estates related safety issues.

1.7 Field Safety Notices and Field Safety Corrective Actions

Field Safety Notices (FSNs) are used by Medical Device manufacturers to inform their customers about Field Safety Corrective Actions (FSCAs) taken by them (the manufacturer) to reduce the risk of death or serious injury from adverse incidents. These are usually, but not exclusively, prompted by investigations of adverse incidents reported by medical device users, and relate particularly to those MHRA/NIAIC and/or manufacturer investigations which have revealed the need to:

- change the design of the device
- remove or replace devices in the field
- make device modifications in the field or amend instructions for use, etc.

The EU Medical Devices Directives legally oblige manufacturers not only to carry out such corrective actions, but also to alert the National Competent Authority (in the UK this is the MHRA) about any corrective actions affecting their products that have been distributed within the UK.

The MHRA risk assesses and investigates each FSCA and determines whether the manufacturer's proposed action is both relevant to the UK and sufficient to protect UK public health. On most occasions it is, and the MHRA will then monitor progress to ensure that it is completed. This approach helps to minimise the need to issue Medical Device Alerts.

The FSN associated with a manufacturer's FSCA are now routinely placed on the MHRA website for information. NIAIC liaison officers are not expected to treat FSNs in the same way as Medical Device/Equipment Alerts.

Action or direct feedback will only be required when an associated Medical Device/Equipment Alert has been issued or an FSN has been received directly from the manufacturer or supplier.

MHRA routinely update the status of FSCAs on their website. This provides greater transparency of our ongoing assessment of the FSCA and associated FSNs. The status updates show whether the:

- FSCA is currently being assessed and that further advice may be issued later
- FSCA has been assessed and the MHRA does not intend to issue further advice

- FSCA has been assessed and the MHRA has issued further advice

It is possible to register on the MHRA website to receive e-mailed updates whenever the FSN/FSCA web pages are updated.

The FSN facilities were developed in close collaboration with national medical device and SABS liaison officers and also support wider initiatives to improve transparency of the European medical device vigilance system. Similar facilities have been introduced on the websites of several other national Competent Authorities, including those in Germany, France, and Switzerland under the banner of the Global Harmonization Task Force

Further information on the work of GHTF can be found on their website (www.ghtf.org).

1.8 European and global co-operation

This year the European Commission published revised and updated '*Guidelines on a medical devices vigilance system*' for medical device manufacturers (MEDDEV 2.12-1 rev 5). The MHRA provided significant input to meetings of the European vigilance experts that developed the document.

The guidance now covers:

- Manufacturers' Field Safety Corrective Actions (recalls)
- the content and structure of manufacturers' Field Safety Notices
- improved co-ordination and exchange of data by EU competent authorities
- the role of the European Commission and Notified Bodies within the vigilance system
- electronic exchange of vigilance data.

The guidance is also of direct relevance to any healthcare establishments that may be involved in the manufacture of medical devices.

The new document is more comprehensive, clearer and easier to use, and harmonises well with the wider, international Global Harmonisation Task Force vigilance guidance.

Since late 2007 the MHRA has been hosting a number of conferences and workshops to promote this revised guidance to UK based medical device manufacturers.

1.9 Haemovigilance

The MHRA's Adverse Incident Centre's haemovigilance team continues to manage SABRE, the haemovigilance incident online reporting system. During 2007 the team completed the first annual summary report exercise. In June 2008 this will be taken a stage further with the submission of an overall UK summary report to the EU Commission.

Enhancement of SABRE was concluded in mid-2007 with the implementation of the Workspace Folder Manager and search facilities. Further development of the SHOT interface is still planned. This remains subject to specification and direct contracting by SHOT.

The haemovigilance team continue to work closely with SHOT, NPSA, the MHRA's own Blood Consultative Committee (BCC), and the BCC's Adverse Events sub-Committee. Future plans include expansion of the haemovigilance team and the creation of an Expert Group to support the team's routine review of reported events and reactions.

2 Reporting and investigation of adverse incidents

2.1 Reporting procedures

The NIAIC regularly produces comprehensive background and procedural guidance on reporting medical device and estates related adverse incidents. The first Medical Device/Equipment Alert and the first Device Bulletin of the year (MDEA(NI)2008/01 and DB(NI)2008/01) give full guidance on how to report adverse incidents and disseminating MDEAs. This MDEA and other safety related documents are available on our website (www.dhsspsni.gov.uk/niaic).

Additional advice on reporting adverse incidents may be obtained directly from NIAIC, either by e-mail: niaic@dhsspsni.gov.uk or by telephone: 028 90523868.

The NIAIC liaison officers appointed locally within HSC organisations will be able to offer specific advice on local procedures for adverse incident reporting and on local risk management systems. These local procedures should ensure that all relevant local staff, including contractors, are kept informed, suitably trained, and regularly reminded of their responsibilities with regard to adverse incident reporting and of any relevant and specific local arrangements.

The NIAIC positively encourages reporters to use our preferred reporting method, reports via e-mail, the AI form is available through the NIAIC website, although paper forms are still readily accepted by post or fax.

Depending on the nature and location of the incident, **other organisations** may also need to be involved following an adverse incident including the reporting of Serious Adverse Incidents to the DHSSPS in accordance with HSS(SQS) 34/07, HSS(SQS) 19/07, HSS (PPM) 02/06 and HSS (PPM) 05/05, the Health and Safety Executive Northern Ireland, or the medicines and blood safety sectors of the MHRA.

2.2 Devices retained or submitted for examination

All items that have been involved in incidents should be quarantined. Until NIAIC has been given the opportunity to carry out an investigation, the devices should not be discarded, repaired or returned to the manufacturer.

More detailed information and advice is given in DB(NI)2008/01. This includes dealing with the manufacturer and, when appropriate, returning devices, dealing with devices required for continued use, and decontamination.

Devices that have been involved in an incident should not be submitted to the NIAIC unless specifically requested.

Despite clear procedural advice being given, some devices are being submitted to NIAIC without having been suitably cleaned prior to decontamination. As a consequence the decontamination process will have been ineffective.

If the NIAIC doubt the decontamination status of a submitted device, arrangements have to be made for further decontamination prior to commencement of any investigation. This causes unnecessary delay in the investigation process.

2.3 Defining an adverse incident – medical device related

An adverse incident is an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of device users (including patients) or other persons. For example:

- a patient, user, carer or professional is injured as a result of a medical device failure or its misuse
- a patient's treatment is interrupted or compromised by a medical device failure
- misdiagnosis due to medical device failure leads to inappropriate treatment
- a patient's health deteriorates due to medical device failure.

Causes of incidents involving devices may include:

- design or manufacture problems
- inadequate servicing and maintenance
- inappropriate local modifications
- unsuitable storage and use conditions
- selection of the incorrect device for the purpose
- inappropriate management procedures
- poor user instructions or training (which may result in incorrect user practice).

Conditions of use may also give rise to adverse incidents:

- environmental conditions (e.g. electromagnetic interference)
- location (e.g. devices designed for hospitals may not be suitable for a community or ambulance setting).

The occurrence of an adverse incident may identify the **potential** for harm, even though **actual** harm has been averted by the timely intervention of healthcare providers or good fortune. The NIAIC is concerned that users should report all incidents, regardless of whether actual harm has or has not been caused.

There is also a distinction between *direct* and *indirect harm*. Indirect harm may be caused by a device which does not normally come into contact with patients. For example, a malfunctioning in vitro diagnostic device such as an automated analyser may lead to delayed or inappropriate treatment of a patient, thus causing indirect harm. These incidents should also be reported.

2.4 Reasons for reporting adverse incidents

The NIAIC is concerned with preventing the occurrence of adverse incidents, not with assigning blame or liability. Our aim is to investigate incidents carefully, objectively and in an open manner and, through this, to prevent similar incidents occurring elsewhere.

No medical device should ever be considered 100% safe. Constant effort is therefore required to reduce both the rate at which adverse incidents occur and the severity of the outcome. Reporting adverse incidents to the NIAIC and onward to the MHRA provides valuable information that may be directly responsible for preventing similar incidents from happening again.

The information provided by device users and manufacturers helps the MHRA to build up a picture of what is happening with medical devices across the UK. This is supplemented by reports from around the world. All this information is regularly reviewed to identify trends and, where appropriate, early action is taken on specific problems.

Experience suggests that although user error may be the cause, or may contribute to the cause, of many incidents, there are often underlying reasons. These may relate to device management and maintenance, or to the adequacy of training for users.

The NIAIC and the MHRA therefore welcome receipt of all incident reports, even where user error may already have been identified as the likely cause. A one-off incident in one health or social care establishment, when combined with information on several others, may identify the need for focussed awareness training or for the amendment of a manufacturer's instructions for use.

The MHRA and the NIAIC may choose to act in different ways in order to prevent occurrence or recurrence of incidents. This may be through:

- initiating enforcement measures
- monitoring action taken by manufacturers to make devices safe or to remove them from the market
- issuing national warnings and recommendations for action to health and social care professionals
- informing relevant authorities in other EU member states and, where appropriate, the Global Harmonisation Task

Force members, so that they can each consider their own need for action.

2.5 Recording and investigating incident reports

In most cases, adverse incident report details will have been recorded on our database within one or two working days of receipt of the incident report. This is followed by a full **risk assessment**. For the most serious incidents (e.g. those involving a death or serious injury), these processes can be completed within hours.

Each risk assessment weighs up the implications of the incident for the safety of patients, healthcare workers and others. This includes an assessment of the severity of the actual or potential injury caused, and the likelihood of recurrence. It is this assessment that determines the level of incident investigation to be conducted.

2.6 Investigation levels

'In depth' investigations will usually follow reports of incidents that have led to **death or serious injury/deterioration in health (or the potential for such)**.

'In depth' investigations are led by the NIAIC, who may ask for a MHRA medical device specialist to take the investigation forwards. Such investigations may involve:

- contact with the device user and manufacturer
- a visit to the site of the incident
- testing of the device involved (either by an independent test house or by the manufacturer).

It is these investigations which typically lead to the NIAIC or the MHRA issuing a Medical Device/Equipment Alert or Medical Device Alert in the case of the MHRA.

'Standard' investigations will usually follow incidents where there is a **minor injury or no injury** (and that had a low potential for more serious injury).

Generally, these incidents are investigated most effectively by the manufacturer of the device. The manufacturer is provided with information about the incident, the location and the device involved. Although the manufacturer has responsibility for resolving the incident, NIAIC will monitor progress and critically review the manufacturer's investigation and report.

There are also adverse incident reports where no immediate action beyond the creation of the database record, acknowledgement of receipt, and an initial risk assessment were considered necessary. These were cases where the situation had already been resolved,

either locally or by the manufacturer. These are categorised as **'information only'** incidents.

Other incident reports may be recorded as **'knowns'**. These are reports that relate to existing investigations of the same particular problem with a particular type of device.

The data gleaned from the 'information only' and 'known' categories, coupled with the incident and investigation records retained in the active and surveillance databases that comprise the NIAIC and the MHRA systems, help NIAIC and MHRA to maintain an up-to-date picture of the various device types and failure modes.

At all stages of all investigations, the available adverse incident report information is subject to regular **review**. This process of reviewing all investigations enables NIAIC to re-assess the assigned level of the investigation and to determine what, if any, additional or changed action is required.

2.7 Maintaining contact with the reporter

Immediately after the risk assessment has been completed, the NIAIC administration team will ensure that the incident reporter receives a formal communication acknowledging receipt of the report and confirming the unique incident reference number that has been assigned. That acknowledgement is also accompanied by a short information note for the reporter that summarises and explains our adverse incident procedures.

After this initial acknowledgement, reporters are routinely kept informed of the progress of the incident investigation and, at the end of an investigation, the reporter is provided with a summary of the incident investigation conclusions.

Wider contact is also welcome – reporters are always free to contact the NIAIC with any general or specific enquiries and comments.

2.8 Medical Device/Equipment Alerts

Medical Device/Equipment Alerts (MDEAs) are the NIAIC's prime means of communicating safety information to HSC organisations and the wider health and social care community. MDEAs can either be generated as a result of local adverse incident investigation, through national incident investigation by bodies in the other UK administrations or through other information received by the NIAIC that may have implications for the safety of service-users, staff or others.

As a result of information received from the NIAIC, a MHRA investigation or other information is obtained by the MHRA that identifies a medical device related safety issue requiring safety

information to be issued; the MHRA may consider taking action by the issue of a Medical Device Alert (MDA) to the NHS in England. The MHRA consults all devolved administrations concerning the issue and content of draft MDAs, allowing the NIAIC (and the other devolved administrations) to take parallel action if required. In Northern Ireland this is by the targeted issue of equivalent MDEAs to the HPSS and wider health and social care community that provides local information on what action to take and appropriate local contact points if required.

Prior to 2003, titles for these alerts included Safety Notice, Hazard Notice, Device Alert and Pacemaker Technical Notes and a number of these are still in force and available on our website.

MDEAs are distributed by the NIAIC to the HSC for direct action and wider health and social care sectors for onward transmission to relevant healthcare professionals.

MDEAs show clearly on the front page: the level of urgency, the medical device or estates system involved, the action required, a summary of the problem, and who is affected by it. Each Alert is assigned one or more of the following level of urgency categories:

- **Immediate Action**
Used in cases of actual death or serious injury, or when death or serious injury would have occurred, but for fortuitous circumstances or the timely intervention of staff or a carer;
 - And where the medical device, non-medical equipment, plant or building item is or likely to be implicated,
 - And where the recipient is expected to take immediate action on the advice.
- **Action**
Used where the recipient is expected to take action on the advice, and where it is necessary to repeat warnings on long standing problems, or to support or follow-up manufacturers' field modifications.
- **Update**
Used when we wish to update the recipient about previously reported incidents or series of incidents, possibly on a topical or device/estates basis, and where further follow-up safety information is judged to be beneficial.
- **Information Request**
Used to alert recipients about a specific issue that may become a problem and where we are requesting feedback. They may contain a form and/or a specific e-mail or website address for ease of returning information.

The MDEA is issued to all SABS liaison officers and HSC Chief Executives (for information). The SABS liaison officer is then

responsible for ensuring distribution of the MDEA within their organisation.

All MDEAs are placed on the NIAIC website and the SABS website. Health and social care professionals are strongly advised to regularly check the website for new safety information.

2.9 The NIAIC in a Northern Ireland Context

Local Issues, Local Action

Should an adverse incident report, received by NIAIC, identify a safety issue requiring possible safety information, the MHRA is informed to determine the national position of adverse events concerning the medical device. However, **should the MHRA consider that national action is not required** but NIAIC consider that a MDEA is appropriate to safeguard the health of HSC service-users or staff, the NIAIC will consult with professional colleagues in Health Estates and DHSSPS on the proposed content of the NIAIC generated MDEA, finalise its content following consultation and issue appropriately. The same will apply to Estates issues except the DH Estates and Facilities will be consulted.

Examples of recent Alerts that would fall into this category include: -

- **MDEA(NI)2004/34: Flexible Endoscopes.**
This Alert was issued following a number of reported incidences of inadequate endoscope decontamination in HSS Trusts in 2004. The Alert recommended extensive action covering the entire area of endoscope use and decontamination and was used as a template of good practice when the Hine Review team examined this area.
- **MDEA(NI)2004/53: Flexible Endoscopes – update to MDEA(NI)2004/34**
This Alert was issued to support the issue of manufacturer's guidance, the issue of such guidance being a direct result of NIAIC action following the endoscope decontamination issues in Northern Ireland. This action not only benefited patient safety in Northern Ireland but has subsequently benefited patients throughout the UK.
- **MDEA(NI)2005/05: Bed Rails**
This Alert was issued following a number of reported incidents to NIAIC that involved the entrapment of a number of patients through the inappropriate use of bed rails.

- **MDEA(NI)2005/70: Operating Theatre patient transfer systems.**

This Alert was issued following a series of incidents at a local Trust, one incident involving the death of a patient. Following investigation by NIAIC and MHRA, action was taken ahead of MHRA national action due to the local nature of the incident.

- **MDEA(NI)2007/112: Enteral Feeding Pumps**

This alert was issued in response to an incident investigated by NIAIC where it was discovered that the Instruction for Use did not clearly identify the risk of free flow through the system if the giving set was incorrectly installed. This alert was subsequently released nationally.

MDEAs should only be issued when they are absolutely necessary. It is important that recipients continue to value the information in MDEAs and their value is not diminished due to inappropriate issue. Therefore before a MDEA is issued the following is considered: -

- Is the information needed? The information could be already available through another source such as a manufacturer recall. Provided that the manufacturer has adequate records of where the product was supplied, such issues are usually left to the manufacturer to action.
- There is also the question if the product is in use in NI. For example, if there is a product that has only been supplied to the NHS but is clearly not used in the HSC, there is no need to issue an MDEA.

Similarly, if the Alert does not reflect DHSSPS policy, the Alert does not need to be issued. There are occasions when the MHRA will issue an Alert that reflects DoH policy, with such policy not applying in NI. An example would be the MHRA Alerts MDA/2002/09 and MDA/2004/46 concerning Cochlear Implants and the increased risk from Pneumococcal Meningitis. It was considered by the DHSSPS that an Alert was an inappropriate way to communicate recommendations concerning vaccine use in Northern Ireland and DHSSPS circulars HSS (MD)23-02 and HSS(MD)30-2004 were issued in place of the MHRA Alerts.

In all of the above examples, are taken through consultation with professional colleagues in Health Estates, DHSSPS and the appropriate Chief Professional Officers. Then the most appropriate targeted guidance to the HSC is agreed and delivered to the HSC and wider health and social care community.

Sensitive or High Profile National and Local Issues

The NIAIC interface for medical device safety issues, mainly flowing from the production of MHRA Alerts, this allows the NIAIC and DHSSPS Medical and Nursing colleagues to brief Minister and

senior Departmental officials in addition to being able to take appropriate action when there are possible sensitive or high profile safety issues associated with the safety of medical devices. Although the NIAIC is not responsible for policy associated with the use of medical devices in the delivery of health and social care services, if medical device safety issues are identified that may impact upon the delivery of health and social care services, the NIAIC provides professional and technical advice and support concerning medical device safety to the appropriate DHSSPS policy holding Directorate and/or Chief Professional Officer.

Examples of issues in this category have been:-

- Single-use diathermy instruments: Following reports of deaths associated with the use of single-use diathermy surgical instruments in GB, the CMO in England suspended the use of such instruments until further investigations were undertaken. Through our interface with MHRA, we were able to brief CMO on the issues, allowing particular NI action to be taken.
- Breathing Circuits Blockages: Following a death in GB from suspected tampering with a breathing circuit, appropriate briefing to CMO and Minister was provided concerning single-use breathing circuit use and the possible impact on the maintenance of HPSS theatre activity. In this case, specific non-alert based guidance was issued by Health Estates that put patient safety as the priority and allowed theatre activity to be maintained.

Non-Medical Device Issues

The NIAIC also covers non-medical equipment, plant or building element safety issues. If potential problems are identified that may impact upon the delivery of health and social care services, NIAIC will review the position and provide appropriate guidance to HSC organisations. Dependent on the circumstances surrounding the safety issue, the appropriate DHSSPS policy holding Directorate and/or Chief Professional Officer may also be advised.

Local Targeted Distribution of MDEAs

The NIAIC MDEAs are distributed by the SABS system to HPSS Chief Executives and SABS Liaison Officers for direct action and for onward transmission within organisations to relevant healthcare professionals. When a medical device, non-medical equipment, plant or building element safety issue is applicable to the wider health and social care community, NIAIC arranges for the necessary distribution through the Central Services Agency (CSA), the Regulation and Quality Improvement Authority (RQIA) or directly through NIAIC. MDEAs are also available to these organisations and members of the public through the NIAIC website and the SABS website.

The NIAIC is therefore able to target distribution to all health and social care providers, principally the HSC, but also DHSSPS Staff, GPs, Dentists, Community Pharmacists, Optometrists, Allied Health Professionals, Private Residential and Nursing Homes, Private Clinics, Hospices and voluntary organisations as necessary.

We are currently reviewing the distribution of MDEAs with the RQIA in respect to issues associated with their independent regulatory and inspection status.

3 Review of NIAIC activity

3.1 Introduction of the Safety Alert Broadcast System (SABS)

SABS(NI) is an electronic system developed by the Northern Ireland Adverse Incident Centre and is the primary method of distributing MDEAs to the healthcare environment across Northern Ireland. It incorporates a feedback mechanism to record acknowledgement of receipt and action taken by trusts following the release of alerts. The SABS liaison officer ensures onward distribution of the alert as appropriate; updates and feedback on action taken is logged on the SABS website.

The NIAIC should be informed about a change of SABS contact on Tel :028 9052 3868 or E-mail: niaic@dhsspsni.gov.uk

NB. A similar SABS system is operated by the Department Health, England to administer safety information to all NHS trusts and primary care trusts in England & Wales and should not be confused with the system which operates within Northern Ireland.

3.2 Enteral Feeding Pump

It was reported to NIAIC that a patient had received an over infusion while connected to an enteral feeding pump. During investigation by technical and nursing staff from NIAIC, it was discovered that the giving set could be accidentally misaligned through the pump, resulting in free flow of feed to the patient, without the pump alarming. This condition was demonstrated to the manufacturer who accepted the findings and during further investigations with the manufacturer it was discovered that they had a number of similar unresolved open incidents. From the findings, a Medical Device/Equipment Alert was drafted and presented to the MHRA and it was decided that the incident warranted national notification. On 17 Dec 2007 the NIAIC released MDEA(NI)2007/112 - Fresenius Kabi, Applix Smart Pump, all models, in parallel with a national Alert.

3.3 Incidents of Self Harm

During the year there has been an increase in the number of reported incidents in which patients have endeavoured to use both fixed and portable estates fixtures to self harm. As a result of direct investigation within Northern Ireland the NIAIC has released two Alerts which have been adopted nationally:

MDEA(NI)2007/101

Rubber / PVC gasket used to provide a weather proof seal on window and door openings

MDEA(NI)2007/83 Curtain tracks and other fixed fittings
in Emergency Admission Units - used
as points of ligature

Similarly, the NIAIC has adopted Alerts issued by Scotland and
England on:

MDEA(NI)2007/100 Window restrictors
MDEA(NI)2007/61 Cubical curtain track rails (anti
ligature): Installation issues with anti
ligature cubical curtain track rails

During the year the three regional Adverse Incident Centres have
come to an arrangement that; where it is deemed that the
information contained in an Alert may be of use to anyone intent on
self harm, the content of the Alert would not be placed on the
respective public websites, but would only be distributed directly to
healthcare personnel.

3.4 Bed Rails

NIAIC continues to receive increased reports of adverse incidents
with bed rails and their use, in respect of the risk to the patient's, the
type of bed or the mattresses used. To re-enforce the issue the
NIAIC has issued MDEA(NI)2007/09 that provides further guidance
their use. We continued to participate with the organisation of
training seminars in conjunction with the HSC Trusts, however,
there remains serious concerns with the use of bed rails in Care
Home settings and we will be seeking to work with the MHRA and
care home associations (RNHA and ECCA) regarding bed rail
adverse incidents and discuss ways to reduce them further.

3.5 Telecommunication Equipment

It was reported to NIAIC that unauthorised fraudulent access could
be gained to telecommunication equipment within a healthcare
building which did not provide adequate password security.
Investigations into the extent of the fraudulent activity, if any, within
the HSC were inconclusive. But it was understood that the
unauthorised access would be for external call routing purposes and
not to gain system access. The NIAIC raised an Alert to identify the
issues and make recommendations of the level of security which
should be put in place

3.6 Automatic External Defibrillator

One Trust reported issues they were experiencing with their
defibrillator policy following a manufacturer's software upgrade. The
documentation with the upgrade indicated that it would have no
effect on user programmed setting. Unfortunately, this was not

totally correct and one of the Trust wide settings was overwritten which affected their training and usage policy of the device. The findings of the NIAIC investigation were reported to the MHRA who felt it was necessary to provide national guidance in the form of a Medical Device Alert.

3.7 IV Giving Sets

It was reported to the NIAIC that one Trust had a problem with a fluid warming IV administration and irrigation set in which they had observed blood ingress into the heating fluid. They had expressed concerns that if blood could escape from the set into the heating fluid, then there was the possibility that non sterile fluid could travel the opposite way and contaminate the blood being administered. Following investigation by the NIAIC this possibility was reported to the manufacturer. The manufacturer had also received similar reports for other areas and was in the process of carrying out internal investigations into their manufacturing process. It was discovered that small holes were found in the inner aluminium lumen of some set which could allow leakage of heating fluid into the giving set with the potential for contamination. Therefore, the manufacturer recalled the entire affected batch, but was unable to guarantee 100% uplift of the product. The MHRA and the NIAIC supported the manufacturers recall by the issue of a Medical Device Alert (MDEA(NI)2007/70) .

3.8 Spinal Needles

A surgeon raised an Adverse Incident report to the NIAIC that indicated he was experiencing problems with the use of a series of spinal needles of a particular size and type. Given the concerns of the surgeon, the NIAIC asked for assistance from a product specialist from the MHRA. Their findings were that, although the issue was common to a number of similar products, there was an underlying issue with how the device was being used. Given the identified clinical procedure issues, they reported their findings to the Royal Colleges to incorporate into future training material. At the same time the MHRA provided informal guidance in an article on a "One Liner" poster.

3.9 Surgical Instruments

The NIAIC received two reports that a rivet had fallen out of a Exeter – Rasp introducer/extractor. Given the size and sterile nature of the instrument the overall risk to patient safety was assessed as minimal, but the failure of the device in use could increase the procedure time and may cause increased distress to the patient. The manufacturer was asked to investigate these incidents and report back their findings. The manufacturer was able to identify a batch of instruments which may experience a similar fault, but given the age of the instruments and the overall risk to patients, it was agreed that it would not be necessary to initiate a total recall of the product. The manufacturer agreed to brief their sales staff to visit

known customers, check their instruments and replace any defective devices. The NIAIC continued to monitor for further device failures but no additional reports were received.

3.10 Pregnancy Test Kits

The NIAIC received a report that one Trust suspected they were having problems with a QA issue with a single use pregnancy test kit, in that they had experienced kits which give a faintly positive result when the patient was negative. As kits were contaminated after use they were destroyed and not available for investigation. This issue was reported to the MHRA with a non conclusive finding. This report together with other similar reports from across the UK allowed the MHRA to approach the manufacturer and the product was taken off the market. The MHRA and the NAIC released a Medical Device Alert (MDEA(NI)2007/56) to advise the healthcare environment of the product withdrawal. As the product was widely used by the general public the NIAIC prepared a Ministerial brief and a press release in the event that the withdrawal would cause public concern.

3.11 Endoscope Cleaning Brush Set

Following the report of an endoscope cleaning brush having stuck in a newly designed gastroscope, the investigation discovered that the cleaning brush length was too short for the endoscope it was labelled for. The manufacturer was advised of the issue and asked to investigate. They discovered that they had tested the new scope with a brush which had a length at the upper end of the design specification, but recently some of the brushes were being produced at the lower end of the design specification and they were not long enough to completely go through the new gastroscope. The manufacturer immediately initiated a product design change to ensure that all brushes were increased in length so that the same brush was suitable of all scopes in their range. Testing of existing stock showed that there was only a low percentage of the shorter length, and these were suitable for all endoscopes except the new gastroscope. Only one Trust in Northern Ireland was known to have the new type gastroscope and they were advised to carry out a brush pre-clean check prior to use, until new stock of the product was available. The NIAIC advised the MHRA of the investigation, but given the limited risk to patient safety the manufacturer's response was deemed to be adequate and no further action necessary.

3.12 Fastload CT Syringe Pack

An incident was reported where a syringe failed and a patient received an air embolus. From investigation it was discovered that the syringe failure and the air embolus were two unrelated incidents which just happened to occur during the one procedure. The air embolus was attributed to a clinical procedure which requires the operator to carry out a series of manual checks prior to

use. The level of air embolus was assessed and deemed to represent only minimal risk to the patient, therefore no further action was deemed necessary on this event. The syringe failure was found to be caused by a training issue which was highlighted to the manufacturer and they have addressed this with an updated training schedule which is being implemented across the company worldwide.

3.13 Blunt Tip Trocar

Following four separate reported incidents over the period of a year regarding a component failure on a Blunt Tip Trocar, the manufacturer was asked to carry out full design audit into the device failures. Following this it has been discovered that one section of the product required a design change to avoid damage during use. This has now been carried out and the product is now being successfully used with no further reported damage. This outcome demonstrates the importance of reporting such adverse events to NIAIC. Without the repeated adverse incident reports from HSC Trusts in Northern Ireland, the design fault in the device may not have been addressed. In this case, patient safety was protected across Europe, not just in Northern Ireland by the action of Trust reporting near a series of misses.

4 Medical Device/Equipment Alerts 2007

The following Medical Device/Equipment Alerts are available on our websites

www.dhsspsni.gov.uk/niaic

sabs.dhsspsni.gov.uk

Number	Issue Date	Level Of Urgency	Title
MDEA(NI)2007/113	20 Dec 07	Action	Volumetric Infusion Pump. Smiths Medical (Graseby) 500 and 505volumetric infusion pumps - all models. There is the possibility of delivering an unintended 1.7ml bolus if the pump door is opened and then immediately closed following a stoppage of the pump (PDF 137 KB)
MDEA(NI)2007/112	18 Dec 07	Action	Enteral feeding pump. Fresenius Kabi Applix Smart Pump - -all models (PDF 241 KB)
MDEA(NI)2007/111	18 Dec 07	Immediate Action	Blood/soloution warming units. All Smiths Medical Level 1-31B air detector clamp (PDF 660 KB)
MDEA(NI)2007/110	18 Dec 07	Action	Infusion pump Schnider model used with Alaris PK pumps manufactured by Cardinal Health (PDF 524 KB)
MDEA(NI)2007/109	10 Dec 07	Action	Kimba Spring Paediatric Buggies Manufactured by Otto Bock (PDF 187 KB)
MDEA(NI)2007/108	7 Dec 07	Immediate Action	Robertshaw endobronchial tubes (rubber, disposable), all sizes. Manufactured by Pheonix Medical, a P3 Medical Ltd company. There is a risk of cuff deflation due to a manufacturing design change. Affected product codes and batch numbers are listed overleaf. The manufacturer has now reverted to the original design. P3 are not able to provide immediate replacement of all affected stock and are not aware of any alternative equivalent devices manufactured from natural rubber (PDF 519 KB)
MDEA(NI)2007/107	7 Dec 07	Immediate Action	External temporary cardiac pacemaker. Bedside model 4170 serial numbers: 1 – 998. Manufactured by APC Medical Ltd. Patients may receive inappropriate fast rate pacing when this temporary pacemaker is being switched off. (PDF 121 KB)
MDEA(NI)2007/106	6 Dec 07	Action	Paediatric respiratory support device -Infant Flow® SiPAP™ manufactured by Viasys Healthcare. There has been an important change to the operator manual that needs to be communicated to end users. (PDF 122 KB)
MDEA(NI)2007/105	6 Dec 07	Immediate Action	This alert has been replaced by MDEA(NI)2008/003
MDEA(NI)2007/104	6 Dec 07	Action	Procure Ltd / Wound drainage set for use in theatres: Privac pre-evacuated drainage set with 10ch drain and 600ml drainage bottle. Product code 24760. Batches 12032006 and 07052007 / Debris from the manufacturing and packaging processes has been found in the sterile packaging of some wound drainage sets from these batches. (PDF 120 KB)
MDEA(NI)2007/103	4 Dec 07	Action	Draeger Medical / Anaesthetic Gas Scavenging System (AGSS) receiver / Reports of anaesthetic scavenging hoses being misconnected to the blanked-off port of the Draeger AGSS receiver. This prevents gases from leaving the anaesthetic breathing system, creating excessive airway pressures, which if undetected could result in serious lung injury. (PDF 155 KB)

Number	Issue Date	Level Of Urgency	Title
MDEA(NI)2007/102	4 Dec 07	Action	Intravenous (IV) infusion lines: all brands / Risk of back-tracking when more than one IV line is connected through a single access point. (PDF 126 KB)
MDEA(NI)2007/101	29 Nov 07	Action	Rubber / PVC gasket used to provide a weather proof seal on window and door openings (PDF 5 KB)
MDEA(NI)2007/100	29 Nov 07	Action	Window restrictors (PDF 5 KB)
MDEA(NI)2007/99	29 Nov 07	Action	LCD patient monitors on fixed mounts: risk of falling (PDF 5 KB)
MDEA(NI)2007/98	28 Nov 07	Action & Update	Injectable polymeric cements used in percutaneous vertebroplasty, balloon kyphoplasty and pedicle screw augmentation: Inappropriate use, or modification, of cement composition leading to serious complication(an update) (PDF 5 KB)
MDEA(NI)2007/97	22 Nov 07	Action	Battery Charger for Powered wheelchair: Mentzer 24v 6A Konstant Charger Model G25-324-6 supplied by Exide, Sunrise Medical and Lomax mobility: The case temperature of the above charger, in normal use, is higher than the temperature requirements of BS EN 12182:1999, which specifies a maximum temperature of 41oC (PDF 133 KB)
MDEA(NI)2007/96	19 Nov 07	Action	Forth Medical Limited / Surgical tool bit/burr - Anspach cutting burrs with expiry dates from June 2008 to August 2011 (inclusive) / Possible breakdown of packaging leading to compromise of the sterile barrier (PDF 156 KB)
MDEA(NI)2007/95	7 Nov 07	Action	Automatic external defibrillator - Welch Allyn AED 20 (PDF 124 KB)
MDEA(NI)2007/94	05 Nov 07	Immediate Action /Information	Spinal implants - locking nuts used in the Medtronic Colorado II spinal implant system. Catalogue number 8634111. Lots: W07G2386, W07G2387, W07G2388, W07G2389, W07G2751, W07H0440, W07H1809 and W07H1810.(PDF 128 KB)
MDEA(NI)2007/93	31 Oct 07	Immediate Action	General Ultrasound scanner: Nemio and Nemio XG Systems Manufactured by Toshiba Medical Systems Ltd (PDF 319 KB)
MDEA(NI)2007/92	30 Oct 07	Action	Counterfeit Durex Condoms / Counterfeit Durex Condoms have been placed on the UK market (PDF 163 KB)
MDEA(NI)2007/91	26 Oct 07	Action	Telecommunication Equipment - Unauthorised fraudulent access can be gained to telecommunication equipment which does not have adequate security controls in place (PDF 118 KB)
MDEA(NI)2007/90	26 Oct 07	Action	Grundy Heated food conveyors: Risk of exposure to Asbestos (PDF 514 KB)
MDEA(NI)2007/89	26 Oct 07	Action	Orthopaedic bone cement restrictor instrumentation. DePuy SmartSeal pressurisers - femoral and acetabular pressurisers (5pack) manufactured by DePuy CMW: Recall of SmartSeal pressuriser as the other pouch seal may be compromised (PDF 119 KB)
MDEA(NI)2007/88	25 Oct 07	Immediate Action & Information	EMS ventilator circuits, product code W196-002 manufactured by Galemed Corporation and supplied by Smiths Medical. These are breathing systems for use with Smiths Medical emergency and transport ventilators including: Parapac, Ventipac, Rescupac and Transpac models: A manufacturing problem has been identified where the valve in these breathing systems will not open, resulting in a blockage and potentially no oxygen being delivered to the patient. Galemed Corporation believes that this issue only affects three lot numbers of EMS ventilator circuits. These lot numbers are: 070528, 070620 and 070910 (PDF 132 KB)

Number	Issue Date	Level Of Urgency	Title
MDEA(NI)2007/87	23 Oct 07	IMMEDIATE	BD Medical Surgical Systems Plastipak / 1ml, 2ml, 5ml and 10ml hypodermic Luer slip syringes manufactured between April 2007 and August 2007 / Multiple reports received of these syringes spontaneously disconnecting from, or failing to maintain a secure connection to, Luer fittings of other devices. (PDF 151KB)
MDEA(NI)2007/86	19 Oct 07	Immediate Action	Implantable Cardioverter defibrillator (ICD lead). Sprint Fidelis manufactured by Medtronic, model numbers: 6930, 6931, 6948 and 6949: ICD lead recall due to risk of inappropriate patient shocks, loss of defibrillation therapy and/or loss pacing output, caused by fracture of the lead conductor (PDF 173 KB)
MDEA(NI)2007/85	16 Oct 07	Action	Boots NPI Healthcare / Home use blood glucose meters: Boots brand blood glucose monitoring system / Dropping or knocking the meter can cause display failure. (PDF 124 KB)
MDEA(NI)2007/84	12 Oct 07	Action	Curtain/bed screens risk of fire due to inadequate flame retardancy: some flame retardant cotton curtains/bed screens may exhibit poor flame retardancy, with resultant risk of fire (PDF 121 KB)
MDEA(NI)2007/83	9 Oct 07	Action	Curtain tracks and other fixed fittings in Emergency Admission Units - used as points of ligature (PDF 120 KB)
MDEA(NI)2007/82	4 Oct 07	Immediate Action	Bioresorbable screw: CALAXO interference screw implants manufactured by Smyth & Nephew Inc. Recall due to pre-tibial soft tissue swelling after implantation of CALAXO screws leading to the need for surgical intervention to remove any screw fragments (PDF 122 KB)
MDEA(NI)2007/81	19 Sep 07	Action	Invacare Action3 wheelchairs fitted with a manual ratchet recliner mechanism. Risk of injury to the user or carer from the sudden failure of the backrest ratchet. (PDF 121 KB)
MDEA(NI)2007/80	19 Sep 07	Action	Invacare Action 2000 wheelchairs (blue frame). Sudden detachment of the seat canvas allowing the user to fall. (PDF 128 KB)
MDEA(NI)2007/79	18 Sep 07	Immediate	Eschmann LTD / Electrosurgery bipolar unit: model TDB (serial numbers with the last six digits from 5D-1201 to 7D-1273 inclusive are affected - see appendix for full list) / Failure of a component in the main control board may lead to the power output being up to four times that displayed on front panel.(PDF 124 KB)
MDEA(NI)2007/78	12 Sep 07	Action	Kimberly-Clark NV/SA / Microcuff paediatric endotracheal tubes / Device may kink during use, which may impede or prevent ventilation (PDF 134 KB)
MDEA(NI)2007/77	11 Sep 07	Immediate	THIS HAS BEEN UPDATED BY MDEA(NI)2007-87
MDEA(NI)2007/76	7 Sep 07	Action	Sterile suction connecting tubing, ref number: UN30025FFM, manufactured by Universal Hospital Supplies Ltd: manufactured up to and including 14 November 2006, NHS Supply Chain code:FWP204: Due to an intermittent manufacturing fault there is a potential for the connectors on this tubing to be partially occluded resulting in ineffective suction. (PDF 667 KB)
MDEA(NI)2007/75	7 Sept 07	Action	Automatic external defibrillator: Lifepak 500 manufactured by Medtronic Ltd: Under certain conditions the defibrillator may deliver a shock at 100J instead of the manufacturer's minimum default setting of 200J. This problem affects defibrillators with operating software versions of 4.4 or lower. (PDF 2 MB)
MDEA(NI)2007/74	5 Sept 07	Immediate	Hip implants for hemiarthroplasty - Austin-Moore, F

Number	Issue Date	Level Of Urgency	Title
		Action	R Thompson and Thompson Modular endoprotheses manufactured by Biomet UK Ltd: Recall due to potential failure of sterile barrier packaging which could compromise product sterility. (PDF 508 KB)
MDEA(NI)2007/73	30 Aug 07	Immediate Action & Update	Hip resurfacing implants.: Adept acetabular cups manufactured by Finsbury Orthopaedics (see appendix for affected lot codes). Inappropriate mixing of head and cup sizes due to incorrect labelling of the cups.The need for early revision due to loose joint fit as a result of mislabelled cups. (PDF 281 KB)
MDEA(NI)2007/72	23 Aug 07	Action	Vaginal specula: all single-use Cusco screw type vaginal specula manufactured by North Eos: All single-useCusco screw type specula supplied before 27 February 2007 have been wrongly labelled as sterile instead of clinically clean. Other models of vaginal specula from this manufacturer are not affected (PDF 147 KB)
MDEA(NI)2007/71	23 Aug 07	Immediate Action	Hospital beds: Hill-Rom TotalCare Duo 2: The manufacturer has omitted to provide suitable decontamination instructions with this pressure relieving hospital bed.The MHRA has received two reports of damaged mattress covers that allowed body fluids to soak into the mattress. No instruction was provided on how to check the condition of the mattress and cover. This presents a risk of cross infection.(PDF 143 KB)
MDEA(NI)2007/70	16 Aug 07	Immediate Action	Fluid warming set: Level1 normothermic IV fluid administration and irrigation sets - D/DI and IR/IRI series manufactured by Smiths Medical: Small holes have been found in the inner lumen (aluminium tube) of some sets which can allow leakage of the heating fluid into the infusate with the potential for contamination (PDF 498 KB)
MDEA(NI)2007/69	16 Aug 07	Immediate Action & Information	Hip resurfacing implants. Birmingham Hip resurfacing (BHR) acetabular cups manufactured by Smith & Nephew Orthopaedics Ltd (see appendix for affected lot numbers). Inappropriate mixing of head and cup sizes due to incorrect labelling of the cups. The need for early revision due to loose joint fit as a result of mislabelled cups (PDF 279 KB)
MDEA(NI)2007/68	15 Aug 07	Immediate Action	Laryngoscope blades: Falcon single-use paediatric Miller blades size 00, 0 & 1, supplied by Draeger medical UK. Poor illumination of the airway and heating of the blade due to manufacturing problems with the bulb (PDF 702 KB)
MDEA(NI)2007/67	14 Aug 07	Immediate	Teleflex Medical / Oxygen humidifier: Hudson RCI large volume nebuliser, product code 41770 (see appendix for lot numbers) / potential for lower than the required oxygen concentration to be delivered due to a manufacturing fault. Manufacturer has recalled devices. (PDF 446 KB)
MDEA(NI)2007/66	8 Aug 07	Action	Abbott Nutrition / Enteral feeding pumps:ClearStar model number M771 / Risk of under-infusion due to cracking/breaking of internal adapter bracket. (PDF 344 KB)
MDEA(NI)2007/65	7 Aug 07	Action	HemoCue Ltd / Point of care blood glucose measurement systems:HemoCue Glucose 201 and HemoCue Glucose 201RT / Potential for false zero readins of blood glucose concentration. (PDF 128 KB)
MDEA(NI)2007/64	23 July 07	Action/Update	Roche Accu-Chek and Glucotrend: Abbott Diabetes Care FreeStyle - Point of Care and Home-use Blood Glucose Meters - Risk of overestimation of blood glucose results when these meters are used on samples from patients on treatments that contain maltose,xylose or galactose. (PDF 125 KB)

Number	Issue Date	Level Of Urgency	Title
MDEA(NI)2007/63	03 July 07	Immediate	ConMed Corporation / Eliminator esophageal PET balloon dilator and pyloric/colonic PET balloon dilator / Various labelling errors and inconsistencies have been identified, which can result in the use of an incorrect balloon size. (PDF 129 KB)
MDEA(NI)2007/62	28 June 07	Action	Profiling bed: Invacare Scanbed 750 (SB 750) with integral bed rails : Risk of asphyxiation to children from the potential for entrapment between the wooden bed rails (PDF 143 KB)
MDEA(NI)2007/61	22 June 07	Action	Cubical curtain track rails (anti ligature): Installation issues with anti ligature cubical curtain track rails (PDF 164 KB)
MDEA(NI)2007/60	21 June 07	Action	TK3 Control Potentiometer (Lighting dimmer): Overheating due to terminal over tightening or forcing unit into back box (PDF 2 MB)
MDEA(NI)2007/59	19 June 07	Action	Advanced Medical Optics (AMO) / Contact lens solution: COMPLETE MoisturePLUS / worldwide product recall - this product is associated with an increased incidence of Acanthamoeba keratitis (PDF 131 KB)
MDEA(NI)2007/58	14 June 07	Action & Information	Total Hip replacement: DePuy Ultima TPS femoral stem used in combination with Ultima metal on metal articulation: Unexplained groin pain and the need for early revision due to periprosthetic soft tissue necrosis. (PDF 763 KB)
MDEA(NI)2007/57	13 June 07	Action	IV extension lines: model 6222 range of V-Green narrow bore extension lines manufactured by Vygon (UK) Ltd: There is a potential for the female connector of the line to crack when used to deliver propofol (an intravenous anaesthetic agent). This may result in leakage of this drug and failure to induce and maintain general anaesthesia. The manufacturer has initiated a recall of specific batch numbers irrespective of the drugs they are being used with. (PDF 124 KB)
MDEA(NI)2007/56	12 June 07	Immediate Action	Pregnancy test kits: Clearview HCG, product code 500158, lot number HG0050: Possibility of false negative pregnancy test results. (PDF 299 KB)
MDEA(NI)2007/55	12 June 07	Action	All brands of needle free intravascular connectors: The instructions of several brands of these devices have changed significantly in the last two years. (PDF 127 KB)
MDEA(NI)2007/54	12 June 07	Action	Electrical Extension Lead (multiple socket outlets): Failure of electrical supply to equipment, including overheating which may lead to fire and possible loss of lives. (PDF 220 KB)
MDEA(NI)2007/53	12 June 07	Action	Single-use capillary blood sampling device: Microtainer Safety Flow Lancets manufactured by BD Preanalytical Systems. Product code 366354, 366355 and 366358. Potential for a sharps injury to patient or user as the blade may become loose and then separate from the main body on activation of the device. The manufacturer has recalled the affected lot numbers of these products. (PDF 127 KB)
MDEA(NI)2007/52	12 June 07	Action	Homecraft Rolyan bath lift hand controls for the Bathmaster 2000, Bathmaster Classic, Bathmaster Xtra and Bathmaster Reclina: The lack of vent holes or the blocking of vent holes in the hand control casing can lead to a build up of battery gases, causing the case to split, which can result in injury to the operators hand. (PDF 185 KB)
MDEA(NI)2007/51	6 June 07	Action	Devices for securing lines, tubes and drains: Drain-Fix 680M and 685M; Central-Gard 667M and 668M; Epi-Fix 670M. All manufactured by Unomedical Ltd. A packaging problem that may affect one in six of

Number	Issue Date	Level Of Urgency	Title
			the manufactured peel pouches, which may compromise the sterility of the devices. Therefore the manufacturer is recalling all affected batches.(PDF 122 KB)
MDEA(NI)2007/50	5 June 07	Action	External defibrillators batteries for Lifepak 20 manufactured by Medtronic. Some Lifepak 20 defibrillators have been fitted with batteries that may have a reduced capacity. Some of the affected batteries have also been sold separately. (PDF 124 KB)
MDEA(NI)2007/49	5 June 07	Action	Laryngoscope handle: Optima XL stubby handle, manufactured by Timesco of London Ltd. Poor contact between Timesco stubby handles and Timesco laryngoscope blades, which may result in the bulb not being lit with subsequent delays to intubation.(PDF 137 KB)
MDEA(NI)2007/48	31 May 07	Immediate Action	Medication cassette reservoir for CADD legacy infusion pumps manufactured by Smiths Medical: model numbers 21-7001-24 and 21-7002-24. In certain batches of medication reservoirs there was a change of material formulation, to include calcium carbonate. There have been reports of shifts in pH of medication, discolouration and occlusions, which may or may not be related to this change (PDF 129 KB)
MDEA(NI)2007/47	31 May 07	Action	Invacare Flamingo mobile patient hoists: Detachment of spreader bar from hoist whilst in use.(PDF 191 KB)
MDEA(NI)2007/46	31 May 07	Action	Boc Medical Gas Outlet Mark IV Valve Plate: No Automatic Isolation Of Medical Gas Supply (PDF 120 KB)
MDEA(NI)2007/45	24 May 07	Action	External pacemakers and temporary cardiac pacing leads. Potential for loss of pacing due to accidental disconnection of temporary pacing leads and lead adaptors (PDF 124 KB)
MDEA(NI)2007/44	24 May 07	Action	Primus anaesthetic workstation supplied by Draeger Medical UK Ltd. potential misconnection of the backup oxygen cylinder (PDF 125 KB)
MDEA(NI)2007/43	22 May 07	Action	This alert has been replaced by MDEA(NI)2007/52 (PDF 182 KB)
MDEA(NI)2007/42	22 May 07	Immediate	BARIATRIC PROFILING BEDS - NIGHTINGALE PRO AXIS AND PRO AXIS PLUS: Ignition of flammable gases from an overcharged battery within the main control box can result in the metal cover being blown off, putting those in the vicinity at risk of injury (PDF 129 KB)
MDEA(NI)2007/41	22 May 07	Immediate.	All Paediatric Ventilator Breathing Systems Containing a water Trap, Manufactured by VIASYS Healthcare: The MHRA has received reports of VIASYS Auto Drain Water Traps Failing to Drain Accumulated Fluid (PDF 127 KB)
MDEA(NI)2007/40	17 May 07	Action	Urine Test Strips: Makromed - all products with expiry dates in 2007 or 2008. Potential for misdiagnosis due to false negative results when testing for blood or ketones in urine (PDF 551 KB)
MDEA(NI)2007/39	10 May 07	Action	Flexible Endoscopes manufactured by Olympus, distributed in UK by KeyMed Limited: The outer sheath and light guide tube of Olympus flexible endoscopes may be damaged by direct exposure to ultraviolet (UV) light, as used in some endoscope storage and drying cabinets (PDF 147 KB)
MDEA(NI)2007/38	2 May 07	Action	Plastic two-part self-assembly Step/Kick stools (PDF 246 KB)
MDEA(NI)2007/37	2 May 07	Action	IV Cannulas used in conjunction with automatic powered injectors (PDF 121 KB)

Number	Issue Date	Level Of Urgency	Title
MDEA(NI)2007/36	26 April 07	Action	UMBILICAL CORDCLAMP CLIPPER MANUFACTURED BY UNOMEDICAL LTD: There is potential for the bald to fall out of the product or break during use of identified lots (PDF 128 KB)
MDEA(NI)2007/35	26 April 07	Immediate Action	POINT OF CARE BLOOD GLUCOSE MEASUREMENT SYSTEMS: HEMOCUE: Potential for unreliable blood glucose readings when testing samples from pre-term neonates (PDF 306 KB)
MDEA(NI)2007/34	26 April 07	Action & Update	PATIENT HOISTS & SLINGS: Falls due to the poor compatibility of slings and hoists, inappropriate laundering of slings and inadequate maintenance of patient hoists used in hospitals and the community(PDF 122 KB)
MDEA(NI)2007/33	19 Apr 07	Action	STOBU Steam stop valve - Sudden failure of the thread in the bush of the valve spindle resulting in valve opening violently whilst under steam pressure on a boiler (PDF 172 KB)
MDEA(NI)2007/32	19 Apr 07	Action	Helicopter Landing Sites - Loose Debris impacting upon the helicopter (PDF 120 KB)
MDEA(NI)2007/31	4 Apr 07	Action	External Defibrillator: Lifepak 20 Defibrillator manufactured by Medtronic. Some Lifepak 20 defibrillators may fail to deliver therapy. Once mains power is disconnected the defibrillators may not turn on with battery power. The display is blank and all indicator lights are off.(PDF 230 KB)
MDEA(NI)2007/30	29 Mar 07	Action	Retrievable permanent inferior vena cava (IVC) filters: Complications associated with filter retrieval (PDF 122 KB)
MDEA(NI)2007/29	22 Mar 07	Immediate	INTAVENT ORTHOFIX LTD / reusable flexible laryngeal mask airway size 2.5, model codes 7125R AND 7125DR / risk of tube kinking in the proximity of the connector, which could lead to the obstruction of airflow to the patient.(PDF 155 KB)
MDEA(NI)2007/28	22 Mar 07	Immediate	GAMBRO / HAEMODIALYSIS MACHINE: INTEGRA / events of insufficient fluid removal have been recorded during ultrafiltration (PDF 150 KB)
MDEA(NI)2007/27	22 Mar 07	Action	GE HEALTHCARE / Patient Monitoring System: APEXPRO/APEXPRO CH Telemetry System / possibility of no visual or audible system failure alarms.(PDF 161 KB)
MDEA(NI)2007/26	21 Mar 07	Immediate Action	EXTERNAL DEFIBRILLATORS: SAMARITAN AED MANUFACTURED BY HEARTSINE: MODELS SAM001, SAM002 AND SAM003. In semi-automatic mode the device incorrectly recognises an unusual ECG rhythm. The rhythm is non-shockable but the device can advise to shock. The manufacturer has advised users not to use these devices in automatic modes until the software has been updated. A copy of the manufacturer's advisory notice is on the field safety notice section of the MHRA website.(PDF 143 KB)
MDEA(NI)2007/25	16 Mar 07	Immediate Action	Update All QUATTROcare spray cans manufactured prior to 5 March 2007, for use in KaVo QUATTROcare dental handpiece maintenance systems. KaVo Dental Ltd have recalled all their QUATTROcare spray cans due to a risk of fire/explosion. QUATTROcare Cans may leak flammable gases when attached to a QUATTROcare maintenance system. (PDF 174 KB)
MDEA(NI)2007/24	16 Mar 07	Action	Boston Scientific Ltd. Vitality and Assure implantable cardioverter defibrillator (ICD) families and Contak Renewal cardiac resynchronisation therapy defibrillator (CRT-D) families. Delay in delivery of therapy during device middle of life phase due to temporarily extended charge time limits. Transition to device end of life (EOL) without prior observation of

Number	Issue Date	Level Of Urgency	Title
			elective replacement indication (ERI) even though battery capacity remains available (PDF 164 KB)
MDEA(NI)2007/23	14 Mar 07	Action	Single use capillary blood sampling device: Unitika 3 Normal, Unitika 3 Comfort and Unistik 3 Neonatal & Laboratory devices. Manufactured by Owen Mumford. Potential for needlestick injury to users and damage to patients sampling site due to a manufacturing fault. (PDF 148 KB)
MDEA(NI)2007/22	14 Mar 07	Action	Callisto Macintosh size 3 (adult) single-use laryngoscope blade, manufactured by Timesco of London Ltd: the fiberoptic core may break and separate from the blade. The manufacturer has initiated a recall of all affected product (PDF 156 KB)
MDEA(NI)2007/21	9 Mar 07	Immediate	UNIPATH LTD / COAGULATION POINT OF CARE TEST: CLEARVIEW SIMPLIFY D-DIMER. Kit lot numbers PT030A and PT031A containing test devices of batch number 682-024 / Increased risk of false negative results (PDF 507 KB)
MDEA(NI)2007/20	20 Feb 07	Action	CONMED CORPORATION / GRASPING FORCEPS - CONMED DETACHA TIP ENDOSCOPIC multiple use grasper and disposable hand held graspers and dissectors (ratcheted and non-ratcheted) / tips of devices manufactured between 25/8/2003 AD 24/3/2005 may be susceptible to breaking (PDF 696 KB)
MDEA(NI)2007/19	15 Feb 07	Immediate	DRAEGER UK Limited / Patient Vital Signs Monitor: DRAEGER Infinity Monitor with Infinity Docking Station (IDS) / The Infinity Docking Station Mechanism may fail on all models of Infinity Monitors. This can result in the monitor falling from its mounting.(PDF 178 KB)
MDEA(NI)2007/18	13 Feb 07	Action	INVACARE Ltd / Patient Hoists: INVACARE C800 series ceiling track / risk of injury resulting from falls due to failures of the motor drive in C800 series hoists manufactured between December (PDF 152 KB)
MDEA(NI)2007/17	13 Feb 07	Action	SMITHS Medical International Ltd / Fluid Warming Administration Set: SMITHS Medical Level 1 Normothermic IV Fluid Administration Set. Catalogue number DI-60HL / manufacturing fault in the administration set can prevent appropriate warming of the blood/fluid to be administered, leading to a delay in patient treatment. (PDF 151 KB)
MDEA(NI)2007/16	8 Feb 07	Action	Laundry damage to patient lifting slings with rigid clips: failure during use (PDF 800 KB)
MDEA(NI)2007/15	8 Feb 07	Action	Electric lifting aids with mechanical anti crush protection: Risk of patient fall/trauma (PDF 142 KB)
MDEA(NI)2007/14	8 Feb 07	Action	Fisher and Paykel Healthcare re-usable CPAP respiratory masks and connectors for obstructive sleep apnoea: Plastic tabs incorporated into the re-usable CPAP mask connectors may break off when in use with the possibility of components entering the patient's airways. The affected connectors are found in most Fisher and Paykel CPAP face, nasal and oral mask kits, and various tubing kits. Fisher and Paykel have now redesigned this connector (available since April 2006) and are recalling all face mask kits with the previous version; the recall notice and fax back form are appended to this alert (PDF 231 KB)
MDEA(NI)2007/13	7 Feb 07	Action	Lucas external cardiac compressor, manufactured by Jolife AB and distributed by Medtronic Ltd: The MHRA has received reports of inadequate ventilation in non-intubated patients, thoracic cage and lung damage and raised levels of atmospheric oxygen in ambulances where the device is powered by an

Number	Issue Date	Level Of Urgency	Title
			oxygen supply (PDF 178 KB)
MDEA(NI)2007/12	7 Feb 07	Action & Information Request	Intensive care continuous renal replacement system: Gambro Prismaflex Model Number 6023014700. All serial numbers. There have been reports of discrepancies between the flow rate set by the user (as displayed on the 'Enter Flow Rate' screen) and the resulting flow rate (as displayed in the 'Status' screen). A software upgrade was issued to correct this flow rate problem, however there is still a risk of flow rate discrepancies occurring after the software is upgraded (PDF 401 KB)
MDEA(NI)2007/11	7 Feb 07	Immediate Action & Update	BOC Ltd, AZ size aluminium medical nitrous oxide cylinders fitted with a key operated pin index valve for use in MRI units. Following the issue of MDEA(NI)2007/07, regarding AZ aluminium medical oxygen cylinders, BOC have informed MHRA that a similar problem has been found in a small number of medical nitrous oxide AZ cylinders. These cylinders have also been fitted with an obsolete pin index valve containing a ferromagnetic component that makes the cylinder potentially hazardous when used in an MRI environment (PDF 209 KB)
MDEA(NI)2007/10	5 Feb 07	Action	BAXTER CONTINU-FLO Solution Sets With Check Valve. Affected Product Codes: EMC 9603, RMC 9603, RMC 9604, RMC 9619 / During secondary infusions there is the potential for solution from the secondary infusion container to pass through the check valve (one-way valve). Backflow can result in inadequate treatment by causing an under-infusion of the secondary infusion (PDF 169 KB)
MDEA(NI)2007/09	1 Feb 07	Action	Bed and grab rails: bed rails can successfully prevent falls, but their incorrect use has resulted in the deaths of bed occupants by asphyxiation due to entrapment (PDF 143 KB)
MDEA(NI)2007/08	1 Feb 07	Action	NEONATAL RADIANT WARMER: DRAEGER RESUSCITAIRE, Model RW82VHA-1C with variable height adjustment: screws that secure the column to the base may loosen over time, allowing the support column to tilt, due to incorrect fitting (PDF 142 KB)
MDEA(NI)2007/07	25 Jan 07	Immediate Action	BOC Ltd, AZ size aluminium medical oxygen cylinders fitted with a key operated pin index valve for use in MRI units: The MHRA has received two reports of AZ aluminium oxygen cylinders fitted with obsolete pin index valves. These obsolete valves contain a metal component that is sufficiently magnetic to make the cylinder potentially hazardous when used in an MRI Environment (PDF 208 KB)
MDEA(NI)2007/06	23 Jan 07	Action	Smiths Medical - Chest Drain: Portex chest drainage system with adjustable straw. Product code 200/870/000, lot number 489962 - Failure to create a seal when the system is connected to the chest drainage bottle leaving the patient at risk of a pneumothorax. The manufacturer is recalling one lot of this device (PDF 142 KB)
MDEA(NI)2007/05	17 Jan 07	Immediate Action	Inditherm OTM1, OTM2, GTM1, RB1 and OTB1 operating theatre blankets and mattresses, used for maintaining patients body temperature: repeated folding of these devices can cause internal damage to the heating element. (PDF 142 KB)
MDEA(NI)2007/04	17 Jan 07	Action	Vygon (UK) Ltd paediatric IV bacterial filter with extension line, product code 0807.205: Cracking of the green hub on the filter has resulted in leakage. The manufacturer has recalled specific batches. (PDF 147 KB)
MDEA(NI)2007/03	12 Jan 07	Action	Ferno Falcon Six and Hawk Six ambulance stretcher trolleys: Weld failure of the foot end lock bracket

Number	Issue Date	Level Of Urgency	Title
			(PDF 194 KB)
MDEA(NI)2007/02	9 Jan 07	Action	Patient Monitoring System - Philips Medical Systems Multi Measurement Server (MMS) Model: M3001A and SpO2 Module M1020B: The pulse oximeter channel of the MMS or the SpO2 module in these monitors when used with disposable SpO2 transducers/probes may display a 100% saturation when the transducer is not attached to a patient. Should this happen in the case of a hypoxic patient, no alarm will be given (PDF 445 KB)
MDEA(NI)2007/01	02 Jan 07	Action	Reporting Adverse Incidents and Disseminating Medical Device/Equipment Alerts (PDF 81 KB)

5 Adverse Incident Reports 2007

The following is a summary of the adverse incidents reported to NIAIC during 2005. The information is presented in a general format that is intended to be illustrative of the range of devices/estates systems and the type of problems encountered that are reported to us. This information may be useful to device users and others when considering if it is necessary to report an adverse incident to us. NIAIC welcomes receipt of all incident reports as a one-off incident in one health or social care establishment, when combined with information on several others, may identify the need for action by NIAIC, MHRA, or the manufacturer.

Product	Brief Description
Suction devices	Disposable metal pooles suction devices - dust inside inner packaging
Neonatal Transport System	Neonatal transport system - failed 4 times during transfer of patient - loss of ventilation
Haemodialysis machine	Hospital Haemodialysis machine - bypass tubing disconnected - patient lost more fluid than indicated by program
Hoist	Hoist - loop came off hoist when patient was being lowered
Spinal Needle	Epidural Needle Sheared Off
Monitor	Blood Pressure Cuff - Electric Shock
IV Infusion Pump	IV Infusion Pump - Failed to transfer over to Battery
Auto suture	Cap appears to have followed through port unnoticed
Diathermy pencil	Coag button fell off
Needle	Novofine needle. Needle stick injury.
Operating table	Operating table. Head attachment became disengaged from main body of bed.
Passenger Lift	Passenger Lift - failed between floors trapping 2 people for 50 mins
Urometer	Urometer - insect found in bag whilst bag was being emptied
Defibrillator	Software problem leading to inaccuracy in CPR instructions
Needle guard box	Needle guard box - needle stick injury to left thumb.
Spinal needle	Spinal Needle - broke - needle stick injury to back
Wheelchair Back Rest	Plastic section broke off the backrest
Perching stool	Perching stool - adjustable jar became lodged within stool leg - unable to retrieve
Walking Aid	Delta Rollator - left brake came off
Syringe Driver	Syringe not moving after being reloaded
PH machine	PH machine - did not read sample and stated sample error
Toilet Seat	Toilet Seat - rubber grips had slipped off the seats.
Laryngoscope blade	Laryngoscope blade - blade snapped off
Wheelchair Back Rest	Backrest post which supports the push handle is fractured and the push handle became dislocated
Fire Alarm Equipment	Engineer 'un-hooked' fire doors to test fire alarm system and forgot to reconnect after completing test.
Insulin Pen	Flexpen - part inside pen loose, causing incorrect dose of insulin to be given.
Ventilator	Ventilator - not delivering set tidal volume
IV Pump	Machine set to administer fluids, but no fluids administered
Single Transducer Kit	Faulty single transducer kit
Rasp introducer / Extractor	Exeter - Rasp introducer/Extractor - rivet fell out after use
Diathermy	Adhesive patient plate electrode - burned patients left thigh
Enteral feeding pump	Enteral feeding pump - incorrect infusion
Clip Applier	Ligaclip - clip applier - clips misfiring out of the device
Dialysis Machine	Discrepancies between filter rate and status screen

Product	Brief Description
Surgical Lag implant screw	Lag implant screw - unable to attach a lag implant to coupling instrument
Feeding Peg Tube	Corflo Peg Tube - patient transferred from hospital with no skirt on peg.
AER	Biopsy connector -fell apart after being removed
Foley catheter	Foley urethral/suprabubic catheter - balloon deflated and became dislodged from patient
Laryngeal Masks	Laryngeal masks - connection on end of mask disconnecting, therefore unusable.
Sharps Bin	Needlestick injury to nurse
4 Wheeled walker	4 wheeled walker - front wheel fell off walking frame
Integrated Wooden Bedrail	Profiling Bed- patient found entrapped in bedrail.
Mobile Image Intensifier	Mobile C-Arm -Equipment exposed unattended
Manual wheelchair	RH backrest post folding mechanism fracture
Walking Aid	Rollator-right side brake failed to operate. Aid ran away from client causing him to fall.
Bed	Bed -released controller sprung up and hit staff member in right eye.
AER	Elevator wire connection - fell apart after being removed from machine
Nebuliser	Snapped at point where yellow and white parts join at nozzle.
Nebulizer Adaptor	Connection to O ₂ point snapped while attempting to place heater in circuit
Bedrails	Metal - bedrails-patient found with head hanging in gap between headboard of bed and bedrail.
X-ray Skull unit	X-ray skull unit - hit patient in the mouth
Electro Therapy Machine	Neurotherm machine - patient jerked in bed when machine turned on to test and impedance.
Cosmetic Laser	Unit can discharge through flast tube, if switched off while in ready mode
Gastroscope	Biopsy forceps opened fully but would not fully close.
Diathermy pencil	Diathermy failed 3 times
Trolley	Collapsed with a patient on it
Decontamination Issue	Patients required inpatient hospital treatment for secondary infections after extraction of lower wisdom teeth
Gall bladder removal bag	Gall bladder removal pouch - metal limbs of instrument separated.
Paediatric anaesthetic circuit	Inner tube of tubing missing
Wheelchair Back Rest	Fracture at left welded joint on backrest
Shower commode chair	Attendant propelled shower commode chair seat not corectly attached
Sterile Nebuliser Adaptor	Broke compromising oxygen supply
Infant Feeding Tube	Infant feed tube - blockage in tube.
Syrine Driver	Did not infuse medications,
Chair	Broken weld on framework of chair
Infusion Pump	Stopped infusion during cycle
Oven	Oven - door shattered whilst oven was in use.
Powered wheelchair	Left castor stem is fractured at end of threaded portion
Electrosurgical electrode	Electrosurgical electrode- ceramic end appeared to combust/breakdown
IV Giving Set	leaking
Syringe Needle	Needle dislodged from syringe
Surgical Instrument	Handle for bolt cutting head - broke during surgery
Infant Feeding Tube	Infant feeding tube - disconnected at part for oral syringes
Endoscope & accessories	Macroplastique Gun, Macropastique Implant & flexible Endoscope Needle - syringe repeatedly fell apart.
Uterine Balloon	Uterine balloon therapy- hole in balloon
Tissue Nibbler	End of broke off and lodged in patient's spine
Pregnancy Test Kit	Rapid hCG Single use pregnancy test - giving faintly positive results when patients are negative
Operating table	Head section fell apart when being moved - Injured carrier.
Angioplasty catheter	Balloon burst during inflation.
Endoscope & accessories	Macroplastique gun, implant & Flexible Endoscopic needle - Needle and implant syringe repeatedly fell apart

Product	Brief Description
Paediatric bagging set	Failed when staff tried to ventilate patient after respiratory arrest.
Curtain Rails	Curtain Rails - Continuously falling off brackets.
Needle	Needle stick injury to left thumb
Surgical gloves	Surgical gloves - 3 pairs ripped
IV Cannula	Wings fell off device whilst being inserted by doctor.
Satin Slip Intubation Stylet	Satin Slip Intubation Stylet - part of plastic left behind after removal
Multi Function Monitor	monitor - delay in obtaining vital signs readings in an emergency
Glass Ampoule	3 glass ampoule tops broke while being opened.
Surgical power tool	Bottom of battery fell into instrument tray.
Cardiovascular implants	Shaft became detached from balloon during transfemoral left angioplasty
Endoscopes & accessories	Flexible Cytoscope - grasper forceps could not get through tip of scope.
AER	Beige elevator/bridge channel connector - pin at centre of connector disconnected
Foley Catheter	Split into two halves
Thermal balloon Ablation	Thermal balloon ablation - pressure within balloon increased then dropped to zero.
Theatre trolley	Theatre trolley - amputation tip left index finger
Ligature clip	Misfired on 3 occasions with 3 different ligature clip instruments.
Dialysis Machine	Did not alarm when replacement bag had emptied
Lens	Appears cloudy and yellow in colour, should be clear and no colour
Defibrillator	Failed to deliver shock
Bedrail/mattress	Extra high (3bar) bed rails, Air flow mattress - patient found lying in between mattress and rail
Oxygen Mask	Oxygen mask and tubing - connection between tubing and mask blocked with plastic
Bacterial Filter	Bacterial filter for lung function testing-filter blew apart and hit patients front tooth when patient blew into it
Cardiac Catheter	Fell apart when being removed after procedure
Manual wheelchair	LH Backrest post folding mechanism fracture
PCA Device	Half Day Infusor - patient received too much morphine
Multi port IV Extension	Bio-connector had dislodges
Giving Set	Rubber connector had come away from the giving set
Waveform Calf Simulator	Discoloured area to patients calf area
Bed	Cot sides off bed
Syringe driver	Malfunction suspected after immersion in water
Feeding Tube	Leaking at connector during feeding operation.
AER	Bridge channel connector - pin disconnected from lead during reprocessing.
AER	Bridge channel connector - pin disconnected from lead during reprocessing.
AER	Bridge channel connector - pin disconnected from lead during reprocessing.
Wound Drain	Difficulty obtaining haemostasis.
Air Tool	Blood stain discovered on hosing connection after sterilization.
BiPAP Ventilator	Transformer malfunctioned causing ventilator to fail.
Condom	Ruptured during transvaginal scan
Wheelchair	Bracket holding wheel to wheelchair snapped
Wheelchair	Crossbar under seat broke
Amiodarone Syringe	Syringe was not patent due to manufacturers defect
Electrically powered reclining chair	Patient received electric shock (L) arm
Diathermy pencil	Connection fell off
X-Ray Machine	No x-ray screening available
Dental Mirror	Disposable Dental Mirror - reflective mirror face fell off
Linear Scope	Unknown residue evident after thorough cleaning
Manual wheelchair	Lower frame tube fractured
Gauze Swab	Gauze Swab - x-ray detectable line became detached from gauze swab.

Product	Brief Description
X-ray detectable gauze swabs	X-ray detectable gauze swabs - went on fire during a procedure.
X-Ray equipment	Fluoroscopy equipment - table 'broke down'
Giving Set	Leak at join between anti siphon valve and the tubing.
Patient Hoist	Faulty and emitting noxious smell due to faulty circuit board
Stainless steel bowl	Sharp edge caused cut to left thumb
Breathing Sensor	Breathing sensor - piece of adhesive file tape found inside the d-lite sensor.
Haemodialysis Machine	Tubing connected to Pi Sensor partially disconnected, resulting in fluid loss
IV Giving Set	Rapid infuser leaked and contaminated heated circulation water system.
IV pump	Failed to administer fluids and did not alarm
Endoscope Cleaning Brush Set	Blue brush stuck in gastroscope and cleaning adaptor
Amiodarone Syrine	Amiodarone Syringe - not patent due to manufacturers defect
Rubber seal within window frame	Rubber seal within window frame - attempted self harm using rubber seal
White sack holder waste bins	White sack holder waste bins - danger of possible self harm using plastic bag or rubber band
Flexi Flow Patrol Pump	Delay in delivering feed
Endonbronchial Tube	Incorrectly labelled
Gilles Forceps	Gilles Forceps - Burn index finger (L) hand
Hoist	Cradle and sling - cradle dipped and base of hoist tipped while patient was being hoisted.
Delivery Forceps'	Broke in the middle of a caesarean section.
Defibrillator	Failed to operate when disconnected from power supply to monitor patient during transfer.
Syringe driver	Not working properly
Defibrillator/monitor	Fault with equipment
Metal Shutter	Fell from window causing damage to vehicle and missing woman and child.
Filshie Clip Applicator	Disengaged during Laparoscopic Sterilisation
Uterine Manipulator	Manipulator - perforated uterus
PCA Device	Locked during use on a set protocol
Perching Stool	Right armrest broke off stool.
Electric bed	Wires on motor of bed became frayed and exposed live wires after being entangled in scissor mechanism of bed.
Spoon	Bite reflex spoon - cracked when client bite down on it.
Image Intensifier	Vascular Intensifier and General Intensifier - both machines failed to function properly
Reverse Osmosis Machine	Reverse Osmosis Machine -Leaking water from a sealed weld.
Gloves	Sterile gloves contained in "Wound care pack option 2" - tear and split easily
Thermachoice machine	Machine alarmed pressure high during balloon ablation procedure
Hoist	Hoist raised up to highest point as soon as it was connected without controls being touched.
Blunt tip trocar	Pin came out of clamp
Dental forceps	Dental forceps' - broke across joining pin
Toilet Door	Toilet door - trapped fingers
Hip Prosthesis	Thompson Hip Prosthesis - Fracture of greater trochanter
Ventilator Sensor	Single Use Flow Sensor - 2 pieces of sensor found in the blue 'T' piece of ET tube
Balloon Catheter	Balloon burst
Suture	Could not remove thread when trying to remove stitch from wound.
Suture Material	Unable to remove suture
Needle	Domestic pricked her finger on needle.
Swabs	4x4 swab - disintegrated after surgery exposing raytec
Chair	Fell apart when patient was being transferred from chair to bed.
Gastrostomy Kit	Direct Gastrostomy Kit - tube had faulty valve.
Syringe Pump	Loud bang heard when flex was attached and pump stopped working

Product	Brief Description
Laboratory Analyser	Clinitest Status Machine - Machine giving wrong results
Atropine Sulphate injection	End of syringe fused and rendered useless
Wheelchair	Modular wheelchair - left caster locked
Needle	Verrus Needle - design alteration
External cardiac pacemaker	Functioning erratically
Adapted motor vehicle	Ford Focus - Adapted motor vehicle - steering wheel became detached from steering column
Oscillating fan	Oscillating fan - caught fire and melted
Disposable vaginal speculum	Disposable vaginal speculum - broke during cervical smear
Endometrial ablation kit	Endometrial ablation disposable device kit - Both Devices failed cavity assessment
Surgical Power Tool	Pneumatic Foot Control drill/cutter - problem with foot pieces
Artificial Limb	Senior foot size 28 Right - keel coming away from foot shell allowing excessive movement
Needle	Novofine Needle - nurse sustained needle stick injury
Ventilator Sensor	Anaesthetic machine - failed to ventilate.
Filohie Clip Applicator	Filohie Clip applicator - found to contain blood products
Wound drainage system	High vacuum wound drainage system - piece of tubing left in patient
Hoist	Hoist - became loose - patient slipped to floor
Rise and Fall Chair	Riser/recliner chair - child put head under chair while being lowered
Monitor	Monitor - failed to operate
Medical O2 cylinder	Connection at top of cylinder shot off , fell to floor and released gas bruising clients right hand and causing stress
Balloon Ablation	Catheter failed to heat to correct temperature to allow procedure to continue.
Image Intensifier	X-ray monitor failed during ERCP procedure
Forceps	Surgical - tendon braiding forceps - 2 reported with teeth missing
Charnley pins and chain	Charnley pins and chain - broke on use
Oxygen Flow meter	Oxygen flow meter - 9 out of 20 oxygen flow meters found to be leaking.
Laryngoscope blade	Laryngoscope blade broke during daily check
Iontophoresis	Patient received burn to left middle finger
Foley Catheter	Catheter - fell out, tear in balloon
Epidural pump lockbox	Epidural pump lockbox -Bolus button cover broken and button exposed
Image Intensifier	Failure of one 'c-arm' fluoroscopy machine due to overheating.
X-ray Equipment	x-ray Equipment - failed to switch on first time
Manual wheelchair	Poor quality brazed joint
PCA Device	Query over PCA device
Dressing Pack	Dressing pack - dead fly discovered in pack
Blunt Tip Trocar	Blunt Tip Trocar - pin of device became disconnected from hinge.
Catheter	Tear in the balloon
Walking Aid	Wheel fell off
Bed with bedrails	Child caught foot between mattress and lower cot side rail.
Trocar Cannular	Filshie clip disposable Trocar - blade did not function correctly
Powered wheelchair	Back collapsed due to bolts snapping
Diathermy Machine	Patient stated he had sustained a diathermy burn
Endrometrial Ablation	Disposable device kit failed on two separate occasions
Intramedullary Nail	Implant failure
Theatre Table	Theatre Table - tilted downward when patient was transferred on to it.
X-ray detectable gauze swabs BP type 13	No red tie around the bundle of swabs.
Powered wheelchair	Hinge spigot and lower hinge is fractured
Powered wheelchair	Castor crown spindle is fractured and separated.
Blunt Tip Trocar	Blunt Tip Trocar - silver pin became disconnected from the Trocar whilst blunt port was being inserted.

Product	Brief Description
Cot side	Two lower rails of cot side fell off
Femoral component	Patient fractured neck of femoral component
Falcon Deep Fat Fryer	Deep fat fryer- overheated and went on fire
Thermal Balloon Catheter	Failed to operate correctly due to prick holes in balloon.
Linear Accelerator	Linear accelerator treatment couch - radiographer's arm got caught between moving bed and base of bed
Estates	Patient locked themselves in bathroom and attempted to self harm
Syringe Driver	Infused drugs over 3 hrs instead of 24
Walking Aid	3 wheeled walker - being used off design - to transport Oxygen bottle.
Theatre Bed	Theatre bed- release button not functioning properly
Cot side	3 rungs have fallen off and 4th is loose
Surgical Instrument	Retrieval basket could not be removed from patient
IV Giving Set	Small crack leaking fluids
Estates	Light bulb/lamp - exploded and glass shattered over floor
Trolley	Faulty shelf on trolley
Commode	Wheel fell off causing patient to fall and bump head
Hoist	Left shoulder loop of sling detached from hoist - client fell fracturing rib.
Surgical tape	Surgical tape - small amount of skin from inner canthus from both eyes attached to tape on removal.
Arthroscopic shaver blade	Shaver-shredding tiny threads into a shoulder wound.
Hoist	Clip on sling fractured patient slide to floor
Image Intensifier	Would not work to finish the case.
Endoscope Cleaning Brush Set	Endoscope Cleaning Brush Set - brushes too short to feed through scope properly.
ASTOPAD	Two patients received burn marks due to mattress overheating
Scopes	Outer casing showed signs of abnormal rippling on the surface.
Internal Pacemaker	Guident - Contak Renewal TR2 - header containing the lead connections was coming away from the device body during elective box change for normal battery depletion. INVESTIGATION BEING DONE BY MHRA
Thermometer	Thermometer - calibrated as oral not tympanic.
Foley Catheter	Catheter split
Dishwasher	Dishwasher - went on fire due to faulty thermostat
Video Endoscope	Badly discoloured after 2 wash cycles
Trocar	Inner central section was released causing gas to escape
Needle	Broke during procedure.
Thermal Balloon Machine	Failed during procedure.
Battery	Battery - exploded when generator failed to start
Coronary Stent	Stent dislodged from delivery balloon during a procedure
Digital Hearing Aid	Digital hearing aid - came apart leaving foreign body in external auditory canal
Ligature clipper	Failed to close properly to prevent bleeding from vessels.
Toilet seat	Toilet seat 4" - client fell off toilet and bumped her head
Nebulizer	Issue with the Instructions for Use. Label obscuring the warming information.
Surgical air tool	Surgical air supply in theatre - ceiling pendant - air hose disconnected from ceiling supply
Plastic Tray Cover	Scope had not been decontaminated. Confusion over tray cover.
Defibrillator Pads	Disposable Defibrillator. Pads - Abrasion to Sternum
Fastload CT Syringe Pack	Air Embolus and syringe failure
Pulse oximeter	Blister Baby's Foot
Wheelchair	Broken castor spindle.

FURTHER ENQUIRIES

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