

Device Bulletin

Guidance on the safe and effective use of batteries and chargers for medical devices

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1 Executive summary

The MHRA continues to receive reports where users/carers have been injured as a result of batteries or chargers failing in use. The reports cover a variety of issues including:

- disastrous failures, where the battery overheats, leaks acid or explodes
- unexpected battery exhaustion during use
- inadequate battery and charger maintenance
- incorrect charging of rechargeable batteries
- use of replacement batteries that do not meet the required specification
- poor training of staff in battery usage, maintenance, charging or replacement requirements
- battery chargers and their leads and connectors overheating
- use of battery chargers that are incompatible with the batteries in the medical device.

This Device Bulletin has been prepared in consultation with a wide range of stakeholders to give general guidance to users, carers, health services, healthcare professionals, manufacturers and others involved in the provision, use and maintenance of medical devices and equipment with a battery.

The content identifies a wide variety of issues affecting batteries and chargers used with medical devices that generate risks to the safety of device users, healthcare staff and others. It gives guidance on reducing or removing the risks associated with battery related applications.

2 Introduction

Batteries are used in many different types of medical devices and equipment from simple assistive technology aids to mobile X-ray equipment and pacemakers. Since batteries allow medical devices to be portable, they are used for powering many personal medical devices, which are worn on the body or are used inside the body. Battery power is also well suited to diagnostic devices used regularly for short periods of time in the home. As a source of electrical power independent of the mains electricity supply, batteries can also provide back-up energy in the case of mains power failure.

The number of battery powered medical devices is expected to continue to grow as more people use them in their own home and local communities.

The electrical energy within a battery comes from electrodes tapping into the chemical reaction inside the battery. The materials within it are specially selected and specified to provide the particular type of required chemical reactions and avoid unwanted reactions, which could cause the battery to rupture, emit gas or interfere with the intended reaction that provides the electrical energy. Ideally, the required chemical reaction only occurs while electrical current is drawn. When the current stops flowing into or from the battery, the chemical reaction stops.

It is normal for a battery to heat up when current is drawn from it or when it is being charged. The ambient temperature affects the speed of the reaction within the battery, changing the electrical characteristics. For medical devices being worn or used at indoor temperatures, the ambient temperature range should not vary widely. Devices used outdoors may have to withstand a wider temperature range.

Some medical devices with a rechargeable battery source will need to be attached to the mains supply when the device battery is being charged. For others the batteries can be removed from the device for charging to allow the device to continue to function using replacement battery(s) whilst the original batteries are being charged. Some devices have constant trickle chargers that operate all the time the device is not being used.

3 Battery types

Batteries generally fall into one of two categories – the disposable non-rechargeable type, known as a primary battery and the rechargeable type, called a secondary battery. The two types differ fundamentally since it is not normally possible to recharge a primary battery and doing so may lead to them rupturing under charge; instead, these must be replaced when exhausted. Secondary batteries may be recharged many times.

Examples of non-rechargeable (primary) batteries	Examples of device
Zinc-air	Hearing aids, cardiac monitors and transmitters
Alkaline manganese	Audiometers, personal monitors, otoscopes
Lithium	Pacemaker, AED (automated external defibrillator)

Examples of rechargeable (secondary) batteries	Examples of device
Lead-acid	Portable X-ray machines, wheelchairs, critical care patient monitors
Lithium-ion	Infusion pumps, defibrillators, myoelectric upper limb prostheses
Nickel-cadmium (NiCd)	Infusion pumps
Nickel-metal hydride (NiMH)	AED (automated external defibrillator), infusion pumps

Lead-acid batteries. Classic versions have a liquid component – sulphuric acid. If placed on its side or at an angle the electrolyte will leak out. This includes most maintenance-free types. The alternatives to ‘liquid’ lead-acid batteries are gel cell and AGM (absorbed glass mat) batteries. The gel cell battery has its electrolyte in a gelled state, whilst in the AGM it is held in a fibre-glass sponge. Both are sealed construction and so cannot leak unless the case is broken.

Some lead-acid batteries are sealed and have vents that only open if the internal pressure exceeds a predetermined value. Lead-acid batteries are

best for high capacity/high current applications, and tend to be big and heavy.

Lithium-ion batteries. This technology offers a high capacity from very small batteries. Commonly used in mobile phones and video recorders, they are just being introduced in medical devices (e.g. defibrillators). Frequent full discharge should be avoided.

Nickel-cadmium (NiCd) and nickel metal hydride (NiMH) batteries. By far the commonest battery type for many medical devices, offering a very long life and good capacity per unit weight – ‘power density’. NiCd batteries are robust devices with a long life, needing little maintenance, however, they do require regular cycles of discharge and recharge to avoid ‘memory effect’ (NiMH batteries are less affected by this).

Note: NiMH batteries are now replacing NiCd batteries in medical devices.

4 General battery functions

A battery can be used in many ways to operate a device. For example, it can:

- supply the power to the device at all times
- be used for back-up power or provide data retention during mains/supply failure (e.g. pre-set functions, clocks, timers etc)
- power accessories attached to a device (e.g. communication aids on a wheelchair)
- be used as a temporary power supply during transportation of patients
- power remote controls which operate devices
- power a number of associated devices in varying sequences via a smart controller (e.g. drive a wheelchair, operate an environmental control unit and power a laptop computer).

Where rechargeable batteries are used, the medical device may incorporate a charger for the batteries or a charger may be supplied as a separate freestanding unit.

5 Battery maintenance

Batteries will naturally discharge over time. If they are not tested and regularly replaced or recharged, they may not operate correctly when required and may even become damaged due to extensive discharge.

Possibly the most important parts to maintaining battery function and life are:

- charging rechargeable batteries correctly in line with the device manufacturer's instructions
- using the correct charger
- keeping the terminals clean and free from debris.

This is particularly relevant for devices that are infrequently used e.g. defibrillators.

Example 1

A battery powered defibrillator apparently failed to deliver sufficient energy for effective treatment. On investigation, the batteries fitted were found to be in poor condition. No other fault with the equipment was found. Batteries should be checked routinely, according to the device manufacturer's instructions.

All devices with rechargeable batteries should be maintained and serviced to the manufacturer's instructions. This may require regular charging and discharging of the battery and use of specialist test equipment to check the output and condition of the battery.

Example 2

A fatality occurred when an intra-aortic balloon pump failed during transportation of a patient in an ambulance. The device battery had not been maintained according to the manufacturer's instructions and a spare battery was not available. When transporting critically ill patients, ensure that a spare, fully charged battery pack is available during long journeys and that the battery status is checked in line with manufacturer's instructions.

Keeping batteries clean and free from debris will help lengthen battery life and prevent them from overheating. If a layer of debris collects on the cover of a battery between the two terminals, there is a chance that the debris may become conductive and speed up the discharge of the battery. Any cleaning should be done in line with the device manufacturer's instructions.

Example 3

A powered medical device, used during surgery, incorporating a strengthened (non-removable) case that housed the batteries, was dropped. This caused a hairline crack that went unnoticed. The device was then autoclaved which let in water/steam. When the device was subsequently used the heat generated by the battery turned the water to steam which caused the case to burst.

Non-rechargeable batteries cannot be repaired if damaged, and should be replaced. Repairs to the outer case of a rechargeable battery may be possible in some circumstances, but should only be carried out by appropriately trained personnel. This may involve the battery being returned to the original manufacturer.

Some patient monitors and infusion pumps have battery capacity indicators. If the batteries have not been charged/recycled to the manufacturer's instructions, the indicator itself may not give an accurate reading. This can result in the device shutting down unexpectedly.

Example 4

An infusion pump was used when transporting a patient between hospitals. Staff checked that the display on the pump said that the battery would last 4 hours (longer than the expected journey time), but the pump batteries expired after 90 minutes. On investigation it was found that the manufacturer's instructions stated that the battery indication was not reliable until 5 minutes after switch on. This had not been noted in training.

Batteries which no longer have any useable life should be removed from the device and replaced in line with manufacturer's instructions. When a device is not going to be used for a significant time it may be beneficial to remove the batteries from the device.

All batteries must be treated with care to avoid physical damage. Batteries can have high short circuit currents, which can rupture the battery or damage the circuit or cause overheating and fire. Safety standards generally stipulate that devices must have over current limit protection, in addition to terminal protection of the battery terminals.

Batteries should be subjected to as little environmental stress as possible. This includes storage or use outside the temperature range intended by the manufacturer e.g. storage in vehicles or unheated outdoor storage. Batteries, wiring and connectors in medical devices which are left outdoors must be protected from damp to avoid corrosion of the case, contacts, terminals or connections. High ambient temperatures will reduce the capacity and life of the battery; low temperatures will reduce the ability of most batteries to deliver their rated output. Batteries should be stored in line with the manufacturer's instructions.

Batteries in implantable medical devices such as pacemakers require no specific maintenance other than voltage monitoring by the clinician in line with the pacemaker manufacturer's instructions, since they are sealed within the implant.

6 Replacement batteries

Replacement batteries must provide the same power and lifecycle as those provided with the original device. If an inappropriate replacement battery is used, the device may not function or recharge properly leading to increased risk to users or healthcare staff. The device manufacturer's instructions and specifications should always be followed with respect to replacement. Replacement battery packs may also have to incorporate specific features such as active memory, current-limiting or capacity-indicating elements that interface with the medical device.

Example 5

A third party carried out the 'refurbishment' of defibrillator battery packs by replacing some of the internal cells but did not replace the original electronic components (thermistors). This produced unexpected depletion of the battery pack and inadequate advanced warning of failure of the defibrillator.

The manufacturer should provide the battery specification so that suitable replacement batteries can be purchased from third party suppliers.

Note: The device manufacturer may upgrade the specification of the battery or pack during the lifetime of the device to allow improved performance. The latest instructions from the manufacturer of the specific device should be followed.

Example 6

A user inserted the batteries the wrong way round in a portable audiometer. No one checked that the audiometer power light would not illuminate. This caused the device to short-circuit the batteries which then overheated and the current damaged internal wiring.

An organisation could be held responsible under health and safety law and civil liability in the event that a patient or member of personnel died or suffered personal injury or damage as a result of inappropriate replacement of batteries.

7 Chargers for batteries that power medical devices

The charger must be compatible with the batteries in a medical device. Incorrect output from a charger or an incomplete charging cycle could result in the battery being undercharged. This may result in a reduced time of operation of the device between charges. In other cases, incorrect output from the charger may result in overcharging with consequent deterioration of the battery performance and of the battery itself. The frequency with which batteries are charged depends upon use.

If batteries are charged incorrectly e.g. for excessive periods or they continue to be used when they are at the end of their lifecycle, they may give off gasses that are hazardous to people breathing the fumes. For lead-acid batteries any hydrogen gas emitted, if ignited, may cause explosion or fire. If manufacturer's instructions for use, charging and replacement parts are adhered to then gas and emissions should not present any problems.

Example 7

Powered wheelchair batteries being charged in a school classroom were not checked for condition and output during maintenance. The battery condition deteriorated over time and subsequent repetitive charging process led to gassing and emission of acid vapour which affected a number of children in a nearby classroom.

Only chargers supplied by the medical device manufacturer or chargers that are of equivalent specification should be used to charge batteries for medical devices, following the manufacturer's written instructions.

If these instructions are not followed then it could lead to the device failing to operate earlier than expected. Adequate time must be made available to ensure that batteries are fully charged at the end of the charging process.

Freestanding chargers should be positioned to allow a free flow of air into and out of the case venting or heat sinks. Chargers should not be covered or placed on long pile carpets. During the operation of charging, the charger should be close enough to the batteries and the mains socket to avoid strain on either of the leads. All usage should be in line with the manufacturer's instructions.

Chargers especially designed for non-rechargeable batteries are being marketed in the UK. Users should be aware that this charging process could be hazardous, and the recharged batteries have an extremely short shelf life. Batteries recharged in this way are not generally suitable for use in medical devices because of their unreliability.

An organisation could be held responsible under health and safety law and civil liability in the event that a patient or member of personnel died or suffered personal injury or damage as a result of supplying an inappropriate charging system.

8 Maintenance of chargers, connectors, cables, plugs and sockets

Connectors, plugs, cables and sockets can become worn or damaged through normal use, accidental damage or abuse, causing increased resistance to the power flow. If they remain in use, the device may fail to operate or they may overheat.

Example 8

A user forced a small, relatively fragile battery charger connector for a patient hoist into the socket the wrong way round, resulting in pin damage. The subsequent increased current through the plastic hand control caused burnt internal components and posed a risk of fire.

Although wear and tear and even heavy usage cannot always be prevented when the device and batteries are in service, every step should be taken to ensure that if damage does occur this is noticed quickly and repairs are made or the device is taken out of service before an adverse incident occurs.

Planned preventative maintenance should be in place for the batteries, chargers, connector cables, plugs and sockets. Systems should be checked on a regular basis by a suitably qualified professional using appropriate test equipment. The check should follow manufacturer's guidelines and include all parts of the battery and charging system including freestanding chargers.

An organisation could be held responsible under health and safety law and civil liability in the event that a patient or member of personnel died or suffered personal injury or damage as a result of inappropriate repair or maintenance of a device including its charging system.

9 Compatibility

During their design processes manufacturers of medical devices set the specification of the battery, charger, all leads and connectors and the charging process, to ensure that the device operates correctly during normal use. Manufacturers will also establish the detailed specification for maintenance and future replacements.

Batteries, chargers or processes that do not meet the specification set by the manufacturer can lead to incorrect operation of the device in use or to failure of the device. The user or others may be put at risk of:

- fire
- shock
- inhalation of fumes
- inappropriate treatment (e.g. misadministration of intravenous fluids via an infusion pump)
- malfunction of a device (e.g. patient hoist which does not operate as expected and leads to injury).

Example 9

A manufacturer of a powered wheelchair did not adequately specify the charging connector to be used. A subsequent change in the material by the third party supplier of the plug terminals lead to overheating of the connector during charging.

For applications where the chargers, batteries and leads are constantly disconnected and reconnected it is essential that the plugs, leads and sockets have been designed to cope with multiple use. Where repair services replace cables, plugs and sockets they must ensure that the device manufacturer's instructions are followed and that the correct cable wiring configuration and plug or socket are used.

If in a specific case it is deemed that the benefit of not using the battery, charger, connectors or charging process specified by the device manufacturer would give improved benefits then a risk assessment should be carried out to ensure that all components within a system are compatible and can be used safely. If a device fails in use following replacement of a part with one not corresponding to the device manufacturer's specification and this leads to the death or serious injury of a patient/user there is a greater likelihood of the organisation responsible for setting up the components being held liable for the injuries caused.

10 Risk management

When medical devices are prescribed or issued, it is essential that any residual risks concerning batteries or chargers are balanced against the anticipated benefits to the user or others. Where risks cannot be removed during the design process, subsequent warnings of any residual risk should be clearly displayed in the user instructions and product markings. All such warnings should be passed on to all users of the device.

The manufacturer should provide sufficient information on how to use the equipment safely which includes the necessary maintenance schedules of batteries and chargers that will keep the device operating safely throughout its intended life. For any applications where human contact is likely British and European Standards give specific detail on surface temperatures for medical devices [1, 2]. BS EN 12182 denotes a maximum surface temperature of 41°C for any equipment that a physically impaired user is likely to contact, regardless of the material, in order to remove potential risks to the user.

The risk to users or others of moving potentially heavy batteries, battery packs, chargers and the complete battery powered device should be carefully assessed and the risks should be removed or reduced to acceptable levels in line with health and safety guidance.

Users, carers and prescribers need to carefully consider the content of all such warnings of risks and the equipment should only be used and maintained in line with the manufacturer's recommendations. If the manufacturer's instructions do not fully cover these points then please report to the MHRA, using the details in section 14.

11 Disposal

Disposal of batteries is at present regulated by the Special Waste Regulations 1996 [3]. In addition, a new Hazardous Waste Directive is being brought into UK legislation, which covers the manufacture of some medical devices. This will include batteries and other waste electrical equipment. The Hazardous Waste Regulations for manufacturers are expected to come into force later in 2005. The purpose is that manufacturers have to prevent hazardous waste from entering the environment during disposal. A charge will probably be payable for collection, treatment and recycling of batteries.

Batteries in implants (pacemakers, defibrillators, neurostimulators, drug pumps) are not removed from the device prior to disposal. Care should be taken not to incinerate the implant (as clinical waste) as it could result in explosion with possible injury to personnel and damage to equipment.

12 Purchase (or prescription) of a battery powered medical device

To reduce the possibility of inappropriate battery powered devices being purchased, it is essential that a full performance specification of the entire system is established before any purchases are made. This must incorporate all elements such as battery type, charger type, charging process, maintenance and use. The main points to consider are set out in Appendix 1.

A similar process could also be carried out before a battery powered device is prescribed or used to ensure that it is the most appropriate device and that any limitations or special requirements set by the manufacturer are known.

A user organisation could be held responsible under health and safety law and civil liability in the event that a patient or member of personnel died or suffered personal injury or damage as a result of inappropriate purchase or prescription of a device.

13 Manufacturer's processes and information

Manufacturers of medical devices have to ensure that their devices meet all the relevant essential requirements of the Medical Devices Regulations [4] before affixing the CE mark and placing their devices on the market.

Once the manufacturer has established who the intended user of the device is, its intended usage and the lifetime of the device they must compile instructions for the use and maintenance of the device. Each device must be accompanied by the information needed to use it safely and to identify the manufacturer, taking account of the training and knowledge of the potential users.

This includes instructions on how to use the device, and for battery powered devices the charging procedures, regular inspection, maintenance and specification for replacement parts e.g. batteries, chargers etc.

For many devices the basic safety operating processes should be clearly labelled on the device and where rechargeable batteries are used, its charger. This will include all the information needed to verify whether the device is properly installed and can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the devices operate properly and safely at all times. For some implantable medical devices that are battery powered, additional information is required for batteries to avoid certain risks such as external interference.

If these instructions are not followed then the device may malfunction or other serious problems may occur.

If the instructions are found to be incomplete or lacking in specific detail the information should be reported to the MHRA as an adverse incident due to the potential risk it raises for users, carers and others (see section 14).

Example 10

A mobile pulse oximeter failed to indicate a low battery which could have led to a failure during transport. This was caused by the manufacturer failing to specify a sufficiently detailed charging regime for the device. As a result of reporting the issue to MHRA, manufacturer's instructions were modified to include a detail of when and how often the device should be charged.

Manufacturer's information as a minimum should include:

- how to access the batteries
- how and when to charge
- how connections are marked to prevent incorrect fitting
- how to connect, disconnect and reconnect
- how to maintain and if necessary how to clean the connectors
- how to test the output of a battery or charger to ensure its performance is adequate
- when to replace batteries
- details of any fuses, overloads, circuit protection and what to do if any of these are activated
- guidance on battery replacement
- battery voltage
- battery type
- time to charge batteries depending on conditions of use or storage
- maintenance required including frequency for batteries, chargers, cables and connectors.

14 Adverse incidents

What is an adverse incident?

An adverse incident is an event that causes, or has the potential to cause, unexpected or unwanted effects involving the safety of patients, users or other persons.

Adverse incidents may arise due to:

- shortcomings in the design or manufacturer of the device itself
- inadequate instructions for use
- inadequate servicing and maintenance
- locally initiated modifications or adjustments
- inappropriate user practices (which may in turn result from inadequate training)
- inappropriate management procedures
- the environment in which a device is used or stored
- selection of the incorrect device for the purpose
- conditions of use may also give rise to adverse incidents.

What should be reported?

Any adverse incident involving a device should be reported to the MHRA, especially if the incident has led to, or were it to occur again, could lead to:

- death, life-threatening illness or injury or the potential for death or injury in the future
- deterioration in health or permanent impairment of body structure or function
- the necessity for medical or surgical intervention
- hospitalisation or prolongation of existing hospitalisation.

You should also inform us of:

- any other device-related adverse incidents
- any minor faults and discrepancies

as these may take on a greater significance when aggregated with other similar events – they may help demonstrate trends or may indicate inadequate design, manufacture or quality assurance on the part of the manufacturer or supplier.

Reports of adverse incidents that appear to be caused by human error are also helpful as:

- the error may be partly (or wholly) due to deficiencies in the design of the device or instructions for use
- they will help prevent repetition of mistakes possibly by promulgation of advice or through improvements to the design of future devices.

Please remember that the MHRA is concerned with preventing the occurrence of adverse incidents, not with assigning blame or liability.

When should an incident report be made?

All incidents should be reported as soon as possible. Serious cases should be reported to the MHRA by the fastest means available, preferably online via our website www.mhra.gov.uk. Fax or e-mail reports should be followed up by a confirmatory telephone call. Telephone reports should be followed up as soon as possible by a written report.

The initial report of an incident should contain as much relevant detail as is immediately available, but should not be delayed for the sake of gathering additional information.

How do I report an incident?

We strongly recommend that, where possible, you report to us online via the MHRA website (www.mhra.gov.uk) or via our site on the NHSnet (nww.medical-devices.nhs.uk). Successful use of this route will provide the reporter with immediate confirmation of receipt and a unique incident reference number.

Paper forms for reporting incidents may be downloaded from the MHRA website (www.mhra.gov.uk) and then either completed electronically and e-mailed or printed and sent by mail or fax

Copies of forms are also available from:

MHRA

Adverse Incident Centre

Market Towers

1 Nine Elms Lane

London SW8 5NQ

E-mail: aic@mhra.gsi.gov.uk

Tel: 020 7084 3080

Fax: 020 7084 3109

Important: Full contact details (name, post held, address and telephone numbers etc) should always be included on your forms and in any telephone messages. This will allow us to contact you to acknowledge receipt of your report or message and to request any further information that may be needed.

Further details are given in DB2005(01) [5].

15 References and further reading

References

1. EN60601-1-8:2004 Medical Electrical Equipment. General requirements for safety. Collateral standard. General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems BSI: 2004.
2. BS EN 12182: 1999 Technical aids for disabled persons. General requirements and test methods BSI; 1999.
3. SI 1996 No 972 Special Waste Regulations. HMSO; 1996.
4. SI 2003 No 1697 and SI 2002 No 618 The Medical Device Regulations Amendment 2003 and The Medical Device Regulations 2002. HMSO; 2003.
5. DB2005(01) Reporting Adverse Incidents and disseminating medical device alerts. Medicines and Healthcare products Regulatory Agency; 2005.

Further reading

BS EN 12184: 1999 Electrically powered wheelchairs, scooters and their chargers. Requirements and test methods. BSI; 1999.

EN ISO 14971: 2000 Medical devices. Application of Risk Management to Medical Devices. BSI; 2000.

SI 1999 No 3242 The Management of Health and Safety at Work Regulations 1999. HMSO; 1999.
[www.hmso.gov.uk]

Department of Health. National Standards, Local Action: Health and Social Care Standards and Planning Framework 2005/06–2007/08; 2004. [www.dh.gov.uk]

Department of Health. Standards for Better Health; 2004.
[www.dh.gov.uk]

Obtaining publications

British Standards Institute (BSI)

389 Chiswick High Road

London W4 4AL

www.bsonline.bsi-global.com (last accessed June 2005)

HMSO

www.hmso.gov.uk

MHRA (and Medical Devices Agency publications)

Business Services

MHRA

Market Towers

1 Nine Elms Lane

London SW8 5NQ

Tel: 020 7084 3297

E-mail: dts@mhra.gsi.gov.uk

www.mhra.gov.uk

16 Glossary

Battery

Two or more cells connected in series (positive terminal of one cell is connected to the negative terminal of another) or parallel (positive terminal of one cell is connected to the positive terminal of another while their negative terminals are similarly connected). Often the term 'battery' is used imprecisely to refer to a single cell (an AA penlight battery is actually a single cell).

Capacity

The capacity of a cell is expressed as the total quantity of electricity involved in the electrochemical reaction and can be quoted in coulombs or more commonly ampere-hours of current that can be withdrawn from a cell under specified conditions (such as temperature, discharge current, load). Capacity can also be considered in terms of watt-hours by taking the voltage of the battery into consideration. Capacities are often quoted per unit volume or per unit mass.

Cycle

Discharge and recharge of a secondary cell or battery returning it to its original condition.

Cycle life

Discharge and recharge of a secondary cell or battery returning it to its original condition.

Deep discharge

Withdrawal of at least 80% of the capacity of a cell or battery.

Discharge

Conversion of chemical energy into electrical energy and the withdrawal of the electrical energy from a cell or battery.

Free electrolyte

Liquid electrolyte which is not immobilised in any way in a cell.

Maintenance-free battery

Battery that does not require electrolyte to be replenished periodically. These batteries still need to be checked for correct operation and level of charge during maintenance checks.

Memory effect

Following repeated cycles to the same depth of discharge (but not full) a battery can temporarily lose capacity (this often applies to nickel-cadmium cells). If discharged repeatedly by a small amount, crystalline deposits form on the electrodes. If a deeper discharge is demanded the

crystalline deposits prevent deeper discharge and the battery appears to 'remember' a particular discharge level. This can be overcome by period conditioning (qv).

Nominal voltage

Voltage of a cell or battery quoted by the manufacturer.

Overcharge

Forcing current into a secondary cell in which all material has already been converted into its charged state. This can lead to overheating and damage.

Period conditioning

Maintenance procedure carried out on some cells over a period to prevent memory effect or other cell imbalances. It often consists of a deep discharge followed by a steady charging cycle.

Primary cell

Cell or battery that is not intended to be recharged and that is discarded once all of the electrical energy available has been used.

Rated capacity

Number of ampere hours a cell or battery can deliver as quoted by the manufacturer. It is measured under specific conditions (such as temperature, discharge current, load). This is also known as the nominal capacity.

Shelf life

Period of time a battery may be stored under specified conditions before capacity is lost due to self-discharge.

Short circuit

A connection accidentally or intentionally made between points on a circuit between which the resistance is normally much greater.

Trickle charge

Maintaining a fully charged state by charging of a cell or battery at a very low rate to account for self discharge or periodic use. Not all types of secondary cells can be trickle charged.

Appendix 1

Points to consider before purchase or prescription of a battery powered medical device.

1 Is a battery powered device necessary or would a fixed mains powered device be more appropriate? Battery powered Mains
If battery powered then continue to 2

2 How long is the device required to be in operation?

- Are spare batteries/battery packs likely to be required to maintain function during this period? Yes No

3 Is a back-up battery required to cover power failure from mains or the main battery? Yes No

4 If the device has rechargeable batteries:

- Who will connect the charger?
- Who will disconnect the charger?
- Who supervises charging?
- Who carries out maintenance?

State any special requirement or limitations for the above tasks

5 If the device has non-rechargeable batteries:

- Who maintains the device?
- Who replaces and/or is in charge of battery replacement?

6 Charging environment

- Will the charging take place indoors or outdoors? Indoors Outdoors
- State any specific limitations due to space, ventilation or humidity

7 Considering the intended user's level of understanding and ability are there any:

- Special requirements that affect the type or design of the device, battery or charging system
- Limitations that affect the type or design of the device, battery or charging system

8 If the device is portable and includes batteries (and where applicable an inbuilt charger) are there any restrictions i.e. what is the maximum mass that can be moved or lifted safely by users, carer or others?

- Risk assessment conclusion including maximum mass that can be safely handled or other limitations

Note: For heavy lead acid batteries there may be a requirement for additional lifting aids during maintenance or replacement

9 If the battery pack is removable or is a separate unit what is the maximum mass that can be lifted safely by the user, carer or others?

- Risk assessment conclusion including maximum mass that can be safely handled or other limitations

Note: For heavy lead acid batteries there may be a requirement for additional lifting aids during maintenance or replacement

10 How long will the device be expected to be in service?

- What procedures are in place for planned replacement when uneconomical to repair/maintain in the future?

If the above points are answered in detail then a performance specification will have been compiled. This can be compared to the types of equipment available before the most cost-effective solution can be obtained.

Distribution

This Device Bulletin is of interest to staff involved in the purchase, fitting, care and maintenance of batteries and chargers, or who manage these processes.

Technical enquiries

Enquiries concerning the content of this Device Bulletin should be addressed to:

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Fax: 01253 596177

Ordering copies

Copies of this Device Bulletin are free to the NHS and public sector social care providers in the UK and may be obtained on written request from:

E-mail: dh@prolog.uk.com
Fax: 01623 724 524
Quoting reference DB2005(03)

Other establishments will be charged £15 per copy on written request from:

Business Services
MHRA
Market Towers 4/1
1 Nine Elms Lane
London
SW8 5NQ

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Medicines and Healthcare products Regulatory Agency

An executive agency of the Department of Health

We enhance and safeguard the health of the public by ensuring that medicines and medical devices work, and are acceptably safe.