

# GUIDANCE BULLETIN



## *Guidance on the Sale, Transfer of Ownership and Disposal of Used Medical Devices*

*Supplement to Medical Device and Equipment  
Management for Hospital and Community-Based  
Organisations (DB 9904 (NI))*



*An Executive Agency of the Department of  
Health, Social Services and Public Safety*

*Áisíneacht Feidhmeannach don Roinn Sláinte,  
Serbhísí Sóisialta agus Sábháilteacht Phoiblí*

***DB 9904 (NI) Supplement 2  
MARCH 2002***



The Medical Devices Agency helps safeguard public health by working with users, manufacturers and lawmakers to ensure that medical devices meet appropriate standards of safety, quality and performance and that they comply with the relevant Directives of the European Union.

Our primary responsibility is to ensure that medical devices achieve their fullest potential to help healthcare professionals give patients and other users the high standard of care they have a right to expect.

*The Medical Devices Agency is an Executive Agency of the Department of Health*



The key aim of the Northern Ireland Adverse Incident Centre (NIAIC), part of Health Estates, is to record and investigate reported adverse incidents involving Medical Devices and equipment used in Health and Personal Social Services in Northern Ireland and to issue warning notices and guidance to help prevent recurrence and avert patient or user injury. NIAIC has direct links with MDA who co-ordinate across the adverse incident centres in England, Scotland, Wales and Northern Ireland. NIAIC also disseminates safety information in Northern Ireland, including information provided by MDA.

*Health Estates is an Executive Agency of the Department of Health, Social Services and Public Safety.*

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## EXECUTIVE SUMMARY

The Medical Devices Regulations 1994 applies to medical devices placed on the market for the first time. There is no legislation specifically covering the resale or reuse of medical devices or equipment. However, there is general legislation within the Consumer Protection Act 1987 and Special Waste Regulations (NI) 1998 that is applicable. This supplement draws these elements together into one guidance document. It aims to give guidance on the sale, transfer of ownership and disposal of unwanted used medical devices. The key points addressed are:

- Transfer of ownership (i.e. sale or donation).
- Decommissioning.
- Disposal as waste.

This guidance is a supplement to our publication DB9904 (NI) 'Medical Device and Equipment Management for Hospital and Community-based Organisations' but it can also be used as a stand-alone document.

## 1. OBJECTIVES

The purpose of this guidance document is to safeguard public safety when used medical devices are disposed of either by sale, donation or as scrap/waste.

This bulletin is aimed at people who intend to dispose of used medical devices, such as hospital equipment managers, loan store managers, laboratory equipment managers, charities, dealers and individual users. The content is intended to provide sufficient background for a person to make an informed decision.

The term "medical device" is used throughout this bulletin to encompass both medical devices and medical equipment. The range covered includes, but is not restricted to:

- medical devices;
- assistive technology for disabled people;
- medical equipment;
- in vitro diagnostic devices (IVDs).

The reuse of single-use medical devices is not recommended. NIAIC Device Bulletin DB2000/4 (NI) advises users not to reuse medical devices intended to be used once, and discusses the implications if this advice is not heeded. The reuse of custom-made medical devices and implants has similar implications and consequences. Therefore this document will not cover implants, custom-made medical devices and single-use medical devices.

This guidance covers medical devices that have been used previously. The reuse of medical devices is increasing. For example the National Audit commission report (Fully Equipped) encouraged increased recycling of medical devices for older/disabled users, in order to maximise NHS resources. The use of previously owned or disposal of medical devices raises particular safety concerns, and there is currently no specific medical device legislation governing this. Medical devices being reused after full refurbishment are covered by the Medical Devices Regulations 1994 and if the goods are resold, the Sale and Supply of Goods Act 1994, the Consumer Protection Act 1987 and the Consumer Protection (NI) Order 1987 apply. In all these there is a requirement for the goods (e.g. used medical devices) to be safe and fit for this intended purpose.

It should be noted that in the majority of cases where a medical device has been issued or supplied by a HSS body, legal ownership is usually retained by the HSS body, even if the equipment is on long-term loan to the user.

This bulletin covers tasks that should be performed prior to transfer of ownership of a medical device and information that should accompany the medical device. A template for a checklist has been compiled to aid with this process (see Appendix I). This bulletin also covers safety aspects and regulations that should be taken into account if a medical device is to be decommissioned or disposed of as waste.

The major topics covered are:

- transfer of ownership;
- decommissioning;
- disposal as waste.

## 2. TRANSFER OF OWNERSHIP

### 2.1 Introduction

This section highlights relevant legislation and information to be supplied with any medical device where the ownership is to be transferred (e.g. on sale or donation to charity) to safeguard public health. Failure to observe statutory requirements when selling used medical devices could lead to prosecution or liability for damages, therefore, precautions should be taken. These are outlined in section 2.3.

### 2.2 Liability

Before sale or transfer of ownership of a medical device, both parties should thoroughly investigate the legal liability aspect in consultation with their own legal advisor. For example, the purchaser may inherit the liability for previous incidents or unpaid hire purchase costs if appropriate contracts are not used. A vendor may request the purchaser to sign a disclaimer, to the effect that the vendor has no future responsibility for the medical device. Alternatively, the product may be 'sold as seen' or 'buyer beware'. In these cases liability is usually transferred to the purchaser. However, the vendor may retain contributory negligence. The level of negligence may be determined by the level of information supplied by the vendor. In general, the more comprehensive the information the lower the inherited liability is likely to be. Therefore, legal advice should be obtained before sale.

### 2.3 Regulations

The Medical Devices Regulations 1994 regulate the placement of all medical devices on the UK market, whether they are single-use or reusable medical devices. However, the Regulations only apply when the medical devices are first placed on the market as new or fully reconditioned.

The Regulations do not apply to CE-marked or non-CE marked medical devices when they are re-sold. These used medical devices (including assistive technology and diagnostic equipment), although not covered by the Medical Devices Regulations, are still required to be safe under other national provisions, including:

- Consumer Protection Act 1987 (Consumer Safety and Product Liability)
- Consumer Protection (NI) Order 1987.
- Sale and Supply of Goods Act 1994.
- Health and Safety at Work (NI) Order 1978 (sections 3 and 6).
- Trade Descriptions Act 1968.
- The Electrical Equipment (Safety) Regulations 1994.
- Unfair Contract Terms Act 1977.
- The Control of Substances Hazardous to Health (NI) Regulations 2000.
- Special Waste Regulations (NI) 1998.

Prosecution is possible under any of the above references. This applies to both new and used medical devices. There are strict product liability provisions where a product has caused harm, whether or not the supplier or manufacturer was negligent within Part 1 of the Consumer Protection Act 1987 if the product is found to be defective (i.e. does not provide an expected level of safety). It is also a criminal offence under the Health and Safety at Work Order (NI) 1978 if the provisions relating to general duties are contravened by carrying out activities that expose patients or staff to risk. In addition, a person who supplies or offers to supply a product which is not reasonably safe may be served with a notice under Part 2 of the Consumer Protection Act 1987 prohibiting the supply of goods or requiring the person to issue, at their cost, a warning about the hazard.

Essential requirement 13b of the Medical Devices Regulations requires the original manufacturer to provide:

"all the information needed to verify whether the medical device can operate correctly and safely, plus details of the nature and frequency of the maintenance and calibration needed to ensure that the device operates properly and safely at all times".

In order to ensure good practice, the vendor should apply this principle to the sale of used equipment or on transfer of ownership, to ensure device safety.

This information should be available for a prospective purchaser to view before sale and be supplied with the medical device on completion of the sale.

On selling or donating used medical devices the following should be supplied with the medical device to the purchaser, by the vendor as a minimum:

- a clear statement that the medical device is being resold;
- documentation of decontamination;
- user manuals and training requirements;
- service history and manual;
- medical device history;
- quality assurance test details.

#### **2.4.1 Decontamination**

Where applicable, medical devices should be decontaminated before reuse, sale or disposal. Manufacturer guidelines normally indicate if this is applicable and the method that should be adopted.

Decontamination is covered in previous NIAIC publications; Device Bulletin DB2000/2: 'Medical Devices and Equipment Management: Repair and Maintenance Provision', and by Microbiology Advisory Committee to Department of Health (1996): Sterilization, Disinfection and Cleaning of Medical Equipment: Guidance on Decontamination - Parts 1, 2 and 3.

All used medical devices, whether being returned to the original manufacturer or transferred to a third party, or being sent for repair or maintenance should be supplied with a certificate of decontamination. Advice on procedures to be followed if medical devices are contaminated and constitute a biohazard is contained in Professional Estates Letter PEL (94)34 and SAN (NI) 95/24. It is illegal to send contaminated items through the post. For more information please see:

- PEL (94) 34 'Decontamination of equipment prior to inspection, service or repair'.
- DHSSPS 'Transmissible spongiform encephalopathy agents: safe working and the prevention of infection'.
- SAN (NI) 94/34 'Decontamination of medical devices and equipment prior to investigation, inspection, service or repair'.
- The Carriage of Dangerous Goods by Road Regulations (NI) 1997.
- The Carriage of Dangerous Goods by Rail Regulations (NI) 1998.

#### **2.4.2 User manuals and training**

The original user manuals should be supplied along with the medical device, in order to ensure clear and safe use of the medical device. Recommendations on any other necessary training should be given. The original equipment manufacturer should be able to provide this information. In addition any updates which have been issued since manufacture should be included. These manuals may otherwise be difficult to obtain (see also section 2.5).

Full details on how to maintain or service the medical device should also be supplied with the used medical device. This may be included in the user manual or supplied separately. Guidance on repair and maintenance is available in two NIAIC Device Bulletins:

DB 2000/2 (NI): 'Medical Devices and Equipment Management: Repair and Maintenance Provision' and also in DB9904 (NI): 'Medical Devices and Equipment Management for Hospital and Community-based Organisations'.

If manuals and training information are not available, the medical device may have been rendered unsuitable for passing onto a new user.

### **2.4.3 Device usage and service history**

A medical device usage and service history should always be available for prospective purchasers before sale and then supplied with the medical device on the point of sale. The medical device should always have been uniquely identified throughout its life.

NIAIC recommends that, as a minimum there should be:

- a record of the reconditioning work carried out on the medical device including a record of replacement parts;
- a copy of all maintenance and servicing that has been carried out on the device including the name of maintenance/servicing organisation;
- a record of usage of the medical device;
- a fault log.

These recommendations are referred to in DB9904 (NI). Before sale or transfer of ownership of a medical device, both parties should thoroughly investigate the legal liability aspect of the service history and consult with their respective legal advisors.

## **2.5 Device Safety Updates**

It is recommended that the vendor should supply along with this information package the appropriate medical device safety updates, including NIAIC and manufacturer documents that have been released since the medical device was first placed on the market. If these are not supplied with the medical device the purchaser should ensure that there have been no product safety updates on this medical device since it was first placed on the market. The purchaser should always ensure that there is a method to keep up to date with any safety updates from the manufacturer in the future. This is because the manufacturer may not be aware who is the present owner of their medical device, and will not put them on their mailing list for safety updates. Alternatively, the manufacturer may have ceased trading.

For an up-to-date list of all safety related publications by NIAIC, refer to our website <http://www.dhsspsni.gov.uk/hea/niac.html>

## **2.6 Risk Management**

Risk Management is an essential tool to aid with the decision making process for disposing of a used medical device in the most appropriate and safe method. HSS bodies should consult their own risk managers and take into account their own corporate governance on this subject. HSS bodies in future may also have to take into account Controls Assurance Standards e.g. Professional and Product Liability.

### 3. DECOMMISSIONING

#### 3.1 Purpose

The purpose of decommissioning is to make the medical device and environment safe prior to disposal of the medical device.

Any medical device deemed not reusable should be decommissioned. Decommissioning of the used medical device should include decontamination, making safe and making unusable (see DB 9904 (NI), section H for further information for criteria determining when a device should be replaced). This is to ensure that an inappropriate person does not use the medical device and expose themselves to potential hazards.

Decommissioning larger medical devices often involves removal from a purpose built room or surroundings. For some medical devices such as tele-therapy treatment machines (e.g. brachy therapy equipment) there are also issues concerning radioactivity. Decommissioning of devices that incorporate radioactive sources must be done in accordance with the Ionising Radiations Regulations (NI) 2000.

For other medical devices that are mobile or housed in non-specific environments, as a minimum general safety checks should be carried out, such as power disconnection and cooling system disconnection. In addition, it is advisable to contact the original equipment manufacturer at this stage for information on decommissioning, even if they are not required to carry out the decommissioning of the medical device. The original equipment manufacturer should be able to provide details of any environmental, disposal, recycling or structural requirements. If the manufacturer has ceased to trade, consider contacting NIAIC for guidance on where to obtain further information.

## 4. MEDICAL DEVICE DISPOSAL

For methods of waste disposal it is of benefit to consult the original equipment manufacturer, as they should be able to provide details of the current techniques and processes applicable to their products.

### 4.1 Examples of Special Waste

Hazardous and difficult waste substances are defined in the Hazardous Waste Directive (Council Decision 94/904/EC) and the Control of Substances Hazardous to Health Regulations (NI) 2000, and may be toxic, harmful, corrosive, irritant or carcinogenic. Any device, which may contain or be contaminated with these substances in quantities above defined thresholds must be disposed of in accordance to the Special Waste Regulations (NI) 1998.

Special waste can include:

- Wastes containing metal (including mercury above 3%).
- Oil wastes (including poly-chlorobiphenyls).
- Wastes from coolants.
- Batteries containing lead, cadmium and mercury.
- Radioactive waste.
- Wastes from human or animal healthcare and/or related research.
- Waste from natal care, diagnosis, treatment or prevention of disease in humans.

### 4.2 Specialist Disposal Guidance

#### 4.2.1 *Electrical and electronic medical devices*

For specific situations regarding electrical and electronic medical devices there is also a draft European Directive on Waste from Electrical and Electronic Equipment (WEEE). It is anticipated that this Directive will come into force mid-2002. Vendors should ensure that purchasers are aware of the provisions of this Directive with regard to disposal of end-of-life electrical and electronic waste. The draft Directive is aimed at:

- the prevention of waste from electrical and electronic equipment;
- the reuse, recycling and other forms of recovery of such wastes;
- minimising the risks and impacts to the environment associated with the treatment and disposal of end-of-life electrical and electronic equipment.

This encourages improvements in the recycling of materials. It also recommends that the producer have responsibility to set up systems so that medical device owners and/or distributors can return end of life equipment (electrical and electronic).

#### **4.2.2 Battery disposal**

Specific guidance on disposal of batteries has been given in Device Bulletin DB9902 (NI).

#### **4.2.3 Packaging**

Packaging requirements are regulated by The Packaging (Essential Requirements) Regulations 1998. Please see section 2.4.1 for decontamination issues.

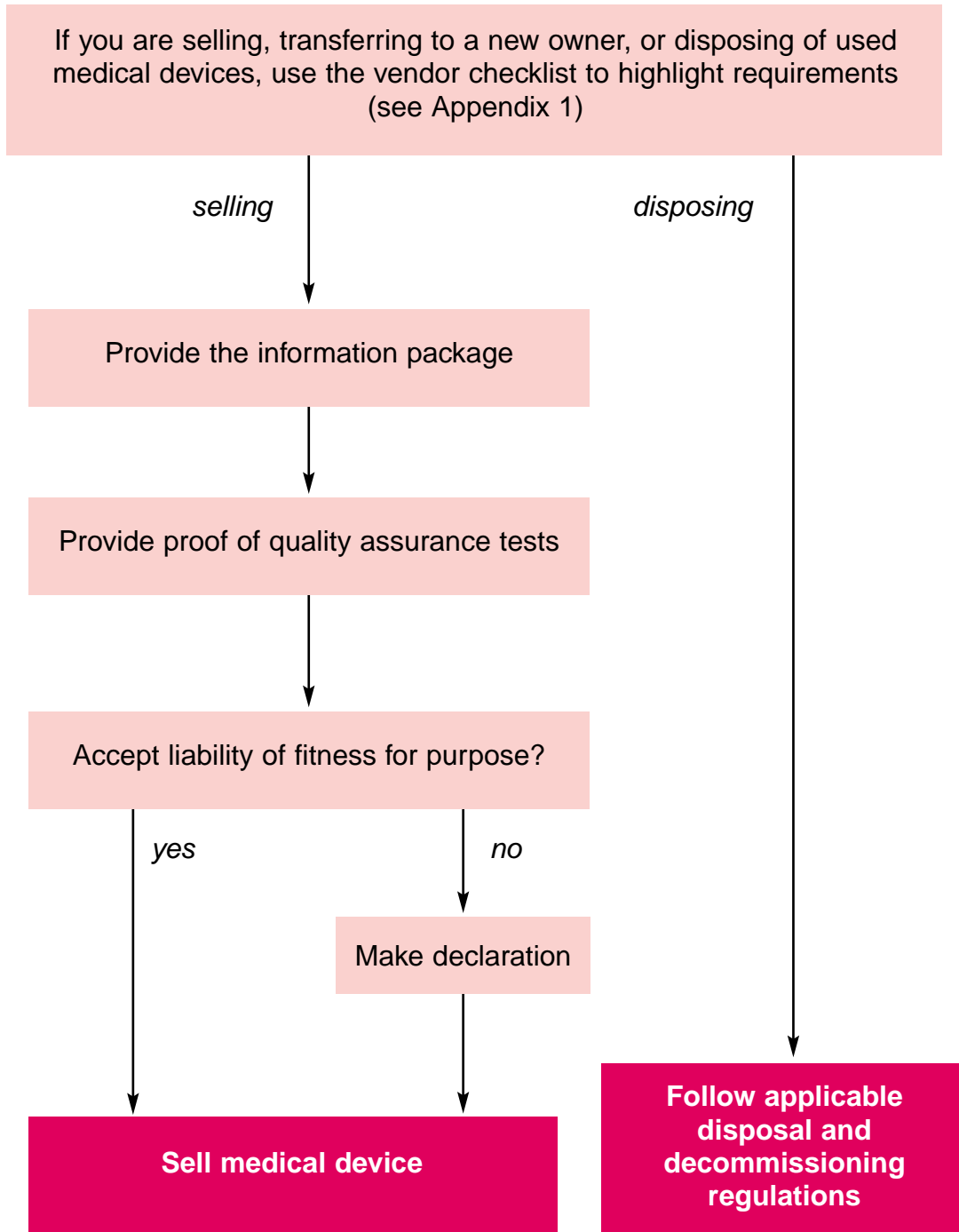
When returning medical devices to the manufacturer at end of life, or when transporting medical devices on other occasions ensure that they are appropriately decontaminated, packaged and secured. Also where road or rail is used the following should be considered:

- The Carriage of Dangerous Goods by Road Regulations (NI) 1997.
- The Carriage of Dangerous Goods by Rail Regulations (NI) 1998.
- Chemicals (Hazard Information and Packaging for supply) Regulations (NI) 2000.

(Note: Decontamination prior to transport or disposal is covered in 2.4.1)

## 5. CONCLUSION

The flow chart below provides a summary of the issues that need to be considered before selling or disposing of used medical devices.



## 6 GLOSSARY

**Disposal** - A process whereby a used medical device is removed from the clinical environment.

**Resale** - Sale of a used medical device to a third party.

**Used medical devices** - Reusable medical devices that have been used for one or more procedures.

**Pre-used medical device** - A medical device that was previously used by one or more users.

**Re-manufactured / Full refurbishment** - This term is used in the Medical Devices Regulations and applies to the re-manufacture and placing on the market of an 'as new' medical device. Devices that are fully refurbished and are placed on the market are covered by the Medical Devices Regulations.

Full refurbishment will vary for a given medical device but is generally considered to consist of:

- stripping into component parts or sub-assemblies;
- checking their suitability for reuse;
- replacement of components/sub-assemblies not suitable for reuse;
- assembly of the replacement components or sub-assemblies, testing of the assembled medical devices against either original or revised release criteria;
- the identification of the fully refurbished device by appropriate means.

**Recycling** - The return of a used medical device to a previous stage of the manufacturing process, especially conversion of waste to a reusable state.

**Transfer** - A transaction whereby ownership of a 'used medical device' is taken by a third party on a non-payment basis.

**Sale** - A commercial transaction whereby ownership of a 'used medical device' is taken by a third party in exchange for payment subject to contract.

## 7. BIBLIOGRAPHY

### 7.1 MDA/NIAIC Publications

DB2000/4 (NI), November 2000: Single-use Medical Devices: Implications and Consequences of Reuse (replaces DB9501 (NI)).

DB2000/2 (NI), November 2000: Medical Devices and Equipment Management: Repair and Maintenance Provision.

SAN (NI) (94) 34, July 1994: Decontamination of medical devices and equipment prior to investigation, inspection, service or repair.

DB9904 (NI), July 1999: Medical Device and Equipment Management for Hospital and Community-based Organisations.

DB9902 (NI), July 1999: The Safe and Effective Use of Batteries for Medical Devices.

Microbiology Advisory Committee to Department of Health: (1996): Sterilization, Disinfection and Cleaning of Medical Equipment: Guidance on Decontamination. Parts 1,2 and 3 ISBN 1 85839 518 6.

#### Other guidance

### 7.2 Health Estates/DoH Publications

Health Estates Professional Estates Letter PEL (94) 34 : Decontamination of equipment prior to inspection, service or repair. Department of Health.

Department of Health (1998) Advisory Committee on Dangerous Pathogens (ACDP)/Spongiform Encephalopathy Advisory Committee (SEAC) guidance: Transmissible spongiform encephalopathy agents: safe working and the prevention of infection. ISBN 0113221665

#### Regulations

### 7.3 Legislation

Consumer Protection Act 1987.

Consumer Protection (NI) Order 1987

Control of Substances Hazardous to Health Regulations (NI) 2000 (SR 2000 No. 479)

Council of the European Communities (1993) 'Council Directive 93/42/EEC of 14 June 1993 concerning medical devices', Off J Eur Comm; L169: 1-43.

Council of the European Communities (2000) 'Commission Decision of 3 May 2000 replacing Decision 1994/3/EC establishing a list of wastes pursuant to Article 1(a) of Council Directive 1975/442/EEC on waste and Council Decision 1994/904/EC establishing a list of hazardous waste pursuant to Article 1(4) of Council Directive 1991/689/EEC on hazardous waste (2000/532/EC)', Off J Eur Comm; L226: 3-4.

Council of the European Communities (2000) 'Proposal for a Directive of the European Parliament and of the Council on waste electrical and electronic equipment', Off J Eur Comm; C 365 E: 184-194.

Health and Safety at Work Order (NI) 1978 (SR 1978 No.384).

Management of Health and Safety at Work Regulations (NI) 1992 (SR1992 No.459).

Sale and Supply of Goods Act 1994.

The Carriage of Dangerous Goods by Rail Regulations (NI) 1998 (SR 1998 No 131).

The Carriage of Dangerous Goods by Road Regulations (NI) 1997 (SR 1997 No 248).

The Chemicals (Hazard Information and Packaging for supply) (amendment) Regulations (NI) 2001 (SR 2001 No168).

The Electrical Equipment (Safety) Regulations 1994 (SI 1994 No 3260).

The Ionising Radiations Regulations (NI) 2000

The Medical Devices Regulations 1994 (SI 1994 No 3017).

The Packaging (Essential Requirements) Regulations 1998 (SI 1998 No 1165).

The Special Waste Regulations (NI) 1998 (SR 1998 No 289).

Trade Descriptions Act 1968.

Unfair Contract Terms Act 1977.

## APPENDIX 1 VENDOR CHECKLIST

	Yes	No	N/A
Are there particular labelling and packaging requirements?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are disclaimers required against future claims?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Has the original manufacturer been notified of the change of ownership?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Has the medical device been the subject of any safety issues (e.g. recalls or product updates) and appropriate action taken?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Do safety warnings or limitations of use need to be provided?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**If selling or transferring the used medical device to a new owner, an information package should be provided including:**

	Yes	No	N/A
Decontamination certificate	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Service history	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Quality assurance tests or performance tests eg: PAT, battery (DB9805)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
User manual	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Service manual	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Usage logbook	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Unique identifier	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Y2K Compliant	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**If selling for export or donating to charities abroad consider:**

	<b>Yes</b>	<b>No</b>	<b>N/A</b>
Is an export certificate required?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Whether any foreign regulations apply?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Does the medical device comply with regional regulations?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are there any special requirements for transport abroad?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

**If disposing consider:**

Is decommissioning of the medical device required?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Has the medical device been adequately disabled?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Are any disposal regulations applicable?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

After completing this checklist, a risk analysis should be completed to establish safety and liability issues regarding the sale of the product





## **DISTRIBUTION**

This Device Bulletin should be brought to the attention of staff who intend to dispose of used medical devices such as hospital equipment managers, estates managers, facilities managers, loan store managers, laboratory equipment managers and individual users.

## **TECHNICAL ENQUIRIES**

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Further copies of this Device Bulletin are free and may be obtained on written request from:

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