

# FIELD BULLETIN

**(Northern Ireland Version)**

*Checks and  
tests for newly  
delivered medical  
devices.*



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

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

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Supplement to “Medical device and equipment management  
for hospital and community-based organisations” DB 9904 (NI)



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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## **Acknowledgments**

We are grateful to Charing Cross Hospital Department of Clinical Engineering for their contribution to Section 4.2.



## EXECUTIVE SUMMARY

This guidance document:

- replaces HEI 95 “Code of practice for acceptance testing of medical electrical equipment”, which is now withdrawn, and extends the scope of pre-first-use checks and tests to non-electrical medical devices;
- replaces HEI 140 part II “Code of practice for acceptance testing of electrically operated hospital laboratory equipment” for *in vitro* diagnostic medical devices, pending further guidance in this area;
- is designed to minimise the risks associated with using a product for the first time;
- is a supplement to DB9904 (NI) “Medical device and equipment management for hospital and community-based organisations”.

User organisations whose procedures require implementation of document updates should insert it in their DB9904 (NI) folder. However the guidance is designed to be self-contained, and this supplement can be used as a stand-alone document.

# 1. OBJECTIVES

## 1.1 Scope

We present a straightforward approach to choosing appropriate pre-first use checks and tests for most newly-delivered products (see Section 2).

However two exceptional product groups need special treatment:

- large, complex products which need installation and commissioning (see Section 4.1).
- products which may need a local certificate of safety - for example products **not** manufactured under the Medical Devices Regulations<sup>1</sup> or supplied second-hand (see Section 4.2).

A risk assessment is needed to ensure that tests and checks are appropriate for a particular product. Section 2 provides a simple rule-based risk assessment which leads directly to appropriate lists of checks and tests for the majority of products. The two exceptional groups involve user organisations in a local risk assessment to determine an appropriate procedure.

Chapter 5 of DB9904 (NI): “When a new device is delivered” is also relevant. This supplement replaces and extends HEI 95 (“Code of practice for acceptance testing of medical electrical equipment”), which is now withdrawn.

## 1.2 Introduction

User organisations should check the safety and functionality of newly-delivered medical devices.

Aims for all devices include:

- checking that the correct product, complete with manuals and accessories, has been supplied;
- providing assurance that product items have been delivered in good condition and (where relevant) in working order;
- ensuring that risks associated with using a particular model for the first time have been minimised.

Additionally, for re-usable devices:

- recording the device on a database, so that appropriate maintenance can be initiated and, in the event of an adverse incident when a new device is first used, evidence of good practice can be produced.
- complying with safety legislation.

These aims are relevant to all medical devices - not just electrically powered devices. As well as pre-use checks and tests, a procedure for managing new devices should identify:

- any training needs;
- appropriate planned preventative maintenance;
- technical support needs of users

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<sup>1</sup>Medical Devices Regulations 1994-SI 1994/3017, see DB9904 (NI) Appendix A1 p. vi. All products covered here are medical devices under the definition in Article 1 of the regulations intended for the “diagnosis, prevention, monitoring, treatment or alleviation of disease...injury or handicap”. Most but not all are therefore subject to the MDR.

Quality, suitability and conformity to standards must be addressed before purchase (DB9904 (NI) Chapter 3). There is no sense in buying something and then deciding that it is not acceptable. The pre-use checks suggested here are the intended to minimise risks associated with using a newly delivered device, and not to provide a belated critique of purchasing decisions.

Many of the tests specified in standards are type tests which pose a challenge to the device, and should only be carried out by the manufacturer or a test house. Product items subjected to types tests are never put into service, in case the test has caused some damage. **Type tests must never be used as pre-use tests.**

## 2. CHOOSING SUITABLE CHECKS AND TESTS FOR A PARTICULAR PRODUCT

### 2.1 Broad guidelines

This section applies to products which are:

- brand new;
- CE-marked under the MDR (see DB9904 (NI) Section A1.4 “CE-marking for purchasers”).

Table 1 distinguishes between bulk-pack products, for which there is a single list of checks (5.1), and products delivered as single items, for which a risk matrix (Table 2) gives guidance on which of the six modules in section 5.2 are needed. Every protocol should include checks that:

- the delivery is complete;
- the product is exactly what was ordered;
- there has been no damage in transit.

Category	Examples	Key issues	Draft form
Sterile and non-sterile bulk products - checks must focus on bulk pack.	medical gloves, tongue, depressors, catheters, syringes, dressings,	<ul style="list-style-type: none"> <li>• stock rotation/use by dates</li> <li>• tracing lots if there is a recall</li> <li>• circulating instructions and safety information when necessary</li> <li>• faulty packaging</li> </ul>	Section 5.1
Individual non-active items	walking frame	<ul style="list-style-type: none"> <li>• device is safe to use</li> </ul>	Assemble from modules (see sections 2.2 and 5.2)
active	infusion pump	<ul style="list-style-type: none"> <li>• device functions as intended</li> </ul>	

**2.2 Building up suitable tests from modules**

Modules A, B and C are delivery checks. Modules D, E and F are safety and calibration test and checks (Table 2).

The appropriate checks and tests for individual product items are chosen from a set of modules, according to Table 3.

<b>DELIVERY CHECKS</b>  see Annex 1 for background	<b>A Paperwork</b>	<ul style="list-style-type: none"> <li>• device checks against order and PPQ</li> <li>• manuals, compliance and calibration certificates, test results all included where relevant</li> <li>• is same model already represented on database? (if not training/documentation needed)</li> <li>• is device included in maintenance system?</li> </ul>
	<b>B Visual inspection</b>	<ul style="list-style-type: none"> <li>• outer packaging intact and undamaged</li> <li>• no damage apparent on inspection</li> <li>• case markings where relevant - CE marking, notified body number, electrical class, applied part type (B/BF/CF)</li> <li>• does the device (or any component part or accessory) need sterilizing before the first use?</li> </ul>
	<b>C Functional check</b>	<ul style="list-style-type: none"> <li>• are accessories/parts compatible?</li> <li>• do indicators and displays function correctly when powered up?*</li> <li>• does it start when you press go?*</li> <li>• action of knobs and switches as intended*</li> </ul> <p>(see Example 1)</p>
<b>SAFETY AND CALIBRATION CHECKS</b>  see Annex 2 for background	<b>D Electric - basic safety</b>	<ul style="list-style-type: none"> <li>• mains leads, plugs, and other connectors undamaged</li> <li>• electrical safety test with Portable Appliance Tester (PAT)</li> </ul>
	<b>E Electric - patient connected</b>	<ul style="list-style-type: none"> <li>• acceptable leakage currents (see p 12)</li> </ul>
	<b>F Calibration and measurement</b>	<p>Use test device to check</p> <ul style="list-style-type: none"> <li>• accuracy of physiological measurements</li> <li>• dose delivery*</li> <li>• energy delivery*</li> <li>• accuracy of other outputs*</li> </ul>

\*only for active devices

	<b>Non-active</b> (simple mechanical devices - no power source)	<b>Active devices</b> (Electrical, electronic, gas pressure powered and complex mechanical)
Lower Risk devices (typically CE class 1)	A,B	A,B,C,D
Moderate (typically classes 2a and 2b) and High Risk (class 3) devices	A,B,C,F	A,B,C,D,E,F

See pp x and xi (DB9904 (NI) Appendix A 1.4) for CE-marking class definitions.

### Example 1 - Functional test from a dialysis machine manual

#### Installation test

- The device must not be connected to a patient during the installation test. Be sure that the test is conducted using a container of water to substitute for the patient.
- If a malfunction alarm occurs during the installation test, the Control Unit has failed the test. Do not use the control unit. Call a trained and qualified technician for service.

#### Procedure

To perform the installation test, follow the steps below:

1. Turn on the control unit as described under “start-up” in the Operation chapter. The control unit performs an initialisation test during the Startup procedure. Verify that the red, yellow, and green lights are illuminated.  
.....  
.....  
.....
10. Press the STOP softkey, then press the END TREATMENT softkey and follow the instructions to unload the set.

### Functional tests

Example 1 gives an extract from a typical manual.

In general such tests check that:

- controls operate as expected;
- motors and actuators move freely - device functions properly;
- displays show appropriate information.

They do **not** aim to show that performance conform to any standard, or exhaustively check every possible error state. The operations included are ones normally carried out by a user - the device is not, for example, placed in engineering mode, or connected to test equipment.

For simple electrical devices it will generally be adequate to simply plug the device in and switch on. A light source, for example, ought to light up.

## 2.3 Training and knowledge which testers need

Checks and testers can only be effective if everyone carrying them out has appropriate training. Table 4 indicates the skills required for the various modules:

Module (see sections 2.2 and 5.2)	Skills Required
A	Familiarity with: <ul style="list-style-type: none"> <li>• ordering system</li> <li>• inventory system</li> <li>• names and appearances of common medical devices</li> <li>• medical device documentation (manuals, certificates)</li> <li>• serial numbers and model identification codes.</li> </ul>
B	Knowledge of areas to check for damage. Familiarity with: <ul style="list-style-type: none"> <li>• the appearance of product in good condition</li> <li>• common defects.</li> </ul>
C	Basic electrical safety training - actions to take in cases where fuse blows or circuit breaker trips. In cases where manufacturer's instructions specify assembly or manipulation (eg loading a set), familiarity with necessary components and accessories sufficient to follow instructions.
D	Training in visual electrical safety inspection techniques. Training in use of simple ("go/no go") PAT tester.
E,F	Tests which should be carried out by a full-trained technician

Everyone carrying out checks and tests needs to be provided with appropriate information:

- **which test modules to apply in a particular case;**
- **where compliance and calibration certificates are necessary;**
- **where to send the device after checking**
- **what to do with manuals and certificates;**
- **what records are needed.**

This system is based on a thorough paperwork check and visual examination carried out by well-trained, but not necessarily technically qualified staff. Annex 1 gives the background to this policy. Bench tests need technically qualified staff have been reduced to the minimum needed to assure safety, on order to increase the time available for work with users. Annex 2 gives background.

## 2.4 Efficient organisation and record keeping

### Eliminating duplication

In many cases tests and checks are carried out in stages, by different people. It is easy to duplicate effort inadvertently, to introduce delays, and to fail to produce coherent records. Table 5 shows the possible sources of relevant information, including the data acquired by the manufacturer before despatch. In many organisations, however, some or all of the functions in this

table will be carried out by single department. If clinical staff need to do checks or tests before first use, they should be alerted - probably best by attaching a label to the device before it is released for use.

<b>Stage</b>	<b>User organisation action</b>	<b>Test modules possibly involved (see sections 2.2 and 5.2)</b>
Before dispatch - manufacturer	Acquire and assess data from manufacturer (function, calibration and safety checks which they have carried out).	C (not for sterile product) D,E,F
Stores/goods inwards	Check damage in transit, order details.	A,B
Engineering departments	Perform technical tests, eg electrical safety.	D,E,F
Medical physics	Check radiation safety, calibration of monitoring equipment.	F
Before use - clinical staff	Check integrity of pack for sterile devices. Perform functional tests where appropriate.	Bulk pack form (5.1) C (not for sterile product)

### **Data from manufacturers**

Some user organisations may wish to use data generated by the manufacturer rather than carry out tests themselves. They must receive adequate documentation of the tests and their results. It is important to establish that any tests were carried out on the actual product item in question, and are not just sample data. Users need to be confident that:

- manufacturers are using appropriate test methods;
- there has been no damage in transit.

### **Record Keeping**

User organisations should keep records of any safety or functional safety or functional test. It should always be possible to find out the test result - who carried it out, when and how:

- Health and Safety Inspectors will expect records to be available;
- a defence in a negligence if documentation is available for the particular devices involved.

It is important that all reusable devices are entered onto a device database, to facilitate efficient equipment management.

### 3. LEGAL REQUIREMENT FOR ELECTRICAL SAFETY TESTING

The Electricity at Work Regulations Northern Ireland (EWR) 1991 (a statutory rule SR1991/13, under the Health and Safety at Work Order (Northern Ireland) 1998 (HASAWO) have regulated electrical safety in the workplace since March 1991, and form the basis of the programmes used by hospital estates department for the regular electrical testing of portable electrical equipment.

HASAWO imposes a duty on employers to provide:

- “plant and systems of work that are, so far as is reasonably possible, safe and without risks to health”?
- “such information, instruction, training and supervision as is necessary.”

EWR states that “no electrical equipment shall be put into use when its strength and capability may be exceeded...” and that “all systems shall be maintained so as to prevent, so far as is reasonably practicable, danger”.

Complying with this legislation has led organisations to implement electrical safety testing programmes, involving pre-use testing of new devices and periodic subsequent tests. The legislation itself does not spell out what tests should be done at which intervals. There is no specific legal obligation - or even guidance - requiring user organisations to do any particular test, but here is a general duty to take necessary steps to protect employees from danger.

### 4. SPECIAL CASES

#### 4.1 Devices which require commissioning

When a new device model is introduced, or when pre-first-use functional checks are complicated, technical and clinical staff should work together to ensure that:

- checks are successfully carried out and documented;
- users have all the technical information and manuals that they need;
- training needs have been identified and acted on;
- technical staff are familiar with how the device performs in a clinical context.

It should be recognised that some single-use products, such as balloon catheters, are complex (and expensive), and staff training needs should be taken into account. In most cases a manufacturer’s representative ought to be present when a novel product of this type is first used.

#### **Installed devices**

When a device needs to be installed, there should be a procedure for commissioning, worked out in collaboration with the supplier and the

**4.2 Devices which might need a local certificate of safety**

organisation doing the installation. This usually occurs when there is a need for any of the following:

- substantial assembly work on site;
- permanent plumbing, electrical and gas pipeline connections;
- permanent fixing in place.

Under the MDR, suppliers must provide instructions for installing a device and bringing it into use. Where appropriate these instructions will include specifications for safety and performance checks. A designated member of staff should have oversight of the commissioning process, and responsibility of deciding that it has been completed satisfactorily.

The purpose of a local safety certificate is to:

- provide assurance that a device is safe and effective;
- put appropriate limits on use.

Categories of products which should be subjected to risk assessment are shown in Table 6.

Some devices fall into more than one category.

Category	Examples
Medical devices manufactured outside the scope of the MDR	Manufactured before the regulations came into force. Purchased by an individual outside EU. In-house manufacture.
Devices which have (or may have) been previously used.	Bought second-hand. Property of patients or staff. Lent by another user organisation.
Devices within cope of MDR, but not CE-marked.	Custom-made for a named patient. Under clinical investigation.

Table 7 gives possible outcomes for the risk assessment.

Category	Evidence (examples)	Outcome
Risk not significantly greater than for a new CE-marked product	Custom-made and clinical investigation products with satisfactory MDR statements. Previously used devices with full maintenance history.	Use modular tests from Section 5.2
Risks significantly greater	Devices of unknown previous ownership. Devices manufactured in house.	Testing for local safety certificate

In the second case (“Risks significantly greater”) risk assessment will lead to a programme of local testing, and the issue of a local safety certificate if this is successfully completed. If not, risks will outweigh possible benefits, and the correct decision will be not to use the device in question. Past history should be taken into account: devices on loan from organisations with a quality assurance system in place for device maintenance are likely to be safe and reliable. Example 2 shows a local safety certificate used by one trust for equipment which needs a comprehensive safety assurance.

**Example 2 - Local Certificate of Safety for devices subject to additional investigation.**

**CERTIFICATE OF ELECTRICAL AND MECHANICAL SAFETY**  
**Applicable only to equipment that has not been commissioned from new**

Item No..... Model/Serial No.....

**VISUAL INSPECTION SECTION**

Suitable 13 Amp plug fitted and correctly wired, fitted with a fuse rated at ..... Amp \_\_\_\_\_  
 Mains cable, outer sheath inspected \_\_\_\_\_  
 Mains cable entry / IEC connector, strain relief adequate \_\_\_\_\_  
 Instrument case provides adequate protection from the mains and all fixings are in place \_\_\_\_\_  
 Are the device mountings suitable and properly fitted? *If none put na* \_\_\_\_\_

**ELECTRICAL MEASUREMENT SECTION**

Electrical Safety Class: 1B, 1BF, 1CF, 2B, 2BF, 2CF <i>Ring which is applicable</i>	(3) Insulation resistance .....M Ohms (4) BF & CF only .....M Ohms (5) Earth bonding resistance 0.....Ohms
---	--

Earth Leakage  $\mu$ A    Enclosure leakage  $\mu$  A    Patient Earth leakage  $\mu$  A    Patient auxiliary current  $\mu$  A  
 Only where if protective earth

6	7	8	9	10	11	12	13	14	15	16
Normal	supply	Normal	earth	supply	Normal	earth	supply	normal	earth	supply
	o/c		o/c	o/c		o/c	o/c		o/c	o/c

**QUALITY CONTROL MUST BE COMPLETED BY TEAM LEADER**

It was necessary to certificate the equipment because no proof of previous quality checks were available.  
*either* - The equipment has no CE mark, and is not known to conform to BS5724 \_\_\_\_\_  
*or* - Other, give reason \_\_\_\_\_

Indicate what the future planned maintenance will be:  
*either* - On a planned maintenance programme (PM interval.....months) \_\_\_\_\_  
*or* - Equipment on fixed term loan. Indicate loan expiry date on licence    licence until \_\_\_\_\_

Comments

### 4.3 Devices loaned by manufacturers

#### **Products being evaluated**

Users should check that all devices on loan from manufacturers are subject to the Regional Supplies Service loan indemnity. This means that the manufacturer has made suitable arrangements, and that the user's exposure to liability is no different than it would be if they had purchased the device under normal conditions of sale. Thus pre-use procedures for loan equipment should be the same as those for purchased equipment.

#### **Products for patients to use at home**

Enteral feeding pumps provide a typical example (see DB9904 (NI), page E4). In cases where ownership and device management remain with the supplier, it may be satisfactory to accept that manufacturer's pre-dispatch tests combined with simple pre-use checks by those responsible for the care of the patient in the community (e.g. community nurse or carer) provide an adequate assurance of safety.



### Module B Visual Inspection

- |                               |     |                          |    |                          |
|-------------------------------|-----|--------------------------|----|--------------------------|
| 1. Outer packaging undamaged? | yes | <input type="checkbox"/> | no | <input type="checkbox"/> |
| 2. Case not dented/broken     | yes | <input type="checkbox"/> | no | <input type="checkbox"/> |
| 3. Panels etc. secure         | yes | <input type="checkbox"/> | no | <input type="checkbox"/> |
| 4. No rattles                 | yes | <input type="checkbox"/> | no | <input type="checkbox"/> |

### Module C Functional check

Plug in, turn on (following instruction manual)

- |                                    |     |                          |    |                          |
|------------------------------------|-----|--------------------------|----|--------------------------|
| 1. Indicator lamps light up        | yes | <input type="checkbox"/> | no | <input type="checkbox"/> |
| 2. Display as described in manual  | yes | <input type="checkbox"/> | no | <input type="checkbox"/> |
| 3. Passes self test routine        | yes | <input type="checkbox"/> | no | <input type="checkbox"/> |
| 4. Moving parts operate properly   | yes | <input type="checkbox"/> | no | <input type="checkbox"/> |
| 5. Knobs and switches act properly | yes | <input type="checkbox"/> | no | <input type="checkbox"/> |

### Module D Electrical safety (basic)

- |   |     |                          |    |                          |
|---|-----|--------------------------|----|--------------------------|
| 1. (Moulded IEC mains connector and mains plug) |     |                          |    |                          |
| Connectors firmly attached                      | yes | <input type="checkbox"/> | no | <input type="checkbox"/> |
| No cores or bare wires visible                  | yes | <input type="checkbox"/> | no | <input type="checkbox"/> |
| Outer insulation intact                         | yes | <input type="checkbox"/> | no | <input type="checkbox"/> |
| Appropriate fuse fitted (see manual)            | yes | <input type="checkbox"/> | no | <input type="checkbox"/> |
| Fuseholder secure                               | yes | <input type="checkbox"/> | no | <input type="checkbox"/> |
| 2. Mains lead permanently attached).            |     |                          |    |                          |
| Cord grips satisfactory                         | yes | <input type="checkbox"/> | no | <input type="checkbox"/> |
| 3. Fuse value                                   |     |                          |    |                          |
| 4. Plugs and sockets mate                       | yes | <input type="checkbox"/> | no | <input type="checkbox"/> |
| 5. Clamps and doors hatch                       | yes | <input type="checkbox"/> | no | <input type="checkbox"/> |
| 6. Passes PAT test                              | yes | <input type="checkbox"/> | no | <input type="checkbox"/> |



**Module F Calibration and measurement.**

Device passes tests in manual

Yes

No

Date

Data

(Insert measurements needed from manual, or locally generated procedure).

## ANNEX 1 BACKGROUND - DELIVERY CHECKS

Simple checks on delivery can save time and avoid trouble - if a device is discovered to be broken or inappropriate only when someone tries to use it for the first time, it can lead to:

- delayed or interrupted treatment;
- waste of clinical staff time;
- difficulties in returning the device and establishing when and where the problem arose;
- invalidation of warranties;
- injury to patients and staff.

Other countries have issued similar guidance (see Example 3)

Delivery checks are plainly cost effective - they are a necessary part of any device management system, and also eliminate unnecessary risks (see Example 4). These checks are uncontroversial - all the manufacturers and user organisations we have consulted agree that they should be applied to all medical devices, including single-use and consumable items.

### **Example 3 AS/NZS 3551: 1996 Technical management programs for medical devices** (An Australian/New Zealand standard)

**“Initial inspection** Persons accepting delivery (e.g. inwards goods staff) shall check the packaging is undamaged. Any damage shall be noted.

**General acceptance inspection** The medical device shall be inspected as soon as possible after delivery to establish that it is complete with specified accessories and that it has not been damaged in transit.”

### **Example 4 Wrong trolley delivered**

A firm supplying a trolley for a transport incubator supplied a unit slightly modified from the sample which the hospital had judged to be satisfactory before purchase. The model supplied did not have the correct clamps, and broke loose when mounted in an ambulance. The error was only discovered after the adverse incident had occurred, but could have become apparent during pre-use testing.

## ANNEX 2 BACKGROUND - PRE-USE TESTS

### Evidence about risk-levels

MDA/NIAIC receives very few adverse incident reports relating to newly delivered products. Table 8, for example, gives details of incidents involving damage in transit.

Category	Number of incidents recorded
Wheelchairs and walking aids	54
Single-use devices	10
Nebulisers/oxygen supply	7
Beds and tables	5
Portable electro-medical devices	4

### Safety tests.

The over-riding principle here is that pre-use tests should not be outside the bounds of normal use:

- Disassembly should be restricted to what is necessary for normal use and cleaning;
- Currents or voltages applied during tests should not exceed those occurring in normal use.

Any test which involves an abnormal stress - for example loading a hoist above its stated maximum working load - carries an unacceptable risk of causing permanent damage, and may invalidate any warranty.

Failure to follow this advice may lead to dangerous devices being put into service.

### Damage in transit

Although faults can arise during transportation:

- adequate packaging should provide any necessary protection;
- delivery checks will detect damage to packaging - a good indicator of possible problems during transport.

Table 8 shows the tiny incidence of damage in transit problems on the MDA/NIAIC adverse incident data base.

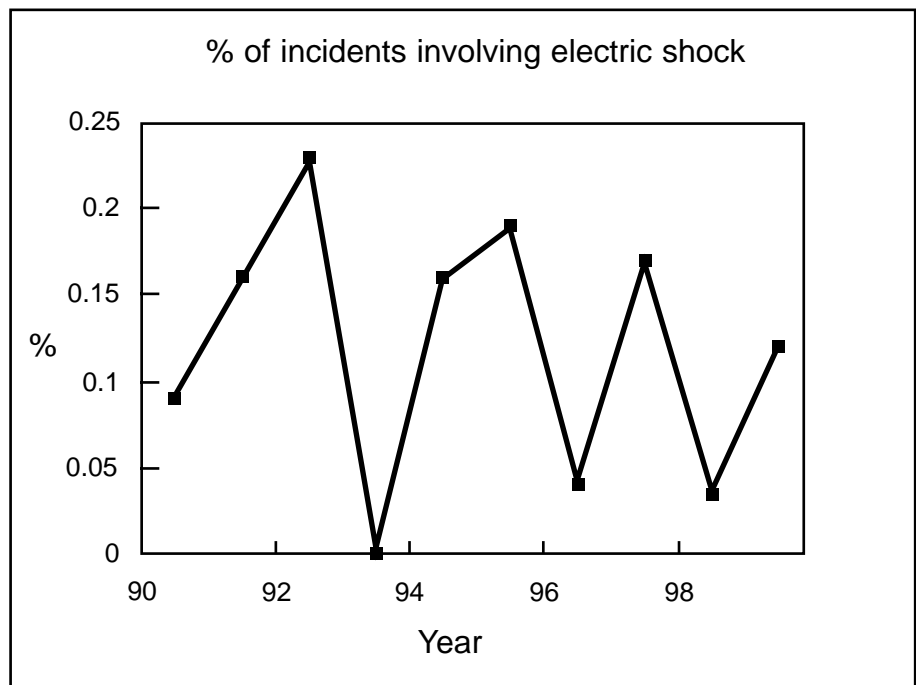
### Manufacturer's guidance

Maintenance instructions may specify tests on a new device (for example, in order to generate baseline data for later comparisons). A pragmatic approach is to avoid duplication - these tests may serve as a functional check and/or a calibration check.

Performing extra tests not required by the manufacturer should be avoided. If a manufacturer's instructions seem to be inadequate to ensure continued safety and adequate performance, this fact should be reported to, MDA and we will take the appropriate action.

### Electrical safety testing

Fig 1 shows all the incidents involving electric shock reported to the MDA over the last 9 years (a total of 43). These do not exceed 0.25 % of reports received in any year, and in 40 of these 43 cases injuries are categorised as "none" or "minor". No deaths by electrocution in the UK are recorded on the MDA database. reports cover all medical devices in service, so risks for new devices are very much lower.



**Fig. 1 Incidents involving electric shock** as a percentage of all reports received by MDA.

Example 5 has quotes from papers given by senior biomedical engineers at a meeting organised by IPEM, ABHI and MDA in March 1998.

**Example 5 Quotes from speakers at “Acceptance testing for medical devices - the way forward?” meeting, organised by IPEM, ABHI and MDA.**

**1) John Conely (John Radcliffe Hospital, Oxford)**

The old HEI 95 ... goes into great detail as to what we should check for electrical safety. What’s the supreme importance of electrical safety over all other safety considerations? In my own department in the last seven years, I can recall two items of equipment which failed electrical safety tests. One took out the fuse when plugged in, and the other had a heater element which caused some high readings. For over seven years it’s an awful lot of effort and not a lot of electrical safety problems.

**2) Richard Mellish, (MDA)**

I think there are two reasons why we have tended to concentrated on electrical safety.

- Because we know how to do it, and that’s a bad reason.
- There is a legal obligation to do safety testing on electrical equipment in use in places of work from time to time to make sure it hasn’t become dangerous.

**3) Nicholas Abraham (Charing Cross Hospital)**

Electrical safety tests have even less value (*than planned preventative maintenance tests*). Fire risks apart, this is the least of our worries. Functional failure of equipment is far more serious, especially for infusion pumps, defibrillators, anaesthetic machines, etc. Electrical safety has a place and shouldn’t be ignored but it really isn’t the be all and end of all safety. We’ve seen a few cases IEC leads with failed earth continuity - just enough to support the testing rule. We’ve seen even fewer failures on patient leakage current - just enough to support testing. We appreciate that if you’re going to rest either of those things, once you’ve got the machine out, the marginal cost of making all the tests is small enough to make it really not worth arguing about. So we might as well do the tests. But remember, it’s quite easy for something quite dangerous to pass electrical safety tests\*. I certainly would not be advocating setting up a whole service from scratch just to do electrical safety testing.

*\* eg an intense light source with a faulty fan will pass an electrical safety test, but overheat dangerously if operated for any length of time.*

Many user organisations have traditionally carried out extensive electrical safety testing programmes, but evidence that these programmes are important for maintaining device safety is weak - one hospital clinical engineering department has told us that it has conducted 13000 electrical safety tests on new equipment without finding a single electricity unsafe device. Published data also shows low rates of electrical safety faults. (Amoore, J.N., Stay, D.G., and Mather, J. “Scheduled inspection of electromedical equipment. Planning and assessment” *Journal of Medical Engineering and Technology* **19** 211-218).

There is thus little evidence that electrically-powered medical devices are a special hazard and no justification for a disproportionate allocation of resources to test them - as compared to non-electrical products with similar risks levels. This document presents a compromise position, recognising that some electrical testing is legally necessary (see Section 3), and that the decision to eliminate some of the tests currently in use is a difficult one to take.

## Methods for electrical testing

### Role of visual examination

Structured visual inspections involve checks of integrity, compatibility, correct fusing, and correct labelling. In general, for double-insulated devices with no accessible metal parts, electrical safety can only be assessed by a structured visual examination.

### Purpose-built appliance testers

A portable tester (PAT) gives a simple pass/fail reading. It requires some training in its use, though no specialist electronic skills. PAT tests normally include earth bonding and insulation resistance.

More sophisticated electrical testers such as the Bioteck electrical safety analyzer print out a list of resistance and current values, and require a higher competency to operate safely, and not to interpret the findings. Some of the tests involve operating the device with its safety earth disconnected and must only be conducted in a suitably equipped workshop. In some circumstances the testing may constitute live working.

### Reducing electrical testing without compromising safety

Table 9 summarises three approaches we considered:

Strategy	For all devices	Additional tests or devices with exposed metal parts	Additional tests for patient connected devices
1 No electrical testing	Structured visual exam + functional test	Accept manufacturer's assurance	Accept manufacturer's assurance
2 Typical estates protocol	Structured visual exam + functional test	PAT tester	Accept manufacturer's assurance
3 Risk-related testing effort	Structured visual exam + functional test	PAT tester	Electrical safety analyzer

**Strategy 1** employs a structured visual inspection and simple functional test for all devices. The functional test will detect electrical faults which cause a fuse to blow, or the device to fail to operate. Otherwise this strategy relies on the manufacturer's inspection before dispatch for electrical safety. See Section 3 for legal requirements in this area.

**Strategy 2** adds a PAT test for any device which is not double-insulated. This will align medical device practice with procedures used for other electrical equipment within the same organisation, for example hospital estates departments testing non-medical devices,

It would seem reasonable for healthcare organisations to adopt a common safety standard for medical devices:

- for use by staff;
- supplied to patients to use themselves (or for their carers to use).

**Strategy 3.** As 2, but with an electrical safety analyser for patient-connected devices. This reduces a very slight risk of electrocution via leads, due to an out-of-box failure. Many biomedical engineers have argued strongly for this option, even if they are persuaded that a full set of electrical tests on every single device is a waste of time.

The modular approach in section 2 is based on strategy 3, but healthcare organisations may find that strategy 2 or even strategy 1 proves acceptable in their particular circumstances, following a risk assessment.





## DISTRIBUTION

This Device Bulletin should be brought to the attention of managers and staff in all HPSS Organisations.

This device bulletin should also be brought to the attention of medical device coordinators, medical engineering and medical physics staff, IT staff, medical and nursing directorate managers, general practitioners, dental practitioners, pathology laboratory managers and staff responsible for medical equipment used in the community.

## TECHNICAL ENQUIRIES

General enquiries concerning this Device Bulletin should be addressed to:-

Mr Brian Godfrey  
Northern Ireland Adverse Incident Centre  
Health Estates  
Estate Policy Directorate  
Stoney Road  
Dundonald  
BT16 1US

Tel: 028 9052 3714  
Fax: 028 9052 3900

email: [brian.godfrey@dhsspsni.gov.uk](mailto:brian.godfrey@dhsspsni.gov.uk)

## FURTHER COPIES

Further copies of this Device Bulletin are free to Health and Social Care providers and may be obtained on written request from:

Northern Ireland Adverse Incident Centre  
Room A7  
Health Estates  
Estate Policy Directorate  
Stoney Road  
Dundonald  
Belfast  
BT16 1US

Tel: 028 9052 3704  
Fax: 028 9052 3900

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