

Neurosurgical implants —

Part 2: Specification for marking and packaging of implantable neural stimulators

Confirmed
January 2010

Committees responsible for this British Standard

The preparation of this British Standard was entrusted by the Health Care Standards Policy Committee (HCC/-) to Technical Committee HCC/24, upon which the following bodies were represented:

- Association for Spina Bifida and Hydrocephalus
- British Association of Paediatric Surgeons
- British Surgical Trades Association
- Department of Health
- Electroencephalographic Society
- Medical Research Council
- Medical Sterile Products Association
- Royal College of Surgeons of England
- Scottish Office
- Society for Research Into Hydrocephalus and Spina Bifida
- Society of British Neurological Surgeons
- Coopted members

This British Standard, having been prepared under the direction of the Health Care Standards Policy Committee, was published under the authority of the Board of BSI and comes into effect on 31 May 1990

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The following BSI references relate to the work on this standard:
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Foreword

This Part of BS 6788 has been prepared under the direction of the Health Care Standards Policy Committee, and is the second Part of BS 6788 to be published. BS 6788-1 covers hydrocephalus shunts.

The neural stimulators covered by this Part of BS 6788 comprise two types, categorized according to the power source of the component that generates the stimulating current, as follows.

a) *Implant pulse generators*. These are self-contained pulse generators having an internal power source, and which may be controlled or adjusted by radio-frequency (RF) or magnetic signals produced by an external programmer.

b) *Implant RF receivers*. These require RF activation from an external source and therefore the implanted component usually contains no power source (although one may be fitted as a stand-by). Implant RF receivers are activated by external equipment which comprises an RF driver and antenna. The RF driver, together with its power source, is usually housed in a portable container (the transmitter). The antenna may be integral with the transmitter or connected to it by a cable. It is intended to be placed next to the skin, near to the implanted RF receiver.

In both types of stimulator, an implantable lead(s) is normally provided to carry current from the implant pulse generator or implant RF receiver to the stimulation electrodes. These leads may be integral with the generator or receiver, or may be separate. The leads may carry connectors, or separate connectors and adaptors may be used. This Part of BS 6788 applies to cables, leads, connectors, adaptors and electrodes whether they form part of an integral device or are separate components of a system capable of being assembled together.

The purpose of this Part of BS 6788 is to ensure that the neural stimulator or component thereof is adequately packaged and that the device and the packaging is labelled with sufficient information. This information needs to be readily available to the patient, surgical team and engineer so as to facilitate decision-making on such matters as the choice of device, the methods of implantation, adjustment and fault diagnosis and to convey user precautions.

Therefore, this Part of BS 6788 does not specify indications or contraindications for the use of implantable neural stimulators, nor does it specify methods of construction or testing or what the range of normal operating variable parameters should be. It does, however, require that information on these matters be included in the documentation accompanying each implant pulse generator or implant RF receiver.

The preparation of further Parts of BS 6788 to cover other neurosurgical implants is under consideration.

It is recommended that implantable neural stimulators and components should be manufactured in accordance with the recommendations in the "Guide to Good Manufacturing Practice for Medical Equipment"¹⁾.

¹⁾ Published by the Department of Health and Social Security, and available from Her Majesty's Stationery Office. ISBN 0 11 320833 2.

It is recommended that if implantable neural stimulators and components are supplied in the sterile condition, they should be manufactured in accordance with the recommendations in the “Guide to Good Manufacturing Practice for Sterile Medical Devices and Surgical Products”²⁾.

A British Standard does not purport to include all the necessary provisions of a contract. Users of British Standards are responsible for their correct application.

Compliance with a British Standard does not of itself confer immunity from legal obligations.

Summary of pages

This document comprises a front cover, an inside front cover, pages i to iv, pages 1 to 6, an inside back cover and a back cover.

This standard has been updated (see copyright date) and may have had amendments incorporated. This will be indicated in the amendment table on the inside front cover.

²⁾ Published by the Department of Health and Social Security, and available from Her Majesty's Stationery Office. ISBN 0 11 320770 0.