INTERNATIONAL STANDARD

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Neurosurgical implants — Marking and packaging of implantable neural stimulators

Implants neurochirurgicaux — Marquage et emballage des neurostimulateurs implantables

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Contents

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

Draft International Standards adopted by the technical committees are circulated to the member bodies for voting. Publication as an International Standard requires approval by at least 75 % of the member bodies casting a vote.

International Standard ISO 10310 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 3, *Neurosurgical implants*.

Annex A of this International Standard is for information only.

Introduction

The purpose of this International Standard is to ensure that the neural stimulator (including implant pulse generators and implant RF receivers) or component thereof is adequately packaged and that the device and packaging are labelled with sufficient information. This information needs to be readily available to the clinician and patient 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.

It is recommended that implantable neural stimulators and components are manufactured in accordance with the ISO 9000 series of Quality Standards and under international or national good manufacturing practices where these exist.

Work on a general standard for active implants (implantable devices with power sources) is under way in CEN/CENELEC with liaison from IEC/SC62D and ISO/TC 150 work.

The contents of this International Standard will be reflected in that work. A subsequent standard that will cover all aspects of neural stimulators will be developed to replace this limited scope standard once the general standard is available.

Neurosurgical implants — Marking and packaging of implantable neural stimulators

1 Scope

This International Standard specifies requirements for marking, labelling, packaging and accompanying documentation for implantable neural stimulators intended for stimulation of the nervous system (brain, spinal cord, peripheral nerves and adjacent structures).

It also covers implanted or external ancillary components, including the external control and programming equipment used for the activation or adjustment of neural stimulators.

This International Standard does not specify indications or contraindications for the use of implantable neural stimulators; nor does it specify testing or the range of normal operating variable parameters. It does, however, require that information on these matters be included in the documentation accompanying each implant pulse generator, implant RF receiver or RF transmitter for use by a clinician for treating a specific patient.

2 Definitions

For the purposes of this International Standard, the following definitions apply.

2.1 neural stimulator: Device for electrically stimulating the nervous system (brain, spinal cord, peripheral nerves and adjacent structures), comprising a pulse generator and all ancillary components, implanted or external to the body, necessary for its function and control.

2.2 implant pulse generator: Implantable device, containing its own power source, that can generate electrical pulses to stimulate the nervous system continuously or intermittently.

2.3 programmer; controller: External device for controlling or adjusting the parameters of a neural stimulator system.

2.4 implant RF receiver: Implantable device, without its own power source, that can generate pulses to stimulate the nervous system using radio-frequency (RF) power transmitted to it by a transmitter and antenna.

2.5 transmitter; driver box: Portable container, having pulse generating and modulating circuits for controlling implant RF receivers.

NOTE 1 The transmitter usually contains a power source. It may also contain the antenna. There may be some user-accessible controls and some internally adjustable controls.

2.6 antenna: Transmitting coil or loop intended for the activation of implant RF receivers.

NOTE 2 The antenna is generally intended to be placed on, or near, the skin, near the implanted RF receiver.

2.7 cable: Insulated wire or conductor intended to connect a transmitter to an antenna, external to the body, with or without an integral connector at one or both ends.

NOTE 3 A cable may contain more than one wire or conductor.

2.8 implant lead [extension]: Insulated wire or conductor intended to be implanted and to connect an implant pulse generator or RF receiver to stimulation electrodes, with or without an integral connector at one or both ends.

2.9 connector: Separate implantable component intended to make electrical connections between implantable components.

2.10 adapter: Component that allows the interconnection of otherwise electrically or physically incompatible components.

2.11 (stimulation) electrode: Electrically conducting part(s) [usually the termination of an implant lead(s)] which is designated to form an interface with nervous tissue or body fluid and which carries the electrical stimulation current.

2.12 unit pack: Pack containing a single unit or kit.

2.13 multiple pack: Pack containing a number of unit packs.

3 Device identification

3.1 Marking

The implant pulse generator, implant RF receivers, programmers and transmitters shall be permanently marked with the following information:

a) name and/or identifying mark of the manufacturer;

b) model designation;

c) serial number or lot number as described in 5.2 c).

3.2 Non-invasive identification

Each implant pulse generator and implant RF receiver shall have a means of identifying the manufacturer and the model designation of the device non-invasively after implantation.

4 Packaging

4.1 Unit packs

Each complete neural stimulator and/or separate component(s) shall be packaged in a unit pack.

Each unit pack shall be supplied with one copy of the relevant accompanying documentation specified in clause 6. In order to gain access to the accompanying documentation, it shall not be necessary to penetrate the package layer that maintains the sterility of devices supplied in the sterile condition.

4.2 Multiple packs

One or more unit packs may be packaged in a multiple pack.

The multiple pack should protect the contents during normal handling, transit and storage.

5 Package marking

5.1 General

The markings should be readily readable, should remain legible after normal handling, transit and storage, and should not adversely affect the contents.

5.2 Unit packs

The unit pack shall bear at least the following information:

a) description of the contents and quantity, including the model designation(s);

b) name and address of the manufacturer and/or supplier;

c) serial number(s) (preceded by either "serial number" or "SN") and/or lot number(s) as appropriate of the contents;

d) date of manufacture or expiration date (month/year), preceded by, for example, "use by", "exp";

e) if appropriate, the word "STERILE" or if nonsterile, a warning statement to that effect;

f) designation on the actual sterile pack that it is the sterile pack;

g) the method of sterilization, if appropriate;

h) if appropriate, the words "for single use" or equivalent;

i) written or pictorial instructions for opening the unit pack;

j) the acceptable conditions of storage and transport.

5.3 Multiple packs

The multiple pack shall bear at least the following information:

a) the name and address of the manufacturer and/or supplier;

b) the number of unit packs and a description (including model designation) of the contents;

c) the acceptable conditions of storage/transport.

6 Accompanying documentation

6.1 General

Each separate piece of accompanying documentation shall include

a) the name and address of the manufacturer and/or supplier;

b) the year of issue of the document.

6.2 Implantable components

Each unit pack containing an implantable component shall be supplied with the appropriate accompanying documentation specified in 6.2.1 and/or 6.2.2.

6.2.1 Implant pulse generators and implant RF receivers

a) Registration document at least in duplicate bearing the following:

1) instruction that one copy of the document be returned to the manufacturer or supplier after implantation of the device and the other copy retained in the patient's record;

2) space for the following:

— model designation of the device and device name or description,

— serial number or lot number of the device,

— identity of the patient,

— date of implantation,

— name and address of the centre at which the device was implanted.

b) One copy of an identification card bearing at least the following:

1) instruction that the card be retained by the patient;

2) space for the following:

— model designation and name of the device,

— serial number or lot number of the device,

— identity of the patient,

— date of implantation,

— name and address of the centre at which the device was implanted,

— a warning regarding MRI examinations,

— recommended procedures regarding security gates and systems.

c) If appropriate, details of the generic composition of any pharmacologically active coating material (e.g. antibiotic) and/or leachable material.

d) Information specific to the type of component contained in the unit pack, giving the range of values for parameters and the value as shipped, where appropriate.

1) implant pulse generators:

— model designation,

— model designation(s) of appropriate programmer(s), if any,

— pulse amplitude, expressed in volts,

— pulse frequency, expressed in hertz or pulses per reciprocal second,

— pulse waveform, expressed as monophasic or biphasic,

— pulse duration, expressed in milliseconds or microseconds,

— cycle-on and cycle-off times for devices that are intended to stimulate cyclically,

— ramp-up and ramp-down times,

— expected device longevity at continuous use at a specified or nominal output,

— if applicable, instructions for recharging or renewing the power source,

— means of external adjustment of the implant pulse generator, if any, or a statement that no means of external adjustment are provided,

— if supplied nonsterile, a recommended method of sterilizing the implant pulse

generator, and the maximum permitted number of sterilizing cycles;

2) implant RF receivers:

— model designation,

— carrier frequency, expressed in kilohertz or megahertz,

— pulse waveform and its amplitude, expressed in volts, as shipped and adjustable range and at maximum adjustable output, where appropriate;

— model designation(s) of the appropriate transmitter(s),

— the model designation(s) of the appropriate antenna(s),

— if supplied nonsterile, a recommended method of sterilizing the implant RF receiver, and the maximum permitted number of sterilizing cycles.

6.2.2 Other implantable components

a) If applicable, details of the generic composition of any pharmacologically active coating material (e.g. antibiotic) and/or leachable material.

b) Information specific to the type of component contained in the unit pack, giving the range of values for parameters and the values as shipped, where appropriate:

1) implant lead(s):

— model designation,

— device(s) with which the implant lead is compatible,

— overall length expressed in centimetres, and outside diameter (where appropriate) expressed in millimetres,

— if supplied nonsterile, a recommended method of sterilizing the implant lead and the maximum permitted number of sterilizing cycles;

2) connectors and adapters:

— model designation,

— device intended to connect or to enable connection,

— overall length expressed in centimetres, and outside diameter (where appropriate) expressed in millimetres,

— if supplied nonsterile, a recommended method of sterilizing the connector or adapter, and the maximum permitted number of sterilizing cycles;

3) electrodes:

— construction material(s),

— diagram of the electrode(s), dimensioned in millimetres,

— for electrodes that are detachable from the implant lead, connector system(s) or the model designation(s) of the implant lead(s) to which they are intended to be connected,

— if supplied nonsterile, a recommended method of sterilizing the electrode, and the maximum permitted number of sterilizing cycles.

6.3 Non-implantable components

Each unit pack containing a non-implantable component shall bear, or contain in a technical information sheet, at least the following information specific to the component, giving the range of values for, and the method of adjustment of each parameter, where applicable.

6.3.1 Programmers

a) model designation;

b) mode of operation (i.e., magnetic, RF, etc.);

c) the model designation(s) of the appropriate implant pulse generator(s);

d) if applicable, instructions for recharging or renewing the power source;

e) the function and range of any controls.

6.3.2 Transmitters

a) model designation;

b) model designation(s) of the appropriate antenna(s) and whether integral or separate;

c) model designation(s) of the appropriate implant RF receiver(s);

d) the function and range of all controls;

e) expected battery longevity at continuous use at a typical or nominal output;

f) type of battery required (where applicable).

6.3.3 Antennas

a) model designation;

b) model designation(s) of the appropriate transmitter(s);

c) model designation(s) of the appropriate cable(s);

d) model designation(s) of the appropriate implant RF receiver(s);

e) recommended method for applying and removing the antenna from the skin where applicable.

6.3.4 Cables

a) model designation;

b) model designations of the devices with which the cable is intended to be connected;

c) overall length expressed in centimetres.

6.4 Information for patient

Each unit pack containing a device having controls whereby adjustments can be made by the patient shall be supplied with documentation that provides information on the adjustments.

This document should be separate from, and additional to, all other documentation required by this International Standard.

6.5 Information for clinician

Each unit pack shall contain information on, and instructions for use of the neural stimulator or component, and which gives at least the following information:

a) indications and contraindications for the use of the neural stimulator or component;

b) recommended method for pre-implantation testing and general guidelines for implantation procedures;

c) recommended method for post-implantation testing of the system;

d) recommended method for using the programmer to set or adjust the implant pulse generator;

e) recommended method for adjusting the implant RF receiver and/or transmitter, stating which adjustments may be made by the patient and which should be made by the clinician;

f) block diagram of the electrical circuit of the neural stimulator;

g) diagram showing the shape(s) of the current pulses delivered by the neural stimulator when using the recommended electrode configuration;

h) flow diagram or recommended method for fault diagnosis;

i) description of the means of non-invasive identification.