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ISO 14708-7

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Implants for surgery — Active implantable medical devices —

Part 7: Particular requirements for cochlear implant systems

Implants chirurgicaux — Dispositifs médicaux implantables actifs — Partie 7: Exigences particulières pour les systèmes d'implant cochléaire

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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.

International Standards are drafted in accordance with the rules given in the ISO/IEC Directives, Part 2.

The main task of technical committees is to prepare International Standards. 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.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights.

ISO 14708-7 was prepared by Technical Committee ISO/TC 150, *Implants for surgery*, Subcommittee SC 6, *Active implants*.

ISO 14708 consists of the following parts, under the general title *Implants for surgery — Active implantable medical devices*:

— *Part 1: General requirements for safety, marking and/or information to be provided by the manufacturer*

— *Part 2: Cardiac pacemakers*

— *Part 3: Implantable neurostimulators*

— *Part 4: Implantable infusion pumps*

— *Part 5: Circulatory support devices*

— *Part 6: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (including implantable defibrillators)*

— *Part 7: Particular requirements for cochlear implant systems*

Introduction

This International Standard specifies particular requirements for ACTIVE IMPLANTABLE MEDICAL DEVICES used to treat hearing impairment via electrical stimulation (for example cochlear implant systems or auditory brainstem implant systems), to provide basic assurance of safety for both patients and users.

A COCHLEAR IMPLANT SYSTEM or AUDITORY BRAINSTEM IMPLANT SYSTEM is an ACTIVE IMPLANTABLE MEDICAL DEVICE comprising implantable and NON-IMPLANTABLE PARTS (external parts). The power source may be externally derived or from an internal battery. The IMPLANT SYSTEM is designed to restore hearing via electrical stimulation of the auditory pathways. Externally or internally processed acoustic information is converted to electrical stimulation signals which are delivered via one or more electrodes. The working parameters of the device may be adjusted via a non-implantable accessory.

This International Standard is relevant to all parts of IMPLANT SYSTEMS, including accessories.

The requirements of this International Standard supplement or modify those of ISO 14708-1, *Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer*.

Figures or tables that are additional to those of Part 1 are numbered starting from 101; additional annexes are lettered AA, BB, etc.

In this part of ISO 14708, terms printed in small capital letters are used as defined in Clause 3. Where a defined term is used as a qualifier in another term, it is not printed in small capital letters unless the concept thus qualified is also defined.

Implants for surgery — Active implantable medical devices —

Part 7:
Particular requirements for cochlear implant systems

1 Scope

This part of ISO 14708 specifies requirements that are applicable to those ACTIVE IMPLANTABLE MEDICAL DEVICES that are intended to treat hearing impairment via electrical stimulation of the auditory pathways. Devices which treat hearing impairment via means other than electrical stimulation are not covered by this part of ISO 14708.

The tests that are specified in this part of ISO 14708 are type tests and are to be carried out on samples of a device to show compliance.

This part of ISO 14708 is also applicable to NON-IMPLANTABLE PARTS and accessories of the devices (see NOTE).

The electrical characteristics of the IMPLANTABLE PART are determined by either the appropriate method detailed in this part of ISO 14708 or by any other method demonstrated to have an accuracy equal to, or better than, the method specified. In the case of dispute, the method detailed in this part of ISO 14708 applies.

NOTE A device that is commonly referred to as an active implantable medical device can in fact be a single device, a combination of devices, or a combination of a device or devices and one or more accessories. Not all of these parts are required to be either partially or totally implantable, but there is a need to specify some requirements of NON-IMPLANTABLE PARTS and accessories if they could affect the safety or performance of the implantable part.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

This clause of ISO 14708-1 applies except as follows:

Additional references:

ISO 10993-1, *Biological evaluation of medical devices — Part 1: Evaluation and testing within a risk management process*

ISO 11607-1, *Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems*

ISO 14155, *Clinical investigation of medical devices for human subjects — Good clinical practice*

ISO 14971, *Medical devices — Application of risk management to medical devices*

IEC 60068-2-27, *Environmental testing — Part 2-27: Tests — Test Ea and guidance: Shock*

IEC 60068-2-31, *Environmental testing — Part 2-31: Tests — Test Ec: Rough handling shocks, primarily for equipment-type specimens*

IEC 60068-2-47, *Environmental testing — Part 2-47: Test — Mounting of specimens for vibration, impact and similar dynamic tests*

IEC 60068-2-64, *Environmental testing — Part 2-64: Tests — Test Fh: Vibration, broadband random and guidance*

IEC 60068-2-75, *Environmental testing — Part 2-75: Tests — Test Eh: Hammer tests*

IEC 60118-6, *Hearing aids — Part 6: Characteristics of electrical input circuits for hearing aids*

IEC 60601-1:2006, *Medical electrical equipment — Part 1: General requirements for basic safety and essential performance*

IEC 60601-1-2, *Medical electrical equipment — Part 1-2: General requirements for basic safety and essential performance — Collateral standard: Electromagnetic compatibility — Requirements and tests*

IEC 61000-4-2, *Electromagnetic compatibility (EMC) — Part 4-2: Testing and measurement techniques — Electrostatic discharge immunity test*

IEC 62304, *Medical device software — Software life cycle processes*

EN 1593, *Non-destructive testing — Leak testing — Bubble emission techniques*

EN 13185, *Non-destructive testing — Leak testing — Tracer gas method*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 14708-1 and the following apply.

3.3.1
cochlear implant system
CIS
active implantable medical device, comprising implantable and NON-IMPLANTABLE PARTS, intended to treat hearing impairment via electrical stimulation of the cochlea

3.3.2
auditory brainstem implant system
BIS
ACTIVE IMPLANTABLE MEDICAL DEVICE, comprising implantable and NON-IMPLANTABLE PARTS, intended to treat hearing impairment via electrical stimulation of the auditory brainstem

3.3.3
implant system
either COCHLEAR IMPLANT SYSTEM or AUDITORY BRAINSTEM IMPLANT SYSTEM

3.3.4
non-implantable part
external part of the IMPLANT SYSTEM

Note 1 to entry: Examples would include, but are not limited to, sound processor, microphone, coil or power source.

3.3.5
stimulator
implantable part of the IMPLANT SYSTEM containing electronic circuitry required to produce electrical stimulation

3.3.6
body-worn
NON-IMPLANTABLE PART of the IMPLANT SYSTEM and worn on the body (e.g. belt or ear level)

3.5.1
electrode contact
electrically conducting part which is designed to form an interface with body tissue or body fluid

3.5.2
electrode array
DISTAL part of a LEAD containing more than one ELECTRODE CONTACT

3.5.3
reference electrode
electrically conducting part designed as return path for electrical stimulation current

3.5.4
distal
located away from the point of attachment to the STIMULATOR

3.5.5
proximal
located closest to the point of attachment to the STIMULATOR

3.9.1
model designation
name and/or a combination of letters and numbers used by a manufacturer to distinguish, by function or type, one device from another

3.9.2
serial number
unique combination of letters and/or numbers, selected by the manufacturer, intended to distinguish a device from other devices with the same MODEL DESIGNATION

3.20.1
output signal
electrical output, either pulsatile or analogue, of an IMPLANT SYSTEM intended to stimulate the auditory pathways

3.20.2
pulse
specified electrical OUTPUT SIGNAL (voltage or current) of a specified amplitude and duration

3.20.3
biphasic pulse
PULSE which has both negative and positive going phases

3.22.1
use-before-date
date after which the manufacturer recommends that the IMPLANT SYSTEM should not be implanted

3.22.2
magnet
component producing an external magnetic flux

4 Symbols and abbreviations

There are no requirements specified in this part of ISO 14708. However this does not preclude the use of symbols defined in other standards nor special symbols defined in the accompanying documentation.

5 General requirements for non-implantable parts

5.1 This subclause of ISO 14708-1 applies.

5.2 *Replacement*

Software of an ACTIVE IMPLANTABLE MEDICAL DEVICE or software that falls within the definition of an ACTIVE IMPLANTABLE MEDICAL DEVICE shall be designed according to software life cycle process activities compliant with IEC 62304 and validated.

6 Inspection and measurement

If this part of ISO 14708 refers to inspection of design analysis documentation provided by the manufacturer, it shall include an inspection of the risk management file as required by ISO 14971.

6.1 Measurement of output signal characteristics

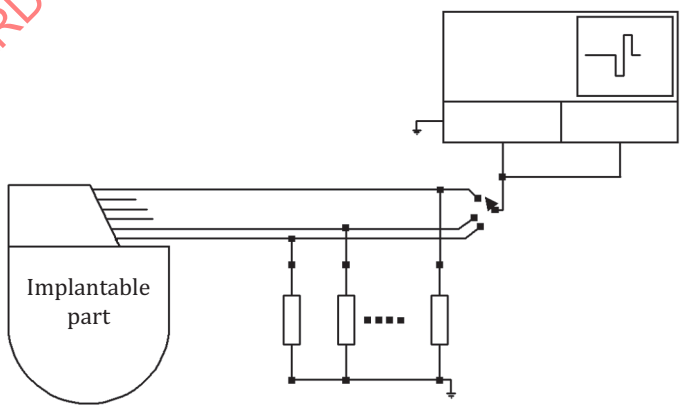
The measurement shall be performed with the implantable part of the IMPLANT SYSTEM at a temperature of (37 ± 2) °C. The IMPLANT SYSTEM shall be configured to use its maximum number of outputs and each output shall be programmed to its maximum value (amplitude and pulse width). An input signal equivalent to 70dB SPL shall be applied to the microphone. Where applicable, the transcutaneous link shall operate over a distance of (5 ± 1) mm. Where the IMPLANT SYSTEM provides alternative OUTPUT SIGNALS each shall be measured and listed separately. To facilitate connection the test sample may be unfinished. The accuracy of the amplitude measurement shall be better than ± 5 % taking all errors into consideration.

6.2 Measurement of the output SIGNAL amplitude and pulse width

A representative sample of the IMPLANT SYSTEM shall have each output connected to a 1 kΩ (±1 %) load resistor (see Figure 101) and configured per 6.1. An oscilloscope shall be adjusted to display the full output at its maximum resolution. The measurement shall be made in the peak of the OUTPUT SIGNAL. Each output shall be in turn connected to the oscilloscope and the amplitude and pulse width shall be measured. The median of the amplitudes and pulse widths and their range shall be recorded and the result shall be expressed in µA and µs.

6.3 Impedance measurement accuracy

Where the IMPLANT SYSTEM allows an impedance measurement (either by telemetry or direct measurement) the manufacturer shall specify the accuracy of the impedance measurement for a 10 kΩ load resistor. The measurement conditions shall be chosen to reflect normal clinical practice. The measurement shall be repeated on every output (see Figure 101). The accuracy of the impedance measurement shall be expressed as a percentage.



NOTE Ground is connected to the external reference electrode, if available.

Figure 101 — Measurement of output signal amplitude and load impedance

7 General arrangement of the packaging

7.1 This subclause of ISO 14708-1 applies.

7.2 This subclause of ISO 14708-1 applies.

8 General markings for active implantable medical devices

8.1 This subclause of ISO 14708-1 applies.

8.2 This subclause of ISO 14708-1 applies.

9 Markings on the SALES PACKAGING

9.1 This subclause of ISO 14708-1 applies.

9.2 This subclause of ISO 14708-1 applies except as follows:

Replacement:

The SALES PACKAGING shall bear the name and address of the manufacturer, the address including at least the city and country. The SALES PACKAGING shall bear the name and address of the authorized representative, if the manufacturer does not have a registered place of business in the European Community.

Compliance is checked by inspection.

9.3 *Replacement*

Where an IMPLANT SYSTEM is supplied in separate sub-assembly packaging, each individual SALES PACKAGING shall bear a description of the contents of the packaging, the model designation or part number and, if applicable the batch number or the serial number.

Compliance is checked by inspection.

9.4 This subclause of ISO 14708-1 applies.

9.5 This subclause of ISO 14708-1 applies.

9.6 This subclause of ISO 14708-1 applies.

9.7 *Replacement*

The SALES PACKAGING of implantable parts of an ACTIVE IMPLANTABLE MEDICAL DEVICE shall bear the USE-BEFORE-DATE, as expressed in 9.6.

Compliance shall be checked by inspection.

9.8 This subclause of ISO 14708-1 applies.

9.9 This subclause of ISO 14708-1 applies.

9.10 This subclause of ISO 14708-1 applies.

9.11 This subclause of ISO 14708-1 applies.

9.12 *Additional subclause*

Where an implant system is supplied in separate sub-assembly packaging, each individual sales packaging shall bear a description of the contents of the packaging, the model designation or part number and, if applicable, the batch number or the serial number.

Compliance shall be checked by inspection.

10 Construction of the SALES PACKAGING

10.1 This subclause of ISO 14708-1 applies.

10.2 This subclause of ISO 14708-1 applies.

10.3 This subclause of ISO 14708-1 applies.

Additional note:

NOTE Removable stickers, which provide supplementary information exceeding the information specified in Clause 9 need not to be subjected to the test specified in 10.3.

10.4 This subclause of ISO 14708-1 applies.

11 Markings on the sterile pack

11.1 This subclause of ISO 14708-1 applies.

11.2 This subclause of ISO 14708-1 applies.

11.3 This subclause of ISO 14708-1 applies.

11.4 This subclause of ISO 14708-1 applies.

11.5 This subclause of ISO 14708-1 applies.

11.6 This subclause of ISO 14708-1 applies.

11.7 This subclause of ISO 14708-1 applies.

11.8 This subclause of ISO 14708-1 applies.

11.9 This subclause of ISO 14708-1 applies.

11.10 This subclause of ISO 14708-1 applies.

NOTE This subclause can be fulfilled using an unambiguous symbol.

12 Construction of the non-reusable pack

12.1 This subclause of ISO 14708-1 applies. except as follows:

Replacement:

The NON-REUSABLE PACK shall comply with ISO 11607-1.

Compliance shall be checked by inspection and by review of records provided by the manufacturer.

12.2 This subclause of ISO 14708-1 applies.

12.3 This subclause of ISO 14708-1 applies.

13 Markings on the active implantable medical device

13.1 This subclause of ISO 14708-1 applies.

13.2 This subclause of ISO 14708-1 applies.

13.3 *Replacement*

Implantable parts of an IMPLANT SYSTEM shall be unequivocally identifiable (particularly with regard to the model designation of the device), when necessary, without the need for a surgical intervention.

Compliance shall be confirmed by inspection of the procedure defined by the manufacturer in the instructions for use (see 28.6).

13.4 This subclause of ISO 14708-1 applies.

14 Protection from unintentional biological effects being caused by the active implantable medical device

14.1 This subclause of ISO 14708-1 applies.

14.2 *Replacement*

Any implantable part of the ACTIVE IMPLANTABLE MEDICAL DEVICE, intended in normal use to be in contact with body fluids, shall cause no unacceptable release of particulate matter when the device is used as intended by the manufacturer.

Test: The implantable part of the IMPLANT SYSTEM shall be removed aseptically from the NON-REUSABLE PACK. The implantable part shall be immersed in a bath of saline solution, approximately 9 g/l and suitable for injection in a neutral glass container. The volume of the saline in millilitres (ml) shall be 5 ± 0,5 times the numerical value of the surface area of the implantable part expressed in cm^2. The container shall be covered with a glass lid and maintained at (37 ± 2) °C for between 8 h and 18 h, the bath being agitated throughout the period. A reference sample of similar volume shall be prepared from the same batch of saline, maintained and agitated in a similar way to the specimen. A sample of liquid from the specimen bath and from the reference bath shall be compared using apparatus suitable for measurement of particle size, such as apparatus operating on the light blockage principle (see method V.5.7.1 of the European Pharmacopoeia) or the electrical zone sensing principle (the Coulter principle, see Appendix XIII of the British Pharmacopoeia).

Compliance shall be confirmed if the excess average count of unintentional particles from the specimen compared to the reference sample does not exceed 100 per ml greater than 5,0 µm and does not exceed 5 per ml greater than 25 µm.

14.3 *Replacement*

This subclause of ISO 14708-1 applies with the addition that ISO 10993-1 shall be used.

14.4 This subclause of ISO 14708-1 applies.

15 Protection from harm to the patient or user caused by external physical features of the active implantable medical device

15.1 This subclause of ISO 14708-1 applies.

15.2 *Replacement*

Implantable parts of an IMPLANT SYSTEM shall have no surface features, such as sharp corners or edges that could cause excessive reaction or inflammation beyond that caused by the implanting procedure, or rough surfaces which are not required for the correct functioning of the device.

Compliance shall be confirmed if records provided by the manufacturer establish that the safety of the physical characteristics has been verified with appropriate methods.

16 Protection from harm to the patient caused by electricity

16.1 *Replacement*

Electrical audio inputs into NON-IMPLANTABLE PARTS of an IMPLANT SYSTEM shall comply with the requirements for electrical safety of the hearing aid standard IEC 60118-6. Other electrical inputs or outputs of NON-IMPLANTABLE PARTS of an IMPLANT SYSTEM that allow the NON-IMPLANTABLE PART to be connected to supply mains or mains powered devices which do not meet the insulation requirements of IEC 60601-1 shall either contain or be provided with a separation device which complies with the applicable clauses regarding insulation of IEC 60601-1 (separation device as defined in IEC 60601-1:2006, 16.5.).

NOTE A separation device is not required for battery powered devices when used alone.

Compliance shall be checked as specified in IEC 60601-1 (if applicable) and by review of the documentation provided by the manufacturer.

16.2 *Replacement*

Except for its intended function, implantable parts of an IMPLANT SYSTEM shall be electrically neutral when in contact with the body. No leakage current (direct current) of more than 0,1 µA shall be sustained in any of the current pathways when the device is in use.

Compliance shall be confirmed by inspection of test procedures and results provided by the manufacturer.

16.3 This subclause of ISO 14708-1 applies.

17 Protection from harm to the patient caused by heat

17.1 This subclause of ISO 14708-1 applies.

17.2 This subclause is to be left vacant for future editions.

18 Protection from ionizing radiation released or emitted from the active implantable medical device

18.1 This subclause of ISO 14708-1 applies.

18.2 This subclause of ISO 14708-1 applies.

18.3 This subclause of ISO 14708-1 applies.

19 Protection from unintended effects caused by the device

NOTE See also 28.20.

19.1 This subclause of ISO 14708-1 applies.

19.2 *Replacement*

If the implantable part of an IMPLANT SYSTEM contains within it a source of power, such as a battery, the IMPLANT SYSTEM shall include an 'indicator' that gives advance notice of energy source depletion to the clinician and user.

Compliance shall be confirmed by inspection of a design analysis provided by the manufacturer, supported by the manufacturer's calculations and data from test studies as appropriate.

19.3 This subclause of ISO 14708-1 applies.

19.4 This subclause of ISO 14708-1 applies except as follows:

Replacement of the assessment:

Side effects and benefits from the intended use of the device shall be identified either by reference to current medical practice and demonstrated by analogy, or by reference to clinical investigations conducted according to ISO 14155.

Additional subclauses:

19.5 The physical, biological and geometric properties of the implantable parts of an IMPLANT SYSTEM shall, as far as necessary, be designed to ensure that device removal and replacement with a device from the same manufacturer is not compromised.

Compliance shall be confirmed by inspection of a design analysis provided by the manufacturer and where available supported by appropriate test and clinical data e.g. post market surveillance data relating to device replacement.

19.6 The implantable STIMULATOR case of an IMPLANT SYSTEM intended in normal use to be in contact with body fluids shall provide sufficient hermeticity so that no fluid can infiltrate the STIMULATOR case.

Tests: Fine and gross leak tests shall be conducted on the hermetic casing of the STIMULATOR of an IMPLANT SYSTEM in accordance with EN 13185 and EN 1593. If a group A technique is used from the EN 13185 standard then a gross leak test is not required; if a group B technique is used then the gross leak test shall follow the fine leak test.

NOTE The manufacturer should include adequate hermeticity testing in their manufacturing process.

Compliance shall be confirmed by inspection of test procedures and results provided by the manufacturer and by the device leak rate not exceeding 5×10^{-9} Pa m^3/s for the fine leak test and no definite stream of bubbles, or two or more large bubbles, originating from the same point of the STIMULATOR case for the gross leak test.

20 Protection of the device from damage caused by external defibrillators

NOTE See also 28.12.

20.1 This subclause of ISO 14708-1 is not applicable to this part of ISO 14708.

20.2 This subclause of ISO 14708-1 applies.

21 Protection of the device from changes caused by high power electrical fields applied directly to the patient

NOTE See also 28.12 and 28.13.

21.1 *Replacement:*

The implantable part of an IMPLANT SYSTEM shall be designed so that stray, high frequency current from surgical equipment (surgical diathermy) flowing through the patient shall not permanently affect the device provided the IMPLANT SYSTEM does not lie directly in the path between cutting and return (RF earth) electrodes (see also requirement for warning advice, 28.13).

Test: Use a signal generator with an output impedance of 50 Ω (R1). The test signal frequency shall be 500 kHz sinusoid and the open loop test signal amplitude 20 V_{pp}.

The IMPLANT SYSTEM shall be switched off. Each output of the implantable part of the IMPLANT SYSTEM shall be connected via a resistor (R) of 4,7 kΩ to a common point which shall be connected to the output of the signal generator (see Figure 102). The REFERENCE ELECTRODE of the implantable part of the IMPLANT SYSTEM shall be connected via a 100 Ω resistor (R3) to the ground of the signal generator.

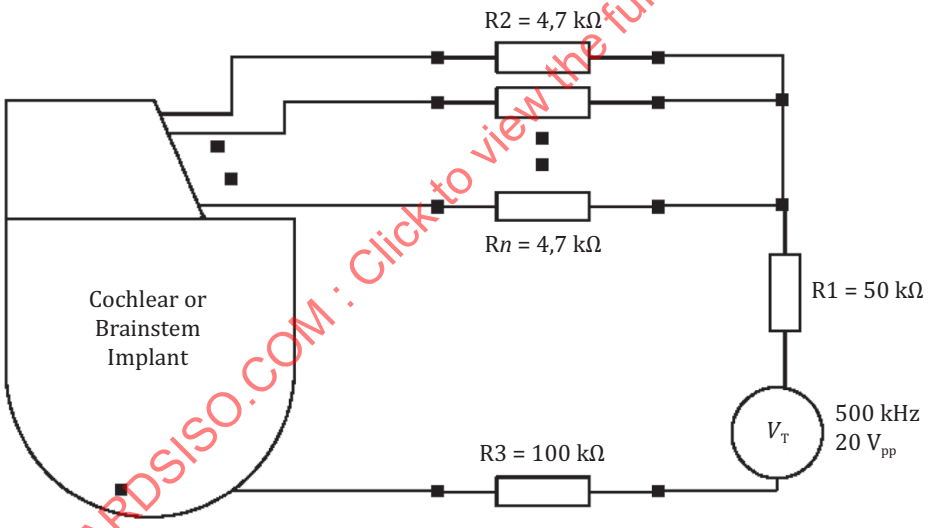


Figure 102 — Test set-up for proof of protection from high frequency currents caused by surgical equipment

Apply the test signal in 10 bursts each for a duration of 1 s, allowing a recovery period of 5 s between bursts.

Compliance shall be confirmed if, after completing the test procedure and reactivating, the IMPLANT SYSTEM characteristics conform with the manufacturer's original specification.

21.2 This subclause is to be left vacant for future editions.

22 Protection of the active implantable medical device from changes caused by miscellaneous medical treatments

NOTE See also 28.12, 28.14 and 28.15.

22.2 Clause 22 of ISO 14708-1 applies.

Additional subclauses

22.2 Implantable parts of an IMPLANT SYSTEM shall be identified where MRI safety is declared by the manufacturer (see 28.8). The manufacturer shall declare (see 28.12) the conditions (including the specific field strengths) under which the safety of MRI testing has been verified. The declaration shall include the risk for demagnetisation, image distortion and instructions for safe performance of MRI investigations, where applicable.

The risks to a subject implanted with an IMPLANT SYSTEM entering an MRI machine may be grouped under the following areas: force from the magnetic field, heat generation, unintentional device output and implant damage. Each of these factors shall be tested as follows:

a) Force

The implantable part of an IMPLANT SYSTEM shall not produce harm to the patient through mechanical forces which might occur during MRI scanning.

Test: The force is calculated from the magnetic field strength of the MRI machine, the magnetic properties of any ferromagnetic or paramagnetic materials incorporated in the implantable part, the strength of any internal magnet and the geometry of the implanted part containing the magnet. Alternatively, the force may be measured.

Compliance shall be confirmed if the maximum force under worst case orientation is below 10 N or no displacement of the implant or magnet is demonstrated.

b) Heat generation

The implantable part of an IMPLANT SYSTEM shall not generate excessive heat during MRI scanning.

Test: Two identical covered plastic containers shall be selected with volume sufficient to contain the entire implantable part of the IMPLANT SYSTEM ensuring that it will be completely submerged. The volume of the saline shall be 3 ± 0,3 × the volume of the implantable part. The volume of the implant plus saline in one container shall be identical to the volume of the saline in the other container. The implantable part of the IMPLANT SYSTEM stored at the temperature of the scanning location of the MRI department for the past 24 h shall be placed in one container. Both containers shall be filled with 9 g/l saline also previously stored for the previous 24 h in the same location. The temperature of each container's saline shall be recorded using a digital thermometer with a resolution of 0,1 °C. Room temperature is also recorded. Both containers are then placed in a position within the MRI machine judged to receive the highest amount of RF power. An MRI test sequence representing the worst case clinical scan typically performed (highest absorption rate) shall be initiated and run for at least 15 min. Immediately after the scan is completed the two containers shall be removed from the MRI chamber and the temperature of each container recorded again. Alternatively ASTM F2182 may be used to test for the temperature rise at the implant and lead.

Compliance shall be confirmed if the temperature difference between the two containers or temperature rise at the implant or electrode tip is less than 2 °C.

c) Unintentional output

The implantable part of an IMPLANT SYSTEM shall not generate harmful output to the patient during MRI scanning.

Test: The implantable part of the IMPLANT SYSTEM shall be placed inside the MRI machine. Two modified IMPLANT SYSTEMS shall be tested: One IMPLANT SYSTEM which has an additional sense resistor R1 placed in series with the REFERENCE ELECTRODE, with access to both ends of R1, and a second IMPLANT SYSTEM with access to the supply voltage of the implant. A receive/transmit optical fibre circuit and oscilloscope shall be connected to the sense resistor R1 as shown in Figure 103. For this test it is essential to use shielded twisted pair cable and a passive low pass filter. The recommended resistors are R1 = 10 kΩ, R2 = R3 = 22 kΩ. The three resistors shall be mounted within

an area of less than 1 cm^2. A low pass filter is formed by the resistors R2 to R5 and the capacitor C1. The input impedance of the optical fibre unit should be taken into account when specifying the values R4 and R5. The cut-off frequency shall be approximately 10 kHz. All components should be constructed using surface mount technology and made of non-magnetic materials. The oscilloscope shall be placed outside the MRI room or a measurement equipment which is not affected by the MRI machine shall be used. The implantable part of the IMPLANT SYSTEM including the ELECTRODE ARRAY and the REFERENCE ELECTRODE shall be placed in a container filled with 9 g/l saline or a gelled phantom material of similar conductivity in a position typical for an implanted device. An MRI test sequence representing the worst case clinical scan shall be performed. The output charge shall be determined from the voltage measured across the sense resistor.

Compliance shall be confirmed if the charge per phase does not exceed 10 nC.

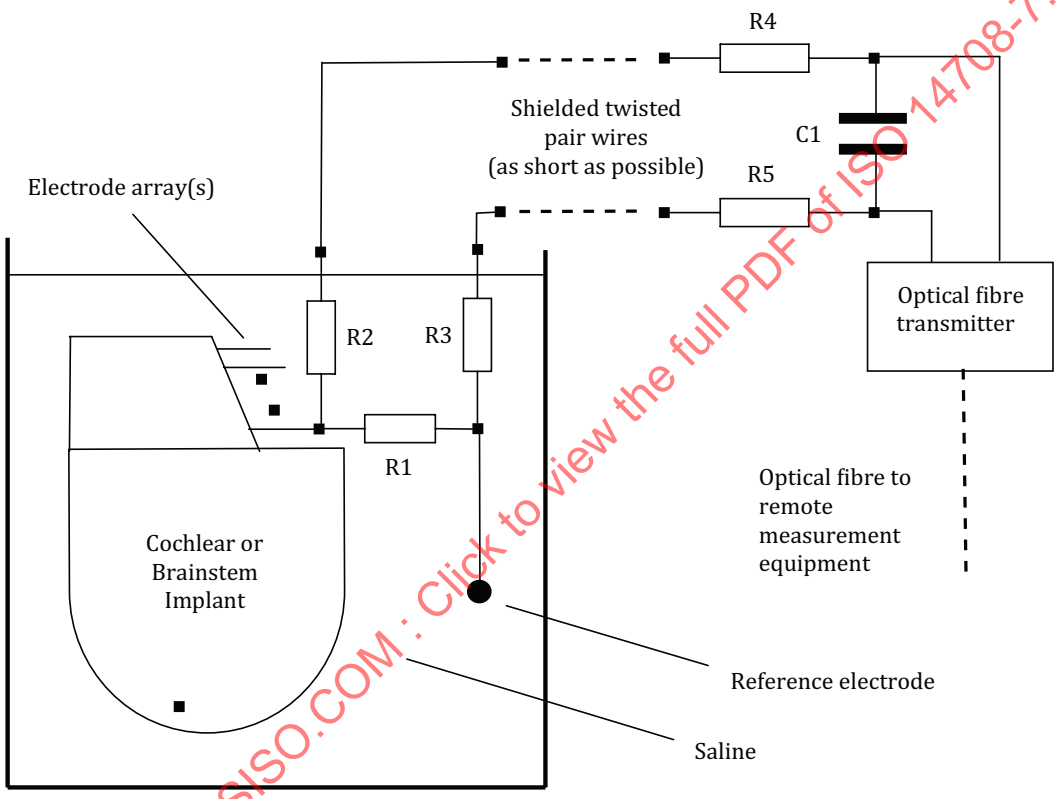


Figure 103 — Test set-up for proof of protection from harmful output during MRI scanning

d) Implant damage

The implantable part of an IMPLANT SYSTEM shall not be damaged during MRI scanning.

Test: The following test shall be applied for each field strength specified as MRI safe by the implant manufacturer. A representative sample of the implantable part of the IMPLANT SYSTEM shall be completely immersed in a non-metallic container filled with 9 g/l saline. The container shall be placed in the centre of the MRI machine and a worst case scan as described in b) initiated.

Compliance shall be confirmed if after the scan the device conforms to the manufacturer's specifications. A reduction in strength of the internal magnet is acceptable providing the manufacturer makes available an alternative fixation method and appropriate information in the labelling (see 28.12).

22.3 The implantable part of an IMPLANT SYSTEM shall withstand levels of therapeutic ionising radiation as specified by the implant manufacturer.

Test: Three samples of the implantable part of the IMPLANT SYSTEM shall be irradiated using Photon radiation with 5 Gray doses to a maximum cumulative dose as specified by the manufacturer. Irradiation shall be delivered at 24 h intervals, at least four times per week. After each exposure the device shall be powered using normal clinical conditions. Before each irradiation the amplitude of the OUTPUT SIGNAL shall be monitored as specified in 6.1 and 6.2. While the OUTPUT SIGNAL amplitude of each sample remains within 10 % of its value before the first irradiation, a further dose is applied. The manufacturer shall state the median dose of the three samples for which the OUTPUT SIGNAL last met the above criteria. The labelling statement (see 28.12) shall include a safety margin of 20 % of this dose.

Compliance shall be checked by review of the test results and documentation provided by the manufacturer.

23 Protection of the active implantable medical device from mechanical forces

23.1 *Replacement:*

NON-IMPLANTABLE PARTS of an IMPLANT SYSTEM that are either hand-held in normal use, portable or BODY WORN and weigh not more than 10 kg, shall be constructed so that shocks caused by mishandling or dropping while in use do not damage the device.

Test: Hand-held, BODY-WORN or portable parts of an IMPLANT SYSTEM weighing up to 10 kg shall withstand the free fall test in accordance with IEC 60068-2-31, under the following conditions:

a) test surface: hard wood, density not less than 630 kg/m^3, thickness between 50 mm and 55 mm;

b) height of fall:

hand-held devices: 1 m;

portable devices: 50 mm;

BODY WORN PART: 1,5 m or the height of normal use whatever is more severe;

c) attitude from which specimen is dropped: attitude as in normal use.

Compliance shall be confirmed if the dropped part operates as stated in the manufacturer's original specification.

23.2 *Replacement:*

The implantable part of the IMPLANT SYSTEM shall be constructed to withstand the mechanical forces that might occur during normal conditions of use, including the time prior to implantation.

Test: The implantable part of the IMPLANT SYSTEM, mounted in accordance with the requirements and guidance given in IEC 60068-2-47, shall withstand a random vibration test in accordance with IEC 60068-2-64, Test Fh, under the following conditions:

a) test frequency range: 5 Hz to 500 Hz;

b) acceleration spectral density: 0,7 $(m/s^2)^2/Hz$;

c) shape of acceleration spectral density curve: flat horizontal, 5 Hz to 500 Hz;

d) duration of testing: 30 min in each of three mutually perpendicular axes.

Compliance shall be confirmed if, after completing the test procedure, the values for the IMPLANT SYSTEM characteristics conform with the values stated in the manufacturer's original specification.

23.3 *Replacement:*

Implantable LEADS outside the STIMULATOR shall withstand the tensile forces that might occur during or after implantation, without fracture of any conductor or deterioration to any functional electrical insulation.

There are two specimens intended for the test:

specimen A shall be the implantable part in the condition as shipped to the customer; if necessary the leads shall be attached in accordance with the manufacturer's instruction before the test;

specimen B shall be the implantable lead without the STIMULATOR.

Procedure: Use a saline preconditioning bath of approximately 9 g/l saline at 37 °C ± 5 °C, a tensile load tester and a voltmeter or an oscilloscope.

Both specimens shall be kept in the preconditioning bath for a minimum of 10 days. Immediately prior to testing, the lead shall be rinsed in distilled or deionised water, then wiped free of surface water.

The manufacturer shall identify that portion of the LEAD which, when implanted, might be subject to elongation. The manufacturer shall devise an appropriate method of clamping the LEAD to include the elongation portion.

a) Test for specimen A:

Specimen A shall be clamped at the STIMULATOR or at the connector, if applicable. Another clamp shall be firmly attached to the most DISTAL part of the LEAD subject to elongation. The distance between the clamping points shall be measured.

The LEAD shall be subjected to an elongation of minimum of 15 mm or a tensile force of minimum 1 N, whichever is reached first. The applied tensile stress shall be sustained for at least one minute then relieved. The tensile load application shall be repeated for each LEAD. The test specimen(s) shall be returned to the saline bath and shall be immersed again for a minimum of one hour before proceeding.

The electrical continuity of each conduction path (open circuit test) and insulation (short circuit test) between each pair of wires inside the LEAD (if applicable) shall be verified.

Compliance shall be confirmed if the specimen A exhibits no permanent functional damage (e.g. no open or short circuits).

b) Insulation test for specimen B:

Specimen B shall be subjected to the same elongation test as specimen A except both sides of the lead shall be clamped. Following the elongation test the insulation shall be subjected to a test voltage. The test signal shall be a 1 kHz square wave with a peak to peak voltage of twice the maximum peak to peak output voltage of the IMPLANT SYSTEM. The test signal shall be applied for a minimum of 15 s between each combination of conducting pairs inside the lead. The impedance between each pair shall be measured.

Compliance shall be confirmed if the lead shows no damage as a result of the elongation test and the impedance between each pair of conducting wires exceeds 100 kΩ.

23.4 This subclause of ISO 14708-1 applies.

23.5 *Replacement:*

Electrode LEADS shall withstand the flexural stresses that might occur during and after implantation, without fracture of any conductor.

Three samples shall be tested for Test 1 and then Test 2.

Test 1: The test samples shall be in the condition as shipped to the customer. The tests shall be performed in dry conditions and at room temperature.

For each sample the LEAD shall be held with a suitable soft clamping mechanism (such that the LEAD will remain securely clamped during the test) 10 mm ± 2 mm PROXIMAL from the most PROXIMAL ELECTRODE CONTACT (see Figure 104). The STIMULATOR shall be held at the same height, adjacent to the clamp and released five times.

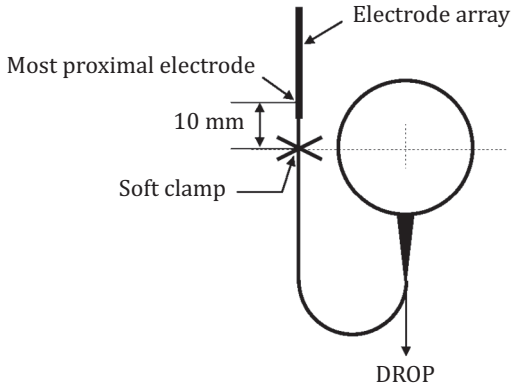


Figure 104 — Stimulator drop test

Compliance shall be confirmed if the measured resistance of each conduction path and each sample is within the manufacturer's specification and each conductor is functionally intact as per the manufacturer's performance specification.

Test 2: The test shall be applied to that region of the LEAD where, after implantation, flexing can occur due to micro movements. The test samples shall be preconditioned the same way as the fully assembled and shipped product. The tests shall be performed in dry conditions and at room temperature.

Use a holding fixture made of rigid material (see Figure 105) to clamp the STIMULATOR.

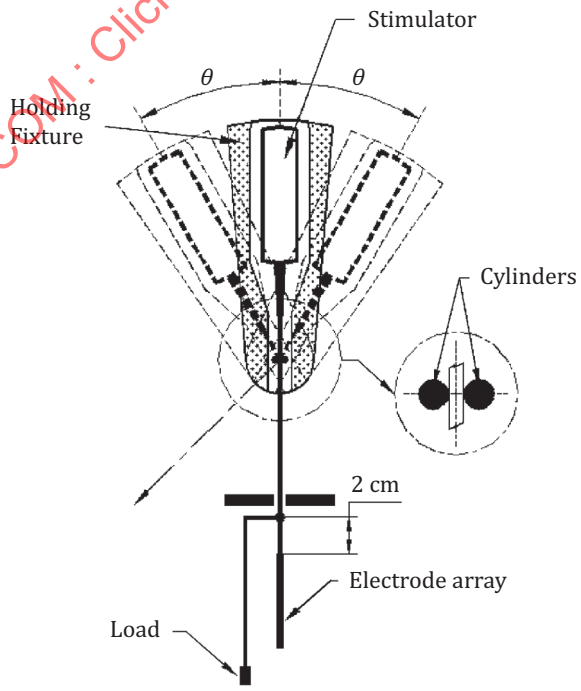


Figure 105 — Flex test fixture

The holding fixture shall be mounted in an oscillating machine that can flex the LEAD either side from the straight direction. The holding fixture shall allow the LEAD to be tensioned in the direction it exits the STIMULATOR. The LEAD shall be fed between two cylinders both touching the LEAD. The pivot point shall be in the middle of the line between the centres of both cylinders. The diameter of the cylinders shall be twice the diameter of the LEAD. Where more than one LEAD exits the STIMULATOR each LEAD shall be tested separately.

The load shall be firmly attached to the LEAD 2 cm ± 0,2 cm PROXIMAL from the most PROXIMAL electrode. The total load shall apply 0,03 N ± 0,01 N.

The holding fixture shall be then oscillated through an angle of 15° (or any greater angle specified by the manufacturer) each side at a rate of approximately 2 Hz for a minimum of 100 000 (hundred thousand) cycles.

Alternatively, an equivalent test may be performed where the STIMULATOR remains stationary and the LEAD is oscillated provided all other test conditions remain the same.

Compliance shall be confirmed if after testing the measured resistance of each conduction path is within the manufacturer's specification and each conductor is functionally intact as per the manufacturer's performance specification.

23.6 *Replacement:*

Implantable connectors, intended for use by physicians to connect implantable parts, shall be identified (see 8.2 and 9.9). The manufacturer shall declare (see 28.4) the intended performance as implanted. The quality of connection shall not degrade during use. Re-connection shall be possible without a degradation in performance of the device.

Compliance shall be confirmed by inspection of a design analysis provided by the manufacturer, supported by the manufacturer's calculations and data from test studies as appropriate.

Additional subclauses:

23.7 The implantable part of an IMPLANT SYSTEM shall be constructed so that minor shocks caused by handling during the implantation procedure do not damage the device.

Test: The implantable part of the IMPLANT SYSTEM shall withstand the mechanical shock test in accordance with IEC 60068-2-27, Test Ea, under the following conditions.

a) Shock shape: half sine or haversine.

b) Severity: peak acceleration: 5 000 m/s^2 (500 g).

c) Duration of shock: 1 ms.

d) Direction and number of shocks: one shock in each direction along three mutually perpendicular axes (total of six shocks).

Compliance shall be confirmed if, after completing the test procedure, the IMPLANT SYSTEM characteristics (refer to Clause 6) conform to the manufacturer's original specification.

23.8 The implantable part of the IMPLANT SYSTEM shall be constructed so that impacts experienced during normal use do not damage the device.

Test: If the STIMULATOR of the IMPLANT SYSTEM is likely to be exposed to mechanical impact when implanted, due to its location, it shall be clamped into a testing apparatus in accordance with IEC 60068-2-75, Test Eha or Ehc, under the following conditions:

a) Impact energy [J] (±5 %): 1,5 J after the date of publication of this part of ISO 14708 and 2,5 J three years thereafter.

b) Number of impacts: 1 per test (protective material + implant).

c) Type of testing apparatus used: pendulum hammer (IEC 60068-2-75, Test Eha) or vertical hammer (IEC 60068-2-75, Test Ehc). Striking element: 5-J-striking element in accordance with IEC 60068-2-75, Table 1.

d) Mounting of the sample undergoing the test: the sample shall be affixed to the rigid and flat supporting surface so that the side facing the cranial bone during normal use (*in situ*) shall lie evenly on the supporting surface. During impact, a piece of silicone (thickness: 3 mm, size: (10 × 10) cm^2, shore hardness: 40° to 60°) shall be placed evenly over the implant, between measuring point and implant (protective material). This piece of silicone shall be renewed for each individual test.

NOTE 1 "Tip" of the striking element, definition cf. IEC 60068-2-75:1997, 4.1.1.

e) Pre-treatment: none.

f) Initial measurements: the function of the sample according to its specification shall be controlled and confirmed.

g) Position and impact locations: the implant shall be affixed so that the surface that during normal use (*in situ*) faces the skin forms the area of impact i.e. on it the protective material comes to rest. The striking element shall hit the specimen (protective material and implant) perpendicularly, i.e. the direction of the striking element's movement shall be normal to the implant's surface. The striking element shall hit the protective material at the centre of the surface that during normal use (*in situ*) faces the skin. In a second test with a new sample (new protective material, new STIMULATOR), the striking element shall hit the implant's casing off-centrically at what is considered to be the "weakest" exposed point of the STIMULATOR.

NOTE 2 The exit of the leads from the stimulator is not considered the implant's casing.

h) Securing of base plates, coverings and similar parts: no special requirements. When performing the test a restriking (e.g. rebound) shall be avoided.

i) Mode of operation and monitoring of functions: function monitoring of the implant is not necessary during impact testing and it shall not be in operation.

j) Evaluation criteria: the requirements have been met if, after complete performance of the procedure for impact testing, both samples continue to comply with the specifications in 28.8.1b) and subsequently fulfils the hermeticity requirements in accordance with 19.6 for gross leak tests. An implantable microphone or other transducer might no longer function after the impact test. This is acceptable provided the failure of the microphone or transducer does not require replacement of the implantable part of the IMPLANT SYSTEM.

k) Follow-up treatment: none.

l) Final measurements: the measurements necessary for review of the specifications of the IMPLANT SYSTEM as well as the hermeticity test in accordance with 19.6. for gross leak tests.

m) A test protocol containing the following statements shall be compiled: denomination of standard and specification, date and time of test, exact description of the sample, impact test procedure (pendulum hammer or vertical hammer), exact position of the point of impact (e.g. described in a drawing), type of silicone piece used (e.g. product name, source of product, mechanical properties), exact description of the testing of specifications prior to and after impact, results of the specification testing, results of the hermeticity test, results of the entire test.

Compliance shall be confirmed according to test results in point j) above provided by the manufacturer.

24 Protection of the active implantable medical device from damage caused by electrostatic discharge

24.1 *Replacement:*

The implantable part and the NON-IMPLANTABLE PART of the IMPLANT SYSTEM shall be designed and constructed so that no irreversible change will be caused by an electrostatic discharge, such as might be experienced during normal conditions of use.

Test: The implantable part shall be completely immersed in a non-metallic container filled with saline solution of approximately 9 g/l at room temperature. The NON-IMPLANTABLE PART shall be coupled at a distance of (5 ± 1) mm to the implantable part. The IMPLANT SYSTEM shall be set to function according to the manufacturer's instructions. The implantable part and the NON-IMPLANTABLE PART of the IMPLANT SYSTEM shall withstand the electrostatic discharge test, applied to the external components, as described in IEC 61000-4-2 (with the climatic conditions as explicitly defined by 8.1.1) with a test voltage of 2 kV in the case of contact discharge to conductive surfaces and 8 kV in the case of air discharge to insulating surfaces. At least 10 discharges at the 2 kV test voltage and 5 discharges at the 8 kV test voltage shall be applied.

Compliance shall be confirmed if the IMPLANT SYSTEM operates in a safe mode and if necessary can be reset to provide all functions as stated in the manufacturer's specification for the IMPLANT SYSTEM when it is checked after performing the test above.

NOTE Resetting may be accomplished by switching the IMPLANT SYSTEM off and on.

24.2 This subclause is to be left vacant for future editions.

25 Protection of the active implantable medical device from damage caused by atmospheric pressure changes

25.1 This subclause of ISO 14708-1 applies.

25.2 Implantable parts of an IMPLANT SYSTEM shall be constructed to withstand foreseeable increases in pressure, which might occur during vocational activities.

Test: The device shall be placed in a suitable water pressure chamber and cycled 20 times from ambient pressure to a maximum pressure, which shall be 1,5 times the pressure specified in the manufacturer's documentation (see 28.21). The rate of pressure change shall be at least 100 kPa per minute and the maximum pressure shall be maintained for at least one minute.

Compliance shall be confirmed by inspection of test procedures and results provided by the manufacturer.

26 Protection of the active implantable medical device from damage caused by temperature changes

26.1 This subclause of ISO 14708-1 applies.

26.2 This subclause of ISO 14708-1 applies.

27 Protection of the active implantable medical device from electromagnetic non-ionising radiation

27.1 *Replacement:*

Implantable parts of an IMPLANT SYSTEM shall not cause HARM because of susceptibility to electrical interference due to external electromagnetic fields under every circumstance which might be encountered in public access areas, whether through malfunction of the device, damage to the device, heating of the device, or by causing local increase of induced electrical current density within the patient.

All protection requirements in 27.3 to 27.4 shall be met for all settings of the IMPLANT SYSTEM. This does not mean that all combinations of settings are considered but at least the following representing the worst case: the IMPLANT SYSTEM shall be configured to continuously produce the maximum value of the output signal defined in 6.2 on at least two output electrodes. The microphone sensitivity shall be adjusted to the normal clinical setting, if applicable.

Compliance shall be confirmed if no permanent damage to the IMPLANT SYSTEM can be demonstrated after exposure at the upper level given in 27.3 and 27.4 and if during exposure no currents larger than the maximum value of the output signal defined in 6.2 are delivered to the tissue. Compliance shall be confirmed according to test results or by an inspection of theoretical modelling provided by the manufacturer, supported by the manufacturer's calculation and data from test studies as appropriate. In case the output current cannot be measured directly or indirectly while the interference signal is present an additional design analysis of the electronic circuit shall demonstrate that the IMPLANT SYSTEM cannot deliver higher output signals than defined in 6.2.

27.2 *Replacement:*

The function of an IMPLANT SYSTEM shall not be significantly influenced by external electromagnetic fields which commonly might be encountered during normal daily living. No significant influence means that there shall be no long term discomfort, however some signal degradation may be tolerated during exposure.

All requirements for not significantly influenced function in 27.3 to 27.4 shall be met for all settings of the IMPLANT SYSTEM. This does not mean that all combinations of settings are considered but at least the following representing the worst case: the device shall be configured to continuously produce between 25 % ("threshold level") and 50 % ("comfort level") of the maximum value of the output signal defined in 6.2 on at least two output electrodes. The microphone sensitivity shall be adjusted to the normal clinical setting, if applicable. The microphone ports may be blocked acoustically and any tele-coil may be switched off, if applicable. The device shall be programmed such that the input frequency range normally available to the user shall be applied to the electrodes.

Compliance shall be confirmed, if any output signal remains below "comfort level" during exposure at the lower level of 27.3 and 27.4. During the exposure the IMPLANT SYSTEM may occasionally drop out stimulation signals. In case that the device completely stops stimulation prior to reaching the lower levels of 27.3 and 27.4 the manufacturer shall declare the level at which this happens (see 28.22.1). Compliance shall be confirmed according to test results or by an inspection of theoretical modelling provided by the manufacturer, supported by the manufacturer's calculation and data from test studies as appropriate.

Additional subclauses:

27.3 Interference signal for frequencies 16,6 Hz ≤ *f* < 10 MHz

The time shape of the interference signal is specified in 27.5. The off-time τ_0 is 10 ms and the burst-on time τ is given in Tables 101 and 102.

Table 101 — Peak magnetic field strength H_P

Frequency	Peak magnetic field strength H_P			
	Lower level	Burst-on time	Upper level	Burst-on time
16,6 Hz	340 A/m	cw	480 A/m	cw
50 Hz	110 A/m	cw	1 200 A/m	cw
1,66 kHz	7,0 A/m	10 ms	150 A/m	10 ms
5 kHz	7,0 A/m	10 ms	150 A/m	10 ms
16,6 kHz	7,0 A/m	10 ms	150 A/m	10 ms
50 kHz	7,0 A/m	10 ms	150 A/m	10 ms
166 kHz	7,0 A/m	10 ms	110 A/m	10 ms
500 kHz	4,0 A/m	3 ms	26 A/m	1,5 ms
1,66 MHz	2,0 A/m	1 ms	5,5 A/m	200 µs
5 MHz	0,15 A/m	500 µs	2,9 A/m	50 µs
NOTE The fields do not have to be homogenous.				

27.4 Interference signal for frequencies 10 MHz ≤ f < 3 000 MHz

The interference signal is specified in 27.5.

Table 102 — Peak electric field strength E_P

Frequency	Peak electric field strength E_P			
	Lower level	Burst-on time	Upper level	Burst-on time
10 MHz	40 V/m	10 ms or cw	200 V/m	400 µs
33 MHz	40 V/m	10 ms or cw	200 V/m	400 µs
100 MHz	40 V/m	10 ms or cw	200 V/m	400 µs
450 MHz	40 V/m	10 ms or cw	200 V/m	400 µs
900 MHz	58 V/m	10 ms or cw	200 V/m	400 µs
1 800 MHz	82 V/m	10 ms or cw	200 V/m	400 µs
2 450 MHz	86 V/m	10 ms or cw	200 V/m	400 µs
NOTE The fields do not have to be homogenous.				

27.5 Specification of interference signal

At frequencies 16 Hz and 50 Hz the interference signal is sinusoidal (continuous wave, cw).

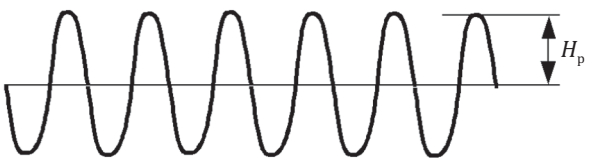


Figure 106 — Interference signal at 16 Hz and 50 Hz

At all other frequencies the interference signal is switched carrier.

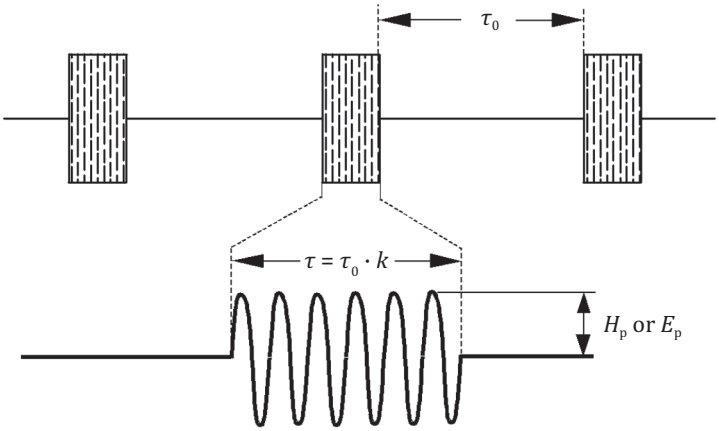


Figure 107 — Interference signal at frequencies above 1 kHz

28 Accompanying documentation

This clause of ISO 14708-1 applies except as follows.

28.1 *Replacement:*

The accompanying documentation shall include the name and address of the manufacturer, the address being the postal address and telephone number, or the name and address of the authorized representative, where the manufacturer does not have a registered place of business in the community.

Compliance shall be confirmed by inspection.

28.2 This subclause of ISO 14708-1 applies.

28.3 This subclause of ISO 14708-1 applies.

28.4 *Replacement:*

If the package contains an implantable part of an IMPLANT SYSTEM intended to be connected to another implantable device or accessory, the accompanying documentation shall provide information on the connector specifications, assembly instructions and connector performance determined according to 23.6.

Compliance shall be checked by inspection.

28.5 This subclause of ISO 14708-1 applies.

28.6 This subclause of ISO 14708-1 applies.

28.7 This subclause of ISO 14708-1 applies.

28.8 *Additional subclauses:*

28.8.1 The accompanying documentation shall include the following information for the implantable part of the IMPLANT SYSTEM, as appropriate:

a) Device description:

a general description, brief explanation of function, available stimulation modes;

a listing and brief description of other functions (impedance measurement, etc.);

the mass (in grams);

the principal dimensions (in millimetres);

the volume without LEAD (in cubic centimetres);

a listing of the materials which will come into contact with human tissue.

b) Performance characteristics:

amplitude and pulse width of the OUTPUT SIGNAL on a 1 kΩ resistor (as specified in 6.2);

impedance measurement accuracy (as specified in 6.3);

level of MRI safety (as specified in 22.2);

the default factory settings of the IMPLANT SYSTEM, if applicable;

recommended methods for determining that the implantable part of the IMPLANT SYSTEM is functioning properly (e.g. impedance measurement).

c) The specification and characteristics for each LEAD and the ELECTRODE ARRAY:

the electrical configurations (monopolar, number of electrically independent electrode contacts, etc.);

the shape and other characteristics (perimodiolar, drug delivering, etc.);

a listing of the materials used for the conductors, ELECTRODE CONTACTS, and insulation of the LEAD;

a statement advising whether the LEAD contains a MEDICINAL SUBSTANCE as an integral component, giving the identity of the MEDICINAL SUBSTANCE;

the physical dimensions, including (nominal value):

the length of the LEAD (in millimetres);

the cross sectional dimensions of the ELECTRODE ARRAY at the PROXIMAL and the DISTAL ends (in millimetres);

the geometric surface area of the smallest and largest stimulating ELECTRODE CONTACTS (in square millimetres);

the distance(s) between ELECTRODE CONTACTS and the distance between the most PROXIMAL and most DISTAL stimulating ELECTRODE CONTACTS (in millimetres);

the connector geometry, if applicable (lengths and diameters in millimetres), or a reference to published connector standards including any designations or markings.

Compliance shall be confirmed by inspection.

28.9 This subclause of ISO 14708-1 applies.

28.10 This subclause of ISO 14708-1 applies.

28.11 This subclause of ISO 14708-1 applies.

28.12 *Replacement:*

The accompanying documentation shall contain warning notices appropriate to the intended use and normal function of the device, including information about the risk due to interference either from or to the implantable device during other clinical procedures or medical treatments. Examples of such treatments are those referred to in (but not limited to) 20.2, 21.1 NOTE, 22.2, 22.3 and Clause 27. Where restrictions are required during treatments (e.g. proximity, energy power levels), the manufacturer will also need to declare in labelling and/or instructions those circumstances and limits beyond which risk might exist for the patient.

Compliance shall be checked by inspection.

28.13 This subclause of ISO 14708-1 applies.

28.14 This subclause of ISO 14708-1 applies.

28.15 This subclause of ISO 14708-1 applies. Also refer to 28.12.

28.16 This subclause of ISO 14708-1 applies.

28.17 This subclause of ISO 14708-1 applies.

28.18 This subclause of ISO 14708-1 applies.

28.19 *Replacement:*

If the IMPLANT SYSTEM has an implanted energy source, the accompanying documentation shall include information about the lifetime of the energy source, both when the IMPLANT SYSTEM is adjusted to the nominal clinical settings specified by the manufacturer and when adjusted to the worst case conditions.

Compliance shall be checked by inspection.

28.20 This subclause of ISO 14708-1 applies.

28.21 This subclause of ISO 14708-1 applies.

28.22 This subclause of ISO 14708-1 applies.

Additional subclause:

28.22.1 The information relating to electromagnetic interference characterization according to 27.2 shall be provided to the clinician upon request.

28.23 This subclause of ISO 14708-1 applies.

Annex AA
(informative)

Relationship between the fundamental principles in ISO/TR 14283 and the clauses of this part of ISO 14708

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708-1	CLAUSES of ISO 14708-7 AND ASPECTS COVERED
3 General principles		
3.1 The implants should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.	8.1 Requires warnings to be prominent.	* retained
3.2 The solutions adopted by the manufacturer for the design and construction of the implants should conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer should apply the following principles in the following order: (a) eliminate or reduce risks as far as possible (inherently safe design and construction), (b) where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated, (c) inform users of the residual risks due to any shortcomings of the protection measures adopted.	(This principle is fundamental to all aspects of a active implantable medical device addressed by this standard. This approach is particularly applicable to the requirements in Clauses 14, 19 and 21.)	* retained
3.3 The implants should achieve the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in subclause 2.1 [of ISO/TR 14283], as specified by the manufacturer.	10.4 Requires accompanying documentation to be physically associated with the device.	* retained

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708-1	CLAUSES of ISO 14708-7 AND ASPECTS COVERED
3.4 The characteristics and performances referred to in subclauses 3.1, 3.2 and 3.3 should not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the implant as indicated by the manufacturer, when the implant is subjected to the stresses which can occur during normal conditions of use.	19.2 Requires power source depletion indicator.	* replacement
	19.3 Defines methodology to ensure single fault conditions are not a hazard.	* retained
	23.1 Defines drop test for non-implantable parts.	* replacement
	23.2 Defines vibration test for patient carried parts.	* replacement
	23.3 Sets test of tensile strength (leads, etc.).	* replacement
	23.4 Requires strain relief (leads, etc.).	* retained
	23.5 Requires fatigue resistance (leads, etc.).	* replacement
	23.6 Requires connections to be reliable.	* replacement
	26.1 Requires protection from heat from powered non-implantable parts.	* retained
	28.4 Requires disclosure of maximum proven connector retention strength.	* replacement
	28.23 Requires warning against patient entry into hazardous environments.	* retained
3.5 The implants should be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.	7.2 Requires sterile pack to be protected by sales packaging.	* retained
	10.1 Requires packaging to be durable.	* retained
	10.2 Requires packaging to be protected against the effects of humidity.	* retained
	10.3 Requires markings on the sales package to be indelible.	* retained
	12.3 Requires markings on the sterile pack to be indelible.	* retained
	26.2 Requires device to be protected against the effect of temperature changes.	* retained
3.6 Any undesirable side-effect should constitute an acceptable risk when weighed against the performances intended.	19.3 Defines methodology to ensure single fault conditions are not a hazard.	* retained
	19.4 Requires investigation of unintended effects caused by the device.	* retained 19.5, 19.6 additional requirements
4 Specific principles regarding design and construction		
4.1 Chemical, physical and biological properties		
4.1.1 The implants should be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in Clause 3 of the “General principles”. Particular attention should be paid to:		

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708-1	CLAUSES of ISO 14708-7 AND ASPECTS COVERED
4.1.1 (a) the choice of materials used, particularly as regards toxicity and, where appropriate, flammability,	14.3 Requires investigation of biocompatibility.	* retained
4.1.1 (b) the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the implant.	14.3 Requires investigation of biocompatibility.	* retained
4.1.2. The implants should be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the implants and to the patients, taking account of the intended purpose of the product. Particular attention should be paid to the tissues exposed and to the duration and frequency of exposure.	14.2 Defines test for particulate contamination.	* replacement
	14.3 Requires investigation of biocompatibility.	* retained
4.1.3 The implants should be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the implants are intended to administer medicinal products they should be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.	19.5 Demonstrate compatibility with medicinal substances	* replacement
4.1.4 Where an implant incorporates, as an integral part, a substance which, if used separately, may be considered to be medicinal product as defined in subclause 2.4 [of ISO/TR 14283] and which is liable to act upon the body with action ancillary to that of the implant, the safety, quality and usefulness of the substance should be verified, taking account of the intended purpose of the implant.	14.4 Requirement for quality and safety of incorporated medicinal substances.	* retained
4.1.5 The implants should be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the implant.	25 Requires implanted parts to withstand pressure changes.	* retained 25.2 additional requirements
4.1.6 Implants should be designed and manufactured in such a way as to reduce, as much as possible, risks posed by the unintentional ingress of substances into the implant taking into account the implant and the nature of the environment in which it is intended to be used.	25 Requires implanted parts to withstand pressure changes.	* retained 25.2 additional requirements
4.1.7 Implants should be designed and manufactured in such a way as to minimize the risks to the patient or user by the systems, including software.	19.3 Requires a design analysis and defines the methodology for the analysis.	* retained
4.2 Infection and microbial contamination		
4.2.1 The implants and manufacturing processes should be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design should allow easy handling and, where necessary, minimize contamination of the implant by the patient or vice versa during use.	14.1 Requires device to be supplied sterile.	* retained

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708-1	CLAUSES of ISO 14708-7 AND ASPECTS COVERED
4.2.2 Tissues of animal origin should originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. Information on the geographical origin of the animals should be retained by the manufacturer. Processing, reservation, testing and handling of tissues, cells and substances of animal origin should be carried out so as to provide optimal security. In particular safety with regard to viruses and other transferable agents should be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.	(Not applicable to active implantable medical devices)	
4.2.3 Implants delivered in a sterile state should be designed, manufactured and packed in protective packaging which provides a microbial barrier to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions stipulated by the manufacturer, until the protective packaging is damaged or opened.	7.1 Requires device to be supplied in non-reusable pack.	* retained
	7.2 Requires sterile pack to be protected by sales packaging.	* retained
	10.1 Requires packaging to be durable.	* retained
	10.2 Requires packaging to be proof against the effects of humidity.	* retained
	11.7 Requires contents of sterile pack to be declared or visible.	* retained
	11.9 Requires the sterile pack to be marked with the instructions for opening it.	* retained
	12.1 Applies ISO 11607 to the reusable pack.	* retained
	12.2 Shall be apparent if sterile pack has been opened.	* retained
	14.1 Requires device to be supplied sterile.	* retained
4.2.4 Implants delivered in a sterile state should have been manufactured and sterilized by an appropriate, validated method.	14.1 Confirmed if device sterilized by a validated process.	* retained
4.2.5 Implants intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.	14.1 Requires device to be supplied sterile.	* retained
	14.2 Defines test for particulate contamination	* revised
4.2.6 Packaging systems for non-sterile implants should keep the product without deterioration at the level of cleanliness stipulated and, if the implants are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system should be suitable taking account of the method of sterilization indicated by the manufacturer.	(Not applicable because subclause requires that implantable parts of an active implantable medical device be provided sterile.)	* idem
4.2.7 The packaging and/or label of the implant should distinguish between identical or similar products sold in both sterile and non-sterile condition.	(Not applicable because subclause requires that implantable parts of an active implantable medical device be provided sterile.)	* idem
4.3 Construction and environmental properties		

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708-1	CLAUSES of ISO 14708-7 AND ASPECTS COVERED
4.3.1 If the implant is intended for use in combination with other devices or equipment, the whole combination, including the connection system should be safe and should not impair the specified performances of the devices. Any restrictions on use should be indicated on the label or in the instructions for use.	9.9 Requires implantable connectors to be identified on sales pack.	* retained
	11.8 Requires implantable connectors to be identified on sterile pack.	* retained
	23.6 Requires connector retention force to be specified.	* replacement
	28.4 Requires disclosure of maximum proven connector retention strength.	* replacement
	28.5 Requires provision of information on accessories that might be required to facilitate the intended use of the device.	* retained
4.3.2 Implants should be designed and manufactured in such a way as to remove or minimize as far as is possible:		
4.3.2 (a) the risk of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features,	15.1 Sets requirement for surfaces of non-implantable parts.	* retained
	15.2 Requires implantable parts to have appropriate physical form.	* replacement
4.3.2 (b) risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration,	23.1 Defines drop test for non-implantable parts.	* replacement
	23.2 Defines vibration test for patient carried parts.	* replacement
	24 Defines electrostatic discharge test for non-implantable parts.	* replacement
	25 Requires implanted parts to be proof against pressure changes.	* retained 25.2 additional requirements
	26.2 Requires implantable devices to be undamaged by extremes of temperature in transit.	* retained
	27 Defines requirement for electromagnetic immunity.	* replacement 27.2, 27.3, 27.4, 27.5 additional requirements

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708-1	CLAUSES of ISO 14708-7 AND ASPECTS COVERED
4.3.2 (c) the risks of reciprocal interference with other devices (such as defibrillators or high frequency surgical equipment) normally used in the investigations or for the treatment given,	20.1 Requires defibrillation protection of external ecg leads.	* not applicable to cochlear implants
	20.2 Defines test to prove defibrillation protection of implanted device.	* retained
	21 Requires protection against diathermy, etc.	* replacement
	22 Requires protection against diagnostic ultrasound.	* retained 22.2, 22.3 additional requirements
	28.12 Requirement for warning notices.	* replacement
	28.13 Requires warning about monitoring device in case of diathermy etc.	* retained
	28.14 Requires warning not to expose device to therapeutic levels of ultrasound.	* retained
	28.15 Requires warning about the effect of therapeutic irradiation on implanted devices.	* retained
4.3.2 (d) risks which may arise where maintenance and calibration are impossible, including (if applicable): - excessive increase of leakage currents, - ageing of the materials used, - excess heat generated by the implant, - decreased accuracy of any measuring or control mechanism.	17 Requires investigation of local heating caused by faulty implanted device.	* retained
	19.1 Requires a design analysis.	* retained
	19.2 Requires power source depletion indicator.	* replacement
4.3.3 Implants should be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal conditions and fault conditions. With the risks during “normal conditions and fault conditions” are meant those risks which have been determined by a risk analysis. Particular attention should be paid to implants whose intended use includes exposure to flammable substances or to substances which could cause combustion.	5 Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.	* retained
4.4 Implants with a measuring function		
4.4.1 Implants with a measuring function should be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the implant. The limits of accuracy should be indicated by the manufacturer.	5 Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.	* replacement
4.4.1.1 The measurements, monitoring and display scale should be designed in line with ergonomic principles, taking account of the intended purpose of the implant.	5 Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.	* replacement
4.4.1.2 When an implant or its accessories bear instructions required for the operation of the implant or indicate operating or adjustment parameters, by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.	13.4 Requirement about visual indicators.	* retained
	5 Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.	* replacement
4.4.2 The measurements made by implants with a measuring function should be expressed in units conforming to the provisions of the ISO 31 series.	5 Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.	* replacement

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708-1	CLAUSES of ISO 14708-7 AND ASPECTS COVERED
4.5 Protection against radiation		
4.5.1 General Implants should be designed and manufactured in such a way that exposure of patients, users and other persons to radiation be reduced as far as possible compatible with the intended purpose, while not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	(See more particular requirements below).	
4.5.2 Intended radiation	(Not applicable to active implantable medical devices).	* idem
4.5.2.1 Where implants are designed to emit hazardous levels of radiation necessary for a specific medical purpose, the benefit of which is considered to outweigh the risks inherent in the emission, the implants should be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters.	—	—
4.5.2.2 Where implants are intended to emit potentially hazardous, visible and/or invisible radiation, they should be fitted, where practicable, with visual displays and/or audible warnings of such emissions.	—	—
4.5.3 Unintended radiation Implants should be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible.	9.1 Requires markings warning of any radioactive substances.	* retained
	18.1 Requirement for sealed sources.	* retained
	18.2 Requires justification of radiation dose on patient.	* retained
	18.3 Requires radiation dose as low as is possible.	* retained
	28.2 Requires information to be provided about radioactive substances.	* retained
4.5.4 Instructions The operating instructions for implants emitting radiation should give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in use.	(Not applicable to active implantable medical devices).	* idem
4.6 Ionizing radiation	(Not applicable to active implantable medical devices).	* idem
4.6.1 Implants intended to emit ionizing radiation should be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled taking into account the intended use.	—	—
4.6.2 Implants emitting ionizing intended for diagnostic radiology should be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose while minimizing radiation exposure of the patient and user.	—	—

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708-1	CLAUSES of ISO 14708-7 AND ASPECTS COVERED
4.6.3 Implants emitting ionizing radiation, intended for therapeutic radiology should be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose.	—	—
4.7 Principles for implants connected to or equipped with an energy source		
4.7.1 Implants incorporating electronic programmable systems should be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. in the event of risks (of the system) as determined by a risk analysis for the particular device/system, appropriate means should be adopted to eliminate or reduce as far as possible their risk.	19.3 Requires a design analysis and defines the methodology for the analysis.	* retained
4.7.2 Implants where the safety of the patients depends on an internal power supply should be equipped with a means of determining the state of the power supply.	19.2 Requires power source depletion indicator.	* replacement
4.7.3 Implants should bear - if practical and appropriate - a code by which they and their manufacturer can be unequivocally identified (particularly with regard to the type of implant); it should be possible to read this code, if necessary, without the need for a surgical operation.	13.3 Requirement stated and expanded.	* replacement
	28.6 Requires an explanation of code to be provided with the device.	* retained
4.7.4 Implants where the safety of the patients depends on an external power supply, the external power supply should include an alarm system to signal any power failure.	5 Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.	* replacement
4.7.5 External devices intended to monitor one or more clinical parameters from an implant should be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.	5 Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.	* replacement
4.7.6 Protection against electrical risks		
4.7.6.1 Implants should be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal conditions and fault conditions provided the implants are installed correctly. With the risks during "normal conditions and fault conditions" are meant those risks which have been determined by a risk analysis for the particular device(s).	5 Applies IEC 60601–1 to the non-implantable parts of the active implantable medical device.	* replacement
	16.1 Sets safety limits for leakage currents from non-implantable parts.	* replacement
4.7.6.2 Active implants should be designed and manufactured in such a way as to minimize the risks connected with the use of energy sources with particular reference, where electricity is used, to insulation, leakage currents and overheating of the devices.	16.2 Sets safety limits for leakage currents from implantable parts.	* replacement
	16.3 Requires testing of electrical insulation (leads, etc.).	* not applicable to cochlear implants
	17 Requires investigation of local heating caused by implanted device.	* retained
	26.1 Requires protection from heat from powered non-implantable parts.	* retained
4.7.7 Protection against mechanical risks		
4.7.7.1 Implants should be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance, stability and moving parts.	5 Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.	* replacement

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708-1	CLAUSES of ISO 14708-7 AND ASPECTS COVERED
4.7.7.2 Implants should be designed and manufactured in such a way as to minimize the risks arising from vibration generated by the implants, taking account of technical progress and of the means available for limiting vibration, particularly at source, unless the vibrations are part of the specified performance.	5 Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.	* replacement
4.7.7.3 Implants should be designed and manufactured in such a way as to minimize the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.	5 Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.	* replacement
4.7.7.4 Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle should be designed and constructed in such a way as to minimize all possible risks.	5 Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.	* replacement
4.7.8 Protection against the risks posed to the patient by energy supplies or substances		
4.7.8.1 Implants should be designed and constructed in such a way that the proper functioning of the programming and control systems, including software, do not jeopardize the safety of the patient and of the user taking account of the intended use.	19.3 Requires a design analysis and defines the methodology for the analysis.	* retained
4.7.8.2 Implants designed to supply energy or administer medicinal substances should be designed and constructed in such a way that the flow-rate can be set and maintained accurately enough to minimize the risk to the patient.	5 Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.	* retained
4.7.8.3 Implants designed to administer medicinal products should incorporate suitable means to prevent and/or indicate any inadequacies in the flow-rate that could pose a danger.	5 Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.	* replacement
4.7.8.4 Implants designed to supply energy or administer medicinal substances should be designed and constructed so that suitable means are incorporated to minimize the risk of accidental release of dangerous levels of energy or the medicinal substance.	5 Applies IEC 60601-1 to the non-implantable parts of the active implantable medical device.	* replacement
4.8 Information supplied by the manufacturer		
4.8.1 Each implant should 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 information comprises the details on the label and the data in the instructions for use. As far as practicable and appropriate, the information needed to use the implant safely should be set out on the implant itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information should be set out in the leaflet supplied with one or more implants. Instructions for use should be included in the packaging for e every implant.	10.4 Requires accompanying documentation to be physically associated with the device.	* retained
	12.3 Requirement that any markings shall be indelible.	* retained

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708-1	CLAUSES of ISO 14708-7 AND ASPECTS COVERED
4.8.2 Where appropriate, this information should take the form of symbols. Any symbol or identification colour used should conform to international standards. Where no standards exist, the symbols should be described in the documentation supplied with the implant.	4. Allows use of symbols, abbreviations and identification colours.	* retained
4.8.3 The label should bear the following particulars:		
4.8.3 (a) the name or trade name and address of the manufacturer;	5 Invokes the labelling requirements of IEC 60601-1 for non-implantable parts.	* replacement
	9.2 Requires name and address of manufacturer on the sales pack.	* retained
	11.1 Requires identification of manufacturer on sterile pack.	* retained
4.8.3 (b) the details strictly necessary for the user to identify the implant and the contents of the packaging;	9.3 Requires description of device and model designation on the sales pack.	* replacement
	9.4 Requires marking with characteristics sufficient to identify device.	* retained
	9.8 Requires sales pack to bear information about accessories provided.	* retained
	9.10 Requires supplementary description, if 9.3 and 9.4 are inadequate to declare purpose.	* retained
	11.6 Requires description of device and mode designation on the sterile pack.	* retained
	11.7 Requires identification of contents of sterile pack.	* retained
4.8.3 (c) where appropriate, an indication that the contents of the packaging are sterile (e.g. “STERILE”);	9.5 Requires statement that the package has been sterilized.	* retained
	11.2 Requires declaration that the package and its contents have been sterilized.	* retained
	11.3 Requires display of the “sterile” symbol	* retained
4.8.3 (d) where appropriate, the batch code or the serial number, preceded by an appropriate identification (e.g. “LOT” or “SN” respectively);	9.3 Requires batch code or serial number on the sales pack.	* replacement
	11.6 Requires batch code or serial number on the sterile pack	* retained
4.8.3 (e) where appropriate, an indication of the date by which the implant should be used;	9.7 Requires marking of a “use-before date”.	* replacement
	11.5 Requires marking of a “use-before date”.	* retained
4.8.3 (f) an indication that the implant is for single use;	28.18 Requires and defines warning notice about reuse of the device.	* retained
4.8.3 (g) where appropriate, any indication of special purpose (e.g. “custom-made device” or “exclusively for clinical investigations”);	9.12 Requires marking of special purpose.	* retained
	11.10 Requires marking of special purpose.	* retained

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708-1	CLAUSES of ISO 14708-7 AND ASPECTS COVERED
4.8.3 (h) any special storage and/or handling conditions;	9.11 Requires marking with information on any exceptional environmental or handling constraints.	* retained
4.8.3 (i) any special operating instructions;	(For implantable parts of an active implantable medical device, all operating instructions are provided in the accompanying documentation.)	
4.8.3 (j) any warnings or precautions to take;	(In the general case, warnings and precautions except for those dealing with special handling conditions [see 4.8.2 (h)] should be described in the accompanying documentation instead of on the label.)	
4.8.3 (k) for active implants, month and year of manufacture;	9.6 Requires marking and defines format.	* retained
	11.4 Requires marking and defines format.	* retained
4.8.3 (l) if applicable, method of sterilization	11.2 Requires method of sterilization to be marked.	* retained
4.8.4 If the intended purpose of the implant is not obvious to the user, the manufacturer should clearly state it on the label and in the instructions for use.	9.10 Requires supplementary description, if 9.3 and 9.4 are inadequate to declare purpose.	* retained
4.8.5 Wherever reasonable and practicable, the implants and detachable components should be identified, where appropriate in terms of serial numbers or batches, to allow all appropriate actions to be taken following discovery of any potential risk posed by the implants and detachable components.	8.2 Requires implanted parts to be traceable.	* retained
	13.1 Requires identification of manufacturer, model, etc. on device.	* retained
	13.2 Requires that if different power sources might have been used, the actual source used shall be identified.	* replacement
4.8.6 Where appropriate, the instructions for use should contain the following particulars:		
4.8.6 (a) the details referred to in 4.8.3, with the exception of (d), (e) and (k);	28.1 Requires name and address of manufacturer.	* replacement
	28.3 Requires description of the device.	* retained
	28.16 Requires statement that implantable parts of a device have been sterilized.	* retained
	28.18 Requires and defines warning notice about reuse of the device.	* retained
	28.21 Requires marking with information on any exceptional handling constraints.	* retained
4.8.6 (b) the performances referred to in subclause 3.3 [of ISO/TR 14283] and any undesirable side-effects;	28.8 Requires information to be provided about the intended use and characteristics, and about possible side effects.	* retained 28.8.1 additional subclause

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708-1	CLAUSES of ISO 14708-7 AND ASPECTS COVERED
4.8.6 (c) if the implant should be used with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct implants or equipment to use in order to obtain a safe combination;	28.4 Requires disclosure of maximum proven connector retention strength.	* replacement
	28.5 Requires provision of information on accessories that might be required to facilitate the intended use of the device.	* retained
	28.9 Requires information to allow selection of device, accessories and related devices.	* retained
4.8.6 (d) all the information needed to verify whether the implant is properly used and can operate correctly and safely, plus, where appropriate, information allowing the lifetime of the energy source to be established;	28.10 Requires definitive instructions for use to be provided.	* retained
4.8.6 (e) where appropriate, information to avoid specified risks in connection with implantation of the implant;	28.11 Requires information on avoiding hazards during implantation are provided.	* retained
4.8.6 (f) information regarding the risks of reciprocal interference posed by the presence of the implant during specific investigations or treatment;	28.12 Requires warning notices on hazards arising from interaction.	* replacement
4.8.6 (g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization;	28.17 Requires precautions for dealing with opened or damaged sterile pack.	* retained
4.8.6 (h) where implants are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization should be such that, if correctly followed, the implant will still comply with the principles in Clause 3 [of ISO/TR 14283];	28.17 Requires instructions for sterilizing accessories that are provided non-sterile.	* retained
4.8.6 (i) details of any further treatment or handling needed before the implant can be used (for example, sterilization, final assembly);	(Not applicable because subclause requires that active implantable medical device be provided sterile.)	
4.8.6 (j) in the case of implants emitting radiation for medical purposes, details of the nature, type intensity and distribution of this radiation.	(Not applicable to active implantable medical devices).	
The instructions for use should also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular: 4.8.6 (k) precautions to be taken in the event of changes in the performance of the implant;	28.19 Requires information allowing the lifetime of the energy source to be estimated.	* replacement
	28.20 Requires information on precautions to be taken to prevent adverse effects from changes in device performance.	* retained
4.8.6 (l) precautions to be taken as regards exposure to, in reasonably foreseeable environmental conditions, e.g. to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources;	28.22 Requires warnings on precautions to avoid adverse environments.	* retained 28.22.1 additional subclause
4.8.6 (m) adequate information regarding the medicinal product or products which the implant in question is designed to administer, including any limitations in the choice of substances to be delivered	28.7 Requires information about medicinal products which the device is designed to administer.	* retained

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708-1	CLAUSES of ISO 14708-7 AND ASPECTS COVERED
4.8.6 (n) precautions to be taken against any special, unusual risks related to the disposal of the implant;	28.24 Requires information on proper disposal of the device.	* retained
4.8.6 (o) medicinal products incorporated into the implant as an integral part in accordance with subclause 4.1.4 [of ISO/TR 14283];	28.8 Requires information to be provided about the intended use and characteristics, and about possible side effects.	* retained 28.8.1 additional subclause
4.8.6 (p) degree of accuracy claimed for implants with a measuring function.		Not applicable
4.9 Clinical evaluation Where conformity with the fundamental principles for implants should be based on clinical data, as in 3.6 [of ISO/TR 14283] such data should be established by either:		
4.9 (a) a compilation of the relevant scientific literature currently available on the purpose intended by the manufacturer, or	19.4 Requires investigation of unintended effects caused by the device.	* retained
4.9 (b) the results of all the clinical investigations carried out in a way that protects the human subjects and ensures the scientific conduct of the investigation.	19.4 Requires investigation of unintended effects caused by the device.	* retained

Annex BB
(informative)

Relationship between the clauses of this part of ISO 14708 and the fundamental principles listed in Annex A

Subclause	Relevant fundamental principle		Subclause	Relevant fundamental principle
4	4.8.2		11.6	4.8.3 (b) and 4.8.3 (d)
5	4.4.1, 4.4.1.1, 4.4.1.2, 4.4.2, 4.7.4, 4.7.5, 4.7.7.1, 4.7.7.2, 4.7.7.3, 4.7.7.4, 4.7.8.2, 4.7.8.3, 4.7.8.4, 4.8.3 and 4.8.6.(p)		11.7	4.8.3 (b) and 4.2.3
7.1	4.2.3		11.8	4.3.1
7.2	3.5 and 4.2.3		11.9	4.2.3
8.1	3.1		11.10	4.8.3 (g)
8.2	4.8.5		12.1	4.2.3
9.1	4.5.3		12.2	4.2.3
9.2	4.8.3 (a)		12.3	3.5
9.3	4.8.3 (b) and 4.8.3 (d)		13.1	4.8.5
9.4	4.8.3 (b)		13.2	4.8.5
9.5	4.8.3 (c)		13.3	4.7.3
9.6	4.8.3 (k)		13.4	4.4.1.2
9.7	4.8.3 (e)		14.1	4.2.1, 4.2.3, 4.2.4 and 4.2.5
9.8	4.8.3 (b)		14.2	4.1.2 and 4.2.5
9.9	4.3.1		14.3	4.1.1 (a), 4.1.1 (b) and 4.1.2
9.10	4.8.3 (b) and 4.8.4		14.4	4.1.4
9.11	4.8.3 (h)		15.1	4.3.2 (a)
9.12	4.8.3 (g)		15.2	4.3.2 (a)
10.1	3.5 and 4.2.3		16.1	4.7.6.1
10.2	3.5 and 4.2.3		16.2	4.7.6.2
10.3	3.5		16.3	4.7.6.2
10.4	3.3 and 4.8.1		17	4.7.6.2 and 4.3.2 (d)
11.1	4.8.3 (a)		18.1	4.5.3
11.2	4.8.3 (c) and 4.8.3 (l)		18.2	4.5.3
11.3	4.8.3 (c)		18.3	4.5.3
11.4	4.8.3 (k)		19.1	4.3.2 (d)
11.5	4.8.3 (e)		19.2	3.4, 4.3.2 (d) and 4.7.2

Subclause	Relevant fundamental principle		Subclause	Relevant fundamental principle
19.3	3.4, 3.6, 4.1.7, 4.7.1 and 4.7.8.1		28.4	3.4, 4.3.1 and 4.8.6 (c)
19.4	3.6, 4.9 (a) and 4.9 (b)		28.5	4.3.1 and 4.8.6 (c)
19.5	4.1.3		28.6	4.7.3
20.1	4.3.2 (c)		28.7	4.8.6 (m)
20.2	4.3.2 (c)		28.8	4.8.6 (b) and 4.8.6 (o)
21	4.3.2 (c)		28.9	4.8.6 (c)
23.1	3.4 and 4.3.2 (b)		28.10	4.8.6 (d)
23.2	3.4 and 4.3.2 (b)		28.11	4.8.6 (e)
23.3	3.4		28.12	4.3.2 (c) and 4.8.6 (f)
23.4	3.4		28.13	4.3.2 (c)
23.5	3.4		28.14	4.3.2 (c)
23.6	3.4 and 4.3.1		28.15	4.3.2 (c)
24	4.3.2 (b)		28.16	4.8.6 (a) [3.8.3 (c)]
25	4.3.2 (b)		28.17	4.8.6 (g) and 4.8.6 (h)
26.1	3.4 and 4.7.6.2		28.18	4.8.6 (a) [4.8.3 (f)]
26.2	3.5 and 4.3.2 (b)		28.19	4.8.6 (k)
27	4.3.2 (b)		28.20	4.8.6 (k)
28.1	4.8.6 (a) [4.8.3 (a)]		28.21	4.8.6 (a) [4.8.3 (h)]
28.2	4.5.3		28.22	4.8.6 (l)
28.3	4.8.6 (a) [4.8.3 (b)]		28.23	3.4
			28.24	4.8.6 (n)

Annex CC
(informative)

Notes on EN 45502-2-3 (basis for this part of ISO 14708)

CC.1 General

This part of ISO 14708 provides background on the development of EN 45502 and its attempts to quantify the essential requirements of Directive 90/385/EEC. In many clauses, the standard does this by detailing a particular aspect of the essential requirements and specifying an assessment procedure or test.

For some hazards, EN 45502 prescribes specific requirements along with compliance measures (e.g. leakage current levels) which, if met, would satisfy an aspect of the essential requirements of the Directive. For other hazards, this part of ISO 14708 requires risks to be assessed and identified, according to ISO 14971. Compliance is checked by review of the risk management file provided by the manufacturer.

In some cases, no laboratory test of limited duration can provide adequate assurance of the characteristics of a particular design, or ensure the performance of the device after several years' implantation. EN 45502 then requires the device manufacturer to prepare documented studies suitable for expert review.

CC.2 Notes on specific subclauses

The following notes on some of the provisions of this part of ISO 14708 are provided as an aid to understanding. This annex is directed towards those who are familiar with the construction or use of active implantable medical devices but have not themselves participated in drafting this part of ISO 14708. The notes in this annex carry the numbers of the relevant clauses of this part of ISO 14708; therefore, paragraph numbering in the annex is not consecutive.

Apart from Clauses 5, 7, and 8, the clauses of this part of ISO 14708 are arranged so they can be addressed in sequence proceeding from checking markings on the outside of the sales pack, then the construction of the sales pack, and so on through to tests on the device, and finally to checks of the accompanying documentation.

[3.3.2], [3.3.3], [3.3.4], [3.3.5] Most currently NON-IMPLANTABLE PARTS could become implantable parts in the future.

[3.20.4] The USE-BEFORE-DATE is required in 9.7 and 11.5.

[5.1] While operating the BODY WORN PART (e.g. changing batteries) the patient becomes an operator and is not a patient in the sense of the IEC 60601-1 and therefore requirements for leakage currents do not apply.

[5.2] EN 45502-1:1997, 5.1, defines those requirements applicable for the NON-IMPLANTABLE PART. These cover electrical safety aspects and EMC requirements, etc., found in IEC 60601-1-2. Current IMPLANT SYSTEMS technology utilizes the transfer of energy through inductive RF coupling between the NON-IMPLANTABLE PART and the implantable part (RF transformer).

[13.3] This subclause addresses the underlying concern expressed by the Directive for any device in use to be identified without performing a surgical operation and without requiring special equipment specific to a manufacturer or model of a device. In practice it might not be possible to add additional markings to IMPLANT SYSTEMS. The present state of the art is to identify the manufacturer and model through X-ray outline profile. For IMPLANT SYSTEMS which do not contain an internal power source, identification of the year of manufacture is not considered significant. Future technological advances might allow telemetry identification, including the serial number or the date of manufacture of a device. Observing the X-ray outline should allow a suitable telemetry device to be selected.

[14.2] As well as the specific requirement that an implant be sterile, the implant should not introduce unnecessary loose particulate matter ("sterile dirt"). The method of compliance assessment is specified so that meaningful quantitative limits can be set for assessing the results of the test. The manufacturer may choose a recognized measurement technique based on the apparatus that is readily available. Particles that have been purposely added (e.g. pharmaceutical agents) to the implant for a therapeutic reason, coating of implants, or elution from implant are not subject to this test.

The number of particles is related to the surface of the device and not its volume. For example, an empty bag (large surface but negligible volume) might present an excessive particle count when soaked in a bath based on the volume of the empty bag. The same bag when filled might pass the test even though the total particle count is the same. The same holds true for devices covered by this part of ISO 14708, especially leads that typically have a large surface area but have a small volume. For IMPLANT SYSTEMS, this approach would specify a bath that is of the same order of magnitude as the volume approach in ISO 14708-1.

The test limits are based on a standard test for particulate contamination in large-volume parenteral injections given in the European Pharmacopoeia.

[15.2] ISO/TC 150/SC6 recognized the need to have appropriate tests done in order to confirm that the physical characteristics of the implantable part do not cause excessive inflammatory reactions. The manufacturer should for instance provide data from animal studies or other appropriate records.

[16.2] Sustained small direct currents (DC) from implanted electrodes might cause tissue damage or electrode corrosion. The safe limit has been reduced to 0,1 µA in accordance with opinion in current literature. The test method should be applicable to a device even while stimulating using levels representing normal clinical practice. The device settings including a rationale for their choice should be documented with the test results. Appropriate steps should be taken to ensure that any transcutaneous link should not interfere with the measurement. Use a DC voltmeter fed through a low pass filter with a time constant of at least one second. This can for instance be implemented by a four element low pass RC filter with the elements built from 1 MΩ resistors and 1 µF metallised polyester capacitors. The input resistance of the DC voltmeter should then be ≥ 400 MΩ.

[19.2] It is desirable that exhaustion of the power supply of an IMPLANT SYSTEM does not cause it to cease functioning without previous warning. The warning mechanism provided should not be invalidated by different stimulation strategies that deplete the power source at differing rates. The indicator can be either internal or external.

[19.5] ISO/TC 150/SC6 recognized that the lifetime of the currently available IMPLANT SYSTEMS might be shorter than the life expectation of the patients, especially when implanting young children. From an ethical point of view and based on the state of the art, IMPLANT SYSTEM replacement should be possible. During the design process the manufacturer should consider the following aspects which might adversely affect the device replacement: compatible dimensions and shape, mechanical robustness and biological effects.

[19.6] ISO/TC 150/SC6 recognized the desirability of manufacturers and experts to provide assurance that the STIMULATOR case sealing will protect from any contact between components included within the case and body fluids. Such failure could induce electronic dysfunctions of the device and/or unintended stimulations at vicinity of the device and/or unintended biological effects caused by inner non-biocompatible parts (i.e. electronic components) in contact with body fluids.

Procedures and failure criteria are common in the electronic industry. The test has been inspired by MIL STD 883 Method 1014. EN 13185 and EN 1593 suggest different methods that the manufacturers may select.

[20.2] Defibrillators usually apply voltages in the order of 5 000 V across the torso, but present implant systems do not have implantable parts in the torso, and the resultant voltage in the area of the implantable part of the implant system is not high enough to warrant concern. However it is conceivable that parts of future devices might be implanted in the torso, for example a battery or a recharging coil. In that case the test specified in ISO 14708-1 would be necessary. If external parts are touched by the defibrillator electrodes it is not considered probable that damage will occur because the ESD requirements as outlined in Clause 24 are comparable.

[21.1] The test verifies some immunity from high frequency electrical currents arising from surgical diathermy. The test frequency of 500 kHz was selected as typical of the majority of electro surgical equipment. The selected amplitude of 20 V pp, to test the protection of the device was adapted from the pacemaker standard EN 45502-2-1. The load resistor of 4,7 kΩ was chosen to reflect the impedance of the neural tissue interface in the cochlea. During the test the IMPLANT SYSTEM should be switched off. The requirement does not provide complete protection, since the voltages picked up during exposure to surgical diathermy are very dependent upon the distances between the diathermy electrodes and any conductive part of the IMPLANT SYSTEM or its electrode array, and the surgeon might not be aware of the positioning of such parts.

[22.1] Note this requirement addresses only exposure to diagnostic ultrasound. In this part of ISO 14708 exposure of an IMPLANT SYSTEM to therapeutic levels of ultrasound is covered by a requirement for a warning notice (see 28.20).

[22.2] ISO/TC 150/SC6 recognized the desirability of manufacturers to provide assurance that patients with an IMPLANT SYSTEM could undergo MRI testing without compromising the safety of the patient. Due to the large variety of MRI machines currently available and the different transcutaneous link characteristics used by the various IMPLANT SYSTEMS it was determined that where a manufacturer states a level of MRI safety in the accompanying documentation (see Clause 28), the field strength of the MRI machines for which safety is claimed is to be stated. Regardless of the level of testing, any decision to authorize an MRI scan remains a medical decision balancing the risk of damage against the benefit of information provided by the MRI scan. The test on MRI safety implies that the implant has been placed in accordance with the manufacturer's surgical guidelines and the implant is appropriately stabilized. The maximum safe force has been determined from References [24] and [25]. The force at the edge of the implant or the magnet (if the magnet is not contained within a rigid structure) is a consequence of the torque and the relevant dimensions of the device and therefore specifying a test for the force was considered sufficient. For the measurement of the force a theoretical approach has been proposed since the ensuing demagnetisation could underestimate the actual force. Alternatively, the methods in the ASTM standards (ASTM F2052, ASTM F2213) can be used to measure force and torque separately.

ISO/TC 150/SC6 recognized that heating at the tip of the lead might be an important issue. At the time of writing the standard, it is possible that an improved measurement method might be developed. The ASTM F2182 standard has been used to test heat generation at the tip of the lead of Active Implantable Medical Devices such as pacemakers and cochlear implants and therefore is considered as a suitable alternative test. The implant is placed under the temporalis muscle which has a good blood supply. Therefore, 2 °C temperature rise is reasonable.

During the tests for heat generation, unintentional output and implant damage, the implantable part has to be held by an appropriate fixture in order to avoid movement of the implant in the MRI machine. MRI scanning will result in image distortion by the implantable part; however this is not considered a safety issue. Also, the potential demagnetisation of the internal magnet resulting from the MRI scanning was not considered a safety issue. Where there is magnetic degradation expected, labelling should contain the appropriate information (see 28.12).

[22.3] ISO/TC 150/SC6 recognized that current and future cochlear implant designs are likely to continue to have a degree of susceptibility to degradation or malfunction following exposure to therapeutic ionising radiation. The group also recognized the need for cochlear implant patients not to be disadvantaged where therapeutic radiation treatment is needed. Although radiation treatment might be targeted over (or close to) the implanted part, it was noted that the majority of treatments will be targeted at other locations. In this latter situation exposure to radiation scatter is likely to be a main concern. In keeping with good clinical practice, active implants should be shielded during radiation therapy, thereby minimising exposure to harmful radiation.

Literature reports of irradiation testing of some cochlear implants (References [14] and [30]) indicate that although current designs have a limited degree of "hardness" to the effects of ionising radiation, no device can be designed and manufactured to be totally immune. The group identified the need for manufacturer's designs to demonstrate a level of immunity but agreed that a minimum radiation "hardness" level would result in unfair discrimination. The solution adopted by ISO/TC 150/SC6 was to agree a defined irradiation test method, based on common radiation treatment patterns (fractional

accumulated dosage). The manufacturer declares the maximum level of accumulated dose after which the device will continue to function normally. Labelling on the basis of this test enables clinicians to judge whether an intended pattern of radiation therapy is likely to permanently affect the functionality of the implanted part.

[23.1] Hand-held programmers and portable device analysers might be subject to severe mechanical shocks during handling by other than the expert user. If such impacts cause damage not immediately apparent to the user, the damaged device might miss-set the implant or give an erroneous analysis, which could subsequently result in an unnecessary explanation.

[23.2] This test is intended to establish minimum requirements for the durability of the implanted part of an IMPLANT SYSTEM with respect to mechanical robustness.

Withdrawal of a test originally called by EN 45502-1 has required a new test to be defined.

The replacement text is based on a new part of EN 60068-2-64:2008.

The test severity is determined by the test conditions a) to d). The range of test frequencies is based on experience with the sinusoidal sweep method in common use for a number of years within the pacemaker industry.

The value for the acceleration spectral density was also derived from the sinusoidal sweep method in 8.1.1 of EN 50061:1988. That test specifies a peak acceleration of 25 m/s^2. This translates into an r.m.s. value of 1,77 g. An acceleration spectral density of 0,7 $(m/s^2)^2/Hz$ translates into an r.m.s. value of 1,86 g. This last calculation is an approximation that might vary slightly depending on the equipment used to generate the random vibration. However, the level of stress on the IMPLANT SYSTEM is comparable to the level in the method in EN 50061.

In general, a short duration test will produce low confidence level results. The duration value for this test is the midpoint of the recommended values in of IEC 60068-2-64:2008, 5.5. It should provide reasonable confidence in the reproducibility of the results while producing a test method whose overall time to complete is also reasonable.

Protection of the device during delivery and storage is provided by appropriate design of the packaging, which is evaluated with respect to vibration in 10.1.

[23.3] Reports in literature indicate that paediatrics will be subject to skull growth of 12 mm (standard deviation of 5 mm) from the round window to the sino-dural angle between birth and adulthood (Reference [24]). Leads forming part of an IMPLANT SYSTEM need to be designed to withstand elongation, which might be experienced during the skull growth period. In case the lead is not allowing elongation of 15 mm the manufacturer's surgical procedure has to avoid extrusion of the electrode array from the cochlea. ISO/TC 150/SC6 considered a force of 1 N to be representative of the elongation force acting during bone growth and during implantation. The test method developed in 23.3, for IMPLANT SYSTEMS takes into consideration the differing designs of lead geometry. Although the most appropriate method of lead attachment is left to the manufacturer discretion, it is required that the critical lead portion subject to elongation by skull growth is identified in the design and subjected to a standard test.

[23.5] When drafting this part of ISO 14708, it was observed that recommended clinical practice was to implant the implantable part of an IMPLANT SYSTEM within a bony bed. This provides maximum stability to the implanted part and its associated electrode array and is considered state of the art. Tests 1 and 2 are intended to establish minimum requirements for the flexural durability of implantable LEADS. Test 1 is designed to simulate any adverse handling conditions, which might be experienced during removal from the STERILE PACK and handling prior to implantation. Test 2 acknowledges that variation in implantation technique might exist and is designed to simulate micro movement of the lead after implantation especially in the region of the temporalis muscle. However, it is also acknowledged that with the recommended implantation technique, micro movement of the LEAD can be significantly reduced.

Although the exact conditions are impossible to determine, it is believed that shearing and bending causes similar stress conditions to those experienced by *in vivo* failures. A 3 g weight is attached to the test segment to force the test sample to conform to the required angular displacement without

providing a significant tensile load. Bending the test sample by ± 15° for 100 000 cycles creates a more severe strain at the electrode than is expected *in vivo*.

[23.6] EN 45502 leaves the method of providing a secure connection to the manufacturer's specification. Thus the manufacturer is required to specify compatible connector parts (see 9.9 and 28.9) so that specified parts can be selected for test, ensuring that implanted connector pairs are reliable when subject to tensile force.

[23.8] ISO/TC 150/SC6 recognized the need for an impact test of the implanted part in order to minimize the risk for failures due to trauma. While adults rarely experience falls which might result in impact damage to the IMPLANT SYSTEM, children are particularly vulnerable due to mobility, height, lack of co-ordination of lower limbs. The test has been designed to give assurance that impacts experienced during normal daily living will not compromise the implantable part. Such impacts would include falls or knocks to the head during walking, running or cycling which would not require medical attention or first aid. A project was commissioned by the German Competent Authority (BFARM) to investigate failure modes and develop appropriate test methods. The outcome was published in Reference [15]. Based on the results of that project the committee has chosen an energy of 2,5 J as the goal of protection. This energy will cover a hit to the head (at the location of the implant) of a hard object with the mass of 1 kg and a velocity of about 2,25 m/s. Based on current field experience of several thousand devices using device models identical to those tested by Holtkamp an energy of (1-1,5) J was deemed sufficient in order to provide an acceptable resistance to environmental impacts. ISO/TC 150/SC6 concluded that at the time the standard becomes mandatory an energy of 1,5 J should be applied during the test and three years after the standard becomes mandatory an energy of 2,5 J should be used providing an additional safety margin. According to the AIMD Directive the manufacturer can demonstrate compliance with the essential requirements also by not using this part of ISO 14708. In that case the manufacturer should demonstrate a comparable level of safety as described in the standard. If the IMPLANT SYSTEM is provided with an implantable microphone or other transducer these might no longer function after the impact test. This is acceptable provided there is redundancy in the system which does not require replacement of the implantable part of the IMPLANT SYSTEM.

[24.1] The test set-up has been chosen to simulate the *in vivo* situation of an implanted subject wearing the BODY-WORN part (e.g. speech processor with coil but without an optional FM unit) The test is applied to the NON-IMPLANTABLE PART. Any surge affecting the BODY-WORN part will also impact the implantable part. The test voltages have been chosen from EN 45502-1:1997, 24.1. Higher test voltages would not be appropriate for the very small external parts (behind-the-ear speech processor) used with IMPLANT SYSTEMS.

[25.2] This test simulates in part increased pressure which might occur during particular occupational or recreational activities such as scuba diving. This was included as a result of increased user expectations.

[27] This requirement covers all currently foreseeable electromagnetic environments the bearer of the IMPLANT SYSTEMS might encounter, even those being encountered hardly ever in areas with public access. The requirement is separated into two sub-requirements: One is for protection against harm, damage of tissue or device and pain to the bearer in public areas under every circumstance even those encountered rarely during normal daily living (27.1). Other guarantees that the device deliver not significantly influenced function during commonly encountered situations during normal living (27.2).

Clause 27 only contains requirements in terms of exposure levels (27.3 and 27.4). It is up to the manufacturer to choose the appropriate means to demonstrate compliance, either theoretical modelling or direct EMI measurements.

Annex BB gives an example how to demonstrate compliance by means of theoretical modelling. Annex CC gives an example how to demonstrate compliance by EMI measurements.

[27.1] This requirement guarantees the device will not be damaged and the bearer will not be harmed under electromagnetic exposure. This requirement corresponds to requirement 8, third indent of Directive 90/385/EEC.

The relevant levels for 27.1 (upper levels of the requirements in 27.3 and 27.4) are derived from the basic restrictions of Recommendation 1999/519/EC for general public covering reasonable peak and localization factors. Theoretically even higher peak amplitudes and local spots are assumed to provide

