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Active implantable medical devices - Part 2-3: Particular requirements for cochlear and auditory brainstem implant systems

Dispositifs médicaux implantables actifs - Partie 2-3: Exigences particulières pour les systèmes d'implant cochléaire et les systèmes d'implant auditif du tronc cérébral

Aktive implantierbare Medizingeräte - Teil 2-3: Besondere Festlegungen für Cochlea-Implantatsysteme und auditorische Hirnstammimplantatsysteme

This draft European Standard is submitted to members for formal vote.
Deadline for CENELEC: 2010-01-08.

It has been drawn up by CEN/CLC/JWG AIMD.

If this draft becomes a European Standard, members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

This draft European Standard was established by CENELEC in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CENELEC member into its own language and notified to the Central Secretariat has the same status as the official versions.

of Austria, Belgium, Bulgaria, Cyprus, the Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, Switzerland and the United Kingdom.

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Foreword

This draft European Standard was prepared by the CEN/CENELEC Joint Working Group AIMD, Active Implantable Medical Devices. Members of the Joint Working Group were nominated by one of the members of either CEN or CENELEC. The lead has been given to CENELEC.

This draft European Standard is submitted to a second formal vote.

The following dates are proposed:

– latest date by which the existence of the EN has to be announced at national level	(doa)	dor + 6 months
– latest date by which the EN has to be implemented at national level by publication of an identical national standard or by endorsement	(dop)	dor + 12 months
– latest date by which the national standards conflicting with the EN have to be withdrawn	(dow)	dor + 36 months (to be confirmed or modified when voting)

The requirements of this particular standard supplement or modify those of the General Standard EN 45502-1:1997, *Active implantable medical devices – Part 1: General requirements for safety, marking and information to be provided by the manufacturer*.

This draft European Standard has been prepared under a mandate given to CEN and CENELEC by the European Commission and the European Free Trade Association and covers essential requirements of EC Directive 90/385/EEC. See Annexes AA and BB.

Although both this European Standard and the Directive deal with the same range of products, the structure and purpose of the two documents are different. Annex AA, BB, CC are rationales, providing some further explanation of particular subclauses of this European Standard. All three annexes are informative.

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Introduction

This European Standard specifies particular requirements for those ACTIVE IMPLANTABLE MEDICAL DEVICES that are intended 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 European Standard is relevant to all parts of IMPLANT SYSTEMS, including accessories.

The requirements of this European Standard supplement or modify those of EN 45502–1:1997*, Active implantable medical devices – Part 1: General requirements for safety, marking and information to be provided by the manufacturer*, hereinafter referred to as Part 1. The requirements of this European Standard take priority over those of Part 1.

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

1 Scope

This Part 2-3 of EN 45502 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 European Standard.

The tests that are specified in EN 45502 are type tests and are to be carried out on samples of a device to show compliance.

This Part of EN 45502 is also applicable to NON-IMPLANTABLE PARTS and accessories of the devices (see NOTE 1).

The electrical characteristics of the IMPLANTABLE PART shall be determined by either the appropriate method detailed in this particular standard 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 particular standard shall apply.

NOTE 1 The 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.

NOTE 2 The terminology used in this European Standard is intended to be consistent with the terminology of Directive 90/385/EEC.

NOTE 3 In this European Standard, 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.

2 Normative references

This clause of Part 1 applies except as follows:

Additional references:

EN ISO 14971 [1)]	2007	Medical devices - Application of risk management to medical devices (ISO 14971:2007)
EN 1593	1999	Non-destructive testing - Leak testing - Bubble emission techniques
EN 13185	2001	Non-destructive testing - Leak testing – Tracer gas method
EN 45502-1	1997	Active implantable medical devices - Part 1: General requirements for safety, marking and information to be provided by the manufacturer
EN 55011 + A2	2007 2007	Industrial, scientific and medical (ISM) radio-frequency equipment - Electromagnetic disturbance characteristics - Limits and methods of measurement (CISPR 11:2003, mod. + A1:2004, mod. + A2:2006)
EN 60068-2-27 [2)]	1993	Basic environmental testing procedures - Part 2: Tests - Test Ea and guidance: Shock (IEC 60068-2-27:1987)

1) Superseded by EN ISO 14971:2009 "*Medical devices - Application of risk management to medical devices*" (ISO 14971:2007).

2) Will be superseded by EN 60068-2-27:2009 "*Environmental testing - Part 2-27: Tests - Test Ea and guidance: Shock*" (IEC 60068-2-27:2008) at the dow of the latter, i.e. 2012-05-01.

EN 60068-2-31 [3)]	2008	Basic environmental testing procedures - Part 2: Tests - Test Ec: Drop and topple, primarily for equipment-type specimens (IEC 60068-2-31:1969 + A1:1982)
EN 60068-2-47	2005	Environmental testing - Part 2-47: Tests - Mounting of specimens for vibration, impact and similar dynamic tests (IEC 60068-2-47:2005)
EN 60068-2-64	2008	Environmental testing - Part 2-64: Tests - Test Fh: Vibration, broadband random and guidance (IEC 60068-2-64:2008)
EN 60068-2-75	1997	Environmental testing - Part 2-75: Tests - Test Eh: Hammer tests (IEC 60068-2-75:1997)
EN 60118-6	1999	Hearing aids - Part 6: Characteristics of electrical input circuits for hearing aids (IEC 60118-6:1999)
EN 60601-1	2006	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance (IEC 60601-1:2005)
EN 60601-1-2	2007	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests (IEC 60601-1-2:2007, mod.)
EN 60801-2 [4)]	1993	Electromagnetic compatibility for industrial-process measurement and control equipment - Part 2: Electrostatic discharge requirements (IEC 60801-2:1991)

3 Definitions

This clause of Part 1 applies except as follows:

Additional definitions:

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

[3)] Will be superseded by EN 60068-2-31:2008 "*Environmental testing - Part 2-31: Tests - Test Ec: Rough handling shocks, primarily for equipment-type specimens*" (IEC 60068-2-31:2008) at the dow of the latter, i.e. 2011-07-01.

[4)] Superseded by EN 61000-4-2:1995, "*Electromagnetic compatibility (EMC) - Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test*" (IEC 61000-4-2:1995).

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 (optional)

NOTE There are no requirements specified in this Part of EN 45502. 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 part 1 applies.*

5.2 *Replacement*

The IMPLANT SYSTEM shall meet the requirements of EN 60601-1-2:2007 for Group 1 equipment as specified in EN 55011:2007.

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

6 Inspection and measurement

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

6.1 Measurement of output signal characteristics

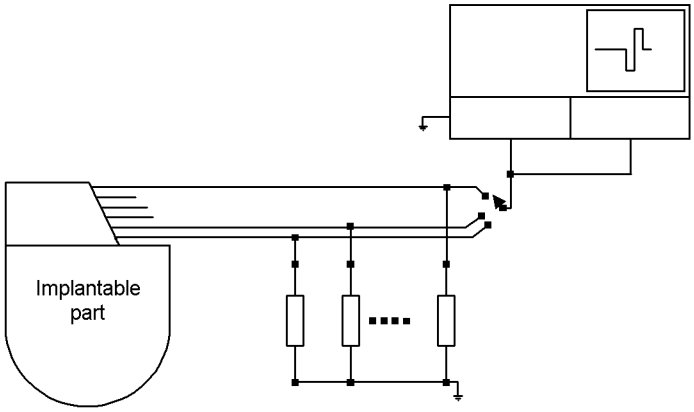
The measurement shall be performed with the implantable part of the IMPLANT SYSTEM at a temperature of (37 ± 2) °C. The IMPLANT SYSTEM shall be configured to use its maximum number of outputs and each output shall be programmed to its maximum value (amplitude and pulse width). An input signal equivalent 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 Part 1 applies.*

7.2 *This subclause of Part 1 applies.*

8 General markings for active implantable medical devices

8.1 *This subclause of Part 1 applies.*

8.2 *This subclause of Part 1 applies.*

9 Markings on the SALES PACKAGING

9.1 *This subclause of Part 1 applies.*

9.2 *This subclause of Part 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 *This subclause of Part 1 applies.*

9.4 *This subclause of Part 1 applies.*

9.5 *This subclause of Part 1 applies.*

9.6 *This subclause of Part 1 applies.*

9.7 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 Part 1 applies.*

9.9 *This subclause of Part 1 applies.*

9.10 *This subclause of Part 1 applies.*

9.11 *This subclause of Part 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 Part 1 applies*

10.2 *This subclause of Part 1 applies.*

10.3 *This subclause of Part 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 Part 1 applies.*

11 Markings on the sterile pack

11.1 *This subclause of Part 1 applies.*

11.2 *This subclause of Part 1 applies.*

11.3 *This subclause of Part 1 applies.*

11.4 *This subclause of Part 1 applies.*

11.5 *This subclause of Part 1 applies.*

11.6 *This subclause of Part 1 applies.*

11.7 *This subclause of Part 1 applies.*

11.8 *This subclause of Part 1 applies.*

11.9 *This subclause of Part 1 applies.*

NOTE This subclause can be fulfilled using an unambiguous symbol.

12 Construction of the non-reusable pack

12.1 *This subclause of Part 1 applies except as follows:*

Replacement:

The NON-REUSEABLE PACK shall comply with EN ISO 11607-1.

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

12.2 *This subclause of Part 1 applies.*

12.3 *This subclause of Part 1 applies.*

13 Markings on the active implantable medical device

13.1 *This subclause of Part 1 applies.*

13.2 *This subclause of Part 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 Part 1 applies.*

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

14.1 *This subclause of Part 1 applies.*

14.2 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 $5 \pm 0{,}5$ 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 Part 1 applies with addition that EN ISO 10993 series shall be used.

14.4 *This subclause of Part 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 Part 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 EN 60118-6:1999. 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 EN 60601-1 shall either contain or be provided with a separation device which complies with the applicable clauses regarding insulation of EN 60601-1 (separation device as defined in EN 60601-1:2006, 16.5.).

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

Compliance shall be checked as specified in EN 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 Part 1 applies..*

17 Protection from harm to the patient caused by heat

17.1 *This subclause of Part 1 applies.*

17.2 *(Vacant)*

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

18.1 *This subclause of Part 1 applies.*

18.2 *This subclause of Part 1 applies.*

18.3 *This subclause of Part 1 applies.*

19 Protection from unintended effects caused by the device

NOTE See also 28.20.

19.1 *This subclause of Part 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 Part 1 applies.*

19.4 *This subclause of Part 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 EN ISO 14155-1:2003.

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 and 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 if the device leak rate does not exceed 5×10^{-9} Pa m³/s for fine leak test and no definite stream of bubbles or two or more large bubbles are originating from the same point of the STIMULATOR case for gross leak test.

20 Protection of the device from damage caused by external defibrillators

NOTE See also 28.12.

20.1 *Not applicable.*

20.2 *This subclause of Part 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.

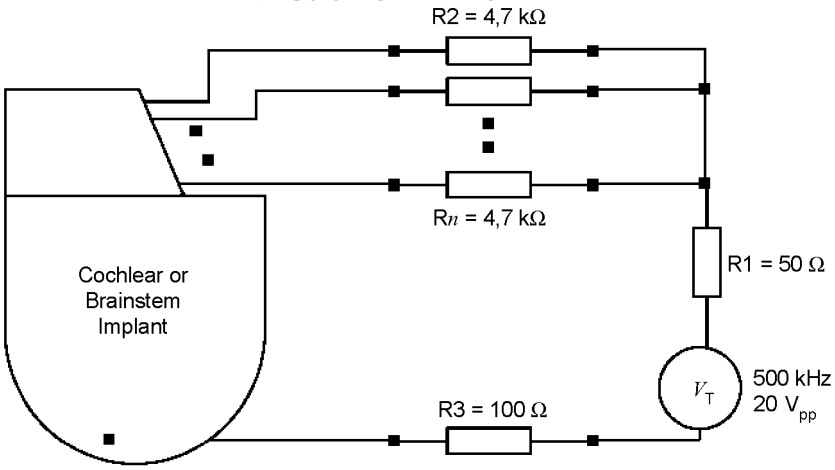


Figure 102 – Test set-up for proof of protection from high frequency currents caused by surgical equipment

Apply the test signal in ten 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 *(Vacant)*

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.

22.1 *This subclause of Part 1 applies.*

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:

1. 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.

2. 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 $3 \pm 0{,}3$ times 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 fifteen minutes. 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 the ASTM F2182 standard 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.

3. 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.

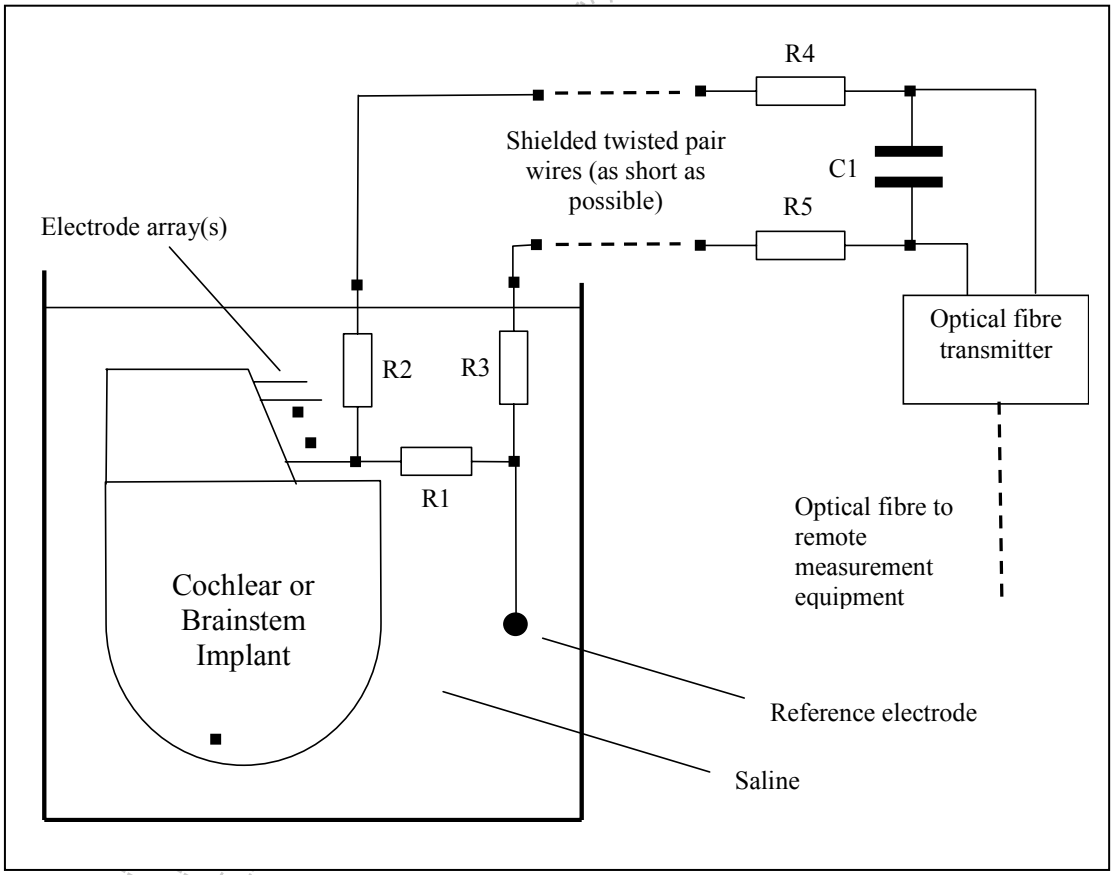


Figure 103 – Test set-up for proof of protection from harmful output during MRI scanning

4. 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 Section 2 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 EN 60068-2-31, under the following conditions:

a) test surface: hard wood, density not less than 630 kg/m³, thickness between 50 mm and 55 mm;

b) height of fall:

   i) hand-held devices: 1 m;

   ii) portable devices: 50 mm;

   iii) 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 EN 60068-2-47, shall withstand a random vibration test in accordance with EN 60068-2-64:2008, 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 Part 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 calmped 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.

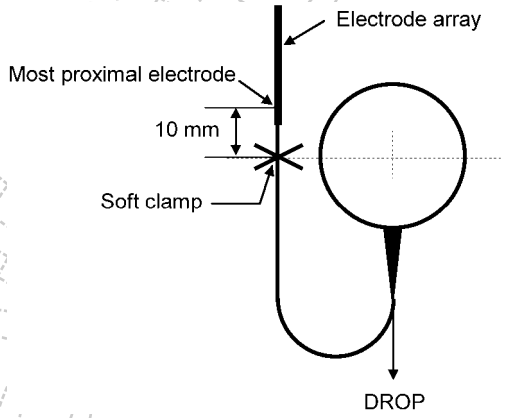


Figure 104 – Stimulator drop test

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.

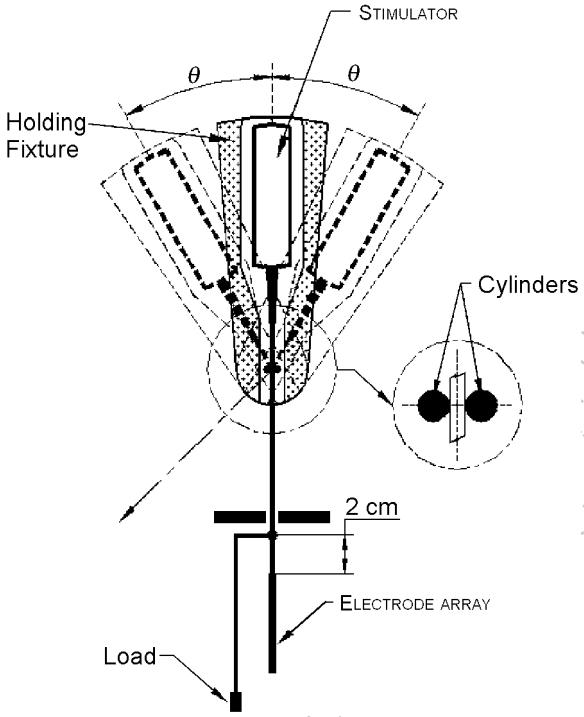


Figure 105 – Flex test fixture

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 EN 60068-2-27:1993, 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 EN 60068-2-75:1997, Test Eha or Ehc, under the following conditions:

a) impact energy [J] (± 5 %): 1,5 J after the date of publication of this standard 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 (EN 60068-2-75:1997, Test Eha) or vertical hammer (EN 60068-2-75:1997, Test Ehc). Striking element: 5-J-striking element in accordance with EN 60068-2-75:1997, 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 [5)] and implant (protective material). This piece of silicone shall be renewed for each individual test;

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 + 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;

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;

---

5) "Tip" of the striking element, definition cf. EN 60068-2-75:1997, 4.1.1.

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 BODY-WORN 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 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 BODY-WORN part of the IMPLANT SYSTEM shall withstand the electrostatic discharge test, applied to the external components, as described in EN 60801-2:1993 (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 1 Resetting may be accomplished by switching the IMPLANT SYSTEM off and on.

24.2 *(Vacant)*

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

25.1 *This subclause of Part 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 Part 1 applies.*

26.2 *This subclause of Part 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 circumstances 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 of 27.3 to 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.

743 **27.2** *Replacement:*

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

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

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

763 *Additional subclauses:*

764 **27.3 Interference signal for frequencies 16,6 Hz ≤ f < 10 MHz**

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

767 **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.				

768

769 **27.4 Interference signal for frequencies 10 MHz ≤ f < 3 000 MHz**

770 The interference signal is specified in 27.5.

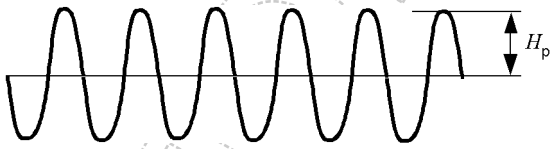
771 **Table 102 – Peak electric field strength E_P**

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.				

772

773 **27.5 Specification of interference signal**

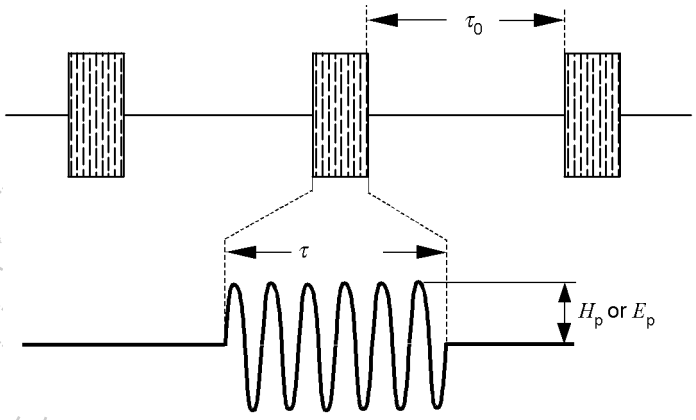
774 At frequencies 16 Hz and 50 Hz the interference signal is sinusoidal (continuous wave, cw).



775

776 **Figure 106 – Interference signal at 16 Hz and 50 Hz**

777 At all other frequencies the interference signal is switched carrier.



778

779 **Figure 107 – Interference signal at frequencies above 1 kHz**

28 Accompanying documentation

This clause of Part 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 Part 1 applies.*

28.3 *This subclause of Part 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 Part 1 applies.*

28.6 *This subclause of Part 1 applies.*

28.7 *This subclause of Part 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:
   1. a general description, brief explanation of function, available stimulation modes;
   2. a listing and brief description of other functions (impedance measurement, etc.);
   3. the mass (in grams);
   4. the principal dimensions (in millimetres);
   5. the volume without LEAD (in cubic centimetres);
   6. a listing of the materials which will come into contact with human tissue.

b) Performance characteristics:
   1. amplitude and pulse width of the OUTPUT SIGNAL on a 1 kΩ resistor (as specified in 6.2);
   2. impedance measurement accuracy (as specified in 6.3);
   3. level of MRI safety (as specified in 22.2);
   4. the default factory settings of the IMPLANT SYSTEM, if applicable;
   5. 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:

1. the electrical configurations (monopolar, number of electrically independent electrode contacts, etc.);
2. the shape and other characteristics (perimodiolar, drug delivering, etc.);
3. a listing of the materials used for the conductors, ELECTRODE CONTACTS, and insulation of the LEAD;
4. a statement advising whether the LEAD contains a MEDICINAL SUBSTANCE as an integral component, giving the identity of the MEDICINAL SUBSTANCE;
5. 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);
6. 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 Part 1 applies.*

28.10 *This subclause of Part 1 applies.*

28.11 *This subclause of Part 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 etc, 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 Part 1 applies.*

28.14 *This subclause of Part 1 applies.*

28.15 *This subclause of Part 1 applies.* Also refer to 28.12.

28.16 *This subclause of Part 1 applies.*

28.17 *This subclause of Part 1 applies.*

28.18 *This subclause of Part 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 Part 1 applies.*

28.21 *This subclause of Part 1 applies.*

28.22 *This subclause of Part 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 Part 1 applies.*

Annex AA
(informative)

Notes on EN 45502-2-3

AA.1 General

This Part of EN 45502 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 European Standard requires risks to be assessed and identified, according to EN 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 assure the performance of the device after several years' implantation. EN 45502 then requires the device manufacturer to prepare documented studies suitable for expert review.

AA.2 Notes on specific subclauses

The following notes on some of the provisions of this European Standard 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 European Standard. The notes in this annex carry the numbers of the relevant clauses of this European Standard; therefore, paragraph numbering in the annex is not consecutive.

Apart from Clauses 5, 7, and 8, the clauses of the standard 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 EN 60601-1:2006 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 EN 60601-1-2:2007. 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 European Standard, 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 Part 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] The working group recognised 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 $\geq$ 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] The working group 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] The working group 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 Part 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 EN 45502 exposure of an IMPLANT SYSTEM to therapeutic levels of ultrasound is covered by a requirement for a warning notice (see 28.20).

[22.2] The Working Group 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 must 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 publications by Hochmair, E. S., Invited editorial: MRI safety of Med-El C40/C40+ cochlear implants; Cochlear Implants Int (2001) 2(2): 98-114 and Gubbels S.P., McMenomey S.O., Safety study of the Cochlear Nucleus 24 device with internal magnet in the 1,5 Tesla Magnetic Resonance Imaging Scanner, Laryngoscope 116; June 2006, 865-871. 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.

The working group recognized that heating at the tip of the lead might be an important issue. At the time of writing the standard a working group was formed under ISO TC 150 SC6 and IEC SC 62B which might lead to an improved measurement method. 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 ºC 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] The Working Group recognised 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 recognised 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 (Baumann, R., Lesinski Schiedat, A., Goldring, J. E., Gnadeberg, D., Rittmann, K. L., Battmer, R. D., Karstens, J., Lenarz, T. The influence of ionizing radiation on the CLARION 1.2 cochlear implant during radiation therapy. Am J Otol (1999) 20(1): 50-52 and Ralston, A., Stevens, G., Mahomudally, E., Ibrahim, I., Leckie, E. Cochlear implants: response to therapeutic irradiation. Int J Radiat Oncol Biol Phys (1999) 44(1): 227-231) 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 the working group 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 the European Standard EN 60068-2-64:2008.

The test severity is determined by the test conditions a) - 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 5.5 of EN 60068-2-64:2008. 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 (Dahm M, Shepherd RK, Clark GM, Archives of Otolaryngology Stockholm, 1993). 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. The working group 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 European Standard the working group 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 $\pm$ 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] The working group recognized the need for an impact test of the implanted part in order to minimise the risk for failures due to trauma. Whilst 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 „Cochlea-Implantate unter Stossbelastung – Auswertung von Unfallszenarien, Ermittlung von Beanspruchungsgrenzen und Entwicklung eines standardisierten Prüfverfahrens", Dissertation Medizinische Hochschule Hannover by Verena Holtkamp, 2004. Based on the results of above 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. The working group 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 European Standard. 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 no risk for persons without implant too, but no known field in the general public really uses such parameters at present. The working group decided not to cover such unrealistic values.

The required exposure levels are specified in 27.3 and 27.4. These subclauses provide two interference levels: requirement for uninfluenced function (lower level) and protection requirement (upper level). Subclause 27.1 applies at the upper level only and does not require uninfluenced function of the IMPLANT SYSTEMS during exposure.

The settings have been chosen to reflect the highest possible output signals. Any significant increase of stimulation signals above the maximum output level might cause harm to the bearer. Therefore the compliance can be demonstrated by the limitation of the increase of output signal level during exposure. Additionally it is to be demonstrated, that the IMPLANT SYSTEMS still function as specified after exposure.

[27.2] The requirement covers commonly encountered electromagnetic environment for the general public and demands for uninfluenced function during exposure. The requirements for 27.2 (lower levels of the requirements in 27.3 and 27.4) are derived from the reference levels of Recommendation 1999/519/EC for general public without taking into account any peak or localisation factors. Nevertheless these lower levels cover almost all known fields too, since these values will be exceeded in very rare situations restricted to short duration and local spots.

The required exposure levels are specified in 27.3 and 27.4. These subclauses provide two interference levels, requirement for uninfluenced function (lower level) and protection requirement (upper level). Subclause 27.2 applies at the lower level only and requires uninfluenced function of the IMPLANT SYSTEMS during exposure.

The settings have been chosen to reflect typically used output signals. Compliance can be demonstrated by the limitation of changes of amplitude and phase of the output signal during exposure. The wording “uninfluenced function” does not mean that there should be no detectable changes of amplitude and phase of the output signal at all, but the function should not be uncomfortable to the user.

[27.3 and 27.4] The requirements are restricted to about two frequencies per decade only to reduce calculation time for exposure simulations of a theoretical modelling or measuring time of EMI measurements. The frequencies are fixed. Such large frequency steps do not cover single narrow resonances of the IMPLANT SYSTEMS but aim to provide confidence of good overall performance. Between 50 Hz and 1,66 kHz no further test frequency is provided, because no powerful field applications are known in this range.

[27.3] Frequency range 16,6 Hz to 10 MHz. The requirements are restricted to pure magnetic fields, because the ratio of acceptable levels for electric and magnetic fields are below $Z_0 = 377$ V/A. Additionally, at low frequency the shielding of the tissue around the implanted part is much stronger for electric fields than for magnetic.

The field strength for the protection requirement (upper level) for frequencies 16,6 Hz and 50 Hz was chosen with respect to the most powerful field sources used in this range, railway systems and power supplies (60 Hz will be covered by 50 Hz test too). At these low frequencies (above 50 Hz and below 1,66 kHz) high field strengths are acceptable for persons without implants, but they are not encountered during everyday life. For frequencies between 1,66 kHz and 100 kHz, the requirement was derived from the basic restrictions of Recommendation 1999/519/EC (which are corresponding to ANSI/IEEE C95.1) supposing a local factor of slightly more than 20, combined with the peak-to-r.m.s. ratio for continuous wave of 1,4. This means, the maximum peak field strength of non-pulsed waves can be about 28 times the reference level (which is r.m.s. value for whole body exposure). The peak factor is 1 for frequencies below 100 kHz. This means, that no exceeded peak values are accepted for pulsed fields. Above 100 kHz the local factor decreases continuously to factor 5 at 10 MHz and the peak factor increases continuously to about 32 at 10 MHz. This means, that the peak field strength is governed by local factor at low frequencies and by peak factor at high frequencies. 1999/519/EC allows the peak field strength for pulsed fields above 10 MHz to be 32 times the reference levels ($23 \cdot 1{,}4 \cong 32$). The upper levels of 27,3 cover both factors, local and peak, whichever is higher. At present, known fields do not use peak factors of more than about 5. Therefore peak factors up to about 5 are covered by the upper levels of this European Standard only.

The field strength for the requirement for uninfluenced function (lower level) reflects the reference level of Recommendation 1999/519/EC. This means that locally increased or pulsed field strengths are covered only partially. The lower levels cover all commonly encountered exposures of whole body but do not cover some localized emitters, for example some EAS devices might still influence the function of the implant. The requirement for uninfluenced function at frequencies between 1,66 kHz and 100 kHz is more than 20 times lower than the protection requirement. Since the peak factor covered here increases moderately from 1 at 100 kHz to 5 above 10 MHz, the difference between upper and lower levels decreases slowly at the upper end or the frequency range. Recommendation 1999/519/EC allows at 5 MHz higher magnetic fields than those specified in the Table 101. However this frequency is used for broadcasting which practically does not provide localized fields. In far field situations ($E/H = 377$ V/A) the E-field component limits the level of the electromagnetic field.

NOTE “Peak magnetic field strength” describes the maximum amplitude of the magnetic field vector and not the maximum short time r.m.s.-value during a burst.

Theoretical modelling as well as measurements should demonstrate that compliance is reached for any direction of field vector.

[27.4] Frequency range 10 MHz to 3 GHz. At frequencies above 10 MHz electric and magnetic component both are relevant. Since most exposures can be covered by far field situations, only the electric field strength is specified.

Theoretically a local factor of 5 and additionally a peak factor of 32 with respect to the reference levels of Recommendation 1999/519/EC would be acceptable for persons without implant. But in real life no such field sources with public access are known. With respect to known far field sources an overall factor of 5 for frequencies up to 450 MHz was chosen, decreasing to 2,5 at 2 450 MHz. This means that not all possible mobile devices emitting pulsed fields which might be held directly towards the implantation site are covered by the requirement.

The field strengths for the requirement for uninfluenced function (lower level) reflect the reference levels of Recommendation 1999/519/EC supporting neither local factor nor peak factor. This covers most commonly encountered far fields with public access.

NOTE "Peak electric field strength" describes the maximum amplitude of the electric field vector and not the maximum short time r.m.s.-value during a burst.

Above 800 MHz especially near field situations are relevant due to common handheld cellular phones. Nevertheless, it seems to be sufficient to specify the electric field strength only.

Theoretical modelling as well as measurements should demonstrate that compliance is reached for any direction of field vector.

[27.5] The modulation / pulse shape should reflect two things. It should have the potential to influence the function but, in case of measurements, it should not have the potential to be confused by the test equipment with the stimulation signal of the implant. The amplitude of the interference signal is defined in 27.3 to 27.4.

At 16,6 Hz (some European railway systems) and at 50 Hz (power supply) the fields usually are sinusoidal wave. At all other frequencies various different technical applications exist which use modulated and pulsed fields. Switched carrier signals seam to provide the maximum potential influence on implants.

[28.4] At the time of writing the standard there is no IMPLANT SYSTEM currently available using implantable connectors. The intention of this subclause is to ensure that the manufacturer provides the necessary information on appropriate connectors and assembly procedures.

[28.12] Whilst tests have been constructed to demonstrate continued safe performance of the IMPLANT SYSTEM either during, or following, the application of certain clinical procedures or medical treatments, warnings might still be required where performance of the IMPLANT SYSTEM remains unaffected but where risks might exist to the patient through its presence during the application of clinical procedures or medical treatments.

[28.15] IMPLANT SYSTEMS can withstand specific levels of therapeutic ionizing radiation. According to 28.12 the manufacturer has to provide information on the maximum allowable dosage according to the test described in 22.3.

[28.19] At the time of writing this European Standard, available IMPLANT SYSTEMS do not have an implanted energy source. Future IMPLANT SYSTEMS are likely to have a rechargeable implanted battery. When estimating the lifetime of the energy source for normal clinical settings and worst case conditions the manufacturer should take the following parameters into consideration: the battery operating time for a single charge, the total number of recharge cycles and the charging time.

Annex BB
(informative)

Notes on theoretical modelling to demonstrate compliance to Clause 27

BB.1 General

The working group identified and discussed the following advantages and disadvantages of theoretical modelling:

a) Advantages:
- no expensive measurement equipment and laboratory is needed;
- no specialists for rf-measurements would be needed;
- after the first development of the model, repetition will be very fast;
- no spurious signals need to be filtered out.

b) Disadvantages:
- no real exposure is used and therefore not all effects can be accounted for;
- sophisticated separation of internal and external effects to the implant is necessary;
- detailed knowledge of the internals of the implant is needed at the same time as experience with fields and current densities inside the human head;
- modelling might have to be repeated in case of internal or external layout changes of the device;
- expert in modelling and validation of models needed.

All proposals given in Annex BB are examples only. It is acceptable to use other models and methods to demonstrate compliance with the requirements.

It would be acceptable to substitute some calculations by partial measurements or vice versa. For example: It might be suitable to calculate the worst case currents and voltages injected into the implanted leads and to measure the immunity of the implant against signals loading its lead-connectors.

It might be possible to reduce the complexity of the calculations by excluding some parts of the device due to measurements, demonstrating a sufficient immunity of these parts separately. For example, it would be possible to neglect induced signals between separated parts of the system if the connection is blocked by appropriate feed through filters.

Theoretical modelling should contain the following:

- a numerical model of the human head sufficiently detailed in the region of ear and cochlea and a numerical method to calculate field strength and induced current densities inside the head (DD.2);
- extension of the numerical model with the implanted device and a numerical method to calculate the induced currents in the implanted leads (DD.3);
- a numerical model of all parts of the device and a numerical method to calculate the induced voltages and currents at internal points in the circuitry when exposed to electromagnetic fields (DD.4). Voltages and currents induced between separate connected parts of the device should be taken into consideration too;
- numerical simulation of the circuitry to demonstrate how the calculated induced voltages and currents (including the injected currents through the leads) disturb the function of the device (DD.5).

BB.2 Numerical model of head (without implant)

Numerical models of human head are available, i.e. “Schutz von Personen mit Cochleaimplantaten in elektromagnetischen Feldern”, Final report of project 37/02, German Federal Ministry of Economics and Work (BMWA), Dec. 2004. Most other available head models are yet not fine enough to represent ear and cochlea in detail; therefore care should be taken to use a head model which is digitized sufficiently fine. The models and the numerical exposure methods originally were optimized with respect to calculation of SAR (specific absorption rate = heating of tissue) and are to be extended to include induced current densities inside the head tissue. Basic experience with such extensions (tissue currents) is available (see DD.3).

BB.3 Calculation of injected currents to the leads

The numerical models of head and the numerical calculation methods for exposure to electromagnetic fields are optimized for continuous dielectric tissue. These are to be extended to allow representation of implanted metallic conductive structures and to calculate voltages and currents induced in implanted wires. Basic experience with such extensions is available from published studies of implanted pacemakers, e.g. Landstorfer, F. M.; Geisbusch, L.; Jakobus, U.; Maier, M.; Ruoß, H.-O.; Spreitzer, W.; Waldmann, J.: Development of a model describing the coupling between electrodes of cardiac pacemakers and transmitting antennas in their close vicinity in the frequency range from 50 MHz to 500 MHz. – Final Report second edition the Institute for High Frequency Technique, University Stuttgart, on behalf of Forschungsgemeinschaft Funk (10.1999).

BB.4 Calculation of induced currents and voltages inside the implant and inside the non-implantable parts and between connected parts

Subclause DD.3 allows to determine the “external” interference signals fed through the leads. The exposure field strength for the NON-IMPLANTABLE PARTS is equal to the requirement of Tables 102 and 103. Subclause DD.2 allows to determine the resulting exposure field strength for the implanted part inside the head tissue. Numerical simulation can be used to determine the “internally” induced interference signals.

BB.5 Description of suppression of interference signals

After carrying out DD.2 to DD.4 all interfering signals will be known. A circuit simulation tool or a design analysis will be needed to determine the disturbance of function.

Annex CC
(informative)

Notes on EMI measurements to demonstrate compliance to Clause 27

CC.1 General

The working group identified and discussed the following advantages and disadvantages of direct EMI measurements:

a) Advantages:
   - real exposure is used and therefore all effects will be covered;
   - no sophisticated separation of internal and external effects to the implant is necessary;
   - same measurement equipment can be used every time, even in case of changes of the device or of its outline;
   - no detailed knowledge of the internals of the implant is needed for measurements.

b) Disadvantages:
   - very high field strength is needed, much higher than for common EMC testing and therefore development of special equipment might be required;
   - sophisticated filtering of output signals of the device is necessary.

All proposals given in Annex CC are examples only. It is acceptable to use other equipment and methods to demonstrate compliance with the requirements.

The test should be performed with the implant inserted into a head simulator, which approximates the behaviour of the human tissue and provides pickup of currents induced inside the body tissue. Clause CC.2 gives an example of a suitable head simulator.

At frequencies below 10 MHz the head simulator is to be exposed to a magnetic field. This field can be achieved by single planar or Helmholtz coils. Clause EE.3 provides hints on how to set up those measurements.

At frequencies above 10 MHz the head simulator is to be exposed to an electromagnetic field. An adequate far field can be achieved in a transversal electromagnetic cell (TEM) or in a gigahertz transversal electromagnetic cell (GTEM). Clause EE.4 provides hints on how to set up those measurements.

At frequencies above 450 MHz the head simulator alternatively can be exposed to an electromagnetic near field. Clause EE.5 provides hints on how to setup those measurements.

Some general hints apply to all measurements:

Due to the acoustic noise that might be present in the test environment the microphone ports may be acoustically blocked for example by a drop of epoxy. In order to evaluate the immunity of the front end stage, typical clinical settings (including microphone amplifier gain and input frequency range) should be used. In order to ensure that the impact of interference is measurable the output should be mapped between 50 % (comfort level) and 25 % (threshold level) of the maximal output signal (measurement for 27.2 only).

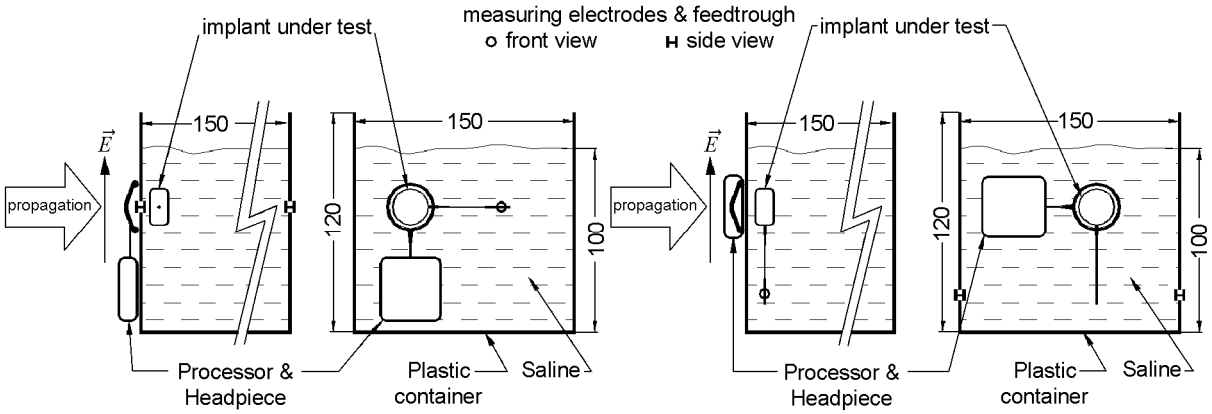
For measurement of the protection requirement (27.1, upper levels) the settings have been chosen to reflect the highest possible output signals. In order to achieve a stable oscilloscope picture the threshold and comfort levels are both set to the same maximum value and only two electrodes are used. In order to increase the signal to noise ratio the output signal may be measured during the off-time τ_0 between the bursts. As the reaction of the device to the interference persists during the off-time of the interference signal any disturbances of the output are most likely detected. The high-pass filter used for the continuous wave (cw) test signals should not distort the output signal under test. In order to suppress interference from the inductive link between the implanted device and the processor a low pass-filter with a cut-off frequency of 100 kHz similar to the one in 22.2 should be used.

CC.2 Head simulator

This head simulator was inspired by ANSI/AAMI PC69:2000 describing a trunk simulator. The head simulator shown below is provided only as an example. The dimensions are 15 cm width, 15 cm length and 12 cm height in order to reflect the head size. The test should be done at room temperature.

The simulator should be filled up to a height of 10 cm with saline, providing appropriate conductivity as defined in ANSI/AAMI PC69:2000.

The head simulator does not need to be rotated. The IMPLANT SYSTEM can be rotated by 90°. Two perpendicular orientations of the device should be tested, for example with the E field vector normal to the output lead of the implant and another having it parallel (orientation 2). For the far field tests above 10 MHz with both orientations shown in Figure CC.101 the E field vector should be vertical and the wave propagation normal to the surface carrying the processor and headpiece.



Example for device orientation 1 Example for device orientation 2

The field and propagation vectors show the situation in the TEM cell.

Figure CC.101 – Head simulator for EMI measurements

For the near field tests below 10 MHz (magnetic field) with both orientations shown in Figure CC.101 the H field vector should be horizontal and normal to both, to the shown E field vector and to the shown propagation direction. Additionally a third orientation with the H field vector normal to the surface carrying the processor and headpiece should be used with one of the shown orientations. Alternatively, the worst case condition should be determined and this should be tested.

For the optional near field tests above 450 MHz the test dipole should be parallel to the E field vectors as shown in Figure CC.101.

CC.3 Exposure to magnetic field at frequencies below 10 MHz

The device under test is switched on and placed into the head simulator (CC.2). The head simulator is placed in such a way into the coil (planar, Helmholtz or similar coil with a diameter of at least 30 cm) that the IMPLANT SYSTEM is in the centre of the coil. The test is performed at discrete frequencies with peak values of field strength according to Table 101. Each test frequency is to be applied for at least 10 s. Each test is to be repeated for three orthogonal orientations of the magnetic field vector with respect to the output lead of the implant. Alternatively, the worst case condition should be determined and this should be tested. It might be necessary to use separate coils with different winding numbers to achieve the required magnetic field strength with reasonable feeding current or amplifier output power. For frequencies above 165 kHz a single winding with a very thick wire or a copper tube of about 1 cm in diameter is to be used to avoid resonance of the coil. It is acceptable to tune the coil with parallel capacitors at any frequency to reduce the feeding current. Due to this, the voltage across the coil is to be calibrated against field strength instead of drive current.

NOTE "Peak magnetic field strength" describes the maximum amplitude of the magnetic field vector. At frequencies above 1 kHz the generator driving the coil does not need to deliver the output power continuously. For example at 5 MHz an average power of 1/200 of the peak power during the burst would be sufficient (crest factor of 23 dB).

Calibration of the coil: For any test frequency the ratio between the feeding voltage across the coil and the field strength at the centre of the coil should be determined with no head simulator inserted. The calibration should be performed with a magnetic probe smaller than 10 cm in diameter and an accuracy of at least ± 10 % and a voltage meter with accuracy of at least ± 5 %. The measurements with the head simulator and the device under test inserted are to be performed with the calibrated voltage across the coil. This kind of calibration differs from commonly used calibration by measuring the feeding current to the coil. The calibration against the voltage across the coil simulates the definition of exposure field strength in absence of the head simulator and device under test. The current calibration rather would simulate the resulting field strength in presence of the head simulator and device under test. It is accepted, that the field of a single planar coil is not homogeneous over the range of the head simulator and that the field is displaced slightly by the head simulator.

CC.4 Exposure to EM far field at frequencies from 10 MHz to 2 450 MHz

The device under test is switched on and placed into the head simulator (CC.2). The head simulator is placed into a TEM cell (restricted to frequencies below 1 GHz only) or a GTEM cell with usable measurement area of at least 30 cm in diameter. The test is performed at discrete frequencies with peak values of electric field strength according to Table 102. The wave propagation direction should be normal to the surface carrying the processor and headpiece.

Calibration: For any test frequency the ratio between the feeding voltage or the feeding power of the TEM or GTEM cell and the electric field strength at the centre of the measurement area in absence of the head simulator and device under test should be determined. The calibration should be performed with an overall accuracy of at least + 30 % and – 25 %. The measurements with the head simulator and the device under test inserted are to be performed with the calibrated voltage or power feeding the TEM or GTEM cell. It is accepted, that the field is disturbed slightly by the head simulator and device under test.

In case of a TEM or a GTEM cell with for example 50 cm height between the plates the maximum voltage amplitude is 100 V corresponding to 71 V r.m.s. for the upper level. The power of the generator during the burst-on time for such a TEM or GTEM cell with 50 Ω impedance would be 100 W r.m.s. for the upper level. But the average r.m.s. power integrated over a whole cycle of the envelope (on-time plus off-time) is about 25 times lower for the test signal at the upper test level. Therefore an amplifier with 4 W r.m.s. average power and 100 W r.m.s. peak power would be sufficient (crest factor 14 dB).

NOTE "Peak electric field strength" describes the maximum amplitude of the electric field vector but "Peak power during burst" describes the r.m.s. power during the short time of the burst.

CC.5 Exposure to EM near field at frequencies above 450 MHz

This test is an alternative to the tests described in CC.4 which avoids high power fields with TEM or GTEM cells at frequencies above 450 MHz. It is easier to perform than the test CC.4, but on the other hand the TEM or GTEM cell will still be needed because of tests below 450 MHz. This near field test especially simulates interference by handheld phones, which seems to be the major source of interference in this frequency band.

The device under test is switched on and placed into the head simulator (CC.2). For each test frequency a separate test dipole is to be used according to ANSI/AAMI PC69:2000. The test is performed at discrete frequencies with peak net dipole power according to Table CC.101 below. Each test frequency is to be applied for two orthogonal orientations of the dipole with respect to the output lead of the implant. There are two options: Either use both sample orientations of Figure CC.101 with the dipole orientated vertically, or use only one sample orientation and rotate the test dipole also to a horizontal orientation. In any case, the distance from the centre of the dipole to the surface of the plastic container carrying processor and headpiece should be 1 cm.

Table CC.101 – Peak net dipole power

Frequency	Peak net dipole power			
	Lower [a] test level	Burst-on time	Upper [b] test level	Burst-on time
900 MHz	40 mW	10 ms	2 W	1,4 ms
1 800 MHz	40 mW	10 ms	2 W	1,4 ms
2 450 MHz	40 mW	10 ms	2 W	1,4 ms

[a] The test levels are taken from ANSI/AAMI PC69:2000. The lower test level corresponds only just to the lower level of peak field strength given in Table 102. This covers distance between handheld cellular phone and implant of 15 cm.

[b] The upper test level corresponds to slightly more than the upper level of peak field strength given in Table 102. This covers distance between handheld cellular phone and implant of 1,3 cm.

For any test frequency the net dipole peak power should have an overall accuracy of at least ± 15 %.

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6) Withdrawn publication.

7) EN 50061:1988 and A1:1995 will be superseded by EN 45502-2-1:2003, "*Active implantable medical devices - Part 2-1: Particular requirements for active implantable medical devices intended to treat bradyarrhythmia (cardiac pacemakers)"*, and EN 45502-2-2:2008, "*Active implantable medical devices - Part 2-2: Particular requirements for active implantable medical devices intended to treat tachyarrhythmia (includes implantable defibrillators)"*, on 2010-05-01.

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