INTERNATIONAL STANDARD

ISO 14708-6

First edition
2010-03-01

Implants for surgery — Active implantable medical devices —

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

Implants chirurgicaux — Dispositifs médicaux implantables actifs —

Partie 6: Exigences particulières pour les dispositifs médicaux implantables actifs destinés à traiter la tachyarythmie (y compris les défibrillateurs implantables)

Reference number
ISO 14708-6:2010(E)

ISO copyright office
Case postale 56 • CH-1211 Geneva 20
Tel. + 41 22 749 01 11
Fax + 41 22 749 09 47
E-mail copyright@iso.org
Web www.iso.org

Published in Switzerland

Contents

Page

Foreword

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

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

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

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

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

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

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

— *Part 2: Cardiac pacemakers*

— *Part 3: Implantable neurostimulators*

— *Part 4: Implantable infusion pumps*

— *Part 5: Circulatory support devices*

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

In this International Standard, the following print types are used:

— Requirements and definitions: roman type.

— *Test specifications: italic type.*

— Informative material appearing outside of tables, such as notes, examples and references: smaller type. Normative text of tables is also in a smaller type.

— TERMS DEFINED IN CLAUSE 3 OF ISO 14708-1, IN THIS PART OF ISO 14708 OR AS NOTED: SMALL CAPITALS

In referring to the structure of this standard, the term

— “clause” means one of the seventeen numbered divisions within the table of contents, inclusive of all subdivisions (e.g. Clause 7 includes subclauses 7.1, 7.2, etc.);

— “subclause” means a numbered subdivision of a clause (e.g. 7.1, 7.2 and 7.2.1 are all subclauses of Clause 7).

References to clauses within this standard are preceded by the term “Clause” followed by the clause number. References to subclauses within this collateral standard are by number only.

In this International Standard, the conjunctive “or” is used as an “inclusive or” so a statement is true if any combination of the conditions is true.

The verbal forms used in this standard conform to usage described in Annex H of the ISO/IEC Directives, Part 2. For the purposes of this standard, the auxiliary verb:

— “shall” means that compliance with a requirement or a test is mandatory for compliance with this standard;

— “should” means that compliance with a requirement or a test is recommended but is not mandatory for compliance with this standard;

— “may” is used to describe a permissible way to achieve compliance with a requirement or test.

Introduction

This part of ISO 14708 specifies particular requirements for IMPLANTABLE CARDIOVERTER DEFIBRILLATORS and the functions of ACTIVE IMPLANTABLE MEDICAL DEVICES intended to treat tachyarrhythmia, to provide basic assurance of safety for both patients and users.

An external defibrillator is a MEDICAL DEVICE used, in the emergency setting, to deliver a high-energy shock to the heart, by means of ELECTRODES applied to the external chest wall, in patients suffering ventricular fibrillation (a rapid, disorganized and potentially lethal heart rhythm abnormality), to restore normal heart action. External defibrillators may also be used, in emergency or elective settings, to terminate other ventricular or atrial tachyarrhythmias by delivery of a high-energy shock, synchronized to the intrinsic cardiac rhythm, a procedure known as CARDIOVERSION. In patients known to be at risk of such arrhythmias, due to the occurrence of previous episodes or the presence of specific predisposing cardiac conditions, an IMPLANTABLE CARDIOVERTER DEFIBRILLATOR may be implanted to perform similar functions. The implantable device, which is much smaller than an external defibrillator, is contained within a sealed, encapsulating enclosure. It generates high voltage PULSES from an enclosed, miniature, electrical battery. The PULSES are transmitted to the heart by means of implanted, insulated conductors with ELECTRODES (LEADS). The IMPLANTABLE CARDIOVERTER DEFIBRILLATOR may also incorporate other sensing and pacing functions, such as rate support for bradycardia and ANTITACHYCARDIA PACING (ATP) to terminate certain tachyarrhythmias without the need of a high-energy shock. The defibrillator may be adjusted non-invasively by means of an electronic device, known as a programmer.

This part of ISO 14708 is relevant to all parts of ACTIVE IMPLANTABLE MEDICAL DEVICES intended to treat tachyarrhythmia other than pacing functions to control bradyarrhythmia. Typical examples are IMPLANTABLE PULSE GENERATORS, LEADS, ADAPTORS, ACCESSORIES, programmers and the related software (bradyarrhythmia pacing functions are dealt with in ISO 14708-2).

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

Figures or tables that are additional to those of ISO 14708-1 are numbered starting from 101.

Annex D describes a coding system that may be used to designate tachyarrhythmia therapy modes. Annex E defines the tissue equivalent interface circuits and low-pass filter required for some compliance tests. Annex F describes a method for selecting the filter capacitor used in the tissue equivalent interface circuits defined by Annex E. Annex G defines the method of calibrating the injection network defined by Annex E. All annexes except Annex E and Annex G are informative.

Implants for surgery — Active implantable medical devices —

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

1 Scope

This part of ISO 14708 specifies requirements that are applicable to IMPLANTABLE CARDIOVERTER DEFIBRILLATORS and the functions of ACTIVE IMPLANTABLE MEDICAL DEVICES intended to treat tachyarrhythmia.

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

This part of ISO 14708 is also applicable to some non-implantable parts and accessories of the devices (see Note 1).

The characteristics of the IMPLANTABLE PULSE GENERATOR or LEAD shall be determined by either the appropriate method detailed in this part of ISO 14708 or by any other method demonstrated to have accuracy equal to, or better than, the method specified. In the case of dispute, the method detailed in this part of ISO 14708 shall apply.

Any aspect of an ACTIVE IMPLANTABLE MEDICAL DEVICE intended to treat bradyarrhythmias is covered by ISO 14708-2.

NOTE 1 The device that is commonly referred to as an ACTIVE IMPLANTABLE MEDICAL DEVICE may 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 device.

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

NOTE 4 Particular requirements for congestive heart failure devices are under consideration. These types of devices are not covered by this part of ISO 14708.

2 Normative references

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

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

Additional references:

ISO 5841-3 + corr. 1, *Implants for surgery — Cardiac pacemakers — Part 3: Low-profile connectors (IS-1) for implantable pacemakers*

ISO 8601, *Data elements and interchange formats — Information interchange — Representation of dates and times*

ISO 11318, *Cardiac defibrillators — Connector assembly DF-1 for implantable defibrillators — Dimensions and test requirements*

ISO 14708-1, *Implants for surgery — Active implantable medical devices — Part 1: General requirements for safety, marking and for information to be provided by the manufacturer*

ISO 14708-2, *Implants for surgery — Active implantable medical devices — Part 2: Cardiac pacemakers*

ISO 15223-1, *Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements*

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

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

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

IEC 60878, *Graphical symbols for electrical equipment in medical practice*

ANSI/AAMI/ISO PC69, *Active implantable medical devices — Electromagnetic compatibility — EMC test protocols for implantable cardiac pacemakers and implantable cardioverter defibrillators*

3 Terms and definitions

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

Additional definitions:

3.3.1
adaptor
special connector used between an otherwise incompatible IMPLANTABLE PULSE GENERATOR and a LEAD

3.3.2
implantable cardioverter defibrillator (ICD)
ACTIVE IMPLANTABLE MEDICAL DEVICE comprising an IMPLANTABLE PULSE GENERATOR and LEAD(S) that is intended to detect and correct tachycardias and fibrillation by application of CARDIOVERSION/DEFIBRILLATION PULSE(S) to the heart

3.3.3
implantable pulse generator (IPG)
part of the ACTIVE IMPLANTABLE MEDICAL DEVICE, including the power supply and electronic circuit that produces an electrical output

NOTE For purposes of this part of ISO 14708, the term IMPLANTABLE PULSE GENERATOR describes any ACTIVE IMPLANTABLE MEDICAL DEVICE that incorporates functions intended to treat tachyarrhythmias.

3.3.4
sensitivity (sensing threshold)
minimum signal required to consistently control the function of the IMPLANTABLE PULSE GENERATOR

[see 6.1.5]

3.3.5
sensor
special part of an IMPLANTABLE PULSE GENERATOR that is designed to detect signals for the purpose of RATE MODULATION or other control purposes

3.5.1
electrode
electrically conducting part (usually the termination of a LEAD), which is designed to form an interface with body tissue or body fluid

3.5.2
endocardial lead
LEAD with an ELECTRODE designed to make a contact with the endocardium, or inner surface of the heart

3.5.3
epicardial lead
LEAD with an ELECTRODE designed to make a contact with the epicardium, or outer surface of the heart

3.5.4
transvenous
approach to the heart through the venous system

3.5.5
insertion diameter (of a lead)
minimum bore of a rigid cylindrical tube into which the LEAD (not including the connector) may be inserted

3.5.6
lead conductor resistance
R_c
ohmic resistance between the ELECTRODE and the corresponding LEAD connector TERMINAL

[see 6.2.1 of ISO 14708-2]

3.5.7
lead pacing impedance
Z_p
impedance that is formed by the ratio of a voltage PULSE to the resulting current [see 6.2.2 of ISO 14708-2]. The impedance is composed of the ELECTRODE/tissue interface and the LEAD CONDUCTOR RESISTANCE

3.5.8
lead sensing impedance
Z_s
source impedance of a LEAD as seen by an IMPLANTABLE PULSE GENERATOR

[see 6.2.3 of ISO 14708-2]

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
beat
ordered spontaneous activity of the heart

3.20.2
pulse
electrical output of an IMPLANTABLE PULSE GENERATOR other than CD PULSE [see 3.3.5] intended to stimulate the myocardium

3.20.3
pulse amplitude
amplitude of the PULSE measured according to the procedure in 6.1.1 of ISO 14708-2

3.20.4
pulse duration
duration of the PULSE, measured between two reference points specified in this part of ISO 14708

[see 6.1.1 of ISO 14708-2]

3.20.5
pulse interval
interval between equivalent points of two consecutive PULSES

[see 6.1.1 of ISO 14708-2]

3.20.6
basic pulse interval
PULSE INTERVAL in absence of sensed cardiac or other electrical influence

3.20.7
automatic sensitivity control
automatic adjustment of the SENSITIVITY in response to available physiological signals

3.21.1
beginning of service; BOS
when an individual IMPLANTABLE PULSE GENERATOR is first released by the manufacturer as fit for being placed on the market

3.21.2
end of service; EOS
when the PROLONGED SERVICE PERIOD has elapsed and no further pacing function is specified nor can be expected

3.21.3
prolonged service period; PSP
period beyond the RECOMMENDED REPLACEMENT TIME during which the IMPLANTABLE PULSE GENERATOR continues to function as specified by the manufacturer

[ISO 14708-2, 3.20.4, modified]

3.21.4
power source indicator
means of indicating the electrical status of the power source during the IMPLANTABLE PULSE GENERATOR'S service life

3.21.5
recommended replacement time; RRT
when the POWER SOURCE INDICATOR reaches the value set by the manufacturer of the IMPLANTABLE PULSE GENERATOR for its recommended replacement. This indicates entry into the PROLONGED SERVICE PERIOD

3.21.6
use-before date
date after which the manufacturer recommends that the ACTIVE IMPLANTABLE MEDICAL DEVICE should not be implanted

3.22.1
antitachycardia pacing; ATP
cardiac pacing sequences intended to terminate re-entry tachycardias

3.22.2
arrhythmia detection interval
interval below which the IMPLANTABLE PULSE GENERATOR will classify a rhythm as a tachyarrhythmia

3.22.3
ATP only device
IMPLANTABLE PULSE GENERATOR capable of delivering rapid sequences of pacing PULSES to terminate ventricular (VT) and atrial (AT) tachycardia and atrial fibrillation (AF)

3.22.4
cardioversion
termination of atrial tachyarrhythmia or ventricular tachycardia by PULSE(S) synchronized to cardiac events

3.22.5
cardioversion/defibrillation pulse (CD pulse)
high-energy monophasic, biphasic, or multiphasic PULSE intended to restore normal rhythm by shocking the heart

3.22.6
capacitor formation
any charge to maximum-programmed energy that dissipates off the capacitors (is not dumped) for at least 10 min

3.22.7
cardioversion/defibrillation lead (CD lead)
LEAD used to conduct a CD PULSE from the IMPLANTABLE PULSE GENERATOR to the heart

3.22.8
charge time
the time required to charge the high-voltage capacitors to a specified CD PULSE ENERGY

3.22.9
delivered cardioversion/defibrillation pulse energy (delivered CD pulse energy)
total energy delivered to a standard load (50 Ω) by all phases of a CD PULSE, measured according to 6.1.3

3.22.10
defibrillation
termination of fibrillation

3.22.11
ICD output voltage
peak voltage of the CARDIOVERSION/DEFIBRILLATION PULSE(S), measured according to 6.1.2

3.22.12
terminal
electrically separate conductive device connection

4 Symbols and abbreviated terms (optional)

This clause of ISO 14708-1 applies.

5 General requirements for non-implantable parts

This clause of ISO 14708-1 applies.

6 (Vacant)

Replacement:

6 Measurement of implantable pulse generator and lead characteristics

6.1 Measurement of IMPLANTABLE PULSE GENERATOR characteristics

The values of the electrical characteristics for the IMPLANTABLE PULSE GENERATOR measured in accordance with the methods described in this clause shall be within the range of values stated by the manufacturer in the accompanying documentation [see 28.8.2].

CAUTION The tests in this subclause may employ the use of high voltage. Failure to use safe laboratory practices may result in severe electrical shock, resulting in personal injury or death to the persons handling the equipment or conducting the test. Also damage to electrical equipment is possible.

The measurements shall be made with the IMPLANTABLE PULSE GENERATOR at a temperature of 37 ºC ± 2 ºC.

The overall measurement accuracy for each test shall be within the limits ± 5 %.

6.1.1 Measurement of the bradyarrhythmia characteristics

Measurement of the bradyarrhythmia characteristics of the IMPLANTABLE PULSE GENERATOR shall be performed using the appropriate methods specified in 6.1 of ISO 14708-2. The bradyarrhythmia characteristics shall be measured with the tachyarrhythmia therapies inactivated.

6.1.2 Measurement of icd output voltage

NOTE This clause does not apply to ATP ONLY DEVICES.

Procedure: use an oscilloscope, with input impedance of nominal 1 MΩ, ≤ 30 pF.

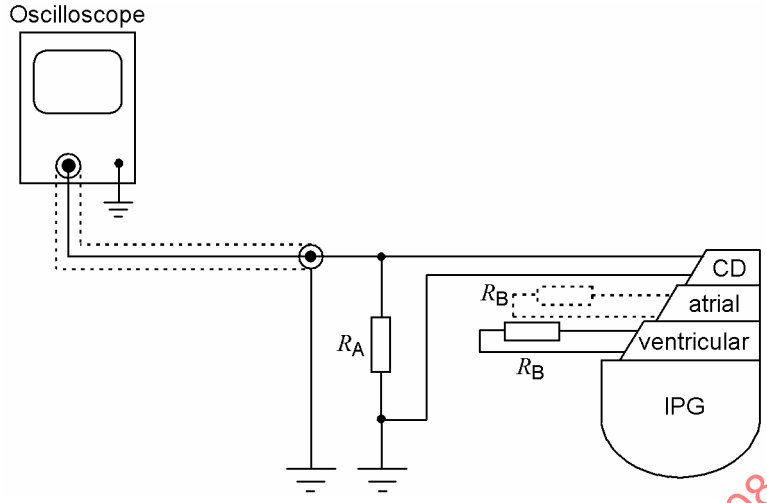

Figure 101 — Measurement of CD PULSE characteristics

The IMPLANTABLE PULSE GENERATOR shall be connected to the oscilloscope as shown in Figure 101. TERMINALS of the IMPLANTABLE PULSE GENERATOR intended to deliver a CD PULSE shall be connected to a low-inductance load of $50\ \Omega \pm 1\ \%$ (R_A). Other inputs/outputs shall be connected to loads of $500\ \Omega \pm 5\ \%$ (R_B). The oscilloscope shall be adjusted to display one phase of the CD PULSE.

The IMPLANTABLE PULSE GENERATOR shall be programmed to the maximum CD PULSE ENERGY setting.

The ICD OUTPUT VOLTAGE (V_{max}) shall be determined by recording the peak amplitude of the voltage across the resistor R_A [see Figure 101 and Figure 102].

The procedure shall be repeated for each type of CD PULSE (i.e. monophasic, biphasic waveform).

The entire procedure shall be repeated for the other required CD PULSE ENERGY settings [see 28.8.2 d) 2)].

The results shall be expressed in volts (V) and shall be within the tolerance of disclosed data [see 28.8.2 d) 2)].

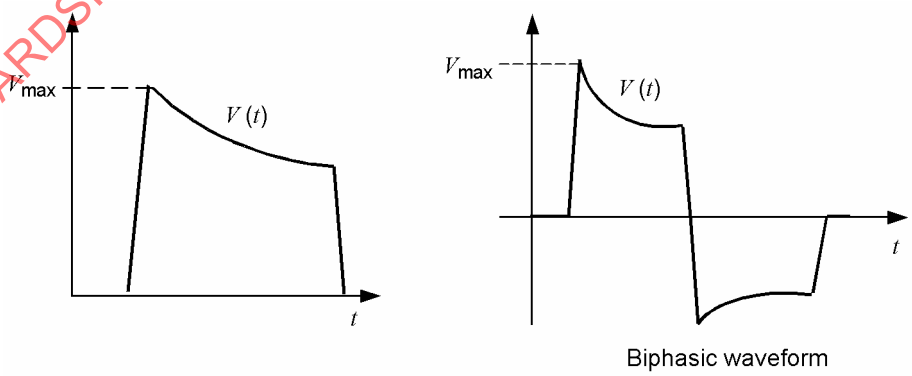

Figure 102 — Measurement of ICD OUTPUT VOLTAGE

6.1.3 Measurement of delivered CD PULSE ENERGY

NOTE This clause does not apply to ATP ONLY DEVICES.

Procedure: use the oscilloscope and measurement set-up specified in 6.1.2.

The oscilloscope shall be adjusted to display one CD PULSE. The IMPLANTABLE PULSE GENERATOR shall be programmed to deliver the maximum CD PULSE ENERGY setting.

The CD PULSE shall be determined by recording the voltage waveform $V_{(t)}$ [see Figure 102] across the resistor R_A [see Figure 101]. The delivered CD PULSE ENERGY, W, shall be calculated by applying the equation:

$$W = \int_0^{Tp} \frac{V^2(t)}{R_A} dt$$

where

T_p = duration (all phases) of the CD PULSE

$V_{(t)}$ = instantaneous voltage

R_A = 50 Ω

For devices with more than two output TERMINALS, the delivered CD PULSE ENERGY (W) shall be determined by the sum of the energies delivered from each TERMINAL, as measured by the manufacturer's disclosed method.

The entire procedure shall be repeated for the other required CD PULSE energy settings [see 28.8.2 d) 2)].

The result shall be expressed in joules (J) and shall be within the tolerance of disclosed data [see 28.8.2 d) 2)].

6.1.4 Measurement of the antitachyarrhythmia pacing PULSE AMPLITUDE

The low-voltage antitachyarrhythmia pacing PULSE AMPLITUDE of an IMPLANTABLE PULSE GENERATOR shall be measured with the device set in the as-shipped mode or as recommended by the manufacturer using the procedure in 6.1.1 of ISO 14708-2.

6.1.5 Measurement of the sensitivity of an implantable pulse generator with automatic sensitivity control

The lowest (most sensitive) SENSING THRESHOLD for both positive and negative polarities shall be measured using a method as specified by the manufacturer [see 28.8.2 d) 4)].

6.1.6 Charge time

NOTE This clause does not apply to ATP ONLY DEVICES.

The values of typical CHARGE TIMES (when the capacitors are fully formed) for maximum CD PULSE ENERGY shall be disclosed at BOS and at RRT, as a minimum [see 28.8.2 d) 5)].

6.1.7 CAPACITOR FORMATION (capacitor maintenance)

NOTE This clause does not apply to ATP ONLY DEVICES.

If applicable the manufacturer shall provide instructions for periodic CAPACITOR FORMATION to be performed at least in connection with patient follow-up sessions, unless the IMPLANTABLE PULSE GENERATOR provides a feature of fully automatic CAPACITOR FORMATION.

6.2 Measurement of the electrical characteristic of a sensing/pacing LEAD

The values of the electrical characteristics of any sensing/pacing LEAD of the IMPLANTABLE CARDIOVERTER DEFIBRILLATOR measured in accordance with the appropriate method specified in 6.2 of ISO 14708-2 shall be within the range of values stated by the manufacturer in the accompanying documentation [see 28.8.3].

7 General arrangement of the packaging

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

Additional subclause:

7.3 The implantable pulse generator shall be shipped with the antitachycardia pacing and/or cardioversion and/or defibrillation inactivated.

Compliance shall be confirmed by inspection.

NOTE When CARDIOVERSION and/or DEFIBRILLATION are inactivated the IMPLANTABLE PULSE GENERATOR is not capable of delivering any CD PULSE(S).

8 General markings for active implantable medical devices

This clause of ISO 14708-1 applies.

9 Markings on the sales packaging

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

9.4

Additional subclauses:

9.4.1 The SALES PACKAGING containing an IMPLANTABLE PULSE GENERATOR shall bear a list of the tachyarrhythmia therapies available.

Compliance shall be confirmed by inspection.

9.4.2 The SALES PACKAGING containing an IMPLANTABLE PULSE GENERATOR shall bear a statement that the PULSE generator's tachyarrhythmia therapies, as shipped, are inactive.

NOTE 1 See 7.3 for the shipping requirements for antitachycardia pacing, cardioversion and defibrillation.

NOTE 2 For ATP ONLY DEVICES, the CD TERMINALS part of the requirement is not applicable.

Compliance shall be confirmed by inspection.

9.4.3 If applicable, the SALES PACKAGING containing an IMPLANTABLE PULSE GENERATOR shall bear a description of the most comprehensive bradyarrhythmia pacing mode available and the mode as shipped.

NOTE Instead of describing the bradyarrhythmia pacing mode in words, the mode codes defined in Annex D of ISO 14708-2 may be used in the MARKINGS and accompanying documentation to designate the bradyarrhythmia pacing mode of the IMPLANTABLE PULSE GENERATOR.

Compliance shall be confirmed by inspection.

9.4.4 If applicable, the SALES PACKAGING containing a LEAD shall bear the information required by 9.4.2 of ISO 14708-2.

Compliance shall be confirmed by inspection.

9.7

Replacement:

9.7 The SALES PACKAGING containing an IMPLANTABLE PULSE GENERATOR, LEAD, ADAPTOR, or other sterile part shall bear the USE-BEFORE DATE, presented in the sequence: year, month, and, if appropriate, day; expressed as numerals as specified in ISO 8601.

Compliance shall be confirmed by inspection.

9.9

Replacement:

9.9 If the intended use of an implantable part of an ACTIVE IMPLANTABLE MEDICAL DEVICE enclosed within the SALES PACKAGING requires that it be connected to other devices or accessories not included in the package, the SALES PACKAGING shall identify the connector type (pace/sense, CARDIOVERSION/DEFIBRILLATION, etc.), the configuration (unipolar, bipolar, etc.), and the connector geometry (lengths and diameters in millimetres or reference to published standards).

Compliance shall be confirmed by inspection.

Additional subclause:

9.12 The SALES PACKAGING containing an IMPLANTABLE PULSE GENERATOR shall be marked with the symbol for "dangerous voltage" [see symbol 03-01 in IEC 60878].

NOTE This clause does not apply to ATP ONLY DEVICES.

Compliance shall be confirmed by inspection.

10 Construction of the SALES PACKAGING

This clause of ISO 14708-1 applies.

11 Markings on the STERILE PACK

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

Additional subclauses:

11.10 The STERILE PACK containing an IMPLANTABLE PULSE GENERATOR shall list the tachyarrhythmia therapies available.

Compliance shall be confirmed by inspection.

11.11 The STERILE PACK containing an IMPLANTABLE PULSE GENERATOR shall bear a statement that the tachyarrhythmia therapies of the IMPLANTABLE PULSE GENERATOR, as shipped, are inactive.

NOTE 1 See 7.3 for the shipping requirements for antitachycardia pacing, cardioversion and defibrillation.

NOTE 2 For ATP ONLY DEVICES, the CD TERMINALS part of the requirement is not applicable.

Compliance shall be confirmed by inspection.

11.12 If applicable, the STERILE PACK containing an IMPLANTABLE PULSE GENERATOR shall bear a description of the most comprehensive bradyarrhythmia pacing mode available and the mode as shipped.

NOTE Instead of describing the bradyarrhythmia pacing mode in words, the mode codes defined in Annex D of ISO 14708-2 may be used in the MARKINGS and accompanying documentation to designate the bradyarrhythmia pacing mode of the IMPLANTABLE PULSE GENERATOR.

Compliance shall be confirmed by inspection.

11.13 The STERILE PACK containing an IMPLANTABLE PULSE GENERATOR shall be marked with the symbol for "dangerous voltage" [see symbol 03-01 in IEC 60878].

NOTE This clause does not apply to ATP ONLY DEVICES.

Compliance shall be confirmed by inspection.

12 Construction of the NON-REUSABLE PACK

This clause of ISO 14708-1 applies.

13 Markings on the ACTIVE IMPLANTABLE MEDICAL DEVICE

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

13.1

Delete and replace with additional subclauses:

13.1.1 Each IMPLANTABLE PULSE GENERATOR shall be permanently marked with the name or trademark of the manufacturer, the MODEL DESIGNATION and the SERIAL NUMBER.

If there is more than one input/output connector, then each connector shall be identified by a MARKING [see 28.8.2 a)].

Compliance shall be confirmed by inspection.

13.1.2 Each LEAD and, if practicable and appropriate, each ADAPTOR shall be permanently and visibly marked with an identification of the manufacturer, the MODEL DESIGNATION, and the SERIAL NUMBER or when appropriate the batch number.

NOTE The MODEL DESIGNATION may be incorporated into the batch or SERIAL NUMBER.

Compliance shall be confirmed by inspection.

13.3

Replacement:

13.3 IMPLANTABLE PULSE GENERATORS shall incorporate a code by which the device and the manufacturer can be unequivocally identified particularly with regard to the MODEL DESIGNATION. It shall be possible to read this code, when necessary, without the need for a surgical operation, using equipment generally available to the physician.

NOTE The MARKINGS identifying the manufacturer and the MODEL DESIGNATION of the IMPLANTABLE PULSE GENERATOR may be in the form of radio-opaque figures or letters.

Compliance is checked by a procedure defined by the manufacturer in the accompanying documentation [see 28.6 of ISO 14708-1].

14 Protection from unintended biological effects being caused by the ACTIVE IMPLANTABLE MEDICAL DEVICE

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

14.2

Replacement:

14.2 Any 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 active IMPLANTABLE MEDICAL DEVICE 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 shall be 5 ± 0,5 times the numerical value of the surface area of the implantable part expressed in cm^2. The container shall be covered with a glass lid and maintained at 37 °C ± 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 2.9.29 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 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.

15 Protection from HARM to the patient or user caused by external physical features of the ACTIVE IMPLANTABLE MEDICAL DEVICE

This clause of ISO 14708-1 applies.

16 Protection from HARM to the patient caused by electricity

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

16.2

Replacement:

16.2 Except for its intended function, an IMPLANTABLE PULSE GENERATOR when in use shall be electrically neutral. No d.c. leakage current of more than 1 µA shall occur in any of the current pathways of the CD LEAD TERMINALS and the case and no more than 0,1 µA in the current pathways of any other TERMINAL.

CAUTION – Care must be taken to ensure that the high-voltage capacitors are discharged. Failure to use safe laboratory practices may result in severe electrical shock, resulting in personal injury or death to the persons handling the equipment or conducting the test.

NOTE 1 For ATP ONLY DEVICES, the CD TERMINALS part of the requirement is not applicable.

Test: use a d.c. voltmeter, having a resolution of at least 2 µV, fed through a low-pass filter with a time constant (τ) of at least 10 s.

NOTE 2 As an example this low-pass filter (LP-filter) can be implemented by a four element low-pass RC filter with the elements built from 100 kΩ resistors and 10 μF metalized polyester capacitors. The input resistance of the d.c. voltmeter should then be ≥ 40 MΩ.

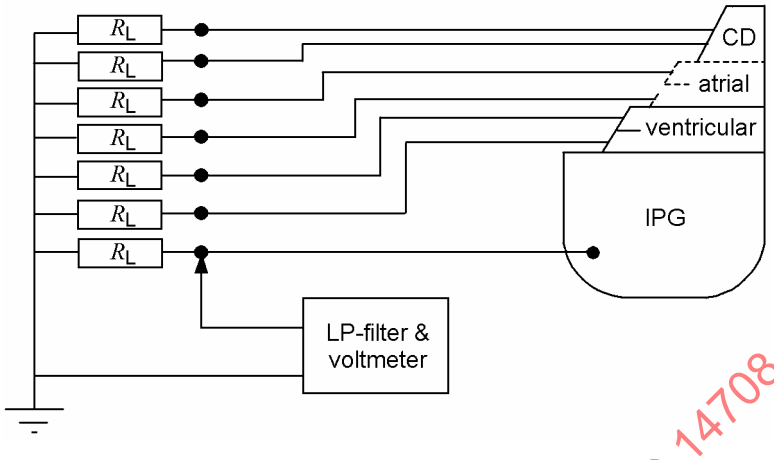

Figure 103 — Test set-up for measurement of electrical neutrality

The tachyarrhythmia therapy functions of the IMPLANTABLE PULSE GENERATOR shall be inactive during the test, and, if applicable, the high-voltage capacitors shall be discharged. If the therapeutic function of the IMPLANTABLE PULSE GENERATOR includes bradyarrhythmia pacing, the IMPLANTABLE PULSE GENERATOR shall be set to the nominal settings recommended by the manufacturer (i.e. factory recommended settings) and the PULSE AMPLITUDE and PULSE DURATION shall be programmed to the highest available settings.

Each electrically conductive part of the IMPLANTABLE PULSE GENERATOR in contact with body tissue when the device is implanted shall be identified and connected to a common bus through load resistors R_L of 500 Ω ± 1 % [see Figure 103].

Measure the average direct voltage across each of the load resistors [see Figure 103]. Steady state conditions shall be reached before the measurement is made.

Compliance shall be confirmed if the absolute value of the potential across each resistor R_L is less than 0,5 mV for any CD LEAD TERMINAL and the IPG-case, and less than 50 μV for any other conductive pathway.

16.3 Not applicable.

Additional subclauses:

16.4 Except for the intended bradyarrhythmia pacing functions, the a.c. leakage current (r.m.s.) delivered through each LEAD shall not create an UNACCEPTABLE HAZARD of fibrillation during charging of the capacitors in the IMPLANTABLE PULSE GENERATOR.

CAUTION — The following test may produce high-voltage shocks. Failure to use safe laboratory practices may result in severe electrical shock, resulting in personal injury or death to the persons handling the equipment or conducting the test. Also damage to electrical equipment is possible.

NOTE This clause does not apply to ATP ONLY DEVICES.

Test: use a true r.m.s. voltmeter, 1 Hz - 1 MHz, sampling period ≤ 1 s, input impedance ≥ 1 MΩ, fed via band pass filter (BP-filter) defined by Figure 104, with C_s *= 15 μF ± 5%,* R_p *= 1 kΩ ± 1%,* R_s *= 10 kΩ ± 1 %, and* C_p *= 0,015 μF ± 5 %. (All resistors shall be low-inductance types.)*

Any bradyarrhythmia pacing output available from the IMPLANTABLE PULSE GENERATOR shall be suppressed during the test.

Each electrically conductive part of the IMPLANTABLE PULSE GENERATOR in contact with body tissue when the device is implanted shall be identified and connected to a common bus through separate 100 Ω ± 1 % resistors R_L as shown in Figure 105. (All resistors R_L shall be 25 W low-inductance types.)

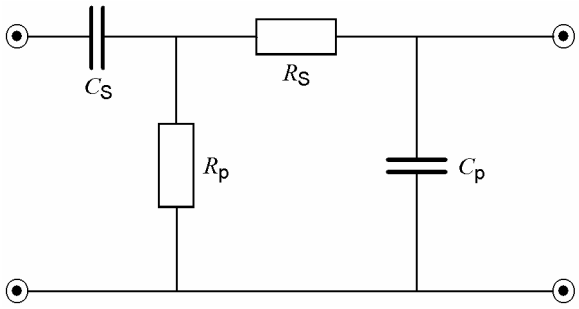

Figure 104 — Band pass filter for a.c. leakage current measurement

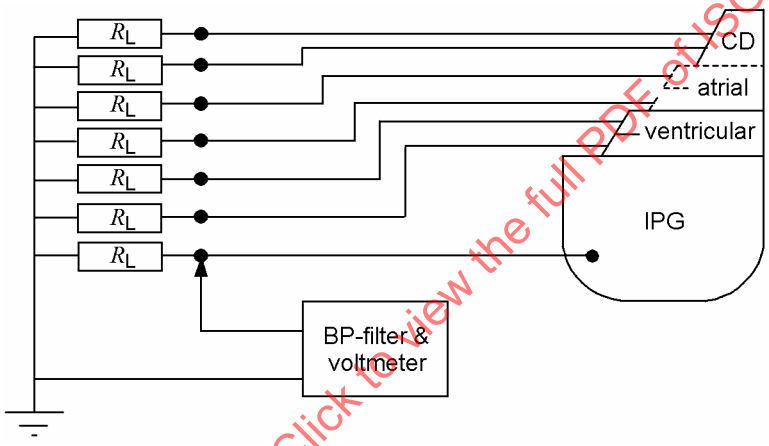

Figure 105 — Test set-up for measurement of a.c. leakage current

Measure the r.m.s. voltage across each resistor R_L [see Figure 105] while the output capacitors in the IMPLANTABLE PULSE GENERATOR are charged to deliver the maximum energy CD PULSE.

Compliance shall be confirmed if the r.m.s. value across each resistor R_L is no more than 1 mV r.m.s. during each charging cycle.

16.5 The d.c. leakage current from an IMPLANTABLE PULSE GENERATOR with charged high-voltage capacitors shall not create an UNACCEPTABLE HAZARD of fibrillation.

CAUTION — The following test may produce high-voltage shocks. Failure to use safe laboratory practices may result in severe electrical shock, resulting in personal injury or death to the persons handling the equipment or conducting the test. Also damage to electrical equipment is possible.

NOTE This clause does not apply to ATP ONLY DEVICES.

Test: use a d.c. voltmeter, input impedance ≥ 1 MΩ, which has demonstrated overall measurement accuracy of better than ± 10 %.

The test shall be performed with the IMPLANTABLE PULSE GENERATOR at a temperature of 37 °C ± 2 °C and any bradyarrhythmia pacing output available from the IMPLANTABLE PULSE GENERATOR shall be suppressed.

Each electrically conductive part of the IMPLANTABLE PULSE GENERATOR in contact with body tissue when the device is implanted shall be identified and connected to a common bus through separate 100 Ω ± 1 % resistors, R_L. (All resistors R_L shall be 25 W low inductance types.)

The IMPLANTABLE PULSE GENERATOR shall be caused to charge ready to deliver a maximum energy DEFIBRILLATION PULSE. With the IMPLANTABLE PULSE GENERATOR held in the charged state, measure the d.c. current through each resistor R_L in turn.

Compliance shall be confirmed if the voltage measured across each R_L is less than 10 mV for any CD LEAD TERMINAL and the IPG-case, and less than 1 mV for any other conductive pathway.

17 Protection from HARM to the patient caused by heat

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

17.1

Replacement:

17.1 No outer surface of IMPLANTABLE PULSE GENERATOR shall be greater than 2 °C above the normal surrounding body temperature of 37 °C. Temperature increases from 2 °C up to 4 °C are allowed for not more than 30 min when implanted and the ACTIVE IMPLANTABLE MEDICAL DEVICE is in normal operation.

For other implanted parts of the ACTIVE IMPLANTABLE MEDICAL DEVICE and ATP ONLY DEVICES, ISO 14708-1 applies.

NOTE The single fault condition for temperature rise is covered by the requirement in 19.3 of ISO 14708-1.

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

18 Protection from ionizing radiation released or emitted from the ACTIVE IMPLANTABLE MEDICAL DEVICE

This clause of ISO 14708-1 applies.

19 Protection from unintended effects caused by the device

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

19.2

Replacement:

19.2 If the implantable part of an ACTIVE IMPLANTABLE MEDICAL DEVICE contains one or more power sources, such as batteries, the ACTIVE IMPLANTABLE MEDICAL DEVICE shall provide advanced warning when depletion of any single power source will significantly limit the future availability of therapeutic functions, e.g. bradyarrhythmia pacing, ATP, post shock pacing.

The PROLONGED SERVICE PERIOD in normal use shall be at least three months under the most severe of the following conditions that is applicable:

1) The IMPLANTABLE PULSE GENERATOR monitoring (no pacing) and delivering 6 thirty joules or maximum energy (whichever is less) CD PULSES into a 50 Ω ± 1 % load. The CD PULSES shall be spaced uniformly over the three month period and the last CD PULSES being delivered at the end of the period; or

2) the IMPLANTABLE PULSE GENERATOR pacing 100 % with the manufacturer's nominal conditions and delivering 3 thirty joules or maximum energy (whichever is less) CD PULSES into a 50 Ω ± 1 % load. The CD PULSES shall be spaced uniformly over the three-month period and the last CD PULSES being delivered at the end of the period.

NOTE 1 For ATP ONLY DEVICES, the CD TERMINALS part of the requirement is not applicable.

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.

The manufacturer shall provide suitable measures, instructions and/or tools to the physicians on the appropriate follow-up period so that RRT (or the status within PSP) will be reliably detected.

NOTE 2 In some European countries the national cardiology society has follow-up guidelines based on state of the art of medical practice that should be taken into consideration.

Additional subclause:

19.5 The IMPLANTABLE PULSE GENERATOR shall be designed so that the implantable defibrillator OUTPUT VOLTAGE shall not permanently affect the device, provided the warning about hazardous positioning of ELECTRODES in 28.11.2 is respected.

CAUTION — The following test employs the use of high voltage. Failure to use safe laboratory practices may result in severe electrical shock, resulting in personal injury or death to the persons handling the equipment or conducting the test.

NOTE 1 This clause does not apply to ATP ONLY DEVICES.

Test: the IMPLANTABLE PULSE GENERATOR shall be connected to deliver CD PULSES to a potential divider network of low inductance, 5 % tolerance resistors of 12,5 Ω (R_{L1}) and 25 Ω (R_{L2}) as shown in Figure 106. If the IMPLANTABLE PULSE GENERATOR has more than two defibrillator output TERMINALS, all positive TERMINALS shall be connected to CD(+) and all negative TERMINALS shall be connected to CD(-).

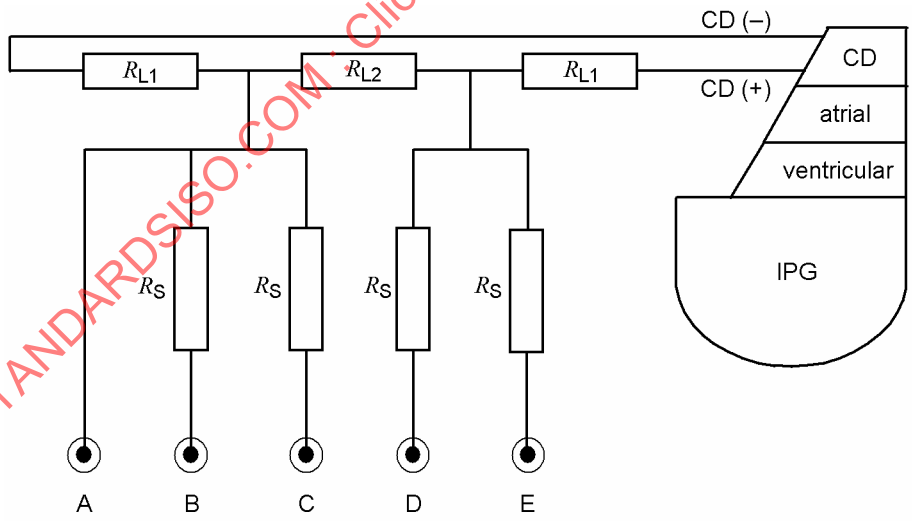

Figure 106 — Test set-up for checking internal DEFIBRILLATION protection

The IMPLANTABLE PULSE GENERATOR shall be programmed to deliver maximum energy CD PULSES. The potential divider is tapped to feed test point A directly and to feed test points B-E through separate 250 Ω ± 5 % resistors (R_S) [see Figure 106].

Two maximum energy CD PULSES are delivered at each of eight configurations defined by Table 101.

NOTE 2 For single channel devices, configurations 3, 4, 5 and 6 are not applicable.

NOTE 3 If the IMPLANTABLE PULSE GENERATOR case is a CD TERMINAL, then configurations 7 and 8 are not applicable.

Table 101 — Connection sequence

Configuration	A	B	C	D	E
1		V_{ring}	A_{ring}	V_{tip}	A_{tip}
2		V_{tip}	A_{tip}	V_{ring}	A_{ring}
3		A_{tip}	A_{ring}	V_{tip}	V_{ring}
4		V_{tip}	V_{ring}	A_{tip}	A_{ring}
5		V_{ring}	A_{tip}	V_{tip}	A_{ring}
6		V_{tip}	A_{ring}	V_{ring}	A_{tip}
7	All P/S [a]			Case	
8	Case			All P/S [a]	
[a] All P/S = all pacing/sensing TERMINALS connected together through separate 250 Ω ± 5 % resistors.					

Compliance shall be confirmed, if after all applicable test cases have been completed the IMPLANTABLE PULSE GENERATOR functions as prior to the test without further adjustment.

20 Protection of the device from damage caused by external defibrillators

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

20.2

Replacement:

NOTE For ATP ONLY DEVICES, the CD TERMINALS part of the requirement is not applicable.

20.2 The IMPLANTABLE PULSE GENERATOR shall be designed so that external DEFIBRILLATION of the patient will not permanently affect the device, provided that the external defibrillator ELECTRODE does not come in direct contact with the implanted part and are placed according to the manufacturer's recommendations.

Test 1 and Test 2, as described below, have to be performed.

Test 1:

Test equipment: use a resistor network circuit defined by Figure 110 [with parameters as in Table 102] and a DEFIBRILLATION PULSE generator providing a damped sinus waveform with the following characteristics:

1,5 ms < T_p < 2,5 ms; 3 ms < T_{w50} < 5,5 ms.

NOTE T_p designates the time interval from start of the DEFIBRILLATION PULSE to the maximum value of the test voltage V_{test}; T_{w50} designates the time interval during which the test voltage is above the 50 % level of the maximum value of V_{test} [see Figure 107]. In Figure 107 a typical DEFIBRILLATION waveform is shown, which can be generated using an RLC circuit as shown in Figure 108 using the following component values, C = 330 µF, L = 13,3 mH and R = 12 Ω.

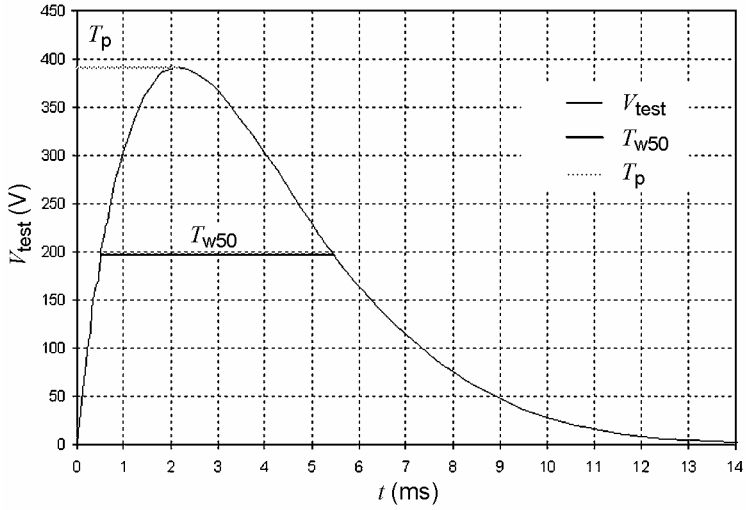

Figure 107 — Damped sinus DEFIBRILLATION waveform

Figure 108 below illustrates an example schematic of a DEFIBRILLATION PULSE generator, where R_L is the resistance of the inductance (L) in ohms and R_G is the DEFIBRILLATION PULSE generator output resistance in ohms.

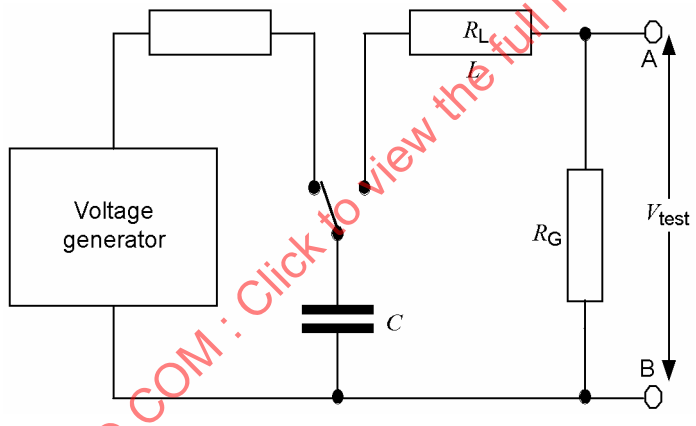

Figure 108 — RCL circuit for generating a damped sinus DEFIBRILLATION waveform

Test procedure (Test 1): connect output A of the DEFIBRILLATION PULSE generator to terminal A of the resistor network shown in Figure 110 (using parameters as in Table 102) and connect output B of the DEFIBRILLATION PULSE generator to terminal B of the resistor network. Adjust the maximum PULSE AMPLITUDE of the DEFIBRILLATION PULSE (V_{test}) at the output of the DEFIBRILLATION PULSE generator to 380 V + 5 – 0 %.

Connect the case TERMINAL of the IMPLANTABLE PULSE GENERATOR to terminal I of the resistor network [Figure 110]; connect the other TERMINALS of the IMPLANTABLE PULSE GENERATOR, as applicable, to the following terminals of the resistor network [Figure 110]: connect CD(+) to C; V_{tip} to D; V_{ring} to E; A_{tip} to F; A_{ring} to G and CD(-) to H.

Test the device by applying a sequence of three voltage PULSES of positive polarity at 20 – 25 s intervals. Then after an interval of minimum 60 s repeat the test with PULSES of negative polarity (for timing sequence see Figure 109).

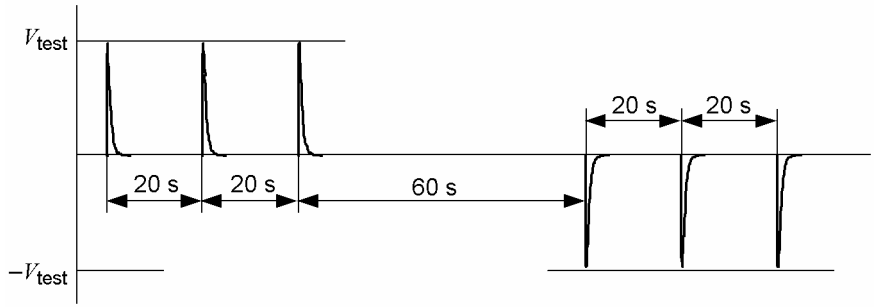

Figure 109 — Timing sequence used for DEFIBRILLATION test

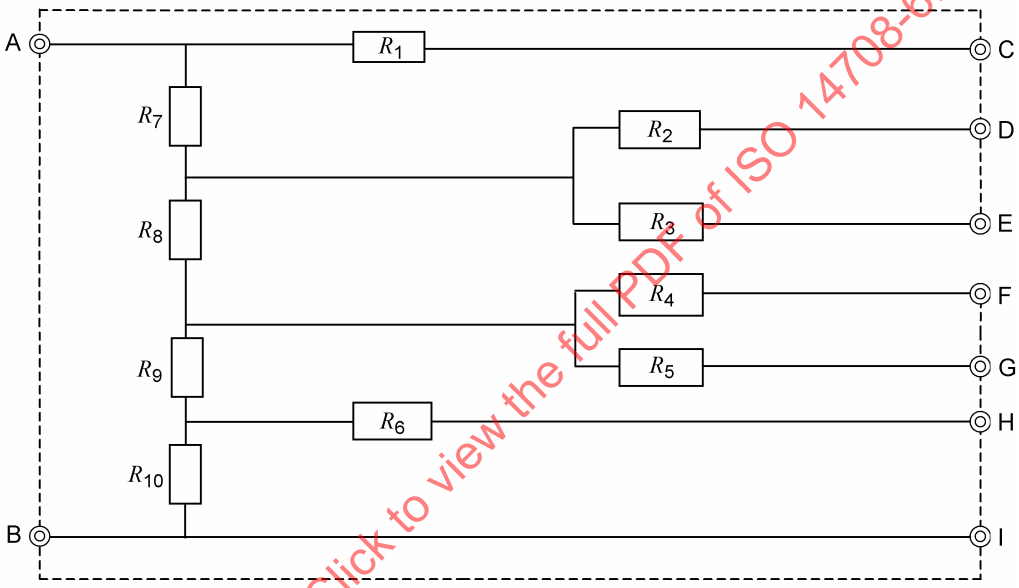

Figure 110 — Resistor network for Test 1 and Test 2

Table 102 — Component values for resistor network shown in Figure 110

R_1	R_2	R_3	R_4	R_5	R_6	R_7	R_8	R_9	R_{10}
50 Ω	800 Ω	400 Ω	800 Ω	400 Ω	50 Ω	5 Ω	5 Ω	25 Ω	30 Ω

All resistors shall be ± 5 %.

Test 2:

Test equipment: use the resistor network circuit defined by Figure 110 [with parameters as in Table 102]; a DEFIBRILLATION PULSE generator providing a truncated exponential waveform with a PULSE DURATION of 10 ms ± 0,5 ms. Figure 111 below illustrates an example schematic of a DEFIBRILLATION PULSE generator for truncated exponential waveform with C_1 = 150 ± 50 μF, and two coupled switches S_1 and S_2.

A monophasic, truncated exponential waveform with duration of T_d = 10 ms ± 0,5 ms will be generated between outputs A and B by activating the coupled switches S_1 from left to right position during a time period of T_d.

A biphasic, truncated exponential waveform is accomplished by changing position of the coupled switches S_2 during the ongoing PULSE after a time of $T_d/2$ (S_2 position altered after nominally 5 ms). The initial position of the coupled switches S_2 determines the initial polarity of the output PULSE.

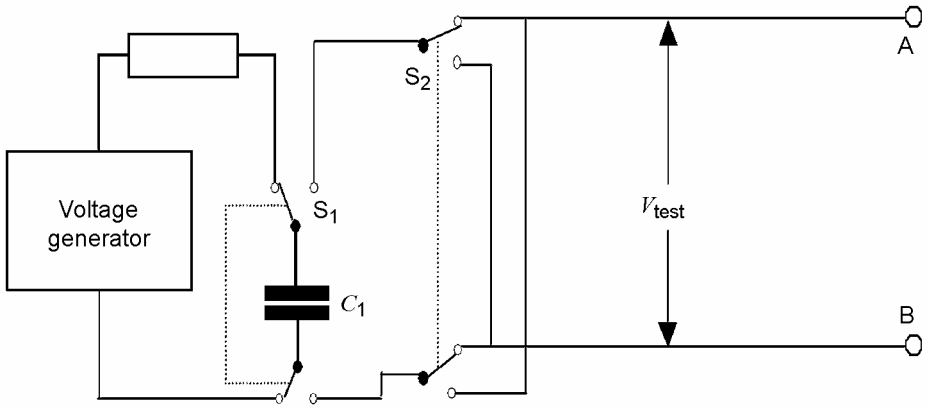

Figure 111 — Test set-up for truncated exponential DEFIBRILLATION waveform

The timing parameters of the test voltage for the truncated exponential waveform shall be within the values shown in Table 103 below [see also Figure 112].

Table 103 — Timing parameters of test signal for Test 2

Waveform	PULSE DURATION T_d	Risetime t_r	Falltime t_f	Commutation time t_c
Monophasic	9,5 ms < T_d < 10,5 ms	1 µs < t_r < 5 µs	1 µs < t_f < 5 µs	Not applicable
Biphasic	9,5 ms < T_d < 10,5 ms	1 µs < t_r < 5 µs	1 µs < t_f < 5 µs	$t_c \leqslant$ 2 ms

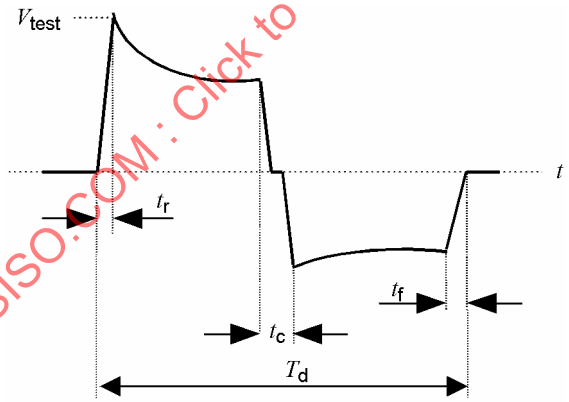

Figure 112 — Biphasic DEFIBRILLATION waveform for Test 2

Test procedure (Test 2): connect output A of the DEFIBRILLATION PULSE generator to TERMINAL A of the resistor network shown in Figure 110 (using parameters as in Table 102); connect output B of the DEFIBRILLATION PULSE generator to TERMINAL B of the resistor network. Adjust the maximum PULSE AMPLITUDE of the DEFIBRILLATION PULSE (V_{test}) at the output of the DEFIBRILLATION PULSE generator to 270 V + 5 % - 0 %.

Connect the case TERMINAL of the IMPLANTABLE PULSE GENERATOR to TERMINAL I of the resistor network [Figure 110]; connect the other TERMINALS of the IMPLANTABLE PULSE GENERATOR, as applicable, to the following TERMINALS of the resistor network:

CD(+) to C; V_{tip} to D; V_{ring} to E; A_{tip} to F; A_{ring} to G and CD(-) to H.

Test the device by applying a sequence of three monophasic voltage PULSES of positive polarity at 20 s to 25 s intervals. Then after an interval of minimum 60 s repeat the test with PULSES of negative polarity [for timing sequence see Figure 109].

Repeat the test by using biphasic voltage PULSES.

Compliance shall be confirmed if after performing the complete procedure (Test 1 and Test 2 above), the device is not permanently affected and the settings are recoverable through reprogramming.

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

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

Additional subclause:

21.2 Protection of the device from damage caused by HF surgical exposure

NOTE For ATP ONLY DEVICES, the CD TERMINALS part of the requirement is not applicable.

The IMPLANTABLE PULSE GENERATOR shall be designed so that stray, high-frequency currents from electrosurgical equipment flowing through the patient shall not permanently affect the device and the settings are recoverable through reprogramming, provided the IMPLANTABLE PULSE GENERATOR does not lie directly in the path between cutting and return (HF-earth) ELECTRODES. [See also requirement for warning advice, 28.13.]

Before conducting the test the device shall be programmed with high-voltage therapy OFF.

Test: use an RF test signal generator, output impedance 50 Ω. Each sensing/pacing input and/or output TERMINAL of the IMPLANTABLE PULSE GENERATOR, as applicable, shall be connected through individual 170 ± 2 % Ω, 1 W resistors (R_L) to ground and the CD TERMINALS shall be connected through individual 50 ± 2 % Ω resistors (R_L) to ground [see Figure 113]. The case of the IMPLANTABLE PULSE GENERATOR shall be connected directly to the signal generator output. If the case is covered with an insulating material, then the IMPLANTABLE PULSE GENERATOR'S case shall be immersed in a bath of 9 g/l saline held in a metal container and the metal container shall be connected directly to the other TERMINAL of the signal generator.

The test signal frequency of the RF test signal generator shall be set to 500 kHz. The open loop test signal amplitude shall be set to 36 V_{pp} continuous sinusoidal wave.

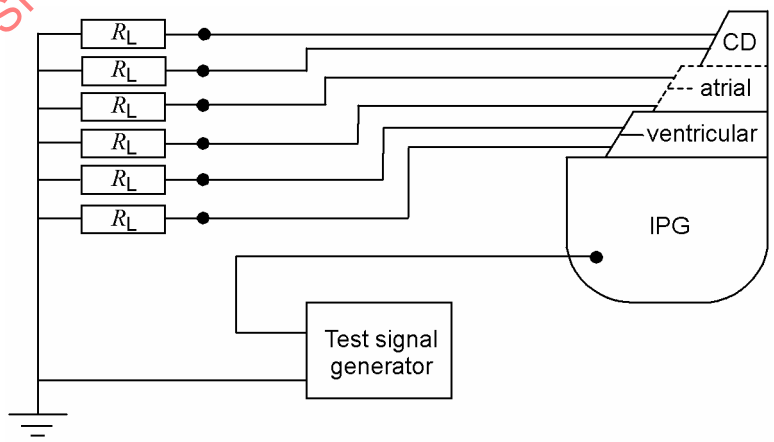

Figure 113 — Test set-up for proof of protection from high-frequency currents caused by surgical equipment

Apply the test signal for a time period of 30 s.

Compliance shall be confirmed if after completing the test procedure, the device is not permanently affected, the settings are recoverable through reprogramming and the values for the IMPLANTABLE PULSE GENERATOR listed in 28.8.2 d) and e) conform with the values stated in the manufacturer's original specification.

22 Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from changes caused by miscellaneous medical instruments

This clause of ISO 14708-1 applies.

23 Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from mechanical forces

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

23.2

Replacement:

23.2 The IMPLANTABLE PULSE GENERATOR shall be constructed to withstand the mechanical forces that may occur during normal conditions of use including the time prior to implant.

Test: The IMPLANTABLE PULSE GENERATOR, mounted in accordance with the requirements and guidance given in IEC 60068-2-47, shall withstand a random vibration test in accordance with IEC 60068-2-64, Test Fh, under the following conditions:

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

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

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

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

Compliance shall be confirmed if, after completing the test procedure, the values for the IMPLANTABLE PULSE GENERATOR listed in 28.8.2 d) and e) conform with the values stated in the manufacturer's original specification.

23.3

Replacement:

23.3 Implantable LEADS shall withstand the tensile forces that might occur after implantation, without fracture of any conductors or joints or breaching of any functional electrical insulation.

CAUTION — The following test employs the use of high voltage. Failure to use safe laboratory practices may result in severe electrical shock, resulting in personal injury or death to the persons handling the equipment or conducting the test. Also damage to electrical equipment is possible.

Test: use a preconditioning bath of approximately 9 g/l saline at 37 °C ± 5 °C, a tensile load tester, a resistance meter, a test bath of 9 g/l saline at 37 °C ± 5 °C with a reference ELECTRODE plate having a noble metal surface with a minimum area of 500 mm^2, a leakage current tester, capable of applying 2 000 V and supplying a current of at least 2 mA, and a 200 µF ± 10 % capacitor (C_1) rated for use at 1 000 V.

Specimens intended for test shall be in the condition as normally shipped to the customer.

Specimens shall be totally immersed in the preconditioning bath for a minimum of 10 d. Immediately prior to testing, the LEAD shall be rinsed in distilled or deionized water, then wiped free of surface water. The test specimen(s) shall be placed in the test bath within 30 min of removal from the preconditioning bath.

The LEAD shall be fitted in the tensile tester, clamped at the metallic surface of the LEAD connector pin and at the appropriate point on the distal end of the LEAD. The distance between the clamping points shall be measured.

The LEAD shall be subjected to a tensile load, limited to a value causing 20 % elongation, otherwise increased to at least 5 N. The tensile load shall be sustained for a at least 1 min then relieved.

The tensile load application shall be repeated for each combination of tip distal end and LEAD connector pin.

NOTE This may be accomplished by using multiple LEADS as the test sample.

The electrical continuity of each conduction path shall be verified by measuring the d.c. resistance.

The insulation integrity of each LEAD shall be verified by immersing the outer covering, other than within 20 mm of an ELECTRODE or TERMINAL, in the test bath, not less than 50 mm nor more than 200 mm from the reference ELECTRODE plate. The LEAD shall be immersed in the test bath for a minimum of 1 h before proceeding.

CAUTION — Care must be taken to ensure that the ELECTRODES and TERMINALS are electrically isolated from the saline bath during this procedure.

The test voltage shall attain the full value within 0,1 s to 5 s. The test voltage shall be maintained at full value for at least 15 s before being lowered to zero.

Insulation between each electrical conductor carrying a CD PULSE and every other conductor, and between each conductor carrying a CD PULSE and the reference ELECTRODE, shall be subjected to a 2 000 V ± 50 V d.c. test voltage. Insulation between each electrical conductor used for pacing and/or sensing and every other conductor not previously exposed to the 2 000 V test voltage, and between each pace/sense conductor and the reference ELECTRODE, shall then be subjected to a 100 V ± 5 V d.c. test voltage.

The electrical continuity of each LEAD carrying a CD PULSE shall be verified by passing current PULSES through the electrical conductors.

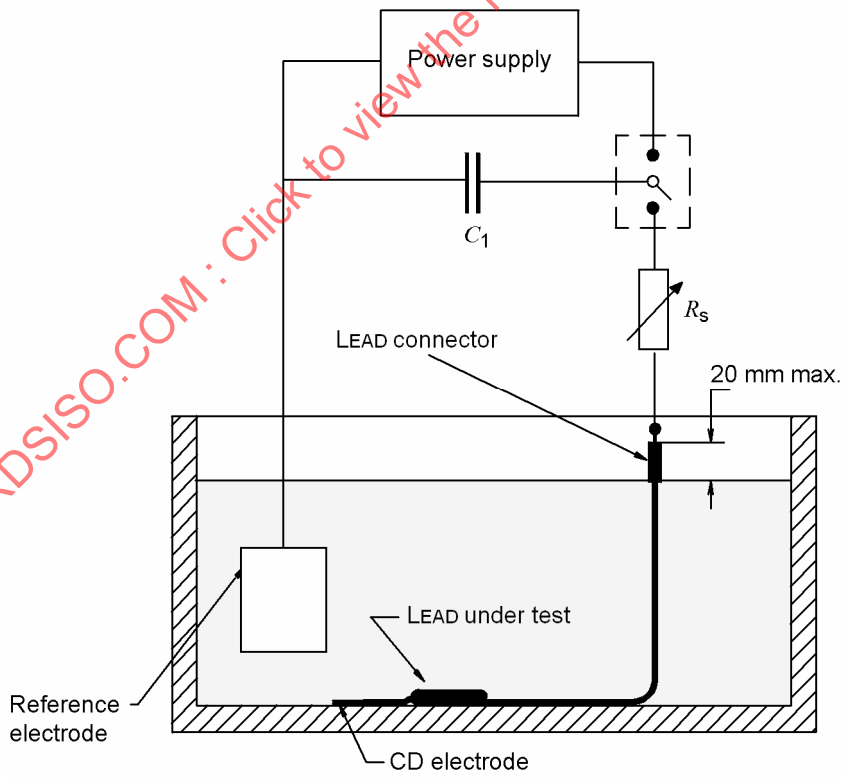

Figure 114 — Conductor current integrity test fixture

The LEAD, other than within 20 mm of the exposed TERMINAL, shall be immersed in the test bath [see Figure 114].

CAUTION — Care must be taken when connecting to the terminal of the lead to assure that high currents will not cause damage. A set-screw is recommended for connection to the terminal.

Each LEAD conductor intended to carry a CD PULSE shall be subjected to ten current PULSES, each sustained for a minimum of 25 ms, produced by discharging the capacitor from 1 000 V ± 50 V. There shall be a minimum of 10 s between current PULSES. If total discharge circuit resistance is less than 20 Ω, a series resistor R_S may be used to increase total system resistance to a maximum of 25 Ω.

Compliance shall be confirmed if:

— the leakage current measured between each conductor and the reference ELECTRODE and between any two conductors that have an exposed conductive surface intended for contact with tissue does not exceed 2 mA during the voltage application;

— the LEAD exhibits no permanent functional damage, nor permanent elongation in excess of 5 % unless the LEAD is intended by the manufacturer to accommodate a longer permanent elongation;

— after performing the complete procedure, the d.c. resistance of the LEAD is within the manufacturer's specification.

23.5

Replacement:

23.5 Implantable LEADS shall withstand the flexural stresses that might occur after implantation without fracture of any conductor.

Procedure: Two tests shall be performed. Test 1 shall be applied to all uniform LEAD segments. Test 2 shall be applied to the segment of the LEAD where the LEAD joins the connector body.

The test samples, whether in the form of complete LEADS or LEAD body segments, shall be preconditioned the same way as fully assembled and shipped product. The tests shall be performed in dry conditions and at room temperature.

Test 1: Use special holding fixture [see Figure 115]. The inside bore of the fixture shall be no greater than 110 % of the diameter of the LEAD segment under test. At the lower end of the fixture, the inside surface shall be formed into a bell mouth having a radius such that when the test segment conforms to the contour of the fixture the centre-line of the test segment forms a 6 mm ± 0,1 mm centre-line bending radius [see Figure 115].

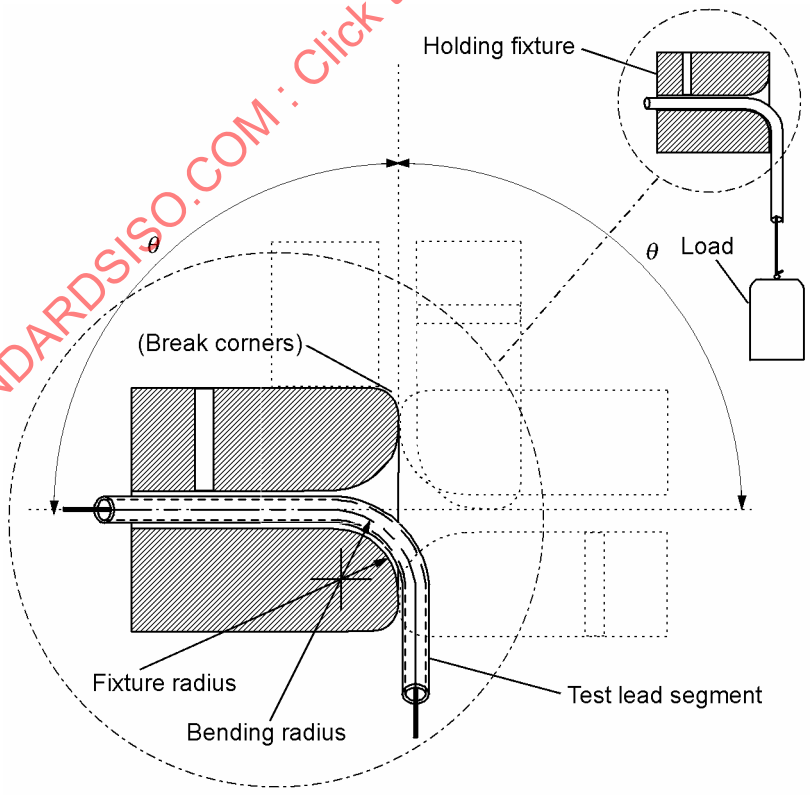

Figure 115 — Conductor flex test fixture

The fixture shall be mounted in a machine that can oscillate the fixture $\theta = 90^{\circ}{}^{+0}_{-5^{\circ}}$ *from the vertical and forces the test segment to flex in the bell mouth of the fixture. The LEAD test segment shall be mounted to hang vertically under gravity in the holding fixture, oriented in the worst-case test condition when the test segment allows multiple orientations.*

A load sufficient to assure that the centre-line of the test segment conforms to the bending radius shall be attached to the lower end of a thin, flexible line (cord) strung through the test segment, or, for LEAD bodies with no accessible lumen, applied directly to the test segment, so that it conforms to the bending radius.

The fixture shall be oscillated through an angle $\theta = 90^{\circ}{}^{+0}_{-5^{\circ}}$ *each side of vertical at a rate of approximately 2 Hz for a minimum of 47 000 cycles.*

NOTE Adjust the centre of rotation between the test fixture and the centre-line of the test LEAD segment so as to minimize vibration.

Compliance shall be confirmed if the measured resistance of each conduction path is within the manufacturer's specifications (adjusted for the length of the LEAD segment under test), and each conductor is functionally intact as per the manufacturer's performance specification.

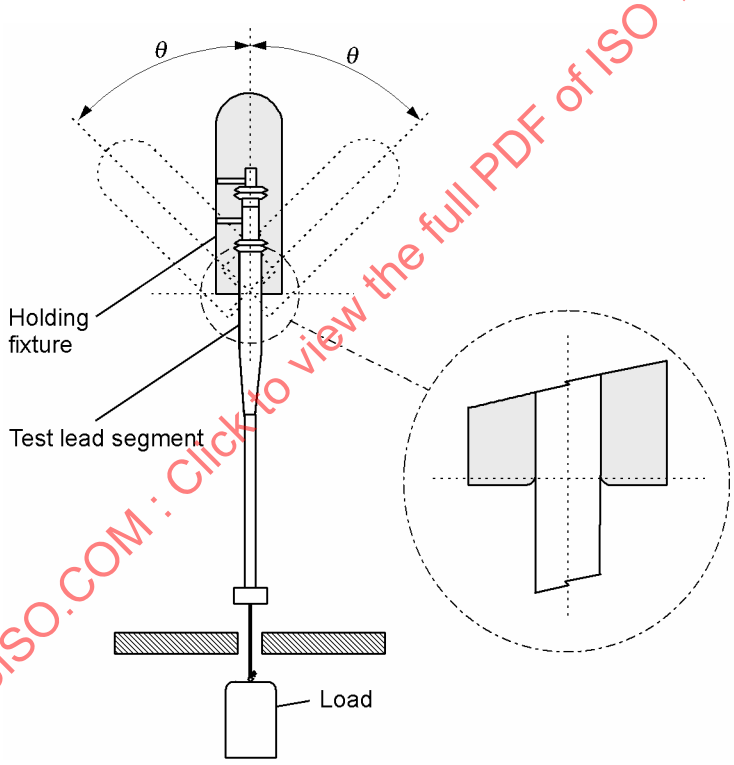

Figure 116 — Connector flex test fixture

Test 2: Use a special holding fixture [see Figure 116] similar in form to the intended PULSE generator connector header. The holding fixture shall be made of rigid material, with the corners that may come in contact with the LEAD connector rounded to a maximum radius of 0,5 mm. The cavity depth shall be set at the minimum allowed in the applicable standard, or as specified by the manufacturer's connector specification if other connector systems are used. Except for the cavity depth and rounding, the test cavity dimensions shall be as specified in Figure 2 of ISO 5841-3 (IS-1), or Figure 4 of ISO 11318 (DF-1), or in accordance with the manufacturer's specifications if another connector system is used.

The holding fixture shall be mounted in a machine that can rotate the fixture ± 45º from the vertical [see Figure 116]. The centre of rotation shall be in the plane where the rounded corners of the holding fixture begin. The holding fixture shall allow the LEAD connector and attached LEAD segment to hang vertically under gravity. The LEAD connector shall be fitted into the holding fixture, oriented in the worst-case test condition, and retained by the set-screw mechanisms.

A load shall be attached to the LEAD segment 10 cm ± 0,5 cm from the centre of rotation of the holding fixture. The load attachment mechanism shall ensure that there shall be no relative motion between the conductor and the tubing at the point of attachment. The load (including the attachment mechanism) shall be 100 g ± 5 g.

The holding fixture shall then be oscillated through an angle Θ = 45° ± 2° each side of vertical at a rate of approximately 2 Hz for a minimum of 82 000 cycles.

The test shall be repeated for each unique connector LEAD body assembly.

Compliance shall be confirmed if the measured resistance of each conduction path is within the manufacturer's specifications (adjusted for the length of the LEAD segment under test), and each conductor is functionally intact as per the manufacturer's performance specification.

23.6

Replacement:

23.6 Implantable connectors, intended for use by physicians to join IMPLANTABLE PULSE GENERATORS and LEADS, shall be identified as to type. The retention force provided by the implantable connector shall be greater than or equal to 7,5 N. The manufacturer shall declare [see 28.4 of ISO 14708-1, 28.8.2 h) and 28.8.3 e)] the intended performance as implanted, determined according to the following test.

NOTE The procedure is applicable only to connector systems without set-screws and/or LEAD connectors not compatible with set-screws.

Test procedure: The implantable connector pair shall be mated in accordance with the manufacturer's instructions and immersed in a saline bath, approximately 9 g/l at 37 °C ± 5 °C, for a minimum of 10 d.

After removal from the saline bath, the connector pair shall be subjected to successive straight pulls of 7,5 ± 0,5 N, and 10 ± 0,5 N each for not less than 10 s.

The maximum force that does not result in disconnection shall be recorded as the test result.

Compliance shall be confirmed by inspection of the test results provided by the manufacturer [see also 28.4 of ISO 14708-1].

Additional subclause:

23.7 The IMPLANTABLE PULSE GENERATOR shall be constructed so that minor mechanical shocks caused by manhandling during the implant procedure do not damage the device.

Test: The IMPLANTABLE PULSE GENERATOR shall withstand the mechanical shock test in accordance with IEC 60068-2-27, test Ea, under the following conditions:

a) shock shape: half sine;

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 IMPLANTABLE PULSE GENERATOR'S characteristics listed in 28.8.2 d) and e) conform with the values stated in the manufacturer's original specification.

24 Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from damage caused by electrostatic discharge

This clause of ISO 14708-1 applies.

25 Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from damage caused by atmospheric pressure changes

This clause of ISO 14708-1 applies.

26 Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from changes caused by temperature changes

This clause of ISO 14708-1 applies.

27 Protection of the ACTIVE IMPLANTABLE MEDICAL DEVICE from electromagnetic non-ionizing radiation

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

Additional warnings:

CAUTION — The tests in the following subclauses may produce high-voltage shocks. Failure to use safe laboratory practices may result in severe electrical shock, resulting in personal injury or death to the persons handling the equipment or conducting the test. Also damage to electrical equipment is possible.

CAUTION — Good high-frequency test procedures should be observed. Modification of the test circuits is allowed as long as electrical equivalence is maintained.

NOTE For ATP ONLY DEVICES, the CD TERMINALS part of the requirement is not applicable.

27.1

Replacement:

27.1 Implantable parts of an ACTIVE IMPLANTABLE MEDICAL DEVICE shall not cause any HARM because of susceptibility to electrical influences due to external electromagnetic fields as covered by this standard, 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.

Compliance shall be confirmed if, after performing the appropriate procedures described in 27.2 to 27.8, the values of the characteristics listed in 28.8.2 d) and e) when measured [see 6.1] are as stated by the manufacturer of the IMPLANTABLE PULSE GENERATOR. All protection requirements shall be met for all settings of the IMPLANTABLE PULSE GENERATOR, except those settings the manufacturer specifies in the accompanying documentation as not meeting the requirements of 27.5.1 [see 28.22.1].

NOTE 1 This does not mean that all combinations of settings are tested but at least the setting to which the device is pre-set by the manufacturer (as shipped) should be tested completely.

NOTE 2 The tests in this section are not intended to cover any embedded telemetry antenna external to the electromagnetic shield of the IMPLANTABLE PULSE GENERATOR, unless such an antenna is an integral part of the LEAD. Electromagnetic susceptibility applicable to these parts is under consideration.

27.2

Replacement:

27.2 The IMPLANTABLE PULSE GENERATOR shall be constructed so that ambient electromagnetic fields are unlikely to cause hazardous local increases of induced electrical current density within the patient.

NOTE 1 The following test is intended to address the compatibility of the intracardiac signal sensing. Any additional physiological SENSORS may be turned off during testing unless otherwise specified. Tests for these additional SENSORS are under consideration.

Test equipment: use the tissue equivalents defined by Figure E.101 and either Table E.101 or Table E.102; the low-pass filter defined by Figure E.104; two oscilloscopes, input impedance nominal 1 MΩ; and test signal generators, output impedance of 50 Ω.

Test signal: two forms of test voltage shall be used.

Test signal 1 shall be a sinusoidal signal of 1 V peak-to-peak. The frequency, f, shall be either swept over the range 16,6 Hz to 20 kHz at a rate of one decade per min, or applied at a minimum of four distinct, well-spaced frequencies per decade between 16,6 Hz and 20 kHz with an evenly distributed dwell time of at least 60 s per decade.

Test signal 2 shall be a sinusoidal carrier signal, frequency 500 kHz, with continuous amplitude modulation at 130 Hz (double sideband with carrier) [see Figure 117]. The maximum peak-to-peak voltage of the modulated signal shall be 2 V. The modulation index (M) shall be 95 %, where:

$$M = \frac{V_{pp} - v}{V_{pp} + v} * 100$$

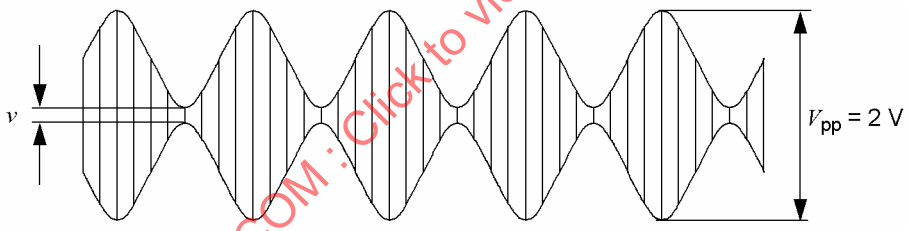

Figure 117 — Test signal 2

NOTE 2 Care must be taken that the test signal generator does not itself produce low-frequency components [see Annex F].

Test procedure: the test signal generator shall be connected through input C of the interface circuit as shown in Figure 118. The test signal shall be measured on the oscilloscope connected to test point D.

The induced electrical current is measured by the oscilloscope connected to test point K of the interface circuit through the low-pass filter [see Figure E.104] as shown in Figure 118. When test signal 1 is being used, the low-pass filter shall be switched to bypass mode.

The capacitor C_x of the interface circuit [see Figure E.101] shall be bypassed unless required to eliminate spurious low-frequency signals produced by the interference signal generator [see Annex F].

NOTE 3 It is not mandatory that a current measurement be made in the period from 10 ms preceding a stimulation PULSE to 150 ms after the stimulation PULSE.

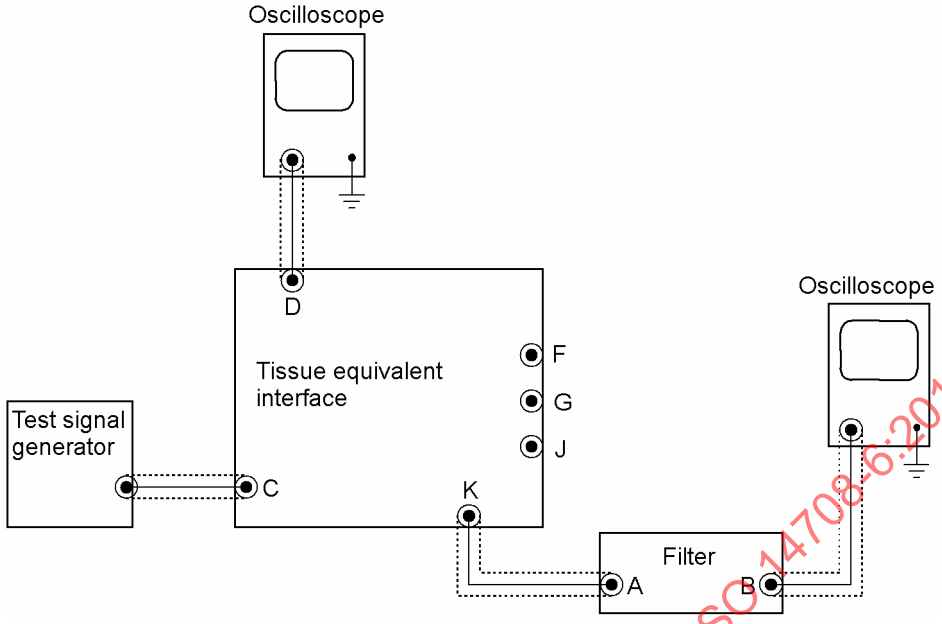

Figure 118 — Test set-up for measurement of induced current flow

The IMPLANTABLE PULSE GENERATOR shall be set to the factory settings (nominal as shipped) during the test. The tachyarrhythmia therapy functions of the IMPLANTABLE PULSE GENERATOR shall be inactive during the test and the high-voltage capacitors, if any, shall not be charged.

CAUTION — Care must be taken to ensure that the high-voltage capacitors are discharged. Failure to use safe laboratory practices may result in severe electrical shock, resulting in personal injury or death to the persons handling the equipment or conducting the test. Also damage to electrical equipment, particularly the tissue equivalent interface circuit, is likely.

1) Measurement of current injected through sensing/pacing TERMINALS.

Select the tissue equivalent interface circuit defined by Figure E.101 and Table E.101. If the IMPLANTABLE PULSE GENERATOR offers multichannel sensing/pacing, every input/output of the IMPLANTABLE PULSE GENERATOR shall be tested in turn. Any sensing/pacing TERMINAL of the IMPLANTABLE PULSE GENERATOR not being tested shall be connected to the equivalent TERMINAL of the channel under test through a resistor of value $R \geq 10\ k\Omega$ as specified by the manufacturer. For safety, CD TERMINALS are loaded with high-voltage 50 Ω, 25 W resistors, R_L.

a) Bipolar sense/pace IMPLANTABLE PULSE GENERATORS shall be tested in two configurations.

Common mode performance shall be tested with the sensing/pacing TERMINALS of the channel under test connected to outputs F and G of the tissue equivalent interface [as shown in Figure 119], and the case connected to output J.

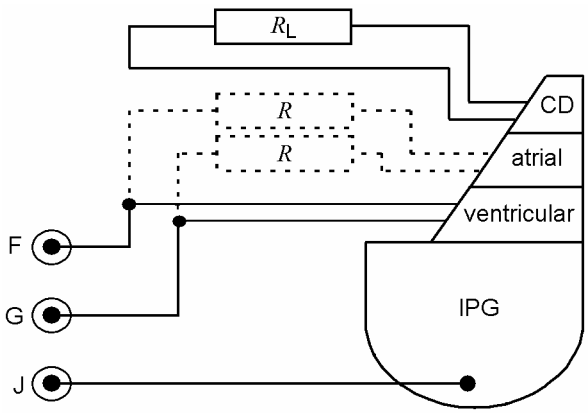

Figure 119 — Common mode connection to multichannel bipolar PULSE generators

Differential mode performance shall be tested using test signals 1 and 2 reduced to one-tenth amplitude. The sensing/pacing TERMINALS of the channel under test shall be connected between coupled outputs F and G and output J of the tissue equivalent interface [as shown in Figure 120].

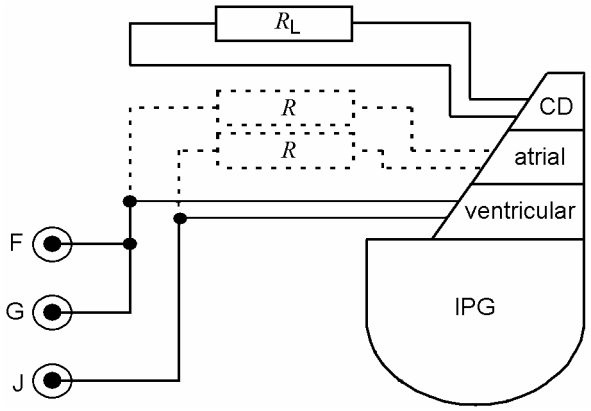

Figure 120 — Differential mode connection to multichannel bipolar PULSE generators

For test signal 1 the current shall be determined by dividing the peak-to-peak voltage reading on the oscilloscope connected to test point K via the low-pass filter switched to bypass mode [see Figure E.104] by 232 Ω.

For test signal 2, the measurement will be taken with a true r.m.s. voltmeter connected to test point B of the low-pass filter switched to filtering mode [see Figure E.104] and divided by 82 Ω.

Alternatively, a true r.m.s. voltmeter with input impedance ≥ 1 MΩ may also be used for test signal 1 to determine the r.m.s. current, in which case the r.m.s. reading shall be divided by 82 Ω and shall be accurate to ± 10 % within a bandwidth of at least 20 kHz.

b) *For an IMPLANTABLE PULSE GENERATOR which uses signals from both sense and CARDIOVERSION/DEFIBRILLATION LEADS for arrhythmia detection, the manufacturer shall provide details of the test method.*

2) *Measurement of current injected through CARDIOVERSION/DEFIBRILLATION TERMINALS.*

Select the tissue equivalent interface circuit defined by Figure E.101 and Table E.102.

The sense/pace TERMINALS shall be loaded with resistor(s), R_L, of 500 Ω ± 5 %. For a multichannel sensing/pacing device, the sense/pace TERMINALS shall be connected through resistors R of ≥ 10 kΩ as shown. The manufacturer shall be free to choose the value of the resistors that are appropriate for the device under test. If the IMPLANTABLE PULSE GENERATOR has more than two CARDIOVERSION/DEFIBRILLATION TERMINALS, the TERMINALS not being tested shall be connected to one of the TERMINALS under test through a resistor R of ≥ 10 kΩ.

If both of the CARDIOVERSION/DEFIBRILLATION TERMINALS under test are intended to be connected to ENDOCARDIAL LEADS, then the test signals shall be reduced to one-tenth amplitude. If one or both of the CARDIOVERSION/DEFIBRILLATION TERMINALS under test are intended to be connected to epicardial ELECTRODES on the heart, the test signals shall be reduced to one-half amplitude. If any of the CARDIOVERSION/DEFIBRILLATION TERMINALS are intended to be connected to a subcutaneous ELECTRODE, then the full test signal amplitude shall be used.

Common mode performance shall be tested with the CARDIOVERSION/DEFIBRILLATION TERMINALS connected to outputs F and G of the tissue equivalent interface [as shown in Figure 121] and the case connected to output J.

NOTE 4 If the case of the IMPLANTABLE PULSE GENERATOR is an active TERMINAL, no common mode test is required.

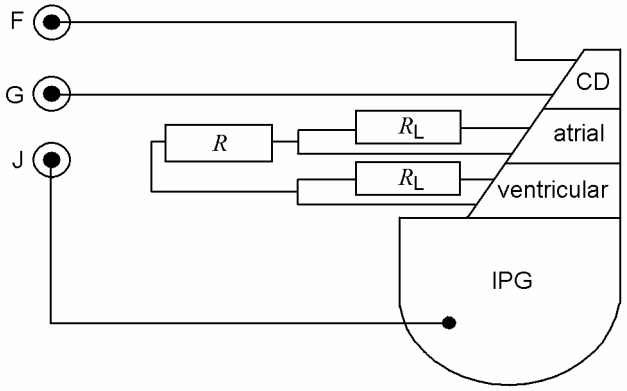

Figure 121 — Common mode connection for CARDIOVERSION/DEFIBRILLATION TERMINALS

Differential mode performance shall be tested with the CARDIOVERSION/DEFIBRILLATION TERMINALS connected between coupled outputs F and G and output J of the tissue equivalent interface [as shown in Figure 122].

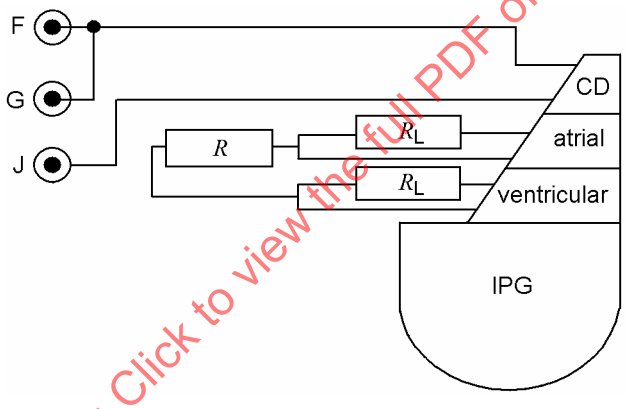

Figure 122 — Differential mode connection for CARDIOVERSION/DEFIBRILLATION TERMINALS

If the IMPLANTABLE PULSE GENERATOR has more than two CARDIOVERSION/DEFIBRILLATION TERMINALS, the test is performed on each pair of TERMINALS in turn.

For test signal 1, the current shall be determined by dividing the peak-to-peak voltage reading on the oscilloscope connected to test point K via the low-pass filter switched to bypass mode [see Figure E.104] by 133 Ω.

For test signal 2, the measurement will be taken with a true r.m.s. voltmeter connected to test point B of the low-pass filter switched to filtering mode [see Figure E.104] and divided by 47 Ω.

Alternatively, a true r.m.s. voltmeter with input impedance $\geqslant$ 1 MΩ may also be used for test signal 1 to determine the r.m.s. current, in which case the r.m.s. reading shall be divided by 47 Ω and shall be accurate to ± 10 % within a bandwidth of at least 20 kHz.

Compliance shall be confirmed if:

— for test signal 1 the current shall be not greater than that specified in Table 104 for sense/pace TERMINALS and Table 105 for CARDIOVERSION/DEFIBRILLATION TERMINALS, and

— for test signal 2 the current at the modulating frequency of 130 Hz shall be not greater than 50μA r.m.s.

Table 104 — Spurious injection current limits for sense/pace TERMINALS

f	Current r.m.s.
16,6 Hz $\leqslant f \leqslant$ 1 kHz	50 µA
1 kHz $\leqslant f \leqslant$ 20 kHz	50 µA * f/1 kHz

Table 105 — Spurious injection current limits for CARDIOVERSION/DEFIBRILLATION TERMINALS

f	Current r.m.s.
16,6 Hz $\leqslant f \leqslant$ 1 kHz	50 µA
1 kHz $\leqslant f \leqslant$ 20 kHz	50 µA* f/1 kHz

Additional subclauses:

27.3 The IMPLANTABLE PULSE GENERATOR shall be constructed so that ambient electromagnetic fields are unlikely to cause any malfunction of the IMPLANTABLE PULSE GENERATOR that persists after the removal of the electromagnetic field.

NOTE 1 The following test is intended to address the compatibility of the intracardiac signal sensing. Any additional physiological SENSORS may be turned off during testing unless otherwise specified. Tests for these additional SENSORS are under consideration.

NOTE 2 The test addresses only device damage. The strength of some fields covered in this clause might cause thermal damage to the heart tissue or induce fibrillation to the patient due to currents induced in the implanted LEAD system [see Annex C rationale for 27.3]

CAUTION — Care must be taken to ensure that the high-voltage capacitors are discharged. Failure to use safe laboratory practices may result in severe electrical shock, resulting in personal injury or death to the persons handling the equipment or conducting the test. Also damage to electrical equipment, particularly the tissue interface equivalent circuits, is likely.

27.3.1 Malfunction due to electromagnetic interference in the frequency range of 16,6 Hz to 10 MHz

Test equipment: use the tissue equivalent interface circuits defined by Figure E.102 and Figure E.103; two oscilloscopes, input impedance nominal 1 MΩ, the oscilloscope connected to point D in Figure 123 shall have an accuracy of ± 10 % within a bandwidth of at least 10 MHz; and a test signal generator, output impedance of 50 Ω.

CAUTION — Good high-frequency test procedures should be observed. Modification of the test circuits is allowed as long as electrical equivalence shall be maintained.

Test signal: the test signal shall be a continuous sinusoidal signal that shall be either swept over the frequency range of 16,6 Hz to 10 MHz at a rate of one decade per min, or applied at a minimum of four distinct, well-spaced frequencies per decade between 16,6 Hz and 10 MHz with an evenly distributed dwell time of at least 60 s per decade.

The test signal amplitude for common mode test shall be as shown in Table 106 below:

Table 106 — Peak-to-peak amplitudes V_{pp} in the range 16,6 Hz to 10 MHz

f	V_{pp}
16,6 Hz $\leqslant f \leqslant$ 20 kHz	1 V
20 kHz $\leqslant f \leqslant$ 140 kHz	1 V * (f/20 kHz)
140 kHz $\leqslant f \leqslant$ 10 000 kHz	7 V * (f/140 kHz) $^{0,162\,4}$

Differential mode performance shall be tested using test signal reduced to one-tenth amplitude.

The IMPLANTABLE PULSE GENERATOR shall be set to the factory settings (nominal as shipped) during the test. The tachyarrhythmia therapy functions of the IMPLANTABLE PULSE GENERATOR shall be inactive during the test and the high-voltage capacitors, if any, are discharged.

CAUTION — Care must be taken to ensure that the high-voltage capacitors are discharged. Failure to use safe laboratory practices may result in severe electrical shock, resulting in personal injury or death to the persons handling the equipment or conducting the test. Also damage to electrical equipment, particularly the tissue interface equivalent circuits, is likely.

27.3.1.1 Malfunction due to electromagnetic interference on the sensing/pacing TERMINALS

Test procedure: select the tissue equivalent interface circuit defined by Figure E.102. The test signal generator shall be connected through input C of the interface circuit as shown in Figure 123. The test voltage shall be measured on the oscilloscope connected to test point D of the interface circuit.

Any sensing/pacing TERMINAL of the IMPLANTABLE PULSE GENERATOR not being tested shall be connected to the equivalent TERMINAL of the channel under test through a resistor of value R of ≥ 10 kΩ as shown. The manufacturer shall be free to choose the value of the resistors that are appropriate for the device under test. For safety, CARDIOVERSION/DEFIBRILLATION TERMINALS are loaded with high-voltage 50 Ω, 25 W resistors, R_L.

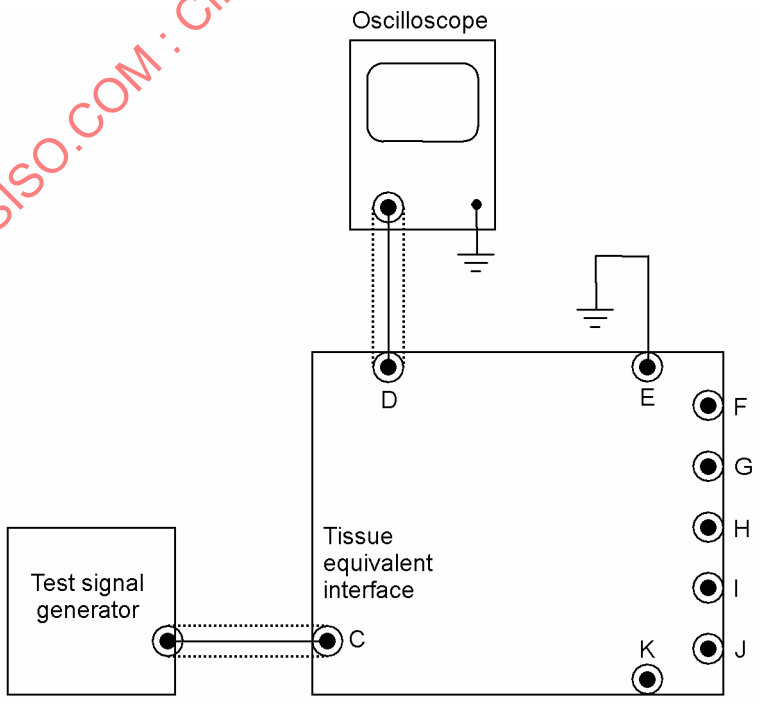

Figure 123 — Test set-up to check for induced malfunction

a) *Bipolar sense/pace IMPLANTABLE PULSE GENERATORS shall be tested in two configurations.*

Common mode performance shall be tested with the pairs of sensing/pacing TERMINALS connected to outputs F and G, H and I of the tissue equivalent interface [as shown in Figure 124], and the case connected to output J.

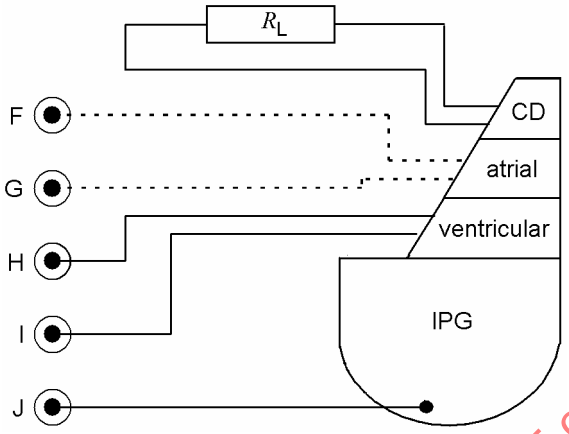

Figure 124 – Common mode connection to multichannel bipolar PULSE generators

Differential mode performance shall be tested using test signal reduced to one-tenth amplitude. Sensing/pacing channels shall be tested in turn. The sensing/pacing TERMINALS of the channel under test shall be connected between coupled outputs H and I and output J [as shown in Figure 125] of the tissue equivalent interface.

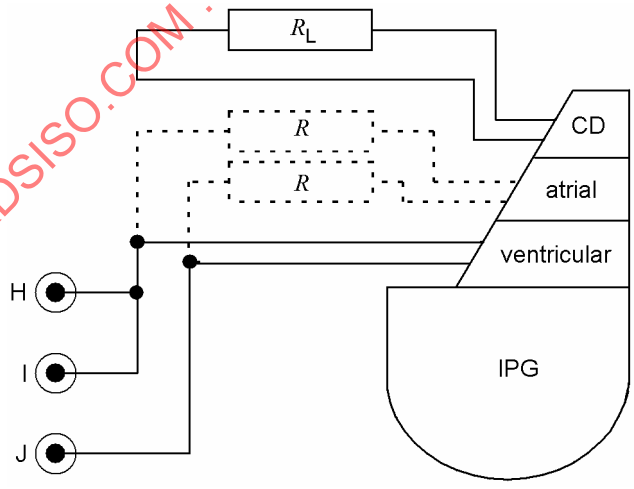

Figure 125 — Differential mode connection to multichannel bipolar PULSE generators

b) For an IMPLANTABLE PULSE GENERATOR which uses signals from both sense and CARDIOVERSION/DEFIBRILLATION LEADS for arrhythmia detection, the manufacturer shall provide details of the test method.

Compliance shall be confirmed if, after application of the specified test signals, the IMPLANTABLE PULSE GENERATOR functions as prior to the test without further adjustment of the IMPLANTABLE PULSE GENERATOR.

27.3.1.2 Malfunction due to electromagnetic interference on the CARDIOVERSION/DEFIBRILLATION TERMINALS

Test procedure: select the tissue equivalent interface circuit defined by Figure E.103. The test signal generator shall be connected through input C of the interface circuit as shown in Figure 126. The test voltage shall be measured on the oscilloscope connected to test point D.

The sense/pace TERMINALS shall be loaded with resistor(s), R_L, of 500 $\Omega \pm 5$ %. For a multichannel sensing/pacing device, the sense/pace TERMINALS shall be connected through resistors of $R \geq 10$ kΩ as shown. The manufacturer shall be free to choose the value of the resistors that are appropriate for the device under test. If the IMPLANTABLE PULSE GENERATOR has more than two CARDIOVERSION/DEFIBRILLATION TERMINALS, the TERMINALS not being tested shall be connected to one of the TERMINALS under test through a resistor R.

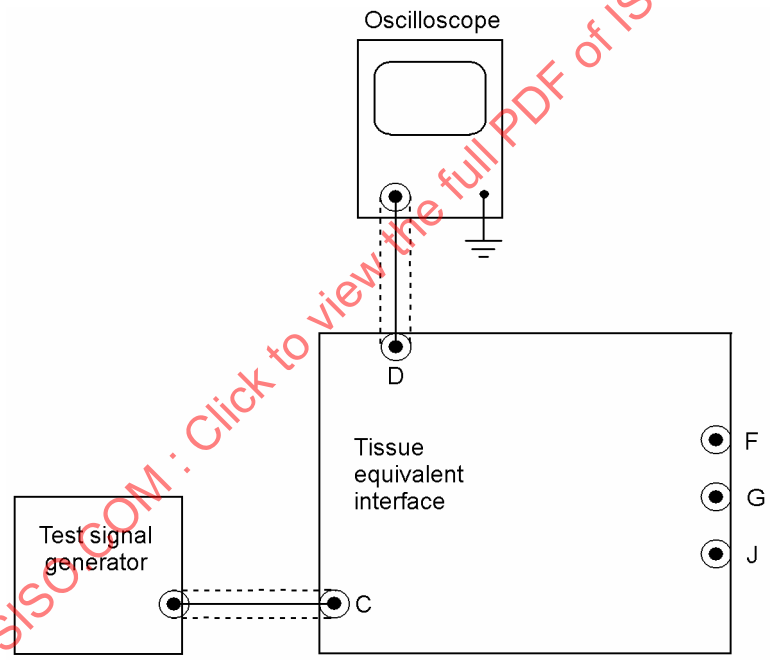

Figure 126 — Test set-up to check for induced malfunction due to voltages induced on CARDIOVERSION/DEFIBRILLATION LEADS

Common mode performance shall be tested with the CARDIOVERSION/DEFIBRILLATION TERMINALS connected to outputs F and G of the tissue equivalent interface and the case connected to output J [as shown in Figure 127].

NOTE If the case of the IMPLANTABLE PULSE GENERATOR is an active TERMINAL, no common mode test is required.

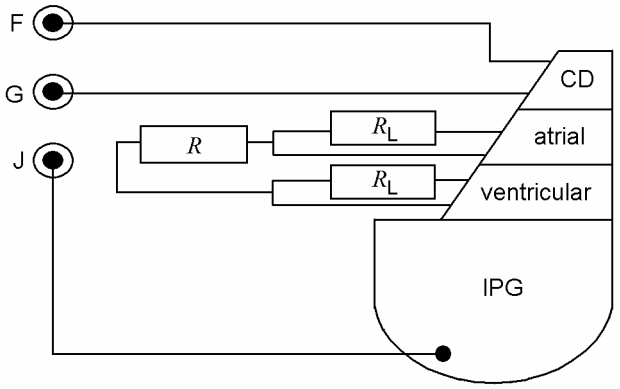

Figure 127 — Common mode connection for CARDIOVERSION/DEFIBRILLATION TERMINALS

Differential mode performance shall be tested with the CARDIOVERSION/DEFIBRILLATION TERMINALS connected between coupled outputs F and G and output J of the tissue equivalent interface [as shown in Figure 128].

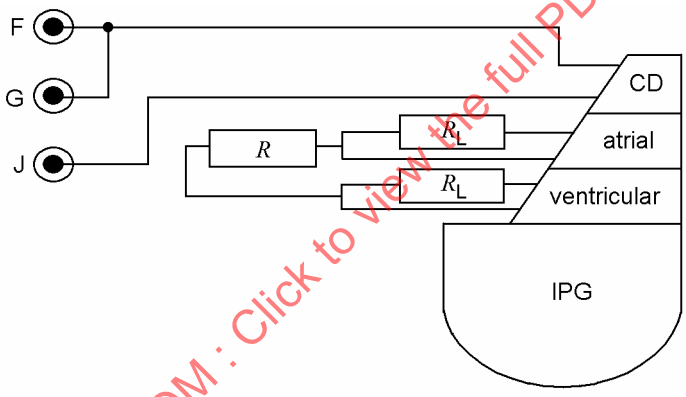

Figure 128 — Differential mode connection for CARDIOVERSION/DEFIBRILLATION TERMINALS

If the IMPLANTABLE PULSE GENERATOR has more than two CARDIOVERSION/DEFIBRILLATION TERMINALS, the tests shall be performed on each pair of TERMINALS in turn.

Compliance shall be confirmed if, after application of the specified test signals, the IMPLANTABLE PULSE GENERATOR functions as prior to the test without further adjustment of the IMPLANTABLE PULSE GENERATOR.

27.3.2 Malfunction due to electromagnetic interference in the frequency range of 10 MHz to 450 MHz

Test equipment: use the injection network defined by Figure E.105; an oscilloscope #1, input impedance 50 Ω, accuracy of ± 10 % within a bandwidth of at least 450 MHz; a test signal generator, output impedance 50 Ω.

Test signal: the test signal shall be a modulated signal, carrier frequency, f, between 10 MHz and 450 MHz as shown in Figure 129. The carrier shall be amplitude modulated with a 130 Hz sinusoidal wave to create modulation bursts of 100 ms duration. The burst-to-burst interval, T, shall be measured leading to leading edge [see Figure 129]. The burst-to-burst interval (T) of the modulated signal shall be set to 700 ms ± 50 ms.

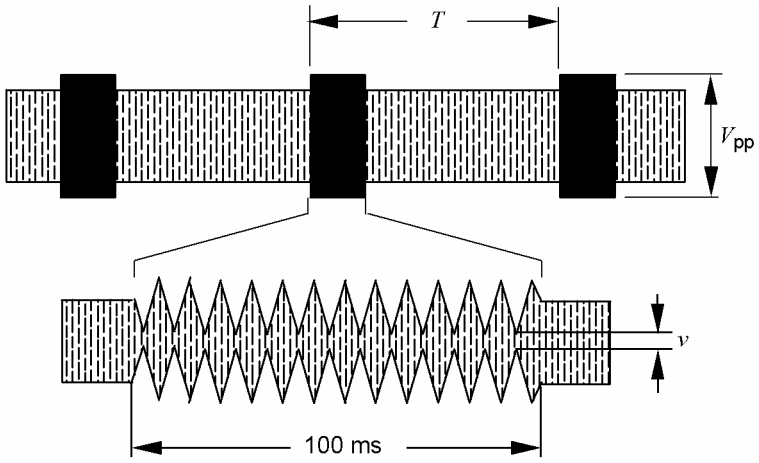

Figure 129 — Test signal for frequencies between 10 MHz and 450 MHz

The modulation bursts shall start and terminate at zero crossings of the modulation signal, thus the envelope starts and terminates continuously. The burst count is 13 complete modulation cycles. The modulation index (M) shall be 95 %, where:

$$M = \frac{V_{pp} - v}{V_{pp} + v} \times 100$$

The amplitude of the test signal (V_{pp}) is defined as the peak-to-peak amplitude of the open circuit voltage driving the IMPLANTABLE PULSE GENERATOR at the outputs (F, G) of the injection network. The amplitude of the test signal, V_{pp}, shall be 14 V. Prior to testing the test set-up has to be calibrated using the procedure in Annex G.

27.3.2.1 Malfunction due to electromagnetic interference on the sensing/pacing TERMINALS

Test procedure: the test signal generator shall be connected to the injection network through input C as shown in Figure 130. The test signal generator shall be adjusted so that the test signal amplitude measured on the oscilloscope connected to monitoring point D (V_{osc}) when multiplied by the calibration factor for the injection network, determined according to the method of Annex G, is equal to the required test signal amplitude, V_{pp}. The test signal shall be applied at a minimum of six distinct, well-spaced frequencies per decade, beginning at 10 MHz and ending at 450 MHz (i.e. 10, 20, 40, 60, 80, 100, 200, 400, 450) with an evenly distributed dwell time of at least 60 s per decade.

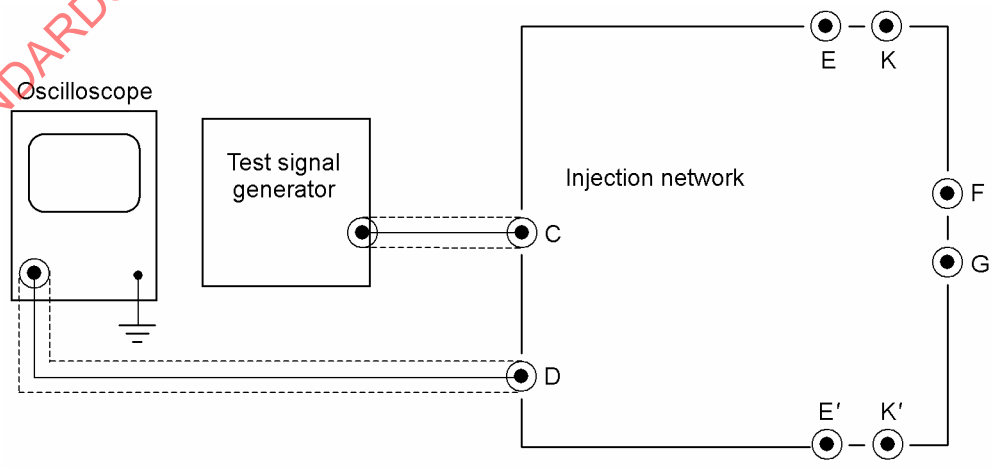

Figure 130 — Test set-up to check for induced malfunction at high frequency

NOTE The peak-to-peak amplitude of the test signal, V_{pp}, cannot be measured directly at any connector of the injection network during the test. Therefore it must be calculated from the voltage at connector D, V_{osc}, by applying the calibration factor, m, of Annex G.

Connections between outputs F and G and the IMPLANTABLE PULSE GENERATOR shall be made with copper straps, width ≥ 5 mm, length ≤ 50 mm (not including the length of the standard connector pin inserted into the device header). Unused RF-ports on the injection network shall be fitted with 50 Ω terminations.

a) A bipolar IMPLANTABLE PULSE GENERATOR shall be connected to outputs F and G of the injection network [as shown in Figure 131], using appropriate RF techniques for all connections. Each channel of a multichannel device shall be tested in turn and any channel not under test shall be turned off and loaded with 500 Ω load resistors (R_L). For safety, cardioversion/defibrillation TERMINALS are loaded with high-voltage 50 Ω, 25 W resistors, R_L as required by the HV therapy configuration.

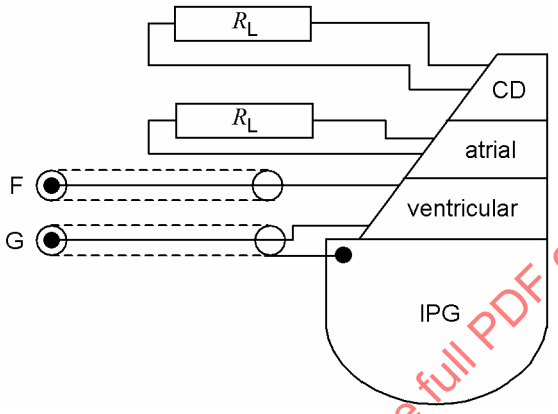

Figure 131 — Connection of the PULSE generator

b) For an IMPLANTABLE PULSE GENERATOR which uses signals from both sense and CARDIOVERSION/DEFIBRILLATION LEADS for arrhythmia detection, the manufacturer shall provide details of the test method.

Compliance shall be confirmed if, after application of the specified test signals, the IMPLANTABLE PULSE GENERATOR functions as prior to the test without further adjustment of the IMPLANTABLE PULSE GENERATOR.

27.3.2.2 Malfunction due to electromagnetic interference on the CARDIOVERSION/DEFIBRILLATION TERMINALS

Test procedure: testing is performed as per 27.3.2.1 with the CARDIOVERSION/DEFIBRILLATION TERMINALS under test connected to outputs F and G of the injection network [instead of the pacing/sensing TERMINALS, as shown in Figure 131]. Any sensing/pacing channel shall be loaded with 500 Ω load resistors (R_L) and any CARDIOVERSION/DEFIBRILLATION TERMINALS not under test shall be loaded with high-voltage 50 Ω, 25 W resistors, R_L.

Compliance shall be confirmed if, after application of the specified test signals, the IMPLANTABLE PULSE GENERATOR functions as prior to the test without further adjustment of the IMPLANTABLE PULSE GENERATOR.

27.3.3 Malfunction due to electromagnetic interference in the frequency range of 450 MHz to 3 000 MHz

Test: the IMPLANTABLE PULSE GENERATOR shall be subjected to the test procedure in 6.4.2 "optional characterization" of ANSI/AAMI PC69:2000, without device monitoring and recording of DUT performance (which is not required for this test).

Compliance shall be confirmed if, after the removal of the field, the IMPLANTABLE PULSE GENERATOR functions as prior to the test without further adjustment of the IMPLANTABLE PULSE GENERATOR.

NOTE Testing according to ANSI/AAMI PC69:2000 is further referred to in 27.5.4 of this part of ISO 14708.

27.4 Temporary response of the IMPLANTABLE PULSE GENERATOR in the presence of ambient continuous-wave electromagnetic fields

The manufacturer shall characterize the performance of the IMPLANTABLE PULSE GENERATOR in the presence of ambient continuous-wave electromagnetic fields. The atrial and ventricular channel may be characterized separately in both AAI and VVI mode in lieu of DDD mode.

NOTE 1 The following test is intended to address the compatibility of the intracardiac signal sensing. Any additional physiological SENSORS may be turned off during testing unless otherwise specified. Tests for these additional SENSORS are under consideration.

CAUTION — This test may produce high-voltage shocks. Failure to use safe laboratory practices may result in severe electrical shock, resulting in personal injury or death to the persons handling the equipment or conducting the test.

Test equipment: use the test set-up as shown in Figure 132, the tissue equivalent interface circuit defined by Figure E.102; two oscilloscopes, input impedance nominal 1 MΩ, the oscilloscope connected to test point D in Figure 132 having an accuracy of ± 10 % within a bandwidth of at least 20 MHz, an inhibition signal generator, output impedance not greater than 1 kΩ, which provides an inhibition signal in the form defined in Annex G [Figure G.101] and a test signal generator, output impedance 50 Ω.

The capacitor C_x of the interface circuit [see Figure E.102] shall be bypassed unless required to eliminate spurious low-frequency signals produced by the interference signal generator [see Annex F].

Test signal: the test voltage shall be a continuous sinusoidal signal applied at a minimum of four distinct, well-spaced frequencies per decade between 16,6 Hz to 167 kHz. At each selected frequency the test voltage shall be slowly increased from zero to a maximum of 1 V peak-to-peak. Differential mode performance shall be tested using the test signal reduced to one-tenth amplitude.

NOTE 2 The test voltage need not be increased further once the IMPLANTABLE PULSE GENERATOR begins to detect the test signal.

Test procedure: the test signal generator shall be connected through input C of the interface circuit as shown in Figure 132. The test voltage shall be measured on the oscilloscope connected to test point D of the interface circuit.

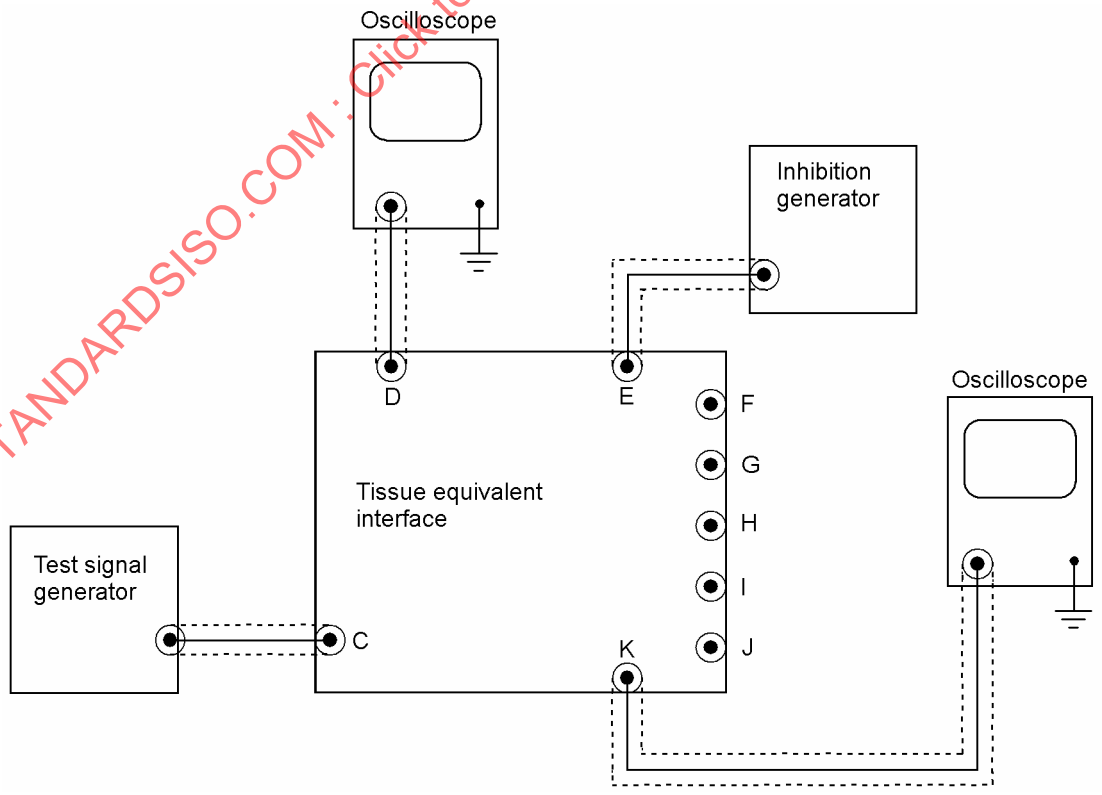

Figure 132 — Test set-up to characterize performance while subject to interference

The test shall be performed in non-synchronized mode, without inhibition signal supplied by the inhibition generator connected to input E. If it is not possible to distinguish between uninfluenced mode and interference mode of operation the test shall be performed in pacing mode and in a synchronized mode.

In synchronized mode the amplitude of the inhibition signal shall be approximately twice the minimum value required for detection by the IMPLANTABLE PULSE GENERATOR, and the interval shall be 90 % of the programmed BASIC PULSE INTERVAL as shipped. The inhibition signal generator shall be connected through input E of the interface circuit.

The IMPLANTABLE PULSE GENERATOR shall be set to its highest SENSITIVITY. Other parameters shall be programmed to values that enable the person conducting the test to observe the point when the test signal is detected by the IMPLANTABLE PULSE GENERATOR.

For a multichannel IMPLANTABLE PULSE GENERATOR, any sense/pace TERMINALS not being tested are connected through resistors of value of $R \geq 10\ k\Omega$ to the corresponding TERMINALS of the channel under test as shown. The manufacturer shall be free to choose the value of the resistors that are appropriate for the device under test. For safety reasons, the CARDIOVERSION/DEFIBRILLATION TERMINALS are loaded with high-voltage 50 Ω (25 W) resistors. The operation of the IMPLANTABLE PULSE GENERATOR shall be monitored by the oscilloscope connected to test point K.

a) Bipolar sense/pace IMPLANTABLE PULSE GENERATORS shall be tested in two configurations.

Common mode performance shall be tested with every pair of sensing/pacing TERMINALS connected in parallel to outputs F and G, H and I of the tissue equivalent interface [as shown in Figure 124] and the case connected to output J.

Differential mode performance shall be tested using the test signal reduced to one-tenth amplitude. The sensing/pacing TERMINALS of the channel under test shall be connected between coupled outputs H and I and output J of the tissue equivalent interface [as shown in Figure 125].

b) For an IMPLANTABLE PULSE GENERATOR which uses signals from both sense and CARDIOVERSION/DEFIBRILLATION LEADS for arrhythmia detection, the manufacturer shall provide details of the test method.

For each predetermined test frequency and SENSITIVITY setting, record the amplitude of the test signal (voltage) when the IMPLANTABLE PULSE GENERATOR begins to detect the test signal.

If the manufacturer's recommended SENSITIVITY is less than the most sensitive setting, the IMPLANTABLE PULSE GENERATOR shall be reprogrammed to the recommended SENSITIVITY setting and the entire test sequence shall be repeated.

Compliance shall be confirmed by inspection of the test results provided by the manufacturer [see also 28.22.4].

27.5 The IMPLANTABLE PULSE GENERATOR shall be constructed so that commonly encountered electromagnetic signals are unlikely to be confused with sensed BEATS and change the therapeutic behaviour of the IMPLANTABLE PULSE GENERATOR.

CAUTION — This test may produce high-voltage shocks. Failure to use safe laboratory practices may result in severe electrical shock, resulting in personal injury or death to the persons handling the equipment or conducting the test.

NOTE The following test is intended to address the compatibility of the intracardiac signal sensing. Any additional physiological SENSORS may be turned off during testing unless otherwise specified. Tests for these additional SENSORS are under consideration. The ICD shall be set to its most sensitive setting for which the manufacturer claims compliance with this standard. The ARRHYTHMIA DETECTION INTERVAL shall be programmed to a value greater than the initial burst-to-burst interval of 350 ms ± 25 ms. For frequencies above 1 kHz the least sensitive setting acceptable for compliance is 0,3 mV SENSITIVITY, or the SENSITIVITY as shipped, whichever is the more sensitive.

27.5.1 Protection from sensing modulated electromagnetic interference (EMI) as cardiac signals in the frequency range 16,6 Hz to 150 kHz

Test equipment: Use the test set-up as shown in Figure 132, the tissue equivalent interface circuit defined by Figure E.102; two oscilloscopes, nominal input impedance 1 MΩ, < 30 pF, the oscilloscope connected to test point D in Figure 132 shall have an accuracy of ± 10 % within a bandwidth of at least 20 MHz, an inhibition signal generator, output impedance not greater than 1 kΩ, which provides an inhibition signal in the form defined in Annex G [Figure G.101] and test signal generators, output impedance of 50 Ω.

The capacitor C_x of the interface circuit [see Figure E.102] shall be bypassed unless required to eliminate spurious low-frequency signals produced by the interference signal generator [see Annex F].

The amplitude of the inhibition signal shall be approximately twice the minimum value required for detection by the IMPLANTABLE PULSE GENERATOR. The inhibition signal generator shall be connected through input E [see Figure 132] of the interface circuit.

Test signal:

test signal 1: The test signal shall be a continuous sinusoidal wave, with a frequency, f, between 16,6 Hz and 1 kHz with peak-to-peak amplitude as shown in Table 107:

test signal 2: The test signal shall be a modulated signal, carrier frequency, f, between 1 kHz and 150 kHz with peak-to-peak amplitudes as shown in Table 107.

Table 107 — Peak-to-peak amplitudes V_{pp} in the range 16,6 Hz to 150 kHz (common mode test)

f	V_{pp}
16,6 Hz $\leqslant f \leqslant$ 1 kHz	2 mV
1 kHz $\leqslant f \leqslant$ 3 kHz	2 mV*(f/1 kHz)^2
3 kHz $\leqslant f \leqslant$ 150 kHz	6 mV* f/1 kHz

For test signal 2 one of the alternative modulations specified below shall be used as specified by the manufacturer.

***Modulation 1**: The carrier shall be switched to create bursts of approximately 100 ms duration. The burst-to-burst interval, T, shall be measured leading to leading edge [see Figure 133]. The burst shall start and terminate at zero crossings of the carrier, and only complete carrier cycles shall be used [true gated signal].*

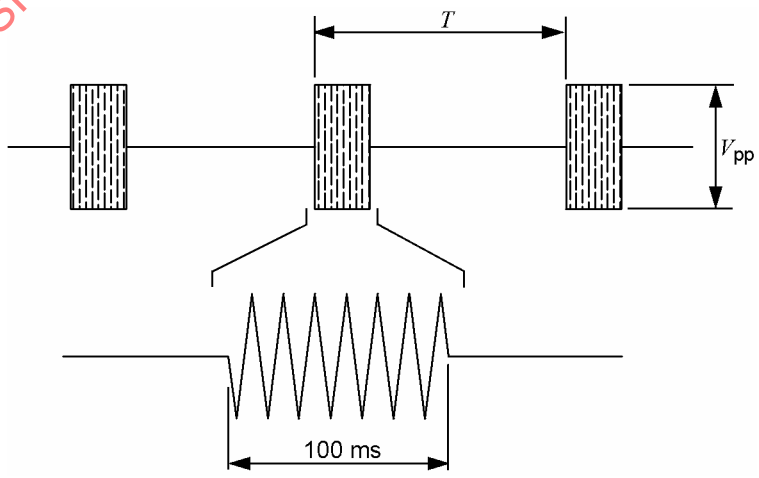

Figure 133 — Modulation 1

Modulation 2 (preferred): *The test signal is a sinusoidal carrier switched smoothly to create bursts with a duration of nominally 100 ms. The envelope of the burst has rise and fall times of nominally 10 ms with linear slopes. The burst duration, 100 ms, as well as the burst-to-burst interval, T, shall be measured at half amplitude of the leading slope of the envelope [see Figure 134].*

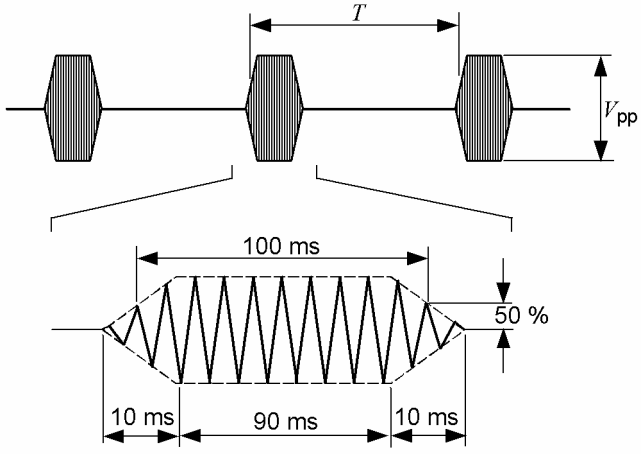

Figure 134 — Modulation 2 (alternative)

Differential mode performance shall be tested using a test signal reduced to 10 % amplitude of the common mode test.

Test procedure: Two possible disruptions of normal operation of the device by the interference are considered: a false positive in which case the EMI is mistaken for an arrhythmia that needs to be treated; and a false negative in which case the EMI prohibits the sensing of an arrhythmia and the needed therapy is withheld. At frequencies below 1 kHz both cases are tested with test signal 1, which simulates the most common continuous interference at these frequencies. At frequencies above 1 kHz both cases are tested with test signal 2, providing burst-to-burst interference interval (T) simulating fibrillation. The false positive case is tested both with an inhibition signal applied and without an inhibition signal. The false negative case need not be tested as sensing of interference signal is implicitly tested.

The atrial and ventricular channel may be tested separately in both AAI and VVI mode in lieu of the mode as shipped.

Test 1: inhibition signal applied at intervals of 800 ms (or 90 % of the programmed BASIC PULSE INTERVAL as shipped, whichever is less) and at frequencies above 1 kHz, burst-to-burst interval set to T = 350 ± 25 ms.

NOTE 1 The test setup of Test 1 seeks to determine if the modulated interference will influence the IMPLANTABLE PULSE GENERATOR during inhibited mode of operation. The burst-to-burst interval (T) is selected to simulate fibrillation.

Test 2: no inhibition signal applied and, at frequencies above 1 kHz, burst-to-burst interval set to T = 350 ± 25 ms.

NOTE 2 The test setup of Test 2 seeks to determine if the detection of the interference will prevent the IMPLANTABLE PULSE GENERATOR from providing bradycardia therapy. The burst-to-burst interval (T) is selected to simulate fibrillation.

Any sense/pace TERMINALS not being tested are connected through resistors of value $R \geq 10\ k\Omega$ to the corresponding TERMINALS of the channel under test. The manufacturer is free to choose the value of the resistors that is appropriate to the device under test. For safety reasons, the CARDIOVERSION/DEFIBRILLATION TERMINALS are loaded with high-voltage 50 Ω (25 W) resistors.

The operation of the IMPLANTABLE PULSE GENERATOR shall be monitored by the oscilloscope connected to test point K. The applicable tests described in paragraphs a) and b) below shall be performed at a minimum of four carrier frequencies per decade.

NOTE 3 Since the IMPLANTABLE PULSE GENERATOR may require that it detect several consecutive input signals before therapy is initiated, sufficient time must be allowed at each frequency tested for the device under test to react to the input interference.

a) Bipolar sense IMPLANTABLE PULSE GENERATOR shall be tested in two configurations.

Common mode performance shall be tested with every pair of sensing/pacing TERMINALS connected in parallel to outputs F and G, H and I of the tissue equivalent interface and the case connected to output J [see Figure 124].

Differential mode performance shall be tested using the test signal reduced to one-tenth amplitude. The sensing/pacing TERMINALS of the channel under test shall be connected between coupled outputs H and I and output J of the tissue equivalent interface [see Figure 125].

NOTE 4 The implantable pulse generator shall be programmed to prevent crosstalk between different channels.

b) For an IMPLANTABLE PULSE GENERATOR which uses signals from both sense and CARDIOVERSION/DEFIBRILLATION LEADS for arrhythmia detection, the manufacturer shall provide details of the test method.

Compliance shall be confirmed if:

While performing Test 1 above, the IMPLANTABLE PULSE GENERATOR is not influenced by the interference signal, i.e. does not exhibit any pacing PULSES and does not deliver a tachyarrhythmia therapy

and

while performing Test 2 above the IMPLANTABLE PULSE GENERATOR is not influenced by the interference signal, i.e. does not exhibit any deviation in pace-to-pace interval that exceeds 10 % of the programmed rate and does not deliver a tachyarrhythmia therapy.

For frequencies below 1 kHz compliance shall be confirmed if the manufacturer discloses in the accompanying documentation the lowest SENSING THRESHOLD (most sensitive) setting or the maximum test signal amplitude for which compliance with this subclause is claimed [see 28.22.1].

27.5.2 Protection from sensing electromagnetic interference (EMI) as cardiac signals in the frequency range 150 kHz to 10 MHz

Test equipment: use test equipment defined in 27.5.1.

The amplitude of the inhibition signal shall be approximately twice the minimum value required for detection by the ICD, and the interval shall be 90 % of the programmed BASIC PULSE INTERVAL as shipped. The inhibition signal generator shall be connected through input E of the interface circuit.

The capacitor C_x of the interface circuit [see Figure E.102] shall be bypassed unless required to eliminate spurious low-frequency signals produced by the interference signal generator [see Annex F].

Test signal: the test voltage for common mode shall be a modulated signal, carrier frequency, f, between 150 kHz and 10 MHz as shown in Table 108 below.

Table 108 — Peak-to-peak amplitudes V_{pp} in the range 150 kHz to 10 MHz

f	V_{pp}
150 kHz $\leqslant f \leqslant$ 167 kHz	6 mV* f/1 kHz
167 kHz $\leqslant f \leqslant$ 1 MHz	1 V
1 Hz $\leqslant f \leqslant$ 10 MHz	1 V* f/1 MHz

Differential mode performance shall be tested using a test signal reduced to 10 % amplitude of the common mode test.

The carrier shall be amplitude modulated with a 130 Hz sinusoidal wave to create modulation bursts of 100 ms duration. The burst-to-burst interval, T, shall be measured leading to leading edge [see Figure 135].

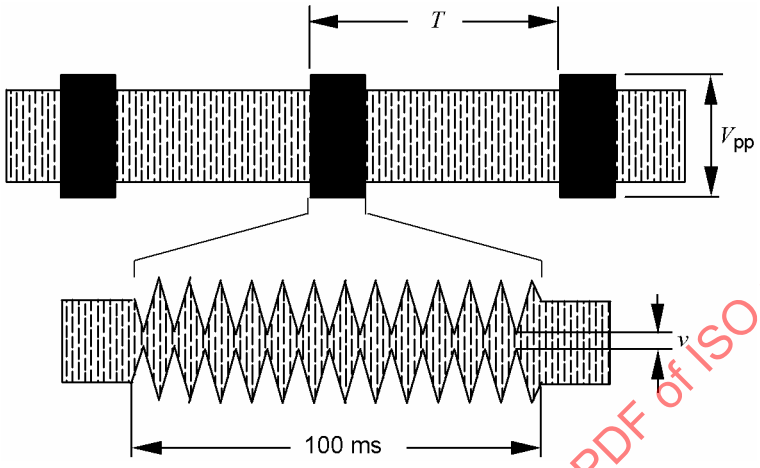

Figure 135 — Test signal for frequencies between 150 kHz and 10 MHz

The modulation bursts shall start and terminate at zero crossings of the modulation signal, thus the envelope starts and terminates continuously. The burst count is 13 complete modulation cycles. The modulation index (M) shall be 95 %, where:

$$M = \frac{V_{pp} - v}{V_{pp} + v} * 100$$

Test procedure: This set-up tests for the detection of the modulated interference as an arrhythmia in the presence of a normal sinus rhythm (i.e. a false positive). The burst-to-burst interval (T) is selected to simulate a fibrillation, which can be detected by the device.

The atrial and ventricular channel may be tested separately in both AAI and VVI mode in lieu of the mode as shipped.

Two possible disruptions of normal operation of the device by the interference are considered: a false positive in which case the EMI is mistaken for an arrhythmia that needs to be treated; and a false negative in which case the EMI prohibits the sensing of an arrhythmia and the needed therapy is withheld. The false positive case is tested with a burst-to-burst interference interval (T) simulating fibrillation and both with an inhibition signal at a normal sinus rate and without an inhibition signal. The false negative case need not be tested as sensing of interference signal is implicitly tested.

The test signal generator shall be connected through input C of the interface circuit as shown in Figure 132. The test voltage shall be measured on the oscilloscope connected to test point D of the interface circuit.

Test 1: inhibition signal applied at intervals of 800 ms (or 90 % of the programmed BASIC PULSE INTERVAL as shipped, whichever is less) and burst-to-burst interval of interference signal set to T = 350 ± 25 ms.

NOTE 1 The test set-up of Test 1 seeks to determine if the modulated interference will influence the ICD during inhibited mode of operation. The burst-to-burst interval (T) is selected to simulate fibrillation.

Test 2: no inhibition signal applied and burst-to-burst interval of interference signal set to T = 350 ± 25 ms.

NOTE 2 The test set-up of Test 2 seeks to determine if the detection of the modulated interference will prevent the ICD from providing bradycardia therapy. The burst-to-burst interval (T) is selected to simulate fibrillation.

Any sense/pace TERMINALS not being tested are connected through resistors of value $R \geq 10\ k\Omega$ to the corresponding TERMINALS of the channel under test. The manufacturer is free to choose the value of the resistors that is appropriate to the device under test. For safety reasons, the CARDIOVERSION/DEFIBRILLATION TERMINALS are loaded with high-voltage 50 Ω (25 W) resistors.

The operation of the IMPLANTABLE PULSE GENERATOR shall be monitored by the oscilloscope connected to test point K. The applicable tests described in paragraphs a) and b) below shall be performed at a minimum of four carrier frequencies per decade.

NOTE 3 Since the IMPLANTABLE PULSE GENERATOR may require that it detect several consecutive input signals before therapy is initiated, sufficient time must be allowed at each frequency tested for the device under test to react to the input interference.

a) Bipolar sense IMPLANTABLE PULSE GENERATORS shall be tested in two configurations.

Common mode performance shall be tested with every pair of sensing/pacing TERMINALS connected in parallel to outputs F and G, H and I of the tissue equivalent interface and the case connected to output J [see Figure 124].

Differential mode performance shall be tested using the test signal reduced to one-tenth amplitude. The sensing TERMINALS of the channel under test shall be connected between coupled outputs H and I and output J of the tissue equivalent interface [see Figure 125].

NOTE 4 The IMPLANTABLE PULSE GENERATOR shall be programmed to prevent crosstalk between channels.

b) For an IMPLANTABLE PULSE GENERATOR which uses signals from both sense and CARDIOVERSION/DEFIBRILLATION LEADS for arrhythmia detection, the manufacturer shall provide details of the test method.

Compliance shall be confirmed if:

While performing Test 1 above, the IMPLANTABLE PULSE GENERATOR is not influenced by the interference signal, i.e. does not exhibit any pacing PULSES and does not deliver a tachyarrhythmia therapy

and

while performing Test 2 above the IMPLANTABLE PULSE GENERATOR is not influenced by the interference signal, i.e. does not exhibit any deviation in pace-to-pace interval that exceeds 10 % of the programmed rate and does not deliver a tachyarrhythmia therapy.

27.5.3 Protection from sensing electromagnetic interference (EMI) as cardiac signals in the frequency range 10 MHz to 450 MHz

Test equipment: use the tissue injection network defined by Figure E.105; an oscilloscope #1, input impedance 50 Ω, accuracy of ± 10% within a bandwidth of at least 450 MHz; an oscilloscope #2, input impedance nominal 1 MΩ; an inhibition signal generator, output impedance not greater than 1 kΩ, which provides an inhibition signal in the form defined in Annex G [Figure G.101]; and a test signal generator, output impedance 50 Ω.

Test signal: the test signal shall be a modulated signal of the form defined in 27.5.2 [see Figure 135]. The modulated test signal shall be applied at a minimum of six distinct, well-spaced frequencies per decade, beginning at 10 MHz and ending at 450 MHz (i.e. 10, 20, 40, 60, 80, 100, 200, 400, 450) with an evenly distributed dwell time of at least 60 s per decade. The amplitude of the test signal (V_{pp}) is defined as the peak-

to-peak amplitude of the open circuit voltage driving the IMPLANTABLE PULSE GENERATOR at the outputs (F, G) of the injection network. The amplitude of the test signal, V_{pp}, shall be 10 V. Prior to testing the test set-up has to be calibrated using the procedure in Annex G.

Test procedure: The test signal generator shall be connected to the injection network through input C as shown in Figure 136. The test signal generator shall be adjusted so that the test signal amplitude measured on oscilloscope #1 connected to monitoring point D (V_{osc}) when multiplied by the calibration factor for the injection network, determined according to the method of Annex G, is equal to the required test signal amplitude, V_{pp}.

Two tests are performed, one with and one without the inhibition signal applied through the inhibition signal generator to input E (E'). In synchronized mode the amplitude of the inhibition signal shall be approximately twice the minimum value required for detection by the IMPLANTABLE PULSE GENERATOR, and the interval of the inhibition signal shall be set to 800 ms or 90 % of the programmed BASIC PULSE INTERVALL as shipped, whichever is shorter. The burst-to-burst interval (T) of the modulated signal shall be set to 700 ms ± 50 ms.

The operation of the IMPLANTABLE PULSE GENERATOR shall be monitored by oscilloscope #2 connected to test point K (K´) [see Figure 136].

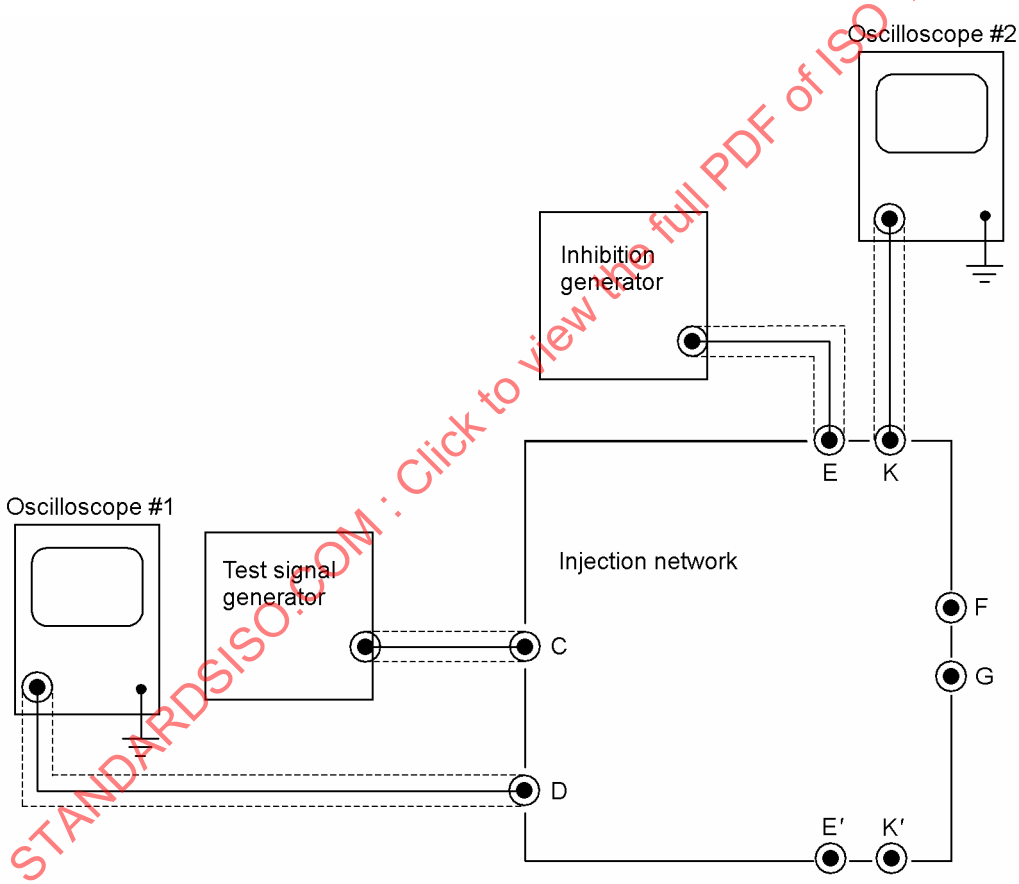

Figure 136 — Test set-up to check for malfunction at high frequency

NOTE The peak-to-peak amplitude of the test signal, V_{pp}, cannot be measured directly at any connector of the injection network during the test. Therefore it must be calculated from the voltage at connector D, V_{osc}, by applying the calibration factor, m, of Annex G.

Connections between outputs F and G and the IMPLANTABLE PULSE GENERATOR shall be made with copper straps, width ≥ 5 mm, length ≤ 50 mm (not including the length of the standard connector pin inserted into the device header). Unused RF-ports on the injection network shall be fitted with 50 Ω terminations.

a) A bipolar IMPLANTABLE PULSE GENERATOR shall be connected to outputs F and G of the injection network [as shown in Figure 137], using appropriate RF techniques for all connections. Each channel of a multichannel device shall be tested in turn and any channel not under test shall be turned off and loaded with 500 Ω load resistors (R_L).

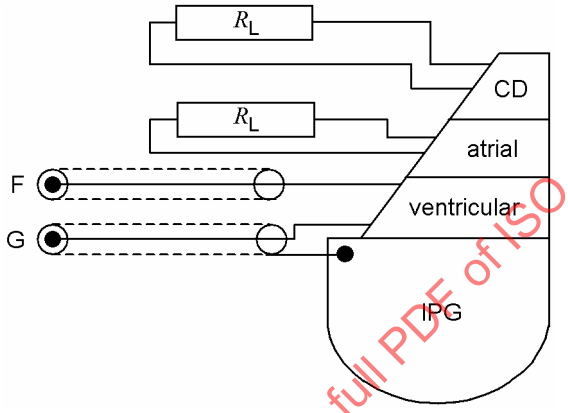

Figure 137 — Connection of the PULSE generator

b) For an IMPLANTABLE PULSE GENERATOR which uses signals from both sense and CARDIOVERSION/DEFIBRILLATION LEADS for arrhythmia detection, the manufacturer shall provide details of the test method.

Compliance shall be confirmed if the IMPLANTABLE PULSE GENERATOR at all times functions in its set mode irrespective of the application of the required modulated signal.

27.5.4 Protection from sensing electromagnetic interference (EMI) as cardiac signals in the frequency range 450 MHz to 3 GHz

Procedure: No test is required for IMPLANTABLE PULSE GENERATORS that provide a feed-through filter at the case for all through-shield connections and the filters can be demonstrated to have an insertion loss of greater than 30 dB when measured with a 50 Ω source impedance or in a balanced 50 Ω system at frequencies of (450, 600, 800, 825, 850, 875, 900, 930, 1 610, 1 850, 1 910, 2 450, and 3 000) MHz.

Test: The IMPLANTABLE PULSE GENERATOR shall be subjected to the required test procedure of ANSI/AAMI PC69:2000, 6.4.1.

Compliance shall be confirmed either

— by inspection of a design analysis of the feed-through filters provided by the manufacturer, supported by data and calculations from test studies as appropriate, or

— the IMPLANTABLE PULSE GENERATOR complies with the applicable performance criteria of ANSI/AAMI PC69:2000, 6.5 at each frequency tested.

27.6 The IMPLANTABLE PULSE GENERATOR shall be constructed so as not to be affected by a static magnetic field of flux density of up to 1 mT.

Test equipment: Use a field coil, capable of generating a uniform magnetic field with a flux density of up to 1 mT ± 0,1 mT in the region to be occupied by the IMPLANTABLE PULSE GENERATOR, and the appropriate monitoring equipment as specified by the manufacturer.

Test procedure: while operating in normal mode the IMPLANTABLE PULSE GENERATOR shall be placed within the coil, centred in its field, and aligned so that the most sensitive axis of the IMPLANTABLE PULSE GENERATOR is parallel to the axis of the coil. The magnetic field shall be slowly increased to a flux density of 1 mT ± 0,1 mT in the region where the IMPLANTABLE PULSE GENERATOR is placed. The magnetic field shall be maintained for at least 1 min.

NOTE The field shall be measured in the absence of the IMPLANTABLE PULSE GENERATOR.

Compliance shall be confirmed if no transition in behaviour of the IMPLANTABLE PULSE GENERATOR is observed while the magnetic field is applied.

27.7 The IMPLANTABLE PULSE GENERATOR shall not remain functionally affected after exposure to strong static magnetic fields of flux density of up to 50 mT.

Test equipment: use a test coil, capable of generating a uniform magnetic field with a flux density of up to 50 mT ± 5 mT in the region to be occupied by the IMPLANTABLE PULSE GENERATOR.

Test procedure: the required flux density shall be generated prior to placing the IMPLANTABLE PULSE GENERATOR in the magnetic field. Then the IMPLANTABLE PULSE GENERATOR shall be slowly placed in the centre of the test coil. After at least 15 s exposure the IMPLANTABLE PULSE GENERATOR shall be slowly removed from the field.

Reorientate the IMPLANTABLE PULSE GENERATOR so that a second orthogonal axis is aligned with the axis of the test coil and again subject the device to the required field. Then repeat again with the third orthogonal axis aligned with the axis of the test coil.

Compliance shall be confirmed if after the magnetic field is removed the IMPLANTABLE PULSE GENERATOR functions as prior to the test without adjustment.

27.8 The IMPLANTABLE PULSE GENERATOR shall be constructed so that ambient time-variable magnetic fields are unlikely to cause any malfunction of the IMPLANTABLE PULSE GENERATOR that persists after removal of the magnetic field.

Test equipment: Use a radiating coil, diameter ⩾ 12 cm and exceeding the largest PULSE generator linear dimension by 50 %, and a calibration coil, diameter ⩽ 4 cm. The radiating coil shall be energized by a signal generator.

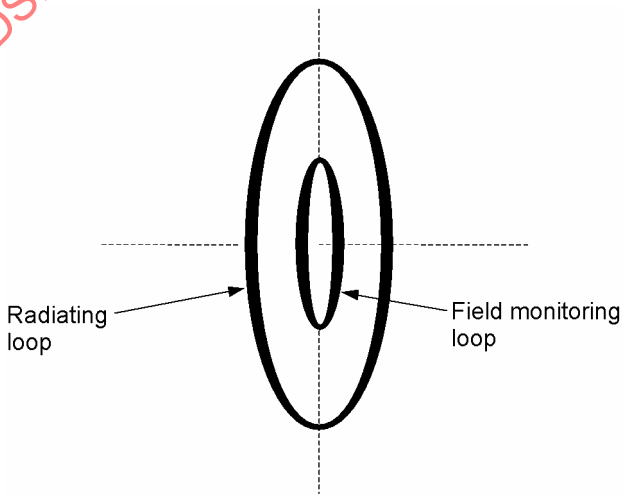

Figure 138 — Loop configuration for varying magnetic field test

Test field: the test magnetic field, H, shall be sinusoidally modulated at a frequency, f, as defined by Table 109.

Table 109 — Sinusoidally modulated magnetic field strengths

f	$H_{r.m.s.}$ min.
1 kHz $\leqslant f \leqslant$ 100 kHz	150 A/m
100 kHz $\leqslant f \leqslant$ 140 kHz	150 A/m $\times$ 100 kHz/f

Test procedure: Using the calibration coil, determine the signal levels applied to the radiating coil that produce the magnetic field, H, in the centre of the radiating coil [see Figure 138]. Remove the calibration coil.

Place the centre of the IMPLANTABLE PULSE GENERATOR at the field intensity calibration point. Load the cardiac LEAD TERMINALS of the IMPLANTABLE PULSE GENERATOR LEAD interface as specified by the manufacturer, using care to minimize loop areas of connections. Generate the required fields either by sweeping the test signal over the required frequency range at a maximum rate of one decade per min or by applying the test signal at four distinct, well-spaced frequencies per decade with an evenly distributed dwell time of at least 60 s per decade.

NOTE Observe care to slowly increase or decrease the field intensity when applying or removing the test signal.

Reorientate the IMPLANTABLE PULSE GENERATOR so that a second orthogonal axis is aligned with the axis of the radiating loop and again subject the IMPLANTABLE PULSE GENERATOR to the required fields. Then repeat again with the third orthogonal axis aligned with the axis of the radiating loop.

Compliance shall be confirmed if after application of the specified test signal, the IMPLANTABLE PULSE GENERATOR functions as prior to the test without further adjustment.

28 Accompanying documentation

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

28.1

Replacement:

28.1 The accompanying documentation shall include the name and address of the manufacturer, the address being the postal address and telephone number.

Compliance shall be confirmed by inspection.

28.8

Additional subclauses:

28.8.1 The accompanying documentation shall include a description of the device, including the following information, as appropriate.

a) For IMPLANTABLE PULSE GENERATORS:

1) an explanation of the tachyarrhythmia therapies;

2) a description of other functions (e.g. bradyarrhythmia pacing features).

NOTE 1 Instead of using words to describe the tachyarrhythmia therapies, the NBD code in Annex D may be used in the markings and accompanying documentation.

NOTE 2 Instead of describing the bradyarrhythmia pacing mode in words, the mode codes defined in Annex D of ISO 14708-2 may be used in the markings and accompanying documentation to designate the bradyarrhythmia pacing mode of the implantable pulse generator.

b) For LEADS:

1) the configuration (unipolar, etc.);

2) other characteristics (e.g. drug dispensing means, etc.).

c) For ADAPTORS:

– the configuration (unipolar, etc.).

Compliance shall be confirmed by inspection.

28.8.2 The device specifications and characteristics for an IMPLANTABLE PULSE GENERATOR shall include the following information, as appropriate.

a) The connector configuration (unipolar, bipolar or other) and the geometry and/or dimensions of the receiving connector and locking mechanism. Any MARKING used to identify a connector shall be explained [see 13.1.1].

b) The physical characteristics, including:

1) the mass of the IMPLANTABLE PULSE GENERATOR (in g);

2) the principal dimensions (in mm);

3) the volume of the IMPLANTABLE PULSE GENERATOR (in cm^3);

4) a general description of the materials, including coatings, which will come into contact with human tissue.

c) If an ELECTRODE is an integral part of the IMPLANTABLE PULSE GENERATOR, then the ELECTRODE material and surface area (in cm^2).

d) The electrical characteristics, nominal as shipped (including ranges and tolerances), at 37 °C ± 2 °C and 50 Ω ± 1 % load, (unless otherwise stated), including as applicable:

1) the available energy settings for the CD PULSES;

2) for each type of CD PULSE (e.g. monophasic, biphasic, etc.), the delivered CD PULSE energy and peak ICD OUTPUT VOLTAGE for the maximum energy setting, minimum energy setting and the energy setting closest to maximum plus minimum divided by 2 (mean value);

NOTE 1 See 6.1.3 for the method of measuring delivered CD PULSE energy and 6.1.2 for the method of measuring ICD OUTPUT VOLTAGE.

3) the maximum and minimum PULSE AMPLITUDEs while providing ANTITACHYCARDIA PACING, measured for each programmable amplitude with the PULSE DURATION and PULSE INTERVAL programmed to the available settings closest to 0,5 ms and 300 ms respectively [see 6.1.4];

NOTE 2 See 6.1.1 of ISO 14708-2 for the method of measuring PULSE AMPLITUDE using load resistors of 500 Ω ± 1 %.

4) if equipped with an AUTOMATIC SENSITIVITY CONTROL, the lowest (most sensitive) SENSING THRESHOLD for both positive and negative polarities and the SENSITIVITY test signal waveform used [see 6.1.5 and Figure G.101];

5) the typical CHARGE TIME (when capacitors are fully formed) for maximum energy setting of the ICD PULSE at BOS and RRT, as a minimum.

NOTE 3 Requirements 1) and 2) above do not apply to ATP ONLY DEVICES.

e) If applicable, the IMPLANTABLE PULSE GENERATOR specifications shall include the electrical characteristics (including ranges and tolerances), nominal as shipped, for all applicable bradyarrhythmia pacing parameters as required in 28.8.2 d) of ISO 14708-2.

NOTE 4 See Clause 6 of ISO 14708-2 for the methods of measuring these parameters.

f) The name of the power source(s) manufacturer and his MODEL DESIGNATION for the power source(s) used.

g) Recommended methods for determining that the IMPLANTABLE PULSE GENERATOR is functioning properly after implantation.

h) Any recommendation regarding the use of LEAD(S) [see also ISO 14708-1, 28.4].

Compliance shall be confirmed by inspection.

28.8.3 The device specification and characteristics for a LEAD shall include the following information, as appropriate.

a) A general description of the materials used for the conductor, connector pin and insulation, and the shape, materials, and configuration of the ELECTRODE(S).

b) A statement advising whether the LEAD contains a medical substance as an integral component, giving the identity of the MEDICINAL SUBSTANCE.

c) The physical dimensions, including (nominal values):

1) the length (in cm);

2) the geometric surface area of ELECTRODE(S) (in mm²);

3) the INSERTION DIAMETER of TRANSVENOUS LEAD (except for connector end) (in mm);

4) the distance(s) between ELECTRODES (bipolar or multipolar ENDOCARDIAL LEADS) (in mm);

5) the maximum depth of penetration into the tissue, if applicable (in mm);

6) the connector geometry (lengths and diameters) (in mm), including any designations or MARKINGS defined in the applicable connector standards;

d) The electrical characteristics of the LEAD [see 6.2], including:

1) the LEAD CONDUCTOR RESISTANCE (in Ω);

2) the LEAD PACING IMPEDANCE (in Ω);

3) the LEAD SENSING IMPEDANCE (in Ω).

e) Any recommendations regarding use with IMPLANTABLE PULSE GENERATORS [see also ISO 14708-1, 28.4].

Compliance shall be confirmed by inspection.

28.8.4 The accompanying documentation for an IMPLANTABLE PULSE GENERATOR shall include information (for example, by diagram) on all PULSE waveforms.

Compliance shall be confirmed by inspection.

28.8.5 The device specification and characteristics for an ADAPTOR shall include the following information, as appropriate.

a) A general description of the materials used for the conductor, connector pin and insulation.

b) The compatible IMPLANTABLE PULSE GENERATORS and LEADS [in particular, see 23.6] and the compatibility with proprietary locking mechanisms of LEADS and IMPLANTABLE PULSE GENERATORS.

c) The physical dimensions (nominal values) including geometry, lengths, and diameters (in mm), including any designations or MARKINGS defined in the applicable connector standards.

Compliance shall be confirmed by inspection.

28.8.6 The device specification and characteristics for accessories shall include a general description of the materials used if they are intended to remain in contact with body tissues.

Compliance shall be confirmed by inspection.

28.9

Additional subclauses:

28.9.1 The accompanying documentation for an IMPLANTABLE CARDIOVERTER DEFIBRILLATOR shall include a description of all recommended LEAD configurations.

Compliance shall be confirmed by inspection.

28.9.2 The accompanying documentation for an IMPLANTABLE CARDIOVERTER DEFIBRILLATOR shall clearly indicate which connections on the IMPLANTABLE PULSE GENERATOR and LEADS are intended for CARDIOVERSION/ DEFIBRILLATION and which connections are intended for sensing and pacing.

NOTE For ATP ONLY DEVICES, the CD TERMINALS part of the requirement is not applicable.

Compliance shall be confirmed by inspection.

28.11

Additional subclauses:

28.11.1 The accompanying documentation for an IMPLANTABLE CARDIOVERTER DEFIBRILLATOR shall include a warning regarding the adverse effects of high-voltage shocks during handling and implantation. The accompanying documentation shall describe how accidents with high-voltage shocks may be avoided during handling and implantation.

Compliance shall be confirmed by inspection.

28.11.2 The accompanying documentation for an IMPLANTABLE CARDIOVERTER DEFIBRILLATOR shall include a warning if there are HAZARDS to the patient or the device due to positioning (i.e. shorting) of ELECTRODES.

Compliance shall be confirmed by inspection.

28.13

Replacement:

28.13 The accompanying documentation for an IMPLANTABLE PULSE GENERATOR shall include a warning to inactivate tachyarrhythmia therapies during surgical procedures, in particular when high-frequency surgery or diathermy is used.

Compliance shall be confirmed by inspection.

28.19

Replacement:

28.19

NOTE 1 The replacement and the additional 28.19.1 and 28.19.2 do not apply to ATP ONLY DEVICES. These devices shall comply with ISO 14708-2, 28.19.

The accompanying documentation for an IMPLANTABLE PULSE GENERATOR shall include information (for example, by graphs) on the average estimated longevity of the device in years as a function of the total number of maximum energy CD PULSES delivered. The total number of maximum energy CD PULSES delivered is spaced uniformly over the estimated life of the IMPLANTABLE PULSE GENERATOR.

The estimated longevity shall be calculated under the following conditions, as applicable:

1) the IMPLANTABLE PULSE GENERATOR is monitoring (no pacing) and delivering the maximum energy CD PULSES into a 50 Ω ± 1 % load;

2) if applicable, the IMPLANTABLE PULSE GENERATOR is pacing 100 % at the manufacturer's specified settings into a 500 Ω ± 5 % load and delivering the maximum energy CD PULSES into a 50 Ω ± 1 % load.

If applicable, any energy used to reform the output capacitors shall be deducted from the total energy available when determining estimated longevity.

NOTE 2 The calculation of estimated longevity shall be based on the manufacturer's battery specifications.

Compliance shall be confirmed by inspection.

Additional subclauses:

28.19.1 The accompanying documentation for an IMPLANTABLE PULSE GENERATOR shall state the PROLONGED SERVICE PERIOD, expressed in months, and the estimated number of maximum energy CD PULSES available between RECOMMENDED REPLACEMENT TIME and END OF SERVICE. When preparing these estimates, the manufacturer shall assume that the IMPLANTABLE PULSE GENERATOR is delivering one maximum energy CD PULSE every 15 d into a 50 Ω ± 1 % load.

Compliance shall be confirmed by inspection.

28.19.2 The accompanying documentation for an IMPLANTABLE PULSE GENERATOR shall include the electrical characteristics after the RECOMMENDED REPLACEMENT TIME. The electrical characteristics shall be measured at 37 °C ± 2 °C with the CD LEAD TERMINALS connected to 50 Ω ± 1 % load(s) and the other TERMINALS connected to 500 Ω ± 5 % load(s).

Compliance shall be confirmed by inspection.

28.22

Additional subclauses:

28.22.1 If the IMPLANTABLE PULSE GENERATOR does not meet the modulated interference requirement in 27.5.1, the accompanying documentation shall include a clear warning listing the lowest SENSING THRESHOLD (most sensitive) setting or the maximum test signal amplitude for which compliance with 27.5.1 is claimed.

Compliance shall be confirmed by inspection.

28.22.2 The accompanying documentation for an IMPLANTABLE CARDIOVERTER DEFIBRILLATOR shall include warnings about recognised hazardous behaviour, if any, of the IMPLANTABLE PULSE GENERATOR when subjected to environmental electric, electromagnetic and magnetic fields that are not covered by tests in this part of ISO 14708. Additionally, the accompanying documentation shall include advice that a clinician may consider providing to the patient on potential interactions with specific equipment, such as anti-theft devices, portable telephones, etc.

Compliance shall be confirmed by inspection.

28.22.3 The accompanying documentation for an IMPLANTABLE CARDIOVERTER DEFIBRILLATOR shall include descriptions of the reversion modes, such as magnet mode and operation during electromagnetic interference, if applicable.

Compliance shall be confirmed by inspection.

28.22.4 The accompanying documentation for an IMPLANTABLE CARDIOVERTER DEFIBRILLATOR shall include information on known potential hazardous behaviour, if applicable, as a result of characterization test conducted under 27.4. Common mode rejection ratio for the frequencies of 16,6 Hz, 50 Hz and 60 Hz shall be disclosed.

Compliance shall be confirmed by inspection.

Annex A
(informative)

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

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1	CLAUSES of ISO 14708–6 AND ASPECTS COVERED
3 **General principles**		
3.1 The implants should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.	8.1 Requires warnings to be prominent.	* retained
3.2 The solutions adopted by the manufacturer for the design and construction of the implants should conform to safety principles, taking account of the generally acknowledged state of the art. In selecting the most appropriate solutions, the manufacturer should apply the following principles in the following order: (a) eliminate or reduce risks as far as possible (inherently safe design and construction), (b) where appropriate take adequate protection measures including alarms if necessary, in relation to risks that cannot be eliminated, (c) inform users of the residual risks due to any shortcomings of the protection measures adopted.	(This principle is fundamental to all aspects of an active implantable medical device addressed by this standard. This approach is particularly applicable to the requirements in clauses 14, 19 and 21.)	* retained

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1		CLAUSES of ISO 14708–6 AND ASPECTS COVERED
3.3 The implants should achieve the performance intended by the manufacturer and be designed, manufactured and packaged in such a way that they are suitable for one or more of the functions referred to in subclause 2.1 [of ISO/TR 14283], as specified by the manufacturer.	10.4	Requires accompanying documentation to be physically associated with the device.	* retained * 6.1 measurement of IPG characteristics * 6.2 measurement of the electrical characteristics of a sensing/pacing lead
3.4 The characteristics and performances referred to in sub-clauses 3.1, 3.2 and 3.3 should not be adversely affected to such a degree that the clinical conditions and safety of the patients and, where applicable, of other persons are compromised during the lifetime of the implant as indicated by the manufacturer, when the implant is subjected to the stresses which can occur during normal conditions of use.	19.2	Requires power source depletion indicator.	* 19.2 replacement * 19.5 additional subclause
	19.3	Defines methodology to ensure single fault conditions are not a hazard.	* retained
	23.1	Defines drop test for non-implantable parts.	* retained
	23.2	Defines vibration test for patient carried parts.	* 23.2 test changed
	23.3	Sets test of tensile strength (leads, etc.).	* 23.3 specific test given
	23.4	Requires strain relief (leads, etc.).	* retained
	23.5	Requires fatigue resistance (leads, etc.).	* 23.5 specific test given
	23.6	Requires connections to be reliable.	* 23.6 test changed * 23.7 additional subclause
	26.1	Requires protection from heat from powered non-implantable parts.	* retained
	28.4	Requires disclosure of maximum proven connector retention strength.	* retained
	28.23	Requires warning against patient entry into hazardous environments.	* retained

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1		CLAUSES of ISO 14708–6 AND ASPECTS COVERED
3.5 The implants should be designed, manufactured and packed in such a way that their characteristics and performances during their intended use will not be adversely affected during transport and storage taking account of the instructions and information provided by the manufacturer.	7.2	Requires sterile pack to be protected by sales packaging.	* retained
	10.1	Requires packaging to be durable.	* retained
	10.2	Requires packaging to be protected against the effects of humidity.	* retained
	10.3	Requires markings on the sales package to be indelible.	* retained
	12.3	Requires markings on the sterile pack to be indelible.	* retained
	26.2	Requires device to be protected against the effect of temperature changes.	* retained
3.6 Any undesirable side-effect should constitute an acceptable risk when weighed against the performances intended.	19.3	Defines methodology to ensure single fault conditions are not a hazard.	* retained
	19.4	Requires investigation of unintended effects caused by the device.	* retained
4 Specific principles regarding design and construction			
4.1 Chemical, physical and biological properties			
4.1.1 The implants should be designed and manufactured in such a way as to guarantee the characteristics and performances referred to in clause 3 of the "General principles". Particular attention should be paid to:			
4.1.1 (a) the choice of materials used, particularly as regards toxicity and, where appropriate, flammability,	14.3	Requires investigation of biocompatibility.	* retained
4.1.1 (b) the compatibility between the materials used and biological tissues, cells and body fluids, taking account of the intended purpose of the implant.	14.3	Requires investigation of biocompatibility.	* retained

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1		CLAUSES of ISO 14708–6 AND ASPECTS COVERED
4.1.2. The implants should be designed, manufactured and packed in such a way as to minimize the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the implants and to the patients, taking account of the intended purpose of the product. Particular attention should be paid to the tissues exposed and to the duration and frequency of exposure.	14.2	Defines test for particulate contamination.	* replacement
	14.3	Requires investigation of biocompatibility.	* retained
4.1.3 The implants should be designed and manufactured in such a way that they can be used safely with the materials, substances and gases with which they enter into contact during their normal use or during routine procedures; if the implants are intended to administer medicinal products they should be designed and manufactured in such a way as to be compatible with the medicinal products concerned according to the provisions and restrictions governing these products and that their performance is maintained in accordance with the intended use.	19.5	Demonstrates compatibility with medicinal substances.	* not applicable to pacemakers
4.1.4 Where an implant incorporates, as an integral part, a substance which, if used separately, may be considered to be a medicinal product as defined in subclause 2.4 [of ISO/TR 14283] and which is liable to act upon the body with action ancillary to that of the implant, the safety, quality and usefulness of the substance should be verified, taking account of the intended purpose of the implant.	14.4	Requirement for quality and safety of incorporated medicinal substances.	* not applicable to pacemakers
4.1.5 The implants should be designed and manufactured in such a way as to reduce to a minimum the risks posed by substances leaking from the implant.	25	Requires implanted parts to withstand pressure changes.	* retained

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1	CLAUSES of ISO 14708–6 AND ASPECTS COVERED
4.1.6 Implants should be designed and manufactured in such a way as to reduce, as much as possible, risks posed by the unintentional ingress of substances into the implant, taking into account the implant and the nature of the environment in which it is intended to be used.	25 Requires implanted parts to withstand pressure changes.	* retained
4.1.7 Implants should be designed and manufactured in such a way as to minimize the risks to the patient or user by the systems, including software.	19.3 Requires a design analysis and defines the methodology for the analysis.	* retained
4.2 **Infection and microbial contamination**		
4.2.1 The implants and manufacturing processes should be designed in such a way as to eliminate or reduce as far as possible the risk of infection to the patient, user and third parties. The design should allow easy handling and, where necessary, minimize contamination of the implant by the patient or vice versa during use.	14.1 Requires device to be supplied sterile.	* retained
4.2.2 Tissues of animal origin should originate from animals that have been subjected to veterinary controls and surveillance adapted to the intended use of the tissues. Information on the geographical origin of the animals should be retained by the manufacturer. Processing, reservation, testing and handling of tissues, cells and substances of animal origin should be carried out so as to provide optimal security. In particular safety with regard to viruses and other transferable agents should be addressed by implementation of validated methods of elimination or viral inactivation in the course of the manufacturing process.	(Not applicable to active implantable medical devices.)	* idem

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1		CLAUSES of ISO 14708–6 AND ASPECTS COVERED
4.2.3 Implants delivered in a sterile state should be designed, manufactured and packed in protective packaging which provides a microbial barrier to ensure that they are sterile when placed on the market and remain sterile, under the storage and transport conditions stipulated by the manufacturer, until the protective packaging is damaged or opened.	7.1	Requires device to be supplied in non-reusable pack.	* retained
	7.2	Requires sterile pack to be protected by sales packaging.	* retained
	10.1	Requires packaging to be durable.	* retained
	10.2	Requires packaging to be proof against the effects of humidity.	* retained
	11.7	Requires contents of sterile pack to be declared or visible.	* retained
	11.9	Requires the sterile pack to be marked with the instructions for opening it.	* retained
	12.1	Applies ISO 11607 to the reusable pack.	* retained
	12.2	Shall be apparent if sterile pack has been opened.	* retained
	14.1	Requires device to be supplied sterile.	* retained
4.2.4 Implants delivered in a sterile state should have been manufactured and sterilized by an appropriate, validated method.	14.1	Confirmed if device sterilized by a validated process.	* retained
4.2.5 Implants intended to be sterilized should be manufactured in appropriately controlled (e.g. environmental) conditions.	14.1	Requires device to be supplied sterile.	* retained
	14.2	Defines test for particulate contamination.	* replacement
4.2.6 Packaging systems for non-sterile implants should keep the product without deterioration at the level of cleanliness stipulated and, if the implants are to be sterilized prior to use, minimize the risk of microbial contamination; the packaging system should be suitable, taking account of the method of sterilization indicated by the manufacturer.	(Not applicable because subclause requires that implantable parts of an active implantable medical device be provided sterile.)		* idem

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1		CLAUSES of ISO 14708–6 AND ASPECTS COVERED
4.2.7 The packaging and/or label of the implant should distinguish between identical or similar products sold in both sterile and non-sterile condition.	(Not applicable because subclause requires that implantable parts of an active implantable medical device be provided sterile.)		* idem
4.3 **Construction and environmental properties**			
4.3.1 If the implant is intended for use in combination with other devices or equipment, the whole combination, including the connection system, should be safe and should not impair the specified performances of the devices. Any restrictions on use should be indicated on the label or in the instructions for use.	9.9	Requires implantable connectors to be identified on sales pack.	* replacement
	11.8	Requires implantable connectors to be identified on sterile pack.	* retained
	23.6	Requires connector retention force to be specified.	* test changed
	28.4	Requires disclosure of maximum proven connector retention strength.	* retained
	28.5	Requires provision of information on accessories that might be required to facilitate the intended use of the device.	* retained
4.3.2 Implants should be designed and manufactured in such a way as to remove or minimize as far as is possible:			
4.3.2 (a) the risk of injury, in connection with their physical features, including the volume/ pressure ratio, dimensional and where appropriate ergonomic features,	15.1	Sets requirement for surfaces of non-implantable parts.	* retained
	15.2	Requires implantable parts to have appropriate physical form.	* retained

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1		CLAUSES of ISO 14708–6 AND ASPECTS COVERED
4.3.2 (b) risks connected with reasonably foreseeable environmental conditions, such as magnetic fields, external electrical influences, electrostatic discharge, pressure, temperature or variations in pressure and acceleration,	23.1	Defines drop test for non-implantable parts.	* retained
	23.2	Defines vibration test for patient carried parts.	* test changed
	24	Defines electrostatic discharge test for non-implantable parts.	* retained
	25	Requires implanted parts to be proof against pressure changes.	* retained
	26.2	Requires implantable devices to be undamaged by extremes of temperature in transit.	* retained
	27	Defines requirement for electromagnetic immunity.	* 27.1 replacement * 27.2 test for induced current density * 27.3 test against malfunction * 27.4 test for temporary response in the presence of EMI * 27.5 test for modulated electromagnetic signals * 27.6 test against weak magnetic fields * 27.7 test against stronger magnetic fields * 27.8 test against time-variable magnetic fields

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1		CLAUSES of ISO 14708–6 AND ASPECTS COVERED
4.3.2 (c) the risks of reciprocal interference with other devices (such as defibrillators or high-frequency surgical equipment) normally used in the investigations or for the treatment given,	20.1	Requires defibrillation protection of external ECG leads.	* retained
	20.2	Defines test to prove defibrillation protection of implanted device.	* replacement
	21	Requires protection against diathermy, etc.	* added test
	22	Requires protection against diagnostic ultrasound.	* retained
	28.12	Requirement for warning notices.	* retained
	28.13	Requires warning about monitoring device in case of diathermy, etc.	* replacement
	28.14	Requires warning not to expose device to therapeutic levels of ultrasound.	* retained
	28.15	Requires warning about the effect of therapeutic irradiation on implanted devices.	* retained
4.3.2 (d) risks which may arise where maintenance and calibration are impossible, including (if applicable): - excessive increase of leakage currents, - aging of the materials used, - excess heat generated by the implant, - decreased accuracy of any measuring or control mechanism.	17	Requires investigation of local heating caused by faulty implanted device.	* retained * 17.1 replacement
	19.1	Requires a design analysis.	* retained
	19.2	Requires power source depletion indicator.	* additional requirements
4.3.3 Implants should be designed and manufactured in such a way as to minimize the risks of fire or explosion during normal conditions and fault conditions. With the risks during “normal conditions and fault conditions” are meant those risks which have been determined by a risk analysis. Particular attention should be paid to implants whose intended use includes exposure to flammable substances or to substances which could cause combustion.	5	Applies IEC 60601–1 to the non-implantable parts of the active implantable medical device.	* retained

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1	CLAUSES of ISO 14708–6 AND ASPECTS COVERED
4.4 **Implants with a measuring function**		
4.4.1 Implants with a measuring function should be designed and manufactured in such a way as to provide sufficient accuracy and stability within appropriate limits of accuracy and taking account of the intended purpose of the implant. The limits of accuracy should be indicated by the manufacturer.	5 Applies IEC 60601–1 to the non-implantable parts of the active implantable medical device.	* retained
4.4.1.1 The measurements, monitoring and display scale should be designed in line with ergonomic principles, taking account of the intended purpose of the implant.	5 Applies IEC 60601–1 to the non-implantable parts of the active implantable medical device.	* retained
4.4.1.2 When an implant or its accessories bear instructions required for the operation of the implant or indicate operating or adjustment parameters, by means of a visual system, such information must be understandable to the user and, as appropriate, the patient.	13.4 Requirement about visual indicators. 5 Applies IEC 60601–1 to the non-implantable parts of the active implantable medical device.	* retained * retained
4.4.2 The measurements made by implants with a measuring function should be expressed in units conforming to the provisions of the ISO 31 series.	5 Applies IEC 60601–1 to the non-implantable parts of the active implantable medical device.	* retained
4.5 **Protection against radiation**		
4.5.1 General Implants should be designed and manufactured in such a way that exposure of patients, users and other persons to radiation be reduced as far as possible compatible with the intended purpose, whilst not restricting the application of appropriate specified levels for therapeutic and diagnostic purposes.	(See more particular requirements below.)	

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1	CLAUSES of ISO 14708–6 AND ASPECTS COVERED
4.5.2 Intended radiation 4.5.2.1 Where implants are designed to emit hazardous levels of radiation necessary for a specific medical purpose the benefit of which is considered to outweigh the risks inherent in the emission, the implants should be designed and manufactured to ensure reproducibility and tolerance of relevant variable parameters. 4.5.2.2 Where implants are intended to emit potentially hazardous, visible and/or invisible radiation, they should be fitted, where practicable, with visual displays and/or audible warnings of such emissions.	(Not applicable to active implantable medical devices.)	
4.5.3 Unintended radiation Implants should be designed and manufactured in such a way that exposure of patients, users and other persons to the emission of unintended, stray or scattered radiation is reduced as far as possible.	9.1 Requires markings warning of any radioactive substances. 18.1 Requirement for sealed sources. 18.2 Requires justification of radiation dose on patient. 18.3 Requires radiation dose as low as is possible. 28.2 Requires information to be provided about radioactive substances.	* retained * retained * retained * retained * retained
4.5.4 Instructions The operating instructions for implants emitting radiation should give detailed information as to the nature of the emitted radiation, means of protecting the patient and the user and on ways of avoiding misuse and of eliminating the risks inherent in use.	(Not applicable to active implantable medical devices.)	* idem
4.6 **Ionizing radiation**	(Not applicable to active implantable medical devices.)	* idem

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1		CLAUSES of ISO 14708–6 AND ASPECTS COVERED
4.6.1 Implants intended to emit ionizing radiation should be designed and manufactured in such a way as to ensure that, where practicable, the quantity, geometry and quality of radiation emitted can be varied and controlled, taking into account the intended use.			
4.6.2 Implants emitting ionizing intended for diagnostic radiology should be designed and manufactured in such a way as to achieve appropriate image and/or output quality for the intended medical purpose whilst minimizing radiation exposure of the patient and user.			
4.6.3 Implants emitting ionizing radiation, intended for therapeutic radiology, should be designed and manufactured in such a way as to enable reliable monitoring and control of the delivered dose.			
4.7 **Principles for implants connected to or equipped with an energy source**			
4.7.1 Implants incorporating electronic programmable systems should be designed to ensure the repeatability, reliability and performance of these systems according to the intended use. in the event of risks (of the system) as determined by a risk analysis for the particular device/system, appropriate means should be adopted to eliminate or reduce as far as possible their risk.	19.3	Requires a design analysis and defines the methodology for the analysis.	* retained
4.7.2 Implants where the safety of the patients depends on an internal power supply should be equipped with a means of determining the state of the power supply.	19.2	Requires power source depletion indicator.	* 19.2 replacement

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1		CLAUSES of ISO 14708–6 AND ASPECTS COVERED
4.7.3 Implants should bear - if practical and appropriate - a code by which they and their manufacturer can be unequivocally identified (particularly with regard to the type of implant); it should be possible to read this code, if necessary, without the need for a surgical operation.	13.3	Requirement stated and expanded.	* replacement
	28.6	Requires an explanation of code to be provided with the device.	* retained
4.7.4 For implants where the safety of the patients depends on an external power supply, the external power supply should include an alarm system to signal any power failure.	5	Applies IEC 60601–1 to the non-implantable parts of the active implantable medical device.	* retained
4.7.5 External devices intended to monitor one or more clinical parameters from an implant should be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.	5	Applies IEC 60601–1 to the non-implantable parts of the active implantable medical device.	* retained
4.7.6 **Protection against electrical risks**			
4.7.6.1 Implants should be designed and manufactured in such a way as to avoid, as far as possible, the risk of accidental electric shocks during normal conditions and fault conditions, provided the implants are installed correctly. With the risks during "normal conditions and fault conditions" are meant those risks which have been determined by a risk analysis for the particular device(s).	5	Applies IEC 60601–1 to the non-implantable parts of the active implantable medical device.	* retained
	16.1	Sets safety limits for leakage currents from non-implantable parts.	* retained

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1		CLAUSES of ISO 14708–6 AND ASPECTS COVERED
4.7.6.2 Active implants should be designed and manufactured in such a way as to minimize the risks connected with the use of energy sources, with particular reference, where electricity is used, to insulation, leakage currents and overheating of the devices.	16.2	Sets safety limits for leakage currents from implantable parts.	* requirement replaced
	16.3	Requires testing of electrical insulation (leads, etc.).	* not applicable * 16.4 additional requirement * 16.5 additional requirement
	17	Requires investigation of local heating caused by implanted device.	* retained * 17.1 replacement
	26.1	Requires protection from heat from powered non-implantable parts.	* retained
4.7.7 **Protection against mechanical risks**			
4.7.7.1 Implants should be designed and manufactured in such a way as to protect the patient and user against mechanical risks connected with, for example, resistance, stability and moving parts.	5	Applies IEC 60601–1 to the non-implantable parts of the active implantable medical device.	* retained
4.7.7.2 Implants should be designed and manufactured in such a way as to minimize the risks arising from vibration generated by the implants, taking account of technical progress and of the means available for limiting vibration, particularly at source, unless the vibrations are part of the specified performance.	5	Applies IEC 60601–1 to the non-implantable parts of the active implantable medical device.	* retained
4.7.7.3 Implants should be designed and manufactured in such a way as to minimize the risks arising from the noise emitted, taking account of technical progress and of the means available to reduce noise, particularly at source, unless the noise emitted is part of the specified performance.	5	Applies IEC 60601–1 to the non-implantable parts of the active implantable medical device.	* retained

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1		CLAUSES of ISO 14708–6 AND ASPECTS COVERED
4.7.7.4 Terminals and connectors to the electricity, gas or hydraulic and pneumatic energy supplies which the user has to handle should be designed and constructed in such a way as to minimize all possible risks.	5	Applies IEC 60601–1 to the non-implantable parts of the active implantable medical device.	* retained
4.7.8 **Protection against the risks posed to the patient by energy supplies or substances**			
4.7.8.1 Implants should be designed and constructed in such a way that the proper functioning of the programming and control systems, including software, does not jeopardize the safety of the patient and of the user, taking account of the intended use.	19.3	Requires a design analysis and defines the methodology for the analysis.	* retained
4.7.8.2 Implants designed to supply energy or administer medicinal substances should be designed and constructed in such a way that the flow-rate can be set and maintained accurately enough to minimize the risk to the patient.	5	Applies IEC 60601–1 to the non-implantable parts of the active implantable medical device.	* retained
4.7.8.3 Implants designed to administer medicinal products should incorporate suitable means to prevent and/or indicate any inadequacies in the flow-rate that could pose a danger.	5	Applies IEC 60601–1 to the non-implantable parts of the active implantable medical device.	* retained
4.7.8.4 Implants designed to supply energy or administer medicinal substances should be designed and constructed so that suitable means are incorporated to minimize the risk of accidental release of dangerous levels of energy or the medicinal substance.	5	Applies IEC 60601–1 to the non-implantable parts of the active implantable medical device.	* retained

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1		CLAUSES of ISO 14708–6 AND ASPECTS COVERED
4.8 **Information supplied by the manufacturer**			
4.8.1 Each implant should be accompanied by the information needed to use it safely and to identify the manufacturer, taking account of the training and knowledge of the potential users. This information comprises the details on the label and the data in the instructions for use. As far as practicable and appropriate, the information needed to use the implant safely should be set out on the implant itself and/or on the packaging for each unit or, where appropriate, on the sales packaging. If individual packaging of each unit is not practicable, the information should be set out in the leaflet supplied with one or more implants. Instructions for use should be included in the packaging for every implant.	10.4	Requires accompanying documentation to be physically associated with the device.	* retained
	12.3	Requirement that any markings shall be indelible.	* retained
4.8.2 Where appropriate, this information should take the form of symbols. Any symbol or identification colour used should conform to international standards. Where no standards exist, the symbols should be described in the documentation supplied with the implant.	4.	Allows use of symbols, abbreviations and identification colours.	* retained
4.8.3 **The label should bear the following particulars:**			
4.8.3 (a) the name or trade name and address of the manufacturer;	5	Invokes the labelling requirements of IEC 60601–1 for non-implantable parts.	* retained
	9.2	Requires name and address of manufacturer on the sales pack.	* retained
	11.1	Requires identification of manufacturer on sterile pack.	* retained

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1		CLAUSES of ISO 14708–6 AND ASPECTS COVERED
4.8.3 (b) the details strictly necessary for the user to identify the implant and the contents of the packaging;	9.3	Requires description of device and model designation on the sales pack.	* retained
	9.4	Requires marking with characteristics sufficient to identify device.	* additional requirements
	9.8	Requires sales pack to bear information about accessories provided.	* retained
	9.10	Requires supplementary description, if 9.3 and 9.4 are inadequate to declare purpose.	* retained
	11.6	Requires description of device and mode designation on the sterile pack.	* retained
	11.7	Requires identification of contents of sterile pack.	* retained
4.8.3 (c) where appropriate, an indication that the contents of the packaging are sterile (e.g. “STERILE”);	9.5	Requires statement that the package has been sterilized.	* retained
	11.2	Requires declaration that the package and its contents have been sterilized.	* retained
	11.3	Requires display of the “sterile” symbol	* retained
4.8.3 (d) where appropriate, the batch code or the serial number, preceded by an appropriate identification (e.g. “LOT” or “SN” respectively);	9.3	Requires batch code or serial number on the sales pack.	* retained
	11.6	Requires batch code or serial number on the sterile pack.	* retained
4.8.3 (e) where appropriate, an indication of the date by which the implant should be used;	9.7	Requires marking of a “use-before date”.	* additional requirements
	11.5	Requires marking of a “use-before date”.	* retained
4.8.3 (f) an indication that the implant is for single use;	28.18	Requires and defines warning notice about reuse of the device.	* retained

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1	CLAUSES of ISO 14708–6 AND ASPECTS COVERED
4.8.3 (g) where appropriate, any indication of special purpose (e.g. “custom-made device” or “exclusively for clinical investigations”);	9.12 Requires marking of special purpose.	* additional requirements
	11.10 Requires marking of special purpose.	* additional requirements * 11.11 * 11.12 * 11.13
4.8.3 (h) any special storage and/or handling conditions;	9.11 Requires marking with information on any exceptional environmental or handling constraints.	* retained
4.8.3 (i) any special operating instructions;	(For implantable parts of an active implantable medical device, all operating instructions are provided in the accompanying documentation.)	
4.8.3 (j) any warnings or precautions to take;	(In the general case, warnings and precautions except for those dealing with special handling conditions [see 4.8.3 (h)] should be described in the accompanying documentation instead of on the label.)	
4.8.3 (k) for active implants, month and year of manufacture;	9.6 Requires marking and defines format.	* retained
	11.4 Requires marking and defines format.	* retained
4.8.3 (l) if applicable, method of sterilization.	11.2 Requires method of sterilization to be marked.	* retained
4.8.4 If the intended purpose of the implant is not obvious to the user, the manufacturer should clearly state it on the label and in the instructions for use.	9.10 Requires supplementary description, if 9.3 and 9.4 are inadequate to declare purpose.	* retained
4.8.5 Wherever reasonable and practicable, the implants and detachable components should be identified, where appropriate in terms of serial numbers or batches, to allow all appropriate actions to be taken following discovery of any potential risk posed by the implants and detachable components.	8.2 Requires implanted parts to be traceable.	* retained
	13.1 Requires identification of manufacturer, model, etc. on device.	* replaced
	13.2 Requires that if different power sources might have been used, the actual source used shall be identified.	* retained

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1		CLAUSES of ISO 14708–6 AND ASPECTS COVERED
4.8.6 Where appropriate, the instructions for use should contain the following particulars:			
4.8.6 (a) the details referred to in clause 4.8.3, with the exception of (d), (e) and (k);	28.1	Requires name and address of manufacturer.	* replaced
	28.3	Requires description of the device.	* retained
	28.16	Requires statement that implantable parts of a device have been sterilized.	* retained
	28.18	Requires and defines warning notice about reuse of the device.	* retained
	28.21	Requires marking with information on any exceptional handling constraints.	* retained
4.8.6 (b) the performances referred to in subclause 3.3 [of ISO/TR 14283] and any undesirable side-effects;	28.8	Requires information to be provided about the intended use and characteristics, and about possible side-effects.	* additional requirements
4.8.6 (c) if the implant should be used with or connected to other medical devices or equipment in order to operate as required for its intended purpose, sufficient details of its characteristics to identify the correct implants or equipment to use in order to obtain a safe combination;	28.4	Requires disclosure of maximum proven connector retention strength.	* retained
	28.5	Requires provision of information on accessories that might be required to facilitate the intended use of the device.	* retained
	28.9	Requires information to allow selection of device, accessories and related devices.	* additional requirements
4.8.6 (d) all the information needed to verify whether the implant is properly used and can operate correctly and safely, plus, where appropriate, information allowing the lifetime of the energy source to be established;	28.10	Requires definitive instructions for use to be provided.	* retained

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1	CLAUSES of ISO 14708–6 AND ASPECTS COVERED
4.8.6 (e) where appropriate, information to avoid specified risks in connection with implantation of the implant;	28.11 Requires information on avoiding hazards during implantation be provided.	* additional requirements
4.8.6 (f) information regarding the risks of reciprocal interference posed by the presence of the implant during specific investigations or treatment;	28.12 Requires warning notices on hazards arising from interaction.	* retained
4.8.6 (g) the necessary instructions in the event of damage to the sterile packaging and, where appropriate, details of appropriate methods of resterilization;	28.17 Requires precautions for dealing with opened or damaged sterile pack.	* retained
4.8.6 (h) where implants are supplied with the intention that they be sterilized before use, the instructions for cleaning and sterilization should be such that, if correctly followed, the implant will still comply with the principles in clause 3 [of ISO/TR 14283];	28.17 Requires instructions for sterilizing accessories that are provided non-sterile.	* retained
4.8.6 (i) details of any further treatment or handling needed before the implant can be used (e.g. sterilization, final assembly, etc.);	(Not applicable because subclause requires that active implantable medical device be provided sterile.)	* idem
4.8.6 (j) in the case of implants emitting radiation for medical purposes, details of the nature, type, intensity and distribution of this radiation.	(Not applicable to active implantable medical devices.)	* idem

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1		CLAUSES of ISO 14708–6 AND ASPECTS COVERED
The instructions for use should also include details allowing the medical staff to brief the patient on any contra-indications and any precautions to be taken. These details should cover in particular:			
4.8.6 (k) precautions to be taken in the event of changes in the performance of the implant;	28.19	Requires information allowing the lifetime of the energy source to be estimated.	* replacement * 28.19.1 additional requirements * 28.19.2 additional requirements
	28.20	Requires information on precautions to be taken to prevent adverse effects from changes in device performance.	* retained
4.8.6 (l) precautions to be taken as regards exposure to, in reasonably foreseeable environmental conditions, e.g. to magnetic fields, external electrical influences, electrostatic discharge, pressure or variations in pressure, acceleration, thermal ignition sources, etc.;	28.22	Requires warnings on precautions to avoid adverse environments.	* retained * 28.22.1 specific warnings about environmental electric and magnetic fields required * 28.22.2 specific warning about sensitivity settings for which compliance with 27.4 is not claimed * 28.22.3 * 28.22.4
4.8.6 (m) adequate information regarding the medicinal product or products which the implant in question is designed to administer, including any limitations in the choice of substances to be delivered;	28.7	Requires information about medicinal products which the device is designed to administer.	* retained
4.8.6 (n) precautions to be taken against any special, unusual risks related to the disposal of the implant;	28.24	Requires information on proper disposal of the device.	* retained
4.8.6 (o) medicinal products incorporated into the implant as an integral part in accordance with subclause 4.1.4 [of ISO/TR 14283];	28.8	Requires information to be provided about the intended use and characteristics, and about possible side-effects.	* additional requirements

FUNDAMENTAL PRINCIPLES	CLAUSES of ISO 14708–1	CLAUSES of ISO 14708–6 AND ASPECTS COVERED
4.8.6 (p) degree of accuracy claimed for implants with a measuring function.	5	* not applicable to IPG
4.9 Clinical evaluation Where conformity with the fundamental principles for implants should be based on clinical data, as in clause 3.6 [of ISO/TR 14283], such data should be established by either:		
4.9 (a) a compilation of the relevant scientific literature currently available on the purpose intended by the manufacturer, or	19.4 Requires investigation of unintended effects caused by the device.	* retained * 19.5 additional subclause
4.9 (b) the results of all the clinical investigations carried out in a way that protects the human subjects and ensures the scientific conduct of the investigation.	19.4 Requires investigation of unintended effects caused by the device.	* retained

Annex B
(informative)

Relationship between the clauses of this standard and the fundamental principles listed in Annex A

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

Subclause	Relevant fundamental principle	Subclause	Relevant fundamental principle
11.2	4.8.3 (c) and 4.8.3 (l)	18.2	4.5.3
11.3	4.8.3 (c)	18.3	4.5.3
11.4	4.8.3 (k)	19.1	4.3.2 (d)
11.5	4.8.3 (e)	19.2	3.4, 4.3.2 (d) and 4.7.2
19.3	3.4, 3.6, 4.1.7, 4.7.1 and 4.7.8.1	28.4	3.4, 4.3.1 and 4.8.6 (c)
19.4	3.6, 4.9 (a) and 4.9 (b)	28.5	4.3.1 and 4.8.6 (c)
19.5	4.1.3	28.6	4.7.3
20.1	4.3.2 (c)	28.7	4.8.6 (m)
20.2	4.3.2 (c)	28.8	4.8.6 (b) and 4.8.6 (o)
21	4.3.2 (c)	28.9	4.8.6 (c)
23.1	3.4 and 4.3.2 (b)	28.10	4.8.6 (d)
23.2	3.4 and 4.3.2 (b)	28.11	4.8.6 (e)
23.3	3.4	28.12	4.3.2 (c) and 4.8.6 (f)
23.4	3.4	28.13	4.3.2 (c)
23.5	3.4	28.14	4.3.2 (c)
23.6	3.4 and 4.3.1	28.15	4.3.2 (c)
24	4.3.2 (b)	28.16	4.8.6 (a) [3.8.3 (c)]
25	4.3.2 (b)	28.17	4.8.6 (g) and 4.8.6 (h)
26.1	3.4 and 4.7.6.2	28.18	4.8.6 (a) [4.8.3 (f)]
26.2	3.5 and 4.3.2 (b)	28.19	4.8.6 (k)
27	4.3.2 (b)	28.20	4.8.6 (k)
28.1	4.8.6 (a) [4.8.3 (a)]	28.21	4.8.6 (a) [4.8.3 (h)]
28.2	4.5.3	28.22	4.8.6 (l)
28.3	4.8.6 (a) [4.8.3 (b)]	28.23	3.4
		28.24	4.8.6 (n)

Annex C
(informative)

Notes on ISO 14708-6

C.1 General

This part of ISO 14708 attempts to quantify the essential requirements of ISO/TR 14283 related to IMPLANTABLE CARDIOVERTER DEFIBRILLATORS and the functions of ACTIVE IMPLANTABLE MEDICAL DEVICES intended to treat tachyarrhythmia. In many clauses, the standard does this by detailing a particular aspect of the essential requirement and specifying an assessment procedure or test. A compliance requirement then allows the particular device under examination to be deemed to meet the aspect of the essential requirement.

This part of ISO 14708 supplements or modifies ISO 14708-1, referred to in this document as ISO 14708-1. ISO 14708-1 must not be applied alone to the devices covered by this part of ISO 14708. The requirements of this part of ISO 14708 take priority over those of ISO 14708-1.

For some HAZARDS, this part of ISO 14708 prescribes specific requirements along with compliance measures (e.g., a.c. and d.c. leakage current levels) which, if met, satisfy an aspect of the fundamental principles of ISO/TR 14283. For other risks, this part of ISO 14708 requires potential HAZARDS to be assessed, identified, and mitigated using a similar procedure to that described in ISO 14971. Compliance is then determined by review of documentation provided by the manufacturer.

In developing this part of ISO 14708, it is recognised that there are cases, particularly where accelerated fatigue testing is involved, where a variety of test methods produce equivalent results. In those cases, the test methods presented in the standard are viewed as "referee tests". The manufacturer may use an alternative test method provided it can be demonstrated that the alternative is equivalent to that in the standard. In a dispute, the method specified in this part of ISO 14708 is to be used.

In some cases, no laboratory test of limited duration can provide adequate assurance of the characteristics of a particular design or assurance of its performance after several years' implantation. The device manufacturer should then be required to prepare documented studies for expert review.

C.2 Notes on specific clauses and subclauses

The following, more detailed, notes on some of the provisions of this part of ISO 14708 are provided as an aid to understanding. This annex is directed toward those who are familiar with the construction and use of IMPLANTABLE CARDIOVERTER DEFIBRILLATORS (and implantable ANTITACHYCARDIA PACING devices) but have not themselves participated in drafting this part of ISO 14708. The notes in this annex carry the numbers of the relevant clauses in the standard; therefore, the numbering in this annex is not consecutive.

[1] The IMPLANTABLE CARDIOVERTER DEFIBRILLATOR (ICD) market and the technology used in the products are still developing and changing rapidly. In drafting this document, the it has been tried to ensure that the requirements specified will not become obsolete, or become unnecessary limitations, as the therapy and the technology develop. For these reasons, this part of ISO 14708 does not include requirements for:

— arrhythmia detection,

— antitachycardia pacing,

— duration of high-voltage PULSES.

The fundamental principles of ISO/TR 14283 were used as guidelines when drafting requirements for this standard.

[6.1] The procedures are specified for devices only at 37 ºC ± 2 ºC. As established designs are not temperature sensitive within such a temperature range, this is believed sufficient to validate an IMPLANTABLE PULSE GENERATOR at thermal equilibrium after implantation.

[6.1.3] Manufacturers employ a variety of ways of expressing the energy in a CD PULSE. Two common approaches are to specify delivered energy or stored energy. Delivered energy is the energy which passes through the CD LEADS and dissipates in the patient or in a resistance of specified value, usually 50 Ω. Delivered energy will always be less than stored energy because some of the stored energy will be dissipated within the ICD. Also, the CD PULSE may be terminated before all of the energy stored in the capacitors is transferred. The delivered energy was chosen as the significant for expressing the output of a device. This choice is consistent with the usual manner in which the output energy of an external defibrillator is specified.

[6.1.7] If an extended period of time elapses between charges, the dielectric material within the high-voltage capacitors may become deformed. This can prolong the first CHARGE TIME following a period of disuse. Therefore the high-voltage capacitors shall be charged regularly, either in connection with patient follow-ups or by an automatic feature within the IMPLANTABLE PULSE GENERATOR. The PULSE generator automatically charges the high-voltage capacitors to maximum voltage if the charge interval has passed without a charge for maximum-voltage therapy. The voltage is not dumped following a capacitor maintenance charge, but decreases gradually. Depending on the voltage attained, the charge dissipates over several minutes.

[9.4 & 9.12] SALES PACKAGING for implantable parts of the ACTIVE IMPLANTABLE MEDICAL DEVICE must bear the information and characteristics necessary to fully identify the device. The information required by these subclauses is the minimum necessary to facilitate selection of a device with the required performance from the shelf. Additionally for safety reasons, the physician is reminded that the IMPLANTABLE PULSE GENERATOR is always shipped with the tachycardia therapies inactivated (see also 7.3) but, as the tachycardia therapies can be activated “in the box”, the hazardous voltage symbol reminds the user that once activated an IMPLANTABLE PULSE GENERATOR can produce dangerous voltages.

[9.9] IMPLANTABLE PULSE GENERATORS and LEADS are often sold separately. Therefore, when assembling a system for implant, it is important that hospital personnel are able to identify connector types, configurations, and dimensions so that appropriate mating components can be selected without opening the STERILE PACK. A reference to an established connector standard, such as DF-1 or IS-1, can satisfy this requirement.

[9.12] See [9.4].

[13.1.1] The MARKINGS on the implant facilitate the identification and tracking of the device if and when it is explanted.

[13.1.2] LEADS and ADAPTORS are usually very small devices with little space for identifying marks. Therefore, the required information may be abbreviated using techniques such as a recognised logo to identify the manufacturer and the incorporation of the MODEL DESIGNATION into the SERIAL NUMBER or, when appropriate, a batch number.

[13.3] For IMPLANTABLE CARDIOVERTER DEFIBRILLATORS, the power source is located in the IMPLANTABLE PULSE GENERATOR. Power source depletion usually limits the life of the implant, so it is essential to be able to identify an IMPLANTABLE PULSE GENERATOR using non-invasive procedures in case of unexpected change in performance. The procedure for non-invasively identifying the IMPLANTABLE PULSE GENERATOR must avoid equipment which is not generally available in hospitals. Device-specific equipment, such as a programmer, is not considered to be acceptable. However, once the unit has been identified, a programmer can be used to obtain the SERIAL NUMBER, or other identifying information, from which the date of manufacture can be determined, possibly by contacting the manufacturer.

[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 recognised measurement technique based on the apparatus that is readily available.

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) may present an excessive particle count when soaked in a bath based

on the volume of the empty bag. The same bag when filled may pass the test even though the total particle count is the same. The same holds true for devices covered by this part of ISO 14708, especially LEADS that typically have a large surface area but a small volume. For IMPLANTABLE PULSE GENERATORS, this approach would specify a bath that is of the same order of magnitude as the volume approach in ISO 14708-1.

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

[16.2] Sustained (long-term) direct currents from implanted ELECTRODES may cause tissue damage or ELECTRODE corrosion. The direct current measurement should include the contribution, if any, resulting from sustained therapeutic functions such as bradyarrhythmia pacing. In most cases, tachycardia therapies are delivered infrequently with long intervals of inactivity between episodes. These therapies do not contribute in any significant way to the sustained d.c. leakage. Therefore, they should be deactivated during the d.c. leakage measurement.

The d.c. leakage current test uses load resistors that simulate the impedance seen by the generator once implanted. The acceptance limits for pacing/sensing TERMINALS are consistent with limits given in ISO 14708-2. For CD TERMINALS the acceptance limits are a factor 10 higher due to the much larger surface area of CD LEADS.

[16.3] The dielectric strength test for LEAD insulation is replaced by the compliance test in 23.3 that checks the integrity of the insulation following a conditioning soak in saline and application of tensile force to the LEAD.

[16.4] IMPLANTABLE CARDIOVERTER DEFIBRILLATORS may produce significant a.c. leakage currents while the high-voltage capacitors are being charged. Low-frequency leakage currents may induce fibrillation or pump failure. High-frequency currents may produce heating effects that result in tissue damage. The primary HAZARD is believed to be induction of fibrillation by lower-frequency a.c. leakage currents (i.e. those below 1 MHz).

The requirement in this subclause is based on the allowable leakage currents specified in IEC 60601-1, 19.3. These current limits are based on studies conducted by Starmer [1] and Watson [2] that established a probability of electrically induced ventricular fibrillation.

The risk of fibrillation is highest and approximately equal for frequencies in the 10 Hz to 200 Hz range. It is lower, by a factor of nearly 5, at d.c. and by a factor of 1,5 at 1 kHz. Beyond 1 kHz, the risk decreases rapidly. In the area of greatest SENSITIVITY, (10 to 200) Hz, the probability of a 10 μA current causing ventricular fibrillation or pump failure when applied through small areas to an intracardiac site is 0,002. The probability that a (50 to 60) Hz current of 50 μA applied directly to the heart through ELECTRODES with surface areas of (1,25 to 2) mm^2 will induce fibrillation is 0,01. For more information see Annex A of IEC 60601-1, 19.3.

The band pass circuit is taken from Figure 15 in IEC 60601-1. A 15 μF capacitor (C_s) and a 1 kΩ resistor (R_p) have been added to provide a breakpoint at 10 Hz.

The measurement of an r.m.s. value requires that a sampling window be established. Commonly available measuring devices compute the r.m.s. value of an input signal over a sampling window of approximately 1 s. In most cases, this should give a sufficiently precise reading of the leakage current. However, if readings close to the limit are obtained, it is recommended that an instrument with a shorter sampling window (e.g. 100 ms) be used to obtain a more precise measurement.

[16.5] d.c. leakage current from PULSE generator TERMINALS raises two specific concerns:

— continuous leakage currents may cause corrosion on the electrode surface of the ICD. This risk of continuous d.c. leakage current is addressed in 16.2;

— with charged capacitors, the leakage current may be much higher.

For a pace/sense LEAD with an ELECTRODE area of less than 10 mm^2, the acceptable leakage current is in the order of 10 μA. The limiting factor is the risk that the leakage current may cause an arrhythmia. A CD LEAD ELECTRODE has a typical surface area exceeding 300 mm^2.

Since the risk for inducing arrhythmia is correlated with current density, the allowable maximum d.c. leakage from the CD LEAD ELECTRODE is in the order of 100 μA without increased risk for arrhythmia induction.

[17.1] Because of its intended function, an ICD can dissipate considerable energy inside the device during normal operation. Functions such as “charge and dump” will result in all of the energy in the CD PULSE being dissipated as heat within the ICD. Current generation devices, however, have sufficient thermal mass to allow this heat to be dissipated without causing a temperature rise of greater than 4 °C at any point on the outside surface.

When considering the effect of temperature rise on tissue, the duration of the exposure to elevated temperature should be taken into account. It has been well established in burn literature that tissue damage should be evaluated as a function of exposure time [3] [4] [5] [6]. Tissue SENSITIVITY is usually assessed by plotting the time to an “isoeffect” versus temperature. An isoeffect is any identifiable and repeatable level of detriment to the tissue. Although absolute SENSITIVITY can vary widely among tissue types, the slopes of isoeffect plots are consistent. Specifically, below 42 °C, for each 1 °C decrement in temperature, the time to reach an equivalent level of detriment is 4 to 6 times longer. This relationship has been demonstrated by many investigators, using both human and rodent tissue [7].

Most ICDS are implanted in adipose and skeletal muscle tissue. Martinez *et al*. conducted a thermosensitivity study of such tissues in normal porcine [8]. (Henriques established porcine tissue as an accepted model for human tissue.) A total of 102 sites on 15 pigs were exposed to steady, elevated temperatures between 40 °C and 50 °C for 30 min. Acute and chronic damage levels were assessed from biopsies taken 24 h and 1 month post-treatment, respectively. Damage levels were graded by two independent observers who were unaware of the corresponding treatment. They found that there was no identifiable acute or chronic damage when the exposure temperature was 42 °C or less.

The results of this study may be used to determine a safe time-temperature relationship for MEDICAL DEVICES adjacent to adipose and/or skeletal muscle tissue. Such a relationship, shown in Figure C.101, was obtained using the isoeffect rule outlined above. For example, since 42 °C was determined safe for 30 min, then 41 °C should be safe for at least 4 times longer, or 2 h, and 40 °C should be safe for 8 h, etc.

It must be emphasized that the specified device surface temperatures are as measured *in vivo* during operation, and not in air. Also, careful attention should be paid to the uncertainty in temperature measurements as this may affect the appropriate exposure time.

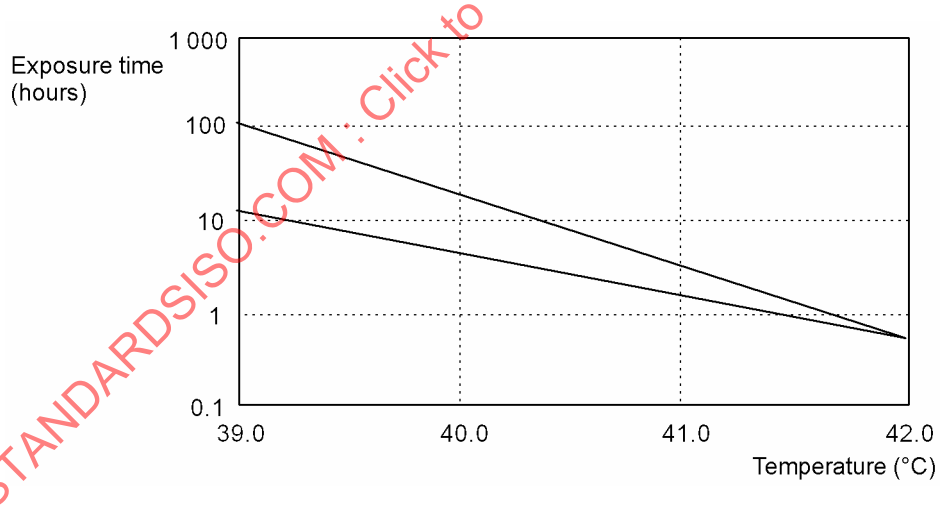

Figure C.101 — Safe exposure times for adipose/skeletal muscle tissue at various temperatures

In more recent publications a 43 °C threshold for damage has been corroborated by numerous investigators. Interestingly, it has also been found that most of the damage caused to muscle and adipose tissue between 43 °C and 45 °C (30 min) is reversible. Above 45 °C, tissue necrosis appears, resulting in irreversible tissue injury (Martinez, et al., as referenced in GM Hahn, Hyperthermia and Cancer, Plenum Press, New York, 1982).

From the studied literature, it may be safe to conclude that localized chronic tissue heating by an ACTIVE IMPLANTABLE MEDICAL DEVICE should be limited to temperatures of and below 41 °C in order not to affect normal tissue function. It seems reasonable, however, that tissue temperatures of up to 42 °C would be well tolerated during acute applications, and would not cause detrimental chronic effects.

A relatively recent publication (C Davies, et al., Adaptation of Tissue to a Chronic Heat Load, ASAIO Journal, 40, 514-517, 1994) reported that temperatures ranging between 43 °C and 46 °C were measured in tissue adjacent to the motor and gear pump of the Cleveland Clinic-Nimbus total artificial heart. The tissues reaching these temperatures belong to the lung and muscle tissue within the chest. At these temperatures, according to the same paper, acute HARM should not be caused, but detrimental chronic effects may appear.

The authors supported these conclusions by referencing the following results from previous studies:

1 At and below 42 °C, polymorphonuclear (PMN) phagocytic function is maintained within normal ranges. At and above 44 °C, however, PMN function is irreversibly damaged, especially when the time of exposure exceeds 30 min. (*J Utoh, et al., The Effects of Heat on Human and Calf Polymorphonuclear Cells (PMN), J Invest Surg, 3, 303, 1990*).

2 Angiogenesis was elicited in the myocardium of mongrel dogs by applying localized heat resulting in tissue temperatures of and above 43 °C. Angiogenesis, evidenced by neocapillarity and increased fibroblastic activity occurred at distances of up to 2 mm from the surface of the probe heaters for chronic exposures of 7 to 31 days (*JC Norman, et al., Heat-Induced Myocardial Angiogenesis, I, Trans. ASAIO, 17, 213-218, 1971*).

3 Experiments carried out on T-lymphocytes (*R Hershkovits, et al., Heat-Stressed CD4+ T Lymphocytes: Differential Modulations of Adhesiveness to Extracellular Matrix Glycoproteins, Proliferative Responses and Tumour Necrosis Factor-+ Secretion, Immunology, 79, 241-247, 1993*) suggest that heat stress at 41 °C (1 h) could suppress immune cell function and reactivity at local sites of elevated temperature due to loss of T-cell adhesion to the extracellular matrix. However, these same studies have demonstrated that heat stress at these temperatures augments T-cell proliferation and tumour necrosis factor-+ secretion, indicating that heat stress at 41 °C itself does not suppress the overall immune function of T-cells. In any case, the effects of heat stress on T-cell adhesion and proliferation were completely reversible within 60 h of exposure.

4 Human red blood cells have shown significant changes in osmotic fragility and surface morphology at temperatures of 48 °C and above (*J Utoh, et al., Comparative Study of Heat Effects on Human and Calf Erythrocytes (RBC), J Invest Surg, 3, 308, 1990*).

Another paper regarding the Cleveland Clinic-Nimbus artificial heart (*H Harasaki, et al., Progress in Cleveland Clinic-Nimbus Total Artificial Heart Development, ASAIO Journal, 40, 494-498, 1994*) reported that tissues surrounding the artificial heart, including the tissue capsule, lung and pericardium, showed localized hyperaemia and vascular engorgement for temperatures above the targeted range of (42 to 43) °C.

Research in the fields of whole-body hyperthermia and hyperthermia-enhanced radiotherapy has also yielded relevant information. In his Ph.D. dissertation, Prionas (*SD Prionas, Thermal SENSITIVITY and Thermotolerance of Normal Mammalian Tissues, Ph.D. Dissertation, Stanford University, 1984*) stated:

Most mammalian cells are readily inactivated at temperatures of 41 °C or higher. Under standard conditions (pH 7,4 and adequate nutrients and oxygen), the shape of the survival curves obtained when cells are exposed to elevated temperatures for varying lengths of time depends upon the temperature of exposure. Above 43 °C such curves resemble survival curves obtained from cells exposed to ionizing radiations: when the logarithm of the surviving fraction is plotted against time of exposure, the curves exhibit a shoulder, followed by a linear segment. The width of the shoulder as well as the slope of the linear part of the curve depend on the temperature. At higher temperatures the shoulder is smaller and the slope steeper. Below 43 °C the curves are more complex, with resistant tails developing as the duration of heating is increased.

Dr. Prionas's experiments demonstrate minimal thermal SENSITIVITY of adipose tissue and skeletal muscle for temperatures under 43 °C (< 1 % of maximal tissue damage). However, damage increases dramatically at temperatures above 43 °C. The heat doses required to induce 50 % of maximal damage (30 min Single-Dose ED50) to skeletal muscle and adipose tissue are reported to be (45,1 ± 0,5) °C and (44,8 ± 0,5) °C respectively.

The 43 °C threshold for damage has been corroborated by numerous other investigators. Interestingly, it has also been found that most of the damage caused to muscle and adipose tissue between 43 °C and 45 °C (30 min) is reversible. Above 45 °C, tissue necrosis appears, resulting in irreversible tissue injury (*Martinez, et al., as referenced in GM Hahn, Hyperthermia and Cancer, Plenum Press, New York, 1982*).

From the studied literature, it may be safe to conclude that localized CHRONIC tissue heating by an ACTIVE IMPLANTABLE MEDICAL DEVICE should be limited to temperatures of and below 41 °C in order not to affect normal tissue function. It seems reasonable, however, that tissue temperatures of up to 42 °C would be well tolerated during acute applications, and would not cause detrimental chronic effects.

An ICD may experience fault conditions, which result in a temperature rise exceeding the 4 °C limit. Examples include an internal short in the battery or any fault condition that results in a fault current that is less than the peak operating current of the device. However, temperature rise is not a major risk to the patient resulting from a fault. The potential inability of the device to deliver a life-saving therapy because of the fault is a far greater HAZARD. Subclause 19.3 of ISO 14708-1 requires that the manufacturer assess the probable HARM being caused by each single fault condition and to document the HAZARD CONTROL implemented to assure that the failure does not cause an UNACCEPTABLE HAZARD. Therefore, it was deemed appropriate to eliminate the temperature rise requirement in a fault condition.

[19.2] ISO 14708-1 specifies that an ACTIVE IMPLANTABLE MEDICAL DEVICE that contains a power source must provide advance warning of the exhaustion of the power supply. ISO 14708-1 further specifies that the warning period in normal use must be at least the recommended interval between clinical checks. The expected longevity of an ICD, however, is subject to a number of patient-dependent factors, including the frequency of charging the high-voltage capacitors. Under certain circumstances, an ICD may go from the onset of RECOMMENDED REPLACEMENT TIME to the point where it can no longer generate one maximum energy CD PULSE in a very short period (possibly within a day). Therefore, the warning period specified in this subclause is a minimum requirement for assessing bench performance of an ICD and is not related to the actual management of the patient that must be based on the physician's evaluation of the patient's clinical status.

The manufacturer specifies the point in time when the replacement of an IMPLANTABLE CARDIOVERTER DEFIBRILLATOR is recommended. However, because of the critical nature of the therapy provided by an IMPLANTABLE CARDIOVERTER DEFIBRILLATOR, it was deemed appropriate to set a minimum requirement for the number of maximum energy CD PULSES that the device can deliver at the time the POWER SOURCE INDICATOR reaches the value indicating elective replacement.

A study of 181 ICD patients was conducted to determine, among other objectives, the average number of full energy equivalent shocks that the patients received per year over the life of the device. The results of that study are shown in Figure C.102. In this study, more than 98 % of the patients averaged less than 24 maximum energy shocks per year. As experience with managing ICD patients has increased, the general trend has been to extend the periods between routine follow-ups. Three months or longer is routine for PACEMAKER patients. Therefore, it was deemed appropriate, for purposes of comparison, to set the recommended interval between clinical checks at three months of monitoring only. Considering this interval and the data presented in Figure C.102, the minimum number of maximum energy shocks following the onset of RECOMMENDED REPLACEMENT TIME was set at 6.

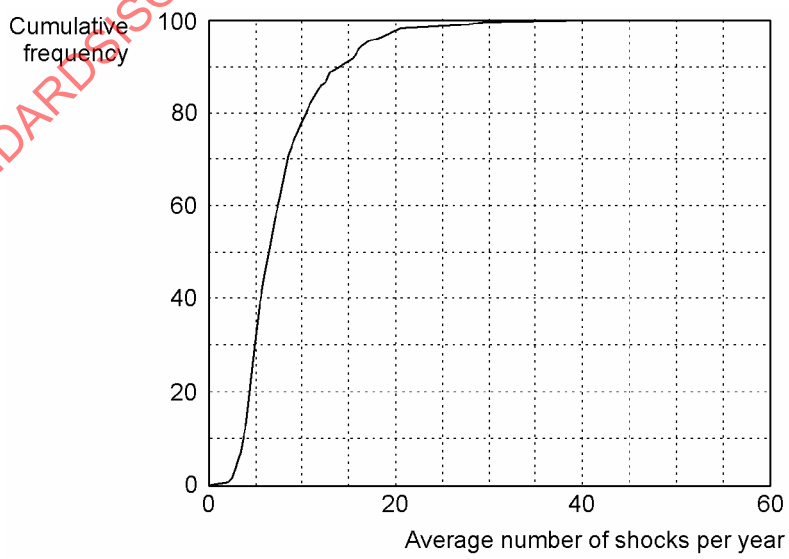

Figure C.102 — Average number of full shocks per year

[19.5] This test imposes the maximum energy CD PULSE across each combination of ring and tip connections in a positive and negative polarity. It was determined that, as a first approximation and with typical ELECTRODE placement, at least one half of the ICD OUTPUT VOLTAGE would be imposed on the sense/pace TERMINALS during a shock.

Test cases 7) and 8) are designed to test common mode performance. If the enclosure or "case" is an active TERMINAL, then there is no common mode and cases 7) and 8) do not apply.

[20.2] Testing is conducted using various types of external DEFIBRILLATION waveforms that the patient may be subjected to.

Test 1 was designed to explore the ability of the PULSE generators to withstand external DEFIBRILLATION applied from units that have monophasic waveforms (such as Edmark, Lown, Pantridge waveforms) or a biphasic waveform (such as the Gurvich waveform). The test stresses the device with a high voltage.

Test 2 was designed to explore the ability of the PULSE generators to withstand external DEFIBRILLATION applied from units with monophasic or biphasic truncated exponential waveform capabilities, employing very fast rise and fall time. The test stresses the device with a high voltage along with a high dV/dt.

The different test voltage levels are aligned with the clinical experience documented in literature teaching that significantly lower DEFIBRILLATION energy is needed when truncated exponential waveform is used compared to a damped sinus waveform. References: 1) Mittal S et alia, *Comparison of a novel rectilinear biphasic waveform with a damped sine waveform for transthoracic ventricular defibrillation*. Journal of the American College of Cardiology. 1999;34:1595-1601; 2) Mittal S et alia, *Transthoracic cardioversion of atrial fibrillation: comparison of rectilinear biphasic versus damped sine wave monophasic shocks.* Circulation. 2000;101:1282-1287; 3) Bardy GH et alia, *Multicenter comparison of truncated biphasic shocks and standard damped sine wave monophasic shocks for transthoracic ventricular defibrillation.* Circulation. 1996;94:2507-2514.

[21.2] The test frequency of 500 kHz was selected as typical of the majority of electrosurgical equipment, and the continuous wave test of 36 V_{pp} of the test signal was selected based on recent work performed within the AAMI EMI taskforce for ANSI/AAMI PC69. It should be noted that this test level may likely result in myocardial damage. Dr. W. Irnich *et al*. [9] indicate that thermal equilibrium can be maintained for induced voltages up to about 5 V r.m.s. (14 V_{pp}) during electrosurgery, raising the temperature from 37 ºC to 43 ºC at the ELECTRODE to heart tissue interface. The selected test amplitude of 36 V_{pp}, to test for damage of the IMPLANTABLE PULSE GENERATOR, is thus well above the tolerable level of 14 V_{pp} with respect to thermal myocardial damage.

The requirement does not provide complete protection, since the voltages picked up during exposure to electrosurgery are very dependent upon the distances between the electrosurgical ELECTRODES and any conductive part of the IMPLANTABLE PULSE GENERATOR or its LEADS, and the surgeon may not be aware of the positioning of such parts.

[23.2] The same test as defined in ISO 14708-2 is performed. The rationale from ISO 14708-2 reads: The test is intended to establish minimum requirements for the durability of IMPLANTABLE PULSE GENERATORS with respect to mechanical robustness.

The test specified in ISO 14708-2 has been replaced because the part of the standard defining the test has been withdrawn.

The replacement text is based on a new part of IEC 60068-2-64.

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

The value for the acceleration spectral density was also derived from the sinusoidal sweep method in 8.1.1 of EN 50061. 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 may vary slightly depending on the equipment used to generate the random vibration. However, the level of stress on the IMPLANTABLE PULSE GENERATOR 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 IEC 60068-2-64. It should provide for reasonable confidence in the reproducibility of the results while providing 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] through [23.5] The tests contained in 23.3 through 23.5 are intended to establish minimum requirements for the durability of implantable LEADS with respect to commonly known mechanical failure modes. There are some LEAD failure modes for which standardized tests cannot yet be established since a scientific consensus has not been reached about either the mechanisms of failure or valid test methods. It is the responsibility of the LEAD manufacturer to define a complete set of LEAD reliability requirements for a particular design.

[23.3] The LEAD is soaked to reproduce any influence body fluids will have on the LEAD joints and materials after implantation.

The manufacturer must determine the distal point on the LEAD where the fracture or permanent deformation of any conductor or joint, or breaching or separation of the insulation, would affect the intended function of the LEAD. By clamping at this point and at the LEAD connector pin it is possible to evaluate the composite strength of the LEAD. Visual inspection of the LEAD at each stage of the procedure is strongly recommended to detect possible functional damage.

Different parts of the LEAD may be exposed to varied levels of tensile force. It is agreed that the tensile forces on an implanted LEAD may be greater on the section of the LEAD outside the vascular system than on the section inside the vascular system. However, assigning different strength requirements to each part of the LEAD would needlessly introduce complexity (and the potential for error or artefact) into the test method. There was unanimous agreement that a 5 N wet pull force is appropriate for the portion of the LEAD outside the vascular system. Therefore, the 5 N wet pull force requirement was used for the entire LEAD. LEADS that meet the composite wet pull requirement of 5 N are thought to have sufficient overall mechanical integrity since some clinically used LEADS that do not meet this criterion for the portion of the LEAD in the vascular system have demonstrated acceptable field performance. A particular design of some joints may not need to survive a 5 N wet pull test in order to produce a clinically acceptable device.

In the body, the maximum possible elongation is not likely to exceed 20 %. The fatigue life of the LEAD is not likely to be compromised if the LEAD is permanently elongated less than 5 %. This has been used as a reasonable acceptance criterion for a long period of time.

It is important that the LEAD is not dried out during the tensile test and that the LEAD after the tensile testing is soaked for purposes of saline penetrating any damage done by the test.

The exposed conductive surfaces must be kept completely isolated from the saline bath during the insulation integrity test to ensure safety for the test personnel.

The d.c. resistance measurement is checking for gross fractures of conductors or separation of joints.

A test signal of 2 000 V d.c. was selected to provide a stress level well above the system voltage that manufacturers expect to employ for the foreseeable future. Further, the test voltage is applied with the LEAD immersed in saline following a minimum of 10 days preconditioning soak. This is intended to ensure that saline has the opportunity to penetrate any flaws in the insulation tubing. Performing the test in saline ensures that all potential leakage paths are exposed to uniform stress.

The allowable leakage current level of 2 mA was selected to avoid tissue damage and to represent an insignificant loss in output when compared to the many amperes typically required to defibrillate a patient. It is likely that a weak spot in the insulation due to inadequate insulation thickness or induced by the application of a tensile force to the LEAD will result in a total breakdown of the insulation when exposed to 2 000 V.

As an example, the compliance requires a lead having two conductors carrying a cd pulse (D1 and D2) and a single pace/sense conductor (PS1) be tested in the following configurations:

1. D1 to D2 (2 000 V d.c.)
2. D1 to PS1 (2 000 V d.c.)
3. D2 to PS1 (2 000 V d.c.)
4. D1 to reference (2 000 V d.c.)
5. D2 to reference (2 000 V d.c.)
6. PS1 to reference (100 V d.c.)

Conductors intended for carrying DEFIBRILLATION currents must withstand the axial load test without impairing their capacity to deliver a maximal shock sequence. A damaged conductor which measures in specification for impedance may nevertheless have lost its ability to carry high current. Therefore, a high current test was considered important.

The test configuration simulates a clinical situation where a 1 000 V DEFIBRILLATION output from a 200 μF capacitor is delivered to a patient presenting a system resistance of between 20 Ω and 25 Ω. 1 000 V and 200 μF are both higher values than manufacturers currently intend to incorporate into defibrillators, which is in agreement with the current-carrying test in Annex B of ISO 11318:1993 (DF-1). A 20 Ω system resistance is at the extreme low end of impedance seen clinically, and results in the highest current. A variable series resistor may be needed to achieve the minimum system resistance of 20 Ω. On the other hand, some LEAD designs may present a higher resistance and no series resistor is needed. A test of ten PULSES was selected to allow confidence that a LEAD with intermittent electrical continuity would not pass the test (multiple current PULSES also provide a stress that could cause damaged conductors to blow open).

The visual inspection is to look for signs of charring or any other indication of the inability of the LEAD to carry the test current. A final resistance check is redundant but is a good verification that the test was performed correctly.

NOTE (See also [23.3] through [23.5] above.)

[23.5] The tests are intended to establish minimum requirements for the flexural durability of implantable LEADS. In accord with this approach, a conductor or connector must withstand a minimum of 47 000 and 82 000 cycles respectively without failure.

Irrespective of conductor and connector design geometries and materials, it is recommended that a margin of safety be established with respect to these minimum requirements. It is left up to each manufacturer to determine the appropriate sample size, data analysis technique and margin of safety, as well as to demonstrate with confidence the minimum cycle requirements can be achieved.

Test 1 is designed to accelerate the fatigue of the conductor and not the insulation, therefore the pass/fail criterion looks for conformity of the conductor. Although test methods designed to accelerate fatigue of conductors can introduce test artefact damage to insulation, fatigue failures of known insulation materials *in vivo* are generally not experienced in the absence of biodegradation mechanisms. The types of insulation damage seen in these accelerated fatigue tests are not necessarily representative of the insulation damage seen in the body.

The bell mouth test was designed with the following conditions in mind: variations in human anatomy, ranges of motion, implant sites, and loading conditions.

Example of determining fixture radius:

— *Fixture radius = Centre-line bending radius - ½ Maximum segment outside width*

— *Maximum segment outside width = 2,05 mm*

— *Centre-line bending radius = 6,00 mm ± 0,10 mm*

— *Usable fixture radii = 4,88 mm to 5,08 mm*

Loading conditions were determined by evaluating coil designs and by observing the morphology of the fracture surface. Each type of fracture surface will produce a characteristic fracture signature or morphology. The fracture sites of both the *in vitro* and *in vivo* samples from the bell mouth test were compared and determined to exhibit the same morphology.

Although the exact conditions are impossible to determine, light microscopy, scanning electron microscopy, and analytical stress analysis have been used to demonstrate that loading by torsional shear or bending in the bell mouth flex test leads to similar loading conditions compared to *in vivo* failure. This is, in fact, evident from the various types of torsional shear or bending induced slant and flat fractures that are found in explanted LEADS. The macroscopic and microscopic details of these are also found to be internally consistent as long as similar load levels are encountered. The field emission gun scanning electron microscopy demonstrates very similar fatigue crack growth fractography up to about 15 000 × in both *in vitro* and *in vivo* failures.

Figure C.103 specifies a Reference Test Coil based on a BIPOLAR LEAD, with established field performance that utilizes the Reference Test Coil as the inner conductor coil. Based on a study of chronic implants and return product analysis, this LEAD has been found to achieve a nominal survival rate from fracture of the inner coils of 99,3 % at 60 months.

Weibull distribution analysis of the Reference Test Coil fractures predicts a minimum population value of 46 476 that supports the observed minimum of 47 908 cycles. The specification minimum is proposed to be set at the sample minimum rounded down to the nearest 1 000 cycles (47 000). The specification minimum is set at the Weibull t_0 value rounded up to the nearest 1 000 cycles (47 000).

Weibull distribution analysis was conducted on 224 samples of the Reference Test Coil tested using the procedure in 23.5. The Reference Test Coil was tested in both a LEAD body and bare coil configuration. Although the standard test is designed to test LEAD body configurations, a majority of the population was tested in a bare coil configuration. Bare coil configurations have been shown to give a slightly different average flex life value than co-axial LEAD body configurations due to structural interactions that are seen in LEAD bodies. The use of the bare coil configuration was used to help remove any discrepancies created when validating a manufacturer's test set-up. The Weibull analysis predicts a B_{50} value of 127 685 and a minimum, t_0, of 46 476 that supports the observed minimum of 47 908 cycles.

By using the same centre bend radius, the same strain conditions will be applied for every different conductor diameter. This approach was chosen because it is consistent with typical strain analysis techniques and with existing LEAD flex test databases. It is recognised that a larger bending radius results in lower strain and a smaller radius results in a higher strain. The minimum flex cycles are reduced with higher strain or increased with lower strain.

The accelerated flex testing described in this part of ISO 14708 purposely imposes higher strain on the LEAD that results in a shorter fatigue life of the test specimens than are expected to occur in implanted LEADS. However, changing the frequency and/or radii may or may not change the morphology of the fracture site of the *in vitro* tests. Regardless, the altered test would need to be verified with field data and evaluations to determine if failure modes of the test specimens are representative of the field.