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Short Range Devices (SRD);
Ultra Low Power Active
Medical Membrane Implants (ULP-AMI-M) and
Peripherals (ULP-AMI-M-P)
operating in the frequency range 30 MHz to 37,5 MHz;
Harmonised Standard covering the essential requirements
of article 3.2 of the Directive 2014/53/EU

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Contents

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Foreword

This Harmonised European Standard (EN) has been produced by ETSI Technical Committee Electromagnetic compatibility and Radio spectrum Matters (ERM).

The present document has been prepared under the Commission's standardisation request C(2015) 5376 final [i.7] to provide one voluntary means of conforming to the essential requirements of Directive 2014/53/EU on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC [i.1].

Once the present document is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of the present document given in table A.1 confers, within the limits of the scope of the present document, a presumption of conformity with the corresponding essential requirements of that Directive and associated EFTA regulations.

National transposition dates	
Date of adoption of this EN:	27 December 2016
Date of latest announcement of this EN (doa):	31 March 2017
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Date of withdrawal of any conflicting National Standard (dow):	30 September 2018

Modal verbs terminology

In the present document "**shall**", "**shall not**", "**should**", "**should not**", "**may**", "**need not**", "**will**", "**will not**", "**can**" and "**cannot**" are to be interpreted as described in clause 3.2 of the ETSI Drafting Rules (Verbal forms for the expression of provisions).

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Introduction

Membrane Implants and associated peripheral equipment are a new technology in the medical field that provides, on a continuing non-invasive basis after the implant is inserted, patient related real time intravenous blood pressure information to the attending physician. This information is used for purposes of diagnosing and treating certain heart related disorders thereby reducing significantly the hospital readmission rate.

The present document is a specific product standard applicable to Ultra Low Power Active Medical Membrane Implants and Peripherals operating in the frequency range 30 MHz to 37,5 MHz.

The frequency usage conditions for the band 30 MHz to 37,5 MHz are EU wide harmonised for the SRD category "active medical implant devices" according to 2013/752/EU [i.10].

The present document is structured in the following way:

- Clauses 1 through 3 provide a general description on the types of equipment covered by the present document and the definitions, symbols and abbreviations used.
- Clause 4 provides the technical requirements, specifications, limits and conformance relative to transmitter, receiver, and spectrum access.
- Clauses 5.1 and 5.2 specify the conditions for testing of the equipment and interpretation of the measurement results with the maximum measurement uncertainty values.
- Clause 5.3 specifies the required measurement methods. In particular clause 5.3.8 describes the monitoring system performance specifications that have been chosen to minimize harmful interference to other equipment or services and minimize the potential for disturbance to this equipment from ambient sources or other medical device users in the band.
- Annex A (normative) provides the relationship between the present document and the essential requirements of Directive 2014/53/EU [i.1].
- Annex B (normative) provides specifications concerning radiated measurements.
- Annex C (normative) provides technical performance of the spectrum analyser.
- Annex D (informative) bibliography; provides additional information.

1 Scope

The present document applies to Ultra Low Power-Active Medical Membrane Implants and Membrane Implant Peripherals as described in Directive 90/385/EEC [i.4], covering all active medical implants, that operate in a Medical Implant Communications System in the frequency band 30 MHz to 37,5 MHz.

Table 1: Ultra Low Power Active Medical Membrane Implants and Peripherals operating in the frequency band 30 MHz to 37,5 MHz

	Ultra Low Power Active Medical Membrane Implants and Peripherals service frequency bands
Transmitters - Ultra Low Power Active Medical Membrane Implants and peripherals	30 MHz to 37,5 MHz
Receivers - Ultra Low Power Active Medical Membrane Implants and peripherals	30 MHz to 37,5 MHz

The present document contains the technical requirements for characteristics of ULP-AMI-M and ULP-AMI-M-P radio equipment which are aligned with annex 12 Sub-band (d) of CEPT/ERC Recommendation 70-03 [i.6].

The frequency usage conditions for the band 30 MHz to 37,5 MHz are EU wide harmonised for the SRD category "active medical implant devices" according to 2013/752/EU [i.10] with the following usage restrictions:

- "*This set of usage conditions is only available to ultra-low power medical membrane implants for blood pressure measurements within the definition of active implantable medical devices in Directive 90/385/EEC.*"

The present document contains requirements to demonstrate that Ultra Low Power Active Medical Membrane Implants and peripherals used in a medical membrane implant communications system "*… shall be so constructed that it both effectively uses and supports the efficient use of radio spectrum in order to avoid harmful interference*" (article 3.2 of the Directive 2014/53/EU [i.1]). It does not necessarily include all the characteristics, which may be required by a user, nor does it necessarily represent the optimum performance achievable.

2 References

2.1 Normative references

References are either specific (identified by date of publication and/or edition number or version number) or non-specific. For specific references, only the cited version applies. For non-specific references, the latest version of the referenced document (including any amendments) applies.

Referenced documents which are not found to be publicly available in the expected location might be found at https://docbox.etsi.org/Reference/.

NOTE: While any hyperlinks included in this clause were valid at the time of publication, ETSI cannot guarantee their long term validity.

The following referenced documents are necessary for the application of the present document.

[1] CISPR 16-2-3 (2010): "Specification for radio disturbance and immunity measuring apparatus and methods. Part 2-3: Methods of measurement of disturbances and immunity - Radiated disturbance measurements".

2.2 Informative references

References are either specific (identified by date of publication and/or edition number or version number) or non-specific. For specific references, only the cited version applies. For non-specific references, the latest version of the referenced document (including any amendments) applies.

NOTE: While any hyperlinks included in this clause were valid at the time of publication, ETSI cannot guarantee their long term validity.

The following referenced documents are not necessary for the application of the present document but they assist the user with regard to a particular subject area.

[i.1] Directive 2014/53/EU of the European Parliament and of the Council of 16 April 2014 on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC.

[i.2] ETSI TR 100 028 (V1.3.1): "ElectroMagnetic Compatibility and Radio Spectrum Matters (ERM); Uncertainties in the measurement of mobile radio equipment characteristics".

[i.3] Void.

[i.4] Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (AIMD Directive).

[i.5] Radiofrequency Radiation Dosimetry Handbook (October 1986), USAF School of Aerospace Medicine, Aerospace Medical Division (AFSC), Brooks Air Force Base, TX 78235-5301.

NOTE: See http://niremf.ifac.cnr.it/docs/HANDBOOK/home.htm.

[i.6] CEPT/ERC Recommendation 70-03: "Relating to the use of Short Range Devices (SRD)".

[i.7] Commission Implementing Decision C(2015) 5376 final of 4.8.2015 on a standardisation request to the European Committee for Electrotechnical Standardisation and to the European Telecommunications Standards Institute as regards radio equipment in support of Directive 2014/53/EU of the European Parliament and of the Council.

[i.8] Recommendation ITU-T O.153: "Basic parameters for the measurement of error performance at bit rates below the primary rate".

[i.9] "Simulated Biological Materials for Electromagnetic Radiation Absorption Studies", by G. Hartsgrove, A. Kraszewski, and A. Surowiec as published in Bioelectromagnetics 8:29-36 (1987).

[i.10] Commission Implementing Decision 2013/752/EU of 11 December 2013 amending Decision 2006/771/EC on harmonisation of the radio spectrum for use by short-range devices and repealing Decision 2005/928/EC.

[i.11] CEPT/ERC Recommendation 74-01: "Unwanted emissions in the spurious domain".

3 Definitions, symbols and abbreviations

3.1 Definitions

For the purposes of the present document, the following terms and definitions apply:

Active Implantable Medical Device (AIMD): any Active Medical Device (AMD) which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure

Active Medical Device (AMD): any medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity

artificial antenna: reduced-radiating dummy load equal to the nominal impedance specified by the applicant

blocking: measure of the capability of the receiver to receive a wanted modulated signal without exceeding a given degradation due to the presence of an unwanted input signal at any frequencies other than those of the spurious responses in adjacent channels or bands

NOTE: See clause 4.2.2.1.

conducted measurements: measurements which are made using a direct connection to the equipment under test

custom antenna: antenna built according to manufacturer's antenna design rules

dedicated antenna: removable antenna supplied and tested with the radio equipment, designed as an indispensable part of the equipment

duty cycle: ratio, expressed as a percentage, of the total transmitter on time to an one hour period under repeated normal operation during the time measurement interval

NOTE 1: Whether the duty cycle is fixed or random depends on how the device is triggered.

NOTE 2: See clause 4.2.1.4.

emission bandwidth: measured as the width of the signal between the points on either side of carrier centre frequency that are 20 dB down relative to the maximum level of the modulated carrier

integral antenna: permanent fixed antenna, which may be built-in, that is designed as an indispensable part of the equipment

out of band emissions: emissions resulting from the modulation process that are outside the emission bandwidth, but excluding unwanted emission in the spurious domain

NOTE: See clause 4.2.1.2.

programmer/controller: equipment used by a physician to communicate with an implanted device

radiated E-field: E-field in the direction of maximum field strength under the specified conditions of measurement

NOTE: See clause 4.2.1.1.

radiated measurements: measurements which involve the absolute measurement of a radiated field

spurious radiations from receivers: emissions radiated from the antenna, the chassis and case of the receiver

NOTE: It is specified as the radiated power of a discrete signal. Included in this definition are modulation products that are outside the 20 dB down point on either side of the fundamental emission. See clause 4.2.2.2.

telecommand: use of radio communication for the transmission of signals to initiate, modify or terminate functions of equipment at a distance

telemetry: use of radio communication for indicating or recording data at a distance

Ultra Low Power Active Medical Implant (ULP-AMI): radio part of an AIMD

Ultra Low Power Active Medical Implant Peripheral (ULP-AMI-P): radio part of equipment outside the human body that communicates with an ULP-AMI

Ultra Low Power Active Medical Implant Membrane (ULP-AMI-M): active medical implant device with resonant transmission capability that operates in a ULP-AMI band and is placed inside the human body for the purpose of performing diagnostic functions and/or delivery of therapeutic treatment

Ultra Low Power Active Medical Implant Membrane Peripheral(ULP-AMI-M-P): transmitter, operating outside of a human body in a ULP-AMI frequency band that transmits energy to a membrane implant with a receiver that receives information from a membrane implant for the purpose of determining pressure within the human body

unwanted emissions in the spurious domain: emissions on a frequency or frequencies which are outside the out of band domain and the level of which may be reduced without affecting the corresponding transmission of information

NOTE: Emissions at frequencies other than those of the carrier and sidebands associated with normal test modulation. See clause 4.2.1.3.

3.2 Symbols

For the purposes of the present document, the following symbols apply:

E	Electrical field strength
f	frequency
P	Power
R	Distance
t	time

3.3 Abbreviations

For the purposes of the present document, the following abbreviations apply:

AIMD	Active Implantable Medical Device
AMD	Active Medical Device
e.r.p.	Effective Radiated Power
EMC	ElectroMagnetic Compatibility
EUT	Equipment Under Test
RF	Radio Frequency
RMS	Root Mean Square
SRD	Short Range Device
ULP-AMI-M	Ultra Low Power Active Medical Implant Membrane
ULP-AMI-M-P	Ultra Low Power Active Medical Implant Membrane Peripheral

4 Technical requirements specifications

4.1 Environmental profile

The technical requirements of the present document apply under the environmental profile for operation of the equipment, which shall be declared by the manufacturer. The equipment shall comply with all the technical requirements of the present document at all times when operating within the boundary limits of the declared operational environmental profile.

4.2 Conformance requirements

4.2.1 Transmitter requirements

4.2.1.1 Effective Radiated Power

4.2.1.1.1 Definition

The effective radiated power is the maximum power radiated during the interval of continuous transmission within the emission bandwidth of the EUT with the highest radiated power in the direction of the maximum level under specified conditions of measurements in the presence of modulation or without modulation as appropriate.

4.2.1.1.2 Limits

The maximum average effective radiated power of an emission within the band 30 MHz to 37,5 MHz shall not exceed 1 milliwatt e.r.p within the emission bandwidth of the EUT. If the normal operational mode of the device uses stepped frequencies, the limit applies to the emission level of each frequency. Correction of peak power measurement by a factor determined by the duration of each pulse and the period of the pulse train at the measurement frequency is permitted to determine compliance with the limit.

4.2.1.1.3 Conformance

Conformance tests as defined in clause 5.3.1 shall be carried out.

4.2.1.2 Out of band emissions

4.2.1.2.1 Definition

Out of band emissions are emissions resulting from the modulation process that are outside the emission bandwidth, but excluding unwanted emissions in the spurious domain (see clause 3.1).

4.2.1.2.2 Limits

The out of band emission shall not exceed 0,01 milliwatt e.r.p.

4.2.1.2.3 Conformance

Conformance tests as defined in clause 5.3.2 shall be carried out.

4.2.1.3 Unwanted emissions in the spurious domain of transmitters

4.2.1.3.1 Definition

Unwanted emissions in the spurious domain are emissions outside the emission bandwidth and excluding Out of band emissions (see clause 3.1).

The spurious domain is defined at frequencies beyond the limit of 250 % of the emission bandwidth above and below the centre frequency of the emission.

The level of any unwanted emission in the spurious domain shall be measured only for frequencies not greater than 1 000 MHz at normal conditions (see clause 5.1.4.3) as:

- Their effective radiated power or field strength when radiated by the cabinet with integral antenna, if applicable, and any other dedicated antenna supplied by the manufacturer.

4.2.1.3.2 Limits

The radiated field strength of unwanted emissions below 30 MHz shall not exceed the generated H-field at 10 m given in table 2.

Table 2 [i.11]

State	Frequency 9 kHz ≤ f < 10 MHz	Frequency 10 MHz ≤ f < 30 MHz
Operating	27 dBµA/m at 9 kHz descending 10 dB/dec	-3,5 dBµA/m
Standby	5,5 dBµA/m at 9 kHz descending 10 dB/dec	-25 dBµA/m

The power of any radiated unwanted emission above 30 MHz shall not exceed the values given in table 3.

Table 3 [i.11]

State	47 MHz to 74 MHz 87,5 MHz to 118 MHz 174 MHz to 230 MHz 401MHz to 406MHz 470 MHz to 790 MHz	Other frequencies between 30 MHz to 1 000 MHz
Operating	4 nW	250 nW
Standby	2 nW	2 nW

For the purpose of the present document, harmonic emissions are exempt from the limits in tables 2 and 3 but should not exceed 0,01 milliwatt e.r.p.

The applicable reference bandwidths are listed in table 7.

4.2.1.3.3 Conformance

Conformance tests as defined in clause 5.3.3 shall be carried out.

4.2.1.4 Duty Cycle

4.2.1.4.1 Definition

For the purpose of the present document the term duty cycle refers to the ratio of the total transmitter on time to an one hour period under repeated normal operation during the time measurement interval (see clause 3.1). Whether the duty cycle is fixed or random depends on how the device is triggered.

4.2.1.4.2 Limits

In a period of 1 hour the duty cycle shall not exceed 10 %.

4.2.1.4.3 Conformance

Conformance is based on the manufacturers declaration that the duty cycle limit is met. See clause 5.3.4.

4.2.2 Receiver requirements

4.2.2.1 Receiver Blocking or Desensitization

4.2.2.1.0 Receiver Classification

The product family of ULP-AMI radio devices is divided into three receiver classes, see table 4, each having its own set of minimum performance criteria. This classification is based upon the impact on persons in case the equipment does not operate above the specified minimum performance level. Applicable equipment classification shall be specified by the manufacturer.

Table 4

Receiver class	Risk assessment of receiver performance
1	Highly reliable ULP-AMI communication media; e.g. serving human life inherent systems (may result in a physical risk to a person)
2	Medium reliable ULP-AMI communication media; e.g. when a failure to operate causes inconvenience to persons, which cannot simply be overcome by other means
3	Standard reliable ULP-AMI communication media; e.g. when a failure to operate causes inconvenience to persons, which can simply be overcome by other means (e.g. manual)
NOTE: In particular where an ULP-AMI-M which may have an inherent safety of human life implication, manufacturers and users should pay particular attention to the potential for interference from other systems operating in the same or adjacent bands.	

For the purpose of the receiver performance tests, the receiver shall produce an appropriate output under normal conditions. Where the indicated performance cannot be achieved or if it is defined differently, the manufacturer shall declare and publish the performance criteria used to determine the performance of the receiver.

4.2.2.1.1 Definition

Blocking is a measure of the capability of the receiver to receive a wanted signal without exceeding a given degradation due to the presence of an unwanted input signal at frequencies other than those of the spurious responses in adjacent channels or bands (see clause 3.1).

4.2.2.1.2 Limits

The blocking level, for any frequency within the specified ranges, shall not be less than the values given in table 5, except at frequencies on which spurious responses are found.

Table 5

Receiver class	Frequency offset (MHz)	Limit
1	All offsets	30 dB
2	±1	21 dB
	±2	25 dB
	±5	25 dB
	±10	26 dB

Class 3 receivers are exempt from this requirement.

4.2.2.1.3 Conformance

Conformance tests as defined in clause 5.3.5 shall be carried out.

4.2.2.2 Receiver Spurious radiation

4.2.2.2.1 Definition

Spurious radiations from receivers are emissions radiated from the antenna, the chassis and case of the receiver (see clause 3.1). It is specified as the radiated power of a discrete signal. Included in this definition are modulation products that are outside the 20 dB down point on either side of the fundamental emission.

4.2.2.2.2 Limits

The mean power in the reference bandwidth of any spurious radiation of the receiver, shall not exceed the value given in tables 2 and 3.

The following reference bandwidths should be used:

- 1 kHz between 9 kHz and 150 kHz;
- 10 kHz between 150 kHz and 30 MHz;
- 100 kHz between 30 MHz and 1 GHz.

The limit is applicable to all receiver classes.

4.2.2.2.3 Conformance

Conformance tests as defined in clause 5.3.6 shall be carried out.

4.3 Mechanical and electrical design

4.3.1 General

The equipment shall be designed, constructed and manufactured in accordance with sound engineering practice and with the aim of minimizing harmful interference to other equipment and services and should not receive harmful interference from other electronic devices. Transmitters and receivers may be individual or combination units.

4.3.2 Controls

Those controls that, if maladjusted, might increase the interference potentialities of the equipment shall not be easily accessible to the user.

4.3.3 Transmitter shut-off facility

If the transmitter is equipped with an automatic transmitter shut-off facility or battery-saving feature and it interferes with testing of the device, it shall be capable of being made inoperative for the purpose of testing.

5 Testing for compliance with technical requirements

5.1 Environmental conditions for testing

5.1.0 General provisions

Tests defined in the present document shall be carried out at representative points within the boundary limits of the declared operational environmental profile.

Where technical performance varies subject to environmental conditions, tests shall be carried out under a sufficient variety of environmental conditions (within the boundary limits of the declared operational environmental profile) to give confidence of compliance for the affected technical requirements.

5.1.1 Presentation of equipment for testing purposes

5.1.1.0 General provisions

Each equipment submitted for testing shall fulfil the requirements of the present document on all frequencies over which it is intended to operate. Compliance with this requirement should be shown by testing each unit.

The provider shall complete the appropriate application form when submitting the equipment for testing. In addition, the provider shall declare the range of operating conditions and power requirements, as applicable; to establish the appropriate test conditions.

Additionally, technical documentation and operating manuals, sufficient to make the test, shall be supplied for all ULP-AMI-M-P and ULP-AMI-M devices.

A human torso or simulator and tissue substitute material for testing ULP-AMI may be used (see clause B.1.1.3).

Measurements shall be performed, according to the present document, on samples of equipment defined in clauses 5.1.1.1 to 5.1.1.3.3.

5.1.1.1 Choice of model for testing

The provider shall supply one or more samples of each model or type of transmitter (ULP-AMI-M and/or ULP-AMI-M-P), as appropriate for testing. Any ancillary equipment needed for testing shall be provided as requested by the testing laboratory.

If an equipment has several optional features, considered not to affect the RF parameters, then the tests need only to be performed on the equipment configured with that combination of features considered to be the most complex or most likely to affect the RF parameters, as proposed by the provider and agreed to by the test laboratory.

5.1.1.2 Testing of equipment with alternate power levels

Equipment designed to operate with different carrier powers shall have each transmitter parameter tested on samples of equipment defined in clause 5.1.1.1. See clause 5.3 for details on testing. Spurious domain emissions tests shall be performed in accordance with requirements in clause 5.3.1.3.

5.1.1.3 Testing of equipment that does not have an external RF connector (integral antenna equipment)

5.1.1.3.0 General Provision

This type of equipment will normally be tested by performing radiated tests at 3 m. For devices with very low radiated field levels, measurements may be made at closer distance and the levels extrapolated to 3 m using an inverse linear extrapolation rate.

5.1.1.3.1 Equipment with an internal permanent or temporary antenna connector

The means to access and/or implement the internal permanent or temporary antenna connector shall be stated by the applicant with the aid of a diagram. The fact that use has been made of the internal antenna connection, or of a temporary connection, to facilitate measurements shall be recorded in the test report.

5.1.1.3.2 Equipment with a temporary antenna connector

The applicant may submit one set of equipment with the normal antenna connected, to enable radiated measurements to be made. The applicant shall attend the test laboratory at the conclusion of the radiated measurements, to disconnect the antenna and fit the temporary connector if needed. The testing laboratory staff shall not connect or disconnect any temporary antenna connector.

Alternatively, the applicant may submit two sets of equipment to the test laboratory, one fitted with a temporary antenna connector with the antenna disconnected and another with the antenna connected. Each equipment shall be used for the appropriate tests. The applicant shall declare that the two sets of equipment are identical in all aspects except for the antenna connector.

5.1.1.3.3 Equipment intended to be implanted in a human body

The provider shall submit the equipment, a human torso simulator if needed as described in clause 5.1.4.8 and annex B, and a sufficient quantity of tissue substitute material to fill the test fixture. The provider and/or test laboratory shall determine and agree on the arrangement of the equipment antenna and any additional device leads on the AIMD holding grid within the fixture as prescribed in annex B.

5.1.2 Declaration by the applicant

When submitting equipment for testing, the applicant shall supply the necessary information required by the test laboratory.

The performance of the equipment submitted for testing shall be a representative of a sample of the equipment.

5.1.3 Auxiliary test equipment

All necessary test signal sources, test fixtures, specialized test apparatus and set-up information shall accompany the equipment when it is submitted for type testing unless alternative arrangements are agreed to by the test laboratory and the manufacturer.

5.1.4 Test Conditions

5.1.4.1 Normal and extreme test conditions

Testing shall be made under normal test conditions, and also, where stated, under extreme test conditions. It should be noted that emissions test on ULP-AMI-M may be performed using the human torso simulator with the tissue substitute material at nominal room temperature. Measured emission levels are not expected to vary significantly from the nominal temperature of 37 °C.

The test conditions and procedures shall be as specified in clauses 5.1.4.2 to 5.1.4.10.

5.1.4.2 Test power source

5.1.4.2.0 General provisions

The equipment shall be tested using the appropriate test power source as specified in clauses 5.1.4.2.1 or 5.1.4.2.2. Where equipment can be powered using either external or internal power sources, the equipment shall be tested using the external power source as specified in clause 5.1.4.2.1 then repeated using the internal power source as specified in clause 5.1.4.2.2.

The test power source used shall be stated in the test report.

5.1.4.2.1 External test power source

During tests, the power source of equipment shall be replaced by an external test power source capable of producing normal and extreme test voltages as specified in clauses 5.1.4.3.2 and 5.1.4.4.2 if possible. The internal impedance of the external test power source shall be low enough for its effect on the test results to be negligible. For the purpose of the tests, the voltage of the external test power source shall be measured at the input terminals of the equipment. The external test power source shall be suitably de-coupled as close to the equipment battery terminals as practicable. For radiated measurements any external power leads should be so arranged so as not to affect the measurements.

During tests the test power source voltages shall be within a tolerance of < ±1 % relative to the voltage at the beginning of each test. The value of this tolerance can be critical for certain measurements. Using a smaller tolerance will provide a better uncertainty value for these measurements.

5.1.4.2.2 Internal test power source

For radiated measurements on portable equipment with integral antenna, fully charged internal batteries should be used. The batteries used should be as supplied or recommended by the applicant. If internal batteries are used, at the end of each test the voltage shall be within a tolerance of < ±5 % relative to the voltage at the beginning of each test. For portable devices where the batteries cannot be measured or replaced but have telemetry readout of battery voltage, it is acceptable to record the starting and ending voltages as provided by the telemetry readout. This shall be stated in the test report.

If appropriate, for conducted measurements or where a test fixture is used, an external power supply at the required voltage may replace the supplied or recommended internal batteries. This shall be stated on the test report.

Equipment intended to be implanted in a human body may be hermetically sealed or packaged in a manner where it may not be possible to measure the battery or other voltage source directly or indirectly. For this type of equipment, it is not necessary to measure the voltage; however, care shall be taken to ensure that the internal power supply voltage does not fall below the manufacturer's specification for normal operating voltage range.

5.1.4.3 Normal test conditions

5.1.4.3.1 Normal temperature and humidity

The normal temperature and humidity conditions for ULP-AMI-M-P shall be any convenient combination of temperature and humidity within the following ranges:

- temperature +15 °C to +37 °C;
- relative humidity 20 % to 75 %.

ULP-AMI operate after implant in a human body. Accordingly, the body tends to serve as an oven to maintain the implant temperature near 35 °C. Therefore, the normal temperature and humidity conditions for ULP-AMI shall be within the following ranges:

- temperature +36 °C to +38 °C;
- relative humidity does not apply.

When it is impracticable to carry out tests under these conditions, a note to this effect, stating the ambient temperature and relative humidity during the tests shall be added to the test report.

5.1.4.3.2 Normal test power source

5.1.4.3.2.1 Mains voltage

The normal test voltage for equipment to be connected to the mains shall be the nominal mains voltage. For the purpose of the present document, the nominal voltage shall be the declared voltage, or any of the declared voltages, for which the equipment was designed.

The frequency of the test power source corresponding to the ac mains shall be between 49 Hz and 51 Hz.

5.1.4.3.2.2 Regulated lead-acid battery power sources

When the radio equipment is intended for operation with the usual types of regulated lead-acid battery power source, the normal test voltage shall be 1,1 multiplied by the nominal voltage of the battery (e.g. 6 V, 12 V, etc.).

5.1.4.3.2.3 Other power sources

For operation from other power sources or types of battery (primary or secondary), the normal test voltage shall be that declared by the equipment provider and agreed by the test laboratory. Such values shall be stated in the test report.

5.1.4.4 Extreme test conditions

5.1.4.4.1 Extreme temperatures

5.1.4.4.1.1 Procedure for tests at extreme temperatures

5.1.4.4.1.1.0 General conditions

Before measurements are made, the equipment shall have reached thermal balance in the test chamber. The equipment shall be switched off during the temperature-stabilizing period.

In the case of equipment containing temperature stabilization circuits designed to operate continuously, the temperature stabilization circuits shall be switched on for 15 minutes after thermal balance has been obtained, and the equipment shall then meet the specified requirements.

If the thermal balance is not checked by measurements, a temperature-stabilizing period of at least one hour, or such period as may be decided by the test laboratory, shall be allowed. The sequence of measurements shall be chosen, and the humidity content in the test chamber shall be controlled so that excessive condensation does not occur.

If the equipment is incapable of transmitting an unmodulated carrier, an actual digital data sequence or a pseudorandom sequence representative of an actual digital data transmission shall be used to modulate the carrier (see clause 5.1.4.5).

5.1.4.4.1.1.1 Procedure for equipment designed for continuous operation

If the applicant states that the equipment is designed for continuous operation, the test procedure shall be as follows:

- before conducting tests at the upper extreme temperature the equipment shall be placed in the test chamber and left until thermal balance is attained. The equipment shall then be switched on in the transmit condition for a period of time specified by the manufacturer to be the maximum time the equipment will transmit in normal operation after which the equipment shall meet the specified requirements;
- for tests at the lower extreme temperature, the equipment shall be left in the test chamber until thermal balance is attained, then switched on for a period of one minute after which the equipment shall meet the specified requirements.

5.1.4.4.1.1.2 Procedure for equipment designed for intermittent operation

If the applicant states that the equipment is designed for intermittent operation, the test procedure shall be as follows:

- before tests at the upper extreme temperature the equipment shall be placed in the test chamber and left until thermal balance is attained in the oven. The equipment shall then either:
  - transmit on and off according to the applicants declared duty cycle for a period of five minutes; or
  - if the applicant's declared on period exceeds one minute, then transmit in the on condition for a period not exceeding one minute, followed by a period in the off or standby mode for four minutes; after which the equipment shall meet the specified requirements;
- for tests at the lower extreme temperature, the equipment shall be left in the test chamber until thermal balance is attained, then switched to the standby or receive condition for one minute after which the equipment shall meet the specified requirements.

5.1.4.4.1.2 Extreme temperature ranges

For tests at extreme temperatures, measurements shall be made in accordance with the procedures specified at the upper and lower temperatures of one of the following ranges.

Table 6: Extreme Temperature Ranges

Category I (General):	-20 °C to +55 °C
Category II (Portable equipment for outdoor use):	-10 °C to +55 °C
Category III (Equipment for normal indoor use) (see note 1):	0 °C to +55 °C
Category IV (Active Medical Implant membrane transmitters) (see note 2):	+25 °C to +45 °C
NOTE 1: The term "equipment for normal indoor use" is taken to mean that the room temperature is controlled and the minimum indoor temperature is equal to or greater than 5 °C.	
NOTE 2: The term "Active Medical Implant membrane transmitters" refers only to equipment that is intended to be placed inside a human body during normal operation. The range of +25 °C to +45 °C is the core body temperature variation over which a human body can survive [i.5].	

The manufacturer may define a different temperature range than specified above for any category provided the EUT meets the conditions set forth below. For specific applications, the manufacturer can specify wider temperature ranges than given as a minimum above. In this case the test report shall show compliance with the limits in the present document over the extended ranges specified by the manufacturer. This shall be reflected in the manufacturers' product literature. Narrower temperature ranges than given above may be implemented provided the reduced range is reflected in the manufacturer's product literature and the test report shows that the device implements techniques which do not allow it to exceed the limits specified in the present document over the minimum ranges given in table 6.

5.1.4.4.2 Extreme test source voltages

5.1.4.4.2.1 Mains voltage

The extreme test voltages for equipment to be connected to an alternating current mains source shall be the nominal mains voltage ±10 %. For equipment operating over a range of mains voltages clause 5.1.4.3.2.1 applies.

5.1.4.4.2.2 Regulated lead-acid battery power sources

When any peripheral device or radio equipment that is part of a membrane implant system is intended for operation from the usual type of regulated lead-acid battery power sources the extreme test voltages shall be 1,3 and 0,9 multiplied by the nominal voltage of the battery (6 V, 12 V, etc.).

For float charge applications using "gel-cell" type batteries the extreme voltage shall be 1,15 and 0,85 multiplied by the nominal voltage of the declared battery voltage.

5.1.4.4.2.3 Power sources using other types of batteries

The lower extreme test voltages for equipment with power sources using batteries shall be as follows:

- for equipment with a battery indicator, the end point voltage as indicated;
- for equipment without a battery indicator the following end point voltages shall be used:

  a) or the Leclanché or the lithium type of battery:

     - 0,85 multiplied by the nominal voltage of the battery;

  b) for the nickel-cadmium type of battery:

     - 0,9 multiplied the nominal voltage of the battery;
     - for other types of battery or equipment, the lower extreme test voltage for the discharged condition shall be declared by the equipment applicant.

The nominal voltage is considered to be the upper extreme test voltage in this case.

5.1.4.4.2.4 Other power sources

For equipment using other power sources, or capable of being operated from a variety of power sources, the extreme test voltages shall be according to manufactures specification.

5.1.4.5 Normal test signals and test modulation

5.1.4.5.0 General provisions

The test modulating signal is a signal which modulates a carrier, is dependent upon the type of equipment under test and also the measurement to be performed. Modulation test signals only apply to products with an external modulation connector. For equipment without an external modulation connector, normal operating modulation shall be used.

5.1.4.5.1 Normal modulation test signals for data

Normal test signals for data are specified as follows:

- D-M2: A test signal representing a pseudo-random bit sequence of at least 511 bits in accordance with Recommendation ITU-T O.153 [i.8]. This sequence shall be continuously repeated. If the sequence cannot be continuously repeated, the actual method used shall be stated in the test report.
- D-M3: A test signal shall be agreed between the test laboratory and the applicant in case selective messages are used and are generated or decoded within the equipment.

The agreed test signal may be formatted and may contain error detection and correction.

For angle modulation, the normal level of the test signal D-M3 shall produce a deviation of 20 % of the channel separation or any other value as declared by the applicant as the normal operating level.

For other forms of modulation, the applicant will provide the modulation source as applicable.

5.1.4.6 Antennas

5.1.4.6.0 General provisions

Equipment operating in the 30 MHz to 37,5 MHz band shall have an integral antenna, an external dedicated antenna or both. If provision for an external antenna connection is made, the connector shall be a unique type to prevent use of an antenna other than a dedicated antenna supplied by the manufacturer. The device will be configured as specified by the manufacturer in normal operation. Use of a human volunteer in the test setup is acceptable if desired.

5.1.4.6.1 Artificial antenna

An artificial antenna that simulates the actual antenna configuration specified by the applicant may be used only as necessary. The test laboratory and the manufacturer shall agree as to the arrangement.

5.1.4.6.2 Artificial antenna for transmitters with 50 Ω impedance connector

With equipment intended for use with an integral antenna, and not equipped with a 50 Ω RF output connector, a suitable test fixture may be used as agreed with the test laboratory, if radiated measurements with the intended antenna cannot be made.

This fixture is a RF coupling device for coupling the integral antenna to a 50 Ω RF terminal at the working frequencies of the equipment under test. This allows certain measurements to be performed using conducted measuring methods. However, only relative measurements may be performed. The test fixture is normally only required for extreme temperature measurements and shall be calibrated only with the equipment under test.

The test fixture shall be fully described by the applicant. The test laboratory, where applicable shall calibrate the test fixture by carrying out the required field measurements at normal temperatures at the prescribed test site. Then the same measurements shall be repeated on the equipment under test using the test fixture for all identified frequency components.

In addition, the test fixture may provide:

- a connection to an external power supply;
- a connection to a data interface.

The performance characteristics of the test fixture shall be agreed upon with the test laboratory, where applicable and shall conform to the following basic parameters:

- the circuit associated with the RF coupling shall contain no active or non linear devices;
- the coupling loss shall not influence the measuring results;
- the coupling loss shall be independent of the position of the test fixture and be unaffected by the proximity of the surrounding objects or people;
- the coupling loss shall be reproducible when the equipment under test is removed and replaced;
- the coupling loss shall remain substantially constant when the environmental conditions are varied.

5.1.4.7 Test fixture for ULP-AMI-M-P

With equipment intended for use with an integral antenna, and not equipped with a 50 Ω RF output connector, a suitable test fixture may be used as agreed with the test laboratory.

This fixture is a RF coupling device for coupling the integral antenna to a 50 Ω RF terminal at the working frequencies of the equipment under test. This allows certain measurements to be performed using conducted measuring methods.

However, only relative measurements may be performed. The test fixture is normally only required for extreme temperature measurements and shall be calibrated only with the equipment under test.

The test fixture shall be fully described by the provider. The test laboratory shall calibrate the test fixture by carrying out the required field measurements at normal temperatures at the prescribed test site. Then the same measurements shall be repeated on the equipment under test using the test fixture for all identified frequency components.

In addition, the test fixture may provide:

- a connection to an external power supply;
- a connection to a data interface.

The performance characteristics of the test fixture shall be agreed upon with the test laboratory and shall conform to the following basic parameters:

- the circuit associated with the RF coupling shall contain no active or non-linear devices;
- the coupling loss shall not influence the measuring results;
- the coupling loss shall be independent of the position of the test fixture and be unaffected by the proximity of the surrounding objects or people;
- the coupling loss shall be reproducible when the equipment under test is removed and replaced;
- the coupling loss shall remain substantially constant when the environmental conditions are varied.

5.1.4.8 Test fixture for ULP-AMI-M

For measurement purposes, to determine compliance with all emission limits, AIMD may be tested in a fixture that approximates the physical conditions of an ULP-AMI-M placed in a human body. This fixture, a human torso simulator, with the ULP-AMI-M mounted inside, shall be filled with a tissue substitute material and placed on the radiated emissions test site turntable with the ULP-AMI-M at a height of 1,5 m above the ground plane for testing purposes. The tissue substitute material shall be sufficiently fluid that it will flow around the ULP-AMI-M without creating any voids. Please refer to annex B for further guidance.

5.1.4.9 Test sites and general arrangements for radiated measurements

For guidance on radiation test sites, see annex B. Detailed descriptions of radiated measurement arrangements are included in annex B.

5.1.4.10 Modes of operation of the transmitter

For the purpose of the measurements according to the present document, there should preferably be a facility to operate the transmitter in an unmodulated state. The method of achieving an unmodulated carrier frequency or special types of modulation patterns may also be decided by agreement between the applicant and the test laboratory. It shall be described in the test report. It may involve suitable temporary internal modifications of the equipment under test. If it is not possible to provide an unmodulated carrier then this shall be stated in the test report.

For the purpose of testing, the normal test signal, see clause 5.1.4.3.1, shall be applied to the input of the transmitter under test with the normal input device disconnected when possible.

5.1.4.11 Measuring receiver

The term "measuring receiver" refers to a selective voltmeter or a spectrum analyser. The bandwidth and detector type of the measuring receiver are given in table 7. Measurements of all emissions up to 1 000 MHz shall be performed.

Table 7

Frequency (f)	Detector type	Bandwidth
9 kHz ≤ f < 150 kHz	RMS	200 Hz to 300 Hz
150 kHz ≤ f < 30 MHz	RMS	9 Hz to 10 kHz
30 MHz ≤ f < 1 000 MHz	RMS	120 kHz

Exceptionally, a different bandwidth may be used for narrow band signals if agreed with the test laboratory. This shall be stated in the test report.

5.2 Interpretation of the measurement results

The interpretation of the results recorded in a test report for the measurements described in the present document shall be as follows:

- the measured value related to the corresponding limit will be used to decide whether an equipment meets the requirements of the present document;
- the value of the measurement uncertainty for the measurement of each parameter shall be included in the test report;
- the recorded value of the measurement uncertainty shall be, for each measurement, equal to or lower than the figures in table 8.

For the test methods, according to the present document, the measurement uncertainty figures shall be calculated in accordance with ETSI TR 100 028 [i.2] and shall correspond to an expansion factor (coverage factor) k = 1,96 or k = 2 (which provide confidence levels of respectively 95 % and 95,45 % in the case where the distributions characterizing the actual measurement uncertainties are normal (Gaussian)).

Table 8 is based on such expansion factors.

Table 8: Maximum measurement uncertainty

RF frequency	$\pm 1 \times 10^{-7}$
RF power, conducted	±1 dB
RF power, radiated	±6 dB
Temperature	±1 °C
Humidity	±5 %
Voltage	±5 %

5.3 Methods of measurement

5.3.1 Maximum Effective Radiated Power

This method applies to equipment with dedicated internal or external antenna and equipment with an external antenna connector. All supplied antennas shall be tested.

Step 1: On a test site, selected from annex B, the equipment shall be placed at the specified height on a non-conducting support and in the position closest to normal use as declared by the provider. Stepped or swept frequency systems shall be tested with the stepping or sweep disabled.

Step 2: The transmitter antenna connector shall be connected to a supplied antenna either internally or externally. The test antenna shall be connected to a measuring receiver and orientated for vertical polarization and the length of the test antenna shall be chosen to correspond to the frequency of the measuring receiver.

Step 3: In the case of pulse modulation the transmitter shall be switched on with test modulation D-M2 (see clause 5.1.4.5.1).

If this is not possible, then the measurements shall be made with the transmitter modulated by the normal modulation or a test signal D-M3, see clause 5.1.4.5.1 in which case the fact shall be recorded in the test report.

The measuring receiver shall be tuned to the fundamental emission frequency.

Step 4: The test antenna shall be raised and lowered through the specified range of heights until a maximum signal level is detected on the measuring receiver.

Step 5: The transmitter shall then be rotated through 360° in the horizontal plane, until the maximum radiated signal level is detected by the measuring receiver and the test antenna height shall be adjusted again for maximum signal level.

Step 6: The maximum signal level detected by the measuring receiver for vertical polarization shall be noted.

Step 7: The transmitter shall be replaced by a substitution antenna as defined in clause B.1.3.

The substitution antenna shall be orientated for vertical polarization and calibrated for the frequency of the emission. The substitution antenna shall be connected to a calibrated signal generator. The frequency of the calibrated signal generator shall be set to the frequency of the fundamental emission. The input attenuator setting of the measuring receiver shall be adjusted in order to increase the sensitivity of the measuring receiver, if necessary.

Step 8: The test antenna shall be raised and lowered through the specified range of heights to ensure that the maximum signal is received. When a fully anechoic test site annex B is used, the height of the antenna need not be varied.

Step 9: The input signal to the substitution antenna shall be adjusted with the signal generator to the level that produces a level detected by the measuring receiver, that is equal to the level noted under step 6.

Step 10: The input level to the substitution antenna shall be recorded as the maximum power level. This level may needs to be corrected to determine an average power level during the interval of transmission to determine compliance.

Step 11: The measurements step 1 to step 10 shall be repeated with the test antenna and the substitution antenna orientated for horizontal polarization.

Step 12: The effective radiated power is the highest of the two power levels recorded at the input to the substitution antenna, corrected to determine the maximum average power level and for the gain of the substitution antenna if necessary.

If applicable, the measurements shall be repeated with the transmitter on standby. The measuring bandwidth and detector type of the measurement receiver shall be in accordance with clause 5.1.4.11.

5.3.2 Out of band emissions

The transmitter shall be connected to all manufacturer supplied antenna(s). The spectrum analyser shall be connected to a linearly polarized antenna placed at any convenient distance from the transmitter antenna.

The transmitter shall be operated at the nominal carrier power or field strength measured under normal test conditions in clause 5.1.4.3. The attenuator shall be adjusted to an appropriate level displayed at the spectrum analyser screen.

The transmitter shall be modulated with standard test modulation if applicable. If the equipment cannot be modulated externally, the internal modulating signal shall be used.

For transmitters using a continuous wideband swept or stepped carrier the measurement shall be made with the sweep or stepping on.

The output of the transmitter, with or without test fixture, shall be displayed using a spectrum analyser with a resolution bandwidth appropriate to accept all major side bands. Normally this would be a resolution bandwidth setting of approximately 1 % of the 20 dB bandwidth. From the spectrum analyzer, determine and record the maximum Out of band emission. The measured power level recorded shall be compared with the limit in clause 4.2.1.2.2 to determine compliance. The test laboratory shall ensure that the spectrum analyser's span is sufficiently wide enough to ensure that the carrier and all its major side bands are captured.

5.3.3 Unwanted Emissions in the spurious domain

This method applies only to equipment with an external antenna connector or permanently connected antenna. Stepped or swept frequency systems shall be tested with the stepping or sweep disabled.

Step 1: On a test site, selected from annex B, the equipment shall be placed at the specified height on a non-conducting support with the antenna and other apparatus in a position closest to normal use as declared by the provider.

Step 2: If applicable, the transmitter antenna connector shall be connected to the antenna supplied with the unit. The test antenna shall be orientated for vertical polarization and the length of the test antenna shall be chosen to correspond to the instantaneous frequency of the measuring receiver. The output of the test antenna shall be connected to the measuring receiver. In the case of pulse modulation the transmitter shall be switched on with test modulation D-M2. (see clause 5.1.4.5.1). If this is not possible, then the measurements shall be made with the transmitter modulated by the normal (internally generated modulation) signal or the test signal D-M3 (see clause 5.1.4.5.1) in which case the fact shall be recorded in the test report.

The measuring receiver shall be tuned over the frequency range 9 kHz to 1 GHz except for the channel on which the transmitter is intended to operate and any adjacent channels.

Step 3: At each frequency at which an unwanted emission in the spurious domain component is detected, the test antenna shall be raised and lowered through the specified range of heights until a maximum signal level is detected on the measuring receiver.

The transmitter shall then be rotated through 360° in the horizontal plane, until the maximum radiated signal level is detected by the measuring receiver and the test antenna height shall be adjusted again for maximum signal level.

Step 4: The maximum signal level detected by the measuring receiver for vertical polarization shall be noted.

Step 5: The transmitter shall be replaced by a substitution antenna as defined in clause B.1.3.

Step 6: The substitution antenna shall be orientated for vertical polarization and calibrated for the frequency of the unwanted emissions in the spurious domain component detected.

The substitution antenna shall be connected to a calibrated signal generator.

The frequency of the calibrated signal generator shall be set to the frequency of the unwanted emissions in the spurious domain component detected. The input attenuator setting of the measuring receiver shall be adjusted in order to increase the sensitivity of the measuring receiver, if necessary.

Step 7: The test antenna shall be raised and lowered through the specified range of heights to ensure that the maximum signal is received. When a fully anechoic test site according to annex B is used, the height of the antenna need not be varied.

The input signal to the substitution antenna shall be adjusted with the signal generator to the level that produces a level detected by the measuring receiver, that is equal to the level noted under step 4.

Step 8: The input level to the substitution antenna shall be recorded as the maximum power level and this level is corrected to determine an average power level during the interval of transmission to determine compliance.

Step 9: The measurements step 1 to step 8 shall be repeated with the test antenna and the substitution antenna orientated for horizontal polarization.

Step 10: The measure of the effective radiated power of the unwanted emissions in the spurious domain components is the highest of the two power levels recorded for each component at the input to the substitution antenna, corrected to determine the maximum average power level and for the gain of the substitution antenna if necessary.

If applicable, the measurements shall be repeated with the transmitter on standby.

For transmitters with an adjustable power level, the equipment shall be adjusted to the highest and lowest setting, as declared by the applicant, and the unwanted emissions in the spurious domain measurements shall be repeated.

5.3.4 Duty Cycle

For manually activated or event dependent devices, with or without software controlled functions, the applicant shall declare whether the device once triggered, follows a pre-programmed cycle, or whether the transmission is constant until the activation mechanism is released or otherwise reset. The applicant shall also give a description of the application for the device and include a typical usage pattern for maximizing duty cycle that would occur in a period of 1 hour. The typical usage pattern as declared by the applicant shall be used to determine the duty cycle. Where an acknowledgement is required, the additional transmitter on-time shall be included and declared by the manufacturer.

5.3.5 Receiver Blocking or desensitization

This measurement shall be conducted under normal conditions.

Step 1: If possible, two signal generators A and B shall be connected to the receiver via a combining network to the receiver either:

a) via a test fixture or a test antenna that close couples to the receiver integral or dedicated antenna; or

b) via a test fixture directly to the receiver permanent or temporary antenna connector.

If this is not possible the method of coupling to the receiver shall be stated in the test report.

Step 2: Signal generator A shall be at the nominal frequency of the receiver, with normal modulation of the wanted signal. Signal generator B shall be unmodulated . Initially signal generator B shall be switched off.

Step 3: Signal generator A shall then be switched on until the wanted criterion is just met: the minimum level giving sufficient response shall be established. For purposes of this test, the minimum level giving sufficient response are met as long as the receiver always protects the health and safety of the patient. For example, techniques that accomplish this may detect corrupted data and mark it as invalid data or the data link may cease functioning during this phase of the testing in which case the non-functioning of the device can be easily overcome by other means such as use of a manual blood pressure cuff. The nature of the technique used to protect the patient and the level at which it functions to provide this protection shall be stated in the test report.

Step 4: The output level of signal generator A shall then be increased by 3 dB if possible. In some cases it may not be possible to use an external modulated source in which case the wanted signal (A) shall be the normal signal level from the implant for reference purposes.

Step 5: The output power of signal generator A shall be noted.

Step 6: Signal generator B is then switched on at approximately +1 MHz from the upper band edge. Signal generator B should then be adjusted in output level until the wanted criteria are just met.

Step 7: The output power of signal generator B shall be noted.

Step 8: The blocking level shall be recorded as the difference between the power level from step 7 and step 5.

Step 9: The measurements shall be repeated at approximately +2 MHz, +5 MHz and +10 MHz from the upper band edge and at approximately -1 MHz, -2 MHz, -5 MHz and -10 MHz from the lower band edge.

5.3.6 Receiver Spurious radiation

This method applies to equipment with an external antenna connector or permanently connected antenna.

On a test site, selected from annex B, the equipment shall be placed at the specified height on a non-conducting support and in the position closest to normal use as declared by the provider.

The test antenna shall be orientated for vertical polarization and the length of the test antenna shall be chosen to correspond to the instantaneous frequency of the measuring receiver. The output of the test antenna shall be connected to a measuring receiver. The receiver shall be switched on and the measuring receiver shall be tuned over the frequency range 25 MHz to 1 000 MHz. At each frequency at which a spurious component is detected, the test antenna shall be raised and lowered through the specified range of height until a maximum signal level is detected by the measuring receiver. When a fully anechoic test site according to annex B is used, there is no need to vary the height of the measurement antenna.

The transmitter shall then be rotated through 360° in the horizontal plane, until the maximum signal level is detected by the measuring receiver and the test antenna height shall be adjusted again for maximum signal level.

The maximum signal level detected by the measuring receiver shall be noted.

The receiver shall be replaced by a substitution antenna as defined in clause B.1.3.

The substitution antenna shall be orientated for vertical polarization and calibrated for the frequency of the spurious component detected.

The substitution antenna shall be connected to a calibrated signal generator.

The frequency of the calibrated signal generator shall be set to the frequency of the spurious component detected.

The input attenuator setting of the measuring receiver shall be adjusted in order to increase the sensitivity of the measuring receiver, if necessary.

The test antenna shall be raised and lowered through the specified range of height to ensure that the maximum signal is received. The input signal to the substitution antenna shall be adjusted to the level that produces a level detected by the measuring receiver, that is equal to the level noted while the spurious component was measured, corrected for any change of input attenuator setting of the measuring receiver. The input level to the substitution antenna shall be recorded as power level, corrected for any change of input attenuator setting of the measuring receiver.

The measurement shall be repeated with the test antenna and the substitution antenna orientated for horizontal polarization.

Annex A (normative): Relationship between the present document and the essential requirements of Directive 2014/53/EU

The present document has been prepared under the Commission's standardisation request C(2015) 5376 final [i.7] to provide one voluntary means of conforming to the essential requirements of Directive 2014/53/EU on the harmonisation of the laws of the Member States relating to the making available on the market of radio equipment and repealing Directive 1999/5/EC [i.1].

Once the present document is cited in the Official Journal of the European Union under that Directive, compliance with the normative clauses of the present document given in table A.1 confers, within the limits of the scope of the present document, a presumption of conformity with the corresponding essential requirements of that Directive, and associated EFTA regulations.

Table A.1: Relationship between the present document and the essential requirements of Directive 2014/53/EU

Harmonised Standard ETSI EN 302 510 The following essential requirements are relevant to the presumption of conformity under article 3.2 of Directive 2014/53/EU [i.1]				
Requirement			**Requirement Conditionality**	
No	**Description**	**Reference: Clause No**	**U/C**	**Condition**
1	Effective radiated power of the fundamental emission	4.2.1.1	U	
2	Out of band emissions	4.2.1.2	U	
3	Unwanted emissions in the spurious domain (of transmitters)	4.2.1.3	U	
4	Duty Cycle	4.2.1.4	U	
5	Receiver blocking or desensitization	4.2.2.1	U	
6	Receiver Spurious radiation	4.2.2.2	U	

Key to columns:

Requirement:

No A unique identifier for one row of the table which may be used to identify a requirement.

Description A textual reference to the requirement.

Clause Number Identification of clause(s) defining the requirement in the present document unless another document is referenced explicitly.

Requirement Conditionality:

U/C Indicates whether the requirement shall be unconditionally applicable (U) or is conditional upon the manufacturer's claimed functionality of the equipment (C).

Condition Explains the conditions when the requirement shall or shall not be applicable for a requirement which is classified "conditional".

Presumption of conformity stays valid only as long as a reference to the present document is maintained in the list published in the Official Journal of the European Union. Users of the present document should consult frequently the latest list published in the Official Journal of the European Union.

Other Union legislation may be applicable to the product(s) falling within the scope of the present document.

Annex B (normative): Radiated Measurement

B.1 Test sites and general arrangements for measurements involving the use of radiated fields

B.1.1 Outdoor test site

B.1.1.0 General remarks

The outdoor test site shall be on a reasonably level surface or ground. For measurements at frequencies 25 MHz and above, a conducting ground plane of at least 5 m diameter shall be provided at one point on the site. In the middle of this ground plane, a non-conducting support, capable of rotation through 360° in the horizontal plane, shall be used to support the test sample in its standard position, at 1 m above the ground plane. The test site shall be large enough to allow the erection of a measuring or transmitting antenna at a distance of $\lambda/2$ m or 3 m whichever is greater. The distance actually used shall be recorded with the results of the tests carried out on the site.

Sufficient precautions shall be taken to ensure that reflections from extraneous objects adjacent to the site do not degrade the measurement results according to the specification of CISPR 16-2-3 [1].

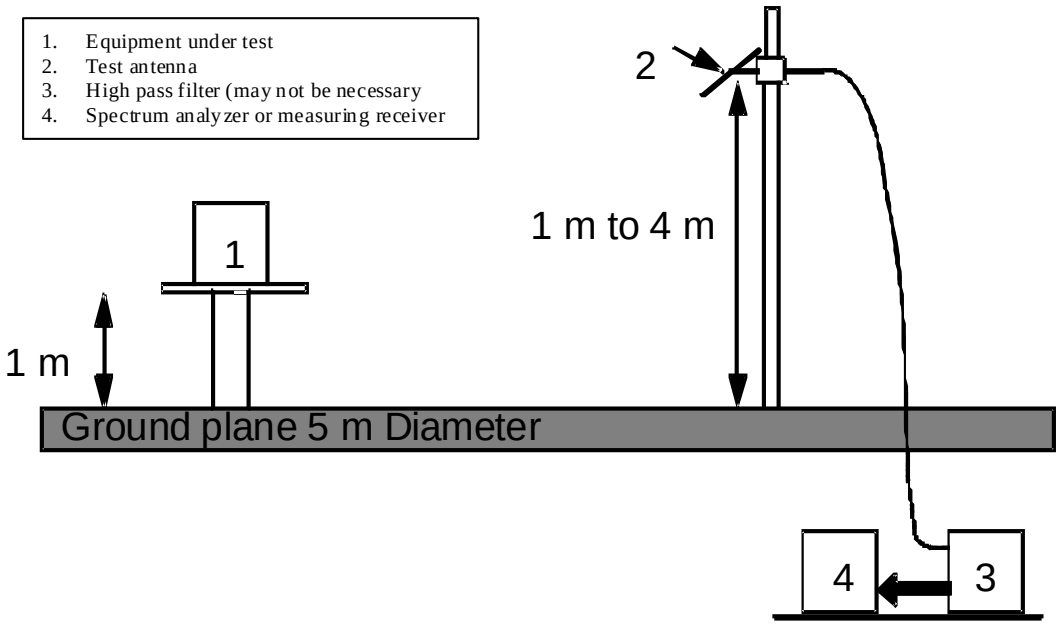


Figure B.1

B.1.1.1 Standard position

The standard position for all programmer/control transmitters used in the Medical Implant Communications Service, except for equipment that is intended to be worn on a person or implanted in a human body shall be as follows:

- for equipment with an integral antenna or dedicated antenna, it shall be placed in the position closest to normal use as declared by the manufacturer;
- for equipment with a rigid or semi-rigid external antenna, the antenna shall be vertical;
- for equipment with non-rigid external antenna, the antenna shall be extended vertically upwards by a non-conducting support.

B.1.1.2 Equipment in close proximity to the human body but external to it

The following provisions apply to equipment designed to be external to but in very close proximity to a human body.

For programmer/control equipment intended to be worn close to the body or hand held, the non-conducting support may, at the request of the provider be replaced with a simulated man, if appropriate. The use of the simulated man shall be stated in the test report.

The simulated man for equipment external to the body shall consist of an acrylic tube, filled with salt water (1,5 g NaCl per litre of distilled water). The tube shall have a length of 1,7 m ± 0,1 m and an internal diameter of 300 mm ± 5 mm with side wall thickness of 1,5 mm ± 0,5 mm.

To reduce the weight of the simulated man it may be possible to use an alternative tube that has a hollow centre of 200 mm maximum diameter.

The sample shall be fixed to the surface of the simulated man, at the appropriate height for the equipment.

The following provisions apply to equipment designed to be implanted in a human body.

B.1.1.3 Human torso simulator for ULP-AMI-M

ULP-AMIs shall be tested in a simulated man constructed as follows in order to simulate operation of the ULP-AMI-M under actual operation conditions as shown in figure B.2.

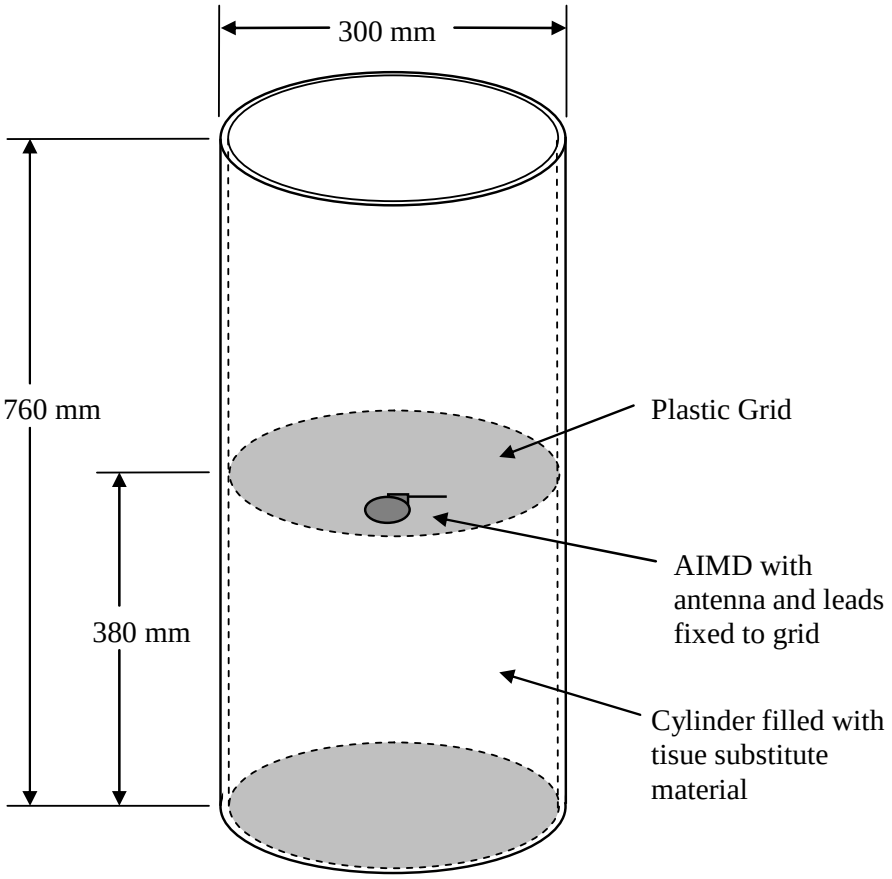


Figure B.2

An appropriate simulator for testing ULP-AMIs consists of a cylindrical acrylic container with an outside diameter of 300 mm ± 5 mm, a sidewall thickness of 6 mm ± 2,1 mm, and a fluid-filled height of 760 mm ± 5 mm. It shall be filled with a material that is sufficiently fluid that it will flow around the AIMD without any voids. The dielectric and conductivity properties of this material shall match the dielectric and conductivity properties of human muscle tissue at 34 MHz. Simple saline solutions do not meet the dielectric and conductivity requirements for use as a substitute for human tissue. All emissions measurements will be made using the above specification with the tissue substitute material at a nominal temperature between 22 °C and 38 °C. This temperature will facilitate testing because it is typical of ambient conditions at many test sites. A mounting grid for the AIMD inside the container shall be provided that permits the radiating element or elements of the AIMD to be positioned vertically and horizontally. The grid should also support any additional AIMD leads associated with the therapeutic function of the AIMD in a fixed repeatable manner such that they do not influence the measurement. The AIMD antenna shall be mounted no further 60 mm ± 5 mm from the sidewall and centred vertically within the container. When switching from vertical to horizontal positioning, it may be necessary to reposition the antenna to maintain a separation of no further than 60 mm ± 5 mm from the sidewall of the test fixture along its length. AIMD leads will be coiled and placed away from the AIMD antenna while maintaining a nominal no further than 60 mm from the sidewall. The above fixture shall be placed on a turntable such that the AIMD will be located at a nominal 1,5 m height above ground and at a 3 m distance from the measurement antenna. Radiated emissions measurements shall then be performed to ensure compliance with the applicable technical specifications.

A formula for a suitable tissue substitute material is defined in the paper "Simulated Biological Materials for Electromagnetic Radiation Absorption Studies" [i.9].

B.1.2 Test antenna

The test antenna is used to detect the radiation from both the test sample and the substitution antenna, when the site is used for radiation measurements. Where necessary, it may be used as a transmitting antenna, when the site is used for the measurement of receiver characteristics provided its radiation characteristics are similar to the antenna normally used with the medical device.

This antenna is mounted on a support such as to allow the antenna to be used in either horizontal or vertical polarization and for the height of its centre above ground to be varied over the range 1 m to 4 m. Preferably a test antenna with a gain characteristic similar to a dipole antenna should be used. The size of the test antenna along the measurement axis shall not exceed 20 % of the measuring distance.

For receiver and transmitter radiation measurements, the test antenna is connected to a measuring receiver, capable of being tuned to any frequency under investigation and of measuring accurately the relative levels of signals at its input. For receiver radiated sensitivity measurements, the test antenna is connected to a signal generator.

B.1.3 Substitution antenna

When measuring in the frequency range up to 1 GHz the substitution antenna shall be a $\lambda/2$ dipole, resonant at the operating frequency, or a shortened dipole, calibrated to the $\lambda/2$ dipole. When measuring in the frequency range above 4 GHz, a horn radiator shall be used. For measurements between 1 GHz and 4 GHz, either a $\lambda/2$ dipole or a horn radiator may be used. The centre of this antenna shall coincide with the reference point of the test sample it has replaced including the torso simulator if used. This reference point shall be the volume centre of the sample when its antenna is mounted inside the cabinet, or the point where an external antenna is connected to the cabinet.

The distance between the lower extremity of the dipole and the ground shall not be less than 0,3 m.

The substitution antenna shall be connected to a calibrated signal generator when the site is used for spurious domain radiation measurements and transmitter effective radiated power measurements. The substitution antenna shall be connected to a calibrated measuring receiver when the site is used for access protocol measurements and the measurement of receiver sensitivity.

The signal generator and the receiver shall operate at the frequencies under investigation and shall be connected to the antenna through suitable matching and balancing networks, as appropriate.

NOTE: The gain of a horn antenna is generally expressed relative to an isotropic radiator.

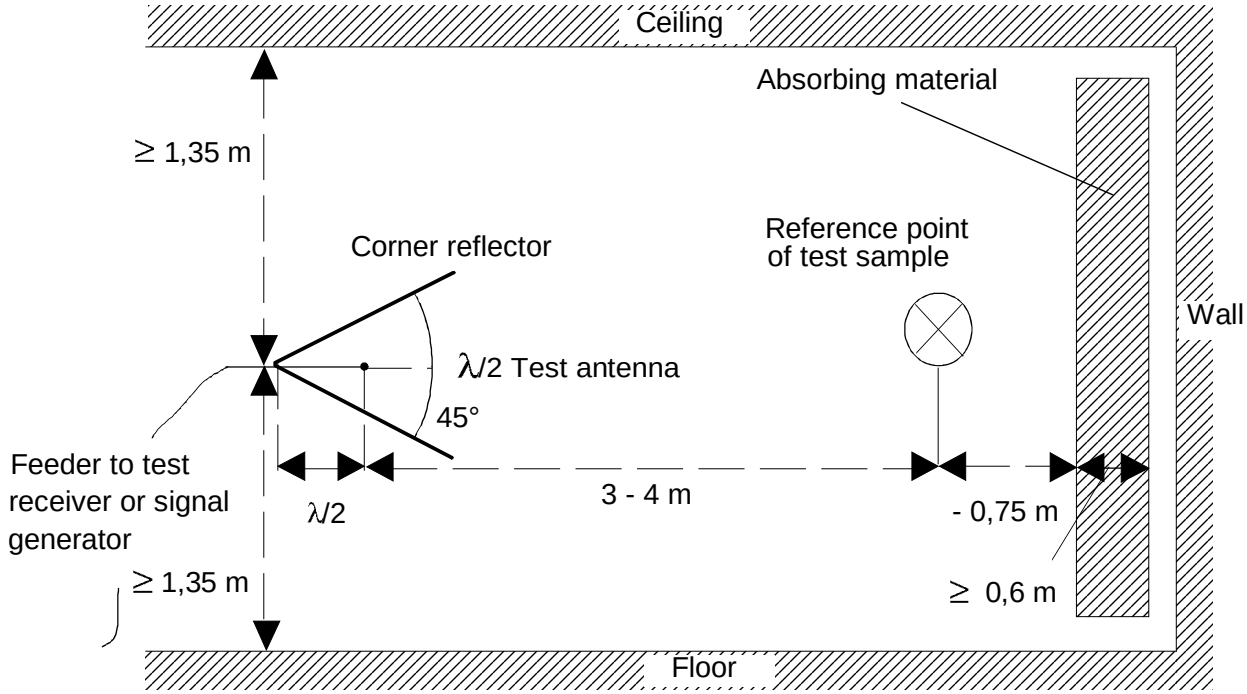


Figure B.3: Indoors site arrangement (shown for horizontal polarization)

B.1.4 Optional additional indoor site

When the frequency of the signals being measured is greater than 80 MHz, use may be made of an indoor test site. If this alternative site is used, this shall be recorded in the test report.

The measurement site may be a laboratory room with a minimum area of 6 m by 7 m and at least 2,7 m in height.

Apart from the measuring apparatus and the operator, the room shall be as free as possible from reflecting objects other than the walls, floor and ceiling.

The potential reflections from the wall behind the equipment under test are reduced by placing a barrier of absorbent material in front of it. The corner reflector around the test antenna is used to reduce the effect of reflections from the opposite wall and from the floor and ceiling, in the case of horizontally polarized measurements. Similarly, the corner reflector reduces the effects of reflections from the sidewalls for vertically polarized measurements. For the lower part of the frequency range (below approximately 175 MHz), no corner reflector or absorbent barrier is needed. For practical reasons, the λ/2 antenna in figure B.3 may be replaced by an antenna of constant length, provided that this length is between λ/4 and λ at the frequency of measurement, and the sensitivity of the measuring system is sufficient. In the same way, the distance of λ/2 to the apex may be varied.

The test antenna, measuring receiver, substitution antenna and calibrated signal generator are used in a way similar to that of the general method. To ensure that errors are not caused by the propagation path approaching the point at which phase cancellation between the direct and the remaining reflected signals occurs, the substitution antenna shall be moved through a distance of ±0,1 m in the direction of the test antenna as well as in the two directions perpendicular to this first direction.

If these changes of distance cause a signal change of greater than 2 dB, the test sample should be re-sited until a change of less than 2 dB is obtained.

B.2 Guidance on the use of radiation test sites

B.2.0 General remarks

For measurements involving the use of radiated fields, use may be made of a test site in conformity with the requirements of clause B.1. When using such a test site, the following conditions should be observed to ensure consistency of measuring results.

NOTE: If this technique is used, the ground reflected component of the measured field strength needs to be accounted for. For purposes of computing e.r.p. levels, the contribution to the measured level that is due to the ground reflected ray is considered to be 5 dB if measurements are performed on an open area test site or equivalent.

B.2.1 Measuring distance

Evidence indicates that the measuring distance is not critical and does not significantly affect the measuring results, provided that the distance is not less than $\lambda/2$ at the frequency of measurement, and that the precautions described in this annex are observed. Measuring distances of 3 m, 5 m, 10 m and 30 m are in common use in European test laboratories.

B.2.2 Test antenna

If performing substitution measurements, different types of test antenna may be used, since the substitution technique reduces the effect of the errors on the measuring results. If performing radiated field strength measurements, a calibrated $\lambda/2$ dipole antenna shall be used.

Height variation of the test antenna over a range of 1 m to 4 m is essential in order to find the point at which the radiation is at a maximum.

Height variation of the test antenna may not be necessary at the lower frequencies below approximately 100 MHz.

B.2.3 Substitution antenna

Variations in the measuring results may occur with the use of different types of substitution antenna at the lower frequencies below approximately 80 MHz. Where a shortened dipole antenna is used at these frequencies, details of the type of antenna used should be included with the results of the tests carried out on the test site. Correction factors shall be taken into account when shortened dipole antennas are used.

B.2.4 Artificial antenna

The dimensions of the artificial antenna used during radiated measurements should be small in relation to the sample under test.

Where possible, a direct connection should be used between the artificial antenna and the test sample. In cases where it is necessary to use a connecting cable, precautions should be taken to reduce the radiation from this cable by, for example, the use of ferrite cores or double-screened cables.

B.2.5 Auxiliary cables

The position of auxiliary cables (power supply and microphone cables etc.), which are not adequately de-coupled, may cause variations in the measurement results. In order to get reproducible results, cables and wires of auxiliaries should be arranged vertically downwards (through a hole in the non-conducting support), or as specified in the technical documentation supplied with the equipment.

Care shall be taken to ensure that test cables do not adversely effect the measuring result.

B.3 Further optional alternative indoor test site using an anechoic chamber

B.3.0 General remarks

For radiation measurements, when the test frequency of the signals being measured is greater than 30 MHz, use may be made of an indoor test site being a well-shielded anechoic chamber simulating a free space environment. If such a chamber is used, this shall be recorded in the test report.

The test antennas, measuring receiver, substitution antenna and calibrated signal generator are used in a way similar to that of the general method, clause B.1. In the range 30 MHz to 100 MHz, some additional calibration may be necessary.

An example of a typical measurement site may be an electrically shielded anechoic chamber being 10 m long, 5 m broad and 5 m high. Walls and ceiling should be coated with RF absorbers of 1m height. The base should be covered with absorbing material 1 m thick and a wooden floor, capable of carrying test equipment and operators. The construction of the anechoic chamber is described in the following clauses.

B.3.1 Example of the construction of a shielded anechoic chamber

Free-field measurements can be simulated in a shielded measuring chamber where the walls are coated with RF absorbers. Figure B.4 shows the requirements for shielding loss and wall return loss of such a room. As dimensions and characteristics of usual absorber materials are critical below 100 MHz (height of absorbers < 1 m, reflection attenuation < 20 dB) such a room is more suitable for measurements above 100 MHz. Figure B.5 shows the construction of an anechoic shielded measuring chamber having a base area of 5 m by 10 m and a height of 5 m.

Ceilings and walls are coated with pyramidal formed RF absorbers approximately 1 m high. The base is covered with absorbers forming a non-conducting sub-floor or with special ground floor absorbers. The available internal dimensions of the room are 3 m × 8 m × 3 m, so that a maximum measuring distance of 5m length in the middle axis of this room is available.

At 100 MHz, the measuring distance can be extended up to a maximum of 2λ.

The floor absorbers reduce floor reflections so that the antenna height need not be changed and floor reflection influences need not be considered.

All measuring results can therefore be checked with simple calculations and the measurement uncertainties have the smallest possible values due to the simple measuring configuration.

B.3.2 Influence of parasitic reflections in anechoic chambers

For free-space propagation in the far field condition the correlation E = Eo (Ro/R) is valid for the dependence of the field strength E on the distance R, whereby Eo is the reference field strength in the reference distance Ro.

It is useful to use this correlation for comparison measurements, as all constants are eliminated with the ratio and neither cable attenuation, nor antenna mismatch, or antenna dimensions are of importance.

Deviations from the ideal curve can be seen easily if the logarithm of the above equation is used, because the ideal correlation of field strength and distance can then be shown as a straight line and the deviations occurring in practice are clearly visible. This indirect method more readily shows the disturbances due to reflections and is far less problematical than the direct measurement of reflection attenuation.

With an anechoic chamber of the dimensions suggested in clause B.3 at low frequencies up to 100 MHz, there are no far field conditions and therefore reflections are stronger so that careful calibration is necessary; in the medium frequency range from 100 MHz to 1 GHz the dependence of the field strength on the distance meets the expectations very well.

B.3.3 Calibration of the shielded RF anechoic chamber

Careful calibration of the chamber shall be performed over the range 30 MHz to 1 GHz.

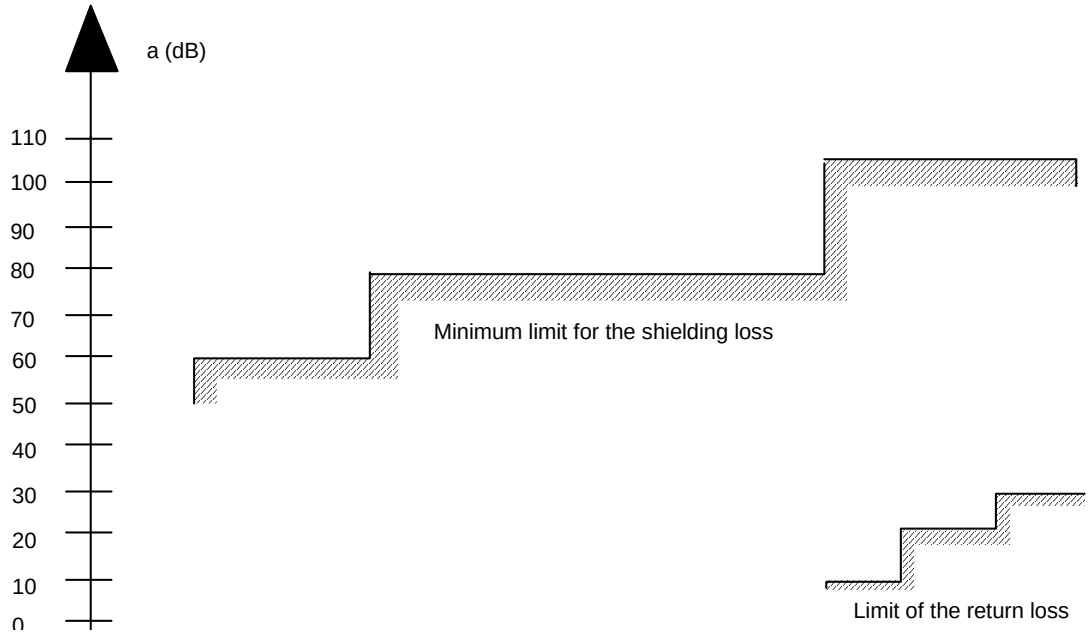
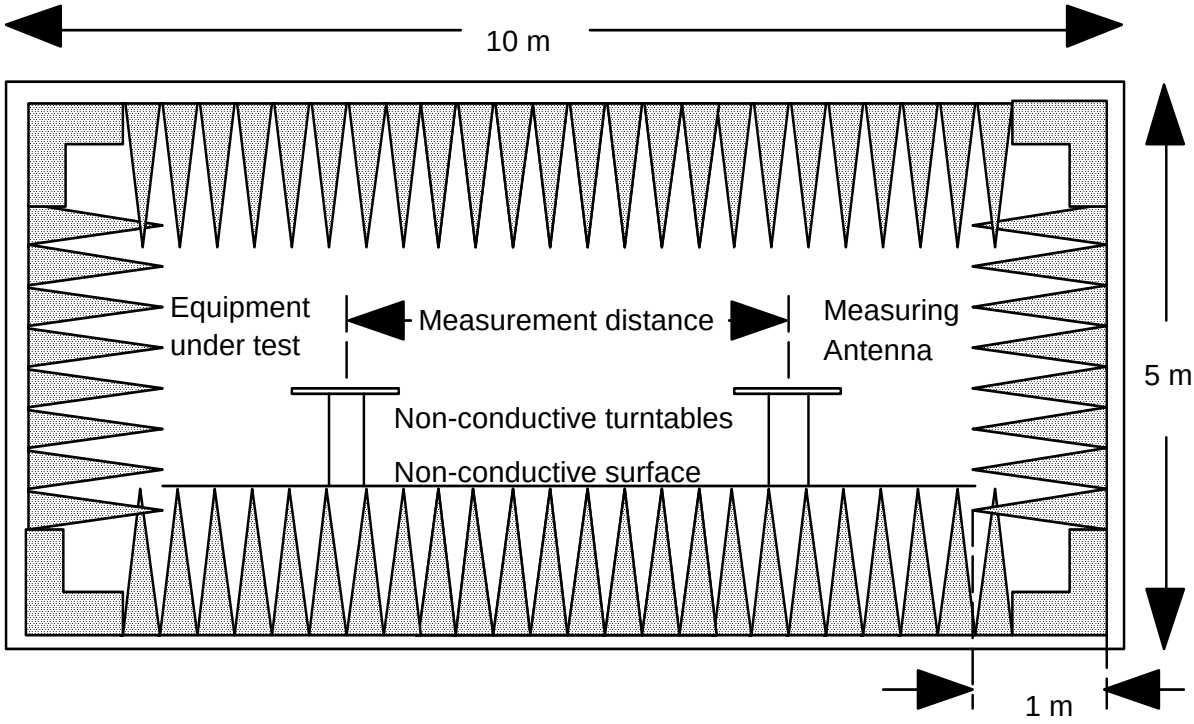


Figure B.4: Specification for shielding and reflections



Ground plan

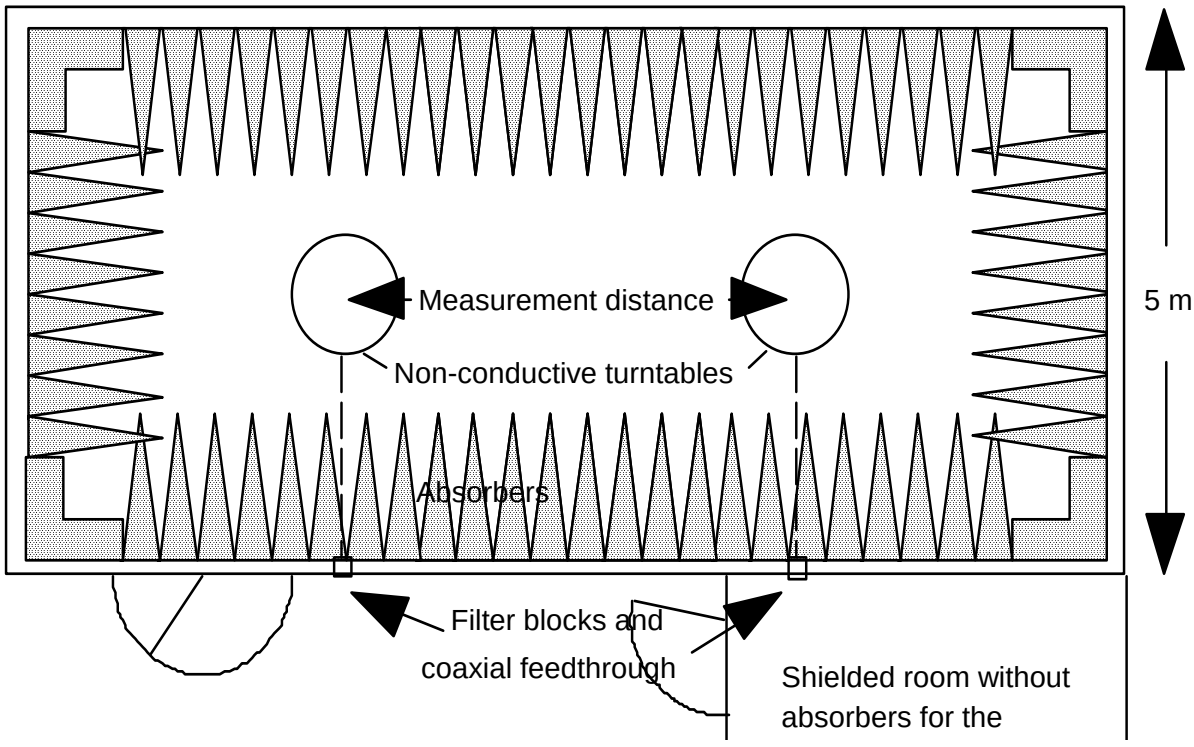


Figure B.5: Example of construction of an anechoic shielded chamber

Annex C (normative): Technical performance of the spectrum analyser

The specification of the spectrum analyser shall include the following requirements:

It shall be possible, using a resolution bandwidth of 1 kHz, to measure the amplitude of a signal or noise at a level 3 dB or more above the noise level of the spectrum analyser as displayed on the screen, to an accuracy of ±2 dB in the presence of a signal separated in frequency by:

a) 10 kHz, at a level 90 dB above that of the signal to be measured for 25 kHz and 20 kHz channel separations; and

b) 6,25 kHz, at a level 80 dB above that of the signal to be measured for a 12,5 kHz channel separation; and

c) 5 kHz, at a level 80 dB above that of the signal to be measured for a 10 kHz channel separation.

The reading accuracy of the frequency marker shall be within ±2 % of the channel separation.

The accuracy of relative amplitude measurements shall be within ±0,5 dB in the measurement frequency range.

The spectrum analyser shall have a resolution bandwidth setting of 1 MHz or greater.

It shall be possible to adjust the spectrum analyser to allow the separation, on the display, of two components with a frequency difference of 1 kHz.

Annex D (informative): Bibliography

- Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations.
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- ETSI TR 102 273-1-1 (V1.2.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Improvement on Radiated Methods of Measurement (using test site) and evaluation of the corresponding measurement uncertainties Part 1: Uncertainties in the measurement of mobile radio equipment characteristics; Sub-part 1: Introduction".

History

Document history		
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