

**Electromagnetic compatibility
and Radio spectrum Matters (ERM);
Short Range Devices (SRD);
Radio equipment in the frequency range 315 kHz to 600 kHz;
Part 1: Technical characteristics and
test methods**



Reference

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Foreword

This European Standard (Telecommunications series) has been produced by ETSI Technical Committee Electromagnetic compatibility and Radio spectrum Matters (ERM), and is now submitted for the Vote phase of the ETSI standards Two-step Approval Procedure.

For non-EU countries the present document may be used for regulatory (Type Approval) purposes.

The present document is part 1 of a multi-part deliverable covering Radio Equipment in the frequency range 315 kHz to 600 kHz for Ultra Low Power Animal Implant Devices and accessory peripheral systems including devices that are intended to be outside the body but in very close proximity to it in normal operation, as identified below:

Part 1: "Technical characteristics and test methods";

Part 2: "Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive".

Proposed national transposition dates	
Date of latest announcement of this EN (doa):	3 months after ETSI publication
Date of latest publication of new National Standard or endorsement of this EN (dop/e):	6 months after doa
Date of withdrawal of any conflicting National Standard (dow):	6 months after doa

1 Scope

The present document applies to transmitters and receivers of Ultra Low Power Animal Implant Devices (ULP-AID) operating in any part or all of the band from 315 kHz to 600 kHz and any associated radio apparatus transmitting in the frequency range of 315 kHz to 600 kHz including external programmers and related telecommunication devices using digital modulation techniques such as, but not limited to, FSK or pulse position modulation. The present document contains the technical characteristics and test methods for radio equipment and is referenced in CEPT/ERC Recommendation 70-03, annex 12 band(c).

The present document does not necessarily include all the characteristics which may be required by a user, nor does it necessarily represent the optimum performance achievable. It is a product standard which may be completely or partially superseded by specific standards covering specific applications.

The present document applies to ULP-AID transceivers conforming to the following:

- inductive loop systems;
- with an antenna connection and/or with an integral antenna;
- for use as telecommunications and telecommand transmission to/from implanted animal systems.

All types of digital modulation for radio devices are covered by the present document.

2 References

The following documents contain provisions which, through reference in this text, constitute provisions of the present document.

- References are either specific (identified by date of publication and/or edition number or version number) or non-specific.
- For a specific reference, subsequent revisions do not apply.
- For a non-specific reference, the latest version applies.

Referenced documents which are not found to be publicly available in the expected location might be found at <http://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.

- [1] ITU-T Recommendation O.153: "Basic parameters for the measurement of error performance at bit rates below the primary rate".
- [2] ETSI TR 100 028 (V1.4.1) (all parts): "Electromagnetic compatibility and Radio Spectrum Matters (ERM), Uncertainties in the measurement of mobile radio equipment characteristics".

3 Definitions, symbols and abbreviations

3.1 Definitions

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

Animal Implant Device: active implant that includes a transmitter, with or without an integral receiver, that operates in the ULP-AID band that is placed inside the body for the purpose of performing diagnostic functions and/or delivery of therapeutic treatment

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

body worn device: physiologic sensor, holter type device, or other physiological data transfer device containing a transmitter or transceiver intended to be operated in close proximity to the animal body, which has its radio antenna external to the body, and is used to sense and/or transfer, via means of radio frequency transmission, physiological parameters or system programming information

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

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

H-field test antenna: electrically screened loop or equivalent antenna, with which the magnetic component of the radio frequency field can be measured

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

magnetic dipole moment: product of (Number of coil turns) \times (coil area) \times (coil current)

NOTE: Air coils only.

mobile station: equipment external to the animal body intended to provide communication capability to an active implant device placed within the body

programmer/controller: ULP-AID equipment used to communicate with an active implant device

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

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 transferring data at a distance

Ultra Low Power-Animal Implant Device (ULP-AID): ultra low power animal implant transmitter operating in accordance with the provisions of annex 12, band (c), to CEPT/ERC Recommendation 70-03

3.2 Symbols

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

E	Electrical field strength
f	frequency
H	Magnetic field strength
H _{ef}	Electric field strength limit converted from H _f
H _f	H field strength limit
m	magnetic dipole moment
P	Power
R	Distance
t	time

3.3 Abbreviations

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

AID	Animal Implant Device
EMC	ElectroMagnetic Compatibility
FSK	Frequency Shift Keying
RF	Radio Frequency
R&TTE	Radio and Telecommunications Terminal Equipment
SRD	Short Range Device
ULP-AID	Ultra Low Power - Animal Implant Device

4 Essential requirements and specifications

4.1 General requirements

4.1.1 Transmitter requirements

See clause 8 for requirements including measurement procedures.

4.1.2 Receiver requirements

See clause 9 for requirements including measurement procedures.

4.2 Presentation of equipment for testing purposes

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 shall be shown by testing on the frequency of operation in the band 315 kHz to 600 kHz.

If equipment is designed to operate with different carrier powers, measurement of each transmitter parameter shall be performed at the highest power level at which the transmitter is intended to operate. Additionally, the spurious emissions shall be measured at each lower power level setting or at the low, middle, and high power settings for multilevel power control systems.

For third party testing the provider shall complete, if necessary, 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 devices operating in the frequency band 315 kHz to 600 kHz.

A torso simulator and tissue substitute material for testing ULP-AID devices operating in the frequency band 315 kHz to 600 kHz may be used (see clause 6.3.1).

Measurements shall be performed, according to the present document, on samples of equipment defined in clauses 4.2 through 4.2.3.3.

4.2.1 Choice of model for testing

One or more samples of each model or type of transmitter operating in the frequency band 315 kHz to 600 kHz, as appropriate for testing. Any ancillary equipment needed for testing shall be provided as requested by the testing laboratory.

If 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.

4.2.2 Testing of equipment with alternative power levels

If equipment is designed to operate with different carrier powers, measurement of each transmitter parameter shall be performed at the highest power level, according to the present document, on samples of equipment defined in clause 4.2.1. Spurious emissions tests shall be performed at all power levels.

4.2.3 Testing of equipment that does not have an external 50 Ω RF connector (integral antenna equipment)

4.2.3.1 Equipment with an internal permanent or temporary antenna connector

The means to access and/or implement the internal permanent or temporary connector shall be stated by the provider 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.

No connection shall be made to any internal permanent or temporary antenna connector during the performance of radiated emissions measurements, unless such action forms an essential part of the normal intended operation of the equipment, as declared by the provider.

4.2.3.2 Equipment with a temporary antenna connector

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

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

4.2.3.3 Equipment intended to be implanted in the body

The provider shall submit the equipment, a torso simulator as described in clause 6.3.1 and annex A if the implant is to be tested in a simulator, and a sufficient quantity of tissue substitute material to fill the test fixture. Tissue substitute material shall have dielectric and conductivity properties equivalent to those of animal tissue for the measurement frequency as applicable. The provider and/or test laboratory shall determine and agree on the arrangement of the equipment antenna and any additional device leads on the ULP-AID holding grid within the fixture as prescribed in annex A.

4.3 Mechanical and electrical design

4.3.1 General

The equipment submitted by the provider should be designed, constructed and manufactured in accordance with sound engineering practice and with the aim of minimizing harmful interference to other equipment and services.

Transmitters and receivers may be individual or combination units.

4.3.2 Controls

Those controls which, if maladjusted, might increase the interfering 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, it shall be made inoperative for the duration of the test.

4.3.4 Receiver power save capability

If the receiver is equipped with a battery-saving circuit, this circuit shall be made inoperative for the duration of the tests if possible.

4.4 Declarations by the provider

The performance of the equipment submitted for testing shall be representative of the performance of the corresponding production model.

4.5 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 testing unless alternative arrangements are agreed to by the test house and the provider.

4.6 Interpretation of the measurement results

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

- the measured value, determined by extrapolation if needed, relating to the corresponding limit shall be used to decide whether an equipment meets the requirements of the present document;
- the measurement uncertainty value for the measurement of each parameter shall be included in the test report;
- the recorded value of the measurement uncertainty shall, for each measurement, be equal to, or lower than, the figures in the table of measurement uncertainty (clause 10).

5 Test conditions, power sources and ambient temperatures

5.1 Normal and extreme test conditions

Testing shall be performed under normal test conditions, and also, where stated, under extreme test conditions. It should be noted that emissions test on active implant devices may, at the option of the provider, be performed using the torso simulator filled with the tissue substitute material at nominal room temperature. The purpose is to facilitate testing at the measurement facility. Measured emission levels at a nominal room temperature of 22°C are not expected to vary significantly from actual levels measured on an implanted device

The test conditions and procedures shall be as specified in clauses 5.2 to 5.4.

5.2 Test power source

The equipment shall be tested using the appropriate test power source as specified in clauses 5.2.1 or 5.2.2. Where equipment can be powered using either external or internal power sources, then the equipment shall be tested using the external power source as specified in clause 5.2.1 then repeated using the internal power source as specified in clause 5.2.2.

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

5.2.1 External test power source

During testing, the power source of the equipment shall be replaced by an external test power source capable of producing normal and extreme test voltages as specified in clauses 5.3.2 and clause 5.4.2. 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 shall be so arranged so as not to affect the measurements.

During tests the test power source voltages shall be within a tolerance of $< \pm 1$ % 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.

5.2.2 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 provider. If internal batteries are used, at the end of each test the voltage shall be within a tolerance of $< \pm 5$ % relative to the voltage at the beginning of each test. For 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 connected to the RF output port is used, an external power supply at the required voltage may replace the supplied or recommended internal batteries. This shall be stated in the test report.

For equipment, intended to be implanted in a body, that is hermetically sealed it may not be possible to measure the battery voltage directly or indirectly. For this type of equipment, it is not necessary to measure the voltage at the end of each test; however, care shall be taken to ensure that the internal battery supply voltage does not fall below the provider's specification for normal operating voltage range. For battery operated devices, it is acceptable to read the battery voltage via telemetry readout.

5.3 Normal test conditions

5.3.1 Normal temperature and humidity

The normal temperature and humidity conditions for tests for devices external to the body shall be any convenient combination of temperature and humidity within the following ranges:

- temperature $+15^{\circ}\text{C}$ to $+37^{\circ}\text{C}$;
- relative humidity 20 % to 75 %.

Active implant transmitters operate after implant in the torso of a body. Accordingly, the body tends to serve as an oven to maintain the implant temperature, The actual temperature will vary as a function of the body but is expected to be near 37°C . Allowing for a variation, the normal temperature and humidity conditions for AID transmitters is within the following ranges:

- temperature $+34^{\circ}\text{C}$ to $+40^{\circ}\text{C}$;
- relative humidity not applicable.

Measured values are not expected to vary within the above range.

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.

5.3.2 Normal test power source

5.3.2.1 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.

5.3.2.2 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.).

5.3.2.3 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.

5.4 Extreme test conditions

5.4.1 Extreme temperatures

5.4.1.1 Procedure for tests at extreme temperatures

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 clauses 6.1 and 6.1.1).

5.4.1.2 Procedure for equipment designed for continuous operation

If the provider 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 provider 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.

5.4.1.3 Procedure for equipment designed for intermittent operation

If the provider 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 providers declared duty cycle for a period of five minutes; or
 - if the provider'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.

5.4.1.4 Extreme temperature ranges

For tests at extreme temperatures, measurements shall be made in accordance with the procedures specified in clause 5.4.1.1, at the upper and lower temperatures of one of the following ranges.

Table 1: 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 implant Device 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 implant transmitters" refers only to equipment that is intended to be placed inside a body during normal operation. The range of +25°C to +45°C is the approximate core body temperature variation over which a body can survive.	

The provider may define a different temperature range than specified in table 1 for any category provided the EUT meets the conditions set forth below. For specific applications, the provider can specify wider temperature ranges than given as a minimum in table 1. In this case the test report shall show compliance with the limits in the present document over the extended ranges specified by the provider. This shall be reflected in the providers' product literature. Narrower temperature ranges than given in table 1 may be implemented provided the reduced range is reflected in the manufacturer provider'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 1.

The equipment shall comply with all the technical requirements of the present document at all times when operating within the boundary limits of the required operational temperature profile.

For special applications, the provider can specify wider temperature ranges than given as a minimum above. This shall be reflected in the provider's product literature.

The test report shall state which range is used.

5.4.2 Extreme test source voltages

5.4.2.1 Mains voltage

The extreme test voltages for equipment to be connected to an ac mains source shall be the nominal mains voltage $\pm 10\%$. For equipment operating over a range of mains voltages clause 5.4.2.4 applies.

5.4.2.2 Regulated lead-acid battery power sources

When the radio equipment 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.

5.4.2.3 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) for 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 provider.

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

5.4.2.4 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.

6 General conditions

The following clauses are written to define conditions for individual units to be separately tested. However, it is not intended to prevent a "system approach" to performing the testing where each individual unit in a given system will be operational during testing. Where individual units have differing requirements, the test report shall list and identify the unit separately together with the information showing compliance with the applicable requirement.

6.1 Normal test signals and test modulation

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.

6.1.1 Normal 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 ITU-T Recommendation O.153 [1]. 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 that is agreed between the test laboratory and the provider 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 provider as the normal operating level.

In case of amplitude modulation, the modulation ratio shall be 60 %, or any value, as declared by the provider, as the normal operating level.

For other forms of modulation, the ratio and level will be as declared by the provider.

6.2 Antenna

Equipment operating in the 315 kHz to 600 kHz band shall have an integral antenna, an external dedicated antenna or both. If provision for an external antenna connection is made, provision shall be made to prevent the use of any antenna other than an antenna or antennas intended to be connected to the equipment by the provider.

6.2.1 Artificial antenna

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

6.3 Test fixture

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 provider. 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.

6.3.1 Alternate test fixture for equipment intended to be implanted within and transmitters worn on the body

For measurement purposes, to determine compliance with all emission limits, active implants and transmitters worn on the body may be tested in a fixture that approximates the physical conditions of an implant transmitter placed in a body. This fixture, a torso simulator, with the implant mounted inside, shall be filled with a tissue substitute material and placed on the radiated emissions test site turntable with the implant at a height of 1,5 m above the ground plane for testing purposes. The tissue substitute material conductivity and dielectric parameters shall be in accordance with clause A.1.1.2. Typically they will be equivalent to those of muscle tissue at the fundamental frequency or alternatively these parameters may be adjusted to correspond to the measurement frequency. The tissue substitute material shall be sufficiently fluid that it will flow around the implant without creating any voids.

6.4 Test sites and general arrangements for radiated measurements

For guidance on radiated measurement test sites, see annex A. Detailed descriptions of radiated measurement arrangements are included in the present annex.

6.5 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 provider 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 clauses 6.1 and 6.1.1, shall be applied to the input of the transmitter under test with the normal input device disconnected when possible.

7 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 2. Measurements above 30 MHz are not required.

Table 2: Detector type and Resolution Bandwidth Setting

Frequency (f)	Detector type	Bandwidth
$9 \text{ kHz} \leq f < 150 \text{ kHz}$	RMS	200 Hz to 300 Hz
$150 \text{ kHz} \leq f < 30 \text{ MHz}$	RMS	9 kHz to 10 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.

8 Transmitter requirements

To meet the requirements of the present document, the transmitter shall be measured as a radiated H-field, conducted current or power level as declared by the provider.

Where the transmitter is designed with an adjustable carrier H-field or RF current, all parameters shall be measured using the highest output level as declared by the provider. The equipment shall then be adjusted to the lowest setting, as declared by the provider, and the spurious emissions measurement shall be repeated (see clause 8.4).

When making transmitter tests on equipment designed for intermittent operation, the duty cycle of the transmitter, as declared by the provider on the application form, shall not be exceeded. The actual duty cycle used shall be stated on the test report form.

If the equipment is supplied with an integral antenna and a permanent antenna connector to be used with a dedicated antenna, the following full tests shall be carried out using the integral antenna and the dedicated antenna connected to the external connector:

- radiated H-field for product class 1 devices (see clause 8.2.1);
- radiated E-field for product class 2 devices (see clause 8.2.2);
- spurious emissions (see clause 8.4).

8.1 Transmitter definitions

Transmitters covered by the present document are considered to have internal and/or dedicated external antennas. In this case, radiated field strength measurements are required. User defined antenna systems are not permitted.

8.1.1 The inductive loop coil transmitters

These transmitters are characterized by:

- a) the loop coil antenna area A shall be $< 30 \text{ m}^2$;
- b) the length of any antenna loop element shall be $< \frac{\lambda}{4}$ ($< \frac{75}{f}$, where f is in MHz) or $< 30 \text{ m}$ whichever is shorter;
- c) the antenna coil may have one or multiple turns.

8.1.2 Product classes

This equipment is defined as Product Class 1 or Product Class 2. The different antenna types are referencing CEPT/ERC Recommendation 70-03.

Product Class 1:

Inductive loop coil transmitter, tested with an antenna as either:

- an integral antenna (antenna type 1); or
- a dedicated antenna supplied with the equipment (antenna type 2).

The following restrictions apply to this product class:

- 315 kHz to 600 kHz frequency range;
- no field customization of the antenna(s);
- loop antenna area $< 30 \text{ m}^2$; and
- the length of any antenna loop element shall be $< \frac{\lambda}{4}$ ($< \frac{75}{f}$, where f is in MHz) or $< 30 \text{ m}$ whichever is shorter.

The transmitter carrier and spurious emissions are by the maximum generated H-field, (see clauses 8.2.1 and 8.4.2 respectively).

Where a provider supplies a range of standard antennas, the equipment shall be tested as Product Class 1 equipment, with the antenna(s) attached. The measurements shall be repeated for each of such antenna.

Product Class 2:

E-field transmitter, tested with each type of antenna to be used.

The transmitter carrier and spurious are limited by the maximum generated E-field, measured as the equivalent H-field, (see clauses 8.2.1 and 8.2.2).

8.2 Transmitter carrier output levels

8.2.1 H-field (radiated)

The provisions of the present clause and subsequent clauses are applicable to devices designed to intentionally radiate an inductive field.

8.2.1.1 Definition

In the case of a transmitter with an integral or dedicated antenna, the H-field is measured in the direction of maximum field strength under specified conditions of measurement.

8.2.1.2 Methods of measurement

The measurements shall be made on an open field test site as specified in annex A. Any measured values shall be at least 6 dB above the ambient noise level.

The H-field produced by the equipment shall be measured at standard distance of 10 m. Where this is not practical, e.g. due to low power of the equipment including the antenna or with use of special field cancelling antenna, then other distances may be used. When another distance is used, the distance used and the field strength value measured shall be stated in the test report. In this case, the measured value at the actual test distance shall be extrapolated to 10 m and stated in the test report. If extrapolation is used, the method of extrapolation shall be stated in the report.

The H-field shall be measured with a shielded loop antenna connected to a measurement receiver. The measuring bandwidth and detector type of the measurement receiver shall be in accordance with clause 7.

The equipment under test shall operate where possible, without modulation. If this is not possible, it shall be stated in the test report and a peak level detector shall be used to make the measurement.

For transmitters using a continuous wideband swept carrier or stepped frequency function, the measurement shall be made with the sweep or stepping off. When it is not possible to turn the sweep off the measurements shall be made with the sweep on using a peak detector and this shall be stated in the test report.

For measurement receivers with a readout in dB μ V/m, the reading should be reduced by the freespace impedance factor 51,5 dB to convert to dB μ A/m.

8.2.1.3 Limits

The limits presented in the present document are the field strengths that allow satisfactory operation of inductive ULP-AID systems. These levels were determined after careful analysis within CEPT.

Maximum field strength under normal and extreme conditions is given in table 3.

For the purpose of assessing conformity with the regulations, the limits in table 3 apply.

In all cases SRDs operate on a non-interference basis. Solutions can range from site engineering to field strength modification and can be used on a case-by-case basis.

Additional information is available in CEPT/ERC Recommendation 70-03.

Table 3: H-field limits at 10 m

Frequency range (MHz)	H-field strength limit (Hz) dB μ A/m at 10 m
$0,315 \leq f \leq 0,600$	-5

8.2.2 Radiated E-field

The provisions of the present clause and subsequent clauses are applicable to devices designed to intentionally radiate an electric field.

8.2.2.1 Definition

The radiated E-field is defined as the E-field in the direction of maximum field strength under the specified conditions of measurement. This is defined for a transmitter with an integral or dedicated antenna.

8.2.2.2 Methods of measurement

The transmitter radiated E-field is based on the equivalent H-field, measured at 10 m.

The H-field shall be measured with a shielded loop antenna connected to a measurement receiver. The measuring bandwidth and detector type of the measurement receiver shall be in accordance with clause 6.6.

For a detailed explanation of the relationship between E-field and H-field, see annex B.

8.2.2.3 Limits

In the frequency range 315 kHz to 600 kHz, the limits of H_{ef} follow the H-fields limits, H_f , as given in clause 8.2.1.3, table 3 with an additional correction factor C. The factor given below is specific for a 10 m measuring distance.

The limit $H_{ef} = H_f + C$

where:

$$C = 20 \times \log (f_c / 4,78 \times 10^6) \text{ dB};$$

and where:

f_c is the carrier frequency in Hz.

8.3 Permitted frequency range of the modulation bandwidth

The permitted frequency range shall be stated by the provider.

8.3.1 Definition

The modulation bandwidth contains all associated side bands above the following level:

- for carrier frequencies in the range of 315 kHz to 600 kHz, at the highest level of either:
 - 20 dB below the carrier or the appropriate spurious limit, see clause 8.4.

Where the assigned frequency band has been divided into sub-bands by the regulatory body, the above measuring levels and bandwidths apply inside these sub-bands.

Devices whose carrier level is below the spurious limit, see clause 8.4, do not have a defined modulation bandwidth.

8.3.2 Method of measurement

The transmitter test shall be with all provider supplied antenna(s). The spectrum analyser shall be connected to a shielded loop 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 8.2. The spectrum analyser's attenuator shall be adjusted to an appropriate level displayed at the spectrum analyser screen.

The transmitter shall be modulated with standard test modulation (see clauses 6.1 and 6.1.1). If the equipment cannot be modulated externally, the internal modulating signal shall be used.

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

The output of the transmitter, with or without test fixture, shall be measured by 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. The power level calibration of the spectrum analyser shall then be related to the power level or field strength measured in clause 8.2. The calculation shall be used to calculate the absolute level of the sideband power.

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.

The difference between the frequencies of the upper and lower points, where the displayed power envelope of the modulation including frequency drift is equal to the appropriate level defined in clause 8.3.1 shall be recorded as the modulation bandwidth.

The measurements shall be made during normal and extreme test conditions (clauses 5.4.1 and clause 5.4.2 applied simultaneously).

8.3.3 Limits

The permitted range of the modulation bandwidth shall be within the limits of the assigned frequency band.

8.4 Spurious emissions

8.4.1 Definition

Spurious emissions are emissions at frequencies other than those of the carrier and sidebands associated with normal test modulation (clause 6.1). The level of spurious emissions shall be measured only for frequencies below 30 MHz at normal conditions (clause 5.3) 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 provider.

8.4.2 Radiated field strength

8.4.2.1 Methods of measurement (< 30 MHz)

This applies to all Product Classes.

The field strength shall be measured for frequencies below 30 MHz. The equipment under test shall be measured at a distance of 10 m on an outdoor test site. The test antenna shall be a calibrated shielded magnetic field antenna. The equipment under test and test antenna shall be arranged as stated in clause A.1.1.

The equipment under test shall be switched on with normal modulation. The characteristics of the modulation signal used shall be stated in the test report. The measuring receiver shall be tuned over the frequency range 9 kHz to 30 MHz, except for the frequency band in which the transmitter is intended to operate.

At each frequency at which a relevant spurious signal is detected the equipment under test and the test antenna shall be rotated until maximum field strength is indicated on the measuring receiver. This level shall be noted.

If the transmitter can be operated in the standby mode, then the measurements shall be repeated in the standby mode.

For measurement receivers with a readout in dB μ V/m, the reading should be reduced by the freespace impedance factor, 51,5 dB, to convert to dB μ A/m.

8.4.2.2 Limits

Radiated spurious emissions below 30 MHz shall not exceed the generated H-field dB μ A/m at 10 m given in table 4.

Table 4: H-field Limits

State	Frequency 9 kHz \leq f < 10 MHz	Frequency 10 MHz \leq f < 30 MHz
Transmit	-25 dB μ A/m	-25 dB μ A/m
Standby	-25 dB μ A/m	-25 dB μ A/m

8.5 Duty cycle

8.5.1 Definitions

For the purpose of the present document the term duty cycle refers to the ratio of the total on time of the "message" to the total off time in any one hour period under repeated operation during the time measurement interval. The device may be triggered either automatically or manually and depending on how the device is triggered will also depend on whether the duty cycle is fixed or random.

8.5.2 Declaration

For software controlled or pre-programmed devices, the provider shall declare the duty cycle for the equipment under test.

For manually activated or event dependant devices, with or without software controlled functions, the provider 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 provider 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 provider 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 provider.

8.5.3 Limit

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

9 Receiver Requirement

9.1 Receiver spurious radiation

These requirements do not apply to receivers used in combination with permanently co-located transmitters continuously transmitting. Co-located is defined as < 3 m. In these cases the receivers will be tested together with the transmitter in operating mode (see clause 8.4). Measurements above 30 MHz are not required.

9.1.1 Definition

Spurious radiation from receivers consists of emissions radiated from the antenna, the chassis and case of the receiver. 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.

9.1.2 Methods of measurement

The method of measurement defined in clause 8.4.2.1 shall be used.

For measurement receivers with a readout in dB μ V/m, the reading should be reduced by the freespace impedance factor, 51,5 dB, to convert to dB μ A/m.

9.1.3 Limits

The spurious components below 30 MHz shall not exceed the generated H-field dB μ A/m values at 10 m according to table 5.

Table 5: Receiver spurious radiation limits

Frequency $9 \text{ kHz} \leq f < 10 \text{ MHz}$	Frequency $10 \text{ MHz} \leq f < 30 \text{ MHz}$
5,5 dB μ A/m at 9 kHz descending 3 dB/oct	-22 dB μ A/m

10 Measurement uncertainty

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

- the measured value related to the corresponding limit shall 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 separately included in the test report;
- the value of the measurement uncertainty shall be, for each measurement, equal to or lower than the figures given below.

Table 6: Measurement uncertainties

Radio frequency	$\pm 1 \times 10^{-7}$
RF power, conducted	$\pm 0,75$ dB
RF power, radiated	± 6 dB
Temperature	± 1 °C
Humidity	± 5 %
Voltage	± 1 %

For the test methods, according to the present document the uncertainty figures shall be calculated according to the methods described in the TR 100 028 [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 % for the case where the distributions characterizing the actual measurement uncertainties are normal (Gaussian)).

The measurement uncertainties given above are based on such expansion factors.

The particular expansion factor used for the evaluation of the measurement uncertainty shall be stated.

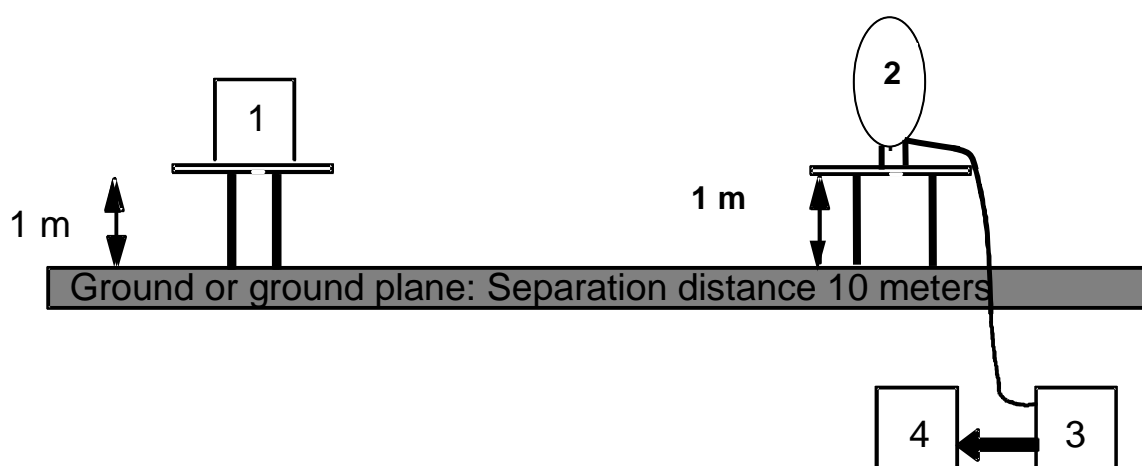
Annex A (normative): Radiated measurements

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

A.1.1 Outdoor test site

The outdoor test site shall be on a reasonably level surface or ground. For measurements at frequencies below 30 MHz no artificial ground plane shall be used and the measurement antenna shall be of a shielded loop type and placed on a table of 1-m height placed 10 meters from the EUT. Closer distances are permitted if measurements of low level emissions are performed. 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 distance actually used, if not 10 meters, 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 measurements results.



- 1 - EUT.
- 2 - Loop Antenna.
- 3 - High or low pass filter as appropriate.
- 4 - Measuring receiver.

Figure A.1: Outdoor test site configuration

A.1.1.1 Standard position

The standard position in all test sites, except for equipment which is intended to be worn on a body or implanted in a body, shall be as follows:

- for equipment with an integral antenna, it shall be placed in the position closest to normal use as declared by the provider;
- for equipment with a 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.

For equipment intended to be worn close to the body or implanted, the non-conducting support may, at the request of the provider be replaced with a torso simulator, if desired. The use of a torso simulator shall be stated in the test report (see clause A.1.1.2). For transmitters worn on the body the device shall be fixed to the surface of the torso simulator.

A.1.1.2 Active implant equipment

Equipment intended to be body worn or implanted in a body for purposes of the present document may be tested in a torso simulator constructed as follows in order to simulate operation of the implant under actual operating conditions as shown in figure A.2.

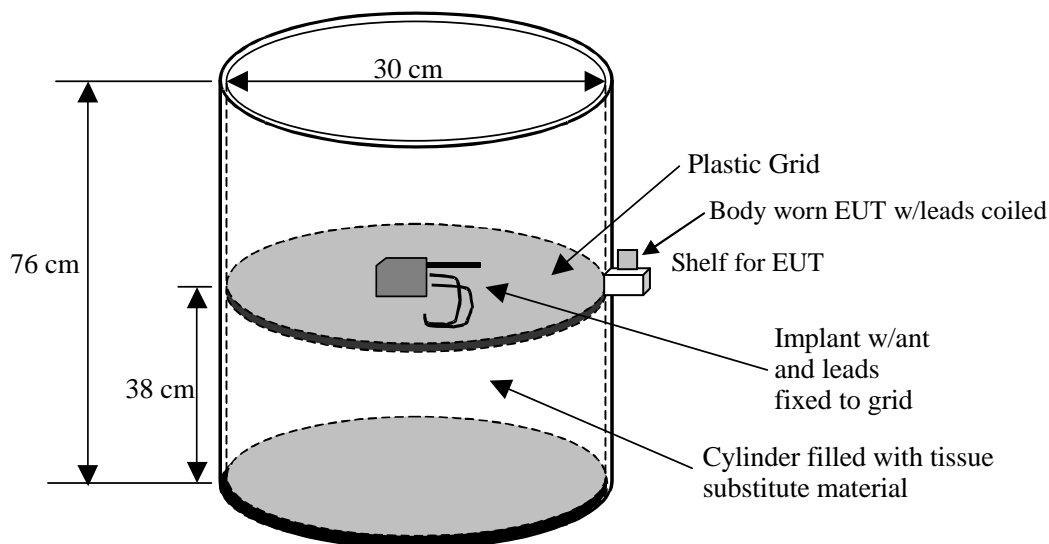


Figure A.2: Torso simulator setup

A torso simulator for testing body worn or implant transmitters consists of a cylindrical Plexiglas container with a diameter of $30\text{ cm} \pm 0,5\text{ cm}$ by $76\text{ cm} \pm 0,5\text{ cm}$ with a sidewall thickness of $0,635\text{ cm} \pm 0,05\text{ cm}$. It shall be completely filled with a material that is sufficiently fluid that it will flow around the implant without any voids.

The dielectric and conductivity properties of this material should match the dielectric and conductivity properties of muscle tissue at the centre frequency of operation or, if desired, at the measurement frequency. The saline solution specified below may be used for this purpose; however, it typically will not match these properties.

All radiated emissions measurements on implanted or body worn devices may be made using the above torso simulator with the tissue substitute material at a nominal temperature between 22°C and 38°C .

NOTE: This temperature range will facilitate testing because it is representative of ambient conditions at many test sites.

A mounting fixture for the implant inside the container or outside for body worn devices shall be provided that permits the radiating element or elements of the EUT to be positioned vertically and horizontally. The fixture should also support any additional device leads associated with the therapeutic function of the device in a fixed repeatable manner such that they do not influence the measurement.

For testing purposes the side of the implant case that is in closest proximity to the internal antenna shall be mounted in a vertical plane no further than $6\text{ cm} \pm 0,5\text{ cm}$ from the sidewall of the container and centred vertically within the container or centred on the external shelf touching the fluid container if body worn. When switching from vertical to horizontal positioning, the device case shall be mounted as above except the side of the case shall be mounted in a horizontal plane. In this case it may be necessary to reposition the device to maintain a separation as above no greater than $6\text{ cm} \pm 0,5\text{ cm}$ from the sidewall of the test fixture along its length for implants and touching the external side of the simulator if body worn. Implant leads shall be coiled and placed away from the implant antenna while maintaining a nominal 6 cm from the sidewall. Body worn device leads shall be coiled and placed away from the antenna.

The above fixture shall be placed on a turntable such that the device transmitter is located at a nominal 1,5 m 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. In situations where the device case that is in closest proximity to the internal antenna is unknown, the device position will be investigated to determine the position producing maximum emissions. Data shall be recorded for this position to determine conformance with the applicable limit.

Implants or body worn devices that are designed to communicate with an external device may require the presence of the external device in order to transmit. Providers should note that it is desirable if possible to activate normal EUT transmitter function via a technique that does not require an external accessory device such as a programmer to be used.

Tissue parameters for various frequencies maybe obtained from the following website: <http://niremf.ifac.cnr.it>, maintained by the Italian National Research Council, Institute for Applied Physics. A formula and details for a suitable tissue substitute material are also defined in the book " Radiofrequency Radiation Dosimetry Handbook" (see bibliography). A saline solution recognized by the medical industry as a tissue medium may be used if desired by the provider. As guidance, a saline solution producing a 375 Ω cm conductivity using a standard test cell meets this requirement.

A.1.2 Test antenna

A.1.2.1 Below 30 MHz

A calibrated loop antenna shall be used to detect the field strength from the test sample. The antenna shall be supported in the vertical plane and be rotated about a vertical axis. The lowest point of the loop shall be 1 m above ground level.

A.2 Guidance on the use of radiation test sites

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

A.2.1 Measuring distance

Evidence indicates that the measuring distance is not critical and does not significantly affect the measuring results when corrected for distance. For ULP-AID inductive systems covered by the present document, the measurement distance should generally be 10 m or less. Precautions described in the present annex shall be observed. Measurements at low frequencies and distances less than $\lambda/2$ are considered in the present document and shall be followed. Measuring distances of 3 m, 5 m, 10 m and 30 m are in common use in European test laboratories. Measurements at distances different to 10 m need to have a correction factor added to give a resultant at 10 m so that comparison with the limit is possible. The correction factor used shall be stated and justified in the test report.

A.2.2 Auxiliary cables

The position of auxiliary cables (power supply cables, therapy 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 when possible (through a hole in the non conducting support) coiled as referenced in clause A.1.1.2, or as specified in the technical documentation supplied with the equipment.

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

Annex B (normative): H-field limit correction factor for generated E-fields

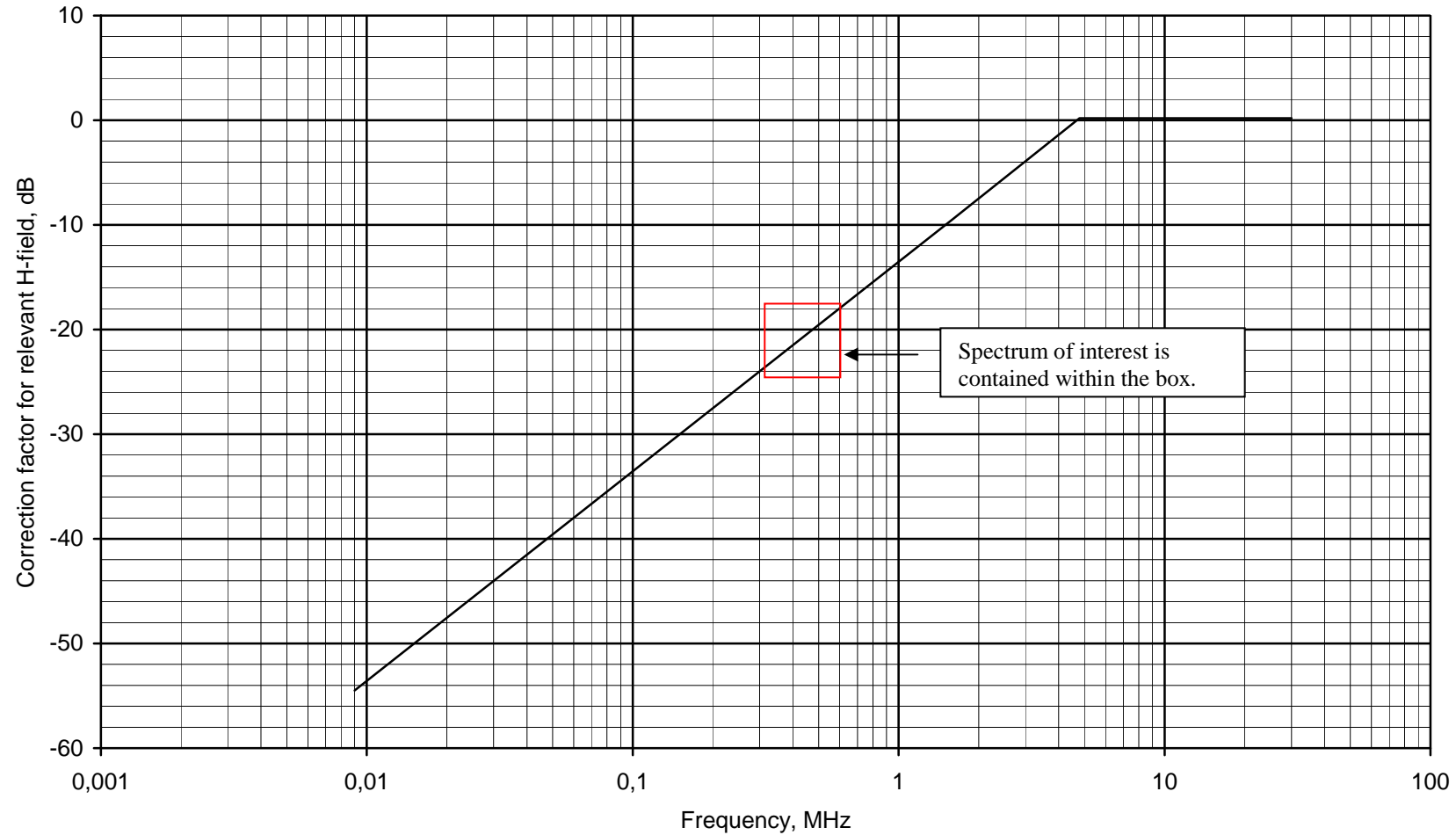


Figure B.1: Correction factor versus frequency

Annex C (informative): E-fields in the near field at low frequencies

E-field at low frequencies is often in the near field and it is in reality only possible to measure the H-field component with the shielded loop antenna; in this case there is also a relation between the E-field and the H-field by the wave impedance Z . In the near field the wave impedance is highly dependent on the type of radiating antenna (loop or open end wire) and the wavelength. If the power density at a certain distance is the same for a H-field and an E-field generated signal, the following calculation can be made:

In the direction of maximum power in the near field, the power density S is:

$$S = \frac{E^2}{Z_e} = H_e^2 Z_e = H_m^2 Z_m \quad (\text{C.1})$$

where:

- S = power density;
- E = electrical field generated by an E-field antenna at distance d ;
- H_e = magnetic field generated by an E-field antenna at distance d ;
- H_m = magnetic field generated by a H-field antenna at distance d ;
- Z_e = wave impedance of a field generated by an E-field antenna at distance d ;
- Z_m = wave impedance of a field generated by an H-field antenna at distance d .

$$Z_m = Z_0 2\pi \frac{d}{\lambda} \quad \text{if } d < \frac{\lambda}{2\pi} \quad (\text{near field}) \quad (\text{C.2})$$

$$Z_e = Z_0 \frac{\lambda}{2\pi d} \quad \text{if } d < \frac{\lambda}{2\pi} \quad (\text{near field}) \quad (\text{C.3})$$

Equation (C.1) gives:

$$H_e = H_m \sqrt{\frac{Z_m}{Z_e}} \quad (\text{A/m}) \quad (\text{C.4})$$

Equations (C.2) and (C.3) into (C.4) give:

$$H_e = H_m \frac{2\pi d}{\lambda} = H_m \frac{2\pi d f_c}{300} \quad (\text{C.5})$$

where f_c is the carrier frequency in MHz.

For $2\pi d/\lambda = 1$, $d = 10$ and $f_c = 4,78$ MHz, and using equation (C.5), this gives:

$$H_e = H_m \frac{f_c}{4,78} \quad (f \text{ in MHz}) \quad (\text{C.6})$$

For $2\pi d/\lambda < 1$ if $f_c < 4,78$ MHz then equation (C.5) is valid, (i.e. near field).

For $2\pi d/\lambda \geq 1$ if $f_c > 4,78$ MHz then $H_e = H_m$, (i.e. far field).

The method allows an electric generated E-field to be measured as a magnetic generated H-field by adding a correction factor derived from (C.6).

Annex D (normative): H-field measurements and limits at 3 m and 30 m

The present document allows field measurements to be made at other distances than 10 m. In this case, the appropriate H-field limit, H_x , for provider requested measurement distance, d_x , shall be determined by the provider. Both the requested measurement distance and the appropriate limit shall be stated in the test report.

The conversion of the H-field limits at 10 m to a new measurements distance is not trivial as the near-field to far-field boundary changes with both frequency and distance. Different combinations of near/far-field and a maximum radiated field strength in either the coaxial or coplanar direction of the loop antenna the conversions of the H-field limits of the present document to 3 m or 30 m are discontinuous curves.

The conversion methods of the present annex are only applicable if the maximum dimension of the loop coil is small in relation to the measurement distance.

D.1 Limits for measurements at 30 m distance

The H-field limit at 30 m, H_{30m} , is determined by the following equation:

$$H_{30m} = H_{10m} + C_{30} \quad (D.1)$$

where:

H_{10m} is the H-field limit in $\text{dB}\mu\text{A}/\text{m}$ at 10 m distance according to the present document; and

C_{30} is a conversion factor in dB which is determined from figure D.1.

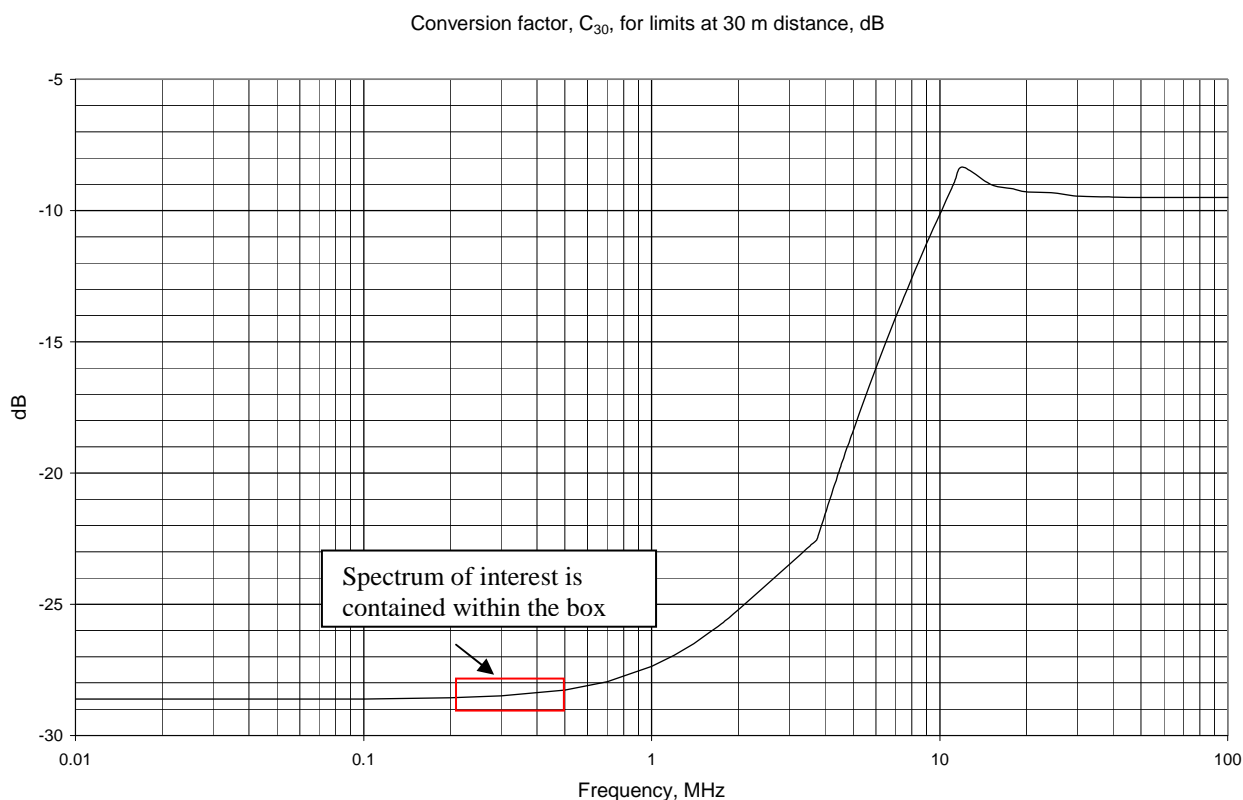


Figure D.1: Conversion factor C_{30} versus frequency

D.2 Limits for measurements at 3 m distance

The H-field limit in dB μ A/m at 3 m, H_{3m} , is determined by the following equation:

$$H_{3m} = H_{10m} + C_3 \quad (\text{D.2})$$

where:

H_{10m} is the H-field limit in dB μ A/m at 10 m distance according to the present document; and

C_3 is a conversion factor in dB determined from figure D.2.

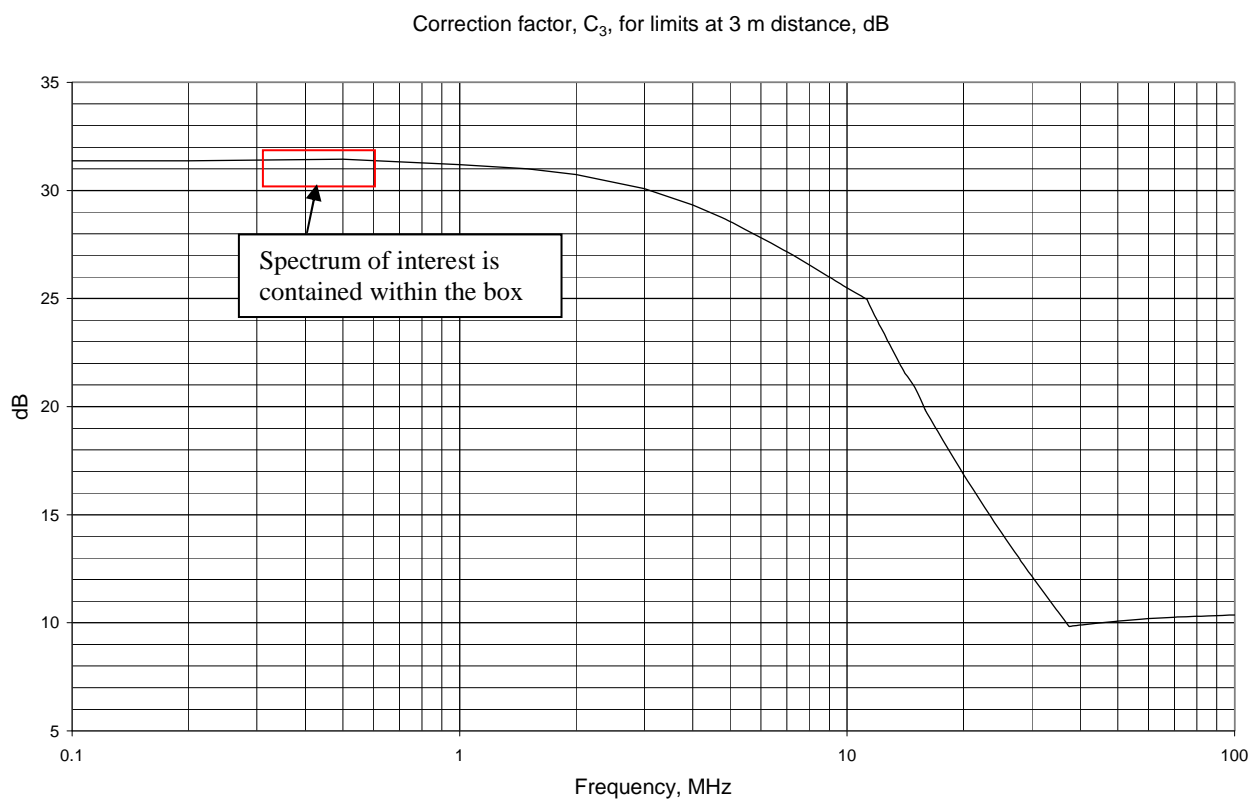


Figure D.2: Conversion factor C_3 versus frequency

Annex E (informative): Bibliography

ETSI TR 102 316: "Electromagnetic Compatibility and Radio Spectrum Matters (ERM); Ultra Low Power Animal Implantable Devices (ULP-AID) operating in the frequency band 315 kHz to 600 kHz; System Reference Document".

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