

# ETSI EN 302 537 V2.1.1 (2016-10)



HARMONISED EUROPEAN STANDARD

**Ultra Low Power Medical Data Service (MEDS)  
Systems operating in the frequency range  
401 MHz to 402 MHz and 405 MHz to 406 MHz;  
Harmonised Standard covering the essential requirements  
of article 3.2 of the Directive 2014/53/EU**

---

Reference

REN/ERM-TG30-307

---

Keywords

harmonised standard, radio, regulation, testing

**ETSI**

650 Route des Lucioles  
F-06921 Sophia Antipolis Cedex - FRANCE

Tel.: +33 4 92 94 42 00 Fax: +33 4 93 65 47 16

Siret N° 348 623 562 00017 - NAF 742 C  
Association à but non lucratif enregistrée à la  
Sous-Préfecture de Grasse (06) N° 7803/88

---

**Important notice**

The present document can be downloaded from:  
<http://www.etsi.org/standards-search>

The present document may be made available in electronic versions and/or in print. The content of any electronic and/or print versions of the present document shall not be modified without the prior written authorization of ETSI. In case of any existing or perceived difference in contents between such versions and/or in print, the only prevailing document is the print of the Portable Document Format (PDF) version kept on a specific network drive within ETSI Secretariat.

Users of the present document should be aware that the document may be subject to revision or change of status. Information on the current status of this and other ETSI documents is available at  
<https://portal.etsi.org/TB/ETSIDeliverableStatus.aspx>

If you find errors in the present document, please send your comment to one of the following services:  
<https://portal.etsi.org/People/CommiteeSupportStaff.aspx>

---

**Copyright Notification**

No part may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm except as authorized by written permission of ETSI.

The content of the PDF version shall not be modified without the written authorization of ETSI.  
The copyright and the foregoing restriction extend to reproduction in all media.

© European Telecommunications Standards Institute 2016.  
All rights reserved.

**DECT™**, **PLUGTESTS™**, **UMTS™** and the ETSI logo are Trade Marks of ETSI registered for the benefit of its Members.  
**3GPP™** and **LTE™** are Trade Marks of ETSI registered for the benefit of its Members and of the 3GPP Organizational Partners.  
**GSM®** and the GSM logo are Trade Marks registered and owned by the GSM Association.

# Contents

Intellectual Property Rights .....	6
Foreword.....	6
Modal verbs terminology.....	6
Introduction .....	6
1 Scope .....	8
2 References .....	9
2.1 Normative references .....	9
2.2 Informative references.....	9
3 Definitions, symbols and abbreviations .....	10
3.1 Definitions .....	10
3.2 Symbols.....	12
3.3 Abbreviations .....	13
4 Technical requirements specifications .....	14
4.1 Environmental profile.....	14
4.2 Conformance requirements .....	14
4.2.1 Transmitter requirements .....	14
4.2.1.1 Frequency error .....	14
4.2.1.1.1 Definition.....	14
4.2.1.1.2 Limits .....	14
4.2.1.1.3 Conformance .....	14
4.2.1.2 Emission bandwidth .....	14
4.2.1.2.1 Definition.....	14
4.2.1.2.2 Limits .....	14
4.2.1.2.3 Conformance .....	14
4.2.1.3 Effective radiated power of the fundamental emission .....	15
4.2.1.3.0 General requirement .....	15
4.2.1.3.1 Definition.....	15
4.2.1.3.2 Limits .....	15
4.2.1.3.3 Conformance .....	15
4.2.1.4 Spurious emissions of transmitter .....	15
4.2.1.4.0 General requirement .....	15
4.2.1.4.1 Definition.....	16
4.2.1.4.2 Limits .....	16
4.2.1.4.3 Conformance .....	16
4.2.1.5 Frequency stability under low voltage conditions .....	16
4.2.1.5.1 Definition.....	16
4.2.1.5.2 Limits .....	16
4.2.1.5.3 Conformance .....	16
4.2.2 Receiver requirements .....	17
4.2.2.1 Spurious radiation of receivers.....	17
4.2.2.1.1 Definition.....	17
4.2.2.1.2 Limits .....	17
4.2.2.1.3 Conformance .....	17
4.2.2.2 Receiver blocking .....	17
4.2.2.2.1 Definition.....	17
4.2.2.2.2 Limits .....	17
4.2.2.2.3 Conformance .....	17
4.2.3 Transmitter and Receiver requirements .....	17
4.2.3.1 Spectrum Access .....	17
4.2.3.1.0 General requirements.....	17
4.2.3.1.1 LBT/AFA spectrum access.....	18
4.2.3.1.2 Low Power Low Duty Cycle spectrum access .....	19
4.3 Mechanical and electrical design.....	19
4.3.1 General.....	19

4.3.2	Antennas .....	19
4.3.3	Controls .....	19
4.3.4	Transmitter shut-off facility .....	19
4.3.5	Void .....	20
4.3.6	Equipment identification.....	20
5	Testing for compliance with technical requirements.....	20
5.1	Environmental conditions for testing .....	20
5.1.0	General remark .....	20
5.1.1	Presentation of equipment for testing purposes .....	20
5.1.1.0	General remark.....	20
5.1.1.1	Choice of model for testing.....	20
5.1.1.2	Testing of equipment with alternative power levels.....	21
5.1.1.3	Testing of equipment that does not have an external 50 $\Omega$ RF connector (integral antenna equipment) .....	21
5.1.1.3.1	Equipment with an internal permanent or temporary antenna connector .....	21
5.1.1.3.2	Equipment with a temporary antenna connector .....	21
5.1.1.3.3	Equipment intended to be implanted in or worn on but totally external to a human body .....	21
5.1.2	Declarations by the provider.....	21
5.1.3	Auxiliary test equipment.....	21
5.1.4	Test Conditions .....	21
5.1.4.1	Normal and extreme test conditions.....	21
5.1.4.2	Test power source .....	22
5.1.4.2.0	General remark .....	22
5.1.4.2.1	External test power source.....	22
5.1.4.2.2	Internal test power source .....	22
5.1.4.3	Normal test conditions .....	22
5.1.4.3.1	Normal temperature and humidity.....	22
5.1.4.3.2	Normal test power source .....	23
5.1.4.4	Extreme test conditions .....	23
5.1.4.4.1	Extreme temperatures.....	23
5.1.4.4.2	Extreme test source voltages .....	24
5.1.4.5	Normal test signals and test modulation.....	25
5.1.4.5.0	General remark .....	25
5.1.4.5.1	Normal modulation test signals for data.....	25
5.1.4.6	Antennas .....	26
5.1.4.6.0	General remark .....	26
5.1.4.6.1	Artificial antenna .....	26
5.1.4.6.2	Artificial antenna for transmitters with 50 $\Omega$ impedance connector.....	26
5.1.4.7	Test fixture for ULP-AMD, ULP-AMD-P and ULP-AMI-P devices .....	26
5.1.4.8	Test fixture for ULP-AMI and ULP-BWD .....	27
5.1.4.9	Test sites and general arrangements for radiated measurements.....	27
5.1.4.10	Modes of operation of the transmitter .....	27
5.1.4.11	Measuring receiver.....	27
5.2	Interpretation of the measurement results .....	27
5.3	Methods of measurement .....	28
5.3.0	General requirement .....	28
5.3.1	Frequency error.....	29
5.3.1.0	General remark.....	29
5.3.1.1	Method of measurement for systems with an unmodulated carrier frequency provision.....	29
5.3.1.2	Method of measurement for systems with a modulated carrier frequency.....	30
5.3.2	Emission bandwidth measurement .....	30
5.3.3	Effective radiated power of the fundamental emission.....	31
5.3.4	Spurious emissions of transmitter.....	32
5.3.5	Frequency stability under low voltage conditions .....	33
5.3.6	Spurious radiation of receivers .....	33
5.3.6.0	Overview .....	33
5.3.6.1	Spurious radiation of receivers.....	33
5.3.6.2	Method of measuring the spurious radiations of receivers.....	33
5.3.7	Receiver blocking .....	34
5.3.7.0	General remarks .....	34
5.3.7.1	Measurement method using out-of-operating-region disturbance.....	34

5.3.7.2	Measurement method using frequency administration commands .....	35
5.3.7.3	Results based on the above test method .....	35
5.3.8	Spectrum Access.....	35
5.3.8.1	LBT/AFA spectrum access .....	35
5.3.8.1.0	General provisions.....	35
5.3.8.1.1	LBT threshold power level .....	36
5.3.8.1.2	Monitoring system bandwidth .....	38
5.3.8.1.3	Monitoring system scan cycle time and minimum channel monitoring period .....	39
5.3.8.1.4	Channel access based on ambient levels relative to the calculated access LBT threshold level, P <sub>Th</sub> .....	40
5.3.8.1.5	Discontinuation of MEDS session if a silent period greater than or equal to 5 s occurs .....	41
5.3.8.1.6	Use of pre-scanned alternate channel .....	42
5.3.8.2	Spectrum access based on low power and low duty cycle .....	44
5.3.8.2.0	Overview .....	44
5.3.8.2.1	Methods of measurement.....	44
<b>Annex A (normative):</b>	<b>Relationship between the present document and the essential requirements of Directive 2014/53/EU .....</b>	<b>46</b>
<b>Annex B (normative):</b>	<b>Radiated measurements .....</b>	<b>47</b>
B.1	Test sites and general arrangements for measurements involving the use of radiated fields .....	47
B.1.1	Outdoor test site .....	47
B.1.1.0	Introduction.....	47
B.1.1.1	Standard position .....	48
B.1.1.2	Equipment in close proximity to the human body but external to it .....	48
B.1.1.3	Human torso simulator for ULP-BWD and ULP-AMI.....	48
B.1.2	Test antenna.....	49
B.1.3	Substitution antenna .....	49
B.1.4	Optional additional indoor site .....	50
B.2	Guidance on the use of radiation test sites .....	51
B.2.0	Introduction .....	51
B.2.1	Measuring distance.....	51
B.2.2	Test antenna.....	51
B.2.3	Substitution antenna .....	51
B.2.4	Artificial antenna.....	51
B.2.5	Auxiliary cables.....	51
B.3	Further optional alternative indoor test site using a fully anechoic chamber .....	52
B.3.0	Introduction .....	52
B.3.1	Example of the construction of a fully anechoic chamber.....	52
B.3.2	Influence of parasitic reflections in fully anechoic chambers .....	52
B.3.3	Calibration of the fully anechoic chamber .....	53
<b>Annex C (normative):</b>	<b>Technical performance of the spectrum analyser.....</b>	<b>55</b>
<b>Annex D (informative):</b>	<b>Bibliography.....</b>	<b>56</b>
History .....		57

---

## Intellectual Property Rights

IPRs essential or potentially essential to the present document may have been declared to ETSI. The information pertaining to these essential IPRs, if any, is publicly available for **ETSI members and non-members**, and can be found in ETSI SR 000 314: "*Intellectual Property Rights (IPRs); Essential, or potentially Essential, IPRs notified to ETSI in respect of ETSI standards*", which is available from the ETSI Secretariat. Latest updates are available on the ETSI Web server (<https://ipr.etsi.org/>).

Pursuant to the ETSI IPR Policy, no investigation, including IPR searches, has been carried out by ETSI. No guarantee can be given as to the existence of other IPRs not referenced in ETSI SR 000 314 (or the updates on the ETSI Web server) which are, or may be, or may become, essential to the present document.

---

## 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.11] 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.2].

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:	12 September 2016
Date of latest announcement of this EN (doa):	31 December 2016
Date of latest publication of new National Standard or endorsement of this EN (dop/e):	30 June 2017
Date of withdrawal of any conflicting National Standard (dow):	30 June 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).

"**must**" and "**must not**" are **NOT** allowed in ETSI deliverables except when used in direct citation.

---

## Introduction

The present document covers the ultra low power radio devices used in a Medical Data Service and the various types of devices that form part of the system providing the service. It includes methods of measurement and requirements for radio systems used in the service that are fitted with an antenna connector and/or having an integral antenna. If a device which is operating in the MEDS and is available on the market is required to be checked, it should be tested in accordance with the methods of measurement specified in the present document.

The present document covers various individual devices which when operating together form a system operating as a Medical Data Service (MEDS) that provides medical practitioners with therapeutic and/or diagnostic information used to provide improved medical treatment of a patient and/or to provide an interactive system for patient control of therapeutic devices. MEDS is intended only for transmission of non-time critical data, the loss of which will not compromise the health and/or safety of the patient.

The present document contains required characteristics considered necessary for the radio sections to meet in order to efficiently use the available spectrum for the purpose of transferring data that is used in diagnosing and delivering therapies to individuals with various illnesses. Of particular importance is the inclusion of spectrum monitoring and access requirements (listen before talk protocol) designed to significantly reduce any interference potential between MEDS systems operating in the band or between a MEDS system and primary users of the band.

The present document is a specific product standard applicable to ultra low power devices that are part of a MEDS system operating in spectrum within the frequency bands 401 MHz to 402 MHz and 405 MHz to 406 MHz.

The frequency usage conditions for the bands 401 MHz to 402 MHz and 405 MHz to 406 MHz are European wide harmonised for "active medical implant devices" according to Commission Implementing Decision 2013/752/EU [i.12] and ERC Decision (01)17 [i.1].

The present document contains the technical characteristics for ultra low power radio equipment and 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.
- 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 systems and accessories operating in spectrum within the bands 401 MHz to 402 MHz and 405 MHz to 406 MHz that operate in a MEDS service for telecommand and telemetry between devices that are part of a MEDS (see definition of MEDS);

Only two types of MEDS system devices are permitted under the present document:

- 1) Frequency agile devices designed to access a minimum of 18 channels evenly distributed across the 401 MHz to 402 MHz and 405 MHz to 406 MHz bands with a minimum of 9 channels for each 1 MHz segment (i.e. 401 MHz to 402 MHz and 405 MHz to 406 MHz).
- 2) Devices capable of operation only on a single channel using low duty cycle and low power for spectrum access in the 401 MHz to 402 MHz or 405 MHz to 406 MHz bands, see clause 4.2.3.1.2 and the following clauses.

The frequency usage conditions for the bands 401 MHz to 402 MHz and 405 MHz to 406 MHz are European wide harmonised for "active medical implant devices" according to Commission Implementing Decision 2013/752/EU [i.12] and ERC Decision (01)17 [i.1] with the following usage restrictions:

- "This set of usage conditions is only available for systems specifically designed for the purpose of providing non-voice digital communications between active implantable medical devices and/or body-worn devices and other devices external to the human body used for transferring non-time critical individual patient-related physiological information."

The present document covers devices utilizing ultra low power radio devices in combination with medical devices, the medical portion of which is regulated by the Medical Device Directive [i.8] (MDD) or the Active Implantable Medical Device Directive (AIMD [i.9]). The radio part of medical devices regulated by the MDD is hereafter referred to as ULP-AMD, ULP-AMD-P for peripheral devices, and ULP-BWD for body worn devices. ULP-BWD are devices, such as a physiological parameter sensor or handheld devices that are intended to operate in very close proximity to the human body, including touching the body, whose radio antenna is external to the body and is used to communicate with a device that is part of a MEDS system. The radio part of medical devices regulated under the AIMD is hereafter referred to as Ultra Low Power-Active Medical Implants (ULP-AMI) and peripherals (ULP-AMI-P) used in a Medical Data Service (MEDS).

Devices covered by the present document are an evolving new technology to be made available worldwide by the medical equipment industry that will provide high speed communications capability between devices associated with an individual patient that are part of a complete MEDS system as defined in clause 3.1. Examples of MEDS devices falling under the scope of the present document are portable body worn physiological sensors that allow ambulatory monitoring, implanted devices and external system devices used to transfer data collected by a MEDS system to medical practitioners that will use the data to diagnose and treat a patient.

The present document contains requirements to demonstrate that Ultra Low Power Medical Data Service (MEDS) Systems operating in the frequency range 401 MHz to 402 MHz and 405 MHz to 406 MHz "*... shall be so constructed that they both effectively use and support the efficient use of radio spectrum in order to avoid harmful interference*" (article 3.2 of the Directive 2014/53/EU [i.2]). 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+AMD1:2010+AMD2:2014: "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] ERC Decision (01)17 (2011 amendment): "Harmonised frequencies, technical characteristics and exemption from individual licensing of Ultra Low Power Active Medical Implant (ULP-AMI) communication systems operating in the frequency band 401 - 406 MHz on a secondary basis".
- [i.2] 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.3] ETSI TR 100 028 (all parts) (V1.4.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Uncertainties in the measurement of mobile radio equipment characteristics".
- [i.4] Recommendation ITU-T O.153: "Basic parameters for the measurement of error performance at bit rates below the primary rate".
- [i.5] "Radiofrequency Radiation Dosimetry Handbook" (October 1986), USAF School of Aerospace Medicine, Aerospace Medical Division (AFSC), Brooks Air Force Base, TX 78235-5301.
- [i.6] ANSI C63.17 (1998): "American National Standard for Methods of Measurement of the Electromagnetic and Operational Compatibility of Unlicensed Personal Communications Services (UPCS) Devices".
- [i.7] "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.8] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (MD Directive).
- [i.9] 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.10] Recommendation ITU-R RS.1346: "Sharing between the meteorological aids service and medical implant communication systems (MICS) operating in the mobile service in the frequency band 401-406 MHz".
- [i.11] 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.12] 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.

---

## 3 Definitions, symbols and abbreviations

### 3.1 Definitions

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

**access protocol:** specification for measuring natural and man-made ambient background levels for the purpose of providing a technique for spectrum access that reduces the potential for harmful interference to/from other users of the spectrum

**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

**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

**Adaptive Frequency Agility (AFA):** ability to determine an unoccupied sub-band or channel of operation in order to minimize interference with other users of the same band

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

**Body Worn Device (BWD):** medical sensor, handheld device, or other medical device intended to be operated in close proximity to the human body, and is used to sense and/or transfer, via means of radio frequency transmission, human physiological parameters or system programming information

**conducted measurements:** measurements that are made using a direct 50  $\Omega$  connection to the equipment under test

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

**effective radiated power:** 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

NOTE: See clause 4.2.1.3.1.

**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

NOTE: Compliance is determined using instrumentation employing a peak detector function and a resolution bandwidth approximately equal to 1 % of the emission bandwidth of the device under test.

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

**LBT threshold power level:** ambient signal power level above which the monitoring system selects spectrum for use in a communication session according to the next available channel with the lowest level of ambient signal power or least interfered channel (LIC)

**Least Interfered Channel (LIC):** channel, among the available channels, that has the lowest potential for causing interference to or receiving interference from other users of the band

**Listen Before Talk (LBT):** combination of the listen mode followed by the talk mode

**listen mode:** action taken by an interrogator to detect an unoccupied sub-band or channel

**Medical Data Service (MEDS):** service that uses a system specifically for the purpose of providing non-voice digital communications between active medical implants and/or body worn devices and other devices external to the human body engaged in transferring non-time critical individual patient related physiological information

**Medical Data Service (MEDS) communication session:** collection of transmissions that may or may not be continuous, between co-operating ULP-AMI, ULP-AMI-P, ULP-BWD, ULP-AMD and ULP-AMD-P

**Medical Data Service (MEDS) system:** collection of medical devices having short range RF communication capability, that are associated with a specific patient, consisting of at least one active medical implant or body worn device together with other devices external to the body, that have the ability to communicate with each other using frequencies in the 401 MHz to 402 MHz and/or 405 MHz to 406 MHz bands

**Medical Data Service (MEDS) System Communication Link (MEDSCL):** collection of transmissions that may or may not be continuous, between MEDS system devices including at least one active medical implant or body worn device together with other devices external to the body engaged in transferring non-time critical patient related physiological information collected by a single MEDS system

**Medical Device (MD):** any instrument, apparatus, appliance, material or other article, whether used alone or in combination, together with any accessories or software for its proper functioning, intended by the provider to be used for human beings in the:

- diagnosis, prevention, monitoring, treatment or alleviation of disease or injury;
- investigation, replacement or modification of the anatomy or of a physiological process;
- control of conception;

and which does not achieve its principal intended action by pharmacological, chemical, immunological or metabolic means, but which may be assisted in its function by such means

**Medical Data Service (MEDS) System Communication Channel:** any continuous segment of spectrum that is equal to the emission bandwidth of the device with the largest bandwidth that is to participate in a MEDS session

NOTE 1: Aggregation of adjacent channels up to a maximum of 100 kHz channel for a single system is permitted.

NOTE 2: As stated in Commission Implementing Decision 2013/752/EU [i.12] and ERC Decision (01)17 [i.1], it is permitted to combine adjacent channels for increased bandwidth up to 100 kHz for each single system channel bandwidth.

**Medical Data Service (MEDS) System Device:** any ultra low power medical device communicating in the 401 MHz to 402 MHz and/or 405 MHz to 406 MHz band

NOTE: Only two types of MEDS system devices are permitted under the present document:

- 1) Frequency agile devices designed to access a minimum of 18 channels evenly distributed across the 401 MHz to 402 MHz and 405 MHz to 406 MHz bands with a minimum of 9 channels defined for each 1 MHz segment (i.e. 401 MHz to 402 MHz and 405 MHz to 406 MHz), see clause 4.2.3.1.1 and the following clauses.
- 2) Devices capable of operation only on a single channel using low duty cycle and low power for spectrum access in the 401 MHz to 402 MHz or 405 MHz to 406 MHz bands, see clause 4.2.3.1.2 and the following clauses.

**monitoring system:** circuitry in an active medical device that assures conformity with the spectrum access protocol requirements based on Listen before Talk for channel selection and Adaptive Frequency Agility to access the channel selected by the LBT process for operation

**provider:** manufacturer or person responsible for placing the apparatus on the market

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

**talk mode:** transmission of intentional radiation by a transmitter

**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

**time-critical data:** data which if not transferred immediately will result in compromising the health and/or safety of the patient

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

NOTE: The medical function of such device is regulated under the AIMD Directive [i.9]. The radio function of such device is regulated under Directive 2014/53/EU [i.2].

**Ultra Low Power Active Medical Implant Peripheral (ULP-AMI-P) device:** radio part of medical equipment outside the human body that communicates with an ULP-AMI, ULP-AMD, ULP-BWD, or other ULP-AMI-P to establish a Medical Data Service (MEDS) System Communication Link

NOTE: The medical function of such device is regulated under the AIMD Directive [i.9]. The radio function of such device is regulated under Directive 2014/53/EU [i.2].

**Ultra Low Power Active Medical Device (ULP-AMD):** radio part of any active medical device (AMD) outside the human body which has its radio antenna external to the body and is used to communicate with a device that is part of a MEDS system

NOTE: The medical function of such device is regulated under the AIMD Directive [i.9] or Medical Device Directive [i.8], as appropriate for its intended use. The radio function of such device is regulated under Directive 2014/53/EU [i.2].

**Ultra Low Power Active Medical Device Peripheral (ULP-AMD-P):** radio part of medical equipment outside the human body that communicates with an ULP-AMD, ULP-BWD, or other ULP-AMD-P to establish a Medical Data Service (MEDS) System Communication Link

NOTE: The medical function of such device is regulated under the Medical Device Directive [i.8]. The radio function of such device is regulated under Directive 2014/53/EU [i.2].

**Ultra Low Power Body Worn Device (ULP-BWD):** radio part of a medical device, such as a physiological parameter sensor or handheld device, that is intended to operate in proximity to the human body (6 cm or less from the skin surface) which has its radio antenna external to the body and is used to communicate with a device that is part of a MEDS system

NOTE: The medical function of such device is regulated under the AIMD Directive [i.9] or Medical Device Directive [i.8], as appropriate for its intended use. The radio function of such device is regulated under Directive 2014/53/EU [i.2].

## 3.2 Symbols

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

B	bandwidth
$B_{lf}$	low frequency band edge (see clause 5.3.8.1.0)
$B_{hf}$	high frequency band edge (see clause 5.3.8.1.0)
dB	decibel
dBm	decibel relative to 1 mWatt
E	electrical field strength
$E_o$	reference electrical field strength (see annex B)
f	frequency
$f_c$	channel centre frequency

$f_e$	frequency under extreme conditions
G	Antenna Gain
$M_c$	Number of pulses captured during the one hour time sweep (see clause 5.3.8.2.1)
NaCl	sodium chloride
P	power
R	distance
$R_o$	Reference distance (see annex B)
$P_{Th}$	maximum threshold power level (see clause 4.2.3.1.1.2)
t	time
$T_t$	Total time of transmission during one hour for each mode of activation (see clause 5.3.8.2.1)
$T_c$	Total time of transmission during an hour with all modes activated (see clause 5.3.8.2.1)
V	Volt
W	Watt
$\lambda$	wavelength

### 3.3 Abbreviations

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

AFA	Adaptive Frequency Agility
AIMD	Active Implantable Medical Device
AMD	Active Medical Device
BWD	Body Worn Device
CISPR	Comité International Spécial des Perturbations Radioélectriques
CW	Continuous Wave
e.r.p.	effective radiated power
EC	European Commission
EFTA	European Free Trade Association
ERC	European Radiocommunications Committee
EU	European Union
EUT	Equipment Under Test
FDD	Frequency Division Duplex
ITU-R	ITU Radiocommunication Sector
LBT	Listen Before Talk
LDC	Low Duty Cycle
LIC	Least Interfered Channel
LP/LDC	Low Power/Low Duty Cycle
MD	Medical Device
MDD	Medical Device Directive
MEDS	Medical Data Service
MEDSCL	Medical Data Service System Communication Link
OATS	Open Area Test Site
RF	Radio Frequency
TDD	Time Division Duplex
ULP-AMD	Ultra Low Power Active Medical Device
ULP-AMD-P	Ultra Low Power Active Medical Device Peripheral to ULP - BWD
ULP-AMI	Ultra Low Power Active Medical Implant
ULP-AMI-P	Ultra Low Power Active Medical Implant Peripheral
ULP-BWD	Ultra Low Power Body Worn Device
VSWR	Voltage Standing Wave Ratio

---

## 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 Frequency error

###### 4.2.1.1.1 Definition

The frequency error, also known as frequency drift, is the difference between the nominal frequency as measured on the devices under test and under normal test conditions (see clause 5.1.4.3) and the frequency under extreme conditions (see clause 5.1.4.4).

###### 4.2.1.1.2 Limits

The frequency error for equipment operating in the 401 MHz to 402 MHz and 405 MHz to 406 MHz bands shall not exceed  $\pm 100$  ppm under normal, extreme or any intermediate set of conditions.

In addition, the single nominal centre frequency of a device accessing spectrum under the provision for low duty cycle low power operation in the 401 MHz to 402 MHz or 405 MHz to 406 MHz in any operational configuration shall be declared by the provider.

###### 4.2.1.1.3 Conformance

Conformance tests as defined in clause 5.3.1 of the present document shall be carried out.

##### 4.2.1.2 Emission bandwidth

###### 4.2.1.2.1 Definition

The emission bandwidth of a device operating in the 401 MHz to 402 MHz and 405 MHz to 406 MHz band(s) is 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. Compliance is determined using instrumentation employing a peak detector function and a resolution bandwidth approximately equal to 1 % of the emission bandwidth of the EUT.

###### 4.2.1.2.2 Limits

The maximum permitted emission bandwidth shall be 100 kHz. If two or more devices operating in a single MEDS communications session operate in different portions of the available spectrum, the combined maximum emission bandwidth from each portion of spectrum used by a device participating in the communications session in that spectrum, shall not exceed 100 kHz. This limits spectrum usage to a maximum of 100 kHz in any single MEDS communications session irrespective of the communication formats such as TDD and FDD. The 100 kHz limitation may be exceeded briefly due to intermittent transmissions that may occur when operating channel acquisitions or changes are required to maintain a communications session.

###### 4.2.1.2.3 Conformance

Conformance tests as defined in clause 5.3.2 of the present document shall be carried out.

### 4.2.1.3 Effective radiated power of the fundamental emission

#### 4.2.1.3.0 General requirement

This measurement applies to equipment provided with an integral antenna and to equipment supplied with a dedicated antenna. Measurements shall be made in both the 401 MHz to 402 MHz and 405 MHz to 406 MHz band(s) as applicable with each type of antenna provided by the provider that attaches to the equipment.

If the transmitter is designed to operate with different carrier powers, the rated power for each level, or range of levels, shall be declared by the provider. Transmitter operation at any power level greater than 250 nanoWatts e.r.p. requires the frequency of operation of the transmitter to be selected by a MEDS system device using LBT and AFA to select the frequency (clause 4.2.3.1.1 applies).

These measurements shall be performed at the highest power level at which the transmitter is intended to operate.

#### 4.2.1.3.1 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.

#### 4.2.1.3.2 Limits

##### 4.2.1.3.2.0 General requirement

The measurement for each type of transmitter operation shall be carried out under normal test conditions only (see clause 5.1.4.3) or as specified in clause B.1.1.3 in the case of ULP-AMI and ULP-BWD.

##### 4.2.1.3.2.1 Systems using LBT and AFA for spectrum access

Equipment that operates in the 401 MHz to 402 MHz and 405 MHz to 406 MHz frequency range as part of system that incorporates a monitoring system to select the frequency of operation using LBT and AFA (see clause 4.2.3.1.1) shall not exceed 25  $\mu$ W e.r.p. in any mode of operation. Measurements shall be made near the centre frequency of each band the device tunes to.

##### 4.2.1.3.2.2 Devices using low duty cycle and low power for spectrum access

Transmitters operating on any frequency in the 401 MHz to 402 MHz and 405 MHz to 406 MHz bands shall not exceed 250 nW e.r.p. unless each time a MEDSCL is initiated, the frequency of operation for the MEDSCL, is selected by a monitoring system using LBT and AFA. The duty cycle for any transmitter operating in the LDC low power mode is limited to 0,1 % (see clause 4.2.3.1.2.2.1). Measurements shall be made on the frequency of operation.

#### 4.2.1.3.3 Conformance

Conformance tests as defined in clause 5.3.3 of the present document shall be carried out.

### 4.2.1.4 Spurious emissions of transmitter

#### 4.2.1.4.0 General requirement

This measurement applies to equipment provided with an integral antenna and to equipment supplied with a dedicated antenna. Measurements shall be made with each type of antenna provided with the equipment attached to it.

If the equipment is designed to operate with different carrier powers, the rated power for each level or range of levels shall be declared by the provider. The following measurements shall be performed at all power levels at which the transmitter is intended to operate in each band of operation.

The measurement shall be carried out by the use of a measuring receiver according to clause 5.1.4.11.

All emissions from each device that fall outside its emission bandwidth but do fall within the 402 MHz to 405 MHz band shall be attenuated to a level of 1 nanoWatt e.r.p.

#### 4.2.1.4.1 Definition

Spurious emissions are emissions at frequencies other than those of the carrier and sidebands associated with normal test modulation. The level of spurious emissions shall be measured as:

- their effective radiated power when radiated by the cabinet and the integral antenna;
- their effective radiated power when radiated by the cabinet and any dedicated antenna provided by the provider.

#### 4.2.1.4.2 Limits

The power of any spurious emission shall not exceed the following values given in table 1 or the level of the fundamental power of the device whichever is lower. For frequencies below 1 GHz reference bandwidth should be 100 kHz. For frequencies above 1 GHz the reference bandwidth shall be 1 MHz.

**Table 1**

<b>Operating State</b>	<b>Frequency Bands 47 MHz to 74 MHz 87,5 MHz to 118 MHz 174 MHz to 230 MHz 470 MHz to 862 MHz</b>	<b>Frequency Band 402 MHz to 405 MHz</b>	<b>Frequency Bands 30 MHz to 47 MHz 74MHz to 87,5 MHz 118 MHz to 174 MHz 230 MHz to 401 MHz 406 MHz to 470 MHz 862 MHz to 1 000 MHz</b>	<b>Frequencies above 1 000 MHz</b>
Operating	4 nW	1 nW	250 nW	1 $\mu$ W
Standby/Receive	2 nW	1 nW	2 nW	20 nW

#### 4.2.1.4.3 Conformance

Conformance tests as defined in clause 5.3.4 of the present document shall be carried out.

#### 4.2.1.5 Frequency stability under low voltage conditions

##### 4.2.1.5.1 Definition

This test applies only to battery-operated devices covered by the present document. The frequency stability under low voltage condition is the ability of the equipment to remain on the nominal operating frequency when the battery voltage falls below the lower extreme voltage level.

##### 4.2.1.5.2 Limits

The equipment shall either:

- remain on the nominal operating frequency, within the limits stated in clauses 4.2.1.1.2, 4.2.1.2.2, 4.2.1.3.2 and 4.2.1.4.2;
- the equipment shall cease to function below the provider's declared operating voltage.

##### 4.2.1.5.3 Conformance

Conformance tests as defined in clause 5.3.5 of the present document shall be carried out.

## 4.2.2 Receiver requirements

### 4.2.2.1 Spurious radiation of receivers

#### 4.2.2.1.1 Definition

Spurious radiations from the receiver are components at any frequency, generated and radiated by receiver circuitry and/or the antenna.

The level of spurious radiation shall be measured by:

- their effective radiated power when radiated by the cabinet and the integral antenna; or
- their effective radiated power when radiated by the cabinet and any dedicated antenna provided by the provider.

#### 4.2.2.1.2 Limits

The power of any spurious radiations shall not exceed the values given below:

- 2 nW below 1 000 MHz, except in the band 402 MHz to 405 MHz the limit shall be 1 nW;
- 20 nW above 1 000 MHz.

#### 4.2.2.1.3 Conformance

Conformance tests as defined in clause 5.3.6 of the present document shall be carried out.

### 4.2.2.2 Receiver blocking

#### 4.2.2.2.1 Definition

Receiver blocking is a measure of the capability to operate as intended (see clause 4.2.3.1) in the presence of an unwanted signal (blocking signal) on frequencies other than those of the operating channel and the adjacent channels.

#### 4.2.2.2.2 Limits

In the presence of a blocking CW signal at  $f_c \pm 2$  MHz (as specified in clause 5.3.7.1) and at a level 35 dB above the LBT threshold power level ( $P_{Th}$ ) set forth in clause 4.2.3.1.1.2, the LBT threshold power level requirement shall still be met.

#### 4.2.2.2.3 Conformance

Conformance tests as defined in clause 5.3.7 of the present document shall be carried out.

## 4.2.3 Transmitter and Receiver requirements

### 4.2.3.1 Spectrum Access

#### 4.2.3.1.0 General requirements

Only two types of MEDS system devices are permitted under the present document:

- 1) Frequency agile devices designed to access a minimum of 18 channels evenly distributed across the 401 MHz to 402 MHz and 405 MHz to 406 MHz bands with a minimum of 9 channels defined for each 1 MHz segment (i.e. 401 MHz to 402 MHz and 405 MHz to 406 MHz), see clause 4.2.3.1.1 and the following clauses.
- 2) Devices capable of operation only on a single channel using low duty cycle and low power for spectrum access in the 401 MHz to 402 MHz or 405 MHz to 406 MHz bands, see clause 4.2.3.1.2 and the following clauses.

It is mandatory that the provider declares a spectrum access method. At least one of the following methods shall be chosen. A provider may choose to implement both methods in his equipment, however, he may operate using both access methods if the total emission bandwidth does not exceed 100 kHz.

- LBT/AFA requirements for the monitoring system are specified in clause 4.2.3.1.1. Providers declaring this spectrum access method shall further conform to the requirements listed in clause 4.2.3.1.1 of the present document, and are not obliged to fulfil the requirements of clause 4.2.3.1.2 of the present document.
- LP/LDC requirements are specified in clause 4.2.3.1.2. Providers declaring this spectrum access method shall further conform to the requirements listed in clause 4.2.3.1.2 of the present document, and are not obliged to fulfil the requirements of clause 4.2.3.1.1 of the present document.

#### 4.2.3.1.1 LBT/AFA spectrum access

##### 4.2.3.1.1.1 Definition

Under this method, spectrum access for a MEDS system is based on the system frequency of operation being under the control of a system device meeting the technical requirements of clause 5.3.8.1.

A monitoring system is the circuitry in a MEDS service system device that assures conformity with the technical requirement for use of the spectrum access protocol specified in clause 5.3.8.1 by use of LBT and AFA for a specific system.

##### 4.2.3.1.1.2 Limits for LBT threshold power level

The monitoring system threshold power level,  $P_{Th}$  (in dBm) shall not be greater than the calculated level given by the equation:

$$10 \log B(\text{Hz}) - 150 + G (\text{dB}_i)$$

where B is the emission bandwidth of the MEDS communication session transmitter having the widest emission bandwidth and G is the monitoring system antenna gain, including any body absorption for implanted and body worn devices, relative to an isotropic antenna.

If an ULP-AMI or ULP-BWD device is used to select the frequency of operation for a MEDS system, the above LBT threshold level requirement may be adjusted higher 1 dB for every 1 dB the e.r.p. of the device performing the LBT and AFA function is below the maximum permitted level of -16 dBm e.r.p. (25  $\mu$ W), provided no other device operating in the MEDSCL has an e.r.p. greater than the device that selects the frequency of operation for the MEDSCL. Thus, for a specific system a device whose output e.r.p. is 10 dB lower than the maximum permitted level of -16 dBm may add +10 dB to the above equation. This adjustment will permit implanted and body worn devices to provide the LBT and AFA function where antenna gain and body absorption significantly affect monitoring system sensitivity relative to external programmer/controllers.

A provider may elect to immediately use a channel that has a threshold power level that is below the permitted maximum level or the provider may elect to only use the least interfered channel method of channel selection. Systems using the above adjustment to permit frequency selection by an implant or body worn device shall use the least interfered channel method of channel selection described below.

It is not necessary to measure the actual threshold power level of a MEDS system, however, it shall be determined that the system uses the LIC selection process if no channel is available with an ambient power level at or below the calculated threshold power level. This test shows the system has sufficient sensitivity to recognize and accurately compare the ambient signals to the calculated threshold power level.

##### 4.2.3.1.1.3 Conformance

Conformance tests as defined in clause 5.3.8.1 of the present document shall be carried out.

#### 4.2.3.1.2 Low Power Low Duty Cycle spectrum access

##### 4.2.3.1.2.1 Definition

Using this method, spectrum access for a device operating as part of a MEDS system is based on a maximum duty cycle and repetitive transmission limit as defined in clause 4.2.3.1.2.2 coupled with a limit on maximum transmit e.r.p. as defined in clause 4.2.1.3.2.2.

##### 4.2.3.1.2.2 Limits for low duty cycle low power spectrum access

###### 4.2.3.1.2.2.1 Duty cycle limit

The maximum duty cycle permitted is 0,1 % under any condition of operation. Compliance is determined by comparison of  $T_t$  and  $T_c$  as recorded in 5.3.8.2.1 with the limit.

###### 4.2.3.1.2.2.2 Repetitive transmission within an hour

The maximum number of repetitive transmissions within a one hour time frame under any condition of operation is limited to 100. Compliance is determined by comparison of  $M^*$  and  $M_c$  as recorded in clause 5.3.8.2.1 with the limit.

###### 4.2.3.1.2.2.3 Effective Radiated Power

The maximum e.r.p. as defined in clause 4.2.1.3.1 of the present document shall not exceed the limit in clause 4.2.1.3.2.2 of the present document.

###### 4.2.3.1.2.3 Conformance

Conformance tests as defined in clause 5.3.8.2 of the present document 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 disturbance to other equipment and services. It should not be disturbed by harmful interference from other electronic devices and users of the band. Transmitters and receivers may be individual or combination units.

#### 4.3.2 Antennas

Equipment operating in the MEDS service 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 provider.

#### 4.3.3 Controls

Those controls which, if maladjusted, might increase the interfering potentialities of the equipment, shall not be accessible to the user.

#### 4.3.4 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.

### 4.3.5 Void

### 4.3.6 Equipment identification

Devices covered by the present document may also have a unique electronic identification that prevents unauthorized access to the telecommand and telemetry functions of the equipment.

---

## 5 Testing for compliance with technical requirements

### 5.1 Environmental conditions for testing

#### 5.1.0 General remark

Tests defined in the present document shall be carried out at representative points within the boundary limits of the operational environmental profile as declared in clauses 4.2.1, 4.2.2 and 4.2.3.

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 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 remark

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 on a frequency near the mid-point of the 401 MHz to 402 MHz and 405 MHz to 406 MHz as applicable.

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 the appropriate application form, if necessary, 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 bands 401 MHz to 402 MHz and 405 MHz to 406 MHz.

A human torso simulator and tissue substitute material for testing ULP-AMI and ULP-BWD devices operating in the frequency bands 401 MHz to 402 MHz and 405 MHz to 406 MHz shall be used (see clause 5.1.4.8).

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

Measurement shall be performed, according to the present document, on samples of equipment defined in clause 5.1.1.1 (clauses 5.1.1.1, 5.1.1.2 and 5.1.1.3).

The provider shall supply one or more samples of each model or type of transmitter operating in the frequency bands 401 MHz to 402 MHz and 405 MHz to 406 MHz, 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 agreed to by the test laboratory.

### 5.1.1.2 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 5.1.1.1. Spurious emissions tests shall be performed at all power levels.

### 5.1.1.3 Testing of equipment that does not have an external 50 $\Omega$ RF connector (integral antenna equipment)

#### 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 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.

#### 5.1.1.3.2 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. If necessary the provider shall make arrangement for the connection and disconnection of any external temporary antenna connection.

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.

#### 5.1.1.3.3 Equipment intended to be implanted in or worn on but totally external to a human body

The equipment, a human torso simulator as described in clause 5.1.4.8 and clause B.1.1.3, and a sufficient quantity of tissue substitute material to fill the test fixture shall be provided. 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 clause B.1.1.3.

## 5.1.2 Declarations by the provider

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

The performance of the equipment submitted for testing shall be a representative 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 testing unless alternative arrangements are agreed to by the test laboratory and the provider.

## 5.1.4 Test Conditions

### 5.1.4.1 Normal and extreme test conditions

The test conditions shall be as declared by the provider. The test conditions and procedures shall be as specified in clauses 5.1.4.2 to 5.1.4.4.

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 and ULP-BWD shall be performed using the human torso simulator with the tissue substitute material at nominal room temperature. The purpose of the present document is to facilitate testing at the measurement facility. Measured emission levels from ULP-AMI and ULP-BWD performed at a nominal room temperature (22 °C) are not expected to vary significantly from measurements made at the nominal body temperature of 37 °C.

#### 5.1.4.2 Test power source

##### 5.1.4.2.0 General remark

The test power source shall meet the requirements of clause 5.1.4.2.

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 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.

##### 5.1.4.2.2 Internal test power source

For radiated measurements on equipment with an internal power source, fully charged internal batteries should be used. The batteries used shall 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 covered by the present document that are 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.

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.

#### 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-P, ULP-AMD and ULP-AMD-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 operates after implant in a human body and ULP-BWD operates in very close proximity to the human body. Accordingly, the body tends to serve as an oven to maintain the implant temperature near 35 °C. Therefore, the normal temperature for these devices shall be within the following ranges:

- temperature +36 °C to +38 °C;

When it is impracticable to carry out tests under these conditions, a note to this effect, stating the ambient temperature 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 batteries (primary or secondary), the normal test voltage shall be declared by the equipment provider and agreed to 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 clauses 5.1.4.5 and 5.1.4.5.1).

###### 5.1.4.4.1.1.1 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.

#### 5.1.4.4.1.1.2 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 conducting 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 provider's declared duty cycle or transmission protocol, as appropriate, for a period of five minutes or for the duration of an expected communications session as declared by the provider and agreed by the test facility; 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.

#### 5.1.4.4.1.2 Extreme temperature ranges

For tests at extreme temperatures, measurements shall be made in accordance with the procedures specified in clause 5.1.4.4.1.1, at the upper and lower temperatures of one of the following ranges:

**Table 2: Extreme temperature ranges**

Category I (General):	-20 °C to +55 °C
Category II (Portable equipment):	-10 °C to +55 °C
Category III (Equipment for normal indoor use) (see note 1):	0 °C to +55 °C
Category IV (ULP-AMI and ULP-BWD) (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 range of +25 °C to +45 °C is the core body temperature variation over which a human body can survive [i.5].	

The provider 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 provider 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 provider. This shall be reflected in the provider's product literature. Narrower temperature ranges than given above may be implemented provided the reduced range is reflected in the 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 above.

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.

The test report shall state which range is used.

#### 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 ac mains source shall be the nominal mains voltage  $\pm 10\%$ . For equipment that operates over a range of mains voltages, clause 5.1.4.4.2.4 applies.

#### 5.1.4.4.2.2 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.

#### 5.1.4.4.2.3 Power sources using other types of batteries

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

- for ULP-AMI and other hermetically sealed devices with no provision for direct measurement of battery voltage the lower extreme test voltage is the level specified by the provider at which the device battery should be replaced in order to continue the medical effectiveness of the device;
- 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:
  - for the Leclanché or the lithium type of battery:
    - 0,85 multiplied by the nominal voltage of the battery;
  - for the nickel-cadmium type of battery:
    - 0,9 multiplied by the nominal voltage of the battery;
- for other types of batteries 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.

#### 5.1.4.4.2.4 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 those agreed between the equipment provider and the test laboratory. This shall be recorded in the test report.

### 5.1.4.5 Normal test signals and test modulation

#### 5.1.4.5.0 General remark

The test-modulating signal shall be a digital signal that modulates the carrier. It may be dependent upon the type of equipment under test and 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 digital 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 pseudorandom bit sequence of at least 511 bits in accordance with Recommendation ITU-T O.153 [i.4]. 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 that is representative of normal transmitter operation if the above pseudorandom sequence cannot be used.

For angle modulation, the normal level of the test signal shall produce a deviation value as declared by the provider as the normal operating level.

## 5.1.4.6 Antennas

### 5.1.4.6.0 General remark

Equipment operating in the 401 MHz to 402 MHz and 405 MHz to 406 MHz band(s) shall have an integral antenna, an external dedicated antenna or both. If provision for an external antenna is made, provision shall be made to prevent the use of an antenna other than an antenna or antennas intended to be used as specified by the provider.

### 5.1.4.6.1 Artificial antenna

Where applicable, tests may be carried out using an artificial antenna that simulates the actual antenna configuration specified by the provider for the specific equipment.

### 5.1.4.6.2 Artificial antenna for transmitters with 50 $\Omega$ impedance connector

For measurements on transmitters with a normal 50  $\Omega$  antenna impedance, tests shall be carried out using an artificial antenna which shall be a substantially non-reactive non-radiating 50  $\Omega$  load connected to the antenna connector. The Voltage Standing Wave Ratio (VSWR) at the 50  $\Omega$  connector shall not be greater than 1,2:1 over the frequency range of the measurement.

### 5.1.4.7 Test fixture for ULP-AMD, ULP-AMD-P and ULP-AMI-P devices

With equipment intended for use with an integral antenna, and not equipped with a 50  $\Omega$  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  $\Omega$  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 and ULP-BWD

For measurement purposes, to determine compliance with all emission limits, ULP-AMI and ULP-BWD devices shall be tested in or adjacent to, respectively, a fixture that approximates the physical conditions of operation for a ULP-AMI placed in a human body or a ULP-BWD placed on a human body. This fixture, a human torso simulator, with the ULP-AMI mounted inside or the ULP-BWD mounted on the surface of the simulator, shall be filled with a tissue substitute material and placed on the radiated emissions test site turntable with the ULP-AMI 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 without creating any voids. The dielectric constant and conductivity characteristics of the tissue substitute material shall be equivalent to those of the human body at a frequency of 403,5 MHz. Refer to clause B.1.1.3 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 this annex.

#### 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 provider and the test laboratory. It shall be described in the test report and 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 5.1.4.5 and 5.1.4.5.1, shall be applied to the input of the transmitter under test with the normal input device disconnected, if applicable.

#### 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 is given in table 3. Analogue smoothing of the measured waveform is permitted (see note in table 3).

**Table 3: Measurement receiver specifications**

Frequency (f)	Detector type	Bandwidth (see note)
$9 \text{ kHz} \leq f < 150 \text{ kHz}$	r.m.s. and Peak detector	200 Hz to 300 Hz
$150 \text{ kHz} \leq f < 30 \text{ MHz}$	r.m.s. and Peak detector	9 kHz to 10 kHz
$30 \text{ MHz} \leq f \leq 1\,000 \text{ MHz}$	r.m.s. and Peak detector	100 kHz to 120 kHz
$1\,000 \text{ MHz} \leq f$	Peak	1 MHz
NOTE: When making emissions measurements of modulated emissions it is permissible to smooth the analogue waveform of the detected modulation characteristic using a video filter setting approximately equal to the resolution bandwidth/30 (see ANSI C63.17 [i.6], clause 6.1.2.2.2).		

Some measurements specified in the present document require the use of a measuring receiver with a peak detector function and an adjustable resolution bandwidth capability typical of most spectrum analysers.

## 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 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 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 4.

For the test methods, according to the present document, the measurement uncertainty figures shall be calculated in accordance with ETSI TR 100 028 [i.3] 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 4 is based on such expansion factors.

**Table 4: Maximum measurement uncertainty**

Parameter	Maximum measurement uncertainty
Radio Frequency	$\pm 1 \times 10^{-7}$
Adjacent channel power	$\pm 3$ dB
RF power, conducted	$\pm 0,75$ dB
Conducted emission of transmitter	$\pm 4$ dB
Conducted emission of receivers	$\pm 3$ dB
Radiated emission of transmitter, valid up to 4 GHz	$\pm 6$ dB
Radiated emission of receiver, valid up to 4 GHz	$\pm 6$ dB
Conducted monitoring test system	$\pm 4$ dB
Radiated monitoring test system	$\pm 6$ dB
Temperature	$\pm 1$ °C
Humidity	$\pm 5$ %
Voltage	$\pm 1$ %

The accumulated measurement uncertainties of the test system in use for the parameters to be measured shall not exceed those given in table 4, this is in order to ensure that the measurements remain within an acceptable standard.

For the test methods according to the present document the uncertainty figures are valid to a confidence level of 95 % calculated according to the methods described in ETSI TR 100 028 [i.3].

## 5.3 Methods of measurement

### 5.3.0 General requirement

In order to conduct transmitter measurements, the provider shall provide a means for causing the equipment under test to operate on a frequency near the middle of the applicable band for devices operating in the frequency bands 401 MHz to 402 MHz and 405 MHz to 406 MHz. Devices operating with low duty cycle and low power operating in these bands shall be tested on the actual frequency of operation. Samples that have been modified to operate on the required frequency may be supplied when necessary. Frequency administration commands that place the device in the correct operating mode may be used if available. Where the transmitter is designed with an adjustable carrier power, then all transmitter parameters shall be measured using the highest power level (e.r.p.), as declared by the provider. The equipment shall then be set to the lower carrier power setting(s) (e.r.p.), as declared by the provider, and the measurements for spurious emissions shall be repeated (see clause 5.3.4).

Only two modes of operation are permitted:

- frequency agile devices using LBT and AFA for selection of the operating frequency . Frequency agile devices shall be designed to access a minimum of 18 channels evenly distributed across the 401 MHz to 402 MHz and 405 MHz to 406 MHz bands with a minimum of 9 channels defined for each 1 MHz segment (i.e. 401 MHz to 402 MHz and 405 MHz to 406 MHz), see clause 4.2.3.1.1 and the following clauses; and
- non-frequency-agile single channel devices that transmit under the provisions for low duty cycle and low power operation. Non-frequency-agile single channel devices shall be designed to operate only on a single channel using low duty cycle and low power for spectrum access in the 401 MHz to 402 MHz or 405 MHz to 406 MHz bands, see clause 4.2.3.1.2 and the following clauses.

Non-frequency-agile single channel devices that operate under the provisions for low duty cycle and low power operation for accessing spectrum within the bands 401 MHz to 402 MHz or 405 MHz to 406 MHz are subject to a duty cycle restriction, low power output, and a limit on the number of transmissions within an hour. Frequency agile devices shall be designed to access a minimum of eighteen channels evenly distributed across the 401 MHz to 402 MHz and 405 MHz to 406 MHz band. A minimum of nine channels shall be defined by LBT and AFA systems for each 1 MHz segment (i.e. 401 MHz to 402 MHz or 405 MHz to 406 MHz).

For ULP-AMI and ULP-BWD, all emissions measurements require the use of the human torso simulator described in clause B.1.1.3. Clause B.1.1.3 specifies the temperature of the tissue substitute material in the simulator to be 22 °C to 38 °C for emission tests. This temperature range is specified for emissions tests in order to eliminate the absolute necessity of preheating and maintaining the temperature of the tissue substitute material at a higher temperature, thus greatly facilitating conducting the tests. Because the nominal conductivity and dielectric constant characteristics of the tissue substitute material vary only slightly with temperature from 22 °C to the nominal temperature of 37 °C, test results will not be materially affected by temperature variance of the tissue substitute material. Neither is it expected that the transmitter emission levels would vary over the limited temperature range from 22 °C to the nominal temperature of 37 °C. Based on these considerations, it is reasonable to conduct emission tests with the tissue substitute material at a temperature within the range of 22 °C to 38 °C. However, if agreed by the testing laboratory and the provider, emissions tests may be conducted with the tissue substitute material at the nominal temperature of  $(37 \pm 1)$  °C.

When making transmitter tests on equipment designed for intermittent operation, the duty cycle of the transmitter, if applicable, shall not normally be exceeded. However, if it is necessary to exceed the duty cycle for the purpose of testing, this is permissible as long as the RF parameters of the transmitter are not degraded or compromised. The actual duty cycle used for the purpose of testing shall be stated on the test report form.

Compliance with transmitter output power and spurious emissions limits shall be determined by measuring radiated fields or using substitution techniques (see clauses 5.3.3 and 5.3.4). For equipment with more than one antenna, either dedicated or permanently attached, measurements shall be performed with each antenna.

The frequency and drift under extreme conditions shall be measured as defined in clause 5.3.1. In addition, the adjacent band or sub-bands spurious emission measurement shall be made as defined in clause 5.3.4.

Devices using listen before talk and frequency agility for channel selection operating in the 401 MHz to 402 MHz and 405 MHz to 406 MHz band(s) may operate without regard to channelization.

## 5.3.1 Frequency error

### 5.3.1.0 General remark

The test for frequency error specified in this clause appropriate to the EUT shall be carried out. The results obtained shall be compared to the limits in clause 4.2.1.1.2 in order to assess compliance with the requirement.

This measurement shall be made for all equipment operating in the 401 MHz to 402 MHz and 405 MHz to 406 MHz band(s). If possible, measurements shall be made with an unmodulated carrier using an artificial antenna. It may be necessary to use a test fixture (see clauses 5.1.4.7 and 5.1.4.8) connected to an artificial antenna for some equipment. ULP-AMI and ULP-BWD are not required to use the human torso simulator for this test.

#### 5.3.1.1 Method of measurement for systems with an unmodulated carrier frequency provision

The carrier frequency shall be measured (in the absence of modulation) with the transmitter connected to a measuring instrument or through the use of an artificial antenna as appropriate. A transmitter without a 50 Ω output connector may be placed in the test fixture (see clause 5.1.4.7) connected to an artificial antenna. The measurement shall be made under normal test conditions (see clause 5.1.4.3) and extreme test conditions (see clause 5.1.4.4), (extreme temperature and supply voltage simultaneously). Due to the design of equipment for various applications in the MEDS service, a suitable artificial antenna or test fixture may not be available. For this case, the radiated carrier signal from the device may be used for making these measurements.

### 5.3.1.2 Method of measurement for systems with a modulated carrier frequency

The carrier frequency shall be measured (in the presence of modulation) with the transmitter connected to an artificial antenna if appropriate. A transmitter without a 50  $\Omega$  output connector may be placed in the test fixture (see clause 5.1.4.7) connected to an artificial antenna. The measurement shall be made under normal test conditions (see clause 5.1.4.3) and extreme test conditions (extreme temperature and supply voltage simultaneously, see clause 5.1.4.4). Due to the design of equipment for various applications in this service, a suitable artificial antenna or test fixture may not be available. For this case, the radiated carrier signal from the device may be used for making these measurements. The frequency error is determined as follows:

- under normal conditions according to clause 5.1.4.3 the reference frequency  $f$  is measured and recorded;
- under all extreme conditions according to clause 5.1.4.4 the frequency  $f_e$  is measured and recorded.

The absolute value of  $(f_e - f)$  is the drift. The limit of 100 ppm is relative to 406 MHz, where:

- $f$  = the frequency measured under normal conditions;
- $f_e$  = the maximum drift frequency under extreme conditions.

The frequencies,  $f$  and  $f_e$ , can be determined by a spectrum analyser which is put in "max hold" position with the transmitting device modulated or unmodulated. For equipment that can only operate in a modulated carrier mode a reference point,  $f_{ref}$ , for  $f$  and  $f_e$  can be used and either set on the slope or determined from the averaging of the two 3 dB frequency points. The 3 dB reference point  $f_{ref}$  is determined by  $(f_{max} - f_{min}) / 2$ , where  $f_{max}$  and  $f_{min}$  are the frequencies corresponding to the 3 dB frequencies.

## 5.3.2 Emission bandwidth measurement

The test for emission bandwidth specified in this clause appropriate to the EUT shall be carried out. The results obtained shall be compared to the limits in clause 4.2.1.2.2 in order to assess compliance with the requirement.

The equipment may be directly connected to a spectrum analyser if it has a 50  $\Omega$  connector or using a test fixture (see clauses 5.1.4.7 and 5.1.4.8) if needed. If the equipment has an integral antenna or unique connector for a dedicated antenna and cannot be connected to the spectrum analyser, a signal from the equipment may be coupled to the spectrum analyser using an antenna connected to the spectrum analyser.

The transmitter shall be operated at its maximum carrier power measured under normal test conditions (see clause 5.3.3).

The transmitter shall be modulated by the normal test signal (see clause 5.1.4.5).

The output power of the transmitter, with or without a test fixture, shall be recorded using a spectrum analyser set to a frequency span of 1 MHz and a resolution bandwidth large enough to accept all major modulation side bands. The detector function shall be set to peak hold with the video bandwidth setting  $\geq$  the resolution bandwidth. The two furthest frequencies, one above ( $f_{high}$ ) and one below ( $f_{low}$ ), the frequency of the maximum measured level of the modulated carrier where the signal level is 20 dB below the maximum measured level of the modulated carrier shall be determined. If it is found that the resolution bandwidth used was not approximately 1 % of the emission bandwidth, then the resolution bandwidth shall be adjusted and the procedure repeated until the resolution bandwidth used is approximately 1 % of the emission bandwidth that was measured with that resolution bandwidth setting. For spectrum analysers that have fixed values of resolution bandwidth, the setting that is nearest to 1 % of the emission bandwidth is acceptable, provided that it is no less than 0,5 % of the emission bandwidth and no greater than 2 % of the emission bandwidth.

The frequencies  $f_{high}$  and  $f_{low}$  for each device shall be recorded for later use. The difference in frequency between  $f_{high}$  and  $f_{low}$  is the emission bandwidth.

For systems designed to utilize multiple devices in a MEDS communications session, the emission bandwidth procedure shall be repeated for each device intended to operate in a session.

### 5.3.3 Effective radiated power of the fundamental emission

The test for effective radiated power of the fundamental emission specified in this clause appropriate to the EUT shall be carried out. The results obtained shall be compared to the limits in clause 4.2.1.3.2 in order to assess compliance with the requirement.

This measurement applies to equipment provided with an integral antenna and to equipment supplied with a dedicated antenna. Measurements shall be made in both the 401 MHz to 402 MHz and 405 MHz to 406 MHz band(s) as applicable with each type of antenna provided by the provider that attaches to the equipment.

If the transmitter is designed to operate with different carrier powers, the rated power for each level, or range of levels, shall be declared by the provider. Transmitter operation at any power level greater than 250 nanoWatts e.r.p. requires the frequency of operation of the transmitter to be selected by a MEDS system device using LBT and AFA to select the frequency (clause 4.2.3.1.1 applies).

The measurement for each type of transmitter operation shall be carried out under normal test conditions only (see clause 5.3) or as specified in clause B.1.1.3 in the case of ULP-AMI and ULP-BWD.

These measurements shall be performed at the highest power level at which the transmitter operates.

Step 1: On a test site, selected from annex B that is appropriate for the EUT, the equipment shall be placed at the specified height on a support, as explained in annex B, and in the position closest to normal use as declared by the provider. Implanted and body worn devices shall be mounted and arranged in the human torso simulator as described in clause B.1.1.3.

Step 2: The test antenna shall be oriented initially for vertical polarization and shall be chosen to correspond to the frequency of the transmitter. The output of the test antenna shall be connected to the measuring receiver.

Step 3: The transmitter shall be switched on if possible, without modulation and the measuring receiver shall be tuned to the frequency of the transmitter under test (see clause 5.1.4.11 for receiver setting). In case of equipment where it is not possible to make the measurement in the absence of modulation, the measurement shall be carried out by the use of a spectrum analyser using a peak detector function with a resolution bandwidth setting  $\geq$  the emission bandwidth (see clause 4.2.1.2). For this measurement, analogue smoothing of the displayed waveform is permitted using a video filter set to approximately the resolution bandwidth/30 (see clause 5.1.4.11). The measurement shall be made over an interval of time when transmission is continuous and at its maximum power level.

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

Step 5: The transmitter shall then be rotated through 360° in the horizontal plane, until the maximum signal level is detected by the measuring receiver. The test antenna shall be raised and lowered again through the specified range of height until a maximum signal level is detected by the measuring receiver.

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.2.3. The substitution antenna shall be orientated for vertical polarization as noted above and the length of the substitution antenna shall be adjusted to correspond to the frequency of the transmitter. The substitution antenna shall be connected to a calibrated signal generator. If necessary, the input attenuator setting of the measuring receiver shall be adjusted in order to increase the sensitivity of the measuring receiver.

Step 8: The test antenna shall be raised and lowered through the specified range of height to ensure that the maximum signal is received. This does not apply for accredited test laboratories using a full anechoic chamber.

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, corrected for any change of input attenuator setting of the measuring receiver, shall be recorded as the power level.

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 measure of the effective radiated power is the highest of the two levels recorded at the input to the substitution antenna, corrected for gain variance of the substitution antenna relative to the gain of a dipole.

This process shall be repeated as needed based on antenna configurations and bands of operation.

### 5.3.4 Spurious emissions of transmitter

The test for spurious emissions specified in this clause appropriate to the EUT shall be carried out. The results obtained shall be compared to the limits in clause 4.2.1.4.2 in order to assess compliance with the requirement.

This measurement applies to equipment provided with an integral antenna and to equipment supplied with a dedicated antenna. Measurements shall be made with each type of antenna provided with the equipment attached to it.

If the equipment is designed to operate with different carrier powers, the rated power for each level or range of levels shall be declared by the provider. The following measurements shall be performed at all power levels at which the transmitter is intended to operate in each band of operation.

The measurement shall be carried out by the use of a measuring receiver according to clause 5.1.4.11.

Measurements shall be made with the transmitter in operating and stand-by modes. ULP-AMI and ULP-BWD shall have the effective radiated power of their spurious emissions measured using the test fixture specified in clause 5.1.4.8.

Step 1: On a test site, selected from annex B that is appropriate for the EUT, the equipment shall be placed at the specified height on a support, as specified in annex B, and in the position closest to normal use as declared by the provider.

ULP-AMI and ULP-BWD devices shall be mounted and arranged in or on the human torso simulator as described in clause B.1.1.3.

Step 2: The test antenna shall be oriented initially for vertical polarization and shall be tuned to each spurious emission frequency from the transmitter as a function of its operation mode. The output of the test antenna shall be connected to the measuring receiver. The transmitter shall have the normal modulation applied (see clause 5.1.4.5) and the measuring receiver shall be tuned over the frequency range 25 MHz to 4 GHz, except for the carrier and sidebands measured according to clause 5.3.2.

Step 3: At each frequency at which a spurious 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 signal level is detected by the measuring receiver and the test antenna height shall be adjusted again for maximum signal level. The test antenna shall be raised and lowered again through the specified range of height until a maximum signal level is detected by the measuring receiver.

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.2.3.

Step 6: The substitution antenna shall be orientated for the vertical polarization as noted above and the length of the substitution antenna shall be adjusted to correspond to the frequency of the spurious emission from the transmitter. The substitution antenna shall be connected to a calibrated signal generator. If necessary, the input attenuator setting of the measuring receiver shall be adjusted in order to increase the sensitivity of the measuring receiver.

Step 7: 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, which is equal to the level noted under Step 4.

Step 8: The input level to the substitution antenna, corrected for any change of input attenuator setting of the measuring receiver, shall be recorded as the power level

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

Step 10: The maximum signal level detected by the measuring receiver for both vertical and horizontal polarization shall be noted.

The measure of the effective radiated power for each spurious emission is the highest of the levels recorded at the input to the substitution antenna, corrected for any gain variance of the substitution antenna relative to the gain of a dipole.

### 5.3.5 Frequency stability under low voltage conditions

This test applies to battery-operated devices covered by the present document.

The test for frequency stability under low voltage conditions specified in this clause shall be carried out. The results obtained shall be compared to the limits in clause 4.2.1.5.2 in order to assess compliance with the requirement.

The procedures in clause 5.3.1 shall be repeated except the measurement shall be made under normal temperature and humidity conditions (see clause 5.1.4.3.1), and the voltage from the test power source shall be reduced below the lower extreme test voltage limit towards zero. As the voltage is reduced, the nominal carrier frequency shall be monitored.

### 5.3.6 Spurious radiation of receivers

#### 5.3.6.0 Overview

This clause provides spurious receiver radiation requirements for receivers or receiver sections of transceivers used in the MEDS service. Medical Data Service systems utilize the transmission and reception capability of various medical devices in order to transmit programming control messages and data streams in a communications session. Implant control messages are typically transmitted, but not always, from an external device to the implant or body worn device. Data streams are typically transmitted, but not always from an implant or body worn device to an external device. As this technology develops, it is expected that many forms of information transmission and system device interaction will evolve.

If a modulated signal from a signal generator is required to conduct a test for receiver spurious emissions measurements as specified in this clause, the appropriate test modulation, D-M2 or D-M3 (see clause 5.1.4.5.1), as it relates to the receive function of the transceiver under test shall be used as the modulation source. Modulated signal bandwidths of the signal generators shall be equivalent to the signal bandwidths that are normally used by the MEDS equipment. D-M2 is used to simulate the reception of bit stream information and D-M3 is defined as the control signal and instruction set format that the MEDS equipment is designed to use.

In order to conduct receiver measurements, the provider shall provide a means for causing the equipment under test to operate on a frequency near the mid band frequency of each band accessed for LBT and AFA systems. For systems using low power and low duty cycle for spectrum access, receiver measurements shall be made on the channel(s) of operation (see clause 5.3.0). The provider shall provide a sample or samples that have been configured to operate on the appropriate frequency when activated.

The present document does not allow the use of Super-Regenerative Receivers for MEDS system communications.

#### 5.3.6.1 Spurious radiation of receivers

The test for spurious radiation of receivers specified in this clause appropriate to the EUT shall be carried out. The results obtained shall be compared to the limits in clause 4.2.2.1.2 in order to assess compliance with the requirement.

This measurement applies to equipment provided with an integral antenna and to equipment supplied with a dedicated antenna. Measurements shall be made with each type of antenna provided by the provider that attaches to the equipment.

The measurement shall be carried out by the use of a measuring receiver with a bandwidth as stated in clause 5.1.4.11 and quasi-peak detector set in accordance with the specification of CISPR 16-2-3 [1], clause 1 for the bands C and D. For measurements above 1 000 MHz, the peak value shall be measured using a spectrum analyser. Analogue smoothing of the displayed waveform is permitted (see clause 5.1.4.11).

#### 5.3.6.2 Method of measuring the spurious radiations of receivers

The test for spurious radiation of receivers specified in this clause appropriate to the EUT shall be carried out according to clause 5.3.4. The results obtained shall be compared to the limits in clause 4.2.2.1.2 in order to assess compliance with the requirement.

## 5.3.7 Receiver blocking

### 5.3.7.0 General remarks

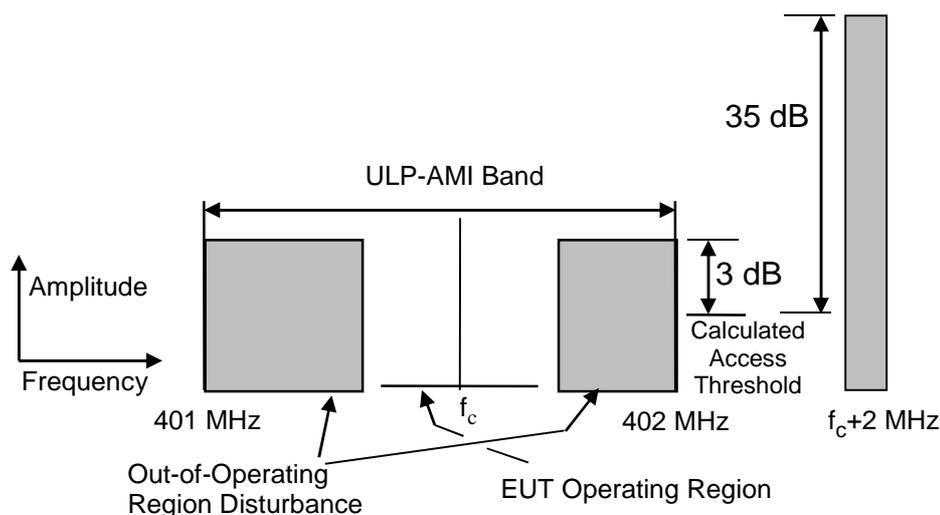
This test shows the system has sufficient sensitivity to recognize and accurately compare the ambient power level to the calculated LBT threshold power level  $P_{Th}$  in the presence of an unwanted signal (blocking signal) on frequencies other than those of the operating channel and the adjacent channels.

#### 5.3.7.1 Measurement method using out-of-operating-region disturbance

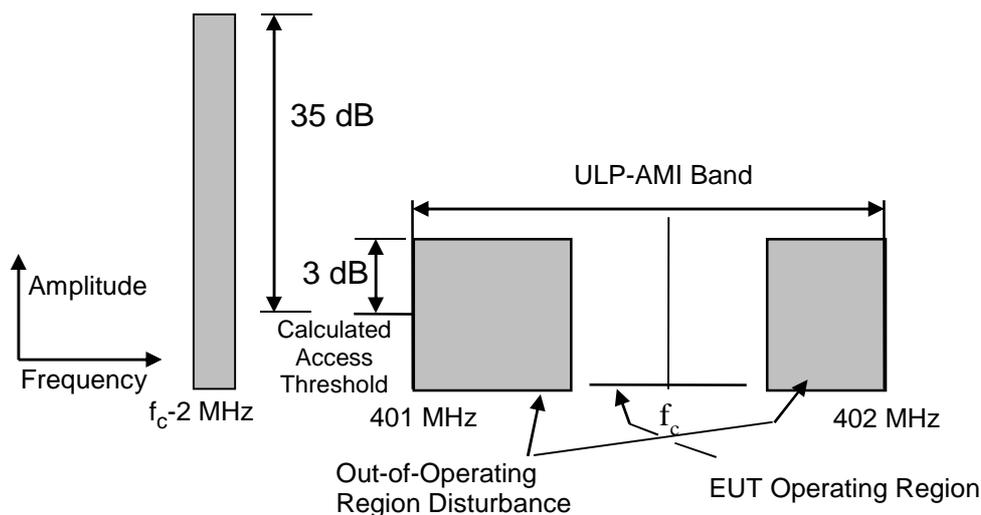
Using a disturbance source, generate the spectrum pattern as shown in figure 2 causing the EUT to operate in a channel (with centre frequency  $f_c$ ) near to the centre of the 401 MHz to 402 MHz band. The width of the spectral notch shall be twice the emission bandwidth measured in clause 5.3.2. Verify that the EUT transmits only on  $f_c$ . If it transmits on a frequency other than  $f_c$ , narrow the notch until it transmits only on  $f_c$ .

Using a CW signal source, include the blocking signal shown in figure 1a at  $f_c + 2$  MHz and at a level 35 dB above the calculated LBT threshold power level  $P_{Th}$ . Place the EUT in a state where it is seeking to initiate a communications session to a ULP-AMI. This measurement shall be repeated with a blocking signal included at  $f_c - 2$  MHz as shown in figure 1b.

The entire measurement in clause 5.3.7.1 shall be repeated using a disturbance source with the spectrum pattern as shown in figure 2 causing the EUT to operate in a channel (with centre frequency  $f_c$ ) near to the centre of the 405 MHz to 406 MHz band, with the blocking signal at  $f_c \pm 2$  MHz and at a level 35 dB above the calculated LBT threshold power level  $P_{Th}$ . Apply figures 1a and 1b by replacing 401 MHz with 405 MHz, and replacing 402 MHz with 406 MHz).



**Figure 1a: Spectrum Mask for Test ( $f_c + 2$  MHz) of clause 5.3.7.1**



**Figure 1b: Spectrum Mask for Test ( $f_c - 2$  MHz) of clause 5.3.7.1**

### 5.3.7.2 Measurement method using frequency administration commands

The procedure in clause 5.3.7.1 is used except that out-of-operating-region disturbance generating equipment is not used to force the EUT to operate on a single channel. The EUT operation is controlled through use of frequency administration commands that force the out-of-operating-region ambient levels to be recognized by the system. Using frequency administration commands, force all channels in the out-of-operating-region above, to have a recognized ambient power level equivalent to 3 dB above the calculated LBT threshold power level. Verify that the EUT transmits only on  $f_c$  in the 401 MHz to 402 MHz band. Using a CW signal source, include the blocking signal shown in figure 1a at  $f_c + 2$  MHz and at a level 35 dB above the calculated LBT threshold power level  $P_{Th}$ . Place the EUT in a state where it is seeking to initiate a communications session to a ULP-AMI. This measurement shall be repeated with a blocking signal included at  $f_c - 2$  MHz as shown in figure 1b.

The entire measurement in clause 5.3.7.2 shall be repeated for the 405 MHz to 406 MHz band. Apply figures 1a and 1b by replacing 401 MHz with 405 MHz, and replacing 402 MHz with 406 MHz).

### 5.3.7.3 Results based on the above test method

The EUT shall not initiate a communications session on a frequency different from  $f_c$  in both the 401 MHz - 402 MHz band and in the 405 MHz - 406 MHz band.

## 5.3.8 Spectrum Access

### 5.3.8.1 LBT/AFA spectrum access

#### 5.3.8.1.0 General provisions

The tests for spectrum access requirements specified in this clause and applicable subsequent clauses shall be carried out. The results obtained shall be compared to the requirements listed in clause 4.2.3.1.1.

Devices operating under the provisions of the product standard using low duty cycle and low power and meeting the technical specifications of clause 4.2.3.1.2 are exempt from the remaining provisions of the present clause.

Providers of MEDS systems shall share the 401 MHz to 402 MHz and 405 MHz to 406 MHz spectrum with other providers on an equal basis in order to protect the safety and health of the patients these systems are designed to serve. The following clauses set forth a LBT and AFA requirement designed to minimize the possibility of interference among MEDS devices and to other users of the band. The use of such a technique was envisioned in the Recommendation ITU-R RS.1346 [i.10] that determined that MEDS operations could be compatible with existing users in the band and prove to be a feasible communications service. Annex A of Recommendation ITU-R RS.1346 [i.10] addresses the need for a mechanism to minimize the potential for interference to MEDS devices from the existing users of the band.

The provisions of the following clauses shall not be used for the purposes of denying fair access to spectrum to other MEDS systems. MEDS communications sessions shall be initiated via LBT (LBT can be performed either by the device participating in the MEDSCL session with the greatest emission bandwidth). Before a MEDS communications session is initiated the requirements as stated specifically in clauses 5.3.8.1.0, 5.3.8.1.1; 5.3.8.1.2, 5.3.8.1.3, 5.3.8.1.4 and 5.3.8.1.5 shall be met. The monitoring system antenna used to determine the power level of any ambient signals shall be the antenna normally used by the device performing the LBT and AFA function for a MEDS communications session.

The diagrams that follow show the set-up for the frequency bands based identifying the band edges in terms of the band edge corresponding to the low frequency band edge as  $B_{lf}$  and the high frequency band edge as  $B_{hf}$ . Thus for the 401 MHz to 402 MHz band, 401 MHz corresponds to  $B_{lf}$  and 402 MHz corresponds to  $B_{hf}$ . For the band 405 MHz to 406 MHz, 405 MHz corresponds to  $B_{lf}$  and 406 MHz corresponds to  $B_{hf}$ . The same diagrams may be used for either band by replacing  $B_{lf}$  and  $B_{hf}$  with the appropriate frequencies in each diagram. The measurement processes generally described below are written for conducted test arrangements and should be applicable to any system submitted for testing or for post market surveillance purposes. If equipment does not permit conducted tests to be performed, the equivalent conditions can be established using radiated signal techniques. If radiated signal techniques are used, the monitoring system antenna shall be oriented in the direction of maximum reception of the radiated broadband and CW RF disturbing fields and the radiated broadband and CW RF interference fields shall be aligned to produce the maximum RF voltage in the monitoring system antenna.

Out-of-operating-region interference can be generated by using either a source capable of generating wideband interference with square spectral notches having a variable width that can be adjusted to the emission bandwidth of the EUT or using an interference source that can generate a sufficient number (approximately  $2 \times 1\,000$ /emission bandwidth in kHz) of independently-controlled CW signals across the 401 MHz to 402 MHz band or the 405 MHz to 406 MHz as applicable to block access to the band except for a notch or notches equal to the emission bandwidth of the EUT. Depending on an individual provider's implementation, frequency administration commands may be used in performing some or all of the tests in clause 5.3.8.

NOTE: If frequency administration commands are used (see clause 5.3.7.2), care needs to be taken to ensure the effect of any monitoring system antenna gain relative to an isotropic antenna is accounted for.

Depending on the specific implementation of an individual provider, some modification of these procedures may be required. In this case, the test facility and the provider should agree on any modification of the monitoring system measurement procedure. When the test facility and the provider agree that a modified procedure or procedures are required to test a system or component of the system due to a specific implementation of the MEDS system, a showing that the MEDS system meets the technical parameter under investigation using the modified procedure is acceptable in lieu of using out-of-operating region interference or administrative commands to show compliance. For newly developed products the report shall document the procedure used.

### 5.3.8.1.1 LBT threshold power level

#### 5.3.8.1.1.0 General provision

It is not necessary to measure the actual threshold power level of a MEDS system, however, it shall be determined that the system uses the LIC selection process if no channel is available with an ambient power level 3 dB below the calculated threshold power level. This test shows the system has sufficient sensitivity to recognize and accurately compare the ambient signals to the calculated threshold power level.

### 5.3.8.1.1.1 Measurement method using out-of-operating-region interference

Calculate the LBT threshold power level,  $P_{Th}$ , for the EUT using the formula in clause 4.2.3.1.1.2 and the emission bandwidth determined in clause 5.3.2 and record the value as  $P_{Th}$ . For purposes of calculating the LBT threshold power level, the provider may specify or the test facility may measure the monitoring system antenna gain above isotropic as agreed between the provider and the laboratory facility. Using an interference source, generate the spectrum pattern shown in figure 2 with the EUT operating region centred on  $f_c$ . The width of the spectral notch shall be twice the emission bandwidth measured in clause 5.3.2. Verify that the EUT will transmit and that it transmits only on  $f_c$ . If it transmits on a frequency other than  $f_c$ , narrow the notch until it transmits only on  $f_c$ . Raise the level of the out-of-operating-region interference by 20 dB and determine that the EUT transmits on  $f_c$ . Set the notch width, if necessary, to the point where the EUT transmits only on  $f_c$ . Lower the level of the out-of-operating-region interference by 20 dB but do not readjust the notch width. Verify that the EUT transmits only on  $f_c$ . This process minimizes the effects of the monitoring system filter bandwidth on the following measurement. Using a CW signal source, inject a signal with frequency,  $f_c$ , at a level 6 dB below the calculated LBT threshold level. Determine if the EUT transmits on  $f_c$ . If the EUT transmits on  $f_c$ , cease transmission and raise the level of the CW signal one dB. Determine if the EUT transmits on  $f_c$ . This process shall be repeated until the EUT does not transmit on  $f_c$  but does transmit on a channel in the out-of-operating-region interference area. Note the level of the CW signal source.

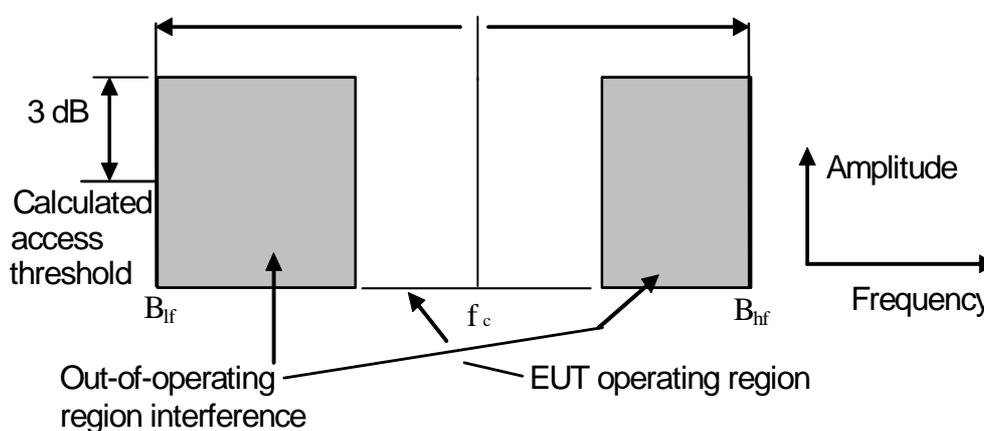


Figure 2: Spectrum mask for test of clause 5.3.8.1.1.1

### 5.3.8.1.1.2 Measurement method using frequency administration commands

Using frequency administration commands, force all channels in the out-of-operating-region above, to have a recognized ambient power level equivalent to 3 dB above the calculated LBT threshold power level. Using a CW signal source, inject a signal at  $f_c$  at a level 6 dB below the calculated LBT threshold power level and determine if the EUT transmits on  $f_c$ . The EUT should transmit on  $f_c$ . If the EUT transmits on  $f_c$ , cease transmission and raise the level of the CW signal one dB. Determine if the EUT transmits on  $f_c$ . This process shall be repeated until the EUT will not transmit on  $f_c$  but does transmit on a channel in the out-of-operating-region interference area. Note the level of the CW signal source.

### 5.3.8.1.1.3 Results based on above test method

Using the level of the CW signal source noted in either clause 5.3.8.1.1.1 or clause 5.3.8.1.1.2, subtract 4 dB and record the power level. Compare the recorded power level with the calculated LBT threshold level for the EUT. The recorded power level shall be less than or equal to the calculated LBT threshold power level.

### 5.3.8.1.2 Monitoring system bandwidth

#### 5.3.8.1.2.0 General provision

The intent of this requirement is to ensure that the EUT measures the power in a bandwidth that is equal to or greater than the emission bandwidth of the transmitter with the widest emission that it will participate with in a MEDS communications session. If an EUT is capable of adjusting its monitoring system bandwidth to correspond to differing emission bandwidths of devices participating in a MEDS communications session, this procedure shall be repeated for each emission bandwidth the EUT can use for communication. In order to ensure the monitoring system bandwidth requirement is met, the operation of the EUT shall be restricted to a single system carrier frequency within the 401 MHz to 402 MHz and 405 MHz to 406 MHz spectrum using frequency-administration commands, out-of-operating-region interference, or other techniques agreed upon by the test facility and the provider. When using out-of-operating-region interference, care should be taken to insure that the generated interference does not cause errors in measurement due to the slope of the monitoring system bandwidth filter.

#### 5.3.8.1.2.1 Measurement method using out-of-operating-region interference

The emission bandwidth of the device with the greatest bandwidth shall be used or if the programmer/controller monitoring system bandwidth is adjustable to correspond to the emission bandwidth of each device, the following process shall be repeated for each emission bandwidth. Using an interference source, generate the spectrum pattern shown in figure 3 with the EUT operating region centred on  $f_c$ . The width of the spectral notch shall be twice the emission bandwidth measured in clause 5.3.2. Verify that the EUT transmits only on  $f_c$ . If it transmits on a frequency other than  $f_c$ , narrow the notch until it transmits only on  $f_c$ . A CW signal at frequency  $f_c$  shall be injected at a level sufficient to block operation on the channel with centre frequency  $f_c$ . Verify that the EUT does not transmit on  $f_c$  and does transmit on a frequency  $f_i$  in the out-of-operating-region interference area. Stop communications and initiate a new request for a communications link while reducing the CW signal level in one-dB steps to a level where the EUT just transmits on  $f_c$  and record the level as  $P_a$ . The CW frequency shall be adjusted to flow, see clause 5.3.2, and its amplitude increased sufficiently to just cause the EUT to transmit on a frequency in the out-of-operating frequency region,  $f_i$ , and the level recorded at  $P_b$ . The CW signal level shall be reduced to  $P_a$  and its frequency shall be adjusted to  $f_{high}$ . Stop communications and initiate a new request for a communications link and verify the EUT transmits on frequency  $f_c$ , see clause 5.3.2. Increase the amplitude of the CW signal sufficiently to cause the EUT to transmit on a frequency in the out-of-operating frequency region,  $f_i$ , and record the level as  $P_c$ . During the above process, as the levels are stepped it may be necessary to allow the system to scan the entire band in order to select the specified operating frequency.

Subtract  $P_b$  from  $P_a$  and record the difference as D1.

Subtract  $P_c$  from  $P_a$  and record the difference as D2.

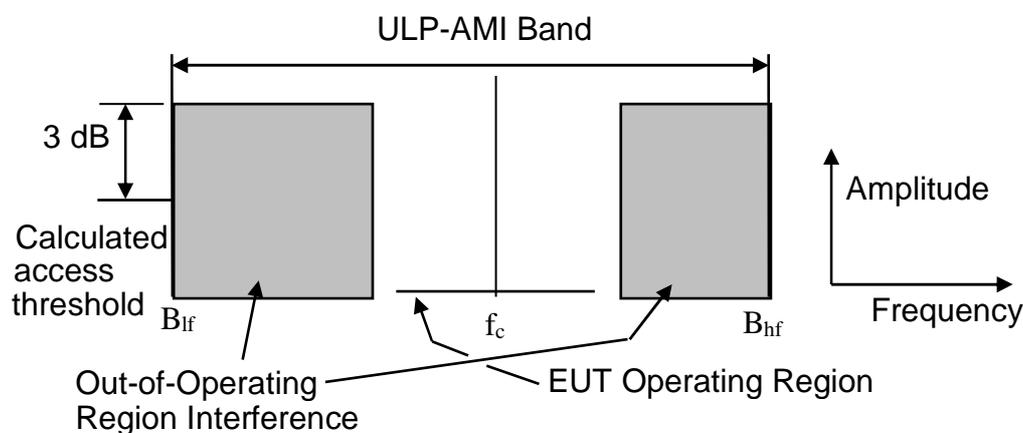


Figure 3: Spectrum mask for test of clause 5.3.8.1.2.1

### 5.3.8.1.2.2 Measurement method using frequency administration commands

The procedure above is used with the exception that out-of-operating-region interference generating equipment is not used to force the EUT to operate on a single channel. The EUT operation is controlled through use of frequency administration commands that force the unit to recognize levels 3 dB above the LBT threshold power level (see clause 4.2.3.1.1.2) for all channels except the intended operating channel. A CW signal is utilized in a manner similar to the process in clause 5.3.8.1.2.1 to determine the difference levels, D1 and D2.

### 5.3.8.1.2.3 Results based on above test method

The monitoring system bandwidth measured at its 20 dB down points shall be equal to or greater than the emission bandwidth of the intended transmission.

Using the procedure above, the requirement is met if D1 and D2 are less than or equal to 20 dB.

## 5.3.8.1.3 Monitoring system scan cycle time and minimum channel monitoring period

### 5.3.8.1.3.0 General provision

The intent of these requirements is to ensure that when the monitoring system updates the detected power levels in the 401 MHz to 402 MHz and 405 MHz to 406 MHz band(s), it scans the tuned band at a rate less than or equal to 5 s and that the monitoring period on each channel is 10 ms or longer in order to detect transmissions that may have silent periods that are less than 10 ms in duration.

### 5.3.8.1.3.1 Measurement method using out-of-operating-region interference

#### 5.3.8.1.3.1.1 Scan cycle time

Using an interference source generate the spectrum pattern shown in figure 3 with the EUT operating region centred on  $f_c$ . The width of the spectral notch shall be twice the emission bandwidth measured in clause 5.3.2. Increase the level of the out-of-operating-region sufficiently high to prevent operation under any circumstances on a channel other than  $f_c$ . Adjust the width of the notch as necessary to allow transmission on  $f_c$ . A CW signal at frequency  $f_c$  shall be injected at a level 3 dB above the out-of-operating-region interference level. Verify that communications do not occur on  $f_c$ .

Place the EUT in a state where it is seeking to initiate a communications session to a MEDS system device. At the same time the EUT is placed in this state, remove the CW signal and measure the time period between the removal of the CW signal and the beginning of transmission of the EUT. Verify that the transmission is at  $f_c$ . If the EUT not always transmits at  $f_c$ , add a 1 second delay between the removal of the CW and placing the EUT in a state where it is seeking to initiate a communications session to a MEDS system device. Repeat adding a 1 second delay until the EUT always transmits at  $f_c$ . Record the time period from removing the CW until the beginning of transmission of the EUT and repeat this process a sufficient number of times to establish a pattern for the cycle time. Subtract 1 second and record the time period each time the process is repeated,  $t_p$ ,  $t_{p1}$ ,  $t_{p2}$ , etc.

#### 5.3.8.1.3.1.2 Minimum channel monitoring period

In order to determine that the channel monitoring period conforms to the requirement, the set-up is similar to the above. Using an interference source generate the spectrum pattern shown in figure 3 with the EUT operating region centred on  $f_c$ . The width of the spectral notch shall be twice the emission bandwidth measured in clause 5.3.2. Increase the level of the out-of-operating-region interference sufficiently high to prevent operation under any circumstances on a channel other than  $f_c$  as specified by the provider. Verify that the EUT transmits on  $f_c$  and adjust the width of the notch as necessary to allow transmission only on  $f_c$ . A CW signal at frequency  $f_c$  shall be injected at a level equal to the out-of-operating-region interference level. Temporarily remove the out-of-operating-region interference, restart the initiation process and verify that communications do not occur on  $f_c$ . Reinsert the out-of-operating-region interference at a level 3 dB above the level used before. Verify that the EUT never communicates outside the EUT operating region at  $f_c$  after reinitiating communication.

The out-of-operating-region interference signal source should then be modulated with a 0,3 ms pulse whose repetition frequency can be adjusted to 100 Hz corresponding to a silent period between pulses of 9,7 ms. Place the EUT in a state where it is seeking to initiate a communications session to a MEDS system device. The EUT shall not initiate a communications session on a frequency different from  $f_c$ . This condition should be monitored several times, at least 10, in order to make sure the EUT is not able to initiate a communications session on a frequency different from  $f_c$ . This test assures that the EUT monitoring period is 10 ms long. Monitoring several times is necessary because channel monitoring and subsequent transmission is a variable function related to the band scanning cycle period of the EUT and the 100 Hz repetition rate of the 0,3 ms pulse.

#### 5.3.8.1.3.2 Measurement method using frequency administration commands

The procedure in clause 5.3.8.1.3.1 is used except that out-of-operating-region interference generating equipment is not used to force the EUT to operate on a single channel. The EUT operation is controlled through use of frequency administration commands that force the unit to operate only on the intended operating frequency,  $f_c$ . A CW signal is utilized in a manner similar to the process in clause 5.3.8.1.3.1.1 to record the cycle time periods,  $t_p$ ,  $t_{p1}$ ,  $t_{p2}$ , etc.

Interference signals modulated as specified in clause 5.3.8.1.3.1.2 are used to ensure that the minimum channel monitoring period is at least 10 ms long. When this signal is applied the EUT shall not be able to initiate a communications session on a frequency different from  $f_c$ .

#### 5.3.8.1.3.3 Results based on above test method

##### 5.3.8.1.3.3.1 Scan cycle time

Within 5 s prior to initiating a communications session, circuitry associated with a MEDS system device shall monitor all the channels in the 401 MHz to 402 MHz and 405 MHz to 406 MHz band(s).

The requirement is met if all values of  $t_p$ ,  $t_{p1}$ ,  $t_{p2}$ ,  $t_{pn}$ , etc., are less than or equal to 5 s.

##### 5.3.8.1.3.3.2 Minimum Channel Monitoring Period

Each MEDS channel shall be monitored for a minimum of 10 ms during each scan cycle of 5 s or less duration.

Conformity with this requirement is shown if, during testing, the EUT is unable to initiate a communications session on a frequency different from  $f_c$  when the interference signals, modulated as specified in clause 5.3.8.1.3.1.2, are injected outside  $f_c$ .

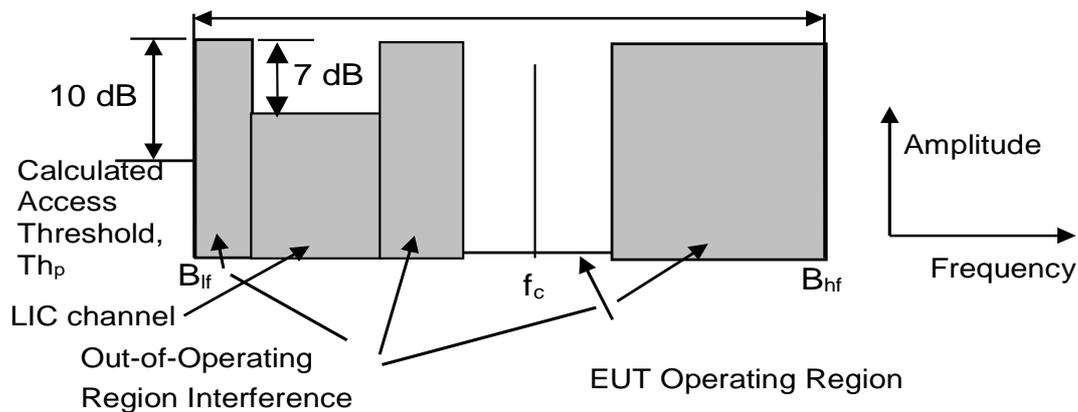
#### 5.3.8.1.4 Channel access based on ambient levels relative to the calculated access LBT threshold level, $P_{Th}$

##### 5.3.8.1.4.0 General provision

MEDS programmer/control transmitters (device performing the spectrum monitoring function) are permitted to initiate a MEDS communications session to a MEDS system device immediately on any channel where the ambient signal level is below the maximum permitted LBT threshold power level,  $P_{Th}$ , referenced to the emission bandwidth of the MEDS device with the widest emission bandwidth that will participate in a MEDS communications session initiated by the EUT. If no channel is available with an ambient power level at or below the maximum permitted  $P_{Th}$ , spectrum access is permitted based on the channel with the lowest ambient power level referred to as the LIC or "least interfered channel". If the provider chooses not to use the LBT threshold power level provisions, spectrum access is permitted based on the LIC referenced to the emission bandwidth of the MEDS device with the widest emission bandwidth that will participate in a MEDS communications session initiated by the EUT. Once a MEDS session is established, it may continue as long as the silent period in two-way communication between co-operating devices does not exceed 5 s.

#### 5.3.8.1.4.1 Access based on lowest ambient level above $P_{Th}$ using out-of-operating-region interference

Using an interference source generate the spectrum pattern shown in figure 4 with the EUT operating region centred on  $f_c$ . The width of the spectral notches centred on  $f_c$  and on the LIC channel shall be twice the emission bandwidth measured in clause 5.3.2. Verify that the EUT transmits on  $f_c$ . If it transmits on a frequency other than  $f_c$ , narrow the notch until it transmits only on  $f_c$ . A CW signal at frequency  $f_c$  shall be injected at a level 3 dB below the calculated LBT threshold power level,  $P_{Th}$ . Initiate a communications session and determine that transmission occurs on  $f_c$ . Cease transmission and increase the CW signal level by 9 dB. Initiate a communications session and determine that transmission occurs on the centre frequency of the LIC channel indicated in figure 4. In setting up the LIC channel, it shall be determined if the programmer/control transmitter uses a predetermined channelization plan. If it uses a predetermined channelization plan, the centre frequency of the LIC channel shall coincide with the centre frequency of one of its channels. If the system does not employ a predetermined channelling plan, this step is not necessary.



**Figure 4: Spectrum mask for test of clause 5.3.8.1.4.1**

#### 5.3.8.1.4.2 Access based on lowest ambient level above $P_{Th}$ using frequency administration commands

The procedure in clause 5.3.8.1.4.1 is used except that out-of-operating-region interference generating equipment is not used to force the EUT to operate on a single channel. The EUT operation is controlled through use of frequency administration commands that force the out-of-operating-region ambient levels, the LIC channel level, and the intended operating frequency,  $f_c$ , channel level to be recognized by the system. A CW signal at frequency  $f_c$  shall be injected at a level 3 dB below the access LBT threshold,  $P_{Th}$ . Initiate a communications session and determine that transmission occurs on  $f_c$ . Increase the CW signal level by 9 dB. Initiate a communications session and determine that transmission occurs on the centre frequency of the LIC channel selected by the frequency administration commands.

#### 5.3.8.1.4.3 Results based on above test method

The EUT shall access and transmit on the Least Interfered Channel (LIC) after the CW signal at frequency,  $f_c$  has been increased by 9 dB from its initial level of 3 dB below the calculated access threshold.

#### 5.3.8.1.5 Discontinuation of MEDS session if a silent period greater than or equal to 5 s occurs

##### 5.3.8.1.5.0 General provision

MEDS systems shall cease transmission in the event the communications session is interrupted for a period of 5 s or more.

#### 5.3.8.1.5.1 Measurement method

Using either of the procedures in clauses 5.3.8.1.4.1 or 5.3.8.1.4.2, establish a communications link between MEDS system devices in the LIC channel by setting the CW signal source at frequency,  $f_c$ , to a level that is 9 dB above its initial value of 3 dB below the calculated access threshold. Verify that the MEDS systems devices are communicating with each other on the LIC channel. Reduce the CW signal generator level to 3 dB below the calculated access threshold and immediately turn off or block the channel for a period of time greater than 5 s. Measure and record the time required for the MEDS system device performing monitoring function to end its transmission thus ending the communications session (i.e. the EUT ceases to try to continue transmission or re-establish transmission) in the LIC channel. Enable the other MEDS system device. The communications session shall not restart in the previous LIC channel. The MEDS system device performing the monitoring function may restart the session on  $f_c$ .

#### 5.3.8.1.5.2 Results based on above test method

Emission from the MEDS system programmer/control transmitter on the initial LIC channel shall cease in an amount of time less than or equal to 5 s after the other MEDS system device is turned off or blocked and the session should not restart on the initial LIC channel. If the time recorded above is less than or equal to 5 s and communication does not restart on the initial LIC channel, the requirement is met.

#### 5.3.8.1.6 Use of pre-scanned alternate channel

##### 5.3.8.1.6.0 General provision

At the time a channel for operation is initially selected and accessed, it is permissible for the monitoring system to select one additional channel for alternate operation for use if the initially selected channel becomes unavailable due to blockage of the channel from unknown disturbing ambient signals. The procedures in this clause determine if the system uses this feature and, if so, if it complies with the requirements for alternate channel selection. MEDS programmer/controllers that do not use the alternate channel provision are required to meet the other provisions of the access protocol.

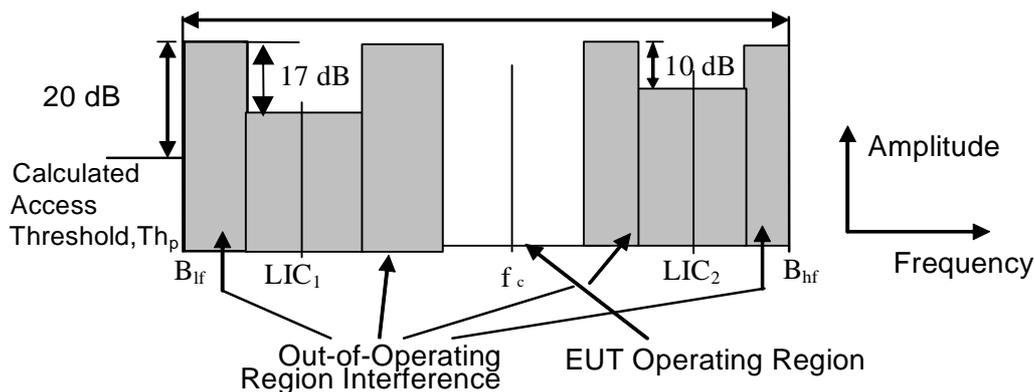
It is necessary to conduct a test to determine if the alternate channel provision is used. The procedure in clause 5.3.8.1.4.1 or clause 5.3.8.1.4.2 may be used. Using a signal from the CW source on  $f_c$  at a level 3 dB below the calculated access threshold level, establish a communications link between the MEDS system devices on frequency  $f_c$  as indicated in figure 5. This will permit the system to place in memory a channel, designated as the LIC channel in figure 4, as the alternate channel. Verify that the MEDS system devices are in communication. Open an additional channel, designated as LIC<sub>2</sub>, with an ambient level 12 dB below the level of the out of operating region interference level. Increase the CW signal source operating on  $f_c$ , sufficiently high to block the communications session and measure the time required for the programmer/control transmitter to initiate a new communications link on the alternate channel.

If the programmer/controller transmitter does not access spectrum or accesses LIC<sub>2</sub> the system does not use the provision for use of a pre-scanned alternate channel and no further tests are necessary. If the programmer/control transmitter accesses the designated alternate channel it uses the alternate channel provision and tests to determine compliance with the following requirements shall be made:

- 1) Before transmitting on the alternate channel, the channel shall be monitored for a period of at least 10 ms.
- 2) The detected power level during this 10 ms or greater monitoring period shall be no higher than 6 dB above the power level detected when the channel was chosen as the alternate channel.

##### 5.3.8.1.6.1 Measurement method for alternate channel selection using out-of-operating-region interference

Set up the interference signals as shown in figure 5.



**Figure 5: Spectrum mask for test of clause 5.3.8.1.6.1**

Using the procedure in clause 5.3.8.1.4.1, establish a communications link from the programmer/control transmitter to a MEDS system device on the intended operating frequency,  $f_c$ , as indicated in figure 5 with the CW signal source operating on frequency  $f_c$  at a level 3 dB below  $P_{Th}$ . This will permit the system to place in its memory the ambient power levels in the LIC<sub>1</sub> and LIC<sub>2</sub> channels. Verify that the MEDS system devices are in communication on the channel with centre frequency  $f_c$ . Using a CW signal source operating on  $f_c$ , inject a signal at a level sufficient to block operation on the channel with centre frequency,  $f_c$ . Verify that the EUT establishes a new communications session on the LIC<sub>1</sub> channel. Reduce the CW signal source power level to its previous value, initiate a new communications session, and verify communications session operation is on the channel with centre frequency  $f_c$ . This allows mapping into memory the ambient power levels in the LIC<sub>1</sub> and LIC<sub>2</sub> channels. With the system operating, using a CW signal source operating on  $f_c$ , inject a signal at a level sufficient to block operation on  $f_c$ . Simultaneously with the injection of this high level CW signal on  $f_c$ , inject a signal source on the centre frequency of the LIC<sub>1</sub> channel that is modulated with a 0,3 ms pulse whose repetition frequency can be adjusted to 100 Hz corresponding to a silent time interval between pulses of 9,7 ms. The amplitude of this signal should be 6 dB above the calculated access threshold level,  $P_{Th}$ . The MEDS system device performing the monitoring function shall establish a new communications link to the other MEDS system device on the LIC<sub>1</sub> channel. Record the time difference between applying the high level CW signal and the programmer/controller transmitter signal appearing on LIC<sub>1</sub> as  $T_1$ .  $T_1$  should always be much less than the maximum band scanning cycle time  $t_{pn}$  recorded in clause 5.3.8.1.3.1.1. Repeat the above process and establish communication on  $f_c$ . Inject a CW signal on  $f_c$  high enough to block operation on  $f_c$  and simultaneously inject the pulse-modulated signal on LIC<sub>1</sub> as above except the amplitude of the signal should be 12 dB above  $P_{Th}$ . This condition should be monitored for several minutes, or until a new session is initiated in LIC<sub>2</sub>. The programmer/control transmitter shall not establish a connection on LIC<sub>1</sub> or in the out-of-operating-region interference portions of the band. Repeat this last process at least 5 times to 10 times to insure that random variables associated with applying signals and session activation sequences do not permit access to occur in the LIC<sub>1</sub> channel. If access occurs on LIC<sub>2</sub>, record the time difference between the application of the high level CW signal and channel access on LIC<sub>2</sub> as  $T_2$ ,  $T_{2a}$ , etc.

### 5.3.8.1.6.2 Measurement method for alternate channel selection using frequency administration commands

The procedure in clause 5.3.8.1.6.1 is used except that out-of-operating-region interference generating equipment is not used to force the EUT to operate on a single channel. The EUT operation is controlled through use of frequency administration commands that force the out-of-operating-region ambient levels, the LIC<sub>1</sub> and LIC<sub>2</sub> channel levels, and the intended operating frequency,  $f_c$ , channel level to be recognized by the system. Interferences from the CW signal and pulse modulated sources are injected in a manner similar to clause 5.3.8.1.6.1. With the 0,3 ms pulse modulated signal at a level of 6 dB above  $P_{Th}$  in the LIC<sub>1</sub> channel, the programmer/controller transmitter shall access LIC<sub>1</sub>. With the pulse-modulated signal at a level of 12 dB above  $P_{Th}$ , the programmer/controller shall not access spectrum except in the LIC<sub>2</sub> channel. This last process shall be repeated 5 to 10 times to ensure access on LIC<sub>1</sub> does not occur. Record the time differentials as above.

### 5.3.8.1.6.3 Results based on above test method

Systems using the alternate channel provision shall monitor the alternate channel for at least 9,7 ms prior to transmitting on the alternate channel. The detected power level during this minimum 10 ms monitoring period shall be no higher than 6 dB above the power level detected when the channel was chosen as the alternate channel. Successful completion of the test using the procedure in either clause 5.3.8.1.6.1 or clause 5.3.8.1.6.2, is indicated by ability to establish a connection on the LIC<sub>1</sub> channel in a time interval much less than the scan cycle time with the pulse modulated signal at an amplitude of 6 dB above the calculated threshold power level. With the pulse modulated signal amplitude at 12 dB above the calculated threshold power level, access on LIC<sub>1</sub> is not permitted and access on LIC<sub>2</sub> is permitted only after the entire 401 MHz to 402 MHz and 405 MHz to 406 MHz band(s) MEDS band(s) is/are re-scanned.

Systems using this provision are not allowed to select more than one alternate channel. In this case the desired alternate channel is defined as LIC<sub>1</sub>. For any occurrences of access on the channel designated as LIC<sub>2</sub>, subtract the recorded time  $T_2$ ,  $T_{2a}$ , etc., from  $T_1$ . In all cases the difference between the two should be approximately equal to or greater than the scanning cycle time for the system. If the difference is short compared to the scan cycle time, the system is not re-scanning the entire band before accessing the LIC<sub>2</sub> channel, which is unacceptable. Any operation in the out-of-operating-region area is not acceptable.

## 5.3.8.2 Spectrum access based on low power and low duty cycle

### 5.3.8.2.0 Overview

This clause applies to devices using low duty cycle, limited repetitive transmission and low power operation for accessing spectrum within the band 401 MHz to 402 MHz or 405 MHz to 406 MHz. Devices covered by the present document operating under the provisions of this clause for spectrum access are subject to a maximum duty cycle restriction, very low power (see clause 4.2.3.1.2), and a limit on the number of repetitive pulses within an hour.

### 5.3.8.2.1 Methods of measurement

The tests for spectrum access requirements specified in this clause and applicable subsequent clause (clauses 4.2.3.1.2.2.1, 4.2.3.1.2.2.2 and 4.2.3.1.2.2.3) shall be carried out. The results obtained shall be compared to the requirements listed in clause 4.2.3.1.2.2.

Place the device on a table together with an oscilloscope. If possible, select an oscilloscope having an RF bandwidth of 500 MHz or better with a variable time/div setting that can be adjusted to 360 sec/div with an event delayed trigger. This will allow one horizontal scan to generate a transmission profile covering the duty cycle calculation time interval and also analysis of each individual RF pulse if needed. If an oscilloscope having this capability is not available, then multiple scan records covering an hour shall be recorded.

Each mode of activation of the device shall be investigated and measured independently. If multiple modes of device operation can be activated at the same time, the maximum duty cycle obtained for this condition of operation shall be determined.

With the device RF power output coupled to the oscilloscope set the vertical sensitivity appropriately with the sweep time/div set to the maximum possible not to exceed a total sweep time of 3 600 seconds, activate the device by selecting one of the activation modes specified by the provider. Let the device operate for an hour and count and record as  $M^*$  (\* refers to the mode of operation) the number of pulses captured during the one hour time sweep. Repeat this process for each mode of operation.

After completing the above, activate all modes at the same time and let the device operate for an hour. Count and record as  $M_c$  the number of pulses captured during the one hour time sweep.

Sum the individual RF pulse events for each activation mode and with all modes activated at the same time and record as  $P_{cm}$ .

Set the scope to look at the first RF pulse from the device from the unit for each single mode of activation. Measure and record the time duration as  $T^*$  (\* refers to the individual pulse event) at the 50 % points. Using the event delayed trigger if needed, repeat the measurement for each pulse emitted over a period of time of one hour.

Sum the individual time durations of each RF pulse event ( $T^*$ ) for each mode of activation to determine the total time of transmission during one hour for each mode of activation and record as  $T_t$ .

Repeat the above process with the ULP-AMI device activated by all possible modes at the same time. Measure and record  $T_c^*$  (\* refers to the individual RF pulse event) the time duration of each pulse event over a period of an hour as it occurs. Sum the individual time durations of each RF pulse event ( $T_c^*$ ) to determine the total time of transmission during an hour with all modes activated and record as  $T_c$ .

For e.r.p. measurement procedures see clause 5.3.3.

## 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.11] 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.2].

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 302 537				
The following requirements are relevant to the presumption of conformity under the article 3.2 of Directive 2014/53/EU [i.2]				
Requirement			Requirement Conditionality	
No	Description	Reference: Clause No	U/C	Condition
1	Frequency error	4.2.1.1	U	
2	Emission bandwidth	4.2.1.2	U	
3	Effective radiated power of the fundamental emission	4.2.1.3	U	
4	Spurious emissions of transmitters	4.2.1.4	U	
5	Frequency stability under low voltage conditions for battery operated equipment	4.2.1.5	U	
6	Spurious radiation of receivers	4.2.2.1	U	
7	Receiver blocking	4.2.2.2	U	
8	Spectrum Access	4.2.3.1	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 manufacturers 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 measurements

### 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 Introduction

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].

If e.r.p. is calculated from a field strength measurement, 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.

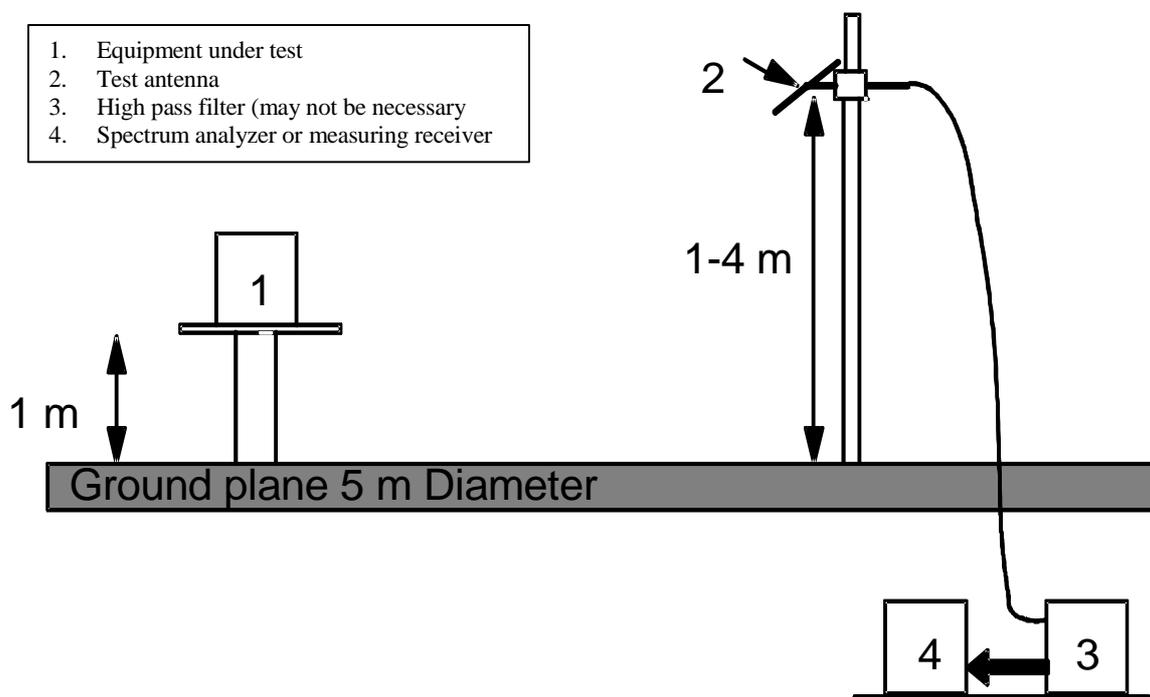


Figure B.1

### B.1.1.1 Standard position

The standard position for all programmer/control transmitters used in the Medical Data 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 provider;
- 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

For equipment designed to be external to but in very close proximity to a human body the use of the torso simulator arrangements provided for in clause B.1.1.3 shall be used with the following changes. MEDS devices in this category shall have the EUT affixed to the outside surface of the torso simulator at a height of 380 mm from the bottom of the simulator. Any leads attached to the EUT shall be tightly coiled in a vertical plane around the EUT and the entire assembly affixed to the surface of the torso simulator. Any RF leads shall be terminated in their respective design impedance. Tissue substitute material and temperature shall be as described in clause B.1.1.3.

### B.1.1.3 Human torso simulator for ULP-BWD and ULP-AMI

ULP-AMIs shall be tested in a simulated man constructed as follows in order to simulate operation of the ULP-AMI under actual operation conditions as shown in figure B.2. Note the addition of a shelf for testing ULP-BWD devices.

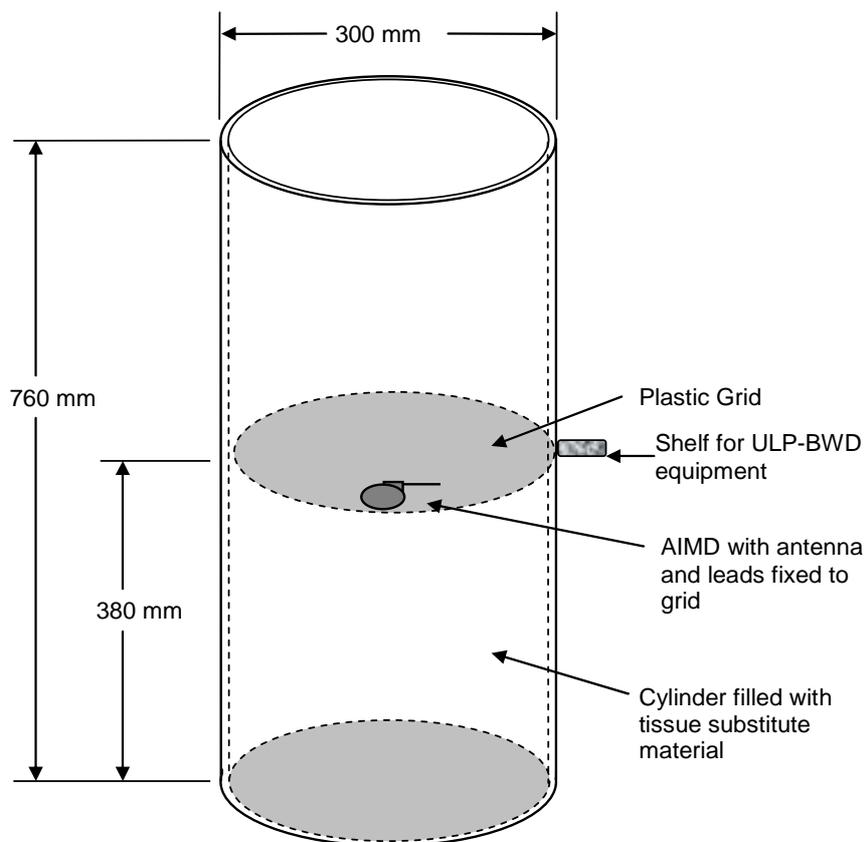


Figure B.2

An appropriate simulator for testing ULP-AMI consists of a cylindrical acrylic container with an outside diameter of  $300 \text{ mm} \pm 5 \text{ mm}$ , a sidewall thickness of  $6 \text{ mm} \pm 2,1 \text{ mm}$ , and a fluid-filled height of  $760 \text{ mm} \pm 5 \text{ mm}$ . 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 403,5 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  $22 \text{ }^\circ\text{C}$  and  $38 \text{ }^\circ\text{C}$ . 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 than  $60 \text{ mm} \pm 5 \text{ mm}$  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  $60 \text{ mm} \pm 5 \text{ mm}$  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 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 insure 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.7].

## 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 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.

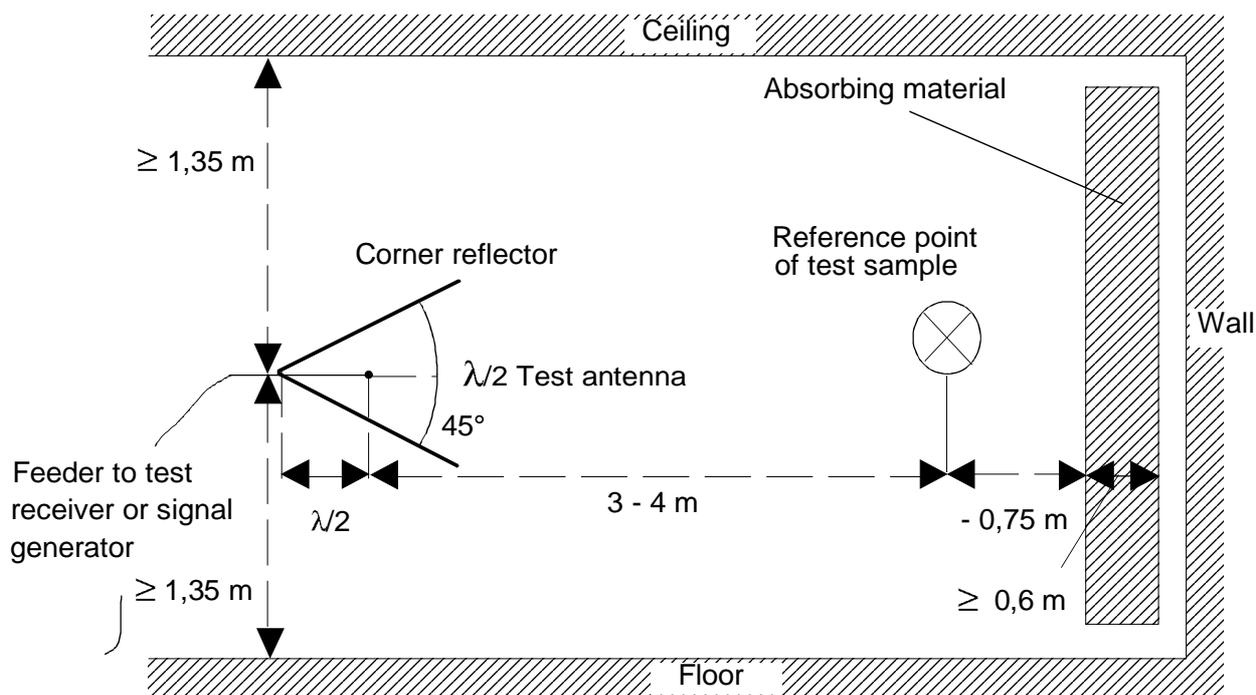


Figure B.3: Indoors site arrangement (shown for horizontal polarization)

### 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  $\lambda/2$  antenna in figure B.3 may be replaced by an antenna of constant length, provided that this length is between  $\lambda/4$  and  $\lambda$  at the frequency of measurement, and the sensitivity of the measuring system is sufficient. In the same way, the distance of  $\lambda/2$  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  $\pm 0,1$  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 Introduction

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.

### 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 for ULP-AMD-P (power supply 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 affect the measuring result.

## B.3 Further optional alternative indoor test site using a fully anechoic chamber

### B.3.0 Introduction

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 fully 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 fully anechoic chamber being 10 m long, 5 m broad and 5 m high. Walls and ceiling should be coated with RF absorbers of 1 m 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.

In the case of making measurements in a fully anechoic chamber, a correction factor may be needed to account for the ground reflection that occurs on an Open Area Test Site (OATS) when a comparison is being made between measured levels taken in a chamber to those measured on an OATS.

### B.3.1 Example of the construction of a fully 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 a fully anechoic 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 5 m length in the middle axis of this room is available.

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

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 fully anechoic chambers

For free-space propagation in the far field condition the correlation  $E = E_0 (R_0/R)$  is valid for the dependence of the field strength  $E$  on the distance  $R$ , whereby  $E_0$  is the reference field strength in the reference distance  $R_0$ .

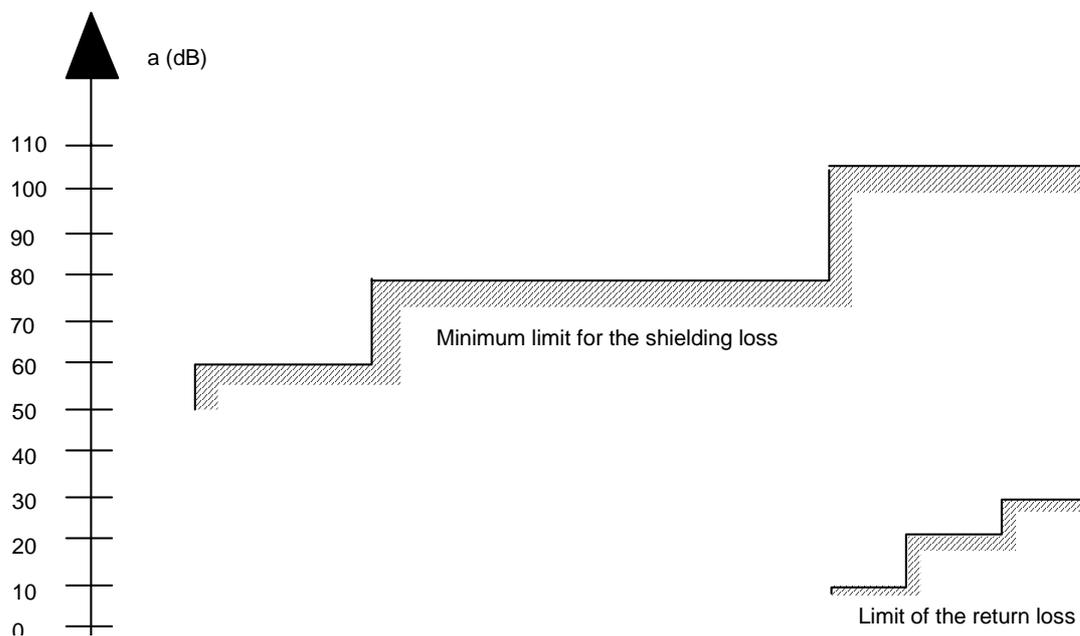
It is useful to use this correlation for comparison measurements, as all constants are eliminated with the ratio and neither cable attenuation, nor antenna mismatch, or antenna dimensions are of importance.

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 interferences due to reflections and is far less problematical than the direct measurement of reflection attenuation.

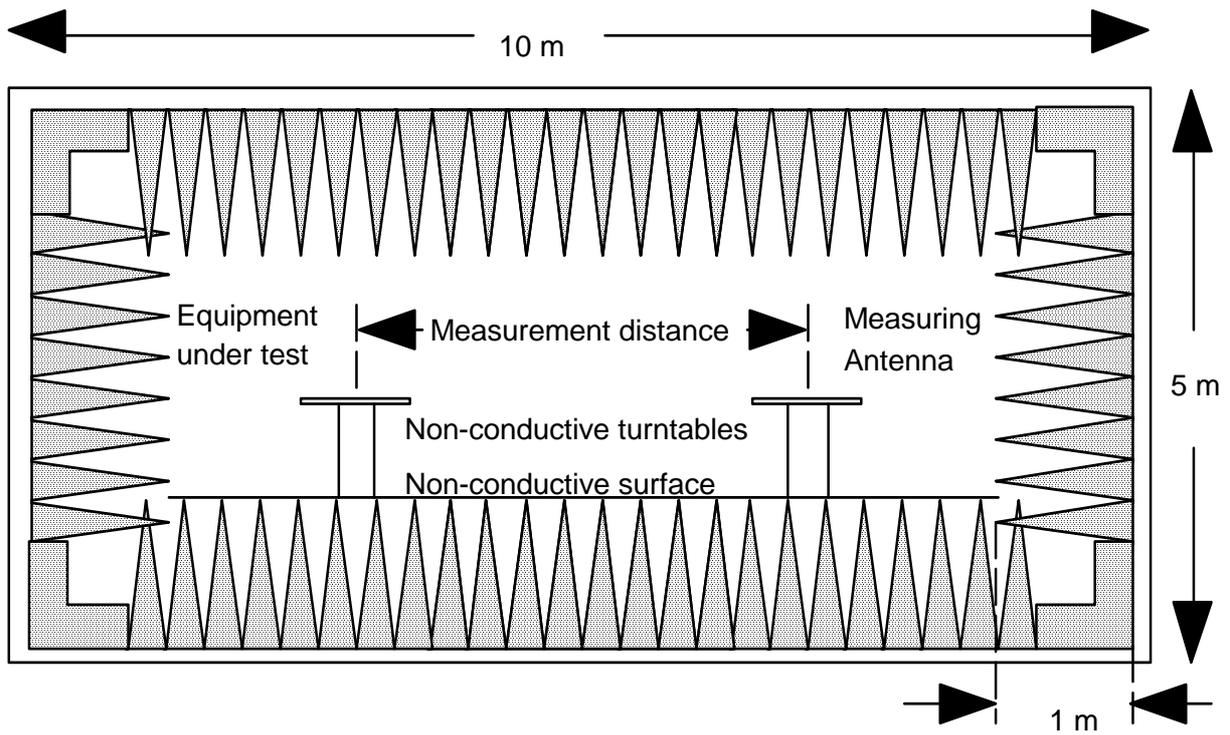
With an anechoic chamber of the dimensions suggested in clause B.3 at low frequencies up to 100 MHz, there are no far field conditions and therefore reflections are stronger so that careful calibration is necessary; in the medium frequency range from 100 MHz to 1 GHz the dependence of the field strength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

### B.3.3 Calibration of the fully 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

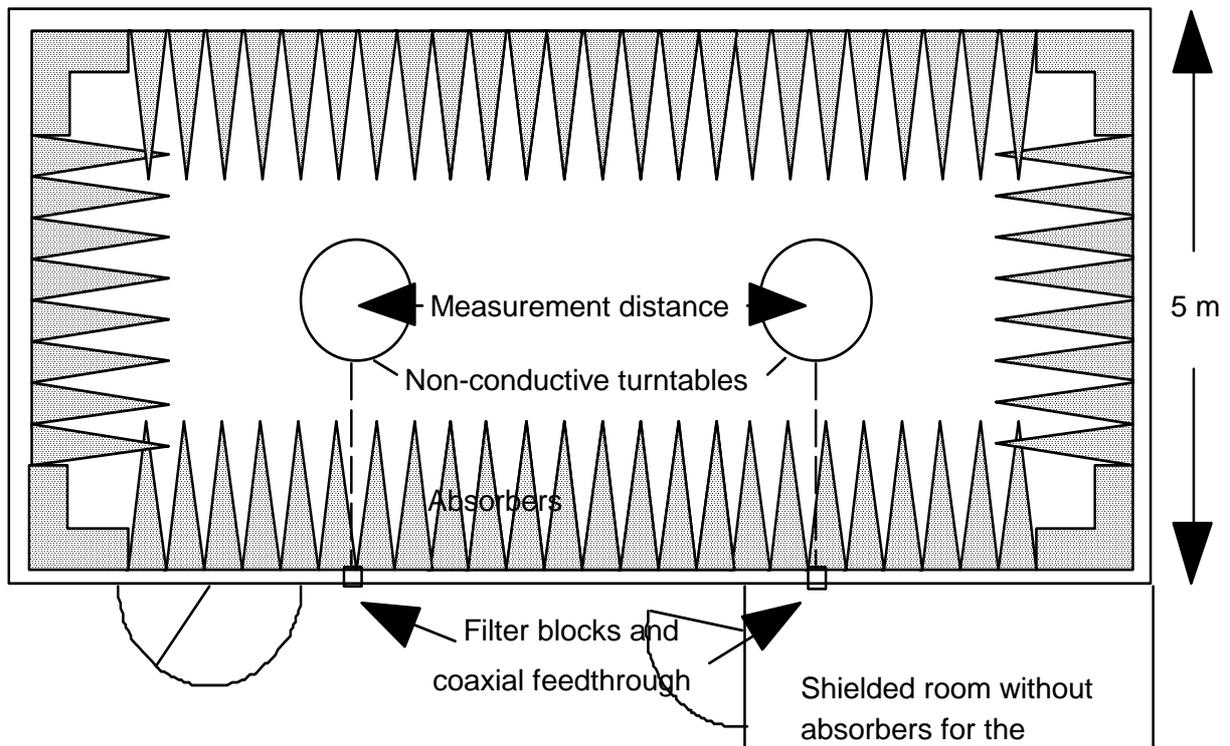


Figure B.5: Example of construction of an anechoic shielded chamber

---

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

If used for conducting measurements to the requirements of the present document, the spectrum analyser performance parameters shall meet the following requirements:

- 1) 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  $\pm 2$  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.
- 2) The reading accuracy of the frequency marker shall be within  $\pm 2$  % of the channel separation.
- 3) The accuracy of relative amplitude measurements shall be within  $\pm 1$  dB.
- 4) The spectrum analyser shall have a maximum resolution bandwidth setting of 1 MHz or greater.
- 5) 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

ICNIRP: "Guidelines for Limiting Exposure to Time-Varying Electric, Magnetic, and Electromagnetic Fields (up to 300 GHz)", International Commission on Non-Ionizing Radiation Protection, Health Physics Vol. 74, No 4, pp 494-522, 1998.

Council Recommendation 1999/519/EC on limitation of exposure of the general public to electromagnetic fields 0 Hz-300 GHz.

---

## History

<b>Document history</b>		
V1.1.2	December 2007	Publication as ETSI EN 302 537 part 1 and part 2
V2.0.1	June 2016	EN Approval Procedure AP 20160911: 2016-06-13 to 2016-09-12
V2.1.1	October 2016	Publication