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Ultra Low Power (ULP) wireless medical capsule endoscopy devices operating in the band 430 MHz to 440 MHz;
Harmonised Standard for access to radio spectrum

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Foreword

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

The present document has been prepared under the Commission's standardisation request C(2015) 5376 final [i.1] 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:	28 May 2019
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Date of withdrawal of any conflicting National Standard (dow):	28 February 2021

Modal verbs terminology

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

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Introduction

The present document is aiming to cover radio and telecommunications terminal equipment within the scope of the EU's Radio Equipment Directive (RED) [i.2].

The present document specifies conformance requirements for the Ultra Low Power Wireless Medical Capsule Endoscopy SRD application, which includes Capsule Camera (CCam) acting as transmitter and associated Data Recorder (DR) receiver devices, as meant by ETSI TR 103 451 [i.3]. The CCam is designed to wirelessly transmit recorded images from inside patient's gastrointestinal tract to the DR receiver, utilizing a single wideband radio channel occupying the entire designated band 430 MHz to 440 MHz. It is intended that this band will be harmonised for European-wide usage by Ultra Low Power Wireless Medical Endoscopy application through relevant CEPT and EU normative documents in the field of SRD spectrum regulation, such as CEPT/ERC/REC 70-03 [i.4].

CCam transmitters will utilize miniature integral antenna encapsulated within its pill-shaped enclosure. The intended use of the CCam transmitter is inside the human body.

DR receivers will use either integral antenna or dedicated external antenna implemented in the form of skin patch or belt. Such dedicated external antenna would ensure optimal reception of weak radio signals by keeping antenna in direct proximity to the patient's body in the area closest to internal passage of CCam.

These devices would offer opportunity of performing medical endoscopy-type examination of the entire human gastrointestinal tract including the small intestine and colon. Thanks to simple application with minimized risks and side effects, while providing the unique ability to visualize the complete gastrointestinal tract, its use would be highly beneficial and attractive to patients and doctors.

The present document is structured as follows:

- Clauses 1 through 3 provide a general description of the types of equipment covered by the present document and the definitions of terms, symbols and abbreviations used.
- Clause 4 specifies the requirements and limits applicable to CCam transmitter and DR receiver.
- Clauses 5.1 and 5.2 specify the test and general conditions for testing of the equipment.
- Annex A (informative) provides an overview of the relationship between the present document and the essential requirements of the RED [i.2].
- Annex B (normative) describes a human torso simulator test fixture to be used for radiated measurements.
- Annex C (normative) describes the Full Anechoic Room test site configuration for radiated measurements.

1 Scope

The present document specifies technical characteristics and methods of measurements for Ultra Low Power Wireless Medical Capsule Endoscopy application (CCam transmitters and associated DR receivers) operating in the designated frequency band 430 MHz to 440 MHz, as meant by ETSI TR 103 451 [i.3].

A possible return (downlink) RF transmission channel from DR to CCam for command and control signalling, if and when implemented, is outside the scope of the present document.

NOTE: The relationship between the present document and essential requirements of article 3.2 of Directive 2014/53/EU [i.2] is given in Annex A.

2 References

2.1 Normative references

References are specific, identified by date of publication and/or edition number or version number. Only the cited version 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.

Not applicable.

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] 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.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 (RED).

[i.3] ETSI TR 103 451: "System Reference document (SRdoc); Short Range Devices (SRD); Technical characteristics for UHF wideband Ultra Low Power Wireless Medical Capsule Endoscopy".

[i.4] CEPT/ERC/REC 70-03: "Relating to the use of Short Range Devices (SRD)".

[i.5] Body Tissue Dielectric Parameters provided by the Federal Communications Commission: "Reference Calculation Tool".

NOTE: Available online at https://www.fcc.gov/general/body-tissue-dielectric-parameters.

[i.6] Bioelectromagnetics (1987): "Simulated biological materials for electromagnetic radiation absorption studies", Hartsgrove G., Kraszewski A. & Surowiec A. 8(1), 29-36.

3 Definition of terms, symbols and abbreviations

3.1 Terms

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

Capsule Camera (CCam): miniature disposable capsule-shaped optical imaging camera with integrated ultra low RF power SRD transmitter, intended to be swallowed

Data Recorder (DR): device worn by the patient in order to record the stream of images received from CCam and store it

NOTE: At the end of diagnostic procedure the stream of images may be downloaded to doctor's PC for examination.

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

integral antenna: permanent built-in antenna, designed as an indispensable part of the equipment

unwanted emissions in the spurious domain: components at any frequency, generated and radiated by active DR receiver or CCam transmitter outside the defined operating frequency band of 430 MHz to 440 MHz

3.2 Symbols

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

dB	decibel
dBm	absolute power level referred to one milliwatt
f	frequency

3.3 Abbreviations

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

CCam	Capsule Camera
CEPT	European Conference of Postal and Telecommunications administrations
DR	Data Recorder
EC	European Commission
EFTA	European Free Trade Association
e.r.p.	effective radiated power
EU	European Union
EUT	Equipment Under Test
FAR	Fully Anechoic Room
RF	Radio Frequency
RMS	Root Mean Square
SRD	Short Range Device
TX	Transmitter
VSWR	Voltage Standing Wave Ratio

4 Technical requirements specifications

4.1 Environmental profile

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

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

4.2 Conformance requirements

4.2.1 Transmitter requirements

4.2.1.1 Effective radiated power

4.2.1.1.1 Definition

The e.r.p. is the total power of CCam TX wanted emissions measured outside test patient's (phantom) body within the designated band 430 MHz to 440 MHz, in the direction of the maximum radiated power under specified conditions of measurements.

4.2.1.1.2 Limit

The e.r.p. of CCam TX shall not exceed -40 dBm/10 MHz total power, -50 dBm/100 kHz e.r.p. density within the designated 430 MHz to 440 MHz band.

4.2.1.1.3 Conformance

The conformance tests for this requirement shall be as defined in clause 5.4.1.1 of the present document.

4.2.1.2 Transmitter emissions mask

4.2.1.2.1 Definition

The transmitter emissions mask envelope shall contain all constituent wanted and unwanted (including the unwanted emissions in the spurious domain) RF emissions of CCam TX as measured outside test patient's (phantom) body in the direction of maximum radiated power under specified conditions of measurements.

4.2.1.2.2 Limits

The transmitter emissions mask limits shall be as given in Figure 1.

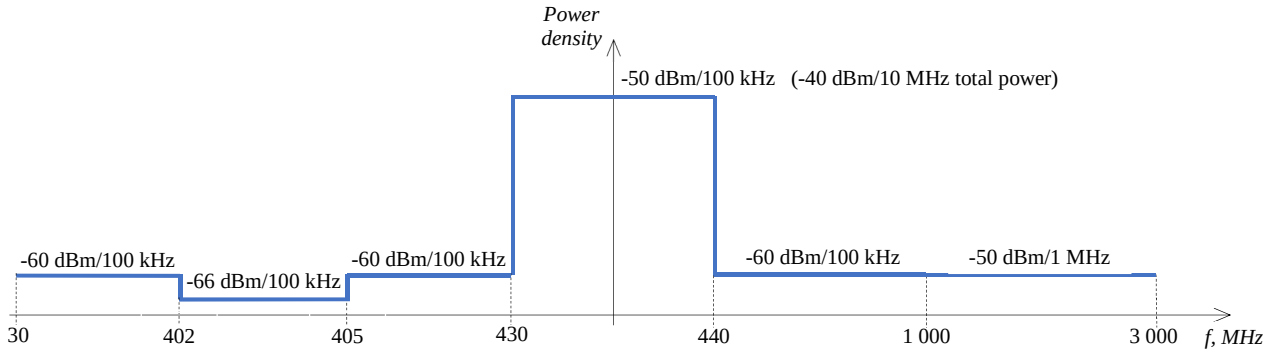

Figure 1: CCam TX emissions mask (not to scale)

The power density limit given in this clause for in-channel portion of the mask is meant to constrain any small-scale power density fluctuations across the transmission bandwidth and as such should not be compared directly or bandwidth-converted to the aggregate e.r.p. limit for the entire useful signal given in the clause 4.2.1.1.2.

4.2.1.2.3 Conformance

The conformance tests for this requirement shall be as defined in clause 5.4.1.2 of the present document.

4.2.2 Receiver requirements

4.2.2.1 Unwanted Emissions in the Spurious Domain

4.2.2.1.1 Definition

Unwanted emissions in the spurious domain from the DR receiver are RF emission components at any frequency, generated and radiated by active receiver circuitry and the antenna.

4.2.2.1.2 Limit

The power of any unwanted emissions in the spurious domain by the DR receiver shall not exceed:

- -60 dBm/100 kHz between 30 MHz and 402 MHz;
- -66 dBm/100 kHz between 402 MHz and 405 MHz;
- -60 dBm/100 kHz between 405 MHz and 1 000 MHz;
- -50 dBm/1 MHz between 1 000 MHz and 3 000 MHz.

4.2.2.1.3 Conformance

The conformance tests for this requirement shall be as defined in clause 5.4.2.1 of the present document.

4.2.2.2 Receiver blocking

4.2.2.2.1 Definition

Blocking is a measure of the capability of the DR receiver to receive a wanted modulated signal from CCam without exceeding a given degradation due to the presence of an unwanted input signal at any frequencies other than those of the spurious responses or the adjacent channels or bands.

4.2.2.2.2 Limits

The blocking levels at the specified frequency offsets shall be equal to or greater than the limits in Table 1, except at frequencies where spurious responses are found.

Table 1: Blocking level parameters

Requirement	Limits
Blocking at ±4 MHz from operating band edge, i.e. at 426 MHz and 444 MHz	≥ -69 dBm
Blocking at ±20 MHz from operating band edge, i.e. at 410 MHz and 460 MHz	≥ -44 dBm

4.2.2.2.3 Conformance

The conformance tests for this requirement shall be as defined in clause 5.4.2.2 of the present document.

4.2.2.3 Receiver sensitivity

4.2.2.3.1 Definition

Sensitivity of the DR receiver is the minimum signal power input to the receiver which ensures demodulation of wanted signal while achieving target link performance, characterized by Frame Error Ratio of not more than 1 %. The test input signal is generated at the nominal DR operating frequency and modulated with normal modulation.

4.2.2.3.2 Limit

The sensitivity of the DR receiver shall be less than or equal to -77 dBm.

4.2.2.3.3 Conformance

The conformance tests for this requirement shall be as defined in clause 5.4.2.3 of the present document.

4.2.2.4 Adjacent signal selectivity

4.2.2.4.1 Definition

The adjacent signal selectivity is a measure of capability of the DR receiver to operate satisfactorily in the presence of an unwanted signal occupying 25 kHz channel adjacent to the DR channel, i.e. positioned immediately outside designated DR operating band of 430 MHz to 440 MHz. The "adjacent signal selectivity" with narrowband interferer of different system had to be used as opposed to "adjacent channel selectivity" because the reference wideband system is designed to be operated utilizing only one channel, occupying the entire designated operating frequency band.

4.2.2.4.2 Limit

The adjacent signal selectivity of the DR receiver shall be equal to or greater than -99 dBm.

4.2.2.4.3 Conformance

The conformance tests for this requirement shall be as defined in clause 5.4.2.4 of the present document.

5 Testing for compliance with technical requirements

5.1 Presentation of equipment for testing purposes

5.1.0 General provisions

The manufacturer 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 tests, shall be supplied.

The physical arrangements used for the testing shall be fully documented in the test report.

5.1.1 Choice of equipment model for testing

One sample (or more when necessary for completion of prolonged/repetitive tests, such as when it is impossible to replace battery in a disposable CCam EUT) of each model or type of CCam transmitter and DR receiver shall be used for testing. Any ancillary equipment used for testing including any technical means employed for suitable activation and control of equipment functions during measurement shall be described in the test report.

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. The description of EUT configuration with justification for choice of optional features shall be provided in the test report.

5.1.2 Human torso simulator

An appropriate human torso simulator as described in clause 5.2.5 and Annex B shall be used for testing. A sufficient quantity of tissue substitute material shall be used to completely fill the test fixture. The manufacturer shall determine the suitable vertical/horizontal arrangement of the CCam EUT (and any additional device supports/leads) on the holding grid within the test fixture and of the DR EUT on the outside of the test fixture. The ultimate arrangements for EUT placement shall be described in the test report.

5.1.3 Testing in external laboratory

When submitting equipment for testing by an external laboratory, the manufacturer shall supply all the necessary information required by the test laboratory. The equipment submitted for testing shall be a representative sample of the equipment as produced.

The equipment used and its set-up information shall be fully described in the test report.

5.2 Test conditions

5.2.1 Test power source

For radiated measurements on CCam and DR equipment with their internal power sources, fully charged internal batteries shall be used. The batteries used shall be as supplied or recommended by the manufacturer. 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 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.

For hermetically sealed CCam it can be impossible to measure battery voltage directly or indirectly. For such equipment, at the end of each test the voltage need not be measured, however, in each test a fresh CCam EUT sample with fully charged battery shall be used and the given test shall be completed within the maximum operational time of tested CCam type as specified by the manufacturer.

5.2.2 Temperature and humidity

The temperature and humidity conditions for DR EUT testing shall be any convenient combination of temperature and humidity within the following ranges:

- temperature +22 °C to +38 °C;
- relative humidity 20 % to 75 %.

The CCam EUT shall be tested while placed within human torso simulator as described in clause 5.2.5 and Annex B.

5.2.3 Test signals and test modulation

As CCam is not designed to provide an external modulation connector, it shall be tested while being in its normal active operating mode with digitally modulated signal corresponding to transmission of its collected imaging information.

5.2.4 Antennas

CCam devices shall be supplied with their integral antennas, while DR devices shall be supplied with integral antenna or external dedicated antenna, or both. The characteristics of the antenna(s) used for DR testing shall be stated in the test report.

5.2.5 Test fixture for CCam

Considering that CCam are intended for operation while passing through gastrointestinal tract of a diagnosed patient, the radiated measurements of CCam EUT shall be performed while it is being placed in a test fixture - a human torso simulator - that approximates the physical conditions of a CCam placed inside a human body. Guidance on implementation of the human torso simulator is provided in Annex B.

5.2.6 Test site and general arrangements for radiated measurements

Radiated measurements on CCam and DR equipment shall be carried out in a Fully Anechoic Room (FAR), or alternatively a Semi-Anechoic Room, test site as described in Annex C.

5.2.7 Measuring receiver

The term "measuring receiver" refers to a selective voltmeter or a spectrum analyser. The reference bandwidth and detector type of the measuring receiver are given in Table 2.

Table 2: Measurement receiver specifications

Frequency	Detector type	Reference bandwidth
30 MHz ≤ f ≤ 1 000 MHz	RMS detector	100 kHz
1 000 MHz ≤ f ≤ 3 000 MHz	RMS detector	1 MHz

5.3 Void

Table 3: Void

5.4 Methods of measurement

5.4.1 Methods of measurement for transmitters

5.4.1.0 General provisions

In order to conduct transmitter measurements, the manufacturer shall provide CCam samples operating within the designated operating frequency band 430 MHz to 440 MHz with suitable activation mechanism.

5.4.1.1 Effective radiated power

A test scenario according to clauses C.1 and C.3 and a test antenna according to clause C.2 shall be used.

Step 1:

The CCam TX EUT shall be placed for radiated measurement in the human torso simulator (see Annex B) and activated to operate at its maximum output power under fully charged battery condition (see clause 5.2.1).

Step 2:

The test antenna shall be chosen appropriate to operating frequency band 430 MHz to 440 MHz and oriented initially for vertical polarization. The output of the test antenna shall be connected to the measuring receiver.

Step 3:

With CCam EUT operating and transmitting its regular modulated signal, the measuring receiver shall be tuned to the operating frequency 435 MHz with measurement bandwidth of 10 MHz.

Step 4:

The human torso simulator with EUT shall then be rotated through 360° in the horizontal plane, until the maximum signal level is detected by the measuring receiver.

Step 5:

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

Step 6:

The human torso simulator with EUT shall be replaced by a substitution antenna as defined in clause C.2.2. The substitution antenna shall be connected to a calibrated signal generator and initially oriented for vertical polarization.

Step 7:

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 5.

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 measure of power level.

Step 9:

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

Step 10:

The measure of the e.r.p. is the larger 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.

5.4.1.2 TX emissions mask compliance measurement

A test scenario according to clauses C.1 and C.3 and a test antenna according to clause C.2 shall be used.

Step 1:

The CCam TX EUT shall be placed for radiated measurement in the human torso simulator (see Annex B) and activated to operate at its maximum output power under fully charged battery condition (see clause 5.2.1).

Step 2:

The test antenna shall be oriented initially for vertical polarization and its output shall be connected to the measuring receiver. The CCam EUT shall be activated and have the normal modulation applied (see clause 5.2.3) and the measuring receiver shall be tuned over the frequency ranges 30 MHz to 3 000 MHz.

Step 3:

In the initial position of the torso simulator the complete spectrum should be measured. At the frequencies with the maximum power values from the initial measurement the human torso simulator with EUT shall be rotated through 360° in the horizontal plane, until the 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 human torso simulator with EUT shall be replaced by a substitution antenna as defined in clause C.2.2.

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 measured salient 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 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 measurements 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 e.r.p. for each salient emission is the larger 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. The obtained results shall be compared for compliance with the emissions mask limit for relevant frequency range.

5.4.2 Methods of measurement for receivers

5.4.2.1 Receiver's unwanted emissions in the spurious domain

In case the DR is intended to be operated with either internal antenna or dedicated external antenna, the measurements specified in this clause shall be done separately with each type of antenna and the conformance with the spurious emissions limits shall be established for both types of operational antennas used.

In case of DR with integral antenna, the DR EUT shall be mounted for radiated measurement on the external surface of the human torso simulator, vertically centred and facing the measurement antenna.

In case of DR with dedicated external antenna, the DR EUT shall be mounted for radiated measurement on the external surface of the human torso simulator with external antenna wrapped around the surface of the human torso simulator cylinder, vertically centred and with EUT antenna plane facing the measurement antenna.

Measurements of unwanted emissions in the spurious domain shall be then carried out following the same multiple step procedure as described in clause 5.4.1.2.

5.4.2.2 Receiver blocking

5.4.2.2.0 Types of measurement

DR EUT with integral antenna (i.e. without a permanent or temporary antenna connector) shall be tested using radiated measurement according to clause 5.4.2.2.1.

DR EUT with a permanent or temporary antenna connector shall be tested using conducted measurement according to clause 5.4.2.2.2.

5.4.2.2.1 Radiated measurement

The appropriate test site shall be used as described in Annex C.

Signal generators A and B together with the combiner, shown in Figure 2, shall be placed outside the test site.

The output of the combiner shall be connected to a measurement antenna, which in this test becomes a transmit test antenna. Polarization of transmit test antenna shall be aligned with that of the EUT antenna.

The EUT shall be placed on the external surface of the human torso simulator described in Annex B, vertically centred and facing the transmit test antenna.

Then the measurements described in clause 5.4.2.2.3 shall be performed.

5.4.2.2.2 Conducted measurement

Two signal generators A and B shall be connected to the EUT via a combining network as shown in Figure 2.

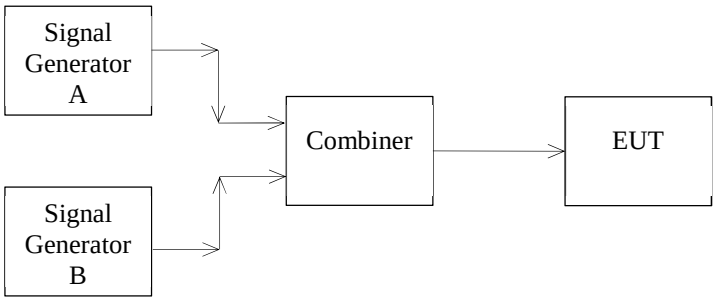

Figure 2: Blocking measurement arrangement

Then the measurements described in clause 5.4.2.2.3 shall be performed.

5.4.2.2.3 Measurement procedure

Signal generator A shall be set to an appropriate modulated test signal emulating CCam transmission at the nominal operating frequency within the operating frequency band. A possible alternative is to use a CCam test fixture with conducted output of generated signal.

Signal generator B shall use unmodulated carrier.

Measurements shall be carried out at frequencies of the unwanted signal at approximately the frequency offsets of ±4 MHz and ±20 MHz from relevant edge of CCam operating band, avoiding those frequencies at which spurious responses occur.

Step 1:

Signal generator B shall be powered off. Signal generator A shall be set to the minimum level which gives the wanted performance criterion of DR EUT as declared by the manufacturer. The output level of generator A shall then be increased by 3 dB.

Step 2:

Signal generator B is powered on and set to operate at one of specified offset frequencies.

Signal generator B is then switched on and the signal amplitude is adjusted to the minimum level at which the wanted performance criterion is not achieved.

With signal generator B settings unchanged, the EUT receiver shall be replaced with a suitable RF power measuring equipment. The power into the EUT receiver shall be measured and noted.

The blocking level for that offset frequency is then established as being equal to the conducted power received from generator B at the EUT antenna connector. The blocking level can either be measured on the antenna connector for conducted test or be calculated for radiated test using one of the two methods described in clause C.4.

The blocking level shall be higher or equal to the relevant blocking power level specified in clause 4.2.2.2.2.

Step 3:

The measurement in step 1 to step 2 shall be repeated with signal offsets at all required frequencies.

Step 4:

The information shown in Table 4 shall be recorded in the test report for each measured signal level and unwanted signal offset.

Table 4: Blocking measurement results recorded in the test report

Value	Notes
Operating Frequency	Nominal centre frequency of the receiver
Signal generator A	Power level of signal generator A
Blocking level	Power level of signal generator B

5.4.2.3 Receiver sensitivity

5.4.2.3.0 Types of measurement

DR EUT with integral antenna (i.e. without a permanent or temporary antenna connector) shall be tested using radiated measurement according to clause 5.4.2.3.1.

DR EUT with a permanent or temporary antenna connector shall be tested using conducted measurement according to clause 5.4.2.3.2.

5.4.2.3.1 Radiated measurement

The appropriate test site shall be used as described in Annex C.

The output of the signal generator shall be connected to a measurement antenna, which in this test becomes a transmit test antenna. Polarization of transmit test antenna shall be aligned with that of the EUT antenna.

The EUT shall be placed on the external surface of the human torso simulator described in Annex B, vertically centred and facing the transmit test antenna.

Then the measurements described in clause 5.4.2.3.3 shall be performed.

5.4.2.3.2 Conducted measurement

The EUT shall be connected to the output of the signal generator.

Then the measurements described in clause 5.4.2.3.3 shall be performed.

5.4.2.3.3 Measurement procedure

The signal generator, modulated with an appropriate test signal, shall be tuned to the operating frequency 435 MHz with test signal bandwidth of 10 MHz. The DR EUT shall be activated.

Step 1:

The level of the input signal to the EUT shall be increased until the DR achieves the target operational performance, i.e. demodulated signal meeting the Frame Error Ratio objective of 1 %, equivalent to losing not more than one frame per 100 transmitted image frames.

Step 2:

The receiver sensitivity is then the power received from test generator at the EUT antenna connector. This can either be measured on the antenna connector for conducted test or be calculated for radiated test using one of the two methods described in clause C.4.

Step 3:

The information shown in Table 5 shall be recorded in the test report to verify the compliance with the receiver sensitivity limit established in clause 4.2.2.3.2.

Table 5: Receiver sensitivity measurement results recorded in the test report

Value	Notes
Test signal	The test signal used
Test configuration	Radiated/conducted, details thereof
Link performance measurement method	Frame Error Ratio, image quality/stability, other
Measurement description	Description of how the established link threshold performance was established/calculated/measured
Receiver sensitivity	Measured signal generator/equivalent power level

5.4.2.4 Adjacent signal selectivity

The measurements of adjacent signal selectivity to verify compliance with the limit established in clause 4.2.2.4.2 shall be carried out according the methods and procedure described in clause 5.4.2.2, except the adjacent signal selectivity shall be measured with the different interfering signal offset values, corresponding to their placement immediately adjacent to the operating bandwidth of DR.

The central frequency values of interfering signal to be used in the adjacent signal selectivity measurements are given in Table 6.

Table 6: Frequencies of interfering signal for adjacent signal selectivity measurements

Measurement Option	Central frequency of interfering signal (25 kHz channel bandwidth)
Interfering signal offset case 1	429,987 5 MHz
Interfering signal offset case 2	440,012 5 MHz

Annex A (informative): 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.1] 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 303 520					
Requirement				Requirement Conditionality	
No	Description	Essential requirements of Directive	Clause(s) of the present document	U/C	Condition
1	E.r.p.	3.2	4.2.1.1	U	
2	Transmitter emissions mask	3.2	4.2.1.2	U	
3	Receiver's unwanted emissions in the spurious domain	3.2	4.2.2.1	U	
4	Receiver blocking	3.2	4.2.2.2	U	
5	Receiver sensitivity	3.2	4.2.2.3	U	
6	Adjacent signal selectivity of receiver	3.2	4.2.2.4	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.

Essential requirements of Directive

Identification of article(s) defining the requirement in the Directive.

Clause(s) of the present document

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 is unconditionally applicable (U) or is conditional upon the manufacturer's claimed functionality of the equipment (C).

Condition Explains the conditions when the requirement is or is not 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): Human torso simulator

B.1 General provisions

The applicative simulator of human torso shall be designed so as to emulate typical usage conditions of CCam inside human body and represent real life radiated emissions of CCam as closely as possible.

Clause B.2 provides one representative example of implementing a human torso simulator. The manufacturer and test laboratory may agree on alternative suitable implementation of human torso simulator, which shall be then fully described in the test report.

B.2 Human torso simulator for CCam radiated measurements

CCam shall be placed for test measurements in a human torso simulator constructed as shown in Figure B.1.

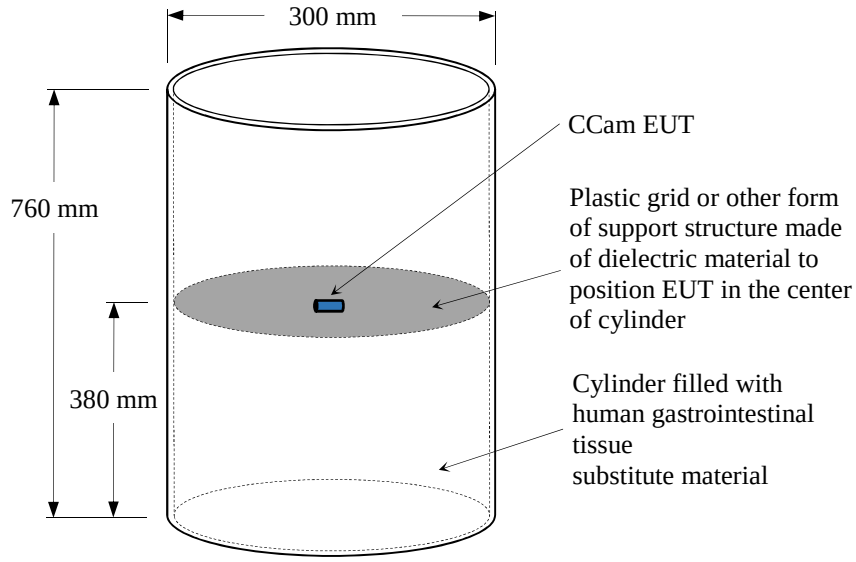

Figure B.1: Human torso simulator fixture (depicted not to scale)

The human torso simulator consists of a cylindrical acrylic container with an outside diameter of 300 mm ± 5 mm, a sidewall thickness of 6 mm ± 2,1 mm, and a fluid-filled height of 760 mm ± 5 mm. A plastic grid shall be mounted centrally in the container to permit representative positioning of CCam EUT inside the simulated human torso. The CCam EUT shall be positioned in the centre of the support grid, i.e. equidistant from the sidewalls.

The container shall be filled with a material that is sufficiently fluid that it will flow around the CCam EUT without any voids. The tissue substitute material to be filled in the torso simulator shall be composed of 57,5 % water, 40 % sugar and 2,5 % salt (weight percentages).

This mixture is designed to match the dielectric and conductivity properties of human gastrointestinal tissue at 435 MHz (estimated composite conductivity of 1,4 and permittivity of 64, based on weighted averaging of the main tissue types constituting gastrointestinal tract area of the body [i.5]).

See also for information published scientific experimental research on the subject, e.g. as found in reference [i.6].

During the testing, the temperature of the tissue substitute material in the human torso simulator shall be maintained in the range of +22 °C to +38 °C.

Radiated emissions measurements shall be then performed in accordance with specific provisions in relevant clause of the present document and otherwise referring to general guidance for setting up the test site as given in Annex C.

Annex C (normative): Test site and antennas for radiated measurements

C.1 Test site description

A Fully Anechoic Room (FAR) shall be normally used for radiated measurements of CCam and DR devices. Alternatively, the manufacturer and test laboratory may agree to use a Semi-Anechoic Room, the setup of which shall be then fully described in the test report.

FAR is an enclosure, usually shielded, whose internal walls, floor and ceiling are covered with radio absorbing material. The chamber usually contains an antenna support at one end and a turntable at the other end. A typical FAR is shown in Figure C.1.

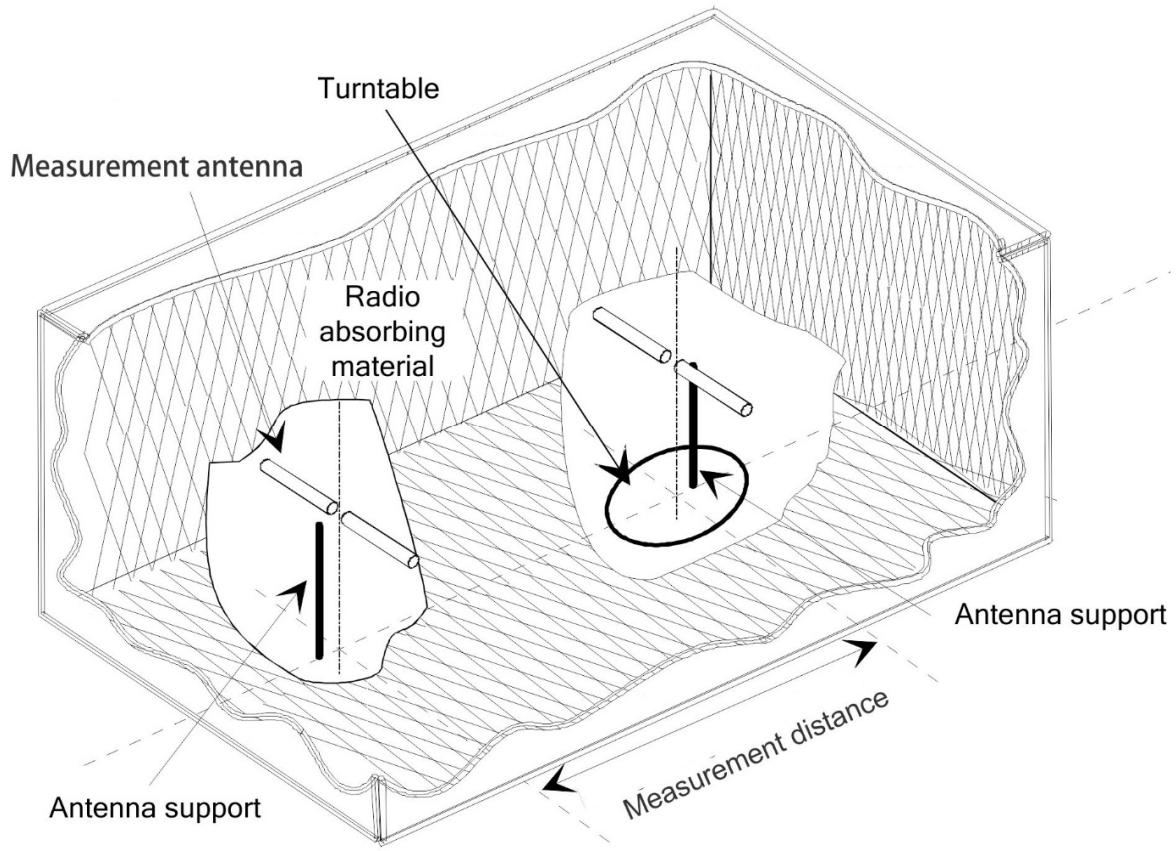

Figure C.1: A typical Fully Anechoic Room

The shielding provides a test space, with reduced levels of interference from ambient signals and other outside effects, whilst the radio absorbing material minimizes unwanted reflections from the walls and ceiling which can influence the measurements. The shielding shall be sufficient to eliminate interference from the external environment that would mask any signals that have to be measured.

A turntable shall be placed at 3 m measurement distance from the measurement antenna. Turntable shall be capable of carrying the weight of human torso simulator fixture described in Annex B and ensure possibility of its rotation through 360° in the horizontal plane. The height of turntable shall be chosen so that the EUT in the centre of the human torso simulator fixture shall be positioned at a height of 1 m to 1,5 m above the ground plane.

C.2 Antennas

C.2.1 Measurement antenna

In emission tests the measurement antenna is used to detect the field from the EUT in one stage of the measurement, and from the substitution antenna in the other stage.

The measurement antenna shall be mounted on a support capable of allowing the antenna to be used in either horizontal or vertical polarization. The measurement antenna shall be mounted at the height of 1,5 m above the ground plane.

Biconical or logarithmic periodic dipole antennas shall be used for measurements described in the present document.

For spurious emission testing, a combination of biconical antennas (commonly termed "bicones") and log periodic dipole array antennas (commonly termed "log periodics") may be used to cover the entire 30 MHz to 3 000 MHz band.

The measurement antenna needs not an absolute calibration.

C.2.2 Substitution antenna

The substitution antenna shall be used to replace the equipment under test in substitution measurements.

Substitution antenna shall be suitable for the frequency range and the return loss of the antenna shall be taken into account when calculating the measurement uncertainty.

The phase centre of the substitution antenna shall coincide with the reference point of the test sample it has replaced. Therefore antennas with a phase centre that changes as a function of frequency (such as log periodic dipole array antennas) are not suitable as a substitution antenna.

The reference point of the substitution antenna shall coincide with the volume centre of the EUT when its antenna is internal, or the point where an external antenna is connected to the EUT.

The distance between the lower extremity of the antenna and the ground shall be at least 30 cm.

The substitution antenna shall be calibrated relative to a half wave dipole.

Calibration figures intended for use above a reflective surface shall not be used in an anechoic chamber or vice versa.

C.3 Guidance on the use of radiation test site

C.3.0 General

This clause specifies procedures, test equipment arrangements and verification that shall be carried out before any of the radiated tests are undertaken.

C.3.1 Site preparation

The cables to the measuring and substitution antenna shall be routed horizontally away from the testing area for a minimum of 2 m (unless a back wall is reached) and then allowed to drop vertically and out through either the ground plane or screen (as appropriate) to the test equipment. Precautions shall be taken to minimize pick up on these leads (e.g. dressing with ferrite beads, or other loading). The cables, their routing and dressing shall be identical to the verification set-up.

Calibration data for all items of test equipment shall be available and valid. For test, substitution and measuring antennas, the data shall include gain relative to an isotropic radiator (or antenna factor) for the frequency of test. Also, the VSWR of the substitution and measuring antennas shall be known.

The calibration data on all cables and attenuators shall include insertion loss and VSWR throughout the entire frequency range of the tests. All VSWR and insertion loss figures shall be recorded in the logbook results sheet for the specific test. Where correction factors/tables are required, these shall be immediately available.

For all items of test equipment, the maximum errors they exhibit shall be known along with the distribution of the error e.g.:

- cable loss: ±0,5 dB with a rectangular distribution;
- measuring receiver: 1,0 dB (standard deviation) signal level accuracy with a Gaussian error distribution.

At the start of measurements, system checks shall be made on the items of test equipment used on the test site.

C.4 Radiated measurement methods for receivers

Radiated measurements on receiving equipment are essentially the reverse of measurements on transmitters, with an output of signal generator being connected to the measurement antenna. Calculation of the power level at receiver input relies on the principle of replacing the EUT with a substitution antenna and suitable measuring equipment.

Clause C.2.2 Substitution antenna applies.

NOTE 1: This does not require an actual half wave dipole, only an antenna with known gain relative to a half wave dipole.

There are two methods:

a) Connect the substitution antenna to a calibrated measuring receiver and read the measurement result directly.

b) Measure the path loss from the measurement antenna to the substitution antenna and subtract this from the signal generator level to reach the measurement result.

NOTE 2: For method a) the level received in some measurements is likely to be too low, so it may be necessary to raise the signal generator by a suitable amount and apply an equivalent offset to the measurement result.

NOTE 3: Method b) means that one calibration measurement can be used for multiple tests.

Annex D (informative): Change history

Version	Information about changes
1.1.1	First version
1.2.1	Clause 4.2.1.2.2 - updated CCam TX emissions limit for 1 000 MHz to 3 000 MHz range; clause 4.2.2.1.2 - updated DR receiver spurious emissions limits.

History

Document history		
V1.1.1	July 2018	Publication
V1.1.2	February 2019	EN Approval Procedure AP 20190528: 2019-02-27 to 2019-05-28
V1.2.1	June 2019	Publication