República Argentina - Poder Ejecutivo Nacional
2017 - Year of Renewable Energy

Resolution

Number: RESOL-2017-4479-APN-ENACOM#MCO

City of Buenos Aires
Monday 5th, June 2017

Reference: EXPENACOM N° 2686/2017 - ACTA 20

THE PRESIDENT OF THE NATIONAL COMMUNICATIONS AUTHORITY (ENACOM) RESOLVES:

ARTICLE 1º – Leave without effect the attributions of the frequency bands from 401 MHz to 402, 405 MHz to 405 MHz and 405 MHz to 406 MHz with secondary category for the use of low power devices provided in Annex I of SC Resolution No. 67/2012 and its amendments.

ARTICLE 2º - Assign the frequency band from 401 to 406 MHz for the Radiocommunications System for Medical Use (SRMED), with secondary category, having to comply with the conditions set out in "DEFINITIONS AND TECHNICAL PARAMETERS OF THE RADIOCOMMUNICATIONS SYSTEM FOR MEDICAL USE (SRMED)" registered in the ELECTRONIC GENERATOR OF OFFICIAL DOCUMENTS as ANNEX IF-2017-05690100-APNDNPYC#ENACOM, which forms an integral part of this measure.

ARTICLE 3º - Approve the technical standard for the devices of the Radiocommunication System for Medical Use (SRMED) as an Annex of "Technical Standard ENACOM Q2-60.15 V17.1 MEDICAL DEVICES" registered in the ELECTRONIC GENERATOR OF OFFICIAL DOCUMENTS as ANNEX IF-2017-05689975-APN-DNPYC#ENACOM, which forms an integral part of this measure.

ARTICLE 4º - It is hereby established that the models of equipment achieved by the present, must be registered in the corresponding records of this NATIONAL COMMUNICATIONS AUTHORITY (ENACOM).

ARTICLE 5 º - It is hereby stipulated that the present resolution will come into force after NINETY (90) days of its publication in the Official Bulletin.

Resolution

ARTICLE 6° - It is established that during the validity of the term established in Article 5, the interested parties will be able to obtain the inscription or renewal in the Telecommunications Materials Register (RAMATEL) for medical devices operating in the frequency bands from 401 MHz to 406 MHz, in accordance with Resolution SC No. 67/12, its amendments, and ENACOM Resolution No. 6038/16.

ARTICLE 7° - It is hereby provided that the devices herein may be used without individual authorization for the use of the frequency bands mentioned.

ARTICLE 8° - Register, communicate, publish, give to the NATIONAL DIRECTION OF OFFICIAL REGISTRY and file.

Annex

Number: IF-2017-05690100-APN-DNPYC#ENACOM

City of Buenos Aires
Friday 7th, April 2017

Reference: EXPENACOM 2686/2017 - ANNEX 1 DEFINITIONS AND TECHNICAL PARAMETERS OF THE RADIOCOMMUNICATIONS SYSTEM FOR MEDICAL USE (SRMED)

DEFINITIONS AND TECHNICAL PARAMETERS OF THE RADIOCOMMUNICATIONS SYSTEM FOR MEDICAL USE (SRMED)

1. Definitions

Radiocommunication System for Medical Use (SRMED): Radiocommunication system consisting solely of electronic devices implanted or used in the human body and its respective "programmer", for medical purposes.

Programmer: Equipment intended to communicate with the implantable electronic device used in the human body for the purpose of data exchange to record medical parameters and configuration processes or adjustments according to the needs of the patient.

2. Technical Parameters

Band structure

- Bandwidth: 401 - 406 MHz
- Channeling: Not required.

Transmission Characteristics

- Maximum level of Electric Field Strength: 18,260 µV/m @ 3 m in OATS.

Emission Bandwidth for Frequency Range

- 401 – 402 MHz: 100 kHz.
- 402 – 405 MHz: 300 kHz.
- 405 – 406 MHz: 100 kHz.

Annex

Device types allowed

- 401 - 402 MHz: Implantable, programmers and used in the body.
- 402 - 405 MHz: Implantable, and programmers.
- 405 - 406 MHz: Implantable, programmers and used in the body.

Protection against interference

It must incorporate a control system for spectrum access in order to minimize the possibilities of interference, in accordance with the technical standard of homologation.

Usage environment

In order to minimize the risks of radio interference, it is recommended to limit the use of the programmer to hospital and / or medical environments, and should be used only by health professionals with sufficient responsibilities.

Annex

Number: IF-2017-05689975-APN-DNPYC#ENACOM

City of Buenos Aires
Friday 7th, April 2017

Reference: EXPENACOM 2686/2017 - Annex II Technical standard ENACOM-Q2-60.15 V17.1 Medical devices

Technical standard ENACOM-Q2-60.15 V17.1 Medical devices

Chapter I: Definitions and Requirements

1. Objective

Specify the minimum necessary conditions, in which Medical Devices must comply with, that favor the effective and efficient use of the radio electric spectrum.

Establish test methods to be used by laboratories for checking the specifications.

2. Scope

This standard will apply to *Medical Devices* to be used as part of a *Radiocommunication System for Medical Use (SRMED).*

This standard may apply to various types of *Medical Devices* that make use of the radioelectric spectrum, including:

- Implantable pacemakers.
- Implantable defibrillators.
- Nerve stimulators.
- Insulin Meters.
- Insulin pumps.

It should be noted that the above list is not exhaustive, so other applications could be reached by this regulation for consideration by ENACOM.

3. Definition of terms and abbreviations

The following definitions and abbreviations are adopted for the sole purpose of this document.

3.1 Definitions

Medical Device: Any instrument, apparatus, material or article, used in isolation or in combination with any other accessory or software that allows its operation, which has been designed and manufactured to be used in humans, under the indication and supervision of professional doctors for:

- Diagnosis, prevention, monitoring, treatment or alleviation of diseases or injuries;
- Research, replacement or modification of the anatomy or of a physiological process;
- Birth or conception control

and which does not achieve its main purpose by pharmacological, chemical, immunological or metabolic Method, but can be assisted in its function by such Method.

Implantable Medical Device (IMD): any *Medical Device* for the purpose of being introduced totally or partially into the human body, surgically or medically or through medical intervention through a natural orifice, and which is used to measure and / or transfer, through a radio frequency transmission, human physiological parameters or system programming information remaining within the body after the implantation procedure

***Medical Device Used in the Body (MDUB)*:** any *Medical Device* intended to be operated in proximity to the human body, and which is used to measure and / or transfer, through a radio frequency transmission, human physiological parameters or system programming information.

Programmer Medical Device (PMD): any *Medical* Device outside the human body that communicates, through a radiofrequency transmission, with an Implantable Medical Device or with a *Medical Device Used in the Body* to transfer patient-related information and / or information of system programming.

Module *(transmitter / transceiver)*: Device consisting of a radio frequency transmitter / transceiver, a radiating system and an electric power stabilization circuit, the operation of which can be evaluated in stand-alone mode under the conditions required by this standard, designed mainly to be incorporated inside another equipment.

3.2 Abbreviations

SE: Spectrum Analyzer
MD: Medical Device
IMD: Implantable Medical Device
PMD: Programmer Medical Device
MDUB: Medical Device Used in the Body
EUT: Equipment Under Test
OATS: Open Area Test Site
ENACOM: National Communications Authority (Ente Nacional de Comunicaciones)
EFCM: Electric Field Current Meter
RAMATEL: Registration of Telecommunication Activities and Materials
MS: Monitoring System
SRMED: Radiocommunication System for Medical Use
MT: Monitoring Threshold

4. Equipment Under Test Preparation (EUT)

4.1 The applicant shall provide the laboratory with at least one representative sample, in terms of its operation, of the production model. It will constitute, for the purposes of this document, the *Equipment Under Test (EUT).*

4.2 The *EUT* will be identified with its corresponding brand, model, country of origin and serial number. In case the representative sample does not have identification, either for a safety issue because it is an Implantable Medical Device or because it is a prototype, the applicant must add the identification on the EUT in a way that can be easily distinguished individually.

4.3 It shall be accompanied by the technical documentation necessary to enable the operation established in the test methods.

Annex

4.4 It should be possible to test at the maximum and minimum frequencies within the operating range provided for the model. In the case of equipment whose tuning cannot be adjusted during the measurements, two samples must be submitted, one tuned to the maximum frequency and another to the minimum.

Medical Devices designed to operate on a single frequency will only be tested at the corresponding frequency.

4.5 If the *Medical Device* is designed to operate with different powers, the EUT will be adjusted to the maximum level to perform the tests.

4.6 In view of the need to use special adapters, connectors, cables or measurement kits, these will be provided by the applicant.

4.7 If a particular test requires the use of other equipment, similar to the *EUT*, as a counterpart of the same, it must be facilitated by the applicant.

4.8 If the *Medical Device* has any automatism or other particular characteristic that prevents the normal recording by the instruments of the laboratory of the average values (for example: transmission in bursts, dynamic allocation of frequencies, etc.), EUT must be accompanied by Adequate test software to enable testing under the conditions set out in this standard.

4.9 During the measurements, you will not be able to modify the *EUT* hardware under any circumstances. For the preparation of the report, only the selected samples will be used, neither of which can be changed until the end of the verifications.

4.10 In the case of testing several samples, the respective results will be included in the report, indicating to which sample each belongs.

4.11 For the previous case, the test will be considered complete when each of the samples complies with the test requirements.

4.12 ENACOM reserves the right to request technical documentation, samples and / or new tests on the homologated product at any time during the validity of the registration in RAMATEL.

5 Technical requirements

5.1 General

The homologated equipment model must comply with the specifications of this regulation for all the operating conditions in which it is expected to be marketed, beyond the conditions under which it was tested.

In all cases, and especially in approved modules, it should be ensured that after their installation, the emitted emissions comply with the limits indicated in this standard.

5.1.1 *Operating Characteristics*

Programmers Medical Devices may transmit data only, excluding voice transmission, communicating with an *Implantable Medical Device* or with a *Medical Device Used in the Body*.

No *Implantable Medical Device* or *Medical Device Used in the Body* shall transmit unless it is:

- In response to a transmission initiated by a *Programmer Medical Device*
- In response to a transmission to an event that requires the immediate transmission of potentially important information to the patient by an *Implantable Medical Device*;
- In response to a transmission to a non-radioelectric external actuation signal, generated by a device with respect to which the *Medical Device* is used (button placed on a *Medical Device Used in the Body*, for example)

Programmers Medical Devices may not be used to transmit information in the 401 - 406 MHz band to a receiver that is not included in an *Implantable Medical Device* or in a *Medical Device Used in the Body*.

5.1.2 Antenna

Transmitters incorporated into Medical Devices shall be provided with an integrated antenna (permanently attached to the equipment), a specific external antenna, or both. In case of an external antenna connection, the manufacturer must take the necessary measures to prevent the use of an antenna other than that provided for the test of this standard.

Equipment whose transmitters are identical but uses different radio-frequency antennas shall be considered as separate materials and shall be tested independently.

The applicant must specify in the registration application in RAMATEL, the type of antenna, its characteristics and must incorporate photographs of the same.

5.1.3 Method of Access to the Spectrum

In order to minimize interference, it is mandatory that the *Medical Device* employs at least one *Method of Access to the Spectrum* before beginning transmission on a channel within said band. The authorized methods of access to the Spectrum under these regulations are:

- Listening Before Talk with Adaptive Frequency Agility
- Low Power Transmission and Reduced Duty Cycle

The manufacturer may implement one or both methods verifying that, in any case, the occupied bandwidth does not exceed the limits defined in point 5.4 of these regulations.

Only the transmissions initiated by an *Implantable Medical Device* in an event that requires the immediate communication of potentially important information to the patient are excluded from the need to use an Spectrum Access Method.

The duration of said transmissions shall be limited to 30 seconds per hour, and may be repeated until the *Implantable Medical Device* that generates it receives a recognition signal from the *Programmer Medical Device* to which the transmission was directed.

The applicant must add in the application for registration in the RAMATEL a detailed description of the method of access to the Spectrum

5.1.3.1 Access to the Spectrum through the method of Listen Before Talk with Adaptive Frequency Agility.

The medical devices that use the Method of Access to the Spectrum through Listen Before Talk with Adaptive Frequency Agility should incorporate a Monitoring System that allows them to verify the state of the transmission channel before starting the communication and thus to be able to select a channel with low Interference signal.

5.1.3.1.1 Characteristics of the Monitoring System

- The antenna used for the Monitoring System must be the same antenna that the Medical Devices use for transmission.

- The bandwidth of the Monitoring System measured at -20dB should be greater than or equal to the transmission bandwidth of the Medical Device transmitting it.

- Prior to the beginning of the communication, and using a time of up to 5 seconds, the circuit associated to the transmitter of the Medical Device must monitor the channel (s) that the system intends to occupy for a minimum period of 10 ms per channel.

- The Monitoring System will be able to select the transmission channel according to two criteria:

    I. After the monitoring of all possible channels, select the one that has the lowest Interfered Signal Level.

    II. Immediately use the first channel whose interfering signal level does not exceed the level of Maximum Monitoring Threshold, which is the maximum level of signal that a channel may possess to be considered suitable for transmission and is defined by the equation

$$10 * \text{LOG } B_{(Hz)} - 150 \text{ (dBm / Hz)} + G\text{(dBi)}$$

    Where B is the width of the transmission band of the Medical Device and G is the gain of the Monitoring System antenna relative to an isotropic antenna.
    If no channel meets this criterion:

- Medical Devices capable of operating on multiple channels may select the transmission channel according to the criterion of Lower Interfered Signal Level, indicated in I.;

- Medical Devices operating on only one channel may not initiate transmission while the interfering signal exceeds the detection threshold of the Monitoring System

- Once the transmission channel is chosen, the Programmer Medical Device may initiate the communication, involving transmissions to or from an Implantable Medical Device or a Medical Device Used in the Body in said channel. The communication can continue as long as any period of silence between continuous data transmissions does not exceed 5 seconds.

- During the process in which a channel is chosen for the transmission, according to the selection criteria mentioned above, the Monitoring System will be able to select an alternative channel to use in case the channel chosen in the first instance is no longer available in an abrupt form. The criteria for selecting a channel as an alternative is that, the channel must present the lowest level of signal interference between the rest of the available channels. In case the Medical Device should resort to using the alternative channel, it should be monitored for a period of 10ms during which the interfering signal level should not be greater than 6dB than the level detected when it was selected as channel alternative. If this requirement is not met, the Monitoring System should begin the channel selection process again.

5.1.3.2 Access to the Spectrum by the Method of Low Power Transmission and Reduced Duty Cycle:

Medical Devices employing the Access Method by Low Power Transmission and Reduced Duty Cycle may initiate transmissions on any channel, without the need for a Monitoring System, if the conditions detailed below are verified:

- Within the 401-402 MHz or 405-406 MHz bands, transmissions must have a bandwidth not exceeding 100 kHz, an electrical field strength level of up to 1,825 μV

/ m, measured at a distance of 3 Meters in an OATS, an activity cycle less than 0.1% and limit the number of consecutive repetitions to 100 in an interval of 1 hour;

- Within the 403.5-403.8 MHz band, transmissions must have a bandwidth not exceeding 300 kHz, an electrical field strength level of 1,154 μV / m, measured at a distance of 3 meters in an OATS, an activity cycle less than or equal to 0.01% and limit to 10 the number of consecutive repetitions in an interval of 1 hour. This type of transmissions can only be indicated by an Implantable Medical Device.

5.2 Frequency of operation.

Medical devices within the scope of this standard may operate in the 401 - 406 MHz band according to the following table.

Band (MHz)	Medical Device Type
401,000 - 402,000	MD Implantable with or without monitoring system MD Programmer with or without monitoring system MD Used in the Body with or without monitoring system
402,000 - 405,000	MD implantable with monitoring system. MD implantable without monitoring system only in the band of 403.5 to 403.8MHz. MD Programmer only with monitoring system
405,000- 406,000	MD Implantable with or without monitoring system MD Programmer with or without monitoring system MD Used in the Body with or without monitoring system

Table 1 - Frequency bands and types of devices.

5.3 Electrical Field Strength Level

The electrical field strength shall be limited in each band by the values specified in the following table according to the method of access to the Spectrum used, measured in an OATS at the indicated distance:

Band (MHz)	Method of Access to the Spectrum		Measurement Distance [m]
	Monitoring system	Low Power and Reduced Duty Cycle	
401,000 - 402,000	18.260 µV/m	1.825 µV/m	3
402,000 - 405,000	18.260 µV/m	1.154 µV/m	3
405,000- 406,000	18.260 µV/m	1.825 µV/m	3

Table 2 - Frequency bands and allowed emission levels.

The applicant shall inform the laboratory of the Method of Access to the Spectrum used by the Medical Device.

5.4 Occupied bandwidth

The occupied bandwidth, measured at -20 dB with respect to the highest transmission level, shall be limited in each band by the values specified in the following table:

Band (MHz)	Bandwidth [KHz]
401,000 - 402,000	100
402,000 - 405,000	300
405,000- 406,000	100

Table 3 - Frequency bands and allowed bandwidth.

5.5 Non-desired Emissions

Non-desired emissions are divided into "Out-of-Band Emissions" and "Spurious Emissions".

5.5.1 Out-of-Band Emissions

Out-of-band emissions are the immediate emissions outside the allocated channel bandwidth, and are the result of the modulation process and the non-linearity of the transmitter, but exclude spurious emissions.

- For Medical Devices operating in the 401-402 MHz and 405-406 MHz bands, in-band transmissions spaced more than 50 kHz from the central frequency of the transmission channel, and emissions apart 100 kHz or less below 401 MHz and above 406 MHz.

- For Medical Devices operating in the 402-405 MHz band, in-band emissions that are more than 150 kHz of the central frequency of the transmission channel and up to 250 kHz or below 402 MHz and above 405 MHz.

The limits that these emissions must comply are indicated in the next table:

Band	Frequency [MHz]	Emission Attenuation	Detector
401 - 402 MHz / 405 - 406 MHz	400,900 MHz ≤ f ≤ [Fc – 50kHz]	20 dBc	Peak
	[Fc + 50kHz] ≤ f ≤ 406,100 MHz	20 dBc	Peak
402 - 405 MHz	401,750 MHz ≤ f ≤ [Fc – 150kHz]	20 dBc	Peak
	[Fc + 150kHz] ≤ f ≤ 405,250 MHz	20 dBc	Peak

Table 4 – Out of band emissions

Where Fc is the transmission channel frequency

5.5.2 Spurious Emissions

Spurious emissions are emissions that are caused by Non-desired transmitter effects such as harmonics, parasites, intermodulation products and conversion products, but exclude out-of-band emissions; namely:

- For Medical Devices operating in the 401 – 402 MHz and 405-406 MHz, spurious emissions are considered emissions at frequencies beyond 100 kHz out of band.

- For Medical Devices operating in the 402-405 MHz band, spurious emissions are considered emissions in frequencies beyond 250 kHz out of band.

The limits that must comply with these emissions are indicated in the following table:

Frequency (MHz)	Electric Field Intensity [µV/M]	Measurement Distance [m]	Detector	Resolution bandwidth
38-88	<100	3	Near peak	100 to 120 kHZ
88-216	<150	3	Near peak	100 to 120 kHZ
216-960	<200	3	Near peak	100 to 120 kHZ
>960	<500	3	Average	1MHz

Table 5 - Spurious Emissions

5.6 Frequency stability.

The frequency stability shall not exceed +/- 100 ppm with respect to the operating frequency within the temperature ranges in the following table:

Medical Device Type	Temperature range
Implantable Medical Devices	25 ºC – 45 ºC
Programmer Medical Devices Medical Devices Used in the Body	0 ºC – 55 ºC

Table 6 – Extreme Temperatures.

Chapter II: Testing Methods

6. Test Conditions

6.1 Enviromental conditions

All measurements included in this standard shall be carried out, unless specify otherwise, under standard enviromental conditions.

Normal enviromental condition is considered to be any combination of temperature, relative humidity and atmospheric pressure within the following limits

Parameter	Min	MAX
Temperature	15 ° C	35 ° C
Relative Humidity	20%	75%
Atmospheric pressure	73.3 kPa (733 mbar)	106 kPa (1060 mbar)

Table 7 - Enviromental Conditions

6.2 Frequency selection

- For tunable equipment (cases in which the EUT operation frequency can be adjusted during the tests), the tests must be repeated for each following conditions:
    - EUT tuned to the equipment lowest frequency carrier of the operating band (lower channel).
    - EUT tuned to the equipment highest frequency carrier of the operating band (upper channel).

- For equipment that can operate on different frequencies but which are not tunable, two samples shall be tested at the frequencies defined below:
    - The first sample will be tuned to the equipment lowest frequency carrier of the operating band (lower channel).
    - The second sample will be tuned to the equipment highest frequency carrier of the operating band (upper channel).

- For equipment designed to operate on a single frequency, it will only be tested at the corresponding frequency.

In all cases, the value of the measured frequency will be indicated in the report.

6.3 Selecting RF transmit power

It must be noted that the Medical Device must comply with the specifications of this Standard throughout the power range declared by the manufacturer.

The tests will be performed with the EUT operating at the maximum transmission power defined by the manufacturer.

6.4 Normal power supply conditions

Normal power supply conditions are considered as follows:

6.4.1 Electric Network Supply

Voltage: 220 VCA
Frequency: 50 ± 1 Hz

6.4.2 Batteries used in vehicles

Voltage: 110% of the rated voltage of the battery (6 V, 12 V, etc.)

6.4.3 Other power sources

The normal conditions defined by the manufacturer must be generated.

6.5 Test power supply

The equipment should be tested with the appropriate power source. For equipment connected to an external power source, the requirements specified in 6.5.1 shall be noted. If the equipment is powered by internal batteries, the specifications in section 6.5.2 will be considered. When the EUT admits both, opt for the first option. In any case, the conditions corresponding to point 6.4 should be reproduced.

The type of power source used shall be recorded in the test report.

6.5.1 External power supply

During the tests the EUT will be powered by an external test source, capable to produce the required power values in each test.

The output voltage will be measured at the input terminals of the EUT. The cables Shall be arranged in such a way that they do not affect the results of the Measurements.

During the test, it shall be ensured that the variation of the supply voltage does not exceeds ± 1% of the measured value at the beginning of the same.

6.5.2 Internal power supply

The EUT will be powered by the battery (s) supplied or recommended by the supplier, fully charged.

During the test, make sure that the voltage variation, measured at the terminals of the battery (s), does not exceed ± 5% of the measured value at the start of the test. When this is not the case, the batteries should be replaced.

6.6 Test setup for radiated measurements

6.6.1 Measurement site

Some of the following test sites may be used to carry out the tests, which are described in the current ENACOM 02.60.14 standard:

- Anechoic chamber
- Anechoic chamber with ground plane
- Open Zone Testing Site (OATS)

Measurements can be made in both absolute and relative terms at these sites.

6.6.2 Torso Simulator.

Tests of radiated emissions on implantable Medical Devices and Medical Devices Used in the Body should be performed using a simulator of the human body, also known as Torso Simulator, which consists of a cylindrical container of Plexiglas, the dimensions of which can be seen in Figure 1, filled with a material of dielectric properties and conductivity coincident with the dielectric and conductivity properties of human muscle tissue at a frequency of 403.5 MHz (conductivity = 0.93 and relative permittivity = 57.2).

Within the container there must be a grid, composed of a material that presents low losses to the radiated emissions, that allows to fix the Medical Device Implantable in the vertical center of the container and to a distance no more than 60 mm of the walls of the same. For the tests of *Medical Devices Used in the Body*, the container must have a support that allows to fix on the periphery and in its vertical center said devices.

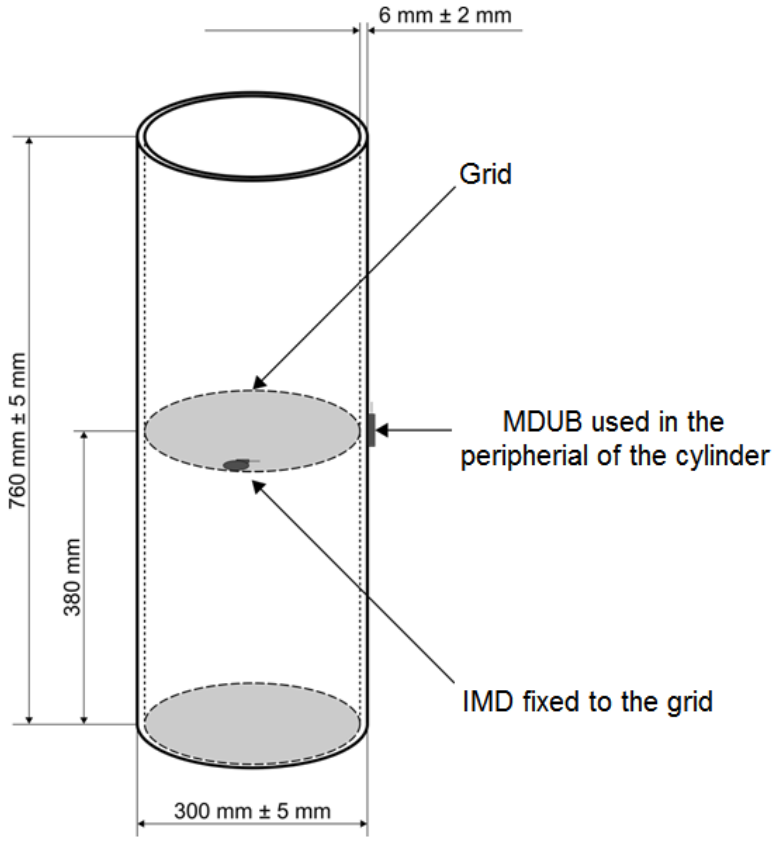

Figure 1 – Torso Simulator

6.6.3 Calibrated Receiver

In order to carry out the measurements required in this standard, the laboratory shall have a *calibrated receiver* composed by the following elements:

- Test antenna
- Mast support
- Measurement receiver

6.6.3.1 Test antenna

A calibrated test antenna shall be selected for the measurements in accordance with EUT transmission frequency.

For operating frequencies, equal to or greater than 30 MHz and up to 1000 MHz, it is recommended the use of dipole antennas, with adequate dimensions to ensure resonance

in the EUT test frequency.

For operating frequencies, equal to or greater than 1000 MHz, both waveguide-type antennas can be used as well as periodic logarithmic dipolar array antennas, known as periodic logarithmic antennas

6.6.3.2 Mast support

The test antenna shall be mounted on an adjustable height mast, constructed of non-metallic low reflection material.

6.6.3.3 Measurement Receiver

The measurement receiver, which will be connected to the test antenna, could be either an Electric Field Strength Meter (EFSM) or a suitable Spectrum Analyzer (AE).

The Detector type and Measurement Bandwidth are defined in each test.

7 Technical requirements test

7.1 Electric Field Strength Level

It will be verified that the level of electrical field strength radiated by the EUT complies as specified in 5.3.

Measurements should be made in accordance with the measurement distance specified in 5.3. Such distance may be modified when it can be demonstrated that the measurements under these conditions are appropriate for the performance characteristics of the device.

7.1.1 Verification Method

At the chosen measurement site (mentioned in 6.6.1) the EUT will be placed on the Turntable at a height of at least 0,80 m and in a Similar position of its normal use, as declared by the manufacturer.
Implantable Medical Devices and Medical Devices Used in Body should be mounted and located on a Torso Simulator as specified in 6.6.2.

An appropriate test antenna must be selected for the test frequencies, which will initially be positioned in vertical polarization.

The output of the Test Antenna will be connected to the input of the Measurement Receiver.

The EUT will be turned on and, if possible, set to transmit without modulation. If it operates with different power levels, it will be adjusted according to 6.3. In cases where it is not possible to configure the EUT to transmit without modulation, the test shall be performed using a peak detector and a resolution bandwidth greater than or equal to the emission bandwidth.

In all cases, it will be added to the test report the Modulation used by the EUT

The *Measurement Receiver* will be tuned to the transmission frequency of the EUT.

The height "h" of the test antenna will be varied till obtain the highest level of signal detected on the *Measurement Receiver*.

Rotate the turntable to the maximum field strength value. The azimuth search in which the highest value is detected must be continuous, for a 360º spin.

In case the continuous search for azimuth could not materialize, the reading must be taken on at least 16 radials, separated 22,5º.

The height “h” of the test antenna must be varied again in order to achieve the maximum level of field intensity received by the Spectrum Analyzer. The value obtained and the azimuth in which the EUT was positioned, will be recorded in the test report (Table 8).

The procedure described above must be repeated with the test antenna in horizontal polarization.

7.1.2 Report

The following table will be made with the results obtained:

	Frequency (MHz)	Vertical Polarization		Horizontal Polarization		Limit [µV/M]	Comply (Yes/No)
		Measured E (µV/m)	Azimuth EUT (º)	Measured E (µV/m)	Azimuth EUT (º)		
Channel 1							
Channel 2							

Table 8

Complementary graphs to the results shown will be included in the table.

7.1.3 Statement

If the electric field E measured is less than the limit defined in 5.3 then it complies, if not it does not comply.

7.2 Used bandwidth.

It will be verified that the EUT transmission bandwidth complies with the specified in 5.4.

7.2.1. Verification Method

If possible, the EUT can be directly connected to a spectrum Analyzer. In the opposite case, a test antenna must be selected according to the EUT transmission frequency which will be connected to the input of a Spectrum analyzer.

The EUT will be turned on and be configured to transmit with modulation. If it operates at different power levels, it will be adjusted as specified in 6.3.

The Spectrum Analyzer will be tuned to the transmission frequency of the EUT, and will be adjusted to display an appropriate frequency range for the test, with peak detector and a resolution bandwidth of approximately 1% of the EUT emission bandwidth.

The frequencies above and below the central frequency of transmission, whose emission

level are 20 dB below the maximum level of the modulated signal will be determined. The difference between the two frequencies will determine the bandwidth measure.

7.2.2 Report

The following table will be made with the results obtained:

	Frequency (MHz)	Measured Bandwidth (Khz)	Limit (KHz)	Comply (Yes/NO)
Channel 1				
Channel 2				

Table 9

Complementary graphs to the results shown will be included in the table.

7.2.3 Statement

If the bandwidth is less than the limit defined in 5.4 then it complies, if not, it does not comply.

7.3 Non-desired Emissions

7.3.1 Out of band emissions

It shall be verified that the detected level of out-of-band emissions radiated by the EUT complies with the limits specified in 5.5.1.

7.3.1.1 Verification Method

If possible, the EUT can be directly connected to a spectrum Analyzer. In the opposite case, a test antenna must be selected according to the EUT transmission frequency which will be connected to the input of a Spectrum analyzer.

The EUT will be turned on and be configured to transmit with modulation. If it operates at different power levels, it will be adjusted as specified in 6.3.
The Spectrum Analyzer will be tuned to the transmission frequency of the EUT, with peak detector and a resolution bandwidth of approximately 1% of the EUT emission bandwidth.

The maximum emission level within the transmission bandwidth shall be measured. Then a spectrum scan will be performed according to the frequency ranges indicated in Table 4 - Out-of-band emissions and the frequency and level of the highest out-band emission will be documented for each channel.

The worst value obtained will be recorded in the test report (Table 10).

7.3.1.2 Report

The following table will be made with the results obtained:

	Fundamental Emission		Out of band Emission		Measured attenuation (dB)	Limit [µV/M]	Comply (Yes/No)
	Frequency (MHz)	Measured E (MV/m)	Frequency (MHz)	Measured E (MV/m)			
Channel 1							
Channel 2							

Table 10

Complementary graphs to the results shown will be included in the table.

7.3.1.3 Statement

If out of band emissions attenuation detected is greater than established in 5.5.1 complies, if not, it does not comply.

7.3.2 Spurious Emissions

It will be verified that the detected level of spurious emissions radiated by the EUT does not exceed the limits specified in 5.5.2.

7.3.2. 1 Verification Method

At the chosen measurement site (mentioned in 6.6.1) the EUT will be placed on the turntable at a height of at least 0,80 m and in a similar position of its normal use, as declared by the manufacturer. Implantable Medical Devices and Medical Devices Used in Body should be mounted and located on a Torso Simulator as specified in 6.6.2.

An appropriate test antenna must be selected for the test frequencies, which will initially be positioned in vertical polarization.

The output of the Test Antenna will be connected to the input of the Spectrum Analyzer.

The EUT will be turned on and be configured to transmit with modulation. If it operates at different power levels, it will be adjusted as specified in 6.3.

The Spectrum Analyzer will be tuned to the transmission frequency of the EUT, and Adjusted as specified in Table 5 .

The height "h" of the test antenna will be varied to obtain the highest level Detected on the measurement receiver.

Rotate the turntable to the maximum field strength value. the azimuth search in which the highest value is detected must be continuous, for a 360 spin.

In case the continuous search for azimuth could not materialize, it should Take the reading on at least 16 radials, separated 22,52º.

The height “h” of the test antenna must be varied again in order to achieve the maximum level of field intensity received by the Spectrum Analyzer.

A spectrum scan will be carried out according to the frequency ranges Indicated in Table 5 and it will be recorded for each sample the frequency and level of Fundamental emission and the frequency and level of the highest spurious emission.

The procedure described above should be repeated with the test antenna in Horizontal polarization.

The worst value obtained will be recorded in the test report (Table 11).

7.3.2.2 Report

Annex

The following table will be made with the results obtained:

	Fundamental Emission		Spurious Emission		Limit [µV/M]	Comply (Yes/No)
	Frequency (MHz)	Measured E (MV/m)	Frequency (MHz)	Measured E (MV/m)		
Channel 1						
Channel 2						

Table 10

Complementary graphs to the results shown will be included in the table.

7.3.2.3 Statement

It will be verified that the level of spurious emissions is less than or equal to the absolute levels values defined in 5.5.2.

7.4 Frequency Stability

It will be verified that the frequency stability of the EUT complies with the specified in 5.6.

7.4.1 Testing method

If possible, the EUT can be directly connected to a spectrum Analyzer. In the opposite case, a test antenna must be selected according to the EUT transmission frequency which will be connected to the input of a Spectrum analyzer.

The EUT will be placed inside the thermal chamber and taken to one of the temperature extremes indicated in Table 6 - Extreme temperatures. The EUT must be turned off during the temperature stabilization process. Once this temperature is reached, the conditions must be maintained for at least 15 minutes before proceeding to the measurement.

The EUT will be turned on and, if possible, it will set to transmit without modulation. If operating at different power levels, it will be adjusted as specified in 6.3. In cases where it is not possible to configure the EUT for transmission without modulation, the test shall be performed using a peak detector and a resolution bandwidth that allows a frequency reference to be set in the emission.

In all cases, it will be added to the test report the modulation used by the EUT

The Spectrum Analyzer will be tuned to the EUT transmission frequency.

The transmission frequency will be determined after the EUT is on for 5 minutes, either continuously or intermittently. The result of the measurement will be compared with respect to the nominal transmission frequency.

Then the heat chamber will then be taken to the other temperature end to repeat the test. The sequence in which the measurements are made is chosen such that no large thermal stresses on the EUT or excessive condensation inside the thermal chamber occur.

7.4.2 Report

The following table will be made with the results obtained:

	Temperature [°C]	Nominal frequency (MHz)	Measured Frequency (MHz)	Error (ppm)	Limit (ppm)	Comply (Yes/No)
Channel 1						
Channel 2						

Table 12

7.4.3 Statement

It will be verified that the frequency stability is less than or equal to the value defined in 5.6.

7.5 EUT Photographs

The test report shall contain photographs of the sample (s) tested, in which the components of the equipment, radiating system, connections, and identification are clearly visible.