

EUROPEAN RADIOCOMMUNICATIONS COMMITTEE

ERC Decision
of 12 March 2001
on harmonised frequencies, technical characteristics
and exemption from individual licensing of
Short Range Devices used for
Ultra Low Power Active Medical Implants
operating in the frequency band 402 - 405 MHz

(ERC/DEC/(01)17)



EXPLANATORY MEMORANDUM

1 INTRODUCTION

The term "Short Range Device" (SRD) is intended to cover radio equipment providing uni-directional or bi-directional communication and which has low capability of causing interference to other radio equipment. SRDs use either integral, dedicated or external antennas and all modes of modulation are permitted subject to available standards or technical specifications. Medical implants are specific SRD's used for active implantable medical devices (See also the EC Directive 90/385/EEC). Usually, SRDs use frequency bands already allocated to other services. SRDs generally cannot interfere with nor claim protection from these services.

Licensing is an appropriate tool for Administrations to regulate the use of radio equipment, ensure the most effective use of the frequency spectrum and to avoid harmful interference. However intervention from the Administrations as far as the installation and use of equipment is concerned needs to be proportionate. Administrations and especially users, retailers and manufacturers will benefit from a more deregulated system of authorising the use of radio equipment.

2 BACKGROUND

In 1997, the ERC adopted Recommendation the 70-03 to deal with SRDs covering many categories of different applications, among which are telecommand and telecontrol, telemetry, alarms, speech and video transmission. For its part, ETSI has developed standards for the majority of these devices.

The ERC Recommendation 70-03, together with these standards, has given a favourable legal framework to accompany the recent development of the use of SRDs.

To achieve the aim of taking a new step towards harmonised use of SRDs, it has been decided to transpose into ERC Decisions the frequency bands (together with the relevant technical characteristics) identified in the Recommendation 70-03. The harmonisation on a European basis would support the Directive 1999/5/EC (the R&TTE Directive).

It is generally agreed that installation and use of radio equipment may be exempted from individual licensing when the efficient use of the frequency spectrum is not at risk and as long as harmful interference is unlikely and usage is on a non-protected/non-interference basis. The Directive 1999/5/EC introduces the principle that individual licensing is only justified for reasons related to the effective/efficient use of the spectrum and the avoidance of harmful interference or matters relating to public health.

When radio equipment is subject to an exemption from individual licensing, anyone can install and use the equipment without requiring individual permission from the Administration. Furthermore, the Administration will not register the individual equipment. The use of the equipment can be subject to general provisions or general licence.

Within countries which have implemented the R&TTE Directive the conformity assessment, placing on the market and putting into service of Short Range Devices is governed by Directive 1999/5/EC (R&TTE). Thus this ERC Decision can not impede EEA countries and countries which have implemented the R&TTE Directive from fulfilling their obligations according to Community law.

This Decision describes the spectrum management requirements for and intends to provide for individual licence exemption for Short Range Devices used for Medical Implants.

3 REQUIREMENTS FOR AN ERC DECISION

The allocation or designation of frequencies for use by a service or system under specified conditions in CEPT member countries is laid down by law, regulation or administrative action. The ERC recognises that for SRDs in general and Medical Implants in particular to pursue their successful development throughout Europe, manufacturers must be encouraged to make the necessary investments in these radiocommunication systems. It is therefore considered necessary to designate frequency bands within which Medical Implants can be operated under specified conditions.

ERC/REC 01-07, adopted in 1995, listed harmonised criteria for the Administrations to decide whether an exemption from individual licence should be applied. The aim of this Decision is also to exempt Medical Implants from individual licensing as they fulfil the criteria for exemption listed in ERC/REC 01-07.

Commitment by CEPT member countries to implement an ERC Decision will provide a clear indication that the required frequency bands will be made available on time and on a European-wide basis.

**ERC Decision
of 12 March 2001**

**on harmonised frequencies, technical characteristics and exemption from individual licensing of
Short Range Devices used for Medical Implants operating in
the frequency band 402 - 405 MHz**

(ERC/DEC/(01)17)

"The European Conference of Postal and Telecommunications Administrations,

considering

- a) that due to the increasing interest in the use of SRDs for a growing number of applications it is necessary to harmonise frequencies and regulations for these devices;
- b) that SRDs in general operate in shared bands and are not permitted to cause harmful interference to other radio services;
- c) that in general SRDs cannot claim protection from other radio services;
- d) that the CEPT Recommendation ERC/REC 70-03 on Short Range Devices identifies frequency bands for Medical Implants;
- e) that European-wide harmonised use of frequencies would support the Directive 1999/5/EC (the R&TTE Directive);
- f) that the technical characteristics shown in Annex 1 have been chosen to ensure the best use of the band identified in *Decide 1* by Medical Implants, minimising interference between SRD equipment and sharing with other radio services operating in this band;
- g) that the equipment referred to in this ERC Decision should comply with the relevant European Telecommunication Standards (EN 300 220) or equivalent technical specifications;
- h) that for frequency planning, frequency co-ordination and in handling interference complaints the national frequency management and enforcement authorities assume Short Range Devices used for Medical Implants comply with receiver performance characteristics given in the informative Annex (Annex 2);
- i) that the CEPT Recommendation ERC/REC 74-01 defines spurious emission limits for radiocommunication equipment;
- j) that when selecting parameters for new SRDs, which may have inherent safety of human life implications, manufacturers and users should pay particular attention to the potential for interference from other systems operating in the same or adjacent bands;
- k) that within the CEPT Administrations there is growing awareness of the need for harmonisation of licensing regimes;
- l) that national licensing regimes should be as simple as possible in order to minimise the burden on Administrations and users of equipment;
- m) that Administrations should work towards the exemption of relevant radio equipment from individual licensing based on harmonised criteria detailed in ERC/REC 01-07;
- n) that Administrations have the right to exercise spectrum/frequency management which may affect the number of service suppliers, in conformity with their international trade obligations and to European Community legislation as far as EU Member States are concerned;

- o) that allocation, assignment and technical co-ordination of frequencies must be done in an objective, timely, impartial, transparent and non-discriminatory manner, and should not be more burdensome than necessary under international rules, in particular, to ensure the efficient use of the frequency spectrum;
- p) that Recommendation ITU-R SA.1346, specifies the feasibility of sharing in the band 401-406 MHz between the Meteorological Aids Service and Medical Implant Communication Systems (MICS) that are in compliance with the technical and operational characteristics described in the Recommendation;
- q) that interference mitigation techniques used by MICS equipment, as described in Annex 1 to Recommendation ITU-R SA.1346 provide a high level of protection to their operation from possible interference by the Meteorological Aids systems;
- r) that the ITU-R, in adopting ITU-R SA 1346, considered Medical Implant Communication Systems to require a single band available worldwide, and may operate in the mobile service currently allocated on a secondary basis in the band 401-406 MHz;

DECIDES

1. to designate the frequency band 402 - 405 MHz for the use of equipment for Medical Implants which comply with the technical characteristics shown in Annex 1;
2. to exempt Short Range Devices for Medical Implants covered by this Decision from individual licensing;
3. that this Decision will enter into force on 12 March 2001;
4. that the CEPT Member Administrations shall communicate the national measures implementing this Decision to the ERC Chairman and the ERO when the Decision is nationally implemented.”

Note:

Please check the ERO web site (www.ero.dk) for the up to date position on the implementation of this and other ERC Decisions.

ANNEX 1

Regulatory Annex: Technical characteristics of Medical Implants using
the frequencies identified in *Decides 1*

Frequency Band	Power/Field strength	Antenna	Channel Spacing	Duty Cycle (%)
402-405 MHz	25 μ W e.r.p.	Integral (no external antenna socket) or dedicated	25 kHz ¹ Individual transmitters may combine adjacent channels for increased bandwidth up to 300 kHz	No duty cycle restriction

¹ The center frequency of the first channel is at a distance of channes spacing/2 from the lower frequency band edge

ANNEX 2

Informative Annex: Additional technical characteristics with which Short Range Devices for medical implants using the frequencies identified in Decides 1 are recommended to comply to ensure efficient use of the spectrum

Note: In this ERC Decision this annex is for information only; however, in cases where the relevant harmonised standard applicable to Short Range Devices for medical implants contains essential requirements for transmitter or receiver parameters, this harmonised standard prevails upon the following information. For the conditions and methods of measurement refer to the relevant ETSI standard (EN 300 220-1).

Transmitters:

Spurious emissions should comply with those specified in ERC Recommendation 74-01.

Receivers:

1. Adjacent channel selectivity - in band

The adjacent channel selectivity of the equipment should not exceed the levels of unwanted signal as stated in the table below.

Channel spacing \leq 25 kHz	Channel spacing $>$ 25 kHz
60.0 dB	70.0 dB

2. Adjacent band selectivity

The band edge selectivity of the equipment should be equal to or greater than the unwanted signal as stated in the table below.

At band edge
60.0 dB

3. Blocking or desensitisation

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

Frequency offset (MHz)	Limit
All	84 dB

4. Spurious radiation

The power of any spurious emission, radiated or conducted, should not exceed the values given below.

- 2 nW below 1 000 MHz;
- 20 nW above 1 000 MHz.