



# ERC Decision (01)17

Harmonised frequencies, technical characteristics and exemption from individual licensing of Ultra Low Power Active Medical Implant (ULP-AMI) communication systems operating in the frequency band 401 - 406 MHz on a secondary basis<sup>1</sup>

**Approved 12 March 2001**

Amended 9 December 2011

Updated 17 November 2017

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<sup>1</sup> Comparable technical specifications to those given in this ECC Decision are given in the amended EC Decision 2006/771/EC for SRD. EU Member States and, if so approved by the EEA Joint Committee, Iceland, Liechtenstein and Norway are obliged to implement the EC Decision.

## EXPLANATORY MEMORANDUM

### 1. INTRODUCTION

**Ultra Low Power Active Medical Implants (ULP-AMI)** communication systems are specific low power devices to provide non-voice digital communications capability between implanted and external devices (See also the EC Directive 90/385/EEC). ULP-AMI communication systems use frequency bands shared with other services.

The frequency band 401-406 MHz is allocated to the mobile service on a secondary basis. This Decision addresses frequency designation within the band 401-406 MHz for the harmonised implementation of ULP-AMI communication systems under this allocation for the mobile service. The frequency band 401-406 is also allocated to the Meteorological Aids Service whereas the band 401-403 MHz is allocated to Space operation, the Earth Exploration Satellite Service and the Meteorological Satellite Service on a primary basis in the three regions of ITU, and in accordance with the European Common Allocation Table (ECA).

### 2. BACKGROUND

Based on the sharing studies given in ITU-R Recommendation RS.1346 and internally conducted WGSE sharing analysis (incl. ECC Report 92), CEPT designated the band 401-406 MHz for use by ULP-AMI communication systems. It should be noted that the ITU-R Recommendation RS 1346 considers ULP-AMI communication systems as operating under the secondary mobile service. Harmonised European standards have been developed by ETSI and approved by the national administrations and show presumption of conformity with the regulations for spectrum usage. These standards include advanced interference mitigation techniques as called for by ITU-R Recommendation RS.1346 to prevent interference to the primary users (mainly meteorological radiosondes) as well as interference between ULP-AMI communication systems.

It is agreed that 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 to and from primary radio services. The harmonisation on a European basis supports the Radio Equipment Directive 2014/53/EU.

When radio equipment is subject to an exemption from individual licensing, anyone can 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 Radio Equipment Directive the conformity assessment, placing on the market, and putting into service of equipment is governed by the Directive. Thus this ERC Decision can not impede EEA countries and countries which have implemented the 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 ULP-AMI communication systems.

### 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 ECC recognises that for ULP-AMI communication systems to pursue their successful development throughout Europe, manufacturers must be encouraged to make the necessary investments in these systems. It is therefore considered necessary to designate frequency bands within which ULP-AMI communication systems can be operated under specified conditions. Consistently with recommendation ITU-R RS.1346, this ERC Decision hence proposes to authorise ULP-AMI in the 401-406 MHz under the secondary mobile service. Such an allocation presents both advantages to, on the one hand, maintaining the non-protected/non-interference status of ULP-AMI to and from primary radio services in this band and, on the other hand, grant a status which confers to ULP-AMI a protection from SRD equipments.

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 ULP-AMI communication systems from individual licensing as they fulfil all the criteria for exemption listed in ERC/REC 01-07.

**ERC DECISION OF 12 MARCH 2001 ON HARMONISED FREQUENCIES, TECHNICAL CHARACTERISTICS AND EXEMPTION FROM INDIVIDUAL LICENSING OF ULP-AMI COMMUNICATION SYSTEMS OPERATING IN THE FREQUENCY BAND 401-406 MHz ON A SECONDARY BASIS (ERC/DEC/(01)17) AMENDED ON 9 DECEMBER 2011 AND UPDATED ON 17 NOVEMBER 2017**

"The European Conference of Postal and Telecommunications Administrations,

*considering*

- a) that ULP-AMI communication systems represent the radio part of Active Implantable Medical Devices (AIMDs), one or more of which is implanted into the human body, used for transferring individual patient-related physiological information;
- b) that the ITU-R, in adopting ITU-R Recommendation RS.1346, considered Medical Implant Communication Systems to require a band that is available worldwide, and may operate in the mobile service currently allocated on a secondary basis in the band 401-406 MHz;
- c) that there is an industry requirement for designation of frequency spectrum within the band 401-406 MHz for harmonised implementation and deployment of Ultra Low Power Active Medical Implant (ULP-AMI) communication systems;
- d) that the frequency band 401-406 MHz is allocated to the Meteorological Aids Service on a primary basis and the band 401-403 to Earth-to-space operation in the Earth Exploration and Meteorological Satellite Services on a primary basis in all regions of ITU and in the European Common Allocation table;
- e) that consistent with Recommendation ITU-R RS.1346, ULP-AMI communication systems operate in the mobile service in the band 401-406 MHz;
- f) that, pursuant to considerings d) and e), ULP-AMI communication systems cannot claim protection from nor cause harmful interference to primary services in the frequency band 401-406 MHz;
- g) that the technical characteristics shown in Annex 1 have been chosen to ensure the best use of the band identified in Decide 1 by ULP-AMI communication systems, minimising interference between ULP-AMI communication systems and sharing with other radio services operating in this band;
- h) that equipment must fulfil the essential requirements listed in the Radio Equipment Directive 2014/53/EU for those countries which are legally bound by it;
- i) that ETSI has developed the product specific harmonised European standards listed in the informative Annex 2;
- j) that for frequency planning, frequency co-ordination and in handling interference complaints the national frequency management and enforcement authorities assume ULP-AMI communication systems comply with receiver performance characteristics given in the ETSI product specific standards shown in Annex 2;
- k) that when selecting parameters for new ULP-AMI communication systems, which may have inherent safety of human life implications, manufacturers and suppliers should pay particular attention to the potential for interference from other systems operating in the same or adjacent bands;
- l) 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;

- m) that Recommendation ITU-R RS.1346, specifies the feasibility of sharing in the band 401-406 MHz between the Meteorological Aids Service and Medical Implant Communication Systems (MICS) operating in the mobile service that are in compliance with the technical and operational characteristics described in the Recommendation;
- n) that interference mitigation techniques used by ULP-AMI communication systems, as described in Annex 1 provide a high level of protection to their operation from possible interference to or from the Meteorological Aids systems.

### *DECIDES*

1. to harmonise the use of the frequency band 401 - 406 MHz for ULP-AMI communication systems on a secondary basis to meteorological radio services;
2. that CEPT administrations shall designate the frequency band 401-406 MHz for ULP-AMI communication systems operating in accordance with technical characteristics given in Annex 1;
3. that protection of existing services from ULP-AMI communication systems shall be ensured in the 401-406 MHz band and in adjacent bands;
4. that protection of ULP-AMI communication systems from short range device applications shall be ensured in the 401-406 MHz frequency band;
5. to exempt ULP-AMI communication systems covered by this Decision from individual licensing;
6. that this Decision enters into force on 9 December 2011;
7. that the CEPT administrations shall communicate the national measures implementing this Decision to the ECC Chairman and the ECO when the Decision is nationally implemented."

### *Note:*

*Please check the Office documentation database <http://www.ecodocdb.dk> for the up to date position on the implementation of this and other ECC Decisions.*

**ANNEX 1: REGULATORY ANNEX: TECHNICAL CHARACTERISTICS OF ULP-AMI COMMUNICATION SYSTEMS USING THE FREQUENCIES IDENTIFIED IN DECIDES 1**

**1. ULP-AMI COMMUNICATION SYSTEMS OPERATING IN THE 402-405 MHz**

This category covers systems specifically designed for the purpose of providing non-voice digital communications between active implantable medical devices and associated peripherals, as defined in Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ L 189, 20.7.1990, p. 17).

Frequency Band	Power	Channel Spacing	Spectrum access and mitigation requirement
402-405 MHz	25 µW e.r.p.	25 kHz Individual transmitters may combine adjacent channels for increased bandwidth up to 300 kHz	As specified in the product specific harmonised European standard (see Annex 2) or equivalent spectrum access and mitigation techniques.

**2. ULP-AMI COMMUNICATION SYSTEMS OPERATING IN THE 401-402 MHz AND 405-406 MHz BANDS:**

This category covers systems specifically designed for the purpose of providing non-voice digital communications between active medical implants and/or body-worn devices and other associated peripherals used for transferring non-time critical individual patient-related physiological information.

Frequency Band	Power	Channel Spacing	Spectrum access and mitigation requirement
401-402 MHz and 405-406 MHz	25 µW e.r.p.	25 kHz Individual transmitters may combine adjacent channels for increased bandwidth up to 100 kHz	As specified in The product specific harmonised European standard (see Annex 2) or equivalent spectrum access and mitigation techniques.

**ANNEX 2: INFORMATIVE ANNEX: ADDITIONAL TECHNICAL CHARACTERISTICS WITH WHICH ULP-AMI COMMUNICATION SYSTEMS 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 European standard applicable to ULP-AMI communication systems contains essential requirements for transmitter or receiver parameters, this harmonised European standard prevails upon the following information. For the conditions and methods of measurement refer to the relevant ETSI standard:

- EN 301 839 for the frequency band 402-405 MHz and
- EN 302 537 for the frequency bands 401-402 MHz and 405-406 MHz