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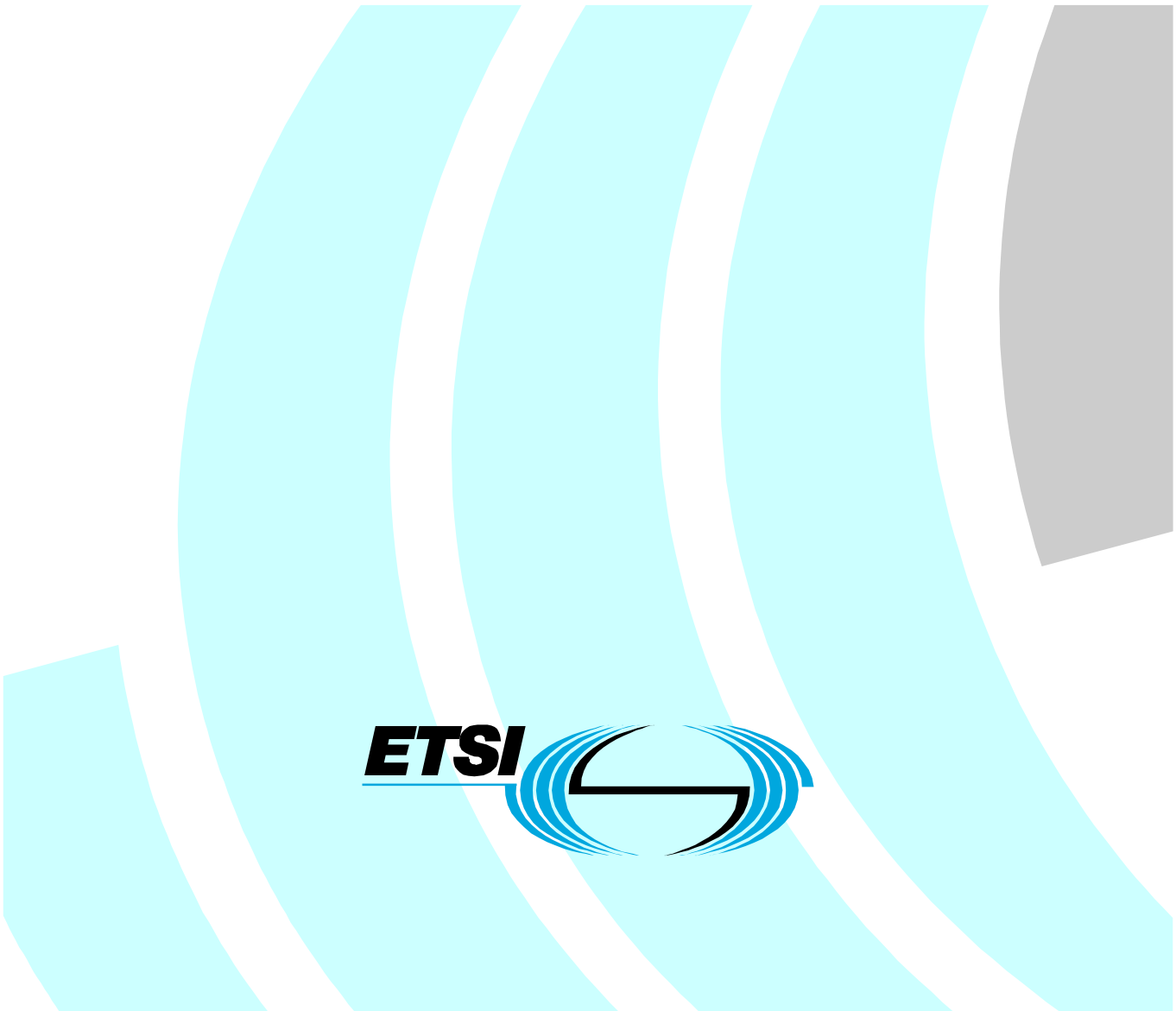
Technical Report

Electromagnetic compatibility and Radio spectrum Matters (ERM); Ultra Low Power Animal Implantable Devices (ULP-AID) operating in the frequency band 315 kHz to 600 kHz; System Reference Document



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ETSI

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

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

Siret N° 348 623 562 00017 - NAF 742 C
Association à but non lucratif enregistrée à la
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Contents

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Foreword

This Technical Report (TR) has been produced by ETSI Technical Committee Electromagnetic compatibility and Radio spectrum Matters (ERM).

1 Scope

The present document defines the requirements for radio frequency usage for inductive loop Ultra Low Power-Animal Implantable Devices (ULP-AID) to be used by the medical and pharmaceutical industries in medically related studies using animals for determining the efficacy and safety of drug and surgical procedures. These devices are typically simplex short range transmitters and receiver systems operating on various frequencies within the range of 315 kHz to 600 kHz.

The present document includes necessary information to support the co-operation between ETSI and the Electronic Communications Committee (ECC) of the European Conference of Post and Telecommunications Administrations (CEPT), including:

- detailed market information (see annex A);
- technical information (see annex B);
- expected compatibility issues (see annex C).

2 References

For the purposes of this Technical Report (TR) the following references apply:

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

[2] ETSI EN 302 195-2 (V1.1.1): "Electromagnetic compatibility and Radio spectrum Matters (ERM); Radio equipment in the frequency range 9 kHz to 315 kHz for Ultra Low Power Active Medical Implants (ULP-AMI) and accessories; Part 2: Harmonized EN covering essential requirements of article 3.2 of the R&TTE Directive".

[3] Directive 1999/5/EC of the European Parliament and of the Council of 9 March 1999 on radio equipment and telecommunications terminal equipment and the mutual recognition of their conformity.

[4] CEPT/SE24 meeting M16, June 2002: "Documents M16-57R1- SE24-30M-ANNEX -2.doc and M16-57R1- SE24-LS to SRDMG on 30 MHz for SRD inductive systems".

[5] CEPT/ERC Report 44: "Sharing between inductive systems and radiocommunications systems in the band 9 - 135 kHz".

[6] ECC/SE(04)015 (2004): "Protection distances for radiocommunication services from inductive SRD applications in the frequency range 135 kHz - 30 MHz".

[7] ITU Radio Regulations - Edition 2001.

3 Definitions, symbols and abbreviations

3.1 Definitions

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

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

radiated measurements: measurements that involve the absolute measurement of a radiated field

ULP-AID: system composed of an ultra low power animal implant transmitter/sensor used in medically related scientific studies that transmits physiological parameter data from an animal to an external receiver

ULP-AMI: transceiver part of an active implantable medical device

3.2 Symbols

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

f	Frequency
H	Magnetic field strength
P	Power
R	Distance
t	Time

3.3 Abbreviations

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

CEPT	European Conference of Post and Telecommunications Administrations
ECC	Electronic Communications Committee
ERM	Electromagnetic compatibility and Radio spectrum Matters
e.r.p	effective radiated power
ISM	Industrial, Scientific and Medical
LF	Low Frequency
PC	Personal Computer
RM	Radio Matters
SRDoc	System Reference Document
ULP-AID	Ultra Low Power-Animal Implantable Device
ULP-AMI	Ultra Low Power-Active Medical Implant

4 Executive summary

4.1 Status of the System Reference Document (SRDoc)

The ERM-RM working group, in its 26th meeting in Helsinki, has reviewed the content of the present document and has since approved it by correspondence.

4.2 Technical Issues

4.2.1 System description

Ultra Low Power-Animal Implantable Devices (ULP-AID) using inductive loop techniques in the Low Frequency (LF) range have found acceptance and application in the medical and pharmaceutical industries for many medically related scientific applications. LF magnetic field technology allows lossless penetration of most materials encountered in medical environments including animal tissue, which is very desirable for implant applications.

Today's inductive loop animal implantable communication system is a biomedical telemetry system that provides communication capability between an implant inside the animals body to a separate receiver located in very close proximity to the animal. Typically, these devices use inductive coupling between the transmitter and receiver antenna coils operating at single fixed frequencies within the frequency range from 315 kHz to 600 kHz. Data rates vary according to manufacturer, number of sensors and application with typical rates of 2 kilobits/s to 15 kilobits/s using pulse position modulation. Alignment requirements between the implant and its associated receiver typically require placement of the receiver coil under the cage holding the animal. Real time data transfer using pulse position modulation results in typical calculated duty cycles of less than 10 % averaged over one hour according to ERC Recommendation 70-03 [1]. Field strength levels for operation in the band from 315 kHz to 600 kHz are extremely low (typically less than -5 dBµA/m at 10 m) with an animal implant device lifetime of the order of 30 to 60 days. Smaller units with lower radiated power tend to have longer lifetimes while larger units used in large animals have a somewhat shorter lifetime.

4.2.2 Short market information

The market for ULP-AID used by hospitals, laboratories and the pharmaceutical industry involved in medically related scientific studies is very small. Currently there are approximately 5 200 of the devices in Europe with expected sales increases of less than 10 % per year with a customer base of approximately 250 institutions. Thus proliferation of these devices is essentially non-existent.

4.2.3 Spectrum requirement and justifications

Frequencies currently used by ULP-AID systems are within the range of 315 kHz to 600 kHz. Typical operating distances are less than 1 m.

Magnetic field strength levels from the implants are so low that measurements must be made at distances of 1 m or less. At a distance of 10 m, the field strength levels of the implants are well below the existing ambient levels for commercial environments at these frequencies. The numbers of these units in relative terms are low, yet, the value to society is immense by insuring that the medical industry can develop safe and effective drugs to prescribe to afflicted patients. Providing a common frequency band or bands for this technology to operate in permits this technology to be made available for research and development and quality control of products and apparatus for human and veterinary medicine and dentistry.

4.2.4 Current regulations

For spectrum conformity testing, the radio will comply with revised harmonized standard EN 302 195-2 [2]. The revision to include this band will be undertaken by ERM-TG30 which has the responsibility for wireless medical systems including ULP-AID devices.

4.2.5 Proposed regulation

It is proposed that CEPT adopt provisions in annex 12 of ERC Recommendation 70-03 [1] for ULP-AID systems to permit operation of animal implantable devices in the frequency band listed in the table below. Incorporation of the additional frequencies in annex 12, band c, specifically for ULP-AID equipment, will provide that other SRDs will not proliferate in this frequency band.

	Frequency Band	Power	Duty cycle	Channel spacing	ERC Decision	Notes
a	402 MHz to 405 MHz	25 uW e.r.p.	No Restriction	25 kHz	ERC DEC (01)17	Individual transmitters may combine adjacent channels for increased bandwidth up to 300 kHz
b	9 kHz to 315 kHz	30 dBµA/m at 10 m	<10 %	No spacing		
c	315 KHz to 600 kHz	-5 dBµA/m at 10 m	<10 %	No spacing		

4.2.6 Compatibility issues

Generally, inductive applications are permitted in the CEPT countries for general usage or specific usage applications. In the band 315 kHz to 600 kHz the ITU allocations are given in clause C.2.

5 Main conclusions

Business, social, humanitarian, international manufacturing, trade and use considerations, dependency of the public on having available safe and effective drugs, reduction in patient related medical cost, and benefit for society in general, justifies the request to permit ULP-AID devices to use the LF spectrum in the range of 315 kHz to 600 kHz:

- Inductive LF ULP-AID systems have been deployed by research institutions worldwide for many years in applications related to testing of drugs and other medical techniques.
- Because of the extremely low magnetic fields from these ULP-AID systems (-9 dBµA/m@10 m) and the extremely small numbers of devices, it is expected that there is little probability of any potential for interference to existing services.
- ULP-AID devices only radiate electromagnetic energy when activated by a laboratory technician and have a very limited lifetime. Further, even during activation, the duty cycle of these devices is typically less than 10 %. Field strength levels for operation in the band 315 kHz to 600 kHz are so low they are below the noise floor at distances of approximately 10 m.

5.1 Expected timing for products to market

Products for use for medically related research are now available worldwide from highly specialized manufacturers.

5.2 Requested ETSI and ECC actions

ETSI requests the ECC to consider the following actions:

- if relevant, verification by ECC/SE24 [4] of the compatibility with, in particular, aeronautical radionavigation, maritime radionavigation (radiobeacons), radionavigation, maritime mobile, mobile (distress and calling), and broadcasting services as needed. (Field test, absolute measurements, modelling analysis);
- incorporation of the band c with the requested parameters in annex 12 of ERC Recommendation 70-03 [1] by the ECC;
- adoption of an ECC DECISION for this application by the ECC.

ETSI actions:

- The spectrum parameters for inductive loop ULP-AID systems that are the subject of the present document are intended to be included as a normative annex to EN 302 195-2 [2] as a revision to include the 315 kHz to 600 kHz frequency band.

Annex A:
Detailed market information

A.1 Range of applications

ULP-AID systems find applications in small (mice), medium (rat), large (dogs) and primate animals. Small size devices are typically single channel using blood pressure, temperature, and/or biopotential sensors. Medium size devices use the same types of sensors as the small animal series, however, they can accommodate multiple sensors in 3 to 4 channel versions. Large devices can use the above sensor devices with the ability to couple multiple sensors in 2 and 3 channel versions.

The market for these devices includes hospitals, laboratories involved in medical research and pharmaceutical manufacturing facilities. As such, they are all within industrialized areas with high levels of existing ambients in the band.

ULP-AID systems covered by the present document use transmitters designed to transmit digital information for the purpose of providing a radio link between an active animal implant and an external receiver. These implants find wide acceptance for applications such as measuring animal physiological parameters such as body temperature, blood pressure, heart rate, biopotential, etc., either as a single physiologic parameter measurement or in multiple configurations.

A.2 Market size and value

Animal implants used world-wide in medically related studies total approximately 15 000 units yearly. Of the 15 000 units, there are about 5 200 units in Europe.

ULP-AID for use in these animal studies are the only technology capable of providing continuous pulse coded data which is required due to the need for constant monitoring of the study subject. These studies ultimately serve to preserve and enhance the quality of life for millions of patients worldwide as physicians prescribe the various medications developed using this technology.

A.3 Traffic evaluation

Spectrum use and efficiency:

- The emission of magnetic fields and the actual frequency usage is extremely low.

The reasons are that:

a) There are relatively very few animal implant transmitters in use at one time. With a total population of 5 200 units in Europe, only about 500 or less are actually in use at a given time and these would be deployed at numerous locations. It is expected that no more than 20 to 30 units would ever be active at a specific location at one time and even this would be rare. The duty cycle for these devices is less than 10 %.

b) Transmitters are only activated on demand and have a limited battery life on average of one month before implant replacement is required. Further, there are only approximately 250 locations within Europe where these medical studies are performed.

Annex B:
Technical information

B.1 Detailed technical description

These devices are very low power animal implant transmitters providing a simplex communications link to an associated nearby receiver. The implant and one or more of a series of different sensors is implanted in an animal being used in a laboratory to determine the efficacy of a drug product or medical technique. The data is transmitted using a pulse position coding providing minimal battery drain to maximize the life of the implant. The associated receiver is located very near the cage containing the implanted animal (typically directly under the cage) to maximize coupling between the implant and receiver.

Animal implants consist of two sections, the physiologic parameter sensor or sensors and the transmitter to enable the telemetry function. The RF pulse drive circuit is typically integrated into a hybrid chip that drives an external coil capacitor circuit. This coil is the radiating antenna for the implant. Generally, the package is sealed in a suitable polymer case with sensor leads extending through the case.

B.1.1 Magnetic field requirements for inductive systems

Implant transmitter field

These systems use a variety of coil configurations using various core sizes. Maximum antenna size is approximately 10 cm diameter with a 20 turn coil. Due to the varied construction used to accommodate different types of animals, a number of units were tested. **For the implanted devices the maximum H field measured was -9 dBµA/m** and minimum H field was -60 dBµA/m. **The requested level of -5 dBµA/m is to address manufacturing tolerances and measurement variations**. Characteristics of this equipment are:

a) they are totally implanted within an animal body;

b) the function they perform in providing physiological data cannot reasonably be obtained by any other method;

c) they are expected to reliably transmit low duty cycle data continuously in performing their intended function for periods of time on average of a month;

d) they are capable of being refurbished and reused at the end of their life cycle;

e) generally they are not capable of being programmed by a programming device.

B.2 Technical justifications for spectrum

B.2.1 Field strength

The maximum requested carrier power level is -5 dBuA/m measured at a 10 m distance. Further, to limit any possible use of this band for devices other than animal implantable devices used in support of medically related scientific studies, it is requested that annex 12, which covers ULP-AMI equipment, be revised to list band c: 315 kHz to 600 kHz only for animal implants.

The ambient noise is dependent on the location of the equipment. Medical facilities can be considered an industrial or commercial environment. In these environments the ambient noise is very high. The main noise sources are the harmonics of different electric equipment, for example switch mode power supplies, PCs, other medical equipment, ISM devices, fluorescent lights, electric distribution in general, etc. According to ERC Report 44 [5], the noise level in this type of environment, measured in a 1 kHz bandwidth, is expected to vary in the range 5 to 30 dBµA/m at 50 kHz. A typical level is 13 dBµA/m at 50 kHz. The noise level falls at a 3,5 dB/octave and it is typically 1 dBµA/m at 600 kHz.

Thus, at the requested power level, ULP-AID devices will be required to operate in close proximity to their associated receiver. Typical operating distances are less than 1 m.

B.2.2 Frequency

The band from 9 kHz to 315 kHz is generally recognized within the CEPT countries for ULP-AMI applications where primary usage is centered in hospital and clinical environments. The manmade contribution to the ambient noise in the band is gradually increasing as the proliferation of noise sources continues to increase. Because this band is in general use by very low power ULP-AMI devices and co-location with those devices would at a minimum raise the noise floor in the band, a new band should be opened for ULP-AID devices. Opening a new band for ULP-AID devices will preclude any increase in the noise floor in the ULP-AMI band and will minimize any disturbance threat that would otherwise exist to the potential co-location of the two types of devices.

Due to the very low power levels from this equipment, the extremely low numbers of active units, the very low duty cycle and the locations of the use of the transmitters in commercial laboratory environments, there is no expectation of interference to any existing services. It is concluded the risk of interference is so low as to be negligible.

B.2.3 Bandwidth and other radio parameters

Several factors have bearing on the circuitry used and therefore the device's operating bandwidth. Prime consideration relative to design is to conserve power to the extent possible. Reduced battery life causing replacement of an implant during a study could invalidate the entire study. One technique to reduce power is the use of pulse position modulation techniques. Another issue is output filtering. Such filtering would obviously have losses. Such losses reduce battery life and thus minimal filtering is incorporated in ULP-AID transmitters. Bandwidth is also a function of the data rate which is related to the number of sensor information channels that are the data source for the transmitters. A high data rate system (15 kHz) has a 20 dB bandwidth of approximately 300 kHz when measured in accordance with the test set up in EN 302 195-2 [2]. EN 302 195-2 [2] will be revised to cover the band 315 kHz to 600 kHz.

B.3 Information on current version of relevant ETSI standard

ETSI intends to revise the current ETSI draft standard, EN 302 195-2 [2], to incorporate the additional frequency band for ULP-AID equipment.

Annex C:
Expected compatibility issues

C.1 Coexistence studies

Work has already been done in this area by CEPT, see in particular:

- Doc SE24M16-57R1: "LS to SRDMG; Generic Limit below 30 MHz for SRD inductive systems" [4].
- ECC/SE(04)015 (2004) "Protection distances for radiocommunication services from inductive SRD applications in the frequency range 135 kHz - 30 MHz"[6].

C.2 Current ITU allocations

ITU Radio Regulations - Edition 2001 [7] lists in Region 1:

315-325 kHz	AERONAUTICAL RADIONAVIGATION Maritime radionavigation (radiobeacons) 5.73 5.72 5.75
325-405 kHz	AERONAUTICAL RADIONAVIGATION 5.72
405-415 kHz	RADIONAVIGATION 5.76 5.72
415-435 kHz	MARITIME MOBILE 5.79 AERONAUTICAL RADIONAVIGATION 5.72
435-495 kHz	MARITIME MOBILE 5.79 5.79A Aeronautical radionavigation 5.72 5.82
495-505 kHz	MOBILE (distress and calling) 5.83
505-526,5 kHz	MARITIME MOBILE 5.79 5.79A 5.84 AERONAUTICAL RADIONAVIGATION 5.72
526,5-1 606,5 MHz	BROADCASTING 5.87 5.87A

Footnotes:

5.72 Norwegian stations of the fixed service situated in northern areas (north of 60° N) subject to auroral disturbances are allowed to continue operation on four frequencies in the bands 283,5-490 kHz and 510-526,5 kHz.

5.73 The band 285-325 kHz (283,5-325 kHz in Region 1) in the maritime radionavigation service may be used to transmit supplementary navigational information using narrow-band techniques, on condition that no harmful interference is caused to radiobeacon stations operating in the radionavigation service. (WRC-97)

5.75 *Different category of service:* in Armenia, Azerbaijan, Belarus, Georgia, Moldova, Kyrgyzstan, the Russian Federation, Tajikistan, Turkmenistan, Ukraine and the Black Sea areas of Bulgaria and Romania, theallocation of the band 315-325 kHz to the maritime radionavigation service is on a primary basis under the condition that in the Baltic Sea area, the assignment of frequencies in this band to new stations in the maritime or aeronautical radionavigation services shall be subject to prior consultation between the administrations concerned. (WRC-2000)

5.76 The frequency 410 kHz is designated for radio direction-finding in the maritime radionavigation service. The other radionavigation services to which the band 405-415 kHz is allocated shall not cause harmful interference to radio direction-finding in the band 406,5-413,5 kHz.

5.79 The use of the bands 415-495 kHz and 505-526,5 kHz (505-510 kHz in Region 2) by the maritime mobile service is limited to radiotelegraphy.

5.79A When establishing coast stations in the NAVTEX service on the frequencies 490 kHz, 518 kHz and 4 209,5 kHz, administrations are strongly recommended to coordinate the operating characteristics in accordance with the procedures of the International Maritime Organization (IMO) (see Resolution **339 (Rev.WRC-97**)).(WRC-97)

5.82 In the maritime mobile service, the frequency 490 kHz is, from the date of full implementation of the GMDSS (see Resolution **331 (Rev.WRC-97**)), to be used exclusively for the transmission by coast stations of navigational and meteorological warnings and urgent information to ships, by means of narrow-band direct-printing telegraphy. The conditions for use of the frequency 490 kHz are prescribed in Articles **31** and **5**2. In using the band 415-495 kHz for the aeronautical radionavigation service, administrations are requested to ensure that no harmful interference is caused to the frequency 490 kHz. (WRC-97)

5.83 The frequency 500 kHz is an international distress and calling frequency for Morse radiotelegraphy. The conditions for its use are prescribed in Articles **31** and **52,** and in Appendix **13**.

5.84 The conditions for the use of the frequency 518 kHz by the maritime mobile service are prescribed in Articles **31** and **52** and in Appendix **13**. (WRC-97)

5.87 *Additional allocation:* in Angola, Botswana, Lesotho, Malawi, Mozambique, Namibia, South Africa, Swaziland, Zambia and Zimbabwe, the band 526,5-535 kHz is also allocated to the mobile service on a secondary basis.

5.87A *Additional allocation:* in Uzbekistan, the band 526,5-1 606,5 kHz is also allocated to the radionavigation service on a primary basis. Such use is subject to agreement obtained under No. **9.21** with administrations concerned and limited to ground-based radiobeacons in operation on 27 October 1997 until the end of their lifetime. (WRC-97)

C.3 Sharing issues

It is anticipated that sharing with existing services will be possible due to the low probability of co-location, the very low magnetic field radiated by ULP-AID equipment and the high roll-off propagation characteristics of the equipment. Furthermore, the extremely limited numbers of active animal implants and the deployment of the animal implants at about 250 locations helps limit any possibility of disturbance to the primary services.

History

Document history		
V1.1.1	March 2004	Publication