

<b>STN</b>	<b>Elektromagnetická kompatibilita (EMC), norma na rádiové zariadenia a služby</b> <b>Časť 35: Osobitné požiadavky na aktívne zdravotnícke implantáty s nízkym výkonom (LP-AMI) pracujúce v pásmach od 2 483,5 MHz do 2 500 MHz</b> <b>Harmonizovaná norma vzťahujúca sa na základné požiadavky podľa článku 3.1(b) smernice 2014/53/EÚ</b>	<b>STN</b> <b>EN 301 489-35</b> <b>V2.1.1</b>  87 1489
------------	---	--

Táto norma obsahuje anglickú verziu európskej normy.  
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 01/18

Obsahuje: EN 301 489-35 V2.1.1:2016

**126036**

Úrad pre normalizáciu, metrológiu a skúšobníctvo Slovenskej republiky, 2018  
Podľa zákona č. 264/1999 Z. z. o technických požiadavkách na výrobky a o posudzovaní zhody a o zmene a doplnení niektorých zákonov v znení neskorších predpisov sa slovenská technická norma a časti slovenskej technickej normy môžu rozmnožovať alebo rozširovať len so súhlasom slovenského národného normalizačného orgánu.



# ETSI EN 301 489-35 V2.1.1 (2016-12)



**ElectroMagnetic Compatibility (EMC)  
standard for radio equipment and services;  
Part 35: Specific requirements for  
Low Power Active Medical Implants (LP-AMI)  
operating in the 2 483,5 MHz to 2 500 MHz bands;  
Harmonised Standard covering the essential requirements  
of article 3.1(b) of Directive 2014/53/EU**

---

**Reference**REN/ERM-EMC-338

---

**Keywords**

---

EMC, harmonised standard, health, radio,  
regulation**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  
Sous-Préfecture de Grasse (06) N° 7803/88

---

**Important notice**

---

The present document can be downloaded from:  
<http://www.etsi.org/standards-search>

The present document may be made available in electronic versions and/or in print. The content of any electronic and/or print versions of the present document shall not be modified without the prior written authorization of ETSI. In case of any existing or perceived difference in contents between such versions and/or in print, the only prevailing document is the print of the Portable Document Format (PDF) version kept on a specific network drive within ETSI Secretariat.

Users of the present document should be aware that the document may be subject to revision or change of status. Information on the current status of this and other ETSI documents is available at  
<https://portal.etsi.org/TB/ETSIDeliverableStatus.aspx>

If you find errors in the present document, please send your comment to one of the following services:  
<https://portal.etsi.org/People/CommiteeSupportStaff.aspx>

---

**Copyright Notification**

---

No part may be reproduced or utilized in any form or by any means, electronic or mechanical, including photocopying and microfilm except as authorized by written permission of ETSI.

The content of the PDF version shall not be modified without the written authorization of ETSI.  
The copyright and the foregoing restriction extend to reproduction in all media.

© European Telecommunications Standards Institute 2016.  
All rights reserved.

**DECT™**, **PLUGTESTS™**, **UMTS™** and the ETSI logo are Trade Marks of ETSI registered for the benefit of its Members.  
**3GPP™** and **LTE™** are Trade Marks of ETSI registered for the benefit of its Members and of the 3GPP Organizational Partners.  
**GSM®** and the GSM logo are Trade Marks registered and owned by the GSM Association.

# Contents

Intellectual Property Rights .....	5
Foreword.....	5
Modal verbs terminology.....	5
1 Scope .....	6
2 References .....	6
2.1 Normative references .....	6
2.2 Informative references.....	7
3 Definitions and abbreviations.....	7
3.1 Definitions.....	7
3.2 Abbreviations .....	8
4 Test conditions .....	8
4.1 General .....	8
4.2 Arrangements for test signals .....	9
4.2.0 General.....	9
4.2.1 Arrangements for test signals at the input of transmitters.....	9
4.2.2 Arrangements for test signals at the RF output of transmitters.....	9
4.2.2.0 General .....	9
4.2.2.1 ULP-AMI transmitters .....	9
4.2.2.2 ULP-AMI-P transmitters.....	9
4.2.3 Arrangements for test signals at the RF input of receivers .....	9
4.2.4 Arrangements for test signals at the output of receivers .....	10
4.2.5 Arrangements for testing transmitter and receiver together (as a system: ULP-AMI together with an associated ULP-AMI-P) .....	10
4.3 RF exclusion band of radio equipment.....	10
4.3.1 General.....	10
4.3.2 Exclusion band for receivers.....	10
4.3.3 Exclusion band for transmitters .....	11
4.4 Narrow band responses of receivers or receivers which are part of transceivers .....	11
4.5 Normal test modulation .....	11
5 Performance assessment.....	11
5.1 General .....	11
5.2 Equipment which can provide a continuous communication link .....	12
5.3 Equipment which does not provide a continuous communication link .....	12
5.4 Ancillary equipment.....	12
5.5 Equipment classification .....	12
6 Performance criteria .....	12
6.1 Classification of LP-AMI and LP-AMI-P devices .....	12
6.2 General performance criteria .....	13
6.3 Performance criteria and table.....	13
6.4 Performance criteria for continuous phenomena applied to transmitters .....	14
6.5 Performance criteria for transient phenomena applied to transmitters .....	14
6.6 Performance criteria for continuous phenomena applied to receivers.....	15
6.7 Performance criteria for transient phenomena applied to receivers.....	15
7 Applicability overview .....	15
7.1 EMC emission .....	15
7.1.1 General.....	15
7.1.2 Special conditions.....	15
7.2 Immunity .....	16
7.2.1 General.....	16
7.2.2 Special conditions.....	16

<b>Annex A (normative):</b>	<b>Relationship between the present document and the essential requirements of Directive 2014/53/EU .....</b>	<b>20</b>
<b>Annex B (normative):</b>	<b>Definitions of types of LP-AMI and LP-AMI-P devices in the scope of the present document.....</b>	<b>22</b>
B.1	LP-AMI and LP-AMI-P devices intended for operation in the frequency range 2 483,5 MHz to 2 500 MHz.....	22
<b>Annex C (normative):</b>	<b>Test fixture for LP-AMI devices (Simulated man) .....</b>	<b>23</b>
History .....		25

---

## Intellectual Property Rights

IPRs essential or potentially essential to the present document may have been declared to ETSI. The information pertaining to these essential IPRs, if any, is publicly available for **ETSI members and non-members**, and can be found in ETSI SR 000 314: "*Intellectual Property Rights (IPRs); Essential, or potentially Essential, IPRs notified to ETSI in respect of ETSI standards*", which is available from the ETSI Secretariat. Latest updates are available on the ETSI Web server (<https://ipr.etsi.org>).

Pursuant to the ETSI IPR Policy, no investigation, including IPR searches, has been carried out by ETSI. No guarantee can be given as to the existence of other IPRs not referenced in ETSI SR 000 314 (or the updates on the ETSI Web server) which are, or may be, or may become, essential to the present document.

---

## 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.6] 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.1].

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.

The present document is part 35 of a multi-part deliverable. Full details of the entire series can be found in ETSI EN 301 489-1 [1].

<b>National transposition dates</b>	
Date of adoption of this EN:	12 December 2016
Date of latest announcement of this EN (doa):	31 March 2017
Date of latest publication of new National Standard or endorsement of this EN (dop/e):	30 September 2017
Date of withdrawal of any conflicting National Standard (dow):	30 September 2018

---

## 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).

"**must**" and "**must not**" are **NOT** allowed in ETSI deliverables except when used in direct citation.

---

# 1 Scope

The present document together with ETSI EN 301 489-1 [1], covers the assessment of all radio transceivers associated with Low Power Active Medical Implants (LP-AMIs) and associated Peripheral devices (LP-AMI-P) in respect of ElectroMagnetic Compatibility (EMC).

The present document covers the EMC requirements for the radio functions of LP-AMI and associated Peripheral devices (LP-AMI-P).

Technical specifications related to the antenna port and emissions from the enclosure port of the radio system of LP-AMI and associated Peripheral devices (LP-AMI-P) are not included in the present document. Such technical specifications are found in the relevant product standards for the effective use of the radio spectrum.

The present document specifies the applicable test conditions, performance assessment, and performance criteria for LP-AMI and associated Peripheral devices (LP-AMI-P).

Definitions of types of LP-AMIs and P-AMI-Ps covered by present document are given in annex B.

In case of differences (for instance concerning special conditions, definitions, abbreviations) between the present document and ETSI EN 301 489-1 [1], the provisions of the present document take precedence.

The environmental classification and the emission and immunity requirements used in the present document are as stated in the ETSI EN 301 489-1 [1], except for any special conditions included in the present document.

The present document, together with ETSI EN 301 489-1 [1], contains requirements to demonstrate an adequate level of electromagnetic compatibility as set out in Directive 2014/53/EU [i.1].

---

## 2 References

### 2.1 Normative 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.

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.

- [1] ETSI EN 301 489-1 (V2.1.1) (11-2016): "ElectroMagnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements; Harmonised Standard covering the essential requirements of article 3.1(b) of Directive 2014/53/EU and the essential requirements of article 6 of Directive 2014/30/EU".

NOTE: Available at [http://www.etsi.org/deliver/etsi\\_en/301400\\_301499/30148901/02.01.01\\_30/en\\_30148901v020101v.pdf](http://www.etsi.org/deliver/etsi_en/301400_301499/30148901/02.01.01_30/en_30148901v020101v.pdf).

- [2] CENELEC EN 61000-4-5:2006: "Electromagnetic compatibility (EMC) - Part 4-5: Testing and measurement techniques - Surge immunity test".

- [3] ETSI EN 301 559 (V2.1.1) (10-2016): "Short Range Devices (SRD); Low Power Active Medical Implants (LP-AMI) and associated Peripherals (LP-AMI-P) operating in the frequency range 2 483,5 MHz to 2 500 MHz; Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU".



## 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] 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.
- [i.2] CEPT/ERC/REC 70-03: "Relating to the use of Short Range Devices (SRD)".
- [i.3] Commission Decision 2006/771/EC of 11 November 2006 on harmonization of the radio spectrum for use by short-range devices as amended by subsequent Commission Decisions.
- [i.4] <http://niremf.ifac.cnr.it/>.
- [i.5] Camelia Gabriel: "Compilation of the dielectric properties of body tissues at RF and Microwave Frequencies", (Physics Department, Kings College, London WC2R 2LS, UK.
- [i.6] 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.

**koniec náhľadu – text ďalej pokračuje v platenej verzii STN**