WIRELESS MEDICAL IMPLANTS

ETSI Workshop “53 shades of RE-D: 6 months to go. How to place compliant radio equipment on the European market?”

Presented by Dr Saad Mezzour - ETSI ERM_TG30 Chairman
1st December 2016 - ETSI Sophia Antipolis, France
ABOUT WIRELESS MEDICAL IMPLANTS
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- Parkinson’s Disease
- Essential Tremor
- Dystonia
- Chronic Pain
- Gastroparesis
- Bowel Disorders
- Urinary Incontinence
- Obsessive Compulsive Disorder*
- Depression*
- Epilepsy*
- Bradycardia
- Heart Failure
- Tachycardia
- Obesity*
- Interstitial Cystitis
Typical Medical Implant Communication System
Spectrum usage scenarios

**Implant**
- Streamlined implant procedure
- Real-time communication of critical data

**In-office**
- Complete wireless follow-up
- Improved comfort for patient

**Remote**
- Pre-scheduled device checks
- Replaces regularly scheduled clinic visits
- Physician selected alert conditions
ABOUT WIRELESS MEDICAL IMPLANTS

Active Implantable Medical Device (ULP-AMI)

Patient Home Monitor (LP-AMI-P)

Physician Programmer (LP-AMI-P)

Wired/wireless standards

Health Care Facility

e.g.: 402-405 MHz band
Range of 2 to 6 m
New devices leveraging existing technologies

- Algorithms from ICD and CRT
- Micro-Electronics & Advanced Packaging
- Electrode Materials & Battery Tech.
- Instruments & Data Management
- Advanced Sensors Development
- Communication/Telemetry Protocols

- Miniaturization
- Intra-body Communication
- Remote monitoring and programming
- New Market with advanced injectable Platform
Trends driving wireless medical innovation

Device miniaturization
- Leadless Pacemaker
- Injectable Device

On-body networks
- ECG & TIR sensor
- SpO2 & Motion sensor

Remote monitoring and programming
- Remote monitoring
- Programming
Diabetes therapy system

The pump can numerically and graphically display wirelessly transmitted data from a continuous glucose sensor.

The pump can wirelessly receive and store blood glucose measurements from a paired blood glucose meter.

The pump has the ability to wirelessly download pump data to a PC for retrospective analysis of therapy.

The pump can wirelessly receive commands from a remote control device.
Gastro-Intestinal (GI) Pillcam

The PillCam capsule is a disposable digestible capsule designed to acquire images during natural propulsion through the Gastro-Intestinal (GI) tract. There are several capsule types, each specifically designed to visualize the anatomically different segments of the gastrointestinal tract, and/or specific diagnostic needs. The different capsule types are for imaging different GI organs.
ABOUT ETSI ERM_ TG30
Officials - ERM TG30:

Chairman: Saad Mezzour (Medtronic)
Secretary: Guillaume Girard (Medtronic)

TG30 members:

Medtronic
St Jude Medical
Biotronik
ELA/Sorin
Boston Scientific
Philips
Toumaz
7 Harmonised Standards covering the essential requirements of article 3.2 of the Directive 2014/53/EU:

- **Ultra Low Power Active Medical Implants (ULP-AMI)**
  - EN 302 195 : 9 kHz to 315 kHz
  - EN 302 510 : 30 MHz to 37,5 MHz
  - EN 301 839 : 402 MHz to 405 MHz
  - EN 302 537 : 401 MHz to 402 MHz & 405 MHz to 406 MHz

- **ULP-AID (Animal Implants)**
  - EN 302 536 : 315 kHz to 600 kHz

- **Low Power Active Medical Implants (LP-AMI)**
  - EN 301 559 : 2483.5MHz to 2500MHz

- **Medical Body Area Network Systems (MBANSs)**
  - EN 303 203 : 2483.5MHz to 2500MHz
List of Harmonised Standards under ERM EMC developed by TG30

- 4 Harmonised Standards covering the essential requirements of article 3.1(b) of the Directive 2014/53/EU:
  - EN 301 489-27: 402 MHz to 405 MHz
  - EN 301 489-29: 401 MHz to 402 MHz & 405 MHz to 406 MHz
  - EN 301 489-31: 9 kHz to 315 kHz
  - EN 301 489-35: 2483.5 MHz to 2500 MHz (LP-AMI)

New Work Items under ERM TG30:

- EN 303 490: Short Range Devices (SRD); Low Power Active Medical Implants (LP-AMI) operating in the 2.4 GHz ISM band; Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU

- ULP-AMI Safety of wireless medical devices Harmonised Standard to cover article 3.1(a) of the Directive 2014/53/EU for Wireless Medical Devices (under TC Safety)
<table>
<thead>
<tr>
<th>Essential Requirement of the RE-D 2014/53/EU</th>
<th>Inductive (9-315KHz)</th>
<th>MICS (402MHz-405MHz)</th>
<th>MEDS (401MHz-402MHz and 405MHz-406MHz)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Article 3.1 (Safety) (Note 1)</td>
<td>EN 45502-1 and EN 60601-1 and EN 62311 (SAR)</td>
<td>EN 45502-1 and EN 60601-1 and EN 62479 (SAR)</td>
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<tr>
<td>Article 3.1b (EMC of the RF link)</td>
<td>EN 301 489-1 and EN 301 489-31</td>
<td>EN 301 489-1 and EN 301 489-27</td>
<td>EN 301 489-1 and EN 301 489-29</td>
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<tr>
<td>Article 3.2 (RF spectrum use)</td>
<td>EN 302 195</td>
<td>EN 301 839</td>
<td>EN 302 537</td>
</tr>
</tbody>
</table>

**Note 1**: New Work Item under TC Safety to develop a new HEN for ULP-AMI Safety of wireless medical devices Harmonised Standard to cover article 3.1(a) of the Directive 2014/53/EU for Wireless Medical Devices.
Harmonised Standards

<table>
<thead>
<tr>
<th>Essential Requirement of the RE-D 2014/53/EU</th>
<th>SRD band (30MHz-1000MHz)</th>
<th>WiFi, BT, BTLE, Zigbee, etc (2400MHz-2483.5MHz)</th>
<th>BT/BTLE (2400MHz-2483.5MHz) From Implant</th>
</tr>
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<tbody>
<tr>
<td><strong>Article 3.1a</strong> (safety) <em>(Note 2)</em></td>
<td>EN 60601-1 and EN 62479 (SAR)</td>
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<td><strong>Article 3.1b</strong> (EMC of the RF link)</td>
<td>EN 301 489-1 and EN 301 489-3</td>
<td>EN 301 489-1 and EN 301 489-17</td>
<td>EN 301 489-1 and EN 301 489-17</td>
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<tr>
<td><strong>Article 3.2</strong> (RF spectrum use)</td>
<td>EN 300 220</td>
<td>EN 300 328</td>
<td>EN 300 328 <em>(Note 3)</em></td>
</tr>
</tbody>
</table>

*(Note 2)*: If the equipment (with integrated RF module) is classified as Medical Equipment under MDD or AIMD then EN 60601-1 applies. Otherwise EN 60950 should be used instead of EN 60601-1.

*(Note 3)*: There are no provisions for implant testing (human torso simulator) in EN 300 328. Human Torso simulator test set up can be used from EN 301 559 BUT opinion must be obtained from a Notified Body. New Work Item under TG30 to develop a new HEN EN 303 490 “Short Range Devices (SRD); Low Power Active Medical Implants (LP-AMI) operating in the 2,4 GHz ISM band; Harmonised Standard covering the essential requirements of article 3.2 of the Directive 2014/53/EU”

**Harmonised Standards**

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<thead>
<tr>
<th>Essential Requirement of the RE-D 2014/53/EU</th>
<th>Inductive RFID (KHz band and 13.56MHz)</th>
<th>UHF RFID (865MHz-868MHz)</th>
<th>RFID (2446MHz-2454 MHz)</th>
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<tr>
<td>Article 3.1a (safety) <em>(Note 4)</em></td>
<td>EN 60950 and EN 50364</td>
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<tr>
<td>Article 3.2 (RF spectrum use)</td>
<td>EN 300 330</td>
<td>EN 302 208</td>
<td>EN 300 440</td>
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*Note 4:* If the equipment (with integrated RFID) is classified as Medical Equipment under MDD or AIMD then EN 60601-1 applies instead of EN 60950.
Note 5: Dates in brown are provided as estimate dates.
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Thank you for your attention!

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