CEPT Workshop on
New spectrum solutions for industry sectors
Healthcare Sector

Dr. Saad Mezzour
Director Corporate Regulatory Affairs
OUR HISTORY OF INNOVATION
HOW WE’VE GROWN OVER THE YEARS

1949
CREATED FIRST BATTERY-OPERATED, EXTERNAL PACEMAKER

1957
WROTE OUR MISSION

1960
INTRODUCED PROSTHETIC HEART VALVE

1977
ESTABLISHED THE MEDTRONIC FOUNDATION

1979
EXPANDED INTO NEURO-STIMULATION

1983
EXPANDED INTO SPINAL CARE

1999
EXPANDED INTO DIABETES CARE

2001
INTRODUCED FIRST REMOTE MONITORING SYSTEM

2002
ACQUIRED COVIDIEN

2015
INTRODUCED THE WORLD’S SMALLEST PACEMAKER AND THE FIRST HYBRID CLOSED LOOP INSULIN DELIVERY SYSTEM

2016
INTRODUCED THE WORLD’S SMALLEST IMPLANTABLE SPINAL CORD STIMULATOR

2017

Developed the first implantable pacemaker
More than 70 conditions in the human body are treated with our therapies, enabling us to address chronic conditions and provide healthcare solutions.
Implantable Cardioverter Defibrillators (ICDs)
Transcatheter Heart Valves
Drug-Coated Balloons
Transcatheter Pacing System

Diagnostic CGM
Mobile Monitoring Tools
Insulin Pumps with built-in Continuous Glucose Monitoring

Navigation Systems
Capnography
Tri-stapling Systems

Deep Brain Stimulation Systems
Revascularization Devices
Integrated Neurosurgery Solutions

Medtronic
MEDTRONIC CONTINUES TO LEAD IN TECHNOLOGY INNOVATION

**Continuous Innovation**
Enhancing the clinical outcomes and economic value of existing products

- VisiaAF™ ICD
- Azure™ Pacing System
- Intellis™ Implantable Neurostimulator
- StealthStation™ SS Surgical Navigation
- Resolute ONYX™ Drug-eluting stent
- Signia™ Surgical Stapling

- CoreValve™ TAVR
- MVAD™ Left Ventricular Assist™
- PillCam™ Capsule Endoscopy
- Reveal LINQ™ ICM
- Solitaire™ Revascularization

**Invention**
Creating and developing new therapies that result in new markets

- MiniMed™ 670G Insulin Pump System
- Surgical Robotics System
- Micra™ Wireless Pacing System
- Arctic Front Advance™ Cryoballoon

**Disruption**
Disruptive therapies in existing markets

*Pipeline — Product concept in development*
CURRENT SPECTRUM SOLUTIONS

Sharing between the meteorological aids service and medical implant communication systems (MICS) operating in the mobile service in the frequency band 401-406 MHz

✓ ERC Decision (01)17 (2001 amended in 2017)
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 MHz - 406 MHz on a secondary basis

Ultra Low Power Active Medical Implant Systems (ULP-AMI) operating in the frequency band 9 kHz – 315 kHz

The coexistence between Ultra Low Power – Animal Implant Devices (ULP-AID) operating in the frequency band 12.5 MHz – 20 MHz and existing radiocommunication systems

✓ ECC Report 92 (2006)
Coexistence between Ultra Low Power Medical Implant Devices (ULP-AMI) and existing radiocommunication systems and services in the frequency bands 401 MHz – 402 MHz and 405 MHz – 406 MHz

✓ ECC Report 149 (2010)
Analysis on compatibility of Low Power Active Medical Implant (LP-AMI) applications within the frequency range 2360 MHz - 3400 MHz in particular for the band 2483.5 MHz - 2500 MHz, with incumbent services

✓ ECC Report 267 (2010)
Coexistence of Wideband Ultra-Low Power Wireless Medical Capsule Endoscopy Application operating in the frequency band 430 MHz - 440 MHz
CURRENT ETSI SOLUTIONS

✓ **EN 301 839**
  Ultra Low Power Active Medical Implants (ULP-AMI) and associated Peripherals (ULP-AMI-P) operating in the frequency range **402 MHz to 405 MHz**

✓ **EN 302 537**
  Ultra Low Power Medical Data Service (MEDS) Systems operating in the frequency range **401 MHz to 402 MHz and 405 MHz to 406 MHz**

✓ **EN 302 195**
  Ultra Low Power Active Medical Implants (ULP-AMI) and accessories (ULP-AMI-P) operating in the frequency range **9 kHz to 315 kHz**

✓ **EN 302 536**
  Radio equipment operating in the frequency range **315 kHz to 600 kHz** for Ultra Low Power Animal Implantable Devices (ULP-AID) and associated peripherals

✓ **EN 302 510**
  Ultra Low Power Active Medical Membrane Implants (ULP-AMI-M) and Peripherals (ULP-AMI-M-P) operating in the frequency range **30 MHz to 37,5 MHz**

✓ **EN 303 203**
  Medical Body Area Network Systems (MBANSs) operating in the **2 483,5 MHz to 2 500 MHz** range

✓ **EN 301 559**
  Low Power Active Medical Implants (LP-AMI) operating in the frequency range **2 483,5 MHz to 2 500 MHz**

✓ **EN 303 520**
  Ultra Low Power (ULP) wireless medical capsule endoscopy devices operating in the band **430 MHz to 440 MHz**
ANNEX 12: ACTIVE MEDICAL IMPLANTS AND THEIR ASSOCIATED PERIPHERALS

Scope of Annex

This annex covers frequency bands and regulatory as well as informative parameters recommended for Active Medical Implants and their associated peripherals.

<table>
<thead>
<tr>
<th>Frequency Band</th>
<th>Power / Magnetic Field</th>
<th>Spectrum access and mitigation requirements</th>
<th>Modulation / maximum occupied bandwidth</th>
<th>ECD/ERC Deliverable</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td>a 9-315 kHz</td>
<td>30 dBμA/m at 10m</td>
<td>≤ 10% duty cycle</td>
<td>Not specified</td>
<td></td>
<td></td>
</tr>
<tr>
<td>b 30-37.5 MHz</td>
<td>1 mW e.r.p.</td>
<td>≤ 10% duty cycle</td>
<td>Not specified</td>
<td></td>
<td></td>
</tr>
<tr>
<td>c 2483.5-2500 MHz</td>
<td>10 dBm e.i.r.p.</td>
<td>LBT+AFA and ≤ 10% duty cycle. The equipment shall implement a spectrum access mechanism as described in the applicable harmonised standard or an equivalent spectrum access mechanism</td>
<td>1 MHz</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
ERC RECOMMENDATION ERC/REC 70-03 – ANNEX 12

ETSI TC ERM LS to WGFM and SRD/MG “Request to reinstate the bands (315 kHz to 600 kHz) and (12.5 MHz to 20 MHz) for ULP - AID equipment in Annex 12 of ERC/REC 70-03”

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<td>a 0kHz - 315kHz</td>
<td>30 dBµA/m at 10m</td>
<td>≤ 10% duty cycle</td>
<td>Not specified</td>
<td>The application is for Ultra Low Power Active Medical Implant systems using inductive loop techniques for telemetry purposes</td>
<td></td>
</tr>
<tr>
<td>b 30MHz, 37.5MHz</td>
<td>1 mW e.r.p.</td>
<td>≤ 10% duty cycle</td>
<td>Not specified</td>
<td>The application is for Ultra Low Power medical membrane implants for blood pressure measurements</td>
<td></td>
</tr>
<tr>
<td>c 2483.5MHz - 2500MHz</td>
<td>10 dBm e.i.r.p.</td>
<td>LBT+AFA and ≤ 10% duty cycle. The equipment shall implement a spectrum access mechanism as described in the applicable harmonised standard or an equivalent spectrum access mechanism</td>
<td>1 MHz</td>
<td>For Low Power Active Medical implants and associated peripherals, covered by the applicable harmonised standard. Individual transmitters may combine adjacent channels on a dynamic basis for increased bandwidth higher than 1 MHz. Peripheral units are for indoor use only. The frequency band is also identified in Annex 2</td>
<td></td>
</tr>
<tr>
<td>d 315 kHz – 600 kHz</td>
<td>-5 dBµA/m at 10m</td>
<td>≤ 10% duty cycle</td>
<td>Not specified</td>
<td>The application is for animal implantable devices</td>
<td></td>
</tr>
<tr>
<td>e 12.5 MHz – 20.0 MHz</td>
<td>-.7 dBµA/m at 10m</td>
<td>≤ 10% duty cycle</td>
<td>Not specified</td>
<td>The application is for ULP active animal implantable devices (ULP-AID), limited to indoor only applications. The maximum field strength is specified in a bandwidth of 10 KHz. The transmission mask of ULP-AID is defined as follows: 3 dB bandwidth 300 kHz, 10 dB bandwidth 800 kHz, 20 dB bandwidth 2 MHz</td>
<td></td>
</tr>
</tbody>
</table>

Temp 19 Rec 70-03 Annex 12 to be sent to WGFM for public consultation
ANNEX 13: MEDICAL DATA ACQUISITION

Scope of Annex

This annex covers frequency bands and regulatory as well as informative parameters recommended for medical data acquisition applications. They cover transmission of non-voice data to and from non-implantable medical devices for the purpose of monitoring, diagnosing and treating patients in healthcare facilities or patient’s home, as prescribed by duly authorised healthcare professionals, including:

- Ultra-Low Power Wireless Medical Capsule Endoscopy (ULP-WMCE) application designed for use in medical doctor-patient scenarios with the aim of acquiring images of human digestive tract;
- Medical Body Area Network System (MBANS) for low-power wireless networking of a plurality of body-worn sensors and/or actuators as well as of a hub device placed on/around the human body.

Active Medical Implants and their associated peripherals are included in Annex 12 of this Recommendation.

<table>
<thead>
<tr>
<th>Table 13: Regulatory parameters</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Frequency Band</strong></td>
</tr>
<tr>
<td>a</td>
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<tr>
<td>b1</td>
</tr>
</tbody>
</table>
**ANNEX 12: ACTIVE MEDICAL IMPLANTS AND THEIR ASSOCIATED PERIPHERALS**

| Annexes to ERC/REC 70-03 | ET | GNV | LTIV | TBI | HBG | VSC | ELF | VSD | APE | 3Z0 | 2AC | 2D | 1N | 122 | 102 | 91 | 8Q | 8D | 8QD | 4R2 | 1AD | 1AC | 166 | 160 | 154 | 152 | 150 | 142 | 140 | 146 | 144 | 140 | 134 | 132 | 130 | 122 |
|--------------------------|---------|---------|---------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| Annex c2: 2446-2454 MHz   | Y       | Y       | Y       | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | N    | Y    | N    | Y    | Y    | Y    | Y    | Y    | N    | Y    | U    |      |
| Annex a: 0.315 kHz        | Y       | Y       | Y       | N    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | N    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    |      |
| Annex b: 30-37.5 MHz      | Y       | Y       | Y       | Y    | N    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    |      |
| Annex c: 2483.5-2500 MHz  | Y       | Y       | N       | Y    | N    | N    | N    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | N    | Y    | N    | Y    | N    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    |      |

**ANNEX 13: MEDICAL DATA ACQUISITION**

| Annexes to ERC/REC 70-03 | ET | GNV | LTIV | TBI | HBG | VSC | ELF | VSD | APE | 3Z0 | 2AC | 2D | 1N | 122 | 102 | 91 | 8Q | 8D | 8QD | 4R2 | 1AD | 1AC | 166 | 160 | 154 | 152 | 150 | 142 | 140 | 146 | 144 | 140 | 134 | 132 | 130 | 122 |
|--------------------------|---------|---------|---------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|------|
| Annex a: 430-440 MHz     | Y       | N       | N       | N    | N    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    |      |
| Annex b1: 2483.5-2500 MHz | Y       | Y       | N       | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    |      |
| Annex b2: 2483.5-2500 MHz | Y       | Y       | N       | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    | Y    |      |
QUESTIONS

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