WIRELESS MEDICAL DEVICES AND ETSI

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A typical generic standard is EN 300 220, for generic Short Range Devices operating in the frequency range 25MHz to 1000MHz.

An example of a product specific standard is EN 301 839 (first published in 2002) for Ultra Low Power Active Medical Implants (ULP-AMI) and associated peripherals operating in the 402MHz to 405MHz.

EN 301 839 specifically excludes audio applications and external to external communications.
Wireless Medical devices (ERM_TG30)

- Ultra Low Power Active Medical Implants (ULP-AMI)
  - 9 kHz to 315 kHz: EN 302 195
  - 30 MHz to 37.5 MHz: EN 302 510
  - 402 MHz to 405 MHz: EN 301 839
  - 401 MHz to 402 MHz and 405 MHz to 406 MHz: EN 302 537

- ULP-AID 315 kHz to 600 kHz: EN 302 536

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

- Medical Body Area Network Systems (MBANSs)
  - 2483.5MHz to 2500MHz: EN 303 203
SRD are devices that can have an e.i.r.p. ranging from 25mW to 400W, depending on the frequency band and applications.

They are accepted by many Administrations on the basis that they must not cause any interference to, and must accept any interference from, other radio-communication services.

They have no status in the international Radio Regulations as a service – in fact, they are the pariahs of the radio world!

The European regulatory ‘bible’ for SRD is the Recommendation ERC/REC 70-03.
European frequencies for SRDs

- 9 – 600 kHz in various bands and power levels for inductive devices, some with specific applications e.g. animal implants.
- 40.66 – 40.7, 138.2 – 138.45, 401 – 406 (limited to Ultra-Low Power Medical Implants), 433.05 – 434.79,
- 863 – 870 MHz, 2.4 – 2.4835GHz, 5.725 – 5.875 GHz, 24 – 24.25 GHz, 61 – 61.5GHz, 122 – 123 GHz, and 244 – 246 GHz
The European Generic SRD bands 863 – 870MHz and 2400MHz-2483.5MHz are planned with various segments and various powers for a number of applications.

With the use of either ‘Low Duty Cycle’ (LDC) or ‘Listen Before Talk’ (LBT) as a medium access protocol, optimum spectrum sharing for all users is achieved.
European Medical Implant communication bands

- 9 - 315kHz for implant communication – typically, a pacemaker
- 30 – 37.5MHz for membrane implants
- 401 – 406MHz for Ultra Low Power Active Medical Implants (ULP-AMI)
- 2483.5 – 2500MHz for Low Power Active Medical Implants (LP-AMI) and Medical Body Area Network Systems (MBANSSs)
Implant receiver power requirements

- Depending upon the demand on the pacemaker, an implant can last between 5 and 20 years.

- The average is about 8 to 10 years before implant replacement is required.

- Rechargeable batteries have been used in certain implantable devices, but problems of energy density, heat while recharging, and physical problems of coupling, as well as difficulties with patients forgetting to charge the battery, remain.
Because of limited power availability, implant receivers have to ‘sleep’ for the majority of the time.

‘Wake up’ can be achieved in several ways, and the lowest component count is with band scanning.

Interference during wake up sniffing can increase current consumption as the wake up system must use processing power to discriminate the interferer from a wanted signal.

High duty cycle interferers are particularly problematic and will adversely affect battery life.
Access Protocols and Power Management

- High duty cycle applications without access protocol in ULP-AMI bands are a major problem, and need to be avoided, especially with the large installed base of implants.

- The 401 – 406MHz band is shared with the Primary Service - meteorological aids – mainly meteorological weather balloons.

- These are rarely transmitting close enough to patients with implants to lead to extended wake up power demands.

- No Non – implantable applications in these bands, especially those used close to patients, require a limitation on duty cycle and a polite access protocol to avoid prematurely discharging the implant battery and to avoid interference with implant transmissions.
The 401 – 406MHz range was assigned for use by Medical Implant Communication Systems (MICS) in ITU-R Recommendation SA (now RS) 1346

This was as a result of sharing studies with meteorological aids, and on the basis of very limited or no outdoor use

Some Administrations treat MICS as a ‘Mobile’ service within the ITU terms: most others treat it as ‘SRD’, and thus an ‘orphan’

Some Administrations also feel that some protection greater than that afforded to SRDs is justified for medical implants
In February 2014 CEPT published in Recommendation ERC/REC 70-03 a new entry for MBANS operating in the 2483.5-2500MHz band

ETSI TG30 developed the new draft Standard EN 303 203

EN 303 203 was published by ETSI in November 2014
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
New devices leveraging existing technologies

Technology Leveraged

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

Features

- 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

- Remote monitoring
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.
Technology Trends – Wireless Medical Device Proliferation

Neurological and Diabetes

Therapy and Market Development

COMMERCIAL
- Tremor
- Peripheral Vascular Disease
- Chronic Pain
- Malignant Pain
- Spinal & Cerebral Spasticity
- Liver Cancer
- Gastroparesis
- Diabetes
- Urinary Incontinence

IN DEVELOPMENT
- Parkinson’s Disease
- Dystonia
- Obsessive-Compulsive Disorder
- Depression
- Epilepsy
- Occipital Neuralgia
- Angina Pain
- Nonopioid Pain
- Obesity
- Diabetes
- Interstitial Cystitis
- Bowel Disorders

MiniMed Pump
Drug Delivery
Neurostimulation
Taking part in Standards and Regulatory work is expensive, but ……

Not doing Regulatory and Standards work can be even more expensive
Thank you for your attention

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