CEPT Workshop on

New spectrum solutions for industry sectors

Healthcare Sector

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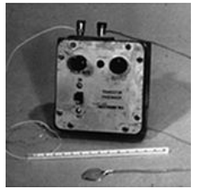
Medtronic
Further, Together

OUR HISTORY OF INNOVATION
HOW WE'VE GROWN OVER THE YEARS

1949 — **MEDTRONIC** IS FOUNDED

1957 — **CREATED FIRST** BATTERY-OPERATED, EXTERNAL PACEMAKER



1960 — WROTE OUR **MISSION**

Developed the first implantable pacemaker

1977 — INTRODUCED **PROSTHETIC HEART VALVE**

1979 — ESTABLISHED THE **MEDTRONIC FOUNDATION**

1983 — EXPANDED INTO **NEURO-STIMULATION**

1999 — EXPANDED INTO **SPINAL CARE**

2001 — EXPANDED INTO **DIABETES CARE**

2002 — INTRODUCED **FIRST REMOTE MONITORING SYSTEM**

2015 — **ACQUIRED COVIDIEN**

2016 — INTRODUCED **THE WORLD'S SMALLEST PACEMAKER** AND THE **FIRST HYBRID CLOSED LOOP INSULIN DELIVERY SYSTEM**

2017 — INTRODUCED **THE WORLD'S SMALLEST IMPLANTABLE SPINAL CORD STIMULATOR**

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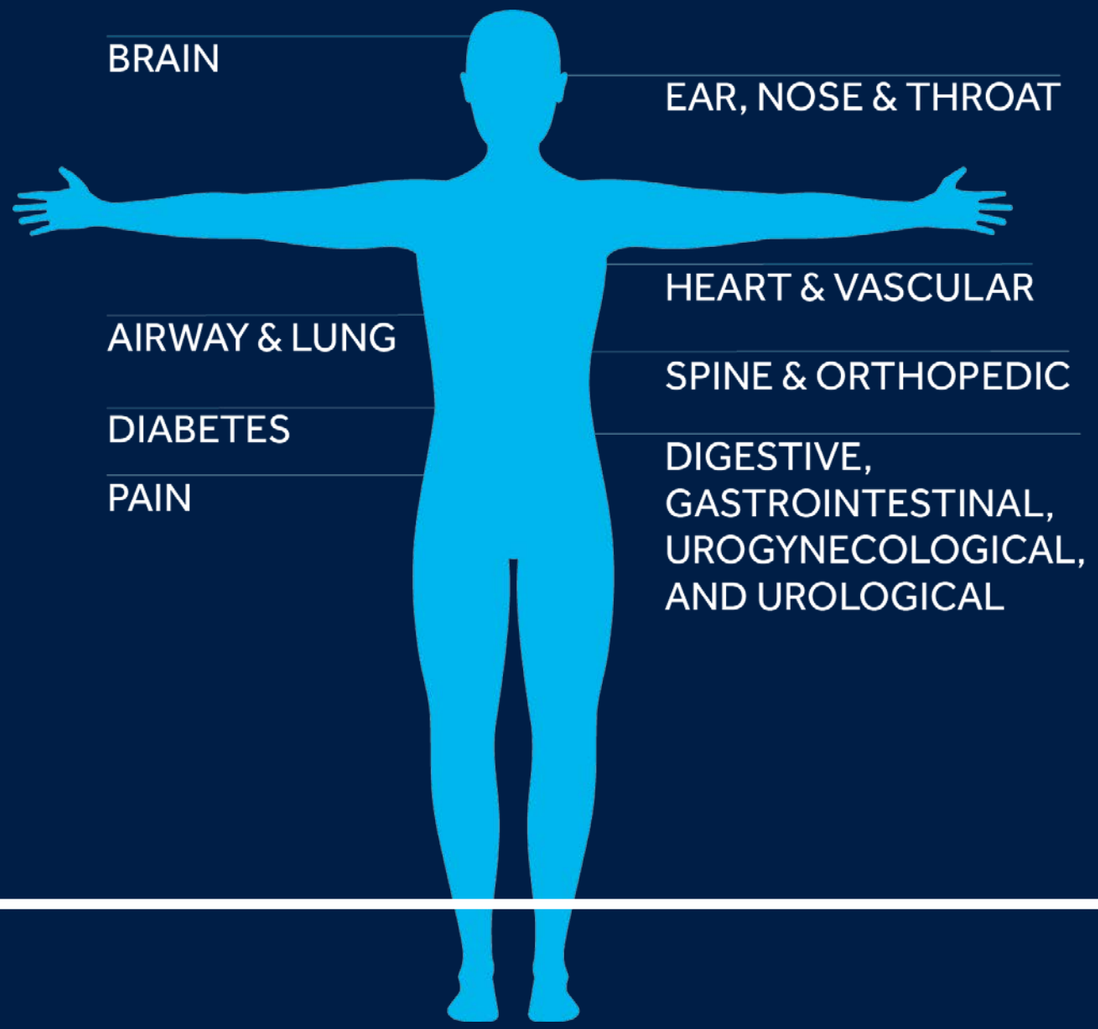
OUR THERAPIES AND SOLUTIONS IMPROVE LIVES



More than 70 conditions in the human body are treated with our therapies, enabling us to address chronic conditions and provide healthcare solutions

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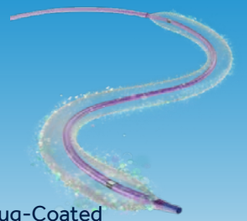
Cardiac & Vascular

Implantable Cardioverter Defibrillators (ICDs)

Transcatheter Heart Valves



Drug-Coated Balloons

Transcatheter Pacing System

Diabetes

Diagnostic CGM

Mobile Monitoring Tools

Insulin Pumps with built-in Continuous Glucose Monitoring

Minimally Invasive Therapy

Navigation Systems

Capnography

Tri-stapling Systems

Restorative Therapy

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

Invention
creating and developing new therapies that result in new markets

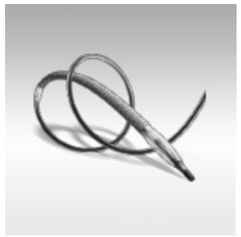
Disruption
Disruptive therapies in existing markets

VisiaAF™ ICD

Azure™ Pacing System

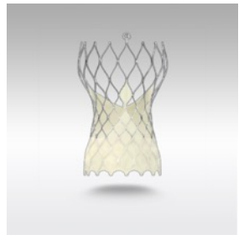
Intellis™ Implantable Neurostimulator

StealthStation™ SS Surgical Navigation



Resolute ONYX™ Drug-eluting stent

Signia™ Surgical Stapling

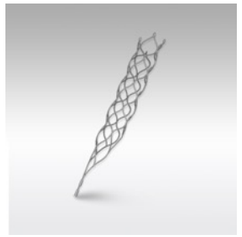


CoreValve™ TAVR

MVAD™ Left Ventricular Assist*

PillCam™ Capsule Endoscopy

Reveal LINQ™ ICM



Solitaire™ Revascularization

MiniMed™ 670G Insulin Pump System

Surgical Robotics System

Micra™ Wireless Pacing System

Arctic Front Advance™ Cryoballoon

*Pipeline — Product concept in development

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CURRENT SPECTRUM SOLUTIONS

✓ **ITU Recommendation ITU-R RS.1346 (1998)**
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

✓ **ECC Report 12 (2002)**
Ultra Low Power Active Medical Implant Systems (ULP-AMI) operating in the frequency band **9 kHz – 315 kHz**

✓ **ECC Report 81 (2006)**
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**

ERC RECOMMENDATION ERC/REC 70-03 – ANNEX 12

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 12: Regulatory parameters

Frequency Band		Power / Magnetic Field	Spectrum access and mitigation requirements	Modulation / maximum occupied bandwidth	ECC/ERC Deliverable	Notes
a	9-315 kHz	30 dBµA/m at 10m	≤ 10% duty cycle	Not specified		The application is for Ultra Low Power Active Medical Implant systems using inductive loop techniques for telemetry purposes
b	30-37.5 MHz	1 mW e.r.p.	≤ 10% duty cycle	Not specified		The application is for Ultra Low Power medical membrane implants for blood pressure measurements.
c	2483.5-2500 MHz	10 dBm e.i.r.p.	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	1 MHz		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

Additional Information

Harmonised Standards
EN 302 195 Sub-band a)
EN 302 510 Sub-band b)
EN 301 559 Sub-band c)

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"

Temp 19 Rec 70-03 Annex 12 to be sent to WGFM for public consultation

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.

Regulatory parameters

	Frequency Band	Power / Magnetic Field	Spectrum access and mitigation requirements	Modulation/ maximum occupied bandwidth	ECC/ERC deliverable	Notes
a	9kHz - 315kHz	30 dBµA/m at 10m	≤ 10% duty cycle	Not specified		The application is for Ultra Low Power Active Medical Implant systems using inductive loop techniques for telemetry purposes
b	30MHz- 37.5MHz	1 mW e.r.p.	≤ 10% duty cycle	Not specified		The application is for Ultra Low Power medical membrane implants for blood pressure measurements.
c	2483.5MHz - 2500MHz	10 dBm e.i.r.p.	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	1 MHz		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
d	315 kHz – 600 kHz	-5 dBµA/m at 10m	≤ 10% duty cycle	Not specified		The application is for animal implantable devices
e	12.5 MHz – 20.0 MHz	-7 dBµA/m at 10m	≤ 10% duty cycle	Not specified		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: 3dB bandwidth 300 kHz 10dB bandwidth 800 kHz 20dB bandwidth 2MHz

ERC RECOMMENDATION ERC/REC 70-03 – ANNEX 13

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 13: Regulatory parameters

Frequency Band		Power / Magnetic Field	Spectrum access and mitigation requirements	Modulation / maximum occupied bandwidth	ECC/ERC Deliverable	Notes
a	430-440 MHz	-50 dBm/100kHz max e.r.p. density but not exceeding a total power of -40 dBm/10MHz (both limits are intended for measurement outside of the patient's body)	No requirement	≤ 10 MHz		ULP-WMCE
b1	2483.5-2500 MHz	1 mW e.i.r.p.	Adequate spectrum sharing mechanisms (e.g. Listen-Before-Talk and Adaptive Frequency Agility) shall be implemented by the equipment and ≤ 10% duty cycle	≤ 3 MHz		MBANS, indoor only within healthcare facilities. The frequency band is also identified in Annex 12

ERC/REC 70-03 - APPENDIX 1: NATIONAL IMPLEMENTATION

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Annexes to ERC/REC 70-03	ALB	AND	AUT	AZE	BEL	BIH	BLR	BUL	CVA	CYP	CZE	D	DNK	E	EST	F	FIN	G	GEO	GRC	HNG	HOL	HRV	I	IRL	ISL	LIE	LTU	LUX	LVA	MCO	MDA	MKD	MLT	MNE	NOR	POL	POR	ROU	RUS	S	SMR	SRB	SUI	SVK	SVN	TUR	UKR
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	Y	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	N	Y	Y	Y	Y	Y	Y	Y	U
ANNEX 12: ACTIVE MEDICAL IMPLANTS AND THEIR ASSOCIATED PERIPHERALS																																																	
Annex a: 9-315 kHz	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	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y
Annex b: 30-37.5 MHz	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	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y
Annex c: 2483.5-2500 MHz	Y	Y	Y		Y	N	N	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	N	Y	Y	Y	Y	N	Y	Y	N	Y	Y	Y	Y	N
ANNEX 13: MEDICAL DATA ACQUISITION																																																	
Annex a: 430-440 MHz	Y																															Y																	
Annex b1: 2483.5-2500 MHz	Y		Y		Y		N	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	N	Y		N	Y	Y	Y	N	N
Annex b2: 2483.5-2500 MHz	Y		Y		Y		N	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	N	Y		N	Y	Y	Y	N	N

QUESTIONS

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