



INAIL

ISTITUTO NAZIONALE PER L'ASSICURAZIONE
CONTRO GLI INFORTUNI SUL LAVORO

Giornata di Studio dedicata alla presentazione dei risultati del progetto: BRIC 2019 - ID28

Pacemaker e defibrillatori impiantabili: valutazione dei rischi da sistemi 5G e sistemi WPT in ambito automotive

Cecilia Vivarelli

AIM: Collect experimental data on EMI from sources/exposure scenarios not covered by ISO 14117

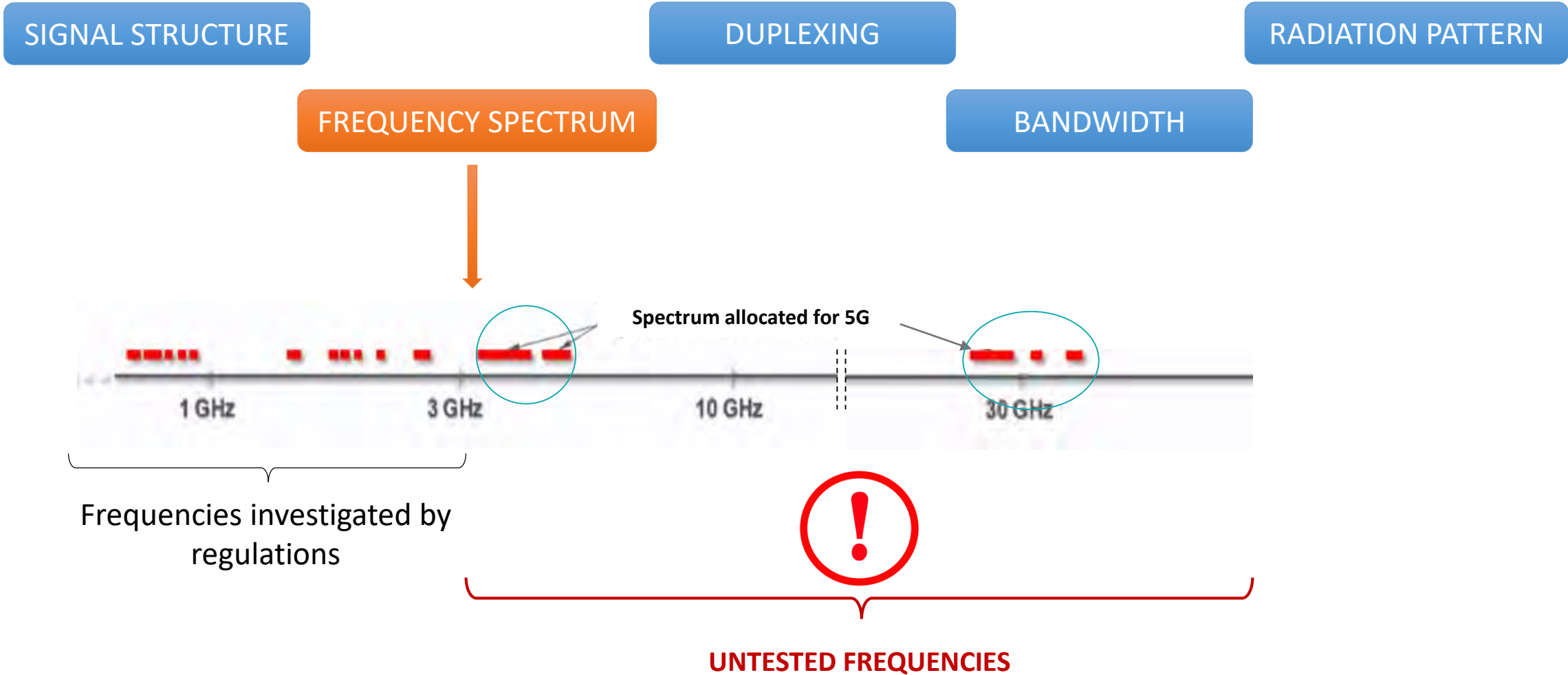
METHODOLOGY:

- Sources characterization
- Identification of exposure scenarios
- Set ups design and development
- Measurements campaigns
- Results analysis

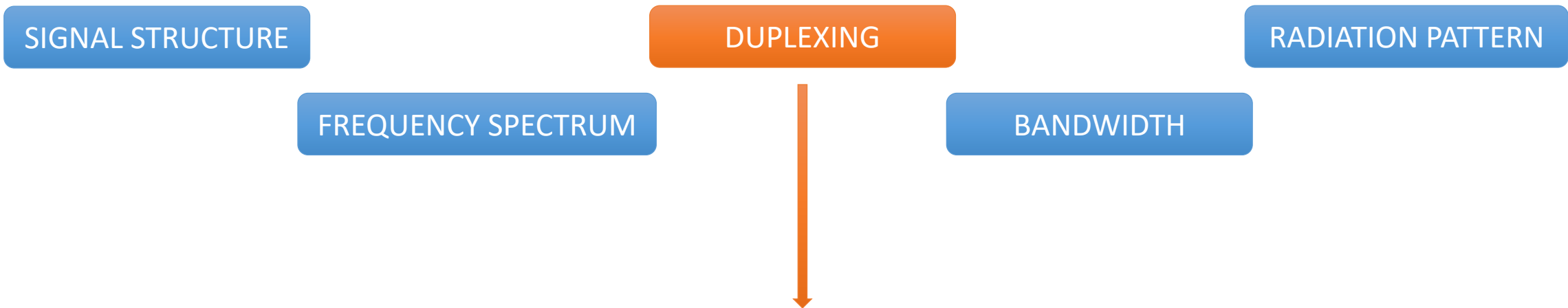
5G Technology



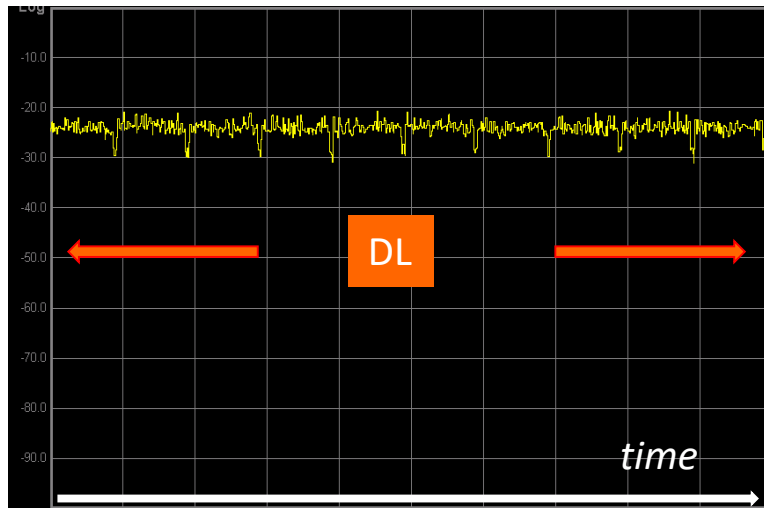
5G: innovations introduced



5G: innovations introduced



Frequency Division Duplex

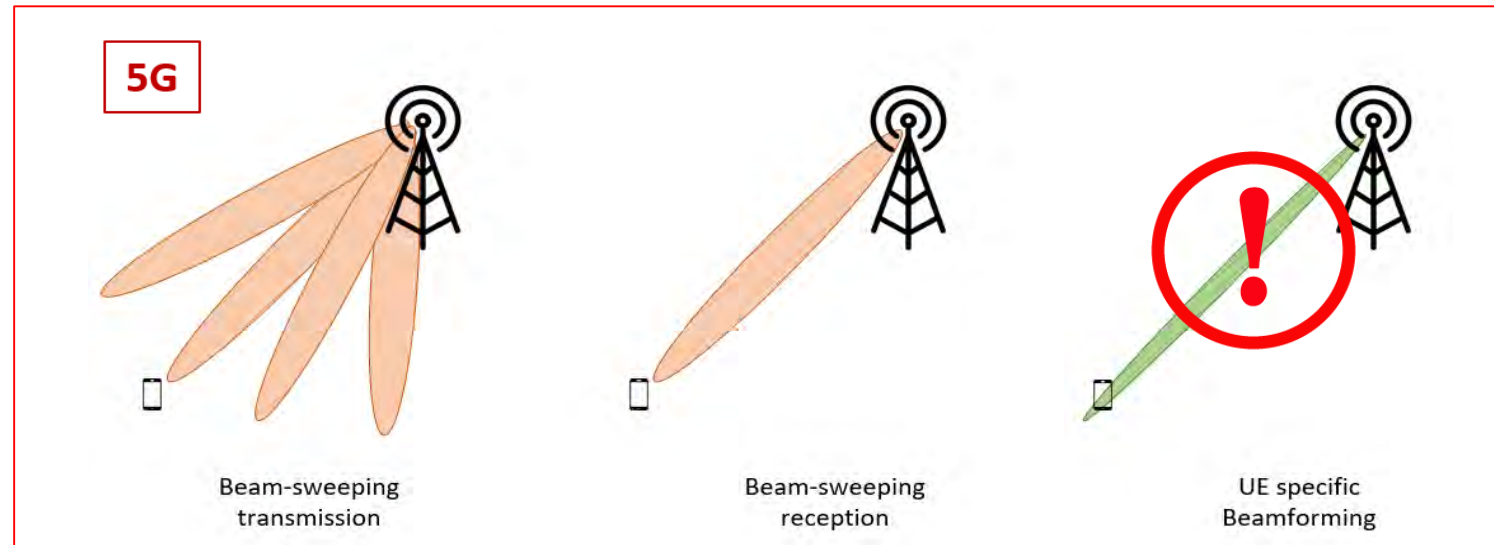
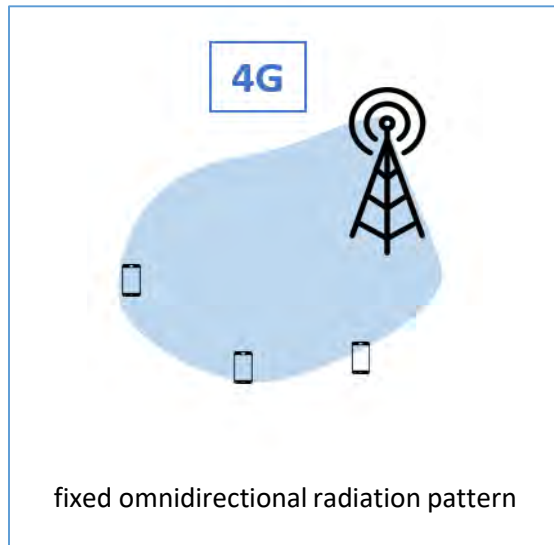
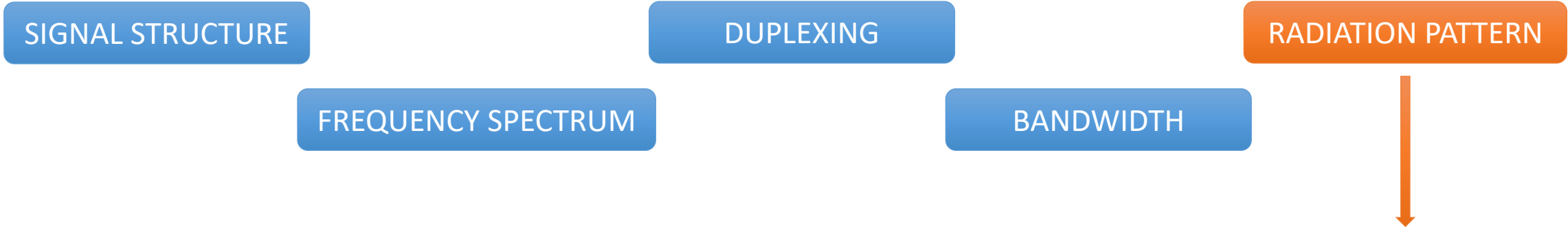


Time Division Duplex



PULSED SIGNAL

5G: innovations introduced

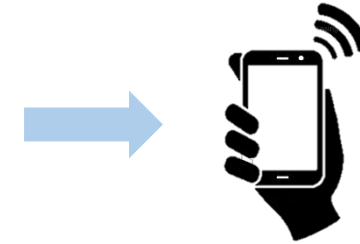


MORE DIRECTIVE RADIATION PATTERN

Identification of exposure scenarios

➤ The source under investigation is the **handheld device**:

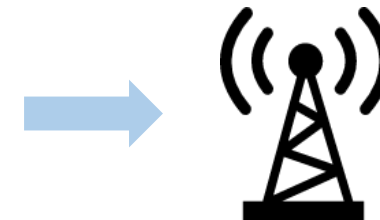
- Implementation of ISO 14117 tests with 700 MHz and 3600 MHz (5G characteristics frequencies)
- Realistic mobile 5G signal testing at 763 MHz and 3680 MHz (bands central frequencies) using ISO 14117 set up



UP LINK
near-field test

➤ The source under investigation is the **base station**:

- Design of a specific set-up able to generate high field levels in controlled conditions to test devices at EMF levels greater than general populations reference levels
- Realistic 5G base station signal testing at 763 MHz and 3680 MHz (bands central frequencies)

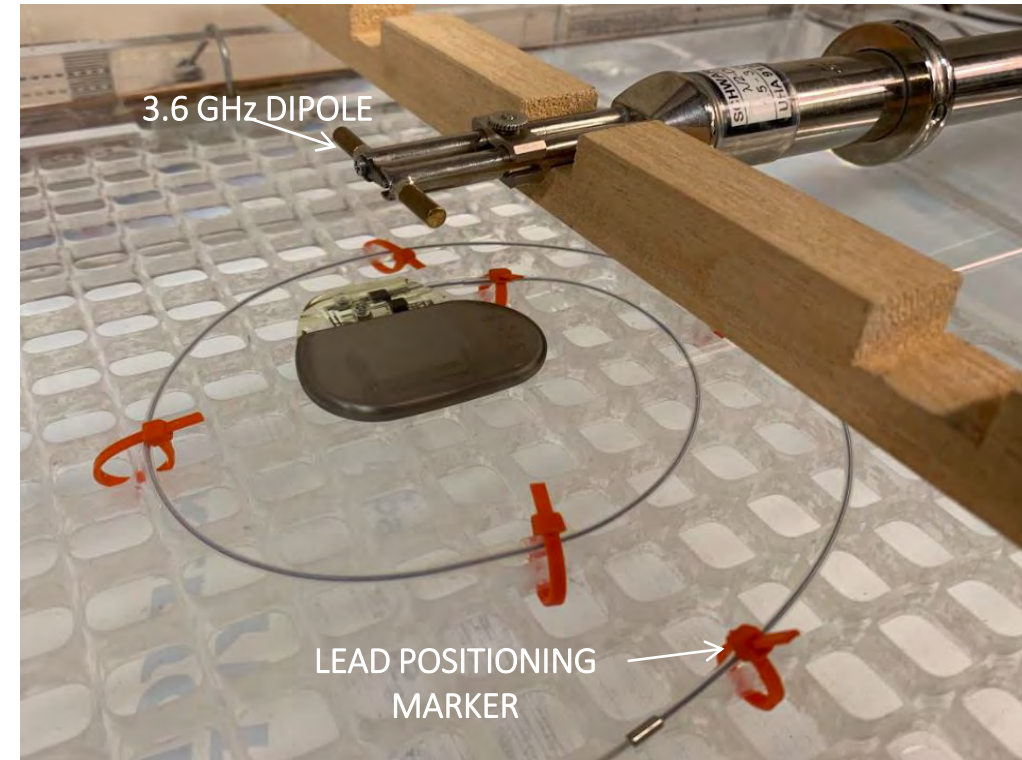
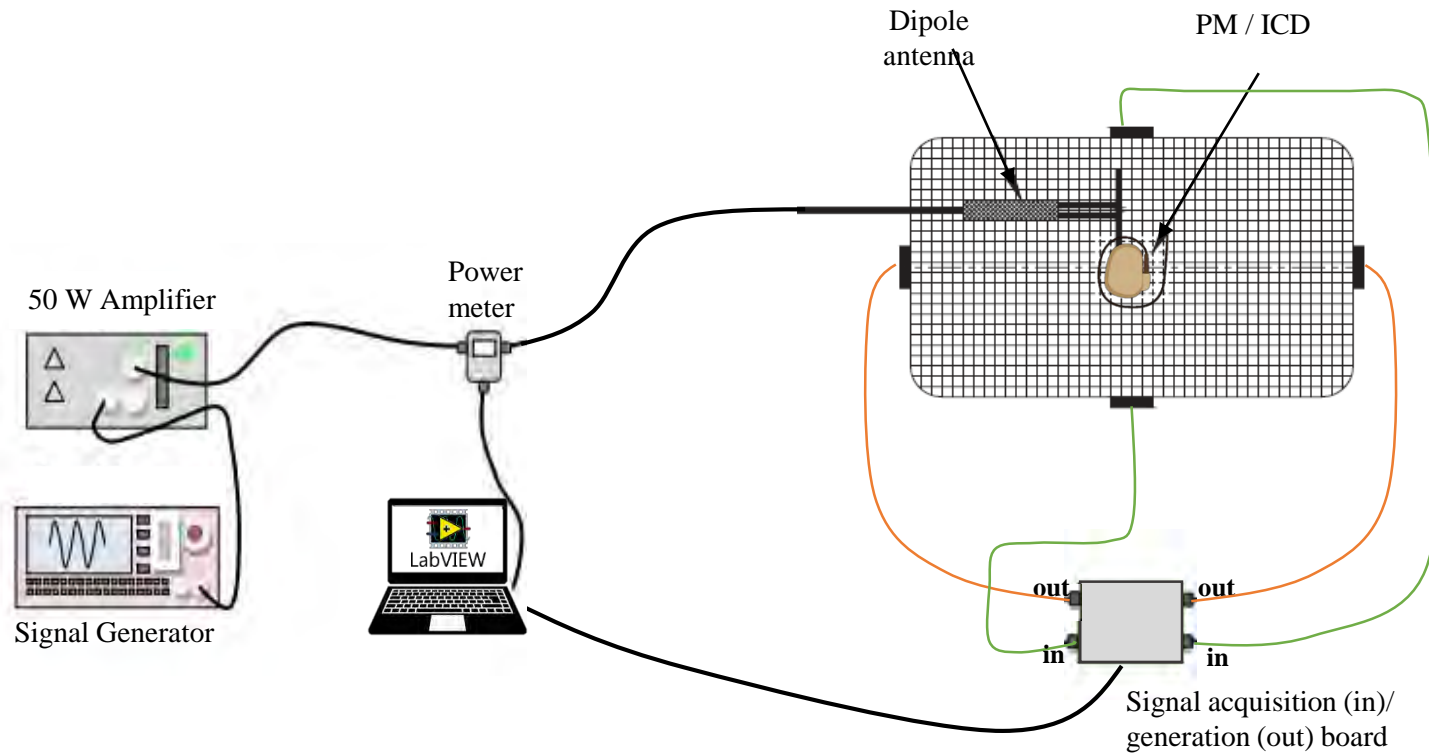


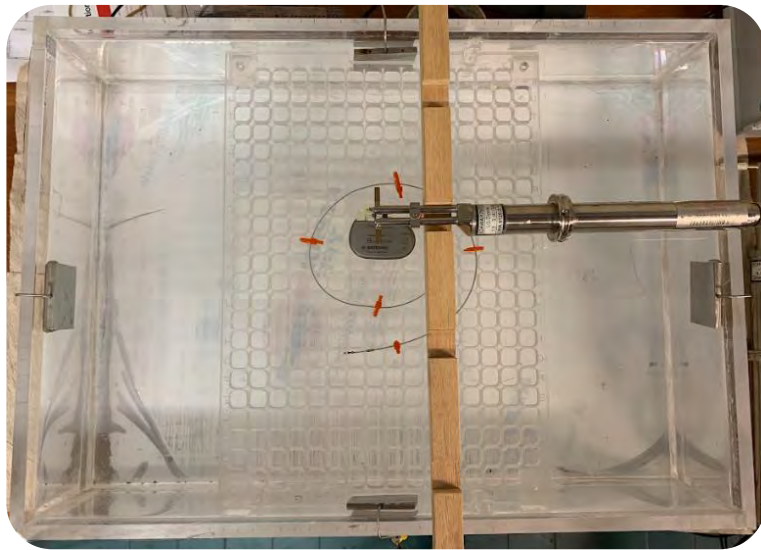
DOWN LINK
far-field test

UP LINK Near-field Mobile terminals



1. ISO 14117 test





TORSO SIMULATOR

- PVC transparent tank (60x40x15 cm^3 , volume ~28.6 l)
- Saline solution (conductivity 0.27 S/m)
- PVC grid to support device under test



SIGNAL MONITORING SYSTEM

- Custom-made signal acquisition and generation board

Exposure set up



3600 MHz



700 MHz

THE RF GENERATION SYSTEM

- **Dipole antennas operating at 700 MHz and 3600 MHz**
- RF signal generator (SMT03, Rohde & Schwarz)
- 50 W power amplifier
- in-line RF power meter

TEST PROCEDURE

- 6 PMs and 4 ICDs tested
- 2 antenna polarizations
- Interference signals:
 - Continuous wave and pulse modulated signal at 700 MHz and 3.6 GHz
 - Tested modulation: #1 25 ms ON and 475 ms OFF (~ equivalent to a heart rate of 120 bpm); #2 25 ms ON and 330 OFF (~mimic a ventricular tachycardia of 170 bpm)
 - Minimum tested power: 120 mW
 - Maximum tested power: 40 W at 700 MHz, 20 W at 3.6 GHz

RESULTS

- Total number of **384** conducted **tests** (256 for PMs and 128 for ICDs)
- 3.6 GHz: no EMI events observed
- 700 MHz: **43 EMI** events observed
 - 22 EMI under the optional power level threshold (2 W at 3.6 GHz and 8 W at 700 MHz)
 - 21 EMI at power input level higher than 2 W (at 3.6 GHz) and 8 W (at 700 MHz)
- All of the tested devices showed an **unperturbed behavior up to 120 mW**, the immunity level

PACEMAKERS – UNIPOLAR SENSING

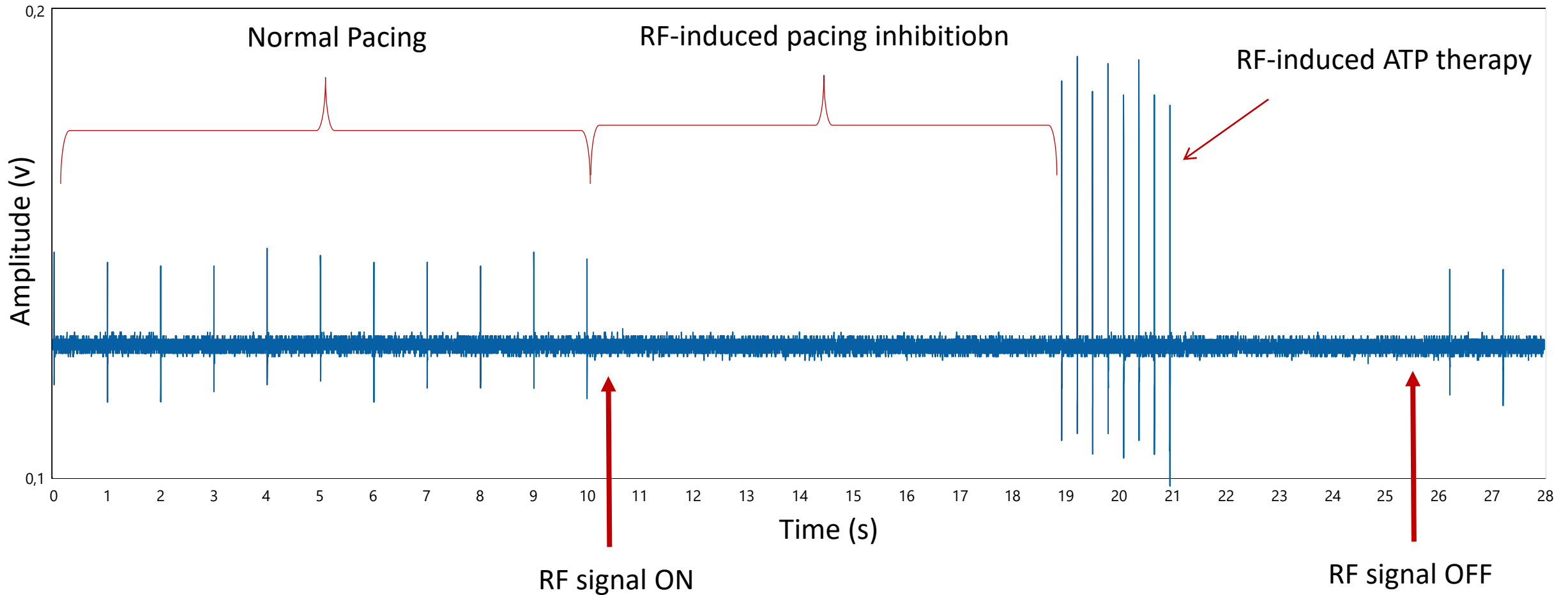
PM	LEAD	RF SIGNAL	PACING TEST		SENSING TEST	
			700 MHZ		700 MHZ	
			ANT. 1	ANT. 2	ANT. 1	ANT. 2
1	BIPOLAR	CW	NO EMI	NO EMI	NO EMI	NO EMI
	BIPOLAR	BRADY	ABOVE 2 W	ABOVE 2 W	NO EMI	NO EMI
	UNIPOLAR	CW	NO EMI	NO EMI	NO EMI	NO EMI
	UNIPOLAR	BRADY	ABOVE 1 W	ABOVE 1 W	NO EMI	NO EMI
2	BIPOLAR	CW	NO EMI	NO EMI	NO EMI	NO EMI
	BIPOLAR	BRADY	ABOVE 10 W	ABOVE 8 W	NO EMI	NO EMI
	UNIPOLAR	CW	NO EMI	NO EMI	NO EMI	NO EMI
	UNIPOLAR	BRADY	ABOVE 6 W	ABOVE 4 W	NO EMI	NO EMI
3	BIPOLAR	CW	NO EMI	NO EMI	NO EMI	NO EMI
	BIPOLAR	BRADY	ABOVE 8 W	ABOVE 7 W	NO EMI	NO EMI
	UNIPOLAR	CW	NO EMI	NO EMI	NO EMI	NO EMI
	UNIPOLAR	BRADY	ABOVE 19 W	ABOVE 7 W	NO EMI	NO EMI
4	BIPOLAR	CW	NO EMI	NO EMI	NO EMI	NO EMI
	BIPOLAR	BRADY	ABOVE 10 W	ABOVE 10 W	NO EMI	NO EMI
	UNIPOLAR	CW	NO EMI	NO EMI	NO EMI	NO EMI
	UNIPOLAR	BRADY	ABOVE 9 W	ABOVE 7 W	NO EMI	NO EMI
5	BIPOLAR	CW	NO EMI	NO EMI	NO EMI	NO EMI
	BIPOLAR	BRADY	ABOVE 40 W	ABOVE 38 W	NO EMI	NO EMI
	UNIPOLAR	CW	NO EMI	NO EMI	NO EMI	NO EMI
	UNIPOLAR	BRADY	ABOVE 10 W	ABOVE 8 W	NO EMI	NO EMI
6	BIPOLAR	CW	NO EMI	NO EMI	NO EMI	NO EMI
	BIPOLAR	BRADY	ABOVE 7 W	ABOVE 4 W	NO EMI	NO EMI
	UNIPOLAR	CW	NO EMI	NO EMI	NO EMI	NO EMI
	UNIPOLAR	BRADY	ABOVE 3 W	ABOVE 2 W	NO EMI	NO EMI

DEFIBRILLATORS

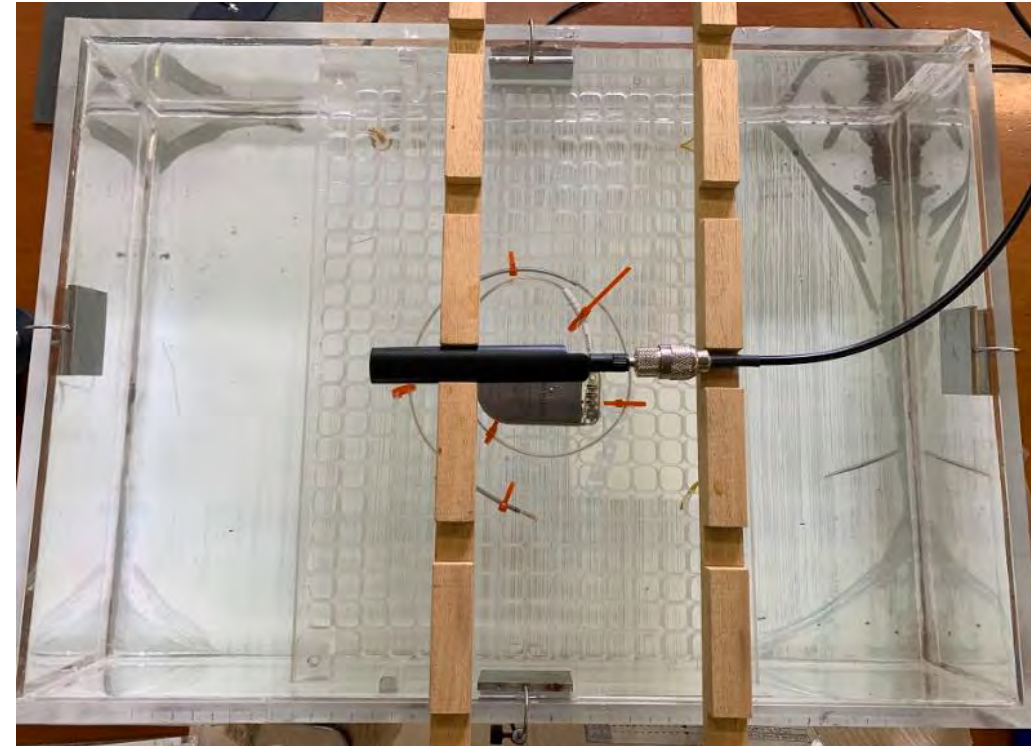
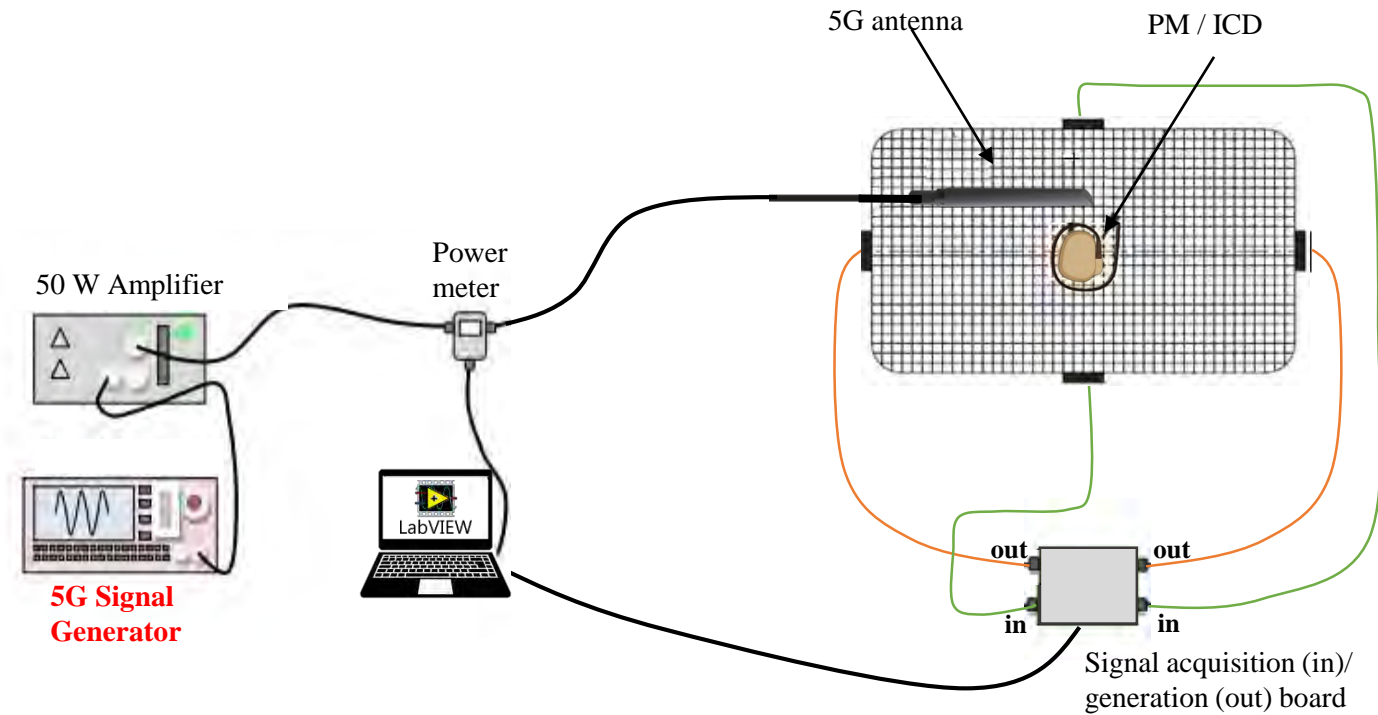
ICD	RF SIGNAL	PACING TEST		SENSING TEST		HIGH VOLTAGE THERAPY TEST	
		700 MHZ		700 MHZ		700 MHZ	
		ANT. 1	ANT. 2	ANT. 1	ANT. 2	ANT. 1	ANT. 2
1	CW	NO EMI*	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI
	BRADY	ABOVE 3 W	ABOVE 5 W	NO EMI	NO EMI	NO EMI	NO EMI
	TACHY	ABOVE 3 W	ABOVE 9 W	NO EMI	NO EMI	NO EMI	NO EMI
2	CW	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI
	BRADY	NO EMI	ABOVE 25 W	NO EMI	NO EMI	NO EMI	ABOVE 25 W
	TACHY	NO EMI	ABOVE 25 W	NO EMI	NO EMI	NO EMI	NO EMI
3	CW	NO EMI*	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI
	BRADY	ABOVE 12W	ABOVE 3 W	NO EMI	NO EMI	ABOVE 12 W	ABOVE 3 W
	TACHY	ABOVE 12 W	ABOVE 3 W	NO EMI	NO EMI	NO EMI	NO EMI
4	CW	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI
	BRADY	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI
	TACHY	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI

 EMI below 120 mW	 EMI above 2 W or 8 W
 EMI below 2 W or 8 W	 NO EMI

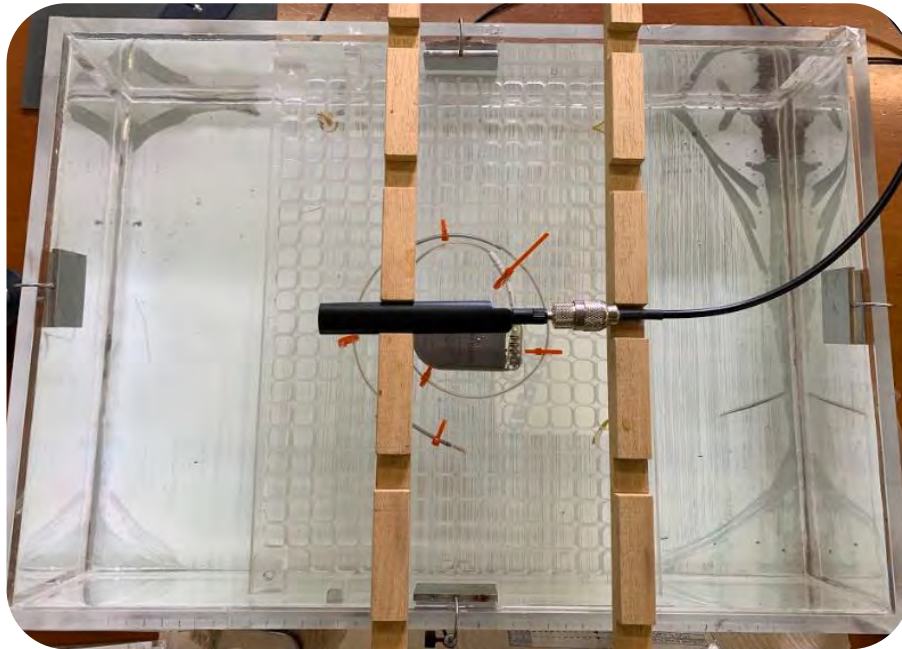
Example of acquired signal on an ICD recording an EMI event



2. 5G Up Link signal test



Exposure set up



TORSO SIMULATOR

- PVC transparent tank (60x40x15 cm^3 , volume ~28.6 L)
- Saline solution (conductivity 0.27 S/m)
- PVC grid to support device under test



THE 5G GENERATION SYSTEM

- **Omnidirectional broadband Sub-6 5G antenna** (from 600 to 5000 MHz)
- **5G signal generator ANRITSU MG3710e**
- Spectrum analyzer FSVA3030 Rohde & Schwarz, 10 Hz - 30 GHz
- 50 W power amplifier
- in-line RF power meter



SIGNAL MONITORING SYSTEM

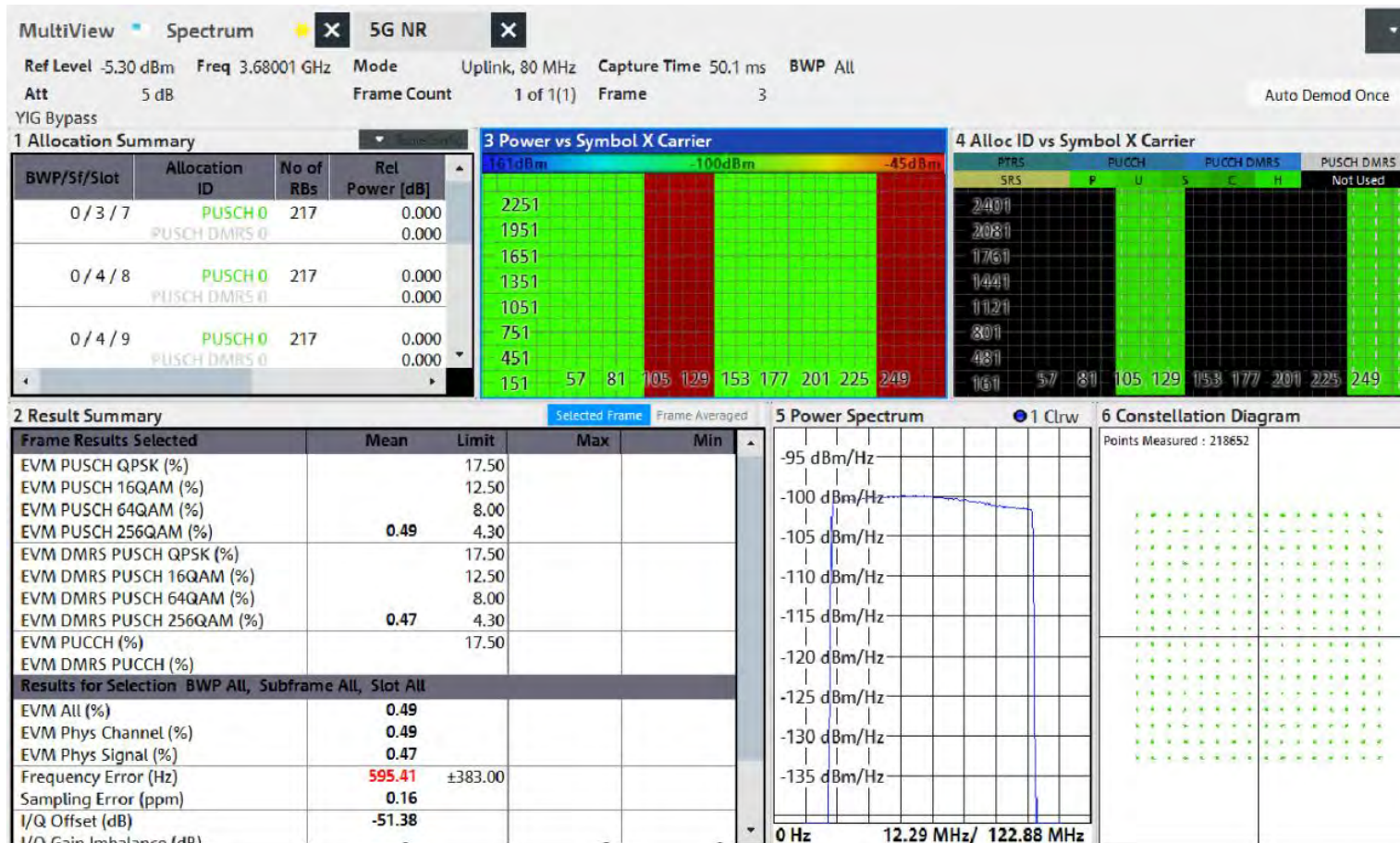
- Custom-made signal acquisition and generation board

TEST PROCEDURE

- 5 ICDs tested
- 2 antenna polarizations
- Interference signals:
 - 763 MHz (central frequency of the 700 MHz band)
 - 5G UP LINK signal, tested power levels: 120 mW, 8 W
 - 3680 MHz (central frequency of the band 3300-3380 MHz)
 - 5G UP LINK signal, tested power levels: 120 mW, 2 W

TEST PROCEDURE

5G UL FULL-TRAFFIC AT 3680 MHz



Central frequency	3601.01 MHz
Numerology	$\mu=1$ (sub carrier spacing=30 kHz)
TDD scheme	DDDDDDDSUDDDDDDDSUU
SSB	Case C
Lmax	8 (on, on, on, on, on, on, off, off)
PDSCH modulation scheme	256QAM
Bandwidth	80 MHz

RESULTS

No EMI events have been detected during exposure

Experimental measurements

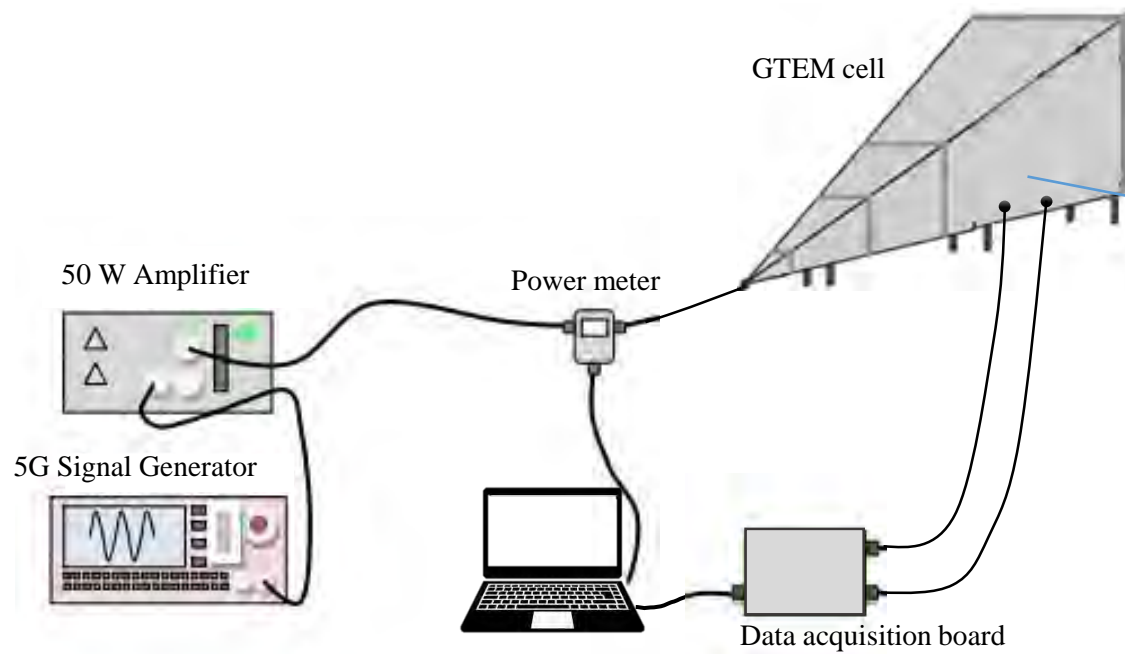
DEFIBRILLATORS

ICDs	5G UL signal	Antenna 1		Antenna 2	
		PACING TEST	SENSING TEST	PACING TEST	SENSING TEST
1	763 MHz (8 W)	NO EMI	NO EMI	NO EMI	NO EMI
	3680 MHz (5 W)	NO EMI	NO EMI	NO EMI	NO EMI
2	763 MHz (8 W)	NO EMI	NO EMI	NO EMI	NO EMI
	3680 MHz (5 W)	NO EMI	NO EMI	NO EMI	NO EMI
3	763 MHz (8 W)	NO EMI	NO EMI	NO EMI	NO EMI
	3680 MHz (5 W)	NO EMI	NO EMI	NO EMI	NO EMI
4	763 MHz (8 W)	NO EMI	NO EMI	NO EMI	NO EMI
	3680 MHz (5 W)	NO EMI	NO EMI	NO EMI	NO EMI
5	763 MHz (8 W)	NO EMI	NO EMI	NO EMI	NO EMI
	3680 MHz (5 W)	NO EMI	NO EMI	NO EMI	NO EMI

DOWN LINK Far-field Base stations



3. 5G Down Link signal test



In collaboration with D. Franci, S. Pavoncello, T. Aureli (ARPA Lazio) and R. Falsaperla, G. Burriesci, S. D'Agostino (INAIL)



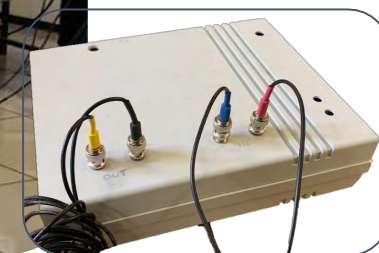
TORSO SIMULATOR

- PVC transparent tank (37x28x8 cm^3)
- Saline solution (conductivity 0.27 S/m)
- PVC grid to support device under test



THE RF GENERATION AND MONITORING SYSTEM

- **GTEM cell**
- **5G signal generator ANRITSU MG3710e**
- 50 W power amplifier
- in-line RF power meter
- Custom-made signal acquisition and generation board

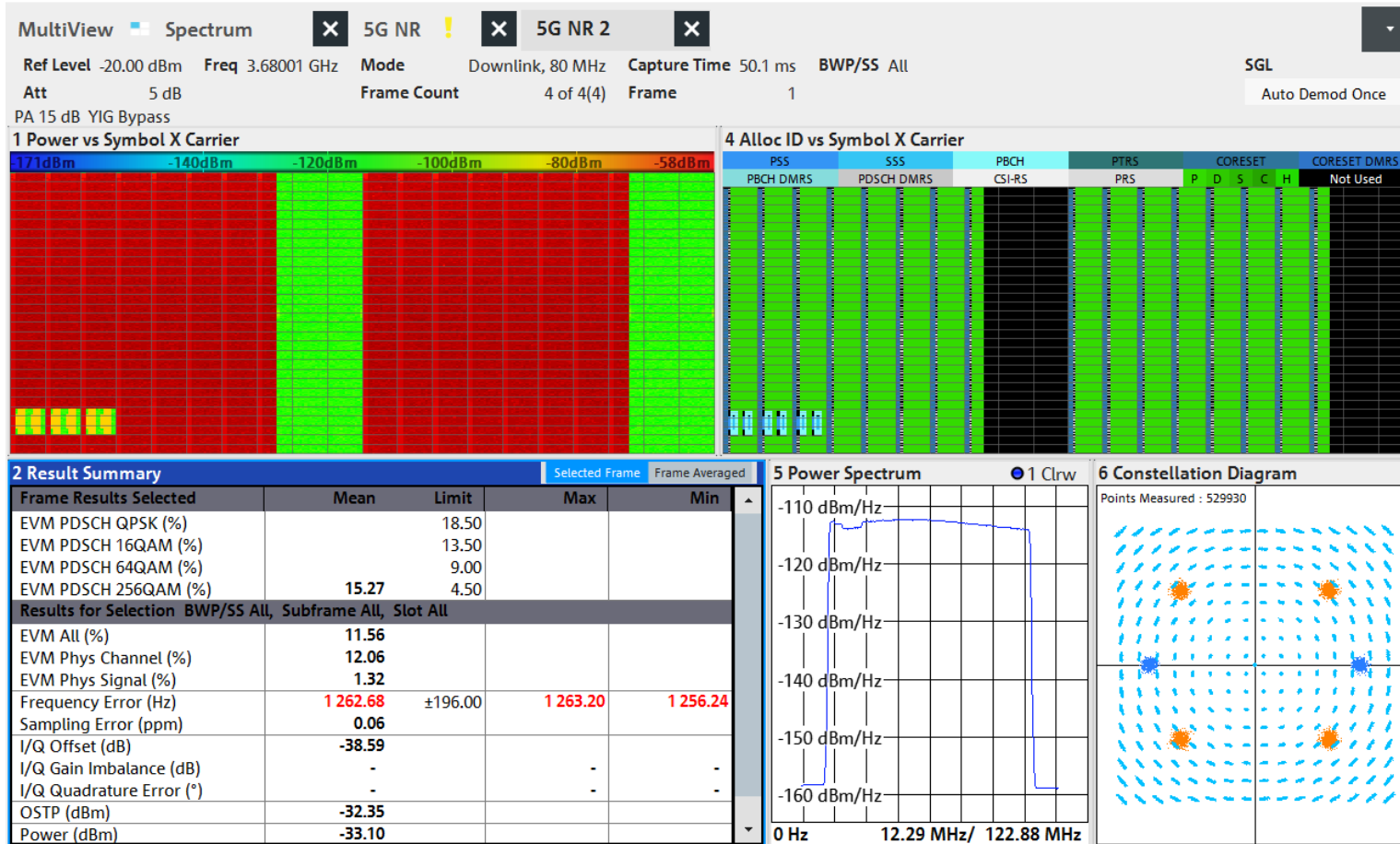


TEST PROCEDURE

- 5 ICDs tested
- Interference signals:
 - Continuous wave
 - 700 MHz: $P_{in} = 50 W$, $E_{meas} = 114 V/m \gg$ ICNIRP general public (36.4 V/m) and occupational (79.4 V/m)
 - 3500 MHz: $P_{in} = 26 W$, $E_{meas} = 66 V/m >$ ICNIRP general public (61 V/m), $<$ occupational (140 V/m)
 - 5G full-traffic (80 MHz bandwidth)
 - 5G gated (25 ms ON, 475 ms OFF)

TEST PROCEDURE

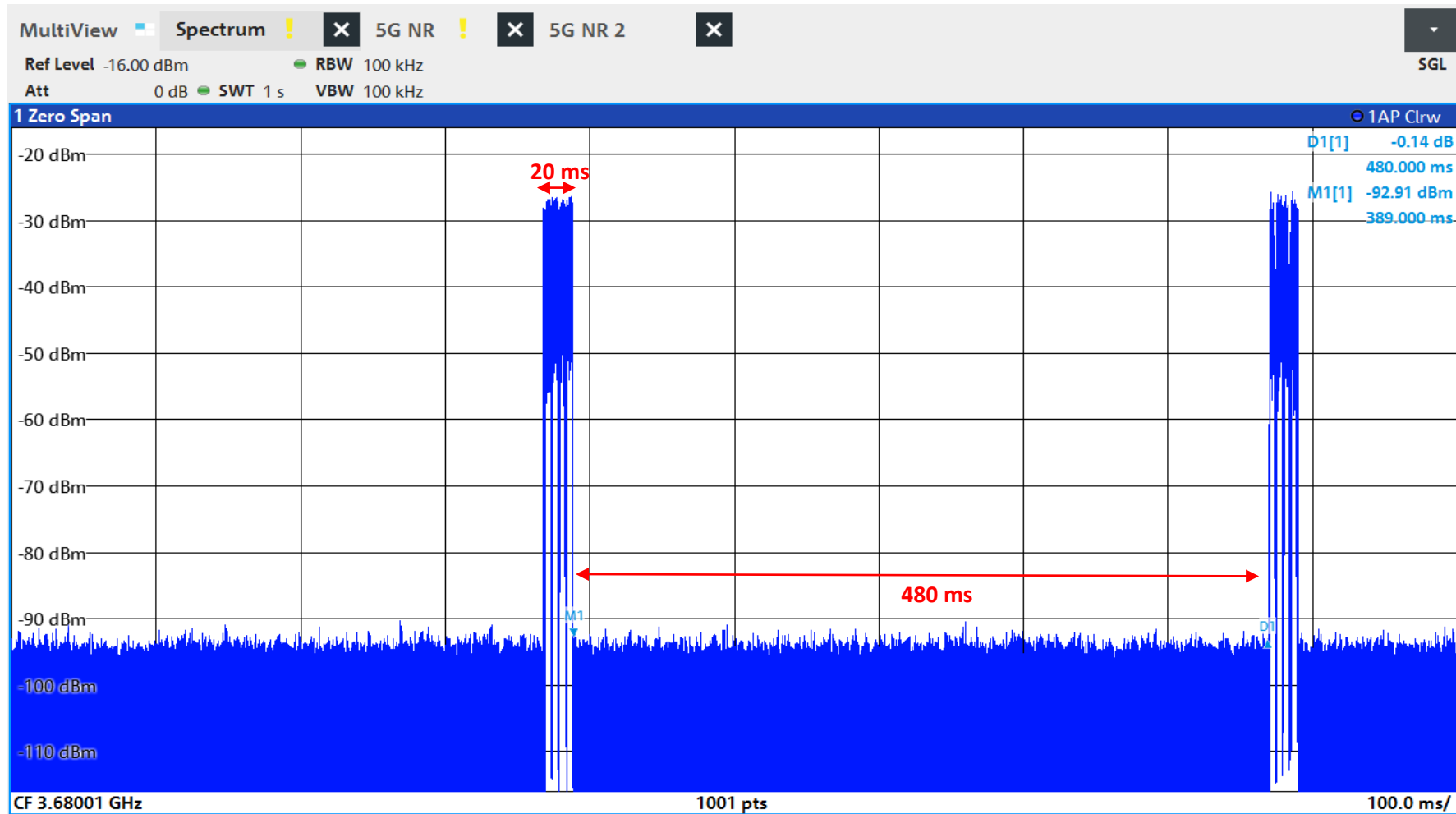
5G DL FULL-TRAFFIC AT 3680 MHz



Central frequency	3601.01 MHz
Numerology	$\mu=1$ (sub carrier spacing=30 kHz)
TDD scheme	DDDDDDDSUDDDDDDDSU U
SSB	Case C
Lmax	8 (on, on, on, on, on, on, off, off)
PDSCH modulation scheme	256QAM
Bandwidth	80 MHz

TEST PROCEDURE

5G DL GATED AT 3680 MHz



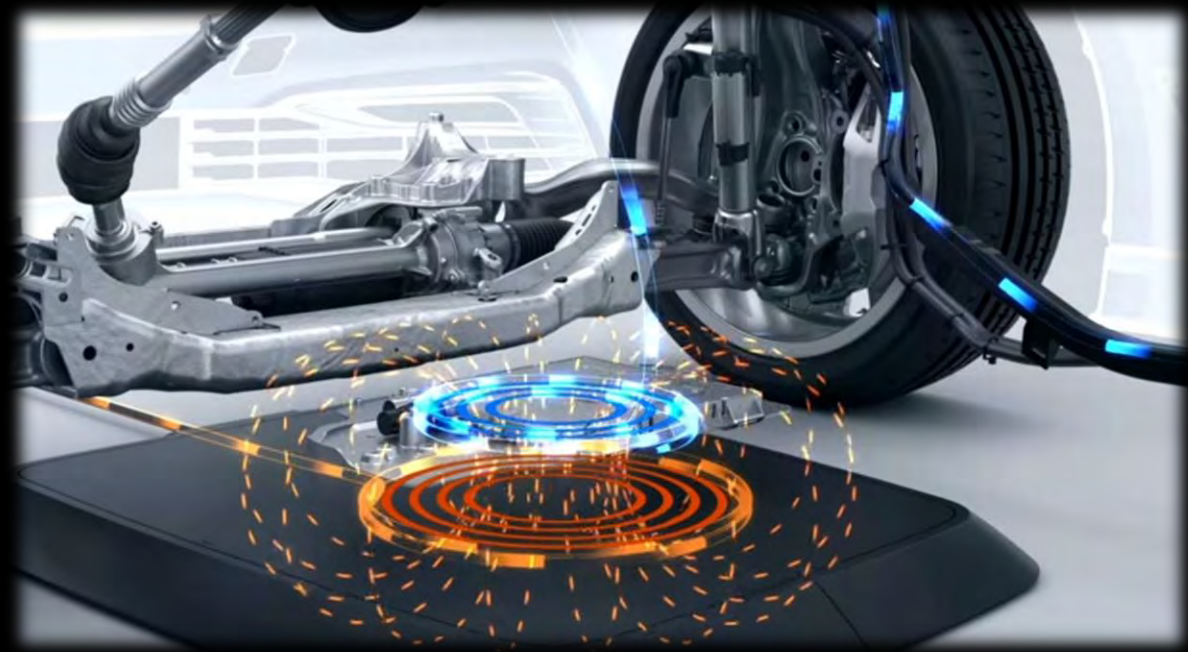
In collaboration with D. Franci, S. Pavoncello, T. Aureli (ARPA Lazio) and R. Falsaperla, G. Burriesci, S. D'Agostino (INAIL)

RESULTS

No EMI events have been detected during exposure

ICDs	5G SIGNAL	700 MHz			3.5 GHz		
		PACING TEST	SENSING TEST	HIGH VOLTAGE THERAPY TEST	PACING TEST	SENSING TEST	HIGH VOLTAGE THERAPY TEST
DEFIBRILLATORS	1	CW	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI
		5G full-traffic	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI
		5G gated	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI
	2	CW	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI
		5G full-traffic	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI
		5G gated	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI
	3	CW	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI
		5G full-traffic	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI
		5G gated	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI
4	CW	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI	
	5G full-traffic	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI	
	5G gated	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI	
5	CW	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI	
	5G full-traffic	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI	
	5G gated	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI	

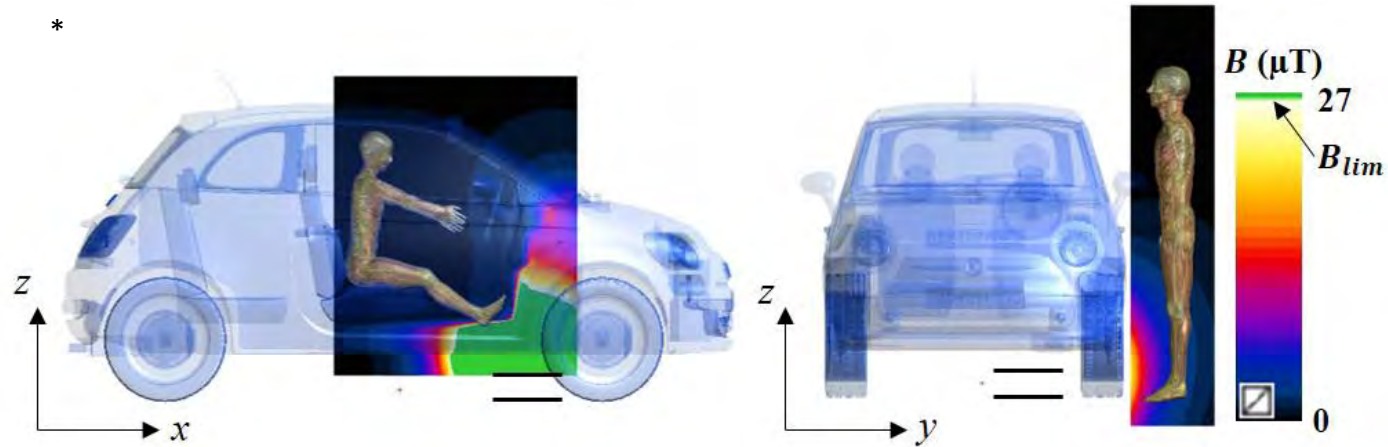
Wireless Power Transfer for automotive



This document does not address the following exposure scenarios:

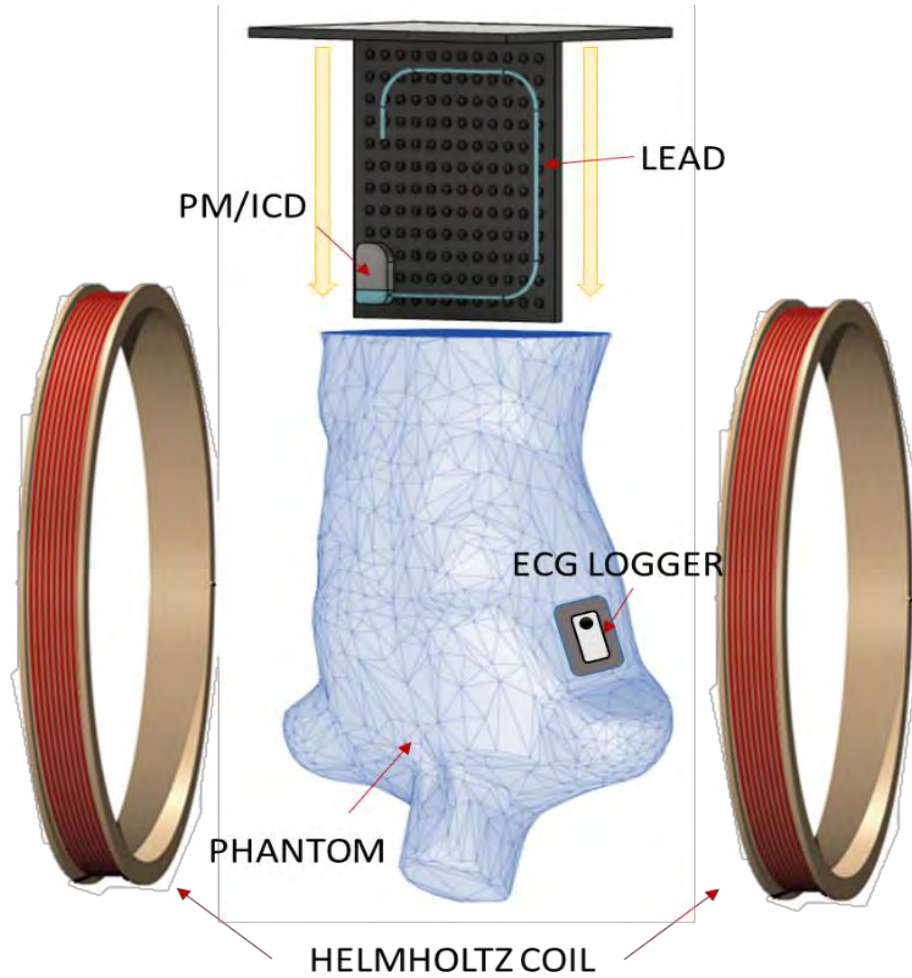
- Exposure to the fields generated by Electronic Article Surveillance (EAS) systems operating at frequencies below 100 kHz. These systems are typically mounted on pedestals, or within floors or walls. Such systems are generally known to interfere with the devices covered by this document. As a result, a consensus-based test for continuous exposure to these emitters is not included in this edition of the standard. Such tests might be considered for subsequent editions of this document as emitter technology or device immunity evolves. Until this happens, patients with devices within the scope of this document are still advised to observe the “don’t lean, don’t linger” recommendations established by the US FDA^[38].
- Exposure to the fields generated by RFID systems operating at frequencies up to 13,56 MHz^{[39][40][46]}.
- **Wireless charging systems for vehicles and personal electronic devices**. The working group is currently evaluating these technologies, and tests or exclusions for them will be considered in subsequent editions of this document.

- WPT technology is not considered in ISO 14117 test
- The static WPT frequency ranges from 22 to 25 kHz or from 79 to 90 kHz; the Dynamic WPT frequency ranges from 79 to 90 kHz



- WPT technology is not considered in ISO 14117 test
- The static WPT frequency ranges from 22 to 25 kHz or from 79 to 90 kHz; the Dynamic WPT frequency ranges from 79 to 90 kHz
- Simulations reveal magnetic field levels greater than general population reference level ($27 \mu T$)

Exposure set up with Helmholtz coils



In collaboration with A. Canova, F. Freschi, L. Giaccone – Politecnico di Torino



TORSO SIMULATOR

- PVC human torso-shaped phantom (volume about 30 L)
- Saline solution (conductivity 0.27 S/m)
- PVC grid (20x38 cm²) to support device under test



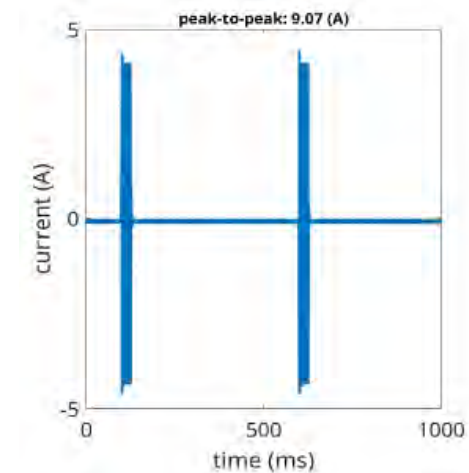
THE B FIELD GENERATION AND MONITORING SYSTEM

- **Custom-made Helmholtz coils** (square coils, edge=60 cm, number of **turns=12**), **working frequency of 85 kHz**
- Custom-made ecg logger



TEST PROCEDURE

- 6 PMs and 5 ICDs tested
- Interference signals:
 - Continuous wave and pulse modulated signals (PMs: 25 ms ON, 475 ms OFF - T=500ms; ICDs: 25 ms ON for all of them, T=355; T=400; T=250; T=200) at 85 kHz that allows to generate desired B field values:
 - 6,25 μT (rms) (general population ICNIRP 1998)
 - 15 μT (rms) (SAE J2954 + ISO 14117)
 - 27 μT (rms) (general population ICNIRP 2010)
 - 50 μT (rms) (intermediate level, no normative reference)
 - 75 μT (rms) (intermediate level, no normative reference)
 - 100 μT (rms) (occupational ICNIRP 2010 + D.lgs. 9 aprile 2008, n. 81)



Pulse modulated signal


RESULTS


- Total number of **168** conducted **tests** (72 for PMs and 96 for ICDs)
- **Total EMI** events recorded: **25**
 - 15 at 100 μT
 - 9 at 75 μT
 - 1 at 50 μT
- All of the tested devices showed an **unperturbed behavior up to 27 μT** , the immunity level

Experimental measurements

PACEMAKERS

PM	LF SIGNAL	MAGNETIC INDUCTION (B)					
		6,25 μ T	15 μ T	27 μ T	50 μ T	75 μ T	100 μ T
1	CW	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI	EMI
	BRADY	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI
2	CW	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI
	BRADY	NO EMI	NO EMI	NO EMI	NO EMI	EMI	EMI
3	CW	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI
	BRADY	NO EMI	NO EMI	NO EMI	NO EMI	EMI	EMI
4	CW	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI
	BRADY	NO EMI	NO EMI	NO EMI	EMI	EMI	EMI
5	CW	NO EMI	NO EMI	NO EMI	NO EMI	EMI	EMI
	BRADY	NO EMI	NO EMI	NO EMI	NO EMI	EMI	EMI
6	CW	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI
	BRADY	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI

 Inappropriate high voltage therapy

 Pacing inhibition

 NO EMI

DEFIBRILLATORS

ICD	LF SIGNAL	MAGNETIC INDUCTION (B)					
		6,25 μ T	15 μ T	27 μ T	50 μ T	75 μ T	100 μ T
1	CW	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI
	TACHY	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI	EMI
	BRADY	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI
2	CW	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI
	TACHY	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI
	BRADY	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI	EMI
3	CW	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI
	TACHY	NO EMI	NO EMI	NO EMI	NO EMI	EMI	EMI
	BRADY	NO EMI	NO EMI	NO EMI	NO EMI	EMI	EMI
4	CW	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI	EMI
	TACHY	NO EMI	NO EMI	NO EMI	NO EMI	EMI	EMI
	BRADY	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI	EMI
5	CW	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI
	TACHY	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI	EMI
	BRADY	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI	NO EMI

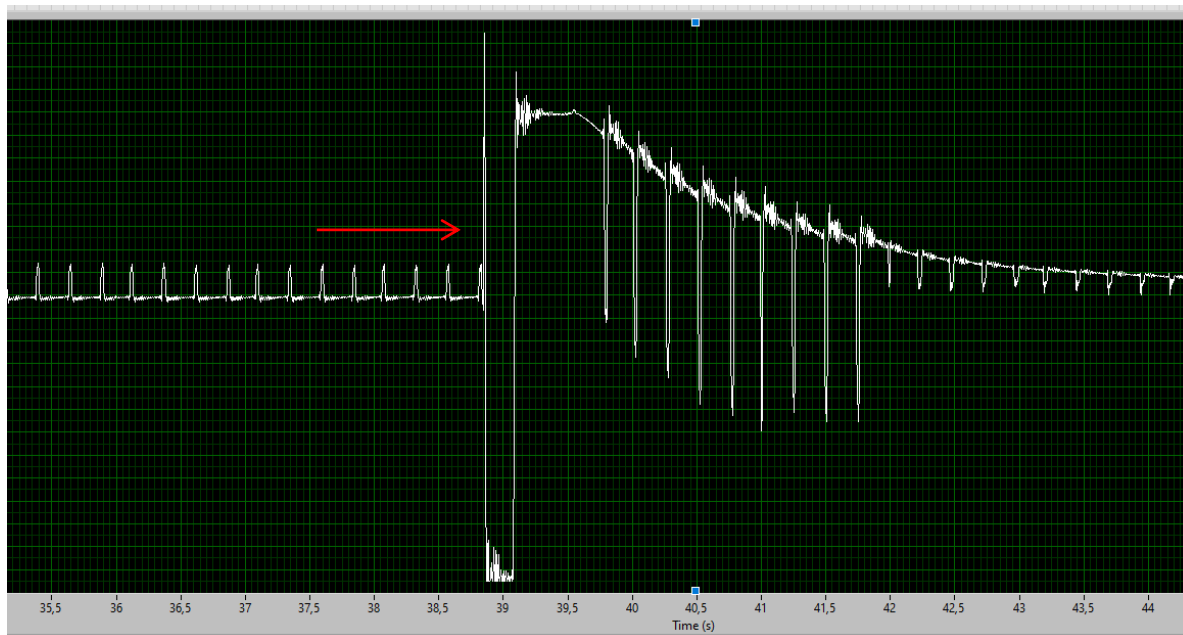
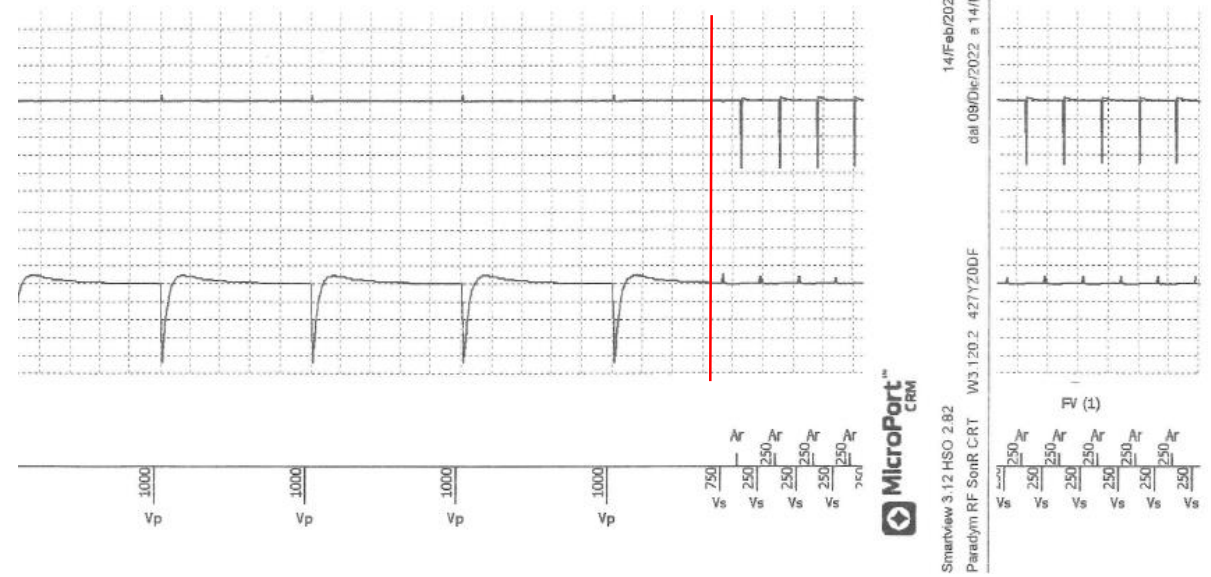
Comparison between acquired signals and device's electrograms

SHOCK 36.5 J

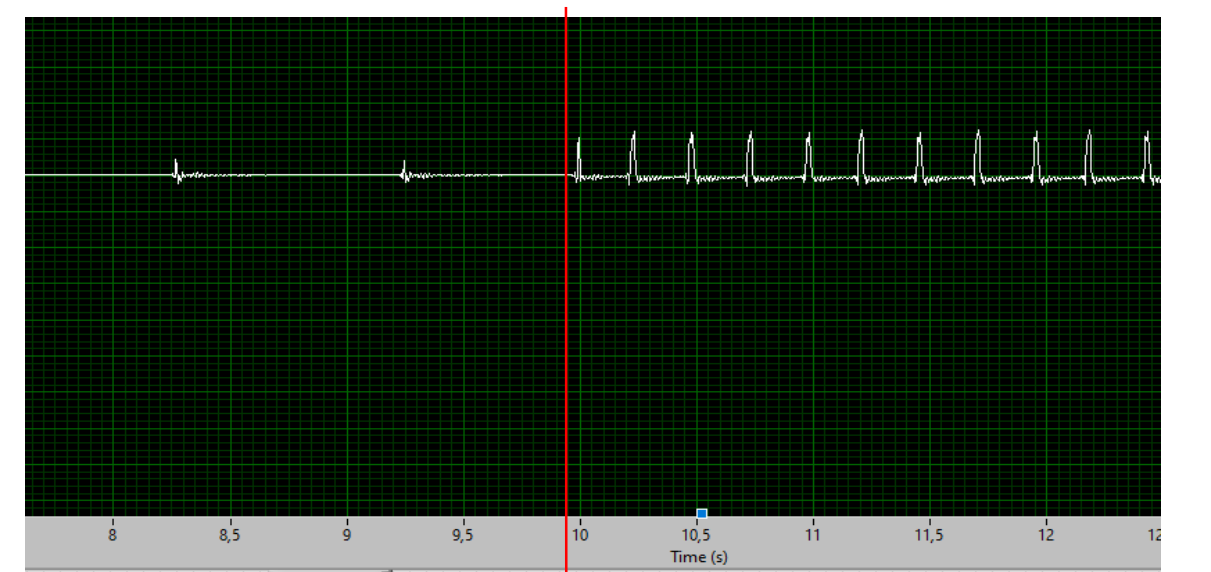


LF SIGNAL ON

ELECTROGRAMS



ECG LOGGER



MicroPart CRM
 SmartView 3.12 HSO 2.82
 Paradym RF SotR CRT W3.120.2 427Y20DF
 14/Feb/2023 - 18:38
 dal 09/Dic/2022 a 14/Feb/2023
 XXXX

➤ **5G technology**

Provocative tests have been conducted using power levels greater than those actually used by real systems, in both up-link and down-link scenarios.

Results revealed that 5G realistic signals, emitted from mobile terminals or base station antennas, do not represent a real risk of interferences.

➤ **WPT system for automotive**

With the proposed set up the high levels magnetic field has triggered EMI events. However, it must be taken into account that:

- Provocative tests were conducted using homogeneous high levels of magnetic field, which are likely to obtain only in small areas in the proximity of the WPT system, not accessible by human.
- The magnetic field decrease dramatically locally and it is \ll than general population reference levels in the surrounding of the vehicle
- Future tests and simulations will be carried out in more realistic scenario to investigate the actual induced voltage at the device input stage caused by WPT exposure.